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# The C8 Health Project: How a Class Action Lawsuit Can Interact with Public Health – History of Events

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# Objectives

1. Learn about perfluorocarbons, what they are used for, and the current state of understanding of their role in the environment and physiology
2. Gain insight into the history and events leading to the class action lawsuit
3. Understand the settlement details, especially as it pertains to the C8 Health Project and the Science Panel
4. Understand the methodology and the timeline used for the data collection in the C8 Health Project
5. Appreciate some of the initial results from the C8 Health Project, including demographic and health survey data, as well as plasma concentrations of perfluorocarbons
6. Understand the importance and context of these results, including the strengths and weaknesses of prevalence data, their relationship to the Science Panel, and the intended environmental purpose of establishing “probable cause”



# Origins of the C8 Health Project

- Created, authorized, and funded in partial fulfillment of the terms of the settlement agreement reached in class action case
  - *Jack Leach, et al. v E. I. duPont de Nemours and Company*
  - No. 01C-608 W. Va., Wood County Circuit Court
- Context
  - Contamination of human drinking water in 6 water districts near the DuPont's Washington Works facility in Parkersburg, West Virginia
- C8 Health Project was created to
  - Gather data from the affected class for epidemiologic purposes
  - Enable the Court appointed Science Panel to assess “probable link” between C8 exposure and human disease



# Outline of Presentation

1. Description of perfluorocarbons & their use
2. Brief review of what is currently known about ecologic and biologic action of perfluorocarbons
3. History of events leading to the filing of the class-action law suit
4. Terms of the settlement
5. How the C8 Health Project was conducted
  - Key actors (Brookmar, Science Panel, WVU)
6. Preliminary findings
7. C8 Health Project in perspective
  - Public health
  - Environmental contamination law suits



# Perfluorocarbons (PFCs)

- Class of man-made compounds
  - C5, C6, C6-Sulfonate, C7, C8, C8-Sulfonate, C9, C10, C11, C12
  - C8: pentadecafluorooctanoic acid also known as perfluorooctanoic acid (PFOA)
  - Acid (PFOA) or salt (ammonium perfluorooctane sulfonate, PFOS) form
- C8 used in the production of fluoropolymers
  - Chemicals with non-stick properties
  - Fabrics with breathable yet water-resistant membranes
  - Teflon®
  - Gore-Tex®
- C8 may result from the breakdown of other PFCs or fluorinated telomers
  - Used as surfactants or to treat surfaces to result in oil, water, dirt and stain repellency
  - StainMaster®
  - Zonyl products



# Perfluorocarbons (PFCs)

- Common commercial uses (past or present)
  - Coat commercially used food packaging (french fry boxes, pizza boxes, Chinese food take out boxes, butter boxes)
  - Microwave popcorn bags
  - Factory treatments for fabrics and carpets for furniture and automobiles
  - Manufacturer pre-treatment of clothing (e.g., “stain-resistant” clothing)
  - High performance dental floss
  - Non-stick coatings for cookware etc.
- Manufactured by 3M® and sold exclusively to DuPont until 2000
  - 3M no longer manufactures C8
  - DuPont now manufactures (NC) and uses it



# Emerging Concern About PFCs

- Convergence of several lines of research:
  1. Presence in environment
  2. Presence in the human sera,
  3. Animal studies have reported carcinogenic properties of C8 and other PFCs



# PFCs in the Environment

- Near ubiquitous presence of PFOA and PFOS in the world's marine ecosystems [\[i\]](#), [\[ii\]](#), [\[iii\]](#), [\[iv\]](#), [\[v\]](#), [\[vi\]](#), [\[vii\]](#), [\[viii\]](#), [\[ix\]](#)
- Presence in fresh water ecosystems [\[x\]](#), [\[xi\]](#), [\[xii\]](#), [\[xiii\]](#), [\[xiv\]](#), [\[xv\]](#)
- Accumulation of PFOA and PFOS in a wide variety of tissues
  - Bioconcentration
  - Biomagnifications
  - Oviparous transfer across generations

## References:

- [\[i\]](#) Yamashita N *et al*, 2005; [\[ii\]](#) Nakata H *et al*, 2006; [\[iii\]](#) Kannan K *et al*, 2002; [\[iv\]](#) Tomy GT *et al*, 2004; [\[v\]](#) Nakata H *et al*, 2006; [\[vi\]](#) Martin JW *et al*, 2004; [\[vii\]](#) Muir D *et al*, 2003; [\[viii\]](#) Borga K *et al*, 2001; [\[ix\]](#) Tao L *et al*, 2006; [\[x\]](#) Furdui VI *et al*, 2007; [\[xi\]](#) Kannan K *et al*, 2005; [\[xii\]](#) Boulanger B *et al*, 2004; [\[xiii\]](#) Martin JW *et al*, 2004; [\[xiv\]](#) Giesy JP *et al*, 2001; [\[xv\]](#) Giesy JP *et al*, 2001





# PFCs & Animal Toxicity

- Immune and anti-inflammatory effects [\[i\]](#), [\[ii\]](#)
- Cell membrane potential [\[iii\]](#), [\[iv\]](#)
- Neuroendocrine effects [\[v\]](#)
- Gestational and developmental effects (mice and rats) [\[vi\]](#), [\[vii\]](#)
- Potential carcinogenic effects [\[viii\]](#), [\[ix\]](#), [\[x\]](#), [\[xi\]](#), [\[xii\]](#), [\[xiii\]](#), [\[xiv\]](#)

## References:

- [\[i\]](#) Kannan K *et al*, 2006; [\[ii\]](#) Taylor BK *et al*, 2005; [\[iii\]](#) Harada KH *et al*, 2006; [\[iv\]](#) Harada K *et al*, 2005; [\[v\]](#) Asakawa A *et al*, 2007; [\[vi\]](#) Lau C *et al*, 2006; [\[vii\]](#) Luebker DJ *et al*, 2005; [\[viii\]](#) Xie Y *et al*, 2003; [\[ix\]](#) Yang Q *et al*, 2001; [\[x\]](#) Panaretakis T *et al*, 2001; [\[xi\]](#) Yang Q *et al*, 2000; [\[xii\]](#) Abdellatif AG *et al*, 1990; [\[xiii\]](#) Kudo N *et al*, 2005; [\[xiv\]](#) Okochi E *et al*, 1999



# Sources of Human Exposure

- Exposure to PFOA and PFOS linked to: [\[i\]](#), [\[iii\]](#), [\[iii\]](#), [\[iv\]](#), [\[v\]](#), [\[vi\]](#), [\[vii\]](#)
  - Drinking water
  - Household dust samples
  - Food packaging
  - Breast milk
  - Cord blood (i.e., cross-placental exposure during pregnancy)
  - Microwave popcorn
- Possible exposure from non-stick cookware [\[viii\]](#), [\[ix\]](#), [\[x\]](#)
  - Finding is inconsistent
  - Results of positive studies suggest nominal exposure levels
- PFOA has been quantified in ambient air samples [\[xi\]](#)
- Occupational studies have shown elevated exposure to those working in manufacturing processes that use PFOA or PFOS [\[xii\]](#), [\[xiii\]](#)

## References:

- [\[i\]](#) Begley TH *et al*, 2005; [\[ii\]](#) Tittlemier SA *et al*, 2007; [\[iii\]](#) Skutlarek D *et al*, 2006; [\[iv\]](#) Kubwabo C *et al*, 2005; [\[v\]](#) Karrman A *et al*, 2007; [\[vi\]](#) So MK *et al*, 2006; [\[vii\]](#) Inoue K *et al*, 2004; [\[viii\]](#) Sinclair E *et al*, 2007; [\[ix\]](#) Begley TH *et al*, 2005; [\[x\]](#) Powley CR *et al*, 2005; [\[xi\]](#) Barton CA *et al*, 2006; [\[xii\]](#) Emmett EA *et al*, 2006; [\[xiii\]](#) Olsen GW *et al*, 2003



# PFCs in Human Sera

- American Red Cross blood donors<sup>[i]</sup>
- Seattle, WA<sup>[ii]</sup>
- NHANES<sup>[iii],[iv]</sup>
- Temporal studies<sup>[v],[vi]</sup>
  - Serum concentrations rose between 1974-1989
  - Stabilized, perhaps even declined, between 2000-2005
- Other, non-American population studies<sup>[vii],[viii],[ix]</sup>
- Trans-national, comparative study<sup>[x]</sup>

## References:

- <sup>[i]</sup> Olsen GW *et al*, 2003; <sup>[ii]</sup> Olsen GW *et al*, 2004; <sup>[iii]</sup> Calafat AM *et al*, 2007; <sup>[iv]</sup> Calafat AM *et al*, 2006; <sup>[v]</sup> Olsen GW *et al*, 2007; <sup>[vi]</sup> Olsen GW *et al*, 2005; <sup>[vii]</sup> Harada K *et al*, 2007; <sup>[viii]</sup> Harada K *et al*, 2004; <sup>[ix]</sup> Jin Y *et al*, 2007; <sup>[x]</sup> Kannan K *et al*, 2004



# PFCs & Possible Human Toxicity

- Few large, human studies have been performed examining the effects of PFC exposure and deleterious health outcomes
- Human *in vitro* studies<sup>[i],[ii],[iii]</sup>
  - PFOA and PFOS have been shown to be genotoxic to hepatocellular liver carcinoma cells
  - Activate receptors that control peroxisome proliferation
  - Have estrogenic effects
- Population studies
  - 1400 women and infants from a general population -- PFOA and PFOS in the maternal plasma was inversely associated with birthweight, but not the risk of preterm birth, low birth weight, or small for gestational age<sup>[iv]</sup>
- Occupation and environmental exposure studies (all n<1500)
  - One study -- link between PFOA and an increase in total cholesterol and aspartate aminotransferase, and a decrease in total bilirubin<sup>[v]</sup>
  - Other studies (including occupational studies reported by 3M) -- no relationships between PFC exposure and health outcomes that could not be explained by demographic or other confounding parameters or that were considered outside normal biologic limits<sup>[vi],[vii],[viii],[ix],[x],[xi]</sup>
  - Largest reported occupational study reported to date (3537 workers in a plant that produced PFOA) -- 3-fold 10 year risk between bladder cancer mortality and working in an exposed job in the plant compared employment in non-PFOA production<sup>[xii]</sup>
  - These findings not supported by a more recent but smaller study

## References:

- <sup>[i]</sup> Ishibashi H *et al*, 2007; <sup>[ii]</sup> Vanden Heuvel JP *et al*, 2006; <sup>[iii]</sup> Yao X *et al*, 2005; <sup>[iv]</sup> Fei C *et al*, available via <http://dx.doi.org/> Online 16 August 2007; <sup>[v]</sup> Sakr CJ *et al*, 2007; <sup>[vi]</sup> Olsen GW *et al*, 1998; <sup>[vii]</sup> Olsen GW *et al*, 2003; <sup>[viii]</sup> Olsen GW *et al*, 2007 Jun 29 Epub ahead of print; <sup>[ix]</sup> Emmett EA *et al*, 2006; <sup>[x]</sup> Grice MM *et al*, 2007; <sup>[xi]</sup> Gilliland FD *et al*, 1996; <sup>[xii]</sup> Gilliland FD *et al*, 1993



# PFCs & the EPA

- 2004
  - Extensive and formal review of the evidence on the health effects of PFOA and its salts
- Process remains ongoing
- Has found sufficient evidence to consider PFOA and PFOS to be either a suggestive or likely carcinogen<sup>[i]</sup>
- 2006
  - PFOA Stewardship Program
  - Goal of reducing PFOA emissions and product content by 95% by 2010
- 2015
  - Targeted date for elimination from emissions and products

## References:

[i] EPA-SAB-06-006. "SAB Review of EPA's Draft Risk Assessment of Potential Human Health Effects Associated with PFOA and Its Salts". All documents available at: [http://www.epa.gov/sab/panels/pfoa\\_rev\\_panel.htm](http://www.epa.gov/sab/panels/pfoa_rev_panel.htm)



# History of PFC Contamination in the Ohio Valley





# History of PFC Contamination in the Ohio Valley

- Family farm near Parkersburg, WV since the late 1960s
- 1984
  - Family sold a portion of their land to DuPont
  - Became the Dry Run Landfill site
- Per court filings, subsequent
  - Death of wildlife
  - Seriously ill family members
  - Death of entire herd of cattle (300 head) within 10 years
- Family-driven series of investigations, studies, reports, involvement from multiple government agencies
- Family agreed to an undisclosed, confidential settlement with DuPont in August of 2001
- Original family consequently obviated all future claims against DuPont
  - Heighten local awareness about potential environmental contamination and its possible sources
- Subsequent investigations, studies, legal proceedings and related court filings span 2 decades
- Matter of public record



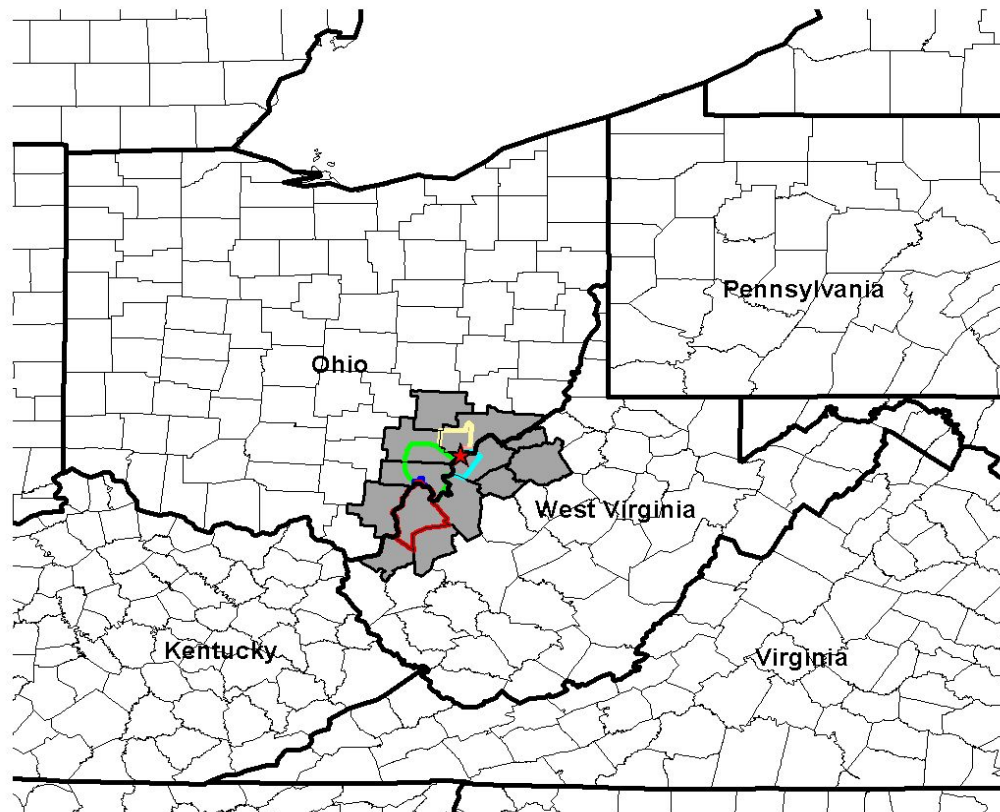
# Timeline of Events

- August 2001
  - 13 plaintiffs filed a lawsuit against DuPont citing violation of the West Virginia Consumer Protection Act
  - Investigations found that C8 had contaminated the local water supply
- April 2002
  - Legal action certified a Class Action under West Virginia Rule of Civil Procedure 23
  - Case was thereafter referred to as *Leach v. E.I. DuPont de Nemours & Co., No. 01C-608*
  - Filed on April 10, 2002 in West Virginia Wood County Circuit Court
  - “Class” was defined as those individuals, in either West Virginia or Ohio, whose drinking water was or had been contaminated by quantifiable levels of C8
- November 2004
  - Out-of-court settlement was reached between the Class and DuPont was announced
  - \$107 million
  - Multiple components and stipulations



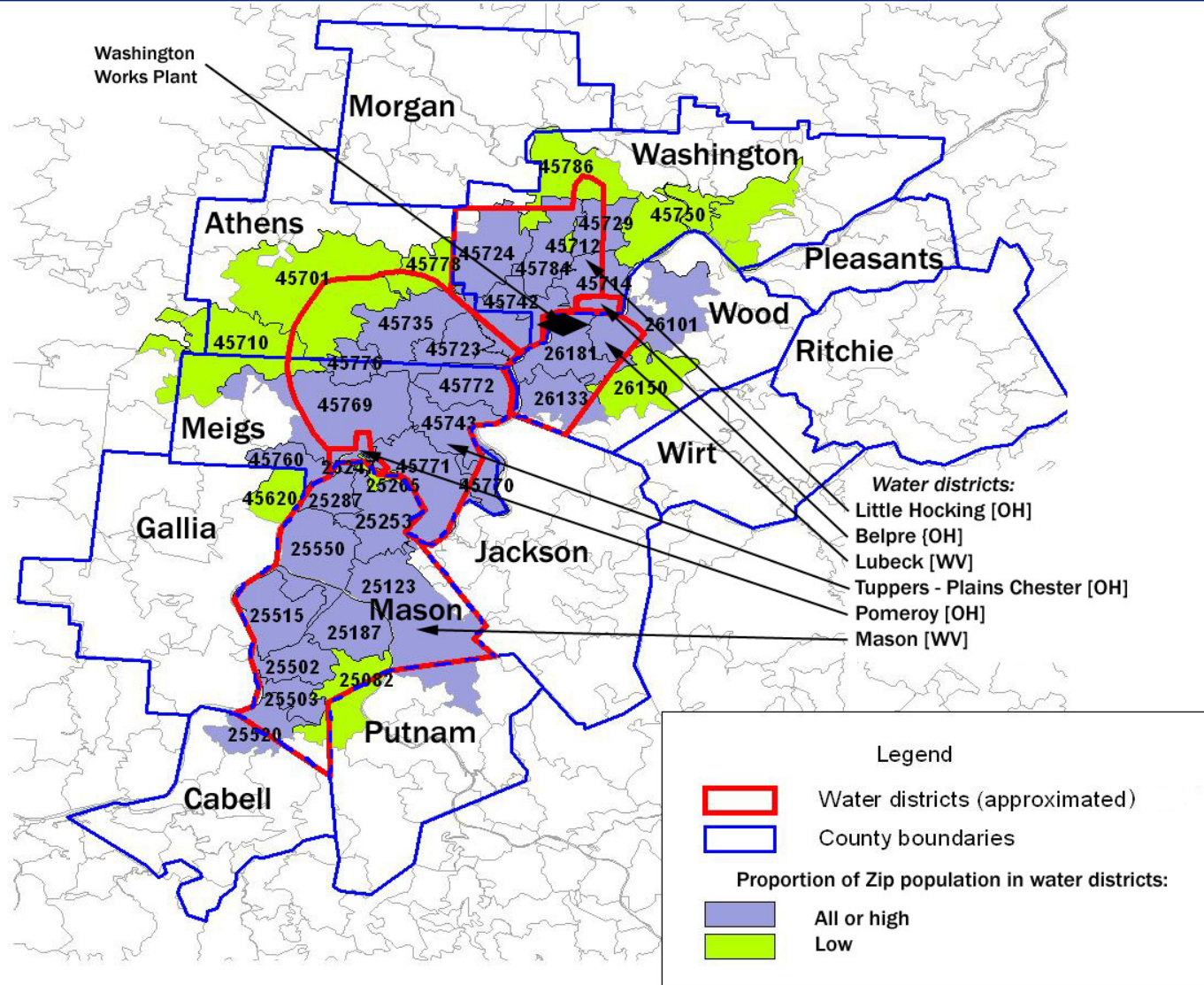
# Map of Affected Area

## C8 Study Area



- ★ Dupont Plant
- Approximate District Boundaries
- Belpre
- Little Hocking
- Lubeck
- Mason County
- Pomeroy
- Tupper Plains-Chester

# Map of Affected Area



Map courtesy Joel Halverson, PhD



# Terms of Settlement Agreement

- Immediate cash payments of \$ 70 million to the Class
  - \$ 20 million was required to be used for health and education projects
- Payment of \$22.6 million for the legal fees and expenses of the Class
- \$10 million to provide water treatment technologies to remove C8 from water supply of the six affected water districts
- \$5 million to fund an independent panel of scientific experts to study the probably link between health and C8 exposure
- In the event that the independent panel determines the existence of a link between C8 exposure and deleterious health outcomes, DuPont agreed to fund a medical monitoring program for area residents in an amount not to exceed \$235 million
- In the event that the independent panel determines the existence of a link between C8 exposure and deleterious health and / or birth outcomes, members of the Class retain their right to file personal injury suits



# Birth of the C8 Health Project

- Settlement outlined broad terms but did not stipulate specific mechanisms or provisions to satisfy the settlement
- Terms, mechanisms for their administration, and timelines to completion were negotiated and agreed upon *post hoc* by the Class, their representative attorneys, and the Court
- C8 Health Project is direct result of these post-settlement agreements
  - Cash payment of \$70 million – would be accomplished through a population-wide study of the health of the Class
  - C8 Health Project
    - Document the health of the population
    - Educate the population as to their exposure to PFCs
    - Serve as the mechanism whereby members of the Class would receive their portion of the cash payment from the settlement
    - Administered by an independent company would be created solely for the design, implementation, and administration of this project



# Key Actors

- **Brookmar, Inc.**
  - Independent company created solely to conduct the C8 Health Project
  - Headed by a retired health care executive and physician from the area
  - Supervised by the Court
  - Authority and responsibility to:
    - Hire the personnel
    - Establish the tools, processes and procedures, and collect information from the Class regarding their health
  - Now in the process of dissolution
- **Science Panel**
  - Group of public health scientists chosen jointly by the lawyers for the Class and DuPont
  - Mission to assess whether there is a probable link between C8 exposure and disease in the community
  - Multiple, on-going (longitudinal) studies
- **WVU Project Team**
  - Initial role as analytic and methodologic support for Brookmar, Inc.
    - Data quality control, data cleaning
  - Report summary results to Class and public through the WVU-based website
  - Tissue bank
  - Follow-up surveys with members of Class
  - Evolving role as collaborators with the Science Panel conducting “scientific-level” analyses and publication



# C8 Health Project Methodology

- Which data and information to collect?
- From whom?
- How?
- How to manage and store data, protect confidentiality?



# Methodology – *Which Data?*

- Settlement finalized in November 2004
- Data collection began in August 2005
- Development and implementation
  - Tools
  - Procedures
  - Infrastructure
- Components of data collection
  - Survey
  - Voluntary blood sample
    - Clinical chemistry analysis
    - Chemical (PFC) analysis



# Methodology – *Which Data?*

- Survey (79 pages)
  - Demographics and “social history”
    - Demographics
    - “Health behaviors”
  - Residential history (25 years)
    - Duration and location
    - Water source and usage at each residence
    - Drinking, bathing, cooking
  - Employment history (past 25 years, positions held for at least 6 months)
    - Duration and location
    - Duties / position
    - Water source
    - Potential exposures
  - Military history
    - Duration and location
    - Duties / position
    - Potential exposures
  - Past medical history
    - Diagnoses
      - Acute, chronic, cancer
    - Symptoms
  - Pregnancy and reproductive history (women)
    - Pregnancies, birth
    - Pregnancy outcomes
    - Birth defects
  - Family history
    - Cancer
    - Other chronic, acute diagnoses





# Methodology – *Which Data?*

- “Verified” data
  - Medical record validation of 18 different diagnoses
  - Addison’s Disease, Amyotrophic Lateral Sclerosis, Anemia, Birth Defects, Cancer, Cerebrovascular Accident, Cushing’s Syndrome, Diabetes, Heart Disease, Liver Disease, Lupus/SLE, Multiple Sclerosis, Pregnancy Complications, Raynaud’s Syndrome, Rheumatoid Arthritis, Scleroderma, Sjogren’s Syndrome, Thyroid Disease
- “Voluntarily” provided information
  - Height, weight, blood pressure
  - Blood sample
    - Clinical chemistry analysis
      - LabCorp, Inc
      - 67 different tests
    - Chemical (PFC) analysis
      - Determination of 9 PFCs
        - » C5 (Perfluoropentanoic Acid)
        - » C6 (Perfluorohexanoic Acid)
        - » C6 Sulfonate (Perfluorohexane Sulfonate)
        - » C7 (Perfluoroheptanoic Acid)
        - » C8 Sulfonate (Perfluorooctane Sulfonate)
        - » C8 (Perfluorooctanoic Acid)
        - » C10 (Perfluorodecanoic Acid)
        - » C11 (Perfluoroundecanoic Acid)
        - » C12 (Perfluorododecanoic Acid)



# Methodology – *From Whom?*

- All members of the Class were eligible to participate
- The Class –
  - Exposure to contaminated water (geographic and concentration criteria)
  - Duration of exposure to the contaminated water
  - Residents of Parkersburg, West Virginia were not eligible to participate in the C8 Health Project as the public water source for Parkersburg did not meet the minimum contamination criteria of 0.05 ppb
- All participants were required to present documentation demonstrating both their identity and eligibility
- Settlement payment was tied to the ability to validate the eligibility of each participants



# Specific Eligibility Criteria

- Class Membership Criteria (Meeting either criterion would disqualify individual):
- Water Contamination Criterion (Criterion must be met):
  - Water containing 0.05 ppb or greater of C8 attributable to release from a DuPont facility (Washington Works or Letart, Dry Run, or Riverbank landfill sites)
- Geographic Criteria (1 criterion must be met):
  1. Qualifying geographical boundaries included any of the following six public water districts
    - Lubeck Public Service District (West Virginia)
    - Mason County Public Service District (West Virginia)
    - City of Belpre (Ohio)
    - Little Hocking Water District (Ohio)
    - Tappers Plains-Chester Water District (Ohio)
    - City of Pomeroy (Ohio)
  2. A water source considered an “Eligible Water Sources”
    - Any private water source within the geographical boundaries defined by the public water sources that is the sole source of drinking water AND certified through testing to contain at least 0.05 ppb C8
    - Required that testing of private water source be requested through DuPont no later than February 25, 2005
    - Presentation of a “C8 Certificate” from a qualified lab citing water testing results
  3. Any private water source specifically listed on Schedule 2.1.1(B) of the Settlement Agreement
- Duration of Exposure (1 criterion must be met):
  - Meeting all of the above criteria with demonstrated exposure for a minimum period of time:
    1. Residence within the geographical boundaries of one the public water sources for a period of at least one year prior to December 4, 2004
    2. Full-time employment at a location within the geographical boundaries of one the public water sources for a period of at least four years prior to December 4, 2004
    3. School attendance on a full-time basis at a location within the geographical boundaries of one the public water sources for a period of at least five (5) years prior to December 4, 2004



# Specific Documentation Criteria

- **List A**
  - Evidence of Eligibility as Class Member Based on Consumption of public water source drinking water Public Water Source Drinking Water
- **List B**
  - Evidence of Eligibility as Class Member Based on Consumption of Eligible Water Source Drinking Water
- **List C**
  - Evidence of Eligibility as Class Member Based on Consumption of Drinking Water From a Well Listed on Schedule 2.1.1(B))
- **List D**
  - Evidence of Identity for an Adult
- **List E**
  - Evidence of Identity for an Child

Please see <http://www.hsc.wvu.edu/som/cmed/c8/healthproject/enrollment.asp>  
for complete “lists”



# Methodology – *How?*

- Extensive communication with the Class
  - Local media outlets
  - Attorneys
- Mobile data collection sites
  - Trailers
  - Different locations in different water districts for different durations, time periods
- “Intent to participate”
  - Completion of the survey
  - Mail or online
  - Triggered scheduling of appointment at a data collection site of choice
- At appointment
  - Copy of required documents
    - Later validation
  - Verification of some survey data
    - Name, address, water district
  - Instructions for submitting blood sample
- Blood sample
- Payments to participants
  - \$150/\$400



# Methodology – *Management & Storage*

- Contracted with a separate IT company based in Charleston, WV
  - CPR Solutions Group
- Custom solution to manage and house data
  - Survey data
  - Interface to facilitate automatic transfer of results from LabCorp
  - Chemical lab test results from 2 different labs
  - Scanned image of all paper document
    - Validity of participants



# Data Quality Assurance

- Validation of Eligibility to Participate
  - Verification and validation of all supporting documents
  - Where eligibility could not be confirmed, or exposure to the specified drinking water for at least one year could not be verified, participants were removed from the C8 Health Project, and payment withheld
- Verification of Responses to Health Questionnaire
  - At appointment, Health Questionnaire responses were verified
- Integrated Information Technology Quality Assurance
  - Programming was used to require that Health Questionnaire responses were both within the expected range and logically consistent
  - Direct programming interface with LapCorp eliminated data entry errors
- "Data Cleaning" Activities
  - WVU and the Science Panel
- Validation of Medical Diagnoses
  - Validation of a select set of medical diagnoses via medial chart review
- Perfluorochemicals
  - Both labs received a set proportion of blinded "blank" and "spiked" samples, as well as "duplicate" participant samples
  - Analysed by Brookmar, WVU, and the Science Panel



# Reporting of Results

- Individual reports to participants
  - Clinical labs
  - Perfluorocarbons
- Aggregate analysis
  - WVU website
    - <http://www.hsc.wvu.edu/som/cmed/c8/>
  - Communication with attorneys
- Scientific analyses
  - Peer reviewed manuscripts





# Reporting of Results – Scientific Analyses

- Collaborative
  - Methodology and epidemiologic results
  - Quality control methods and results
- Cross-sectional associations
  - Group 1 (WVU lead)
    - Liver function
    - Thyroid function
    - Hormones
    - Childhood lipids (age <18)
    - Insulin/glucose
    - Iron and red blood cells (including hemoglobin, hematocrit)
    - Electrolytes.
    - Immune function (including ANA, WBC count, ANA, and CRP) among children (<18) cells)
    - Self-reported cardiovascular disease
    - Self-reported thyroid and liver disease
    - Self-reported respiratory disease (children, <18)
  - Group 2 (Science Panel lead)
    - Vitamins (B12, folate)
    - Immune function (including ANA, WBC count, ANA, and CRP) among adults (>=18)
    - Cancer markers (PSA, CEA, etc)
    - Adult lipids (>=age 18), ie total cholesterol, HDL, LDL, triglycerides
    - Uric acid
    - Self-reported diabetes
    - Self-reported respiratory disease (adults, >=18)
    - Self-reported cancer



# Preliminary Results

- These are **PRELIMINARY** results
- Cross-sectional, univariate associations only
- Results for all participants with detectable levels of C8 and C8 Sulfonate are included
  - Subsequent analyses may use different inclusion/exclusion criteria, population substrata, etc
  - Current summary a synopsis which may be further refined by far more detailed work that will be submitted to peer-review journals

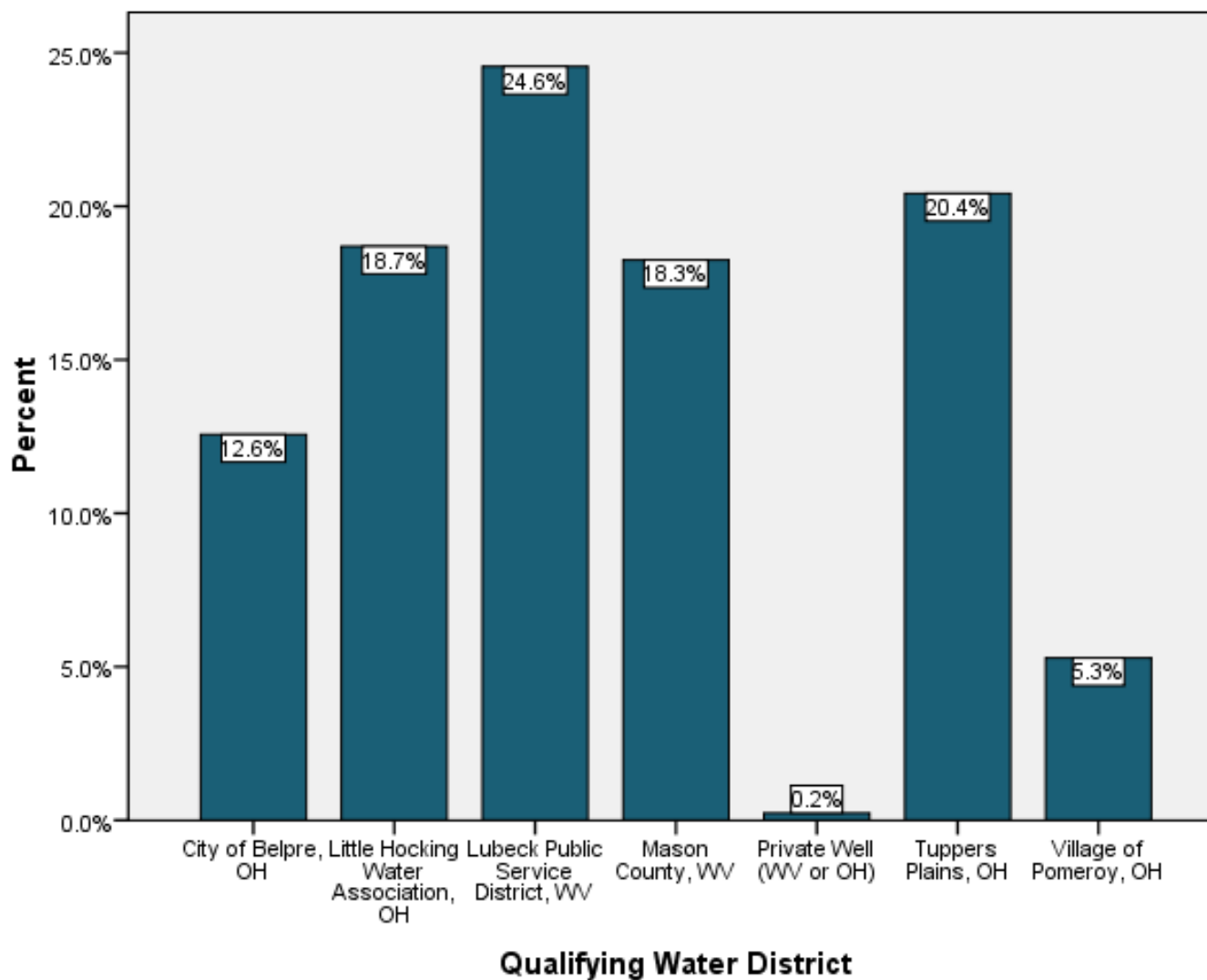


# Preliminary Results – Participants

**Participant - Category of Participation**

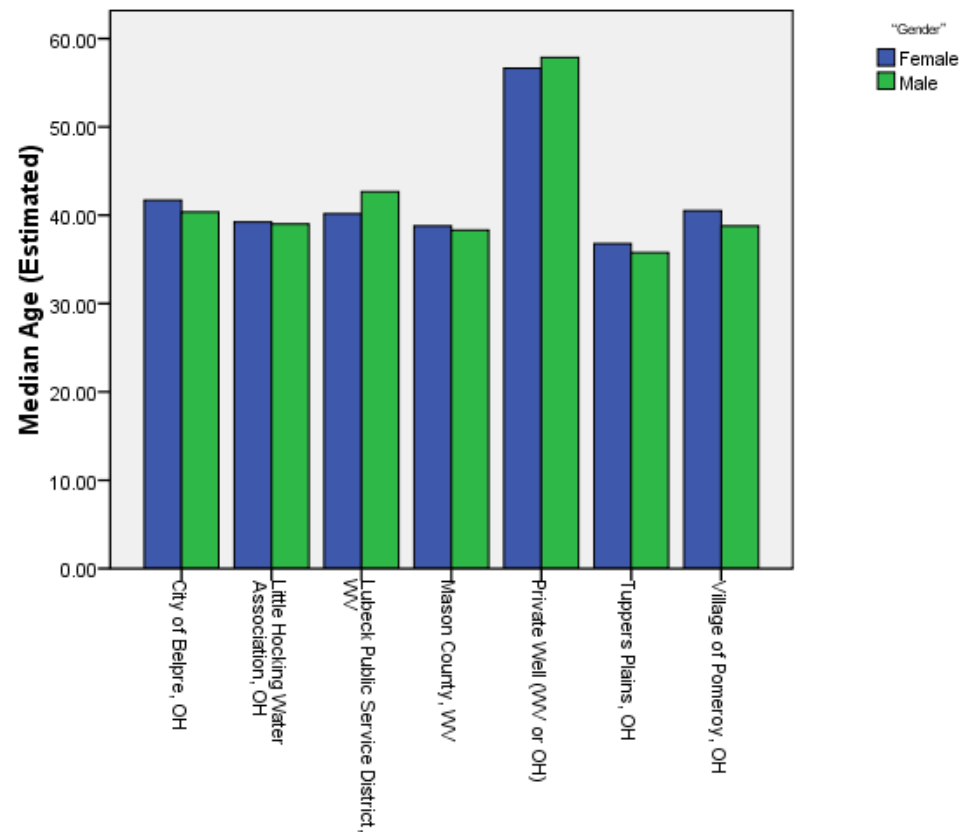
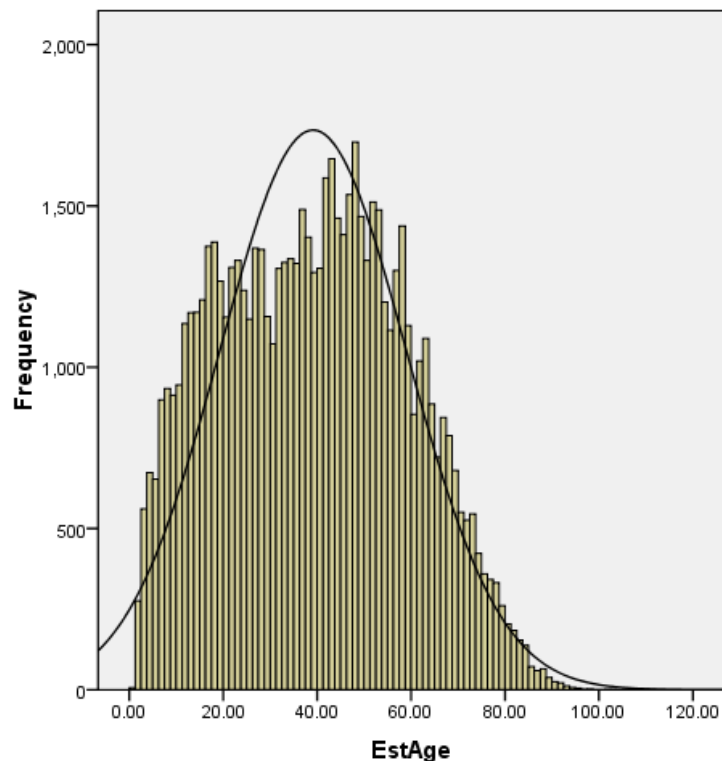
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid No Lab Results	2085	3.0	3.0	3.0
Chemical Analysis Only Lab Results	250	.4	.4	3.4
Chemical and Clinical Lab Results	66660	96.6	96.6	99.9
Clinical Lab Only Results	35	.1	.1	100.0
Total	69030	100.0	100.0	

# Preliminary Results – Participants



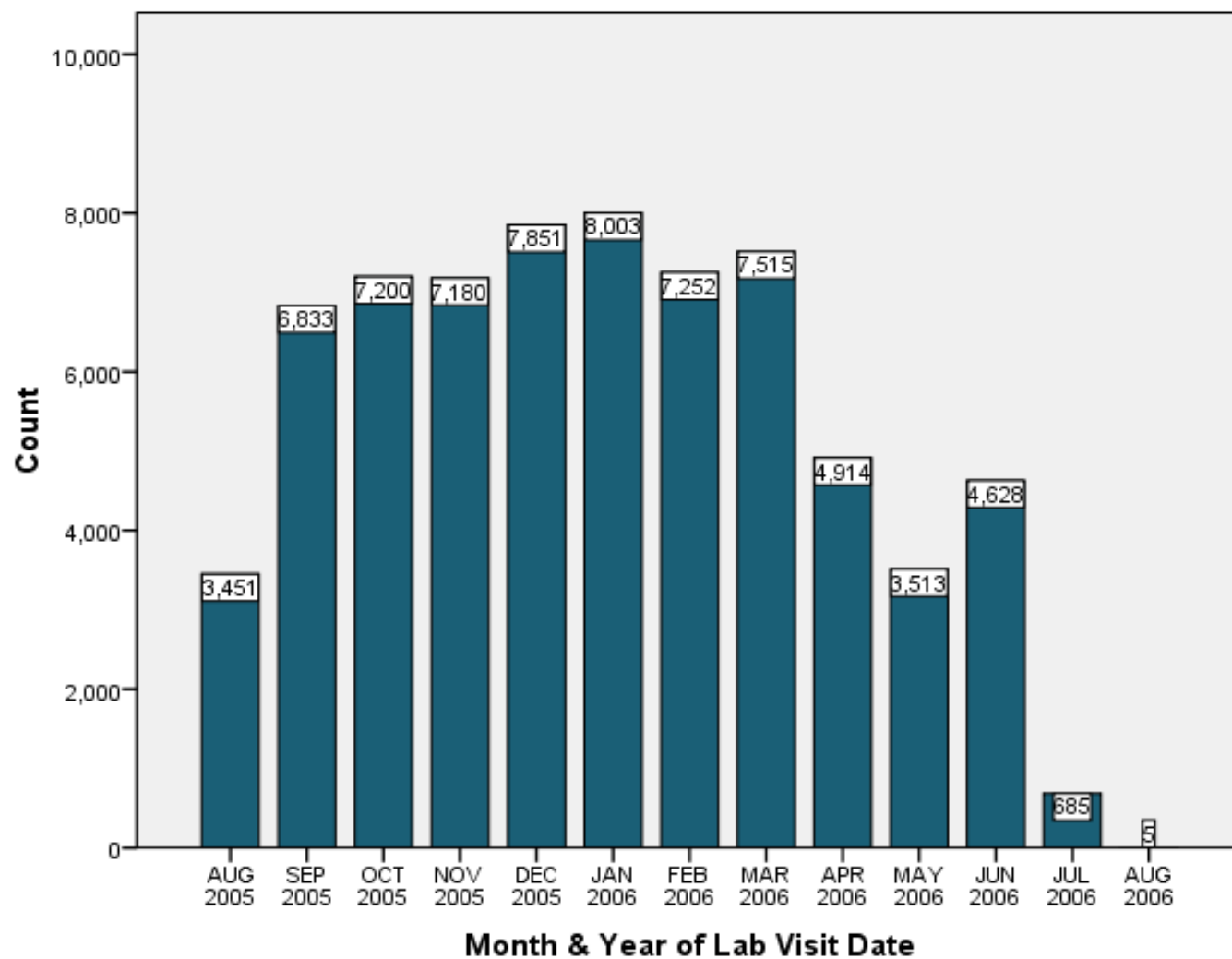


# Preliminary Results – Participants



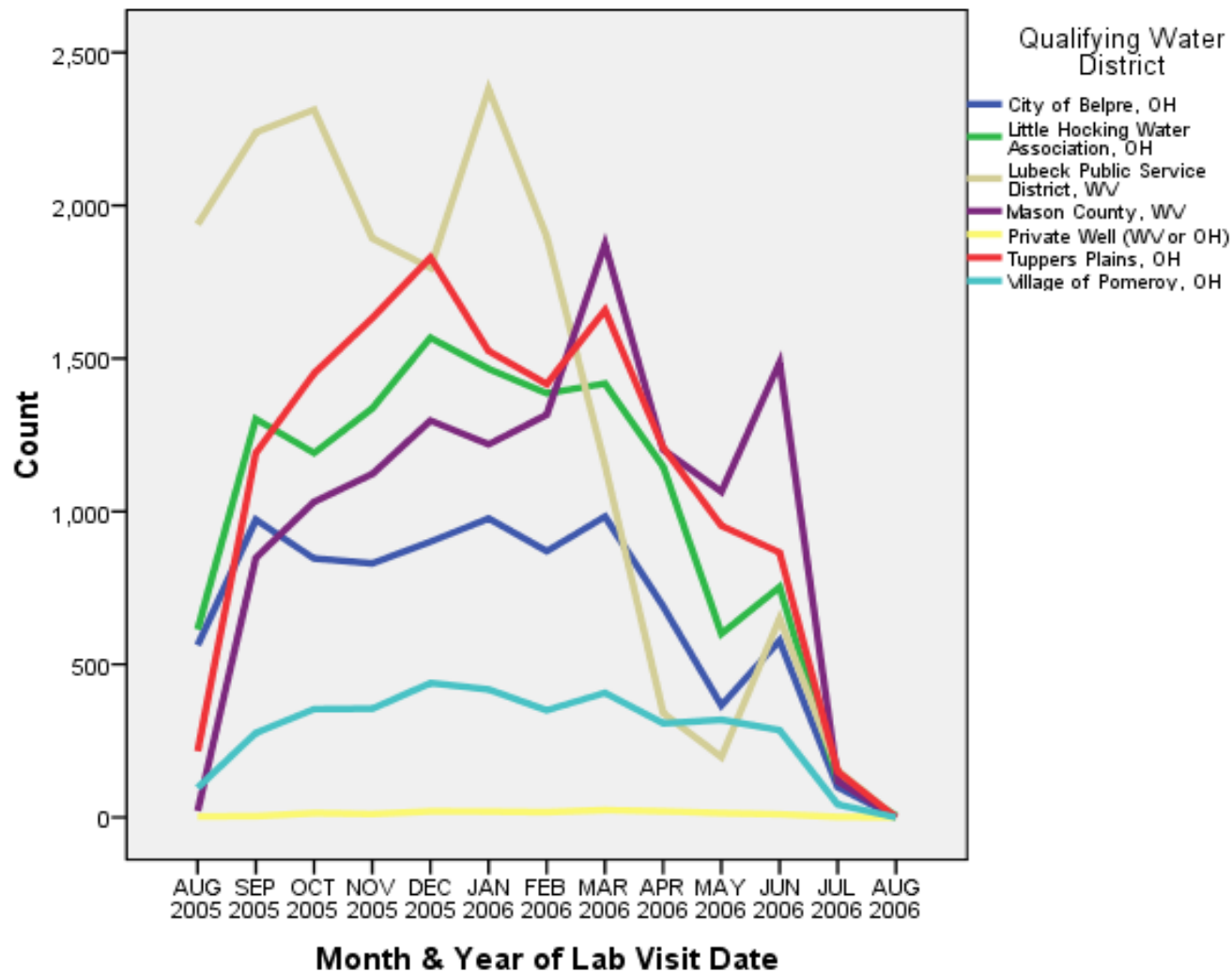


# Preliminary Results – Participants



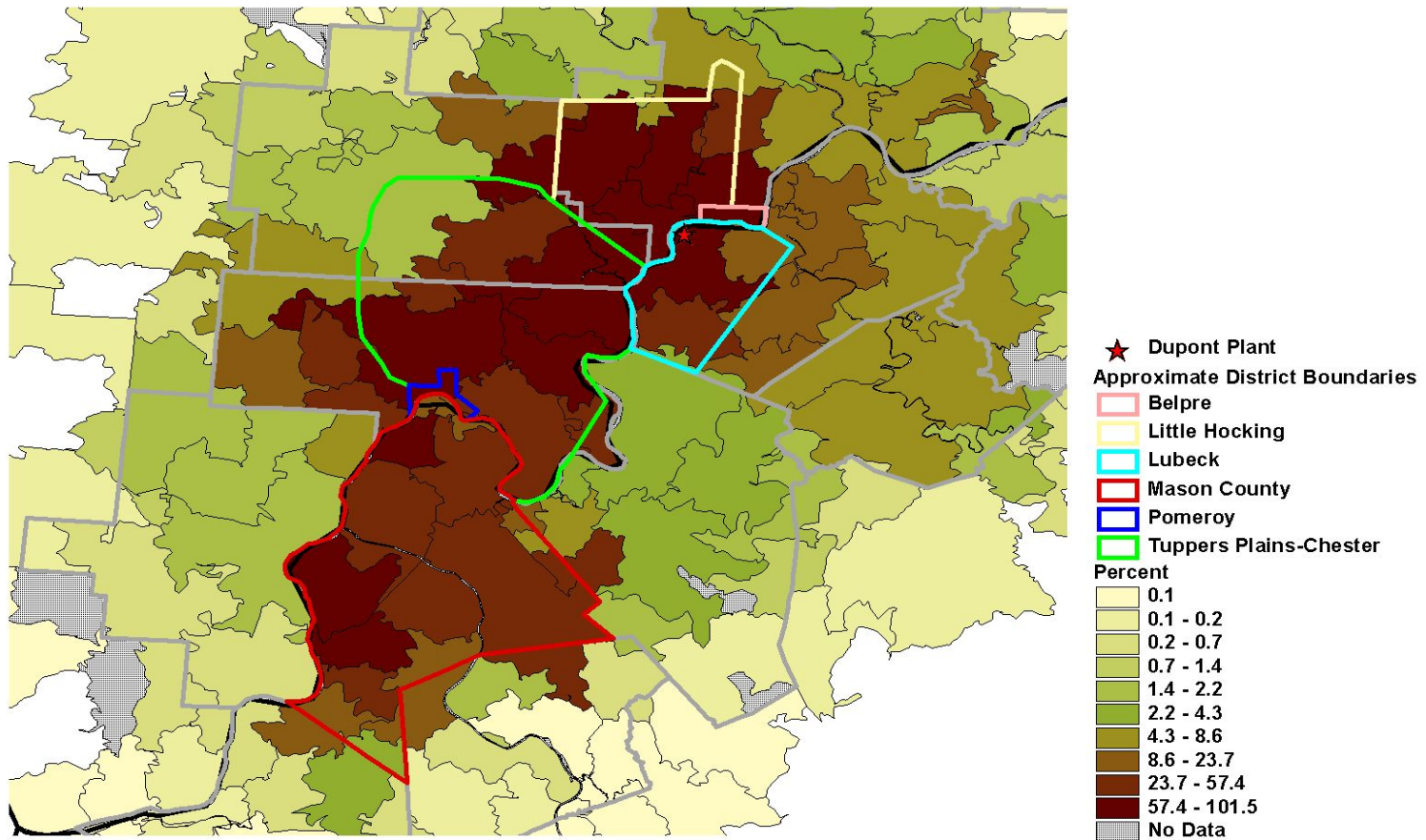


# Preliminary Results – Participants



# Preliminary Results – Participants

**Percent of C8 Study Participants in Relation to Total 2000 Census Population  
For ZIP Code Tabulation Areas (ZCTAs)**





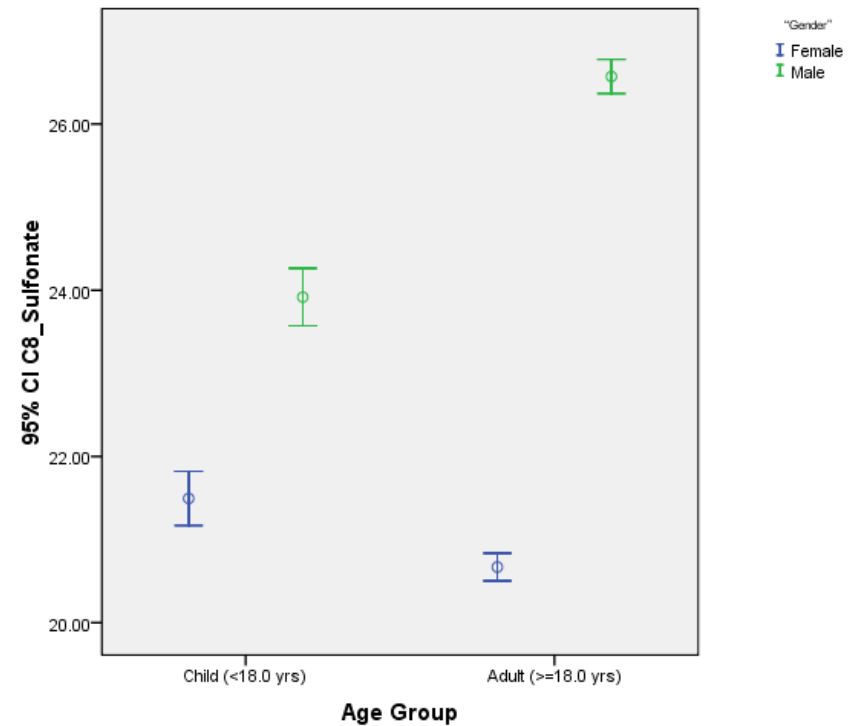
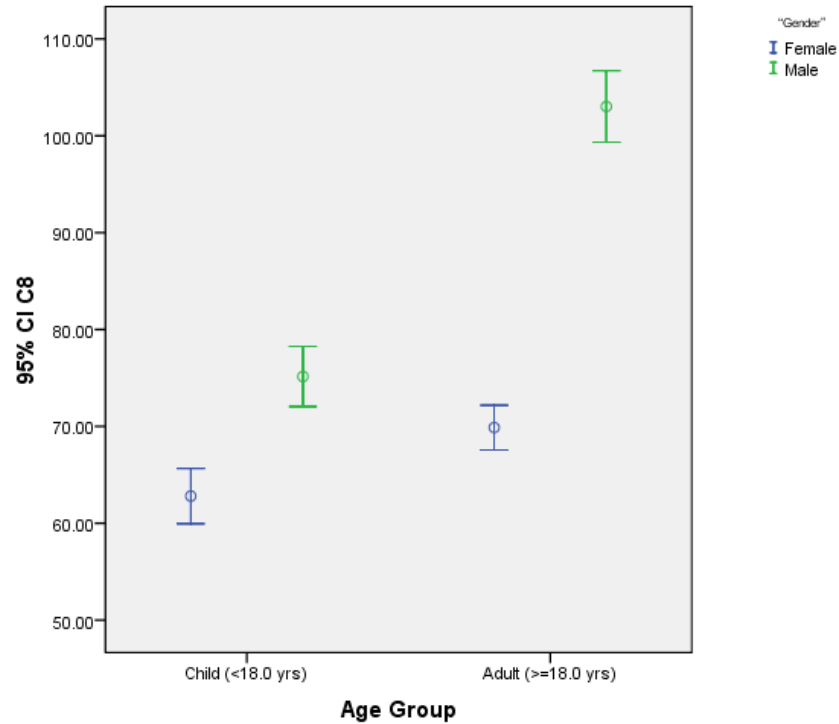


# Preliminary Results – Serum PFCs

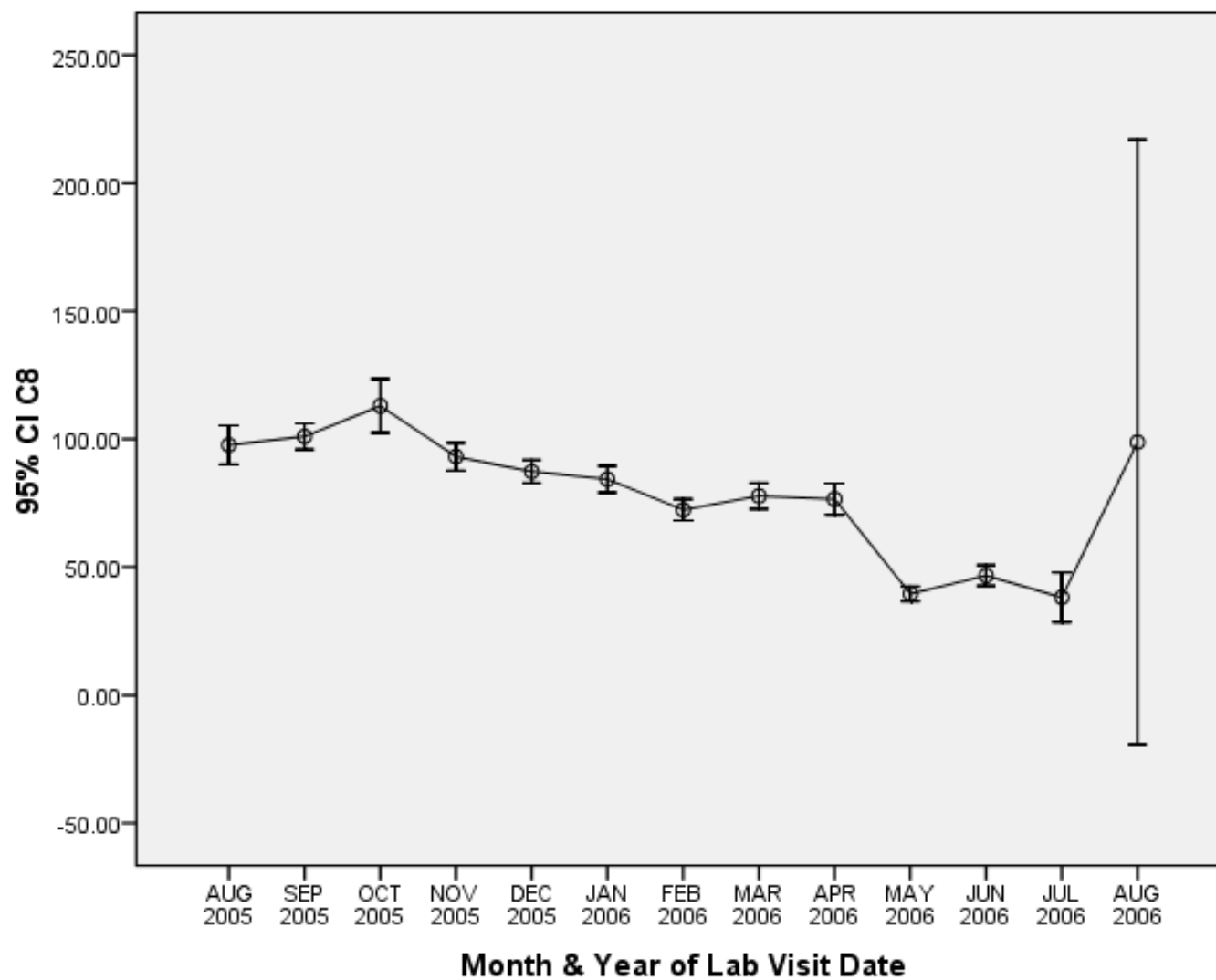
	N	Median	Std. Error of Mean	Std. Deviation	Geometric Mean	NHANES Study*
C5	3247	0.6	0.015	0.85	0.651757	
C6	35573	1	0.006643	1.25	1.134379	
C6_Sulfonate	65499	3.3	0.039241	10.04	3.488315	
C7	25095	0.9	0.007736	1.22	0.99218	
C8	66857	28.2	0.931397	240.83	33.01522	5.2 (4.7-5.7)
C8_Sulfonate	66600	20.2	0.060097	15.51	19.58719	
C9	65348	1.4	0.003359	0.86	1.444741	
C10	30996	0.7	0.003677	0.65	0.707902	
C11	5835	0.6	0.006845	0.52	0.668317	
C12	488	0.6	0.035236	0.78	0.629175	

\*Calafat AM et al 2007. (Geometric Mean)

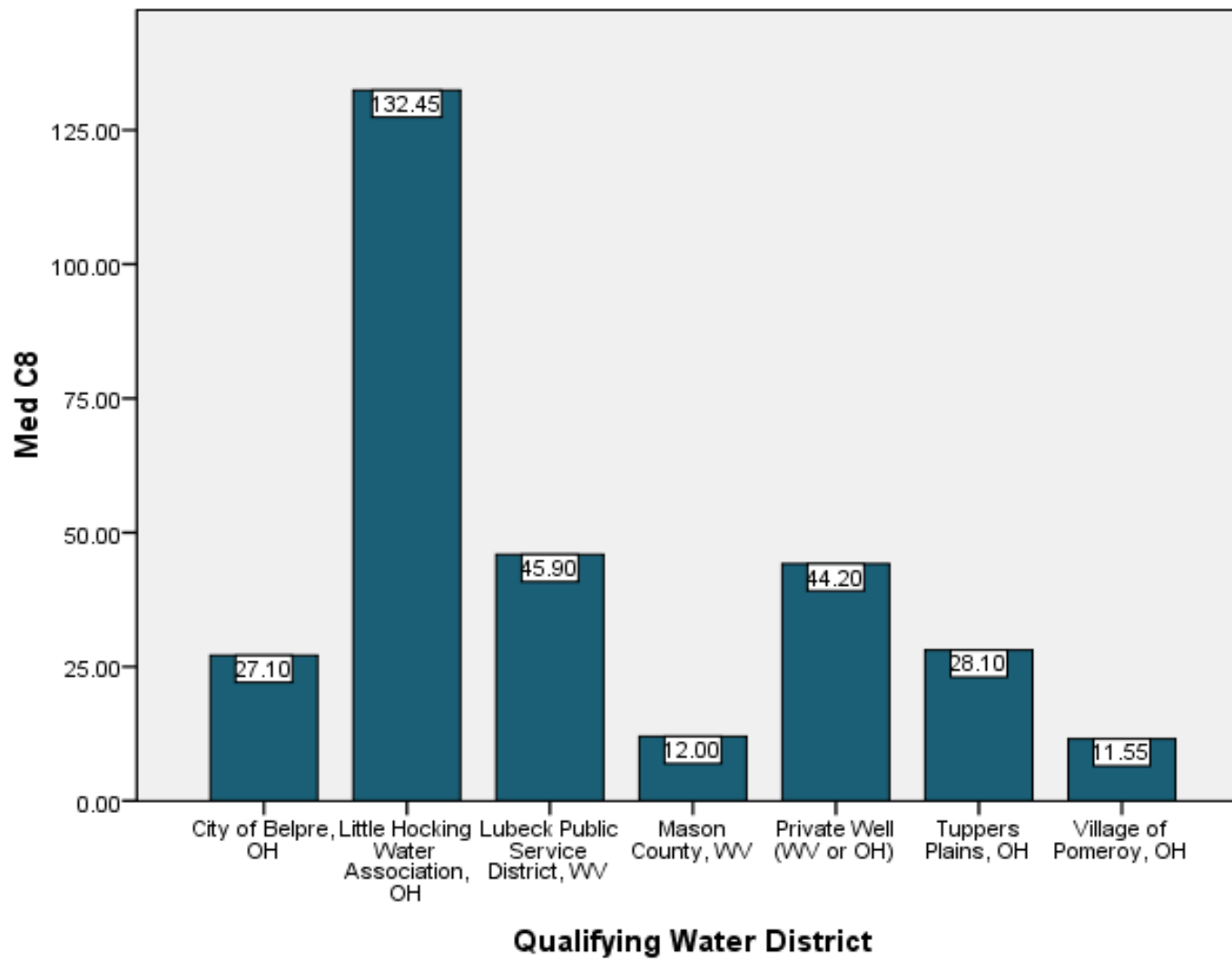
# Preliminary Results – Serum PFCs



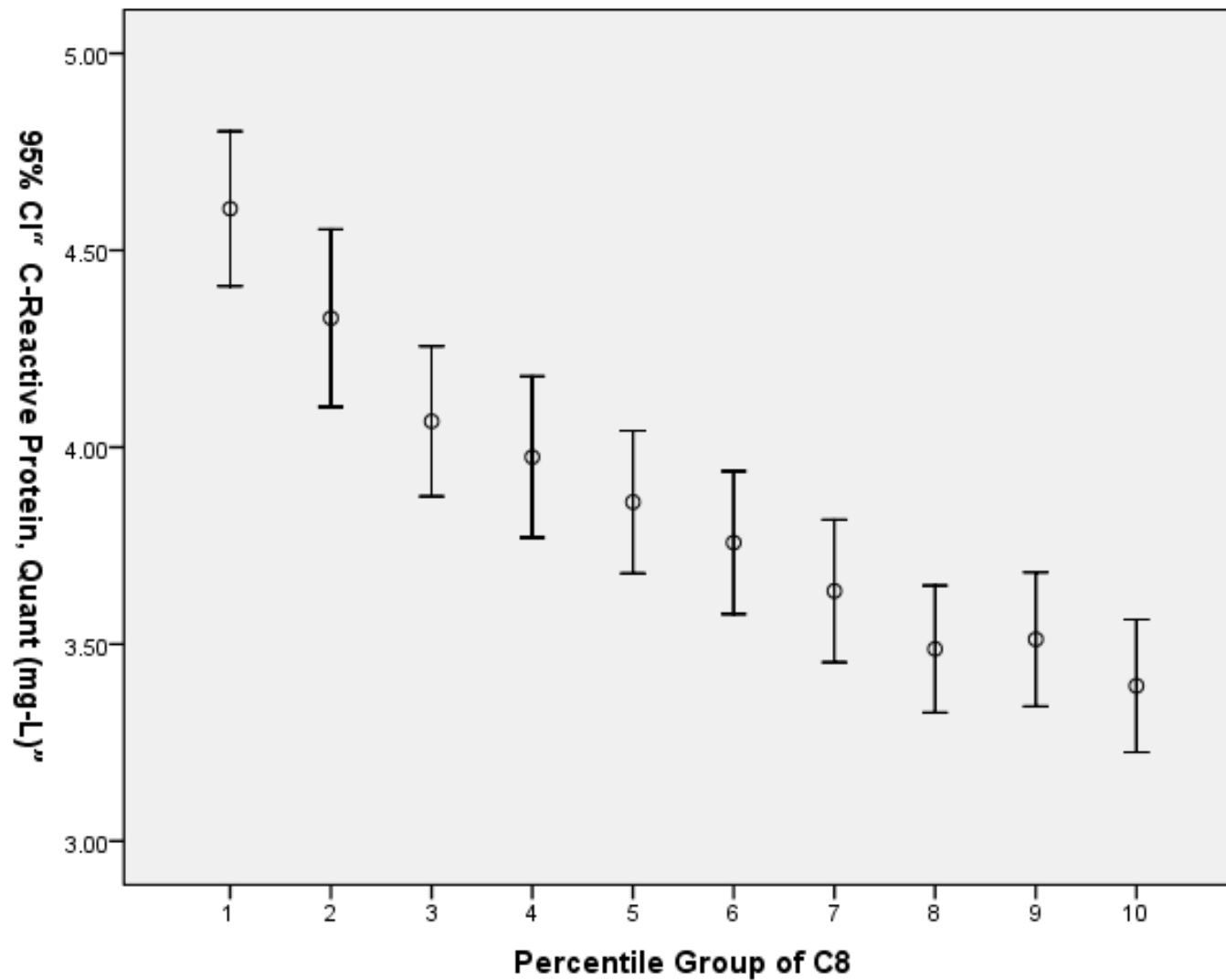
# Preliminary Results – Serum PFCs



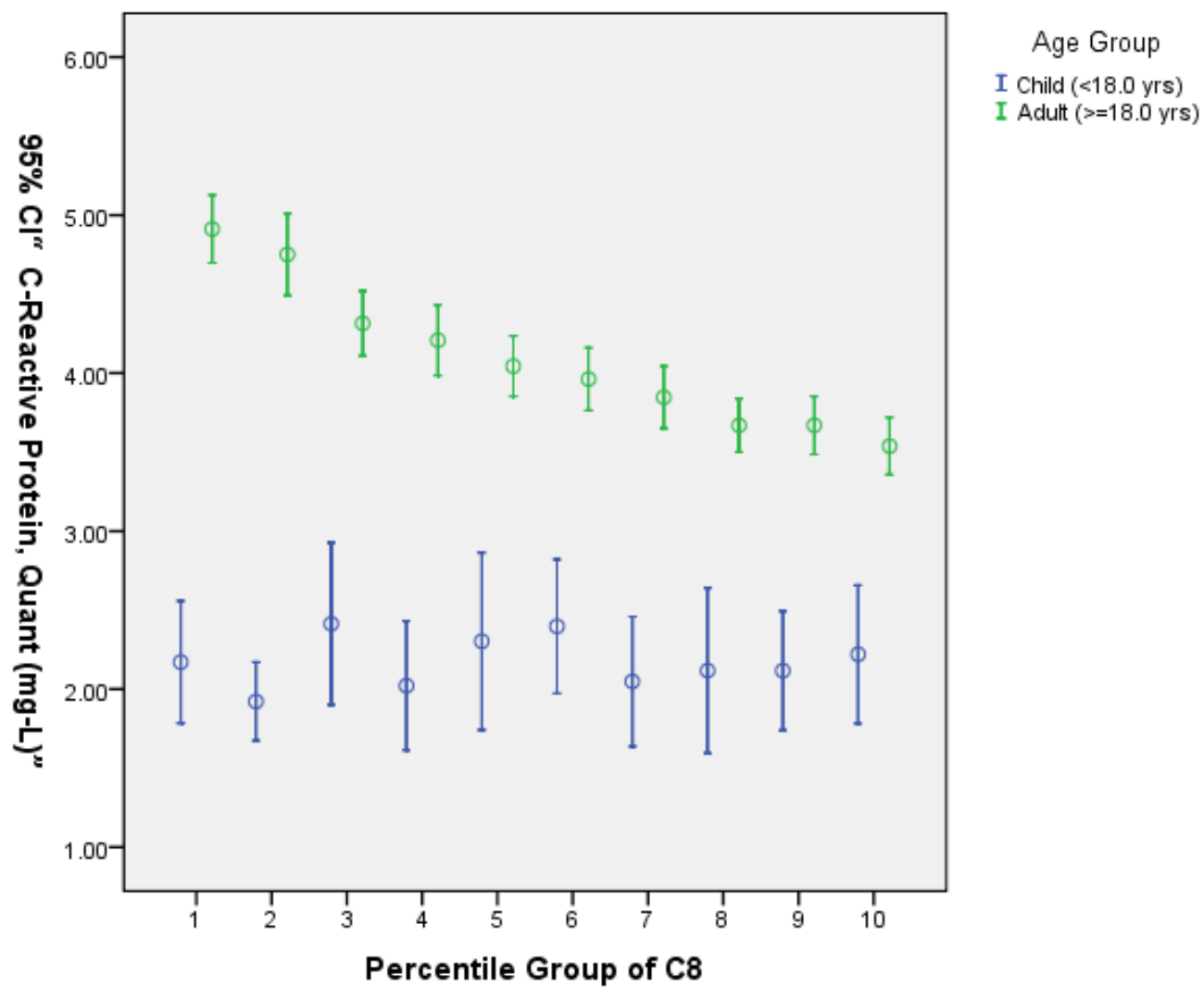
# Preliminary Results – Serum PFCs



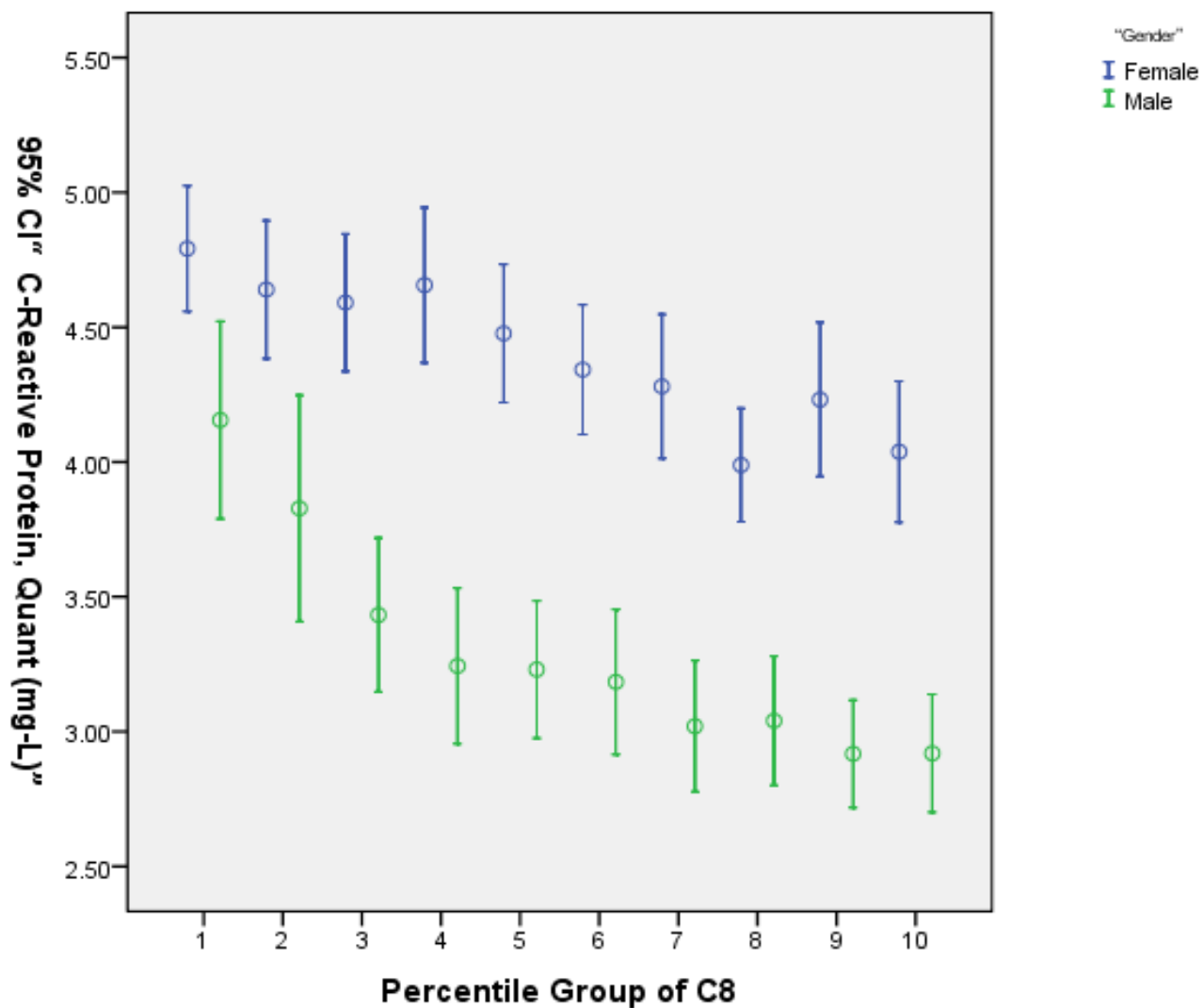
# Preliminary Results – C8 & Inflammation



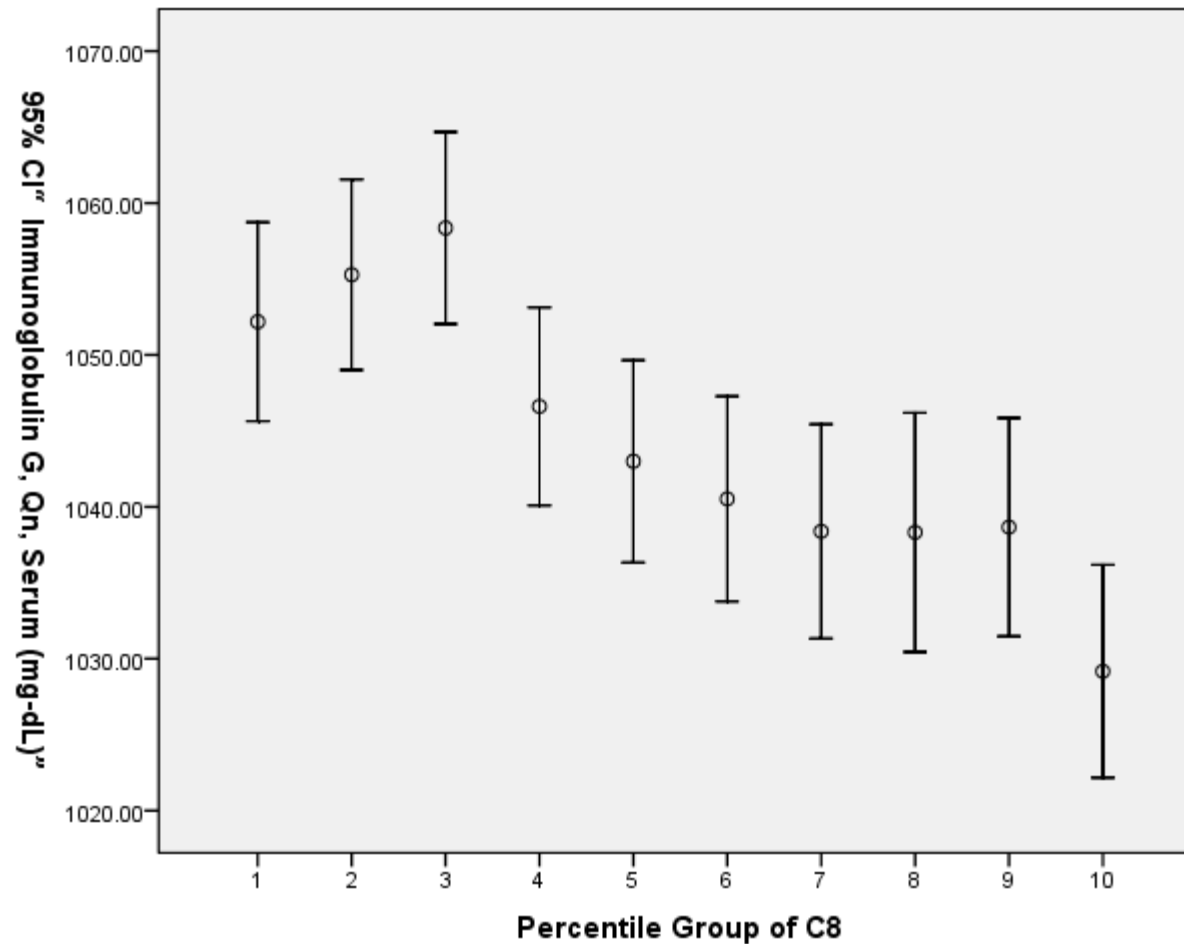
# Preliminary Results – C8 & Inflammation



# Preliminary Results – C8 & Inflammation

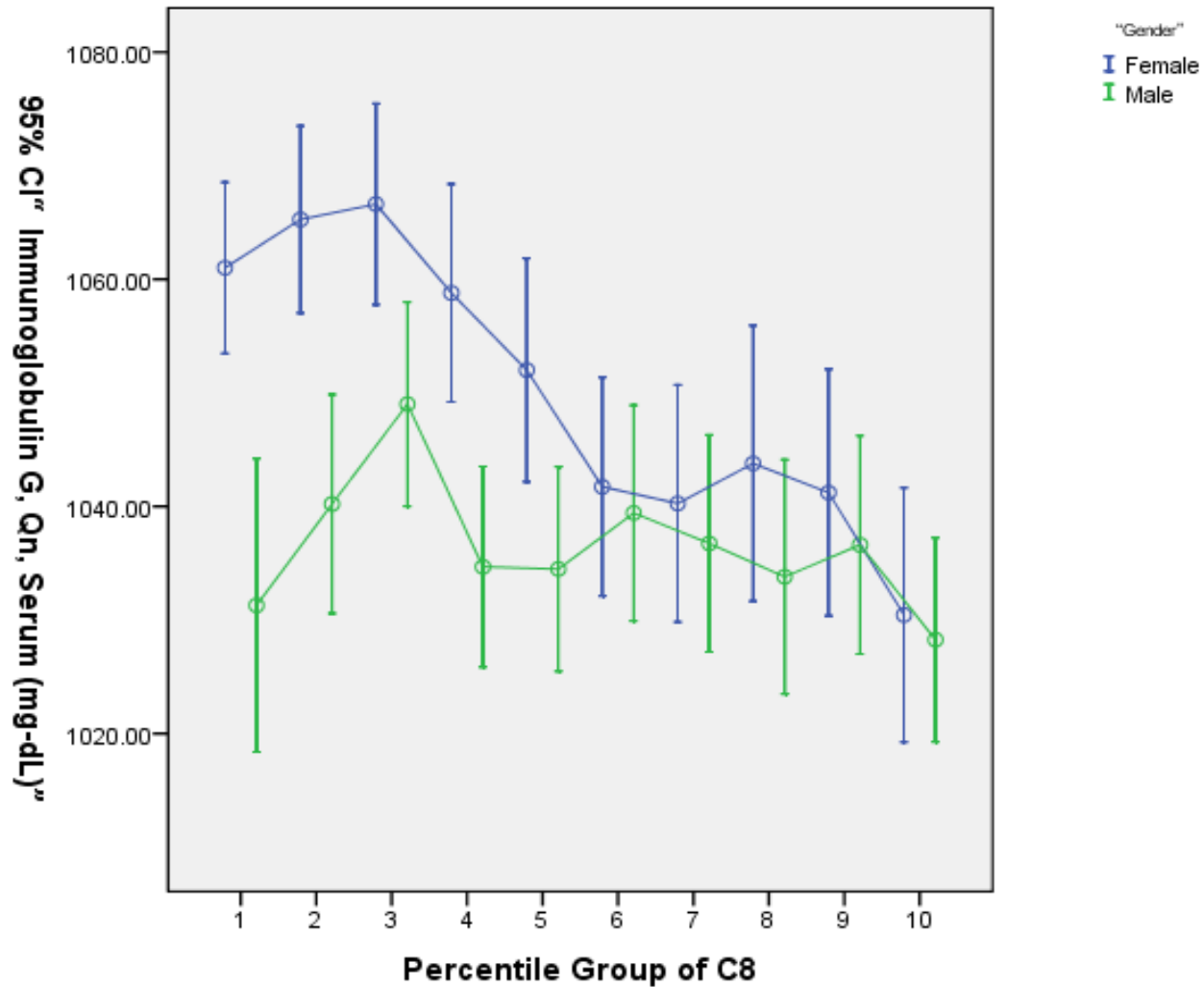


# Preliminary Results – C8 & Immune Function



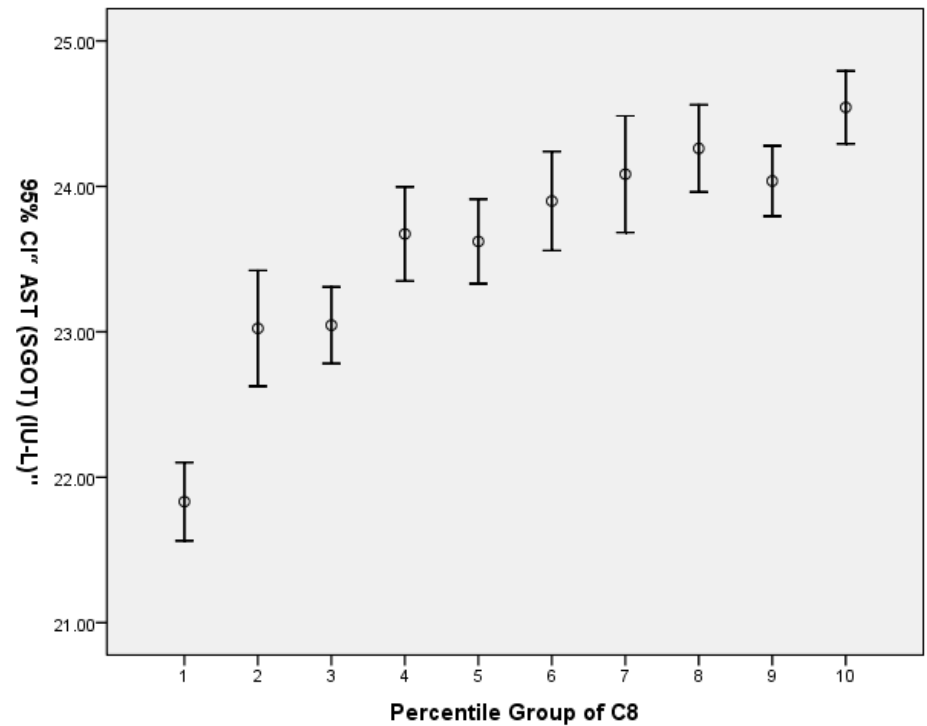
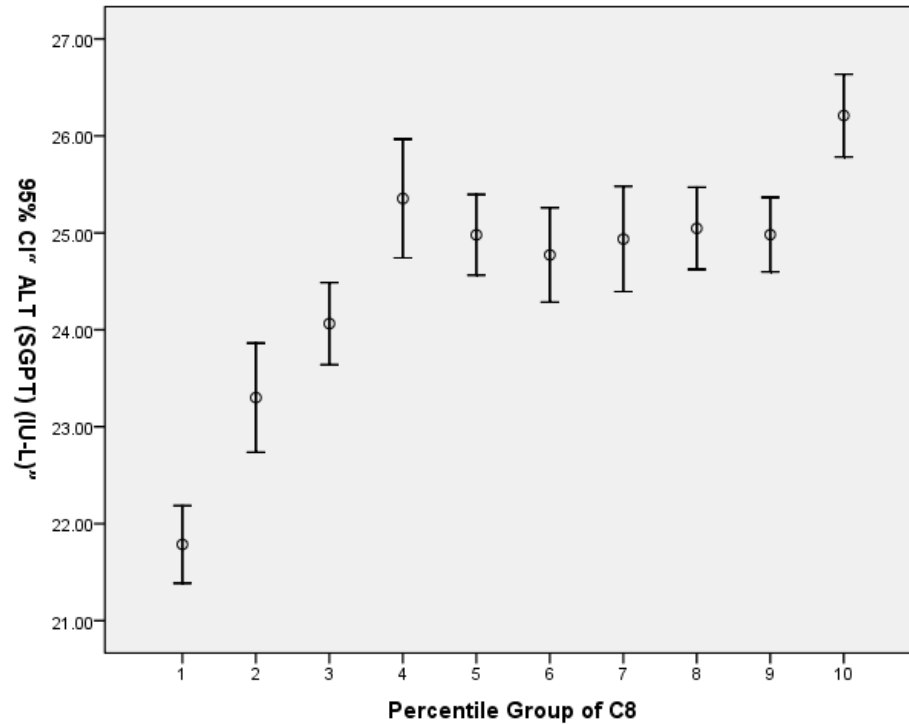


# Preliminary Results – C8 & Immune Function

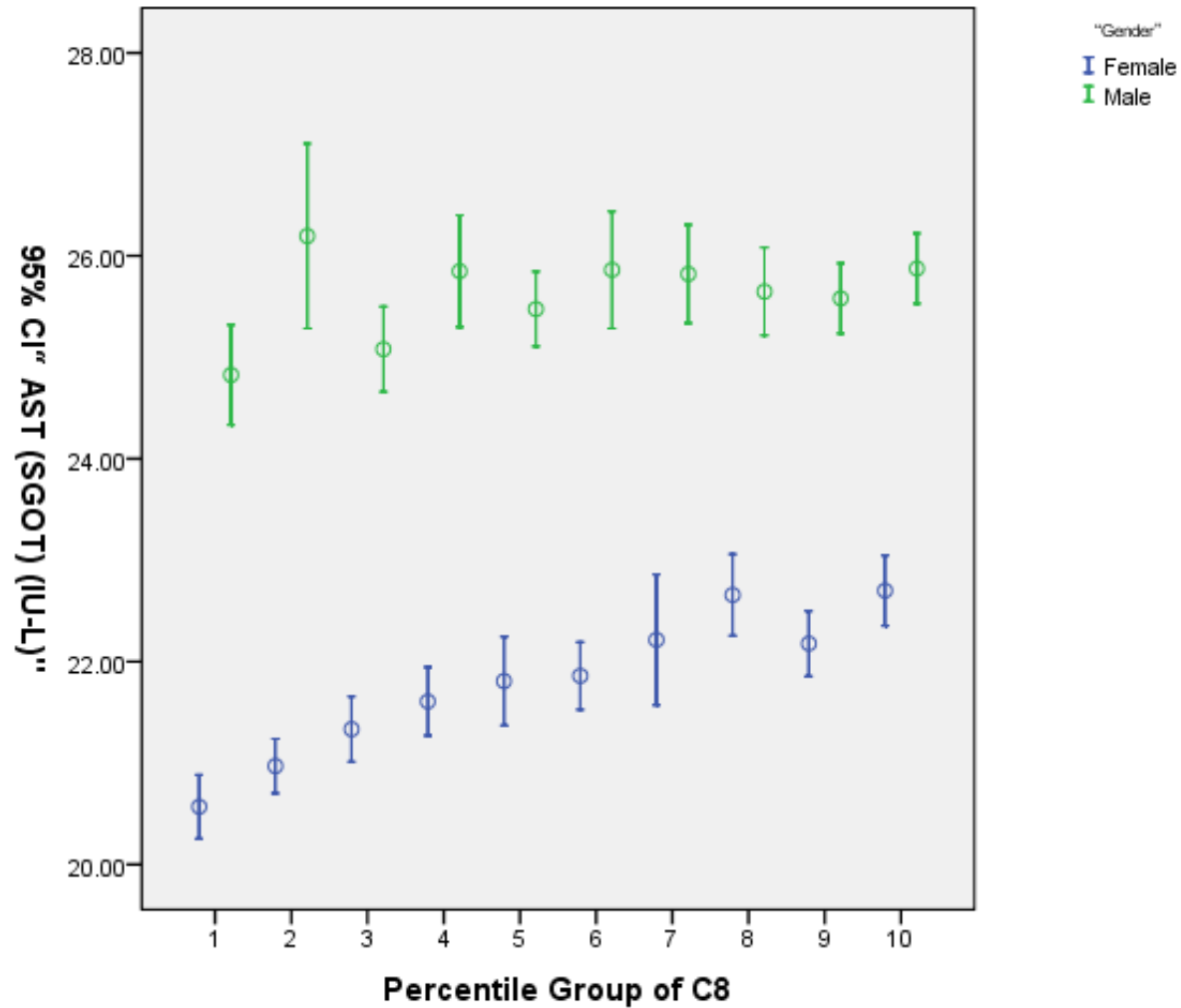




# Preliminary Results – C8 & Liver Function

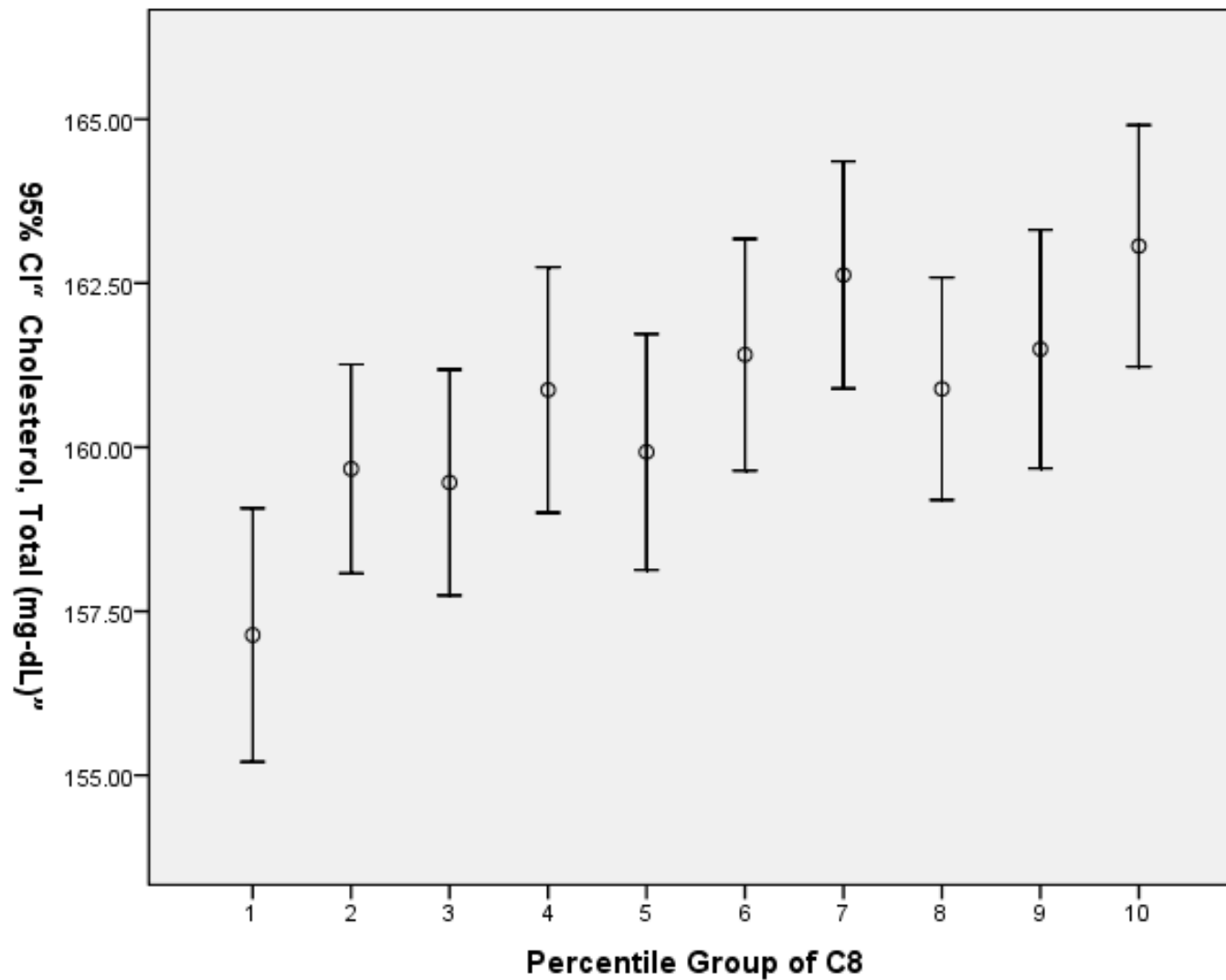


# Preliminary Results – C8 & Liver Function

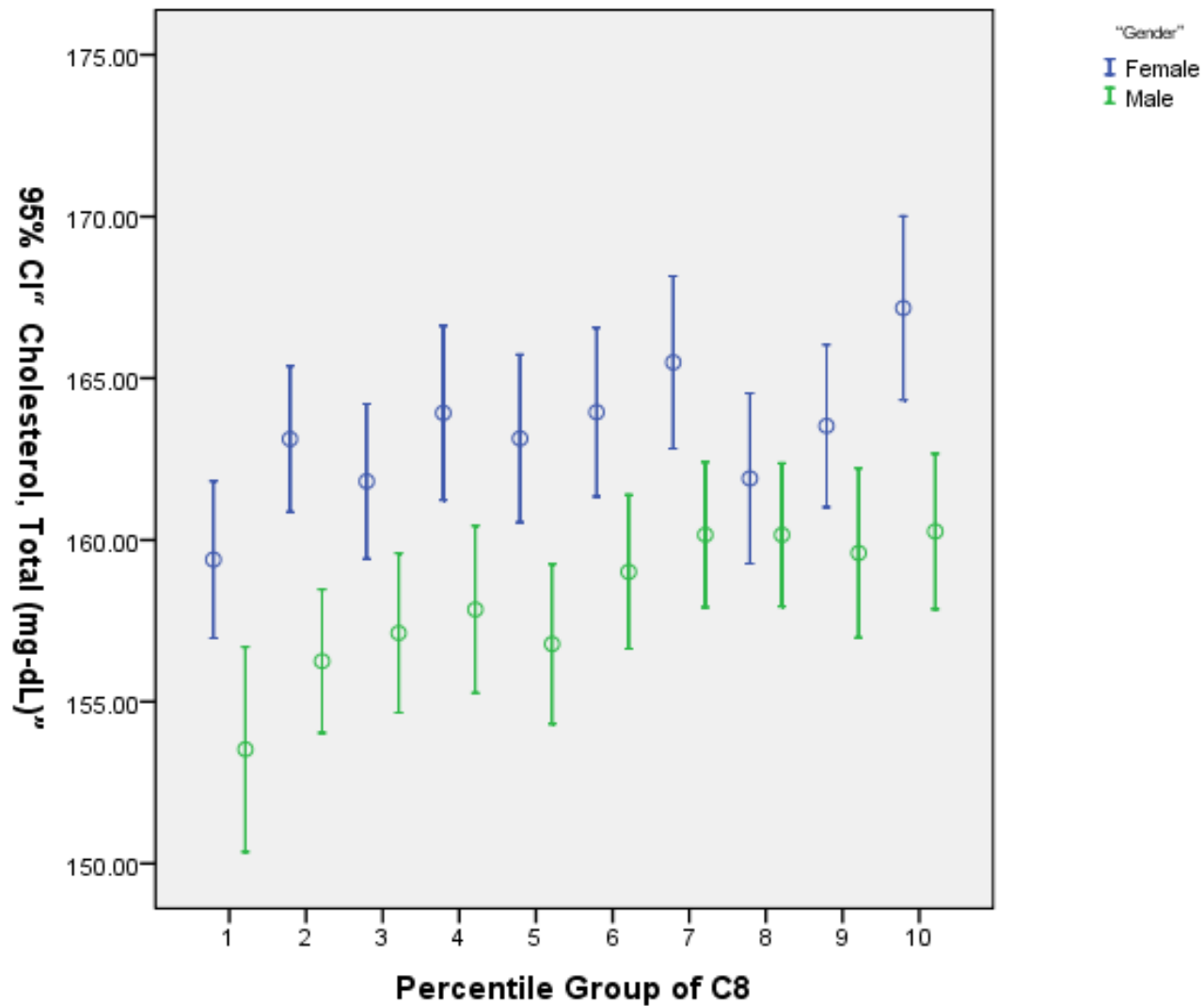




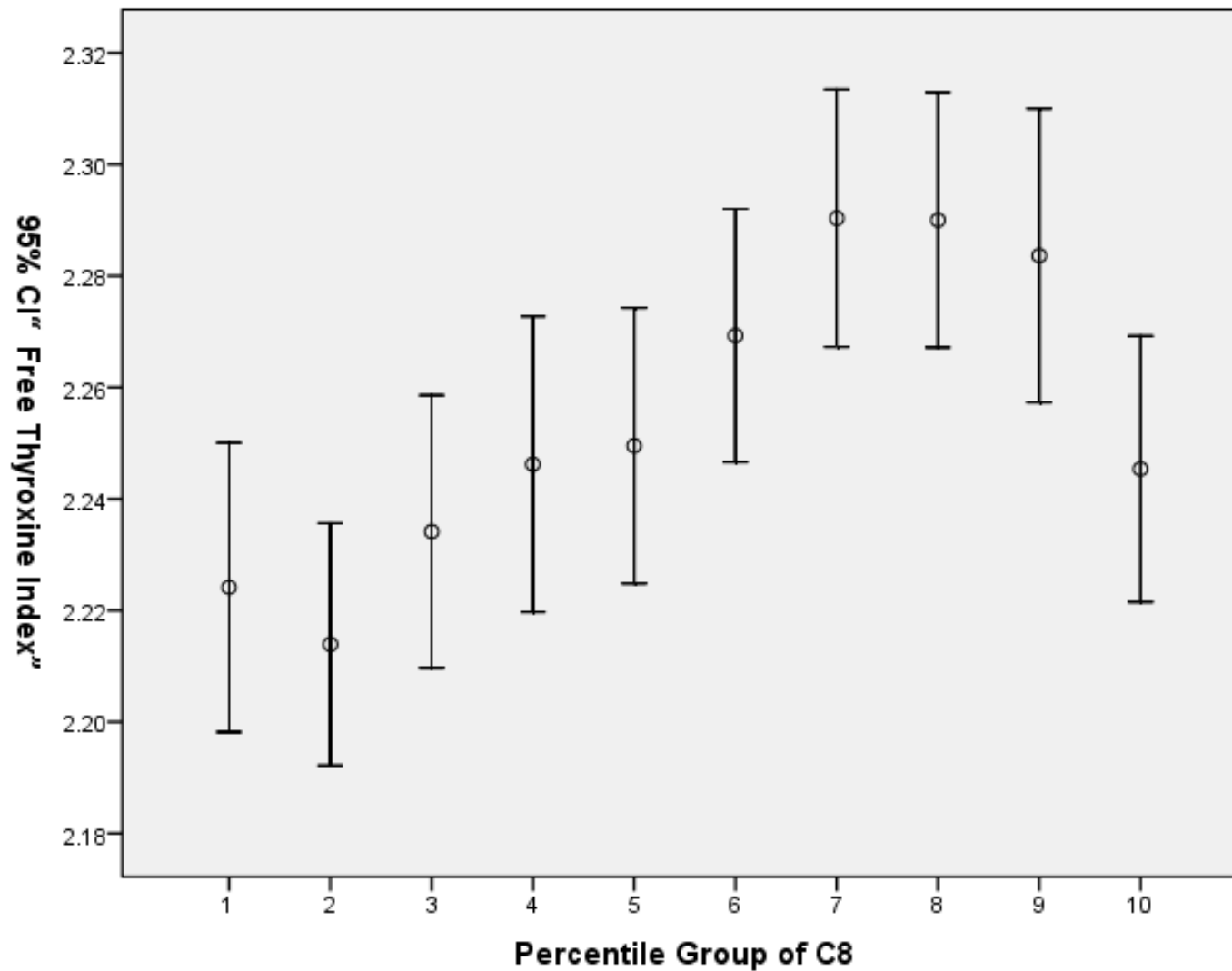
# Preliminary Results – C8 & Cholesterol in Children



# Preliminary Results – C8 & Cholesterol in Children

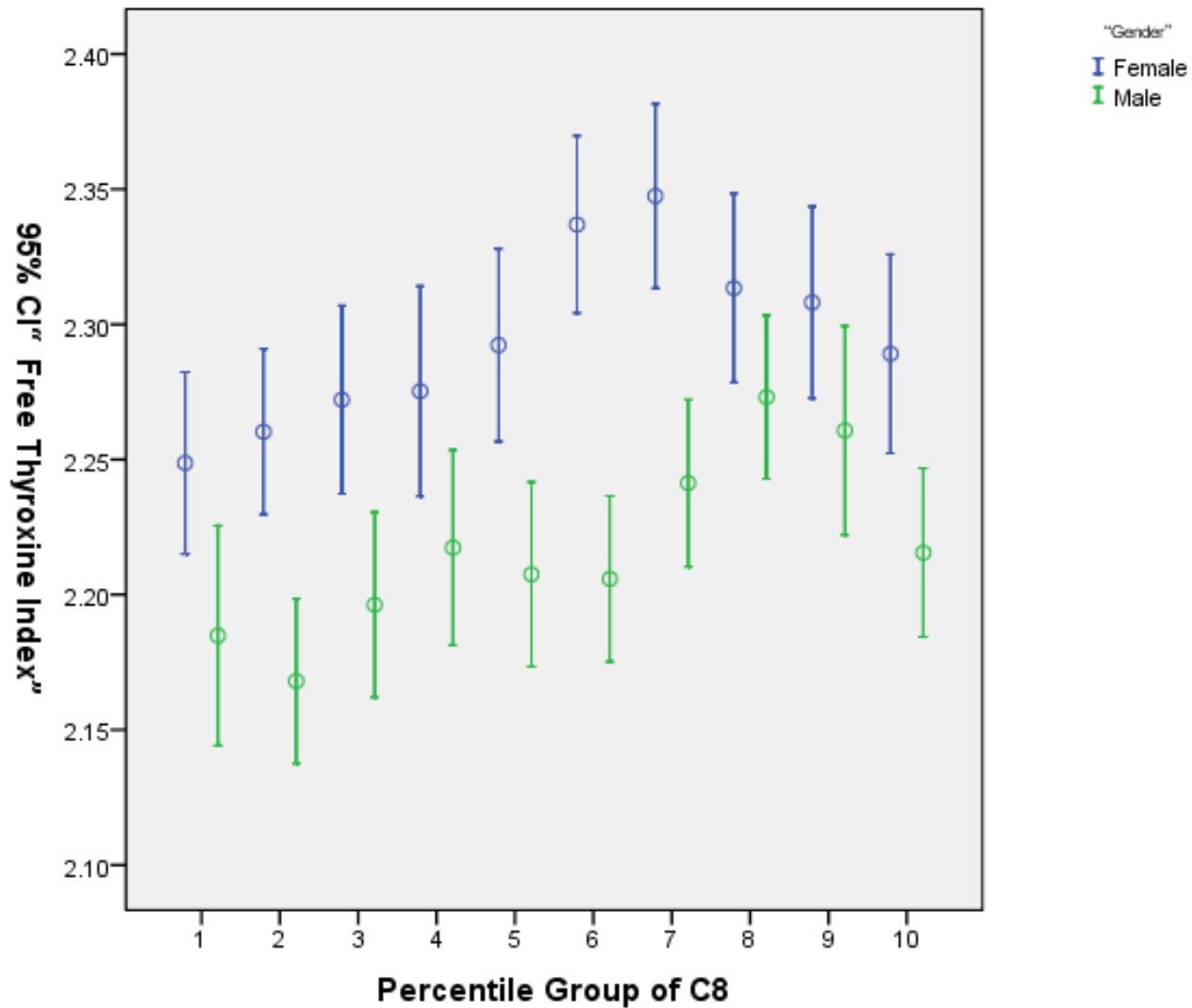


# Preliminary Results – C8 & Thyroid Function





# Preliminary Results – C8 & Thyroid Function





# Recap of Preliminary Results

- 69,030 participants
- Differences in serum concentrations based on age, gender, qualifying water district
- Concentrations in this population appear, at this point, to be higher than in previously reported studies
- Based on preliminary analysis, appear to be associations between C8 and
  - CRP
  - Immune function
  - Liver function
  - Cholesterol
  - Thyroid function





# What's Next

- More rigorous data cleaning
- Analysis
  - Summary reporting to Class
  - Scientific, peer-review
- “Priority Topics”
  - Liver function
  - Thyroid function
  - Hormones
  - Lipids
  - Insulin/glucose
  - Iron and red blood cells (including hemoglobin, hematocrit)
  - Electrolytes.
  - Immune function (including ANA, WBC count, ANA, and CRP)
  - Cardiovascular disease
  - Thyroid and liver disease
  - Vitamins (B12, folate)
  - Cancer markers (PSA, CEA, etc)
  - Uric acid
  - Diabetes
  - Cancer



# C8 Health Project in Context – Public Health

- Strengths
  - Enormous amount of data collected very quickly
  - Wide array of data
    - Extensive clinical labs
    - PFC
    - Validated diagnoses (>38,000)
  - Sample size
- Weaknesses
  - Prevalence data
  - Self-report survey
  - Speed of data collection a 2-edged sword



# C8 Health Project in Context – Intersection of Public Health & the Legal System

- Corporate dilemma
  - Information is liability
  - Toxic ignorance
- Growing instances where court is creating the opportunity and resources to “do science”
  - Pros
  - Cons
- How to maximize opportunities?



# Brookmar, Inc.

- Dr. Paul Brooks, Jr.
- Art Maher
- Patsy Flensburg
- Susan Martin
- Rick Hudson
- CPR
  - Troy Young
  - Richard Whitener



# Science Panel

- Tony Fletcher, PhD, London School of Hygiene and Tropical Medicine
- David Savitz, PhD, Mount Sinai School of Medicine
  - Cheryl Stein, PhD, Post-doctoral Fellow
- Kyle Steenland, PhD, MS, Rollins School of Public Health, Emory University
  - Cathy Lally, MPH, Data Manager
  - Jessica MacNeil, MPH, Research Projects Manager
- Ongoing projects
  - Cardiovascular Risk Factors Measured in the Blood
  - The Immune Function, Liver, Hormone Disorders and Cancer Prevalence Study Based on the C8 Health Project
  - The Community Follow-Up Study
  - The Worker Follow-up Study
  - The Study of Birth Outcomes in the Mid-Ohio Valley
  - The Study of Birth Outcomes among the C8 Health Project Participants
  - The Geographic Patterns of Cancer Study
  - Follow-up Study on Immune Function, Liver and Hormone Disorders
  - The Exposure Study
  - The Half-life Study
- <http://www.c8sciencepanel.org/index.html>



# WVU Project Team

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- Stephanie Frisbee, MSc
- Gerry Hobbs, PhD
- Miriam Mutambudzi, BA
- Shaun Stanley
- Charlotte Firestone
- Erin Bunner
- Joel Halverson, PhD
- Chuanfang Jin, MD, MPH
- Kevin Leyden, PhD
- Xiao-qiang "Sean" Wang
- Yaping Wang
- Wen Hu



# Additional Information & Questions

<http://www.hsc.wvu.edu/som/cmed/c8/index.asp>