Effective Health Care

Diagnosis of Treatable Anemia in Pre-operative Patients

Results of Topic Selection Process & Next Steps

The nominator, the College of American Pathologists (CAP), is interested in a new evidence review on the diagnosis of treatable anemia in pre-operative patients to develop new clinical practice guidelines.

Due to limited program resources, the program is unable to develop a review at this time. No further activity on this nomination will be undertaken by the Effective Health Care (EHC) Program.

Topic Brief

Topic Name: #0800 Diagnosis of Treatable Anemia in Pre-Operative Patients

Nomination Date: 06/29/2018

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Background

Anemia is common concern among patients undergoing surgery. Depending on the underlying disease condition and type of surgery contemplated, the prevalence of anemia ranges from 10-55%.[1-3] The presence of anemia among preoperative patients increases the risk for allogeneic blood transfusions (ABT) during the perioperative period as well as the risk for unfavorable surgical outcomes.[4-6] ABT in and of itself puts the patient at risk for significant complications.[7,8] In addition, ABT is not cheap. Studies show that mean cost for one unit of red blood cells purchased from a supplier was $211 and the mean charge to the patient was $344.[9]

The most common causes for anemia among preoperative surgical patients is iron-deficiency anemia and anemia of chronic inflammation with or without chronic kidney disease (55-87% of preoperative patients with anemia).[1-3] These conditions have been collectively termed as “iron-responsive” or “treatable” as supplementation by iron either orally or parenterally can help correct the anemia and allow for a safer surgical procedure for the patient.[10] In addition, patients can also be treated using erythropoiesis stimulating agents such as recombinant human erythropoietin.

Medical societies all agree about the need for detecting anemia in the preoperative period so treatments can be instituted in a timely manner.[11-13] Recently, organized programs called patient blood management programs (PBMs) were established to minimize the need for transfusion and reduce the risk for adverse outcomes among surgical patients.[14,15] Of note, PBMs designate tests and procedures in the preoperative, intraoperative, and postoperative settings. Thus, detection and correction of iron-responsive anemia is just one component of a broader program.

Several aspects of how best to diagnose iron-responsive anemia however are unclear. Whether diagnosis of iron-responsive anemia by laboratory-organized PBMs leads to less ABTs and better clinical outcomes compared to diagnosis at the provider level is not known. Efficiency of panel testing versus sequential testing has not been compared. Lastly, the optimal cut-off hemoglobin levels to begin iron therapy, the target values after correction, and whether these targets should be differentially set based on gender are unclear. Of note, establishment of PBMs requires money.[16] Thus, examining the evidence on clinical outcomes in the context of resources expended will be a consideration for institutions contemplating PBM implementation.

Nominator and Stakeholder Engagement: The nominator, the College of American Pathologists (CAP), is in need of a systematic review to serve as the basis of a new clinical practice guideline that will focus on accurate diagnosis of treatable anemia in pre-operative patients (See Appendix C). Based on a search of clinical practice guidelines on the CAP website revealed that they do not have an existing guideline on this topic. Note that CAP’s overarching goal is to tackle all causes of anemia in the future as well as other components (perioperative and postoperative) of PBMs but they recognize that it is a very comprehensive topic and they thus opted to address the larger overarching topic piecemeal.

Key Questions and PICOTS

The key questions for this nomination are:

Key Question 1: What is the effectiveness of the preoperative component of patient blood management programs on reducing transfusions among adult patients undergoing elective surgery?

> a. What is the effect of preoperative evaluation for chronic kidney disease and/or inflammatory conditions as part of a patient blood management program on the need for transfusion among adult patients undergoing elective surgery?

Key Question 2: What is the effect of different preoperative target hemoglobin levels on the need for perioperative transfusion among adult patients with iron-responsive anemia undergoing elective surgery?

a. Does the effect of different preoperative target hemoglobin levels differ between men and women?

Key Question 3: What is the comparative accuracy of different laboratory testing strategies for detecting iron-responsive anemia among adult patients undergoing elective surgery?

To define the inclusion criteria for the key questions we specify the population, interventions, comparators, outcomes, timing, and setting (PICOTS) of interest (Table 1).

Table 1. Key Questions and PICOTS

	KQ1: Patient Blood Management Program	**KQ2: Target Hemoglobin Levels**	**KQ3: Laboratory Testing Strategies**
Population	Adult patients undergoing elective surgery	Adult patients undergoing elective surgery with iron-responsive anemia (i.e. patients with iron deficiency anemia and anemia of chronic disease with iron deficiency)	Adult patients undergoing elective surgery
Interventions	[1] PBM program (focus on preoperative component usually involving a laboratory algorithm) [1a] Pre-operative evaluation of CKD and inflammatory conditions (as part of PBM program)	Specified preoperative target hemoglobin levels *Include: Non-PBM approaches*	Any diagnostic strategy including single tests, combined tests, reflex tests, laboratory algorithms for identifying patients with iron-responsive anemia *Include: Non-PBM approaches*

	KQ1: Patient Blood Management Program	KQ2: Target Hemoglobin Levels	KQ3: Laboratory Testing Strategies
Comparators	Standard of care (no PBM program)	[2] Different target levels compared to each other [2a] Male vs. female gender	Specific diagnostic tests/strategies/approaches compared to each other Comparison or interest: - *panel vs. cascade/ sequential testing*
Outcomes	Primary: Need for allogeneic transfusion; number of transfusions Secondary: Postoperative anemia, postoperative infection, ischemic events, mortality, length of stay, delay of surgery, cost comparison, adverse events	Primary: Need for allogeneic transfusion; number of transfusions Secondary: Postoperative anemia, postoperative infection, ischemic events, mortality, length of stay, delay of surgery, adverse events	Accuracy of diagnostic tests/strategies/ approaches in identifying iron-responsive patients including sensitivity, specificity, positive predictive value, negative predictive value, AUC, adverse events
Timing	Pre-operative (intervention); peri-operative/immediate post-operative (outcomes)	Pre-operative (intervention); peri-operative/immediate post-operative (outcomes)	Pre-operative
Setting	Hospital (out- and in-patient)	Hospital (out- and in-patient)	Hospital (out-patient)

Abbreviations: PBM=patient blood management; CKD=chronic kidney disease; AUC=area under the receiver-operator characteristics curve

Methods

We assessed nomination 0800 Diagnosis of Treatable Anemia in Pre-operative Patients, for priority for a systematic review or other AHRQ EHC report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix A for detailed description of the criteria.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years on the key questions of the nomination. See Appendix B for sources searched.

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of a New Evidence Review

We conducted a literature search in PubMed from August 2013 and August 2018. To increase our specificity, we conducted separate searches for each KQ. The number of citations resulting from each KQ-specific search was less than 300 (82 for KQ1, 14 for KQ2, and 23 for KQ3). Thus, all abstracts for these citations were reviewed for potential inclusion in a systematic review. Recognizing that the evidence base for a clinical topic likely grows exponentially over time, the size of a new systematic review was estimated by doubling the number of abstracts found to be relevant to KQs. See Table 2, Feasibility Column, Size/Scope of Review Section for the citations of included studies. See Appendix C for the PubMed search strategy and links to the ClinicalTrials.gov search.

Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change; and if a partner organization would use this evidence review to influence practice.

Results

See Appendix A for detailed assessments of all EPC selection criteria.

Appropriateness and Importance

This is an appropriate and important topic. This topic represents important uncertainty for decision makers as well as significant cost burden in the United States due to the high cost of blood transfusions and processing of blood products.

Desirability of a New Review/Duplication

We did not find any high-quality systematic reviews that addressed the three KQs. See Table 2, Duplication column.

Impact of a New Evidence Review

A new systematic review may have high impact as the procedures employed by PBM programs in detecting and managing iron-responsive anemia vary by institution.

Feasibility of New Evidence Review

We found 11 studies that were relevant to KQ1[17-27] and one randomized controlled trial (RCT) that were relevant to KQ2.[28] All KQ1-relevant studies employed an observational study design. The RCT related to KQ2 specifically examined preoperative hemoglobin and outcomes in patients with chronic kidney disease undergoing cardiac surgery. No studies were found that was relevant to KQ3.

We also found one prospective non-randomized trial on ClinicalTrials.gov relevant to KQ1. We found no trials relevant to KQ2 and KQ3. See Table 2 and Appendix C for hyperlinks.

As PBM programs are complex, one consideration potentially impacting feasibility is a literature base wherein studies may not report the level of detail needed to tease out information specifically related to just the anemias treatable with iron supplementation, which may pose a challenge to the EPC. Also, algorithms employed by PBM programs do not have specific names which imposes further challenges to literature searches.

Table 2. Key Questions and Results for Duplication and Feasibility

Key Question	Duplication (08/2015-04/2018)	Feasibility (08/2013-08/2018)
KQ1: Patient Blood Management Program	Total number of identified systematic reviews: 0	Size/scope of review Relevant Studies Identified: 11 • RCT – 0 • Observational studies – 11[17-27] Clinicaltrials.gov • Recruiting: 1
KQ2: Target Hemoglobin Levels	Total number of identified systematic reviews: 0	Size/scope of review Relevant Studies Identified: 1 • RCT – 1[28] Clinicaltrials.gov • None

Key Question	Duplication (08/2015-04/2018)	Feasibility (08/2013-08/2018)
KQ3: Laboratory Testing Strategies	Total number of identified systematic reviews: 0	Size/scope of review Relevant Studies Identified: 0 Clinicaltrials.gov • None

Abbreviations: KQ=Key Question; RCT=Randomized Controlled Trial

Value

The potential for value is high. The nominator had identified additional partner societies who may use a new systematic review for guideline development.

Summary of Findings

- Appropriateness and importance: The topic is both appropriate and important.
- Duplication: A new review would not be duplicative of an existing product. We found no published or in-process systematic reviews that address the KQs.
- Impact: A new systematic review would have high impact potential.
- Feasibility: A new review is feasible. The evidence base is likely limited to small.
- Value: The potential for value is high.

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Appendix A. Selection Criteria Summary

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes, this topic represents interventions available in the U.S.
1b. Is the nomination a request for a systematic review?	Yes, this topic is a request for a systematic review.
1c. Is the focus on effectiveness or comparative effectiveness?	The focus of this review is on both effectiveness and comparative effectiveness.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes, it is biologically plausible. Yes, it is consistent with what is known about the topic.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes, this topic represents a significant burden in a large proportion of the US population.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes, this topic affects heath care decisions with significant cost differences based on choice of treatment intervention. Clinical outcomes may vary as well.
2c. Represents important uncertainty for decision makers	Yes, this topic represents important uncertainty for decision makers.
2d. Incorporates issues around both clinical benefits and potential clinical harms	Yes, this nomination addresses both benefits and potential clinical harms.
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes, the mean cost for one unit of red blood cells purchased from a supplier was $211 and the mean charge to the patient was $344.
3. Desirability of a New Evidence Review/Duplication	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	Yes, a new systematic review would not be redundant. We did not find any systematic reviews that address the KQs.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Yes, the characteristics and standard procedures employed by PBMs vary by institution (ex. some employ a panel of test while others use a sequential cascade of tests). There is also a greater uptake of formal PBM programs in large hospitals compared to smaller community hospitals. Certification programs exist but are voluntary.* The optimal processes to increase accuracy and improve outcomes but keep cost low is unclear.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Yes, recommendations among societies and international guideline groups (such as the AABB and the Joint Commission**) vary leading to practice variation. This includes variation in employment of PBMs vs. provider-level management where additional practice variation exists.
5. Primary Research	

Selection Criteria	Assessment
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	*Size/scope of review:* We estimate that the total size of the relevant literature may be approximately 24 studies across the three key questions (low confidence). The scope of the review is likely limited to small. *ClinicalTrials.gov*: We found one prospective non randomized trial relevant to KQ1.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes, this topic will inform clinical decision-making on managing patients with iron-responsive anemia undergoing surgery.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes, CAP will use a systematic review to formulate a new guideline. Moreover, CAP has identified potential partner societies including ASH and AACC. They will work closely with these organizations and several other stakeholder organizations to promote dissemination of the AHRQ report's findings.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; KQ=Key Question; CAP= College of American Pathologists; AABB=American Association of Blood Banks; ASH=American Society of Hematology; AACC=National Academy of Clinical Biochemistry

* *http://www.aabb.org/press/Pages/pr160127.aspx*

** *https://www.jointcommission.org/standards_information/pbm_requirements.aspx*

Appendix B. Search for Evidence Reviews (Duplication)

Listed are the sources searched.

AHRQ: Evidence reports and technology assessments, USPSTF recommendations
VA Products: PBM, and HSR&D (ESP) publications, and VA/DoD EBCPG Program
Cochrane Systematic Reviews and Protocols http://www.cochranelibrary.com/
PubMed
PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/

Appendix C. Search Strategy & Results (Feasibility)

Topic: Diagnosis of Treatable Anemia in Pre-Operative Patients
Date: August 1, 2018
Database Searched: PubMed
Limited to last 5 years, English language

CONCEPT	SEARCHES
Key Question 1	
Elective surgery Preoperative	((preoperative[Title/Abstract] OR pre-operative[Title/Abstract] OR "pre operative"[Title/Abstract])) OR (("Elective Surgical Procedures"[Mesh]) OR ("Perioperative Care"[Mesh] OR "Perioperative Period"[Mesh] OR "surgery" [Subheading]))
AND	
Anemia	(anemia[Title/Abstract]) OR "Anemia"[Mesh]
AND	
Patient blood management	(("Patient blood management") OR PBM[Title/Abstract]) OR (("blood management"[Title/Abstract]) AND (patient[Title/Abstract] OR advanced[Title/Abstract] OR advanced[Title/Abstract] OR transfusion[Title/Abstract]))
AND	
Systematic Review	systematic[sb]
N=4	
RCT (Cochrane Sensitive Hedge for PubMed)	((((((((groups[tiab])) OR (trial[tiab])) OR (randomly[tiab])) OR (drug therapy[sh])) OR (placebo[tiab])) OR (randomized[tiab])) OR (controlled clinical trial[pt])) OR (randomized controlled trial[pt])
N=20	
Other	
N=58	
Key Question 2	
Elective surgery Preoperative	((preoperative[Title/Abstract] OR pre-operative[Title/Abstract] OR "preoperative"[Title/Abstract])) OR (("Elective Surgical Procedures"[Mesh]) OR ("Perioperative Care"[Mesh] OR "Perioperative Period"[Mesh] OR "surgery" [Subheading]))
AND	
Anemia	(anemia[Title/Abstract]) OR "Anemia"[Mesh]
AND	
Target hemoglobin levels	(Hemoglobin[Title/Abstract]) AND (level[Title/Abstract] OR levels[Title/Abstract] OR target[Title/Abstract] OR targets[Title/Abstract] OR goal[Title/Abstract] OR goals[Title/Abstract] OR index[Title/Abstract])
AND	
Systematic Review	systematic[sb]
N=0	
RCT (Cochrane Sensitive Hedge for PubMed)	((((((((groups[tiab])) OR (trial[tiab])) OR (randomly[tiab])) OR (drug therapy[sh])) OR (placebo[tiab])) OR (randomized[tiab])) OR (controlled clinical trial[pt])) OR (randomized controlled trial[pt])
N=5	
Other	
N=9	
Key Question 3	

CONCEPT	SEARCHES
Elective surgery Preoperative	((preoperative[Title/Abstract] OR pre-operative[Title/Abstract] OR "preoperative"[Title/Abstract])) OR (("Elective Surgical Procedures"[Mesh]) OR ("Perioperative Care"[Mesh] OR "Perioperative Period"[Mesh] OR "surgery" [Subheading]))
AND	
Anemia	(anemia[Title/Abstract]) OR "Anemia"[Mesh]
AND	
Laboratory Testing Strategies	("Clinical Laboratory Services"[Mesh]) OR ((laboratory tests[Title/Abstract] OR laboratory test[Title/Abstract] OR lab tests[Title/Abstract] OR lab test[Title/Abstract] OR lab testing[Title/Abstract] OR laboratory testing[Title/Abstract]))
AND	
Systematic Review	systematic[sb]
N=0	
RCT (Cochrane Sensitive Hedge for PubMed)	(((((((groups[tiab])) OR (trial[tiab])) OR (randomly[tiab])) OR (drug therapy[sh])) OR (placebo[tiab])) OR (randomized[tiab])) OR (controlled clinical trial[pt])) OR (randomized controlled trial[pt])
N=7	
Other	
N=16	

ClinicalTrials.gov

31 studies found for: “surgery” and “blood management” (relevant trials broken down by KQ below)
https://clinicaltrials.gov/ct2/results?cond=surgery+blood+management+&term=&cntry=&state=&city=&dist=&Search=Search

KQ 1 (Patient Blood Management Program)

Prospective non-randomized trial using a before vs. after design (recruiting)
https://clinicaltrials.gov/ct2/show/NCT02147795?cond=surgery+blood+management&lupd_s=08%2F01%2F2013&lupd_e=08%2F01%2F2018&rank=5

KQ 2 (Target Hemoglobin Levels)

None

KQ3 (Laboratory Testing Strategies)

None