EDITORIAL

On March 11, 2020, the World Health Organization (WHO) officially announced the pandemic status of COVID-19, which by that time had affected more than 118.000 people in more than 114 countries worldwide. The 100-year pandemic cycle has returned. The novel coronavirus disease (COVID-19), as we know it, is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) and is highly contagious with no yet effective treatment nor approved vaccine. With an average R0 of 3.3 and as of August 5, 2020, responsible for a total death of 696.147 out of 18.354.342 cases globally, COVID-19 has been wreaking havoc in all aspect of life worldwide. The world is anxiously hopeful for an effective and approved vaccine to put this pandemic to an end.

The World Health Organization holds a crucial role in managing the worldwide impact of this health crisis, which has generated further complex socioeconomic problems, dragging the world on a brink of a global recession. Pandemic knows no geographical boundaries, traversing through international borders and impacting millions of lives along the way, with no clear view of the finish line for now. Indonesia, being one of the most impacted countries, has the highest overall death toll in Southeast Asia with official death number of more than 6.600 (as of August 20) and total cases of more than 153.000. Still, this numbers is most likely to be underestimated considering the testing rate per capita in this country to be among the lowest in the world. During the early course of this pandemic, many countries chose to impose a lockdown policy, imposing borders closure and obliging the people to stay and work from home. Indonesia has chosen a laxer approach of large-scale social restriction (*Pembatasan Sosial Berskala Besar* or PSBB), implemented by local governments with approval from the Ministry of Health. Most people comply with the restriction, especially in the earlier months, prompting people to stay at home and halting redundant travels throughout the region. School and work are done remotely, business that deemed as inessential were forced to close until just recently. Only the healthcare sector has remained unhinged, even busier for some as more COVID-19 cases are filling up the wards and intensive care units. For other subspecialties, more time is spared as limited worktime in hospitals are imposed, and in the abundance of time during this work-at-home period, this is among the better time to conduct research and write publications.

Studies related to COVID-19 have come up profusely to the surface, in the race to find answers and better understanding of the disease. On the contrary, social restrictions, physical distancing, travel limitations, or the consideration for limiting potential COVID-19 exposure and transmission have created new challenges in studies of other non-COVID19 related matter, leading to extra efforts and additional difficulties in meeting protocol-specified procedures. These restrictions along with COVID-19 health emergency itself, unfortunately have a negative impact in medical research works, especially for clinical trials. Protocols that mandates physical visits from trial participants might face the biggest challenge, as people

are more reluctant than ever to visit hospitals to avoid being exposed to COVID-19. The US Food and Drug Administration (FDA) has recognized these problems and implied that some protocol modifications may be required, which leads to an unavoidable protocol deviation due to COVID-19 health crisis. Even so, many of these halted clinical trials are crucial for further advancement of medical field, therefore its continuity is essential. Special considerations must be taken to ensure the safety of trial participants while still adhere to good clinical practice (GCP) principles and minimize risks to trial integrity. Special modification for in-site follow up protocol will be needed, and in some circumstances; remote, virtual, non-physical follow up might be considered as a replacement if feasible. The need for modifying existing process is variable, depending on each trial protocol and local situation. Further assessment to consider assessment delay, or protocol changes due to current situation, or withholding further recruitment, or even withdrawing certain participants of the trial should be discussed and carried out accordingly. Involvement of the ethical committee might be needed in each case.

As we continuously evolve to the new normal era, things have not yet returned to normal, posing further challenges for researchers to carry out clinical trials. A huge obstacle that needs to be addressed, but by no means putting an end to our passion of evidence-based medicine. Good publications, in any types of research, will still be needed to improve our knowledge in the medical field. In the limitations of conducting clinical trials, other types of publication might be worth to consider. Case reports, case series, review articles or metanalysis are among the types of publication easier to deliver during this time as we have in this edition. And as the chief editor of this journal, I would like to invite and encourage all of you to keep on writing and share your knowledge with all of us.

Prof. Dr. dr. Widya Artini SpM(K)

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