Washington State Health Care Authority, HTA Program
FINAL Key Questions and Background
Ultrasonography (Ultrasound) in Pregnancy

Introduction

HTA has selected Ultrasonography or ultrasound in pregnancy to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input about available evidence. Key questions guide the development of the evidence report. They are posted for public review and comment. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Despite recommendations by organizations such as the US Preventive Services Task Force to the contrary, routine and serial use of ultrasonography in pregnancy is growing. There are concerns about efficacy, safety, cost, and health impact of routine and serial ultrasound in pregnancy. Information about when ultrasound is clinically indicated and what maternal or fetal health outcomes it improves is needed.

Key Questions

For patients who are pregnant:

1. What is the evidence of efficacy and effectiveness of screening ultrasonography? Including consideration of:
    a. Test accuracy
    b. Change in patient management
    c. reductions in perinatal morbidity and mortality
    d. rate of labor induction for post-term pregnancy
    e. rate of Caesarian section
    f. rate of abortion for fetal anomaly

2. What is the evidence on optimal timing or frequency on improved efficacy or effectiveness of screening ultrasonography?

3. What is the evidence of the safety of ultrasonography? Including consideration of:
    a. Adverse events type and frequency (mortality, major morbidity, other)

4. What is the evidence that ultrasonography has differential efficacy or safety issues in sub populations? Including consideration of:
    b. Gestational age
    c. Other patient characteristics or evidence based patient selection criteria
    d. Type of scanning machine and software, reader training, and other operational factors
    e. Provider type, setting or other provider characteristics
    f. Health care system type, including worker's compensation, Medicaid, state employees

5. What is the evidence of cost implications and cost-effectiveness of ultrasonography? Including consideration of:

g. Costs in short term
h. Costs in long term

Technology Background

Technology: Ultrasound is performed in a significant number of pregnancies (49% in 1989, 58% in 1992 and probably 70-80% currently). Ultrasound of the fetus can be used to estimate fetal age, detect multiple pregnancies, detect fetal malformations, detect intrauterine growth retardation, determine fetal presentation and detect low-lying placenta. Many of these conditions may be associated with maternal or perinatal morbidity and mortality. However, the US Preventive Services Task Force (USPSTF) and other evidence states that neither early, late nor serial ultrasound has been proven to improve perinatal morbidity or mortality. Ultrasound does detect multiple pregnancies and congenital malformations earlier in pregnancy but there is not current evidence that early detection results in improved outcomes or increased rate of induced abortion. Information about when ultrasound is clinically indicated and what maternal or fetal health outcomes it improves is needed.

Public Comment and Response

HTA received two timely public comments requesting clarification about the underlying rationale and more specification for the key questions. HTA reviewed the public comments, consulted clinical committee members and the technology assessment centers, and gathered follow up information from the nominating agencies. A summary of the input and modification to key questions is below.

The primary comment is the assertion that ultrasound, even without a high risk or suspected anomaly is routine clinical practice that is unlikely to change. The focus of this review is routine and serial use of ultrasound in low-risk pregnancies. As noted above, current evidence is needed about the clinical indication, timing and frequency of ultrasound, tied to improvement in maternal or fetal health outcomes. A second key question was added to clarify this focus.

CURRICULUM VITAE

EDGAR E. CLARK, MD

PERSONAL

Birthdate: 10 October 1942
Birthplace: Los Angeles, California
Residence: 248 SW Kingston Ave.
Portland, Oregon 97201
Family Status: Married; two grown children

EDUCATION

College: BS in Chemistry, Stanford University; 1964
Medical School: MD, Univ. of California, San Francisco (UCSF), Calif.; 1968
Internship: Straight Medical Internship, Univ. of Washington Affiliated Hospitals, Seattle, Wa.; 1968-9
Residency: Diagnostic Radiology, Univ. of California, San Francisco; 1971-4
Nuclear medicine, Univ. of California, San Francisco; 1974-5
Health Administration: Masters of Science in Health Administration, University of Colorado School of Business, Denver, Colorado; 1994

ACADEMIC AWARDS AND HONORS

BS with Distinction, Stanford University, 1968
Merck Manual and Mosby Scholarship Book Award for Academic Excellence at MD Graduation, UCSF, 1968
Alpha Omega Alpha Honor Fraternity, UCSF, 1968
Chief Resident, Diagnostic Radiology, UCSF, 1973-4

MILITARY SERVICE

General Medical Officer, Captain, US Army, 1969-71;
US Kenner Army Hospital, Ft Lee, Va.

EMPLOYMENT

Staff Radiologist, Portland Adventist Hospital, Portland, Oregon, 1975-86
Medical Director, Outpatient Radiology Center, Portland, Oregon, 1986-- 1999
Owner/Medical Director, Body Imaging Radiology, Portland, Oregon, 1998-- 1999
Staff Radiologist, Body Imaging Radiology, Portland, Oregon, 2000—2003

Medical Director for Pacific Northwest, HealthHelp, Inc. (Radiology Utilization Management). 2001-- May, 2004.
Locum Tenens Radiologist, 2004—2006.
Consultant, Center for Evidence-based Policy, Oregon Health and Science University, Portland, OR, 2006—present
Consultant, AllMed Healthcare Management, Portland, OR., 2006- present

COMMITTEES AND COMMUNITY SERVICE

*Member of Audit, Cancer, Institutional Review, Safety, Radiation Committees (Chair of *Cancer and Institutional Review Committees), Portland Adventist Hospital, 1975-88.
*Member of Radiology Chairman Search Committee, Oregon Health Science Univ.,1988
*Member of MSAC Committee, Blue Cross Blue Shield of Oregon) 1986-present
*Board, Portland Adventist Hospital IPA, 1985-8
*Board of Trustees, Oregon Episcopal School, 1988-91; Chair, Development Committee
*Clinical Instructor, Department of Public Health and Preventive Medicine, Oregon Health Science University, 1994—1997
*Volunteer, The Nature Conservancy, 2000-- present; work with Cynthia Beckwith in Development and Dan Salzer on Assessment and Monitoring project
*Board of Trustees, The Nature Conservancy of Oregon, 2007-- presemt

MEMBERSHIPS IN PROFESSIONAL SOCIETIES

Diplomate, American Board of Radiology, 1974
Diplomate, American Board of Nuclear Medicine, 1975
Member, American College of Radiology and Oregon Radiological Society, 1976- 2005
Member, Multnomah Medical Society, 1975- present
Member, Oregon Medical Association, 1975- present
American Roentgen Ray Society, 2003- 6

PUBLICATIONS

Clark, EE and Hattner, RS. Brain Scintigraphy in Recurrent Medulloblastoma, Radiology 119: 633-6, June 1976.
Clark, EE and Hattner, RS Recurrent Medulloblastoma, Yearbook of Nuclear Medicine 1977, 156-7
Stevens, JS and Clark, EE. Liver Metastases of Colon Adenocarcinoma Demonstrated on 99m Tc Pyrophosphate Bone Scan. Clinical Nuclear Medicine 2: 270, 1977.
Burke, LF and Clark, EE. Ileocolic Intussusception: A Case Report. J. Clinical Ultrasound 5: 346, 1977.

HTA 2010 – Agency Experience: Routine Ultrasound (US) in Pregnancy

Jeffery Thompson, MD MPH

What are the issues and what are we asking of the committee?

Key questions considering us in normal/low risk pregnancy :

- effectiveness/efficacy,
- timing/frequency,
- safety,
- cost effectiveness

Questions from the AMDG?

1. Is this benefit overused and/or is there unexplained variation?

2. Are there limits that can balance quality, access and costs?

3. What are opinions and wants from the science and need

UMP /PEP/DSHS combined data for US in Pregnancy

Figure 1: UMP /PEP/DSHS combined data

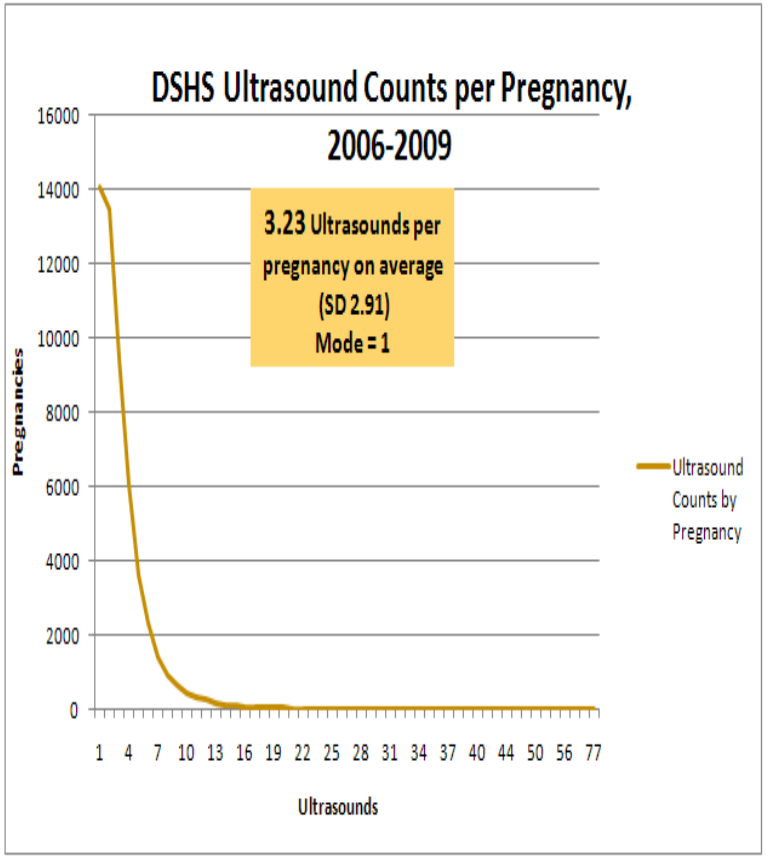
Year	2006	2007	2008	2009	Overall*
Ultrasound Count	50,584	52,654	56,356	40,713	**200,307**
Pregnancy Count	19,111	19,064	19,547	12,647	**59,653**
Avg # of Ultrasounds/ Pregnancy/Year	2.65	2.76	2.88	3.22	**3.36**
Total Cost of Ultrasounds	$5,049,915	$5,146,072	$5,676,992	$4,193,088	**$20,066,067**
Average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

Figure 2a –Ultrasound counts by Pregnancy, 2006-2009

Medicaid

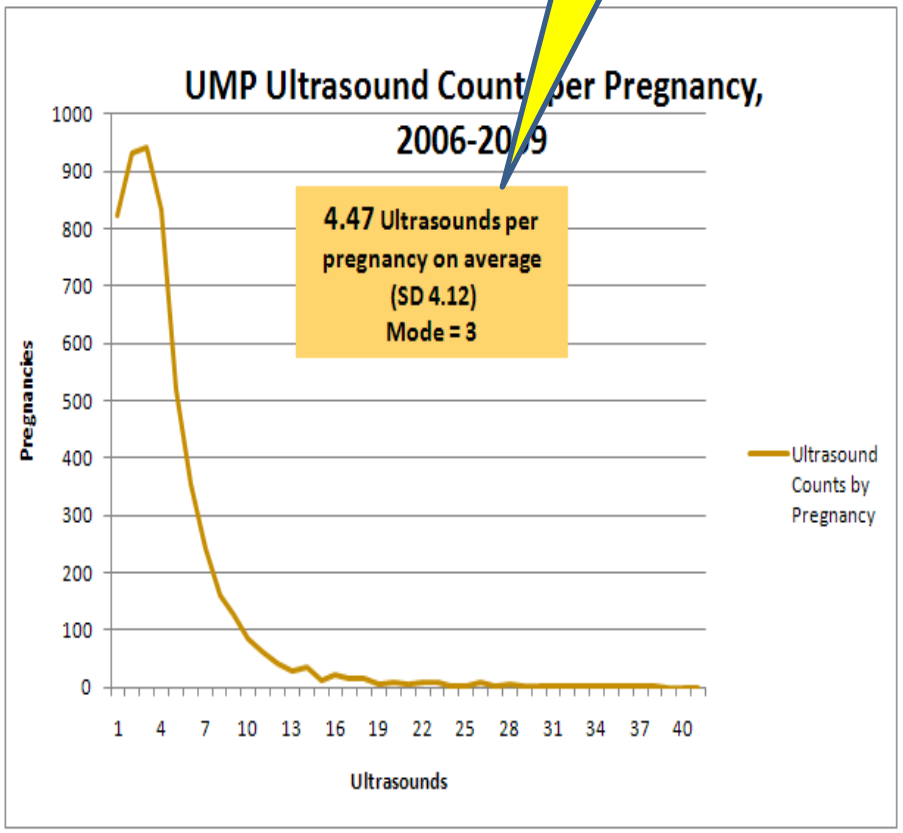
Figure 2b – DSHS Ultrasound counts by Pregnancy, 2006-2009



UMP

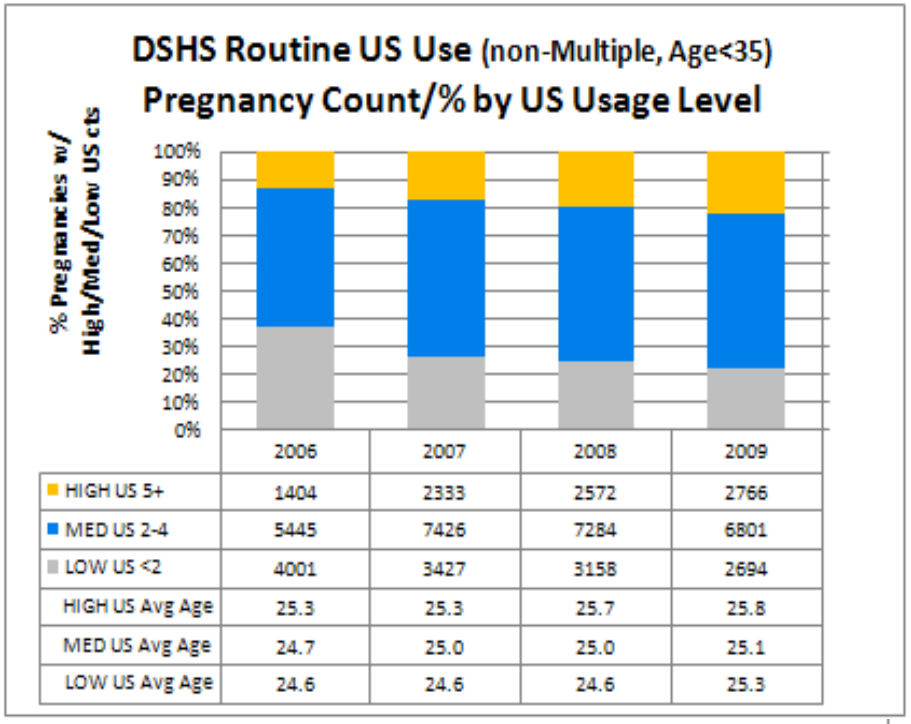
TA 2010 – Agency Experience: Routine Ultrasound(US) in Pregnancy

gure 2a –Ultrasound counts by Pregnancy, UMP 2006-2009 (Aetna ex



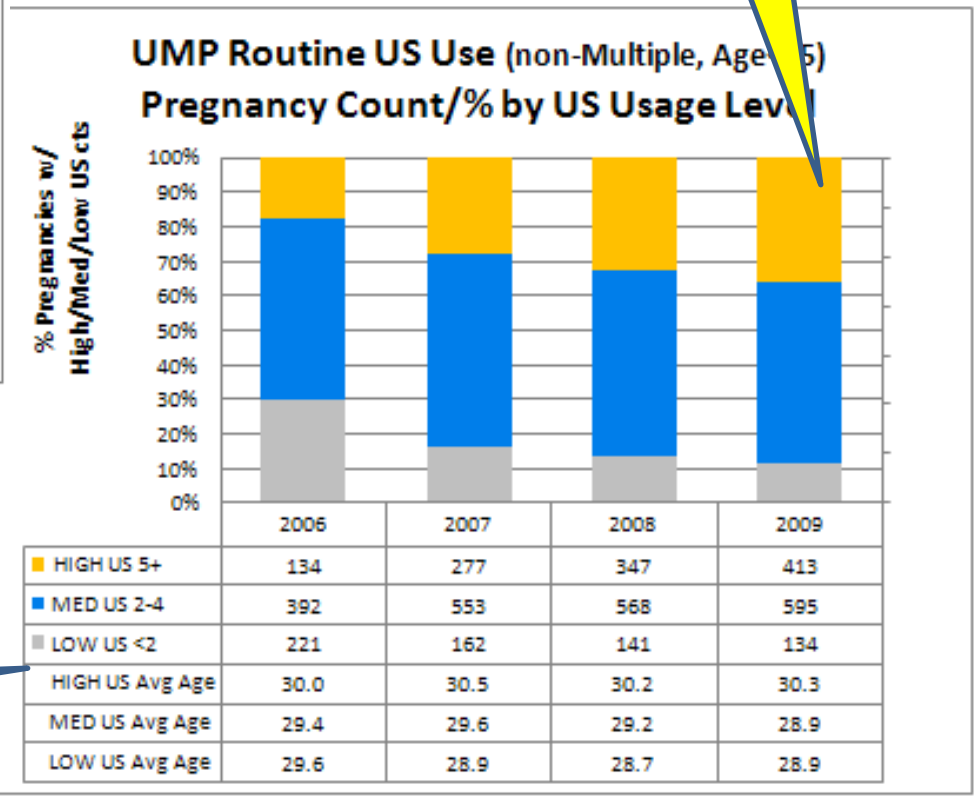
UMP Moms have 38% more studies

Figure 6b. DSHS Routine (low risk) US Use by Usage Level



	2006	2007	2008	2009
HIGH US 5+	1404	2333	2572	2766
MED US 2-4	5445	7426	7284	6801
LOW US <2	4001	3427	3158	2694
HIGH US Avg Age	25.3	25.3	25.7	25.8
MED US Avg Age	24.7	25.0	25.0	25.1
LOW US Avg Age	24.6	24.6	24.6	25.3

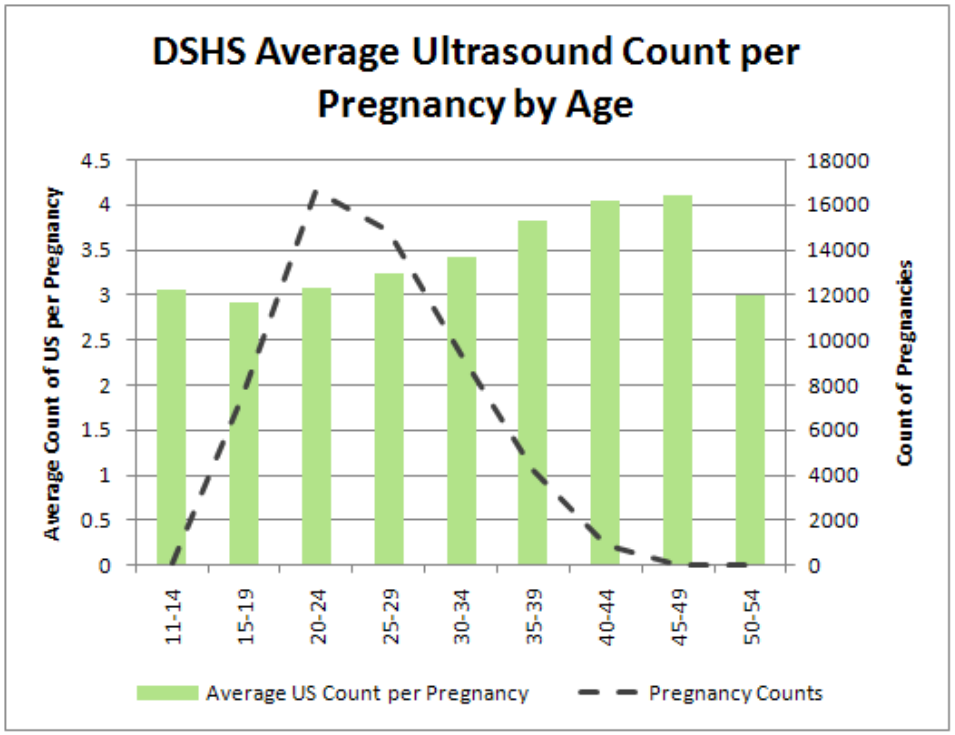
UMP Moms tend have more US 36% vs. 22%



	2006	2007	2008	2009
HIGH US 5+	134	277	347	413
MED US 2-4	392	553	568	595
LOW US <2	221	162	141	134
HIGH US Avg Age	30.0	30.5	30.2	30.3
MED US Avg Age	29.4	29.6	29.2	28.9
LOW US Avg Age	29.6	28.9	28.7	28.9

UMP Moms tend to be older

Figure 3a: Average Ultrasound Count per Pregnancy by Age Group – 2006-2009



Older Moms in UMP have more US by 2-3 times

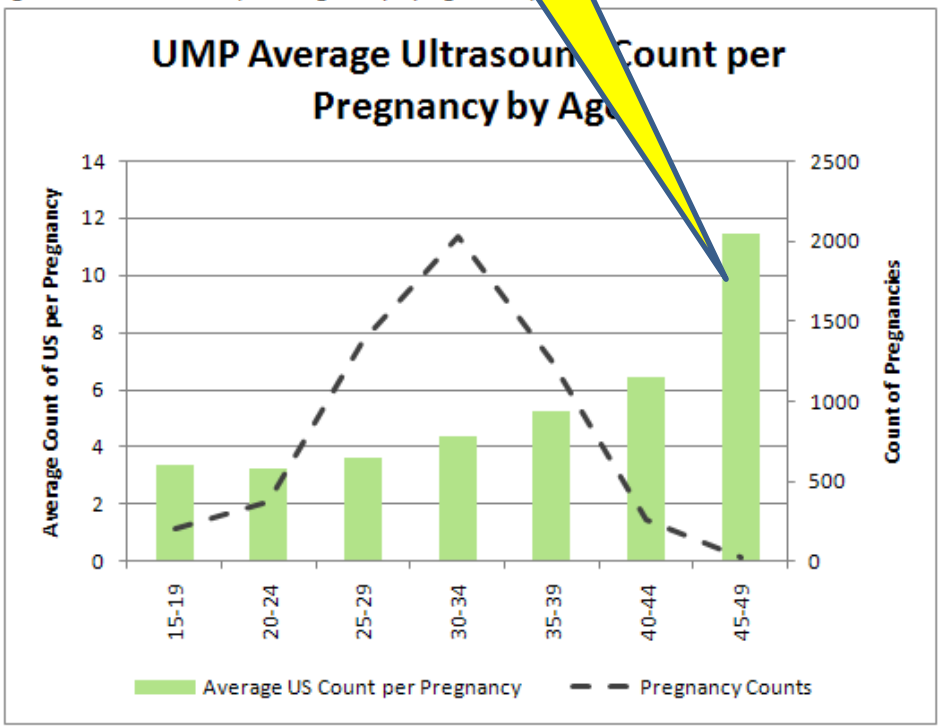
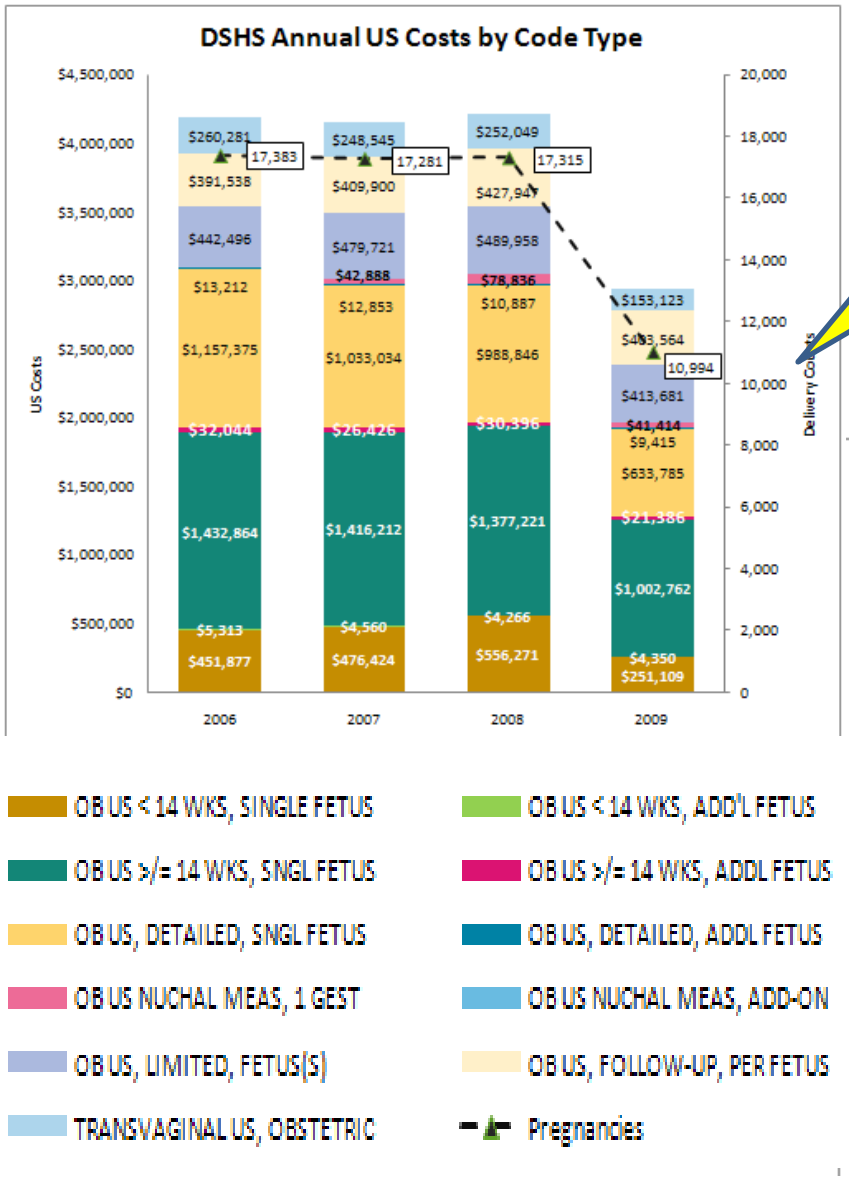


Figure 4b: Annual US Costs by Code/ Type, 2006-2009



DSHS Moms have more > 14 wk US studies

UMP Moms have more TVUS, Nuchal checks, and <14 wk

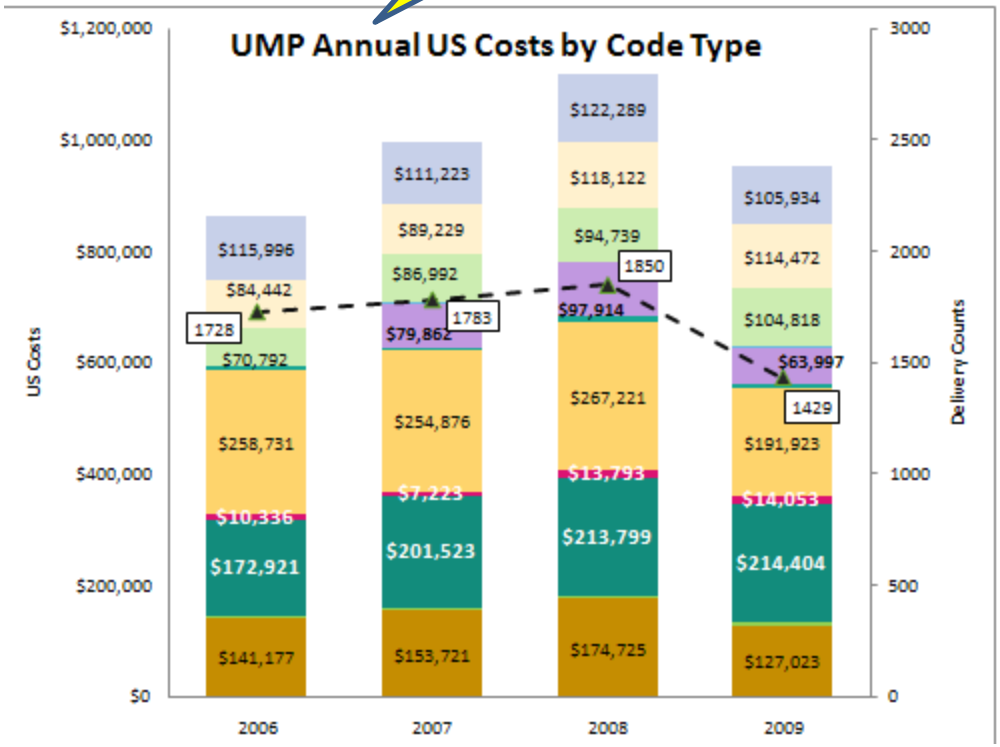
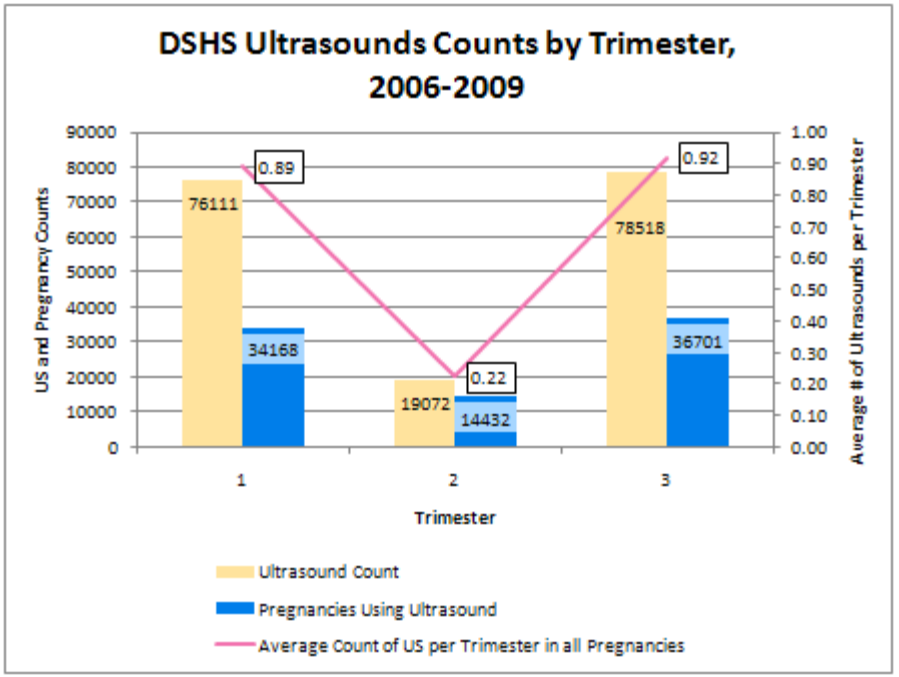
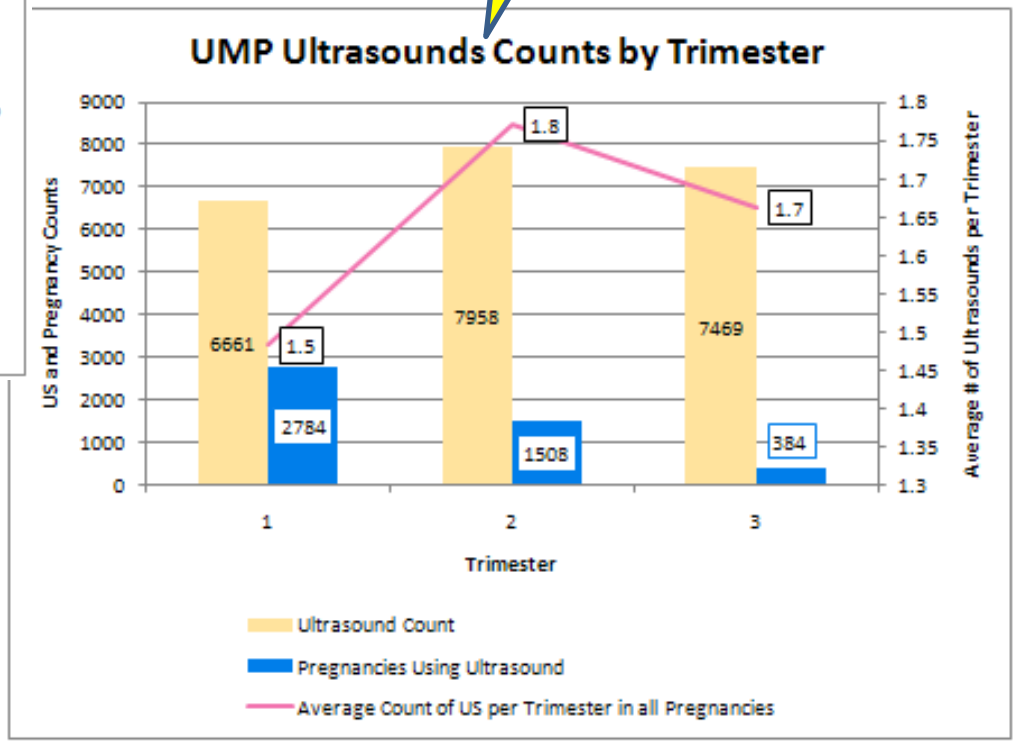


Figure 5a: US Counts by Trimester,2006-2009



UMP with more US in all trimesters by almost 2X



BALANCING ACCESS QUALITY AND COSTS

AGENCY DATA SUGGEST:
1) Over utilization of US
2) Medicaid and UMP moms are being treated differentially

National guidelines for US in low risk pregnancy are graded poor to fair in evidence

There is a lack of std protocols and documentation of all recommended screening items do not occur

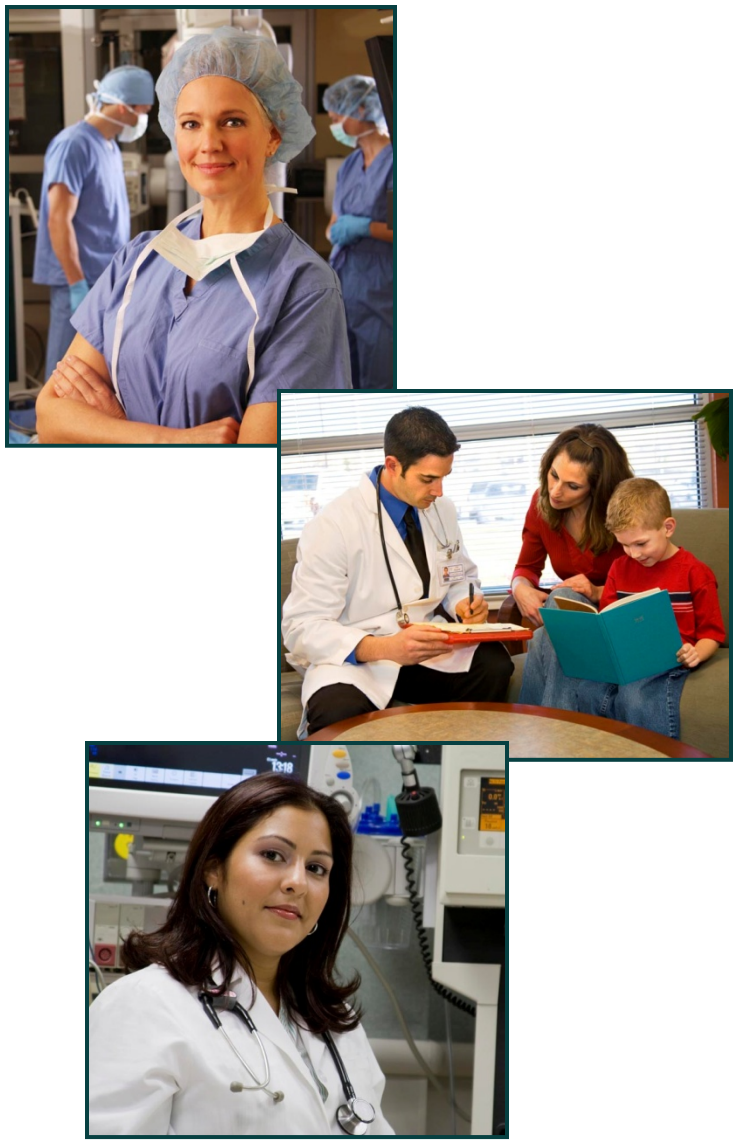
AMDG Recommendations for US in Normal Pregnancy

Benefits: Normal pregnancy allowed **one** US (18-22 weeks)

Benefits for all other US utilization require medical necessity

The are many Medical Necessity Options (high risk):

- Build into a global,
- PA, EPA,
- Look into contracts with Radiologists,
- Look in efficient networks
- Gold Card efficent providers



Ultrasonography (Ultrasound) in Pregnancy

Teresa Rogstad, MPH
Senior Medical Research Analyst
Louisville, KY

Hayes

Analysts

This report was prepared by:

Teresa L. Rogstad, MPH (senior medical research analyst)

Gopika Chandra, MD, PhD (senior medical research analyst)

Anita Rihal, MPH (medical research analyst)

Presentation Overview

- Policy Context
- Practice Guidelines
- Key Questions
- Background
- Methods
- Findings
- Summary of Findings
- General Conclusion & Gaps in the Evidence

Policy Context

- Increasing use
  - # US scans/pregnancy: 1.5, 1995-1997; 2.7, 2005-2006; increases in low and high risk
  - No difference in Medicaid vs private insurance
  - More common in Northeast and West
- Clinical utility?
- FDA and CMS
  - Broad approval for medical reasons
  - “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*
- Institute for Clinical Systems Improvement (ISCI) – *fair*

Key Questions

1. **What is the evidence of efficacy and effectiveness of ultrasonography? Including consideration of:**
   a. Test accuracy
   b. Change in patient management
   c. Reductions in perinatal morbidity and mortality
   d. Rate of labor induction for postterm pregnancy
   e. Rate of Caesarian section
   f. Rate of abortion for fetal anomaly
   g. What is the evidence of the safety of ultrasonography? [Including consideration of adverse events type and frequency (mortality, major morbidity, other)]
2. **What is the evidence that ultrasonography has differential efficacy or safety issues in subpopulations? Including consideration of:**
   a. Gestational age
   b. Other patient characteristics or evidence based patient selection criteria
   c. Type of scanning machine and software, reader training, and other operational factors
   d. Provider type, setting, or other provider characteristics
   e. Healthcare system type, including worker's compensation, Medicaid, state employees
3. **What is the evidence of cost implications and cost-effectiveness of ultrasonography? Including consideration of:**
   a. Short-term costs
   b. Long-term costs

Screening/Surveillance Options

- US alone (transvaginal or transabdominal)
- Biophysical profile (BPP)
  - Fetal heart rate tracing plus US to monitor fetal body movements, fetal breathing movements, amniotic fluid index, nonstress test
- Fetal and umbilical Doppler US (DUS)
- Utero-placental DUS
- Cardiotography (CTG) (electrical fetal monitoring)
- Fetal echocardiography

Purpose of Ultrasound (US) in Pregnancy

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

Measuring Cervical Length

- Cervical insufficiency + obstetrical history is best predictor of preterm birth (PTB)
- Short cervix can be treated in asymptomatic patients
  - Cerclage
  - Progesterone
- 90% of women with symptoms of preterm labor (PTL) will NOT deliver within 7 days
- Treatment for PTL (tocolysis and steroids) have harms

Therefore, cervical length measured by transvaginal ultrasound (TVU) — surveillance or screen

Methods: Report Focus and Search Strategy

- Systematic and critical assessment of clinical utility
- Descriptive information regarding accuracy
- Systematic reviews (SRs) and any type of controlled study:
  - Pregnant women
  - **US used for screening purposes or for guiding patient management**
  - **Compared with no screening, screening by other methods, or concealment of US findings**
  - Assessment of change in patient management; maternal and fetal health outcomes, including PTB; frequency of Cesarean section (C-section), induction or labor (IOL), or abortion
- Searched major databases for SRs, including Hayes Knowledge Library, and economic evaluations (EEs); MEDLINE and EMBASE for additional systematic reviews and primary studies; through September 2010

Methods: Report Focus and Search Strategy (cont.)

- 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)
  - Utero-placental DUS

Accuracy of US

- Accuracy depends on target condition
- For screening, often in combination
- 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
- Most studies in Europe

US in Low-Risk Early Pregnancy: Findings

- 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*)
- 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)
- 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)
- ↑abortion, fetal anomaly; 0.10% absolute (5 RCTs; n=28,256) (*high*)
- In general: 1 scan, 2nd trimester

US in Low-Risk Late Pregnancy: Findings

US Screen (generally 1 scan in 3rd semester)

- Patient Management
  - No effect (*low-moderate quality)*
- 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*)
- C-section; IOL
  - No effect (5 to 6 RCTs; n=21,035 to 22,663) (*moderate*)

Serial DUS; same results (single RCT) (*low*)

US in High-Risk Pregnancy: Search Results

- Cochrane Review and meta-analysis (MA) of fetal and umbilical DUS (Alfirevic et al., 2010)
  - 18 RCTs; late surveillance of mixed populations
- Cochrane Review and MA of TVU-PTL (Berghella et al., 2009)
  - 5 RCTs; screen in presence of PTL symptoms
  - Determine need for tocolysis/progesterone/steroids
- Systematic review of TVU-Surveillance (Blikman et al., 2008) & 1 RCT (Simcox et al. (2009)
  - Blikman et al.: 2 RCTs, 4 observational
  - Surveillance vs patient history alone
  - Determine need for cerclage

US in High-Risk Pregnancy: Findings (DUS Surveillance)

- ↓antenatal admissions (*moderate quality)*
- ↓perinatal mortality; NNT=200 (16 RCTs; n=10,125) (*very low*)
- ↓serious neonatal morbidity; NNT=36 (3 RCTs; n=598) (*very low*)
- ↓any C-section; NNT=39 (14 RCTs; n=7918) (*low*); similar for emergency C-section
- ↓IOL; NNT=31 (10 RCTs; n=5633) (*low*)
- DUS alone compared with CTG alone (3 RCTs; n=1473) (*high*)
  - ↑elective C-section by > 50%
  - ↓emergency C-section by 44%; −45% absolute; NNT=12

US in High-Risk Pregnancy: Findings (TVU)

- No significant effect on patient management (either use)
- TVU-PTL, no significant pooled effect *(low quality):*
  - ↓PTB; nonsignificant RR 0.59 (2 RCTs; n=256)
  - Better study: 13% vs 36.3% (*P*=0.01)
- TVU-Surveillance in twin pregnancy, no effect (single RCT) (*low*)
- TVU-Surveillance with high-risk history, no effect *(moderate*)
  - PTB (3 RCTs; n=423)
  - Early pregnancy loss (1 small RCT)

Safety of Routine US: Search Results

- 1 MA (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) MA
- 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
  - ↓ 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 (7 RCTs; n=295) (*low quality*)
  - ↓ IOL only in 2nd (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*)

Differential Efficacy/Safety: Findings (cont.)

- 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)
  - Short-term direct costs, ↓44% (relative)
  - Long-term direct costs, ↓21% (relative)
  - Unclear validity of assumed detection rate of structural abnormality
  - Results may not apply to more fragmented United States system
- 6 strategies for US screening for fetal anomaly (Ritchie et al., 2005; Scotland)
  - Least expensive (short-term costs): 1st trimester US for estimate gestational age, 2nd trimester double serum test
  - All strategies included some use of routine US; no sensitivity analysis

Cost Implications and Cost-Effectiveness (cont.)

- Routine 2nd trimester US vs no US or selective US (Vintzileos et al., 2000; United States)
  - Direct *and* indirect (productivity) costs measured
  - Short-term *savings*: $13,030/patient if initial screen in tertiary center; $2230 if in nontertiary
  - Long-term *savings*: $97 to $189/patient if initial screen in tertiary center
  - Long-term *loss*: $69 to $161/patient if initial screen in nontertiary center
  - Accuracy based on RADIUS trial; estimation of abortion rate may not be applicable to mild/moderate anomalies
  - Costs were in 1998 dollars

Cost Implications and Cost-Effectiveness (cont.)

- Universal TVU to assess cervical length; add-on to routine 2nd trimester US; (Cahill et al., 2010; Medicaid perspective)
  - Saved costs, prevented PTB, and produced quality-adjusted life-year (QALY) gains
  - But only in women *without* history of PTB
  - Assumes availability of TVU in all facilities
  - Results not applicable if 2nd trimester US is not already considered standard practice
  - May not apply to multiple gestation, fetal abnormality, short cervix defined at thresholds > 15 mm, non-use of progesterone, TVU in PTL

Cost Implications and Cost-Effectiveness (cont.)

- 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 nonsignificant (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 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: Effectiveness, High-Risk Patients

Indication; Form of US	Findings	Evidence
Monitor high-risk patients with Doppler US	✓Evidence supports	Very Low to Low Quality Lack of standard treatment protocols
TVU to assess PTL	✓Evidence supports	Low Quality Lack of standard treatment protocols
TVU surveillance, history of PTB	Evidence does *not* support	Low to Moderate Quality

Summary of Evidence: 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
- Preliminary evidence:

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 •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 •Assessment of safety and effectiveness in 1st and 3rd trimesters •Studies with newer more potent or sophisticated machines, including 3D and 4D •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 •Studies restricted to low-resource settings

Thank you. Questions?