

Department of Health Care Access and Information (HCAI)

Informational Webinar Part 2: Transcatheter Aortic Valve Replacement (TAVR) Outcomes Reporting April 14, 2022

Transcripts

Welcome this is Holly Hoegh with HCAI

We're going to go ahead and get started. This is our second outreach webinar on TAVR outcomes reporting by Department of healthcare access and information.

This is a follow up to our February webinar that we had about the future reporting of transcatheter aortic valve replacement (TAVR) outcomes.

Agenda for today

- an introduction
- brief overview of the webinar in February
- update from our recent clinical advisory panel meeting
- Timeline next steps the timeline
- Q&A from the first webinar
- Q&A is from the recent survey
- New questions

The webinar in February covered:

- 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

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.

At the November 2021 meeting, the CAP did recommend mandatory hospital level outcomes, reporting for TAVR and confirmed the need for expertise on the panel in TAVR. HCAI went forward with a recruitment and two new panel members were nominated and both of those panel members accepted the positions to be on the panel.

The new members are Dr. Andrew Rossi and Dr. Mamoo Nakamura, both interventional cardiologists with great experience and knowledge in TAVR.

Regarding the STS ACC TVT Registry, I will refer to it as the TVT Registry in the rest of this presentation. As a requirement of Centers for Medicare & Medicaid Services (CMS) reimbursement, hospitals that perform TAVR must participate in a prospective, national, audited registry and the TVT Registry is the approved registry. Most California hospitals participate already participate so this should result in minimum burden for hospitals and no duplicate reporting.

At yesterday's (April 13, 2022) CAP meeting the CAP recommended that data elements be acquired from the TVT Registry. They also recommended that all TAVR, hospitals be required to participate in the TVT Registry and confer rights to share their data, regardless of volume.

The next steps include:

Outreach to stakeholders

- Today's informational webinar
- Future webinars bimonthly or quarterly
- Kick-Off webinar once regulations are in place
- 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

The next slides show the projected timeline for the first TAVR Report, which is anticipated will use the 2022 data and hopefully released in late 2023.

If you would like link to the recording of the first webinar, contact us at TAVR@hcai.ca.gov. This webinar and the Q&As from all webinars will be posted to the HCAI TAVR webpage. We will let you know when that is available.

Questions and Answers from first webinar

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. It will be posted on the TAVR web page as soon as it is available.

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. Volunteer hospitals are only in the data if you meet certain percent requirements for the metrics, so a lot of the California hospitals are missing (one requirement is volume). 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.

Questions/Concerns and Answers from the recent survey

Thank you for those who participated at added questions to the recent survey:

Will the TAVR data be audited? Possibly, HCAI will look to the CAP for a recommendation at future meetings. HCAI will likely evaluate the first year's data.

Will hospitals have to submit TAVR data to HCAI? No, they will submit directly to the 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 TAVR component of the TVT Registry database but will only use the data elements necessary for any specific analysis.

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. HCAI will determine these hospitals by comparing TVT Registry data to HCAI administrative data.

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 primarily 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.

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.

HCAI is open to suggestions on the best ways to present our data. So, if you have any when you do look at our current reports and you have any suggestions. Feel free to send those along.

Will data be audited and validated for standardization across California hospitals? I feel the support from NCDR is insufficient to establish this. 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.

Why can't NCDR just run you a TAVR report - the other info mitral etc. should not be shared - only see what is needed? Reports from the TVT Registry would compare to national results, not California results. HCAI will receive only the TAVR component of the TVT Registry data and only data necessary for the outcome reports will be utilized.

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? 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. Hospital level reports may initially be emailed with the hopes that if it is determined that these could be useful to your teams HCAI might have a site to log into where these could be posted. It is anticipated that the first public report utilizing 2022 data will be released in late 2023.