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THE DEFINITION OF PANDEMIC: CAUSES AND CONSEQUENCES OF ITS ADJUSTMENT IN 2009 AND 2011

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The article considers results of the study evaluating historical and epidemiological events that preceded and accompanied adjustment of the pandemic description on the WHO website in 2009 and 2011.

The analysis covered publications related to epidemics and pandemics issues, the WHO documents, the WHO website. The descriptions of pandemic mostly focused on "enormous numbers of cases and deaths". Since May 2009, new description of pandemic was published, focusing on disease prevalence. In 2011 it reverted to initial one with no comments. From perspective of the WHO document of 2009, declaration of swine flu pandemic in June 2009 seemed justified. However, considering previous pandemic history, common sense and consequences of declaring pandemic of disease with low both number of cases and mortality, it was premature move.

Since primary factor hindering development of pandemic is effectiveness of infectious disease treatment, to minimize likelihood of new pandemic it is necessary to improve special medical education quality and to study and to adapt to modern conditions all effective medications and methods used in the past.

Key words: pandemic; epidemic; swine flu; the WHO; H1N1.

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"For years, the organization's web site defined an influenza pandemic as causing 'enormous numbers of deaths and illness.' But the agency recently pulled the definition, apologizing for causing confusion and anxiety."

(*The New York Times*, 8 June 2009)

Introduction

Infectious diseases, as well as epidemics, have been well-known since ancient times. The Chinese Yellow Emperor's Inner Canon, believed to date from the tenth century BC, describes external pathogens that can cause acute infectious diseases which affect many people simultaneously [1]. At that time, doctors knew that the course of a disease in each case depended on the patient's initial state and his "defense energy" (Wei Qi) [2]. By "defense energy," one can mean a complex response of the immune and other body systems involved in the pathogenetic and sanogenetic reactions of the patient.

Despite the variety of external pathogens represented by thousands of viruses and bacteria, the human body has a limited set of protective reactions known in modern pathophysiology as inflammation, fever, hypoxia, general adaptation syndrome, and others. These pathogenetic syndromes are accompanied by nonspecific symptoms, such as fever, weakness, chills or feeling hot, headache, cough, shortness of breath, nausea, vomiting, diarrhea, skin rash, discoloration of the skin, and so on, which have similar pathogenesis, regardless of the causative agent of the infectious disease.

With all the variety of pathogens, in the case of the development of any febrile disease, only two main mechanisms are involved that lead to an increase in temperature — an increase in heat production or a decrease in heat transfer [3]. Similarly, 2–3 mechanisms are involved in forming each clinical syndrome.

About 1800 years ago, Dr. Zhang Zhongjing studied the results of previous generations of research and developed a theory of acute infectious diseases that explained the diagnosis and treatment of leading syndromes. According to this theory, in the case of the development of an acute infectious process, there is a change in six phases of the disease, reflecting the gradual inclusion of various levels of protection. Each phase can proceed according to one of two or three options. Thus, the variety of clinical syndromes associated with acute infectious diseases can be reduced to ten or twelve options, each of which a protocol of etiopathogenetic treatment has been developed [4]. When symptoms change and, accordingly, when the clinical syndrome changes, a new treatment must be selected. Therefore, in treating one patient, the protocol for the use of drugs was constantly changed following changes in the main symptoms of the disease. This phenomenon could ex-

plain failed clinical trials conducted by modern scientists unfamiliar with phases of an infectious disease.

There are some examples of treatment of the initial phases of infectious diseases: in the case of initial fever with general cold feelings without sweating — *Herba Ephedrae* was recommended; if there is initial fever with general hot feelings — *Folium Mori Albae* or *Herba Menthae Haplocalycis* should be used; if there is initial fever with intensive sweating or tension in the muscles — *Ramulus Cinnamomi Cassiae* was recommended; in the case of fever with alternating cold and hot feelings — *Radix Bupleuri*, was used, and so on. A change in symptoms pointed to a change in the phase of the disease and required an adjustment of therapy. If a patient has a severe fever with hemorrhagic symptoms, skin rashes, kidney and liver impairment, delirium, and other symptoms of aggravation of the disease — *Radix of Isatis tinctoria* should be applied [5]. In the succeeding centuries, protocols for treating infectious diseases were updated following a new understanding of the etiology and pathogenesis of diseases and advances in pharmacology.

A modern physician who has studied Hans Selye's General Adaptation Syndrome [6] is only familiar with a limited version of Dr. Zhang's theory of acute infectious diseases and needs more knowledge to apply it at the patient's bedside.

It can be assumed that the development of an epidemic or pandemic depends not so much on the danger of an external pathogen but on the knowledge and experience of the doctor and on his ability to choose an individual treatment corresponding to the current phase of the acute disease. Therefore, training a doctor who knows how to use effective means and methods of treatment should be the basis for a successful fight against future pandemics. Otherwise, we are in for a series of pandemics reminiscent of those that occurred in 2009–2010 and 2020–2023, when the main hope was placed on quarantine, movement restrictions, and mass vaccination.

Materials and methods

Since the cause of the change of the description of a pandemic on the WHO website in 2009 and 2011 is not clear, analyses of the literature related to the epidemics and pandemics, WHO documents, WHO website, and articles published in journals and the Internet pages have been done. This study aims to reveal the main historical and epidemiological events that preceded and accompanied the adjustment of the description of a pandemic on the WHO website in 2009 and 2011.

To optimize this study, pages of the WHO website dedicated to the description of a pandemic were collected in a thematic digest containing text and page screenshots [7].

Results

A brief overview of the pre-1999 definition of a pandemic

In a dictionary published in London in 1791, the term epidemic (*epidemius*) refers to a disease that affects

many people simultaneously and then disappears. In the same dictionary, the word pandemic (*pandemiis*) is explained as a synonym for the word epidemic [8].

In a dictionary published in Philadelphia in 1874, there is an explanation, that the term 'Epidemic' (*Epidemiis*) derived from the Greek words — ἐπί (epi), meaning "upon", and δῆμος (dēmos), meaning "people" is applied to any disease which seems to be upon the entire population of a country at one time [9]. A term 'Pandemia' also derived from Greek words — παν (pan), that means "all" or "everything", and δῆμος (dēmos), that means "people". This term refers to the disease which affects the people of a country generally [10].

At the end of the 20th century, the term "epidemic" took on a broader meaning and began to be applied to an unusual increase in the number of cases of a particular disease, both infectious and non-infectious. The term "pandemic" is used to describe an epidemic affecting a very high proportion of the population of a significant geographic region but "customarily restricted to diseases such as cholera, plague, and influenza" [11, 12].

The discussion of the contradictions between the necessity and legitimacy of using the term "pandemic" began in early May 2009 [13], i.e., about a month before June 11, 2009, when the Director-General of the World Health Organization (WHO), Dr. Margaret Chan, stated: "*The world is now at the start of the 2009 influenza pandemic*" [14].

Definition of the "pandemic" in the WHO documents published in 1999–2017

In 1999, the WHO issued a document, the "Influenza Pandemic Preparedness Plan". It referred to influenza pandemics that occurred in 1918, 1957, and 1968 and provided a detailed description of the phases of pandemic development, including the Inter-Pandemic phase, the Preparedness phase (three levels), and the Pandemic period (four phases), after which the Post-Pandemic period, that is the same as the Inter-Pandemic one began again [15].

The 1999 document did not define what a pandemic was but clarified that "A pandemic will be declared when the new virus sub-type has been shown to cause several outbreaks in at least one country, and to have spread to other countries, with consistent disease patterns indicating that serious morbidity and mortality is likely in at least one segment of the population" [15]. Thus, the criterion for the onset of a pandemic was *serious morbidity and mortality*.

Due to the emergence of sporadic cases of avian influenza a new document was issued in 2004, where the following description of the emergence of a pandemic was given: "An influenza pandemic occurs with the appearance of a new influenza virus against which none of the population has any immunity. This results in several simultaneous epidemics worldwide with *enormous numbers of cases and deaths*. With the increase in global transport and communications, as well as urbanization and overcrowded conditions, epidemics resulting from a new influenza virus are likely to be established quickly around the world" [16]. Thus, the main pandemic crite-

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rion as *enormous numbers of cases and deaths* remained unchanged.

The following are the descriptions of the pandemic presented in the WHO documents in subsequent years, suggesting that the characteristics of the pandemic have remained the same. For example, “Influenza pandemics are associated with *high morbidity, excess mortality, and social and economic disruption*” (January 2005). [17] “Influenza pandemics (worldwide epidemics) have occurred at irregular and unpredictable intervals, and have been associated with *substantial morbidity, mortality and economic cost*” (March 2005) [18]. “An influenza pandemic (or global epidemic) occurs when a new influenza virus subtype appears, against which no one is immune. This may result in several simultaneous epidemics worldwide with *high numbers of cases and deaths*. With the increase in global transport and urbanization, epidemics caused by the new influenza virus are likely to occur rapidly around the world.” (Spring 2005) [19]. “Influenza pandemics (worldwide epidemics) ... have been associated with *substantial morbidity, mortality and economic cost* (October 2005) [20]. In addition, documents of the WHO emphasized that the pandemic virus may lead to several simultaneous epidemics worldwide, resulting in *high numbers of cases and deaths* [18], or *considerable morbidity and mortality* [21].

In March 2005, the WHO prepared one more document — “WHO Global Influenza Preparedness Plan” [22] which, like the previous documents, stated that the pandemic virus could cause significant *morbidity and mortality* in all age groups. This new document mentioned the 1918, 1957, and 1968 influenza pandemics, which claimed millions of lives. It also provided a detailed description of six phases of the development of a pandemic, all of which were characterized by an increased and sustained transmission in the general population.

The first objective for the WHO leadership during a pandemic (phase 6) was “to minimize morbidity and mortality” associated with current human infections [22]. Thus the pandemic was still characterized by *high morbidity and mortality*; otherwise, there would be no reason to lower these parameters.

The development of the following WHO document — “Pandemic Influenza Preparedness and Response,” was completed in the spring of 2009. According to a ‘Google search,’ the new edition was published on April 26, 2009 [23], on the very next day after the first meeting of the Emergency Committee convened by the WHO Director-General to address the swine flu outbreak [24].

Like the previous analog document, published in 2005, the new one mentioned the 1918, 1957, and 1968 influenza pandemics, which claimed millions of lives; however, the occurrence of the word ‘mortality’ or ‘death’ in the new document has decreased by half. The new document retained the six-phase structure. The Phase 6 (the pandemic phase) was characterized “by community level outbreaks in at least one other country in a different WHO region in addition to the criteria defined in Phase 5” [23].

There was no definition of a pandemic; various pandemic phases differ only in the prevalence of infection without considering the severity of the course of the disease and mortality. According to the new document, WHO did not commit “*to minimize morbidity and mortality*,” as it was in the document issued in 2005. This document was used as a guide to declare the swine flu pandemic on June 11, 2009.

In the document issued by the WHO in 2017 — “Guidelines on Regulatory Preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries,” it was mentioned that a pandemic could cause several simultaneous epidemics worldwide with *high numbers of cases of clinical disease and deaths* [25].

Definition of the term “pandemic” on the WHO website before May 4, 2009

In 2003–2005, the section on infectious diseases was entitled “Communicable Disease Surveillance & Response.” In October 2005, this page was renamed “Epidemic and Pandemic Alert and Response.” On July 10, 2009, the WHO website dedicated to infectious diseases was named “Global Alert and Response” [7].

The first description of a pandemic, available on the WHO website, dates back to February 2, 2003. In particular, it says: “An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in several, simultaneous epidemics worldwide with *enormous numbers of deaths and illness*”. Further: “With the increase in global transport and communications, as well as urbanization and overcrowded conditions, epidemics due the new influenza virus are likely to quickly take hold around the world” [7]. This description was similar to that which appeared in the WHO document published in 2005 [19].

In the second half of June 2004, an addendum appeared on the WHO website: “Outbreaks of influenza in animals, especially when happening simultaneously with annual outbreaks in humans, increase the chances of a pandemic, through the merging of animal and human influenza viruses. During the last few years, the world has faced several threats with pandemic potential, making the occurrence of the next pandemic just a matter of time” [7].

In October 2008, minor changes were made on the WHO website: “An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide with enormous numbers of deaths and illness”. This definition of a pandemic remained on the WHO website until May 4, 2009 [7].

The historical and epidemiological events that preceded the adjustment of the description of a pandemic on the WHO website in May 2009

For several years, commencing in 2003, scientists in many countries have warned about the possible beginning of an avian influenza pandemic. Under the 1999 Pandemic Preparedness Plan, the WHO initiated the re-

search necessary to produce a new vaccine rapidly. However, after a small peak in deaths in 2006, they began to decline in subsequent years, and by the end of 2008, it was clear that the threat of an avian influenza pandemic had subsided [26].

Despite declining demand for an avian influenza vaccine, development and production continued. In January 2009, the Austrian pharmaceutical company Baxter sent containers with a “vaccine” against influenza (H3N2) to biological laboratories in Germany, the Czech Republic, and Slovenia. It was soon discovered that the “vaccine” contained live avian influenza (H5N1) virus. At first, a Baxter spokesman said that the vaccine was contaminated accidentally. However, he later admitted that “experimental viral material” was sent instead of vaccines, which was not noticed in the accompanying documents. By the beginning of April 2009, the discussion of the spread of the contaminated vaccine had reached the international level. On April 8, 2009, a lawsuit was filed against the Austrian branch of Baxter and against AVIR Green Hills Biotechnology [27].

On April 17, 2009, the Center for Disease Control and Prevention (CDC) determined that two cases of febrile respiratory illness in southern California were infected with a swine influenza A (H1N1) virus [28]. On April 23, 2009, Dr. Anne Schuchat (Director of CDC's National Center for Influenza and Respiratory Diseases), reported about five new cases and informed that the causative agent of the new disease was a reassortant virus consisting of the genes of four strains of influenza, namely North American swine, North American avian, Eurasian swine, and human seasonal [29]. On April 24, 2009, Richard Besser, acting director of the CDC, declared that a swine flu epidemic had begun in Mexico and the United States [30].

On April 25, 2009, the first meeting of the Emergency Committee convened by the Director-General of WHO took place [24]. Two days later, after the second meeting of the Committee, the pandemic influenza alert level was raised from Phase 3 to Phase 4 [31]. On April 29, 2009, WHO Director Dr. Chang stated: “Based on assessment of all available information, and following several expert consultations, I have decided to raise the current level of influenza pandemic alert from phase 4 to phase 5.” She also urged all governments to activate their pandemic preparedness plans and be on “high alert for unusual outbreaks of influenza-like illness and severe pneumonia” [32].

However, on April 30, 2009, Mexican officials said the swine flu epidemic was stable for several days. Of the 168 deaths attributed to swine flu, only 12 have been confirmed [33]. On May 3, 2009, the Mexican Health Minister, Jose Angel Cordova, said the swine flu virus peaked between April 23 and 28, and the evolution of an epidemic began to decline. He also assumed businesses would return to regular activity during the week and schools would be opened for studies [34].

On May 4, 2009, Dr. R. Besser announced a change in reporting of morbidity, which should now include confirmed and probable cases of the infection with the 2009 H1N1 virus [35]. On the same day, during a press

conference held by WHO staff, a CNN reporter expressed doubt about a possible pandemic announcement and pointed out that on the WHO website, the flu pandemic was characterized by “enormous numbers of deaths and illness”. To this remark, WHO's public relations representative, Natalie Boudou, replied, “It was a mistake, and we apologize for the confusion. The definition was put up a while ago and paints a rather bleak picture and could be very scary” [13]. On the evening of May 4, the definition of a pandemic disappeared from the WHO website [7], and a new definition appeared on May 6, 2009. It read as follows: “What is an influenza pandemic? A disease epidemic occurs when there are more cases of that disease than normal. A pandemic is a worldwide epidemic of a disease. An influenza pandemic may occur when a new influenza virus appears against which the human population has no immunity. With the increase in global transport, as well as urbanization and overcrowded conditions in some areas, epidemics due to a new influenza virus are likely to take hold around the world, and become a pandemic faster than before. WHO has defined the phases of a pandemic to provide a global framework to aid countries in pandemic preparedness and response planning. Pandemics can be either mild or severe in the illness and death they cause, and the severity of a pandemic can change over the course of that pandemic” [7].

On June 11, 2009, WHO Director Dr. Margaret Chan stated: “...I have conferred with leading influenza experts, virologists, and public health officials. In line with procedures set out in the International Health Regulations, I have sought guidance and advice from an Emergency Committee established for this purpose. On the basis of available evidence, and these expert assessments of the evidence, the scientific criteria for an influenza pandemic have been met. I have therefore decided to raise the level of influenza pandemic alert from phase 5 to phase 6. The world is now at the start of the 2009 influenza pandemic” [14].

In mid-July 2009, the WHO representative stated: “This pandemic has been characterized, to date, by the mildness of symptoms in the overwhelming majority of patients, who usually recover, even without medical treatment, within a week of the onset of symptoms”. Therefore it was recommended to stop testing for the swine flu virus [36].

The historical and epidemiological events that preceded the adjustment of the description of a pandemic on the WHO website in 2011

The increase in the pandemic phase to the sixth level was accompanied by the intensification of anti-pandemic measures. Most government officials and doctors around the world followed the recommendations of the WHO, in connection with which mass production and purchase of antiviral drugs and vaccines began. At the same time, some scientists and journalists believed that the pandemic announcement lacked common sense because mortality from the new virus did not exceed the seasonal influenza statistics [37, 38].

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Besides, there were criticisms from professionals and officials. In particular, on November 5, 2009, Polish Minister of Health, Dr. Ewa Kopacz, speaking at a meeting of the Polish Parliament, said that the new disease is not more dangerous than seasonal flu, and before starting to purchase vaccines, it is necessary to study the results of clinical trials, the list of ingredients, and reports on side effects which had not been provided. She also noted that vaccine manufacturers should be held responsible for side effects [39].

The most severe blow to the “pandemic” was the statement of journalists who found signs of financial interest in WHO experts when declaring a pandemic [40].

At the end of January 2010, the Parliamentary Assembly of the Council of Europe (PACE) adopted a resolution to investigate the influence of pharmaceutical companies on the global swine flu campaign, focusing on the extent of the pharmaceutical industry’s influence on the WHO [41].

On June 24, 2010, PACE approved the conclusions of its Health Committee. According to the Assembly, the actions of the WHO, the health institutions of the European Union, and national Governments have led to unjustified concerns about the health risks faced by Europeans during the swine flu pandemic and the wastage of large sums of public money. The adopted resolution states that there was irrefutable evidence that WHO staff overestimated the severity of the pandemic, which led to a distortion of public health priorities. Paul Flynn, a speaker from the UK, reported on identifying severe shortcomings in the transparency of decision-making about the pandemic outbreak, which raised concerns about the influence of the pharmaceutical industry on decisions made. He also noted that the WHO wanted to deny making changes to the definition of a pandemic and revising the forecast of further development of the pandemic. Flynn also urged the media to avoid sensationalizing and stirring up panic in public health [42].

On August 10, 2010, WHO Director-General Dr. Margaret Chan announced that the H1N1 influenza pandemic was over, and the post-pandemic period had begun [43].

The new description of a pandemic on the WHO website had been in place for a little more than two years. In 2011, between July 8 and August 7, the WHO website reverted to the description of a pandemic that was prior to May 4, 2009, namely: “An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide *with enormous numbers of deaths and illness*”. This description was on the WHO website until September 2011. Subsequent WHO influenza pandemic pages are not available [7].

Discussion

A comparison of the WHO documents and pages on the WHO website published in different years revealed fundamental differences in the description of a pandemic.

In the WHO document issued in 1999, there was an explanation that the characteristic attributes of a pan-

demic were *high morbidity and mortality* [15]. In 2005, when leading epidemiologists predicted the imminent start of an avian influenza pandemic, the emphasis that a pandemic virus could cause an epidemic with high morbidity and mortality was retained. Therefore, the first objective of WHO during a pandemic was to unite the efforts of the health systems of various countries *to minimize morbidity and mortality* [22].

In the WHO document published in the spring of 2009, the emphasis on high morbidity and mortality associated with a pandemic virus and pandemic was removed [23], in connection with which there was no need for a unifying effort by WHO *to minimize morbidity and mortality*.

On the WHO website, the description of a pandemic familiar to many, such as the “*enormous numbers of deaths and illness*,” had been present for over six years [7]. With a slight change in wording but without change in meaning, it was used by the governments of Canada, the United States, the United Kingdom, and other officials who prepared documents dealing with the pandemic in 2004–2008 [44–46].

Nevertheless, during a press conference held on May 4, 2009, Natalie Boudou, a WHO communications officer, said that the definition of a pandemic, which included “*enormous numbers of deaths and illness*,” was wrong and would be corrected [13]. Sometime later, another WHO representative, Gregory Hartl, stated that the definition of a pandemic with *enormous numbers of deaths and illness* was posted on the website in 2004, however, it was not official, so the Pandemic Preparedness Guide should be read [47].

In the following months, changing the definition of a pandemic was discussed many times, but WHO staff insisted that there was no change in the definition of a pandemic [42]. Actually, it was true since WHO has never formally defined pandemic influenza either in the WHO documents or on the WHO websites [48]. However, in mid-summer 2011, the description of a pandemic on the WHO website reverted to its original definition with *enormous numbers of deaths and illness* [7].

Conclusion

The concept of epidemics caused by external pathogens has been known for many centuries. The term “pandemic” appeared later than “epidemic” and could have several meanings. It was used as a synonym for an epidemic, or to describe an epidemic that covered a vast territory, or to indicate an epidemic of an infectious disease accompanied by high mortality, like a pandemic of plague, smallpox, or cholera. In the 20th, the term “pandemic” began to be used with severe influenza epidemics and non-communicable diseases that increased mortality in most countries.

From the formal perspective of the WHO document issued in 2009, the declaration of a swine flu pandemic in June 2009 seemed justified. However, taking into account the previous history, common sense, and the consequences of declaring a pandemic for a disease not accompanied by a high number of cases and high mortality, it was a somewhat premature move, which was re-

flected in the resolution of the Health Committee of the Parliamentary Assembly of the Council of Europe.

Despite the achievements of modern medicine, in less than a quarter of the 21st century, humanity managed to survive two pandemics that could not have happened. From a practitioner's point of view, the difference between a pandemic, an epidemic, and one infectious disease case is irrelevant. A knowledgeable and experienced physician will not focus on the name of the virus or its strain since, in each case, individual pathogenesis-based treatment is used, considering the leading clinical syndrome.

To minimize the likelihood of a new pandemic studying and implementing all effective medicines and methods from ancient times to the present is necessary. Medical Universities should include Dr. Zhan's universal theory of acute infectious diseases in the curriculum. According to this theory, the progression of any viral infectious disease is accompanied by a succession of specific clinical syndromes, reflecting the inclusion of various phases of the pathogenesis of the infectious process. Assessing the patient's complaints is sufficient to use this theory in practice. The development of modern drugs, used in the past according to Dr. Zhan's theory, will effectively treat any new infectious disease without waiting for the results of clinical trials.

Thus, by improving the quality of the university education and postgraduate medical specialization, the problem of successful treatment of new infectious diseases can be solved, and future epidemics and pandemics be prevented.

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