

You're Collecting What??

Designing In-Home Collection of Stool and Water Samples

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Overview

- Approached by the Wisconsin Longitudinal Study (WLS) about their desire to expand their social science dataset to include additional biomarkers, in particular – the human microbiome.
- In November 2014, UWSC launched pilot effort to collect a full stool sample, food diary, in-home water sample and test.
- In this presentation I will talk about:
 - our overall field protocol,
 - the materials we used, and
 - some preliminary results.

Background of the Wisconsin Longitudinal Study (WLS)

- Wisconsin High school seniors from 1957
- Mostly white and in their mid-70's
- In 2010-2012, UWSC conducted 2.5 hour in-person interviews which included physical measures, salivary DNA samples, Medicare and Social Security records, and a paper survey.



WLS Microbiome Pilot: Focus Groups

- We began by conducting focus groups with WLS participants in the Madison area.
- What we learned:
 - The ick factor – not really an issue
 - Who is conducting the research and what the sample is being used for were important
 - Concerned about connection with “Big Pharma”

WLS Microbiome Pilot: Field Effort

- Fielded 500 cases between November 2014 and March 2015.
- Participants were located in Dane County (Madison), Milwaukee County, the space between them as well as two rural counties in northern WI.
- All participants had completed the in-person interview in 2010-2012.
- We worked with a microbiologist at UW and his lab processed all of the stool and water samples.

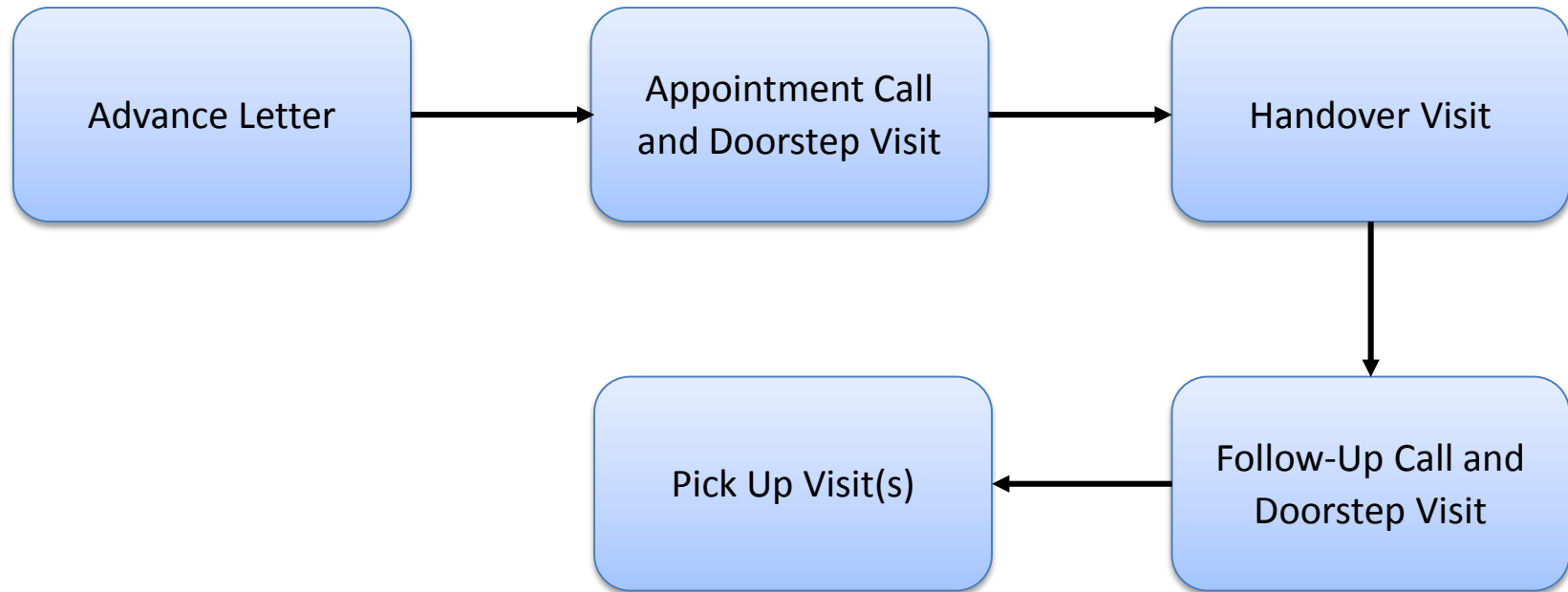
Making Contact



Handover Visit

- Explain effort and consent form
- Explain and hand-over:
 - stool collection kit
 - paper survey
 - food diary, usual diet, medications, antibiotics, pets
- Ask participant to call as soon as they produced the specimen.
- Spouses included as a convenience sample

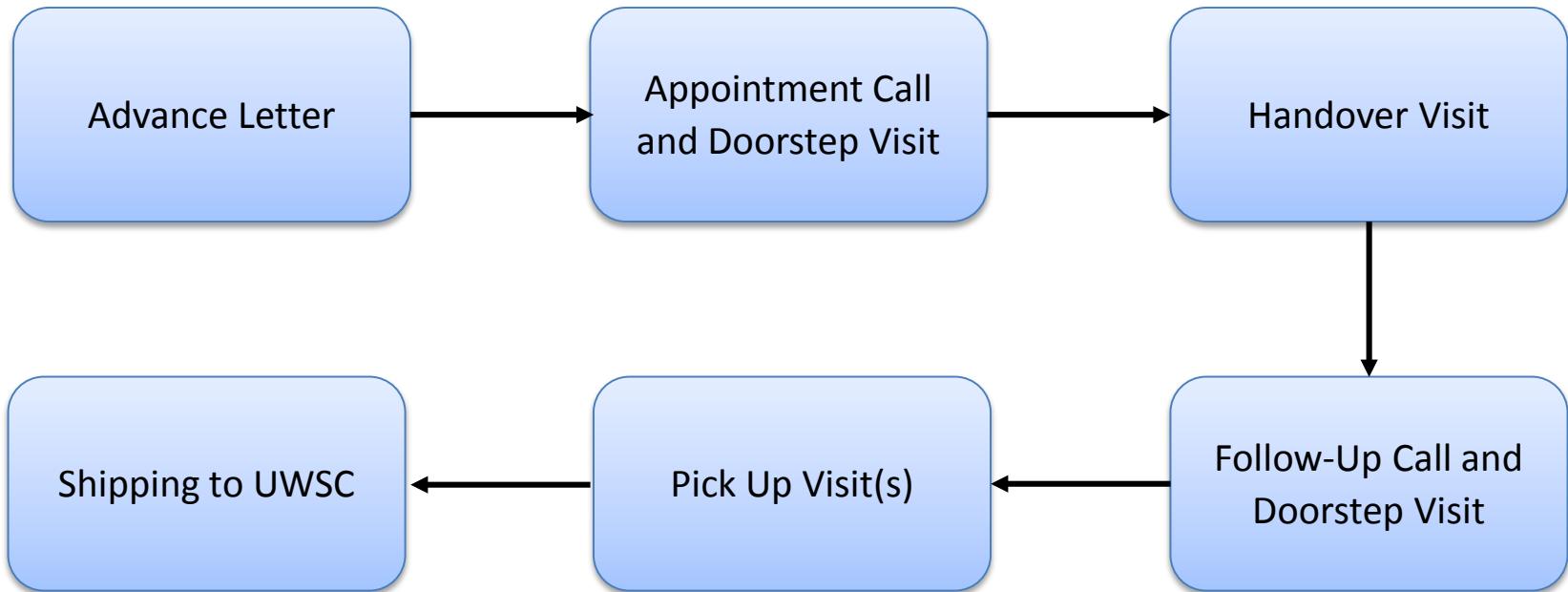
Making Contact



Pick-Up Visit

- Pick-up stool sample
- Pack into cooling box
- Collect paper survey
- Collect water sample
- Conduct water quality test

Making Contact



The Materials

- Personalized Respondent Packet (PRP)
- Stool Collection Kit
- Water Sample and quality test
- NanoCool© Shipping Box

Stool Collection Kit

- The stool sample collection kit included:
 - a plastic frame that sits between the rim and toilet seat,
 - a container that fits within the frame, and
 - a lid.
- Fit on any toilet and the participant could use the toilet normally.
- Most hygienic collection process – did not require any direct contact with the actual specimen.

Stool Collection Kit

- Potentially confusing markings on container
- Tracked down the manufacturer and had them make the container and lid with no markings.
- Added our own sticker with the information we wanted.



Water Collection Bottle

- 500 mL Neoprene plastic bottle
- Collected a sample of the participant's main drinking source in the home during the pick-up visit.
- Separate samples from participant and spouse
- Conducted a water quality test of that water, 5 measures total.



Refrigeration and Transport

- Both stool and water samples need to be refrigerated continuously.
- Requirements:
 1. Continuous refrigerator temps for 48+ hours
 2. Could be used by participants, if needed
 3. No more than 10-15 pounds
 4. Ready at a moment's notice

NanoCool© Shipping Box

- Insulated box with cooling cartridge
- Uses water evaporative technology to keep box cool for over 48 hours.
- Starts cooling within 5 seconds
- Weighs about 10 lbs



NanoCool© Shipping Box: Considerations

- Created custom foam insert to keep stool sample in place during shipping
- Needed to use an ice pack to maintain cool temperature until box was fully cooled.
- Provided an espresso tamper to participants to push the activation buttons.



Shipping Samples

- Compared shipping companies – ultimately went with FedEx.
- Samples shipped overnight or driven to UWSC by interviewers.
 - **313** were shipped
 - **118** were driven in
- Interviewers were provided pre-paid shipping labels
 - Not considered “Hazardous Materials”

Intake at Headquarters

- Samples brought directly to UWSC:
 - Secure room
 - Staffed for Saturday delivery
 - Box contained other materials
 - Quality control
- Created a place to intake samples in UWSC basement.
 - Trained UWSC staff to be intake specialists

Intake Room



Biosafety

- Consulted with Office of Biosafety at UW.
 - Project deemed Biosafety Level 2

Intake Requirements

- Ventilation and airflow
- Eyewash station
- Personal Protective Equipment (PPE)
 - Lab coat, safety glasses, gloves
- Safe handling and cleaning protocols

Field Requirements

- Personal Protective Equipment (PPE)
 - Gloves
 - Biohazard specimen bags
 - Spill Kit
 - Safe handling protocols
-
- UWSC developed biosafety training for field and intake staff.

Preliminary Results

- Total stool samples collected: **431**
- Response rate: **68.7%**
 - If we exclude those believed to be snowbirds: **75%**
 - Lower bound rate – no refusal conversion attempted
- **99.1%** completed the paper survey (food diary)
- **83%** of the samples arrived at UWSC **within 3 days** of being produced by the participant.
- Only **16 NanoCool boxes** were left behind for the participant to store their sample until the interviewer could pick it up.

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