Effective Health Care Program

Future Research Needs Paper
Number 19

Future Research Needs for Noncyclic Chronic Pelvic Pain Therapies for Women

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Future Research Needs for Noncyclic Chronic Pelvic Pain Therapies for Women

Identification of Future Research Needs From Comparative Effectiveness Review No. 41

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The information in this report is intended to help health care researchers and funders of research make well-informed decisions in designing and funding research and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of scientific judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical research and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

An important part of evidence reports is to not only synthesize the evidence, but also to identify the gaps in evidence that limited the ability to answer the systematic review questions. AHRQ supports EPCs to work with various stakeholders to identify and prioritize the future research that is needed by decisionmakers. This information is provided for researchers and funders of research in these Future Research Needs papers. These papers are made available for public comment and use and may be revised.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The evidence reports undergo public comment prior to their release as a final report.

We welcome comments on this Future Research Needs document. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Future Research Needs for Noncyclic Chronic Pelvic Pain Therapies for Women

Structured Abstract

Objectives. The objective of this future research needs project is to identify high-priority research needs for noncyclic chronic pelvic pain in women. This report builds on the research needs and methodologic issues identified in the comparative evidence review published in January 2012.

Data Sources. We recruited stakeholders to participate in a teleconference to identify a comprehensive list of research questions and methodologic recommendations for future research on noncyclic chronic pelvic pain. Stakeholders completed two Web-based surveys to prioritize research questions and recommendations. The first survey used a 5-point Likert scale to rate the overall importance of the research needs identified from the comparative effectiveness review and the stakeholder conference call. Stakeholders were then asked to rank the highest-rated research using a 5-point scale across six prespecified criteria modified from the Effective Healthcare Program criteria. We also searched U.S. and international trial registries to identify currently funded and recently completed research on therapies to treat noncyclic chronic pelvic pain.

Results. Twelve stakeholders representing patient advocacy groups, academic research, obstetricians and gynecologists, the payor perspective, and national foundations agreed to participate. Stakeholder participation exceeded 50 percent throughout the project. In the first Web-based survey, stakeholders rated 63 research needs related to etiology, diagnosis, treatment and methodological issues. Using a cutoff of 4.3, survey results generated a listed 31 research questions to promote to the final prioritization survey. Seven stakeholders completed the prioritization survey to generate a list of high-priority research needs for noncyclic chronic pelvic pain. The top-tier research needs consisted of items with an overall score of at least 4.0 (n=6); the second-tier consisted of research needs with an overall score of 3.75–3.99 (n=9).

Conclusions. We used a multistep process to identify and prioritize research questions to address specific knowledge gaps related to therapies for noncyclic chronic pelvic pain. The highest priority research questions encompass numerous topics related to noncyclic chronic pelvic pain, reflecting the ubiquity of gaps in the relevant literature.

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Executive Summary

Background

In a recently published comparative effectiveness review (CER) of therapies for noncyclic chronic pelvic pain (CPP), several research gaps within the CPP evidence base were identified. The purpose of this report is to present recommendations for future research on CPP based on the findings from that review and input from stakeholders. We describe a preliminary but reproducible process that relied upon stakeholder engagement and feedback across prespecified criteria to transform identified research gaps into prioritized research needs.

CPP in women is a commonly occurring and poorly understood condition. Little consensus on the definition of the condition exists—the duration of pelvic pain considered chronic in published studies varies from 3 to more than 6 months, and the location and pathology of the pain are largely unspecified.[1] The American College of Obstetricians and Gynecologists defines chronic pelvic pain as "noncyclical pain of at least 6 months' duration that appears in locations such as the pelvis, anterior abdominal wall, lower back, or buttocks, and that is serious enough to cause disability or lead to medical care."[2] Noncyclic CPP excludes chronic pelvic pain that is limited to dysmenorrhea (pain with menstruation), or dyspareunia (pain with intercourse), dyschezia (pain with bowel movement), or dysuria (pain with urination).[3,4] Mixed CPP refers to the combination of noncyclic CPP and another pelvic pain that is cyclic or associated with intercourse, bowel movement, or urination. CPP as described throughout this report refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

Little is known about treating women with CPP and that care is highly variable. Hysterectomy is common treatment option for pelvic pain, but little evidence exists to guide treatment decisions. In 2011, the Vanderbilt Evidence-based Practice Center completed an Agency for Healthcare Research and Quality (AHRQ)-funded systematic review of therapies for women with noncyclic CPP.

Despite a prevalence for CPP rivaling that of widely studied conditions such as asthma,[5] little research assessing therapies exists. While there are many publications regarding pelvic pain, there are relatively few addressing noncyclic CPP, and of those, few provide high-quality evidence creating significant gaps in the research literature for treatment of women with noncyclic CPP.

Methods

Table A outlines the project's methods, which were modified from those used in prior future research needs projects.[6] Briefly, we used a multistep process to identify evidence gaps, beginning with a distillation of the research gaps as reported in the CER. We organized individual research needs using the following categories: standardized definitions and diagnostic criteria, etiology, iatrogenic pain, impact and resource utilization, and methodologic issues. We presented these along with a summary of relevant ongoing research to individuals who agreed to participate in the project as stakeholders.

Table A. Summary of steps for developing future research needs

	Approach to Evidence Gap Identification
1.	Generate preliminary list of research gaps based on findings of the CER.
2.	Form stakeholder workgroup with representatives from advocacy organizations, provider community, research community, and funding agencies.
3.	Locate ongoing trials and other funded research.
4.	Conduct conference call with stakeholders to refine initial list of evidence gaps.
	Approach to Prioritization and Stakeholder Engagement for Prioritization
5.	Invite stakeholders to rate perceived importance of individual research gaps.
6.	Cull list of research needs based on stakeholder voting.
7.	Invite stakeholders to prioritize research needs using modified EHC selection criteria.
	Approach to Research Question Development and Considerations for Potential Research Designs
8.	Determine potential study designs to address final list of research needs.
9.	Obtain stakeholder input on the draft research needs report.
10.	Finalize research needs report.

Abbreviations: CER=comparative effectiveness review; EHC=Effective Health Care Program

We sought representation from known experts and others active in the field of noncyclic CPP to provide input on the list of research needs and add additional questions as necessary. Stakeholders were identified from initial lists developed for potential Key Informants and Technical Expert Panel members for the CPP CER. This list was augmented by referrals from the investigative team to form a group broadly representative of research, clinical care, patients, and funders. Potential stakeholders were invited to participate by email. We obtained conflict of disclosures from each participant for review by the Task Order Officer prior to the first scheduled conference call.

We engaged stakeholders agreeing to participate in the project via an initial conference call to introduce the project and to add to the list of gaps identified from the report. This call was followed by an email message including the revised list of gaps and inviting stakeholders to edit or add questions as necessary.

We presented the expanded list of questions to stakeholders via a Web-based survey that asked stakeholders to rate each item using a 5-point Likert scale. We asked stakeholders to consider the overall importance of the question for noncyclic CPP research but did not proscribe specific criteria for prioritizing in the initial survey. We extracted the highest rated items for an additional ranking activity using prespecified criteria.

Using a second Web-based survey, we asked stakeholders to prioritize research needs across six prespecified criteria modified from the Effective Health Care program selection criteria7:

- Potential for new knowledge
- Potential for significant health impact
- Potential to reduce variation in clinical practices
- Potential for significant economic impact
- Potential risk from inaction.
- Potential to address inequities

Stakeholders ranked each question on each of the criteria using a 1 (low) to 5 (high) point scale. We tallied scores across each criterion to determine an overall score for each question and divided questions into top, middle, and lower tiers for both treatment- and methods-focused

needs according to overall scores. We provided considerations for each of the top-tier treatment-related needs and proposed a potential research design.

Results

Stakeholders

Stakeholders broadly represented clinical, research, and advocacy perspectives in CPP. The panel comprised a total of eleven stakeholders including clinical researchers with expertise in CPP, physical therapists, and a patient advocate.

Needs Identified in CER

From the CER, the project team organized a list of research gaps to present to the stakeholder group. These needs were initially organized by topic-based and methods-based research gaps. The project team further characterized the research needs into clinical and research related categories (Appendix C of the main report) which was distributed to the stakeholders along with a summary table of ongoing research (Appendix B of the main report).

Needs Identified From Stakeholder Input

Of 12 individuals who agreed to participate, 11 participated in one of two conference calls. Stakeholders were asked to comment on the list of research gaps from the CER and discuss research issues pertinent to the topic. The moderator (SR) encouraged call participants to propose research needs related to noncyclic CPP that were not captured by the CER-generated list. From these calls, we generated an expanded list of research needs that included 63 items, with 28 derived from the stakeholders and 35 derived from the CER (Appendix E of the main report).

Round One Prioritization

We presented the expanded list of research needs to stakeholders in an initial survey. (Appendix F of the main report) We asked stakeholders to rate the research needs according to perceived degree of importance using a 5-point Likert scale. Six of the 12 stakeholders completed the survey. The highest rated research needs (i.e., items scoring at least 4.3 points) needs) were identified from the initial rating survey results.

Round Two Prioritization

In the second survey we organized the highest rated research needs identified in the initial survey broadly by area of focus and presented them by category in no particular order. (Appendix G of the main report). We asked stakeholders to rank each of the 31 research needs across the following prespecified selection criteria[7] using a 1 (low) to 5 (high) point scale:

- Potential for new knowledge
- Potential for significant health impact
- Potential to reduce inappropriate variation in clinical practices
- Potential for significant economic impact
- Potential risk from inaction
- Potential to address inequities

Seven stakeholders completed the survey. Results were analyzed based on the responses received. We tallied the scores for each question on each criterion to determine an overall score. We considered those questions with an overall score of at least 4.0 (n=6) to comprise the top-tier of research needs (Table B).

Table B. Top-tier research needs[a]

Score	Research Need
4.31	Determine which patients are likely to benefit from surgery.
4.22	Develop standardized diagnostic criteria.
4.16	Identify risk associations and women at risk for developing noncyclic chronic pelvic pain.
4.15	Determine the overall role of surgery.
4.04	Conduct studies on the management of patients who have failed pharmacologic treatment.
4.03	Identify the most cost effective diagnostic and management strategies.

Notes: [a] Research needs with an average score of 4.0 or higher from second survey

Items with an overall score of 3.75–3.99 (n=9) comprise the second-tier of research needs (Table C). Of note, the scores were all very close, and no set of recommended studies should be considered low priority. The rating provides a relative measure; all of the research questions are important, but a subset comprises a priority set that should be addressed first.

Table C. Second-tier research needs[a]

Score	Research Need
3.98	Conduct studies on cognitive behavior therapy.
3.94	Standardize diagnostic evaluations including history and physical.
3.90	Standardize optimal surgical outcomes including followup interval (e.g., long-term outcomes).
3.86	Determine the accuracies of individual and combined diagnostic tests.
3.84	Conduct studies on patient education.
3.82	Determine patient dissatisfaction with care.
3.80	Document the treatment effect of diagnostic laparoscopy.
3.80	Conduct studies on provider education.
3.78	Assess the impact of noncyclic chronic pelvic pain on the use of health services.

Notes: [a] Research needs with an average score between 3.75–3.99 from second survey

Research Design Considerations

The investigative team independently developed suggestions and considerations for potential study designs relevant to each of the top-tier research needs (Table D). The top-tier research needs underscore the lack of findings reported in the initial CER while others, such as diagnosis or cost effectiveness, are more general and indirectly related to the CER, although still partially within the scope of the CER.

Table D. Top-tier research needs: PICOTS, study designs, considerations, and relationship to CER

Research Need Source	PICOTS Element(s)	Potential Study Designs and Considerations	Relationship to CER
Determine which patients are likely to benefit from surgery. CER	**P:** Women with noncyclic CPP **I:** Surgical **C:** Surgical or nonsurgical **O:** Symptom resolution; QOL **T:** >12 months **S:** Community and clinic	Diagnostic and treatment RCT with subpopulation analysis and/or strict inclusion criteria of a well-defined population • Comparison of treatment may be surgery A vs. surgery B or surgery vs. nonsurgical intervention or surgery vs. sham-surgery. • Standardizing surgical interventions can be problematic. Surgical care is a highly technical, complex process and requires the coordination of many individuals and systems.	Addressed specifically by KQ2 and KQ3 of the CER. Of seven studies addressing KQ2, one was assessed as good, one as fair, and five as poor quality. No studies addressing KQ3 were identified.
Develop standardized diagnostic criteria. CER	**P:** Women with pelvic pain **I:** Diagnostic test/criteria **C:**Diagnostic test/criteria **O:** Diagnostic accuracy **T:** N/A **S:** Clinic	Validation study of consensus-developed diagnostic criteria, in the light of systematic reviews (international, multisite, between-subjects design) • Requires an international effort. (Comparison process: Rome I, II, III criteria for diagnostic criteria for IBS and validation, diagnostic criteria for headache, complex regional pain syndrome, and psychiatric disorders). • Challenge precluding a RCT is that there is no gold standard diagnostic test.	Addressed indirectly by all KQs of the CER. Across all studies for therapeutic interventions there were large inconsistencies noted in the CER for diagnostic criteria. May benefit from a systematic review to assess status of existing, if any, diagnostic criteria for CPP.

Table D. Top-tier research needs: PICOTS, study designs, considerations, and relationship to CER (continued)

Research Need Source	PICOTS Element(s)	Potential Study Designs and Considerations	Relationship to CER
Identify risk associations and women at risk for developing noncyclic chronic pelvic pain. CER	**P:** Women with and without noncyclic CPP **I:** N/A **C:** N/A **O:** Noncyclic CPP diagnosis and diagnosis of an at-risk comorbid condition **T:** >12 months **S:** Community and clinic	Observational study: prospective cohort (longitudinal) or case-control study • Cohort study would need to be large and long term. Expensive because development of CPP 'rare': a solution would be to add to a larger prefunded cohort study. • Case-control studies can be very efficient; but only one outcome per study; threats to validity include recall bias, control selection, and response rates. • Other challenges include the difficulty imposed by confounding (mixing of effects) and risk factor interaction (synergy, antagonism).	Addressed partially by KQ1 of the CER. Additional systematic review may be needed to identify studies not included within the scope of CER.
Determine the overall role of surgery. Stakeholders	**P:** Women with noncyclic CPP **I:** Surgical **C:** Surgical or nonsurgical **O:** Symptom resolution; QOL **T:** >12 months **S:** Community and clinic	Prospective cohort • Common critiques are that observational research studies systematically overestimate treatment effect and are limited by unavoidable confounding and bias. To account for these potential limitations, investigators can use several statistical and methodological techniques, including regression, stratification, and patient matching. • Standardizing surgical interventions can be problematic. Surgical care is a highly technical, complex process and requires the coordination of many individuals and systems.	Addressed specifically by KQ2 of the CER. Of seven studies addressing KQ2, one was assessed as good, one as fair, and five as poor quality.
Conduct studies on the management of patients who have failed pharmacologic treatment. CER	**P:** Women with noncyclic CPP that have failed prior treatment **I:** Surgical or nonsurgical **C:** Surgical, nonsurgical, no treatment **O:** Symptom resolution; QOL **T:** >6 months **S:** Clinic	RCT (optimal design for therapy should be placebo-controlled, double-blind, parallel group, and randomized to treatment allocation) • Well-defined inclusion and exclusion criteria will be necessary, to define "failure" for every pharmacologic treatment. • Challenges include high placebo response rate, fluctuating symptoms, heterogeneous and complex mechanisms, avoiding bias, contamination by over-the-counter treatments or drugs for other conditions, avoiding harm, duration of the treatment intervention, frequency of treatment, and difficulty blinding the intervention	Addressed specifically by KQ5 of the CER; however, no studies addressing KQ5 were identified in the CER.

Table D. Top-tier research needs: PICOTS, study designs, considerations, and relationship to CER (continued)

Research Need Source	PICOTS Element(s)	Potential Study Designs and Considerations	Relationship to CER
Identify the most cost effective diagnostic and management strategies. CER	**P:** Women with noncyclic CPP **I:** Diagnostic test, surgical or nonsurgical therapy **C:** Diagnostic test, surgical or nonsurgical therapy **O:** Resource utilization outcomes **T:** >12 months **S:** Clinic	Decision analytic modeling comparison of two or more alternatives or designed within a clinical trial (RCT: running in parallel with the main study is a prospective economic analysis) • Not appropriate for placebo-controlled or sham-surgery as comparator, because the placebo arm limits generalizability to clinical practice.	Not addressed by KQs of the CER. Consider systematic reviews to identify studies focused on diagnosis of CPP.

Abbreviations: CER=comparative effectiveness review; CPP=chronic pelvic pain; IBS=irritable bowel syndrome; KQ=Key Question; N/A=not applicable; PICOTS=population, intervention, comparator, outcome, timing, setting; QOL=quality of life; RCT=randomized controlled trial.

Discussion

The findings of this future research need project suggest that the current status of scientific knowledge regarding treatment for noncyclic CPP is limited in both overall quality and quantity. During discussions with the stakeholders, concerns for lack of standardized definitions, diagnosis and outcome measures recurrently eclipsed specific objectives for specific treatment options as these deficiencies markedly limit the scientific field as a whole. Stakeholders prioritized future research needs identifying general uncertainties about CPP over more specifically defined topics, including specific treatment modalities and therapies. None of the identified needs were completely beyond the scope of the CER, however, some were only partially addressed in that project and additional systematic reviews may be warranted to fully assess the status of published studies concerning those specific needs and research gaps, as indicated in Table D.

One of the strengths of our process included the constituents of the stakeholder participants. CPP is a multifactorial condition treated and managed by a variety of provider types and specialties. Reflective of this variety in providers, we were able to recruit a diverse group of stakeholders for this project. We utilized an internet-based data management system, REDCap™ (Research Electronic Data Capture), to solicit Web-based survey responses from the stakeholders. REDCap allows for variable output formats, facilitating data analysis and synthesis. Our hope was that this would increase efficiency in soliciting stakeholder responses, allowing them to complete the surveys at times and locations convenient to them. REDCap also facilitated data consolidation and review of survey results.

Participation was acceptable during all phases of the project. Stakeholder participation exceeded 50 percent, although it did not reach 100 percent for any step; it is unknown whether other methods could have improved participation. Additional work is needed to further validate the use of this tool in this future research need process.

Methodology for conducting future research need projects is evolving; presently, there are few prescribed methods for research needs prioritization. We elected to follow the paradigm suggested in a draft AHRQ methods report, with some modifications dictated by the nature of the condition under study.

Presently, the state of clinical research for treatments of noncyclic CPP is incomplete and limited by knowledge gaps in fundamental understanding and characterization of the condition. The future research needs identified and prioritized by a diverse group of stakeholders through the process described in this report acknowledge these gaps and suggest that future research in CPP is needed and should be prioritized to address many of these fundamental concerns.

During these discussions with the stakeholders, concerns for lack of standardized definitions, diagnosis and outcome measures recurrently eclipsed specific objectives for specific treatment options as these deficiencies markedly limit the scientific field as a whole.

Conclusion

The authors of this report built upon the findings from a previous systematic review of therapies for noncyclic CPP to identify a comprehensive list of research gaps for ranking and prioritization. Specific research gaps reflected extensive needs for future research in the areas of diagnosis, standardization, etiology and treatment. Needs were predominately general in nature, reflecting a broad scope of uncertainties within the current state of the science. Specific deficiencies addressed the need for standardized approaches to diagnosis and outcome assessment, and methods to improve management of a poorly characterized condition.

Our multistep process for identifying, expanding, and prioritizing research needs to advance research in the area of noncyclic CPP resulted in a list of research topics to fill specific knowledge gaps. The highest priority research questions were general, reflecting the recognition of broad gaps in the evidence. These research needs include diagnostic criteria validation, identification of subpopulations, comorbid conditions and risk factors, and the role of surgery as a therapeutic intervention. All research studies would be enhanced by multiple site involvement. Although strict inclusion criteria would confer a group of subjects with a similar condition, the more strict the inclusion criteria, the less applicable the results will be for real-world clinical practice. For therapeutic interventions, the recognition of a significant placebo effect in chronic pain informs the recommendation for randomized controlled trials. For therapeutic intervention studies, study design should include a commitment to a choice of superiority, equivalence, or noninferiority design, and a sample size calculation that accounts for the range of possible effect size, placebo effect, and chance.

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Introduction

Systematic reviews are the standard for synthesizing current scientific knowledge on a particular clinical topic. Thorough and appropriately conducted reviews will often conclude with remarks on the research gaps and highlight areas of uncertainty discovered during analysis of the primary literature. Organized presentation of identified gaps may lead to more rapid generation of subsequent research and aptly direct resources to key future research needs.

The systematic comparative effectiveness review (CER) of noncyclic chronic pelvic pain (CPP) therapies for women was published on the Agency for Healthcare Research and Quality (AHRQ) Web site in January 2012.[1] The publication details the methods used to plan and execute the systematic review of clinically important questions on management of noncyclic CPP. The results include evidence-based conclusions about the comparative effectiveness of various surgical and nonsurgical therapies for noncyclic CPP, as well as harms of nonsurgical therapies for CPP. The report includes a preliminary discussion on potential future research based upon gaps in knowledge uncovered by the systematic review. The purpose of this report is to present recommendations for future research on CPP that builds upon the findings from the recent systematic review and input from stakeholders. We describe a preliminary but reproducible process that relied upon stakeholder engagement and feedback across prespecified criteria to transform identified research gaps into prioritized research needs.

Background

CPP in women is a commonly occurring and poorly understood condition. Little consensus on the definition of the condition exists—the duration of pelvic pain considered chronic in published studies varies from 3 months to more than 6 months, and the location and pathology of the pain are largely unspecified.[2] The American College of Obstetricians and Gynecologists defines chronic pelvic pain as "noncyclical pain of at least 6 months' duration that appears in locations such as the pelvis, anterior abdominal wall, lower back, or buttocks, and that is serious enough to cause disability or lead to medical care."[3] Mixed CPP refers to the combination of noncyclic CPP and another pelvic pain that is cyclic or associated with intercourse, bowel movement, or urination. Noncyclic CPP excludes chronic pelvic pain that is limited to dysmenorrhea (pain with menstruation), or dyspareunia (pain with intercourse), dyschezia (pain with bowel movement), or dysuria (pain with urination).[4, 5] Noncyclic CPP is sometimes described simply as "chronic pelvic pain" in the literature because many subdivide the pain syndromes into dysmenorrhea, dyspareunia, and nonmenstrual CPP.[3] CPP as described throughout this report refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

The causes of CPP are not well understood and may be associated with gynecologic (e.g., endometriosis) and non-gynecologic (e.g., irritable bowel syndrome) conditions. Diagnosis of an underlying cause is complicated because the pain is rarely associated with a single underlying disorder or contributing factor.[6] Frequently diagnosed etiologies include endometriosis, adhesions, irritable bowel syndrome, and interstitial cystitis/painful bladder syndrome;[7] however, a definitive diagnosis is often not made.

Noncyclic CPP Therapies Systematic Review

In 2011, the Vanderbilt Evidence-based Practice Center completed an AHRQ-funded systematic review of therapies for women with noncyclic CPP. The review nomination,

submitted by a health plan medical director, noted that little is known about treating women with CPP and that care is highly variable. Hysterectomy is common treatment option for pelvic pain, but little evidence exists to guide treatment decisions.

The review of therapies for women with CPP was published on the AHRQ Effective Health Care Web site in January 2012. The report focused on the following Key Questions related to therapy:

Key Question 1. Among women who have been diagnosed with noncyclic/mixed cyclic and noncyclic CPP, what is the prevalence of the following comorbidities: dysmenorrhea, major depressive disorder, anxiety disorder, temporomandibular joint pain disorder, fibromyalgia, irritable bowel syndrome, interstitial cystitis/painful bladder syndrome, complex regional pain syndrome, vulvodynia, functional abdominal pain syndrome, low back pain, headache, and sexual dysfunction?

Key Question 2. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of surgical interventions on pain status, functional status, satisfaction with care, and quality of life?

Key Question 3. What is the evidence that surgical outcomes differ if the etiology of noncyclic/mixed cyclic and noncyclic CPP is identified after surgery?

Key Question 4. Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of nonsurgical interventions on pain status, functional status, satisfaction with care, quality of life, and harms?

Key Question 5. What is the evidence for choosing one intervention over another to treat persistent or recurrent noncyclic/mixed cyclic and noncyclic CPP after an initial intervention fails to achieve target outcome(s)?

Key Findings of the Evidence Report

The literature addressing therapies for CPP in women is of largely poor quality and inconclusive. While half of the literature comprised randomized controlled trials (RCTs), only two were good quality[8,9] and three were fair.[10-12] Studies providing cross-sectional data about the prevalence of comorbidities varied in quality but were largely poor. Nonetheless, some conclusions can be drawn.

Among studies reporting data on the prevalence of comorbidities, prevalence estimates tended to be more clustered in those studies that employed validated diagnostic criteria (e.g., Rome criteria for irritable bowel syndrome), and studies using validated criteria were of higher quality. Studies of nonsurgical approaches addressed hormonal management of endometriosis-related CPP and were not placebo controlled, thus limiting our ability to understand whether hormonal therapies would be beneficial for women with CPP without endometriosis and whether pain relief reported is due simply to the placebo effect. Some studies reported benefits of other nonsurgical approaches, but non-hormonal and non-pharmacologic management remain understudied.

Across the literature, higher quality intervention studies tended to demonstrate a lack of benefit: lysis of adhesions showed no benefit,[9] a selective estrogen receptor modulator had a

negative effect on pain.[8,13] Some studies suggest benefit of some approaches including depot leuprolide for endometriosis-associated CPP.[12]

Aside from the lack of benefit reported for adhesiolysis,[9] little evidence demonstrates the effectiveness of surgical approaches. Studies reported no differences in improvements in pain scores between groups in studies comparing surgical interventions with diagnostic laparoscopy alone or active surgical interventions. Studies comparing hysterectomy and nonsurgical management[14,15] reported similar improvements in pain scores between groups and greater patient satisfaction among women undergoing hysterectomy in a sample of women electing hysterectomy.[15] Despite numerous surgical techniques used extensively in treating CPP, few studies included more than 50 participants, and few were considered high quality (two good-quality studies, three fair-quality studies, and 16 poor-quality studies). All of the studies with comparison data failed to demonstrate that surgery in general or any specific surgical technique was more efficacious than either nonsurgical intervention or the comparator technique in improving pain status in patients. No surgical technique was superior, and the evidence to conclude that surgical intervention is either effective or ineffective for the treatment of CPP is insufficient.

Indeed, the strength of evidence for effectiveness across interventions ranges from insufficient to low with few studies comparing the same intervention and variable patient populations. The literature lacks placebo-controlled studies, studies of non-hormonal interventions, studies of non-pharmacologic interventions, and studies comparing medical and surgical management. Studies establishing the benefit of surgery as a treatment option for CPP are also lacking.

Despite a prevalence for CPP rivaling that of widely studied conditions such as asthma,[16] little research assessing therapies exists. While there are many publications regarding pelvic pain, there are relatively few addressing noncyclic CPP, and of those, we evaluated few as providing high-quality evidence. In sum, the literature overall is muddled by a lack of standardized definitions for CPP and unclear diagnostic evaluation that make it difficult to determine whether studies truly include women with CPP. Similarly, understanding comorbidity prevalence with CPP is difficult as conditions may be considered part of the differential diagnosis or a concomitant condition.

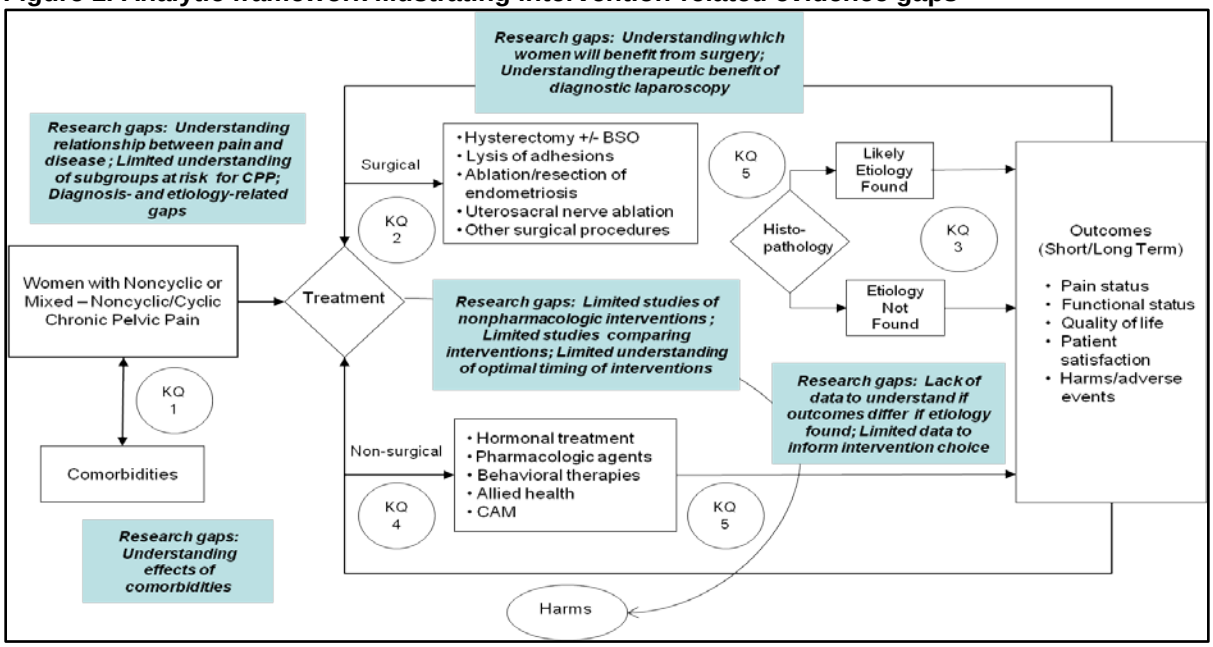
Improved characterization of the targeted condition, intervention, and population in CPP research is necessary to inform treatment choices for this commonly reported entity. A uniform definition of CPP and standardized evaluation of participants are lacking across the literature; study populations vary, and studies may be reporting effects from treating symptoms rather than a diagnosed condition. Thus our understanding of potential treatment effects is diluted.

Gaps in Areas of Research

The CER identified significant gaps in the research literature addressing women with CPP. Specifically, the review found that research addressing therapies for CPP is largely composed of trials of active agents or approaches with little placebo-controlled research and little evidence of thorough identification of patient characteristics and potential etiologies for CPP. Notably, the review did not identify any studies providing evidence that surgical outcomes differ if the etiology of CPP is identified after surgery (Key Question 3). No studies providing evidence for choosing one intervention over another to treat persistent or recurrent CPP after an initial failed intervention (Key Question 5) were found. We added indications for these preliminary gaps to the analytic framework from the full report. The analytic framework illustrates the KQs,

population, interventions, comparators, outcomes, timeframes, and settings (PICOTS), and identified research gaps below in Figure 1.

Figure 1. Analytic framework illustrating intervention-related evidence gaps



Abbreviations: CAM=complementary and alternative medicine; KQ=Key Question; BSO=bilateral salpingo-oophorectomy

The following sections summarize the gaps in the literature and future research needs described in the CER related to standardized definitions and diagnostic criteria, etiology, iatrogenic pain, impact and resource utilization, followed by a description of methodologic issues relevant to noncyclic CPP.

Standardized Definitions and Diagnostic Criteria

As noted in this review and previous studies,[2] definitions of CPP vary across the literature and may conflate noncyclic and cyclic pain. Employing standardized definitions of CPP is a critical need in future research to establish the condition under study and the effects of specific therapies. The lack of a standardized conception of CPP likely leads to a dilution of treatment effects that may be present, and clarifying our understanding of patient populations can help to bring treatment outcomes into focus. Similarly, few studies reporting comorbidity data used validated tools to diagnose comorbidities, and many relied on patient self-report. Future research needs related to defining and diagnosing CPP and comorbid conditions include:

- Widespread use of accepted definitions of CPP across studies
- Standard use of validated tools in studies to inform our understanding of the true prevalence of conditions reported to co-occur with CPP
- Larger, prospective studies examining the extent to which comorbidities modify treatment approaches and outcomes in CPP

Diagnostic Approaches

Standardized, thorough diagnostic approaches are an important area for future study as the literature lacks clear delineation of patient populations. Moreover, standardized evaluations can be help to ensure that clinicians are treating the actual cause(s) of CPP versus pain symptoms.

The International Pelvic Pain Society has published a clinical assessment document that could be utilized to standardize the initial evaluation of potential participants.[17] Research needs in this area include:

- Estimation of the accuracy of individual and combinations of diagnostic tests for CPP
- Role of magnetic resonance imaging and positron emission tomography scan in narrowing the differential diagnosis of CPP
- Development and validation of pain assessment tools to capture the multidimensional experience of pelvic pain

Etiology

The causes of CPP are not well understood and may be associated with gynecologic (e.g. endometriosis) and non-gynecologic (e.g., irritable bowel syndrome) conditions. Diagnosis of an underlying cause is complicated because the pain is rarely associated with a single underlying disorder or contributing factor. Based on the findings of the CER, future research needs related to etiology of CPP include:

- Analyses of distribution of the underlying causes of CPP
- Identification of subgroups at risk of developing CPP
- Investigations of pelvic floor myofascial dysfunction in CPP
- Effects of sex steroid hormone levels on pain perception

Iatrogenic Pain

Iatrogenic pain (pain resulting from a procedure or complication of a procedure performed by a clinician) is another understudied etiologic factor for CPP. Emerging causes of iatrogenic pain include use of permanent mesh (post-mesh pain syndrome), tubal ligation/occlusion (post-tubal syndrome), and endometrial ablation (post-ablative pain syndrome). The CER identified the following future research needs related to iatrogenic causes of CPP:

- Benefits and harms of interventions to treat pelvic organ prolapse and uterine bleeding
- Assessment of chronic postoperative incisional pain as a factor contributing to CPP
- Role of repeat surgeries in the same location as a source of pain
- Identification of the etiology of pain prior to hysterectomy

Standardized Outcome Measures

Studies included in the CER used numerous outcomes measures to assess pain, quality of life, and patient satisfaction. While typically used as a measure for pain, visual analog scales varied, making comparisons across studies difficult. Similarly, quality of life measures varied and patient satisfaction was typically reported using instruments not yet validated. The CER concluded that future research on CPP should include the standardized outcome measures such as those recommended by the IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) consensus conference.[18]

Nonsurgical and Nonpharmacologic Management

Studies meeting criteria for inclusion in the CER largely assessed surgical and pharmacologic management of CPP, despite research suggesting the need to consider psychological and sociodemographic factors in understanding and treating chronic pain.[19-23] Studies of nonsurgical or non-pharmacologic approaches were generally of poor quality but reported some benefit from

a pelvic physiotherapy technique,[24] ultrasonography plus counseling,[25] and an integrated treatment approach.[26]

The CER authors noted that a better understanding of allied health, integrative medicine, and behavioral approaches (e.g., acupuncture, transcutaneous electrical nerve stimulation, physiotherapy, cognitive behavioral therapy) to CPP is needed. Future research on nonsurgical and non-pharmacologic management of CPP should also include:

- Studies on advice and communication about pain, and education
- Studies of health care settings and consultation styles and their impact on CPP treatments
- High-quality assessments of multidimensional treatment

Pharmacologic Approaches

Much of the literature addressing pharmacologic interventions for CPP investigated hormonal therapies in women with endometriosis-associated CPP. Few studies included in the CER were placebo-controlled. The CER recommended that future research on pharmacologic therapy for CPP include placebo-controlled study designs and evaluate nonhormonal agents such as tanezumab.

Surgical Compared With Nonsurgical Approaches

The CER found that the current literature also lacks studies comparing surgical and nonsurgical approaches. Two poor-quality cohort studies comparing surgical and nonsurgical approaches reported similar effects on pain status between modalities[14, 15] and greater patient satisfaction with hysterectomy compared with nonsurgical management in one study.[15] High-quality comparative studies addressing common surgical and medical treatment approaches for CPP are needed.

Benefits of Surgical Treatment

The CER revealed that another important area for research lies in establishing whether surgical approaches are of benefit for CPP treatment, and if so, which approaches are superior. One study comparing laparoscopic uterine nerve ablation with diagnostic laparoscopy alone (sham laparoscopic uterine nerve ablation) reported similar outcomes between approaches.[10, 27] One study reported no benefit of lysis of adhesions compared with laparoscopy alone,[9] and one comparing active approaches (laparoscopic uterine nerve ablation vs. utero-sacral ligament resection)[28] reported no differences in pain outcomes between groups. Future research should include large, well conducted studies to help determine surgical outcomes, patients likely to benefit from surgery, and optimal timing of intervention as well as research to classify the therapeutic benefit of diagnostic laparoscopy which is often used as a standard control arm in surgical studies.

Impact and Resource Utilization

CPP accounts for an estimated 1 in 10 outpatient gynecology visits, and an estimated $1.2 billion per year is spent on outpatient management of CPP in the United States (adjusted for inflation from $880 million in 1996).[29] To understand better how to manage CPP care, future research should seek to understand the impact of CPP on the use of health services and conduct economic analyses to determine the most cost-effective diagnosis and management strategies.

Methodologic Issues

In addition to identifying condition-specific gaps in the available evidence, the systematic review of the primary literature on therapy for CPP revealed methodologic limitations of the literature and other important considerations for future study designs.

The evidence report found that few of the 17 RCTs included in the review adhered to standard study design and reporting conventions. In particular, few trials adequately concealed treatment assignments from participants, investigators, and outcome assessors, and just under half of the RCTs (7/17) reported an intention-to-treat-analysis. The drop-out rate exceeded 10 percent in eight studies and more than 20 percent of participants were lost to followup in six out of 17 trials. Most trials (12/17) did report an a priori primary outcome of interest and sample size calculation. Ten adequately reported missing or incomplete outcome data. Among the three included cohort studies, none employed blinded outcome assessors, and one provided an a priori sample size calculation. The dropout rate exceeded 10 percent for all three studies.

The CER found that definitions of CPP and outcome measures varied across studies and few studies provided long-term followup data. Future studies should extend the followup period to assess the degree to which outcomes are durable, especially as many women with CPP fail to achieve adequate pain relief despite multiple interventions. RCTs in this literature also typically included fewer than 150 women with CPP, despite the high reported prevalence of CPP. Future research including larger sample sizes should yield greater confidence in treatment effects.

A thorough diagnostic investigation is necessary to effectively treat any chronic pain. For many conditions, this investigation typically follows a predetermined algorithm, but no such algorithm exists for CPP. The CER recommended that future studies outline and report the diagnostic process for participants. Pelvic pain researchers would improve the overall quality of literature if an established diagnostic algorithm was developed and put forward for use. A standardized assessment of potential study participants and standardized inclusion criteria would permit systematic analysis of data from multiple trials.

Only three trials included in the CER were placebo controlled; the bulk of nonsurgical studies compared active agents, and no surgical studies used a placebo. A major source of both false positive and false negative results in trials of treatment for pain is the placebo effect, which in analgesic trials is often substantial and may have a duration of weeks or months.[30]

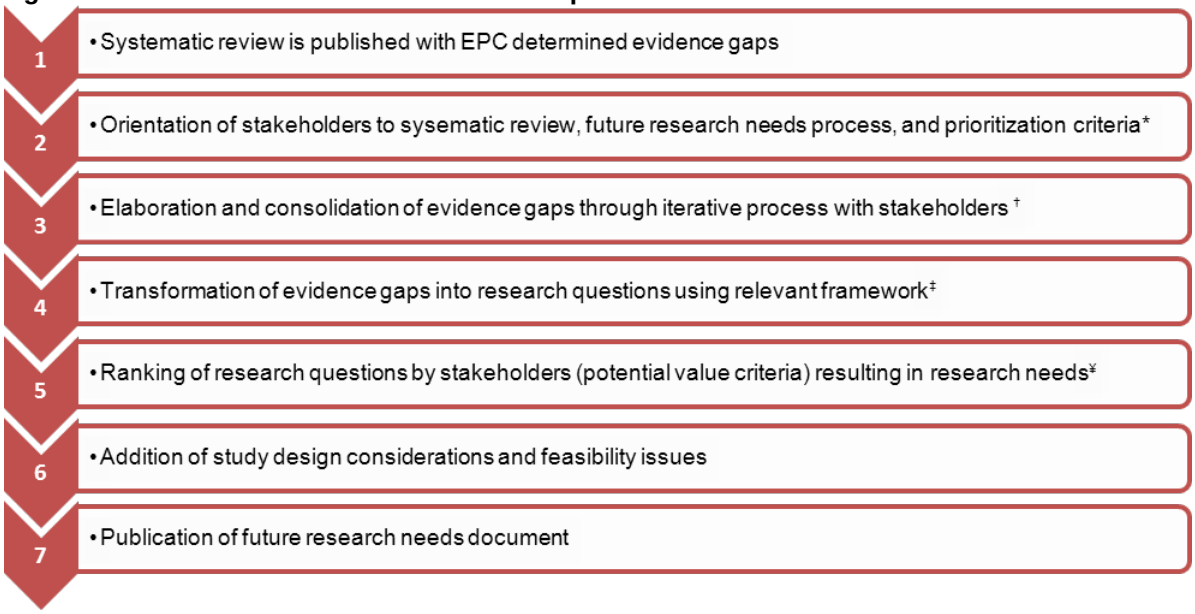
Placebo-controlled trials of any surgical interventions are exceedingly rare. A challenge in interpreting observation trials of surgery, or randomized trials of surgical versus nonsurgical therapy, is that patients could not reasonably be blinded to the intervention,[31] which may be responsible for some overestimation of surgical benefits for pain relief.[32] Based upon the very small number of placebo-controlled randomized trials, the magnitude of the placebo effect of surgery for pain is about 35 percent.[33] As recommended in the CER, future research of interventions for relief of CPP should be placebo-controlled with the exception of small pilot studies to evaluate the potential of a new intervention.

Scope and Objective

The small and methodologically flawed evidence base discussed in the CER is inadequate to inform treatment decisions for this commonly reported entity. We employed a systematic process to build on research needs identified in the CER and incorporate multiple stakeholder viewpoints. Our objective was to develop a categorization of future research needs related to surgical and nonsurgical interventions for women with CPP with sufficient detail for researchers and individuals or organizations financing a part or all of a project's cost to use for developing

into research proposals or solicitations, respectively. We describe a sequential process for prioritizing research gaps into future research needs (Figure 2). This process begins with identification of evidence gaps from the original systematic review, followed by prioritization of these evidence gaps by stakeholders using prioritization criteria. The top tier of prioritized evidence gaps is research needs. Research questions are developed from these research needs. This process yielded a set of prioritized research needs/research questions and potential study designs to address questions.

Figure 2. Flowchart of future research needs process



Notes: * May include identification of additional evidence gaps. † Reduction through topic consolidation, preliminary prioritization, and consideration of ongoing research (duplication criteria). ‡ Evidence gaps that address specific methods issues would not use PICOTS framework. ¥ May require iterative steps

Methods

In the Agency for Healthcare Research Quality (AHRQ) Future Research Needs Methods Report, Robinson et al.[34] define a research gap as a topic or area for which missing or inadequate information limits the ability of reviewers to reach a conclusion for a given question. This is distinguished from a research need, which they define as a gap that limits the ability of health care decisionmakers (e.g., patients, physicians, policymakers, etc.) from making decisions. The report further notes that a research gap may not be a research need if filling the gap would not be of use to stakeholders that make decisions in health care.[35] Table 1 outlines the methods we used to identify and prioritize research needs. We expand on the table's brief description in each of the following sections.

Table 1. Summary of steps for developing future research needs

	Approach to Evidence Gap Identification
1.	Generate preliminary list of research gaps based on findings of the CER
2.	Form stakeholder workgroup with representatives from advocacy organizations, provider community, research community, and funding agencies
3.	Locate ongoing trials and other funded research
4.	Conduct conference call with stakeholders to refine initial list of evidence gaps
	Approach to Prioritization and Stakeholder Engagement for Prioritization
5.	Invite stakeholders to rate perceived importance of individual research gaps
6.	Cull list of research needs based on stakeholder voting
7.	Invite stakeholders to prioritize research needs using modified EHC selection criteria
	Approach to Research Question Development and Considerations for Potential Research Designs
8.	Determine potential study designs to address final list of research needs
9.	Obtain stakeholder input on the draft research needs report
10.	Finalize research needs report

Abbreviations: CER=comparative effectiveness review; EHC=Effective Health Care Program

Identification of Evidence Gaps

We identified evidence gaps that limited conclusions about each Key Question from the discussion and future research sections of the comparative effectiveness review (CER). One investigator extracted research gaps from the review. A senior investigator then reviewed the list for accuracy and completeness and added gaps as appropriate.

Identification of Ongoing Research

To characterize the most recent evidence and current research, we updated the literature searches used in the CER and searched registries and other sources for ongoing research trials that have not yet published study results.[35] To identify currently funded or recently completed research studies examining treatment of chronic pelvic pain in women or prevalence of comorbidities in women with chronic pelvic pain (CPP) (Appendix B) we conducted searches of U.S. government resources (ClinicalTrials.gov, NIH Reporter), international trial registries (e.g. Current Controlled Trials), and other potential funding sources such as relevant associations and organizations (e.g. American Academy of Family Physicians, American Association of Birth Centers; America's Health Insurance Plans, International Pelvic Pain Society). Our searches were broad, employing the use of the keywords "chronic pelvic pain," scanning retrieved items

to identify relevant studies examining CPP treatment or comorbidity prevalence in women. We consulted the methods outlined in the future research needs methods series[35] to confirm that we searched the key sources of information for current research.

Engagement of Stakeholders, Researchers, and Funders

We sought to convene a group of stakeholders broadly representative of research, clinical care, patients, and funders to provide input on research gaps. We generated lists of potential stakeholders via a review of potential Technical Expert Panel members and Key Informants for the CER, review of investigators in studies included in the CER, review of advocacy and other agencies relevant to CPP, and through consultation with our Task Order Officer. We invited potential stakeholders by email, briefly describing the project purpose and scope and obtained voluntary consent forms from each individual agreeing to participate. To assess potential conflicts, we asked participants to review and complete the standard AHRQ conflict of interest disclosure form. We forwarded the completed forms to the Task Order Officer for review prior to the first scheduled conference call.

As the stakeholder group was largely comprised of individuals with many professional and academic roles, we anticipated that lack of time would contribute to a moderate level of attrition. To achieve the best possible participation rate, we used Web-based surveys, provided clear instructions, and indicated the expected time required to complete surveys. We used email reminders to improve participation in the second survey.

Initial stakeholder engagement began with orientation to the topic, goals, process, and expectations (Figure 1, bullet 2). We scheduled two 1-hour long conference calls and distributed a brief project overview, a link to the CER, and a list of research gaps identified from the CER via email. Each conference call was followed by electronic correspondence including the revised list of gaps and a second invitation for stakeholders to edit or add questions as necessary. To enhance public engagement, the draft report will be made available for public input for four weeks and stakeholders will be invited to provide comments on the final report.

Criteria for Prioritization

Round One Prioritization

We presented the expanded list of questions to stakeholders via a Web-based survey (Appendix F) that asked stakeholders to rank the importance of each question using a 5-point Likert scale. We a priori considered those questions receiving at least 4.3 points to comprise the highest-rated research needs for further prioritization.

Round Two Prioritization

We sent a second Web-based survey (Appendix G) to stakeholders asking them to rank the selected research needs using a prespecified criteria, modified from the Effective Health Care program selection criteria (Table 2) and described in AHRQ Effective Health Care methodologic guidance.[35] Stakeholders ranked each research need across the six criteria below using a 5-point Likert scale from 1 (low) to 5 (high). We tallied the number of points for each question across all criteria and present the top scoring questions overall in the Results section below. We a priori considered the research needs receiving a score of 4.0 or more as the highest priority. We selected a second grouping with a score of 3.75–3.99 as second-tier research needs.

Study data were collected and managed using REDCap™ (Research Electronic Data Capture), a secure, Web-based application hosted at Vanderbilt University.[36]

Table 2. Prespecified criteria for prioritization of top-rated research needs

Potential value criteria (for significant health impact): addressing evidence gap (knowledge, translation, implementation)
Potential for new knowledge (Research would not be redundant: Strength of evidence is not high for specific outcome (confidence in the estimate of effect is moderate or low); Question not sufficiently researched, including completed and in-process research; Utility of available evidence limited by changes in practice, e.g., disease detection or evolution in technology); more evidence needed about values and preferences influencing balance of benefits and harms/risks.
Potential for significant health impact on the current and projected health status of people with respect to burden of the disease and health outcomes: mortality, morbidity, and quality of life.
Potential to reduce important inappropriate (or unexplained) variation in clinical practices known to relate to quality of care. Potential to resolve controversy or dilemmas in what constitutes appropriate health care. Potential to improve decision-making for patient or provider, by decreasing uncertainty.
Potential for significant economic impact related to the use of health service resources. Many healthcare resource use factors may be expressed as cost. Potential to reduce unnecessary or excessive costs; to reduce high costs due to high volume use; to reduce high costs due to high unit cost or aggregate cost. Costs may impact consumers, patients, care-givers, employers, health care systems, or payers.
Potential risk from inaction: Unintended harms from lack of prioritization of proposed research; opportunity cost of inaction; potential to allow assessment of ethical, legal, social issues pertaining to the condition.
Addresses inequities, vulnerable, diverse populations (including issues for patient subgroups); potential to reduce health inequities; potential to allow assessment of ethical, legal, social issues pertaining to the condition.

Research Needs Development and Research Design Considerations

Key research questions for each evidence gap were generated through an online survey instrument and discussions by the stakeholder panel. The project team compiled a final list of research questions taking the feedback of the panel into consideration. The project team evaluated potential study designs to address each of the top-tier research needs. Consistent with AHRQ published guidance,[35] we describe key considerations and study design to address an evidence gap within the context of the following criteria:

- Appropriateness and ability of a given design to yield relevant, valid results
- Advantages and disadvantages of given designs relative to the area of research
- Resource use and ethical, legal, and social considerations
- Availability of relevant data
- Alignment with the system of care for CPP

The project team relied on this framework as a guide during discussions of the least biased study design that was likely to be feasible and affordable. Public comments received after the document is posted will be incorporated into the final report.

Results

Needs Identified in CER

From the comparative effectiveness review (CER), the project team organized a list of research gaps to present to the stakeholder group. These needs were initially organized by topic based and methods based research gaps. The project team further characterized the research needs topically and presented in an outline format (Appendix C) which was distributed to the stakeholders along with a summary table of ongoing research. (Appendix B)

Engagement of Stakeholders

Stakeholders broadly represented clinical, research, and advocacy perspectives in noncyclic chronic pelvic pain (CPP). Of the 12 individuals who agreed to participate as stakeholders, five served previously as a Key Informant or a Technical Expert Panel member for the CPP CER. After agreeing to participate, one stakeholder did not respond to scheduling requests for the initial conference call. The participating panel consisted of a total of eleven stakeholders including clinical researchers with expertise in CPP, physical therapists, and a patient advocate.

All stakeholders provided statements disclosing any conflict of interests. Three stakeholders documented participation as board members in professional societies dedicated to conditions of pelvic pain. There were no disclosures that were judged to be significant enough to preclude participation in the project.

Conference Calls

Eleven stakeholders participated in one of two conference calls. Stakeholders were asked to comment on the list of research gaps from the CER and discuss research issues pertinent to the topic. The moderator (SR) encouraged call participants to propose research needs related to noncyclic CPP that were not captured by the CER-generated list. Appendix D includes a summary of discussion from the initial stakeholder call. From these calls, we generated an expanded list of 63 research needs; 28 were derived from the stakeholders and 35 were derived from the CER (Appendix E).

Round One Prioritization

We presented the expanded list of research needs to stakeholders in an initial survey. (Appendix F) We organized questions broadly by area of focus and present them by category in no particular order. We asked stakeholders to rate the research needs according to perceived degree of importance using a 5-point Likert scale. Six of the 12 stakeholders completed the survey. Table 3 lists the highest rated items (i.e., research needs with an average score of at least 4.3) identified via the initial rating survey.

Table 3. Highest rated research needs[a]

Rank	Research Need
1.	Conduct studies on patient education.
2.	Clinician education on communication of laparoscopy results to patients.
3.	Determine which patients are likely to benefit from surgery.
4.	Develop standardized scales to assess quality of life for patients with noncyclic chronic pelvic pain.
5.	Develop standardized diagnostic criteria.
6.	Standardize diagnostic evaluations including history and physical.
7.	Collect and analyze data to inform health care utilization and cost relationship.
8.	Determine the accuracies of individual and combined diagnostic tests.
9.	Assess the impact of noncyclic chronic pelvic pain on the use of health services.
10.	Determine the role of musculoskeletal evaluations on resource use.
11.	Conduct studies on self-management.
12.	Standardize optimal surgical outcomes including followup interval (e.g., long-term outcomes).
13.	Determine the overall role of surgery.
14.	Determine optimal followup to assess outcomes following surgical interventions.
15.	Determine the role of idiopathic causes in the pathophysiology of noncyclic chronic pelvic pain.
16.	Identify risk associations and women at risk for developing noncyclic chronic pelvic pain.
17.	Document the treatment effect of diagnostic laparoscopy.
18.	Determine the direct and indirect costs that contribute to health care expenditures and economic impact.
19.	Conduct studies on physiotherapy.
20.	Conduct studies on cognitive behavior therapy.
21.	Conduct studies on provider education.
22.	Conduct studies on the management of patients who have failed pharmacologic treatment.
23.	Determine the optimal timing of surgical intervention.
24.	Determine the role of surgical or pathologic diagnosis on treatment outcomes.
25.	Characterize and document the distribution and prevalence of comorbidities and conditions associated with noncyclic chronic pelvic pain.
26.	Identify the most cost effective diagnostic and management strategies.
27.	Characterize chronic pelvic pain subtypes, including the significance of differentiation between cyclic and noncyclic.
28.	Characterize the distribution of symptom components (e.g., dyspareunia, dysmenorrhea, etc.) of noncyclic chronic pelvic pain.
29.	Characterize the role of the patient-provider relationship on surgical outcomes.
30.	Determine the role of condition-specific causes (e.g., endometriosis, pelvic adhesions, pelvic congestion, etc.) in the pathophysiology of noncyclic chronic pelvic pain.
31.	Determine patient dissatisfaction with care.

Notes: [a] Items with an average rating of 4.3 or higher

Round Two Prioritization

In the second survey we asked stakeholders to score each of the 31 high priority needs across the following selection criteria from the AHRQ Prioritization Criteria Method (PiCMe)[37] using a 1 (low) to 5 (high) point scale:

- Potential for new knowledge
- Potential for significant health impact
- Potential to reduce inappropriate variation in clinical practices
- Potential for significant economic impact

- Potential risk from inaction
- Potential to address inequities

We sent a link to the second survey approximately 2 weeks after the close of the first survey. The survey was open for one week, at which point five stakeholders had completed the survey. We sent an email reminder and extended the survey deadline by 3 business days. In total, seven stakeholders completed the second survey. Results were analyzed based on the responses received. We did not further query the nonresponders.

We tallied the scores for each question on each criterion to determine an overall score. We considered those questions with an overall score of at least 4.0 (n=6) to comprise the top tier of research needs (Table 4).

Table 4. Top-tier research needs[a]

Score	Research Need
4.31	Determine which patients are likely to benefit from surgery.
4.22	Develop standardized diagnostic criteria.
4.16	Identify risk associations and women at risk for developing noncyclic chronic pelvic pain.
4.15	Determine the overall role of surgery.
4.04	Conduct studies on the management of patients who have failed pharmacologic treatment.
4.03	Identify the most cost effective diagnostic and management strategies.

Notes: [a] Research needs with an average score of 4.0 or higher on the second survey

We also extracted items with an overall score of 3.75–3.99 (n=9) to comprise the second tier of research needs (Table 5). Of note, the scores were all very close, and no set of recommended studies should be considered low priority. The rating provides a relative measure; all of the research questions are important, but a subset comprises a priority set that should be addressed first. The results from the second survey are presented in Appendix H and a rank ordered list of all research needs is presented in Appendix I.

Table 5. Second-tier research needs[a]

Score	Research Need
3.98	Conduct studies on cognitive behavior therapy.
3.94	Standardize diagnostic evaluations including history and physical.
3.90	Standardize optimal surgical outcomes including followup interval (e.g., long-term outcomes).
3.86	Determine the accuracies of individual and combined diagnostic tests.
3.84	Conduct studies on patient education.
3.82	Determine patient dissatisfaction with care.
3.80	Document the treatment effect of diagnostic laparoscopy.
3.80	Conduct studies on provider education.
3.78	Assess the impact of noncyclic chronic pelvic pain on the use of health services.

Notes: [a] Research needs with an average score of 3.75-3.99 on second survey

Research Design Considerations

The investigative team reviewed and discussed the top and second tier research needs in light of the CER, ongoing research, and initial discussions with the stakeholders. The lead investigator developed suggestions for potential study design for each of the top-tier research needs. We also highlight methodologic challenges and issues specific to each research need that may encumber

efforts to transform the question into a practical research agenda (Table 6). The top-tier research needs underscore the lack of findings reported in the initial CER while others, such as diagnosis or cost effectiveness, are more general and indirectly related to the CER, although still partially within the scope of the CER.

Table 6. Top-tier research needs: PICOTS, study designs, considerations, and relationship to CER

Research Need Source	PICOTS Element(s)	Potential Study Designs and Considerations	Relationship to CER
Determine which patients are likely to benefit from surgery. CER	**P:** Women with noncyclic CPP **I:** Surgical **C:** Surgical or nonsurgical **O:** Symptom resolution; QOL **T:** >12 months **S:** Community and clinic	Diagnostic and treatment RCT with subpopulation analysis and/or strict inclusion criteria of a well-defined population • Comparison of treatment may be surgery A vs. surgery B or surgery vs. nonsurgical intervention or surgery vs. sham-surgery. • Standardizing surgical interventions can be problematic. Surgical care is a highly technical, complex process and requires the coordination of many individuals and systems.	Addressed specifically by KQ2 and KQ3 of the CER. Of seven studies addressing KQ2, one was assessed as good, one as fair, and five as poor quality. No studies addressing KQ3 were identified.
Develop standardized diagnostic criteria. CER	**P:** Women with pelvic pain **I:** Diagnostic test/criteria **C:**Diagnostic test/criteria **O:** Diagnostic accuracy **T:** N/A **S:** Clinic	Validation study of consensus-developed diagnostic criteria, in the light of systematic reviews (international, multisite, between-subjects design) • Requires an international effort. (Comparison process: Rome I, II, III criteria for diagnostic criteria for IBS and validation, diagnostic criteria for headache, complex regional pain syndrome, and psychiatric disorders). • Challenge precluding a RCT is that there is no gold standard diagnostic test.	Addressed indirectly by all KQs of the CER. Across all studies for therapeutic interventions there were large inconsistencies noted in the CER for diagnostic criteria. May benefit from a systematic review to assess status of existing, if any, diagnostic criteria for CPP.

Table 6. Top-tier research needs: PICOTS, study designs, considerations, and relationship to CER (continued)

Research Need Source	PICOTS Element(s)	Potential Study Designs and Considerations	Relationship to CER
Identify risk associations and women at risk for developing noncyclic chronic pelvic pain. CER	**P:** Women with and without noncyclic CPP **I:** N/A **C:** N/A **O:** Noncyclic CPP diagnosis and diagnosis of an at-risk comorbid condition **T:** >12 months **S:** Community and clinic	Observational study: prospective cohort (longitudinal) or case-control study • Cohort study would need to be large and long term. Expensive because development of CPP "rare": a solution would be to add to a larger prefunded cohort study. • Case-control studies can be very efficient; but only one outcome per study; threats to validity include recall bias, control selection, and response rates. • Other challenges include the difficulty imposed by confounding (mixing of effects) and risk factor interaction (synergy, antagonism).	Addressed partially by KQ1 of the CER. Additional systematic review may be needed to identify studies not included within the scope of CER.
Determine the overall role of surgery. Stakeholders	**P:** Women with noncyclic CPP **I:** Surgical **C:** Surgical or nonsurgical **O:** Symptom resolution; QOL **T:** >12 months **S:** Community and clinic	Prospective cohort • Common critiques are that observational research studies systematically overestimate treatment effect and are limited by unavoidable confounding and bias. To account for these potential limitations, investigators can use several statistical and methodological techniques, including regression, stratification, and patient matching. • Standardizing surgical interventions can be problematic. Surgical care is a highly technical, complex process and requires the coordination of many individuals and systems.	Addressed specifically by KQ2 of the CER. Of seven studies addressing KQ2, one was assessed as good, one as fair, and five as poor quality.
Conduct studies on the management of patients who have failed pharmacologic treatment. CER	**P:** Women with noncyclic CPP that have failed prior treatment **I:** Surgical or nonsurgical **C:** Surgical, nonsurgical, no treatment **O:** Symptom resolution; QOL **T:** >6 months **S:** Clinic	RCT (optimal design for therapy should be placebo-controlled, double-blind, parallel group, and randomized to treatment allocation) • Well-defined inclusion and exclusion criteria will be necessary, to define "failure" for every pharmacologic treatment. • Challenges include high placebo response rate, fluctuating symptoms, heterogeneous and complex mechanisms, avoiding bias, contamination by over-the-counter treatments or drugs for other conditions, avoiding harm, duration of the treatment intervention, frequency of treatment, and difficulty blinding the intervention.	Addressed specifically by KQ5 of the CER; however, no studies addressing KQ5 were identified in the CER.

Table 6. Top-tier research needs: PICOTS, study designs, considerations, and relationship to CER (continued)

Research Need Source	PICOTS Element(s)	Potential Study Designs and Considerations	Relationship to CER
Identify the most cost effective diagnostic and management strategies. CER	**P:** Women with noncyclic CPP **I:** Diagnostic test, surgical or nonsurgical therapy **C:** Diagnostic test, surgical or nonsurgical therapy **O:** Resource utilization outcomes **T:** >12 months **S:** Clinic	Decision analytic modeling comparison of two or more alternatives or designed within a clinical trial (RCT: running in parallel with the main study is a prospective economic analysis) • Not appropriate for placebo-controlled or sham-surgery as comparator, because the placebo arm limits generalizability to clinical practice.	Not addressed by KQs of the CER. Consider systematic reviews to identify studies focused on diagnosis of CPP.

Abbreviations: CER=comparative effectiveness review; CPP=chronic pelvic pain; IBS=irritable bowel syndrome; KQ=Key Question; N/A=not applicable; PICOTS=population, intervention, comparator, outcome, timing, setting; QOL=quality of life; RCT=randomized controlled trial.

Discussion

For this project, we used a three-step iterative process for identifying and prioritizing evidence gaps and research questions related to therapies for women with noncyclic chronic pelvic pain (CPP), incorporating input from a stakeholder panel. Initially, we included evidence gaps identified and future research needs proposed by the original comparative effectiveness review (CER) and solicited additional suggestions from the stakeholders during the first step of this process. We modified the wording of some future research needs for clarity and combined similar future research needs when redundant. This resulted in a list of 63 future research needs.

During the second step, stakeholders provided initial prioritizations on the inclusive list of future research needs, based on responses to a Web-based survey, narrowing the list to 31 items. In the final step, stakeholders prioritized the top-tier of future research needs using prespecified criteria to develop the final list of top-priority future research needs. The final six top-tier future research needs identified from the stakeholder engagement process, reflect the breadth of Key Questions from the original CER, which covered prevalence of comorbidities (Key Question 1), surgical treatments (Key Question 2), the role of etiology identified after surgery on surgical outcomes (Key Question 3), nonsurgical treatments (Key Question 4) and treatment options for failed interventions (Key Question 5).

As noted in the original CER, the findings of this future research need project suggest that the current status of scientific knowledge regarding treatment for noncyclic CPP is limited in both overall quality and quantity of impactful research. It may not be unexpected, therefore, that the research gaps and future research needs are broad in scope and generalized with regards to terminology. It also may not be unexpected that most of the highest priority needs overlap with the research gaps identified in the original CER. Many of our stakeholders remarked on how poorly understood CPP is in terms of disease characterization, definition, and etiology. Furthermore, they acknowledged that definitions of outcomes inherent to studies concerning therapies were not standardized and thus often not comparable. During these discussions with the stakeholders, concerns for lack of standardized definitions, diagnosis and outcome measures recurrently eclipsed specific objectives for specific treatment options as these deficiencies markedly limit the scientific field as a whole. Perhaps reflective of these concerns, in the final steps of this process stakeholders prioritized future research needs identifying general uncertainties about CPP over more specifically defined topics, including specific treatment modalities and therapies.

We did not specifically evaluate the future needs prioritizations in either step according to stakeholder characteristics and did not solicit information regarding stakeholders' preferences for ranking certain topics. We felt the limited number of stakeholders precluded meaningful categorization of members and thus any insight from analyzing the results according to stakeholder characteristics would be of questionable benefit. Furthermore, it may jeopardize the anonymity of the prioritization process. The anonymous and individualized aspect of our prioritizing methods allows equal representation from all stakeholders, regardless of background or experience with the clinical condition.

None of the six top future research needs is currently being addressed by ongoing clinical studies, based on the results of our search. Some of the ongoing trials at least partly address future research needs delegated to the lower tiers of prioritization. While we felt that none of the identified needs were completely beyond the scope of the CER, some were only partially addressed in that project and additional systematic reviews may be warranted to fully assess the status of published studies concerning those specific needs and research gaps, as indicated in

Table 6. One of the strengths of our process included the constituents of the stakeholder participants. CPP is a multifactorial condition treated and managed by a variety of provider types and specialties, including allied health professionals and others. Reflective of this variety in provider types, we were able to recruit a diverse group of providers as stakeholders for this future research need project, which strengthens the face validity of the results of the research prioritization. In addition, our investigator team was comprised of two members from the original CER, including the Principal Investigator (JA). This afforded familiarity and expertise with the topic and current status of existing research within the field.

No stakeholders disclosed financial or other conflicts of interest that could bias the findings related to the future research need project. Participation was acceptable during all phases of the project. All stakeholders were present on the initial telephone conference call, albeit individual participation in that discussion was varied and immeasurable, which is a recognized difficulty in this process.[35] Participation in the prioritization process was moderate, with 55 and 64 percent of stakeholders responding to the first and second surveys, respectively. We did not solicit feedback from the stakeholders regarding their experience with participation in this project, so we are unable to comment on why participation varied during each step of the process. Stakeholder engagement and retention may vary because of the nature of clinical condition or topic or because of logistical or technical aspects of planning and engagement. As we were concerned with limiting the scheduling and effort burdens that may be imposed on the stakeholders, during planning for this project, we tried to incorporate methods (e.g. Web-based survey and email correspondence) that would facilitate convenience, although we did not systematically evaluate whether this affected participation rates.

In this project, we utilized an emerging technological feature to solicit Web-based survey responses from the stakeholders. REDCap™ (Research Electronic Data Capture) is an internet-based data management system that allows direct data population and storage for survey responses. It also allows for variable output formats, facilitating data analysis and synthesis. Our hope was that this would result in increased efficiency in soliciting stakeholder responses, allowing them to complete the surveys at times and locations convenient to them. This was of particular interest as our stakeholder group contained European members, which added to potential scheduling conflicts for teleconferencing. The use of REDCap also facilitated data consolidation and review after the surveys were completed. This approach resulted in stakeholder participation rates of over half of the team members; it is unknown whether other methods could have improved this participation rate. Additional work is needed to further validate the use of this tool in this future research need process.

Methodology for conducting future research need projects is evolving; presently, there are few prescribed methods for research needs prioritization. We elected to follow the paradigm suggested in a draft Agency for Healthcare Research and Quality (AHRQ) report using the Prioritization Criteria Methods (PiCMe), with some modifications dictated by the nature of the condition under study. One component of the PiCMe paradigm is development of specific research questions designed around the “patient, intervention, comparator, outcome, setting” (PICOS) framework and integrating this into the final research needs prioritization. Because relatively nonspecific and broad knowledge gaps were identified by the original CER and stakeholder input, we did not feel such specific details were appropriate as they may be interpreted as being overly proscriptive in nature and may in fact hinder investigator-initiated research.[35]

Presently, the state of clinical research for treatments of noncyclic CPP is incomplete and limited by knowledge gaps in fundamental understanding and characterization of the clinical condition. Through the process described in this report a diverse group of stakeholders acknowledged known gaps and suggested that ample future research in CPP is needed and that research efforts to address these gaps should be prioritized.

Conclusion

The authors of this report built upon the findings from a previous systematic review of therapies for noncyclic chronic pelvic pain (CPP) to identify a comprehensive list of research gaps for ranking and prioritization. Specific research gaps reflected extensive needs for future research in the areas of diagnosis, standardization, etiology and treatment. Needs were predominately general in nature, reflecting a broad scope of uncertainties within the current state of the science. Specific deficiencies addressed the need for standardized approaches to diagnosis and outcome assessment, and methods to improve management of a poorly characterized condition.

Our multistep process for identifying, expanding, and prioritizing research needs to advance research in the area of noncyclic CPP resulted in a list of research topics to fill specific knowledge gaps. The highest priority research questions were general, reflecting the recognition of broad gaps in the evidence. These research needs include diagnostic criteria validation, identification of subpopulations, comorbid conditions and risk factors, and the role of surgery as a therapeutic intervention. All research studies would be enhanced by multiple site involvement. Although strict inclusion criteria would confer a group of subjects with a similar condition, the more strict the inclusion criteria, the less applicable the results will be for real-world clinical practice. For therapeutic interventions, the recognition of a significant placebo effect in chronic pain informs the recommendation for randomized controlled trials. For therapeutic intervention studies, study design should include a commitment to a choice of superiority, equivalence, or noninferiority design, and a sample size calculation that accounts for the range of possible effect size, placebo effect, and chance.

Acronyms and Abbreviations

ADL	Activities of daily living
AHRQ	Agency for Healthcare Research and Quality
BDI	Beck Depression Inventory
CI	Confidence interval
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CPP	Noncyclic chronic pelvic pain
EPC	Evidence based Practice Center
g,G	Group
GnRH	Gonadotropin releasing hormone
IBS	Irritable bowel syndrome
IHS	International Headache Society
IC	Interstitial cystitis
IC/PBS	Interstitial cystitis/Painful bladder syndrome
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
KQ	Key question
LUNA	Laparoscopic utero-sacral nerve ablation
MPQ	McGill Pain Questionnaire
MRI	Magnetic resonance imaging
n, N	Number
NR	Not reported
OCP	Oral contraceptive pills
OR	Odds ratio
PBS	Painful bladder syndrome
PET	Positron Emission Tomography
QOL	Quality of life
RCT	Randomized controlled trial
RR	Relative risk
SERM	Selective estrogen receptor modulator
SOE	Strength of evidence
TENS	Transcutaneous Electrical Nerve Stimulation
TEP	Technical Expert Panel
VAS	Visual analog scale

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Appendix A. Literature Search

Table A1. PubMed search results

	Search terms	Results
#1	"chronic pelvic pain"	2,113
#2	chronic OR recurrent OR recurring OR chronic disease[mh] OR noncyclic OR non-cyclic OR mixed	1,204,037
#3	"pelvic pain" OR pelvic pain[mh]	8,796
#4	(musculoskeletal diseases[mh] OR myofascial[tiab]) AND (pelvic[tiab] OR pelvis[tiab] OR pelvis[mh] OR pelvic pain[tiab])	7,698
#5	#1 OR (#2 AND (#3 OR #4)) AND eng[la] AND humans[mh] AND 1990:2012[dp]	2,521
#6	#5 NOT (case reports[pt] OR letter[pt] OR comment[pt] OR editorial[pt] OR review[pt] OR meta-analysis[pt] OR practice guideline[pt])	1,389

Last updated 3/29/2012; n=109 since last search for CER (5/3/2011). Key: [mh] Medical Subject Heading; [la] language; [pt] publication type; [dp] publication date; [tiab] title/abstract word.

Appendix B. Ongoing and Recently Completed Studies

Study Name, Location Trial Identifier Sponsor	Inclusion/Exclusion Criteria	Interventions	Start Date—Est. Completion Date Est. Enrollment
Female Chronic Pelvic Pain, Denmark NCT01255345 Copenhagen University Hospital at Herlev	Inclusion Criteria: · Women ≥ 18 years · Living in Copenhagen Country (Region H) · Capable of reading, writing and speaking Danish Exclusion Criteria: · Pain limited solely to the perineal skin or introitus (vulvodynia) · Pregnancy, cancer, active pelvic inflammatory disease · Operation in the pelvic during the last 6 months · Cognitively impaired individuals	Physiotherapeutic examination of abnormal muscular findings, i.e. tonus, elasticity and strength, in the pelvic area connected to female CPP	January 2011 - December 2012 2500
Observational Study of Control Participants for the MAPP Research Network, United States NCT01098292 National Institute of Diabetes and Digestive and Kidney Diseases	Includes health controls and positive controls.	N/A	December 2009 -- December 2012 630
Global Study of Women's Health, United States NCT00849173 Eunice Kennedy Shriver National Institute of Child Health and Human Development	Inclusion Criteria: · Premenopausal female 18 to 45 years of age · Attending for her first diagnostic laparoscopy or for laparoscopy for tubal sterilisation · Has no previous history of endometriosis diagnosis through surgery Exclusion Criteria: · Already has a surgically-confirmed diagnosis of endometriosis · Aged less than18 or greater than 45 · Aged 18-45 but post-menopausal	N/A	February 2009 -- NR 2950

Study Name, Location Trial Identifier Sponsor	Inclusion/Exclusion Criteria	Interventions	Start Date—Est. Completion Date Est. Enrollment
Addition of Pudendal Blocks to Pelvic Floor Physical Therapy for the Treatment of Pelvic Floor Tension Myalgia, United States NCT00928564 University of California, Irvine	Inclusion Criteria: · Non-pregnant women over the age of 18 with the diagnosis of pelvic floor tension myalgia that are naive to pelvic floor physical therapy. · Able to provide informed consent. · Subjects must be willing to accept randomization. Exclusion Criteria: · Previously treated with physical therapy. · An allergy to any component within the pudendal block. · Bleeding disorders. · Active vaginal infection. · Inability to complete the questionnaires. · Inability to read English (validated questionnaires are available in English only). · Inability to complete the follow-up visits.	Active: Drug: Pudendal block: 8ml of 0.5% bupivicaine, 1ml of 10mg/ml triamcinolone, 1ml of 8.4% sodium bicarbonate for a total volume of 10ml. Five ml will be used at each block site. Placebo: 5ml of saline at each block site.	April 2009 - June 2011 140

Study Name, Location Trial Identifier Sponsor	Inclusion/Exclusion Criteria	Interventions	Start Date—Est. Completion Date Est. Enrollment
Follow-up Strategies for Improved Postoperative Recovery After Benign Hysterectomy, Sweden NCT01526668 University Hospital, Linkoping	Inclusion Criteria: · Women between 18 and 60 years of age. · Women who are scheduled for vaginal or abdominal total or subtotal hysterectomy for benign gynecological diseases (including cervical dysplasia). · Women who understand and speak Swedish fluently. · Women who give signed informed consent to participate in the study. · Women who have access to a telephone and/or internet. Exclusion Criteria: · Women where the hysterectomy is carried out in association with surgery for genital prolapse · Women with genital malignancies (does not include cervical dysplasia). · Women where the operation is planned or expected to comprise more than the hysterectomy with or without unilateral salpingooophorectomy and appendectomy en passant. · Women with previous bilateral salpingooophorectomy. · Women who are physically disabled to a degree so that mobilization postoperatively cannot be expected as for a normal individual. · Women who are mentally disabled to a degree so she cannot complete the forms in the study or understand the tenor of the participation or it is considered doubtful from an ethical point of view to participate. · Women with psychiatric disease or is on medication for severe psychiatric disease so that the physician consider participation in the study unsuitable. · Women with current drug or alcohol abuse.	Behavioral: Follow-up strategy Comparison of different follow-up strategies	October 2011 -- January 2015 600
Transcranial Direct Stimulation in Chronic Pelvic Pain, United States NCT01143636 Spaulding Rehabilitation Hospital	Inclusion Criteria: · Providing informed consent to participate in the study · 18 to 64 years old · Having symptoms of pelvic pain for more than 6 months with an average of 3 on a 0-10 VAS scale (for pelvic pain subjects only) · No history of or current genitourinary tuberculosis as self reported · No history of urethral cancer as self reported	Transcranial Direct Current Stimulation	April 2010 - April 2012 68

Study Name, Location Trial Identifier Sponsor	Inclusion/Exclusion Criteria	Interventions	Start Date—Est. Completion Date Est. Enrollment
	· No history or current bladder malignancy, high grade dysplasia or carcinoma in situ as self reported · No occurrence of ovarian, vaginal or cervical cancer in the previous 3 years as self reported · No current vaginal infection as self reported · No active herpes in previous 3 months as self reported · No antimicrobials for urinary tract infections in previous 3 months as self reported · Never treated with cyclophosphamide as self reported · No radiation cystitis as self reported · No neurogenic bladder dysfunction (due to a spinal cord injury, stroke, Parkinson's disease, multiple sclerosis, spina bifida or diabetic cystopathy) as self reported · Absence of bladder, ureteral or urethral calculi for previous 3 months as self reported · No urethritis for previous 3 months as self reported · No urethral dilatation, cystometrogram, bladder cystoscopy with full anesthesia or bladder biopsy in previous 3 months as self reported · Must not be pregnant · Eligible to MRI according to MRI screening checklist · No contraindications to Transcranial Direct Stimulation: · No history of alcohol or drug abuse within the past 6 months as self reported · No use of carbamazepine as self reported · Does not have severe depression (with a score of >30 in the Beck Depression Inventory) · No history of neurological disorders as self reported · No history of unexplained fainting spells as self reported, · No history of head injury resulting in more than a momentary loss of consciousness as self reported · Have had no neurosurgery as self reported · No history of psychological disorders as		

Study Name, Location Trial Identifier Sponsor	Inclusion/Exclusion Criteria	Interventions	Start Date—Est. Completion Date Est. Enrollment
	self reported · Must have the ability to feel pain as self reported		
Duloxetine for the Treatment of Chronic Pelvic Pain, United States NCT01451606 University of Maryland; Eli Lilly and Company	Inclusion Criteria: · Premenopausal adult women, aged 18-30 · Have chronic pelvic pain, as defined by the American College of Obstetrics and Gynecology · Able to read and speak English Exclusion Criteria: · Chronic Pelvic Pain only presenting in low back or vulva, or only present during menstruation or vaginal intercourse · Self-report or documentation that all CPP sites were attributed by a prior physician to IBS, IC/PBS, urinary tract infection, urinary stones, inflammatory bowel disease (ulcerative colitis or Crohn's disease), cancer or shingles. · Currently pregnant or lactating · A primary psychiatric diagnosis of major depression or history of suicide attempt as assessed by medical history. Also, those who would be considered to have Major Depressive Disorder (MDD) on the basis of DSM-IV criteria will excluded, as well as those selecting "3" or "4" on item #9 of the BDI (suicidal ideation). · A history of bipolar disorder · A history of seizure disorders · Orthostatic Hypertension · Exclusions based on the effects of duloxetine: o Known hypersensitivity to duloxetine or the inactive ingredients in Cymbalta; o Treatment with an monoamine oxidase inhibitor (MAOI) within 14 days of randomization, or potential need to use an MAOI during the study or within 5 days of discontinuation of the drug; o Treatment with cytochrome P450 enzyme inhibitors; o Uncontrolled narrow-angle glaucoma; o Concurrent use of thioridazine o Renal Impairment (serum creatinine of 1.5 or greater) o History of jaundice or	Drug: Duloxetine 30 mg dose once daily, administered orally for 1 week, 60 mg dose once daily, administered orally for 5 weeks, 30 mg dose once daily, administered orally for 1 week	June 2011 -- September 2012 120

Study Name, Location Trial Identifier Sponsor	Inclusion/Exclusion Criteria	Interventions	Start Date—Est. Completion Date Est. Enrollment
	hepatomegaly o Hepatic Insufficiency (elevated AST,ALT, bilirubin, or Alkaline Phosphatase), tested at the screening period, after the first week of study medication, and again at the midpoint of the study. · Participants who are taking SSRIs, SSNRIs, MAOIs, or tricyclics within 14 days of randomization will be excluded. · Participants who currently meet DSM-IV diagnostic criteria for Alcohol Abuse or Dependence · Weight exceeding 285 pounds · Hyponatremia, as determined by blood test results		
Investigation and Treatment of Central Nervous System Dysfunction in Chronic Pelvic Pain, United States 5R21DK081773-03 Spaulding Rehabilitation Hospital; National Institute of Diabetes and Digestive and Kidney Diseases	NR	NR	September 2009--July 2012
Multi-Disciplinary Approach to the Study of Chronic Pelvic Pain (MAPP), United States 5U01DK082344-04 National Institute of Diabetes and Digestive and Kidney Diseases	NR	NR	September 2008—June 2013
Psychosocial Treatment for Gynecology Patients with Co-Morbid Depression and Pain, United States 5K23MH079347-05 University of Rochester; National Institute of Mental Health	NR	NR	March 2007—May 2012

Study Name, Location Trial Identifier Sponsor	Inclusion/Exclusion Criteria	Interventions	Start Date—Est. Completion Date Est. Enrollment
Guided Self-Help for Women with Chronic Pelvic Pain (CPP) in Primary Care, United Kingdom ISRCTN95540596 National Institute for Health Research (NIHR) (UK)—Research for Patient Benefit (RfPB) Programme (ref:PB-PG-0408-16192; University of Manchester (UK)	Inclusion Criteria: · Women ≥ 18 years · Pelvic pain greater than 3 months duration · Pain not necessarily related to menstrual cycle or sexual activity · Has a common diagnosis which falls under the umbrella of CPP · Has a symptom profile attributed to CPP, in the absence of a diagnosis Exclusion Criteria: · Pregnancy or within 12 months delivery · Serious underlying pathology · Insufficient English to engage in self-help · Participation in other pain management research	Pilot trial of an evidence-based self-care guide for women with CPP that will be facilitated by their GP.	November 2010—December 2011 140
The Action of Gabapentin for the Management of Chronic Pelvic Pain in Women (GaPP), United Kingdom ISRCTN70960777 University of Edinburgh (UK)	Inclusion Criteria: · Women aged between 18-50 · Consented to a routine diagnostic laparoscopy · Pelvic pain of > 6 months · Pain located within the true pelvis or between and below anterior iliac crests, associated functional disability · No obvious pelvic pathology Exclusion Criteria: · Known pelvic pathology e.g. endometriosis, cyst · Undergoing major surgery e.g. hysterectomy · Estimated Glomerular Filtration Rate (eGFR) >60	Gabapentin versus placebo. 300mg dose increasing in weekly increments to a maximum dose of 2700mg if pain has not been reduced by 50% each week. Daily administration (TID) and by oral capsule, treatment given for 6 months.	February 2012—November 2013 60

Abbreviations: BTXA = Botulinum Toxin Type A; CPP = chronic pelvic pain; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, Fourth edition; EMG = electromyogram; GnRH = gonadotropin releasing hormone; HAM-A = Hamilton anxiety Scale; HAM D = Hamilton depression Scale; HCV = hepatitis C; HTPMFD =High Tone Pelvic Floor Dysfunction; MRI = magnetic resonance imaging; PID = pelvic inflammatory disease; VAS = visual analog scale; NR = not reported.

Appendix C. Translation of Evidence Gaps From CER Into Research Needs

1. Definition and standardization of CPP:
    a. Establish and validate a standardized definition of CPP, including differentiation between cyclic and non-cyclic subtypes
    b. Establish and validate standardized diagnostic criteria for CPP
    c. Standardize diagnostic evaluations for patients potentially with CPP
    d. Estimation of the accuracy of individual and combinations of diagnostic tests for CPP
    e. Develop and validate a new pain assessment tool to capture the multidimensional experience of CPP

2. Outcome measures
    a. Use of standardized outcome measures, such as those recommended by the IMPACT consensus

3. Research Quality and study design
    a. Use of appropriately designed clinical trials, following CONSORT guidelines
    b. Use of placebo control
    c. Appropriate power/sample size for primary outcome and/or subgroup analyses

4. Etiology and co-morbidities
    a. Understanding pathophysiology of the condition and relationship between pain and disease
        i. Idiopathic/de novo
        ii. Iatrogenic causes
        iii. Condition-specific causes (endometriosis, pelvic adhesions, pelvic congestion etc.)
    b. Analyses of distribution of the various symptom components of non-cyclic CPP, including dyspareunia, dysmenorrhea, etc.
    c. Document the distribution and prevalence of various co-morbidities and associated conditions that co-occur with CPP
    d. Use of specific standardized and validated tools to inform our understanding of the true prevalence of conditions reported to co-occur with CPP
    e. Analyses examining the extent to which comorbidities modify treatment approaches and outcomes in CPP
    f. Identify risk associations and women at risk for developing CPP
    g. Develop preventive strategies

5. Non-surgical/non-pharmacologic treatment
    a. Systematically assess the role in CPP treatment for:
        i. Physiotherapy
        ii. Cognitive-behavior therapy
        iii. Psychological counseling
        iv. Acupuncture
        v. TENS

6. Pharmacologic treatment
    a. Studies of non-hormonal agents, such as tanezumab
    b. Additional studies on hormonal agents, with focus on:
        i. Optimization of administration, including timing, dosing, duration
        ii. Appropriate selection of patients for hormone therapy
    c. Treatment of pharmacologic failures

7. Surgical treatment
    a. Determine the optimal timing of surgical intervention
    b. Determine which patients are likely to benefit from surgery
    c. Standardize optimal surgical outcomes
    d. Determine the role of surgical or pathologic diagnosis (including diagnostic laparoscopy) for the effective treatment of CPP
    e. Further study on the role of hysterectomy with or without castration for the treatment of CPP
    f. Other specific procedures/techniques

8. Impact and resource utilization
    a. Assessment of the impact of CPP on the use of health services
    b. Economic analysis to determine the most cost effective diagnostic and management strategies for CPP

Appendix D. Stakeholder Conference Call Summary

Participants

- Anna Albrecht, MPH (Director, Wellness Initiatives, Women's Health Foundation, Chicago, IL)
- Dee Hartmann, DPT, PT (Treatment of Women's Health and Chronic Pelvic Dysfunction, Chicago, IL)
- Linda McGowan, PhD, MSc (Senior Lecturer, University of Manchester, Manchester, UK)
- Eric Wall, MD, MPH (Senior Medical Director, Qualis Health, Seattle, WA)
- Priscilla Abercrombie, PhD, RN, NP (Nurse Practitioner, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California San Francisco, San Francisco, CA)
- Jane Daniels, MSc (Department of Obstetrics & Gynaecology, Birmingham Women's Hospital, UK
- Esther Eisenberg, MD, MPH (Professor, Department of Obstetrics and Gynecology, Vanderbilt University Medical Center, Nashville, TN)
- Cynthia Neville, DPT, PT, WCS, BCB-PMD (Director, Women's Health Services, Brooks Rehabilitation, Jacksonville, FL)
- Steve Phurrough, MD, MPA (Chief Operating Officer and Senior Clinical Director, Center for Medical Technology and Policy, Baltimore, MD)
- John Steege, MD (Chief, Division of Gynecology, University of North Carolina, Chapel Hill, NC)
- Frank Tu, PMD, MPH (Director, Division of Gynecological Pain and Minimally Invasive Surgery, NorthShore University Health System, Chicago, IL)

Introductions and Purpose

The purpose of this call was to review and discuss the preliminary list of research gaps identified in the Comparative Effectiveness Review, "Noncyclic Chronic Pelvic Pain Therapies for Women" and to solicit stakeholder input on key research gaps and questions of relevance to CPP.

Following brief introductions, Dr. Reynolds facilitated a discussion using the outline of research needs included in the meeting agenda that was distributed previously to call participants.

Specifically, call participants were asked to: 1) review and comment on the initial list of research gaps and; 2) suggest potential research topics and questions not included in the initial list of research gaps.

Stakeholder Comments

Stakeholder comments and suggestions are summarized below:

1. Definition and standardization of CPP

· The stakeholders noted that CPP definitions are arbitrary agreed that standardization of the definitions for CPP is important.
· The stakeholders also stated that there is a lack of consensus for key descriptors and terminology for CPP (e.g., "pelvic", "duration" and "chronicity").
· The stakeholders noted that there is a need for standardized scales to assess quality of life for patients with CPP.

- The stakeholders also stated that patient history and patient questionnaires are important tools for assessing and diagnosing women with pelvic pain
- Is there any value to using unrelated procedures or conditions to evaluate the quality of pain?
- The stakeholders noted that characterization of the pelvic pain including location, duration, subtypes is important.
- In clinical practice, noncyclic and cyclic pain mixed. What is the qualitative perspective?

2. Outcome measures
   - Stakeholders agreed that standardized outcome measures are needed, specifically for quality of life and functional capacity.
   - CPP outcome measures and scales should be established and validated.
   - Stakeholders added that reliable measures of patient-reported outcomes would be beneficial for research of therapies for CPP.
   - Is there a way to capture data about internal pain?
   - Stakeholders suggested that standardized lists be focused on the needs of payers, patients, and clinicians in addition to researchers.

3. Research quality and study design
   - Call participants agreed that good quality, appropriately designed clinical trials of CPP are needed to build a robust and useful body of literature.
   - Stakeholders added that the methodologies that support evaluation of multidimensional treatments are important.

4. Etiology and co-morbidities
   - Stakeholders suggested that understanding disease pathophysiology and elucidation of the relationship between pain and disease is critical to evaluation and management of CPP.
   - Where possible, research should seek to sort out what is a co-morbidity and what is a cause.
   - What is the role of myofascial dysfunction and musculoskeletal problems (e.g. low back pain, hip pain, pelvic and abdominal visceral pain) in CPP?
   - Stakeholders recommended that future research investigate the role of trauma to CPP diagnosis, etiology, and treatment. Trauma, both iatrogenic and external, should be listed as a separate category for research needs.
   - Stakeholders agreed that the role of sexual dysfunction in CPP is an important topic for future research.
   - Stakeholders emphasized the value of patient history and proper physical examination in CPP.
   - Research to improve the understanding of the relationship between certain events early in life (e.g., abuse, childhood urinary tract infection, external trauma) and the incidence of CPP would be helpful.
   - Stakeholders recommended that future research examine co-morbidities in terms of other pain syndromes.

- Stakeholders added that psychological attributes including fear, avoidance, and pain catastrophizing should be further examined as relevant co-morbidities or etiological factors.
- Stakeholders suggested that genetic susceptibility be considered.

5. Non-surgical/non-pharmacologic treatment
   - The stakeholders agreed that there is a need for research on non-surgical/non-pharmacological strategies to manage CPP.
   - In addition to those identified, stakeholders suggested that self-management, and education (for providers and patients) be added to list of non-surgical/non-pharmacological treatments.
   - One stakeholder noted that research on mechanisms of pain using functional magnetic resonance imaging (fMRI) may offer valuable insights for CPP.
   - Patients are often unsatisfied with care and seek alternative treatments.
     In addition to those identified, stakeholders suggested that diet therapy, integrative medicine, and the centering model be included.

The stakeholders noted that herbal and other nutritional supplements are widely used and should therefore be researched.

6. Pharmacologic treatment
   - In addition to hormonal therapies, the list of research needs should include opioid analgesics, steroid injections, lidocaine injections, botox injections, cymbalta, and muscle relaxants (vaginally and rectally administered).
   - Stakeholders agreed that studies of gabapentin would also be useful.
   - What is the role of gabapentin on pain when given preoperatively?

7. Surgical treatment
   - Stakeholders noted that surgery has not been shown to be successful.
   - Long term followup of surgery treatment is needed to assess outcomes.
   - What is the role of the patient provider relationship on outcomes?
   - What is the role of MRI before laparoscopy?

8. Impact and resource utilization
   - Stakeholders agreed that in order to investigate impact and resource use, a standard classification is needed.
   - There is not diagnostic code for CPP in the United Kingdom.
   - Stakeholders suggested that claims analysis or charge data for CPP would be interesting.
   - Stakeholders agreed that information to inform economic analysis, health care utilization, and cost relationship is important.
   - Research on health care expenditures, and missed work due to CPP has the potential to highlight the prevalence and impact of CPP.
   - Stakeholders agreed that it would be interesting to know more about patients who have had multiple laparoscopies and repeat CT scans.
   - Stakeholders suggested that musculoskeletal evaluations are the least expensive and simple exam that should be done.

- Stakeholders agreed that the health care costs related to imaging in this patient population is significant

9. Other
   - Focus on research that translates to clinical practice (e.g., in the context of practice-based research networks).
   - Use research to educate and increase awareness among a range of health care providers (e.g., physician assistants).
   - Examine the variation in practice patterns and choice of treatment/intervention based on provider specialty. For example, how do urologic, gynecologic, colorectal specialists differ in diagnosis, approach, and management of patients? How do outcomes vary for patients treated by different clinical specialists?
   - What is the role of self-management for CPP patients?
   - What is the role of self-diagnosis? One stakeholder gave the example of somatoform disorder.
   - Stakeholders agreed that primary care providers would benefit from improved awareness of what CPP is and how best to manage/refer patients.

Next Steps
- Prioritize refined list of gaps with stakeholders
- Review list of high priority research needs with stakeholders
- Reprioritize list of top tier/high priority needs with stakeholders

Appendix E. Research Needs for Initial Rating

	Research Need	Source
1.	Develop standardized scales to assess quality of life for patients with noncyclic chronic pelvic pain.	Stakeholders
2.	Characterize chronic pelvic pain subtypes, including the significance of differentiation between cyclic and noncyclic.	CER
3.	Develop standardized diagnostic criteria.	CER
4.	Standardize diagnostic evaluations including history and physical.	Stakeholders
5.	Determine the accuracies of individual and combined diagnostic tests.	CER
6.	Develop standardized outcome measures and scales for quality of life and functional capacity.	Stakeholders
7.	Develop and validate a new pain assessment tool to capture the multidimensional experience of noncyclic chronic pelvic pain.	CER
8.	Develop and standardize an assessment tool to evaluate quality of life.	Stakeholders
9.	Determine the role of idiopathic causes in the pathophysiology of noncyclic chronic pelvic pain.	CER
10.	Determine the role of iatrogenic causes in the pathophysiology of noncyclic chronic pelvic pain.	CER
11.	Determine the role of condition-specific causes (e.g., endometriosis, pelvic adhesions, pelvic congestion, etc.) in the pathophysiology of noncyclic chronic pelvic pain.	CER
12.	Determine the role of trauma in the pathophysiology of noncyclic chronic pelvic pain.	Stakeholders
13.	Determine the role of genes and genetic susceptibility in the pathophysiology and pain related to noncyclic chronic pelvic pain.	Stakeholders
14.	Characterize the distribution of symptom components (e.g., dyspareunia, dysmenorrhea, etc.) of noncyclic chronic pelvic pain.	CER
15.	Characterize and document the distribution and prevalence of comorbidities and conditions associated with noncyclic chronic pelvic pain.	CER
16.	Distinguish between a comorbidity and an etiological factor in noncyclic chronic pelvic pain.	Stakeholders
17.	Determine the extent to which comorbidities modify treatment approaches and outcomes in noncyclic chronic pelvic pain.	CER
18.	Identify risk associations and women at risk for developing noncyclic chronic pelvic pain.	CER
19.	Conduct studies on physiotherapy.	CER
20.	Conduct studies on cognitive behavior therapy.	CER
21.	Conduct studies on psychological counseling.	CER
22.	Conduct studies on acupuncture.	CER
23.	Conduct studies on transcutaneous electrical nerve stimulation (TENS).	CER
24.	Conduct studies on self-management.	Stakeholders
25.	Conduct studies on provider education.	Stakeholders
26.	Conduct studies on patient education.	Stakeholders
27.	Conduct studies on diet therapy.	Stakeholders
28.	Conduct studies on integrative medicine.	Stakeholders
29.	Conduct studies on the Centering Model.	Stakeholders
30.	Conduct studies on nutritional and herbal supplements.	Stakeholders
31.	Conduct studies on the nonhormonal agent, tanezumab (anti-NGF monoclonal antibody RN624).	CER
32.	Conduct studies on the nonhormonal agent, gabapentin (Neurontin).	Stakeholders

33.	Conduct studies on opioid analgesics.	Stakeholders
34.	Conduct studies on steroid injections.	Stakeholders
35.	Conduct studies on lidocaine injections.	Stakeholders
36.	Conduct studies on botox injections.	Stakeholders
37.	Conduct studies on the nonhormonal agent, duloxetine (Cymbalta).	Stakeholders
38.	Conduct studies on muscle relaxants (administered vaginally or rectally).	Stakeholders
39.	Conduct studies on gabapentin as a preoperative agent.	Stakeholders
40.	Conduct studies on the optimization of hormonal agent administration including timing, dosing, and duration.	CER
41.	Conduct studies on the appropriate selection of patients for hormone therapy.	CER
42.	Conduct studies on the management of patients who have failed pharmacologic treatment.	CER
43.	Determine the optimal timing of surgical intervention.	CER
44.	Determine which patients are likely to benefit from surgery.	CER
45.	Standardize optimal surgical outcomes including followup interval (e.g., long-term outcomes).	CER
46.	Determine the role of surgical or pathologic diagnosis on treatment outcomes.	CER
47.	Determine the role of hysterectomy with or without oophorectomy.	CER
48.	Determine the overall role of surgery.	Stakeholders
49.	Determine optimal followup to assess outcomes following surgical interventions.	Stakeholders
50.	Characterize the role of the patient-provider relationship on surgical outcomes.	Stakeholders
51.	Examine the role of magnetic resonance imaging (MRI) before laparoscopy.	Stakeholders
52.	Document the treatment effect of diagnostic laparoscopy.	CER
53.	Assess the impact of noncyclic chronic pelvic pain on the use of health services.	CER
54.	Identify the most cost effective diagnostic and management strategies.	CER
55.	Determine the role of musculoskeletal evaluations on resource use.	Stakeholders
56.	Establish a distinctive administrative diagnostic code for noncyclic chronic pelvic pain.	Stakeholders
57.	Collect and analyze data to inform health care utilization and cost relationship.	Stakeholders
58.	Determine the direct and indirect costs that contribute to health care expenditures and economic impact.	Stakeholders
59.	Conduct additional research specifically on patients who have had multiple interventions (e.g., multiple laparoscopies).	Stakeholders
60.	Conduct additional research specifically on patients who have undergone repeat diagnostic imaging (e.g., computed tomography scans).	Stakeholders
61.	Determine costs related to diagnostic imaging in patients with noncyclic chronic pelvic pain.	Stakeholders
62.	Determine patient dissatisfaction with care.	Stakeholders
63.	Characterize patient healthcare-seeking for alternative treatments.	Stakeholders

Abbreviations: CER=comparative effectiveness review

Appendix F. Survey 1: Rating Survey

Confidential

Future Research Needs-- Therapies for Noncyclic Chronic Pelvic Pain in Women

Thank you for your participation in the Future Research Needs Project for Noncyclic Chronic Pelvic Pain Therapies for Women

Our project team has compiled a list of questions and recommendations for noncyclic chronic pain research based on input from stakeholders and the findings from a recently conducted comparative effectiveness review.

We are asking you to complete this survey to rate the importance of these research gaps and needs for future research on noncyclic chronic pelvic pain in women. The survey will also give you the opportunity to provide general feedback on the research questions and recommendations and offer additional research needs and gaps not already identified.

We anticipate that it will take between 20 and 40 minutes to complete the survey. We ask that you complete the survey by June 1, 2012.

If you have any questions or concerns regarding the survey or overall project, please contact Shannon Potter at shannon.potter@vanderbilt.edu.

Your answers to the following questions will remain confidential. We are collecting this information in order to describe survey respondents. This information will not be reported at an individual level or in aggregate to allow for identification of an individual respondent.

List your associated professional organization(s) relevant to noncyclic chronic pelvic pain _____

Please check one or more of the following choices to describe your interest and/or expertise in noncyclic chronic pelvic pain:

- ☐ Patient care
- ☐ Research
- ☐ Health care policy
- ☐ Patient advocacy
- ☐ None of the above
- ☐ Other

List other expertise/interest in noncyclic chronic pelvic pain. _____

How many years have you been involved with and/or interested in care, research, policy, and/or advocacy for noncyclic chronic pelvic pain?

- ☐ 0-5 years
- ☐ 6-10 years
- ☐ 11-15 years
- ☐ 16 or more years

Future Research Needs: Noncyclic Chronic Pelvic Pain Therapies for Women This survey contains 63 consecutive items corresponding to specific research gaps/needs. Use the 5-point scale below to indicate your opinion on an item's importance to future research for noncyclic chronic pelvic pain in women: 1. Strongly agree 2. Agree 3. Neither agree or disagree 4. Disagree 5. Strongly disagree Survey items are organized by section based on the categories below; however, we are asking you to consider the importance of each survey item to future research needs for noncyclic chronic pelvic pain overall. -Definitions and standardization; -Outcome measures; -Etiology and comorbidities; -Nonsurgical and nonpharmacologic treatment; -Pharmacologic treatment; -Surgical treatment; -Impact and resource utilization. Each section is followed by two, optional open-text fields so you may: 1) provide comments on the research gaps and needs in the survey; and 2) list additional research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Research Gaps and Future Research Needs: Definition and Standardization of Noncyclic Chronic Pelvic Pain

1.	Develop standardized scales to assess quality of life for patients with noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
2.	Characterize chronic pelvic pain subtypes, including the significance of differentiation between cyclic and noncyclic.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
3.	Develop standardized diagnostic criteria.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
4.	Standardize diagnostic evaluations including history and physical.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
5.	Determine the accuracies of individual and combined diagnostic tests.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree

COMMENTS ON RESEARCH GAPS Optional: Use the space below to add comments on the research gaps related to definition and standardization listed above.

ADDITIONAL GAPS OR FUTURE RESEARCH NEEDS Optional: List a knowledge gap or research need related to CPP definition and standardization that is not addressed above. Be specific and number individual gaps or research questions if listing more than one. Include only those research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Research Gaps and Future Research Needs: Outcome Measures for Noncyclic Chronic Pelvic Pain

6. Develop standardized outcome measures and scales for quality of life and functional capacity.
   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Neither agree nor disagree
   - ☐ Disagree
   - ☐ Strongly disagree

7. Develop and validate a new pain assessment tool to capture the multidimensional experience of noncyclic chronic pelvic pain.
   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Neither agree nor disagree
   - ☐ Disagree
   - ☐ Strongly disagree

8. Develop and standardize an assessment tool to evaluate quality of life.
   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Neither agree nor disagree
   - ☐ Disagree
   - ☐ Strongly disagree

COMMENTS ON RESEARCH GAPS AND FUTURE RESEARCH NEEDS Optional: Use the space below to add comments on the research gaps related to outcome measures listed above.

ADDITIONAL RESEARCH GAPS OR FUTURE RESEARCH NEEDS Optional: List a knowledge gap or research need related to outcome measures that is not addressed above. Be specific and number individual gaps or research questions if listing more than one. List only those research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Research Gaps and Future Research Needs: Etiology and Comorbidities Related to Noncyclic Chronic Pelvic Pain

9.	Determine the role of idiopathic causes in the pathophysiology of noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
10.	Determine the role of iatrogenic causes in the pathophysiology of noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
11.	Determine the role of condition-specific causes (e.g., endometriosis, pelvic adhesions, pelvic congestion, etc.) in the pathophysiology of noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
12.	Determine the role of trauma in the pathophysiology of noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
13.	Determine the role of genes and genetic susceptibility in the pathophysiology and pain related to noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
14.	Characterize the distribution of symptom components (e.g., dyspareunia, dysmenorrhea, etc.) of noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
15.	Characterize and document the distribution and prevalence of comorbidities and conditions associated with noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
16.	Distinguish between a comorbidity and an etiological factor in noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
17.	Determine the extent to which comorbidities modify treatment approaches and outcomes in noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree
18.	Identify risk associations and women at risk for developing noncyclic chronic pelvic pain.	☐ Strongly agree ☐ Agree ☐ Neither agree nor disagree ☐ Disagree ☐ Strongly disagree

ADDITIONAL COMMENTS ON RESEARCH QUESTIONS Optional: Use the space below to add comments on research gaps related to etiology and comorbidities listed above.

ADDITIONAL GAPS OR FUTURE RESEARCH NEEDS Optional: List a knowledge gap or research need related to etiology and comorbidities that is not addressed above. Be specific and number individual gaps and research questions if listing more than one. List only those research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Research Gaps and Future Research Needs: Nonsurgical and Nonpharmacologic Treatment for Noncyclic Chronic Pelvic Pain

19. Conduct studies on physiotherapy.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

20. Conduct studies on cognitive behavior therapy.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

21. Conduct studies on psychological counseling.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

22. Conduct studies on acupuncture.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

23. Conduct studies on transcutaneous electrical nerve stimulation (TENS).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

24. Conduct studies on self-management.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

25. Conduct studies on provider education.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

26. Conduct studies on patient education.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

27. Conduct studies on diet therapy.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

28. Conduct studies on integrative medicine.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

29. Conduct studies on the Centering Model.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

30. Conduct studies on nutritional and herbal supplements.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

ADDITIONAL COMMENTS ON RESEARCH QUESTIONS Optional: Use the space below to add comments on research gaps related to nonsurgical and nonpharmacologic treatment listed above.

ADDITIONAL GAPS OR FUTURE RESEARCH NEEDS Optional: List a knowledge gap or research need related to nonsurgical and nonpharmacologic treatment that is not addressed above. Be specific and number individual gaps and research questions if listing more than one. List only those research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Research Gaps and Future Research Needs: Pharmacologic Treatment for Noncyclic Chronic Pelvic Pain

31. Conduct studies on the nonhormonal agent, tanezumab (anti-NGF monoclonal antibody RN624).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

32. Conduct studies on the nonhormonal agent, gabapentin (Neurontin).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

33. Conduct studies on opioid analgesics.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

34. Conduct studies on steroid injections.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

35. Conduct studies on lidocaine injections.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

36. Conduct studies on botox injections.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

37. Conduct studies on the nonhormonal agent, duloxetine (Cymbalta).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

38. Conduct studies on muscle relaxants (administered vaginally or rectally).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

39. Conduct studies on gabapentin as a preoperative agent.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

40. Conduct studies on the optimization of hormonal agent administration including timing, dosing, and duration.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

41. Conduct studies on the appropriate selection of patients for hormone therapy.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

42. Conduct studies on the management of patients who have failed pharmacologic treatment.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

ADDITIONAL COMMENTS ON RESEARCH QUESTIONS Optional: Use the space below to add comments on research gaps related to pharmacologic treatment listed above.

ADDITIONAL GAPS OR FUTURE RESEARCH NEEDS Optional: List a knowledge gap or research need related to pharmacologic treatment that is not addressed above. Be specific and number individual gaps and research questions if listing more than one. List only those research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Research Gaps and Future Research Needs: Surgical Treatment for Noncyclic Chronic Pelvic Pain

43. Determine the optimal timing of surgical intervention.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

44. Determine which patients are likely to benefit from surgery.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

45. Standardize optimal surgical outcomes including followup interval (e.g., long-term outcomes).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

46. Determine the role of surgical or pathologic diagnosis on treatment outcomes.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

47. Determine the role of hysterectomy with or without oophorectomy.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

48. Determine the overall role of surgery.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

49. Determine optimal followup to assess outcomes following surgical interventions.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

50. Characterize the role of the patient-provider relationship on surgical outcomes.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

51. Examine the role of magnetic resonance imaging (MRI) before laparoscopy.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

52. Document the treatment effect of diagnostic laparoscopy.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

ADDITIONAL COMMENTS ON RESEARCH QUESTIONS Optional: Use the space below to add comments on research gaps related to surgical treatment listed above.

ADDITIONAL GAPS OR FUTURE RESEARCH NEEDS Optional: List a knowledge gap or research need related to surgical treatment that is not addressed above. Be specific and number individual gaps and research questions if listing more than one. List only those research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Research Gaps and Future Research Needs: Impact and Resource Utilization Related to Chronic Pelvic Pain

53. Assess the impact of noncyclic chronic pelvic pain on the use of health services.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

54. Identify the most cost effective diagnostic and management strategies.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

55. Determine the role of musculoskeletal evaluations on resource use.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

56. Establish a distinctive administrative diagnostic code for noncyclic chronic pelvic pain.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

57. Collect and analyze data to inform health care utilization and cost relationship.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

58. Determine the direct and indirect costs that contribute to health care expenditures and economic impact.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

59. Conduct additional research specifically on patients who have had multiple interventions (e.g., multiple laparoscopies).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

60. Conduct additional research specifically on patients who have undergone repeat diagnostic imaging (e.g., computed tomography scans).
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

61. Determine costs related to diagnostic imaging in patients with noncyclic chronic pelvic pain.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

62. Determine patient dissatisfaction with care.
- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

63. Characterize patient healthcare-seeking for alternative treatments.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

ADDITIONAL COMMENTS ON RESEARCH QUESTIONS Optional: Use the space below to add comments on research gaps related to impact and resource utilization not listed above.

ADDITIONAL GAPS OR FUTURE RESEARCH NEEDS Optional: List a knowledge gap or research need related to impact and resource use that is not addressed above. Be specific and number individual gaps and research questions if listing more than one. List only those research needs or gaps that you consider very important to the future research for noncyclic chronic pelvic pain.

Additional comments on future research for noncyclic chronic pelvic pain therapies in women: _____

Appendix G. Survey 2: Prioritization Survey

Confidential

Prioritization Survey: Future Research Needs for Noncyclic Chronic Pelvic Pain Therapies

Thank you for your participation in the Future Research Needs Project for Noncyclic Chronic Pelvic Pain Therapies for Women

Our project team has compiled a list of the highest-rated research needs resulting from the previous survey findings.

In this final survey, we ask that you rank each item from 1 (lowest) to 5 (highest) across seven AHRQ prioritization criteria:

-Potential for significant health impact

-Potential to reduce variation in clinical practices

-Potential for significant economic impact related to the costs of health service

-Potential risk from inaction

-Potential to address inequities

-Potential to allow assessment of ethical, legal, social issues

-Potential for new knowledge

Based on survey results, we will present the highest ranking questions for each criterion in the final future research needs report.

We anticipate that it will take between 20 and 40 minutes to complete the survey. We ask that you complete the survey by June 22, 2012.

If you have any questions or concerns regarding the survey or overall project, please contact Shannon Potter at shannon.potter@vanderbilt.edu.

Your answers to the following questions will remain confidential. We are collecting this information in order to describe survey respondents. This information will not be reported at an individual level or in aggregate to allow for identification of an individual respondent.

Conduct research on patient education

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Clinician education on communication of laparoscopy results to patients.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine which patients are likely to benefit from surgery.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Develop standardized scales to assess quality of life for patients with non-cyclic chronic pelvic pain.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Develop standardized diagnostic criteria.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Standardize diagnostic evaluations including history and physical.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Collect and analyze data to inform health care utilization and cost relationship.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine the accuracies of individual and combined diagnostic tests.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Assess the impact of non-cyclic chronic pelvic pain on the use of health services.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine the role of musculoskeletal evaluations on resource use.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Conduct studies on self-management.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Standardize optimal surgical outcomes including followup interval (e.g., long-term outcomes).

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine overall role of surgery.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine optimal follow-up to assess outcomes following surgical interventions.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine the role of idiopathic causes in the pathophysiology of non-cyclic chronic pelvic pain.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Identify risk associations and women at risk for developing non-cyclic chronic pelvic pain.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Document the treatment effect of diagnostic laparoscopy.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine the direct and indirect costs that contribute to health care expenditures and economic impact.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Conduct studies on physiotherapy.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Conduct studies on cognitive behavior therapy.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Conduct studies on provider education.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Conduct studies on the management of patients who have failed pharmacologic treatment.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine optimal timing of surgical intervention.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine the role of surgical or pathological diagnosis on treatment outcomes.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Characterize and document the distribution and prevalence of co-morbidities and conditions associated with non-cyclic chronic pelvic pain.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Identify the most cost effective diagnostic and management strategies.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Characterize chronic pelvic pain subtypes, including the significance of differentiation between cyclic and non-cyclic.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Characterize the distribution of symptom components (e.g., dyspareunia, dysmenorrhea, etc.) of non-cyclic chronic pelvic pain.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Characterize the role of the patient-provider relationship on surgical outcomes.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine the role of condition-specific causes (e.g., endometriosis, pelvic adhesions, pelvic congestion, etc.) in the pathophysiology of non-cyclic chronic pelvic pain.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

Determine patient dissatisfaction with care.

Potential for significant health impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to reduce variation in clinical practices.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for significant economic impact.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential risk from inaction.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to address inequities.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential to allow assessment of ethical, legal, social issues pertaining to the condition.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)
Potential for new knowledge.	☐ 1 (low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (high)

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Appendix H. Survey 2 Results

Domain	ID 1	ID 2	ID 3	ID 4	ID 5	ID 6	ID 7	Domain Average	Item Average	Rank Order
healthimpact_1	4	3	5	5	5	5	5	4.57	3.84	11
reducevariation_1	4	3	4	3	2	5	5	3.71		
economicimpact_1	4	2	4	4	4	5	5	4.00		
inaction_1	3	2	4	4	3	4	4	3.43		
inequities_1	3	3	5	4	4	3	4	3.71		
elsissues_1	3	3	4	5	2	2	4	3.29		
newknowledge_1	5	2	4	4	4	5	5	4.14		
healthimpact_2	4	3	5	5	4	3	4	4.00	3.39	27
reducevariation_2	4	4	5	5	4	3	5	4.29		
economicimpact_2	4	3	4	4	4	1	3	3.29		
inaction_2	4	2	4	5	2	2	4	3.29		
inequities_22_b93	2	2	4	5	2	1	3	2.71		
elsissues_22_6f6	3	2	5	5	2	1	4	3.14		
newknowledge_22_e80	1	3	5	4	3	2	3	3.00		
healthimpact_22_40a	5	5	5	4	4	5	5	4.71	4.31	1
reducevariation_22_ab3	5	4	4	4	4	5	5	4.43		
economicimpact_22_2e4	5	5	5	5	5	5	5	5.00		
inaction_22_d5d	5	5	4	2	4	4	4	4.00		
inequities_2	5	3	4	4	4	3	5	4.00		
elsissues_2	5	3	4	4	4	1	4	3.57		
newknowledge_2	5	4	5	4	3	5	5	4.43		
healthimpact_3	5	4	4	5	5	3	4	4.29	3.72	17
reducevariation_3	5	4	4	3	4	2	5	3.86		
economicimpact_3	5	3	3	4	4	2	4	3.57		
inaction_3	3	4	3	4	4	1	4	3.29		
inequities_3	3		3	5	4	1	5	3.50		
elsissues_3	3	4	3	5	4	1	5	3.57		
newknowledge_3	2	5	4	5	4	3	5	4.00		
healthimpact_4	5	5	4	5	4	5	5	4.71	4.22	2
reducevariation_4	5	5	4	5	4	5	5	4.71		
economicimpact_4	5	5	5	4	4	4	5	4.57		
inaction_4	3	4	5	4	4	3	5	4.00		
inequities_4	4	3	5	5	4	1	5	3.86		
elsissues_4	3	3	4	4	4	1	5	3.43		
newknowledge_4	2	5	5	5	4	4	5	4.29		
healthimpact_5	4	4	5	4	4	5	5	4.43	3.94	8
reducevariation_5	5	4	5	4	4	5	5	4.57		
economicimpact_5	3	4	3	4	4	4	5	3.86		
inaction_5	3	4	4	3	4	3	5	3.71		
inequities_5	2	3	4	4	4	1	5	3.29		

Domain	ID 1	ID 2	ID 3	ID 4	ID 5	ID 6	ID 7	Domain Average	Item Average	Rank Order
elsissues_5	3	4	4	4	4	1	5	3.57		
newknowledge_5	3	4	5	4	4	4	5	4.14		
healthimpact_6	5	4	5	4	3	3	3	3.86	3.73	16
reducevariation_6	4	5	5	3	4	4	3	4.00		
economicimpact_6	5	5	5	5	5	4	5	4.86		
inaction_6	3	3	4	3	3	3	4	3.29		
inequities_6	1	3	4	4	4	2	4	3.14		
elsissues_6	3	3	5	3	3	1	4	3.14		
newknowledge_6	2	4	5	4	4	4	4	3.86		
healthimpact_7	4	5	5	4	4	3	4	4.14	3.86	10
reducevariation_7	4	5	5	4	4	3	4	4.14		
economicimpact_7	4	5	4	4	5	3	5	4.29		
inaction_7	4	5	4	4	4	1	4	3.71		
inequities_7	3	5	4	4	4	1	2	3.29		
elsissues_7	3	4	4	3	4	1	3	3.14		
newknowledge_7	5	5	5	4	4	3	4	4.29		
healthimpact_8	3	3	5	4	3	5	3	3.71	3.78	15
reducevariation_8	1	2	5	3	3	5	3	3.14		
economicimpact_8	5	3	5	5	5	5	4	4.57		
inaction_8	3	3	4	4	3	3	3	3.29		
inequities_8	5	4	4	4	4	3	4	4.00		
elsissues_8	5	4	5	3	4	1	4	3.71		
new_knowledge_8	4	3	5	4	3	4	5	4.00		
healthimpact_9	5	3	5	2	3	3	5	3.71	3.42	26
reducevariation_9	5	3		2	3	3	5	3.50		
economicimpact_9	5	3	4	2	3	3	5	3.57		
inaction_9	5	3	4	2	3	1	4	3.14		
inequities_9	5	2	4	3	3	1	5	3.29		
elsissues_9	5	2	4	3	3	1	4	3.14		
newknowledge_9	5	2	5	3	3	2	5	3.57		
healthimpact_10	5	4	5	5	5	1	5	4.29	3.71	18
reducevariation_10	5	3	5	3	4	1	3	3.43		
economicimpact_10	5	4	4	5	4	1	4	3.86		
inaction_10	4	3	4	4	4	1	3	3.29		
inequities_10	4	3	5	5	4	1	3	3.57		
elsissues_10	4	3	5	5	4	1	3	3.57		
newknowledge_10	4	4	5	5	5	1	4	4.00		
healthimpact_11	5	4	5	5	3	5	5	4.57	3.90	9
reducevariation_11	5	4	5	4	3	5	3	4.14		
economicimpact_11	5	4	5	4	3	5	3	4.14		
inaction_11	5	3	4	3	3	4	3	3.57		
inequities_11	5	4	5	4	3	1	3	3.57		
elsissues_11	5	4	5	3	3	1	2	3.29		

Domain	ID 1	ID 2	ID 3	ID 4	ID 5	ID 6	ID 7	Domain Average	Item Average	Rank Order
newknowledge_11	5	4	5	4	2	4	4	4.00		
healthimpact_12	5	5	5	5	4	5	5	4.86	4.15	4
reducevariation_12	5	4	4	5	4	5	4	4.43		
economicimpact_12	5	4	5	5	5	5	5	4.86		
inaction_12	5	4	5		4	5	3	4.33		
inequities_12	5	3	5	4	4	1	2	3.43		
elsissues_12	5	3		4	4	1	2	3.17		
newknowledge_12	5	3	4	4	3	5	4	4.00		
healthimpact_13	5	4	4	5	3	4	5	4.29	3.55	22
reducevariation_13	5	4	4	5	3	4	4	4.14		
economicimpact_13	5	3	4	4	3	4	3	3.71		
inaction_13	4	3	4	4	3	3	4	3.57		
inequities_13	4	2	4	4	3	1	2	2.86		
elsissues_13	4	2	4	4	3	1	2	2.86		
newknowledge_13	3	3	4	4	3	4	3	3.43		
healthimpact_14	3	3	5	5	4	4	5	4.14	3.43	24
reducevariation_14	1	3	5	4	4	3	4	3.43		
economicimpact_14	3	3	5	5	4	3	3	3.71		
inaction_14	1	3	5	5	3	2	3	3.14		
inequities_14	1	2	5	5	4	1	2	2.86		
elsiusses_14	3	2	5	5	4	1	2	3.14		
newknowledge_14	2	2	5	5	4	3	4	3.57		
healthimpact_15	5	4	5	5	5	5	5	4.86	4.16	3
reducevariation_15	4	3	4	4	4	3	4	3.71		
economicimpact_15	5	4	4	4	5	5	5	4.57		
inaction_15	5	4	4	4	4	3	4	4.00		
inequities_15	3	3	4	4	4	3	5	3.71		
elsissues_15	3	4	5	5	4	1	5	3.86		
newknowledge_15	3	4	5	5	5	4	5	4.43		
healthimpact_16	5	4	5	5	2	5	5	4.43	3.80	13
reducevariation_16	5	3	5	5	2	5	5	4.29		
economicimpact_16	5	4	4	4	4	5	5	4.43		
inaction_16	5	4	4	4	2	3	4	3.71		
inequities_16	3	3	4	5	2	1	4	3.14		
elsissues_16	5	2	4	4	2	1	4	3.14		
newknowledge_16	2	3	5	4	2	4	4	3.43		
healthimpact_17	5	3	5	4	3	3	4	3.86	3.55	22
reducevariation_17	4	4	5	5	3	2	3	3.71		
economicimpact_17	5	4	5	5	5	3	5	4.57		
inaction_17	2	3	4	4	3	2	4	3.14		
inequities_17	1	2	5	5	4	1	4	3.14		
elsissues_17	1	2	5	4	3	1	4	2.86		
newknowledge_17	2	3	5	4	4	3	4	3.57		

Domain	ID 1	ID 2	ID 3	ID 4	ID 5	ID 6	ID 7	Domain Average	Item Average	Rank Order
healthimpact_18	5	3	5	3	4	3	5	4.00	3.67	21
reducevariation_18	5	3	5	1	4	3	4	3.57		
economicimpact_18	5	3	5	2	4	3	5	3.86		
inaction_18	5	2	4	2	4	2	5	3.43		
inequities_18	5	2	5	2	4	1	5	3.43		
elsissues_18	5	2	5	3	3	1	5	3.43		
newknowledge_18	5	3	5	3	4	3	5	4.00		
healthimpact_19	4	4	5	5	5	5	5	4.71	3.98	7
reducevariation_19	4	3	5	3	4	3	4	3.71		
economicimpact_19	4	3	5	4	4	5	5	4.29		
inaction_19	3	3	4	3	4	2	5	3.43		
inequities_19	3	2	5	4	4	1	5	3.43		
elsissues_19	3	4	5	4	4	1	5	3.71		
newknowledge_19	4	3	5	5	5	5	5	4.57		
healthimpact_20	3	3	5	5	5	5	5	4.43	3.80	13
reducevariation_20	3	5	4	5	4	5	5	4.43		
economicimpact_20	1	4	4	4	4	2	5	3.43		
inaction_20	2	3	4	4	4	1	5	3.29		
inequities_20	2	4	4	4	4	1	5	3.43		
elsissues_20	2	3	5	5	4	1	5	3.57		
newknowledge_20	2	4	5	4	5	3	5	4.00		
healthimpact_21	5	3	5	5	5	5	4	4.57	4.04	5
reducevariation_21	5	4	5	3	4	5	4	4.29		
economicimpact_21	5	3	5	5	4	5	3	4.29		
inaction_21	5	3	5	4	4	3	4	4.00		
inequities_21	3	2	5	4	4	1	3	3.14		
elsissues_21	5	2	5	4	4	1	3	3.43		
newknowledge_21	5	3	5	5	5	5	4	4.57		
healthimpact_22	3	5	5	4	3	5	4	4.14	3.69	20
reducevariation_22	5	4	5	4	2	5	4	4.14		
economicimpact_22	4	4	5	4	4	5	5	4.43		
inaction_22	3	4	5	3	2	5	4	3.71		
inequities_22	1	3	5	4	2	1	4	2.86		
elsissues_22	1	2	5	3	2	1	4	2.57		
newknowledge_22	4	4	5	4	2	5	4	4.00		
healthimpact_23	4	3	4	4	3	3	5	3.71	3.18	31
reducevariation_23	5	3	4	4	2	3	3	3.43		
economicimpact_23	5	2	4	4	4	3	4	3.71		
inaction_23	4	2	3	3	2	2	3	2.71		
inequities_23	2	2	4	4	2	1	3	2.57		
elsissues_23	4	2	4	3	2	1	3	2.71		
newknowledge_23	5	2	4	4	2	3	4	3.43		
healthimpact_24	3	4	5	5	5	5	5	4.57	3.71	18

Domain	ID 1	ID 2	ID 3	ID 4	ID 5	ID 6	ID 7	Domain Average	Item Average	Rank Order
reducevariation_24	4	3	4	4	4	3	4	3.71		
economicimpact_24	3	3	4	4	4	4	4	3.71		
inaction_24	1	3	4	4	4	4	5	3.57		
inequities_24	1	2	4	5	4	1	5	3.14		
elsissues_24	1	2	4	4	4	1	5	3.00		
newknowledge_24	2	3	5	5	5	5	5	4.29		
healthimpact_25	5	3	5	4	5	5	4	4.43	4.03	6
reducevariation_25	5	3	5		5	5	4	4.50		
economicimpact_25	5	4		5	5	5	5	4.83		
inaction_25	5	3	4	3	5	5	5	4.29		
inequities_25	3	2	4	3	5	1	5	3.29		
elsissues_25	3	1	5	3	4	1	3	2.86		
newknowledge_25	5	2	5	3	5	5	3	4.00		
healthimpact_26	4	4	4	5	4	3	4	4.00	3.24	30
reducevariation_26	5	4	4	4	3	5	3	4.00		
economicimpact_26	3	3	3	4	3	3	3	3.14		
inaction_26	3	3	3	4	3	3	3	3.14		
inequities_26	3	3	3	5	3	1	1	2.71		
elsissues_26	2	3	3	5	3	1	1	2.57		
newknowledge_26	1	3	4	5	2	4	3	3.14		
healthimpact_27	5	3	4	5	5	3	3	4.00	3.31	29
reducevariation_27	5	3	3	4	5	2	4	3.71		
economicimpact_27	5	2	3	4	4	2	3	3.29		
inaction_27	3	2	3	3	4	3	3	3.00		
inequities_27	3	2	3	4	5	1	2	2.86		
elsissues_27	3	2	3	4	4	1	1	2.57		
newknowledge_27	3	2	4	4	5	4	4	3.71		
healthimpact_28	1	4	4	5	4	5	3	3.71	3.37	28
reducevariation_28	5	4	3	4	4	5	3	4.00		
economicimpact_28	1	3	3	4	4	5	4	3.43		
inaction_28	2	3	3	4	3	3	3	3.00		
inequities_28	2	2	3	5	4	1	4	3.00		
elsissues_28	2	2	4	4	4	1	4	3.00		
newknowledge_28	1	3	5	4	3	5	3	3.43		
healthimpact_29	3	5	5	5	4	3	5	4.29	3.43	24
reducevariation_29	1	4	4	5	4	3	4	3.57		
economicimpact_29	2	4	4	4	4	3	4	3.57		
inaction_29	2	4	3	4	4	3	4	3.43		
inequities_29	1	3	3	4	4	1	1	2.43		
elsissues_29	1	2	3	5	4	1	2	2.57		
newknowledge_29	2	4	5	5	4	4	5	4.14		
healthimpact_30	5	4	5	5	5	3	3	4.29	3.82	12
reducevariation_30	5	4	5	4	4	3	4	4.14		

Domain	ID 1	ID 2	ID 3	ID 4	ID 5	ID 6	ID 7	Domain Average	Item Average	Rank Order
economicimpact_30	3	3	4	4	4	3	2	3.29		
inaction_30	3	4	4	4	4	2	3	3.43		
inequities_30	5	4	5	5	4	1	3	3.86		
elsissues_30	5	3	5	5	4	1	3	3.71		
newknowledge_30	3	4	5	5	4	4	3	4.00		

Appendix I. Survey 2 Rank-Ordered Results

Rank	Research Need
1	Determine which patients are likely to benefit from surgery.
2	Develop standardized diagnostic criteria.
3	Identify risk associations and women at risk for developing noncyclic chronic pelvic pain.
4	Determine the overall role of surgery.
5	Conduct studies on the management of patients who have failed pharmacologic treatment.
6	Identify the most cost effective diagnostic and management strategies.
7	Conduct studies on cognitive behavior therapy.
8	Standardize diagnostic evaluations including history and physical.
9	Standardize optimal surgical outcomes including followup interval (e.g., long-term outcomes).
10	Determine the accuracies of individual and combined diagnostic tests.
11	Conduct studies on patient education.
12	Determine patient dissatisfaction with care.
13	Document the treatment effect of diagnostic laparoscopy.
13	Conduct studies on provider education.
15	Assess the impact of noncyclic chronic pelvic pain on the use of health services.
16	Collect and analyze data to inform health care utilization and cost relationship.
17	Develop standardized scales to assess quality of life for patients with noncyclic chronic pelvic pain.
18	Conduct studies on self-management.
18	Characterize and document the distribution and prevalence of comorbidities and conditions associated with noncyclic chronic pelvic pain.
20	Determine the optimal timing of surgical intervention.
21	Conduct studies on physiotherapy.
22	Determine optimal followup to assess outcomes following surgical interventions.
22	Determine the direct and indirect costs that contribute to health care expenditures and economic impact.
24	Determine the role of idiopathic causes in the pathophysiology of noncyclic chronic pelvic pain.
24	Determine the role of condition-specific causes (e.g., endometriosis, pelvic adhesions, pelvic congestion, etc.) in the pathophysiology of noncyclic chronic pelvic pain.
26	Determine the role of musculoskeletal evaluations on resource use.
27	Clinician education on communication of laparoscopy results to patients.
28	Characterize the role of the patient-provider relationship on surgical outcomes.
29	Characterize the distribution of symptom components (e.g., dyspareunia, dysmenorrhea, etc.) of noncyclic chronic pelvic pain.
30	Characterize chronic pelvic pain subtypes, including the significance of differentiation between cyclic and noncyclic.
31	Determine the role of surgical or pathologic diagnosis on treatment outcomes.

Notes: Top tier: Items ranked 1–6 (research needs with an overall score above 4.0); Second tier: Items ranked 7–15 (research needs with an overall score of 3.75–3.99)