DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock

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 *Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 December 26, 2024.

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 *Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock.* 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 *Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/ems-blood-transfusion/protocol.*

This is to notify the public that the EPC Program would find the following information on *Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock* 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)

KQ 1

a. What are the benefits and harms of transfusion of whole blood for patients requiring prehospital hemorrhagic shock resuscitation?

b. Are the benefits and harms modified by:

i. EMS protocols (including but not limited to transfusion volume, adjuvant medication coadministration such as tranexamic acid [TXA] and calcium salts, or crystalloid fluid coinfusion; transfusion equipment, and transfusion route)?

ii. Patient characteristics (including but not limited to age, sex, comorbidities, preexisting medications [anti-platelets, anti-coagulants, heart rate control medications], or mechanism of injury/condition)?

iii. Characteristics of the EMS system (including air/helicopter medical ambulance, ground ambulance, EMS clinician certification, or service delivery model [such as fire-based, private, third service], and logistics related to blood administrations [intercept model, blood stored on ambulance])?

KQ 2

a. What are the benefits and harms of transfusion of PRBCs for patients requiring prehospital hemorrhagic shock resuscitation?

b. Are the benefits and harms modified by:

i. EMS protocols (including but not limited to transfusion volume, adjuvant medication coadministration such as TXA and calcium salts, or crystalloid fluid coinfusion; transfusion equipment, and transfusion route)?

ii. Patient characteristics (including but not limited to age, sex, comorbidities, preexisting medications [anti-platelets, anti-coagulants, heart rate control medications], or mechanism of injury/condition)?

iii. Characteristics of the EMS system (including air/helicopter medical ambulance, ground ambulance, EMS clinician certification, or service delivery model [such as fire-based, private, third service], and logistics related to blood administrations [intercept model, blood stored on ambulance])?

KQ 3

a. What are the benefits and harms of transfusion of plasma for patients

requiring prehospital hemorrhagic shock resuscitation?

b. Are the benefits and harms modified by:

i. EMS protocols (including but not limited to transfusion volume, adjuvant medication coadministration such as TXA and calcium salts, or crystalloid fluid coinfusion, transfusion equipment, and transfusion route)?

ii. Patient characteristics (including but not limited to age, sex, comorbidities, preexisting medications [anti-platelets, anti-coagulants, heart rate control medications], or mechanism of injury/condition)?

iii. Characteristics of the EMS system (including air/helicopter medical ambulance, ground ambulance, EMS clinician certification, or service delivery model [such as fire-based, private, third service], logistics related to blood administrations [intercept model, blood stored on ambulance])?

KQ 4

a. What are the benefits and harms of infusion of crystalloid fluids for patients requiring prehospital hemorrhagic shock resuscitation?

b. Are the benefits and harms modified by:

i. EMS protocols (including but not limited to volume infused, or adjuvant medication coadministration such as TXA and calcium salts, or transfusion equipment and transfusion route)?

ii. Patient characteristics (including but not limited to age, sex, comorbidities, preexisting medications [anti-platelets, anti-coagulants, heart rate control medications], or mechanism of injury/condition)?

iii. Characteristics of the EMS system (such as air/helicopter medical ambulance, ground ambulance, personnel certification, or service delivery model [such as fire-based, private, third service], and logistics related to blood administrations [intercept model, blood stored on ambulance])?

KQ 5

a. What are the benefits and harms of different strategies (therapeutic, logistical, or both combined) and interventions (whole blood, PRBCs, plasma, and crystalloid fluid) for patients requiring prehospital hemorrhagic shock resuscitation?

b. Are the benefits and harms modified by:

i. EMS protocol (including but not limited to transfusion volume, adjuvant medication coadministration such as TXA and calcium salts, or crystalloid fluid coinfusion, and transfusion equipment and transfusion route)?

ii. Patient characteristics (including but not limited to age, sex, nature of illness, comorbidities, preexisting medications [anti-platelets, anti-coagulants, heart rate control medications], or mechanism of injury/condition)?

iii. Characteristics of the EMS system (including air/helicopter medical ambulance, ground ambulance, EMS clinician certification, or service delivery model [such as fire-based, private, third service], logistics related to blood administrations [intercept model, blood stored on ambulance])?

KQ 6

What specific areas of future research are essential for closing existing evidence gaps surrounding prehospital hemorrhagic shock resuscitation and prehospital blood transfusion? What are the precise scientific questions, optimal study designs, targeted study populations, and the various transfusion intervention protocols that need to be studied?

Contextual Question (CQ)

CQ 1

What are the barriers to and facilitators of implementation of effective prehospital blood product transfusion programs utilizing a systems-level approach? Barriers and facilitators could include EMS agency costs, EMS agency reimbursement, cost effectiveness, blood product maintenance and logistics, partnerships with blood banks, medical oversight including real-time medical direction, and diagnostic tools.

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

PRELIMINARY PICOTS CRITERIA

PICOTS	Inclusion criteria	Exclusion criteria
Populations	• Patients requiring prehospital hemorrhagic shock resuscitation treated in the prehospital setting by emergency medical services clinicians.	• Individuals who do not require prehospital hemorrhagic shock resuscitation. • Individuals not treated by emergency medical services clinicians.
Intervention	• *KQ1:* whole blood • *KQ2:* PRBCs. • *KQ3:* plasma (*e.g.,* fresh frozen, liquid, dried, etc.). • *KQ4:* crystalloid fluids. • *KQ5:* strategies as specified in each publication. • *KQ6:* NA. • *CQ1:* NA.	• Other types of resuscitation.
Comparator	• *KQ1 to 4* ○ Head-to-head comparisons between transfusion options to treat prehospital hemorrhagic shock patients. ○ Comparison to usual care as specified in each publication in another group or time period. • *KQ5:* strategies as specified in each publication. • *KQ6:* NA. • *CQ1:* NA.	• KQ1 to KQ5: no comparison.
Outcomes	*Patient Health Outcomes (highest priority)* • Mortality/survival. ○ To arrival at hospital. ○ To hospital discharge. ○ Any period less than or equal to 30 days post-emergency. • Morbidity after discharge.	• Cost-effectiveness, other outcomes.

PRELIMINARY PICOTS CRITERIA—Continued

PICOTS	Inclusion criteria	Exclusion criteria
	○ Glasgow Outcome Scale, Glasgow Outcome Scale Extended, Modified Rankin Scale, Cerebral Performance Category. • Length of stay. ○ Hospital free days. ○ ICU free days. *Intermediate Outcomes* in the prehospital or ED setting. • Physiological indicators (including but not limited to the following). ○ Systolic blood pressure. ○ Diastolic blood pressure. ○ Mean arterial pressure. ○ Heart rate. ○ Respiratory rate. ○ Respiratory failure. ○ ROSC. ○ Shock index. ○ Body temperature. ○ End tidal CO2 (EtCO2). ○ Level of Consciousness. ■ GCS. ■ AVPU. ○ Blood lactate level. *Process Outcomes*. • Time from EMS arrival to initial transfusion of blood product or infusion of crystalloid fluid. • Amount of blood product transfused or crystalloid fluid infused (total: prehospital and hospital) vs. (hospital only). *Adverse Events/Harms (including but not limited to the following)*. • Allergic reaction. • Febrile nonhemolytic reaction. • Acute hemolytic reaction. • Transfusion-related acute lung injury [TRALI]. • Transfusion-associated circulatory overload [TACO]. • Infection. • Fluid overload. • Citrate toxicity. • Delay to definitive care based on arrival time. • Isoimmunization. • Hemolysis. • Harms related to the method of administration. • Risk of clotting when Ringer's lactate solution combined with blood.	
Timing	• Outcomes up to 30 days post-injury	• Outcomes more than 30 days post-injury.
Setting	• Prehospital • US and International studies published in English language from Very High and High HDI [a] countries..	• ED. • Inpatient, surgery. • Studies conducted in countries rated less than High in the HDI [a].
Study Design	• RCTs • Prospective comparative studies • Retrospective comparative studies • Case control studies • Before/after studies • Time series • For CQ1 only: qualitative studies that specifically collect data about barriers to and facilitators of implementing prehospital blood product transfusion programs (*e.g.,* descriptive case studies, evaluations, QI reports), interviews, focus groups.	• Systematic reviews (we will use reference lists to identify studies for possible inclusion). • Case series. • Descriptive studies. • Letters to the editor. • Opinion papers. • Studies published prior to 1990, to focus on contemporary evidence and practices relevant to current prehospital hemorrhagic shock resuscitation protocols.

Abbreviations: AVPU = Alert, Voice, Pain, Unresponsive; CQ = Contextual Question; ED = emergency department; EMS = emergency medical services; GCS = Glasgow Coma Scale; HDI = Human Development Index; ICU = intensive care unit; KQ = Key Question; NA = not applicable; PICOTS = population, interventions, comparators, outcomes, timing, and setting; PRBC = packed red blood cell; QI = quality improvement; RCT = randomized controlled trial; ROSC = return of spontaneous circulation.

[a] United Nations Development Programme. Human Development Index. Retrieved from *https://hdr.undp.org/data-center/human-development-index#/indicies/HDI*.

Dated: November 21, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–27679 Filed 11–25–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–25–0728; Docket No. CDC–2024–0095]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Notifiable Diseases Surveillance System. This data collection provides the official source of statistics in the United States for nationally notifiable conditions.

DATES: CDC must receive written comments on or before January 27, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0095 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

National Notifiable Diseases Surveillance System (OMB Control No. 0920–0728, Exp. 3/31/2027)—Revision—Office of Public Health Data, Surveillance, and Technology (OPHDST), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The National Notifiable Diseases Surveillance System (NNDSS) is based on data collected at the State, territorial and local levels because of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Each year, the Council of State and Territorial Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance, under which a set of uniform criteria used to define a disease for public health surveillance to enable public health officials to classify and count cases consistently across reporting jurisdictions.

CDC requests a three-year approval for a Revision for the NNDSS (OMB Control No. 0920–0728, Exp. 03/31/2027) to: (1) receive case notification data for Chagas disease, yersiniosis (non-pestis), and injuries related to firearms, new conditions under standardized surveillance; and (2) receive new disease-specific data elements for toxoplasmosis and congenital toxoplasmosis. Like all other conditions NNDSS receives data for, CSTE voted to add the standardized public health case definition of these cases and data elements. Revising the NNDSS information collection to include these cases is necessary for NNDSS to receive these voluntary data as standardized case information. Data submission from reporting jurisdictions on these and all other NNDSS conditions is voluntary.

The NNDSS currently facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: public health departments in every U.S. State, New York City, Washington DC, five U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and three freely associated States (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau). This information is shared across jurisdictional boundaries and both surveillance and prevention and control activities are coordinated at regional and national levels.

Approximately 90% of case notifications are encrypted and submitted to NNDSS electronically from already existing databases by automated electronic messages. When automated transmission is not possible, case notifications are faxed, emailed,