

# 6 Evaluating Genetic Tests: A Socratic Seminar Discussion

## Introduction

In this lesson, students apply the ethical skills and scientific knowledge they have acquired over the previous lessons to: 1) determine whether BRCA1 testing meets the standards of a useful genetic test, or 2) participate in a discussion of the potential risks and benefits of direct-to-consumer (DTC) genetic testing. Students or teachers may choose from one of two readings, after which students participate in a Socratic Seminar to deepen their understanding of genetic testing. Through the seminar discussion of the first reading, students become familiar with a framework for considering genetic tests in terms of their clinical validity and the availability of effective treatment. Through the seminar discussion of the second reading, students learn about the concerns some groups have about the risks of DTC genetic testing, the response of some people in the DTC industry, and preliminary data on what consumers think of DTC genetic testing. After the seminar, students are supported in developing an individual position about genetic testing through the integration of scientific facts, stakeholder viewpoints, and ethical considerations. In Lesson Six, students learn how bioethicists might use bioinformatics tools in their career.

## Learning Objectives

At the end of this lesson, students will know that:

- Genetic tests differ in their clinical validity and usefulness.
- There are some conditions for which there are genetic tests but no effective treatment.
- Medical conditions differ in their penetrance and the number of genes involved.

At the end of this lesson, students will be able to:

- Identify ethical issues related to genetic tests.
- Compare and contrast genetic tests with respect to their clinical validity and the efficacy of treatments.
- Discuss the ethical issues related to providing different types of tests to patients.

## Key Concepts

- Genetic tests can be characterized by their clinical validity and by the availability of effective treatments.
- Considerations related to the ethical, legal, and social implications of a genetic test are influenced by the characteristics of the test and the nature of the disorder.
- Bioinformatics tools are used by people in many careers, including bioethicists.

## Class Time

One class period (50 minutes). If the article and supporting handouts are assigned as homework, class time could be decreased by 15-20 minutes, or more time would be available for discussion.

## Prior Knowledge Needed

- A basic understanding of Mendelian genetics.
- An understanding of how mutations in genes can result in disease.
- How to have a classroom discussion in a way that is respectful of others.
- Helpful, but not required: background in ethical theories and perspectives.

## Common Misconceptions

- Genetic tests are all basically the same.
- Genetic tests always provide useful information.

## Materials

Materials	Quantity
Copies of Student Handout— <i>Careers in the Spotlight</i> (handed out in Lesson One)	1 per student
Student Handout— <i>Categorizing Genetic Tests</i>	1 per student -OR- 1 each for half of the students
Student Handout— <i>Weighing the Risks and Benefits of Direct-to-Consumer Genetic Testing: Who Should Decide?</i>	1 per student -OR- 1 each for half of the students
Student Handout— <i>Critical Reasoning Analysis Form</i> (optional, see Procedure)	1 per student
Student Handout— <i>Open-Ended Questions for a Socratic Seminar</i> (optional, see Procedure)	1 per student
Student Handout— <i>Socratic Seminar Discussion Partner Evaluation</i> (optional, see Procedure)	1 per student
Teacher Resource— <i>Socratic Seminar Rubric</i>	1

Computer Equipment, Files, Software, and Media
Computer with internet access and projector to display PowerPoint slides.
<b>Alternative:</b> Print PowerPoint slides onto transparencies and display with overhead projector.
Lesson Six PowerPoint Slides— <i>Evaluating Genetic Tests: A Socratic Seminar Discussion</i> . Available for download at: <a href="http://www.nwabr.org/curriculum/introductory-bioinformatics-genetic-testing">http://www.nwabr.org/curriculum/introductory-bioinformatics-genetic-testing</a> .
A student version of lesson materials (minus teacher answer keys) is available from NWABR's Student Resource Center at: <a href="http://www.nwabr.org/students/student-resource-center/instructional-materials/introductory-bioinformatics-genetic-testing">http://www.nwabr.org/students/student-resource-center/instructional-materials/introductory-bioinformatics-genetic-testing</a> .

[**Note:** It is recommended that students read one of the Socratic Seminar readings (Student Handout—*Categorizing Genetic Tests* or Student Handout—*Weighing the Benefits of Direct-to-Consumer Genetic Testing*) as homework in advance of class.]

## Teacher Preparation

- Load the classroom computer with the Lesson Six PowerPoint slides.
- Make copies of the Student Handout, one per student.
- Divide the number of classroom chairs in half and set up two circles – an inner circle and an outer circle.

## Procedure

### WARM UP

1. As students enter the classroom, show **Slide #1**, which highlights bioethicist Kelly Edwards, PhD

Evaluating Genetic Tests: **Slide #1**



**BIOETHICIST**  
 KELLY EDWARDS, PhD

**Place of Employment:**  
University of Washington

**Specialties and Interests:**  
Community-based research practices, environmental justice, and integrating ethics into training programs and public policy.

"Genetics researchers often work with distinct communities. To take moral account of how their research affects these communities, they need a richer conception of justice and they need to make those communities equal participants in decision-making about how the research is conducted and what is produced and published out of it."

2. Have students retrieve Student Handout—*Careers in the Spotlight* from *Lesson One*.
3. Students should think about, and write down, the kind of work a bioethicist might do (Bioethicist Question #1). This will be revisited at the end of the lesson, including how a bioethicist might use bioinformatics in her or her job.
4. Tell students to keep their *Careers in the Spotlight* handout available for a future lesson.

### PART I: Background on Reading Content

5. Explain to students the **aim of this lesson**. Some teachers may find it useful to write the aim on the board.

#### Lesson Aim:

- To understand the factors involved in evaluating genetic tests.

Teachers may also wish to discuss the *Learning Objectives* of the lesson, which are listed at the beginning of this lesson plan.

6. Introduce the lesson activities by saying ***“What if a rare genetic disorder ran in your family and a company was offering a genetic test for it? What would you want to know about the test before taking it?”***

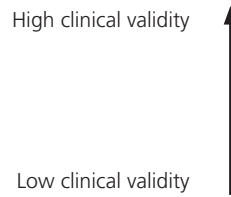
Students may cite expense, what kind of sample they would have to give, and privacy concerns. Direct student responses towards the concerns of ***clinical validity*** and ***effective treatment***.

7. Help frame this conversation for students by first defining both terms:
  - **Clinical Validity:** How accurately a test predicts whether a person will get a particular disease or symptom (known as the “clinical outcome”).
  - **Effective Treatment Availability:** Whether there are treatment options available for a particular disease or condition. This is sometimes thought of as a “cure” although most genetic conditions are “treated” rather than “cured.”
8. Discuss with students the terms **penetrance** and **polygenic traits**.
  - **Penetrance:** The probability that individuals with a specific genotype will express a specific phenotype. For example, as students saw in Lesson Three, approximately 85% of women with particular BRCA1 mutations will develop breast or ovarian cancer.
  - **Polygenic:** A polygenic trait is one that involves multiple genes. For example, cat coat color is known to involve multiple genes, including ones for white, orange, and black coloring. Many common diseases, like heart disease and diabetes, are thought to be polygenic.

Penetrance and polygenic traits are important components of clinical validity. There may be genetic tests available for a particular condition, but if the trait has low penetrance, the clinical validity of tests for particular mutations may be low. If the condition is polygenic, studying mutations in only one gene will not provide doctors, genetic counselors, and bioethicists with a complete assessment of patient risk.

9. In both of the Socratic Seminar readings, the authors discuss the ***clinical validity*** of genetic tests. In one of the readings, the authors also evaluate genetic tests based on whether there is ***effective treatment available***.

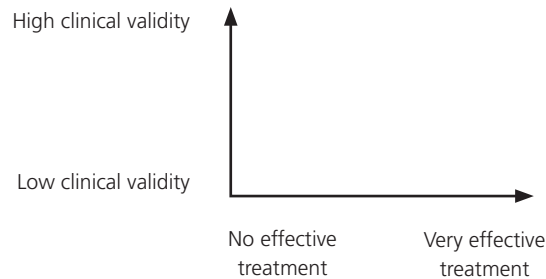
10. Draw a **y-axis** on the board, as shown below:



11. Ask students, **“What does it mean for a genetic test to have high clinical validity?”** [If a person who carries the genetic variant for a disease or condition has a 100% chance of developing that disease or condition (100% penetrance), then the genetic test for that condition has high clinical validity.]

12. Ask students, **“What does it mean for a genetic test to have low clinical validity?”** [A test with low clinical validity means that, even though a person may carry the genetic variant associated with a disease or condition, they may have a low chance of developing that disease or condition. Perhaps the environment plays an equal or greater part in developing the disease or condition than does genetics, the variant has very low penetrance, or the condition is polygenic.]

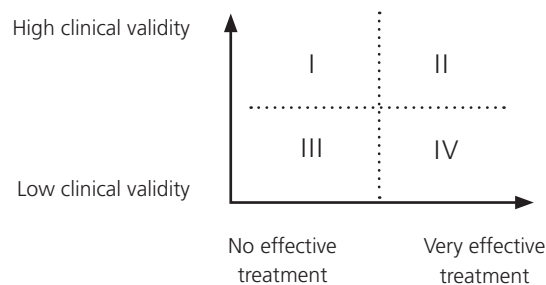
13. Add an **x-axis** to the graph, as shown below:



14. Ask students, **“What does it mean if there is no effective treatment for a disease or condition?”** [There is no “cure” or treatment. Nothing can be done to treat the disease or condition itself, although patients can still receive care to help alleviate the symptoms.]

15. Ask students, **“What does it mean if there is effective treatment for a disease or condition?”** [There are treatments, medications, or therapies that help treat the disease. Remember, most genetic conditions are treated rather than “cured.”]

16. This graph framework provides a way to think about genetic tests in different quadrants of the graph. A test in quadrant II would be ideal.



17. Tell students that this framework can help bioethicists evaluate whether a particular genetic test should be recommended for approval for use in patients. It can also help genetic counselors and patients make decisions about the validity of genetic tests. In addition, different ethical issues arise in each quadrant. These are explored in the reading on Student Handout—*Categorizing Genetic Tests* and can be discussed further in the seminar.
18. It is possible that genetic testing may have negative effects, such as anxiety, or positive effects, such as increased exercise or decreased fat intake. These issues are explored in the reading on Student Handout—*Weighing the Risks and Benefits of Direct-to-Consumer Genetic Testing* and can be discussed further in the seminar.

## **PART II: Before the Socratic Seminar**

19. Introduce the seminar and its purpose: to facilitate a deeper understanding of the ideas and values in the text through shared discussion.
20. Have students read the article from Student Handout—*Categorizing Genetic Tests* or Student Handout—*Weighing the Risks and Benefits of Direct-to-Consumer Genetic Testing*. It is important that every student read the text, since the quality of the discussion depends on contributions from each participant. It may be helpful to allow time in class for students to read the article(s).
21. Students may use one of several formats to process the information. Student Handout—*Critical Reasoning Analysis Form* and/or Student Handout—*Open-Ended Questions for a Socratic Seminar* can be used to help students understand the content. If students have been given the reading as homework, the completed handouts can be used as the “entry ticket” to participate in the seminar.

**Suggested scoring for Student Handout—*Critical Reasoning Analysis Form*: +2 points per question for a total of 16 possible points.**

**Suggested scoring for Student Handout—*Open-Ended Questions for a Socratic Seminar*: +2 points per question for a total of 10 possible points.**

22. In addition to the classroom discussion norms you may have already set, it is important to include the following norms:
- Do not raise hands.
  - Talk to (and look at) each other, not the teacher.
  - Listen carefully.
  - Address one another respectfully.
  - Base any opinions on the text.
  - Monitor your airtime so that everyone can share.
23. Encourage students to pose questions as well as build on the comments of others.

**PART III: During the Socratic Seminar Discussion**

24. To create the discussion groups, divide the class in half and form two circles (an inner circle and an outer circle). The inner circle will be engaged in the discussion, and the students in the outer circle will be listening to the inner circle discussion. If the class contains fewer than 20 students, a single discussion group may also be possible.
25. Students in the outer circle will take notes and write down ideas or comments on what they hear in the inner circle discussion. After approximately ten minutes (or another appropriate time period), flip the circles so that students in the inner circle and outer circle trade places. Teachers can use Student Handout—*Socratic Seminar Discussion Partner Evaluation* to help focus students during the discussion, if needed (see *Assessment*). Different questions can be asked in each half of the seminar.
26. To begin the discussion, the teacher/facilitator may pose the starting question(s) or the participants may agree upon questions to begin the discussion. If students completed Student Handout—*Open-Ended Questions for a Socratic Seminar*, many of the questions generated could be used as guiding questions for the discussion. Some teachers may want to start with a few factual questions such as **“What is penetrance?”** and **“What is clinical validity?”**

**Recommended starting questions:**

Interpretive/supported by both articles:

(Students need to refer to specific parts of the article in their answers.)

- Why was this article written? What was the need for the article?
- Who is the audience for this article?
- What are the authors’ concerns regarding genetic tests?
- What do the authors recommend regarding genetic tests?
- What do the authors consider to be the most important ethical considerations related to testing?
- What are some assumptions the authors make?
- Which is the most important paragraph and why?

Interpretive/supported by *Categorizing Genetic Tests*:

- Do the authors believe that the framework applies equally well to all genetic tests?
- What do the authors believe to be the most challenging aspect of evaluating genetic tests?
- Does this framework relate to direct-to-consumer genetic tests? If so, how?
- What are the implications of this framework for health care?

Interpretive/supported by *Direct-to-Consumer Genetic Testing*:

- What do the authors consider to be the most important risks of direct-to-consumer genetic testing?

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[**Caution:** Use evaluative questions once the discussion of interpretive questions is finished. These questions tend to lead the discussion off into student opinions, so the conversation must be managed more carefully. If this is your first seminar, you may choose not to use these kinds of questions at all.]

- What do the authors consider to be the most important benefits of direct-to-consumer genetic testing?
- What are some of the limitations of the studies cited in the article, and what effect could they have on the conclusions reached?
- What are the implications of this article for health care?

#### Sample questions to move the discussion along:

- Where do you find evidence for that in the text?
- Who has not yet had a chance to speak?
- Is there something in the text that is unclear to you?
- Who can summarize the main ideas we have discussed so far?
- Who has a different point of view?

27. You can choose to facilitate the discussion by asking clarifying questions, summarizing comments, and highlighting understandings and misunderstandings. You can restate the opening question if the conversation gets off track or ask for different ideas if it stalls.

28. Later in the discussion, “evaluative” questions that refer to students’ experiences and their own judgments can also be used. For example, **“Is it right that....?”** **“Do you agree with the author?”** or **“Has anyone changed his or her mind?”** These do not require reference to the text for an answer.

#### Evaluative/personal position questions:

- Do you agree with the authors’ conclusions? Why or why not?
- Who should decide how much information should be provided to patients?
- What do you think has been left out of the article?
- Do you think that clinical validity or the possibility of treatment is more important in determining whether to use a test?

#### PART IV: After the Seminar

29. Ask the whole group questions such as: **“Do you think that you understand the article at a deeper level?”**, **“How did we do in meeting our goals and norms?”** or **“What was one thing you noticed about the seminar?”**

30. Share the experience you had facilitating the seminar.

#### PART V: Reflection

31. After the seminar, ask students to write one or two paragraphs about the “big ideas” from the Socratic Seminar discussion, regarding either the paper they were assigned to read or both articles. In their reflection, students should discuss whether they believe that direct-to-consumer genetic testing companies should be required to offer genetic counseling to their patients. In addition, ask them to write one paragraph about how the ideas from the Seminar apply to *BRCA1* testing, and how those ideas relate to their initial views about *BRCA1* testing. This may also be completed as homework.

## Closure: Careers in the Spotlight

32. Return to the picture of the bioethicist from the Careers in the Spotlight in **Slide #1**.

Evaluating Genetic Tests: **Slide #1**

**BIOETHICIST**  
KELLY EDWARDS, PhD

**Place of Employment:**  
University of Washington

**Specialties and Interests:**  
Community-based research practices, environmental justice, and integrating ethics into training programs and public policy.

"Genetics researchers often work with distinct communities. To take moral account of how their research affects these communities, they need a richer conception of justice and they need to make those communities equal participants in decision-making about how the research is conducted and what is produced and published out of it."

33. Show **Slide #2**, which provides job information for a bioethicist. Review this information with students.

Evaluating Genetic Tests: **Slide #2**

**CAREERS IN SPOTLIGHT:**  
**BIOETHICIST**

**What do they do?**  
Bioethicists study the ethical controversies that arise from advances in biology and medicine. They advise patients, researchers, public policy makers, and/or medical doctors about a wide range of ethical issues, from genetic testing and medical treatment to medical privacy and stem cell research.

**What kind of training is involved?**  
Training varies widely from a certificate program completed during or after a Bachelor's degree in another subject to Doctoral (PhD) programs specifically in Bioethics.

**What is a typical salary for a Research Scientist?**  
Depending upon training, anywhere from \$50,000/year (\$24/hour) to over \$100,000/year (\$48/hour).

34. Ask students, **"How does a bioethicist fit into today's lesson?"**

Point out that:

- The initial decision to approve genetic tests for use in patients is made by committees of medical doctors, genetic counselors, and bioethicists who weigh issues of clinical validity, availability of effective treatment, and the effect of the test results on the well-being of patients.
- The decision about whether an individual patient should have a particular genetic test is often made under the guidance of someone with bioethics training, like a medical doctor or a genetic counselor.
- Bioethicists often consult public policy makers about genetic testing issues and regulations, including whether to regulate direct-to-consumer genetic testing companies, and whether these companies should be required to offer genetic counseling to their clients.



35. Ask students to answer Bioethicist Question #2 on their *Careers in the Spotlight* handout, which has students explain how this lesson has changed their understanding about the kind of work a bioethicist does.
36. Ask students to also answer Bioethicist Question #3 on their *Careers in the Spotlight* handout, which has students explain how a bioethicist might use bioinformatics in his or her work.
37. Tell students to keep their *Careers in the Spotlight* handout available for future lessons.

## Homework

See *Part V: Reflection*, above.

## Adaptations

Some teachers ask students who are observing the discussion to take note of who said what, and then to incorporate these ideas into their reflection. Student Handout—*Critical Reasoning Analysis Form* can also be used as homework after the seminar instead of a writing assignment in advance. Teacher Resource—*Socratic Seminar Rubric* could also be adapted for student self-assessment, peer-assessment, or for teachers' own assessment of student participation. **Suggested scoring for Student Handout—Socratic Seminar Rubric: +10 points per Dimension for “Exemplary” performance, +8 for each “Proficient” performance, +6 for each “Partially Proficient,” and +3 for each “Developing,” for a total of 40 possible points.**

## Assessment Suggestions

The students' *Critical Reasoning Analysis Form* can be used as a formative assessment to prepare for the Socratic Seminar. **Suggested scoring for Student Handout—Critical Reasoning Analysis Form: +2 points per question for a total of 16 possible points.**

To help engage students in the Socratic Seminar discussion, you can have them evaluate another student's participation. This can be done by pairing each student in the inner circle with a student in the outer circle and using Student Handout—*Socratic Seminar Discussion Partner Evaluation* to help students evaluate each other. Student Handout—*Socratic Seminar Discussion Partner Evaluation* can also be modified so that students reflect on their own participation.

## Teacher Background: Socratic Seminar

In a Socratic Seminar, the participants bear responsibility for the quality of the discussion. Good discussions occur when participants study the text closely in advance, listen actively, share their ideas and questions in response to the ideas and questions of others, and search for evidence in the text to support their ideas. The discussion is not about right answers; it is not a debate. Students are encouraged to think out loud and to exchange ideas openly while examining ideas in a rigorous, thoughtful manner.

In a Socratic Seminar, there are several basic elements:

- A text containing important and powerful ideas that is shared by all participants. It is helpful to number the paragraphs in a text so that participants can easily refer to passages, as seen in the readings for this lesson.
- A distinctive classroom environment: seating students in a circle and using name cards helps facilitate discussion. The students should have a clear understanding of the discussion norms, which should be prominently posted.
- An opening question that requires interpretation of the text and is genuine (with no predetermined answer). For example, ***“What is the most important passage?”*** or ***“What is the author driving at in the text?”*** Recommended questions can be found in the Procedure section.

## Glossary

**Alzheimer’s disease:** A brain disease that causes problems with memory (such as difficulty remembering people and events), thinking, and behavior. It is most common in people over 65, but up to five percent of people with the disease have early-onset Alzheimer’s (also known as younger-onset), which can appear in the patient’s 40s or 50s. Alzheimer’s worsens over time, and there is no cure, though some treatment options are available that appear to reduce the speed with which the condition worsens.

**Carrier test:** A genetic test to determine whether an individual carries a particular gene but may not show any conditions themselves. For example, a carrier test may be used to determine whether two parents both carry a copy of a recessive trait, which may be passed on to their child(ren).

**Clinical validity:** How accurately a test predicts whether or not a person will get a particular disease or symptom (known as the “clinical outcome”). This is often related to the penetrance of the gene involved, and whether or not the condition is polygenic.

**Diagnostic test:** A genetic test used to identify (or rule out) a particular genetic condition. For example, diagnostic genetic testing is used to determine whether a baby has Phenylketonuria (PKU).

**Effective treatment availability:** Whether or not there are treatment options available for a particular disease or condition. This is sometimes thought of as a “cure” although most genetic conditions are “treated” rather than “cured.”

**Hemochromatosis:** An autosomal recessive genetic disease that results in the body absorbing too much iron from food. This extra iron is stored in the body, including in organs like the liver and pancreas. The extra iron results in pain, organ damage, cancer, heart problems, and in some cases, death. Symptoms usually begin around age 30 to 40, but may begin in childhood. There is no cure, but the condition can be controlled with a specific diet, removal of blood (to remove the extra iron), and medication.

**Huntington’s disease (HD):** An autosomal dominant genetic disease causing nerve cells to waste away gradually, resulting in uncontrolled movements, severe problems with balance, clumsiness, emotional distress, problems swallowing, and loss of mental function. The condition usually begins when a person is in their 40s, and gets worse with age. The condition is ultimately fatal, and there is no cure.

**In vitro fertilization:** A process in which egg cells are fertilized by sperm outside the body. This is often used to help couples who have difficulty getting pregnant.

**Penetrance:** The frequency that individuals with a specific genotype will express a specific phenotype. For example, as seen in *Lesson Three*, approximately 85% of women with particular *BRCA1* mutations will develop breast or ovarian cancer. *BRCA1* is said to have “high penetrance” because an individual with a cancer-causing mutation in *BRCA1* has a large chance of developing breast cancer.

**Phenylketonuria (PKU):** A rare autosomal recessive genetic disease in which the body does not make an enzyme necessary to convert the amino acid phenylalanine to the amino acid tyrosine, causing phenylalanine to build up in the body to unsafe levels. This can cause mental retardation, brain damage, and seizures during infancy and early childhood. While a modified diet, including special protein supplements, can reduce the severity of PKU’s symptoms, new research suggests that diet alone is not enough to prevent symptoms.

**Pre-implantation Genetic Diagnosis (PGD):** Performing a genetic test on an embryo created by *in vitro* fertilization before placing it in the mother.

**Prenatal:** Before birth. For example, some genetic tests are performed on a developing fetus while s/he is still in the mother’s womb.

**Polygenic:** A polygenic trait is one that involves multiple genes. For example, cat coat color is known to involve multiple genes, including ones for white, orange, and black coloring. Many common diseases, like heart disease and diabetes, are thought to be polygenic.

## Resources

The Genetic Information Nondiscrimination Act of 2008 (“GINA”) is a federal law that prohibits discrimination in health coverage and employment based on genetic information. A handout prepared by the Department of Health and Human Services (HHS) with information about GINA for researchers and health care professionals is provided in the *Appendix*. This handout is designed to provide a brief overview of what legal protections are now in place regarding genetic testing, genetic privacy, and genetic discrimination.

## Credit

The Socratic Seminar procedures are based on materials shared by Walter Parker, PhD, University of Washington; Paula Fraser, Bellevue PRISM program, Bellevue, WA; Jodie Spitze and Dianne Thompson, Kent Meridian High School, Kent, WA. We also gratefully acknowledge the influence of the Coalition of Essential Schools and the National Paideia Center.

*Categorizing Genetic Tests* was adapted with permission from: Burke, W., Pinsky, L., and Press, N. (2001). Categorizing genetic tests to identify their ethical, legal, and social implications. *American Journal of Medical Genetics*, 106:233-240.

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Name \_\_\_\_\_ Date \_\_\_\_\_ Period \_\_\_\_\_

# 6

## Categorizing Genetic Tests

Based on Burke, W., Pinsky, L., and Press, N. (2001). "Categorizing genetic tests to identify their ethical, legal, and social implications." *American Journal of Medical Genetics*, 106:233-240. Adapted with permission.

- 1 What if you could go to the doctor and present a card that contained all your genetic information? Your doctor could scan the card and see whether you were more likely to have an allergic reaction to a particular drug, or whether you were at increased risk for a disease or disorder. Every year, scientists come closer to making this scenario a reality. More than 1,500 genetic tests are currently available<sup>1</sup>, and the number of tests available has more than doubled in the past eight years. Genetic testing companies are making it increasingly possible for consumers to have portions of their DNA sequenced, and to receive some information about what the results might mean. The growth of these "direct-to-consumer" testing companies has resulted in the ability of individuals to learn unprecedented amounts of information about their own genes.
- 2 There are a variety of genetic tests available. For example, some tests are performed on early embryos formed by **in vitro fertilization** (in which egg cells are fertilized by sperm outside the body) to determine whether they are disease-free and should be implanted in a woman (**Pre-implantation Genetic Diagnosis, or PGD**). **Prenatal** genetic tests test cells from a developing fetus before birth. Newborn screening tests are provided to children immediately upon birth. **Diagnostic tests** are used to identify (or rule out) a particular genetic condition and **carrier tests** are used to identify whether an individual who may not show any condition him/herself carries a particular gene.
- 3 Genetic tests have tremendous value in helping doctors diagnose and treat diseases. They can also predict who may develop a disease in the future, helping patients take a proactive role in their health care. Knowing an individual's genetic makeup may also help doctors identify the best treatments, as some drugs might be more effective for patients with particular genetic variations. They can also provide information to individuals that may affect their choices about having children in the future.
- 4 However, genetic tests also raise some challenging issues. For example, patients might encounter discrimination in various forms, or might experience stress as a result of knowing the outcome of a test. While the federal Genetic Information Non-Discrimination Act (GINA) of 2008 sets a baseline for patient protection with regard to insurance and employment, there are areas it does not cover (for example, companies with fewer than fifteen employees are exempt). GINA also does not prohibit health insurers from obtaining and using genetic test results to determine who should receive health insurance payments. Another concern is that the results of genetic tests impact not only the individual taking the test but entire families, who often share much of the same genetic information. Even a test that shows that a person does not have a genetic disorder might cause stress in the form of "survivor guilt" if other family members are affected by the disorder.
- 5 Genetic tests can be characterized according to their **clinical validity** and the availability of effective treatments. The term "clinical validity" means how accurately a test predicts a certain clinical outcome (such as getting a particular disease or symptom). Different types of tests raise different ethical issues and require different types of genetic counseling.  
**High Clinical Validity – Lack of Effective Treatment**
- 6 Traditionally, genetic counselors have been guided by the view that recommendations should be "non-directive;" in other words, people should be provided with information and then allowed to make their own choices. This view acknowledges that many decisions regarding health care are currently driven

by personal preference. For example, the decision of whether to terminate a pregnancy because of a genetic disorder is viewed as a private matter. Non-directive approaches also apply to some genetic testing situations that do not involve reproductive choices. For example, an individual whose parent had **Huntington's disease (HD)** might want to find out if he or she carries the mutation that results in the disease. Because HD has a high penetrance (in other words, an individual with the mutation has a large chance of developing the disease), an individual who tests positive receives information that might be helpful in planning for his or her life. However, there are currently no effective treatments to delay or prevent the disease, so an individual who tests positive for the HD mutation cannot use this information to make decisions about medical treatments that might help them.

- 7 In addition, there is the possibility that a person with a positive test may face discrimination or harmful psychological effects (including the stress of knowing that they have the mutation). A counselor might explain the different concerns and issues related to taking the genetic test, but the decision to test is ultimately left to the patient. Ethical issues often focus on making sure that people consider the kind of information the test will provide and the lack of treatment options.

### High Clinical Validity – Effective Treatment

- 8 Newborn screening tests, by contrast, are required by all states. Newborns are screened for a variety of disorders. In some states, parents may choose not to have their children screened (for example, for religious reasons). A classic example of a newborn screening test is the test for a disease called **Phenylketonuria (PKU)**. If a child who has the PKU mutation is diagnosed early in life, a modified diet can be given and mental retardation prevented. There is broad agreement that testing for PKU is extremely beneficial because a highly successful treatment—a modified diet—exists. Ethical concerns related to such genetic tests often focus on making sure that eligible people have access to the tests and treatment.
- 9 These examples show that the availability of an effective treatment makes a big difference in thinking about the implications of a genetic test, whether the use of that test is justified, and how health care providers should counsel families. In fact, health care providers have a duty (supported by court cases) to clearly tell patients if there are tests available in cases where successful treatments exist and non-treatment can lead to serious harm. If there are no effective treatments, non-directive counseling provides an appropriate framework for talking to patients about the possibility of testing.

### Low Clinical Validity – Lack of Effective Treatment

- 10 Clinical validity is affected not only by the penetrance of the mutation, but also by how good a test is at predicting whether someone will eventually get the disease. In other words, if a patient receives a positive test, how high is the likelihood that they will eventually become ill with that disease? In some cases, such as testing for the ApoE4 genotype (which may result in an increased risk for **Alzheimer's disease**), a positive result may show an increased risk, but the actual lifetime risk for the disease is uncertain. People with two ApoE4 alleles are ten times more likely to have Alzheimer's disease than those with other versions of the gene, but because Alzheimer's can occur late in life, someone might have two ApoE4 alleles and die of something else before Alzheimer's sets in. No treatment is available to reduce the risk.
- 11 As with testing for HD, the main risks are related to psychological effects on those who are tested, as well as discrimination. However, the HD test provides a highly accurate prediction about future risk. The risk associated with the ApoE4 test is less certain. Many experts recommend not testing for ApoE4, based on the ethical obligations for health care providers to avoid harm. Many genes that contribute to human disease have been identified. However, since the corresponding genetic tests may not be clinically valid, the real impacts of a positive test may be difficult to interpret, and few treatments may be available. Many direct-to-consumer tests fall into this category; they provide information related to disease risk that is difficult to evaluate due to uncertainty about the validity of the test as well as a lack of effective treatment.

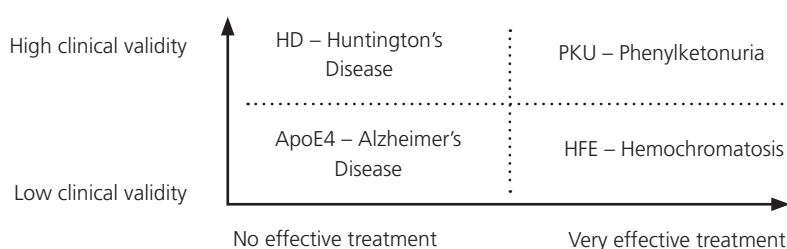
### Low Clinical Validity – Effective Treatment

- 12** So far, the examples presented have been ones that either predict diseases well (HD and PKU), but differ as to the treatments available, or that do not predict the disease well and also do not have an effective treatment (Alzheimer's – ApoE4). A fourth case is when there is an effective treatment, but the test is not clinically valid. For example, mutations in the HFE gene can lead to susceptibility to a disease called **hemochromatosis**. This disease causes iron overload and has potentially life-threatening consequences. However, only a small proportion of individuals with mutations in both copies of their HFE gene actually show symptoms of disease (low penetrance); therefore, the clinical validity of the test is low. Periodic blood draws, however, can help prevent dangerous complications such as liver cancer. So, in the case of HFE, the clinical validity of the test is low, but the treatment is minimal and beneficial. The benefit to the patient in terms of health outcomes may outweigh the potential psychological effects of testing or the potential social stigma of being labeled a carrier of a genetic disease. Ethical discussions about these types of tests, therefore, tend to be framed in terms of balancing potential harms and benefits. Tests that do not predict outcomes very well might be acceptable when the "label" associated with the disease has little social stigma (for example, hypertension).
- 13** *BRCA1* and *BRCA2* are interesting to analyze using this framework. There is uncertainty about how penetrant the *BRCA1* and *BRCA2* mutations are. The lifetime risk of breast cancer associated with *BRCA1* or *BRCA2* mutations ranges from 36%-85%, with a wide variation in how the cancer manifests itself (as breast cancer, ovarian cancer, or both). The penetrance is probably determined by the exact type of mutation (many *BRCA1* and *BRCA2* mutations are known) as well as environmental and other genetic factors. In a "high risk" family (four or more relatives affected by breast/ovarian cancer before age 60), females with mutations in *BRCA1* or *BRCA2* are estimated to have a lifetime risk of 85% for breast cancer. The effectiveness of the different treatments offered to carriers of *BRCA1* or *BRCA2* mutations is also subject to debate. The options include early mammograms, ovarian cancer screening, and surgery before any cancer appears. Most women with *BRCA1* or *BRCA2* mutations do not opt for such preventative surgery, especially if they do not have other risk factors in their history. However, those in a "high risk" family might consider the test to be highly predictive and the treatment effective.
- 14** A genetic test, therefore, should be evaluated based on both the test's clinical validity and the treatments available for those individuals with positive results. It may take many years for researchers to gauge how accurate a test is at predicting a disease outcome. The development of treatments and tests of their effectiveness in patients also requires time. This framework can help guide researchers in making decisions about which kinds of information to seek about tests, and can help patients think about the characteristics of the tests they are considering. It also explains why some tests have become widely accepted while others have not. As more genetic tests with limited clinical validity and predictive value become available, and more direct-to-consumer tests are marketed to the general public, it will be increasingly important to consider carefully how those tests are used.

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### Genetic Test Categories





### Genetic Conditions Glossary

**Alzheimer's disease:** A brain disease that causes problems with memory (such as difficulty remembering people and events), thinking, and behavior. It is most common in people over 65, but up to five percent of people with the disease have early-onset Alzheimer's (also known as younger-onset), which can appear in the patient's 40s or 50s. Alzheimer's worsens over time, and there is no cure, though some treatment options are available that appear to reduce the speed with which the condition worsens.

**Carrier test:** A genetic test to determine whether an individual carries a particular gene but may not show any conditions themselves. For example, a carrier test may be used to determine whether two parents both carry a copy of a recessive trait, which may be passed on to their child(ren).

**Clinical validity:** How accurately a test predicts whether a person will get a particular disease or symptom (known as the "clinical outcome"). This is often related to the penetrance of the gene involved, and whether or not the condition is polygenic.

**Diagnostic test:** A genetic test used to identify (or rule out) a particular genetic condition. For example, diagnostic genetic testing is used to determine whether a baby has Phenylketonuria (PKU).

**Effective treatment availability:** Whether or not there are treatment options available for a particular disease or condition. This is sometimes thought of as a "cure" although most genetic conditions are "treated" rather than "cured."

**Hemochromatosis:** An autosomal recessive genetic disease that results in the body absorbing too much iron from food. This extra iron is stored in the body, including in organs like the liver and pancreas. The extra iron results in pain, organ damage, cancer, heart problems, and in some cases, death. Symptoms usually begin around age 30 to 40, but may begin in childhood. There is no cure, but the condition can be controlled with a specific diet, removal of blood (to remove the extra iron), and medication.

**Huntington's disease (HD):** An autosomal dominant genetic disease causing nerve cells to waste away gradually, resulting in uncontrolled movements, severe problems with balance, clumsiness, emotional distress, problems swallowing, and loss of mental function. The condition usually begins when a person is in their 40s, and gets worse with age. The condition is ultimately fatal, and there is no cure.

**In vitro fertilization:** A process in which egg cells are fertilized by sperm outside the body. This is often used to help couples who have difficulty getting pregnant.

**Penetrance:** The frequency that individuals with a specific genotype will express a specific phenotype. For example, as seen in *Lesson Three*, approximately 85% of women with particular *BRCA1* mutations will develop breast or ovarian cancer. *BRCA1* is said to have "high penetrance" because an individual with a cancer-causing mutation in *BRCA1* has a large chance of developing breast cancer.

**Phenylketonuria (PKU):** A rare autosomal recessive genetic disease in which the body does not make an enzyme necessary to convert the amino acid phenylalanine to the amino acid tyrosine, causing phenylalanine to build up in the body to unsafe levels. This can cause mental retardation, brain damage, and seizures during infancy and early childhood. While a modified diet, including special protein supplements, can reduce the severity of PKU's symptoms, new research suggests that diet alone is not enough to prevent symptoms.

**Pre-implantation Genetic Diagnosis (PGD):** Performing a genetic test on an embryo created by *in vitro* fertilization before placing it in the mother.

**Prenatal:** Before birth. For example, some genetic tests are performed on a developing fetus while s/he is still in the mother's womb.



Name \_\_\_\_\_ Date \_\_\_\_\_ Period \_\_\_\_\_

## 6

## Weighing the Risks and Benefits of Direct-to-Consumer Genetic Testing: Who Should Decide?

### Concerns about Direct-to-Consumer Genetic Testing

- 1 Direct-to-consumer (DTC) genetic testing has offered personal genetic data to consumers since 2006, without the need for—or potential benefit of—medical doctors or genetic counselors. However, medical providers and those in government have been concerned that the risks of DTC genetic testing may outweigh the benefits.
- 2 What if the estimates for how likely someone is to develop a disease prove to be incorrect, either overestimating or underestimating a person's risk? If someone found out that their risk for a disease like Alzheimer's was well above average, would they become depressed? Would they alter their behavior for better, for worse, or perhaps not at all?
- 3 These concerns have led some states – including New York and California – to either ban DTC genetic testing, or strictly limit it. According to a report by the Genetics and Public Policy Center in June 2007, only about half the states in America permitted DTC genetic testing with no restrictions.<sup>1</sup>
- 4 The US Food and Drug Administration (FDA) does not currently provide oversight of the DTC genetic testing industry. In March 2011, the Molecular and Clinical Genetics Panel, an advisory committee to the FDA, suggested more oversight. They expressed concern that consumers may misunderstand genetic results without medical counseling, or that the disease risk estimates provided in those results may be incorrect, as there is currently no standard about the level of evidence needed by DTC genetic test manufacturers to make claims about their genetic tests. The FDA panel noted that, while DTC genetic tests seem similar to other at-home medical tests like those for blood sugar or pregnancy, “many DTC clinical genetic tests often carry a disclaimer stating that they are intended for ‘educational and informational’ purposes, and that the individual receiving the test results may wish to take them to their clinician for follow-up.”<sup>2</sup>
- 5 A member of the FDA panel noted that companies have a right to sell their products to the public, but the FDA has an obligation to compare the risks and benefits of these products, set product standards, and make sure information is understandable by the public.

### Response from a DTC Company: 23andMe

- 6 23andMe is a DTC company. According to the creators of the company, “23andMe was founded on the belief that individuals have a right to access their own genetic information, and this conviction is still as firmly held as ever,” but 23andMe is assured that the FDA will take a “reasoned approach to integrating the feedback it received from the panel.”<sup>3</sup> However, they hope that feedback will come from all involved parties, as 23andMe notes that the FDA panel had a panel member who represented the consumer and the patient, but they did not “hear directly from consumers and others who have first-hand experience with the information provided by direct-access genetic testing services.”<sup>3</sup> 23andMe encourages consumers to make their voices heard about their experiences with DTC genetic testing.
- 7 In addition, DTC genetic testing companies like 23andMe use the genetic information of their customers to further our understanding of human genetics, if customers consent. In a study published in the scientific journal PLoS Genetics, 23andMe used customer data and web-based surveys to evaluate genetic variation in a number of common human genetic traits, such as hair color, eye color, and freckling.<sup>4</sup> This may not seem like a giant scientific breakthrough, but it makes an important contribution to our understanding of **how** we can conduct genetic research. Genetic studies often require a great deal of time and money to recruit study participants, perform genotyping, document phenotypes, and perform genetic analyses. The 23andMe approach offers a potentially powerful new way to conduct these types of studies with willing DTC genetic testing customers, using less time and at lower cost.

### Challenges to Understanding Genetic Test Results

- 8** According to the American Medical Association (AMA), “[t]he results of genetic tests (whether DTC or ordered by a physician) can be challenging to interpret. A positive result does not necessarily indicate a clinical diagnosis. Often, a positive result indicates an increased risk for developing a disease or condition.”<sup>5</sup> The AMA goes on to say that the same mutation in different people can mean different things, based on penetrance, environment, and other factors. “Also, since only a fraction of testable mutations are identified for genetically based diseases, a genetic test with a negative result is not indicative of the absence of disease risk.” The AMA recommends that any patient undergoing genetic testing (DTC or otherwise), do so “under the guidance of a qualified health care provider.”<sup>5</sup>
- 9** The American Society for Human Genetics (ASHG) noted in a report released in September 2007 that the federal government currently has limited oversight of the “analytic validity” of genetic tests (the ability of the test to correctly detect a particular genetic variant), and no oversight of the “clinical validity” of genetic tests (the ability of the test to correctly predict whether someone will develop a particular disease).<sup>6</sup> The ASHG recommends that all DTC genetic testing companies provide consumers with information about genetic testing accuracy, including the strength of the scientific evidence about genetic test results, and that the federal government improve regulation of DTC genetic testing companies, to ensure the accuracy of the information provided to consumers.
- 10** However, some are concerned that, without direct government oversight, the DTC genetic testing industry may not do a good job regulating themselves. The Government Accountability Office (GAO) testified in 2010 before the US House of Representatives about their 2006 investigation of DTC genetic testing companies. They obtained 10 genetic tests from four DTC genetic testing companies, using DNA from two donors, and compared the results.<sup>7</sup> According to the GAO report, “GAO’s fictitious consumers received test results that are misleading and of little or no practical use.” One fictitious donor received contradictory results from each of the companies: below average, average, and above-average risks of developing hypertension and prostate cancer. Many of the estimates of genetic disease risks are based on scientific studies, but often these studies contain too few African American or Asian participants to make meaningful conclusions about these groups. In addition, “follow-up consultations offered by three of the companies failed to provide the expert advice that the companies promised.”<sup>7</sup> There were also examples of deceptive marketing, in which two companies claimed that donor genetic information could be used to create personalized supplements to “repair damaged DNA” or cure disease, or predict which sports donors’ children would do well in. Experts say these claims lack scientific evidence, and the GAO has referred all four of the companies “for appropriate action” to the FDA and the Federal Trade Commission (which regulates marketing of products).<sup>7</sup>

### What Do Consumers Think about DTC Genetic Testing?

- 11** But is all of this concern really necessary? If these tests are truly for “educational and informational purposes only,” do we really need government agencies to regulate them as they would regulate genetic tests in a doctor’s office? What do patients think? Has anyone asked them? Two studies provide insights about what DTC genetic testing consumers think about these products.
- 12** A paper published in the *New England Journal of Medicine* in February 2011 describes preliminary results from the Scripps Genomic Health Initiative, which measures the psychological and behavioral effects of DTC genetic testing on subjects recruited from health and technology companies.<sup>8</sup> Study subjects purchased genetic tests using the Navigenics Health Compass (Navigenics is a DTC genetic testing provider) at a discounted price—\$225 instead of \$400 to \$2,000. Researchers then followed the subjects for three months using web-based surveys to measure anxiety level, diet, exercise, whether the DTC genetic tests caused subjects any distress, and whether subjects used more medical screening tests after receiving their genetic test results.

- 13** What did these researchers find? About half of the study subjects said that they intended to use more medical screening tests after receiving their DTC genetic test results, and about half did not. There was no clear increase in anxiety level, dietary fat intake, and exercise behavior among these subjects—who were all in general good health at the beginning of the study. About 10% of the subjects said they discussed their test results with the Navigenics board-certified genetic counselor, and about 26% said they discussed their results with their doctor. In fact, most of the study subjects did not do anything different after obtaining their study results: they did not talk to their doctor, they did not change their diet or exercise, and they did not seem to be upset by any of their test results.
- 14** In another report published in *Health Economics* in 2010, researchers studied how much, if anything, people would be willing to pay for DTC genetic tests that predicted their risk of future diseases.<sup>9</sup> The study included 1,463 people randomly chosen to participate through web-based surveys. They were asked about their willingness to pay for testing for Alzheimer’s disease, arthritis, breast cancer, or prostate cancer, using tests that were “perfect” or “not perfectly accurate.” Between 70-88% of study participants said they would pay for these genetic tests, with rates lower for Alzheimer’s or “not perfectly accurate tests” and higher for prostate cancer or “perfect” tests, even if there were no direct impact on the person’s medical treatment options.
- 15** The costs of DNA sequencing and analysis technologies continue to go down, making genetic testing available to more people at lower costs. Consumers, DTC genetic testing companies, and the US government will have to decide how best to move forward – balancing the rights of companies to sell their products, the rights of individuals to have access to their own genetic information through accurate and scientifically valid genetic testing, and the obligations of the federal government to protect its citizens.

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Name \_\_\_\_\_ Date \_\_\_\_\_ Period \_\_\_\_\_

# 6

## Critical Reasoning Analysis Form



<p><b>Point of View</b></p> <p>What is the point of view of the authors, and how does that particular perspective show through</p>	
<p><b>Purpose</b></p> <p>Why was this material written?</p>	
<p><b>Questions</b></p> <p>What questions are addressed by the authors? What questions do you have about the material?</p>	
<p><b>Information</b></p> <p>What are some of the most important facts included?</p>	

# LESSON 6

## HANDOUT

<p><b>Concepts</b></p> <p>What are the main ideas and concepts addressed?</p>	
<p><b>Implications</b></p> <p>What is the larger meaning? What are the consequences of the decision to be made?</p>	
<p><b>Assumptions</b></p> <p>What assumptions are the authors making? Are any of these assumptions questionable?</p>	
<p><b>Inferences</b></p> <p>What can you infer and conclude based on the material?</p>	

Credit: Foundation for Critical Thinking, <http://www.criticalthinking.org>, and Paula Fraser, Bellevue School District PRISM Program.

Name \_\_\_\_\_ Date \_\_\_\_\_ Period \_\_\_\_\_

# 6 Open-Ended Questions for a Socratic Seminar



When preparing for a Socratic Seminar, write questions using these sentence frames to stimulate your thinking about the article you read. Choose and complete five of the following:

- What puzzles me is... \_\_\_\_\_  
\_\_\_\_\_
- I'd like to talk with people about... \_\_\_\_\_  
\_\_\_\_\_
- I'm confused about... \_\_\_\_\_  
\_\_\_\_\_
- Don't you think this is similar to... \_\_\_\_\_  
\_\_\_\_\_
- Do you agree that the big ideas seem to be... \_\_\_\_\_  
\_\_\_\_\_
- I have questions about... \_\_\_\_\_  
\_\_\_\_\_
- Another point of view is... \_\_\_\_\_  
\_\_\_\_\_
- I think it means... \_\_\_\_\_  
\_\_\_\_\_
- Do you think... \_\_\_\_\_  
\_\_\_\_\_
- What does it mean when the author says... \_\_\_\_\_  
\_\_\_\_\_

**6**

**Socratic Seminar Discussion**  
**Partner Evaluation**



**Name of person you are observing** \_\_\_\_\_

1. Record a check for each time your partner contributed in a meaningful way:
2. On a scale of 1–5, with 5 being the highest, how well did your partner do at the following?

<p><b>Analysis &amp; Reasoning</b></p> <p>Points: _____</p>	<p><b>Did your partner...</b></p> <ul style="list-style-type: none"> <li>• Cite reasons and evidence for his/her statements with support from the text?</li> <li>• Demonstrate that he/she had given thoughtful consideration to the topic?</li> <li>• Provide relevant and insightful comments?</li> <li>• Demonstrate organized thinking?</li> <li>• Move the discussion to a deeper level?</li> </ul>	<p><b>Notes/Comments:</b></p>
<p><b>Discussion Skills</b></p> <p>Points: _____</p>	<p><b>Did your partner...</b></p> <ul style="list-style-type: none"> <li>• Speak loudly and clearly?</li> <li>• Stay on topic?</li> <li>• Talk directly to other students rather than to the teacher?</li> <li>• Stay focused on the discussion?</li> <li>• Invite other people into the discussion?</li> <li>• Share “air time” equally with others (didn’t talk more than was fair to others)?</li> </ul>	<p><b>Notes/Comments:</b></p>
<p><b>Civility</b></p> <p>Points: _____</p>	<p><b>Did your partner...</b></p> <ul style="list-style-type: none"> <li>• Listen to others respectfully?</li> <li>• Enter the discussion in a polite manner?</li> <li>• Avoid inappropriate language (slang, swearing)?</li> <li>• Avoid hostile exchanges?</li> <li>• Question others in a civil manner?</li> </ul>	<p><b>Notes/Comments:</b></p>



**6**

**Socratic Seminar Rubric**

<b>Dimension</b>	<b>Exemplary</b>	<b>Proficient</b>	<b>Partially Proficient</b>	<b>Developing</b>	<b>Comments</b>
<b>Analysis &amp; Reasoning</b>	Clearly references text to support reasoning.	Occasionally references text to support reasoning.	Rarely references text; may reference text incorrectly.	Does not reference text.	
	Demonstrates thoughtful consideration of the topic.	Demonstrates consideration of the topic.	Demonstrates awareness of the topic but little reflection on it.	Demonstrates little or no consideration of the topic.	
	Provides relevant and insightful comments; makes new connections.	Provides relevant comments.	Comments are mostly relevant.	Comments are off-topic or irrelevant.	
	Demonstrates exceptionally logical and organized thinking.	Thinking is clear and organized.	Thinking is mostly clear and organized.	Thinking is confused, disorganized, or stays at a very superficial level.	
	Moves the discussion to a deeper level.				
<b>Discussion Skills</b>	Speaks loudly and clearly.	Speaks at an appropriate level to be heard.	Mostly speaks at an appropriate level but may need to be coached.	Cannot be heard, or may dominate the conversation.	
	Stays on topic and brings discussion back on topic if necessary.	Stays on topic and focused on the discussion.	Sometimes strays from topic.	Demonstrates inappropriate discussion skills.	
	Talks directly to other students (rather than the teacher).	May occasionally direct comments to teacher.	Talks directly to teacher.	Does not talk.	
	Shares “air time” equally with others.	Aware of sharing “air time” with others.	Occasionally dominates the conversation.	Dominates the conversation.	

Dimension	Exemplary	Proficient	Partially Proficient	Developing	Comments
<b>Discussion Skills (Continued)</b>	Invites other people into the discussion.	May invite other people into the discussion.		Does not invite other people into the discussion.	
	References the remarks of others.			Does not reference the remarks of others.	
	Stays focused on the discussion.			May be distracted or not focused on the conversation.	
<b>Civility</b>	Listens to others respectfully by making eye contact with the speaker, and waiting their turn to speak.	Listens to others respectfully.	Listens to others respectfully, but may not always look at the speaker or may sometimes interrupt.	Interrupts frequently.	
	Remarks are polite and demonstrate a high level of concern for the feelings of others.	Remarks demonstrate a concern for the feelings of others.	Remarks demonstrate an awareness of feelings of others.	Remarks demonstrate little awareness or sensitivity to the feelings of others.	
	Addresses others in a civil manner, using a collegial and friendly tone.	Uses appropriate language and tone.	Uses inappropriate language or tone.	Uses an aggressive, threatening, or otherwise inappropriate tone.	