Developing Evidence-Based Hysterectomy Guidelines

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Chair, Hysterectomy Workgroup
Member, Bree Collaborative
Background
2011 Health Care Environment

Low Quality  →  Broken Healthcare System  →  Advanced Imaging Management Project  →  Bree Collaborative  →  Little Equity

High Cost  ←  Bad Outcomes
House Bill 1311

20 Members

QI Organizations
Employers
Hospitals
Health Plans
Public Purchasers
Others
Physicians

Identify health care services with high:
- Variation
- Utilization
Without producing better outcomes
Recommendations Formed in Clinical Workgroups

- Financial Incentives
- Provider Feedback Reports
- Shared Decision Aids
- Evidence-Based Guidelines
- Data Transparency
- Centers of Excellence
- Public Reporting

Clinical Committee
Meeting Monthly for 9-12 Months

Public Comment

Recommendations to improve health care quality, outcomes, and affordability in Washington State

The Health Care Authority

Broader Health Care Community
Report and Recommendation Process

**Formulation**

- **Select Topics**
  Bree Collaborative members discuss potential topics with high variation in the way that care is delivered, that are frequently used but do not lead to better care or patient health, or that have patient safety issues. Determination of three new topics by Bree Collaborative member majority vote.

- **Determination of workgroup Chair** (typically Bree Collaborative member)

- **Convene Workgroup**
  Selection and recruitment of workgroup members including from health plans, providers, hospitals, and other relevant stakeholders including at least two members of the specialty or subspecialty society most experienced with the health service

- **Approval of workgroup charter and roster by Bree Members**

**Development**

- **Workgroup** develops initial scope, problem statement, and focus areas. Also identify barriers, drivers of change, and indicators or proxies for success.

- **Updates at Bree Meetings**
  - Engagement with expert speakers
  - Development of stakeholder-specific recommendations
  - Development of implementation strategy and action steps (e.g., financial incentives, data transparency)

- **Presentation at Bree Meeting for vote for dissemination for public comment**

- **Public Comments**
  Public comment opportunity including online survey and outreach to specific stakeholder groups.

- **Workgroup meets to address public comments and make any necessary changes to Report and Recommendations**

- **Presentation at Bree Meeting for final adoption**

**Implementation**

- **Approval by Director of the Health Care Authority.**
  "...all state purchased health care programs must implement the evidence-based best practice guidelines or protocols and strategies..."

- **Dissemination of final approved Reports and Recommendations.**

- **Annual reports to Legislature and Governor’s Office.**

- **Working with hospitals, health systems, clinics, health plans, purchasers, patients, quality organizations, the Legislature, and the Health Care Authority to implement recommendations.**

- **Re-review**
  Reports may be selected for re-review annually or if there is new evidence one year after adoption
Topic Areas

- Obstetrics (2012)
- Cardiology (2012)
- Elective Total Knee and Total Hip Replacement Bundle and Warranty (2013 and 2017)
- Elective Lumbar Fusion Bundle and Warranty (2014 and 2018)
- Elective Coronary Artery Bypass Surgery Bundle and Warranty (2015)
- Bariatric Surgical Bundled Payment Model and Warranty (2016)
- Low Back Pain (2013)
- Spine SCOAP (2013)
- Hospital Readmissions (2014)
- End-of-Life Care (2014)
- Addiction and Dependence Treatment (2015)
- Prostate Cancer Screening (2016)
- Pediatric Psychotropic Drug Use (2016)
- Behavioral Health Integration (2017)
- Guidelines for Prescribing Opioids for Pain (2015-Present)
- Opioid Use Disorder Treatment (2017)
- Alzheimer’s Disease and Other Dementias (2017)
- Hysterectomy (2017)
- LGBTQ Health Care (2018)
- Collaborative Care for Chronic Pain (2018)
- Suicide Care (2018)
Implementation

- **Agency Medical Directors Group (AMDG)** reviews and approves recommendations which are then forwarded to the Director of the Health Care Authority (HCA)

- **HCA Director** reviews and decides whether to apply to state-purchased health care programs

- Legislation does not mandate payment or coverage decisions by private health care purchasers or carriers
  - Delivery systems and providers not required to implement recommendations
Why Select Hysterectomy?

Figure 9: Map shows which residential areas in the Puget Sound showed higher and lower rates of hysterectomies performed in 2012.

Larger circles mean the use pattern reaches across more patient age and gender groups.

The color of each circle tells the direction of the difference.
- Red: Higher than rest of region.
- Blue: Lower than rest of region.
- Purple: Mixed. Some groups receive the service more commonly, some less commonly than rest of region.

Why Select Hysterectomy?

- Surgical removal of all or part of the uterus
- One of the most common procedures among women
  - ~600,000 annually
- Highly variable based on location (previous slide), highly variable cost
- Overutilized as primary treatment option without trial of conservative therapy
- Underutilization of less invasive surgical approaches (vaginal)
- Shift from inpatient to outpatient ambulatory facilities
  - ~40% outpatient
- Most common indications: uterine fibroids, abnormal menstrual bleeding, benign neoplasm or ovarian cyst, endometriosis, and uterine prolapse
- Risk of complications, racial disparities
Citations

- American Congress of Obstetricians and Gynecologists. Benign Hysterectomy Episode and Quality Measures. www.acog.org/About-ACOG/ACOG-Departments/Payment-Reform/APMs/BenignHyst
Recruiting Workgroup Members

- Balance of clinical expertise and representation of clinicians working within large health systems
- Inclusion of patient voice
- Health plan voice
- Iteratively adding members in first couple meetings when we learn about gaps in expertise
Workgroup Members

- **Chair:** Jeanne Rupert, DO, PhD, Bree Member
- Pat Kulpa MD, MBA, Medical Director, Regence BlueShield
- Sharon Kwan, MD, MS, Interventional Radiologist, University of Washington Medical Center
- John Lenihan, MD, Medical Director of Robotics and Minimally Invasive Surgery, MultiCare Health System
- Jennie Mao, MD, Clinical Assistant Professor, Department of Obstetrics and Gynecology, University of Washington
- Rachelle McCarty, ND, MPH, Patient Advocate
- Sarah Prager, MD, Chair, Washington State Section of ACOG (through the WSMA)
- Kevin Pieper, MD, Chief, Women's and Children’s, Providence Regional Medical Center Everett
- Kristin Riley, MD, FACOG, Assistant Professor, Department of Obstetrics and Gynecology, University of Washington
- Anita Showalter, DO, FACOOG, Associate Professor and Chair, Women's Health, Pacific Northwest University of Health Sciences
- Susan Warwick, MD, Obstetrics and Gynecology, Kaiser Permanente
Developing the Guidelines

- Need to develop focus areas around which to build recommendations
  - Clear, based in evidence
- Need to have inclusions and exclusions clearly defined
- Guideline has to be attractive to clinicians (make life easier), payers (add value), and patients (add value, aligned with their goals/values)
- Collaboration always means compromise
  - Will not be innovative enough for some, will go too far for others
Shared decision making integrated into most Bree Collaborative recommendations – including Hysterectomy

“Shared decision making is a process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient’s values and preferences.

Patient decision aids are tools that can help people engage in shared health decisions with their health care provider. Research shows that use of patient decision aids leads to increased knowledge, more accurate risk perception, and fewer patients remaining passive or undecided about their care. For example, a patient decision aid could help a pregnant woman who previously had a cesarean section to determine if she is a good candidate for a vaginal birth after cesarean.”

Source: [www.hca.wa.gov/about-hca/healthier-washington/shared-decision-making](http://www.hca.wa.gov/about-hca/healthier-washington/shared-decision-making)
“Washington State law recognizes that certification plays a significant role in assuring the quality of decision aids used by consumers, providers and payers.

With support from the Gordon and Betty Moore Foundation, we worked with state and national stakeholders to develop a process to certify high quality patient decision aids for use by providers and their patients in Washington State. Washington State’s leadership in creating the decision aid certification process provides a model that other states can adopt.

HCA began accepting patient decision aids for certification in April 2016.”

HCA Certification and Bree Recommendations – Current State

- **Obstetrics**: HCA has certified DAs for certain areas of obstetrics – amniocentesis, down syndrome screening, birth options for big baby, birth options after c-section, prenatal genetic testing.

- **Surgical Bundles**: HCA has certified DAs for hip osteo, knee osteo, spinal stenosis

- **End of Life/Advanced Illness**: HCA has certified (many) DAs for end of life care: CPR, CPR (specific conditions), dialysis over 75, advanced cancer, advanced disease, advanced heart failure, lung, family meetings in ICU, SNF, hospice advanced cancer, extremely premature infants, dementia, breathing aids, tube feeding, lung cancer

- **Cardiac care**: HCA received eight submissions

- Next steps are aligned with Bree Collaborative topic areas
Three Focus Areas for Hysterectomy

- Assessment and medical management, by indication
- Uterine sparing procedures, by indication
- Surgical procedure including follow-up care, emphasizing the enhanced recovery after surgery protocol and use of a minimally invasive approach
Inclusions and Exclusions

The recommendations apply to the following conditions (i.e., inclusions):

- Uterine leiomyoma (Fibroids)
- Abnormal menstrual bleeding
- Endometriosis
- Uterine prolapse
- Adenomyosis
- Pain

The recommendations do not address the following clinical scenarios (i.e., exclusions):

- Pregnancy
- Cancer and cancer prevention
- Emergency situations (e.g., due to trauma, childbirth)
- Gender reassignment surgery
- Incidental hysterectomy with indicated oophorectomy
Assessment and Medical Management

- Full gynecologic workup
  - Lack of viable pregnancy, fertility discussion, documentation of symptoms, comorbidities, assessments by indication
- Patient engagement
  - Shared decision-making, including goals of care, risks and benefits of medical management and indications for uterine-sparing procedures.
- Trial of medical management unless symptoms are severe. Checklist by indication.
- Document use of medical management, severe symptoms, or patient preference and selection, to move forward with uterine-sparing procedures.
<table>
<thead>
<tr>
<th>Indication</th>
<th>Assessment</th>
<th>Medical Management</th>
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| Uterine Leiomyoma (Fibroids) | Patients will present with variable clinical manifestations as symptoms associated with fibroid(s) relate to location, size, and number  
• Confirmation of absence of an active infection  
• Confirmation of diagnosis through cross-sectional imaging (preferably ultrasound) | Treatment will be based on size, number, and location    
• Trial of nonsteroidal anti-inflammatory drug (NSAID), if not contraindicated  
• Trial of hormonal management, if not contraindicated  
• Gonadotropin-releasing hormone (GnRH) agonist, unless contraindicated. More than six months without hormonal add-back therapy is not recommended.  
• Other hormonal modulators |

[ACR Appropriateness Criteria® radiologic management of uterine leiomyomas.](https://acsearch.acr.org/docs/69508/Narrative)  
1. Discuss uterine sparing procedures with the patient. Use checklist by indication as defined in Table 2.

2. Document use of uterine sparing procedures, severe symptoms, or patient preference and selection to move forward with hysterectomy. Discuss the hysterectomy approach with the patient including which route will maximize benefits and minimize risks based on the patient’s individual clinical situation.
<table>
<thead>
<tr>
<th>Indication</th>
<th>Uterine Sparing Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterine Prolapse</td>
<td>• Repair of cystocele, rectocele/enterocele&lt;br&gt;• Colpocleisis</td>
</tr>
<tr>
<td>Adenomyosis</td>
<td>• Endometrial ablation&lt;br&gt;• Laparoscopic/open adenomyomectomy</td>
</tr>
<tr>
<td>Pelvic Pain</td>
<td>Refer to earlier section</td>
</tr>
</tbody>
</table>
Enhanced recovery after surgery (ERAS) protocol, minimally invasive approach

Laparoscopic or robotic surgical approaches are recommended over abdominal routes when a vaginal approach is not appropriate.

Providers could consider referrals to providers and/or hospitals or health systems that can perform a minimally-invasive approach if not available in their facility.
Surgical Procedure: Key Considerations

1. Prior to surgery
   Minimize preoperative fasting, avoid bowel preparation, preemptive analgesia, prophylactic antibiotics. Administer appropriate peri-operative course of antibiotics, use appropriate skin prep by patient prior to surgery.

2. Limit use of nasogastric tubes and drains

3. Minimize risk of deep venous thrombosis and embolism

4. Optimize pain management and anesthesia pre- and post-operatively

5. Use a minimally invasive approach, if not contraindicated, using a decision pathway as similar to that in Schmidt et al 2017 for benign disease.

6. Consider need to reduce the risk of post-hysterectomy prolapse.

7. Removal of urinary catheters within six hours of surgery.

8. Enhance gastrointestinal motility with early nutrition.


10. Discharge planning including patient education and care plan.
Procedure Choice: Schmidt et al 2017

- If uterus is accessible transvaginally
  - Yes
    - Uterus <280 grams (<12 weeks gestation)
      - Yes – **Vaginal hysterectomy**
      - No – Uterine size <18 weeks gestation
        - Yes – **Laparoscopic or robotic hysterectomy**
        - No – **Abdominal hysterectomy**
  - No
    - Uterine size <18 weeks gestation
      - Yes – **Laparoscopic or robotic hysterectomy**
      - No – **Abdominal hysterectomy**
Additional Stakeholder Actions and Quality Improvement Strategies

• Patients
  • “Talk with your provider and care team about assessment, medical management, and uterine sparing procedures as outlined in tables 1 and 2”
  • Additional resources (November 2017) Choosing Wisely from American Association of Gynecologic Laparoscopists

• Health Plans
  • Develop prior authorization protocol for hysterectomy in-line with this guideline including documentation of discussion of medical management and uterine sparing procedures to reduce administrative burden on providers.

• Employers
  • Support employees in following clinical recommendations to avoid complications.

• Washington State Health Care Authority
  • Certify patient decision aids for hysterectomy.
Outcomes Measures
From ACOG 2017 Hysterectomy Bundle

- Emergency room visits, inpatient admissions, and outpatient hospital visits for conditions related to the hysterectomy within 45 days of the procedure including:
  - Disruption of the wound
  - Gastrointestinal (GI) complaints and complications (nausea, vomiting, bowel obstruction, etc.)
  - Hemorrhage
  - Infection
  - UTI
  - Pain
  - Post-procedural circulatory complications (including PE/DVT)
  - Post-procedural respiratory complications (pneumonia, etc.)
  - Nerve injury
  - Urine retention

- **Proxy for trial of conservative therapy:** Use of non-procedural therapy for patients under age 55 with abnormal uterine bleeding (ABU) and fibroids in the year prior to the hysterectomy.

- Oophorectomy in women under age 65 without a family history of relevant cancer Patient-reported outcomes
  - Pain
  - Regret
  - Fatigue
  - Sexual function, and
  - Satisfaction

Source: American Congress of Obstetricians and Gynecologists. Benign Hysterectomy Episode and Quality Measures. [www.acog.org/About-ACOG/ACOG-Departments/Payment-Reform/APMs/BenignHyst](www.acog.org/About-ACOG/ACOG-Departments/Payment-Reform/APMs/BenignHyst)
Lessons Learned

• Value in the bottom-up approach to developing standards rather than those imposed from above
• Guideline development is easy compared to implementation
• The patient voice is paramount
• Balance between standardization and need for individualized medicine
• Primary care needs to be involved in the care pathway and in development of the recommendations