Health Technology Clinical Committee Findings and Coverage Decision

Topic: Coronary Computed Tomographic Angiography
Meeting Date: November 14, 2008
Final Adoption:

Number and Coverage Topic

20081114A – Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease.

HTCC Coverage Determination

Coronary Computed Tomographic Angiography (CCTA) is **covered benefits with conditions** consistent with the criteria identified in the reimbursement determination**.**

HTCC Reimbursement Determination

❖ Limitations of Coverage

1) Patients with low to intermediate risk of coronary artery disease;
2) For investigation of acute chest pain in an emergency department or hospital setting; and
3) Using Computed Tomography machines with 64-slice or better capability.

❖ Non-Covered Indicators

Patients who are asymptomatic or at high risk of coronary artery disease;

CCTA used for coronary artery disease investigation outside of the emergency department or hospital setting; and

CT scanners that use lower than 64- slice technology.

❖ Agency Contact Information

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

P.O. Box 42712 • Olympia, Washington 98504 • www.hta.hca.wa.gov • 360-923-2742 • FAX 360-923-2766 • TTY 360-923-2701

Computed Tomographic Angiography Background

The Computed Tomographic Angiography topic was selected and published in August 2007 to undergo an evidence review process. Heart disease is the leading cause of death and disability in the US: with 700,000 deaths. The most common heart disease in the US is coronary artery disease (CAD), which can lead to heart attack. CAD is a narrowing of one or more coronary arteries that result in an insufficient supply of oxygen to the heart muscle and is a leading cause of death in the US and developed countries. CAD may be asymptomatic or lead to chest pain (angina), heart attack, myocardial infarction (MI) or death. *Non invasive tests include:* Stress Echocardiograms – tests that compare blood flow with and without exercise and visualize the heart. Single-photon emission computed tomography (SPECT), also known as nuclear stress testing or myocardial perfusion imaging. *Invasive tests include:* The "gold" standard is the conventional coronary angiography which involves placement of a catheter and injection of contract material into a large artery or vein, followed by 2-dimensional visualization with x-rays. Coronary computed tomographic angiography (CCTA) is a minimally invasive radiological technique used to provide images of the heart and surrounding vessels.

CCTA has been suggested as an alternative or useful complementary approach to other non-invasive methods of diagnosing coronary artery disease (CAD). Due to its ability to visualize coronary anatomy, CCTA has been suggested as a strategy to rule out significant CAD among patients at low or intermediate risk of significant disease, thereby giving greater reassurance than other non-invasive methods and potentially reducing the number of patients ultimately sent for invasive coronary angiography (ICA). Potential drawbacks include radiation exposure; duplicative or additional testing; incidental findings; and uncertainty about whether the test results in better health outcomes.

In September 2008, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed, Computed Tomographic Angiography report is 125 pages, identified 8 relevant studies for the Emergency room setting and 34 relevant studies for outpatient, Medicare coverage and 4 expert treatment guidelines. These studies represent the best available information; including a randomized controlled trial for the emergency room setting from which evidence based conclusions were drawn.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on November 14th, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov in the committee section.

Summary of Committee Findings

The committee found that it had the most complete information: a comprehensive and current evidence report, public comments, and agency utilization information. The committee concluded that the current evidence on Computed Tomographic Angiography demonstrates that there is sufficient evidence a decision about use in an emergency

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setting to cover investigation of acute chest pain in an emergency room department or hospital setting for those who are at low-to-intermediate risk of coronary artery disease. The committee concluded that there is not sufficient, reliable evidence developed to make a determination for other coronary CTA uses, including the outpatient setting. For low-to-intermediate risk patients in the Emergency department setting the diagnostic accuracy of the 64-slice as a triage tool was supported by one RCT and several case series. For low-to-intermediate risk outpatients, no RCT or long-term cohort evidence was available. Modeling suggests a lower rate of false negatives than SECHO and SPECT, and a lower rate of false positives than SPECT, but these differences change with underlying prevalence of CAD and involves other trade-offs.

Based on these evidentiary findings, the committee voted: 2 for non-coverage and 7 for coverage with conditions.

- ***Is it effective?***

The committee identified multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology was effective. Summary of committee consideration, discussion, and comments are listed below.

- ✓ *Diagnostic Accuracy – Sensitivity*: the committee agreed as a whole that CCTA has a high level of sensitivity. The technology report sensitivity rate was 98%; which compared favorably to stress echo at 76-94% and SPECT at 88-98%. The indeterminate rates were also lower, with CCTA at 3% versus Stress ECHO at 13% and SPECT at 9%.
- ✓ *Diagnostic Accuracy – Specificity*: the committee agreed equivalent specificity. Some uncertainty about lower prevalence population was shared amongst the committee members. The technology report specificity rate was comparable at 82-88%; compared to stress echo at 88% and SPECT at 77%.
- ✓ *Reduction in invasive CA*: the committee agreed that modeling suggests reduced ICA, but trial evidence data was inconclusive with Rubenstien trial showing reduction and Goldstein shiwoing slight increase, especially when compared to alternative diagnostic tools.
- ✓ *Replace other tests*: most modeled analysis and clinical trials used CCTA in conjunction with other tests. Committee agreed that CCTA wouldn't replace other non-invasive technologies.
- ✓ *Incidental findings*: committee discussed as an issue both we respect to efficacy and safety and concluded that evidence demonstrates incidental findings are not infrequent events. Incidental findings can provide valuable information for diagnosis of previously undetected other diseases but also often leads to uncertainty or further tests to rule out questionable findings. The committee agreed that there is currently no evidence regarding improved patient health outcomes balancing cost and potential harms from further testing and anxiety.
- ✓ *Effect in real world*: Committee discussed several technology assessment key unknowns: whether more disease found will help or harm patients, especially at lower disease levels (clinical relevance is questionable); whether broad dissemination will result in lower test thresholds that may not result in better overall health outcomes but more radiation; and the extent to which CCTA can replace and not add to tests. Additionally, certification of machines and readers

was also discussed; hospitals require JAHCO accreditation and thus have some standards.

- ***Is it safe?***

The committee identified multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology was safe. Summary of committee consideration, discussion, and comments are listed below.

- ✓ *Radiation Exposure* is an important safety outcome to the committee. The committee discussed the technology assessment report findings of an overall cancer risk of .22% for women and .08% for men. Radiation dosage can be reduced through technique and machine type, but it is unknown whether these lowest dosage techniques/machines are used in WA settings. Overall exposure reported at between 2.0-8.0mSV for lower range is equivalent to SPECT; and 12.0 to 14.0 range for higher dose which is equivalent to A-bomb survivor at 2.3 kilometer distance. The committee concluded that there are small but definite risks, within appropriate norms. The radiation risks are high enough to obviate benefit when applied to very low risk patients.
- ✓ *Incidental findings* are also an important safety outcome that the committee discussed as an issue both we respect to efficacy and safety and concluded that evidence demonstrates incidental findings are not infrequent events. Incidental findings can provide valuable information for diagnosis of previously undetected other diseases but also often leads to uncertainty or further tests to rule out questionable findings. The committee agreed that there is currently no evidence regarding improved patient health outcomes balancing cost and potential harms from further testing and anxiety.

- ***Does it provide value (improve health outcome)?***

The committee discussed cost and cost-effectiveness as a whole. This topic generated the least discussion. There are several cost studies for ED and outpatient showing cost savings. The technology assessment report also modeled costs for ED and outpatient showing cost savings using Medicare reimbursement rates. No analysis included costs related to incidental findings or harms. Current state agency reimbursement rates do not correlate with modeled costs (Agency reimbursement for CCTA is higher and for comparators is lower).

- ✓ Committee members were split, with four considering the cost effectiveness currently unproven and five concluding that CCTA is either equivalent or more cost effective in some situations.

Consistency with Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the Medicare coverage decision and expert guidelines as identified and reported in the technology assessment report.

- There is no national coverage decision (NCD), however a coverage analysis and memo was issued in 2008 and summarized: there is uncertainty regarding any potential health benefits or patient management alterations from including coronary CTA in the diagnostic workup of patients who may have CAD. No adequately powered study has established that improved health outcomes can be casually attributed to coronary CTA for any well-defined clinical indication, and the body of evidence is of overall limited quality and limited applicability to Medicare patients

with typical co-morbidities in community practice. The primary safety concerns with cardiac CTA are the exposure to radiation and the use of contrast and blocker medications.

- Four expert guidelines were identified that address the use of CCTA for detection of CAD, but not the setting (ED versus outpatient).
    - American Heart Association (2006): evidence supports the use of CCTA for patients with low-to-intermediate stenosis and may obviate the need for ICA.
    - Multi-Society Statement of Appropriateness Criteria for Cardiac Computed Tomography (2006): Appropriateness reviews deemed the use of CCTA for detection of CAD to be appropriate for the following patient populations: chest pain syndrome with intermediate pre-test probability of CAD and uninterpretable EKG or inability to exercise; chest pain and uninterpretable or equivocal stress test results; acute chest pain with intermediate pre-test probability of CAD and no EKG changes and serial enzymes negative; and symptomatic patients requiring evaluation of suspected coronary anomalies.
    - American College of Radiology (2006): CCTA is appropriate for assessment of CAD, although its usefulness for patients with low pre-test probability is unknown. Appropriateness rating of 7 out 9 for the evaluation of chronic chest pain.
    - SCCT/NASCI Consensus Update (2007): CCTA to be appropriate in the following circumstances: (1) to rule out significant coronary stenosis; (2) to evaluate patients with equivocal or discordant results on a stress perfusion or wall motion study; (3) to rule out stenosis in patients with a low pre-test likelihood of CAD and (4) to potentially replace diagnostic catheterization in patients undergoing non-coronary cardiac surgery.

The committee concluded that their decision is consistent with applicable policy and guidelines. There is no national Medicare coverage decision. The decision is consistent with treatment guidelines in that low to intermediate triage will be covered, with the coverage decision being more specific in identifying the place of service. The committee decision is based on all evidence, including public and agency comments and the comprehensive technology assessment report.

Committee Authority

Washington State believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. The HTA gathers and assesses the quality of the latest medical evidence using a scientific research company, takes public input at all stages, and asks a committee of eleven independent health care professionals to review all the information and render a decision at an open meeting. The Washington State Health Technology Clinical Committee (HTCC), an independent committee of 11 health practitioners, determines how selected health technologies are covered by several state agencies. See RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on the 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.

Coronary Artery Computed Tomography as an Alternative to Invasive Angiography after Cardiac Stress Testing: IMPACCT trial

Gilbert L. Raff, Michael J. Gallagher,
Kavitha M. Chinnaiyan, Laxmi S. Mehta, Aiden Abidov

William Beaumont Hospital, Royal Oak, MI

(www.clinicaltrials.gov ID: NCT000465335)

Disclosures

- Gilbert Raff, M.D., FACC
  - Siemens Medical Solutions (research grant)
  -Bayer (research grant)
  - Blue Cross/Blue Shield of Michigan (research grant)
- Kavitha M. Chinnaiyan, M.D.
  -Bayer (research grant)

Background

- Cardiac stress testing provides the initial assessment for many patients with suspected CAD; those with high-risk features (large/multivessel perfusion defects, or PD) subsequently require invasive coronary angiography (InCA)

- However, millions of patients who have either normal scans, small PD, equivocal or nondiagnostic stress tests are still referred for InCA most likely due to discrepant clinical symptoms or ischemic ECG changes during exercise stress

- Role of coronary computed tomographic angiography (CCTA) as an alternative to InCA in diagnostic workup of low-risk, equivocal or nondiagnostic stress test pts has not been determined

Study Hypothesis

CCTA is an effective diagnostic tool that is able to safely replace InCA in the population of patients in whom diagnostic stratification remains unclear after low-risk or equivocal/nondiagnostic stress myocardial perfusion test results either due to the clinical, historical or ECG data discrepant with findings on the stress test imaging study

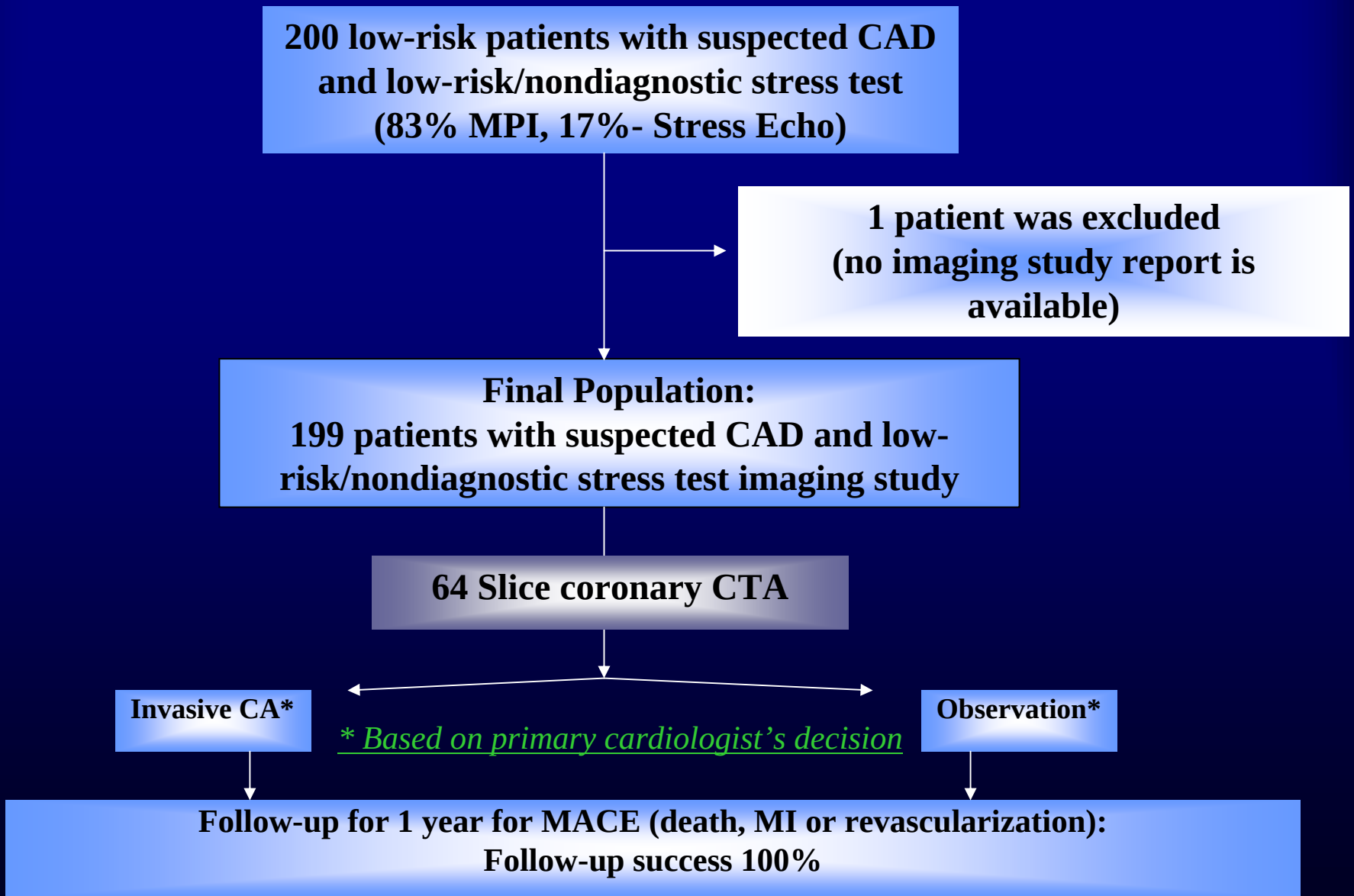
Methods

- We prospectively enrolled 200 sequential patients referred by cardiologists for CCTA after stress tests
- Before CCTA, physicians identified a "planned catheterization" group of patients who would undergo InCA if CCTA results were not available
- In our analyses we determined:

  1. The diagnostic and prognostic accuracy of CCTA findings as compared to subsequent invasive and non-invasive testing or adverse cardiac events (MACE), such as Cardiac Death, MI or revascularization (PCI or CABG)

  2. The extent to which CCTA has replaced initially planned catheterizations, and safety of such an approach during 1-year of follow-up

IMPACCT study design



Definitions

- Normal stress-perfusion study = when reported as definitely normal and no further diagnostic work-up is suggested
- Abnormal stress test = definitive perfusion defect on myocardial perfusion stress test
- Equivocal/nondiagnostic test = presence of borderline small perfusion abnormalities/ inability to achieve 85% Max HR
- Mildly abnormal scan = mild PD involving ≤ 2 segments of the LV

Clinical Characteristics of the Study Population

Demographics	Normal Scan (n=62)	Mildly Abnl Scan (n=81)	Equiv/Nondx Scan (n=56)	P-value
Age (yrs)	52±11	56±12	54±13	0.131
Male gender	29 (47%)	50 (62%)	28 (50%)	0.165
Race, Caucasian	57 (92%)	75 (94%)	49 (88%)	0.478
Hypertension	23 (37%)	36 (44%)	33 (59%)	0.055
Hyperlipidemia	34 (55%)	55 (68%)	22 (54%)	0.165
Diabetes	3 (5%)	8 (10%)	12 (21%)	0.016
Smoker	5 (8%)	10 (12%)	8 (15%)	0.532
Typical Angina	17 (27%)	7 (9%)	13 (23%)	0.010
Atypical Angina	29 (47%)	33 (41%)	14 (25%)	0.043
Nonanginal CP	5 (8%)	6 (7%)	6 (11%)	0.783
SOB	7 (11%)	8 (10%)	12 (21%)	0.125
Asymptomatic	7 (11%)	26 (32%)	19 (34%)	0.006
Pre-test CAD Lk	46±28	39±24	40±26	0.217
BMI	27.0±5.0	28.2±5.0	30.5±4.4	<0.001

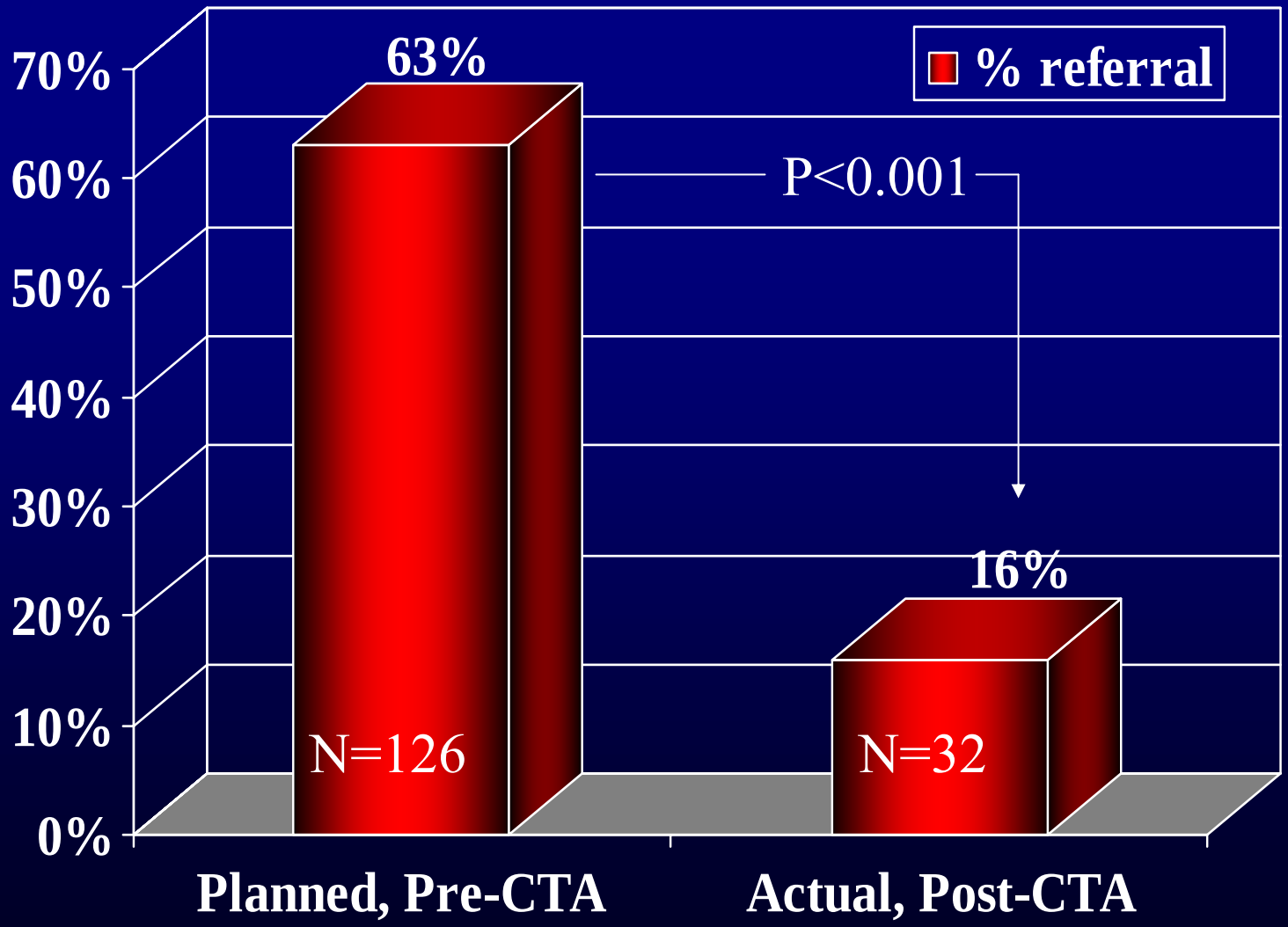
Hemodynamic Parameters in the Study Population

Parameters	Normal Scan (n=62)	Mildly Abnl Scan (n=81)	Equiv/Nondx Scan (n=56)	P-value
LVEF, %	65.1±7.6	64.2±8.8	64.7±9.0	0.855
Rest SBP, mmHg	128±19	132±17	136±22	0.132
Rest DBP, mmHg	79±11	81±12	81±12	0.598
Rest HR, bpm	70±11	69±11	68±13	0.702
Nondiagnostic ECG	19 (31%)	26 (32%)	19 (34%)	0.930
Ischemic Stress ECG	19 (31%)	21 (26%)	12 (21%)	0.523

CTA Results: Association with Pre- and Post-CTA Decision to Refer the Patients to Invasive CA

Test Results	Normal Scan (n=62)		Mildly Abnormal Scan (n=81)		Equivocal/Nondx Scan (n=56)	
	Isch ECG N=19	Non-Isch ECG N=43	Isch ECG N=21	Non-Isch ECG N=60	Isch ECG N=12	Non-Isch ECG N=44
Normal CTA:	N=12	N=20	N=6	N=29	N=4	N=22
Cath done after CTA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Cath planned before CTA	5 (42%) *	9 (41%) *	5 (83%) *	20 (69%) *	2 (50%) *	15 (68%) *
Any CAD on CTA:	N=7	N=23	N=15	N=31	N=8	N=22
Cath done after CTA	0 (0%)	9 (39%)	1 (7%)	9 (29%)	3 (37%)	10 (45%)
Cath planned before CTA	7 (100%)*	13 (59%)*	9 (60%)*	23 (74%)*	6 (75%)*	11 (50%)*

Impact of CTA on the Actual vs Planned Referral for Invasive Coronary Angiography

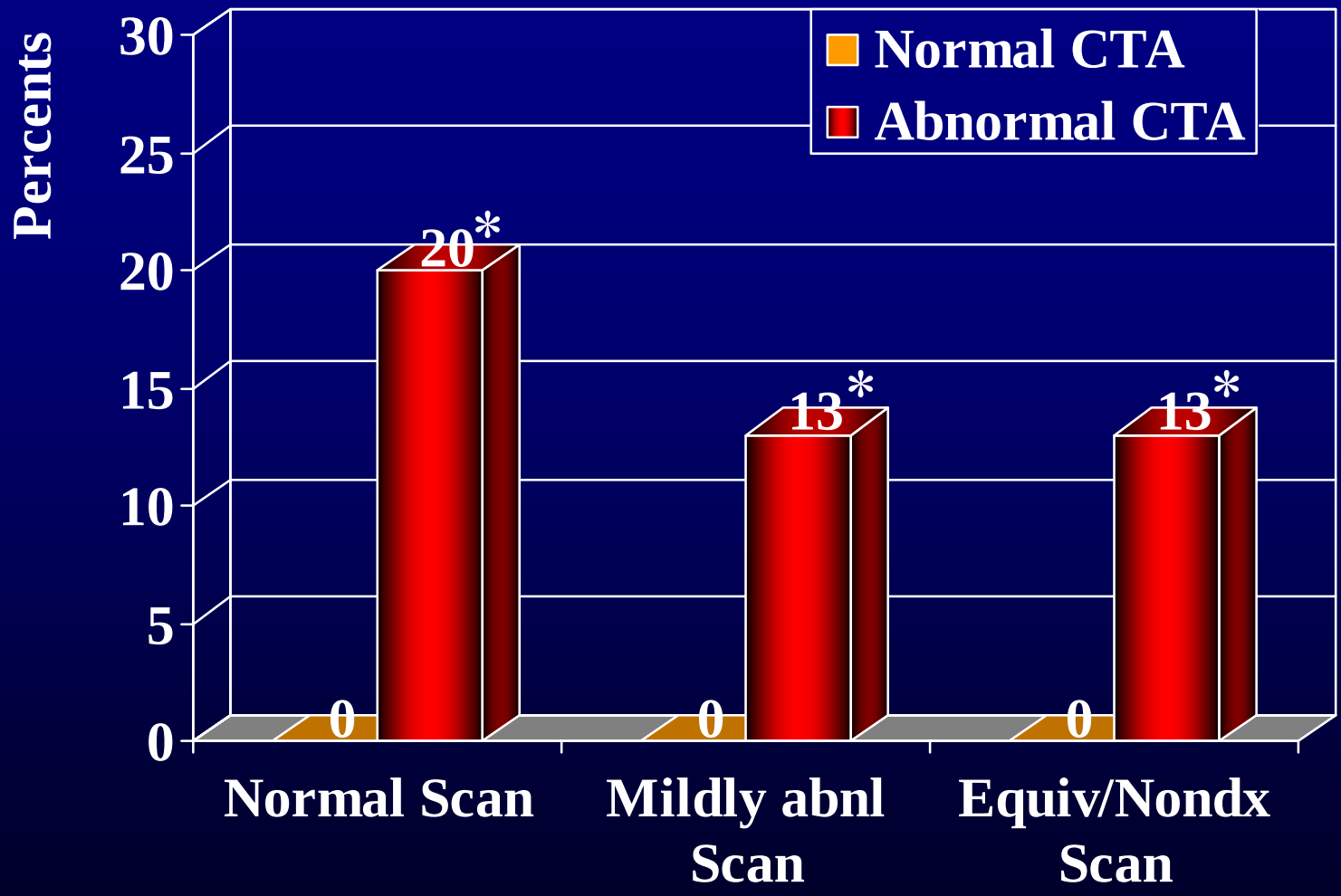


Diagnostic Performance of CTA

Test Results	Normal Scan (n=62)		Mildly Abnormal Scan (n=81)		Equivocal/Nondx Scan (n=56)	
	Isch ECG N=19	Non-Isch ECG N=43	Isch ECG N=21	Non-Isch ECG N=60	Isch ECG N=12	Non-Isch ECG N=44
Normal CTA:	N=12	N=20	N=6	N=29	N=4	N=22
CAD>50% by cath	N/A	N/A	N/A	N/A	N/A	N/A
CAD>50% missed by CTA	N/A	N/A	N/A	N/A	N/A	N/A
Any CAD on CTA:	N=7	N=23	N=15	N=31	N=8	N=22
CAD>50% by cath	N/A	5/6 (83%)	1/1 (100%)	6/6 (100%)	0/0 100%)	4/4 (100%)
CAD>50% missed by CTA	N/A	1/3	0	0	0	0

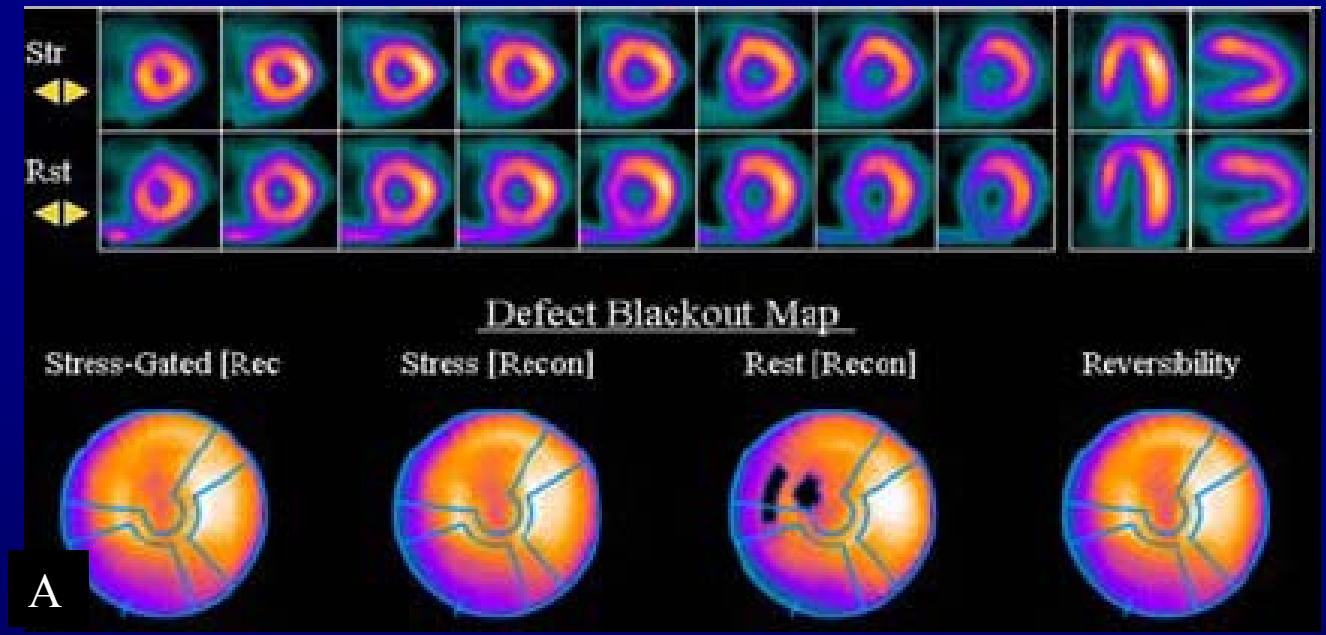
Overall for the Dx of CAD>50%:
Sensitivity 90%, Specificity 91%,
PPV 53% and NPV 99%

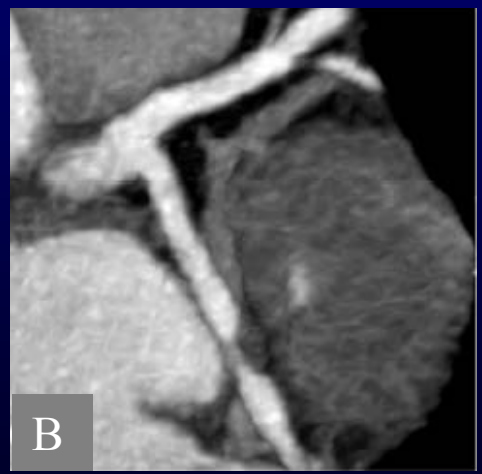
Follow-Up Events (Death, MI or Revascularization)
Follow-Up Duration=1 year

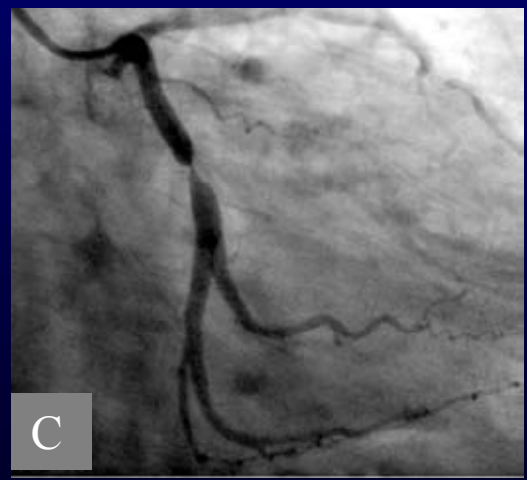


**=All FU Events were Revascularizations (PCI)*

Clinical Example: CTA in Low-Risk MPI*







* The patient is a 49 yo M with hypertension, hyperlipidemia and family history of CAD, who had atypical angina and near-normal MPI (panel A). CCTA and invasive CA demonstrated obstructive disease in the LCX (panels B and C)

Conclusions

- In the population of patients with low-risk perfusion scans, CTA is an independent diagnostic and prognostic marker, effectively identifying patients with no significant CAD
- CTA appears to be an effective “gatekeeper” in the population of patients with suspected CAD and inconclusive previous clinical data and stress tests
- Patients with normal CTA after an abnormal or inconclusive perfusion test and /or abnormal stress ECG can be safely and effectively observed and treated noninvasively with excellent prognosis

Control/Tracking Number: 09-A-60369-ACC
Activity: ACC.09 Abstract
Current Date/Time: 10/5/2008 6:49:57 PM

Coronary Computed Tomographic Angiography Effectively Directs Healthcare Resource Utilization

Author Block: Kavitha M. Chinnaiyan, Aiden Abidov, Michael J. Gallagher, James Stewart, Gilbert L. Raff, William Beaumont Hospital, Royal Oak, MI, William Beaumont Hospital, Troy, MI

Abstract:
Background: Coronary computed tomography angiography (CCTA) has high diagnostic accuracy when compared to invasive coronary angiography (CATH) for the diagnosis of coronary artery disease (CAD) but there are limited data on its clinical effectiveness.
Methods: All patients undergoing CCTA imaging at William Beaumont Hospitals Royal Oak and Troy, MI are enrolled in a prospective quality assurance registry, including demographics, coronary risk factors, test findings and 3 month follow-up for cardiac events and testing.
Results: Between July 1, 2007 and Oct. 3, 2008 2,671 patients completed CCTA, data collection and 3 month follow-up. Among these, 2,089 (78.2%) patients had no reported CAD, whereas 582 (21.8%) cases reported prior CAD (see Table). In patients without prior CAD, EC visits were similar, but hospitalizations were markedly reduced if CCTA showed no obstructive lesions (7.0% vs. 38.6%) as were noninvasive tests (3.9% vs. 11.9%). CATH were similarly reduced (2.4% vs. 48.0%), as were coronary interventions (0.6% vs 19.8%) and coronary bypasses (0.2% vs. 6.7%); p values all < 0.001. Resource utilization in patients with prior CAD but no CCTA stenosis > 50% was similarly reduced with exception of stress tests.
Conclusions: CCTA reduces use of hospitalization, noninvasive and invasive procedures in low-risk patients.

Healthcare Resource Utilization 3 Mo After CCTA

Patients No Known CAD N=2089	CT Sten <=50% N=1760 (84.3%)	CT Sten >50% N=327 (15.7%)	P Value
Hospital stays	123 (7.0%)	127 (38.6%)	<0.001
Stress tests	68 (3.9%)	39 (11.9%)	<0.001
Caths	42 (2.4%)	158 (48.0%)	<0.001

PCIs	10 (0.6%)	65 (19.8%)	<0.001
CABGs	4 (0.2%)	22 (6.7%)	<0.001
Patients with Hx CAD N=582	CT Sten <=50% N=308 (52.9%)	CT Sten >50% N=274 47.1%	
Caths	27 (8.8%)	78 (28.5%)	<0.001
PCIs	8 (2.6%)	38 (13.9%)	<0.001
CABGs	11 (3.6%)	50 (18.2%)	<0.001

:

Category (Complete): CT Coronary Angiography
Keyword (Complete): CT Coronary Angiography ; Resource Utilization ; Noninvasive cardiology
Institution Information (Complete):
***Responsible Institution 1:** : William Beaumont Hospital
***City:** : Royal Oak
State: Michigan
***Country:** United States
Responsible Institution 2: : William Beaumont Hospital
City: : Troy
State: Michigan
Country: United States

Learning Objective (Complete):
***Learning Objective 1:** : Define the impact of low risk findings by CCTA on use of hospitalization, testing and revascularization.

Presentation Preference (Complete): Oral or Poster Presentation
Payment (Complete): Your credit card order has been processed on Sunday 5 October 2008 at 6:49 PM.
Status: Complete

March 27, 2009

Washington State Health Care Authority

RE: Health Technology Clinical Committee Findings and Coverage Decision: Coronary Computed Tomographic Angiography

To Whom it May Concern:

On behalf of the Society of Cardiovascular Computed Tomography (SCCT), the international professional society representing physicians, scientists and technologists advocating for research, education and clinical excellence in the use of cardiovascular computed tomography, I am writing to express our concerns regarding the findings of the Washington State Technology Assessment on coronary computed tomographic angiography (CCTA) for the detection of coronary artery disease (CAD).

The totality of evidence to date suggests that CCTA is a cost-effective approach for evaluation of low risk patients with acute chest pain in the emergency department (ED) as well as intermediate risk patients with stable chest pain in the outpatient settings.

The results of the Institute for Clinical and Economic Review (ICER) report indicate a favorable conclusion for the ED patients, but an uncertain conclusion for outpatients. In this regard, we are disappointed that the ICER report considered only a fraction of the available evidence to date. Specifically, the ICER report fails in its goals in the following respects:

1) The assumptions of costs for CCTA and other tests are questionable, thereby evoking erroneous conclusions of cost effectiveness.
2) The diagnostic performance characteristics of CCTA are erroenously deflated. "Nonevaluable" segments were considered "positive." This is not the standard of practice with clinical CCTA. One single non-evaluable segment does not uniformly provoke the downstream occurrence of invasive angiography; in fact, this is rarely the case.
3) The diagnostic performance characteristics of other tests (e.g., SPECT) are inflated, and are not in accordance with ACC/ASNC scientific and practice guidelines.
4) The current report does not account for the favorable benefits of primary prevention with medical therapy (e.g., statin medications and aspirin) of those diagnosed with CCTA. In light of the recent COURAGE trial, optimal medical therapy should be promoted as the first-line strategy for individuals with coronary artery disease.
5) Standards of care, as defined by the ICER report, do not reflect general clinical practice. Stress echocardiography, which was utilized as a prominent focus of the ICER report, is used at approximately 10% the rate of nuclear stress testing.

The aforementioned limitations of the ICER report reflect egregiously erroneous assumptions and, in this regard, the conclusions of the ICER report—particularly as they relate to the stable outpatient setting—cannot be reliably accepted. We encourage the state of Washington to evaluate the totality of evidence of CCTA in the stable outpatient setting, where the level of evidence that has been thus far accumulated exceeds the level of evidence to justify its worth in the evaluation of symptomatic patients with suspected coronary artery disease.

Thank you for the opportunity to provide these public comments.

Sincerely,

Daniel Berman, MD
President
Society of Cardiovascular Computed Tomography

MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

1300 North 17th Street ▪ Suite 1752
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

VIA ELECTRONIC MAIL

March 27, 2009

Mr. Steve Hill
Administrator, Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

RE: Computed Tomographic Angiography (CTA for Cardiac Care)

Dear Administrator Hill,

The Medical Imaging and Technology Alliance (MITA) is pleased to submit comments regarding the coverage of Computed Tomographic Angiography (CTA) to the Washington State Health Technology Assessment Program (SHTAP). As the leading trade association representing companies whose sales comprise over ninety percent of the global market for medical imaging, we are pleased that SHTAP acknowledges that CTA is an integral part of a patient's clinical management plan, which provides a less invasive measure for visualizing blood flow in the diagnosis of coronary artery disease (CAD) and the SHTAP should adopt a policy that will allow intervention in CAD by clinicians.

MITA respects the importance and necessity of implementing a sound, reasonable coverage analysis of CTA MITA believes that while there are many positive aspects in the coverage decision on CTA, MITA would like to specifically comment on a few aspects of the coverage decision and request that the SHTAP reconsider its proposed final decision on CTA.

- Specifically, MITA believes that restricting coverage for CTA to only a hospital setting could have the adverse effect of denying access to the improved precision in disease detection and treatment decisions related to this imaging service, which provides exceptionally precise imaging of the heart.
- MITA believes that randomized control trials (RCT) are inappropriate to make a coverage decision on a diagnostic device and using only comparative RCT to determine the evidence for coverage of a diagnostic test will set an unreasonable standard for future coverage decisions by the SHTAP.
- Finally, we believe that the comment period on the draft recommendation was too short and did not allow sufficient time for meaningful public input. The SHTAP should consider adopting a minimum one month comment period that would permit stakeholders to make thoughtful comments and assist the SHTAP in their task.

Therefore, MITA recommends that SHTAP amend the CTA coverage decision to also permit outpatient CTA to investigate low to intermediate rick patients to diagnose acute chest pain as well as emergency room and hospital based coverage.

Access to Outpatient CTA

While the general value of CTA is not debated, the SHTAP choose not to accept outpatient literature when making the final determination in the CTA coverage decision. The Committee commented in the Final Coverage decision that there is "not sufficient, reliable evidence developed to make a determination for other coronary CTA uses, including the outpatient setting" and further stated that "additionally, certification of machines and readers was also discussed; hospitals require JAHCO accreditation and thus have some standards." In its report to the SHTAP, the Institute for Clinical and Economic Review (ICER) included 34 relevant peer-reviewed articles examining the value of CTA in an outpatient setting and demonstrating the value of diagnosing CAD on the outset and early intervention of the disease. Furthermore, appropriateness criteria created by the American College of Radiology (ACR), American College of Cardiology Foundation (ACC) and the American Heart Association (AHA) cited in the evidence review includes outpatient settings for the investigation of CAD as an appropriate and cost effective method of diagnosis. Furthermore, ACR and the Intersocietal Accreditation Commission (IAC) have accreditation requirements for CT equipment that apply outside of the hospital setting. Therefore, well-established accreditation requirements for the CT equipment used to perform CTA in the outpatient setting could be used to ensure the quality of machines and readers beyond just the hospital.

MITA believes that the literature shows that access to CTA in multiple settings beyond the hospital will allow early intervention in CAD and prevent more invasive, potentially dangerous tests at a later point. The final coverage decision should be amended to include outpatient CTA, as well as emergency and hospital-based coverage. CTA should be performed wherever the technology is available by qualified, trained personnel in accredited facilities in accordance with the strenuous practice guidelines developed by ACR, ACC and AHA and not limit CTA to a particular location. Additionally, the goal of SHTAP is to "ensure medical treatments and services paid for with state health care dollars are safe and proven to work" but choosing not to include outpatient literature in the final coverage determination seems to add requirements to the technology assessment process outside the original scope of the program. The SHTAP should confine its activities to the evaluation of specific services rather settings. MITA believes that limiting coverage to only a hospital setting would restrict access to this important tool in detecting and treating CAD.

Use of Randomized Controlled Trials is Inappropriate for Diagnostic Interventions

One of the reasons cited by the SHTAP for limiting CTA usage to the hospital is the lack of a randomized controlled trial (RCT) for the outpatient setting, other than the emergency room. MITA believes that requiring RCTs to evaluate diagnostic tests

does a disservice to the patient and is unnecessarily prohibitive. RCTs are the gold standard for the study of the clinical effectiveness of therapeutic interventions but are less appropriate for comparative studies of diagnostic effectiveness. Methods for comparing the effectiveness of therapeutic treatments correctly use patient outcomes (e.g., mortality, morbidity, quality of life) as the endpoint. Diagnostics, on the other hand, provide information that is used to determine the most effective treatment for the patient. Once an innovative diagnostic devices has been shown to provide a more accurate diagnosis through the use of new, less-invasive method, the value of the device is assessed by examining its effect on subsequent treatment, not patient outcomes. Consequently, evaluation of diagnostics must use changes in medical decisions (e.g., surgery vs. medical therapy), as the endpoint. An RCT using traditional patient outcome endpoints would not capture the full benefit of a new diagnostic test and would not show improvement upon the already high level of diagnostic sensitivity provided by CTA. The SHTAP should consider data presented by ICER that shows the clinical effectiveness in an outpatient setting for CTA, not exclude a treatment location based on RCT data and refrain from using RCT data for diagnostic devices in the future.

Concerns with the Comment Period

Finally, MITA would like to comment on the process that the SHTAP is using to make the final coverage determination. While MITA applauds the openness that SHTAP has shown during the coverage process. MITA is concerned that a small breach of the procedure, when the SHTAP conditionally approved the CTA decision during the public meeting teleconference on March 20th before the close of the comment period, could taint the process. We can understand that this may lead the Committee to presume that the CTA standards are unopposed, but it is still necessary for the Committee to withhold any form of approval of the standards until after the comment period has closed so to ensure the integrity of the process.

Also, MITA believes that a two week comment period is insufficient for many stakeholders to prepare thoughtful comments to help guide the SHTAP to make reasonable coverage decisions for the people of Washington. SHTAP should consider adopting a one month comment period that would permit stakeholders to make thoughtful comments and assist the SHTAP in their task in the future.

Conclusion

Cardiac CTA is a proven and well researched non-invasive diagnostic tool to provide precise and comprehensive anatomic information about the heart and as such offers extraordinary promise for revolutionizing cardiac care. The rapidly increasing scientific literature is quite positive about its impact in removing physician (educated) guess work in diagnosing the correct and precise sources, among many possibilities, of heart ailments. Given the power of this diagnostic tool, restricting coverage for CTA to only a hospital setting would have the adverse effect of denying access to the improved precision in disease detection and treatment decisions related to this imaging service, which provides exceptionally precise imaging of the heart. Also,

using RCTs as a determining factor for coverage will set an unreasonable standard for future coverage decisions for diagnostic services being examined by the SHTAP. Finally, we believe that the comment period on the draft recommendation was too short and that the SHTAP should consider adopting a more open and sound comment period that would permit stakeholders to make thoughtful comments and assist the SHTAP in their task. Therefore, MITA recommends that SHTAP not adopt the CTA coverage decision and revisit the decision in order to include outpatient settings in the coverage decision as well as emergency room and hospital based coverage.

If you have any questions or would like to discuss these matters further, please contact me at 703-841-3250 or via email at breuwer@medicalimaging.org .

Thank you for consideration of these comments.

Sincerely,

Brian R. Reuwer
Director, Health Policy and State Government Relations
MITA

We would like to provide some comments on the Findings and Coverage Decision for Coronary Computed Tomographic Angiography (CCTA), which was discussed on March 20, 2009.

We agree with your findings that CCTA has a lower rate of false negatives than stress ECHO and SPECT and a lower rate of false positives than SPECT. We also agree that the evidence supports the fact that it has practical value in the emergency department setting for making prognostic decisions on patients with chest pain. We commend you on a strong review of the scientific evidence to date.

However, we see administrative issues with how to identify some aspects of the CCTA services, and raise concern that a failure to address these administrative issues is likely to leave us with a brilliant evidence based strategy, that has serious implementation flaws. For example:

- One of your Limitations of Coverage states that the CT machines need to be "64-slice or better capability". Is there a practical way to administer this capability based upon information on a claim form? In the absence of such, would it provide net benefit or net harm if a payer cannot differentiate between scanners with lower from higher resolution?
- Another Limitation of Coverage states that this service is covered for "patients with low to intermediate risk of coronary artery disease". Is there a standard mechanism by which low to intermediate risk patients can easily be distinguished on a claim or clinical record? Are there accepted guidelines and documentation standards to distinguish what patients/ scenarios which would clearly not be low to intermediate risk of coronary artery disease, (such as previous diagnosis of coronary artery disease)?

We have wrestled with these issues relative to this technology. The technology obviously has great promise, but appears to be limited by a lack of an agreed upon administrative framework, to allow its effective (and selective) utilization to those who would most benefit from it.

Given these unresolved concerns, broader questions about whether the technology as a whole should be adopted and covered by third party payers are pertinent to the consideration of this technology. We are concerned that an evidence based review that fails to address the entire picture of what is required to produce net benefit to the health of our society comes up short of the higher purpose we are all working toward.

Thomas E. Paulson, MD, MBA

Medical Director for Care Management

Premera Blue Cross

Thomas.Paulson@Premera.com

Submitted by:

Susan Loewus, RN, MHA, CPHQ

Medical Services Administrator – Medical Policy

Premera Blue Cross

Thanks for calling my attention to this topic.

It looks like the committee has done a thoughtful and careful review of the current data on CCTA. I think the limitation with current data remains the lack of outcomes data, even in the emergency department seting of acute chest pain, there are no studies showing benefit to patients of using CCTA compared to conventional diagnostic strategy. The one RCT (Goldstein) that is cited is small, short term (6 months) and there were zero clinical events in either group, it was a very low risk population. There was a much higher rate of angiography in the CCTA group in that RCT, which is also commonly seen in practice with CCTA, a lot more low risk people are referred on for invasive coronary angiography. Thus, I do not think there is an evidence base at this time to support coverage in an ED setting, outcomes data is needed. Clinical trials to address this question are currently underway and more are planned. I don't think cost-effectiveness will be known until we know more about how the test is used, the number of incidental findings and additional testing, both related to the incidental findings and to the indeterminate and positive and false positive findings on CCTA, and the radiation risks.

I hope these comments are helpful.

RITA F. REDBERG, M.D., M.Sc., F.A.C.C., F.A.H.A.
UCSF School of Medicine
Editor, Archives of Internal Medicine
Professor of Medicine
505 Parnassus Ave., Suite M-1180
San Francisco, California 94143-0124
E-MAIL: redberg@medicine.ucsf.edu
PHONE: 415-476-6874
ASS'T: 415 502 8960, FAX 415 502 7949
FAX: 415-353 9190

Health Technology Clinical Committee
Date: March 20, 2009
Time: 3:00 pm – 5:00 pm
Teleconference Bridge: 1-309-946-5000 Access Code: 9461464

***D*R*A*F*T* Updated April 6, 2009**

HTCC MINUTES

Members Present: Brian Budenholzer; Michelle Simon; Michael Souter; Louise Kaplan; Richard Phillips and Michael Myint.

Members Absent: C. Craige Blackmore; Carson Odegard and Jay Klarnett.

HTCC FORMAL ACTION

1. **Call to Order**: Dr. Budenholzer, Chair, called the meeting to order at 3:07 p.m. Sufficient members were present to constitute a quorum.
2. **November 14, 2008 Minutes:** Chair referred members to the draft minutes and called for a motion and discussion.
   - *Outcome:* The committee unanimously approved the November 14, 2008 minutes.
3. **Artificial Disc Replacement Findings and Decision:** Chair referred members to the updated draft findings and decision and called for a motion and discussion.
   - *Outcome:* The committee unanimously approved the Artificial Disc Replacement updated findings and decision document.
4. **Computed Tomographic Angiography Findings and Decision:** Chair referred members to the draft findings and decision and called for a motion and discussion.
   - *Outcome:* The committee unanimously approved the Computed Tomographic Angiography findings and decision document with a condition. Approval is subject to a review by the Chair of any additional comments received through March 27th.
   - If editorial changes are needed the Chair will update and finalize the document. If comments raise the need for full committee review or major changes are needed, the document and comments will be reviewed by the committee at the next public meeting.
5. **Upright MRI Re-Review Request:** Chair referred members to a request to re-review Upright MRI, heard requestor's testimony, and called for a motion and discussion.
   - *Outcome:* The committee unanimously agreed that new evidence was not sufficient to necessitate a re-review of the Upright MRI in the 2009 round.
6. **Retreat Feedback:** The Chair summarized feedback from committee members received at retreat and proposed changes to the discretionary meeting operations and structure in order to gather comments from the committee members before finalizing his decision.
   - *Outcome:* Clinical Expert – Pilot having a clinical expert at the next two clinical committee public meetings.

- *Outcome:* Public Comment – Continue three minutes for those individuals who show up the day of and streamline stakeholder comments to five minutes each within overall 45 minute time frame. The Chair will work with HTA staff to update the public comment guide.
- *Outcome:* Receipt of Materials at Meeting – Committee should receive all meeting materials one week prior to the public meeting. And all publicly submitted materials need to be submitted to the vendor to be integrated into the technology assessment evidence report. The committee Chair directed HTA staff to update the public comment and meeting guide to indicate this.

SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Opening Remarks

The Health Technology Clinical Committee (HTCC) met on March 20, 2009. The primary topics for discussion include:

- ✓ Review and adoption of the November 14, 2008 public meeting minutes.
- ✓ Review and adoption of the Artificial Disc Replacement Findings & Decision.
- ✓ Review and adoption of the Computed Tomographic Angiography Findings & Decision.
- ✓ Discussion regarding the Upright MRI Re-review request.
- ✓ Retreat discussion and feedback.

Agenda Item: November 2008 Meeting Minutes

Dr. Brian Budenholzer, Committee Chair, presented the draft minutes from the November 2008 meeting. The minutes were drafted by HTA staff and circulated to committee members for comments. No committee comments were received. Chair referred members to the November minutes and called for further discussion, or a motion to approve.

- ✓ Motion and second to approve minutes made. No further discussion
- ✓ Minutes were unanimously approved

Agenda Item: Artificial Disc Replacement Findings & Decision

Chair referred committee members to the updated draft findings and decision for artificial disc replacement. Staff (HTA director) reviewed the updated draft Findings & Decision for Artificial Disc Replacement: the document was drafted by HTA staff; circulated to committee members and posted for public comments on December 12th, 2008 for a three week public comment period ending January 2nd, 2009. No committee comments received, 1 agency comment, 1 industry comment and 1 association comment were received by the program. Primary comments were to separate Cervical and Lumbar ADR and remove access to structured intensive multidisciplinary program from conditions for Cervical ADR because it wasn't included in the Cervical ADR discussion by committee at the public meeting. HTA Staff consulted with chair and updated draft to reflect public comments consistent with record and clarity. Chair, referred members to the draft Findings & Decision for Artificial Disc Replacement, and called for further discussion, or a motion to approve.

- ✓ Motion and second to approve document made. Discussion ensued
- ✓ Artificial Disc Replacement Findings & Decision were unanimously approved

Agenda Item: Cardiac Computed Tomographic Angiography Findings & Decision

Chair referred committee members to the draft findings for Computed Tomographic Angiography. Staff reviewed the draft Findings & Decision for CCTA: the document was drafted by HTA staff; circulated to committee members and posted for public comments on March 13th, 2009 for a two week comment period ending March 27th, 2009. No committee comments were received. Staff also conducted additional outreach efforts to individuals who commented at the November public meeting and during the draft evidence report public comment period. No public comments received. Staff noted that the public comment period ends after the meeting date, and normally would occur prior to meeting.

Dr. Budenholzer proposed a conditional approval of the draft Findings & Decision, pending the completion of the full public comment period. Chair would review any public comments received after

March 20th, 2009, and would accept minor edit changes. However, if comments raise the need for full committee review or need for large changes the draft Findings & Decision and comments would be re-presented at the next public meeting. Committee discussed document and proposal. Chair referred members to the draft Findings & Decision for Cardiac Computed Tomographic Angiography and called for further discussion, or a motion to approve based on the provisions discussed and set.

- ✓ Motion and second to approve document, with condition made. Discussion ensued
- ✓ Cardiac CTA Findings & Decision were unanimously approved with condition

Agenda Item: Upright MRI Re-review Request

Chair referred to request for re-review submitted by Attorney Robert Battles, representing Capital Imaging, LLC. Chair noted this is the first direct request for topic review or re-review to committee and explained that the decision before the committee today was whether a re-review should be commissioned, not a discussion about changing the previous Upright MRI coverage decision itself. HTA staff referenced the meeting package materials and brought to the committee's attention the Upright MRI request and the HTA prepared re-review summary. Additionally, three UCLA study related documents were submitted by the requester and included in the meeting package materials. HTA Staff summarized background: May 2007, the clinical committee determined insufficient evidence existed to approve coverage, and referenced specifics of coverage decision. In September 2008, the HTA program published the 2009 topic selection and two re-review topics and circulated to committee for comments. A PUB MED scan was done on Upright MRI by the HTA clinical consultant, and no significant new evidence and/or concerns were identified by the search, no issues raised by the Agency Medical Directors. One public comment from Mr. Battles' office was received indicating a re-review should be granted and including studies referenced in the committee's material. The HCA Administrator reviewed the request for re-review and did not find sufficient new evidence to merit a re-review, and did not select the topic for re-review. The requester then petitioned the clinical committee for committee action.

The Chair opened the meeting to the requestor for a ten minute presentation led by Mr. Robert Battles. The requestor presented a rationale in support of the re-review, as outlined in the letter of request and referenced the three UCLA articles included in the committee meeting package as well as provided new information on the cost charged by a facility and new CMS issued codes and charges.

Committee discussed the petition, review of studies submitted, views on evidence, and asked follow-up questions to the requestors. Highlights of discussion included: level of evidence presented is not substantially different or inconsistent with previously reviewed trials; evidence is low quality and does not focus on patient or therapy alteration outcomes; updated cost information needs to be submitted in advance and did not address issue of expense from multiple views. Chair called for any further discussion, or a motion. Staff recommended amendment to motion to clarify that the motion for re-review is for the 2009 selection (further re-review cycles occurring at least every 18 months may produce different evidence and outcomes).

- ✓ Motion and second made. Discussion ensued.
- ✓ No re-review of Upright MRI for 2009 cycle approved unanimously.

Agenda Item: Retreat Feedback

Chair noted that he appreciated the committee's thoughts and feedback at the February 2009 retreat. Based on the discussions held at the retreat, the Chair proposed a few different approaches to the current meeting structure and requested committee perspectives prior to finalizing any decisions.

Clinical Expert – Chair proposed a pilot of having a clinical expert available at the next two public meetings, with roles and responsibilities outlines. Within budgetary constraints, the best option would be for the technology assessment vendor to provide a clinical expert (e.g. peer reviewer from the evidence report) to be available; otherwise, having the HTA program's clinical consultant find a clinical

expert. Committee clarified that it would be inappropriate for the clinical expert to be part of the decision-making process. Clinical expert should only be directed questions, and only at the general discussion phase, not when coverage decision is being made. Leah Hole-Curry, HTA Director, expressed that this meeting structure request are not by-law changes and can be made at the Chair's discretion.

- ✓ Outcome: Committee unanimously agreed to pilot the clinical expert for the next two public meetings. HTA staff will work with Chair on process and technical and financial feasibility.

Public Comment – Chair provided background regarding how the committee has handled public comments thus far. Leah Hole-Curry, HTA Director, provided a detailed summary on how the program handles public comments submittals and allocation on time.

- ✓ Outcome: Committee unanimously agreed to continue to allow 45 minutes for public comments. Three minutes will be allotted for individuals who show up the day of the public meeting, and five minutes will be allotted to stakeholders who request time in advance of the public meeting.
- ✓ Outcome: HTA staff will work with Chair to update the public comment guide to reflect these changes.

Receipt of Materials at Meeting – Chair commented on the value of receiving information from the public (materials), but stressed the need to do it in a timely manner and through the evidence based evaluation process. Chair stressed that the program needs to submit meeting materials to the committee at least one week in advance of the public meeting. Chair stressed that stakeholders needed to use the program process in submitting materials to the committee, so it can be integrated into the technology evidence report. The process for any "last minute – late breaking evidence" is the re-review process.

- ✓ Outcome: Committee unanimously agreed that receipt of committee materials needs to be submitted one week prior to the public meeting. The committee unanimously agreed that all stakeholder materials need to be submitted to the program to be included in the technology evidence report. No materials will be accepted by the committee at the public meeting.
- ✓ Outcome: HTA staff will work with Chair to update the public comment and meeting guide to reflect these changes.