

Evidentiary Characteristics for Coverage with Evidence Development

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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.



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Registries' role in CED

- In “partnership” with RCTs, 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 to assess treatments in relatively modest patient subgroups not well suited for RCTs .



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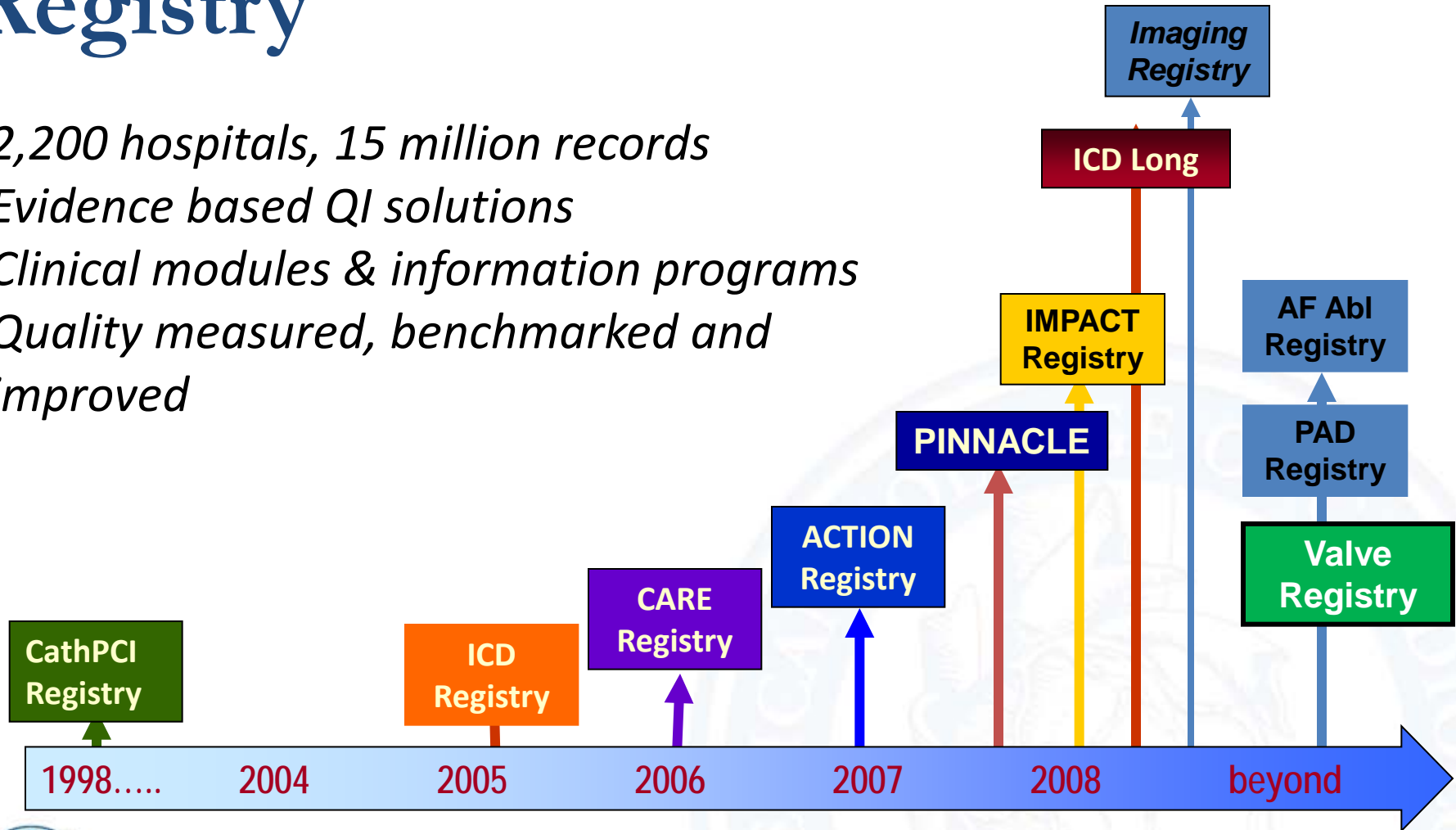
National Cardiovascular Data Registry

2,200 hospitals, 15 million records

Evidence based QI solutions

Clinical modules & information programs

Quality measured, benchmarked and improved



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NCDR infrastructure supports research...

Effectiveness

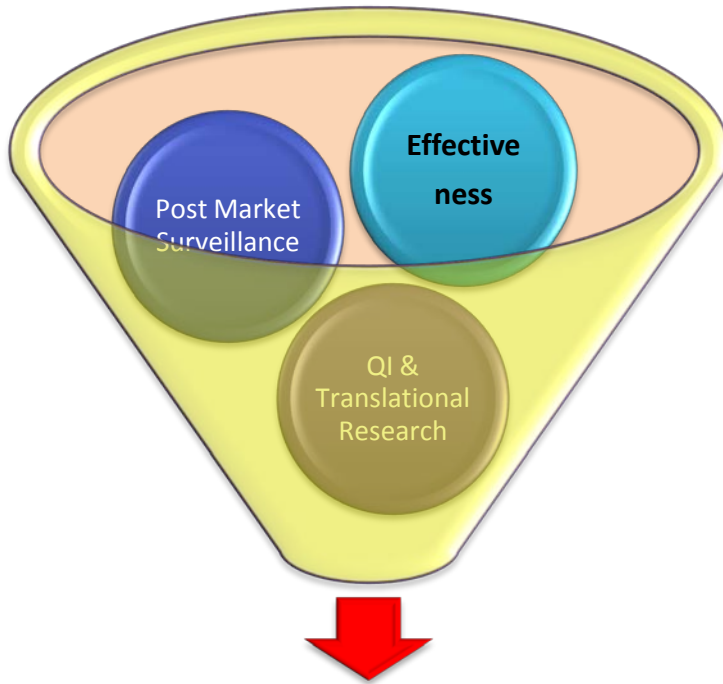
- Diffusion of new technologies

Post Market Surveillance

- Adverse/sentinel events
- Device performance trends
- Off-label use
- Follow up studies

QI & Translational Research

- Performance gaps
- QI intervention effect
- Guideline adherence
- Performance measure development



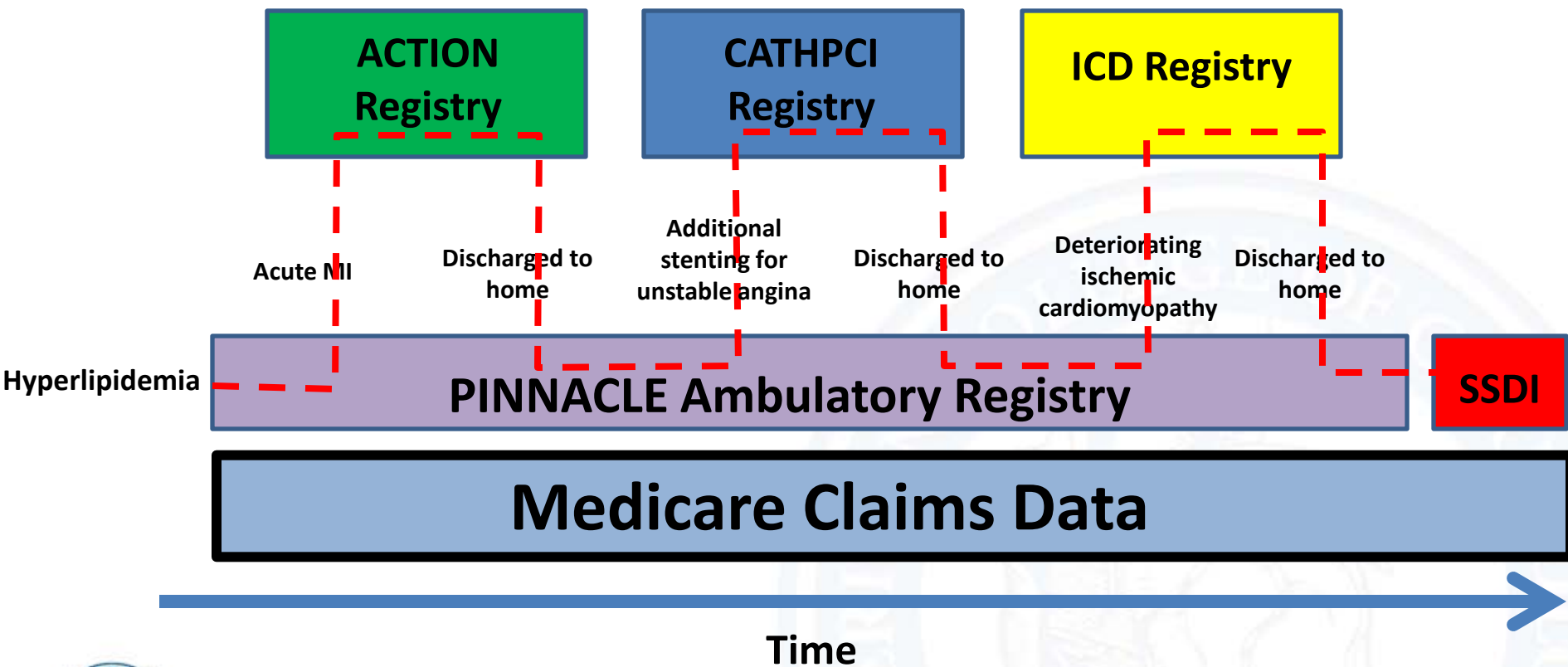
**REGISTRY SUPPORTED
RESEARCH**



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Studying across lifecycle of CV disease

*Putting **CED** to work to generate high fidelity clinical and economic outcomes studies*



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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?



Potential CED Examples

TAVR (TCT Registry)

- “Valve in Valve” therapy.
- Unicuspid/bicuspid valve or non-calcified AV
- Pre-existing prosthetic heart valve in any position, prosthetic ring, or severe mitral insufficiency.
- Severe ventricular dysfunction with LVEF <20.
- Renal insufficiency (Creatinine > 3.0) and/or end stage renal disease (ESRD) requiring chronic dialysis.
- Low gradient low output aortic stenosis.
- Assoc. valvular lesions which cannot be Rx'd surgically.



Comparable Effectiveness

- Identify and close gaps in quality of care
- Reduce wasteful and inefficient care variations
- Implement effective, continuous quality improvement processes



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Goals in CED Evidence Review

- Well-defined clinical questions formulated with input from clinical experts and the specialties most likely to provide the services in question.
- A reasonable timeframe for evaluation of data collected as part of the CED.
- Data analysis plans outlining how CMS will use data collected through CED.



Goals in CED Evidence Review

- Need inherent mechanisms for modifying data capture elements as knowledge evolves through ongoing analysis during the CED period.
- Need transparent evaluation criteria that describe how CMS will determine whether evidence collected through CED is sufficient to justify national coverage.
- Need flexibility to reflect the changing clinical science – periodic evaluation and updating as needed of CED



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Non-Binary Paradigm

- Chronic therapy for evolving disease or for patients with multiple diseases may not fit into binary paradigm
- Evidentiary thresholds for non-binary CED need to be flexible
 - May broadly apply when treatments with FDA indications show promise, but don't quite meet reasonable and necessary standard
 - Could include narrow safety-efficacy ratio, availability of alternatives, conflicting studies



Evidentiary Review

- It is necessary to review evidence to determine the status of both the therapy and the coverage
- Review should answer questions that are defined at the outset of CED, producing coverage, non-coverage, or revised CED.
- Review could also be triggered by new evidence from valid studies/trials



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