Hanford Epidemiology Study

Update

10/4/2012

How This Started

Action F-3.3.3 in the CAP:

"Charter a separate/independent epidemiologic study by a qualified entity (e.g., a university) to assemble the Hanford surveillance data in cohort design to clearly describe beryllium sensitization and CBD risk in the workforce and help identify opportunities for prevention."

External Study Team

- National Jewish Health
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  - Lisa Maier, MD, MSPH
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  - Gina Mondello, BS
  - Bri Barkes, MPH
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  - Kate Serrano, MS
  - Lori Silveira, PhD
  - Dan Khadem, BS
- Titan Consulting
  - Naoyo Mori, PhD

Timeline So Far

- RFA issued 10/2010
- NJH initial proposal submitted 11/10
- Study Team meetings to revise study objectives 3/2011
- Revised proposal submitted 5/2011
- Responded to MSA technical questions 6/2011
- Notice to proceed 8/2011
- Initial study team meeting 10/2011
- Stakeholder meetings 11/2011
- Site tour/meetings with site SMEs 12/2011
- Worker focus groups 3/2012
- Final study protocol 6/2012
- Review of final protocol 7/2012
- IRB submission and review 8/2012
- Study kick-off presentation 10/2012
- Enrollment begins 10/2012

Stakeholder Meetings

- CSC (medical provider)
- Former Workers
- Site IHs
- HR representatives
- Contractor management
- DOE oversight
- HAMTC (Union)
- BAG (affected workers group)

Goals of Stakeholder Meetings

- Make sure objectives of the study meet the needs of stakeholders
- Talk to the Hanford experts
  - Best ways to identify cases/controls
  - Best ways to recruit participants
  - Availability of work history/IH records
  - Address information security issues
  - Logistics, logistics, logistics

Preliminary Information Gathering

- Site tour
- Publicly available reports and literature
- OUO reports and literature
- Site maps
- Lists of buildings
- Lists of job titles
- Lists of processes

Hanford Focus Groups

- 8 groups
- 5-10 workers per group
- Two hour meeting per group
- Recruited through BAG, HAMTC
- Task and area based approach
  - 300 Area
  - PFP
  - D&D workers
  - Reactors
  - Trades/Maintenance
  - PNNL
  - Tank Farms
  - IH (historical and current)

Focus Group Objectives

1. Establish level of detail that we could expect a worker to recall.
2. Learn more about specific processes (fuel production, PFP, PNNL, and reactor exposures).
3. Learn about work organization in crafts, construction, and D&D work.
4. Discuss production era exposures with production era IHs.
5. Determine feasibility of using exposure interview methods from Y-12 and RFETS.

Study Objectives

- Primary
  - Identify past and present high risk jobs, areas, or processes.
    - Guide beryllium medical surveillance activities
    - Identify opportunities for exposure prevention
- Secondary
  - Characterize the prognosis of BeS/CBD at Hanford
  - Characterize prevalence of other potentially beryllium-related health symptoms and medical diagnoses among BeS and CBD cases.
  - Provide data on potential risk factors for sarcoidosis at Hanford

Cases at Hanford

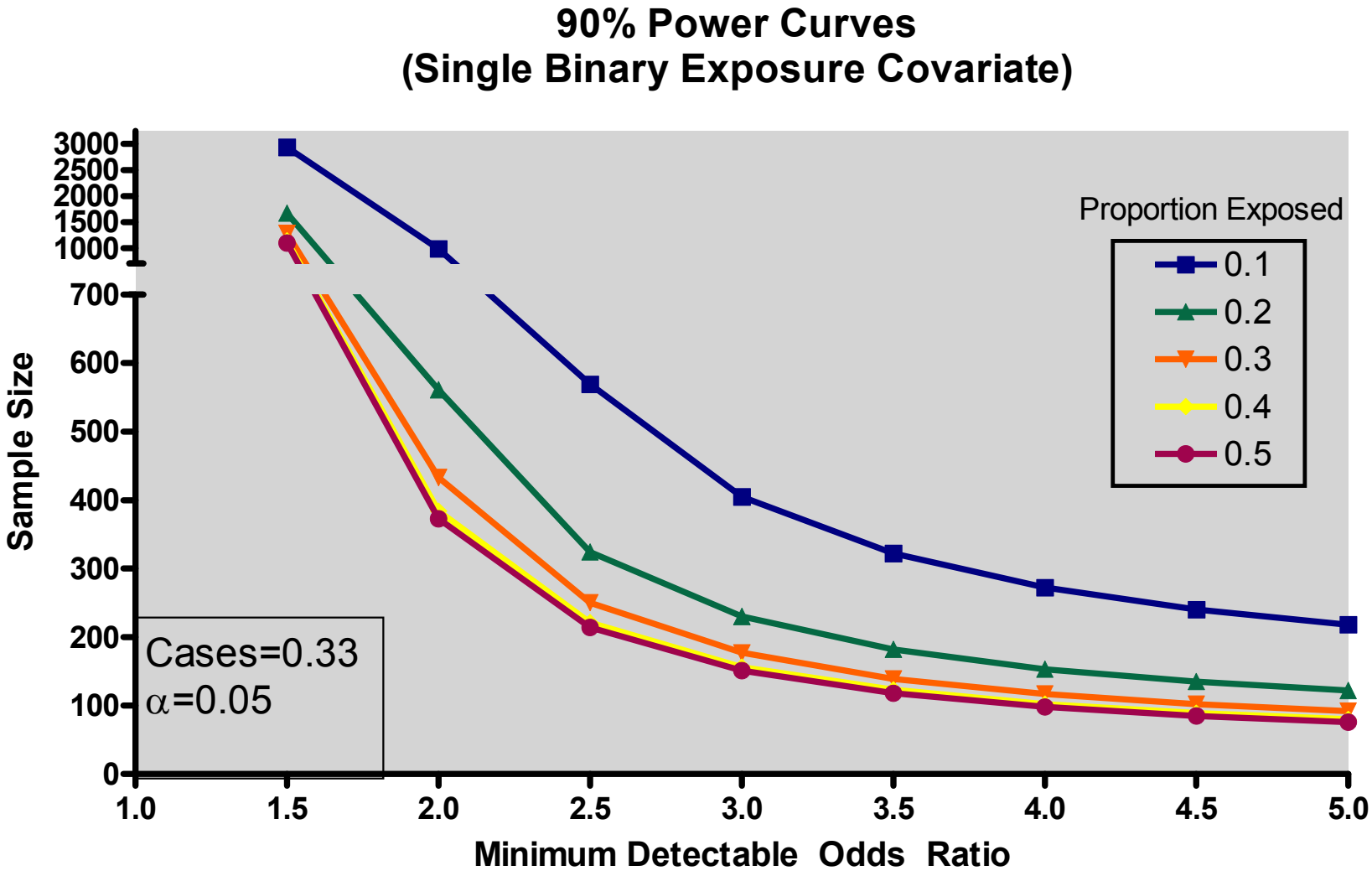
Case Status	Total Cases	Current Worker Cases
BeS	125	84
CBD	33	17
Sarcoidosis	21	14

Study Design

- Case-control study (Current and Former Workers)
  - Cases (BeS, CBD, and Sarcoidosis)
  - Controls
    - Be exposure + 2 normal BeLPTs with one in the last 5 years
    - Enroll 2 controls per case
    - Frequency matched on gender, race, ethnicity, and decade of hire
- Individual exposure/work history interviews
- Medical symptom/diagnosis questionnaire
- Collect available existing IH and medical data

- 1-2 hour time commitment for each participant

Power


90% Power Curves
(Single Binary Exposure Covariate)
Sample Size
3000
2500
2000
1500
1000
700
600
500
400
300
200
100
0
1.0
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
Minimum Detectable Odds Ratio
Proportion Exposed
0.1
0.2
0.3
0.4
0.5
Cases=0.33
α=0.05

Study Recruitment

- Letters: site medical surveillance roster
- BAG meetings
- Site-wide email
- Contractor newsletters
- Website
- Local Media
- Flyers
- Hanford S&H Expo
- NJH onsite presentations

Exposure Interviews

- Method developed using focus groups of Hanford workers
- Questionnaire will be administered by experienced Industrial Hygienists/Researchers
- Interviewers blinded to case-control status
- Work histories will be used by interviewers during interview to help clarify dates
- Workers will classify their work rather than directly assess their exposure
- Similar process used at Y-12 and RFETS

Y-12/RFETS/Hanford Exposure Interview

Interviewer:

Identification #:

Chronologically identify time periods with consistent work practices regardless of job title. A job title might be listed more than once if it consists of distinctly different exposure periods, (different tasks, different control methods, respiratory protection, higher production, etc.) Refer to coding keys.

Work History (Y-12 and other possible Be Exposure Jobs)

#	[redacted]	[redacted]	Facility*	Job Title	Salaried/Non	Task Type*	Task	Exposure Type*	% Time Task	% Time Be	Type of Be*	[redacted]	[redacted]	Buildings*

Coded Tasks, (mill, lathe, grind, etc)

Coded Job Title

0 to 100%

Coded Job Title*:

Notes:

***Refer to attached coding key**

AVERAGE HOURS WORKED PER WEEK:

Beryllium Exposure Assessment

- Starts after exposure interviews completed
- Process based beryllium exposure information
  - Site-wide IH database
  - De-identified IH data
  - 300 complex "Be Books"
  - Existing building characterizations
  - Be registry data
- NJH IH meetings with contractor IH representatives
- Likely will rely on exposure surrogates
  - Building
  - Area
  - Job
  - Process

Exposure Metrics Directly from Interview

Exposure Metric	Units	Description
Beryllium exposure years	Years	Number of years worker was exposed to beryllium
Years since first exposure	Years	Number of years since first beryllium exposure
Process/Bldg related exposure	None	Ever/Never Worked in specific process or building (e.g., Ever/Never Machinist)
Process/Bldg related exposure years	Years per Process	Years worked in specific process or building (e.g., Years as a machinist)
Highest reported exposure type	None	Highest reported exposure (e.g., directly altering a beryllium part, work in same room as beryllium operation, etc.)
Exposure type years	Years per Exp Type	Cumulative time in years reporting a specific exposure type

Quantitative Exposure Reconstruction

Job Title	Job Time (yrs)	Task	% Task	Be Task Exposure ($\mu g/m^3$)	Be Job Exposure ($\mu g/m^3$-yrs)
Janitor	0.08	Cleaning	1.0	0	0
Chem Op Pu Recovery	0.75	Pu Recovery	1.0	0	0
Chem Op 444 Foundry	2.08	Casting	1.0	73.0	152
Clerk Packer	6.17	Etch serial numbers	0.1	1.0	0.6
		Transport Be parts	0.9	0.7	4.3
Clerk Packer	5.25	Transport non-Be Parts	1.0	0	0
Total Work Time:	**14.33**			Cumulative Exposure:	**156.9**

Lifetime-weighted average exposure = 156.9 $\mu g/m^3$-years ÷ 14.33 years = 10.9 $\mu g/m^3$

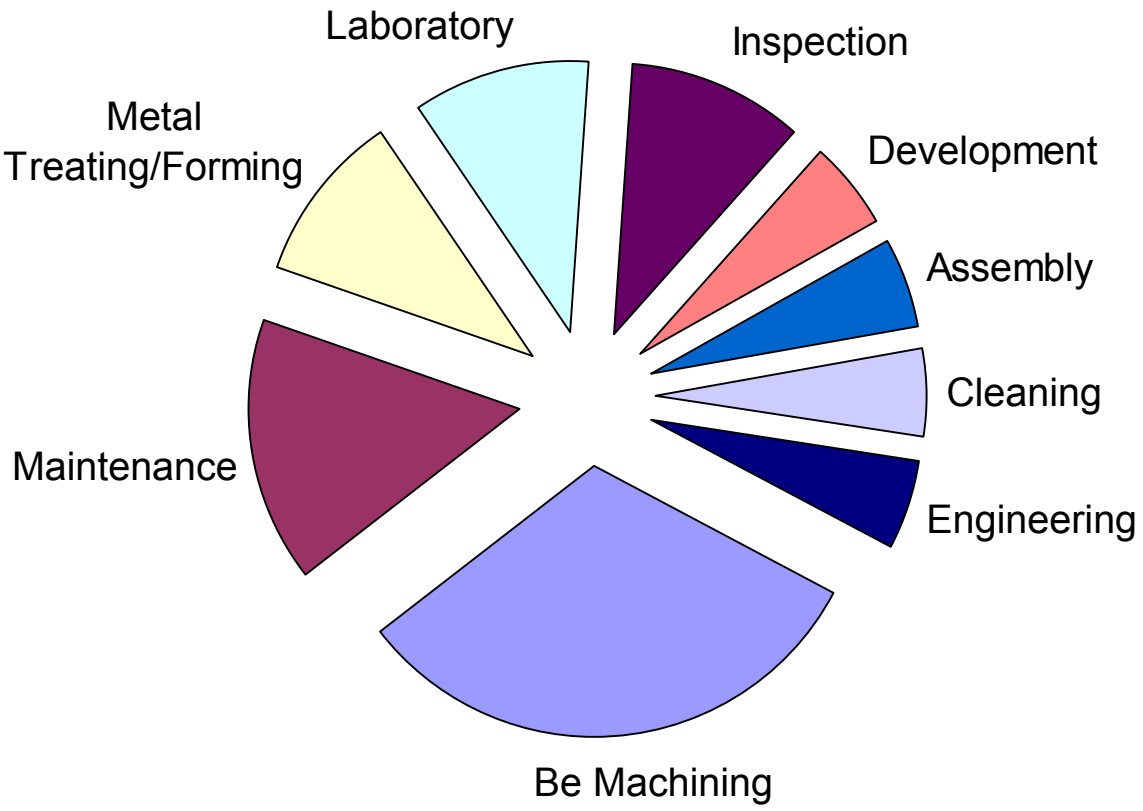
Challenges

- Wide time frame of work histories
- Many job changes
- Existing work histories not necessarily reflective of work locations and tasks
- Production/D&D operations changed frequently
- Very large site with many potential beryllium exposure locations
- Large number of maintenance and construction personnel
- Some beryllium related activities may be classified
- General lack of knowledge of some beryllium operations

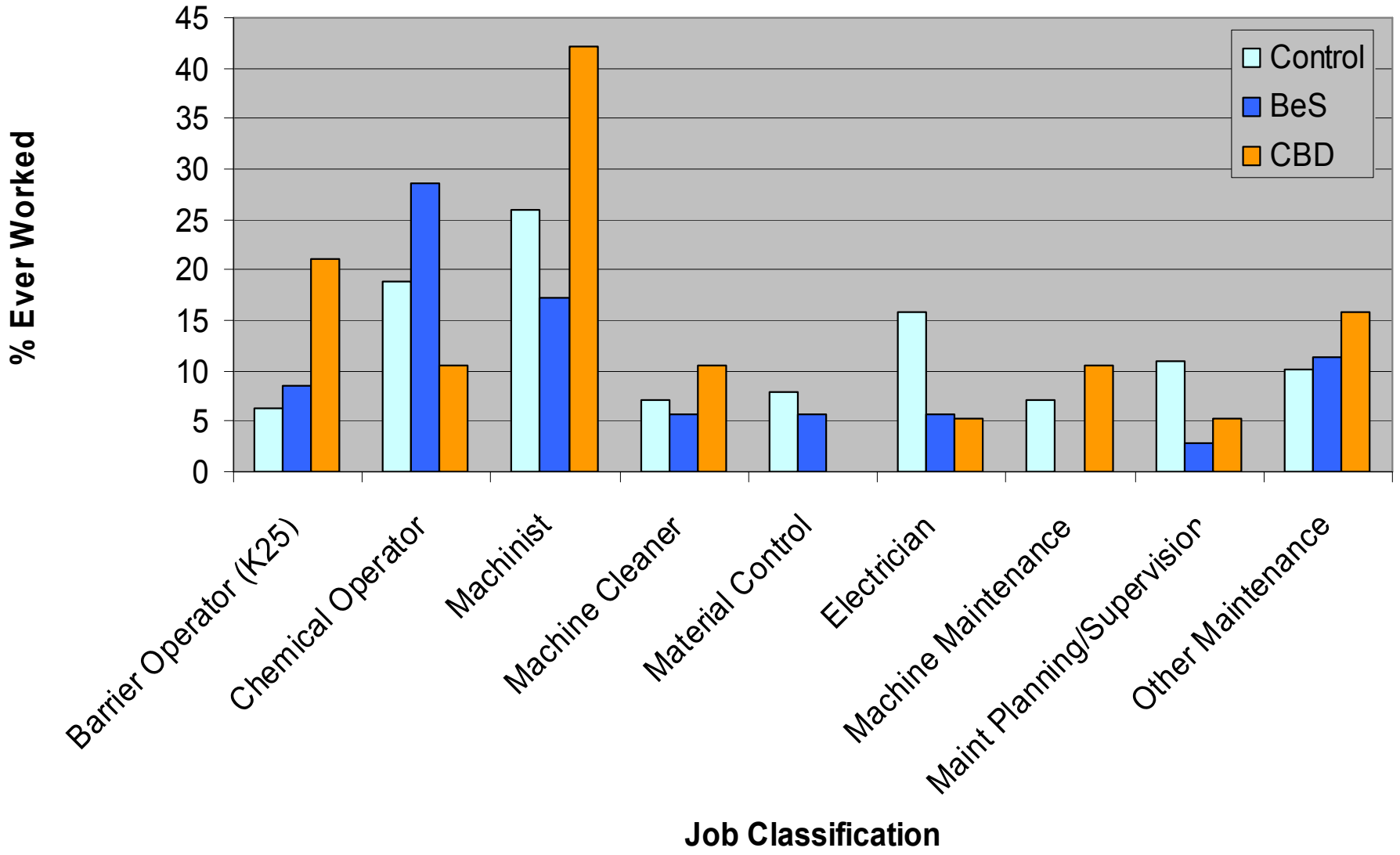
More Challenges

- All current contractors fairly new to the site
- Consider frequent job changes due to RAD exposure
- “Follow the non-sparking tools”
- Fundamental differences in stimulus-related work

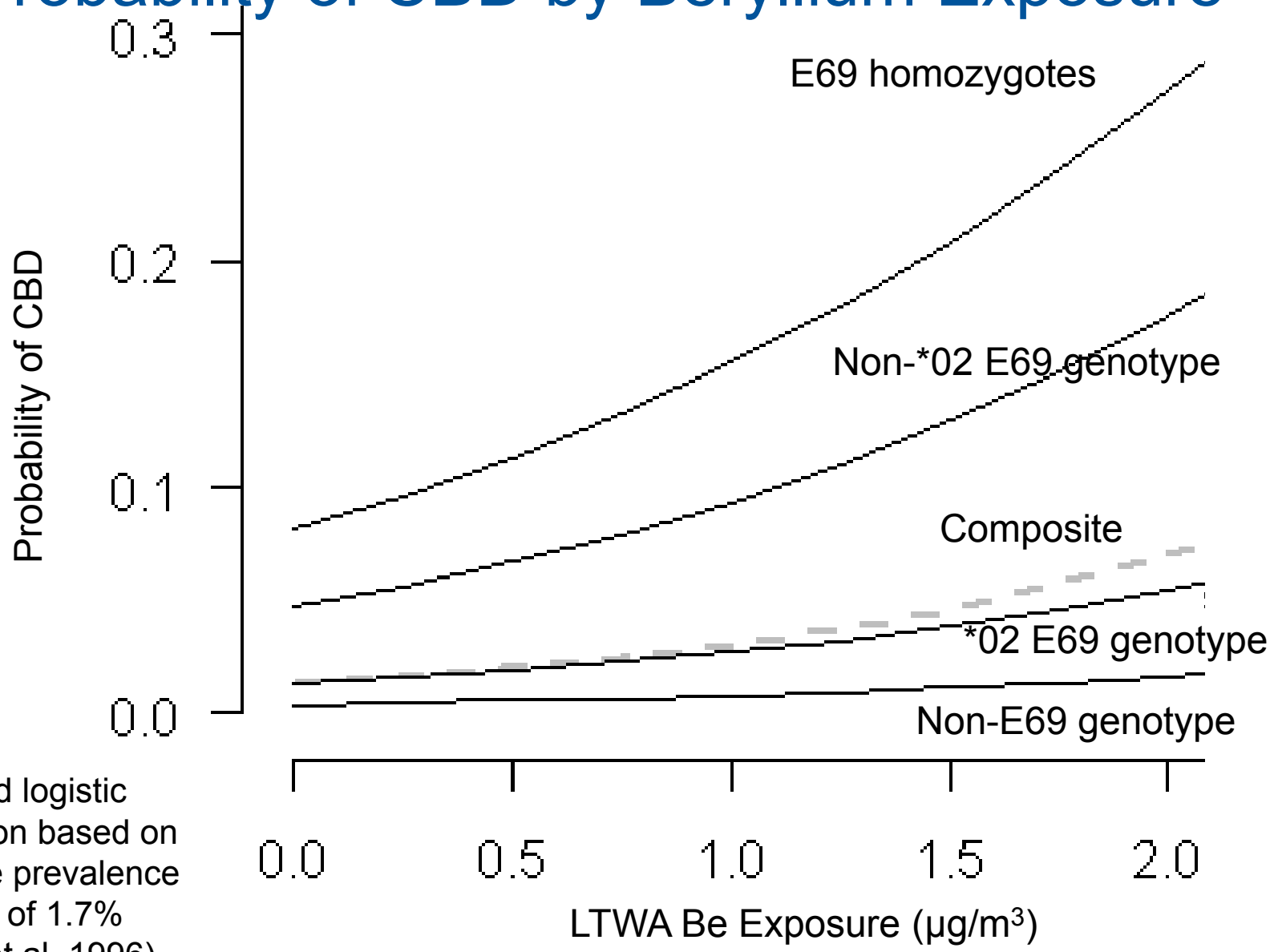
Example Findings from Y-12 Work Categories for CBD Cases



Example Findings from Y-12 Case Status by Job Category



Example Findings from RFETS
Probability of CBD by Beryllium Exposure



Weighted logistic regression based on site-wide prevalence estimate of 1.7% (Kreiss et al. 1996)

Study Timeline

- Study Enrollment – 10/2012 – 2/2013
- Data Acquisition, Management, and Analysis – 2/2013 – 12/2013
- Final Report – 1/2014

Questions?