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The ENVISION Approach: A Participant-Centered Informed Consent Process

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Learning objectives

1. Understand the benefits of the ENVISION approach
2. Practice the RIVER communication framework in research scenarios
3. Reflect and discuss how the ENVISION approach can be used in your work

ENgaging with Values to Inform research enrollment deciSIONs

Quality informed consent promotes understanding, supports values-aligned decision-making, and establishes trust

ENVISION **consent form** prioritizes readability, visual accessibility, and focus on decision-making

ENVISION **communication framework** focuses on relationships and supporting deliberative engagement about values and priorities

Slido poll question

What words come to mind when you think of consent forms?

ENVISION approach to informed consent

Readability

- Reading level
- Wording choice

Visual accessibility

- Formatting
- Illustrations

Focus on decision-making

- Emphasis on key information section
- Reasons why someone may want to enroll or not

Novel vs. Traditional



Study activities

This study will take about six hours of your time over six weeks.

- There will be a second in-person visit in four weeks.
- You will get extra medical tests and answer questions about your health.
- You will get paid up to $202.50 for your time and effort.

IF I AGREE TO JOIN THE STUDY, WHAT WOULD I NEED TO DO?

If you agree to take part in the study, you will come to the study site for a total of 2 study visits over approximately the next 4 weeks. Additionally, you will participate in a follow up phone call approximately two weeks after your last study visit. Regardless of whether you decide to be in the study or not, your doctor will decide what antibiotics to use to treat your pulmonary exacerbation.

If you join the study, you will have some tests and exams which are described below.

If you meet the requirements to be in the study, during the first visit, you will be *assigned to one of two* interventions:

- Take IV tobramycin and β-lactams for 14 days (± 2 days)
- Take IV β-lactams only for 14 days (± 2 days)

Which intervention you are assigned to is done by chance. It is similar to flipping a coin. You and your doctor will know which group you are in.

Explanation of Study Procedures:

The tests that would be done if you join the study include:

- **Informed Consent:** We will explain the study to you. If you decide to participate you will be asked to review, sign, and date the consent and HIPAA authorization forms.
- **Medical History:** Your medical chart will be reviewed and you will be asked questions about your health including current and past illnesses and use of medications.
- **Demographic Information:** We will collect information about you such as sex at birth, birthdate and race.
- **Physical Exam**: Your doctor will examine your body for any abnormal signs and symptoms.
- **Weight and Height**: Your weight and height will be measured for this study.
- **Paper Questionnaires:** You will be asked questions about your health, quality of life, if you have ringing in your ears (known as tinnitus), and if you are having any problems with your balance (feeling dizzy or unsteady).
- **Electronic Questionnaires:** You will be asked to complete questions about your health and quality of life outside of clinic visits using your own cell phone or tablet device. To do this, you would need to download an application to your device. The application may not be able to be downloaded on some types of devices. If you are able to download the application, you would then register yourself by entering personal information such as your name, email address and mobile phone number. You will be asked to agree to the application Terms of Use. If you decide you do not want to agree, then you can choose not to use the application and still participate in the study. While the Terms of Use of the application may include statements limiting your rights if you are harmed in this study, you do not release the investigator, sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the application in this research

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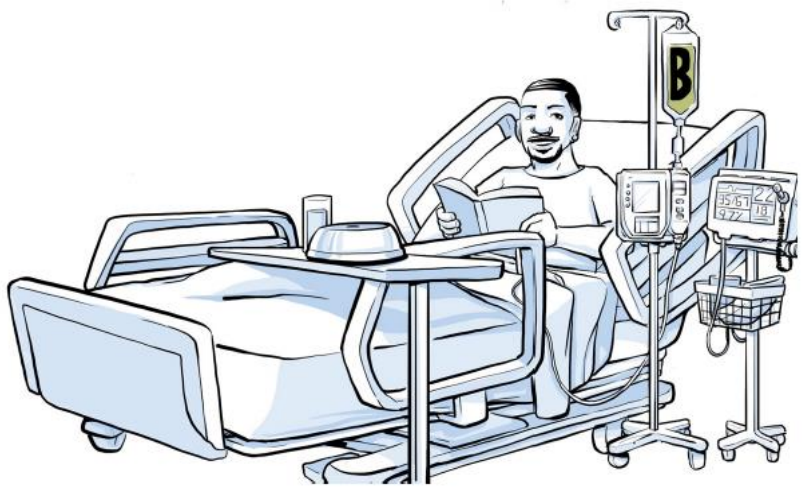
Novel vs. Traditional



Benefits and risks

Medication
It is possible that a beta-lactam alone can treat your pulmonary exacerbation without the side effects that come with an aminoglycoside. But if you only get a beta-lactam, your exacerbation might not improve as much as if you got both a beta-lactam and an aminoglycoside.

Medical tests
There can be discomfort from some of the medical tests, such as the pulmonary function test and sputum collection. These discomforts are the same as when you do these tests at your regular CF clinic visits.

WHAT ARE THE RISKS OR DISCOMFORTS THAT CAN HAPPEN FROM THIS RESEARCH?

There are potential harms or risks if you take part in this study. These risks are described in the table below.

Types of Antibiotic Medications:

The two types of antibiotics that will be studied will be prescribed clinically by your doctor and are approved for the treatment of pulmonary infections. It is likely that you have been treated with these types of antibiotics before for a pulmonary exacerbation. There are known risks related to these types of antibiotics.

Type of Antibiotic	Possible Risk Associated with this Type of Antibiotic:
Beta-lactams	The most commonly reported side effects include abdominal pain, diarrhea, nausea and vomiting, skin rash, decreased white blood cells, decreased platelets, and decreased appetite. Less common but serious side effects can include an allergic reaction with swelling of the tongue and throat or difficulty breathing.
Aminoglycosides (Tobramycin is a type of aminoglycoside)	The risks include kidney injury, permanent hearing loss, ringing in the ears, permanent balance problems, and rarely muscle weakness and allergic response (including a severe allergic reaction called anaphylaxis).

Study Procedures:

There are some minimal risks related to the procedures used in the study. Some of these procedures you may have had at your standard clinic visits. In addition, these procedures may involve risks that are unexpected.

Procedure	Possible Risk Associated with Procedure
Expectorated Sputum	Coughing up sputum may cause brief coughing and shortness of breath.
Spirometry	There is a small risk of wheezing, shortness of breath and lightheadedness. If you have recently had an air leak from your lungs (pneumothorax) or you are coughing up blood, you should tell your study doctor or study nurse to help them to decide if you should do spirometry.
Questionnaires	Some questions may feel too personal or make you uncomfortable. If this happens, please talk to the study team about why that question is being asked. If you are still uncomfortable, you may choose not to answer.
Electronic Questionnaires	We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a

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RIVER communication framework



Step 1: **R**elationship

Goal: Form a connection to facilitate the research conversation

- Introduce yourself to everyone in the room
- Acknowledge the potential participant's personal and clinical situation
- Check if it's a good time to talk about research and if they need to attend to anything beforehand

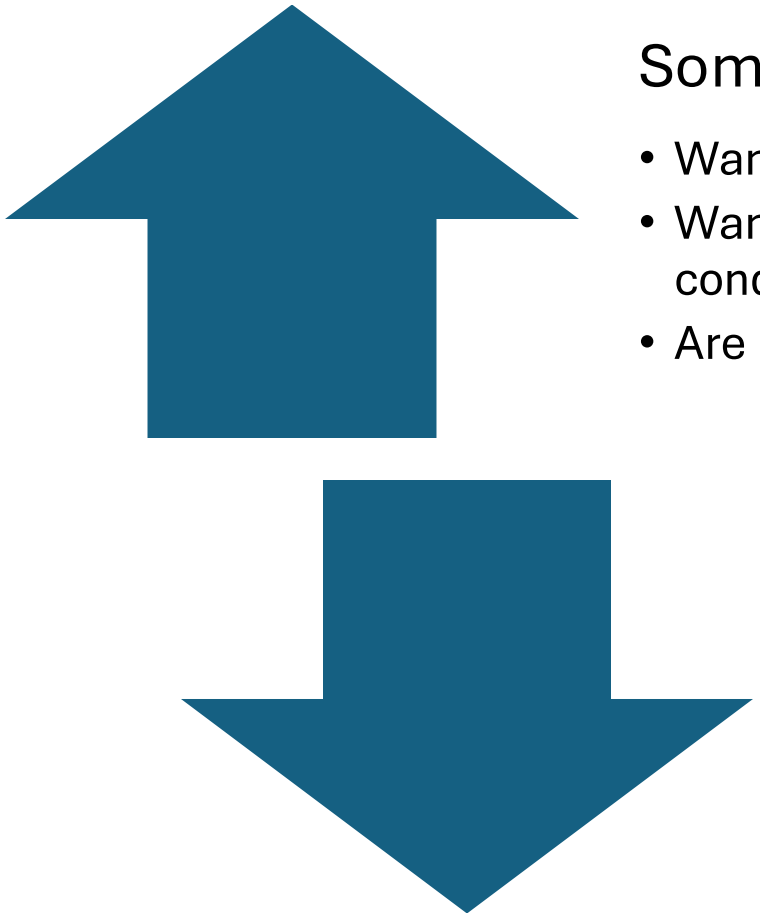
The research conversation will be more productive if they're ready to talk and feeling comfortable. No need to rush into it!

Step 2: Information

Goal: Share information about the study

- Orient them to the materials
- Start with the Overview section
- Explore topics they're most interested in
- Check in about understanding
- Elicit questions and make a list
- Explore reasons for participation at the end of the Overview section, then move on to the Detailed Information

Reasons for and against participating



Someone might want to join if they:

- Want to contribute to research.
- Want to help improve care for others with the same condition.
- Are comfortable with the risks of this study.

Someone might not want to join if they:

- Do not have time for extra study visits and questions.
- Prefer to choose their treatment with their care team.
- Are uncomfortable with the risks of this study.

Step 3: **V**alues **E**xploration

Goal: Elicit and examine relevant values

- Build on reasons for and against participating
  - Which ones resonate? What other potential reasons do they have?
  - How do these weigh against each other?
- Elicit relevant priorities – e.g., health-related, life priorities during study period
- Elicit concerns or barriers and how to navigate them

Use active listening to reflect values and allow further exploration.

Step 3: **V**alues **E**xploration

Poll Question

What is an example of a question you might ask to start a discussion about values?

Step 3: **V**alues **E**xploration

Questions you could ask:

- When you think about whether this study is something you want to take part in, what things are important to you?
- Imagine you joined the study, how do you see it fitting with your other priorities?
- Is there anything else you've heard so far that might be an issue for you?

Step 4: **R**esolution

Goal: Confirm a values-aligned decision

- Reflect, confirm, and validate their key reasons, priorities, and concerns/barriers/solutions
- Check in on their decision
- If they express conflict and/or aren’t ready to decide, validate and offer time

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Role plays

Goals

1. Practice using RIVER in real-world scenarios
2. Test out wording and find language that feels natural

Simulation learning agreement

1. We appreciate you taking the time to be here – our goal is to make this helpful for all levels of experience.
2. Role playing can be awkward! Try to suspend disbelief and pretend it's a real conversation.
3. Messing up, restarting, trying a different approach are okay, expected, and encouraged. Feel free to say "let me try that again."
4. We're here to learn from and support each other. Keep comments constructive and respect confidentiality.

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Role play logistics

1. Divide up into groups of 4
2. We will present a short description of a potential participant
3. One person will play the participant; one will play the coordinator
   - Character descriptions include their initial thoughts about research
   - The other two people will observe the conversation
4. Start the conversation and work through as much as feels reasonable
   - You may not come to a full resolution – that's okay!
   - Pause at a natural point
5. We will help you debrief
   - What went well?
   - What would you change next time?
6. Rotate roles for the next one

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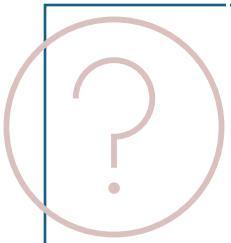
RIVER communication framework

Relationship
Goal: Form a connection



Information
Goal: Share about the study

Values Exploration
Goal: Elicit and examine relevant values

Resolution
Goal: Confirm a values-aligned decision

Role Play 1 – Study information

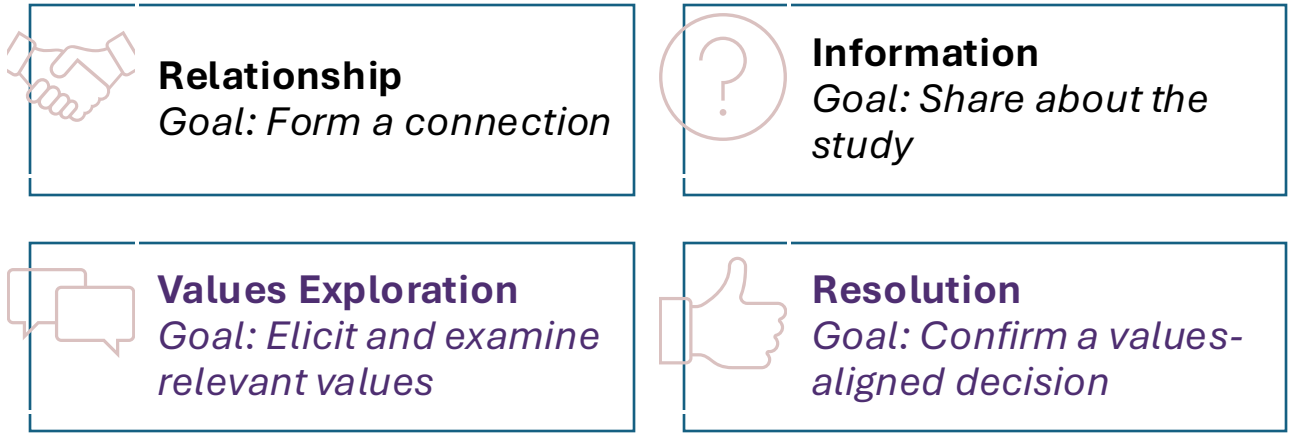
- You are a clinical research coordinator enrolling participants in a clinical trial evaluating the efficacy of a new dual-medication inhaler for asthma.
  - Participants are identified and approached following routine asthma clinic visits.
  - Eligible participants will be asked to discontinue their current single-medication inhaler and begin the study inhaler.
  - The study inhaler will be taken 2 puffs twice daily, every day, for 12 months.
  - Every 3 months, participants will complete study surveys and undergo lung function testing.

Role Play 1 – Potential participant information

- Jordan is 20 years old and has a history of asthma. They have used a single-medication inhaler for several years. Jordan continues to experience some daily asthma symptoms, including cough and exercise intolerance, but has not had an asthma exacerbation in a few years.
- Jordan works for an outdoor equipment design company, travels internationally, and lives with their parents and younger siblings.
- Jordan has just finished a routine asthma clinic visit with their clinician. After the visit, you introduced Jordan to the clinical trial and reviewed the study **overview** and most of the **detailed study** information.
- Jordan is interested in the study and says they would like to contribute to medical research. But they are also hesitant because they have heard some bad things happening to people who participate in research and are worried about something harmful happening to them.

Role Play 1 – Instructions

- Choose one person to play the participant and one to play the coordinator
- The other two people should observe and be ready to give feedback
- Refer to the RIVER framework below
- Pick up the conversation by wrapping up the information sharing step, then starting with the values exploration step (7 minutes for role play)



Role Play 1 – Discussion

(3 minutes for small group debrief, then 5 minutes to share with the whole group)

- What went well from each person's perspective?
  - Potential participant
  - Coordinator
  - Observers
- How did it feel using the RIVER approach?
- What might you try differently next time?

Role Play 2 – Study information

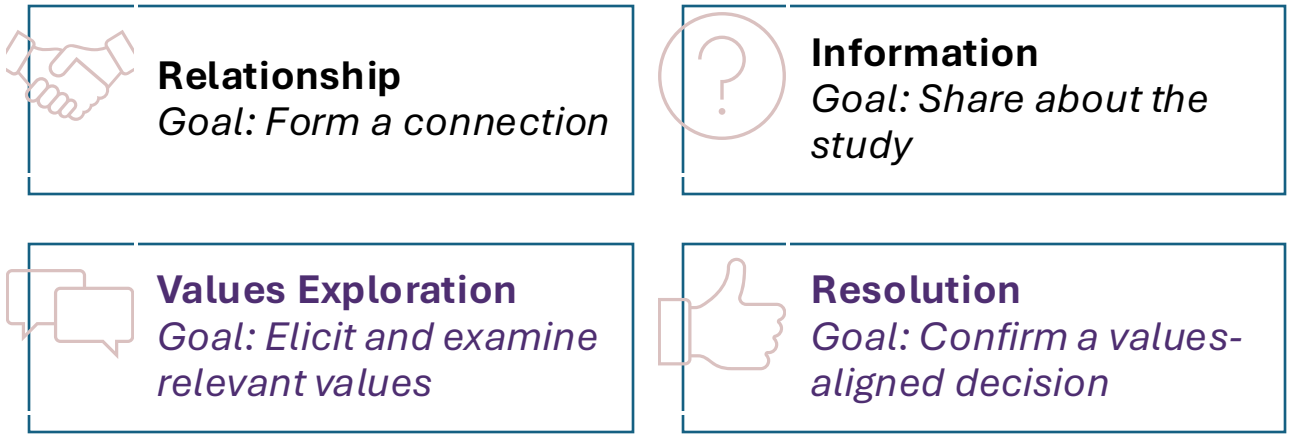
- Your goal is to enroll patients in a qualitative research study to better understand the patient experience at a family medicine clinic
  - A random sample of patients at the clinic will be invited to consider participating
  - Participants enrolled will complete 3 virtual interviews over the course of one year
  - The interviews explore participants' experiences and satisfaction with and perspectives on the quality and continuity of care they receive at this practice
  - Data from the interviews will be de-identified and participant responses will not impact the care they receive

Role Play 2 – Potential participant information

- Cameron is 25 years old and attends community college. They recently moved into an apartment with a roommate. They work as a nanny and enjoy online gaming.
- Cameron has received medical care at the same family medicine practice for the past 10 years.
- You spoke with Cameron earlier today and reviewed the overview and detailed information with Cameron. Cameron didn't say much during the conversation, so you offered to continue the discussion later.
- You are now meeting Cameron again, with the goal of exploring values and coming to a resolution. Cameron doesn't know much about research and doesn't know what questions to ask before deciding whether to participate

Role Play 2 – Instructions

- Choose one person to play the participant and one to play the coordinator
- The other two people should observe and be ready to give feedback
- Refer to the RIVER framework below
- Pick up the conversation with the goal of coming to a resolution (7 minutes to role play)



Role Play 2: Discussion

(3 minutes for small group debrief, then 5 minutes to share with the whole group)

- What went well from each person's perspective?
  - Potential participant
  - Coordinator
  - Observers
- How did it feel using the RIVER approach?
- What might you try differently next time?

Thank you for participating today!

QUESTIONS?

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