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ISSUE DESCRIPTION

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SUBMITTED BY	Gergely Levente Remsei and Laura Specht, Presidents of the United Nations Educational, Scientific and Cultural Organisation
APPROVED BY	Szófia Tóth, President of the General Assembly

Introduction

Science and its inventions have long been bringing around advancements in people's everyday lives and improvements in their standard of living. However, similarly to everything that was created by people, scientific discoveries and theorems are not always perfect and immaculate, therefore they need to undergo a series of experiments before reaching the public. This triggers the question of how far humanity can go to prove the benefits and recognise the handicaps and side effects of a product.

The largest industry that is engaged in the production of agents that in several ways affect the human body, its functions, and its structure is pharmaceutical manufacturing. The field is committed to developing chemicals that are used to diagnose or treat an illness, ease their temporary and long-lasting symptoms, and restore, correct, or modify organic functions. After the unification of research in the 20th century in the sectors of chemistry and physiology, scientists gained a deeper understanding of the interactions between the human body and drugs, and the subsequent processes and reactions. The production of pharmaceuticals containing engineered compounds and chemical synthetics began.

On the never-ending timeline of history, scientists have always tried out their concepts on their fellow human beings or used animals to test their theorem before applying that to their peers. Nevertheless, regulations were not ready for what the technological advancements of the 20th century brought. Many researchers with little compassion saw nothing but test subjects in other people, who with little knowledge of the topic usually did not know what they could have expected to be exposed to. The same fate was awaiting all animals and people who fell victim to the curiosity of their contemporary scientists. Sometimes even the experiment differed from

its description. Either a different chemical was given alongside, the adequate one to test a completely different discovery from what was promised, or there was no treatment and the whole procedure aimed to observe the symptoms of the disease while it progressed, and the health of the human being was sacrificed on the altar of science.

Even though several frameworks and books of law have been introduced since the Second World War aiming to regulate these kinds of experiments, protests have still been going on in the last decades calling upon further measures to be taken where scientific and ethical principles are able to meet.

Definition of Key Terms

Animal Rights - moral or legal entitlements attributed to nonhuman animals, usually because of the complexity of their cognitive, emotional, and social lives or their capacity to experience physical or emotional pain or pleasure.

Ethical guidelines - Defined principles and standards ensuring the moral integrity of experiments.

Informed consent - Voluntary agreement obtained from individuals participating in experiments, based on a clear understanding of potential risks and benefits.

Medical Research Council UK (MRC) - The MRC is a government-funded organization in the UK that coordinates and funds medical research with a mission to prevent illness, develop therapies, and improve human health.

Scurvy Experiment - The first controlled clinical trial in which James Lind tried to find the most promising cure for scurvy.

SDG3: Goal 3 of the Sustainable Development Goals 2030 Agenda, is the following: “Ensure healthy lives and promote well-being for all at all ages”.

Vivisection: The use of living animals in tests that are intended to increase human knowledge of human diseases and the effects of using particular drugs.

3 R's principle: REPLACE animals with non-animal methods where possible, REDUCE the number of animals used, and REFINE practices to minimize suffering.

General Overview

The evolution of human trials traverses a long and fascinating journey. World's very first open uncontrolled experiment on people is recorded in the Bible. According to the "Book of Daniel" it was conducted by King Nebuchadnezzar, a resourceful military leader in Babylon. He believed that it would keep his soldiers in sound physical condition if they had only eaten meat and drunk wine. He ordered so, however, young royal descendants didn't want to give up on their diet that was composed of vegetables. Therefore, the king let them eat only legumes and drink water for the following ten days. When that period ended, he found that those who followed the vegetarian diet were in better shape. The first rules concerning the regulation of human trials were described in the 11th century in an encyclopedia, however, there is no extant evidence to prove their implementation. The first human trial that resulted in the improvement of healing methods was an accident. In 1537, a surgeon responsible for treating the wounds of the soldiers ran out of oil that was traditionally used for these injuries way before he could apply it to every wounded. To save the others he created a digestive. The next morning he found that those who received the unconventional, less painful treatment regenerated more quickly. However, this experiment remained uncontrolled and in a worst-case scenario could have caused numerous deaths or permanent complications.

These experiments continued to go on for the following centuries, however, they became more controlled, and several new procedures evolved. Even though the ancient Hippocratic Oath protected human subjects, it was not respected when it came to human experimentation. A trial conducted by the Medical Research Council UK in 1943 to investigate the effect of patulin, an extract of Penicillium patulinum, on the common cold supports this statement. The experiment was based on the double-blind concept. Both the subjects and the physicians were kept blind to the treatment. it was the nurses' responsibility to file the record counterfoil separately, which were later analyzed by the statisticians. Nonetheless, awareness wasn't raised until the end of the Second World War, when the cruel inhuman experimentations saw daylight. Several victims of the Holocaust endured trials in the camps of Auschwitz suffered mass massacres and had their organs autopsied. By this time, the world could no longer turn a blind eye to the growing demand for the establishment of a framework for the regulation of human trials. The Nuremberg Code was created in 1947 to prevent the recurrence of the horrors committed in the camps. The declaration set guidelines governing research on human beings, from which 10 principles focused on the consent and autonomy of the subjects.

Despite the numerous declarations published, regulations introduced and conferences held since the last century, the issue became significantly less concerning but remained a matter of debate. There are three fundamental pillars of a just procedure. The first is informed consent, which requires the detailed information of the subject about the aim, and the possible positive and negatives outcomes of the experiment. The second one is the question of beneficence. It aims to maximize the benefits for the research participants while minimizing or eliminating the possible harm to them. The last one is that justice stands for the rightful selection of human subjects and non-discrimination against them. The most common damage to these principles occurs among people from vulnerable social groups including impoverishment, political underrepresentation and powerlessness. In the cases when the subjects have received limited education or are unfamiliar with science, unclear and lengthy sentences set back their understanding, and they might consent to something, they would otherwise not be willing to do. Usually, their lack of knowledge results in ignorance, therefore they might consent without having been informed, which is a violation of fundamental human rights. Furthermore, those coming from minorities can be more easily manipulated because of their weak social status.

Secondly, animals have been experimented on as well, dating back to ancient Greek . They were used to advance the understanding of anatomy, physiology, pathology, pharmacology and even a few surgeries were tested on them before applying them to humans. Even though protests have not been stopped yet there is apparent evidence that drugs placed on the market without having undergone animal experimentation are not always reliable. The lack of this step usually ended in fatal disasters for thousands of people, therefore it remained part of the process.

According to law, animals had long been considered legal things, meaning that they were classified as objects, with no feelings or emotions, before they were granted rights that aimed to protect their mental and physical well-being. Therefore, it was not surprising that besides their easy trade, they were exposed to their owners' will. This concluded animal experiments as well. After human trials had been strictly regulated and the demand for the number of subjects increased, scientists turned towards the species from the animal kingdom hence they resemble the human body the best. In the 20th century technology experienced rapid growth, the assessment of the effectiveness of new medicinal products, and testing of the human health and environmental safety of consumer and industry products such as cosmetics, household cleaners, food additives, pharmaceuticals and industrial or agro-chemicals came to the fore. The easiest and most effective way was to use animals for these purposes. However, due to social pressure in the late 1900s, multinational cosmetic companies had to give up on the process and introduced rigorous policies forbidding animal trials.

Numerous non-animal policies have been introduced worldwide, including the 3 R's principle, which declares the replacement of animals with non-living models, the reduction in the use of animals and the refinement of animal use practices. In spite of these measures, animal trials still remain a debated issue. It is supported by the fact that even though these experiments can prevent mass deaths caused by new drugs, in most cases the reaction of the human body differed from what was observed on animals. According to the Humane Society International, approximately 115 million animals are used in laboratory experiments a year worldwide. They endure painful injections, forced feeding exposure to toxins, drugs, chemicals or infectious diseases for negligible benefits.

Major Parties Involved

WHO (World Health Organization): As a global health authority, WHO plays a pivotal role in setting health standards and guidelines, making it essential to address the ethical dimensions of experiments on a worldwide scale.

ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use): ICH develops global guidelines for Good Clinical Practice, ensuring ethical conduct in international clinical trials and harmonizing standards across different regions.

EAR (European Animal Research Association): EARA is an organization advocating for transparency and communication about animal research and it publishes guidelines for safe animal testing.

EMA (European Medicines Agency): EMA plays a crucial role in establishing and overseeing ethical standards for clinical trials involving humans.

United States of America: As a leader in scientific research and funding, the U.S. influences global research standards through entities like the National Institute of Health (NIH), actively contributing to the shaping of ethical norms in experimentation.

People's Republic of China: Being a significant player in the realm of research and innovation, China plays a crucial role in promoting global inclusivity and upholding ethical standards in experiments, fostering international collaboration.

Germany: With historical contributions to ethical guidelines post World War II, Germany's stance on experimentation is significant in shaping international discourse.

Timeline of Events

Pre-18th Century - Pioneering Experimental Medicine:
Early instances of unregulated experiments on animals and human subjects mark the emergence of experimental medicine

1747 - James Lind's Scurvy Experiment:
Lind's groundbreaking scurvy trial underscores the need for systematic approaches to clinical research while raising ethical questions.

1800 - Arrival of Placebo in clinical trials:
The introduction of the placebo in clinical trials influences the ethical considerations of experimental design and informed consent.

19th Century - Rise of Vivisection Debates:
Debates on the ethical use of live animals for experimentation shaped discourse on humane treatment during the 19th century.

1947 - Nuremberg Code:
Post World War II, the Nuremberg Code establishes ethical principles for human experimentation, highlighting the need for guidelines.

1979 - Belmont Report:
The Belmont Report outlines ethical principles and guidelines for research involving human subjects, setting standards for informed consent and subject welfare.

1986 - European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes:
The convention addresses the ethical treatment of animals used in experiments, contributing to international standards.

1990s - Advances in Biotechnology and Genetic Research:
Rapid advancements in biotechnology and genetic research necessitate updated ethical frameworks for experiments on animals and humans.

2000s - Increased Globalization of Clinical trials:
Clinical trials become more globalized, emphasizing the need for standardized international regulations to ensure ethical practices.

Current Day - Emerging Ethical Challenges:
Contemporary challenges in experimental research, including gene editing, artificial intelligence, and personalized medicine, demand a comprehensive and adaptable framework.

Previous Attempts to Solve the Issue

Governments, United Nations committees, and NGOs have undertaken various efforts to address the concerning issue. While these initiatives have led to some advancements, there remains a need for the establishment of an international framework to enhance the collective response and further address the issue at hand.

Several organizations have already published guidelines for animal and human testing, such as the EARA (European Animal Research Association) and the EMA (European Medicines Agency), both emphasizing the 3 R's principles.

Possible Solutions and Approaches

Many countries encourage the development and utilization of alternative methods to minimize reliance on animal and human testing. At the same time, some alternatives to animal and human testing already exist, although many scientists and governments criticize them for not being sufficiently developed or as effective as traditional methods.

To start with, some believe computer models could predict biological responses, offering fast results and cost-effectiveness. However, their limitations include accuracy issues and the potential for unforeseen consequences in real-world scenarios.

Furthermore, tissue printing can be used for testing purposes, involving the precise recreation of human tissues. Challenges still exist, including technical hurdles in reproducing the complexity of certain tissues and potential ethical concerns related to the sourcing of biomaterials.

In general, there is also a suggestion for increased public awareness about the ethical challenges, fostering a sense of responsibility and accountability. Increasing international collaboration can help create a framework as well.

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