



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

MASAC Document #269
(Replaces Document #132)

**STANDARDS AND CRITERIA FOR THE CARE OF PERSONS
WITH CONGENITAL BLEEDING DISORDERS**

The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on March 11, 2022, and adopted by the NHF Board of Directors on April 27, 2022.

Standards and Criteria for the Care of Individuals with Bleeding Disorders

“Hemophilia Treatment Centers (HTCs) provide value to people with hemophilia and other congenital coagulation disorders, their families and caregivers, health care providers, insurers, and policymakers in the form of integrated disease management. This integration is made possible through a core care team including a hematologist/medical director, nurse coordinator, physical therapist, and social worker, along with access to a specialized coagulation laboratory. This is complemented by an extended team, comprising professionals in related disciplines such as orthopedic surgery, as well as dentists and dental hygienists, gastroenterologists, infectious disease experts, nutritionists, genetic counselors, psychologists, and others available upon referral. Other extended team members include those who facilitate research activities at the HTC, such as data managers and clinical research nurses.^{1,2,3}

Hemophilia Treatment Centers (HTCs) provide early diagnosis and intervention to prevent complications and support optimal health for children, youth and adults with bleeding disorders. All HTC teams within the United States Hemophilia Treatment Center Network (USHTCN) must share a commitment to the delivery of high quality, patient-centered culturally competent, comprehensive care of persons with bleeding disorders. Teams must incorporate best practices, up-to-date standards of care, and treatment options in this rapidly changing health care environment. Optimal care to prevent complications and support health and wellbeing requires a multi-disciplinary team with integrated services. Professional practices should be consistent with guidelines, recommendations, and standards developed by Health Resources and Services Administration (HRSA), the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF), International Society on Hemostasis and Thrombosis, World Federation of Hemophilia², Centers for Disease Control and Preventions and the USHTCN.

GENERAL REQUIREMENTS

1. Core HTC team:

¹ Valentino LA, Baker JR, Butler R, Escobar M, Frick N, Karp S, Koulianos K, Lattimore S, Nugent D, Pugliese JN, Recht M, Reding MT, Rice M, Thibodeaux CB, Skinner M. Integrated Hemophilia Patient Care via a National Network of Care Centers in the United States: A Model for Rare Coagulation Disorders. *J Blood Med.* 2021 Oct 21;12:897-911. doi: 10.2147/JBM.S325031. PMID: 34707421; PMCID: PMC8544265.

² Srivastava, A, Santagostino, E, Dougall, A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia.* 2020; 26(Suppl 6): 1- 158. <https://doi.org/10.1111/hae.14046>

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- a. Core team member staff: Hematologist, Specialized Hemophilia Nurse, Physical Therapist and Social Worker.
- b. Each core team member must have adequate, clearly defined time and effort dedicated to the HTC, including time for patient care during and between comprehensive clinic visits, as needed.
- c. Core team participates regularly in continuing education, team conferences and program development.
- d. A hematologist with expertise in bleeding disorders must be available 24/7 for consultation.
- e. Round-the clock access to a specialized coagulation laboratory should be considered part of the core integrated care team.
- f. Team configuration and FTE are determined by the needs of the population served. HTC must reassess resources as diagnostic, treatment and patient needs change and evolve.

Patient-centered care means that by virtue of their lived experience people living with bleeding disorders are subject matter experts in their own condition and thus should be considered an integral part of an individual patient’s care team.

2. Training:

- a. All core team members should demonstrate a high level of understanding of the diagnosis, treatment and care of people with bleeding disorders.
- b. All HTC team members must maintain expertise and remain current on best clinical practices and new therapies. HTC institutions must provide enough time and support for this continuing education.

COMPREHENSIVE INTEGRATED DISEASE MANAGEMENT SERVICES

Patients Served

The patient population for HTCs include people with one or more diagnosed bleeding disorder(s), including but not limited to von Willebrand disease, hemophilia and other clotting factor deficiencies, and platelet disorders. Also, people with bleeding of unknown cause (BUC) (e.g., an unclassified bleeding disorder in a patient with increased bleeding score but negative hemostasis evaluation) and those with confirmed or potential hemophilia carrier status should receive care at an HTC.

Equitable access to diagnosis and treatment must be provided to all patients served at the HTC. Equity is defined as the consistent and systematic fair, just and impartial treatment of all individuals, including but not limited to individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely impacted by persistent poverty or inequality.³

Strategies to reduce health care disparities must be identified and initiated at the HTC-level. Plans to address barriers to health care access, health disparities, and health literacy must be established. Progress toward meeting access and literacy needs should be evaluated through continuous quality improvement and patient and family satisfaction surveys. Outreach to underserved populations through provider and community partnerships must be performed.

³ Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009, at § 2(a) (Jan. 20, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf>.

Diagnostics and Therapeutics

Best practices in medical care must be maintained, including culturally competent care that is specific to each patient's specific diagnosis, age, needs and health care goals. Plan of care must include shared decision-making including discussion about potential risks and benefits of each treatment option. This includes preventive medicine, carrier screening and detection, genetic and prenatal counseling, telemedicine, patient education and engagement in care, blood product and pharmaceutical use and management, rapid assessment of bleeding events and recognizing and managing complications of therapies, and pain assessment. All appropriate diagnostic and screening laboratory and imaging studies should be obtained, and results communicated to patients in a timely fashion and in preferred language.

Assessment and Patient/Family Education

Patient/family education must be ongoing throughout the lifespan and based on the assessment of individual patient/family needs, their preferred method of learning and assessed gaps in knowledge. Education should be provided in the primary language of the patient/family and meet health literacy needs. Education products should be created and disseminated broadly including patient outreach materials, clinical care information and tools to promote health and collaboration with other health care providers, schools, employers and insurance plans. Emergency and travel plans should be created in conjunction with patients and families.

Health care transition is the process of moving from a child-to-adult model of health care with or without a transfer to a new clinician.⁴ Adolescents and young adults and their parents require specific assessment, education and encouragement to prepare for independence in health care as adults. In addition, support for transitions in education, employment, and living situations should be provided.

Physical Therapy

A comprehensive physical therapy evaluation must be conducted at regular intervals, especially for those individuals at risk of musculoskeletal complications from their bleeding disorder. The evaluation and assessment must be adapted to each specific patient and consider their medical or surgical history, activity levels, use of prophylaxis, history of hemarthroses, and type and severity of bleeding disorder. The evaluation should include anticipatory guidance on activities and physical fitness throughout the lifespan. Additionally, appropriate treatment interventions should be developed and implemented based on evaluation findings. Consultation to community therapists is vital if services cannot be provided at the HTC. Physical therapists should also serve as an educational resource for the patients, other providers, and the broader bleeding disorder community.

Psychosocial Evaluation

Psychosocial evaluation and intervention must be provided to all patients and their caregivers/families. Services must be developmentally appropriate, culturally competent, and based on individual patient and their caregiver/family needs, beliefs, intentions, and goals. Services include mental health and substance use screening and assessment, and support with coping with a chronic health condition.

⁴ White PH, Cooley WC; Transitions Clinical Report Authoring Group; American Academy of Pediatrics; American Academy of Family Physicians; American College of Physicians. Supporting the Health Care Transition From Adolescence to Adulthood in the Medical Home. *Pediatrics*. 2018;142(5):e20182587

When appropriate, interventions and referrals to address mental health and substance use must be provided. The psychosocial professional must also assess if basic needs are being met and if there are barriers to access to care (transportation, finances, insurance). If needs are identified, the psychosocial professional must provide resources and referrals to help with these challenges, as well as coordinate with local social service agencies. Additional services may include support and advocacy with schools, employers, and within the local or national community. Vocational guidance or resources should be provided as indicated by the needs of each patient.

Genetic Education/Counseling

The HTC team will provide thorough education about the inheritance of the bleeding disorder in the family, conduct an appropriate family history, provide genetic testing as indicated with appropriate pre- and post-test counseling, provide guidance on risks for future family members and conduct necessary outreach to family members at risk for the bleeding disorder or carrier status. In addition, the team will arrange and advocate for adequate insurance coverage for genetic testing. This care can be provided by the medical team or a genetic counselor in the clinic. All patients who need access to more specific genetic evaluation/ counseling should receive this on site or through referral.

Women's Health Services

HTCs must provide bleeding disorder diagnostic and treatment services to women, girls and people with the potential to menstruate. Best practices and current treatment must be provided to each of these individuals in the HTC and should include diagnosis, counseling, individual and family history, mitigating barriers to access to care issues and on demand or prophylactic treatment recommendations. Treatment plans and recommendations for prenatal, labor and delivery, and post-partum care, as well as treatment planning and recommendations for the care of a newborn with a potential bleeding disorder should be provided.

Female relatives and others at risk for bleeding disorder carrier status should be provided appropriate diagnostic testing, pre- and post-test counseling and reproductive options. This can be in conjunction with a team genetic counselor or through referral to an experienced genetic counselor or genetics service. HTCs must collaborate with OB/GYNS or Adolescent Care Providers to establish a pathway to routine and specialized care for these patients. HTCs should also consider participating in the Foundation for Women and Girls with Bleeding Disorders network for provider resources and guidance in developing and maintaining a multi-disciplinary clinic.

Because many patients are seen in other settings than the HTC, efforts should be made to provide guidance to affected patients who reach out for help with surgery or treatment. Such individuals should be counseled to seek care through the HTC.

Dental Care

Basic education about dental hygiene and reminders of the need for routine dental care should be provided to each patient, beginning in childhood. HTC staff should assist families in identifying appropriate dental providers, when needed. Treatment plans for safe dental procedures for patients with bleeding disorders must be coordinated by the HTC team and communicated to dental providers and the patient/family.

Treatment Products and Therapeutic Modalities

All FDA approved products for treatment and management of bleeding disorders should be available, on site (340B or HTC pharmacies), through home care agencies, or pharmacies. Education about the indications, safe administration, potential contraindications, and timing of each prescribed treatment product must be provided to each patient/caregiver. Patients must have choice in their treatment plan and choice in dispensing pharmacy used, as allowable based on insurance plans. This choice must be discussed between the HTC and the patient and/or family.

Health Care Transition

HTC teams should prepare adolescents and young adults for independence in health care and transition to adult-centered care. Each HTC should have a written Transition Plan that is shared with patients and families. Teams should actively assess transition readiness and areas of need for each adolescent/young adult to facilitate successful and safe transition to adult care.

Collaboration

HTC teams should promote a patient-centered medical home and must coordinate care through close collaboration with primary care providers, other specialty providers, hospital staff, residential facilities, personal care assistants, schools, childcare facilities and the justice system to ensure appropriate care and management of individuals with bleeding disorders.

HTCs should actively collaborate with the NHF and other patient advocacy organizations to advance the interests of patients/families. Patients/families rely on NHF for its infrastructure, which includes local chapters that provide community support, essential education and advocacy.

OUTREACH AND EDUCATION

Patient/family education must be provided in a culturally competent manner with the methods preferred by the learner and considering health literacy levels. Explanation of the diagnosis, inheritance, treatment, complications, risks and benefits of therapeutic products and regimens must be included. The patient and team must develop a collaborative care of plan to meet the patient's goals. This plan should be updated regularly. Assessment of the patient/family ability or interest in adhering to the plan and adjustments to the plan to enhance adherence is important.

The team should help the patient identify a trusted support person/group and can facilitate education/communication with support people with consent of the patient.

All communication with the patient/ family/caregivers should be sensitive to the needs of the patient and be culturally competent. Translators, interpreters and appropriate support for diverse populations must be included. All related disability access (e.g., Americans with Disabilities Act) and privacy (e.g., Health Insurance Portability and Accountability Act (HIPPA)) guidelines must be followed. The HTC must provide education about bleeding disorders and their treatment to primary care providers, other health care providers, hospital staff, school staff, employers and other community agencies as appropriate.

COMMUNICATION

All providers must actively follow HIPAA, institutional, ethical and professional guidelines in communicating among team members, as well as with patients, families, other health care providers and other community agencies. HTC teams must have a plan to meet, in person or virtually, to review care, develop a care plan and identify needs for each patient. The HTC must also promote and facilitate communication with patients to develop a shared plan of care, provide a summary of each visit with treatment recommendations, and address acute needs and routine questions between visits. Patient portals, written letters, phone trees and other methods can help facilitate patient/provider communication. Written communication should be shared with the individual's primary care provider after every evaluation.

Patient/Family Feedback

Each HTC should have a plan for eliciting feedback from patients and families. This can include patient satisfaction surveys, surveys or assessments after clinic visits, contacting identified families for specific questions and/or a Patient/Family Advisory Panel that includes diversified representation of the population served. Feedback can be in person or virtual and should be conducted on a regular schedule.

REFERRALS

HTCs may not house every service or specialty needed by every patient. For these circumstances, a plan should be in place to refer patients to other services in their institution, other HTCs or to outside institutions with the ability to best meet patients' needs. These services can include such specialties as Cardiology, Gastroenterology, Infectious Disease, Surgery, Orthopedics, Childhood Development, Genetic testing and services, Fetal Medicine, Rehabilitation, Mental Health Services, Occupational Health, Specialized laboratories, Gene Therapy sites, Dental providers, Nutrition, Pain Management Clinics etc. Referrals should be made to reputable, certified and experienced teams and providers to assure optimal care for patients and families. Specialized genetic and coagulation laboratories with specific expertise and certification should be identified to assist with needed diagnostic evaluation or implementation of appropriate care. Procedures to facilitate such referrals, communication with the other providers, support for accessing the services should be implemented by the HTC team. HTCs should provide all patients/families with information about and the availability of local/national patient organizations, programs and services.

RESEARCH

HTCs must participate in on-going surveillance and should encourage research participation in studies to help determine answers to unanswered questions, e.g., arthropathy, bleed treatment, novel therapies, non-factor therapies, gene therapy, inhibitor prevention, prophylaxis strategies as appropriate for each patient, impact on health-related quality of life, etc. Also, participation should be encouraged in studies in the diagnosis and management of women with bleeding disorders, rare bleeding disorders and BUC. Discussion should include role of community voices (experts) diversity equity and inclusion, and the reason for the study and specific patient related outcomes. Participation in longitudinal observational research studies should be encouraged and facilitated by the HTC (e.g., ATHN, Community Counts Data Surveillance Project, WFH World Bleeding Disorders (WBDR) registry and WFH World Gene Therapy Registry (WGTR)). Research should not be limited by patient's primary language, health literacy or developmental status whenever possible.

POLICIES AND PROCEDURES

HTCs should have written protocols or processes that outline the provision of services to diagnose, treat, educate and support individuals with bleeding disorders and their families. These protocols should be regularly reviewed and updated to reflect changes in current practices or new therapeutic products. HTCs must follow established regional processes, policies or procedures including but not limited to oversight and monitoring requirements and HRSA and 340B program regulations.

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