BLOOD COMPONENT UTILIZATION REVIEW

A KNOWLEDGE BRIEF

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"WHAT'S YOUR NAME AND DO YOU REALLY NEED THAT STUFF IN THE FIRST PLACE?"

AVOIDING ADVERSE OUTCOMES IN BLOOD TRANSFUSIONS THROUGH AN INTEGRATED APPROACH TO RISK, QUALITY, AND RESOURCE MANAGEMENT

PRESENTED AT THE NORTHEAST LABORATORY CONFERENCE
OCTOBER 2008

HUMAN FOIBLE

"DON'T BE CRAZY. THAT WILL NEVER HAPPEN IN A MILLION YEARS." *COMPLACENCY*

"WE'LL DEAL WITH IT WHEN IT HAPPENS." *UNDERESTIMATION*

"IT CAN'T HAPPENED TO US." *OVER CONFIDENCE*

CATASTROPHE

"HOW COULD THIS HAVE HAPPENED?!"

WARNING

THERE SHOULD NEVER BE ANY ADMINISTRATIVE DELAY IN THE DELIVERY OF ANY BLOOD COMPONENT WHEN THE PATIENT'S LIFE IS IN DANGER

ALL PERSONNEL INVOLVED WITH TRANSFUSION PRACTICE IN THE HOSPITAL SETTING SHOULD BE INFORMED VERBALLY AND IN WRITING THAT PATIENT EMERGENCY OUTWEIGHS ANY UTILIZATION POLICY. UTILIZATION REVIEW POLICY DOCUMENTS SHOULD INCLUDE THIS WARNING AS THE FIRST PARAGRAPH.

1 EVENT

In the fall of 1979, a medical student was assigned to the Cardiac Care Unit [**CCU**] of a large metropolitan hospital. Many of the cardiac patients were occupying regular ward beds due to lack of **CCU** beds. One patient, an elderly lady with congestive heart failure, was admitted onto one of these wards at approximately 3:00 PM. The ward resident was not informed of the primary diagnosis and, without taking a history or doing a physical exam, noted from the doorway that the patient was short of breath and could barely sit up. He ordered an initial unit of blood for immediate transfusion but did not order any laboratory tests or consult with the **CCU**. It was now 3:30 PM.

Less than an hour later a **CCU** bed became available for that patient. She had yet to be transfused. The **CCU** director came over to review the chart prior to the transfer and noticed the blood order. He informed the ward resident that it was not appropriate for this patient. That what he saw was due to her congestive heart failure and not anemia. That, transfusion could have harmed her or worse. The ward resident, being jammed up with work, never got to the chart to cancel the order. The chart was sent up to the **CCU**. As soon as that bed was changed another female patient was admitted to that room from the Emergency Department. She was heavily sedated with centrally acting pain medications.

It was now approximately 5:00 PM. The nursing day shift was over. About a half hour later, while the medical student and resident were waiting in the ward hallway for the **CCU** fellow to evaluate another patient, an evening shift nurse walked into the new patient's room with a unit of blood. The patient could be heard asking the nurse why she was getting blood. The nurse could be heard assuring her that the physician had ordered it. Fifteen minutes later, still standing in the hallway, a horrible sound issued from the patient's room. She was crying out for help in a thin, desperate, pleading voice. The student and resident rushed into the room to find her unconscious. Despite resuscitative efforts she did not recover expiring that evening.

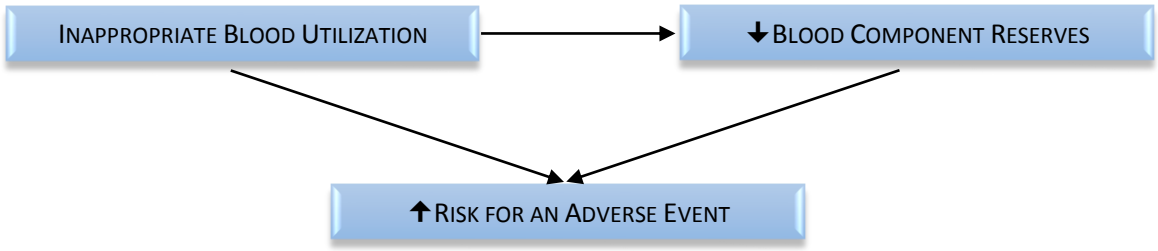
2 SITUATION

As the complexity of healthcare grows, the risk for an adverse event rises. Often, the personnel involved in monitoring for these risks and implementing procedures for avoiding, preventing, and mitigating them, tend to place too much emphasis on high frequency, low impact events while ignoring low frequency, high impact events. The outcome? What appears to be an adequate risk management activity, that is, in fact, misdirected to watching over insignificant issues while ignoring those that could do significant damage to the patient and the institution. Utilization policies and procedures in transfusion medicine are an example.

We have grown up in a society that has eliminated or greatly reduced many catastrophic events that used to impact our daily lives. Transfusion of blood to treat life threatening hemorrhage and chronic refractive anemias are two means by which this progress has been achieved. However, with any step forward, we inevitably introduce other risks, perhaps not as serious or as frequent, but none the less significant. In the case of blood product use we face several interrelated risks pertaining to patient safety that can lead to significant adverse events that threaten not only the patient but also other patients who might be denied timely receipt of a much-needed resource. Then there is the risk to the reputation of the primary care provider utilizing this resource, as well as the liability of the institution in which this event takes place.

Most of the focus in transfusion safety has been on avoiding an incompatible transfusion through the assurance of appropriate patient identification. And this presentation will cover that aspect of the event described above since it is such an ideal illustration of what can go wrong in with that effort. However, just as important are the risks implied in inappropriate utilization of blood products. Although this has been dealt with in the laboratory field, the emphasis on this has not been as strong. In part, this has been due to the introduction of hematopoietic stimulators such as erythropoietin that have replaced the use of blood as a means of maintaining the blood volume of patients with chronic refractive and secondary anemias. Yet,

there are still a significant number of clinicians who give blood more reflexively than thoughtfully thereby using scarce resources to the detriment of other patients while exposing the transfused patient to an increased risk for an adverse event due to the inherent and not fully avoidable risks of transfusion.



PATIENT SAFETY OUTCOMES:

Over the past forty-five years, several problems have been identified with inappropriate blood component utilization leading to:

- Increased risk for adverse patient outcomes
- Decreased quality of care
- Increased utilization of scarce resources

These include but are not limited to:

- Risk for allogenic transfusion reactions leading to patient morbidity and mortality
- Risk for transmitting potentially deadly infectious organisms leading to patient morbidity and mortality
- Increased costs for obtaining and processing blood leading to reduced resources for risk management
- Decreased supplies of blood relative to demand leading to inadequate reserves and delayed treatment
- Increased regulatory complexity for laboratory and hospital practice leading to error.

3 PROBLEM

How do hospitals implement an effective blood component utilization program while assuring:

RISK	*Maximize patient safety* with correct and timely ordering of blood components with maintenance of patient identification throughout the entire process
QUALITY	*Minimize* discomfort and the pain *suffered* due to wrong or delayed transfusion of blood components matched to patient diagnosis and clinical status
UTILITY	*Minimize expenditure* of scarce blood component resources through use of clinical criteria via paper-based or electronic forms

More specifically:

- How does the laboratory influence clinical transfusion practice so that the appropriate blood product is ordered only when clinically justified, yet avoid an adverse patient outcome through imposition of overly restrictive criteria that thwart independent clinical judgment on the part of the physician?

- How can the laboratory prevent the complex interactions and communications that occur between nurses, clinicians, and technologists during the ordering and delivery of blood products from adversely impacting patient safety?

4 SOLUTION

The solution to the above stated problem is the implementation of a comprehensive Integrated Blood Component Management System [**IBCMS**] that provides the means to efficiently monitor and correct blood bank utilization patterns while building a cooperative framework with key hospital staff to deal effectively with risk and quality issues. This approach is facilitated by integrating all aspects of healthcare management to secure a balance between over and under treatment of our patients with blood components while assuring that, when transfused, they are appropriate, properly given, and to the correct patient.

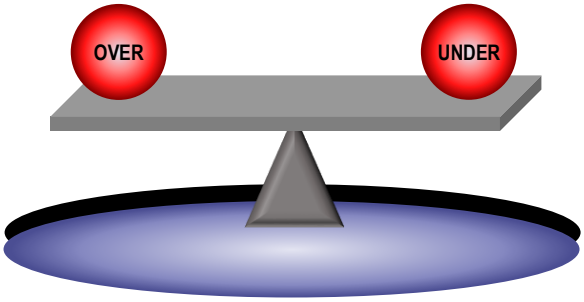
5 STRATEGIC MANAGEMENT APPROACH – INTEGRATED SYSTEMS MANAGEMENT

There are three critical areas of healthcare management that are interrelated. This interrelation includes bth synergy and conflict that can make it difficult to maintain balance between over and under treatment of our patients. In very general terms these are:

RISK MANAGEMENT: Delivering safe blood components to the right patient while minimizing the impact of adverse reactions that cannot be entirely prevented or avoided.

QUALITY MANAGEMENT: Delivering blood components in a timely manner with minimal discomfort to the patient assuring the personnel involved with this process are fully supported.

RESOURCE MANAGEMENT: Transfuse blood component(s) only when clinically appropriate, while avoiding under treatment that may harm the patient.



OVERVIEW OF THE TRIAD OF RISK, QUALITY, AND UTILITY IN HEALTH CARE PRACTICE

Experience informs us that the most effective means of improving healthcare delivery is to combine Risk, Quality, and Utility Management into Integrated Systems Management [**ISM**]. Below is a brief overview of the three components to establish a unified terminology for effective communication with hospital personnel and to define what each means operationally.

INTEGRATED SYSTEMS MANAGEMENT

RISK MANAGEMENT – Patient Safety

The continuous process of risk reduction through:

- **AVOIDING**: Not pursuing an activity all together due to an unacceptable threat to patient safety and liability to the institution
- **PREVENTING**: Putting into place changes that reduce the number of adverse events from occurring if the activity cannot be avoided
- **MITIGATING**: Intervening early to reduce the adverse effects of an event that could not be prevented through placement of monitors on critical steps in an activity's processes
- **TRANSFERING**: Reducing financial loss when an unavoidable, unpreventable, and unmitigated event leads to actionable harm to the patient.

QUALITY MANAGEMENT – Patient and Personnel Perception of Service

The continuous process of monitoring the outcome of operations against measurable standards established by customer and client expectations for the services rendered, as well as requirements imposed by regulatory agencies that oversee those activities, to improve the experience and abide by rules of behavior imposed on the laboratory and hospital. These are:

- **CUSTOMER**: The Patient's comfort and convenience – reduction in pain and suffering.
- **CLIENT**: Clinician's efficiency, efficacy, and convenience – reduction of complexity/anxiety.
- **OVERSEER**: CMS, FDA, OSHA, AABB, CAP, EPA, OSHA, and JCAHO rules.

RESOURCE MANAGEMENT – Value of Activity to Patient, Personnel, and Institution

The continuous process of ensuring the greatest good for patient using limited resources:

- **CORRECT USE**: Most effective use of a product or service in delivering **effective** patient care,
- **MEDICAL NECESSITY**: Correct product or service in delivering care **required** to treat the patient, and
- **OPTIMAL DELIVERY**: Timely application of resources in the **efficient** delivery of a product or service.

INTEGRATION NOT SEPARATION:

It should be noted that each of these three activities is:

- **INTERDEPENDENT**: Breach of patient safety leads to poor hospital image and increased legal costs.
- **OVERLAPPING**: The fewer unnecessary procedures the fewer adverse outcomes.
- **CONFLICTING**: Insist on too much patient convenience and you often risk patient safety.

Therefore, the most effective form of organizational management is **ISM**. From the beginning Risk, Quality, and Utility are planned and implemented in a mutually supportive manner. Ideally a single institutional department should handle all three activities together to assure the fullest achievable integration. Even where there is no agreement, identification of this as early as possible provides a means of directing further investigations to avoid, prevent, and mitigate error. Although, this is rarely attainable in the healthcare institution, the laboratory is in a unique position to implement **ISM** through reference to regulatory compliance coupled to patient safety issues in making a case and gaining cooperation.

6 EXAMINATION OF THE TRANSFUSION EVENT BY SYSTEMS ANALYSIS

One of the problems faced by the laboratory is a peculiar cultural bias that exists in our society. Specifically, we tend to focus our attention on high frequency low impact events. These common events lend themselves to statistical analysis which has become a healthcare management tool of choice. It has had an unfortunate effect leading to the refrain: "**IF IT CANNOT BE MEASURED IT DOESN'T MATTER.**" And, yes, these high frequency events can indicate a much more serious problem that could lead to an adverse outcome. However, this causes low frequency high impact events tend to be ignored. For example; an ABO incompatible transfusion. Often, these low frequency high impact events are a convergence of multiple errors that, taken separately, rarely raise an alarm.

A FATAL LAW OF HUMAN BEHAVIOR

HIGH FREQUENCY ERRORS WITH WHICH WE ARE FAMILIAR TEND TO LEAD TO **LOW IMPACT OUTCOMES**

LOW FREQUENCY ERRORS WITH WHICH WE ARE NOT FAMILIAR TEND TO LEAD TO **HIGH IMPACT OUTCOMES**

ABO TRANSFUSION REACTIONS EPTOMIZE THE LOW FREQUENCY / HIGH IMPACT ERROR

RESULT OF A RECONSTRUCTING THE BLOOD TRANSFUSION EVENT:

Retrospective review of the above recounted event using Failure Mode and Effect Analysis [**FMEA**] allows the classification of its components and identification of critical aspects that lead to the patient's death. The take home lessons are:

- If the resident had not ordered the blood inappropriately for a congestive heart failure patient the transfusion would never have happened. This would have saved a unit of blood and the lives of both patients: Volume overload for the first and ABO incompatible transfusion for the second.

- If there had been an effective patient identification process in place the ABO incompatible transfusion **probably** would not have occurred.

CRITICAL ASPECTS OF THE ABO INCOMPATIBLE TRANSFUSION

FAILURE MODE AND EFFECT ANALYSIS [FMEA]

CATEGORY	ITEMS
SYSTEM	
	NO PROCEDURE FOR PROPERLY IDENTIFYING THE PATIENT AT THE TIME OF THE DRAW – BED NUMBERS WERE USED
	NO PROCEDURE FOR MATCHING REQUISITIONS TO BLOOD UNITS IN THE LAB – LOG SYSTEM BY BED NUMBER USED
	THE RESIDENT WAS OVERWORKED AND DISTRACTED BY SYSTEM ISSUES LEADING TO PATIENT NEGLECT
TOOLS	
	NO FORM TO CONSOLIDATE AND DOCUMENT PATIENT IDENTIFICATION CHECKS
PROCESSES	
	THE PROCEDURE FOR IDENTIFYING PATIENTS AT TIME OF TRANSFUSION WAS FAULTY AT SEVERAL POINTS
	THE PROCEDURE FOR MONITORING PATIENTS DURING TRANSFUSION INADEQUATE – NO 'HAND AND WATCH'
PERSONNEL	
	THE RESIDENT WAS INEXPERIENCED LEADING TO THE NEXT TWO EVENTS
	THE RESIDENT DID NOT PROPERLY EVALUATE THE PATIENT
	THE RESIDENT DID NOT PROPERLY UTILIZE BLOOD BANK RESOURCES
	THE TRANSITIONING NURSING STAFF DID NOT PROPERLY COMMUNICATE A CHANGE OF PATIENT IN THE ROOM
	THE NURSE HANGING THE BLOOD DID NOT FOLLOW PATIENT IDENTIFICATION PROCEDURE THAT DID EXIST
	THE NURSE HANGING THE BLOOD DID NOT → LISTEN TO THE PATIENT ← !!!

THE RISK:

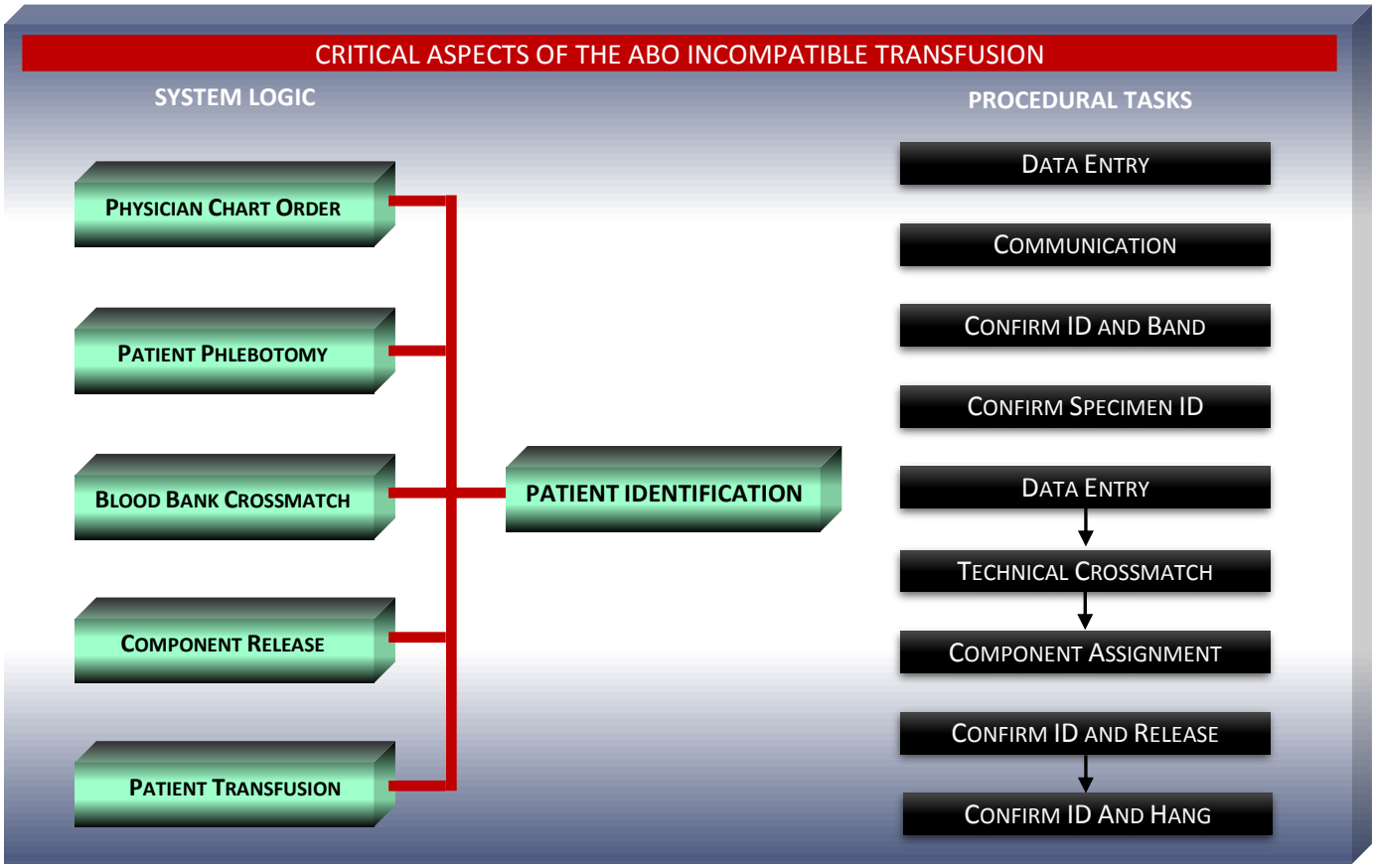
A search of the literature shows that the rate of acute hemolytic transfusions varies from 1 in 25,000 to 1 in 33,500! Most of these are ABO incompatible transfusions. Almost all (80% +) are due to misidentification of the patient and are, therefore, preventable. Although some do not result in significant clinical findings, most result in significant short- or long-term morbidity *including but not limited to one or more of the following:*

- **Renal failure**
- **Pulmonary damage**
- **Myocardial infarction**
- **Congestive heart failure**
- **Liver damage**
- **Bowel ischemia with infarction**

Studies show that as little as 10 – to – 20 ml's of ABO incompatible blood can cause death. The reported incidence of fatal hemolytic transfusion reactions varies widely in the literature and ranges from as little as 1 in 700,000 up to 1 in 160,000. Since many of these events go unreported, the rate is probably much higher.

THE COST:

Unfortunately, there are no good sources available for calculating the total cost of an ABO incompatible transfusion. However, court costs and awards by judgment or settlement can range from several hundred thousand to several million dollars. The additional loss of community confidence in the hospital as well as the psychological devastation to the family and administering health care workers is incalculable.



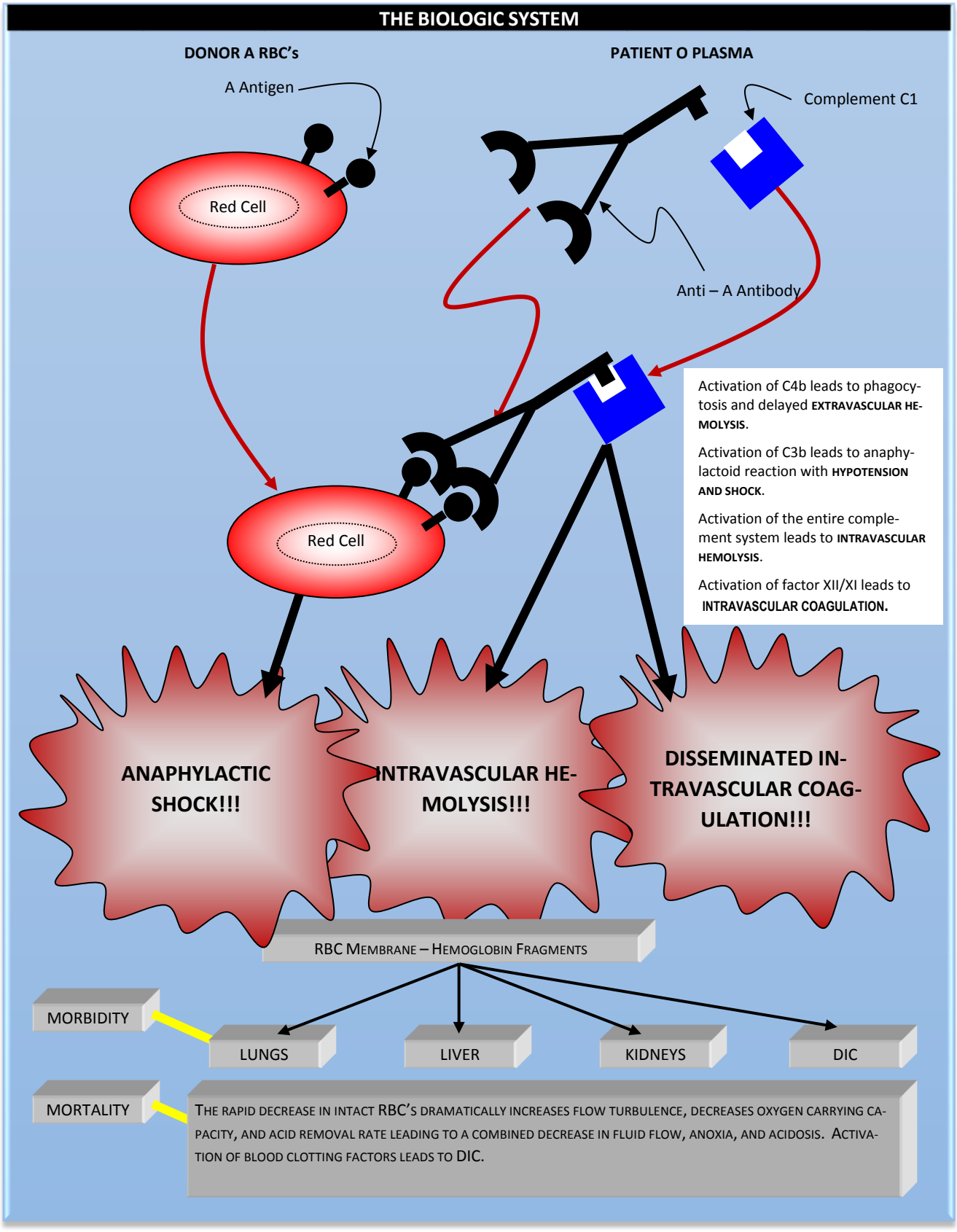
THE SCHEMA ABOVE AND LITERATURE REVIEW IDENTIFIES WHERE TRANSFUSION ERROR OCCURS

- Mislabeling of type and cross-match requisitions.
- Transcription of one patient's information onto the card and requisition of another.
- Misidentification of patients with similar names in the same hospital.
- Improper patient identification when obtaining specimen.
- Mislabeling or failure to label blood specimens at the bedside.
- Misidentification of patients without ID bands who are unable to effectively communicate or object.
- Taking the wrong blood unit(s) to the wrong ward/clinic/operating room.
- Blood unit mix up when two or more patients require blood simultaneously.
- Incorrect blood release form presented to blood bank.
- Healthcare personnel taking blood from the blood bank without permission.
- Release of the wrong unit by the blood bank.
- Failure to compare information on the blood unit with patient ID.
- Improper patient identification when giving the transfusion.

ADDITIONAL RISKS ASSOCIATED WITH BLOOD COMPONENT TRANSFUSIONS

In addition, although not within the scope of this presentation, there are many other causes of fatal transfusion reactions including but not limited to:

- Unusual incompatible antibodies
- Thermal damage to RBC's
- Hepatitis
- Bacterial contamination
- Respiratory distress
- Circulatory overload with congestive heart failure and pulmonary edema
- TRALI – Transfusion related acute lung injury
- Anaphylaxis
- White-cell antigens
- Inappropriate additions to blood products before or during the transfusion



7 AN OVERVIEW OF AN INTEGRATED BLOOD COMPONENBT MANAGEMENT SYSTEM

The Integrated Blood Component Management System [IBCMS] is a set of interrelated tasks carried out co-operatively by technologists, nurses, physicians, and pathologists. This process is implemented and codified through a structured document system that includes the following elements:

- **PLANS:** to define one or more **goals** and expected **outcomes**;
- **POLICIES:** to define **measurable objectives** and **results** for each goal;
- **GUIDELINES:** that define clinically appropriate **transfusion criteria** for each component;
- **MONITORS:** based on guidelines to track, analyze, and modify **utilization patterns**;
- **FORMS:** to establish **process integration** and capture **data** for **analysis**;
- **PROCEDURES:** to document the **methods** by which the system is implemented; and
- **AUTOMATION:** to provide **real time management** capabilities as well as **messaging**.

PLANS: A plan must be developed that clearly states the problem(s) to be solved, defines goals, proposes solution(s), presents a process of implementation, and provides general statements about expected results and limitations that represent the rewards and risks. As an example, this article is organized in plan form.

POLICIES: Each policy should define one or more measurable objectives to achieve a single goal. Each justifies the goal to hospital staff regarding the most important aspects of blood component management. Only **what** is to be done is included in the policy. All details of **how** and **when** this is to be done is kept out to simplify the policy by removing complicated procedural aspects that may change from time to time. Finally, the policy must establish clear non-overlapping lines of authority and responsible for each '**what**'.

GUIDELINES: Practice guidelines in transfusion medicine contain clinical criteria developed in cooperation with clinical staff and appropriate supervisory committees informed by the literature for the transfusion of each component usually collated and published in a Blood Component Management Form [**BCMF**].

NOTE: Criteria provided in this document are examples only – each institution's criteria may be different.

MONITORS: The laboratory, clinical staff, and appropriate supervisory committees establish which critical aspects of the transfusion activity are to be monitored regarding application of the guidelines to assure appropriate utilization while avoiding under transfusion to balance the risks identified. These Criteria for intervention should be established through a **Risk Assessment** prior to implementation and passed through the appropriate institutional committee(s) and decision-making system to assure institution wide support for any intervention in clinical practice that might be required to assure success.

FORMS: Based on the guidelines and monitoring criteria, the entire transfusion system is integrated into one streamlined process backed up by one or more forms that

- Establish task chronology, authority, and responsibility;
- Assure task completion; and
- Document all significant events and actions.

Integration assures maximum compliance by all staff involved in blood component therapy, proper execution of each task in the system, and minimal expenditure of administrative time and personnel resources to achieve defined goals. The back of the form permits monitoring of key clinical and administrative data before, during, and after the transfusion further integrating quality assurance and risk management into the process. The form title is: Blood Component Infusion Form [**BCIF**]

NOTE: The monitoring criteria are provided as examples only – each institution's criteria may be different.

PROCEDURES: Once the policies, guidelines, and monitors have been implemented through a forms-based system, the processes required to achieve system goals and objectives are codified in a set of procedural documents that serve as reference material for regulatory requirements as well as resource and training documents for technologists, nurses, clinicians, and pathologists.

AUTOMATION AS A MEANS OF EFFICIENT INTEGRATION OF BLOOD TRANSFUSION PROCESSES:

More and more hospital information systems have the capability of designing on-screen entry forms that provide some automation. Ideally, an automated blood ordering and transfusion system checks patient hematologic indices in the laboratory results database against the quantitative transfusion criteria and checks the patient's problem list against the qualitative practice criteria to determine if the order is justified.

Criteria checking is most easily implemented when there is an integrated Electronic Health Record [**eHR**] based on a relational database so that Structured Query Language [**SQL**] declarations can be made against the appropriate data tables. Several levels of ordering control can be established using this approach. For example, the system could prevent the routine ordering of any component without a physician providing the appropriate justification or an override for medical emergencies. Or, an automatic message could be sent to the blood bank, the ward, and the ordering physician warning of any irregularities for any order that did not meet practice guidelines. This model provides effective real-time component management that maximizes quality of service to the patient while minimizing adverse patient outcomes. At the end of this presentation is an example set of automated forms based on the VA Computerized Patient Record System [**CPRS**] proposed at the Togus VAMC in Maine in late 2008.

8 AN OVERVIEW OF IMPLEMENTATION OF BLOOD UTILIZATION POLICY THROUGH A COOPERATIVE EFFORT

There are four important requirements for the successful implementation of a blood component management system. Each requirement should be pursued concurrently and continuously to maximize success:

- **EDUCATION**: Enlighten and convince all involved of the goals and objectives.
- **NEGOTIATION**: Disagreeing without being disagreeable to attain cooperation.
- **RATIFICATION**: Making it through the administrative maze to attain legitimacy.
- **IMPLEMENTATION**: Incremental to avoid shock, consolidate gains, and validate each step.

EDUCATION: Laboratory technologists and pathologists need to develop and implement an ongoing education activity to define appropriate blood component utilization for physicians and safe transfusion practices for nurses. The educational phase familiarizes the hospital staff with key features of good blood component practice and makes them comfortable with and more accepting of the laboratory personnel providing the education and their follow up suggestions on implementing blood utilization policy.

In addition, the educational process should start out by orienting everyone involved in transfusion therapy to the philosophy:

- **RISK**: Patient safety – **FIRST**
- **QUALITY**: Patient experience – **SECOND**
- **UTILITY**: Value of each transfusion balanced against all costs – **THIRD**

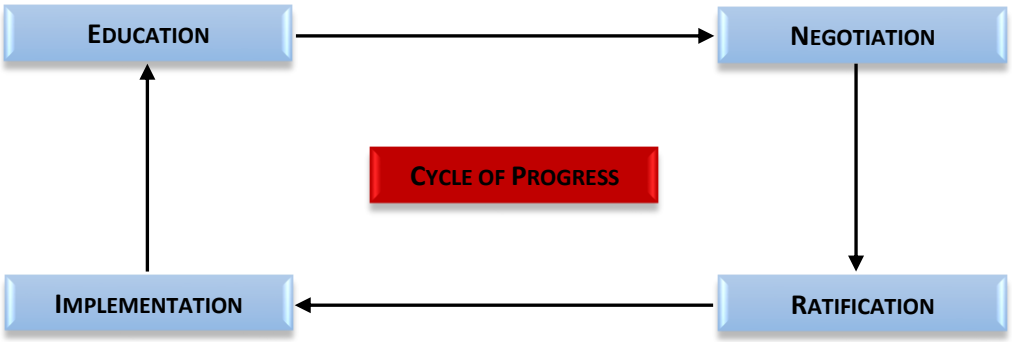
This will begin the process of establishing:

- **GOOD JUDGMENT**: in using and giving blood components.
- **IDENTITY OF PURPOSE**: amongst all those involved in this activity.

NEGOTIATION: Once the educational presentations are in progress, laboratory personnel doing the educating need to suggest implementing a blood component management system to key nursing and physician staff. Cooperation and firm support can be obtained by giving them a role in the development of the program which then gives them a personal stake in its success.

RATIFICATION: Finally, the program is presented to the appropriate hospital committee(s) for evaluation, debate, and ratification. Note that this process may take weeks or months and requires patience and persistence.

IMPLEMENTATION: It is one thing to design a comprehensive blood component management system; another to get it successfully implemented. It is recommended the program be designed for maximum flexibility so that, in any event, some portion of it can be implemented to the benefit of the patient, the hospital staff, and the laboratory. Once one part is proven, other elements follow more easily.



9 AN OPERATIONAL OVERVIEW OF IMPLEMENTATION OF A BLOOD COMPONENT UTILIZATION PROGRAM

There are three models by which a blood component utilization review program can be run. Each has certain advantages and disadvantages. However, as we shall see, the one that takes the most effort on the front end saves the most resources on the back end, both in terms of blood components as well as personnel time not to mention reduction in risks:

- **RETROSPECTIVE MODEL**: The easiest to implement but provides least benefit.
- **CONCURRENT MODEL**: Moderate difficulty to implement and provides moderate benefit.
- **PROSPECTIVE MODEL**: The hardest to implement yet provides greatest benefit.

RETROSPECTIVE MODEL:

This means that blood utilization review occurs after the blood component(s) have been ordered.

Here, the problem is that errors can occur which might have been captured using either of the other models. It may be difficult to implement even this model, depending on what level of cooperation is offered by the nursing staff, the amount of time that is available to the technologist to check each form, and whether the pathologist is able to contact the physician(s) in a timely manner. If the effort causes an inappropriate delay of transfusion, then quality of therapy may be compromised. It may be necessary for the technologist to enter the patient's quantitative hematology indices on a form and deliver the blood components even when criteria are not met. Offending forms are sent to the pathologist for post-transfusion evaluation, chart review, and referral according to policy long after an error occurs that could compromise patient safety.

CONCURRENT MODEL:

This means that blood utilization review occurs at the time the blood component(s) are ordered.

It will be difficult to implement all features of the concurrent transfusion model. There may be resistance or lack of resources. In this case, a partial implementation is made. For example, only the quantitative hematology indices are entered by the nurse and sent to the blood bank with the patient specimen. At this point, the technologist checks the form to see if the patient indices meet the printed criteria. If they do not, the pathologist is notified and attempts to contact the physician for further information prior to releasing the blood component.

PROSPECTIVE MODEL:

This means that blood utilization and risk management are taught prior to blood component ordering and the physician is responsible for justifying their use of component(s) in order to be allowed to execute an order.

As you will have guessed by now, I chose the prospective model with all its up-front difficulties as the model of choice in establishing transfusion policy in general and implementing utilization review standards specifically. The management technique laid out above has proven itself generally effective over time depending on the degree of support the laboratory gets from the institution's administration and the diplomatic and verbal skills of the pathologist. Below is a more detailed overview of how this model is organized and run.

There is a set of key phases in the transfusion activity under which the critical aspects of risk, quality, and resource management should be defined explicitly and followed continuously. The utilization review component is integrated into this system to save time and assure continuity of monitoring of all-important aspects of transfusion activity. In very general terms these phases can be defined as follows:

- **ORDER PHASE – BASED ON PRIOR EDUCATION AND TRAINING WITH JUSTIFICATION REQUIRED**
- **PATIENT IDENTIFICATION PHASE**
- **TECHNICAL PHASE**
- **TRANSFUSION PHASE**
- **TRANSFUSION REACTION PHASE**
- **POST TRANSFUSION EFFECT PHASE**
- **ANALYSIS AND EVALUATION PHASE**
- **ARCHIVE PHASE**

This model is driven by well-crafted forms that provide:

- **WORK FLOW**: Flow chart to assure the health care provider knows what to do next
- **FLAGS CRITICAL TASKS**: Patient safety effort is re-enforced with written instructions
- **GUIDELINES**: Criteria to help the health care provider make clinically appropriate decisions
- **DOCUMENTATION**: Simultaneously documenting those tasks and outcomes being monitored

Below is a brief overview of what constitutes each phase in terms of its critical steps:

ORDER PHASE – CLINICAL DECISION MAKING: This starts the ball rolling – hopefully in the right direction. Ideally, the system should be implemented prospectively where physicians have been previously educated and refer to quantitative/clinical criteria printed on a blood component management form to help them make four key decisions:

- Whether or not to transfuse a patient
- Which component(s) is/are indicated for the patient's clinical condition
- When and what order to transfuse the component(s)
- How they are to be transfused – that is, what associated fluids may or may not be co-infused

The clinician's decision to order one or more components is justified, either by meeting the quantitative criteria, or by checking the appropriate clinical criteria. If none of the quantitative or clinical criteria are met, the clinician enters a textual justification and signs the form. At this point, if properly designed the component order form can include a Patient Informed Consent Section [**PICS**]. Either the clinician, or if hospital policy allows, the nurse visits with the patient, double checks the patient identification, executes the **PICS**, and signs the form. If the clinician is off site and hospital policy allows, the nurse fills out the form according to faxed or verbal instructions and the clinician signs the form in the chart later.

PATIENT IDENTIFICATION PHASE – THE BLOOD DRAW:

At the bedside the person drawing the blood:

- Checks the order(s) and determines what specimen tube(s) to use
- Asks the patient to state their full name if possible [***does not ask others – see below***]
- Asks the patient to state their full social security number if possible [***does not ask others – see below***]
- **If the patient is unable to identify themselves place a unique ID band for transfusion purposes**
- Check the blood transfusion wrist band (if used by the institution)
- Carries out the appropriate phlebotomy following hospital/laboratory procedures
- Enters time and date of draw onto the specimen label at bedside
- Initials label at the time of the blood draw
- Delivers to the blood bank in a timely fashion with associated paper work to the appropriate personnel

TECHNICAL PHASE – THE CROSS MATCH:

In the blood bank the technologist verifies that the form is properly completed, the specimen is properly draw in the correct container, the specimen is properly identified, and matches all patient identification against the order. The specimen is accessioned; the specimen accession number is entered in the appropriate form and is signed/initialed. The appropriate compatibility testing is completed according to laboratory procedures, the blood component is made ready for delivery, and the ward is notified. Any compatibility problems are documented on the work the form. The pathologist is then notified. If a decision is made to continue with the transfusion process, appropriate documentation is entered the work form signed by the pathologist.

TRANSFUSION PHASE – RECONFIRMATION AND COMMITMENT:

The nursing staff receives the blood component from the laboratory after checking patient identification and verifying component identification number(s) - which are then placed onto the transfusion form. Both sign the form. A final patient identification check is done at the bedside before transfusion begins and the form is signed again by the person hanging the blood. During transfusion the Blood Component Infusion Form [**BCIF**] is used to document patient vital signs with any adverse reactions entered in an infusion grid". (Note: The time intervals and monitors shown in the accompanying form examples only. Each hospital may use a

different protocol.) If more than one unit is transfused, the back of a form is copied; the patient identification marked in it, the component transfused marked in the copy, the copied form stapled to the original form, and completed as necessary. When the transfusion is completed, the post transfusion tests defined on the form are automatically ordered for each component transfused, drawn, and delivered to the laboratory along with the empty bag and the signed infusion form after a copy has been placed in the patient chart.

TRANSFUSION RESPONSE PHASE – CLINICAL MONITORING:

If the nursing staff identifies an adverse reaction during or soon after the transfusion, the unit is disconnected immediately. This is the first step. Then clinical findings are entered in the **BCIF**, the blood bank is notified, and any necessary clinical treatment is started. The residual unit is sent with the **BCIF** back to the laboratory where a transfusion reaction workup is initiated. The reaction workup results are documented in the **BCIF** and sent to the pathologist for final review, diagnosis, and signature. In addition, delayed transfusion reactions are completed on the same form. (Note: Although the "Laboratory findings" box in the model **BCIF** included is free-form, your laboratory may wish to create a set of predefined data fields to direct technologist data entry. In addition, your hospital may have criteria for calling a transfusion reaction which may be incorporated into the **BCIF**.)

POST TRANSFUSION EFFECT PHASE - EFFICACY:

At the appropriate time after the end of transfusions predefined laboratory studies are carried out to determine efficacy of each component given. If therapeutic efficacy falls below acceptable limits, the clinician should be notified to determine the probable cause and decide if additional studies, procedures, and/or transfusions are necessary. In addition, a delayed transfusion reaction may have occurred, so the clinician should be educated to look for the signs and symptoms and order the appropriate workup in the laboratory.

ANALYSIS AND EVALUATION PHASE:

After all results are entered in the **BCIF**, the blood bank supervisor evaluates them for deviation from appropriate utilization guidelines and expected efficacy of therapy. Those results flagged for further review are sent to the pathologist on an immediate basis if they require action to maintain patient safety.

Periodically, all utilization review and transfusion outcome documentation should be collated for review and evaluation against well-defined monitors by the blood bank supervisor and Medical Director.

EVENT MANAGEMENT:

Based on previously set policies and procedures, the pathologist determines if any cases may involve inappropriate blood component utilization and refers this information to the ordering physician, their supervisor, and/or appropriate committee as required by hospital policy.

TREND MANAGEMENT:

If any inappropriate trends are identified they are addressed in a timely manner. For example, if one or more clinicians always avoids filling out the component order form and enters the same reason into the free text box, then there may be a problem with the blood ordering behavior of that clinician that needs to be brought to his or her attention and, if necessary to their supervisor.

ARCHIVE PHASE:

When all the above phases of the system are completed, copies of the form are placed in the patient chart, in the blood bank files, and, when indicated by hospital policy, with the appropriate committee minutes.

10 EXPECTED RESULTS [OUTCOMES]

A well-designed, judiciously implemented, and effectively maintained blood component management system will pay significant dividends by reducing unnecessary, wasteful transfusions, thereby reducing costs while simultaneously reducing the risk for adverse patient outcomes due to inappropriate component therapy; and

Ensuring that the right blood component(s) are transfused in each clinical situation thereby increasing the quality of hospital care given while further reducing the risk for an adverse patient outcome due to delay of treatment.

11 LIMITATIONS

Any proposed solution introduces its own set of problems. In particular, implementation of any of the three review models described above will incur administrative overhead. Unlike quantitative changes in blood component utilization patterns, a costly adverse event avoided cannot be directly measured, and increased overhead may be difficult to justify in simple economic terms. Rare catastrophic events, although very costly, are not considered in terms of ongoing operations, so it is imperative that the appropriate administrative staff be enlightened about the various benefits of integrating risk management, quality assurance, and utilization review.

12 CONCLUSION

Implementation of an Integrated Blood Component Management System [**IBCMS**] is the key to establishing appropriate blood component utilization. It assures:

- Prevention, avoidance, and mitigation of adverse patient outcomes
- High quality of service to the patient and hospital personnel
- Appropriate utilization of scarce resources needed by others

The long-term benefits to patient care, reduction in confusion as to what happens during the ordering and giving of blood products, enhanced hospital image in the community, and reduced liability for the institution are all well worth the time, effort, and costs of implementing this system.

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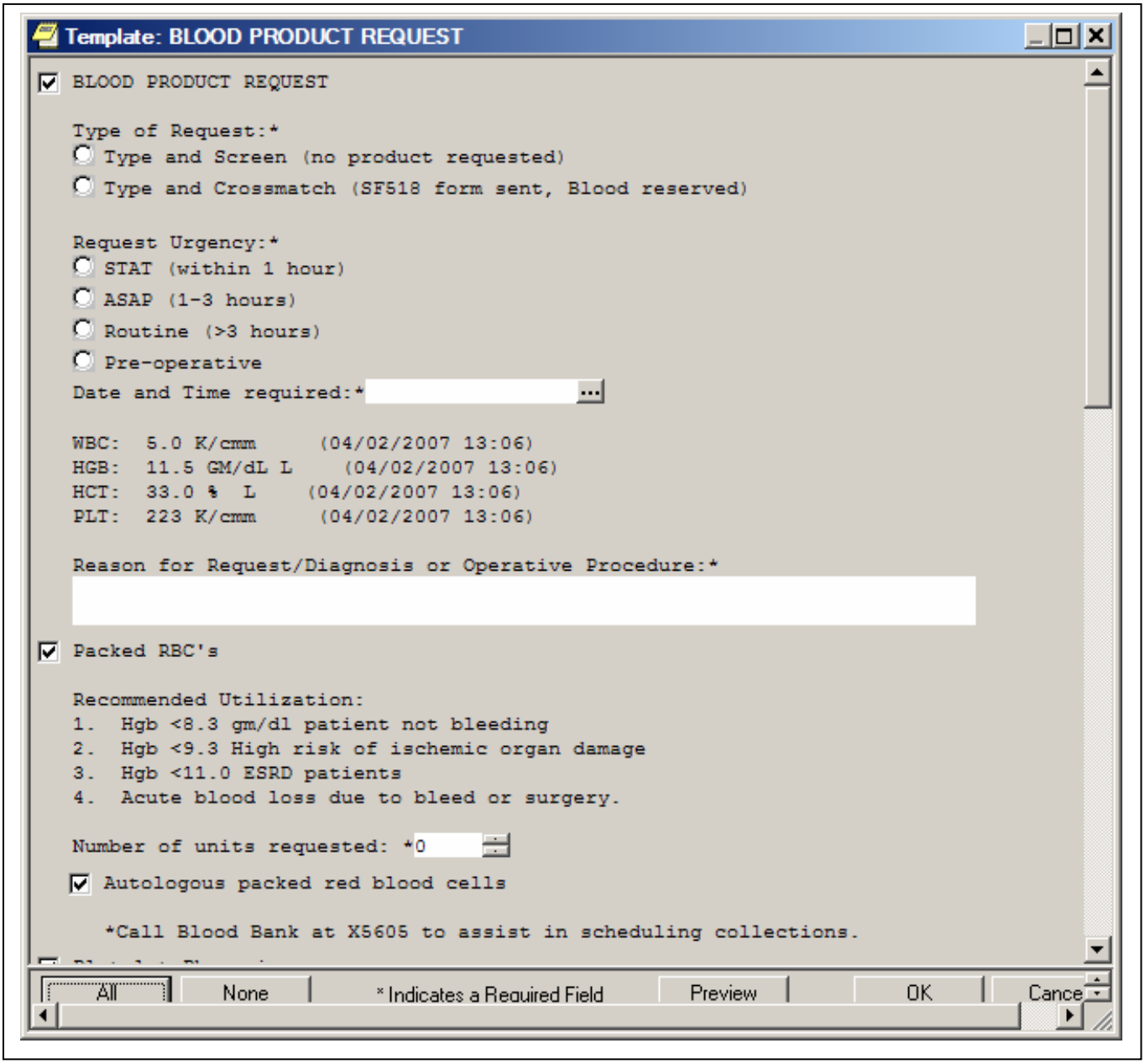
13 APPENDIX

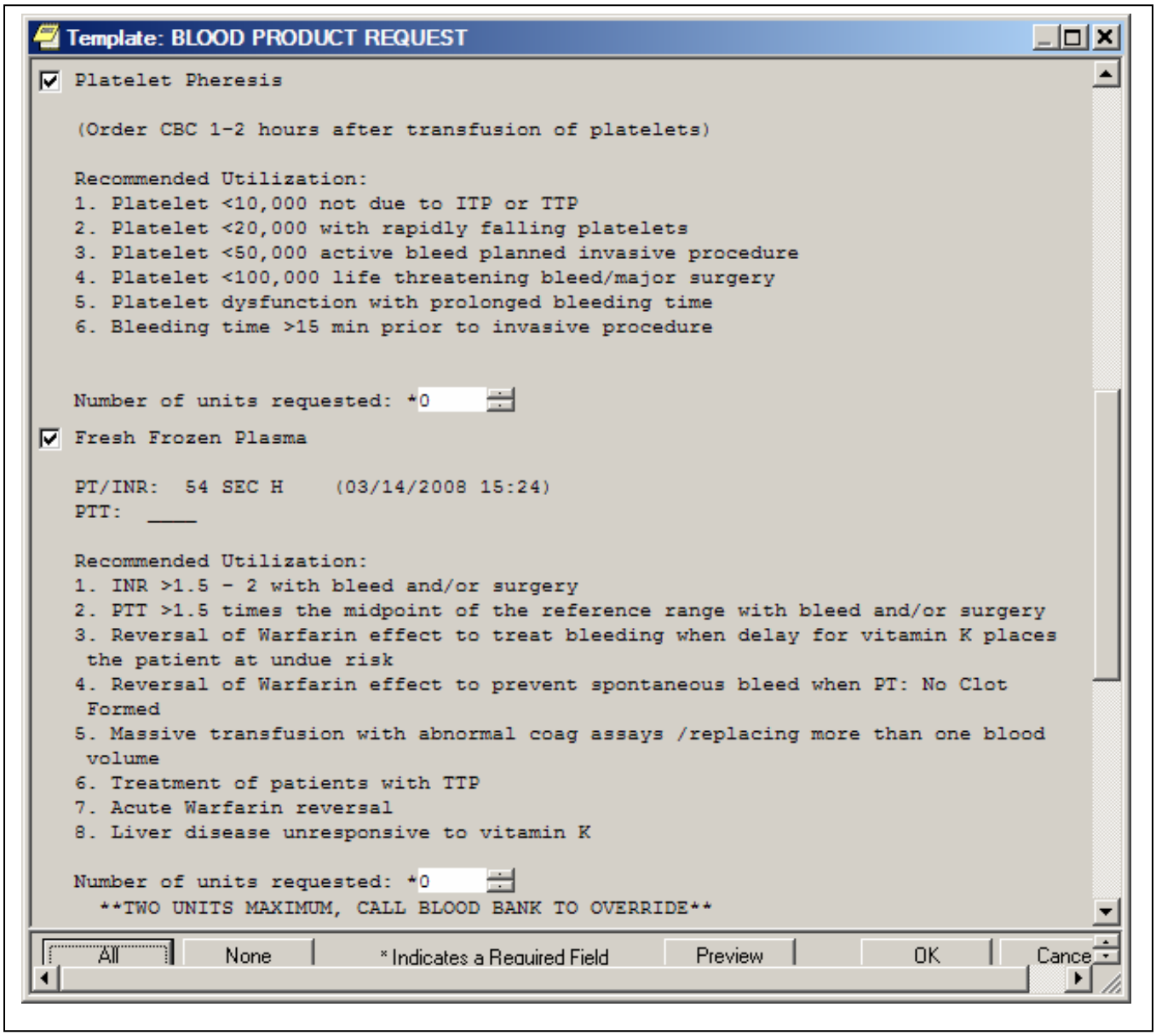
AUTOMATED FORMS BASED MODEL

Present day computer automation allows for interposing a set of required forms to be read and completed by the clinician prior to their being allowed to order a component. These forms follow the same format as the paper-based version provided in the separate **Integrated Blood Transfusion Form**. It can even bring in the most recent hematology indices and, if a certain number of days prior to the order, ask the clinician to reorder these prior to transfusing the patient if this there is no emergency. All criteria are displayed on the screen and feedback as to whether the clinician needs to further justify the order may also be considered as an additional configurable function. Below is a model developed by Cathy Frisby formerly blood bank supervisor at the Togus VAMC, Maine in 2008.

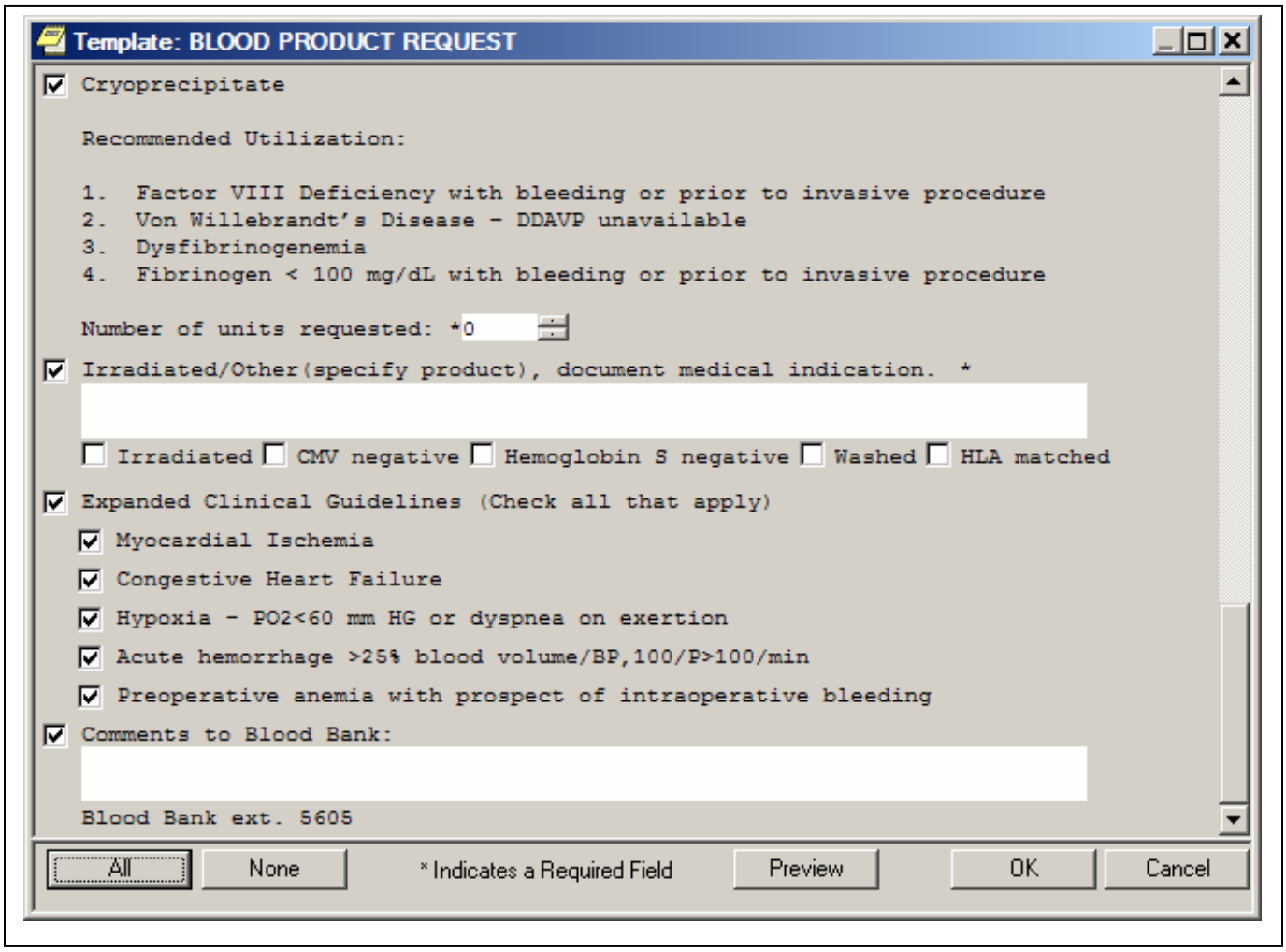
ADMINISTRATIVE HEADER AND PACKED RBC ORDER FORM



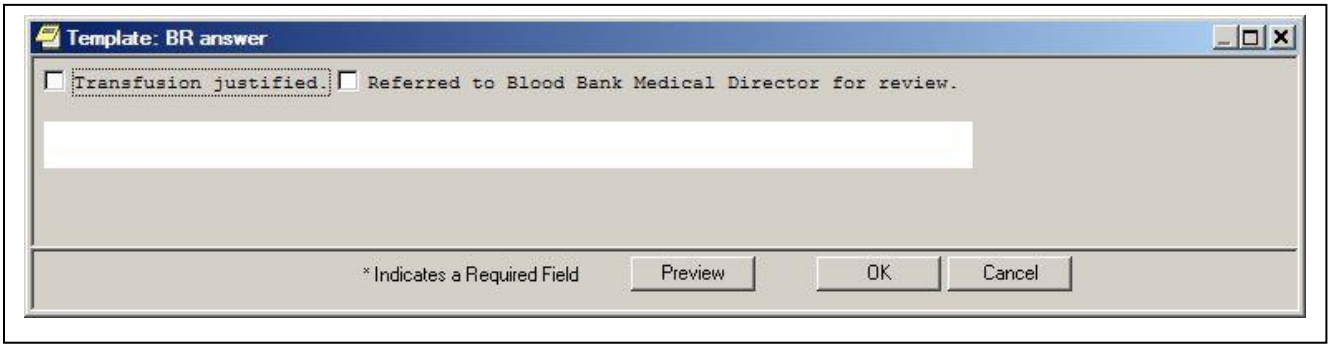
COAGULATION "DISORDER" FORM – PLATELETS AND FRESH FROZEN PLASMA



COAGULATION "DISORDER" FORM CONTINUED – CRYOPRECIPITATE



UTILIZATION REVIEW FORM



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