



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY



Health Literacy and Informed Consent

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Disclosures



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What AHRQ Does

Health Systems Research

AHRQ invests in research to understand how to make healthcare safer and improve quality

Practice Improvement

AHRQ creates materials to teach and train healthcare professionals and systems to improve care for their patients

Data & Analytics

AHRQ generates measures and data used to track and improve performance and evaluate progress of the U.S. health system

My Mother



Overview

- Health Literacy: What Is It and Why Is It Important?
- Health Literacy Strategies for the Informed Consent Discussion
- Creating Easy-to-Understand Consent Forms and Educational Materials

Health Literacy: What Is It and Why Is It Important?

“Polling” Question

Which is an example of health literacy?

(Choose all that apply)

- A.** When people can read and understand health information
- B.** When people can act on health information to make informed decisions
- C.** When organizations make sure that people can find the health information they need
- D.** When organizations ensure that people can equitably access and use health services

What Is Health Literacy

Answer: All of the above

Health literacy is about people being able to find, understand, and use information to inform health-related decisions and actions for themselves and others.



Health Literacy Is a Combination of Personal and Organization Health Literacy

**Personal
Health Literacy**



Skills/Abilities

x

**Organizational Health
Literacy**



Ease or Complexity

=

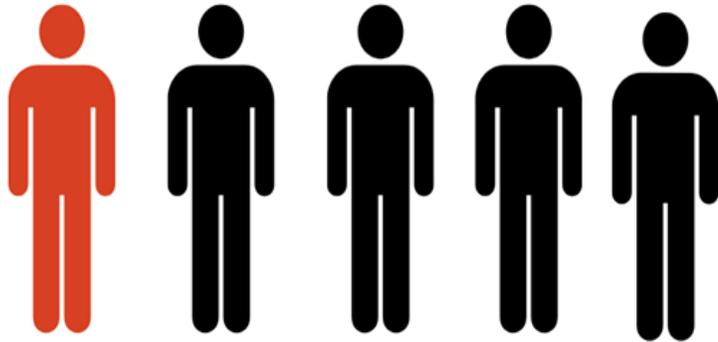


Health Literacy

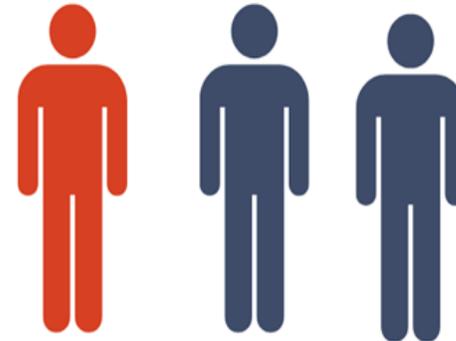
Many in the U.S. Struggle with Reading and Math

Among working age adults in the U.S.

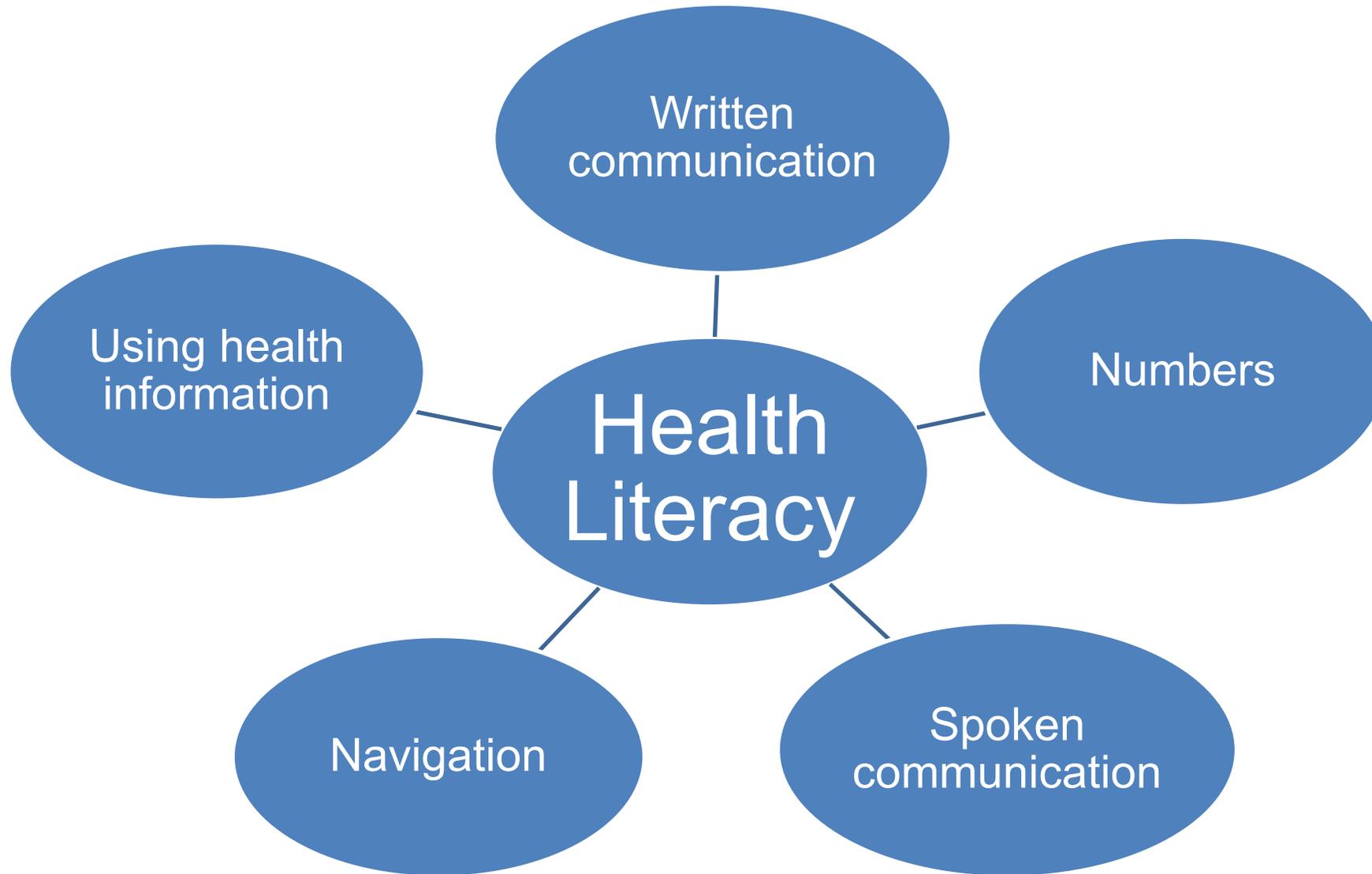
1 in 5 have **low literacy**



1 and 3 have **low numeracy**



Not Just Reading and Math



Why Health Literacy Is Important

People need to find, understand, and use information to get and stay healthy.

Understand
your
condition

Know your
options

Assess risks
& benefits

Choose what
makes sense
for you

Know when
& how to
follow-up

What Happens If You Don't Address Health Literacy?



Medical errors

- Toni Cordell had surgery for “women’s problems.” She didn’t learn until afterwards her womb had been removed.

Organizational Health Literacy in the U.S. Is Low



- Health information (including informed consent forms) is routinely written at a level that the **majority of adults can't understand.**
- Clinicians frequently **don't check patients' understanding** when asking for consent.
- When communicating risk, clinicians may use **statistics that are hard to understand**

Anyone Can Experience Low Personal Health Literacy



Health literacy is dynamic.

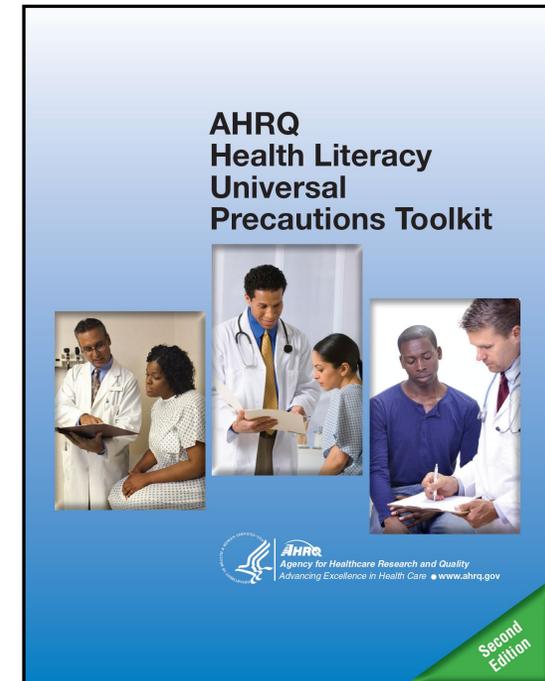
A person's ability to find, understand, and use health information and services is affected by whether they are:

- Tired or sick
- Frightened
- Overwhelmed
- Under time pressure

Use Health Literacy Universal Precautions

Structure health information and the delivery of care as if everyone may have limited health literacy

- You can't tell by looking
- Higher literacy skills \neq understanding
- Health literacy is a state not a trait
- Everyone benefits from clear communication



Health Literacy Is Critical to Achieving Health Equity



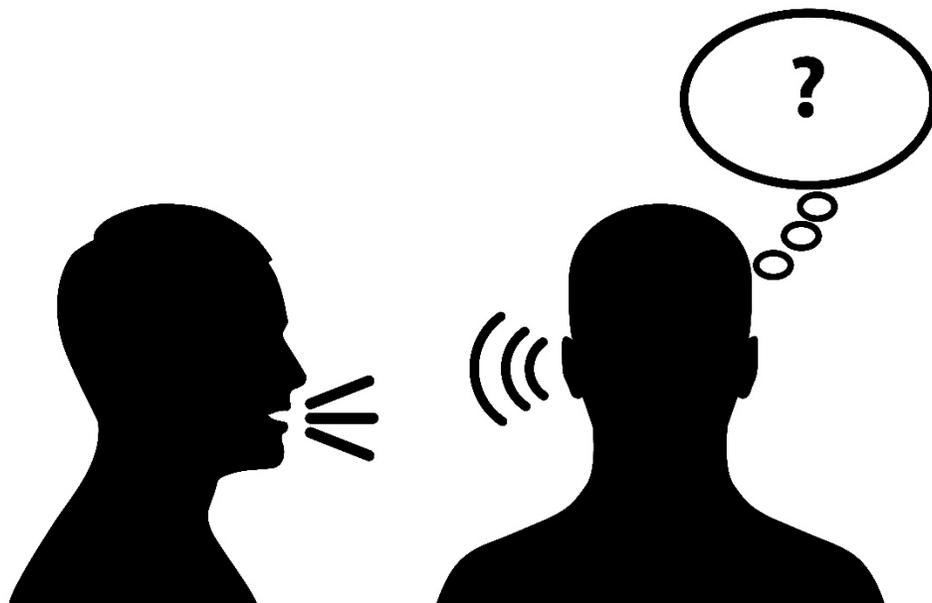
Health literacy strategies:

- Are integral to delivering culturally and linguistically appropriate services
- Improve cross-cultural communication
- Have the potential to reduce disparities because minority adults are more likely to have low personal health literacy

Making the Informed Consent Discussion Easy to Understand

The greatest problem with communication is the illusion it has occurred.

- Attributed to George Bernard Shaw



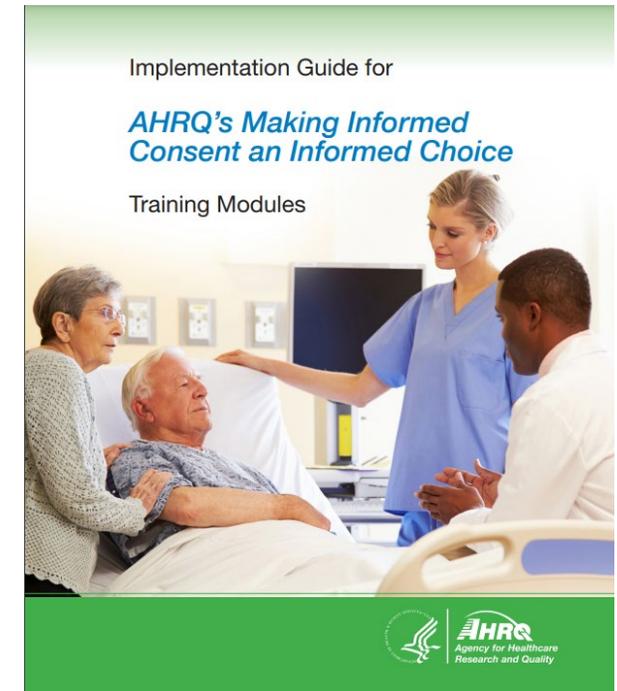
Prepare the Workforce to be Health Literate

- Hire diverse staff with health literacy expertise
- Set and meet goals for teaching **all** staff health literacy and informed consent strategies
 - ▶ Orientations and other trainings
 - ▶ Online training
- Track your progress!

Internal Training and Education is a Leap Frog Standard:

Does your hospital have a training program on informed consent that tailors different training topics to different staff roles, and has your hospital made the training:

- a required component of onboarding for the appropriate newly hired staff, and
- required for the appropriate existing staff who were not previously trained?



[AHRQ's Making Informed Consent an Informed Choice: Training Modules for Health Care Leaders and Professionals](#)

Improve Spoken Communication During the Consent Discussion

Communicate Clearly

- Address language differences
- Use the consent form as a guide to discuss things in a logical order
- Use plain language
- Listen, slow down, show respect
- Make numbers easy
- Encourage questions
- Repeat key points
- Confirm understanding with teach-back
- Use communication assessment tools (self, observation, patient)

Additional Resources:

- [Guide to implementing the Health Literacy Universal Precautions Toolkit: Spoken Communication](#)
- [Communication Self-Assessment; Communication Observation Form; Patient Feedback Form](#)
- [Teach-Back Method; Teach-back Learning Module](#)

Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers (Continued)

Strategies to identify patient language include:

- Informing patients of their right to a free interpreter
- Asking which language they prefer
- Using “I speak” cards, touch-screen menus, or over-the-phone patient language identification

Important

Never let friends, family members, or children serve as the interpreter!

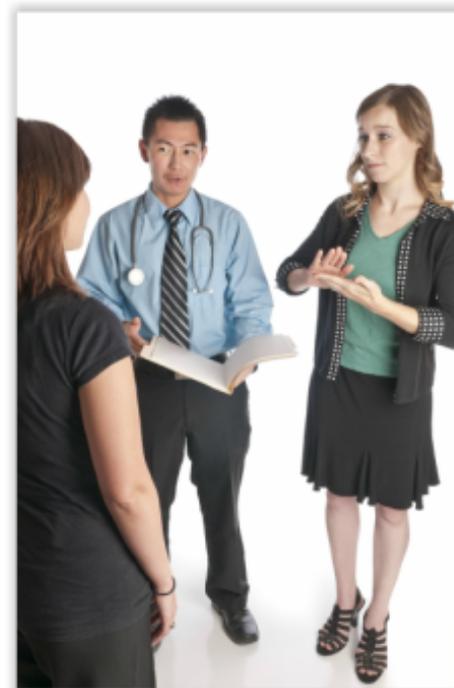
Options for high quality language assistance:

[Bilingual staff](#)

[Bilingual staff as interpreters](#)

[Qualified medical interpreters](#)

Select each button to learn more.



Team with Your Interpreter

Create psychological safety.

- Ask interpreter to let you know if they think the patient does not understand anything.



Source: [TeamSTEPPS® limited English proficiency \(LEP\) module](#)

Examine Your Assumptions

Culturally diverse populations may differ on:

- Familiarity with medical concepts (e.g., contagion, titration)
- Western medicine
- Health beliefs
- Religious beliefs
- Health practices
- Diet and supplements

Use Plain Language Don't Use Jargon

Say	Not
Pain killer	Analgesic
Swelling	Inflammation
Feverish	Febrile
High blood pressure	Hypertension
Wound	Lesion
Injury	Insult

Use Common, Everyday Language

Say	Not
Use	Utilize
Enough	Sufficient
Helpful	Beneficial
Make worse	Exacerbate
Come back	Recur
About	Regarding

Make Numbers Easy

- Don't be vague – put a number on it.
- Use frequencies instead of decimals or percentages.
- Keep denominators and timeframes the same when you compare numbers.
- Give absolute risk instead of relative risk.
- State risk in both positive and negative terms to eliminate subconscious bias.
- Do the math for patients – don't make them calculate.

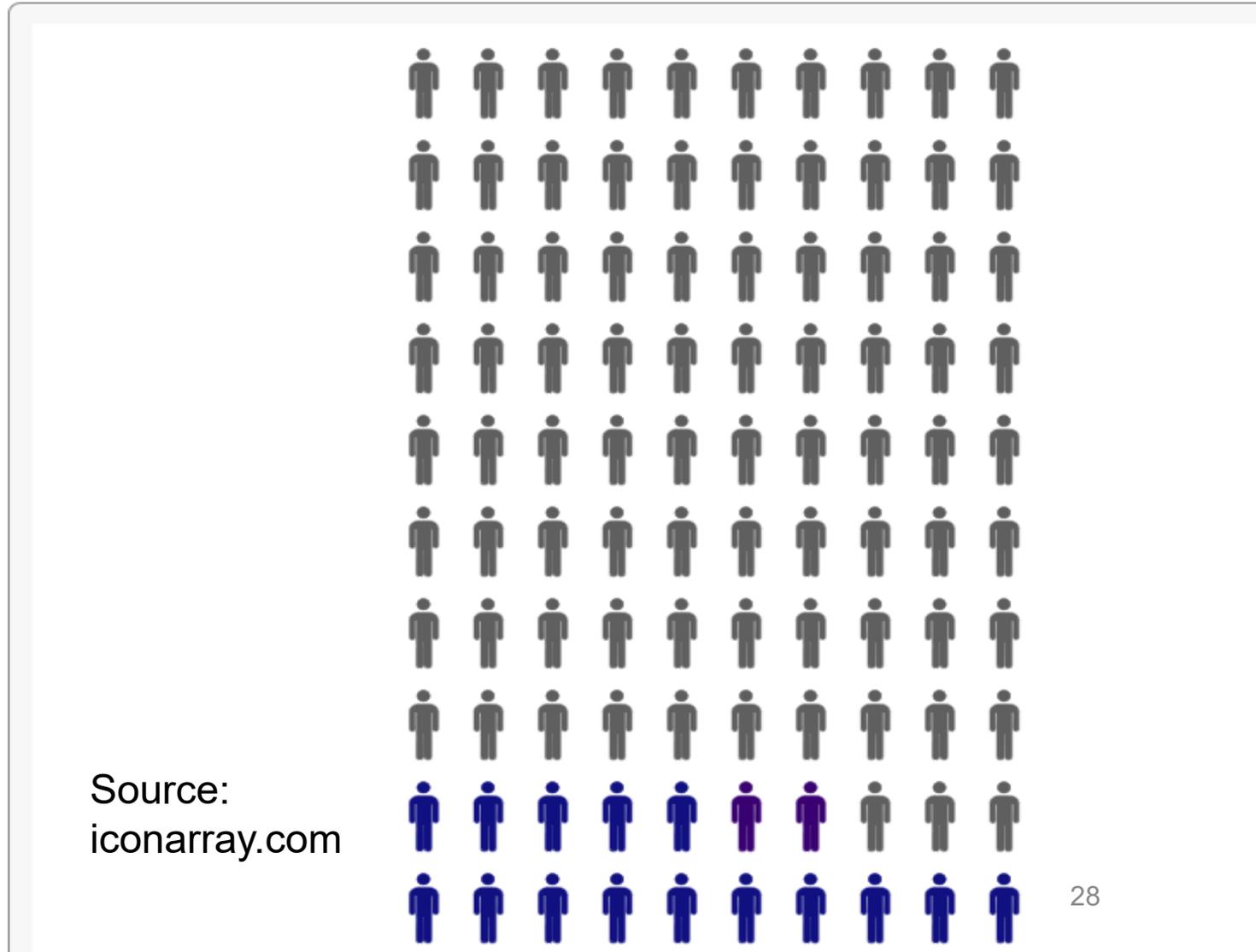
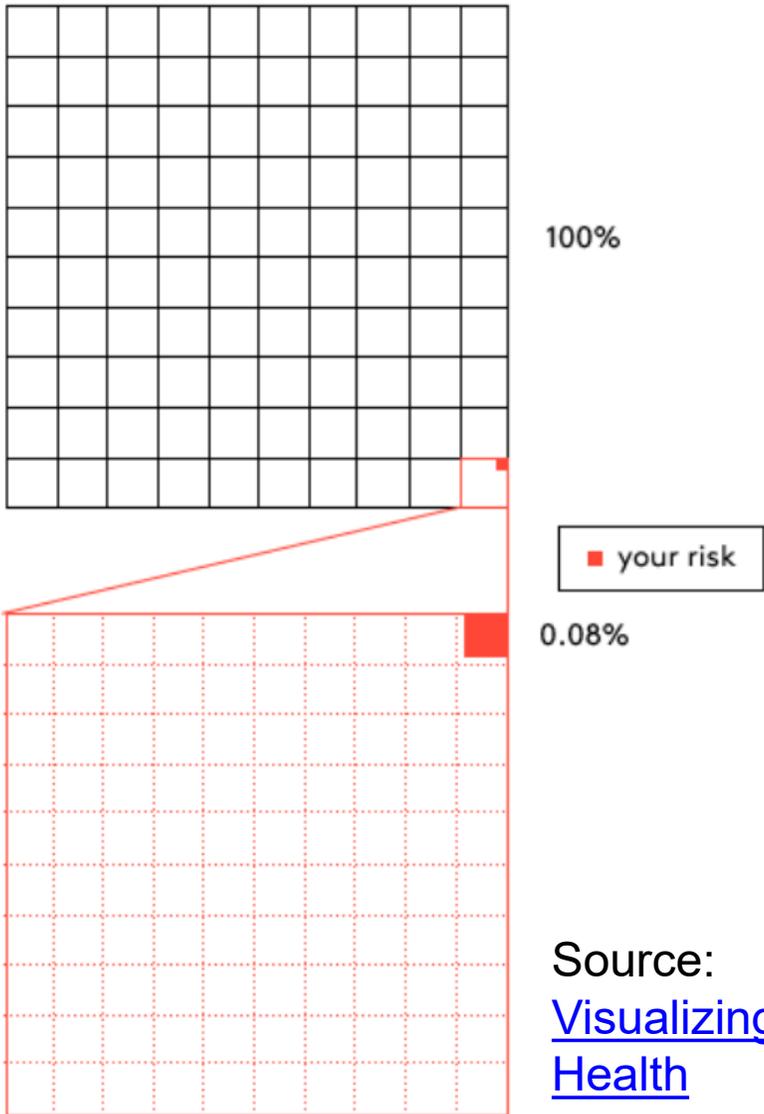
1 in 100 people will bleed after a growth is removed.

99 people
will not bleed

1 person
will bleed

Source: [Communicating Numbers to Your Patients: A Reference Guide for Health Care Providers, AHRQ](#)

Use Visuals to Enhance Understanding



The What and Why of Decision Aids

The What

Decision aids:

- Are tools to communicate unbiased information about options, their benefits, harms, and risks
- Can help patients and families figure out what matters most to them
- Can be paper-based, audio-visual, web-based, interactive

The Why

Decision aids:

- Help clinicians structure the conversation.
- Improve patients' understanding of their options and weigh their choices
- Prepare patients to cope with outcomes, including adverse events

Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #2 - Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)



How do you know whether you have a high-quality decision aid?

Check whether the decision aid:

- Comes from a reliable source
 - With experience
 - With testing history
 - With no vested interest
- Is complete
 - Shows all feasible options
 - Shows benefits, harms, and risks
 - Shows option of no treatment
- Is based on up-to-date scientific evidence
- Is unbiased
- Is understandable
 - Uses health literacy strategies
 - Uses moderately paced and distinct audio
 - Uses multiple languages
- Helps patients to clarify their goals and values

Important

Test high-quality decision aids with clinicians and a diverse range of patients to make sure they are useful and practical in your hospital.

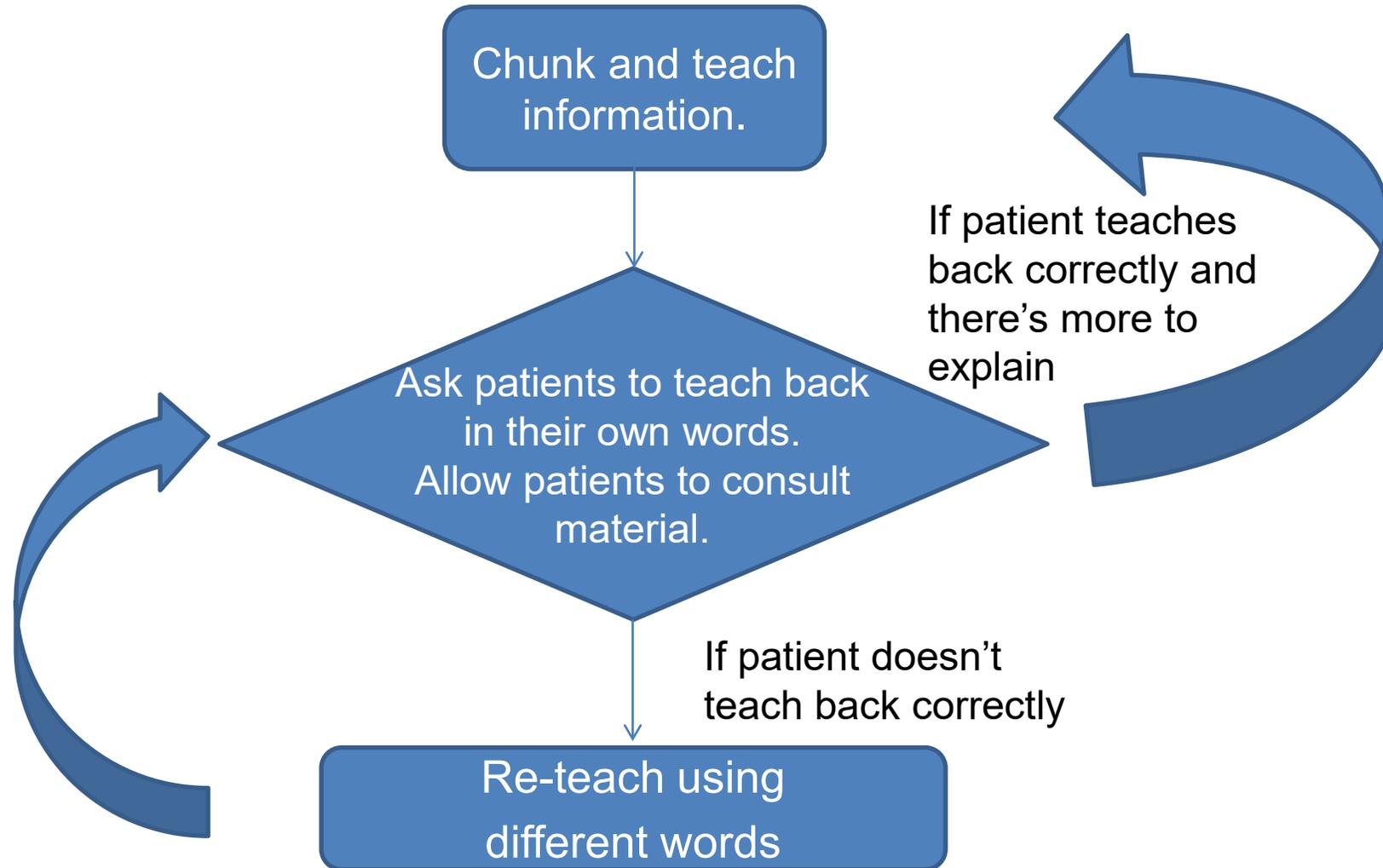
Encourage Questions



Understanding a patients' concerns and priorities is key to a safe primary care visit.

- Let patients know you expect questions.
 - ▶ What questions do you have? (**NOT** Do you have any questions?)
 - ▶ "[Treatment] may be new to you, and I expect that you have some questions. What would you like to know more about?"
- Use body language to invite questions
 - ▶ Sit, look, listen, show you have the time

The Teach-Back Method



Section 2: Strategies for Clear Communication: Strategy 4: Use Teach-Back (Continued)

Teach-back Questions and Phrases



- 
- "Just to make sure that I explained things well, can you tell me in your own words what will happen if you choose to have this procedure done?"

Select each image of a health care worker for a teach-back example.

Section 2: Strategies for Clear Communication: Strategy 4: Use Teach-Back (Continued)

Teach-back Questions and Phrases



- 
- "It's my job to make sure I explained things clearly. To make sure I did, can you please tell me in your own words what good results you expect from this treatment? How likely do you think it is that you will get those results?"

Select each image of a health care worker for a teach-back example.

Section 2: Strategies for Clear Communication: Strategy 4: Use Teach-Back (Continued)

Teach-back Questions and Phrases

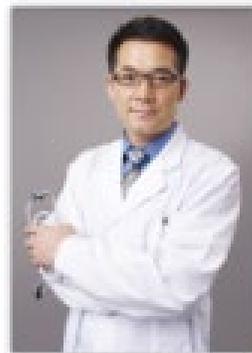
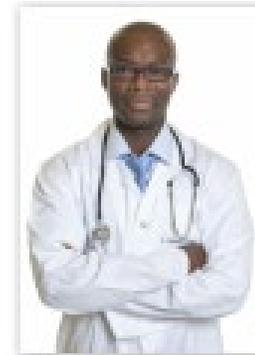


- Is there any downside to this treatment? To prompt the patient further about this, you can say:
 - "Do you expect to experience any pain? For how long?"
 - "Will you be limited in your activities? For how long?"

Select each image of a health care worker for a teach-back example.

Section 2: Strategies for Clear Communication: Strategy 4: Use Teach-Back (Continued)

Teach-back Questions and Phrases

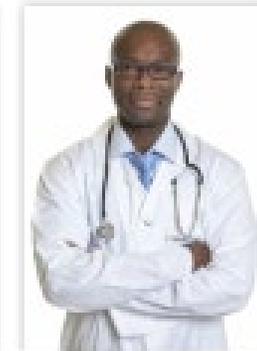


- "Every treatment has some risks. Can you tell me in your own words about the risks of this procedure?" To prompt the patient further about this, you can say:
 - "What about the possible side effects we discussed?"
 - "What could go wrong in surgery?"
 - "Remember how we talked about allergic reactions?"

Select each image of a health care worker for a teach-back example.

Section 2: Strategies for Clear Communication: Strategy 4: Use Teach-Back (Continued)

Teach-back Questions and Phrases



- "We've talked about some other treatments you could choose. Can you tell me what are some of the pros and cons of these alternative treatments?"

Select each image of a health care worker for a teach-back example.

Section 2: Strategies for Clear Communication: Strategy 4: Use Teach-Back (Continued)

Teach-back Questions and Phrases



- 
- "What if you choose not to get any treatment? Can you tell me in your own words what might happen?"

Select each image of a health care worker for a teach-back example.

Re-teach and Re-check

“Let's talk about your choices again, because I think I may have not explained it clearly.”

THEN

“So, how would you describe your alternatives to having this diagnostic test?”

If people cannot teach-back correctly, they cannot give informed consent.



Creating Easy-to-Understand Consent Forms and Educational Materials

Use an Inclusive Writing Process

- Involve:
 - ▶ Clinicians
 - ▶ Patients and families
 - ▶ Lawyers
 - ▶ Plain language experts
- Use writing guides and good sample forms
- Pilot test with diverse patients before roll out

Additional Resources:

- CMS [Toolkit](#) for Making Written Material Clear and Effective
- The Patient Education Materials Assessment Tool ([PEMAT](#))
- Clear Communication Index ([CCI](#))

Write Effectively



Design Tips

- Use a large font size.
 - ▶ Minimum 14-point Times Roman or equivalent for readers with visual impairment
- Readers are intimidated by a wall of words. Make documents friendlier by using:
 - ▶ White space
 - ▶ Short sections
 - ▶ Informative headings
 - ▶ Bulleted lists
- Short lines (like a newspaper) are easier to read.
 - ▶ Optimal: 40-44 characters
 - ▶ Left justify

“Chunk” Related Information (before & after)

Procedures

If you agree to participate, a research phlebotomist (blood draw specialist) will ask you to give a blood sample at your home or another place of your choice. The blood draw will involve pricking the vein of your arm to collect 7 tubes of blood, which is less than 3 tablespoons total. In this study, we will use information from this blood draw along with information from the telephone interview (if you had one) and information collected from your medical records about medical conditions, medicines, and risk factors such as blood pressure and cholesterol. The blood samples will be tested for genetic markers in blood cells. Genetic markers are inherited characteristics. Some of the genetic testing to be done in this study will measure thousands of genetic markers in an effort to identify new inherited characteristics important for health and disease. We are gathering this information by studying groups of people, and this study is not meant to test your personal medical status. These tests are done for research purposes only and are not useful for patient care. For these reasons, no individual study results can be provided. However, we will give you a newsletter that will tell you about the research studies we are doing. If you have questions about whether any genetic tests would be useful to you, you should talk with your physician. We will also do a blood count test using part of the blood sample and will tell you if the results suggest a health problem.

Grade level = 10.9
Reading ease = 53.8 or “fairly difficult”

What will happen if I join the study?

If you decide to be in the study, we will ask you to do two things:

- 1) **Have some blood drawn.** The blood draw will take place at your home or another location of your choice. The study blood draw specialist will take 7 tubes of blood from your arm, which is less than 3 tablespoons total. Afterward, we’ll mail you a check for \$20 as a thank you.
- 2) **Let us collect some information from your Group Health medical record.** We won’t need to look at your individual records or the notes your doctor writes. Instead, we’ll use a computer to collect information about your health conditions, medicines you take, and results from blood pressure and cholesterol tests.

We’ll combine information from your phone survey (if you had one), your blood sample, and your medical record. Our study results will be based on information like this from thousands of people.

What will you do with my blood samples?

We’ll test your blood samples for genetic markers related to heart disease and other heart problems. This means we’ll look for traits you inherited from your parents that may affect your chances of getting a heart condition.

We do these tests on large groups of people and don’t plan to test your personal health status. The results aren’t helpful for patient care and will be used for research only. We won’t give the test results to you or your doctor. But we will do a blood count test on part of your sample, and we’ll let you know if the results show that you might have a health problem. We’ll also send you a newsletter from time to time telling you about the research studies we’re doing.

If you have questions about whether other genetic tests might help you, please talk to your doctor.

Grade level = 6.5
Reading ease = 75.3 or “fairly easy”

Source:
C. Trudeau,
Center for
Health
Literacy

But Won't It Be Too Long?

- Keep documents short
 - ▶ Keep to “need to know” information. Remove information that is not required and distracts
 - ▶ Be direct – don’t be afraid to say “we”
- But sometimes being clear takes more words
- People prefer longer documents that they can easily read rather than dense short documents

Questions?

