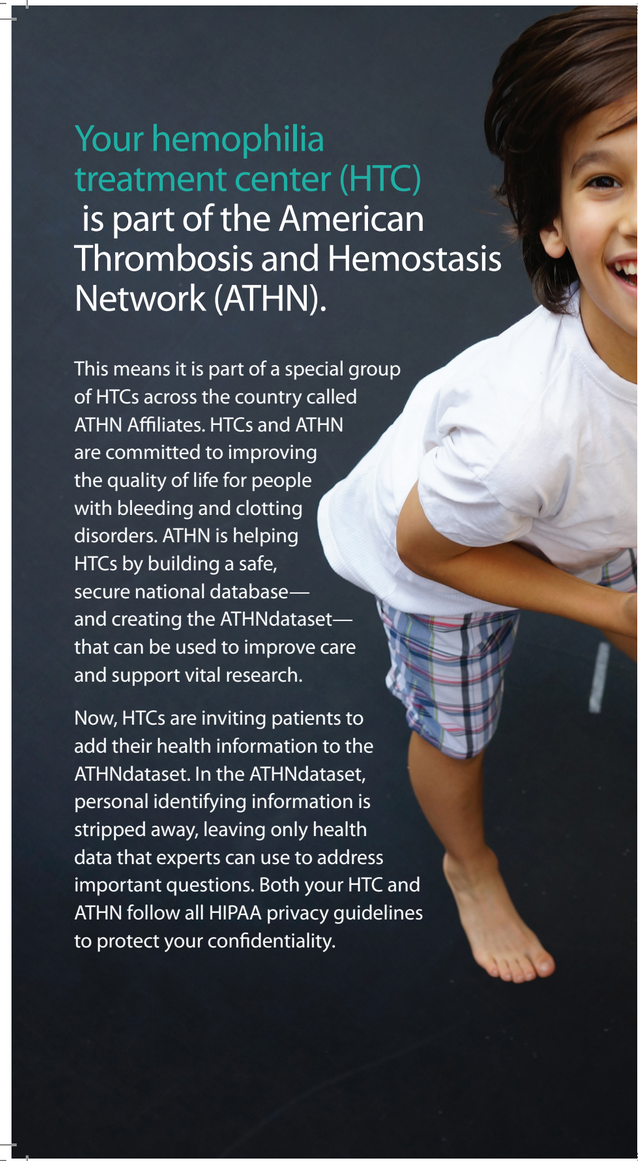

Your hemophilia treatment center (HTC) is part of the American Thrombosis and Hemostasis Network (ATHN).

This means it is part of a special group of HTCs across the country called ATHN Affiliates. HTCs and ATHN are committed to improving the quality of life for people with bleeding and clotting disorders. ATHN is helping HTCs by building a safe, secure national database—and creating the ATHNdataset—that can be used to improve care and support vital research.

Now, HTCs are inviting patients to add their health information to the ATHNdataset. In the ATHNdataset, personal identifying information is stripped away, leaving only health data that experts can use to address important questions. Both your HTC and ATHN follow all HIPAA privacy guidelines to protect your confidentiality.

Some key facts

- ATHN is a not-for-profit 501(c)3 organization founded in 2006.
- ATHN partners with the bleeding disorder community, government and industry to develop technology systems and to provide research and surveillance services that improve quality care for patients.
- ATHN Affiliates are hemophilia treatment centers (HTCs) providing multi-disciplinary comprehensive care to more than 45,000 people with bleeding and clotting disorders. There are more than 135 of these centers of excellence.
- A multi-stakeholder Board of Directors representing ATHN Affiliates, regional leaders, patients and consumers governs ATHN. The Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA) Maternal and Child Health Bureau, and the National Heart, Lung and Blood Institute (NHLBI) provide input through liaisons to the Board and key committees.
- In addition to managing the ATHNdataset, ATHN provides funding for national data collection and research efforts of bleeding and clotting disorders care providers in the U.S.

our vision.

To advance and improve the care of individuals affected by bleeding and thrombotic disorders.

our mission.

To provide stewardship of a secure national database, adherent to all privacy guidelines, which will be used to support clinical outcomes analysis, research, advocacy and public health reporting in the hemostasis and thrombosis community.

our values.

Improving clinical outcomes and care, facilitating continuity of care, fostering collaboration, maintaining confidentiality and conserving resources through a common infrastructure.

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american thrombosis & hemostasis network

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Phone: 800-360-2846

www.athn.org

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Secure a future of even better care—for yourself and the bleeding and clotting disorders community.

PATIENT INFORMATION BROCHURE

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The need for a national database and the ATHNdataset

The population of the United States with bleeding and clotting disorders is large and diverse, making the need for a national database a high priority. The vitally important information that makes up the safe, secure national database and the ATHNdataset will help us gain a better understanding of bleeding and clotting disorders, transform care and improve lives.

Doctors, scientists, policy makers and other health care providers need a large pool of patient data to answer scientific, public health and policy questions: What is the safest and most effective way to care for patients with bleeding and clotting disorders? How can we reduce the social and economic costs for patients and families? Are we preventing complications? Researchers can use the information from the ATHNdataset to answer such questions. The more patients contribute their information, the richer the ATHNdataset will become—and the more certain we can be that decisions made represent the whole bleeding and clotting disorders community, not just a select few.

Understanding terms

ATHN is working to help clarify many of the terms used when discussing health data and health care technology.

The following words address related, but different issues and often get confused:

Privacy: Protecting the confidentiality of patient health information due to its sensitivity nature.

Security: The way in which an organization safeguards data from unauthorized access.

Database: Collection of data stored in a central repository.

Data set: A subset of data extracted from a database. The ATHNdataset is a data set.

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What am I being invited to do?

Your HTC and ATHN are inviting you to allow your health information to become part of the ATHNdataset for research purposes, for quality improvement and to aid in policy decision-making. More than 25,000 patients across the country have already signed up to be part of the ATHNdataset. Rest assured, your health information will not directly identify you. Your name will not be linked to the data and your name or other identifying information will never be used in any reports produced as a result of studies using this data.

What kind of information will be included in the ATHNdataset?

If you agree to let your health information be part of the ATHNdataset, it will include things like:

- Your type of bleeding or clotting disorder
- The date you were diagnosed
- Your family history of the disorder
- Laboratory test results used to diagnose and keep an eye on your condition
- Your treatments and how they are used to stop bleeding and clotting problems from occurring or getting worse*
- How your body responds to drugs used to treat blood disorders
- Routine care and trauma
- Allergies
- Types of bleeds you have and how well the bleeding is controlled*
- Genetic information

The health information provided to the ATHNdataset will be updated regularly to reflect your current health status.

Will ATHN have my name and other personal information?

Absolutely not! Only the HTC responsible for a patient's care will have access to the personal identifying information. In compliance with the federal HIPAA Privacy Rule, ATHN will not receive your name or any of the other 16 categories of information that may directly identify you or enable you to be contacted by ATHN or by anyone else. If you agree to take part, ATHN will receive what is known as a limited data set, which, according to the federal Privacy Rule, requires that all 16 categories of direct patient identifiers must be removed from shared health information.

*You may report bleeding and infusion information using tools such as ATHNadvoy.

**The ATHNdataset Patient Authorization process exceeds federal HIPAA Privacy Rule requirements for non-identifiable limited data sets.

> "Participation defines a database's success: the more the community supports it, the more it can give back."
>
> —HTC physician

The following information will NOT be included in the ATHNdataset:

- Name
- Postal address, other than town or city and ZIP code
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security number
- Medical records numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license numbers
- Device identifiers and serial numbers
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including fingerprints and voiceprints
- Full-face photographic images and any comparable images

How will my health information be identified in the database and the ATHNdataset?

At the HTC, a unique, computer-generated code will be assigned to you or your child(ren). Once that unique code is assigned to you, it will be used instead of your name to label information about you. This enables researchers to use your health data without knowing who you are. This unique code system has been applied in a number of settings in which confidentiality is a priority.

How do I know my health information will be secure and that my privacy will be protected?

Your HTC is required by law to protect your health information. Your HTC will share your health information with ATHN only if you sign the ATHNdataset Patient Authorization (release) Form. ATHN is bound by an agreement with your HTC and is required by the federal HIPAA Privacy Rule to protect your information.

Where is the database and is it secure?

The database used by your HTC to generate the ATHNdataset is kept at a secure off-site commercial facility in an encrypted (non-readable) form. A backup copy is stored at a disaster recovery site in a separate geographic location. All information is sent through a secure Internet-based data transfer mechanism that is password protected and encrypted. This offers greater protection and security than paper records and email.

What are the benefits of participating in the ATHNdataset?

One of the greatest benefits of the ATHNdataset is its power to begin addressing questions that haven't been answered before about bleeding and clotting disorders, inhibitors and treatment. When you join, your health information will be combined with data from thousands of other patients around the country to help advance knowledge and transform care.
This will lead to:

- Increased knowledge of the genetics of bleeding and clotting disorders.
- The ability to study the results of treatments in order to learn how well they work and develop standards of care.
- Better understanding of the clinical, social and economic issues involved in these disorders.
- A closer watch on the safety of FDA-approved medicines for bleeding and clotting disorders.

By participating, you are helping to improve the care of all patients with bleeding and clotting disorders.

Will I have to get any special blood tests or undergo other procedures?

No. There are no special blood tests, procedures or treatments required.

What will it cost me to be part of the ATHNdataset?

Nothing. There is no cost to you to be part of the ATHNdataset.

Does being part of the ATHNdataset require me (or my family) to take part in clinical research studies?

No. You are not agreeing to be part of any clinical research studies. Also, letting ATHN use your health information will not change your care in any way. You may join clinical research studies offered through your HTC if you wish. It is always your decision to participate or not.

What is the relationship between the ATHNdataset and Community Counts, the CDC Public Health Surveillance Project for Bleeding Disorders?

These are separate projects. However, some of the same data is needed for both. Community Counts includes:

- The HTC Population Profile: a de-identified dataset with 10 elements. It serves as a census about how many patients with bleeding and clotting disorders are receiving care at HTCs.
- The Registry for Bleeding Disorders: a HIPAA-compliant limited data set of clinical information about patients with bleeding disorders receiving care at HTCs. It will help inform prevention strategies.

If you are part of the ATHNdataset and Community Counts, there are several common data elements that HTCs collect and enter only once into their system.

How will I be affected if I choose not to take part in the ATHNdataset?

If you decide not to participate, your HTC will not send any of your health information to the ATHNdataset. Whatever you decide, your choice will not affect the level of care provided by your HTC's health care team.

As a result of taking part in the ATHNdataset, will ATHN or others have the right to contact me directly?

No. Maintaining confidentiality is one of ATHN's core values. ATHN will not have your name or any other information that directly identifies you or allows you to be contacted.

What if I change my mind and no longer want ATHN to use my health information?

You may change your mind and stop taking part in the ATHNdataset at any time for any reason. Please be sure to speak with your HTC about any concerns. If you decide to stop participating, you must inform your HTC in writing. After that, your HTC will stop sending your health data to ATHN. Please note that any health information that has already been shared with ATHN will remain part of the ATHNdataset, but no new information will be added.

How can I learn about progress of the database and the ATHNdataset?

Visit the ATHN website, www.athn.org, and watch for articles about ATHN in your chapter and HTC newsletters.

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