




<p>MODULE 3: UNDERSTANDING THE RESEARCH PROCESS</p>    <p>Veterans Health Administration Durham VA Health Care System</p> <p>VA HEALTH CARE HONORING SERVICE EMPOWERING HEALTH</p>	<p>Welcome participants back to the training. If helpful, review names of participants by asking everyone to introduce themselves again. Optional: ask participants to share something they learned during the last training.</p> <p>Remind participants to feel free to step out of the room and take breaks as needed.</p>
<p>Objectives</p> <ul style="list-style-type: none"> • Review information covered in Modules 1 and 2 • Provide an overview of the research process <ul style="list-style-type: none"> • 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 	<p>Talking Points:</p> <ul style="list-style-type: none"> - This training will build upon the information covered in Modules 1 and 2 - First, we will briefly review what we talked about in Modules 1 and 2 - Next, we will delve deeper into the research process. We will discuss things including: <ul style="list-style-type: none"> ○ The elements of research studies ○ Research questions ○ Study design ○ Research methods ○ Timeline for the research process, from planning to sharing results ○ How research is done in VA - Many of these concepts in these trainings are quite technical and things researchers learn through many years of schooling. Please don't feel like you have to completely understand all these concepts today. We created this session, in part, to help familiarize everyone with common terminology used in developing and conducting research. We hope the session will give you a better foundation for providing input and recommendations to researchers. You also will have opportunities to continue learning about these concepts throughout your time with VetREP. - Please feel free to ask questions throughout. Also, please let us know if you'd like further training about these or other topics. We will keep a list of these ideas for future trainings.

Review

Talking Points:

- In previous modules, we talked about the *what* and *why* of research. We discussed what research is, why research is important, who is involved, your role as VetREP members, and research ethics. Let's review these concepts before we move on today.

Option 1: Discussion activity. Briefly discuss the previous training (purpose is to jog participants' memory of these concepts). Questions to ask may include:


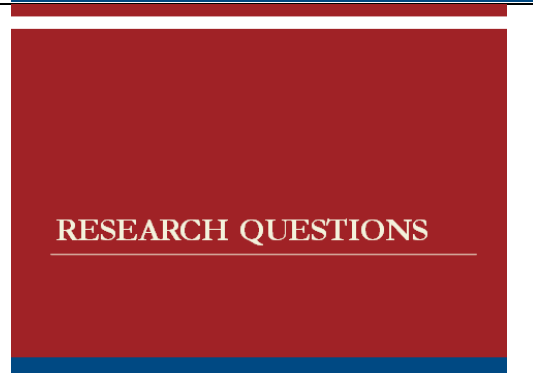
- With a partner, briefly discuss: what is research and why is it important?
- What additional questions arose after our last training?
- What did you find most interesting about our last training?
- What was most confusing from our last training?

Option 2: Review Riddle (See Appendix A).

- Approach 1: Participants work in pairs or small groups, and complete the review questions in order to spell out the answer to a riddle. See attached activity in Appendix A. If needed, review the answers as a group.
- Approach 2 (energizer) - put the answers on post-it notes, along with their associated letter, and place the notes around the room. Participants walk around the room to locate the correct answers and solve the riddle.



Option 3: Jeopardy. Break the group into two teams. Play "Jeopardy" using the questions from the review worksheet in Appendix A and/or other questions about content from Modules 1 and 2.

Option 4: Poll Anywhere. Use "poll anywhere" technology, if available, to ask people to respond to the questions from Appendix A (will need to transform questions into multiple choice). The group can review the answers and see how others responded in real-time.

 <p>ELEMENTS OF RESEARCH</p>	<p>We've mentioned some of the elements of research in previous modules without defining them, so we want to briefly lay out what the elements of research are. We will be focusing on some of these elements today.</p>
<p>What are the Elements of Research?</p> <ul style="list-style-type: none">• Forming the Research Question• Designing the Study• Recruiting Subjects/Participants• Collecting and Analyzing Data• Drawing Conclusions and Sharing Findings <p><small>Content adapted from David Edelman, MD "Elements of Clinical Research"</small></p>	<p>Talking Points:</p> <ul style="list-style-type: none">- There are many important elements and steps in the research process.- To do a research study, researchers must decide what to study, figure out how they will study it, recruit participants, collect and analyze data, draw conclusions from the data, and figure out how to share their findings with different stakeholders- We will talk about most of elements listed here in more depth. These are the kind of things that VetREP members will provide input about- The first step in conducting a research study is deciding what you want to study, and developing a good research question. <p>(Content adapted from David Edelman, MD "Elements of Clinical Research")</p>
 <p>RESEARCH QUESTIONS</p>	

<p style="text-align: center;">Research Question</p> <ul style="list-style-type: none">• A research question describes the issue you want to study• A good research question is:<ul style="list-style-type: none">✓ Interesting✓ Practical✓ Specific✓ New✓ Ethical✓ Important to society <p style="text-align: center; font-size: small;">Content adapted from David Edelman, MD "Elements of Clinical Research"</p>	<p>Talking points:</p> <ul style="list-style-type: none">• A research question describes the issue you want to study<ul style="list-style-type: none">• E.g., Can drug X treat high blood pressure better than drug Y?• A good research question is:<ul style="list-style-type: none">• Interesting• Practical<ul style="list-style-type: none">• Do we have enough time? Do we have enough money?• Specific<ul style="list-style-type: none">• Is the question too broad?• New<ul style="list-style-type: none">• Will it help us learn something new, or help us better understanding things we've learned from other studies?• Ethical• Important to society <p>(Content adapted from David Edelman, MD "Elements of Clinical Research")</p>
<p>Real Research Questions: Good and Better</p> <p>How could these research questions be improved?</p> <ol style="list-style-type: none">1) Why do Veterans get PTSD?2) Does Problem Solving Therapy help people live healthier lives?3) Does health coaching improve clinical outcomes? <div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto; margin-right: auto;"><p style="font-size: x-small;">A good research question is: Interesting Practical Specific New Ethical Important to society</p></div>	<p>Talking points:</p> <ul style="list-style-type: none">- Even good, interesting research questions can be improved. We are going to look at three examples of research questions and talk through how we can make them stronger. These examples were pulled from the work of researchers in this room.

<p>Real Research Questions: Good and Better</p> <p>How could these research questions be improved?</p> <p><input type="checkbox"/> Why do Veterans get PTSD?</p> <p>> What demographic, psychological, and military experience factors are the most important predictors of PTSD among Veterans returning from deployment?</p> <div data-bbox="541 435 699 553" style="border: 1px solid black; padding: 5px; margin-top: 10px;"><p>A good research question is:</p><ul style="list-style-type: none">InterestingPracticalSpecificNewEthicalImportant to society</div>	<p>Discuss: “Why do Veterans get PTSD?” How can this question be improved? (note- stronger question appears after click)</p> <ol style="list-style-type: none">1. If helpful, can go through each criterion listed in box on the right. Ask, “<i>Is this question interesting, practical, etc.? How can we make it more interesting, practical, etc.?</i>”2. Discuss why stronger question is stronger
<p>Real Research Questions: Good and Better</p> <p>How could these research questions be improved?</p> <p><input type="checkbox"/> Does Problem Solving Therapy help people live healthier lives?</p> <p>> Compared to standard care, does training in Problem Solving Therapy increase the likelihood that someone will [quit smoking, increase physical activity, lose weight]?</p> <div data-bbox="520 816 678 935" style="border: 1px solid black; padding: 5px; margin-top: 10px;"><p>A good research question is:</p><ul style="list-style-type: none">InterestingPracticalSpecificNewEthicalImportant to society</div>	<p>Discuss: “Does Problem Solving Therapy help people live healthier lives?” How can this question be improved? (note- stronger question appears after click)</p> <ol style="list-style-type: none">1. If helpful, can go through each criterion listed in box on the right. Ask, “<i>Is this question interesting, practical, etc.? How can we make it more interesting, practical, etc.?</i>”2. Discuss why stronger question is stronger
<p>Real Research Questions: Good and Better</p> <p>How could these research questions be improved?</p> <p><input type="checkbox"/> Does health coaching improve clinical outcomes?</p> <p>> Among adults, what is the effectiveness of health coaching on blood pressure, blood glucose markers, and weight when compared to standard care?</p> <div data-bbox="531 1198 688 1317" style="border: 1px solid black; padding: 5px; margin-top: 10px;"><p>A good research question is:</p><ul style="list-style-type: none">InterestingPracticalSpecificNewEthicalImportant to society</div>	<p>Discuss: “Does health coaching improve clinical outcomes?” How can this question be improved? (note- stronger question appears after click)</p> <ol style="list-style-type: none">1. If helpful, can go through each criterion listed in box on the right. Ask, “<i>Is this question interesting, practical, etc.? How can we make it more interesting, practical, etc.?</i>”2. Discuss why stronger question is stronger

<p>Practice Developing a Research Question</p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;"> <p>A good research question is:</p> <ul style="list-style-type: none"> Interesting Practical Specific New Ethical Important to society </div>	<p>Activity: Ask participants to split into small groups and choose a health related topic from the choices below to develop a research question about. After developing their research questions, ask each small group to share with the larger group. Allow group members to provide feedback on how to make the question stronger. When introducing the activity, emphasize that there is more than one research question that can come from each of these topics, and that every research question can be improved.</p> <p>Topics:</p> <ul style="list-style-type: none"> • Treatments for PTSD • Addressing Veteran insomnia • Understanding why Veterans are overweight
<p>How do Researchers come up with Research Questions?</p> <ul style="list-style-type: none"> • Personal interest of researcher <div style="display: flex; align-items: flex-start;">  <div style="font-size: 0.8em; line-height: 1.2;"> <p>"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</p> </div> </div>	<p>Talking points:</p> <ul style="list-style-type: none"> - Researchers come up with research questions in different ways. On this and the next few slides, VA researchers from our Durham HSR&D center have provided examples of how they came up with research questions <p>Allow time for participants to read slide. If helpful, facilitator may read aloud or ask for a volunteer to do so. Or researchers themselves may attend and read (or briefly present) their example.</p>
<p>How do Researchers come up with Research Questions?</p> <ul style="list-style-type: none"> • Clinical experience/expertise of researcher <div style="display: flex; align-items: flex-start;">  <div style="font-size: 0.8em; line-height: 1.2;"> <p>"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</p> </div> </div>	<p>Allow time for participants to read slide. If helpful, facilitator may read aloud or ask for a volunteer to do so. Or researchers themselves may attend and read (or briefly present) their example.</p>

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 Gienski, PhD

Allow time for participants to read slide. If helpful, facilitator may read aloud or ask for a volunteer to do so. Or researchers themselves may attend and read (or briefly present) their example.

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 to 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 Provenziale, MD, MS


Allow time for participants to read slide. If helpful, facilitator may read aloud or ask for a volunteer to do so. Or researchers themselves may attend and read (or briefly present) their example.


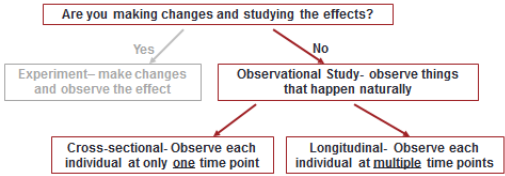
STUDY DESIGN


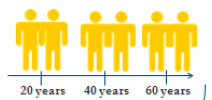

Talking Points:



- After we have our research question, we can start thinking about how to design our study.
- *Who here has heard of an experiment?* [Allow participants to raise hands and share what they already know]
- An experiment is just one type of study design. In this next section, we will go over a few ways that research can be done.


<p style="text-align: center;">Types of Study Design</p> <div style="text-align: center;"> <p>Are you making changes and studying the effects?</p> <p>Yes / No</p> <p>Experiment- make changes and observe the effect / Observational Study- observe things that happen naturally</p> </div> <p style="font-size: small; text-align: center;">Content adapted from David Edelman, MD "Elements of Clinical Research"</p>	<p>Talking Points:</p> <ul style="list-style-type: none"> - The main difference between an experimental study design and an observational study is that in experimental studies, the researcher is making changes and then observing the effect, and in observational studies, they observe or measure what is already happening. <p>(Content adapted from David Edelman, MD "Elements of Clinical Research")</p>
<p style="text-align: center;">Types of Study Design: Experiment</p> <div style="text-align: center;"> <p>Are you making changes and studying the effects?</p> <p>Yes / No</p> <p>Experiment- make changes and observe the effect / Observational Study- observe things that happen naturally</p> </div> <ul style="list-style-type: none"> • The strongest experiments are "randomized" <ul style="list-style-type: none"> • The researcher should <u>not</u> 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 <p style="font-size: x-small; text-align: center;">Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITT IRB Training Module 2006, www.vetrep.com and David Edelman, MD "Elements of Clinical Research"</p>	<p>Talking Points:</p> <ul style="list-style-type: none"> - In an experimental design, the research makes changes and then observes or measures the effect. In health research, these changes are often treatments. Treatments such as medication, procedures, counseling techniques and programs (like exercise programs) can be tested through experimental designs. - The strongest experiments are randomized. <i>Does anyone know what it means for an experiment to be "randomized"?</i> [After responses, click to display reasons written on slide] <ul style="list-style-type: none"> ○ Randomization means that you randomly choose which treatment the participant gets ○ The researcher should not know what treatment is better before the study ○ The treatment given is decided randomly, like flipping a coin ○ Often there is a "control" group that gets no treatment or gets the current treatment [Note: no one would ever be denied standard care or life-saving treatment for the sake of research (e.g. cancer patients under active treatment)] ○ Some experiments test and compare different treatments ○ "Treatment" is not limited to drugs or medicines – could be a program, procedure, use of specific equipment, etc. - For example, if I wanted to see if participating in a healthy cooking class helped people lose weight, I might flip a coin and say that anyone with heads will do the cooking class, and anyone with tails will be in the control group where they are not offered the class. Afterwards, I would compare weight changes among people in both groups to see if there are any differences. <p>(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill,</p>


	<p>CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD “Elements of Clinical Research”)</p>
<p>Types of Study Design: Experiment</p> <ul style="list-style-type: none"> • Randomizing is a way to avoid “bias.” <ul style="list-style-type: none"> • 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.  <p><small>Content adapted from David Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD “Elements of Clinical Research”</small></p>	<p>Talking points:</p> <ul style="list-style-type: none"> - Randomization helps us avoid bias, which means unfairly putting certain participants in a specific group, or letting participants choose which group they are in. - If you choose who goes in which group, there might be something in common with everyone in one group that would affect your results, even if you don’t know what that is. - Randomizing helps control for, or even out, things that might be different between the two groups, so that we can be more confident that differences we see are due to the treatment - [If seems necessary, provide example before moving on to activity]. For example, if we are studying a healthy cooking class and weight loss and let people choose between a cooking class group and a no-cooking class group, maybe the people who choose the cooking class really like to cook and are already trying to learn about healthy cooking recipes and techniques. Maybe their weight is already different from the other group because they have been trying to cook healthy foods. We won’t know if a change in weight is due to the program we’re trying to test. <p>(Content adapted from Daniel Nelson and Darren Dewalt, University of North Carolina-Chapel Hill, CITI IRB Training Module (2004), www.citiprogram.org and David Edelman, MD “Elements of Clinical Research”)</p>
<p>Activity</p>	<p>Activity: Randomization Simulation</p> <p>Explain to group that we are going to simulate a couple different ways we could choose groups for an experiment. Tell them this experiment will test whether a new group exercise program can help improve people’s blood pressure.</p> <p>Round 1: Ask everyone to pick a group: group exercise program, or control group (information about physical activity) - by moving to a corner of the room. Discuss: What do you notice about these groups? Why did you choose the group that you did? How could people’s choices affect our ability to draw conclusions from this experiment?</p> <p>Round 2: Each person flips a coin- heads goes to the group exercise program corner, tails to the control group corner. Discuss: What do you notice about these groups? Are they different than last</p>


	<p>time, and how? How can flipping a coin make us more confident in drawing conclusions from the experiment?</p>
<p>Types of Study Design: Experiment</p> <ul style="list-style-type: none"> Randomizing is not always ethical or feasible. Examples: <ul style="list-style-type: none"> 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  <p><small>Content adapted from David Nelson and Dennis Drazak, University of North Carolina-Chapel Hill, CTRT IRB Training Module (2006), www.ctrtrn.com and David Edelman, MD "Elements of Clinical Research"</small></p>	<p>Talking Points:</p> <ul style="list-style-type: none"> Randomizing is not always ethical or feasible. Examples: <ul style="list-style-type: none"> 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 In situations like these, scientists may use a different study design. For example: <ul style="list-style-type: none"> They may use a <i>quasi-experimental design</i> where they have a delay on one group getting the treatment, or they measure effects on the same group before and after the treatment is given They may use an observational study design. We are going to talk about this design next
<p>Types of Study Design: Observational</p>  <p><small>Content adapted from David Edelman, MD "Elements of Clinical Research"</small></p>	<p>Talking points:</p> <ul style="list-style-type: none"> Now that we have talked about experimental studies, let's talk about observational studies. In observational studies, researchers observe or measure things that are already happening. For example, they might measure different people's heart rate or blood pressure, they might ask for people's opinions about exercise, or they might survey participants to learn about their lifestyle habits <p>(Content adapted from David Edelman, MD "Elements of Clinical Research")</p>

<p style="text-align: center;">Types of Study Design: Observational</p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; width: 45%;"> <p style="text-align: center; font-size: small;">Cross-sectional- Observe each individual at only one time point</p>  <p style="text-align: center; font-size: x-small;">Snapshot of characteristics of individuals at the same point in time</p> </div> <div style="border: 1px solid black; padding: 5px; width: 45%;"> <p style="text-align: center; font-size: small;">Longitudinal- Observe each individual at multiple time points</p>  <p style="text-align: center; font-size: x-small;">Characteristics of the same individual(s) observed at different points in time</p> </div> </div>	<p>Talking points:</p> <ul style="list-style-type: none"> - There are two main types of observational studies - In a cross-sectional study, you observe each person only once. For example, you might measure blood pressure for a group of 20 year olds, 40 year olds, and 60 year olds, and then compare the average blood pressure for each group - In a longitudinal study, you observe the same person or people over time. For example, you might measure BP of a group of 20 year olds, then find them again when they are 40 and 60 to take their blood pressure. Then, you can see how blood pressure has changed over time among the same people.
<p style="text-align: center;">Experimental Design: Comparing Intervention Group and Usual Care Group</p> <div style="display: flex; align-items: flex-start;">  <div style="margin-left: 10px; font-size: x-small;"> <p>92341</p> <p>A randomized controlled trial to evaluate the effectiveness of CouPLES: A spouse-assisted lifestyle change intervention to improve low-density lipoprotein cholesterol *</p> <p>Cornine I. Voils^{1,2}, Cynthia J. Coffman^{1,2}, William S. Yancy Jr^{1,2}, Morris Weinberger^{1,2}, Amy S. Jeffreys¹, Santanu Datta¹, Stacey Kovac¹, Jamiya McKenzie¹, Rose Smith¹, Hayden B. Bosworth¹</p> </div> </div>	<p>Talking points:</p> <ul style="list-style-type: none"> - Next, we wanted to show you some examples of real VA research projects that have used these different designs. - This slide shows an example of an experiment. In this study, Veterans with high LDL cholesterol and their spouses were randomly assigned to an intervention group or a usual care group. Veterans in the intervention group received nine monthly goal-setting telephone calls, and their spouses received nine monthly support planning calls. Patients in the usual are group received resources typically available to patients, such as referral to nutrition and a lipid clinic. While LDL cholesterol didn't differ between the two groups, the estimated rate of physical activity was 20% higher in the intervention group, and the intervention group had significantly lower fat intake than those receiving usual care. - Reference to study: https://www.ncbi.nlm.nih.gov/pubmed/23146744 - Ask: What can this study tell us? <ul style="list-style-type: none"> o <i>This intervention could be an addition to usual primary care to improve adherence to lifestyle behaviors.</i>

<p style="text-align: center;">Cross-Sectional Design: Administering a Survey One Time</p>  <p style="font-size: small;">Research article The prevalence of binge drinking and receipt of provider drinking advice among US veterans with military service in Iraq or Afghanistan</p> <p style="font-size: x-small;">Patrick S. Cahoon, PhD, Annie R. Schry, PhD, H. Ryan Wagner, PhD, Nathan A. Kimbrell, PhD, Paul Deross, PhD, Scott D. McDonald, PhD, Jason C. Beckham, PhD, Eric A. Soderst, PhD, Harold Kadner, MD & Kristy Spradley-Peterson, PhD Pages 395-397 Received 11 Jun 2015, Accepted 05 May 2015, Published online 26 Jul 2015</p>	<p>Talking points:</p> <ul style="list-style-type: none"> - This slide shows an example of a cross-sectional study design. In this study, OEF/OIF Veterans completed a survey at one point in time. The researchers analyzed the survey results, and found that 51% of the Veterans who took the surveys had at least one episode of binge drinking in the past year, and 19% were frequent binge drinkers. They also found that Veterans who used the VA were more likely to receive drinking advice from a health care provider than Veterans not using the VA. - Reference to study: https://www.ncbi.nlm.nih.gov/pubmed/26154366 - Ask: What can this study tell us? <ul style="list-style-type: none"> o <i>That binge drinking is an issue among many Veterans in this population (OEF/OIF). This information might tell us, for example, that providers seeing OEF/OIF Veterans should ask them about binge drinking.</i>
<p style="text-align: center;">Longitudinal Design: Following Participants for 15 years</p>  <p style="font-size: small;">Research Article Military Generation and Its Relationship to Mortality in Women Veterans in the Women's Health Initiative</p> <p style="font-size: x-small;">Donna L. Washington, MD, MPH^{1,2}, Chloë E. Bird, PhD³, Michael J. LaMonte, PhD, MPH⁴, Karen M. Goldstein, MD, MSPH⁵, Eileen Williams-Sun, PhD, MPH⁶, Marcia L. Stefanick, PhD⁷, Nancy F. Woods, PhD, RN, FAAN⁸, Lori A. Bastian, MD, MPH⁹, Margery Gass, MD¹⁰, and Julie C. Weitlauf, PhD¹¹</p>	<p>Talking points:</p> <ul style="list-style-type: none"> - This slide shows an example of a cross-sectional study design. In this study, researchers followed a group of women Veterans for an average of about 15 years to examine causes of mortality. - Reference to study: https://www.ncbi.nlm.nih.gov/pubmed/26768386 - Ask: What can this study tell us? <ul style="list-style-type: none"> o <i>About the different causes of mortality in women Veterans, and some of the different demographic factors that might be associated with various causes. This might help us develop better, more targeted health interventions.</i>
<p style="text-align: center; font-size: 2em; font-weight: bold;">BREAK!</p>	

<p>STUDY DESIGN, CONTINUED.....</p>	
<p>In months where people eat more ice cream, there are more drownings.</p> <p>Does eating ice cream cause people to drown?</p> 	<p>Discussion:</p> <ul style="list-style-type: none">- Ask participants to discuss the issue presented on the slide:<ul style="list-style-type: none">o <i>In months where people eat more ice cream, there are more drownings. Does eating ice cream cause people to drown?</i>- Participants should realize that no, ice cream does not cause drowning.- At this point, ask: <i>If ice cream doesn't cause drowning, what could explain this relationship?</i><ul style="list-style-type: none">o Ex. people both eat more ice cream and go swimming more in the summer.
<p>Correlation vs. Causation</p> <p>Correlation: there is a pattern between two things – easy to determine</p> <p>Causation: one thing causes another thing – very hard to determine</p>	<p>Talking Points:</p> <ul style="list-style-type: none">- The ice cream example shows that just because two things seem related, doesn't mean they cause one another to happen.- Correlation vs. causation is a really important concept in research and something that many people are confused about.- Correlation means there is a pattern between two things. It is fairly easy to determine.- Causation means one thing causes another thing. It very hard to determine, because there are often lots of other factors that might be contributing to what we see. We often don't even know what these factors might be!

<p style="text-align: center;">Correlation vs. Causation</p> <p>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]</p> <p>Experimental study designs allow us to be more confident in making conclusions about what causes something to happen. [Causation]</p> <hr style="border: 2px solid blue;"/>	<p>Talking Points:</p> <ul style="list-style-type: none"> - 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] <ul style="list-style-type: none"> o Ask: <i>Why is this?</i> <ul style="list-style-type: none"> ▪ Because we know what we are changing, and the situation is controlled. When we randomly put people in different groups for an experiment, we can assume that both groups are very similar. This means it is more likely that any changes are due to the treatment given in the experiment. - The reason we are talking about the difference between correlation and causation is because we want you to understand that, depending on the study design, we may not be able to draw certain conclusions - this could affect how we communicate with Veterans about the study and how we present the results of the study. The difference between correlation and causation is a common misconception in the public. <ul style="list-style-type: none"> o For example, if we find a correlation between eating apples and being happy, we shouldn't say that eating apples <i>causes</i> people to be happy. In fact, if we said "people who eat apples are happier", people still might rush to the store to buy apples! We need to be careful about how we frame results so that people understand what the study can and can't show.
<p>If we find a pattern showing that people who drink green tea tend to weigh less.....</p> <p>What factors besides green tea might be contributing to what we see?</p> <div style="text-align: center;">  </div> <hr style="border: 2px solid blue;"/>	<p>Discuss:</p> <p><i>If we find a pattern showing that people who drink green tea tend to weigh less.....</i></p> <p><i>What factors besides green tea might be contributing to what we see?</i></p> <p>Examples could include:</p> <ul style="list-style-type: none"> - Maybe people who drink green tea are more health conscious and are doing other things that could affect their weight, like exercising more - Maybe people who drink green tea have more money and are able to buy healthier foods

<p style="text-align: center;">RESEARCH METHODS</p>											
<p style="text-align: center;">Type of Research Methods</p>  <p style="font-size: small;">Photo credit: https://undesign.cc/s-crash-course-in-ux-design-research-es00c3307682</p>	<p>Talking points:</p> <ul style="list-style-type: none"> - Another aspect of designing a research study that we wanted to talk about is quantitative vs. qualitative methods. <p>Discuss: Take a look at this cartoon. What do you think the difference is between quantitative and qualitative research methods?</p>										
<p style="text-align: center;">Types of Research Methods</p> <table border="1" data-bbox="210 966 682 1218"> <thead> <tr> <th>Quantitative</th> <th>Qualitative</th> </tr> </thead> <tbody> <tr> <td>Type of data: Data is changed into numbers; Data is analyzed using statistics</td> <td>Type of data: Data is mainly verbal; Data (text) is analyzed to find themes</td> </tr> <tr> <td>Goal: (often) to make conclusions about a larger population</td> <td>Goal: (often) to learn about the experience of individuals in a specific group</td> </tr> <tr> <td>Types of measures: Surveys, physiological data (heart rate, blood pressure, weight), etc</td> <td>Types of measures: Interviews, focus groups (group discussions)</td> </tr> <tr> <td>Sample Research Question: What percentage of people in Time Square will accept free ice cream?</td> <td>Sample Research Question: What are the barriers that prevent people in Time Square from accepting free ice cream?</td> </tr> </tbody> </table> <p style="font-size: x-small;">Mixed Methods Research uses both Quantitative and Qualitative methods in the same study.</p> <p style="font-size: x-small;">Content modified from Alzheimer-Europe webpage: http://www.alzheimer-europe.org/Research/Understanding-dementia-research/Types-of-research/The-four-main-approaches</p>	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?	<p>Talking points:</p> <ul style="list-style-type: none"> - The main difference between quantitative and qualitative data is that quantitative data is numbers, and qualitative data is verbal, meaning written or spoken words - In quantitative research, we study numerical data such as answers to survey questions and health data. We use statistics to analyze the data. - In qualitative research, we gather information for topics we are studying through methods like interviews and group discussions. We review what people say and try to find themes, or ideas that are mentioned repeatedly. The goal is to learn about the experiences of people in a certain group. - In mixed methods research, we use both quantitative and qualitative methods in the same study. <p>(Content modified from Alzheimer-Europe webpage: http://www.alzheimer-europe.org/Research/Understanding-dementia-research/Types-of-research/The-four-main-approaches)</p>
Quantitative	Qualitative										
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<p style="text-align: center;">Type of Research Methods</p> <p style="text-align: center;">Mixed-Methods Research =</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>Quantitative Methods</p> </div> <div style="text-align: center;"> <p>Qualitative Methods</p> </div> </div> <p style="font-size: small;">Photo credit: https://uxdesign.cc/a-crash-course-in-ux-design-research-ea00c3307d82</p>	<p>Talking points:</p> <ul style="list-style-type: none"> - In mixed methods, we might use quantitative methods first, then use qualitative methods to help us understand the results (e.g., combining the two pictures here) - Or we could do qualitative methods first to find out how to design the experiment (e.g., how should we advertise the ice cream so that people would be more likely to take it)
<div style="background-color: #800000; color: white; padding: 20px; text-align: center;"> <h2 style="margin: 0;">RESEARCH TIMELINE</h2> <p style="margin: 0;">From planning the study to sharing the results ...</p> </div>	
<p style="text-align: center;">Research Process and Timeline</p>	<p>Talking points:</p> <ul style="list-style-type: none"> - Here we have included some more details about the research process and timeline. As we discussed in our activity, these fall into three overall parts of the research process- planning the study, doing the study, and sharing the results of the study. - The time between applying for funding to do a study, to receiving the funding varies - can take up to 1 year or more - Studies typically last 1-5 years from start of funding to finish - Results of are studies typically shared within 1-2 years of study completion



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 approval for any changes to the study
- Organizing data so it can be analyzed
- Analyzing data
- Getting research published



Talking points:

- As you might guess, there are lots of places within the research process where we might experience delays
- Here we have listed a few areas where we often experience delays:
 - Hiring staff
 - Getting approval from IRB to do study
 - Sometimes they are very busy, or ask you to make changes to the study
 - Getting permission to use existing data
 - There is often an application process for this
 - Recruiting participants
 - Sometimes it's hard to recruit participants.
 - Ask: What are some reasons this might be difficult?
 - Ex. Health requirements to participate, participants don't want to travel to medical center, phone numbers don't work
 - Unexpected or negative (adverse) issues
 - If something goes wrong during the study, this will slow the process. Investigators have to report these issues and may be required to change, or rarely, stop their project
 - Getting approval for any changes to the study
 - If you make changes, you have to send them to IRB for approval
 - Organizing data so it can be analyzed
 - Sometimes data is incomplete or messy. Organizing it into a form that you can use takes time
 - Analyzing data
 - Analysis is often done in teams of people. Analyzing the data and checking your analysis takes time.
 - Getting research published
 - Different journals have different requirements
 - Journals may reject papers or request that authors make changes

<p>Research Results: Getting the Word Out!</p> <ul style="list-style-type: none"> Common ways results of studies are shared: <ul style="list-style-type: none"> Final report to people who fund the study Presentations at research conferences Articles in research journals Other ways results are shared: <ul style="list-style-type: none"> Summaries written for the public Community presentations News stories 	<p>Talking Points:</p> <ul style="list-style-type: none"> - Sharing and then using research results is a very important part of the research process. This is the ultimate reason that research is done! - Common ways results of studies are shared include: <ul style="list-style-type: none"> ○ Final report to people who fund the study ○ Presentations at research conferences ○ Articles in research journals - Other ways results are shared are: <ul style="list-style-type: none"> ○ Summaries written for the public ○ Community presentations ○ News stories <p>Discussion:</p> <ul style="list-style-type: none"> - Which of these methods of research sharing will reach the broadest audience? - Is it important for the public to be able to see research results? Why or why not? - Has anyone seen research results in news stories? What did you think about these stories? Are there any issues with sharing research results in the news? <ul style="list-style-type: none"> ○ <i>Issues may include: the news article might just share the results and not talk about limitations; the public might not understand limitations about research; people might put too much weight on one study</i>
<p>Research Results: Getting the Word Out!</p> <ul style="list-style-type: none"> A concern of researchers is bias in publishing: <ul style="list-style-type: none"> 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 	<p>Talking Points:</p> <ul style="list-style-type: none"> - 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). This means that we might not know if something has been studied before and not worked. It also makes it harder to compare the results of multiple studies, if only the positive results are published. - In public media, stories can be twisted or sensationalized in ways that are misleading, as in the picture on the slide. <p>Activity:</p> <p>Ask: <i>Has anyone heard the statistic that 22 Veterans take their own lives each day?</i></p> <p>Say: <i>We are going to listen to an audio recording from NPR that talks about this number and how it was obtained.</i></p>

	<p>Listen to the “22 Veterans A Day” clip on NPR – approx. 4 minutes long (http://www.npr.org/2015/10/01/444999996/the-number-22-is-there-a-false-narrative-for-vet-suicide)</p> <p>Discuss:</p> <ul style="list-style-type: none"> - <i>What is the main point of this audio clip?</i> - <i>What are issues with reporting 22 Veterans a day commit suicide?</i> <ul style="list-style-type: none"> o It doesn’t apply to all groups Veterans o It might contribute to stereotypes about Veterans - <i>How can media be more responsible in how they report about issues like this?</i>
<p>Sharing and Using Research Results</p> <p>Getting the research <i>into</i> the healthcare system can take a long time.</p> <p>Some studies have estimated that it takes an average of 17 years for research results to start being used within the health care setting <small>(Hannay et al. 2015)</small></p> <p>However, sometimes the VA can start using research results more quickly.</p> <p><small>Hannay, S. R., Castro-Casta, S., Grant, J., Gohari, S., Marshall, C., Moore-Fernandez, J., ... & Tieding, S. (2015). How long does biomedical research take? Studying the time delay between biomedical and health research and its translation into products, policy and practice. <i>Health Research Policy and Law</i>, 13(1), 1.</small></p>	<p>Talking Points:</p> <ul style="list-style-type: none"> - Getting the research <i>into</i> 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 - In VA, may happen more quickly because it is an integrated system, or because of specific VA priorities (e.g., Nicki Hastings’ STRIDE project, an in-patient walking intervention – clinical project, had success and was implemented in the Durham VA very soon after and now there are plans to implement it VISN-wise.) <p>Discuss: Why do you think it takes so long for research to be used in practice?</p> <ul style="list-style-type: none"> - <i>Example answers:</i> <ul style="list-style-type: none"> o One study often isn’t enough to show that things work o Studies might show conflicting results o Changing policy and institutional practices takes time o Getting the information to people who will use it can be challenging

<p style="text-align: center;">VA Research vs. Other Research</p> <p>Similarities:</p> <ul style="list-style-type: none"> • Research is overseen by IRB • Same general elements of research process and timeline <p>Differences:</p> <ul style="list-style-type: none"> • 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 <hr style="border: 2px solid blue;"/>	<p>Talking points:</p> <ul style="list-style-type: none"> - Before we wrap up, we wanted to briefly share some of the ways that research in the VA is similar and different to research conducted in other places, such as universities. - Similarities: <ul style="list-style-type: none"> ○ Research is overseen by IRB ○ Same general elements of research, process, and timeline - Differences: <ul style="list-style-type: none"> ○ All research in VA 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. <ul style="list-style-type: none"> ▪ VA medical records are a unique resource, because they have information for any healthcare Veterans have received within any VA facility. Outside of the VA, people often get their healthcare from many different facilities that have separate medical record systems. ▪ Using VA data often requires submitting an application and getting approval from multiple people ○ Along with the IRB, an Information Security Officer (ISO) and Privacy Officer (PO) oversee research because government research is so regulated that there are specific people whose job it is to oversee privacy and information security issues ○ VA leadership may ask researchers to conduct a specific study <ul style="list-style-type: none"> ▪ In this case, the researcher would not have to apply for funding
<p>How have your ideas about research changed?</p> <p>What questions do you have?</p> <p>What more do you want to learn?</p> <hr style="border: 2px solid blue;"/>	<p>Talking Points:</p> <ul style="list-style-type: none"> - This concludes our third training module! Thank you for your participation. We know we covered a <u>lot</u> of topics in a short amount of time, and want to emphasize that this is just the beginning of our learning process! - As we wrap up today, let's take some time to reflect on what we've learned and what we want to learn more about. <p>Discussion: Discuss the following questions. Discussion can be large group, or participants can break into smaller groups and then share their group's thoughts with the larger group. Record their ideas on poster paper for future reference.</p> <ul style="list-style-type: none"> - <i>How have your ideas about research changed?</i> - <i>What questions do you have?</i> - <i>What more do you want to learn?</i>

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Appendix A: Review Activity

What do you call a song sung in an automobile?

 1 2 3 4 5 6 7 8 9

<ol style="list-style-type: none"> 1. What is research? 2. What is one reason that research is important? 3. Who is a Principal Investigator? 4. What is one way VetREP members can contribute to improving VA research? 5. What guidelines did the Belmont report establish to help make sure that research is conducted safely? 6. What is informed consent? 7. Fill in the blank: In research projects, the benefits should outweigh the _____. 8. Who should be able to participate in research? 9. What does an institutional review board do? 	<p>Reviewing study materials and giving feedback to researchers.... A</p> <p>Anyone who could benefit from the results of the research..... O</p> <p>A way to answer questions using an organized and systematic approach A</p> <p>Reviews research projects to make sure they are ethical..... N</p> <p>Risks..... O</p> <p>The person responsible for all aspects of the study..... C</p> <p>Respect for persons, benefits outweigh harms, and justice..... R</p> <p>A process where participants are given all the information about the project, they have time to ask questions, and they agree to participate..... T</p> <p>It allows us to test and compare different approaches..... SPACE</p>
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