



Informational Webinar Part 2: Transcatheter Aortic Valve Replacement (TAVR) Outcomes Reporting

April 14, 2022

Agenda

- Introductions
- Overview of Webinar Part 1
- Update from Clinical Advisory Panel Meeting
- Next Steps
- Timeline
- Q and A from first webinar
- Q and A from survey
- New Q and A

Overview of Webinar 1

- Covered history of CABG and PCI reporting at HCAI
- Highlighted recent changes to legislation
- Recent Legislation
- Role of Clinical Advisory Panel (CAP)
- STS/ACC TVT Registry Data

Revisions to Health and Safety Code for Cardiovascular Outcomes Reporting

- HCAI shall publish at least one risk-adjusted outcome report for CABG, TAVR, or any type of interventional cardiovascular procedure for procedures performed in the state. For any type of interventional cardiovascular procedure other than CABG or TAVR, the department shall only select from interventional cardiovascular procedures recommended by the CAP, not to exceed one additional interventional cardiovascular procedure every three years
- Upon recommendation of the CAP, HCAI may add any clinical data elements included in the STS database or other relevant databases to be collected from hospitals.
- If, at the time HCAI decides to report on a procedure, the CAP does not have members with expertise in that procedure, HCAI shall seek to appoint two new members with expertise in that procedure from a list submitted by the CA ACC.

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 Meeting – November 2021

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

CAP membership

- CA ACC Nominated two interventional cardiologists who both accepted the nomination

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 (TVT Registry)

- As a requirement of Centers for Medicare & Medicaid Services (CMS) reimbursement, hospitals that perform TAVR must participate in a prospective, national, audited registry.
- TVT Registry approved by CMS to meet the registry requirements*
- Most California hospitals participate
 - Minimum burden for hospitals
 - No duplicate reporting

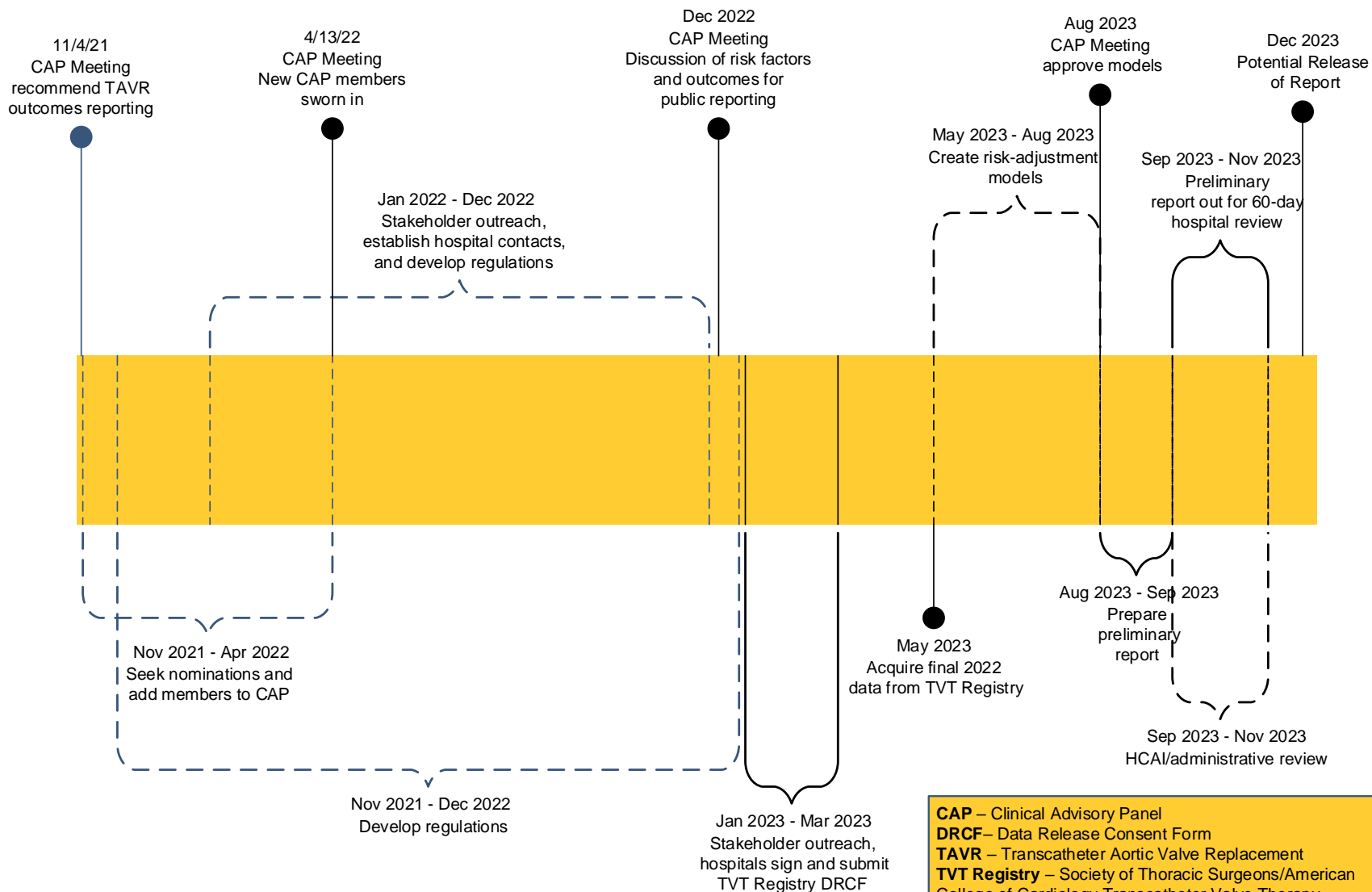
April 13th CAP Meeting

- CAP recommended data from the TVT Registry for California TAVR hospitals be shared with HCAI
- CAP recommended all TAVR hospitals be required to participate in TVT Registry and confer rights to share data to HCAI, **regardless of volume.**

Next Steps

- Outreach to stakeholders
 - Today's informational webinar
 - Future webinars
 - Questions can be sent to: TAVR@hcai.ca.gov
- Finalize 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 Public Report on TAVR (2022 Data)



CAP – Clinical Advisory Panel
DRCF– Data Release Consent Form
TAVR – Transcatheter Aortic Valve Replacement
TVT Registry – Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry

Q and A from Webinar 1

- Q and A document was emailed to TAVR data contacts
- Will be available on HCAI TAVR webpage in the next week or two

Q and A from Webinar 1

- Please provide more information about the TVT Registry Data Release Consent Form (DRCF).
 - The DRCF is being developed by the registry
 - Hospitals will sign and submit the DRCF to the registry, then send an executed copy to HCAI
 - Form will need 3 signatures, cardiologist, cardiac surgeon, hospital participant (up to hospital to determine)
 - Hospitals only need to submit the DRCF once not annually
 - The DRCF is not yet available, tentative for late 2022 or early 2023

Q and A from Webinar 1

- What is the targeted value add of another set of data outside of the already lengthy National Cardiovascular Data Registry (NCDR) reporting? Can NCDR reports be run with specific filtering by facilities in California?
 - Although the NCDR public reports do allow filtering by state, the TVT Registry public reporting is voluntary only and includes percent requirements for the metrics. These public reports and the summary reports to hospitals compare to national totals. HCAI public reporting will include all TAVR California hospitals and compare to California totals.

Q and A from Survey

Question	Answer
Will the TAVR data be audited?	Possibly, HCAI will look to the CAP for a recommendation at future meetings.
Will hospitals have to submit TAVR data to HCAI?	No, they will submit to TVT Registry.
Will hospitals have to participate in the TVT Registry?	Yes, regulations will require this.
When will the data release consent form (DRCF) be available?	The DRCF will be available in late 2022 or early 2023.
When is the DRCF due?	The signed DRCF will be due to the TVT Registry on March 1, 2023.
Which data elements from the TVT Registry will be pulled?	HCAI plans to request the complete TVT Registry database but will only use the data elements necessary for any specific analysis.

Concerns from Survey

Concerns	Response
What if hospitals do not participate in the TVT Registry?	Hospitals that perform TAVR and do not participate in the TVT Registry will be identified as non-compliant in the HCAI public report.
What if hospitals refuse to share their TVT Registry data?	Hospitals that perform TAVR and do not agree to share their TVT Registry data with HCAI will be identified as non-compliant in the HCAI public report.
What additional resources or time will be required from hospitals to share their TVT Registry data?	The appropriate people will need to sign the DRCF. Beyond that, resources and time will primary be for communications with HCAI in the form of planned webinars and reviewing preliminary reports.
How will hospital's TVT Registry data be protected?	The TVT Registry data will be stored on HCAI servers in the same manner as all confidential patient level data. For specific details contact TAVR@hcai.ca.gov .

Concerns from Survey

Concerns	Response
Will there be a preliminary report for facilities to view their data prior to public release?	Yes, per statute, hospitals will be provided a review period in advance of the public report. Any comment letters will be posted on the HCAI website with the report.
Specific metrics and measures that will be published, and whether these outcomes will be risk adjusted.	The metrics and measures will be determined based on recommendations from the CAP. Statute requires HCAI to risk-adjust outcome measures, however other information that is not risk-adjusted may be included in the public report.
What will be the report format? Will HCAI be doing an "independent interpretation of the reported results? (ie - Average, Better, Worse??)	The format for the report will likely be similar to HCAI's other risk-adjusted outcomes reports and will include performance ratings.

Concerns from Survey

Concerns	Response
<p>Will data be audited and validated for standardization across California hospitals. I feel the support from NCDR is insufficient to establish this.</p>	<p>HCAI will discuss audit options and costs once data is available and will look to the CAP for recommendations. HCAI hopes to convene regular webinars that could include training on interpreting data element definitions and standardized coding.</p>
<p>Why can't NCDR just run you a TAVR report - the other info mitral etc. should not be shared - only see what is needed</p>	<p>Reports from the TVT Registry would compare to national results, not California results. Although HCAI will receive the complete TVT Registry data, only data necessary for the outcome reports will be utilized.</p>
<p>How will we view our reports from the state when they are available? Will they be sent to us or is there a dashboard we can login to view? What is the timeline for the public reporting launch for our viewing?</p>	<p>State-level reports will be posted on the HCAI website. If hospital-specific reports/dashboards are created, HCAI will work with TAVR hospitals to determine the best approach for sharing that information. It is anticipated that the first public report utilizing 2022 data will be released in late 2023.</p>

New Q and As

Thank you!

Feel free to contact us at:

TAVR@hcai.ca.gov