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.