MODULE 2

BUILDING CONFIDENCE

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Overview of Module 2: Building Confidence

In this section, we will:

- Remind you of why **your perspective is important** and must be heard.
- Remind you of why **you are uniquely qualified** to be a research study investigator partner.
- Show examples of how **you can make a difference**
- Show you how to **use your curiosity and questions** to make a difference.
- Give you **suggested questions to ask the research team**
- *Provide a review/quick quiz to test your knowledge and understanding*

Estimated Time Commitment: *15 to 25 minutes*

You do not need to go through the module in one sitting. Feel free to take breaks and complete at your own pace!

Key Terms Used in this Module

- You will hear a lot of **new terms** during this module that you might not know
- We **do not expect you to know what these terms mean right away or memorize them** – just to familiarize yourself with the words
- Here is a **link to the key terms** used in this module that you can reference as you go through – click here

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Why Now? Recognizing the Importance of Patients and Caregivers to Research

Over the last several years researchers and different federal organizations have realized the importance of including feedback from patients and caregivers in research.

Different recommendations have been created to provide guidance on how to include input from patients/caregivers. Here are some organizations that are advocating to include patients/caregivers:

U.S. Food and Drug Administration (FDA)	Patient-focused drug development to include the patient perspective on deciding which drugs guidelines designed to and treatment needs are most important to patients
Patient-Centered Outcomes Research Institute (PCORI)	This organization created a Patient Engagement Rubric or framework (https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf) to help researchers understand the different ways they can and should include patients/caregivers.
National Organization for Rare Disorders (NORD)	This organization is driven by patients and families to help speed the approval of treatments for rare diseases---those that affect fewer than 1 per 1000
National Institutes of Health (NIH)	Patients are part of the council that decides which high-quality studies should be funded. NIH is also recognizing the importance of patient advisors.
COPD Foundation and other advocacy organizations	Patient advocacy organizations like the COPD Foundation have been fighting for including patient and caregiver input in research. The COPD Foundation has a policy that any studies they are in charge of must include a patient or caregiver investigator.

The Value You Bring to Any Research Team

Your life experiences or “Experiential Knowledge”

Your personal understanding of the disease

Your perspective – will see and know things that people without the disease won’t

Your ability to “fill in gaps” based on your unique perspective and experiences

Your curiosity and questions can lead others to see things differently and create better studies

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Why Your Experiential Knowledge is So Important

Experiential Knowledge is knowledge or wisdom gained through life experiences, rather than formal training or education.

Patient/Caregiver Investigators bring valuable experiential knowledge to a research team.

Examples of "experiential knowledge" that you may bring to a research team	
Travel Issues	Someone with COPD or their caregiver understands **traveling issues** such as needing extra time **or the unique concerns of** traveling with oxygen that can make study visits difficult.
Language Issues	Terms that would seem common to researchers are not common to other people. You can let researchers know they need to use **clear, plain language** when possible, for all materials.
Time Issues	Patients, especially those with COPD, often need **more time** to complete certain tasks. Something as simple as walking 2-3 blocks to a study site, can be difficult for someone with COPD to manage.

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Your Experience and Curiosity are Critical

Don’t assume a researcher knows what your issues are; your role is to tell them and make sure they are thinking about the patient perspective.

One thing they DO NOT know, is what it is like to be a patient with COPD or someone who cares for someone with COPD.

Your curiosity, your interest is a valuable skill that will help find issues others cannot see.

Other team members WANT to hear from you—so if something isn’t clear, ask questions.

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Examples of How Patients/Caregivers Make a Difference Throughout a Study

Designing the Study	In one study, the patient investigator noticed that the measurements for the wearable vests participants were expected to wear were French sizes and had not been translated to US sizes. No one else noticed this on the research team—the patient investigator's finding saved a lot of time and money in making sure the right sizes were chosen for participants to wear.
Recruitment Materials	In another study, the patient investigator found several language issues with the recruitment materials that were going to be used to ask people to join the study. The language was too complicated and some of the terms used could create fear. It was not clear what was being asked of people as well. If the language is not clear, it will make it more difficult to recruit for the study. The patient partner helped make the materials clearer using plain language which helped with recruiting for the study.
Interpretation of Results	In looking at a pulmonary rehabilitation study, based on the results, it looked like there was no benefit. However, the patient investigator commented that maybe the process did not work because it was too hard or too expensive for the people enrolled—maybe it was not because the idea was wrong. For example, maybe they need to have home-based pulmonary rehabilitation for those who have trouble getting out or live too far from a center. It was not the pulmonary rehabilitation that did not work—it was not understanding the limitation faced by people with COPD or those living in rural areas.

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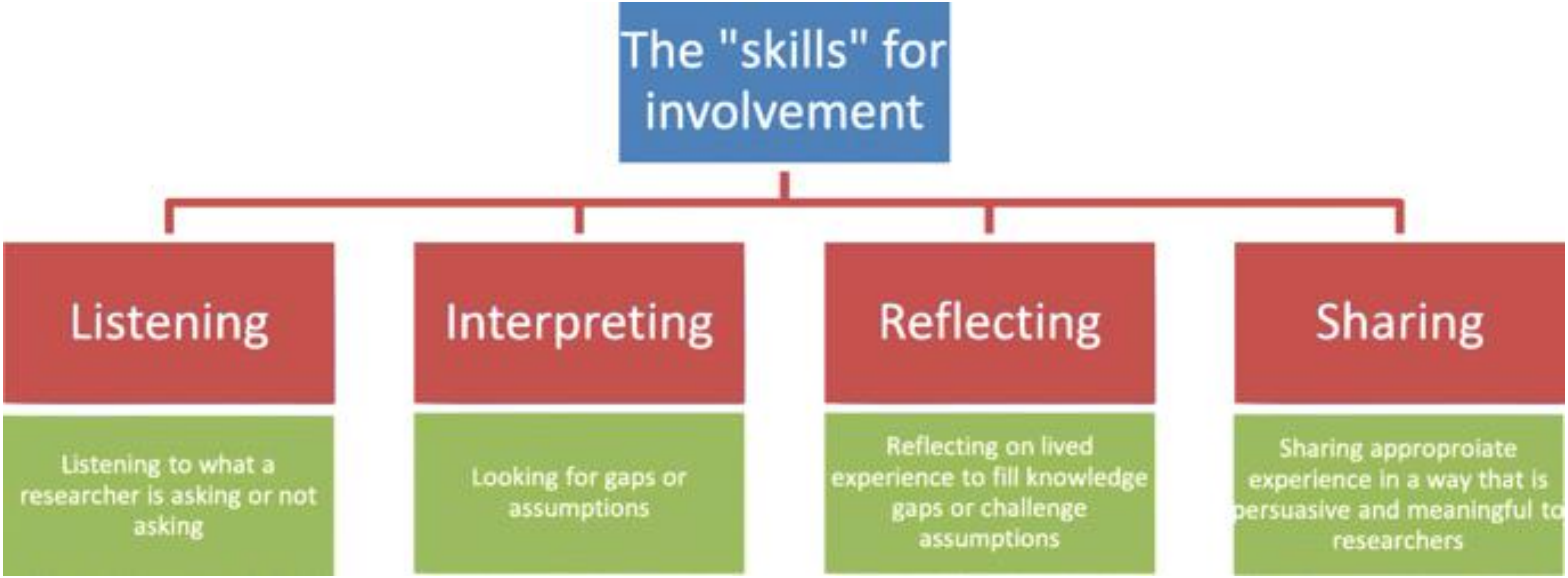
Communicating with Other Study Team Members

- Importance of soft skills
    - *Soft skills are the traits that make you a good team member, such as etiquette, communication, listening and getting along with other people (see next slide)*
- Telling your story is a way to convey your point/perspective
- Don’t be afraid to speak up or say when you don’t know something
- Don’t be afraid to ask to speak to another investigator or the research manager separately
- Remind other study team members to use plain language – avoid jargon (acronyms, technical terms)
    - *Speak up if they are using language you don’t understand*
- **You are teaching them just as much as you are learning from everyone**

Sharing What You Know...



The "skills" for involvement

Listening

Listening to what a researcher is asking or not asking

Interpreting

Looking for gaps or assumptions

Reflecting

Reflecting on lived experience to fill knowledge gaps or challenge assumptions

Sharing

Sharing approproiate experience in a way that is persuasive and meaningful to researchers

taken from: Staley, K., Cockcroft, E., Shelly, A. et al. 'What can I do that will most help researchers?' A different approach to training the public at the start of their involvement in research. Res Involv Engagem 5, 10 (2019) doi:10.1186/s40900-019-0144-4

Research Team Liaisons

A research team member should be **designated as your personal liaison**.

- A liaison should be available **to answer your questions one-on-one**, providing you with further clarification on topics, outside of the team's regular meetings and phone calls
- Having a research team liaison **doesn't mean you should not ask questions** during team meetings
- Having a liaison simply means you have **someone available to you as questions arise** and who can **give you more in-depth information and explanations** that may not always be possible during a team meeting
- Having a research team liaison is **one way to make you feel more comfortable** during the study—particularly during your first study as a co-investigator

Questions to Ask the Study Team Before Starting a Study

Time Commitment How much of my time will this take? How long is the project? How long are the meetings? How many times a month will we meet? Do I have to go somewhere for the meetings?	**Logistics** How will we communicate? Will I have to travel? Who is my main contact? Do I need to have a special computer?
Payment Will I receive payment for my time?	**Expectations** What do you hope I will contribute?
General Can you send me a plain language summary of the study? Can I have a list of roles and responsibilities for myself and other team members? Are there key terms I need to know before starting?	**Liaison** Who on the research team will be my primary contact/liaison when I need clarification or have questions that are difficult to ask during team calls?

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Researcher Testimonial of Working with Patients

"Including patients and families as members of our research teams has taught me a great deal and improved our studies. For example, I often thought that hospitalization and death were the most important outcomes, but in some studies improving quality of life and the ability to do activities are more important outcomes. Without patients and families, we would have studied the wrong thing." Barbara Yawn, MD, MSc

Watch Dr. Yawn's Researcher Testimonial video by clicking here

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MODULE 2: REVIEW QUESTIONS

- The next few slides have some questions to help you review and remember what we have presented in this Module.
- This is not a graded test and is meant to only help you retain the information from this Module. There is an answer key at the end.
- Here is a link to the key terms that might help as you go through the review questions – click here
- If you have any questions, please email BRIDGE@copdfoundation.org

MODULE 2: REVIEW QUESTIONS

1.) Over the last several years, the importance of including patients'/caregivers' perspective in research studies has been recognized.

a. True
b. False

2.) What is NOT Experiential Knowledge?

a. Your personal experience
b. Formal training
c. Your experience living with a disease or caring for someone with a disease

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MODULE 2: REVIEW QUESTIONS CONTINUED...

3.) What are some important skills for being part of a team?

a. Listening
b. Sharing
c. Reflecting
d. All of the above

MODULE 2: REVIEW QUESTIONS ANSWER KEY

1.) True

Explanation: Major federal organizations and other groups have realized in the last several years that the patient perspective needs to be included in studies and have taken steps to include patients/caregivers in more active roles on studies.

2.) b

Explanation: Experiential knowledge is not based on formal training. Experiential knowledge is all about one's personal experience.

3.) d

Explanation: Listening, sharing and reflecting are all important skills needed to be part of an effective team.

LINKS TO KEY RESOURCES FOR MODULE 2

Below is a table with links to key resources and information that you might find useful

Key Articles about Being a Patient/Caregiver Investigator *(optional reading)*	• Learning to “Swim” with the Experts: Experiences of Two Patient Co-Investigators for a Project Funded by the Patient-Centered Outcomes Research Institute http://www.thepermanentejournal.org/issues/2016/spring/6150-learning-to-swim.html • Reflections and experiences of a co-researcher involved in a renal research study https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-018-0120-4 • ‘What can I do that will most help researchers?’ A different approach to training the public at the start of their involvement in research https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-019-0144-4
Takeaway Documents	• **Key questions to ask study team before starting a study: click here** • **Glossary of Key Terms: click here** • **Module 2 Review Questions with Answer Key and Explanations: click here**

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NEXT STEPS

Congratulations! You have completed Module 2!

When you are ready, please go on to ***Module 3 – Types of Research***

You don't have to do this right away – you can do it when you have time.

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