

Description

[vc_row][vc_column][vc_column_text]Pharmacovigilance (PV) deals with drug-related problems: detecting, understanding, and preventing adverse effects. Patient safety is the key goal of PV. Many approved medicines carry a risk of adverse effects. Although the benefits to the patient outweigh these risks, physicians and researchers need to remain cautious about any serious side-effects.

A successful PV system collects, analyses, and shares drug safety data while aiming to reduce risk to patients in the shortest time possible. PV applies to both; approved drugs and those under clinical trials.

During the COVID-19 pandemic, PV is more important than ever. Clinical trials, of both vaccinations and potential treatments for COVID, are taking place around the world. For example, the new anti-viral drug ‘remdesivir’ is being trialed, while several old drugs are being repurposed. Understandably, this research is receiving far more media attention than a “normal” clinical trial would. At the same time, many rumors – some based in fact, most not – about possible treatments are circulating on social media.

Doctors, public health specialists, and other healthcare providers urgently need accurate and up-to-date safety information on COVID-linked drugs and trials. Pharmacovigilance also has an important role to play in helping to fight misinformation.

Pharmacovigilance During COVID-19

Unfortunately, even work as vital as pharmacovigilance has not been immune to the impact of the pandemic. Many clinical trials, for example, have been forced to halt or pause, amidst local or national lockdowns, staff quarantine, problems with the supply chain, and multiple other challenges. In addition, some routine audits and safety inspections have been unable to proceed as normal, due to social distancing restrictions and/or quarantine, and closure of facilities.

in response to the pandemic, the governments of some countries have introduced more flexible rules on post-marketing (i.e. after the drugs are released onto the market) reporting of adverse effects. The US Food and Drug Administration (FDA), European Medicines Agency (EMA), and the UK Medicines and Health Regulatory Authority (MHRA) have all issued guidance for stakeholders on reporting of clinical trials and post-market adverse effects. This intends to reduce the burden on overstretched healthcare providers, and ensure business continuity for drug manufacturers, among other things.

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While there is justification for this step, it is vital to continue reporting adverse effects, keeping in mind patient safety. Where this is challenging, governments advise that the most serious adverse effects should be a reporting priority.

Pharmacovigilance Beyond COVID-19

COVID-19 has undoubtedly thrown up many challenges for PV. However, there are also opportunities. Some pharmacovigilance specialists hope that this pandemic may bring pharmacovigilance and healthcare practice closer.

During the COVID-19 crisis, physicians frequently require to make treatment decisions that are not yet completely addressed by clinical trials. Instead, doctors must rely on observational data such as that found in adverse event databases. Swift analysis of this data will help to provide the guidance that doctors need on an urgent basis to keep their patients safe.

We tend to overlook the fact that even experienced healthcare workers are learning with time; this pandemic is new for everyone! This has led to different countries responding to the pandemic in very different ways. While some governments have ordered strict lockdowns and made the use of personal protective equipment mandatory, others have taken a “wait-and-see” approach or relied on social distancing alone.

Thanks to the wealth of reporting, on both mainstream and social media, the public is very aware of disagreements both within and between governments on how to handle this unprecedented situation. For this reason, effective risk communication is vital. Transparency and honesty will be key as the pandemic approaches its second year. Detecting and correcting false information, and effectively communicating risk to both the public and healthcare workers, is both a challenge and an opportunity for PV.

Information sharing within the PV community is also important. In particular, well-funded PV teams have the opportunity to assist colleagues in low-income countries, who may not have access to the same knowledge and resources. By facilitating access to PV databases, countries on the opposite side of the world could equally benefit from data sharing. Such collaborations could – and should – persist long after this pandemic is over, potentially improving safety for millions of patients.

New Initiatives for the Future

The Pharmacovigilance community has been quick to respond to the pandemic.

In anticipation of the many COVID-19 therapies expected to be available in near future, the UK’s MHRA has launched a new online reporting system, called the Yellow Card. The Yellow Card service aims to track reports of adverse effects in any treatments, vaccines, diagnostic methods, or medical devices that might be used in the care of COVID-19 patients. This should create a robust knowledge base of safe treatments for the disease.

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“While our aim is to ensure that potentially lifesaving COVID-19 treatments and medical equipment reach patients as quickly as possible, patient safety is our highest priority,” said Dr. June Raine, Chief Executive of the MHRA.

Some companies are using Big Data analytics in the fight against COVID-19. This refers to the in-depth analysis of data from multiple different sources. This technique should reveal patterns in the data that might not be possible to detect from any single database. Additionally, it may not only assist in finding solutions to the current medical issues but also predict any prospective problems.

Finally, the WHO has five established Collaborating Centres, set up to advance PV in countries around the world. The five centers handle Drug Monitoring, Statistics and Methodology, Advocacy and Training in PV, Strengthening PV Practices, and PV in Education and Patient Reporting, respectively.

Do you work in PV? How has the pandemic affected your work? What challenges and/or opportunities have you seen? Share your thoughts and experiences in the comments below.

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