INVESTIGATING GLOBAL CARDIAC ANOMALY REGISTRIES:

Unveiling trends, implementation characteristics, and cross-country comparisons (2018 – 2024)



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In loving memory of my grandfather, Arturo Saucedo Almanza, whose lifelong advocacy for Chicano identity and cultural pride contributed meaningfully to the Civil Rights Movement and the broader struggle for educational and social equity. His legacy remains a guiding force in the ongoing pursuit of justice and inclusion.

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Lastly, I would like to dedicate this thesis to my East Los Angeles, California community. We deserve a seat at every table.

AUTHOR DECLARATION

I certify that this dissertation has not been submitted for consideration for any other academic award and that the work was completed in compliance with the guidelines of the University of Oxford. Other than where explicitly mentioned in the text, everything of the work in this piece is original to me. Work done in conjunction with others or with their support is labeled as such. All the content in this dissertation that is not original to me has been properly cited and acknowledged. I have cited the original author wherever I have paraphrased or otherwise included their work in my references. The author's opinions are represented throughout the dissertation, aside from cited sources.

Hannah Tyler Marie Contreras, 10 October 2024

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Abbreviations

ASD	Atrial Septal Defect
ASO	Arterial Switch Operation
BAV	Bicuspid Aortic Valve
BD	Birth Defects
CAR	Congenital Aortic Regurgitation
CAVM	Congenital Aortic Valve Malformation
CBDMP	California Birth Defects Monitoring Program
CCHD	Critical Congenital Heart Defects
CCTGA	Congenitally Corrected Transposition of the Great Arteries
CDC	United States Centers for Disease Control and Prevention
CHD	Congenital Heart Defect
CoA	Coarctation of the Aorta
CVD	Cardiovascular Disease
CVS	Chorionic Villus Sampling
DORV	Double Outlet Right Ventricle
d-TGA	d(dextro)-Transposition of the Great Arteries
EHR	Electronic Health Records
EUROCAT	European Registration of Congenital Anomalies and Twins
HIC	High Income Country
HIT	Health Information Technologies
HLHS	Hypoplastic Left Heart Syndrome
IAA	Interrupted Aortic Arch
ICBDSR	International Clearinghouse for Birth Defects Surveillance and Research
ICD	Inherited Cardiovascular Diseases
ICD-9	International Statistical Classification of Diseases and Related Health Problems, Ninth revision
ICD-10	International Statistical Classification of Diseases and Related Health Problems, Tenth revision
IMR	Infant Mortality Rate
IPCCC	International Pediatric and Congenital Cardiac Code
LMIC	Low- and Middle-Income Country
MACDP	Metropolitan Atlanta Congenital Defects Program
MP	Management Pathway
MPA	Modified British Pediatric Association
MR	Mitral Regurgitation
MRI	Magnetic Resonance Imaging

NBDPN	National Birth Defects Prevention Network
NCD	Non-Communicable Diseases
NIPT	Non-Invasive Prenatal Testing
NOS/ NS	Not Otherwise Specified/ Not Specified
PA	Pulmonary Atresia
PAA	Pulmonary Artery Aneurysm
PAH	Pulmonary Arterial Hypertension
PDA	Patent Ductus Arteriosus
PFO	Patent Foramen Ovale
Post-MI VSD	Post-Myocardial Infarction Ventricular Septal Defect
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta-Analyses - Scoping Review
PS	Pulmonary Stenosis
RENAC	La Red Nacional de Anomalías Congénitas de Argentina
RVH	Right Ventricular Hypertrophy
SDG	Sustainable Development Goals
SDI	Socio-Demographic Indices
TAPVC	Total Anomalous Pulmonary Venous Connection
TOPFA	Termination of Pregnancy for Fetal Abnormality
TGA	Transposition of the Great Arteries
UHC	Universal Health Coverage
USA	United States of America
WHO	World Health Organization
YLD	Years Lived with Disability

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Abstract

Congenital anomaly registries play a pivotal role in understanding the prevalence, characteristics, and global variations in congenital anomalies (CA)s. This rapid scoping review aims to comprehensively explore the landscape of cardiac congenital anomaly registries worldwide, focusing on the period from 2018 to 2024. With the overarching questions centered on the key characteristics, levels of implementation, and the influence of income classification on registry development, this review seeks to shed light on the effectiveness and functionality of these registries on a global scale. The aim of the current research project is to i) determine how comprehensive the literature on global cardiac congenital anomaly registries was and ii) identify the key characteristics and levels of implementation observed on a global scale from 2018 to 2024 iii) evaluate the challenges and opportunities for the successful implementation of congenital anomaly registries. By synthesizing existing literature, the overarching goal is to provide a nuanced understanding of the status quo, facilitating informed discussions and potential advancements in the field of congenital anomaly surveillance.

1 Introduction

1.1. Topic and Scope

Registry-based research plays a pivotal role in advancing new medical understanding, particularly in identifying uncommon outcomes that require long-term studies and sizable sample sizes. More specifically, when applied in the context of global health issues, medical registries and surveillance systems have proved to be crucial in addressing approaches to CAs by facilitating the development of services for prevention and care. Notably, these surveillance programs typically aim to identify shifts in the prevalence of CAs and investigate patterns between those shifts and any suspected teratogens.

1.2. Background

Registries and surveillance provide the backbone to public health monitoring, research, and policymaking. The primary purpose is to gather comprehensive data on the epidemiology of diseases; however, they differ in their approach. A registry is more focused and detailed, often tracking specific patients with a particular condition while surveillance is broader, less-detailed, and typically population-focused. Registries are often used for research and clinical care improvements, while surveillance is used to detect patterns, inform public health policy, and initiate timely interventions. Nevertheless, in some cases, a registry can be part of a broader surveillance system. For example, a CHD registry may contribute to CHD surveillance efforts by providing detailed data on a subset of patients, while the surveillance system looks at the overall trends and incidence rates of CAs in a population.

Surveillance of CAs is vital for planning and improving healthcare services for affected individuals and their families. By understanding the burden and distribution of CAs, healthcare systems can more efficiently allocate resources to patients such as medical, surgical, and other supportive services. In essence, surveillance data informs the development of specialized care centers, allocation of healthcare resources, and training healthcare professionals to address the needs of individuals with CAs. Therefore, surveillance aids in establishing referral networks and multidisciplinary teams to provide comprehensive care.

Another important purpose of CA surveillance is to raise public awareness about CAs and their impact. By disseminating surveillance findings through public reports, health campaigns, and educational programs, local authorities can inform communities about the importance of prenatal care, early detection, and intervention. Increased awareness

not only encourages patients to seek timely medical advice, adopt healthy behaviors, and participate in screening programs, but also encourages proactive engagement and responsibility to become their own advocates for prevention and early management of congenital anomalies. The ongoing collection and analysis of data ensures that public health strategies are informed by evidence, leading to healthier populations and a better quality of life.

1.3. Congenital Anomalies

Congenital anomaly registries, with their profound impact on public health, have been instrumental in providing essential data for monitoring trends, identifying risk factors, and evaluating the effectiveness of preventive measures. The integration of cutting-edge technologies and global collaboration continuously evolve registries to improve data accuracy, facilitate real-time surveillance, and uncover complex patterns and associations that may not be apparent through standard procedure.

1.3.1. Etiology

The global impact of congenital anomalies is staggering, with the majority of their causes still unknown. Approximately 7.9 million newborns worldwide, constituting 6% of all births, are born with severe birth abnormalities every year.[1] Even though some of these problems are manageable and treatable, a little over 3.2 million children are permanently impaired. Furthermore, congenital malformation is one of four primary causes of death among neonates, the others being premature birth, birth complications (birth asphyxia/trauma), and newborn infections, accounting for nearly 4 out of every ten fatalities in children under the age of five. These disorders can have a variety of causes: some are inherited, others are brought on by dangerous environmental substances called teratogens, and many are multifactorial, involving a complicated interaction between environmental and genetic variables. However, around half of all cases of congenital anomalies still have unidentified causes.[1]

Birth malformations have three primary genetic causes: multifactorial factors, single-gene problems, and chromosomal abnormalities. However, it's crucial to note that the prenatal environment plays a significant role in the development of all three categories of abnormalities, especially for those with complex causes. This underscores the importance of early intervention and the potential for preventing or mitigating the impact of these conditions.[3]

Congenital heart defects (CHDs) affect about 1% of live births worldwide, making them one of the most prevalent forms of congenital disabilities. Superficial flaws that may go away on their own or require little treatment for major deformities requiring significant surgical and medicinal therapy are all part of the spectrum of CHDs. With an estimated

8–10 cases worldwide for every 1,000 live births, congenital heart disease (CHD) is a severe public health concern. The forms and prevalence of CHD might differ depending on the population's demographics and geographic location. Technological developments in prenatal screening, diagnosis, and newborn treatment have improved the early identification of affected individuals and their outcomes in industrialized nations. However, poor access to healthcare resources frequently leads to delayed diagnosis and more excellent rates of CHD-related morbidity and mortality in LMICs.

Anatomical and physiological features are used to categorize CHDs. They are generally separated into Cyanotic CHDs: These abnormalities cause the blood not to oxygenate enough, resulting in cyanosis or bluish skin. Tetralogy of Fallot and transposition of the major arteries are two examples. In terms of acyanotic CDHs, usually, cyanosis is not brought on by the aforementioned abnormalities. These encompass ailments such as atrial and ventricular septal defects. Additionally, CHDs can be categorized according to how they affect the body physiologically. Examples of these include complex anomalies, including numerous anatomical abnormalities, shunt lesions like patent ductus arteriosus, and obstructive defects like pulmonary valve stenosis.

1.3.1.1. Genetic Causes

Genetic mutations and chromosomal abnormalities account for 20-30% of CHDs. With the aid of diagnostic tools and medical advancements, chromosomal abnormalities such as large-scale duplications and deletions of chromosomal regions can be identified during conception. These anomalies cause zygotes to incompletely develop into embryos; embryos that do develop, however, frequently have disorders such as Down syndrome (trisomy 21), Patau syndrome (trisomy 13), and Edwards syndrome (trisomy 18). These types of genetic syndromes involve overexpression of genes that play a role in disrupting molecular pathways involved in cell division, differentiation and apoptosis as well as normal developmental processes of the heart and embryo. Children with Patau or Edwards syndromes frequently pass away soon after birth, whereas those with Down syndrome typically have a lengthy lifespan (March of Dimes, 2006). Up to 50% of infants with Down syndrome have CHDs, more specifically atrioventricular septal defects, ventricular septal defects, and Tetralogy of Fallot. This association highlights the need for a comprehensive approach to understanding and managing these conditions.

The role of single-gene defects in CHDs is a crucial area that demands further research and understanding. These defects, typically inherited, are significant contributors to the prevalence of CHDs. For instance, phenylketonuria (PKU), an oxidative stress and collateral metabolic abnormality that causes cardiac defects, is brought on by a malfunction of the PAH (Pulmonary Arterial Hypertension) enzyme, is the consequence

of a defect in the PAH gene on chromosome 12. Another example of a single-gene defect can be seen in mutations in the NKX2-5 gene, a transcription factor crucial for early heart development, which are linked to atrial septal defects and other heart malformations. Moreover, there is a widely varied prevalence of single-gene anomalies among different racial and ethnic groups (due to genetic diversity, founder effects, selective pressures, and historical migration patterns) which highlight the need for a comprehensive understanding of these defects. For example, Tay-Sachs and Sandhoff diseases are more common in Ashkenazi Jews; sickle-cell anemia in African, Indian, and Mediterranean communities; Cystic Fibrosis in Northern Europeans, etc.

1.3.1.2. Environmental Causes and Maternal Factors

Genetic mutations and environmental factors combine to cause multifactorial birth abnormalities. Exposure to certain medications, chemicals, and substances during pregnancy can act as teratogens, disrupting fetal heart development. For example, the use of isotretinoin (a retinoid used to treat severe acne) during pregnancy is associated with a substantial risk of CHDs.

The environment in which a fetus develops is of utmost importance. It influences nutrition, exposure to pollutants, and maternal health. Historical instances, such as the use of Agent Orange during the Vietnam War, serve as stark reminders of how environmental contaminants can affect the frequency of birth abnormalities. Voluntary exposures like smoking and alcohol usage are also linked to congenital anomalies such as cleft lip/palate and fetal alcohol syndrome.

Various maternal conditions and behaviors are associated with an elevated risk of CHDs in offspring, which includes maternal nutrition, infection, and age. For instance, folate deficiency, thought to play a role in homocysteine metabolism and DNA methylation, has been linked to an increased risk of neural tube defects and CHDs. Regarding maternal infections, rubella during pregnancy, the Rubella virus crosses the placental barrier, replicates in the fetus's cells, and disrupts the normal cellular processes of the heart, leading to defects such as patent ductus arteriosus and pulmonary stenosis. Moreover, with pregestational and gestational diabetes, infants born to mothers with poorly controlled diabetes have a higher incidence of cardiac malformations, including transposition of the great arteries and ventricular septal defects. Likewise, advanced maternal age is associated with an increased risk of chromosomal abnormalities due to the general aging and deterioration of the nondisjunction process, meiotic spindle quality, and chromosomal cohesion; geriatric mothers are more likely to give birth to babies with Down syndrome, which in turn elevates the risk of CHDs.

1.3.1.3. Complex of Multifactorial and Epigenetic Causes

Genetic predispositions and environmental factors interact to cause many CHDs. Since heart growth involves many intricate signaling pathways and interactions, it can be disrupted by various circumstances. Most CHDs result from the interaction of multiple genetic and environmental factors, a phenomenon known as multifactorial inheritance; this complexity makes it challenging to pinpoint specific causes in many cases. For instance, the same genetic mutation might result in different phenotypic outcomes depending on the presence of other genetic variants or environmental exposures.

Lastly, epigenetic modifications such as DNA methylation, histone modification, and non-coding RNA contribute to CHDs. These modifications can be influenced by genetic factors, environmental exposures, and overall maternal health conditions. For example, maternal smoking can lead to epigenetic changes that affect fetal heart development, increasing the risk of CHDs.

1.3.2. Prevention

1.3.2.1. Maternal Health

Preventing CHDs is critical for reducing infant mortality and morbidity and improving the quality of life of affected individuals. One approach to preventing CHD involves improving access to affordable healthcare and promoting preconception health, which consists of optimizing maternal health and nutrition and avoiding harmful substances. For instance, managing chronic diseases such as diabetes and hypertension can reduce the risk of congenital anomalies. Strict control of blood glucose levels before and during pregnancy reduces the risk of congenital anomalies, including heart defects.[6] Effective management of hypertension through lifestyle changes and medication helps mitigate the risk of heart defects and other pregnancy complications.[7] Regular exercise and adequate intake of essential nutrients are vital for fetal development, which means that increasing intake of folic acid and eating a diet rich in fruits, vegetables, whole grains, and lean proteins significantly reduces the risk of neural tube defects and supports overall maternal health and fetal development[4]. Moreover, avoiding harmful substances such as tobacco, alcohol, and illicit drugs significantly reduces the risk of developmental issues and congenital anomalies.

After conception, prenatal care becomes a priority. Regular prenatal visits are essential for monitoring the health of both the mother and the fetus. These visits provide opportunities for early detection of health issues, management of chronic conditions, and guidance on maintaining a healthy pregnancy in which access to diagnostic tools, genetic testing, and other screening tools can provide additional knowledge and options for the prevention and care of congenital anomalies. Fetal echocardiography, performed between 18 and 20 weeks of gestation, is a crucial tool for identifying structural

abnormalities in the fetal heart.[9] Early detection allows for better planning and management, including potential interventions before or immediately after birth.[8] Moreover, for families with a history of congenital heart defects or known genetic conditions, prenatal genetic testing can offer valuable insights. Often, tests such as Chorionic Villus Sampling (CVS) are performed between 10 and 13 weeks of gestation to detect chromosomal abnormalities linked to congenital anomalies[9], and amniocentesis is carried out, which involves analysis of amniotic fluid at 15 – 20 weeks of gestation.

If the patient is at higher risk due to family history, medical history, or initial screening results, they may be encouraged to use advanced screening technologies and genetic counseling. Advanced screening technologies can include Non-Invasive Prenatal Testing (NIPT) and fetal cardiac MRI.[5] NIPT involves analyzing cell-free fetal DNA in maternal blood to screen for chromosomal abnormalities with high accuracy. While primarily used for detecting Down syndrome, NIPT can also indicate an increased risk for other anomalies, including some associated with congenital heart defects.[10] Moreover, a fetal cardiac MRI provides detailed fetal heart imaging and is particularly useful for diagnosing complex cardiac defects that may not be visible through traditional ultrasound.[11] Regarding genetic counseling, family history is assessed to identify patterns or genetic conditions that may increase the risk of congenital heart defects, determine the risk of recurrence in future pregnancies, and offer guidance on managing risks.[12] In essence, advanced screening and genetic counseling help prospective parents understand the implications of test results and make informed decisions.

Preventing cardiac congenital anomalies requires a multifaceted approach that includes optimizing preconception health, ensuring effective prenatal care, providing genetic counseling, managing maternal health, and implementing public health initiatives. Medical technology and research advances continue to enhance our ability to detect and manage congenital heart defects, offering hope for better outcomes and reduced incidence of these conditions. By addressing these factors comprehensively, we can significantly reduce the burden of cardiac congenital anomalies and improve affected individuals' health and quality of life.

1.3.3. Infant mortality

Infant mortality rate (IMR) is a critical indicator of the overall health of a population, reflecting the effectiveness of healthcare systems, maternal health, and socioeconomic conditions. HIC typically exhibits low IMR due to well-developed healthcare systems, comprehensive prenatal and postnatal care, and effective public health policies. For example, countries like Japan, Sweden, and Germany have IMRs (Infant Mortality Rate) below 5 per 1,000 live births.[13] In contrast, LMICs often face higher IMRs due to factors such as inadequate healthcare infrastructure, limited access to essential medical

services, malnutrition, and infectious diseases. Sub-Saharan Africa and South Asia, for instance, have some of the highest IMRs, with rates exceeding 50 per 1,000 live births in several countries.[14]

Cardiac congenital anomalies are among the most common congenital abnormalities and can range from mild to severe. In HIC, advanced prenatal diagnostics, including fetal echocardiography, enabled the early detection of cardiac defects. Parents are often given the option of TOPFA when severe defects are identified, which can lead to high morbidity or mortality.[15] The decision to terminate a pregnancy in such cases is often guided by the severity of the defect, the potential for surgical correction, and the anticipated quality of life for the child. In LMIC, the scenario is markedly different. Limited access to prenatal diagnostic tools means that many cardiac defects are not detected until after birth. Furthermore, the lack of advanced pediatric cardiac care facilities in many LMICs restricts the options for surgical intervention, contributing to higher infant mortality rates for children born with severe cardiac anomalies.[16]

In HICs, the use of advanced medical technologies has significantly reduced the mortality associated with cardiac congenital anomalies. Surgical advancements and specialized pediatric cardiac care have notably improved the survival rates and quality of life for affected infants. In contrast, in LMICs, the IMR for infants with cardiac CAs remains high due to delayed diagnosis, inadequate medical infrastructure, and lack of access to specialized care.

The disparities in the termination of pregnancy for fetal abnormality and infant mortality rates between HICs and LMICs underscore the need for global efforts to improve healthcare access. HICs benefit from advanced medical technologies, supportive legal frameworks, and robust healthcare systems, while LMICs face significant challenges, including limited access to prenatal diagnostics, restrictive laws, and inadequate healthcare infrastructure. Addressing these disparities requires concerted global efforts to enhance healthcare access, improve prenatal and postnatal care, and support legal and cultural shifts toward more comprehensive maternal and child health services.

1.3.3.1. Livebirth Prevalence of Congenital Anomalies

Research and data availability also contribute to the differences observed between HICs and LMICs. HICs have the resources to conduct extensive research on CHDs, leading to a better understanding of their causes, prevention, and treatment. Detailed epidemiological data helps develop targeted interventions and policies to address these defects. Conversely, in LMICs, there is often a lack of reliable data on the prevalence and outcomes of CHDs. Limited research funding and infrastructure mean that these countries cannot conduct large-scale studies or maintain comprehensive health

records. This data gap makes it challenging to develop effective health policies and interventions, perpetuating the cycle of poor outcomes.[17]

HICs benefit from a higher ratio of healthcare workers to the population, including specialists and primary care providers. For instance, the density of physicians in HICs is approximately 3.3 per 1,000 population, compared to 0.9 in LMICs.[1] This difference ensures that patients in HICs receive timely and specialized care. In contrast, LMICs face significant shortages of healthcare professionals, which is exacerbated by brain drain, where skilled workers migrate to HICs for better opportunities.[1]

HICs generally focus on managing chronic diseases, such as heart disease, diabetes, and cancer, which are prevalent due to aging populations and lifestyle factors. These countries invest heavily in preventive measures, early detection, and advanced treatments to manage these conditions. LMICs, on the other hand, face a dual burden of disease: the persistent challenge of infectious diseases like malaria, tuberculosis, and HIV/AIDS, alongside the rising incidence of non-communicable diseases (NCDs).[18] The limited resources in LMICs are often stretched thin trying to address both infectious diseases and NCDs. Additionally, LMICs are more vulnerable to outbreaks of infectious diseases, as seen with the Ebola virus and COVID-19, due to weaker health systems and inadequate disease surveillance.

HICs have better access to medicines and medical technologies, including new and expensive treatments. They benefit from robust pharmaceutical industries and regulatory frameworks that ensure the availability of high-quality drugs and innovative therapies. The development and approval of new drugs are faster and more efficient in these countries. Conversely, LMICs often face challenges in accessing essential medicines and technologies. Factors such as high costs, inadequate supply chains, and weak regulatory systems hinder the availability of necessary treatments. Generic medicines are more commonly used in these regions to reduce costs, but even these can be out of reach for many due to financial constraints.

The stark differences in the statistics of CHDs between HICs and LMICs can be attributed to several interrelated factors. In HICs, advanced healthcare infrastructure, higher socioeconomic status, robust public health policies, and extensive research capabilities lead to better diagnosis, treatment, and outcomes for individuals with CHDs. In contrast, LMICs face significant challenges, including inadequate healthcare infrastructure, economic constraints, limited public health initiatives, and a lack of reliable data. Addressing these disparities requires a concerted global effort to improve healthcare access, enhance public health policies, and invest in research and data collection in LMICs. Only through such measures can the global burden of cardiac congenital anomalies be equitably reduced.

CHDs represent a significant global health challenge, affecting millions of people worldwide. Congenital heart disease is the leading group of CAs with 13.3 million patients worldwide in 2019,1 and a worthy cause of NCDs. In 2017, CHD caused approximately 261,247 deaths globally, with a significant reduction in mortality rates by 34.5% from 1990.[19] Despite this decline, CHD remains a leading cause of infant mortality, particularly in low and low-middle socio-demographic index (SDI) regions. The prevalence of CHD at birth remained relatively stable over the study period, resulting in an estimated 11,998,283 people living with CHD in 2017, an increase of 18.7% from 1990. This rise in prevalence underscores the growing burden of CHD as more individuals survive into adulthood.[19]

HICs have seen substantial improvements in CHD survival rates due to advancements in diagnostic and treatment capabilities. In contrast, LMICs continue to experience high mortality rates among infants with severe CHD forms, largely due to limited access to surgical interventions and adequate medical care. Consequently, most CHD-related deaths occur in low and low-middle SDI regions. The findings highlight the need for targeted interventions and resource allocation to improve CHD outcomes, particularly in LMICs. Improving screening, treatment, and data collection efforts are crucial to addressing the global inequities in CHD care. This thesis underscores the importance of achieving the Sustainable Development Goals (SDGs), particularly those related to reducing neonatal and child mortality, and emphasizes the integral role of CHD in these efforts.

CHD remains a significant global health burden, with notable improvements in survival rates in HICs but persistent challenges in LMICs. Comprehensive and accurate data on CHD prevalence and outcomes are essential for informing policy decisions and prioritizing healthcare resources. This study provides a vital foundation for future efforts to reduce the global burden of CHD and improve the quality of life for those affected by this condition.

CHD mortality trends are indicative of the effectiveness and accessibility of congenital cardiac care across different regions and age groups. Despite global progress in reducing CHD mortality over the past three decades, substantial disparities remain, particularly in LMICs. These disparities pose a significant challenge to achieving the SDG targets for reducing under-5 and NCD mortality by 2030.[19] In 2019, CHD was responsible for 217,000 deaths globally, with the highest mortality rates in India, China, Pakistan, and Nigeria, accounting for 39.7% of global deaths. CHD remains the leading cause of non-communicable disease (NCD) deaths in individuals under 20 years of age. From 1990 to 2019, high Socio-Demographic Index (SDI) countries showed a significant decline in CHD mortality rates, with an annual reduction of 2.41%. In contrast, low-SDI countries experienced a much smaller reduction of 0.62% per year.[20]

Notably, countries like South Korea and the United States exhibited favorable mortality reductions, while 52 countries showed stagnated or increasing mortality trends.[20] There is a global shift in the age distribution of CHD deaths from pediatric to adult populations. However, Mexico and Pakistan displayed increasing mortality trends among those aged 10-34 years. Improvements in CHD mortality is predominantly seen in younger cohorts in high- and high-middle-SDI countries. Significant disparities in CHD mortality trends exist, particularly in low-middle-SDI and low-SDI countries. For example, India, Pakistan, and several African nations face worsening or stagnated mortality trends. Unfavorable period and cohort effects highlight gaps in healthcare provision, especially in countries like Saudi Arabia and Kazakhstan.

There is a necessity for continuous global investment in congenital cardiac care to improve outcomes across all age groups. Enhancing CHD healthcare beyond pediatric settings to accommodate the increasing number of adults surviving with CHD is crucial. This approach will help reduce mortality risks for future generations and support the global health agenda of reducing premature deaths from NCDs. There is a need for targeted health policies and resource allocation to address the disparities in CHD care. Countries with unfavorable trends must prioritize improving access to and quality of congenital cardiac care to meet international health goals. The study's methodology also offers a valuable framework for tracking progress in other NCDs that benefit from early intervention and active treatment.

1.3.3.2. Termination of Pregnancy for Fetal Abnormality (TOPFA)

TOPFA and infant mortality rates (IMR) are not just local issues, but critical indicators of maternal and child health on a global scale. These measures reflect the healthcare infrastructure and the diverse sociocultural and economic contexts of different regions. TOPFA, a medical procedure performed when severe fetal abnormalities are detected during pregnancy, and IMR, which often result from these abnormalities, are significant factors in the health of mothers and children worldwide. The practice of TOPFA varies widely globally due to differences in legal, ethical, and cultural perspectives.

In HIC, the availability of advanced prenatal screening and diagnostic tools is a key factor in the early detection of fetal abnormalities. Legal frameworks in many HICs, such as those in Europe and North America, generally support the option of TOPFA under specific circumstances, thus providing parents with the choice to terminate the pregnancy if severe abnormalities are detected.[22]

Conversely, in many LMIC, access to prenatal diagnostic services is limited, and the legal and cultural acceptance of TOPFA varies significantly. In many LMICs, restrictive abortion laws, limited healthcare infrastructure, and the pervasive influence of

sociocultural stigmas contribute to fewer TOPFAs. This lack of access often results in higher birth rates of infants with severe abnormalities, who may then experience higher mortality rates and significant morbidity.[22]

1.3.3.3. Public Health Implications

Given the high incidence and complex management of CHDs, due to the need for prompt medical and surgical care, there is a substantial strain on healthcare systems globally. However, by focusing on early detection and intervention, outcomes can be significantly improved for affected patients and their families. Registry data is invaluable for informing public health policies and planning. Healthcare providers can use the data to design and implement targeted prevention programs, allocate resources effectively, and monitor the impact of public health interventions.[23]

Although survival rates have increased dramatically due to improvements in addressing malnutrition and infectious diseases, the severity of CHDs still stands as a critical public health issue due to deeply entrenched systematic socioeconomic factors. Since access to clean water and adequate healthcare services, proper nutrition, and maternal education are often limited in low-income regions, the risk of congenital heart defects can be exacerbated by factors such as poor prenatal care, higher exposure to teratogens, and lack of timely medical interventions. These disparities contribute to variations in survival rates, health outcomes, and access to corrective surgeries for children born with these anomalies, highlighting the need for targeted public health strategies and resource allocation to address these inequities.

LMICs have higher rates of nutritional deficiencies, such as folic acid and iodine, contributing to a higher incidence of related congenital anomalies.[23] HICs have extensive public health campaigns promoting folic acid supplementation, vaccination, and maternal health. LMICs may struggle with implementing and sustaining such programs due to resource constraints. In HICs, higher income levels and better education contribute to greater awareness and understanding of prenatal care and CAs. Expectant mothers in HICs are more likely to receive regular prenatal care, which, in turn, contributes to early detection of CHDs.[25] Additionally, the financial resources available in HICs mean that families can afford the necessary medical treatments and surgeries, even when they are expensive. On the other hand, in LMICs, poverty and lack of education can severely limit access to healthcare. Many families cannot afford prenatal care, and even if CHDs are detected, the costs of surgery and long-term treatment can be prohibitive. The financial burden often falls on families, leading to delayed or foregone medical care, and, ultimately, higher morbidity and mortality rates observed in LMICs.[23]

Furthermore, political instability and lack of funding can hinder the implementation of effective public health strategies. HICs typically have more financial resources to

allocate toward healthcare. HICs are equipped with well-funded healthcare systems strengthened by advanced medical technologies, highly trained healthcare professionals, and comprehensive health services. In contrast, LMICs often struggle with limited financial resources, leading to underfunded healthcare systems. According to the World Health Organization (WHO), HICs spend an average of 12% of their GDP on healthcare, whereas LMICs spend around 5%.[23] The disparity in funding affects the availability and quality of healthcare services. HICs can afford advanced diagnostic tools, state-of-the-art medical facilities, and continuous medical research. LMICs, however, often lack basic medical supplies, suffer from inadequate healthcare infrastructure, and have limited access to essential medicines. Moreover, in LMICs, health information systems are often rudimentary, relying on paper-based records and lacking integration. This hampers the ability to collect, analyze, and utilize health data effectively, which is very necessary for monitoring public health, managing outbreaks, and implementing health policies.

Healthcare delivery in HICs is often characterized by universal health coverage (UHC) and well-organized public health systems. Countries like the United Kingdom, Canada, and Sweden provide healthcare through publicly funded systems that aim to ensure that all citizens have access to necessary medical services without financial hardship. In contrast, many LMICs have fragmented healthcare systems with a mix of public and private providers. The public sector often provides basic and essential health services, while the private sector caters to those who can afford to pay out-of-pocket. This dual system can lead to inequities in healthcare access and outcomes, where wealthier individuals receive higher-quality care compared to the disadvantaged. Moreover, while HICs have an abundant access to resources, many LMICs lack the necessary medical equipment and trained healthcare professionals to diagnose and treat CHDs effectively, let alone access to specialized care.[23] This results in delayed or missed diagnoses, leading to higher morbidity and mortality rates. According to the WHO, around 90% of children born with CHDs in LMICs do not receive the necessary surgery or treatment due to these systemic healthcare deficiencies.

1.3.4. Coding and Classifications of Congenital Anomalies

The International Classification of Diseases (ICD) has been the foundation for categorizing and coding CAs globally. With the 10th revision (ICD-10) and the upcoming 11th revision (ICD-11), CAs are assigned specific codes based on the type and location of the anomaly. This classification system, which includes defects like neural tube defects or congenital heart anomalies, is a crucial part of the field.[26] The classification of cardiac CAs has undergone significant evolution, driven by the need for a more comprehensive and detailed system to address the complexity of these conditions.

Historically, general disease classification systems such as the ICD were insufficient in capturing the full range of cardiac congenital anomalies, as they lacked specific and comprehensive codes for many heart defects. To address these limitations, specialized nomenclature systems such as The International Pediatric and Congenital Cardiac Code (IPCCC) were developed. This system, which emerged from the collaborative efforts of pediatric cardiology and cardiac surgery experts, offers a highly detailed and clinically relevant framework for diagnosing and treating pediatric and congenital cardiac diseases. The IPCCC, with its over 7,000 terms, each associated with a six-digit code, allows for a precise description of morphological phenotypes, procedures, symptoms, and even genetic syndromes related to congenital heart disease.[27] This coding system is especially important for multicenter studies and international comparisons of outcomes, fostering a sense of global connection and collaboration among healthcare providers. It enables healthcare providers to stratify risk, analyze treatment efficacy, and ensure that CHD data can be universally understood, regardless of the geographical or healthcare context in which it is collected.[27] The IPCCC also integrates with broader health information systems such as the ICD, further extending its utility in both clinical and research settings.[26]

Many coding systems integrate: (1) morphological classification which describes specific CHDs in a detailed manner, allowing clinicians to differentiate between closely related conditions. For example, the system provides distinct codes for varied ventricular septal defects (VSD)s, amongst the other five most common CHDs (2) procedural coding which includes codes for surgical and catheter-based interventions, making it useful for tracking diagnoses and treatments and their outcomes (3) non-cardiac anomalies and syndromes which accounts for related non-cardiac anomalies, which are frequently seen in patients with complex congenital heart disease. Coding systems, like IPCCC, also provide codes for genetic syndromes that may present alongside CAs, such as Down syndrome and other chromosomal abnormalities.[27]

The accurate classification and coding of CAs, particularly CHDs, facilitate clinical governance and best practice by enabling the comparison of outcomes between institutions this is particularly important for CHD patients who require high-risk and complex surgeries. Classification systems like the IPCCC facilitate improvements in clinical outcomes and healthcare quality by standardizing how anomalies and interventions are reported.

1.3.5. Economic Impact

The economic burden of CHDs is comprehensive, encompassing direct healthcare costs such as surgeries, hospital stays, and long-term medical care, as well as indirect costs like lost productivity and long-term disability. The management of CHDs over a

patient's lifetime can be particularly costly, with early interventions and surgeries being the tip of the iceberg. In 2017, congenital heart disease accounted for nearly 600,000 years lived with disability (YLD), a metric that underscores the chronic nature of the disease and its impact on individuals' quality of life from infancy through adulthood.

Regions with lower socio-demographic indices (SDI) face challenges, as the lack of access to adequate medical care and surgical interventions significantly increases morbidity and mortality rates associated with CHD. Studies have shown that the mortality rates for CHD are inversely related to the SDI, highlighting the disparity in outcomes based on geographic and economic factors.[20] In HICs, advancements in medical technology, prenatal screening, and neonatal care have dramatically improved the survival rates of infants born with CHDs. For instance, in HICs, survival into adulthood for children born with CHD now exceeds 90%.[20] In contrast, in LMICs, the lack of adequate diagnostic facilities, limited access to specialized care, and fewer resources for surgery and post-operative care result in higher mortality rates and poorer long-term outcomes. Financially, HICs are better equipped to bear the economic load of CHDs, with more substantial healthcare budgets and insurance systems that cover high medical costs. Conversely, in LMICs, the economic impact is disproportionately severe, often leading to catastrophic health expenditures for families. High costs for medical care combined with a lack of financial protection plunge families into poverty, exacerbating the social and economic instability in these regions.

The economic impact of CHD is profound, encompassing direct medical costs, long-term care expenses, and indirect costs such as lost productivity and familial financial strain. In the United States, the cost of hospitalizations related to CHD exceeded $6 billion in one year, with ongoing expenses likely much higher when considering lifelong management.[28] Globally, the economic challenges are even more daunting, especially in countries with limited healthcare resources. The WHO estimates that non-communicable diseases (NCDs), including CHD, will cost LMICs countries about $7 trillion in economic losses from 2011 to 2025, highlighting the significant financial strain of chronic health conditions.[29]

1.4. Surveillance

1.4.1. Types of Surveillance

Active surveillance involves trained staff members who systematically review and verify medical records, hospital logs, and other data sources to identify and collect detailed CA information; this method ensures high completeness and accuracy of the data. However, the intensive nature of active surveillance makes it resource-heavy, requiring significant workforce, funding, and coordination. Programs like the Metropolitan Atlanta

Congenital Defects Program (MACDP) and the California Birth Defects Monitoring Program (CBDMP) are notable examples that provide high-quality data that can significantly impact public health initiatives and research.[30]

Passive surveillance relies on healthcare providers to report cases of CAs to a central registry, typically using standardized reporting forms. This approach is less resource-intensive than active surveillance and more accessible to implement across large geographic areas. However, passive surveillance often faces challenges related to underreporting and incomplete data, as it depends on the initiative of healthcare providers to submit reports. The National Birth Defects Prevention Network (NBDPN) exemplifies passive surveillance, collecting data across various states in the U.S. Despite its limitations, passive surveillance remains a valuable tool for collecting widespread data on congenital anomalies with relatively low operational costs. [31]

Sentinel surveillance focuses on selected locations or healthcare facilities, known as sentinel sites, which are chosen for their ability to provide high-quality data on CAs. This method is beneficial for identifying trends and potential outbreaks of CAs. The primary advantage of sentinel surveillance is the quality and timeliness of the data collected from these specialized sites. However, the limitation lies in its potential lack of representativeness, as the data from sentinel sites may not reflect the broader population. EUROCAT (European Surveillance of Congenital Anomalies) utilizes sentinel surveillance effectively across various European countries, offering valuable insights while maintaining manageable resource requirements. [32]

Population-based surveillance encompasses all births within a defined geographic area, ensuring comprehensive data collection on congenital anomalies in that population. This approach provides a complete and representative dataset, making it extremely useful for public health planning and policymaking. However, the extensive nature of population-based surveillance can be resource-intensive and requires robust coordination across multiple data collection sites. The Texas Birth Defects Registry is a prime example, capturing data on live births, stillbirths, and pregnancy terminations across Texas, thereby offering a detailed understanding of the prevalence and types of congenital anomalies within the state.[33]

Registry-based surveillance leverages existing data registries, such as vital records or hospital discharge databases, to identify and collect information on CAs. This cost-effective method utilizes already available data sources, reducing the need for extensive new data collection efforts. However, the quality and completeness of the data can be variable, and the existing records may need more detailed clinical information necessary for comprehensive surveillance. The U.S. National Vital Statistics System (NVSS) is an

example of registry-based surveillance, integrating data with broader health statistics to enhance overall understanding.[34]

Enhanced surveillance combines active, passive, and registry-based methods. This hybrid approach aims to maximize the strengths of each method while mitigating their weaknesses. Enhanced surveillance often requires significant resources and coordination but results in highly accurate and comprehensive datasets. The CDC Enhanced Surveillance Projects illustrate this approach, integrating multiple data sources and collection methods to provide a thorough picture of CAs. [30]

1.4.2. History of Surveillance

Health registry-based research has a rich historical significance, playing a significant role in advancing medical science and public health. The earliest form of medical research can be traced back to ancient Egypt, 1550 BC in which papyruses texts were kept by Egyptian scribes to record medical information and provide educational insight to diseases, diagnosis, surgery, and a variety of holistic, spiritual remedies.[35] Later, applications of medical records could be seen in the form of smallpox vaccination records dated back to 18th century England. These early records laid the foundation for the systematic collection of health data and became the status quo as new vaccines began to develop against diseases like polio, measles, and mumps.[36] By the 19th century, the importance of health registries became more apparent with the advent of mandatory reporting of infectious diseases, which was crucial for controlling outbreaks.

In the early 20th century, cancer registries began to emerge, with the first population-based cancer registry established in Hamburg, Germany, in 1926. This cancer registry was the first noted attempt to systematically gather data on cancer incidence through questionnaire and population-focused research. Insights into cancer incidence, survival rates, and treatment protocol effectiveness paved the way for registries for other health conditions.

In the late 1950s, the Thalidomide tragedy, described to be the “biggest anthropogenic medical disaster,” drove the need for CA surveillance when a German pharmaceutical company, Chemie–Grunenthal, marketing Thalidomide as a morning sickness medication for pregnant women led to severe, life-threatening CAs in over ten thousand newborns. [37] This disaster highlighted the need for systematic monitoring of CAs and stimulated the establishment of CA registries.

In 1967, the Metropolitan Atlanta Congenital Defects Program (MACDP) was established as one of the first population-based CA surveillance programs in the United States.[38] MACDP, was coded using a modified British Pediatric Association six-digit code and reviewed and classified by clinical geneticists. The aim was to collect, analyze, and

interpret data on CAs to understand their epidemiology and develop preventive measures. The creation of MACDP is now recognized for conducting descriptive, risk factor, and prognostic research on CAs such as studies on Agent Orange exposure in Vietnam War veterans and assessing preventive measures for neural tube defects.[39] Following the success of early registries like MACDP, many countries have established their own respective CA registries. In Europe, EUROCAT was founded in 1979 to collect and analyze data on CAs from multiple countries.[40]

In the US, the National Birth Defects Prevention Network (NBDPN) was established in 1997 to promote collaboration among state CA programs and improve data quality and use. The NBDPN supports developing and implementing uniform methods for CA surveillance and fosters research to identify risk factors and preventive measures. [41]

Incentives to transition to electronic health records (EHRs) and data integration technology advancements soon emerged and while they have significantly enhanced CA registries' capacity and efficiency, this factor has largely broadened the gap between HICs and LMICs. Modern registries can now create comprehensive patient and population profiles that ultimately link multiple data sources, such as hospital records, laboratory reports, and vital statistics. This integration allows for more accurate and timely identification of congenital anomalies and facilitates large-scale epidemiological studies.[43] Moreover, as technological advances have contributed to centralized data, the development of genetic and genomic databases have provided more opportunities for understanding the genetic basis of CAs. Genomic databases aid researchers to identify genetic mutations and explore gene-environment interactions, overall, providing more extensive knowledge of CAs and options for prevention and care for patients.

2 Methodology

2. Rapid Scoping Review

2.1.1. Research Design

The PRISMA-ScR is a methodology created to quickly map the available evidence on a particular topic, identify key concepts, gaps in research, and types of evidence. The PRISMA guidelines ensure transparency and reproducibility while providing a rapid overview of the literature. PRISMA-ScR involves defining clear objectives, developing a robust search strategy, screening and selecting relevant studies, extracting and synthesizing data, and reporting findings. [44]

2.1.2. Protocol

2.1.2.1. Objective of the Scoping Review

Objective 1: How comprehensive is the literature on global cardiac congenital anomaly registries from 2018 to 2024?

Objective 2: What are the key characteristics and levels of implementation observed in cardiac congenital anomaly registries on a global scale?

Objective 3: What are the challenges and opportunities for the successful implementation of congenital anomaly registries?

2.1.2.2. Inclusion and Exclusion Criteria

Inclusion criteria include: (1) Studies, reports, and articles published between 2018 and 2024; (2) literature that focuses on cardiac CA registries globally; (3) journal articles written in English. Screening instructions were set to examine the titles and abstracts to determine whether the article discusses cardiac CA studies. Two reviewers independently screen titles and abstracts against inclusion/exclusion criteria. Screeners were to check that the article is in line with the criteria. If unsure, screeners add it to the full-text review. For full-text screening, based on the titles and abstracts, they were to find complete text of articles that meet the criteria. Screeners assess whether the article provides information on the availability, scope, depth and key characteristics of a CA database. If the article does not meet the inclusion criteria, they were to record the reasons for its exclusion. If both screeners do not come to the same conclusions regarding screening and eligibility of literature, a third-party is used to come to an agreement. Regarding sampling and sampling size, all sources provided by search

will be used unless it fails to meet the inclusion/exclusion criteria and is deemed ineligible. Exclusion criteria entail: (1) studies not related to CA registries; (2) literature published before 2018 or after 2024; (3) non-English language documents, (4) congenital infectious syndromes.

2.1.2.3. Search Strategy

PubMed and Ovid Embase were searched on 17/04/2024 from 2018 to search date in the English language only. The search strategies were created with a librarian (EH) to retrieve relevant literature about global congenital anomaly registries, searching for the terms: “registry” or “registries” or “database” or “databases” or "surveillance system*" only to increase the specificity, and searching for "urogenital defect*" or hypospadias or "renal agenesis" or hypoplasia or "posterior urethral valves" or cloaca* or "anterior anus" or "digestive system defect*" or "tracheoesophageal fistula*" or "tracheoesophageal fistula*" or "esophageal atresia" or "large intestinal atresia" or stenosis or "anorectal atresia" or gastroschisis or Hirschsprung or "meconium ileus" or "abdominal wall defect*" or omphalocele or gastroschisis or "congenital diaphragmatic hernia" or exomphalos or "congenital heart defect*" or "common truncus" or "congenital ≠diaphragmatic hernia*" or "transposition of great arteries" or "pulmonary valve atresia" or "tricuspid valve atresia" or "Tetralogy of Fallot" or "ventricular septal defect" or "hypoplastic left heart syndrome" or "interrupted aortic arch" in the abstract and title field only. All references were exported to EndNote 21 (Thomas Reuters, New York, NY).

Due to the limitation of time and resources of this Master's thesis, the original search strategy was limited solely to cardiac congenital anomalies with the intent to expand to other body systems at a later time.

2.1.2.4. Cardiac Congenital Anomalies of Interest

Common Truncus Arteriosus (or "Common Truncus") is a rare CHD where the truncus arteriosus arises from the heart instead of the pulmonary artery and the aorta. This condition occurs when the embryonic structures, meant to separate into the aorta and pulmonary artery, fail to properly divide.[45] In Common Truncus, blood from both the left and right ventricles mix in the truncus before distributing to the body and the lungs. There, oxygen-poor blood flows to the body and oxygen-rich blood to the lungs, leading to inefficient blood oxygenation and overloading of the heart and lungs. Symptoms can include cyanosis (bluish skin due to lack of oxygen), heart failure, and difficulty breathing. Surgical correction is usually required soon after birth, involving the separation of the common truncus into the aorta and pulmonary artery, and, thus, creating a conduit to connect the right ventricle to the pulmonary arteries. [46]

Pulmonary Valve Atresia is a CHD where the pulmonary valve, which controls blood flow from the right ventricle to the pulmonary artery, is absent or severely malformed. In this condition, there is no functional valve, or the valve is obstructed, which prevents blood from flowing from the right ventricle to the lungs. Blood flow to the lungs depends on the patent ductus arteriosus (PDA) or other shunts present at birth.[47] Symptoms often include cyanosis, difficulty breathing, and heart failure. Initial management typically involves using prostaglandins to keep the PDA open and provide blood flow to the lungs. Surgical options can include creating a new pathway for blood flow or placing a pulmonary valve. [48]

Tricuspid Valve Atresia is a CHD where the tricuspid valve, which normally separates the right atrium from the right ventricle, is absent or blocked. In tricuspid valve atresia, the right ventricle is either underdeveloped or absent. Blood cannot flow properly from the right atrium to the right ventricle, so it must flow through an atrial septal defect (ASD) or patent foramen ovale (PFO) to reach the left side of the heart and then to the lungs.[49] Symptoms include cyanosis, fatigue, and poor feeding in infants. Over time, the condition leads to heart failure and inadequate oxygenation of blood. Treatment typically involves a series of surgeries to redirect blood flow and improve oxygenation. The initial procedure often involves creating a connection between the right atrium and pulmonary arteries (e.g., a Glenn shunt) and eventually constructing a pathway from the right atrium to the pulmonary arteries (Fontan procedure).[50]

Hypoplastic Left Heart Syndrome (HLHS) is a severe CHD characterized by underdevelopment of the left side of the heart, more specifically, the left ventricle, left atrium, and mitral and aortic valves. In HLHS, the left side of the heart cannot effectively pump blood to the body. Blood diverts to the systemic circulation, via a PDA and an ASD, resulting in inadequate blood flow to the systemic circulation and, oftentimes, severe heart failure.[51] Symptoms typically include cyanosis, rapid breathing, and signs of heart failure, i.e. swelling, fatigue, etc. HLHS is often diagnosed shortly after birth due to the severity of symptoms. The treatment generally involves staged surgical procedures to reconstruct the heart's circulation, e.g. the Norwood procedure as the first step, followed by the Glenn procedure and the Fontan procedure.[52]

Interrupted Aortic Arch (IAA) is a CA with a gap or interruption in the aorta, the major artery that carries blood from the heart to the rest of the body. The IAA is often This interruption typically occurs between the left subclavian artery (which supplies blood to the left arm) and the ductus arteriosus or the left common carotid artery.[53] The disruption in blood flow results in poor perfusion of the lower body and may lead to severe heart failure and shock. Symptoms include cyanosis, respiratory distress, and signs of shock. IAA is often diagnosed in the neonatal period or early infancy. Immediate surgical

intervention is necessary to repair the gap in the aorta and restore normal blood flow. The surgery usually involves resection of the interrupted segment and end-to-end anastomosis or bypass grafting. [54]

Tetralogy of Fallot (TOF) is a CHD that involves a combination of four specific heart malformations: (1) Ventricular Septal Defect (VSD), a hole between the left and right ventricles; (2) pulmonary stenosis, narrowing of the outflow tract from the right ventricle to the pulmonary artery; (3) overriding aorta, the aorta is positioned directly over the VSD and straddles both ventricles; (4) Right Ventricular Hypertrophy (RVH), the thickening of the muscular walls of the right ventricle.[55] These defects cause oxygen-poor blood to flow from the right ventricle to the aorta instead of the pulmonary arteries, leading to cyanosis and increased workload on the heart. Symptoms include cyanotic spells (tetralogy spells), difficulty breathing, and fatigue. The severity of symptoms can vary from mild to severe. Surgical repair is typically performed during infancy and involves closing the VSD relieving the outflow obstruction and widening the narrowed pulmonary artery. [56]

Transposition of the Great Arteries (TGA) is a severe CHD where the positions of the aorta and pulmonary artery are reversed. Essentially, the aorta arises from the right ventricle, and the pulmonary artery from the left ventricle. In TGA, the systemic and pulmonary circulations are parallel rather than sequential. Oxygen-poor blood is circulated through the body, and oxygen-rich blood is circulated through the lungs, resulting in severe oxygen deprivation in the body tissues. Symptoms include severe cyanosis, difficulty breathing, and signs of heart failure.[55] The primary treatment for TGA is surgical. The most common procedure is the arterial switch operation which involves switching the aorta and pulmonary arteries to their correct positions and reconstructing the coronary arteries to fit the new anatomy.[56]

Table I: Descriptions of Most Common Congenital Heart Defects

Congenital Anomalies	Pathologies	Birth Prevalence Globally per 10,000 Total	Risk Factors	Treatment	Prognosis
Congenital Heart Defects	Structural or functional abnormality of the heart or major blood vessels that are present at birth.	80	Genetic factors	Depending on the nature and extent of the defect, treatment options can vary from medication and catheterization to open heart surgery and heart transplantation.	Varies greatly depending on the kind and extent of the defect. With the right care, many children with congenital heart defects can have normal lives, however some may experience long-term health problems.
Common Truncus	The truncus arteriosus comes out of the right and left ventricles, instead of the pulmonary artery and the aorta. This leads to the mixing of oxygen-poor and oxygen-rich blood.	0.7-1.4	Genetic syndrome Maternal diabetes Certain medications	Surgical repair, typically within the first few weeks of life, separates the pulmonary and systemic circulations.	Many children recover from early surgery, but frequently need lifelong cardiology care and follow-up treatments.
Transposition of Great Arteries	The positions of the pulmonary artery and the aorta are swapped, causing oxygen-poor blood to circulate through the body and oxygen-rich blood to circulate through the lungs.	2.3-4.7	Genetic factors Maternal Diabetes Older maternal age	Arterial switch operation within first weeks of life	Many children recover from early surgery, but frequently need lifelong cardiology care and follow-up treatments.
Tetralogy of Fallot	A combination of four defects: ventricular septal defect, pulmonary stenosis, right ventricular hypertrophy, and an overriding aorta. This results in oxygen-poor blood being pumped to the body.	3.5-5.8	Genetic conditions Maternal diabetes Maternal phenylketonuria (PKU)	Surgical repair typically within the first year of life	Many children recover from early surgery but may need additional surgeries or interventions and frequently need lifelong cardiology care and follow-up treatments.
Pulmonary Valve Atresia	The pulmonary valve does not form properly, preventing blood from flowing from the right ventricle to the lungs.	0.8-1.3	Genetic factors Maternal illness Certain medications	Series of surgeries, including shunt placement and valve repair or replacement, to ensure blood flow to the lungs	Varies depending on the severity and presence of other heart defects. Regular follow-up is necessary.
Tricuspid Valve Atresia	The tricuspid valve is missing or abnormally developed, obstructing blood flow from the right atrium to the right ventricle.	1.0-1.5	Genetic factors Maternal diabetes Older maternal age	Series of surgeries to redirect blood flow, including the Glenn and Fontan procedures.	Many children have good outcomes with surgical intervention but require lifelong cardiology care.
Hypoplastic Left Heart Syndrome	The left side of the heart is underdeveloped, affecting normal blood flow through the heart.	1.0-2.1	Genetic factors Maternal diabetes Maternal smoking	Series of surgeries (Norwood, Glenn, and Fontan procedures) or heart transplant.	With surgery, many children can survive and grow, but they often face ongoing medical issues and require lifelong follow-up.
Interrupted Aortic Arch	A portion of the aorta is missing or interrupted, affecting blood flow from the heart to the lower part of the body.	0.2 -0.3	Genetic conditions Maternal illness	Surgical repair shortly after birth to reconnect the aorta.	With early surgery, many children do well, though they require regular follow-up and sometimes additional interventions.

2.1.2.5. Data Extraction

Data will be extracted from papers included in the scoping review by one other independent reviewer, total of two reviewers, using a data extraction tool developed by the reviewer. The data extracted will include specific details about the concept, context, study methods and key findings relevant to the research questions and objectives. Data to be extracted includes author, date of publication year, title, type of source, source name, language, country, country income level, reporting guideline used, number of institutions, health system coverage, rural urban classification, public/private, registry/database name, cause specific, anatomical region specific, funding/resources, and any other points of relevance. Missing data is to be expected. This project aims to identify gaps or missing data and identify patterns and trends through the given data. A PRISMA-Sr flow diagram was constructed in the process, see Figure A1.

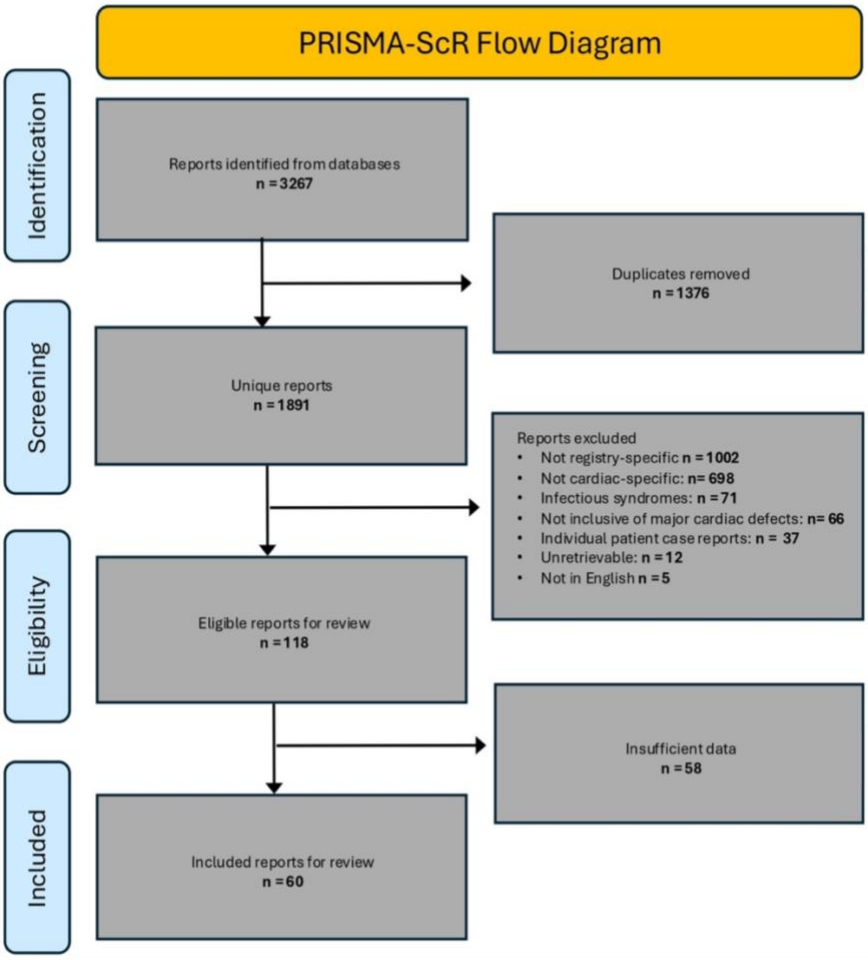


Figure A1: PRISMA-ScR Flow Diagram Illustrating the Study Filtering and Selection Process

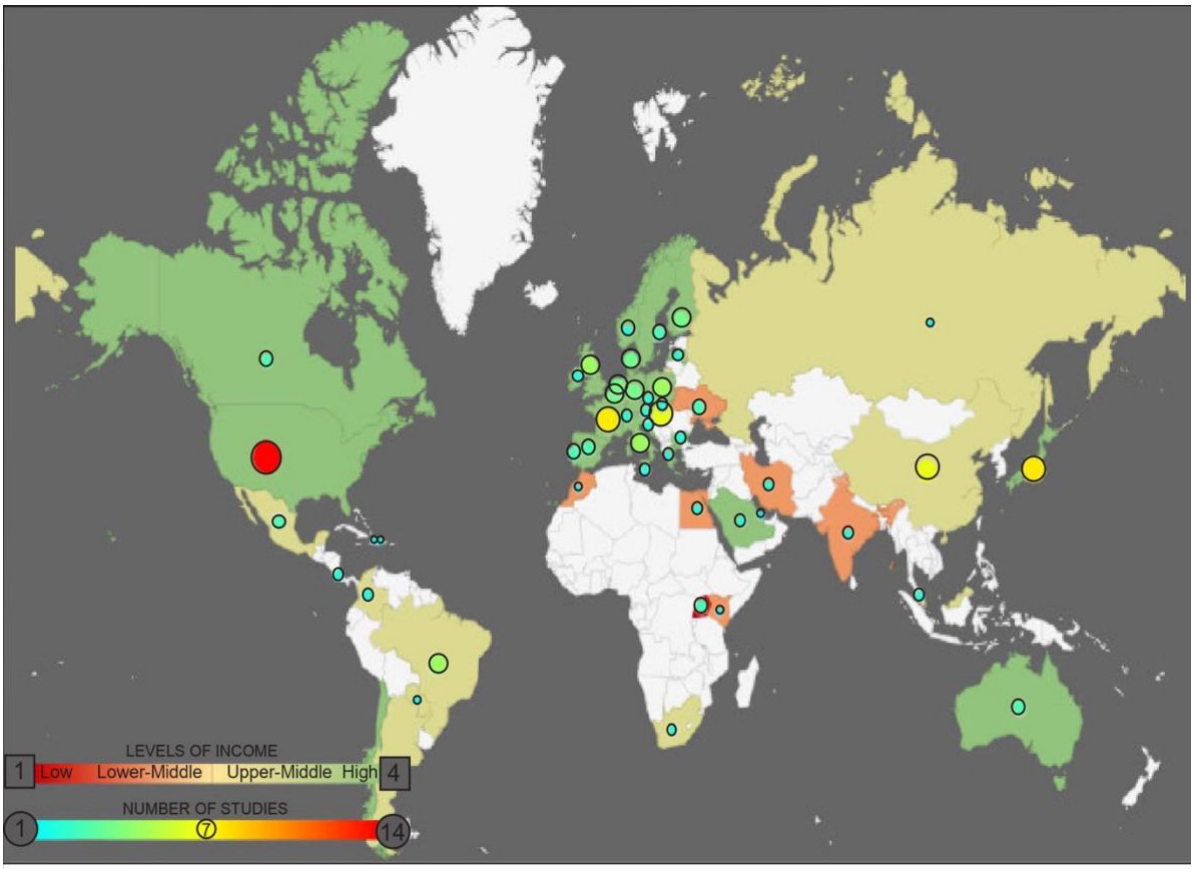


Figure A2 : Output of PRISMA-ScR Protocol and World Map Comparisons. The circular data points depict the number of studies that fit the rapid scoping review criteria while the color scale indicates each country's respective level of income. Majority of registries were at the lower spectrum, with an output of 1 study, while remaining

2.1.3. Ethical Considerations

The author primarily uses publicly available information and peer-reviewed journal articles. The research does not involve direct interaction with patients, nor does it access or utilize patient registries or hospital records. Given the nature of the study, which focuses on the synthesis of existing literature and does not involve human or animal subjects, additional ethics approval was not required.

2.1.4. Limitations of the Study

Despite the comprehensive nature of this rapid scoping review, several limitations affect the conclusions that can be drawn. The scope of the study, focusing on literature from 2018 to 2024, may not capture long-term trends or the evolution of registries over a more extended period. Additionally, the variability in data quality and registry comprehensiveness across different regions poses significant challenges. Data from

HICs are often more complete and more reliable due to better healthcare infrastructure and reporting mechanisms. In contrast, LMICs frequently face issues such as underreporting and incomplete data, which can skew comparative analyses.

The study is also limited by language barriers, as the literature review primarily focuses on sources available in English, which essentially means that valuable data is missing from non-English speaking regions, which in most cases is not representative of LMICs. Moreover, the rapid nature of the scoping review means that in-depth analysis and longitudinal studies are not feasible, which could provide more detailed insights into the effectiveness and implementation of these registries.

Globally, CA registries encounter several inherent limitations. One significant issue is the heterogeneity in registry designs and data collection methods. Different countries and even regions within countries may use varying definitions, classifications, and diagnostic criteria for CHDs, leading to inconsistencies in data. This variability complicates cross-registry comparisons and global analyses.

2.2. Grading Scale

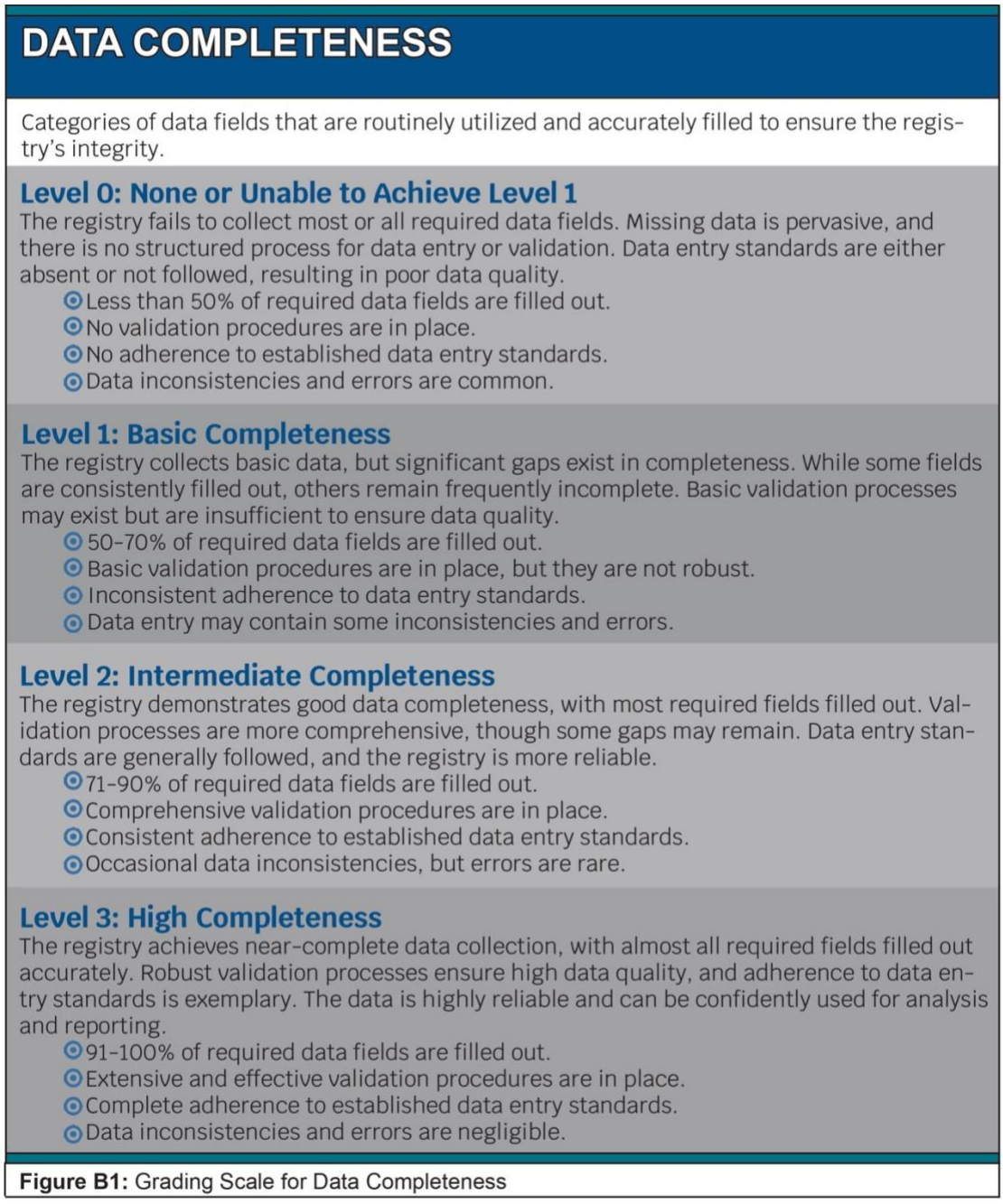


Figure B1: Grading Scale for Data Completeness

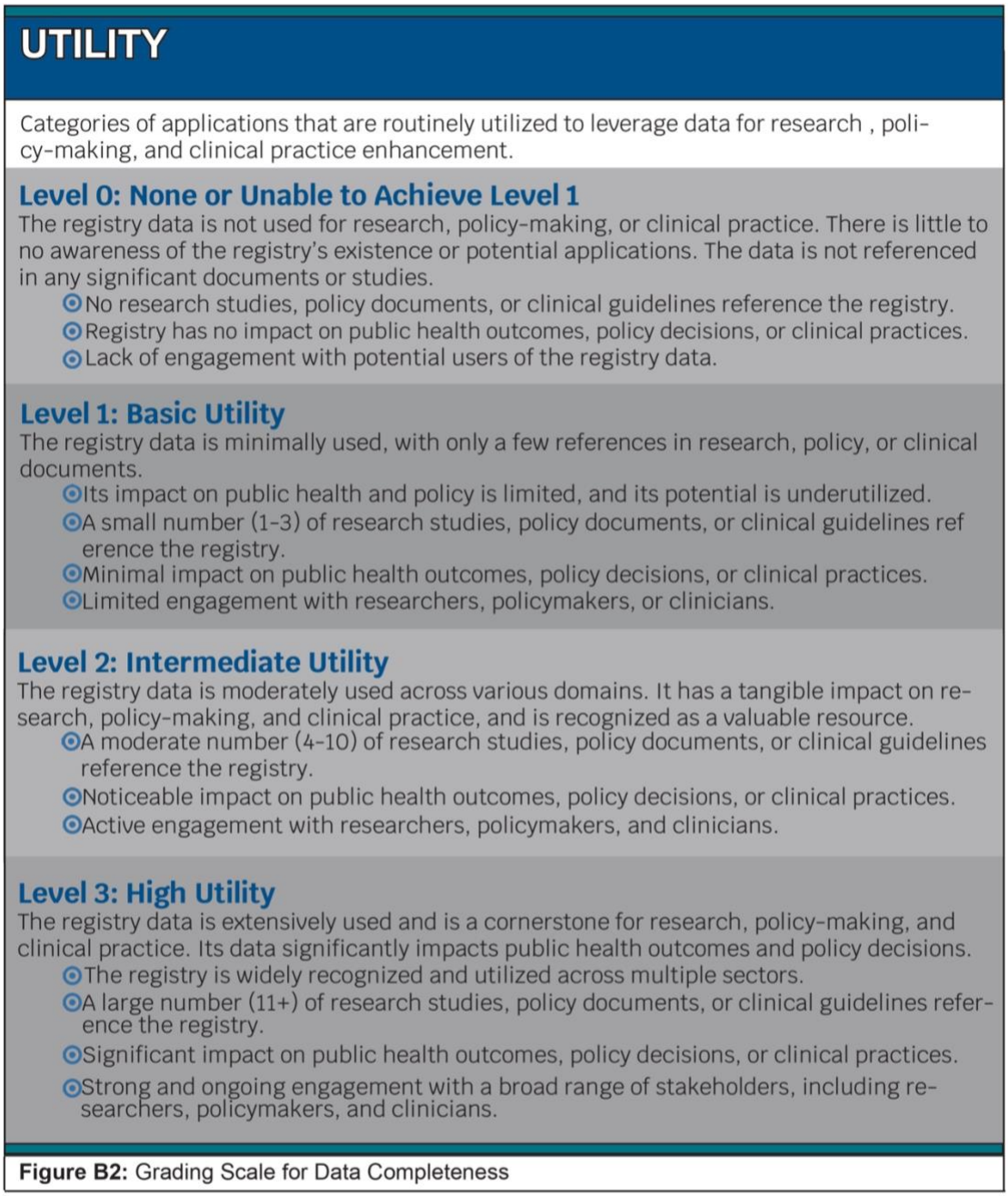


Figure B2: Grading Scale for Data Completeness

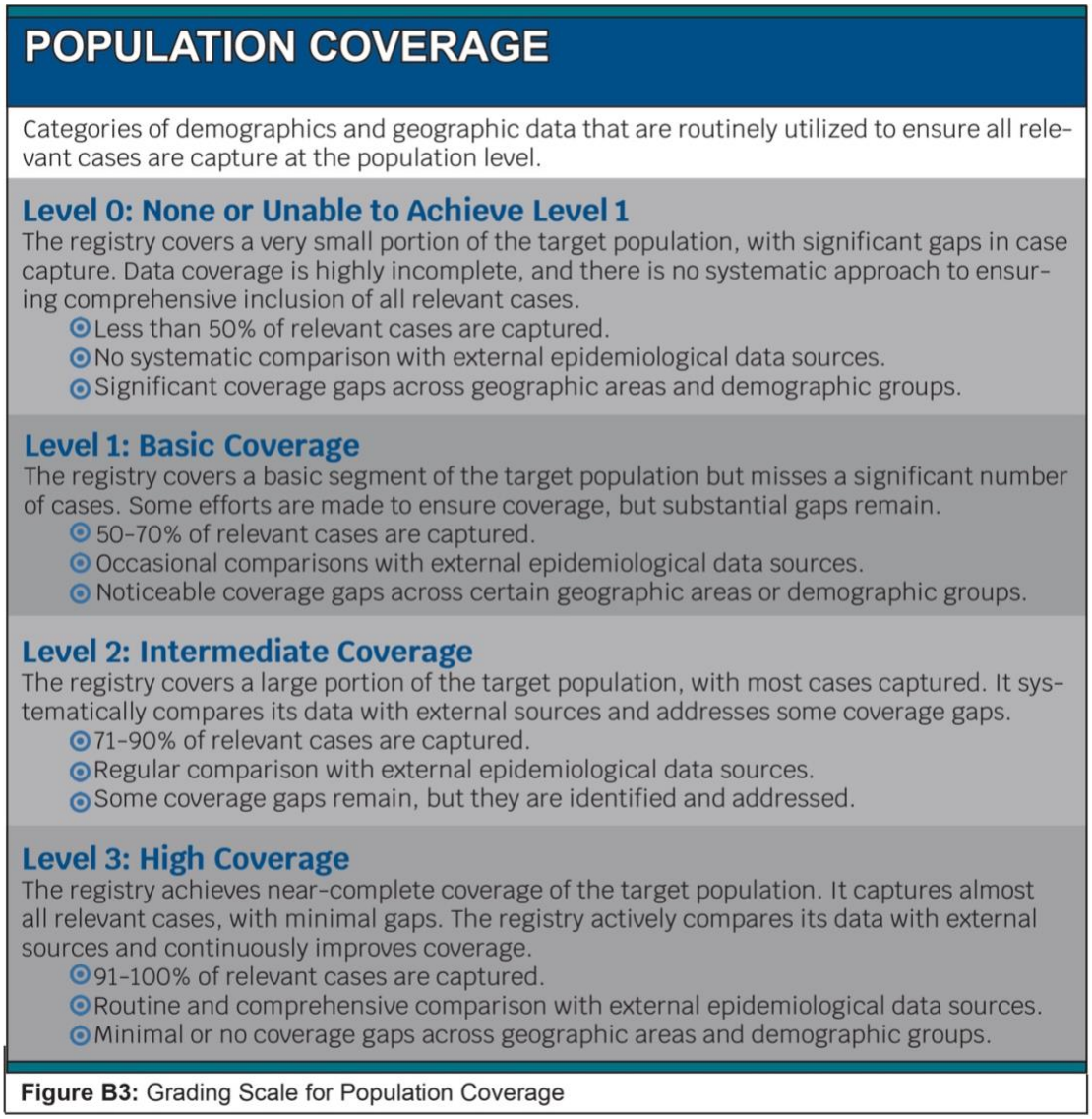


Figure B3: Grading Scale for Population Coverage

2.2.1. Grading Scale Tiers Levels Explained

Improving the quality and effectiveness of CHD registries requires a detailed and structured approach. A grading scale, ranging from Level 0 (None or Unable to Achieve Level 1 of standard practice) to Level 3 (High Impact, High Quality Data), was constructed to measure a registry's capacity for data completeness, utility, and population coverage. Traditionally, there has been a lack of uniform criteria to evaluate the effectiveness of CA registries, particularly for cardiac conditions. The introduction of this grading scale bridges that gap by providing specific, measurable criteria at four

distinct levels of performance for each dimension to identify the strengths and weaknesses of each country's registry and, in doing so, suggest more concrete ways a country can progressively elevate the performance of its registries from a Level 1 to a Level 3.

2.2.1.1. Moving From Level 1 to Level 2 (Basic to Intermediate)

2.2.1.1.1. Data Completeness

At Level 1, a registry captures 50-70% of required data fields, but there are still significant gaps in data entry. Moving to Level 2, where 71-90% of fields are filled, not only signifies a significant improvement in data completeness but also enhances the reliability and accuracy of the registry. However, this transition may pose challenges such as the need for augmented training, standardization, and more comprehensive validation processes.

The benefits of training and standardization are significant. By training data collectors on standardized protocols, the occurrence of incomplete or inconsistent data can be significantly reduced. Clear data definitions and standards, along with uniformity across various collection points, will enforce the reduction in inconsistencies.[167] Moreover, the advantages of implementing more comprehensive validation processes contribute to the accuracy and completeness of a registry. Moving to Level 2 requires meticulous validation mechanisms that automatically flag missing or erroneous entries and trigger alerts for corrections. The introduction of double-entry checks, consistent auditing, and cross-referencing data with external datasets further boosts confidence in collected data. Moreover, supplementing these processes with technological solutions improves overall quality and output. For instance, the automation of data collection and minimizing manual input through integrating electronic health records (EHRs) can significantly reduce errors which greatly tackles the issue of inconsistent adherence to data entry standards.[168]

2.2.1.1.2. Utility

To move from Basic to Intermediate Utility, we look towards increasing stakeholder engagement and public health implications to increase both direct and indirect impact. Engaging with a broader range of researchers, clinicians, and policymakers, whether through workshops or collaboration with national health agencies, is beneficial for raising awareness of a registry's value.[168] Moreover, developing partnerships with research institutions ensures that the data is widely used in academic and clinical studies. These ideas have a trickledown effect and go hand in hand with public health implications; showing a tangible impact on health outcomes can improve the perceived utility of the registry. Countries can achieve this by setting specific public health goals and measuring how data from the registry inform these outcomes. For example, a

reduction in infant mortality from CHDs based on registry data-driven policies is a measurable goal.[168]

2.2.1.1.3. Population Coverage

At Level 1, only 50-70% of relevant cases are captured. Moving to Level 2 (71-90%) requires improved case capture and external data approaches. Systematic processes for identifying and enrolling all eligible cases across the country are essential in improving the capture of cases. Establishing better communication between hospitals, clinics, and regional health centers can ensure wider coverage; this includes using national disease surveillance systems, which can provide a comprehensive overview of disease patterns and help identify potential cases, to ensure all geographic areas are included. Likewise, we can also improve population coverage by utilizing comparative analyses with external data. By regularly comparing registry data with external epidemiological data sources, such as national surveys or international registries, the registry can identify and address gaps in population coverage. This practice involves cross-referencing the registry data with external sources to ensure that all relevant cases are captured, and that the registry provides a comprehensive view of the population's health status.

2.2.1.2. Moving From Level 2 to Level 3 (Intermediate to High)

2.2.1.2.1. Data Completeness

Achieving Level 3 means accurately filling out 91-100% of data fields. Level 3 requires comprehensive data collection systems and regular audit & feedback mechanisms. Expanding the use of advanced digital tools, like machine learning and AI algorithms, for real-time data validation can help achieve near-complete data capture.[168] Using cloud-based platforms for data sharing between hospitals ensures timely and accurate data submission. Furthermore, instituting routine audits with feedback loops will help maintain the integrity of the data. Automated alerts for missing data and discrepancies should be followed by prompt corrective actions, with accountability measures in place.

2.2.1.2.2. Utility

At Level 3, a registry is at a heightened level of research, policy-making, and clinical practice. To achieve a Level 3 status, there should be evidenced, strategic dissemination of data and evidence-based policy. Widespread data entails widely available and easily accessible to public health officials and the scientific community. By publishing regular reports and datasets, a registry can increase citations and references in policy documents and academic publications. At a Level 3, registries should demonstrate evidence-based policies; this could involve regular presentations to policymakers or producing key data that inform healthcare decisions, like resource allocation for CHD interventions.

2.2.1.2.3. Population Coverage

To achieve 91-100% coverage in population coverage, a registry should demonstrate national mandates and have a comprehensive integration with health systems. Governmental mandates and legislation requiring all healthcare facilities to report relevant CA cases contribute to well-endowed coverage. Moreover, integrating a registry with national health systems ensures that all patients, regardless of location or socioeconomic status, are included; this requires interoperability between health systems, including public and private healthcare providers.[168]

3

Results and Discussion

3. Global Overview

3.1.1. Africa

3.1.1.1. Egypt

Most of the data and research on CAs in Egypt come from hospital-based studies or regional surveys, which indicate the prevalence and types of CAs but may only comprehensively cover some of the population due to the lack of a national registry. Globally, CAs affect approximately 3-7% of neonates, with a sizable portion involving the cardiovascular system.[57] Studies from various governorates across Egypt report differing prevalence rates of CHDs. For instance, a study conducted in Fayoum Governorate found a 7.4% prevalence of CAs among neonates, with 32.4% cardiac CHDs.[58] Another notable statistic comes from Al-Ahrar Teaching Hospital in Zagazig, where CAs had a spot incidence of 2.47%, with 19% of the anomalies representing cardiac CAs. [59]

A myriad of studies highlight the significant impact of consanguinity, rural residence, poor antenatal care, and multiparity on the prevalence of CHDs in Egypt. The study from Fayoum emphasized that an 82.4% of neonates with malformations were from rural areas, and a substantial number were related to consanguineous marriages.[58] These factors underscore the crucial role of genetic counseling and targeted public health interventions in high-risk populations, making it a necessary service for these communities.

The outcomes for neonates with CHDs in Egypt vary but generally reflect the need for enhanced healthcare services. High mortality rates associated with severe defects underline the urgency for early detection through prenatal screening and the importance of advanced neonatal care. The availability of technologies such as echocardiography, crucial for diagnosing CHDs, remains limited in resource-constrained settings such as Egypt.[60]

(See 3.1.7 Multi-National Registry)

3.1.1.2. Kenya

Kenya does not have a comprehensive national registry specifically for CAs. However, there have been efforts toward better surveillance and reporting within the healthcare system. In Kenya, cardiac CAs are critical to pediatric health concerns, with Kenyatta

National Hospital (KNH) in Nairobi serving as a primary referral and treatment center. Studies indicate that the prevalence of congenital heart disease in Kenya is comparable to global figures, with about 1 in every 100 children affected.[61]

The management of pediatric CHDs in Kenya has evolved over the years yet remains challenged by systemic and resource limitations. A significant study at KNH assessed the congenital heart disease Management Pathway (MP), revealing that although there has been progress in the management and follow-up phases, critical gaps still exist in early diagnosis and intervention. The incidence of CHDs such as VSDs, atrioventricular canal defects, and Tetralogy of Fallot reflects a broad spectrum of CHD prevalence in the Kenyan pediatric population. The mean ages for CHD detection stand at over 35 and 43 weeks, respectively, with interventions often delayed to around 47.5 weeks. This delay significantly deviates from global best practices where interventions are recommended within the first few months' post-diagnosis. [61]

The outcomes for CHD interventions in Kenya are sobering, with a high mortality rate observed before *and* after surgical interventions. Among patients diagnosed, only about 35% receive the necessary surgeries, with operative mortality rates for these surgeries alarmingly high.[61] Such outcomes underscore the need for improved surgical capacities and healthcare strategies tailored to early and effective intervention.

In the broader context of the Middle East and Africa, the presence of a collaborative multinational registry in Kenya could bridge the gap resource allocation, expertise sharing, and technological access. Kenya’s contribution to the Multidetector Computed Tomography (MDCT) study for CHDs is a prime example. Such collaborations lead to improved data accuracy, a broader impact on public health policies, and enhanced clinical practices across the regions involved. Kenya's cardiac CA management, though improving, still faces critical challenges that affect the outcomes and quality of life for children born with CHD.

(See 3.1.7 Multi-National Registry)

3.1.1.3. Morocco

Morocco has made a significant leap in addressing CAs with the establishment of the Moroccan Registry of Congenital Anomalies which gathers and analyzes healthcare facility data nationwide. The prevalence of CHDs in Morocco aligns with the global incidence rates of about 8 per 1000 live births, with critical congenital heart diseases (CCHD) occurring in approximately 2.5 to 3 per 1000 live births. These conditions significantly contribute to neonatal morbidity and mortality, making early detection and intervention crucial.[62] Despite advancements, challenges remain in achieving early diagnosis due to the limitations in screening and diagnostic facilities across the country.

Recent initiatives in Morocco, including the pilot study of pulse oximetry screening at Mohammed VI University Hospital in Marrakesh, have shown promising results. This screening helps in early detection of CCHD by measuring pre- and post-ductal saturations (the measurement of oxygen in a newborn's hand and foot) and has been applied to a significant portion of newborns, although coverage is not yet universal. [63]

While the registry collects a broad range of data, it faces challenges such as incomplete coverage and inconsistent data quality across different regions. The utility of the registry data is primarily focused on estimating prevalence and aiding health planning but has limited impact on broader public health outcomes and policy decisions. Moreover, specific demographic segments remain underrepresented in the data collection, underscoring the urgent need for more inclusive data-gathering strategies.

The Moroccan Registry's strength lies in its ability to compile extensive data to guide public health policies and facilitate healthcare improvements for children with CHD. However, enhancing the data validation processes and expanding coverage to achieve more comprehensive national data integration are crucial to optimizing its impact. Morocco must focus on standardizing data collection methods across all regions and enhancing diagnostic capabilities to improve early detection rates. Expanding the use of non-invasive screening methods like pulse oximetry and integrating these practices into routine neonatal care can significantly improve the detection rates of CCHD. Moreover, fostering international collaborations could provide insights and technical support to refine the registry operations and outcomes. [63]

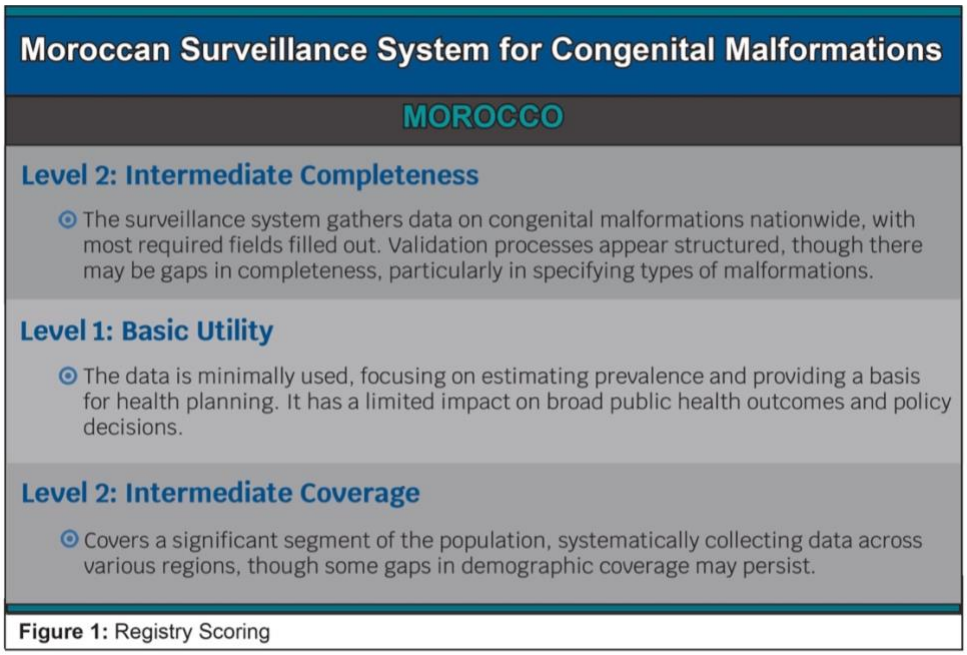


Figure 1: Registry Scoring

3.1.1.4. South Africa

South Africa is actively working towards enhancing its surveillance and management of CHDs through initiatives like the South African Congenital Disorders Association (SACDA). These efforts aim to fortify the recording and understanding of CAs to improve public health outcomes significantly. The integration of CA registries, such as the PROTEA project, showcases a concerted effort to bridge gaps in epidemiological data necessary for advancing maternal and child health services in a resource-limited setting.[64]

The complexity of South Africa is compounded by socio-economic disparities affecting healthcare access and quality. National initiatives like SACDA and PROTEA are pivotal in structuring an effective response to this public health challenge. These programs aim to consolidate data from diverse regions to create a cohesive strategy for managing congenital disorders locally and nationally. [64] The prevalence of CHD in South Africa aligns with global incidence rates but is aggravated by unique regional challenges such as limited access to specialized care. The PROTEA registry, a notable initiative in this domain, serves as a multicenter CHD registry and biorepository. Although initially focused on Western Cape Province, the project's expansion into other parts of South Africa and Namibia signifies a growing recognition of the need for broader coverage. [65]

The utility of the PROTEA registry facilitates research into the epidemiology and genetic determinants of CHD. However, the impact remains moderate as detailed insights into broader international policy or practice changes are limited. The research output from such registries is essential for formulating targeted interventions and allocating resources more effectively.[65] Despite progress, the challenges of comprehensive national coverage still need to be addressed. With an intermediate level of population coverage, the registry's reach is substantial but needs to be more encompassed. Resource limitations and uneven healthcare infrastructure across different regions hinder the achievement of a fully integrated national CA registry. Moreover, the varying quality and depth of data collection across regions pose additional hurdles in standardizing CHD management protocols.

The outcomes related to CHD management in South Africa show a promising trend toward improved survival and quality of life, reflecting global advancements in pediatric cardiac care. However, the need for more specialized centers and trained healthcare professionals is acute, given the rising prevalence of CHD and its complexities. Enhancing surgical and interventional capabilities within the country is critical to reducing the reliance on international medical missions, which are not sustainable long-term solutions.

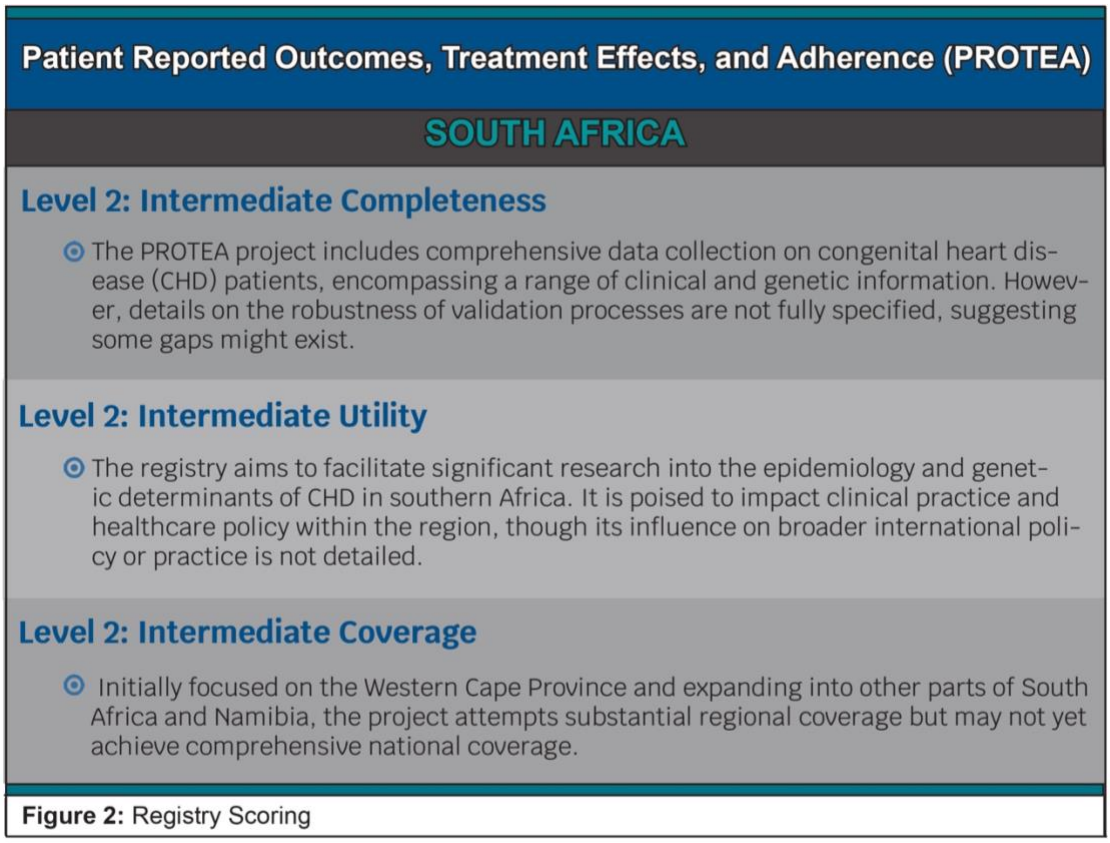


Figure 2: Registry Scoring

3.1.1.5. Uganda

In Uganda, the estimated prevalence of CHD is a significant concern, ranging from 8 to 12 per 1000 live births, which translates to approximately 1,280 to 1,920 babies born with CHD annually.[67] The most prevalent types of CHD in Uganda are VSDs and ToF, with the latter being the most common cyanotic heart disease observed. Despite efforts to establish a national registry for CAs, the system struggles with data completeness, utility, and coverage.[66]

The challenges of managing CHD in Uganda are compounded by limited resources and infrastructure, particularly in rural areas where many children with CHD are born. This often leads to delayed access to healthcare services, severely impacting the diagnosis and timely treatment of CHD. The Uganda Heart Institute (UHI) is a central facility that provides surgeries and interventions, but the reach is limited, and the cost is often prohibitive for many families.[67]

Initiating a CA surveillance system aims to enhance data collection across several Kampala hospitals. However, the system has encountered significant staffing and

resource challenges, limiting its effectiveness and coverage to a few urban hospitals rather than achieving nationwide reach.[66] So far, the data collected through this system has had minimal utility beyond local health policy adjustments, failing to contribute significantly to broader research or international policy frameworks.

The surveillance and studies conducted reveal a pattern where most children diagnosed with significant CHD do not receive the necessary treatment, and about one-third of these children do not survive beyond their first month.[67] The UHI and other stakeholders have been crucial in training healthcare professionals across the country, but the overall impact remains constrained by systemic deficiencies.

Efforts to expand the registry's coverage and improve data utility are crucial. Training and integration of healthcare providers into the registry system, coupled with increased governmental and international support, could enhance the effectiveness of CHD management in Uganda. Early diagnosis and intervention strategies need to be prioritized to improve outcomes for children with CHD.

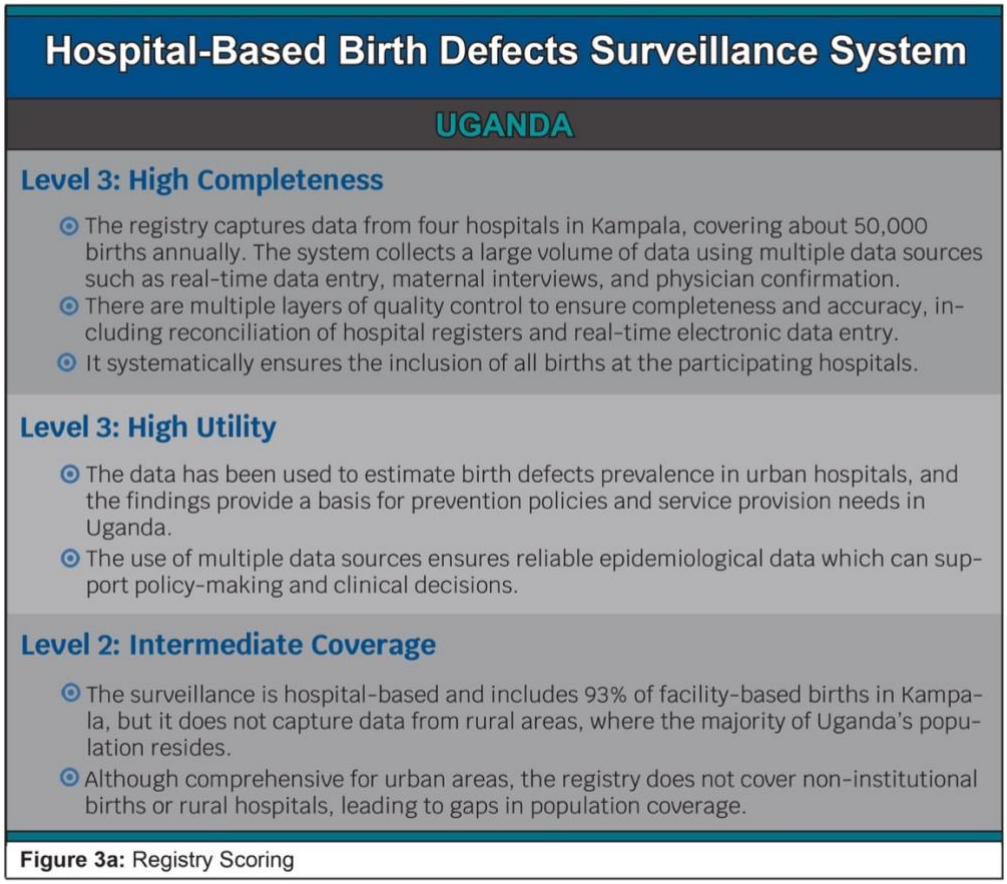


Figure 3a: Registry Scoring

Ugandan Birth Defects Surveillance System

UGANDA

Level 1: Basic Completeness

- The system captures basic data with some inconsistencies and errors. It employs basic validation processes but struggles with the completeness and reliability of data due to staffing and resource constraints.

Level 1: Basic Utility

- The data is minimally used, potentially impacting local health policies and practices but not extensively contributing to broader research or policy changes.

Level 1: Basic Coverage

- The system covers a significant but limited portion of the population in Kampala, focusing on several major hospitals but not achieving broader geographic coverage.

Figure 3b: Registry Scoring

Hospital-Based Birth Defects Surveillance System in Kampala, Uganda

UGANDA

Level 1: Basic Completeness

- The study assesses the management of in-hospital cardiac arrests in a limited setting with basic data collection on intervention efficacy and immediate outcomes.

Level 1: Basic Utility

- The utility is minimal beyond the immediate clinical setting, providing baseline data that might inform local improvements but not broadly impacting wider clinical or policy decisions.

Level 1: Basic Coverage

- The study is limited to a single hospital setting, providing insights into cardiac arrest management in that specific context but not covering a broader patient population effectively.

Figure 3c: Registry Scoring

3.1.2. Asia

3.1.2.1. China

China has seen a steady increase in CHDs. A recent study in the Haitian District of Beijing reported a cumulative birth prevalence of CHDs of 80.77 per 10,000 births from 2013 to 2022, indicating an upward trend primarily due to the diagnosis of non-critical CHDs expedited by advancements in diagnostic technologies.[68]

Registries such as the Chinese Birth Defects Monitoring Program in China (CBDMP) are often augmented by local registries, studies, and collaborative multinational registries which provide more comprehensive insights into regional trends and outcomes. The types of CHDs most frequently identified include VSDs, patent ductus arteriosus (PDA), and ASDs with non-critical CHDs constituting most cases. This shift towards a higher diagnosis of non-critical CHDs suggests an improvement in the availability and application of advanced diagnostic methods across the country, such as fetal echocardiography and genetic testing. [69]

The survival rates for children with CHDs have not shown significant improvement alongside the increase in diagnostic rates. This highlights the urgent need for enhanced medical procedures and healthcare policies that better address the treatment and management of these conditions. China's cardiac CA registries provide a critical framework for understanding and addressing the burden of CHDs. However, the increasing prevalence, especially of non-critical CHDs, calls for a balanced approach of proper diagnoses, treatment, and appropriate use of medical resources. [70]

(See 3.1.7 Multi-National Registry)

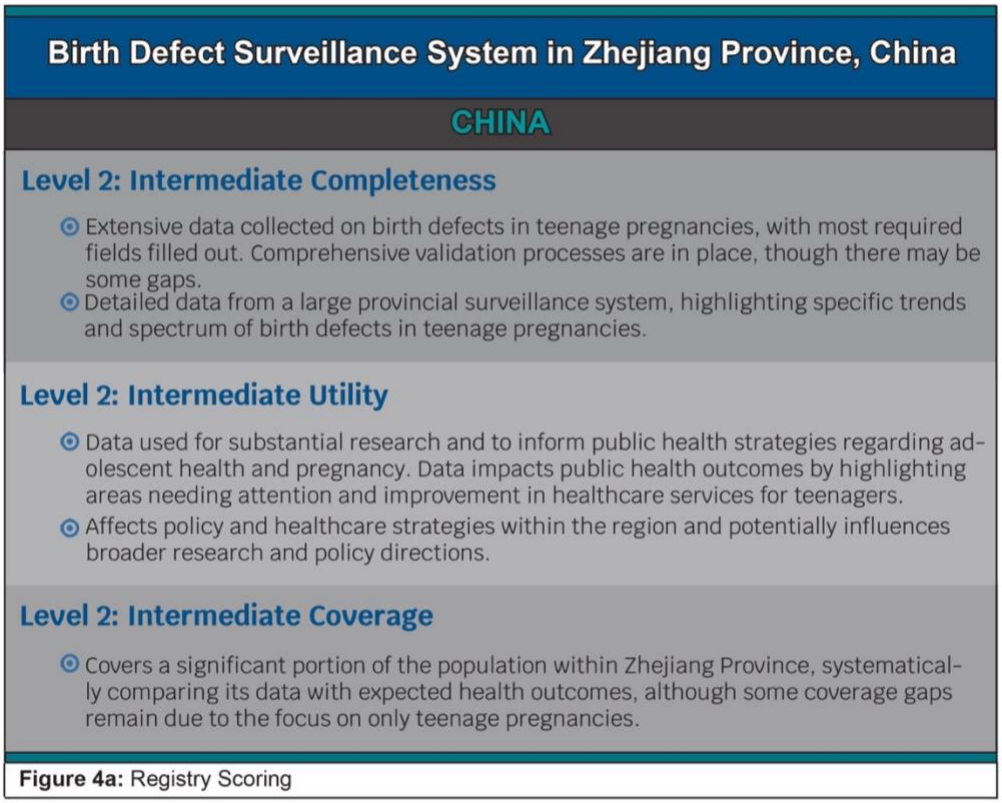


Figure 4a: Registry Scoring

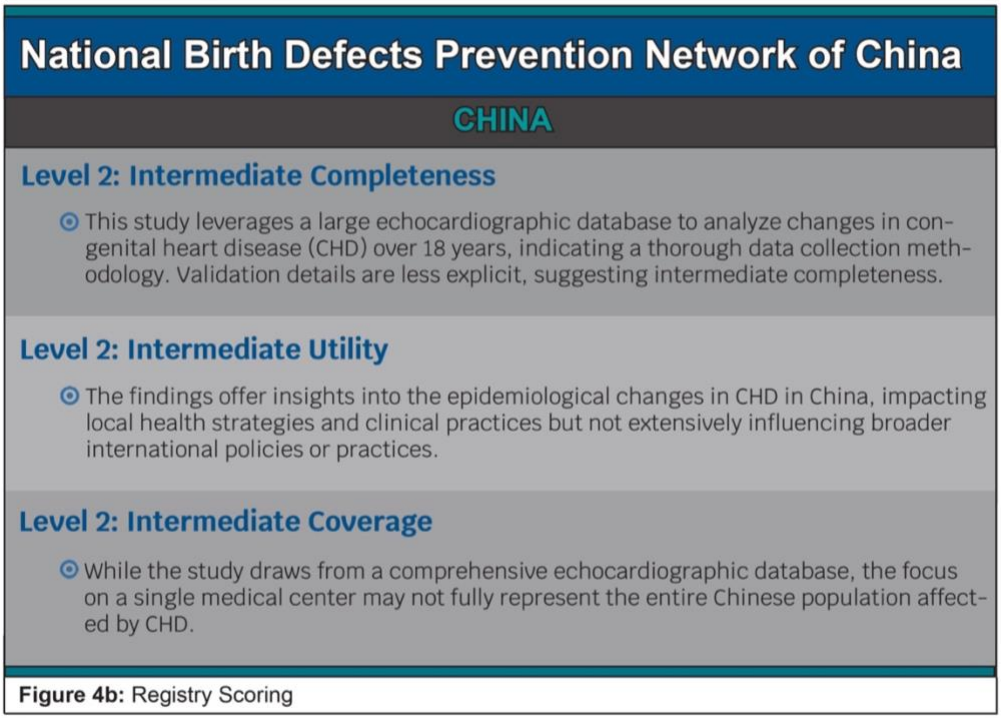


Figure 4b: Registry Scoring

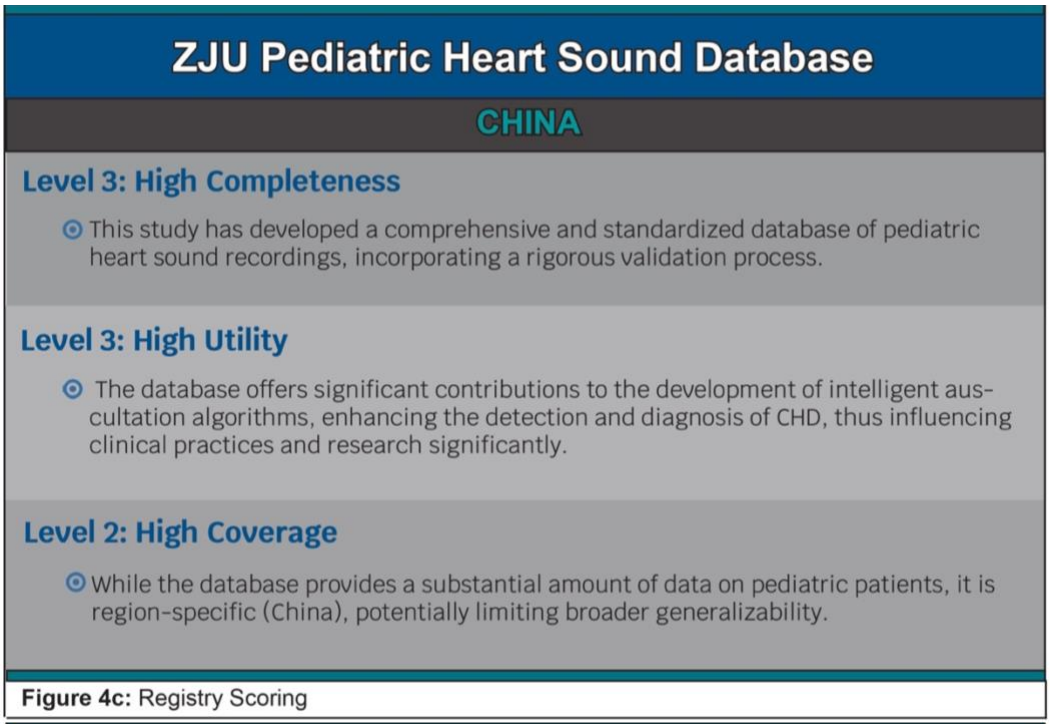


Figure 4c: Registry Scoring

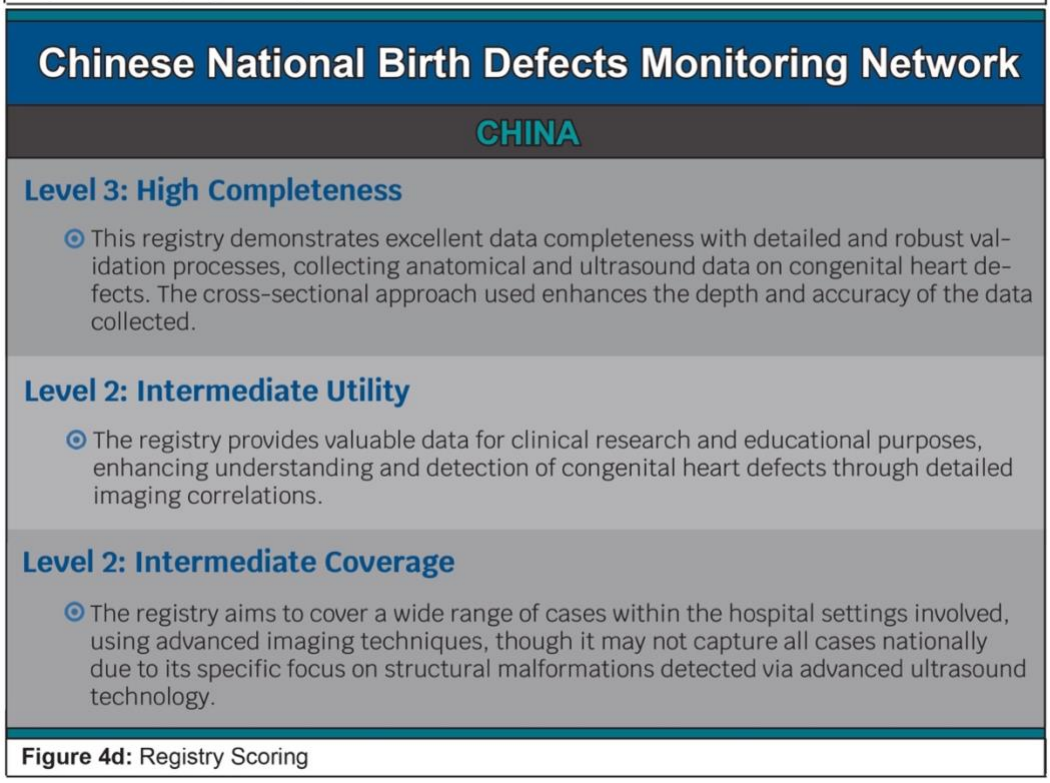


Figure 4d: Registry Scoring

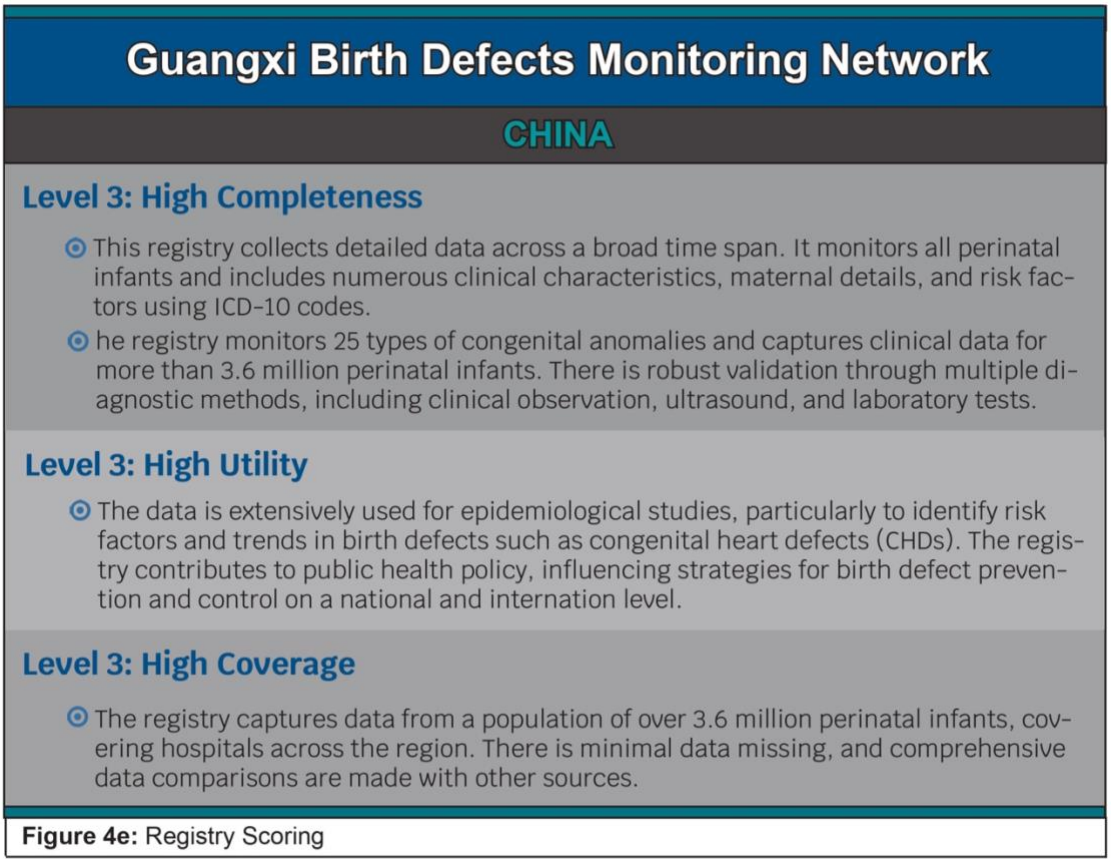


Figure 4e: Registry Scoring

3.1.2.2. India

India, with its diverse and populous landscape, faces significant public health challenges. The National Birth Defects Registry of India (NBDRI) collects comprehensive data from various healthcare facilities to aid in the surveillance and enhancement of maternal and child health outcomes. The prevalence of CHDs in India is estimated to be between 8-12 per 1,000 live births, translating to approximately 1,280 to 1,920 babies born with CHD annually. The most common types include VSD, PDA, and ASD, with ToF being the most prevalent cyanotic heart disease. These conditions vary in severity and the necessity for medical intervention, often requiring surgical procedures that are not readily accessible across all regions of India.[71]

Despite the substantial framework of the NBDRI, challenges persist in data completeness, utility, and population coverage. Studies like those on managing Tetralogy of Fallot in infants highlight these issues, with data completeness rated at Level 2 (Intermediate Completeness) due to detailed yet regionally limited data collection efforts. The utility of such studies is significant at a local level but less so on a

national or international scale, primarily impacting local health policies and clinical practices rather than contributing broadly to the field.[72]

The data from the NBDRI and related studies have significantly influenced several public health interventions to reduce the incidence and severity of cardiac CAs. These include prenatal screening programs, public health campaigns on maternal health, and initiatives to improve surgical outcomes for affected children. However, the reach of these programs is often curtailed by logistical, financial, and infrastructural limitations, particularly in rural and underserved areas.[71]

(See 3.1.7 Multi-National Registry)

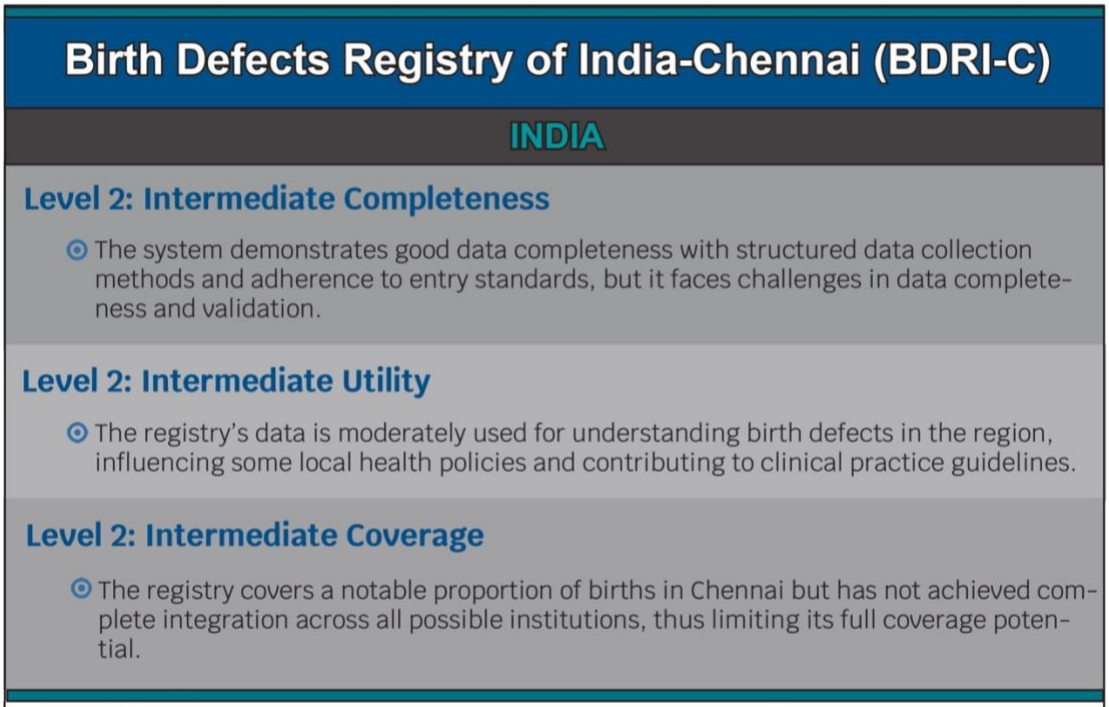


Figure 5: Registry Scoring

3.1.2.3. Iran

Iran has made significant strides in addressing cardiac CAs by establishing the Iranian Registry of Congenital Anomalies (IRCA). This registry collects comprehensive data from hospitals and healthcare facilities nationwide and contributes to enhancing the understanding of CHD epidemiology. In Iran, the IRCA, supported by the Ministry of Health and Medical Education, plays a vital role in monitoring and managing CHDs The IRCA's significant contributions toward identifying high-risk populations and trends in

disease prevalence, accentuates its importance in the fight against these significant health issues.[73]

CHD prevalence varies significantly, with reported incidences worldwide averaging around 8 cases per 1000 live births. In Iran, specific prevalence and incidence rates of CHD have been challenging to determine due to varying diagnostic capabilities and reporting standards across regions. However, initiatives like the Persian Registry of Cardiovascular Disease/Congenital Heart Disease (PROVE/CHD) in Isfahan have been pivotal in collecting data on pediatric patients.[74] The establishment of the IRCA marked a significant step towards structured data collection. The registry was designed to gather a wide array of patient data, facilitated by advancements in cardiovascular diagnostics and surgery, which have enabled the detection of complex CHDs even during the intrauterine period.[73]

Despite large-scale data collection efforts, challenges such as incomplete data validation and potential gaps in field completeness still need to be addressed. The registry initially focused on the urban center of Isfahan and involved several outpatient clinics and referral hospitals, reflecting a region-specific approach that might only capture part of the spectrum of CHD cases across Iran.[75] The utility of the IRCA and associated registries like PROVE/CHD has been primarily within local and regional contexts, providing data crucial for understanding CHD epidemiology and identifying risk factors. While these registries have influenced local healthcare practices, their impact on national or international policy has been limited. However, their focus has facilitated significant research into CHD's epidemiology and genetic determinants, contributing to improved clinical practices and healthcare policy within Iran. [75]

While significant, these registries' population coverage has yet to achieve comprehensive national coverage. The focus has remained on specific urban centers and associated healthcare facilities, which may not fully represent Iran's rural and less accessible regions. Future strategies should aim to expand the reach of these registries to ensure a more inclusive and comprehensive national health surveillance system.

(See 3.1.7 Multi-National Registry)

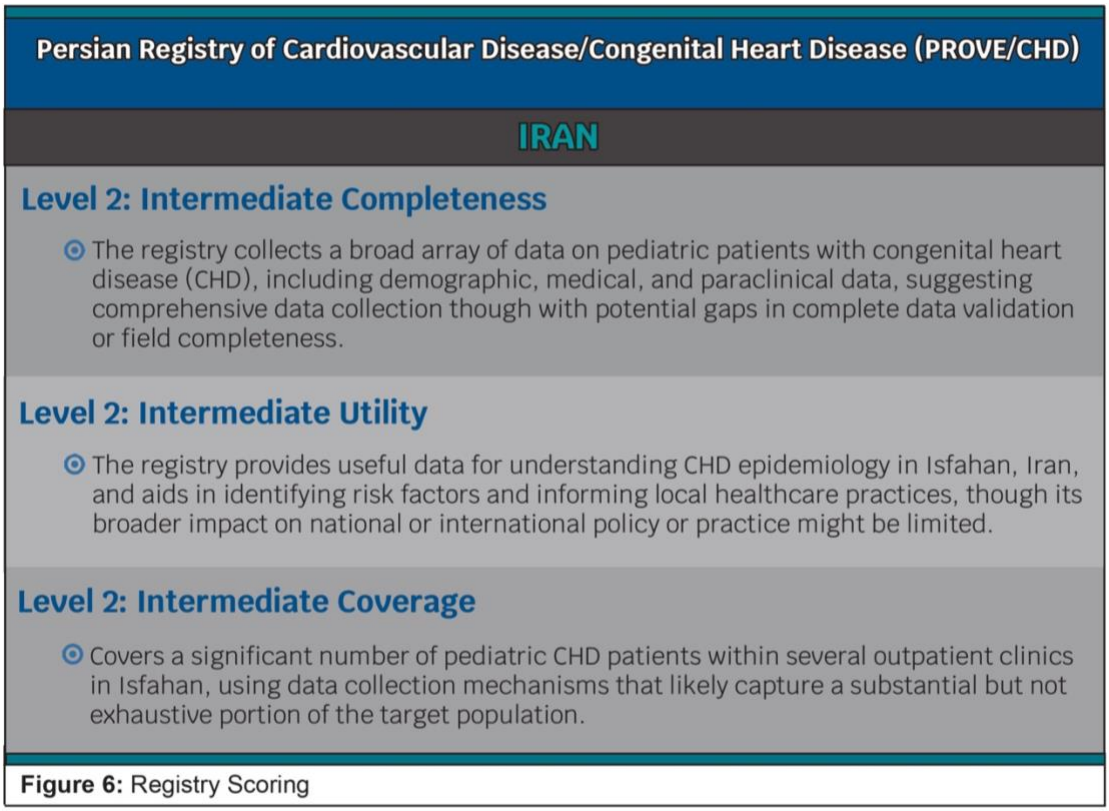


Figure 6: Registry Scoring

3.1.2.4. Japan

Japan, recognized for its advanced healthcare system, has developed an intricate network of registries to monitor cardiac CAs. The Japanese Congenital Anomalies Surveillance System (J-CASS) provides data from healthcare facilities nationwide, aiming to enhance public health surveillance and healthcare services for affected children. This, coupled with the Japanese Cardiovascular Surgery Database (JCVSD), initiated in 2008, has since expanded to include nearly all institutions performing cardiovascular surgeries in Japan, with about 10,000 new registrations annually.[76] This comprehensive participation ensures a vast coverage of CHD surgery cases, providing a robust dataset for monitoring surgical outcomes and postoperative complications across the country.

The JCVSD exemplifies high data completeness standards, with meticulous data collection across various surgeries. The registry includes extensive details on surgical procedures and outcomes, backed by substantial validation processes that ensure the accuracy and reliability of the data. This level of detail supports the creation of reliable

risk models tailored explicitly for CHD surgery in Japan, aiding in performance evaluations and benchmarking of institutions .

The JCVSD's near-complete national coverage allows for a comprehensive analysis of CHD surgeries. The registry captures data from most institutions and ensures that the data reflects a broad demographic spectrum. This vast coverage facilitates a detailed understanding of the epidemiological patterns of CHDs across Japan, providing valuable insights into trends and treatment outcomes over time.

Despite its extensive utility and coverage, the JCVSD faces challenges, particularly expanding its scope to include long-term outcomes and postoperative quality of life. Future direction could involve integrating follow-up/ post-operative data, allowing for a better understanding of the long-term efficacy of surgical interventions and their overall impact on patients' lives.

(See 3.1.7 Multi-National Registry)

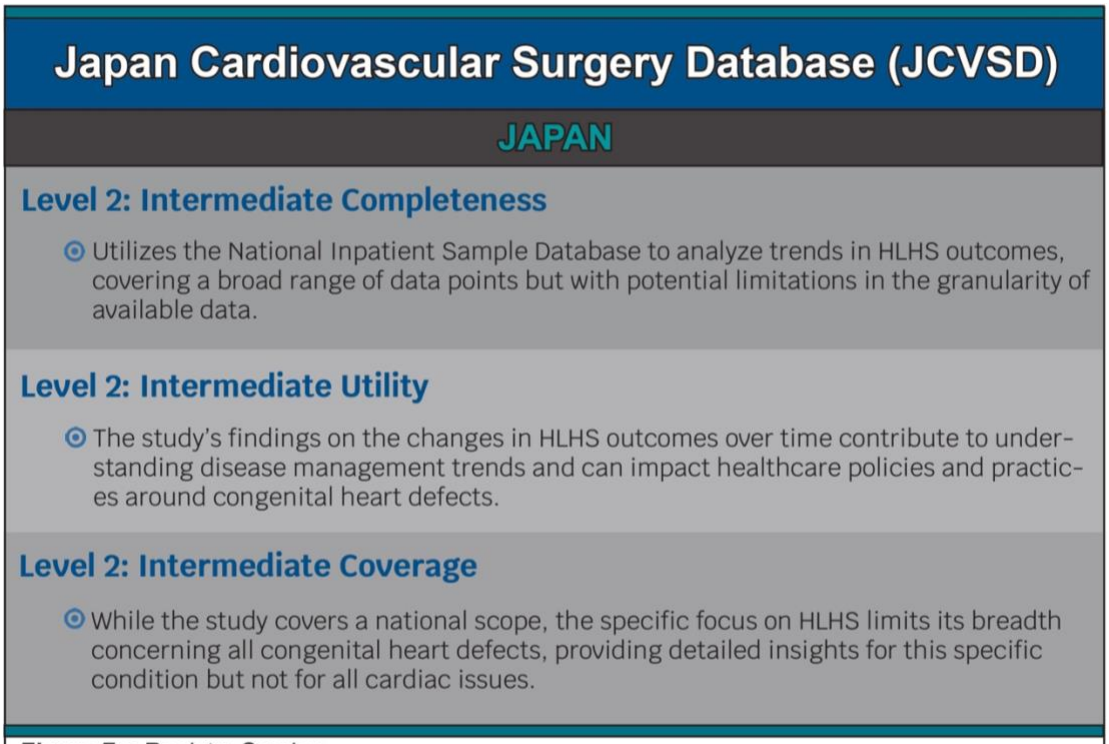


Figure 7a: Registry Scoring

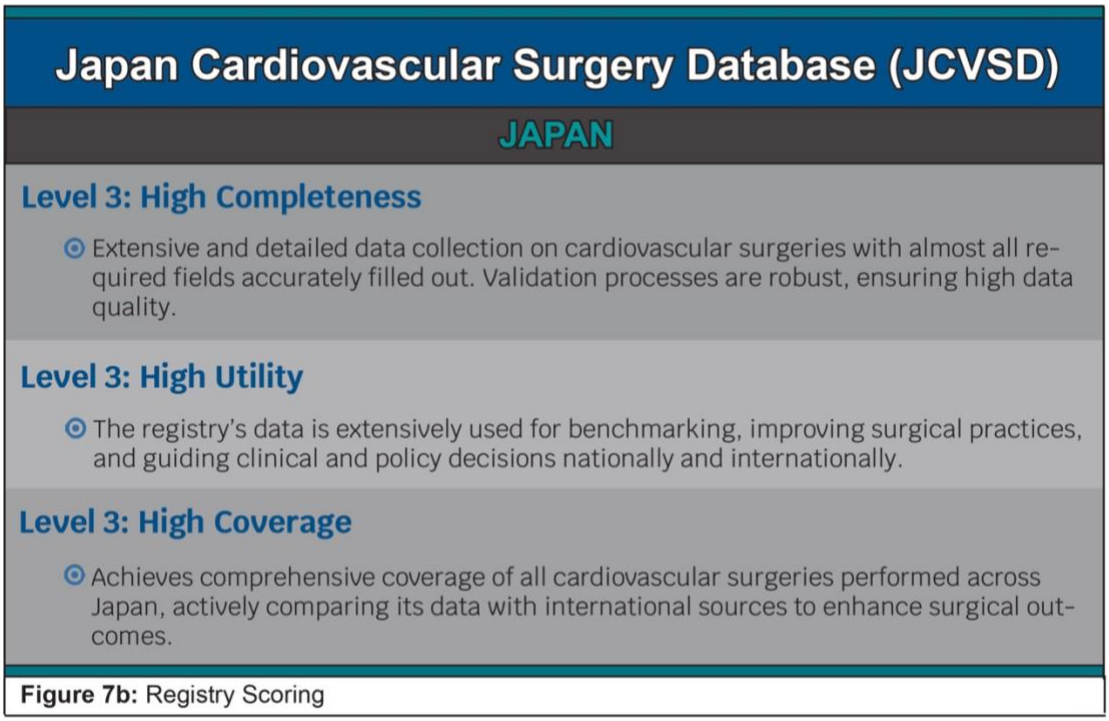


Figure 7b: Registry Scoring

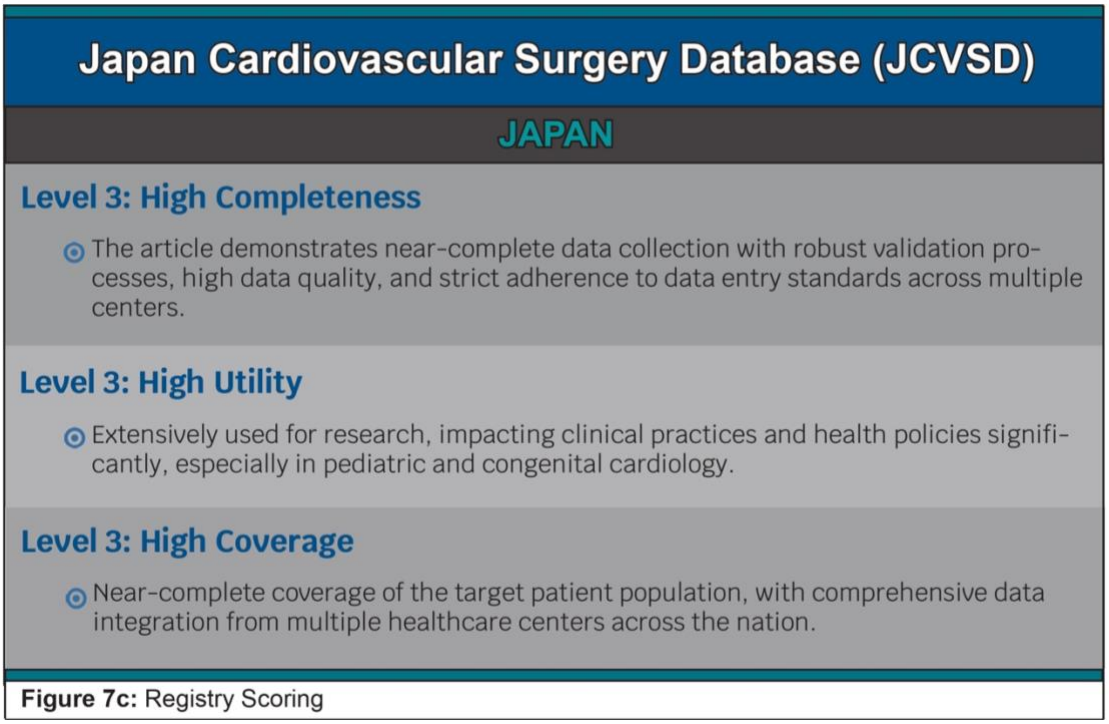


Figure 7c: Registry Scoring

Japan Cardiovascular Surgery Database (JCVSD)

JAPAN

Level 3: High Coverage

- Utilizes the Japan Cardiovascular Surgery Database (JCVSD) with a comprehensive set of 255 variables.
- High standard for data completeness, including rigorous data collection and standardized variables that are comparable to international databases like Society of Thoracic Surgeons.

Level 2: Intermediate Utility

- The registry is used to improve understanding and outcomes for a rare, critical condition (post-MI VSD), influencing surgical techniques and healthcare practices.
- While the registry informs practice significantly within Japan, broader impact or international utility isn't clearly documented.

Level 3: High Coverage

- Represents a nationwide dataset within Japan, ensuring a wide demographic and geographic coverage within the national context.
- The registry covers a substantial portion of the target population at a national level, likely capturing most relevant cases.

Figure 7d: Registry Scoring

Japanese Network of Cardiovascular Departments for Adult Congenital Heart Disease Registry

JAPAN

Level 3: High Completeness

- The registry demonstrates near-complete data collection with accurate, comprehensive validation processes ensuring high data quality.

Level 3: High Utility

- The registry is extensively used for research, improving clinical practices, and informing policy decisions significantly within the field of adult congenital heart disease in Japan.

Level 3: High Coverage

- It achieves comprehensive coverage of the target population of adults with congenital heart disease, representing a major national resource.

Figure 7e: Registry Scoring

3.1.2.5. Malaysia

In Malaysia, approximately 5,000 new cases of CHDs are estimated annually, with two-thirds requiring surgical intervention.[77] This statistic presents a significant challenge given the limited number of facilities capable of performing complex pediatric cardiothoracic surgeries. The National Heart Institute (NHI) and a few other centers are the main facilities handling such cases, with others often facing long waiting times and excessive costs. The Pediatric Cardiothoracic Program (PCP) was initiated to address these issues by sending patients to the Narayana Health Institute of Cardiac Sciences in India.[77]This initiative has been remarkably successful in significantly reducing surgery costs and wait times. The program mainly benefits patients from vulnerable communities facing accessibility and affordability issues.

The outcomes from Malaysia's initiatives indicate a postoperative mortality rate of only 1.7%, showcasing the high success rate of the surgical interventions facilitated through the PCP.[77] These results reflect the program's effectiveness in providing critical care to those in need and underline the potential benefits of further expansion and support for such registries. Malaysia's focused approach towards pediatric CHD through the PCP is commendable, but there is a significant opportunity to enhance outcomes and registry impacts through increased regional and global collaboration.

(See 3.1.7 Multi-National Registry)

3.1.2.6. Qatar

Qatar has significantly bolstered its capacity to monitor CHDs through the Sidra Medicine Cardiac Registry. This registry serves as an integral part of Qatar's expansive medical data infrastructure and gathers extensive data from a diverse range of cardiac patients along with CHDs. It stands as a crucial resource for healthcare professionals and researchers committed to enhancing cardiac care outcomes in Qatar. [78]

Notably, VSDs, ASDs, and TGAs are among the most common forms observed in Qatar. The birth prevalence of CHDs in Qatar, a reflection of the region's advanced diagnostic capabilities, contributes to a higher reported prevalence compared to less developed areas. One of the most striking findings from the registry is the high incidence of parental consanguinity associated with CHDs. Approximately 32% of the subjects studied were born to parents who are first-degree cousins, a factor that significantly correlates with the occurrence of CHDs.[79] This genetic predisposition underscores the complex interplay between genetics and environmental factors in the development of CHDs. Additionally, the registry also underscores the need for further investigation into the impact of maternal health on CHD prevalence, particularly via factors such as pre-gestational diabetes mellitus.

Despite its comprehensive approach, the registry needs help achieving full national coverage and granularity in its data validation processes. Expanding coverage and enhancing data collection methodologies can provide more detailed and actionable insights, which in turn can lead to more effective interventions, improved patient outcomes, and a better understanding of the global impact of CHDs.

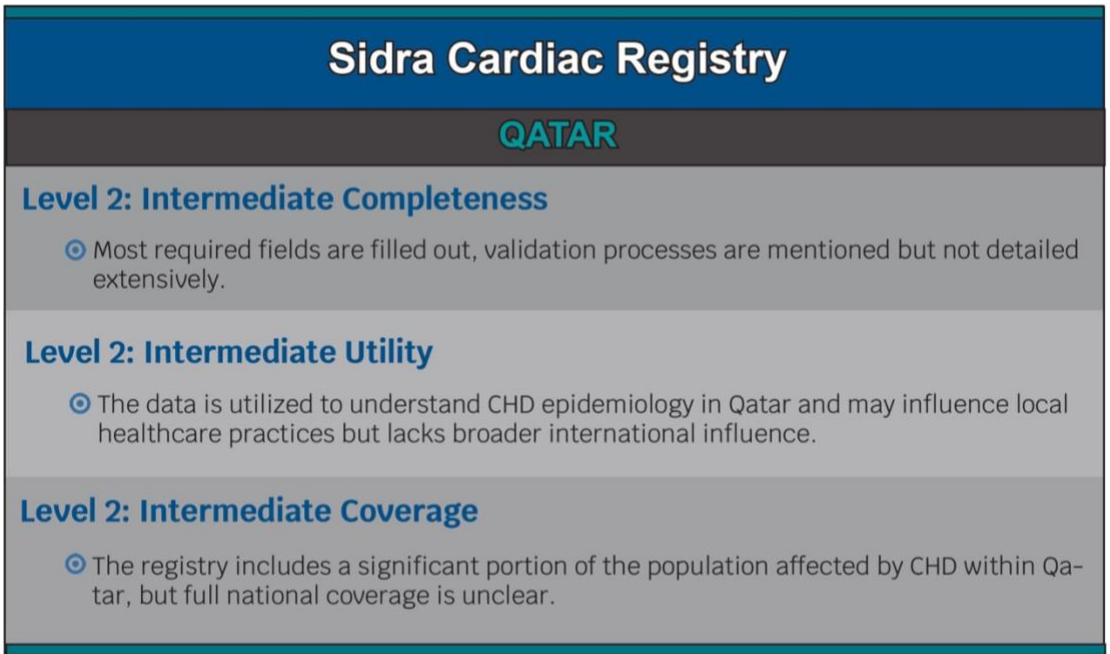


Figure 8: Registry Scoring

3.1.2.7. Saudi Arabia

Saudi Arabia, facing a significant burden of CHDs, has developed various registries and programs to monitor and manage these conditions effectively. The prevalence of CHD in the country is mirrored by global statistics[80], indicating a consistent need for more substantiated healthcare strategies to address these complex conditions from infancy through adulthood.

The Saudi registries show a predominance of complex cyanotic heart diseases, which are among the most severe forms of CHD. These conditions require intricate surgical interventions and meticulous long-term management, including regular check-ups, medication, and lifestyle adjustments. The high rate of these complex cases, aligns with global observations, suggesting that early and accurate detection combined with comprehensive management plans can lead to better outcomes.

Studies and registry reports from Saudi Arabia highlight a prevalence rate that requires significant medical and surgical intervention. However, the outcomes linked to these interventions, as recorded in the registries, reflect a mixed spectrum of success-with some patients showing significant improvement while others continue to face challenges, largely dependent on the timing of diagnosis and the comprehensiveness of care provided. The Saudi health system's integration with advanced diagnostic tools like Multidetector Computed Tomography (MDCT), a multinational collaboration, has significantly enhanced diagnostic accuracy, improving procedural outcomes for affected individuals. These collaborations often enhance data completeness, utility, and coverage, making them valuable models for improving registry impacts on public health policies and clinical practices.

(See 3.1.7 Multi-National Registry)

3.1.3. Europe

3.1.3.1. Austria

Austria participates in EUROCAT, which collects detailed data on CHDs across Europe. This registry's inclusiveness allows for an expansive view of CHD trends across multiple countries, offering a unique vantage point to assess prevalence and patterns over time.[81] The Austrian registry identifies prevalent CHDs and tracks changes in their occurrence over time. The integration into the broader European context allows for comparisons across regions and healthcare systems, providing valuable insights into the epidemiology of CHDs and associated healthcare outcomes.

The collaborative nature of the EUROCAT registry, involving Austria and other European nations, significantly enhances data completeness. By pooling resources and data, the registry offers a worthy platform for monitoring CHD trends and outcomes, facilitating effective public health strategies and medical research. This enables detailed analysis of survival rates, the success of various surgical interventions, and long-term health outcomes for individuals with CHDs.

(See 3.1.7 Multi-National Registry)

3.1.3.2. Belgium

Belgium has developed a robust framework for the surveillance of CHDs through the integration of administrative and clinical data, as exemplified by the BELgian COngenital heart disease Database. This comprehensive approach allows for detailed epidemiological studies and the evaluation of healthcare services nationwide.

Belgium, in line with Western countries, has maintained a stable birth prevalence of CHDs, standing at approximately 9.4 per 1000 live births.[82] This stability, a testament to

the advancements in medical treatments and diagnostic techniques, provides a reassuring outlook on the current situation for our healthcare professionals, researchers, and policymakers. BELCODAC merges data from university hospitals in Leuven, Ghent, and Brussels with mortality and socio-economic data from the official Belgian statistical office, and healthcare use data from the InterMutualistic Agency.[82] This integration creates a multidimensional dataset with over 60 variables with multiple entries over time, encompassing a wide range of demographic, medical, and economic factors. Such a robust database instills confidence in its utility for extensive research and healthcare planning tailored to the needs of CHD patients.

The database indicates that among the registered patients, a significant portion has mild to moderately complex CHD forms, reflecting the broader epidemiological shift towards older patients with milder forms of CHD who require ongoing but less intensive care. This shift accentuates the urgent need for adaptive healthcare systems that can cater to the evolving needs of this patient population. Integrating clinical and administrative data in the BELCODAC allows for a nuanced understanding of CHD impacts across different life stages and healthcare settings. It provides insights into healthcare utilization, clinical outcomes, and the economic burden associated with CHD. BELCODAC informs healthcare policies and practices, highlighting the registry's utility in patient management and shaping public health strategies.

(See 3.1.7 Multi-National Registry)

3.1.3.3. Bulgaria

Bulgaria's participation in the EUROCAT network is instrumental in facilitating extensive data collection and validation across Europe. This integration significantly contributes to achieving high data completeness, utility, and population coverage standards. In Bulgaria, cardiac CAs are monitored through regional registries, such as Pleven. From 1988 to 2006, over 47,622 births were surveyed in the Pleven region, identifying 1,225 cases of CAs. [83]

The prevalence of CHDs within these registries provides significant insights into the trends and management effectiveness. For instance, in the Pleven region, there has been a noted increase in the prevalence of CAs from 17.76 per 1,000 births in 1988 to 29.40 in 2006.[83] Notably, CHDs accounted for a considerable portion of these anomalies, underscoring the registry's pivotal role in tracking these conditions.

By adhering to EUROCAT standards, the Bulgarian registry ensures data completeness at a level that supports extensive epidemiological surveillance and facilitates the identification of teratogenic exposures.[84] The registry's data utility provides a comprehensive dataset aid in the early warning of new teratogenic exposures and

evaluates the effectiveness of primary prevention strategies and prenatal screening policies.

(See 3.1.7 Multi-National Registry)

3.1.3.4. Croatia

The Croatian registries, such as the Zagreb Registry, cover several regions and are part of the EUROCAT initiative. From 1983 to 1993, Croatia recorded a mean prevalence rate of 18.86 per 1,000 births for CAs, with the most frequent being congenital heart diseases, limb defects, and oral clefts. [85] Over the years, the prevalence and types of CAs registered have shown significant variation, which could be attributed to genetic and environmental factors. Notable is the fluctuation in prevalence rates of Down's syndrome and the regional disparities in anomaly rates within the country, which are tenfold higher compared to routine statistical data.

As part of the EUROCAT system, Croatian cardiac registries achieve a high level of data completeness and utility, contributing to valuable insights into the trends and efficacy of CHD management strategies across Europe. The collaboration with EUROCAT enhances data completeness and enriches the utility and coverage of registry data. The development of pediatric cardiac services in Croatia, supported initially by humanitarian missions and later by national efforts, including increased funding and the establishment of specialized healthcare facilities, illustrates the positive shifts in handling CHD due to improved registry data and international collaboration.

(See 3.1.7 Multi-National Registry)

3.1.3.5. Cyprus

Cyprus, a member of EUROCAT, has taken significant strides in monitoring CHDs through comprehensive data collection and registry initiatives. The country's unique geographical position and historical genetic influences have necessitated extensive public health strategies to address inherited cardiovascular diseases (ICDs) and CHDs.

The Cyprus Institute of Cardiomyopathies and other national registries have established specialized centers for systematically collecting and analyzing data on ICDs, including various cardiomyopathies and syndromes prone to sudden cardiac death among young people and athletes.[87] These efforts are crucial given the unique challenges Cyprus faces due to its closed society dynamics, which tend to have higher incidences of hereditary diseases due to limited genetic diversity.

Cyprus's commitment to staying at the forefront of research is evident in its active and important participation in international research collaborations. These collaborations, such as the European Research Study of Arrhythmogenic Cardiomyopathy, play a crucial role in reinforcing the local and regional understanding of CHDs and ICDs and contribute significantly to global health.

The establishment of the Cyprus Institute of Cardiomyopathies has facilitated numerous educational and preventive measures. Particularly noteworthy is the proactive step of creating a genetic DNA bank, which significantly reinforces research capabilities regarding inherited cardiovascular diseases and demonstrates Cyprus's commitment to addressing these diseases.[88]

Despite these advancements, challenges remain, particularly in ensuring the completeness and utility of the registry data. While significant patient data is collected, gaps in data completeness persist due to the exclusion of studies and potential losses of follow-up data, such as when patients move or change their contact information. The utility of the registry is primarily focused on clinical practices with less emphasis on broader public health policies.

Cyprus's approach to managing CHDs through its registry and its role in the broader regional research context as part of EUROCAT provides a model of integrating genetic research with public health initiatives. Continued efforts to improve data completeness, utility, and population coverage will enhance the registry's effectiveness in reducing the burden of congenital heart diseases in Cyprus.

(See 3.1.7 Multi-National Registry)

3.1.3.6. Czech Republic

The Czech Republic's commitment to high medical data gathering and utilization standards is underscored by its integration into the EUROCAT network. The national registry, which encompasses various regional centers, shows a mean prevalence rate of 18.86 per 1,000 births for CAs, reflecting a broad spectrum of CHDs. [89]

The Czech registries, mainly through their collaboration with EUROCAT, achieve high data completeness, utility, and extensive population coverage. The data collected has led to improved screening protocols and intervention strategies, enhancing the early detection and treatment of CHDs and improving patient outcomes. For instance, prenatal screening and diagnostic techniques advancements have led to a high detection rate of critical CHD forms.

(See 3.1.7 Multi-National Registry)

3.1.3.7. Denmark

Denmark has been at the forefront of CA surveillance, particularly in tracking cardiac CAs through national registries, such as the Danish National Birth Cohort (DNBC), and multinational registries such as EUROCAT. Denmark's meticulous approach to managing data on CAs integrates comprehensive data collection from prenatal and postnatal healthcare services across the country. The Danish Health Care Registries, particularly the DNBC, collect extensive information that enables monitoring trends and the effectiveness of healthcare interventions for children with CAs.

The DNBC is noted for its exemplary data completeness and utilizes regularly updated and validated national-level health data, which ensures a high standard of information accuracy. Denmark's registry data are comprehensive and actively used to foster improvements in health policy and clinical strategies. These data help identify teratogenic exposures that lead to CAs and evaluate the effectiveness of primary prevention and prenatal screening policies. Moreover, from 1995 to 2008, there was an observed increase in the prevalence of CAs, particularly chromosomal, renal, and cardiac anomalies, likely influenced by advancements in prenatal screening technologies and changes in public health policies.[91]

One interesting outcome from the registry data is the substantial decrease in fetal and infant mortality associated with CAs, particularly since the enhancement of prenatal screening programs introduced in 2005.[90] These programs have successfully led to early detections that facilitate timely medical interventions, and ultimately offer hope for future prevention. Despite its successes, the Danish system faces challenges such as the potential underreporting of CHDs from stillborn infants and those detected in prenatal screenings, leading to terminations. Addressing these issues involves continuous adaptation and enhancement of registry methodologies to ensure all affected births are registered.

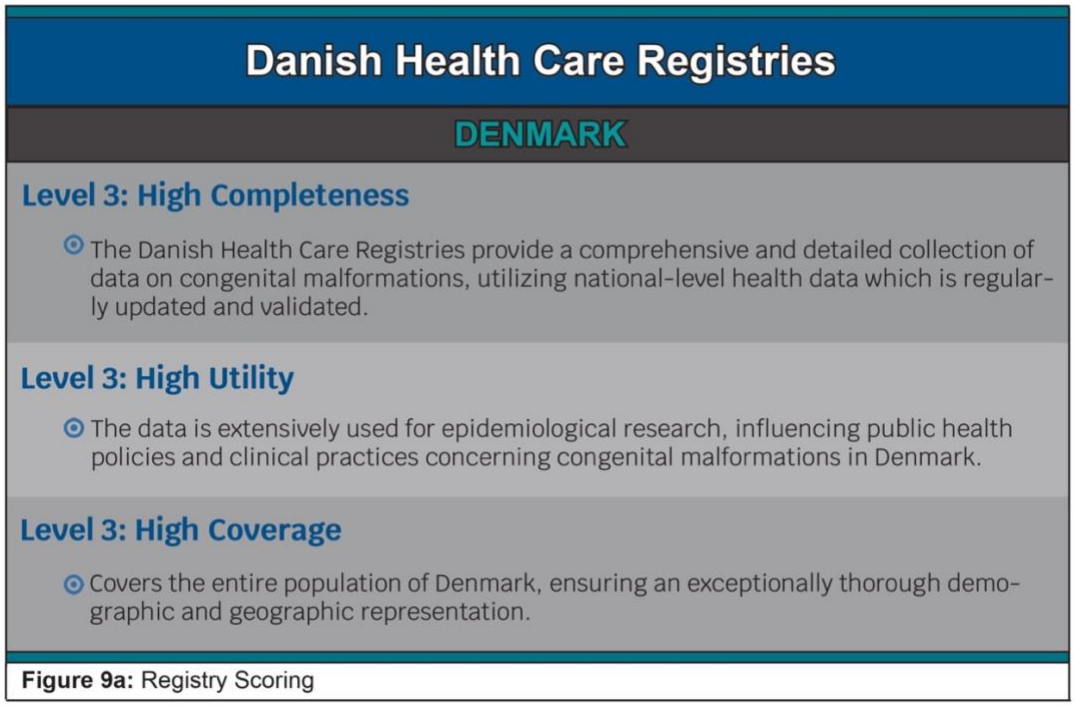


Figure 9a: Registry Scoring

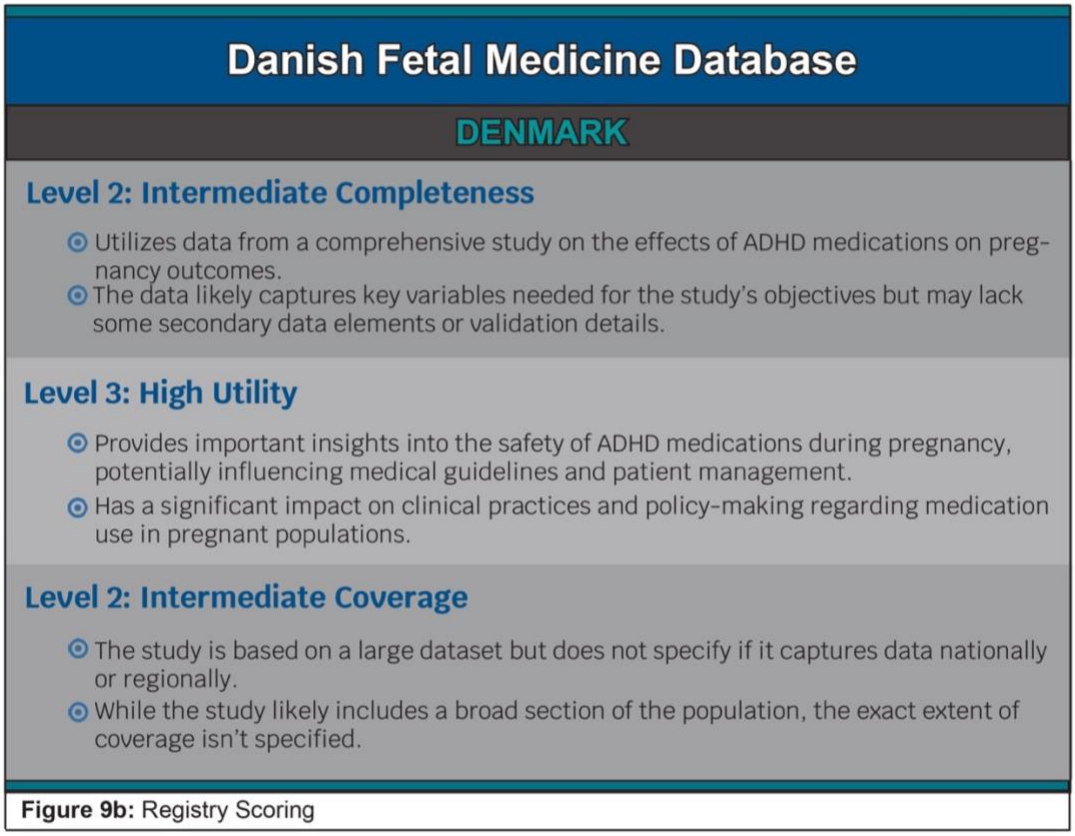


Figure 9b: Registry Scoring

3.1.3.8. Finland

Finland's also contributes to the EUROCAT registry and records approximately 500 new cases of CHDs annually. The registry employs a structured questionnaire post-delivery to assess environmental and genetic risk factors associated with CHDs. This questionnaire covers a wide range of factors including parental health history, maternal lifestyle during pregnancy, and potential teratogenic exposures. This degree of analysis reveals epidemiological trends and effectiveness of interventions over time; for instance, between 1982 and 1983, significant associations were noted between parental cardiovascular malformations and those in offspring. [92]

As part of the EUROCAT system, Finland's registry achieves exemplary data completeness, utility, and population coverage. The integration into EUROCAT allows for an enhanced understanding of CHD trends within Finland and across Europe. This multinational collaboration, like efforts seen with the Czech Republic's involvement in the registry, leads to improved data accuracy and a broader impact on public health policies and clinical practices across member countries. Studies reflect the historical progress and current outcomes of pediatric cardiac surgery in Finland, showing overall favorable survival compared to natural disease courses.[91]Surgical advancements have increased the treatability of complex CHDs, with long-term follow-up data indicating substantial improvements in survival and quality of life for affected individuals.

(See 3.1.7 Multi-National Registry)

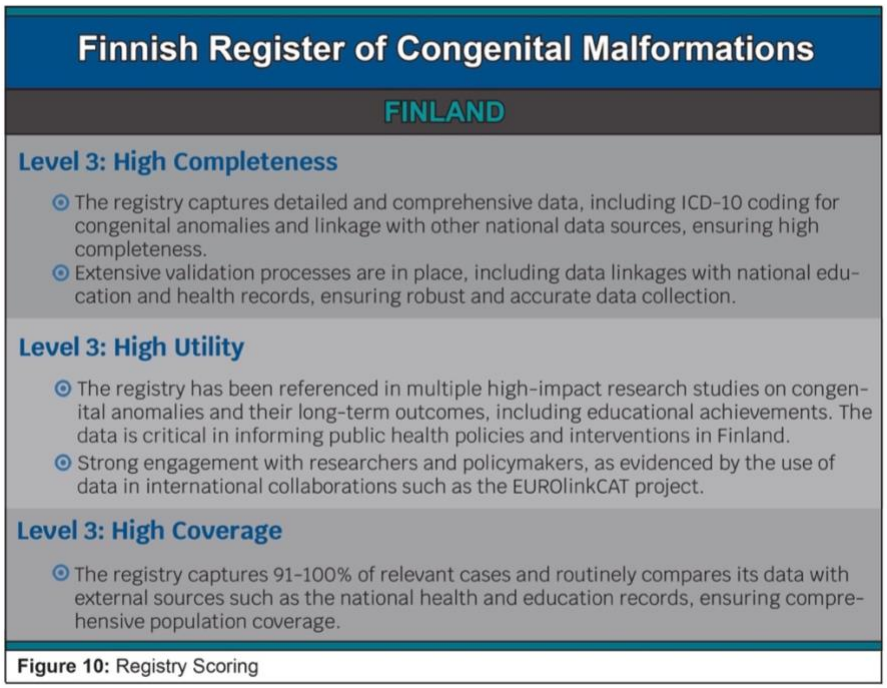


Figure 10: Registry Scoring

3.1.3.9. France

France manages its CHD data through the French National Registry of Congenital Anomalies (REMERA), an active participant of EUROCAT. The registry collects comprehensive data from hospitals and diagnostic centers across France, providing vital information for public health surveillance. According to assessments, the French registry typically achieves high data completeness and validation standards. These processes ensure that the data captured is reliable and comprehensive, allowing for detailed analyses of congenital heart disease trends and outcomes across the population. Insights from REMERA contribute to better prenatal screening protocols, more effective newborn screening programs, and enhancements in clinical interventions for CHDs.[93] For example, the registry's data have supported research into genomic sequencing for newborn screening, a promising avenue that holds the potential to revolutionize early detection and treatment approaches for various conditions, including cardiac defects.

While REMERA aims to cover the entire French population, challenges such as regional variations in reporting and potential underreporting in less connected areas might affect the comprehensiveness of the data. However, the registry's coverage is generally extensive, reflecting a sizable portion of the national demographic, which should reassure you about the representativeness of the data. Compared internationally, France's registry often exhibits similar or superior data completeness and utility relative to other national registries. The detailed genetic and environmental data collected allow for a nuanced understanding of CHDs, which are essential for developing targeted interventions to reduce the incidence and improve the outcomes of these conditions.

(See 3.1.7 Multi-National Registry)

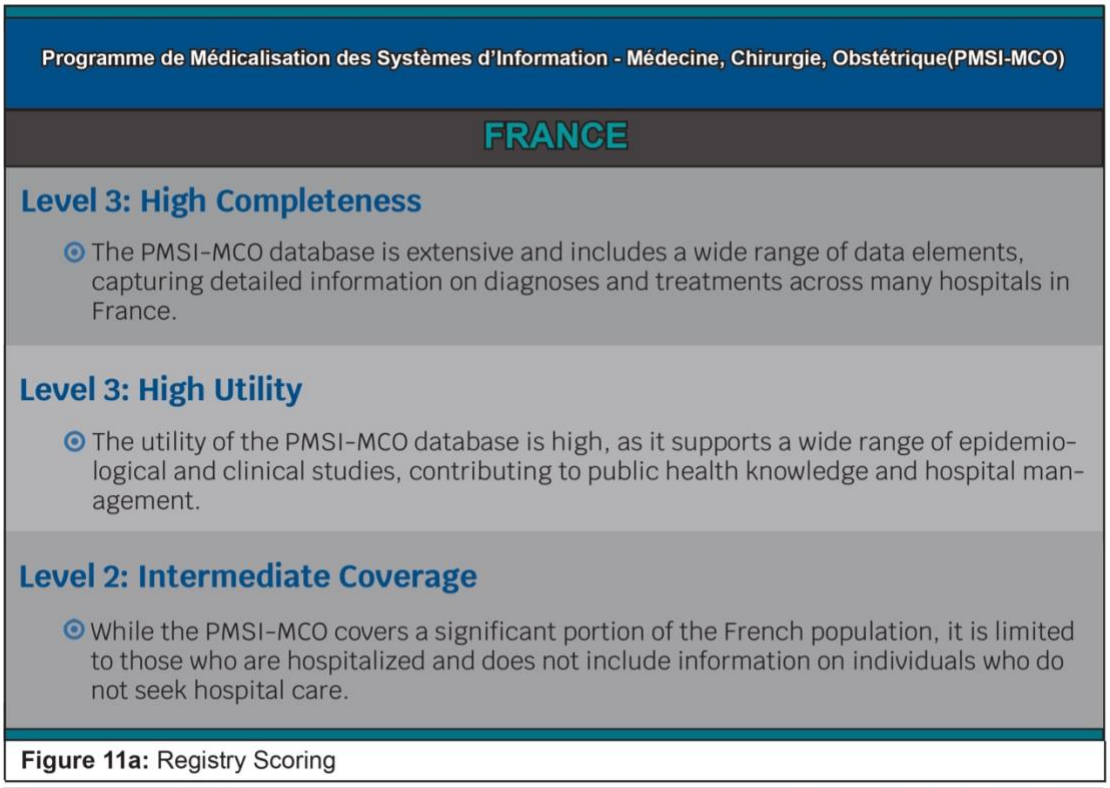


Figure 11a: Registry Scoring

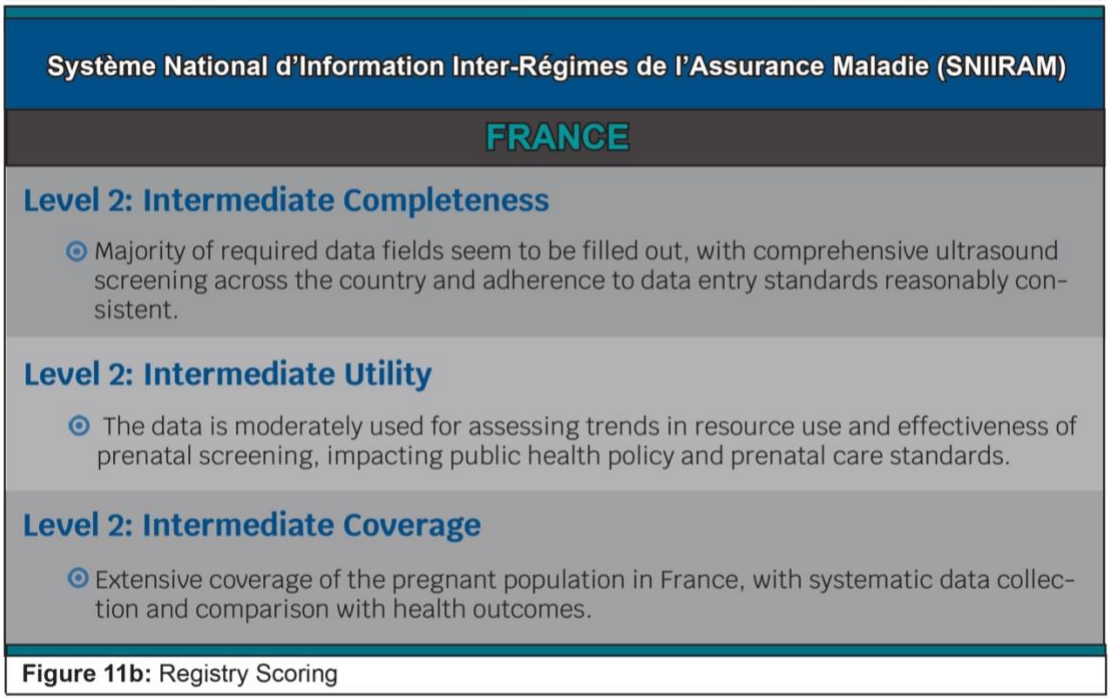


Figure 11b: Registry Scoring

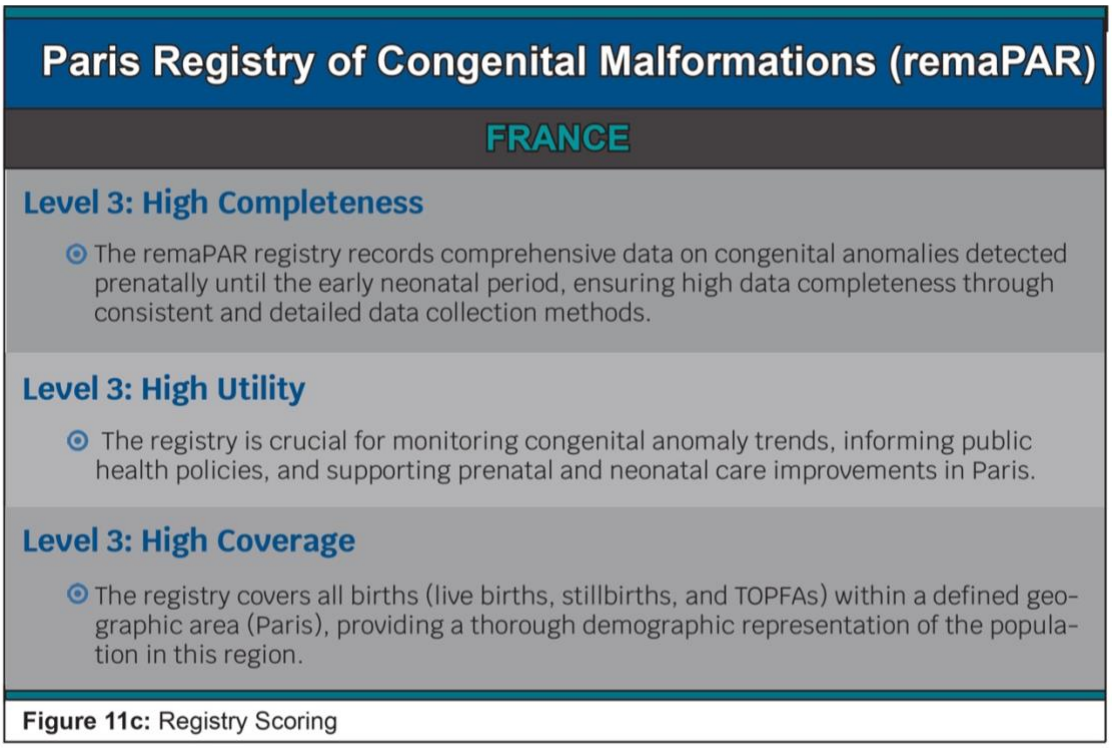


Figure 11c: Registry Scoring

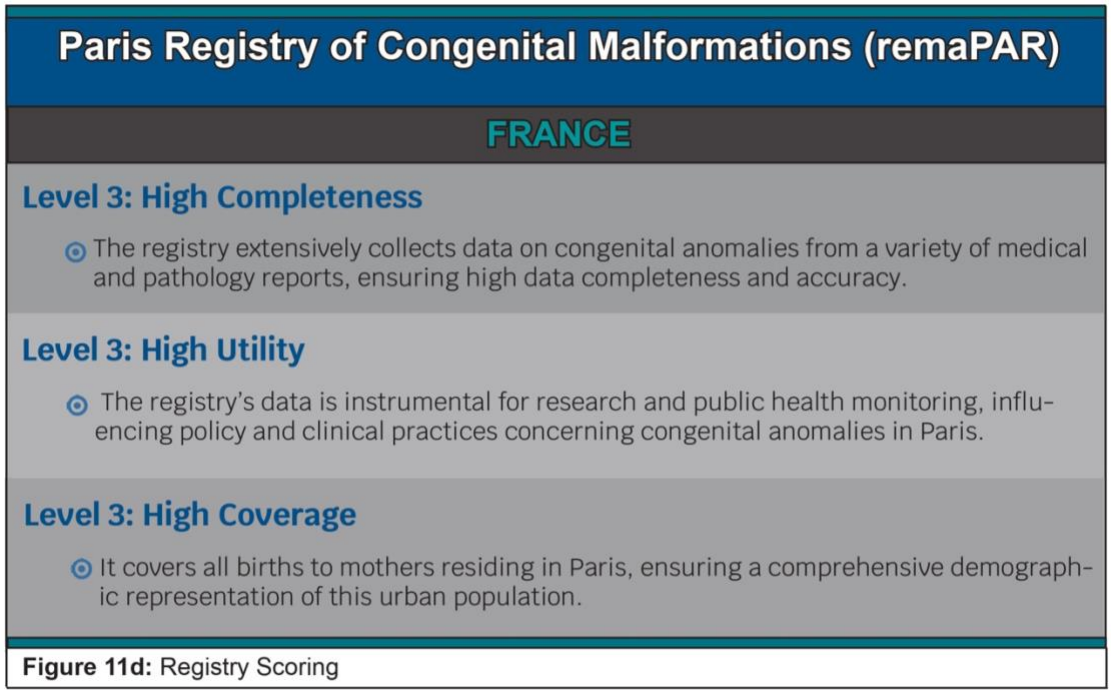


Figure 11d: Registry Scoring

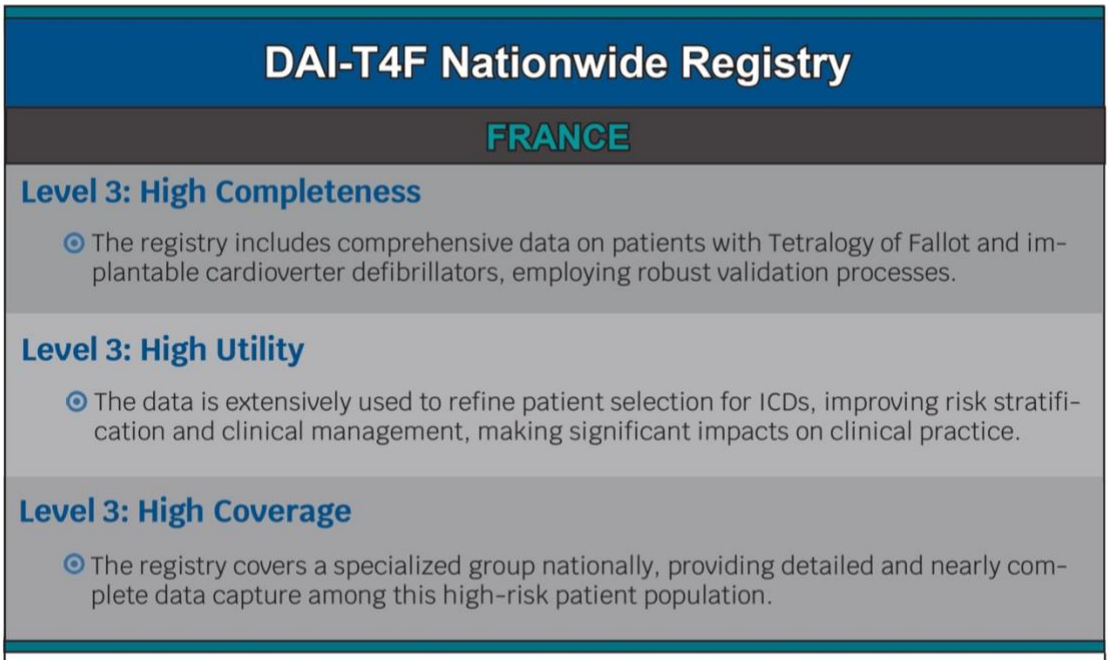


Figure 11e: Registry Scoring

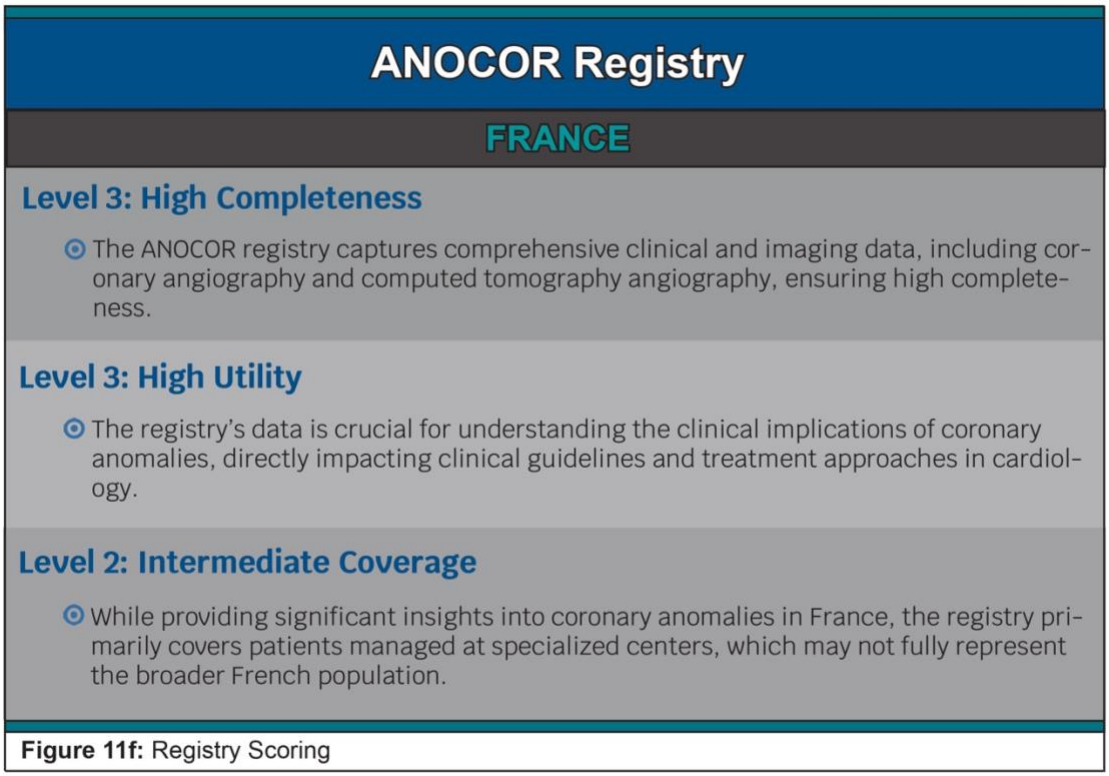


Figure 11f: Registry Scoring

3.1.3.10. Germany

Germany contributes significantly the pan-European data collection through EUROCAT. The nation's registries stand out for their meticulous data collection, which is integrated with multiple sources for verification. This approach ensures high standards in data completeness, utility, and population coverage.

Over the years, the German registry has noted significant shifts in CHD trends. Data from the Federal Statistical Office of Germany indicates a nuanced view of CHD mortality, revealing a significant decrease in mortality rates from 1998 to 2010, followed by a slight increase towards 2018. The most frequent underlying CHDs associated with death include hypoplastic left heart syndrome and left ventricular outflow tract obstruction. [94]

The German national data reflect a complex landscape of CHD management, with substantial improvements in survival rates and clinical outcomes over time. However, the slight increase in mortality rates since 2010 suggests areas for ongoing attention, particularly in high-risk neonates and infants.

(See 3.1.7 Multi-National Registry)

3.1.3.11. Greece

CHDs represent a significant concern in Greece, with approximately 1,000 new CHD cases annually, contributing to a considerable population of adults living with these conditions. Historically, Greece lacked a unified national registry, which impeded systematic data collection and long-term outcome assessments necessary for advancing patient care and research.[95] In response, the Hellenic Cardiological Society took a proactive step and introduced the CHALLENGE registry- a dedicated electronic database for adult CHD. This initiative, led by the Society, aims to gather comprehensive data on the prevalence and outcomes of CHD, marking a pivotal step towards aligning Greece with European standards where registries like EUROCAT provide extensive insights through collaborative data pooling.[96]

The establishment of the CHALLENGE registry is expected to illuminate trends and patterns previously obscured by the lack of centralized data. This new source of comprehensive data will not only provide a clearer understanding of long-term outcomes and the efficacy of various treatments across the patient's lifespan but also pave the way for significant improvements in patient care. The early indications suggest that while surgical interventions have dramatically improved survival rates, there remains a substantial burden of adult CHD that requires ongoing clinical attention and resource allocation. The CHALLENGE registry is a beacon of hope, promising to improve outcomes for patients across all stages of life.

With improved registry inputs, Greece can more accurately gauge CHD prevalence and refine its approach to managing these complex conditions. For instance, data from collaborative European studies show variability in CHD outcomes, emphasizing the importance of specialized care and early intervention (ECHSA-CHSD Study).[97] By participating in larger registries, Greece benefits from benchmarking against broader European data, identifying gaps in care and areas for improvement.

(See 3.1.7 Multi-National Registry)

3.1.3.12. Hungary

Hungary's robust approach to tracking CHDs is exemplified by the Hungarian Congenital Abnormality Registry (HCAR), established in 1962. This registry, one of the oldest globally, has earned recognition for its longevity and comprehensive data collection and is complemented by the CSONGRAD Registry, which collects detailed data on congenital heart diseases, including advanced echocardiographic measurements and long-term follow-up outcomes. [98]

The Hungarian approach to CA surveillance is marked by its comprehensive data collection, which includes detailed echocardiographic and clinical parameters from various specialized studies like the CSONGRAD Registry and the MAGYAR-Path Study.[99] These registries collectively enhance the understanding of the morphological and functional outcomes of congenital heart diseases, such as Tetralogy of Fallot, by employing advanced imaging techniques like 3-D speckle-tracking echocardiography. This approach not only benefits the Hungarian healthcare system but also contributes to the global understanding and management of CHDs.

Data completeness and utility within these registries are commendable, as evidenced by their ability to capture many data on pediatric patients, including demographic, medical, and paraclinical data. This detailed data collection supports in-depth research and influences clinical practices, thus contributing significantly to medical knowledge and patient management strategies.

Population coverage, while extensive within the confines of treated or operated cases at specific centers such as the University of Szeged, indicates a focus on sub-national rather than full population coverage. The gap in coverage suggests the registries provide crucial insights predominantly about the regional patient populations, which may limit their extrapolation to the broader Hungarian or global context.

(See 3.1.7 Multi-National Registry)

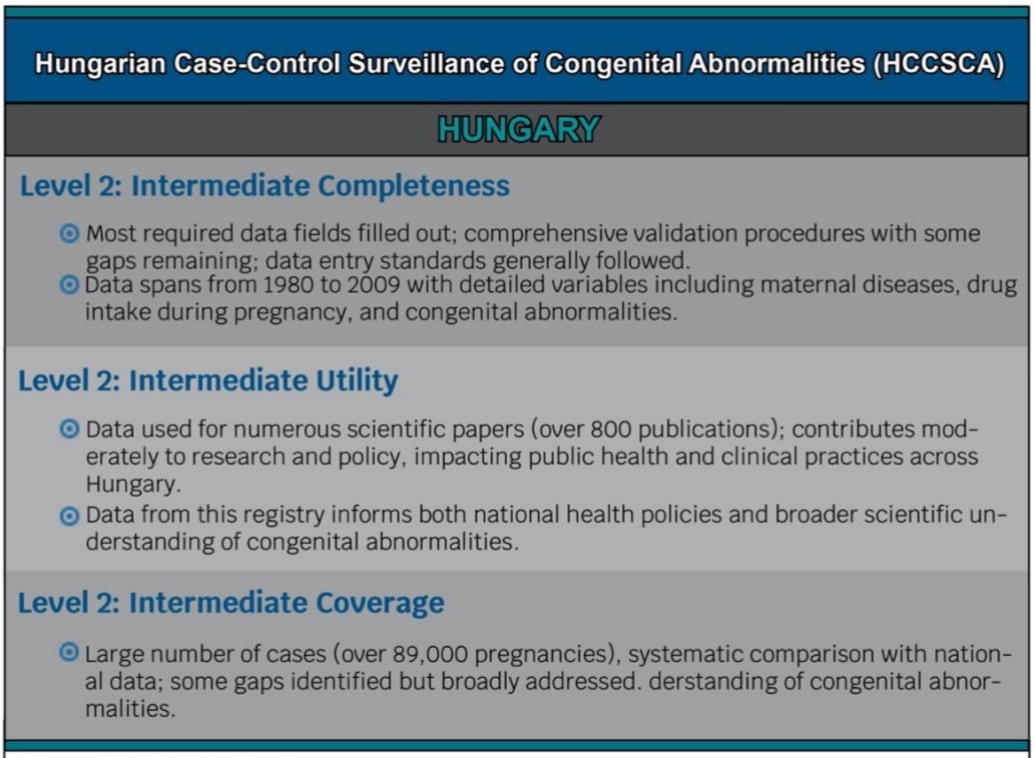


Figure 12a: Registry Scoring

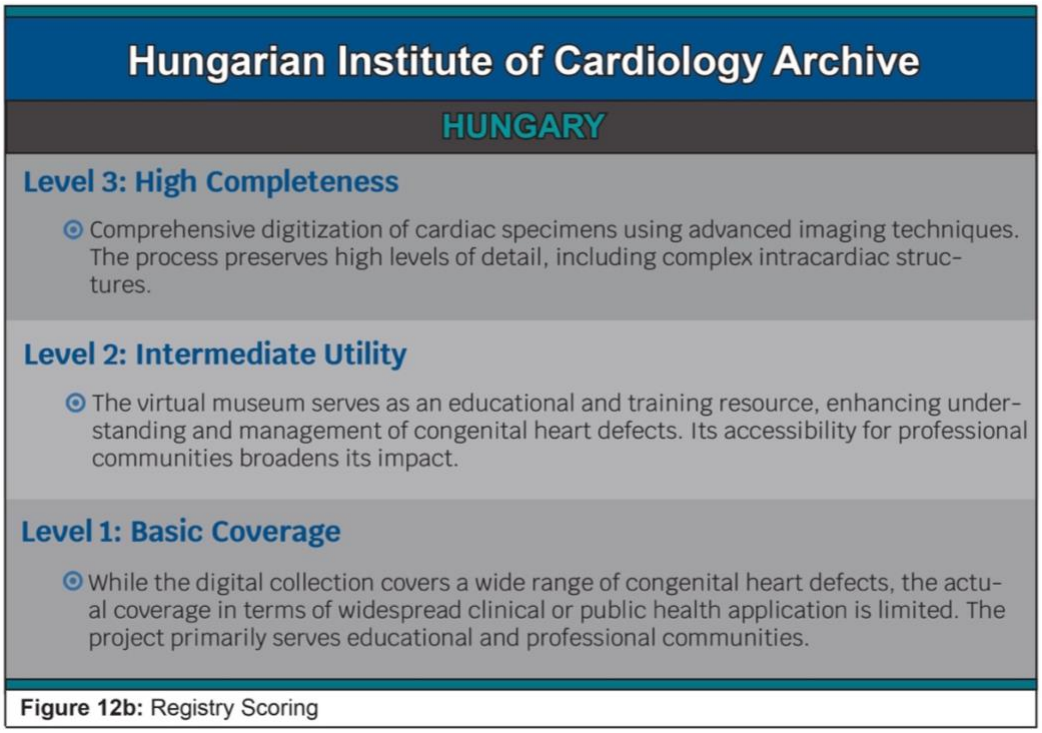


Figure 12b: Registry Scoring

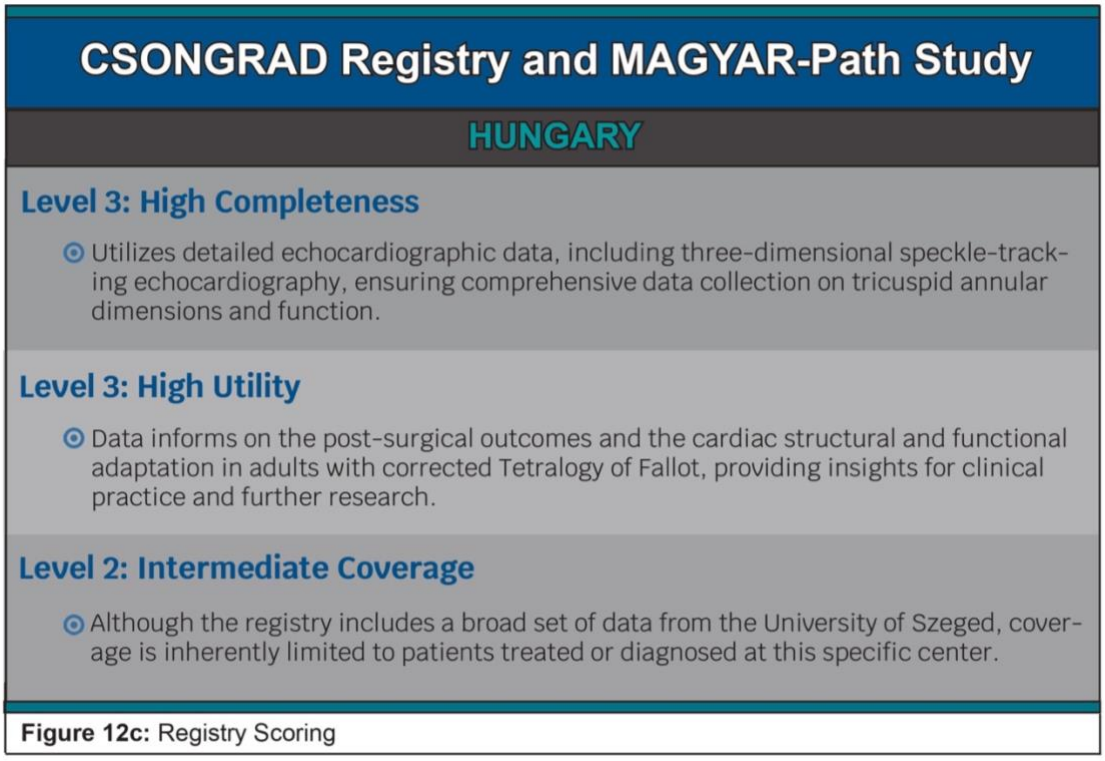


Figure 12c: Registry Scoring

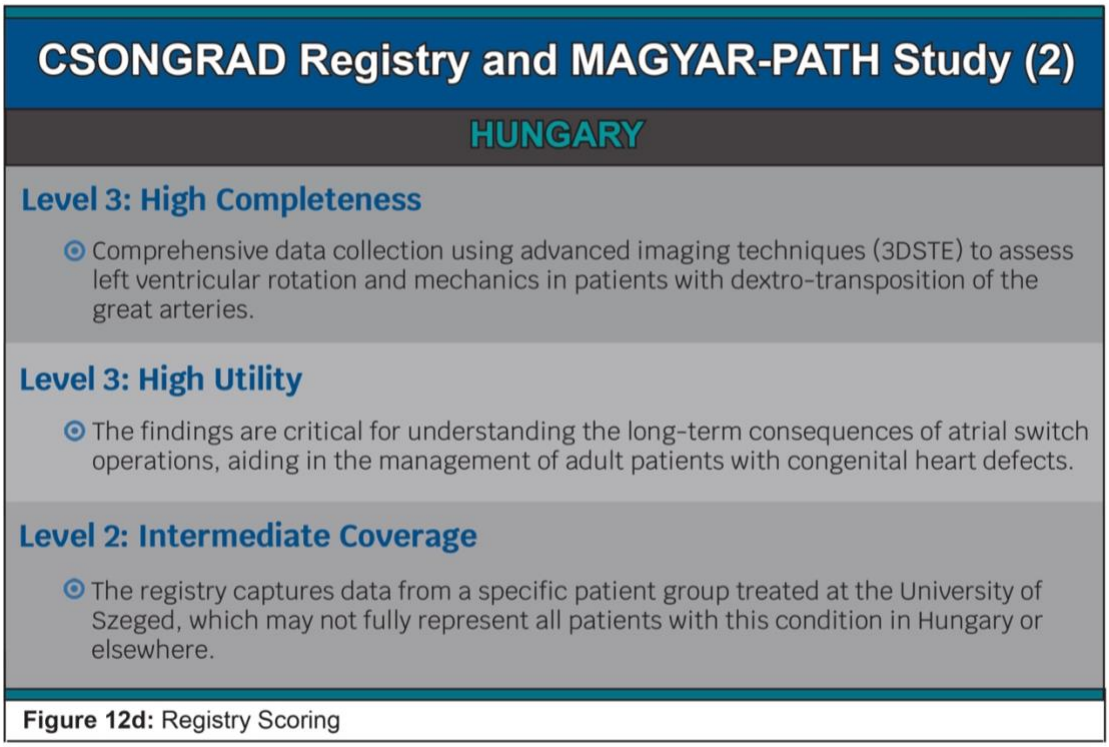


Figure 12d: Registry Scoring

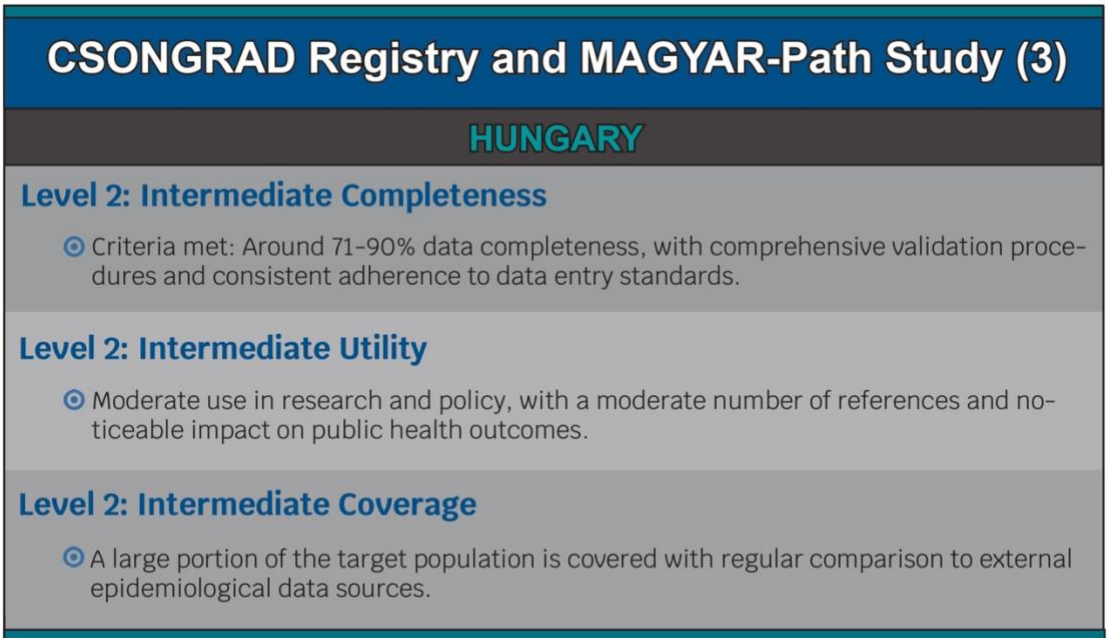


Figure 12e: Registry Scoring

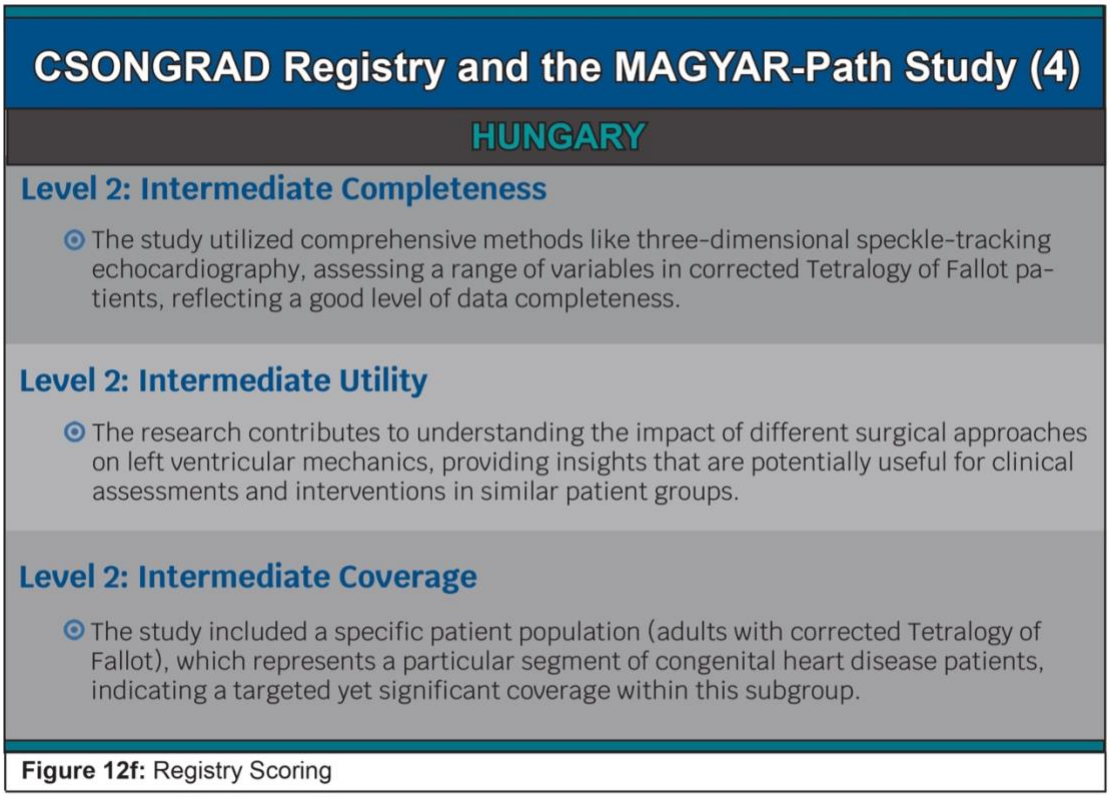


Figure 12f: Registry Scoring

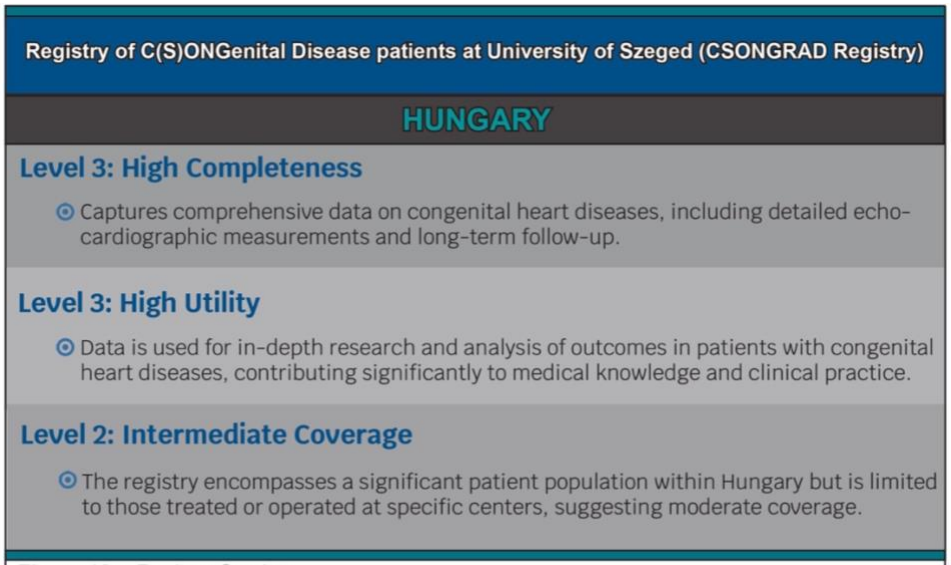


Figure 12g: Registry Scoring

3.1.3.13. Ireland

In Ireland, approximately 1,000 babies are born with CHD each year; this translates into a substantial clinical and public health burden.[100] The integration into EUROCAT has benefited Ireland from a standardized data collection and sharing approach across Europe.

Historically, Ireland has faced challenges in achieving high prenatal detection rates of CHD due to variable access to specialized fetal anomaly scans across different health centers. However, recent efforts have aimed at standardizing these screenings to improve early detection rates. For example, studies have shown that prenatal detection of CHD significantly optimizes pre- and post-operative outcomes, with prenatal diagnosis associated with better pre-operative stability and lower one-year mortality rates.[101]

Ireland's participation in the EUROCAT registry ensures a high standard of data completeness, utilizing multiple data sources for verification, which is critical for effectively tracking CHD trends and outcomes. As part of the All-Island Congenital Heart Network, the implementation of regional pediatric cardiology services in Ireland exemplifies the country's commitment to bringing specialized care closer to patients' homes.[102] This approach reduces the need for patient transfers and alleviates the emotional and financial strain on affected families, demonstrating the registry's utility in improving service delivery across the healthcare system.

(See 3.1.7 Multi-National Registry)

3.1.3.14. Italy

The Italian Registry of Congenital Anomalies (IRCA) has a significant collaboration with EUROCAT. Established to integrate data from hospitals and diagnostic centers, IRCA provides a comprehensive epidemiological platform that enhances research and public health planning in Italy, while also contributing to the global understanding of CHDs.[103]

IRCA stands out due to its exceptional data completeness, achieving a Level 3 grading indicative of its truly extensive data collection and validation processes. The prevalence of CHDs in Italy aligns with the comprehensive data collection strategies of IRCA. With the integration of regional registries, the national scope of data collection ensures minimal gaps in surveillance, allowing for effective monitoring and timely intervention in public health matters.

IRCA's utility actively informs public health policies and prevention programs, mainly through primary prevention measures. This proactive approach aids in reducing the incidence of CHDs but also enhances the overall health outcomes for affected children. Despite its strengths, IRCA faces challenges typical to large-scale registries, such as ensuring uniform data collection across various regions and maintaining the accuracy of diagnostic criteria. However, these challenges present opportunities for continuous improvement and adaptation of the registry to meet evolving healthcare needs.

(See 3.1.7 Multi-National Registry)

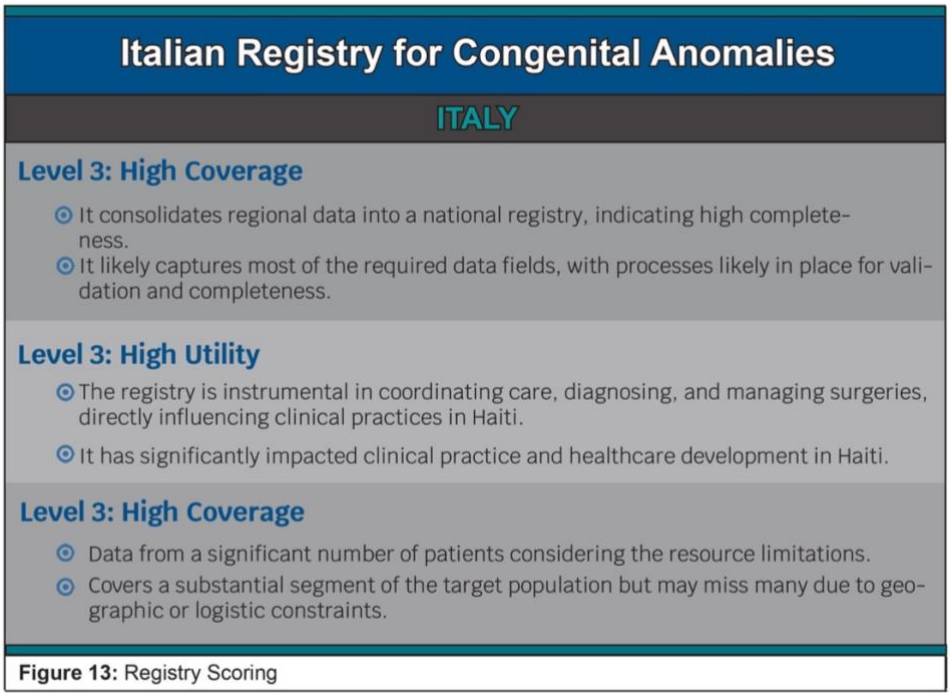


Figure 13: Registry Scoring

3.1.3.15. Latvia

Latvia's approach to CA monitoring is supported by three central registries: the Medical Birth Register (MBR), the National Causes of Death Register (NCDR), and the Register on Congenital Anomalies (CAR). These registries collect data on live births, stillbirths, and genetically confirmed cases of congenital anomalies.[104] The MBR, established in 1996 and computerized since 2000, collects data on all newborns diagnosed with CHDs up to the fourth day of life.[104] Meanwhile, the NCDR provides data on stillbirths and infant deaths up to one year of age, including CAs as causes of death, with a high rate of autopsy confirmation. CAR, operational since 1994 in alignment with EUROCAT requirements, has historically played a significant role, although its activity has varied over the years.

From 2000 to 2010, the live birth prevalence rate of CAs in Latvia was noted at 319.7 per 10,000 live births, with significant CAs at 211.4 per 10,000.[104] This indicates a slight decrease over the decade, which may be attributed to advancements in prenatal screening and perhaps a higher rate of terminations for diagnosed anomalies.

Latvia's participation in the EUROCAT network is a significant milestone, as its collaboration has significantly enhanced the comprehensiveness and reliability of Latvia's CA data. Essentially, EUROCAT has allowed Latvia to take part in a larger dataset that includes 25 population-based registries across 14 countries.[104] Despite these systems, there are noted challenges in the Latvian registry system, particularly in data completeness and inter-registry linkage. The lack of unified databases and inconsistent data entry practices need improvement. Recommendations have been made to adopt practices from Nordic countries, like introducing unique mother and child identification numbers to enhance linkage across different health registries and ensuring more accurate follow-ups. While the current systems provide significant data, there is a continuous and urgent need for improvements in data collection, validation, and registry integration.

(See 3.1.7 Multi-National Registry)

3.1.3.16. Malta

Malta, a small island nation in the Mediterranean, possesses a unique genetic makeup that significantly influences the prevalence and management of CHDs. This distinct genetic profile, coupled with the country's participation in the EUROCAT network, enhances its capabilities in monitoring and research through collaborative, registry-based studies.

The Malta Congenital Anomalies Register is a critical component of Malta's public health infrastructure, collecting data on all babies born on the islands diagnosed with CAs until

the age of one. Over 20 years, from 1995 to 2014, a total of 1,307 babies were registered with some form of CHD, which accounted for more than 40% of all registered defects. This registry tracks these conditions' occurrence and helps evaluate long-term outcomes and the efficacy of interventions. [106]

The prevalence of CHDs in Malta has shown intriguing patterns, possibly due to the island's isolated population and genetic factors. Studies have indicated an excess of lesions causing right ventricular outflow tract obstruction. According to data spanning 1995 to 2014, severe CHDs had an overall population prevalence rate of 30.6 per 10,000 births, with no statistically significant change over the study period. [106]

Malta's participation in EUROCAT significantly enhances the completeness, utility, and population coverage of its registry. However, despite the supplement of EUROCAT, there are challenges in data completeness and diagnosis accuracy, primarily due to the varying capabilities across different health facilities and the evolving nature of diagnostic technologies. Moreover, the genetic predisposition observed in the Maltese population for certain types of CHDs, such as those causing right ventricular outflow tract obstruction, underscores the need for targeted genetic studies and enhanced prenatal screening protocols.

(See 3.1.7 Multi-National Registry)

3.1.3.17. Netherlands

The Dutch CA Register (DCAR), operational since the inception of the EUROCAT network, serves as an exemplary model for monitoring and understanding CHDs across the Netherlands. Established to foster comprehensive epidemiological research and enhance public health strategies, DCAR's integration with EUROCAT facilitates data collection from many sources, such as hospitals and diagnostic centers, ensuring a broad capture of CHD data. The DCAR is a repository of data and aids in formulating health policies and clinical practices tailored to address the specific needs of the CA spectrum.[108] Funded by the Dutch Ministry of Health, Welfare, and Sports, DCAR's association with the University Medical Centre Groningen further enhances its research capabilities, allowing it to stay at the forefront of congenital health issues.

DCAR's strength lies in its population-based approach, covering all babies born to resident mothers within the registration area. This area initially included around 7,500 births annually and has since expanded.[108] This approach ensures that the registry encapsulates a comprehensive demographic profile, instilling confidence in the reliability and effectiveness of the data for public health planning. DCAR's meticulous data collection process spans multiple sources, including obstetric records, hospital administration data, and genetic tests, ensuring the richness and depth of the data

captured. Such detailed data collection is instrumental in identifying trends, performing longitudinal studies, and enhancing the overall understanding of congenital anomalies within the population. Looking forward, DCAR's integration with EUROCAT offers many possibilities for expanded research and a deeper understanding of CHDs within the Netherlands and across Europe.

(See 3.1.7 Multi-National Registry)

3.1.3.18. Norway

Norway's healthcare system is supplemented by the resources of EUROCAT. Norway's approach to CHD registries is comprehensive, involving multiple sources such as the Medical Birth Registry of Norway and the Clinical Registry for Congenital Heart Defects at Oslo University Hospital. These registries compile data on all pregnancies and their outcomes, including live births, stillbirths, and terminations of pregnancies due to fetal anomalies.

From 2004 to 2016, around 0.4% of all pregnancies were affected by severe CHDs, with many of these children surviving past two years of age. The detailed tracking and classification of these defects allow for precise monitoring and targeted medical interventions, crucial for improving patient outcomes.[109] For instance, a study focusing on unexpected deaths among children with severe CHD revealed that while advancements have significantly reduced preoperative and postoperative mortality, unexpected deaths still occur, particularly in complex cases with comorbidities. The detailed findings from such studies underscore the importance of continuous monitoring and adaptation of clinical practices, define the dynamic nature of healthcare.

Despite the strengths of the Norwegian CHD registries, challenges still need to be addressed, particularly in unexpected outcomes and the management of complex cases. The registries help identify risk factors such as prematurity, low oxygen saturation, and comorbidities, which are crucial for tailoring follow-up and treatment plans.[110] Integrating genetic and environmental data, which could provide deeper insights into the etiologies of CHDs, is a continual need to enhance the utility of the registry data. Moreover, focusing on descriptive data such detailed follow-up plans and intervention outcomes could significantly improve patient management and survival rates.

(See 3.1.7 Multi-National Registry)

3.1.3.19. Poland

Poland has an established national framework for monitoring CHDs through the Polish Registry of Congenital Malformations (PRCM). This registry has been operational since 1997 and is a critical tool for public health surveillance and healthcare service for

affected children. The registry's comprehensive scope and integration with international efforts like EUROCAT highlight its role in addressing CHDs across Poland.

The PRCM was initially launched as a scientific project funded by the Polish Ministry of Health and the State Committee for Scientific Research.[111] Over the years, it has evolved under various health programs aimed at enhancing diagnostics and intrauterine therapy for fetal diseases and malformations. This evolution reflects a sustained commitment to improving fetal and newborn health outcomes through targeted public health initiatives, funding support from the National Centre for Healthcare Information Systems, and continuous government backing.

The registry, with its broad demographic coverage and data collection from multiple provinces across Poland, ensures an extensive understanding of CHDs. PRCM started with coverage of select provinces and expanded to include the entirety of the nation in 2007.[112] The registry's comprehensive data capture is facilitated through traditional paper notifications and modern web-based electronic submissions, enhancing the ease and accuracy of data collection. The registry mandates healthcare providers to report CHDs, ensuring a systematic and wide-reaching data collection network. Since its inception, the PRCM has significantly influenced the landscape of pediatric cardiology and CA management in Poland.

The registry supports extensive research and policymaking by providing a detailed understanding of CHD distributions and outcomes. This has led to improved prenatal screening programs and significantly enhanced healthcare systems' ability to provide early interventions. The PRCM has also facilitated the development of specialized healthcare services and informed the allocation of medical resources and training for healthcare professionals across Poland.

Despite its successes, the registry faces challenges, such as the need for enhanced data completeness and the integration of advanced diagnostic technologies. Future directions include utilizing artificial intelligence and machine learning to predict trends more accurately and to refine intervention strategies. Moreover, expanding the registry's capabilities to include genetic and environmental factors could provide deeper insights into the etiologies of CHDs.

(See 3.1.7 Multi-National Registry)

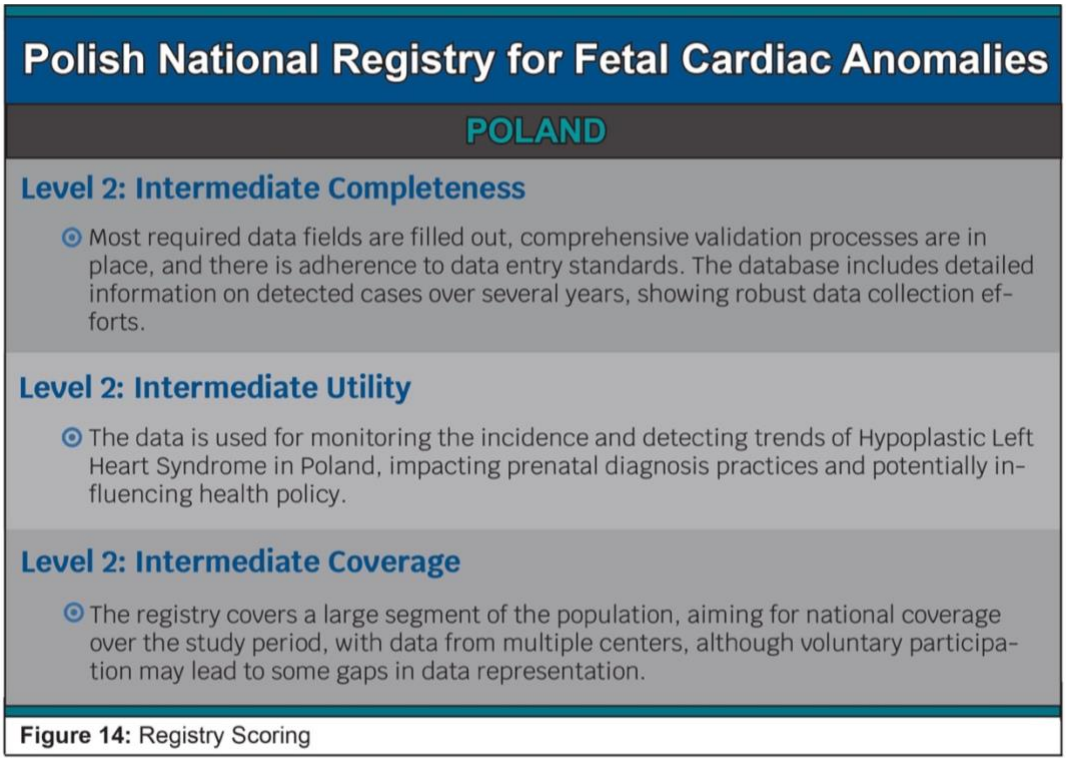


Figure 14: Registry Scoring

3.1.3.20. Portugal

Portugal provides a network of registries such as the Portuguese National Registry of Congenital Anomalies (Registo Nacional de Anomalias Congénitas or RENAC), complemented by the EUROCAT collaboration. In 2015, the prevalence of CHDs in Portugal was reported at 8.3 per 1000 births, with critical congenital heart diseases accounting for a considerable proportion of these cases.[113] As part of EUROCAT, Portugal benefits from a standardized approach to data collection across Europe, which enhances data completeness, utility, and population coverage. This collaboration allows for better tracking of trends across regions and countries, aiding in identifying risk factors and the effectiveness of intervention strategies.

According to the Journal of Portuguese Cardiology, the prevalence of CHDs in Portugal was lower than in many other international studies, suggesting potential underdiagnosis or reporting inconsistencies.[113] These inconsistencies could be due to variations in diagnostic criteria, differences in healthcare access and quality across regions, or even cultural factors affecting reporting. The most common defects identified were VSDs, ASDs, aortic coarctation, ToF, and pulmonary stenosis; such data help identify trends over time and assess the effectiveness of prenatal screening programs. The detailed records from RENAC enable an analysis of survival rates and clinical

outcomes. For instance, a retrospective analysis from a tertiary referral center in Portugal highlighted that survival rates in CHD patients could be significantly improved through early diagnosis and intervention. The study noted a prevalence rate of 6 per 1000 live births, with significant improvements in survival rates due to advancements in medical and surgical treatments.[114] These advancements include the development of less invasive surgical techniques, improved post-operative care, and the use of advanced imaging technologies for early detection and monitoring of CHDs.

Despite these advancements, challenges remain, particularly in ensuring uniformity in diagnosis across different regions and improving the prenatal detection rates of critical defects. The significant regional disparities in CHD prevalence reported within the country indicate the need for more targeted health policies and improved registry participation. However, these challenges also present opportunities for significant improvements in the future.

(See 3.1.7 Multi-National Registry)

3.1.3.21. Russia

Russia's involvement in multinational registries offers a comprehensive view of the country's CHDs landscape. These collaborative efforts enhance data collection, significantly improving outcomes and broadening the understanding of CHDs across various populations. However, systematic registration is only mandatory for certain severe forms like transposition of great vessels and hypoplasia of the left heart. This selective data collection contributes to the gaps in comprehensive data availability, as highlighted by studies indicating variations in the prevalence of CHDs across different regions of Russia.[115]

While Russian registries collect significant patient data, they need to improve intermediate completeness with missed and lost data challenges. This limitation impacts these registries' overall effectiveness in providing a complete picture of CHD prevalence and outcomes. The selective nature of mandatory reporting for specific CHDs suggests a pressing need for broader data collection policies to encompass a wider spectrum of CAs.

The utility of these registries extends to influencing clinical practice, mainly by incorporating modern diagnostic techniques like Multidetector Computed Tomography (MDCT), the multinational collaborative study. However, the impact on broader public health strategies and policy formulation still needs to be improved, pointing to a potential area for expansion. By increasing the scope of data utility, Russia can better integrate findings from CHD registries into public health planning and intervention strategies.[115]

The population coverage of CHD registries in Russia is substantial but needs to be improved regarding geographic and demographic representativeness. This issue is particularly pronounced in remote and less accessible areas, which may not be adequately represented in national data collections. Expanding the reach of these registries to include underrepresented populations would enhance the accuracy and utility of the data collected.[115] For instance, these collaborations could facilitate the exchange of best practices in CHD management, enable the validation of Russian data against global benchmarks, and foster the development of joint research projects to address common challenges in CHD care.

(See 3.1.7 Multi-National Registry)

3.1.3.22. Slovakia

The Slovak National Registry, as part of the broader EUROCAT system, benefits from standardized data collection and reporting protocols, which enhance the comparability of data across different countries. Prenatal detection of critical congenital heart defects (CCHDs) in Slovakia remains relatively low compared to other European countries, with only 13% of such cases detected prenatally.[116] This lower detection rate may influence affected newborns' overall management and outcomes, highlighting the significant potential impact on healthcare management and the relevance of our research.

The prevalence of CCHDs in Slovakia and other participating countries varies, but critical cases necessitate significant medical interventions shortly after birth. Improving prenatal diagnosis rates is crucial as it allows for better preparedness and the provision of tailored healthcare at the point of delivery. This individualized care could potentially reduce the morbidity and mortality associated with these severe conditions.[117]

(See 3.1.7 Multi-National Registry)

3.1.3.23. Spain

Spain's role in the EUROCAT network provides a framework for high data completeness and utility, facilitating detailed analyses of CHDs. Spain's specific contributions, such as identifying patterns and trends within the broader European context, have a major influence on public health strategies and medical research on a continental scale. However, data from the Spanish sector of the EUROCAT registry indicates a pressing need for effective surveillance and management strategies for CHDs. The prevalence of CHD, specifically in regions like Valencia, was recorded at 91.1 per 10,000 births between 2007 and 2014, with notable stability over the years, except for a slight increase in 2014.[118] The high prevalence rates, particularly ASDs and VSDs, underline the critical need for immediate action in addition to its existing partnership to EUROCAT.

Despite the strengths of the Spanish registry system, regional disparities in the prevalence and detection of CHDs suggest the need for adaptations to localized health policies. The differences in CHD detection rates across various Spanish regions may indicate disparities in access to prenatal screening technologies and healthcare services, which could impact outcomes (ckx186.181). However, studies have shown that the outcomes for CHD patients in Spain have significantly improved due to early diagnosis and interventions facilitated by registry data. The collaborative nature of registries like EUROCAT allows for analyzing long-term trends and the effectiveness of different treatment modalities, thereby guiding public health policies and clinical practices more effectively.

(See 3.1.7 Multi-National Registry)

3.1.3.24. Switzerland

In Switzerland, cardiac CA monitoring is facilitated through several registries such as the Swiss Adult Congenital Heart disease Registry (SACHER) and EUROCAT. Established in 2013, SACHER aims to improve the understanding of long-term outcomes in adults with CHD, integrating data from multiple national centers.[119] This registry captures a broad spectrum of congenital heart lesions, which is crucial for tailoring patient management and clinical research.

Switzerland has implemented rigorous methods to capture CHDs. According to the SACHER, from its inception in May 2014 to December 2016, 2836, patients were enrolled, highlighting a diverse array of congenital heart lesions, ranging from valve and shunt lesions to complex cyanotic defects.[120] The detailed data collection facilitated by registries like SACHER not only aids in immediate patient care but also enriches clinical research, providing a foundation for studies aimed at improving diagnostic techniques and treatment interventions. For instance, SACHER's design allows for prospective data analysis of detailed, CHD lesion-specific outcomes, ultimately aiming to enhance long-term patient outcomes.

Despite its strengths, the Swiss registry system faces challenges, such as ensuring consistent data quality across different regions and integrating newer data collection and analysis technologies. The future direction, which involves expanding registry inputs to include pediatric cases, has the potential to significantly enhance the management of CHD. This expansion will enable a comprehensive lifespan approach to managing CHD from infancy through adulthood, providing a more holistic view of the disease and improving patient outcomes.

(See 3.1.7 Multi-National Registry)

3.1.3.25. Sweden

Swedish registers, such as the Medical Birth Register, the Register of Congenital Malformations, and the Hospital Discharge Register, are underpinned by comprehensive data collection methodologies. Each source offers unique insights into the incidence and management of CHD, ensuring thorough and reliable data from the neonatal stages to adult follow-ups.[121]

The reported prevalence of CHD in Sweden has significantly increased over the years. Data from recent studies indicate a notable rise in the recorded birth prevalence of CHD over the last half-century, with rates steadily rising due to advancements in diagnostic techniques. From 1970 to 2017, the prevalence of CHD increased from 5.7 per 1000 live births to approximately 20 per 1000 live births, highlighting the urgent need for improved screening and diagnosis, particularly for mild CHD lesions.[122]

Being part of EUROCAT and the BELgian COngenital heart disease database (BELCODAC) allows Sweden to participate in a more extensive cross-country collaboration that enhances the quality and scope of data on CHDs. This collaboration has improved data completeness and utility, facilitating extensive studies across different populations and geographic regions. However, the detailed tracking enabled by the Swedish registries has also revealed a significant shift in the types of interventions for CHD. As diagnostic methods improve and less severe cases are identified more frequently, there has been a noticeable decrease in the overall percentage of cardiac interventions. However, the data shows that interventions for complex CHD cases have increased, demonstrating Sweden's adaptability to evolving medical practices and technologies.

(See 3.1.7 Multi-National Registry)

3.1.3.26. Ukraine

Ukraine's surveillance of CAs has been heavily influenced by past environmental disasters, notably the Chernobyl accident. Studies have shown that regions affected by Chernobyl exhibited a higher prevalence of CAs immediately following the disaster. However, recent data suggest these numbers have stabilized over the past 25 years.[123] The CAs in Ukrainian children have been closely monitored to assess the long-term impacts of radiation exposure and other ecotoxic factors on public health.

The incidence of CAs in Ukraine has increased by 59.5% over the past 25 years, surpassing the growth of general morbidity within the child population of Ukraine. This increase is particularly pronounced in regions with significant industrial pollution, which suggests a vital environmental component to the etiology of these defects.[123] The birth

rate of children with CAs was notably higher in industrially polluted areas, reflecting the impact of environmental toxicity. [123]

Ukraine's participation in EUROCAT has enhanced the country's capacity to track and analyze CHDs. This collaboration has improved data completeness, utility, and population coverage. Through EUROCAT, data from Ukraine is aggregated with findings from other countries, providing a comprehensive view that supports cross-national studies on CHD trends and the efficacy of public health interventions.[123]

The variability in CHD incidence across different Ukrainian regions underscores the urgent need for targeted healthcare interventions. Despite their historical contamination, areas within the territories of radiological control have shown a decrease in CAs over the years, suggesting effective mitigation strategies and healthcare interventions. Conversely, industrial regions still report high rates of CHDs, highlighting ongoing challenges in public health management and the pressing need for targeted interventions to address these issues.

(See 3.1.7 Multi-National Registry)

3.1.3.27. United Kingdom

As a member of the EUROCAT, the UK benefits from a network that provides a comprehensive registry framework, contributing significantly to data completeness, utility, and population coverage. The UK's approach to monitoring CHDs involves several specialized registries and databases integrating data from various health systems nationwide. This integration allows for detailed tracking of CHDs from prenatal stages through to adulthood. [124]

Recent studies indicate that the UK has a consistent prevalence of CHDs, with ongoing research pointing to genetic and environmental factors as key contributors to these anomalies. The UK's registry data, corroborated with EUROCAT findings, show a prevalence of approximately 8 per 1,000 live births for CHDs. The data from the UK and EUROCAT registries are extensively used for clinical research, influencing public health policies and clinical practices in the UK and across Europe.[125] Studies using this data have led to improvements in surgical techniques, postoperative care, and long-term management of individuals with CHDs, resulting in enhanced survival rates and quality of life for affected individuals.

While the UK's CHD registries are extensive, challenges remain in data integration across different health systems and enhancing patient follow-up. However, the UK is committed to improving these aspects to ensure more comprehensive data coverage and better patient outcomes. Additionally, there is a push towards utilizing registry data

to further personalize medical treatments based on genetic insights and individual health profiles, offering hope for the future of CHD research.

(See 3.1.7 Multi-National Registry)

3.1.4. South America

3.1.4.1. Argentina

Argentina has established the National Network of Congenital Anomalies of Argentina (RENAC) to monitor and improve the health outcomes of children with CAs. Since its inception in 2009, RENAC has been pivotal in collecting data from a vast network of public and private healthcare institutions across the country. RENAC involves neonatologists from across the nation who contribute data monthly, ensuring a robust database for ongoing surveillance and research. RENAC's data from 2009 to 2018 indicates a prevalence of critical congenital heart diseases (CCHD) at 11.46 per 10,000 births, with significant efforts towards prenatal detection and reducing perinatal mortality. [126]

Despite its comprehensive coverage, accounting for 39% of all births in Argentina, RENAC faces challenges, including economic fluctuations impacting public health funding and priorities. The variability in data uniformity and depth across regions highlights a disparity in healthcare access and reporting standards.[127] Moreover, prenatal detection rates and perinatal mortality vary significantly between the public and private sectors, underscoring the need for improved diagnostic and reporting consistency across different healthcare settings.

The prevalence of CCHD in Argentina is notably lower than that observed in other registries like the United States (NBDPN) and Europe (EUROCAT), suggesting potential underreporting or differences in diagnostic capabilities. However, the achievement of prenatal detection occurs in 43.93% of cases, and the perinatal mortality rate of 5% indicates a critical need for early detection strategies. The potential impact of these strategies is significant, offering hope for improve death outcomes.[128]

RENAC's strength lies in its extensive network and the capability to gather comprehensive data on a national scale. The registry's role in understanding the epidemiological landscape of CHD in Argentina is invaluable, particularly for shaping public health policies and clinical practices. However, to enhance its impact further, RENAC could benefit from integrating more sophisticated data validation processes and expanding its coverage to include a higher percentage of births.

(See 3.1.7 Multi-National Registry)

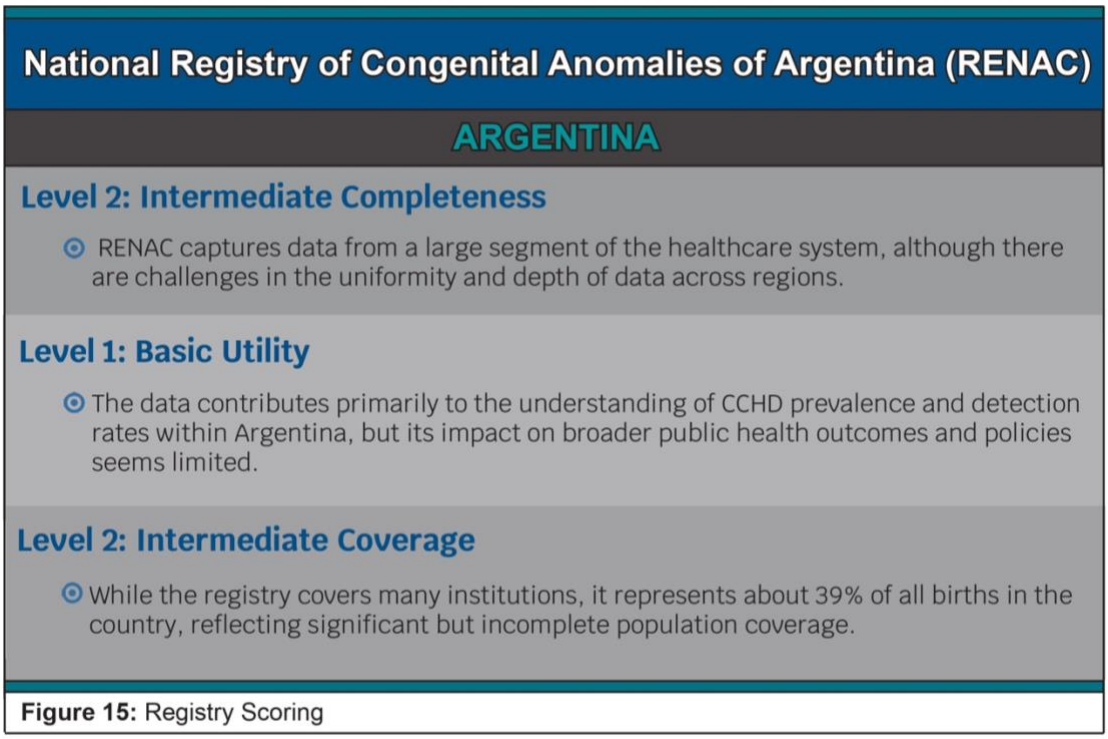


Figure 15: Registry Scoring

3.1.4.2. Brazil

The establishment of Brazil's Live Birth Information System (Sinasc) in 1999 marked a significant step in the nation's efforts to enhance the monitoring and treatment of CHDs. Covering over three million births annually, Sinasc's standardized data collection facilitates consistent and comprehensive epidemiological surveillance across the vast nation, supporting efforts to improve healthcare outcomes for affected children.

The utility and impact of this registry are exemplified by its role in significant studies such as the Brazilian Neonatal Network Database. This database, which specifically examines the prevalence and outcomes of CHDs in exceptionally low birth weight preterm infants, highlight's the registry's capability to provide crucial insights into vulnerable populations, thus driving improvements in clinical practices and policymaking at a national level.[129]

Brazil faces unique challenges due to its size and the diverse socio-economic conditions across its regions, which influence the diagnosis and treatment outcomes of CHD. Despite technological advances and improved diagnostic techniques, such as the widespread use of oximetry and echocardiography, regional disparities persist, affecting survival rates, especially in the neonatal period. The mortality rates associated with CHD

are significant, prompting ongoing research and policy adjustments to address these disparities.[131]

The Brazilian Ministry of Health has implemented initiatives to advance the care of children with CHD. This includes the federal project launched in 2017 aimed at increasing the number of procedures by 30% annually.[132] This is part of a broader strategy to reduce neonatal mortality associated with CHD, highlighting the government's commitment to enhancing health infrastructure and professional training to meet the needs of this patient population.

(See 3.1.7 Multi-National Registry)

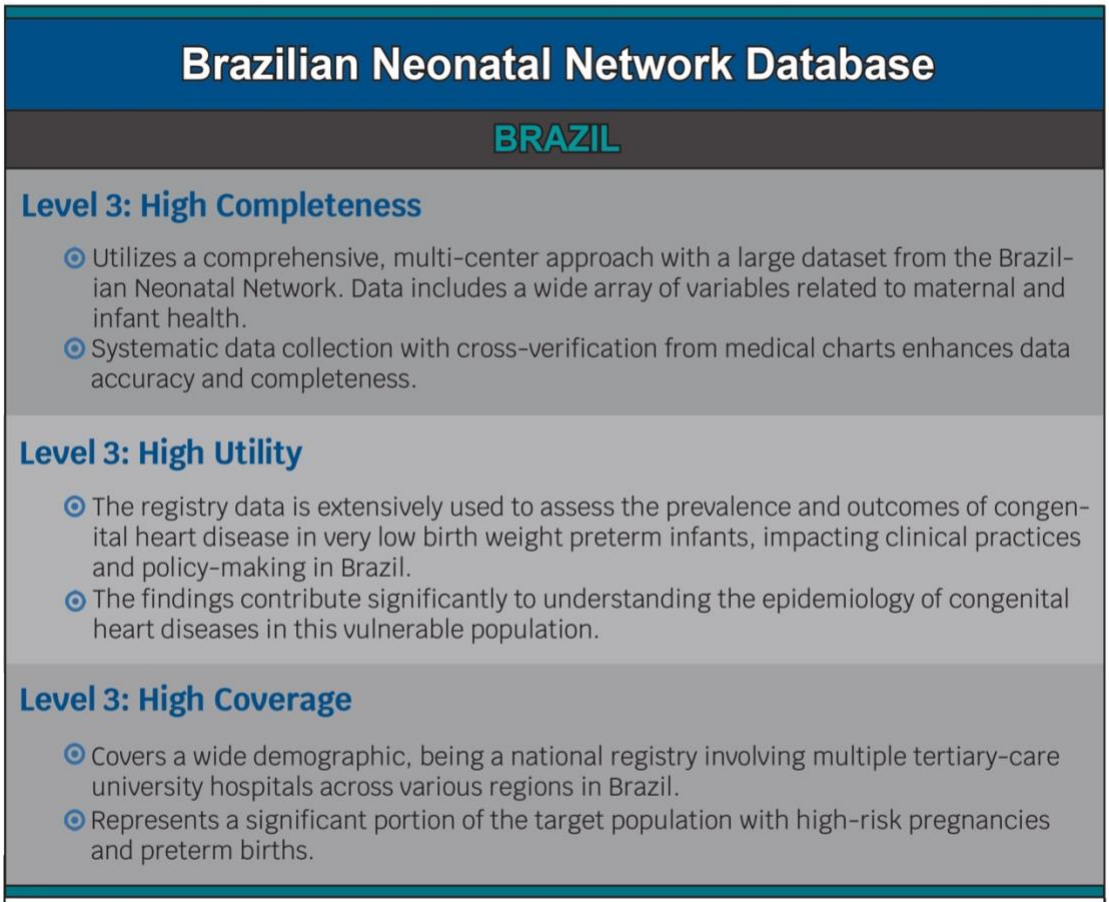


Figure 16: Registry Scoring

3.1.4.3. Chile

Chile's CHD registries primarily cover urban centers, with a notable lack of coverage in rural or remote areas.[133] The absence of fully established nationwide transition services for CHD patients transitioning from pediatric to adult care further limits the registry's ability to provide continuous coverage for young adults. This deficiency in transition services contributes to the loss of continuity in care, potentially causing complications in adult life due to gaps in monitoring.

Chile's CHD registries are confronted with a significant challenge- the absence of transition programs for adolescents with CHDs. This gap often results in patients losing follow-up care during the critical transfer period from pediatric to adult services.[133] The lack of patient education and preparation for managing their conditions as they transition to adulthood poses a significant risk to long-term health outcomes, underscoring the urgent need for action in this area.

Geographical disparities also pose significant challenges for the registry. While urban centers like Santiago are well-served, rural areas often have limited access to specialized congenital heart disease monitoring. This disparity creates substantial gaps in population coverage, particularly for those from lower socioeconomic backgrounds who rely on the public healthcare system. It underscores the urgent need for equitable healthcare access across all regions.

(See 3.1.7 Multi-National Registry)

3.1.4.4. Colombia

Colombia's involvement in international CHD registries allows for integrating advanced diagnostic tools like Multidetector Computed Tomography (MDCT), significantly enhancing structural and functional analysis. This integration supports a comprehensive understanding of the disease burden within the country and aids in formulating effective health strategies to manage and treat these conditions. [134]

Colombia, like many countries involved in large-scale registries, reports a diverse range of CHDs. These registries help identify not just the common forms of CHDs, such as VSDs and ASDs, but also more complex conditions like cyanotic heart disease, which is prevalent in significant numbers across the cohorts studied. The data gathered aids in recognizing trends over time, including increases or decreases in certain types of CHDs, which can be pivotal for public health planning and resource allocation. [135]

Despite the strengths of its registry system, Colombia faces challenges such as data gaps and the need for broader geographic and demographic coverage. These challenges hinder the comprehensive understanding of CHD trends and the effective planning of

public health initiatives. Future efforts are focused on expanding the reach and depth of data collection to include more rural and underserved populations. This would help understand and address disparities in CHD outcomes nationwide. Enhancing data collection methodologies and increasing participation in international registries are key development areas.

(See 3.1.7 Multi-National Registry)

3.1.4.5. Costa Rica

CHDs in Costa Rica have shown a rising trend in recent decades. The birth prevalence increased from 6.1 per 1,000 live births in 2006-2007 to 7.5 per 1,000 live births between 2009-2018.[136] Costa Rica benefits from a unified healthcare system, the Costa Rican Social Security Fund (CCSS), which provides universal national coverage. Nearly all births (99%) occur in hospitals, with 94% in public institutions. The national CHD registry, managed by the Costa Rican Birth Defects Register Center (CREC), tracks cases nationwide. Coverage is extensive, though concentrated in urban centers where access to specialized care, such as the National Children's Hospital (NCH), is more available. The NCH is responsible for nearly all pediatric cardiac surgeries in the country.

Costa Rica has made significant strides in reducing infant mortality from CHDs. The introduction of neonatal screening by pulse oximetry in 2016, coupled with enhancements in prenatal care, has led to a remarkable decrease in both infant and neonatal mortality rates from CHDs. Between 2000 and 2019, infant mortality from CHDs plummeted by 41%, from 13.6 per 10,000 to 8.1 per 10,000.[136] These achievements, buttressed by investments in pediatric cardiac care, including a specialized cardiac surgery program at the NCH, have significantly improved postoperative outcomes, instilling hope for the future of pediatric cardiac care in Costa Rica.

While Costa Rica's centralized healthcare system ensures high coverage, there are still significant challenges. Rural areas may not have immediate access to advanced diagnostics like fetal echocardiography. The country also faces challenges in prenatal detection of CHDs, with less than 5% of cases diagnosed before birth.[137] Additionally, limitations in post-surgical care and follow-up programs for adolescents and adults with CHDs hinder long-term outcomes for many patients. One of the most pressing issues is the lack of a standardized national transport system for critically ill neonates, which represents a significant barrier to equitable access to specialized care. Addressing these challenges is crucial to improving outcomes for children with CHDs in Costa Rica.

(See 3.1.7 Multi-National Registry)

3.1.4.6. Paraguay

Data from multinational surveillance networks such as the Latin American Collaborative Study of Congenital Malformations (ECLAMC) suggest that the prevalence of CHDs in Paraguay is consistent with broader regional patterns. However, there is no dedicated national registry for CHDs. Instead, Paraguay contributes to multinational registries like ReLAMC and ECLAMC.[138] This contribution allows Paraguay to track CAs, though detailed, localized prevalence data specific to CHDs is limited.

Paraguay's CA surveillance is hospital-based, with data primarily collected from large public hospitals in urban centers like Asunción.[138] While this enables some CA monitoring, particularly in metropolitan regions, it also underscores the urgent need for comprehensive national coverage. The reliance on multinational networks means that Paraguay's data is often aggregated with that of other countries, making it difficult to extract detailed national statistics on CHDs. The lack of comprehensive national coverage, particularly in rural and remote areas, is a pressing issue that needs to be addressed to fully capture the burden of CHDs across the entire population.[139]

Another significant challenge is the potential for underdiagnosis and underreporting of CHDs due to the lack of infrastructure and resources for congenital anomaly surveillance. Paraguay has a small number of clinical geneticists and a lack of specialized healthcare services in rural areas, which hinders both diagnosis and long-term management of CHDs.[139] These systemic limitations are a cause for concern and need to be addressed to ensure that all cases of CHDs, particularly those outside of major urban centers, are accurately diagnosed and reported.

(See 3.1.7 Multi-National Registry)

3.1.5. North America

3.1.5.1. Canada

Canada's national strategy for surveillance of CAs is coordinated through the Canadian Congenital Anomalies Surveillance System (CCASS), a tool that collects data from provincial and territorial health departments. The CCASS, integrated within the broader Canadian Perinatal Surveillance System, ensures a nationwide, high-quality, population-based surveillance mechanism. Each provincial system contributes to this national effort by addressing local public health priorities by surveilling diverse populations across varying geographical landscapes. The system's extensive reach, covering various regions and demographics, is supported by its collaboration with entities like the Canadian Institute for Health Information (CIHI). This collaboration uses the Discharge Abstract Database (DAD) to ascertain cases of CAs. However, the data collection faces challenges such as incomplete data capture, particularly in areas like

stillbirths and elective terminations for fetal anomalies (ETOPFA), which are crucial for a comprehensive understanding of congenital anomalies across the nation. [140]

Canada's approach to CA surveillance includes detailed data collection methodologies that involve multiple data sources, such as hospital discharge data and pathology records, to ensure data completeness and accuracy. The Public Health Agency of Canada (PHAC) has developed methodologies for linking infant admissions data to follow up on cases up to one year of age, although this system does not entirely capture all congenital anomalies. This gap indicates a pressing need for improved data collection methods. [140]

The surveillance practices vary significantly across provinces, with some using advanced data linkage systems to enhance the accuracy of their registries. For instance, some provincial systems integrate data from clinical genetics and cytogenetics, providing an effective framework for understanding the genetic components of CHDs.[141] The CCASS and its provincial counterparts are exceedingly helpful in shaping public health strategies, particularly concerning CHDs, which are among the leading causes of infant mortality in Canada. Strategies such as folic acid fortification have been instrumental in reducing the prevalence of neural tube defects, highlighting the significant impact of effective surveillance and preventive public health policies.

Despite its comprehensive coverage, the CCASS faces several challenges, such as underreporting elective terminations and environmental exposures, which can skew the understanding of congenital anomalies' prevalence and trends. Future enhancements in the system could include integrating more detailed ecological exposure data and the improvement of data collection methodologies to cover elective terminations and stillbirths more comprehensively.

(See 3.1.7 Multi-National Registry)

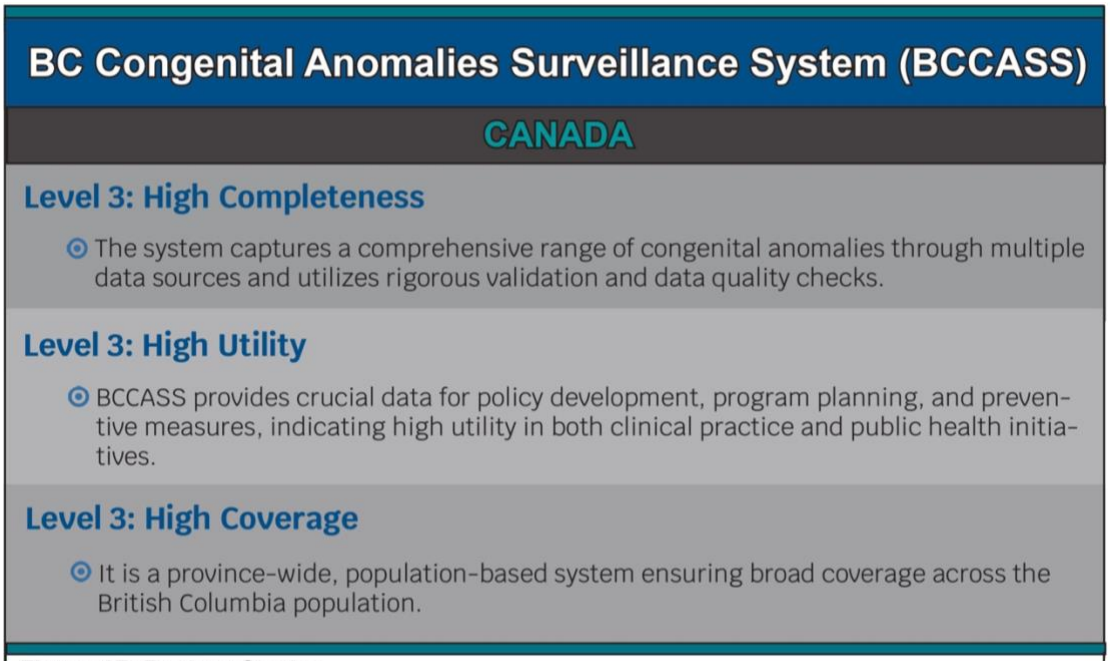


Figure 17: Registry Scoring

3.1.5.2. Dominican Republic

Established as the first Adult Congenital Heart Disease Registry in the Caribbean, this registry is the principal resource for collecting and analyzing data on adults with CHDs in the Dominican Republic. This registry is crucial for tracking demographic details, defect severity, treatments administered, and patient outcomes. It primarily targets adults transitioning from pediatric care, emphasizing the ongoing need for specialized cardiovascular care throughout a patient's lifespan.[142]

The registry's scope captures fundamental data sets, including demographic information, clinical diagnostics, and treatment modalities. While this provides a foundational understanding of CHD impacts on adults, the data collected is limited, focusing on essential metrics without encompassing broader epidemiological details. However, establishing this registry is a pioneering step, a beacon of hope that underlines the need for broader data inclusion that could enrich the national understanding of CHD epidemiology.[143]

In terms of utility, the registry's impact remains modest but foundational; it aids healthcare professionals and policymakers by offering insights into the prevalence and characteristics of adult CHDs within the country. The registry focuses on adults evaluated at pediatric cardiac surgical programs and demographic represents a segment transitioning from pediatric to adult care, highlighting a critical gap in

continuous cardiac care. The registry's narrow focus points to an urgent need for expanded coverage that includes newly diagnosed adults and those not previously integrated into pediatric programs. [144]

The primary challenge facing the Dominican Republic's CHD registry is its limited scope and depth of data collection, which could restrict comprehensive national strategies for CHD management.[145] However, the potential impact of expanding the registry to include a wider array of data points and incorporating more sophisticated tracking systems is immense. It could significantly enhance its utility and transform the landscape of CHD management in the Caribbean.

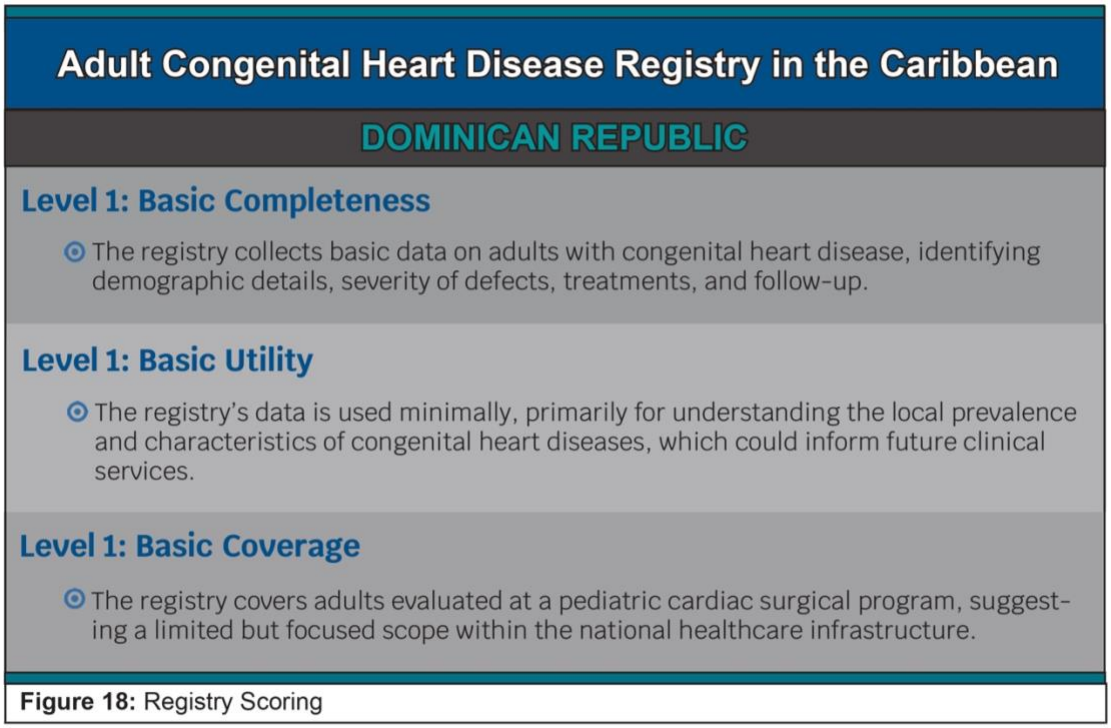


Figure 18: Registry Scoring

3.1.5.3. Haiti

Haiti, with a population of approximately 11.6 million, is confronted with significant public health challenges, particularly in managing CHDs.[146] Despite its limited resources, efforts to establish a national registry for CAs are underway. The Haitian healthcare system faces formidable challenges due to limited infrastructure and resources, exacerbated by political instability and natural disasters. The country's capacity to manage non-communicable diseases, especially cardiovascular diseases (CVDs), which constitute a significant cause of mortality, is notably insufficient.146 Currently,

Haiti lacks local cardiac surgical capacity, significantly impacting the management of CHDs, which require surgical intervention.

The emergent stages of a national registry for CA aim to collect data from healthcare facilities nationwide. This initiative is crucial for cataloging the incidence and types of cardiac CAs and facilitating research and public health interventions. Data from this registry would ideally be used to track trends, identify risk factors, and prioritize healthcare services towards Haiti's most impacted regions and demographics. [147]

Developing and maintaining a CA registry in Haiti faces numerous challenges. More advanced medical facilities and equipment are needed to ensure comprehensive data collection and accurate diagnosis of CHDs. There is a dire need for trained healthcare professionals who can diagnose, report, and manage CHDs effectively. Financial constraints significantly limit the scope of the registry's operations, from data collection to analysis and reporting. Frequent political unrest and poor security conditions disrupt healthcare services and data collection efforts. Although the registry is in its developmental phase, initial efforts have focused on gathering data from available healthcare institutions. For instance, studies conducted at the Saint-Damien Hospital have provided preliminary insights into the prevalence and management of conditions like Tetralogy of Fallot, a common CHD in Haiti. [148]

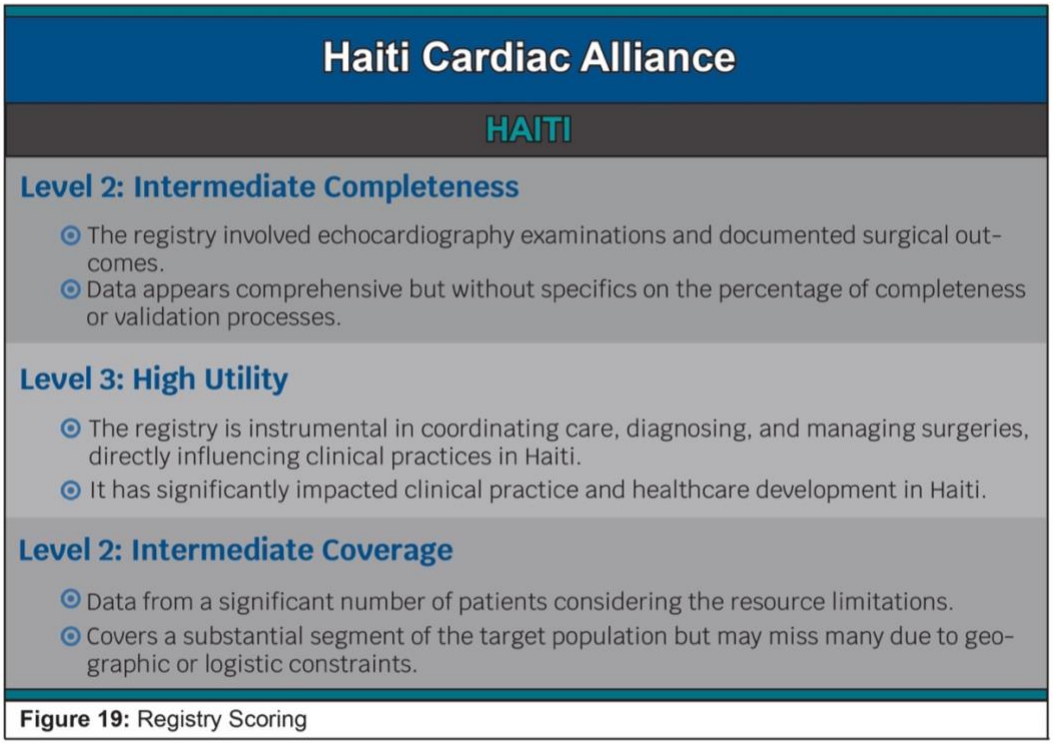


Figure 19: Registry Scoring

3.1.5.4. Mexico

Mexico does not have a national registry for CHDs, however, Mexico's active participation in international collaborations does allow comprehensive data collection that aids in diagnosing, monitoring, and treating these conditions. The data collated from various centers across the country helps identify demographic trends, common types of CHDs, and their management outcomes, thereby facilitating targeted public health interventions and clinical practices. [149]

Despite striving for comprehensive data capture, Mexico's registries often need help with missing or incomplete data, hindering complete data completeness. The registries aim to collect extensive patient data, including demographic details, severity of defects, and treatment outcomes. However, gaps remain due to logistical and technological limitations within the healthcare infrastructure. The utility of these registries in Mexico, while significantly improving clinical practices, especially in using Multidetector Computed Tomography (MDCT) for diagnosing CHDs, only somewhat influences broader policy or public health strategies as it might in more developed healthcare systems. [150] The registries primarily document procedural safety and efficacy, thereby improving clinical outcomes for individual patients rather than shaping national health policies.

The coverage of these registries in Mexico extends to many patients across multiple centers, offering a substantial dataset that reflects a wide array of CHDs and related medical interventions.[151] However, the geographical and demographic representativeness of the data could be enhanced to provide a more detailed national picture of CHD prevalence and outcomes.

One of the main challenges facing Mexican CHD registries is the need for enhanced infrastructure to support more detailed data collection and real-time data integration. Future directions should focus on advancing technology to close the gaps in data collection and analysis, thereby improving the registries' comprehensiveness and utility. Encouraging partnerships with international bodies can also increase registry functionalities, making the data more robust and reflective of the diverse Mexican population.

(See 3.1.7 Multi-National Registry)

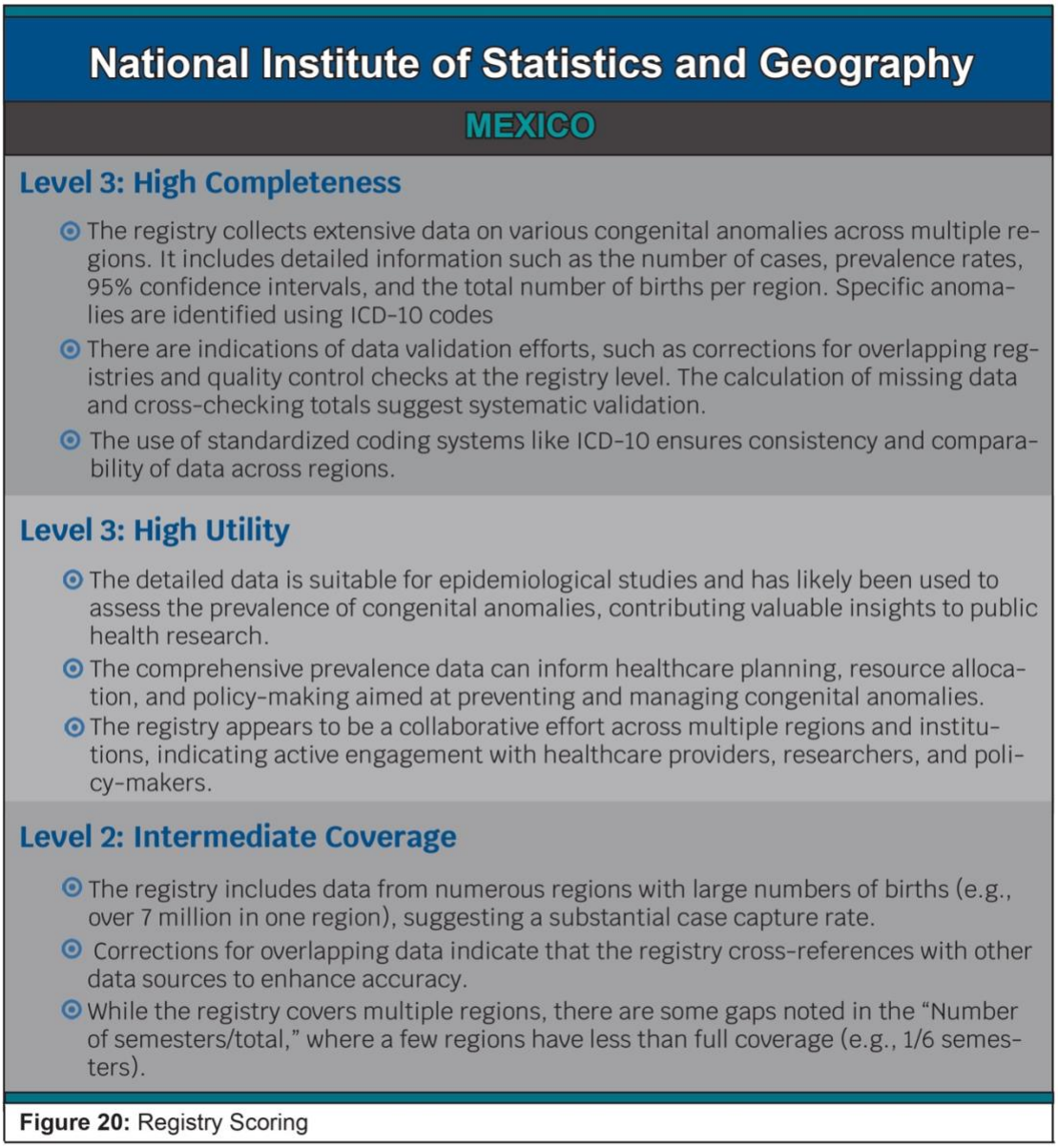


Figure 20: Registry Scoring

3.1.5.5. United States

The landscape of cardiac CA registries in the United States is characterized by a complex and comprehensive network of data collection systems that provide an insightful look into CHDs, their prevalence, patterns, and outcomes. CHDs are the most common type of CA in the US, affecting nearly 1% of, about 40,000, births per year. Of these, approximately 25% are critical congenital heart defects (CCHD)s, which require surgery

or other procedures within the first year of life to prevent severe health problems or death.[153]

The incidence and patterns of CHDs in the U.S. have been meticulously recorded through various regional and national registries, coordinated under the National Birth Defects Prevention Network (NBDPN) umbrella. These registries, like the Metropolitan Atlanta Congenital Defects Program (MACDP) and the South Carolina Birth Defects Program (SCBDP), employ extensive methodologies to ensure comprehensive data collection and validation.[154] The data from these registries reveal significant trends in the prevalence of several types of CHDs and highlight the profound impact of interventions like newborn screening programs, which have become standard across nearly all states. These screening programs are crucial as they allow for the early detection and timely treatment of CCHDs, significantly improving survival rates and health outcomes. This wealth of information is enlightening and keeps us informed about the progress in the field.[154]

The survival rates and outcomes for children with CHDs have improved dramatically over the decades due to advancements in surgical techniques and better postoperative care. For instance, the survival rates following surgeries for severe CHDs like truncus arteriosus and transposition of the great arteries have seen considerable improvements. Multi-institutional studies and database analyses, such as those conducted using the Pediatric Cardiology (2021) database, provide evidence that with current medical practices, most children with CHDs now survive into adulthood.[154]

The utility of these registries extends beyond patient care. They are a fundamental resource for epidemiological studies that inform public health policies and healthcare practices. For example, the data collected helps in understanding the geographical and racial disparities in the prevalence of CHDs and can influence policy decisions regarding resource allocation for pediatric cardiac care services across different regions. The SCBDP, for instance, demonstrates elevated levels of data completeness and utility, as it captures comprehensive information from all delivering hospitals within the state. Such detailed data collection is advantageous for improving patient outcomes and reinforcing the quality of care provided to those affected by CHDs.

A vital strength of the U.S. CA registries is the high level of data completeness. For instance, SCBDP showcases an active population-based surveillance system that captures approximately 97.1% of CHD cases within six months after the birth cohort year closes, reflecting substantial data completeness and compelling case ascertainment.[156] This is achieved through trained medical staff actively reviewing maternal and infant medical records. However, gaps do exist, particularly in the timely entry and validation of data due to variations in reporting standards and practices across different states.

The utility of these registries is not just theoretical, but practical and impactful. They have been instrumental in connecting affected families to intervention services and informing public health strategies aimed at reducing the incidence and severity of CAs. For example, findings from these registries have been used to promote folic acid supplementation programs aimed at preventing neural tube defects. This is a clear demonstration of the positive influence these registries can have on public health policies and clinical practices, giving us reason to be hopeful about the future. However, the impact on broader policy changes can be limited by fragmented data sharing between states and incomplete integration with national health objectives.

Registries in the US are designed to be comprehensive, including all hospitals within the state, ensuring a representative sample of the population and enhancing the registry's coverage. This inclusivity supports a broad public health mandate to monitor and mitigate birth defects across diverse populations. However, the representativeness and coverage can vary significantly from one registry to another, influenced by local policies, funding, and healthcare infrastructure disparities. These disparities should be considered when working towards a more equitable distribution of healthcare resources, as they can lead to the underrepresentation of rural or underserved populations, impacting the generalizability of findings and the equitable distribution of healthcare resources. Global health dynamics, including advancements in diagnostic technologies, changes in healthcare delivery practices, and international collaborations on public health initiatives, play a significant role in shaping the performance of CHD registries in the U.S. The integration of genetic testing and newer imaging modalities has notably enhanced the early detection and classification of CAs, leading to more targeted and effective interventions.

(See 3.1.7 Multi-National Registry)

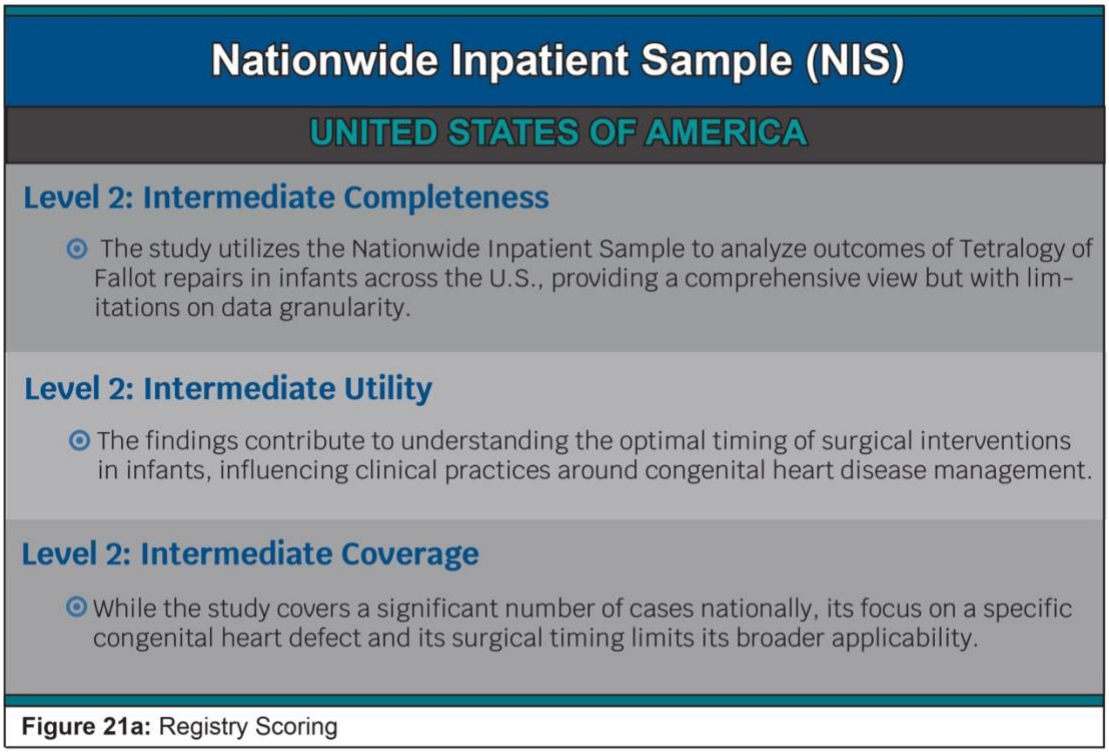


Figure 21a: Registry Scoring

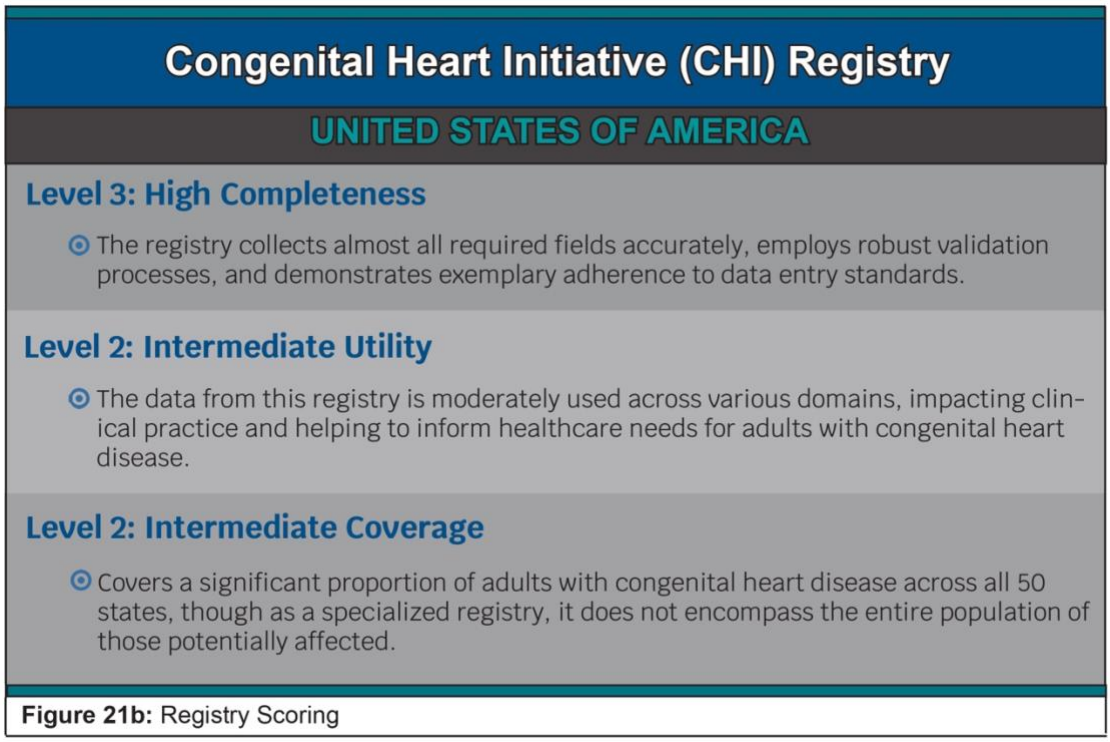


Figure 21b: Registry Scoring

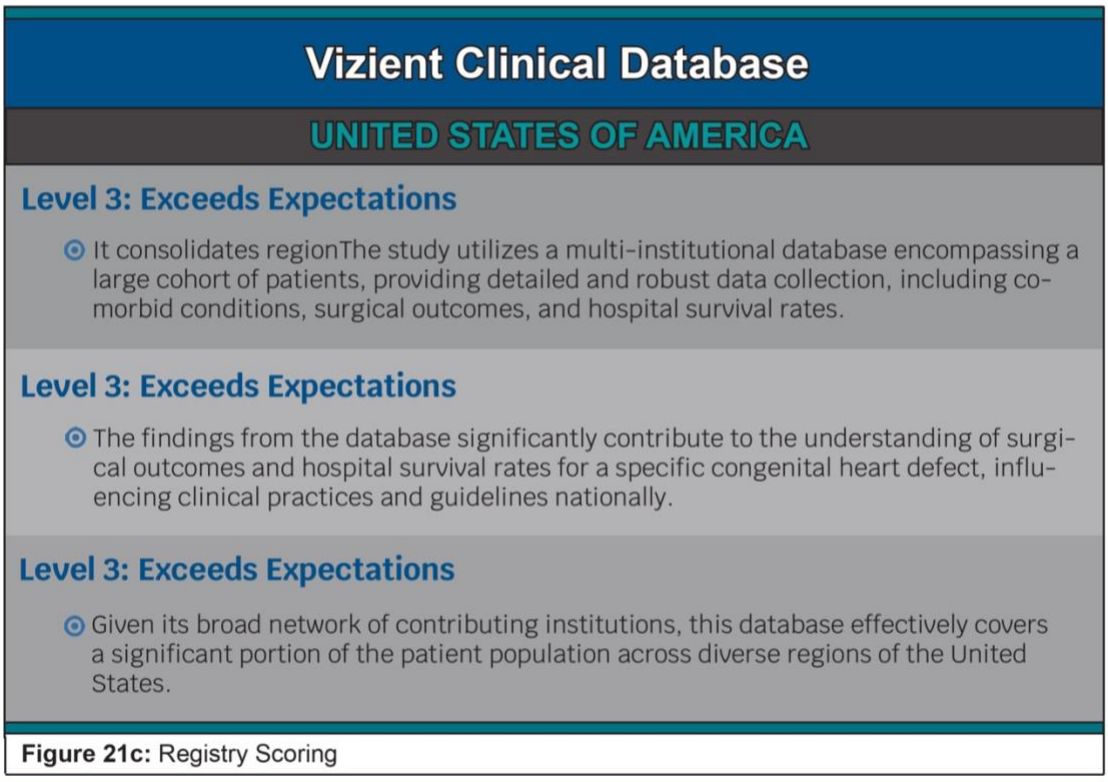


Figure 21c: Registry Scoring

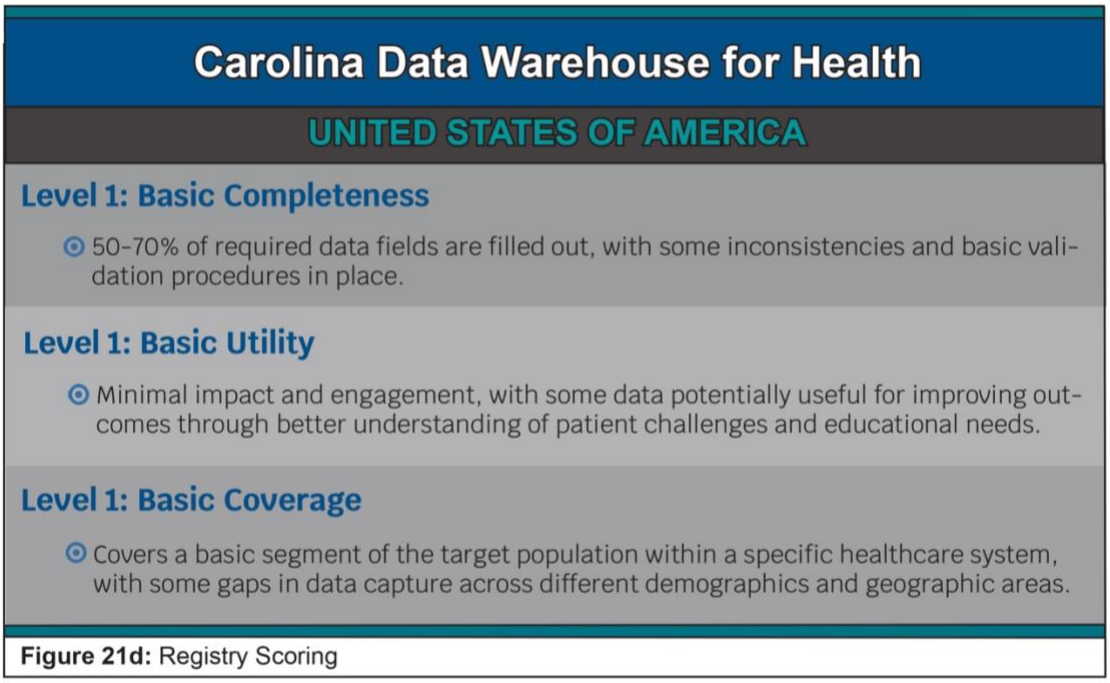


Figure 21d: Registry Scoring

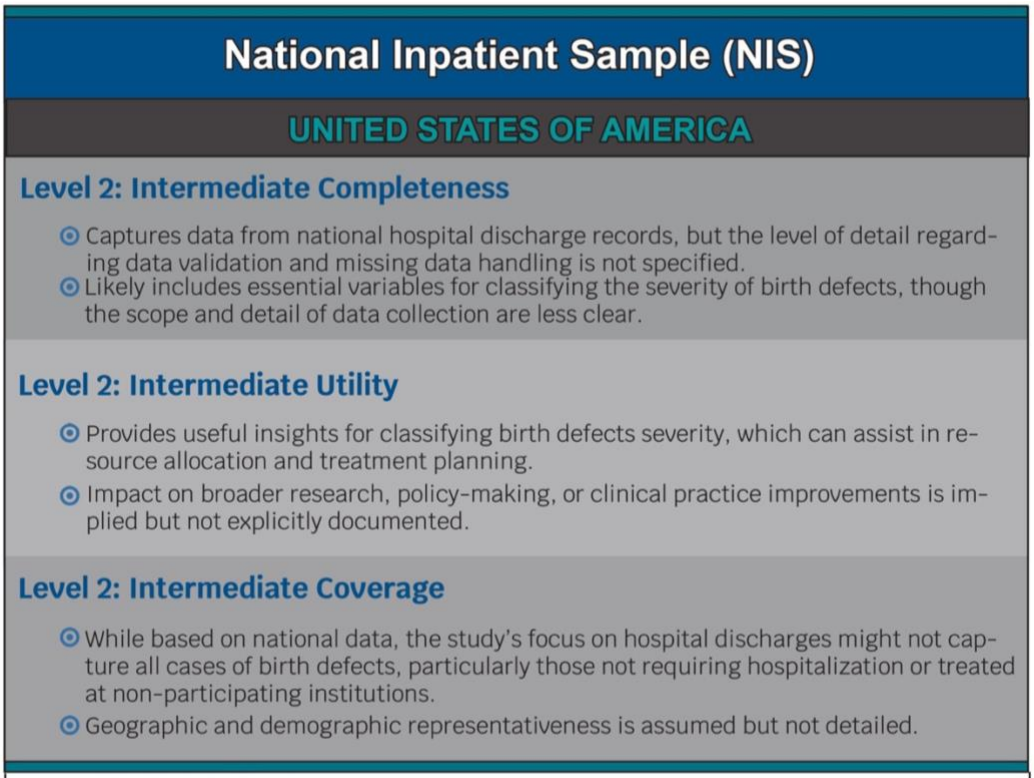


Figure 21e: Registry Scoring

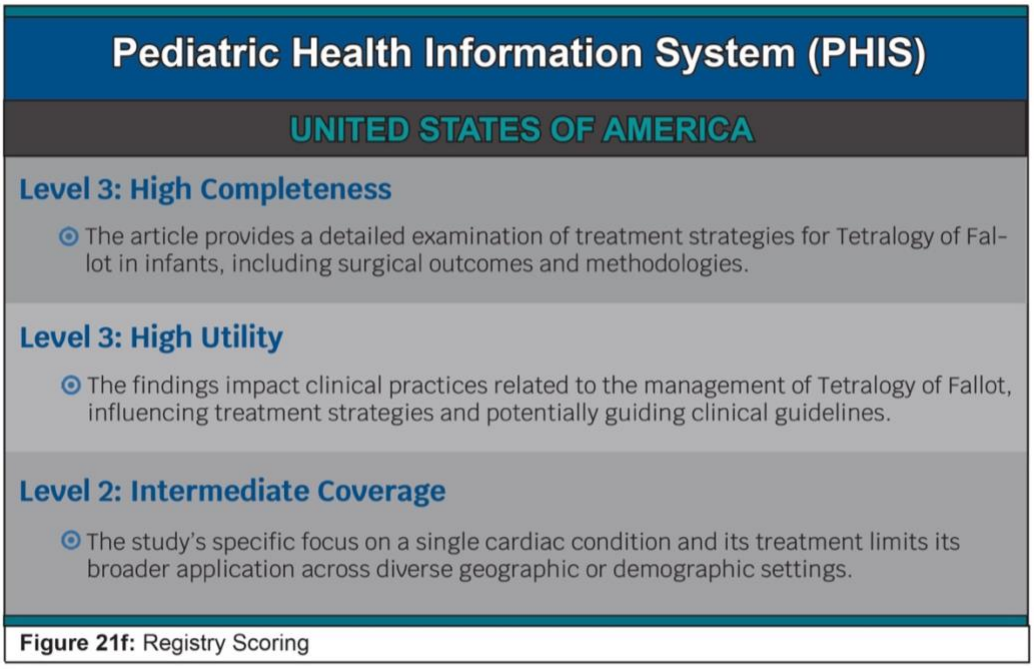


Figure 21f: Registry Scoring

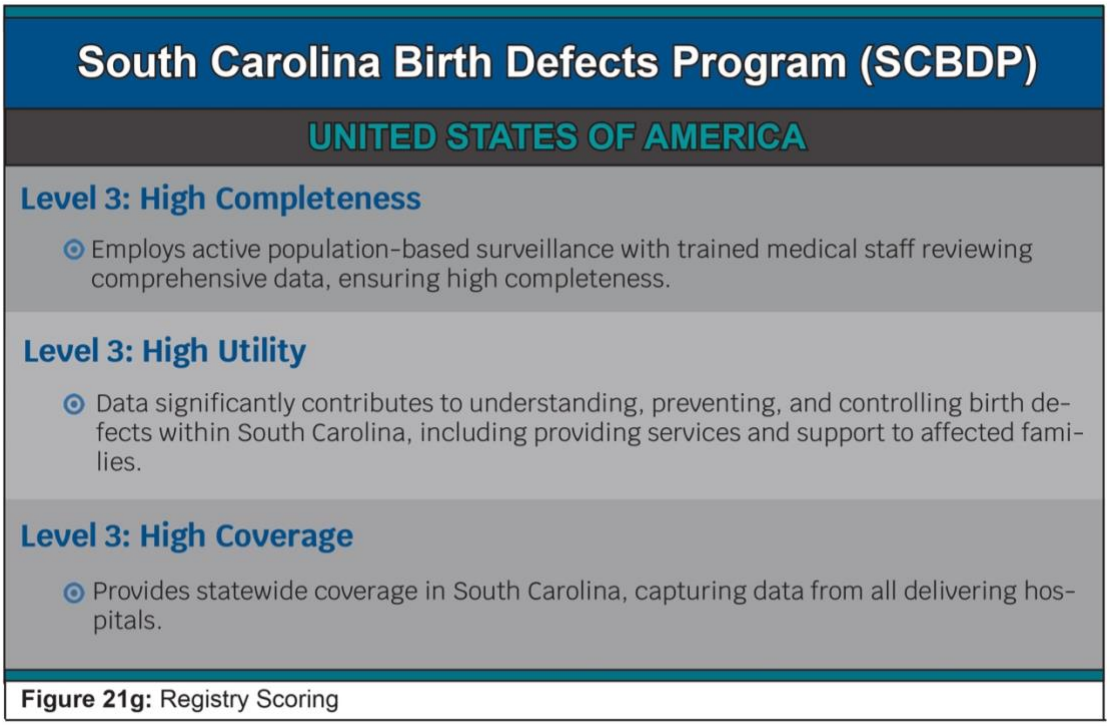


Figure 21g: Registry Scoring

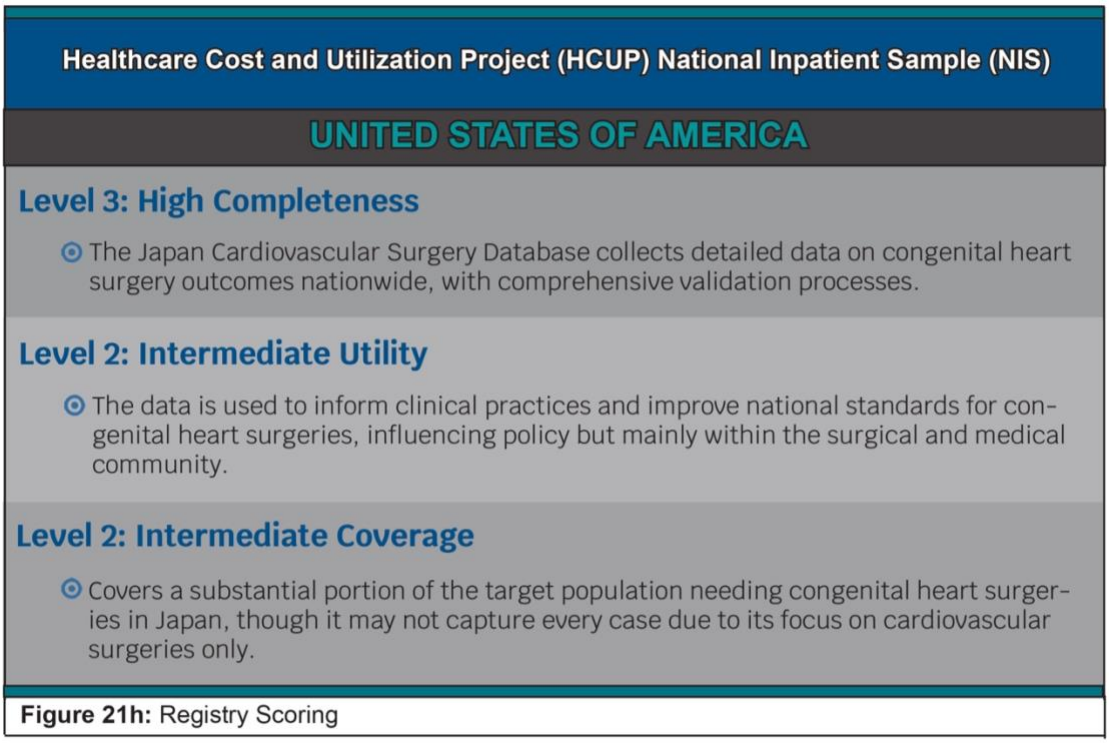


Figure 21h: Registry Scoring

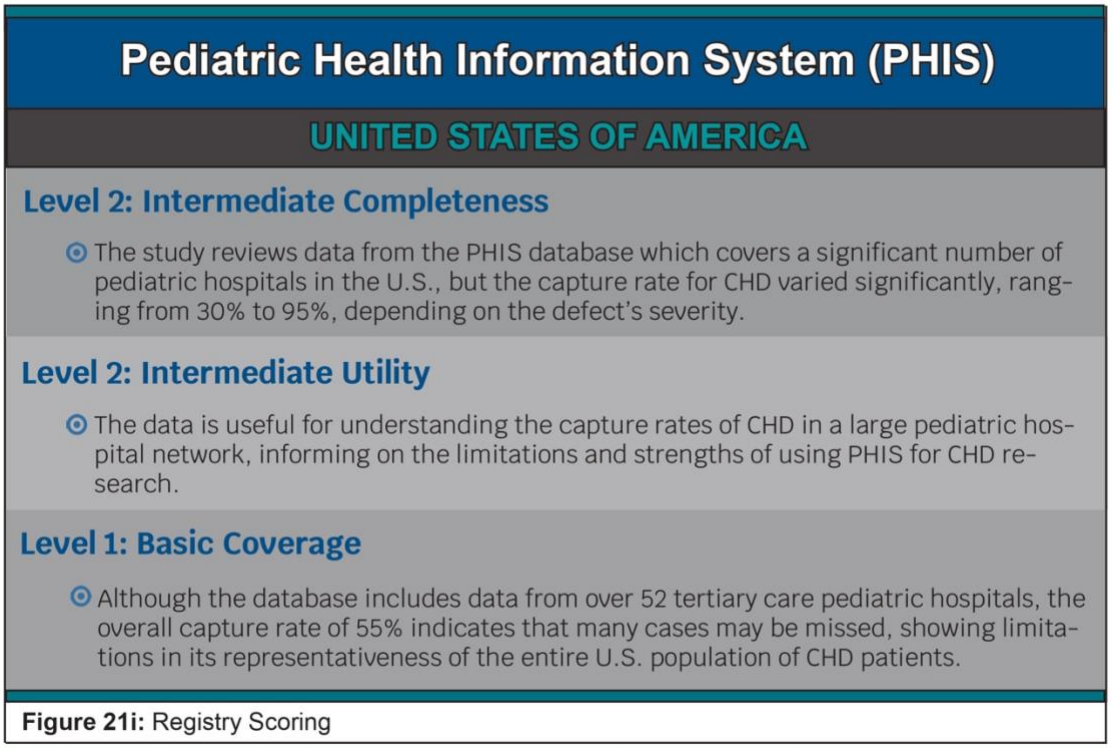


Figure 21i: Registry Scoring

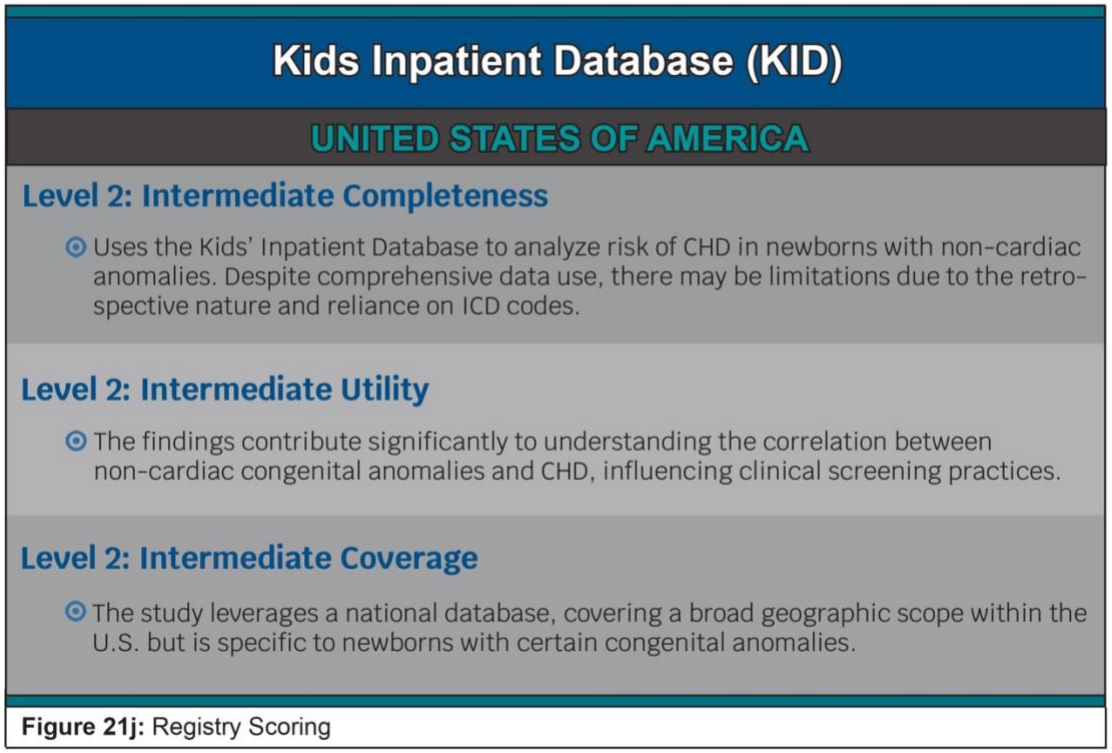


Figure 21j: Registry Scoring

3.1.6. Oceania

3.1.6.1. Australia

Australia maintains comprehensive registries that track CHDs from birth onwards, collecting data on prevalence, outcomes, and the efficacy of various treatments. The integration of advanced diagnostic tools like Multidetector Computed Tomography (MDCT) into these registries has not just improved, but significantly enhanced the precision of CHD diagnostics across the country.

Australian registries aim for a high data completeness standard, capturing a broad spectrum of patient data across different demographics and geographical regions. However, as noted in broader international studies, challenges such as missed or lost data, data entry errors, and the need for more advanced data analysis tools can impact the overall completeness, suggesting areas for further improvement in data collection processes and technology. [157]

The utility of cardiac CA registries in Australia extends beyond clinical applications to influence health policies and resource allocation. Data from these registries support public health officials and healthcare providers in developing strategies for early intervention and improved patient care protocols. The insights gained also contribute to broader public health strategies, although the direct impact on policy can vary and may require further enhancement to reach its full potential.

The Australian CHD registries cover a substantial portion of the population, including diverse ethnic and socio-economic groups. Efforts are made to ensure that the data is representative of the entire population.[157] However, there may be variances in coverage that need addressing to ensure all groups are equally represented and benefit from advancements in CHD diagnosis and treatment.

Australia's participation in international registries facilitates the exchange of valuable data and best practices; this collaboration not only enhances the quality and scope of domestic registries but also allows Australia to contribute to and benefit from global research on CHDs. Such international collaborations enrich the data's utility, enabling more comprehensive studies on trends, treatment outcomes, and epidemiological insights crucial for advancing global health initiatives, making the audience feel part of a larger, impactful initiative. Key challenges for Australia include integrating the latest technological advancements in data collection and analysis to close data completeness and utility gaps. Future directions could involve enhancing interoperability between health information systems to streamline data collection and expand registry parameters to include genetic and environmental factors contributing to CHDs.

(See 3.1.7 Multi-National Registry)

3.1.7. Multi-National Registries

3.1.7.1. BELgian COngenital Heart Disease Database (BELCODAC)

BELCODAC, a significant leap in CHD research, offers comprehensive and longitudinal data on CHD patients in Belgium. The potential impact of this database on healthcare services is immense, as it is designed to enhance outcomes through the combination of clinical, administrative, and socio-economic data sources.

BELCODAC, with its data from 18,510 CHD patients, covers a wide spectrum of malformations. The database's most common diagnosis is VSD, affecting 21% of the population, followed by ASD at 14%.[158] Patients are categorized by the complexity of their heart defects: 48% have mild defects, 41% have moderately complex defects, and 11% have complex defects.[158] Importantly, this database offers comprehensive coverage across multiple regions in Belgium, Canada, and Sweden, ensuring its representativeness and reliability in the CHD research field.

Additionally, BELCODAC combines socio-economic data from StatBel, including education level, household type, and employment, enabling researchers to analyze the impact of socio-economic factors on CHD outcomes. Integrating clinical and socio-economic data is essential for health services research and understanding CHD's broader implications on patients' lives. Despite its strengths, BELCODAC has some limitations. Selection bias toward more complex cases may exist, as the data are drawn from university hospitals that tend to handle more severe CHD cases. Furthermore, physical examination data and non-reimbursed healthcare use (such as visits to dieticians or specific psychotherapy sessions) are not included, potentially limiting the depth of analyses related to patient care.

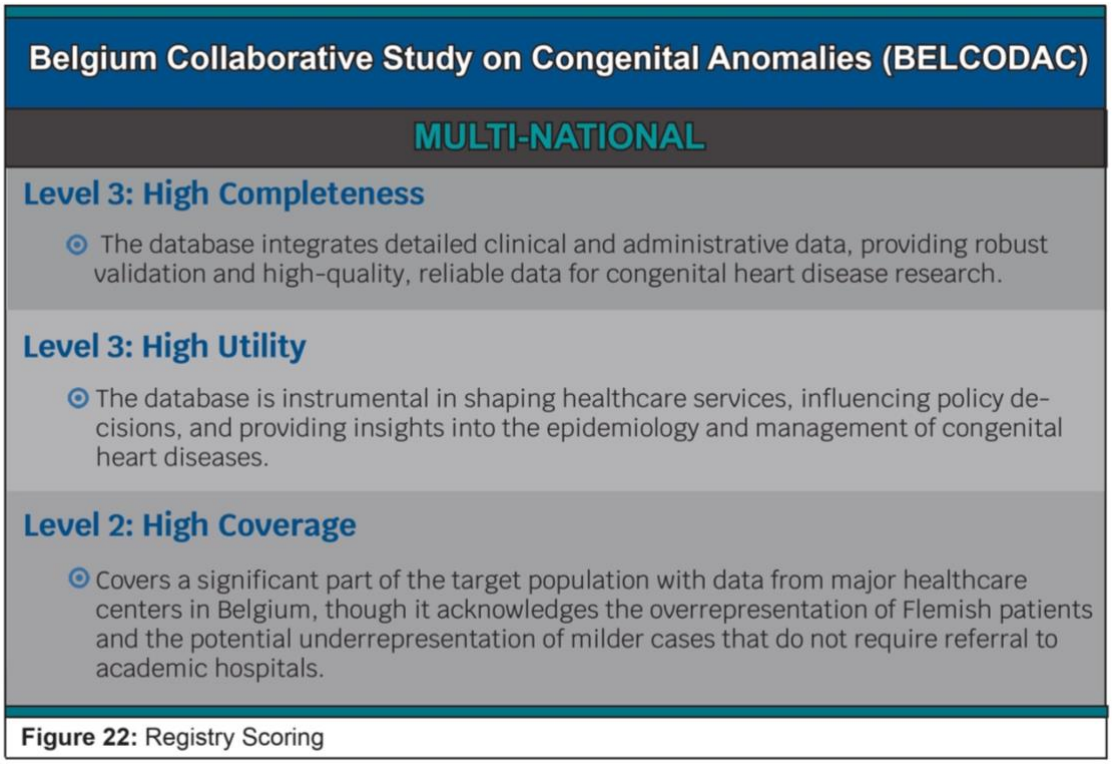


Figure 22: Registry Scoring

3.1.7.2. European Registration of Congenital Anomalies and Twins (EUROCAT)

Established as a cooperative research network of population-based registries for the epidemiological surveillance of CAs, EUROCAT monitors over 1.7 million births annually across Europe, covering a substantial portion of the continent's population. Since its inception in the late 1970s, EUROCAT's broad scope includes data collection on more than 80 types of CAs across its member countries, making it one of the most comprehensive data sources in this field.[160] EUROCAT is a vital resource for tracking the health of Europe's future generations; its comprehensive data collection, wide population coverage, and substantial impact on public health policy and practice make it an exemplary international health surveillance and collaboration model.[159] The insights garnered from the EUROCAT registry play a sweeping role in shaping public health strategies and interventions, contributing to the reduction of the burden of CAs across Europe. [161]EUROCAT includes data from 14 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Spain, Sweden, Switzerland, Ukraine, and United Kingdom.

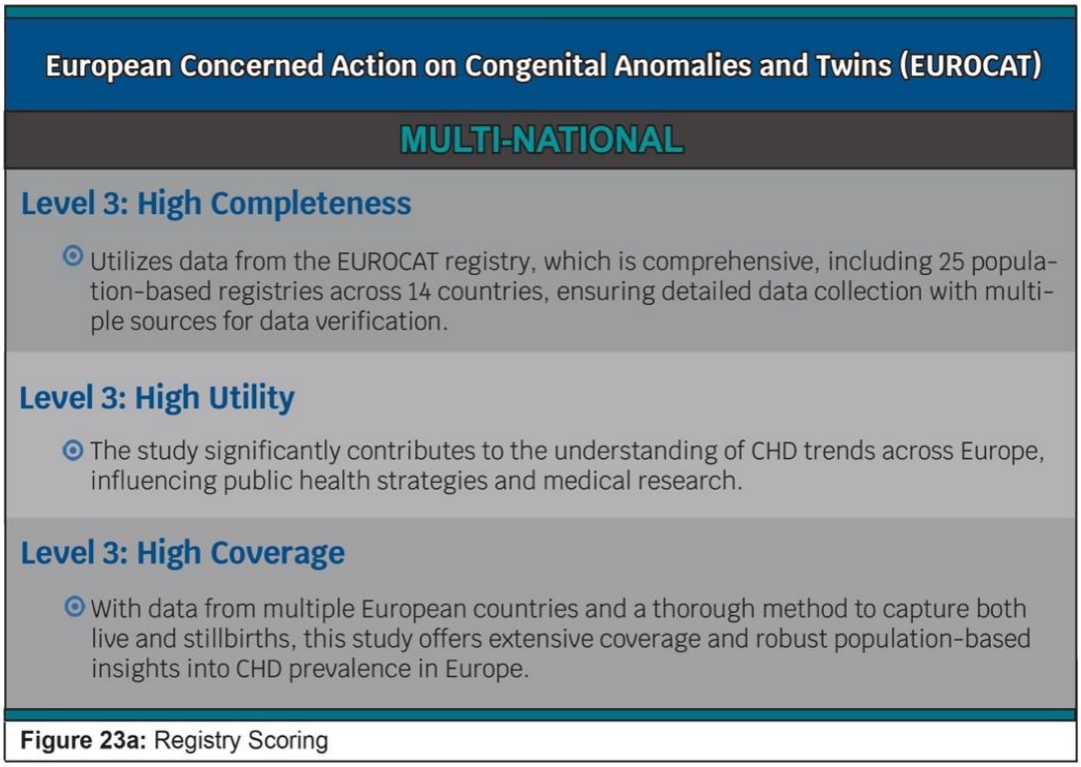


Figure 23a: Registry Scoring

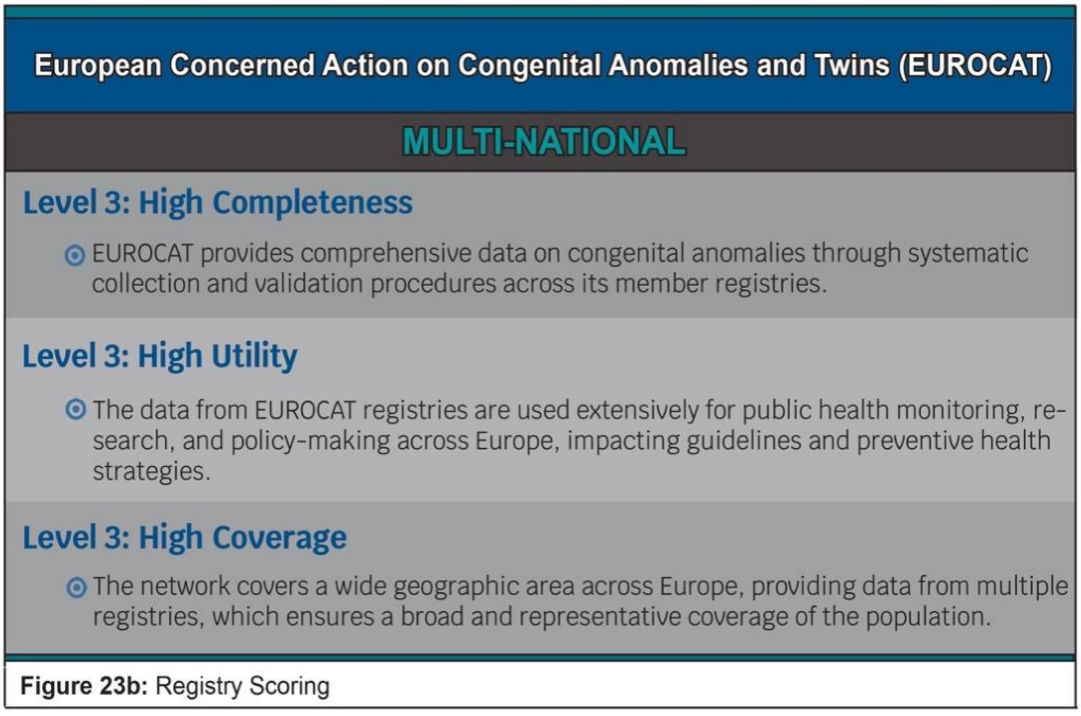


Figure 23b: Registry Scoring

3.1.7.3. European Congenital Heart Surgeons Association Congenital Heart Surgery Database (ECHSA-CHSD)

Initially founded as a tool for internal benchmarking, ECHSA-CHSD has played a pivotal role in enhancing surgical procedures. It has evolved into a comprehensive database analyzing the outcomes from 125 centers in Europe and 13 in China, covering over 82,181 procedures over a 13-year period from 2006 to 2018.[163] The database collects detailed information, including patient demographics, procedural details, and outcomes, which are vital for ensuring high-quality surgical care and facilitating effective international comparisons. The considerable progress in surgical procedures facilitated by the ECHSA-CHSD is a testament to its importance in the medical field. The ECHSA-CHSD includes data from: Greece, Italy, Finland, Poland, Germany, Netherlands, United Kingdom, Japan, and China.

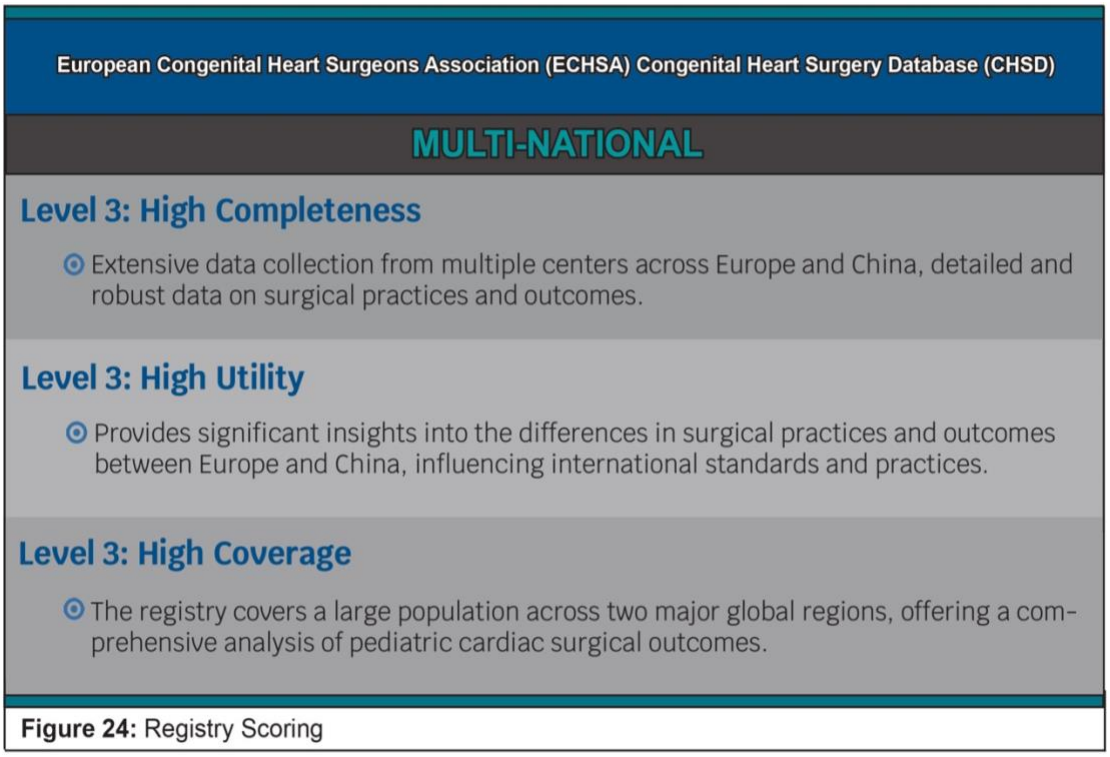


Figure 24: Registry Scoring

3.1.7.4. International Fetal Cardiac Intervention Registry (IFCR)

The International Fetal Cardiac Intervention Registry (IFCIR) is a testament to the power of collaboration in the management of congenital heart defects (CHDs) diagnosed in utero. This registry is critical in accumulating, standardizing, and analyzing global data on fetal cardiac interventions, with a primary focus on conditions such as pulmonary atresia with an intact ventricular septum (PAIVS) and critical pulmonary stenosis.[164]The IFCIR was established to collate detailed procedural and outcome data related to fetal cardiac interventions from many international centers. It aims to bridge the gap in knowledge regarding the management of complex cardiac anomalies diagnosed before birth, fostering a collaborative platform for practitioners globally.[164]The registry includes comprehensive descriptions of fetal and maternal characteristics, procedural details, complications, and short and long-term outcomes, inspiring all of us to contribute to this global effort. The IFCIR includes data from 10 countries: United States, Canada, Argentina, Belgium, Poland, Spain, Germany, Portugal, Netherlands, and Brazil.

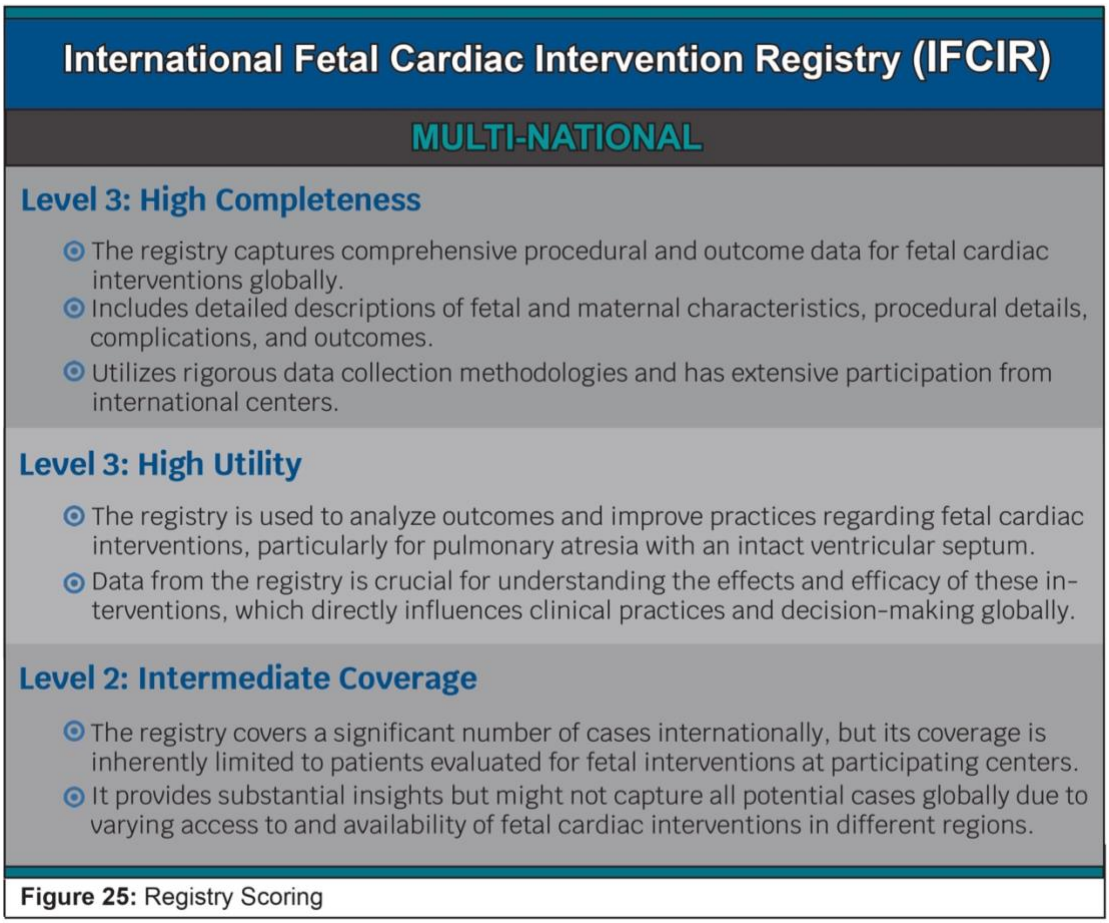


Figure 25: Registry Scoring

3.1.7.5. Multidetector Computed Tomography (MDCT) Registry

The MDCT registry for CHD in Africa and the Middle East, a collaborative effort aimed at aggregating and analyzing data on patients undergoing MDCT scans, represents a significant leap in the region's healthcare capabilities. This registry, which draws data from multiple centers, is designed to delineate patient demographics, clinical profiles, and procedural specifics. The median patient age was 12 months, with a sizable portion under two years, indicating a high burden of early childhood CHDs in these regions. This registry includes data from South Africa, Argentina, Australia, Brazil, China, Colombia, Egypt, India, Iran, Italy, Japan, Kenya, Malaysia, Mexico, Russia, Saudia Arabia, Ukraine, United Kingdom, and the United States.

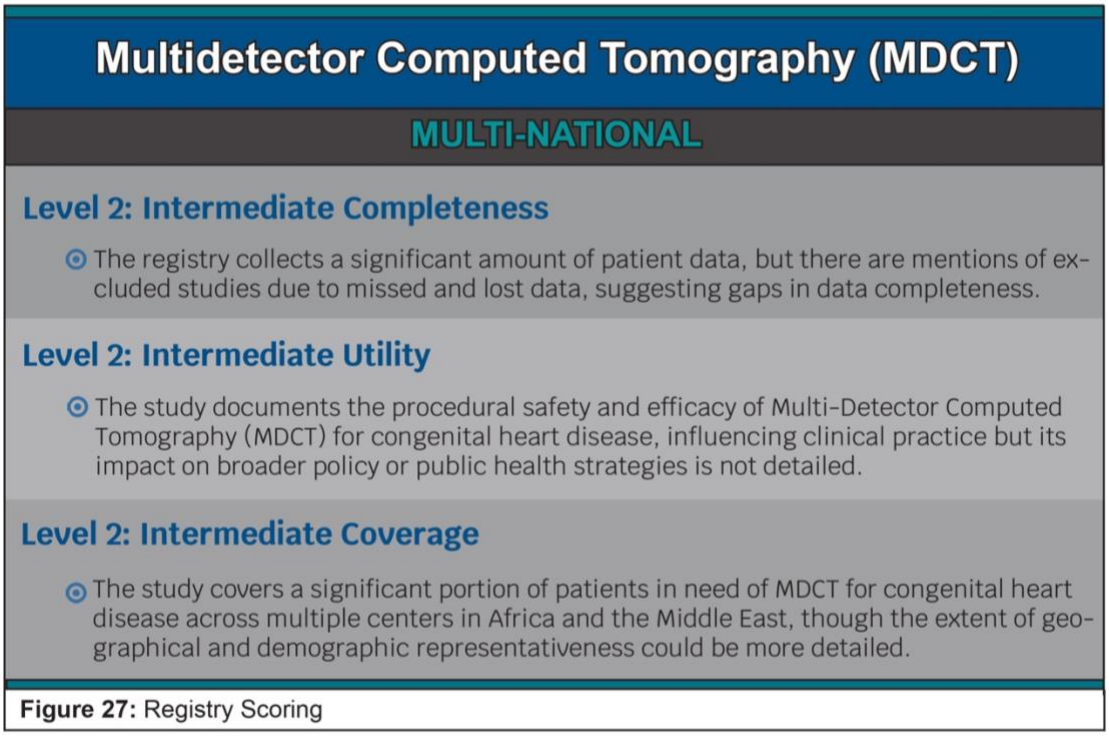


Figure 27: Registry Scoring

3.1.7.6. Latin America Network of Congenital Malformation Surveillance (ReLAMC)

ReLAMC's coverage of a substantial portion of Latin America's births is a significant feat, with an estimated overall prevalence rate of CAs at 1.11% of the total births between 2017 and 2019, based on data from more than 9 million births. It encompasses multiple national and regional registries across countries such as Argentina, Brazil, Chile, Costa Rica, and Paraguay. ReLAMC, in close collaboration with institutions like ECLAMC (the

Latin American Collaborative Study of Congenital Malformations) and following international models such as the ICBDSR, has been instrumental in providing valuable data for CCHDs, microcephaly, and Down syndrome. This data allows for earlier detection and response to potential public health crises. Despite its strengths, ReLAMC's coverage is heterogeneous, with significant gaps in reporting and data collection from private hospitals or regions not yet integrated into the network. There are also operational differences between registries that must be harmonized urgently to improve the quality of the shared data further. Underreporting, especially in stillbirths, remains a challenge due to the lack of uniform reporting standards and the socio-economic disparities across the region. Additionally, the reporting of conditions like CAs in stillbirths varies significantly across registries, from as low as 3% in Costa Rica to 23% in the ECLAMC network, highlighting underreporting in some regions. However, ReLAMC's historical importance and its potential for future public health impact make it a significant initiative in Latin American healthcare infrastructure, underscoring its ongoing relevance and its role in shaping the region's healthcare landscape.

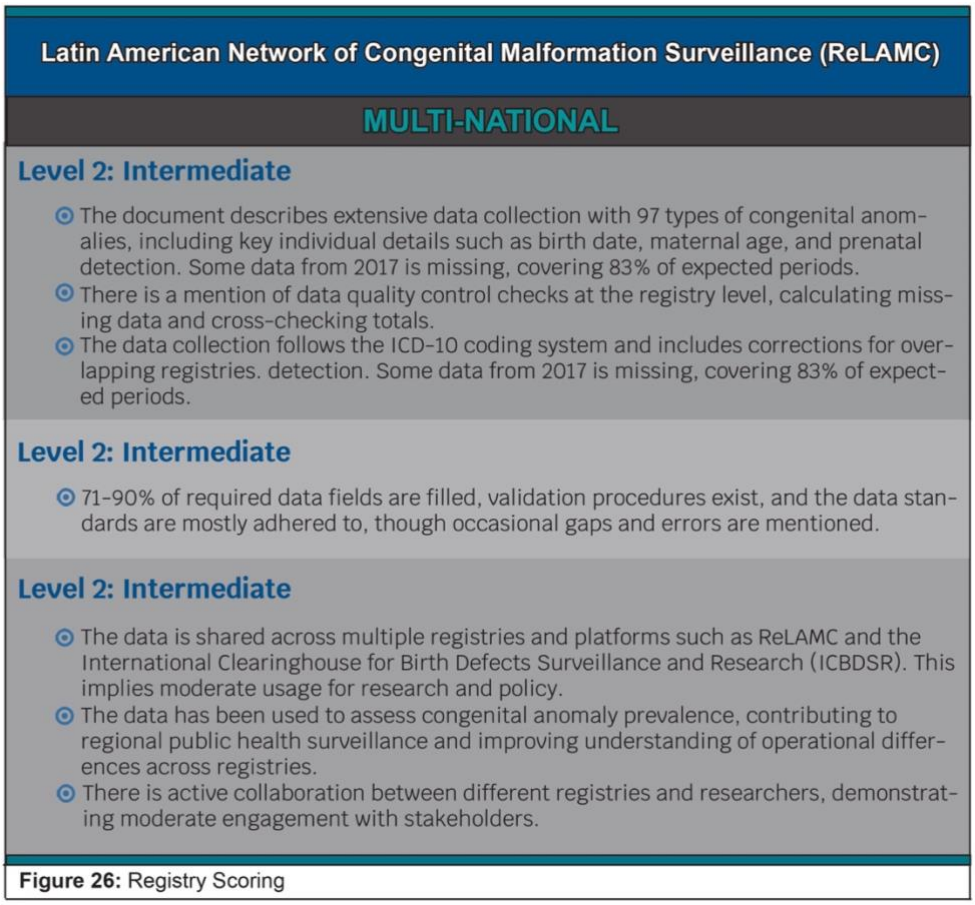


Figure 26: Registry Scoring

3.1.7.7. World Database for Pediatric and Congenital Heart Surgery (WDPCHS)

The World Database for Pediatric and Congenital Heart Surgery (WDPCHS) represents a significant milestone in global healthcare collaboration. It is a testament to the power of collective effort in the medical field. Focusing on the treatment and outcomes of congenital heart defects, this database was initiated under the auspices of the World Society for Pediatric and Congenital Heart Surgery (WSPCHS).[164] WSPCHS amalgamates extensive surgical data from across the globe, setting a new standard for medical data completeness, utility, and population coverage. WDPCHS includes data from 22 countries: Brazil, China, Colombia, Costa Rica, Egypt, Guatemala, India, Indonesia, Kazakhstan, Malaysia, Mexico, Nicaragua, Nigeria, Pakistan, Peru, Philippines, Russia, Saudi Arabia, Ukraine, Uzbekistan, Vietnam, and the United States. However, the specific journal article incorporated in the scoping review, specifically draws data from the United States and Canada.

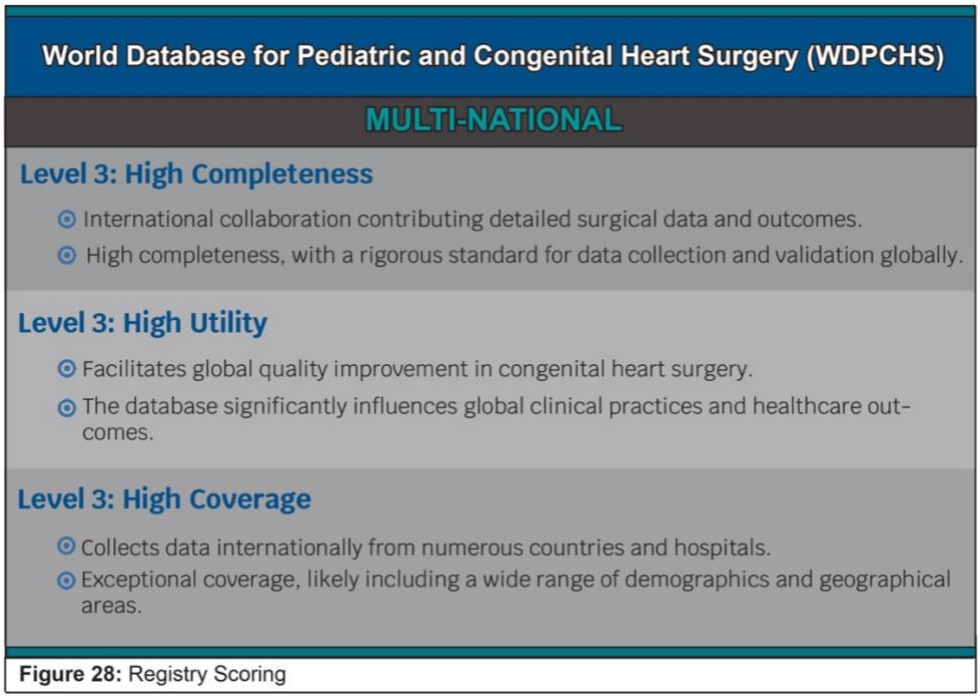


Figure 28: Registry Scoring

3.2. Visual Summary of Results



Figure 29: Multiple Registry Analysis for Selected Countries and Scores of Multinational Registries Evaluation of cardiac congenital anomaly (CA) registries across various countries and multinational scales, based on data completeness, utility, and population coverage. See appendix for each country's specific registry breakdown.

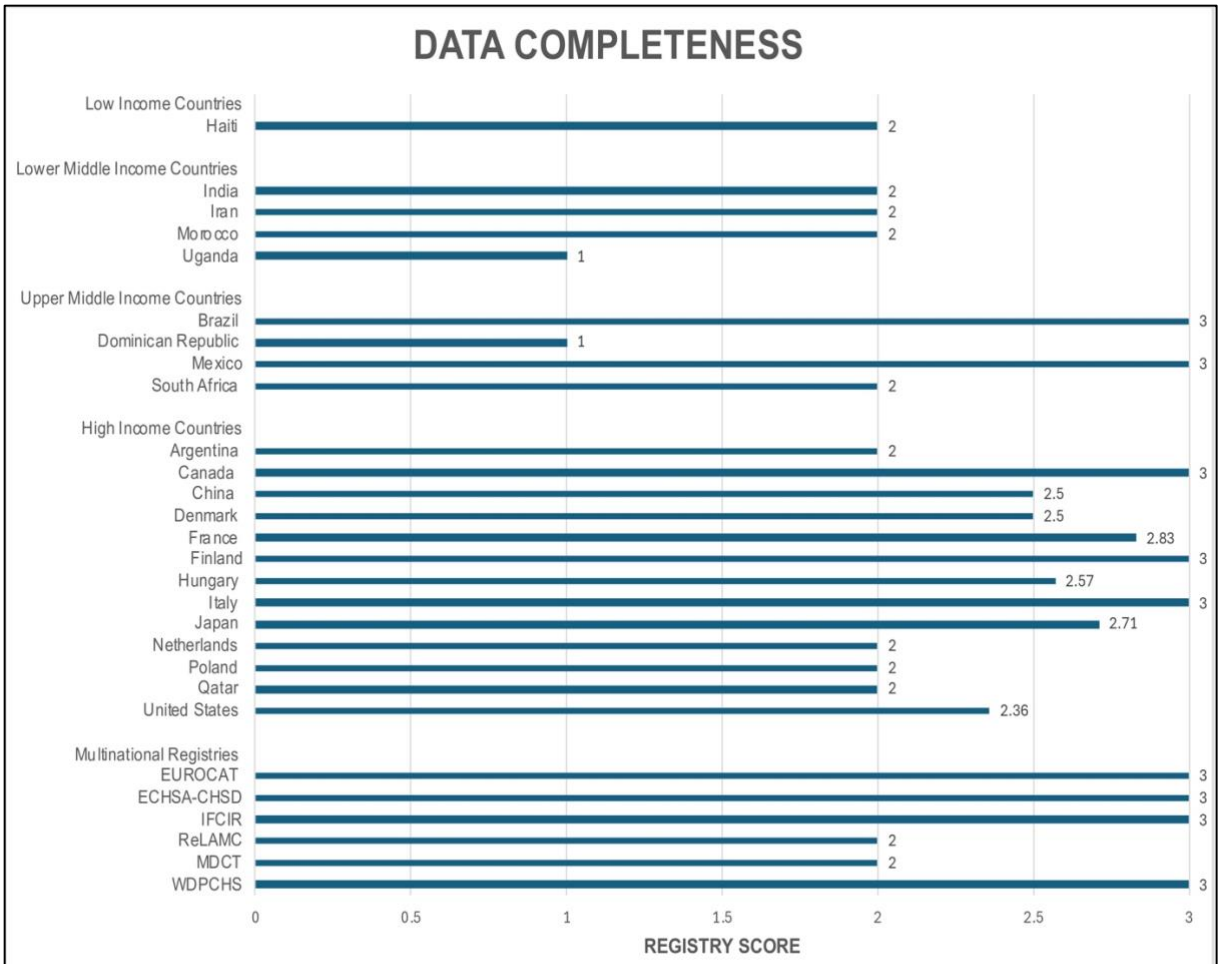


Figure 30: Data Completeness Results Country and multinational registry scores on data completeness, ranging from 0 to 3, for cardiac CA registries. The chart is organized by income levels, with high-income countries typically displaying higher completeness scores, indicating more robust and thorough data capture in their registries.

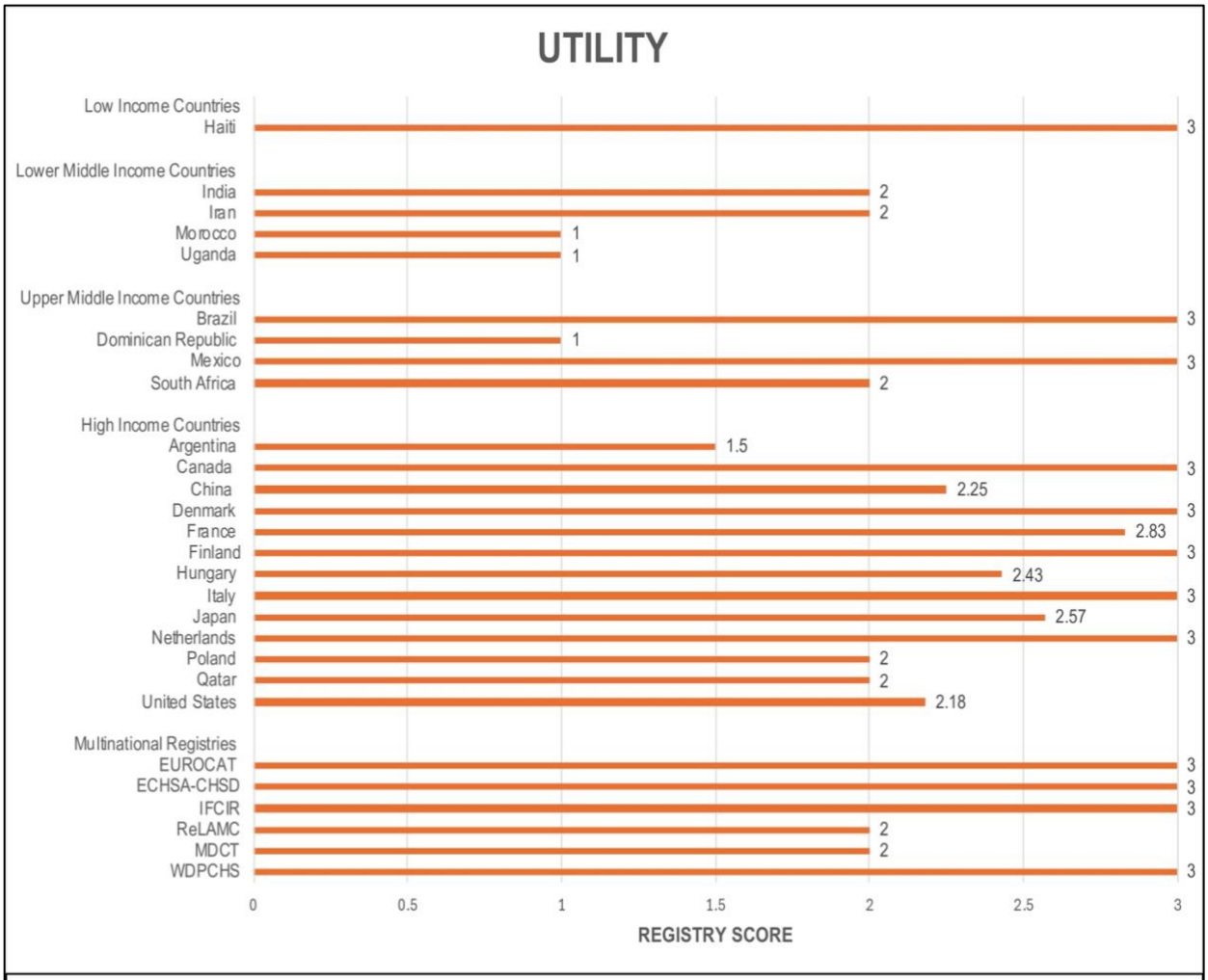


Figure 31: Utility Results Countries categorized by income level and multinational registries, comparing their population coverage based on a grading scale from 1 to 3 for cardiac CA registries. Each horizontal bar represents an averaged score of registries for each respective country. Notably, Japan and Hungary show higher variability within the high-income group, illustrating diverse registry effectiveness across different regions.

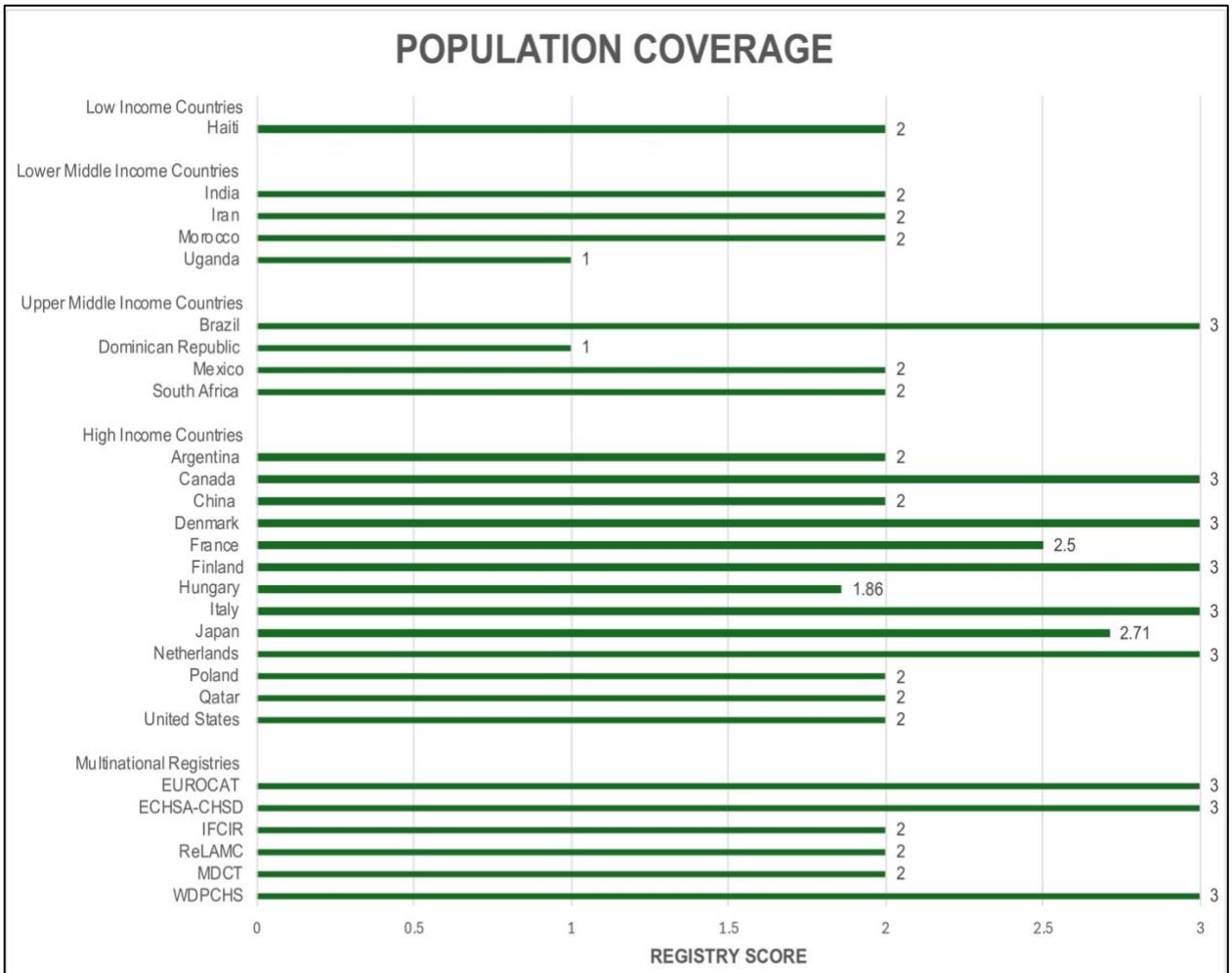


Figure 32: Population Coverage Results Comparison of population coverage for cardiac CA registries across countries, categorized by income level, and multinational registries, based on a grading scale from 1 to 3. Each data bar represents the average score of registries within each country. Note the variability observed within high-income countries, particularly in Japan and Hungary, which emphasize differences in registry effectiveness across regions.

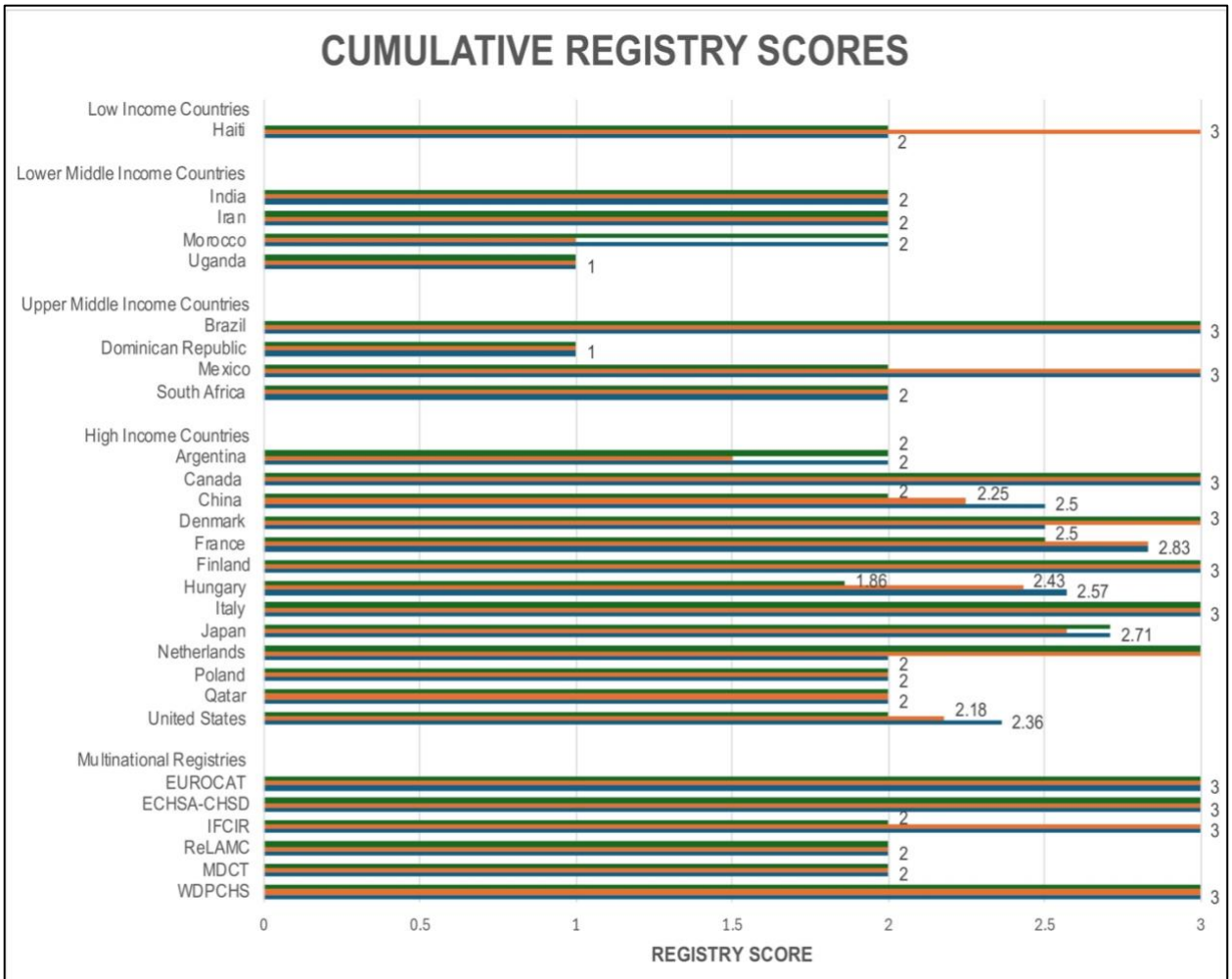


Figure 33: Cumulative Registry Scoring Results Cumulative grading scores for cardiac CA registries across countries and multinational registries, categorized by income level. High-income countries typically demonstrate higher cumulative scores, reflecting more comprehensive and complete registry data. In contrast, lower-middle and upper-middle income countries exhibit greater variability in both coverage and utility.

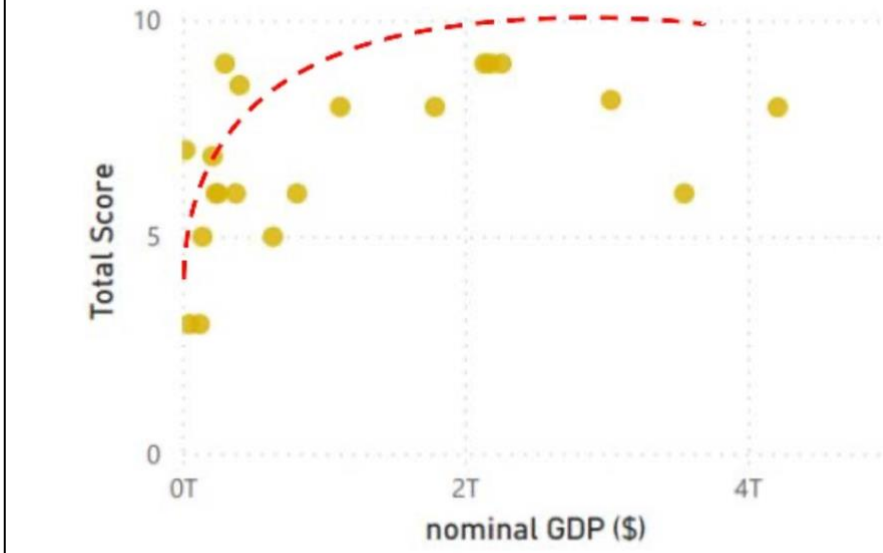


Figure 34: Additive Score vs Nominal GDP The total scores of cardiac congenital anomaly registries against the nominal GDP of various countries are shown.There appears to be a trend showing that countries with higher GDPs tend to have higher total scores in their registries, suggesting that economic resources might correlate with the overall effectiveness and comprehensiveness of congenital anomaly registries.

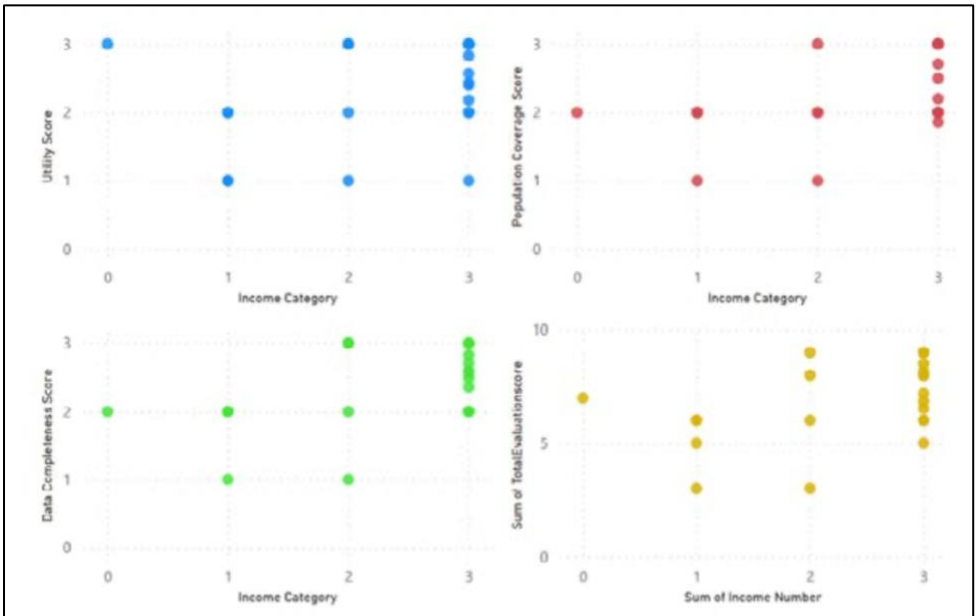


Figure 35: Countries Categorized by Income Category vs Grading Scores Higher income categories generally show higher utility scores, supporting the notion that wealthier countries may leverage registry data more effectively for health interventions and policy-making. Additionally, variability across income levels is shown, indicating that income alone does not fully determine the extent of population coverage in registries.

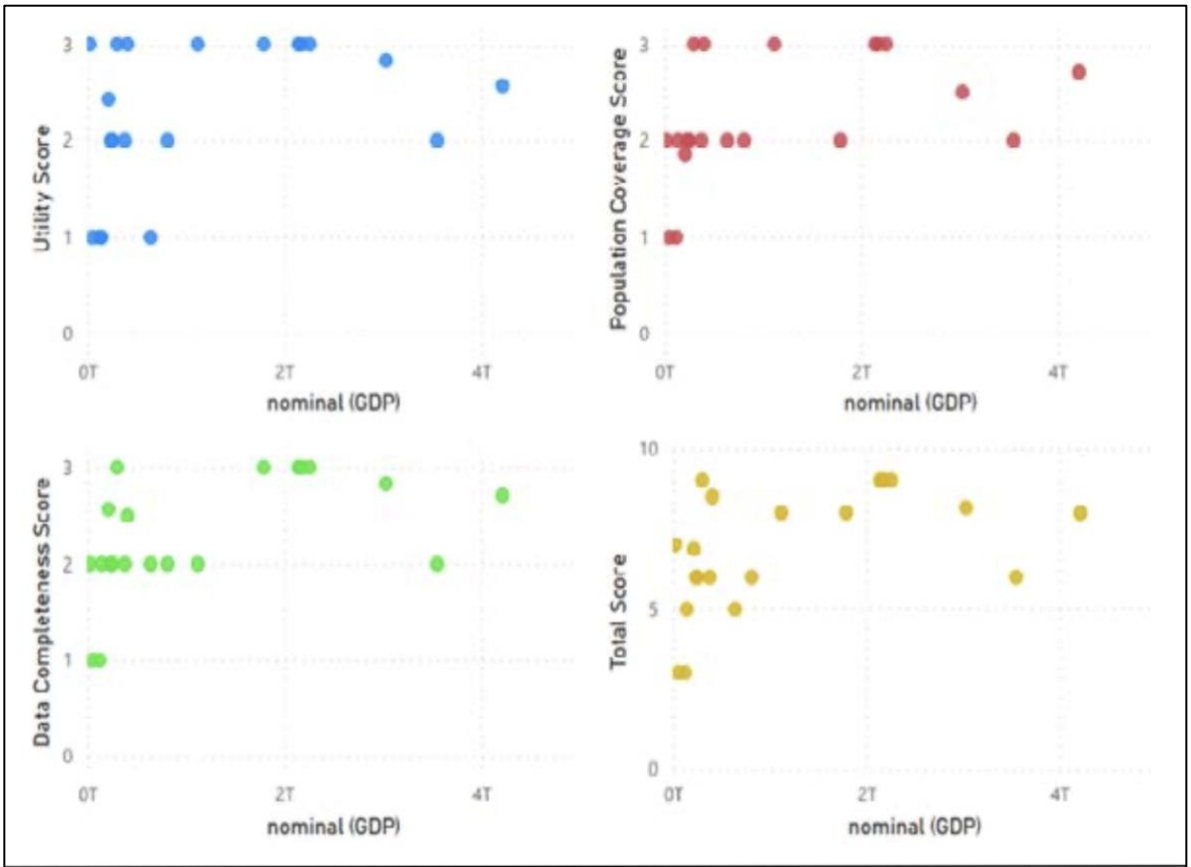


Figure 36: Breakdown of Scores Against Nominal GDP Countries with higher GDPs tend to have higher utility scores, indicating better usage of registry data in research and healthcare improvement.There is a less clear correlation between GDP and population coverage scores, suggesting that other factors besides economic status may influence how comprehensively registries capture data across populations.

3.3. Discussion

3.3.1. Challenges of the Study

3.3.1.1. Underreporting and Missing Data

Underreporting and missing data are significant challenges for CHD registries, particularly in LMICs. Factors such as limited healthcare access, lack of awareness, and inadequate reporting systems contribute to incomplete data. This can result in underestimations of CHD prevalence and hinder the ability to identify trends and risk factors accurately. Efforts to improve data collection practices and increase reporting compliance are essential to address these issues. In LMICs, prevalence rates are harder to ascertain due to underreporting and incomplete data. However, the work of registries like the Haitian Cardiac Alliance and PROTEA (a Southern African CHD registry) is historically significant, as they address the stark disparities in healthcare access and

outcomes in these regions. These registries have laid the groundwork for improving care and outcomes, despite the ongoing challenges in data completeness and coverage.

The key strengths of LMIC registries lie in their ability to impact clinical practice and public health policies, even in cases where data completeness and coverage are less than optimal. The World Database for Pediatric and Congenital Heart Surgery, Italian Registry, and EUROCAT stand out for their comprehensive coverage and global influence, setting benchmarks for how registries can function at a national and international level.

Conversely, the primary weaknesses lie in regions with limited resources, such as Haiti, Iran, Uganda, India, Morocco, and parts of South America. These registries often struggle with incomplete data, logistical barriers, and insufficient population coverage despite demonstrating high utility by directly improving clinical care and surgical outcomes. Historical significance in these areas is rooted in overcoming adversity and laying the foundation for future growth in healthcare infrastructure and registry development.

3.3.1.2. Financial and Logistical Constraints

Financial and logistical constraints pose substantial barriers to the establishment and maintenance of CHD registries. In LMICs, limited funding and resources can impede the development of comprehensive surveillance systems. Challenges include insufficient staffing, lack of training for healthcare providers, and inadequate infrastructure for data collection and storage. Addressing these constraints requires sustained investment and international support to build capacity and enhance registry functionality.

3.3.1.3. Legal and Ethical Issues

Legal and ethical issues related to data privacy and confidentiality are critical considerations for CHD registries. Ensuring the secure handling of sensitive personal and medical information is paramount to maintaining public trust and compliance with regulations. Balancing data accessibility with these ethical considerations is essential for the responsible use of registry data. Legal and ethical frameworks also need to address disparities in healthcare access and outcomes. Efforts to establish and maintain registries in LMICs must consider the unique challenges faced by these regions and prioritize equity in healthcare delivery; ethical considerations should guide the allocation of resources and the implementation of public health interventions to ensure that all populations benefit from advancements in CHD understanding and management.

3.3.1.4. Geographic and Demographic Trends

The prevalence and types of CHDs can vary significantly across different geographic regions and demographic groups. High-income countries (HICs) often report lower prevalence rates of severe CHDs due to better access to prenatal care and advanced diagnostic technologies. In contrast, Low and Middle-Income Countries (LMICs) face

higher rates of CHDs due to factors such as limited healthcare infrastructure, higher exposure to environmental risks, and inadequate maternal nutrition.

The registries in question span across continents, representing countries from North America, Europe, Africa, Asia, and Latin America. For example, the Haitian Cardiac Alliance focuses on coordinating care and improving surgical outcomes in a resource-limited setting, while the Italian Registry for Congenital Anomalies integrates data across regional levels into a national system. Moreover, global initiatives, such as the World Database for Pediatric and Congenital Heart Surgery, contribute internationally by compiling data from numerous countries. These initiatives reflect a diverse demographic range, from LMICs such as Haiti and Morocco to highly developed regions such as Europe and the United States.

Certain demographic factors, such as maternal age and ethnicity, are associated with variations in the prevalence and types of CHDs. Demographic variability is also evident in the target populations. For instance, the Haiti registry primarily supports pediatric cardiac surgery in resource-poor environments, facing challenges such as incomplete data due to logistical constraints. In contrast, European and North American registries often benefit from robust healthcare systems that ensure comprehensive coverage of CHDs, with registries like EUROCAT offering detailed data across several countries in Europe.

3.3.2. High-Quality Output Without Established Registries: Paradox Explained

Countries capable of large-scale studies, such as Mexico, often have extensive healthcare networks and advanced medical technologies that allow for widespread data collection. Despite this, even resource-rich nations sometimes lack the infrastructure for a centralized congenital anomaly registry. This results in limited nationwide data and fragmented coverage, where specific regions or hospital networks collect and report data but are not part of a unified system. The impact of this fragmentation is particularly felt in rural and underserved areas, where the lack of comprehensive national coverage can lead to disparities in healthcare provision. While national health systems can support data collection, registries often remain isolated, leading to data quality and population coverage inconsistencies. For instance, despite their ability to conduct large-scale studies, they still rely on multinational collaborations, such as the Latin American Collaborative Study of Congenital Malformations (ECLAMC), rather than developing independent, centralized national registries. This leaves gaps in comprehensive national coverage, especially for rural and underserved areas.

The primary strength of countries capable of large-scale studies lies in the robust healthcare systems supporting data collection at scale. Advanced diagnostic technologies, such as fetal echocardiography, allow for early detection of CHDs, which improves outcomes and contributes to substantial data for large-scale studies. These technologies enhance data quality and play a crucial role in improving patient care. Also, these countries can establish sophisticated healthcare data systems and implement technologies such as digital health records and cloud storage, which enhance data accessibility and research efforts.

Moreover, collaboration with international networks allows these countries to participate in global congenital anomaly surveillance, increasing access to comparative data and international expertise. This strengthens local data and creates opportunities for participating in multinational studies, further advancing congenital heart disease research. Despite their capability, several factors hinder the establishment of dedicated congenital anomaly registries. One significant barrier is funding and resource allocation. Creating a registry requires sustained investment for initial setup and long-term maintenance, data quality control, and expansion into underserved regions. The lack of dedicated financial support often leads to fragmented data collection efforts, where only specific regions or hospital systems participate, leaving coverage gaps, especially in rural or economically disadvantaged areas.

Data coordination is another challenge. With a centralized system, individual hospitals or regions may collect and manage data independently, resulting in consistency in recording and reporting data. Moreover, differences in coding systems, data collection methods, and validation processes can lead to variations in data quality, reducing the reliability of findings at the national level. Furthermore, a lack of policy frameworks can prevent the establishment of registries. Even in countries with solid healthcare systems, the absence of clear governmental or institutional mandates for registry development can delay efforts to create unified congenital anomaly tracking systems. The presence of such mandates is crucial as it provides a clear direction and commitment from the government or institutions, which is essential for the successful establishment and maintenance of registries. Political will and stakeholder engagement are critical for overcoming these barriers, but bureaucratic challenges often impede progress.

While resource-rich countries have the capacity to conduct large-scale congenital anomaly studies, several factors hinder the establishment of national registries. These include challenges in funding, data coordination, and policy frameworks. Without addressing these issues, countries will continue to rely on fragmented data collection systems and multinational networks, limiting their ability to conduct comprehensive national surveillance of congenital heart diseases.

4

Conclusion and Outlook

4. Summary of the Study

This rapid scoping review explored the landscape of cardiac defect registries worldwide, focusing on the period from 2018 to 2024; it highlighted the key characteristics, levels of implementation, and the influence of income classification on registry development. The study underscored significant disparities between HICs and LMICs in terms of registry coverage, data quality, and accessibility.

Registries are indispensable tools for understanding and managing congenital heart defects. While considerable progress has been made, particularly in HICs, substantial challenges remain in LMICs. Addressing these disparities through international collaboration, capacity building, and technological integration is crucial for improving global health outcomes. By enhancing registry quality and functionality, we can improve the quality of life for individuals affected by CHDs to ensure they receive the care and support they need, ultimately contributing to healthier populations and more equitable healthcare systems worldwide.

The geographic and demographic diversity of the 60 registries in this analysis illustrates the varying levels of success in capturing data on CHDs. While some registries excel in data completeness, utility, and population coverage, others continue to face challenges due to limited resources and infrastructure. The historical significance of these efforts, particularly in LMICs, cannot be understated, as they represent critical steps toward global health equity in the management of congenital heart disease. As technology and healthcare infrastructure improve, these registries are likely to play an even more significant role in shaping public health policies and improving patient outcomes worldwide.

In summary, developing a grading system to evaluate data completeness, utility, and population coverage in cardiac congenital anomaly registries represents a valuable contribution to global health and medicine. Creating a standardized tool for assessing registry performance enhances the quality and comparability of congenital heart disease data across countries and regions. It promotes the improvement of data collection processes, ensures that the data gathered can be meaningfully applied to patient care and policymaking, and expands the inclusivity of registries to represent diverse populations better. As such, this grading system has the potential to significantly

advance research, policy, and clinical practice in the field of congenital heart disease, ultimately leading to improved health outcomes for affected populations worldwide.

The rapid scoping review revealed significant disparities in the development and functionality of cardiac congenital anomaly registries between HICs and LMICs . Key findings include:

- HICs generally have more comprehensive and complete registries due to better healthcare infrastructure and funding. In contrast, LMICs struggle with underreporting and incomplete data, largely due to limited resources and healthcare access.
- Registries in HICs often adhere to international standards such as ICD (International Classification of Diseases) coding, ensuring higher data quality and comparability. LMICs face challenges in maintaining data consistency due to variability in healthcare practices and reporting systems.
- The prevalence of cardiac defects varies geographically, influenced by factors such as socioeconomic status, maternal health, and access to prenatal care. HICs report lower prevalence rates of severe defects, partly due to effective prenatal screening and intervention programs.
- Lower income status countries can outperform high income status countries depending on the presence of international collaboration and NGO support, government prioritization and policy, historical context, and community engagement. Moreover, LMICs have the potential to perform at a similar level as a HIC with a well-established registry.
- HICs typically have better data accessibility, enabling extensive research and informed public health interventions. LMICs often lack the infrastructure for efficient data sharing, limiting the use of registry data for research and policymaking.

4.1. Road Map Toward Improving Registries

Step 1 **Baseline Assessment:** The first step in our strategic health registry improvement plan is comprehensively reviewing the existing data infrastructure and registry capabilities. This crucial assessment will provide us with a clear understanding of what data is currently collected, how it is managed, and where gaps exist in the system. It will serve as the foundation for our future enhancements.

Step 2 **Establish Clear Goals and Standards**: It is imperative to define specific, clear, and achievable goals for the registry. These goals should be based on national health priorities and international best practices, providing a clear roadmap for our improvement efforts. We will

enhance data completeness, utility, and population coverage to ensure the registry's effectiveness.

Step 3 Strengthen Data Collection Methods: Implement active and passive surveillance methods to enhance data collection. Training healthcare providers on the importance of data collection and providing them with the tools to record data accurately can improve reporting rates and data quality.

Step 4 Technology and Infrastructure: Let's embrace the future of healthcare by investing in health information technologies that support data collection, storage, and analysis. For LMICs, the potential of cost-effective solutions like mobile health technologies to facilitate remote data collection and monitoring is a reason for optimism.

Step 5 Capacity Building: Focus on building local expertise through training programs for medical and technical staff. Strengthening regional capacity is essential for sustainable registry operations and can be achieved through partnerships with international health organizations and academic institutions.

Step 6 **Public Awareness and Engagement:** Increasing public awareness about congenital anomalies and the importance of registry data is a crucial strategy. By engaging communities, we can foster a better understanding of the significance of their participation in the registry. This can lead to higher participation rates and improve data completeness.

Step 7 Legal and Ethical Frameworks: Develop or refine legal and ethical guidelines to protect individuals' privacy and ensure data is used responsibly. This will build trust in the registry system and encourage participation.

Step 8 Sustainable Funding: Secure sustainable funding sources to support registry operations. This could include government funding, international aid, and partnerships with non-governmental organizations.

Step 9 Continuous Monitoring and Evaluation: We will not rest on our laurels. We will regularly evaluate the registry's performance against the set goals and make adjustments as needed. This commitment to continuous improvement will ensure the registry's relevance and effectiveness are maintained.

Step 10 Collaboration and Networking: Encourage collaboration between local health departments, international agencies, and other countries' registries. Networking can facilitate sharing best practices and improve the overall quality of congenital anomaly surveillance.

4.2. Contributions to the Field

Developing a grading system to evaluate the data completeness, utility, and population coverage of CHD registries is a significant stride in global health and medicine,

particularly in the field of surveillance and epidemiology. The substantial health, social, and economic burdens posed by cardiac CAs accentuate the significant need for tools to assess data quality and registries. This grading system, a key component of this master's thesis, is poised to significantly improve public health outcomes, resource allocation, and policymaking. In global health, standardized evaluation methods are the basis of cross-country comparisons, collaborative research, and the development of global or regional guidelines. By establishing a standard set of benchmarks, this grading system is a significant stride towards this goal and has the potential to equip researchers and healthcare authorities with a uniform approach to assess registries, thereby enhancing the reliability of data generated across regions and fostering global health research.

Data completeness is one of the most fundamental requirements for any health registry, as incomplete data can lead to biased or inaccurate findings. The grading system's attention to varying degrees of completeness—ranging from no data to comprehensive data at Level 3—allows registry operators to understand gaps and prioritize improvement efforts. For instance, a grading guideline can guide approaches to consistent data collection across different healthcare settings, thereby enhancing the quality of the data and the accuracy of the estimates of the burden of CHDs. Improving data completeness has direct implications for medical research and public health interventions. With more complete data, researchers can more accurately assess the incidence, survival rates, risk factors, and long-term outcomes of individuals born with CHD. Moreover, policymakers can design more effective prevention, intervention, and healthcare support programs based on the insights derived from comprehensive and accurate data.

Data utility refers to how well the information collected by registries can be applied to decision-making, research, and patient care. This grading system's inclusion of a detailed assessment of data utility can more easily recognize when data collection is insufficient; the data must also be relevant, accessible, and actionable. By measuring data utility, the grading system encourages registries to gather comprehensive datasets and ensure they are usable for clinical decision-making, policy development, and public health interventions. This focus on utility enhances the impact of CHD data, ensuring that registries are not just passive data collectors but active contributors to the healthcare system's ability to respond to the needs of CHD patients. For instance, at the highest level (Level 3), registries should provide data supporting local and international research, integrate seamlessly with other health information systems, and inform patient management and health policies. In this way, the grading system promotes the operationalization of data for meaningful health outcomes, advancing clinical care and research on a global scale.

Population coverage contributes to a registry's ability to capture data representing the full spectrum of affected individuals across diverse populations. CHD affects people from various socioeconomic, geographical, and ethnic backgrounds, and registries with limited population coverage may fail to provide an accurate reflection of the burden of disease. The grading system's explicit focus on population coverage addresses this issue by evaluating whether registries include different sub-populations, account for migratory and underserved populations, and support equity in healthcare access. Improving population coverage is particularly vital for global health, as it enables the identification of health disparities and inequities in care for individuals with congenital heart defects. By highlighting gaps in coverage, this grading system encourages the development of more inclusive registries with the hopes that no patient group is overlooked in research or the delivery of healthcare services. Consequently, a grading system facilitates more equitable health policymaking and resource distribution, a central goal of global health initiatives.

The broader impact of this grading system lies in its ability to support global research and collaborative public health initiatives. CHD is a worldwide concern, and accurate, comprehensive data is needed to track trends, identify risk factors, and monitor the effectiveness of interventions across different regions. Registries are necessary in providing this data, but the lack of systematic evaluation tools often complicates their efficacy. This grading system aids in filling that gap by providing a robust tool for evaluating and improving registry performance, therefore facilitating the creation of high-quality, comparable datasets globally. It is with the use of this grading scale that there will be wide-reaching implications for international collaborations in CHD research, enabling more effective meta-analyses and multi-center studies, which are essential for understanding the global epidemiology of CHDs.

Furthermore, the grading system is not an isolated effort; it aligns with international initiatives to improve CHD surveillance, such as those led by the World Health Organization (WHO) and the International Society for Cardiovascular Diseases in the Young (ISCDY). By providing a practical, implementable framework, this system can be a catalyst for these organizations to enhance their registries and data systems, thereby strengthening global efforts to combat CHDs.

4.3. Future Research Directions

Future research directions stemming from this thesis should focus on expanding the initial groundwork laid by the rapid scoping review and the development of the grading system. One significant recommendation is conducting a more in-depth and comprehensive analysis, such as a full-scale scoping review, to gather and assess global data on cardiac congenital anomaly registries. While a rapid scoping review offers a

valuable snapshot, it is limited by time constraints. It often needs more depth to fully explore the nuances of data completeness, utility, and population coverage on a global scale. A thorough scoping review would allow future researchers to engage with a broader range of sources, gather more diverse data, and achieve a more nuanced understanding of registry performance worldwide. This more comprehensive approach also helps to identify best practices across different regions and healthcare systems, fostering global collaboration and further enhancing the quality of congenital anomaly surveillance. Your involvement in this global effort is crucial and greatly appreciated.

Furthermore, future research should not be limited to cardiac congenital anomalies but also explore other congenital anomalies in body systems, such as neural tube defects, limb abnormalities, or gastrointestinal malformations. Expanding the scope of the grading system to include multiple types of congenital anomalies is crucial. This expansion would offer a more comprehensive view of CA surveillance and enable evaluating data systems that handle a broader spectrum of health conditions. Such an approach is urgent and significant, as it would lead to improved data collection and analysis across the field of congenital anomalies, empowering public health systems to better monitor and address a wider range of birth defects.

Finally, future research could explore the potential of integrating the grading system into existing international frameworks for congenital disability surveillance, such as those developed by the WHO or regional congenital anomaly registries. By aligning with international standards, this research could support global efforts to improve data quality, consistency, and comparability, fostering more effective public health interventions and research collaborations.

It is crucial for future research to include multiple language resources to overcome language barriers. While English remains the most widely used language in academic research, many critical studies and registries exist in other languages. By hiring translators to access non-English sources, future studies could include more diverse data, thus more accurately reflecting the global state of congenital anomaly registries. This would significantly improve the inclusivity and accuracy of findings, making the research more applicable across diverse cultural and linguistic contexts. Ultimately, this approach would elevate the quality of global health research by ensuring that it captures contributions from non-English-speaking countries, particularly in regions where congenital anomalies may be underreported or differently categorized. In conclusion, the proposed future research, with its focus on conducting a more in-depth scoping review, expanding the scope to other congenital anomaly systems, and incorporating multilingual resources, has the potential to significantly impact the global health community. These steps would not only enhance the accuracy and relevance of

research in this critical area of public health but also inspire and motivate researchers, public health professionals, and policymakers to contribute to this important work.

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Appendix

# A	Author Name	Year	Title	Source	Registry Name	Time Frame	Country	Income Level	Do the statistics Include live birth, fetal death or TOPFA?	# Medical Center Coverage	Global, National, or Regional	Population, Hospital, or Facility-Based	Sample Size
1	Kannane	2024	Congenital Malformations in the Moroccan Surveillance System: Contribution to Prevalence Estimation	Glob. Heal. Epidem. and Gen.	Moroccan Surveillance System for Congenital Malformations	2017 - 2021	Morocco	Lower Middle	Live Birth	3,145	National	Hospital	NS
2	Aldersley	2021	PROTEA, A Southern African Multicenter Congenital Heart Disease Registry and Biorepository: Rationale, Design, and Initial Results.	Fronti. in Pediatrics	Patient Reported Outcomes, Treatment Effects, and Adherence (PROTEA)	2017 - 2019	South Africa	Upper Middle	Live Birth	7	Regional	Hospital	1473
3a	Mumpe-Mwanja	2019	A Hospital-based birth defects surveillance system in Kampala, Uganda.	BMC Preg. and Birth	Hospital-Based Birth Defects Surveillance System	2015 - 2017	Uganda	Low Income	All	4	Regional	Hospital	69,766
3b	Namale-Matovu	2020	Overcoming staffing challenges when implementing a birth defects surveillance system: a Ugandan experience.	Journ. of Glob. Heal. Rep.	Ugandan Birth Defects Surveillance System	2015 - 2017	Uganda	Low Income	All	4	Regional	Hospital	50,000
3c	Serunjogi	2021	Comparative analysis of perinatal outcomes and birth defects amongst adolescent and older Ugandan mothers: evidence from a Hospital-based surveillance database.	Reproduc. Heal.	Hospital-Based Birth Defects Surveillance System in Kampala, Uganda	2015 - 2018	Uganda	Low Income	All	4	Regional	Hospital	100,189
4a	Chen	2022	Epidemiology of birth defects in teenage pregnancies: Based on provincial surveillance system in eastern China	Fronti. in Pub.Heal.	Birth Defect Surveillance System in Zhejiang Province, China	2012 - 2018	China	Upper Middle	All	90	Regional	Hospital	1,910,977
4b	Hu	2023	An 18-year evolution of congenital heart disease in China: An echocardiographic database-based study	Journ.of Card.	National Birth Defects Prevention Network of China	2003 - 2020	China	Upper Middle	All	1	Regional	Hospital	37,200
4c	Jia	2023	ZCHSound: Open-Source ZJU Paediatric Heart Sound Database with Congenital Heart Disease	IEEE Transactions on Biomedi.Engin. 2024	ZJU Pediatric Heart Sound Database	2020 - 2022	China	Upper Middle	Live Birth	NS	Regional	Hospital	1,259
4d	Yang	2018	The construction and application of an ultrasound and anatomical cross-sectional database of structural malformations of the fetal heart	Prenat.Diagn.	Chinese National Birth Defects Monitoring Network	2012 - 2019	China	Upper Middle	Live Birth	45	Regional	Hospital	160
4e	Peng	2023	Epidemiology of birth defects based on a birth defects surveillance system in southwestern China and the associated risk factors.	Fronti. in Ped.	Guangxi Birth Defects Monitoring Network	2016 -2020	China	Upper Middle	All	NS	Regional	Hospital	3,627,108
5	Velayudhan	2021	Evaluation of a Hospital-based surveillance system for birth defects in Chennai, India.	InterNa. Journ. of Com. Medi. and Publ. Heal.	Birth Defects Registry of India-Chennai (BDRI-C)	2013 - 2014	India	Lower Middle	All	750	National	Hospital	81,209
6	Ahmadi	2020	Early Results of the Persian Registry of Cardiovascular Disease/Congenital Heart Disease (PROVE/CHD) in Isfahan	Journ. of Tehran Univ. Heart Centr.	Persian Registry of Cardiovascular Disease/Congenital Heart Disease (PROVE/CHD)	2016 -2019	Iran	Lower Middle	Live Birth	5	Regional	Hospital	1,252
7a	Hirata	2018	Current status of cardiovascular surgery in Japan 2013 and 2014: A report based on the Japan Cardiovascular Surgery Database. 2: Congenital heart surgery.	Gen Thorac Cardiovasc. Surg.	Japan Cardiovascular Surgery Database (JCVSD)	2013 - 2014	Japan	High	Live Birth	120	National	Hospital	10,000
7b	Hirata	2021	Status of cardiovascular surgery in Japan: A report based on the Japan Cardiovascular Surgery Database 2017–2018	Asian Cardiovasc. & Thorac. Annals	Japan Cardiovascular Surgery Database (JCVSD)	2017 - 2018.	Japan	High	Live Birth	120	National	Hospital	10,000
7c	Inohara	2019	The effect of body weight in infants undergoing ventricular septal defect closure: A report from the Nationwide Japanese Congenital Surgical Database.	Journ. of Thorac. and Cardiovascular Surgery	Japan Cardiovascular Surgery Database (JCVSD)	2012 - 2016	Japan	High	Live Birth	121	National	Hospital	4,947
7d	Sakaguchi	2019	Surgical Repair of Post-Infarction Ventricular Septal Defect — Findings from a Japanese National Database.	Circ. Journ.	Japan Adult Cardiovascular Surgery Database (JCVSD)	2008 - 2014	Japan	High	NS		National	Hospital	1,397
7e	Yao	2022	Status of Adult Outpatients with Congenital Heart Disease in Japan: The Japanese Network of Cardiovascular Departments for Adult Congenital Heart Disease Registry.	Journ. of Cardi.	Japanese Network of Cardiovascular Departments for Adult Congenital Heart Disease Registry	2011 - 2019	Japan	High	NS	54	National	Hospital	24,048
8	Almasri	2023	Epidemiology of Congenital Heart Disease in Qatar: Preliminary Findings from the Sidra Medicine Cardiac Registry	MedRxiv	Sidra Cardiac Registry	2019 - 2022	Qatar	High	Live Birth	1	Regional	Hospital	76
9a	Broe	2020	Congenital Malformations in Denmark: Considerations for the Use of Danish Health Care Registries.	Clinic. Epidem.	Danish Health Care Registries	1997 - 2017	Denmark	High	All	NS	National	Population	1,340,774
9b	Kolding	2021	Associations Between ADHD Medication Use in Pregnancy and Severe Malformations Based on Prenatal and Postnatal Diagnoses: A Danish Registry-Based Study	Journ. of Clinic. Psych: Focus on Women's Mental Health	Danish Fetal Medicine Database	2007 - 2014	Denmark	High	All	NS	Regional	Population	364, 012
10	Roustaei	2023	Educational achievement of children with selected major congenital anomalies and associated factors: a Finnish registry-based study.	Euro. Journ. of Publ. Heal.	Finnish Register of Congenital Malformations	1995 - 2002	Finland	High	Live Birth	NS	National	Population	401,544
11a	Bourdon	2024	Epidemiology of congenital heart defects in France from 2013 to 2022 using the PMSI-MCO (French Medical Information System Program in Medicine, Surgery, and Obstetrics) database.	Plos One	Programme de Médicalisation des Systèmes d'Information - Médecine, Chirurgie, Obstétrique(PMSI-MCO)	2013-2022	France	High	All	NS	National	Hospital	88,759

11b	Ferrier	2019	Trends in resource use and effectiveness of ultrasound detection of fetal structural anomalies in France: a multiple registry-based study.	BMJ Open 2019;9:e025482	Système National d'Information Inter-Régimes de l'Assurance Maladie (SNIIRAM)	2006 - 2014	France	High	All	3	Regional	Population	15,989
11c	Monier	2024	Population-based surveillance of congenital anomalies over 40 years (1981–2020): Results from the Paris Registry of Congenital Malformations (remaPAR)	Journ.of Gynec. Obstet. and Hum. Reprod.	Paris Registry of Congenital Malformations (remaPAR)	1981 - 2020	France	High	All	NS	Regional	Population	518,539
11d	Monier	2023	Postnatal diagnosis of congenital anomalies despite active systematic prenatal screening policies: a population-based registry study	Ameri. Journ. of Obstet. and Gynec. MFM 2023 Vol. 5(11)	Paris Registry of Congenital Malformations (remaPAR)	2001 - 2021	France	High	All	NS	Regional	Population	16,602
11e	Waldmann	2021	Long-term follow-up of patients with tetralogy of Fallot and implantable cardioverter defibrillator—The DAI-T4F nationwide registry	Circulation	DAI-T4F Nationwide Registry	2010 - 2019	France	High	Live Birth	40	National	Hospital	165
11f	Aubry	2023	Le registre ANOCOR	Annales de cardiologie et d'angéiologie	ANOCOR Registry	2010 -2013	France	High	NS	71	National	Hospital	496
12a	Acs	2019	First data from the new, unified database of the Hungarian case-control surveillance of congenital abnormalities.	Journ. of Maternal-Fetal and Neon. Med.	Hungarian Case-Control Surveillance of Congenital Abnormalities (HCCSCA)	1980 - 2009	Hungary	High	All	NS	National	Population	89,576
12b	Kiraly	2019	Virtual museum of congenital heart defects: digitization and establishment of a database for cardiac specimens.	Quanti. Imag. in Med. and Surg.	Hungarian Institute of Cardiology Archive	1960 - 1999	Hungary	High	NS	NS	National	Hospital	400
12c	Nemes	2019	Mitral annulus is enlarged and functionally impaired in adult patients with repaired tetralogy of Fallot as assessed by three-dimensional speckle-tracking echocardiography—results from the CSONGRAD Registry and MAGYAR-Path Study.	Cardiovasc. Diagnos. and Therap.	CSONGRAD Registry and MAGYAR-Path Study	1961 - 2019	Hungary	High	NS	NS	Regional	Hospital	105
12d	Nemes	2022	Left ventricular rotational abnormalities in patients with transposition of the great arteries late after atrial switch operation: detailed analysis from the CSONGRAD Registry and MAGYAR-Path Study.	Cardiovasc. Diagn. and Therap.	CSONGRAD Registry and MAGYAR-PATH Study (2)	1961 - 2013	Hungary	High	NS	10	Regional	Hospital	196
12e	Nemes	2021	Left ventricular rotational abnormalities in adult patients with corrected tetralogy of Fallot following different surgical procedures (Results from the CSONGRAD Registry and MAGYAR-Path Study)	Cardiovas. Diagn. and Therap.	CSONGRAD Registry and MAGYAR-Path Study (3)	1961 - 2019	Hungary	High	NA	NS	Regional	Hospital	63
12f	Nemes	2021	Tricuspid annular abnormalities following different surgical strategies in adults with corrected tetralogy of Fallot (Results from the CSONGRAD Registry and MAGYAR-Path Study)	Cardiovasc. Diagn. and Therap.	CSONGRAD Registry and the MAGYAR-Path Study (4)	1961 - 2019	Hungary	High	NA	NS	Regional	Hospital	57
12g	Racz	2021	Left ventricular strains correlate with aortic elastic properties in adult patients with corrected tetralogy of Fallot (Results from the CSONGRAD Registry and MAGYAR-Path Study).	Cardiovasc. Diagn. and Therap.	Registry of C(S)ONGenital Disease patients at University of Szeged (CSONGRAD Registry)	1961 - 2019	Hungary	High	NA	NS	Regional	Hospital	67
13	Taruscio	2018	The Italian Registry for congenital anomalies: a tool for surveillance and primary prevention.	Reprod. Toxicol.	Italian Registry for Congenital Anomalies	2018 - 2022	Italy	High	All	NS	National	Population	NS
14	Sokolowski	2020	Detection screening and seasonality evaluation of hypoplastic left heart syndrome in the Polish National registry for fetal cardiac anomalies from the years 2004 to 2016.	Prenat. Diagn.	Polish National Registry for Fetal Cardiac Anomalies	2004 - 2016	Poland	High	All	28	National	Population	791
15	Groisman	2022	Detection of critical congenital heart disease among newborns in Argentina through the National surveillance system of congenital heart disease (RENAC).	Arch Argent Pediatr	National Registry of Congenital Anomalies of Argentina (RENAC)	2009 - 2018	Argentina	Upper Middle	All	161	National	Hospital	2,202,994
16	Anderson	2021	Prevalence and Outcomes of Congenital Heart Disease in Very Low Birth Weight Preterm Infants: An Observational Study from the Brazilian Neonatal Network Database.	Ped. Critic. Care Med.	Brazilian Neonatal Network Database	2010 - 2017	Brazil	Upper Middle	Live Birth	20	National	Hospital	13,955
17	Nava de Escalante	2022	Implementation of the BC Congenital Anomalies Surveillance System (BCCASS).	Canadi. Journ. of Pub. Heal.	BC Congenital Anomalies Surveillance System (BCCASS)	2002 - 2019	Canada	High	All	NS	Regional	Population	NS
18	Rosario	2021	The First Adult Congenital Heart Disease Registry in the Caribbean.	Journ. Amer. Col. Card.	Adult Congenital Heart Disease Registry in the Caribbean	2020	Dominican Republic	Upper Middle	NS	NS	Regional	Hospital	501
19	Wilentz	2020	A National Coordinated Cardiac Surgery Registry in Haiti: The Haiti Cardiac Alliance Experience.	Journ. Amer. Col. Card.	Haiti Cardiac Alliance	2013 - 2019	Haiti	Lower Middle	All	NS	National	Hospital	1,502
20	Sánchez-Barriga	2018	Mortality trends from congenital malformations of the heart and the great vessels in children and adults in the seven socioeconomic regions of Mexico, 2000-2015.	Congen. Heart Dis.	National Institute of Statistics and Geography	2000 - 2015	Mexico	Upper Middle	All	NS	National	Population	70,741
21a	Hamzah	2019	Outcomes of hypoplastic left heart syndrome: analysis of National Inpatient Sample Database 1998–2004 versus 2005–2014.	Europ. Journ. of Pediat.	United States Nationwide Inpatient Sample (NIS)	2006 - 2014	United States	High	Live Birth	NS	National	Hospital	20,649
21b	John	2023	The Congenital Heart Initiative: The Design of a Patient-Centered Registry for Adults with Congenital Heart Disease.	BMC Preg. and Childbirth	Congenital Heart Initiative (CHI) Registry	2020 - 2022	United States	High	NS	NS	National	Population	2,588

21c	Jones	2021	Hospital Survival After Surgical Repair of Truncus Arteriosus with Interrupted Aortic Arch: Results from a Multi-institutional Database.	Pediat.Cardi.	Vizient Clinical Database	2002 - 2016	United Staes	High	Live Birth	160	National	Hospital	645
21d	Khoury	2017	Feasibility of a Healthcare System-Based Tetralogy of Fallot Patient Registry	Cardi. in the Young	Carolina Data Warehouse for Health	2004 - 2015	United States	High	NS	1	Regional	Hospital	158
21e	Matas	2019	Exploring classification of birth defects severity in National Hospital discharge databases compared to an active surveillance program.	Birth Def. Res. 2019;111:1343	National Inpatient Sample (NIS)	2012 - 2014	United States	High	Live Birth	NS	National	Hospital	97,298
21f	Ramakrishnan	2018	Symptomatic Tetralogy of Fallot in Young Infants: Primary Repair or Shunt—Pediatric Health Information System Database Analysis.	World Journ. for Pedi. and Congen. Heart Surg.	Pediatric Health Information System (PHIS)	2008 - 2014	United States	High	Live Birth	45	National	Hospital	821
21g	Samson	2021	Evaluation of an Active Population-Based Surveillance System for Major Birth Defects in South Carolina	Birth Def. Res.	South Carolina Birth Defects Program (SCBDP)	2016-2018	United States	High	Live Birth	41	Regional	Population	55,000
21h	Yang	2019	Impact of Timing on In-Patient Outcomes of Complete Repair of Tetralogy of Fallot in Infancy: An Analysis of the United States National Inpatient 2005–2011 Database.	BMC Cardiovasc Dis.	Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS)	2005 - 2011	United States	High	Live Birth	1,050	National	Hospital	5,538
21i	Fink	2020	Capture Rate of Congenital Heart Defects in the Pediatric Health Information System Database.	Birth Def. Res.	Pediatric Health Information System (PHIS)	2010 - 2014	United States	High	All	52	National	Hospital	8,334
21j	Ghimire	2021	Risk of Congenital Heart Disease is Increased Among Newborns with Non-Cardiac Congenital Anomalies: Survey-Based Analysis Using 2016 Kids' Inpatient Database.	Ultraso. Obstet Gynecol.	Kids Inpatient Database (KID)	2016	United States	High	Live Birth	NS	National	Hospital	6,266,285
22	Ombelet	2020	Creating the BELgian COngenital Heart Disease Database Combining Administrative and Clinical Data (BELCODAC): Rationale, Design, and Methodology.	Int'l Journ. Of Car.	Belgium Collaborative Study on Congenital Anomalies (BELCODAC)	2002 - 2013	Multinational	High	Live Birth	3	National	Hospital	18,510
23a	Santoro	2022	Temporal and Geographical Variations in Survival of Children Born with Congenital Anomalies in Europe: A Multi-Registry Cohort Study.	Pediatric and Perinatal Epidemiology	European Concerned Action on Congenital Anomalies and Twins (EUROCAT)	1995 - 2014	Global	High	Live Birth	NS	Global	Population	115,219
23b	Mamasoula	2022	Prevalence of Congenital Heart Defects in Europe, 2008–2015: A Registry-Based Study.	Birth Defects Research	European Concerned Action on Congenital Anomalies and Twins (EUROCAT)	2008 - 2015	Global	High	Live Birth	NS	Global	Population	26,115
24	Herbst	2021	Pediatric Cardiac Surgical Patterns of Practice and Outcomes in Europe and China: An Analysis of the European Congenital Heart Surgeons Association Congenital Heart Surgery Database.	Congen.Heart Dis. 2021 Vol. 16(1) Pages 17-25	European Congenital Heart Surgeons Association (ECHSA) Congenital Heart Surgery Database (CHSD)	2006 - 2018	Multinational	Multiple	Live Birth	138	Multinational	Hospital	1,525
25	Hogan	2020	Fetal Cardiac Intervention for Pulmonary Atresia with Intact Ventricular Septum: International Fetal Cardiac Intervention Registry.	Fetal Diagn Ther 2020;47:73739	International Fetal Cardiac Intervention Registry (IFCIR)	2001 - 2018	Multinational	High	Live Birth	14	Multinational	Hospital	142
26	Orioli	2020	The Latin American Network for Congenital Malformation Surveillance: ReLAMC.	Ameri. Journ. of Med. Genet.	Latin American Network of Congenital Malformation surveillance (ReLAMC)	2017 - 2019	Multinational	NA	All	NS	Multinational	Population	9,152,674
27	Ezzeldin	2021	Multidetector Computed Tomography for Patients with Congenital Heart Disease: A Multi-Center Registry from Africa and Middle East; Patients' Characteristics and Procedural Safety.	Egypt Heart Journ.	Multidetector Computed Tomography (MDCT)	2016 - 2019	Global	Lower Middle	Live Birth	NS	Global	Hospital	2,518
28	St. Louis	2019	The World Database for Pediatric and Congenital Heart Surgery: A Call to Service for North American Congenital Heart Surgery Programs	Semin. in Thorac. Surg.	World Database for Pediatric and Congenital Heart Surgery (WDPCHS)	2017 - 2018	19 countries	NA	All	51	Global	Hospital	12,183