



Effective Health Care

Uterine Fibroid Management Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Uterine fibroid management could be considered for a potential new research project within the Effective Health Care (EHC) Program.

Topic Description

Nominator: Government agency

Nomination Summary: This topic stems from a desire to take the next steps in exploring the research gaps identified in an updated AHRQ evidence review completed in July 2007 titled *Management of Uterine Fibroids: An Update of the Evidence*. The nominators wish to see uterine fibroid management move forward as potential new research. Listed below are unrefined key questions pertaining to subtopics of the more broad uterine fibroid management concept, which the nominator suggests reflect many of the research gaps and important areas to pursue. The nominator asserts new research project(s) could entail identifying important outcomes, data elements, analytic plans, and other relevant issues surrounding the creation of a multistakeholder registry - designed to longitudinally help explore natural history of disease (fundamentals of anatomical, biological, physiological differences in disease development, subclinical criteria and presentation/symptoms of disease, comparisons in treatment and intervention approaches, coordination of care, and patient clinical outcomes (e.g., fibroid regrowth, fertility, menses, and other clinical outcomes).

Key Questions from Nominator: Questions pertaining to advancing methodology for measuring and monitoring comparative effectiveness of uterine fibroid management:

1. What individual interventions and/or combinations are most frequently used as primary treatment in outpatient and inpatient uterine fibroid management particularly in a select population (i.e., African Americans) age 20 and above and for select fibroid subtypes and/or uterine locations? What are the health outcomes of these interventions? Interventions to be evaluated for uterine fibroid management may include but are not limited to: GnRH agonists, NSAIDs, homeopathy and alternative medicine therapies, contraceptive medications, total abdominal and vaginal hysterectomy, hysteroscopy, uterine artery embolization, MRI guided focused ultrasound, endometrial ablation, and myomectomy.
2. Are there variations in usage of select therapies as primary and secondary management for uterine fibroids (for patients with inadequate symptom relief, multiple fibroids or history of regrowth) based upon demographics (i.e., age), geographical region, or both? How does variation affect patient health outcomes?
3. Are there differences among treatments in how long on average the intervention has

- beneficial health outcomes before needing additional intervention(s) for treatment?
4. Are there differences among interventions in how long on average until fertility is achieved and in both short-term and long-term fertility and pregnancy outcomes?
 5. Are there differences among interventions in costs (inpatient, outpatient, duration of inpatient stay, duration of recovery, time to work onset/return to work, incidence of adverse effects or harms, complication rates, rate of additional ancillary/medical services required and fees, incidence of comorbidities, mortality, rates of repeat interventions or alternative procedures by fibroid type, miscellaneous costs associated with interventions)?
 6. Are there differences among interventions in short- and long-term outcomes on incidence and type of patient symptoms: including physical limitations and emotional stressors and/or psychological symptoms and diagnoses?
 7. What methods or models are effective in coordinating and monitoring care for women with symptoms of uterine fibroids? What education and behavioral modalities are effective in supporting and helping women cope with uterine fibroids, management and treatment?

Questions pertaining to a potential uterine fibroid registry to explore MRI-guided focused ultrasound technology:

1. Is MR -focused ultrasound technology a safe treatment for leiomyomas? What is the incidence of minor and serious short-term complications?
2. Is MR -focused ultrasound technology an effective treatment for leiomyomas? What is the likelihood of symptom relief?
3. How durable is the treatment? What is the likelihood of a subsequent procedure or medical therapy to treat recurrent symptoms of leiomyomas?
4. What is the likelihood that a woman who undergoes MRI-guided ultrasound and plans subsequent pregnancy will be able to conceive and deliver a subsequent intrauterine pregnancy?
5. Is there a difference in outcome based on device (product size, primary and secondary embolic material) used?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Uterine fibroids is a costly condition that is often underdiagnosed and is being increasingly recognized as an important cause of morbidity and mortality. This topic may represent important variation in clinical care in what constitutes appropriate first-line and second-line therapies in patients with different types of uterine fibroids across variations in patient populations and subgroups. The current evidence base is insufficient to ascertain differences in treatment outcomes with existing and newer technologies and in the effective measurement of select clinical outcomes.
- Potential new research on this topic could help address the gaps in evidence for patients who are candidates for these procedures; the short- and long-term clinical outcomes; harms and benefits of

these procedures, including the impact on quality of life; and future childbearing and control of gynecologic symptoms and recurrence.