HHS CUTS THREATEN THE BLEEDING DISORDERS COMMUNITY AND HEMOPHILIA TREATMENT CENTERS!

What are Hemophilia Treatment Centers (HTCs)?

HTCs are centers of excellence that specialize in the management of not only hemophilia, but a wide range of bleeding disorders. Unlike most hospitals, HTCs provide what is known as “comprehensive care” or “integrated care,” which involves a holistic approach to healthcare that addresses all aspects of a patient's well-being, including their physical, mental, social, and emotional needs. The HTC core care team includes hematologist, nurse coordinator, social worker and physical therapist. HTCs may also have other specialists on staff, such as dentists, genetic counselors, psychologists and orthopaedic surgeons. HTCs are able to diagnose rare bleeding disorders, which is beyond the ability of some hospitals. In addition to providing comprehensive care for individuals with bleeding disorders, HTCs provide individualized treatment plans, preventative medicine, education, specialized laboratory services, physical therapy, psychological services and genetic counseling, as well as other services. Approximately 95% of HTCs are located within large teaching hospitals or university medical centers where specialized expertise and resources are more readily available.

The Affordable Care Act (ACA), in 2013, designated hemophilia treatment centers as essential community providers (ECPs). ECPs are defined as health care providers who serve predominantly low-income, and/or medically underserved individuals. ECPs are a key component of the ACA's network requirements for Qualified Health Plans (QHPs), ensuring that these plans include a sufficient number of providers who can reach these vulnerable populations.

Why are HTCs important?

HTCs are staffed by specialists who are knowledgeable about bleeding disorders—many of which are rare and seen only infrequently at most hospitals. Studies have demonstrated a 40% decrease in patient mortality (death) among people with hemophilia who are treated at an HTC, as well as fewer complications, fewer hospitalizations and lower costs. (Soucie, et. al., 2000, PMID: 10887103)

HEMOPHILIA COUNCIL OF CALIFORNIA

The CDC & Our HTCs

Who is served by HTCs?

The 143 hemophilia treatment centers in the US—members of the Hemophilia Treatment Center Network—treat over 60 rare bleeding & clotting disorders, including hemophilia, von Willebrand Disease, platelet disorders & others.

- 45,746 individuals were served in 2024 (2024 Hemostasis & Thrombosis Data Set)
- The number of patients served by HTCs has increased by 40.7% over the past 10 years (mainly due to new diagnosis of von Willebrand Disease)
- In the latest 2023 National HTC Patient Satisfaction Survey, 95% of the more than 5,000 HTC patients who responded indicated they were always/usually satisfied with HTC care (www.htcsurvey.com/)

What is the Hemophilia Treatment Center Network?

The Hemophilia Treatment Centers Act of 1975 authorized federal funding to establish a network of hemophilia comprehensive care centers called the United States Hemophilia Treatment Center Network. Today, the network is comprised of eight regional hemophilia networks and 143 hemophilia treatment centers across the US, with 10 centers located in California.

The regional hemophilia networks are recipients of the HRSA National Hemophilia Program grants (see "How HTCs are funded"), which they then distribute to the HTCs within their region. The regional networks are also charged with:

- Building HTC comprehensive care teams
- Using the best available research to inform how care is given
- Putting into practice quality improvement initiatives
- Providing capacity building expertise to the HTCs within their region

How are HTCs Funded?

There are four primary funding sources for HTCs:

1. **Reimbursement** by payors such as Medicare, Medicaid or private insurance. In California, this includes Medi-Cal, California Children's Services (CCS) and the Genetically Handicapped Persons Program (GHPP). Many services provided by HTCs in the course of providing integrated care are not billable. This includes services such as urgent or emergency telephone triage encounters and medical care coordination encounters. And in most cases, encounters for psychosocial services, vocational services and outreach clinics are non-billable services. This presents a

challenge for HTCs, as HTCs have come under increasing pressure from their host hospitals to pull their own weight financially or face a reduction in services, or closure.

2. **Health Resources & Services Administration (HRSA) Grant**, for the National Hemophilia Project, under Maternal and Child Health Bureau of Special Projects of Regional & National Significance (SPRANS). Each of the eight regional hemophilia networks is the grant recipient and is responsible for administering the grant, including dispersing funds to the HTCs in their region and compiling data to fulfill the grant requirements. Grants are on a five-year cycle. This is year 3 of the current grant cycle. Grant amounts are modest (typically $15-20,000 annually per center) and funding has remained flat for many years, despite the number of HTCs having increased from 12 in 1975 to the current 143 and the patient population having ballooned since inception of the grant.
3. **CDC Community Counts Registry for Bleeding Disorders Surveillance,** is a public health surveillance program managed by the CDC's Division of Blood Disorders & Public Health Genomics (DBDPHG) in a cooperative agreement with the American Thrombosis and Hemostasis Network (ATHN) and the U.S. Hemophilia Treatment Center Network.

   Community Counts is focused on monitoring the health outcomes of people with bleeding disorders cared for at US HTCs. It aims to gather and share information about common health issues, medical complications, and causes of death related to bleeding disorders. Essentially, it's a national effort to collect and analyze data to improve care and outcomes for individuals with bleeding disorders.

   Community Counts started in 2011 and consists of three components: the Registry for Bleeding Disorders Surveillance, the Mortality Reporting Project and the HTC Population Profile. Participation in the project by HTCs and individuals is voluntary and HTCs that do participate (which is almost all) receive a small grant through ATHN (grant funded by the CDC). The grant is often about the size of the HRSA grant. Like the HRSA grant, funding for this grant has also remained flat for many years, even though the HTC patient population has ballooned.

4. **340B Drug Pricing Program income** (also known as the Public Health Service Program [PHS]). As HRSA Grantees, HTCs are eligible to certify as a "340B Covered Entity," allowing them to participate in the HRSA 340B program and purchase hemophilia therapies (such as factor concentrate) at a reduced price, which is then sold at or below market value. Profits generated from the sale of hemophilia therapies help support HTC programs. Most HTCs participate in the 340B Program and it is a critical source of funding for HTCs: a majority of centers use 340B income to provide more than 90% of support staff salaries for coordination of care and case management services.

HOW CDC CUTS WILL NEGATIVELY AFFECT THE BLEEDING DISORDERS COMMUNITY AND HTCs

What is the CDC and what is its purpose?

The Centers for Disease Control and Prevention (CDC), under the Department of Health and Human Services (HSS), is the nation's leading science-based, data-driven, service organization that protects the public's health. The CDC's mission is to protect America from health, safety and security threats, both foreign and in the U.S. This includes detecting and responding to new and emerging health threats, such as COVID-19, H1N1 influenza virus, SARS-CoV-2, MERS-CoV and many other contagious diseases.

In addition to collecting health data of individuals receiving care at an HTC through the Community Counts program, people who have hemophilia or von Willebrand type 3 and who are enrolled in the Community Counts program are able to obtain free inhibitor testing. The development of inhibitors in people with hemophilia or von Willebrand type 3 is a serious complication in which the person's immune system incorrectly identifies infused clotting factor (aka "hemophilia medicine") as a foreign protein and inactivates the factor—rendering the therapy less effective or even useless. Because it is more difficult to stop bleeding in people with inhibitors, these individuals have a 70% greater risk of dying from a bleeding episode as compared to others with hemophilia who do not have inhibitors.

CDC researchers have also developed a new inhibitor detection method to complement the standard blood test for inhibitors. This new method (called a fluorescence immunoassay) was developed to address the problem of unclear results with the standard test.

What is the issue?

As part of HHS secretary Robert F. Kennedy Jr.'s April 1st reduction in force at HSS, all but two staff members of the CDC's Division of Blood Disorders & Public Health Genomics were put on administrative leave, with termination notices expected in 60 days. These layoffs essentially eliminated the entire Division of Blood Disorders. With no clear plan how or if the services will continue, people with bleeding disorders have lost critical services impacting safety of, and access to, treatment and care.

In addition, HHS disbanded the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), the federal advisory committee that provided guidance to the HHS secretary on policy issues related to the safety and availability of blood, blood products, tissues and organs. (As an aside, the CDC was first to identify three cases of AIDS in people with hemophilia in 1982, and continued to track the incidence of AIDS in the hemophilia community for years to come.)

What are the critical concerns?

Threat to Public Health Surveillance

The Division of Blood Disorders funds and manages the Community Counts Registry for Bleeding Disorders Surveillance, the essential national surveillance of individuals with bleeding disorders. This unified health database is critical to improving health outcomes and ensuring the safety of individuals with bleeding disorders through monitoring of joint health, comorbidities and treatment outcomes.

This data has advanced scientific findings and progress. Without it, we lose the ability to track disease progression, treatment effectiveness and emerging complications. The data also helps clinicians provide evidence-based care and allows researchers to develop improved treatments.
Additionally, this project supplies data used to track progress toward HRSA Regional Grant program objectives.

OUR REQUEST

Take immediate action to ensure the continuation of these essential functions

The CDC Division of Blood Disorders maintains an essential national surveillance of bleeding disorders through the Community Counts Registry for Bleeding Disorders. This unified health data is critical to improving health outcomes and to ensure the safety of individuals with bleeding disorders through monitoring of joint health, comorbidities and treatment outcomes.

Additionally, and critically, the bleeding disorders community and the American public broadly, needs to be assured that the nation's blood supply is safe. All monitoring must immediately be restored and conducted with transparency and accountability.

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