

# Transcatheter Aortic Valve Replacement Outcomes Reporting

Assembly Bill 133 (Chapter 143, Statutes of 2021) included revisions to existing statute that allows the Department of Health Care Access and Information (HCAI) to expand its cardiovascular outcomes reporting efforts. The revised Health and Safety Code (HSC) now requires HCAI to publish at least one risk-adjusted<sup>1</sup> outcome report for coronary artery bypass graft surgery (CABG), transcatheter aortic valve replacement (TAVR), or any type of interventional cardiovascular procedure performed in the state. The statute also states that upon recommendation of the Clinical Advisory Panel (CAP), HCAI may add any clinical data elements included in the Society of Thoracic Surgeons' database or other relevant databases to be collected from hospitals.

HCAI currently produces hospital performance reports on both CABG and percutaneous coronary intervention (a less invasive option to open heart CABG). TAVR is a less invasive alternative to traditional surgical (open heart) aortic valve replacement, with equivalent or superior outcomes. The success and increase in use of TAVR are a result of advances in technology, greater physician experience, and improved outcomes.

At its November 4, 2021, meeting the CAP recommended HCAI move forward with hospital-level TAVR outcomes reporting. This recommendation was informed by the dramatic increase in TAVR volume since it was first utilized in 2011, coupled with the option of acquiring high quality clinical data from the Society of Thoracic Surgeons / American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT Registry<sup>TM</sup>). As participation in the registry is mandatory to receive reimbursement from the Centers for Medicare and Medicaid Services for TAVR procedures, most California TAVR hospitals contribute data to the registry. New regulations will detail the process for TAVR hospitals to share their data with HCAI.

The revised HSC also requires that CAP membership include experts on any reported procedure or intervention. Two new interventional cardiologists who are TAVR experts were nominated for the CAP by the California Chapter of the American College of Cardiology and sworn in at the April 13, 2022, CAP meeting. All [CAP meetings](#) are open to the public.

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<sup>1</sup> The purpose of Risk-adjustment is to make fair comparisons among different hospitals. Hospitals with higher-risk (sicker) patients are more likely to have higher death rates than hospitals with lower-risk (healthier) patients. More information is available here: [https://hcai.ca.gov/wp-content/uploads/2020/10/DataPulse\\_Risk\\_Adjustment\\_Sep2017.pdf](https://hcai.ca.gov/wp-content/uploads/2020/10/DataPulse_Risk_Adjustment_Sep2017.pdf)

The list below includes planned program activities through December 2023.

Projected Timeline	Period Program Activities
October 2021 to December 2021	<ul style="list-style-type: none"> <li>• Conducted outreach to California Chapter of the American College of Cardiology</li> <li>• Conducted November 4, 2021, CAP meeting</li> <li>• Sought nominations for new CAP members</li> </ul>
January 2022 to March 2022	<ul style="list-style-type: none"> <li>• Began rulemaking process, including workshopping with TAVR-performing hospitals</li> <li>• Began evaluating process to acquire data from the STS/ACC TVT Registry™</li> </ul>
April 2022 to June 2022	<ul style="list-style-type: none"> <li>• Continue outreach and workshopping</li> <li>• Appointed two new CAP members with TAVR expertise at April 13, 2022, meeting</li> </ul>
July 2022 to December 2022	<ul style="list-style-type: none"> <li>• Conduct Fall 2022 CAP meeting</li> <li>• Complete rulemaking package that details the process for TAVR hospitals to share their STS/ACC TVT Registry™ data with HCAI</li> <li>• Continue working with STS/ACC TVT Registry™ on process to acquire data</li> </ul>
January 2023 to March 2023	<ul style="list-style-type: none"> <li>• Work with TAVR hospitals to complete Data Release Consent Forms</li> <li>• Review test data from STS/ACC TVT Registry™</li> <li>• Conduct Spring 2023 CAP meeting</li> </ul>
April 2023 to June 2023	<ul style="list-style-type: none"> <li>• Receive final 2022 TAVR data from STS/ACC TVT Registry™</li> <li>• Create TAVR risk-adjustment models</li> </ul>
July 2023 to December 2023	<ul style="list-style-type: none"> <li>• Conduct Fall 2023 CAP meeting to approve risk-adjusted models</li> <li>• Finalize and publish 2022 TAVR risk-adjusted outcomes report</li> </ul>

**-- Fact Sheet updated April 28, 2022**