MODULE 3: UNDERSTANDING THE RESEARCH PROCESS

Veterans Health Administration

Durham VA Health Care System

VA HEALTH CARE

HONORING SERVICE EMPOWERING HEALTH

Objectives

- Review information covered in Modules 1 and 2
- Provide an overview of the research process
  - Elements of research studies
  - Research questions
  - Study design
  - Research methods
  - Timeline for research process, from planning to sharing results
- Describe ways that VA research is similar to/different from other research

Review

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ELEMENTS OF RESEARCH

What are the Elements of Research?

- Forming the Research Question
- Designing the Study
- Recruiting Subjects/Participants
- Collecting and Analyzing Data
- Drawing Conclusions and Sharing Findings

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Content adapted from David Edelman, MD "Elements of Clinical Research"

RESEARCH QUESTIONS

Research Question

- A research question describes the issue you want to study

- A good research question is:
  - ✓Interesting
  - ✓Practical
  - ✓Specific
  - ✓New
  - ✓Ethical
  - ✓Important to society

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Real Research Questions: Good and Better

How could these research questions be improved?

1) Why do Veterans get PTSD?
2) Does Problem Solving Therapy help people live healthier lives?
3) Does health coaching improve clinical outcomes?

A good research question is:

- Interesting
- Practical
- Specific
- New
- Ethical
- Important to society

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Real Research Questions: Good and Better

How could these research questions be improved?

- Why do Veterans get PTSD?
  - What demographic, psychological, and military experience factors are the most important predictors of PTSD among Veterans returning from deployment?

A good research question is:

- Interesting
- Practical
- Specific
- New
- Ethical
- Important to society

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Real Research Questions: Good and Better

How could these research questions be improved?

- Does Problem Solving Therapy help people live healthier lives?
  - Compared to standard care, does training in Problem Solving Therapy increase the likelihood that someone will [quit smoking, increase physical activity, lose weight]?

A good research question is:

- Interesting
- Practical
- Specific
- New
- Ethical
- Important to society

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Real Research Questions: Good and Better

How could these research questions be improved?

- Does health coaching improve clinical outcomes?
  - Among adults, what is the effectiveness of health coaching on blood pressure, blood glucose markers, and weight when compared to standard care?

A good research question is:

- Interesting
- Practical
- Specific
- New
- Ethical
- Important to society

Practice Developing a Research Question

A good research question is:

- Interesting
- Practical
- Specific
- New
- Ethical
- Important to society

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How do Researchers come up with Research Questions?

- Personal interest of researcher

"I have been studying services for patients with end-stage renal disease since learning about it from a close family friend over a decade ago. Progression of kidney disease to kidney failure drastically changes the lives of patients and their loved ones. Kidney disease is so intricately related to diabetes, heart disease, and hypertension, yet has received less attention than these other chronic conditions. The unique features of how services for kidney disease are organized and financed has held my interest from a research and social justice perspective. And it is too important to be ignored: a growing number of patients will develop kidney disease and health services research is needed to address the challenges of improving services and quality of care to patients with kidney disease. " – Virginia Wang, PhD

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How do Researchers come up with Research Questions?

- Clinical experience/expertise of researcher

"I saw so many patients who were unable to control their diabetes despite receiving regular treatment in the clinic setting, so I started to think of ways to reach those people who weren't responding to clinic-based care. We designed a telehealth intervention that that utilized existing VA telemedicine services for delivery, and combined daily reporting of blood sugars and bi-weekly self-management support and medication management. We found that it helped most participants improve their A1c by 1% or more in 6 months." – Matt Crowley, MD

How do Researchers come up with Research Questions?

- Results of previous research that showed gaps in care or outcomes

"Our research team found that African Americans with osteoarthritis had more severe pain than Caucasians, and that one key explanatory factor was the types of pain coping skills used. This was "actionable" information in terms of identifying a potential intervention to reduce these racial disparities, and we are now conducting a clinical trial of a pain coping skills training program tailored for African Americans with osteoarthritis." – Kelli Allen, PhD

"In our last trial of smoking cessation among Veterans, we found that those with depression did not quit at the same rates as those without depression. In our next trial, we worked specifically with Veterans with depression and tested if the best standard of care counseling treatment for smoking cessation may be enhanced if augmented with skills that help participants deal with their depression before we asked them to try to quit smoking." – Jennifer Gierisch, PhD

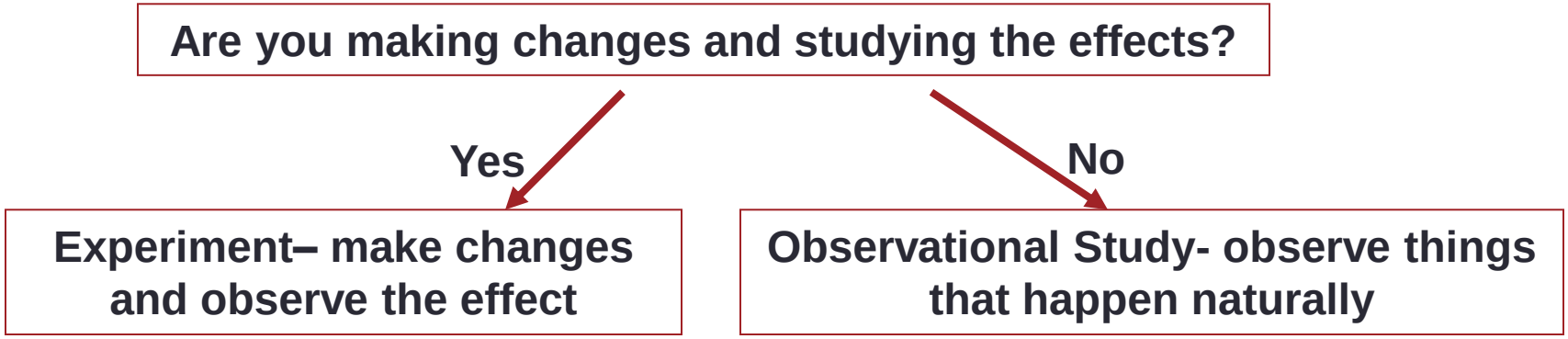
How do Researchers come up with Research Questions?

- Priorities identified by the VA or other organizations that fund research

"There has been a lot of research done about the health of Veterans who served during the 1990-1991 Gulf War Era, but many Veterans are still experiencing health problems that we don't understand. VA leadership felt that they needed information from a large number of Veterans to be able expand the types of research studies conducted with this group. They asked me to create this cohort because of my experience conducting large studies in the past. Because of this, we designed a research project where we collected blood samples and survey data from Veterans who served during 1990-1991. Now, researchers can use this information to conduct many different studies about the health of these Veterans." – Dawn Provenzale, MD, MS

STUDY DESIGN

Types of Study Design



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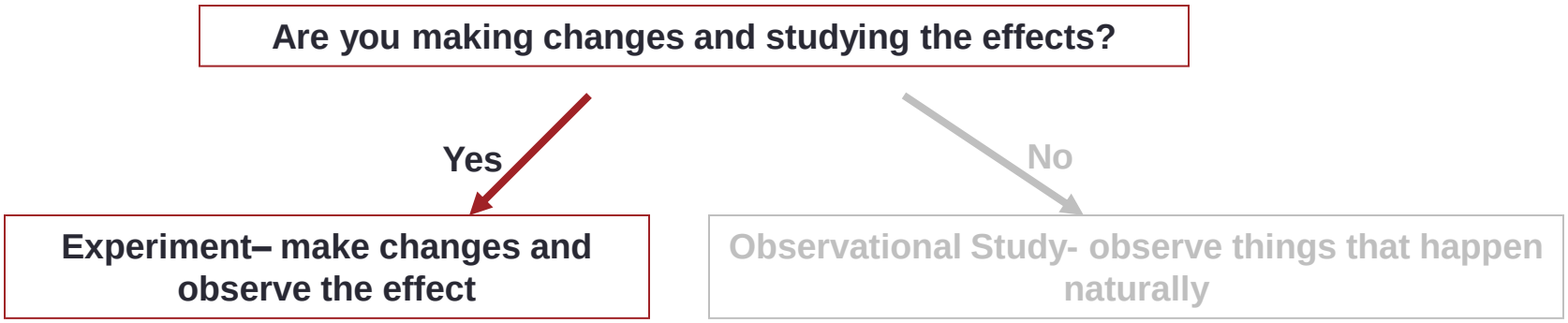
Types of Study Design: Experiment



- The strongest experiments are "randomized"
  - The researcher should not know what treatment is better before the study
  - The treatment each participant gets is decided randomly, like flipping a coin
  - Often there is a "control" group that gets no treatment, or gets "standard care"
  - Some experiments test and compare different treatments

Types of Study Design: Experiment

- Randomizing is a way to avoid "bias."
  - Researchers unfairly putting certain participants into a specific group
  - Participants choosing to be in a specific group
- Randomizing helps control for things about participants that we don't know about that could affect the outcome of the study.

Activity

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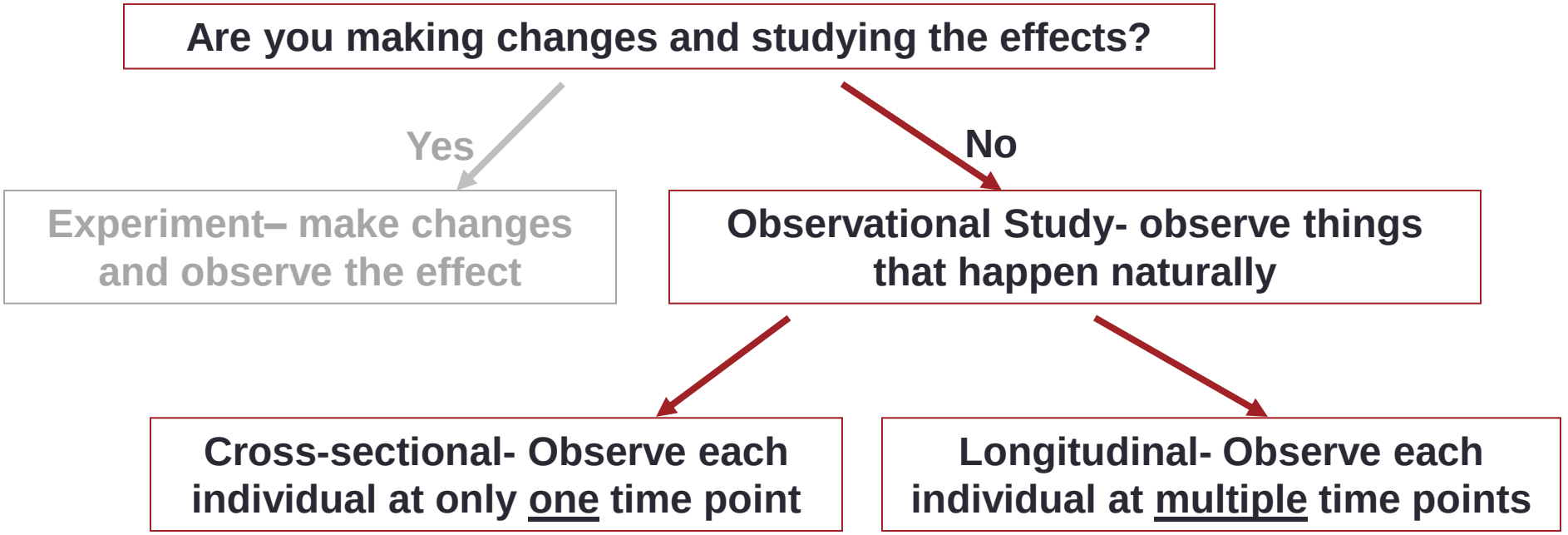
Types of Study Design: Experiment

- Randomizing is not always ethical or feasible.
  Examples:
  - Randomizing participants to a group in which they're given no treatment for a given period of time
  - Randomizing participants to be given a disease or harmful treatment
  - Randomizing participants to test a specific diet over a long period of time

Types of Study Design: Observational



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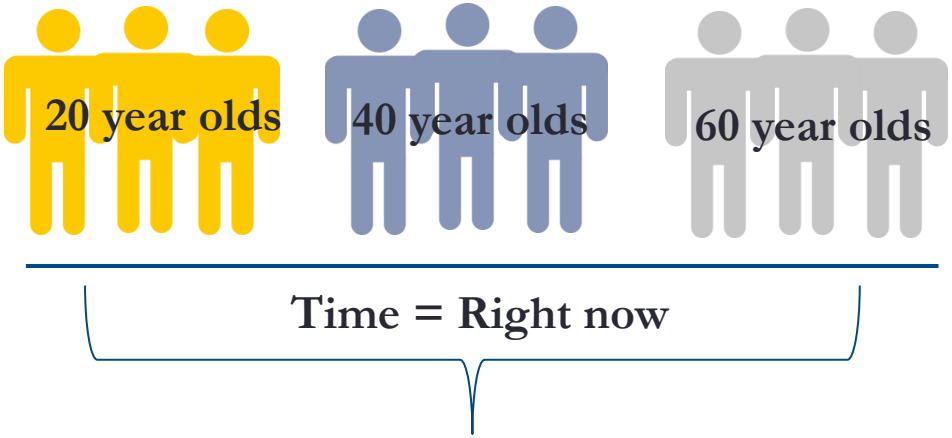
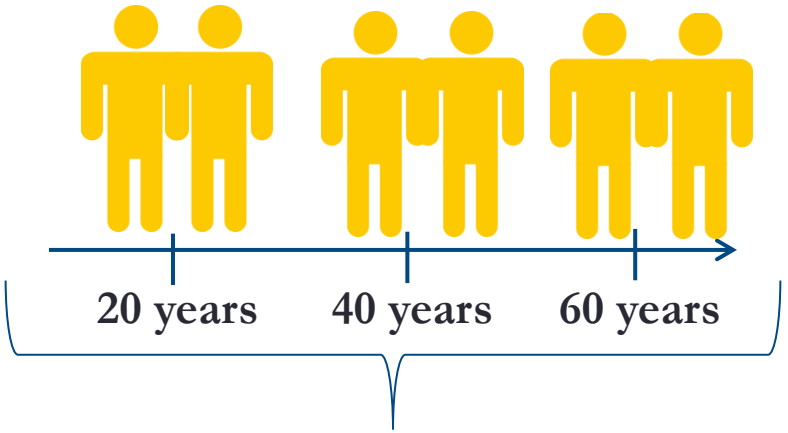
Types of Study Design: Observational

Cross-sectional- Observe each individual at only one time point



Snapshot of characteristics of individuals at the same point in time

Longitudinal- Observe each individual at multiple time points



Characteristics of the same individual(s) observed at different points in time

Experimental Design: Comparing Intervention Group and Usual Care Group

9234||

A randomized controlled trial to evaluate the effectiveness of CouPLES: A spouse-assisted lifestyle change intervention to improve low-density lipoprotein cholesterol ☆

Corrine I. Voils[a, b], Cynthia J. Coffman[a, c], William S. Yancy Jr.[a, b], Morris Weinberger[a, d], Amy S. Jeffreys[a], Santanu Datta[a, b], Stacey Kovac[a], Jamiyla McKenzie[a], Rose Smith[a], Hayden B. Bosworth[a, b]

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Cross-Sectional Design: Administering a Survey One Time

Research article

The prevalence of binge drinking and receipt of provider drinking advice among US veterans with military service in Iraq or Afghanistan

Patrick S. Calhoun ✉, PhD, Amie R. Schry, PhD, H. Ryan Wagner, PhD, Nathan A. Kimbrel, PhD, Paul Dennis, PhD, Scott D. McDonald, PhD, Jean C. Beckham, PhD, Eric A. Dedert, PhD, Harold Kudler, MD & Kristy Straits-Troster, PhD

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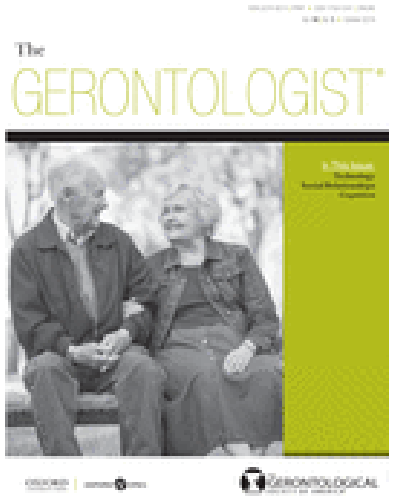
Longitudinal Design: Following Participants for 15 years



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OXFORD

Research Article

Military Generation and Its Relationship to Mortality in Women Veterans in the Women's Health Initiative

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BREAK!

STUDY DESIGN, CONTINUED…….

In months where people eat more ice cream, there are more drownings.

Does eating ice cream cause people to drown?

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Correlation vs. Causation

Correlation: there is a pattern between two things – easy to determine

Causation: one thing causes another thing – very hard to determine

Correlation vs. Causation

Observational study designs usually can only allow us to see if there is a pattern between two things. There are many factors outside of our control that may be affecting what we see. [**Correlation**]

Experimental study designs allow us to be more confident in making conclusions about what causes something to happen. [**Causation**]

If we find a pattern showing that people who drink green tea tend to weigh less…..

What factors besides green tea might be contributing to what we see?

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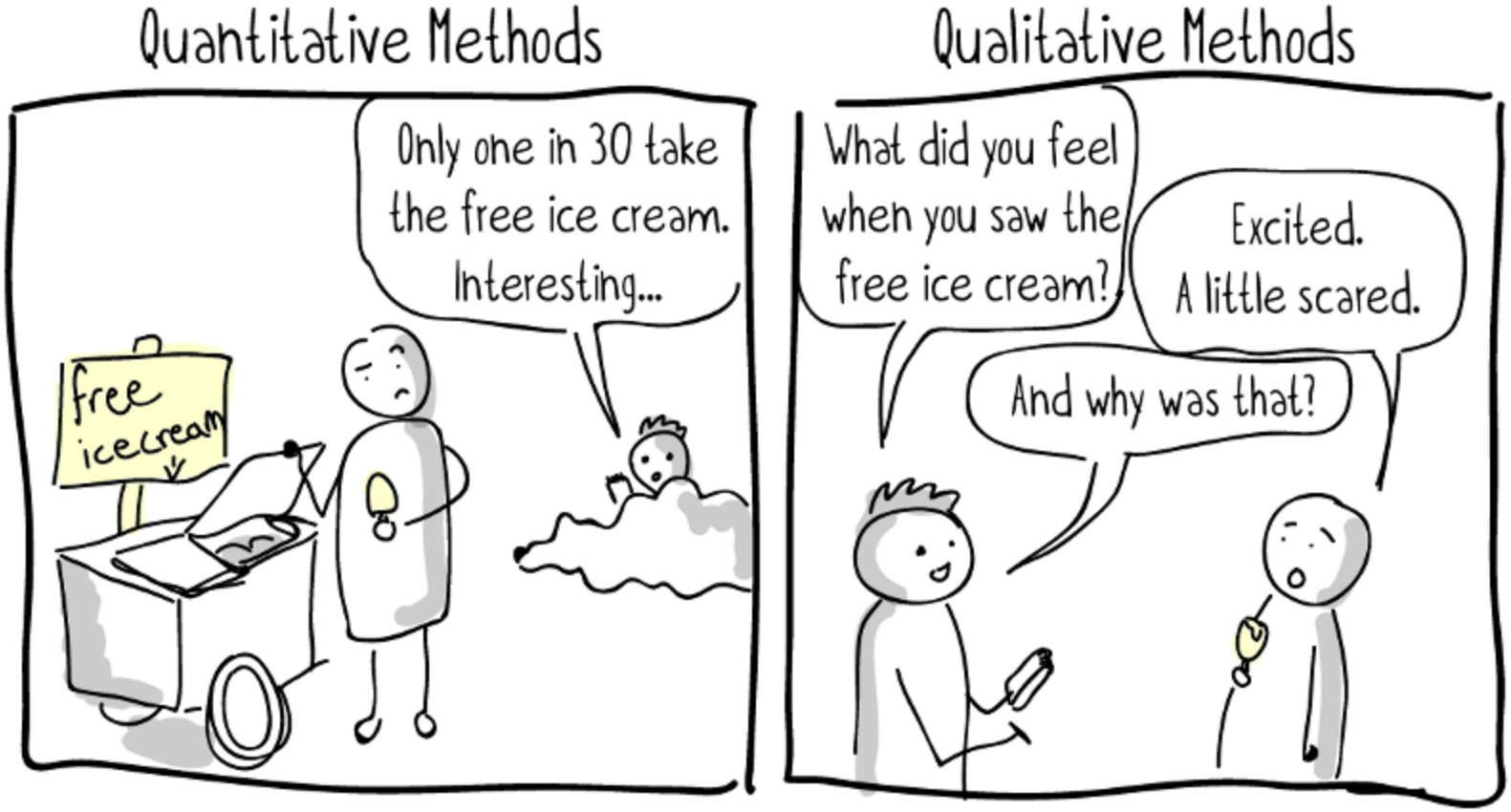
RESEARCH METHODS

Type of Research Methods



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Types of Research Methods

Quantitative	Qualitative
Type of data: Data is changed into numbers; Data is analyzed using statistics	**Type of data:** Data is mainly verbal; Data (text) is analyzed to find themes
Goal: (often) to make conclusions about a larger population	**Goal:** (often) to learn about the experience of individuals in a specific group
Types of measures: Surveys, physiological data (heart rate, blood pressure, weight), etc.	**Types of measures:** Interviews, focus groups (group discussions)
Sample Research Question: What percentage of people in Time Square will accept free ice cream?	**Sample Research Question:** What are the barriers that prevent people in Time Square from accepting free ice cream?

Mixed Methods Research uses both Quantitative and Qualitative methods in the same study.

Content modified from Alzheimer-Europe webpage: http://www.alzheimer-europe.org/Research/Understanding-dementia-research/Types-of-research/The-four-main-approaches

Type of Research Methods

Mixed-Methods Research =

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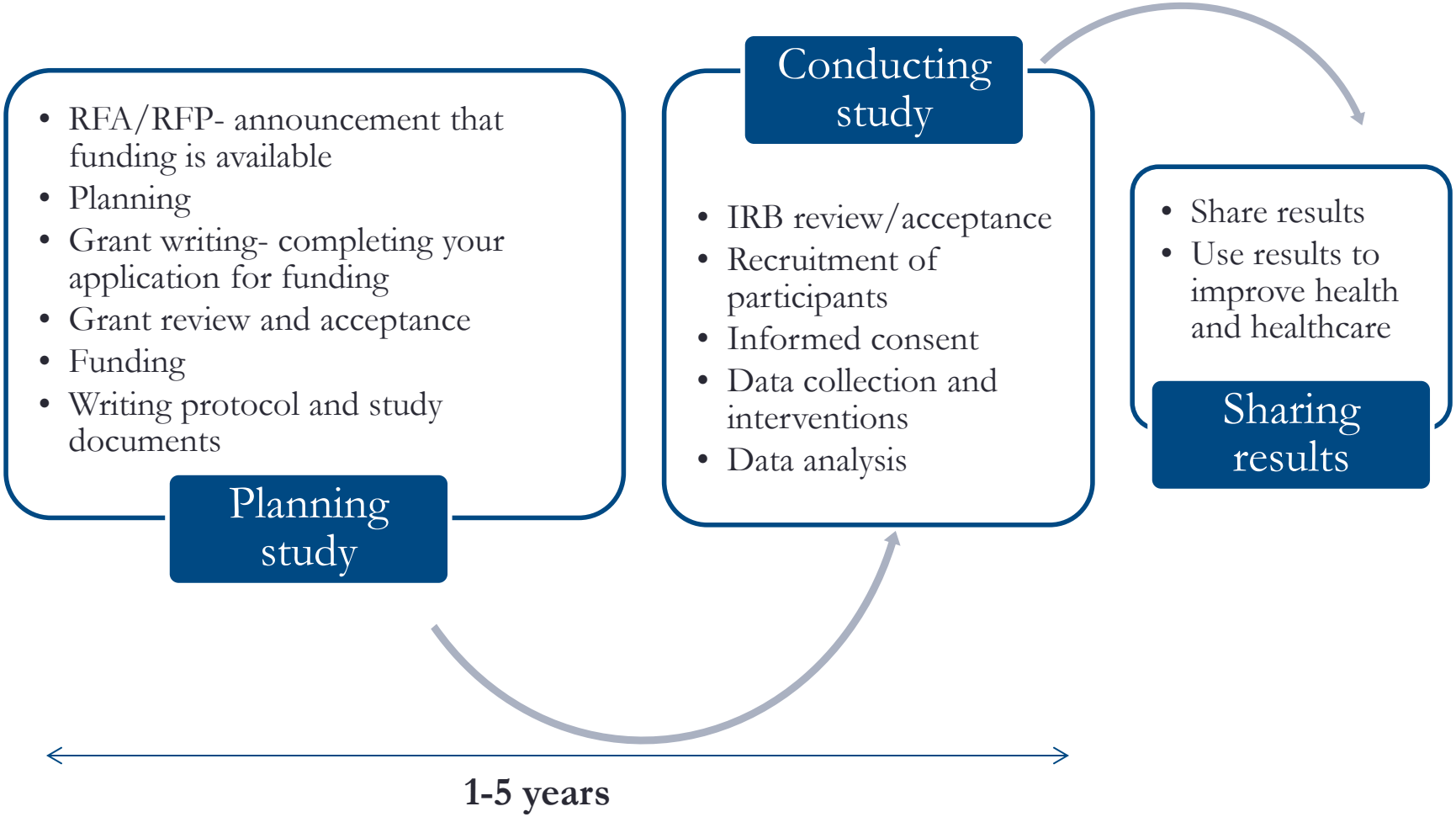
RESEARCH TIMELINE

From planning the study to sharing the results…

Research Process and Timeline



Common Roadblocks: Research Delays

- Hiring staff
- Getting approval from IRB to do study
- Getting permission to use existing data
- Recruiting participants
- Unexpected or negative (adverse) issues
- Getting IRB approval for any changes to the study
- Organizing data so it can be analyzed
- Analyzing data
- Getting research published

Research Results: Getting the Word Out!

- Common ways results of studies are shared:
  - Final report to people who fund the study
  - Presentations at research conferences
  - Articles in research journals
- Other ways results are shared:
  - Summaries written for the public
  - Community presentations
  - News stories

Research Results: Getting the Word Out!

- A concern of researchers is bias in publishing:
  - In scientific journals, there is a bias against publishing "null findings" (i.e., when you try an intervention and it does not work).
  - In public media, stories can be twisted or sensationalized in ways that are misleading.
- A Veteran-focused example of misrepresentation of data in mass media: 22 Veterans a day

SCIENCE

Andrew M Brown is the Costa del Sol submerging under an avalanche of custard creams? telegraph.co.uk/blogs

Health warning: exercise makes you fat

Re-programming body fat is the key to weight loss, not working out, says
Richard Gray

More people in Britain do the recommended amount of exercise - at least 30 minutes of moderate-intensity activity at least five times a week - than did 12 years ago

Use of personal trainers and gyms has soared over the past five years. The amount spent on the latter has grown by 50 per cent, to more than £1.25bn

One in 10 children is obese when

People exercise heavily then eat a chocolate muffin

Sharing and Using Research Results

Getting the research *into* the healthcare system can take a long time.

Some studies have estimated that it takes an average of 17 years for research results to start being used within the health care setting (Hanney et al. 2015)

However, sometimes the VA can start using research results more quickly.

Hanney, S. R., Castle-Clarke, S., Grant, J., Guthrie, S., Henshall, C., Mestre-Ferrandiz, J., ... & Wooding, S. (2015). How long does biomedical research take? Studying the time taken between biomedical and health research and its translation into products, policy, and practice. *Health Research Policy and Systems*, *13*(1), 1.

VA RESEARCH VS. OTHER RESEARCH

VA Research vs. Other Research

Similarities:

- Research is overseen by IRB
- Same general elements of research process and timeline

Differences:

- All research is conducted for the benefit of Veterans (participants are Veterans, Veteran family members, or providers)
- May use VA data sources, such as VA medical records
- Along with the IRB, an Information Security Officer (ISO) and Privacy Officer (PO) oversee research
- VA leadership may ask researchers to conduct a specific study

How have your ideas about research changed?

What questions do you have?

What more do you want to learn?

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