The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than February 13, 2025.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414. Comments can also be sent electronically to *Comments.applications@chi.frb.org:*

1. *UIR Acceptance Corporation, Lemont, Illinois;* to become a bank holding company by acquiring Easton Bancshares, Inc., and thereby indirectly acquiring Community Bank of Easton, both of Easton, Illinois.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–00599 Filed 1–13–25; 8:45 am]

BILLING CODE 6210–01–P

[11] The maximum penalty amount for an institution is the lesser of this amount or 1 percent of total assets.

[12] The maximum penalty amount for an institution is the lesser of this amount or 1 percent of total assets.

[13] These amounts also apply to CMPs in statutes that cross-reference 12 U.S.C. 1818, such as 12 U.S.C. 2601, 2804(b), 3108(b), 3349(b), 4009(a), 4309(a), 4717(b); 15 U.S.C. 1607(a), 1681s(b), 1691(b), 1691c(a), 1693*o*(a); and 42 U.S.C. 3601.

[14] The maximum penalty amount for an institution is the lesser of this amount or 1 percent of total assets.

[15] The $157-per-day maximum CMP under 12 U.S.C. 1828(h) for failure or refusal to pay any assessment applies only when the assessment is less than $10,000. When the amount of the assessment is $10,000 or more, the maximum CMP under section 1828(h) is 1 percent of the amount of the assessment for each day that the failure or refusal continues.

[16] The maximum penalty amount for an institution is the lesser of this amount or 1 percent of total assets.

[17] The maximum penalty amount for an institution is the greater of this amount or 1/100,000th of the institution's total assets.

[18] The maximum penalty amount for an institution is the greater of this amount or 1/50,000th of the institution's total assets.

[19] The maximum penalty amount for an institution is the lesser of this amount or 1 percent of total assets.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on The Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submission.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *The Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before February 13, 2025.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *The Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine.* AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *The Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/lumbar-spinal-fusion/protocol.*

This is to notify the public that the EPC Program would find the following information on *The Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements, if relevant: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must

be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://effectivehealthcare.ahrq.gov/email-updates.*

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

Questions on Surgery (KQ 1–4)

In adults with symptomatic, stable degenerative lumbar spondylolisthesis (DLS) with or without radiculopathy or neurogenic claudication

- *Key Question 1.* What are the benefits and harms of surgery with instrumentation in addition to decompression compared with decompression alone?

In symptomatic adults with unstable or stable DLS with or without radiculopathy or neurogenic claudication undergoing instrumented fusion:

- *Key Question 2.* What are the benefits and harms of the addition of an interbody cage to instrumentation (*e.g.,* pedicle screws) compared to use of instrumentation alone (*i.e.,* posterolateral fusion)?

- *Key Question 3.* What are the benefits and harms of the use of bone graft extenders and biologic substitutes compared to the use of autografts?

In adults with symptomatic, degenerative lumbar spine disease undergoing instrumented fusion:

- Key Question 4. Does the use of intraoperative monitoring (IONM) decrease perioperative neurological injuries compared with not using IONM?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

TABLE 1—EPC PROPOSED PICOTS AND CORRESPONDING INCLUSION AND EXCLUSION CRITERIA KEY QUESTIONS 1,2,3 AND 4 ON SURGERY

	Inclusion	Exclusion
Population	Key Questions (1–3) • Symptomatic adult patients with a radiographic diagnosis (based on dynamic (flexion and extension radiographs) of degenerative lumbar spondylolisthesis (any grade) who remain symptomatic following conservative treatment • Patients with or without evidence of nerve compression (radiculopathy, neurogenic claudication) KQ 1 • Stable (non-mobile, static) DLS (<3 mm slip on extension/flexion radiographs) KQ 2, 3 • Patients with unstable or stable DLS on radiographs KQ 4 • Patients with symptomatic degenerative lumbar spine disease undergoing fusion of 5 or fewer levels (stratify by presence of DLS)	ALL Key Questions • Patients <18 years old. • Asymptomatic patients. • Other forms of spondylolisthesis are excluded (*i.e.,* excluding dysplastic, isthmic, traumatic, and pathologic causes/forms). • Patients with osteoporosis, vertebral compression fractures. • Exclude pts undergoing revisions or repeat procedures. • Patients having reoperation/repeat procedures. KQs 1–3 • Patients without degenerative spondylolisthesis. • Studies with <80% of patients have spondylolisthesis. KQ 1 • Patients with unstable (dynamic) DLS: (exclude study if stable is not specified, is unclear).
Interventions	ALL Key Questions • FDA approved devices or materials (or in Phase III trials) as applicable to the KQ • Open and minimally invasive (*e.g.,* endoscopic) procedures KQ 1 • Decompression (discectomy, indirect and direct methods) with instrumented spinal fusion (*e.g.,* with pedicle screws, interbody cages, or other hardware) KQ 2 • Surgical decompression and instrumented posterolateral fusion (*e.g.,* using pedicle screws) with addition of interbody cage (expandable or static, ALIF, TLIF, LLIF) KQ 3 • Decompression and spinal fusion using bone graft extenders or biologic substitutes (demineralized bone matrix, cadaveric allograft, cortical fibers, bone morphogenic protein, cellular allografts KQ 4 • IONM (Motor Evoked Potentials (MEP), Somatosensory Evoked Potentials (SSEP), Free Running EMG (electromyography) Direct Stimulation	ALL Key Questions • Devices or materials that are not FDA approved or in Phase III trials (as applicable to the question) or not available in the U.S. • Mesenchymal stem cells (MSCs) • Procedures that don't include decompression • Non-instrumented fusions • Coflex, interspinous fixation • Minimally invasive lumbar decompression (MILD) procedure • Surgical procedures not listed KQ 4 • Other monitoring formats (*e.g.,* imaging, computer assisted navigation systems, etc.) • Combinations of graft materials (other than with autograft) • Comparison of graft materials with each other

TABLE 1—EPC PROPOSED PICOTS AND CORRESPONDING INCLUSION AND EXCLUSION CRITERIA KEY QUESTIONS 1,2,3 AND 4 ON SURGERY—Continued

	Inclusion	Exclusion
Comparators	ALL Key Questions • FDA approved devices or materials (or in Phase III trials) as applicable to the KQ • Open and minimally invasive (*e.g.,* endoscopic) procedures KQ 1 • Decompression alone KQ 2 • Decompression and instrumented posterolateral spinal fusion (*e.g.,* using pedicle screws alone) KQ 3 • Decompression and instrumented spinal fusion using autograft KQ 4 • No use of IONM	ALL Key Questions • Conservative care, non-operative care, usual care • Devices or materials that are not FDA approved or in Phase III trials (as applicable to the question) or not available in the U.S. • Mesenchymal stem cells (MSCs) KQ 1 • Other surgical procedures KQ 2, 3 • Non-instrumented fusion, • Instrumentation prior to 2000 • Coflex, interspinous fixation KQ 3 • Combinations of graft materials with autograft
Outcomes	ALL Key Questions • Validated measures for pain and symptoms ○ Pain (*e.g.,* VAS) ○ Function (*e.g.,* ODI) ○ Quality of Life (*e.g.,* SF–36, SF–12) • Peri- and post-operative harms (including serious AEs/harms, persistent pain, sacro-iliac joint pain, instrument failure) Additional outcomes by KQ KQ 1: Reoperation rates KQ 2: Fusion (arthrodesis) rates KQ 3: Fusion (arthrodesis) rates KQ 4: Persistent neurological damage based on clinical exam (*e.g.,* foot drop)	ALL Key Questions • Measures of pain, function that are not validated • Measures/outcomes not listed • Radiographic parameters (*e.g.,* evidence of global spinal alignment)
Timing	Key Questions 1–3 • Pain, function, reoperation: 3, 6 and ≥12 months (up to 60 months) • Reoperation-any time (KQ 2): • Harms: any time KQ 4 • Any time during post-operative followup	KQ 1 • Re-operation beyond 12 months KQs 1–3 • Outcomes measured less than 3 months (except harms) KQ 4 • Alerts and responses to alerts during surgery
Settings	ALL Key Questions • Inpatient care followed by care in specialty and primary care clinics • Outpatient ambulatory surgery centers	
Study designs	ALL Key Questions • RCTs for effectiveness/efficacy outcomes • FDA SSED if there is inadequate information from published studies • Studies published in 2000 or later KQ 1–3: NRSIs will be considered for harms only and must be specifically designed to evaluate/report on AE/harms and control for confounding and focused on rare or long-term harms. KQ 4: NRSIs on effectiveness and harms	ALL Key Questions • NRSI that do not control for confounding • NRSI that include historical controls • NRSI of treatment with fewer than 50 patients per treatment arm • Case reports, case-series, single-arm and pre-post studies • Publication types: Conference abstracts or proceedings, editorials, letters, white papers, citations that have not been peer-reviewed, single site reports of multi-site studies • Studies published prior to 2000 • Studies not in English KQ 1–3 • Trials with fewer than 15 patients per treatment arm

Serious adverse events are defined as events that are life-threatening or require additional medical attention. AE = adverse event; ALIF = anterior lumbar interbody fusion; DLS = degenerative lumbar spondylolisthesis; EQ–5D = EuroQol 5D scale; FDA = Food and Drug Administration; IONM = intraoperative neurological monitoring; KQ = Key Question; LLIF = lateral lumbar interbody fusion; MCID = minimum clinically important difference; NRSI = nonrandomized studies of intervention; ODI = Oswestry Disability Index; RCT = randomized controlled trial; RMD = Roland-Morris Disability Questionnaire; SSED = Summary of Safety and Effectiveness Data; SF–36/12 = Short Form 36 or 12 questionnaire; TLIF = transforaminal lumbar interbody fusion; U.S. = United States; VAS = visual analog scale.

KQ 5 and 6: Questions on Non-Surgical Procedures for Chronic Low Back Pain Due To Degenerative Spine Disease

Key Question 5. In adult patients with chronic low-back pain (≥3 months) resulting from degenerative disease what are the benefits and harms of lumbar epidural steroid injections, intra-articular (facet) injection, medial branch blocks, or radio frequency ablation?

Key Question 6. In adult patients with chronic low-back pain (≥3 months) resulting from degenerative disease of the lumbar spine, does symptomatic improvement to therapeutic challenge with lumbar epidural steroid injections, intra-articular (facet) injection, medial branch blocks or radio frequency ablation predict positive outcomes after lumbar fusion surgery?

Special populations and factors for Key Questions 5 and 6: Age, sex, BMI, presence of psychological comorbidities, presence of medical comorbidities, baseline pain severity, presence and type of concomitant degenerative lumbar spine disease, presence and severity of DLS.

TABLE 2—EPC PROPOSED PICOTS AND CORRESPONDING INCLUSION AND EXCLUSION CRITERIA: KEY QUESTIONS 5 AND 6 ON SPECIFIC PROCEDURES IN PATIENTS WITH CHRONIC LOW BACK PAIN DUE TO DEGENERATIVE SPINE DISEASE

	Inclusion	Exclusion
Population	KQ 5, 6 • Adult patients with chronic low-back pain (≥3 months duration) resulting from degenerative disease	KQ 5, 6 • Patients with acute or subacute LBP • Patients with disc herniation • Patients with failed back surgery syndrome • Sacroiliac pain • Patients having reoperation
Interventions	KQ 5, 6 • Epidural steroid injections (ESI) • Intra-articular (facet) injections • Radiofrequency Ablation (RFA) • Medial branch blocks	KQ 5, 6 • Discoblock, provocative discography • Neuromodulation (*e.g.,* spinal cord, dorsal column, dorsal root stimulation, peripheral nerve stimulation) • Injections: exclude other biologics (*e.g.,* PRP), intradiscal injections • Minimally invasive lumbar decompression (MILD), percutaneous decompression • Selective nerve root blocks • Intraosseous basivertebral nerve ablation • Combinations of procedures; Studies evaluating additive benefits of one procedure with another
Comparators	KQ 5 • Other nonoperative treatment, no treatment, sham KQ 6 • No therapeutic challenge; (prognostic/predictive modeling study)	KQ 5, 6 • Combinations of procedures; Studies evaluating additive benefits of one procedure to another KQ 5 • For ESI, exclude comparison with disc procedures (*e.g.,* discography); comparisons of medications • For RFA exclude comparisons of different types of neurotomy (conventional vs. pulsed [cooled] RF; RF vs. alcohol ablation)
Outcomes	KQ 5 and 6: Harms (*e.g.,* serious peri-procedural and post-procedural harms) KQ 5 • Validated measures for pain and symptoms ○ Pain (*e.g.,* VAS, NRS) ○ Function (*e.g.,* ODI) ○ Quality of Life (*e.g.,* SF–36, SF12) KQ 6 • Response to challenge: Improvement in symptoms vs. non-improvement; [stratify other outcomes by response] • Validated measures for pain and symptoms following fusion surgery ○ Pain (*e.g.,* VAS, NRS) ○ Function (*e.g.,* ODI) ○ Quality of Life (*e.g.,* SF–36, SF–12) ○ Symptoms associated with neural compression • Successful arthrodesis [as radiographically determined via x-ray/computed tomography or by proxy (*e.g.,* lack of revision, pedicle screw loosening)]	KQ 5, 6 • Measures of pain, function that are not validated • Measures/outcomes not listed
Timing	KQ 5 and 6 • Serious harms—periprocedural KQ 5 • 3-month and 6-month periods following the procedure KQ 6 • Outcomes measured at 3, 6 and ≥12 months after surgical procedure (up to 24 months)	
Settings	KQ 5 • Outpatient KQ 6 • Outpatient care for therapeutic challenge. Inpatient care followed by care in specialty and primary care clinics for surgical procedure • Outpatient ambulatory surgery centers for surgery	

TABLE 2—EPC PROPOSED PICOTS AND CORRESPONDING INCLUSION AND EXCLUSION CRITERIA: KEY QUESTIONS 5 AND 6 ON SPECIFIC PROCEDURES IN PATIENTS WITH CHRONIC LOW BACK PAIN DUE TO DEGENERATIVE SPINE DISEASE—Continued

	Inclusion	Exclusion
Study designs	KQ 5 • RCTS for effectiveness/efficacy outcomes • Prospective NRSIs that control for confounding will be considered for effectiveness in the absence of RCTs • NRSIs for harms must be specifically designed to evaluate/report on serious AE/harms and that control for confounding OR focused on rare or long-term harms KQ 6 • Predictive/prognostic modeling studies evaluating the association of procedure response impact on outcomes that control for confounding	KQ 5, 6 • NRSI that do not control for confounding • NRSI that include historical controls • NRSI with fewer than 50 patients per treatment arm • Case reports, case-series, single-arm and pre-post studies • Publication types: Conference abstracts or proceedings, editorials, letters, white papers, citations that have not been peer-reviewed, single site reports of multi-site studies • Studies not in English

Serious adverse events are defined as events that are life-threatening or anything needing additional medical attention. AE = adverse event; DLS = degenerative lumbar spondylolisthesis; EQ–5D = EuroQol 5D scale; ESI = epidural steroid injection; FDA = Food and Drug Administration; IONM = intraoperative neuro monitoring; KQ = Key Question; LBP = low back pain; MCID = minimum clinically important difference; NRSI = nonrandomized studies of intervention; ODI = Oswestry Disability Index; RCT = randomized controlled trial; RF = radiofrequency ablation; RMD = Rolland-Morris Disability Questionnaire; SSED = Summary of Safety and Effectiveness Data; SF–36/12 = Short Form 36 or 12 questionnaire; VAS = visual analog scale.

Dated: January 7, 2025.

Marquita Cullom,

Associate Director.

[FR Doc. 2025–00548 Filed 1–13–25; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submission.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before February 13, 2025.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, *Attn:* EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, *Attn:* EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review.*

AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/hypofractionated-radiation-therapy/protocol.*

This is to notify the public that the EPC Program would find the following information on *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements, if relevant: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying