



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Malnutrition in Hospitalized Adults

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

ACTION: Request for supplemental evidence and data submissions.

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 *Malnutrition in Hospitalized Adults*, 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

E-mail 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.):

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5600 Fishers Lane

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FOR FURTHER INFORMATION CONTACT:

Jenae Benms, Telephone: 301-427-1496 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 Malnutrition in Hospitalized Adults. AHRQ is conducting this systematic 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 *Malnutrition in Hospitalized Adults*, including those that describe adverse events. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/malnutrition-hospitalized-adults/protocol>

This is to notify the public that the EPC Program would find the following information on *Malnutrition in Hospitalized Adults* helpful:

- A list of completed studies that your organization has sponsored for this indication. 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: 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 indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including 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 indication 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 indications 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 e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic 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 (KQs)

Key Question 1. What is the association between malnutrition and clinical outcomes among hospitalized patients?

- a. How do outcomes vary depending on measures or tools used to detect malnutrition?

- b. Are patient-related risk factors, such as increased age or certain pre-existing health conditions, associated with poorer clinical outcomes?

Key Question 2. What is the effectiveness of screening or diagnostic assessment for malnutrition among hospitalized adults?

- a. In studies that report on clinical outcomes, what is the diagnostic accuracy of screening or diagnostic assessment for malnutrition?
- b. In studies that report on clinical outcomes, what is the effectiveness of screening or diagnostic assessment on measures of nutrition (nutritional stores)?
- c. What is the impact of screening or diagnostic assessment on clinical outcomes?

Key Question 3. Among patients diagnosed with malnutrition, what is the effectiveness of hospital-initiated interventions used to treat malnutrition on clinical outcomes?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Category	Definition
Population	<p>Key Question 1 and 2: Hospitalized adults aged 18 years or older (see Methods section for exceptions).</p> <p>Key Question 1b subgroups include adults with no risk of malnutrition, adults with risk of malnutrition, and adults with baseline malnutrition. Risk factors of interest to this report include:</p> <ul style="list-style-type: none"> • Older patients (>65 years) • Racial and ethnic minorities • Low income (e.g. Medicaid beneficiaries) • Patients with malignancy • Patients with gastrointestinal disease and subsequent malabsorption, including ulcerative colitis and Crohn’s disease • Patients with chronic liver disease • Patients with stroke • Patients with chronic kidney disease • Patients with dementia

Category	Definition
	<ul style="list-style-type: none"> • Patients with critical illness • Sepsis/infection <p>Key Question 3: Adults diagnosed with protein-energy malnutrition.</p>
<p>Interventions/ Exposures</p>	<p>Key Question 1: Positive screening for nutrition risk and/or diagnosis of malnutrition vs no malnutrition.</p> <p>Key Question 2: Malnutrition screening and diagnostic assessment tools (utilized within the U.S., Australia, New Zealand, Canada, and Europe). Examples of tools of interest include:</p> <p><u>Screening</u></p> <ul style="list-style-type: none"> • Malnutrition Screening Tool (MST) • Malnutrition Universal Screening Tool (MUST) • Nutritional Risk Index (NRI) • Nutrition Risk in Critically Ill (NUTRIC) score <p><u>Diagnostic Assessment</u></p> <ul style="list-style-type: none"> • Subjective Global Assessment (SGA) • Patient Generated Subjective Global Assessment (PS-SGA) • Mini Nutritional Assessment (MNA) • AND (Academy of Nutrition and Dietetics)-ASPEN (American Society for Parenteral and Enteral Nutrition) Malnutrition Consensus Criteria (MCC) • Global Leadership Initiative on Malnutrition (GLIM) <p>Key Question 3: Hospital-initiated malnutrition interventions. Examples of interventions include:</p> <ul style="list-style-type: none"> • Parenteral nutrition • Enteral nutrition • Oral nutrition supplements • Nutrition team consultation, includes dietitian counseling • Pharmacologic interventions
<p>Comparators</p>	<p>Key Question 1: Hospitalized patients without malnutrition, or direct comparisons of different definitions of malnutrition.</p> <p>Key Questions 2: Radiographic imaging or SGA will be used as the reference standard.</p> <p>Key Question 3: Usual care or another hospital-initiated malnutrition-related intervention.</p>

Category	Definition
Outcomes	<p data-bbox="378 184 776 216"><u>Clinical Outcomes (All Key Questions)</u></p> <ul data-bbox="427 247 1373 793" style="list-style-type: none"> <li data-bbox="427 247 784 279">• Mortality (inpatient and 30-day) <li data-bbox="427 310 613 342">• Length of stay <li data-bbox="427 373 662 405">• 30-day readmission <li data-bbox="427 436 613 468">• Quality of life <li data-bbox="427 499 1373 531">• Functional status, includes gate speed, Karnofsky Index, handgrip strength, days on ventilator <li data-bbox="427 562 646 594">• Activities of daily <li data-bbox="427 625 824 657">• Hospital Acquired Condition (HAC) <li data-bbox="427 688 621 720">• Wound healing <li data-bbox="427 751 686 783">• Discharge disposition <p data-bbox="378 825 699 856"><u>Intermediate Outcomes (KQ 2)</u></p> <p data-bbox="378 888 675 919">Diagnostic accuracy outcomes</p> <ul data-bbox="427 951 675 1182" style="list-style-type: none"> <li data-bbox="427 951 581 982">• Sensitivity <li data-bbox="427 1014 581 1045">• Specificity <li data-bbox="427 1077 630 1108">• Predictive value <li data-bbox="427 1140 675 1171">• Area under the curve <p data-bbox="378 1203 789 1234"><u>Intermediate Outcomes (KQ 2 or KQ 3)</u></p> <p data-bbox="378 1266 1349 1297">Nutrition Stores: Direct measures of nutrition status (nutrition stores) during and post hospitalization.</p> <p data-bbox="378 1329 557 1360">Examples include:</p> <ul data-bbox="427 1392 1422 1665" style="list-style-type: none"> <li data-bbox="427 1392 1105 1423">• Cross-sectional areas for lumbar skeletal muscle and adipose tissue <li data-bbox="427 1455 678 1486">• Skeletal Muscle Index <li data-bbox="427 1518 1422 1665">• Regional or total fat mass and muscle mass assessed using validated gold standard methods, such as body composition measures derived through Computed Tomography (CT) scans, Dual X-ray Absorptiometry (DXA), and Magnetic Resonance Imaging (MRI)
Timing	Up to 30 days post-discharge
Setting	Acute care hospitalizations

Dated: November 5, 2020.

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Associate Director.

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