A Strategic Approach to Emerging Infections and Other Microbial Threats to Health: How CDC Responds

Advisory Committee On Blood Safety and Availability – January 26, 2005

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CDC's Futures Initiative
Creating the Future of CDC for the 21st Century

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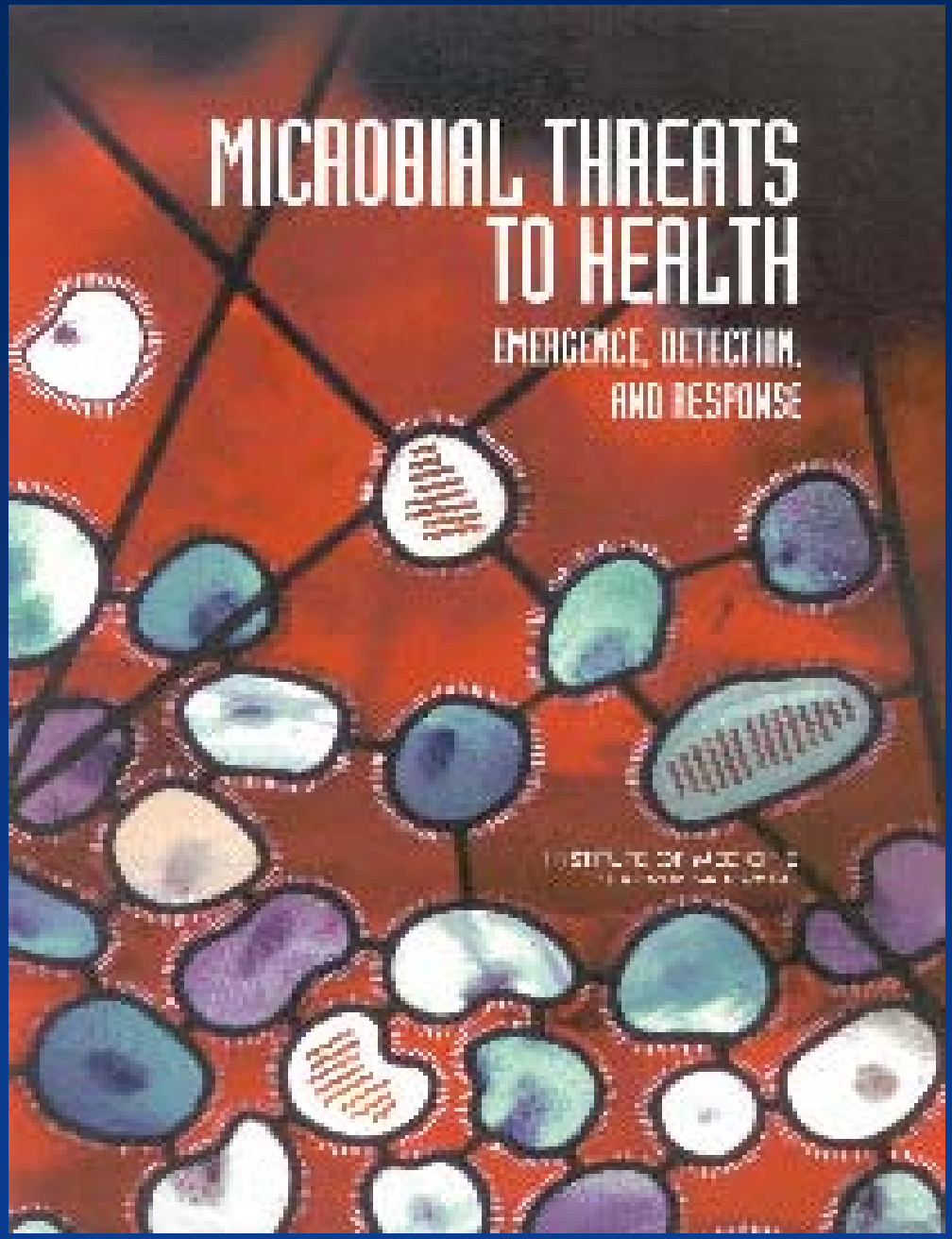

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Selected Factors in Emergence of Microbial Threats to Health

- Microbial adaptation and change
- Human susceptibility to infection
- Technology and industry
- Breakdown of public health measures
- War and Famine
- Intent to harm

- **Antimicrobial resistance**
- **Food and water safety**
- **Vectors and animal health**
- ***Blood safety***
- **Infections that cause chronic diseases**
- **Opportunistic infections**
- **Maternal and child health**
- **Health of travelers and refugees**
- **Vaccines**

When Diseases Emerge
Approaches to Blood Safety Issues

- Suspected to be transmitted person-to-person?
- Transmitted through use of donated biologic tissues, e.g., blood or blood products?
- Endemic, epidemic, globally imported, or a bioterrorism threat?
- Available and accurate diagnostic test?
- Cause recipient disease?

Recent Concerns in Blood Safety

- Prions
  - variant CJD
- Viruses
  - West Nile virus, human herpesvirus 8
- Bacteria
- Parasitic diseases
  - Chagas, malaria, babesiosis, leishmaniasis
- The Unknown
  - future emerging pathogens
  - White Particulate Matter
  - leukoreduction filter-associated reactions

Addressing the Threats: IOM recommendations

- Advances in Health Care: Blood, Organ, and Tissue Product Safety
- Selected Recommendations relevant to Blood, Organ, and Tissue Product Safety
  - **Improving surveillance through better reporting**
  - **Exploring innovative systems of surveillance**
  - **Developing and using diagnostics**
  - **Educating and training multidisciplinary workforce**
  - **Comprehensive infectious disease research agenda**

Addressing the Threats

A sample of CDC's recent blood safety activities

- Surveillance for transfusion-transmitted CJD (DVRD)
- HHV-8 in donors and/or transfusion recipients (DVRD)
- Surveillance for transfusion-transmitted viral hepatitis (DVHP)
- ArboNet blood donor reporting - West Nile Virus (DVBID)
- Enhanced malaria exposure risk assessment, Natural history of *Babesia microti* in blood donors, Evaluation of laboratory methods for Chagas' Disease (DPD)
- Assessment of transfusion-associated sepsis, investigations of White Particulate Matter and Leukoreduction Filters (DHQP)
- Universal Data Collection/ Thalassemia Data Projects (DHBD)
- Global AIDS Program initiatives in Developing Countries (NCHSTP)
- Linked Blood Donor-Recipient Serum Repository (NIH)

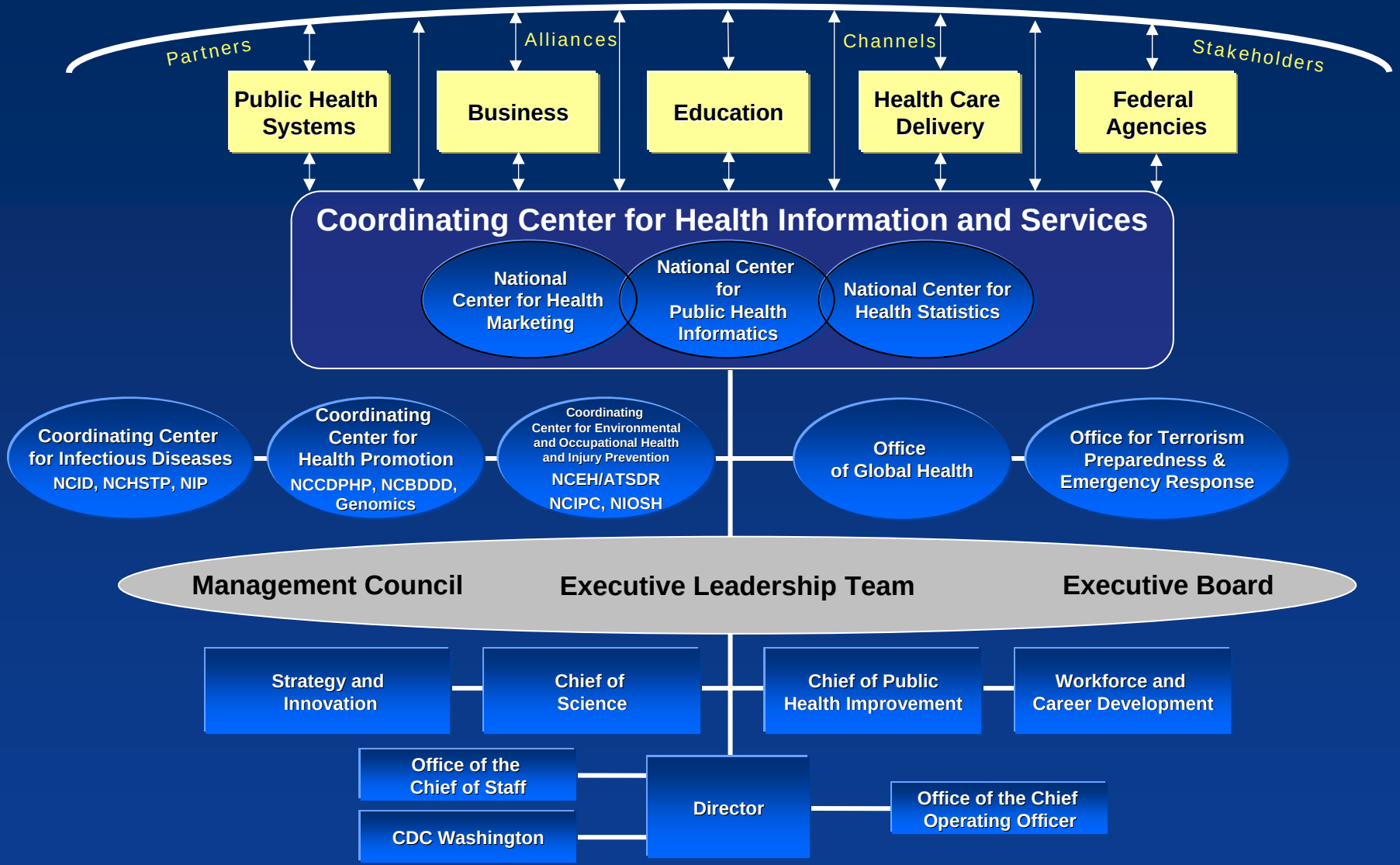
The Futures Initiative: Achieving Health Impact

Organizational Design Principles

- **Strategy and goals derive from population health assessments (“customers’ health”) to achieve health impact**
- **Strategy and goals drive agency’s priorities and allocations**
- **Emphasis on research and innovation**
- **Health protection “marketing”**
- **Consolidation of business & other cross-cutting services**

Customers

SAFER • HEALTHIER • PEOPLE



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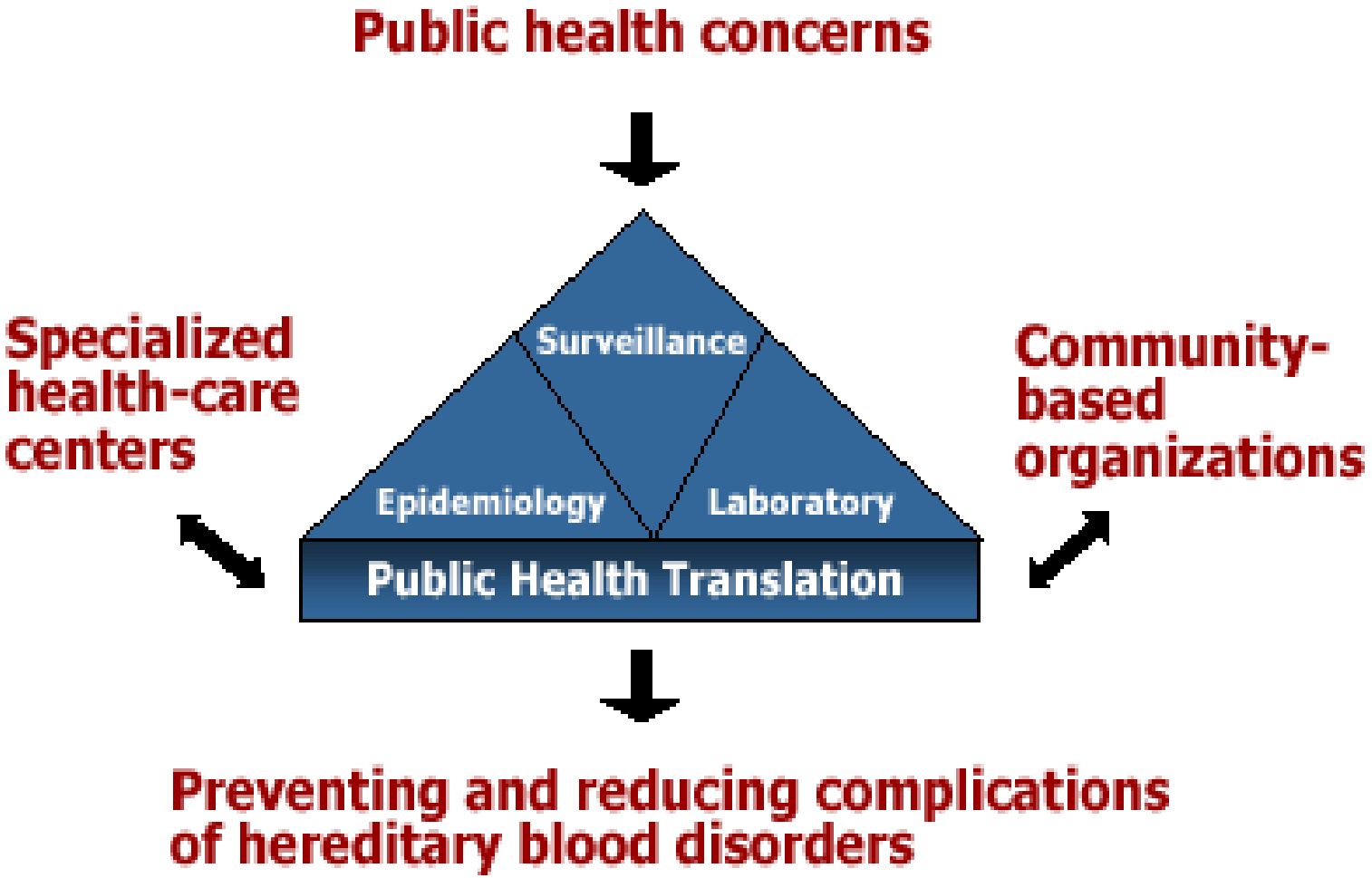
FROM	TO
• **No overall measure of success**	• Clearly articulated goals and performance measurement
• **Lack of customer segmentation**	• Segmented customer approach

• **Limited partner capacity (state and local health depts)**	• Strong partner network
	  • Revitalized state & local health departments
	  • Media, business, health care delivery, schools, communities

Division of Hereditary Blood Disorders

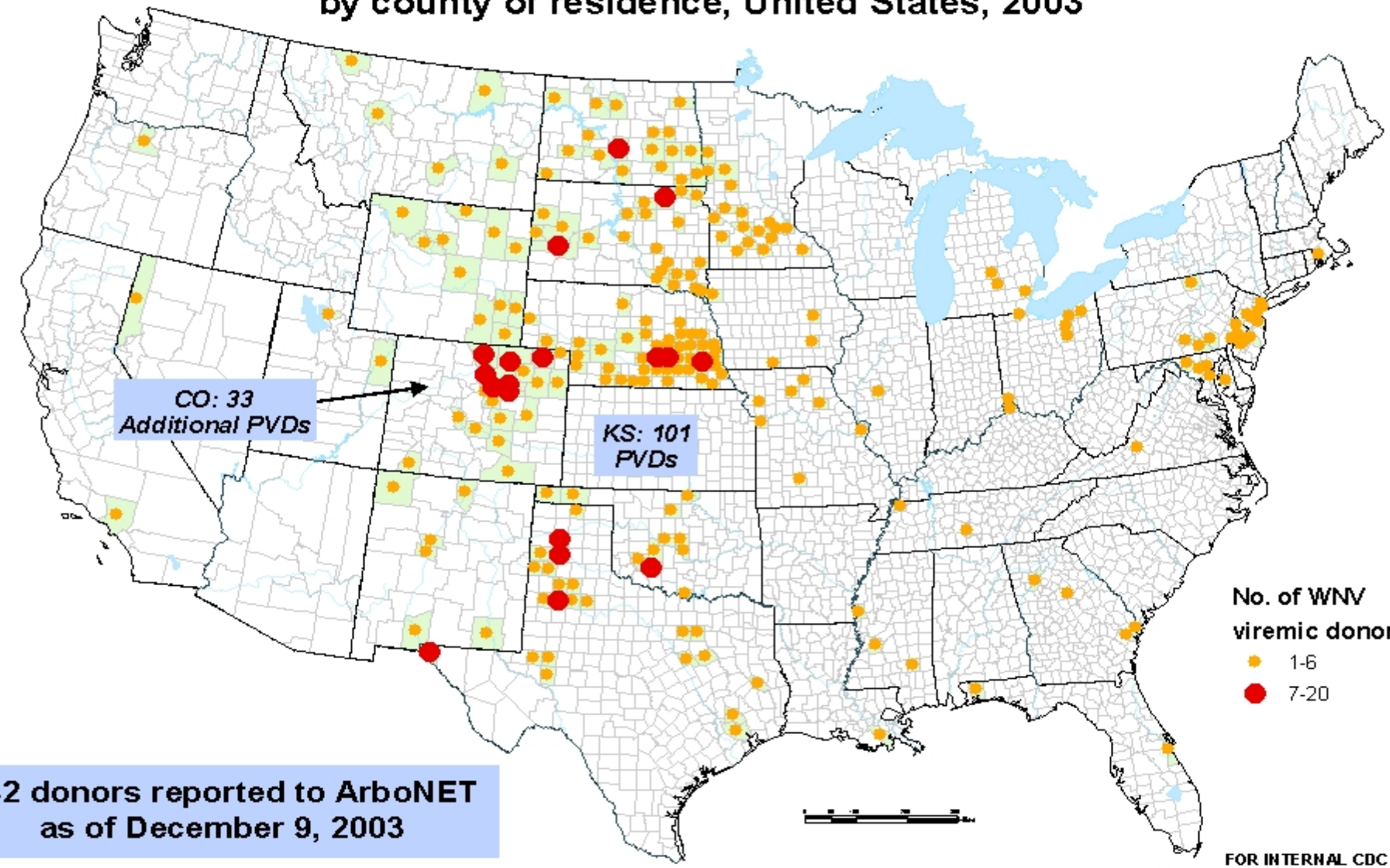


Universal Data Collection Program

Purpose

- Monitor blood safety among product recipients with hereditary blood disorders
- Monitor extent and progression of joint disease
- Identify issues for further study

West Nile viremic blood donors,* by county of residence, United States, 2003



742 donors reported to ArboNET as of December 9, 2003

FOR INTERNAL CDC USE ONLY

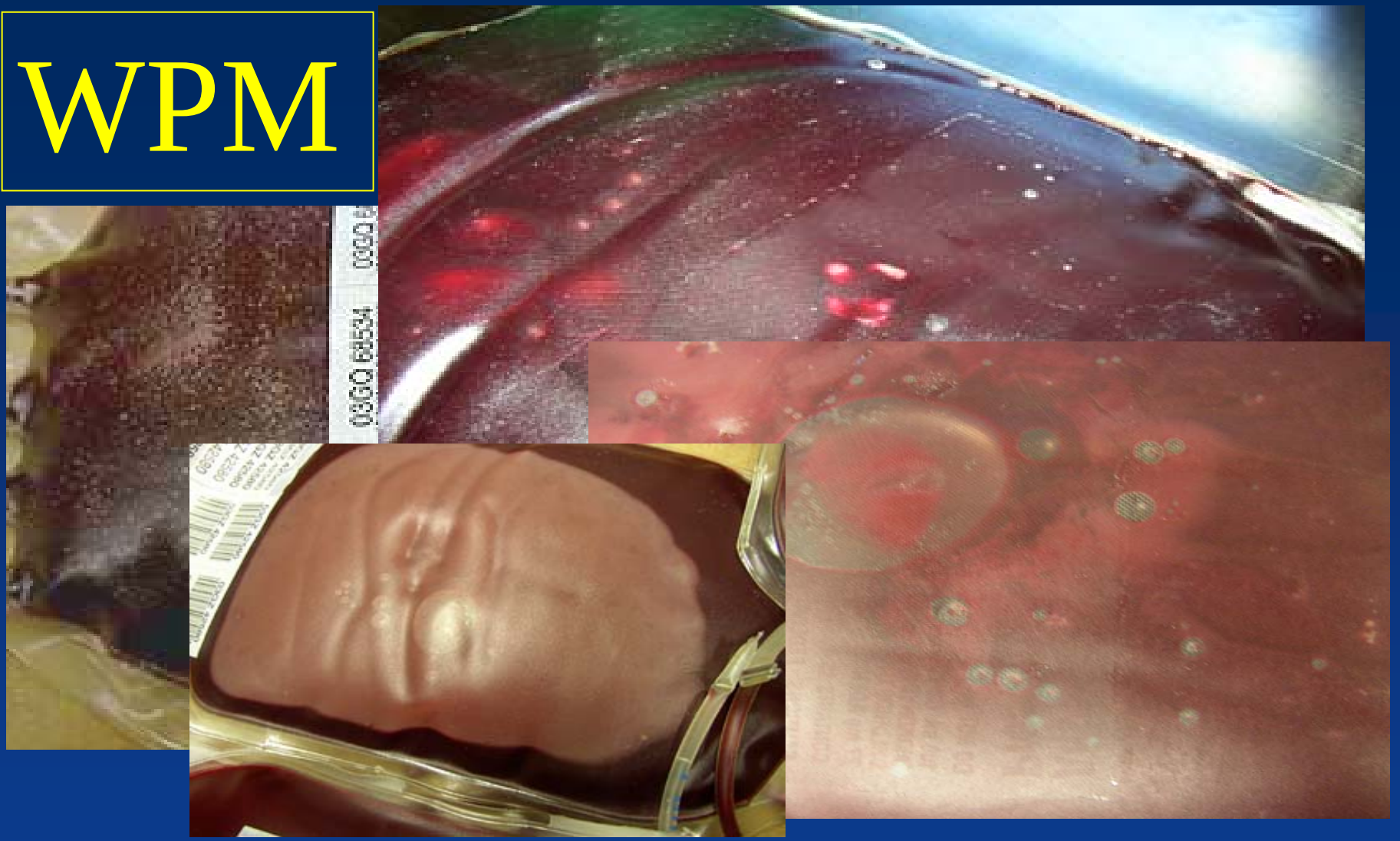
** Reported to CDC/ArboNET by state and metropolitan health departments. Reports are presumptive and confirmatory investigations may be ongoing. Some viremic donors known to the blood banks and health departments may not be reported here. For more summary information on reported viremic blood donors, go to the MMWR online at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5232a3.htm.*

ArboNET

CDC

Malaria Yellow Book Mapping Project

WPM



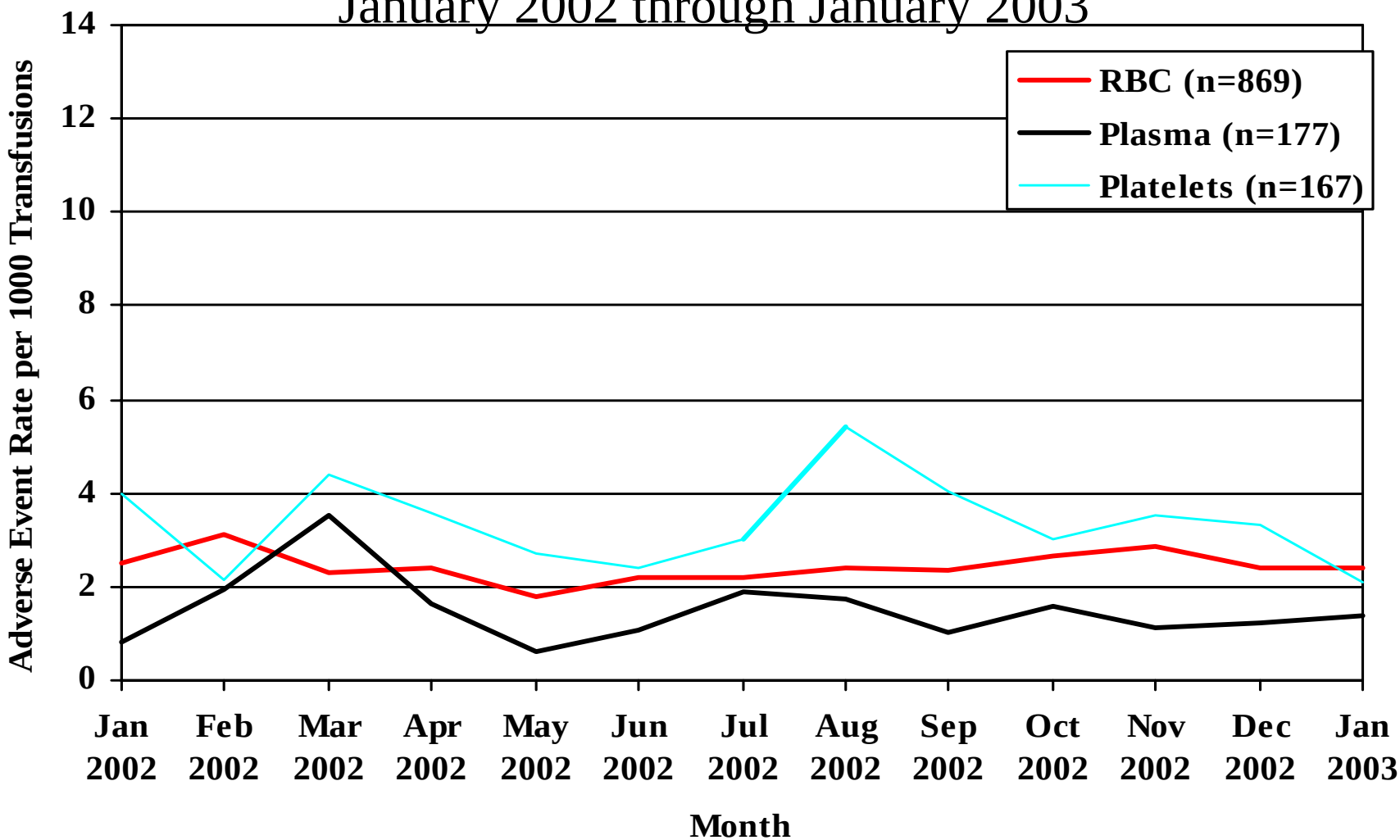
Type I matter: Small white particulates, “crystalline”, “starry sky”, “galaxy”, “dandruff”

Type II matter: Large white particulate matter, “fat”, “waxy”, “gunk”

Type III Matter: “oily” bubbles

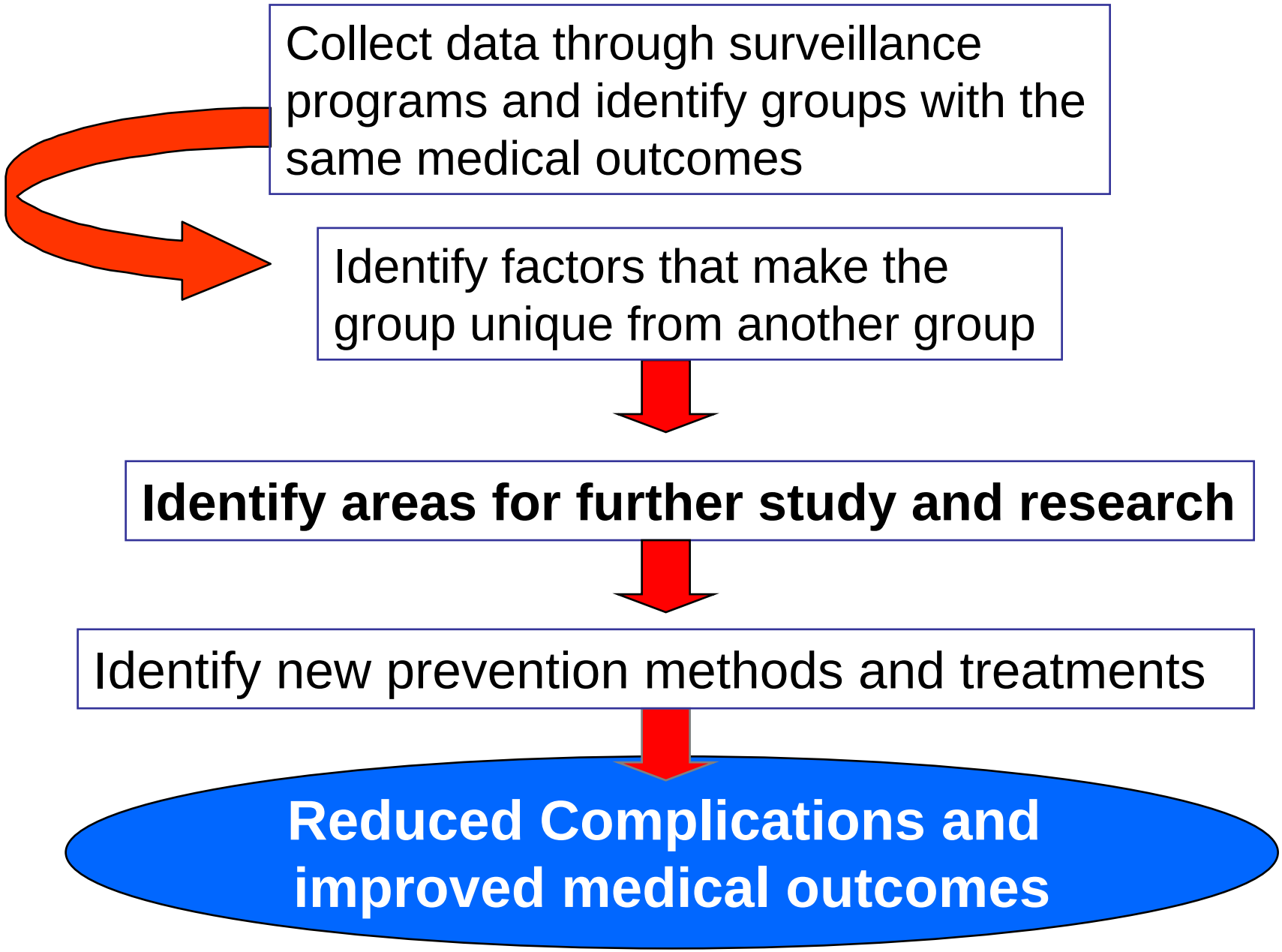
Type IV matter: Yellow or white “oil slick”

Reaction Rates reported by Georgia Transfusion Services by Component Type, January 2002 through January 2003



Iwamoto M, et al. (*Transfusion*, 2004)

CDC Surveillance



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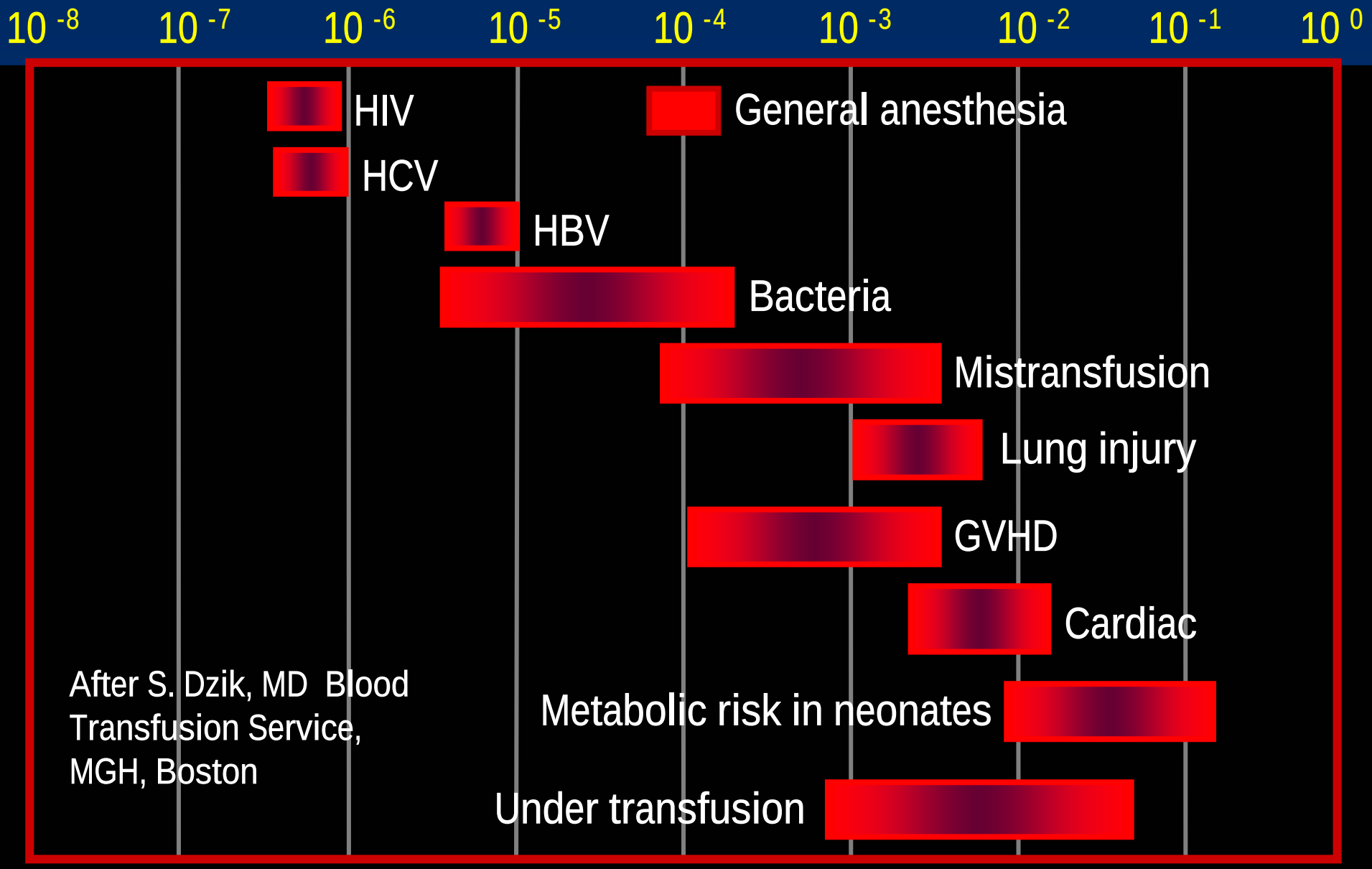
Current Risks of Transfusion

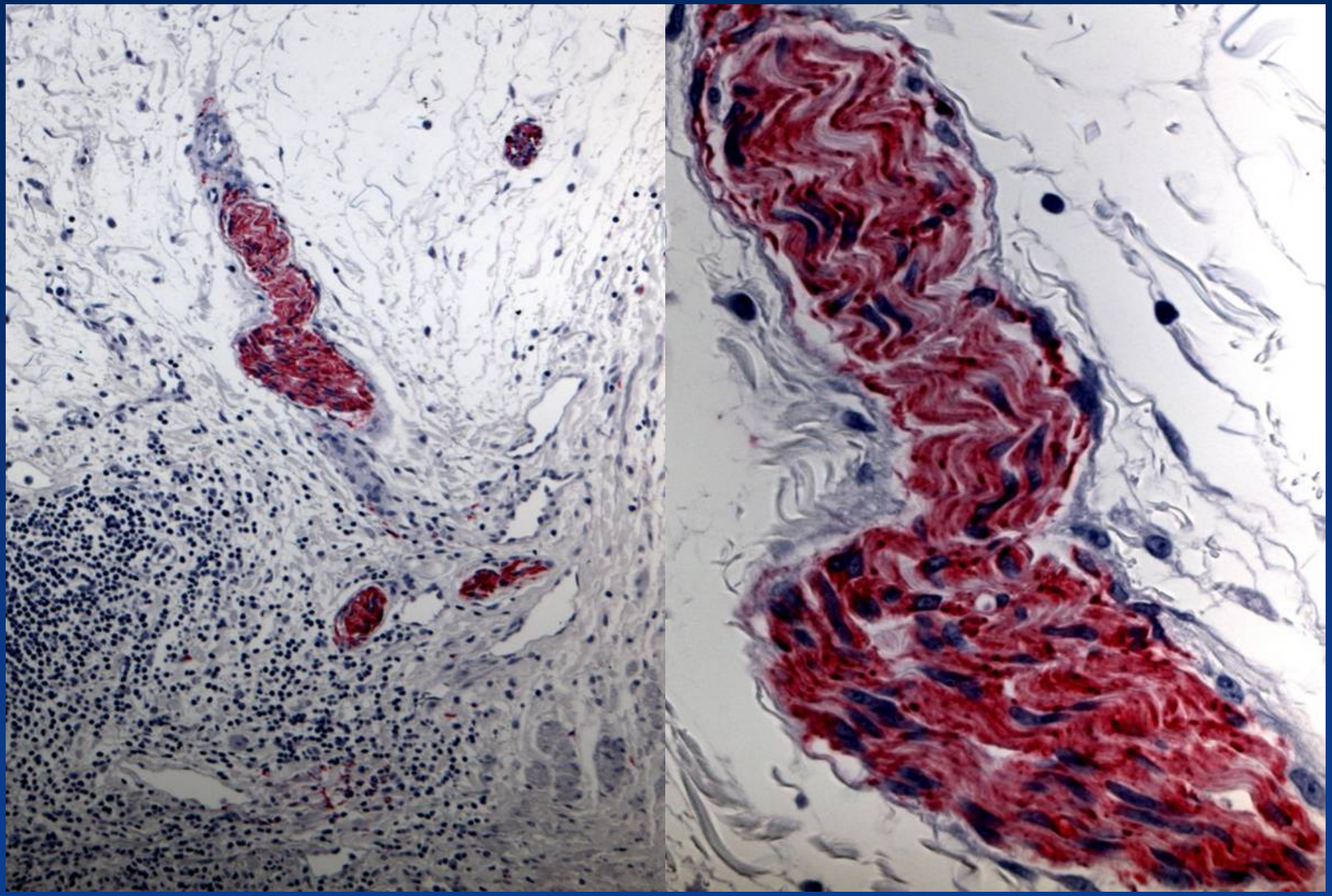


Interventions for Hemovigilance
Need for "Transfusion Optimization Teams"?

- **Goals and Activities**
  - **Promote safe and effective transfusion therapy**
  - **Track hospital performance through active surveillance, error reporting**
  - **Educate clinical staff on appropriate usage**
  - **Oversee proper implementation and cost / benefit of new technology**

Emily Cooley Lecture 2002 (*Transfusion*, 2003)

McClelland and Contreras (*BMJ*, 2005)



Nerves in transplanted kidney

(Zaki et al, IDPA)

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Recent Concerns in Organ and Tissue Safety

- Organ Transplant-Transmitted Disease
  - Rabies
  - Lymphocytic Choriomeningitis
  - Chagas
- Tissue (e.g., allograft)-Transmitted Pathogens
  - Hepatitis C
  - *Clostridium* spp.
  - Group A Streptococcus
  - *Candida albicans*

Hemovigilance
(blood, blood products)

Biovigilance
(blood, organs, tissues, and other products derived from human and animal sources)

INTEGRATED THINKING IS NEEDED!

Identifying the Gaps

- CDC's Blood, Organ, and other Tissue Safety Working Group, with Interagency Task Force Groups, are assessing gaps for intervention
  - PHS Blood Safety Committee
  - ACBSA
  - PHS EID Committee
  - Blood Products Advisory Committee
  - AABB Transfusion-Transmitted Diseases Committee

Proposed Needs for "National Biovigilance"

- **Collaboration: donor collection, laboratory test diagnostics, transfusion / transplant services, clinicians, public health**
  - **Donor assessment and management (e.g., testing results)**
  - **Recipient assessment and management (e.g., adverse events)**
  - **Diagnostic test development**
  - **Implementation of new technologies**
  - **Stored repository analysis**

“Biovigilance” Options

Unusual Event	Denominator	Common Event
Sentinel Events (e.g., fatal clusters) **Epi-Aid Investigation** **Laboratory Protocols**	**“Universal” Data** **Outcome-driven**	**Routine Events Benchmarking** **National surveillance template**

What's Needed

Risk Assessment

- Relevant Expertise
- External Partnerships
- Priority Development
- Data Coordination
- Communication

Risk Management

CDC Strategic Approach
Blood, Organs, Other Tissues

- Blood safety
  - patchwork of programs needing coordination
  - successful responses to emerging threats
  - mission focused on risk assessment and communication
- Organ and tissue safety
  - inclusion for comprehensive approach
- Interventions to improve “biovigilance”
  - definition of transfusion and transplant recipient health goals and outcomes
  - collaboration as a “community”