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 knows 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.

[FR Doc. 2011–30796 Filed 11–30–11; 8:45 am]

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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.

[FR Doc. 2011–30877 Filed 11–30–11; 8:45 am]

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