BIOMED

Taking Action in Your Community: Health Equity

Public Health Agencies

Developed in partnership with: Discovery Education and Ignited

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Cover Image This is an illustration of coronavirus particles. BIOMED / TAKING ACTION IN YOUR COMMUNITY: HEALTH EQUITY

Public Health Agencies

DRIVING QUESTION

Why is it important for regulatory agencies to maintain independence and not be infused by politics or private interests?

OVERVIEW

Like other medical treatments and technologies, vaccines are heavily regulated. Due to their widespread usage, this is left not to private agencies but government regulatory bodies. With research often directed and funded by the National Institute of Health (NIH), and oversight primarily supplied by the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC), vaccine development and usage is tightly controlled and monitored.

In this lesson, students will learn which government agencies are involved in vaccine development, testing, and monitoring. They will examine the importance of accessibility and the hurdles that still exist for many families. Students will learn about the importance of keeping vaccine policy unencumbered by politicization or private interest groups' influence. The class will conclude this lesson by crafting a flow chart detailing the process of vaccine approval and the government agencies that oversee each step.

ACTIVITY DURATION

Five class sessions (45 minutes each)

ESSENTIAL QUESTIONS

How do government agencies ensure the safety of approved vaccines?

Under what circumstances are you required to be vaccinated?

What is the danger of allowing politics and special interest groups to have a role in vaccine development and policy?

OBJECTIVES

Students will be able to:

Distinguish between the roles of the FDA and CDC in vaccine regulation and monitoring.

Investigate barriers to vaccination for low-income families.

Create a flow chart detailing the vaccine approval process.

Materials

FDA vs. CDC Capture Sheet

FDA vs. CDC Skit Rubric

Skit Response Exit Ticket

Medical Research Initiative Capture Sheet

Pipeline Vaccines Chart

Pipeline Vaccines Chart Rubric

Encourage Vaccination Rubric

Politics in Vaccines Anticipation Guide

Vaccination Flow Chart Rubric

Large Sheets of Paper

Markers or Colored Pens

Design Journal

Pedagogical Framing

Instructional materials are designed to meet national education and industry standards to focus on in-demand skills needed across the full product development life cycle—from molecule to medicine which will also expose students and educators to the breadth of education and career pathways across biotechnology.

Through this collection, educators are equipped with strategies to engage students from diverse racial, ethnic, and cultural groups, providing them with quality, equitable, and liberating educational experiences that validate and affirm student identity.

Units are designed to be problembased and focus on workforce skill development to empower students with the knowledge and tools to be the change in reducing health disparities in communities.

SOCIAL-EMOTIONAL LEARNING

Students need to exhibit selfmanagement skills, such as good communication and cooperation, every day as they work in various groups. They will be learning about how illness and healthcare access can impact lower-income families. Learning about the struggles of others will encourage the use of self-awareness skills, such as empathy and acknowledgement of others' difficulties. This lesson will empower students to take action. build awareness, and make substantial changes to improve access and services. Students will demonstrate empathy and compassion, while identifying solutions for personal and social problems.

CULTURALLY AND LINGUISTICALLY RESPONSIVE INSTRUCTION

Students look for connections between vaccine development and health initiatives directed toward at-risk and underserved populations. Instructional strategies are used to provide culturally responsive options for peer interaction and validation of diverse cultures. The investigation of how vaccination initiatives are not appropriately reaching lower-income communities will allow for the bridging between students' realworld experiences and the content.

ADVANCING INCLUSIVE RESEARCH

In order for a therapy to be approved for use, it is mandated that the clinical trials used to test the treatment meet a certain level of diversity. Without testing a drug on a wide array of trial participants, it is impossible to know how differences in our genetic makeup might impact our response to the therapy.

COMPUTATIONAL THINKING PRACTICES

By crafting a flow chart that details the vaccine approval process, students are using the computational thinking strategies of decomposition and building algorithms. These strategies are especially useful for decoding processes and exploring the components of complex systems such as government regulation.

CONNECTION TO THE PRODUCT LIFE CYCLE

In this lesson, students craft a flow chart detailing the process of vaccine approval and the government agencies that oversee each step. The vaccine approval process includes clinical trials, FDA review and approval, technical operations, and input from commercial, medical, and government groups. A wide range of career fields are involved, including manufacturing, scientific, and political. This task hits on all four phases of the product life cycle: **discover**, **develop**, **manufacture**, and **commercialize**.



Have you ever wondered...

What role does the government play in vaccine development?

A variety of government entities oversees the research, testing, and monitoring of vaccines. The NIH works to promote and fund valuable research initiatives. The FDA monitors the clinical trial process, and, once approved, both the FDA and CDC keep track of adverse reaction reporting.

How does the government protect its citizens from unsafe vaccines?

The standard for vaccine approval and continuation is extremely high. Because vaccines are usually given to otherwise healthy individuals, any negative impact is weighed heavily. Healthcare providers, patients, and family members can file vaccine adverse reaction reports, which are closely watched for any trends. If individuals believe a vaccine has hurt them, they are welcome to bring these complaints to court through the Vaccine Injury Compensation Program (VICP).

MAKE CONNECTIONS!

How does this connect to the larger unit storyline?

Vaccines are a mainstay of doctors' appointments for our nation's children. They are often a requirement for attending school, recommended for overseas travel, as well as being a line of defense against pandemics. As a medical intervention is administered to most of the population, government agencies must closely monitor its development, distribution, and safety. This responsibility is shared across multiple groups, such as the FDA, NIH, and CDC. While vaccines are most often routine in the face of spreading infectious disease, they can become paramount in defending a population. As vaccine development fights against the clock to save lives, it becomes even more important to have strong support and safety nets for their development to protect citizens.

How does this connect to careers?

Health service officers of the FDA or CDC are responsible for ensuring that every pill we take and every injection we receive meet high standards of safety and efficacy. Without these organizations and their experienced professionals, the public would be exposed to innumerable dangers and lose faith in vaccination as a form of protection against disease.

4 4 5

How does this connect to our world?

While the idea of government involvement with vaccines leads to some conspiracy theories, the truth is that government oversight is required to guarantee the safety of millions of people. Vaccines must be effective, and they must be safe to keep a population healthy. Multiple agencies are hard at work monitoring clinical trials and studying trends in adverse reporting data to make certain of this.

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Students will be able to:

Role-play as CDC or FDA employees.

Research the role of government agencies in vaccine production and safety testing.

Procedure

| Whole Group (8 minutes) | | | |
|-------------------------|--|--|--|
| 1 | Show <i>The Journey of Your Child's Vaccine Infographic</i> to the whole class to introduce some of the regulatory agencies involved in securing a vaccine's safety. | | |
| 2 | Have the class simply <i>Give a Shout Out</i> for the answers to: What are some of the government agencies you heard mentioned in the infographic? | | |

Small Group (25 minutes)

Have students break into groups of three to four. They will review the following websites, detail the role of the FDA and the CDC in vaccine development, and safety testing. Each group will create a two- to-three-minute skit of an interaction between employees of the FDA and the CDC. Students will use the *FDA vs. CDC Capture Sheet* to outline the roles and write their skits.

FDA—Ensuring the Safety of Vaccines in the United States

CDC—Vaccine Safety Monitoring

Teacher Note > Depending on your students, it may be beneficial to assign group members to defined roles, such as actors, skit writers, or graphic organizer scribes. Otherwise, let the groups choose the roles among themselves.

Whole Group (12 minutes)

Have students perform their skits for the class. They should complete the *Skit Response Exit Ticket*.

Teacher Note > *Use the FDA vs. CDC Skit Rubric to assess student work.*

Explain to students that the FDA maintains MedWatch. MedWatch is a web-based reporting system that gives consumers and health professionals the chance to voluntarily report major adverse events and other significant problems that they believe are linked to the use of a particular FDA-regulated product. Allow advanced students to read the article Adverse Event Detection, Processing, and Reporting to learn how agencies respond to reports of adverse events.

INDUSTRY AND CAREER CONNECTION

Students will be learning about FDA guidelines while completing this assignment. They will also need to maintain organized notes to differentiate between the roles of the two agencies.

LEARNING OUTCOMES

Students will be able to:

Relate vaccine development to research initiatives for at-risk groups.

Investigate illnesses for which there may be a forthcoming vaccine.

CULTURALLY AND LINGUISTICALLY RESPONSIVE INSTRUCTION

This type of culturally responsive participation protocol allows for students to control their participation.

COMPUTATIONAL THINKING IN ACTION

These "pipelines" are examples of how to use the computational thinking strategies of decomposition and developing algorithms to break down a process into sub-steps.



Procedure

Whole Group (5 minutes)

Introduce students to the role of the NIH through the video *Interview with Anthony Fauci M.D.: The Value and Impact of NIH Funded Research*. Ask a couple of student volunteers to summarize the main points from the video.

Small Group (15 minutes)

In pairs, have students explore the NIH's current overarching *Medical Research Initiatives*. Groups should identify four initiatives that focus on at-risk or underserved groups and may conduct research that would be beneficial during a pandemic. Students should use the *Medical Research Initiative Capture Sheet*.

Whole Group (5 minutes)

Show the *What is the World Health Organization?* video to the class (start at the 15 second mark). After, ask the class for two to four questions, and ask as many students to volunteer to answer, using the *Train or Pass It On* strategy.

Individual Work (20 minutes)

Have students select four "pipeline vaccines" from the *Immunization, Vaccines and Biologicals* website. They should use the *Pipeline Vaccines Chart* to record important information about the illness being combated, where outbreaks occur, and how the illness is transmitted and treated.

Students can use the CDC's *Infectious Disease A to Z List* website to complete the chart.

Teacher Note > Use the Pipeline Vaccines Chart Rubric to assess students' work. If these vaccines are in the pipeline and not currently available, ask students to hypothesize why the vaccines do not already exist. Explain that not enough people get the disease and/or the organism changes too frequently.

LEARNING OUTCOMES

Students will be able to:

Investigate barriers to vaccine access for low-income families.

Devise an initiative to increase timely vaccinations in a community.



Procedure

Whole Group (5 minutes)

Pose the question to the class: Vaccination rates for children in lower-income households lag behind the vaccination rates for those in more affluent households. What may be some barriers for lower-income families in obtaining these vaccinations? Let students know that they will use a silent group instructional strategy to answer this question.

Small Group (5 minutes)

Shift students into groups of four. Students should work at tables or move their desks together to participate in an instructional strategy called *Paper Chat*. Each group will receive a large sheet of paper, and every student should be given a different colored marker or pen. Stress to students that this is a SILENT exercise. Students should write their responses to the whole group question on the paper. The purpose of this strategy is to help students develop critical thinking and communication skills, while providing a format for every student to have a voice.

Teacher Note > *This initial response should be brief as it is just a preview of the article they will be reading. Responses do not have to be in full sentences.*

Small Group (20 minutes)

1

2

Play a read aloud video version of the article *The Other Reason Kids Aren't Getting Their Vaccinations: Poverty and Healthcare Access.* While they listen, students should respond to the article using the *Paper Chat* strategy with a large sheet of paper. They can write personal reactions, quotes, questions, and/or highlight connections to previous notations to identify reasons why families sometimes struggle with vaccinations.

Teacher Note > *The audio recording is about four minutes long.*

Paper Chat is a cooperative teaching and learning strategy that enables students to take part in group activities. Use this strategy when there are broad essential questions that engender deep discussion and everyone in the room needs to be involved without judgment. The Paper Chat strategy helps students develop critical thinking and communication skills, in addition to developing patience and respect.

COMPUTATIONAL THINKING IN ACTION

The large sheet of paper will be swapped out for a second sheet of paper (groups should retain the first sheet). Have students now read a different article independently, *Is It Lawful and Ethical to Prioritize Racial Minorities for COVID-19 Vaccines?* They will repeat the activity from before—silent reading and "speaking" to each other using the instructional strategy *Paper Chat*.

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Procedure

Small Group (15 minutes)

- 1 Government organizations around the world must consider how to encourage their populations to become vaccinated in order to discourage outbreaks and epidemics. Various countries have tried different tactics over the years, with this Australian initiative being one of the more highly publicized and controversial attempts: *No jab no pay immunisation requirements.* Share this example with students.
- 2 Students are tasked with devising a way to encourage communities to get their families up to date on their vaccinations. They are encouraged to use their table notes from before. Their strategy should focus on underserved populations. Students should create some artifact about their initiative. In order to influence leaders, educate the public, and/or gain community trust, students can write a report, create a PowerPoint presentation, make a poster, shoot a video, etc.

Teacher Note > *Use the Encourage Vaccination Rubric to assess student work.*



LEARNING OUTCOMES

Students will be able to:

Discuss the dangers of politicizing vaccines.

Respond to private interest groups influencing vaccine policy.



Procedure

Individual Work (5 minutes)

Have students examine why it is important to keep political and private interests out of vaccine development, testing, and policies. Ask them to complete the *Politics in Vaccines Anticipation Guide Capture Sheet*.

Small Group (20 minutes)

1

Direct students to form groups of three. Once in their groups, have students independently read the The New England Journal of Medicine article *Beyond Politics—Promoting COVID-19 Vaccination in the United States.*

Teacher Note > Help any struggling readers and/or English language learners by providing definitions for any difficult vocabulary present in the article. Words that might need definitions include "partisan," "emblematic," and "antibody." Another option is to do a shared reading activity of the introduction and then Jigsaw the remaining content.

2

Each student will fold a sheet of paper into four quadrants. In the upper left-hand quadrant, have students respond to the prompt: Why is it important to keep political influence out of vaccine development and testing? Then, students will pass their papers to the student on their left. In the upper right-hand quadrant, students will respond to their classmates' writing. Once finished, students pass the papers to the student on their left. In the lower left-hand quadrant, students will respond to both writings. Finally, the report will return to the original writer, who will respond to their groupmates' writing.

Teacher Note > It is helpful to have the prompt visible on the board for all students to see. Some students may process information and/or write faster than others, so that is an important consideration when forming groups.

LEARNING OUTCOMES

Students will be able to:

Create a flow chart detailing the vaccine approval process.

COMPUTATIONAL THINKING IN ACTION

By creating a flow chart, students are getting hands-on experience with the computational thinking strategy of developing algorithms, which are stepby-step instructions on how to complete a task.

Procedure

Whole Group (5 minutes)

Present the *How to Use Flow Charts* video to demonstrate how to create an effective flow chart for the class. Ask students to take notes while watching the video.

Small Group (40 minutes)

1

- Ask students to work in pairs to construct a flow chart detailing the steps of the vaccine approval process. They should use the CDC's *Vaccines for Your Children* website to construct their flow charts.
- 2 Students can create a poster, presentation, Canva project, or Padlet detailing their findings. Students should use the *Vaccination Flow Chart Rubric* as a guide.
- 3 Invite students to use their **Design Journal** to respond to the guiding questions and capture how content learned in this lesson connects to the culminating social awareness campaign project. They will summarize the government's role in vaccine approval and policy.

National Standards

| Next Generation Science Standards | Science and Engineering Practices Constructing an explanation Evaluate the claims, evidence, and/or reasoning behind currently accepted explanations or solutions to determine the merits of arguments. Compare and evaluate competing arguments or design solutions in light of currently accepted explanations, new evidence, limitations (e.g., trade-offs), constraints, and ethical issues |
|--|--|
| Career and Technical Education | A7.1 Identify agencies at the local, state, and federal levels. |
| (CTE) | A7.2 Be aware of the role of agencies in promoting patient safety, quality control, and entrepreneurship. |
| | A2.5 Describe the dilemma of health care costs related to advancements in biotechnology and public access to treatments. |

FDA vs. CDC Capture Sheet

Directions

Review the websites, which detail the role of both the FDA and the CDC in vaccine development and safety testing. Work with your group to create a two- to three-minute skit of an interaction between employees of the FDA and the CDC. Use this graphic organizer to outline the roles and write their skit.

FDA Ensuring the Safety of Vaccines in the United States

CDC Vaccine Safety Monitoring

Food and Drug Administration (FDA)

1. Does this organization work on the safety of a vaccine before it is approved? If so, how?

Once you have all the information needed, network as a group to write your skit of CDC and FDA employees interacting. Some considerations would be: Will they be discussing how they work together? Arguing about who has a more important job? Discussing how they will manage a raging epidemic? The choice is yours!

Center for Disease Control (CDC)

1. Does this organization work on the safety of a vaccine before it is approved? If so, how?

- 2. Does this organization work on the safety of a vaccine after it has been approved for the public? If so, how?
- 2. Does this organization work on the safety of a vaccine after it has been approved for the public? If so, how?

FDA vs. CDC Skit Rubric

| Score | 3 | 2 | 1 |
|----------------------|--|---|--|
| Graphic Organizer | Completed with fidelity, several useful details recorded. | Mostly completed, lacked details. | Not completed. |
| CDC Employee | The role of the CDC in vaccine production and monitoring was well explained. | Skit touched on the role of the CDC, but the information was minimal. | Skit did not explain the role of the CDC in vaccine safety and monitoring. |
| FDA Employee | The role of the FDA in vaccine production and monitoring was well explained. | Skit touched on the role of the FDA, but the information was minimal. | Skit did not explain the role of the FDA in vaccine safety and monitoring. |
| Interaction | Interaction of characters taught the audience about the roles of each organization in vaccine safety and monitoring. | The interaction did not explain much about the two agencies. | Employee interaction was not related to vaccines. |
| Performance | Students made a great effort to inform and entertain their classmates. | Students made an effort to deliver lines and act out a skit. | Students could not be heard, barely spoke, or declined to participate. |
| Final Score | | | |

Skit Response Exit Ticket

Directions

Reflect on the today's performances and answer the questions.

- 1. Whose skit did you find most informative? Why?
- 3. Reflect on the pros and cons of your skit. What were the strengths of your skit and what were elements that need improvement?

- 2. Whose skit was the most fun to watch? Why?
- 4. What was the most important piece of information that you learned from watching your classmates' performances?

Medical Research Initiative Capture Sheet

Directions

In pairs, explore the NIH's current overarching Medical Research Initiatives. Identify four initiatives that focus on at-risk or underserved groups and may conduct research that would be beneficial during a pandemic.

| National Institutes of Health Initiative | What is the goal of this initiative? | What underserved group does this study benefit? | How might this study aid people during a pandemic? |
|---|--|--|--|
| Example: NIH Heal Initiative | The goal is to speed up scientific solutions to the opioid crisis. | It benefits those suffering from opioid drug addiction, which disproportionately affects people of color and those in lower socio- economic levels. | Opioid addiction leads to pre-existing conditions and weakened immune systems. By aiding these communities, we could reduce the number of infections and slow the spread of disease. |
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Pipeline Vaccines Chart

Directions

Select four "pipeline vaccines" from the Immunization, Vaccines and Biologicals website. Identify important information about the illness being combated, where outbreaks occur, and how it is transmitted and treated.

| Pipeline Vaccine Name | Information About Illness Being Combated | Where Outbreaks Occur | How It is Transmitted | How It Is Treated |
|--------------------------|--|--------------------------|-----------------------|-------------------|
| | | | | |
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Pipeline Vaccines Chart Rubric

| | Score | 3 | 2 | 1 |
|--|-------------|--|---|---|
| | Vaccine #1 | Information on vaccine includes details of illness, location of outbreaks, transmission, and treatments. | Vaccine information covers some topics of illness, location, transmission, and treatments. | Information on vaccine is mostly or entirely missing. |
| | Vaccine #2 | Information on vaccine includes details of illness, location of outbreaks, transmission, and treatments. | Vaccine information covers some topics of illness, location, transmission, and treatments. | Information on vaccine is mostly or entirely missing. |
| | Vaccine #3 | Information on vaccine includes details of illness, location of outbreaks, transmission, and treatments. | Vaccine information covers some topics of illness, location, transmission, and treatments. | Information on vaccine is mostly or entirely missing. |
| | Vaccine #4 | Information on vaccine includes details of illness, location of outbreaks, transmission, and treatments. | Vaccine information covers some topics of illness, location, transmission, and treatments. | Information on vaccine is mostly or entirely missing. |
| | Final Score | | | |
| | | | | |

Encourage Vaccination Rubric

| Score | 3 | 2 | 1 |
|-------------|--|---|--|
| Appearance | Final product is attractive, eye-catching, and professional looking. | Some effort was put into the presentation, but it is minimal. | Final products is rushed and sloppy with obvious spelling and grammatical errors. |
| Encouraging | Final product is encouraging and supportive of completing vaccinations. | Moderate effort is made to encourage vaccination with little detail and information given. | Information encouraging vaccination is mostly or entirely missing. |
| Informative | Final product is very informative on the importance of up-to-date vaccinations, where to access them, etc. | Some information on the importance of timely vaccinations is given, but no details are provided. | No information is given. |
| Sympathetic | Demonstrates an understanding of barriers that may prevent or discourage vaccination. | Some sympathy or understanding of barriers to vaccination is demonstrated. | No sympathy or under- standing of barriers to vaccination is demonstrated. |
| Final Score | | | |

Politics in Vaccines Anticipation Guide

Directions

Examine why it is important to keep political and private interests out of vaccine development, testing, and policies. Respond to whether you agree or disagree with each statement. Briefly share your reasoning in the appropriate column.

| | | Support | Concerns |
|--|---|---------|----------|
| The government should be involved in vaccine policy. | Agree Disagree | | |
| The government should be allowed to encourage the development of a vaccine. | ☐ Agree ☐ Disagree | | |
| Politicians can set deadlines for when vaccines are approved. | ☐ Agree ☐ Disagree | | |
| The government's strong or weak management of a public health crisis can change how someone may vote. | ☐ Agree ☐ Disagree | | |
| Vaccination policies can and should be changed with different governing administrations. | ☐ Agree ☐ Disagree | | |

Vaccination Flow Chart Rubric

| | Score | 3 | 2 | 1 |
|--|------------------------------|---|---|---|
| | Appearance | Flow chart is neat and easy to navigate, writing is legible. | Some effort made in creating presentation, mostly readable. | Flow chart is sloppy and difficult to read. |
| | Appropriate Use of Shapes | Student appropriately used elongated ovals, squares, and diamonds. | Student used standard flow-chart shapes, but not consistently or correctly. | Student made no effort to use correct shapes. |
| | Process Steps | All steps of the vaccine approval process are present and correctly ordered. | Some steps missing or in the incorrect order. | Flow chart missing approval process. |
| | Information | Students concisely summarized each step of the process. | Some information provided but incorrect or very minimal. | Students do not supply any information about the steps. |
| | Government Agency | All government oversight mentioned where appropriate. | Some steps included government agencies. | No mention of an associated overseeing government agency. |
| | Final Score | | | |