Developing a FHIR Implementation Guide for Extended RBC Phenotyping Information

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Disclosures

In the past 12 months, I have not had any significant financial interest or other relationship with the manufacturers of the products or providers of the services that will be discussed in my presentation.

Introduction

- The problem
  - How it became apparent
  - Why it's important to address
- The solution
  - How to use HL7 standards to solve the problem
  - Why it's important to discuss this approach

The Problem: Path to Awareness

- My background
  - Not a subspecialty trained blood banker
  - Not a subspecialty trained molecular pathologist
  - Not a subspecialty trained informaticist
  - Right place / right time and old enough to have broad experience
- As medical director for a regional blood bank
  - Prior lab experience: identified inefficiencies of RBC inventory management
  - Prior work in molecular diagnostics: collaborative LDT (genotyping assay using targeted NGS)
  - Hospital client: How to get results back without rekeying?
  - Aha moment: Rekeying data? **There are NO interfaces.**

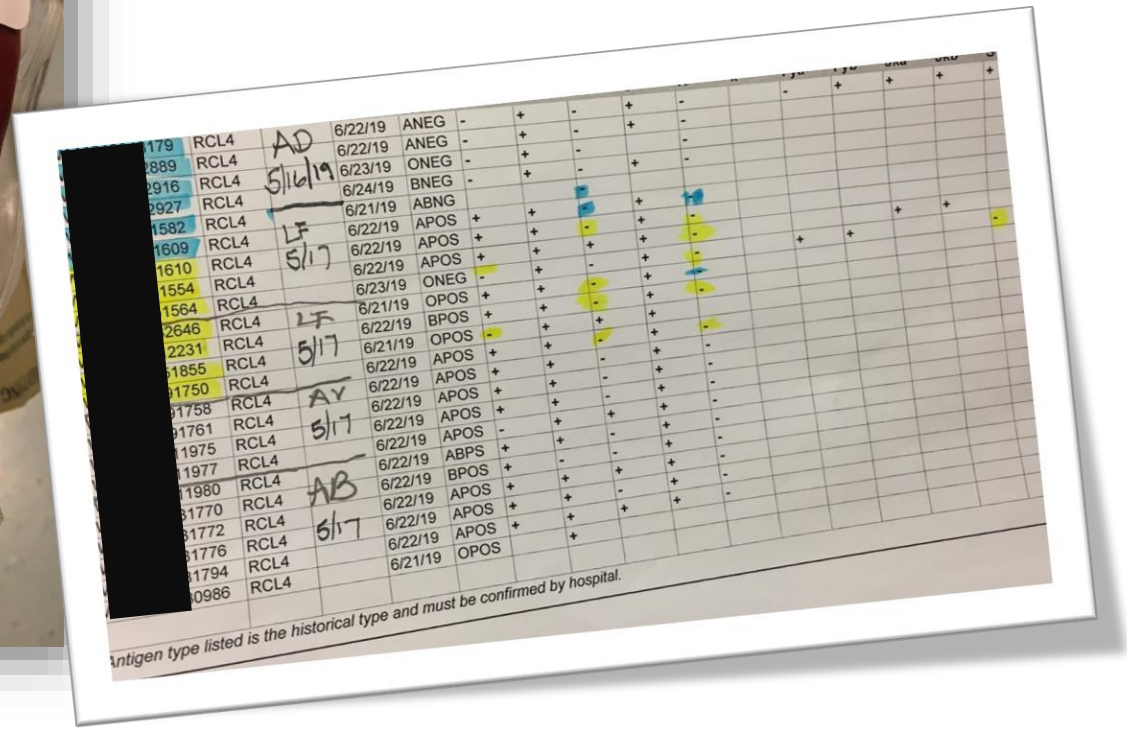
Shifting Data Landscape

- Collision of manual processes with expanding information
- Manual blood product registration was tolerable with limited metadata
- Molecular techniques are rapidly increasing the amount of data:
  - Serologic characterization is expanding
  - Molecular techniques (arrays, targeted sequencing, gene sequencing) are expanding and becoming cost-effective for more patients and donors
  - Provenance and molecular characterization information becomes critical when donors become patients
  - Search for *potentially* compatible blood can become automated and less laborious

Current Situation

- Blood donor centers
  - Computer systems geared toward effective and safe production of blood products
  - Blood establishment computer systems (BECS)
- Health system blood banks
  - Computer systems geared toward effective and safe transfusion of blood products
  - Blood bank laboratory information systems (BBLIS)
- Both systems manage:
  - Blood products
  - Associated metadata
- Barcodes provide a minimal digital interface—most of the metadata about the products must be rekeyed.

Current Situation



Photos taken at leading academic medical center / © Lantana Consulting Group

Donor & Patient Phenotype Reports are Expanding

Donor Genotype

Screen Print for DNMDN1 Date: 03/01/2021 Time: 9:11:32

(DNR/BLD) Donor Phenotypes - Update NEXT: ____ _____ DN

(SDBB) Pg 1/1

Id : [redacted]

Name : [redacted] Blood Type: O-

CMV: Positive

ABS: Negative

---------- Donor Phenotype Information ----------

S	Phenotype	Indicator
_	C	- Negative
_	c	+ Positive
_	E	- Negative
_	e	+ Positive
_	V	- Negative
_	VS	- Negative
_	K	- Negative
_	k	+ Positive
_	Kpa	- Negative
_	Kpb	+ Positive
_	Jsa	- Negative
_	Jsb	+ Positive
_	Fya	- Negative
_	Fyb	+ Positive
_	Jka	+ Positive
_	Jkb	+ Positive
_	M	+ Positive

1 BA 2 QA 3 SB 4 SF 5 HE 6 CL 7 PB 8 PF

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Patient Genotype

Practitioner Name: [redacted]

Requesting Hospital: [redacted]
Center

Address: [redacted]

Specimen Type: Whole Blood

Date of Collection: 12/10/2020

Date Received: 12/11/2020

Accession Number: [redacted]

Date Test Performed: 12/24/2020

Test Report Date: 12/24/2020

Tested Predicted Phenotypes and Results

Panel: Patient Red Cell Antigen Genotype

Group: ABO

Predicted Phenotypes	Results
A	Negative
B	Positive
O	Positive

Group: Duffy

Predicted Phenotypes	Results
Fya	Positive
Fyb	Negative
GATA	Positive

Group: Rh

Predicted Phenotypes	Results
D	Positive
C	Positive
E	Negative
c	Positive
e	Positive
V	Negative
VS	Negative
hrB	Positive
[illegible]	Positive

Group: Kell

Predicted Phenotypes	Results
K	Negative
k	Positive
Kpa	Negative
Kpb	Positive
Jsa	Negative
Jsb	Positive

Importance

We need a standard way to describe semantics.

- Examples:
  - Sickle cell disease (SCD) patients and Rh diversity
  - Pregnancy and maternal-fetal considerations
  - Rare blood types and anticipated transfusions
- Current system does not work for all patient populations:
  - Lack of resources to characterize blood products
  - Expense of searching for rare types
  - No digital information transfer methods

Importance

- What we have doesn't work well
  - Inventory management is challenging with the limited information set
  - Iterative improvement in assessing transfusions will require more granular data
- Inadequate information exchange leads to disparate health outcomes
  - Unintentional institutional biases against people of color
  - Lack of early resources results in more expensive care delivery
- This is improvable
  - Extended information of donor pool suggests “walking inventory”
  - Computational cross-matching means finding best matches for further assessment

Why Develop an Exchange Standard?

- Exchanging extended RBC phenotyping information with identical semantics addresses several aspects of the problem.
- The absence of any interface between BECS and BBLIS streamlines transition/implementation (no legacy interface concerns).
- Extended phenotype descriptions are necessary for both patients AND blood products.
- The sporadic nature of data interchange suggests a RESTful approach may be most facile.

Why HL7 and Why FHIR

- Open standards are developed through a regulated, consensus-driven process.
- Open standards make interoperability possible, creating a common specification.
- Health Level Seven International (HL7®) standards are available under a no-cost licensing agreement.
- HL7 Fast Healthcare Interoperability Resources (FHIR®) is a flexible, scalable standard that streamlines information exchange between healthcare systems.
- HL7 FHIR is endorsed for federal projects under NIH, CDC, CMS, and other HHS agencies.

RELATIONSHIP BETWEEN FHIR BIOLOGICAL PRODUCT AND A FHIR PATIENT

Process of finding a successful donor for patient blood transfusion match

1

DONOR

Descriptor of Biological Product

Date, Site, Infections

PATIENT

FHIR Patient Information

Name, Age, Hospital, Physician

FHIR biological derived product

FHIR RBC phenotyping results

2

Indicators have the same electronic representation, different metadata

3

Identifying Inventory for Testing

Identifying potential donor units for compatibility testing

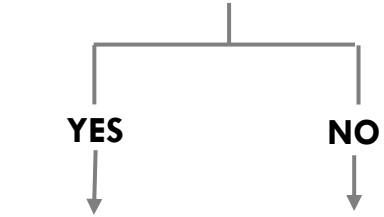
	Patient 1	Donor 1	...	Donor X
A	+	+		-
B	-	+		-
O	-	+		-
c	+	-		-
c	+	-		+
D	-	+		+
.	-	+		+
.	-	-		+

Compatibility filtering is completed electronically. Identified units move to final testing.

4

Final Compatibility Testing

Possible Transfusion



Once a patient–donor match has been found, antibody serology is conducted to screen for unexpected antibodies in and outside the ABO system. If no match is found, testing of a different unit is performed until a match is obtained.

Process (aka Spinosa Gets an Education)

- Develop HL7 FHIR Implementation Guide
  - Idea → Project Proposal → Project Scope Statement → Release
  - Identify possible related activities
  - Learn and follow HL7 Processes
- Recruit supporters
  - Professionals, exchange participants, professional organizations, vendors, government agencies
  - Resource determination, resource support (in-kind and/or financial)

Process

HL7 FHIR Implementation Guide: Overview

- Convene domain stakeholders
- Represent blood product genotyping and phenotyping information for BECS and BBLIS incorporation
- Create a common set of resources:
  - for blood product phenotyping
  - compatible with the FDA biologically derived products effort
  - compatible with International Society of Blood Transfusion (ISBT) consensus vocabulary of blood phenotypes
- Test for feasibility, ballot as national standard, and publish

Benefits of Standardizing

A standard representation of extended RBC phenotyping promotes:

- Better management of blood product inventory by:
  - Preventing accidental release of rare blood phenotypes
  - Streamlining the search for rare phenotypes
- Safer transfusion practices by:
  - Finding the most compatible blood product for testing
  - Identifying rare units through local, regional, super-regional, and national searches
- More efficient public health reporting of adverse reactions, especially when combined with biologically derived product information

Progress

Current activities:

- Distributing a white paper and inviting additional support and signatures
- Socializing the effort via HL7 Work Groups (Orders & Observations, Clinical Genomics, Patient Care)
- Engaging professional organizations (AABB, CAP, ASCP, ISBT)
- Recruiting vendors and health care organizations (health systems and blood donor centers, software and instrument vendors)

Full project launch is dependent on stakeholder support—endorsement, participation, fund raising for ballot preparation, and management.

Current Status

- Moving through HL7 processes
  - PP approved and sponsored by Orders & Observations Work Group
  - PSS submitted with ongoing approvals (Terminology and TSC)
- Building awareness and interest
  - Socializing the effort (API and additional venues)
  - Recruiting vendors (especially software vendors; marketable solution)
- Identifying sources of financial and in-kind support
  - Government agencies
  - Organizations, consortia, vendors
  - Health systems and regional blood banks

Next Steps

- Explore fit and learn more
  - Read white paper
  - Explore participation:
    - In standards effort (HL7 O&O PSS)
    - In prototyping (e.g., HL7 Connectathon)
    - As a stakeholder
- Contact:
  - John Spinosa - john.spinosa@lantanagroup.com
  - Liora Alschuler – liora.alschuler@lantanagroup.com

Other Observations of API Meeting

- AI/ML
- Digital Pathology, AI/ML
- Lab data and AI/ML
- Digital Pathology and proteomics/expression
- Genomics and AI/ML
- Anything and AI/ML

QUESTIONS?

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