HCAi
Department of Health Care Access and Information

Informational Webinar: Transcatheter Aortic Valve Replacement (TAVR) Outcomes Reporting

February 17, 2022

* Formerly the Office of Statewide Health Planning and Development (OSHPD)

Agenda

- Introduction
- History
- Recent Legislation
- Clinical Advisory Panel
- STS/ACC TVT Registry Data
- Next Steps
- Timeline
- Q and A

History of Cardiovascular Outcomes Reporting in California

Voluntary CABG Data Collection and Outcomes Reporting

- Started in 1995 for hospital risk-adjusted mortality rates
- Three reports issued: 1997-1998,1999, 2000-2002

Added to Health and Safety Code (HSC) in 2001

- In 2001 Senate Bill SB 680 “converted” the voluntary program to mandatory
  - included physician reporting
  - established the Clinical Advisory Panel (CAP)
- Consumers Union, the CA chapter of American College of Cardiology (ACC), and CA Medical Association (CMA) were all actively involved in refining/negotiating legislation
  - Ensured physician involvement
  - Added CCORP CAP and surgeon review and appeal process
- Data collection started in 2003

California CABG Outcomes Reporting Program (CCORP)

- Hospitals submit a subset of STS data elements to HCAI via online system
  - Automatic edits
  - Data quality reports and data discrepancy report that compare the clinical data to the administrative data submitted by the hospital's HIT team
  - Annual audit of selected hospitals
- Outcome reports since 2003
  - Include hospital risk-adjusted mortality annually
  - Surgeon mortality every other year (until 2019)
  - Outcomes not restricted to mortality

Public Reports

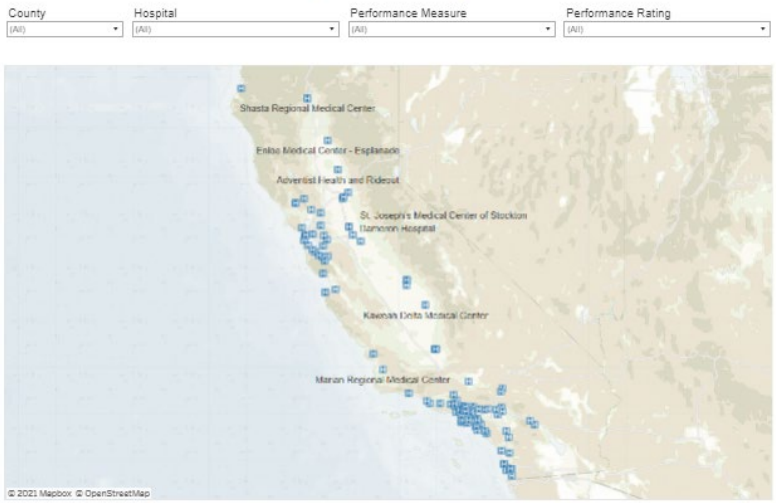
- In addition to iso-CABG mortality, reports now include hospital outcomes for:
  - iso-CABG post-op stroke
  - iso-CABG readmissions
  - CABG + valve mortality
- Reports include internal mammary artery usage rates
- Salvage patients excluded from outcomes calculations
- Preliminary results provided to:
  - Hospitals for 60-day review to provide written comments
  - Surgeons for 30-day to “appeal” their results

Public Reports

Coronary Artery Bypass Graft: Hospital Performance Ratings, 2019

This report provides performance ratings on four key risk-adjusted outcomes: operative mortality for isolated CABG, operative mortality for CABG + Valve, post-operative stroke, and unplanned hospital readmissions within 30 days. 123 state-licensed hospitals performed adult CABG surgery during 2018-2019. The statewide isolated CABG mortality rate for 2019 was 2.19%.

Hospital Results PDF

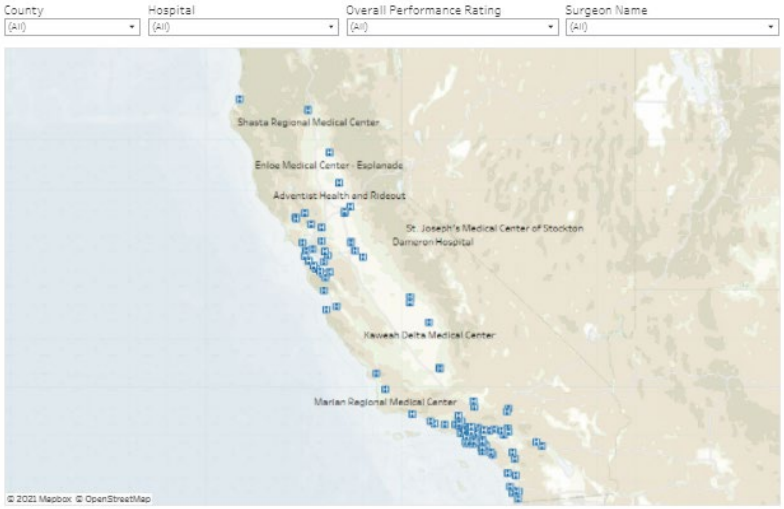


Coronary Artery Bypass Graft: Surgeon Performance Ratings, 2017-2018

283 physicians performed adult CABG surgery during 2017-2018 with an isolated CABG mortality rate of 2.33%.

This report provides performance ratings based on risk-adjusted operative mortality for isolated CABG surgery. This is the eighth report on California surgeons since 2003-2004 to provide ratings on isolated Coronary Artery Bypass Graft Surgery (CABG) performance.

Surgeon Results PDF



Interactive reports at
https://hcai.ca.gov/data-and-reports/healthcare-quality/

California Elective Percutaneous Coronary Intervention (PCI) Program

Elective PCI Pilot Program

- 2008 legislation established a pilot program that allowed the California Department of Public Health (CDPH) to authorize up to 6 eligible California hospitals without onsite surgical backup to perform scheduled, elective PCIs.
- Established advisory committee
  - To oversee and monitor program
  - To make recommendations on whether elective PCI without onsite cardiac surgery should be continued in California
  - With CDPH, issued final report that found no increased risk to patients receiving elective PCIs performed at pilot hospitals

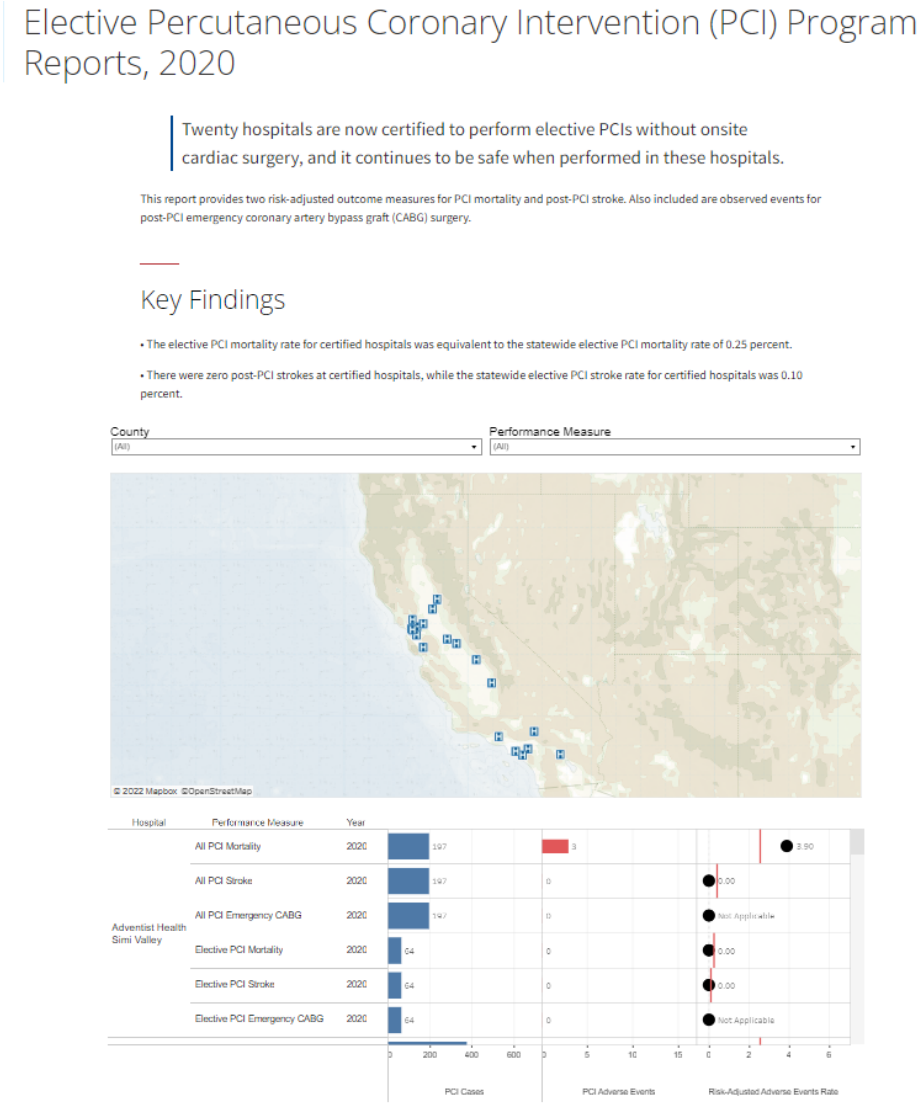
Elective PCI Program

- Established in 2014 - allows CDPH to certify hospitals without onsite surgical backup to perform elective PCIs.
- Hospitals must:
  - Comply with the recommendations of the Society for Cardiovascular Angiography and Interventions (SCAI)
  - Participate in the American College of Cardiology-National Cardiovascular Data Registry (NCDR)
  - Confer rights to transfer NCDR data submitted pursuant to HCAI
- HCAI: develops annual report on certified hospitals' performance on mortality, stroke rate, and emergency CABG rate.
- CDPH may establish an oversite committee.
- CDPH contracts with UC Davis to administer the program.

Elective PCI Public Reports

- Annual outcome reports produced since 2016 data
- Hospital reports include risk-adjusted outcome rates for:
  - Mortality
  - Post PCI Stroke
  - Post PCI Emergency CABG (beginning with 2018 data, no longer risk-adjusted)
- 20 hospitals included in 2020 report

Interactive reports
https://hcai.ca.gov/data-and-reports/healthcare-quality/


Elective Percutaneous Coronary Intervention (PCI) Program Reports, 2020

Twenty hospitals are now certified to perform elective PCIs without onsite cardiac surgery, and it continues to be safe when performed in these hospitals.

This report provides two risk-adjusted outcome measures for PCI mortality and post-PCI stroke. Also included are observed events for post-PCI emergency coronary artery bypass graft (CABG) surgery.

Key Findings

- The elective PCI mortality rate for certified hospitals was equivalent to the statewide elective PCI mortality rate of 0.25 percent.
- There were zero post-PCI strokes at certified hospitals, while the statewide elective PCI stroke rate for certified hospitals was 0.10 percent.

County (All) Performance Measure (All)

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Hospital	Performance Measure	Year
Adventist Health Simi Valley	All PCI Mortality	2020
	All PCI Stroke	2020
	All PCI Emergency CABG	2020
	Elective PCI Mortality	2020
	Elective PCI Stroke	2020
	Elective PCI Emergency CABG	2020

PCI Cases | PCI Adverse Events | Risk-Adjusted Adverse Events Rate

Department of Health Care Access and Information

Recent Legislation and Revisions to California Health and Safety Code (HSC) § 128745 and 128748

- Early 2021 HSC expansion opportunity (AB 133)
  - Previous CAP discussions
  - Evolving/emerging cardiovascular techniques
  - Flexibility in reporting on cardiovascular measures
  - Opportunity to work with the CA ACC
  - Developed and refined statutory language

Revisions to Cardiovascular Outcomes Reporting

- HCAI has the authority to collect/acquire additional data from hospitals or from registries they submit data to, such as the STS/ACC TVT Registry
- Flexibility in administering the program, in collaboration with the CAP:
  - to publish risk-adjusted performance reporting for additional interventional cardiovascular procedures such as TAVR
  - on level of reporting (hospital, provider group, or individual physician level)
- Provide the CAP flexibility to include other health related topics in their scope
- Expand the membership of CAP to ensure members have expertise in any new recommended procedures or interventions for reporting
  - Experts nominated by CA ACC

CAP Role per Original Statute

- Review and approve the risk-adjustment methodology and models
- As a part of the appeal process, review the physician statements and make a final determination
- Approve new or delete clinical data elements
- Advise in report structure for consumer understanding

Expanded CAP Role per New Statute

- Recommend new interventional cardiovascular procedures for public reporting
- Recommend the collection of any clinical data elements included in the Society of Thoracic Surgeons' database or other relevant databases

CAP "Blue Sky" Discussions 2013-2021

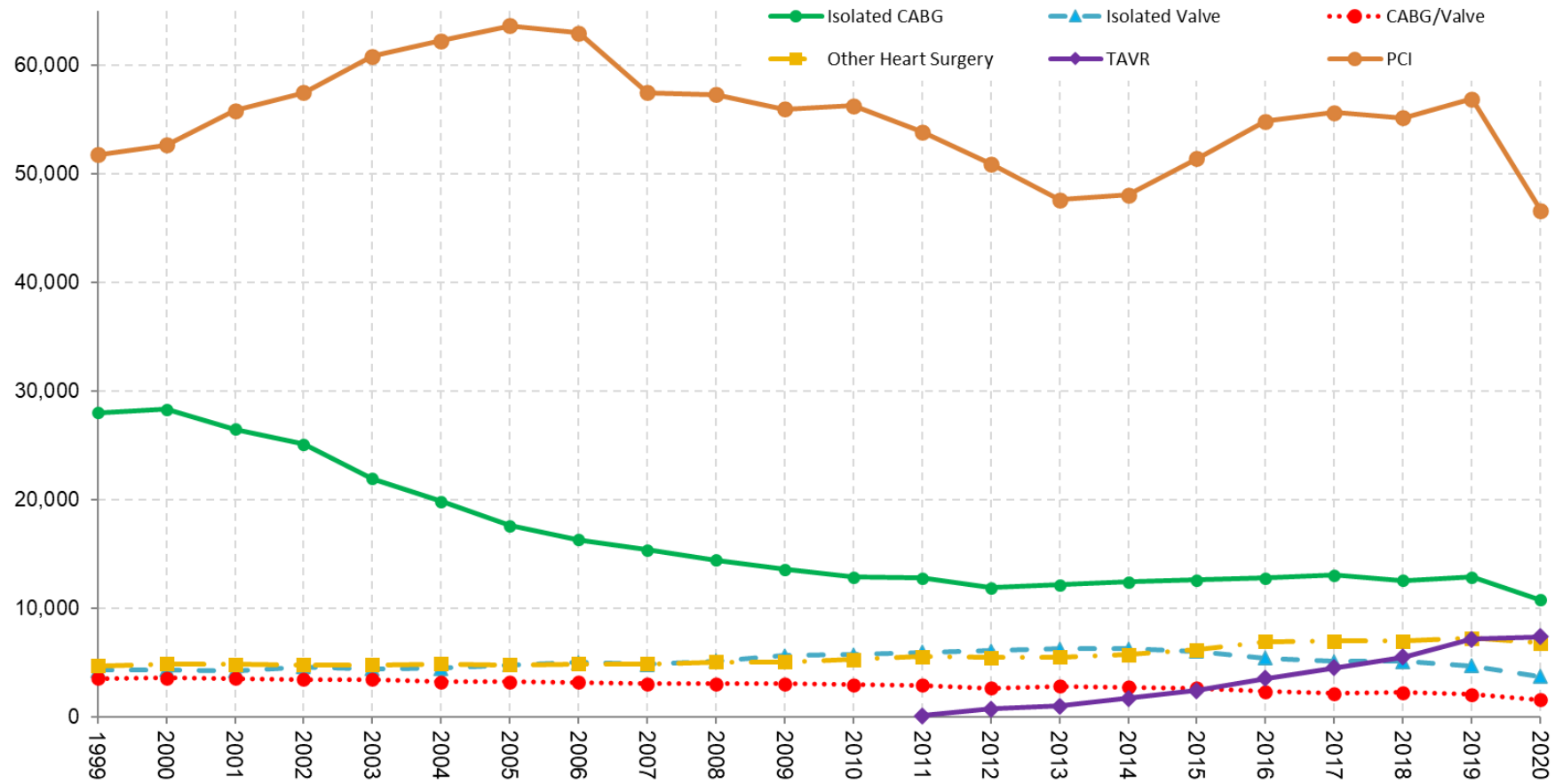
Expansion ideas discussed at CAP meetings over the years

- PCI public reporting
- PCI and CABG one-year mortality rates
- Appropriateness- both PCI and CABG
- Stress test data- assess appropriateness- degree of ischemia
- PCI/CABG revascularization ratio
- Isolated valves
- CV surgery composite measures
- Price transparency
- Social determinants of health
- **TAVR Outcome reporting**

CAP Meeting – November 2021

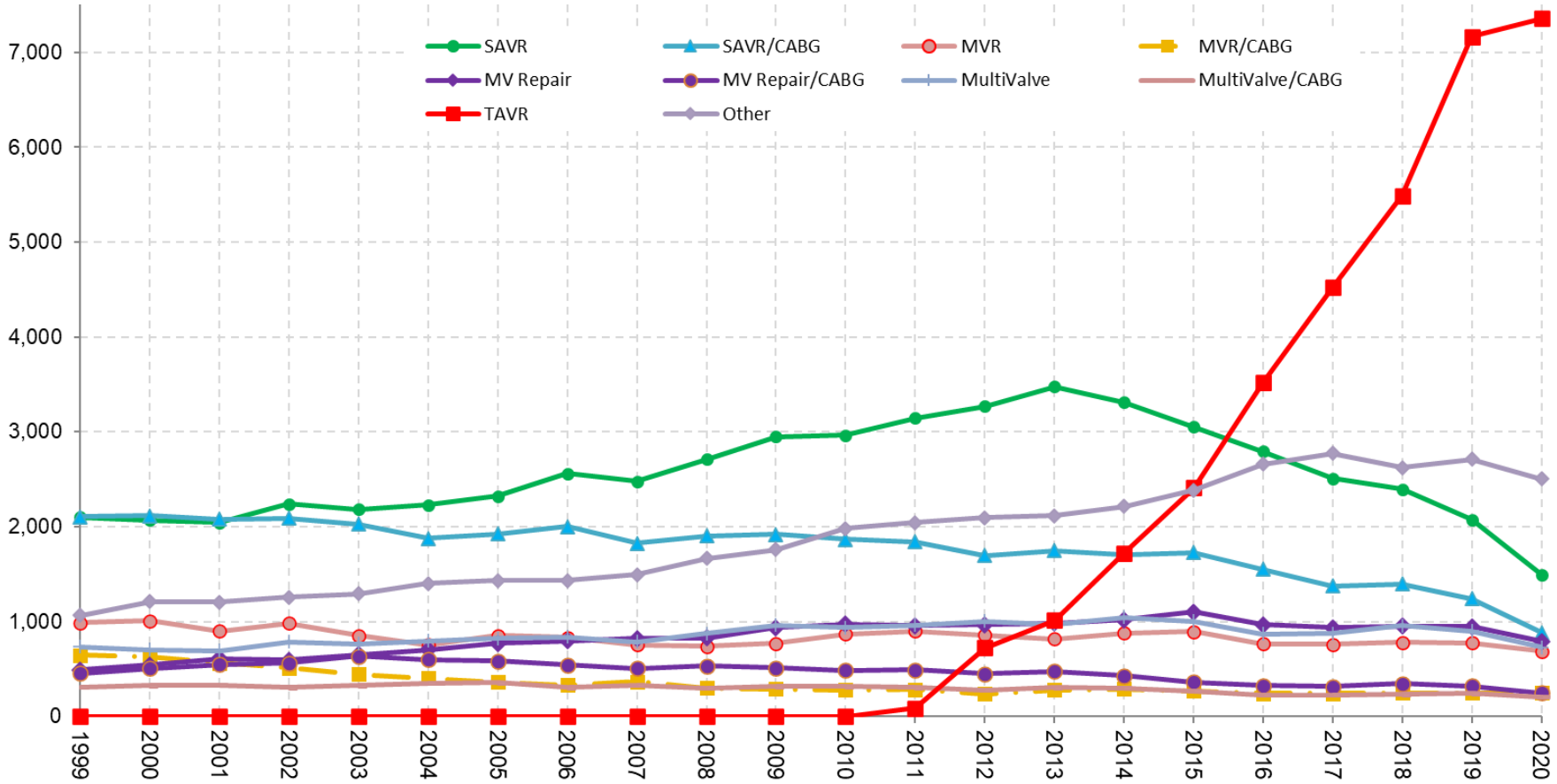
- Panel recommended mandatory hospital level outcomes reporting for TAVR
- Panel confirmed need for expertise in TAVR on the panel

Volume of Cardiovascular Procedures and Interventions 1999-2020



Data Source: HCAI PDD, AS, ED

Volume of Valve Procedures and Interventions 1999-2020



Data Source: HCAI PDD, AS, ED

Clinical Advisory Panel (CAP)

The current CAP includes 11 members nominated by the following:

- California Chapter of the American College of Cardiology
- California Medical Association
- Consumer Organizations

Panel Member	Role	Nominated by
Ralph G. Brindis, M.D., MPH (Chair)	Interv. Cardiologist (Ret)	California ACC
Cheryl Damberg, Ph.D.	Healthcare Researcher	Consumers Union
Gordon L. Fung, M.D., MPH, Ph.D.	General Cardiologist	California Medical Association
Hon S. Lee, M.D.	CV Surgeon	California Medical Association
James MacMillan, M.D.	CV Surgeon	California Medical Association
Rita F. Redberg, M.D.	General Cardiologist	Consumers Union
Richard J. Shemin, M.D.	CV Surgeon	California ACC
J. Nilas Young, M.D.	CV Surgeon	California ACC
Maribeth Shannon, M.S.	Consumer Representative	Consumers Union
Andrew Rassi, M.D.	Interv. Cardiologist	California ACC
Mamoo Nakamura, M.D., Ph.D.	Interv. Cardiologist	California ACC

STS/ACC TVT Registry

CMS Requirement

As a requirement of Centers for Medicare & Medicaid Services (CMS) reimbursement, hospitals that perform TAVR must participate in a prospective, national, audited registry (CMS TAVR Decision Memo).

NCA - Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R) - Decision Memo

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Decision Summary

The Centers for Medicare & Medicaid Services (CMS) will cover Transcatheter Aortic Valve Replacement (TAVR) for the treatment of symptomatic aortic valve stenosis through Coverage with Evidence Development (CED).

A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:

5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56.

   The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:

   i. Stroke;
   ii. All-cause mortality;
   iii. Transient Ischemic Attacks (TIAs);
   iv. Major vascular events;
   v. Acute kidney injury;
   vi. Repeat aortic valve procedures;
   vii. New permanent pacemaker implantation;
   viii. Quality of Life (QoL).

6. The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary). Specifically, for the CED question iv, this must be addressed through a composite metric. For the below CED questions (i-iv), the results must be reported publicly as described in CED criterion k.

STS/ACC TVT Registry

- Approved by CMS to meet the registry requirements*
  - https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR
- TVT Registry developed in collaboration with
  - Federal Drug Administration (FDA),
  - CMS
  - Society for Cardiovascular Angiography and Intervention
  - American Association for Thoracic Surgery

*Participation in TVT Registry is required for CMS reimbursement

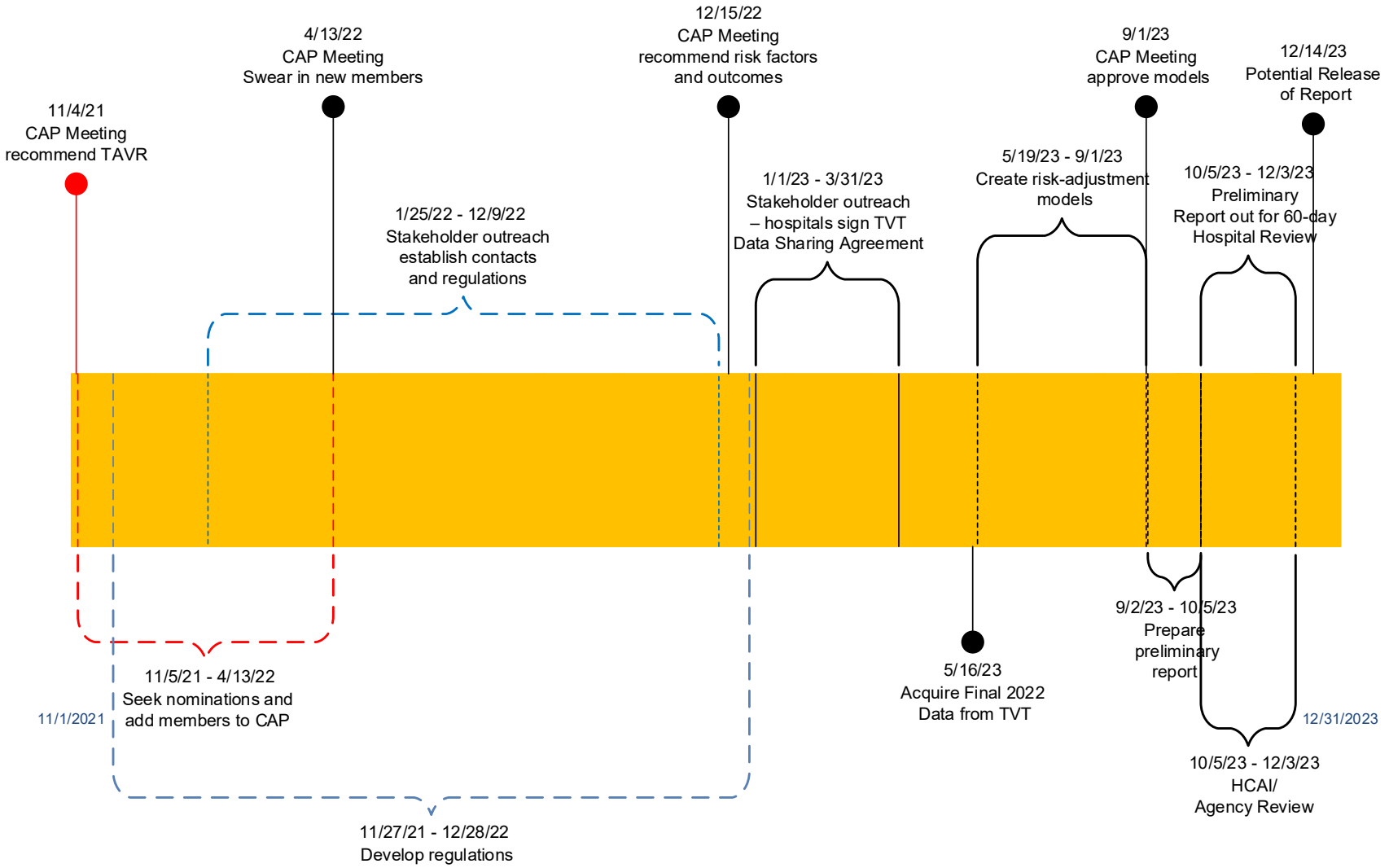
Why Use TVT Registry Data?

- Nearly 100% participation by California TAVR Hospitals
  - Minimum burden for hospitals
  - No duplicate reporting
- Clinical data is higher quality than administrative data
  - Necessary for risk-adjustment
  - Allows for expanded analysis if needed
- Findings can be compared to national results

Next Steps

- CAP Meeting April 13, 2022
  - https://hcai.ca.gov/public-meetings/
  - Swearing in of new interventional cardiologists
- Outreach to stakeholders
  - Today's informational webinar
  - Future webinars
  - Questions can be sent to: TAVR@hcai.ca.gov
- Develop regulations to clearly outline hospitals' responsibilities
  - Participate in TVT Registry
  - Complete, sign and submit DRCF
  - Hospitals that do not meet these requirements will be listed as non-compliant in the public report
  - Provide data contacts for communications with HCAI

Projected Timeline for Initial Hospital Level Report on TAVR



Q and A