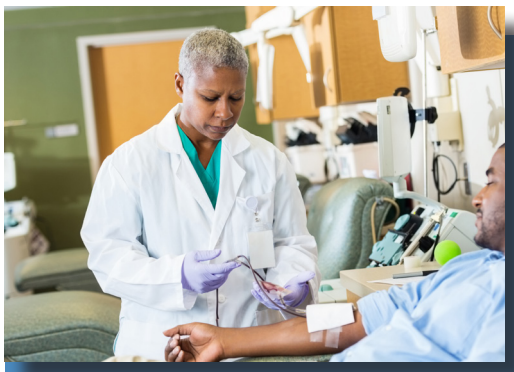


Lessons Learned From Attempted Implementation of a Patient Antibody Registry in Georgia

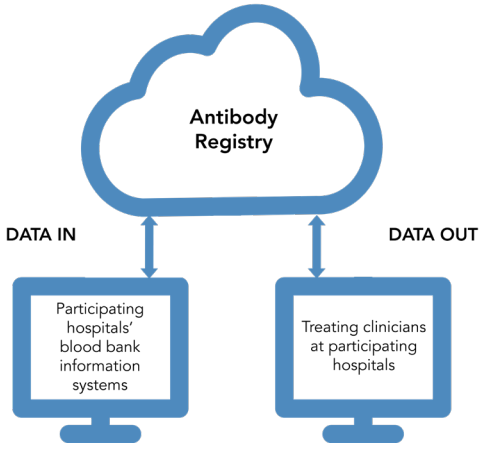
September 2021

The Problem

Many individuals with sickle cell disease and thalassemia require therapeutic red blood cell transfusions as part of their care. But blood transfusions carry their own significant risks, including alloimmunization and subsequent life-threatening reactions. This risk is higher when a complete patient transfusion history, including a history of antibodies developed in response to previous blood transfusions, is not available to providers.[1,2]

Without interoperable medical record and blood bank data information systems, obtaining a reliable and complete transfusion and antibody history across multiple health systems is difficult. Patient-managed approaches — including mobile apps, transfusion cards, or letters — have been tried; while they may improve information flow in some cases, they present their own challenges and risks.

As part of the REdHHoTT project,* which aims to characterize and reduce complications of therapeutic transfusion among people with hemoglobin disorders like thalassemia and sickle cell disease, the Georgia Health Policy Center and its clinical partners initiated an effort to test the feasibility of implementing an antibody registry system at multiple Georgia hospitals (2014-2019). While ultimately implementation was not successful, this brief provides an overview of the process undertaken and lessons learned that can inform future related efforts.



Data In: Data are automatically uploaded to the registry on a scheduled basis from participating hospitals' blood bank information systems. Data elements include personal patient identifiers such as name, sex, date of birth, and encrypted social security numbers. This data enables treating clinicians to find patients and facilitate linking of data for an individual patient transfused at multiple sites.

Data Out: Treating clinicians at participating hospitals search the registry for their patient and review their transfusion history including dates, volumes, reactions, blood antigens, and antibodies. Data also include prior transfusion locations and providers for treating clinicians to contact if needed.

REdHHoTT
Improving transfusion practice through data sharing and education

Georgia Health Policy Center
404.413.0314
ghpc.gsu.edu
ghpc@gsu.edu

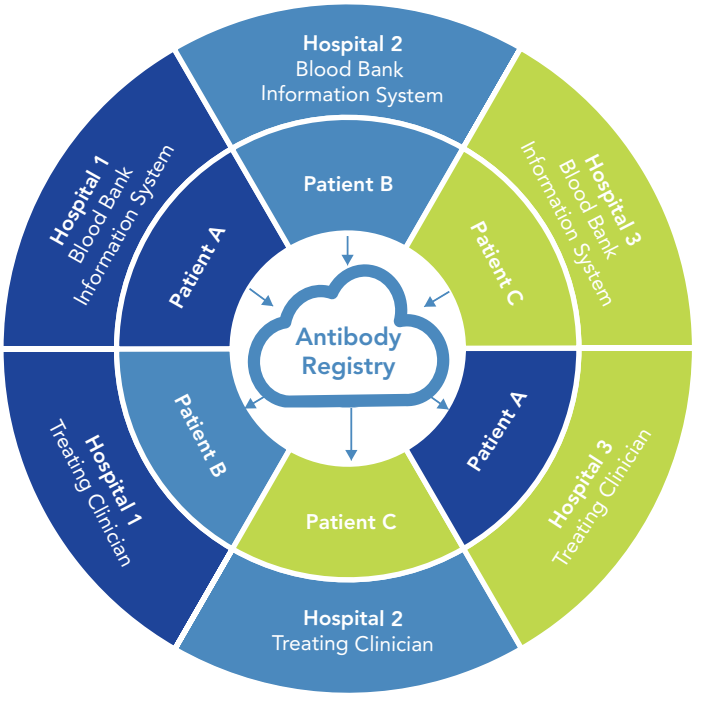
Georgia State University | Andrew Young School of Policy Studies

The Collaborators

- The Georgia Health Policy Center of Georgia State University, which provided coordination and initial funding under the REdHHoTT project.
- Three hospital-based transfusion services that are affiliated with the state's three comprehensive sickle cell treatment centers — Children's Healthcare of Atlanta, Augusta University Hospital, and Grady Health System.
- Validation Partners Inc., developers of the software solution the project sought to implement, the National Patient Antibody Registry (NPAR).

The Process

Health services research and the experience of partnering sickle cell and thalassemia experts indicated a need for an antibody registry in Georgia. The initial plan was to create a software solution in RedCap,® an online research data-collection application. When members of the project team learned of the existence of NPAR, designed expressly for the desired purpose, they invited Validation Partners to Atlanta to demonstrate the software. The team subsequently selected this application for the pilot.



In this illustration, Patient A, who has been transfused several times over their lifetime at Hospital 1, enters the emergency room at Hospital 3 while vacationing in another city. Hospital 3 clinicians determine the patient needs a blood transfusion. Before ordering it, they consult the registry and discover that several years ago, the patient created an antibody that did not show up on today's test. Based on this information, Hospital 3 is able to locate red blood units that are negative for that antigen and avoid the risk of hemolytic transfusion reaction.

Phase 1: Establish contractual agreements.

One contract was needed between Georgia State University and Validation Partners to pay setup and initial subscription fees (within the project funding period) for satisfactory implementation at three partnering health systems. Separate agreements were made between each health system and Validation Partners. Each of these involved a complex negotiation of legal, information technology, privacy, security, and cost and payment terms. While ultimately all obstacles were resolved and contracts were fully executed, the process took longer than anticipated.

Phase 2: Install software interfaces at participating institutions and establish workflow protocols.

Technical challenges were extensive — from security, hardware, and storage requirements to interfacing with disparate hospital information systems. Addressing these issues was compounded by communications challenges (e.g., connecting the right client experts with the right vendor experts, with coordination and lag times between messages). The troubleshooting demands, lags, and communications confusion taxed participating clinical, laboratory, and information technology (IT) staff at participating health systems. In addition, one institution changed its information system platform midprocess and another learned that additional hardware and programming, not budgeted for in the project, would be needed.

Phase 3: Active use and evaluation.

First one, then a second health system determined they could no longer invest staff time in the NPAR implementation effort. Even though the goal of having a platform like NPAR was to facilitate cross-system data access, the third partner initially was willing to continue and at least test the operation of the software within its single system. There too, however, obstacles soon were deemed insurmountable, and effort ceased.

Lessons Learned

An accurate transfusion history is essential to reducing the risk of transfusion-related complications, particularly for patients with sickle cell disease or thalassemia receiving care from more than one provider. The following lessons were learned during this pilot to establish a patient antibody registry in Georgia:

1. All relevant experts and parties at participating health systems should be involved from the very beginning — including the vetting of potential vendors and establishment of contractual agreements. This means health system personnel with legal, privacy and security, IT, laboratory management, and clinical care roles, as well as vendor personnel with legal, sales and marketing, privacy and security, and programming expertise.
2. A thorough baseline evaluation of each hospital system's capacity (staffing, technology, etc.) could facilitate better planning and more timely implementation.
3. In addition to involving technical experts, engagement of patients, caregivers, and advocates is strongly recommended early and throughout the process. In this case, patient advocates did participate in the planning and selection phases. Their questions and input regarding potential patient perspectives and concerns were helpful, and their continued involvement likely would have been even more important if the effort had progressed through implementation and potential expansion.
4. Direct lines of communication should be established between knowledgeable counterparts of the vendor and subscriber institutions. Highly technical information is not passed efficiently or effectively through intermediaries; live, bidirectional communication is the only way to do this satisfactorily.
5. Investigation of references with implementation experience prior to product selection may have averted some of the challenges experienced here. It became clear that the NPAR software had not been thoroughly and successfully tested in a real-world application yet, leaving some claims unproven (such as turnkey interoperability with multiple major health information technology platforms).
6. The test case here was of a privately owned product, with, at minimum, installation and annual fees for each participating hospital or clinic. Because the value of such a registry builds on its widespread use, a solution requiring low to no local cost — and one made available nationwide or beyond — would be the best way to ensure accurate, timely information that prevents life-threatening consequences.

Although unsuccessful on this attempt, all involved remain convinced that establishing such a registry is likely the best solution to a serious problem, and rebooting such an effort deserves further attention.

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* The Georgia Health Policy Center is the data-coordinating center for multi-institutional projects focused on surveillance of and health promotion for individuals with blood disorders, including the REdHHoTT project — Registry and Education for Hemovigilance in Hemoglobinopathy Transfusion Therapy in Georgia. This work was supported by Cooperative Agreement DD14-1408, funded by the Centers for Disease Control and Prevention (CDC). Content of this brief is solely the responsibility of the authors and does not necessarily represent the official views of the CDC or the U.S. Department of Health and Human Services.

[1.] Harm, S. K., Yazer, M. H., Monis, G. F., Triulzi, D. J., AuBuchon, J. P., & Delaney, M. (2014). A centralized recipient database enhances the serologic safety of RBC transfusions for patients with sickle cell disease. *American Journal of Clinical Pathology, 141*(2), 256-261.

[2.] Delaney, M., Dinwiddie, S., Nester, T. N., & Aubuchon, J. A. (2013). The immunohematologic and patient safety benefits of a centralized transfusion database. *Transfusion, 53*, 771-776.