Department of Health Care Access and Information
2020 West El Camino Avenue, Suite 800
Sacramento, CA 95833
hcai.ca.gov

NOTICE OF PUBLIC MEETING:
Clinical Advisory Panel (CAP)

Date:
November 3, 2023
8:30 a.m. – 1:00 p.m.

Locations:
Department of Health Care Access and Information
2020 West El Camino Ave.
Conference Room 1237
Sacramento, CA 95833

Ronald Reagan UCLA Medical Center, Center for Health Sciences
10833 Le Conte Ave
Bel-Air Conference Room (CHS 17-323)
Los Angeles, CA 90095

MS Teams Link:
Click here to join the meeting

Call in Line:
Call in Line: 1-916-535-0978
(Access Code) 860 995 278#

*Note: All Committee members are required to attend this meeting in person. Members of the public can join at the in-person location or via the teams link

Agenda

1. Call to Order, Welcome and Meeting Minutes
Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair
Call to order, welcome and introductions, and approval of minutes from April 5, 2023 meeting.

2. Swearing in of New Panel Member
Scott Christman, Chief Deputy Director, HCAI
One new member has been appointed to the CAP and will be sworn in.

3. HCAI Director's Office Report
Scott Christman, Chief Deputy Director, HCAI
Presentation on department policy and program activities of interest.

4. **HCAI Office of Information Services Update**
   Christopher Krawczyk, Ph.D., Chief Analytics Officer, HCAI
   Update on the Office of Information Services activities and data analytics products.

5. **California Cardiovascular Outcomes Reporting Program (CCORP) Update**
   Holly Hoegh, Ph.D., HCAI
   Status of public reports, statewide trends in cardiac procedures, update on data collection and acquisition and other program information.

6. **Chair's Report**
   Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair
   Presentation on the latest studies and news in cardiovascular care.

7. **30-day Mortality as a Risk-adjusted Outcome for Transcatheter Aortic Valve Replacement (TAVR)**
   Mark Kishiyama, Ph.D., HCAI
   Presentation on the risk model and methods for developing the outcome measure. Vote on recommendations and approval of the risk model and methods for generating hospital-level results for a public report.

8. **Post-operative 30-day Stroke as a Risk-adjusted Outcome for TAVR**
   Mark Kishiyama, Ph.D., HCAI
   Presentation on the risk model and methods for developing the outcome measure. Vote on recommendations and approval of the risk model and methods for generating hospital-level results for a public report.

9. **Upcoming TAVR Hospital-level Outcomes Report**
   Holly Hoegh, Ph.D., HCAI
   Discussion of HCAI's recommendations on the 2022 report contents.
   - 2022 risk-adjusted TAVR 30-day mortality rates for hospitals.
   - 2022 risk-adjusted TAVR post-operative 30-day stroke rates for hospitals.

10. **Public Comment**
    Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair

11. **Adjournment**
    Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair

Note: Action may be taken on any item listed in this agenda.

The CAP agenda can be viewed on the HCAI website: https://hcai.ca.gov/public-meetings/clinical-advisory-panel-cap-meeting/. Meeting materials will be posted on this website before the meeting. Please contact Holly Hoegh at holly.hoegh@hcai.ca.gov or (916) 326-3868 with questions regarding the meeting.

Every effort will be made to address each agenda item as listed. However, the agenda order is tentative and subject to change without prior notice. The CAP may take a brief break during the meeting.

Individuals with disabilities may request an accommodation or modification to observe or participate in the meeting by contacting Holly Hoegh or sending a written request to 2020 West El Camino Avenue, Suite 1100, Sacramento, CA 95833. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

California Coronary Artery Bypass Graft (CABG)
Outcomes Reporting Program (CCORP)
Clinical Advisory Panel
Minutes of April 5, 2023, Meeting

Meeting location (with a virtual option):
Department of Health Care Access and Information
2020 West El Camino Avenue
Room 1237
Sacramento, CA 95833

Clinical Advisory Panel Members present:

Ralph Brindis, M.D., MPH, FACC, Chair	James MacMillan, M.D.
Joanna Chikwe, M.D.*	Mamoo Nakamura, M.D.*
Cheryl Damberg, Ph.D.*	Andrew Rassi, M.D.*
Gordon L. Fung, M.D., Ph.D.	Rita F. Redberg, M.D.*
Hon Lee, M.D.	Maribeth Shannon, M.S.*
	Richard Shemin, M.D.*

*Attended virtually

HCAI Staff and Others present:

Scott Christman, HCAI Chief Deputy Director	Chris Krawczyk, Ph.D., Healthcare Analytics Branch Manager
Michelle Church-Reeves, Staff Counsel	Holly Hoegh, Ph.D., Healthcare Analytics Branch
	Limin Wang, M.D., Ph.D., Healthcare Analytics Branch

1. Call to Order, Welcome and Meeting Minutes

Ralph Brindis, M.D., Chairperson, called the meeting to order at 8:37 a.m. Panel members introduced themselves. A quorum was present to conduct business.

Action: The Clinical Advisory Panel unanimously approved the minutes from the November 1, 2022 meeting.

2. Swearing in of New Panel Members – Scott Christman, Chief Deputy Director, Department of Health Care Access and Information

Chief Deputy Director Christman administered the Oath of Office to one new panel member, Joanna Chikwe, M.D.

3. HCAI Director's Office Report – Scott Christman, Chief Deputy Director, Department of Health Care Access and Information

Chief Deputy Director Christman thanked and welcomed everyone. He discussed the proposed 2023-2024 budget, which was released in January 2023, pointed out the $22.5 billion shortfall in revenue. The governor proposed a number of solutions, including almost $400 million in delays in HCAI's Workforce Development Programs. He highlighted a few significant programs HCAI will be implementing to provide access to reproductive health care and to address seismic safety requirements in small and rural hospitals.

Chief Deputy Director Christman noted the continued implementation of the Office of Health Care Affordability (OHCA) and work on the CalRx Biosimilar Insulin Initiative. He shared his excitement around the expansion of HCAI's cardiovascular public reporting programs and expressed his appreciation for the CAP. He noted the TAVR outcomes reporting effort and welcomed the CAP's recommendations on the upcoming report.

Dr. Redberg asked about the initial priorities of OHCA and Chief Deputy Director Christman responded that the first piece of work is setting a methodology for gross spending targets in the industry. The second effort is focused on market consolidation. Dr. Damberg asked if HCAI will create a database tracking these and make it available to interested parties. Chief Deputy Director Christman responded that HCAI is still in the early stages of planning, so that has not been decided. In response to a question from Dr. Shemin, he shared that OHCA is supported by a special fund and there should not be an impact to CCORP projects.

4. HCAI Office of Information Services Update – Christopher Krawczyk, Ph.D., Chief Analytics Officer

Dr. Krawczyk provided a summary of key work in the Office of Information Services (OIS). As of January 1st, 2023, the hospital administrative data will include patient address. OIS is providing data governance, technology support, and analytical technical assistance to OHCA. The first two data products in support of HCAI's workforce program were released and the Healthcare Payments Data Program (HPD) is on track to release its first public reports. The Hospital Equity Measure Reporting Program is working towards September 2025 when hospitals will be required to submit their first equity measures and action plans. Finally, HCAI is moving forward with expansion of CCORP and shared an update on TAVR reporting later in the meeting.

Dr. Krawczyk acknowledged and thanked the CAP for the discussion, feedback, input, and recommendations at the previous meeting. He recognized the expansion and implementation of new HCAI programs, leading to the decision to not include CABG surgeon-level reporting in the next report, but revisiting the decision in the future. The CAP discussed future opportunities to use HPD data in conjunction with CCORP data to evaluate cost and quality. Dr. Chikwe

shared her experiences in New York and the CAP discussed surgeon-level reporting and other possible ways to evaluate CCORP data.

5. CCORP Program Update – Holly Hoegh, Ph.D.

Dr. Hoegh gave an update on cardiovascular outcomes reporting. She reminded everyone of the role of the panel that includes:

- Recommend interventional cardiovascular procedures for public reporting
- Consult on report materials
- Recommend data elements (may be from the Society of Thoracic Surgeons (STS) or other databases)
- Review and approve development of the risk-adjustment model to be used in preparation of the outcome report
- Review physician statements

Dr. Hoegh reminded the group of the name change - California Cardiovascular Outcomes Reporting Program (CCORP). She noted for 2022 there will be 22 hospitals in the Elective PCI Report. She presented slides on CABG hospital and surgeon volume and cardiovascular procedure trends. To align with STS National Database, HCAI removed COVID-19 cases from 2020 and 2021 data for public reports. These patients will be included in risk-adjusted analyses and reports for 2022 data. STS stated that the impact of COVID-19 on operative risk will continue to be an active area of investigation and future policy may be implemented as understanding evolves and the data warrants.

6. Chair's Report, Ralph Brindis, M.D., M.P.H., F.A.C.C.

Dr. Brindis presented national data related to the SAVR/TAVR universe. Around 2015-2016 when intermediate risk was approved there was a crossover between TAVR and isolated SAVR volume. Around 2018-2019 when low risk patients were approved, all forms of TAVR exceeded all forms of SAVR. Nationally, by the end of 2021, there were 90,000 TAVRs and less than 17,000 isolated SAVRs, showing that TAVR is truly a predominant strategy for isolated aortic valve disease. He also presented information on aortic valve interventions by age, noting the changes that have occurred over time related to TAVR versus SAVR.

Next, Dr. Brindis shared information about the TVT Registry voluntary public reporting website, which include a 30-day composite measure that includes death, stroke, life-threatening major bleed, acute kidney injury, and moderately severe perivalvular leak. For the initial rollout 30 percent of the national TVT sites consented, including 24 of the California sites (out of 87).

Dr. Brindis discussed the feedback on public reporting from organizations and TAVR sites. Issues included a possible relationship between hospital stroke center designation and reported stroke rates, ascertainment bias, challenges in risk-adjusted outcomes, and the potential impact

on physician and site behavior in response to public reporting. One editorial noted the importance of selecting metrics that will lead to the intended improvements in quality in patient outcomes, rather than metrics that may affect physician or institutional behavior to the detriment of best practices in patient care.

Regarding concerns about stroke reporting, Dr. Brindis note the TVT Registry uses the stroke definition from the Valve Academic Research Consortium: An acute episode of a focal or global neurologic deficit with the duration of greater than 24 hours caused by ischemic, hemorrhagic, or undetermined ideology, and confirmed by neurologic and neurosurgical specialists, or neuroimaging. The TVT Registry is also in the process of researching the relationship between certified stroke centers and stroke incidence.

Another concern raised is with cerebral protection in TAVR with the idea that focusing on disabling stroke would lessen the impact of ascertainment bias. Dr. Shemin asked if there is a way to find out what centers are using neuroprotection and whether it affects stroke risk. Dr. Brindis replied that about 16 percent of TAVRs nationally utilize cerebral protection devices, typically in high volume centers as opposed to low volume centers. Dr. Shemin noted the possibility of low volume bias.

Dr. Redberg shared that there is no benefit for cerebral embolic protection devices and suggested that stroke centers may be over reporting and/or the non-stroke centers may be underreporting. Dr. Nakamura commented that the health of the patient explains some of the causes of stroke and whether a stroke is captured in the chart may rely on whether or not imaging was done. Dr. Rassi also shared concerns related to documenting stroke. He also commented on ascertainment bias and that some centers are more equipped to monitor these events. He added that centers using cerebral embolic detection devices are likely doing it with good intention. Centers not using these devices are also doing it with good intentions, with the hopes that the trials would have good outcomes. Unfortunately, it has not been shown that these devices change the clinical outcomes for the patients. This may change with larger samples, and Dr. Rassi suggested not using this as a quality metric if it has not been shown to change the outcomes.

Dr. Chikwe noted the importance of stroke as an end point for patients, particularly in patients where the goal is quality of life not necessarily length of life. There should be a way to adjudicate it fairly, and not penalize centers for having a more aggressive approach to outcomes.

7. Results of the 2021 CCORP Audit, Holly Hoegh, PhD, HCAI

Dr. Hoegh shared the results of the 2021 CCORP audit. Based on the modified process used since COVID-19, HCAI offered hospitals the option of a remote reabstraction. Of the 27 hospitals selected for audit, 15 were completed remotely. The goals of the audit were to determine the quality of risk factors and outcomes captured by CCORP, evaluate whether over-

or under-coding of risk factors changes hospital outlier status, and verify data quality in hospitals with poor response to HCAI's data discrepancy and risk factor coding reports.

For 2021, there were 14,796 CABG cases submitted from 120 hospitals of which 12,124 were isolated CABGs. Hospitals were selected based on were preliminary outlier or near outlier status for outcomes of mortality/stroke. Hospitals with suspected coding problems were added in and the remaining hospitals were randomly selected. For each of these hospitals, primary cases were selected proportional to isolated CABG volume for a minimum of 18 cases and a maximum of 119 CABG cases. HCAI strives to have at least 20% of the non-isolated cases at each hospital. Cases selected for audit included all in-hospital deaths and post-operative strokes. Other cases were selected proportionate to predicted death or post-op stroke risk. A set of secondary records was selected for each hospital in case the primary record could not be located, or the procedure turned out not to be a CABG. The audit found a number of surgeries submitted as isolated CABG that were found to be non-isolated, and others submitted as non-isolated CABG were found to be isolated. This revised the total number of isolated CABGs for the year to 12,150 and non-isolated CABG to 2,646.

Previous interventions, CVA, CVA timing, diabetes, cardiac arrhythmia, number of diseased vessels, incidence, IMA use, and complications were in good agreement with the audited values. Chronic lung disease and immunocompromise continue to be among the most challenging risk factors to capture.

Dr. Hoegh presented slides displaying the change in the agreement of CCORP and audit data over time. The trend indicates coding continues to improve for most risk factors over time.

The pre/post audit outcome results showed one hospital classified as "no different" for mortality was reclassified as "worse" post-audit and two hospitals classified as "worse" for readmissions were reclassified as "no different" post-audit.

The panel briefly discussed the results and the overall benefits of continuing the audit. A member of the public suggested on option of hospitals to challenge audit results. Dr. Brindis recommended implementing some best practices at the time of the audit including discussion with the hospital. Dr. Hoegh suggested using the bi-monthly conference calls to discuss the audit process.

8. Mortality as a Risk-Adjusted Outcome for Isolated CABG Surgery – Limin Wang, M.D., Ph.D., HCAI (Action Item)

Dr. Wang first presented summary statistics for all CABGs and outcomes from 2016-2021. She noted that CABG + Valve volume has dropped 36.3% since 2015-2016. Next, she walked through the methods used to develop the CCORP risk-adjusted models including:

- Bivariate analysis

- Stepwise logistic regression
- Model review
- Logistic regression model calculation
- Model fitting and evaluation, including discrimination and calibration
- Compares model with previous models, adjustments if necessary

Dr. Wang next presented the model for isolated CABG surgery for 2021. The operative mortality rate was 2.39%. The model included 24 risk factors of which 12 were significant and the c-statistic was 0.821. The panel reviewed the model and there was some discussion about pneumonia and immunocompromise.

Action: The Clinical Advisory Panel unanimously approved the mortality model for isolated CABG surgery.

9. Mortality as a Risk-Adjusted Outcome for CABG + Valve Surgery – Limin Wang, M.D., Ph.D., HCAI (Action Item)

Dr. Wang first presented a table showing the volume and mortality rates for the different types of CABG + valve surgeries, noting the higher mortality rates for the CABG + valve types. For the 2020-2021 data the operative mortality rate for CABG + valve (aortic and/or mitral) was 5.84%. The model included 21 risk factors including 8 that were significant. The c-statistic was 0.768. Dr. Chikwe asked about the volume of data used in model development and asked if HCAI had considered leveraging the STS models. Dr. Wang explained the models are calculated every year based on the California data and the unique risk of California patients.

Dr. Wang presented details about low volume related to performance ratings for CABG + valve over the last three public reports. The panel further discussed some risk factors.

Action: The Clinical Advisory Panel unanimously approved the mortality model for CABG + Valve surgery.

10. Post-operative Inpatient Stroke as a Risk-Adjusted Outcome for Isolated CABG - Surgery Limin Wang, M.D., Ph.D., HCAI (Action Item)

Dr. Wang presented the 2020-2021 risk-adjusted inpatient post-operative stroke model for isolated CABG surgery. The post-operative stroke rate was 1.57%. The model included 18 risk factors including 7 that were significant and had a c-statistic of 0.710. The panel discussed possible differences in stroke outcomes for on-pump and off-pump patients.

Action: The Clinical Advisory Panel unanimously approved the post-operative inpatient stroke model for isolated CABG surgery.

11. Hospital Readmission as a Risk-Adjusted Outcome for Isolated CABG Surgery – Limin Wang, M.D., Ph.D., HCAI (Action Item)

Dr. Wang presented the risk-adjusted 30-day hospital readmission models for isolated CABG surgery using data from 2020 and 2021. The readmission rate was 11.36%. The final model included 19 risk factors (13 were significant) and had a c-statistic of 0.650.

Action: The Clinical Advisory Panel unanimously approved the hospital 30-day hospital readmission model for isolated CABG surgery.

12. Upcoming CCORP Hospital Level Report – Holly Hoegh, Ph.D. (Action Item)

Dr. Hoegh shared the proposed contents for the 2020-2021 public report:

2021 risk-adjusted isolated CABG mortality rates for hospitals
2020-2021 risk-adjusted CABG + Valve mortality rates for hospitals
2020-2021 risk-adjusted isolated CABG post-operative inpatient stroke rates for hospitals
2020-2021 risk-adjusted isolated CABG 30-day all cause readmission rates for hospitals
2021 internal mammary artery usage rates for hospitals

Action: The Clinical Advisory Panel unanimously approved the contents of the 2020-2021 public report.

13. Transcatheter Aortic Valve Replacement (TAVR) Outcomes Reporting
Holly Hoegh, Ph.D. and Mark Kishiyama, Ph.D., HCAI

Dr. Hoegh presented a summary of the work HCAI has done to implement TAVR outcomes reporting, including outreach to hospitals, implementation of regulations, a contract with ACCF-NCDR and working with hospitals on the data release consent forms. Once the 2022 TVT Registry data is received HCAI will develop risk models based on today's recommended outcomes for public reporting. Dr. Hoegh next shared the final regulatory language. Based on HCAI administrative data, 87 hospitals currently perform TAVRs. The majority of those already participate in the TVT Registry and HCAI is working with the remaining to ensure that happens. The risk models will be presented at the next CAP meeting with the 2022 public report hopefully released in late 2022 or early 2023.

Dr. Kishiyama presented a review of the Placement of Aortic Transcatheter Valves (PARTNER) Medtronic CoreValve, and Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) randomized controlled trials. He then shared the work of Desai et al. (2021) and the findings of the TVT Registry Workgroup on TAVR Outcomes. He also shared the work of Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) Michigan Structural Heart Consortium (MISCH) TAVR Outcomes. Dr. Kishiyama presented the risk factors and outcomes used in the TVT public report and the BMC2 internal reports.

HCAI recommended moving forward with outcomes of stroke and mortality in the first year of public reporting. The panel discussed these outcomes as well as outcomes of quality of life, life threaten bleeds, acute kidney injury, atrial fibrillation, and pacemakers. Significant discussion followed regrading the use of the Kansas City Cardiomyopathy Questionnaire (KCCQ) to measure quality of life.

Dr. Brindis noted that clinical trial patients are not included in the TVT as the FDA made an agreement with industry to exclude these. There was discussion from the CAP and members of the public regarding outcomes that are not captured in the TVT Registry data. Dr. Hoegh confirmed that at least initially, only data collected in the TVT Registry will be used as risk factors and outcomes. It was also noted that the public reports would include hospital volume as well as the performance measures. HCAI will investigate using additional sources of data to report on volume to account for clinical trail patients not reported in the TVT Registry data.

The CAP further discussed which outcomes HCAI should prepare risk-adjusted models for presentation at the next meeting.

Action: The Clinical Advisory Panel unanimously approved the development of a risk-adjusted mortality model for presentation at the next CAP meeting.

Action: The Clinical Advisory Panel unanimously approved the development of a risk-adjusted stroke model for presentation at the next CAP meeting.

14. Public Comment

There was public comment regarding what TAVR outcome variables are available in the TVT registry data.

15. Adjourn

Dr. Brindis thanked everyone and adjourned the meeting at 1:26 p.m.

Dr. Vincent DeFilippi has been a practicing cardiac surgeon for 27 years. He was educated at Duke University and Columbia University College of Physicians and surgeons did surgical training and research at the University of Chicago and Fellowship at New York Hospital/Cornell Medical Center and Memorial Sloan Kettering Cancer Center. He was recruited 16 years ago by Stanford as a Clinical Professor and to run the affiliated program in Salinas. He then joined the Salinas Valley Medical Clinic and is presently the Chairman of Surgery. He has performed over 5000 open heart procedures, co-founded the TAVR program 5 years ago, has been chairman of their peer review and transfusion committees among others. He was in NY when they began unblinded public reporting for CABG and in New Jersey when they initiated public reporting in 1997.

California Cardiovascular Outcomes Reporting Program Update

Holly Hoegh, PhD
Manager, Quality and Performance Section
Clinical Advisory Panel Meeting
November 3, 2023

Statutory Role of Clinical Advisory Panel

- Recommend interventional cardiovascular procedures for public reporting - 128745(c)(2)
- Recommend data elements (may be from STS or other databases) - 128745(c)(3-4)
- **Review and approve development of the risk-adjustment model to be used in preparation of the outcome report- 128748(d)(3)**
- **Consult on report materials - 128748(e)**
- Review physician statements - 128750(b)(3)

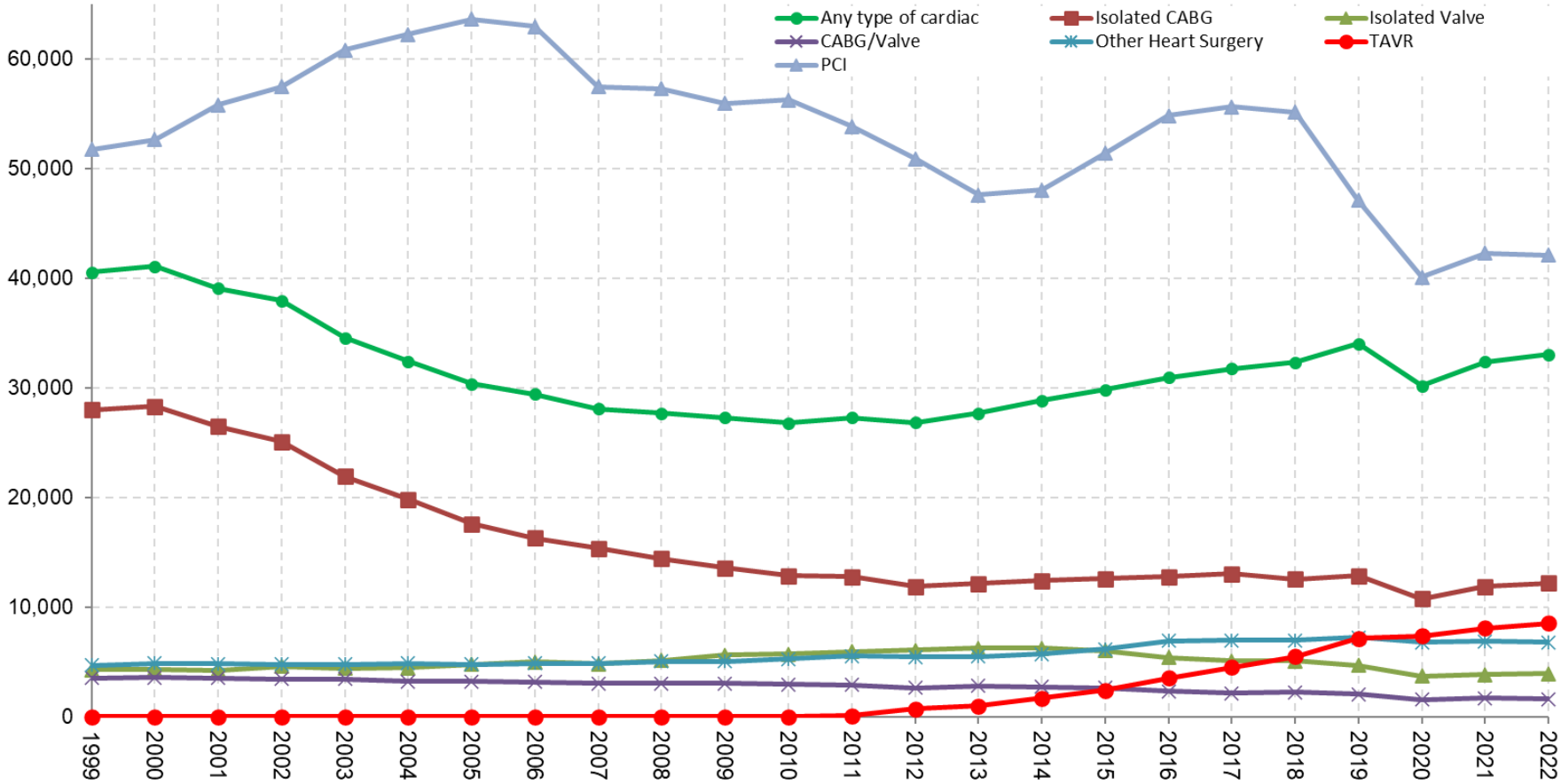
Program Update

- CABG
  - 2021 hospital-level outcomes report released Sept 13
    2022 data audit – under way
  - Training of hospital data managers held Sept 7
- TAVR
  - 2022 data received from TVT
    - 83 hospitals, 4 TAVR hospitals not included
  - Data restructuring complete
  - Risk-models completed – results shared today
- PCI
  - 2022 data received from NCDR
  - Data restructuring complete
  - Work on risk-models underway

Program Update

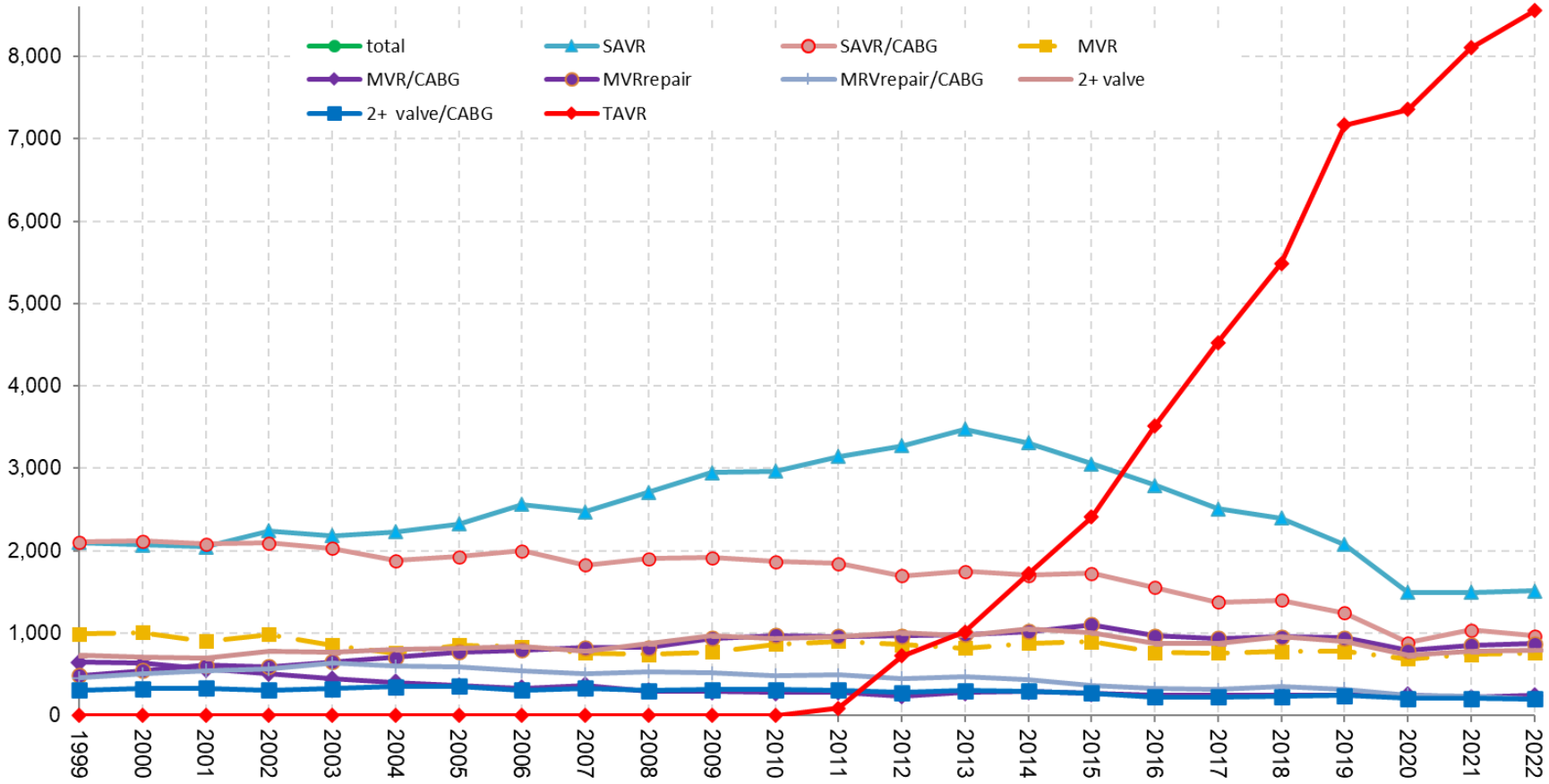
- Ongoing work
  - Working to improve hospitals submissions of PCI administrative data to HCAI
  - Data viz - CABG readmissions related to complications
  - Data viz - CABG volume per capita and mortality rates by age, race and assigned sex at birth
  - Data viz – PCI trends by sociodemographic comparisons
- Collaborative and outreach efforts
  - Ongoing outreach to TAVR hospitals
  - Bi-monthly calls with CABG/TAVR hospitals
  - California Cardiovascular Quality Collaborative (CCQC)
    - California STS and all cardiac data managers

Volume of Cardiovascular Procedures and Interventions 1999-2022



Source: HCAI PDD, AS, ED

Volume of Valve Procedures and Interventions 1999-2022



Source: HCAI PDD, AS, ED

Acknowledgements

Department of Health Care Access and Information	
Michael Valle Deputy Director, Office of Information Services	Christopher Krawczyk, Ph.D. Manager, Healthcare Analytics Branch (HAB)
Denise Stanton CCORP (CABG) Data Specialist	Ying Yang, M.S. HAB Research Scientist Supervisor
Limin Wang, M.D., Ph.D. CABG (CABG) Research Scientist	Mark Kishiyama, Ph.D. CCORP (PCI/TAVR) Research Scientist
Robert Springborn, Ph.D. CCORP (CABG) Research Scientist	Nancy Coronado CCORP (PCI/TAVR) Data Specialist
Samuel Tekle, M.S. CCORP (PCI/TAVR/CABG) Research Scientist	Alveena Bidwal HAB Student Assistant
Consultants	
J. Christopher Matchison, M.D. (cardiologist)	Beate Danielsen, Ph.D. (statistician)

HCAi
Department of Health Care Access and Information

Proposed Risk Models for the 2022 Transcatheter Aortic Valve Replacement (TAVR) Outcomes Public Report

Mark Kishiyama, PhD

Department of Health Care Access and Information

November 3, 2023

TAVR Volume & Hospitals: 2022

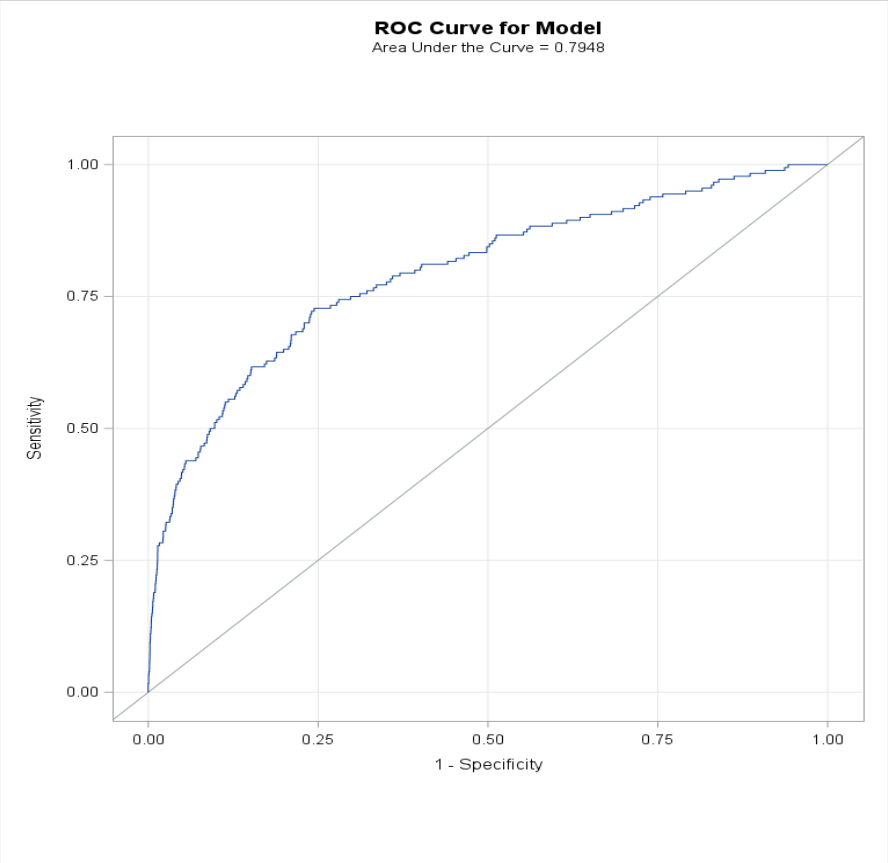
- **TAVR Program 2022**
  - Data Source: National Cardiovascular Data Registry's (NCDR's) Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapies (TVT) Registry
  - TAVR volume: 8,223
  - Hospitals: 83

TAVR 30-Day Mortality 2022

- 30-Day Deaths: 187 (2.27%)
  - Desai et al. (2021): 30-day death (as part of composite) (3.2%)
- Candidate Risk Factors
  - Combination of 50 total Risk Factors from the TVT (Desai et al., 2021) & Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) Models
  - 31 variables were significant from the bivariate analysis
- Parsimonious Stepwise Model
  - 18 Risk Factors did not meet the criterion for entry or retention in the model
  - 10 Risk Factors were significant & 3 were not significant

TAVR 30-Day Mortality 2022

- Refined Model
  - 10 Risk Factors: 9 significant risk factors from the parsimonious model plus Age (see handout)
  - C-statistic: 0.7948
  - Bootstrap validation:
    - Mean C-Statistic: 0.8014
  - Hosmer-Lemeshow = 0.8495



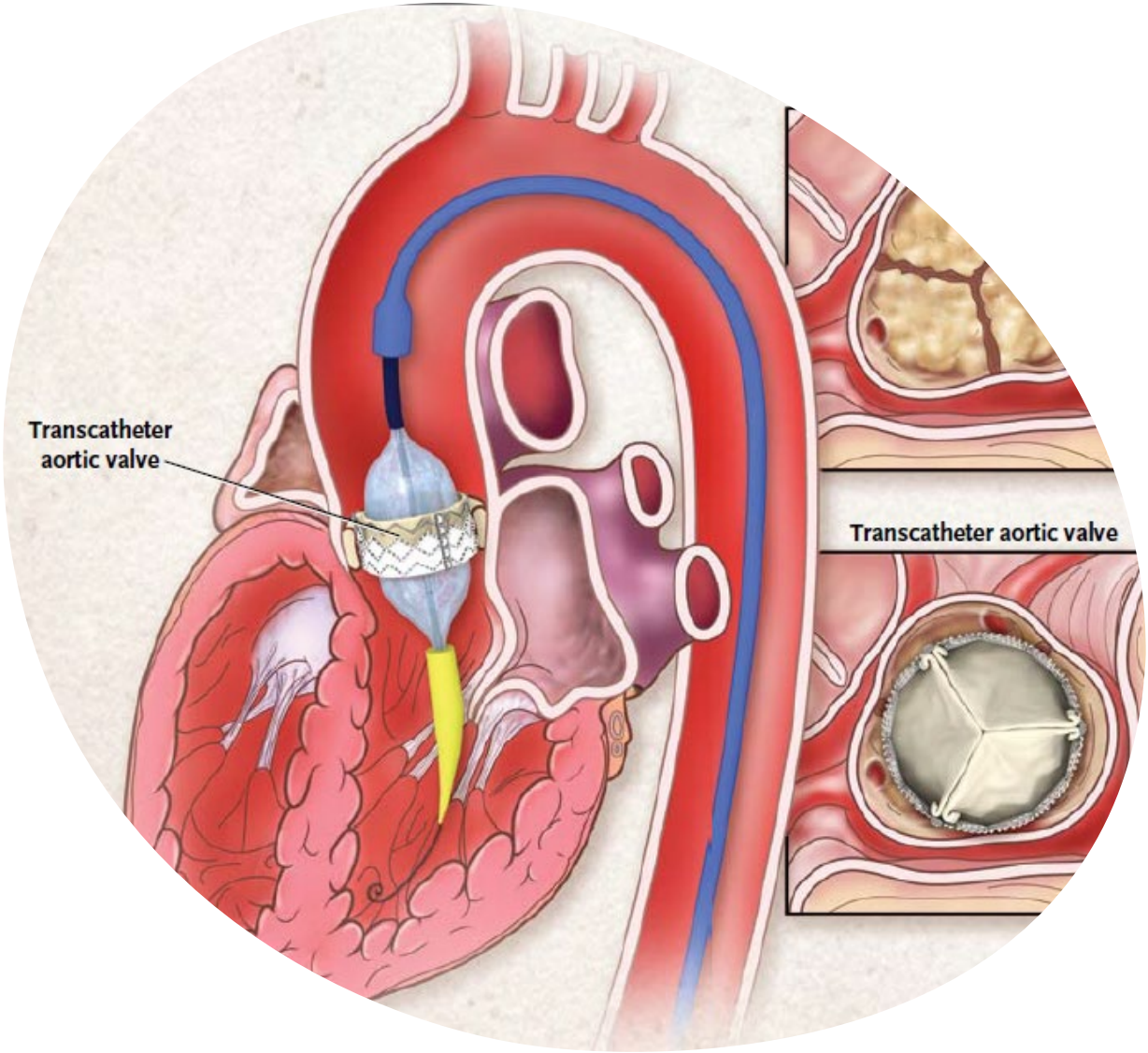
TAVR 30-Day Mortality 2022

- Handout 1
- Risk Factors (10 – significant risk factors in bold):
  - **Age**
  - **Acuity**
  - **Atrial Fibrillation/Atrial Flutter**
  - **Body Surface Area (BSA)**
  - **Currently on Dialysis**
  - **Female**
  - **Mechanical Support**
  - Tricuspid Regurgitation
  - Cardiac Arrest (w/in 24 hrs)
  - **Race**

TAVR 30-Day Mortality 2022

Decile	Cases	Observed Events	Predicted Events	Difference	95% CI of Predicted Events	
1	779	3	3.08	0.08	1.80	5.36
2	780	7	4.34	-2.66	2.62	7.31
3	780	6	5.52	-0.48	3.29	9.41
4	780	3	6.84	3.84	4.06	11.70
5	780	9	8.32	-0.68	5.02	13.96
6	780	8	10.14	2.14	6.11	17.11
7	780	9	12.69	3.69	7.51	21.73
8	780	18	16.75	-1.25	9.69	29.47
9	780	27	24.82	-2.18	13.87	45.65
10	782	84	81.50	-2.50	42.68	144.51

No overall systematic over or under estimation of event at the extremes



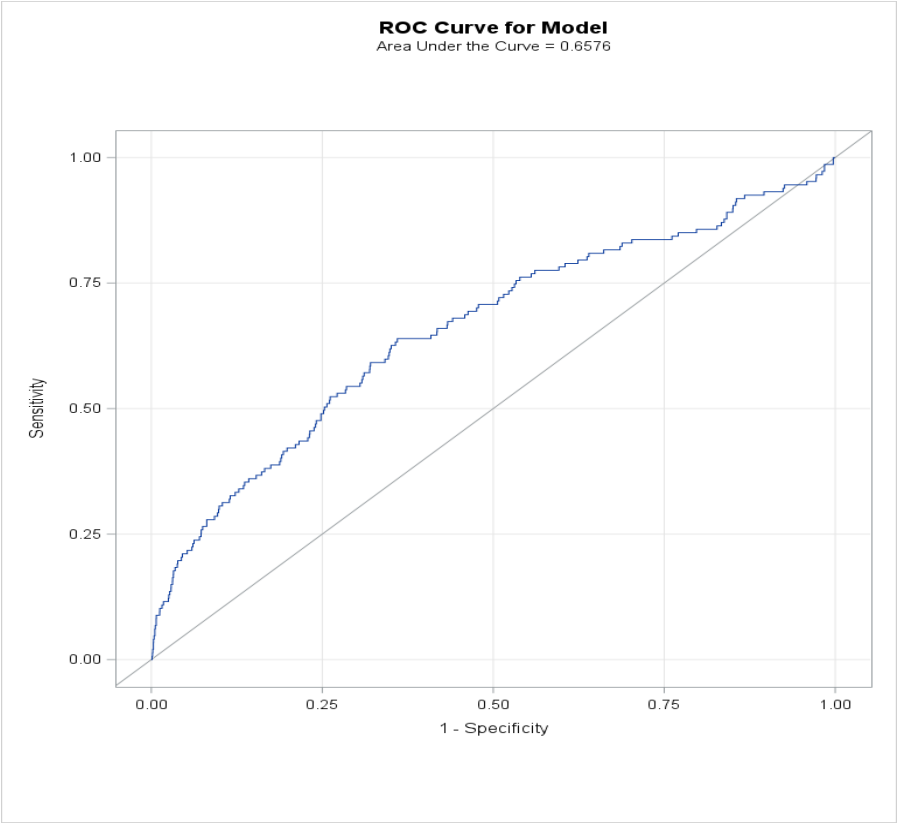
Discussion

TAVR 30-Day Stroke 2022

- 30-Day Strokes: 161 (1.96%)
  - Desai et al. (2021): 30-day stroke (as part of composite) (2.0%)
- Candidate Risk Factors
  - Combination of 50 total Risk Factors from the TVT (Desai et al., 2021) & Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) Models
  - 11 variables were significant from the bivariate analysis
- Parsimonious Stepwise Model
  - 6 Risk Factors did not meet the criterion for entry or retention in the model
  - 4 Risk Factors were significant & 1 was not significant

TAVR 30-Day Stroke 2022

- Refined Model
  - 12 Risk Factors: 4 significant risk factors from the parsimonious model plus 1 non-significant risk factor, 6 risk factors that did not meet the stay or entry criteria for this model, & 1 non-significant risk factor from the bivariate analysis
  - C-statistic: 0.6576
  - Bootstrap validation:
    - Mean C-Statistic: 0.6757
  - Hosmer-Lemeshow = 0.3747



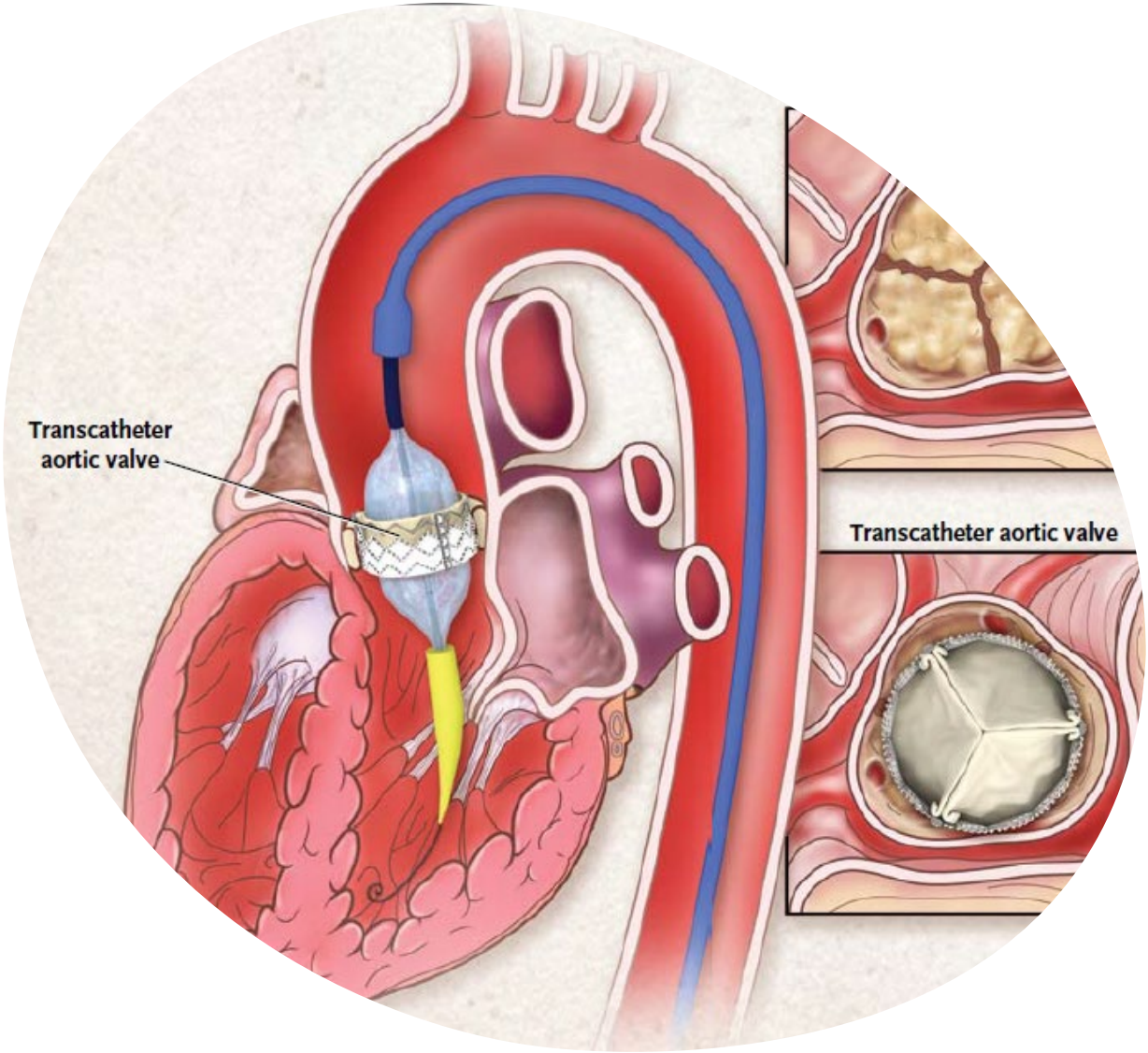
TAVR 30-Day Stroke 2022

- Handout 2
- Risk Factors (12 – significant risk factors in bold):
  - Age
  - Acuity
  - Body Surface Area (BSA)
  - Female
  - Glomerular Filtration Rate (GFR)
  - **Mechanical Support**
  - Myocardial infarction (MI)
  - Peripheral Artery Disease (PAD)
  - Cardiogenic Shock (w/in 24 hrs)
  - NYHA Class (w/in 2 weeks)
  - **Transient Ischemic Attack (TIA)/Cerebrovascular Accident (CVA)**
  - **TVT Access Site**

TAVR 30-Day Stroke 2022

Decile	Cases	Observed Events	Predicted Events	Difference	95% CI of Predicted Events	
1	794	10	6.37	-3.63	3.61	29.83
2	795	11	8.12	-2.88	4.89	13.91
3	795	4	9.21	5.21	5.58	15.69
4	795	7	10.3	3.30	6.23	17.52
5	795	11	11.45	0.45	6.90	19.62
6	795	10	12.76	2.76	7.64	21.95
7	795	14	14.29	0.29	8.35	25.22
8	795	19	16.35	-2.65	9.38	29.09
9	795	19	19.75	0.75	10.72	37.49
10	794	42	38.39	-3.61	15.97	91.16

No overall systematic over or under estimation of event at the extremes



Discussion

Handout #1 : Logistic Regression Risk Model for TAVR 30-Day Mortality, 2022

Risk Factor		Frequency			Coefficit	Standard Error	p-value	Odds Ratio (OR)	95% CL	
		N	Total	%					Lower Level	Upper Level
Intercept					-8.51	0.95	<.0001			
Age					**0.03**	**0.01**	**0.0056**	**1.03**	**1.01**	**1.05**
Acuity	Elective	95	6,693	1.4%	Reference					
	Emergency/Salvage/Cardiac Arrest	**12**	**37**	**32.4%**	**2.74**	**0.46**	**<.0001**	**15.49**	**6.33**	**37.93**
	Shock/Inotrope/ Support Device	**16**	**217**	**7.4%**	**1.15**	**0.32**	**0.0004**	**3.16**	**1.68**	**5.95**
	Urgent	**57**	**975**	**5.8%**	**1.15**	**0.18**	**<.0001**	**3.15**	**2.21**	**4.50**
Atrial Fibrillation/Atrial Flutter	No	81	5,194	1.6%	Reference					
	Yes	**99**	**2,728**	**3.6%**	**0.73**	**0.17**	**<.0001**	**2.07**	**1.49**	**2.89**
Body Surface Area (BSA)					**0.02**	**0.01**	**0.0092**	**1.02**	**1.01**	**1.04**
Currently on Dialysis					**1.25**	**0.24**	**<.0001**	**3.50**	**2.18**	**5.64**
Female					**0.46**	**0.17**	**0.0061**	**1.58**	**1.14**	**2.19**
Mechanical Support					**2.91**	**0.36**	**<.0001**	**18.28**	**9.01**	**37.07**
Tricuspid Regurgitation	None	30	1,056	2.8%	Reference					
	Mild	**59**	**2,971**	**2.0%**	**-0.64**	**0.24**	**0.0089**	**0.53**	**0.33**	**0.85**
	Moderate	37	1,026	3.6%	-0.38	0.27	0.1681	0.69	0.40	1.17
	Severe	16	227	7.0%	-0.14	0.36	0.6902	0.87	0.43	1.75
	Trace/Trivial	**38**	**2,642**	**1.4%**	**-0.62**	**0.26**	**0.0175**	**0.54**	**0.32**	**0.90**
Cardiac Arrest (w/in 24 hrs)					1.08	0.77	0.1568	2.96	0.66	13.28
Race	White	128	6,121	2.1%	Reference					
	American Indian/Alaska Native	**2**	**15**	**13.3%**	**2.56**	**0.78**	**0.0011**	**13.00**	**2.80**	**60.42**
	Asian	10	438	2.3%	-0.13	0.36	0.7163	0.88	0.44	1.77
	Black	6	197	3.0%	-0.01	0.48	0.9850	0.99	0.39	2.55
	Hispanic	32	1,129	2.8%	0.25	0.22	0.2499	1.28	0.84	1.96
	Native Hawaiian/Pacific Islander	2	22	9.1%	1.28	0.82	0.1191	3.59	0.72	17.88

Bolded text indicates statistically significant (p≤0.05).

Handout #2: Logistic Regression Risk Model for TAVR 30-Day Stroke, 2022

Risk Factor		Frequency			Coefficien	Standard Error	P value	Odds Ratio (OR)	95% CL	
		N	Total	%					Lower Level	Upper Level
Intercept					-6.69	1.07	<.0001			
Age					0.02	0.01	0.0532	1.02	1.00	1.04
Acuity	Elective	115	6,726	1.7%	Reference					
	Emergency/Salvage/Cardiac Arrest	3	38	7.9%	0.75	0.84	0.372	2.11	0.41	10.89
	Shock/Inotrope/Support Device	5	212	2.4%	-0.34	0.64	0.6009	0.71	0.20	2.52
	Urgent	24	972	2.5%	0.05	0.25	0.8318	1.05	0.65	1.71
Body Surface Area (BSA)					0.01	0.01	0.1984	1.01	0.99	1.03
Female					-0.04	0.18	0.8005	0.96	0.68	1.35
Glomerular Filtration Rate (GFR)					-0.002	0.00	0.5405	1.00	0.99	1.00
Mechanical Support					**1.77**	**0.52**	**0.0007**	**5.89**	**2.12**	**16.35**
Myocardial Infarction (MI)					0.29	0.21	0.157	1.34	0.89	2.02
Peripheral Artery Disease (PAD)					0.12	0.21	0.5747	1.13	0.74	1.72
Cardiogenic Shock (w/in 24 hrs)					0.35	0.79	0.6555	1.42	0.30	6.72
NYHA Class (w/in 2 weeks)	Class I	7	419	1.7%	Reference					
	Class II	38	2,842	1.3%	-0.26	0.42	0.5349	0.77	0.34	1.75
	Class III	73	3,677	2.0%	0.03	0.40	0.932	1.04	0.47	2.29
	Class IV	29	1,010	2.9%	0.27	0.44	0.5414	1.31	0.55	3.13
Transient Ischemic Attack (TIA)/Cerebrovascular Accident (CVA)	No	114	6,844	1.7%	Reference					
	Yes	**33**	**1,104**	**3.0%**	**0.49**	**0.20**	**0.0157**	**1.64**	**1.10**	**2.44**
TVT Access Site	Femoral Artery	132	7,677	1.7%	Reference					
	Axillary Artery	1	19	5.3%	0.54	1.09	0.6203	1.72	0.20	14.57
	Carotid	7	166	4.2%	0.69	0.42	0.0975	1.99	0.88	4.49
	Direct Aortic	**2**	**11**	**18.2%**	**2.71**	**0.80**	**0.0007**	**15.09**	**3.16**	**72.00**
	Iliac	0	9	0.0%	-11.30	757.90	0.9881	<0.001	<0.001	>999.99
	Other	0	4	0.0%	-11.54	1113.20	0.9917	<0.001	<0.001	>999.99
	Subclavian Artery	**5**	**57**	**8.8%**	**1.49**	**0.50**	**0.0027**	**4.46**	**1.68**	**11.84**
	Transapical	0	3	0.0%	-11.47	1300.80	0.993	<0.001	<0.001	>999.99
	Transseptal via Femoral Vein	0	2	0.0%	-11.51	1617.80	0.9943	<0.001	<0.001	>999.99

Bolded text indicates statistically significant (p≤0.05).