Three years after the end of World War II and the subsequent formation of the United Nations, the World Health Organization (WHO) was created to combat the spread of communicable diseases. Their initial priority was the coordination of health affairs around the world, achieved by working alongside member countries of the United Nations, to identify prevalent public health concerns and assist with health research within those nations.¹ Now, with more than 150 member countries, the organization’s main goal is to help identify and classify diseases that continue to run rampant in the world. Although WHO’s priority is addressing public health issues, they are unable to enforce them due to International Health Regulations which state that WHO has no authority to determine what individual member countries do within their own borders.

Increased use of Technology in Healthcare

Statement of the Issue:

One of the most important and fastest growing sectors of the healthcare industry is the use of technology and medical devices in everyday operations. Medical technology includes a myriad of devices from stethoscopes to pacemakers, which are utilized throughout the medical field and around the world. As the use of technology has expanded across borders and innovation has created life saving devices, the need for regulation has become increasingly necessary. Regulation ensures public health benefits and the safety of patients and health workers. The upholding of these regulations should be a priority for the WHO as they embark on providing healthcare services to different nations.

As technology advances, the costs of access and maintenance of these medical devices has increased exponentially. Health systems in low-income countries are often the most in need of medical devices but are also most likely to fall victim to unsafe medical practices, by way of unregulated devices.2 Currently, one of the many barriers to having an international guideline on regulation and safer practices is that every nation has their own laws and enforcement measures, which makes international harmonization a difficult task. Of the 193 member nations in the WHO, only 58% have a

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regulation for medical devices in place, which has led to increased oversight in many procedures.³

To ensure that a single and unified form of inspection and regulation is practiced, five participant countries (Australia, Brazil, Canada, Japan and the United States) came together in 2014 to create the Medical Device Single Audit Program (MDSAP). ⁴ Although these efforts were made in the hopes of developing a single audit process, they did not include low-income countries that are truly in need of medical device regulations. Due to a lack of financing and proper organization of resources, low income nations are left out of the conversation. Essentially, they are left without the proper medical devices, and without access to potentially life-saving procedures.

History:

Medical technology is a broad topic that encompasses an array of innovations from pharmaceuticals and bandages to larger devices like MRI machines and prosthetic limbs. Although it is difficult to say when the first form of medical technology was invented, some of the most amazing milestones in the medical industry date all the way back to ancient Rome—where historical evidence proves that medical devices were in widespread use.⁵ Since the days of the early Romans, medical devices have evolved,

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⁵ “Surgical Instruments from Ancient Rome.” Ancient Roman Surgical Instruments, exhibits.hsl.virginia.edu/romansurgical/.
allowing for the integration of artificial organs and ventilators that have been the delineating marker between life and death for many.

The medical technology industry is a global behemoth with market revenues reaching around US $456.9 billion.Collectively, the largest market share of the industry belongs to the United States at 40%, with Europe and Japan following behind at 25% and 15% respectively. This continent and country hold the second rankings for market share sizes in the global medical device market. Because they have a significant impact on everyday life, it is important that medical devices are properly regulated; this is where many nations seem to come to a different conclusion on the legal framework and definition of medical devices. Each nation has their own ruling body that determines the use and definition of these items. In the United States, the regulatory body is the Food and Drug Administration (FDA), while in Europe the UK has the Medicines and Healthcare products Regulatory Agency (MHRA) and Italy has the Ministero Salute.

The WHO has made several efforts to improve access to safe, effective and appropriate medical devices, despite the differences in legislation across member nations. The committee’s commitment to ensuring quality healthcare in every nation led to the convening of the First Global Forum on Medical Devices in March 2010. The objective of this program was to bring together policy makers of different member nations to stress the need for appropriate regulation of and access to medical devices.

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6 “Global Medical Device Market 2020 Size To Increase Due to Rising Infections And Chronic Disease Cases As Per The Business Research Company’s Medical Devices Global Market Opportunities And Strategies.” Global NewswireNewsRoom, globenewswire.com

As medical technologies expand and research development enhances collaboration between countries, the WHO’s greatest priority should be regulating this increased use of technology and ensuring that it includes proper safety practices. This can be achieved by improving training and increasing accessibility across all borders.

**Analysis:**

The medical device industry has provided physicians with tools to improve patient care through therapy, remediation and life changing surgeries. However, due to the continued innovation of technology, the costs of acquiring these products and procedures tends to be expensive. This has led to a list of issues—including improper device usage, lack of adequate training and lack of accessibility—all of which prevent the WHO from properly distributing and providing access to medical devices. Although there are several private organizations, including Medical Device International, that strive to provide access to those in need, more work is still required to achieve a model standard. To ensure that patients get the best usage out of medical devices, it is important that both physicians and medical volunteers are properly trained on how to use such technology. Usually, there are organizations, such as NSF International, that provide regulatory certification and medical device training however, most programs are for private organizations and companies, and therefore, they do not benefit the low-income countries that are in the most need.

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Furthermore, the rise and increased use of technology in the healthcare industry has unfortunately come with drawbacks, the most troubling of which are data breaches— or the access of private information without authorization. The United States is the most commonly targeted country. In the past 5 years there have been over 6,825 instances of data breaches in several industries. According to the most recent statistics, healthcare is the most targeted industry, with a total of 2,248 breaches. These medical breaches pose a dangerous threat to the livelihood of millions of people, and their secure information. This is a common threat to the care of people in developing nations. Therefore, it must also be of priority to bring such technologies to regions with limited access while taking care to address security concerns.

Despite the efforts made by private organizations and the WHO, there is still a lack of access to medical technology, especially in the regions that are most in need. The best initiatives will be those that take into consideration the holistic needs of all countries involved. This includes increased access to medical devices, higher security of personal health data, and improved training to increase safety in medical procedures.

Conclusion:

Modern medical technology has played an important role in ensuring that millions are kept healthy and in helping to cure many diseases. The WHO has funded and worked alongside a handful of initiatives to ensure a unified regulatory system. However, it will take more than just one body within the committee to solve the issues of

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international regulation and access. The difficulty of this problem lies not only in creating unified legislation, but also ensuring that every member nation achieves equity in the field of medicine.

Questions to a Resolution Must Answer:

1. Does medical technology impose more unnecessary dangers than it empowers?
2. What systems can be implemented to ensure that medical data is secured and not used without consent?
3. Are there other actions that the WHO should be taking to ensure all countries have access to modern medical technologies?
4. What are some ways that the WHO can finance the spread of new technologies?
5. How can the WHO implement the use of modern medical technologies in countries that have strict legislations that make technology usage difficult?
Resources


“Surgical Instruments from Ancient Rome.” *Ancient Roman Surgical Instruments*, exhibits.hsl.virginia.edu/romansurgical/.