NYU Grossman School of Medicine

DIVISION OF MEDICAL ETHICS
HIGH SCHOOL BIOETHICS PROJECT

Synthetic Biology

Overview

Synthetic biology is an emerging field of science that integrates engineering principles with biology to design and build new biological systems (Kaebnick et al. 2014). Put a different way, synthetic biologists intentionally create cells or organisms with different characteristics. The applications of synthetic biology are wide-ranging, including developing better treatments for diseases, controlling mosquito populations, and creating more sustainable energy sources. The transformative power of synthetic biology has the potential to significantly change our lives.

In fact, programming cells and organisms for useful purposes is exactly the goal of synthetic biology. Ever since Hershey and Chase discovered that DNA was the molecule of heredity in 1952, scientists have been experimenting with ways to recombine and manipulate DNA to alter the traits or behavior of organisms (Johns Hopkins University 2017). The definition of synthetic biology remains fluid, and there are often overlapping and ambiguous boundaries between related terms such as genetic engineering, genome engineering, and biotechnology (Kuiken 2022).

Even so, synthetic biology is generally regarded as a step beyond traditional genetic engineering. If genetic engineering can be compared to adding an extra leg to a table to enhance its stability, synthetic biology in this analogy would be building the table from scratch by designing and assembling different parts (Massachusetts Institute of Technology 2014).

Harnessing knowledge built up over the past few decades as well as new genetic engineering tools (such as CRISPR), the capabilities and power of synthetic biology have gradually expanded. However, greater possibilities also bring greater risks, raising significant ethical concerns about the use, potential misuse, and regulation of synthetic biology.

What have scientists already achieved in the field of synthetic biology? What are its current applications and how might it be used in the future? How will synthetic biology affect us, and what are the ethical and social implications? In this module, students will delve into these questions to gain a fundamental understanding of the current uses, future applications, and ethical considerations associated with synthetic biology.

Contents

Learning Outcomes

1. Explore significant scientific accomplishments in the field of synthetic biology
2. Learn about various real-world applications of synthetic biology in different areas and assess the potential benefits and harms
3. Think critically about related ethical and social concerns and formulate opinions
4. Understand the challenges of public engagement

Procedures and Activities

This module uses a student-led, interactive approach. Activities are structured to promote student engagement and collaboration through a mix of individual tasks, partner work, group projects, and teacher-led class discussions.

1. Introduction to the Topic

Individual and Partner Activity

The purpose of this activity is to encourage students to start brainstorming about the possibilities of synthetic biology without requiring prior knowledge of the subject. Students will begin by answering the following questions individually.

- If you could program cells and organisms to do anything you want, what would you do? Consider applications in different areas, including but not limited to medicine, environmental protection, energy production, industries, and agriculture.
- If your plan were to come true in real life, who would benefit it?
    - Would the benefits be fairly distributed? Or limited to certain groups of people?
- Is it likely to be misused? What would be some risks involved?
    - Who might be harmed?
- Do potential benefits and risks accrue to the same people?
- How might you regulate synthetic biology? Would you regulate research, or applications, or both?

Next, students will discuss their responses with a partner. Identify any gaps in their partners' answers and revise them together.

2. History and Evolution of Synthetic Biology

References to "synthetic biology" appeared as early as 1912, when Stéphane Leduc proposed that chemical and physical processes may enable biological processes or “life” (Barbara Kubica 2014; Clément 2015). However, it was not until decades later that scientists started to be able to truly understand these relationships and use that knowledge to design and create new forms of life.

Recombinant DNA (rDNA) technology, the method of combining DNA segments from different sources, is the predecessor of synthetic biology. Scientists first became capable of manipulating DNA and genes at the molecular level in the 1970s (Massachusetts Institute of Technology 2014). In 1973, Herbert Boyer and Stanley Cohen inserted two antibiotic resistant genes into a plasmid vector, a small circular piece of DNA that exists naturally in bacterial cells, and introduced this recombinant plasmid into harmless strains of *Escherichia coli*, a type of bacteria commonly found in the human gut (Science History Institute; Science

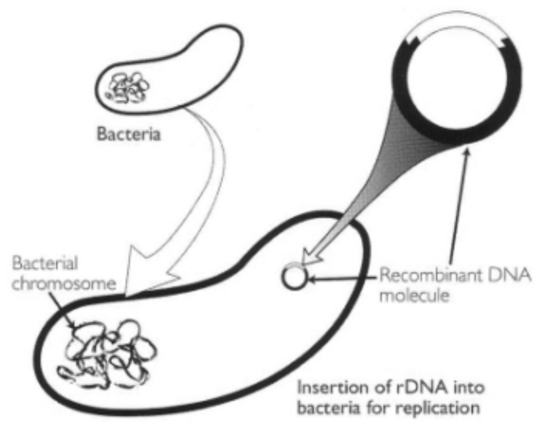

Image Credit: Science History Institute

Learning Lab 2014).

This experiment quickly garnered attention among the scientific community, which collectively agreed that rDNA research should proceed, but it must be accompanied with appropriate safeguards due to concerns and uncertainty about the risks of manipulating genetic material (Johns Hopkins University 2017). In 1976, the National

Institutes of Health released the Guidelines for Research Involving Recombinant DNA (rDNA) Molecules, which established conditions for the conduct of experiments involving rDNA (these guidelines have been periodically updated, most recently in 2024) (Department of Health and Human Services and National Institutes of Health 2024).

In the early stages of genetic engineering, researchers were able to make *E. coli* produce human insulin and the human growth protein somatostatin by inserting synthetic versions of the related human genes into the bacteria (Amgen). In 1980, a Supreme Court ruling clarified that live, human-made microorganisms are patentable (U.S. Supreme Court 1980).

Since then, scientists have gone beyond manipulating the expression of existing genes and started to program new biological systems such as metabolic pathways, tissues, and even entire organisms with an engineering approach. In 1999, Adam Arkin and Drew Endy proposed a list of “systematized biological components that can be generically assembled to create custom biological circuitry,” similar to how one might use building blocks to make a Lego house (Arkin and Endy 1999). In 2002, the polio virus was constructed from scratch using commercially available nucleic acid base pairs, raising concerns about potential intentional misuse or unintentional harm (Josefson 2002). This was followed by the first synthetic bacterial genome in 2008 (National Human Genome Research Institute 2019). Many people consider 2010 to be the true beginning of synthetic biology, when the J. Craig Venter Institute created the first “synthetic organism”: the researchers synthesized the full *Mycoplasma mycoides* genome and transplanted it into the cell of a different organism, which survived and self-replicated with only synthetic DNA (Johns Hopkins University 2017; Kaebnick et al. 2014).

Synthetic biology has emerged as a powerful and rapidly growing engineering discipline, dedicated to designing new genetic circuits, interactions, and organisms to exhibit functions not found in nature. Why does all of this matter? The answer lies in its applications.

3. Applications

Synthetic biology and genome engineering have enormous potential and a wide range of applications, including improving the commercial production of ethanol, a key biofuel, and β-carotene, a widely used natural pigment in food, pharmaceutical, and nutrition industries (Adebami et al. 2021; Wang et al. 2021). In fact, products using genetic engineering and synthetic biology approaches are more common than you might think.

- Food Industry

A synthetic version of vanillin—an important flavor component of vanilla beans—is produced by genetically modified yeast that contain additional plant genes. Synthetic vanillin now captures 88.7% of the market (Future Market Insights 2024).

- Fashion Industry

Yeast can also be genetically modified to produce spider silk proteins that are used to make fully biodegradable fibers. With this method, fabrics can be produced with less environmental impact than traditional textile manufacturing, which often requires plastic fibers that persist in the environment (Bolt).

- Ecology

Synthetic biology is increasingly being applied to ecological contexts, with projects ranging from creating new variations of organisms for aesthetic novelty to ideas about large-scale species reintroduction. The firefly petunia, a genetically engineered flower that glows in the dark, was named one of Time's "Best Inventions of 2024" (Light Bio 2025). Sold commercially for $39.99 per pack, its widespread availability and lack of regulatory oversight raises questions about accidental release into the environment (Lisy 2024).

In a more complex application, researchers from Colossal Laboratories have used synthetic biology to "revive" the extinct dire wolf by editing gray wolf cells, incorporating 20 genetic changes across 14 genes. Their stated goal is "reintroducing species—both endangered and extinct—to the natural habitats that need them." Colossal also seeks to bring back the woolly mammoth, the dodo, and the Tasmanian tiger (Colossal Inc. 2025). The return of species to ecosystems may restore them or cause a new set of unanticipated changes.

Synthetic biology is also being explored as a tool for engineering microbes to break down ocean plastics or modifying coral symbionts to increase resilience to bleaching (Nguyen et al. 2023). While these innovations offer promising solutions to human-induced challenges, the risks of unintended ecological consequences cannot be overlooked.

- Health

Genetic engineering was used to create a treatment for spinal muscular atrophy (SMA), the second most common severe hereditary disease of infancy and childhood after cystic fibrosis (Cleveland Clinic). SMA patients are born with a missing or nonworking *survival motor neuron 1 gene (SMN1)* gene, which is essential for controlling muscle movement. First approved by the U.S. Food and Drug Administration in 2019, the treatment involves delivering a new, working *SMN* gene to the patient's motor neuron cells using a vector made from a virus (Mahajan 2019). This one-time therapy replaces the function of the *SMN1* gene, preserving essential muscle function (Novartis Gene Therapies 2023). There are now a number of genetically modified gene and cell therapies on the market for different types of genetic diseases, as well as for cancers (FDA 2024).

- Agriculture

Biotechnology company Pivot Bio has re-engineered a type of bacteria to alter its genome and nitrogen-fixing pathways, enabling it to provide nitrates to crops that it would not normally associate with. This development is now available to most farmers in the United States, providing them a more sustainable alternative to conventional nitrogen fertilizers with chemicals harmful to the environment (Garner 2021).

On dairy farms, cows typically undergo dehorning to reduce the risk of injury to other animals and dairy workers. However, this procedure can be painful, raising concerns about animal welfare. Researchers at the University of California, Davis, have developed hornless cows by using an engineered bacterial plasmid to introduce a naturally occurring allele for hornless trait. This method offers a pain-free alternative to traditional dehorning (Quinton 2019).

- Synthetic Genome for Research Purposes

Building on earlier work in creating synthetic microorganisms, a group of researchers at New York University has completed the development of the first synthetic eukaryotic designer genome, known as Sc (*Saccharomyces cerevisiae*) 2.0. Since its inception in 2007, this project has expanded into a global initiative, engaging hundreds of high school and undergraduate students who have thereby achieved impressive results in genome synthesis and assembly (Boeke 2024). As these students gain hands-on experience in cutting-edge synthetic genomics, they are actively advancing the field of genetic engineering. The Sc 2.0 project is not only exciting from a scientific standpoint but also innovative in its engagement of young scientists, serving as an impressive example of genetics education alongside technical accomplishment. See more: https://syntheticyeast.github.io/

- Engineering animals for human (xeno)transplantation

In April 2024, surgeons at New York University Langone Health performed a groundbreaking procedure combining a mechanical heart pump with a gene-edited pig kidney and thymus gland transplant. This followed earlier successes in pig heart-human transplant, with the first being in January 2022 at the University of Maryland Medical Center (Kotz 2023). The organs came from a pig in which genetic alterations were made to make their organs suitable for transplant. For example, some changes, such as editing out the gene responsible for producing the sugar alpha-gal, were made to prevent immune reactions and reduce the chance of rejection (New York University Langone Health 2024). Other genetic alterations limit organ growth and prevent inflammation and blood clot formation in the transplanted organ (Revivicor). Advances in genome editing offer new hope for making xenotransplantation a viable option for patients facing terminal illnesses and organ shortages.

4. Ethical and Social Implications

Group Activity

Synthetic biology raises many ethical concerns, including issues of equity and access to new technologies, the potential for unintended consequences, and the moral implications of "playing God" by redesigning life. In this section, students will evaluate the following scenario that synthetic biology has made possible and answer the questions in small groups. This activity will help students think critically about the ethical concerns associated with exercising the power of synthetic biology.

Gene drives are naturally occurring or genetically engineered mechanisms that enable specific genes to spread in populations much more rapidly than other genes. Recently, scientists have been exploring the use of gene drives to eradicate certain species—in the case of Paul Thomas and his colleagues, invasive mouse populations on islands. By changing an essential female fertility gene to the natural gene drive *t haplotype*, they were able to disable 80% of the fertility genes in one generation of the mouse population, rendering the female mice incapable of becoming pregnant. Eventually, the population would be completely eliminated. This approach offers a potentially more effective alternative to traditional pest control methods like poisoning or trapping (Le Page 2022). However, gene drives could unintentionally spread beyond the intended populations, or disrupt the food chain in unanticipated ways, leading to serious irreversible ecological impacts. Additionally, the deployment of gene drives raises ethical concerns about humans' relationship with the environment and questions about who holds the authority to make decisions that could permanently alter ecosystems.

Discuss the following questions together:

- What benefits would there be? To whom would the benefits accrue?
- What level of harm must a species cause to justify its elimination?
- Is eliminating a species from an island inherently wrong or is this an appropriate use of technology? Why?
- Are humans wielding too much power or are they acting as responsible stewards of the environment?

A. Balancing Opinions

You might have encountered disagreements in the process of working with others to answer the questions. In a situation when there was no definite right or wrong, did your group come to an agreement? Now, imagine you are various stakeholders affiliated with different organizations and carrying different interests—residents of the nearby area, individual scientists, pharmaceutical companies, academic research institutions, and national-level federal agencies. Developing a multi-stakeholder approach for the governance of synthetic biology is crucial for incorporating diverse voices that may be impacted by policy, but it also presents its own challenges. Whose opinions would hold more value in the decision-making process? Who would represent the voices of the general public, who may also be affected?

B. Playing God

Advances in synthetic biology can make some people feel uncomfortable. The engineered cells and organisms might be considered "unnatural" and the scientists as abusing their powers and "playing God" (Garner 2021). The phrase suggests that humans have transgressed fixed limits to our role and broken an established natural order. Is there a boundary to be drawn between the natural and unnatural, what humans are allowed to do and not allowed to do?

Embodying this opinion is scientist Pat Mooney, in his response to J. Craig Venter seeking a patent on the synthetic organism *Mycoplasma laboratorium*. "For the first time, God has competition. Venter and his colleagues have breached a societal boundary," said Mooney. Venter's goal in claiming monopoly on the engineered bacterial cell *Mycoplasma laboratorium* was to seek future commercial gains, as he had envisioned it to be a basic platform for building other industrially useful and profitable synthetic organisms (ETC 2007).

However, some think that the playing God argument adds little to the debates about synthetic biology. Philosopher Keith Douglass Warner noted, "Religious ethics can play a more constructive role in the debate on agricultural biotechnology by addressing [the] patent regime rather than by raising questions about 'playing God' through genetically engineering germplasm, questions that are hard to answer and unlikely to be resolved in industrial societies" (van den Belt 2009).

While the "playing God" phrase can be viewed as merely an alarmist slogan, its popularity in news and media indicates public concern about the appropriateness of some human actions. Should we set a limit to scientific progress out of reverence for “the natural”? Is synthetic biology tampering with nature in inappropriate ways?

C. Equity and Access

Applications of synthetic biology have to be economically viable to come to realization (Massachusetts Institute of Technology 2014). If synthetic biology yields new treatments and cures for diseases, who will have access to them?

The gene therapy for treating SMA, mentioned in the previous application section, was priced at $2.125 million for the one-dose treatment (Mahajan 2019). While these new therapies have the potential to be lifesaving and even curative, their high costs raise significant justice concerns, creating a financial barrier for many patients with significant unmet medical needs. Perhaps even more devastating than an untreatable illness is the inability to pay for existing life-sustaining medical care. Should such products even be commercialized if they can further exacerbate inequality in access to healthcare and medicines? What, if anything, should be done to maximize access?

Equity concerns are not limited to an individual level, but also exist on a global scale. Pharmaceutical companies might not be financially motivated to develop and sell synthetic biological products for underdeveloped, poorer markets, where the people who would benefit might be unable to pay (Buchanan and Powell 2011). As industries transition to biomass-derived feedstocks for energy production, the demand for plant material will increase substantially. Biomass used in the process will largely be cultivated in the global South, which has historically been a primary source of raw materials due to the low production costs and favorable climate. This shift will disrupt already fragile ecosystems and cause further environmental damage from industrial agriculture (Friends of the Earth et al. 2012). Should the global South bear this extra burden? If not, what region will?

D. Dual Use

Dual use research refers to research with legitimate scientific purpose but also has the potential to provide knowledge that endangers public health and/or national security. This category of research gained significant public attention after the anthrax attacks in 2001, during which letters containing the dangerous infectious anthrax spores were sent to legislators and to several news media offices, causing the deaths of five people (Johns Hopkins University 2017). Researchers have the ability to synthesize dangerous pathogens that can spread extensively and cause severe illness and death. While such efforts can improve our understanding of diseases and accelerate the development of effective countermeasures like vaccines, they also carry inherent risks of accidental release (Johns Hopkins University 2017). If lab workers become infected, they may unknowingly transmit it to others, starting a larger outbreak. Alternatively, the engineered pathogens may fall into the hands of those with malicious intentions, turning the products of legitimate scientific research into biological weapons. Dual use research raises significant ethical concerns because of the potential for harm. Recently, an executive order, "Improving the Safety and Security of Biological Research," was released which calls for the development of new policy on dual use research, including "dangerous gain-of-function research on biological agents and pathogens" (The White House, 2025).

Teacher-Directed Class Discussion

Some speculate that Covid-19 may have originated in Wuhan, China, due to gain-of-function research conducted at the Wuhan Institute of Virology, which involves modifying pathogens to increase their transmissibility or pathogenicity in order to study potential treatment or prevention methods (U.S House of Representatives Select Subcommittee on the Coronavirus Pandemic Committee on Oversight and Accountability 2024). However, this theory is difficult to definitively confirm and zoonotic, or natural, origins are still considered possible (Select Subcommittee on the Coronavirus Pandemic, 2024). If the pandemic was caused by a lab leak, it would represent the most catastrophic scientific accident in scientific history. In the opening statement at the hearings on "Investigating the Origins of Covid-19," Dr. Jamie Metzl said: "If we do not get to the bottom of what went wrong with the Covid-19 pandemic, if we fail in our efforts to fearlessly understand all shortcomings and shore up the vulnerabilities this crisis has so clearly exposed, the victims of the next pandemic, our children and grandchildren, will ask us why we failed to protect [them] when we knew what was at stake and had the chance" (Committee On Oversight and Accountability 2024).

After discussing the varying theories of the origins of the Covid-19 pandemic, teachers should divide students into two groups to evaluate the implications if the lab leak theory were proven true.

Would it change your perspective on dual-use research and its regulation? How would your opinions be influenced by your personal experience living alongside a global pandemic? Students should discuss within their groups first, then come together as a class and share their responses.

E. Environmental Impacts

As seen in the previous section, potential applications for engineered organisms are vast, and many involve releasing them to the environment. As many microorganisms can take up DNA from other organisms in the environment (Friends of the Earth et al. 2012), it's possible that synthetic DNA may persist in the environment even after the organisms die. What are the environmental impacts of introducing modified organisms into the ecosystem? We can make predictions, but we will not know for certain until it happens. Is it irresponsible, then, to release something we cannot control?

Most people believe that humans have an ethical responsibility to value and care for the environment, instead of treating it as a free-to-take resource to be exploited for our own benefits. However, this sometimes conflicts with the social responsibility to conduct life science research to improve people's livelihoods, particularly by solving major world challenges such as access to food, water, and medical treatments (The Academy of Medical Sciences 2011). How can we balance the two, while also fulfilling our responsibility to leave a habitable environment for future generations?

Group Activity

- Divide the class into small groups and assign each group either a pro or con stance on introducing genetically engineered organisms to the environment.
- Each group will research, discuss, and develop key arguments supporting their position.
- Then, students will present their arguments to the class by group, explaining their reasoning and supporting evidence.
- After all presentations, facilitate an open discussion where students can challenge each other's arguments and consider counterpoints.

5. Public Engagement

In 2010, the Presidential Commission for the Study of Bioethical Issues issued a report that highlighted the need for "scientific, religious, and civic engagement" with the public on matters of scientific research and its broader societal impacts (Presidential Commission for the Study of Bioethical Issues 2010). Given that scientific advancements often impact society-at-large, scientists have a responsibility to engage the public in discussions about their work. This process should be a collaborative two-way communication: the scientific community should not only inform the public about their latest research (and the risks involved) transparently, but also actively hear citizens' concerns and incorporate their opinions into decision-making processes (Johns Hopkins University 2017).

In addition to providing researchers with valuable insights into societal values, public engagement also fosters trust between scientists and the broader community and helps ensure that research outcomes will ethically address real-world concerns and needs (Mackelprang et al. 2021).

Public engagement, while essential, can be challenging to implement. The complexity of the science as well as the ethical issues, the rapid pace of technological development, and the technical language involved can create barriers to meaningful dialogue, especially for those without a related educational background. Cultural differences in diverse societies and the spread of misinformation can also make it more difficult to conduct civil, effective debates about morally contested science (Johns Hopkins University 2017).

Individual and Partner Activity

The purpose of this section is to present students with the challenges and considerations involved in public engagement design. Students will answer the questions individually and then compare their response with a partner.

Imagine you are a scientist and want to engage the public in your work. How would you go about this? What are some different possibilities? How would you design your engagement? Explain why you made certain choices and reflect on the opportunities and challenges.

- Who exactly will you ‘engage’?
    - Age:
    - Education level:
    - Level of interest:
    - Location:

- What are the goals?
    - Facilitate debate and increase awareness
    - Build consensus
    - Influence decisions
    - Combat misunderstandings
    - Other?

- How will people be ‘engaged’?
    - Online polling
    - Forums and conferences
    - Citizen juries
    - Public debates
    - Interviews

6. Concluding Assignment

Individual Activity

Write a short paragraph summarizing your thoughts and reflections.

Some prompts to get you started:
What did you learn? Did anything surprise you? Were you inspired to learn more about a specific topic? What questions do you still have?

7. References and Additional Resources

Additional Resources

Synthetic biology - Latest research and news:
https://www.nature.com/subjects/synthetic-biology

Synthetic biology 2020–2030: six commercially-available products that are changing our world:
https://doi.org/10.1038/s41467-020-20122-2

Dual use research: https://www.nih.gov/news-events/videos/dual-use-research-dialogue

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