

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule (PDF file, 450 KB. PDF Help) relating to the listing and operation of PSOs. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs. AHRQ has accepted a notification from HealthWatch, Inc., PSO number P0010, which is a component entity of Quality Health Strategies, Inc., to voluntarily relinquish its status as a PSO. Accordingly, HealthWatch, Inc. was delisted effective at 12 Midnight ET (2400) on November 1, 2011.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: November 16, 2011.

Carolyn M. Clancy,
Director.

[FR Doc. 2011-30798 Filed 11-30-11; 8:45 a.m.]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Pressure Ulcer Treatment Medical Devices

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

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of pressure ulcer treatment medical devices, such as (but not limited to): Ultrasonic wound care systems, negative pressure therapy units, turning & positioning systems, special mattresses, mattress covers, pillows, cushions, etc. Scientific information is being solicited to inform our Pressure Ulcer Treatment Strategies: A Comparative Effectiveness Review, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and

unpublished pertinent scientific information on these devices will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

DATES: Submission Deadline on or before January 3, 2012.

ADDRESSES: Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/>. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents. Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239-3098.

FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Research Librarian, Telephone: (503) 494-0147 or Email: ehcsrc@ohsu.edu.

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for pressure ulcer treatment strategies.

The EHC 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 systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on pressure ulcer treatment strategies, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: <http://effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=838#3870>.

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: 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 withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.

- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program Web site 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: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The Key Questions

A preliminary set of KQs was posted on the Effective Health Care Program Web site of the Agency for Healthcare Research and Quality (AHRQ), and public comments were collected and evaluated.

A Summary of the Public Comments

Most of the public comments addressed specific patient or treatment characteristics and settings. Commenters suggested that the review

should address combinations of treatments, co-morbid conditions, and ulcer characteristics that require an individualized approach to treatment. These comments led us to expand the potential range of treatments evaluated in the review. Because treatment goals for patients in hospice care differ widely from patients with pressure ulcers in other settings (wound healing may not be a goal of hospice care), we excluded hospice from the list of care settings to be reviewed. The final set of KQs is as follows:

Final Key Questions

Question 1

In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: Complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?

Question 1a

Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

Question 1b

Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: Age; race/ethnicity; body weight; specific medical co-morbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Question 1c

Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

Question 2

What are the harms of treatments for pressure ulcers?

Question 2a

Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

Question 2b

Do the harms of treatment strategies differ according to patient characteristics, including: Age, race/ethnicity; body weight; specific medical

co-morbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Question 2c

Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

The following PICOTS were identified for each KQ and include:

Population

- Adults ages 18 and older with pressure ulcers.

Interventions

- Various treatment strategies for pressure ulcers including but not limited to therapies that address the underlying contributing factors (e.g., support surfaces and nutritional supplements); therapies that address local wound care (e.g., absorbent wound dressings and biological agents); surgical repair; and adjunctive therapies (e.g., physical therapy).

- Combined treatment modalities (co-interventions) will also be evaluated (such as comparing two treatments in combination with a single treatment).

Comparators

- Placebo or active control, usual care, or other interventions.

Outcomes

- For effectiveness: Complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection.
- For harms of treatment: Pain, dermatologic complications, bleeding, and infection.

Timing

- Any duration of follow-up.

Settings

- Patient care settings, such as home, nursing facility, or hospital.

Dated: November 16, 2011.

Carolyn M. Clancy,

AHRQ, Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0327]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-3794, Jonnalynn.Capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On May 26, 2011, the Agency submitted a proposed collection of information entitled "Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0697. The approval expires on November 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: November 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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