

agreements must be negotiated with the selected single IRB each time a study is funded, unless otherwise specified. This requirement may at least initially counteract the expected gains in efficiency. The NIH hopes that use of existing IRB-agreement templates will expedite this process. It appears prudent for institutions to also discuss roles and responsibilities prior to the notice of award. Second, the NIH discourages but does not prohibit duplicative ethics review by local IRBs. Institutions might therefore impose local-IRB review under certain conditions and before study enrollment at their center. Since IRB agreements are often negotiated individually, this provision may affect some but not all participating centers and may result in considerable delay of study commencement.

The NIH expects that the benefits of this transition will be realized as use of single IRBs increases, but it will monitor outcomes such as time to research initiation and threats to

the protection of participants. Since utilization of single-IRB review has been limited, data on long-term outcomes have not been available or have not been published. We do not yet know whether streamlining IRB review will affect an IRB's ability to protect the welfare of human participants. Widespread adoption of single-IRB review will provide a wealth of empirical data for assessing the utility of this practice in the United States. IRBs do not typically divulge information regarding deliberations or administrative metrics, although metrics may be examined internally. These data need to be accessible, collected, analyzed, and reported systematically.¹

We anticipate that with time, angst over this new policy will lessen, as evidence is collected to confirm the prophesied advantages. Implementation of the policy should be seen as a work in progress, and modifications and clarifications may be required as outcomes data are analyzed. Ultimately, a high-quality, efficient

ethics-review process is a public health good.

Disclosure forms provided by the authors are available at [NEJM.org](http://www.nejm.org).

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Breakthroughs for Whom? Global Diabetes Care and Equitable Design

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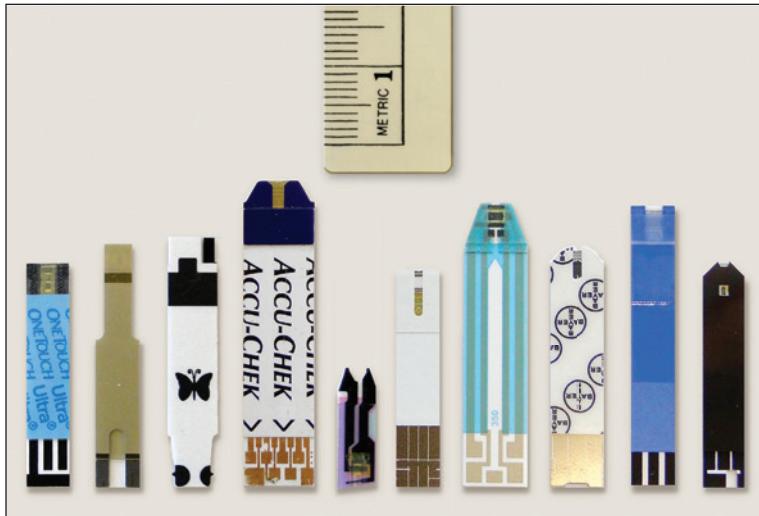
Ms. L. showed me the empty container of test strips and a box with butterflies on it. They were for a glucometer model I'd never seen before, called a FreeStyle. She explained that the machine had been given to her a few years earlier by a student philanthropic group from Arkansas on a "medical mission" trip to her village in Belize. She'd also been given a 3-month supply of the

costly testing strips the machine required, which she'd stretched for nearly a year. Then she ran out, and there was nowhere in Belize to get more strips. That was 2 years ago.

I hesitantly agreed to bring her more strips when I next returned from the United States. They were unavailable at CVS, but I located some at Walgreens. At \$70, they seemed both too expensive and

completely insufficient — only a 30-day supply. But this dilemma turned out to be beside the point: Ms. L. had a FreeStyle Lite, not an original FreeStyle, so after a return trip down miles of dusty back-country roads in a borrowed truck, we discovered that the strips didn't work on her machine.

It would be difficult to overstate the magnitude of such problems for global diabetes care. As



Testing Strips for a Variety of Glucometer Models.

a medical anthropologist, I have seen dozens, if not hundreds, of dormant or broken glucometers during my research in Belize and elsewhere. Such meters require strips specifically designed not just for the right brand, but for the particular model — so users need to pay painstaking attention not only to which manufacturer made their device, but also to each micro-specification (see photo). Is your glucose meter an AccuCheck Aviva, AccuCheck Nano, or AccuCheck Compact? A Compact or a Compact Plus? Managing these meters' messy assemblages of lancets, calibration fluid, and specialty lithium batteries often becomes a family affair. The endless stream of makes and models can be difficult to keep track of even for well-insured patients overwhelmed in the aisles of U.S. pharmacies — let alone for people trying to keep glucometers functioning in far-flung rural villages.

The manufacturers argue that these models' features provide useful innovations and updated options for users and that their products are made from expensive materials (now including gold

as an inner component of many test strips). Although some of these features have improved accuracy, others are aesthetic enhancements or luxury bells and whistles.

In many ways, this story parallels that of insulin, for which pharmaceutical companies have continued developing one small innovation after another.¹ Each tweaked formula is arguably better than its predecessor, yet these breakthroughs have also resulted in renewed patents and persistently high prices for a nearly-95-year-old drug (and even the most basic forms of insulin remain surprisingly expensive in much of the world).² Though perhaps not intentional, the effect such processes have on access for poor patients is clearly foreseeable.

The growing global diabetes epidemic demands reconsideration of these long-standing problems. The International Diabetes Federation (IDF) estimates that some 80% of people with diabetes live in low- or middle-income countries, with rates quickly increasing among the world's poorest populations.³ I had difficulty com-

prehending the IDF's estimate that diabetes now kills twice as many people as HIV-AIDS each year until I began to see how many patients with diabetes still struggle to obtain a consistent supply of insulin, let alone maintain a glucometer to safely monitor optimal doses.

Discussions about social justice in global health often begin with questions targeting delivery and distribution. Projects like that of the Arkansas group that gave Ms. L. her meter are increasingly common, and many manufacturers have also established philanthropic programs, donating glucometers to patients who can't afford them. Such programs provide islands of help. Yet even the best distribution-oriented programs do little to reconfigure the design inequalities that sustain a global system in which uniquely matched strips and proprietary meters necessitate daunting feats of international coordination and leave many patients and health systems scrambling or unable to obtain or provide this basic care.

I met patients like Ms. D., who resorted to monitoring her glucose levels by tasting her urine; or Mr. J., who died at 22 from complications of diabetes shortly after his aunt pawned his glucometer to buy groceries for the family. I got to know caregivers like Nurse S., who preferred not to prescribe insulin for rural patients with type 2 diabetes, having seen several of them "bottom out" into nearly lethal comas when they couldn't gauge their dose (a particular concern in poorer families who must sometimes choose between insulin and food, and in whom hunger can make daily blood glucose levels less predictable).

I observed how earnestly pa-

tients and caregivers seemed to be trying — engaging in the “tinkering” required to find livable diabetes regimens.⁴ Yet I was repeatedly struck by how much about physician–patient relations and outcomes was shaped somewhere far beyond the clinics where these encounters occurred, in distant laboratories and factories.

What would it take to think about such tinkering on the level of equitable design — designing technologies so as to maximize robust access for most people who need them to survive? Scholars of science, technology, and society argue that we need to pay more attention to what Ruha Benjamin calls “discriminatory design” built into our health technologies.⁵ (And like many forms of discrimination, the social norms that exclude certain populations from access may produce worrisome effects without being deliberately unjust.) Diabetes care is an important case study in these debates about technological advances amid health care disparities. A growing epidemic makes it difficult to ignore the uncomfortable truth that global access to decades-old standards of basic care for diabetes treatment remains unevenly fragile and at times inadequate enough to become life-threatening for many patients — not just despite ongoing advances in diabetes technologies, but at least partially because of them.

How would it affect the quality of care delivery if more diabetes technologies were designed with these global contexts in mind? Such questions require ongoing public discussion and collaborative rethinking of “innovation” beyond slight enhancements to existing technologies. How can

we enable advances such as sustained commitments to availability of affordable generics, measurement products with transparently designed or interchangeable parts, or other standardized methods of blood glucose management engineered to be functional and repairable in the parts of the world where most people with diabetes actually live today?

These questions are always in the back of my mind when I read about breakthroughs in diabetes research. There’s a steady flow of headlines: the promise of a bionic pancreas and saliva glucose testing; the news of islet transplants; an amazing variety of monitoring gadgets being invented and refined. I always have mixed emotions when I encounter such news items: it’s impressive that such ingenuity can contribute to sustaining dignified life despite a chronic condition, but it’s unsettling when cutting-edge devices seem like salubrious toys in a world where so many people with diabetes still struggle to obtain an almost-century-old lifesaving drug and basic access to decades-old monitoring tools.

Stories like Ms. L.’s warrant brainstorming about attentive design and raise questions about what norms are taken for granted. What is “best care,” for whom? From whose perspective do we assess what a “better” technology is? The important work of organizations like the Belize Diabetes Association leverages transnational networks to circulate glucometers to patients, but current norms of “black box” design make such delivery-oriented collaborations unnecessarily costly and prone to breakdowns.

Many patients and doctors managing blood glucose levels

need standard, easily maintained parts that work across platforms. Perhaps pioneering companies will respond. Meanwhile, some relevant projects are gathering momentum: José Gómez-Márquez’s team at MIT’s Little Devices Lab aims to craft a high-quality glucometer whose open design would be published online so that national labs could produce the device affordably, and Achira Labs in India is working to create low-cost woven-fabric test strips that sense glucose using enzyme-sprayed silk threads that conduct electrochemical signals and don’t require a machine at all.

Though some people worry that designing tools with the realities of scarcity in mind risks contributing to a two-tiered health system, in this case I see it instead as engaging in the struggle against the unjust system that already exists. Global diabetes-related mortality reveals that the “trickle-down” model of technology design and hardware development is failing large portions of the world.

Disclosure forms provided by the author are available at www.nejm.org.

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