



# Personal Genetics Education Project

## Ethical, Legal and Social Issues in Personal Genetics

### Personalized Medicine

**Aim:** How might personalized medicine impact healthcare?

**Time:** This lesson can be adjusted to fill 1 or 2 days.

#### **Guiding questions:**

- What are the most exciting possibilities in personalized medical approaches for patients?
- What are some of the challenges in making personalized medicine available for everyone?
- What role do genes play in how effective a medicine might be?

#### **Learning objectives:**

By the end of the lesson, students will be able to:

- Define personalized medicine.
- Explain the hope for personalized medicine to improve people's health and lives and, at the same time, have an awareness of the challenges ahead.
- Understand how personalized medicine might impact their own health.

**Materials:** Projector or Smartboard, laptop or markers/colored pencils, paper, handouts, printer.

#### **Common Core Standards:**

[CCSS.ELA-LITERACY.RST.11-12.2](#). Determine the central ideas or conclusions of a text; summarize complex concepts, processes, or information presented in a text by paraphrasing them in simpler but still accurate terms.

[CCSS.ELA-LITERACY.RST.11-12.6](#). Analyze the author's purpose in providing an explanation, describing a procedure, or discussing an experiment in a text, identifying important issues that remain unresolved.

[CCSS.ELA-LITERACY.RST.11-12.7](#). Integrate and evaluate multiple sources of information presented in diverse formats and media (e.g., quantitative data, video, multimedia) in order to address a question or solve a problem.

**Next Generation Science Standards:**

*This pgEd lesson integrates some of the NGSS practices and cross cutting concepts associated with the following disciplinary core ideas. The relevant portion of each disciplinary core idea is written out below.*

**[HS-LS3: Inheritance and Variation of Traits](#)*****LS3.A: Inheritance of Traits***

– The instructions for forming species’ characteristics are carried in DNA. All cells in an organism have the same genetic content, but the genes used (expressed) by the cell may be regulated in different ways.

***LS3.B: Variation of Traits***

– Although DNA replication is tightly regulated and remarkably accurate, errors do occur and result in mutations, which are also a source of genetic variation.

Environmental factors can also cause mutations in genes.

– Environmental factors also affect expression of traits, and hence affect the probability of occurrences of traits in a population. Thus the variation and distribution of traits observed depends on both genetic and environmental factors.

**Background information and note to teachers:**

Personalized medicine, also known as precision medicine, holds great promise to improve healthcare. The [National Cancer Institute](#) says personalized medicine integrates “information about a person’s genes, proteins, and environment to prevent, diagnose, and treat disease.” As the cost of genetic analysis decreases and research advances, it is becoming increasingly possible to include a person’s genetic make-up in the repertoire of tools that inform their healthcare. High school students will be taking charge of their own healthcare in a few short years, and having a foundation in the concepts of personalized medicine may help them become informed advocates for themselves as they enter adulthood.

Doctors and scientists are focused on four major approaches to connecting genetics and healthcare. First, personal genome sequencing can be used to diagnose patients with rare conditions when other approaches have failed. Second, genetics is increasingly used to predict a person’s susceptibility to a medical condition. Third, a growing number of medications are prescribed based on a person’s genetic make-up. And fourth, new drugs are being developed to treat certain diseases that are linked to specific genetic variants.

This lesson focuses on the third and fourth approaches listed above – a field known as pharmacogenomics. According to the National Institutes of Health’s [Genetics Home Reference](#), “this relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and

their functions) to develop effective, safe medications and doses that will be tailored to a person's genetic makeup."

It is estimated that nearly 70% of Americans take at least one prescription medicine. Many of these medications may be overprescribed, underused or given to people for whom the drug is not working as hoped. Could personalized medicine approaches help? Traditionally, when prescribing a medication, a doctor may take into account a patient's age, weight, kidney and liver function, and then wait to see how the patient responds. A more personalized approach would also include looking at genetic factors that might add a crucial layer of information about how a person is likely to respond to a drug. An example of a pharmacogenomics in action is warfarin. Warfarin (also known as Coumadin and several other brand names) is a drug to prevent blood clots. It is widely prescribed and effective, but its dose may need to be [adjusted](#) based on genetic markers that influence a person's metabolism in order to minimize side effects.

While pharmacogenomics may help reduce the risks of medications, research is still ongoing to determine if genetics-informed dosing is safe and efficient.

To read more, see:

["Smarter medication could save \\$213B in health care costs,"](#) by CBS staff, June 2013, *CBS News*.

["A Very Personal Problem,"](#) by Dina Fine Maron, May 2016, *Scientific American*.

Going forward in personalized medicine, a number of challenges related to genetic complexity, ethnicity, and cost will need to be addressed. Projects are underway to increase the ethnic diversity of participants in medical research, such as the NIH's All of Us program. Because clinical studies in North America and Europe have traditionally focused on people of European descent, genetic variants or health conditions that are more prevalent in non-White populations are often understudied. In order to make sure that personalized medicine is available for everyone, researchers and physicians must overcome distrust stemming from a history of ethical breaches and discrimination within many underrepresented communities.

Developing genetically-targeted treatments is expensive, and those costs are frequently passed on to patients. Insurance companies are struggling with whether or how to cover the costs for patients. Making sure that all patients, regardless of socioeconomic status, will be able to benefit from these medical advances will be a crucial question to tackle.

This lesson asks students to delve into the hopes and challenges of personalized medicine and to consider the applications of genetic analysis in

medicine. Students are asked to synthesize the broader medical, scientific and social issues, and put the goals of personalized medicine in context as they develop their own educational brochure.

**Note:** We have included a number of news articles and videos throughout this lesson plan. However, as the technology evolves at a rapid pace, we recommend visiting <http://pged.org/personalized-medicine/> for regular updates related to this lesson.

**Here is an outline of the resources and activities in this lesson:**

1. Reading for students (page 4)
2. Do Now exercise (pages 4-5)
3. Creating a brochure (pages 5-9, student handout on page 12, rubric on page 13)
4. List of additional resources (pages 10-11)
5. Short quiz (page 14, answer key on page 11)

**Reading for students:**

Students should read Anahad O'Connor's July 2016 *New York Times* article, "[For Coffee Drinkers, the Buzz May Be in Your Genes](#)" for homework before the lesson. This article introduces the concept of a personalized approach to medicine that uses genetic tests to predict how different people's body reacts differently to a substance (in this case, caffeine). The idea is that not everyone will have the same response to a drug as a result of factors including metabolism, genetic differences and health history.

**Activities:** Do Now exercise (10-15 minutes), create a brochure (40-60 minutes).

**Part 1: Do Now exercise - Video, questions and classroom discussion (10-15 minutes)**

We offer three options below for teachers to introduce the concept of personalized medicine. Students may watch a brief video (A) or animation (B) or read a short article (C), and then answer the questions that follow. Students should read the questions in advance, so they know what information to seek from the video or text. Once students have thought about their answers individually, you can have a short group discussion to check for understanding before proceeding to the next activity.

(A) "[What is Personalized Medicine?](#)" is a 2-minute YouTube video. Since YouTube may be blocked at some schools, we offer two alternative sources in (B) and (C) below.

If necessary, provide students with the following definitions before the video:

Adverse - causing harm

Efficacy - the power to produce a desired result

Prone - likely to be or act a certain way

1. How does Max's doctor choose which drugs to give him?
2. How does Max respond to treatment?
3. How do the genetic tests that Hannah undergoes impact how her doctor treats her illness?
4. How is "treating the patient" different than "treating the disease"?

(B) If you cannot access YouTube but have a projector, we recommend the animated slideshow, "[Your Doctor's New Genetic Tools](#)," from the Genetic Science Learning Center.

1. Why is Purinethol not helpful to all patients?
2. In the 1990s, what did researchers discover about how the drug is broken down in the body?
3. How did genetic testing impact how Latrice's doctor treated her cancer?

(C) If you cannot access a projector, this article, "[What is Personalized Medicine?](#)" from the Jackson Laboratory covers similar material.

1. Why has the traditional approach to prescribing medicines to patients not always been a success?
2. Explain two ways that personalized medicine is changing medicine.

## **Part 2: Create a personalized medicine brochure (40-60 minutes)**

Divide students into groups to write a brochure showcasing the hopes, breakthroughs and limits of personalized medicine. The audience for the brochure is a member of the general public who encounters this brochure in a doctor's office or health center and may benefit from personalized medicine, but is unfamiliar with the field.

All the brochures should provide an overview of personalized medicine and address the success stories and challenges in the field, but there are three

sub-topics to assign to your student groups. This will allow students to have a broad view of the subject while becoming familiar with specific examples.

Depending on your class size, you may have multiple groups working on the same sub-topic. All groups will read several common articles, as well as a few articles focused on their specific sub-topic.

The 3 sub-topics are: 1) Genetic testing applied to rare disease with the hope of finding a diagnosis and/or a treatment plan; 2) Using genetic testing to decide which drug, in what dose, might work for a patient; and 3) Developing or prescribing drugs, for diseases such as cancer, that are targeted to the genetic makeup of specific patients.

The instructions are formatted as a student handout on page 12 of this document, and a rubric is included on page 13. Each brochure should address the following questions and can include more topics if students do additional research:

- A. Why are doctors and patients excited about personalized medicine?
- B. How has personalized medicine helped patients already?
- C. How might people with cystic fibrosis, cancer, or an undiagnosed condition benefit from personalized medicine?
- D. What are the challenges of tailoring medicine to individuals or small numbers of people?
- E. What are the implications of personalized medicine for healthcare costs?
- F. How can we make sure that access to personalized medicine is fair and equitable?

***Brochure preparation:***

1. Divide students into groups of 4-5.
2. Assign each group a sub-topic, and then, each student a different article to read from the list below. You may want to pair students to ensure that the essential information is being addressed in the brochure.
3. Students should create a rough draft of their brochure and check the rubric in advance, so they are clear on the requirements.
4. Students will either use markers/colored pencils and white paper or a computer to create the final brochure.

### **Articles for brochure research:**

Below, we have provided links to articles for students to reference. We suggest assigning specific articles and topics to individual students within the groups, so each student can be accountable for reading and synthesizing the information for the group.

Teachers may choose one or more articles in each of sections A, B, C and D that are to be read by all groups making a brochure. They vary in length and reading level and teachers may need to tailor for their classroom.

- A. The following introductory articles discuss how a personalized approach to medicine based on genetics may contribute to patients' health.
- "[Treating illness and preventing disease with genetic testing](#)," by Clara Gaff and Ivan Macciocca, February 2014, *The Conversation*.
  - "[Frequently asked questions about pharmacogenomics](#)," National Institutes of Health (content updated in 2017).
- B. Pharmacogenomics is the use of DNA testing to determine whether a patient can safely take a drug and at what dose. This can be a relatively inexpensive procedure that can improve treatment and save lives, but such tests have not been shown to be useful or effective in all cases.
- "[Genetic Testing Falls Flat in Large Patient Drug Trials](#)," by Susan Young Rojahn, November 2013, *MIT Technology Review*.
  - "[When a Genetic ID Card Is the Difference Between Life and Death](#)," by Ed Yong, October 2015, *The Atlantic*.
- C. One of the concerns about personalized medicine is whether patients will be able to afford it, especially when many insurance companies are not covering the cost of the drugs or the genetic tests needed to identify the individuals who may benefit from such drugs.
- "[The \\$300,000 drug](#)," by Joe Nocera, July 2014, *New York Times*.
  - "[Promising New Cancer Drugs Won't Go Far Unless Everyone Gets Genetic Testing](#)," by Emily Mullin, June 2017, *MIT Technology Review*.
- D. In order for personalized medicine to achieve its potential benefits, genetic studies must be inclusive of underrepresented communities so that the relevant genetic variants may be identified. But to fix the traditional bias in clinical medicine towards studying people of European descent, researchers will have to overcome distrust by these underserved communities that arose from a history of discrimination and abuse.
- "[To advance medicine's future, the NIH tries to win the trust of communities mistreated in the past](#)," by Lev Facher, September 2017, *STAT*.

With the foundation of the ideas in the articles in sections A-D, groups assigned one of the following sub-topics can choose one or more articles to make their brochures.

**Topic 1: Genetic testing applied to rare disease with the hope of finding a diagnosis and/or a treatment plan**

Nic Volker is a young boy, now thriving, who had been terribly sick with a rare, undiagnosed medical condition. He spent most of his life in a hospital and endured over 100 surgeries by age 4. A portion of Nic's genome was sequenced to look for a genetic mutation that caused his illness. Nic is the first child to receive a diagnosis and successful treatment as a result of genome sequencing.

- "[Cord blood transplant saves boy, 6, from baffling ailment](#)," by Michael Inbar, December 2010, *NBC News/The Today Show*.
- "[The First Child Saved By DNA Sequencing](#)," by Matthew Herper, January 2011, *Forbes*.

Layla Richards was 11 months old when all conventional treatments for her leukemia, a type of cancer that affects blood and bone marrow, had failed. Layla then became the first child to be treated for leukemia via donated immune cells that were genetically engineered for her body and type of cancer. The cells were altered to ensure Layla's immune system would not perceive the new cells as dangerous, which would have prompted her body to reject them. The transplant was a success, and as of the most recent report in early 2017, Layla remained cancer-free.

- "[A Groundbreaking Gene-Editing Therapy Eliminated Cancer in Two Infants](#)," by Kristen Brown, January 2017, *Gizmodo*.



## **Topic 2: Using genetics to determine what drug, and in what dose, might best treat an individual patient**

The field of pharmacogenomics hopes to use genetic testing to find the most effective drug or drug dosage based on the specific genetic makeup of the patient. Often, doctors use genetic tests to look for genetic variants in a patient that influence how they metabolize the drug, which could affect whether the patient experiences side effects or even a fatal reaction. Pharmacogenomic tests have been developed for medications such as painkillers or psychiatric drugs. While an area of great hope, much research is still needed to realize the potential of this approach to medication.

- "[Why Codeine is Dangerous in Some Kids after Tonsillectomy](#)", by David Kroll, February 2013, *Forbes*.
- "[Finding the Right Medication: Gene Test May Help Treat Depression](#)", by Shamard Charles, August 2017, *NBC News*.

## **Topic 3: Developing or prescribing drugs, for diseases such as cancer, that are targeted to the genetic makeup of specific patients**

In recent years, a number of medications have been developed to treat subsets of patients with conditions such as cystic fibrosis or Duchenne muscular dystrophy. These patients have particular genetic variants targeted by the drugs. While most of these drugs do not cure the diseases, they do provide hope to patients for better quality of life.

- "[FDA clears Vertex's new treatment for cystic fibrosis](#)," by Robert Weisman, July 2015, *Boston Globe*.
- "[First drug approved to treat rare form of muscular dystrophy](#)," by Liz Szabo, September 2016, *CNN*.

One promising area of personalized medicine is in developing cancer drugs tailored for patients with specific genetic mutations. For example, the drug Herceptin can be used to treat certain types of breast cancer, specifically those that make too much HER2 protein, and HER2 testing is now routinely performed in people diagnosed with breast cancer. However, there is still much debate among doctors and scientists about how well this approach actually works.

- "[HER2 positive breast cancer: what is it?](#)" by Sandhya Pruthi, April 2012, *Mayo Clinic*.
- "[Should We Sequence the DNA of Every Cancer Patient?](#)" by Antonio Regalado, June 2016, *MIT Technology Review*.

### **Additional resources for teachers:**

["Next-gen sequencing: The clinical conundrum,"](#) by Craig Hildreth, May 2018, *Medpage Today*.

["DNA on Drugs: How genetic tests could make prescriptions more precise,"](#) by Carolyn Abraham, March 2018, *Globe and Mail*.

["What's Behind Many Mystery Ailments? Genetic Mutation, Study Finds"](#), By Carl Zimmer, March 2018, *New York Times*.

["When Even Genome Sequencing Doesn't Give a Diagnosis,"](#) by Emily Mullin, April 2017, *MIT Technology Review*.

["Turning Piglets Into Personalized Avatars for Sick Kids,"](#) by Ed Yong, December 2017, *The Atlantic*.

["The Paradox of Precision Medicine,"](#) by Jeneen Interlandi, April 2016, *Scientific American*.

["Precision Medicine's Post-Racial Promise,"](#) by Vann Newkirk II, June 2016, *The Atlantic*.

["Pharmacogenetics: The right drug for you,"](#) by Liam Drew, September 2016, *Nature*.

["Perspective: The precision-oncology illusion,"](#) by Vinay Prasad, September 2016, *Nature*.

["A new way to study cancer and its treatments,"](#) by Lenny Bernstein, June 2015, *Washington Post*.

["Gene test helps patients avoid thyroid surgery,"](#) by Susan Young, February 2014, *MIT Technology Review*.

["Patient Zero,"](#) a series by Mark Warren and Tom Junod, November 2013, *Esquire*. An extensive story of the journey and, ultimately, [death](#) of a cancer patient from Mississippi for whom a team of researchers tried to develop a personalized therapy.

["A New Treatment's Tantalizing Promise Brings Heartbreaking Ups and Downs,"](#) by Gina Kolata, July 2012, *New York Times*.

["In Treatment for Leukemia, Glimpses of the Future,"](#) by Gina Kolata, July 2012, *New York Times*.

["One In A Billion: A boy's life, a medical mystery,"](#) a series by Mark Johnson and Kathleen Gallagher, December 2010, *Milwaukee Wisconsin Journal Sentinel*.

For additional information about the science of pharmacogenomics and its medical applications, we recommend the materials on [Pharmacogenomics](#) developed by the Wellcome Trust Sanger Institute.

**"Personalized medicine" quiz answer key (see page 14 for quiz):**

1. True
2. d) All of the above.
3. Answers will vary but students should explain that these are examples of conditions for which people can take a genetic test that might indicate whether a particular drug will be effective for them.
4. Answers will vary but can include cost, the need for further research to prove effectiveness, and the challenge of increasing the diversity of communities that are included in studies.

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

### **Personalized medicine brochure: Student instructions**

Your group will write a brochure showcasing the hopes, breakthroughs and limits of personalized medicine. The brochure should provide an overview of personalized medicine and address the success stories and challenges in the field. The audience for your brochure is a member of the general public who encounters this brochure in a doctor's office or health center and may benefit from personalized medicine, but is unfamiliar with the field.

Your brochure should address the following questions:

- A. Why are doctors and scientists excited about personalized medicine?
- B. How has personalized medicine helped patients already?
- C. How might people with rare genetic conditions, cystic fibrosis or cancer benefit from personalized medicine?
- D. What are the challenges of tailoring medicine to individuals or small numbers of people?
- E. What are the implications of personalized medicine for healthcare costs?
- F. How can we make sure that access to personalized medicine is fair and equitable?

### ***Steps for preparing your brochure:***

1. You will be responsible for reading and analyzing a news article for your group.
2. As a group, create a rough draft of your brochure. Read the rubric and this handout carefully, so you are clear on the requirements.
3. Use either markers/colored pencils and white paper or a computer to create the final brochure.

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

### **Personalized medicine brochure rubric**

Each student clearly worked on a particular piece of the brochure.  
Individuals should add their name to the section they worked on

15 pts \_\_\_\_\_

Brochure addresses the following points clearly and accurately:

What is personalized medicine (PM) 15 pts \_\_\_\_\_

Addresses at least one success story 10 pts \_\_\_\_\_

Describes how PM may help patients with a specific disease 10 pts \_\_\_\_\_

The challenges and limitations of this new field 10 pts \_\_\_\_\_

How personalized medicine may impact healthcare costs 10 pts \_\_\_\_\_

Brochure includes at least two pictures and is neat and visually appealing 10 pts \_\_\_\_\_

The group worked together well, and clearly and evenly divided the assignments 10 pts \_\_\_\_\_

Rough Draft 10 pts \_\_\_\_\_

Total score: \_\_\_\_\_

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

### **"Personalized Medicine" quiz**

1. Some patients can take a genetic test to determine how well a specific drug will work for them. T/F
2. Personalized medicine allows doctors and healthcare providers to
  - a) use genetic information to diagnose more patients.
  - b) create specific treatments for patients with fewer side effects.
  - c) prescribe the right medications in the right dose without having to use "trial and error" in trying to determine whether the medicine will help.
  - d) all of the above.
3. How might people with cystic fibrosis or cancer benefit from personalized medicine?
4. What are some of the challenges to making personalized medicine available to all patients?