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*Regulation of Healthcare Systems to
Prevent Shortages of Drugs and
Treatment During Global Pandemics*

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RESEARCH
REPORT



Forum: Health Committee (SA3)

Issue: Regulation of healthcare systems to prevent shortages of drugs and treatment during global pandemics

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Introduction

The world is currently experiencing a massive increase in drug shortages due to the COVID-19 Pandemic. Even before the pandemic, the numbers were extremely high, and now, drug shortages are causing numerous deaths all around the world through delayed treatment, medication rationing and denial of treatment. There's a number of reasons for drug shortages, and some of these include the sudden increase in patients, errors with the manufacturer, abuse of retail drugs by the concerned public and the unavailability of a medicine. With the spread of the COVID-19 and the increase it caused in shortages, the main reasons for the issue became challenges in supply. Even though the situation improved itself through the ends of 2020, there are still some issues remaining which include logistical and transport challenges, decreased manufacturing capacity and increased purchasing costs.

Currently, a universal definition of drug shortage doesn't exist, meaning different organizations define it in various ways. This uncertainty makes it difficult to determine the existence of a shortage. The Food and Drug Administration (FDA) defines a shortage as "a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level." Whereas, the European Medicines Agency (EMA) refers to the simple definition of "when the supply of medicine is unable to meet the demand". The key point of this issue is the lack of cooperation and unity. With the sudden outbreak of COVID-19, everybody, from civilians, to governments to the UN had to take immediate action, leaving no room for cooperation or established unity. This also majorly affected the increase in global medicine shortages.

Lastly, there is a long list of medicines that went into shortage with the break of COVID-19. Some of these are known to be possible treatments for the COVID-19, explaining their shortage and also emphasising on how many possible treatments are absent in such a global pandemic. The medicine that went into shortage the most include: Hydroxychloroquine sulfate tablets (possible treatment), Chloroquine phosphate tablets (possible treatment), Albuterol sulfate inhalers, Fluticasone propionate inhalers, Azithromycin injection and tablets, and such.

Definition of Key Terms

Global Pandemic: Epidemics that occur worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people.

Epidemic: A sudden increase in the number of cases of a disease above what is normally expected in that population in that area.

Zoonotic Origin: The phrase is used for viruses and diseases that originated in the animal kingdom which then transferred to humans.

Just-In-Time (JIT) Inventory: This is an inventory management strategy aimed to reduce costs of companies by keeping the supply meet the demand but also avoiding the excess of supply used by either small businesses or major corporations.

Medication Rationing: Controlling the distribution of medicine in order to sustain the limited supply of treatment.

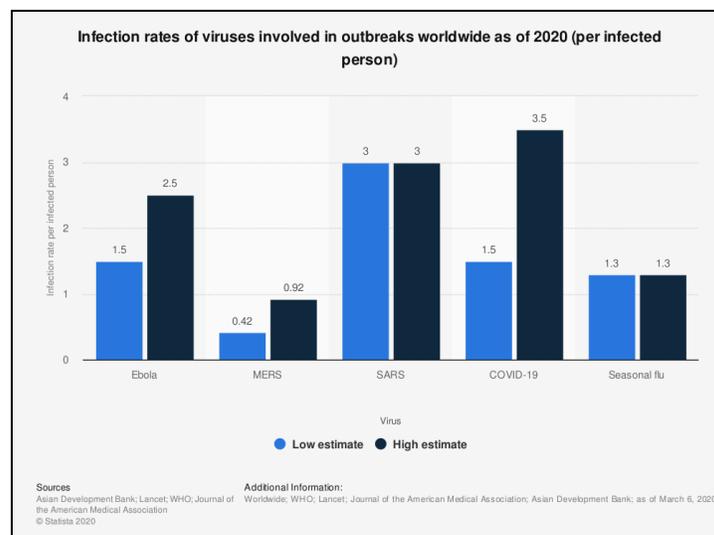
Retail drugs: Drugs one can find in their retail pharmacies, brand name and generic drugs.

Drug Shortage: Even though it doesn't have a universal definition, different organisations define it on their own. The FDA uses the definition of a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level.” Whereas, the European Medicines Agency (EMA) refers to the simple definition of “when the supply of medicine is unable to meet the demand”.

Pandemic Influenza: A viral Global Pandemic with zoonotic origin, specifically the Influenza A virus.

General Overview

Global pandemics have been one of humanity's most important battles ever since the agricultural revolution. Around 10,000 years ago, people started settling permanently in certain lands and began producing their own resources by practicing agriculture. This meant that they were living side-by-side with many animals at all times, easing the spread of many viruses and bacteria between cattle and humans. Some epidemics that root from bacteria include Cholera, which first appeared in Haiti, as a result of drinking large amounts of contaminated water in temporary refugee camps. Most global pandemics are caused by viruses such as measles, influenza, HIV etc. It's easier for these viruses to mutate and adapt to human infection and human transmission. Just one sneeze can be enough to infect hundreds of people, which then establish contact with others and spread the virus even more.



Graph of infection rates from viral pandemics in 2020

The greatest global pandemic is Pandemic Influenza. Influenza is a respiratory disease that has been infecting people for centuries. Much like many other diseases including SARS and COVID-19, Influenza also has a zoonotic origin. But for the disease to turn into an epidemic, it also spread amongst humans. Pandemics can occur annually but not as often as epidemics. Epidemics are most likely to be seasonal, meaning they occur around a specific time every year. Even though they affect a large number of people in a very wide area, seasonal epidemics are not pandemics. The main difference between pandemics and epidemics is that pandemics spread to various communities while epidemics affect one. Some epidemics include seasonal flu, chicken-pox, cholera, etc. The Flu Pandemic generally occurs every autumn and winter, making the disease seasonal. Evidently, epidemics are as deadly as pandemics meaning they could be treated similarly depending on the disease. Since many people have already been exposed to Influenza in its previous seasons, they only experience the virus mildly.

However, this does not mean that the Influenza virus should be taken lightly. In the early 2000's, Professor Vaclav Smil(a Czech-Canadian scientist and policy analyst) calculated the probability of sudden disasters large enough to change history and amongst all wars or natural disasters, he found that the highest probability belonged to a severe flu pandemic. Which we now can see is accurate, considering COVID-19. Experts claim that the best treatment for viral pandemics are vaccines. With the production of new or better vaccines, many pandemics including Malaria, Tuberculosis, HIV, Pneumonia, Diarrhea, Flu and COVID-19 could permanently come to an end. For example, production of such vaccines have officially erased pandemics like Smallpox and Polio off the face of Earth.

Much like Influenza, COVID-19 is an airborne respiratory disease that has a zoonotic origin and eventually became a global pandemic. Currently, the aim of scientists is treating COVID-19 enough to make it a seasonal epidemic just like what happened with influenza. However, a definite and effective treatment hasn't been discovered yet. Countries like the USA and China started launching and exporting some vaccines even though they mostly contain horrible side-effects and haven't been fully tested yet. This further confirms that the world is still far away from achieving said goal. Currently, some drugs and inhalers are seen as possible solutions to the Coronavirus. Unfortunately, most of these treatments are in a massive shortage. The world is experiencing a failure in cooperation and unity. Every government is trying to ensure the safety of their citizens first, which takes quite a lot of time and worsens the issue during such a global pandemic. Evidently, there are some countries that managed to lower the rates of COVID-19 amongst their citizens and remain in control, avoiding major shortages in their treatments.

While countries are all trying to keep their cases low and scientists working to find proper solutions to the virus, some organizations such as the the FDA, EMA, American Society of Health-System Pharmacists (ASHP) etc. have been taking action as much as they can to aid the solution of this issue. They've taken many actions including closely monitoring countries' drug shortage rates, releasing acts, arranging events and much more.

Major Parties Involved and Their Views

USA (United States of America)

The United States of America is currently the country with the highest rates of drug shortages in the world. The medication distribution system of the nation utilises a JIT (just-in-time) inventory system. Meaning the healthcare institutions don't carry any excess inventory for drugs. Therefore, in case of a global pandemic such as the COVID-19, mass shortage of drugs occur all across the country. The same result may take place with something way less serious than a global pandemic, such as a supply problem of the manufacturer, making the US medication distribution system inconsistent and unsustainable. The country also is the source of most researches and actions taken to prevent the issue of drug shortages.

PRC (Peoples' Republic of China)

PR China is also currently experiencing a major drug shortage. The country has many responses to end this crisis and has done quite well in keeping the COVID-19 pandemic under control, even though the virus originated in Wuhan. China has very few cases of COVID-19 and is exporting medicine and vaccines for Corona to other nations.

FDA (Food and Drugs Administration)

The Food and Drugs Administration is a federal agency of the Department of Health and Human Services in the USA. It is connected to the government of the US and has been deeply active on the issue of drug shortage. It has been releasing acts, conducting worldwide researches and events on this particular issue.

EMA (European Medicines Agency)

The European Medicines Agency is simply the European equivalent of the FDA and has also been extremely active on the issue of drug shortage. The agency is under the regulation of the European Union (EU) and has been closely aiding its member states.

WHO (World Health Organisation)

The World health Organisation is the UN's office for global health. It's purpose is to aid the world in times of crisis related to health and ease access to health in its member states. The organisation failed to properly respond to the COVID-19 global pandemic due to its lack of exercised authority. It failed to unite its members to take action and by the time WHO came up with a proper solution, most member states had already initiated their approaches.

UNODC (United Nations Office on Drugs and Crime)

The UN's Office on Drugs and Crime generally refers to crime prevention, criminal justice and issues like drug trafficking, although they have been deeply affected from the global shortage of drugs that increased highly as a result of the COVID-19 pandemic. This is due to some civilians panicking and stocking their medicine, causing an increase in medicinal drug trafficking and shortages in pharmacies.

Timeline of Events

31 Dec 2019	<i>Wuhan Municipal Health Commission, China, reported a cluster of cases of pneumonia in Wuhan, Hubei Province. A novel coronavirus was eventually identified.</i>
March 2020	<i>COVID-19 got declared a global pandemic by the WHO.</i>
31 March	<i>Hydroxychloroquine Sulfate Tablets went into shortage</i>
02 April 2020	<i>Number of people infected from COVID-19 worldwide reached 1.000.000</i>
10 April 2020	<i>The highest rate in the increase of medicine shortages occurred, with three anesthesia treatments (Dexmedetomidine Injection, Etomidate Injection, Propofol Injectable Emulsion) in one day.</i>
June 2020	<i>Medication shortages due to the Coronavirus global pandemic have officially reached 87% that of the shortages reported in 2019.</i>
January-July 2020	<i>27 new shortages on medications were announced (the number has always been between 5-31 until 2020).</i>

Treaties and Events

Drug Shortage Summit of November 2010: Held by ASHP, the American Society of Clinical Oncology, the ISMP, and the American Society of Anesthesiology. This summit focused on causes of the issue, emphasized its importance and determined an action plan toward its solution.

FDA Drug Shortage Public Meeting: Aiming to determine causes and effects of drug shortages- on September 26, 2011. This was a workshop organised to discuss why the United States is experiencing shortages of certain drugs, especially those for treating cancer, and to discuss solutions.

FDA Law on Drug Shortages: In July 2012 granted the organisation additional tools to address the issue of drug shortages.

FDA Safety and Innovation Act of July 12, 2012: Asked companies to notify FDA of any potential supply disruptions 6 months in advance or as soon as predictable. This way, the FDA would be notified and prepared for an upcoming drug shortage.

Release of Safety and Innovation Act's Plan for Preventing and Mitigating for Drug Shortages on October 31, 2013: This plan was simply the part of the Act that focused on the solution of drug shortages, it contained FDA's plans on how to mitigate the issue.

EU Parliament Resolution on Drug Shortages, September 11 2020: With this resolution, the EU members unified their actions on the issue and discussed solutions to medicine shortages.

Evaluation of Previous Attempts to Resolve the Issue

As stated previously, the way to a solution of medicine and treatment shortages, especially in times of global pandemics, is unity. In times of global pandemics, panic overtakes everybody from citizens, to organizations, to governments and the UN. This panic causes authorities to act as quick as they can in order to prevent as many deaths as possible. However, quick actions are not unified, and cause further crises including medicine shortages. Noticing this, organizations including the EMA and FDA have started taking action to unify their members' responses to drug shortages, and create platforms to gather all the information on the issue. Both organizations have been holding records of drugs that went into shortage, their purposes and the dates they went into shortage. Additionally, EMA has been recommending certain responses to its members on battling drug shortages. A new monitoring system was recently set in the EU in order to mitigate shortages of certain medicine needed for COVID-19 treatment. Not to mention, vaccines for the treatment of COVID-19 are currently being produced in some countries, these vaccines will contribute to the prevention of medicine shortages by simply lowering the number of infected. Evidently, this is a very recent issue and these responses have just begun, meaning there is no way of determining if they have worked yet.

Possible Solutions

The issue of drug shortages, just like any other crisis, cannot be prevented by a single action, the world needs to come together and draft a set of steps towards solving it. These steps would begin from the simplest action, defining the issue. It's known that detecting treatment shortage is especially difficult due to the absence of a universal definition. Secondly, since the supply and demand is trying to be balanced, increasing the supply is crucial. For this, research on COVID-19 vaccine development and drug manufacturing needs to be supported. However, just increasing the supply won't be enough on its own, that is why the UN needs to support organisations like the FDA and the EMA alongside ensuring the prevention of citizens abusing pharmacies to stock up on medicine, resulting in a massive decrease in demand. After these three essential steps, solutions for making sure the issue doesn't peak again may be found.

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