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

Clinical Advisory Panel

AGENDA
October 8, 2024
8:30 a.m. – 2:00 p.m.

The Panel may not discuss or act on any matter raised during the public comment section that is not included on this agenda, except to place the matter on a future meeting agenda. (Government Code §§ 11125, 11125.7, subd. (a).)

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 90094

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(Access Code) 102 222 725#

1. Call to Order, Welcome and Vote to Approve Meeting Minutes from the April 2, 2024, meeting
Ralph Brindis, M.D., M.P.H., F.A.C.C., CAP Chair

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

3. HCAI Office of Information Services update on activities and data analytics products.
Christopher Krawczyk, Ph.D., Chief Analytics Officer, HCAI

4. Quality and Performance Section Update - Status of public reports, statewide trends in cardiac procedures, update on data collection and correction activities, outcomes definitions, and other program information.
Holly Hoegh, Ph.D., CCORP Manager, HCAI

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

6. Mortality as a Risk-adjusted Outcome for Transcatheter Aortic Valve Replacement (TAVR) - Presentation on the methods and risk model for developing the outcome measure. Vote to approve methods for generating hospital-level results for a public report.
Mark Kishiyama, Ph.D., Research Scientist, HCAI

7. Stroke as a Risk-adjusted Outcome for TAVR - Presentation on the methods and risk model for developing the outcome measure. Vote to approve methods for generating hospital-level results for a public report.
Mark Kishiyama, Ph.D., Research Scientist, HCAI

8. Upcoming TAVR Hospital-level Report – Discussion and vote to approve HCAI's recommendations on the 2023 report contents.

- 2023 risk-adjusted TAVR inpatient/30-day mortality rates.
- 2023 risk-adjusted TAVR inpatient hospital/30-day stroke rates.
- 2023 TAVR volume from HCAI administrative data.

Holly Hoegh, Ph.D., CCORP Manager HCAI

9. Scheduling of next meeting date and discussion of agenda items
Holly Hoegh, Ph.D., CCORP Manager HCAI

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

Board Members:	Ralph G. Brindis, M.D., MPH (Chair) Joanna Chikwe, M.D. Cheryl Damberg, Ph.D. Vincent DeFilippi, M.D. Gordon L. Fung, M.D., MPH, Ph.D. Hon S. Lee, M.D. Mamoo Nakamura, M.D., Ph.D. Andrew Rassi, M.D. Rita F. Redberg, M.D. Maribeth Shannon, M.S. Richard J. Shemin, M.D.
HCAI Staff:	Elizabeth Landsberg, Director Scott Christman, Chief Deputy Director Christopher Krawczyk, Ph.D. Chief Analytics Officer Holly Hoegh, Ph.D., CCORP Manager Mark Kishiyama, Ph.D., Research Scientist

The Clinical Advisory Panel agenda and other notices about meetings are posted online and can be found by searching for the Clinical Advisory Panel and meeting month at https://hcai.ca.gov/public-meetings.

For further information about this meeting, please contact Holly Hoegh at 916-326-3868, holly.hoegh@hcai.ca.gov or send a letter to The Department of Health Care Access and Information, 2020 West El Camino Avenue, Sacramento, CA 95833.

The Panel may take action under any agenda item.

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. Items not listed on the agenda will not be considered. The Panel may take a brief break during the meeting. Members of the public are NOT required to identify themselves or provide other information to attend or participate in this meeting. If Microsoft Teams (or other platform) requires a name, you may enter “Anonymous”. You may also input fictitious information for other requested information if required to attend the meeting (e.g., anonymous@anonymous.com).

This meeting is accessible to persons with a disability. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Holly Hoegh at holly.hoegh@hcai.ca.gov or sending a written request to that person at 2020 West El Camino Avenue, Sacramento, CA 95833. Providing your request at least seven (7) business days before the meeting will help ensure availability of the requested accommodation.

If you need help understanding or translating into another language, or if you need sign language services, please contact Holly Hoegh at holly.hoegh@hcai.ca.gov. Let us know at least seven days before the meeting so we can set up the services you need.

Spanish/ Español

Si necesita ayuda para comprender o traducir a otro idioma, o si necesita servicios de lenguaje de señas, póngase en contacto con Holly Hoegh at holly.hoegh@hcai.ca.gov. Avísenos al menos siete días antes de la reunión a fin de que podamos programar los servicios que necesita.

Korean/韓國人

내용을 다른 언어로 이해 또는 번역하는 데 도움이 필요하거나 수화 서비스가 필요한 경우 다음 연락처로 문의하시기 바랍니다: Holly Hoegh at holly.hoegh@hcai.ca.gov. 필요한 서비스를 제공할 수 있도록 회의 개최 7일 전까지 알려주십시오.

Chinese Simplified/簡體中文

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Tagalog/Tagalog

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Vietnamese/Tiếng Việt

Nếu quý vị cần trợ giúp để hiểu hoặc để dịch sang ngôn ngữ khác hoặc nếu quý vị cần dịch vụ ngôn ngữ ký hiệu, vui lòng liên hệ Holly Hoegh at holly.hoegh@hcai.ca.gov. Vui lòng cho chúng tôi biết ít nhất bảy ngày trước cuộc họp để chúng tôi có thể bố trí các dịch vụ mà quý vị cần

Chinese Cantonese(Traditional)/中文 粵語

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California Coronary Artery Bypass Graft (CABG)
Outcomes Reporting Program (CCORP)
Clinical Advisory Panel
Minutes of April 2, 2024 Meeting

Meeting location (with a virtual option):
Department of Health Care Access and Information
2020 West El Camino Avenue
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 90094

Clinical Advisory Panel Members present:

Ralph Brindis, M.D., MPH, FACC, Chair	Andrew Rassi, M.D.
Cheryl Damberg, Ph.D.	Rita F. Redberg, M.D.
Vincent DeFilippi, M.D.	Richard Shemin, M.D.
Mamoo Nakamura, M.D.	

HCAI Staff and Others present:

Scott Christman, HCAI Chief Deputy Director	Chris Krawczyk, Ph.D., Healthcare Analytics Branch Manager
Camille Dixon, 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 9:07 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, 2023 meeting.

2. 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 provided updates on the proposed 2024-2025 budget, discussed an estimated $37.9 billion deficit. This results in a proposed $140 million delay in HCAI's Health Workforce

Programs as well as a $189 million delay for various behavioral health programs. The overall budget for fiscal year 2024-25 is $523 million with 748 positions, illustrating HCAI's growth. There is no impact to the CCORP.

Chief Deputy Director Christman shared the launch of a Certified Wellness Coach website to support The Certified Wellness Coach Employer Support Grant Program. The Office of Health Care Affordability (OHCA) recommended to their Board a 3% statewide spending target for years 2025-2029. In an effort to slow spending growth, OHCA is promoting high-value system performance via alternative payment model standards, goals, and benchmarks. OHCA finalized emergency regulations implementing its cost and market impact review program.

Dr. Redberg asked about how the targets are being set and who they apply to. Chief Deputy Director Christman responded to questions from the Panel on how targets are set and unintended consequences.

3. 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). The Healthcare Analytics Branch (HAB) has been focusing on the data release component of the Healthcare Payments Data Program (HPD). Regulations for HPD data release are underway, with expectations of getting the regulations in place later this year. Two HPD data visualizations have been released with a third product focusing on fee-for-service retail prescription costs planned for release soon. The Hospital Equity Measure (HEM) Program is working on regulations and a measures submission guide that will outline what hospitals will be required to submit in their first report and action plan that are due September 2025. The measures were selected based on recommendations from the HEM Advisory Committee and input from stakeholders while being mindful of what information hospitals already collect. Dr. Damberg expressed concerns about small numbers when stratifying the data. Dr. Krawczyk responded that data de-identification guidelines will be used and HCAI will provide assistance on how to roll-up categories with small numbers. In 2027 the HEM Advisory Committee will have the opportunity to update their recommendations.

Dr. Krawczyk noted the recent release of the 2022 Elective PCI report and that the first TAVR outcomes report for 2022 data is currently under review.

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

Dr. Hoegh reminded everyone of the role of the Panel that includes:

- Recommend interventional cardiovascular procedures for public reporting
- Consult on report materials
- Recommend data elements

- Review and approve development of the risk-adjustment model to be used in preparation of the outcome report
- Review physician statements

Dr. Hoegh gave an update on the Cardiovascular Outcomes Reporting Program. The 2022 Elective PCI Report was released in March and included 21 hospitals. The 2022 TAVR Report is under final review and will be released soon. In response to Panel questions, she shared the stakeholder outreach that went into implementing TAVR outcomes reporting, highlighting the monthly conference call with the hospital data managers.

Dr. Hoegh presented slides on CABG hospital and surgeon volume and cardiovascular procedure trends. To align with STS and CMS public reporting, HCAI excluded 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 and beyond.

Dr. Redberg discussed the potential for perhaps overuse of TAVR when there is no evidence-based need. Aortic stenosis does benefit from surgical intervention at the right time - symptomatic severe aortic stenosis, but there is some concern that patients may be getting TAVR when not necessary - among the patient cohort with asymptomatic aortic stenosis. Dr. Rassi discussed ongoing clinical trials assessing patients with asymptomatic aortic stenosis and also argued that there are many patients being treated too late, as well as other patients who might now be potential candidates for TAVR and are not being offered TAVR or surgical AVR treatment. Dr. Redberg asked about potential for selection bias related to the disparities in the actual hospital PCI volume and what is being reported by HCAI. Dr. Hoegh responded that the issue is related to hospitals failing to submit the correct ambulatory surgery data to HCAI. Dr. Damberg requested surgeon-level outcomes reporting be addressed at a future meeting.

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

Dr. Brindis presented national STS/ACC TVT Registry data related to TAVR outcomes. There are now 838 sites performing TAVR procedures in the United States compared to the 1,009 US hospitals sites that perform open heart surgery (other STS/ACC TVT Registry site data include 566 - M-TEER, 536 - TMVR, and 222- Tricuspid – with Tricuspid procedures all "off label"). The FDA has recently approved tricuspid repair using the Abbott Medical's Tri Clip G4 System based on a clinical trial demonstrating no statistically significant difference in hospitalizations or mortality. Dr. Brindis provided insights on patient reported outcomes from Triluminate, showing an improvement in the KCCQ score assessing patient reported outcome measures over time. The Panel further discussed challenges in assessing the merits/clinical benefits of tricuspid replacement or repair along with challenges in optimal patient selection for this procedure.

Dr. Brindis congratulated Dr. Chikwe who is serving as the Vice Chair of the writing group for the 2024 Clinical Performance and Quality Measures for Adults with Valvular and Structural Heart Disease. Dr. Shemin noted STS's efforts to add frailty to their data collection.

6. Results of the 2022 CCORP Audit, Holly Hoegh, PhD, HCAI

Dr. Hoegh shared the results of the 2022 CCORP audit. 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. A total of 27 hospitals were audited, with 7 on-site and 20 remote audits.

For 2022, there were 15,200 CABG cases submitted from 118 hospitals of which 12,537 were isolated CABGs. Hospitals were selected based on preliminary outlier or near outlier status for outcomes of mortality/stroke. A few hospitals were selected based on suspected coding problems and the remaining hospitals were randomly selected. For each hospital, primary cases were selected proportional to isolated CABG volume, with an effort to include 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. The audit found several discrepancies on the coding of isolated verses non-isolated cases, resulting in a revised total number of 12,579 isolated and 2,621 non-isolated CABGs.

Previous interventions, CVA, CVA timing, diabetes, cardiac arrhythmia, incidence, IMA use, and post-op stroke were in good agreement with the audited values. Chronic lung disease continues to be one of the most challenging risk factors to capture, however it has been improving over the past two years.

The pre/post audit outcome results showed one hospital classified as "No Different" for mortality was reclassified as "Better" post-audit. For readmissions, one hospital classified as "No Different" was re-classified as "Better" post-audit and one hospital classified as "Worse" was re-classified as "No Different" post-audit.

The Panel briefly discussed the results and the overall benefits of continuing the audit process. Dr. Shemin asked a question regarding whether it is beneficial for hospitals to outsource their data collection. Dr. Hoegh responded by acknowledging that we are seeing a trend with hospitals outsourcing, but it is too soon to tell. There is one major vendor that works for many hospitals which could result in consistent coding. Dr. Damberg suggested keeping track of which hospitals are utilizing AI tools for data collection.

7. 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 2016-2022. She noted that CABG + Valve volume has decreased in the last two years. She briefly discussed COVID-19 and its effect on analysis, highlighting that COVID-19 patients covered over 13% of total CABG cases in 2022. 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 2022. The operative mortality rate was 2.47%. The model included 24 risk factors of which 11 were significant and the c-statistic was 0.810. The Panel reviewed the model and there was some discussion about whether COVID-19 should be included in the risk model. There was discussion of the Hosmer-Lemeshow test.

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

8. 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 2021-2022 data the operative mortality rate for CABG + valve (aortic and/or mitral) was 5.78%. The model included 23 risk factors including 8 that were significant. The c-statistic was 0.787.

The HCAI team had discussed unexpected impact of myocardial infarction (MI) in the model prior to the meeting. The Panel discussed this result and recommended removing MI from the model.

Action: The Clinical Advisory Panel unanimously approved eliminating MI from the CABG + Valve model.

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

9. 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 2021-2022 risk-adjusted inpatient post-operative stroke model for isolated CABG surgery. The post-operative stroke rate was 1.51%. The model included 18 risk factors including 10 that were significant and had a c-statistic of 0.712. Dr. Wang clarified the exclusion of full open mazes from the isolated CABG cohort.

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

10. 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 2021 and 2022. The readmission rate was 11.29%. The final model included 22 risk factors (16 were significant) and had a c-statistic of 0.660. There was some discussion about the Hosmer-Lemeshow test decreasing compared to previous years. There was discussion of the Hosmer-Lemeshow test.

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

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

Dr. Hoegh shared the proposed contents for the 2021-2022 public report:

- 2022 risk-adjusted isolated CABG mortality rates for hospitals
- 2021-2022 risk-adjusted CABG + Valve mortality rates for hospitals
- 2021-2022 risk-adjusted isolated CABG post-operative inpatient stroke rates for hospitals
- 2021-2022 risk-adjusted isolated CABG 30-day all cause readmission rates for hospitals
- 2022 internal mammary artery usage rates for hospitals

Action: The Clinical Advisory Panel unanimously approved the contents of the 2021-2022 public report.

12. Public Comment

There was no public comment.

13. Adjourn

Dr. Brindis thanked everyone and adjourned the meeting at 11:55 a.m.

California Cardiovascular Outcomes Reporting Program Update

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

1

Housekeeping

- Bagley Keene Open Meeting Act will be followed.
- This meeting is being held in person in LA/Sacramento for panel members. Staff and members of the public are allowed to attend remotely.
- The Chair will ask for Public Comment after each agenda item and at end of meeting.
- To provide comment:
  - From MS Teams press the “hand raise” feature
  - From a phone dial *5.
- All members of the public will be kept on mute throughout the meeting.
- The Chat function is disabled for this meeting.
- There are not transcription services for this meeting. It is being recorded via MS Teams. Please remember to state your name when speaking.
- Microphones pick up background noise. Please limit side conversations.

2

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)

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3

Program Update

- CABG
  - 2022 hospital-level outcomes report released July 30th
  - 2023 data audit – under way
  - 2024 - Down to 117 hospitals performing CABG
    - Clovis Community MC started CABG (left elective PCI program)
    - Regional Medical Center of San Jose discontinued CABG in 2023
- TAVR
  - 2022 hospital-level outcomes report released June 4th
    - 83 hospitals, 4 TAVR hospitals not included
  - 2023 data received from TVT
    - Methods and risk-models shared today
- PCI
  - 2023 data – 23 hospitals, data restructuring complete
  - Work on methods and risk-models underway

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Program Update

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

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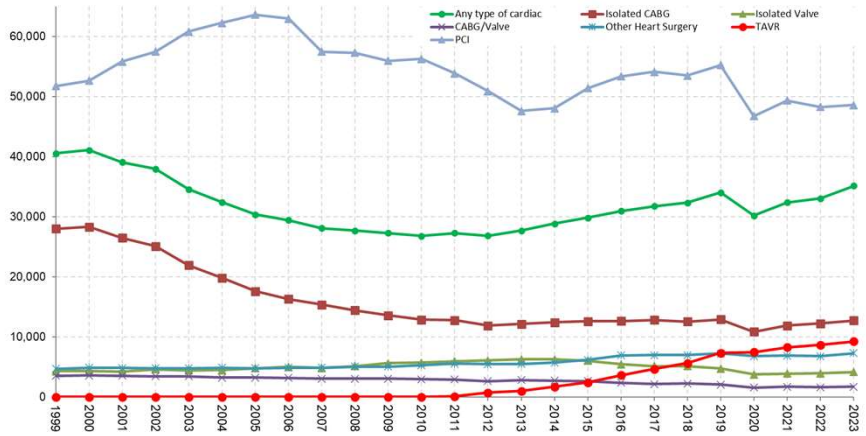
5

Volume of Cardiovascular Procedures and Interventions 1999-2023



Source: HCAI PDD, AS, ED

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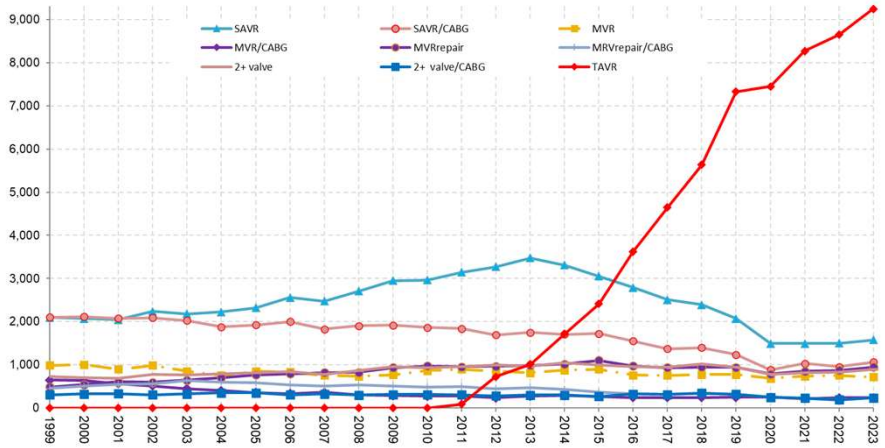
6

Volume of Valve Procedures and Interventions 1999-2023



Source: HCAI PDD, AS, ED

7

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. CCORP (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)

8

Proposed Risk Models for the 2023 Transcatheter Aortic Valve Replacement (TAVR) Outcomes Public Report

Mark Kishiyama, PhD
Department of Health Care Access and Information
October 8, 2024

1

TAVR Volume & Hospitals: 2023

- **TAVR Program 2023**
  - 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: 9,064
  - Hospitals: 85

2

TAVR In-hospital/30-day Mortality 2023

- Deaths: 181 (2.00%)
- 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
  - 33 variables were significant from the bivariate analysis

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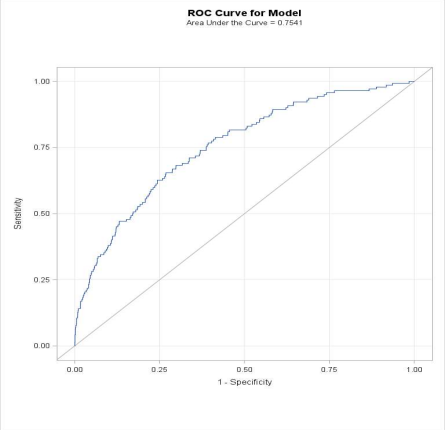
TAVR In-hospital/30-day Mortality 2023

- Refined Model
  - 16 Risk Factors (see handout)
  - C-statistic: 0.7541
  - Bootstrap validation:
    - Mean C-Statistic: 0.7685
  - Hosmer-Lemeshow = 0.9081



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TAVR In-hospital/30-day Mortality 2023

- Handout 1
- Risk Factors (16 – significant risk factors in bold):
  - Atrial Fibrillation/Atrial Flutter
  - Age Group
  - Glomerular Filtration Rate (GFR) Stage
  - Chronic Lung Disease Severity
  - **Dementia**
  - Diabetes Control
  - Female
  - **Hemoglobin**
  - **Kansas City Cardiomyopathy Questionnaire (KCCQ)-12 Summary Score**
  - Left Ventricular Ejection Fraction (LVEF) Category
  - Prior Myocardial Infarction (MI)
  - Number Prior Cardiac Operations
  - Peripheral Artery Disease (PAD)
  - Mitral Regurgitation
  - **Prior Cardiogenic Shock**
  - Race

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TAVR In-hospital/30-day Mortality 2023

Decile	Cases	Observed Events	Predicted Events	Difference	95% CI of Predicted Events	
1	762	3	2.42	-0.58	1.25	4.93
2	763	2	3.72	1.72	1.99	7.22
3	763	4	4.93	0.93	2.63	9.56
4	763	6	6.22	0.22	3.34	11.95
5	763	11	7.77	-3.23	4.17	15.00
6	763	7	9.77	2.77	5.17	19.01
7	763	14	12.47	-1.53	6.52	24.66
8	763	19	16.41	-2.59	8.49	32.51
9	763	24	23.51	-0.49	11.71	48.13
10	767	52	54.79	2.79	24.44	116.74

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

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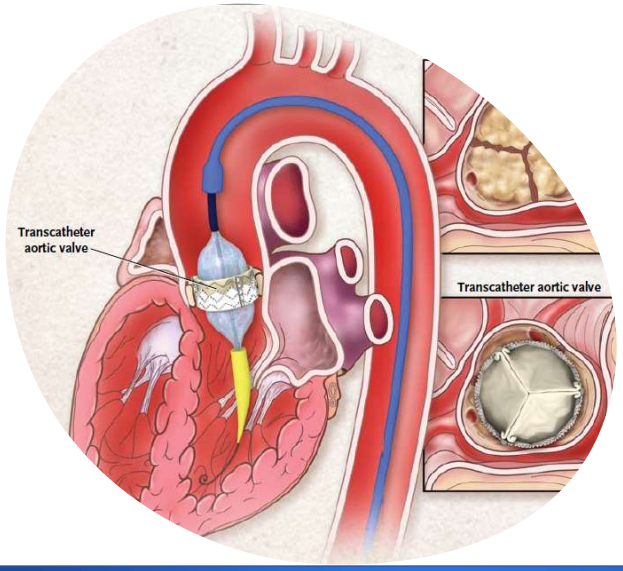
6



Discussion

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7

TAVR In-hospital/30-day Stroke 2023

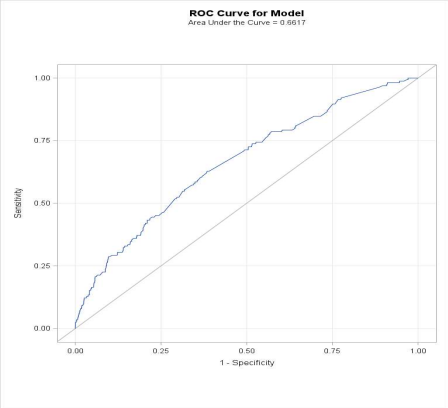
- Strokes: 183 (2.02%)
- Candidate Risk Factors
  - Combination of 50 total Risk Factors from the TVT (Desai et al., 2021) & Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) Models
  - 18 variables were significant from the bivariate analysis

HCAi Department of Health Care Access and Information

8

TAVR In-hospital/30-day Stroke 2023

- Refined Model
  - 13 Risk Factors (see handout)
  - C-statistic: 0.6617
  - Bootstrap validation:
    - Mean C-Statistic: 0.6795
  - Hosmer-Lemeshow = 0.6908



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TAVR In-hospital/30-day Stroke 2023

- Handout 2
- Risk Factors (13 – significant risk factors in bold):
  - **Acuity**
  - Atrial Fibrillation/Atrial Flutter
  - Age Group
  - Carotid Artery Stenosis
  - Dementia
  - **Female**
  - Left Main Disease
  - Prior Myocardial Infarction (MI)
  - Number Prior Cardiac Operations
  - Peripheral Artery Disease (PAD)
  - **Prior Transcatheter Aortic Valve Replacement (TAVR)**
  - Race
  - **Transient Ischemic Attack (TIA)/Cerebrovascular Accident (CVA)**

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TAVR In-hospital/30-day Stroke 2023

Decile	Cases	Observed Events	Predicted Events	Difference	95% CI of Predicted Events	
1	823	5	6.71	1.71	3.55	12.89
2	994	8	10.51	2.51	7.41	15.00
3	648	12	7.50	-4.50	4.15	13.69
4	826	10	10.51	0.51	6.42	17.55
5	820	12	12.93	0.93	6.59	25.81
6	863	14	15.73	1.73	11.57	21.46
7	790	18	15.56	-2.44	8.70	28.28
8	851	22	18.90	-3.10	11.21	32.65
9	784	16	22.64	6.64	11.71	44.71
10	821	46	43.00	-3.00	19.73	92.54

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

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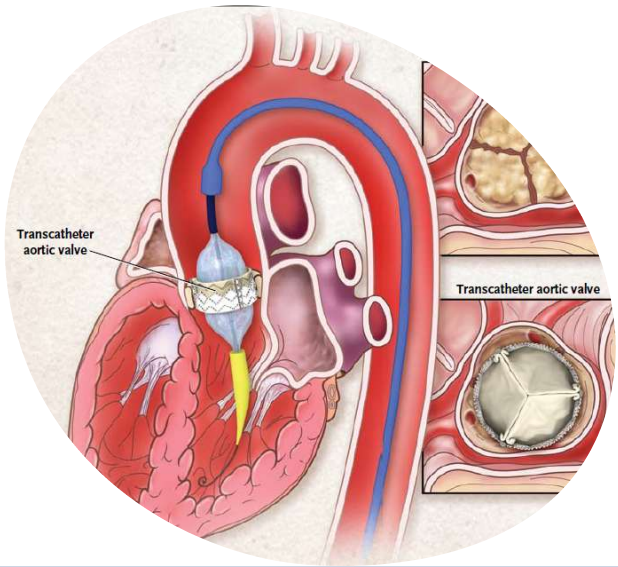

Discussion

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Handout #1 : Logistic Regression Risk Model for TAVR In-hospital/30-day Mortality, 2023

Risk Factor		Frequency			Coefficien	Standard Error	p-value	Odds Ratio (OR)	95% CL	
		N	Total	%					Lower Level	Upper Level
Intercept					-1.40	0.67	0.0372			
Atrial Fibrillation/Atrial Flutter	No	81	5,184	1.6%	Reference					
	Yes	61	2,449	2.5%	0.11	0.18	0.5298	1.12	0.79	1.60
Age Group	<70	20	1,046	1.9%	Reference					
	>=70	122	6,587	1.9%	-0.06	0.26	0.8141	0.94	0.57	1.55
Glomerular Filtration Rate (GFR)	GFR stage 1-2	60	4,820	1.2%	Reference					
	GFR stage 3,4,5	82	2,813	2.9%	0.35	0.18	0.0615	1.41	0.98	2.03
Chronic Lung Disease Severity	Not Severe	131	7,412	1.8%	Reference					
	Severe	11	221	5.0%	0.54	0.34	0.1105	1.71	0.89	3.30
Dementia	No	137	7,561	1.8%	Reference					
	Yes	**5**	**72**	**6.9%**	**1.39**	**0.49**	**0.0045**	**4.01**	**1.54**	**10.44**
Diabetes Control	No Diabetes	72	4,835	1.5%	Reference					
	Insulin	29	763	3.8%	0.42	0.24	0.0873	1.52	0.94	2.44
	Non-Insulin	41	2,035	2.0%	0.26	0.20	0.2037	1.30	0.87	1.93
Gender	Male	72	4,391	1.6%	Reference					
	Female	70	3,242	2.2%	0.13	0.18	0.4646	1.14	0.80	1.62
Hemoglobin					**-0.20**	**0.05**	**<.0001**	**0.82**	**0.74**	**0.90**
Kansas City Cardiomyopathy Questionnaire (KCCQ)-12 Summary Score					**-0.02**	**0.00**	**<.0001**	**0.98**	**0.98**	**0.99**
Left Ventricular Ejection Fraction (LVEF) Category	>=50%	99	6,333	1.6%	Reference					
	30%-49%	36	992	3.6%	0.34	0.22	0.1173	1.41	0.92	2.15
	<30%	7	308	2.3%	-0.38	0.43	0.3705	0.68	0.30	1.57
Prior Myocardial Infarction (MI)	No	106	6,562	1.6%						
	Yes	36	1,071	3.4%	0.24	0.21	0.2667	1.27	0.84	1.92
Number Prior Cardiac Operations					0.11	0.18	0.5294	1.12	0.79	1.58
Peripheral Artery Disease (PAD)	No	106	6,357	1.7%	Reference					
	Yes	36	1,276	2.8%	0.26	0.20	0.2116	1.29	0.87	1.93
Mitral Regurgitation	Not Severe	136	7,530	1.8%	Reference					
	Severe	6	103	5.8%	0.71	0.46	0.1182	2.04	0.83	4.98
Prior Cardiogenic Shock	No	131	7,541	1.7%	Reference					
	Yes	**11**	**92**	**12.0%**	**1.21**	**0.37**	**0.0011**	**3.36**	**1.62**	**6.98**
Race	White	100	5,566	1.8%	Reference					
	Asian	11	448	2.5%	0.05	0.34	0.8880	1.05	0.54	2.03
	Black	3	192	1.6%	-0.55	0.60	0.3600	0.58	0.18	1.87
	Hispanic	21	1,108	1.9%	-0.24	0.25	0.3366	0.78	0.48	1.29
	Other	7	319	2.2%	-0.01	0.41	0.9808	0.99	0.45	2.20

Bolded text indicates statistically significant (p≤0.05).

Handout #2: Logistic Regression Risk Model for In-hospital/30-day TAVR Stroke, 2023

Risk Factor		Frequency			Coefficie	Standard Error	P value	Odds Ratio (OR)	95% CL	
		N	Total	%					Lower Level	Upper Level
Intercept					-5.00	0.30	<.0001			
Acuity	Elective	120	6,982	1.7%	Reference					
	Emergency/Salvage/ Cardiac Arrest	**3**	**38**	**7.9%**	**1.28**	**0.65**	**0.0490**	**3.58**	**1.01**	**12.74**
	Shock/Inotrope/Support Device	7	259	2.7%	0.43	0.40	0.2797	1.54	0.71	3.36
	Urgent	**34**	**941**	**3.6%**	**0.60**	**0.21**	**0.0036**	**1.82**	**1.22**	**2.72**
Atrial Fibrillation/ Atrial Flutter	No	99	5,540	1.8%	Reference					
	Yes	65	2,680	2.4%	0.16	0.17	0.3542	1.17	0.84	1.63
Age Group	<70	14	1,129	1.2%	Reference					
	>=70	150	7,091	2.1%	0.46	0.29	0.1098	1.58	0.90	2.77
Cartotid Artery Stenosis	No	143	7,421	1.9%	Reference					
	Yes	21	799	2.6%	0.19	0.25	0.4495	1.21	0.74	1.96
Dementia	No	159	8,134	2.0%	Reference					
	Yes	5	86	5.8%	0.85	0.48	0.0748	2.34	0.92	5.97
Gender	Male	73	4,757	1.5%	Reference					
	Female	**91**	**3,463**	**2.6%**	**0.55**	**0.16**	**0.0007**	**1.74**	**1.26**	**2.39**
Left Main Disease	No	150	7,793	1.9%	Reference					
	Yes	14	427	3.3%	0.48	0.30	0.1088	1.62	0.90	2.91
Prior Myocardial Infarction (MI)	No	131	7,018	1.9%	Reference					
	Yes	33	1,202	2.7%	0.23	0.21	0.2769	1.26	0.83	1.89
Number Prior Cardiac Operations					-0.10	0.20	0.6290	0.91	0.61	1.35
Peripheral Artery Disease (PAD)	No	136	6,802	2.0%	Reference					
	Yes	28	1,418	2.0%	-0.16	0.22	0.4691	0.85	0.56	1.31
Prior TAVR	No	158	8,169	1.9%	Reference					
	Yes	**6**	**51**	**11.8%**	**1.52**	**0.46**	**0.0010**	**4.57**	**1.84**	**11.34**
Race	White	113	6,014	1.9%	Reference					
	Asian	10	470	2.1%	0.13	0.34	0.7097	1.13	0.59	2.19
	Black	7	216	3.2%	0.41	0.41	0.3209	1.50	0.67	3.35
	Hispanic	25	1,187	2.1%	0.10	0.23	0.6586	1.11	0.71	1.73
	Other	9	333	2.7%	0.29	0.36	0.4223	1.33	0.66	2.68
TIA/CVA	No	123	7,039	1.7%	Reference					
	Yes	**41**	**1,181**	**3.5%**	**0.58**	**0.19**	**0.0024**	**1.78**	**1.23**	**2.59**

Bolded text indicates statistically significant (p≤0.05).