Towards high-quality clinical trials and
implementation of genomic medicine

Communication with Patients when Providing the Results of Clinical Comprehensive Genomic Profiling of Cancers

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2. Communication when providing the results of comprehensive genomic profiling of cancers
   - Know the basic elements of communication
   - Communication tips
   - Points to note for comprehensive genomic profiling of cancers

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Patients' Understanding of Comprehensive Genomic Profiling of Cancers

- Molecular tumor profiling study: From an interview survey on the expectations of tests by cancer patients who participated in the MoST Program* (n = 20)
  - Black box: Although participant knowledge of genomics was generally poor, faith in their oncologists and the scientific process encouraged them to undergo testing

- Molecular tumor profiling study: Questionnaire survey on knowledge about molecular tumor profiling by cancer patients who participated in the MoST Program (n = 777)
  - Participants had poor to moderate knowledge of molecular tumor profiling at the time of providing consent to undergo molecular tumor profiling

Best MC, et al. *BMC Cancer*. 2019; 19(1) 753
Davis G, et al. *Transl Oncol*. 2020; 13(9) 100799

* The Molecular Screening and Therapeutics (MoST) Program, Australia

Patients' Expectations of Comprehensive Genomic Profiling of Cancers

- Molecular tumor profiling study: From a questionnaire survey on the benefits and drawbacks of molecular tumor profiling considered by patients participating in the MoST Program* (n = 569)
  - Benefits: Access to personalized therapy (42%), research would help others, contribute to scientific advances (32%), identify cancer risk for family members (18%), provides hope and possible cure (4%)
  - Drawbacks: No drawbacks (38%), coping with negative results and possibly other negative information (20%), discrimination (10%)
- Molecular tumor profiling study: From an interview survey on expectations of tests by cancer patients who participated in the MoST Program (n = 20)
  - Obvious agreement to participate, primarily because of the desire for new treatments and altruism
  - Survival is the priority – Receiving treatment to prolong life was the priority for all participants, whereas other issues such as identification of a germline variant were generally considered as ancillary

Best MC, et al. *BMC Cancer*. 2019; 19(1) 753

* The Molecular Screening and Therapeutics (MoST) Program, Australia

Patient Feedback

At the time of the test

- *Expectations of personalized treatment.*
- *Have slight hope for improvement.*
- *Only 10% of cases lead to treatment. I am tempering my hope.*

Expectations of the test

Patient Feedback

At the time of the test

- *Expectations of personalized treatment.*
- *Have slight hope for improvement.*
- *Only 10% of cases lead to treatment. I am tempering my hope.*
- *I am depressed because the treatment isn't very effective.*
- *I am depressed about recurrence.*
- *(My health is poor) I feel like I'm bothering my family.*

Expectations of the test

Cancer treatment is the first priority

Patient Feedback

At the time of the test

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- *Only 10% of cases lead to treatment. I am tempering my hope.*
- *I am depressed because the treatment isn't very effective.*
- *I am depressed about recurrence.*
- *(My health is poor) I feel like I'm bothering my family.*
- *This is first time I heard about it, and it was explained to me, but I don't really understand.*
- *I've heard that it's expensive, but I wonder how much it costs.*
- *Does the test tell me about my genetic disorder?*
- *I don't understand what type of test it is.*

Expectations of the test

Cancer treatment is the first priority

I don't really understand the test

Patient Feedback

After disclosure of test results

- *There is a mutation, and I'm happy treatment is available.*
- *I had no initial expectations.*
- *There is currently no treatment, but I hope that "a new treatment may be found in the future."*

Expectations of the test

Patient Feedback

After disclosure of test results

- *There is a mutation, and I'm happy treatment is available.*
- *I had no initial expectations.*
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- *The number of clinical trial options has increased, but I'm concerned about whether I can enter any of the trials.*
- *I now know there are no effective drugs, and I am anxious about the future.*
- *It is good to know that there are no drugs that match my condition.*

Expectations of the test

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- *It is good to know that there are no drugs that match my condition.*
- *I don't understand how the test results will be used for treatment.*
- *They found a mutation, but I don't know whether that's good or bad.*

Expectations of the test

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- *There is a mutation, and I'm happy treatment is available.*
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- *I now know there are no effective drugs, and I am anxious about the future.*
- *It is good to know that there are no drugs that match my condition.*
- *I don't understand how the test results will be used for treatment.*
- *They found a mutation, but I don't know whether that's good or bad.*
- *I was told it may be hereditary and I am worried it will be passed onto my children.*

Expectations of the test

Cancer treatment is the first priority

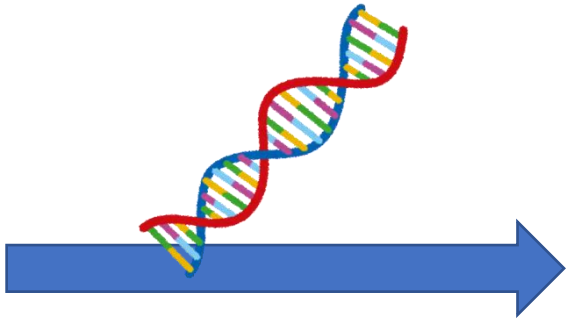
I don't really understand the test

Concern about cancer predisposition syndrome

“Explanation before the test” and “Explanation of the test result” for Comprehensive Genomic Profiling of Cancers

“Appropriate explanation before the test” and “explanation of the test results and treatment strategies based on the test” are both important

・Expectations of the test
・I don’t really understand the test



・What is the future strategy based on the results?

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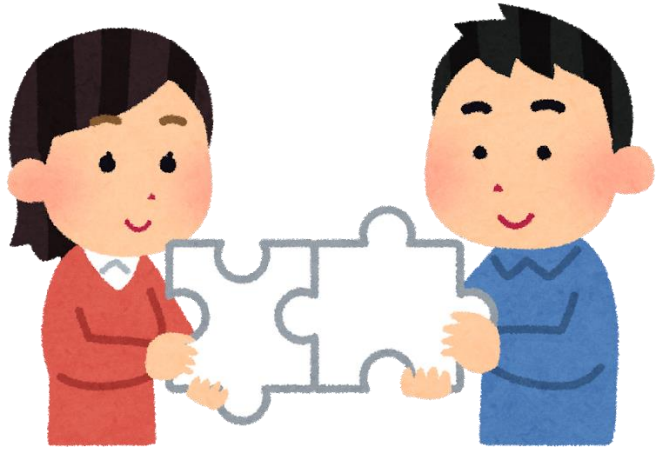
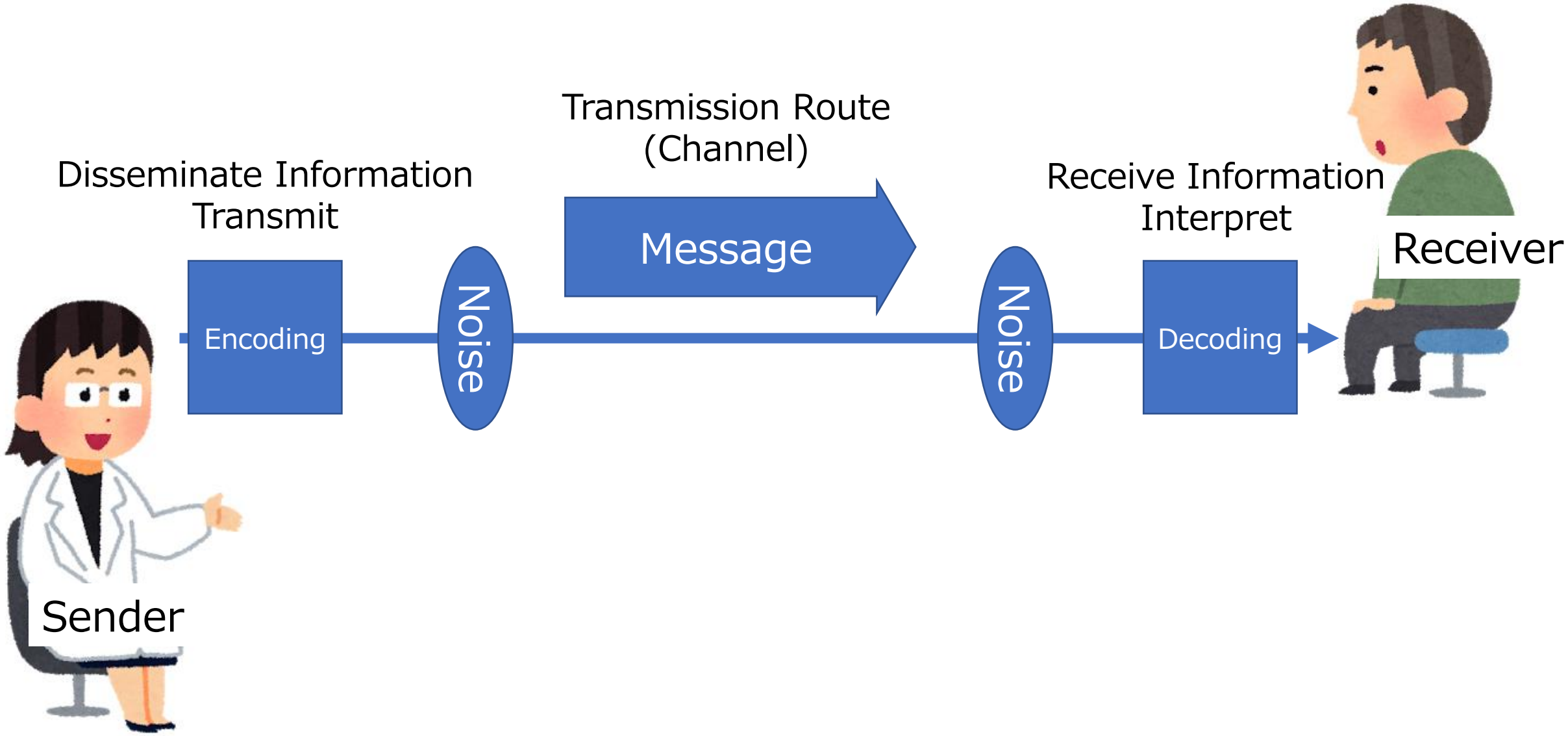
What is Communication?

- Etymology of Communication
  - Communicare （”to share” in Latin）
    Communis （”shared” in Latin）



- Communication is not just telling something to another person.
- It's about the process of sharing something and the state of something being shared.

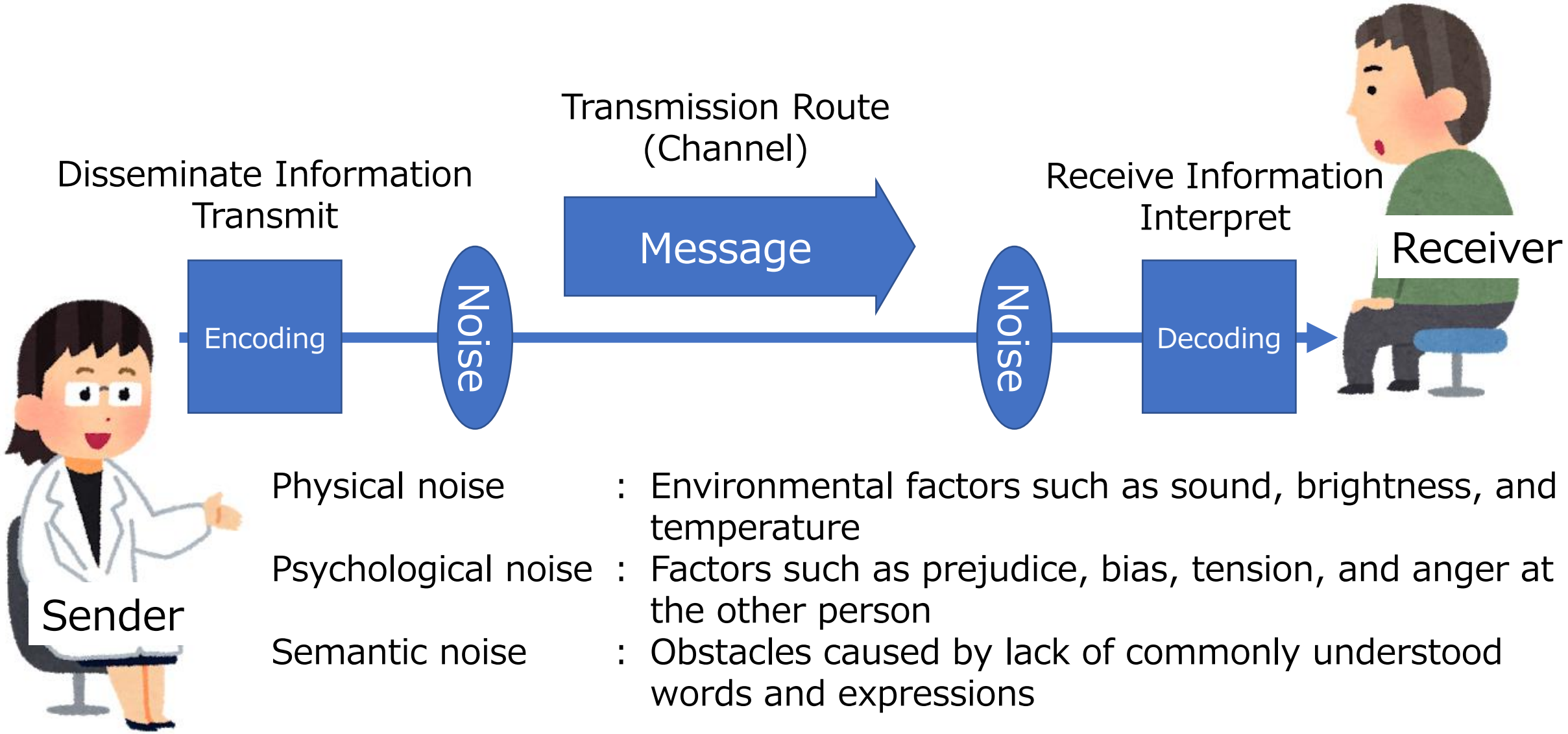
Communication Models



Transmission Route (Channel) Classifications

	Oral	Non-oral	
Verbal	Spoken word	Written word, sign language	
Non-verbal	Quasi-verbal communication ・Voice pitch ・Voice volume ・Speaking speed ・Intonation ・Tone ・Pauses between words etc.	Body movement	Gesture, facial expression, gaze, posture, unintentional movement (Example: physical behavior habits), etc.
		Contact behavior	Handshake, physical contact, etc.
		Physical features	Appearance, hair color, fingernail length, etc.
		Spatial distance, position	Interpersonal distance, seating position (front, side, corner position), etc.
		Artifacts	Clothing, makeup, perfume, accessories, etc.
		Environmental factors	Lighting, temperature, interior, etc.

Communication Model

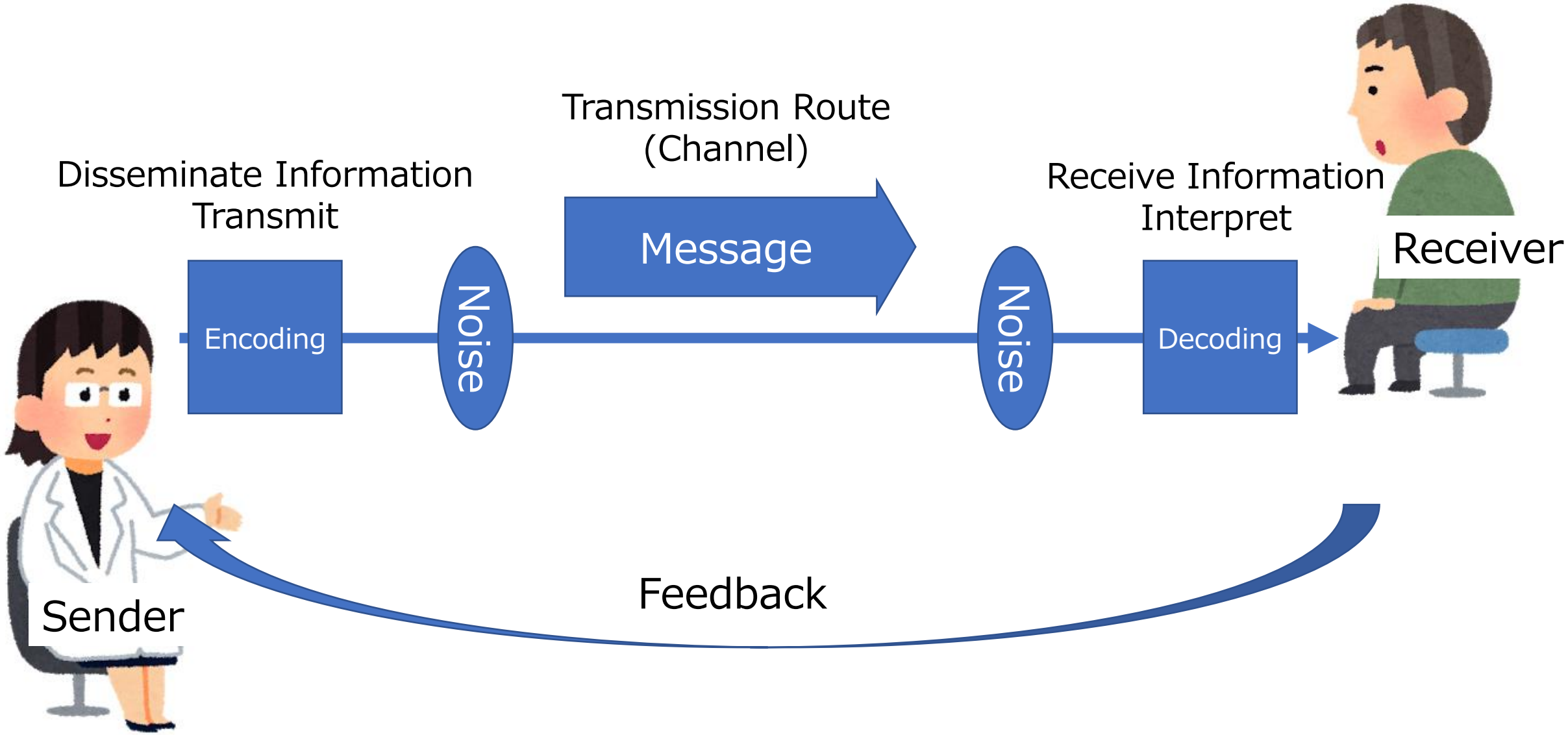


Physical noise : Environmental factors such as sound, brightness, and temperature

Psychological noise : Factors such as prejudice, bias, tension, and anger at the other person

Semantic noise : Obstacles caused by lack of commonly understood words and expressions

Two-way Communication



Communication Context

Meaning is easily understood without verbal communication.

Example: Conversations between people in the same specialist field, conversations within a family

Meaning is not understood without more careful explanation.

Example: Conversations with unknown classmates, conversations with people working in other departments

Detailed explanation is needed to convey meaning.

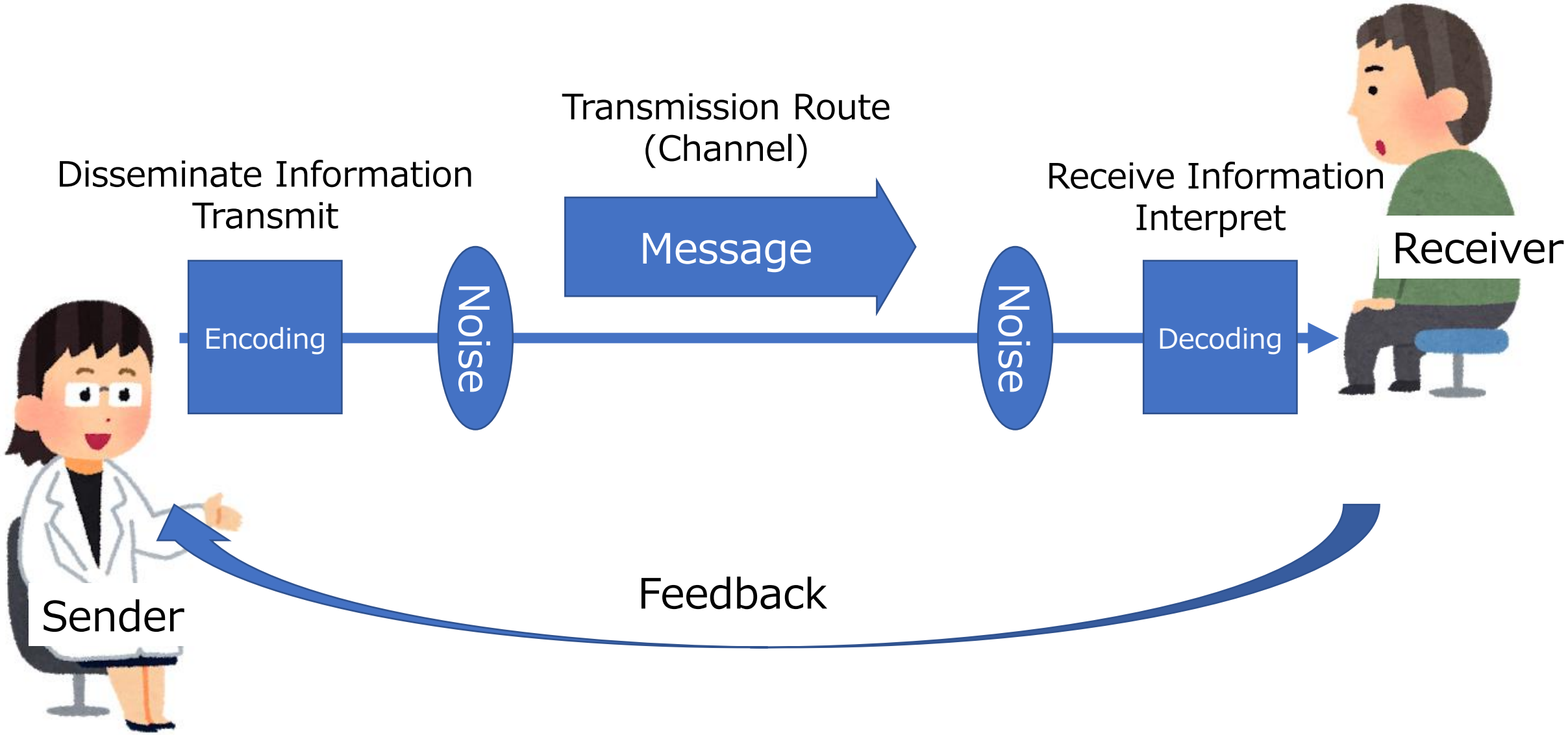
Example: Conversations between patient and medical staff, conversations when meeting someone for the first time

High Context ← → **Low Context**

High ← **Extent of shared culture and information** → **Low**

Contents

Two-way Communication



To Achieve Better Communication

It is useful to consider the concept of active listening.

Microskills are an example (Microcounseling: Ivey AE, et al). Microskills are effective not only for assistive interviews, but also in everyday communication settings.

(1) Attending behavior
(2) Open-ended questions, closed-ended questions
(3) Client observation skills
(4) Encouraging, paraphrasing, summarizing
(5) Reflection of feeling

Make sure that using these skills does not become the end goal!

Microskills (1)
Attending Behavior → Basics of Effective Active Listening

① Make eye contact

- It is not always ideal to maintain direct eye contact or stare at the other person. Use appropriate eye contact to match the cultural background of the other person.
- Maintain eye contact while making a point, and then allow your gaze to wander freely.

② Pay attention to body language

- Be aware of where your body is facing, lean forward slightly, maintain appropriate facial expressions, nod, and be aware of your own unconscious behaviours.
- Pay attention to the other person's and your own body language.

③ Pay attention to the tone of your voice

- Change the tone depending on the other person/match the other person.

④ Verbal tracking

- Do not change the subject of the other person's story. Listen carefully to the other person and respond naturally.
- Do not think about what you are going to say next while listening to the person.

Microskills (2) Open-ended Questions, Closed-ended Questions → Awareness of Different Questioning Methods

Open-ended question

What? How?

- The respondent can answer the question relatively freely.
- The respondent has the initiative.
- The amount of response is greater on the respondent side.

Do not say “Why?” immediately Patients may feel pursued or cornered

Closed-ended question

Answered with Yes, No (answered with short words)

- Question with one-word answers.
- The questioner has the initiative.
- This method is useful if there are facts that one must ask about.

Suitable for asking about facts

Microskills (3) Client Observation Skills

- Keywords used repeatedly by the other person
  ⇒ May lead to understanding of the other person and/or promote the interview
- Specifically described content, abstractly described content
  ⇒ Specifically…Actual experience?
  Abstractly…Expectation?
- Contradictions in what the other person is saying, contradictory verbal and non-verbal behavior
  ⇒ Confused? Facts or emotions they do not want to face?

Microskills (4) Encouraging, Paraphrasing, Summarizing→ Communicate active listening to the other person

Encouraging

Non-verbal encouraging

- Attending behavior, nodding, facial expressions

Verbal encouraging

- “Yes,” “And?,” “Would you mind telling me a bit more?”
- Repeating one or two words
- Repeating the last few words of the patient’s story verbatim

Paraphrasing

→ Repeating the essence of what the other person said

→ Adding your own words to the important words spoken by the other person

Effective “paraphrasing”

- Use the other person’s name
- Use phrases that are the most important to the other person
- Capture, condense, and clearly convey the essence of what the other person has said

Microskills (4) Encouraging, Paraphrasing, Summarizing→ Communicate active listening to the other person

Summarizing

→ Can help to organize the other person's ideas and thoughts

→ Can confirm with the other person that you have correctly heard what was said (how the other person's story was heard)

Summarizing: A broader meaning than paraphrasing

- Repeat, shorten, and specify the important parts of the story
- Avoid incorrectly summarizing the information

Microskills (5) Reflection of feeling→ Focus on the feelings of the other person and verbalize

- Be aware of the other person's sentiments and feelings and convey this understanding to the other person → This reassures the other person

  (Patient) "Will the new treatment work?...I'm worried that it won't work."

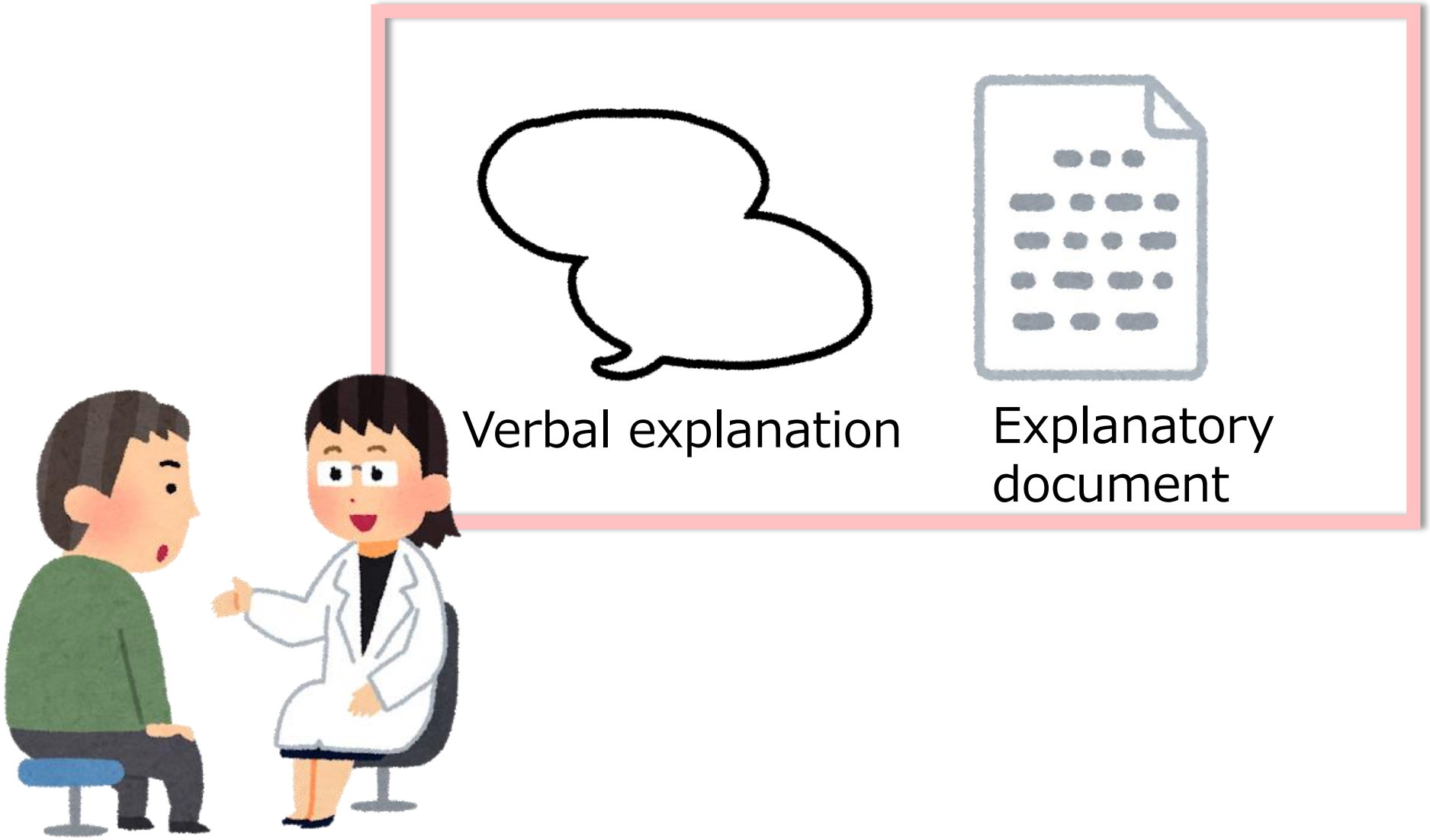
  (Medical staff) "You feel anxious about whether the new treatment will work, don't you?"

- Be aware of the other person's "confused feelings" and "contradictory feelings"

  Double bind feelings can present as confusion

  Do not pry into feelings that the person themselves does not acknowledge or, at times, cannot face

Communication to Provide Information



Communication to Provide Information: Explanatory Document

Explanatory document

Content of information

- State the purpose of the document
- Remove unnecessary information, avoid too much information
- Include information of interest to the patient

Viewability

Readability

Excerpt from Suitability Assessment of Materials: Doak CC, et al. Teaching Patients with Low Literacy Skills (2nd ed). 1996. J.B. Lippincott

Communication to Provide Information: Explanatory Document

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Viewability

- Visually express important points with figures, tables, and illustrations
- Use a suitable layout, size, and type of font
- Divide information into small lots and add headings

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Communication to Provide Information: Explanatory Document

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- State the purpose of the document
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Viewability

- Visually express important points with figures, tables, and illustrations
- Use a suitable layout, size, and type of font
- Divide information into small lots and add headings

Readability

- Use easy-to-read sentences and avoid complex terminology
- Add headings

Excerpt from Suitability Assessment of Materials: Doak CC, et al. Teaching Patients with Low Literacy Skills (2nd ed). 1996. J.B. Lippincott

Communication to Provide Information: Verbal Explanation

Verbal explanation

[Before providing information]

- Is the patient ready to listen?
- Confirm the patient's knowledge, concerns, and expectations

Communication to Provide Information: Verbal Explanation

Verbal explanation

[Before providing information]

- Is the patient ready to listen?
- Confirm the patient's knowledge, concerns, and expectations

[While providing information]

- Communicate the information while paying attention to the patient's attending behavior (eye contact, body orientation, speaking speed, etc.)
- Take care when using jargon
- Encourage the patient to ask questions
- Hand over any educational material that would be useful for the patient and introduce reliable websites
- Use the teach-back method to check the patient's understanding

Communication through a Mask･･･

- Communicating through a mask makes it more difficult to read the other person’s facial expression, hear his or her voice, and convey feelings than when not wearing a mask.

Therefore, it is advisable to do the following more often than normal

- ＊ Nod, provide back-channel feedback more frequently, and use more gestures
- ＊ Speak clearly and at an easy-to-understand pace
- ＊ Speak in a tone that easily conveys feelings
- ＊ Use eye contact

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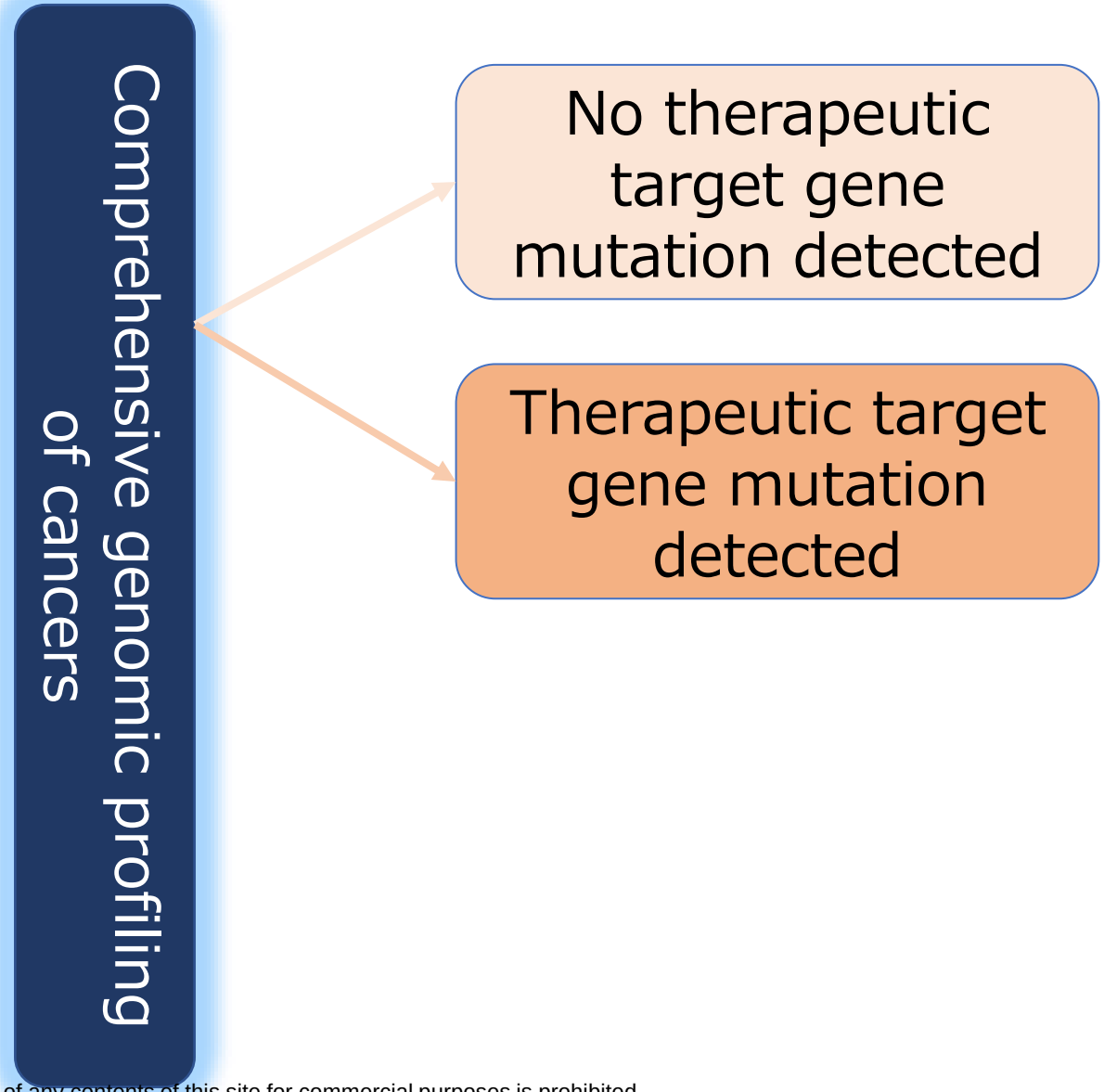
Communication Challenges in a Medical Setting

- There is a power imbalance
  - Medical professionals have a great deal of specialized knowledge and information, and they are often regarded as having a high social status. The greater this power gap, the more difficult is communication
- Perspectives differ
  - Medical professionals approach biomedical diseases as problems to be resolved, whereas patients view illnesses as problems within their own lives, including the psychosocial aspects of their lives
- Content of communication is difficult
  - Specialized medical terms
  - Probability expressions based on statistical concepts
- Environment surrounding the communication is specific
  - Patients with cancer and their families are in an unstable psychological state
  - Medical professionals may be forced to provide explanations in a limited time.

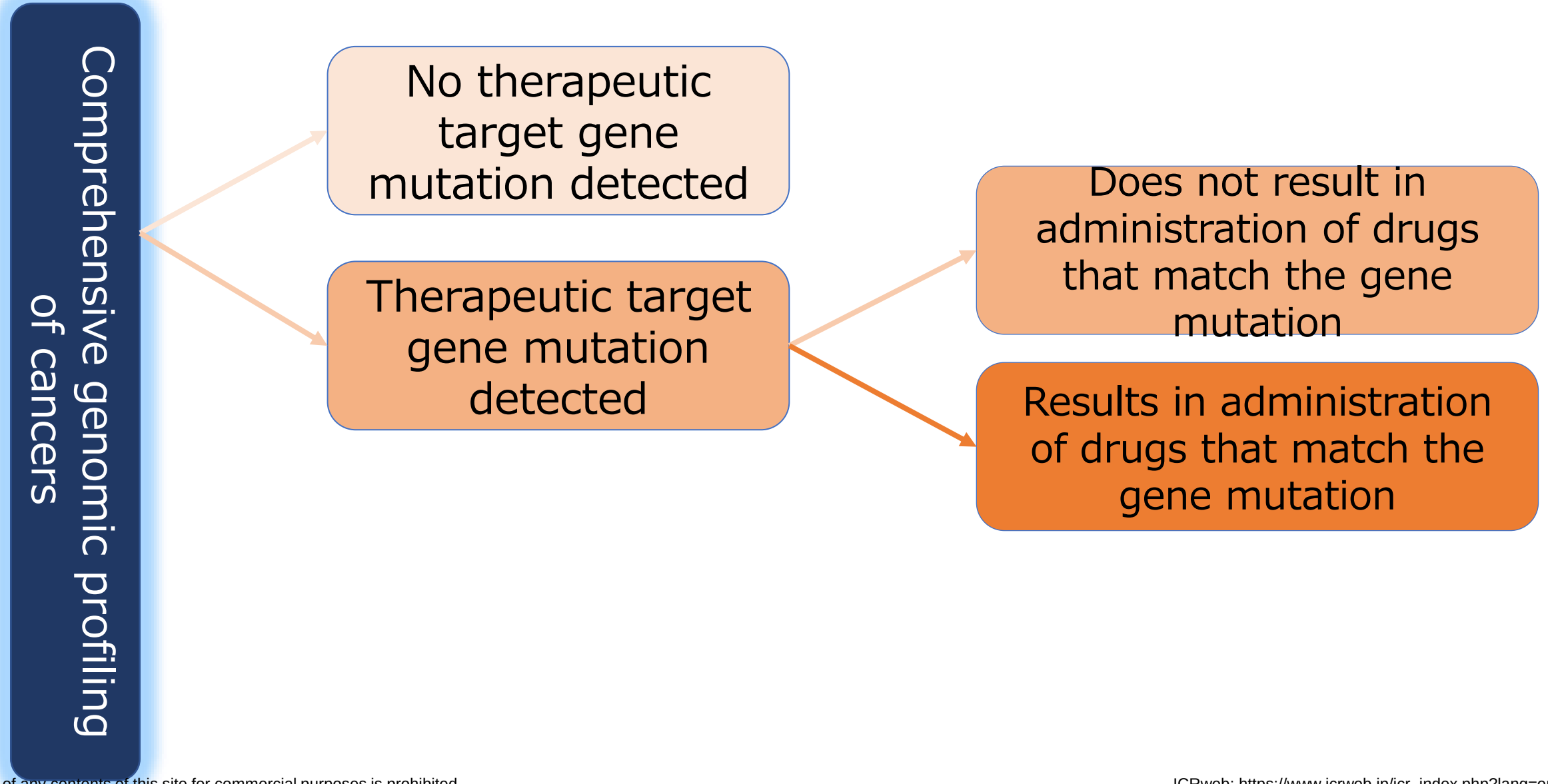
Comprehensive Genomic Profiling of Cancers and Utilization of Results

Comprehensive genomic profiling of cancers

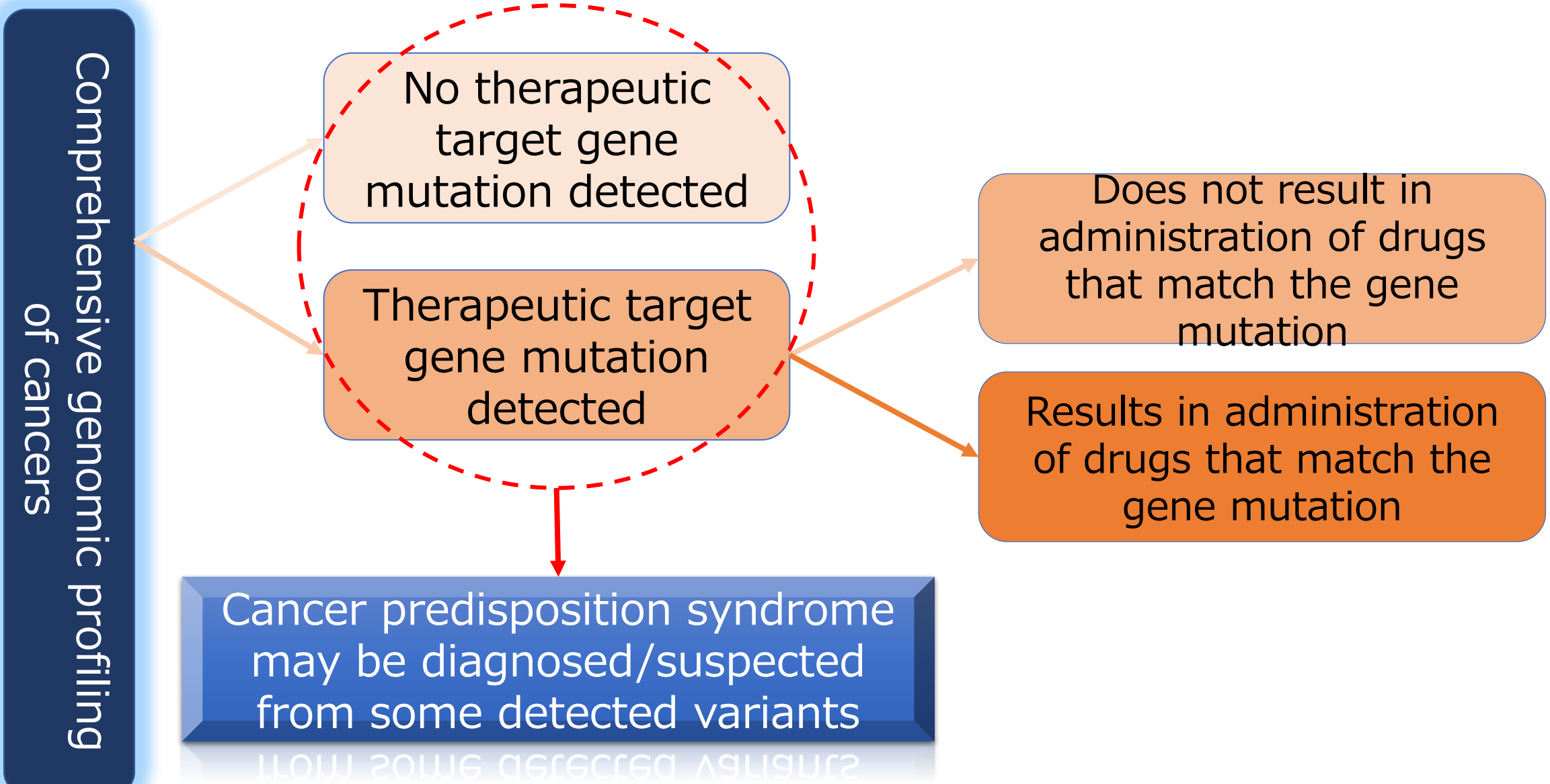
Comprehensive Genomic Profiling of Cancers and Utilization of Results



Comprehensive Genomic Profiling of Cancers and Utilization of Results



Comprehensive Genomic Profiling of Cancers and Utilization of Results



“Explanation before the test” and “Explanation of the test results” for Comprehensive Genomic Profiling of Cancers

Explanation before the test

- The purpose of the test is to comprehensively examine characteristics of cancer using genetic analysis, and investigate the possibility of suitable drugs, treatments, or clinical trials in which the patient can participate
- Information useful for drug selection may or may not be found
  - Only around 10% of patients with solid tumors receive treatment or can participate in clinical trials based on the test results
- The tests do not always work
- Specimen, collection method, analysis method
- Findings indicating a hereditary predisposition to cancer may be discovered (information that should be shared with family members)
- Cost, time, and data handling

Explanation of the test results

- Information useful for drug selection was detected/was not detected
  - Treatment covered by insurance or not
  - Introduction to clinical trials; however, there are conditions for participation, and it is not always possible to participate in the preferred clinical trial
- Genetic variants indicative of a hereditary predisposition to cancer may be discovered or suspected
  - Refer to genetic counselling

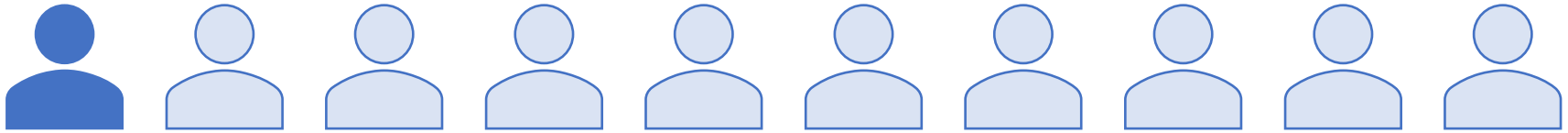
Know the Features of Various Types of platform for Comprehensive Genomic Profiling of Cancers

- Solid tumor profiling test or hematologic malignancies profiling test
- Tumor-only sequencing or tumor-normal matched sequencing
- Specimens used to detect genetic abnormalities in cancer (for solid tumors)
  - Tumor cells/DNA extracted from tissue
  - Circulating tumor DNA in plasma

Communicating Probability

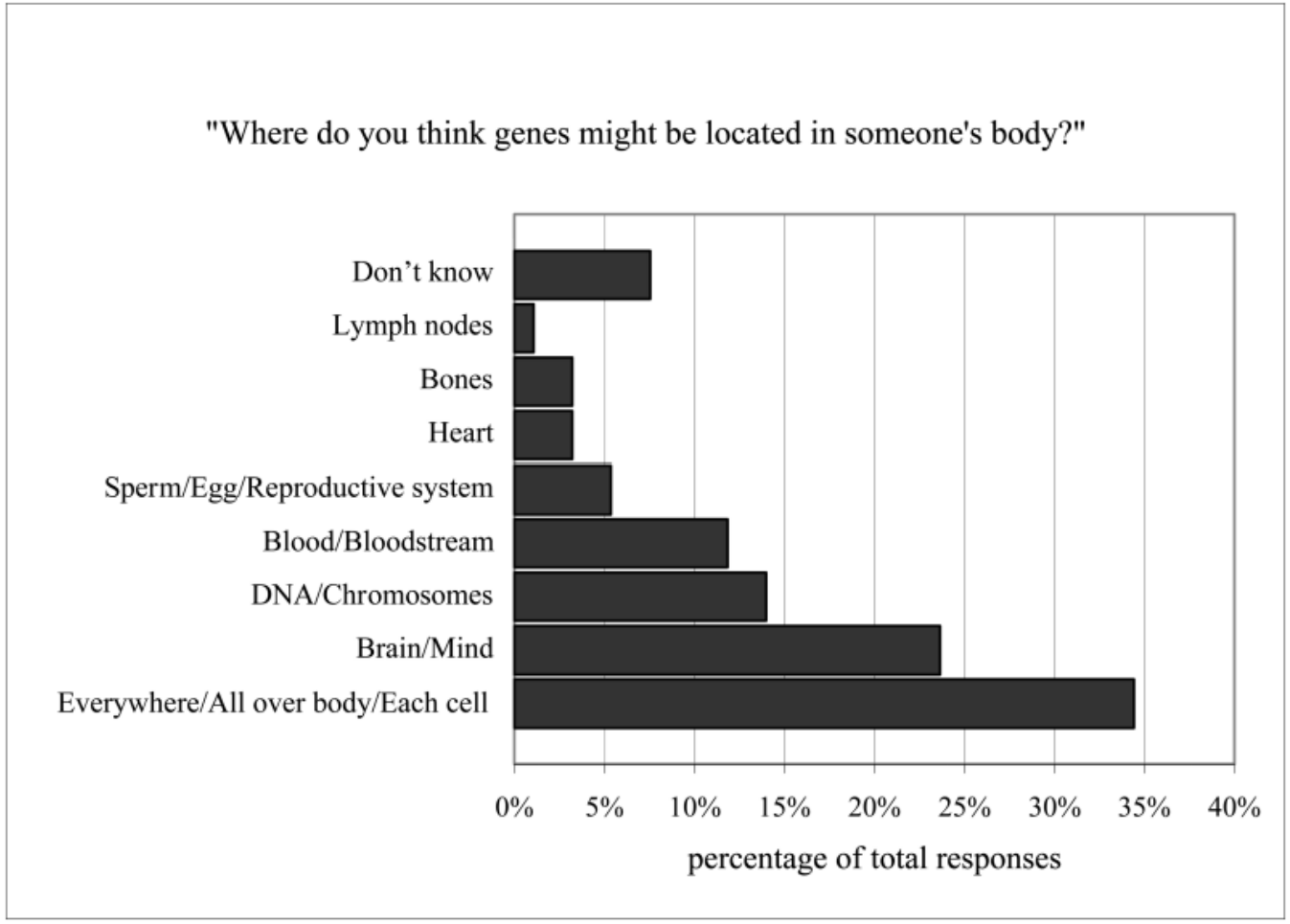
“Around 10% of patients receive treatment or are able to participate in clinical trials based on the test results”

“Around 10%, or 1 in 10, of patients receive treatment or can participate in clinical trials based on the test results”
“Treatment or clinical trials based on the test results are not found for 90%, or 9 in 10, patients”



10%
1 in 10 people

Varied Level of Understanding of “Genes” by Patients



Lanie AD, et al. *J Genet Couns*. 2004; 13(4) 305-320

Remember that patients may not have a high level of understanding of the term “genes”

* Tumors develop when genetic abnormalities accumulate
* Genetic abnormalities found only in the tumor are not inherited
* Some detected genetic abnormalities may be hereditary innate variants (these may be shared with blood relatives = cancer predisposition syndrome)

Sometimes Cancer Predisposition Syndrome May Be Diagnosed/Suspected

- 85–86% of patients with cancer want to be informed of information related to the risk of cancer in their own family and information on preventable or treatable hereditary diseases, which can be determined from comprehensive genomic profiling of cancers.

  Best M, et al. *Psychooncology*. 2020; 29(10) 1533-1539
  Bijlsma R, et al. ESMO Open. 2020; 5(2) e000619

- 33% of patients with cancer want their families to have access to information on preventable or treatable hereditary diseases while the patient is still alive. 30% of patients want the hospital to proactively contact their families, even without the patient's intervention.

- 82% of patients with cancer want their families to have access to information on preventable or treatable hereditary diseases after the patient has died.

  Bijlsma R, et al. ESMO Open. 2020; 5(2) e000619

- For the patient, cancer treatment is the first priority, and he or she may not have an appropriate mindset to inform family members of the germline findings.

  Best MC, et al. *BMC Cancer*. 2019; 19(1) 753

- Patients with advanced cancer may perceive conveying information about cancer risk to relatives as burdensome.

  Miller FA, et al. *Eur J Hum Genet*. 2014; 22(3) 391-395

- Patients may feel that they require an expert to assist with explaining relevant test results to family members.

  Smit AK, et al. *Patient Educ Couns*. 2021; 104(5) 944-952

Sometimes Cancer Predisposition Syndrome May Be Diagnosed/Suspected

Tumor-normal matched sequencing Tumor only sequencing

- Purpose of disclosing a diagnosis/possible diagnosis of cancer predisposition syndrome to the patient
  - Being aware of the cancer risk can result in early detection and/or early treatment of cancer (However, for the patient themselves, their condition depends on the disease stage and treatment status; thus, this information may not directly benefit the patient)
  - Diagnosing relatives, including those who have not developed cancer, may be useful for managing the health of relatives

If diagnosed with cancer predisposition syndrome
*Regular surveillance screening in line with the individual cancer risk
*Risk-reducing surgery and oral medication

There are disadvantages in not knowing

Some people feel psychologically burdened

Summary

- Patients often have little knowledge on comprehensive genomic profiling of cancers but may also have high expectations of the test.

- Genomic profiling of cancers is an unfamiliar test to patients; the following points are important for ensuring good communication when implementing the test:
  - Be aware of attending behavior (eye contact, body orientation, tone of voice, etc.) and questioning methods, encouraging, and paraphrasing
  - Use suitable explanatory documents when providing information, take note of technical terms, encourage questions from the patient, and check the patient’s understanding of the test
  - Know that this test is used to comprehensively examine genes
  - When cancer predisposition syndrome is diagnosed or suspected, collaborate with the genetic medicine team