

PROCEDURAL HARM

Reducing Over-Utilization of Blood and Blood Products Change Package



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DEPTH AND BREADTH OF PROCEDURAL HARM

The National Quality Forum (NQF) has identified a list of “Serious Reportable Events” (SREs), i.e. serious and largely preventable, harmful clinical events. The SREs fall into the following categories: surgical or invasive procedures, products or devices, patient protection, care management, and environmental, radiologic, and potential criminal events. (http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx) The NQF’s list of serious reportable events provides one framework for assessing the risks of patient harm that could result from surgical and invasive procedures. The list is not exhaustive, however. Harm events listed under other categories (e.g. care management) may arise during a surgical or invasive procedure. Types of patient harm that may potentially occur during surgical and invasive procedures as well as care management events (see Appendix I) are already addressed in some of the other AHA HRET-HEN change packages. A review of all the change packages is therefore recommended.

This procedural harm change package focuses on the over-utilization of blood and blood products.

PROCEDURAL HARM: REDUCING OVER-UTILIZATION OF BLOOD AND BLOOD PRODUCTS

Background

- More than 20 million blood components are transfused each year in the U.S.; transfusions are the most common inpatient hospital procedure.¹⁷
- While blood transfusions can be life-saving, they also carry risks that range from mild complications to death.²¹
- Research has shown that the rate of morbidity and mortality is increased after receiving as little as 1 unit of blood or of blood products.⁷
- Transfusions of blood and blood products carry well-documented risks of acute and long-term complications, such as infection, volume overload, hyperkalemia, and iron overload.¹
- Additional complications that have been recently identified after transfusions include allergic and immune transfusion reactions, increased susceptibility to non-transfusion-mediated infections, and increased mortality and morbidity.¹
- Variations in clinical transfusion standards and practices may contribute to unnecessary transfusions which waste a limited resource and may lead to blood product shortages.

- Lack of transfusion medicine expertise in a hospital may contribute to blood product overuse.⁷
- The use of evidence-based guidelines, standards, and best practices can improve the safety of ordering and administering blood and blood products.²¹

Suggested AIM:

- Reduce the incidence of procedural harm due to blood and blood product transfusions by 40% by December 8, 2014.

Outcome Measures:

Indicator Name: **Blood transfusions per 1,000 patient days (EOM: OPT-HEN-PROCHARM-17)**

Numerator: Number of blood transfusions

Denominator: Number of patient days

Source: American Association of Blood Banks (AABB) RBC Transfusion Guideline

Indicator Name: **Appropriate blood transfusions per 1,000 patient days (EOM: OPT-HEN-PROCHARM-18)**

Numerator: Number of blood transfusions in stable patients with a Hgb < 7 g/dl

Denominator: Number of patient days

Source: AABB RBC Transfusion Guideline

Potential Process Measures:

Transfusion Indication: The percentage (or raw number) of patients receiving RBC units who have documented pre-transfusion HGB or HCT results and clinical justifications for the transfusion. (EOM: OPT-HEN-PROCHARM-19)

Transfusion Consent: The percentage (or raw number) of patients receiving transfusions who signed an informed consent. (EOM: OPT-HEN-PROCHARM-20)

Administration Documentation: The percentage (or raw number) of transfused units/bags with complete documentation. (EOM: OPT-HEN-PROCHARM-21)

KEY ELEMENTS	IDEAS TO TEST
Staff Awareness	<ul style="list-style-type: none"> Educate practitioners regarding the unintended consequences of providing blood and blood product transfusions. Complete periodic evaluations of clinical transfusion practices. Confirm the assessment and determination of risk/benefit ratios and the documentation of justifications for transfusions.
A Formal Blood Management Program	<ul style="list-style-type: none"> Develop criteria for transfusions for a variety of scenarios based on national guidelines. Scenarios may include but are not limited to patients who are actively bleeding, patients who are not actively bleeding, and patients in the operating room. Use the criteria for appropriate utilization of blood and blood components to identify clinical situations for which it will be necessary and advisable to institute hard stops, i.e. "Choosing Wisely" reminders. Identify subject matter experts within the organization to provide guidance and input. In conjunction with physicians and pharmacists, develop standard blood management order sets based on safety principles and the transfusion criteria and guidelines.
Learning and Monitoring	<ul style="list-style-type: none"> Develop an audit tool to assess practitioners' competency in blood management. The tool should address key elements in decision-making and competent practice, such as clinical justifications for transfusion, laboratory test results that support the justification, as well as documentations of signed patient informed consents. Conduct an interdisciplinary Failure Modes and Effects Analysis (FMEA) to identify unnecessary transfusions, as well as practitioner knowledge gaps, in a non-punitive manner. Monitor, identify, understand, and mitigate practitioner noncompliance with blood management policies and procedures. Based on assessment and monitoring results, re-design processes and re-educate and train practitioners on the new standards and guidelines.
Smart Use of Technology	<ul style="list-style-type: none"> Use focused audits to identify practice patterns and system failures. Prompt real-time learning from each failure. Align order sets with recent lab test values and clinical indications. Require documented clinical justifications for transfusions via an alert or hard stop. Design alerts and hard stops to help the practitioner "do the right thing." Use data/information from alerts, hard stops, and overrides to revise and improve standardized order sets and protocols. Use alerts to prompt reconsideration and justification for choices. (Help providers "choose wisely.") www.choosingwisely.org
Patient and Family Engagement	<ul style="list-style-type: none"> Provide patient education in a language and at a literacy level all can understand. Develop an informed consent specific to blood and blood product transfusions. Engage patients and family members in the development of the informed consent process by soliciting input on verbal scripts and document readability. Fully discuss benefits and risks, but keep informed consent discussions at the patients'/families' comprehension level.

Key Resources:

- Implementation Guide for Joint Commission Patient Blood Management Performance Measures 2011. Retrieved from http://www.jointcommission.org/patient_blood_management_performance_measures_project/
- Blood transfusion: Indications, administration, and adverse reactions. Retrieved from <http://www.guideline.gov/content.aspx?id=34955>
- Administrative and Clinical Standards for Patient Blood Management Programs. Retrieved from <http://www.sabm.org/publications>
- Choosing Wisely. Website: <http://www.choosingwisely.org/>

PROCEDURAL HARM: REDUCING OVER-UTILIZATION OF BLOOD AND BLOOD PRODUCTS DRIVER DIAGRAM

AIM: Reduce the incidence of procedural harm due to blood and blood product transfusion by 40% by December 8, 2014.

PRIMARY DRIVER	SECONDARY DRIVER	CHANGE IDEAS
Staff Awareness	<ul style="list-style-type: none"> Promote awareness of Procedural Harm due to the overuse of blood and blood product transfusions. Educate practitioners regarding the unintended consequences of providing blood and blood product transfusions. 	<ul style="list-style-type: none"> Assess current staff knowledge and competency in this arena. Develop a toolkit of clinical educational materials, which includes the risks and benefits of transfusions, for MDs throughout the learning continuum. Provide education about transfusion risks and avoidance, and about medically-effective alternatives to transfusion. Disseminate best practices and guidelines (which are supported by evidence) for decision-making about transfusions. Complete periodic evaluations of clinical transfusion practices. Confirm the assessment and determination of risk/benefit ratios and the documentation of justifications for transfusions.
A Formal Blood Management Program	<ul style="list-style-type: none"> Establish a committee to review and develop criteria for transfusions for a variety of scenarios based on national guidelines. Develop standard blood management order sets based on safety principles and the transfusion criteria and guidelines. 	<ul style="list-style-type: none"> The committee should review key literature and develop criteria for transfusions for a variety of scenarios based on national guidelines. Scenarios may include patients who are actively bleeding, patients who are not actively bleeding, and patients in the operating room. Identify subject matter experts within the organization to provide guidance and input. In conjunction with physicians and pharmacists, develop standard blood management order sets based on safety principles and the transfusion criteria and guidelines. <ul style="list-style-type: none"> Obtain examples of order forms utilized at other institutions, and ask, "What would we need to modify?" Include key elements in the order sets, e.g. clinical justifications for transfusions, specific laboratory values that support the need for transfusions. Integrate standard orders into the EMR, and add automatic alerts to providers when criteria for a transfusion have not been met. Eliminate mandates for a minimum number of units to be transfused. Evaluate patients after each unit. The committee should meet on a regular basis to develop and assess quality indicators (processes and outcomes). QI assessment should be implemented after each transfusion. Standard orders should be reassessed and modified, as appropriate. Use the criteria for appropriate utilization of blood and blood components to identify clinical situations for which it will be necessary and advisable to institute hard stops, i.e. "Choosing Wisely" reminders.
Learning and Monitoring	<ul style="list-style-type: none"> Assess practitioner competency in this arena. Monitor practitioner performance and promote accountability with regard to organizational standards. Measure individual practitioner transfusion practices through monitoring of practitioner specific performance data (i.e. Joint Commission, HFAP, or NIAHO) 	<ul style="list-style-type: none"> Develop an audit tool to assess practitioners' competency in blood management. The tool should address key elements in decision-making and competent practice, such as clinical justifications for transfusion, laboratory test results that support the justification, as well as documentations of signed patient informed consents. Conduct an interdisciplinary Failure Modes and Effects Analysis (FMEA) to identify unnecessary transfusions, as well as practitioner knowledge gaps, in a non-punitive manner. Monitor, identify, understand, and mitigate practitioner noncompliance with blood management policies and procedures. Based on assessment and monitoring results, re-design processes and re-educate and train practitioners on the new standards and guidelines.

PROCEDURAL HARM: REDUCING OVER-UTILIZATION OF BLOOD AND BLOOD PRODUCTS DRIVER DIAGRAM

AIM: Reduce the incidence of procedural harm due to blood and blood product transfusion by 40% by December 8, 2014.

PRIMARY DRIVER	SECONDARY DRIVER	CHANGE IDEAS
<p>Smart Use of Technology</p>	<ul style="list-style-type: none"> • Link order sets to lab values and clinical documentation. • Redesign standardized orders and protocols to include alerts and hard stops when appropriate. • Use alerts wisely. 	<ul style="list-style-type: none"> • Align order sets with recent lab test values and clinical indications. Require documented clinical justifications for transfusions via an alert or hard stop. • Design alerts and hard stops to help the practitioner “do the right thing.” • Do not allow alert overrides without obtaining a documented justification. • Use data/information from alerts, hard stops, and overrides to revise and improve standardized order sets and protocols. • Use technology to alert key staff in real time when alerts have been triggered. Prompt real-time learning from each failure. • Use focused audits to identify practice patterns and system failures. • Use alerts to prompt reconsideration and justification for choices. (Help providers “choose wisely.”) www.choosingwisely.org
<p>Patient and Family Engagement</p>	<ul style="list-style-type: none"> • Develop specific informed consents. • Provide comprehensible information to patients and families. • Always consider literacy and comprehension levels in written and oral communications. 	<ul style="list-style-type: none"> • Provide patient education in a language and at a literacy level all can understand. • Develop an informed consent specific to blood and blood product transfusions. • Engage patients and family members in the development of the informed consent process by soliciting input on verbal scripts and document readability. • Fully discuss benefits and risks, but keep informed consent discussions at the patients’/families’ comprehension level.

PREVENTION OF PROCEDURAL HARM DUE TO OVER-UTILIZATION OF BLOOD AND BLOOD PRODUCT TRANSFUSIONS

Decision-making based on clinical indications for blood and blood product transfusions varies greatly from practitioner to practitioner.⁶ Lack of practitioner expertise in this arena significantly contributes to the overuse of blood.¹³ An understanding of the risks as well as the benefits of transfusions is critical to properly assess the need for a transfusion in a specific patient. For example, a transfusion may not be indicated in a patient with anemia that is treatable with medications.^{14,16} A multi-disciplinary Blood Management Program can significantly reduce unnecessary blood transfusions in a healthcare institution.⁴

Studies have shown that many transfusions continue to be ordered without sufficient evidence to support their benefits. Therefore, the American Red Cross has recommended that organizations monitor their blood transfusion practices and focus their surveillance on practitioner adherence with restrictive transfusion policies.^{5,10}

For example, transfusion policies that limit transfusions to patients with specific laboratory result levels and clinical conditions have demonstrated effectiveness in reducing unnecessary blood transfusions. However, variations remain in recommended transfusion practices among countries, hospitals, disciplines, and individual physicians.

In the United States, the National Blood Collection and Utilization Survey notes, transfusion volume in 2008 was 15 million red blood cell (RBC) units (unchanged from 2006), 2 million apheresis platelet equivalent units (a 16.7 percent increase from 2006), and 4.5 million plasma units (an 11.8 percent increase from 2006). 60,000 adverse reactions were reported in 2008. According to the Agency for Healthcare Research and Quality, blood transfusions were given during 10 percent of all hospital stays that included a procedure.^{1,2}

The Department of Health and Human Services' Advisory Committee on Blood Safety and Availability (ACBSA) has released a statement discussing the over-utilization of blood products. The committee identified the significant role played by unnecessary transfusions in increasing the costs and diminishing the quality of healthcare. Findings included:

- Blood transfusions carry significant risks that may outweigh their benefits in some settings and add unnecessary costs.

- Wide variability in the use of transfusions suggests that there is both excessive and inappropriate use of blood transfusions in some U.S. settings.
- Medical advances and aging of the population are expected to drive growing demands for transfusions. These demands could exceed supplies within 1-2 decades.
- The quality of blood products and the safety of their use have greatly improved, but guidelines for appropriate utilization of transfusions have been slower to evolve.
- Additional data on the relationships between blood utilization and clinical outcomes need to be collected and analyzed to develop and support effective evidence-based practices.
- Patient-oriented blood management programs based on expert decision-making at some hospitals have demonstrated significant reductions in blood use, without increases in patient harm. (Effective practices have included medical management of anemia and coagulopathies, minimization of blood loss, and conservative use of blood products).³

An effective blood management program goes beyond the blood utilization review whose goal is simply to minimize unnecessary transfusions. An institution-wide management program focuses on implementing an evidence-based multidisciplinary approach which optimizes the care of patients who might need a transfusion. It includes early interventions performed during the preparation of medical and surgical patients for procedures or treatment, as well as techniques and strategies implemented in the pre-operative, operative, and post-operative periods or after completion of treatment. A blood management program also promotes the development of evidence-based clinical practice guidelines which include alternatives to transfusions, as well as physician education and assessment. The program requires the identification of critical opportunities in the continuum of patient care to enhance communication and coordination between different disciplines which can reduce the likelihood that a patient will require an allogeneic transfusion.⁴

Suggested AIMS

Reduce the incidence of procedural harm due to blood and blood product transfusion by 40% by December 8, 2014.

STAFF AWARENESS

Deficiencies in transfusion knowledge can adversely affect patient safety. Accordingly, provider education on the risks and benefits of blood transfusions and alternative treatment modalities will help to facilitate changes in clinical practice and reductions in unnecessary transfusions.⁸

To inform practitioners and other staff about the institution's blood management program, and to assist each staff member to better understand his or her role, how to use the tools and resources provided, and how to obtain necessary support or guidance, educational/training sessions will be needed. The development and dissemination of guidelines alone has been insufficient to alter long-standing practices. To promote a reduction in the prescription of transfusions, clinicians, laboratory technical staff, and other relevant personnel will require formal mentoring in the new policies and procedures.

Secondary Driver: Assess staff knowledge and promote staff awareness.

Studies have shown the value of providing broad training for all staff involved in the transfusion process. Hospitals which provide accessible education, adopt best practices, and implement careful oversight and monitoring of blood utilization and management demonstrate improved patient outcomes. Ongoing reviews and analyses of data from clinical practice at staff meetings allow practitioners to share experiences, identify best practices, revise protocols, and reduce harm from unnecessary transfusions.

Secondary Driver: Disseminate best practices.

Not all best practices are appropriate for every hospital. Hospitals can elect to implement specific guidelines and recommendations that are relevant to their own blood and blood product utilization.

Secondary Driver: Develop a toolkit of clinical educational materials.

In some cases, ordering physicians may be unaware of recommended criteria to guide their decisions about whether or not a blood product transfusion is medically indicated and/or effective. As a result, they may order blood product transfusions without sufficient justification, and thereby unnecessarily expose patients to risk. Initial and ongoing education about the transfusion process promoted increased awareness, knowledge, and skills. Members of the transfusion committee at each institution along with well-respected, expert clinicians can serve as champions and peer educators for clinical staff.

Change Ideas

- Educate practitioners regarding the risks and unintended consequences of blood and blood product transfusions.
- Implement ongoing and regular reviews of transfusion practices.

Suggested Process Measures

- Calculate the percentage of staff who has received formal training in the institution's transfusion policies and practices.

“Hardwiring” Staff Education in Improvement Plans

“Hardwiring” of staff education in an organization's culture is enhanced if the training is combined with regular assessments of competency and performance. Communicate the results of the assessments and provide necessary education and training to relevant stakeholders across the organization.

A FORMAL BLOOD MANAGEMENT COMMITTEE

A multi-disciplinary Blood Management Committee should be developed to promote improved performance management and coordinate assessments and analyses. Committee members should be drawn from a breadth of relevant specialties within the hospital, including medicine, nursing, transfusion services, and quality assessment and improvement. The Committee should develop and implement policies, processes, and procedures in alignment with the national standards and guidelines for effective transfusion management, as well as oversee the monitoring, capture, assessment, and investigation of noncompliance with these standards. The standard orders and protocols developed should customize and incorporate specific safety precautions for target groups such as patients of advanced age or with chronic or high-risk conditions/diseases.

Secondary Drivers: Develop blood utilization criteria.

Criteria should be developed for each blood component from evidence-based transfusion practice guidelines for both adult and pediatric patients. The criteria should address conditions for which transfusion may be considered a reasonable, but not a mandatory, practice.

Secondary Drivers: Develop standard order sets.

Partner with ordering physicians to develop standard order sets for blood and blood product transfusions which incorporate well-described safety principles.

Secondary Drivers: Eliminate the prescription of a minimum number of units to be transfused; evaluate patients after transfusion of each unit.

One unit of RBCs is expected to result in a hemoglobin increase of 1 g/dl or a hematocrit increase of 3% in a typical adult. One unit of RBCs can replace a blood loss of 500 ml. The patient should be assessed and post-transfusion hemoglobin measured to monitor the effectiveness of transfusion after each unit to avoid unnecessary or over-transfusion. Lack of observable clinical benefits or improvement in laboratory results may indicate that the patient has ongoing blood loss or cardiac or pulmonary disease.²¹

Change Ideas

- Review key literature.
- Use the criteria for appropriate utilization of blood and blood components to identify clinical situations for which it will be necessary and advisable to institute hard stops, i.e. “Choosing Wisely” reminders.
- Create standard orders.
 - Obtain examples of order forms utilized at other institutions, and ask, “What would we need to modify?”
 - Include key elements in the order sets, e.g. clinical justifications for transfusions, specific laboratory values that support the need for transfusions.
 - Integrate standard orders into the EMR, and add automatic alerts to providers when criteria for a transfusion have not been met.

Suggested Process Measures

- The percentage of patients for whom the designated criteria were utilized in decision-making about blood transfusions.
- The percentage of patients with a Hgb >7 g/dL who received blood or blood products without documentation of clinical justification for the transfusion.

“Hardwiring” a Formal Blood Management Committee in Improvement Plans

Involving local clinicians in the development and design of processes will enhance their understanding of the rationale behind these quality improvement changes and promote their buy-in, adoption of, and adherence with these changes. Physicians can not only be aid in defining the order sets but in determining how the order sets will be delivered and which prompts will be most helpful to guide users.

LEARNING AND MONITORING

Decision-support provides practitioners with additional information and resources to aid in problem solving, as well as controls to prevent unnecessary blood and blood product transfusions. Decision-support is successful when information is provided “at-just-the-right-time” to help ordering clinicians make more informed and accurate decisions.

Monitoring of blood transfusion practices and documentation of adverse events have become requirements of many regulatory and accrediting agencies, including The Joint Commission, and the American Association of Blood Banks (AABB). The Joint Commission-required, data-driven performance and quality improvement standards cover transfusion services. These agencies do not mandate how healthcare institutions should achieve these objectives, only that they be achieved. To address these agency expectations, each hospital should develop a blood management program and appoint a Blood Management Committee (BMC) to oversee the collection and analysis of data about transfusion performance and patient outcomes.

Secondary Drivers: Assess and enhance practitioner competency and promote practitioner accountability.

Practitioner competency and compliance with blood and blood product transfusion guidelines should be assessed on an ongoing basis using defined quality improvement techniques such as practice and administration audits. Noncompliance with blood and blood product transfusion policies and procedures can be identified through the audit process. Results can be collected, tracked, analyzed, and reported in the aggregate as well as by individual practitioner. Appropriate interventions such as provider training or policy revision can then be implemented.

Secondary Drivers: Assess individual practitioner transfusion practices as part of OPPE.

Persistent noncompliance with blood management policies and procedures places patients in potential harm. Providing education and training to practitioners under the guidance of physician experts and champions can promote improved adherence with policies and enhance provider competency and patient outcomes.

Secondary Driver: Monitor performance and outcomes on a regular basis.

One of the primary functions of the BMC is to develop standards and guidelines for blood transfusion practices. Meeting on a regular basis to review the application of and compliance with these standards is an important role for the BMC and contributes to successful and sustainable quality improvement for the health-care organization.

Secondary Drivers: Monitor the number and quantity of blood and blood product transfusions.

Data about blood and blood product transfusions can be collected locally within a clinical service or hospital-wide. The data can be analyzed for over-utilization according to case or procedure types to identify potential areas for improvement.

Change Ideas

- Develop an audit tool to assess practitioners' competency in blood management. The tool should address key elements in decision-making and competent practice, such as clinical justifications for transfusion, laboratory test results that support the justification, as well as documentations of signed patient informed consents.
- Conduct an interdisciplinary Failure Modes and Effects Analysis (FMEA) to identify unnecessary transfusions, as well as practitioner knowledge gaps, in a non-punitive manner.
- Monitor, identify, understand, and mitigate practitioner non-compliance with blood management policies and procedures.
- Based on assessment and monitoring results, re-design processes and re-educate and train practitioners on the new standards and guidelines.

Suggested Process Measures

- Measure the percentage of practitioners who have achieved a designated benchmark upon audit for utilization of blood or blood product transfusions.

“Hardwiring” Monitoring and Learning in Improvement Plans

Many of the interventions above are not only implementation strategies but also “hardwiring” strategies. Hardwiring includes performing systematic audits to ensure that blood is being used appropriately, as well as anticipating and preventing potential overuse issues that could generate unintended negative consequences.

SMART USE OF TECHNOLOGY

Utilizing technology effectively will help to identify and mitigate noncompliance with the blood management program. Advancements such as electronic order entry and computerized decision-support have improved physicians' awareness of evidence-based practices related to transfusion guidelines. These technologies can provide pre-approved prompts to assist practitioners in decision-making and can identify non-compliance with policies and guidelines. Prompts include alerts, soft stops, and hard stops.

Secondary Driver: Link order sets for transfusions to recent lab values and to documentation of clinical indications.

In addition to other clinical indications, physicians can consider laboratory test results when making treatment decisions. Criteria can be developed to link order sets for transfusions in the EMR to specific lab test values or to documented justifications based on clinical indications.

Secondary Driver: Use data/information from alerts and overrides to redesign standardized processes.

Requiring documentation of justification for a transfusion to override a hard stop spurs clinicians to think twice about stepping outside the recommended guidelines and protocols. The “override reason” documentation can subsequently be reviewed to improve protocols and identify education and training needs. Additionally, monitoring the override rate can provide clues about trends and patterns in processes and systems. Many individual reasons exist for overrides to occur, but patterns of overrides suggest possible system failures. These failures could range from human errors to inadequate order sets. Analysis of override patterns may identify care areas that are likely to require process improvement.

Secondary Driver: Use alerts wisely.

Overuse of alerts and hard stops can cause alert fatigue and frustration. This frustration can lead to the use of “work-arounds” that may increase risk and reduce safety.

Change Ideas

- Align order sets with recent lab test values and clinical indications. Require documented clinical justifications for transfusions via an alert or hard stop.
- Design alerts and hard stops to help the practitioner “do the right thing.”
- Use alerts to prompt reconsideration and justification for choices. (Help providers “choose wisely.”)
- Use focused audits to identify practice patterns and system failures.

- Prompt real-time learning from each failure.
- Use data/information from alerts, hard stops, and overrides to revise and improve standardized order sets and protocols

Suggested Process Measures

- The number and rate of alerts triggered by each individual practitioner.

“Hardwiring” Smart Use of Technology in Improvement Plans

Soft stops, hard stops, and alerts are all examples of hardwiring. A soft stop is a reminder that requires no action. A health care provider can proceed past a soft stop simply by pressing a key or clicking the mouse. A hard stop requires a specific and appropriate action, such as a documented justification, before the provider is allowed to proceed.

PATIENT AND FAMILY ENGAGEMENT

Involvement of the patient and family in the decision-making process can be an important step in reducing unnecessary transfusions. Informing patients about the risks as well as the benefits of blood transfusions and discussing therapeutic alternatives will allow patients to participate in their care and to provide informed consent.

Secondary Driver: Develop an informed consent process specific to blood and blood product transfusions.

A recent survey found that approximately 25 percent of all written complaints from patients and families centered on poor communication. Patients are asking to be treated with dignity and respect, and express a desire to be more actively involved in their care. Before patients or family members can be further engaged, however, they must be given the knowledge needed to participate in and contribute to decision-making, i.e. information about the benefits, side effects, and potential risks of blood transfusions.¹¹

Secondary Driver: Engage the patient and family in decisions about blood transfusions.

There is little research evidence on how interested patients are in blood transfusion processes. However, patients do expect “the right care at the right time.” There is evidence to support that patients prefer greater involvement in their care and the ability to make decisions about their health. They want information presented in a way that they can understand, but they don’t want to be told what to do. We need to keep these basic concepts in mind as we care for and communicate with our patients.¹¹

Secondary Driver: Always consider literacy level.

The Institute for Medicine defines Health Literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”²¹

Negative outcomes have been tied to low levels of health literacy in patients. Providing information and education at a level and in a language that is understood will assist patients and their families in making truly informed decisions and providing truly informed consent.

Change Ideas

- Provide patient education in a language and at a literacy level all can understand.
- Develop an informed consent specific to blood and blood product transfusions.
- Engage patients and family members in the development of the informed consent process by soliciting input on verbal scripts and document readability.
- Fully discuss benefits and risks, but keep informed consent discussions at the patients’/families’ comprehension level.

Suggested process measures

- The percentage of patients who received an informed consent specific to blood and blood product transfusions.

“Hardwiring” Patient and Family Engagement in Improvement Plans

Communicate, communicate, communicate. You cannot communicate too often or too little with your patients and their families. Seek to understand patients’ feelings or perceptions about blood transfusions prior to a transfusion’s necessity. Offer alternatives to transfusion if available, but, if not, inform patients about the potential need for a transfusion as far in advance as possible. Making enhanced communication with patients a habit can change your hospital’s culture and promote positive patient outcomes.

POTENTIAL BARRIERS

- In the past, the decision to transfuse red blood cells was based upon the “10/30 rule,” i.e. transfusion was used to maintain a blood hemoglobin (Hgb) concentration above 10 g/dL (100 g/L) and/or a hematocrit above 30 percent. Other options are available today for physicians to consider that may be clinically effective and avoid the risks of transfusions.
- Physicians may resist using standard orders, believing that the orders represent “cookbook medicine.” Educating physicians regarding the proven value of standard order sets in reducing unnecessary blood transfusions and improving patient outcomes can mitigate this resistance and increase adoption. Presenting customized options and “opt-outs” for patients with special needs can promote acceptance.
- Recognize that, for many physicians, technology will demand changes in their practice. The use of alerts, hard stops, and decision-support mechanisms may be new and invoke perceptions of a loss of control and of “being told how to practice medicine.” To help engage physicians in the use of technology, recruit one or two early-adopting physician champions to serve as ambassadors and mentors for these changes.
- Technology involves a learning curve. Different practitioners will adapt to new technologies and processes at different rates. Provide adequate training and support for practitioners unfamiliar with new systems and technologies.

Useful Links

- American Association of Blood Banks.
Website: <http://www.aabb.org/Pages/Homepage.aspx>
- American Red Cross.
Website: <http://www.redcross.org/>
- British Blood Transfusion Society.
Website: <https://www.bbts.org.uk/>
- International Society of Blood Transfusion.
Website: <http://www.isbtweb.org/home/>
- Transfusion and Tissue Transplantation Guidelines.
Website: <http://www.transfusionguidelines.org.uk/>
- Transfusion Medicine.
Website: [http://onlinelibrary.wiley.com/journal/10.1111/
%28ISSN%291365-3148](http://onlinelibrary.wiley.com/journal/10.1111/%28ISSN%291365-3148)
- Choosing Wisely. Website: <http://www.choosingwisely.org/>

Appendix I – National Quality Forum (NQF)’s Serious Reportable Events: Surgical or Invasive Procedure and Care Management Events

EVENT	RESOURCES
1. SURGICAL OR INVASIVE PROCEDURE EVENTS	
1A. Surgery or other invasive procedure performed on the wrong site.	HRET HEN Surgical Site Infections Change Package (See Section Two: Safe Surgery) WHO Surgical Safety Checklist
1B. Surgery or other invasive procedure performed on the wrong patient.	HRET HEN Surgical Site Infections Change Package (See Section Two: Safe Surgery) WHO Surgical Safety Checklist
1C. Wrong surgical or other invasive procedure performed on a patient.	HRET HEN Surgical Site Infections Change Package (See Section Two: Safe Surgery) WHO Surgical Safety Checklist
1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure.	HRET HEN Surgical Site Infections Change Package (See Section Two: Safe Surgery) WHO Surgical Safety Checklist
1E. Intra-operative or immediately post-operative/post-procedure death in an ASA Class 1 patient.	HRET HEN Airway Safety Change Package HRET HEN Failure to Rescue Change Package
4. CARE MANAGEMENT EVENTS	
4A. Patient death or serious injury associated with a medication error.	HRET HEN Adverse Drug Events Change Package
4B. Patient death or serious injury with unsafe administration of blood products.	HRET HEN Procedural Harm Change Package
4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy.	HRET HEN Obstetrical Harm Change Package
4D. Death or serious injury of a neonate associated with labor or delivery in a low risk pregnancy.	HRET HEN Obstetrical Harm Change Package
4E. Patient death or serious injury associated with a fall.	HRET HEN Reducing Harm from Falls Change Package
4F. Any Stage 3, Stage 4, and non-stage-able pressure ulcers acquired after admission.	HRET HEN Pressure Ulcers Change Package

Appendix II: Procedural Harm-Blood Management Top Ten Checklist

Procedural Harm-Blood Management Top Ten Checklist

TOP TEN EVIDENCE BASED INTERVENTIONS				
PROCESS CHANGE	IN PLACE	NOT DONE	WILL ADOPT	NOTES (RESPONSIBLE AND BY WHEN?)
Establish a Blood Management Program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Monitor noncompliance with Blood Management criteria by ordering practitioners.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Blood transfusion criteria require assessment of patients' hemoglobin (e.g. Hgb 7-8 g/dl), their capacity to compensate for acute anemia, and their additional risk factors.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Require an informed consent specific to blood and/or blood product transfusions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Develop a Blood Management educational tool kit for ordering practitioners.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Use focused audits to identify inappropriate prescribing practice patterns and system failures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Establish an ordering policy that limits orders for transfusion to "one unit" at a time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Informed consents are available in several literacy levels and languages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Use technology to incorporate alerts and hard stops in order sets as appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Require documentation of clinical justification for blood or blood product transfusions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Additional resources, such as the driver diagram and change package, can be found at www.HRET-HEN.org

REFERENCES

- ¹ American Association of Blood Banks (AABB): National Blood Collection and Utilization Survey. Retrieved at: <http://www.aabb.org/research/hemovigilance/nbcus/Documents/11-nbcus-report.pdf>
- ² Agency for Healthcare Research and Quality: Healthcare Cost and Utilization Project Facts and Figures. Statistics on Hospital-Based Care in the United States, 2009, Section 3. Retrieved at: http://www.hcup-us.ahrq.gov/reports/factsandfigures/2009/pdfs/FF_2009_section3.pdf
- ³ Ison M. Office of the Secretary, Department of Health and Human Services: Recommendations on Blood Safety, 2011.
- ⁴ AABB Best Practices for Patient Blood Management Program, 2012.
- ⁵ SABM Administrative and Clinical Standards for Patient Blood Management Programs, 2013.
- ⁶ Carson, et al. Red Blood Cell Transfusion: A Clinical Practice Guideline From the AABB. *Ann Intern Med.* 157(1):49-58. 2012.
- ⁷ Hebert PC, Wells GF, Blajchman MA, Marshall JF, Martin CF, Pagliarello GF, Tweeddale M, Schweitzer I, Yeltsin E. A multicenter, randomized, controlled clinical trial of transfusion requirements in critical care. Transfusion Requirements in Critical Care Investigators, Canadian Critical Care Trials Group. *N Engl J Med* 1999; 340:409-417.
- ⁸ Smith A, et al. Does time matter? An investigation of knowledge and attitudes following blood transfusion training. *Nurse Education in Practice* (2013). Retrieved at: <http://dx.doi.org/10.1016/j.nepr.2013.08.016>
- ⁹ Carson J, Kleinman S. Indications and hemoglobin thresholds for red blood cell transfusion in the adult. Retrieved at: <http://www.uptodate.com/contents/indications-and-hemoglobin-thresholds-for-red-blood-cell-transfusion-in-the-adult>
- ¹⁰ Quraishy, et al. Compendium of Transfusion Practice Guidelines, The American Red Cross, 2010.
- ¹¹ Patient Involvement and Engagement in Transfusion (2013). Retrieved at: <http://www.transfusionguidelines.org.uk>
- ¹² McClelland DBL. Handbook of Transfusion Medicine (2007). Retrieved at: <http://www.transfusionguidelines.org.uk>
- ¹³ The Joint Commission and the American Medical Association: Physician Consortium for Performance Improvement, Proceedings from the National Summit on Overuse, 2012.
- ¹⁴ Institute for Clinical Excellence: Blood Transfusion Improvement Collaborative, 2003.
- ¹⁵ University of North Carolina Hospitals Criteria for Transfusions accessed on March 20, 2014. Retrieved at: www.unhealthcare.org
- ¹⁶ Weinstein R. Clinical practice Guideline on Red Blood Cell Transfusion, American Society of Hematology, 2012.
- ¹⁷ Goodnough L., et al., Blood Transfusion: Concepts of Blood Transfusion in Adults, *Lancet*, v. 381 May 25, 2013. Retrieved at: www.thelancet.com
- ¹⁸ Wang JK, Klein HG., Red blood cell transfusion in the treatment and management of anemia: the search for the elusive transfusion trigger, *Vox Sang.* 2010; 98(1):2.
- ¹⁹ Carson JL, Carless PA, Hébert PC. Outcomes using lower vs higher hemoglobin thresholds for red blood cell transfusion. *JAMA* 2013; 309:83.
- ²⁰ Institute of Medicine – National Research Council. *Health Literacy: A Prescription to End Confusion*. Washington, DC. The National Academies Press, 2004. Retrieved at: <http://www.collaborationhealthcare.com/7-20-10IOMHealthLiteracyExecutiveSummary.pdf>
- ²¹ Spiess B, Blood Transfusion and Outcomes Research, *World Journal of Gastroenterology*, 2000;6:70-3. 9.
- ²² American Red Cross. Retrieved at: <http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics>
- ²³ National Quality Forum Serious Reportable Events. Retrieved at: http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx#sre2