



Blood Transfusion Safety in Georgia

*The transition to a
voluntary donor pool / not-for-profit model*

National CDC, Georgia

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Disclosures

- **As a member of the FDA Blood Product Advisory Committee...**
 - **Any views or opinions that are expressed in this presentation are my own**, *based on my own scientific expertise and professional judgement; they do not necessarily represent the views of either the Blood Products Advisory Committee or the formal position of FDA, and also do not bind or otherwise obligate or commit either Advisory Committee or the Agency to the views expressed*
- **Consultant/speaker:** Grifols Diagnostic Solutions, Terumo
- **Coinvestigator:** Department of Defense-funded clinical trial of pathogen reduction using a commercial technology

Disclaimers

I am **NOT** a health economist
This is **NOT** my domain of expertise

Objectives

1. Provide a brief overview of blood banking in the United States
 - Infectious risk
 - Testing work flow
 - Financial model
2. Review reasons for transition to **nonprofit design** and **100% voluntary donation**
3. Describe the **potential challenges**
4. ~~Offer some approaches based on available models~~

points to consider

Is the US model appropriate for Georgia?
What lessons might be applied to Georgia?

Abbreviations

TTIs: Transfusion Transmissible Infections

VNRBDs: Voluntary Non-Remunerated Blood Donors

1 brief History of TTIs

Pre-HIV era

1900-1982

1915

Transfusion-transmitted
syphilis first described

By **1941**, there were already 138
described cases in the literature

Orton S. Transfus Med Rev 2001;**15**: 282-91.

1950's

screening test for syphilis

1962

Incidence of post-transfusion viral
hepatitis **fourfold higher** in
recipients of blood from paid vs.
voluntary donors

Grady GF, Chalmers TC. N Engl J Med 1964;**271**: 337-42.

1965

Australia antigen → HepB sAg

1971

Screening begins

- Life was **simple**
- **Unregulated**
- Donor infectious disease testing
confined to **Syphilis and HepBsAg**

Post-HIV 1985-present

HIV is **transformative** to blood banking → spurs 30yrs of overhaul spanning policy, regulation, donor selection and testing

1985

Implementation of **anti-HIV 1** and

Busch MP, et al. Blood 2019;133: 1854-64..

1986

Hepatitis B Core Antibody (**Anti-HBc**)

1989

non-A, non-B hepatitis

HCV

1990

Anti-HCV

1999

Minipool-Nucleic Acid Testing

HIV and HCV MP-NAT

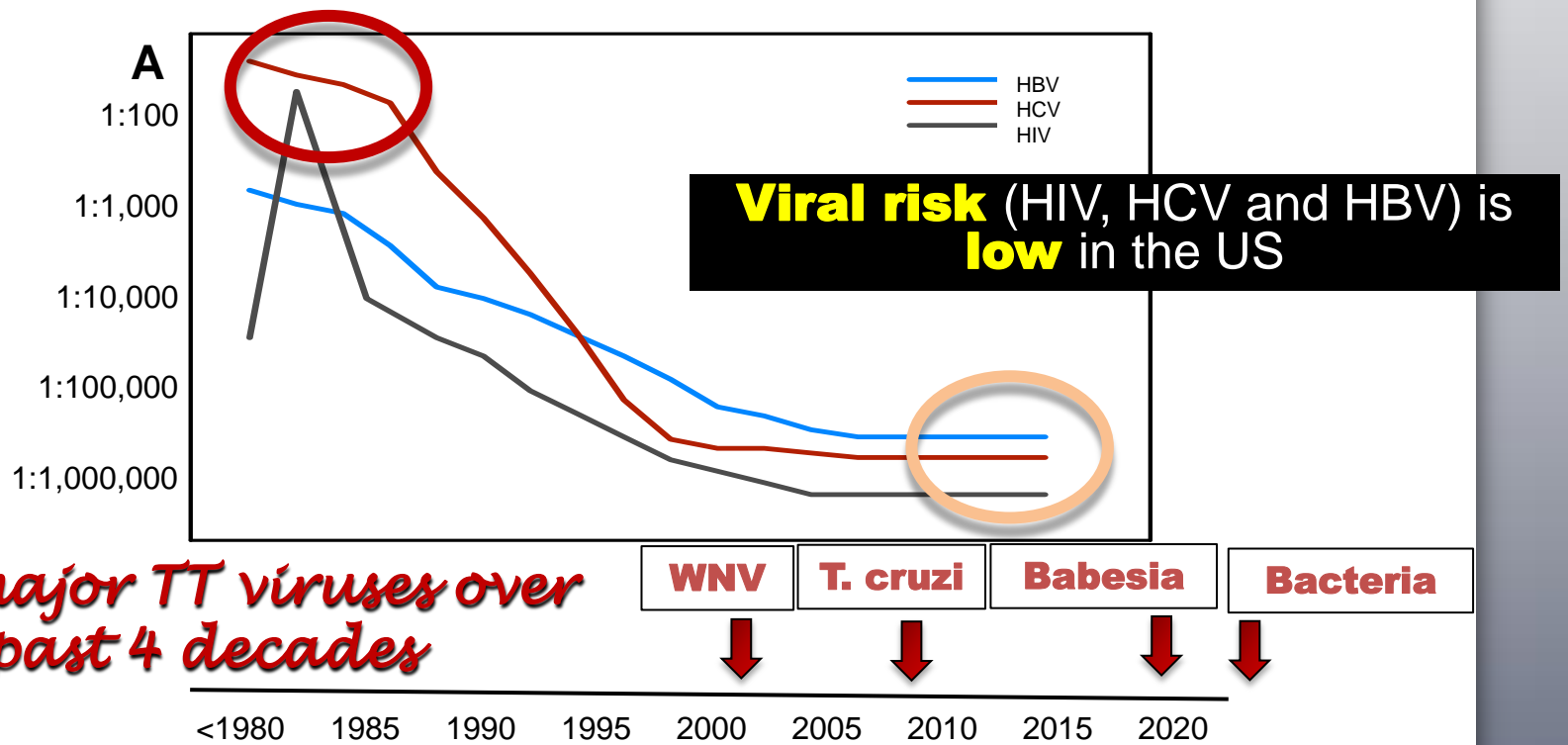
2009

HBV MP-NAT

No cases transfusion transmitted syphilis reported in the US since 1960s

Inverse testing algorithm

– Screening using a **treponemal specific assay**



Viruses

- **HIV I/II**
- **HBV and HCV**
- HTLV I/II
- Zika virus
- WNV
- (CMV)

Bacteria

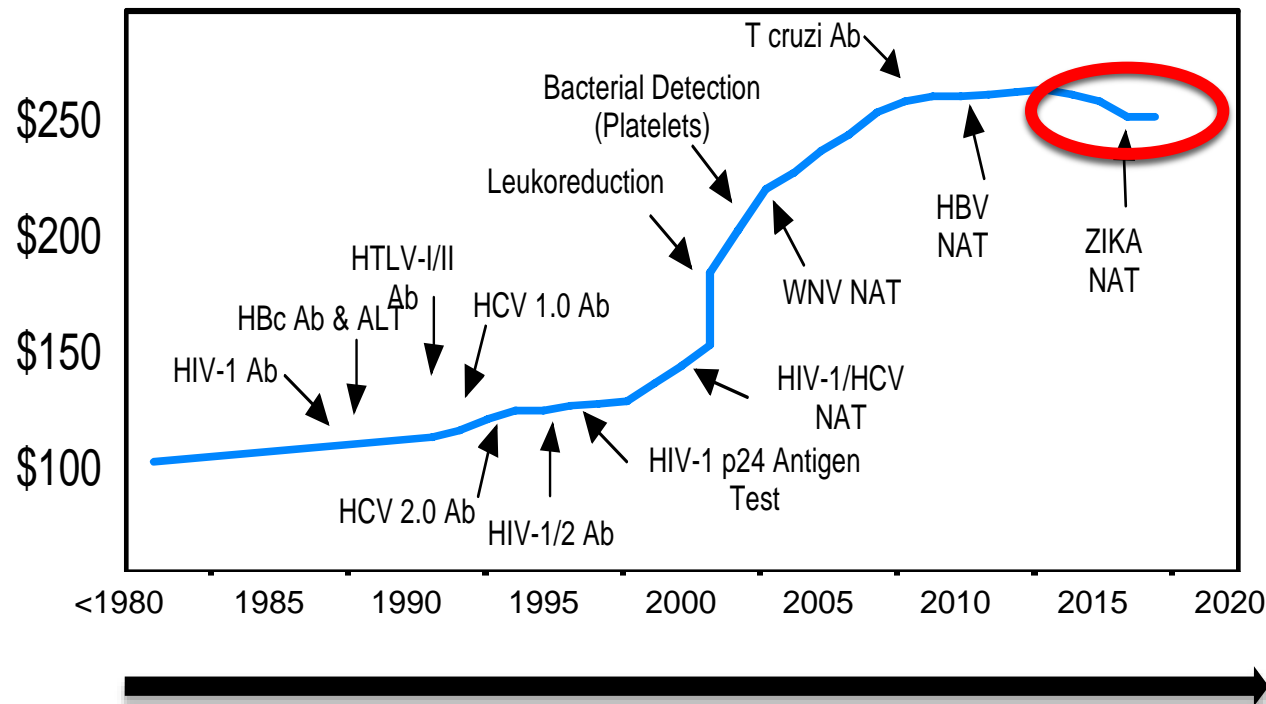
- Conventional bacteria (platelets)
- ***T. pallidum* (syphilis)**

Protozoa

Babesia spp. (babesiosis)
Trypanosoma cruzi (Chagas disease)

Donor screening in the US

Temporal relationship of **interventions** to **acquisition costs** of blood in the US



Those costs are not reflected in the pricing of blood

Dr. Louis Katz
America's Blood Centers
Busch MP, et al. Blood 2019.

Financial complexity of US healthcare

Other considerations...

Inpatient care (majority of blood use)

- Mostly **predetermined rates** per hospital stay depending on a diagnosis (Diagnostic Related Group) i.e. regardless of how much is used
- **Medicare** (US national health insurance program for young people with disability and those aged ≥ 65 years in the United States) → Reimbursement constantly changing
- **Hospitals pay blood centers at negotiated prices** that do not vary with the payments they receive for the stay service

Pressure on hospitals to reduce blood costs

2002

Squeezing the Blood Supply

Median house price \$175,600

Price unit RBCs: **US\$202.74**

Big Mac: \$0.79



Median house price \$ \$327,000

4% ↑

Price unit RBCs:
US\$211



\$1.09 38% ↑

86% ↑



2018

Klein HG, Hrouda JC, Epstein JS.

Crisis in the Sustainability of the U.S. Blood System.

N Engl J Med 2017;377: 1485-8.

Economic Challenges

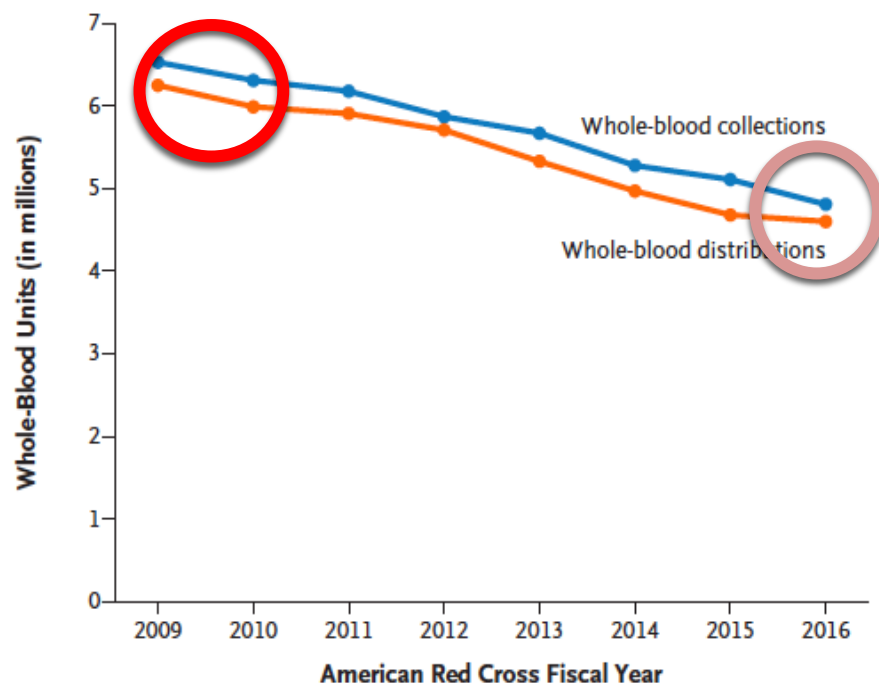


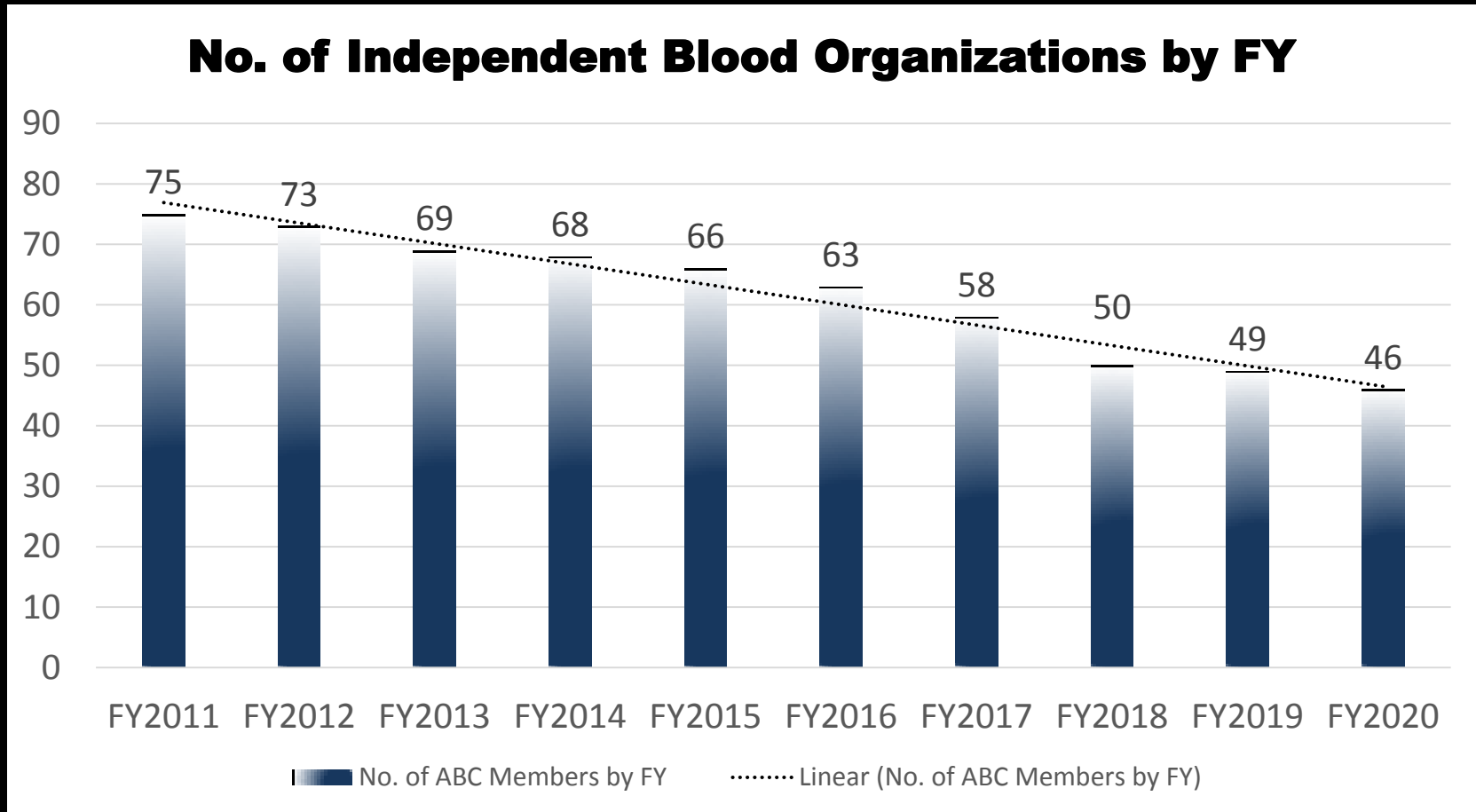
Figure 1. American Red Cross Whole-Blood Collections According to Fiscal Year (July 2009–June 2016).

Collections declined by 26.3% and distributions declined by 26.4% from July 2009 through June 2016.

- Projected **40%↓** by 2020
 - patient blood management
 - hospital cost-containment
- **Median price per unit RBCs ↓**
2013-2015: true cost of collection not reflected in reimbursement

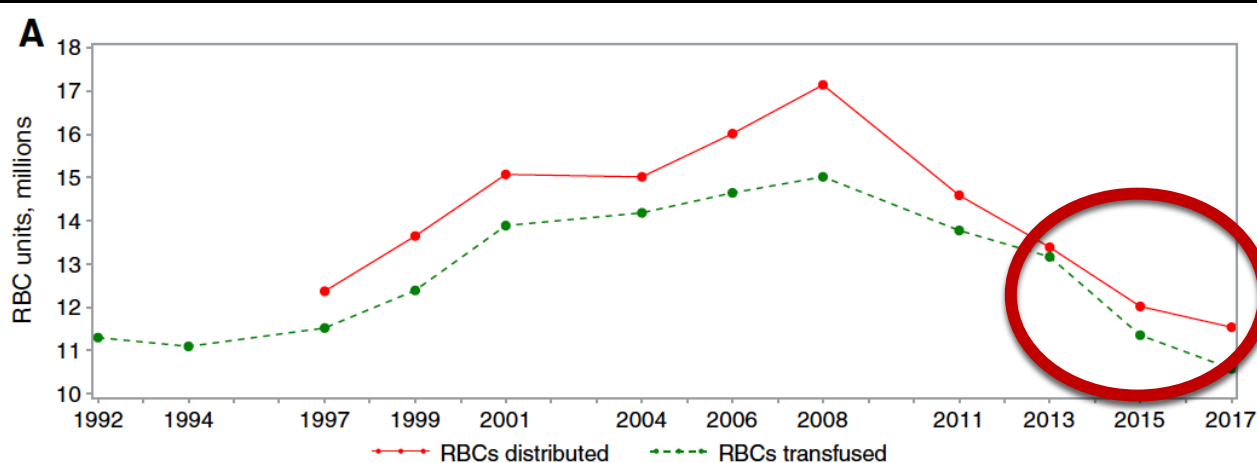
Risk intolerance “safety at any cost” vs. sustainability

Number of Independent Blood Centers FY2011-2020

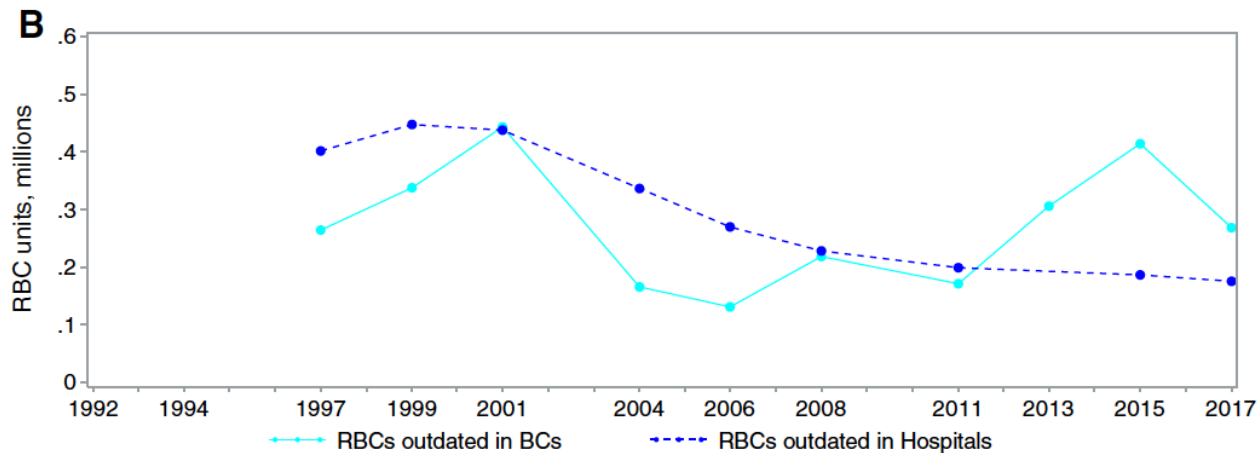


**Started over 20 years ago → costs of infectious testing,
regulatory oversight → patient blood management 2010**





Slowing decline in blood collection and transfusion in the United States – 2017



The National Blood Collection and Utilization Survey (NBCUS)

- **Declines in blood collection and transfusion** in US
- **2013-2015: 11.6%** in RBC collections and **13.9%** in RBC transfusions



Why non-profit model for Georgia?

The better question is why one wants to avoid a for-profit model

Non-profit model

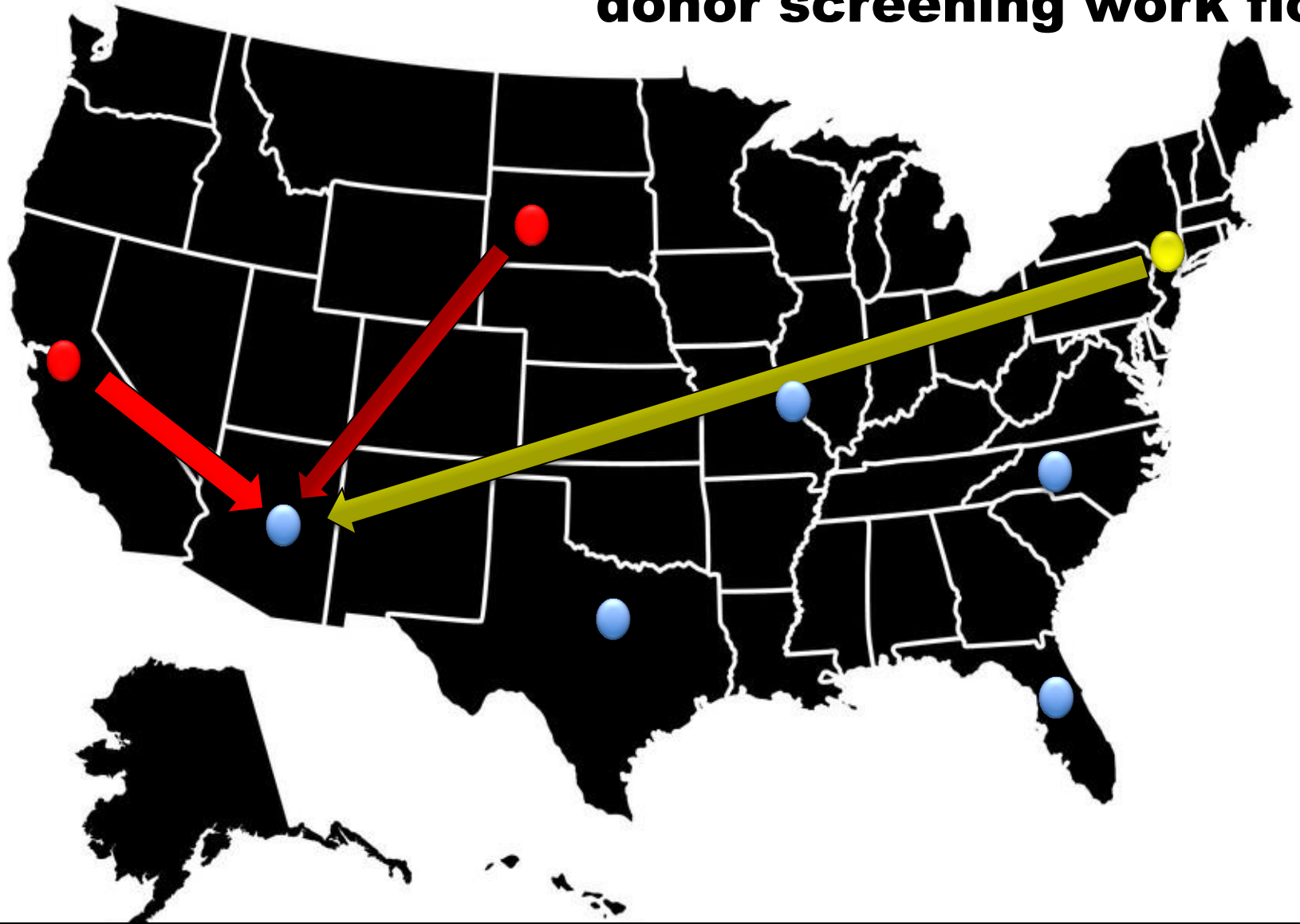
- Generally dedicated to furthering a particular **social cause**
- **Surplus revenue used to further its objective**
 - Income not distributed to the shareholders, leaders, or members.
- **Tax-exempt** or charitable

By contrast...

- **An unchecked for-profit model incentivizes cost cutting**, which is may be at odds with public health mission

A little more positive

Lessons learned donor screening work flow



8 million blood donor samples (70 % of U.S. blood supply) tested at **5 laboratoryies** located in Charlotte, Dallas, Phoenix, St. Louis and Tampa

**Approaches to
contend with TTIs**

Donor selection,

Rigorous **donor selection** avoids reliance on laboratory testing to identify infectious individuals

Screening

e.g. serology +

highly sensitive assays

Why is voluntary donation important?

**Confirmatory
testing**

e.g. IFA, EIA,
repeat NAT

highly specific assays

**Pathogen
reduction**

**Supplementary
testing**

e.g. VDRL or RPR testing

**Eg Photochemical
inactivation**

**Do
Nothing**

Donor **manage and counselling**



Donor recruitment and mobilization

BRIEF REPORT

Relative safety of first-time volunteer and replacement donors in West Africa

ELSEVIER
MASSON

Transfusion Clinique et Biologique 16 (2009) 444–447

General review

HIV, HCV, HBV and syphilis rate of positive donations among blood donations in Mali: Lower rates among volunteer blood donors

Recruitment of blood donors in Burkina Faso: how to avoid donations from family members?

Honorine Dahourou^{a,*}, Jean-Baptiste Tapko^b, Kisito Kienou^c, Koumpingnin Nebie^c, Mahamoudou Sanou^c

^a Regional Blood Bank

^b World Health Organization

^c National Blood Bank

ORIGINAL PAPER

ISBT Science Series (2010)

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Journal compilation © 2010 International Society of Blood Transfusion

Volunteer safer than replacement donor blood: a myth revealed by evidence

J.-P. Allain

Transfusion Medicine, University of Cambridge, Cambridge, UK

TTI risk of replacement and paid donation is well established

Voluntary non-remunerated blood donation (VNRBD)

- **WHO advocates exclusively** for voluntary non-remunerated blood donation
- **VNRBD lowest risk for TTIs**
 - Lower risk than general population
- **First time donors are high risk**
 - They have not yet been vetted
 - Uncertain motivation → possibility of test seeking behavior
- If donation is incentivized, **risk in donors approximates or exceeds** that of the general population
 - **Replacement and paid donors are high risk for TTIs**

HCV and Blood safety in Georgia

- High prevalence of HCV
 - 1998:** 6.9% blood donors anti-HCV+
 - 2015:** 5.4% of adults (~150,000 persons) chronic HCV infection
 - Blood transfusion independent risk factor for HCV**
- 2015-2017:** An analysis of blood donor infectious screening data (n= 251,428 donations, representing 112,093 unique donors)
 - Donor pool: 68.5% male and **51.2% of donors paid or replacement**
 - Multivariable analysis: **first time and paid donor** status associated with seropositivity for all four infectious markers
 - Odds of being seropositive for a TTI is **1.9-3.6x higher in paid donors**

TABLE 3. Multivariable analysis of risk factors for infectious marker seroreactivity in blood donors in Georgia, 2015-2017

	Infectious markers							
	Anti-HCV positive		HBsAg positive		HIV positive		<i>T. pallidum</i> positive	
	Unadjusted OR (95% CI)	Adjusted* OR (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Donor type								
Repeat	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
First time	4.94 (4.47-5.46)	7.95 (7.12-8.88)	6.88 (6.01-7.88)	7.67 (6.66-8.84)	1.60 (1.23-2.09)	1.66 (1.25-2.21)	2.08 (1.85-2.34)	2.43 (2.13-2.78)
Remuneration								
Volunteer	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Paid	1.71 (1.55-1.90)	3.59 (3.21-4.02)	0.90 (0.79-1.02)	2.00 (1.74-2.30)	1.22 (0.86-1.72)	1.90 (1.29-2.79)	2.14 (1.81-2.54)	3.86 (3.20-4.67)
Replacement	1.90 (1.71-2.10)	1.17 (1.02-1.34)	1.93 (1.73-2.15)	1.25 (1.08-1.44)	1.48 (1.05-2.08)	1.19 (0.78-1.81)	3.51 (3.00-4.12)	2.39 (1.97-2.89)

Review reasons for transition to nonprofit design and 100% voluntary donation

- **Blood is a public good, not a commodity**
- **Infectious Risk**
- **Alignment with international standards in US and EU**
- **Sustainability**
- **Cost?**

Navigating the obstacles

Legislation and policy

Mandate participation in blood safety programs

Motivators and deterrents

Challenge

For to Non-profit model: predictable resistance

**Prosocial motivation
Indirect reciprocity**

Durable recruitment strategy

Public health campaign

- **Education**
- Advertising e.g. TV and radio
 - expensive but effective
- Social media

Conclusion

Paid and replacement donation are high risk for TTIs voluntary donor model

- **Need to transition to voluntary donor pool**
 - Not simple → diverse factors at play
- **Blood transfusion in the US and other HICs is remarkably safe** → donor selection and testing → highly efficient workflow

Not-for-profit model important for public health

- **US blood system is highly complex**
- Likely **better economic models** for Georgia

Current challenges and changes

- **Donor recruitment** → change behavior, cost
- **Standardization of screening** and diagnostic follow-up, quality assurance and post-transfusion surveillance

Acknowledgements

Kate Fry (America's Blood Centers)

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