Cancer Patients Can Not Afford To Put Their Struggle on Hold

With widescale collaboration among companies, academia, and the science community to solve COVID-19, we can hope that this crisis has acted as a catalyst to increase positive perception for the biopharma industry.

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The COVID-19 pandemic is impacting global health and economies worldwide and here in the US it has exposed major health disparities. People who have less access to information and healthcare are the ones who are experiencing the greatest hardships. COVID-19 doesn't discriminate and as of June we have nearly 110,000 deaths in the US alone. Amidst this public health crisis there is a very special subset of patients who are being adversely impacted by the pandemic: cancer patients. According to the American Cancer Society,1 in 2019 more than 600,000 people in the US died from cancer. The disruption in access to healthcare caused by the COVID-19 pandemic will unfortunately lead to a dramatic increase in the number of cancer-related deaths in 2020.

It is simply not possible to mandate a patient's cancer to "self-quarantine" and stop growing while we wait for the pandemic to end. By its very nature, if left untreated, cancer cells grow and spread until the burden they impose on a patient's body can no longer be borne. If treatment for cancer patients is disrupted, the break in therapy allows the tumor cells to resume growing and can accelerate their spread throughout the body. Most cancer patients have to make weekly or monthly trips to a clinic to receive their treatment. For those patients who are now unable to access treatment, the result could be rapid disease progression and potential organ failure and death.

The COVID-19 pandemic has simply overwhelmed the infrastructure of many healthcare institutions and forced them to reallocate their resources to treat the influx of COVID-19 patients. The urgent need to reprioritize patient care has resulted in an interruption of treatment for cancer patients and it is impacting newly diagnosed patients, those already in treatment and those with advanced stage cancer.

For newly diagnosed cancer patients this reprioritization results in a delay in evaluation, diagnosis, appropriate health care, and treatment. With a disease like cancer that can, and often does, progress very rapidly, any time lost to the initiation of treatment can have a devastating effect. For newly diagnosed patients having to wait for their diagnosis and treatment plan, there's a physical toll but also a mental one as they are forced to deal with the anxiety of waiting an indeterminate amount of time for a definitive diagnosis and treatment to fight against the disease along with the new reality of being diagnosed with cancer.

For patients already receiving treatment in a hospital setting (versus taking an oral drug), their standard of care may be impaired by modified, delayed and cancelled treatment sessions. Limited appointments and travel to receive an intravenous injection, as many chemotherapies and immunotherapies are generally administered, could cause treatment schedules to be disrupted. Moreover, many patients rely on assistance from services or family members for transportation to and from the hospital for their treatment. For these patients if the services are disrupted by COVID-19 restrictions, or their family members are not able to get time off from work they may find that they are simply unable to get to treatment centers. As cancer is a systemic disease, many patients, usually those with advanced stages of cancer, are also immune-compromised and thus may be at higher risk of being infected or having more severe consequences of COVID-19 infection. These patients may have to skip treatments as they are forced to choose between having their cancer get worse and contracting and potentially dying from COVID-19.

One of the most vulnerable groups of cancer patients are those with advanced stage cancer who have run out of options after approved treatments have failed to control their disease. During normal times, these patients seek out clinical trials of new experi-

mental treatments, hoping that one of them will be effective in controlling or eradicating their cancer. For those patients who started in a trial pre-pandemic, many are experiencing delays and interruption due to clinical site closures and drug supply interruption. For those patients who are trying to enroll in a clinical trial as a new patient, there are logistical hurdles to overcome such as travel restrictions, site closures and lack of healthcare personnel to treat them. Unfortunately, as these trials are experimental in nature with no guarantee of beneficial results, they have been deprioritized by many hospitals and health care clinics that must focus resources on treating COVID-19 patients. In some cases basic cancer research has been stopped due to the COVID-19 pandemic, meaning the discovery and development of novel cancer therapies will also be indeterminately delayed. In the clinical arena, according to a May, 2020 Nature Reviews Drug Discovery article evaluating active oncology studies in the US and Europe, only 20% and 14%, respectively, were continuing to enroll subjects at the usual rate. The large majority of institutions in both regions were either not enrolling or had a lower enrollment rate. In support of this, ClinicalTrials.gov data showed that over 200 oncology studies were suspended as of April, 2020. There was no clear timetable for the resumption of the previous pace with estimates of up to six months before full operations resumed.

According to an April 2020 preprint on ResearchGate, the authors calculated that one year from now there will be over 6,000 excess deaths among cancer patients in England and approximately 34,000 excess deaths among cancer patients in the US. In this especially susceptible population, the underlying cause of these deaths may be cancer, COVID-19, or comorbidity. As I mentioned above, the real impact will be on the ability of patients who have exhausted all approved treatments, to enroll in clinical trials. These are patients who could benefit from drugs that are still in experimental clinical trials, but due to travel restrictions and the increased burden on hospital infrastructures, may have their access to these trials delayed for months at the most critical time for them.

The clinical trials that are managing to move forward are doing so due to the dedication and commitment of health care workers who keep the clinical trial sites open and operating for patients. One challenge is that many health care centers are forced to reallocate the doctors and nurses who run these trials to help with the increased burden of COVID-19 patients. Another challenge is that many health care centers are altering the schedule of health care workers to limit their exposure as well as the exposure of non-COVID-19 patients. This means fewer appointments are available for those patients who are willing and able to travel to clinical trial sites. A March, 2020 JAMA retrospective analysis in 355 Italian patients who died from COVID-19 revealed that active cancer patients accounted for 20% of deaths. This reflects the fact that cancer subjects are older, have comorbidities, and are often immunosuppressed compared with the rest of the population. Cancer patient COVID-19 deaths will also affect clinical trial endpoints, especially those on survival.

The biopharma industry is also playing a role in keeping clinical trials going despite major challenges today. From trouble shooting manufacturing, and supply chain issues to finding financing for clinical trials. At Vigeo, our goal is to deliver treatments to these patients that will extend their lives and improve their quality of life. Amazingly, in April we were able to initiate an expansion of a Phase 1b/2 clinical trial evaluating our lead candidate in patients with ovarian cancer, pancreatic cancer, triple negative breast cancer, glioblastoma, and a tissue agnostic group of patients with high CD36 expressing tumors. While it's been a slow and arduous process to enroll and dose patients, we are gradually screening and enrolling more patients with the goal of ultimately enrolling approximately 75 patients. Pre-COVID this would have happened in 6-8 months. In today's environment we don't expect to reach full enrollment for 12-14 months

The National Cancer Institute's clinical trial structure has also been severely affected by COVID-19. They have seen NCI-funded clinical trial accrual decrease by 50%. Similar to Vigeo's modifications, NCI has adopted measures to counteract this disruption by directly shipping oral drugs to subjects where possible, and increasing flexibility regarding how clinic visits are to be conducted, and in the timing and type of follow up testing. They are also launching studies of the effect of COVID-19 on cancer subjects.

While FDA is focused on reviewing preIND's, INDs, and rolling review of products to treat or prevent COVID-19 or new antivirals, diagnostics, and vaccines, they are still approving new cancer treatments for patients, thankfully. As of May 15, FDA has approved 10 new cancer treatments in 2020.

COVID-19 is undoubtedly the biggest public health crisis of this decade and has taken a massive toll. With widescale collaboration among companies, academia, and the science community happening globally to solve COVID-19, we can only hope that this crisis has acted as a catalyst to propel science and truth into the spotlight and increase positive perception for the biopharma industry. It's critical that as an industry and as a country, the millions of patients dealing with the devastating disease of cancer are not forgotten or deprioritized during the pandemic. Their struggle is not put on hold due to the pandemic, so the fight to help them should not be put on hold either. PE

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REFERENCES

1. http://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html