Forum

The Roles of Government in Improving Health Care Quality and Safety

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The Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System*[1] brought the issues of quality and patient safety to the forefront of the attention of the United States. A subsequent report, *Crossing the Quality Chasm*,[2] also called for concerted action by the public and private sectors to address the health care quality challenge. These reports stimulated the consideration of a fundamental and recurring question in health care policy discussions: What is the proper role of government?

Discussions surrounding the role of government have been and continue to be a favorite American pastime. In this article, we briefly survey the diversity of views on this issue and illustrate the various ways in which the federal government contributes to improvements in the quality and safety of health care. We provide a framework for understanding the roles that various government agencies play in health care quality and provide examples of each role; opinions about the government's successes and failures in achieving these roles are left to the reader.

Americans and the Role of Government

The complementary roles of the public and private sectors in patient safety proposed by the IOM and the policy discussions that have followed reflect the broader discussion of the role of government in health care quality. For the purpose of this article, we refer to the definition of quality developed by the IOM in 1990: "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional

Article-at-a-Glance

Background: Discussions surrounding the role of government have been and continue to be a favorite American pastime. A framework is provided for understanding the 10 roles that government plays in improving health care quality and safety in the United States. Examples of proposed federal actions to reduce medical errors and enhance patient safety are provided to illustrate the 10 roles: (1) purchase health care, (2) provide health care, (3) ensure access to quality care for vulnerable populations, (4) regulate health care markets, (5) support acquisition of new knowledge, (6) develop and evaluate health technologies and practices, (7) monitor health care quality, (8) inform health care decision makers, (9) develop the health care workforce, and (10) convene stakeholders from across the health care system.

Conclusion: Government's responsibility to protect and advance the interests of society includes the delivery of high-quality health care. Because the market alone cannot ensure all Americans access to quality health care, the government must preserve the interests of its citizens by supplementing the market where there are gaps and regulating the market where there is inefficiency or unfairness. The ultimate goal of achieving high quality of care will require strong partnerships among federal, state, and local governments and the private sector. Translating general principles regarding the appropriate role of government into specific actions within a rapidly changing, decentralized delivery system will require the combined efforts of the public and private sectors.

knowledge."[3(pp. 128–129)] This discussion echoes debates familiar to historians and political scientists who have explored fundamental questions about the appropriate role of government in society.

The question about whether to allow the free market to ensure provision of public goods, as Adam Smith[4] espoused, or to rely on government to provide such goods, as James Madison[5] advocated, is exemplified in health policy.[6] In the United States, concern about the plight of the uninsured (and many Americans' fear of joining their ranks) competes with concern about the size and power of government. Anger directed at the constraints of managed care competes with anxiety about the growth of federal regulation of health care. Surveys consistently describe health care as one of Americans' principal concerns, and nearly 9 in 10 Americans believe there is a role for government in health care quality.[7]

It has been argued that government has a responsibility to ensure "recognition of dignity and worth" by providing for those who cannot provide for themselves.[8] Beyond this social good, there is general agreement about government's role in providing public goods that benefit all, whether the recipients pay or not, even if it may not be in the interest of any individual to provide those goods.[4]

Some political scientists argue that the "new role of government" is to "[create] and [maintain] the parameters within which the market operates,"[9(p. 367)] such that "government shifts toward becoming a referee, setting the rules of the game to ensure, among other things, competition."[9(p. 373)] Government bureaucracies help develop the systems in which the market operates by setting the standards, practices, guidelines, prototypes, models, and informal procedures.[10]

The belief that government has a legitimate role in promoting the commonwealth through social goods, public goods, and regulation may coexist with a distrust of government. One view is that government intervenes in a zero-sum economy, whereby whatever power the government subsumes is subtracted from the public share. An alternative view is that government intervention may be liberating and may create efficiency by imposing order through regulations (such as rules about where to drive on the road, speed limits, and signs that regulate traffic flow).[11]

Each of the generic responsibilities of government—to provide for those who cannot provide for themselves, to supply social and public goods, to regulate the market, and to instill trust and accountability—directly translates into potential paths by which government can improve the quality of health care.

The Government's Roles in Improving the Quality and Safety of Health Care

Government can play a role in improving the quality and safety of health care in the United States at almost all levels of authority—federal, state, and local. This article focuses on the roles of the federal government, while noting that in some areas, state and local government involvement are more important and more influential than that of federal agencies.

We developed a framework outlining the 10 roles that government may play in health care quality and safety in the United States (Table 1, pages 49–50). Examples of these roles are illustrated by actions taken as part of the federal response to *To Err Is Human* under the aegis of the Quality Interagency Coordination Task Force (QuIC)[12,13]* The relationship of each role to the 4 generic roles of government outlined above are listed in Table 1. The examples that follow constitute a sample of federal activities in the area of health care quality and safety rather than a comprehensive list of all government activities.

1. Purchase Health Care

In the United States, the federal government purchases health care for 40 million elderly and disabled Americans through Medicare; 0.5 million of its own employees, retirees, and their dependents through the Federal Employee Health Benefits Plan; 36 million low-income individuals through Medicaid via matched payments to states; the 4.6 million children who had ever been enrolled in the State Child Health Insurance Program as of fiscal year 2001; and about 40% of the care for 8.5 million military retirees and their dependents through the TriCare program.[14–17]

Like every other purchaser, the government has a responsibility to purchase on the basis of value—not just cost. A mark of its move toward value-based

* The QuIC is an interdepartmental cooperative in the federal government, with the goal of ensuring that all federal agencies involved in purchasing, providing, researching, or regulating health care services are working in a coordinated way toward the common goal of improving quality.

Table 1. The Roles of Government in the United States in Improving the Quality and Safety of Health Care and Potential Research Areas*

Role of Government (Relationship to Generic Role of Government)†	Examples	Research Areas
1. Purchase health care (to supply social and public goods)	CMS will require participating hospitals to maintain medical error reduction programs. OPM will encourage plans' preferred hospitals to use integrated data systems.	Areas where government purchasing leverage outweighs private-sector interventions; how government can purchase based on quality and cost
2. Provide health care (to provide for those who cannot provide for themselves)	DoD, VA, and IHS will expand their use of electronic patient records.	Innovative ways to provide high-quality care in government-run facilities
3. Ensure access to quality care for vulnerable populations (to supply social and public goods; to provide for those who cannot provide for themselves)	HRSA is building quality oversight functions into the community health center program.	How the growing number of uninsured in the U.S. has a direct bearing on quality of care; how to reach underserved pockets of the population with quality health care
4. Regulate health care markets (to regulate the market)	FDA will institute new patient safety standards for drug development and manufacture.	Government's role in price setting as a means to control health care costs; government's role in setting malpractice insurance limits
5. Support acquisition of new knowledge (to supply social and public goods)	CQuIPS will conduct and disseminate research on medical errors.	Increased government funding for research on health care quality; direction of the research agenda at government agencies
6. Develop and evaluate health technologies and practices (to supply social and public goods; to instill trust and accountability)	Federal agencies will encourage use of medical technologies that will enhance the safety of the health care system.	Intersection of government regulation and private-sector development of technologies; evaluation of health care technologies by government agencies
7. Monitor health care quality (to supply social and public goods; to instill trust and accountability)	AHRQ's national quality report will provide statistics on medical errors.	How to standardize health care quality measures; how to standardize collection of information on health care quality among government agencies and private-sector organizations
8. Inform health care decision makers (to supply social and public goods; to instill trust and accountability)	Reporting systems will inform the public of patient safety practices adopted by hospitals and institutions.	How to present information on health care quality most effectively to the public; how to collaborate with employers to inform health care decision makers
9. Develop the health care workforce (to supply social and public goods)	Federal agencies will help develop skills for analysis of adverse events and near misses.	Government's role in affecting the supply of health care professionals; government collaboration with teaching institutions to provide training in patient safety

continued

Table 1. The Roles of Government in the United States in Improving the Quality and Safety of Health Care and Potential Research Areas* *(continued)*

Role of Government (Relationship to Generic Role of Government)	Examples	Research Areas
10. Convene stakeholders from across the health care system	QuIC recommendations call for collaboration with many partners, including the National Quality Forum; federal agencies will hold national summits to share information on patient safety.	Avenues of collaboration with state and local governments, the private sector, and the nonprofit sector; how to coordinate research funding in areas of health care quality

* CMS, Centers for Medicare & Medicaid Services; OPM; Office of Personnel Management; DoD, Department of Defense; VA; Department of Veterans Affairs; IHS, Indian Health Service; HRSA, Health Resources and Services Administration; FDA, Food and Drug Administration; CQuIPS, Center for Quality Improvement and Patient Safety; AHRQ, Agency for Healthcare Research and Quality; QuIC, Quality Interagency Coordination Task Force.

† As applicable.

purchasing is its adoption of the Consumer Assessment of Health Plans Survey (CAHPS®), a tool developed by the Agency for Healthcare Research and Quality (AHRQ) to aid federal health purchasers and individual patients in making their choices among health plans. CAHPS® reports consumers' ratings of the quality of care and services they receive from their health plans. The Office of Personnel Management, Medicare, Department of Defense (DOD), more than 20 state Medicaid plans, the National Committee for Quality Assurance, and several large employers have adopted CAHPS®, and a hospital-level survey is currently under development.[18]

2. Provide Health Care

In addition to its role as a major purchaser of care, by which it can practice value-based purchasing, the federal government offers health care directly to active-duty military employees and their beneficiaries, veterans, American Indians and Alaskan natives, and the prison population. The federal government operates hospitals and nursing homes, employs health professionals, and has the opportunity to develop model programs for the delivery of high-quality care.

The Veterans Health Administration (VHA), the DoD, and the Indian Health Service (IHS) have developed major initiatives to evaluate and improve the quality of care they provide. For example, the VHA has adopted guidelines to assist clinicians who are making decisions about diagnosis, treatment, and management of 10 common conditions. Moreover, the VHA and the DoD have partnered to develop new guidelines to build on this effort. According to the U.S. General Accounting Office, these clinical guidelines "help standardize treatment, improve the quality of patient care, and promote the cost-effectiveness of prescriptions."[19(p. 9)]

3. Ensure Access to Quality Care for Vulnerable Populations

In a more indirect way of making health care available, the government has increased access to care for the general population through the federal tax exclusion, which provides employers with an implicit public subsidy for making health care coverage available to employees. For more vulnerable populations, the government supports programs, such as community health centers, that provide care to these groups. In this latter role, the federal government is neither the primary purchaser nor provider of care, but it maintains standards as conditions of its financial support of health care programs. These standards are intended to ensure that quality care is provided for beneficiaries. For example, in fiscal year 2002, the Health Resources and Services Administration (HRSA) supported community health centers in 3,400 medically underserved areas nationwide. These community health centers offer primary and preventive care to millions of Americans, many of whom are low-income, uninsured, or homeless.[20]

4. Regulate Health Care Markets

Several characteristics of the health care system of the United States suggest that it does not fulfill the expectations of a perfect free market. Consumers do not have full information about the performance and the quality of goods and services. Freedom to enter and exit the market is limited by licensing laws and other restrictions. Certain buyers and sellers can alone influence price, which would not occur in a perfect market. Sellers have the ability to induce demand for their services.

Much of the regulation related to quality of care relies on mechanisms within state and local governments. These include state authority over licensing of health care professionals and institutions as well as mandatory reporting of medical errors, which is currently required in 18 states and being considered in others.[21] The federal government, however, plays an important role in establishing rules for health care commerce. For example, the Food and Drug Administration (FDA) sets and enforces standards for the quality of medical products, such as drugs, medical devices, vaccines, and human blood. Efforts to reduce the potential for medical errors include better standards for proprietary drug names to avoid name confusion, standards for packaging to prevent dosing errors, and label standards that will highlight drug–drug interactions.[22]

Regulation may also serve as an impetus for quality improvement (QI). For example, in 1992 Congress passed the Mammography Quality Standards Act. According to a General Accounting Office review of the impact of these standards and regulations, before the act was enacted, 11% of facilities tested were unable to pass x-ray image quality tests; by 1997, only 2% of facilities failed the tests.[23]

By serving in its primary role as the nation's largest purchaser of health care, CMS assumes an enormous presence in the health care market. Title IV of the Balanced Budget Act of 1997 requires Medicare-contracted health plans to improve quality as part of their internal quality assurance programs.[24] CMS also provides deemed status to Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation to satisfy requirements for hospital participation in Medicare. Because the majority of hospitals participate in the Medicare program and most choose to take advantage of deemed status, the majority of hospitals depend on JCAHO accreditation for Medicare reimbursement eligibility. In these examples, CMS serves in its primary role as a purchaser, yet with its substantial influence on the quality standards of providers and plans that contract with Medicare, CMS becomes quasiregulatory in nature by influencing the minimum standard of care provided to the general population—not just to its beneficiaries.

5. Support Acquisition of New Knowledge

One of the most important public goods is knowledge that emanates from scientific research. Research in medicine spans a continuum from the foundation of biologic research sponsored by the National Institutes of Health (NIH) to population-based research at the Centers for Disease Control and Prevention (CDC) to health services research supported by AHRQ, the latter of which underpins the science of quality measurement and QI. AHRQ exists to fulfill the government's responsibility to provide health care information, including information on quality, cost, and access.[25] AHRQ-sponsored research has served as the foundation for many national efforts to improve quality of care. For example, as a result of an AHRQ research finding that only 21% of eligible patients receive recommended beta-blockers after heart attack, the American Medical Association identified the appropriate use of this medication as an achievable aim for improved quality of care for older Americans.[26]

Research on QI is also a priority area in other federal agencies. For example, the National Cancer Institute has launched a Quality of Cancer Care Initiative, which strives to ensure that all Americans receive high-quality cancer care.[27] At the VHA, the National Department of Veterans Affairs (VA) Surgical Quality Improvement Program provides valid and comparative information about the outcomes of surgery among 123 VA medical centers performing major surgery. Researchers and health professionals in both the VA and private sector use this information to identify the factors that contribute to high-quality surgical care and to identify best practices.[28]

6. Develop and Evaluate Health Technologies and Practices

Government also supports the availability of another public good—health technologies and new

practices. This role may be carried out through the development of innovations or through the evaluation of technology developed by others. With a budget of more than $23.4 billion in 2002, NIH is the largest federal agency that supports and funds development of medical technologies and practices, broadly defined. Many of the NIH-funded advancements lead to new or better ways to detect and treat illnesses, which in turn elevate the quality of medical care that becomes available to the general public. Other arms of the federal government—the VA and the DoD, for example—develop and implement rehabilitation and trauma care technologies principally to improve the quality of care for their constituent populations. They also serve as leaders in the application of computer technology to health care, having designed and developed some of the nation's most sophisticated enterprisewide, integrated clinical and health care management information systems.[29]

In addition to developing technology or sponsoring its development, the federal government also has the responsibility to ensure that medical technologies and practices show evidence that they can improve the quality, effectiveness, and appropriateness of clinical practice. One important way in which this is accomplished is through AHRQ's 12 Evidence-Based Practice Centers, which develop evidence reports and technology assessments on clinical topics in collaboration with partner organizations. The partner organizations use the findings to develop educational programs, practice guidelines, and other tools to improve quality.[30]

7. Monitor Health Care Quality

Government plays an important role in measuring and monitoring the quality of care and in developing the tools to monitor quality. As with the government's provision of reliable leading economic indicators to inform and guide the business community and economic policymakers, information on the quality of health care can inform and guide health policymakers. Moreover, the government is responsible for monitoring the quality of care in organizations that receive federal funding.

AHRQ's Healthcare Cost and Utilization Project (HCUP) Quality Indicators (QIs) project is one tool used by individual hospitals, communities, and states to assess quality of care and access to care. For example, after the Hospital Association of New York State applied HCUP QIs to hospitals statewide, a large health system in New York was prompted to create a center of excellence for diabetes care.[31] AHRQ's Medical Expenditure Panel Survey (MEPS) monitors health care use and expenditure, health insurance coverage, and availability, costs, and scope of private health insurance benefits among Americans. Researchers have used MEPS to show that physicians prescribed potentially inappropriate medications for nearly a quarter of all elderly Americans living in the community in 1987 and that regardless of income, the uninsured and individuals without a usual source of health care received less screening, follow-up care, and pharmacologic treatment for hypertension than did others with this condition in 1987.[32]

As mandated by Congress in its 1999 reauthorization, AHRQ will release the first *Report to the Nation on Health Care Quality*, which was scheduled for release for late 2003 and annually thereafter. This report will be used to identify potential quality problems, such as disparities in health care quality, offer opportunities for QI, and monitor progress toward improved health care quality. A section will be devoted to data on patient safety.[33]

8. Inform Health Care Decision Makers

Information is a linchpin in QI activities, and the Internet offers government a mechanism to provide those making health care decisions—consumers and patients, clinicians and institutions, purchasers and policymakers—with reliable information when it is needed. The federal government maintains several electronic information databases to help clinicians and health care systems provide better quality care. For example, AHRQ, in partnership with the American Association of Health Plans and the American Medical Association, sponsors the Web-based National Guideline Clearinghouse™. The Clearinghouse provides health professionals with rapid access to key recommendations and assessments on hundreds of medical topics and is now being complemented with the development of the National Quality Measures Clearinghouse.[34,35]

Two federal Web sites have been designed to provide accurate and reliable health information to the general public and to help the public choose quality health care.

Healthfinder®[36] is a gateway designed to offer the best and latest information on a wide variety of health topics. The U.S. Consumer Gateway[37] links consumers to a broad range of federal information resources available online, including information on health-related topics.

Federal agencies also have actively produced print material on health care quality for dissemination to the general public. Despite these efforts, fewer than 3 in 10 Americans report to have seen any information comparing the quality of different doctors, hospitals, or health plans. Of those who saw information on quality, 8 in 10 said the information would be useful to someone making decisions on health plans, physicians, or hospitals.[7]

9. Develop the Health Care Workforce

Investment in education and career development is a central role for the federal government,[9] and few would challenge the importance of promoting professionalism in health care quality. Although competitive market forces will have a powerful effect on the career decisions of young physicians, the difficulty for markets in creating human capital mandate a substantial level of government involvement.[38] This includes funding medical residency programs for health care workers to acquire the core clinical and cognitive abilities that will equip them for clinical practice, as well as ensuring that future health care workers are trained in the principles of evidence-based practice and QI that will enable continued progress over time.

Under the Medicare program, CMS makes direct payments to hospitals for the training of medical interns and residents. The government also has a responsibility to help foster an environment in which health care professionals can learn from their errors and the near misses that would have resulted in medical errors if they had not been caught in time. The QuIC has recommended that federal agencies assist health care providers in developing the skills for analysis of adverse events and near misses.[22]

10. Convene Stakeholders from Across the Health Care System

Dr. William Roper, former Administrator of the Health Care Financing Administration, explained in his testimony to the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry: "The strength of the Federal Government is its ability to convene and to mobilize a variety of other parties towards a common goal. The visibility, the stature, the power of the Federal Government is unparalleled."[39(p. 15)]

In response to the commission's final report, in 1998 the President established the QuIC. The QuIC has been instrumental in coordinating efforts within the federal government and convening stakeholders from the private sector.[13] For example, in October 1999 four member agencies of the QuIC—AHRQ, the National Institute for Occupational Safety and Health, the Department of Labor, and the VA, sponsored the conference "Effect of Working Conditions on Quality of Care."[40] In October 2000 these four QuIC agencies and other partners focused on a specific aspect of health care quality—patient safety—in the follow-up conference "Enhancing Working Conditions and Patient Safety: Best Practices."

Although the QuIC is designed to convene primarily stakeholders in the federal government, the National Forum on Quality Measurement and Reporting is designed to bring together public and private purchasers, consumers, health plans, and health care professionals to improve the quality of health care through improved and standardized measures of quality. The QuIC agencies have collaborated with the National Quality Forum to improve patient safety by asking the forum to identify a set of egregious errors that are preventable and should never occur. These measures may serve as criteria for government-sponsored reporting systems. The National Quality Forum has also been asked to identify patient safety practices that institutions should undertake.[22]

Federal agencies are also actively collaborating with the private sector and state governments in programs to improve health care quality and safety. In September 2000 the QuIC held a national summit to assess the current state of patient safety research, set coordinated research agendas, and develop adequate reporting mechanisms. Participants in the summit included research funders from both the public and private sectors.[22] Through partnerships with medical professional societies, the government can promote dialogue about strategies to improve the quality of care

in the United States without undermining the public's trust in the health care system.

Conclusion

It is anchored in the foundations of political and economic theory that government has a responsibility to protect and advance the interests of society, which includes the delivery of high-quality health care, a value expressed by most Americans. Because the market alone cannot ensure all Americans access to quality health care, the government must preserve the interests of its citizens by supplementing the market where there are gaps and regulating the market where there is inefficiency or unfairness.

The 10 roles outlined in this article whereby government can work together with the market to deliver high-quality care provide a useful framework for the characterization and consideration of government actions in health care quality. The execution of some or all of the 10 roles may cause conflicts. For example, having the same agency that supports the development of new technologies also regulate the introduction of new medical devices into the market would represent a conflict of interest. For this reason, different agencies in the federal government are charged to execute different roles. For example, whereas the NIH may fund development of new medical devices, the FDA regulates market entry of medical devices and drugs. Conversely, there are many areas where the role of one government agency complements the role of another agency. For example, AHRQ, in its capacity to fund research on technology assessment, is collaborating with CMS to apply the results of its technology assessment studies to Medicare coverage decisions—the result of which is direct public benefit from evidence-based research.

The examples of government roles, which highlight federal actions, are intended neither to provide an exhaustive list of federal accomplishments and goals in the area of health care quality and safety nor to discount the important and influential contributions of state and local governments, nongovernmental organizations, professional organizations, interest groups, and businesses. The framework described in this article can serve as a template for future research in many of these areas, including some unanswered questions, such as the relative importance of one role of government compared to others or the successes and failures of fulfilling each of the roles. A sample of potential research areas is listed in Table 1.

Although more can be done by federal agencies to improve the quality and safety of care in the United States, state and local governments are positioned to better address certain areas. For example, licensure and recertification of medical professionals and regulations on maximum number of work hours for medical professionals lies in the domain of state government. Moreover, it may be easier for state or local government to set minimum standards of care or other kinds of regulations to reduce medical errors and improve health care quality in various health care delivery facilities. This may be the case for nursing homes, rehabilitation facilities, and hospice care, where CMS has not placed specific requirements for accreditation. All this suggests that the ultimate goal of achieving high quality of care will require strong partnerships among federal, state, and local governments and the private sector. Translating general principles regarding the appropriate role of government into specific actions within a rapidly changing, decentralized delivery system will require the combined efforts of the public and private sectors. The perceived urgency of issues related to patient safety is likely to challenge many prior conceptions of the boundaries between federal, state, and local governments, as well as the boundaries between the government and the private sector. Together, we must advance our shared goal of providing the best possible care to all Americans. J

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