**Health Technology Clinical Committee**
**Date: October 22nd, 2010**
**Time: 8:00 am – 5:00 pm**
**Location: Port of Seattle – International A (London / Amsterdam) conference room**
**Teleconference Bridge: 1-877-597-2663 Access Code: 5855297**
**Adopted: December 10th, 2010**

## HTCC MINUTES

**Members Present:** Dr. Carson Odegard; Dr. Richard Phillips; Dr. Craige Blackmore; Dr. Marie-Annette Brown; Dr. Kevin Walsh; Dr. Christopher Standaert and Megan Morris.

**Teleconference:** Dr. Michael Myint (8 am – 9 am) and Dr. Brian Budenholzer

**Absent:** Dr. Michelle Simon and Dr. Michael Souter

## HTCC FORMAL ACTION

1. **Call to Order**: Dr. Blackmore, Vice-chair, called the meeting to order. Sufficient members were present to constitute a quorum.
2. **August 20th, 2010 Meeting Minutes**: Vice-chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.
   - *Action: Seven committee members approved the August 20th, 2010 meeting minutes. Two committee members abstained from voting.*
3. **Breast MRI (BMRI) draft Findings & Decision:** Vice-chair referred members to the draft findings and decision and called for further discussion or objection. The Breast MRI findings & decision was approved and adopted by the committee.
   - *Action: Seven committee members approved the Breast MRI findings & decision document. Two committee members abstained from voting.*
4. **Spinal Cord Stimulators (SCS) draft Findings & Decision:** Vice-chair referred members to the draft findings and decision and called for further discussion or objection. The Spinal Cord Stimulators findings & decision was approved and adopted by the committee.
   - *Action: Seven committee members approved the Spinal Cord Stimulation findings & decision document. Two committee members abstained from voting. Amended with editorial changes.*
5. **Total Knee Arthroplasty (TKA):** The HTCC reviewed and considered the Total Knee Arthroplasty technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. 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.

| HTCC COMMITTEE COVERAGE DETERMINATION VOTE | | | |
|---|---|---|---|
| | **Not covered** | **Covered Unconditionally** | **Covered Under Certain Conditions** |
| **Computer Navigated Total Knee Arthroplasty (CN-TKA)** | 3 | 5 | 0 |
| **Uni-compartmental Knee Arthroplasty (UKA)** | 2 | 6 | 0 |
| **Multi-compartmental Partial Knee Arthroplasty** | 8 | 0 | 0 |

- *Action:* The committee vice-chair directed HTA staff to prepare a Findings and Decision document on Total Knee Arthroplasty surgical techniques reflective of the majority vote.

6. **Routine Ultrasound for Pregnancy:** The HTCC reviewed and considered the Routine Ultrasound technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. 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.

| HTCC COMMITTEE COVERAGE DETERMINATION VOTE | | | |
|---|---|---|---|
| | **Not covered** | **Covered Unconditionally** | **Covered Under Certain Conditions** |
| **Routine Ultrasound** | **0** | **0** | **8** |

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Routine Ultrasound reflective of the majority vote.

## SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

### Agenda Item: Welcome & Introductions

- ✓ The Health Technology Clinical Committee (HTCC) met on October 22nd, 2010.

### Agenda Item: Meeting Open and HTA Program Update

Dr. Craige Blackmore, HTCC Vice-chair, opened the public meeting.

- ✓ Leah Hole-Curry, HTA Program Director, provided an overview of the agenda, meeting guide and purpose, room logistics and introductions.

### Agenda Item: Previous Meeting Business

August 20th, 2010 Meeting Minutes: Vice-chair referred members to the draft minutes and called for a motion and discussion. Minutes were circulated prior to the meeting and posted.

- ➢ *Action: Seven committee members approved the August 20th, 2010 meeting minutes. Two committee members abstained from voting.*

Breast MRI (BMRI) Findings and Decision: Vice-chair referred members to the draft findings and decision and called for further discussion. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. Four public comments were received and were included in the committee meeting packets.

- ➢ *Action: Seven committee members approved the Breast MRI findings & decision document. Two committee members abstained from voting.*

Spinal Cord Stimulation (SCS) Findings and Decision: Vice-chair referred members to the draft findings and decision and called for further discussion. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. Thirty-seven public comments were received and were included in the committee meeting packets.

Discussion on comments opposing draft decision for non-coverage with focus on a perception that the Turner study was weighted over three other RCTs and these RCTs were undervalued; and inadequate consideration of treatment guidelines and Medicare NCD; and whether important RCTs were not included. The committee confirmed that no identified RCTs were omitted; and that treatment guidelines conflicted and the Medicare NCD was over 10 years old, made prior to any of the primary studies, and did not consider evidence. Regarding RCT evidence, committee discussed report findings that all RCTs were small, and comparators were weak. Additionally they were focused on short term pain effect (weak effect demonstrated in 2 of 3), but that all other important patient outcomes (QOL, function, pain medication, mid-and long term) were not impacted or not measured. The Turner study complimented rather than trumped RCTs in finding that real world application and measurement of multiple outcomes showed no improvement.

- ➢ *Action: Seven committee members approved the Spinal Cord Stimulation findings & decision document. Two committee members abstained from voting. Amended with editorial changes.*

### Agenda Item: HTA Program Review

- ➢ Leah Hole-Curry, HTA Program Director, provided the HTA context for the meeting and an update on program activities including:

- Introduced the newly appointed committee member, Marie Annette-Brown
- State purchasing context and budget reductions and reform efforts, medical technology is driver of increased medical costs and has quality gaps
- HTA is designed to use reliable science and independent committee to get best information on what works, what is safe and what provides value
- HTA outcomes include transparency; reports and articles reviewed; and coverage decisions made
- Comparison with private industry and Medicare decisions completed
- Program has received recent recognition from public media, clinical press, and various medical and health policy groups with either story highlights or invited presentations

## Agenda Item: Total Knee Arthroplasty (TKA) Topic Review

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Staff provided an overview of the timeline and referred HTCC members to the included key questions and population of interest for Total Knee Arthroplasty review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert, Dr. Paul Manner an orthopedic surgeon from the University of Washington. Dr. Manner completed a conflict of interest and indicated no conflicts.

## Agenda Item: Public Comments

The Vice-chair called for public comments.

- ✓ Scheduled Public Comments: Two stakeholders scheduled time for public comments.
  - o Dr. Bert Thomas, Smith & Nephew, expressed concerns on the key questions. Furthermore, he stated that mechanical alignment is critically important since it helps improve function. Referred committee members to the Dotson study which had over 1,000 patients with shorter hospital stays and patients walking sooner with computed assisted surgery. Dr. Thomas believes that the Dotson study suggested that computer assisted surgery improves alignment, function, decreases hospital stay and diabolic events.
  - o Tim Frandsen, Smith & Nephew, believes that all level I studies should be weighed appropriately (Dotson and Chung studies). Furthermore, Dr. Frandsen stated that some of the words used in the evidence report are misleading and open to interpretation. Believes that the Novak study illustrates how computer assisted surgery is cost effective. Disagreed with the evidence vendor to include the Bowen study (level III study) since it had poor quality data.
- ✓ Open Public Comments: no individuals provided comments during the open portion.

## Agenda Item: Total Knee Arthroplasty Topic – Agency Comments

Dr. Gary Franklin, Department of Labor & Industries, Medical Director, presented the agency utilization and outcomes for Total Knee Arthroplasty to the committee, full presentation published with meeting materials.

- ✓ TKA Treatment Background:

- TKA is an effective treatment for knee pain with loss of function caused by osteoarthritis (OA) or rheumatoid arthritis (RA) when other treatments have failed.
- Evolution of conventional TKA to include computer navigation may improve on conventional techniques.
- Less invasive procedures to replace only 1 or 2 (of 3) compartments may be alternatives to TKA.

✓ Agency Concerns:

- Safety: Low – TKA has proven relatively safe and cost effective.
- Efficacy: Low – Unclear benefit from new alternative procedures. Newer procedures potentially lead to broader usage.
- Cost: Medium – TKA is a high cost procedure for knee OA; any advances to TKA that increase cost should be demonstrated to be cost-effective, in addition to being at least equally safe and effective; Australian HTA estimates CN-TKA adds $1,500 and the number of procedures done each year is increasing (average of 12% increase per year for last three years, agency total).

✓ Coverage Overview:

- UMP and DSHS have no explicit policy or guideline and currently reimburse for TKA procedures, including various techniques, but may not separately pay for computer navigation. L&I covers TKA, unicompartmental (UR/PA) and computer navigated (add on CPT code is payable, $234). L&I does not cover bicompartmental TKA.

✓ TKA Agency Costs (2009)*

| Agency | Average/patient | Total |
|---|---|---|
| UMP | $14,723 | $10,703,617 |
| L&I | $20,087 | $8,798,222 |
| DSHS | $11,505 | $4,410,825 |

** All costs are based on All Services, Day of Surgery figures. Patients may have had more than one procedure of the type specified but are counted only once per year.*

✓ Evidence: Safety and Efficacy

| Treatment | Comparator | Safety | Efficacy |
|---|---|---|---|
| CN-TKA | Conv-TKA | Possibly lower risk of embolism, longer surgery time | At least equal |
| Uni-compartmental | Conv-TKA | About equal | About equal |
| Bi-compartmental | UKA | Very limited evidence | Very limited evidence |

✓ Evidence: Differential efficacy

| Treatment | Factors |
|---|---|
| Conv-TKA: | Equivalent effectiveness including: age, sex, obesity, other co-morbidities, hospital or surgeon volume. |
| Uni-compartmental | Younger age associated with higher revision rate (same as TKA), otherwise no consistent effects. |
| Staged vs simultaneous | No difference in pain, function or revision.<br><br>**Increase in mortality for simultaneous TKA** |

✓ Cost-effectiveness

| Treatment | Comparator | C/E |
|---|---|---|
| CN-TKA | Conv-TKA | Evidence is insufficient to show CN- cost-effectiveness |
| Uni-compartmental | Conv-TKA | Evidence suggests Uni- may be as cost-effective as TKA |
| Bi-compartmental | UKA | No evidence |

✓ AMDG Recommendations: when TKA or UKA are medically necessary – Coverage with criteria

- TKA: covered for patients with 2 or 3 compartments when conservative treatment has failed;
- Uni-compartmental: for patients with only 1 diseased compartment and who have failed conservative treatment;
- Per FDA approved indications and contraindications; No age limitation; No BMI limitation;
- Computer navigated TKA: not covered due to limited data on cost-effectiveness, and evidence that CN-TKA reduces risk of unsatisfactory alignment, but alignment is not linked to functional outcomes.
- Bi-compartmental: not covered due to limited evidence base.

## Agenda Item: Evidence Review Presentation

Spectrum Research presented an overview of their evidence report on Total Knee Arthroplasty, full presentation in meeting materials.

- ✓ *Background:* Conventional total knee arthroplasty (CONV-TKA) is an effective treatment for end stage knee arthritis. Over time, technologies to improve CONV-TKA have been introduced. Whether these technologies improve CONV-TKA and are efficacious or cost-effective is uncertain. Two of these technologies, computer-navigated total knee arthroplasty (CN-TKA) and partial knee arthroplasty are the subject of this HTA. *Indications for CN-TKA – similar to CONV-TKA:* Moderate to severe arthritic knee pain that has not adequately responded to a prolonged course of nonsurgical treatment, **and r**adiological evidence of joint damage, **and** lower quality of life due to clinically significant limitations in function
- ✓ *Indications for partial knee arthroplasty:* Similar to TKA except that the arthritis is limited to one compartment (medial or lateral for unicompartmental) or to two compartments (medial or lateral and patellofemoral for bicompartmental). Partial knee arthroplasty traditionally reserved for relatively inactive elderly patients, but is being used with increasing frequency in younger, more active patients.
- ✓ *Literature Search:*

| 5. Publications included | |
|---|---|
| CN-TKA | (n = 48) |
| Partial KA | (n = 29) |
| Subpopulations | (n = 27) |
| Cost Effectiveness | (n = 3) |

- ✓ *Key Question 1: Efficacy of CN-TKA vs. CONV-TKA* – ROM reported by 6 RCTS
    - o No significant differences between groups in 5 studies either post-op or at 2 years. CN-TKA range: 102º to 129º. CONV-TKA range: 100º to 129º.
    - o One study recorded slightly greater flexion in the CN-TKA group (132º vs. 125º), p=.001
- ✓ *Radiographic Alignment:* Odds ratio of achieving satisfactory alignment defined as $\leq$3º from the mechanical axis (Australian HTA)
    - o 25 studies (5 RCTs, 6 quasi-RCTs, and 14 cohort studies). Of these, 10 studies were also reported in the Bauwens et al
    - o CN-TKA had 4.14 times higher odds of achieving satisfactory alignment compared with CONV-TKA (odds ratio: 4.14; 95% CI, 3.03, 5.66; P < .00001).
- ✓ *Summary CN-TKA Efficacy:* CN-TKA reduces the proportion of patients with misalignment. However, this does not appear to have an effect on short term pain or functional outcomes. Whether CN-TKA improves long term outcomes to include revision rates is not yet known.
- ✓ *Key Question 2: Bi-UKA* – no RCTs found. One small retrospective cohort study: no difference in functional scores at a minimum of 4 years follow-up. No revisions recorded in either group.
- ✓ *Summary PKA Efficacy / Effectiveness:* with limited evidence, we found similar functional outcomes between UKA and TKA. UKA revision rates tended to be higher than TKA revision rates at 10 and 15 years following surgery
- ✓ *Key Question 3: Safety* –
    - o CN-TKA: CN-TKA: 25 RCTs and 14 nonrandomized studies provided safety data.
    - o VTE: CN-TKA, which does not use intramedullary alignment rods, may lead to fewer embolic events
    - o Bi-UKA, Bicompartmental KA – 2 cases (9%) of intraoperative fracture of the tibial spine in 1 retrospective cohort study of bi-UKA. No complication data available from the 2 registry studies of bicompartmental knee arthroplasty.
- ✓ *Key Question 4: Differential Efficacy / Safety* –
    - o CONV-TKA: Diagnosis of RA vs. OA associated with greater improvement in function compared with baseline (may be related to lower baseline function). No other factors consistently associated with outcome to include: obesity; age; sex; comorbidities; hospital and/or surgeon volume.

- CN-TKA: Morbid obesity (BMI >40) was associated with greater blood and hemoglobin loss and superficial infection compared with non obesity (BMI <30) in 1 retrospective study
- UKA: Younger age was consistently associated with higher revision rates among several large registries and cohort studies (<65 vs. >65). Similar association for CONV-TKA (not differential). No other characteristics were associated with failure to include obesity, sex or provider facility
- Simultaneous vs. staged bilateral TKA: No RCTS, 11 cohort studies. No difference in pain or function in 5 cohort studies at follow-up from 3-15 years. Revision and prosthesis survival was similar in 2 studies, one with 3 year and one with 10 year F/U. Mortality appears to be higher among those receiving simultaneous TKA vs. staged.

✓ *Key Question 5: Cost effectiveness –*

- CN-TKA: Limited data. One US study calculating ICER ($45,554 per QALY).
- UKA: 3 studies. Varying assumptions.

✓ Points to Consider:

- CN-TKA: CN-TKA reduces the risk of unsatisfactory alignment of the mechanical axis (> 3º) compared with CONV-TKA. Despite this, there is no evidence in the short term (<3 years) that CN-TKA results in better patient reported, clinical or QoL outcomes. Only short term revision rates are available from small studies and they are inconsistent. To determine the effect of CN-TKA on revision rates, longer follow-up is needed. There appears to be fewer emboli following CN-TKA than CONV-TKA as measured by the Mayo Clinic Score. This is attributed in part to the absence of use of the femoral IM guide in CONV-TKA. However, its clinical importance is not known. VTE events are similar between CN-TKA and CONV-TKA as are wound and other complications. Postoperative transient confusion occurred slightly less frequently one RCT and markedly less frequently in a second among those receiving CN-TKA.
- UKA and bicompartmental KA: Pain and function appear to be similar comparing UKA and TKA in patients with unicompartmental disease. ROM is consistently higher in patients receiving UKA. Revision rates tend to be slightly higher in the UKA vs. TKA group in most studies up to 10 years of follow-up. Likewise, prosthesis survival slightly favors TKA at 10-14 year follow-up. The safety profile with respect to mortality, VTE, wound complications and other complications is similar between UKA and TKA. Bicompartmental knee arthroplasty in two large registry studies had similar survival 2-4 years following surgery. The longer term effect is not known. The safety profiles of bicompartmental knee arthroplasty and bi-UKA are not known.
- Differential Efficacy: Younger age at the time of UKA is associated with higher revision rates. This is thought to be related to activity level. The age cut off used by many studies was 65years; however, there is some evidence of a dose response. Though there is an association between age and revision, this is not differential; that is, lower age is also associated with higher revision rates in TKA. Mortality is slightly higher among patients receiving simultaneous bilateral TKA compared with staged. However, whether this difference is real or a function of selection bias is not known. These data are taken from registries and only individuals completing the second stage were included in the staged group. Therefore, a "healthy patient" bias may result.
- Cost-Effectiveness: There is insufficient revision data to conclude whether CN-TKA is cost effective. Modeling suggest that the 10 year revision rate would need to be reduced between 33%-50% of CONV-TKA for potential cost savings. There is some evidence that UKA and TKA have similar cost and QALY outcome profiles in older patients (mean age of 70 years), but this evidence depends on assumption that need verification with longer studies.

## Agenda Item: HTCC Total Knee Arthroplasty Discussion and Findings

Dr. Blackmore, Committee Vice-chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of Total Knee Arthroplasty beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

### 1. Evidence availability and technology features

1.1 The evidence based technology assessment report indicates that in 2005, over 555,000 TKA procedures were performed in the United States, a 69% increase compared with 1997. The high prevalence of knee arthritis in the population is reflected in the high cost of treatment, which has been estimated at $6.3 billion per year.

1.2 The evidence based technology assessment report summarized the evidence on CONV-TKA for end stage knee arthritis as effective in improving short and long term outcomes and quality of life. However, questions remain about when the procedure is most appropriate and for whom, and whether certain types of knee replacement procedures produce better results.

1.3 The evidence based technology assessment report summarized TKA as a procedure in which articular surfaces of the medial and lateral compartments are replaced. The patellofemoral articular surface may or may not be replaced in TKA. The conventional method of achieving limb alignment in TKA includes use of anatomic landmarks and special jigs provided with the knee prosthesis. Conventional TKA (CONV-TKA) is the current standard for knee arthroplasty. Computer-navigated (CN-TKA), a more expensive procedure, provides an alternative method of achieving correct limb alignment.

1.4 Less invasive procedures that seek to treat only the diseased compartments of the knee have been recently developed and are now being advocated for younger more active patients. These procedures are referred to as partial knee arthroplasty and include the unicompartmental knee arthroplasty (UKA) or bicompartmental knee arthroplasty (BKA).

1.5 Evidence included in the technology assessment review was obtained through systematic searches of the medical literature for relevant systematic reviews including meta-analyses, other diagnostic studies, randomized controlled trials and economic studies. Selected national guidelines and previous technology assessment were also summarized in the technology assessment report.

1.6 The evidence based technology assessment report identified six expert treatment guidelines and there is no National Coverage decision on TKA and various surgical techniques.

1.7 The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, clinical expert, HTA program, the public and agency medical directors.

**2. Evidence about the technology's safety**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

2.1 Overall safety outcomes for TKA: The evidence based technology assessment report reported several key outcomes related to safety of TKA, including: deep vein thrombosis (DVT), pulmonary embolism (PE), ischemic events, tourniquet time, infections, wound and other complications. In general, the evidence was low but did not suggest significant differences in safety outcomes between surgical techniques for TKA.

2.2 CONV-TKA and CN-TKA: The evidence based technology assessment report concluded that high evidence was found to suggest that CN-TKA is as safe as CONV-TKA.

- Several RCTs and cohort studies reported no significant differences between CN-TKA and CONV-TKA with respect to thromboembolic events, infection or all other complications other than ischemic events.
- The evidence based technology assessment report concluded that one RCT reported no significant differences in acute myocardial infarction and one reported no difference in transient ischemia following CN-TKA vs. CONV-TKA.

2.3 CONV-TKA and UKA or bi-UKA: The evidence based technology assessment report concluded very low evidence exists that complications were infrequent, and the risk of

complications was similar between UKA and TKA in one RCT and nine cohort studies. One small cohort study reported 2 cases (9%) of intraoperative fracture of the tibial spine in the bi-UKA group. No other complications reported.

2.4 Simultaneous or staged bilateral TKA: The evidence based technology assessment report concluded low evidence from four cohort studies which reported 30 day mortality rates following either staged or simultaneous TKA. Three of the four cohort studies reported significantly higher rates in the simultaneous group.

- The evidence based technology assessment report concluded from nine cohort studies no significant differences in thromboembolic events, wound complications, or other complications between simultaneous and staged bilateral TKA.

**3. Evidence about the technology's efficacy and effectiveness**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

3.1 Overall identified efficacy outcomes for TKA: The evidence based technology assessment report reported several key outcomes related to efficacy of TKA, including outcomes of: revision and removal rates; pain relief; functional improvement; quality of life; range of motion; prosthesis survival and radiographic outcomes.

3.2 *Knee Pain, Function and Quality of Life – CN-TKA vs. CONV-TKA:* The evidence based technology assessment report concluded that several high evidence randomized controlled trials reported similar results in pain, function and quality of life outcomes when comparing patients receiving either CN-TKA or CONV-TKA at various follow-up times ranging from 3 months to 2 years. The data are similar with respect to nonrandomized cohort studies with 1 to 3 year follow-up. No comparative data are available for these outcomes past 2 to 3 years.

3.3 *Revision – CN-TKA vs. CONV-TKA:* The evidence based technology assessment report concluded low evidence from two RCTs and two cohort studies which reported similar, low rates between CN-TKA and CONV-TKA groups of less than 2%. A third RCT reported half as many revisions following CN-TKA (3.7% vs. 8.0%) after 3 years. Due to the small sample sizes, short follow up, and inconsistent rate of revision among the RCTs renders low evidence concerning the relative short term revision rates between surgeries. Conclusions on whether CN-TKA affects long term revision rates are premature.

3.4 *Alignment– CN-TKA vs. CONV-TKA :* The evidence based technology assessment report concluded that high evidence from 2 meta-analyses of several RCTs and cohort studies demonstrate that the risk of unsatisfactory alignment by more than 3° is significantly less using CN-TKA compared with CONV-TKA.

3.5 *UKA vs. TKA – Knee Pain and Function:* Moderate evidence exists that knee pain and function were comparable between UKA and TKA in one RCT and 14 cohort studies over a variety of follow-up times ranging from 3 months to 15 years. Range of motion was consistently higher in the UKA group in the studies comparing mean motion and the proportion of patients achieving ≥120° of flexion at a variety of follow-up times.

3.6 UKA vs. TKA – Revision, prosthesis survival: Low evidence exists that revision rates were comparable between UKA and TKA in one RCT at 5 and 15 year follow-up. In 9 cohort studies that rates of revision were slightly higher in the UKA compared with TKA group in 8, mean follow up between 2 and 10 years. Survival of the arthroplasty in two large studies at 10 and 14-15 years slightly favored TKA.

3.7 Bi-UKA vs. TKA – Knee Pain, Function and Revision: Only one small retrospective cohort very low evidence study compared bi-UKA with TKA. No difference was found in functional scores at a minimum of 4 year follow up. No revisions were recorded in either group.

3.8 Bicompartmental knee arthroplasty vs. TKA – Revision: Two large registry studies comparing revision between bicompartmental knee arthroplasty and tricompartmental TKA found similar revision rates and 2 to 4 year implant survival.

**4. Special Populations**

4.1 CONV-TKA : the evidence based technology assessment reported concluded ~

- *Age, sex, obesity, comorbidity:* very low evidence from one HTA and studies published after the HTA reported inconsistent results as to whether age, sex, obesity or comorbidity significantly affected outcomes.
- *Type of arthritis:* moderate evidence from one HTA reported greater improvement in baseline functional scores among rheumatoid arthritis (RA) patient compared with Osteoarthritis (OA) patients. One prospective study published after the HTA indicated no difference in function/quality of life outcomes based on type of arthritis type.
- *Hospital, surgeon volume and other characteristics:* very low evidence from one systematic review of several studies reported mixed results with respect to morbidity, mortality and length of stay. One study reported on possible associations between preoperative pain levels, length of hospital stay, waiting time, year of follow-up, education, SF-36 mental health scores and ethnicity and outcomes.

4.2 CN-TKA: the evidence based technology assessment reported concluded ~

- *Obesity:* one very low evidence retrospective study reported that morbidly obese patients experienced a significantly greater mean total blood loss, mean hemoglobin loss, and superficial infection rate compared with those of normal weight.

4.3 UKA: the evidence based technology assessment reported concluded ~

- *Age:* five of six registry studies reported a statistically significant higher revision rate among patients < 65 years of age versus those > 65 years of age. The higher quality studies consistently found a greater risk among patients < 65 years of age; therefore, there is high evidence to suggest that younger patients are at greater risk of failure after UKA than older patients.
- *Obesity:* among three retrospective cohort studies evaluating obesity as a risk factor, one found higher rates among obese, one found lower rates among obese, and the 3rd found no statistically significant difference.
- *Sex:* five of seven high evidence published studies found no association between sex and UKA failure. Among the two that found an association, both were LoE III retrospective cohort studies. One reported a higher revision rate among males, the other a higher revision rate among females. The higher quality studies consistently found no association between sex and revision.
- *Multi-compartmental:* One LoE II registry study reported higher rates of revision among patients with RA compared to those with OA.
- *Provider Facility:* Two low evidence LoE II studies found no statistically significant difference in revision rates among caseloads ≤ 10 or > 10 UKAs per year; and one study did not find an association between different surgeons or different hospitals on revision rates.

**5. Evidence about the technology's value and cost-effectiveness**

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

5.1 CN-TKA: the evidence based technology report concluded that there is insufficient data to make strong conclusion about the long-term cost effectiveness of CN-TKA.

- Modeling suggests that CN-TKA is potentially cost effective intervention compared with CONV-TKA if the 10-year revision rate is reduced by between 33 to 50%; this assumption is not supported by current high or moderate quality clinical evidence.

5.2 UKA vs. TKA: the evidence based technology report concluded some evidence exists to indicate that UKA and TKA have similar cost and quality-adjusted outcome profiles from a health care perspective. Lack of data precludes assessment of the cost effectiveness of UKA in people under the age of 65.

5.3 Washington state agency utilization and cost information indicated that the UMP, L&I and DSHS have paid a total of $80.6 million dollars on TKA related costs in the last 4 years.
- L&I additional payment for Computer navigation CPT Code is $234.00

**6. Evidence on Medicare Decision and Expert guidelines**

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

6.1 Centers for Medicare and Medicaid Services (CMS) – no NCD policy.

6.2 Guidelines – the evidence based technology assessment report identified six guidelines though a search of the *National Guideline Clearinghouse* identified no guidelines specific to unicompartmental, bicompartmental, bi-unicompartmental, total knee arthroplasty, or computed-assisted knee arthroplasty for the treatment of end-state knee arthritis.
- *National Institute for Health and Clinical Excellence (NICE)* -- No specific guidelines were found that addressed unicompartmental, bicompartmental, bi-unicompartmental, total knee arthroplasty, or computer-assisted knee arthroplasty for the treatment of end-stage knee arthritis from the National Institute for Health and Clinical Excellence (NICE), which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales.
- *NIH Consensus Statement on Total Knee Replacement* -- Technical factors in performing surgery may influence both the short- and long-term success rates. Proper alignment of the prosthesis appears to be critical in minimizing long-term wear, risk of osteolysis, and loosening of the prosthesis. Computer navigation may eventually reduce the risk of substantial malalignment and improve soft tissue balance and patellar tracking. However, the technology is expensive, increasing operating room time, and the benefits remain unclear.
- *Ontario Health Technology Advisory Committee (OHTAC)* -- Concluded that computer-assisted arthroplasty using navigation systems is considered to be in the investigational stage. Current studies have only assessed short-term outcomes, and long-term effectiveness (need for revision, implant longevity, pain, and functional performance) has not been demonstrated.
- *Osteoarthritis Research Society International (OARSI*) -- OARSI published 23 treatment guidelines for the management of hip and knee osteoarthritis identified from a literature search, including six opinion-based, five evidence-based and 12 based on both expert opinion and research evidence.
  - Relevant guidelines for this report are: unicompartmental knee replacement is effective in patients with knee osteoarthritis restricted to a single compartment.
  - For the young and physically active patient with significant symptoms from unicompartmental knee osteoarthritis, high tibial osteotomy may offer an alternative intervention that delays the need for joint replacement some 10 years.
- *American Academy of Orthopedic Surgeons (AAOS)* -- No specific clinical guidelines for knee arthroplasty were found; however, recommendations are due to be published in September 2010.

## Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

**1. Evidence availability and technology features**

The committee concludes that the best available evidence on Total Knee Arthroplasty has been collected and summarized.

1.1. This evidence review summarized the evidence on the accuracy and efficacy of CONV-TKA compared with conventional techniques (CN-TKA, UKA, Bi-UKA, bicompartmental, bi-unicompartmental) for end stage knee arthritis.

**2. Is it safe?**

The committee concludes that the comprehensive evidence indicates that CN-TKA and unicompartmental is equally safe to CONV-TKA. Key factors to the committee's conclusion included:

2.1. The committee agreed that CN-TKA compared with CONV-TKA reported no significant safety outcomes. A total of 25 RCTs and 14 nonrandomized studies (seven prospective and seven retrospective) were identified.

2.2. The committee agreed that CN-TKA compared with CONV-TKA showed equivalent mortality and morbidity outcomes.

2.3. The committee agreed that secondary outcomes may differ between CN-TKA and CONV-TKA; however, no real statistical difference between the two procedures.

2.4. The committee agreed that Unicompartmental was at least equally, if not more, safe than CONV-TKA.

2.5. The majority of the committee agreed that unproven data exists to state that multi-compartmental is better than CONV-TKA.

**3. Is it effective?**

The majority of the committee concludes that the comprehensive evidence shows that CN-TKA is equally an effective treatment compared to CONV-TKA. The committee agreed that it is unclear if multi-compartmental is a better treatment compared to CONV-TKA. The committee agreed that uni-compartmental is equally as safe as CONV-TKA.

3.1. The committee agreed that sufficient evidence exists to conclude that CN-TKA is an equally effective treatment compared to CONV-TKA to help improve knee pain, quality of life, patient satisfaction, range of motion, and revision.

3.2. The committee agreed that insufficient evidence exists to conclude that multi-compartmental (partial knee arthroplasty) is as safe as CONV-TKA. Only one RCT and 19 cohort studies were identified that reported data on clinical or functional outcomes following UKA compared with CONV-TKA. No statistical difference was found in knee function improvement, revision rates, survival rate, and/or pain between UKA and CONV-TKA. The UKA group showed a significantly greater percentage improvement for range of motion.

3.3. The committee agreed that no significant differences were identified in the two RCTs providing data on the efficacy of HTO compared with UKA in knee pain, knee function, failure or revision, or ROM between the groups.

**4. Evidence about the technology's special populations, patient characteristics and adjunct treatment**

The committee agreed that no compelling evidence exists to differentiate sub groups or special populations.

4.1. The committee agreed with the evidence based report that while some differences exist; there is some adequate evidence to conclude that morbidly obese patients with CN-TKA have a higher true blood volume loss and the mean hemoglobin loss was also greater. The committee agreed that the difference in tourniquet time was not statistically significant the morbidly obese and non-obese sub populations.

**5. Is it cost-effective?**

The committee concludes that the Total Knee Arthroplasty is unproven to be cost effective; agreeing with the comprehensive evidence review that no evidence based conclusions about cost effectiveness can be drawn.

5.1. The evidence report adequately summarized the very low quality evidence on cost which helped the committee conclude that CN-TKA is an add-on technology that may increase diagnostic and therapeutic costs.

5.2. Washington state agency utilization and cost information indicated that the UMP, L&I and DSHS have paid a total of $80.6 million dollars on TKA related costs in the last 4 years.

## 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 Total Knee Arthroplasty demonstrates that there is sufficient evidence to cover computer navigated and unicompartmental knee arthroplasty for treatment of osteoarthritis and rheumatoid arthritis of the knee. The committee agreed that there is insufficient evidence on multi-compartmental arthroplasty; therefore, the committee unanimously agreed to not cover. 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 5 to 3 to cover computer navigated TKA. Based on these findings, the committee voted 6 to 2 to cover unicompartmental TKA. Based on these findings, the committee voted 8 to 0 to not cover multi-compartmental TKA.

## Total Knee Arthroplasty Coverage Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

### Total Knee Arthroplasty Evidentiary Votes:

***Computer Navigated Total Knee Arthroplasty (CN-TKA) --***

**Is there sufficient evidence under some or all situations that Computer Navigated Total Knee Arthroplasty (CN-TKA) for treatment of osteoarthritis and rheumatoid arthritis is:**

| | **Unproven** (no) | **Equivalent** (yes) | **Less** (yes) | **More** (yes) |
|---|---|---|---|---|
| **Effective** | 0 | **6** | 0 | **2** |
| **Safe** | **1** | **7** | 0 | 0 |
| **Cost-effective Overall** | **7** | 0 | **1** | 0 |

***Unicompartmental Knee Arthroplasty (UKA) --***

**Is there sufficient evidence under some or all situations that Unicompartmental Knee Arthroplasty (UKA) for treatment of osteoarthritis and rheumatoid arthritis:**

| | **Unproven** (no) | **Equivalent** (yes) | **Less** (yes) | **More** (yes) |
|---|---|---|---|---|
| **Effective** | **1** | **4** | **3** | 0 |
| **Safe** | 0 | **4** | 0 | **4** |
| **Cost-effective Overall** | **4** | **3** | **1** | 0 |

***Multi-compartmental (bicompartmental and bi uni-compartmental) Partial Knee Arthroplasty --***

**Is there sufficient evidence under some or all situations that multi-compartmental Partial Knee Arthroplasty for treatment of osteoarthritis and rheumatoid arthritis is:**

| | **Unproven** (no) | **Equivalent** (yes) | **Less** (yes) | **More** (yes) |
|---|---|---|---|---|
| **Effective** | **7** | **1** | 0 | 0 |
| **Safe** | **7** | **1** | 0 | 0 |
| **Cost-effective Overall** | **8** | 0 | 0 | 0 |

TKA Coverage Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

| **HTCC COMMITTEE COVERAGE DETERMINATION** | | | |
|---|---|---|---|
| | **Not covered** | **Covered Unconditionally** | **Covered Under Certain Conditions** |
| **Computer Navigated Total Knee Arthroplasty (CN-TKA)** | **3** | **5** | 0 |
| **Unicompartmental Knee Arthroplasty (UKA)** | **2** | **6** | 0 |
| **Multi-compartmental Partial Knee Arthroplasty** | **8** | **0** | 0 |

- Action: The committee vice-chair directed HTA staff to prepare a Findings and Decision document on TKA reflective of the majority vote for final approval at the next public meeting.

- For treatment of end stage osteoarthritis and rheumatoid arthritis of the knee:
  - Total Knee Arthroplasty with Computer Navigation is a covered benefit.

- For individuals with uni-compartmental disease, uni-compartmental partial Knee Arthroplasty is a covered benefit.
- Multi-compartmental partial knee arthroplasty, (including bi-compartmental and bi-uni compartmental) is not a covered benefit.

The committee discussed Clinical guidelines and Medicare decision. There is no National Medicare Coverage decision, and many treatment guidelines did not address surgical technique for knee arthroplasty. While many guidelines did not recommend computer navigation based on experimental status, the committee found that the evidence review summarized the most recent, relevant evidence and assessed its quality along with addressing key questions relevant to the committee's statutory criteria including evidence on safety, efficacy, effectiveness and cost that were not addressed or transparent in clinical guidelines.

## Agenda Item: Routine Ultrasound in Pregnancy Topic Review

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Staff provided an overview of the timeline and referred HTCC members to the included key questions and population of interest for spinal cord stimulator review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert, Dr. Edgar Clark a radiologist from Portland and consultant to evidence based programs such as MED. Dr. Clark prepared a COI with no conflicts listed.

## Agenda Item: Public Comments

The Vice-chair called for public comments.

- ✓ Scheduled Public Comments: No stakeholder groups requested scheduled time for public comments.
- ✓ Open Public Comments: Four individuals provided comments during the open portion.
    - o Michael Gravett, University of Washington, stated that he disagreed with several findings within the evidence report on the role of ultrasound for gestational age. Believes that the evidence report overlooked compelling evidence in screening ultrasound (Finland study). Lastly, concerned that the evidence report does not address maternal mortality and morbidity which can be life saving for the mother.
    - o Dr. Mark Lewin, Director, Seattle Children's Hospital Prenatal diagnosis and treatment program, commented that specific high risk complications does find meaningful evidence to help conclude birth defects, and does not represent over utilization.
    - o Dr. Dale Reisner, Washington State Obstetrical Organization (WSOA), commented that fairly low quality data exists for low risk populations. Concerned regarding determining who is considered low risk. Stated that 1st trimester ultrasound (11 to 13 weeks) would include prenatal diagnosis; however, not everything is picked up on the first ultrasound. Therefore, a second ultrasound should be done in the 2nd trimester (18 to 22 weeks) to help detect other specific anomalies.

## Agenda Item: Routine Ultrasound – Agency Data

Dr. Jeff Thompson, Department of Social & Health Services, Medical Director, presented to the committee the agency utilization and outcomes for Routine Ultrasound. Full PowerPoint slides in meeting materials.

- ✓ UMP / PEP / DSHS Combined Data for US in Pregnancy
- ✓ DSHS/Medicaid US Counts per pregnancy: 3.32
- ✓ UMP US counts per pregnancy: 4.47
- ✓ Age difference is not significant
- ✓ Why differential treatment.

Figure 1: UMP /PEP/DSHS combined data

| Year | 2006 | 2007 | 2008 | 2009 | Overall* |
|---|---|---|---|---|---|
| Ultrasound Count | 50,584 | 52,654 | 56,356 | 40,713 | **200,307** |
| Pregnancy Count | 19,111 | 19,064 | 19,547 | 12,647 | **59,653** |
| Avg # of Ultrasounds/ Pregnancy/Year | 2.65 | 2.76 | 2.88 | 3.22 | **3.36** |
| Total Cost of Ultrasounds | $5,049,915 | $5,146,072 | $5,676,992 | $4,193,088 | **$20,066,067** |
| Average Cost of Ultrasounds/ Pregnancy/Year | $264 | $270 | $290 | $332 | **$336** |

*Pregnancies are double counted when they extend into a second year. Overall costs and counts (last column) reflect the number of individual pregnancies, so are more accurate.

- ✓ Balancing Access Quality and Costs:
  - o Over utilization of Ultrasound in pregnancy; Medicaid and UMP moms are being treated differentially; National guidelines for Ultrasound in low risk pregnancy are graded poor to fair in evidence
  - o There is a lack of std protocols and documentation of all recommended screening items do not occur
- ✓ AMDG Recommendation for Ultrasound in Normal Pregnancy:
  - o Benefits: Normal pregnancy allowed one Ultrasound (18 – 22 weeks)
  - o Benefits for all other Ultrasound utilization require medical necessity
    - ▪ There are many medical necessity options (high risk) options could be to build into a global; prior authorization; EPA; look into contracts with radiologists; look in efficient networks and gold card efficient providers.

## Agenda Item: Evidence Review Presentation

Hayes presented an overview of their evidence report on Routine Ultrasound. A full set of slides and information is included in the meeting materials.

- ✓ *Policy Context:* increasing use on number of US scans per pregnancy (1.5 US scans in 1995-1997; 2.7 US scans in 2005-2006), which increase depending on low or high risk. No difference in Medicaid versus private insurance. "Keepsake videos" not FDA approved.
- ✓ *Practice Guidelines:* American Institute of Ultrasound Medicine (AIUM) = poor; American College of Obstetricians and Gynecologists (ACOG) = fair; American College of Radiology (ACR) = fair; and the Institute for Clinical Systems Improvement (ISCI) = fair.
- ✓ *Screening / Surveillance Options:* US alone (transvaginal or transabdominal); biophysical profile (BPP); fetal and umbilical Doppler US (DUS); utero-placental DUS; cardiotography (CTG) and fetal echocardiography.

| Pregnancy Stage | Key Purposes |
|---|---|
| **1st Trimester (routine)** | •Estimate gestational age<br>•Detect multiple gestations<br>•Measure markers for fetal aneuploidy |
| **2nd Trimester (routine)** | •Fetal anatomical survey<br>•Further assess fetal aneuploidy<br>•Estimate fetal weight; revise gestational age<br>•Detect/evaluate gynecological abnormalities |
| **3rd Trimester (selected)** | •Monitor high-risk pregnancy<br>•Confirm/evaluate a specific condition |

- ✓ *Measuring Cervical Length:* cervical insufficiency + obstetrical history are the best predictor of preterm birth (PTB); short cervix can be treated in asymptomatic patients; 90% of women with symptoms of preterm labor (PTL) will NOT deliver within 7 days; treatments for PTL (tocolysis and steroids) have harms. *Therefore,* cervical length measured by transvaginal ultrasound (TVU) — surveillance or screen
- ✓ *Methods: Report Focus and Search Strategy Exclusions* -- SRs and EEs published before 2000; routine screening for single abnormalities or maternal conditions; screening for Down syndrome; US to monitor twin-to-twin transfer syndrome (TTTS) and/or utero-placental DUS.
- ✓ *Accuracy of US:* Accuracy depends on target condition. For screening, often in combination.
  - o Review articles: sensitivities 40% to 90%. No information on specificity, positive predictive value, negative predictive value
- ✓ *US in Low-Risk Pregnancy Search Results:* 2 MAs (Cochrane Reviews) -- routine US (single scan) in *early* pregnancy (< 24 weeks); 11 trials (Whitworth et al., 2010). Routine US in *late* pregnancy (> 24 weeks); 8 trials (Bricker et al., 2008). US in unselected or low-risk patients vs. no US or selective US for specific clinical indication; RCTs plus a few quasi-randomized studies and most studies in Europe.
- ✓ *US in Low-Risk Early Pregnancy Findings:* In general: 1 scan, 2nd trimester
  - o Patient Management: No effect, hospitalization; 5 RCTs (n=17,685) (*high quality*). ↓Inappropriately timed serum scan and repeat US fetal anomaly scan (single RCT) (*low*)
  - o Perinatal Outcomes (*high):* No effect on mortality (10 RCTs; n=35,735). No effect on morbidity (4 to 8 studies; n=3906 to 19,337)
  - o C-sections; IOL (*moderate*): No effect on C-sections (5 RCTs; n=22,193). ↓IOL; 1% absolute reduction; NNT=100 (7 RCTs; n=24,790)
  - o Abortion: ↑abortion, fetal anomaly; 0.10% absolute (5 RCTs; n=28,256) (*high*)
- ✓ *US in Low-Risk Late Pregnancy Findings:* US Screen (generally 1 scan in 3rd semester)
  - o Patient Management: No effect (*low-moderate quality)*
  - o Perinatal Mortality/Morbidity: No effect on perinatal mortality (7 RCTs; n=24,276) (*moderate quality*). Slight or no effect on morbidity (1 to 4 RCTs; n=4510 to 20,298) (*moderate*)
  - o C-section; IOL: No effect (5 to 6 RCTs; n=21,035 to 22,663) (*moderate*)
  - o Serial DUS: same results (single RCT) (*low*)
- ✓ *Safety of Routine US Search Results:* 1 meta-analysis (Torloni et al., 2009) -- 41 studies; mostly RCTs, also other prospective and retrospective controlled observational studies, including case-control (CC) studies. US generally performed in 2nd trimester. Low-risk singleton pregnancy.

- Some pooled data from Whitworth et al. (2010) meta-analysis
- 3 RCTs: Carlan et al. (1997); Newnham et al. (1993); Simcox et al. (2009)
- 4 observational studies: Rodriguez and Waldenstrom (2008); McLaughlin et al. (2009); Stalberg et al. (2008); Grether et al. (2010)

✓ *Safety of Routine US Findings:* dose-response relationship (≥ 3 vs. 1 scan) (*moderate quality*) -- ↓ birth size and ↓ perinatal mortality.
- No overall adverse effects -- on maternal admission to hospital, fetal mortality, perinatal mortality, perinatal morbidity (9 to 13 RCTs; up to 46,553 patients per study) (*moderate quality*)
- No impact on postpartum complications (observational studies)

✓ *Safety of routine US Findings Following Birth:* Congenital malformations: No effect in general (2 RCTs; n=15,281) (*moderate quality*). But almost double risk of congenital cardiac defect (2 large cohort studies) (*low*).
- Childhood cancer: No effect (large volume of observational data) (*moderate*)
- Childhood growth/development: No effect (*low*)
- Non-right-handedness: No overall effect (*moderate*). But ↑ in boys (including dose-response effect)
- Small adverse effect on intellectual performance in men but no increase in mental illness (*low*)

✓ *Differential Efficacy / Safety Search Results:* 1 systematic review of US in emergency department (ED) for assessment of 1st trimester bleeding (McRae et al., 2009). Other evidence from studies selected for other key questions

✓ *Differential Efficacy / Safety Findings:*
- Effects in 1st trimester vs. 2nd (Whitworth) -- ↑ Detection of multiple pregnancy only in 2nd trimester (7 RCTs; n=295) (*low quality*). ↓ IOL only in 2nd trimester (8 RCTs, n=25,516) (*moderate*). No difference, perinatal mortality (9 RCTs; n=34,923) (*high*).
- Early (1st and 2nd) vs. late (3rd) (Whitworth vs. Bricker): 14 RCTs, n=48,179, <24 wks vs. >24 wks. No difference , except ↓IOL only in early
- 1st vs. 2nd vs. 3rd trimester: No association with childhood brain tumor or autism (2 case-control studies) (*low*)
- High- risk DUS surveillance vs. low-risk screen (Alfirevic vs. Whitworth/Bricker): Perinatal mortality/morbidity reduced only in high-risk studies
- TVU-PTL screen vs. TVU-Surveillance -- PTB reduced only with TVU-PTL screen
- ED vs. radiological/gynecological performance: more efficient rule-out of ectopic pregnancy, improved outcomes (*very low*).
- No differential effects in other comparisons (*very low to low*)

✓ *Cost Implications and Cost-Effectiveness:*
- Consumer-oriented websites: $200-$440 for cost of fetal US; screening increased utilization from 0.6 scans/pregnancy to 2.2 scans/pregnancy (Ewigman et al., 1993; RADIUS trial); organized program of universal 2nd trimester US vs. usual practice (Vanara et al., 2004; Italy); 6 strategies for US screening for fetal anomaly (Ritchie et al., 2005; Scotland); routine 2nd trimester US vs. no US or selective US (Vintzileos et al., 2000; United States); universal TVU to assess cervical length; add-on to routine 2nd trimester US; (Cahill et al., 2010; Medicaid perspective).
- US in ED for evaluation of possible ectopic pregnancy: could save $299 to $1244 (1992-1998 costs) (Durston et al., 2000; staff model HMO in United States). Lower cost but difference non-significant (Pierce et al., 2001; payer perspective).

✓ *Summary of Evidence: Effectiveness, Low-Risk Screen*

| Indication | Findings | Evidence |
|---|---|---|
| **Routine, early pregnancy (<24 wks)** | Evidence does *not* support for most outcomes | Moderate to High Quality<br><br>Might not apply to low-resource settings. |
| | Doubles rate of abortion for fetal anomaly (0.10 percentage absolute increase) | High Quality |
| **Routine, late pregnancy (>24 wks)** | Evidence does *not* support | Low to Moderate Quality |

✓ *Summary of Evidence for Safety:*

| Type of Outcome | Findings | Quality of Evidence |
|---|---|---|
| **Serious short-term adverse effects** | Safe | Moderate |
| **Developmental outcomes** | No general impact | Mixed |
| Findings may not apply to newer, stronger machines or to 1st or 3rd trimester | | |

✓ *Summary of Evidence – Differential Effectiveness / Safety:*

| Comparison | Findings |
|---|---|
| **Routine US , 2nd trimester vs 1st** | More likely to detect multiple births |
| **Routine US , 2nd trimester vs 1st or 3rd trimester** | More likely to reduce IOL |
| **Routine US, 1st vs 2nd vs 3rd trimester** | No differential effect on perinatal mortality |
| **High-risk vs low-risk** | US reduces perinatal morbidity and mortality only with DUS surveillance of high-risk patients or TVU screen for PTL |
| **Other comparisons** | Generally no effect |

✓ *Summary of Evidence – Cost Effectiveness: No definitive statements*

| | |
|---|---|
| **Routine 2nd trimester US screen for fetal anomaly vs no US or usual practice (3 studies)** | **May reduce short- or long-term costs** |
| **Universal TVU screen for short cervix, as add-on to 2nd trimester anatomical US (1 study)** | **May prevent PTB and save direct short- and long-term costs in low-risk pregnancies** |
| **US to rule out ectopic pregnancy (2 studies)** | **Less costly if performed in ED** |

✓ *Key Conclusions:*

- DUS screening in high-risk pregnancies improves outcomes (*v. low quality evidence*) but routine US in low-risk pregnancies does not (*moderate-high*)
- Routine US in 2nd trimester is safe
- 2nd trimester US is most likely to detect multiple pregnancy and reduce IOL
- Gestational age at time of US does not affect perinatal mortality
- Preliminary evidence suggests potential cost savings with particular strategies of US in pregnancy
- Existing guidelines do not address the issue of clinical utility

✓ *Gaps in the Evidence:*

| Population/ Issue | Needed |
|---|---|
| **High-risk pregnancy** | •Large RCTs powered to detect clinically meaningful differences<br>•Definition of most effective follow-up protocols |
| **Any pregnancy** | •Good RCTs conducted in the United States |
| **Differential effectiveness and safety** | •Comparison of different strategies for routine US<br>•Assessment of safety and effectiveness in 1st and 3rd trimesters<br>•Studies with newer more potent or sophisticated machines, including 3D and 4D<br>•Studies or subgroup analyses of obese women, women with low socioeconomic status, and other subpopulations |
| **Impact patient mgmt** | •Direct assessment of whether clinicians change management plans after US |
| **Results by setting** | •Comparison of outcomes by tertiary, secondary, or primary care facility<br>•Studies restricted to low-resource settings |

## Agenda Item: HTCC Routine Ultrasound Discussion and Findings

C. Craige Blackmore, Committee Vice-chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of Routine Ultrasound beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

**1. Evidence availability and technology features**

1.1 The evidence based technology assessment report indicates that ultrasound (US) is used in prenatal care for monitoring fetal development and maternal well being, including the important objective of preventing preterm birth.

1.2 Alternatives for screening and monitoring pregnancy include biophysical profile; pre-natal exams; ultrasound; fetal and umbilical Doppler ultrasound (DUS); utero-placental DUS; cardiotography; and fetal echocardiography.

1.3 The evidence based technology assessment report indicates that routine use of US in pregnancy is increasing (for example from an average of 1.5 exams in 1996 to 2.7 in 2006) ; the imaging provides a information about pregnancy status and fetal status and is considered reasonably safe; however evidence is very limited on the clinical utility of US and how the routine use of US impacts fetal or maternal health outcomes.

1.4 Despite low evidence of impact on health outcomes with routine screening, US is commonly used in united states:

- During the first trimester (6 days of gestation up to 13 weeks) an US may be performed for a variety of reasons, including estimation of gestational age diagnosis, evaluation of multiple gestations, or measurement of markers for fetal aneuploidy (abnormal chromosome number).
- In the second trimester (between 16 weeks and 22 weeks), US can be performed to assess anatomical fetal growth and development (fetal anatomical survey), screen for markers for fetal aneuploidy, estimate fetal weight, detect and evaluate gynecological abnormalities, and detect fetal anatomical abnormalities.

- In the United States, routine US is not typically performed in the third trimester unless the pregnancy is considered a high-risk pregnancy or a specific indication has developed.

1.5 A systematic and critical assessment of literature for evidence about the clinical utility of routine or screening use of US was gathered for use US in pregnant women for screening, guiding patient management as compared with no screening, screening with other methods, or concealment of US findings; along with descriptive information on US accuracy. Two meta-analysis: which included 11 RCTs on routine US in early pregnancy, and 8 RCTs on routine US in late pregnancy. Other studies relating to accuracy are also described.

**2. Evidence about the technology's safety**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

2.1 The evidence based technology assessment report includes moderate-quality evidence from a 2009 meta-analysis (Torloni et al., 2009) that included 41 studies, mostly RCT's; 3 additional RCTs and 4 observational studies. For major outcomes US shown to be a reasonably safe procedure with no serious short-term adverse effects. Evidence of mixed quality suggests no general impact on developmental outcomes after birth but further research, particularly with respect to neurological development, is needed to allow definite conclusions. The applicability of most of the safety evidence is diminished by the fact that most studies were using older, weaker machines. There is also very little evidence on the safety of US performed in the first and third trimesters.

2.2 The evidence based technology assessment report indicates that the FDA considers US to be a safe technology. The FDA does, however, considers "keepsake videos" to be an unapproved US.

2.3 The evidence based technology assessment report indicates that a large volume of moderate-quality evidence from RCTs has shown that routine US during pregnancy does not adversely affect maternal hospitalization, fetal or perinatal death, or perinatal morbidity.

2.4 The evidence based technology assessment report indicates that low-quality evidence shows no impact on postpartum complications, Apgar score, or birth weight. Moderate-quality evidence shows no impact on the overall rate of congenital abnormality, but there is low-quality evidence to suggest that the risk of cardiac congenital abnormality is increased. Moderate-quality evidence shows no association with childhood cancer. According to low-quality evidence, use of TVU to measure cervical length does not increase the risk of infection.

2.5 Torloni et al. (2009) concluded that in-utero exposure to US is relatively safe for mother and fetus but cautioned that not all effects, particularly long-term effects, are known. They also were not able to identify the safest use of US in terms of gestational age, US parameters, or fetal position. Whitworth et al. (2010) did not state a conclusion about the safety of US but did call for more research on long-term neurological effects.

- The evidence based technology assessment report indicated an RCT (Carlan et al., 1997) included in the systematic review by Berghella et al. (2009), an RCT (Newnham et al., 1993) included in the systematic review by Bricket et al. (2008), and a trial selected from the recent primary literature for its evaluation of TVU determination of cervical length (Simcox et al., 2009) also reported safety-related data. Four additional observational studies published after the search time frame observed by Torloni et al. (2009) were selected. These assessed the association between in utero US and non–right-handedness (Rodriguez and Waldenström, 2008), neuroblastoma (McLaughlin et

al., 2009), childhood brain tumor (Stålberg et al., 2008), and autism spectrum disorders (Grether et al., 2010).

**3. Evidence about the technology's efficacy and effectiveness**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

3.1 *Accuracy*: the evidence based technology assessment report provided a descriptive review of accuracy. As a screening tool, US is often combined with other tests. However, review articles report sensitivities ranging from 40% to 99% depending on the target condition or use. Information on specificity, positive predictive value, and negative predictive value was not readily available.

3.2 *Overall Evidence, Routine/ Screening Use:* The evidence based technology assessment report indicated moderate- to high-quality evidence for US in early pregnancy (< 24 weeks) does not change patient management or improve health outcomes or substantially affect delivery mode, at least not in high-resource settings.

- High-quality evidence indicates that a single routine US in high-resource settings has no effect on hospital utilization although, according to low-quality evidence, it may reduce inappropriately-timed serum scans and repeat fetal anomaly scans. High-quality evidence from large randomized controlled trials (RCTs) supports a conclusion that in high-resource settings, routine US does *not* reduce perinatal or neonatal mortality or morbidity even though it doubles the rate of abortion for fetal anomaly (mortality and morbidity can be due to conditions unrelated to a congenital abnormality).
- Moderate-quality evidence shows no effect on the frequency of Cesarean section in high-resource settings but a modest reduction in the frequency of induction of labor. US in this population more than doubles the rate of abortion for fetal anomaly, but the absolute increase is only 0.10 percentage points (high-quality evidence). These various findings might not apply to low-resource settings where perinatal mortality is high and not as likely to be attributable to fetal abnormality and might not apply to all strategies for US timing and follow-up intervention.

3.3 The evidence based technology assessment report indicated low- to moderate-quality evidence has not shown routine US in late pregnancy (> 24 weeks) to change patient management, affect delivery mode, or improve health outcomes. Low- to moderate-quality evidence has shown no effect on antenatal admission, follow-up US scans, or use of in cardiographs. To date, the evidence shows no effect from either routine US (moderate-quality evidence) or routine serial US plus DUS (low-quality evidence) in late pregnancy on perinatal mortality or morbidity.

- However, a single study suggests that routine US combined with placental grading could reduce stillbirths (low-quality evidence). Moderate-quality evidence indicates that routine US in late pregnancy has no effect on the frequency of Cesarean section or induction of labor.

3.4 The evidence based technology assessment report indicates routine US performed between 14 and 24 weeks (second trimester) is most likely to detect multiple births (low-quality evidence) and to reduce the frequency of induction of labor (moderate quality), compared with US at other gestational ages. However, high-quality evidence shows no differential effect by gestational age on perinatal mortality, and very-low-quality evidence has shown no differential effect on childhood brain cancer or autism.

3.5 *Gestational Age:* An analysis of the best method of gestational age estimation for research purposes cited studies showing that differences in accuracy between US dating and dating based on last menstrual period are not clinically meaningful (Lynch and Zhang, 2007).

3.6 *Fetal Abnormalities:* US is used during the first and second trimester for assessment of fetal anatomical abnormalities, some of which are caused by chromosomal abnormalities. Aneuploidy, or chromosomal abnormality, is often associated with both major anatomical malformations and with minor markers (or soft signs) that show up on US. During the first trimester, measurement of the soft marker fetal nuchal translucency (NT) (a measure of the thickness of the area below the skin in the back of the neck) and maternal serum markers (β-HCG and PAPP-A) is a highly sensitive screening test for Down syndrome. This combined first-trimester testing has been found to have detection rates between 82% and 87% with a false-positive rate of 5%. The optimal time for performance of NT is 11 to 13 weeks of gestation. NT is also associated with chromosomal aneuploidy other than the abnormality associated with Down syndrome and with structural defects and sometimes appears in fetuses that have normal outcomes. There is an association between increased NT and cardiac defects in euploid (normal number of chromosomes) fetuses. Overall, US has a sensitivity of approximately 40% (range 13-82%) for detecting fetal anomalies. This estimate is based on a review, cited in guidelines published by the American College of Obstetrics and Gynecology (ACOG), of 36 studies (n=900,000 fetuses). Accuracy varied by how anomaly was defined, characteristics of the population studied, expertise of operators, and how anomalies were ascertained (ACOG, 2009).

- Another review reported that US screening during the first and second trimesters has 81% sensitivity for open neural tube defects, 96% to 100% for anencephaly, 5% to 60% for congenital heart disease, and 60% for genitourinary abnormalities (ACOG, 2007; Flood and Malone, 2008; Shaw et al., 2008; Gagnon et al., 2009; Pathak and Lees, 2009).

3.7 *Multiple Gestation:* the sensitivity and specificity of US in detection of chorionicity are 89.8% and 99.5%, respectively, during the first trimester. Sensitivity remains the same but specificity decreases to 94.7% in the second trimester. In the systematic review selected as evidence of the effectiveness of routine US in early pregnancy (Whitworth et al., 2010), US was found to significantly reduce the failure to detect multiple pregnancy by 24 to 26 weeks by 93% in pooled analysis (1% failure versus 39% failure) and to significantly reduce failure to detect multiple pregnancy before birth by 88% (no failures versus 9% failure). Furthermore, the detection of fetal anomaly for multiple gestations in early pregnancy was more than three times more likely with the use of US (Martin et al., 2009; Whitworth et al., 2010).

3.8 Attempts to assess differential effects according to multiple versus singleton pregnancy and maternal risk factors have failed to show significant differences (low-quality evidence). Very-low-quality evidence has suggested that serial US plus DUS, compared with routine US, does not improve outcomes and may reduce birth size.

- Performance of US in the emergency department for evaluation of first-trimester bleeding rather than by radiological or gynecological specialists may be less burdensome to the patient and improve surgical outcomes in ectopic pregnancy (very-low-quality evidence). There was no evidence pertaining to the effect on outcomes of different types of US scanning software, reader training, operational factors (other than the emergency department and ectopic pregnancy issue), or type of healthcare financing system. More frequent surveillance may increase the rate of Cesarean section and induction of labor (low-quality evidence).

## 4. Special Populations

4.1 The evidence based technology reported indicated routine US performed after 14 weeks but before 24 weeks (roughly, second trimester), is effective in reducing the risk of failure to detect multiple pregnancy (low-quality evidence) and the frequency of induction of labor (moderate-quality evidence), whereas routine US performed before 14 weeks (first trimester) or after 24 weeks (roughly, third trimester) does not have these effects. However, the impact on perinatal mortality does not differ between first and second trimesters (high-quality evidence). There

are no data specifically pertaining to the safety of US in the first or third trimester, except for two case-control studies showing no association between US exposure in the first, second, or third trimester and either childhood brain tumor or autism. Low-quality evidence has shown no difference in the rate of Cesarean section between twice weekly and every-other-week surveillance for impaired fetal growth, but an increase in the rate of induction of labor with the more frequent regimen. Very-low-quality evidence has suggested that routine serial US plus DUS in late pregnancy does not improve outcomes and may reduce birth size. Very-low-quality evidence suggests that US performed in the emergency department rather than by radiological or gynecological specialists may lead to more efficient rule-out of ectopic pregnancy and improved outcomes. Very-low- to low-quality evidence (has failed to show differential impact on outcomes of DUS screening in high-risk patients, comparing either singleton with multiple-birth pregnancies or comparing patients with different risk factors. Low-quality evidence suggests that routine US in low-risk or unselected patients does not differ in its effects according to maternal or fetal risk factors. No other evidence pertaining to differential effectiveness was available.

4.2 *Gestational Age*: the two Cochrane Reviews of US for fetal assessment in low-risk or unselected populations dealt separately with US in early pregnancy (< 24 weeks) and late pregnancy (> 24 weeks) (Bricker et al., 2008; Whitworth et al., 2010). The meta-analyses included in these two reviews suggest that routine US performed in early pregnancy is effective in reducing induction of labor while routine US performed in late pregnancy is not. US had no effect in early or late pregnancy on the other outcomes in common between the two reviews (perinatal death, mean birth weight, Apgar score ≤ 7 at 5 minutes).

- Whitworth et al. (2010) analyzed differences among studies in which US was performed before or after 14 weeks (before 14 weeks would be first trimester). The risk of not detecting multiple pregnancies by 24 weeks to 26 weeks was greatly reduced when US was performed after 14 weeks, but US had no effect when performed before 14 weeks (RR 0.89, NS). The before-14-weeks results come from a single study of only 9 patients, while the after-14-weeks results were from 6 studies (total, n=286).

4.3 *Other Patient Characteristics or Evidence-Based Patient Selection Criteria:* Alfirevic et al. (2010) conducted subgroup analyses according to singleton versus multiple births and according to five risk factors (small for gestational age or IUGR, hypertension/preeclampsia, diabetes, prolonged pregnancy, and previous pregnancy loss).

4.4 *Type of Scanning Machine and Software, Reader Training, and Other Operational Factors:* Torloni et al. (2009) conducted a subgroup analysis comparing the in utero exposure of B-mode (routine) US and DUS on perinatal, neonatal, and maternal outcomes. No statistically significant increased risk was reported with the use of DUS compared with routine US.

4.5 *Provider Type, Setting, or Other Provider Characteristics*: A systematic review has shown that emergency department targeted ultrasonography (EDTU) in women presenting to the emergency department with first trimester bleeding may lead to more efficient rule-out of ectopic pregnancy (McRae et al., 2009). Eight studies (n > 1778; one study did not report sample size) assessing the effect of EDTU on surgical rupture, time to diagnosis, treatment of ectopic pregnancy, or emergency department length of stay (LOS) were selected. Most were retrospective chart reviews and three studies were published only as abstracts. Two studies (total, n=131) showed that time to surgery was significantly reduced by a mean of 145 minutes to 211 minutes in patients with ectopic pregnancy. Five studies (total, n=1419) showed a significant reduction in emergency department LOS by 59 minutes to 149 minutes, which represents a reduction in the burden on patients. Two of the five studies assessing LOS (total, n=1534), including the largest study selected by McRae et al., excluded patients with ectopic pregnancy; thus LOS evidence applies largely to the effectiveness of EDTU in confirming IUP, not in accelerating the diagnosis and treatment of ectopic pregnancy. A separate analysis by McRae et al. found EDTU to be highly specific for the detection of intrauterine pregnancy (IUP). Only one study (n=340) assessed actual clinical outcomes; this study showed that the proportion of patients who were found to have ectopic pregnancy were

less likely to rupture during surgical exploration; time to surgery was not measured in this study.

**5. Evidence about the technology's value and cost-effectiveness**

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

5.1. The evidence based technology report included two economic evaluations have suggested that the use of second trimester US to screen for fetal anomaly may save costs. The first, a cost-effectiveness modeling study (Vintzileos et al., 2000) a United States societal perspective, suggested that universal second trimester US screening for fetal anomaly may generate short-term, direct medical cost savings of $2312 to $13,376 per patient screened, depending on whether the screening were conducted in a nontertiary care center or a tertiary center. The same study also showed that long-term costs, including care for and loss of productivity in individuals born with abnormality, would be reduced with the use of US screening but only if the screening were conducted in a tertiary center. The other economic evaluation, also a modeling study, (Vanara et al., 2000) showed that in Italy, a structured program of universal US screening for fetal abnormality, combined with well-defined protocols, has the potential of reducing short- and long-term costs, as well as reducing the incidence of birth with structural abnormality.

5.2. The evidence based technology assessment report indicated recent modeling evidence from the United States (Cahill et al., 2010) suggests that compared with strategies that do not include screening for short cervix, universal TVU screening of women with no history of preterm birth, followed by treatment with vaginal progesterone for short cervix, may prevent preterm birth and save direct costs, taking into account the long-term costs associated with caring for individuals born with serious abnormality.

5.3. Washington state agency utilization and cost information indicated costs of US of $20M for the past four years (average of $5M per year and per treatment costs averaging $336).

**6. Evidence on Medicare Decision and Expert guidelines**

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

6.1 Centers for Medicare and Medicaid Services currently cover ultrasounds. Ultrasound diagnostic procedures are listed on their website and are divided into two categories. Medicare coverage is extended to the procedures listed in Category I. Periodic claims review by the intermediary's medical consultants should be conducted to ensure that the techniques are medically appropriate and the general indications specified in these categories are met. Techniques in Category II are considered experimental and should not be covered at this time.

6.2 Guidelines – a search of the core sources and relevant specialty groups identified four guidelines for US (American Institute of Ultrasound Medicine, 2007; American College of Obstetricians and Gynecologists, 2009; American College of Radiologists, 2208-2009; and the Institute of Clinical Systems Improvement, 2010).

- Fair-quality guidelines from ACOG, ACR, and ICSI are consistent with each other and with the literature in describing US as a reasonably safe procedure that accurately provides a wealth of information about pregnancy status and fetal health. Although the guidelines from ACOG allude to the questionable relationship between routine use of US and maternal and fetal outcomes, recommendations were not formed with this in mind. The ICSI guidelines take into consideration the lack of evidence supporting routine use of US in low-risk pregnancy, especially in late pregnancy, but do not fully address the use of US in high-risk pregnancy. None of the guidelines considers evidence pertaining

to the long-term effects on child growth and development, differential effectiveness and safety, or cost-effectiveness.

## Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

### 1. Evidence availability and technology features

The committee concludes that the best available evidence on Routine Ultrasound has been collected and summarized.

1.1 The goal of review was to identify evidence about the impact on pregnancy outcomes of routine use of ultrasound; to identify any patients most likely to benefit and the optimal timing of testing. Common outcomes to measure include changes in patient management; frequency of Cesarean section and abortion; maternal and fetal health outcomes, including preterm birth.

1.2 Literature about US accuracy is very broad and was summarized as the focus of the review was on clinical utility. Evidence about the clinical utility of routine or screening use of US consisted primarily of two meta-analyses: which included 11 RCTs on routine US in early pregnancy, and 8 RCTs on routine US in late pregnancy and one meta-analysis on safety of US with 41 studies, most of which are RCTs. Other studies relating to subpopulation and cost analysis were also described.

1.3 Despite a robust amount of evidence, the quality of evidence on the clinical utility of routine US is generally low and moderate. This is consistent with USPSTF statement: "Despite the lack of evidence on its positive impact on health outcomes and the 1996 USPSTF recommendation against its routine use, ultrasonography in pregnancy has become common practice in the U.S."

### 2. Is it safe?

The committee concludes that the comprehensive evidence indicates that Routine Ultrasound is equally safe to alternative treatments. Key factors to the committee's conclusion included:

2.1. The relatively large body of moderate-quality evidence shows that for major outcomes US shown to be a reasonably safe procedure with no serious short-term adverse effects and no general impact on developmental outcomes.

2.2. A large volume of moderate-quality evidence has shown that routine US during pregnancy does not adversely affect maternal hospitalization, fetal or perinatal death, or perinatal morbidity.

2.3. While not specifically identify in the literature presented, not using US may lead to higher risk where the fetal age is unknown and where other fetal or maternal anomalies identified by US were unknown.

2.4. Further research, particularly with respect to neurological development, is needed to allow definite conclusions about longer term impacts, especially given higher strength machines and more usage in different trimesters.

### 3. Is it effective?

The majority of the committee concludes that the comprehensive evidence about Routine Ultrasound is more effective.

3.1. The committee agreed with the overall evidence conclusion that clinical utility of routine use of ultrasound is generally low.

3.2. Routine US (e.g. low risk or asymptomatic women) did not impact patient management; perinatal mortality or morbidity, or rates of C-section. Use of routine US may result in a slight increase in abortion related to fetal anomaly detection and a second trimester US may reduce the incidence of induction of labor.

3.3. There are several important informational benefits of a routine ultrasound to the overall management and monitoring of pregnancy that may not be measured by a patient outcome change, including: estimation of gestational age, detection of multiple pregnancies; estimation of fetal weight; detection of fetal anomalies. Moderate to high quality evidence supports the accuracy of routine US in establishing gestational age and fetal weight, and detecting fetal anomalies. This information cannot optimally be collected at one gestational time point.

**4. Evidence about the technology's special populations, patient characteristics and adjunct treatment**

The committee agreed that no compelling evidence exists to differentiate sub groups or special populations.

4.1. The committee agreed with the evidence based report that there is inadequate evidence to identify characteristics that either enhance or reduce the efficacy of US such as gestational age; other patient characteristics or evidence-based selection criteria; type of scanning machine and software, reader training or other operational factors; or provider type, setting or other provider characteristics.

4.2. The committee agreed with the evidence based report that insufficient evidence is available pertaining to the effect on outcomes of different types of US scanning software, reader training, operational factors (other than the emergency department and ectopic pregnancy issue), or type of healthcare financing system.

**5. Is it cost-effective?**

The committee concludes that Routine Ultrasound is more cost effective.

5.1. The committee agreed that the cost of routine use of US screening on a unit level is relatively small ($336); however given the population and increasing number of use per pregnancy, it is important to identify prudent practice.

5.2. Cost analysis studies suggest cost savings from routine screening based on prevention or reduction of direct costs of preterm birth and induction of labor, and taking into account the long-term costs associated with caring for individuals born with serious abnormality.

## 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 Routine Ultrasound demonstrates that there is sufficient evidence to cover with conditions the use of Routine Ultrasound. 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 8 to 0 to cover with conditions Routine Ultrasound.

## Routine Ultrasound Coverage Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Routine Ultrasound Evidentiary Votes:

**Is there sufficient evidence under some or all situations that Routine Ultrasound:**

| | **Unproven** (no) | **Equivalent** (yes) | **Less** (yes) | **More** (yes) |
|---|---|---|---|---|
| **Effective** | **0** | 0 | 0 | **8** |
| **Safe** | **2** | 3 | **0** | 3 |
| **Cost-effective** | **0** | 0 | **0** | 8 |

Routine Ultrasound Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

| **HTCC COMMITTEE COVERAGE DETERMINATION** | | | |
|---|---|---|---|
| | **Not covered** | **Covered Unconditionally** | **Covered Under Certain Conditions** |
| **Routine Ultrasound** | **0** | 0 | **8** |

- Action: The committee vice-chair directed HTA staff to prepare a Findings and Decision document on Routine Ultrasound reflective of the majority vote for final approval at the next public meeting.

- For pregnant women, routine screening ultrasound is a covered benefit, with the following conditions:
    1. One Ultrasound in week 13 or earlier
    2. One Ultrasound in weeks 16 thru 22
    3. Other Ultrasound subject to agency determination

Note: the committee acknowledged that optimal timing, clinically, for routine ultrasounds are in a narrower window (e.g. between weeks 11 and 13 for first trimester and between 18 and 20 weeks second trimester) but a narrower payment policy might unintentionally limit access when applied.

The committee reviewed the Clinical guidelines and Medicare decision. Clinical guidelines generally indicate that routine US may be offered and Medicare decision includes coverage for specific pregnancy related codes and indications. It does not appear that the decision will conflict either with guidelines or the Medicare national coverage decision, though this decision is more explicit in timing and number for routine use. For any potential conflict, the committee noted that the Medicare decision was made 1997 and prior too many of the studies reviewed by the committee, and that the Medicare population would likely not fall into a routine screening for pregnancy. Further neither the guidelines nor Medicare addressed outcomes of clinical utility or cost.