



CROSS-CULTURAL COMMUNICATION FOR CLINICAL TRIAL STAFF



"At Merck, we have a commitment to the study of diverse patient populations, including minorities, women, and children, in our clinical trials in all regions of the world. As a result, we strive to obtain information among diverse populations, ensuring a thorough evaluation of the safety and efficacy of our medicines and vaccines. These efforts allow us to seek regulatory approvals throughout the world and thereby offer our medicines globally to patients who need them."

- Kenneth C. Frazier, Chairman and CEO, Merck



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This brochure will help you learn new strategies to improve your communication with patients from diverse cultures.

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What is cross-cultural communication?

Cross-cultural communication is the ability to successfully communicate with people from different cultures and with different languages than your own. The goal of cross-cultural communication in health care is to help improve quality and eliminate racial and ethnic health disparities.¹



Why is cross-cultural communication important for clinical trials?

The United States is becoming more racially and ethnically diverse. Not only are there many languages spoken in the United States, but there are wide-ranging concepts regarding health care.

Effective cross-cultural communication can help bring about these positive outcomes:²⁻⁴

- Enhance interactions with clinical trial participants and build trusted relationships
- Improve protocol adherence for participants
- Meet legislative, regulatory, and accreditation mandates
- Reduce racial and ethnic health care disparities
- Ensure that clinical trial data better represents diverse cultures and ethnicities of the United States population

Key steps to improve cross-cultural communication

To improve your cross-cultural communication, consider these 3 steps⁵:

1. Take a cultural awareness self-assessment
2. Learn about patients’ cultures
3. Apply strategies for effective cross-cultural communication

1. TAKE A CULTURAL AWARENESS SELF-ASSESSMENT

Cultural awareness is a reflective process to identify and understand your own cultural and professional⁶:

- Background
- Values
- Beliefs
- Biases
- Assumptions

Cultural awareness helps you understand how culture impacts your communication with others. Being aware of your own biases and norms is the first step in improving cross-cultural communication because it helps you avoid imposing your own cultural beliefs and values on others.

See the Cultural Awareness Self-Assessment Checklist on the next page. Review this as an inventory of your current practices and then on an ongoing basis as you build your cross-cultural communication skills.

Cultural Awareness Self-Assessment Checklist⁷ (created by Georgetown University)

Read each statement below and:

- 1. Check the ones that you agree with and often do as part of your work
- 2. Review statements that you didn't check

- I treat all of my participants with respect for their culture
 - I do not impose my cultural beliefs or values on my participants or their family members
 - I learn about acceptable behaviors and customs that are common in my participants' cultures
 - I recognize that my participants from culturally diverse backgrounds may desire varying degrees of assimilation into the dominant culture
- I recognize that the roles of family members, such as gender roles, may differ within or across cultures or families
 - I accept that religion, culture, and other beliefs may influence how participants and families respond to symptoms, disease, and death
 - I accept that the value of medical treatment and health education may vary greatly among cultures
 - I use bilingual staff members or trained interpreters to communicate with participants who have limited English proficiency
 - I consider the cultural and linguistic background of my participants when I select educational materials such as pictures, brochures, videos, and apps

For more cultural awareness self-assessment tools, visit the National Center for Cultural Competence at www.nccc.georgetown.edu.

2. LEARN ABOUT YOUR PATIENTS' CULTURES

After you assess your own cultural values and beliefs, the next step is to learn about your patients.

Every individual holds values, beliefs, and practices to consider when providing health care services. The best way to learn about these is to respectfully ask patients about their way of life. This helps you understand how their values may impact their health care and helps you create an acceptable and culturally relevant health plan.

See the table on the next page for some example questions and consider noting their answers in their medical record.⁸⁻¹⁰

Every interaction is cross-cultural

Each person is a unique individual and may or may not hold certain beliefs of practices common in their culture.¹⁰ There are as many differences within cultures as between cultures. Always use questions with every participant to learn about their beliefs and values.¹¹



Cultural value and health belief	Example questions ^{8,10,12,13}
Beliefs about the cause of illness or disease, such as whether or not you can prevent disease	<ul style="list-style-type: none">• How does your health problem affect you?• Why do you think it started when it did?
Customs, such as using home remedies, herbs, or other treatments	<ul style="list-style-type: none">• Is there anything I should know about your culture or ethnicity that would help me take better care of you?• Have you used any home remedies for this problem?• What results have you had from other treatments you used?
Religious practices, such as fasting or refusing blood transfusions	<ul style="list-style-type: none">• What kind of treatment do you think you should or should not receive?• What are the most important results you hope to receive from the treatment?
Interpersonal customs, such as eye contact and personal distance	<ul style="list-style-type: none">• What did you like about your last health care provider? What did you dislike?• What did you like about your past health care experience? What did you dislike?• I need your help so I can be most helpful to you. Please tell me what you want to know more about or would like me to repeat.• I would appreciate your feedback about any interpersonal customs related to eye contact and personal space/distance, so that I can be helpful and respectful

In addition to asking key questions, consider improving your cultural knowledge overall, including health-related beliefs and values.¹ Learn more by reading cultural background resources:

- www.cdc.gov/healthliteracy/developmaterials/understandaudience/index.html
- <http://refugeehealth.ca/>
- <https://ethnomed.org/culture>
- Virginia Department of Education Resource Manual for Cultural Competence: http://www.doetest.virginia.gov/special_ed/tech_asst_prof_dev/self_assessment/disproportionality/cultural_competence_manual.pdf
- <https://minorityhealth.hhs.gov/assets/pdf/checked/toolkit.pdf>
- <https://scholarworks.gvsu.edu/cgi/viewcontent.cgi?article=1014&context=orpc>

3. APPLY STRATEGIES FOR EFFECTIVE CROSS-CULTURAL COMMUNICATION

To bridge cultural differences between your own and your patients' norms, you can apply both written and verbal communication strategies. These strategies can help you build a relationship with your patients, find common ground, and deliver patient-centered care.¹⁴

Use the RESPECT Model to build trust and show respect

The RESPECT Model provides a framework to help you remain open, show respect, and build trust with patients from diverse cultures.¹⁵

The Respect Model¹⁵

Skill	Description	Examples
R apport	<ul style="list-style-type: none">• Connect on a personal level• Try to understand the patient’s point of view	<ul style="list-style-type: none">• Welcome the patient• Introduce yourself and your role• Ask them what name they prefer
E mapthy	<ul style="list-style-type: none">• Verbally acknowledge and validate the patient’s feelings• Remember the patient has come to you for help• Seek to understand the patient’s rationale for his/her behaviors• Recognize that he/she may be unfamiliar with the clinical trial environment	<ul style="list-style-type: none">• Listen for underlying feelings• Verbally respond to validate the underlying feeling, using a phrase such as “I hear you saying...” or “You seem to be feeling...”
S upport	<ul style="list-style-type: none">• Ask about barriers to participating in the clinical trial and following medical advice• Help the patient overcome barriers• Ask who they consider family and how they’d like them involved• Reassure the patient you are available to help	<ul style="list-style-type: none">• Ask “What is hardest for you?”• Show you are actively listening through head nods, smiles, and leaning forward• Use phrases to assure you’re here to help, such as “I’m here if you need help”• Highlight contact information so it’s easy to find in paperwork
P artnership	<ul style="list-style-type: none">• Check for understanding using the teach-back method• Use verbal communication strategies	<ul style="list-style-type: none">• Ask open-ended questions to check understanding, such as “How will you take your study drug at home?”• Use simple, common words, such as “able to” instead of “eligible”• Replace jargon and define need-to-know technical terms using simple language
E xplanations	<ul style="list-style-type: none">• Check for understanding using the teach-back method• Use verbal communication strategies	<ul style="list-style-type: none">• Ask open-ended questions to check understanding, such as “How will you take your study drug at home?”• Use simple, common words, such as “able to” instead of “eligible”• Replace jargon and define need-to-know technical terms using simple language
C ultural Competence	<ul style="list-style-type: none">• Respect the patient’s cultural beliefs• Consider that the patient’s views of you may be defined by ethnic and cultural stereotypes• Be aware of your own cultural norms and biases• Know your limitations in addressing health issues across cultures• Understand your personal communication style and recognize when it may not be working with a given patient	<ul style="list-style-type: none">• Take a cultural awareness self-assessment to know your own limitations, biases, and norms, such as limited knowledge of certain cultural groups• Understand your communication style, such as your pattern of:<ul style="list-style-type: none">- Expressing your feelings and opinions- Listening or interrupting- Using facial expressions
T rust	<ul style="list-style-type: none">• Recognize that self-disclosure may be difficult for some patients• Work to establish trust	<ul style="list-style-type: none">• Encourage patients to ask questions by saying, “Let’s make sure we answer all your questions so you feel comfortable”• Always follow up when you say you will

Adapted from the US Office of Minority Health, “The RESPECT Model,” in the Guide to Effective Communication and Language Assistance Services. (www.thinkculturalhealth.hhs.gov)

Apply written communication strategies when developing materials for your site

- Apply health literacy principles to make your materials easy to understand
- To learn health literacy principles, visit www.cdc.gov/ccindex/index.html
- Make important materials available in multiple languages when possible
- Use visual models, diagrams, and pictures to illustrate a procedure or condition
- Consider using multimedia tools such as apps and videos
- Provide easy-to-understand signage^{2,10,15-17}

Apply verbal communication strategies

- Communicate in a language most comfortable to the patient
- Avoid medical jargon and technical terms
- Use the teach-back method to confirm understanding – don’t assume the patient understands, even if they say “yes” when you ask them
- Be positive, curious, and nonjudgmental toward all patients
- Ask questions – for example, ask about their preferences and customs related to communication
- Encourage patients to ask you questions^{10,15,16}

Pay attention to nonverbal behaviors

- Watch your patient’s nonverbal communication and body language for cues
- Follow the patient’s lead for communication
- Be aware of interpersonal norms regarding nonverbal cues, such as:
 - Eye contact
 - Body language, especially the gestures meaning “yes” and “no,” such as smiles and nods
 - Silence
 - Tone of voice
 - Facial expression

- Pay close attention to important relationships, family dynamics, and social roles that influence decision-making and communication. For example, some patients may^{10,15,16}:
 - Look to the another family member for advice or decision-making
 - Respect and seek advice from other family members

Summary

Using effective cross-cultural communication:

- Includes cultural self-awareness, cultural insight, and targeted communication strategies
- Enhances understanding of a patient’s needs, values, and preferences in order to provide appropriate information and build trusted relationships
- May lead to better quality of care and improved clinical trial adherence





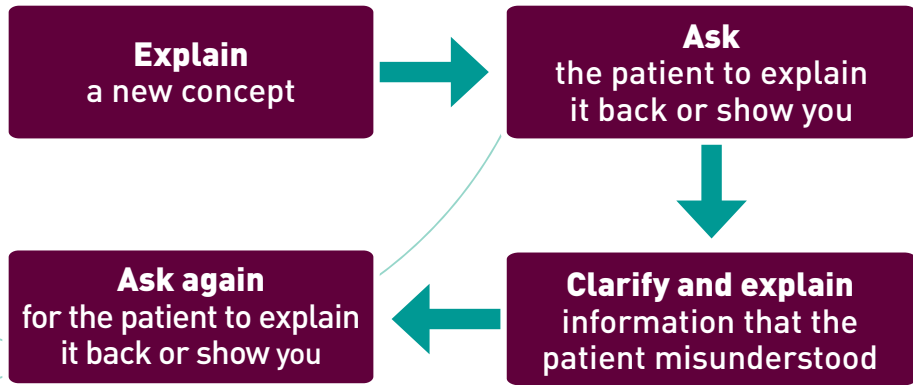
HOW TO USE THE TEACH-BACK METHOD
TO IMPROVE COMMUNICATION FOR CLINICAL TRIALS

What is teach-back?

Teach-back is an evidence-based communication strategy to confirm that you explained information in a way that your patient understood.^{18,19} Teach-back asks patients to explain back or demonstrate information to²⁰:

- Check their understanding
- Help them remember information

Teach-back technique²¹



How do I use teach-back?

Here are tips to help you effectively communicate during each step of the teach-back technique.^{22,23}



STEP 1: EXPLAIN A NEW CONCEPT

- Organize the information so important points come first
- Break down complex information into chunks
- Use simple, common words instead of medical jargon
- Explain any need-to-know, technical terms using simple language
- Use active voice
 - For example, say “Take this study drug with water” instead of “This study drug should be taken with water”

STEP 2: ASK THE PATIENT TO EXPLAIN THE INFORMATION BACK TO YOU IN HIS OR HER OWN WORDS

Use open-ended questions, which usually start with “what,” “when,” or “how” and can’t be answered with a “yes” or “no.” Preface your questions with a comment such as, “I’d like to make sure I explained that clearly” – this prevents teach-back from feeling like a test of knowledge.

Here are some examples of open-ended questions²³:

- When is the best time for you to take your study drug?
- What side effects are possible from this study drug?
- What should you do if you feel dizzy or your chest hurts?
- How will you contact the study staff?

Avoid closed-ended questions, such as²³:

- Do you understand?
- Do you have any questions?
- Do you know how to use the device?
- Do you know when to take the study drug?
- Are we clear on when to come in for treatment visits?

Here are some statements to have the clinical trial patient demonstrate an action²⁴:

- Tell me in your own words how you’ll take this study drug
- Please show me how you’ll use the glucose meter.
- Show me how you will do that.
- Tell me who you will contact if you have a question about any part of the study.
- Please tell me about other medications you may be taking.

If the patient correctly explains back or demonstrates the information, you can move on to explain the next concept.

STEP 3: CLARIFY AND EXPLAIN INFORMATION THAT THE PATIENT MISUNDERSTOOD

If the patient misunderstood your explanation, you’ll need to clarify and explain the concepts in a different way. For example:

- Use simpler language
- Break up the information into smaller chunks or steps to focus on less information at one time
- When explaining actions that have multiple steps, pause between steps to let the patient ask questions

STEP 4: ASK AGAIN FOR THE PATIENT TO EXPLAIN THE INFORMATION BACK TO YOU

Ask open-ended questions until you feel confident the patient understands the information. Repeat steps 3 and 4 until the patient can correctly tell you in their own words what they are going to do.

Tips to make teach-back part of your routine

Teach-back is a skill, and like any skill, it requires practice. Here are some tips to help make it part of your routine²⁵:

- Start slowly – use teach-back with just 1 patient a day
- Practice teach-back – slowly add teach-back to more visits so it becomes part of your routine
- Plan how you’ll ask for a teach-back – think about the information you present and how you’ll ask depending on the type of information
- Reflect on your use of teach-back – what went well? What can you change for next time?
- Identify explanations and communication strategies that patients often misunderstand
- Talk about teach-back with your coworkers and staff to share ideas to help it go more smoothly

When should I use teach-back?

Use the teach-back technique whenever you explain a new, important concept to a patient, such as¹⁸:

- Informed consent details
- Screening and protocol procedures
- Instructions for taking the study drug
- Important adherence factors for study participation

Teach-back doesn’t take longer

Teach-back is simple and should not add more time to your visits.^{22,24}

Teach-back is an effective technique, but save it for the most important information at a visit to avoid seeming condescending to a clinical trial patient.²⁵

Why is teach-back important?

Misunderstanding health information is a common problem

Almost 9 out of 10 adults lack the skills needed to manage their health and prevent disease. Communication factors related to patients and clinical trial staff can also lead to misunderstandings. As a result, people often leave health care visits without knowing what they need to do²⁶:

- People immediately forget 40% to 80% of medical information explained by a health care professional^{20,27,28}
- Almost 50% of the information that is remembered is incorrect²⁷

Teach-back improves understanding and satisfaction

When health care professionals used teach-back²⁹:

- Recall of information rose from 61% to 84%
- Satisfaction improved

Teach-back improves health outcomes

The effective use of teach-back is linked to:

- Better glycemic control for diabetic patients^{21,29}
- 30% drop in hospital readmissions and visits to the emergency department³⁰
- Improved patient adherence and outcomes¹⁹

Teach-back example

Here is an example of how you can use teach-back to confirm a patient in a clinical trial understands how to take a study medicine.

Scenario:

Ms. Taylor, 40, was diagnosed with type 2 diabetes 8 months ago. She joined a clinical trial for type 2 diabetes to test a new investigational medicine. She is talking with the clinical trial staff about how to take her study drug doses.

Conversation:

Clinical trial staff: It's very important that you take this study drug exactly as you are supposed to Ms. Taylor. I want to make sure that I have explained everything clearly. When will you take your doses after you leave the clinic today?

Ms. Taylor: I need to take the pills in this bottle twice a day. I'll take one in the morning and one before bed.

Staff: Not exactly. I don't think I explained that very well. Let me try again.

You will take both pills from this bottle at dinner time. If you forget, you can look at the instructions on the label or in your dosing diary, and they will remind you what to do.

So, when will you take the pills?

Ms. Taylor: Oh, right, both at dinner time.

Staff: Exactly. Two pills at dinner time. Will you take these with food?

Ms. Taylor: I guess so.

Staff: Right after you eat is best, as they may upset your stomach a little if you take them before food. It might help if you always open the dosing diary first and then you will remember to take your pills right after dinner.

Ms. Taylor: OK, I'll take both pills after I eat dinner, I understand now. Thank you.

What do you think?

Discuss these with your other staff members.

1. What open-ended questions did the staff use to ask for teach-back? What statements did staff use to ask for teach-back? What other open-ended questions could be used?
2. How did the staff approach the fact that they needed to re-explain the information?
3. Were there places where the teach-back technique could have been used more effectively? What might the revised approach sound like?



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