PLEASE SIGN IN (NAME AND EMAIL)

CNS Annual Meeting 2013

Joint CV Section Executive Council Meeting

Sunday, October 20th

4-6 pm

San Francisco Marriott Marquis Hotel

Pacific J Room

Meeting Agenda

Call to Order (Dr. Friedlander)

Approval of Minutes from AANS 2013 (Dr. Lavine)

Treasurer's Report (Dr. Zipfel)

AANS Dev Commit One Ask Concept/NREF (Drs Haid and Tippett)

Annual Meeting Updates
2013 CNS Meeting (Drs Mocco and Nakaji)
2014 CV Sect Annual Meeting (Drs Bambakidis, Mocco, Evandro de Oliveira)
2014 ISC Meeting (Drs Mack, Welch, Cockroft)
2014 AANS Meeting (Drs Mocco, Nakaji)

Standing Committee/Project Updates

Washington Committee (Katie Orrico Dr John Wilson)
Coding & Reimbursement (Dr Vates and Woo)
Joint Guidelines Committee/CV Section Guidelines Committee (Dr. Cockroft)
National Quality Forum (Dr Cockroft and Khalessi)
Cerebrovascular Coalition, , Proposed changes to CSC certification, Abbott CMS CAS Coverage (Drs. Bambakidis, Cockroft, Amin-Hanjani, Wilson)
Metrics for Hemorrhagic Stroke (Dr. Zipfel)
Rapid Response Committee (Dr. Woo)
SNIS update (Dr. Albuquerque)
SVIN Liaison (Dr. Mocco)
International Liaison (Dr. Niemela)
Neuro-Critical Care Society Update (Dr. Amar)
YNS Liaison (Dr Fox)
Brain Attack Coalition (Dr.Huang)
Membership Update (Dr Mocco)
Fundraising Committee (Dr. Zipfel)
Dempsey Fellowship (Drs. Baskaya and Turner)
Newsletter Committee (Dr. Bulsara, Ducruet)
Website Committee (Drs Zipfel, Welch, Carter)
Curriculum Development and Education Committee (Dr. Bendok)
MOC Vascular Module (Drs. Bendok and Siddiqui)
Matrix and Milestones (Dr. Bambakidis)
Bylaws/Rules & Regulations Committee (Dr. Schirmer)
CAST/ Training Standards (Drs Siddiqui & Woo)

Old Business Updates
N2QOD (Drs. Connolly & Mocco)
Resident and fellow courses (Drs Mocco, Veznedaroglu, Arthur)
IAC carotid stent facility accreditation standards (Drs. Cockroft & Albuquerque)
3C meeting (Dr Siddiqui)
Brain Aneurysm Foundation, BAF/CV Sect C. Getch Research Award (Drs David & Zipfel)

New Business
Clinical Trials Advisory Committee (Drs Carter, Friedlander, Zipfel)
ARUBA Commentary (Dr Bambakidis)
Acute Stroke Trials Editorial (Drs Khalessi and Mocco)

Approval of Minutes

Dr. Sean D. Lavine

Treasurer's Report

Dr. Greg Zipfel

AANS/CNS Section on Cerebrovascular Surgery
Statement of Financial Position
As of June 30, 2013 and 2012

	Current Year 06/30/13	Prior Year 06/30/12
ASSETS		
Checking & Short Term Investments	$149,705	$149,113
Accounts Receivable, net of Allowance for Uncollectible Accounts	4,495	7,095
Prepaid Expenses	52,465	30,575
Long-Term Investment Pool, at Market	666,617	601,163
TOTAL ASSETS	$873,283	$787,946
LIABILITIES AND NET ASSETS		
Liabilities		
Accounts Payable and Current Liabilities	$21,130	$500
Deferred Dues	34,625	33,639
Total Liabilities	**$55,755**	**$34,139**
Net Assets		
Unrestricted	$598,133	$585,352
Unrestricted - Donaghy	$52,815	$48,359
Unrestricted - Galbraith	$28,857	$26,710
Unrestricted - Resident	($15,472)	($12,805)
Unrestricted - Leussenhop	$19,938	$19,215
Unrestricted - Drake	$10,794	$10,423
Unrestricted - Yasargil Lectureship	$58,742	$53,228
Net Revenue (Expense)	63,720	23,324
Total Net Assets	**$817,527**	**$753,807**
TOTAL LIABILITIES AND NET ASSETS	$873,283	$787,946

	FY '10 Final	FY '11 Final	FY '12 Final	YTD FY '13	FY '13 Budget	FY '14 Budget
REVENUES						
Membership Dues	46,750	54,648	55,348	66,264	62,550	64,000
Mailing List Sales	0	295	0	250	0	0
Contributions/Sponsorships	7,500	85,000	7,773	37,500	37,500	37,500
Advertising Revenue	0	1,300	0	0	0	0
Contributions for Operating Expenses	9,143	9,347	8,153	8,221	9,409	13,395
Annual Meeting Revenue	167,709	255,771	324,392	0	50,300	0
TOTAL REVENUES & SUPPORT	231,102	406,361	395,666	112,235	159,759	114,895
EXPENSES						
Audio Visual	1,477	1,192	279	4,329	1,500	1,500
Bank Fee	518	930	756	849	751	914
Contributions & Affiliations	60,000	10,000	30,000	10,000	10,000	15,000
Decorating	607	741	415	405	750	750
Facility	0	0	0	801	0	800
Food & Beverage	8,160	9,959	8,989	17,632	10,000	12,600
Honoraria & Awards	35,890	40,960	32,204	39,815	36,350	42,000
Office & other Supplies	343	200	100	382	300	380
Photocopy	95	1	9	0	25	25
Postage & Distribution	468	901	1,400	790	825	825
Printing/Typesetting	0	1,282	0	1,113	0	1,200
Newsletter Postage	0	998	0	0	1,025	0
Newsletter Printing	0	2,015	0	0	2,025	0
Newsletter Professional Fees	0	195	0	0	200	0
Website	540	699	1,140	0	30,000	10,000
Staff Travel	0	0	71	240	250	250
Telephone	566	268	550	709	325	600
Tours & Transportation	0	0	0	761	0	0
Volunteer Travel	386	0	0	1,526	1,000	1,000
Staff Coordination	10,081	11,539	9,930	12,313	19,431	18,314
Annual Meeting Expense	198,562	239,529	293,441	22,324	0	0
TOTAL EXPENSES	317,693	321,409	379,284	113,989	114,757	106,158
Investment Earnings	55,192	85,240	6,942	65,475	27,765	28,683
NET REVENUE	(31,399)	170,192	23,324	63,721	72,767	37,420

AANS/CNS SECTION ON CEREBROVASCULAR SURGERY

NOTES TO FINANCIAL STATEMENTS

June 30, 2013

General and Administrative

Expenses

Audio Visual – Budget $1,500, Actual $4,329

Due to the room layout in New Orleans, 2 screens and 2 projectors were needed for the section EC meeting. This increased A/V equipment and A/V labor costs. In addition, an A/V technician was required to be in the room during the meeting to monitor the microphones and sound equipment.

Facility – Budget $0, Actual $801

The Section was charged a room rental fee for the EC meeting at the SNIS/CV Annual Meeting. The Section has not previously incurred this charge at their annual meetings.

Food & Beverage – Budget $10,000, Actual $17,632

The CV Section Past Presidents Dinner was new this year and was not anticipated at budget time.

Honoraria and Awards – Budget $36,350, Actual $39,815

In years past, the Luessenhop Lecture has been paid from the CV Annual Meeting budget. Because of the joint meeting with SNIS, this was paid from CV general funds.

Printing/Typesetting – Budget $1,113, Actual $0

The cost of designing the updated Corporate Sponsorship Brochure was not included in the budget.

Newsletter Production – Budget $3,250, Actual $0

A printed newsletter was not produced in FY13.

Website – Budget $30,000, Actual $0

The new website was not live at the end of FY13. The cost of the new website will be depreciated over the next three years.

Tours & Transporation – Budget $0, Actual $761

The Section contracted transportation to the EC Dinner, which had not been done in the past.

Sponsorship Update - 6/30/13

CV Section

Budgeted Sponsorships:	Budgeted Amount	Date Received	Amount Received
Synthes	$ 7,500.00	9/19/2012	$ 7,500.00
Resident Research Award -1	$ 15,000.00	3/11/2013	$ 15,000.00
Resident Research Award -2	$ 15,000.00	3/11/2013	$ 15,000.00
Total Amount Received for FY13			**$ 37,500.00**

AANS Development Committee: One Ask/NREF

Drs. Haid and Tippett

2013 CNS Meeting
San Francisco, CA

Drs. Mocco and Nakaji

CNS CV Section
Moderators for Oral Abstracts: Alex Khalessi; William Mack
Moderators for Neurosurgical Forum Session: Eric Sauvageau; Andy Grande
Abstract Graders: Eric Sauvageau; Andy Grande; Alex Khalessi; William Mack

Section on Cerebrovascular Surgery
The Evolution of Neurosurgery
Moderators: Peter Nakaji, J Mocco
Learning Objectives:
Upon completion, participants will be able to:
Incorporate practical lessons learned into patient management plans related to neurovascular Problems. Define the forces shaping the future management of patients with cerebrovascular Problems. Enumerate the ways in which the evolution of cerebrovascular surgery has affected its current practice
2:00 – 2:05 PM
Introduction of Drake Lecturer Friedlander
2:05 – 2:30 PM Drake Lecture Dade Lunsford
2:30 – 2:45 PM
The future evolution of the Cerebrovascular Neurosurgeon: Implications for Training Greg Thompson
2:45 – 3:00 PM
How Japanese Neurosurgery has embraced acute stroke therapy: a lesson for the U.S.? Yuichi Murayama
3:00 – 3:15 PM
The thinning of the specialty: are we evolving ourselves towards too many CV specialists who provide worse care? Ray Turner
3:15 – 3:30 PM
Future Treatments for Cerebrovascular Pathology: After Clipping and Coiling Gary Steinberg

2014 CV Section/SNIS

San Diego, CA

Drs. Bambakidis, Mocco, Evandro de Oliveira

2014 Annual Meeting
"Adaptive Ingenuity"

- San Diego Hard Rock Hotel
- Mon – Tues Feb 10 – 11
  (Fellow course Feb 8-9: William Mack)
  - ISC Feb 12 – 14
  - Scientific Program Committee
    - Ncb, J Mocco, P Nakaji, A Arthur, R Hanel
    - M Kelly (SNIS)

2014 Annual Meeting

- Preliminary Program completed
  - 2 Didactic Sessions, 4 Concurrent Sessions, 4 Abstract Sessions, Complication Avoidance Session, Clinical Trials Update Session
- International Partner – SBN
  - Honored Guest: Evandro de Oliveira
- Luessenhop Lecture – Chris Ogilvy
- Abstract Center closed Oct. 30
  - 123 Abstracts submitted; grading now
- Registration opens Nov. 1
- Ongoing close communication with SNIS regarding budget for meeting

2014 ISC Meeting

San Diego, CA

Drs. Mack, Welch, Cockroft

2014 AANS Meeting
San Francisco, CA

Drs. Mocco and Nakaji

Standing Committees/ Project updates

AANS/CNS Washington Committee

Washington Committee Update

Katie Orrico, Dr Wilson

Coding and Reimbursement Subcommittee

Dr. Edward Vates

Joint Guidelines Committee & CV Section Guidelines Committee

Dr. Cockroft

AHA/ASA Projects

Management of Cerebral & Cerebellar Infarction With Swelling

- Babu Welch (Lead Reviewer)
- Stavropoula Tjoumakaris
- Chirag Gandhi
- Jared Knopman
- Clemens Schirmer

(Bob Carter was writing group representative)

STATUS: Reviews completed. Endorsed 08/21/13

AHA/ASA Projects

Guidelines for Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack (Secondary Prevention)

- William Mack (Lead Reviewer)
- Alexander A. Khalessi
- Nathaniel Brooks
- Sean Christie
- Jack Jallo
- John Kestle

(John Wilson is writing group representative)

STATUS: Reviews completed. Endorsed 9/23/13.

AHA/ASA Projects

Palliative and End-of- Life Care in Stroke

- Ketan Bulsara (Primary)
- Justin Fraser
- Roc Chen
- Bill Ashley
- Rabih Tawk

(Greg Zipfel writing group rep)

STATUS: Review completed, endorsement recommended, awaiting AANS/CNS letter.

AHA/ASA Projects

Women's Guideline for the Prevention of Stroke

- Gregory Zipfel (Lead Reviewer)
- J Mocco
- Christopher Madden
- Marjorie C. Wang
- Christopher Zacko

(Issam Awad was writing group representative)

STATUS: Initial review completed. Revision received.

AHA/ASA Projects

Risk of Cervical Arterial Dissection After Cervical Manipulation Including Chiropractic Manipulative Therapy

- Pascal Jabbour (Primary)
- Bill Mack
- Nick Bambakidis
- Henry Woo
- John Reavey-Cantwell

(Felipe Albuquerque writing group rep)

STATUS: Initial review complete, awaiting revision from writing group.

AHA/ASA Projects

Guidelines for the Primary Prevention of Stroke

- Kevin Cockroft (Lead Reviewer)
- Steve Casha
- Kathryn Holloway
- Reavey-Cantwell
- Bill Mack
- Krystal Tomei

(John Wilson is writing group representative)

STATUS: In peer review.

Upcoming Guidelines/Statements

Guidelines for Management of Unruptured Intracranial Aneurysms

- **GregThompson**
- Robert Brown
- Joe Broderick
- **Kevin Cockroft**
- **Sander Connolly**
- Gary Duckwiler
- **Sepi Amin-Hanjani**
- Catherine Harris
- Virginia Howard
- Clay Johnston
- Phil Meyers
- Andrew Molyneux
- **Chris Ogilvy**
- **Andy Ringer**
- James Torner

Upcoming Guidelines/Statements

- **Scientific Rationale for the Inclusion and Exclusion Criteria for Intravenous Thrombolysis**- ANS/CNS writing group representative is **Alex Khalessi**

- **Guidelines for the Management of Spontaneous Intracerebral Hemorrhage** – AANS/CNS writing group representative is **Bernard Bendok** (note: this guideline was commissioned in March, 2012, but on hold until March, 2013)

Thank You to All Committee Members

Sepideh Amin-Hanjani, MD. UIC

William W. Ashley Jr., MD PhD MBA, Loyola

Mark Bain, MD, Cleveland Clinic

Nicholas Bambakidis, MD, Case Western

Ketan Bulsara, MD, Yale University

Roc Chen, MD, University of Texas, Houston

Carlos A. David, MD, Lahey Hospital & Medical Cntr.

Justin F. Fraser, MD, University of Kentucky

Chirag Ghandi, MD, UMDNJ

Nestor Gonzalez, MD, UCLA

Andrew Grande, MD, University of Minnesota

Brian Hoh, MD, University of Flordia

Judy Huang, MD, Johns Hopkins

Pascal Jabbour, MD, Jefferson

Babak Jahromi, MD, University of Rochester

Robert James, MD, East Carolina

Alexander A. Khalessi, MD, UCSD

Shah Naz Kahn, MD, University of New Mexico

Jared Knopman, MD, New York Presbyterian

William J. Mack, MD, USC

J. Mocco, MD, Vanderbilt

Aditya Pandey, MD, University of Michigan

John Reavey-Cantwell, MD, VA Commonwealth Univ.

Clemens M. Schirmer, MD, PhD, Baystate/Tufts

Scott Simon, MD, Penn State University

Rabih G. Tawk, MD, Mayo - Jacksonville

Stavropoula Tjoumakaris, MD, Jefferson

Babu G. Welch, MD, Univ. of Texas, Southwestern

Henry Woo, MD, Stony Brook University

Greg Zipfel, MD, Washington University

National Quality Forum

Dr. Kevin Cockroft

Dr. Alex Khalessi

NATIONAL QUALITY FORUM

Neurology Endorsement Maintenance – Phase I

DRAFT TECHNICAL REPORT FOR COMMENT

July 13, 2012

Measure group #5: Mortality and Readmissions

Number and Title	0467 Acute Stroke Mortality Rate (IQI 17)	2026 Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following an acute ischemic stroke hospitalization	2027 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following an acute ischemic stroke hospitalization
Measure focus	In-hospital death	Death (any cause) within 30 days of index admission	Readmission (any cause) within 30 days of index discharge
Patient population	Patients 18+, principal dx=stroke	Patients 65+, 12 months FFS Medicare Part A/B, principle dx=acute ischemic stroke	Patients 65+, 12 months FFS Medicare Part A/B, principle dx=acute ischemic stroke
Denominator exclusions	Transferring to another short-term hospital, MDC 14 (pregnancy, childbirth, and puerperium), missing discharge disposition, gender, age, quarter, year or principal diagnosis	Transferred from another acute care hospital, with inconsistent or unknown mortality status or other unreliable data, discharged against medical advice (AMA), enrolled in the Medicare hospice program any time in the 12 months prior to the index hospitalization including the first day of the index admission	Within hospital death, transferred to another acute care facility, discharged against medical advice (AMA), without at least 30 days post-discharge claims data, only one 30-day readmission counted, no hospitalization counted as both a readmission and an index admission
Timeframe	In-hospital	Within 30 days	Within 30 days
Level of analysis	Facility	Facility	Facility
Data source	Administrative claims	Administrative claims, other	Administrative claims

Cerebrovascular Coalition/CSC Certif/ Abbott CMS Coverage

Drs. Bambakidis, Cockroft, Amin-Hanjani, WIlson

Comment on Coverage with Evidence Development Policy for CAS

- Formal request that CMS open National Coverage Decision for CAS to symptomatic patients with FDA-approved indications
- Also propose expanded coverage for a subset of asymptomatic patients, proposed enrollement in a CREST-2 companion registry
- CV Section has formal response
  - To be discussed at CVC call to attempt to gain consensus

Cerebrovascular Coalition (CVC)

- Coalition members include:
  - · American Academy of Neurology
  - · AANS/CNS Cerebrovascular Section
  - · American Society of Neuroradiology
  - · Society of NeuroInterventional Surgery
  - · Society of Vascular and Interventional Neurology

CVC Agreement approved and endorsed

- Each member gets one vote (one for CNS, one for AANS)
- Meet annually at ISC meeting

Ongoing Projects

- Response to CSC certification requirements submitted Oct 1 signed by all members
  - Supported changes to aneurysmal SAH to 35 annually (from 20); 10 clip and 20 coil minimum (from 15 coil or clip)
  - Advocated for adopting 10 case annual minimum for IAT
  - Addressed requirement that Neurosurgeon on call cannot be on call at any other hospital or for any other hospital service

Metrics for Hemorrhagic Stroke

(Dr. Zipfel)

Rapid Response Committee

(Dr. Woo)

SNIS Update

Dr. Albuquerque

Update on SNIS 2013

Felipe C. Albuquerque, MD
Treasurer, SNIS

Board of Directors

Philip Meyers, MD

Peter Rasmussen, MD

Don Frei, MD

Felipe Albuquerque, MD

Richard Klucznik, MD

Lee Pride, MD

Blaise Baxter, MD

William Mack, MD

Shazam Hussain, MD

Michael Alexander, MD

Joshua Hirsch, MD

Michael Kelly, MD, PhD

Charles Prestigiacomo, MD

Lee Jensen, MD – ex officio

Rob Tarr, MD – ex officio

Cooperative Projects

- ***Brain Attack Coalition – Stroke care issues***
- ***Neurovascular Coalition – Neurovascular issues***
- ***ACGME Endovascular Surgical Neuroradiology Fellowship***
- ***Meeting programming***
- ***Standards***

Ischemic stroke

Performance and training standards for endovascular ischemic stroke treatment

Writing Group for the American Academy of Neurology, AANS/CNS Cerebrovascular Section, Society of NeuroInterventional Surgery, and the Society of Vascular & Interventional Neurology, P M Meyers,[1] H C Schumacher,[2] M J Alexander,[3] C P Derdeyn,[4] A J Furlan,[5] R T Higashida,[6] C J Moran,[4] R W Tarr,[7] D V Heck,[8] J A Hirsch,[9] M E Jensen,[10] I Linfante,[11] C G McDougall,[12] G M Nesbit,[13] P A Rasmussen,[14] T A Tomsick,[15] L R Wechsler,[16] J R Wilson,[17] O O Zaidat[18]

[1]New York Presbyterian Hospital, Columbia University, College of Physicians & Surgeons, Neurological Institute, New York, New York, USA [2]Albert Einstein College of Medicine, New York, New York, USA [3]Cedar Sinai Medical Center, Los Angeles, California, USA [4]Washington University,

ABSTRACT

Stroke is the third leading cause of death in the USA, Canada, Europe, and Japan. According to the American Heart Association and the American Stroke Association, there are now 750 000 new strokes that occur each year, resulting in 200 000 deaths, or 1 of every 16 deaths, per year in the USA alone. Endovascular therapy for patients with acute ischemic stroke is an area of intense inves-

At present, the only therapy demonstrated to improve clinical outcomes from acute ischemic stroke is thrombolysis of the clot responsible for the ischemic event.[5] Specifically, the only Food and Drug Administration (FDA)-approved stroke therapy is intravenous tissue plasminogen activator within 3 h of stroke onset.[5] Endovascular therapy for patients with acute ischemic stroke is an area of intense in-

Standards

- **Currently writing/revising standards pertaining to the management of aneurysms with flow-diversion, vertebroplasty/kyphoplasty, carotid revascularization with stent-angioplasty, platelet testing for INR procedures, and dural fistulas**

Meetings

SNIS Annual Meeting

Miami, FL

640 attendees

IESC/Joint CV Section Annual Meeting

Honolulu, HI

530 attendees

Publications - Journal Update

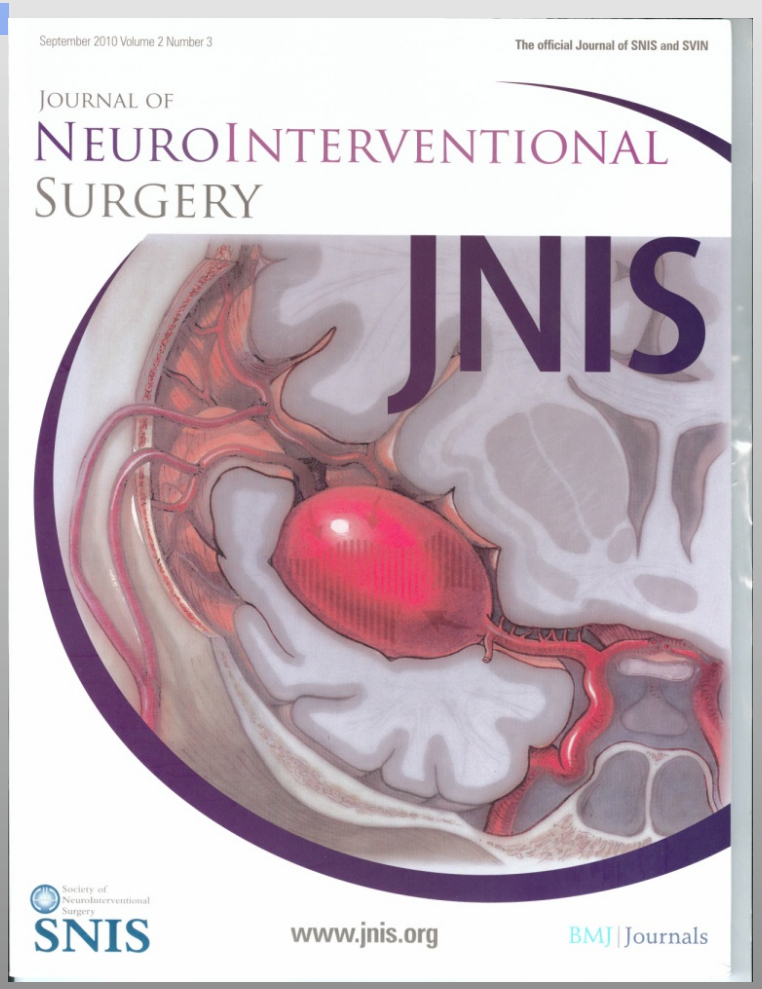
Initial publication July 2009 as a quarterly journal

Indexed in Thomson-Reuters 2010

Impact factor 1.378 (50% increase from 2012)

Pub Med / Medline indexing September 2011

With increased U.S. and International submissions will transition to publication 10 times/year in January 2014



Societal Converging Goals

- ***Quality outcomes data***
- ***Pay for performance evaluation and issues***
- ***Medicare reductions in payment***
- ***Standards of practice – stroke, carotids, aneurysms***
- ***Defining the appropriate randomized trials***
- ***Coding – angiography bundling***
- ***"Comprehensive Stroke Center" designation***
- ***Refining standards of training in Endovascular***
- ***Generating resident interest in Neurovascular***

Other SNIS Efforts

- **Developing a Fellows Committee within SNIS Executive Committee to address vital needs such as getting jobs out of training and developing future leadership of the SNIS and JNIS**

SNIS Update Summary

Healthy membership growth of this multi-disciplinary society

Successful annual meetings and more involvement with CV Section

Indexing of JNIS journal in Pub Med, and transition to bi-monthly publication

SVIN Liaison

Dr. J Mocco

International Liaison

Dr. Niemela

Neurocritical Care Society Liaison

Dr. Amar

YNS Liaison

Dr Fox

Brain Attack Coalition

Dr. Judy Huang

Joint Commission Criteria for Comprehensive Stroke Center (CSC) Certification

- Jan 28, 2013 letter
- CV Section, AANS, CNS, ABNS, SNS, SVIN, SNIS, AAN
- Recommendations for SAH care
  - 1) ≥ 30 procedures for aneurysms (minimum 10 clipping & 20 endovascular)
  - 2) ≥ 35 patients annually with aSAH
- Acute ischemic stroke – minimum 10 cases

Membership Update

Dr Mocco

Fundraising Committee

Dr. Zipfel

Research Fellowship Committee

Drs. Baskaya, Turner, Dempsey

University of Wisconsin
SCHOOL OF MEDICINE
AND PUBLIC HEALTH

Department of Neurological Surgery

Cerebrovascular Research Award Update – 2013

As Chair of the Robert J. Dempsey, MD, Cerebrovascular Research Award, I am pleased to report the Cerebrovascular Section of the American Association of Neurological Surgeons and The Congress of Neurological Surgeons once again awarded two $15,000 Resident Research Awards in Cerebrovascular Disease in 2012-13. There were a record number of applications this year. All were outstanding, but judged to be winners of this award for 2012-13 are:

Dr. Stanley Hoang of Stanford Hospital and Clinics for his study, "Effects of optogenetic neuronal stimulation of the primary motor cortex on axonal outgrowth, synaptogenesis and angiogenesis following cerebral ischemia", and Dr. Luis Enrique Kolb from Yale-New Haven Hospital for his study, "Whole Exome Sequencing of Sporadic AVM". Winners of this award will be acknowledged at the 2014 AANS/CNS Cerebrovascular Section Meeting.

The reviewers for the past year were: Drs. Robert Dempsey, Robert Friedlander, Mustafa Baskaya, Dandan Sun, and G. Edward Vates. We appreciate their help and hope they will be able to continue in the future.

The Joint Section has taken on the responsibility of fundraising to establish ongoing funding. Assuming the funding will again be successful, information and applications for the 2014 award will be sent to program directors, neurosurgery journals, and appropriate websites in October and November, with applications due by March 1, 2014. We look forward to another year promoting resident research.

Sincerely,

Robert J. Dempsey, MD
Chairman and Manucher J. Javid
Professor of Neurological Surgery
Department of Neurological Surgery

RJD:lvb

Newsletter Committee

Drs. Bulsara, Ducruet

Website Committee Report

Drs Zipfel, Welch, Carter

Committee Members

Bill Ashley
Bernard Bendok
Bob Carter
Roc Chen
Amir Dehdashti
Aclan Dogan
Rose Du
Edward Duckworth
Chirag Gandhi
Fernando Gonzalez
Andrew Grande
Rob James
Bill Mack
Aditya Pandey
Clemens Schirmer
Scott Simon
Rabih Tawk
Babu Welch

Update

Contract signed with Vividsites	September 6, 2012
Website kickoff meeting	September 14, 2012
Sitemap and content development	Oct to Nov, 2012
Sitemap finalized	December 7, 2012
Website Design	January 17, 2012
Website Beta	April 25, 2012
Website “Go Live”	June-July, 2012

Website Beta Version

- http://cv-section.vsstaging.com
- http://cv-section.vsstaging.com/_admin

Curriculum Development & Education Committee

Dr. Bernard Bendok

MOC Vascular Module

(Drs. Bendok and Siddiqui)

Matrix and Milestones

(Dr. Bambakidis)

Matrix and Milestones

- SNS asked for formation of ad hoc committee from CV Section for development of matrix and milestone specific educational content for use in Portal Project
- NCB (chair), S. Amin-Hanjani, G. Zipfel, P. Nakaji, A. Khalessi, S. Quintero
- Implementation awaiting decision on mechanism of implementation between AANS, CNS, SNS, ABNS

Bylaws/Rules & Regulations Committee

Dr. Schirmer

Bylaws/Rules & Regulations Commitee

Dr. Schirmer

- Call for interested members to become committee members (need 2)

CAST/Training Standards

(Dr. Bambakidis)

Old Business

N2QOD

Dr. Connolly

IAC Carotid Stent Facility Accreditation Standards

Dr Cockroft & Albuquerque

Intersocietal Accreditation Commission for Carotid Stent Facilities (IACCSF)

is now

IAC – Carotid Stenting|IACCSF

IAC – Carotid Stenting | **IACCSF**

- On-line application process
- Application includes: procedure logs with outcome data, descriptions of care processes, neurological assessment info, procedure reports
- Randomly selected procedures are evaluated for clinical appropriateness, image quality, technique, outcome & documentation quality
- Random audits & site visits

IAC – Carotid Stenting | **IACCSF**

- As of September 2013
  - 6 facilities accredited
  - 2 facilities deferred
  - 25 applications requested
- Most common deficiencies (45 procedures reviewed)
  - Overestimation of stenosis
  - NIHSS/mRS not consistently performed
  - Lack of 30 day follow-up
  - Complications not reported correctly
  - Incorrect evaluation of symptomatic status

2013 IAC Research Award

- One year awards supporting innovative and meritorious research relevant to accreditation and quality improvement
- For 2013, 4 grants funded totaling $100,000 and for 2014, 3 proposals totaling $135,000 were funded
- For 2015, grants up to a maximum of $75,000 will be awarded
- Application process involves a letter of intent, and if accepted a full proposal
- Call for Proposals will go out February 2014

Resident & Fellow Endovascular Courses

Drs Arthur, Mocco and Veznedaroglu

Resident and Fellow Courses

- Introduction to Cerebrovascular Neurosurgery for Junior Residents Practical Clinic .
  - To expose Jr. residents to what it means to be a combined cerebrovascular surgeon
  - Held at AANS meeting
  - Erol Veznedaroglu and J Mocco
- 3D Anatomy for Residents (emphasis on vacscular)
  - To review anatomy with emphasis on open cerebrovascular approaches
  - Held in Houston each August
  - Michael Lawton
- AANS Endovascular and Open Cerebrovascular Course for Senior Residents
  - To practice endovascular and open surgical techniques with reperfused cadaver and live models
  - Held at MERI, November 7-9
  - Erol Veznedaroglu, Michael Lawton, Adam Arthur
- ENRG Boot Camp for Beginning Endovascular Fellows
  - To prepare fellows entering fellowship
  - Held at 3C meeting
  - Andy Ringer
- CV Section/SNIS Joint Fellows Courses
  - To expose fellows in training to didactics and new technology
  - Held at CV Section and SNIS Meetings
  - 1 CV Section and 1 SNIS director
- AANS/SNIS/SVIN Endovascular Course for Senior Fellows
  - To practice endovascular techniques with live models
  - Held at MERI, October 4-6
  - Erol Veznedaroglu and Adam Arthur

3C meeting

Dr Adnan Siddiqui

Brain Aneurysm Foundation/C. Getch Research Award

Dr Carlos David & Zipfel

New Business

Clinical Trials Advisory Committee

Drs. Carter, Friedlander, Zipfel

ARUBA Commentary

Dr. Bambakidis

ARUBA Commentary

- Written in response to DSMB decision to halt ARUBA in May, 2013
- Preliminary data presented at ESC in London
- Event rate 3x higher in intervention group vs. medical management group
- Commentary in response published in Neurosurgery, 2013 Aug:73(2):E379-81)

Acute Stroke Trials Editorial

Drs Khalessi, Mocco

Thank you!

Minutes AANS/CNS Cerebrovascular Section Executive Council Meeting
April 28, 2013
New Orleans, LA – New Orleans Marriott

ATTENDEES

Sepideh Amin-Hanjani, Chair	John Wilson	Alex Coon
Brian Hoh	Philip Stieg	William Mack
Carlos David	Scott Simon	Robert James
Kevin Cockroft	Nicholas Bambakidis	Fernando Gonzalez
J. Mocco	Ed Vates	Babu Welch
Clemens Schirmer	William Ashley	Alexander Khalessi
Adam Arthur	Henry Woo	
Alex Valadka	Robert Friedlander	
David Langer	Greg Zipfel	
Bernard Bendok	Adtya Pandey	Invited Guest SNIS President and CV Section Member: Michael Alexander (SNIS)
David Hasan	Stavropoula Tjoumakaris	
P. Roc Chen	Adnan Siddiqui	
Judy Huang	Pascal Jabbour	
Robih Tawk	Sean Lavine	
Ketan Bulsara	Sander Connolly	

I.	**Call to Order** *Dr. Amin-Hanjani*	Sepi Amin-Hanjani, Chair, called the meeting to order at 4:00 PM	
II.	**Approval of Minutes from CNS 2012** *Dr. Lavine*	The minutes were presented to the members in attendance for review and approval. No comments were proposed.	**MOTION was made for approval, which was seconded and unanimously approved.**
III.	**Treasurer's Report** *Dr. Hoh*	In Dr. Hoh reported they recently received the financial statement from the SNIS regarding the CV Section annual meeting. Total revenue loss was 41K that was split between CV and SNIS. Therefore, we incurred a 21K loss. Two components that added to the loss were location (Hawaii) and last minute registrations (200) that lead to additional food and beverage costs. Additionally, there was a faculty dinner that is not usually a component of the CV Section stand-alone meeting. Compared to past meetings losses in 2009/San Diego (41K) and 2010 San Antonio (31K) this meeting was not out of the ordinary. Dr. Hoh will be in contact with Marie Williams at SNIS to discuss options for keeping expenses down for the 2014 meeting. One option is to slightly increase registration fees. However, total financial picture is the Section is 74K in the black for FY13. Dr. Hoh announced that he has now completed his term as Treasurer and indicated what a pleasure and honor it was to serve the CV Section in this role. Dr. Alexander reported that unlike past years and years going forward, the 2013 meeting incurred a meeting room rental fee of 14K. This is typically free due to number of registrants that are housed at the hotel. Therefore, the 2014 meeting will not have that additional charge. Dr. Cockroft suggested that the Chair, Treasurer, Scientific Committee and	

		SNIS should review and discuss budget prior to the meeting so that everyone is aware of any unforeseen expenses. Dr. Amin-Hanjani suggested that the Treasurers from both the CV Section and SNIS discuss budget with the Scientific Committee for items related to registration fees, speaker expenses and food and beverage costs so there are no major surprises.	
IV.	**Annual Meeting Updates** **2014 SNIS/CV Sect Annual Meeting** *Drs. Alexander and Cockroft*	The association with the Japanese was considered very successful at this meeting, and many of their speakers were involved in the scientific program. It was felt that the next joint meeting would be benefitted by partnering with the South American Vascular Specialists. Dr. Alexander reported that the venue is being confirmed with the SNIS for San Diego at the Hard Rock Hotel. The two day format will be continued for Monday and Tuesday with the pre-meeting fellow course. Budgetary issues will be discussed with SNIS to keep costs down and possible revenue increase of registration fees. The abstract center cost through the SNIS was 6K. It was discussed to investigate a lower cost option for the 2014 meeting.	**<u>MOTION</u> was made for to consider partnering with the South American Society, which was seconded and unanimously approved.**

	2014 ISC Meeting *Drs. Cockroft, Mack*	Dr. Amin-Hanjani indicated that the ISC will continue to allow the CV Section involvement in the ISC meeting program. It took a significant effort to keep three neurosurgical representatives on the program committee. Dr. Cockroft congratulated both Drs. Amin-Hanjani and Murat for their encouragement and reminder to ISC of the CV Section involvement that was agreed upon with the ISC. He commented that many CV Section EC members will be involved in their upcoming meeting sessions. Three sessions have been submitted so far. Members are encouraged to submit additional sessions, it is acceptable to suggest yourself or your group as moderators or speakers. The number of sessions are related to the numbers of abstracts submitted.	
	2013 AANS Meeting *Drs. Bambakidis*	Dr. Bambakidis reported that section session is set for Wed. afternoon. Dr. Charbel will be giving the Donaghy Lecture. Drs. Cockroft and Connolly will be talking about issues related to patient outcomes and safety. There are 10 abstracts for presentation.	
	2013 CNS Meeting *Dr. Mocco*	Dr. Mocco was not present. Dr. Amin-Hanjani represented slide on fall meeting with "Evolution of Neurosurgery" as the theme. The Drake Lecture is tbd.	

V.	**Standing Committees/Project Updates**		
	Washington Committee Update (*Dr. Wilson and Katie Orrico)*	Dr. Wilson stated his appreciation of the CV Section to allow the Washington Committee involvement with their endeavors. He asked if there are any specific items that need to be addressed at this time. The CV EC indicated that there were no major issues to discuss at the moment.	
	Coding & Reimbursement (*Dr. Vates*)	Dr. Vates was unable to attend due to the RUC Committee. Dr. Woo reported that the one code that just was reviewed at the RUC was the retrograde open carotid angioplasty and stenting. The RUC is going to recommend valuation at 50%, which is the median. It will probably get knocked down to 25% when it eventually goes to the CMS. The fall RUC will likely have the thrombosis codes reviewed. SIR and radiology tabled that discussion until then. Josh Hirsch from the SNIS will also be involved.	
	Joint Guidelines Committee/CV Section Guidelines Committee (*Dr. Cockroft*)	Dr. Cockroft reported on the status of the flagship guidelines for treatment of unruptured aneurysms is in progress with good representation from this group. Review of two other guidelines including palliative care and cervical carotid	

		dissection is currently underway. We were involved with 8 AHA Flagship Guidelines from 2009-10. The exception was acute stroke, but we will be involved in the next rendition.	
	National Quality Forum (*Drs. Cockroft and Khalessi*)	Per Dr. Cockroft, there are no updates at this time.	
	Cerebrovascular Coalition (*Drs. Bambakidis and Cockroft)*	Formerly called the Neurovascular Coalition. Dr. Bambakidis stated there was a conference call with SNIS, SVIN and a memorandum of understanding has been circulated and approved. Each of the organizations gets one vote in terms of endorsement of documents. Dr. Amin-Hanjani stated that a press release will be out mid/late July prior to print of the Khalessi/Mocco article regarding the trio of studies related to acute stroke intervention that were recently published. Discussion of placing this on the website. Issue of copyright raised if this article is published in neurosurgery.	
	Rapid Response Committee (Dr. Woo)	Dr. Woo reported on the reperfusion grading that was generated from the STAIR meeting. The TICI Scores were vetted. Also a major discussion was the best current acute stroke trial, THERAPY or SWIFT. Topics also included Broderick's NEJM commentary and a possible new journal titled "Stroke Intervention".	
	SNIS Update (*Dr. Alexander*)	Dr. Alexander reported that the attendance for the 2013 meeting and fellows'	

		course was terrific. 2014 meeting will be in San Diego/2015 San Francisco. JNIS – 8 issues for 2013/every other month. Last year was first full year for the foundation yielding 275K and funded 7 endovascular fellowship grants July – Funding young investigator research cerebrovascular grant awards Website being updated including instructional videos for patients. SNIS has chosen a comprehensive CV database. Not going with NQ2OD. Have gone with M2S database platform beginning with 3 modules: CAS, aneurysms, and thrombectomy. Cost and proven record were major considerations.	
	SVIN Liaison (Dr. Mocco)	Dr. Mocco was not present. Dr. Amin-Hanjani reported that there were no major updates to report other than responding to controversial statements made by Dr. Yavagal from the SVIN.	
	Neurocritical Care Society Update (Dr. TBD)	No representative at this meeting Need to communicate with them to formalize representation on both sides	
	Young Neurosurgeons's Committee (Dr. Fox)	Dr. Chris Fox reported that the other liaison, Randy Bell, is unable attend due to currently serving in Afghanistan.	

	Brain Attack Coalition (*Dr. Huang*)	Dr. Fox announced a new fellowship for medical students. Inaugural two-year fellow will attend the 2014 AANS meeting with financial support.	
	Membership Update (*Dr. Zipfel*)	Dr. Huang unable to attend. Dr. Amin-Hanjani reported the most prominent issue is the comprehensive stroke center certification. A multi-societal letter has been generated to challenge the number of patients proposed for certification. The commission is currently considering the consensus recommended changes. Dr. Zipfel reported that a recruitment e-blast was sent to non-members registered for the annual meeting, offering a one-year free membership and have had three apply so far. Continue with additional recruitment e-blasts to partnering organizations.	
	Fundraising Committee (*Drs. Hoh and Rasmussen*)	Thanks were given to Dr. Zipfel's outstanding work over the last several years. Dr. Mocco has been chosen by Dr. Amin-Hanjani to take over this important position. Dr. Hoh reported the annual corporate prospectus going out in the fall. 30K was raised for Dempsey research award with the efforts of Ray Turner. Dr. Hoh suggested that the Dempsey Research Award name to change to the Dempsey Fellowship Award. This will be important for Corporate Sponsorship, as the research term complicates their ability to donate. Better recognition of the award at the annual meeting was recommended.	
	Research Fellowship (*Drs. Baskaya and*		

	Turner)	Dr. Baskaya reported on the two fellowship recipients. There were 21 applications total.	
	Newsletter Committee (*Drs. David and Bulsara*)	Dr. David stated that due to the size of the newsletter an eblast will be sent with a link to direct members to the CV Section website where the newsletter will be posted. Many members were not able to access or open the file through traditional email. Next newsletter will be available late summer/early fall. Dr. Bulsara will take over primary responsibility for the newsletter. Thanks to Dr. David for his excellent work.	
	Website Committee (*Drs. Zipfel and Carter*)	Dr. Zipfel reported that within a month or two they should be finalizing content and go live. More patient content included on procedures in "For Patients" tab. Listing of CV members by state and region. Working with AANS to create login and password to coincide with their AANS login. Case of the month and blogs will be added.	
	Curriculum Development and Education Committee (*Dr. Bendok and Siddiqui*)	Will look into abstract submissions through our website. Dr. Bendok reported that there are three simultaneous projects 1 Creation of vascular MOC 2 AANS MOC Book – Case based/references	

		3 SANS CNS MOC June 1 - Deadline to submit questions July 1 – Questions to ABNS Webinar on how to write questions planned. Chapters for the MOC book will mirror topics covered in the questions. These will be requested from individuals with a 6 month turn-around time. A vascular component on the SANS exam will be the 3rd arm of this project. It was suggested that we collaborate with the SNIS for question-writing as they generate a board-certification exam.	
	Matrix and Milestones (*Dr. Bambakidis*)	Currently in process with the assistance of all organizations, but in particular the SNS. The goal is for residents to track their development throughout their training.	
	Bylaws/Rules & Regulations Committee (*Dr. Prestigiacomo*)	Dr. Amin-Hanjani requested those interested in participating with the milestones concept to please notify us	
	Old Business Updates	Dr. Amin-Hanjani reported that there were some recent Bylaws/Rules & Regulation changes that were approved at the EC in Hawaii and put out membership approval. Both the AANS and CNS also voted and approved of the changes during the AANS meeting in New Orleans. Dr. Prestigiacomo was thanked for his service as the committee chair. Dr. Clemens Schirmer will be taking over this responsibility.	

	N2QOD (*Dr. Mocco*)	Dr. Mocco reported that there is one more round for vetting the modules. SNIS sub-committees also reviewed and hope to have final product in hand in the near future. Cerebrovascular and Tumor modules will be the primary focus. Packages will be sent out soon for commitment from CV Section members. Would like to have cross-talk with the SNIS to have identical measurements for areas such as stroke in the database they choose. Cost remains an issue. The database needs to be CMS qualified.	
	Junior Resident Endovascular Course (*Drs. Mocco and Veznedaroglu)*	Dr. Mocco stated the junior resident course was moved this year from as part of the CV annual meeting to a practical clinic course during the AANS meeting. Robust attendance at 58 registrants. No direct industry financial support. Social evening event still a component. AANS supported. Dr. Amin-Hanjani suggested that this format and time frame be set the same for next year. We will also participate in the fellows' course at the back end of the SNIS meeting in Miami this summer.	
	IAC carotid stent facility accreditation		

	standards *(Dr. Cockroft & Albuquerque)*	Dr. Cockroft reported the most active issue is research arm for proposals for grant initiation.	
	Brain Aneurysm Foundation (*Dr. David*)	Dr. David reported that they will be on Capitol Hill on May 21 for their lobbying initiative. They are also in the process of restructuring their board.	
	Meri Institute/CV Sect Resident & Fellows Courses, AANS open course, AANS/SNIS/SVIN endovascular Fellows Course (Drs. Mocco, Ho, Veznedaroglu, Arthur	Dr. Arthur reported there will be a combined endovascular fellow course with the faculty from the CV Sect, SNIS and SVIN Oct 4-6 at the Meri Institute. Nov. 7-9, first combined open and endovascular course for mid-level residents, including swine, flow-models and cadavers.	
	3C Meeting (*Drs. Levy and Siddiqui*)	Dr. Mocco reported is 3C meeting will be June 27-30 with a very significant international component.	
	New Business		
	CTAF (Dr. Khalessi)	Dr. Khalessi reported that the CTAF (California Tech Assessment Force) held a meeting that included a spirited debate about the use of mechanical thrombectomy for acute stroke. This group advises BC/Blue Shield. There was	

V.	**Standing Committees/Project Updates**		
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October 1, 2013

Jean E. Range, M.S., R.N., C.P.H.Q.
The Joint Commission
Standards and Survey Methods
One Renaissance Blvd.
Oakbrook Terrace, IL 60181

RE: Proposed Requirements for Advanced Comprehensive Stroke Centers Certification

Dear Ms. Range,

This is a joint letter on behalf of the Cerebrovascular Coalition (CVC). The CVC represents the views of the Society of Neurointerventional Surgery (SNIS), the Joint Cerebrovascular Section of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), the Society of Vascular and Interventional Neurology (SVIN) and the American Academy of Neurology Stroke System Work Group (AAN SSWG). This letter is related to the most recent recommendations by the Joint Commissions' Comprehensive Stroke Center Certification Technical Advisory Panel (CSC TAP) addressing requirements for endovascular acute stroke intervention capabilities at comprehensive stroke centers. We wish to comment positively on many of the recommendations of the CSC TAP; however we still have reservations regarding some aspects of the recommendations. In particular, this document aims to express the common position of the CVC that Joint Commission CSC certification recommends a minimum case volume of an average of 10 cases per year over three years for endovascular acute stroke therapy at comprehensive stroke centers.

With respect to the most recent recommendations of the CSC TAP regarding aneurysm treatment and management of aneurismal subarachnoid hemorrhage (SAH), we are pleased that our multi-societal recommendations for 10 clip/20 coil, and 35 aneurysmal SAH cases annually have been adopted. Though not as high as many of us would like, this is a major improvement on the prior 15 coil or clip requirements. We applaud the CSC TAP for incorporating these minimum standards.

We remain, however, disappointed that the recommendations regarding procedural volumes for Intra-arterial Therapy (IAT) were not adopted. We strongly believe that, akin to the intracranial aneurysm model, volume requirements should also be in place for endovascular stroke therapy for reasons outlined below.

The Joint Commission's current proposed recommendations that fail to include any volume requirements for endovascular stroke therapy are based on the perception derived from recent randomized trials that the clinical

benefit of endovascular therapies for acute stroke is uncertain. Two of these recent trials (IMS3 and SYNTHESIS EXPANSION) have addressed the benefit of endovascular therapy either as adjunct to IV t-PA (IMS3) or as standalone therapy (SYNTHESIS EXPANSION) in IV t-PA eligible patients compared to IV t-PA alone. These studies have found no significant differences in clinical efficacy or safety between endovascular therapy and IV t-PA in this patient population. Nonetheless, even within the limitations of the recanalization modalities used in IMS3 and SYNTHESIS EXPANSION, data emerging from these studies supports the notion that patients presenting within the time window for IV t-PA who are not candidates for IV thrombolysis (for instance due to concurrent anticoagulation treatment or recent major surgery) are likely to benefit from endovascular therapy compared to no reperfusion therapy. This benefit has in fact been proven in a randomized trial (PROACT II) and reinforced by meta-analyses that included other randomized trials. Therefore, endovascular therapy for **IV t-PA ineligible patients** presenting within the time window for iv t-PA is considered level IB evidence and endorsed as such by several professional organizations, including the American Heart Association/ American Stroke Association, in their guidelines statement for treatment of acute ischemic stroke. In support of this approach, a recent editorial published by the executive committee of the IMS 3 trial recommends that endovascular therapy for acute stroke in IV t-PA ineligible patients should continue to be reimbursed by insurance companies.

Furthermore, in keeping with findings from previous studies, stroke due to concomitant MCA and ICA occlusion is associated with particularly poor outcomes, even in patients undergoing IV t-PA. In IMS 3 the rate of favorable outcomes in patients with this vascular constellation was 4%. While insufficiently powered to detect a significant difference, in this trial, a trend towards favorable outcome was seen in the endovascular treatment arm in which 26% of patients achieved a favorable outcome. Of note, in IMS 3 these patients made up approximately 25% of all patients who underwent a baseline CTA and therefore represent a significant proportion of patients presenting with stroke of moderate or severe deficit.

We therefore believe that available data justifies mandating availability of endovascular treatment for acute stroke in IV t-PA ineligible patients presenting within the time window for IV t-PA. Certain subgroups of patients treated with IV t-PA who are highly likely to have devastating outcomes despite IV t-PA treatment, such as stroke due to ICA/MCA occlusion or stroke due to basilar artery occlusion failing to recanalize with t-PA, also justify the requirement of endovascular therapy as adjunctive treatment options at comprehensive stroke centers.

Similar to other complex interventions, emerging data supports the concept that procedural volumes by treating centers have a significant impact on outcome in endovascular therapy for acute stroke. Acute stroke interventions represent one of the most complex multidisciplinary functions a medical institution chooses to undertake. Reperfusion treatment achieved within the shortest period of time is widely accepted as a prerequisite for optimal clinical outcomes. Several studies, including the recently completed IMS3 have demonstrated that for every 30 minute delay in time to revascularization there is a 10% decrease in the likelihood of a good outcome from endovascular stroke therapy. There are many steps from stroke onset to completion of treatment and optimal execution of each of these steps is necessary to achieve the stated goal. It is highly doubtful that fine tuning of a process that entails this degree of complexity is possible by performing only a handful of procedures every year. In support of the notion that high volumes are necessary to optimize endovascular acute stroke care, a recent retrospective study conducted on 442 patients demonstrated that high volume centers defined as performing greater than 50 endovascular stroke procedures per year had shorter CT to groin puncture time and shorter overall procedural times which, in addition to the higher

recanalization rates observed at these centers are likely to explain the higher rates of favorable outcomes seen at high volume centers compared to low volume centers.

In patients presenting beyond the IV t-PA time window, evidence of benefit for endovascular therapy is lacking. However, prospective data in non-treated patients obtained from MR RESCUE demonstrate rates of good outcomes in 25% and mortality in 21% of patients, confirming previous reports that the natural history of acute stroke due to large vessel occlusion is poor. Therefore, improved treatment modalities need to be developed that will require validation through randomized clinical trials. In keeping with the overall mission of comprehensive stroke centers, availability of endovascular treatment should be required for treatment of patients presenting beyond the IV t-PA time window to advance stroke care by participation in clinical trials. A new generation of endovascular devices for stroke is currently in use across the country that has been shown to yield superior results in terms of recanalization rates, speed of recanalization, and safety compared to older modalities used in the recently published randomized trials. While superiority of these devices compared to IV t-PA or standard medical therapy remains to be proven in randomized trials, there are reasons to believe that use of these newer generation devices may have yielded different results than those reported in the recently published randomized trials. In fact, 3 randomized controlled trials of endovascular therapy with the new generation devices are now underway in the US: SWIFT-Prime, THERAPY and Separator 3D. Consistent recruitment of patients at CSCs in these vital RCT's requires CSCs to have a minimum annual case volume. Of course, the minimum case volume would also ensure that the proficiency of operators at a given center enrolling in these clinical trials is maintained at a high level.

In summary, we believe that the evidence supporting clinical benefit of endovascular therapy in patients presenting within the IV t-PA time window who are not eligible for IV t-PA should serve as the primary justification for requiring availability of endovascular stroke therapy at comprehensive stroke centers. The systems of care necessary for effective treatment implementation of this complex procedure are different from all other emergent neuroendovascular procedures with emphasis on the critical time to treatment aspect that is unique in importance to acute stroke interventions. As such, availability of the procedure alone is not sufficient to ensure optimal care of patients requiring such therapies. The complex infrastructure necessary for timely, safe and effective treatment of stroke patients undergoing percutaneous interventions can only be sustained within the framework of a continuous quality improvement process that requires a minimum of patients treated every year. Just like with aneurysm treatment, based on available data we believe that this minimum should be an average of 10 cases of endovascular acute ischemic stroke therapy per year measured over three years.

Finally, we are concerned regarding the requirement that neurosurgeons with expertise in cerebrovascular surgery cannot be concurrently on-call at any other hospital service or any other hospital. This unfounded lack of parity toward neurosurgeons regarding coverage requirements is without justification or merit. Neurosurgeons with cerebrovascular expertise should not be singled out regarding on-call responsibilities or hospital service when compared to other stroke specialists. If there is a concern regarding the ability of a CSC to provide emergency neurosurgical care, then time-to-treatment measures should be developed and would be more appropriate in determining adequacy of stroke therapies. If developed, such measures should be evenly applied across treatment team members, and not implemented to single out any one subspecialty.

Thank you for considering our comments. If you have any questions, or need additional information, please don't hesitate to contact us.

Sincerely,

American Academy of Neurology
American Association of Neurological Surgeons
Congress of Neurological Surgeons
AANS/CNS Joint Cerebrovascular Section
Society of Neurointerventional Surgery
Society of Vascular and Interventional Neurology

Contact:
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Washington State Health Care Authority
Health Technology Assessment

Health Technology Clinical Committee
Draft Findings and Decision

Topic: **Carotid Artery Stenting**
Meeting Date: **September 20, 2013**
Final Adoption:

Meeting materials and transcript are available on the HTA website at:
http://www.hta.hca.wa.gov/past_materials.html

Number and Coverage Topic:

20130920B – Carotid Artery Stenting

HTCC Coverage Determination:

Carotid Artery Stenting is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination:

Limitations of Coverage:

Concurrent with the placement of a Food and Drug Administration (FDA) -approved carotid stent and an FDA-approved or -cleared embolic protection device; and in accredited facilities as determined by the state agencies, the following additional criteria apply:

- For patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >50%.
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80%.

Non-Covered Indicators

Carotid Artery Stenting of intracranial arteries is **not covered.**

Definition of high risk includes:

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include, but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30 %;
- Unstable angina;
- Contralateral carotid occlusion;
- Recent myocardial infarction (MI);

Requirements Specific to Comprehensive Stroke Center Certification

a. The Comprehensive Stroke Center demonstrates that care is provided to 20 or more patients per year with a diagnosis of subarachnoid hemorrhage. b. The Comprehensive Stroke Center demonstrates that 15 or more endovascular coiling or surgical clipping procedures for aneurysm are performed per year.

c. The Comprehensive Stroke Center monitors annual aneurysm clipping and coiling mortality rates. d. The Comprehensive Stroke Center demonstrates that IV tissue plasminogen activator (tPA) is administered 25 or more times per year for eligible patients. Note 1: Providing IV tPA to an average of 25 eligible patients per year over a two year period is acceptable.

Note 2: IV tPA administered in the following situations can be counted in the requirement of 25 administrations per year: - IV tPA ordered and monitored by the CSC via telemedicine with administration occurring at another hospital. - IV tPA administered by another hospital which then transferred the patient to the comprehensive stroke center. e. Documentation exists to reflect tracking of performance measures and indicators.

1076 1077 1078 1079 1080 1081 1082 1083 1084 1085 1086 1087 1088 1089

a. The comprehensive stroke center demonstrates that care is provided to 35 or more patients per year with a diagnosis of subarachnoid hemorrhage. b. The comprehensive stroke center demonstrates that it is capable of treating aneurysms by performing a minimum of 10 microsurgical clippings per year.

Note: Performing␣30 microsurgical clippings over a three year period is ␣␣␣␣␣␣␣␣␣␣␣ c. ␣␣ ␣␣␣␣␣␣␣␣␣␣␣␣␣␣␣␣␣ performing a minimum of 20 endovascular coiling procedures per year.

Note: Performing␣60 endovascular coiling procedures over a three-year period␣␣␣␣␣␣␣␣␣␣␣␣␣␣␣

d. The comprehensive stroke center monitors annual aneurysm clipping and coiling mortality rates. e. The comprehensive stroke center demonstrates that: - Intravenous (IV) tissue plasminogen activator (tPA) is administered 25 or more times per year for eligible patients. Note 1: Providing IV tPA to an average of ␣␣ eligible patients␣over a two-year period

is acceptable. Note 2: IV tPA administered in the following situations can be counted in the requirement of 25 administrations per year: - IV tPA ordered and monitored by the comprehensive stroke center via telemedicine with administration occurring at another hospital - IV tPA administered by another hospital, which then transferred the patient within 24 hours to the comprehensive stroke center f. Documentation exists to reflect tracking of performance measures and indicators.

- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Definition of symptoms of carotid artery stenosis include: carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale ≥ 3) shall be excluded from coverage.

Agency Contact Information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC Coverage Vote and Formal Action

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Carotid Artery Stenting demonstrates that there is sufficient evidence to cover with conditions. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions Carotid Artery Stenting.

Carotid Artery Stenting

HTCC Committee Coverage Determination Vote			
	Not Covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Carotid Artery Stenting	0	0	**11**

Discussion

The Chair called for discussion of conditions of coverage for Carotid Artery Stenting following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

Limitations of Coverage:

Concurrent with the placement of a Food and Drug Administration (FDA) -approved carotid stent and an FDA-approved or -cleared embolic protection device; and in accredited facilities as determined by the state agencies, the following additional criteria apply:

- For patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >50%.
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80%.

Non-Covered Indicators

Carotid Artery Stenting of intracranial arteries is **not covered.**

Definition of high risk includes:

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include, but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30 %;
- Unstable angina;
- Contralateral carotid occlusion;

- Recent myocardial infarction (MI);
- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Definition of symptoms of carotid artery stenosis include: carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale ≥ 3) shall be excluded from coverage.

Action

The committee checked for availability of a Medicare coverage decision. There is a national coverage determination (NCD) for Carotid Artery Stenting (CAS). The committee reviewed the NCD and determined that based the availability of more recent study evidence to: cover extracranial CAS without a requirement of study participation for patient at high risk for CEA with stenosis of 50 to 70%; to cover without a requirement of study participation for asymptomatic patients at high risk of surgery for CEA with >=80% stenosis. These criteria provide access to coverage similar to the NCD without study participation as a requirement.

The committee determined noncoverage for intracranial stents based on evidence indicating serious safety concerns, and recognizing that state agency programs may provide coverage in the context

The committee Chair directed HTA staff to prepare a Findings and Decision document on Carotid Artery Stenting reflective of the majority vote for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

CV Section Response

Abbott's CMS Carotid Artery Stent (CAS) Coverage Expansion Strategy:

The CV Section leadership and selected membership representing both open and endovascular trained neurosurgeons have been engaged in discussions in response to a draft proposal by Abbott to a formal request that CMS open National Coverage Decision (NCD) 20.7 for reconsideration.

We believe it is the appropriate time for CMS to reconsider the current NCD, in light of: 1) the recently completed Carotid Revascularization Endarterectomy versus Stent Trial (CREST), which led the FDA to expand the indication for Abbott Vascular's CAS system to include standard surgical-risk *symptomatic* and *asymptomatic* patients, 2) the recent ACC/AHA Multi-Society Guideline publication with a Level I (Level of Evidence: B) recommendation for CAS as an alternative to CEA in *symptomatic* patients with a low risk of endovascular complication, and a Level IIb recommendation for *asymptomatic* patient, and 3) CMS' recent Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting held in January 2012. In addition, there is increasing evidence of improvements in the medical regimen to prevent stroke and death in asymptomatic patients. Finally, a number of industry-sponsored post-market extension studies have closed (CABANA-Boston Scientific and CHOICE-Abbott Vascular), creating access challenges for Medicare beneficiaries.

The following coverage proposal is a draft document to highlight areas of consensus and others where consensus could not be reached during discussions within the CV Section. It is drafted to comment on specific proposals noted in the Abbott document. The Abbott proposal utilizes CMS' Coverage with Evidence Development (CED) authority, a coverage model developed by CMS that seeks to align the interests of diverse stakeholders.

Symptomatic Patients:

Abbott Proposal: For symptomatic patients with carotid stenosis ≥ 50% stenosis by angiography or ≥ 70% by ultrasound, magnetic resonance angiography (MRA) or computed

tomography angiography (CTA), regardless of surgical-risk status, carotid artery stenting (CAS) would be a Medicare-covered treatment option subject to the coverage restrictions described below:

- Mandatory participation in a CMS-approved national database registry (e.g. NCDR-CARE[*], SVS-VQI[†], CAS-QI[‡]) is required for all symptomatic patients undergoing CAS.
    - CMS, in consultation with the professional community and registry programs would set minimum standards for data elements collected (i.e., NIH stroke scale determination at 30 days, peri-procedural adverse events). These same registry data would serve as the basis for site- and operator-level outcomes analyses required for reporting and accreditation.
- Mandatory facility certification by a CMS-approved independent accrediting body (e.g. ACE or IACCSF) is required for all symptomatic patients undergoing CAS.
    - Similar to above, CMS, in consultation with the professional community and accreditation bodies, would set minimum standards for accreditation (i.e., facility requirements, operator training and experience). Utilizing each facility's national database registry data, as well as other facility-level criteria, independent accrediting organizations would make determinations concerning accreditation in an unbiased and objective manner. Sites that do not adhere to minimum data collection / reporting requirements or that have inadequate patient safety outcomes according to pre-established guidelines for symptomatic patients (e.g., AHA 6% 30-day death & stroke benchmark) will be required to undergo remediation and/or lose their accreditation and therefore their ability to offer CAS as a treatment option for Medicare patients.

The costs of participation in such a CED-based program for *symptomatic* patients would be borne by the facilities performing carotid stenting procedures; these facilities would be required to subscribe and submit data to a national database registry, as well as obtain the necessary accreditation

[*] National Cardiovascular Disease Registry® - CARE.
[†] Society for Vascular Surgery – Vascular Quality Initiative®.
[‡] Carotid Artery Stenting Quality Initiative™.

by a CMS approved body. Such a request would follow the approach taken in other recent CMS national coverage decisions.

CV Section Response:

1. **There was broad consensus that coverage should be expanded for younger (age <65) standard risk symptomatic patients with carotid stenosis ≥ 70% stenosis by angiography from the current status of coverage limited to high surgical risk patients with symptomatic carotid stenosis ≥ 70% stenosis.**
2. **There was also consensus that for patients with high surgical risk who have symptomatic carotid stenosis ≥ 50% but <70% stenosis by angiography there should be no expansion of coverage for the concern that maximal medical therapy remains an excellent alternative in light of the reported high risk of stroke and death in high-risk CAS registries and the lower natural history of stroke in this population.**
3. **There was no consensus reached over expansion of CAS coverage for standard surgical risk patients who have symptomatic carotid stenosis ≥ 50% but <70% stenosis by angiography.**
4. **There was broad consensus for the additional stipulations in regards mandatory participation in national registries and mandatory facility certification.**

Asymptomatic Patients:

Abbott Proposal: Currently, the medical community remains divided on how to interpret the evidence regarding treatments for asymptomatic patients with significant carotid artery disease. The aforementioned organizations acknowledge that no direct head-to-head randomized trials have been conducted to date comparing CAS to contemporary best medical therapy. Furthermore, questions have been raised regarding the relevance of prior randomized trials comparing CEA to medical therapy.

Not surprisingly, there is agreement that better risk-stratification tools are needed to prospectively determine stroke risk of asymptomatic patients. These issues were articulated at January's MEDCAC meeting.

At this time, representatives of various specialty societies are discussing potential studies to address 'data gaps' for patients with asymptomatic carotid artery disease. Therefore, we propose that the NCD be separated by symptomatic status. While coverage for symptomatic patients should be extended, with the coverage restrictions discussed above, coverage for asymptomatic patients should move forward in the context of a separate and distinct CED program. Under such a program, societies, manufacturers and phyisicians would propose prospective clinical studies of asymptomatic patients to be reviewed and approved by CMS.

As has recently been done in other NCDs, we recommend that CMS set a timeline for the submission of proposals for such studies, perhaps two years from finalization of the NCD. We believe this is a realistic time frame to allow for submission of pragmatic studies that will continue to build the evidence base. In addition, CMS should outline an overarching research question these studies should seek to address. For example, do Medicare beneficiaries who are asymptomatic for carotid artery disease and undergo carotid revascularization procedures (CAS or CEA), in addition to receiving optimal medical management, experience a clinically significant reduction in stroke risk, compared to patients who receive optimal medical management alone? In addition, CMS should consider providing direction regarding sub-questions as well. Below, we propose a number of such questions:

- What are the positive and / or negative predictors of stroke in patients with asymptomatic carotid artery disease?
- What diagnostic and imaging modalities best differentiate patients' stroke risks? Which of these modalities can be reasonably and effectively integrated into health care organizations?

- Do specific patient subgroups have different stroke risk profiles? Is there a natural progression of carotid atherosclerosis, and if so, does stroke risk fluctuate with progression of disease?
- What facility and operator factors are associated with favorable and/or worse CAS outcomes, and how can these factors be used to improve CAS outcomes?

Finally, CMS should articulate standards of scientific integrity and relevance to the Medicare population, as has been done in recent NCDs.

CV Section Response:

1. **There was broad agreement with Abbott's proposal that there remains lack of adequate data comparing ANY intervention; CEA or CAS, to current maximal medical therapy for asymptomatic patients.**
2. **There was also strong support to study this population through additional registries and trials designed at addressing the many areas of 'data gap'.**
3. **Therefore, there was consensus in recommending no expansion of coverage for asymptomatic patients.**

Requirements Specific to Comprehensive Stroke Center Certification

a. The Comprehensive Stroke Center demonstrates that care is provided to 20 or more patients per year with a diagnosis of subarachnoid hemorrhage. b. The Comprehensive Stroke Center demonstrates that 15 or more endovascular coiling or surgical clipping procedures for aneurysm are performed per year.

c. The Comprehensive Stroke Center monitors annual aneurysm clipping and coiling mortality rates. d. The Comprehensive Stroke Center demonstrates that IV tissue plasminogen activator (tPA) is administered 25 or more times per year for eligible patients. Note 1: Providing IV tPA to an average of 25 eligible patients per year over a two year period is acceptable.

Note 2: IV tPA administered in the following situations can be counted in the requirement of 25 administrations per year: - IV tPA ordered and monitored by the CSC via telemedicine with administration occurring at another hospital. - IV tPA administered by another hospital which then transferred the patient to the comprehensive stroke center. e. Documentation exists to reflect tracking of performance measures and indicators.

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a. The comprehensive stroke center demonstrates that care is provided to 35 or more patients per year with a diagnosis of subarachnoid hemorrhage. b. The comprehensive stroke center demonstrates that it is capable of treating aneurysms by performing a minimum of 10 microsurgical clippings per year.

Note: Performing␣30 microsurgical clippings over a three year period is ␣␣␣␣␣␣␣␣␣␣␣ c. ␣␣␣ performing a minimum of 20 endovascular coiling procedures per year.

Note: Performing␣60 endovascular coiling procedures over a three-year period␣␣␣␣␣␣␣␣␣␣␣␣␣␣␣␣

d. The comprehensive stroke center monitors annual aneurysm clipping and coiling mortality rates. e. The comprehensive stroke center demonstrates that: - Intravenous (IV) tissue plasminogen activator (tPA) is administered 25 or more times per year for eligible patients. Note 1: Providing IV tPA to an average of ␣␣ eligible patients␣over a two-year period

is acceptable. Note 2: IV tPA administered in the following situations can be counted in the requirement of 25 administrations per year: - IV tPA ordered and monitored by the comprehensive stroke center via telemedicine with administration occurring at another hospital - IV tPA administered by another hospital, which then transferred the patient within 24 hours to the comprehensive stroke center f. Documentation exists to reflect tracking of performance measures and indicators.

Overall, despite limitations in design, endovascular technologies, and suboptimal study populations, these reviewed trials provide essential data in the continued refinement of endovascular therapy for large-vessel ischemic stroke. We strongly support further high-quality prospective investigations. In the interim, current data strongly support the reasonable offering of endovascular therapy for patients with LVO.

Disclosures

Dr Mocco serves a consultant for Endeavor Endovascular and Lazarus Effect. He is an investor in Blockade Medical. Dr Khalessi serves on Clinical Events Committees and provides physician device training for Stryker Neurovascular and Covidien-ev3. These are minor financial conflicts by CNS guidelines. Dr Khalessi further serves on the AHA Writing Group for Extended Use of iv-tPA on behalf of the AANS and the National Steering Committee for Stroke Outcomes for the University Healthcare Consortium (UHC). These Committee assignments are potential related fiduciary but not financial conflicts. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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Preliminary Results of the ARUBA Study

Arteriovenous malformations (AVMs) are congenital lesions that, when left untreated, portend a lifelong cumulative risk of stroke and death. The fact that eradicating an AVM to eliminate its natural risk comes at a price to the patient is not news and does not warrant investigation. What is worthy of scrutiny is the need to value and scale this induced morbidity in the light of the gain achieved, ie: a life with long lasting cure. ARUBA tells us what we already know: there is an initial price attached to the intervention. It does not tell us whether the price is too high for any specific AVM. Yet, in spite of the grave methodological shortcomings of the trial that highly bias its results from the outset against intervention, intervention still emerged a superior option for the Spetzler-Martin Grade 1 AVM. The message is clear. There never was clinical equipoise to justify randomizing grade 1, and almost certainly grade 2 patients. Equally, there never was equipoise for the enrolled grade 4 patients, who should be, by and large, left untreated. A registry of at least all unselected grade 3 patients is what is needed to evoke meaningful data that can preserve external validity.

On May 10, 2013, the National Institute of Neurological Disorders and Stroke (NINDS) announced that A Randomized Trial of Unruptured Brain AVMs study (ARUBA) had prematurely stopped enrollment—a result of the pre-planned interim analysis performed by the trial's independent Data and Safety Monitoring Board (DSMB), which demonstrated an event rate three times higher in the intervention group than in the medical management group.[1]

ARUBA was a randomized, multi-center trial comparing "best possible AVM eradication" with non-invasive, medical management to the primary endpoint, a composite of symptomatic stroke or death. Methods to eradicate brain arteriovenous malformations (BAVM) included radiosurgery, microsurgical resection, and endovascular embolization, alone or in combination. The secondary outcome measure was disability as measured by the Rankin Score at 5 years post-randomization. The initial study design had called for enrollment of 800 patients, but this number was later reduced to 400

patients after an interim sensitivity analysis. The final number enrolled became significantly smaller still, with only 223 patients at the time enrollment was halted. Patients with previous BAVM hemorrhage or treatment, and those with BAVMs considered untreatable for complete removal or eradication, were excluded from the trial. As a result of the decision by the trial's DSMB, the study investigators stopped enrollment but will continue to follow patients already enrolled.

On May 31, 2013, the preliminary results from ARUBA were presented at the European Stroke Conference in London, England. In summary form only, the study was reported to have enrolled 223 patients from 65 certified sites. A great majority of the patients were recruited from centers not in the United States, with slightly more than 40 patients enrolled in the United States. One hundred twenty six patients were managed medically while 97 were treated with interventional modalities. Most patients presented with symptoms of seizure (43%) or headache (52%) while focal deficits were rare (14%). Ninety-four patients (42%) were asymptomatic at the time of diagnosis. BAVMs in the study cohorts were relatively well matched for size, location, and venous drainage pattern as well as for Spetzler-Martin (S-M) Grade. The majority was comprised of S-M grade 1, 2, or 3 (approximately equal) with a few grade 4 patients (10%) and no grade 5 patients enrolled. The average follow-up period was 33 months.

In an analysis based on the treatment received, the authors report that ten adverse events (7.9%), defined as death or stroke, occurred in the medical management arm while 34 adverse events (35.1%) occurred in the interventional therapy arm (RR = 0.35, 95% CI = 0.19-0.65). There was no significant difference in the number of deaths (two in the medical management arm vs three in the interventional arm). When analyzed according to S-M Grade, patients with grade 1 BAVMs fared better in the interventional group while adverse events were much higher in patients with grades 2 to 4 lesions. Of interest, 45% of patients assigned to interventional therapy in the United States were still awaiting treatment at the time the study was halted. In patients followed for 24 months (n = 123), the modified Rankin Score was >2 (secondary endpoint) in 36.1% of patients in the interventional arm and 9.7% in the medical management arm. No specific data was provided in the presentation about methods used to treat patients in the interventional arm (radiotherapy vs endovascular vs microsurgery vs combination therapy), and the trial was not powered to evaluate treatment effect by modality.

While intending to shed light on the best management of unruptured BAVMs, the ARUBA trial has not been free of criticism. Multiple difficulties with the study have been previously described.[2,3] Among these are the lack of physician accreditation to participate in ARUBA beyond a statement that more than ten BAVMs are treated annually at participating centers. This diverges from more rigorous physician accreditation required by other recent trials investigating comparatively homogeneous cerebrovascular disorders, such as those performed for the management of carotid stenosis and intracranial stenosis.[4-6] Clear differences in end-point morbidity exist between radiosurgical intervention compared with endovascular or microsurgical interventions, yet the trial was not powered to examine these treatment-specific variations. While some cerebrovascular centers have extensive experience in the treatment of BAVMs, inclusion of centers without extensive experience is problematic. Finally, initial surgical morbidity in a study with short-term follow-upsuch as ARUBA can have a profound effect on outcomes, particularly when compared to medical management in a lesion with a relatively low but life-long annual risk of hemorrhage or disability.

A major limitation of studies such as ARUBA is selection bias. External validity of ARUBA (applicability to BAVM patients in general) depends on the sample population of the study patients. Given enrollment of only 223 patients, compared with the greater number of BAVMs actually evaluated, only certain patients were selected for trial participation. Treatment of BAVMs has evolved along several well-established patterns of therapy. It is quite possible that those patients thought to be at high risk for BAVM rupture without treatment by study investigators were excluded from enrollment and treated outside of the confines of the trial. The International Study of Unruptured Intracranial Aneurysms (ISUIA) study demonstrated similar limitations as high-risk aneurysms were, by their very nature, pre-selected out of the study, leaving a group of patients enrolled in ISUIA with a lower risk for aneurysmal rupture.[7,8] Lack of equipoise and the discomfort with natural history risk among clinicians who treat large numbers of BAVMs in tertiary care centers in the United States has likely resulted in the low number of participating US centers as well as the low study accrual rate.

Moving forward, the ARUBA investigators are requesting additional funding to continue monitoring the 223 enrolled patients, potentially for up to 10 years. On first inspection, this request seems like an appropriate response to criticisms that the existing trial follow-up is too short. However, ARUBA was already enormously expensive and it is important to carefully assess the usefulness of such a decision.

Longer-term follow-up could potentially show equality in outcomes or even the superiority of intervention as untreated patients in the medical arm of ARUBA experience clinical events. Similarly, treated patients in the interventional arm commonly demonstrate progressive neurological improvement over time, at least for the secondary outcome measure (modified Rankin score). However, such a reversal will not alter the external validity of the trial. A crossover of outcomes such that patients managed non-invasively suffer a higher incidence of stroke and death than those treated should not lead to changes in management algorithms: even then it would be inappropriate to conclude that all persons with unruptured BAVM should necessarily be treated. We feel that the next most appropriate step in the investigation of management of unruptured BAVMs would be to create and promote a long-term, comprehensive, and adjudicated registry inclusive of all BAVM patients.

In conclusion, the preliminary data presented from the ARUBA trial are not surprising. Any randomized trial attempting to determine management paradigms for lesions as heterogeneous

and rare as BAVMs is limited in the interpretation of its results and in its external validity. The trial results reinforce our knowledge of the high complication rates for interventional treatment of high-grade (S-M 4-5) BAVMs as well as our knowledge of the safety of intervention for grade 1 lesions. Selection bias in ARUBA may make it impossible to extrapolate any of its conclusions to the management of all unruptured BAVMs. The small number of study patients will also make *post hoc* analysis of specific subgroups problematic. In light of these limitations, it may be more productive to study such rare and heterogeneous lesions using multicenter, adjudicated, consecutive patient registries to capture all patients without bias.

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The Temporoparietal Fiber Intersection Area and Wernicke Perpendicular Fasciculus

In their recent article, Martino et al[1] highlighted the anatomy and surgical importance of the temporoparietal fiber intersection area (TPFIA). We very much enjoyed reading their detailed description based upon postmortem fiber dissections, in vivo diffusion tensor imaging, and tractography as well as clinical case reports, but we noticed one significant mistake.

The authors consistently mislabel the outermost, ie, lateral, of the 7 white matter tracts identified in the TPFIA as the "horizontal portion of the superior longitudinal fasciculus (SLF)" in all of their figures, the abstract and part of the text (second page of the article). Yet, the tract the authors refer to is obviously not taking a horizontal but a vertical course (cf. Figures 2 and 6 in their article). At the beginning of the results section, the authors identify it with the "posterior portion of the SLF." According to Makris et al,[2] the only vertical component of the SLF belongs to its fourth subdivision (SLF IV), ie, the vertical part of the arcuate fasciculus (AF), which Martino et al[1] identify with the second fiber tract in the TPFIA.

So if the outermost, vertically running fiber pathways of the TPFIA do not belong to the SLF or AF, respectively, what are they and are these fibers surgically relevant? These particular association fibers had originally been discovered by Wernicke[3] in monkey brains and have subsequently been called Wernicke perpendicular (or vertical occipital) fasciculus (WpF).[4-7] According to the early seminal investigation by Sachs,[8] a disciple of Wernicke in Wrocław (the former Silesian Breslau), WpF is part of the stratum verticale, ie, the stratum profundum convexitatis, lateral to the AF and the stratum sagittale externum which itself contains the inferior longitudinal fasciculus. The WpF connects the inferior parietal with the lower temporal and occipital lobe, and its fibers are crossed by posterior callosal commissure fibers, projection and association pathways. These crossing fibers may cause failures to identify this tract (i) in one-fourth of the postmortem dissections of Martino et al[1] and (ii) in diffusion tensor imaging as well as streamline tractography. According to our own data,[9] probabilistic tractography with crossing fibers modeling can reduce such false-negative trackings in the presence of perifocal tumor edema, for example. Crossing fibers also emphasize that the tracts of the TPFIA are not arranged in strictly separate but partially interwoven layers.

WpF is clinically relevant and should be preserved from surgical damage whenever possible. Lesions to WpF have—in addition to those involving Mill's basotemporal language or the visual word forming area, posterior callosal fibers and the inferior longitudinal fasciculus —been associated with preangular alexia without agraphia.[10-13] In this peculiar syndrome, patients are unable to read but can still write (eg, text short-message-service messages). The closer a lesion is located to the left inferior parietal lobule, the more likely it is accompanied by agraphia or other neuropsychological symptoms subsumed by Gerstmann syndrome, whereas the closer a lesion is to the inferior temporal lobe, the more likely it will involve disorders of face or color identification (eg, hyperfamiliarity for faces or color anomia).[14,15] Furthermore, the anterior portion of WpF may be part of a brain network processing the age of faces.[16]

We have ourselves observed 4 cases in which tumors of and/or surgical access through the TPFIA (eg, to approach subsplenial or posterior hippocampal lesions from laterally) have led to alexia without agraphia that we relate to damage to the WpF. Such WpF disconnection syndrome may be transient, but the associated deficit

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Symptomatic Patients:

Abbott Proposal: For symptomatic patients with carotid stenosis ≥ 50% stenosis by angiography or ≥ 70% by ultrasound, magnetic resonance angiography (MRA) or computed

tomography angiography (CTA), regardless of surgical-risk status, carotid artery stenting (CAS) would be a Medicare-covered treatment option subject to the coverage restrictions described below:

- Mandatory participation in a CMS-approved national database registry (e.g. NCDR-CARE[*], SVS-VQI[†], CAS-QI[‡]) is required for all symptomatic patients undergoing CAS.
    - CMS, in consultation with the professional community and registry programs would set minimum standards for data elements collected (i.e., NIH stroke scale determination at 30 days, peri-procedural adverse events). These same registry data would serve as the basis for site- and operator-level outcomes analyses required for reporting and accreditation.
- Mandatory facility certification by a CMS-approved independent accrediting body (e.g. ACE or IACCSF) is required for all symptomatic patients undergoing CAS.
    - Similar to above, CMS, in consultation with the professional community and accreditation bodies, would set minimum standards for accreditation (i.e., facility requirements, operator training and experience). Utilizing each facility's national database registry data, as well as other facility-level criteria, independent accrediting organizations would make determinations concerning accreditation in an unbiased and objective manner. Sites that do not adhere to minimum data collection / reporting requirements or that have inadequate patient safety outcomes according to pre-established guidelines for symptomatic patients (e.g., AHA 6% 30-day death & stroke benchmark) will be required to undergo remediation and/or lose their accreditation and therefore their ability to offer CAS as a treatment option for Medicare patients.

The costs of participation in such a CED-based program for *symptomatic* patients would be borne by the facilities performing carotid stenting procedures; these facilities would be required to subscribe and submit data to a national database registry, as well as obtain the necessary accreditation

[*] National Cardiovascular Disease Registry® - CARE.
[†] Society for Vascular Surgery – Vascular Quality Initiative®.
[‡] Carotid Artery Stenting Quality Initiative™.

by a CMS approved body. Such a request would follow the approach taken in other recent CMS national coverage decisions.

CV Section Response:

1. **There was broad consensus that coverage should be expanded for younger (age <65) standard risk symptomatic patients with carotid stenosis ≥ 70% stenosis by angiography from the current status of coverage limited to high surgical risk patients with symptomatic carotid stenosis ≥ 70% stenosis.**
2. **There was also consensus that for patients with high surgical risk who have symptomatic carotid stenosis ≥ 50% but <70% stenosis by angiography there should be no expansion of coverage for the concern that maximal medical therapy remains an excellent alternative in light of the reported high risk of stroke and death in high-risk CAS registries and the lower natural history of stroke in this population.**
3. **There was no consensus reached over expansion of CAS coverage for standard surgical risk patients who have symptomatic carotid stenosis ≥ 50% but <70% stenosis by angiography.**
4. **There was broad consensus for the additional stipulations in regards mandatory participation in national registries and mandatory facility certification.**

Asymptomatic Patients:

Abbott Proposal: Currently, the medical community remains divided on how to interpret the evidence regarding treatments for asymptomatic patients with significant carotid artery disease. The aforementioned organizations acknowledge that no direct head-to-head randomized trials have been conducted to date comparing CAS to contemporary best medical therapy. Furthermore, questions have been raised regarding the relevance of prior randomized trials comparing CEA to medical therapy.

Not surprisingly, there is agreement that better risk-stratification tools are needed to prospectively determine stroke risk of asymptomatic patients. These issues were articulated at January's MEDCAC meeting.

At this time, representatives of various specialty societies are discussing potential studies to address 'data gaps' for patients with asymptomatic carotid artery disease. Therefore, we propose that the NCD be separated by symptomatic status. While coverage for symptomatic patients should be extended, with the coverage restrictions discussed above, coverage for asymptomatic patients should move forward in the context of a separate and distinct CED program. Under such a program, societies, manufacturers and phyisicians would propose prospective clinical studies of asymptomatic patients to be reviewed and approved by CMS.

As has recently been done in other NCDs, we recommend that CMS set a timeline for the submission of proposals for such studies, perhaps two years from finalization of the NCD. We believe this is a realistic time frame to allow for submission of pragmatic studies that will continue to build the evidence base. In addition, CMS should outline an overarching research question these studies should seek to address. For example, do Medicare beneficiaries who are asymptomatic for carotid artery disease and undergo carotid revascularization procedures (CAS or CEA), in addition to receiving optimal medical management, experience a clinically significant reduction in stroke risk, compared to patients who receive optimal medical management alone? In addition, CMS should consider providing direction regarding sub-questions as well. Below, we propose a number of such questions:

- What are the positive and / or negative predictors of stroke in patients with asymptomatic carotid artery disease?
- What diagnostic and imaging modalities best differentiate patients' stroke risks? Which of these modalities can be reasonably and effectively integrated into health care organizations?

- Do specific patient subgroups have different stroke risk profiles? Is there a natural progression of carotid atherosclerosis, and if so, does stroke risk fluctuate with progression of disease?
- What facility and operator factors are associated with favorable and/or worse CAS outcomes, and how can these factors be used to improve CAS outcomes?

Finally, CMS should articulate standards of scientific integrity and relevance to the Medicare population, as has been done in recent NCDs.

CV Section Response:

1. **There was broad agreement with Abbott's proposal that there remains lack of adequate data comparing ANY intervention; CEA or CAS, to current maximal medical therapy for asymptomatic patients.**
2. **There was also strong support to study this population through additional registries and trials designed at addressing the many areas of 'data gap'.**
3. **Therefore, there was consensus in recommending no expansion of coverage for asymptomatic patients.**