Board of Scientific Counselors (BSC)
National Center for Environmental Health (NCEH)/
Agency for Toxic Substances and Disease Registry (ATSDR)
June 25th & 26th, 2019

Centers for Disease Control and Prevention
4770 Buford Highway, Atlanta, Georgia 30341
(Building 106, Conference Room 1B)

Members who attended the meeting:

Melissa Perry
Kenneth Aldous
Paloma Beamer (Phone)
Aaron Bernstein
Darryl Brown (Phone)
Suzanne Condon
Daniel Hryhorczuk
Joan Rose
Marilyn Underwood
Nsedu Obot Witherspoon

Federal Experts
Wayne E. Cascio
Ruth M. Lunn
Paul J. Middendorf
Joey Y. Zhou

NCEH/ATSDR Program Responses
to BSC Guidance
William Cibulas, PhD, MS
Acting Division Director
Division of Toxicology and Human Health Sciences

Key Presentations from Last BSC Meeting:

- **Update on ATSDR ToxProfiles™**
  - William Cibulas, Jr., PhD, MS
- **Overview of Cannabis and Public Health**
  - CAPT Althea Grant-Lenzy, PhD
- **Pediatric Environmental Health Specialty Units**
  - Michael Hatcher, DrPH

NCEH/ATSDR Responses to BSC Guidance (ToxProfiles™):

- **BSC Members requested that NCEH/ATSDR should**
  - perform testing to determine the feasibility of using cell phones, tablets, and other mobile devices as new methods to disseminate the ToxProfiles™ to a new generation of users.
  - recruit summer interns, graduate students, or fellows to produce brief 30-second videos as marketing tools for the ToxProfiles™.
  - explore the possibility of adopting other forms of systematic review, including

risk of bias. ATSDR also should produce evidence to show that its existing methods are "tried and true" and generate a fair assessment of a good quality study. Moreover, ATSDR should publish its systematic review process for the ToxProfiles™ in the peer-reviewed literature.
- take a "one-health" approach in the ToxProfiles™ by synthesizing the environmental state content and animal toxicity data for a particular toxin.
- develop new ToxProfiles™ on microcystins and brevetoxins.

NCEH/ATSDR Responses to BSC Guidance (Cannabis):

- **BSC Members requested that NCEH/ATSDR should**
  - add new questions to its national surveys to determine the frequency by which mixtures of marijuana products and other drugs, particularly fentanyl, are being used.
  - target more of its current research efforts to systematically track and monitor health outcomes from new marijuana delivery methods.
  - provide states with more data to support their policy debates on the critical importance of maintaining smoke-free laws.
  - promote DLS's recent accomplishments and provide strong leadership to support the development of a new marijuana research agenda at the federal level.
  -

NCEH/ATSDR Responses to BSC Guidance (PEHSUs):

- **BSC Members requested that NCEH/ATSDR should**
  - place much stronger emphasis on widely marketing the PEHSUs program.
  - strengthen relationships with and become much more integrated in HRSA Maternal Child Health Bureau's (MCHB) outreach efforts.
  - consult with EH professional associations to launch innovative and effective marketing campaigns for the PEHSU program.
  - leverage its existing relationship with NIEHS to utilize its network of Environmental Health Sciences Core Centers as a marketing tool for the PEHSUs.

CCARE: Controlling Childhood Asthma, Reducing Emergencies
Kanta Sircar, PhD, MPH
CCARE Lead
Commander, US Public Health Service

- **Asthma costs more than $80 billion annually in medical expenses, missed work and school days and deaths.**
- **1 in 6 visit the emergency department (ED)**
- **1 in 20 are hospitalized for asthma**
- **38% have uncontrolled asthma**
- **About 50% miss ≥ 1 school day due to asthma**
- **Prevent half a million**
  hospitalizations and
  emergency department visits among children with asthma in 5 years.

EXHALE: six strategies to reduce asthma burden:

- **Education on asthma self-management**
- **X-tinguishing smoking and secondhand smoke**
- **Home visits for trigger reduction and asthma self-management education**
- **Achievement of guidelines-based medical management**
- **Linkages and coordination of care across settings**
- **Environmental policies or best practices to reduce asthma triggers from indoor, outdoor, and occupational sources**

Medicaid pays disproportionally for hospitalization and ED visits for children with asthma

- **47% of children with asthma are on Medicaid**
- **About 56% of hospitalization and ED visits are paid for by Medicaid**
- **Medicaid spends $10.2 billion each year to treat asthma**

Fund State Partners to Implement Strategies

- **A comprehensive public health approach to asthma control through evidence-based interventions**

Fund NGO Partners to Implement Strategies

- **Allergy & Asthma Network**
- **American Lung Association**
- **Asthma and Allergy Foundation of America**
- **National Environmental Education Foundation**

Measurement and Evaluation

- **Model to estimate impact and create targets**
- **Collect performance measures and surveillance data within co-operative agreement to monitor outcomes**
- **Incorporate evaluation into all parts to inform quality improvement**

Comprehensive, Evidence-Based Intervention Package

- **Asthma self management education**
- **Home visits**
- **Quality improvement**
- **Care coordination**
- **Smoking cessation**
- **Environmental health policies**

Strategic Partnerships

- **Hasbro Children's Hospital**
- **Saint Joseph Health Center**
- **Green and Health Housing Initiative**
- **CDC's 6|18 Program**
- **Environmental Protection Agency**
- **CMS Innovation Center**

Metrics and Measurement

- **Evaluation program**
- **Asthma surveillance system**
- **Supported by CDC co-operative agreement**

CDC's Controlling Childhood Asthma, Reducing Emergencies (CCARE) initiative will…

- **Prevent half a million hospitalizations and emergency department visits among children with asthma in 5 years**

NCEH/ATSDR Involvement in *Per- and Polyfluoroalkyl Substances (PFAS)*

Christopher M. Reh, PhD
Associate Director
Agency for Toxic Substances and Disease Registry

NCEH/ATSDR's Overarching Approach on PFAS

- **Assessing and reducing/eliminating community PFAS exposures**
- **Addressing community health concerns related to existing or previous PFAS exposures, to support action on the basis of scientific information**
- **Conducting health studies on exposure and health endpoints to provide actionable information to communities and health care providers**

Steps CDC/ATSDR Taking to Address Exposure

- **Health consultations and site work**
- **Exposure assessments**
- **Pease study**
- **Multi-site health study**
- **Additional PFAS projects**
- **Development of tools and resources**

Health Consultations and Site Work in 40+ Communities

- **ATSDR and our state health partners are investigating exposure to and possible health effects associated with PFAS in 40+ communities across the US.**
- **Most of these communities have concerns about PFAS in their drinking water connected with PFAS production facilities or fire training areas where aqueous film forming foam (AFFF) was regularly used.**

PFAS Exposure Assessments

- **Piloted PFAS exposure assessments in PA and NY in partnership with ASTHO and PA DOH and NYS DOH**
- **Expanding exposure assessments to eight additional sites with resources from National Defense Authorization Act**
- **Exposure assessments will produce information that can be used by public health professionals across the nation to help communities affected by PFAS**

Pease Study

- **Association between health outcomes and PFAS exposure to expand PFAS science**

base

- **Allow CDC/ATSDR to evaluate study procedures and methods to improve design of multi-site health study**
- **Pease Study data will be integrated with data from other sites in multi-site health study to maximize impact**

Multi-Site Health Study

- **Expand science about relationships between PFAS exposure and certain health outcomes**
- **Seek to enroll 6,000 adults and 2,000 children exposed to PFAS through drinking water**
- **Help people better understand their risk for health effects**

Additional PFAS Projects Underway

- **Conduct analysis using previously collected data to look for associations between PFAS exposure and cancer**
- **Examine how psychosocial stress related to PFAS exposures can pose independent health risk**
- **Develop pharmacokinetic models to estimate PFAS serum levels in blood/serum resulting from water exposures**
- **Develop PFAS research agenda**
- **Convene PFAS National Summit**

Tools and Resources for States and Communities

- **PFAS Exposure Assessment Technical Tools (PEATT)**
- **Draft Toxicological Profile for Perfluoroalkyls**
- **PFAS Factsheets**
- **PFAS Guidance for Clinicians**

Visit online: https://www.atsdr.cdc.gov/pfas/

Improving National Laboratory Capability and Capacity to Measure Human Exposure to Synthetic Opioids
Rudy Johnson
Chief, Emergency Response Branch

- **CDC is responding to opioid epidemic**
  - Quality laboratory testing is essential for accurate detection of cases
  - Public, private, and academic labs lack ability to detect relevant fentanyls and lack reference materials needed for high quality measurements
- **NCEH laboratory is addressing these problems by developing and sharing**
  - Reference materials for broad array of relevant fentanyls to all DEA registered US labs
  - General, adaptable diagnostic tests

Proficiency testing, training and safety resources

Laboratory Response Network for Chemical Threats (LRN-C)

- **Partnership (2002-Present)**
  - CDC
  - Association of Public Health Laboratories
  - Federal Bureau of Investigation
- **Structure**
  - CDC is the reference laboratory
  - 44 state public health laboratories
  - Local, national strategic resources
- **Focus of testing**
  - Clinical samples
  - Chemical Weapons Convention, Schedule 1
  - Department of Homeland Security Priorities
- **States may use LRN-C for any local need**
  - Funded by CDC Cooperative Agreement
  - Resources include LC/MS, GC/MS, ICP/MS, staffing, supplies
  - Leadership by Governor, State Epidemiologist, Public Health Department

Developing Fentanyl Clinical Tests

- **Targeted MS tests**
  - 14 Fentanyl analogs, 3 fentanyl-related compounds, 2 metabolites, and 1 synthetic precursor
  - DEA Emerging Threat Reports, NFLIS
  - Surveillance
- **Simple, adaptable methods**
  - Solid-liquid extractions
  - Reversed phase chromatography
  - Low resolution tandem mass spectrometry
- **Clinical matrices**
  - Plasma / Serum / Urine
- **Immunoassays**
  - Not broadly characterized for fentanyl analogs
  - Known cross reactivity is not consistent
  - Poor cross reactivity contributes to false negative results
- **Following data is reported from**
  - Manufacturers
  - Publications
- **Analog comparisons include**
  - 30 analogs from NFLIS and DEA Emerging Threat Reports
  - 2015-2017

References for Commercial Kit Data

- **Manufacturer specifications**
- **Literature**
  - Helander, A., Stojanovic, K., Villen, T., Beck, O. “Detectability of fentanyl and designer fentanyls in urine by 3 commercial fentanyl immunoassays.” *Drug Test*

Anal, 2018; 1-8.
- Guerrieri, D., Kjellqvist, F., Kronstrand, R., Green, H. "Validation and Cross-Reactivity Data for Fentanyl Analogs with the Immunalysis Fentanyl ELISA." *Journal of Analytical Toxicology*, 2018; 1-7.
- Schackmuth, M., Kerrigan, S. "Immunoassay-based detection of fentanyl analogs in forensic toxicology." *Forensic Toxicology*, 2018.

Developing Fentanyl Clinical Tests

- **Observations**
  - < 2% cross reactivity for classes 2 and truncated (class 7)
  - < 20% cross reactivity for classes 1,6
- **Primary approach to promote better characterization and improvements**
  - Share reference materials with private, academic, public laboratories
  - Anticipate improvements from private and academic laboratories

CDC Support for Laboratories

- **CDC contracted development of traceable opioid material kits**
  - Promote consistency across laboratories
  - Improve surveillance
  - Provide precision and accuracy using heavy isotope internal standards
- **CDC will publish two example laboratory methods in blood and urine matrices**
- **Available to public, private, academic laboratories**

Traceable Opioid Material* Kits

- **Two kits**
  - Opioid Certified Reference Material (CRM) Kit
  - Fentanyl Analog Screening (FAS) Kit
- **Focus**
  - Synthetic opioids
  - Metabolites
  - Synthetic precursors
- **Not for diagnostic testing**
  - FDA Language for Laboratory Developed Tests

Opioid CRM Kit

- **Designed for mass selective testing**
- **Contract**
  - 14 fentanyl analogs (99% of DEA Emerg. Threat Report)
  - 3 fentanyl-related compounds (U-47700, U-48800, U-49900)
  - 2 fentanyl analog metabolites (norfentanyl, norcarfentanil)
  - 1 synthetic precursor (4-ANPP)
  - 20 matched ^{13}C, ^{15}N – stable isotope internal standards
- **Third party conformity assessment**

One Opioid CRM Kit's Laboratory Consumption

- **If Opioid CRM Kit contains**

        - 1 mg per opioid, metabolite, or precursor
        - 1 mg per heavy isotope internal standard
    - **And qualitative test consumes 40 ng of CRM per sample**
        - 40 ng = 0.000040 mg
        - 1 mg of each CRM / 0.000040 mg = 25,000 samples
    - **Then, with testing rate ~ 200 samples/week, kit will support 125 weeks of analysis**

Fentanyl Analog Screening (FAS) Kit

- **Contract**
    - 120 Fentanyl analogs
    - 200 micrograms each, in 2 microliters glycerin
    - Limited production
- **Designed for screening protocols**
    - Mass selective
    - Immunoassays
    - Limited replicates
- **Third party conformity assessment**

Kit Requests

- **Laboratories requesting one or both kits**
    - Can be from any sector
    - Must be located in US
    - Must have current DEA controlled substances registration
    - Must comply with respective state and local regulations

Kit Suppliers

- **Contractor websites**
    - Opioid CRM Kit - Cerilliant.com
    - FAS Kit - CaymanChem.com
- **Ordering**
    - Direct from contractors
    - Domestic US labs only
- **Available at no cost**

Collaborations and Safety

- **Public Partners**
    - Association of Public Health Laboratories (APHL)
        - ❖ LRN-C laboratories
    - Federal partners
        - ❖ DEA, FBI, DHS, FDA, HHS
- **Safety Protocols for Clinical Laboratorians**
    - APHL Opioid Task Force
    - Focus on clinical samples, laboratory processing

Summary

- **CDC is improving US laboratory testing**

    - Will improve surveillance of opioid use
- **Proficiency testing, training, and generic protocols**
    - Enables laboratories to adapt to changing opioid threats
    - Improve quality of fentanyl testing
- **Collaborations and safety**
    - New technologies from academics and private companies

Development of laboratory safety protocols

NCEH/ATSDR – NCEZID Vector-Borne Diseases Workgroup

Melissa J. Perry, ScD, MHS, FACE
Professor and Chair of Environmental and Occupational Health
Milken Institute School of Public Health
The George Washington University

VBD Workgroup Membership

Co-Chairs and alternate representatives

- Melissa Perry, Representative, NCEH/ATSDR Board of Scientific Counselors
- John Meeker, Alternate representative, NCEH/ATSDR Board of Scientific Counselors
- Jim LeDuc, Representative, OID Board of Scientific Counselors
- Kristy Bradley, Alternate representative, OID Board of Scientific Counselors

Workgroup members

- Bryon Backenson, New York State Department of Health
- Kristen Healy, Department of Entomology, Louisiana State University
- Susan Jennings, Office of Pesticide Programs, U.S. Environmental Protection Agency
- Christian Krupke, Department of Entomology, Purdue University
- Shannon LaDeau, Cary Institute of Ecosystem Studies
- Greg Lanzaro, Department of Entomology, University of California at Davis
- John D. Stark, Department of Entomology, Washington State University
- Dan Strickman, Global Health Program, Bill & Melinda Gates Foundation

Designated Federal Officials

- Sarah Wiley, Designated Federal Official, OID Board of Scientific Counselors
- Yulia Carroll, Alternate Designated Federal Official, NCEH/ASTDR Board of Scientific Counselors
- Yulia Carroll, Co-Designated Federal Official – Vector-Borne Diseases Workgroup
- Ben Beard, Co-Designated Federal Official – Vector-Borne Diseases Workgroup
- Holley Hooks, Note taker, Division of Vector-Borne Diseases, CDC/OID/NCEZID

VBD Workgroup Tasks

1. Developing and evaluating VBD prevention and control tools, including conducting a public health assessment of the safety, efficacy, and feasibility of available and innovative vector control methods.
2. Clarifying CDC/ATSDR's role in monitoring human exposures and adverse health effects subsequent to pesticide applications
3. Establishing a strong public health workforce in vector control,
4. Enhancing collaborations between public health organizations, academia, and industry

5. Improving overall risk communications for VBD

VBD Workgroup Activities to date

- 6 July 2018—Teleconference
  - Establish WG membership
  - Review WG tasking
  - Identify key issues from OID and NCEH
  - Discuss timeline
- I Oct 2018—Teleconference
  - Presentation of DVBD 2018 strategic plan (Ben Beard)
  - Presentation of NCEH 2018 activities and plan (John Sarisky)
  - Discussion
- 7 Nov 2018—Teleconference
  - Discussion of progress made to date
  - Discussion of tasks to WG and center's additional comments
  - Discussion of areas of expertise within each center
  - Noted pending release of DHHS Tick-borne Disease Report
- 29 Mar 2019—Teleconference
  - Review of draft National Strategy on Vector-borne Diseases

Progress to Date

- Sharing each Center's strategic plans and the subsequent discussions have helped staff from both Centers to better appreciate opportunities for collaboration
- Common themes have been identified:
  - *Training and workforce development*
  - *Communications and need for clear, coordinated messaging,* especially during emergencies
  - *Common "customer"*—State and Local Health Departments
  - *Common interests in environmental factors related to* vectors of disease
- Identified expertise of NCEH/ATSDR relevant to VBD
  - *Toxicology* of pesticides and integrated pest control
  - Building state climate resilience
  - Multi-disciplinary *prevention and control subject matter expertise*
- Valuable comments from WG members
- Began in-depth discussion of risk communications
  - Importance to the public of CDC endorsement of control strategies to be used
  - Consideration of how to better coordinate messaging during emergencies

NCEH/ATSDR Activities related to Vector control and prevention

- Consulting with jurisdictions on effective vector control strategies during emergency response
- Assisting with development of integrated vector management plans
- Conducting assessments to address mosquitoes, rodents, and other disease vectors during emergency response
- Building state and local health departments climate health resilience, modelling and mapping of vectors

NCEH Activities related to pesticides

- Environmental Health Tracking, data on pesticides from poison control centers **https://ephtracking.cdc.gov/showPesticidesExposuresLanding.action**
- NHANES measures pesticides: The "National Report on Human Exposures to Environmental Chemicals, Update Tables March 2018 (Vol 1)" found at **https://www.cdc.gov/exposurereport/** provides data tables for the pesticides that has been measured.
- Chemicals measured and reported by NCEH lab are found at **https://www.cdc.gov/exposurereport/pdf/Report_Chemical_List.pdf**
- Integrated Vector Management

https://www.cdc.gov/nceh/ehs/elearn/vcehp.html

ATSDR Activities related to pesticides

- Toxicological profiles, **https://www.atsdr.cdc.gov/toxprofiledocs/index.html**

(e.g. 2,4-Dichlorophenoxyacetic Acid; DDT, glyphosate, Chlordecone, Mirex, Chlorpyrifos, Chlordane)

- Most recent, April 2018: Mixtures of Insecticides: Pyrethroids, Organophosphorus Compounds, and Carbamates

https://www.atsdr.cdc.gov/interactionprofiles/ip-15/ip15.pdf

- Community investigations

Public Health Assessments **https://www.atsdr.cdc.gov/hac/PHA/search.asp**
Epi-aid investigation **https://www.atsdr.cdc.gov/methylbromide/index.html**

National Strategy for Vector-Borne Disease Prevention and Control in the U.S

Mission: Protect people from illness, suffering, and death due to vector-borne diseases.
Goals:

- Understand when, where, why, how often, and how people are exposed to and get sick or die from vector-borne diseases (*Increase/Improve understanding*)
- Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases (*Detect & Diagnose*)
- Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases (*Prevent & Control*)
- Develop and assess drugs and treatment strategies for vector-borne diseases (*Treat and Mitigate*)
- Disseminate and support the use of effective public health and vector control products, tools, and programs to detect, diagnose, and respond to vector-borne disease threats (*Disseminate tools, Facilitate processes, and Build capacity*)

Role of NCEH/ATSDR to support the goals of the National Strategy

- Strengthen capacity to implement safe and effective vector-borne disease diagnostics, surveillance, control, and prevention programs.
- Translate/adapt public health tools for programmatic implementation at local, tribal, territorial, state, and international levels
- Monitor, evaluate, and further adapt public health programs

Next Steps

- Meeting to discuss disbanding of the workgroup
- Generating a final report
- Continuing working together

Cancer Cluster Investigation Guidelines – Update

Tegan Boehmer, PhD, MPH
Chief, Health Studies Section, NCEH
Suzanne Condon, MSM
Chair, BSC NCEH/ATSDR Cancer Cluster Guidelines Workgroup
Stephanie Foster, MPH, MA
Lead, Geospatial Epidemiology and Applied Research Unit, ATSDR

Outline

- **Rationale for cancer cluster guidelines update**
- **Overview of approach and activities to date**
- **Update on BSC NCEH/ATSDR Cancer Cluster Guidelines Workgroup**
- **Next steps**

Cancer Cluster Investigations – Background

- **Health departments respond to numerous inquiries about cancer occurrence in their communities**
- **Challenges to responding and assessing potential cancer clusters**
    - Communicating with individuals and families
    - Methodological limitations
    - Findings are often inconclusive
    - Resource and labor intensive

Cancer Cluster Investigations – NCEH/ATSDR's Role

- **Develop guidance for health departments**
    - Focus on residential and community settings
- **Provide technical assistance to health departments**
    - Verify state/local approach adheres to current guidelines
    - Review documents: survey instruments, analysis plans, reports
    - Develop communication strategies
- **Respond to direct requests for investigations**

CDC Cancer Cluster Guideline Update – Rationale

- **Scientific and technological advances in areas such as**
    - Data availability
    - Analytic and geospatial methods
    - Cancer genomics
- **Update communication strategies and tools**
- **CDC received $1M in FY19 to implement Section 399V-6(c) of Trevor's Law**
    - Develop, publish, and periodically update guidelines for investigation of potential cancer clusters

CDC's Guidelines Development Process

1. **Determine need for new or revised guideline**
2. **Plan process for guideline development**
3. **Decide on need to solicit external input**
4. **Obtain and appraise quality of the evidence**
5. **Write (and revise) the guideline document**
    - Internal and external review and vetting
6. **Plan translation, dissemination, evaluation, and updates**

Cancer Cluster Guidelines Update – Steering Committee

- **Tegan Boehmer, NCEH/DEHSP (co-lead)**
- **Stephanie Foster, ATSDR/DTHHS (co-lead)**
- **Johnni Daniel, NCEH/DEHSP**
- **Elizabeth Irvin-Barnwell, ATSDR/DTHHS**
- **Nicole Dowling, NCCDPHP/DCPC**
- **Doug Trout, NIOSH/DFSE**
- **Vivi Siegel, NCEH/DEHSP**
- **Science Coordinator: Alisha Etheredge (NCEH/DEHSP)**
- **Policy Coordinator: Brian Kennedy (NCEH/DEHSP)**

Cancer Cluster Guidelines Update – BSC Workgroup

- **Charge**
    - Gather information on current methods and practical approaches for CDC/ATSDR to consider when updating cancer cluster guidelines
- **Deliverable**
    - Report identifying essential processes and procedures that can be used by STLT public health agencies for assessing and responding to potential cancer clusters

Cancer Cluster Guidelines Update – BSC Workgroup

- **15 Workgroup members invited**
- **Kick-off meeting June 28, 2019**
    - Background and rationale for update
    - Overview of CDC/ATSDR process
    - Review Workgroup charge and deliverable
- **In-person meeting in September 2019**
    - Develop Workgroup report outline
- **Final report will be presented to full BSC for consideration and potential recommendation to NCEH/ATSDR**

Cancer Cluster Guidelines Update – Inputs

- **Published Literature Topics of Focus**
    - Epidemiologic investigations of cancer clusters in community or residential settings
    - Geospatial and temporal methods
    - Rare event and small area statistical methods
    - Novel approaches for grouping cancers by molecular characteristics

    - Approaches for engaging, educating, and communicating with affected communities
- **Grey Literature**
    - Unpublished health department reports
    - Health department protocols

Cancer Cluster Guidelines Update – Inputs

- **Federal Register Notice was released May 15, 2019**
    - Open for comment through July 15, 2019
    - Disseminated to stakeholders via
        - ❖ CDC media statement
        - ❖ Partner emails (NCEH/ATSDR, NIOSH, and NCCDPHP/DCPC)
        - ❖ NCEH/ATSDR social media
        - ❖ ATSDR Regional Directors
- **Considering other ways to solicit input from community members and groups**

Next Steps: State and Local Health Department Input

- **Online Survey**
    - All state and territorial health departments and subset of local health departments
    - Assess current activities and needs
- **Focus Groups**
    - Representative sample of STLT public health agencies (~15)
    - Multidisciplinary staff (epidemiology, cancer registry, environmental health, communications)
    - Gather information about approaches and barriers to effectively assess and respond to potential cancer clusters in communities

Next Steps: Additional Subject Matter Expert Input

- **NCEH/ATSDR Office of Science Seminar Series**
- **Potential areas of expertise**
    - Cancer genomics
    - Geospatial and temporal methods
    - Rare events and small area estimation statistical methods

Others as requested by BSC Workgroup

Board of Scientific Counselors: Requested Input

- **Feedback on next steps**
    - Approaches for gathering input from community members and groups
    - Assessment of STLT Health Departments
    - Individual SMEs

The Intersection of Place and Health
ATSDR's Geospatial Research, Analysis, and Services Program and Social Vulnerability Index
Andrew L. Dent, MA, MBA
Program Director

Geospatial Research, Analysis, and Services Program

Outline

- **Introduction to the Geospatial Research, Analysis, and Services Program (GRASP)**
- **The Work of GRASP: The Intersection of Place and Health**
- **Feature: GRASP Social Vulnerability Index**
- **GRASP: The Road Ahead**

GRASP Mission

The mission of GRASP is to provide leadership and expertise in the application of the concepts, methods, and tools of geography and geospatial information science to public health research and practice.

GRASP Objectives

- **Research and analyze geospatial trends and patterns relevant to, public health, environmental health, and emergency preparedness.**
- **Collaborate with scientists and researchers at the CDC/ATSDR and among our public health partners to address public health, environmental health, and emergency preparedness and response issues.**
- **Geospatially enable Agency scientists and systems with data, consulting, technology, and training.**
- **Contribute to a vibrant geospatial community among public health professionals.**
- **Embrace, leverage, and promote GIS and geospatial technology.**

Analysis, Visualization and Training

- **GRASP applies geospatial concepts, methods, and tools to public health practice**
- **Develops/delivers GIS for Public Health Training for CDC/ATSDR**
- **Feature project**
    - **Coldwater Creek Environmental Sample Analysis**

Geospatial Epidemiology and Applied Research

- **Conducts applied geospatial research**
- **Develops and shares methods applicable to public health research and practice**
- **Feature project**
    - **Polycythemia Vera space and time cluster analysis**

Emergency Preparedness and Response

- **GRASP applies geospatial science and technology to support the CDC Emergency Operations Center**
- **GRASP helps CDC/ATSDR address all hazard events**
    - **Disease outbreaks, acute chemical exposures, environmental disasters and public health emergencies**
- **Feature project**
    - **Haiti Earthquake/Cholera Outbreak (2010)**

GIS Technology

- **GRASP applies GIS technology to support online mapping, GIS applications, interactive cartography and geospatial data sharing**
    - **Management of GATHER Shared Services**
    - **Provides consultation to CIOs that desire to share geospatial information and integrate program data management and surveillance efforts with GIS visualization, tools, and data**
- **Feature project**
    - **Environmental Public Health Tracking GIS Portal**

Social Vulnerability Index (SVI) Background and Rationale

- **Background**
    - **Social vulnerability refers to the demographic and socioeconomic factors that affect the resilience of communities to prepare for, respond to, and recover from public health emergencies of all types.**
- **What is the SVI?**
    - **An index of 15 socio-demographic variables used to characterized the social vulnerability populations across the US.**
- **Impact**
    - **SVI has enabled public health partners to better prepare for and respond to public health emergencies of all types.**

SVI Validation: Hurricane Sandy

- **Purpose**
    - **Examine relationship between population SVI and ability to confront and recover from environmental disasters**
- **Result**
    - **Positive correlation between SVI and FEMA Impact Rank associated with Hurricane Sandy**

What can partners do with the SVI?

- **Mapping and analysis**
    - **Identify areas with socially vulnerable populations**
    - **Target interventions**
- **Facilitate decision-making**
    - **Combine the SVI with other data resources (hazard, hospital or nursing home locations) and analyze data to prioritize funding and actions**
    - **Helpful in emergency preparedness, response, recovery, and mitigation**

SVI Strategic Plan 2019-2020

- **Strategy 1 (Maintenance)**
    - **Build on current SVI foundation and enhance SVI database to state-of-the-art capability**
    - **Features: (1) Develop and release 2018 CDC SVI by February 2020; (2) Enhance online interactive map**
- **Strategy 2 (Research)**
    - **Strengthen SVI research partnerships and increase quantity of SVI-related**

research in literature
    - **Features: Disseminate SVI validation research including 2 from GRASP, 2 from CDC partners, and 1 from external partner**
- **Strategy 3 (Outreach)**
    - **Expand level of SVI outreach and improve upon existing training activities and resources**
    - **Features: Update training videos and documents; develop classroom case study**

GRASP: The Road Ahead

- **Institutionalized GIS**
    - **GIS concepts, measures and reporting integrated into public health surveillance, research, and organizational processes**
- **Place-aware research**
    - **Activity space**
    - **Place history**
    - **Volunteered Geospatial Information and Social Media**
- **Process metadata**
    - **For geospatial processes…**
- **Organizational structure**
    - **Better organizational structure at CDC/ATSDR to support and advance geospatial efforts among public health partners**

Assessment of Ethylene Oxide
Public Health Issues
Mark Johnson, PhD, DABT
Regional Director, Region 5, ATSDR
Ted Larson, MS
Epidemiologist, DTHHS, ATSDR

Topics

- **EtO background and assessment of cancer risks**
- **Case study: Sterigenics medical device sterilization facility in Willowbrook, IL**
- **Community outreach**
- **Proposal to use EtO biomarkers to evaluate exposure**
- **Cancer incidence review results from three medical device sterilization facilities**
- **Potential next steps to address PH concerns: multi-site cancer incidence**

Background – Ethylene Oxide (EtO)

- **Most EtO used as precursor for industrial chemicals (e.g., ethylene glycol), plastics, and PVC pipes**
- **Less than 1% used to sterilize medical equipment, consumer products, and certain foods (e.g., spices) that cannot be steam sterilized**
- **50% of sterilized medical equipment uses EtO**

Used as fumigant for some agricultural products

Mechanism of Ethylene Oxide

- **Very potent alkylating agent**
- **Forms protein and DNA adducts**
- **Mutagenic-chromosomal aberrations**
- **Carcinogenic**
    - **International Agency for Research on Cancer (IARC)**
        - **"Carcinogenic to Humans"**
    - **National Toxicology Program (NTP)/DHHS**
        - **"Known to be a Human Carcinogen"**
    - **Environmental Protection Agency (EPA)**
        - **"Known Human Carcinogen"**

Occupational EtO Exposure and Cancer

- **NIOSH cohort of 18,235 men and women in 14 US commercial sterilization facilities**
    - **Average EtO exposure: 4.7 ppm (1975), decreasing to <1 ppm (1986)**
- **Increased cancer mortality**
    - **Lymphoid cancers (Non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) for men in highest cumulative exposure group**
    - **Female breast cancer for highest cumulative exposure group**
- **Increased female breast cancer incidence**

EPA EtO Cancer Risk Assessment

- **EPA reassessment of EtO cancer potency released in December 2016***
- **Concluded that: *"there is strong evidence of an increased risk of cancer of the lymphohematopoietic system and of breast cancer in females."***
- **Inhalation Unit Risk (IUR) value, which reflects lifetime cancer potency, was increased 30-50 fold**
- **Revised IUR value used in recent EPA National Air Toxics Assessment (NATA), which highlighted gas sterilization facilities and chemical industries as contributing to elevated cancer risk**

CDC/ATSDR Conclusions and Recommendations

- **ATSDR conclusions for residents and off-site workers in Willowbrook**
    - **Elevated cancer risk calculated assuming long-term exposure**
    - **Non-cancer health effects unlikely to result from EtO exposures**
- **ATSDR recommendations**
    - **Sterigenics take immediate action to reduce EtO emissions *(Completed)***
    - **US EPA initiate long-term air monitoring to determine effectiveness of actions taken to reduce EtO emissions *(Completed)***
    - **Illinois Department of Public Health investigate whether there are elevated cancers in Willowbrook community *(Completed)***

Community Health Concerns

- **Current and historical exposures to ethylene oxide at residences and business near Sterigenics**
- **Civic alert on Village of Willowbrook website**

- **Public meetings (Aug 29, 2018; Nov 29, 2018; May 29, 2019)**
- **Medical webinar for local physicians (Nov 28, 2018)**
- **Significant media coverage and political involvement**
- **Illinois EPA issued Seal Order closing operations at Sterigenics (Feb 15, 2019)**
- **June 21st- Illinois legislature enacted 2 bills with stringent regulations for EtO facilities**

Impact on Medical Equipment Supplies

- **FDA Commissioner's Statement**
  - **Actively working to prevent potential medical device shortages resulting from closure of Sterigenics facility**
  - **Direct communication to FDA through "Device Shortage Mailbox"**
  - **Initiate Innovation Challenge to industry for alternative methods to ethylene oxide for medical supply sterilization**
  - **Coordination with CDC on Healthcare Infection Control Practices Advisory Committee (HICPAC; https://www.cdc.gov/hicpac)**

EtO Exposure Biomarkers

- **Hemoglobin adducts**
  - **EtO reacts with valine amino acid on N-terminus of globin protein**
  - **Adducts detected as N-2-hydroxyethylvaline (HEVal)**
  - **HEVal levels could be used as time-weighted estimate of EtO exposure; RBC has 120 day lifespan**
  - **HEVal levels to be reported in upcoming NHANES study**
- **Pilot Exposure Assessment**
  - **considering evaluation of EtO exposure in communities using hemoglobin adduct biomarker**
  - **Evaluate HEVal levels from blood samples of individuals currently exposed to industrial sources of EtO in ambient air**
  - **Analysis of HEVal levels by NCEH Laboratory (Dr. Hubert Vesper)**
- **Interpretation of results**
  - **No clinical criteria to determine level associated with health impacts**
  - **Comparison to national HEVal levels that will be released in upcoming NHANES report**
  - **Consider the impact of smoking (cotinine levels)**

Ethylene Oxide Health Consultation

- **Michelle Colledge, DCHI/Region 5**
- **Mark Johnson, DCHI/Region 5**
- **James Durant, DCHI/SSB**
- **Dennis Helsel, Practical Stats**
- **Andrew Berens, DTHHS/GRASP**
- **David Rickless, DTHHS/GRASP**
- **Mark Harnett, DTHHS/GRASP**

Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015

Review of Willowbrook Cancer Investigation

- **IDPH completed cancer assessment study**
  - **Examined 21 years (1995-2015) using high quality data from Illinois State Cancer Registry**
  - **Two study areas defined by modeled EtO exposure area**
  - **Two comparison groups (Collar Counties and DuPage County)**
  - **Standardized Incidence Ratio - calculating observed/expected cancer cases and confidence intervals**
  - **Statistical significance set at $p<0.05$ level**
- **Focused cancers**
  - **Breast (female, invasive)**
  - **Lymphoid (Hodgkin's lymphoma, non-Hodgkin lymphoma, myeloma, lymphocytic leukemia)**
  - **Other major cancer sites**
  - **Pediatric**

Summary of Findings – EtO Associated Cancer Sites

- **No elevations seen in males**
- **Hodgkin's lymphoma statistical increase among women**
  - **Moderate associations for Study area 1 compared to county (SIR 1.86, 1.12-2.91) and five collar counties (SIR 1.89, 1.14-2.95)**
  - **Not many prior studies focused on this tumor**
- **Female breast cancer statistical increase**
  - **Compared to five collar counties (SIR 1.1, 1.02-1.18)**
  - **Observed 747 cases (expected 681) in Study Area 1**
  - **Observed 1,548 cases (expected 1,445) in Study Area 2**
  - **Not statistically significant when compared to county**
- **Trend in non-Hodgkin's lymphoma among women**
  - **Slow increase in SIR's over time period**
  - **Significantly elevated in 2009-2015 in both Study Areas**

Summary of Findings – Other Cancer Sites

- **Pediatric lymphoma moderately elevated among females**
  - **1995-2015, Study Area 1 (SIR 2.96, 1.19-6.11)**
- **Other adult cancers observed to be statistically elevated in Study Area 1**
  - **Prostate (SIR 1.07, 1.02-1.13)**
  - **Female pancreatic cancers (SIR 1.29, 1.02-1.61)**
  - **Ovarian cancers (SIR 1.29, 1.03-1.6)**
  - **Female bladder cancer (SIR 1.33, 1.05-1.66)**
- **Sites observed to be statistically lower than expected**
  - **Lung cancer in both men and women of Study Area 2**
  - **Leukemia in women of Study Area 1**

Conclusions

- **Some cancers were observed to be elevated**
  - **Treat with caution**

    - **Inconsistences across gender, study areas, and cancer sites**
- **Study limitations**
    - **Multiple comparisons**
    - **Imprecise population figures**
    - **No data on behavioral factors**
    - **Residential history**
    - **Residing near facility a proxy for EtO exposure**
    - **Complex cancer etiology**
    - **Some comparisons based on very small numbers (<10)**
    - **Exposures were assumed to be homogeneous within study areas**
- **Additional study needed to confirm findings**
    - **Larger populations (but other studies of this type would have same limitations**
    - **Additional EtO emitters**

Cancer Incidence Studies at Three Sites

- **2019 studies of urban populations residing near medical sterilization facilities**
    - **Sterigenics Inc., Willowbrook, IL**
    - **Terumo Inc., Lakewood, CO**
    - **Viant Medical, Inc., Grand Rapids, MI**
- **All three studies had an ecologic design and are limited by aggregation bias (an association observed between variables at the aggregate level does not necessarily mean there is a an association at the individual level)**

Next Steps

- **On-going EtO ambient air monitoring being conducted around Medline (EtO gas sterilization) and Vantage Chemical (EtO use as precursor) in Lake County, IL); ATSDR has been requested to conduct a health consultation**
- **ATSDR considering multi-site cancer incidence study**
- **ATSDR, with NCEH labs, considering evaluation of EtO exposure in communities using hemoglobin adduct biomarker**
- **Physician education regarding EtO exposures and health effects, as needed**
- **Updated Toxicological Profile for EtO in preparation**

NIEHS/NTP Update
Ruth M. Lunn, DrPH
National Institute of Environmental Health Sciences

- **3rd International Workshop of Chronic Kidney Disease of Unknown Origin in Mesoamerica and Other Regions**
    - **Sponsored: NIEHS**
    - **San Jose, Costa Rica. March 20-22, 2019**
- **Converging on Cancer Workshop**
    - **Sponsored: NTP**
    - **Washington DC, April 29-30, 2019**
    - **https://ntp.niehs.nih.gov/events/webinars-workshops/2019/coc/index.html**

Aims of Health Effect Innovation

- **Define and build a strategic assessment pipeline for key environmental health effects**
- **Understand the mechanism of action, mode of action (MOA), health effect continuum for these areas**
- **Increase confidence in the predictivity of MOA assessments**
- **Align our capability development to problems we're trying to solve**
- **Maximize the collective strength of the NTP organization**
- **Build novel partnerships in and outside NIH**

Update from the Department of Energy
Joey Zhou, Ph.D., M.S.
Office of Domestic and International Health Studies
Department of Energy

DOE Support for National Study of One Million U.S. Radiation Workers and Veterans

- **Awarded a new $5 millions grant (09/01/18~08/31/23) to National Council on Radiation Protection and Measurements (NCRP)**
- **DOE Workers consist of a significant portion of the Million Person Study (MPS)**

Second Follow-up of DOE Uranium and Plutonium Workers

- **The new grant focuses on previously studied DOE cohorts (1990s and before)**
- **Add more than 20 years of follow-up (~30% vs. ~70% deceased)**
- **Standardized dosimetry (external and internal) methodology among the cohorts**
- **Comprehensive tracing methodology to determine vital status and obtain cause of death**

Why Study One Million Persons Exposed to Radiation ?

- **Low dose (<100 mGy) radiation health effects**
- **Prolonged exposure: much is known about radiation effects when exposure is received all at once (briefly/the atomic bomb survivors), but the gap in understanding is when radiation is received gradually over time**
- **Statistical ability to precisely estimate radiation risks**

The appropriation bills specify funding for an "Epidemiologic Study of One Million U.S. Radiation Workers and Veterans".
Appropriations Bills (PUBLIC LAW 115–31 & 115-141) – 'line items' that specify support for MPS

NIOSH Update
Paul J Middendorf, PhD, CIH
NIOSH Deputy Associate Director for Science

New Programs and Initiatives

- **Future of Work**

Addresses issues affecting the future of workplace safety and health such as new work arrangements, differences in organizational design, technological advances, and changes in

demographics.

- **Artificial Intelligence**

NIOSH has launched an AI Interest Group which brings together those scientists across the Institute that are using AI methods to see new relationships in occupational safety and health data. A new webpage is being developed to showcase that work.

- **Faces of Work-related COPD**

Faces of Work-related COPD is an impact video series that is part of a NORA Respiratory Health Cross-Sector Council initiative.

The National Firefighter Registry

- **The Firefighter Cancer Registry Act of 2018**
- **Previous studies, including a study completed by NIOSH, indicate that career firefighters are at higher risk of cancer.**
- **Studies are limited by the inclusion of small numbers of women and minorities, and a lack of data on volunteer firefighters.**
- **Goal is to track firefighters' cancer risk over time to better understand the link between workplace exposures and cancer.**
- **The Firefighter Registry will include ALL firefighters, not just those with a cancer diagnosis**
- **Goal is to enroll 200K, include enough minorities and female and subspecialties to be able to study**

NIOSH OCCUPATIONAL EXPOSURE BANDING:
A NEW TOOL FOR EVALUATING CHEMICAL HAZARDS

- **A mechanism to quickly and accurately assign chemicals into "categories" or "bands" based on their health outcomes and potency considerations**
- **Does not replace Occupational Exposure Limits**

Update from US EPA
Wayne Cascio, MD

Lead (Pb)
EPA-ORD is participating in the Federal Lead Action Plan and conducting research in the following areas:

- **Determine key drivers of blood Pb levels from multimedia exposures to inform assessments and decisions.**
- **Generate data, maps and mapping tools to identify high exposure communities or locations.**
- **Generate data to address critical gaps for reducing uncertainty in Pb modeling and mapping for exposure/risk analyses.**
- **Identify approaches to prevent, mitigate and communicate about Pb exposures and risks.**

PFAS
EPA-ORD is conducting research on PFAS compounds in four main areas:

- **Human Health/Toxicity – This research is focused on understanding human**

health toxicity and health effects. It include high throughput toxicity testing and assessments.

- **Analytical Methods – ORD is working with EPA programs and regions to establish validated methods for measuring PFAS in different environmental media.**
- **Site Characterization/Exposure – We are developing sampling methods to characterize sources and contaminated sites and conducting research to identify and estimate human exposure to PFAS from different sources.**
- **Treatment/Remediation – We are working to identify/evaluate methods to reduce PFAS exposures and identify/evaluate methods to treat and remediate drinking water and contaminated sites.**

State Engagement

- **ORD has actively engaged state partners in developing our strategic research plans to ensure our research is useful and practical for states to address their most pressing challenges – this engagement has happened primarily through ECOS and ASTHO.**
- **We are also working to strengthen connections between ORD, EPA's regions and the states on science issues.**

Public Engagement

ORD is engaging with public health partners to enhance our understanding of environmental health challenges at the local/state levels and to share ORD resources that are relevant to these challenges.

We are doing this through MOUs with:

- **Association of Public Health Laboratories**
- **American Public Health Association**
- **National Environmental Health Association**
- **National Association of County and City Health Officials**

Our goals through this engagement is to:

- **Put scientific tools and resources into the hands of those who need it most - the professionals on the front lines of protecting health in communities, cities, counties and states.**
- **Collaborate and share information on common areas of interest such as the health impacts of air pollution on cardiovascular health, harmful algal blooms, lead, chemicals such as PFAS found in the environment, and emergency response/homeland security efforts.**
- **Provide training and information exchanges between EPA researchers and the public health community.**

Cyanobacteria Assessment Network Mobile Application (CyAN app)

- **The CyAN app accesses satellite data to provide an easy-to-use, customizable interface to scan water bodies for changes in cyanobacteria occurrence without requiring computer programming expertise.**
- **Now available for download on Google Play™.**

There were two public comment periods: 2:30 –2:45pm on June 25th & 10:10 – 10:25am on June 26th
There were no public comments made at either period.

There were no formal recommendations made by the Board of Scientific Counselors.

Attendees:
Jim Nowizk
Rudolph Johnson
Alesha Thompson
Lina Balluz
David Williamson
Caroline McDonald
Peter Kowalski
Alan Parham
Heather B
Sara Collins
Alan Yarbrough
Antonia Calafat
Amy Mowbray
Zachary Myles
Quin P
Meredith Shoemaker
Halie O'Brien
Michele P
Christine Pfeiffer
Sharunda Buchanan
Cassandra Smith
Shirley Ding
Elizabeth Irvin
Marilyn
Janet Hamilton
Theresa Grant
Brad Goodwin
James Durant
Kevin Horton
John Sarisky
Laura Brown
Brian Hubbard
Clara W
Laurie Johnson
Jamie Mutte
Kim Gehle
Linde Parcels
Rhonda Kutzel
Yulia Carroll

Maria Mirabelli
Athena Gemella
Amy Lavery
Emma Hines
Rob Robinson
Jerry Thomas
Medinu Govindu
Chelsea Austin
Fuyuen Yip
Chinaro Kennedy
Stephanie Davis
Michael Hatcher
Hope Roobel
Sylvia Allen Lewis
Alisha Etheredge
Angela Ragin Wilson
Elizabeth Irvin
Gedaliah Dreyfus
Cassandra Smith
Stephanie Foster
Vivi Siegel
Hatice Zahrar
Cathy Bailey
Rich Nickle
Custodio Muiange
Josephine Malilay
Moiz Mumtaz
Vou Roebuik
Erik Svedsen
Mina Zadeh

CHAIR'S CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date	Melissa Perry, ScD, MHS Chair, NCEH/ATSDR Board of Scientific Counselors