In public comments on the European reforms, the drug industry raised objections to the release of clinical study reports. Although companies have no trade-secrecy right to hide safety data on medicines, they make a reasonable point regarding the danger of substantial competitive harm from full transparency. Governments offer non–patent-based incentives for special categories of drugs, such as orphan drugs and biologics. These incentives have frequently rested on data exclusivity, prohibiting other companies from using data for regulatory approval purposes. To the extent that transparency disrupts data-exclusivity incentives and the timing of generic entry, both domestically and internationally, the law will need to be adjusted in order to restore the competitive position of the companies. The alternative is to delay data releases until many years after a drug is approved, but neither the progress of science nor public safety should wait for full transparency. The companies will also retain the full force of patent law to block premature generic entry. If this issue is resolved, the onus will be on the industry to articulate why clinical study reports should not be immediately released when a drug is approved.

An audio interview with Professor Outterson is available at NEJM.org

After decades of criticism about bias in the clinical trial enterprise, new norms are being established that promote transparency. Additional transparency is particularly welcome in the United States, since the Supreme Court has increasingly constrained the FDA's ability to regulate off-label marketing activities. In the deregulatory environment fostered by First Amendment challenges, clinical trial transparency is perhaps the best remaining option for informing physicians and protecting patients.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

From Boston University School of Law, Boston.

1. Ioannidis JPA, Greenland S, Hlatky MA, et al. Increasing value and reducing waste in research design, conduct, and analysis. Lancet 2014;383:166-75.
2. Mello MM, Francer JK, Wilenzick M, Teden P, Bierer BE, Barnes M. Preparing for responsible sharing of clinical trial data. N Engl J Med 2013;369:1651-8.
3. Wieseler B, Wolfram N, McGauran N, et al. Completeness of reporting of patient-relevant clinical trial outcomes: comparison of unpublished clinical study reports with publicly available data. PLoS Med 2013; 10(10):e1001526.
4. Kesselheim AS, Mello MM. Confidentiality laws and secrecy in medical research: improving public access to data on drug safety. Health Aff (Millwood) 2007;26:483-91.
5. Nisen P, Rockhold F. Access to patient-level data from GlaxoSmithKline clinical trials. N Engl J Med 2013;369:475-8.

DOI: 10.1056/NEJMp1402969

Putting Quality on the Global Health Agenda

Kirstin W. Scott, M.Phil., and Ashish K. Jha, M.D., M.P.H.

In 2005, after years of persistently high maternal mortality rates, India implemented Janani Suraksha Yojana (JSY), a conditional cash-transfer program in which women were paid to deliver their babies in health care institutions. The program's effect was as profound as it was disappointing: although the rates of institutional deliveries soared, there was no detectable effect on the country's maternal mortality rate.[1]

This paradox — a substantial increase in access to health care services with little improvement in patient outcomes — holds a critical lesson. Universal health coverage has been proposed as a potential umbrella goal for health in the next round of global development priorities.[2] The reasons for focusing on such a goal are compelling: for much of the world's population, access to health care is severely limited and often financially out of reach. Policymakers have responded by developing creative financing plans, workforce training efforts, and other programs that enhance a country's capacity to provide health care services while ensuring financial protection for its citizens. Though these efforts are necessary, lessons from recent interventions that focus primarily on enhancing access — such as JSY in India — remind us that augmenting access will not be enough. In order to improve the health of the world's population, we need to simultaneously ensure that the care provided is of sufficiently high quality, an issue that has garnered far less concrete attention.

Although there is no single definition of high-quality care, the Institute of Medicine describes it as having six key features: it is safe, effective, patient-centered, efficient, timely, and equitable. All these features are important, but there is recent evidence of particularly substantial deficiencies in the first three (see table).

Importance of Three Quality Domains and Sample Metrics.*

Quality Domain	Importance	Examples of Metrics
Patient safety	Iatrogenic harm is a major source of disability and death globally. For example, there are an estimated 23 million disability-adjusted life-years lost annually owing to harm from common inpatient adverse events.[3]	Rate of medication errors, hospital-acquired infections, foreign body left in body during surgical procedure
Effectiveness	Providers often fail to provide basic evidence-based diagnosis or treatment to patients. For example, only 12% of children in India presenting with diarrhea received appropriate treatment.[4]	Rate of cervical-cancer screening, glycemic control for patients with diabetes, appropriate treatment for childhood diarrhea
Patient-centeredness	Patients may opt out of care or not be adherent to treatments if they lack confidence in the health system. For example, the WHO World Health Survey found that in Ghana, 57.4% of patients reported poor involvement in health care decisions.	Average score on overall perception of hospital care, patients reporting being shown respect by health care providers, proportion of patients who would recommend their provider to other patients

* Information is from the World Health Organization (WHO) World Health Survey (www.who.int/healthinfo/survey/en/), the Health Care Quality Indicators project of the Organization for Economic Cooperation and Development (www.oecd.org/els/health-systems/health-care-quality-indicators.htm), the WHO Performance Assessment Tool for Quality Improvement in Hospitals (www.pathqualityproject.eu), RAND Europe (www.rand.org/content/dam/rand/pubs/technical_reports/2010/RAND_TR738.pdf), and the WHO Essential Medicines and Health Products Information Portal (http://apps.who.int/medicinedocs/en/).

Safety is a critical concern. Recent evidence from research supported by the World Health Organization (WHO) suggests that adverse events — iatrogenic injuries — are most likely a major cause of disability and death throughout the world, especially among people living in low- and middle-income countries.[3] This analysis estimated that just seven types of in-hospital adverse events result in 43 million injuries each year, and these injuries probably represent 1 of the top 20 causes of disability and death globally.[3]

Even when care does not result in harm, it is far too often ineffective. In a study involving standardized patients in India, for example, nearly 7 in 10 medical providers failed to ascertain the basic pertinent history for common ailments such as angina, asthma, and childhood diarrhea and incorrectly diagnosed a large majority of cases.[4] Consequently, their treatment advice was usually inappropriate, and for some conditions it was more often harmful than helpful (e.g., recommending anticholinergic medications for children with viral diarrhea). Such findings suggest that ineffective care is both common and dangerous. Simply expanding access to the current level of care without a concomitant effort to improve effectiveness is unlikely to improve health.

In addition, a puzzling issue confronting many policymakers is why, when formal public health care delivery systems are available (and often free), patients pay out of pocket to seek care from private providers. A recent review of studies from low- and middle-income countries suggests that private providers may be more responsive and patient-centered than public providers, although there was much room for improvement in both groups.[5] Despite broad consensus that patient-centered care is important, patients' actual experience often falls far short of the ideal. When people are not treated with basic dignity and respect by providers, they are likely to avoid future interactions with those providers. Thus, even if care is safe, effective, and widely available, it is of little use if patients choose not to use it.

These deficiencies suggest that in order for improved access to translate into better health, we need to ensure that care is safe, effective, and patient-centered. How can we do that? We would argue that, at its core, the agenda for quality could focus on systematic measurement of performance, and the resulting data could be fed back to both providers and policymakers. Without a basic understanding of the current level of quality of care, it will be difficult to improve. Policymakers might consider additional strategies beyond measurement, such as promoting transparency (e.g., through public reporting), financially incentivizing high-quality care, and investing in health information and communications technologies. Although each of these strategies holds promise, focusing on robust and timely

collection of data on meaningful quality metrics is foundational.

As policymakers attempt to operationalize the agenda for high-quality care, they are likely to encounter at least three sets of challenges. First, until recently, we had few validated metrics with which to assess the quality of health care. Fortunately, over the past decade, we have begun to make important strides in developing validated structure, process, and outcome measures in each quality domain. Though much more work remains, health care leaders are increasingly using metrics, such as those developed by the Health Care Quality Indicators project of the Organization for Economic Cooperation and Development and the WHO Performance Assessment Tool for Quality Improvement in Hospitals, to assess and improve their care. As policymakers and providers prioritize quality, they could develop new metrics. Such new measures will be especially important for ambulatory and community-based care, where current measures are not as robust as those available for the hospital arena.

Second, even if equipped with useful metrics, policymakers in low- and middle-income countries may confront a dearth of data sources for evaluating quality. In high-income countries, some of the data used for measuring quality is generated from billing or claims forms, but in poorer countries, care is more often paid for out of pocket. Nonetheless, many low- and middle-income countries have health management information systems for monitoring vertical programs (e.g., those focused on HIV–AIDS or tuberculosis), and policymakers could leverage those systems — as Rwanda has done[2] — for collecting data on a broader set of clinical conditions. Furthermore, new technologies, especially mobile technology and related e-health innovations, have the potential to capture useful data on quality, such as rates of hospital-acquired infections, rates of correct treatments, and elements of patients' experiences. A strong focus on quality measurement by policymakers, nongovernmental organizations, and funders would further spur innovation in this area.

Finally, prioritizing quality would require tackling one of the biggest challenges of all: resistance to change. Quality improvement requires that providers and policymakers identify their own weaknesses and address them directly. Few health care organizations are used to engaging in this kind of self-assessment, and most are generally not rewarded for acknowledging deficiencies. Indeed, in countries that rely heavily on international donors for support of health care services, donors have primarily focused on metrics of access (e.g., the number of pills dispensed), not on metrics of improvement (e.g., numbers of errors averted). In such countries, funders can play a key role: by supporting robust quality assessments and rewarding improvement, they can align incentives to encourage providers to pay sufficient attention to quality and strive to provide care that improves health outcomes.

We believe we are at a critical inflection point for global health. With recent progress toward combating individual killers such as HIV–AIDS, tuberculosis, polio, and malaria, policymakers have increasingly realized that the next set of battles will be won through strong health care systems. Whether the task being set is to reduce maternal mortality, save trauma victims, or manage complex noncommunicable diseases, the world will require care that is safe, effective, and responsive to patients. Investing in programs to improve access to health care services is critically important — but will not be enough to improve the health of the world's population. We need to prioritize both access and quality, because doing more isn't better. Doing better is better.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Initiative on Global Health Quality, Department of Health Policy and Management, Harvard School of Public Health (K.W.S., A.K.J.), and the Division of General Medicine, Brigham and Women's Hospital (A.K.J.) — both in Boston; and the Interfaculty Initiative in Health Policy, Harvard University, Cambridge, MA (K.W.S.).

1. Randive B, Diwan V, De Costa A. India's conditional cash transfer programme (the JSY) to promote institutional birth: is there an association between institutional birth proportion and maternal mortality? PLoS One 2013;8(6):e67452.
2. Jamison DT, Summers LH, Alleyne G, et al. Global health 2035: a world converging within a generation. Lancet 2013;382:1898-955. [Erratum, Lancet 2014;383:218.]
3. Jha AK, Larizgoitia I, Audera-Lopez C, Prasopa-Plaizier N, Waters H, Bates DW. The global burden of unsafe medical care: analytic modelling of observational studies. BMJ Qual Saf 2013;22:809-15.
4. Das J, Holla A, Das V, Mohanan M, Tabak D, Chan B. In urban and rural India, a standardized patient study showed low levels of provider training and huge quality gaps. Health Aff (Millwood) 2012;31:2774-84.
5. Berendes S, Heywood P, Oliver S, Garner P. Quality of private and public ambulatory health care in low and middle income countries: systematic review of comparative studies. PLoS Med 2011;8(4):e1000433.

DOI: 10.1056/NEJMp1402157