WASHINGTON STATE DEPARTMENT OF HEALTH RULE-MAKING PROCESS FOR
Non-Emergent Percutaneous Coronary Interventions (PCI)

THE STAKEHOLDER COMMITTEE'S

# Third Meeting

**Monday, 15 January 2008 9:00 a.m. – 3:50 p.m.**
SeaTac Doubletree Hotel Northwest Room 1
18740 International Blvd. SeaTac, WA

# DRAFT SUMMARY

OF THE KEY DISCUSSIONS, DECISIONS AND AGREEMENTS

*ATTENDEES:*

**COMMITTEE MEMBERS: Pat Bailey**, Auburn Regional Medical Center; **Kris Becker**, Sacred Heart Medical Center, Spokane; **Marc Berg**, Southwest Washington Medical Center, Vancouver; **Dr. Terry Block**, Valley Medical Center, Renton; **Diane Buelt**, Legacy Salmon Creek Hospital, Vancouver; **Jody Carona**, Health Facilities Planning and Development, Seattle; **Dr. Larry Dean**, University of Washington Medical Center, Seattle, and the American Heart Association; **Bart Eggen**, Facilities and Services Licensing, Washington State Department of Health, Olympia; **Dr. Nancy Fisher**, Washington State Health Care Authority (HCA), Olympia; **Frank Fox**, Health Trends/Swedish Medical Center, Seattle;; **Jim Good**, Franciscan Health, Tacoma; **Dr. Mary Gregg**, COAP Medical Director; **Dr. Dennis Hansen**, Highline Medical Center, Burien; **Chuck Hawley**, Providence Health and Services, Seattle; **Scott Laubisch**, PeaceHealth/St. John Medical Center, Longview; **Dr. Howard Lewis**, Swedish Medical Center; **Dr. Rubin Maidan**, Evergreen Hospital, Kirkland; **Dr. Vinay Malhotra**, Good Samaritan Hospital, Puyallup; **Corinne Murphy-Hines**, Yakima Regional Medical Center; **Dr. Mike Ring**, Sacred Heart Medical Center; **Steve Saxe**, Facilities and Services Licensing, Washington State Department of Health; **Dr. Robert Stewart**, Skagit Valley Hospital, Mt. Vernon; **Dr. David Warth**, Northwest Hospital; **Gail Weaver**, Yakima Memorial Hospital; and **Jim Reid**, The Falconer Group (facilitator)

**CAUCUS MEMBERS AND GUESTS: Bill Alkire**, Auburn Regional Medical Center; **John Capps**, Swedish Medical Center; **Matt Crockett**, Highline Medical Center, Burien; **Dan Dixon,** Swedish Medical Center; **Mary Filipovic**, Northwest Hospital; **Brith Grinnel**, Capital Medical Center, Olympia; **Lisa Grindl**, Health Facilities Planning and Development; **Thomas Hightower**, Grays Harbor Hospital; **Ben Lindekugel**, Evergreen Healthcare; **Gail McGaffick**, Health Facilities Planning and Development; **Richard Milne**, Pacific Public Affairs; **Ken Mills**, Evergreen Healthcare; **Dan Nelson**, Skagit Valley Hospital; **David Olson**, consultant; **Kirk Raboin**, PeaceHealth/St. John Medical Center; **Janis Sigman**, Facilities and Services Licensing, Washington State Department of Health; **Kristin Sitkov**, COAP; **Jeff Uyyek**, University of Washington Medical Center; and **Dr. Thomas Wharton**, Exeter Hospital, Exeter New Hampshire, and SCIA

## COMMITTEE AGREES THAT A ROBUST DATA SET IS NEEDED TO ENSURE ACCOUNTABILITY

The Committee's discussion about ensuring or improving access to care evolved into a discussion about data needs. Committee members articulated two common interests: 1) provide the best quality care for every patient undergoing Percutaneous Coronary Intervention, no matter where the procedure is performed; and 2) ensure that the institutions and physicians who perform non-emergent PCI services are held accountable to meet standards and expectations.

To ensure accountability, the Committee agreed that the State, hospitals and the public need a robust data set that documents and highlights outcomes. Some Committee members referred to this data as "COAP Plus." Some on the Committee suggested the data needs to be accessible to the public, while a number of members stated that in establishing standards and holding hospitals accountable, there must be penalties for not achieving the standards.

A proposal was offered for identifying data needs: Convene a committee of physicians to develop a risk stratification process. Another proposal was offered to oversee the collection, analysis, and monitoring of the data related to outcomes: Establish an internal monitoring committee of clinicians, administrators and representatives of the State. Both proposals have a common element that seemed of interest to the group: peer review.

The Committee requested that Dr. Mary Gregg provide data on the number of PCIs performed by each physician during a recent year to get a better understanding about outcomes. Dr. Gregg agreed to present the data at the Committee's next meeting. The information will also include the number of physicians and procedures per hospital.

In opening the discussion about access, Jody Corona, speaking on behalf of a number of the Committee members and the hospitals they represent, stated that if the policy goal is to increase local access, the Certificate of Need (CON) rules would reflect these principles:

- Minimum facility volumes necessary to ensure safety and quality—based on evidence.
- Acknowledgment that access is of concern and improving access to PCI will improve mortality and morbidity (assuming minimum volume and infrastructure is in place).
- Planning area boundaries recognize the importance of timely, local access to PCI and the inextricable link between emergent and non-emergent.
- Minimize competition between qualifying communities/hospitals for new programs.
- A need methodology that recognizes some existing volumes will be redistributed to improve access.
- Protections for existing providers focus on volumes necessary to maintain a quality program, but again acknowledge some redistribution is beneficial for the greater good.

Chuck Hawley, speaking on behalf of other Committee members and the hospitals they represent, defined criteria for access that the State should use:

- Are travel times reasonable?
- Are underserved populations served?
- Are there significant wait times for patients?

## COMMITTEE REACHES CONSENSUS ON FACILITY STANDARDS AND TRANSFER AGREEMENTS

Resuming a discussion that began at the Committee's December meeting, Committee members presented their positions on facility and transfer agreement standards that should be met by hospitals performing non-emergent PCI without surgical backup. The discussion resulted in a consensus among the members, with the possible exception of one standard.

The Committee agreed that hospitals performing non-emergent PCI without surgical backup need:

- written, signed transfer agreements with the hospital or hospitals to which patients would be transferred in event of an emergency, and similar agreements between the hospitals' surgeons;
- as part of the agreements between the hospitals, commitment or a demonstration of the ability to achieve door-to-balloon times within 90 minutes, and to begin the procedure within 120 (two hours);
- a staffing plan;
- on-call schedule with operation of the laboratory 24 hours-per-day, seven days-per-week;
- prearranged mode of transportation to facilitate transfers;
- to communicate to the patient that the non-emergent PCI will be conducted without surgical backup on the premises;
- to communicate with hospitals with which they have transfer agreements, including alerting the partner (receiving hospitals) that the procedure is about to be conducted; and
- a process for communicating with partner hospitals to ensure continuous quality improvement, and the process needs to involve the clinicians.

One feature or standard that was not agreed to was creating a video link between hospitals.

The Committee appeared to conclude that transfer agreements should fit the guidelines of surgical (receiving) hospitals because they should not be expected to drastically alter their systems and procedures. The members also expressed the pragmatic perspective that agreements between hospitals will reflect the interests and needs of both institutions. Thus, the State need not dictate the terms and conditions of transfer agreements, but in reviewing them. should be able to conclude that the hospitals have created a partnership that will ensure high quality care.

Finally, the Committee strongly expressed the sentiment that surgeons need to influence the terms of transfer agreements and must be involved in the "lessons learned" dialogue between hospitals that produces continuous quality improvement.

## PARTIES PRESENT THEIR POSITIONS ON HOSPITAL VOLUMES

The parties presented their positions on hospital volumes, with Dr. Thomas Wharton, Dr. Michael Ring, and Chuck Hawley opening the discussion.

On behalf of the Committee members who advocate that hospitals without on-site surgical backup be allowed to apply for a CON to perform non-emergent PCIs, Dr. Wharton proposed that hospitals performing at least 150 or 200 non-emergent PCIs annually should be allowed to apply for the CON. He stated that if a principal consideration is improving access, 150 could be the volume threshold; if the principal consideration is ensuring the same level of quality currently achieved by hospitals with surgical backup, then the minimal threshold for being able to apply for

the CON could be 200. Regarding the latter proposal, he referred to studies that indicate there is no difference in quality (outcomes) between hospitals performing 200 PCIs annually and those that annually perform 400 or more.

The evidence upon which Dr. Wharton based his proposal is a study from The Society for Cardiovascular Angiography and Interventions (SCAI), "The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions." In addition, he cited other studies and papers.

Dr. Wharton also suggested that while volume standards are relevant and necessary, they are "not the be all and end all." He said that door-to-balloon times are a better surrogate for quality than volumes. And he pointed to the unintended consequences of volume thresholds that are set too high, including pressures placed on hospitals or physicians to perform the procedure when it may not be appropriate or when another treatment may be more appropriate.

In seeking clarification about Dr. Wharton's proposal and findings, some Committee members questioned how the SCAI reduced by fifty percent the proposed volume standard in two years (the Fall 2005 guidelines versus the 2007 report). And some Committee members cited standards used by other states to suggest that the volumes proposed by Dr. Wharton may be too low. New York, which has established hospital volumes at 400 per year, was the example cited for the Committee.

In proposing an alternative to Dr. Wharton's recommendations, Chuck Hawley stated that his position is to not prevent hospitals without on-site surgical backup from performing non-emergent PCI, but to ensure that quality outcomes are achieved, and the criteria for evaluating CON applications are applied.

Dr. Ring and Chuck Hawley recommended that the standards proposed by the Department of Health in its first preliminary draft rules be adopted, including the "ramping up" schedule between years one and three. Hospitals applying for the CON would have to demonstrate that they would perform 300 PCIs during the first year, and by the third would be performing 400. The basis for their proposal is the Health Management Associates (HMA) report and recommendations that were provided to DOH in September 2007. In addition, they cited the positions of the American College of Cardiologists (ACC) and the American Heart Association (AHA).

In addition to the volume standards, Chuck proposed that the Department monitor hospital volumes to ensure compliance and revoke the CON if volumes fell below the minimum thresholds. Furthermore, he endorsed the "COAP Plus" data set so that the State can in the future monitor and hold accountable existing and new providers of non-emergent PCI services.

Finally, not unlike Dr. Wharton's idea about placing greater emphasis on outcomes than volumes, Chuck suggested that over time the focus of the CON process should be shifted from volumes to outcomes.

In seeking to clarify the position articulated by Chuck Hawley and Dr. Mike Ring, some Committee members voiced concern that if their proposed volume standards were adopted by the State, no hospitals without on-site surgical backup would be granted a CON to perform non-emergent PCIs. They also expressed concern that raising the volume standard between the first and third years of a hospital's program would signify that the CON process is changing from one

that establishes and holds hospitals accountable for achieving minimal standards for ensuring patient care and safety to one that is holds them accountable for achieving optimal standards.

As the discussion concluded, there appeared to be agreement on these two points:

1. No hospital performing less than 150 PCIs annually should be allowed to perform non-emergent PCI without on-site surgical backup.

2. Minimum volume thresholds or standards are needed, but outcomes are also important. Over time the standard or emphasis (the primary consideration or factor in granting a CON, and in determining whether or not its terms and conditions are being achieved) could become the outcomes achieved by hospitals rather than their annual volumes.

### COMMITTEE AGREES ON HOW TO ADDRESS IMPACTS ON EXISTING PROVIDERS

The Committee agreed that in submitting a CON application, the applicant should not only forecast the volumes it expects to achieve, but should also identify the impact on existing providers' volumes, including the University of Washington, and project whether or not granting the CON would reduce the volumes of existing providers below the minimum volume thresholds.

### COMMITTEE DISCUSSES ESTIMATING AND FORECASTING NEED AND DETERMINING PLANNING AREAS BOUNDARIES

The day's last discussion centered on estimating and forecasting need, which Committee members related to determining planning area boundaries.

Frank Fox presented an idea for a methodology to estimate and forecast need that included these provisions:

- To calculate the mean planning area volume, use the planning area's PCI volumes for residents for the three most recent years. Distinguish volumes for people 18-64 and people 65 and older.
- Calculate a PCI utilization rate per 1,000 residents for these two age groups using the mean PCI volume and the planning area population estimates for the year that corresponds to the most recent year of actual PCI volumes for the two groups.
- Use COAP statistics, as available, to distinguish between "emergent" and "non-emergent" PCIs.

More specifically, to forecast need, Frank proposed:

- Prepare forecasts for seven years from the date of the most recent actual PCI volume statistics.
- Determine the planning area population forecast for the two age groups (18-64 and 65 and over).
- Use the State of Washington's Office of Financial Management (OFM) population statistics and projections, as available. Use OFM's "medium series" population projections, as available.

- Use the mean PCI utilization rate for each age group, multiplying it by the forecasted population, by year, for each age group.

These steps would establish the projected number of PCIs for planning area residents. Then:

- Estimate the in-migration and out-migration percentages for PCIs in the planning area using the three-year mean percentage as a percent of the planning area PCI total for each age group.
- Apply the in-migration and out-migration adjustments to planning area projected PCI volumes. Assume constant migration percentages. This establishes planning area and planning area provider PCI projected volumes.

These steps will identify the "demand" for PCIs. To estimate "supply," Frank suggested:

- Use volume estimates from CHARS for the most recent year, supplemented by COAP data as available;
- Planning area PCI providers would survey data that is compiled by the Department as part of the due diligence associated with an applicant's request.

The DOH would prepare a forecast analysis of "demand" for PCIs, as defined above, and "supply," as defined above, by subtracting supply from demand. The arithmetic estimate would be considered "shortage" if positive, and "surplus" if negative.

- Applicants would submit a detailed analysis of their projected volume for total and the elective PCIs over a seven-year-forecast period.

- Applicants would indicate whether their projections include planning area resident PCIs that currently are provided at the University of Washington Medical Center. If there are such PCI volumes, applicants would describe how their projects would not affect UW PCI volumes.

- Over time, estimating/forecasting formula would be refined by creating a two-step process using CHARS data as is currently done, supplemented by COAP data in the second step, to more effectively and accurately capture volumes and outcomes.

Finally, any hospital providing PCI procedures must allow disclosure of COAP data to estimate PCI volumes and forecast need.

The initial reaction to the proposal was that it was sound. One amendment to the recommendation was to use trends rather than averaging. Two suggestions for determining supply were: a) divide the demand by some volume to estimate the expected number of PCI providers; or b) identify the number of cath labs, determine the capacity of each (how many PCIs could be performed in each one given limitations of time), and add up the number of procedures that could be performed in all the cath labs of the planning area.

By the conclusion of the discussion, there appeared to be a tentative consensus on how to forecast demand, although there are a couple options, such as using trends rather than averages, for which there was not an agreement. There was not a consensus on how to determine supply. And there appeared to be agreement on the five points:

1. Existing providers should be protected from dropping below a minimal volume threshold related to quality.
2. The burden to demonstrate need is on the applicant.

3. The methodology to estimate need should be practical, meaning that whatever methodology is used, data can be obtained to apply it, and it should not be overly complicated.
4. Data should be gathered for the most three recent years, but in forecasting future need, rather than looking seven years out, the State and applicants should look five years ahead.
5. The numbers used to calculate need should not be "moving targets," but instead should be predictable and consistent.

## NEXT COMMITTEE MEETING IS TO BE DETERMINED

The Committee is likely to have one more meeting. Facilitator Jim Reid will work with the Department of Health staff to find proposed two or three dates in February for the next meeting, and these dates will be offered to the Committee members to determine which one is most convenient for the greatest number of people.