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REFORMING CIVIL RIGHTS WITH SYSTEMS REFORM: HEALTH CARE DISPARITIES, TRANSLATION SERVICES, & SAFE HARBORS

Sidney D. Watson¹

Looking gaunt but determined, 59 year-old Robert Tools was introduced on August 21, 2001, as a medical miracle—the first surviving recipient of a fully implantable artificial heart. At a news conference, Tools spoke with emotion about his second chance at life and the quality of his care. His physician looked on with obvious affection, grateful and honored to have extended Tools's life. Mr. Tools has since lost his battle for life, but will be remembered as a hero for undergoing an experimental technology and paving the way for other patients to undergo the procedure. Moreover, the fact that Tools was African American and his doctors were white seemed, for most Americans, to symbolize the irrelevance of race in 2001. According to two recent polls, a significant majority of Americans believe that African Americans like Tools receive the same quality of healthcare as whites.

Behind these perceptions, however, lie a sharply contrasting reality. A large body of published evidence reveals that racial and ethnic minorities experience a lower quality of health services, and are less likely to receive even routine medical procedures than are white Americans. Relative to whites, African Americans—and in some cases, Hispanics—are less likely to receive appropriate cardiac medication or to undergo coronary artery bypass surgery, are more likely to receive peritoneal dialysis and kidney transplantation, and are likely to receive a lower quality of basic clinical services, even when variations in such factors as insurance status, income, age, co-morbid conditions, and symptom expression are taken into account. Significantly, these differences are associated with greater mortality among African American patients.²

So begins the Institute of Medicine report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare*. Race and ethnicity

¹ Professor of Law, St. Louis University School of Law, Center for Health Law Studies. My thanks to the Washington and Lee School of Law for hosting a Symposium on Race and Access to Health Care. I appreciate the helpful suggestions provided by the student attendees and Professors Tim Jost, Anne Massie, and Vernellia Randall. My thanks to Payal Mather and Erin McHugh for research help, and Sarah Giesting and Jesse Goldner for editorial assistance.

² BRIAN D. SMEDLEY ET AL. EDS., *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* 2-3 (2002).

count when one talks about health care. Race and ethnicity are consistently linked with different, poorer patterns of health access, health treatment, and health status.

The law typically identifies racial disparities in medical care as a civil rights issue. Title VI of the 1964 Civil Rights Act was passed, in part, to end racially segregated health care. For almost forty years, civil rights theory has provided the paradigm for redressing racial and ethnic disparities in care. However, racial and ethnic disparities in medical care present a quality problem. As such, they should be part of quality improvement efforts. This article shows how one popular quality improvement strategy, the systems reform movement, offers a promising approach to reducing racial and ethnic disparities in minority health care.

The systems reform movement stresses that most quality problems are the result of faulty systems, rather than incompetent people. It counsels that efforts are better directed at improving the system through which care is delivered rather than trying to identify the bad actors. Systems reform emphasizes the need to improve the performance of all caregivers, while traditional quality assurance efforts have tended to be preoccupied with punishing the person who erred. While quality improvement strategies can operate separately, paralleling civil rights initiatives, they can also be incorporated into civil rights enforcement. This article shows how a system reform model can be incorporated into civil rights enforcement.

Section I examines the recent research on racial and ethnic disparities in medical care. By all measures of quality of care—outcome, process, and structure—minority Americans receive poorer quality care than do white Americans. The causes are complex with interlocking roots in history, poverty, geography, culture, and stereotyping. They operate on multiple levels—societal, institutional and individual.

However complex the causes, quality of care problems ought to invoke quality improvement strategies. Section II advocates adoption of a systems reform approach to reduce racial and ethnic disparities in care. Systems reform can be either an internal management tool or a regulatory model. In either version, systems reform focuses on designing better overall systems of care. It stresses the importance of on-going training, standardized protocols, and performance feedback. It requires data about the outcomes and processes of care by which to measure progress in improving the systems by which care is delivered.

Systems reform efforts have dramatically improved quality and reduced errors in the airline industry and anesthesiology. Many, including the Institute of Medicine, have urged adoption of systems reform throughout medical care. Section II describes how systems reform can address racial and ethnic disparities in care. Section III explains how systems reform

initiatives can strengthen health care civil rights. Health care civil rights enforcement suffers from multiple problems: an underfunded enforcement agency, the lack of public data reporting and proof requirements that do not reflect the complex causes of health care racial and ethnic disparities. Incorporating systems reform initiatives into civil rights enforcement can cure these ailments.

Section IV shows how systems reform can become part of health care civil rights enforcement. The U.S. Department of Health and Human Services Office for Civil Rights (DHHR/OCR) recently issued Title VI civil rights Policy Guidance on language assistance to persons with limited English ability. The Guidance includes a Key Elements Safe Harbor to providers who implement a language assistance program which includes four components: a community needs assessment, a comprehensive written policy on language access, staff training and regular monitoring. The Key Elements Safe Harbor grants deemed compliance status to health care providers who adopt a systems reform model for their translation services. The Safe Harbor shows how systems reform—and a focus on quality improvement—can supplement more traditional civil rights initiatives.

I. RACIAL AND ETHNIC DISPARITIES AS A QUALITY OF CARE ISSUE

By any of the traditional measures for assessing quality of medical care—outcome, process, or structure³—minority Americans get poorer care than do white Americans. Minority health outcomes are worse, the processes by which care is provided are poorer, and the institutions that treat minorities are typically underfunded and overcrowded.

Minority Americans are in worse health than majority Americans. African Americans, Latinos, and Native Americans all have higher mortality rates than whites.⁴ African Americans and Native Americans are more likely to die of heart disease, cancer and HIV.⁵ Infant mortality rates are two and a

³ For a discussion of these factors, see AVEDIS DONABEDIAN, *THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT*, VOL. 1, 79-84 (1980). Structure refers to the human, physical and financial resources by which care is delivered. The process of care is the activities that occur between patient and caregiver. The outcomes of care are changes in a patient's current and future health status that can be attributed to antecedent health care. *Id.*

⁴ See KAISER FAMILY FOUNDATION, *KEY FACTS: RACE, ETHNICITY AND MEDICAL CARE 9* (1999), available at <http://www.kff.org/content/2003/6069> (last visited Sept. 26, 2003) (showing that only Asians have lower mortality rates than whites). However, aggregating diverse ethnic groups likely masks higher mortality rates for certain Asian populations, like Vietnamese. *Id.*

⁵ U.S. COMMISSION ON CIVIL RIGHTS, *THE HEALTH CARE CHALLENGE: ACKNOWLEDGING DISPARITY, CONFRONTING DISCRIMINATING, AND ENSURING EQUALITY*, VOL. I. THE ROLE OF GOVERNMENTAL AND PRIVATE HEALTH CARE PROGRAMS AND INITIATIVES 10 (1999).

half times higher for African Americans,⁶ twice as high for Native Hawaiians,⁷ and one and a half times higher for Native Americans.⁸ Controlling for socio-economic conditions reduces, but does not eliminate these racial and ethnic disparities.⁹

Minority Americans also have poorer clinical outcomes and higher mortality rates after treatment.¹⁰ African American, Latino and Native Americans are hospitalized more often than whites.¹¹ African Americans are more likely to be discharged in an unstable condition than others and are more likely to have longer hospital stays.¹²

Moreover, studies evaluating the processes of care find that minority Americans get less and poorer care than do white Americans. African American and Latino children and adults have fewer doctors visits and get less primary care.¹³ When hospitalized, African Americans receive fewer surgical interventions, diagnostic tests, medical services, and less optimal interventions than whites.¹⁴ When treated on an outpatient basis, African

⁶ *Id.* at 11.

⁷ *Id.* at 33.

⁸ *Id.*

⁹ KAISER FAMILY FOUNDATION, *supra* note 4, at 79-84.

¹⁰ See SMEDLEY, *supra* note 2, at 2-3.

¹¹ See Paul Eggers & Linda G. Greenberg, *Racial and Ethnic Differences in Hospitalization Rates Among Aged Medicare Beneficiaries*, 21 HEALTH CARE FINANCING REVIEW 91 (2000) (Asian Americans have lower hospitalization rates than whites); Marian E. Gornick et al., *Effects of Race and Income on Mortality and Use of Services Among Medicare Beneficiaries*, 335 NEW ENG. J. MED. 791 (1996).

¹² Katherine L. Kahn, *Health Care for Black and Poor Hospitalized Medicare Patients*, 271 JAMA 1169 (1994).

¹³ See KAISER FAMILY FOUNDATION, *supra* note 4; see also Gornick et al., *supra* note 11 (African American Medicare enrollees have fewer mammograms, flu vaccinations and visits to physicians for ambulatory care); Jan Blustein, *Medicare Coverage, Supplemental Insurance, and the Use of Mammography by Older Women*, 332 NEW ENG. J. MED. 1138 (1995); *Report on Monitoring the Impact of Medicare Physician Payment Reform on Utilization and Access*, Health Care Pol'y Rep. (BNA) (Oct. 23, 1995); DEP'T OF HEALTH AND HUMAN SERVICES, ANNUAL REPORT TO CONGRESS (1994) (rate of physician visits are lower for African American Medicare recipients than for whites); *Physician Payment Assessment Commission Report*, Medicare Rep. (BNA) (May 14, 1993) (stating that African American Medicare patients receive only 89% of the primary care that whites receive and that African American Medicare patients use physicians only 82% as much as whites).

¹⁴ See, e.g., Eric Peterson et al., *Racial Variation in the Use of Coronary-Revascularization Procedures: Are the Differences Real? Do they Matter?*, 336 NEW ENG. J. MED. 480 (1997) (racial differences remained even after controlling for personal and hospital characteristics (for severity of disease and other characteristics)); D. Robert Harris et al., *Racial and Gender Differences in Use of Procedures for Black and White Hospitalized Adults*, 7 ETHNICITY AND DISEASE 91 (1997); Gornick et al., *supra* note 11; see also A. Marshall McBean et al., *Differences by Race in the Rates of Procedures Performed in Hospitals for Medicare Beneficiaries*, 15 HEALTH CARE FINANCING REVIEW 77 (1994); Z. Ayanian et al., *Racial Differences in the Use of Revascularization Procedures After Coronary Angioplasty*, 269 JAMA 2642 (1993) (differences remain even after controlling for clinical condition); Jose J. Escarce et al., *Racial Differences in the Elderly's Use of Medical Procedures and Diagnostic Tests*, 83 AM. J. PUBLIC HEALTH 948 (1993); Paula A. Johnson, *Effect of Race on the Presentation and Management of Patients with Acute Chest Pain*, 118 ANN. INT. MED. 593 (1993) (even after adjusting for multiple clinical factors African Americans still had much lower rates of coronary artery bypass); John Yergan, Ann Barry Flood, James P.

American patients are less likely to be prescribed antidepressants for major depression,¹⁵ antiretroviral therapy for HIV infection,¹⁶ or get adequate treatment for cancer-related pain.¹⁷ While less is known about the processes of care for minority patients other than African American, the few available studies find similar disparities for Hispanics and Native Americans. Both Hispanics and Native Americans are significantly less likely to receive cardiac bypass surgery and angioplasty.¹⁸ Hispanics are less likely to receive major therapeutic procedures¹⁹ or adequate pain treatment.²⁰ Although most studies only document disparities in the rates of procedures based upon the patient's race and ethnicity, those that examine the actual quality of care provided to patients tend to confirm that minority patients not only get fewer procedures, but also less optimal processes of care.²¹

Contrary to popular belief, these gaps in minority health outcomes and treatment cannot be attributed solely to insurance status, income or class. Given the greater poverty among minority Americans, racial and ethnic disparities in care are virtually inevitable in a system in which one must

LoGerfo, & Laula Diehr, *Relationship Between Patient Race and the Intensity of Hospital Services*, 25 BNA MED. REPORT 592, 600 (1987) (African American pneumonia patients receive fewer hospital services than white patients, even when the study controlled for source of payment, income and location where services were delivered); M.B. Winnerker & A.M. Epstein, *Racial Inequalities in the Use of Procedures for Patients with Ischemic Heart Disease in Massachusetts*, 261 JAMA 253 (1989) (racial differences remain even after controlling for insurance status); see, Maynard et al., *Blacks in the Coronary Artery Surgery Study (CASS): Race and Clinical Decision Making*, 76 AM. J. PUB. HEALTH 1446 (1986) (racial differences remain even after controlling for clinical characteristics). A 1994 longitudinal study of 172 medical procedures found that for 36 procedures, whites had higher procedure rates than African Americans in at least 7 of the 8 years of the study. White patients receive more advanced and intensive treatments like coronary bypass, antherosopic surgery, kidney transplants, and procedures related to the circulatory and musulatory systems than did African Americans. In contrast, African Americans received more procedures related to renal failure, abortion, glaucoma, and limb amputations. U.S. COMM'N ON CIVIL RIGHTS, REPORT 9, 14 (1999); PUBLIC HEALTH SERVICE, DEP'T OF HEALTH AND HUMAN SERVICES, AGENCY FOR HEALTH CARE AND POLICY RESEARCH, TRENDS IN HOSPITAL PROCEDURES PERFORMED ON BLACK PATIENTS AND WHITE PATIENTS: 1980-1987 5-7 (1994).

¹⁵ Jo Anne Sirey, *Predictors of Antidepressant Prescription and Early Use Among Depressed Outpatients*, 156 AM. J. PSYCH. 690 (1999).

¹⁶ Richard D. Moore, *Racial Differences in the Use of Drug Therapy for HIV Disease in an Urban Community*, 330 NEW ENG. J. MED. 763 (1994).

¹⁷ Charles S. Cleeland, *Pain and Treatment of Pain in Minority Patients with Cancer*, 127 ANN. INT. MED. 813 (1997).

¹⁸ Eggers & Greenberg, *supra* note 11, at 99; D.M. Carlisle, B.D. Leake, & M.F. Shapiro, *Racial and Ethnic Differences in the Use of Invasive Cardiac Procedures Among Cardiac Patients in Los Angeles County*, 1986-1988, 85 AM. J. PUBLIC HEALTH 352 (1995).

¹⁹ Nancy De Lew & Robin M. Weinick, *An Overview: Eliminating Racial, Ethnic, and SES Disparities in Health Care*, 21 HEALTH CARE FINANCING REV. 1, 2 (2000) (citing Andrews & Elizhauser, *Access to Major Procedures: Are Hispanics Treated Differently than Non-Hispanic Whites?* (1998) (unpublished manuscript, Agency for Health Care Policy and Research).

²⁰ See generally Cleeland, *supra* note 17 (Latinos less likely to get adequate treatment for cancer-related pain); see also Knox H. Todd, *Ethnicity as a Risk Factor for Inadequate Emergency Department Analgesia*, 269 JAMA 1537 (1993) (Latinos are twice as likely as whites to receive no pain medication when treated in the emergency room for bone fractures).

²¹ See SMEDLEY, *supra* note 2, at 55.

purchase health care.²² However, controlling for income and insurance status reduces but does not erase racial and ethnic disparities in health care.²³ Studies that control for biology, age, gender, clinical condition, severity of disease and insurance status still report racial and ethnic differences in clinical procedures and clinical outcomes.²⁴ Race and ethnicity—not just insurance and money—influence the processes of care.

Caregivers, like most Americans, have deep-seated, often unconscious stereotypes about patients of other races and ethnic groups.²⁵ Hospital emergency room staffs more often classify African Americans as ward patients and whites as private patients, even when they have similar sources of payment.²⁶ Health care professionals, like Americans in general, tend to treat Asians, Pacific Islanders and Latinos as homogenous groups, when, in fact, each is a highly diversified group of minorities with different health statuses, health needs, and cultures.²⁷ Stereotypes abound: African Americans overuse the emergency room, Asians will not discuss symptoms, Hispanics will not lose weight, and Native Americans are likely to be drunk.²⁸

Cultural insensitivity also contributes to treatment disparities. Many caregivers are ignorant about other cultures' attitudes toward authority, descriptions of pain, and world-views about wellness and illness.²⁹ At the same time, many minority patients do not always trust white caregivers or the medical care system.³⁰

²² See Mark Schlesinger, *Paying the Price: Medical Care, Minorities, and the Newly Competitive Health Care System*, 65 MILBANK Q. 270, 275-77 (Supp. 2 1987).

²³ SMEDLEY, *supra* note 2, at 77; KAISER FAMILY FOUNDATION, *supra* note 4.

²⁴ SMEDLEY, *supra* note 2, at 2.

²⁵ Michelle van Ryn, *The Effect of Patient Race and Socio-Economic Status on Physicians' Perceptions of Patients*, 50 SOC. SCI. & MED. 813 (2000) (physicians tend to perceive African Americans and poor people negatively). In one recent study researchers used video-taped patient-actors who looked similar, dressed the same, and used the same script so all the "patients" would have the same occupation, insurance status, and risk. The videotaped patient interviews were presented to 720 primary care physicians who were asked to make a treatment recommendation based upon the videotaped encounter. The study results shows that men and whites were the most likely patients to be referred for cardiac catheterization. See Kevin A. Schulman et al., *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 NEW ENG. J. MED. 618 (1999).

²⁶ Council on Ethical and Judicial Affairs, *Black-White Disparities in Health Care*, 263 JAMA 2344, 2345 (1990).

²⁷ See Lin Fu, *Population Characteristics and Health Care Needs of Asian Pacific Americans*, 103 PUBLIC HEALTH REPORTS 18 (1988); See also Pedro Ruiz, *Cultural Barriers to Effective Medical Care Among Hispanic-American Patients*, 36 ANN. REV. MED. 63-71 (1985).

²⁸ KAISER FAMILY FOUNDATION, PERCEPTIONS OF HOW RACE & ETHNIC BACKGROUND AFFECT MEDICAL CARE: HIGHLIGHTS FROM FOCUS GROUPS 2, 4 (Oct. 1999) available at <http://www.kff.org/content/1999/1524/focus%20GROUP.pdf>.

²⁹ Laura Uba, *Cultural Barriers to Health Care for Southeast Asian Refugees*, 107 PUBLIC HEALTH REP. 545 (1992).

³⁰ See Vernellia R. Randall, *Slavery, Segregation and Racism: Trusting the Health Care System Ain't*

Language barriers also factor into the equation. Over fourteen million Americans do not speak English at home³¹ and twenty percent of patients report language barriers when trying to communicate with health care professionals.³² Cross cultural and cross-class communication can be difficult not only when the participants speak different languages, but even when they appear to share a tongue.³³

Institutional racism also plays a role. A variety of institutional practices disproportionately impact the care minority Americans receive. Many standard operating procedures have a disproportionate and adverse impact on people of color. Most primary care providers do not have evening or weekend hours. Many physicians refuse to care for or severely limit the number of Medicaid patients they will treat. Others hire few, if any, minority or bilingual health care professionals. Most use signs and consent forms written only in English. Still others make pre-admission inquiries into patients' citizenship, national origin or immigration status. Each of these policies makes it more difficult for racial and ethnic minorities to access the care provided white Americans.

Moreover, some of the racial and ethnic disparities in outcomes and treatments are the result of differences in the structure of care--the physical, financial, and human resources by which care is delivered. Minority Americans disproportionately rely on public hospitals and outpatient clinics.³⁴ Private hospitals and private physicians avoid locating in primarily minority neighborhoods.³⁵ The public facilities that serve these areas typically are underfunded. They suffer from deteriorating physical plans, outdated equipment, staff shortages, overcrowding and long waits for care.³⁶ The care they provide is rushed and episodic. As a result, minority

Always Easy! An African American Perspective on Bioethics, 15 St. LOUIS U. PUB. L. REV. 191 (1996).

³¹ See SMEDLEY, *supra* note 2, at 87-88.

³² *Nationwide Survey Shows Minorities Get Shortchanged on Medical Services*, 13 Health Care Pol'y Rep. (BNA) 56 (Mar. 27, 1995).

³³ See ANNE FADIMAN, *THE SPIRIT CATCHES YOU AND YOU FALL DOWN* (1997); Beverly Coleman-Miller, *A Physician's Perspective on Minority Health*, 21 HEALTH CARE FIN. REV. 45, 49 (2000). See generally Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association, *Health Literacy: Report of the Council on Scientific Affairs*, 281 JAMA 552 (1999); Lisa Cooper-Patrick et al., *Race, Gender, and Partnership in the Patient Physician Relationship*, 282 JAMA 583 (1999).

³⁴ Christopher Forrest & Ellen-Marie Whelan, *Primary Care Safety-Net Delivery Sites in the United States: A Comparison of Community Health Centers, Hospital Outpatient Departments, and Physicians' Offices*, 284 JAMA 2077 (2000) (Hispanics are less likely than whites to have private physicians and are more likely to rely on hospital emergency rooms and outpatient clinics for primary care); *Physician Payment Assessment Commission Report*, Medicare Rep. (BNA) (May 14, 1993) (stating that African American Medicare patients use the emergency room 2.7% more than whites).

³⁵ See Sidney D. Watson, *Health Care in the Inner City: Asking the Right Question*, 71 N.C. L. REV. 1647, 1649-50, 1664-65 (1993).

³⁶ Cassandra Butts, *The Color of Money: Barriers to Access to Private Health Care Facilities for African-Americans*, 26 CLEARINGHOUSE REV. 159, 160 (1992).

Americans are less likely than whites to have an established relationship with a primary care physician and a medical home to turn to for care.³⁷

Inevitably, the lack of minority health professionals compounds the problem. African Americans make up only three percent of physicians, two percent of dentists, and four percent of registered nurses. Hispanics numbers are similar: doctors, five percent; dentists, three percent; and nurses, one percent.³⁸

Racial and ethnic disparities exist in every measure of quality—outcomes, processes and structure. Minority Americans receive poorer care than do white Americans.³⁹ Conceptualizing racial and ethnic disparities as a quality of care issue is helpful because it labels the underlying problem for what it is: a quality concern.⁴⁰ Quality of care problems call for quality improvement strategies to improve the structures by which care are provided, the processes of care, and, ultimately, health outcomes.

Commentators have suggested a variety of quality improvement techniques for reducing racial disparities in care: outcomes report cards indexed by patient race and ethnicity,⁴¹ practice guidelines and protocols,⁴² financial incentives,⁴³ and increased financial support for safety net providers.⁴⁴ However, much of the activity around quality improvement initiatives has moved from a focus on discrete quality improvement techniques to urging systems reform initiatives that incorporate an array of design improvements.

II. A SYSTEMS REFORM APPROACH TO IMPROVING MINORITY ACCESS AND CARE

A systems reform approach to quality improvement focuses on designing better systems for delivering care. Systems reform posits that

³⁷ SMEDLEY, *supra* note 2, at 108-12.

³⁸ PUBLIC HEALTH SERVICE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTHY PEOPLE 2000: NATIONAL HEALTH PROMOTION AND DISEASE PREVENTION OBJECTIVES 542 (1991).

³⁹ SMEDLEY, *supra* note 2, at 3-4.

⁴⁰ *See id.* at 3. The Institute of Medicine defines quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." *Id.* at 31.

⁴¹ David Barton Smith, *Addressing Racial Inequities in Health Care: Civil Rights Monitoring and Report Card*, 23 J. HEALTH POL'Y & L. 75 (1998).

⁴² Council on Ethical and Judicial Affairs, *Black-White Disparities in Health Care*, 263 JAMA 2344, 2345 (1990); Kevin Fiscella et al., *Inequality in Quality: Addressing Socioeconomic, Racial, and Ethnic Disparities in Health Care*, 283 JAMA 2579 (2000).

⁴³ Sidney D. Watson, *Race, Ethnicity and Quality of Care: Inequalities and Incentives*, 27 AM. J. L. & MED. 203, 223-24 (2001).

⁴⁴ SMEDLEY, *supra* note 2, at 182-84.

most quality problems are caused by faulty systems, not incompetent or ill-meaning individuals. It counsels that energy is better directed toward improving the system by which care is delivered than seeking out and blaming "bad apples."

Systems reform is cropping up throughout medical care both as an internal management tool and as a regulatory model for quality improvement. Over three quarters of hospitals have incorporated a systems reform approach into their internal quality assurance and risk management programs.⁴⁵ Systems reform is credited with transforming anesthesiology practice and dramatically increasing patient safety.⁴⁶ The Institute of Medicine (IOM) has embraced systems reform as part of its broad initiative to improve the quality of medical care.⁴⁷ In 2000, the IOM Committee on Quality Improvement strongly endorsed systems reform as the best method for reducing medical errors.⁴⁸ More recently, another IOM work group, the Committee on Assessing the System for Protecting Human Research Participants, recommended systems reform to protect the health and safety of human research participants.⁴⁹

This interest in systems reform is fueled from two directions: the internally focused Continuous Quality Improvement (CQI)/Total Quality Management (TQM) movement and the externally focused human factors research on safety and error reduction.⁵⁰ CQI/TQM is a management theory derived from Japanese industrial practice.⁵¹ Human factors research examines the nature of human performance and the causes of error.⁵² While CQI/TQM promotes systems reform as an internal management tool, the human factors movement sees systems reform as the basis for a regulatory model for improving quality of care.⁵³

⁴⁵ See BARRY FURROW ET AL., HEALTH LAW 28 (2001) (citing Linda Oberman, *Quality Unary: Little Clinical Impact Yet*, AM. MED. NEWS, Apr. 25, 1994, at 3 (finding that two-thirds of hospitals surveyed were adopting a total quality management or continuous quality improvement systems approach)).

⁴⁶ Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851 (1991). Anesthesiology adopted a systems approach to error reduction and over a ten year period mortality rates declined from one in 10,000 to only one in 200,000. *Id.*

⁴⁷ TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM ix-x (Linda T. Kohn et al. eds., 2003) [hereinafter TO ERR IS HUMAN].

⁴⁸ *Id.* at 5.

⁴⁹ See generally RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS (Daniel D. Federman et al. eds., 2002).

⁵⁰ For a discussion of TQM/CQI in the health care industry, see Timothy S. Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market*, 37 ARIZ. L. REV. 825 (1995). For an explanation of the impact of human factors research on safety and error reduction, see Leape, *supra* note 46.

⁵¹ Jost, *supra* note 50, at 838.

⁵² Leape, *supra* note 46, at 1854.

⁵³ See TO ERR IS HUMAN, *supra* note 47, at 63.

In either its internal or external iteration, systems reform efforts shift the quality improvement spotlight from who erred to how can the system design be improved.⁵⁴ Acknowledging that people are fallible, systems reform stresses the need for on-going training, standardized protocols, and performance feedback to improve the performance of the average caregiver.⁵⁵ It also stresses the need for safeguards to prevent and correct errors before they cause harm.⁵⁶ One of the main attractions of systems reform is this positive, non-punitive focus.⁵⁷

System reform envisions quality improvement as a continuous, never-ending process of evaluation, design adjustment, re-evaluation and further adjustment as needed.⁵⁸ Both CQI/TQM and human factors research stress the need to involve all levels of management and staff.⁵⁹ CQI/TQM also emphasizes the role of patient satisfaction as an indicator of quality of care.⁶⁰

Data is at the core of systems reform. Systems reform initiatives require good information about the structures, processes, and outcomes of care.⁶¹ While outcomes data is particularly important because it identifies errors, information about the processes and structures of care and input can also pinpoint potential design flaws.⁶² A systems reform approach to quality improvement requires that data be collected on a regular basis to monitor the system of care and evaluate the effectiveness of system changes.⁶³

In systems reform, data can be important both for internal evaluation and external accountability. The internally focused CQI/TQM movement uses data as an internal management tool.⁶⁴ The human factors patient safety movement urges public reporting of data as part of a regulatory systems reform strategy.⁶⁵

Public reporting as part of a regulatory systems reform strategy serves two important roles.⁶⁶ First, public reporting provides information by which consumers can evaluate and compare physicians, hospitals, and managed care organizations. Data reporting makes providers publicly

⁵⁴ *Id.* at 5; Jost, *supra* note 50, at 845.

⁵⁵ Jost, *supra* note 50, at 838-39.

⁵⁶ Leape, *supra* note 46, at 1854.

⁵⁷ Jost, *supra* note 50, at 839.

⁵⁸ *Id.*; Leape, *supra* note 46, at 1855.

⁵⁹ See Leape, *supra* note 46; Jost, *supra* note 50, at 839.

⁶⁰ Jost, *supra* note 50, at 838-39.

⁶¹ TO ERR IS HUMAN, *supra* note 47, at 86-90; Jost, *supra* note 50, at 836-37.

⁶² Jost, *supra* note 50, at 837.

⁶³ Jost, *supra* note 50, at 839; TO ERR IS HUMAN, *supra* note 47, at 4-5.

⁶⁴ Jost, *supra* note 50, at 839.

⁶⁵ See TO ERR IS HUMAN, *supra* note 47, at 86-131.

⁶⁶ *Id.* at 86-87.

accountable for their performance. Second, public reporting supplies crucial information about better systems design. It reports what works and what does not. In the airline industry, one of the first to adopt a regulatory systems approach to safety, the FAA requires public reporting of accidents and confidential reporting of near misses. Analysis of these reports has provided crucial information on how to design air travel to make it safer.⁶⁷

Systems reform offers promise as a quality improvement tool to reduce racial and ethnic disparities in medical care. A systems reform approach reminds us that the issues that confront and confound attempts to reduce racial and ethnic disparities in medical care are design flaws inherent in America's health care institutions, the nation's history as a segregated society, and human fallibility. Individual caregivers' actions, no matter how well intentioned, are colored by deep-seated, often unconscious racial and ethnic stereotypes. Individual health care institutions exhibit the same characteristics and flaws.

A systems reform approach allows us to acknowledge these flaws, but does not require us to point the finger of blame. Instead, systems reform urges us to design health care systems that anticipate these human and institutional failings. Systems reform's primary purpose is not to punish individuals or institutions after they discriminate—be it through racial stereotyping, cultural insensitivity or other thoughtless or thoughtful behavior. Rather, systems reform seeks to reduce racial and ethnic disparities through design improvements—better training, standardized protocols, and error safeguards—to prevent the inevitable failures that befall both humans and their institutions of care.

Thus, systems reform offers a forward-looking, positive model for addressing what ails minority health care. Systems reform, relieved of the need to blame a particular individual or a particular practice, allows caregivers to experiment with and evaluate design models that have the potential to reduce racial and ethnic disparities.

However, systems reform initiatives also require that health care providers collect, report and analyze data about the race and ethnicity of their patients, the care they receive, their outcomes and satisfaction. Without this information, racial and ethnic disparities cannot be identified as problems that infect the process of care particularly in an understandable atmosphere of denial of the existence of such disparities. Only with this information can design reforms be tested for their effectiveness in reducing racial disparities.

The learning curve on reducing racial and ethnic disparities in care is just beginning. Public reporting of data that identifies designs, training and

⁶⁷ Leape, *supra* note 46, at 1855.

protocols that reduce racial and ethnic disparities—and those that do not—will help medicine advance more quickly toward reducing racial and ethnic disparities and improving minority health care. Public reporting of race and ethnicity data also holds providers accountable to the communities they serve—and those they should be serving but may not.

Thus, systems reform offers promise as a quality improvement strategy for reducing racial and ethnic disparities in care. While quality improvement strategies can operate separate and apart from civil rights initiatives, systems reform also offers promise as a civil rights strategy. Its forward-looking focus combined with its emphasis on the need for data on patient race and ethnicity offers an alternative technique for civil rights enforcement.

III. TITLE VI, CIVIL RIGHTS ENFORCEMENT AND THE BENEFITS OF INCORPORATING SYSTEMS REFORM INTO CIVIL RIGHTS

Title VI of the Civil Rights Act of 1964⁶⁸ has served as the primary legal tool for redressing racial and ethnic disparities in care. Congress passed Title VI, in part, to ensure that federal money could no longer be used to support segregated health care facilities.⁶⁹ Prior to the passage of the 1964 Civil Rights Act, health care facilities openly discriminated against African Americans. Most hospitals barred African American patients and African American physicians. Hospitals that did admit African Americans relegated them to segregated wards.⁷⁰

Title VI prohibits recipients of federal financial assistance, including hospitals, nursing homes, managed care organizations, and doctors who accept Medicaid or Medicare, from discriminating on the basis of race, color, or national origin.⁷¹ The statute prohibits intentional discrimination and its implementing regulations prohibit facially neutral policies and practices that have a disproportionate adverse impact on minorities, even in the absence of discrimination.⁷² The regulations also require recipients of

⁶⁸ Civil Rights Act of 1964, 42 U.S.C. § 2000d–2000d-4 (2003).

⁶⁹ See 110 CONG. REC. 1658 (1964).

⁷⁰ DAVID BARTON SMITH, HEALTH CARE DIVIDED: RACE AND HEALING A NATION 12 (1999).

⁷¹ See 42 U.S.C. § 2000d–2000d-4 (2003). The operative section provides that “[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” *Id.* at 2000d.

⁷² These regulations prohibit “criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a

federal funds to take affirmative steps to overcome the effects of prior discrimination,⁷³ prohibit recipients from subjecting individuals to separate or segregated treatment on the basis of race,⁷⁴ and prohibit recipient hospitals and other institutions from establishing facility locations with discriminatory effects.⁷⁵

Enactment of Title VI quickly and dramatically ended the most blatant forms of intentional health care segregation.⁷⁶ The “White Only” signs came down and hospital wards integrated. However, Title VI has not eliminated racial and ethnic disparities in health care; minority Americans still get less and poorer health care than do white Americans.

One of the major difficulties in using Title VI to redress racial and ethnic disparities in health care is that Title VI, unlike the other titles of the 1964 Civil Rights Act, depends primarily on administrative action rather than judicial enforcement. The Department of Health and Human Services Office for Civil Rights (DHHS/OCR) has primary responsibility for ensuring that federally funded health care providers comply with Title VI. Individuals have a private right of action to pursue claims of intentional discrimination, but only DHHS/OCR can enforce claims of disparate impact discrimination.⁷⁷

Chronically underfunded and understaffed, DHHS/OCR’s Title VI enforcement record is dismal. DHHS/OCR has never routinely collected data on minority health care access and treatment.⁷⁸ One reason recent research studies reporting racial and ethnic disparities are so shocking is that for years no data was available by which to measure minority health care. Even now, DHHS/OCR requires no routine data reporting by which to monitor Title VI civil rights compliance.⁷⁹

For almost two decades, during the Reagan-Bush I administrations,

particular race, color or national origin.” 45 C.F.R. § 80.3(b)(1)(vii)(2) (2002). For a history of the case law upholding these regulations, see Sidney D. Watson, *Reinvigorating Title VI: Defending Health Care Discrimination—It Shouldn’t Be So Easy*, 58 FORDHAM L. REV. 939, 948-55 (1990).

⁷³ 45 C.F.R. § 80.3(b)(6)(i) (2002).

⁷⁴ *Id.* § 80.3(b)(1)(iii), 80.5(a).

⁷⁵ *Id.* § 80.3(b) (3).

⁷⁶ SMITH, *supra* note 70, at 217.

⁷⁷ *Alexander v. Sandoval*, 532 U.S. 275 (2001). *Sandoval* involved a Title VI claim against the Alabama Department of Public Safety. Plaintiffs sought to enjoin the department’s practice of administering driver’s license tests only in English alleging that the practice violated Title VI because of a disparate impact on those with limited English proficiency. A fractured court, reflecting the fractured history of Title VI’s private right of action, held that private individuals do not have a private right of action to sue to enforce the Title VI disparate impact regulations. However, many commentators believe that *Sandoval* does not foreclose a section 1983 action to enforce Title VI disparate impact regulations against a governmental actor. See *Leading Cases*, 115 HARV. L. REV. 497 (2001).

⁷⁸ See *Madison-Hughes v. Shalala*, 80 F.3d 1121 (6th Cir. 1996) (alleging that DHHS/OCR violated Title VI by failing to require health care providers to routinely report race and ethnicity data).

⁷⁹ SMEDLEY, *supra* note 2, at 21-22.

DHHS/OCR limited its enforcement efforts to responding to individual complaints of discrimination.⁸⁰ Following these administrations' general civil rights philosophy, the agency only investigated Title VI complaints for signs of intentional discrimination. DHHS/OCR refused to look for patterns of racial and ethnic disparities in access and care that might indicate possible disparate impact discrimination.⁸¹ While the agency now investigates complaints of disparities that might indicate disparate impact discrimination,⁸² individual compliance actions can be contentious affairs.

Using Title VI compliance actions to redress racial and ethnic disparities in care can be complicated, time consuming and expensive. In a Title VI case, the complainant must prove that the health care provider either intentionally discriminated or used policies or practices that have an unjustified, disproportionate adverse impact.⁸³ In an intentional discrimination claim, the plaintiff must prove motive. In a claim alleging disproportionate adverse impact, the plaintiff must identify a particular racially neutral policy or practice that has a statistically significant adverse effect on a protected racial or ethnic group.⁸⁴ Once the plaintiff establishes this prima facie case, the burden shifts to the defendant to justify the challenged practice by establishing a legitimate, nondiscriminatory reason for the policy or practice.⁸⁵

Racial disparities in health care are the result of multiple, complicated, historically rooted factors that do not fit neatly into Title VI proof requirements. Some disparities result from unconscious bias and stereotypes. Others are the result of institutional policies and practices which operate together, not separately as demanded by traditional disparate impact theory, to exclude minority patients. Title VI complaints challenging economic discrimination with a disproportionate adverse impact tend to become expensive, protracted legal battles over the appropriate weight to accord to health care providers' cost concerns.⁸⁶

DHHS/OCR simply does not have the resources to pursue large

⁸⁰ See generally COMMITTEE ON GOVERNMENT OPERATIONS, INVESTIGATION OF THE OFFICE FOR CIVIL RIGHTS IN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (1987).

⁸¹ *Id.*

⁸² See CIVIL RIGHTS DIVISION, U.S. DEP'T OF JUSTICE, TITLE VI LEGAL MANUAL 47 (2001), available at <http://www.usdoj.gov/crt/cort/coord/vimanual.pdf>.

⁸³ For a discussion of these two theories of discrimination, see Watson, *supra* note 72 at 948-49.

⁸⁴ See *Elston v. Talladega County. Bd. of Educ.*, 997 F.2d 1394, 1407 (11th Cir. 1993). See also Watson, *supra* note 72, at 939.

⁸⁵ See *Elston*, 997 F. 2d at 1407 (holding that even if the defendant can establish a legitimate non-discriminatory reason, the plaintiff may still prevail by demonstrating that the health care provider's legitimate interest can be met by using a less discriminatory alternative. See Watson, *supra* note 72, at 956-58.

⁸⁶ See Watson, *supra* note 43, at 219.

numbers of compliance actions.⁸⁷ Over the last twenty years, DHHS/OCR's after inflation annual budget has shrunk by sixty percent.⁸⁸ During this same time, the agency has assumed other high visibility enforcement obligations including the Americans with Disabilities Act and HIPAA. Moreover, an enforcement strategy that relies primarily on compliance actions breeds hostility between the agency and the health care provider community.

A systems reform approach to civil rights enforcement offers a prescription for easing much of what complicates Title VI compliance actions. Title VI proof requirements are complex because enforcement actions look backwards in an attempt to identify the "bad apple"—the person or policy—to blame. Compliance actions are contentious because they seek to lay blame. The systems reform movement redirects attention away from the past and toward the future. It focuses on redesigning systems so they function better. It uses the present racial and ethnic disparities in care, not to prove past bad conduct but to measure future progress in creating a more equitable system.

While a systems approach cannot and should not replace the strict proof requirements of discrimination law, it does offer an alternative way of conceptualizing civil rights regulatory effort to racial and ethnic disparities in care. Civil rights enforcement actions set the minimum acceptable behavior by identifying prohibited discrimination. Systems reform initiatives aspire to create better, more equitable systems for delivering medical care. Grafting systems reform into civil rights enforcement also reminds us that racial and ethnic disparities in care are a quality of care problem as well as a civil rights issue.

In August 2000, the DHHS/OCR initiated its first major pro-active civil rights compliance initiative in over two decades: a Policy Guidance on translation services for persons with limited English language proficiency.⁸⁹ The Guidance offers federally funded health care providers who implement a systems reform approach to translation services a Title VI safe harbor. The Guidance illustrates the first step towards incorporating systems reform into health care civil rights enforcement.

⁸⁷ See generally SMITH, *supra* note 73.

⁸⁸ See SMEDLEY, *supra* note 2, at 188 (showing that when adjusted for inflation, HHS/OCR's fiscal year 2000 budget was 60 percent less than its 1981 budget).

⁸⁹ Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as It Affects Persons with Limited English Proficiency, 65 Fed. Reg. 52,762 (Aug. 30, 2000).

IV. SYSTEMS REFORM AND CIVIL RIGHTS SAFE HARBORS

On August 30, 2000, DHHS/OCR issued "Policy Guidance on the Title VI Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency."⁹⁰ This Guidance, colloquially referred to as the Limited English Proficiency or LEP Guidance, does not create new policy or administrative requirements.⁹¹ It reiterates long standing DHHS/OCR policy: To comply with Title VI, health care providers who receive federal financial assistance must take steps to ensure that persons with limited English proficiency have meaningful access to their services.⁹² Meaningful access requires that patients have access to free translation services. Patients should not be required to pay for translators nor should they be expected to rely on friends and family for translation.⁹³

Obviously, limited ability to speak and understand English contributes to racial and ethnic disparities in care for national origin minorities. Over 14 million individuals living in the U.S. cannot speak, read, write or understand English well enough to communicate effectively with their caregivers.⁹⁴ Although English language difficulties can arise in many settings, the consequences are especially tragic in the health care setting. Medical care requires a free and full flow of confidential, sometimes embarrassing information. It requires a close relationship built on empathy, confidence and trust. Building such a relationship is problematic when the caregiver and patient speak different languages.⁹⁵

Communication and trust problems are compounded when patients must rely on family members or friends to translate.⁹⁶ These untrained "interpreters" often do not understand the medical and technical terms that need to be translated. Even when they do, their presence can inhibit conversation with the health care providers. Many patients are reluctant to discuss intimate, private matters with friends or family members. These problems become particularly acute when patients must rely on minor children to translate.

Language problems can cause a variety of access and quality problems: care can be denied when staff do not understand what a person

⁹⁰ *Id.* at 52764-69.

⁹¹ *Id.* at 52762.

⁹² *Id.* at 52765.

⁹³ *Id.*

⁹⁴ SMEDLEY, *supra* note 10, at 87-88.

⁹⁵ Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as It Affects Persons with Limited English Proficiency, 65 Fed. Reg. 52,762, 52,763 (Aug. 30, 2000).

⁹⁶ *Id.* at 52762.

needs, care can be delayed while attempts are made to find a translator, and care can be in error when based upon inaccurate or incomplete information.⁹⁷ While factors such as culture and racial stereotyping contribute to ethnic disparities in care, language is the primary barrier to care for non-English speakers.

For decades, courts and regulatory agencies have recognized that the failure to affirmatively assist those with limited English skills may constitute prohibited Title VI discrimination based on national origin.⁹⁸ In some circumstances, English only policies are a pretext for intentional national origin discrimination.⁹⁹ In others, the lack of translation services has an unjustified disproportionate adverse impact on ethnic minorities.¹⁰⁰ Under both scenarios, the U.S. Supreme Court has declared that health care providers and others who receive federal financial assistance have an affirmative responsibility to assure that non-English speaking persons have meaningful access to their services.¹⁰¹

DHHS/OCR has investigated thousands of individual complaints about the lack of language assistance for persons with limited English ability applying the U.S. Supreme Court's meaningful access standard.¹⁰² The purpose of the LEP Guidance is to make public the criteria the agency uses in these investigations.¹⁰³ It codifies the standards the agency has developed

⁹⁷ See, e.g., Glenn Flores et al., *Errors in Medical Interpretation and their Potential Clinical Consequences in Pediatric Encounters*, 111 PEDIATRICS 6 (2003).

⁹⁸ See, e.g., *Lau v. Nichols*, 414 U.S. 563 (1974) (holding that San Francisco school system's failure to provide supplemental English language instruction violated Title VI and its implementing regulations because it had the effect of excluding non-English speaking Chinese students from the school system's educational programs); *Garcia v. Gloor*, 618 F.2d 264 (5th Cir. 1980), *cert. denied*, 449 U.S. 1113 (1981) (to a person who speaks only one tongue or to a person who has difficulty using another language other than the one spoken in his home, language might well be an immutable characteristic like skin color, sex or place of birth); *United States v. Uvalde Consol. Indep. Sch. Dist.*, 625 F.2d 547 (5th Cir. 1980) (upholding amendment to the Voting Rights Act eliminating discrimination against language minorities by prohibiting English-only elections).

⁹⁹ See, e.g., *Gutierrez v. Mun. Court of S. E. Judicial Dist.*, 838 F.2d 1031, 1039 (9th Cir. 1988), *vacated as moot*, 490 U.S. 1016 (1989) (use of English only as mask for national origin discrimination); Tom McArthur, *Comment: Worried About Something Else*, 60 INT'L J. SOC. LANGUAGE, 87, 90-91 (1986).

¹⁰⁰ See, e.g., *Lau v. Nichols*, 414 U.S. 563 (1974) (San Francisco school system's failure to provide supplemental English language instruction violated Title VI and its implementing regulations because it had the effect of excluding non-English speaking Chinese students from the school system's educational programs); *Garcia v. Gloor*, 618 F.2d 264 (5th Cir. 1980), *cert. denied*, 449 U.S. 1113 (1981) (to a person who speaks only one tongue or to a person who has difficulty using another language other than the one spoken in his home, language might well be an immutable characteristic like skin color, sex or place of birth).

¹⁰¹ *Lau*, 414 U.S. at 568.

¹⁰² Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as It Affects Persons with Limited English Proficiency, 65 Fed. Reg. 52,762, 52,764 (Aug. 30, 2000).

¹⁰³ *Id.*

over thirty years enforcing Title VI.

While the Policy Guidance contains no new legal requirements,¹⁰⁴ it prompted a loud outcry from health care providers grown accustomed to benign neglect of civil rights issues and Title VI compliance.¹⁰⁵ Part of the outcry is a knee jerk reaction to “government mandates.” Other complaints are fueled by providers’ fears that they will have to pay for translation services if they are unable to rely on patients’ family and friends. In response, on February 1, 2001, DHHS/OCR republished the Guidance requesting additional comments on the benefits, burdens and costs of providing assistance to persons with limited English proficiency.¹⁰⁶ The agency has yet to publish a response to these comments.

Lost in the controversy is the Guidance’s landmark status as DHHS/OCR’s first proactive civil rights enforcement strategy in decades. The Guidance seeks to preempt the need for individual complaints about translation services by giving federally funded health care providers notice of the standards by which such complaints are evaluated.¹⁰⁷ The Guidance also provides technical assistance on how to provide translation services, and offers examples of promising practices and a model written plan for providing language assistance in a hospital that serves a large number of persons with limited English ability.¹⁰⁸

The LEP Guidance sets minimum criteria for meaningful access to language services: the patient may not be required to pay for translation services or be expected to rely on friends and family for translation.¹⁰⁹ However, contrary to what some have charged,¹¹⁰ the Guidance does not mandate that every health care provider must pay for translation services. The “meaningful access” test requires an individualized determination that takes into account the size of the health care provider, the size of the eligible population with limited English, the nature of the program or services, the objectives of the program, the total resources available, the frequency with which particular languages are encountered, and the frequency with which persons with limited English come into contact with the program.¹¹¹

¹⁰⁴ *Id.*

¹⁰⁵ See, e.g., Brandy Glasser & Bryan A. Liang, *Hearing Without Understanding: A Proposal to Modify Federal Translation Guidelines to Improve Healthcare for Citizens with Limited English Proficiency*, 35 J. HEALTH L. 467 (2002).

¹⁰⁶ Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as It Affects Persons with Limited English Proficiency, 65 Fed. Reg. 52,762 (Aug. 30, 2000).

¹⁰⁷ *Id.* at 52,767.

¹⁰⁸ *Id.* at 52,771.

¹⁰⁹ *Id.* at 52,765.

¹¹⁰ See, e.g., Glasser & Liang, *supra* note 105.

¹¹¹ Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin

Above its minimum requirements, the meaningful access standard requires a fact sensitive inquiry.¹¹² The Guidance stresses that appropriate language assistance varies with the circumstances. It can encompass a wide variety of services ranging from posting notices in languages other than English, to translating written materials, to providing access to oral translation services via bilingual staff, community volunteer translators, or paid translators.¹¹³ Most interesting is the LEP Guidance's Key Elements Safe Harbor which offers providers an alternative to this individualized compliance inquiry. The Key Elements Safe Harbor offers health providers who "effectively incorporate and implement" four elements—a community needs assessment, a comprehensive written policy on language access, staff training and regular monitoring—Title VI compliance status.¹¹⁴ Health care providers who implement all four elements are assured that DHHS/OCR will find them in compliance with Title VI. Failure to implement any of these four elements does not necessarily mean that a provider is in violation of Title VI. It does mean that DHHS/OCR will review the provider's language assistance services under an individualized totality of the circumstances test to determine whether LEP persons have meaningful access to services.¹¹⁵

The first key element in the Safe Harbor is a community needs assessment to determine the number of non-English speaking persons who live in the health care provider's service area and the number who are likely to need services.¹¹⁶ The needs assessment also identifies the language needs of LEP persons, the contact points where language assistance is likely to be needed, and the resources available to provide language assistance, both within and outside the health care entity.¹¹⁷

The second key element is development of a comprehensive written policy on language assistance.¹¹⁸ The LEP Guidance provides a checklist of components for a good language assistance system including procedures for identifying LEP patients and methods for providing oral language assistance, notice of the right to free language assistance in languages that limited English speakers understand, and translation of written materials. For each component, the Guidance offers a variety of suggestions on systems design.

Discrimination As It Affects Persons With Limited English Proficiency, 65 Fed. Reg. 52,762 at 52765. The Guidance also provides three illustrations of how DHHS/OCR would weigh these factors for a sole medical practitioner, a county welfare program, and a large national corporation. *Id.* at 52,769.

¹¹² *Id.* at 52,767.

¹¹³ *Id.* at 52,766.

¹¹⁴ *Id.* at 52,765.

¹¹⁵ *Id.* at 52,768.

¹¹⁶ *Id.* at 57,266.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 57,266-67.

For example, depending upon the data gathered in the community needs assessment, oral language interpretation might be provided through bilingual staff, staff interpreters, outside interpreter service, volunteer community interpreters or telephone language interpreter service. The LEP Guidance also contains specific safe harbors for translation of written materials which, although not required, if satisfied assure a provider of Title VI compliance status.

The third Safe Harbor key element is staff training.¹¹⁹ The Guidance discusses staff training both as a part of the development of a comprehensive written policy and as a separate key element. The Guidance stresses that written LEP policies only become practice when employees implement them. Staff need to understand language assistance procedures and be trained to work effectively with interpreters.

The final Safe Harbor key element is titled “vigilant monitoring.”¹²⁰ For safe harbor status, the Guidance requires at least yearly monitoring of the community’s needs, the language assistance system, staff knowledge, and feedback from patients and their advocates.¹²¹

Since DHHS/OCR is still taking comments on the Policy Guidance, it is not yet clear exactly how the Key Elements Safe Harbor will protect a provider in the event of an individual complaint alleging denial of meaningful access to translation services. Apparently, it allows a health care provider to defeat such a complaint by showing that it has implemented all four key elements—a community needs assessment, a comprehensive written policy on language access, staff training and regular monitoring—and is operating a language assistance program that comports with its own written policy.¹²² The Key Elements Safe Harbor avoids a fact sensitive inquiry by DHHS/OCR.

The genesis of the Key Elements Safe Harbor is DHHS/OCR’s thirty years experience investigating language complaints. In DHHS/OCR’s experience, effective language assistance programs typically contain a community needs assessment, a comprehensive written policy on language access, staff training and on-going monitoring.¹²³ DHHS/OCR’s experience shows that attention to systems design produces language assistance programs that provide meaningful access to persons with LEP.

The Key Elements Safe Harbor amounts to a systems reform approach to LEP services and civil rights monitoring. The community needs

¹¹⁹ *Id.*

¹²⁰ *Id.* at 52,765-66.

¹²¹ *Id.*

¹²² *Id.* at 52,765.

¹²³ *Id.* at 52,765-66.

assessment identifies the initial data needed to design a language assistance program. The comprehensive written policy on language assistance is the process by which the health care provider designs a system of care to address the needs identified in the community needs assessment. On-going staff training is a component of all systems reform. It is the process by which the design is implemented. On-going monitoring is the process of evaluation and re-design that characterizes the continuous nature of system reform initiatives and acknowledges quality improvement efforts as an on-going process of refinement. DHHS/OCR encourages health providers to use this process to design their language assistance services and trusts this systems design process to produce meaningful access to services for persons with LEP.

The Key Elements Safe Harbor is probably an indirect outgrowth of the CQI/TQM management movement. Most hospitals use CQI/TQM as an internal management tool. These institutions are likely to rely on systems reform principles when developing translation services. These systems reform efforts have come full circle offering an alternative route to Title VI compliance.

Using safe harbor status to encourage systems reform is an artful way to incorporate systems reform into civil rights enforcement. Civil rights mandates tend to focus on what covered entities should not do rather than what they could do to improve minority care and treatment. Safe harbor status does not require providers to implement systems reform. However, it rewards those that do by granting them Title VI compliance status. The Key Elements Safe Harbor is an interesting, although apparently unintentional, melding of civil rights enforcement and systems reform.

Had DHHS/OCR focused consciously on using a systems reform approach to civil rights enforcement it would have added one more element to the Safe Harbor and required federally funded health care providers to disclose their community needs assessment and their annual monitoring reports. Proponents of regulatory uses of systems reform stress the need for public reporting of data about the inputs, outcomes and processes of care. Data tells regulatory agencies what works and what does not. Public reporting supplies important information about how to design better systems. Data reporting can also hold providers publicly accountable for their performance. With LEP services, it can provide local communities with data by which they can evaluate how well institutions of care are providing meaningful access to people with limited English skills.

A public reporting requirement as part of the Key Elements Safe Harbor would not be burdensome. Providers who elect the Key Elements Safe Harbor will be generating a community needs assessment and an annual monitoring reports. Data reporting merely requires that this information be

shared with the public.

Granting health care providers with safe harbor compliance status for purposes of Title VI language services should carry an obligation to report to their community and to the general public on their progress in providing language assistance and providing meaningful access to services for people with limited English proficiency. However, the Key Elements Safe Harbor is still an important step towards melding quality improvement into civil rights enforcement.

CONCLUSION

Reducing racial and ethnic disparities in care means designing the health care system at all levels to make it more accessible and more responsive to the needs of a diverse population. Building accessibility and responsiveness into processes of care is a more effective way to reduce disparities than blaming individuals. The focus should shift from blaming individuals for past discrimination to a focus on improving minority health by designing accessibility and responsiveness into systems.¹²⁴

Racial and ethnic disparities in health care are both a quality problem and a civil rights issue. Offering a civil rights safe harbor to providers who implement a systems reform approach to reducing racial and ethnic disparities is one way to encourage providers to use this quality improvement strategy that holds promise for improving minority health care.

Melding systems reform quality of care initiatives into civil rights enforcement also offers a way to strengthen civil rights enforcement. Systems reform shifts the focus from blame-laying, creates a format and justification for data reporting, and supplements agency enforcement with more internal and external accountability.

The LEP Key Elements Safe Harbor is a first step towards incorporating systems reform into civil rights enforcement. The next initiative should also include a public reporting requirement.

¹²⁴ See TO ERR IS HUMAN, *supra* note 47, at 4-5 (using similar language to advocate for systems reform to reduce error).