

Criteria for Coverage with Evidence Development

Presenter: Ralph G. Brindis, MD, MPH, MACC

Presentation for Medicare Evidence Development
& Coverage Advisory Committee (MEDCAC)
February 13-14, 2023



AMERICAN
COLLEGE of
CARDIOLOGY®

Disclosures

Ralph G. Brindis, MD, MPH, MACC

Commercial and Non-Commercial Entity	Relationship	Compensation Level
AC Wellness Network	President	Significant (\geq \$5,000)
QURE	Consultant Fees/Honoraria	Modest ($<$ \$5,000)
ACC	Senior Medical Officer, External Affairs, NCDR	Significant (\geq \$5,000)
California Technology Assessment Forum-ICER	Consultant Fees/Honoraria	Modest ($<$ \$5,000)
FDA CV Device Panel	Member, Special Government Employee	Modest ($<$ \$5,000)
State of California HCAI	Chair, Clinical Advisory Panel	None (\$0)
U.C.S.F.	Clinical Professor of Medicine	None (\$0)

CED

- CED is an extremely powerful mechanism offering tremendous value to payers, clinicians but most importantly our patients.
- CED has been demonstrated to be an ingenious technique allowing the diffusion of diverse innovative CV technologies/services into the marketplace while simultaneously promoting timely clinical safety and effectiveness evaluations
- ACC supports the use of CED to provide Medicare beneficiaries with prompt access to new technologies/services when early evidence suggests, but does not yet convincingly demonstrate, a net benefit for beneficiaries.

Registries' Role in CED

- Registries such as ACC's NCDR provide a valuable, cost-effective mechanism to help meet the needs for CED evaluation while also fostering improvements in the quality of care.
- CED-mandated Registry participation—when appropriate—promotes a powerful national research and data collection infrastructure for large patient populations allowing assessment of treatments in relatively modest-sized patient subgroups not well suited for RCTs .

National Cardiovascular Data Registry

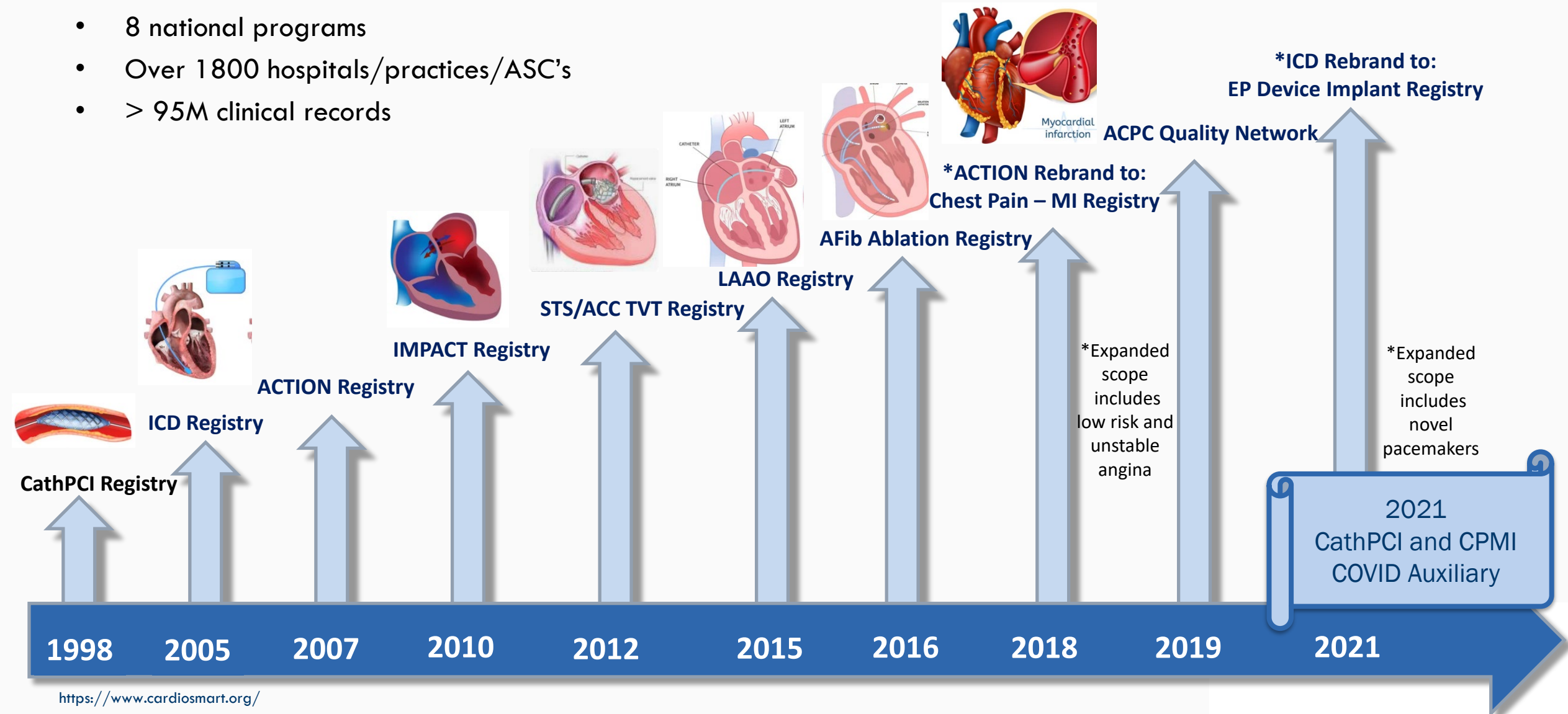
DATA



- Largest, most comprehensive, **outcomes-based cardiovascular patient data repository** in the world
- **Eight registries/quality programs**
- **Two collaborations:** SVS/VQI & Veradigm®
- Over **95 Million** patient records
- **25 years** of experience

Current State of Registry Operations

- 8 national programs
- Over 1800 hospitals/practices/ASC's
- > 95M clinical records



NCDR Registry Scope

Name	Disease or Device	Facility	Sites	Patient Records
CathPCI	Percutaneous coronary interventions Diagnostic catheterizations	Hospital/Free Standing	1,758	25,320,000
Cath PCI COVID option *	Optional: Patient COVID status related to percutaneous coronary interventions	<i>Same facilities that participate in the registry</i>	106	219,000
EP Device Implant	Implantable cardioverter defibrillators Novel pacemakers	Hospital/Free Standing	726	2,320,000
Chest Pain - MI	Acute coronary syndrome STEMI & NSTEMI; Low risk & Unstable Angina	Hospital/EMS	702	2,240,000
Chest Pain – MI COVID option *	Optional: Patient COVID status related to acute coronary syndrome	<i>Same facilities that participate in the registry</i>	48	53,000
IMPACT	Congenital heart disease treatments Pediatric and Adult	Hospital	105	220,000
STS/ACC TVT	Transcatheter Valve Therapy	Hospital	813	580,000
LAAO	Left atrial appendage occlusion procedures	Hospital	787	190,000
AF Ablation	AF ablation procedures	Hospital	186	130,000

 Indicates procedure with current CED or prior CED

NCDR Data Serves Many Purposes



Stakeholders

Administrators
Researchers
Consumers

Industry
Providers
Payers
Regulators

Quality and
performance
improvement

Evidence based
medicine

Reimbursement

Research

Surveillance

Performance
monitoring

State and
federal QI

Public
reporting for
consumers

CED Examples

Longitudinal ICD Registry Study

- B1: What are the rates of device therapies during the first three years after implantation for patients with LVEF 31-35% and patients with LVEF $\leq 30\%$?
- B2: What are the rates of device therapies during the first three years for patients with diagnosis of nonischemic cardiomyopathy for less than nine months and patients with diagnosis greater than or equal to nine months?
- B3: What are the rates of device therapies during the first three years for patients who are NYHA Class IV at time of implantation of a CRT-D device and for patients who are Class III at the time of CRT-D placement?

CED Examples TAVR, Mitral, TEER (STS/ACC TVT Registry)

Aortic Valve Replacement	Mitral Valve Repair (TMVR-2014) Mitral Valve Repair (TEER-2021)	Tricuspid Valve (Pre-market Data)
Valve in valve therapy	Valve in valve and valve in ring	Pending published literature: quality of life, HF readmissions, outcomes,
Bicuspid/Tricuspid valve or non-calcified AV	Quality of life	
Pre-existing prosthetic heart valve in any position, prosthetic ring, or severe mitral insufficiency	Sex based differences in outcomes	
Use of DOACs in patients with atrial fibrillation	Association of pulmonary hypertension and BMI with outcomes	
Renal insufficiency (Creatinine > 3.0) and/or end stage renal disease (ESRD) requiring chronic dialysis	30-day outcomes for valve in valve, valve in ring, and native with severe annular calcification	
Effect and relationship of frailty indices/geographic access	Prevalence and impact of atrial fibrillation on 1-year outcomes	

CED Examples

LAAO Registry

- Clinical outcomes
- Patient level analysis and procedural safety
- Sex differences in procedural outcomes
- Clinical impact of residual leaks
- Antithrombotic therapy post procedure in patients with atrial fibrillation

<https://cvquality.acc.org/NCDR-Home/research/published-research>

Analysis of Requirements for CED

- Support updating criteria to modernize and promote increased transparency and replicability.
- This should be done without adding undue burden and costs to CED collaborators that would create barriers to access to novel therapeutics and hinder evidence development.
- It is essential that CED programs are designed with collaborative input from all relevant stakeholders including clinical experts and specialties most likely to provide the services in question.

Coverage With Evidence Development Proposed Revised Requirements	ACC Response
SPONSOR: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.	Though a very operational requirement, the addition to the language of “sponsors/investigators with the resources and skills” is not well specified and may cause delays in CMS achieving its objectives in evidence development. Specifications of the resources and skills required to demonstrate sufficiency for evaluation purposes should be made clear so entities can interact meaningfully and understand when to opt into CED.
CONTEXT: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified knowledge gap and provide evidence of net benefit.	Improvement from current requirement.
CONTEXT: Sponsors/investigators establish an evidentiary threshold for the primary outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.	For this proposed criterion to be fully actionable, CMS needs to promote resources to organizations electing to meet the CED requirements and to the providers participating in the CED requirements necessary to support these studies. Moreover, the requirements should take registries into account or include separate requirements for registry-style data collection so as not to inhibit the efficiencies achieved with registries. As illustrated on slide 8, an enormous benefits of a registry is the ability to reuse the data for multiple purposes.
OUTCOMES: The primary outcome(s) for the study are clinically meaningful and important to patients. A surrogate outcome that reliably predicts these outcomes may be appropriate for some questions.	Support inclusion of new requirement.

Coverage With Evidence Development Proposed Revised Requirements	ACC Response
GENERALIZABLE: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their usual sites of care, although randomization to receive the product may be in place.	Improvement from current requirement.
REPRODUCIBILITY: Sponsors/investigators using secondary data will demonstrate robustness of results by conducting alternative analyses and/or using supplementary data.	Would be burdensome for studies to now include analysis of other data sources when clinical trials do not have this requirement.
REPORTING: The study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication.	Peer reviewed scientific publication is not the only rigorous way to report study results. It depends on a number of variables, including data collection mechanism, the therapy in question.
SHARING: The sponsors/investigators commit to sharing analytical output, methods, and analytic code with CMS or with a trusted third party in accordance with the rules of additional funders, institutional review boards, and data vendors as applicable. The schedule for sharing is included among the study milestones. The study should comply with all applicable laws regarding subject privacy, including section 165.514 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).	Sharing of analytical output, methods, and analytic code associated with sponsors/investigators achieving the CED aims as stated in the initial application is reasonable; however, in some instances, the underlying data used for analysis, such as with a clinical data registry, may be unique to the sponsor such that the results may not be able to be replicated against other data sets. This provision should not go so far as to require that data be shared with CMS or with other third parties unless mutually agreed to by the sponsor since regulatory compliance, contractual requirements, and data management and oversight associated with vetting additional third parties and providing data access would create burden on the sponsor.



**AMERICAN
COLLEGE of
CARDIOLOGY®**

Advancing Heart Care Worldwide