A Comparison of Respondent Burden, Approaches for Minimizing Respondent Burden, and Outcomes

Lessons Learned from Two Cohort Studies with Nested Designs for Congressional and Court Mandated Research

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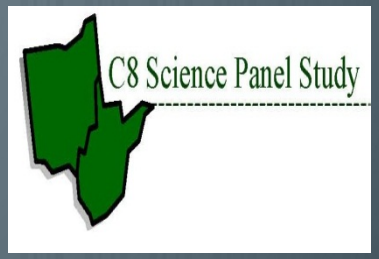
Charlie Knott, Christopher Lyu

Battelle Health & Analytics



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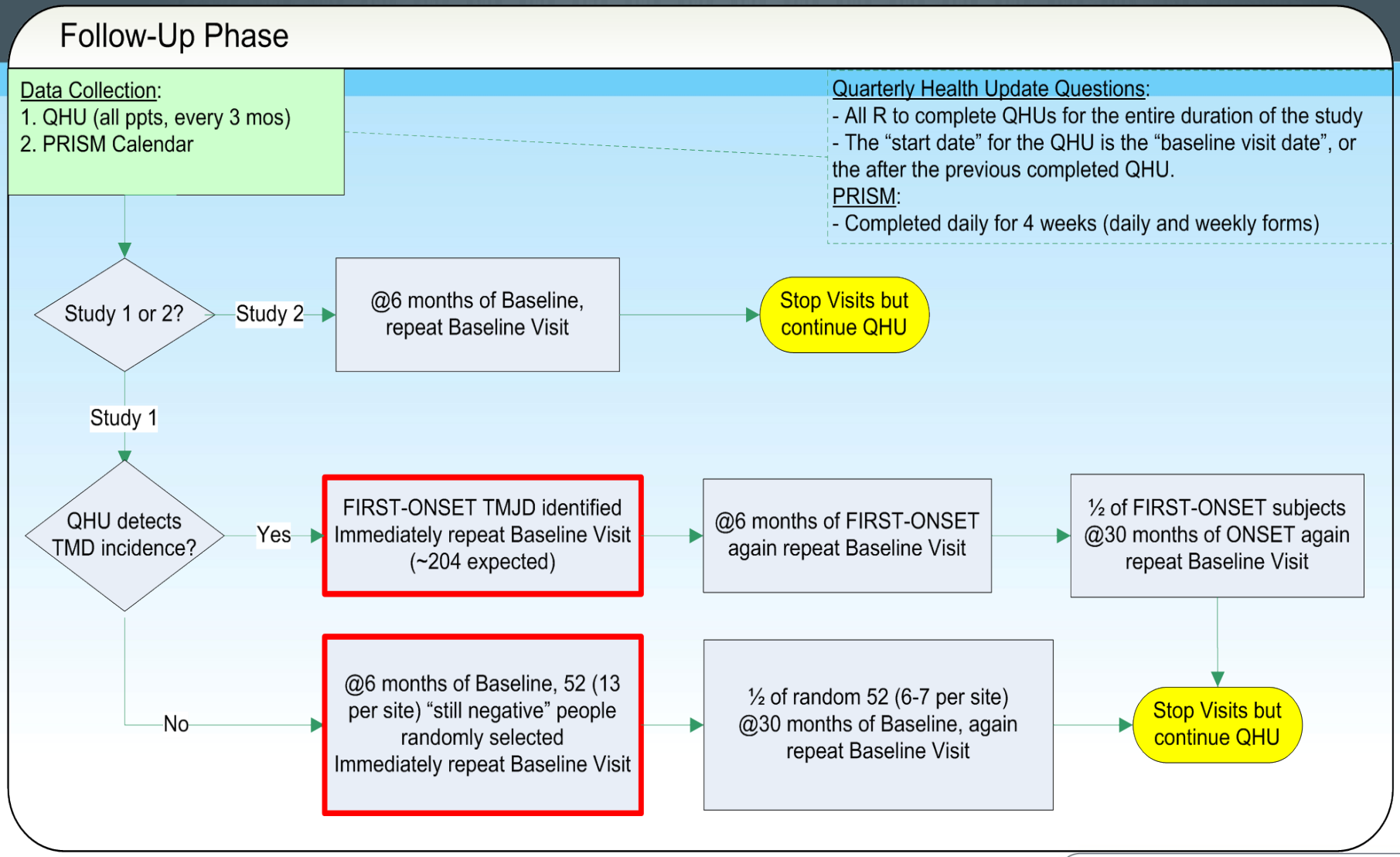
Overview

- 2 Case Examples involving 3 Studies
- Backgrounds
- Methods
- Response Rates
- Conclusions

Case #1: Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) Background

- Prospective Cohort Study (aka Study #1)
  - with a nested Case-Control Study (aka Study #2)
- 4 US Eastern Dental Schools and Clinics
  - UNC, Chapel Hill, NC
  - UF, Gainesville, FL
  - UMD, Baltimore, MD
  - UB, Buffalo, NY
- Ages 18-44
- Live in area for the next two years
- Short-term active follow-up

OPPERA Active Follow-up



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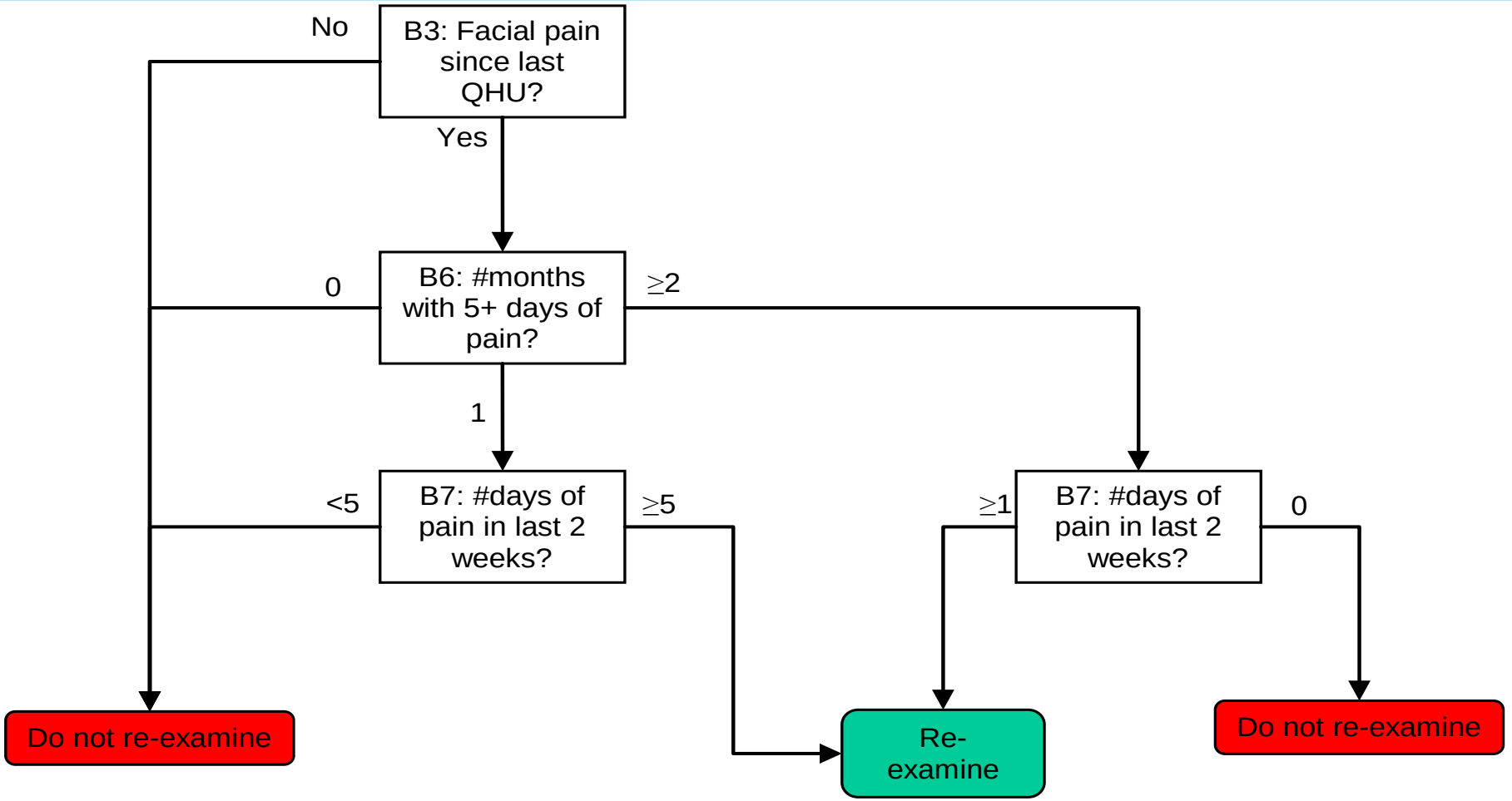
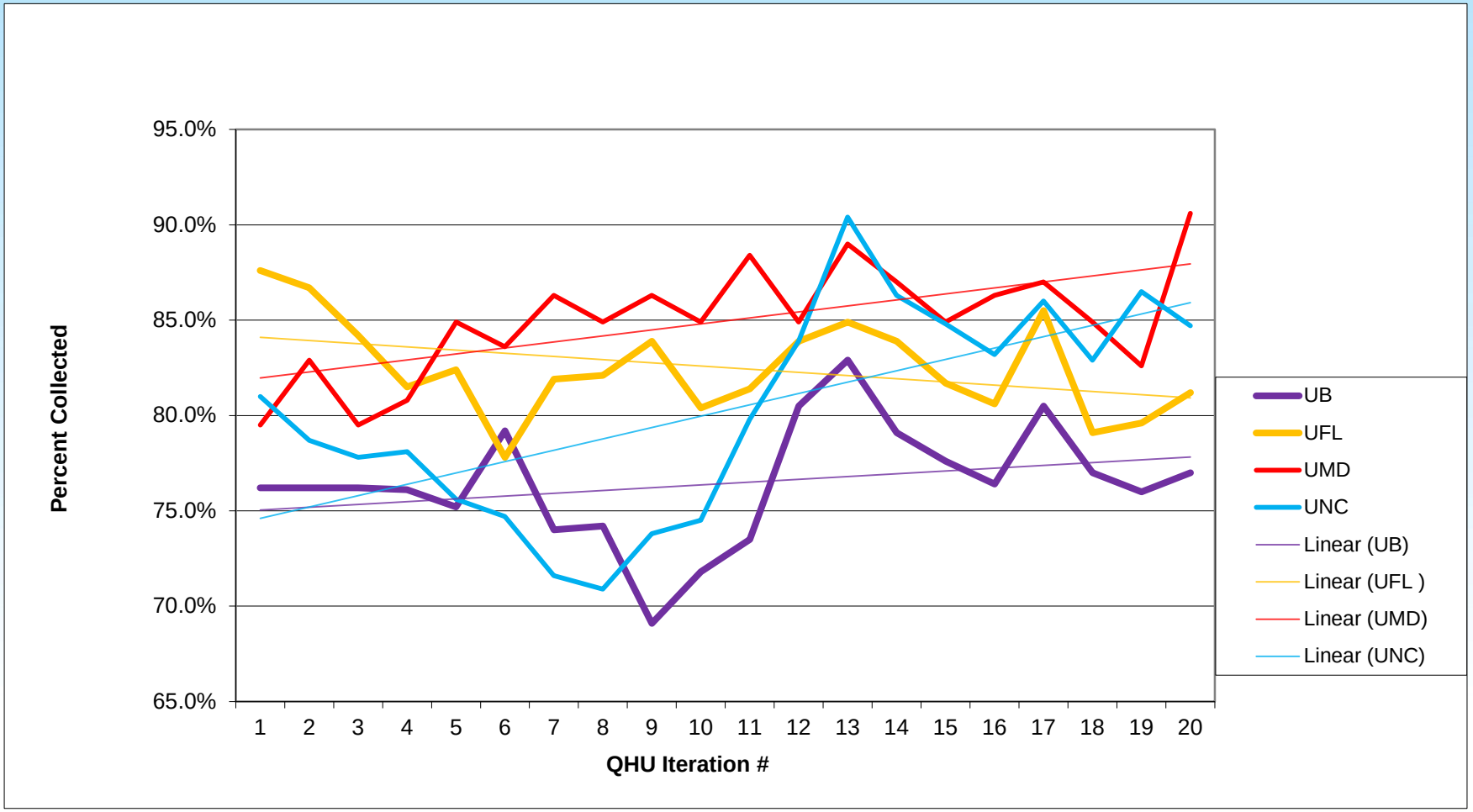
OPPERA Quarterly Health Updates (QHU)

- Critical active follow-up component due to triggers
- Content:
  - Pain and Symptoms
  - Risk Factors (e.g., accidents, injury, orth. treatment)
  - Health Updates
  - Medications
  - Psychological factors (e.g., stress, mood)
- Multi-mode (scan SAQ, web, CATI) data collection options
- Incentives: $5 each, $10/year bonus

QHU Clinic Visit Triggers



QHU Secular Compliance, Females



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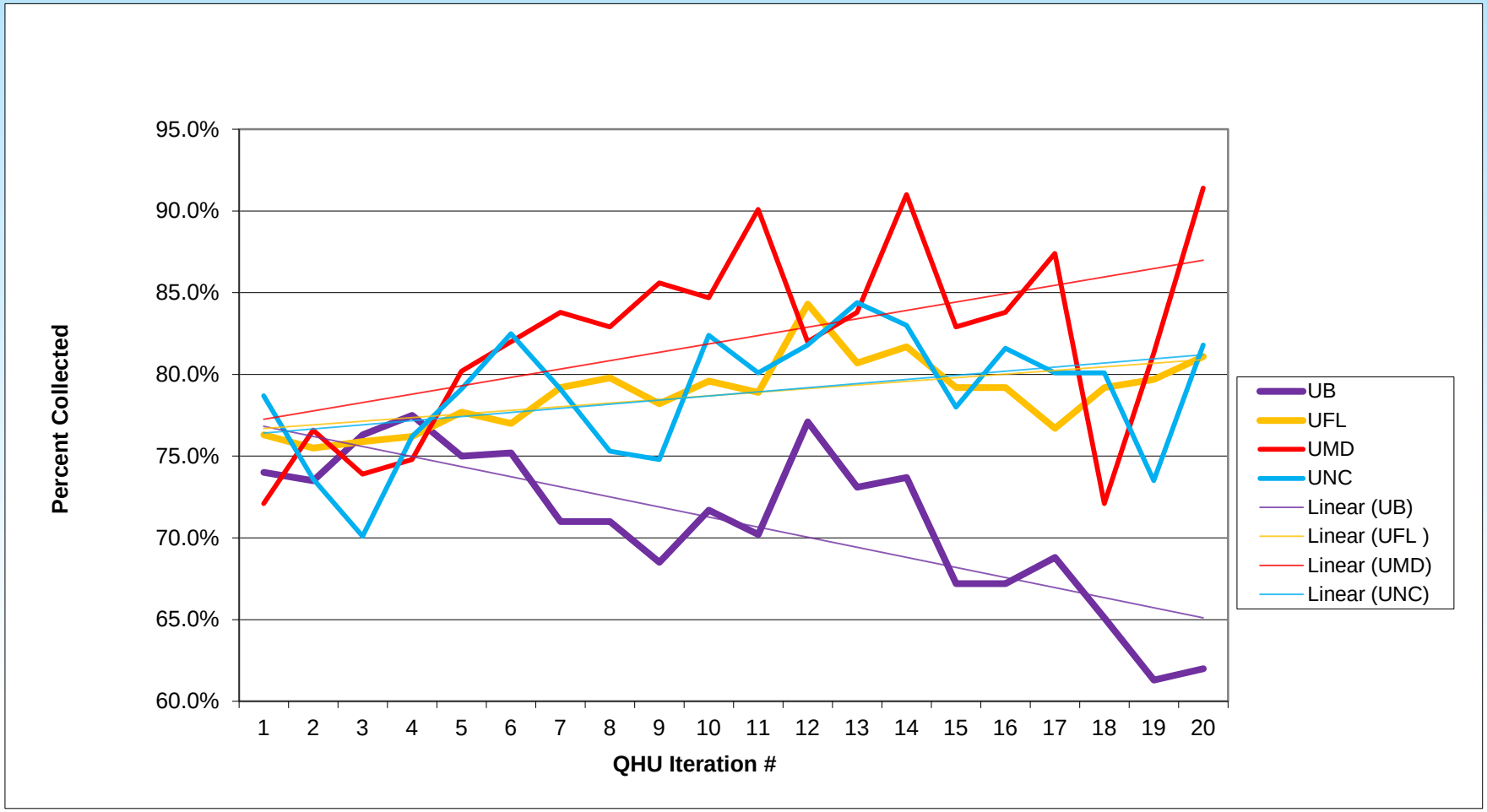
QHU Secular Compliance, Males



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Principles for Minimizing Burden and Maximizing Responses, QHU OPPERA

- Integrated technologies and web tracking system
  - Multi-mode data collection
    - ✓added CATI embedded in tracking system
  - "Referent Dates" controlled within application
  - "Important Events" date reminders gathered in each iteration
  - Emails, automated reminders and appointments system generated
  - Secular web reports available and monitored from day one
  - Prime and DCC can monitor all appointments and sites
  - System controls all data collection events and mapped out all QHU iterations for staff and participants
  - System generated, secure updates to # of QHUs processed daily
  - System generated, secure triggers events routed to authorized personnel and staff

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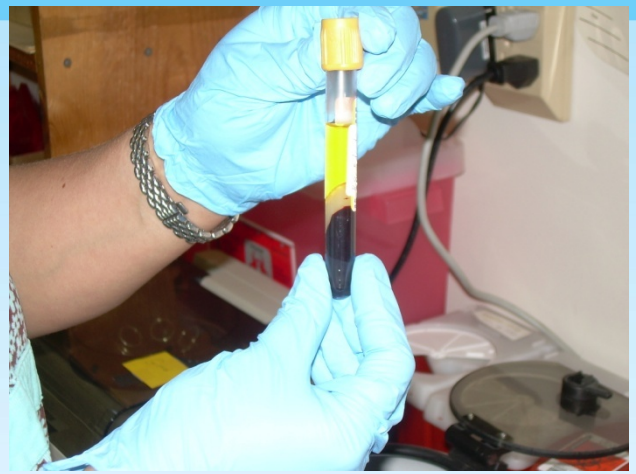
Principles for Minimizing Burden and Maximizing Responses, QHU OPPERA

- Tracing iterative design: from Site to DCC, as needed
- Newsletter and cohort communication
- Relying on trust with dental schools and staff
- Refresher trainings and focus
- Short-term follow-up to longer-term
  - Success in exceeding recruitment goals allows for scientific trade-offs
  - 2-4 years now in year 6
- Diligence, diligence, diligence

Case #2 & #3: C8 Study Background

- Communities in OH and WV were exposed to contaminated drinking water from pollutions caused by a chemical plant
- About **C8 (or PFOA)**: perfluorooctanoic acid, a synthetic (man-made) chemical, has wide manufacturing and industrial applications
- 2005 Class Action Lawsuit Settlement established **C8 Science Panel**
- Objectives: To determine the **probable links** between exposure to C8 and human diseases
- Cohort Population: original ~ 70,000 CAL members; ~ 40,000 provided consent to be contacted for future studies (Baseline study done in 2006)
- Studies selected for this discussion: (part of the C8 Science Panel Studies)
  - Community-Based Cohort Study of Disease Incidence in Ohio and West Virginia (N = ~ 40,000) ***aka the C8 Community Cohort Study***
  - PFOA (C8) Half Life Study (N = 200, a subset of the above study) ***aka the C8 Half Life Study***

Some C8 Half Life Project Photos



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Study Design Comparison

C8 Community Cohort Study

- Longitudinal follow-up study
- Objectives: to follow up and collect information on disease incidence from the study cohort
- Survey at 2 points (2008, 2010); baseline was done in 2006
- Medical records abstraction
- NDI data linkage & death certificate abstraction
- Cancer registry data linkage

C8 Half Life Study

- Longitudinal follow-up, field study
- Objectives: to collect data for construction of a pharmacokinetic model of the processes of absorption, distribution, metabolism, and storage of C8 in human
- Survey at 8 points (Baseline and 1, 2, 3, 6, 12, 24, & 48 months post Baseline)
- Blood sample collection at 8 points, stet schedule

Participant Burden and Risk Comparison

C8 Community Cohort Study

- Complete 2 Survey Interviews
  - FU1: 25 – 30 minutes
  - FU2: 20 – 25 minutes
- Provide Authorization to Release Medical Information
- Overall Burden: Time and Inconvenience
- Potential Risk: Anxiety caused by survey questions, loss of privacy, and breach of confidentiality

C8 Half Life Study

- Complete 8 Survey Interviews
  - Baseline: 5 – 15 minutes
  - FUs: ~ 10 minutes
- Provide written consent per visit
- Provide 1 blood sample per visit
- Overall Burden: Time and Inconvenience, pain and small chance of adverse effect associated with blood draw
- Potential Risk: Small chance of adverse effect associated with blood draw, loss of privacy, and breach of confidentiality

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Basic Principles for Minimizing Burden and Maximizing Responses

- Examine objectives, requirements and characteristics of the study population to develop strategies that will work for the target population
- Use appropriate data collection approach/technology
- Minimize time required for the respondent to complete study activities
  - Streamline data collection procedures
  - Eliminate data collection items that will not be used for analysis
- Train data collectors to ensure efficient/effective operations
- Implement a comprehensive QA/QC plan to ensure data quality and minimizing errors that may require recontacting respondents
- Provide lots of flexibility and help with easy-to-use communication
- Provide appropriate, effective participant incentives

Participant Characteristics Comparison

- The study cohort was predominantly white (over 90%), more female (54%) than male, and with a median age of 55
- Compared to the statewide data (i.e., WV & OH, US Census), the study cohort was older (median age 55 vs. 40) and had slightly more female (54% vs. 51%)
- Compared to the US data, the study cohort was much older (median age 55 vs. 37) and had slightly more female (54% vs. 51%)
- The participant characteristics were similar for the C8 Community Cohort Study and the C8 Half Life Study
- All participants were exposed to C8

Approaches for Minimizing Resp. Burden

- Applied basic principles and tailored approaches to meet individual study requirements
- Customized study materials: using language for lower SES and larger font so the study materials will be easy to read and understand, pilot testing materials with subjects of similar characteristics
- Implemented streamlined data collection procedures:
  - Send intro letter (including study background, participant's right, study activities, what info/data will be collected, incentive, project contact info)
  - Send additional letters per study protocol and conduct reminder calls and remailing
  - Provide project toll-free number, project e-mail, project website
  - Timely response to participant questions/requests
  - Develop project Tracking System to monitor project activities

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Approaches for Minimizing Resp. Burden

C8 Community Cohort Study

- Offered multi-mode (CATI and web) data collection options
- Extensive efforts on developing survey questionnaires and data collection instruments:
  - Eliminating redundant/repeated questions, if appropriate
  - Simplifying questionnaire and language (i.e., for lower SES population)
  - Conducting multiple pilot tests
  - Importing data collected from FU1 to FU2 survey to facilitate FU2 survey
- Used prompts and standardized Q&A to facilitate survey response
- Incentives: $40 VISA gift card for completing FU1 and $20 "major retailer" gift card for completing FU2

C8 Community Cohort Study Questionnaires

FU1 Survey Questions

(25 – 30 minutes)

- Respondent verification
- Physical Activity
- Caffeine Consumption
- Occupational History
- Smoking History
- Alcohol History
- Medical History
- Reproductive History (female only)
- Demographics

FU2 Survey Questions

(20 – 25 minutes)

- Respondent verification
- Medical History
- Reproductive History (female only)
- Residential History and Source of Drinking Water
  - to facilitate responses, a Residential History Chart was mailed to each respondent

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Approaches for Minimizing Respondent Burden

C8 Half Life Study

- Used CATI for survey data collection (by separating survey and blood collection, we reduced the time required for home visit and simplified field operations)
- Used similar efforts for developing survey questionnaires and data collection instruments (*see the Community Cohort Study*)
- Developed a Web Tracking System to manage field visit appointments – offering real time communication with the field staff
- Used experienced and study-trained phlebotomists for blood collection; assigned the same staff to the same participants as much as possible
- Offered appointment flexibility: blood collection can be done at the participant's requested location and time
- Incentives: Offer $50 USPS money order for completing each data collection visit (up to 8 visits in 4 years); individual blood test results

C8 Half Life Study Questionnaires

Baseline Survey Questions

(5 - 15 minutes)

- Eligibility screening
- Informed consent scripts
- Residency and location
- Water source
- Water use at home and at work
- Water filter
- Locally grown fruits & vegetables
- Next appointment schedule

* A Field Data Log was also used to collect field visit info

Follow-up Survey Questions

(~10 minutes)

- Respondent verification
- Informed consent scripts
- Residency and location
- Water source
- Water use at home and at work
- Water filter
- Locally grown fruits & vegetables
- Verify appointment schedule

* A Field Data Log was also used to collect field visit info

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Comparison of Outcomes

Data Collection Event	CATI Survey	Blood Collection
T0 - Baseline	200	200
T1 - 1 Month	200	200
T2 - 2 Months	200	200
T3 - 3 Months	199	199
T4 - 6 Months	198	197
T5 - 12 Months	196	197
T6 - 24 Months	192	192
T7 - 48 Months	185	185
Actual Total	1,570	1,570
Target Total (8 x 200)	1,600	1,600
% of Target Total	98%	98%

C8 Community Cohort Study

- FU1: 81% response rate
- FU2: 82% response rate
- About 40% Web and 60% CATI

C8 Half Life Study

- Baseline: 100% Target
- FUs: 93% retention at 48 months
- 48-Month Overall: 98% Target

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Conclusions & Lessons Learned

- Overall respondent satisfactions and response rates were high for both studies
- Strategies for minimizing burden and maximizing response seemed to work well for both studies; however, the C8 Half Life Study experienced better outcomes although it had more challenges
- By separating the survey task and blood collection task, we reduced the time required for home visit, simplified field operations, and increased flexibility/convenience for Resp.
- More personal contact and effective incentives likely contributed to better outcomes for the C8 Half Life Study
- Incentives may become a burden: Some participants had troubles using the VISA gift card (mostly older participants); as a result, we used “retailer” gift cards for FU2

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Questions?

Contact Information:
Charlie Knott
919.544.3717
knott@battelle.org