



General Assemblies *Topic Guide*

WHO

World Health Organization

Yale Model United Nations China III

May 15-17, 2026

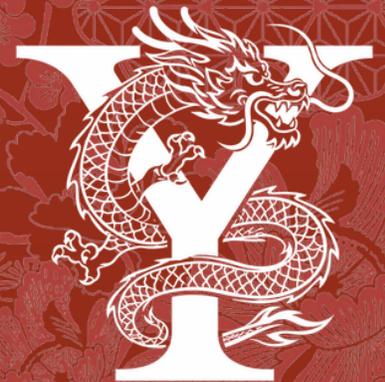


Table of Contents



Introduction

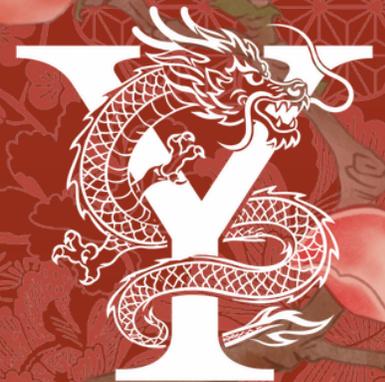
Welcome Letter
Committee History

Topic 1

Introduction
Glossary
Topic History
Current Situation
Questions to Consider
Additional Resources

Topic 2

Introduction
Glossary
Topic History
Current Situation
Questions to Consider
Additional Resources



Letter from the Dais

Dear Delegates,

I would like to welcome you to the World Health Organization (WHO) committee for Yale Model United Nations China 2026! My name is Iverlyn Alicon, a sophomore at Yale studying Electrical Engineering with a certificate in Korean. I hail from the sunny golden state, Los Angeles, California, and in my free time, I enjoy late-night beach bonfires, sunset walks, and playing video games! I am currently in the process of finishing *It Takes Two* with my younger brother, and I am eyeing *Metroid Prime* as my next one!

WHO is a specialized agency of the United Nations, whose mission is to promote global healthcare through various means, for example, research and development, responding to health emergencies such as pandemics like COVID-19, and regulating medical devices. The specialized agency is composed of 194 Member States, representing a global demographic that comprises diverse health statuses. Member states are directly elected by the people of their respective states to six-year terms, with each state having two representatives despite its population. Additionally, the Member States in the WHO are not just limited to doctors and scientists, but also embrace professionals in diverse fields such as economics and statistics to better support their mission of promoting global health.

This committee aims to tackle two issues: Risk of a Superbug and Access to Advanced Medical Devices. Both topics were picked with the intention of promoting debate from various perspectives, building understanding of the numerous factors that enter the picture, and challenging you to collaborate and come up with solutions! I encourage all delegates to share their thoughts, develop innovative policy solutions, and come prepared and ready to collaborate.

Feel free to email me about any questions you have; it does not need to directly relate to this committee. I look forward to meeting you all in China!

Warm regards,
Iverlyn Alicon
iverlyn.alicon@yale.edu



Committee History



The primary catalyst for the creation of the specialized agency of the World Health Organization (WHO) within the United Nations was the need for a unified global health authority following the large devastation of World War II, and addressing infectious diseases. Proposed in 1945 by representatives of Brazil and China, the international health organization came into existence on April 7, 1948.

WHO's mission has expanded from its original purpose to include promoting global public health, ensuring the highest possible level of health for all people, improving access to medicine and health products, setting international health standards, and responding to healthcare emergencies. The WHO's authority is defined by its constitution, which was drafted at the 1946 International Health Conference held in New York and signed by representatives of 61 states on July 22, 1946.

The drafting of the constitution occurred in the aftermath of World War II, when countries recognized that disease and health crises crossed borders and required coordinated international actions. As such, the Constitution was designed to create a permanent global body to direct and coordinate international health work. As stated in Article 1, the central objective of WHO is "the attainment by all people of the highest possible level of health." Additionally, other key principles that are included are that health is a fundamental human right without discrimination, global health is essential to peace and security, and that governments are responsible for protecting the health of their populations. In other words, the Constitution reframes health as a universal human right and aims to make international cooperation the core strategy. Under Article 2, the Constitution authorizes the WHO to act as the directing and coordinating authority on international health work, assist countries in strengthening health services, provide assistance and emergency aid when requested, work on disease control and research, and develop international health regulations and set standards.

Through the Constitution, the WHO consists of three main organs. Membership is open to all states, which makes the WHO a global body.

1. World Health Assembly (WHA) – this organ is the supreme decision-making body and consists of delegations from all 194 Member States
2. Executive Board – this organ implements WHA decisions and handles urgent matters
3. Secretariat – this organ is led by the Director-General and manages day-to-day operations

WHO is funded through two main sources – Member States assessed contributions (countries' membership dues) and voluntary distributions. The assessed contributions vary and are dependent on the country's wealth and population; however, the majority of the WHO's funds come from voluntary contributions. Voluntary contributions (VCs) in the WHO make up about 80% - 90% of the primary funding source, which finances specific health programs, emergency responses, and support for Member States.

Throughout history, the WHO has contributed to a plethora of achievements that have improved lives for millions. Among their multitude of accomplishments, some of the most relevant ones include improvement of water/sanitation in Sub-Saharan countries like Chad and in South Asia, development of vaccines against smallpox, polio, Ebola, and malaria, discovery of antibiotics, and response to global pandemics such as COVID-19.

Additionally, although antimicrobial resistance (AMR) in bacteria is nothing new, it has become a rising pressing concern for public health that the WHO has responded to. During the World Health Assembly in May 2015, the WHO passed the Global Action Plan, which established five key objectives, encouraging countries to:

- Improve awareness
- Strengthen surveillance
- Reduce infection rates
- Optimize antibiotic use
- Invest in new medicine

WHO also urged states to develop national AMR action plans, regulate antibiotic use in agriculture and healthcare, and maintain the Global Antimicrobial Resistance Surveillance System (GLASS) in order to monitor the resistance of AMR worldwide. Approved in 2015, GLASS aims to standardize the collection, analysis, and sharing of data on AMR among participating countries, as well as identify and map rising resistance (World Health Organization). GLASS is designed to strengthen national surveillance systems, harmonize global standards, and analyze collected data to evaluate prevention and control strategies. This surveillance system is important because it provides the needed data to guide treatment guidelines, inform stewardship policies, and support the research and development of new diagnostic and therapeutic tools.



General Assemblies
Topic Guide

1



Topic
One



Risk Of A Superbug

Introduction

Due to the overuse and misuse of medicine in agriculture, the rapid rise of antimicrobial resistance (AMR) has transformed once treatable infections into dangerous superbugs that threaten global health stability.

Glossary

- **Antimicrobial Resistance (AMR):** Occurs when germs develop resistance to the drugs designed to kill them.
- **Antibiotic Resistance:** A type of AMR where bacteria evolve defense against antibiotics, which are designed to kill them
- **Carbapenems:** Powerful “last resort” antibiotics used for severe or multidrug-resistant infections
- **Medical Tourism:** The practice of traveling across international borders to receive medical care
- **Superbugs:** Strains of bacteria, viruses, parasites, and fungi that have developed resistance to most commonly used antibiotics and medications
- **Stewardship:** The careful and responsible management of the well-being of the population to slow resistance
- **Prophylaxis:** Actions or measurements taken to prevent a disease
- **Therapeutic Use:** Using antibiotics to treat an existing infection
- **Horizontal Gene Transfer (HGT):** Movement of genetic information between existing organisms that are not in a parent-offspring relationship
- **Selective Pressure:** Environmental pressure that favors the survival of resistant bacteria
- **Surveillance Systems (AMR context):** Programs aimed at monitoring and tracking antimicrobial resistance patterns

- **Outpatient (in context of antibiotics):** When individuals receive treatment such as antibiotics outside of a hospital
- **Swine:** a pig

Topic History

In 1954, British physician Lindsey W. Batten warned, “We may come to the end of antibiotics. We may run clean out of effective ammunition, and then how the bacteria and moulds will lord it.” At the time, these words were perceived to be overly pessimistic. Antibiotics transformed modern medicine, reducing deaths from infectious diseases that could easily be acquired from a single scratch, and increasing life expectancy. Yet, soon after, the world witnessed Batten’s warning come to fruition. The development, overuse, and global spread of antibiotics over the past century have led to the rise of antibiotic resistance, creating a health crisis in today’s modern era.

Penicillin was discovered in 1928 by Alexander Fleming. Its production boomed during World War II, allowing penicillin to be distributed among Allied troops. By the 1940s and 1950s, antibiotics were being produced at a large scale, becoming available over the counter. This period in time is often referred to as the “Golden Age of Antibiotics,” – major discoveries of antibiotics, rapid development pace, and a heavy scientific focus. During these two decades, almost two-thirds of all antibiotic drug classes were introduced, such as tetracyclines, macrolides, aminoglycosides, and cephalosporins. These drugs assisted in combating once treatable infections, allowing for shifts in other medical advancements, and revolutionized healthcare.

However, antibiotics were like a double-edged sword. Due to antibiotics’ increased production, they became widely prescribed in hospitals, sold over-the-counter in multiple countries, and used in industrial agriculture to prompt growth and aid in the prevention of disease due to the crowded farming conditions. This large and often unnecessary use of antibiotics led to bacteria gaining exposure to non-lethal levels of dosage, promoting bacterial mutation. Because of this, antimicrobial resistance emerged quickly.

In 1961, just two years after methicillin was introduced, British scientists discovered methicillin-resistant *Staphylococcus aureus* (MRSA), with resistant strains spreading to hospitals. By the 21st century, Carbapenem-resistant Enterobacteriaceae (CRE) (from global/US), drug-resistant tuberculosis (TB) (from Africa, Southeast Asia), and extensively drug-resistant (XDR) typhoid (from Asia/Africa) were spreading. Additionally, due to an increase in travel and trade, resistant strains spread over borders with ease.

Antibiotic resistance develops when bacteria evolve defense mechanisms to survive antibiotics. Within the bacterial population, small genetic variations may already be present; it is through those mutations that help them survive exposure to antibiotics. Thus, when used, antibiotics kill those susceptible but allow resistant

ones to survive. The bacterial strains that survived would then multiply and spread their resistance traits through mutation or horizontal gene transfer. The more frequently antibiotics are misused or overused, the faster this evolutionary process occurs.

Today, the rise of antibiotic resistance poses a threat as a public health crisis because bacteria are evolving faster than new treatments are being developed, rendering common medicines no longer effective in recovery or medical procedures such as surgeries and chemotherapy. Without antibiotics, infections once treatable could once again become deadly. It is important to understand how resistance is developed in order to preserve their effectiveness for both the present and future generations.

Current Situation

Throughout the following paragraphs, we will discuss why antibiotic resistance is of utmost importance today, gain a better understanding of the scientific and medical realities, analyze the various positions of countries, and discuss what has been done to combat this issue.

I. Global Antibiotic Resistance Crisis

The World Health Organization (WHO) has identified antimicrobial resistance (AMR) as one of the top global public health threats of the 21st century. According to the World Health Organization, Global Antimicrobial Resistance and Use Surveillance System (GLASS) conducted in October 2025, there are a multitude of antibiotics that have lost their effectiveness. The WHO report highlights that third-generation cephalosporins – a crucial antibiotic for treating severe, resistant, gram-negative infections such as hospital-acquired pneumonia – are losing effectiveness due to high resistance in bacteria such as E.coli. Additionally, it notes that the last-resort treatment for severe infections, carbapenems, is growing resistant. WHO's data on AMR has estimated about 1.27 million deaths in 2019 to be caused by antibiotic-resistant infections and attributed 5 million deaths to resistant bacterial infections overall. Additionally, these resistant antibiotics have threatened to undermine the advancements made in modern medicine.

Antibiotic resistance is difficult to address because, unlike many diseases, it does not spread through an outbreak or one virus. Antibiotics multiply and spread through several media, such as hospitals, international travel, farms, and wastewater. It is prevalent that we address the issue of antibiotics, providing a long-term solution, because modern healthcare heavily relies on effective antibiotics for surgeries and organ transplants. Therefore, to ensure the continuous effectiveness of medical practices such as the ones mentioned above, addressing antibiotic resistance is necessary for a global solution.

Furthermore, antibiotic resistance is a global issue; there is no region that is left unscathed by its effects. And it is because of this great disparity in healthcare access and incomes in nations that the dangers of antibiotic resistance are disproportionate, as lower-income economies have a weaker healthcare structure, limited diagnostic capacity, and over-the-counter access. While higher-income nations contribute to the issue a lot more due to the availability of antibiotics,

which leads to their misuse and overuse, and their usage in other fields, such as agricultural production. In addition to death, the World Bank estimates that AMR could result in US\$ 1 trillion additional healthcare costs by 2050, and US\$ 1 trillion to US\$ 3.4 trillion gross domestic product (GDP) losses per year by 2030 (World Health Organization).

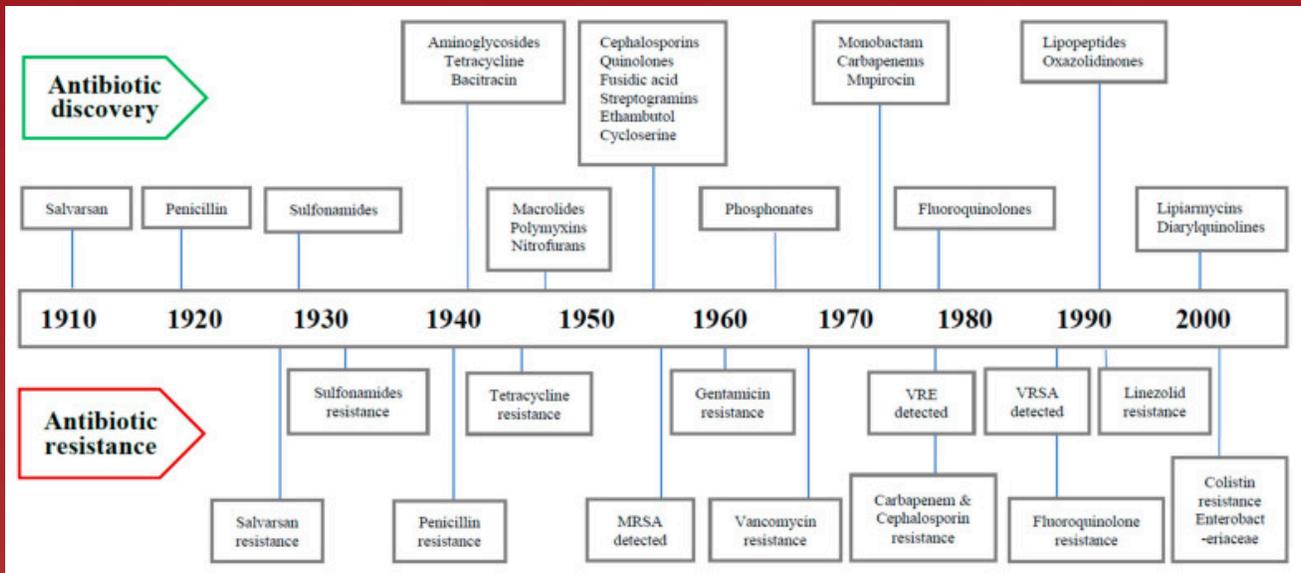


Figure 1: Timeline of major antibiotics and antibiotic resistance (National Library of Medicine)

II. The Rise of Superbugs

The term superbug refers to strains of bacteria, viruses, parasites, and fungi that have developed resistance to the most commonly used antibiotics and antimicrobial medications, making them increasingly difficult to treat. The examples included below demonstrate the rapid pace at which bacteria are mutating and the inability to keep up with the development of antibiotics to combat the mutant strains.

Key Modern Superbugs

1. *Klebsiella pneumoniae*

This Gram-negative bacterium is a common cause of healthcare-associated infections like pneumonia and bloodstream infections; those deemed especially susceptible are vulnerable patients, such as newborns, the elderly, and immunocompromised individuals. Globally, the drug-resistant *K. pneumoniae* infections has been associated with more than 600,00 deaths annually (Global Antibiotic Research & Development Partnership). It has become notoriously difficult to treat due to the many strains that now produce enzymes that dismantle nearly all beta-lactam antibiotics, including our “last resort” options.

K. pneumoniae spreads easily through healthcare environments like person

contact to contact, contaminate surfaces or tools. Its resistance genes are then accelerated through horizontal gene transfer. First detected in Taiwan in 1986, it has spread epidemically through China, South Korea, and Japan, with some cases being reported in India and Europe (Global Antibiotic Research & Development Partnership).

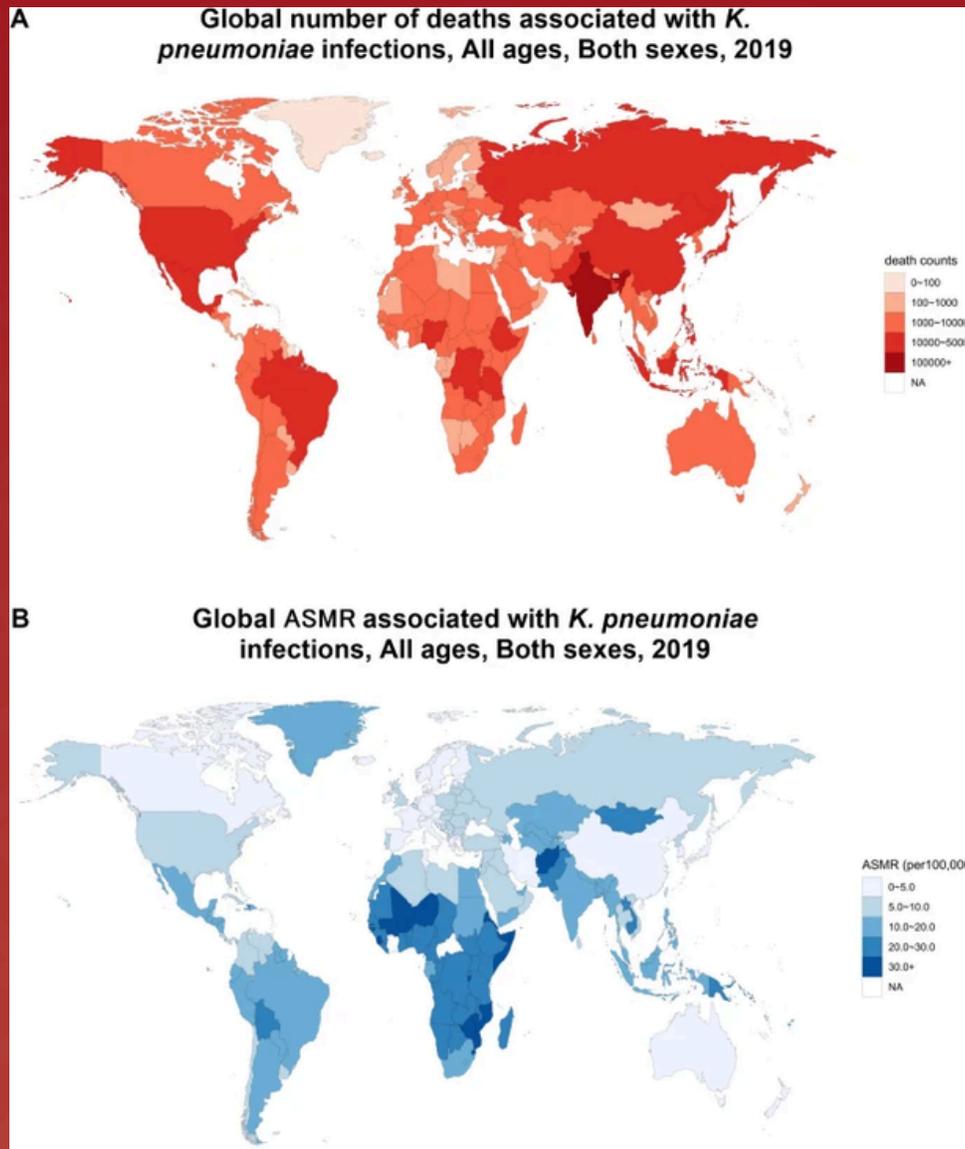


Figure 2: Global number of deaths and age-standardized mortality rates associated with *K. pneumoniae* infections in 204 countries and territories (BMC Infectious Diseases)

2. Carbapenem-resistant Enterobacteriaceae (CRE)

CRE are a group of Gram-negative Carbapenem that includes *E. coli* and *Klebsiella*, that has developed resistance to carbapenems – powerful antibiotics that have often been reserved for the most severe infections. Because carbapenem is often only used when other antibiotics fail, resistance to this family limits the remaining therapeutic options. CRE causes severe and, at times, fatal infections with high mortality rates. Owing to CRE being prominently contracted in hospital settings, those most susceptible are hospitalized patients, those with weakened immune systems, or uses of

of medical devices such as ventilators (U.S. Centers for Disease Control and Prevention).

3. Methicillin-resistant Staphylococcus aureus (MRSA)

MRSA is a version of common “staph” bacteria that has become resistant to the penicillin-class antibiotics traditionally used to treat ordinary staph infections. MRSA commonly causes skin and soft-tissue infections, although it can also cause serious infections in the lungs such as bone and joint infections, pneumonia, bloodstream infections, and endocarditis. If a MRSA infection cannot be solved with antibiotics it can lead to severe complications, leading to life altering consequences such as amputation and organ failure (Cleveland Clinic). It spreads via skin-to-skin contact, crowded conditions, or contaminated surfaces. It can survive on fabrics, towels, equipment, and other surfaces for up to days. Those most susceptible are individuals with open wounds, hospitalized, those with weakened immune systems, or in close contact conditions .

4. Multidrug-resistant Tuberculosis (MDR-TB)

MRSA is a version of common “staph” bacteria that has become resistant to the penicillin-class antibiotics traditionally used to treat ordinary staph infections. MRSA commonly causes skin and soft-tissue infections, although it can also cause serious infections in the lungs such as bone and joint infections, pneumonia, bloodstream infections, and endocarditis. If a MRSA infection cannot be solved with antibiotics it can lead to severe complications, leading to life altering consequences such as amputation and organ failure (Cleveland Clinic). It spreads via skin-to-skin contact, crowded conditions, or contaminated surfaces. It can survive on fabrics, towels, equipment, and other surfaces for up to days. Those most susceptible are individuals with open wounds, hospitalized, those with weakened immune systems, or in close contact conditions .

5. Extensively Drug-Resistant (XDR) Typhoid

XDR Typhoid is a strain of Salmonella Typhi that is resistant to almost all recommended antibiotics. Outbreaks, especially in South Asia, have revealed that only one or two oral antibiotic options work to a certain extent, increasing the difficulty of addressing the bacteria and making it more expensive to combat, such as hospitalization. Typhoid spreads mainly through contaminated food and water, leaving those in poor sanitation and dense populations most susceptible. Left untreated, and it can lead to severe complications such as internal bleeding, septic shock, death, and intestinal perforation. Although typhoid vaccines exist, they have limitations. The vaccines are not approved for young children, often require multiple doses, and in some cases have efficacy rates as low as 50% (Yale School of Public Health).

Threat	Change in Rates or Number of Infections***				
	2020 vs. 2019	2021 vs. 2020	2022 vs. 2021	2022 vs. 2019	
URGENT*	Hospital-onset CRE	Increase ▲	Increase ▲	Stable ▬	Increase ▲
	Hospital-onset Carbapenem-resistant <i>Acinetobacter</i>	Stable ▬	Stable ▬	Stable ▬	Increase** ▲
	Clinical Cases of <i>C. auris</i>	Increase ▲	Increase ▲	Increase ▲	Increase ▲
SERIOUS*	Hospital-onset MRSA	Increase ▲	Stable ▬	Decrease ▼	Stable ▬
	Hospital-onset VRE	Increase ▲	Increase ▲	Stable ▬	Increase ▲
	Hospital-onset ESBL-producing Enterobacterales	Increase ▲	Stable ▬	Stable ▬	Increase ▲
	Hospital-onset MDR <i>Pseudomonas aeruginosa</i>	Increase ▲	Increase ▲	Stable ▬	Increase ▲

* Threat level for each pathogen, as categorized in CDC's *Antibiotic Resistance Threats in the United States, 2019*.
** There was no statistically significant difference in rate of hospital-onset carbapenem-resistant *Acinetobacter* in 2020, 2021, and 2022 when compared to the previous year. However, there was a statistically significant increase in rate of hospital-onset carbapenem-resistant *Acinetobacter* in 2022 when compared to 2019.
*** Hospital-onset rates were described using multivariable models for all threats except *C. auris*. Please note that in above table, stable indicates there was no statistically significant increase or decrease, decrease indicates a statistically significant decrease where $p < 0.05$, and increase indicates a statistically significant increase where $p < 0.05$, for all threats except for *C. auris*. Increases or decreases in *C. auris* were indicated by changes in the number of clinical cases reported nationally without hypothesis testing.

Figure 3: Antimicrobial Resistance threats in the United States from 2019 to 2022 (U.S. Centers For Disease Control and Prevention)

III. Causes of Modern Crisis

We will now discuss the main drivers of the modern crisis.

Human Medical Misuse

Antibiotic resistance causes an estimated 2 million infections and 23,000 deaths annually in the United States. Among the other developed countries, approximately 80%–90% of antibiotic use occurs among outpatients, causing antibiotic resistance to become one of the greatest public health threats to modern time (U.S. Centers for Disease Control and Prevention). One of the primary drivers for antibiotic resistance is the misuse of antibiotics in human medicine. When used incorrectly, it not only fails to cure the patient but also actively trains bacteria to evolve and mutate to survive future treatments. Oftentimes, though antibiotics are designed to kill bacteria or inhibit their growth, they are prescribed for viral infections such as the common cold, sore throats, or influenza, which have no effect. Instead, it attacks the harmless bacteria and allows for the resistant bacteria to multiply in numbers without competition.

The scale of this misuse is significant. Based on global clinical audits and patient interviews, researchers estimate that approximately 29.5% to 36.5% of antibiotics worldwide are used inappropriately, with 30.8% of global antibiotic consumption resulting from unnecessary prescriptions by healthcare workers (National Library of Medicine). The frequent unnecessary use of antibiotics leads to improper dosing, doing more harm than good, as the bacteria are now familiar with the drug at a non-lethal dosage, allowing them to mutate and develop defense mechanisms. Additionally, there is the failure to complete the proper course of dosage intake. More often than not, patients stop taking their medication as soon as they get better, leaving the most resilient bacteria alive. It is through those surviving

bacteria that reproduction of mutated bacteria occurs, so that the next time that person gets sick, there is no guarantee the original antibacterial will work efficiently.

Agricultural Use

Antibiotics are not strictly used in human medicine; they are also used in agriculture for various purposes, such as growth promotion, and therapeutic and prophylactic use. Unlike antibiotics in human medicine, the main purpose of using them in agriculture is not to cure sick animals but to sustain high-intensity industrial farming. This allows for bacteria to develop resistance away from a hospital setting. According to a recent U.S. Food and Drug Administration report summarized by the Center for Infectious Disease Research and Policy (CIDRAP), about 6.2 million kilograms of medically important antibiotics were sold for use in food-producing animals in 2022, and these drugs accounted for 56% of all antibiotics sold for livestock (CIDRAP). Antibiotics are often added to animal feed in low doses to promote faster growth and prevent infections caused by crowded spaces. However, the constant low exposure allows for bacteria to become resistant and then spread through means of water supplies and fertilizers used on crops. The FDA data reflects that swine (43%) and cattle (41%) account for the majority of medically important antibiotics, demonstrating the concentrated use in industrial meat production (CIDRAP). The concern with this practice is that the drugs used in livestock are similar to the ones used in human medicine, which makes these infections life-threatening to people. As such, the responsible use of antibiotics in agriculture is essential for the preservation of effectiveness of antibiotics in human medicine.

Table 2a
Antimicrobial drugs approved for use in food-producing animals¹
Actively marketed in 2018
Domestic sales and distribution data
Reported by medical importance and drug class

	Drug Class	Annual Totals (kg) ²	% Subtotal	% Grand Total
Medically Important³	<i>Aminoglycosides</i>	293,298	5%	3%
	<i>Amphenicols</i>	56,056	1%	<1%
	<i>Cephalosporins¹</i>	31,448	1%	<1%
	<i>Fluoroquinolones</i>	23,350	<1%	<1%
	<i>Lincosamides¹</i>	125,514	2%	1%
	<i>Macrolides</i>	473,038	8%	4%
	<i>Penicillins¹</i>	731,863	12%	6%
	<i>Sulfas</i>	278,562	5%	2%
	<i>Tetracyclines¹</i>	3,974,179	66%	34%
	<i>NIR^{1,4}</i>	48,832	1%	<1%
	Subtotal	6,036,140	100%	52%
Not Medically Important⁵	<i>Ionophores</i>	4,562,260	82%	39%
	<i>NIR⁶</i>	968,524	18%	8%
	Subtotal	5,530,784	100%	48%
	Grand Total	11,566,924		100%

Figure 4: Antimicrobial drugs approved for use in food-producing animals (FDA)

Pharmaceutical Market Failure

Due to the fact that antibiotics are used for short periods and kept in “reserve”, pharmaceutical companies are not drawn to their development as it has poor returns on investment compared to the development of chronic disease medications. Developing a new antibiotic can take 10 - 15 years and over a \$1 billion to develop, and even then there is no guarantee that the antibiotic will ultimately reach patients. These odds are only more exacerbated when it comes to developing an entirely new class of antibiotics where only about 1 in 30 candidates reach their patients, demonstrating the financial strain antibiotic development is (Wellcome). As a result, many pharmaceutical companies have reduced investment in antibiotic research, leading to smaller biotechnology companies responsible for most of the development efforts, leading to a disproportionate ratio of new antibiotics and new resistant bacteria levels. 93% of the antibiotics in clinical development is being conducted by small companies and biotech firms (PEW). A United Nations interagency group on antimicrobial resistance estimates the number of deaths due to drug resistant disease is projected to rise to 10 million a year by 2050 if no action is taken, far exceeding the amount of people who currently die from cancer worldwide every year (Nature).

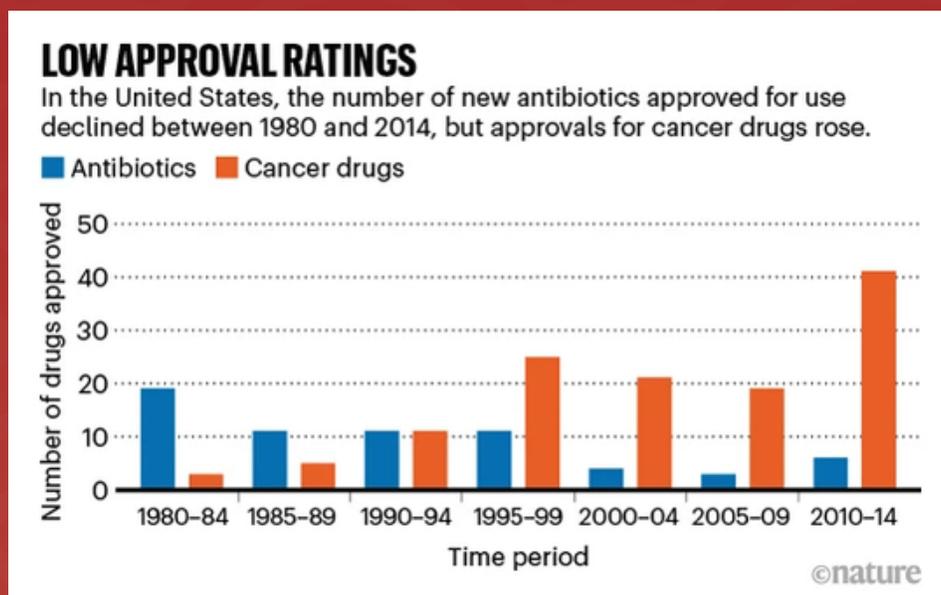


Figure 5: Big Pharma’s Development of New Drugs (Nature)

Globalization

In modern society, travel and trade, whether it be international or domestic acts as a transit system for superbugs, allowing for resistant bacteria to traverse borders in a short amount of time. This is only amplified through medical tourism, when sick patients may unintentionally carry or bring back highly resistant bacteria to the respective country they are entering in their attempt to seek medical aid or into their home healthcare systems. The large displacement of refugees is another environment that is ideal for the mutation of bacteria due to the overcrowded,

unsanitary, and limited access to clean water. These resistant bacteria then spread through people, food, and cargo, posing a threat to become a global issue.

What Has Been Done So Far?

We will now delve into what has been done so far.

National Stewardship Programs in Healthcare:

Antimicrobial stewardship programs (ASPs) aim to coordinate efforts within healthcare settings to optimize antibiotic use while minimizing AMR. According to the National Library of Medicine, ASPs significantly reduced antibiotic use. A review of 52 studies, involving more than 1.7 million patients found that stewardship interventions led to a 10% reduction in antibiotic prescriptions, a 28% reduction in antibiotic consumption. Aside from reducing unnecessary prescriptions, ASPs also lower resistance rates. While studies have reported a decline in resistant organisms after sustained stewardship efforts, it is important to know the limitations of antimicrobial stewardship programs. For starters, resistance takes years to change, therefore the reduction of prescriptions will not have an immediate effect on the reduced AMR rates. Additionally, it is difficult to overcome the resource limitations and behavioral barriers that have been occurring for years. An effective stewardship program is reliant on trained physicians, thus low-income countries with a shortage of trained pharmacists and/or microbiologists, limited technology, and surveillance may have difficulty implementing this practice. Furthermore, stewardship is easier to conduct within hospitals, and to reduce outpatient poses a challenge as clinicians often have to face time pressure, limited diagnostic information, and fewer feedback mechanisms, all of which contribute to higher rates of inappropriate antibiotic prescribing. Lastly, behavior barriers is another challenge because patients and physicians prescribe antibiotics “just in case,” which is a mentality engraved and practiced widely, that it would be difficult to change.

Case Study: Veterans Health Administration National Antimicrobial Stewardship Initiative

The Veterans Health Administration implemented a nationwide antimicrobial stewardship initiative across more than 140 facilities that served approximately 6 million patients yearly. After implementing the stewardship program, there was a significant 12% reduction in inpatient antibiotic use, along with decreased use of high-risk agents such as carbapenems. These changes coincide with improved clinical outcomes, including declining hospital readmissions and mortality rates (Cambridge).

Agricultural Restrictions on Antibiotics:

Agricultural antibiotic restrictions have been widely implemented to reduce antimicrobial resistance, beginning with Sweden's 1986 ban on growth promoters and later the European Union's 2006 region-wide prohibition, and as of 2022, also prohibited the prophylactic use. Sweden experienced roughly a 55% reduction in animal antibiotic use, leading to a decline in resistant bacteria. However, some countries such as Denmark, following their 1999 antibiotic usage ban, reported an increase in therapeutic antibiotic use and higher disease rates in livestock. However, after time the ban demonstrated that the elimination of growth-promoting antibiotics is feasible when combined with better animal health management and surveillance systems such as improving farm hygiene.

Incentive for Research and Development:

The World Health Organization promotes global antibiotic research and development (R&D) to combat AMR by coordinating public-private partnerships and implementing both “push” (funding research) and “pull” (market incentive) tactics. By recognizing that market failures drive away interest in research and development, WHO works with G7 and G20 nations to provide early-stage funding, grants, and market rewards that make antibiotic development financially feasible. Through the Global Antibiotic Research & Development Partnership (GARDP), a non-profit organization focused on developing treatments for drug resistant infections, such as sexually transmitted infections, while ensuring global access. This organization collaborates with other groups such as the AMR Action Fund to gather investment into the cause of antibiotics. Additionally, WHO guides the R&D of antibiotics through the publication of priority pathogen lists, global analysis, and ensuring research aligns with the public's need.

In conclusion, antibiotic resistance poses a large threat to public health today. Driven by human misuse, widespread agricultural use, and pharmaceutical market failures among other factors, resistant bacteria and “superbugs” hinder the medical progress humans have made and have the ability to pose as a global threat. While high-income nations contribute heavily through overuse and misuse of antibiotics, low- and middle-income countries often face disproportionate accessibility due to weaker healthcare infrastructures and limited diagnostic capacity. Efforts such as national antimicrobial stewardship programs, agricultural restrictions, and incentives for research and development provide important strategies to hinder resistance, but they face limitations in resources, behavior change, and implementation. Ultimately, addressing antibiotic resistance requires coordinated international action, consistent investment in new therapeutics, and responsible use of existing drugs.

Questions to consider:

1. How can the international community simultaneously reduce antibiotic overuse in high-income countries while also increasing access to them in low and middle-income communities without furthering the process of evolution?
2. To what extent should humanity attempt to control microbial evolution?
3. How can food security be ensured if agricultural antibiotic use is significantly reduced?
4. If antimicrobial resistance continues to accelerate, how should governments prepare their healthcare systems for the realistic possibility of a post-antibiotic era?
5. Should countries be obligated to report emerging resistant strains immediately?
6. How should governments incentivize the development of new antibiotics without encouraging overuse?
7. How can governments reduce misuse without inadvertently limiting access for populations who rely on informal or remote healthcare systems?

Additional Resources:

<https://www.who.int/publications/i/item/B09585>

<https://pubmed.ncbi.nlm.nih.gov/11442345/>

<https://fefac.eu/newsroom/news/antibiotic-use-and-farming-why-do-farmers-need-to-use-antibiotics/>

<https://www.ncbi.nlm.nih.gov/books/NBK559438/>

<https://pmc.ncbi.nlm.nih.gov/articles/PMC12360106/>

<https://pmc.ncbi.nlm.nih.gov/articles/PMC10318557/>

<https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>

<https://gardp.org/stories/meet-klebsiella-pneumoniae/#:~:text=While%20often%20detected%20in%20healthcare,sort%20of%20'invisibility%20cloak'.>

<https://www.cdc.gov/cre/about/index.html>

<https://my.clevelandclinic.org/health/diseases/11633-methicillin-resistant-staphylococcus-aureus-mrsa>

https://www.ccohs.ca/oshanswers/diseases/mdr_tb.html

<https://ysph.yale.edu/news-article/study-identifies-countries-vulnerable-to-extensively-drug-resistant-typhoid/>

<https://pubmed.ncbi.nlm.nih.gov/articles/PMC10340576/>

<https://link.springer.com/article/10.1186/s12879-025-12120-w>

<https://pubmed.ncbi.nlm.nih.gov/articles/PMC12121568/#:~:text=Based%20on%20average%20prevalence%20obtained,annual%20antibiotic%20consumption%20of%20China.>

<https://www.cdc.gov/antibiotic-use/media/pdfs/Core-Elements-Outpatient-508.pdf>

[https://www.fda.gov/media/133411/download#:~:text=Key%20observations%20from%20the%20report%20include:&text=%2D%20decreased%20by%2038%25%20from%202015,12%25%20from%202017%20through%202018.&text=Of%20the%202018%20domestic%20sales,1%25%20\(Table%202a\).&text=swine%2C%20an%20estimated%2011%25%20intended,/unknown%20\(Table%204a\).&text=of%20tetracyclines%20were%20intended%20for,medically%20important%20to%20human%20medicine.](https://www.fda.gov/media/133411/download#:~:text=Key%20observations%20from%20the%20report%20include:&text=%2D%20decreased%20by%2038%25%20from%202015,12%25%20from%202017%20through%202018.&text=Of%20the%202018%20domestic%20sales,1%25%20(Table%202a).&text=swine%2C%20an%20estimated%2011%25%20intended,/unknown%20(Table%204a).&text=of%20tetracyclines%20were%20intended%20for,medically%20important%20to%20human%20medicine.)

<https://www.cidrap.umn.edu/antimicrobial-stewardship/new-fda-report-shows-more-antibiotics-being-sold-food-animals#:~:text=According%20to%20the%20FDA's%20Center%20for%20Veterinary,%20Cattle%20accounted%20for%2041%25%20of%20sales>

<https://www.pew.org/en/research-and-analysis/articles/2024/07/15/world-health-organization-warns-that-antibiotic-innovation-still-insufficient>

<https://wellcome.org/insights/articles/why-is-it-so-hard-develop-new-antibiotics>

<https://www.nature.com/articles/d41586-020-02884-3>

<https://pubmed.ncbi.nlm.nih.gov/articles/PMC9912134/>

<https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/report-of-the-efforts-of-the-veterans-health-administration-national-antimicrobial-stewardship-initiative/6BE60E1A5052964F445A269B798FD04C>



General Assmeblies
Topic Guide

2

Topic
Two



凤凰
特色黄牛粉

羊肉粉

我随我

家路我

化房

Access To Advanced Medical Devices



Introduction

The rapid evolution of medical technology has transformed modern healthcare, offering unprecedented opportunities to diagnose, treat, and even prevent disease. However, access to these innovations remains largely disproportionate both across and within nations.

Glossary

- **Personal Protective Equipment:** Clothing and gear made to minimize exposure to hazards that cause serious workplace injuries, illnesses, or infections. Common types include gloves, masks, gowns, respirators, goggles, hard hats, and safety shoes.
- **Supply Chain:** The interconnected network of people, organizations, resources, and technology involved in creating and delivering a product from raw materials to the final customer.
- **Brain drain:** The emigration of highly trained or intelligent people from their home country or organization, usually in search of better pay, improved living conditions, or professional opportunities.
- **Regulation System:** A structured framework of laws, policies, and oversight processes established by governments or authorities to ensure that medical devices and other health products are safe, effective, and perform as intended.
- **International Regulatory Harmonization:** The process by which different countries align their medical device regulations and standards to reduce duplication, improve global safety, and facilitate international trade and access to healthcare technologies.
- **Medical Device:** Any instrument, apparatus, or implant used for medical purposes, such as monitoring, preventing, diagnosing, or treating
- **Accessibility (in healthcare context):** The ability of individuals and healthcare systems to obtain, afford, and effectively use medical technologies

- **Regulatory Fragmentation:** The existence of different regulatory standards across countries that require separate approval processes
- **Export Controls:** Government restrictions imposed on export goods to preserve the domestic supply
- **Medical Tourism:** The practice of patients traveling abroad to receive medical treatment
- **Market Entry:** The process by which a product becomes legally approved and commercially available in a country

Topic History

According to the Food and Drug Administration (FDA), medical devices are defined as items that are used for the “diagnosis, cure, mitigation, treatment, or prevention of disease” and are not absorbed or metabolized by the body. As such, medical devices encapsulate a large variety of medical supplies such as latex gloves, syringes, and imaging equipment. Therefore, the medical device industry is an imperative component in the broader scheme of the healthcare system and in improving healthcare accessibility. However, the benefits of these devices have not been distributed evenly across populations, creating persistent disparities in access to advanced medical care.

Medical devices have evolved tremendously throughout the course of time, from ancient stone tools for surgical procedures to robotic-assisted surgery systems. These advances have contributed to an increased life expectancy, improved quality of life, and personalized care delivered with greater rates of precision and efficiency.

The stethoscope, invented by French physician Rene Laennec in 1816, is considered to be the first modern medical device. As time continued, the continuous advancements made in new technologies combined with cases of fraudulent therapeutic machines caused governments to begin forming regulatory systems to ensure that device oversight guarantees safety, effectiveness, and that the medical devices perform as intended. In the United States, the FDA – the oldest comprehensive consumer protection agency– began in 1906 when President Theodore Roosevelt signed the Pure Food and Drugs Act, aimed at preventing the manufacture, sale, and transportation of adulterated, misbranded, or poisonous food and drugs. Since then, Congress has expanded the FDA’s role to oversee the protection and promotion of biological products, cosmetics, human and veterinary drugs, and medical devices. The expansion of the FDA in the oversight of medical devices arose in part from the 1937 Elixir Sulfanilamide Incident, which killed over 100 people, many of whom were children. After the discovery of sulfanilamide and its shown curative effects, there was a demand for the drug in liquid form. Through experimentation, it was found that sulfanilamide would dissolve in diethylene glycol. As a result, the Tennessee company, S.E. Massengill adjusted the flavor, appearance, and fragrance to their satisfaction and began shipping the product without conducting any safety and toxicity studies. This negligence led to many deaths, and the inadequacy of the FDA could no longer be overlooked. This prompted the U.S. Congress to enact the Federal Food, Drug, and Cosmetic Act (FD&C) of 1938, which expanded FDA authority over food, drugs, and cosmetics, and included a limited provision about medical devices.

However, the major catalyst for comprehensive medical device regulation in the United States occurred due to the problems associated with the Dalkon Shield, an intrauterine device (IUD), which was intended to prevent pregnancy and marketed as a superior alternative to birth control. But due to the widespread and severe complications, such as pelvic inflammatory disease (PID), septic abortions, infertility, and death, the device caused significant public concern. In response, Congress passed the Medical Device Amendments of 1976 to the FD&C Act. This act is intended to provide reasonable assurance of the safety and effectiveness of medical devices. It created a three-class risk-based classification system for all medical devices, established regulatory pathways for new devices, implemented key postmarket requirements, and authorized the FDA to ban unsafe devices.

In Europe, the regulatory oversight of medical devices developed following a different timeline. The Medical Device Directive (MDD) – renamed the Medical Device Regulation (MDR) in 2017 – was established in 1993 and created a harmonized framework for the safety and performance of medical devices across the European Union. This act was a response to the growing public’s concerns after the 1950s/60s thalidomide scandal and subsequent device failures. In the late 1950s and early 1960s, thalidomide was prescribed to pregnant women to treat morning sickness by the German pharmaceutical company Chemie-Grünenthal. The drug was marketed and distributed across 46 countries, such as the United Kingdom, Australia, and Germany. The “wonder drug” caused over 10,000 children to be born with defects such as missing or malformed limbs and miscarriages.

At a global level, the World Health Organization (WHO) develops international guidelines, standards, and policies on medical device quality, safety, and efficacy. Additionally, it aims at increasing accessibility, especially in low and middle-income countries.

While regulatory frameworks such as the MDD and FDA were created to improve device safety and oversight, they did not address the inequalities that come with the accessibility of these devices. Cost, infrastructure, and systems healthcare disparities continue to limit equitable distribution. As such, the accessibility of medical devices experienced by countries, even people within a country vary, and needs to be addressed.

Current Situation

Throughout the following paragraphs, we will discuss why access to advanced medical technologies is of utmost importance today and gain a better understanding of the factors that affect the distribution of medical devices.

I. Why Does This Topic Matter?

Over the course of history, the development of medical technology has dramatically transformed healthcare outcomes. From commonly used diagnostic tools to high-tech, life-sustaining equipment such as the electrocardiogram (ECG/EKG), which monitors the heart's electrical activity to detect arrhythmias or damage, medical devices play a critical role in modern care. The widespread reliance on these technologies demonstrates that medical devices are indispensable for improving diagnostic accuracy, treatment precision, and overall patient outcomes. The global medical device market was valued at \$518.5 billion in 2023 and is projected to grow to \$886.6 billion by 2032 (ASPE, 2025).

However, despite rapid innovation, access to advanced medical devices remains highly disproportionate both across and within countries. This gap directly contributes to preventable morbidity and mortality in low-resource settings, where patients may lack access to even basic diagnostic equipment. Accessibility goes far beyond whether a hospital or country can purchase a device; it is also contingent on reliable infrastructure, trained healthcare personnel, effective regulatory systems, maintenance capacity, and dependable supply chains. Addressing these disparities is essential for achieving global health equity and remains a critical priority for the international community.

COVID-19

The COVID-19 pandemic exposed the critical structural weakness in the global medical device supply chain and distribution systems. According to the World Health Organization, during the early months of the pandemic, personal protective equipment (PPE) supplies experienced a “severe and mounting disruption” due to the surging demand, panic buying, and widespread export restrictions (World Health Organization, 2020). These shortages highlighted the fragility of a highly globalized manufacturing and distribution system of medical supplies that varies by region and is heavily interdependent. Advanced industrial economies such as the United States and Germany specialize in high-tech medical devices, while countries with lower-cost manufacturing, such as China and Malaysia, produce and supply essential consumables such as personal protective equipment, including gloves, face masks, face shields, and gowns. When COVID-19 cases surged, many governments imposed export controls to preserve domestic supply, which significantly affected the global distribution of necessary devices.

Analysis conducted by the U.S. Department of Health and Human Services' Assistant Secretary for Planning and Evaluation (ASPE) suggests that the leading factors for medical device shortages are often due to structural supply chain vulnerabilities, heavy reliance on foreign suppliers, transportation issues, and demand shocks. The report notes that while increasing globalization and geographic concentration of medical device manufacturing is economically more efficient, it has made the supply chain susceptible to disruptions should a major region of production implement export restrictions or experience slowdowns, especially for countries with a heavy reliance on imports for essential medical supplies. These vulnerabilities became prevalent during COVID-19, when supplier countries such as China were unable to provide a continuous supply of medical devices to keep up with the surging global demand.

To better understand the heavy reliance on supplier countries, 47% of the world's exports of face masks came from China in 2019 (UN Comtrade 2020), while the next largest exporters were Germany with 7% and the United States with 6%. As the number of domestic cases increased in China, combined with the economic shutdown of the country, Chinese authorities decided to prioritize their internal demand to overcome the pandemic that at the time was concentrated in China. As a result of the inability of supplier countries like China to keep up with the surging demand for medical device production, there was an increase in available products, with the price of masks reported to have increased by 12 times (\$0.50 to \$6.00) and that of a mechanical ventilator by 2 times (\$25,000 to \$50,000) (ASPE, 2025).

In many regions, frontline healthcare workers were unable to be properly equipped with the necessary PPE, leaving them inadequately equipped to properly care for their patients while minimizing the probability of infections. The shortage soon after affected other frontline workers who interacted with the community through their services. The shortage in medical devices was not limited simply to PPE but included ventilators, diagnostic testing supplies, and oxygen delivery devices, which were also limited. As a result, countries heavily reliant on imports, especially low- and middle-income health systems, were affected. Financially stable hospital systems were better positioned to respond to surging demand, while smaller providers – particularly rural hospitals – often lacked the purchasing power to serve all patients effectively.

The medical device shortages during the pandemic were addressed through, but not limited to, rationing and patient prioritization, using alternative devices, procedures, or treatments, revising hospital staff who needed to make patient contact, sharing resources within hospitals, and asking for donations. For civilians, the shortages directly translated to the quality of the healthcare they received. With a sharp increase in prices, out-of-pocket payments increased, and with the limited availability of ventilators, oxygen equipment, and diagnostic tools, it meant that not all patients who needed care would receive it in a timely manner.

While wealthier communities and countries were more likely to have access to the limited medical devices, they still struggled to overcome the challenges, which were exacerbated in lower-income regions. While COVID-19 is an extreme example of the limited access to medical devices, the factors that caused the large health inequities persist in modern life.

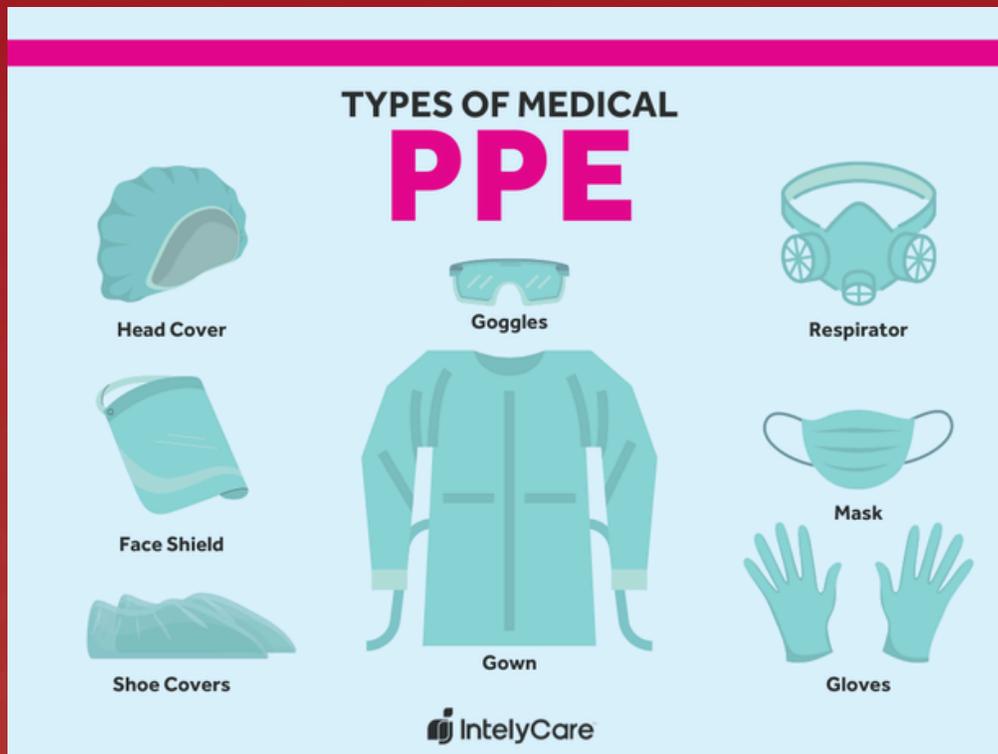


Figure 1. Personal Protective Equipment (U.S. Department Of Labor)

Imaging Equipment

Aside from the medical device shortages that arose from the pandemic, structural inequities continue to affect access to medical devices worldwide. While approximately 70% of healthcare decisions are made based on diagnostic test results, the WHO reports that two-thirds of the world's population (roughly 3.5 to 4.7 billion people) lack access to diagnostic imaging, such as X-rays and ultrasound. The limited access to imaging equipment leads to delayed treatments, increased mortality rates, and higher out-of-pocket costs. Ultimately, unequal access to advanced medical technology limits the global healthcare experienced by civilians. Addressing the systemic gaps that cause such a large disparity in accessibility is essential not only for ensuring quality healthcare to all but also to prepare for any future public health emergency.

II. Causes Of Inequitable Distribution

We will now dive into the main causes of inequitable distribution.

Cost Barriers

Medical tourism is the practice of patients traveling to other countries to obtain healthcare. Reasons for this practice can be summarized as affordable, accessible, available, acceptable, and additional.

Affordable – Treatment is cheaper abroad, especially for patients who are from countries like the United States and the United Kingdom, where private healthcare is not fully covered by insurance and is expensive.

Available – When the needed treatment is not available locally, or patients may not trust their local medical services.

Accessible – Patients seek care abroad to avoid the long waiting list in their home country.

Acceptable – Even though a patient's home country has the treatment, it may conflict with religious, political, or social preferences.

Additional: Patients may find better medical care quality abroad, such as through advanced technology or specialized doctors.

Medical tourism is an attractive option as it is more affordable, especially in countries where healthcare is expensive. For example, a coronary artery bypass graft (CABG) costs \$113,000 in the United States but only \$10,000 in India. Heart valve replacements cost \$150,000 in the US but only \$9,500 in India. It has been observed that Medical treatments such as surgeries in countries like India, Thailand, and Singapore cost a fraction of the prices in the US, 5% to 10% to be exact, without giving up quality. Due to the practice of medical tourism, countries attempt to bring in specialists from all over the world. In doing so, they gather specialists in one location, which tends to be a private hospital. The act of gathering specialized doctors results in internal brain drain, a term used to describe when specialized doctors stop serving in the public sector to serve the private sector. Some countries, like Malaysia, have formed a special committee tasked with the promotion of medical tourism. However, the majority of the medical devices used in medical tourism are used in private hospitals, which aim at serving the wealthy and foreign, whereas the public sector continues to have limited access.

Additionally, it is important to consider how infrastructure limitations and workforce shortages pose a challenge that hinders the widespread accessibility of medical devices. Even if medical technology is accessible, in the sense that a hospital or organization has acquired the device, accessibility is not guaranteed. Whether the doctors or healthcare staff know how to adequately and appropriately operate the technology is a factor of accessibility. In many cases, there have been

healthcare staff members who are unaware or unfamiliar with how certain devices and their software systems are used, and as a result are unable to update their clinical protocols as required to ensure the safety and effective use of the medical device. Furthermore, the presence of staff who can be sought out for technical support, such as repairs, ordering replacement parts, and ensuring the acquisition of new equipment, can be under-resourced, which would complicate the usage of the device without worry.

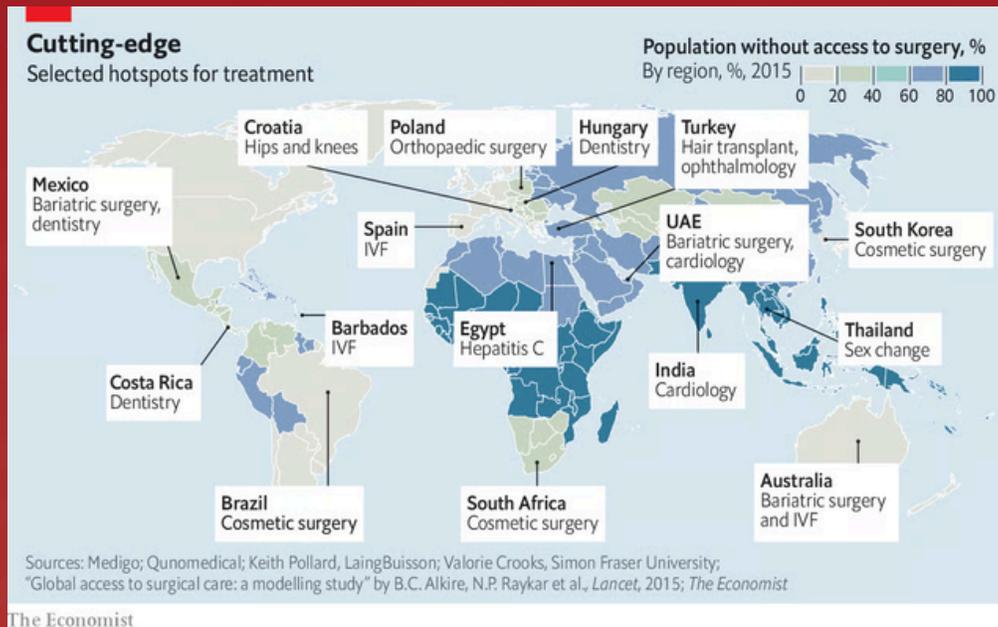


Figure 2: Medical Tourism across the world (The Economist)

Case Study: Thailand

Thailand is one of the widely recognized destinations for medical tourism. The affordable costs, internationally accredited hospitals, and well-versed physicians attract tourists from all over the world to receive medical treatment in Thailand. Among the many private hospitals catering to medical tourism, Bumrungrad International Hospital in Bangkok, Thailand, is one of the largest private hospitals in Southeast Asia and the unofficial leader for medical tourism within Thailand. Thailand makes up 40% of the medical tourism market, with Singapore and India falling right after. Patients who go abroad to Thailand for medical tourism can expect to pay 25% - 75% lower costs than in the United States (International Trade Association). In 2019, the medical technology sector accounted for 4.47% of Thailand's GDP, with the primary medical device export being single-use items such as rubber gloves (Thailand Board of Investment). As such, the majority of the advanced medical technology they utilize for advanced care, such as MRI and CT scan machines come from imports, although the government and Board of Investment (BOI) are attempting to reduce this reliance on imports through tax incentives to attract foreign investment in order to push for local manufacturing.

But despite obtaining these technologies, the distribution of the devices is unequal; Thailand's private and public sectors reflect a dual structure. On one side, well-funded private hospitals serving international and affluent patients possess cutting-edge equipment such as MRI scanners, CT machines, and specialized surgical tools. On the other side, public hospitals – particularly in rural regions – often face shortages of both equipment and trained personnel.

Market incentives play a major role in this imbalance. Because private facilities can profit from foreign patients, they are more likely to invest in expensive technologies, while public facilities that serve the majority of Thai citizens have more limited budgets. Additionally, the migration of skilled healthcare workers from public hospitals to the more lucrative private sector further concentrates both expertise and device capacity in urban centers.

Thailand's experience reveals that while medical tourism can drive technological advancement, it can also deepen internal inequalities in medical device access unless strong policies ensure more equitable distribution.

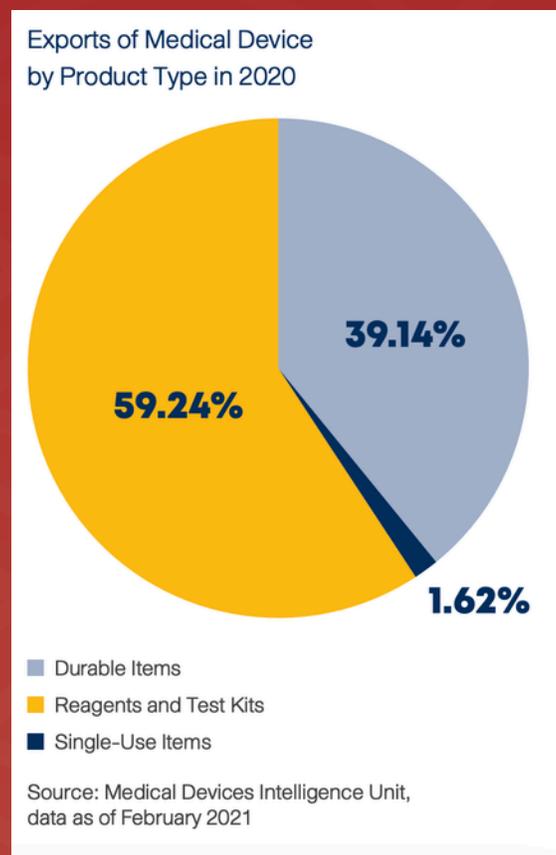


Figure 3: Exports of Medical Device by Product Type in 2020

Regulatory Fragmentation

Although the regulation system of medical devices varies throughout countries, the underlying goal of ensuring public health by verifying that devices are safe and

efficient before and after they are introduced to the medical technology market, and of high quality, remains the same throughout. While the regulatory system assists in ensuring the safety and quality, the different processes that need to be met can cause a delay in the market entry, increase manufacturing costs, and contribute to unequal access to medical devices.

Case Study: United States

The U.S. Food and Drug Administration (FDA) regulates all medical devices sold in the United States. There are multiple ways in which a manufacturer who wishes to put their device in the market can take, as well as three classes in which devices are categorized based on risk, affecting the requirements they must fulfill.

Class I: Devices with the lowest risk, for example, bandages

Class II: Devices with moderate risk, such as imaging systems

Class III: Devices with the greatest risk and need approval for market, such as implanted devices

According to the National Library of Medicine, more than 99% of all the medical devices that the FDA reviews in a given year are cleared for marketing through the 510(k) Premarket Notification process (Food and Drug Administration). This process checks whether the device's submitted intended use matches its performance, as well as gives the FDA the ability to ask for additional information. The FDA's regulatory system is one of the most stringent processes that ensures safety and efficiency; however, this long process also causes the time and cost that the FDA spends reviewing to affect the product's accessibility. Due to the tedious process that companies must comply with, the rigorous checks and costly process, oftentimes, there is an increased price for the product. While this is a minuscule issue that big hospitals can get by with, smaller companies may struggle to buy equipment. Additionally, this may hinder manufacturing companies, as smaller ones may look to other countries with faster approval pathways to release their devices to the market. As a result, the U.S. patients may have to experience delayed access to certain technological innovations as they have to undergo the FDA review process. At the same time, the regulatory system builds trust in device quality and decreases the chances of the device causing harm to the patient.

III. Attempts to Improve Medical Device Accessibility

National Strategies to Incentivize Local Manufacturing

Many countries are aiming to promote domestic manufacturing through incentives. Through the strengthening of local production, it mitigates risks of global disruption, facilitates faster regulatory compliance, and is tailored to the needs of the region.

Case Study: India

Passed in 2023, the National Medical Devices Policy aims to place the Indian medical device sector on an accelerated growth path (Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India). However, even prior to this policy, the Indian government has been making efforts to prompt domestic growth. Passed in 2020, the Production Linked Incentive (PLI) scheme for medical devices offers financial incentives for companies to manufacture domestically, puts focus on devices like CT scanners, and aims to reduce India's historically high dependence on medical device imports.

International Regulatory Harmonization

According to the U.S. FDA, the process of international regulatory harmonization, which is the process of aligning technical requirements for developing and marketing medical products, would promote faster market entry, lower development costs, and reduce unnecessary duplication. Through actions such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), regulators have adopted standardized guidelines and the Common Technical Document (CTD), allowing pharmaceutical companies to submit one core application to multiple regulatory authorities. By doing this, it reduces the need to repeat clinical trials and safety studies for different countries, lowers research and development expenses that can go over \$2 billion per drug. Regulatory harmonization has been shown to improve approval timelines and global access to medicine as seen during COVID-19, when regulatory cooperation enabled faster, parallel review of vaccines across regions. Through the minimization of redundant testing, reducing administrative burden, and facilitating simultaneous approvals, regulatory harmonization strengthens global public health systems and improves timely access to life-saving treatments.

In conclusion, access to medical devices is a fundamental component of effective healthcare and for global health equity. As seen throughout this topic guide, disparities in accessibility are impacted by a plethora of factors including but not limited to high prices, workforce shortages, and regulatory fragmentation. While efforts to reduce inequities, and ensure access to medical devices have been implemented, there are obstacles that hinder the extent of access. Ultimately, addressing these challenges is critical for preparing for future health crises and achieving a more equitable, resilient, and effective global healthcare landscape.

Questions to consider:

1. To what extent should governments intervene in regulating the cost, distribution, and privatization of medical devices?
2. How can governments address the widening gap in medical device accessibility?
3. What role should the public and private sectors have in improving affordability and accessibility?
4. What should be done to prevent a global medical supply chain vulnerability like COVID-19 from occurring once more?
5. How can we ensure that healthcare personnel are properly trained in advanced medical technology?
6. How can we mitigate the occurrence of internal brain drain?
7. How can we ensure that lower-income countries have access to advanced medical devices without putting a large financial strain?

Additional Resources:

<https://www.aspe.hhs.gov/sites/default/files/documents/31d55ee974565dad6f308ac9ea4cba3f/medical-device-shortage-landscape-analysis.pdf>

https://www.jstor.org/stable/4415494?searchText=rapid+growth+in+medical+technology&searchUri=%2Faction%2FdoBasicSearch%3FQuery%3Drapid%2Bgrowth%2Bin%2Bmedical%2Btechnology%26so%3Drel&ab_segments=0%2Fbasic_search_gsv2%2Fcontrol&refreqid=fastly-default%3Ad2ca18ddb3d53d853f99b346d23b2d79&seq=1

<https://pmc.ncbi.nlm.nih.gov/articles/PMC3206745/#b2-squmj-11-444>

<https://www.trade.gov/country-commercial-guides/thailand-medical-devices-and-technology>

<https://pmc.ncbi.nlm.nih.gov/articles/PMC3883860/>

<https://pmc.ncbi.nlm.nih.gov/articles/PMC3883836/#:~:text=For%20those%20who%20rely%20on,early%20to%20say%20anything%20definitively.%E2%80%9D>

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>

<https://www.congress.gov/crs-product/R47374#:~:text=Medical%20devices%20are%20regulated%20based,special%20labelling%20or%20postmarket%20studies>.

https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

<https://www.fda.gov/drugs/cder-international-program/international-regulatory-harmonization>

<https://www.osha.gov/personal-protective-equipment>

<https://www.economist.com/business/2018/07/28/how-the-medical-tourism-business-thrives>



General Assemblies *Topic Guide*

WHO

World Health Organization

Yale Model United Nations China III

May 15-17, 2026

