out-of-network billing. N Engl J Med 2021; 384:1381-3.
2. Kliff S. Coronavirus tests are supposed to be free. The surprise bills come anyway. New York Times, September 9, 2020 (https://www.nytimes.com/2020/09/09/upshot/coronavirus-surprise-test-fees.html).
3. Joyce A. Analysis: hospital price transparency data lacks standardization, limiting its use to insurers, employers, and consumers. San Francisco: Kaiser Family Foundation, April 9, 2021 (https://www.kff.org/health-costs/press-release/analysis-hospital-price-transparency-data-lacks-standardization-limiting-its-use-to-insurers-employers-and-consumers/).
4. Richman BD, Hall MA, Schulman KA. Overbilling and informed financial consent — a contractual solution. N Engl J Med 2012; 367:396-7.
5. Richman BD, Kitzman N, Milstein A, Schulman KA. Battling the chargemaster: a simple remedy to balance billing for unavoidable out-of-network care. Am J Manag Care 2017;23:e100-e105.
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Integrating Research into Community Practice — Toward Increased Diversity in Clinical Trials

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The Covid-19 pandemic has underscored health inequities affecting racial and ethnic minority and other underserved communities in the United States, highlighting, among other critical needs, the importance of increasing the diversity of participants in clinical trials. Clinical trials provide evidence of medical products' safety and effectiveness (or lack thereof). Physicians' ability to extrapolate from trial results to their own patients would be dramatically improved if a trial's participants reflected the product's intended patient population as accurately as possible. Yet in 2020, industry-sponsored clinical trials that supported Food and Drug Administration (FDA) approval of new molecular entities and original therapeutic biologics included 8% Black or African American, 6% Asian, and 11% Hispanic or Latino participants.[1]

Many strategies have been developed to increase enrollment of diverse populations, but they have produced mixed results. One strategy that has not been scaled up in a sustainable way is engaging community clinicians in research.

There is considerable evidence that clinician recommendations play an important role in helping patients to consider participating in clinical trials.[2] Yet such engagement is not widespread. Multiple barriers impede clinician engagement in research, starting with a lack of awareness and knowledge about clinical research. Many U.S. clinicians are not affiliated with large academic medical centers or research institutions and may therefore be unaware of current research efforts, even if research is being conducted at nearby sites. Additional barriers are lack of time and compensation for discussing trial participation with patients, failure to see clinical trials as an integral part of the care continuum, concerns that participation may interfere with established patient–clinician relationships, and lack of recognition for referring patients to trials.[2] Community clinicians are usually not offered the training, mentorship, ongoing support, and resources they need to enable sustained participation in research.

Lack of trial access is a particularly problematic barrier for both clinicians and patients. For example, less than 8% of patients with cancer participate in clinical trials, even though more than 50% will participate when offered the opportunity.[3] Community clinicians can't present these opportunities to their patients if the trials are not accessible.

Typical site-selection practices create another substantial barrier: often, to meet recruitment goals and timelines, industry sponsors repeatedly use the same large sites and investigators to conduct clinical research. These sites and investigators generally do not provide care to underserved populations and are often not easily accessible to diverse communities. In addition, much research that is sponsored by the U.S. government is conducted at major medical centers, which may serve patients in their local communities but often do not engage community-based clinicians.

Engaging community clinicians in clinical research could have multiple benefits. These clinicians are dedicated to the populations they serve and committed to addressing the health issues of those populations. The clinicians' established, trusting pa-

tient relationships allow for transparency and open dialogue, as well as sharing knowledge about the benefits and risks of trial participation. Incorporating community clinicians into the clinical research enterprise would also address accessibility challenges faced by patients: these clinicians are in the same neighborhoods as their patients, who might therefore face fewer difficulties with adjustments to work schedules and transportation.

Moreover, frontline clinicians have much to contribute to trial planning — for example, ensuring that trial logistics and enrollment criteria are achievable and do not create additional barriers. Enlisting community clinicians could also broadly extend the reach of clinical research by adding a vast pool of potential participants, thereby reducing recruitment delays, while increasing the likelihood that the trial population will resemble the products' eventual users. Finally, expanding the pool of clinical researchers will make it easier to translate from research results to clinical care.

How might such a change be accomplished? Clinical research challenges during the current pandemic have been a wake-up call for both government- and industry-based trial sponsors. While tens of thousands of people were falling ill and requiring hospitalization in U.S. communities, many traditional research sites faced competition for participants and slow enrollment, which impeded the development of critical knowledge. Sponsors of clinical research, both public and private, increasingly recognize the need to broaden the research base. Some initiatives to develop opportunities for nontraditional research sites are ongoing, including models that bring clinical trials and care delivery studies to people in their own communities.[4,5] These models, however, have not been sustainably scaled across geographic areas.

Community clinicians' established, trusting patient relationships allow for transparency and open dialogue, as well as sharing knowledge about the benefits and risks of trial participation.

Robust and ongoing funding, from both public and private sources, will be necessary to provide community clinicians who wish to participate as investigators with the time, training, and financial and logistic support to do so. In places where such clinicians are participating in a referral network, they will need ongoing training in best practices for discussing clinical trials with patients; up-to-date information about trial opportunities for patients; support for patient education, decision making, and navigation translated into the languages spoken by their patients and tailored to their cultures; and assistance with care coordination. In addition, technology solutions that facilitate data collection and monitoring (e.g., remote or wearable patient-monitoring devices), enhance enrollment of demographically and geographically diverse populations, and reduce the burden of participation will need to be made available. Such solutions currently exist but would need to be tailored to the needs of each community site.[4,5]

The time has come for stakeholders in the clinical research ecosystem — the biomedical industry, policymakers, government agencies, contract research organizations, and patient advocates — to support the development and long-term sustainability of an infrastructure that unites clinical research with clinical care. This investment will acknowledge that access to clinical research is an essential component of providing equitable health care to our diverse population. The FDA remains committed and will continue to work with all stakeholders to achieve this important goal.

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1. 2020 drug trials snapshots summary report. Silver Spring, MD: Food and Drug Administration, February 2021 (https://www.fda.gov/media/145718/download).

2. Clark LT, Watkins L, Piña IL, et al. Increasing diversity in clinical trials: overcoming critical barriers. Curr Probl Cardiol 2019;44:148-72.
3. Unger JM, Hershman DL, Till C, et al. "When offered to participate": a systematic review and meta-analysis of patient agreement to participate in cancer clinical trials. J Natl Cancer Inst 2021;113:244-57.
4. National Cancer Institute Community Oncology Research Program (NCORP) (https://ncorp.cancer.gov/).
5. Unger JM, Hershman DL, Osarogiagbon RU, et al. Representativeness of Black patients in cancer clinical trials sponsored by the National Cancer Institute compared with pharmaceutical companies. JNCI Cancer Spectr 2020;4:pkaa034.

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