her husband to help with positioning her on the standing weight scale. The regulations stipulate that a practice "cannot require a patient with a disability to bring someone along with them to help during an exam."[3] The medical practice is responsible for providing its staff with appropriate training in operating accessible MDE, and liability considerations cannot prevent provision of equitable care to patients with disability.

Most notably, the new rule specifies enforcement procedures and mandates periodic compliance reviews. This proactive stance responded to public concerns that "without 'teeth,' the regulation is not useful and will have no effect."[3] In addition to the standard periodic compliance reviews, consumers can file complaints within 180 days after allegedly experiencing discrimination, triggering an expedited process. DHHS aims for prompt investigations and cooperative, rather than punitive, efforts to resolve concerns.

Physicians often question the potential costs of disability accommodations, citing expense as a barrier to providing equitable care.[1] A Department of Justice Regulatory Impact Assessment (RIA; cost–benefit analysis) found that a standard exam table costs $1,875, as compared with $3,375 for an accessible exam table (price differential, $1,500 per unit), and a standard weight scale costs $1,467, as compared with $2,056 for an accessible weight scale (differential, $589 per unit).[4] A separate DHHS RIA of the accessible-MDE provision found — largely because of difficulties in quantifying anticipated benefits (e.g., improved health outcomes, decreased disability discrimination) — that the overall benefits in financial terms do not exceed costs (in 2022 dollars). For oncology care, however, the DHHS RIA found that accessible MDE could yield potential benefits of $145.5 million per year (range, $97.0 million to $193.9 million) by eliminating delays in cancer diagnosis and treatment. Using accessible mammography machines as a test case, the RIA estimated that anticipated benefits from this equipment alone could reach $290.9 million per year within 5 years after implementation.[5]

Requiring accessible MDE in all health care delivery settings is long overdue. Accessible MDE could mitigate health care disparities affecting people with disability, improving the quality of their care and their health outcomes. DHHS's new Section 504 MDE regulations thus strengthen civil rights protections for Americans with disability, increasing their likelihood of receiving equitable care.

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Ensuring a Safe and Sufficient Global Blood Supply

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A safe and sustainable blood supply remains elusive for many low- and middle-income countries (LMICs). The World Health Organization (WHO) considers blood and blood components to be essential medicines, which underscores their importance to health systems. Essential medicines are products that are deemed to be necessary to meet the health care needs of the majority of the population and therefore must be in adequate supply, accessible, and affordable, with their quality assured. Yet nearly two thirds of countries — including countries in central, eastern, and western sub-Saharan Africa, Oceania, and South Asia — lack sufficient blood to meet clinical demand.[1]

There are substantial disparities in the availability and safety

of blood between high-income countries and LMICs. Forty percent of the global blood supply is collected in high-income countries, despite these countries having less than 20% of the world's population.[1] The WHO recommends collecting a minimum of 10 units of blood per 1000 population; as of 2018, the donation rate in high-income countries was 31.5 units per 1000 people, as compared with 6.6 units and 5.0 units per 1000 people in lower-middle-income countries and low-income countries, respectively. Evidence supporting both the WHO's minimum target and the application of a single global target is weak, however. Limited availability of blood in LMICs has meant that transfusion practices differ between high-income countries and LMICs. For example, hemoglobin thresholds for administering transfusions to children are lower in LMICs (4 to 5 g per deciliter) than in high-income countries, although recent trials indicate that this cutoff may be appropriate for some children.[2]

The global blood deficit has wide-ranging adverse effects, given that many clinical disciplines (e.g., obstetrics, pediatrics, hematology, oncology, emergency medicine, and surgery) depend on blood transfusion. There are notable effects on maternal and child health. For example, one quarter of maternal in-hospital deaths caused by peripartum hemorrhage in sub-Saharan Africa have previously been attributed to blood shortages.[3] The Fluid Expansion as Supportive Therapy (FEAST) trial, conducted in Uganda, Kenya, and Tanzania, found that more than half of children who presented with febrile illness and severe anemia (i.e., a hemoglobin level below 5 g per deciliter) died when transfusion was delayed for more than 8 hours after admission, whereas 4% died when transfusion occurred within 8 hours.[4] Lack of adequate blood is an impediment to achieving the United Nations Sustainable Development Goals for reducing the burden of maternal death and deaths among children younger than 5 years of age. Treatment strategies that are the standard of care in high-income countries (e.g., hematopoietic stem-cell transplantation and cardiac surgery) are severely limited or unaffordable in many LMICs.

We believe three challenges deserve specific attention. The first relates to the composition of the donor pool, which affects both safety and sustainability of the blood supply. Voluntary, nonremunerated blood donors have long been considered the safest donor group. But replacement donors (i.e., friends or family members of the intended recipient) and, to a lesser extent, paid donors account for a substantial portion of donors in many LMICs. Transfusion of blood obtained from replacement and paid donors is known to confer a higher risk of transfusion-transmissible infections than that obtained from voluntary, nonremunerated donors, since the circumstances surrounding replacement donation (i.e., relatives or friends who are in need) and paid donation (i.e., the money the donor would receive) may discourage donors from reporting high-risk behaviors. This issue is nuanced, however. When controlling for first-time versus repeat donor status, infection risk (as measured by the prevalence of transfusion-transmissible infections) doesn't differ dramatically between voluntary and replacement donors.[5] There is also geographic variation in risk. For example, paid donation is sometimes employed in Africa when blood is in short supply. By contrast, paid donation is routine practice in some former Soviet Bloc countries; although infection risk isn't as low as it is with voluntary, nonremunerated donors in this context, this practice may be acceptable for repeat donors, given the ease of recruiting such donors. We aren't advocating for paid donation; voluntary donation should remain the goal. There is support, however, for emphasizing donor retention rather than categorization of donors by voluntary, paid, or replacement status alone, at least pending attainment of a voluntary donor pool.

Second, the inappropriate use of blood — which can involve administering transfusions for improper indications, transfusing too much or too little blood, or failing to consider alternative treatment options (e.g., iron supplementation for patients in stable condition with iron deficiency) — is an important area for improvement. Evidence-based transfusion thresholds for a range of clinical indications generally favor a restrictive transfusion strategy, but lack of adherence to guidelines can result in blood being wasted. The third challenge involves dependence on external funding, which is vulnerable to changes in politics and policy, for transfusion services in LMICs. For example, selected countries received massive infusions of funding for transfusion services in the mid-2000s as part of HIV/AIDS-mitigation initiatives. Despite the success of this support in bolstering blood-transfusion safety, funding has since diminished, which has impeded further progress. Deliberate, phased transitions to self-reliance in LMICs should be carefully considered as part of funding efforts.

Inattention to blood transfusion reflects broad neglect of pathology and laboratory services in LMICs.

Deficiencies include a lack of government support for national blood services, limited infrastructure and staffing, suboptimal or incomplete laboratory-based donor testing with quality assurance, limited or absent post-transfusion surveillance, and insufficient regulatory oversight. Challenges also extend beyond structural considerations. Outside of major disasters such as earthquakes, laboratory services and blood transfusion often fail to capture public attention — and, consequently, support from funding agencies — despite being indispensable to modern medical practice.

We believe blood transfusion should be considered a global health priority. Despite limited resources and myriad systemic challenges, access and safety have improved in some instances. A partnership between the Eswatini National Blood Transfusion Services and the U.S. Centers for Disease Control and Prevention nearly tripled the number of donated units of blood after education and operational outreach. In Rwanda, government support for the National Center for Blood Transfusion yielded an exclusively voluntary, nonremunerated donor pool as part of a centralized blood-center model that included an expanded network of blood-collection sites. In Zimbabwe, an innovative, low-cost initiative known as the Pledge 25 Club has recruited young people (a group at relatively low risk for HIV infection) to be repeat blood donors. This approach has been adopted regionally.

Successful blood-safety initiatives have also been reported from outside Africa. In Georgia, blood-transfusion services have been prioritized under a national hepatitis C elimination program; this focus has spurred a complete overhaul of the blood-donation system, from policy and regulatory oversight to donor selection and testing and post-transfusion surveillance. Nicaragua achieved 100% voluntary donation within 3 years after implementing interventions that involved raising public awareness about blood donation, educating donors, and training clinicians within the framework of a nascent national blood system. In Cambodia, a collaboration between the Cambodian Blood Service and the Australian Red Cross has made progress toward its goal of achieving accreditation by meeting international standards, such as those established by the African Society for Blood Transfusion. That organization has introduced a stepwise approach to accreditation for blood services for LMICs. Interventions in Cambodia included training and education, donor selection and counseling, and strengthening capacity for blood-component manufacturing.

Global indicators of blood safety and availability suggest improvement, but such metrics may be biased by success in a subgroup of countries. Furthermore, obtaining accurate data is difficult because both donations and transfusions happen at the level of individual hospitals. Successful models have yet to be implemented in a number of countries.

Though we acknowledge that there are numerous competing priorities in global health, we believe steps should be taken to ensure blood safety and availability. A holistic approach will be required to address each element in the pathway from blood collection to transfusion. One solution could be to implement more effective messaging that involves promoting the status of blood products as essential medicines, akin to antibiotics and anesthetics. Another could involve engaging with stakeholders to prioritize transfusion in national health systems, along with adoption of evidence-based transfusion practices. Finally, situational analysis is needed to provide robust evidence regarding blood deficits in LMICs. Under the current circumstances, the continued neglect of blood safety and availability represents a tacit acceptance of suboptimal standards for LMICs.

The views expressed in this article are those of the authors and do not necessarily reflect those of the U.S. Food and Drug Administration or its Blood Products Advisory Committee, of which Dr. Bloch is a member.

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