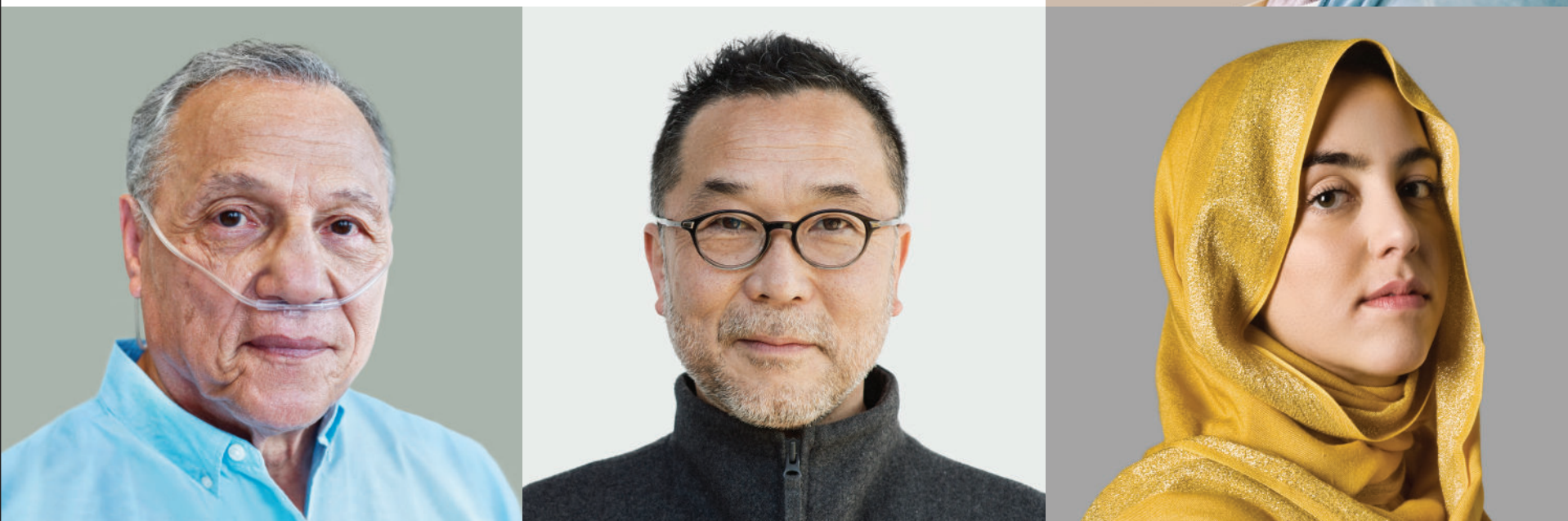




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Why clinical trial diversity is key to increasing access to routine care and innovative treatment options

By: Luther T. Clark, MD, Deputy Chief Patient Officer, Merck

The COVID-19 pandemic has shone a light on longstanding health care disparities and amplified the importance of clinical trial diversity, especially participation of those patients and communities disproportionately impacted by the disease being studied. Since clinical trials function as the gatekeeper to bringing new medicines safely to patients and communities, it has become increasingly important that diverse communities be represented in our research efforts.

Clinical trial participation provides access to possible new and innovative treatment options for patients, an especially important benefit for those who have conditions with limited treatment options – such as some forms of advanced cancer. It is important to note that, while not all clinical trial participants will receive the investigational treatment being evaluated in the clinical trial, all patients receive high quality standard-of-care, which is the standard treatment that is used for the health condition.

During the COVID-19 pandemic many patients have delayed or avoided routine medical care for underlying conditions – a hidden harm that has further amplified its already enormous health toll. While pandemic associated medical care delays and avoidance may be understandable, safely returning to essential care is imperative for improving patient outcomes and reducing disparities as well as increasing patient access and ability to participate in clinical research.

Pandemic Associated Medical Care Delays and Avoidance

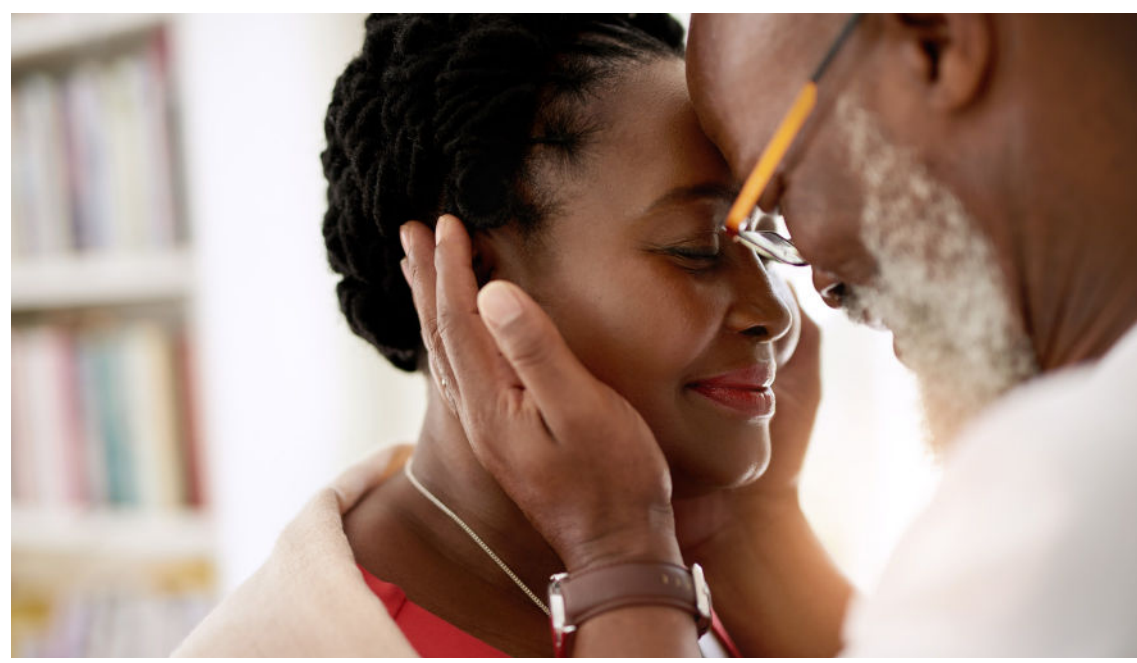
During the COVID-19 pandemic, delays and/or avoidance of medical care for both routine and serious conditions have been widely reported. According to one recent analysis (1) an estimated 41% of adults in the U.S. delayed or avoided medical care because of concerns about COVID-19 – including both routine care (31.5%) and urgent or emergency care (12.0%). Avoidance of urgent or emergency care was more prevalent among individuals with underlying medical conditions, Black adults, Hispanic adults, young adults, persons with disabilities and unpaid adult caregivers. When patients delay or avoid medical care, they increase both their morbidity and mortality risks. For example,

- Vaccines play an important role in helping to protect people from preventable diseases, but data show concerning decreases in vaccination rates since the onset of the COVID-19 pandemic. A recent international poll revealed that 73% experienced disruptions in vaccine demand.
- Similarly, while routine cancer screenings have contributed to important cancer survival gains, screening rates have dropped during the pandemic. In the U.S. alone, approximately 285,000 breast cancer screenings, 95,000 colon cancer screenings and 40,000 cervical exams were missed between March 15 and June 16, 2020.

Cancer is a particularly powerful example of how longstanding inequities in care coupled with the pandemic's impact on reduced access/utilization of routine health care can converge and create an even more devastating impact on patients, families and communities. Cancer incidence is known to be disproportionately higher in under-represented minorities compared to other groups, and access -- to timely diagnosis, quality care and to clinical trials of promising therapies -- is suboptimal among people of color. Furthermore, cancer and its treatment predispose to many other health outcome disparities, as demonstrated by the disproportionate impact of COVID-19 on morbidity and mortality rates among people with cancer.

Social Determinants of Health (SDOH)

Social and economic factors, referred to as social determinants of health (i.e., education, economic stability, neighborhood, health and health care access, social and community context) not only contribute to healthcare disparities but may also negatively impact the decision and the ability of patients to participate



in clinical research (2-4). By recognizing and understanding the SDOH, we can help accelerate return to medical care, overcome barriers to minority participation in research, and ultimately improve patient outcomes. Effective and meaningful community engagement, collaborations, and partnerships are critically important for addressing all of the SDOH, and especially helpful for increasing awareness, education and building trust.

Bridging the Digital Divide

Digital technologies have many potential benefits for improving healthcare, including the potential to improve healthcare quality, patient safety and reduce disparities (5). However, inequities in access to virtual technologies do exist and may lead to or exacerbate disparities. Often referred to as the “digital divide”, there is a considerable difference between those patients/communities that have access to digital technologies and the ability to understand and use them effectively (digital literacy) and those who do not. For example, access and utilization of digital health-

care technologies are known to be significantly lower among older Black and Hispanic patients than their white or Asian counterparts. In addition to differences in access and digital literacy, structural inequities (i.e., lack of broadband internet availability) impact disproportionately some groups and communities – racial and ethnic minorities, rural communities and individuals of lower socioeconomic status (6). Without recognition and action, the digital divide will only widen.

Summary and Conclusions

It is important for the medical and public health community, policymakers, employers and health advocates around the world to come together to encourage people within our communities to get the care they need.

- As we join the multi-sector effort to combat COVID-19, we must also focus on helping people in our communities get the routine care they need to protect their long-term health.
- It's vital to support individuals and patients in returning to care because delays or cancellations

are associated with significant health risks. While the COVID-19 pandemic has caused unprecedented disruption to the healthcare system, it has also led us to identify opportunities to strengthen it for the future. We are committed to working with stakeholders to enact solutions that will improve patient care and help protect public health over the long term.

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