

COORDINATION ASPECTS OF PHARMACOVIGILANCE SYSTEM ADJUSTMENT IN TERMS OF THE GLOBAL COVID-19 PANDEMIC

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The purpose is to overview the crucial pharmacovigilance system adjustment measures concerning COVID-19 widespread pandemic and enlightens main current aspects of pharmacovigilance system revamp.

Materials and methods. There were used common science theoretical methods (system analysis, generalization and systems approach); bibliographic method (elaboration of scientific related literature on topic).

Results. Revamping pharmacovigilance system requires being improved in regulatory capacities, the use of appropriate public-health-driven science-based and user-friendly technologies, including digital technologies, and innovations to expand access to quality medical and relevant information. These proposals can promote health by putting pharmacovigilance at the center of efforts to achieve a sustainable healthcare system that uses universal health coverage and the health-related Sustainable Development Goals.

Conclusion. Vaccine safety is very important for the success of any vaccination program. A robust vigilance system will help detect, report and prevent any adverse reactions associated with vaccination. Effective pharmacovigilance of the COVID-19 vaccine, when ready for use, will prevent any adverse events associated with the vaccine and dispel any unreasonable concerns among vaccine users.

Key words: pharmacovigilance, COVID-19, vaccination, side effects.

Introduction. The world is now struggling with a crisis of unseen proportions so far. Since its detection in the Chinese city of Wuhan in late December, the virus has infected almost 250 million people worldwide with severe acute respiratory syndrome (hereafter – SARS-CoV-2). By mid-November, more than 5 million people had died from the 2019 coronavirus pandemic (hereafter – COVID-19). [1] No country is currently isolated from COVID-19, and this has caused enormous medical, economic and social offsets in both high- and low-income countries. Some historians even believe that the impact of the COVID-19 pandemic would be more widespread and disastrous than World War II. [2] There are currently no specific drugs for the treatment of COVID-19. Researchers are testing a variety of possible treatments. Some drugs are being repurposed and some are used off-label in patients with COVID-19. [3] FDA has authorized the emergency use of the antiviral drug remdesivir for the treatment of suspected or laboratory-confirmed COVID-19. [4] Several other drugs, such as hydroxychloroquine, favipiravir, and dexamethasone caused a blink of hope, but ended up with mixed results. [3] It is a clear truth that, despite numerous statements, we are still fighting for an effective remedy against COVID-19. However, scientists and researchers are working with great effort to find a safe and effective remedy for it. Not only drugs, but also researchers

are looking for an effective vaccine to combat this pandemic.

Mass vaccination is a powerful weapon to return to normal society during a global pandemic, triggering collective immunity. Infectious disease experts, epidemiologists, health agencies and federal governments recognize the paramount importance of an effective vaccine in the fight against a pandemic and thus are collaborating to develop an effective vaccine and improve its safety as soon as possible. Prominent mutation pharmaceutical companies and world-renowned universities and organizations have worked together at this essential stage to find a powerful vaccine. According to the DRAFT landscape of vaccine candidates against COVID-19, prepared by the World Health Organization (hereafter – WHO), in the mid-November there are 130 vaccine candidates for clinical evaluation and 194 candidate vaccines for preclinical evaluation. [6]

It is plausible to imagine that many well-established regulations and pharmacovigilance platforms could be overwhelmed by the huge number of adverse events following immunization (hereafter – AEFI) reported over the next year as implementation continues. The deployment of vaccination in the 2009 H1N1 swine flu pandemic has shown that pandemic preparedness plans in several countries adequately addressed vaccine safety monitoring [7]. Pharmacovigilance platforms have failed to confirm or rule out

associations between AEFI and the H1N1 vaccine, and this contributed to the erosion of trust in the vaccine. Thus, global coordination with scientists, medical and healthcare professionals, pharmaceutical / manufacturing companies, and increased real-time analysis and reporting capabilities are of prime importance to ensure robust pharmacovigilance of COVID-19 vaccines.

In addition to standard vaccine safety pharmacovigilance issues, COVID-19 vaccines pose additional challenges for post-licensing surveillance, making it difficult to assess the risks and benefits of safety signals. These include several authorized or approved vaccine types, the potential interchangeability of vaccine types, dosing interval flexibility, and high comorbidities in the target population. Additional concerns may arise as COVID-19 vaccines are being rolled out in low- and middle-income countries (hereafter – LMICs), where the high prevalence of malnutrition and infectious diseases may affect the type of AEFIs and immune responses observed in the context of less reliable pharmacovigilance programs.

Brighton Collaboration (<https://brightoncollaboration.us> (Global Vaccine Research Safety Network) has harmonized global safety evaluation tools and identification for COVID-19 vaccines, which are regularly updated).

The study **aims to** overview the crucial pharmacovigilance system adjustment measures concerning COVID-19 widespread pandemic and enlightens main current aspects of pharmacovigilance system revamp.

Materials and methods. There were used common science theoretical methods (system analysis, generalization and systems approach); bibliographic method (elaboration of scientific related literature on topic).

The results and their discussion. The collaboration of patients, caregivers, private portioners, government doctors, field-level health care workers, AEFI and pharmacovigilance program staff is more important than ever. Adequate information on adverse reactions to the vaccine used against COVID-19 is very important, and it is crucial that all adverse reactions are recorded and reported as early as possible so that remedial action can be taken quickly. This will not only help protect the health of vaccine recipients, but will also decrease unnecessary skepticism about COVID-19 vaccination. International cooperation and data exchange between national agencies managing the vigilance program is necessary during a crisis of this magnitude, as it will disseminate information on any suspected

adverse reactions and help limit its adverse effects on the enormous majority of the population.

In this COVID-19 pandemic, when many clinical trials have been conducted in both conventional and AYUSH systems, the main need is to increase their effectiveness with limited resources to provide comprehensive care to patients through interdisciplinary hand-holding. There should be harmonization on regulatory aspects and implementation of pharmacovigilance schemes. The pandemic has introduced new knowledge and a reporting system to strengthen regulatory issues.

The healthcare system has emerged with new directions in the management of clinical trials from initial recruitment to support patient care and lifestyle modification. In addition, the pandemic given us the opportunity to recreate the entire health observatory with a system of data mining tools to report adverse effects and safety. COVID-19 was opened windows to use multi-system healthcare. To do this, creating a safe and transparent system is an important goal for all types of medical practice. Global as well as local acceptance of traditional medicine can be a leading path for inclusive growth. This acceptance may be possible due to the correlation of traditional drug systems with modern sciences. Thus, there is an urgent need to integrate many scientific advances and create reliable pharmacovigilance systems in two ways.

First, global regulation is necessary for the global market. An effective operating framework is the second improvisation needed to combine drug safety with true independence.

Second, the active expectation of side effects in the coming years, although the field of pharmaceutical research has achieved great success and is able to effectively fight many diseases for the sake of humanity.

Revamping pharmacovigilance system requires being improved in regulatory capacities, the use of appropriate public-health-driven science-based and user-friendly technologies, including digital technologies, and innovations to expand access to quality medical and relevant information. These proposals can promote health by putting pharmacovigilance at the center of efforts to achieve a sustainable healthcare system that uses universal health coverage and the health-related Sustainable Development Goals.

Conclusions. Vaccine safety is very important for the success of any vaccination program. A robust vigilance system will help detect, report and prevent any adverse reactions associated with vaccination. Effective

pharmacovigilance of the COVID-19 vaccine, when ready for use, will prevent any adverse events associated with the vaccine and dispel any unreasonable concerns among vaccine users. Seven different COVID-19 vaccines for immediate use dossiers have been accepted for review in many countries. As accurate data from long-term safety trials of COVID-19 vaccines is missing, there is an urgent need to strengthen post-marketing surveillance of side effects data, especially in low- and middle-income countries. This will require constant monitoring of vaccinated patients for possible adverse reactions to COVID-19 vaccines.

Література

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It is essential to take safety measures, systematic strategies and timely assessment of any adverse incidents. Active monitoring of pharmacovigilance with the involvement of all stakeholders in COVID-19 vaccination is required to prevent and document possible adverse reactions associated with COVID-19 vaccines.

Future studies perspectives. The future papers will be dedicated to new approaches ascertainment concerning pharmacovigilance system adjustment and enhancing of pharmacovigilance system coordination in terms of the global COVID-19 pandemic.

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КООРДИНАЦІЙНІ АСПЕКТИ НАЛАГОДЖЕННЯ СИСТЕМИ ФАРМАКОНАГЛЯДУ В УМОВАХ ГЛОБАЛЬНОЇ ПАНДЕМІЇ COVID-19

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Ціль: розглянути найважливіші заходи щодо налагодження системи фармаконагляду щодо поширення пандемії COVID-19 та висвітлити основні поточні аспекти оновлення системи фармаконагляду.

Матеріали та методи. Використовувалися загальнонаукові теоретичні методи (системний аналіз, узагальнення та системний підхід); бібліографічний метод (опрацювання наукової пов'язаної літератури з теми).

Результати. Оновлення системи фармаконагляду потребує покращання регуляторного потенціалу, використання відповідних науково обґрунтованих та зручних для користувачів технологій, у тому числі цифрових технологій, а також інновацій для розширення доступу до якісної медичної та релевантної інформації. Ці пропозиції можуть сприяти здоров'ю, ставлячи фармаконагляд у центрі зусиль для забезпечення стійкої системи охорони здоров'я, яка використовує загальне медичне страхування та цілі сталого розвитку, орієнтовані на стан здоров'я.

Висновки. Безпека вакцин дуже важлива для успіху будь-якої програми вакцинації. Надійна система фармаконагляду допоможе виявити, повідомити та запобігти будь-яким побічним ефектам, пов'язаним з вакцинацією. Ефективний фармаконагляд вакцини проти COVID-19, коли вона буде готова до використання, дозволить запобігти будь-яким несприятливим явищам, пов'язаним з вакциною, та розвіяти будь-які необґрунтовані занепокоєння серед тих, хто вакцинується.

Ключові слова: фармаконагляд, COVID-19, вакцинація, побічні ефекти.

КООРДИНАЦИОННЫЕ АСПЕКТЫ НАЛАЖИВАНИЯ СИСТЕМЫ ФАРМАКОНАДЗОРА В УСЛОВИЯХ ГЛОБАЛЬНОЙ ПАНДЕМИИ COVID-19

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Целью исследования является рассмотрение важнейших мер по налаживанию системы фармаконадзора касательно распространения пандемии COVID-19 и освещение основных текущих аспектов обновления системы фармаконадзора.

Материалы и методы. Использовались общенаучные теоретические методы (системный анализ, обобщение и системный подход); библиографический метод (обработка научно связанной литературы по теме).

Результаты. Обновление системы фармаконадзора требует улучшения регуляторного потенциала, использования соответствующих научно обоснованных и удобных для пользователей технологий, включая цифровые технологии, а также инноваций для расширения доступа к качественной медицинской и релевантной информации. Эти предложения могут способствовать здоровью, ставя фармаконадзор в центре усилий для обеспечения устойчивой системы здравоохранения, использующей общее медицинское страхование и цели устойчивого развития, ориентированные на состояние здоровья.

Выводы. Безопасность вакцин очень важна для успеха любой программы вакцинации. Надежная система фармаконадзора поможет выявить, сообщить и предотвратить любые побочные эффекты, связанные с вакцинацией. Эффективное фармаконадзорение вакцины против COVID-19, когда она будет готова к использованию, позволит предотвратить любые неблагоприятные явления, связанные с вакциной, и развеять любые необоснованные беспокойства среди тех, кто вакцинируется.

Ключевые слова: фармаконадзор, COVID-19, вакцинация, побочные эффекты.

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation;

D – writing the article; E – critical revision of the article; F – final approval of the article.

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