

Developing a Research Proposal



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ALASKA NATIVE
TRIBAL HEALTH
CONSORTIUM

EPIDEMIOLOGY CENTER

Land Acknowledgement

The background of the slide is a photograph of a natural landscape. In the foreground, several tall, slender stalks of purple flowers, likely Salix, are in bloom. The middle ground shows rolling green hills and a valley. In the distance, a large body of water, possibly a bay or a wide river, is visible under a sky filled with soft, grey clouds. The overall scene is peaceful and scenic.

Thank you to the Dena'ina people, on whose traditional lands I live. Thanks for their past and present stewardship of the waters, plants, animals and spiritual practices of this place.

What is a research proposal?

A detailed description of a proposed research study that you're designing to investigate a particular problem



Why would you write one?

For your employer/university

For IRB and tribal review

For funding

So you (and your team) know what you're doing

So you can identify gaps in your research

Your proposal may look a little different for each audience!

Case Study:

**Randomized controlled trial of the
stool DNA test to improve
colorectal cancer screening among
Alaska Native people
(R01CA247642)**



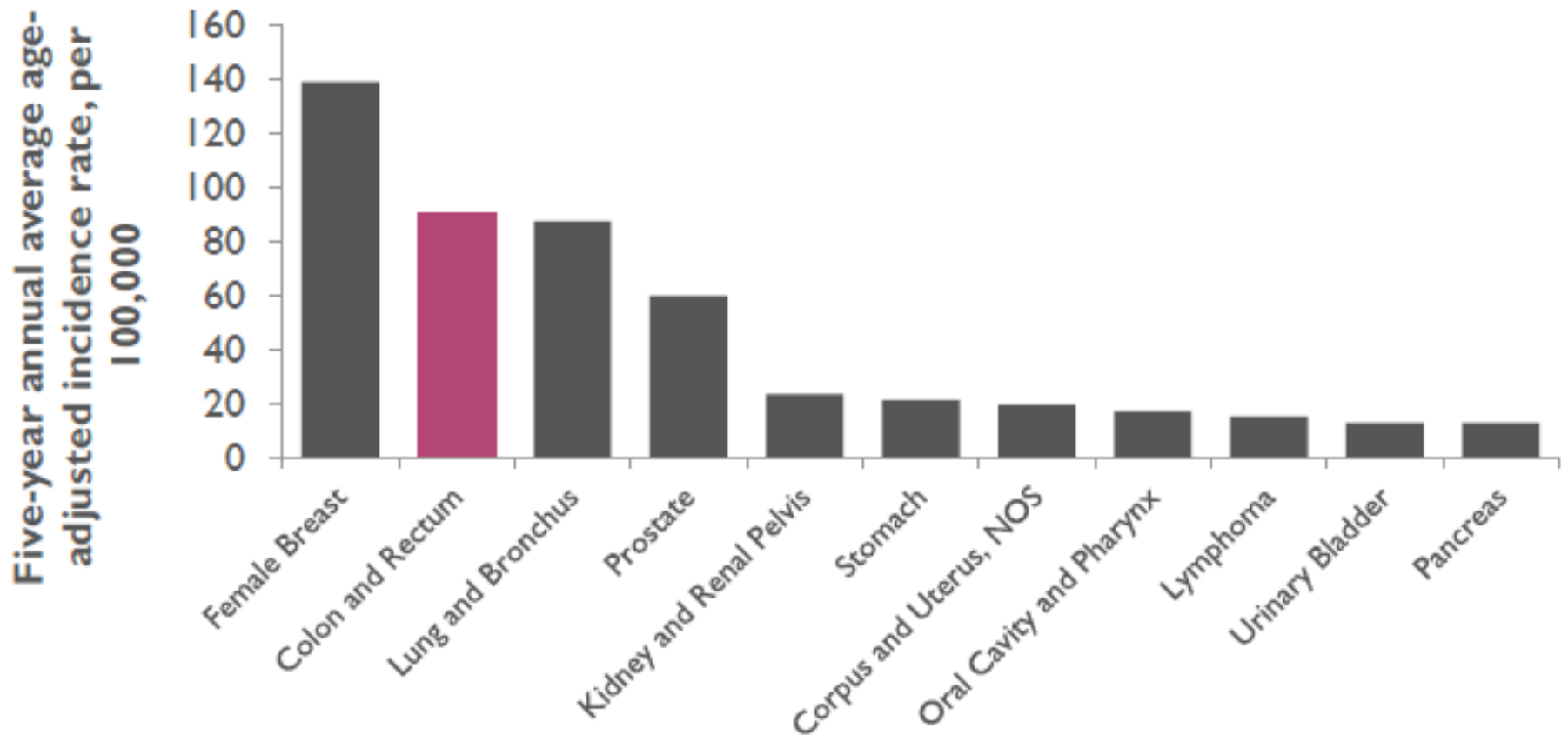
Before you get started

Select your topic

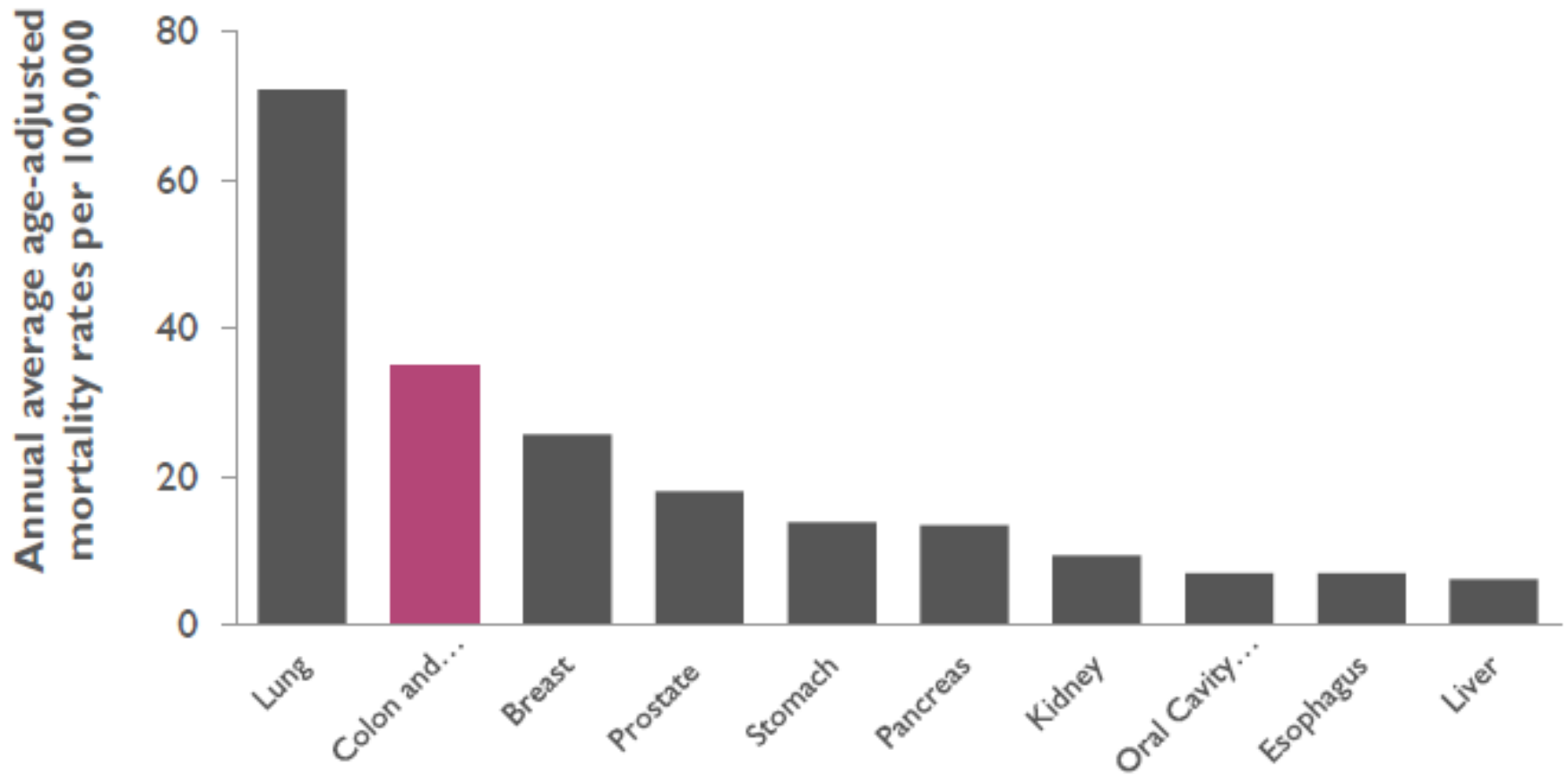


IDEA

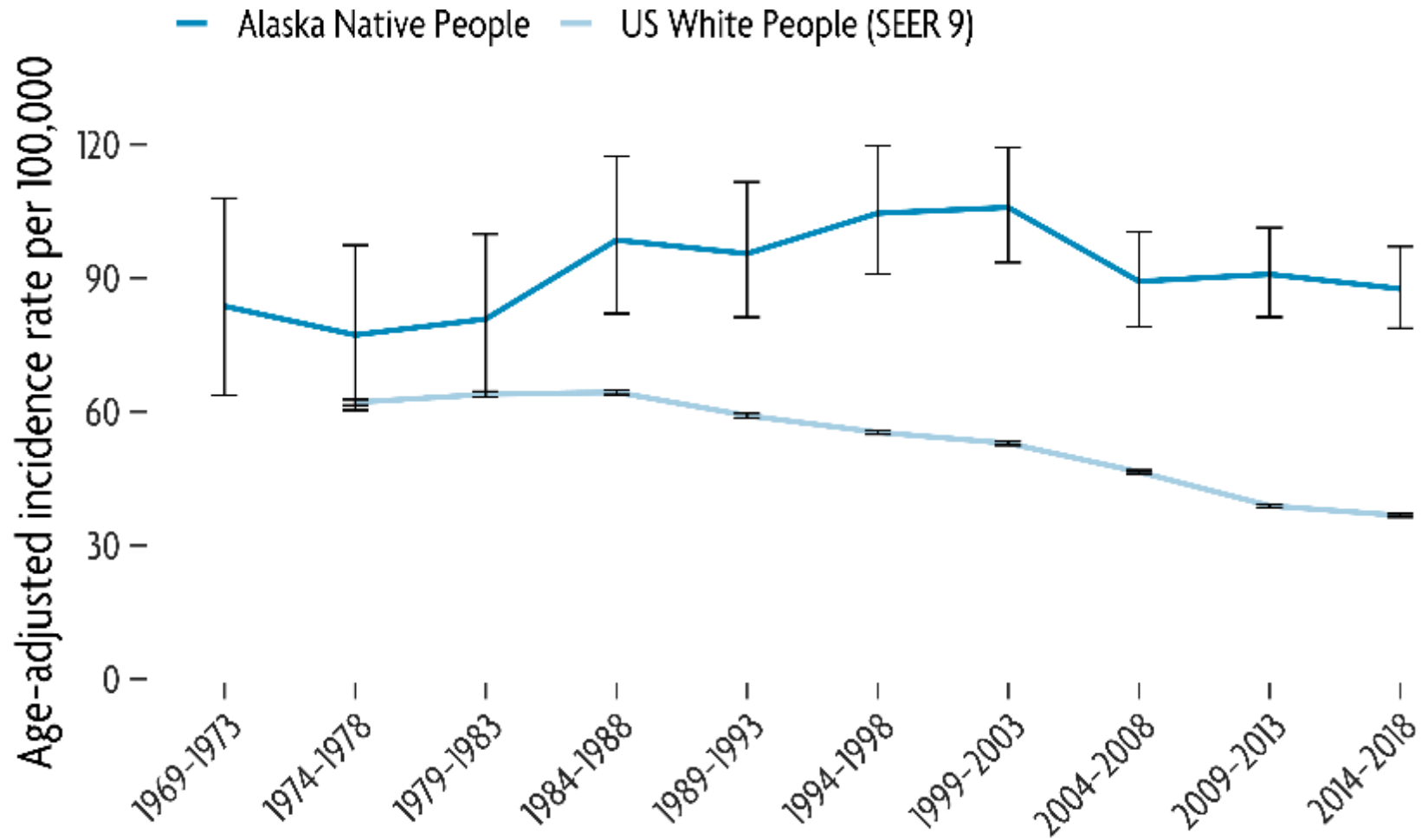
Colorectal cancer is the second most common cancer among AN people



...And the second leading cause of cancer death



Disparities in CRC incidence have persisted for over 40 years.



Source: Alaska Native 50 Year Report, Alaska Native Tumor Registry, 2021

Before you get started

Select your topic

Perform a literature
review



- Alaska Native people have among the highest rates of CRC in the world
- Due to the geographic and health care delivery challenges of CRC screening in Alaska, only around 68% of Alaska Native people have been adequately screened for CRC
- A new screening method, the stool DNA test, is now available, but hasn't been used in the Alaska Tribal Health System

Before you get started

Select your topic

Perform a literature
review

Gather your team





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EPIDEMIOLOGY CENTER



Yukon-Kuskokwim
HEALTH CORPORATION



MAYO
CLINIC



Before you get started

Select your topic

Perform a literature
review

Gather your team

PLAN PLAN PLAN



Elements of a research proposal

Title

Abstract

Introduction

- Problem statement

- Objectives

- Hypothesis

Methods

Sharing results

Title

Should be:

Concise

Descriptive

Catchy

Comprehensible



A randomized controlled trial of the stool DNA screening test using high and medium intensity patient navigation to improve colorectal cancer screening among Alaska Native people living in remote Alaskan communities

vs.

Randomized controlled trial of the stool DNA test to improve colorectal cancer screening among Alaska Native people

Abstract

Brief summary, ~300 words

Summarize all the elements of the project

Stand-alone

Highlight the importance of the work

Only 59% (29-73%) of Alaska Native people have been adequately screened for colorectal cancer (CRC), which could save lives, despite having the highest reported incidence of CRC in the world. A new at-home multi-target stool DNA screening test (MT-sDNA; Cologuard®) with high sensitivity for pre-cancerous polyps and CRC is now available. MT-sDNA has not been tested for feasibility or acceptability within the Alaska tribal health care delivery system, and it is unknown whether use of this new test will increase Alaska Native CRC screening rates. Our long-

Problem Statement

C-attributable mortality. The objective of this application is to test screening in Alaska Native communities using a mixed methods, community-based participatory research (CBPR) approach. The study will be conducted in collaboration with regional Tribal health organizations who are responsible for providing health care to geographically remote Alaska Native communities. This research has been requested by Tribal organizations. Although the proposed implementation strategy is evidence-informed and promising, it is novel in that MT-sDNA has not been evaluated in the tribal health setting or among rural/remote populations. Using the Social Ecological Model, our research will be multi-level, examining influence on patients, providers, and tribal health organizations (THOs). This research study will pursue two specific aims: (1) Identify patient-, provider-, and system-level factors associated with CRC screening preferences, uptake, and follow-up; and (2) test the effectiveness of graded intensity MT-sDNA intervention in the Alaska Native community setting. For the first aim, focus groups with Alaska Native people who are non- or inadequately adherent to CRC screening guidelines, and surveys and interviews with healthcare providers will be used to identify individual, interpersonal (provider), and health system factors for future intervention. For the second aim, a three-arm cluster randomized controlled trial (high intensity with patient navigation, medium intensity with mailed reminders, usual care) will provide evidence on the usefulness of MT-sDNA in remote tribal communities as well as the first data on MT-sDNA diagnostic follow up adherence rates in the Alaska Native population. This aim will also provide evidence on the usability of MT-sDNA in the Alaska setting by evaluating MT-sDNA sample quality and neoplastic yield, which will inform plans to scale-up the intervention model. This project is innovative because an effective strategy for achieving higher screening rates than current practice could lead to increased prevention or early detection of CRC cases among Alaska Native people. The proposed research is significant because it will address a health disparity of community concern. This research has the potential to sustainably improve public health by increasing CRC screening rates among a rural/remote

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term goal is to improve screening and reduce CRC-attributable mortality. The objective of this application is to test the effectiveness of MT-sDNA for increasing CRC screening in Alaska Native communities using a mixed methods, community-based participatory research (CBPR) approach. The study will be conducted in collaboration with regional Tribal health organizations who are responsible for providing health care to geographically remote Alaska Native communities. This research has been requested by Tribal organizations. Although the proposed implementation strategy is evidence-informed and promising, it is novel in that MT-sDNA has not been evaluated

in the tribal health setting, especially in remote populations. Using the Social Ecological Model, our research will be multi-level,

How this study will address the problem

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Introduction

Gives readers background information, rationale, context

Introduction: Problem statement

The major problem of interest and significance that your study will address



Introduction

Why this study?

**What's the
relevance?**

**What other research
has been done?**

Introduction: Objectives

What goals do you want your research to achieve?

Can be

General/Specific

Primary/Secondary



Do not make too many, or too ambitious

General objective:

To find new CRC screening methods for Alaska Native people

Specific objectives:

To identify factors associated with CRC screening preferences

To see if use of the stool DNA test will increase CRC screening among Alaska Native people

Introduction: Hypothesis

Tentative prediction of what you think you might find

For exploratory research, you may not have a hypothesis

Remember: you don't set out to prove your hypothesis, you set out to test it

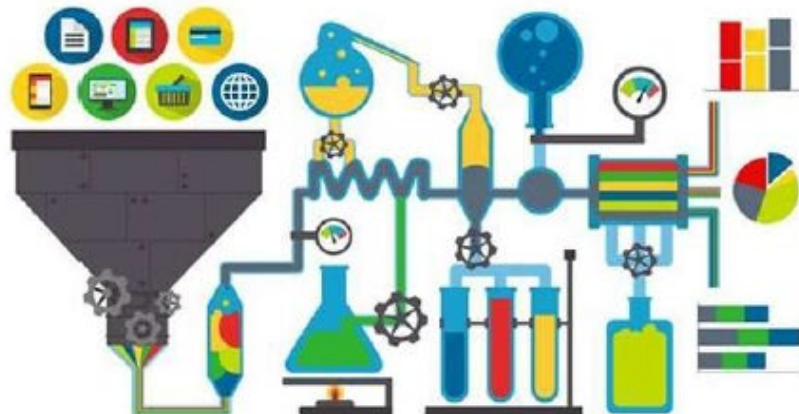
People who are offered the stool DNA test will be more likely to complete screening than those offered just colonoscopy

High intensity navigation will lead to more people being screened than medium intensity or usual care

Methods

Arguably the most important section

Tells your audience how you will answer the research question



Methods: Research design

What study design will you use?

Experimental

Observational



For more information about study designs, see the Coursera Course “Study Designs in Epidemiology”

Methods: Study participants

Who will your participants be?

Inclusion/exclusion criteria

Comparison group

Sampling method

How do participants withdraw?



- Adults ages 45-75
- No history of colorectal cancer
- Eligible for screening colonoscopy and stool DNA test



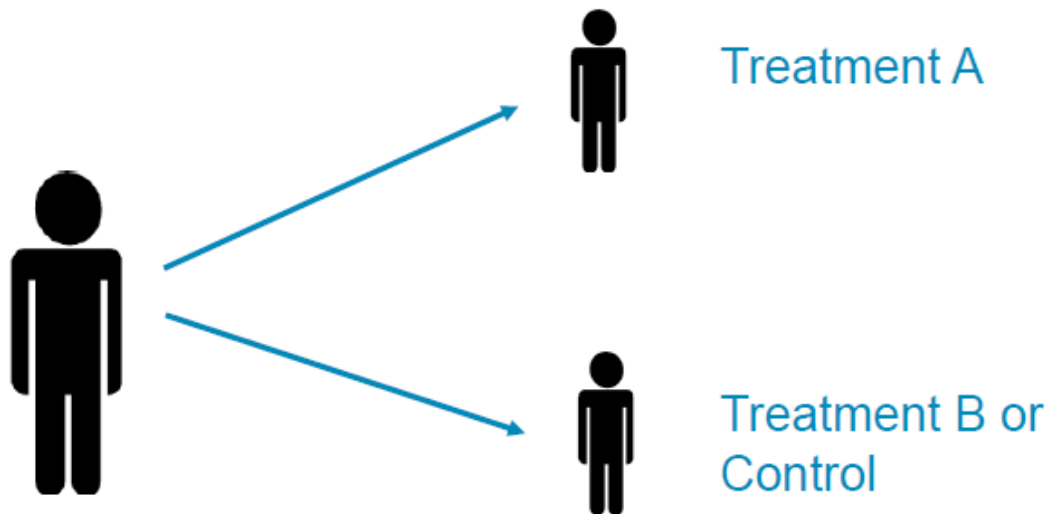
Methods: Intervention

What is the intervention?

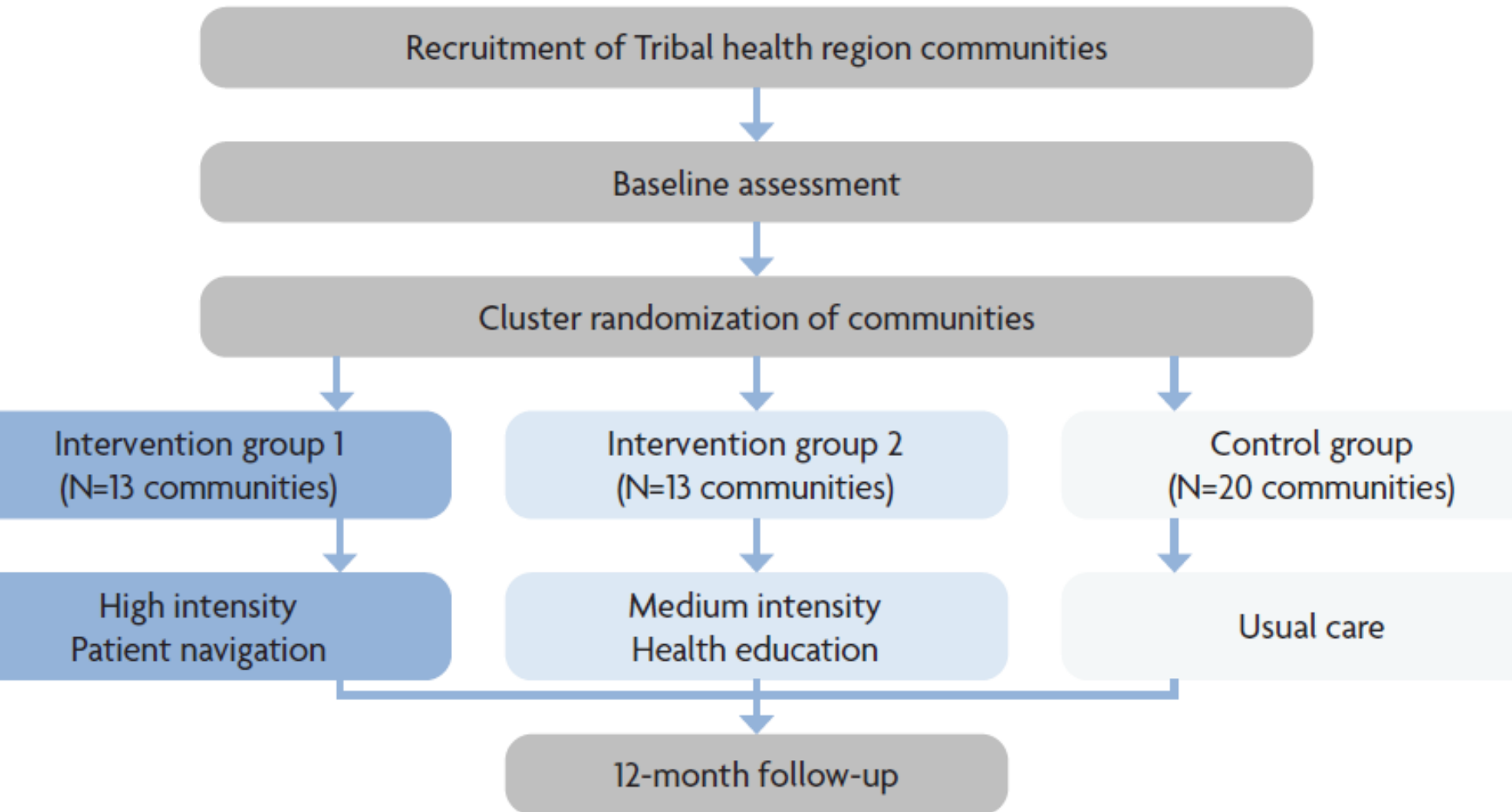
How will it be delivered?

Who will it be delivered to?

What's your control group?



Cluster Randomized Design



Methods: What will you measure?

Independent variables:

Exposure variables. The things you think might cause the outcome(s) of interest



Methods: What will you measure?

Dependent variables:

The outcome(s) of interest

Methods: What will you measure?

“Background” variables:

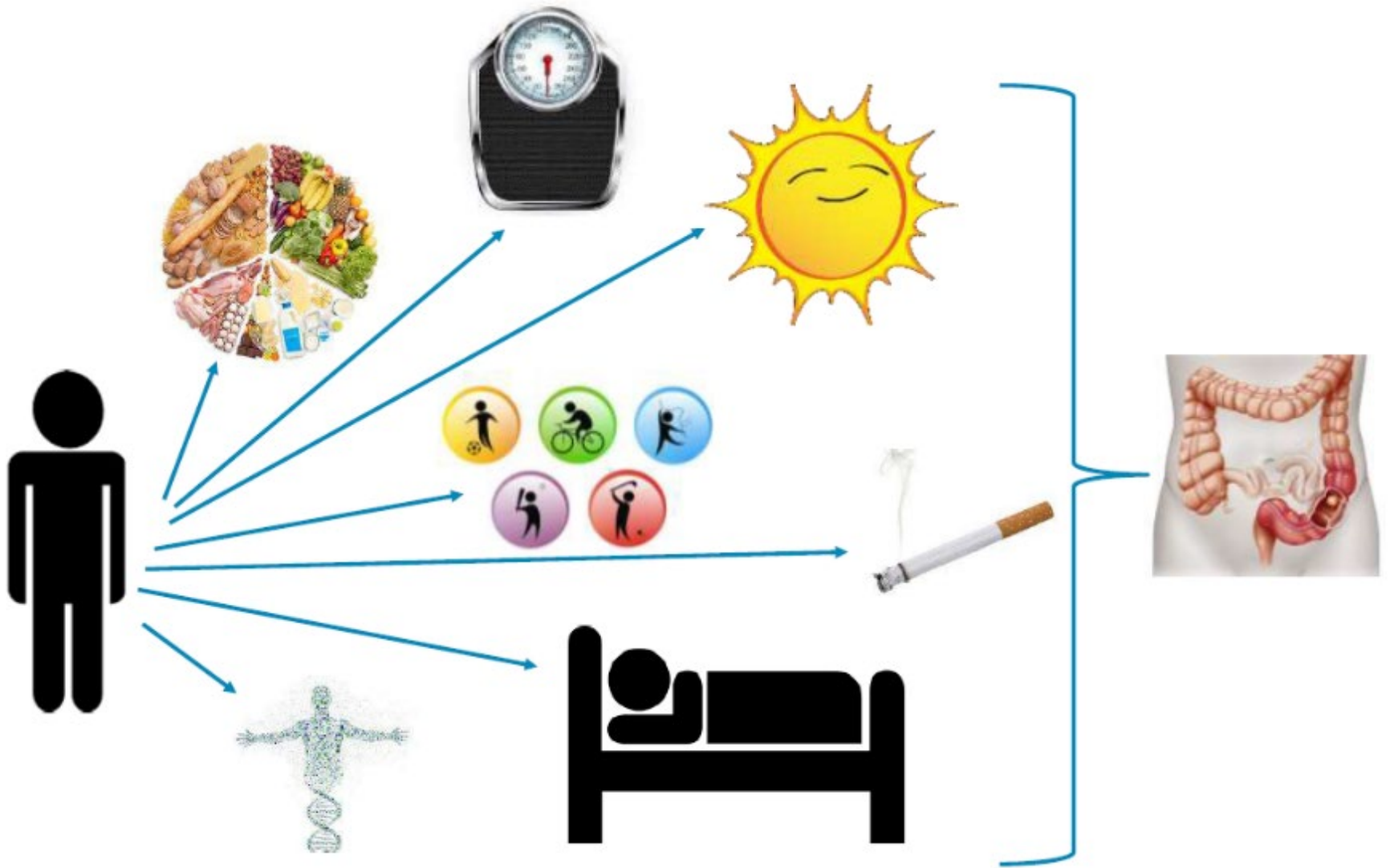
Other things that might affect the exposure or outcome



Considering context

How do the variables in your system fit together?





Methods: How will you measure it?



Your **Study instruments** should be included as an appendix

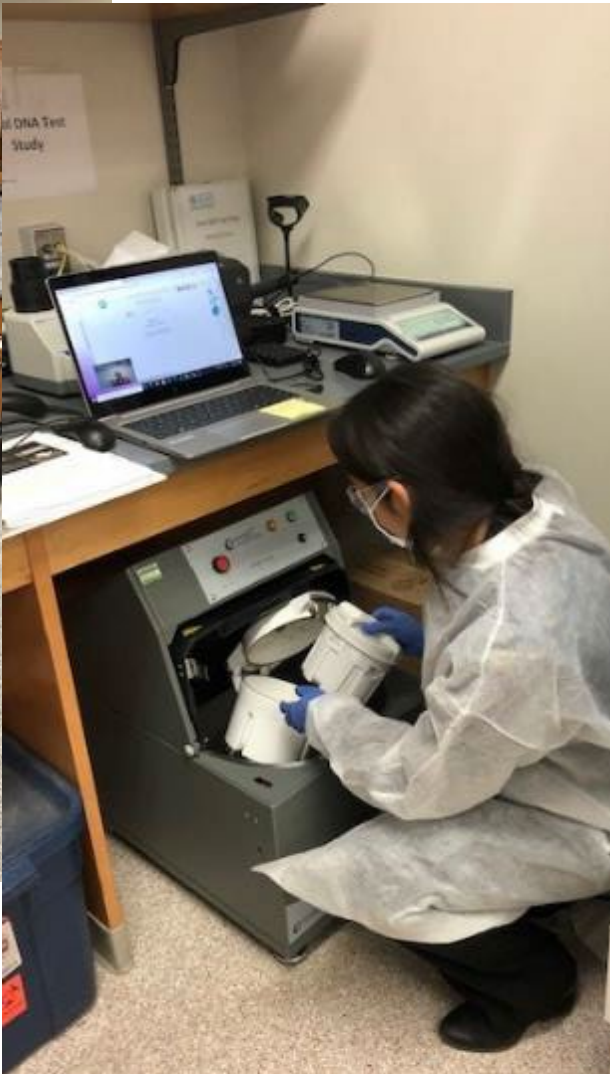
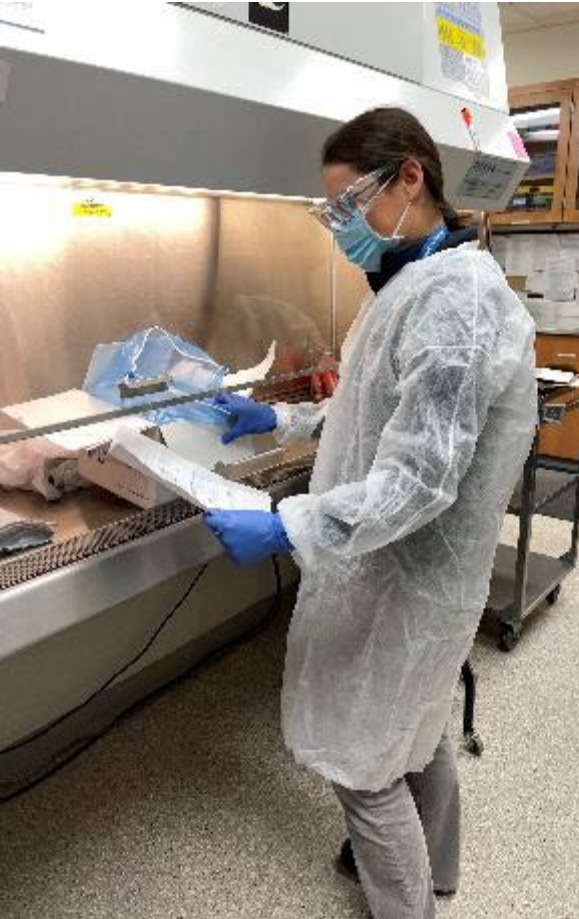
What will be your study process?

What will happen as part of your study?

Walk through the process, like a “dress rehearsal”



Photo courtesy of Bristol Bay Area Health Corporation



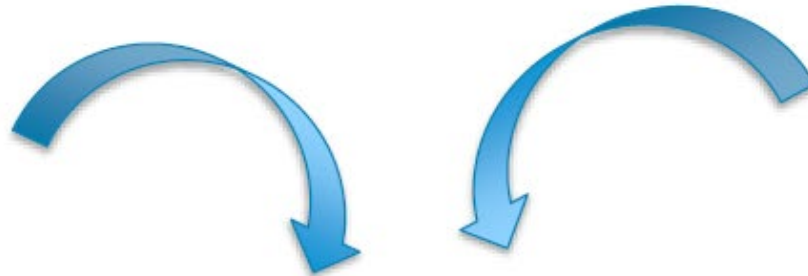
Methods: Sample size

How many participants do you need to test your hypothesis?



(A biostatistician can help with this, and many other things)

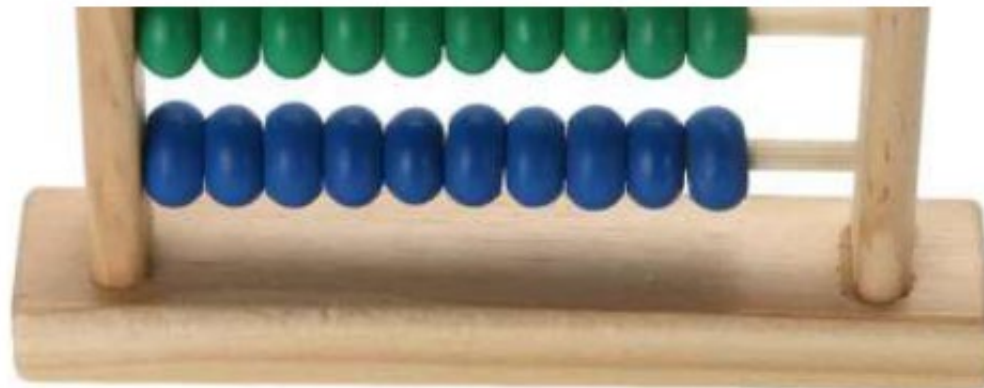
Methods: Data storage and security



Methods: Data analysis



Hint: your biostatistician should
write this part!



Dissemination of results

Dissemination is a critical part of community-engaged research

Plan ahead how you will share results with participants, community members, and tribal health leaders



Conclusions

Give some expected outcomes

Reiterate how your proposed study will answer the research question and provide useful information to the world

What happens next? How will your research lead to more research or programs?

Ethics of a research proposal

Describe how the study will be conducted in accordance with relevant ethical guidelines

USA: Common Rule

Reviewing your research proposal in three questions

Is the proposed study adequate to answer the research question?

Is the research feasible?

Does the proposal provide enough detail that another investigator could do the study?

Lessons learned?

Iterative process

Gather your team early (and use them!)

Involve the community early and often

Think about the end at the beginning

Resources

<https://cancercontrol.cancer.gov/is/funding/sample-grant-applications>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3282423/>

Coursera Courses:

Study Design in Epidemiology

Understanding Clinical Research

Statistical Inference

Thank You

qagaasakung baasee' tsin'aen quyanaq
dogedinh quyanaa igamsiqanaghalek
'awa'ahdah gunalchéesh chin'an mahsi'
tsin'e e way dankoo háw'aa quyana

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