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ETHICS IN ACTION

Finding Ways to Alleviate the Impact of War on Patients and Clinical Research

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After nearly six months of war, life for patients in Ukraine continues to get harder. The World Health Organization (WHO) has reported that people's health has been imperiled by difficulty in accessing emergency care and essential medicines.

Dr. Hans Henri P. Kluge, WHO Regional Director for Europe, noted that there had been more than 260 verified attacks on healthcare in Ukraine by early June, resulting in some health facilities being destroyed and others struggling to cope with people seeking care from trauma and injuries.

The war has also made it extremely difficult for patients with chronic conditions, such as diabetes, to access the medicines they require. While pharmaceutical companies remain committed to ensuring patients everywhere receive life-saving products, some pharmaceutical companies have suspended operations in Russia for non-essential medications, which has the potential to further exacerbate supply chain bottlenecks.

Manufacturing and the supply of finished medicines, as well as raw materials in the region, have also been severely affected. Many insurance companies implemented tougher requirements to cover Ukraine supply contracts, which restricted cooperation with international suppliers. Fortunately, local manufacturers been able to use their expertise to step in and negotiate new terms to ensure the supply of active pharmaceutical ingredients, excipients, packaging materials, and other raw materials. However, managing the supply routes of medicines and raw materials in Ukraine has been challenging due to ongoing attacks and the closure of airports and seaports. In response, suppliers have had to quickly adjust routes.

Effects on Clinical Trials

Further, the war has stopped many clinical trials in the region, with GlobalData's Clinical Trials Database claiming that by April, eight Phase II and Phase III trials had been disrupted and another eight trials were in jeopardy as sponsors were forced to suspend enrollment in Russia and Ukraine.

The impact is likely to be more extensive, with the U.S. Food and Drug Administration noting that around 250 drugs and devices were undergoing clinical trials in Ukraine. Trials in Russia have also been impacted, with Moscow State Medical University noting that international pharmaceutical companies have halted recruitment of new patients to its 120 ongoing trials.

Mitigating the Harm of War on Patients

There are steps that compassionate leaders within sponsors, contract research organizations, and study sites can take to ease this crisis with clinical trials and, wherever possible, ensure patients keep participating. A priority should be to maintain ongoing follow-up with patients and doctors involved in the trials, do what they can to track where patients are located, and, where possible, enable them to continue to participate in other parts of the world.

Clinical trial data should also be accessible via online channels, from when treatment starts to when it is completed, while of course doing whatever is needed to prevent unblinding of participants. To achieve that objective, companies should put in place processes to safeguard those data, such as implementing data provenance, data privacy, traceability, and auditability.

Another important step will be to provide emergency contact details to patients who have been displaced by the war so they can get the care they need.

Experiences from previous wars offer examples of mitigation steps that can help to ensure patients get the care they need. However, the most valuable lessons may be from the COVID-19 pandemic, which required companies to quickly pivot in order to ensure business continuity. In particular, technology and digital enablement came to the fore during the pandemic. Clinical trials are becoming increasingly decentralized and healthcare providers are turning more and more to telehealth or digital health to connect with patients.

These innovative processes are now being used to provide virtual care to patients in need. As an example, the nonprofit organization Health Tech Without Borders (HTWB) was founded in 2022 in response to the war in Ukraine and acts as a hub to connect digital innovation with medical care. HTWB's Ukraine Telehealth Relief aims to help hospitals cope with the rapid increase in patients, provide psychological help to those affected by the conflict, and support Ukrainian refugees across Europe.

Taking a Stand

As providers and consultants in the healthcare industry, we are committed to using our expertise to help pharmaceutical clients, for example through the establishment of a network, or advisory alliance. This alliance is working across the industry and with nongovernment organizations and healthcare providers to identify unmet needs, urgent priorities, and vital solutions and recommendations to support patients in impacted regions.

Among the steps we have been taking internally is outreach to colleagues who have been affected, ensuring they are protected and giving them the flexibility that they might need to do their jobs. We are both proud and supportive of our colleagues in Poland and Ukraine who are doing what they can to support refugees and provide humanitarian aid. For example, many of our staff members in Poland are hosting Ukrainian families. Money raised by colleagues globally has been used to ensure refugees are properly fed, but also to bring some joy to children affected by war, such as with a trip to the zoo.

For all of us in healthcare and the life sciences, mitigating the suffering of patients has to remain our primary concern.

Thomas Dobmeyer, MD, is CEO of PharmaLex, with more than 20 years of experience in late-stage clinical development, medical affairs, and pharmacovigilance for a variety of therapeutic areas. He is a physician by training, as well as a researcher and investigator in immunology, haematology, and infectious diseases.