Patient organisations: COVID-19 concerns related to human research

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Patient organisations support and advocate for the patient communities they represent while also increasing the role of patients in improving and shaping healthcare practices, policies, and systems. During the coronavirus pandemic, patient organisations have provided their patient communities with relevant information on COVID-19 and have brought patients' perspectives into the dialogue around COVID-19. Moreover, they have advocated for patients' needs and concerns related to the pandemic's effects on human research and to coronavirus vaccine development and authorisation. This article summarises several of the issues facing patient communities during the pandemic and provides examples of patient organisations' responses to these issues.

Patient's perspectives

Patient organisations represent some of the most vul- nerable patient groups in this pandemic: many have chronic conditions, are at a higher risk for illness and death from COVID-19, and may experience substantial disruptions to ongoing care and treatment due to the pandemic. Raising awareness of these issues is one focus of patient organisations during the pandemic. In Decem- ber 2020, the Swiss patient organisation SPO wrote an open letter (in German) to the Swiss Federal Council and representatives of the cantons calling for more solidarity with ill and elderly people as well as healthcare workers. This was, however, one of the rare initiatives from Swiss atient organisations to our knowledge. Rare Diseases Europe (EURODIS), an alliance that gives voice to over 30 million Europeans affected by rare diseases, initiated a survey of almost 7000 people with rare diseases in 36 countries across Europe to ascertain how COVID-19 has impacted them. The survey shows that the pandemic has not only caused severe disruptions to care for people with rare diseases, but it has also increased their levels of uncertainty and anxiety. The survey also reveals posi- tive developments, for example that the pandemic has resulted in more people using online health services.

The suspension or termination of human research during the pandemic

Patient organisations have been following and responding to the pandemic's effects on human research. As the result of COVID-19 becoming the focus of much research (i.e. the "covidisation" of research), attention and resources have been diverted from other research projects. Early on in the pandemic in May 2020, BioPharma Dive shared details on the disruption of clinical trials: three out of every four clinical trials

worldwide had to be ended prematurely or put on hold. Later, studies performed in August 2020 identified the persistent impact of COVID-19, with over 60% reporting an “average” or greater level of impact on ongoing trials and the initiation of new trials. Respondents specifically highlighted challenges in patient enrolment and recruitment (see article in Applied Clinical Trials from October 2020). Those obstacles drove a discernible shift toward conducting decentralised trials and using telemedicine and mobile technologies in order to reduce contact with patients – and thus potentially lowering research costs.

Slowing down or stopping clinical research has resulted in both a disruption to care for patients receiving treatment in affected trials and a delay in the development and authorisation of the tested treatments for the whole group of patients. In an open memo to the health indus- try, the European Patients Forum (EPF), which represents patient organisations throughout Europe and over 150 million Europeans who are affected by chronic conditions, advocates for patients to be informed in a timely manner and supported if clinical trials are changed, suspended, or terminated. The EPF’s memo also highlights the need for patients to continue receiving treatment if needed. In an open letter to policy makers, EURODIS draws attention to the fact that there are no effective treatments for most rare diseases and emphasises the importance of continu- ing research and clinical trials related to rare diseases, even during the pandemic. As a way to avoid prematurely ending non-COVID-19 clinical trials and to keep them from being put on hold, the clinical research service provider WIRB-Copernicus Group (WCG) proposes using independent sites that do not treat COVID-19 patients for clinical trials (see article on WCG’s website).

Coronavirus vaccine development, testing, and authorisation

The development, testing, and authorisation of corona- virus vaccines has occurred at an unprecedented pace. While there is a great urgency to develop and approve effective vaccines against the coronavirus, patient organisations have been advocating for patient safety to remain the top priority throughout all steps of the process. In a statement on patient safety as it relates to coronavirus vaccines, the EPF asserted that “regulatory ‘shortcuts’ must not lead to lowering standards of safety or efficacy that should remain under the strict control of EMA [European Medicines Agency]”.

In addition to advocating for patient safety, patient organisations are calling for transparency in the vaccine development and authorisation processes in order to foster the public’s trust in these processes, pharma- ceutical companies, and the authorities. This trust will in turn increase the acceptance of approved vaccines. Together with the EPF, EURODIS successfully encouraged the EMA to hold public stakeholder meetings on the development and authorisation of COVID-19 vaccines and on the approval and roll-out of vaccines. During these meetings, the EMA provided the public and stakeholders with information on its processes and collected feedback from participants. The EMA also adapted its processes for more transparency.

Many of the patients represented by patient groups are at higher risk of becoming seriously ill or dying from COVID-19, so they are some of the first people who are able to receive coronavirus vaccines. Although these vaccines have gone through rigorous testing and approval processes, certain adverse effects may only become clear when the vaccines have been administered on a large scale for a longer period of time. In its statement on patient safety, the EPF calls for “an even greater level of vigilance and protection of patients’ rights in case of adverse reactions”. The EPF also asserts that corona- virus vaccines need to be subject to the same liability regulations as other vaccines and recommends creating a mechanism that ensures prompt compensation to vaccinated people who develop severe adverse reactions.

Conclusion

Throughout the coronavirus pandemic, patient organisations have made sure patients’ voices and concerns are heard. In addition, they have drawn attention to the disruption to patient care resulting from the

suspension or termination of research projects during the pandemic. And while patient organisations have welcomed the fast development and authorisation of vaccines, they have also emphasised the need for transparency and a focus on patient safety in those processes.