April 2026

A Next Generation Hemovigilance Module

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OBJECTIVES

1. Describe the historical context for the Hemovigilance Module.

2. Explain how CDC, healthcare facilities, and health departments are collaborating to improve hemovigilance.

3. Demonstrate when and how to report to the revised Hemovigilance Module.

Chat and Q&A features are limited to only 1000 participants.

OBJECTIVES

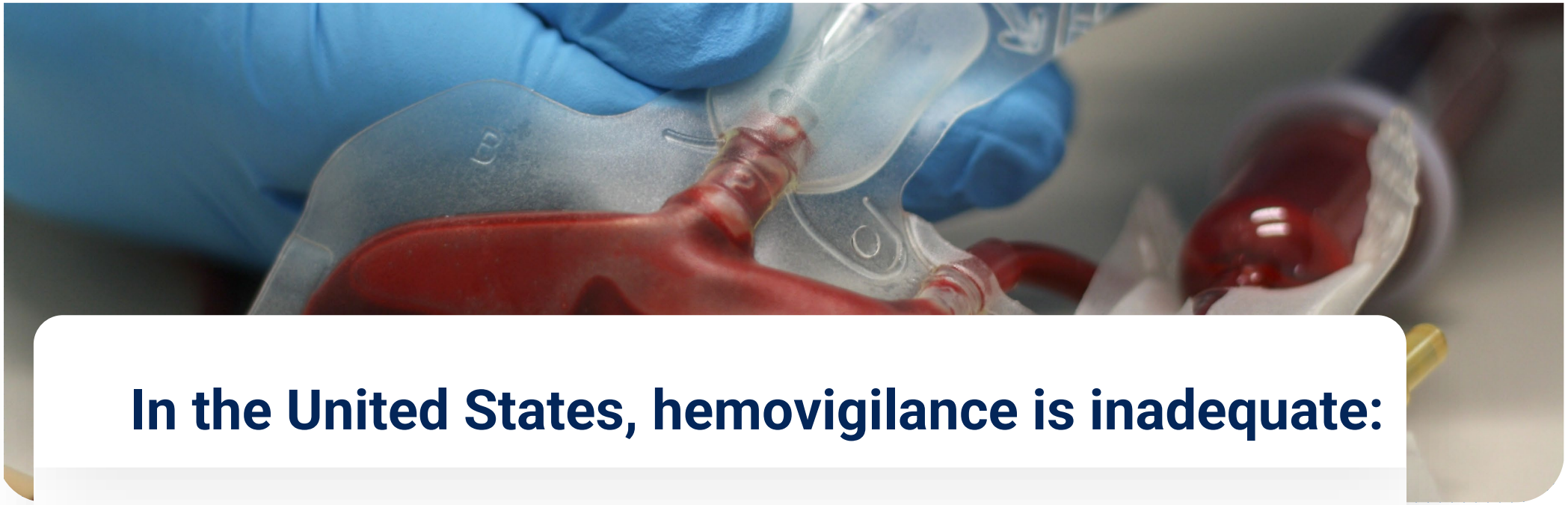
HISTORICAL CONTEXT

COLLABORATING TO IMPROVE HEMOVIGILANCE

REPORTING TO THE REVISED HEMOVIGILANCE MODULE

Transfusion-associated adverse reactions can be severe and result in death.

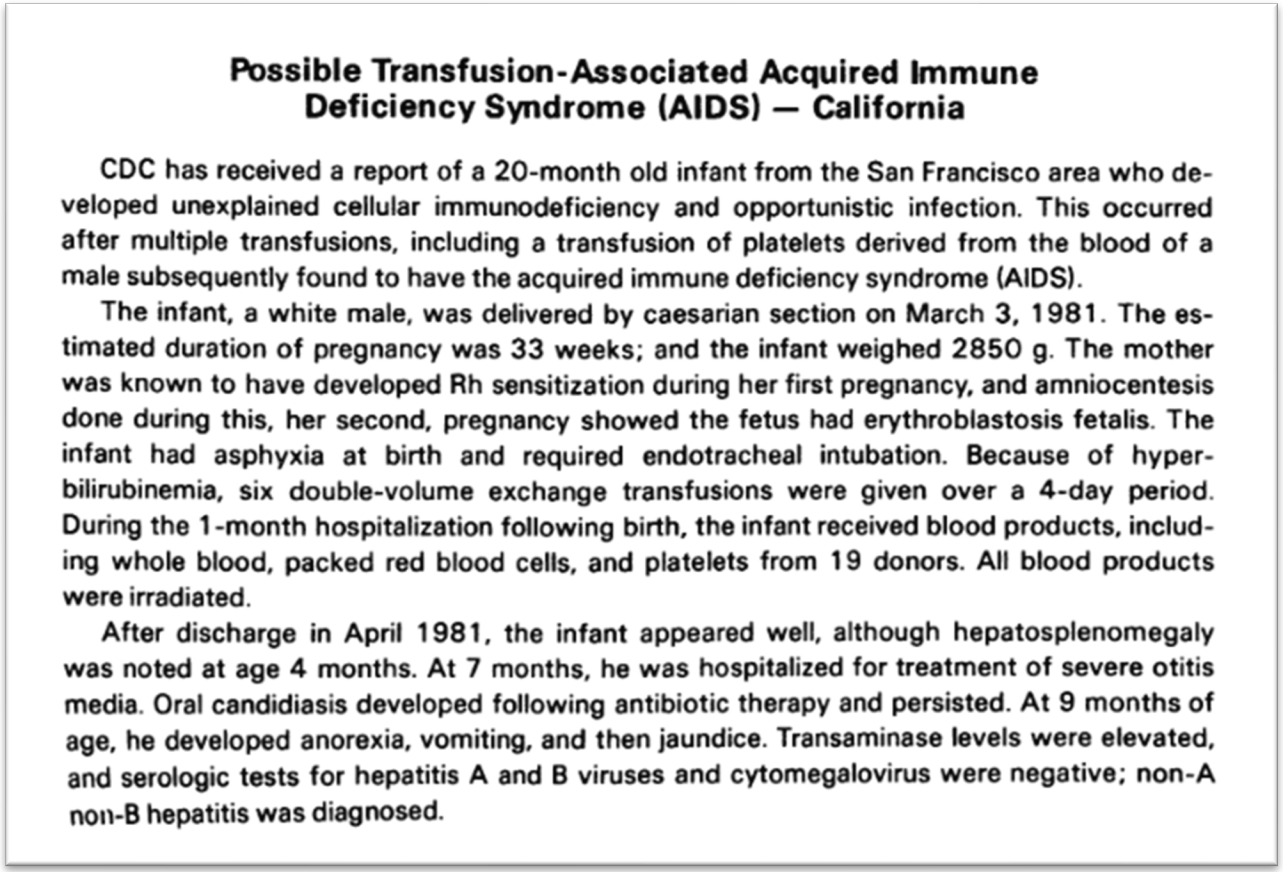
Chat and Q&A features are limited to only 1000 participants.



In the United States, hemovigilance is inadequate:

- **No requirement for transfusing hospitals to report transfusion-transmitted infections (TTIs) or other serious acute transfusion reactions to the Hemovigilance Module**
- **Transfusion history is not a required field on most case report forms for nationally notifiable diseases**
- **Ongoing risk of emerging pathogens in the U.S. blood supply**

HIV spread through the blood supply.



Possible Transfusion-Associated Acquired Immune Deficiency Syndrome (AIDS) — California

CDC has received a report of a 20-month old infant from the San Francisco area who developed unexplained cellular immunodeficiency and opportunistic infection. This occurred after multiple transfusions, including a transfusion of platelets derived from the blood of a male subsequently found to have the acquired immune deficiency syndrome (AIDS).

The infant, a white male, was delivered by caesarian section on March 3, 1981. The estimated duration of pregnancy was 33 weeks; and the infant weighed 2850 g. The mother was known to have developed Rh sensitization during her first pregnancy, and amniocentesis done during this, her second, pregnancy showed the fetus had erythroblastosis fetalis. The infant had asphyxia at birth and required endotracheal intubation. Because of hyperbilirubinemia, six double-volume exchange transfusions were given over a 4-day period. During the 1-month hospitalization following birth, the infant received blood products, including whole blood, packed red blood cells, and platelets from 19 donors. All blood products were irradiated.

After discharge in April 1981, the infant appeared well, although hepatosplenomegaly was noted at age 4 months. At 7 months, he was hospitalized for treatment of severe otitis media. Oral candidiasis developed following antibiotic therapy and persisted. At 9 months of age, he developed anorexia, vomiting, and then jaundice. Transaminase levels were elevated, and serologic tests for hepatitis A and B viruses and cytomegalovirus were negative; non-A non-B hepatitis was diagnosed.

Image Credit: Centers for Disease Control and Prevention (U.S.) MMWR. Morbidity and Mortality Weekly Report, Vol. 31, No. 48, December 10, 1982

Hemophiliacs were being diagnosed with AIDS at an alarming rate.

How many…

“How many people [with hemophilia] have to die? Is three enough? Is six? Is ten? Is a hundred enough? Just give us the number so we can set the threshold!”

- CDC official Don Francis

The meeting produced no recommendations or changes.

Research News

Health Officials Seek Ways to Halt AIDS

A recent workshop considered the options for preventing the spread of the new immune disease; an easy solution is unlikely

On 4 January the Centers for Disease Control (CDC) convened a workshop at its Atlanta headquarters to assess the options for halting the spread of the new disease called acquired immunodeficiency syndrome or, more commonly, AIDS. The main topic of discussion was the possibility that the disease, which may kill up to 70 percent of the patients within 2 years of diagnosis, might be spread in blood and blood products.

The CDC recently reported that hemophiliacs are at high risk of contracting AIDS, which may be transmitted by an infectious agent in the blood clotting factor preparations that they take (*Science*, 7 January, p. 42). The Center's Bruce Evatt told the workshop that AIDS was the second leading cause of death for hemophiliacs in 1982, even though the disease was first discovered in hemophiliacs in the summer of that year. Eight hemophiliacs who had none of the other known risk factors died from AIDS, compared to some 40 who died of bleeding. James Curran, head of the CDC task force investigating AIDS, says, "The sense of urgency is greatest for hemophiliacs. The risk for others [who receive blood products] now appears small, but is unknown."

Suspicion has been cast on blood products in addition to clotting factor, however. An infant contracted AIDS after receiving red blood cells that had come from a man who developed the disease several months after he donated the blood. The CDC is also investigating the cases of two adults who developed AIDS after receiving blood transfusions during surgery. The two did not belong to any of the known high-risk groups, which include, in addition to hemophiliacs, homosexual and bisexual men who are extremely active sexually, users of intravenous drugs, and Haitians. In each case, investigators have identified a blood donor who has certain characteristics associated with AIDS, including a particular immune defect, although neither donor has actually developed the disease.

The CDC investigators have also identified several AIDS patients who donated blood. None of the recipients has contracted the condition, but there is still cause for worry. Thomas Spira of the CDC points out that there may be a long lag period, a year or more, between the time of exposure to the causative agent and the onset of AIDS. In other words, although there is currently no firm evidence linking ordinary blood transfusions to transmission of the disease, it is too early to rule out such a link.

The workshop participants easily reached agreement on some preventive measures that might check the spread of AIDS. About 75 percent of the AIDS victims are homosexual or bisexual men in whom the disease is thought to be sexually transmitted. There was general agreement that homosexual men should avoid sexual contact with known or suspected AIDS patients, minimize the number of their sexual partners, and refrain from anonymous sexual contacts. Heterosexuals might follow the same suggestions because, according to Curran, there are indications that AIDS may also be transmitted by heterosexual sex and other forms of intimate personal contact, such as that between mother and child.

> "The sense of urgency is greatest for hemophiliacs. . . ."

The seriousness of the threat of AIDS transmission by blood products and what, if anything, ought to be done in the current state of uncertainty remained thorny issues for the workshop participants. Not everyone agrees with the conclusion, accepted by CDC officials and many other investigators, that AIDS is caused by an infectious agent, presumably a virus, which could contaminate blood products. Louis Aledort, the medical director of the National Hemophilia Foundation, says, "I think it is too easily concluded that there is a transmissible agent. I can't rule it out but the data are not there yet." Aledort favors the idea that hemophiliacs, as well as homosexuals and intravenous drug users, because they are exposed to a great number of foreign antigens, experience a high degree of antigenic stimulation that effectively wears out their immune systems.

Nevertheless, because of the seriousness of AIDS, many participants were in favor of introducing measures to prevent persons who might be carrying an infectious agent from donating blood or plasma. The question is how to do this, especially in view of the long latent period of the disease and the possibility that many individuals who do not have full-blown AIDS may have a milder form or be asymptomatic carriers of an infectious agent.

Asking members of high-risk groups to voluntarily refrain from donating blood is one relatively uncontroversial approach, although it would probably not eliminate all potential carriers. Automatically excluding all members of high-risk groups is another, although this measure has the disadvantage of stigmatizing all homosexual males when only a fraction—those who are extremely sexually promiscuous—are likely to transmit an AIDS agent. Past and present users of intravenous drugs, who may be hepatitis carriers, and hemophiliacs are already excluded. Potential donors may also be screened for AIDS symptoms through a physical examination or a medical history.

Finally, the blood itself may be screened. Since the agent has not been identified, it would be necessary to use a "surrogate agent" as a marker for AIDS infectivity. The best candidate for this is an antibody to the core antigen of the hepatitis B virus. According to Spira, testing for this antibody in donated blood would detect about 90 percent of the donors who might transmit an AIDS agent, including persons with full-blown AIDS, those with the milder symptoms, and members of high-risk groups.

Some workshop participants favored requiring the test for all blood collection centers, but Aaron Kellner of the New York Blood Center dissented. "It is one thing to do these tests in the laboratory and another in the real world," he said. Kellner suggests that a few blood collection centers in the cities where AIDS is most prevalent—New York, San Francisco, and Los Angeles—undertake pilot

21 JANUARY 1983

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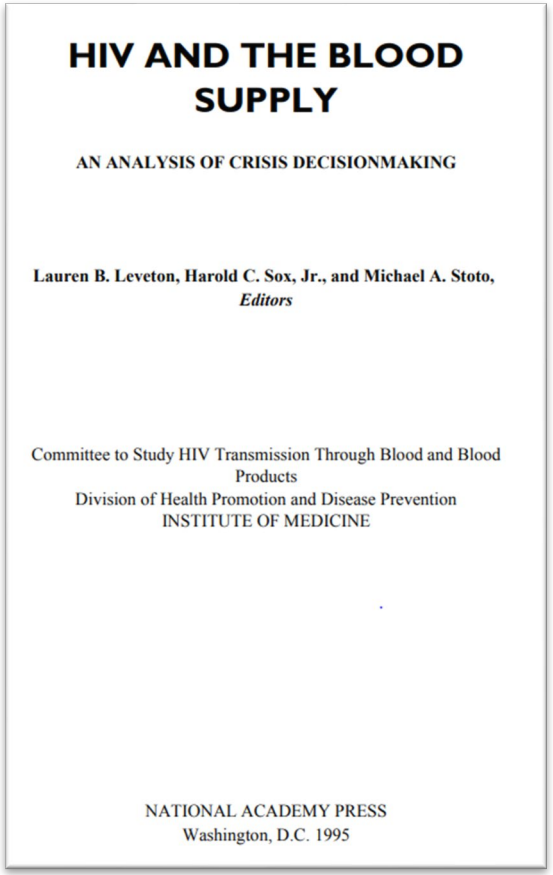
Image credit: Hemophilia Federation of America. Retrieved from History of Bleeding Disorders - Hemophilia Federation of America accessed on 5/15/25.

Institute of Medicine

- The Secretary of the Department of Health and Human Services (DHHS) asked a Committee of the Institute of Medicine (IOM) to review the scientific evidence that was available to decisionmakers during the early 1980s when the AIDS epidemic emerged, to examine the decision-making processes, and to evaluate the actions taken to contain the epidemic

- In 1995, the committee published 2 recommendations for CDC:

  - The PHS should establish a surveillance system, within CDC, that will detect, monitor, and warn of adverse effects in the recipients of blood and blood products.


HIV AND THE BLOOD SUPPLY

AN ANALYSIS OF CRISIS DECISIONMAKING

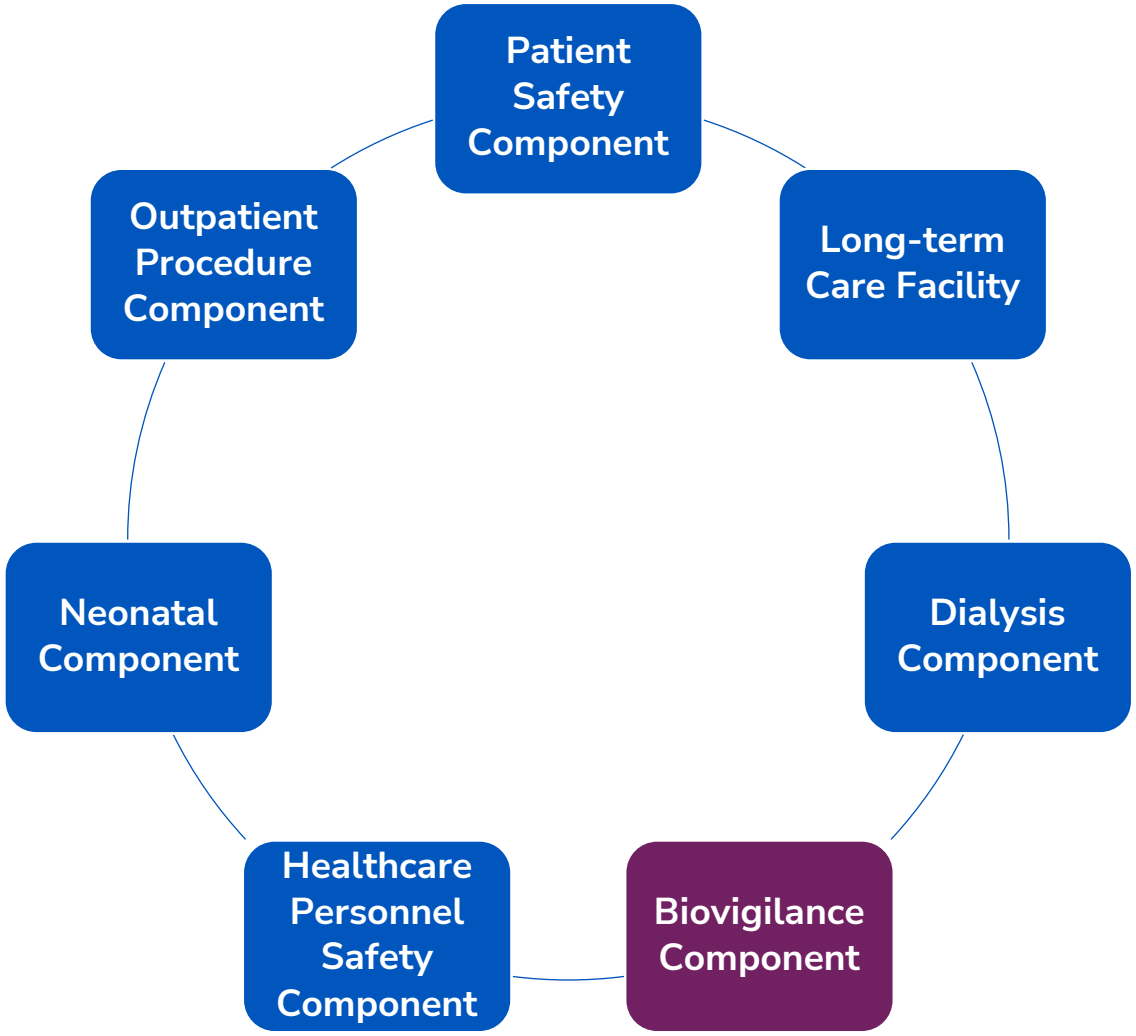
Lauren B. Leveton, Harold C. Sox, Jr., and Michael A. Stoto, *Editors*

Committee to Study HIV Transmission Through Blood and Blood Products
Division of Health Promotion and Disease Prevention
INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C. 1995

References: Institute of Medicine (US) Committee to Study HIV Transmission Through Blood and Blood Products. *HIV And The Blood Supply: An Analysis Of Crisis Decisionmaking*. Edited by Lauren B. Leveton et. al., National Academies Press (US), 1995. doi:10.17226/4989; Institute of Medicine. Emerging Infections. Washington, D.C.: National Academy Press, 1992.

National Healthcare Safety Network (NHSN)



The Biovigilance Component - Hemovigilance Module serves as the only national surveillance platform for recipient hemovigilance.

OBJECTIVES

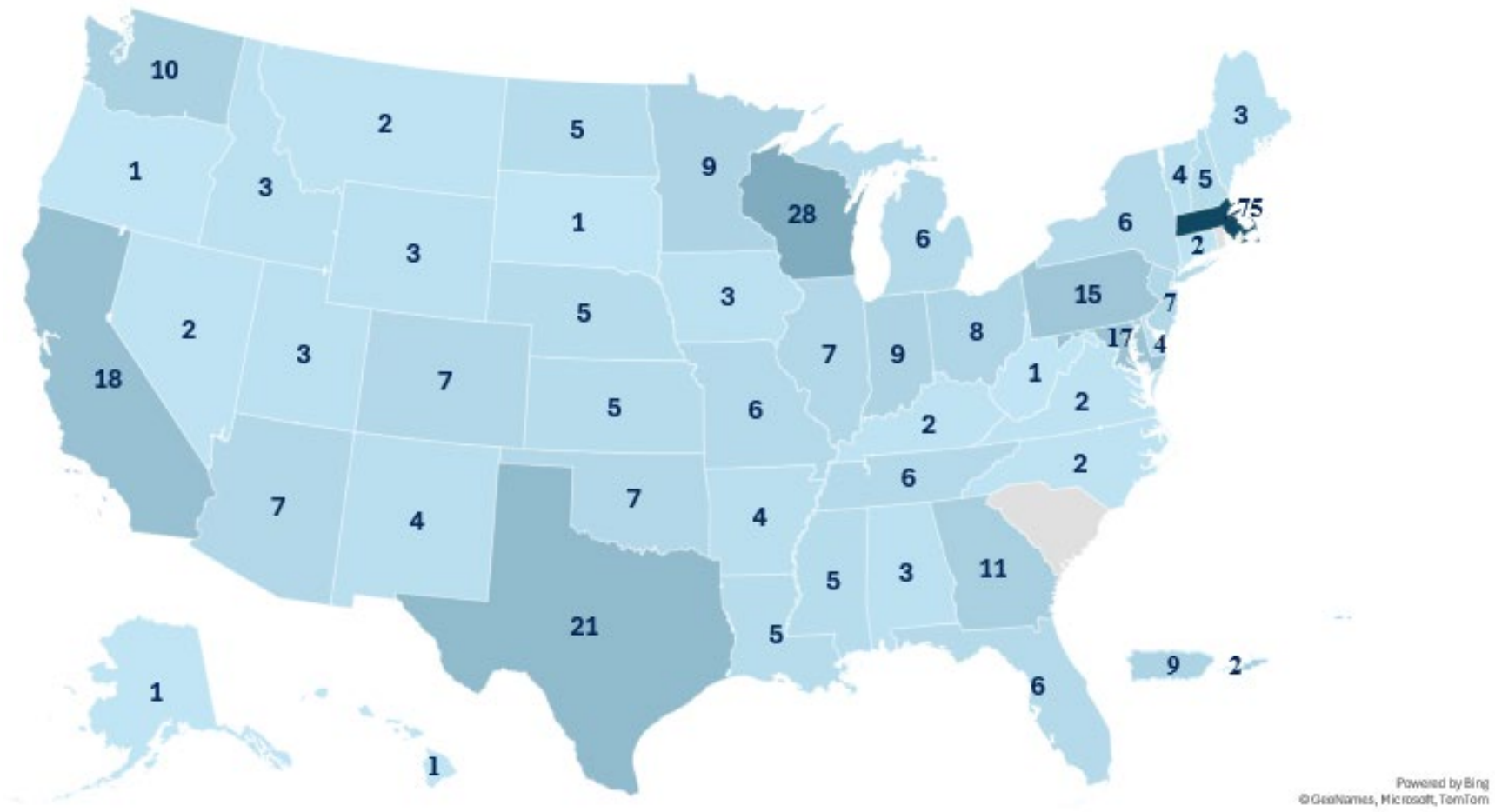
HISTORICAL CONTEXT

COLLABORATING TO IMPROVE HEMOVIGILANCE

REPORTING TO THE REVISED HEMOVIGILANCE MODULE

Chat and Q&A features are limited to only 1000 participants.

Facilities enrolled in NHSN Hemovigilance Module, November 2025



- **379 facilities are actively enrolled** in the Hemovigilance Module
- **5,948** potential facilities
- **Only 3 TTIs** were reported in 2025

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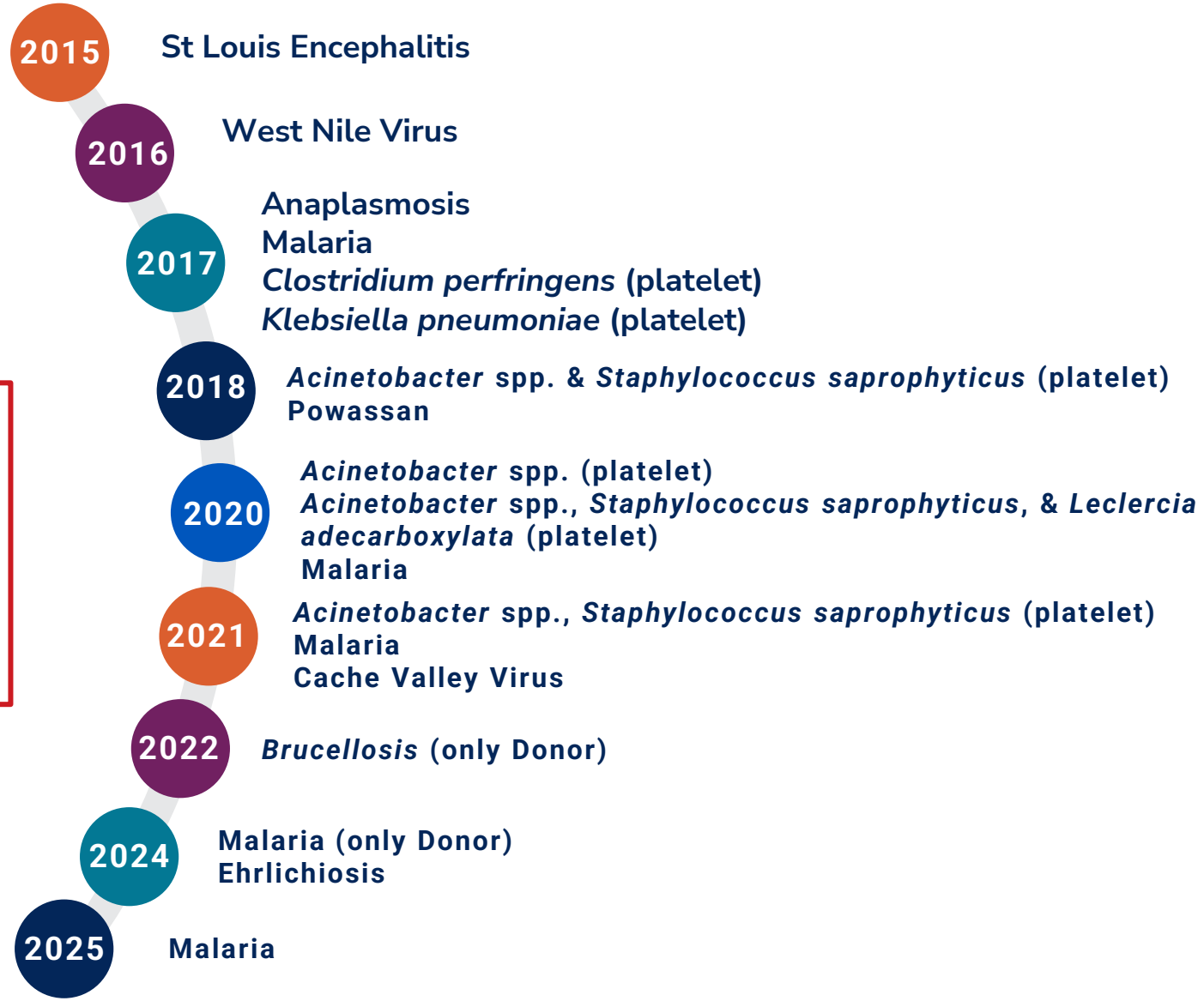
TTI investigations by CDC over the years, 2015-2025

None of these were reported through the Hemovigilance Module – it is likely that serious TTIs may be unrecognized.



The Next Generation Hemovigilance Module

Streamlined so that every facility can participate.

Hemovigilance Module v2.9

Annual Acute Care Facility Survey
Annual Facility Survey Non-Acute Care Facility

Adverse Reactions
AHTR
TACO
TRALI
Other Transfusion Reaction

Adverse Reactions
Transfusion Transmitted Infection (TTI)

Monthly Reporting Plan	ATR
Monthly Reporting	HTR
Denominators	FNHTR
Incident Form	DSTR
Monthly Incident	TAGVHD
Summary	PTP
DHTR	Unknown Transfusion
TAD	Reaction

The Next Generation Hemovigilance Module

Annual Facility Survey
(one form instead of two)
January 2026

Adverse Reaction Investigation Form
(one form instead of four)

TTI Rapid Alert + **TTI Investigation Form**
March 2026

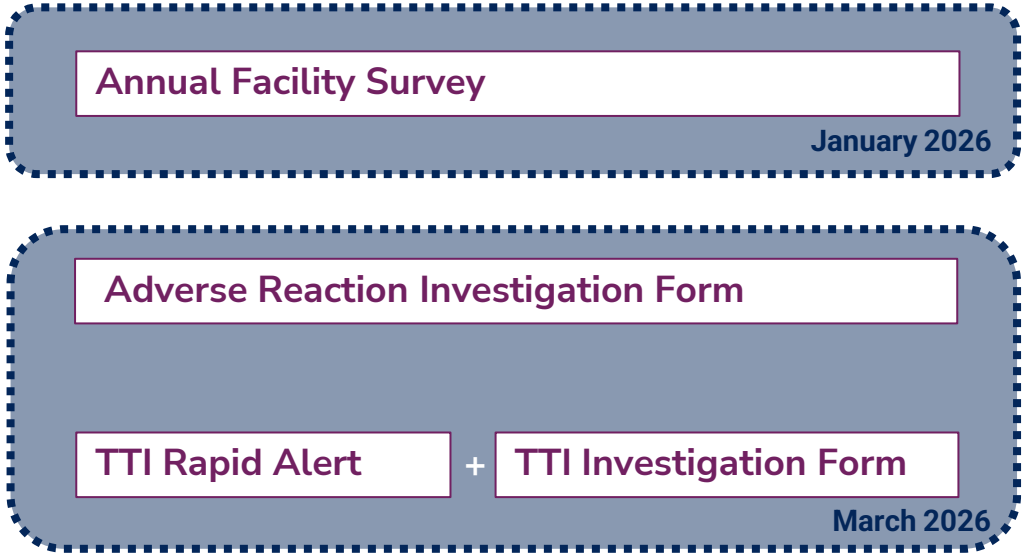
No longer reported to Hemovigilance Module

Chat and Q&A features are limited to only 1000 participants.

Abbreviations: AHTR, acute hemolytic transfusion reaction; DHTR, delayed hemolytic transfusion reaction; TACO, transfusion-associated circulatory overload; TRALI, transfusion-related acute lung injury; TTI, transfusion transmitted infection; TAD, transfusion-associated dyspnea; ATR, allergic transfusion reaction; HTR, hypotensive transfusion reaction; FNHTR, febrile non-hemolytic transfusion reaction; DSTR, delayed serologic transfusion reaction; TAGVHD, transfusion-associated graft versus host disease; PTP, post-transfusion purpura.

These adverse reactions are rare.

The Next Generation Hemovigilance Module



- 1 submission annually
- Est. 30 minutes

- Submission based on occurrence
- TACO: 19.3 per 100,000 transfusions[1]
- TRALI: 1.0 per 100,000 transfusions[1]
- AHTR: 1.66 per 100,000 transfusions[1]
- Est. 20 minutes/occurrence

- Submission based on occurrence
- TTI ~0.25 per 100,000 transfusions[1*]
- Rapid Alert: Est. 5 min/occurrence
- TTI Investigation Form: Est. 60 min/occurrence

There may be years where a facility may not have any reactions to report to the module.

[1]Griffin IS, Kracalik I, McDavid K, et al. Supplemental findings of the 2023 National Blood Collection and Utilization Survey. Transfusion. Published online August 1, 2025. doi:10.1111/trf.18336
*May vary by pathogen

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HEMOVIGILANCE MODULE V3.0

CDC's NEW Annual Facility Survey

- Facility characteristics
- Electronic monitoring of transfusions and adverse events
- Total units transfused by blood component

Chat and Q&A features are limited to only 1000 participants.

HEMOVIGILANCE MODULE V3.0

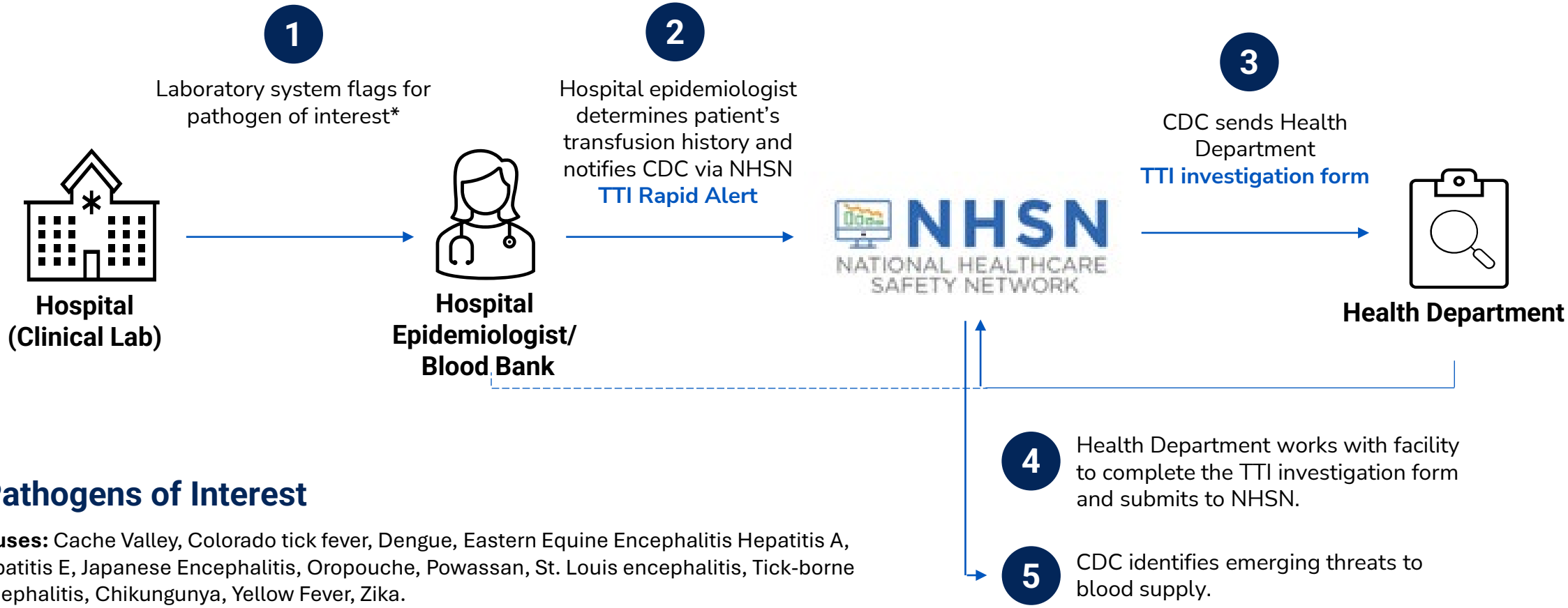
CDC's NEW Adverse Reaction Investigation Form

Simplified to one form for TACO, TRALI, AHTR or Other Transfusion Reaction

- Recipient Information
- Adverse Reaction Details
- Clinical Presentation
- Treatment
- Outcome
- Laboratory Test Results
- Investigation Findings

Chat and Q&A features are limited to only 1000 participants.

Proposed TTI Reporting Structure



*Pathogens of Interest

Viruses: Cache Valley, Colorado tick fever, Dengue, Eastern Equine Encephalitis Hepatitis A, Hepatitis E, Japanese Encephalitis, Oropouche, Powassan, St. Louis encephalitis, Tick-borne encephalitis, Chikungunya, Yellow Fever, Zika.
Bacteria: *Acinetobacter baumannii*, *Anaplasma phagocytophilum*, *Brucella* spp., *Coxiella burnetii* (Q Fever), *Ehrlichia* spp., *Leclercia adecarboxylata*, *Rickettsia rickettsii*.
Parasites: *Babesia* spp., *Leishmania* spp., *Plasmodium* spp. (Malaria).

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HEMOVIGILANCE MODULE V3.0

CDC's NEW TTI Rapid Alert Form

Hemovigilance Module
Transfusion Transmitted Infection (TTI)
Rapid Alert Form

*Required fields

***Facility ID#:** _____ ***Reporter Name:** [Dropdown based on current Facility users] ***Patient ID:** _____

***Date of Birth:** ____/____/___ ***Medical Record #:** _____

***Sex:** ☐ M ☐ F ☐ Not Available/Missing ***State of Residence:** _____

* ☐ **Pathogen of interest[1] has been detected: [Multiselect Dropdown – Pathogens of Interest]**

* ☐ **Patient received a transfusion in the 30 days prior to symptom onset or infection identification**

[1]Pathogens of Interest:

Viruses: Cache Valley virus, Colorado tick fever virus, Dengue virus, Eastern Equine Encephalitis virus, Hepatitis A virus, Hepatitis E virus, Japanese Encephalitis virus, Oropouche virus, Powassan virus, St. Louis encephalitis virus, Tick-borne encephalitis virus, Chikungunya virus, Yellow Fever virus, Zika virus.

Bacteria: *Acinetobacter baumannii*, *Anaplasma phagocytophilum*, *Brucella* spp., *Coxiella burnetii* (Q Fever), *Ehrlichia* spp., *Leclercia adecarboxylata*, *Rickettsia rickettsii*.

Parasites: *Babesia* spp., *Leishmania* spp., *Plasmodium* spp. (Malaria).

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HEMOVIGILANCE MODULE V3.0

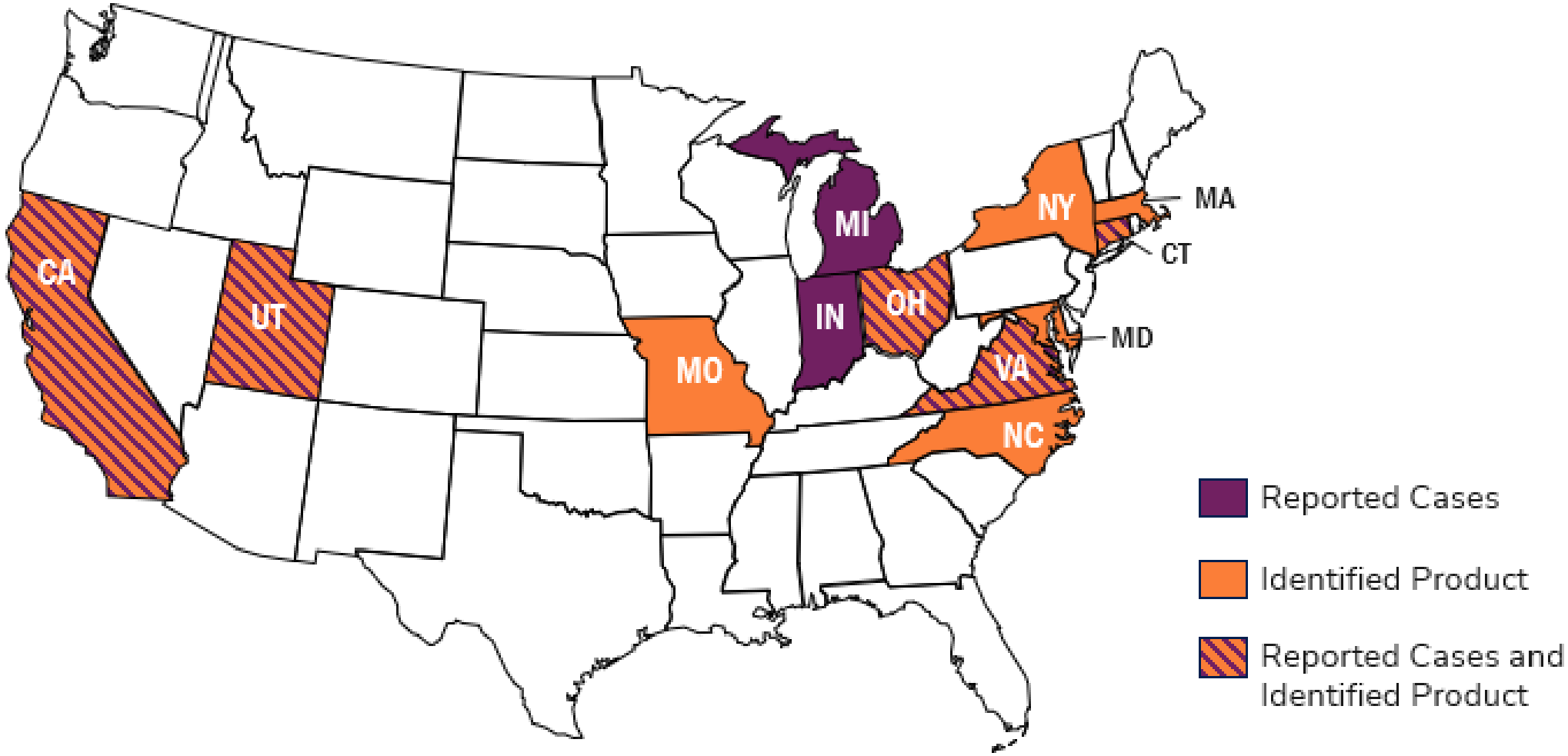
CDC's Updated TTI Investigation Form

- Patient Information
- Patient Medical History (reason for transfusion)
- Adverse Reaction Details
- Laboratory Test Results
- Signs and Symptoms
- Patient Treatment
- Recipient Epidemiologic Risk Assessment (to rule out transfusion)
- Component Details (ISBT-128 product codes, pathogen detected)
- Donor Investigation (mosquito or tick exposures, travel history)
- Investigation Findings (Case Definition, Severity, Imputability)
- Facility Investigation Notes
- CDC Investigation Notes

Chat and Q&A features are limited to only 1000 participants.

Nationwide platelet contamination

CDC and FDA identified 8 cases and 20 contaminated products in 12 states.

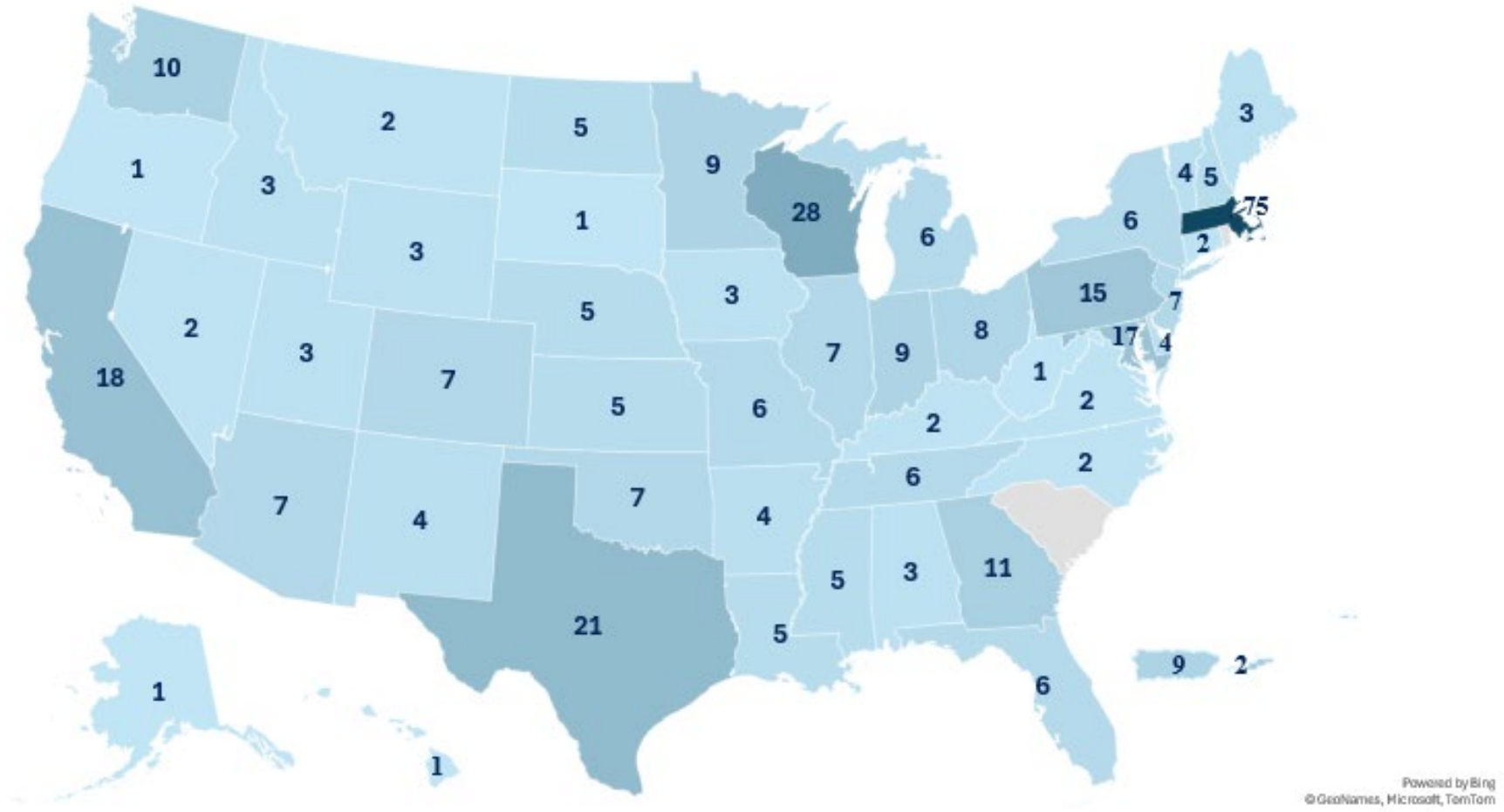


Nationwide platelet contamination

Investigation Findings

- **Environmental isolates** from the bag manufacturing facilities were **genetically related** to clinical **sepsis cases and contaminated products.**
- Issues with **collection set sterility** were observed during inspection of the facility.

Currently, do we think the module would provide an early warning system for a similar outbreak?



379 facilities are actively enrolled in the Hemovigilance Module

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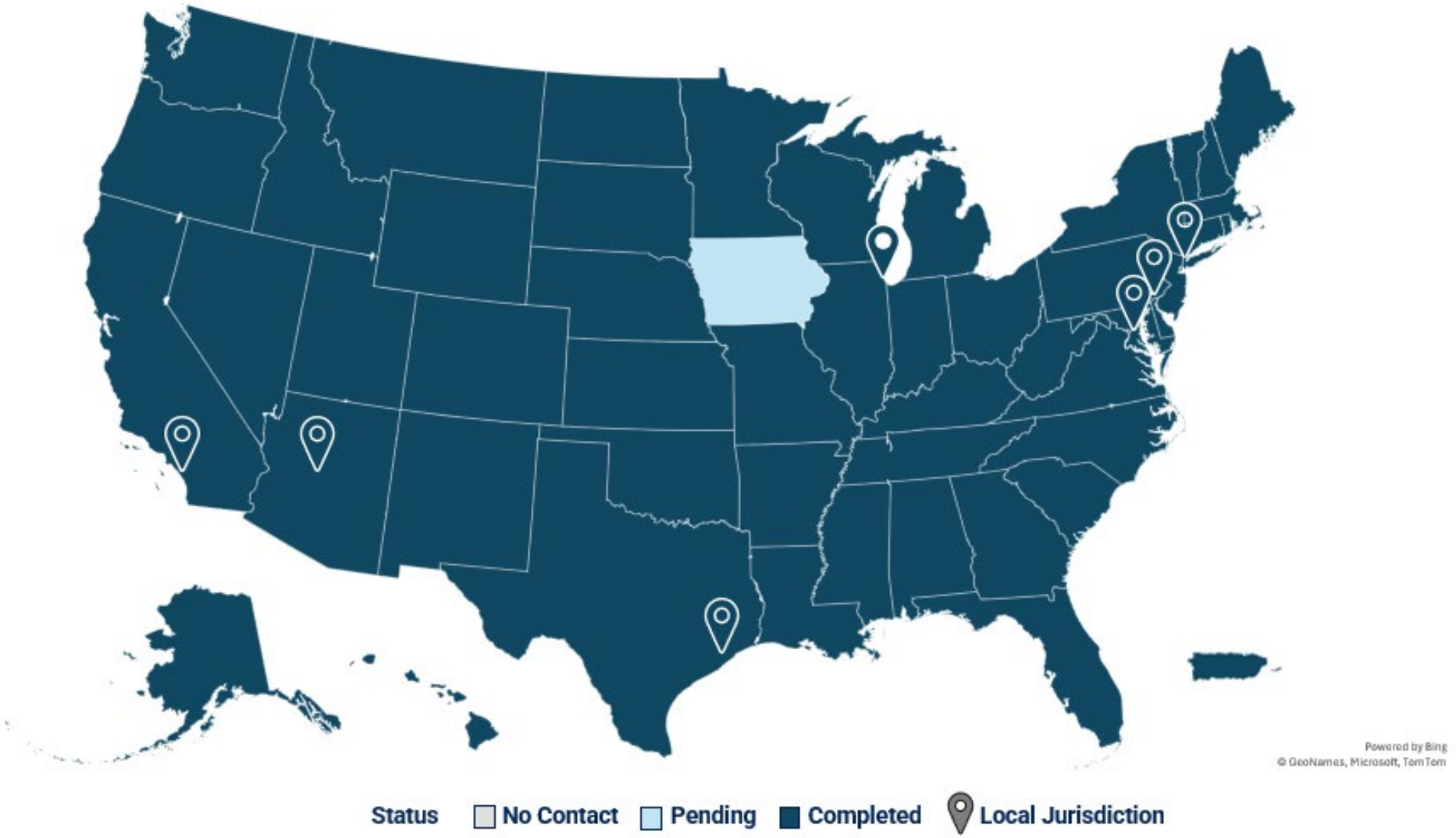
Collaboration with Health Departments

Health Department Partners, March 2026



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Met 1:1 with 58/65 health departments about the Hemovigilance Module

Facility Outreach

5,948 facilities nationwide

Region 1
223 facilities
Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Region 2
359 facilities
New Jersey, New York (NYC), Puerto Rico, US Virgin Islands

Region 3
472 facilities
DC, Delaware, Maryland, Pennsylvania, Virginia, West Virginia

Region 4
1125 facilities
Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

Region 5
1024 facilities
Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Region 6
1023 facilities
Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Region 7
516 facilities
Iowa, Kansas, Missouri, Nebraska

Region 8
368 facilities
Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

Region 9
605 facilities
Arizona, California, Hawaii, Nevada

Region 10
233 facilities
Alaska, Idaho, Oregon, Washington

Chat and Q&A features are limited to only 1000 participants.

Support for Reporting

HEALTH DEPARTMENTS

- Ongoing Collaboration
- NHSN Hemovigilance Groups

CDC

- Monthly Office Hours
- Weekly Q&A sessions

Chat and Q&A features are limited to only 1000 participants.

Benefits of Healthcare Facility Participation

- Early warning system for emerging pathogens
- Facilities can systematically track the safety of transfusions
- Save lives through rapid reporting and investigation of TTIs
- Nationwide estimates of serious adverse reactions

Chat and Q&A features are limited to only 1000 participants.

OBJECTIVES

HISTORICAL CONTEXT

COLLABORATING TO IMPROVE HEMOVIGILANCE

REPORTING TO THE REVISED HEMOVIGILANCE MODULE

Chat and Q&A features are limited to only 1000 participants.

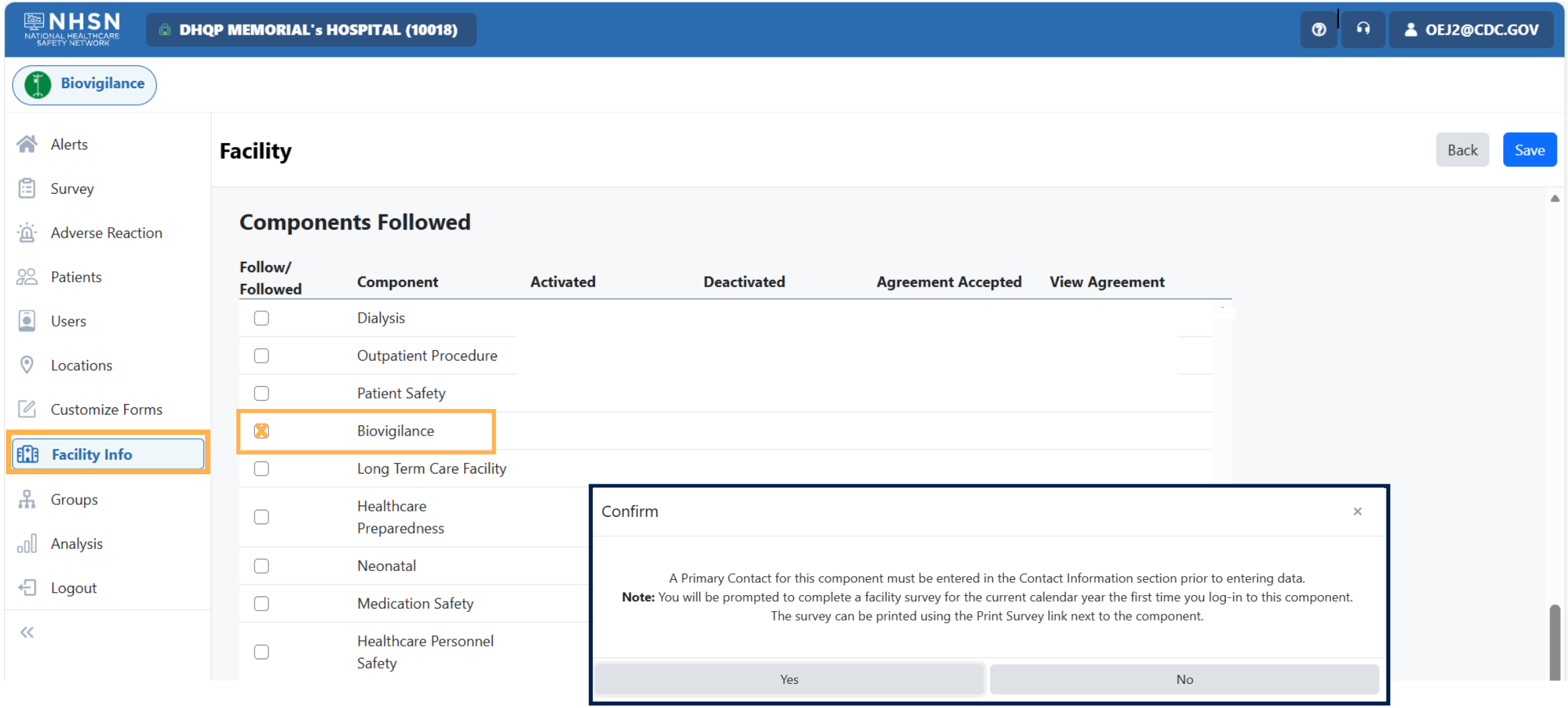
How to Report to the Module

- Activate the Hemovigilance Module
- Complete the Hemovigilance Annual Facility Survey
- Submit a Transfusion-Transmitted Infection Rapid Alert, upon occurrence
- Complete a TTI Investigation Form and Adverse Reaction Form, upon occurrence

Chat and Q&A features are limited to only 1000 participants.

Activating the Hemovigilance Module

Only a NHSN Facility Administrator can add their facility to a component.



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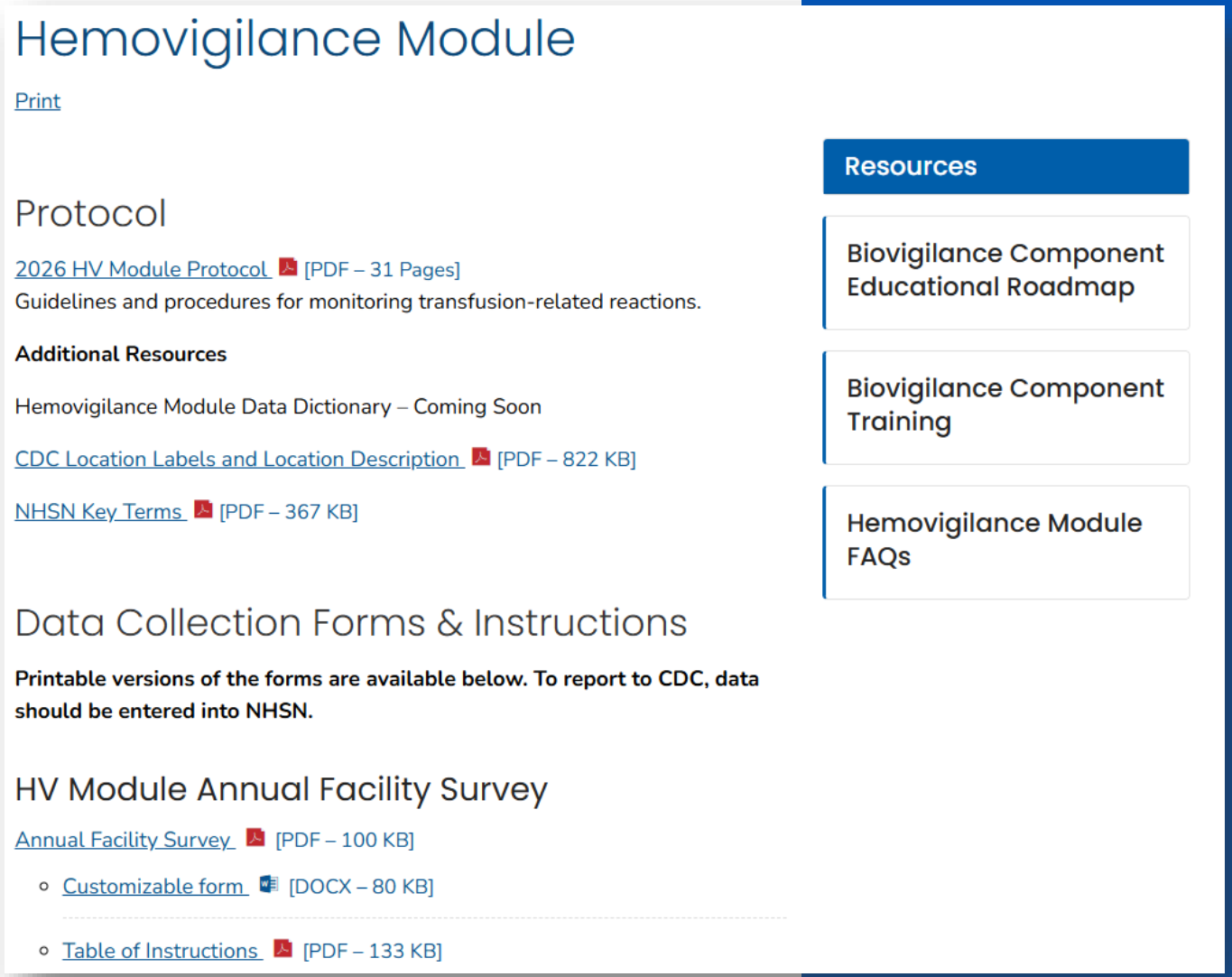
Hemovigilance Module Resources

WWW.CDC.GOV/NHSN/BIOVIGILANCE



Hemovigilance Module

Print

Protocol

2026 HV Module Protocol [PDF – 31 Pages]
Guidelines and procedures for monitoring transfusion-related reactions.

Additional Resources

Hemovigilance Module Data Dictionary – Coming Soon

CDC Location Labels and Location Description [PDF – 822 KB]

NHSN Key Terms [PDF – 367 KB]

Data Collection Forms & Instructions

Printable versions of the forms are available below. To report to CDC, data should be entered into NHSN.

HV Module Annual Facility Survey

Annual Facility Survey [PDF – 100 KB]

- Customizable form [DOCX – 80 KB]
- Table of Instructions [PDF – 133 KB]

Resources

Biovigilance Component Educational Roadmap

Biovigilance Component Training

Hemovigilance Module FAQs

Chat and Q&A features are limited to only 1000 participants.

What can you do now?

- Activate the Hemovigilance Module (Biovigilance Component) for your facility
- Submit your Annual Facility Survey
- Report any potential transfusion-transmitted infections via a TTI Rapid Alert

Chat and Q&A features are limited to only 1000 participants.

Knowledge Check

CDC began operating the NHSN Hemovigilance Module in response to the Institute of Medicine's recommendation to do which of the following?

A. Establish a surveillance system to detect, monitor, and warn of adverse effects in recipients of blood and blood products.

B. Pilot a surveillance system for blood and blood products for a small group of hospitals focused on HIV.

C. Track all blood transfusions in real-time nationally.

Chat and Q&A features are limited to only 1000 participants.

Knowledge Check

Revisions to the Hemovigilance Module are designed to:

A. Create more work for everyone.

B. Focus on elements with the highest public health priority.

C. Reduce reporting burden.

D. B and C

Knowledge Check

What next steps are recommended for facilities?

A. Activate the Biovigilance Component (Hemovigilance Module) in NHSN, if you haven't already.

B. Complete the Annual Facility Survey, if you haven't already.

C. Report potential transfusion-transmitted infections via a TTI Rapid Alert

D. All of the above

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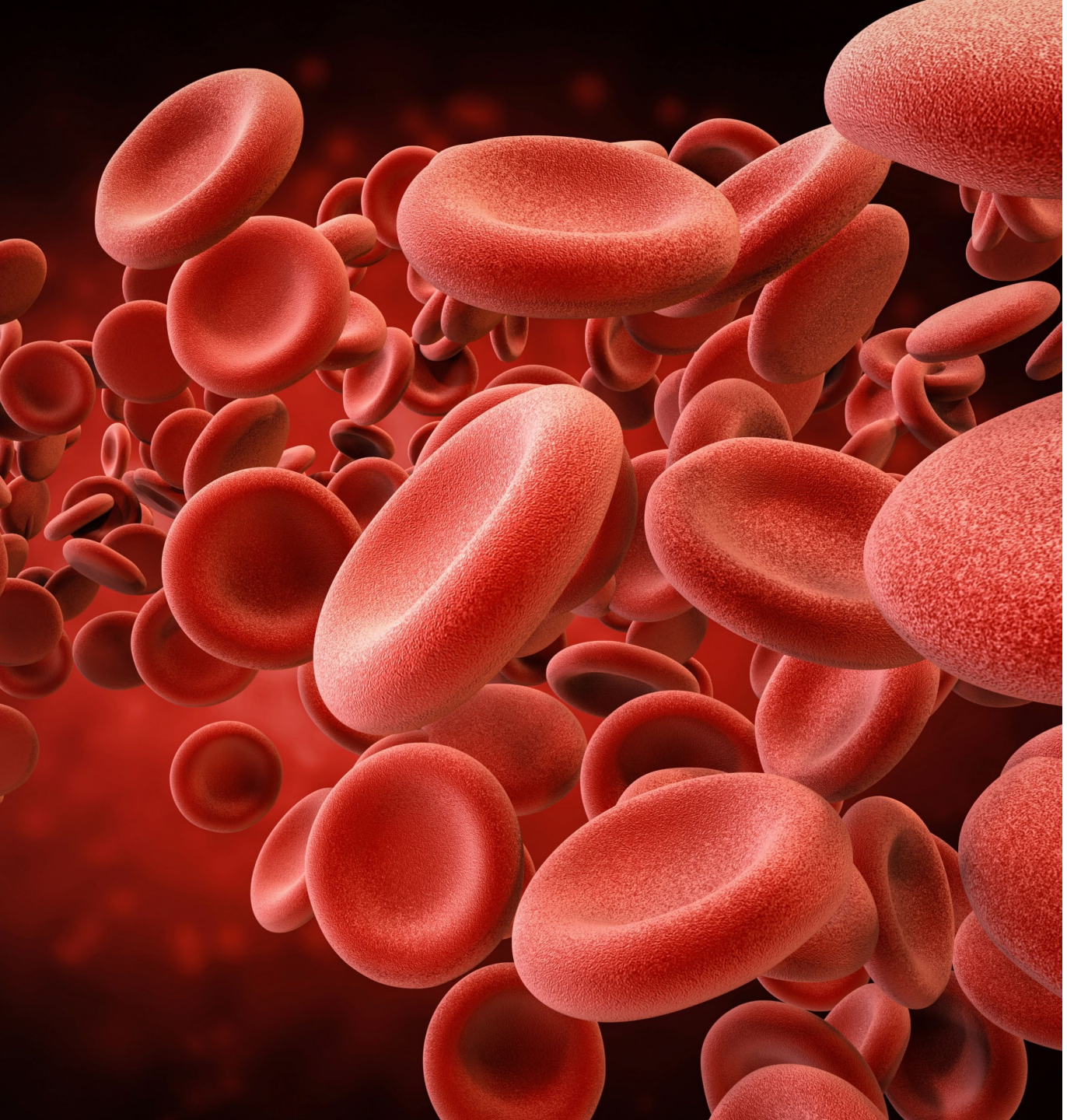

Questions?

Email our team directly at **hemovigilance@cdc.gov**.

Thank you.

For any questions or concerns, contact the NHSN Helpdesk

- **NHSN-ServiceNow** to submit questions to the NHSN Help Desk.
- Access new portal at **https://servicedesk.cdc.gov/nhsncsp** .
- If you do not have a SAMS login, or are unable to access ServiceNow, you can still email the NHSN Help Desk at nhsn@cdc.gov.

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 https://www.cdc.gov/
Follow us on social **@CDCgov**

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