

Writing the “Methods”

Partnering for Impact - Consortial
Publications, Workshop #8

Greg Guest, PhD

Research Scientist

UNC Center for Health Equity Research



Brief Introductions (in Chat)

- Name
- Institution/ Community organization
- Email
- Experience writing/publishing peer-review articles
- Ideal 10-day vacation. Cost not an issue!



- Research Scientist on RADx-UP at UNC
- A fair amount of writing experience
- Ukraine (when stable!)

Workshop Structure and Objectives

Structure

- Introductions
- Some slides
- Q & A
- Exercise and discussion

Objectives

At the end of this workshop, participants will:

- Know the primary elements expected in a “Methods” section
- Be able to avoid common pitfalls associated with Methods sections



Review from Past Writing Workshops

Q: What is the most important rule to consider and employ when writing a paper?

A: Don't annoy the reviewer!



Methods Section - The Essentials

The Three Seeds of a Methods Section

- Transparency
 - Explain any shortcomings
- Citations
 - When procedure/method less-known
- Details
 - More = better



“Methods” – Purpose and Content

- “Introduction” tells the reader WHY you’re doing something
- **“Methods” tell the reader WHEN, WHERE and HOW**
- Journals often have prescribed sub-header titles, but content usually covers four general methodological aspects
 1. Study design and context
 2. Participants/sampling/recruitment
 3. Data collection
 4. Data analysis

Better if these are clearly demarcated, but:

- Some journal requirements are unique
- Not all paper topics/designs are the same

Published Papers Vary ... A Lot

Process & Method

- Systematic reviews
- Non-systematic reviews
- Opinion pieces
- Process descriptions
- Primary research (bench vs. humans)

Human Subjects

- *Clinical, social-behavioral*
- *Quantitative, qualitative, mixed methods*
- *Cross-sectional vs. cohort/prospective*
- *Experimental, quasi-exp., observational*

Topic & Focus



Standardized Guidelines can Help

Systematic Reviews – PRISMA

<https://prisma-statement.org/>

Randomized Controlled Trials (RCT) – CONSORT

<http://www.consort-statement.org/>

Observational Studies – STROBE

<https://www.strobe-statement.org/>

Qualitative Studies – COREQ

<https://academic.oup.com/intqhc/article/19/6/349/1791966>



Study Design & Context



Describing the Study Design

- Start with a simple declarative statement that describes the overall study design

- Some common descriptors:

"cross-sectional" "cohort/prospective" → **Temporal dimension**

"observational" "quasi-experimental" "experimental" → **Degree of control**

"mixed methods" "qualitative" "survey" → **Data type(s)**

"formative research"

"needs assessment"

"evaluation"

"case-control"

"review"

"meta-analysis"

- Can mix and match *"This mixed methods cohort study among 831 Latinx adults..."*

- May also include sample size

- Include a statement about IRB approval at the end of the last paragraph

"This study was approved by the [XX] Institutional Review Board"



Study Design Example - RCT (DeGarmo et al. 2022)

Methods

Study Design

This cluster randomized trial used wait-listing to enroll participant sites.¹⁹ Testing participants and testing staff were blind to the intervention condition, but community-based organizations (CBOs) and county health agencies were not. Participants provided a written waiver for the use of deidentified count totals for each testing event. All consent procedures and protocols were reviewed and approved by the Committee for Protection of Human Subjects and the University of Oregon Institutional Review Board. The trial protocol is available in Supplement 1. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline extension for cluster randomized trials.

Several steps were taken for site-level randomization. First, a facilities-location-problem approach²⁰ was used to optimize 38 site locations in 9 Oregon counties with geo-mapping Latinx population concentrations to determine potential locations for testing events. Second, we focused the community engagement collaboration on instrumental aspects of testing, such as site access, optimizing visibility of events, and ensuring overall perceived safety (e.g., real or perceived antagonism by community members opposed to testing, virus transmission during events, or US Immigration and Customs Enforcement authorities showing up). Given less than 10 participating counties with up to 6 possible sites, using a random-number generator, we randomized within county to minimize threats to internal validity.¹⁹ Sites were randomized to either the intervention group or the OAU wait-listed control group.

Describing the Study Design E.G. – Qualitative (Lee et al. 2022)

MATERIALS AND METHODS

Qualitative Interview Design, Recruitment, and Consent

This needs assessment utilized 30-min qualitative semi-structured interviews to gather a broad range of perspectives across six Massachusetts communities. First, in November 2020, the lead author conducted interviews with staff members at nine participating community health centers. Next, from November 2020 to February 2021, the lead author and two research assistants used a snowball sampling approach to conduct interviews with staff and volunteers from organizations the health center staff identified as current or future partners in COVID-19 testing. Types of organizations interviewed included community coalitions, local boards of health, housing authorities and shelters, food banks, and immigrant advocacy groups. Finally, from December 2020 to February 2021, four additional research assistants conducted resident interviews in English, Spanish, Vietnamese, and Arabic, reflecting primary languages in the participating communities. Separate interview guides (see Appendix A) for staff, partners, and residents were developed with parallel questions to capture actionable feedback to inform changes to testing practices and communications. Study staff worked with health center and partner organization staff to recruit a convenience sample of community residents for interviews, distributing recruitment flyers in four languages through newsletters, social media, and via online community meetings. Residents contacted study staff by phone or email to learn about the study activities, risks and benefits, and to schedule the interview. Verbal consent detailing the study purpose, logistics, and confidentiality was obtained prior to the start of each interview and a written consent script was also distributed to participants via email or text. The study was approved by the Harvard Longwood Campus Institutional Review Board.

Adding the Broader Study Context

- Consider including if study is part of a larger study/program
 - e.g., complementary or formative study for a clinical trial or large national study
 - e.g., part of government program or an evaluation of a program/intervention
 - e.g., part of a consortium such as RADx-UP
- Description length – from a few sentences to a few paragraphs
- Note: some current, single-site, RADx-UP publications include, some do not
- For multi-site RADx-UP analyses/papers (e.g., CDEs), need to include context

Study Context Example - Simple and Effective (Rivera-Núñez et al. 2022)

As part of NJ HEROES TOO (New Jersey Healthcare Essential Worker Outreach and Education Study- Testing Overlooked Occupations), we conducted group- and one-on-one interviews online. This study was part of the NIH Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) Initiative which aims to understand disparities in underserved populations, with particular focus on COVID-19 testing¹⁷.

¹⁷. NIH. Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) 2020 <https://www.nih.gov/research-training/medical-research-initiatives/radx>



Sometimes, “Context” is in the Introduction . . . (Lee et al. 2022)

. . . there is limited research on the unique barriers to testing faced by people with limited English proficiency and immigrant populations in the U.S.

 **Gap statement**

Given the widespread need for COVID-19 testing support, following Congress-approved funding in April 2020, the National Institutes of Health (NIH) created the Rapid Acceleration of Diagnostics (RADx) program. The aim of the RADx program is to develop innovative diagnostic technologies and strategies to increase testing access. One of the four RADx programs is Rapid Acceleration of COVID-19 Testing in Underrepresented Populations (RADx-UP), which aims to understand factors that have led to the disproportionate burden of the pandemic on underserved populations and to support improved access and uptake of COVID-19 testing through community-engaged efforts (28).

The RADx-UP program funded our project in Massachusetts (RADx-MA), one of over 70 RADx-UP projects throughout the U.S. This project is led by a collaboration between the Harvard T.H. Chan School of Public Health, Massachusetts General Hospital, and the Massachusetts League of Community Health Centers and is supported through the infrastructure of the Implementation Science Center for Cancer Control Equity (ISCCCE). It builds on existing and new partnerships between CHCs and community organizations in six Massachusetts COVID-19 hotspot communities with both high rates of illness and racial/ethnic gaps. The aim of this project is to work with the CHC-community partnerships to develop expanded testing implementation strategies and to conduct a series of community engaged pilot studies to assess the impact of different approaches to addressing barriers to testing. To prepare for the planned work supporting implementation of testing strategies to reach underserved populations, we conducted a rapid, comprehensive needs assessment with stakeholders at multiple levels. In this paper, we explore the perceptions of COVID-19 testing barriers among community health center staff, community partners, and residents gathered through this rapid needs assessment. We also describe how these community-identified needs and assets can be translated to build tailored clinical-community strategies for addressing testing inequities.

Participants, Sampling & Recruitment



Participants & Sampling – Some Terms

- **“Study population”** = the type of individuals/communities of interest to study
 - Eligibility criteria
- **“Sampling”** = how one goes about selecting sub-set of population for study
 - Common examples: simple random, purposive, stratified, convenience
- **“Sample size”** = number of people in study
 - Overall, and by method/site/etc. (if more than one method, site, etc.)
- **“Participants”** = all those who participated in study
 - aka by other (less flattering) terms: subjects, respondents, informants
- **“Recruitment”** = how approach/notify people about study

Note: not a description of actual participants. Save that for the “Results”

Sampling Example - Simple but Effective

We purposively sampled Black and Latinx individuals who worked as staff for 4 health care employers in New Jersey, including both in-patient (2 urban university hospitals) and outpatient (long-term care and homecare) settings in 4 counties with high numbers of Black/Latinx populations and COVID-19 burden. Employees over age 18 years who identified as Black or Latinx and identified English or Spanish as their primary language were eligible.

If complex, use a table!

	KAYA	HOUNDÉ	TOTAL
Total FGD	15	15	30
Female caregivers, rural	2	2	4
Female caregivers, urban	2	2	4
Male caregivers, rural	2	2	4
Male caregivers, urban	2	2	4
Other caregivers, rural*	2	2	4
Other caregivers, urban*	2	2	4
Traditional birth attendants	1	1	2
Traditional healers	1	1	2
Village administrators	1	1	2
Total IDI	14	14	28
Chief of Medicine at the district level	1	1	2
Community health worker	1	1	2
Head of vaccine services	1	1	2
Chief of infirmary	1	1	2
Community leader (unspecified)	1	1	2
Traditional chief	2	2	4
Religious leader (unspecified denomination)	3	3	6
Leader of non-governmental organization	2	2	4
Traditional birth attendant	1	1	2
CSPS birth attendant	1	1	2
Director from the National Malaria Control Program			1
TOTAL data collection events	29	29	59

*Other caregivers included aunts, uncles, and grandparents

Sampling & Recruitment Example (Yeager et al. 2022)

Methods

Participants and eligibility

Between October 28, 2020 and September 10, 2021, people aged ≥ 18 or older who injected drugs within the last month and lived in San Diego County or Tijuana were recruited through street outreach, as previously described¹⁸. Recruitment took place using a recreational vehicle whereby potential participants were approached by outreach workers in various locations, such as on the street, parks, shelters, motels, river canyons and vacant lots. All participants provided written informed consent. Protocols were approved by the Human Research Protection Program at the University of California San Diego and institutional review board at Xochicalco University in Tijuana. The study was conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

Eligibility and recruitment

Consent

IRB approvals

Note: author chose to include # of participants in Results



Participants Example – Integrated (Hallgren et al. 2021)

2.1. Design, setting, participants

This study was part of a larger project designed to implement a SARS-CoV-2 testing program at syringe exchange programs in Oregon as part of the National Institutes of Health Rapid Acceleration of Diagnostics for Underserved Populations initiative (RADx-UP). We partnered with an Oregon-based non-profit to implement a SARS-CoV-2 testing program at nine syringe exchange programs across the state of Oregon, representing four counties (two rural, two small urban). As part of the testing program, data characterizing vaccine deliberation/hesitancy were routinely collected from each individual tested. Thus, participants were syringe exchange clients who utilized the SARS-CoV-2 testing program between March 3, 2021 and June 22, 2021 ($N = 350$ unique individuals). For participants who utilized the testing program multiple times, the individual's most recent data were analyzed to incorporate the most current individual information. Syringe exchange clients had to be 18 years or older to participate in the survey. People who were not syringe exchange clients but engaged in testing at an exchange were excluded from analyses (e.g., staff, people who were utilizing other services on site). Individuals provided informed consent prior to participation and were given a \$10 gift card for their participation in the survey and testing. The survey included information on demographics and common data elements required by the funding agency on vaccine status and vaccine deliberation. This study was approved by the University of Oregon Institutional Review Board.

Context

Data collection

Eligibility criteria

Consent & incentives

Survey content

IRB approval

Recruitment Example – RCT (DeGarmo et al. 2022)

Promotores de Salud Outreach

The intervention used a community-based participatory approach that relied on partnerships with ongoing knowledge exchange among researchers, stakeholders, and the community toward development of a culturally responsive intervention.²¹ Promotores were bilingual (Spanish and English) and bicultural community members (N = 19) recruited through close partnerships with and hired by CBOs (eg, regional farm worker advocacy center, nonprofit organization providing integrated social services, and advocacy groups for rural underrepresented populations). A subset of the promotores consented and provided demographic information (n = 16). Of those, 7 (44%) had completed high school or General Educational Development, and 5 (31%) had some college or an associate's degree. A total of 8 (50%) had lived in the US their entire life, and 7 (44%) had lived in the US at least half of their life. Promotores were trained to conduct outreach that highlighted common Latinx cultural values (eg, collective welfare); to disseminate information on testing events in Spanish, reasons to get tested, and COVID-19-related resources; to mitigate misinformation; and to increase trust. Strategies were tailored to local communities, including promoting testing via texting, in-person promotion at locations frequented by Latinx members (ie, specialty grocery stores, Spanish-language church services, schools, and workplaces), and advertising in print media and Latinx radio stations. All social media posts, flyers, and print outreach materials were prepared in Spanish and English. Regular meetings were held with Latinx community partners, the Oregon Health Authority, county health agencies, community and scientific advisory boards, CBOs, and promotores to (1) share up-to-date information and resources about the state's pandemic mitigation strategies, (2) plan testing event locations vis-à-vis other regional COVID-19 mitigation events, and (3) problem solve and continuously share outreach strategies twice weekly with regional CBOs. Interpreters for Mam, an Indigenous Mayan language used in Oregon, were onsite at some locations.

Q: Is this much detail necessary?



Data Collection



Describing Data Collection

- Dates data collected
- Region of country/city, type of place
- How data collected
- Type of Instrument
 - Structure and format (including # of questions)
- Sample questions provided where appropriate (may also include in “Results”)
- If/how instrument pre-tested
- Informed consent process

Data Collection Example – Qualitative (Rivera-Núñez et al. 2022)

Data Collection

We recruited 23 HCW, 3 were not eligible and 3 did not attend. We conducted 2 group- and 8 individual interviews with Black and Latinx HCW (N = 17) between December 2020 and February 2021 using a secure Zoom platform. Variation in HCW work schedules made group interviews largely prohibitive. After completing 2 group interviews, we began recruiting participants for individual interviews in order to accommodate their schedules and ensure our approach was responsive to their needs. Group interviews were led by a primary and secondary facilitator and included two study team members for notetaking and technical assistance. We used a semi-structured interview guide for group- and individual interviews, which the team iteratively developed through literature review, prior experience, and debrief meetings after initial interviews. All interviews were recorded and transcribed verbatim. Group interviews lasted approximately 90 minutes, and individual interviews 20–30 minutes. In conducting the interviews over time and interview format, perspectives expressed by the respondents were remarkably consistent, thus leading to our conclusion of reaching thematic saturation.

Data Collection Example – Quantitative (Hallgren et al. 2021)

Data collection

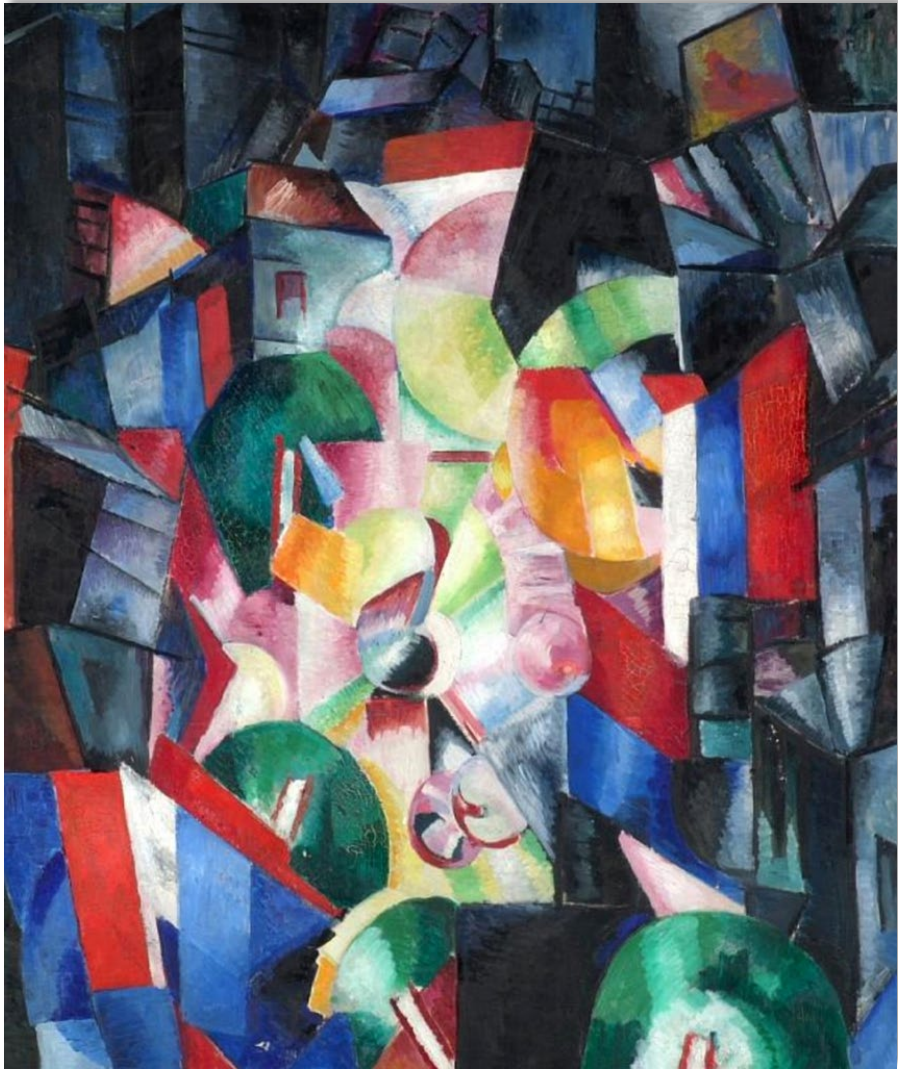
Respondents completed the survey using REDCap while they waited for the required 15 minutes of observation after receiving the COVID-19 vaccine. The survey took participants approximately 10 minutes to complete. Participants completed the survey in their preferred language (i.e., English, Spanish, or Marshallese). Bilingual study staff translated text responses to open-ended questions provided in Spanish or Marshallese to English.

Instrument

The survey captured demographics, vaccine hesitancy, and facilitators for overcoming barriers related to the COVID-19 vaccine. Demographic items included age, sex, race/ethnicity, education, marital status, and employment status. Sociodemographic factors were assessed using questions from the Behavioral Risk Factor Survey.²⁰ To assess COVID-19 vaccine hesitancy, we modified a single-item measure of general vaccine hesitancy.^{12,21} The survey asked, “Thinking specifically about the COVID-19 vaccine, how hesitant were you about getting vaccinated?” Possible response options were: “not at all hesitant,” “a little hesitant,” “somewhat hesitant,” “very hesitant,” and “prefer not to answer.”



Data Analysis



Describing Data Analysis – General Components

- General approach to analysis
 - exploratory? confirmatory? other?
 - theory-driven?
- Specific analytic methods used
- Software used
- Cite methods is not well-known

Qualitative Analysis

- General approach to analysis?
 - Inductive, deductive, both?
 - Thematic analysis, Content (word-based) analysis, both?
 - Transcription procedures described (if applicable)
- How were themes identified and codified?
- How were themes arranged/organized, and why?

Is it really “Grounded Theory”? or just Inductive Thematic Analysis?

Qualitative Analysis, Cont'd

Coding Reliability

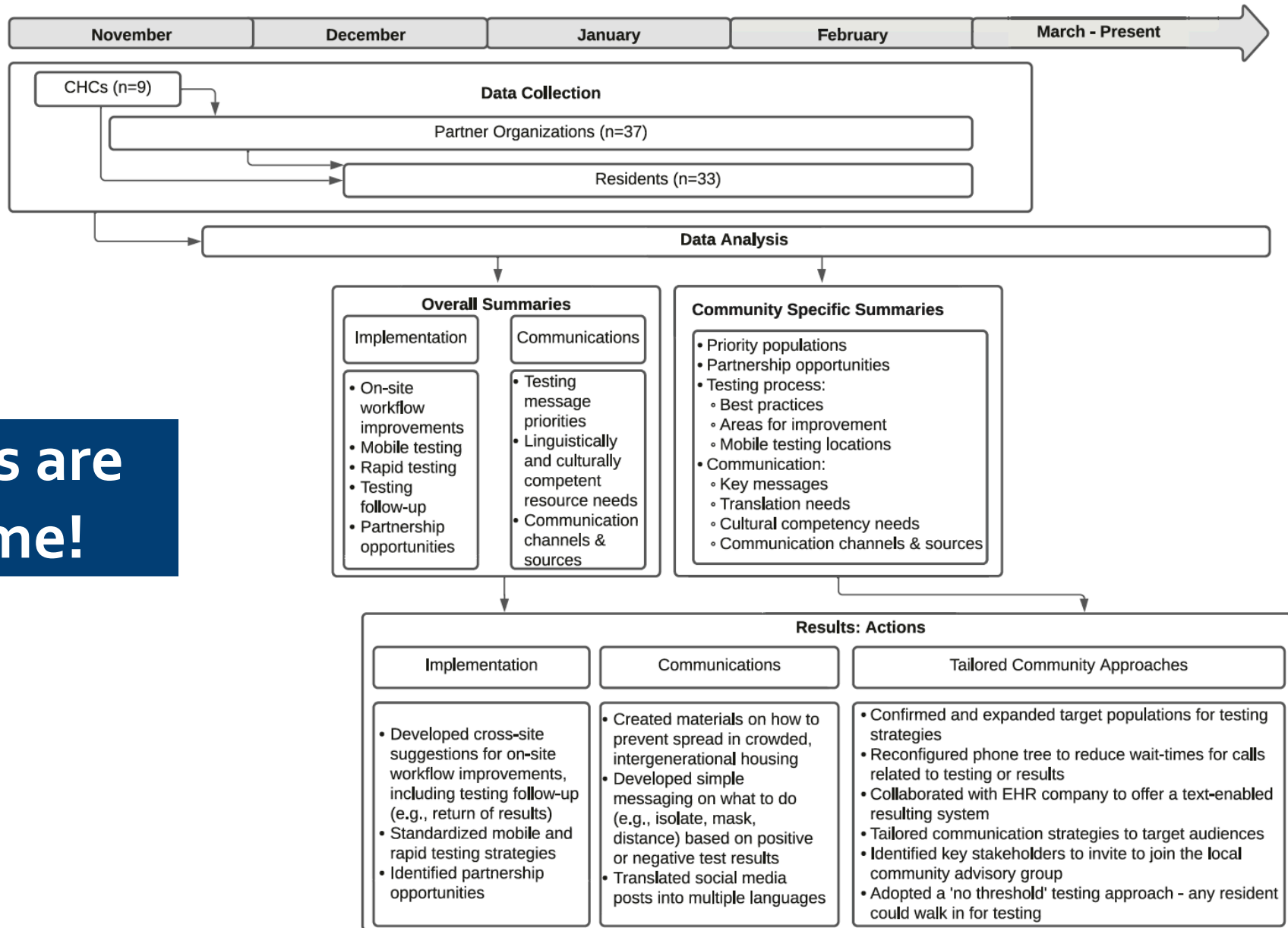
- How was it assessed?
- Multiple coders used?
- Inter-coder agreement (ICA)?
 - If done: How? How often? How reported? Conflicts resolved?

Qualitative Data Analysis Examples (Lee et al. 2022)

Qualitative Analysis

We conducted a 2-phase framework analysis (29) to facilitate rapid return of results (30, 31) and utilization of data for action (Figure 1). First, two coders (SA and VH) categorized and summarized content from health center and partner interviews to share with the RADx project testing implementation team and communication team in January 2021. In March 2021, community-specific summaries from health center, partner, and resident interviews were developed for local action. In the second phase, the research team conducted an in-depth thematic analysis, deductively coding interviews into the five levels of the Social-Ecological Model (policy and environmental; community; organizational; interpersonal; individual) (32) according to the framing described by the interviewees and into three pre-figured codes drawn from the interview guide (testing process, communications, and partnerships). This was followed by inductive coding to develop constructs and sub-constructs within these five levels. This framework was selected to emphasize the multilevel influences on COVID-19 testing experience. A codebook was developed and shared with other members of the research team to gather feedback and define agreed upon constructs. The same coders proceeded to double-code 16 interviews, reconciling codes, and revising the codebook in consultation with the senior author as appropriate. The remaining transcripts were single coded, divided between the two coders. Analyses were conducted using NVivo qualitative data analysis software Version 11 and then summarized and condensed into salient themes.

Figure 1. RADx-MA rapid qualitative needs assessment process and results



Diagrams are Awesome!

Quantitative Analysis

- Statistical tests performed
- Weighting procedures (if applicable)
- Procedures for dealing with missing/incomplete data
- Predetermined parameters set for significance (e.g., $p < .05$, $. < 01$, etc.)
- Software used

Good News! Section often written by statistician!

Quantitative Data Analysis Example (McElfish et al. 2022)

2.3. Analyses

Data were analyzed using STATA 15.1 SE. Arkansas 2019 census estimates for age, race, and sex were used to generate weights using raking ratio estimation. We present results for parents/guardians whose oldest child was age 11 or younger (n = 171) or between ages 12 and 17 (n = 198), including weighted descriptive statistics and bivariate analyses including Pearson χ^2 statistics with Rao and Scott second-order correction^{23,24}. We present only descriptive statistics (mean) for age across the five possible responses of the dependent variable. Missing data comprised less than 5% of the total and were handled through pairwise deletion.

Note: this section preceded by *Section 2.2* which included detailed descriptions of primary measures

“Methods” Section – Dos and Don’ts

Do . . .

- Be transparent
- Include details
- Cite lesser-known methods
- Justify less-than-rigorous methods

Don’t . . .

- Forget key details, such as IRB approval statements
- Include information that is not methods-related
- Misplace content into incorrect sub-section

Writing the “Methods”: Step-by-Step

1. Look at similar articles in your target journal. How are Methods structured?
2. Use your “Methods” section from a proposal and “pastify” it
and/or
2. Create an outline with the four methods sub-sections described in slide #4
3. Make a bullet list of all the details under each sub-section
4. Check against guidelines for your type of paper/analysis
5. Transform into a narrative
6. Ask colleague to read....can they visualize what you did?

You Are NOT Alone!

- The CDCC is here to support your team through the writing & submission process

- 1 on 1 mentoring/consultation

Greg (gguest@med.unc.edu)

- Manuscript editing. Request at:

<https://myhome.radx-up.org/analysisproposalsupportrequest/>

- And, more workshops . . .



Workshop Series List

- #1 Consortial Publication Process (5/17/22)
- #2 Data Dashboard/Available Data (5/24/22)
- #3 Choosing a Peer-Reviewed Journal (8/08/22)
- #4 The Journal Submission Process (8/15/22)
- #5 Search Engines – The Basics (8/25/22)
- #6 Reference Management Software (8/29/22)
- #7 Writing the “Introduction” (9/12/22)
- #8 Writing the “Methods” (9/19/22)**
- #9 Writing the “Results” (9/26/22)**
- #10 Writing the “Discussion” (10/3/22)**

Link to Workshop Recordings

<https://myhome.radx-up.org/cdcc-resources/meetings/>



Q & A

Exercise

- Retrieve an article that is of interest to you, by whatever means is easiest, or . . .
- For those without access to an article, choose one of the four provided articles:

“Qualitative”

“Quantitative”

“Review”

“Process”

- Read the Abstract and then the Methods
- Jot down your impressions of the Methods
 - Did it contain the four primary components?
 - Was the section terminology different?
 - Was it missing any key information?
 - How could it be improved (if at all)?
- Discussion

Evaluation

- Please click on the link in the Chat to answer 5 brief questions about the workshop
- All responses are anonymous
- Will only take about 1 minute!

Thank You!