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## “TRANSFUSION SAFETY TAKES A BOLD LEAP FORWARD”

### A Preventable Complication

When a young woman was admitted to a major medical center for a transfusion to treat her anemia, the blood bank performed routine testing and detected no clinically significant antibodies. She had previously tested positive for multiple antibodies at another nearby facility, but unfortunately that information was not conveyed. The transfusion caused a serious hemolytic reaction.

This real-life case inspired the creation of the National Patient Antibody Registry (NPAR).

### Large Numbers

Every year, nearly 5 million people in the United States receive life-saving blood transfusions<sup>1</sup>. According to the American Red Cross, every two seconds someone in America needs blood<sup>2</sup>.

This is the demand that Blood Banks across the country encounter every day. A great deal of time, effort, and resources are expended by hospitals and blood centers to ensure that compatible blood and components are available for patients when needed.

Although acute hemolytic transfusion reactions are relatively rare, (estimated at 1 in 38,000 to 70,000 transfusions)<sup>3</sup>; their consequences can be devastating. Delayed hemolytic reactions occur more often (1 in 5,000 to 1 in 11,000 transfusions)<sup>4</sup>.

### The Push for Patient Safety

In 1999, the Institute of Medicine of the National Academies (IOM) published a landmark report, “To Err is Human”<sup>5</sup>. It became one of the most influential forces driving national health policy and focused all healthcare providers on patient safety as

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<sup>1</sup> <http://www.nlm.nih.gov/medlineplus/bloodtransfusionanddonation.html>

<sup>2</sup> 2005 Nationwide Blood Collection and Utilization Survey Report. Bethesda, MD: AABB, 2005.

<sup>3</sup> AABB Technical Manual. 15th Edition Bethesda, MD. 2005. p634

<sup>4</sup> AABB Technical Manual. 15th Edition Bethesda, MD. 2005. p 634, p637

<sup>5</sup> To Err is Human: Building A Safer Health System. Institute of Medicine, National Academy Press. Washington, DC 1999.

the number one priority. The report described the prevalence and dangers of errors in the public health system and stated that *“as many as 98,000 people die in [U.S.] hospitals each year as a result of medical errors that could have been prevented”*.

Since that time, regulatory agencies have raised the bar for patient safety, with the most recent policies tying patient management to capital reimbursements. In January 2004, President Bush called for the U.S. health-care industry to embrace electronic health records, setting a goal of having electronic health records available to all U.S. residents within the next 10 years<sup>6</sup>. Now in 2009, President Obama has continued to place a priority on computerized medical records stating, that electronic medical records will cut waste, eliminate red tape and reduce the need to repeat expensive medical tests, and... will save lives by reducing the deadly but preventable medical errors that pervade our health-care system.<sup>7</sup> The American Recovery and Reinvestment Act of 2009 includes \$19 billion to speed the adoption Health Information Technology<sup>8</sup>.

### **Inaccessible Information**

So where do we, the Blood Bank community, stand today with regards to ensuring patient safety and implementing electronic medical records? Ten years have passed since the IOM report, and over five years since the President Bush’s directive, yet most of the day to day operations of the hospital transfusion service remain unchanged.

Today, nearly all Blood Banks in the country utilize computer systems for record-keeping with built-in safety features that help reduce the likelihood of issuing incompatible components. Blood Banks accredited by the AABB are required to permanently maintain records of patients with clinically significant antibodies and to review such records before red cells are issued for transfusion<sup>9</sup>. When a patient is discharged from a given hospital, however, all of that information remains silently behind.

Patients may be seen at more than one facility for a variety of reasons, including needing specialized or emergency treatments, changes in insurance carriers or in doctor-hospital affiliations, and because of relocation

### **Unnecessary Delays**

During pre-transfusion testing, an antibody screen found to be positive requires further testing to identify the antibody, or antibodies, involved. Complex work-ups may take several hours or days, with samples often referred to outside reference laboratories for resolution.

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<sup>6</sup> [http://en.wikipedia.org/wiki/American\\_Recovery\\_and\\_Reinvestment\\_Act\\_of\\_2009#Healthcare](http://en.wikipedia.org/wiki/American_Recovery_and_Reinvestment_Act_of_2009#Healthcare)

<sup>7</sup> <http://abcnews.go.com/Health/President44/Story?id=6606536&page=1>

<sup>8</sup> [http://en.wikipedia.org/wiki/American\\_Recovery\\_and\\_Reinvestment\\_Act\\_of\\_2009#Healthcare](http://en.wikipedia.org/wiki/American_Recovery_and_Reinvestment_Act_of_2009#Healthcare)

<sup>9</sup> Standards for Blood Banks and Transfusion Services. 23<sup>rd</sup> Edition. Bethesda, MD: AABB, 2005. pp39,72

The transfusion history is a vital piece of information needed to correctly identify a red cell antibody. Patients may not be able to provide information about their prior hospitalizations, or may not be aware of problems that were encountered during previous pre-transfusion testing.

In the event that a patient is able to provide this information, the blood bank still must locate contact information for the transfusing facilities where previous testing was performed, locate staff members at those facilities by phone, and finally obtain the needed information to aid in finding compatible blood. Delays in obtaining information may be even more exaggerated if the patient presents during off-hours or weekends when staff is limited and supervisory staff are not routinely scheduled.

Rapid access to prior test results would dramatically reduce the amount of time spent with this process.

### **Testing Limitations**

Limitations in the serologic work-ups can be attributed to several causes. Inadequate specimens, abbreviated hospital stays, and reagent sensitivity may result in incomplete testing or falsely negative antibody screens. Additionally, red cell antibodies can fall below detectable levels, causing the initial screening test to be negative.

It has been estimated that alloimmunization occurs in unselected immunocompetent recipients with a risk of 1% to 1.6% per RBC unit<sup>10</sup>. Even more disconcerting is that once alloimmunization has occurred, blood group antibodies can become undetectable, especially those of the Kidd system. One investigator reported<sup>11</sup> that this occurred to 29% of antibodies after a median of 10 months and to 41% of antibodies after 5 or more years.

### **Consequences**

Lack of information regarding patient red cell antibody history can cause delays in transfusions, delays in surgery, unexpected complications in the form of delayed hemolytic transfusion reactions, extended hospital stays, and increased labor and reagent costs for serologic investigations.

## **Enter NPAR**

What if blood banks across the nation could share patient antibody information instantly? Blood Banks and Blood Centers will soon have the ability to do just that.

National Patient Antibody Registry, LLC has developed an on-line database service called The National Patient Antibody Registry (NPAR). Participating institutions periodically

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<sup>10</sup> Lostumbo MM, Holland PV, Schmidt PJ. Isoimmunization after multiple transfusions. *N Engl J Med* 1966; 275:141-4

<sup>11</sup> Ramsey G, Larson P. Loss of red cell antibodies over time. *Transfusion* 1988;28:162-5

upload patient red cell antibody information to NPAR, which makes that information accessible to subscribers via secure web connections. This service was previewed at the AABB Annual meeting and is currently available.

## **Patient Searches**

NPAR users search on patient name, sex, date of birth, blood type, and/or Social Security Number. NPAR ranks potential matches and displays:

- Patient demographics
- Antibodies identified
- Date of identification
- Facility that supplied the information.
- Transfusion summary
- History of recorded transfusion reactions
- Contact information for the identifying facility

## **Protecting Patient Confidentiality**

NPAR complies with HIPAA by allowing access only to healthcare providers in the blood bank community. Each user is assigned a password-protected account, similar to other hospital information systems. Access is limited to those with a clinical need to know, and the information displayed is restricted to that required for the services provided by the blood bank. All user sessions are logged for security purposes.

Social Security Numbers receive special protection. SSNs are hashed and encrypted<sup>12</sup> at the subscriber site during the data extraction process, prior to transmission to the NPAR. This technique allows NPAR to rapidly locate patients with matching SSNs, without storing the actual value.

## **Usefulness**

How often does one encounter a patient with antibodies, and what is the likelihood of a patient being admitted to more than one facility?

A survey of records from 23 hospitals in the U.S. and Canada, with a combined total of more than 2.6 million patients with blood bank records, showed that 3.5% (approximately 91,000) of those patients had histories of positive antibody screens and/or difficult crossmatches.

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<sup>12</sup> For more information, see: [http://en.wikipedia.org/wiki/Cryptographic\\_hash\\_function](http://en.wikipedia.org/wiki/Cryptographic_hash_function)

The data also showed that 5.8% of patients in this limited sample visited more than one hospital.

One such patient record demonstrates scenarios occasionally encountered by blood banks. The patient visited 4 different hospitals and had 5 antibodies identified in a five-and-a-half year period. (See antibody history in the table below). It was noted that during her stays at the last hospital, initially only the anti-C was detected. Later in the same year, at the same facility, anti-Leb and anti-N were detected in addition to Anti-S and anti-Fy<sup>a</sup>. Clearly this patient utilized considerable resources at each of the facilities where she was admitted, and had a significant risk for transfusion reactions.

**Record of patient with multiple antibodies identified at various facilities**

	1999	2000	2002	Early 2004	Late 2004	2005
Hospital A	Anti-C,S,& Fy <sup>a</sup>					
Hospital B		Anti-C,S, &Fy <sup>a</sup>				
Hospital C		Do AHG XM	Anti-C,S,& Fy <sup>a</sup>	Anti-Le <sup>b</sup>		
Hospital D				Anti-C	Anti-Le <sup>b</sup> ,S,Fy <sup>a</sup>	Anti-N

## Reference Library

The NPAR webpage provides a reference library which allows users to quickly find information regarding the serologic and clinical characteristics of each antibody, as well as the incidence of the corresponding antigen in various populations. This information guides the technologist in finding compatible red cells for patients with antibodies.

## Additional Uses

NPAR can also serve as a component of blood banks' emergency preparedness plans. Patient antibody information can be available through NPAR even during internal hospital or blood bank scheduled or unscheduled computer downtime. Additionally, the patient red cell antibody information would be available in the event of a national disaster, natural or otherwise. Patient records could be retrieved even when patients are geographically scattered as was the case after Hurricane Katrina.

Another feature offered by NPAR is the ability to produce individual facility management reports of system usage, totals, patterns, and trends.

## NPAR Team

Each member of the NPAR team brings unique talents and expertise to the table.

Janet Molny, President of Validation Partners, Inc, has vast experience with the validation and functionality of blood bank information systems. She founded VPI 10 years ago, and deals with blood banks and transfusion services across the country.

Adam Molny, Technical Director, has extensive expertise with data extractions and has worked on all major blood bank computer systems. He has worked closely with most of the software vendors throughout data conversion projects where clients are migrating to a new blood bank information system.

DJ Molny, NPAR Systems Architect, has nearly 30 years of experience in developing high-reliability software. His broad knowledge of computer technologies and software quality practices help ensure that NPAR will deliver rock-solid performance.

Claire Iannacone, Director of Validation and QA, has over 30 years experience working in transfusion services of varying complexities. Her background is in quality management, and has been certified to perform quality audits and assessments. She understands the regulatory and legal issues facing blood bank administrators.

## Conclusions

NPAR improves patient safety and lowers costs.

For more information about NPAR, please visit us at: [www.npar.com](http://www.npar.com)