Personal Genetics Education Project

Ethical, Legal and Social Issues in Personal Genetics

Title: Personalized Medicine

Aim: How might personalized medicine impact our healthcare?

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

Guiding questions:
- What are the most exciting possibilities in developing personalized medical approaches for patients?
- What are some of the challenges that personalized medicine presents for doctors and drug developers?
- 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:
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.

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.

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.

Background information and note to teachers:
Personalized medicine, also referred to as precision medicine, holds great promise to improve healthcare. According to the National Cancer Institute, 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 his or her healthcare. Realizing this vision presents a number of challenges, and much research is needed. Still, there are already a number of success stories that illustrate the potential for improving people's health. For example, personal genome sequencing has been used to diagnose children with rare conditions when other approaches have failed and has been applied in efforts to predict a person's susceptibility to a medical condition. In addition, a growing number of medications are prescribed based on a person's genetic make-up.

This lesson focuses on this idea of tailored treatments and the goal of using a person's genetic make-up to identify medications that will be most effective with minimal side effects. Traditionally, doctors prescribe a medication and then wait to see how the patient responds; some will respond positively, some will not respond at all, and some will have a negative reaction and suffer side effects. It is estimated that nearly 70% of Americans take at least one prescription medicine, and there are many questions about the risks of medications that are overprescribed, underused or given to people for whom the drug is not working as hoped. To read more, see "Smarter medication could save $213B in health care costs," by CBS staff, June 2013, *CBS News*.

The hope of personalized medicine is that a doctor can test a patient's DNA and better predict how he or she might react to a drug; in this way, the doctor will be treating the patient rather than the illness. The idea is to translate the knowledge that a patient's genes can impact the efficacy of and dosage for some medications into the ability to prescribe medicines more narrowly and with more precision. According to the National Institutes of Health's Genetics Home Reference, "pharmacogenomics is the study of how genes affect a person's response to drugs. 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."

A number of drugs, including those that can treat HIV, cystic fibrosis, depression, breast cancer and leukemia, have pharmacogenomic information in their label regarding an individual's genetic make-up. With genetic testing before treatment, people may avoid medications that will cause harm or be

ineffective, and hopefully find the drug that will most effectively treat their illness. In some cases, drugs are intended only for people with a specific genetic make-up. For example, Kalydeco is a cystic fibrosis drug that was approved in the United States in 2012 to treat the 4% of cystic fibrosis patients who carry a specific mutation in the CFTR gene. (More on Kalydeco is here: http://www.cff.org/treatments/therapies/kalydeco/.) Similarly, a number of cancer therapies are designed to target cancers that have acquired specific genetic mutations. Your genetic make-up can also influence how quickly you break down or metabolize certain drugs, which may make the same dosage of a medication work for one person, but ineffective or toxic for another. Warfarin, commonly known as Coumadin, is an anticoagulant used to prevent blood clots and is an example of a widely prescribed and successful drug for which the dosage can be adjusted based on genetic markers that influence a person's metabolism. The medical community is not uniformly aligned on the benefits of genetic testing for warfarin dosing, and research is continuing to examine whether genetic testing is helpful in finding the most safe and effective dose for patients and reducing the frequency of adverse reactions and hospitalizations. The field is still developing, and a targeted drug therapy approach informed by genetic testing will not yet work for every patient.

This lesson asks students to delve into the hopes and challenges of personalized medicine and to consider the practical applications of genetic analysis in medicine. Much of the emphasis is on pharmacogenomics. We also highlight cases of two children, Alexis Beery and Nic Volker, who suffered from rare conditions that were diagnosed and later treated as a result of genome sequencing. Articles about each family are included later in the lesson plan. Students are asked to synthesize the broader medical and scientific issues, and put the goals of personalized medicine in context as they develop their own educational brochure.

Here is an outline of the resources and activities in this lesson.
1. Reading for students (pages 3-4)
2. Do Now exercise (pages 4-5)
3. Creating a brochure (pages 5-7, handout on page 9, rubric on page 10)
4. List of additional resources (page 7)
5. Short quiz (answer key on pages 7-8, handout on page 11)

Reading for students:
Students should read Andrew Pollack's December 2008 *New York Times* article, "Patient's DNA May Be Signal to Tailor Medication" for homework before the lesson. This article introduces the concept of a personalized

approach to medicine that relies on genetic tests to identify drugs that may help or harm patients. The idea is that not all patients 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), creating a brochure (30-45 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 they are seeking 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 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 1990's, 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, the 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 (30-45 minutes)
Break students into groups to 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 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.

The instructions are formatted as a student handout on page 9 of this document, and a rubric is included on page 10. Each brochure should address the following questions and can include more topics if students do additional research:

A. Why are doctors and scientists excited about personalized medicine?
B. How has personalized medicine helped patients already?
C. How might people with asthma, cystic fibrosis or cancer benefit from personalized medicine?
D. What are the challenges of tailoring medicine to individuals or small numbers of people?
E. How could personalized medicine reduce health care costs in the United States?
F. Why might some drug companies resist the move to more personalized care?

Brochure preparation:
1. Divide students into groups of 4-5.
2. Assign each student a different article to read (see below for a list of articles). 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. The articles are broken into 7 topics. We suggest assigning topics to individual students within the groups, so each student can be accountable for reading and synthesizing the information for the group.

1. The following introductory articles discuss diseases for which genetic tests have helped determine who should or should not be treated with specific drugs. Articles vary in length and reading level; students need to read only one.
- "The benefits of personalized medicine," *The Jackson Laboratory.*
- "Frequently asked questions about pharmacogenomics," *NIH.*
- "Drug Companies Pursue Personalized Medicine Approach," by Andrew Pollack, November 2010, *New York Times.*

2. Nic Volker is a 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.
- "The First Child Saved By DNA Sequencing," by Matthew Herper, January 2011, *Forbes.*
- "Cord blood transplant saves boy, 6, from baffling ailment," by Michael Inbar, December 2010, *NBC News/The Today Show.*

3. The Beery twins were misdiagnosed with cerebral palsy as babies. Years of medical treatments, mysterious symptoms and a search for answers ensued. After having their genomes sequenced as teenagers, they were accurately diagnosed and successfully treated.
- "Gene Sequencing Helps Twins With Rare Disorder," by Jennifer Goodwin, June 2011, *US News and World Report.*
- "Genome Maps Solve Medical Mystery for California Twins," by Richard Knox, June 2011, *National Public Radio.*

4. These articles highlight conditions for which personalized medicine is beginning to yield some promising results. As noted in the article, the asthma findings are preliminary and the subject of on-going research.
- "Cystic fibrosis drug Kalydeco approved by FDA: What does it mean for patients?," by CBS news staff, January 2012, *CBS News.*
- "Asthma Treatment May Be Headed Toward Personalized Medicine," by Jeffrey Norris, October 2011, *University of California San Francisco News*.

5. The drug Herceptin can be used to treat certain types of breast cancer, specifically those that make too much HER2 protein. HER2 testing is routinely performed in people diagnosed with breast cancer.
   - "HER2 positive breast cancer: what is it?" by Sandhya Pruthi, April 2012, *Mayo Clinic.*

6. This article addresses some of debate around personalized medicine.
   - "Treating illness and preventing disease with genetic testing," by Clara Gaff and Ivan Macciocca, February 2014, *The Conversation*.

7. Personalized medicine has the potential to increase or decrease health costs. Students should note the advantages and disadvantages for drug companies to create more tailored medical treatments.
   - "Qiagen expands manufacturing," by Stephen Overly, August 2011, *Washington Post.*

Additional resources for teachers:

"Gene test helps patients avoid thyroid surgery," by Susan Young, February 2014, *Technology Review*.

"Personalized Medicine may be Good for Patients but Bad for Drug Companies Bottom Line," by Henry I. Miller, September 2013, *Forbes*.

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

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

"One In A Billion: A boy's life, a medical mystery," by Mark Johnson and Kathleen Gallagher, *Milwaukee Wisconsin Journal Sentinel*.

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

"Personalized Medicine" quiz answer key (see page 11 for quiz):
1. True
2. d) all of the above
3. Personalized medicine means a doctor can tailor a treatment plan based on the specific needs and physiological profile of an individual. For certain

conditions, doctors may be able to use genetic tests to determine the best treatment for an individual patient, for example to gain insight into how a patient may respond to a certain drug or treatment before beginning treatment. This is in contrast to a "trial and error" approach to prescribing medicine or a "one size fits most" model.

4. Answers will vary but 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.

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 asthma, cystic fibrosis or cancer benefit from personalized medicine?
D. What are the challenges of tailoring medicine to individuals or small numbers of people?
E. How could personalized medicine reduce health care costs in the United States?
F. Why might some drug companies resist the move to more personalized care?

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 his or her name to the section s/he 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 limitations of this new field   10 pts _____

How personalized medicine may impact health care 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 health care 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" to try to determine whether the medicine will help d) all of the above.

3. Explain what it means to "treat the patient" instead of "treat the disease."

4. How might people with asthma, cystic fibrosis or cancer benefit from personalized medicine?