

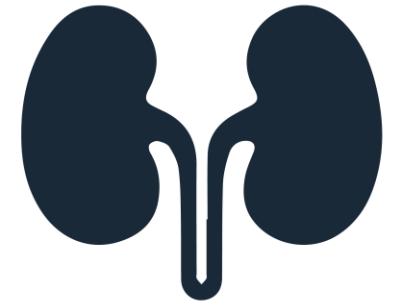
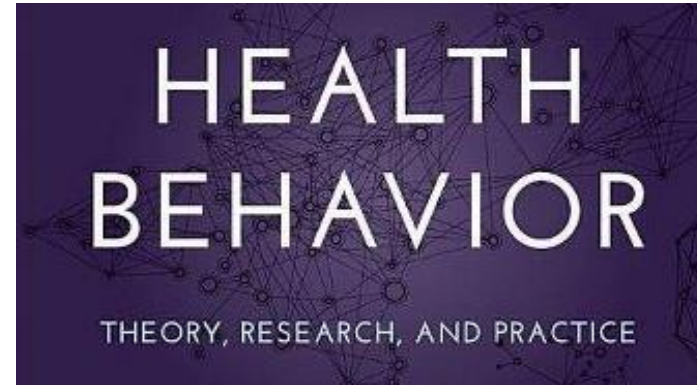
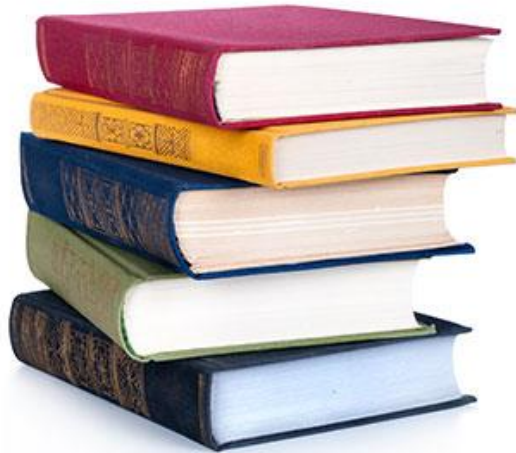
# Patient-Centered Research and Meaningful Stakeholder Engagement

**NRP Education Session**  
**September 16, 2021**

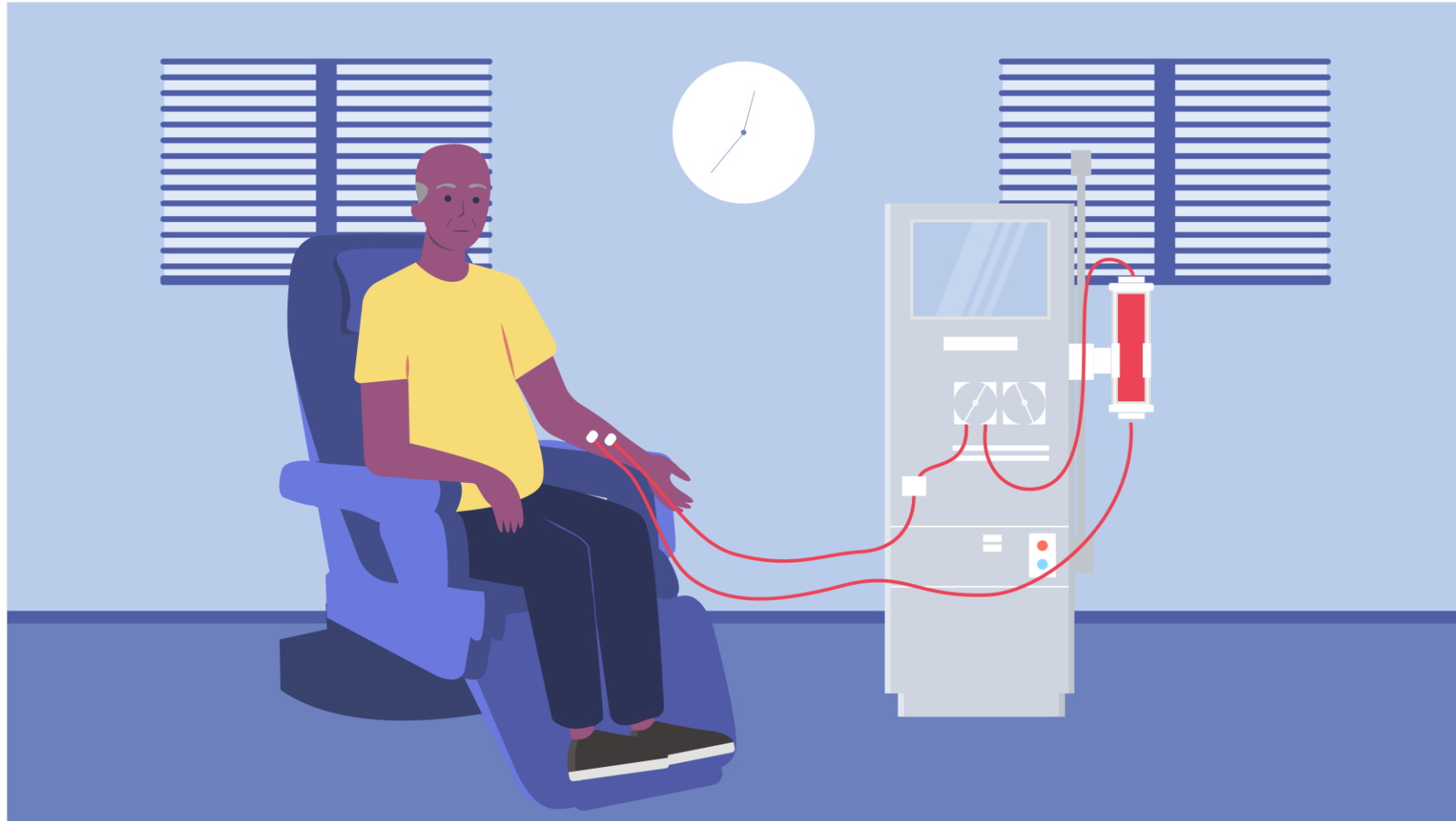
**Adeline Dorough, MPH**  
**UNC Kidney Center**

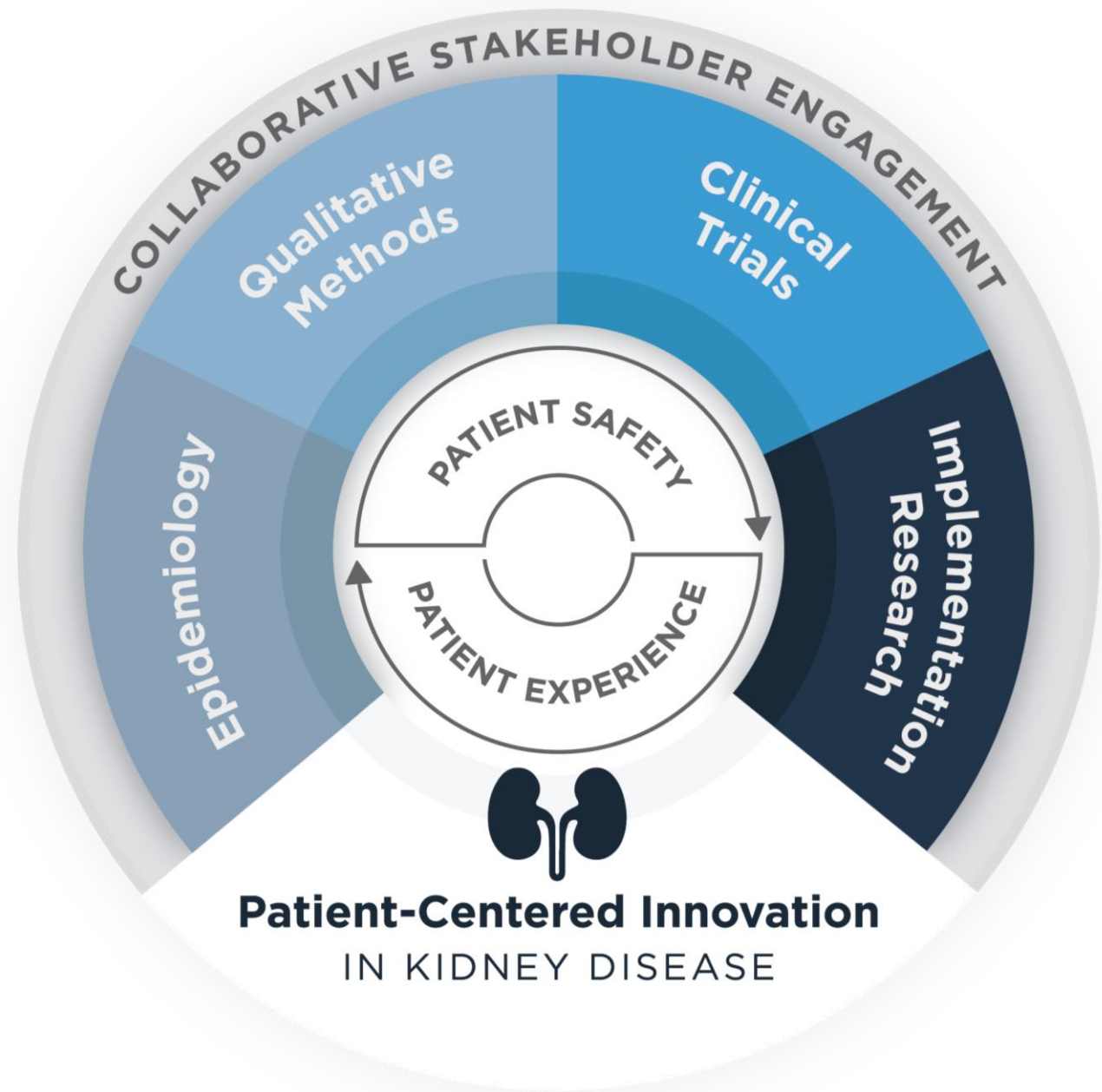


# Who I am



# Who I am not



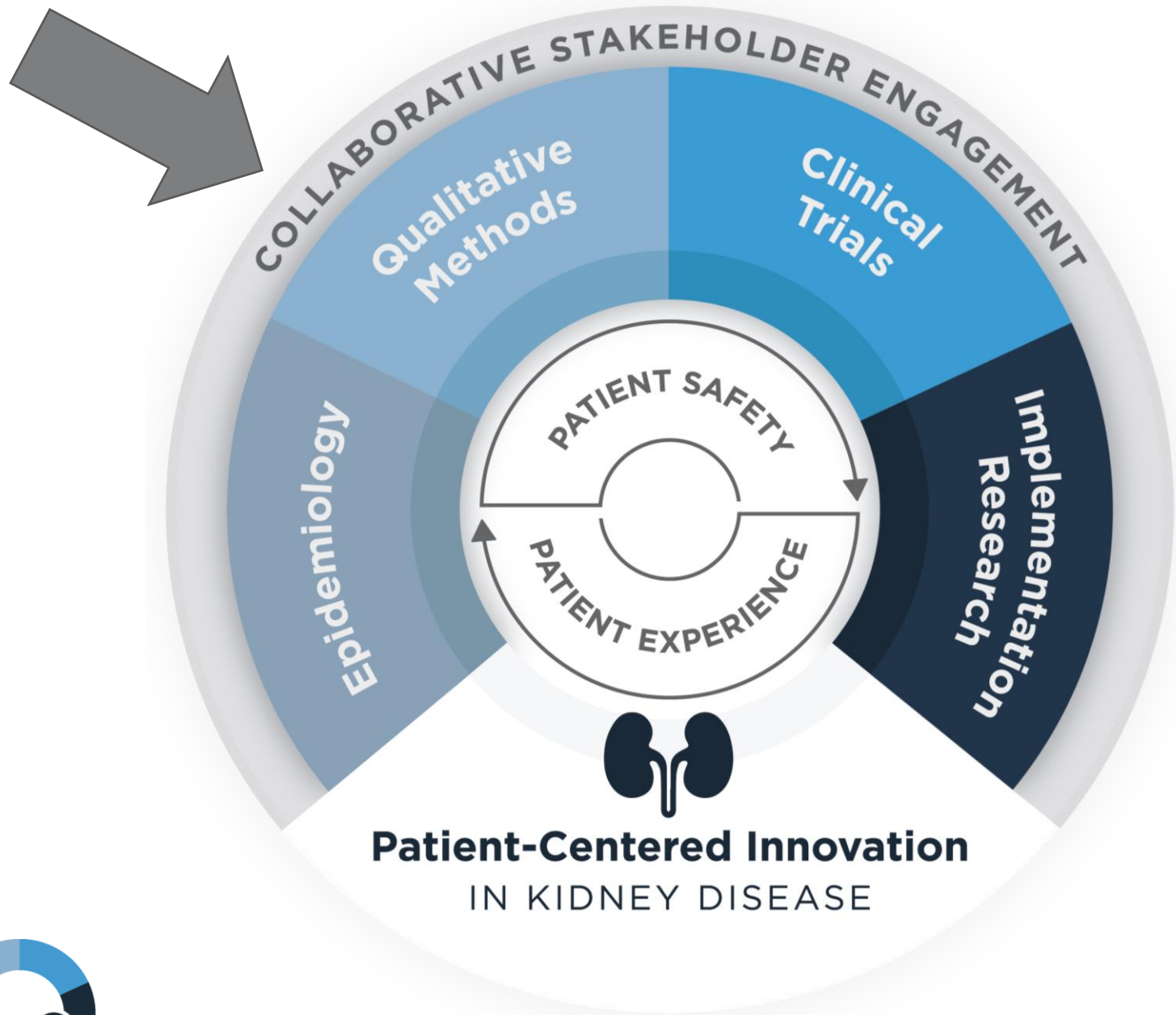


 **UNC**  
HEALTH CARE  

---

KIDNEY CENTER





 **UNC**  
HEALTH CARE  
KIDNEY CENTER



Your work will **always**  
benefit from engaging with  
the people directly  
impacted by your research.



# Agenda

- Definitions
- 2 examples of stakeholder-engaged research
- 4 steps towards patient-centered research
- A patient's perspective
- Q&A



# Definitions

- **Meaningful:** having a significant, important, or useful purpose





# Definitions

- **Meaningful:** having a significant, important, or useful purpose
- **Stakeholder:** an individual who has experience living with, caring for, advocating for, and/or treating those with a condition



# Stakeholder Types and Examples

Stakeholder Type	Example(s)
<b>Patients</b>	Those with current or past experience with illness, family members or care givers, patient advocacy organization representatives
<b>Clinicians</b>	Physicians and Advance Practice Providers, nurses, rehabilitative professionals, pharmacists, mental health care providers
<b>Researchers</b>	Investigators and coordinators
<b>Purchasers</b>	Those who purchase health benefits for employees and dependents
<b>Payers</b>	Insurers
<b>Industry</b>	Sponsors
<b>Hospitals / Health Systems</b>	Public and private hospitals, community health centers, urgent care
<b>Policy Makers</b>	Federal, state, and local government officials
<b>Training Institutions</b>	Universities and their administration



# Definitions

- **Meaningful:** having a significant, important, or useful purpose
- **Stakeholder:** an individual who has experience living with, caring for, advocating for, and/or treating those with a condition
- **Engagement:** the ~~interaction~~ partnership between researchers and stakeholders for the mutually beneficial transfer of knowledge, methods, and resources



meaningful stakeholder  
engagement =

shaping research  
through partnership



# Examples of Stakeholder-Engaged Research



## Building Research Capacity In The Dialysis Community At The Local Level

A 10-member stakeholder panel guided:

- Focus groups to identify barriers/facilitators to dialysis research
- Development of research education materials
- Planning and execution of a national workshop



**UNCC**  
Dialysis Research Education Video Script

**Introduction to Research**

Let's start with what the word "research" means. Research is a process used to find out new knowledge or new information. It starts with an idea or a question. Research can be scientific experiments in a lab or studies with patients in a clinic. Research allows us to find new treatments and help patients. For example, the dialysis machines and medications we use today were created and tested through research—research that focused greatly on cost.

Most often, the goal of research is to make discoveries that will help future patients. Research can be exciting and can lead to promising treatments, but like many things, it can come with challenges. Research can take a long time, and it doesn't always give clear answers. It can involve a participant in research, you may not see its effect on your own medical care, but it could help others in the future. Many people think about research when they hear the word research. As a dialysis patient, you may like to know what you can do to help researchers. As a clinic staff, you may give patients CPE or care. Years of research went into building these machines and thousands of patients who used and doctors made them possible by participating in the research studies that tested them. It was a TEAM effort.

**Types of Research**

Now, let's take a moment to talk about types of research. There are a lot of different types of research. There are studies that test new medicines to find out how they work. There are studies that look at ways to better manage and control blood pressure, sleep, and all others about how to increase the quality of life for patients.

So far, we've talked about research that helps researchers to do something like take a medicine or complete a task. This may have been called a "clinical trial." A "clinical trial" is a type of study that tests health-related treatments or procedures. But research is more than clinical trials. Research can include learning what factors can lead to kidney disease or why people who have kidney disease live longer or shorter.

Research covers all stages and sizes. Studies can be done with a few patients at just one clinic or they can be big with thousands of patients from many countries. Clinics can be about such as dialysis and care education, or they can be big, where patients are followed over several years. If you study in a lab (CPE),

As general, research is to learn something, and answer certain questions and get information that they have can be used to improve the lives of future patients.

**DIALYSIS RESEARCH**

Video Script

**DIALYSIS RESEARCH**

**What's It All About?**

This brochure explains the basics of dialysis research. It will help you understand what research is and what it might mean to participate. This information may be helpful for patients, care partners, or dialysis clinic staff.

**What's Inside?**

What Is Research?	2
What Are Some Types of Research?	4
What Do You Need to Know?	7
What Are Your Research Rights?	8
Why Participate?	10
What Questions Might You Ask?	11

**DIALYSIS RESEARCH**

Educational Brochure

**Dialysis Clinic Research Readiness**  
Lunch & Learn Discussion Guide

Use this guide to facilitate a lunch & learn session or staff meeting about dialysis research. In 30-45 minutes, you will learn about general research concepts and discuss your thoughts about research. The session is for all clinic staff, regardless of role or past research experience.

If you have the opportunity to interact with research teams in the future about specific research studies, share your ideas and ask questions. Information on page 11 may help you prepare for research involving your clinic.

**What is it all about?**

This guide was developed to promote **clinic research readiness**. A **research-ready clinic** has the interest and capacity to host or help with research, meaning that the staff and patients understand general research concepts and feel prepared to take on research of all types.

**Directions**

1. Choose a facilitator leader and go to [go.unc.edu/uncdialysisresearchtoolkit](http://go.unc.edu/uncdialysisresearchtoolkit)
2. Watch the dialysis research education video.
3. Read the dialysis research education brochure (optional).
4. Discuss and take notes on the group discussion (page 11).
5. Review questions you might want to ask researchers (page 11).

**Suggested Discussion Questions**

- What is something new about research that you learned from the video or brochure?
- What information about research stood out to you the most?
- Are there any other ways to help with research?
- What was it like?
- What was hard?
- What did you learn?
- What questions about research came to mind when watching the video or reading the brochure?
- What concerns about research do you have?

Go to page 11 to take notes and review questions for researchers.

**DIALYSIS RESEARCH**

Lunch & Learn Guide

**10 Tips For Researchers Conducting Studies In Dialysis Settings**

Tips developed with input from over 100 dialysis stakeholders including patients, care partners, clinic generalist, medical providers, and corporate dialysis representatives.

**Understand the dialysis environment**

1. **Understand the environment.** On the ground stakeholders can offer valuable insight regarding clinic workflow, operations, and research capacity. Prior to hosting your research plans, review your study protocol with clinic generalist and patients to assess their interest and participation on feasibility.
2. **Seek involvement and input.** Corporate dialysis organizations may be able to help research protocol development, provide infrastructure plans, expedite their early in-house design development. Once you have a pre-protocol, have that protocol review that stakeholders may take a while—plan for potential delays.

**Build trust and gain buy-in**

3. **Introduce yourself.** Clinic generalist and patients want to be connected to research involving their clinics. Introduce the research team at study sites. Be visible to formal (patients, visitors, or pre-research) visits, tell clinic stakeholders who you are and why you care about your research.
4. **Bridge the trust gap.** Trust may be necessary patient care partners and clinic generalist engagement in research. Try using a "warm hand-off" approach where trusted individuals, like clinic generalist, introduce research team members to generalist study participants.

**Provide ongoing research education and training**

5. **Provide research education.** Clinic generalist and patients have varying levels of research knowledge. Consider providing general research education prior to study start. Recommended resource: [go.unc.edu/uncdialysisresearchtoolkit](http://go.unc.edu/uncdialysisresearchtoolkit)
6. **Plan for generalist training and coaching.** Clinic generalist research training and coaching are essential for successful study implementation. Such training requires time and money, but will worth the investment.
7. **Support generalist success.** Clinic generalist success is invaluable. Allocate additional time and money to train new staff.

**Communicate and follow-up**

8. **Set expectations.** Clinic generalist and study participants want study progress updates. At study start, set clear expectations about what and when they can expect to hear from the research team. Periodic updates help maintain buy-in and enthusiasm.
9. **Use clear language.** Research, especially in the context of study materials and key, provides updates to bring language, with colors and graphics to increase interest.
10. **Use thank-you.** Researchers should thank clinic generalist and participants for their time and effort. Being intentional and generalist in thanking stakeholders helps build research readiness.

**DIALYSIS RESEARCH**

Researcher Tips

Dialysis Research

Watch Later Share

**DIALYSIS RESEARCH**

MORE VIDEOS

A pesquisa está acontecendo ao nosso redor o tempo todo!

7:50 / 9:14

CC YouTube







## MY DIALYSIS PLAN

### Team Member (#)

Nephrologist (2)

Patient (Co-lead + 4)

Internist (1)

Family Medicine Practitioner (1)

Dialysis Social Worker (1)

Dialysis Clinic Operations (1)

Nurse Practitioner (1)





# Program Materials

Let's Talk about Dialysis Care Planning

Watch later Share



**DAVE**  
TRANSPLANT RECIPIENT  
FORMER DIALYSIS PATIENT

Mi plan de salud me ayudó porque fue personalizado a lo que necesité. Le dije a mi equipo de cuidado lo que necesité, y me ayudó a conseguirlo.

MORE VIDEOS

1:34 / 3:48

CC Settings YouTube



Program Overview



Patient Brochure



Care Team Guide



Use Cases



Meeting Logistics



Meeting Scripts



Care Plan



Spanish Translations



[go.unc.edu/mydialysisplan](http://go.unc.edu/mydialysisplan)

# Broad Application of Findings: *Materials Development*

- **Accessibility is key**
  - Translate content into several languages
  - Develop mixed-media (video + written)
  - Create guides/supports for research participants and facilitators
  - Iterate responsively (i.e., listen to your end-users)
- **Aesthetics matter**
  - Use a thoughtful color palette and large, clear font
  - Make things match – it's easier to locate and use



# Broad Application of Findings: *Stakeholder Engagement*

- **Communication is key**
  - Co-develop a communication plan: frequency, timing, mode
  - Re-assess and iterate the communication plan, as needed
- **Flexibility matters**
  - Plan ahead, but meet people where they are
  - Account for different schedules, resources, and health status changes
  - Have a backup plan (i.e., embrace your inner creativity)



# 4 Steps Toward Patient-Centered Research



# Step 1: Engage and Educate



# Partnership is Critical

- Connect with stakeholders who have diverse perspectives
  - Create a space for them at the table
  - Empower them to comfortably speak and share
    - Use collaboration tools and offer training/support
    - Foster shared decision-making and incorporate patient-led discussions
  - Listen, take note, and incorporate what they say



# **Tokenism**

(“engaging” stakeholders  
to check a box )



# Partnership is Critical

- Connect with individuals who have diverse perspectives
  - Create a space for stakeholders at the table
  - Empower stakeholders to comfortably speak and share
    - Use collaboration tools and offer training/support
    - Foster shared decision-making and incorporate patient-led discussions
  - Take note and incorporate what stakeholders say
- Build trust, gain buy-in, sustain relationships
  - Introduce yourself at the study site
  - Explain the study, timeline, and goals
  - Bridge the trust gap





## Short Education Sessions

- 10-30 minute session(s)
- Supply food/drink
- Print-out short study explanation
- Show pictures of study staff
- Identify champions



## LUNCH AND LEARN

**MONDAY, OCTOBER 5**  
**12:00-12:15pm & 12:45-1:00pm**



Dr. Jenny Flythe and her research team will tell us about their upcoming research study about the diuretic drug furosemide (or “Lasix”)





## Diuretic Drug Research Study

Investigator: Dr. Jenny Flythe



*A research study will be starting in this clinic soon.*

**Why is this study being done?** To understand if the diuretic drug, furosemide (or “Lasix”), is safe for dialysis patients and will help them increase the amount of pee/urine they produce.

**Why should I think about taking part in the study?** Increasing the amount of pee/urine can potentially help patients reduce fluid overload and the need for rapid fluid removal during dialysis treatments. Your participation would help us better understand your experience as a dialysis patient and understand the right drug dose that will be both safe and effective for dialysis patients.

**Would I receive anything for participating in the study?** You may have the opportunity to receive up to \$199 for participating in the whole study.

Dr. Flythe and her research team will be in this clinic over the next few weeks asking some patients if they would like to participate in this study.

**Not all patients will be able to participate in the study.**

### You might be able to participate in this study if...

- You receive your dialysis treatments 3 times per week at this clinic
- You can speak comfortably in English or Spanish
- You are 18 years old or older
- You make at least 1 cup of pee/urine over 24 hours
- You are willing to and choose to participate in the study



### You might not be able to participate in this study if...

- You have been on dialysis for fewer than 2 months
- You have been hospitalized more than once in the weeks leading up to the study
- You are not willing to do all of the study testing

**For more information, contact Julia Narendra**, Study Coordinator:

Phone: (919) 445-2686

Email: [julia\\_narendra@med.unc.edu](mailto:julia_narendra@med.unc.edu)

Approved by the UNC IRB

## Transparent Recruitment Fliers

- Why the study matters from a participant perspective
- Remuneration information
- Inclusion/exclusion criteria
- Contact information



# Step 2: Optimize Study Plans



# Incorporate Feedback

- Modify what you can
  - Create a plan to overcome stakeholder-identified barriers
  - Update participant-facing documents
  - Note recommendations for future use



# Patient-Friendly Consent

**DIALYSIS  
RESEARCH**

**UNC**  
HEALTH CARE  
KIDNEY CENTER

## Research Interviews about Goals and Dialysis Care Plans

### Study Staff



**Jenny Flythe,**  
Lead Researcher



**Derek Forfang,**  
Lead Researcher



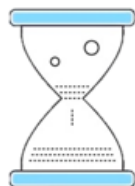
**Adeline Dorough,**  
Study Coordinator

### What is the purpose of this study?

- We are trying to understand how to better match hemodialysis care with your personal goals.
- This is part 1 of a 3-part study. This part is only an interview.

### What would I do in this study?

If you choose to participate, you would take part in a 45-60 minute interview.



### What would we talk about in the interview?

- We will talk about your personal goals and your experience with dialysis care plans.
- We also want to hear your thoughts on how to personalize your dialysis treatment plans.



### What if I start the interview but decide that I want to stop?

You can stop at any time.  
Participation in the study is voluntary.

### What are some possible benefits to being in this study?

- Discussing your dialysis experience in a supportive environment.
- Helping future dialysis patients.

### Would I receive anything for participating?

You will receive \$30 for interview participation.

### When would I know the results of the study?

- We will give an update on what we are learning in about 3 months.
- We expect all 3 parts of the study to be done by the end of 2019.
- We will share the final results with you if you are interested.

### What will study staff do with the information I share?

Our conversation is private. Your answers will help our team figure out how to better match patient goals with dialysis treatment plans.



### What if I have more questions in the future?

Contact Adeline Dorough, Study Coordinator:  
Email: [dorough@med.unc.edu](mailto:dorough@med.unc.edu) | Phone: (919) 445-2898



# Incorporate Feedback

- Modify what you can
  - Create a plan to overcome stakeholder-identified barriers
  - Update participant-facing documents
  - Note recommendations for future use
- Reduce participant burden
  - Collapse visits (study + care) when feasible
  - Provide resources to support participation (transportation, etc.)
  - Provide fair remuneration



# Stay in Touch

- Provide periodic study progress updates
  - Set clear expectations about when participants *and* study sites will hear from the research team
  - Be honest about the research process (i.e., we're behind)
  - Keep it short and sweet
- Create a database of individuals who may want to participate in future research (with permission)



# Step 3: Create Plain Language Materials





# Simplify Everything. Twice.

- What core information would you **want** to read/see/hear?
- Does each sentence/word add meaning?
- Are there too many words crammed onto this page?
- What are the readability statistics?
  - Avoid symbols/abbreviations, volume equivalents in tsp/tbsp
- *Vet draft(s) through patient stakeholders*

Hill-Briggs F, Schumann KP, Dike O. **Five-step methodology for evaluation and adaptation of print patient health information to meet the < 5th grade readability criterion.** *Med Care.* 2012;50(4):294-301. PMID: 22354210



# Examples of Plain Language Docs

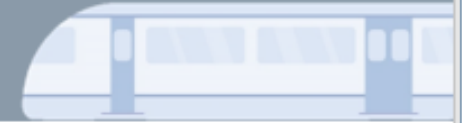
- Recruitment fliers
- Recruitment call scripts
- Study reminders
- Study progress updates
- Final reports
- Thank you's and gratitude



# Follow Up after Study End

- Study title
- Summary of what the participant did
- Images of study staff
- Final products/findings
- Next steps
- Invitation to participate in research

Getting Ready:  
**Your Vascular  
Access Journey**



August 2021

Hi XX,

Thank you for participating in our research study about dialysis vascular access. It's been a while! As a reminder, we talked about your experiences with dialysis access about a year ago. Thanks to you sharing your story and feedback, we created resources on dialysis access to help people who may need dialysis:

- Brochure (included)
- Video (you can watch on our website: [go.unc.edu/dialysisaccess](https://go.unc.edu/dialysisaccess))

Everybody deserves information before making big decisions. We hope our brochure and video will help kidney patients feel confident and prepared for their access journey. Please reach out if you have questions or want to be involved in more research studies. Together, we can create a better future for dialysis!

All the best,



Jennifer E. Flythe, MD  
Kidney Doctor & Researcher  
Phone: (919) 966-2561



Adeline Dorough, MPH  
Researcher & Project Coordinator  
Phone: (919) 445-2898



*Do you have a smartphone?*

*Scan this QR code with your camera. The resources (video, brochure) will open on your phone's internet browser!*



# Step 4: Account for Extra Resources



# Time is Money

- Budget for the time it takes to...
  - Develop participant-friendly, plain language materials
  - Gather feedback on study plans (logistics, conduction, follow-up)
  - Iterate materials before disseminating them
  - Conduct lunch and learns (logistics, conduction)
  - Get everything approved by the IRB



# Money Matters

- Line-item considerations:
  - Color ink or paper
  - Printing
  - Food (snacks, coffee, meals)
  - Translation and Verification
  - Thank you cards
  - Stamps
  - Travel (mileage/airfare, lodging, meals)
    - Study visits and/or stakeholder activities
  - Topic experts (TraCS, Odum institute, etc.)



# Final Takeaways



# Final Takeaways

## **Meaningful Stakeholder Engagement**

- Stakeholders are important and make research better
- There is room for stakeholder engagement at every research phase
- Meaningful engagement requires resources (time + money)

## **Patient-Centered Research**

- Use participant-friendly, plain language
- Communicate frequently
- Show appreciation





# UNCKC Collaborators & Stakeholders



# A Patient's Perspective



# Questions?

**Adeline Dorough**  
[dorough@med.unc.edu](mailto:dorough@med.unc.edu)

**Derek Forfang**  
[derek.forfang@gmail.com](mailto:derek.forfang@gmail.com)

