The Network for Public Health Law

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Establishing an Environmental Exposure Registry: Operational and Legal Lessons from the Flint Registry

2:00 p.m. – 3:00 p.m. EST | June 30, 2022

Moderator

Peter D. Jacobson, J.D., M.P.H., Co-Director, Network for Public Health Law – Mid-States Region Office

Presenter

Nicole Jones, MS, Ph.D., Assistant Professor and Director of Flint Registry, Michigan State University, College of Human Medicine, Division of Public Health & Department of Pediatrics and Human Development

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Felicia Eshragh, J.D., MPH, Flint Registry Program Manager, Michigan State University, College of Human Medicine, Division of Public Health

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Establishing an Environmental Exposure Registry

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Agenda

- Background Flint Water Crisis & Flint Registry

- Overview of Operations

- Overview of Legal Issues

- Summary of Lessons learned

- Conclusion

Background:
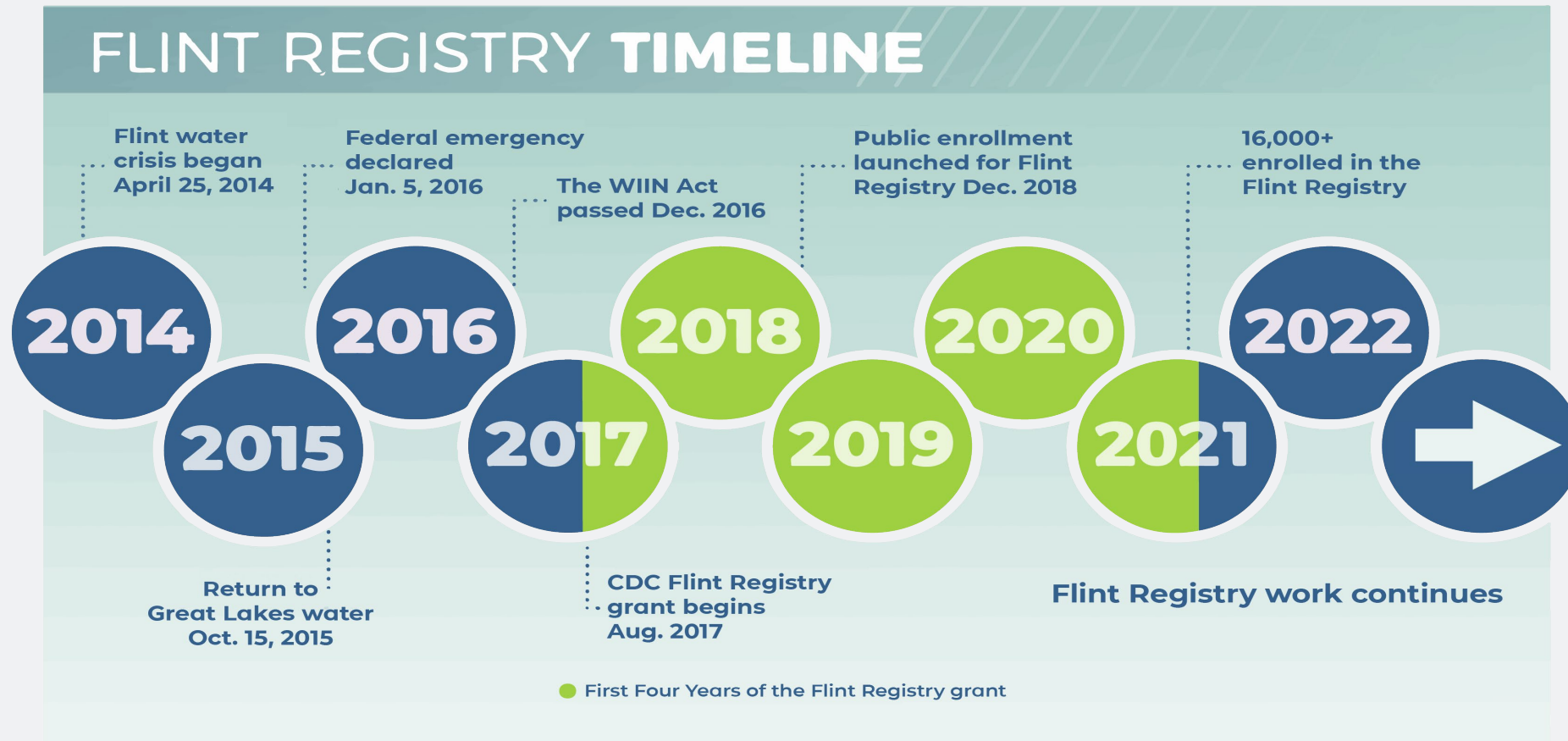# Flint Water Crisis & Flint Registry

- McClaren Hospital Tap Water During Flint Water Crisis (left) and after switching back to Detroit Water (right). Photo courtesy of Dr. Marc Edwards Flintwaterstudy.

Background:
Flint Water Crisis & Flint Registry

FLINT REGISTRY **TIMELINE**

Flint water crisis began April 25, 2014

Federal emergency declared Jan. 5, 2016

The WIIN Act passed Dec. 2016

Public enrollment launched for Flint Registry Dec. 2018

16,000+ enrolled in the Flint Registry

2014

2015

2016

2017

2018

2019

2020

2021

2022

Return to Great Lakes water Oct. 15, 2015

CDC Flint Registry grant begins Aug. 2017

Flint Registry work continues

● First Four Years of the Flint Registry grant

Creating the Flint Registry: The Foundation

- Public Health Goals
  - Set by the Center for Disease Control and Prevention (CDC)
- Community Engagement and Partnerships
  - Community Informed Survey
  - Community Advisory Board
  - Partnerships with other community organizations

Flint Registry Public Health Goals

Participants will use preventive services.

Participants will reduce environmental lead exposures where they live, work, and play.

Participants will experience better health and fewer developmental delays.

Registry data collection will lead to increased knowledge about the effectiveness of different types of prevention services leading to improved outcomes.

Registry data collection will lead to increased quality and quantity of data to inform policy and program administration for lead poisoning prevention and elimination.

Registry data collection will lead to increased knowledge about acute and long-term impacts of lead exposure.

Community Voice

- Parents Partners

- Flint Youth Justice League

- Community Advisory Board

- Focus Groups

- Pre-enrollment Feedback

- Local Presentations/Events

- Registry Ambassadors

- Director of Community Based Implementation and Engagement

- Local Community Ethics Review Board Approval

Creating the Flint Registry: The Operations

Marketing and Outreach

- Traditional and Social Media
- Mailed Materials
- Community Outreach Partners

Multi-Modal Survey

- Paper
- Phone
- Online
- Email or Phone Number not required

Referral Process

- Closed Loop Community Platform
- Collaboration with Community Programs

Interfacing Systems

- REDCap for Survey
- Epic for Participant Files

Operational Procedures within University system

- Hiring
- Phone and Technology Solutions
- Purchasing and Financial Systems

Flint Registry Impact

Flint Registry Enrollees

Demographics

31% Children

69% Adults

Youngest participant **2 years** and oldest participant **104 years**

Residency at Time of Enrollment

- Flint 83%
- Genesee County, not Flint 11%
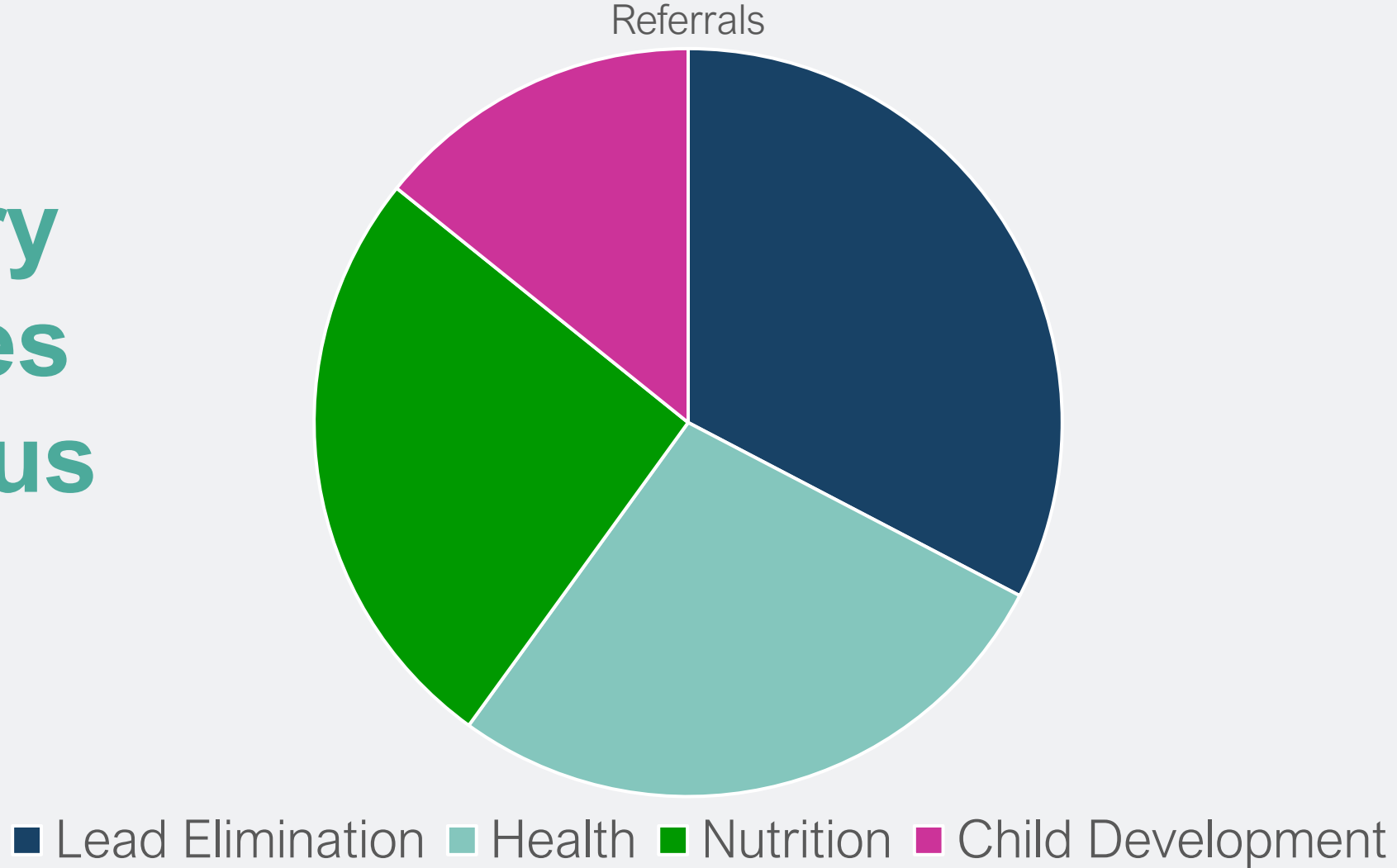- Michigan, not Genesee County 4%
- U.S., not Michigan 2%
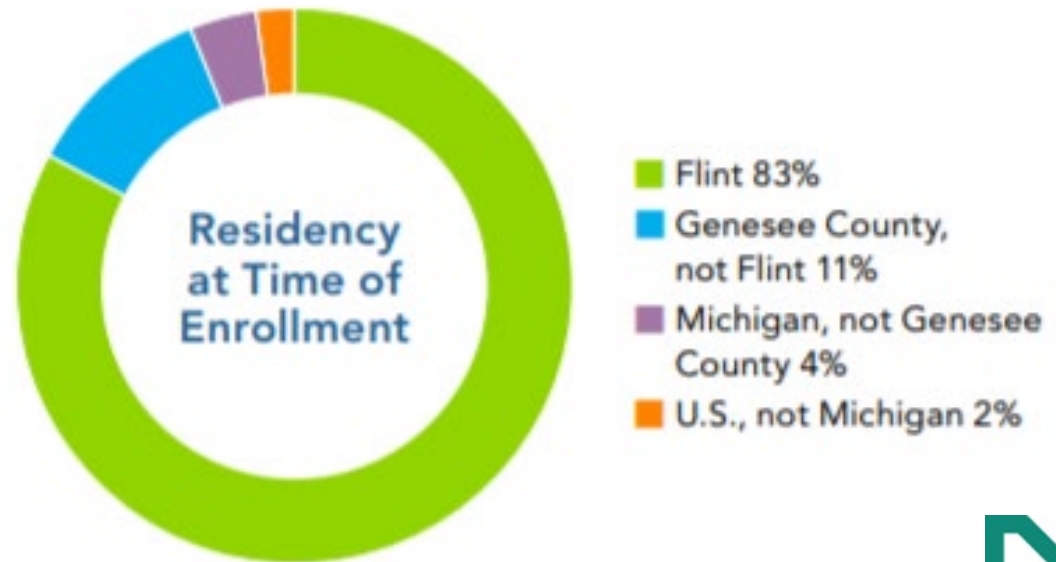
Key Outcomes

- Increased use of preventive services

- Better health and fewer developmental delays among participants
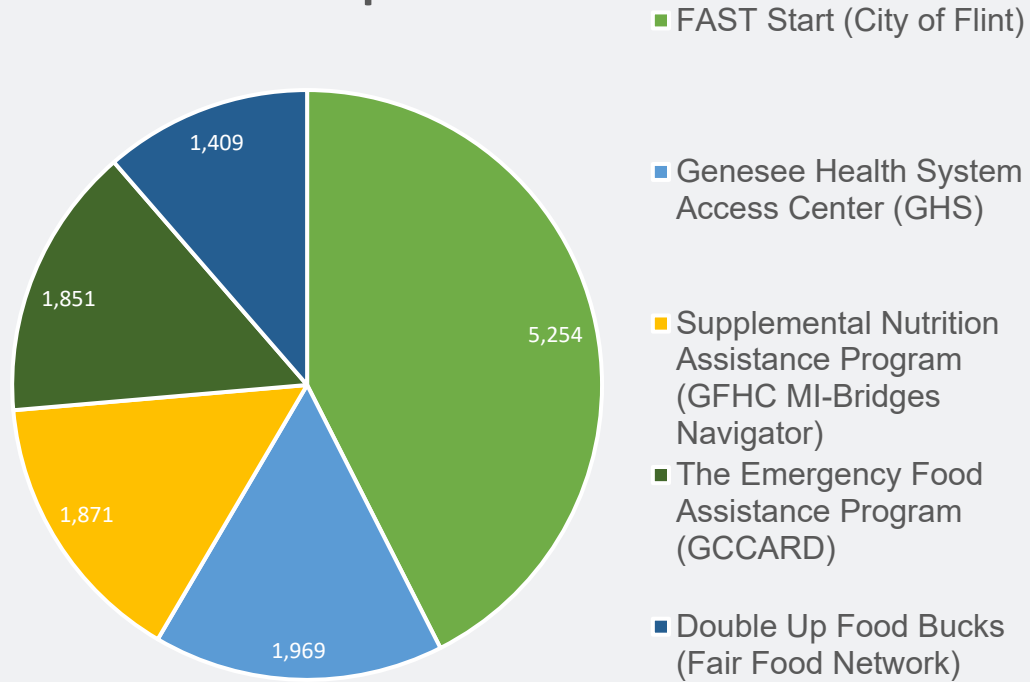
- Describe how Flint families are doing
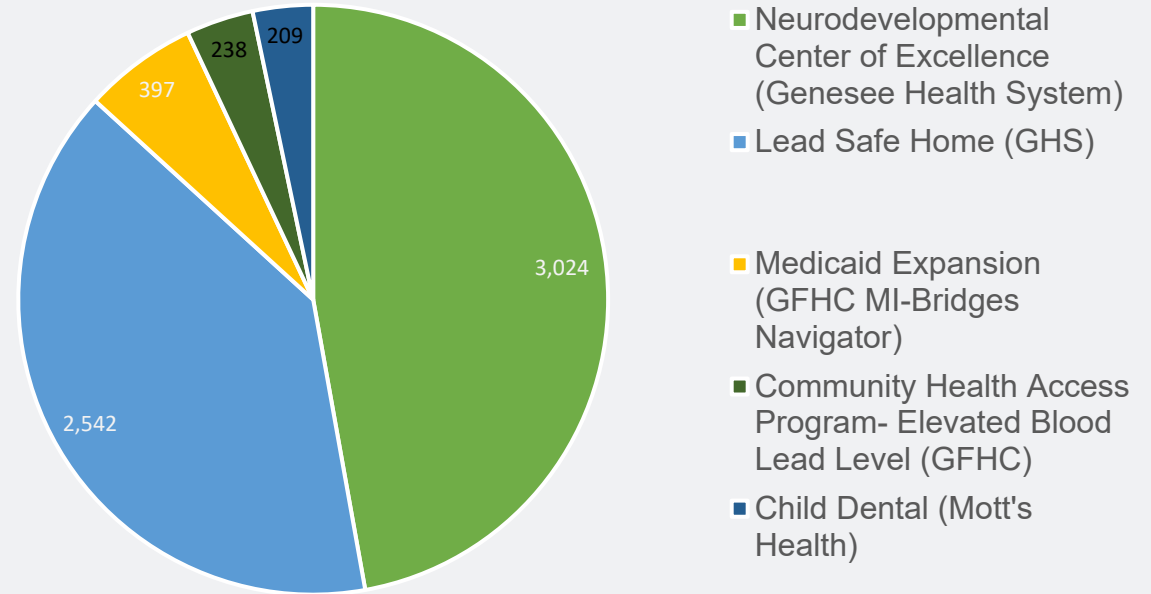
- Identify gaps in resources

Adult and Child Needs based on Referrals

Top Adult Services

- FAST Start (City of Flint)
- Genesee Health System Access Center (GHS)
- Supplemental Nutrition Assistance Program (GFHC MI-Bridges Navigator)
- The Emergency Food Assistance Program (GCCARD)
- Double Up Food Bucks (Fair Food Network)

5,254
1,969
1,871
1,851
1,409

Top Child Services

- Neurodevelopmental Center of Excellence (Genesee Health System)
- Lead Safe Home (GHS)
- Medicaid Expansion (GFHC MI-Bridges Navigator)
- Community Health Access Program- Elevated Blood Lead Level (GFHC)
- Child Dental (Mott's Health)

3,024
2,542
397
238
209

Total Referrals: 23,870 Adult: 16,846 Child 7,024

Adult Health

Physical Health
In general, how would you describe your physical health?

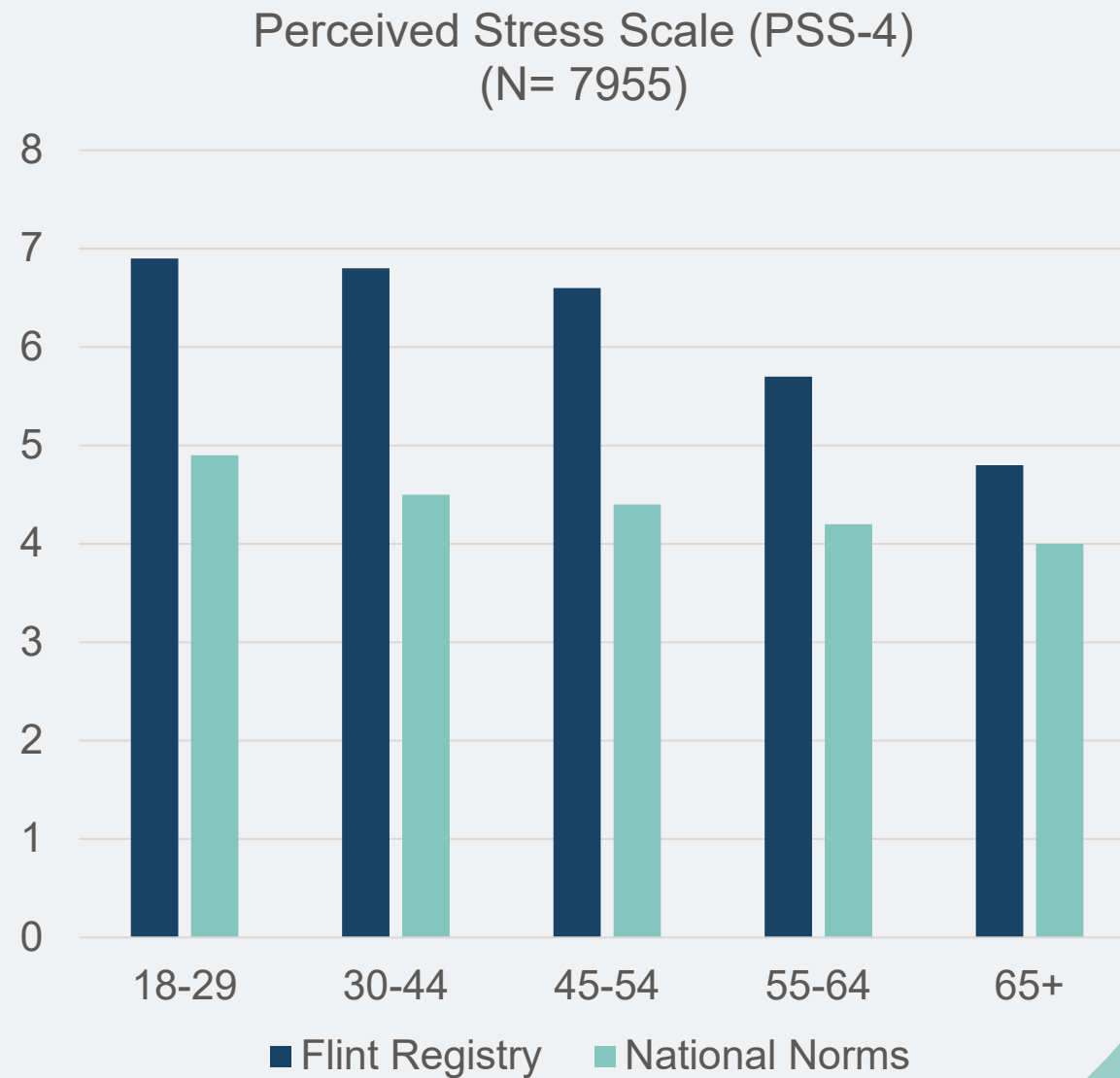| Rating	Percentage
Excellent	6%
Very Good	17%
Good	40%
Fair	29%
Poor	8%
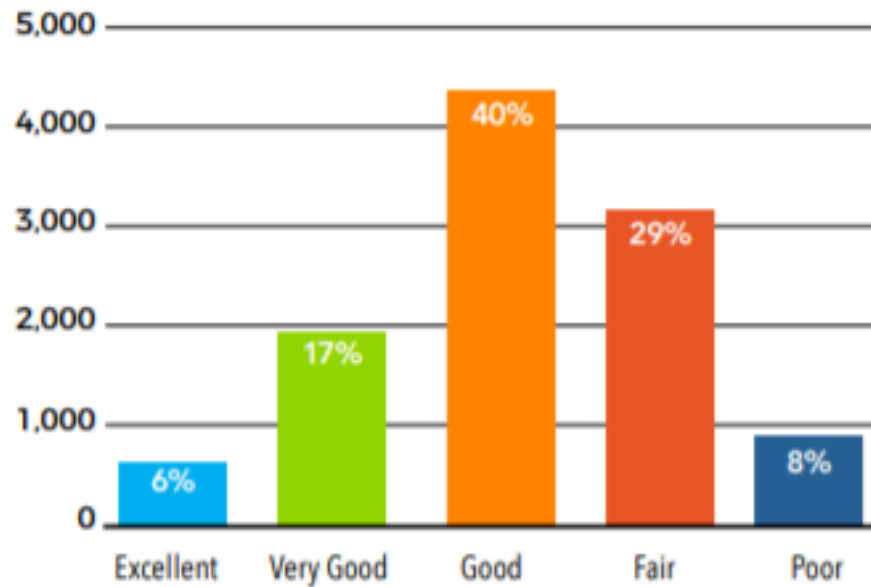
Mental Health
In general, how would you rate your mental health, including your mood and your ability to think?

Rating	Percentage
Excellent	12%
Very Good	20%
Good	34%
Fair	26%
Poor	8%

Adult Perceived Stress

Perceived Stress Scale (PSS-4)
(N= 7955)

Legend: Flint Registry, National Norms

X-axis categories: 18-29, 30-44, 45-54, 55-64, 65+

Adult Nutrition Access

Nutrition

Within the past 12 months, were you worried that your food would run out before you got money to buy more?

- **No** 56%
- **Yes** 43%
- **Don't Know** 1%

Please tell us your opinion about the following statement: A large selection of fresh fruit and vegetables is available in your neighborhood:

Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
14%	38%	22%	19%	7%
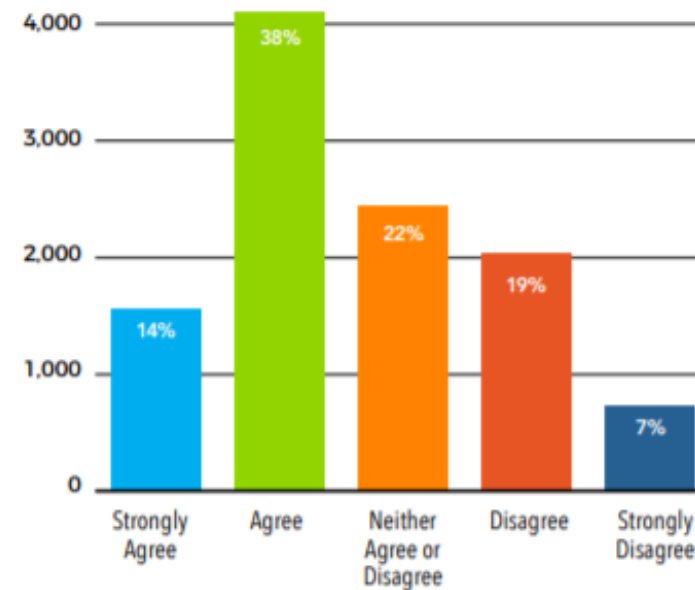
Child Health

Physical Health
In general, how would you describe your child's physical health?

Rating	Percentage
Excellent	32%
Very Good	35%
Good	23%
Fair	8%
Poor	2%

Mental Health
In general, how would you say your child's mental health is?

Rating	Percentage
Excellent	28%
Very Good	29%
Good	27%
Fair	13%
Poor	3%

FLINTREGISTRY
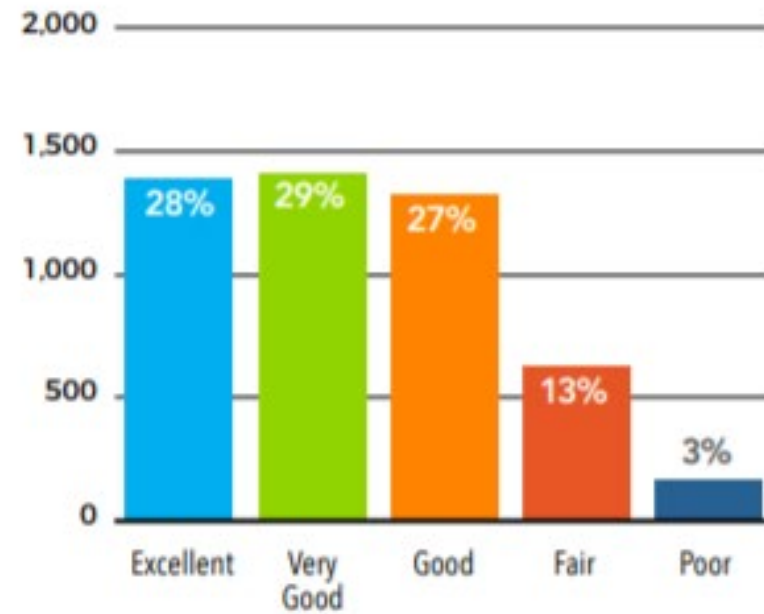
Child and Family Financial Security

very hard to cover basics like food and housing
(n=5253)

- very often — 11%
- somewhat often — 35%
- rarely — 38%
- never — 16%
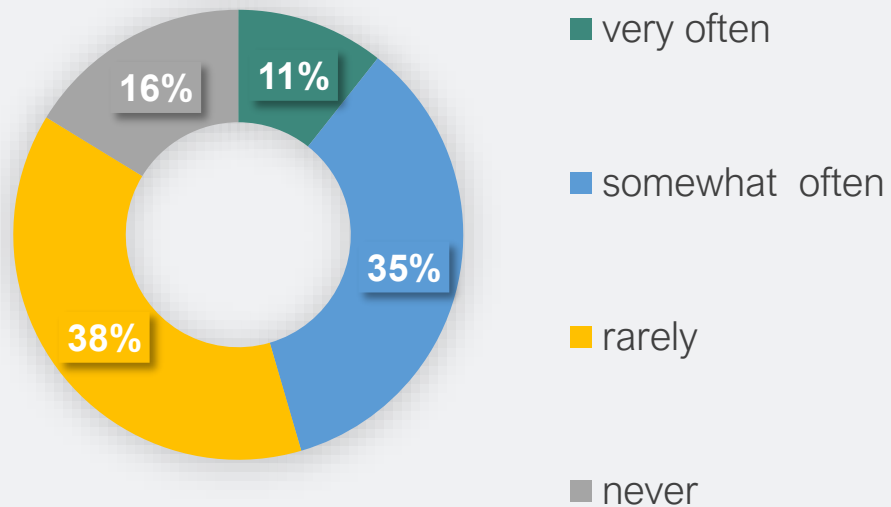
which best describes your food situation in the past 12 months
(n=5223)

- often we could not afford enough to eat — 2%
- sometimes we could not afford enough to eat — 15%
- we could always afford enough to eat but not always the kinds of food we should eat — 50%
- we could always afford to eat good nutritious meals — 33%

Child Behavioral and Mental Health

BASC-3
Percent of Children At Risk or Clinically Significant
(N=3487)
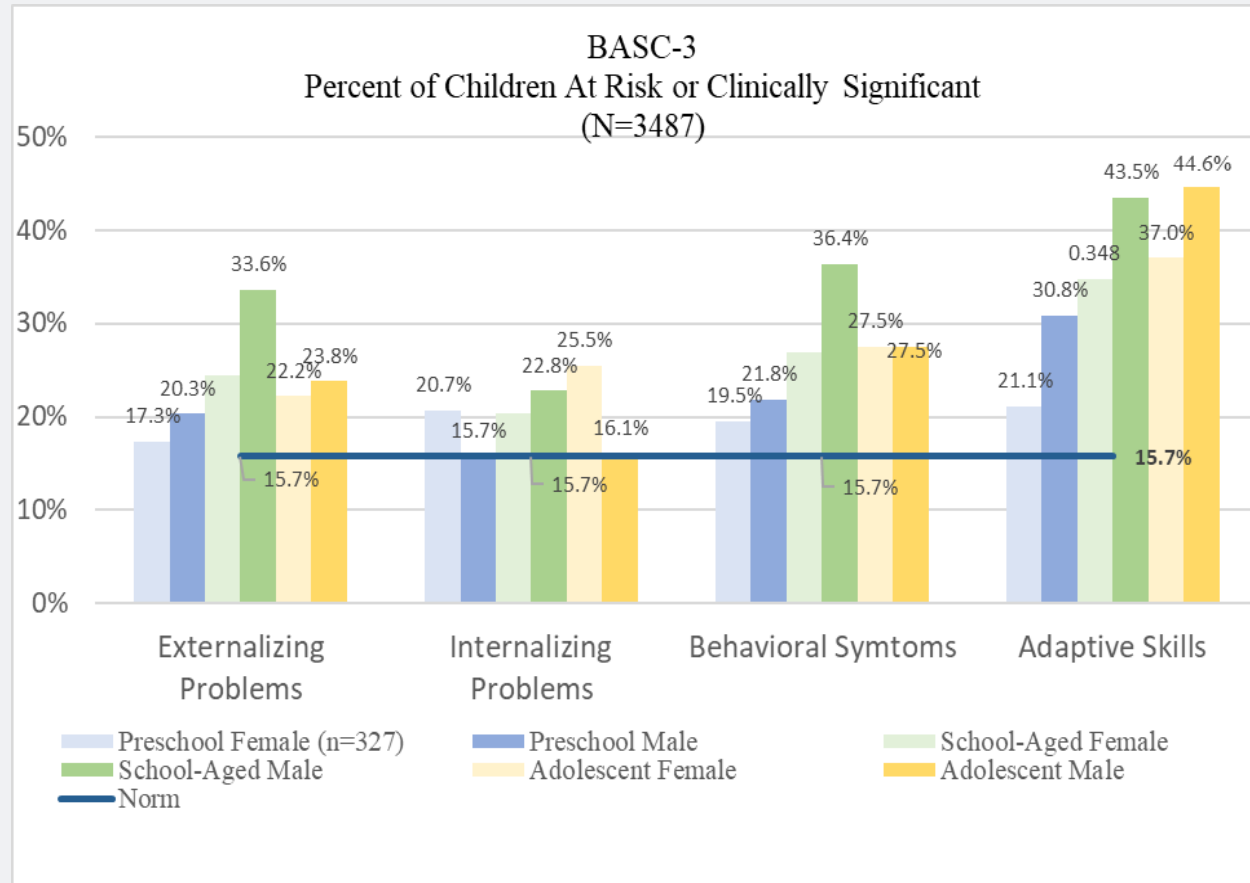
Legal Issues

Preliminary considerations

- **Public health registries** provide a systematic way to collect and monitor health information, typically about individuals who share a common health-related characteristic.

  - *See* 1 Registries For Evaluating Patient Outcomes: A User's Guide 24 (Richard E. Gliklich, Nancy A. Dreyer, and Michelle B. Leavy, eds., 3d ed, 2014), https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/registries-guide-3rd-edition_research.pdf

- Primary function: public health practice vs. research

Legal authority to establish and operate a public health registry

- **Governmental public health agencies** (e.g., Mich. Dept. of Health and Human Services)
  - State public health code
  - Supreme Court precedent: Planned Parenthood of Missouri v. Danforth, 428 U.S. 52 (1976); Whalen v. Roe, 429 U.S. 589 (1977)
  - HIPAA public health exception (45 CFR 164.512(b))
    - A covered entity may disclose PHI without individual authorization to a public health authority that is authorized by law to collect or receive the information for public health purposes.

Legal authority to establish and operate a public health registry

- **University** (e.g., MSU)
  - ➢ No inherent authority to collect data, even for public health purposes
  - ➢ MSU acted on behalf of CDC to establish Flint Registry
    - o Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, Pub. L. No. 114-322, § 2203(b) ➔ directed HHS Secretary to establish a Flint lead exposure registry, either directly or through a grant/contract
    - o CDC granted funds + public health legal authority to MSU to establish Flint Registry
  - ➢ Grant of public health authority is necessary, not sufficient, to obtain data needed

Data collection

General legal considerations

➢ Two major phases of data collection: recruitment and outcomes

   ○ Key difference is ability to obtain consent

➢ Providing data is generally voluntary → relationship building and trust are essential

➢ Patchwork of data laws (e.g., HIPAA, FERPA, state laws)

➢ Initial steps for data sharing:

Checklist of Factual Information Needed to Address Proposed Data Collection, Access and Sharing to Improve the Health of Communities:

https://www.networkforphl.org/resources/checklist-of-information-needed-to-address-proposed-data-collection-access-and-sharing/

Data collection

- **Legal issues associated with recruitment**
  - Cannot obtain consent
  - Often gathered from non-traditional sources
  - Examples from Flint Registry:
    - Michigan Dept. of State
      - Received based on public health authority
    - Local school districts
      - Unsuccessful – did not receive data
    - Michigan Dept. of Health and Human Services
      - Executed DUA to receive data under grant of public health authority

Data collection
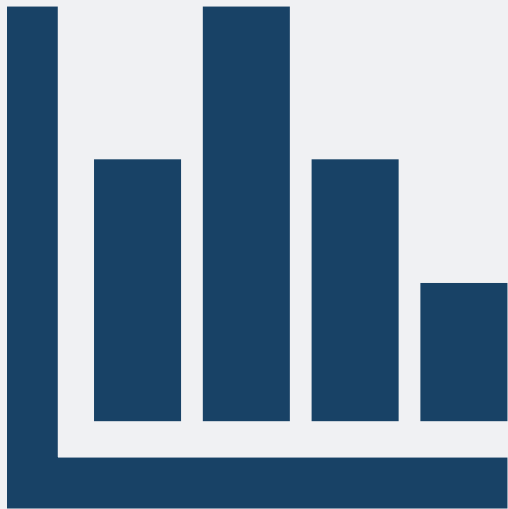
- Legal issues associated with obtaining outcomes data from MDHHS
  - ➤ Possible to obtain consent
  - ➤ Every data source subject to different laws, each with different disclosure criteria and consent requirements
  - ➤ Flint Registry adopted two-prong approach:
    - o Executed DUA to obtain data under public health authority
    - o Sought consent from Registry participants to obtain data

Participation and Consent

- Consent for:
  - Participation in the Registry
  - Third parties to share data with the Registry
  - Disclosure of information to service providers

- Law + Ethics
  - Consent must be competent, voluntary, informed, understood
  - Respect of persons, beneficence, justice
  - Confidentiality

Law defines what an agency can do. Ethics define what an agency should do.

Participation and Consent

- Developing a consent form & process
  - Benefits:
    - Provides transparency and builds trust
    - Allows for broader data collection
  - HIPAA authorization requirements
  - Proxy consent

Other Legal Considerations

- Federal Privacy Act

- Federal Certificate / Assurance of Confidentiality

- Electronic transaction laws

Practical Considerations & Lessons Learned

- Operational considerations
  - Community Engagement Strategy
  - Enrollment without requiring email
  - Building Community Trust
  - Pre-enrollment
  - IT infrastructure and communication options
  - Multi-layered consent process
  - Referral process and availability of services

Practical Considerations & Lessons Learned

- Legal challenges
  - ➢ Community distrust of government and institutions
  - ➢ Interagency cooperation
  - ➢ Obtaining lists of potential enrollees
  - ➢ Legal barriers

Recommendations

- Practice
  - Outreach, Pre-Enrollment, and Referral Communications
  - Off the Shelf technology vs. Custom Build
  - Utilize marketing to explain processes and limitations including information about data collection
- Policy and Legal Implications
  - Improvements to data laws (e.g., more flexible consent processes; agency guidance to facilitate sharing data for PH purposes)
  - FERPA needs a public health exception and/or guidance
  - State policy should default to disclosure to a PH authority

Find all this and more in the recently published "Legal Handbook for Establishing a Public Health Registry"

https://www.networkforphl.org/resources/legal-handbook-for-establishing-a-public-health-registry/

Conclusion

Acknowledgments

- Peter D. Jacobson – Director, Network for Public Health Law – Mid-States Region Office

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- Flint Registry Team Members

- Greater Flint Health Coalition

- Flint Community Partners

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Presenters

- Nicole Jones, MS, Ph.D., Assistant Professor and Director of Flint Registry, Michigan State University, College of Human Medicine, Division of Public Health & Department of Pediatrics and Human Development (warnerni@msu.edu)

- Felicia Eshragh, J.D., MPH, Flint Registry Program Manager, Michigan State University, College of Human Medicine, Division of Public Health (eshraghf@msu.edu)

- Denise Chrysler, J.D., Director, Network for Public Health Law – Mid-States Region Office (dchrysler@networkforphl.org)

- Colleen Healy Boufides, J.D., Deputy Director, Network for Public Health Law – Mid-States Region Office (chealyboufides@networkforphl.org)

Thank you for attending

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The New Reproductive Health Landscape
2:00 p.m. – 3:00 p.m. EST | July 7, 2022

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