Topic Brief: Updating Treatments for Fecal Incontinence

Date: 10/26/2020
Nomination Number: 0929

Purpose: This document summarizes the information addressing a nomination submitted on July 17, 2020 through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: Since the publication of the Agency for Healthcare Research and Quality's (AHRQ) 2016 report on treatments for fecal incontinence (FI), new evidence surrounding various non-surgical treatment modalities has emerged.

Program Decision: The scope of this topic met all EHC Program selection criteria and was considered for a systematic review. However, it was not selected.

Key Findings

- We found a sufficient number of studies to justify a new systematic review.

Background

Fecal incontinence (FI) is a condition that impacts approximately eight percent of adults in the United States, as reported in 2009.[1] The condition is characterized by recurrent involuntary loss of feces, which is further defined by the frequency of episodes (such as daily or weekly episode counts) and the consistency of the feces (solid, liquid, or mucus).[2] One relatively recent study found that the average annual cost of FI was $4,110 per-person annually in the United States, with costs rising in association with FI severity.[3] Fecal incontinence can greatly negatively impact quality of life, with effects including embarrassment, social isolation, and loss of employment.[1]

A 2016 report from the Agency for Healthcare Research and Quality (AHRQ) found limited evidence to support any FI treatments beyond 3 to 6 months.[4] The report noted that the strength of evidence for most treatments for FI in adults was either low or insufficient, "suggesting that future studies of higher quality that better comply with standards for study conduct might change the report's conclusions." Additionally, the need for careful descriptions of patients in clinical studies, evidence of treatment combinations, and uniform use of definitions of FI, among other things, would help fill in gaps in the evidence base.[2] Since the publication of AHRQ's report, a number of newly approved treatments for FI have become available, such as advancements in anal inserts, vaginal bowel control systems, stem cell therapy, anal slings, nerve stimulation, and sphincter augmentation.[5]

Nomination Summary

- The American Urogynecologic Society (AUGS) requested that the 2016 AHRQ report on treatments for FI[4] be updated to reflect recent treatment modalities and publications. The nominators intend to use an updated AHRQ report to educate physicians, patients, and third-party payers regarding the evidence for FI treatment.
- AHRQ received a total of 14 nominations about fecal incontinence, all focused specifically on the evidence for treatment with Non-Animal Stabilized Hyaluronic Acid (NASHA) or Solesta.

Scope

1. What is the comparative effectiveness of treatments to improve quality of life and continence and lessen the severity of fecal incontinence in affected adults?
    a. What adverse effects are associated with specific treatments for adults with fecal incontinence?

- Contextual question: How is fecal incontinence defined?

Table 1. Questions and PICOTS (population, intervention, comparator, outcome, timing and setting)

Questions	1. Comparative effectiveness and harms of treatments for fecal incontinence
Population	Adult outpatients with patient- or investigator-reported FI that occurs at least monthly Evaluate women and men separately
Interventions	FDA-approved treatments for FI, including medications used off-label and available for use in the US Separate by surgical, nerve stimulation, other treatments (e.g., physical therapy, medication, intravaginal device), and combination treatments
Comparators	All other treatment options, alone or in combination. Placebo or sham controls.
Outcomes	Benefits: *Severity and impact*: changes from baseline (e.g., FI frequency/consistency, CCFIS, FISI, Vaizey score, Pescatori score, SMFIS, fecal urgency, change in FI coping behaviors, emotional and psychological outcomes, social activity, and sexual function), 50% reduction in FI episodes *Quality of life* (e.g., FIQL scale) *Health status* (e.g., SF-36) *Other*: satisfaction with treatment, effectiveness of treatment, improvement Harms: Pain, FI frequency/severity, GI symptoms (e.g., cramping, bloating, difficulty evacuating bowels, constipation), surgical complications (e.g., infection, need for revision surgery or other surgery), emotional/psychological effects, other (e.g., local dermatitis, skin breakdown, urinary tract infection, headache, nausea)
Timing	Follow-up: Minimum of 6 weeks for non-surgical/invasive interventions, three-month minimum for surgical/invasive interventions.
Setting	Outpatient (community-dwelling)

Abbreviations: CCFIS = Cleveland clinical fecal incontinence score; FDA = food and drug administration; FI = fecal incontinence; FISI = fecal incontinence severity index; FIQL = fecal incontinence quality of life scale; GI = gastrointestinal; SF-36 = short form survey, 36-item; SMFIS = St. Mark's fecal incontinence score; US = United States.

Assessment Methods

See Appendix A.

Summary of Literature Findings

We found a significant number of studies addressing the comparative effectiveness and harms of treatments for fecal incontinence. Treatments involving nerve stimulation, surgical interventions, and other interventions (e.g., physical therapy, medication, intravaginal device) were found.

The contextual question addressing the definition of fecal incontinence will be addressed in the course of further scoping if a new systematic review is funded.

Table 2. Literature Identified for Each KQ

Question	Systematic reviews (10/2017-10/2020)	Primary studies (10/2015-10/2020)
Question 1: Comparative effectiveness and harms of treatments for fecal incontinence	Total: 0	Total: 59 (from a sample of 200) • RCT: 20 • Pre-post: 28 • Clinicaltrials.gov: 11

Abbreviations: KQ = key question; RCT = randomized controlled trial.

See Appendix B for detailed assessments of all EPC selection criteria.

Summary of Selection Criteria Assessment

We found sufficient literature for a new systematic review on treatments for fecal incontinence that would serve as an update to the 2016 AHRQ systematic review on treatments for fecal incontinence. This new systematic review would also include a review of evidence to inform a definition of fecal incontinence. The nominator intends to use this review to inform a new guideline on fecal incontinence in women.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

References

1. Whitehead WE, Borrud L, Goode PS, et al. Fecal incontinence in US adults: epidemiology and risk factors. Gastroenterology. 2009;137(2):512-7. e2. doi: https://dx.doi.org/10.1053/j.gastro.2009.04.054 PMID: 19410574.

2. Achanta G, Domino F, Fordis M. Treatments for Fecal Incontinence: Current State of the Evidence. EHC Clinician Summary. 2016. https://effectivehealthcare.ahrq.gov/products/fecal-incontinence/clinician.

3. Xu X, Menees SB, Zochowski MK, et al. Economic cost of fecal incontinence. Dis Colon Rectum. 2012;55(5):586-98. doi: https://dx.doi.org/10.1097/DCR.0b013e31823dfd6d. PMID: 22513438.

4. Forte ML, Andrade KE, Butler M, et al. Treatments for Fecal Incontinence. Agency for Healthcare Research and Quality. 2016;Comparative Effectiveness Review No. 165. https://effectivehealthcare.ahrq.gov/products/fecal-incontinence/research/. PMID: 27099893.

5. Da Silva G, Sirany A. Recent advances in managing fecal incontinence. F1000Res. 2019;8. doi: https://dx.doi.org/10.12688/f1000research.15270.2 PMID: 31448087.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years October 23, 2017 – October 23, 2020 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
  - AHRQ Evidence Reports https://www.ahrq.gov/research/findings/evidence-based-reports/index.html
  - EHC Program https://effectivehealthcare.ahrq.gov/
  - US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/
  - AHRQ Technology Assessment Program https://www.ahrq.gov/research/findings/ta/index.html
- US Department of Veterans Affairs Products publications
  - Evidence Synthesis Program https://www.hsrd.research.va.gov/publications/esp/
  - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program https://www.healthquality.va.gov/
- Cochrane Systematic Reviews https://www.cochranelibrary.com/
- PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/
- PubMed https://www.ncbi.nlm.nih.gov/pubmed/

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a limited literature search in PubMed from the last five years October 23, 2017 - October 23, 2020. Because a large number of articles were identified, we reviewed a random sample of 200 titles and abstracts for each question for inclusion. We classified identified studies by question and study design, to assess the size and scope of a potential evidence review. We then calculated the projected total number of included studies based on the proportion of studies included from the random sample.

Search strategy

Ovid MEDLINE ALL 1946 to October 23, 2020

Date searched: October 26, 2020

1 *Fecal Incontinence/ (6531)

2 ((anal or fecal or faecal) adj incontinen*).ti,kf. (3672)

3 or/1-2 (7262)
4 exp *Therapeutics/ (2522988)
5 (biofeedback or device* or diet* or drug or drugs or exercis* or intervention* or manag* or medicat* or nonpharmac* or non-pharmac* or nonsurgical or non-surgical or ointment* or pharmac* or physiotherap* or stimulat* or surger* or surgical* or therap* or training or treat*).ti,kf. or (dt or su or th).fs. (8377021)
6 or/4-5 (9373045)
7 and/3,6 (4712)
8 limit 7 to "all adult (19 plus years)" (2486)
9 (Aged/ or "Aged, 80 and over"/ or Frail Elderly/ or Men/ or Middle Aged/ or Women/) not (Adolescent/ or exp Child/ or exp Infant/) (4106043)
10 ((adult* or aged or elder* or men or senior* or women) not (adolescen* or child* or infant*)).ti,kf. (810961)
11 or/8-10 (4586056)
12 and/7,11 (2550)
13 limit 12 to english language (2220)
14 (meta-analysis or systematic review).pt. or (metaanaly* or meta-analy* or ((evidence or systematic) adj3 (review or synthesis))).ti,kf. (269801)
15 12 and 14 (56)
16 limit 15 to yr="2017 -Current" (12)
17 (controlled clinical trial or randomized controlled trial).pt. or (blind or blinded or control or controlled or groups or placebo or random* or trial).ti,ab,kf. (5588906)
18 13 and 17 (762)
19 limit 18 to yr="2015 -Current" (187)
20 Case-Control Studies/ or Retrospective Studies/ or Cohort Studies/ or Follow-Up Studies/ or Longitudinal Studies/ or Prospective Studies/ or Controlled Before-After Studies/ or Cross-Sectional Studies/ or Historically Controlled Study/ or Interrupted Time Series Analysis/ (2529586)
21 Observational Study.pt. or (Case-Control or Retrospective or Cohort or Follow-Up or Longitudinal or Prospective or (before adj2 after) or Cross-Sectional or "Interrupted Time Series").ti,ab,kf. (2921928)
22 or/20-21 (3911236)
23 13 and 22 (1306)
24 limit 23 to yr="2015 -Current" (323)

Ovid EBM Reviews - Cochrane Central Register of Controlled Trials September 2020
Date searched: October 26, 2020
1 ((anal or fecal or faecal) adj incontinen*).ti. (584)
2 (biofeedback or device* or diet* or drug or drugs or exercis* or intervention* or manag* or medicat* or nonpharmac* or non-pharmac* or nonsurgical or non-surgical or ointment* or pharmac* or physiotherap* or stimulat* or surger* or surgical* or therap* or training or treat*).ti. (690067)
3 and/1-2 (402)
4 limit 3 to yr="2015 -Current" (119)

Ovid EBM Reviews - Cochrane Database of Systematic Reviews 2005 to October 22, 2020
Date searched: October 26, 2020
1 ((anal or fecal or faecal) adj incontinen*).ti. (15)
2 (biofeedback or device* or diet* or drug or drugs or exercis* or intervention* or manag* or medicat* or nonpharmac* or non-pharmac* or nonsurgical or non-surgical or ointment* or

pharmac* or physiotherap* or stimulat* or surger* or surgical* or therap* or training or treat*).ti. (5272)
3 and/1-2 (12)
4 limit 3 to last 3 years (2)

ClinicalTrials.gov
Date searched: October 26, 2020
(anal incontinence OR fecal incontinence OR faecal incontinence) AND (biofeedback OR device OR diet OR drug OR drugs OR exercise OR intervention OR managing OR management OR medication OR nonpharmacological OR non-pharmacological OR nonsurgical OR non-surgical OR ointment OR pharmacological OR pharmaceutical OR physiotherapy OR stimulation OR surgery OR surgical OR therapy OR training OR treating OR treatment) | Recruiting, Active, not recruiting, Completed, Enrolling by invitation Studies | Adult, Older Adult | First posted from 01/01/2017 to 10/26/2020 (154)

https://clinicaltrials.gov/ct2/results?cond=&term=%28+anal+incontinence+OR+fecal+incontinence+OR+faecal+incontinence+%29+AND+%28+biofeedback+OR+device+OR+diet+OR+drug+OR+drugs+OR+exercise+OR+intervention+OR+managing+OR+management+OR+medication+OR+nonpharmacological+OR+non-pharmacological+OR+nonsurgical+OR+non-surgical+OR+ointment+OR+pharmacological+OR+pharmaceutical+OR+physiotherapy+OR+stimulation+OR+surgery+OR+surgical+OR+therapy+OR+training+OR+treating+OR+treatment+%29&sfpd_s=01%2F01%2F2017&sfpd_e=10%2F26%2F2020&cntry=&state=&city=&dist=&Search=Search&show_xprt=Y&recrs=a&recrs=d&recrs=e&recrs=f&age=1&age=2

Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change; and if a partner organization would use this evidence review to influence practice.

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the US?	Yes.
1b. Is the nomination a request for an evidence report?	Yes.
1c. Is the focus on effectiveness or comparative effectiveness?	Yes.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	FI is a condition that is estimated to impact approximately 8% of adults in the US, as reported in 2009.[1]
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. FI is a condition that is estimated to impact approximately 8% of adults in the US, as reported in 2009.[1] One relatively recent study found that the average annual cost of FI was $4,110 per-person annually in the US, with costs rising in association with FI severity.[3]
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes.
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. One relatively recent study found that the average annual cost of FI was $4,110 per-person annually in the US, with costs rising in association with FI severity.[3] This condition can also result in the inability to work.[1]
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	Yes. We did not identify a recent systematic review.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Newer evidence is available about additional treatments that could be incorporated into guidance.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	There may be practice variation around the use of newer interventions.
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	We found 59 studies on the effectiveness and harms of treatments for FI in the sample of 200 studies reviewed. The estimated size of a new systematic review would likely be large.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes. We received 14 nominations about fecal incontinence treatments, from professional societies, clinicians and patients. This indicates a high-level of interest in this topic and particularly in the effectiveness of newer interventions.

6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes. The intent is to update the existing 2016 AHRQ systematic review on treatments for fecal incontinence. The new systematic review would serve to inform a guideline by AUGS.

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; AUGS = American urogynecologic society; FI = fecal incontinence; US = United States.