



Securing Data.
Advancing Knowledge.
Transforming Care.




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Community
Counts!

CDC Public Health Surveillance
for Bleeding Disorders

Becky Dudley,
Associate Director, National Surveillance



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Community Counts: Project Overview

Community Counts! CDC Public Health Surveillance Project for Bleeding Disorders is a project funded through a cooperative agreement awarded to ATHN in **September 2011** to work with the regional core centers and HTC. It includes the HTC Population Profile, Mortality Reporting and the Registry for Bleeding Disorders: Goals are:

- Provide descriptive knowledge about the populations of hemophilia, von Willebrand disease, other bleeding disorders and VTE receiving care at HTCs (**HTC Population Profile**)
- Monitor health indicators among populations with bleeding disorders (**Registry and Mortality Reporting**)



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Community Counts

Launch dates:

- HTC Population Profile (HTC PP) – September 2012
- Mortality Reporting – September 2013
- Registry for Bleeding Disorders Surveillance (Registry) – December 2013



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Community Counts: Included Diagnoses

Factor Clotting Deficiency

- VIII (8)
- IX (9)
- I (fibrinogen)
- II (prothrombin)
- V (5)
- VII (7)
- X (10)
- XI (11)
- XIII (13)
- Von Willebrand Disease (VWD)
- Inherited or Functional Platelet Disorder
- Bleeding Disorder, no laboratory diagnosis
- Connective Tissue Disorder
- Venous Thromboembolism (VTE) without any of these diagnoses

HTC Population Profile

Community Counts! HTC PP

Patient authorization or consent is NOT required for HTC PP because:

- The set of elements to be collected qualifies as a de-identified data set under HIPAA as all 18 identifiers are removed.
- HTC PP is public health surveillance and not human subject research.
- ATHN's public health authority granted for this project by CDC.



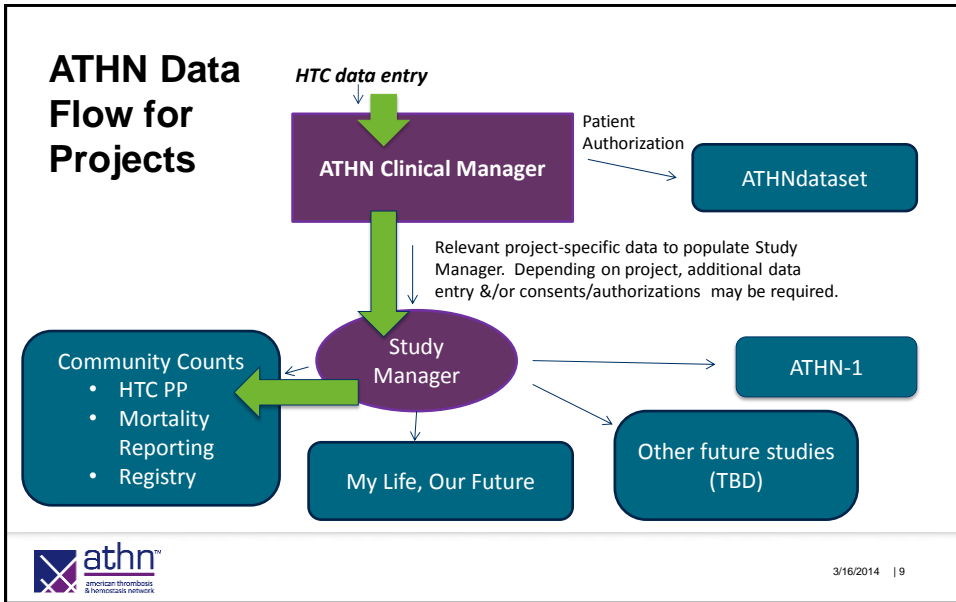
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Submission of HTC PP Forms

HTC PP Forms are completed and submitted to CDC by HTC staff utilizing the ATHN Clinical Manager and Study Manager.



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ATHN STUDY MANAGER

 ? HTC Representative Gillian Anderson
 Profile | Log Out

Master Study List / CDC Community Counts Subjects / Cummings, Leta

CDC Community Counts
Protocol # N/A

ATHN Demo

Study Coordinator: Becky Dudley	Email: bdudley@athn.org	Phone:
Cummings, Leta	Subject ID: #ZR7ne9T	Add Form

2013	draft	draft	03/16/14	
draft 03/16/2014				
1	Year of Birth	<input type="text" value="1900"/>	←	
2	Gender	<input type="text" value="Male"/>		
3	Ethnicity	<input type="text"/>		
4	Race	<input type="text"/>		
5	Zip code of residence at time of visit	<input type="text"/>		
6	Health insurance status at time of visit	<input type="text"/>		
7	Primary Diagnosis or VTE	<input type="text" value="Bernard Soulier syndrome"/>		
8	History of HCV infection?	<input type="text" value="Yes"/>		
9	History of HIV infection?	<input type="text" value="Yes"/>		
10	Year of visit at which information was collected	<input type="text" value="2013"/>		

[Delete Draft](#) [Save Draft](#) [Cancel](#) [Submit](#)

HTC Population Profile

Number of HTCs submitting forms	123
Number of unique participants	35,584
Number of forms by year	
2012	24,274
2013	23,707
2014	2,047
Total	50,096

**THANK
YOU!**



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HTC Population Profile – Southeast Region

Number of HTCs submitting forms	18
Number of forms by year	
2012	3,168
2013	2,825
2014	203
Total	6,196
Percent of National Total	12.4%

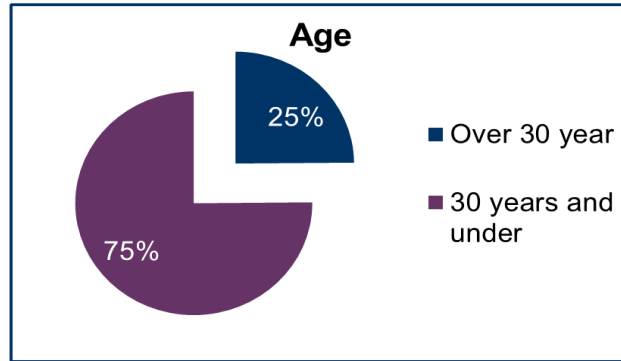
**GOOD
WORK!**



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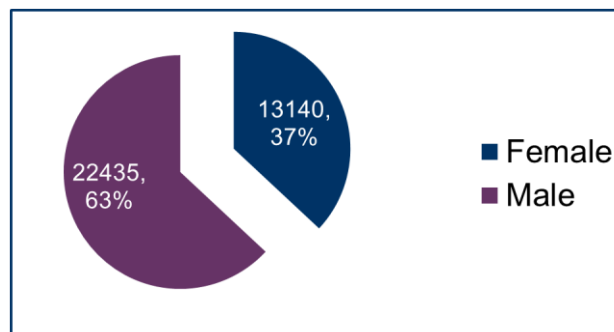
HTC PP: Age

N = 35,584 unique patients (50,096 visits)



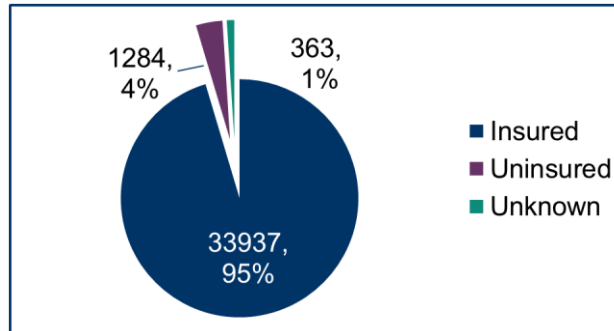
HTC PP: Gender

N = 35,584 unique patients (50,096 visits)



HTC PP: Insurance Status

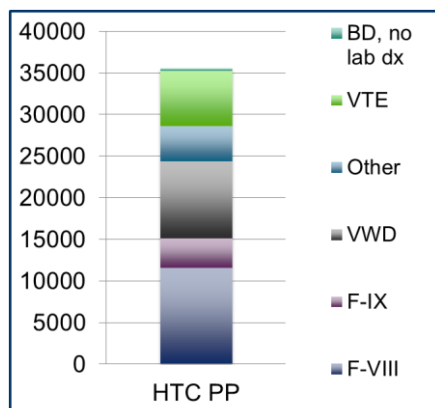
N = 35,584 unique patients (50,096 visits)



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HTC PP: Diagnoses of Patients

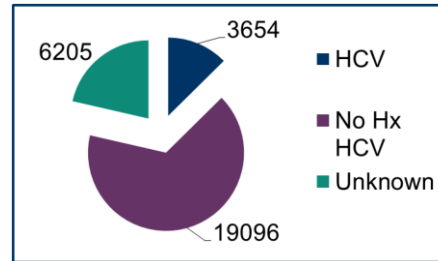
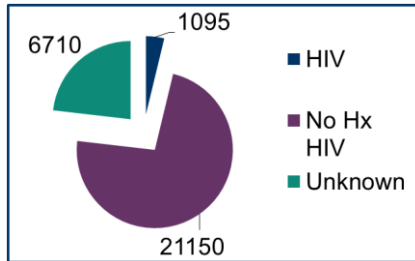
Diagnosis	Freq	Percent
Factor VIII	11,564	32.5
Factor IX	3,576	10.05
VWD	9,244	25.98
VTE	6,629	18.63
Bleeding Disorder, no lab dx.	326	0.91
Rare BD, Platelet, Disorders, Connective Tissue Disorder	4,245	11.93



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HTC PP: Co-Morbidities

History of HIV or HCV	Frequency	Percent
HIV	1095	3.78
HCV	3654	12.62



Mortality Reporting

Community Counts! Mortality Reporting

Patient authorization or consent is NOT required for Mortality Reporting because:

- The set of elements to be collected qualifies as a de-identified data set under HIPAA as all 18 identifiers are removed. (Like HTC PP)
- Human subjects' protections are not indicated because the subjects of data collection are not living persons.
- ATHN's public health authority granted for this project by CDC.



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Submission of Mortality Reporting Forms

1. Print MR Form
2. Complete MR Form – **Use preprinted Subject ID label**
3. Scan MR Form and title the document "Mortality SID 123456789"
4. Retain a copy of MR Form until receipt confirmation and as required by home institution
5. Email scanned MR Form to Brandi Cooke at CDC with Subject Line: "Mortality Reporting Form Attached – SID 123456789"
6. Review monthly report of MR Forms received



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**For Forms, Submission Process & Definitions:
Go to Study Manager –
Community Counts:
Study Info**

ATHN STUDY MANAGER HTC Representative Gillian Anderson
Home | Log Out

Master Study 181 / HTC Population Profile Info

HTC Population Profile Protocol # N/A

Demo Center 1

Study Coordinator: Lewis Watson Email: LewisW@athn.org
Phone: (120) 123-1234

Subjects Study Info

Study Info

Short Title: HTC Population Profile
Test Article #: N/A
Protocol #: N/A
Full Name: CDC HTC Population Profile
Type Of Study: HTC Population Profile
IND #: N/A
SIS #: N/A
Date Open to Enrollment: 01/01/2011
Date Closed to Enrollment: 01/01/2019

Contraindicated Medications while on Study

Contact Information

Sponsor: pi	Email: sponsor@pi.com	Phone: (120) 123-1234
Study Coordinator: Lewis Watson	Email: pi@pi.com	Phone: (120) 123-1234
	Email: LewisW@athn.org	Phone: (120) 123-1234

General Information

» description of the project

Master Study Documents

Download Download

See next slide for document list.

Master Study Documents

1.0 Community Counts Document Listing 2-15-14.docx	Download
1.1.Community Counts Registry Initial Visit Form for Paper Submission 12-1-13.pdf	Download
1.10.Community Counts Registry Incident Case Form Definitions 12-1-13.pdf	Download
1.11.Quick facts for HTCS about the Registry for Bleeding Disorders Surveillance REVISED 12-1-13.pdf	Download
1.12.Community Counts Registry Project Description FINAL.pdf	Download
1.2.Community Counts Registry Initial Visit Form Definitions 12-1-13.pdf	Download
1.2a.Community Counts Registry Patient Authorization 7-5-13.pdf	Download
1.2aa.Community Counts Registry Patient Authorization FINAL.doc	Download
1.2b.Community Counts Registry Patient Authorization - Spanish 1-31-14.pdf	Download
1.3.Community Counts Registry Form Submission Process 12-1-13.pdf	Download
1.4.Community Counts Registry Blood Specimen Procedures Manual 12-1-13.pdf	Download
1.5.Community Counts Registry Specimen Form 1-27-14.pdf	Download
1.6.Community Counts Registry Specimen Form Submission 1-27-14.pdf	Download

Mortality Reporting

Total number of forms submitted	128
Total number of forms submitted by Southeast Region	21

Registry

Community Counts! Registry

The Registry for Bleeding Disorders Surveillance is a collection of **more detailed clinical information** related to bleeding disorders and their impact on patients. **Specimen testing is also included.** Data will be used to:

- Monitor trends
- Measure rates of, and risk factors for, complications
- Identify high-risk populations for prevention programs
- Identify issues that require further study



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Registry Items

1. Patient Authorization or Informed Consent (Indicate in Clinical Manager)
2. Initial Visit Form (First year enrolled, then Subsequent Visit Form)
3. Specimens (*Order supplies from CDC*)
 - Plasma – Inhibitors (Only FVIII, FIX, VWD-Type 3)
 - Serum – Blood borne agents such as HCV, HBV, HIV (All)
4. Specimen Form
5. Shipment Notification Form



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Submission of Registry Form:

1. Print Registry Form
2. Complete Registry Form – **Use preprinted Subject ID label**; see reminders in Community Counts Registry Email #4
3. Copy Registry Form and mail original to CDC in provided envelope (Within 30 days of visit)
4. Retain a copy of Registry Form until receipt confirmation and as required by home institution
5. Review monthly report of Registry Forms received



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Submission in Study Manager

ATHN STUDY MANAGER ? HTC Representative Gillian Anderson
Profile | Log Out

Master Study List / CDC Community Counts Subjects

CDC Community Counts

Protocol # N/A

ATHN Demo

Study Coordinator: Becky Dudley

Email: bdudley@athn.org

Phone:

Subjects Study Info

Subjects: 60

Search

Reset Filters

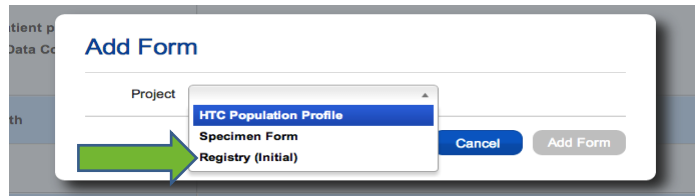
Show Filters

Name	Patient ACM ID	Subject ID	Form	Status	Last Update	Data Forms
Archer, Jonathan	639007	K3H7DSe	HTC PP - 2014	draft	03/14/14	
Armstrong, Hertha	348559	k2zWZ3fc	RegistryInitialForm - Registry (Initial)	draft	03/14/14	
Armstrong, Oran	710154	KTpRSBFZb	RegistryInitialForm - Registry (Initial)	draft	03/12/14	
Aurelius, Marcus Cornelius	281893	bjXuqPMr	RegistryInitialForm - Registry (Initial)	draft	03/10/14	



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Submission in Study Manager



Registry (Initial)		draft	03/14/14	
draft 03/14/2014				
Step 1 > Step 2 > Step 3 > Step 4 > Step 5 > Step 6 > Step 7				
1	Date of visit	<input type="text"/> <input type="text"/> <input type="text"/>		
2	Did this participant give permission to store his/her blood specimens for future testing?	<input type="text"/>		
3	Did this patient participate in the Universal Data Collection (UDC) project?	<input type="text"/>		
4	Date of Birth	January 2, 2004		
5	Gender	Female		
6	Ethnicity	Not Hispanic, Latino/a, or Spanish origin		
7	Race	Asian, White		
8	Weight (kg) (most recent)	<input type="text"/>	Date collected	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
9	Height (cm) (most recent)	<input type="text"/>	Date collected	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Specimens

Be sure to REVIEW: Community Counts Registry Blood Specimen Procedures Manual

Includes: algorithms, collection and processing instructions, shipping directions, supplies ordering information

Tip: Click on item in Table of Contents and it will take you to that page!

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For Community Counts Registry Initial Visit Form & Definitions, Blood Specimen Procedures Manual, Submission Processes, etc.: Go to Study Manager – Community Counts: Study Info

ATHN STUDY MANAGER HTC Representative Gillian Anderson Profile | Log Out

Master Study List | HTC Population Profile Info

HTC Population Profile Protocol # N/A

Demo Center 1

Study Coordinator: Lewis Watson Phone: (123) 123-1234 Email: LewisW@athn.org

Subjects Study Info

Study Info

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 Protocol #: N/A
 Full Name: CDC HTC Population Profile
 Type Of Study: HTC Population Profile
 IND #: N/A
 IRB #: N/A
 Date Open to Enrollment: 01/01/2011
 Date Closed to Enrollment: 01/01/2010

Contraindicated Medications while on Study

Contact Information

Sponsor	a sponsor	Email	sponsor@sponsor.com	Phone	(123) 123-1234
PI	a pi	Email	pi@pi.com	Phone	(123) 123-1234
Study Coordinator	Lewis Watson	Email	LewisW@athn.org	Phone	(123) 123-1234

General Information

A description of the project.

Master Study Documents

HTC_PP_Elements_and_Data_Entry_Tools_0_30_12_1_.pdf	Download
CDC_HTC_PP_Project_Letter_and_Notice_of_Award_1_.pdf	Download



Specimen Form Submission

1. Print Specimen Form.
2. Complete Specimen Form and **use preprinted Subject ID label.**
3. Before shipping FAX Specimen Form to Brandi Cooke at CDC.
4. Include Specimen Form in shipping box with specimens. (Change for original process.)
5. Retain copy of Specimen Form until receipt confirmation and as required by home institution.
6. Review monthly report of Specimen Forms received.



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Name	Status	Date	Details
Specimen Form	draft	03/14/14	

draft
03/14/2014

1	CDC ID (optional, if allowed)	123456789123 or <input type="text"/>
2	Specimen draw date	January <input type="text"/> 1 <input type="text"/> 2014 <input type="text"/>
3	Is a plasma specimen being submitted?	No <input type="text"/>
4	Date of Birth	January 2, 2004
5	Gender	Female
6	Diagnosis	Factor VIII, hereditary, Alpha-2 Antiplasmin Deficiency
7	History of HCV Infection?	Yes <input type="text"/>
8	History of HIV Infection?	Yes <input type="text"/>
9	Draw date of most recent available inhibitor titer	<input type="text"/> <input type="text"/> <input type="text"/> or Not Done <input type="text"/>
10	Has patient ever had a detectable inhibitor titer?	Yes <input type="text"/>

Shipment Notification Form

1. Complete all fields on the form and **use preprinted Subject ID labels**
2. FAX this form to the CDC Serum Bank **before** making each blood specimen shipment.
3. Include a copy of this form with the blood specimen shipment.
4. Retain copy of Shipment Notification Form until receipt confirmation and as required by home institution.
5. If the contents or status of the shipment change after sending the fax, please notify the serum bank.



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Registry

Number of HTCs with institutional approval	79	SE - 14
Number of specimens received at DBD laboratory	259	SE - Not available
Total number of Specimen Forms received	168	SE - Not available
Number of HTCs contributing forms	19	SE - Not available



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Registry

Number of HTC's submitting Initial Visit Forms	16	SE - 3
Total number of Initial Visit Forms received	119	SE - 5
Highest number of forms submitted by an HTC	38	SE - 3



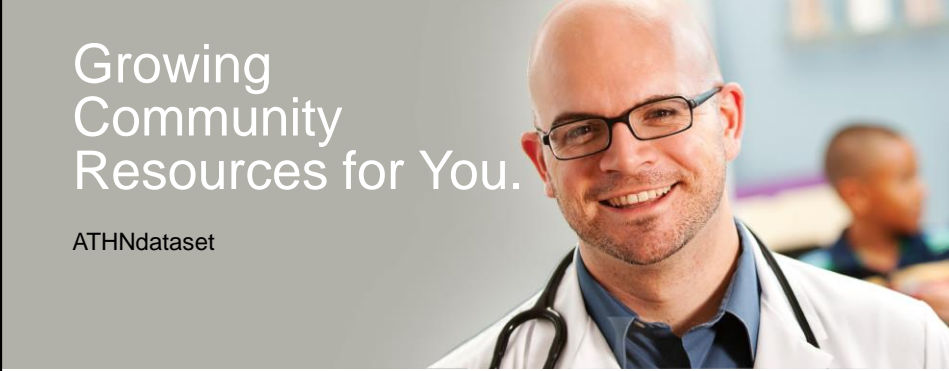
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Thank You, HOG!

The new electronic report forms for Community Counts! are made possible in part through the generous support of Hemophilia of Georgia.




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Growing
Community
Resources for You.

ATHNdataset



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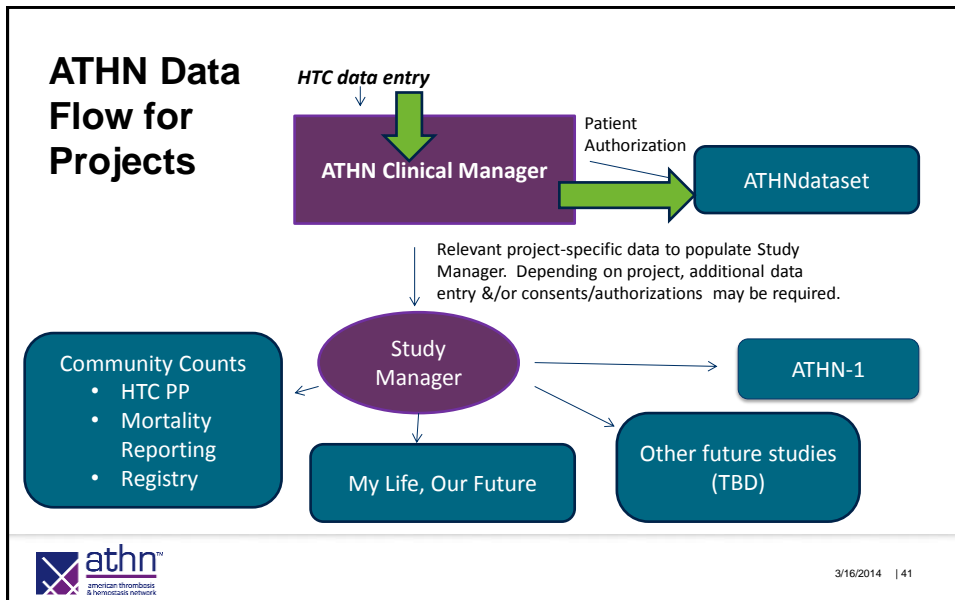
ATHNdataset: Project Overview

Our mission is 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**. The ATHNdataset is this national database!

- Clinical patient-level data
- Patients “opt in” and authorize data sharing (HIPAA compliant limited data set)
- Data for patients who have opted in is pushed by the HTC to ATHN. ATHN does not simply “take” data



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ATHNdataset: Included Populations

- **Any patient** treated at a federally funded HTC is eligible to participate
- Priority for Patient Authorizations
 1. Hemophilia A and B
 2. Von Willebrand Disease (VWD)
 3. Rare disorders
 4. Platelet disorders
 5. Thrombosis patients

ATHNdataset: Where We Are Today

- Over 20,000 patient authorizations obtained!
- Available for download at ATHN Resource Center (www.athn.org)
 - ATHNdataset Research Report Brief (9/2013)
 - ATHNdataset Core Data Elements List
 - ATHNdataset flyer, article, brochure



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ATHN Research Report Brief

- ATHNdataset growth over time
- Demographic profile:
 - Age and sex by region and total US
 - Race and ethnicity by region and total US
 - Types of bleeding and clotting disorders within the population
- Factor VIII Deficiency and Factor IX Deficiency including:
 - Disease severity by region and total US
 - HIV and Hepatitis C by age group
 - Payer profile by region and total US



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Why Ask Patients to Opt In?

The power is in the number. A large pool of data is needed

The ATHNdataset will be used to monitor trends and address questions that haven't been answered before about bleeding and clotting disorders, inhibitors, and treatment.

Performance
Improvement

Advocacy

Research

Contact ATHN for an application for using the data in the ATHNdataset



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ATHN Approach to Data Collection



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ATHN Approach to Data Collection

- Leverages ATHN sponsored data collection system currently deployed at the HTC's
- Standardized, reusable data elements for reporting
- Validated data
 - Field level validations to ensure data quality at point of entry
 - Form level validations to ensure data quality at point of submission to CDC
 - Routine data audits conducted by HTC's supported by ATHNdata.quality.counts grants

Watch for
DQC 6!
Soon!



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ATHN Information Infrastructure

ATHN Clinical Manager

- Supports routine collection of clinical data and surveillance data
- In use at 130 HTC's

ATHN Study Manager

- Deployed to HTC's in 2012 after CDC testing
- Presents electronic study form prefilled with data from ATHN Clinical Manager that is reviewed, validated and submitted by HTC staff
- Enables completion and submission of an HTC PP form in less than 5 minutes



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Meeting Multiple Data Needs

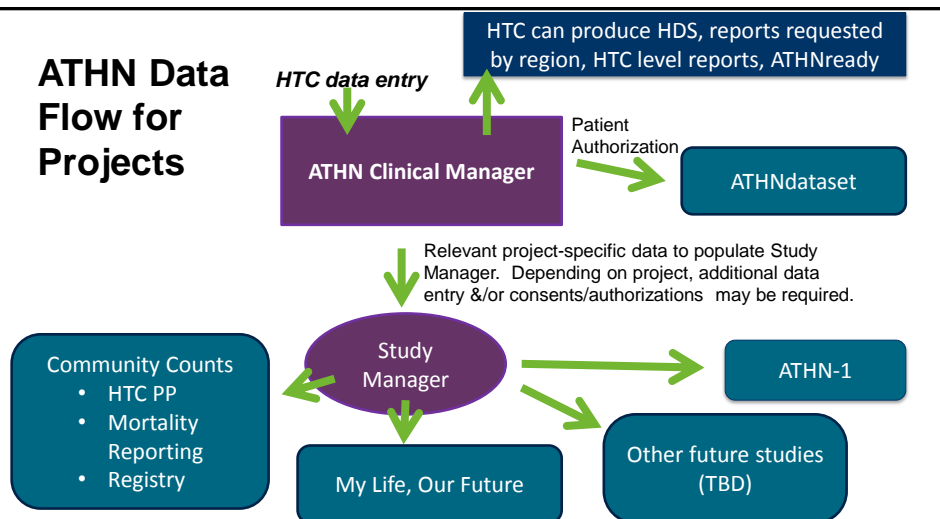
ATHN's information infrastructure makes it possible

- ATHN Projects (ATHNdataset, Community Counts, ATHN -1 Cardiovascular Disease Project, My Life Our Future, etc.)
- Hemophilia Data Set (HDS)
- Required regional reporting
- HTC level reporting
- HTC level data needs for programs, research, evaluation, quality improvement, staffing needs, etc.



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ATHN Data Flow for Projects



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Common Data Elements Across ATHN Projects and HDS

	Primary Diagnosis	Diagnosis Baseline Lab Value	Inhibitor Diagnosis	Medications	Surgeries/ Procedures
HDS	YES	YES	YES	NO	NO
ATHNdataset	YES	YES	YES	YES (priority – factor products)	YES (priority – CVAD, joints)
Community Counts (All)	YES	YES	YES	YES (priority-factor products)	YES
ATHN - 1 (CVD Study)	YES	NO	YES	YES (anti-coagulant meds and factor products)	YES
My Life, Our Future	YES*	YES*	NO	NO	NO



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Questions?



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