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The Pediatric Critical Care Transfusion and Anemia Expertise Initiative Consensus Conference Methodology

Melania M. Bembea, MD, PhD¹, Stacey L. Valentine, MD, MPH², Scot T. Bateman, MD², Lisa M. Wilson³, Blair Anton, MLIS, MS⁴, Nancy Harger, MLIS, RN⁵, and Karen A. Robinson, PhD⁶ for the Pediatric Critical Care Transfusion and Anemia eXpertise Initiative (TAXI), in collaboration with the Pediatric Critical Care Blood Research Network (BloodNet), and the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network^{*}

¹Department of Anesthesiology and Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore, MD

²Department of Pediatrics, University of Massachusetts Medical School, Worcester, MA

³Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

⁴William H. Welch Medical Library, Johns Hopkins University School of Medicine, Worcester, MA

⁵Lamar Soutter Library, University of Massachusetts Medical School

⁶Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD

Abstract

Objective—This article describes the methodology used for Pediatric Critical Care Transfusion and Anemia Expertise Initiative (TAXI) Consensus Conference.

Corresponding Author: Melania M. Bembea, MD, PhD, Johns Hopkins Hospital, 1800 Orleans Street, Bloomberg Suite 6321, Baltimore, MD 21287, Phone: 410-955-6412, mbembea1@jhmi.edu.

^{*}TAXI Members listed in Appendix 1

Authors M. M. Bembea & S. Valentine contributed equally.

Conflicts of Interest and Sources of Funding:

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Design—Consensus conference of international experts in pediatric critical care and transfusion medicine, following standards set by the Institute of Medicine, using the Research And Development/University of California, Los Angeles (RAND/UCLA) appropriateness method, modeled after the Pediatric Acute Lung Injury Consensus Conference. Topics related to red blood cell transfusion (RBC) in children with or at risk for critical illness were divided into nine subgroups with a systematic review of the literature.

Methods—The panel of 38 content and 4 methodology experts met three times over the course of two years and collaborated to develop evidence-based and when evidence was lacking, expert-based clinical recommendations as well as research priorities for RBC transfusions in critically ill children or those at risk for critical illness. Electronic searches were conducted using PubMed, Embase, and Cochrane Library (CENTRAL) databases from 1980 to May 2017. Agreement was obtained using the RAND/UCLA appropriateness method. We used a standardized data extraction form to construct evidence tables, and graded the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Main Results—The consensus conference resulted in 102 recommendation statements, of which 57 were clinical (20 evidence-based and 37 based on expert consensus), and 45 detailed recommendations for future research. Dissemination was done via decision tree, a primary publication listing all statements, and separate publications for each subtopic that include supporting arguments for each recommendation.

Conclusions—A consensus conference of experts from around the world developed recommendations for RBC transfusions in critically ill children or children at risk for critical illness, the identification of current research gaps, and future research priorities.

Keywords

blood; red blood cell; transfusion; hemoglobin; intensive care; child; pediatric critical care; evidence-based; consensus development conference

INTRODUCTION

The Pediatric Critical Care Transfusion and Anemia Expertise Initiative (TAXI) is a collaboration of the Pediatric Critical Care Blood Research Network (BloodNet), the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI), the AABB and the Society for Critical Care Medicine (SCCM). TAXI was designed to create comprehensive evidence-based recommendations, supplemented by recommendations based on expert opinion where scientific evidence was lacking, in the area of red blood cell (RBC) transfusions in critically ill children, with pre-determined goals to guide clinical practice as well as future research efforts. TAXI included an organized and structured conference series, with participation of international and multidisciplinary experts in RBC transfusion in critically ill children. We describe here the process and methodology used to develop the TAXI recommendations (1).

EXECUTIVE COMMITTEE

The concept for TAXI was proposed at the BloodNet PALISI meeting in 2015 by two BloodNet members (S.V. and S.B.), and was subsequently fully endorsed by the BloodNet

Executive Committee. The design of the conference series was modeled after the Pediatric Acute Lung Injury Consensus Conference (PALICC), which was conducted by PALISI in 2012–2013 (2). A TAXI Executive Committee was formed with the purpose to directly oversee and provide guidance through the entire TAXI process as outlined in Figure 1. The TAXI Executive Committee was chaired by the two TAXI leaders (S.V. and S.B.), and composed of the BloodNet Executive Committee members and evidence-based medicine experts from the Johns Hopkins Evidence-Based Practice Center. Responsibilities of the TAXI Executive Committee included: defining the subtopics of focus and inviting experts for each subtopic; obtaining funding and support from international scientific societies; coordinating the systematic reviews and grading of evidence; organizing the recommendation revision and voting process; organizing and overseeing three TAXI meetings; editing manuscripts for submission and coordinating dissemination of the recommendations.

EXPERT PANEL COMPOSITION

The TAXI Executive Committee invited subtopic group members (content experts) based on national and international reputation as active researchers in the field of blood management research, and a record of peer-reviewed publications in the past five years on the subtopic of interest. Forty-two content experts were invited to participate, of which two declined and two accepted initially but had to leave the panel due to personal reasons. We therefore assembled a committee of 38 subject-matter experts from 32 academic institutions in eight countries. The following medical specialties were represented: pediatric critical care medicine, pediatric anesthesiology, pediatric cardiology, pediatric hematology, pediatric neurology, pediatric nephrology, pediatric surgery and pediatric transfusion medicine. The expert panel also included five non-voting evidence-based clinical practice guideline consultants and implementation science experts. All experts signed a commitment letter agreeing to participate in the three meetings and to perform the work required between meetings. They were required to disclose potential conflicts of interest, and none were reported.

The three TAXI meetings were paired with the following professional conferences to facilitate expert travel: The PALISI Network Meeting, Austin, TX (October 2015), the 8th World Congress on Pediatric Intensive and Critical Care, Toronto, Canada (June 2016) and the Symposium on Patient Blood Management, Montreal, Canada (June 2017). We obtained grant support for limited travel and lodging reimbursement.

The expert panel was tasked with completing a systematic review of the literature for each assigned subtopic, drafting the recommendations (short text), drafting the supporting arguments for the recommendations (long text), and participating in the discussion, revisions, and voting for all recommendations.

SYSTEMATIC REVIEWS

We conducted systematic reviews of the literature on RBC transfusion in critically ill children and children at risk for critical illness (defined as hospitalized and at risk for, or

with, potentially life-threatening illness). The panel members vetted and agreed upon topics for the reviews during the first TAXI meeting. Children were defined as full term newborns 36 weeks gestational age up to 18 years.

Systematic reviews were organized around nine subtopics agreed upon by all experts at the first TAXI meeting: 1A) hemoglobin/hematocrit thresholds used for RBC transfusion in the general pediatric critical care patient; 1B) physiologic thresholds used for RBC transfusion in the general pediatric critical care patient; 2) RBC transfusion indications for critically-ill children with respiratory failure; 3) RBC transfusion indications for critically-ill children with shock (excluding hemorrhagic shock); 4) RBC transfusion indications for critically-ill children with hemorrhage/hemorrhagic shock; 5) RBC transfusion indications for critically-ill children with traumatic brain injury, stroke, and other neurocritical care conditions; 6) RBC transfusion indications for critically-ill children with congenital and acquired heart disease; 7) RBC transfusion indications for critically-ill children with sickle cell disease and oncologic disease; 8) RBC transfusion indications for critically-ill children requiring extracorporeal membrane oxygenation (ECMO), renal replacement therapy, and/or ventricular assist devices; and 9) indications for RBC transfusion using alternative processing methods of RBC (e.g., washed, leukoreduced, irradiated, etc). Experts were assigned into these specific subgroups so that each group had 3 to 6 experts. The subgroup experts presented their work to the entire expert panel throughout the TAXI process.

The experts agreed upon common definitions to apply to all subtopic reviews and recommendations, as follows: a) *RBC transfusion* - any transfusion of RBC, whatever the volume or the type of blood product (RBC units or whole blood) transfused; b) *critically ill children or those at risk for critical illness* - pediatric patients within a PICU, an ICU which admits full term infants and any child up to at least 18 years of age; c) *hemodynamically stable* - mean arterial pressure is not less than 2 standard deviations below normal mean for age and cardiovascular support (vasopressors/inotropes and fluids) has not been increased in the last 2 hours as defined by the TRIPICU study (3); d) *severe pediatric acute respiratory distress syndrome (PARDS)* - as defined by PALICC (4); and e) acute hypoxemic respiratory failure as defined by the TRIPICU study (3).

We searched PubMed, Embase, and Cochrane Library (CENTRAL) databases, from 1980 to May 2017, using a combination of medical subject heading terms and text words for concepts of RBC transfusion and the 10 subtopics listed above. Electronic searches were conducted with formal guidance from the Evidence-based Practice Center (EPC) at Johns Hopkins University and the assistance of clinical informationists from the William H. Welch Medical Library, Baltimore, MD, and the University of Massachusetts Medical School Library, Worcester, MA. Search strategies are detailed in Supplemental Digital Content 1.

Studies were eligible for inclusion if the study population was composed of children (newborn >36 weeks gestation and <18 years of age) who were critically ill or at risk for critical illness, with evaluation of RBC transfusion(s). Studies were excluded if they were 1) not related to indications for RBC transfusion in critically ill children or children at risk for critical illness within each group's disease(s) of interest; 2) study intervention or dependent variable of interest not related to RBC transfusion; 3) adult-only study population (defined

as all patients < 18 years, or mixed pediatric and adult population with inability to separate data for patients <18 years); 4) animal-only studies; 5) not original data (i.e., reviews, editorials, commentaries, meeting proceedings); 6) case report or case series with sample size < 10; and 7) language: not in English and unable to determine eligibility.

Questions for the systematic reviews were developed by members of each of the nine subgroups using the (P) population, (I) intervention, (C) comparison, (O) outcome, (S) setting, format. The systematic reviews considered randomized and non-randomized controlled trials, controlled before/after studies, concurrent cohort studies, interrupted time series studies, historically controlled studies, cohort studies, cross-sectional studies, and uncontrolled longitudinal studies. References for scoping reviews, systematic reviews, meta-analyses, guidelines, clinical policies, and consensus statements were manually reviewed.

RBC transfusion exposure was assessed by: 1) number of transfusion events per patient; 2) total volume transfused per patient; 3) donor exposure (individual donor RBC units, number of donors per patient); 4) hemoglobin concentration and/or physiologic parameter (e.g., cerebral oximetry, lactate, mixed venous saturation, etc.) prior to the RBC transfusion; 5) proportion of study participants not exposed to RBC transfusion; and 6) RBC characteristics (e.g., length of storage, special processing).

The outcomes of interest included: mortality; transfusion-related adverse events (e.g., transfusion related acute lung injury, transfusion related circulatory overload, etc.); immediate post-transfusion outcomes (i.e., change in physiologic parameter of interest post- vs pre-transfusion); development of multiple organ dysfunction syndrome, nosocomial infections; ventilator-free days; organ failure-free days; intensive care unit and hospital length of stay; physiologic parameters (i.e. lactate), mixed venous saturation and neurofunctional outcomes.

Two independent reviewers screened search results using Abstrackr (5). Discrepancies were resolved by a third reviewer. Full text screening was also conducted by two independent reviewers. A summary of abstract, full text screening results and articles included in the systematic reviews is presented in Supplemental Digital Content 2. Data from articles included in the final review were abstracted into the Systematic Review Data Repository (SRDR) (6) by one reviewer, with a second reviewer checking for accuracy. Studies included in the final reviews were evaluated for risk of bias using the Cochrane risk of bias assessment tool for randomized trials (7) and the Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies (8). Risk of bias assessment was conducted independently by two reviewers. Due to high heterogeneity, we were not able to pursue quantitative analysis.

GRADING OF EVIDENCE

The expert panel analyzed the supporting evidence, when present, for each recommendation, using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology (9) and GRADEPRO™ (10). Key elements considered were the magnitude of effect and certainty in the evidence. Using the GRADE approach, the panel

determined the strength of each recommendation, weighing the balance between benefits, risks, burden and costs, as well as the certainty of the evidence (i.e., “high quality evidence” or level A, “moderate quality evidence” or level B, and “low quality evidence” or level C) (11). Using GRADE methodology, a “strong” (or level 1) recommendation indicated the judgment that all, or almost all, well-informed people would make the same choice, while a “weak” (or level 2) recommendation indicated the judgment that a majority of well-informed people would make the same choice, but a substantial minority would not.

DRAFTING AND DEVELOPING AGREEMENT OF RECOMMENDATIONS

Each of the nine groups developed recommendations for their respective subtopic. Each recommendation was clearly labeled as based on the pediatric evidence yielded by the systematic reviews, versus the expertise of the panel members, when the systematic reviews yielded no results in pediatric patients. For those recommendations based on pediatric evidence, the GRADE of the recommendation was provided. Each recommendation was rated using the Guideline Implementability Appraisal (GLIA) tool (12) and, if necessary, modified to optimize application in the clinical or research setting. Subgroup members presented the recommendations and the corresponding supporting arguments for their respective subtopic at the second TAXI meeting, in Toronto, Canada. Each recommendation was discussed in detail and revised, evaluated for redundancies, inconsistencies and omissions.

Recommendations developed by each group were pooled and subsequently scored by the entire expert panel using the Research And Development/University of California, Los Angeles (RAND/UCLA) appropriateness scale ranging from 1 (strongly disagree) to 9 (strongly agree) (13). Scoring was conducted anonymously using an online tool (SurveyMonkey.com®). Scores of 1, 2, and 3 represented disagreement, 4, 5, and 6 represented equipoise, and 7, 8, and 9 represented agreement. Comment areas were provided for each recommendation, to justify disagreement or equipoise. Agreement was defined *a priori* as 80% of the experts rating the recommendation a 7, 8, or 9. Recommendations that did not achieve agreement were returned to the respective subgroup experts for revision, with the associated comments from the voting process. A second round of voting was performed for all revised recommendations. The first two voting rounds took place between the second and third TAXI meeting. During the third meeting, the final recommendations that reached consensus were discussed. Any recommendation that was reworded or refined for clarity during this third meeting was sent for a final round of voting to ensure agreement. TAXI members abstained from voting on recommendations on subtopics outside of their expertise.

Once final recommendations were developed, the panel developed a decision tree to guide clinical decision making around RBC transfusion in critically ill children or children at risk for critical illness, a manuscript listing all recommendations (short text), one manuscript for each of the nine subtopics that includes supporting arguments for each recommendation (long text), and one manuscript detailing implementation plans.

CONCLUSIONS

The TAXI consensus series represents the first effort to convene a group of international experts with diverse expertise in RBC transfusion practices in critically ill children, and to conduct systematic reviews of the literature published on RBC transfusion practices in this population, with the goals of developing recommendations for RBC transfusion practices. Controversies and knowledge gaps in RBC transfusion in critically ill children were identified and discussed, in an effort to guide future research, by setting research priorities and providing recommendations for study design that could optimize future research endeavors. We engaged experts in evidence-based medicine and implementation science to ensure that the systematic reviews of the literature, grading of evidence, and drafting and dissemination of recommendations were performed with rigor and consideration for uptake and implementation by clinicians and hospital systems.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix 1: Pediatric Critical Care Transfusion and Anemia Expertise Initiative (TAXI) Members

(* for Executive Committee) Co-chairs: Stacey L. Valentine MD MPH* and Scot T. Bateman MD*, *University of Massachusetts, USA*, Content Experts: Section 1. General pediatric critical care patient based on physiologic and hemoglobin thresholds: Andrew Argent MD MBBCh, *University of Cape Town, South Africa*, Jeffrey L. Carson MD, *Rutgers Robert Wood Johnson Medical School, USA*, Jill M. Cholette MD*, *University of Rochester, USA*, Allan Doctor MD*, *Washington University of St. Louis, USA*, Jacques Lacroix MD*, *Université de Montréal, Canada*, Kenneth Remy MD, *Washington University of St. Louis, USA*, Section 2. Respiratory failure: Pierre Demaret MD MSc, *CHC Liege, Belgium*, Guillaume Emeriaud MD PhD, *Université de Montréal, Canada*, Nabil E. Hassan MD, *University of Illinois, USA*, Martin C.J. Kneyber MD PhD, *University of Groningen, Netherlands*, Marisa Tucci MD*, *Université de Montréal, Canada*, Section 3. Shock, excluding hemorrhagic shock: Nina Guzzetta MD, *Emory University, USA*, Mark W. Hall MD, *Ohio State University, USA*, Jennifer A. Muszynski MD MPH, *Ohio State University, USA*, Philip C. Spinella MD, *Washington University of St. Louis, USA*, Duncan Macrae MB ChB, *Imperial College London, UK*, Section 4. Hemorrhagic shock and non-life-threatening bleeding, Oliver Karam MD PhD, *Virginia Commonwealth University*, Robert T. Russell MD MPH, *University of Alabama, USA*, Philip C. Spinella MD*, *Washington University of St. Louis, USA*, Paul Stricker MD, *University of Pennsylvania, USA*, Adam M. Vogel MD, *Texas Children's Hospital, USA*, Section 5. Acute brain injury: Philip C. Spinella MD*, *Washington University of St. Louis, USA*, Robert C. Tasker MA MD MBBS, *Harvard University, USA*, Alexis F. Turgeon MD MSc, *Université Laval, Canada*, Section 6. Acquired or congenital heart disease, Jill M. Cholette MD*, *University of Rochester, USA*, Steven M. Schwartz MD, *University of Toronto, Canada*, Ariane Willems MD, *University of Brussels, Belgium*, Section 7. Sickle cell/oncologic disease, Cassandra D. Josephson MD, *Emory University, USA*, Naomi LC Luban MD, *George Washington University, USA*, Leslie E. Lehmann MD, *Harvard University, USA*, Robert I. Parker MD*, *Stony Brook University, USA*, Simon J. Stanworth MD, *NHS Blood and Transplant, Oxford, UK*, Marie E. Steiner MD MS*, *University of Minnesota, USA*, Nicole D. Zantek MD PhD, *University of Minnesota, USA*, Section 8. Receiving support from extracorporeal, ventricular assist and renal replacement therapy devices: Melania M. Bembea MD PhD*, *Johns Hopkins University, USA*, Timothy Bunchman MD, *Virginia Commonwealth University, USA*, Ira M. Cheifetz MD, *Duke University, USA*, James Fortenberry MD, *Emory University, USA*, Marie E. Steiner MD MS*, *University of Minnesota, USA*, Section 9. Selection and processing of red blood cell components: Meghan Delaney DO, MPH, *Children's National*

Health System USA, Cassandra D. Josephson MD, *Emory University, USA*, Robert I. Parker MD*, *Stony Brook University, USA*, Leo van de Watering MD, *Leiden University, Netherlands*, Nicole D. Zantek MD PhD, *University of Minnesota, USA*, Evidenced-Based Medicine: Karen A. Robinson PhD, *Johns Hopkins University, USA*, Melania M Bembea MD PhD*, *Johns Hopkins University, USA*, Implementation Science: Sara Small MS, *Washington University of St. Louis, USA*, Katherine Steffen MD, *Stanford University, USA*

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PEDIATRIC CRITICAL CARE TRANSFUSION and ANEMIA EXPERTISE INITIATIVE (TAXI)

Figure 1.
 Timeline and overview of the Pediatric Critical Care Transfusion and Anemia Expertise Initiative. RAND/UCLA= Research And Development/University of California, Los Angeles