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Short communication

Clinical trials, adaptability and the COVID-19 pandemic

Ramez N. Eskander, Bhavana Pothuri, Leslie Randall, David O'Malley, Brian Slomovitz, Kathleen Moore, Robert Coleman, Thomas Herzog, Bradley J. Monk, Larry Copeland

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ABSTRACT

Despite the impact of the COVD-19 pandemic and public health crisis on health care delivery, the GOG-Foundation has continued to prioritize the delivery of novel and state-of-the-science treatment options to patients via clinical trials.

Despite the impact of the COVID-19 pandemic and public health crisis on health care delivery, the GOG-Foundation has continued to prioritize the delivery of novel and state-of-the-science treatment options to patients via clinical trials. Since the first document case of COVID-19 in the United States on January 20, 2020, there have been over 10.3 million individuals infected, with over 241, 000 deaths. Globally, over 52 million cases have been documented, with nearly 1.3 million COVID related deaths (Johns Hopkins University CSSE). Although mitigation strategies, including incorporation of symptoms screening, face masks, and social distancing have been advocated regionally and internationally, the number of infections continues to rise.

Even prior to the pandemic, physicians and health care workers faced burnout, stress, anxiety, depression, substance abuse, and suicidality (Dzau et al., 2020). In context of the above, it is important to continue to focus on providing support to the workforce that tirelessly commit themselves to the care of patients suffering from gynecologic malignancies. As we continue with the academic school year, which is being predominantly conducted on virtual platforms due to case numbers, these responsibilities are confounded by needs to coordinate home and childcare activities, while balancing clinical obligations. School closings have necessitated that parents adopt novel approaches to accommodate education, including work-from-home, telehealth opportunities, as well as time off. These duties have impacted health care providers, research coordinators, support staff and regulatory specialists both personally and professionally. Compounding the above are limited child care opportunities, as the child care industry faces economic strains and concerns about transmission (Gilliam et al., 2020).

In the clinical trial arena, this external pressure has impacted the function of Clinical Trials Office staff, mandating the development of strategies, including "flex" schedules to provide clinical trial coordinators with the necessary plasticity to meet their various obligations. Understandably, solutions are likely to vary based on clinical practice structure, team size, and geographic location, although with over 970 clinical trials halted as of November 2020 due to the pandemic, the need to adapt is clearly evident (Cancer Research Institute). Examples of accommodations include remote monitoring of clinical trial results, remote site visits for trial initiation and monitoring, and use of electronic signature for patient consent. Specific statements issues by both the National Cancer Institute, and the US Food and Drug Administration further outline guidance for clinical trial activities during the ongoing pandemic.

These pressures may be more pronounced for women physicians (accounting for nearly half of the gynecologic oncology workforce) and health care employees (Brubaker, 2020; Minello, 2020). Understandably, there will be significant geographic variation in COVID-19 related disruption based on current COVID-19 burden. It is encouraged that efforts be made for continued support of clinical trial staff as they work to manage personal and professional expectations. Working collectively to ensure staff are supported in this arena is critical to the success of clinical operations enabling access to novel treatment options for our patients.

Author contributions

All authors contributed to the development of the clinical commentary.

Declaration of Competing Interest

Dr. Eskander reports personal fees and/or institutional support/grants for clinical research outside of the submitted work; AstraZeneca, Clovis, Merck, GSK/Tesaro, Eisai, Genentech/Roche, Myriad and GOG Foundation. Institutional PI for industry sponsored trials from CLOVIS, Roche/Genentech, and AstraZeneca.

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