U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 1/22/25

Title:	Surveillance of Public Health Burden of Persistent Tic Disorders including Tourette Syndrome in Children, Adolescents, and Young Adults
Project Id:	0900f3eb821bf062
Accession #:	NCBDDD-EART-7/12/23-b1964
Project Contact:	Rebecca Bitsko
Organization:	NCBDDD/DHDD/CDD/EART
Status:	**Pending Regulatory Clearance**
Intended Use:	**Project Determination**
Estimated Start Date:	09/01/2024
Estimated Completion Date:	08/31/2029
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	7/17/23	Campbell_Scott (sic3) CIO HSC
PRA: **PRA Applies**		7/20/23	Perou_Ruth (rzp4) OMB / PRA

Description & Funding

Description

Priority:	Standard
Date Needed:	08/01/2023
Priority Justification:	
CDC Priority Area for this Project:	Not selected
Determination Start Date:	07/20/23
Description:	This project will initiate surveillance of persistent tic disorders (PTD) including Tourette syndrome (TS) among children, adolescents, and young adults to • Document the public health burden (i.e., outcomes [not prevalence]) of these disorders • Generate data that can be used to inform education and outreach activities to improve the health and well-being of individuals with tic disorders and their families. Proposed activities for this NOFO include the following: • Collaborate with CDC and other awardees to identify measures for priority areas of burden including cost, healthcare transition, suicidality, and co-occurring disorders. • Collaborate with CDC and other

	awardees to determine the best assessment approach, obtain needed approvals (e.g., human subjects, data sharing), and establish data sharing logistics. • Collect and share de-identified data with CDC. • Summarize and disseminate findings. Populations to be Included/Represented: The main audiences for this NOFO are children, adolescents, and young adults with PTD/TS and their families. Populations should include diversity among individuals with PTD/TS including by sex, race/ethnicity, and geography.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Submitted through IMS Clearance Matrix:	Not selected
Primary Scientific Priority:	Not selected
Secondary Scientific Priority (s):	Not selected
Task Force Responsible:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The purpose of this project is to establish surveillance to document the Public Health burden (i.e., outcomes) of PTD/TS among diverse populations, including cost, healthcare transition, and suicidality, as well as co-occurring disorders among children, adolescents, and young adults with PTD/TS. This information is intended to inform future education and outreach efforts to improve the health and well-being of individuals with PTD/TS and their families.
Objective:	The main objective for this project is to establish surveillance of the Public Health burden of PTD/TS across multiple (i.e., at least 2) sites that include a diverse (by sex, race/ethnicity, geographic status) population of individuals with PTD/TS. Children, adolescents, young adults, and their parents will be recruited from tic specialty clinics and complete surveys that assess priority areas of burden including cost, healthcare transition, suicidality, and co-occurring disorders. Deidentified, cleaned data will be shared by sites with CDC. The use of identical instruments across sites will allow for improved understanding of the burden of PTD/TS among subpopulations of individuals (e.g., girls/women, racial/ethnic minorities, individuals living in rural areas).
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	Not Selected
Does your project investigate underlying contributors to health inequities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	Not Selected
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other - children, adolescents, and young adults with PTD/TS and their parents/caregivers
Tags/Keywords:	Tourette Syndrome ; Child Health ; Adolescent Health
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight ; CDC is providing funding
Method Categories:	Survey
Methods:	Clinic-based samples of children, adolescents, and young adults (ages 6-24 years) with current PTD/TS will be identified by funded sites. The sites will apply a unique participant ID to each eligible individual. Clinicians will assess for the current presence and severity of tics using a standardized measure (e.g., Yale Global Tic Severity Scale, YGTSS). The individuals and caregivers will be asked to complete surveys related to healthcare and outcomes associated with PTD/TS, including the priority areas of cost, healthcare transition, suicidality, and co-occurring disorders. Survey content, census tract level data, and clinical data will be finalized through collaboration between CDC and the funded sites. Survey logistics (e.g., whether surveys are completed during clinic visits, online, by mail, or by phone) will be finalized with sites upon funding. However, this NOFO prioritizes survey

	administration that is streamlined, requiring minimal effort by participants and personnel. For example, surveys could be added as part of intake or check-in paperwork as part of regular clinic visits. When possible, survey questions will be pulled from existing national or state population-based surveys (e.g., suicide questions from the Youth Risk Behavior Survey), and population-based estimates will be used for comparison. All surveys will include the eligible individual's unique participant ID. Completed paper surveys will be double-entered into a secure database by separate individuals at each site, after which discrepancies will be corrected. The funded sites will link census tract-level data pertaining to the residence at time of survey recruitment (e.g., % unemployment in county of residence, median household income in county of residence, distance to specialty clinic). Sites will also link relevant clinical information including current presence and severity of tics and diagnoses of co-occurring disorders. Sites will then de-identify and transmit the resulting dataset via a secure data-transfer system to CDC. Using the unique participant ID, CDC will create a de-identified multi-site analytic dataset for the project with common data across sites.
Collection of Info, Data or Biospecimen:	Clinical information will be collected from healthcare providers providing care for individuals identified. Data on outcomes of children, adolescents, and young adults with PTD/TS, including diagnostic information, presence of co-occurring disorders, and information on cost, healthcare transition, and suicidality will be collected from surveys that are completed by the individuals and/or their parents or caregivers. Survey logistics (e.g., whether surveys are completed during clinic visits, online, by mail, or by phone) will be finalized with sites upon funding. All data will be entered into a common database at each site. Sites will de-identify their data prior to transmission to CDC. Using the unique participant ID provided by sites, CDC will develop a complete and de-identified multi-site analytic dataset for the project.
Expected Use of Findings/Results and their impact:	Findings will be presented at national conferences, submitted for publications in peer-reviewed journals, and disseminated via newsletters posted to project-specific website. Findings may improve understanding of the strengths and limitations of clinic-based surveillance among children, adolescents, and young adults with PTD/TS; costs associated with PTD/TS, healthcare transition, suicidality, and co-occurring disorders, as well as differences by sociodemographic characteristics including sex and race/ethnicity. Information will be used to inform future education and outreach activities to improve the health and well-being of individuals with PTD/TS and their families.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	No
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Surveillance of Public Health Burden of Persistent Tic Disorders including Tourette Syndrome in Children, Adolescents, and Young Adults		2024	3	750000.00

HSC Review

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO?	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects	
Do you anticipate this project will be exempt research or non-exempt research	

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPAA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection

Registerable clinical trial No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identfiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Will you be working with an outside Organization or Institution? Yes

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Helena Hutchins	09/01/2026		07/08/2025			Co-Investigator	pne8@cdc.gov	404-498-2822	EVALUATION & APPLIED RESEARCH TEAM
Lara Robinson	08/29/2026		05/18/2025			Co-Investigator	lpr0@cdc.gov	404-498-3822	EVALUATION & APPLIED RESEARCH TEAM
Mary Witten	08/28/2026		12/31/2021			Project Officer	muw4@cdc.gov	404-498-3023	EVALUATION & APPLIED RESEARCH TEAM
Rebecca Bitsko	07/09/2026	12/13/2021	07/13/2026			Principal Investigator	dvk2@cdc.gov	404-498-3556	EVALUATION & APPLIED RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 3/3/25

Proposed Data Collection End Date: 9/29/29

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:	
Data Use Contact:	Rebecca Bitsko at dvk2@cdc.gov
Public Access Justification:	Persistent tic disorders including TS affect about 1 in 50 children, and the estimate is lower for older adolescents and adults. Collection of information on characteristics of tics and co-occurring disorders may result in data being potentially identifiable. The data will be restricted to protect the potentially identifiable data and shared with external researchers only after approval from project collaborators. Access will be granted if a researcher's proposal is approved by the project publication committee, is sponsored by a site principal investigator, and after a Confidentiality and Data Use Acknowledgement form has been signed and returned to the project officer. The Confidentiality and Data Use Acknowledgement form will assure that the data will not be used to learn the identity of any person or establishment, and that reasonable measures will be used to protect all individual-level data from observation, theft, or accidental loss or misplacement.
How Access Will Be Provided for Data:	After a data analysis proposal is approved by the project publication committee, and before obtaining the data, the interested party must sign a Confidentiality and Data Use Acknowledgement form assuring they will not use these data in any way except for statistical reporting and analysis; they will not share the data with anyone; they will not attempt to use the dataset to learn the identity of any person or establishment, and they will use reasonable measures to protect all individual-level data from eye observation, theft, or accidental loss or misplacement. Once the form has been signed and returned, the project coordinator will grant access to the sharefolder containing a de-identified dataset for CDC staff or will transmit the de-identified dataset through a secure data-transfer system (such as SAMS) for external partners.
Plans for Archival and Long Term Preservation:	Direct personal identifiers of participants at each site, including the link to unique participant ID, will be securely stored at each respective site; CDC will not have access to identifiers. Personal identifiers will never be shared between sites. Data will be kept on restricted and/or password protected systems that only individuals working on the respective surveillance system can access. Sites will not share personally identifiable information of individuals with CDC but will send de-identified survey data. Sites may also share a minimal set of de-identified individual or aggregate-level data (e.g., age, sex, condition) of eligible non-responders with CDC. Survey data will be processed at CDC by the CDC data manager. Data from all sites' completed surveys will be stored at CDC. All data will be kept on password protected systems only accessible by CDC project staff.

Spatiality

Spatiality (Geographic Locations) yet to be added .....

Dataset

Dataset Title	Dataset Description	Data Publisher/Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

No Supporting Info