Statement on Quality of Care

National Roundtable on Health Care Quality
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Institute of Medicine

National Roundtable on Health Care Quality

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NOTICE: The project that is the subject of this statement was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competencies and with regard for appropriate balance.

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Support for this project was provided by The Agency for Health Care Research and Policy (DHHS), The Commonwealth Fund, the National Research Council, the Department of Defense (Health Affairs), and Pfizer Inc. The views presented in this statement are those of the Members of the National Roundtable on Health Care Quality and are not necessarily those of the funding organizations.

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PREFACE AND ACKNOWLEDGMENTS

The National Roundtable on Health Care Quality was established in 1995 by the Institute of Medicine. The Roundtable consists of experts formally appointed through procedures of the National Research Council (NRC) who represent both public and private sector perspectives and appropriate areas of substantive expertise (not organizations). From the public sector, heads of appropriate Federal programs serve. It offers a unique, nonadversarial environment to explore ongoing rapid changes in the medical marketplace and the implications of these changes for the quality of health and health care in this nation. The Roundtable convenes nationally prominent representatives of the private and public sector (regional, state and federal), academia, patients, and the health media to analyze unfolding issues concerning quality, to hold workshops and commission papers on significant topics, and when appropriate, to produce periodic statements for the nation on quality of care matters. By providing a structured opportunity for regular communication and interaction, the Roundtable fosters candid discussion among individuals who represent various sides of a given issue. Biographical sketches of each member of the Roundtable are included at the end of this statement.

Additional Contributors to the Roundtable

In addition to appointed members of the Roundtable, several individuals from government programs provided special assistance to the Roundtable. They are: from the Agency for Health Care Policy and Research, Lisa Simpson, M.B., B.ch., F.A.A.P., Deputy Administrator; Sandy Robinson, Acting Director, Center for Quality Measurement and Improvement; and Irene Fraser, Director, Center for Organization and Delivery Studies; from the Health Care Financing Administration, Helen Smits, M.D., Deputy Administrator and Peter Bouxsein, J.D., Acting Director, Office of Clinical Standards and Quality; from the Department of Defense (Health Affairs) Colonels David Shutt and William Strampel, Directors of Quality Management OSD/Clinical Services; and from the Department of Veterans Affairs, Nancy J.Wilson, M.D., M.P.H., Department for Quality Management. In addition to stepping in for the program head on occasion, all the individuals provided helpful information about their program's work.

Although the Roundtable does not provide advice or make recommendations on any specific issue or policy pending before any government agency or other entity, it can make public statements on the state of health and the quality of health care in the nation. Such documents are subject to the formal report review procedures of the National Research Council and distill what is known on key issues, promote public awareness of these issues, and serves as a credible source of information on the "quality" of quality measurement and improvement. The charge to the Roundtable was:

1. To identify important issues related to the quality of health care in the United States, including its measurement, assessment, and improvement.

2. To identify important strengths and weaknesses in the current healthcare system that affect the quality of health care and options for improvement that might be considered by the public or private sector.
3. To identify issues related to the quality of health care that should be recommended for formal Institute of Medicine studies through the various Boards of the Institute.
4. To identify issues related to the quality of health care that should be clarified by workshops, symposia, invited presentation, or commissioned papers.
5. To provide representation to the Quality Coordinating Committee leading to that committee's peer-reviewed assessment of the quality of health care and resulting in periodic reports, including specific recommendations for action.
6. To identify other roles of the Roundtable consistent with Institute of Medicine and National Research Council policies that would lead to enhanced quality of health care in the United States.

The Roundtable met six times in formal plenary sessions between February, 1996 and January, 1998. It invited presentations from experts, convened two conferences, and commissioned papers. Individuals who made presentations at meetings of the Roundtable were: Jo Ivey Boufford, M.D., Dean, Wagner Graduate School of Public Service, New York University; Janet Corrigan, Ph.D., Executive Director, Advisory Commission on Consumer Protection and Quality in the Health Care Industry; James E.Jensen, Director, Office of Congressional and Government Affairs, National Academy of Sciences; Stanley B.Jones Director, Health Insurance Reform Project George Washington University and Chair, IOM Committee on Choice and Managed Care); Charles Kahn, J.D., (then) Majority staff, House Ways and Means Subcommittee on Health; Lawrence Lewin, M.B.A. Chief Executive Officer, The Lewin Group; and Harold S.Luft, Ph.D., Caldwell B.Esselstyn Professor of Health Policy and Economics Director, Institute for Health Policy Studies, University of California, San Francisco.

CONTEXT OF THIS STATEMENT

Based on its deliberations over a two-year period, two major conferences, guest presentations, and commissioned papers, the Roundtable members determined that a statement outlining its conclusions was warranted. The statement presented here has been reviewed by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the authors and the IOM in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The content of the review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We wish to thank the following individuals for their participation in the review of this report: Paul Griner, M.D., Vice President and Director, Center for the Assessment and Management of Change in Academic Medicine, Association of American Medical Colleges; John Ludden, M.D., Senior Vice President for Medical Affairs, Harvard Pilgrim Health Care; Arnold Milstein, M.D., M.P.H., Managing

Director, William M.Mercer, Inc.; David Nash, M.D., M.B.A., Associate Dean and Director, Health Policy, Thomas Jefferson University; and Gail Warden, President & Chief Executive Officer, Henry Ford Health System. Although the individuals listed above have provided many constructive comments and suggestions, responsibility for the final content of this statement rests solely with the authoring committee and the IOM

The contributions of many other individuals to the work and conclusions of the Roundtable are gratefully acknowledged. In addition to those mentioned above the roles of these people are described below.

ACTIVITIES OF THE ROUNDTABLE

Conferences

Two conferences sponsored by the Roundtable contributed significantly to the conclusions expressed in this statement. These conferences were

"State of the Art of Quality Measurement," September, 1996. This conference was summarized in IOM. Measuring the Quality of Health Care—State of the Art. Summary of a Conference, MS Donaldson and KN Nolan, eds. April, 1997. (available online at http://www2.nas.edu/quality/212a.html) and Donaldson, M.S. and Nolan, K. Conference. Measuring the Quality of Health Care: State of the Art. *Journal on Quality Improvement* 23:283–292, 1997; and

"Integrating Strategies for Health Care Quality Improvement," Airlie House, Va, October, 1997. The conference included presentations of commissioned papers, panels of respondents, a rapporteur, and a synthesis session. The papers and commentaries on the conference topic will be published in a forthcoming issue of *The Milbank Quarterly.*

Authors who wrote papers for presentation at this conference were:

"A Report Card on Continuous Quality Improvement." David Blumenthal, M.D., M.P.P., Chief of Health Research Policy and Development, Massachusetts General Hospital and Charles M.Kilo, M.D., M.P.H., Institute for Healthcare Improvement.

"Accelerating the Impact of Continuous Quality Improvement on Clinical Practice: Assessing the Evidence and Recommendations for 'Improvement.'" Stephen M.Shortell, Ph.D., Professor of Health Services Management, Professor of Organization Behavior, Northwestern University, Charles L.Bennett, M.D., Ph.D., Associate Professor of Medicine, Northwestern University Medical Center, VA Chicago Health Care System-Lakeside Division and Gayle R.Byck, M.P.H., Research Associate Institute for Health Services Research and Policy Studies, Northwestern University.

"The Impact of Financial Incentives on Quality of Health Care." R.Adams Dudley, M.D., M.B.A., Assistant Professor, Department of Medicine, Institute for Health Policy Studies, University of California, San Francisco, Harold S.Luft, Ph.D. (IOM), Caldwell B.Esselstyn Professor of Health Policy and Economics, Director, Institute for Health Policy Studies, University of California, San Francisco and Robert H.Miller, Ph.D., Institute for Health Policy Studies, University of California, San Francisco.

"Increased Competition and the Quality of Health Care." Jane Sisk, Ph.D., Professor, Columbia University, School of Public Health.

"The Role of Regulation in Quality Improvement." Troy Brennan, M.D., J.D., Executive Director, Brigham and Women's Hospital

Many other invited participants at the two conferences sponsored by the Roundtable provided information about their work as well as valuable insights about quality of care, how it can be measured and improved. They include: Irma Arispe, Ph.D., Projector Officer, AHCPR; John R.Ball, M.D., J.D., President and CEO Pennsylvania Hospital, Philadelphia, PA; Catherine Borbas, Ph.D., Executive Director Health Care Education and Research Foundation, Alan Bredt, M.D., Assistant to Associate Medical Director, Southern California Permanente Medical Group; Peter Budetti, M.D., J.D., Professor of Health Services, Management, Preventive Medicine and Law and Director, Institute for Health Services Research and Policy Studies Northwestern University; Charles R.Buck, Sc.D.Leader, Health Care Quality and Strategy Initiatives, General Electric Co.; David Classen, M.D., Latter Day Saints Hospital, Intermountain Health System, Molly Joel Coye, M.D., M.P.H., Director, West Coast Office, The Lewin Group; Charles Darby, Co-Project Officer, AHCPR, Thomas J.Davies, J.D., M.P.A., Manager of Managed Care, GTE Services Corporation; Don E.Detmer, M.D., Senior Vice President, University of Virginia; Mary L. Durham, Ph.D., Vice President and Director, Center for Health Research, Kaiser Permanente; Susan Edgman-Levitan, P.A., Executive Director, Picker Institute, Lynn Etheredge, Ph.D., Consultant, Paul B. Ginsburg, Ph.D., President, Center for Health System Change, Sheldon S.Greenfield, M.D., Director, Primary Care Outcomes Research Institute, New England Medical Center; Jerome H.Grossman, M.D., Chairman and CEO, Health Quality; David H.Gustafson, Ph.D., Professor, Department of Industrial Engineering, University of Wisconsin; Jack Hadley, Ph.D., Director, Institute for Health Policy and Research, Georgetown University; Clark C.Havighurst, J.D., Wm. Neal Reynolds Professor of Law, Duke University School of Law; Lisa I.Iezzoni, M.D., M.Sc., Associate Professor of Medicine, Division of General Internal Medicine, Beth Israel Hospital, Jacqueline Kosecoff, Ph.D., President and Co-Chief Executive Officer, Value Health Sciences, Inc.; Lucian Leape, M.D., Professor of Health Policy, Harvard School of Public Health, Arthur Levin, M.P.H., Director, Center for Medical Consumers; Jarod M.Loeb, Ph.D., Director, Research and Evaluation and Chief Scientific Officer, Joint Commission on Accreditation of Healthcare Organizations; Kathleen N.Lohr, Ph.D., Director, Health Services Policy and Research, Research Triangle Institute; Patrick Mattingly, M.D., Senior Vice President Planning and Development, Harvard Pilgrim Health Care, Catherine McDermott, Ph.D., President and CEO, National Committee on Quality Health Care; Catherine G.McLaughlin, Ph.D., Associate Professor, University of Michigan, School of Public Health; Barbara McNeil, M.D., Head, Department of Health Care Policy, Harvard Medical School; Josephine Musser, M.B.A., (then) Commissioner, Office of the Commissioner of Insurance State of Wisconsin; Alan R.Nelson, M.D., Executive Vice President, American Society of Internal Medicine; Mark V.Pauly, Ph.D., Bendheim Professor, Wharton School, University of Pennsylvania; James S.Roberts, M.D., Senior Vice President, Voluntary Hospitals of America; Marc Rodwin, Ph.D., Associate Professor of Law and Public Policy, School of Public and Environmental Affairs, Indiana University; Gary E.Rosenthal, M.D., Associate Professor of Medicine, Case Western Reserve University Cleveland VA Medical Center; Neil Schlackman, M.D., Senior Corporate Medical Director, AETNA U.S. Healthcare; Col. David C.Schutt, M.D., (then) Director, Quality Management Division, Health Affairs, Department of Defense; Gary Sennett, M.D., Vice President for Performance Measurement National Committee for Quality Assurance; Hugh Straley, M.D., Medical Director, Group Health Cooperative-Puget Sound; James R.Tallon, Jr., President, United Hospital Fund of New York; Robert O.Valdez, Ph.D., M.H.S.A., Professor, Department of Health Services, School of Public Health, University of California, Los Angeles; and Alan Zwerner, M.D., J.D., President and Chief Executive Officer, The Medical Quality Commission.

Sponsors

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Several members of the staffs of these organizations graciously provided help to the Roundtable. They include Margaret Keyes, Project Officer, Center for Quality Measurement and Improvement, AHCPR; Brian Biles, M.D., Senior Vice President and David Sandman, M.P.H., Program Associate of the Commonwealth Fund; and at Pfizer Inc Frederick Telling, Ph.D., Vice President, Corporate Strategic Planning and Policy and Alison Keith, Ph.D., Director, Economic Policy Analysis.

Support to the Roundtable by the Institute of Medicine

The Roundtable also wishes to acknowledge the officers and staff of the Institute of Medicine. They include Kenneth I.Shine, M.D., President; Karen Hein, M.D., Executive Officer; Clyde J.Behney, Deputy Executive Officer; Molla S.Donaldson, Project Director; Kay Harris, Financial Analyst; Kathleen Nolan, Research Assistant; Evelyn Simeon, Administrative Assistant; and Tracy McKay, Project Assistant.

The Urgent Need to Improve Health Care Quality

Institute of Medicine National Roundtable on Health Care Quality
Mark R.Chassin, MD, MPP, MPH[1]; Robert Galvin[2]; and the National Roundtable on Health Care Quality[3,4,5,6]

ABSTRACT

Objective—To identify issues related to the quality of health care in the United States, including its measurement, assessment, and improvement, requiring action by health care professionals or other constituencies in the public or private sectors.

Participants—The National Roundtable on Health Care Quality, convened by the Institute of Medicine, a component of the National Academy of Sciences, comprised 20 representatives of the private and public sectors, practicing medicine and nursing, representing academia, business, consumer advocacy, and the health media, and including the heads of federal health programs. The roundtable met 6 times between February 1996 and January 1998. It explored ongoing, rapid changes in health care and the implications of these changes for the quality of health and health care in the United States.

Evidence—Roundtable members held discussions with a wide variety of experts, convened conferences, commissioned papers, and drew on their individual professional experience.

Consensus Process—At the end of its deliberations, Roundtable members reached consensus on the conclusions described in this article by a series of discussions at committee meetings and reviews of successive drafts, the first of which was created by the listed authors and the IOM project director. The drafts were revised following these discussions and during the formal report review process of the National Research Council of the National Academy of Sciences.

Conclusions—The quality of health care can be precisely defined and measured with a degree of scientific accuracy comparable with that of most measures used in clinical medicine. Serious and widespread problems exist throughout American medicine. These problems, which may be classified as underuse, overuse, or misuse, occur in small and large communities alike, in all parts of the country, and with approximately equal frequency in managed care and fee-for-service systems of care. Very large numbers of Americans are harmed as a direct result. Quality of care is the problem, not managed care. Current efforts to improve will not succeed unless we undertake a major, systematic effort to overhaul how we deliver health care services, educate and train clinicians, and assess and improve quality.

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[2] Motorola Inc., Schaumburg, Ill.
[3] A completelist of the members of the National Roundtable on Health Care Quality appears at the end of this article.
[4] All members are expressing their individual views and not necessarily those of agencies or organizations with which they may be affiliated.
[5] Information about the roundtable's work can be found at http:/www2.nad.edu/hcs/.
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CONSENSUS STATEMENT

Few issues are more central to the ongoing debate about health care in the United States than quality of care. The Institute of Medicine (IOM) a component of the National Academy of Sciences, Washington DC, convened the National Roundtable on Health Care Quality to bring together a wide variety of individuals to engage in a series of discussions about health care quality, a process that took place over a 2-year period. The roundtable solicited presentations from experts, convened conferences, and initiated a parallel set of detailed discussions about managed care and quality.

The roundtable, which met 6 times between February 1996 and January 1998, reached consensus on the conclusions delineated here by a process of examining the information it received from these processes and the experience of its members. The consensus evolved during the final meetings of the roundtable. The first draft of a document reflecting these conclusions was created by the listed authors and the IOM project director. Revisions were made in accordance with discussion at roundtable meetings and comments from individual members. The final document was approved following the formal report review process of the National Research Council of the National Academy of Sciences.

The roundtable concluded that, following a period of appropriate and intense concern about health care costs, a national focus on improving the quality of health care is imperative. The roundtable reached this conclusion by the following reasoning:

1. The quality of health care can be precisely defined.[1,2] In many instances, quality measures have the same degree of accuracy as the majority of measures used in clinical medicine to make vital decisions about patient care. These quality measures have been used in a wide array of scientifically valid studies to assess the nature and magnitude of specific quality problems.
2. At its best, health care in the United States is superb. Unfortunately, it is often not at its best. Problems in health care quality are serious and extensive; they occur in all delivery systems and financing mechanisms. Americans bear a great burden of harm because of these problems, a burden that is measured in lost lives, reduced functioning, and wasted resources. Collectively, these problems call for urgent action.
3. A few health plans, hospitals, and integrated delivery systems have made impressive efforts to improve their quality of care, and a number of successes in improving quality for specific patient groups have been documented.[3–5] However, many more institutions have made little, if any, effective effort to improve, and major obstacles lie in the way of rapid, systemwide progress. There are no available data identifying individual health plans, hospitals, or health care systems that deliver care that is uniformly and consistently of the highest quality. Therefore, there are no clear role models of exemplary delivery systems.
4. Taken together, these circumstances require a major effort to rethink and reengineer how we deliver health care services and how we assess and try to improve the quality of care.

QUALITY CAN BE DEFINED AND MEASURED

The IOM council addressed these quality-of-care issues in 1994.[1] The roundtable concurs with the council's view that the IOM's definition of quality, developed in 1990, has been widely accepted and is still robust today: "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 knowledge."[2]

Several ideas in the definition deserve elaboration. The term *health services* refers to a wide array of services that affect health, including those for physical and mental illnesses. It includes services aimed at preventing disease and promoting health and well-being; as well as acute, long-term, rehabilitative, and palliative care. Furthermore, the definition applies to many types of health care practitioners (e-.g, physicians, nurses, various other health care professionals) and to all settings of care (from hospitals and nursing homes to physicians' offices, community sites, and even private homes).

Including both *individuals* and *populations* draws attention to the different perspectives that need to be addressed. On one hand, we are concerned with the quality of care that individual health plans and clinicians deliver to individuals in specific episodes of care. On the other hand, we must direct attention to the quality of care across the entire system. In particular, we must ask whether all parts of the population have access to needed and appropriate services and whether their health status is improving.

The phrase *desired health outcomes* refers to health outcomes that patients desire and highlights the crucial link between how care is provided and its effect on health, as well as the need to ensure that patients and their families are well informed about alternative health care interventions and their expected outcomes. It underscores the importance of being mindful of people's ability to function as well as possible in their daily lives in addition to attending to more narrowly defined medical outcomes of disease. It also includes a consideration of patient and family satisfaction with health care services

The definition emphasizes that high-quality care *increases the likelihood* of beneficial outcomes. It reminds us that quality is not identical to positive outcomes. Poor outcomes occur despite the best possible health care, because disease often defeats our best efforts. Conversely, patients may do well despite poor quality care, because humans are resilient. Assessing quality thus requires attention to both processes and outcomes of care.

Current professional knowledge emphasizes that health care professionals must stay abreast of the dynamic knowledge base in their professions and use that knowledge appropriately. No matter how good our understanding or measures of quality are today, we must always be prepared to revise them as new knowledge is generated about what works and what does not in health care to produce positive outcomes for patients. Although the knowledge and practices of individual clinicians are important for high-quality care, today we realize that no health professional can deliver high quality alone. Increasingly, health care professionals practice within groups and systems of care. The functioning of those systems in preventing and minimizing errors and the harm such errors may cause, coordinating care among settings and various practitioners, and ensuring that relevant and accurate health care information is available when needed are critical factors in ensuring high-quality care.

For more than 25 years, experts have worked to create reliable and valid measures with which to assess the quality of health care over a wide range of diagnostic and therapeutic services and for a broad array of health and medical problems. For some health care fields, such measurement tools can be put to immediate, widespread use, but in others, the science of quality measurement is in an early stage of development. There have been many advances as well as refinements in the field of quality measurement. As the acceptance of these measures has increased, so has the audience for them. With this wider attention has come the need to broaden the domain of measures to include outcomes as well as processes of care and to speak to the concerns of consumers by developing outcome measures that go beyond immediate morbidity and mortality to include various kinds of functional status.

In general, either processes or outcomes may be valid measures of quality. For an outcome to be a valid measure, it must be closely related to processes of care that can be modified to affect the outcome. For example, the proportion of patients with inoperable lung cancer who develop metastases within 6 months of diagnosis is an important outcome measure but not a valid quality measure, because no known processes of care can influence this outcome. For a process to be a valid measure, it must be closely

related to an outcome that we care about. Thus, controlling hypertension is a process that is a valid measure of quality because it has been shown to reduce the occurrence of strokes and death.

A number of specific examples of different types of quality measures and their uses were discussed at the September 1996 IOM conference, Measuring the Quality of Health Care: State of the Art. As this experience made clear, quality of care for a great variety of specific clinical conditions and procedures can be measured with sufficient precision to make judgments and take needed actions to bring about improvement. The inventory of useful measures continues to grow. The Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, Ill and the National Committee for Quality Assurance, Washington, DC, have stimulated interest in developing quality measures and in quality measurement. A large number of valid measures have been used to assess the magnitude of various quality problems.

QUALITY PROBLEMS ARE SERIOUS AND EXTENSIVE

Health care quality problems may be classified into 3 categories, underuse, overuse, and misuse. *Underuse* is the failure to provide a health care service when it would have produced a favorable outcome for a patient. Missing a childhood immunization for measles or polio is an example of underuse. *Overuse* occurs when a health care service is provided under circumstances in which its potential for harm exceeds the possible benefit. Prescribing an antibiotic for a viral infection like a cold, for which antibiotics are ineffective constitutes overuse. *Misuse* occurs when an appropriate service has been selected but a preventable complication occurs and the patient does not receive the full potential benefit of the service. Avoidable complications of surgery or medication use are important misuse problems. A patient who suffers a rash after receiving penicillin for a strep throat despite having a known allergy to that antibiotic is an example of misuse. Evidence from careful research studies demonstrates a large number of serious problems in each of these categories. A recent review of quality research published from 1993 to 1997 reached the same conclusion[6,7] as did the report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.[8]

Underuse of proven effective interventions leads to major foregone opportunities to improve health and function. Undetected and untreated hypertension or depression, failure to immunize children, and prenatal care begun too late in pregnancy are examples of important underuse problems. The magnitude of these problems is considerable. Failure to use effective treatments (e.g. thrombolytics, B-blockers, aspirin, and angiotensin-converting enzyme inhibitors) for acute myocardial infarction for all patients who could benefit from these interventions may lead to as many as 18,000 preventable deaths each year in the United States.[9] One recent study showed that in one group of elderly acute myocardial infarction patients, 79% of eligible patients did not receive B-blockers; their subsequent mortality at 2 years was 75% greater than those who had received B-blockers.[10]

Underuse is by no means confined to managed health care plans, which have financial incentives to reduce the amount of care they provide. Several studies have shown that between 40% and 60% of patients in selected health maintenance organization and fee-for-service populations do not receive needed care for specific effective services. One study, for example, showed that 59% of hypertensive patients had controlled blood pressures in fee-for-service plans compared with 46% in managed care plans.[11] The same study also documented that 65% of women treated in fee-for-service settings received scheduled mammograms compared with 45% of those in managed care plans. Another study showed a failure to detect and treat depression by general medical clinicians in 58% of managed care patients compared with 46% of fee-for-service patients.[12] These data and others like them have led the roundtable members to conclude that quality is the problem, not managed care.

Underuse problems are exacerbated when people lack health insurance, a problem that is faced by more than 40 million Americans. The net health effect of the barrier to access to care that results from being uninsured is measured in shortened lives and increased disability. One study found that those without health insurance had a 25% greater chance of dying within 12 years, controlling for age, race, education, income, and comorbidity.[13] Other work has confirmed these findings and extended them to show that lack of insurance is associated with poor functional status and that loss of health insurance, particularly Medicaid, can be associated with deterioration in chronic disease secondary to reduced access to effective care.[14–17]

Overuse is also common in US medicine. Two recent studies showed that 21% of all antibiotic prescriptions (a total of 23.8 million prescriptions) given to ambulatory adults or children in 1992 were used to treat colds, other upper respiratory tract infections, or bronchitis, conditions for which antibiotics are ineffective and pose the risk of life-threatening reactions and an increase in antibiotic resistance.[18,19] The RAND Health Services Utilization Study, the results of which are now 17 years old, is the largest study of overuse, and, to our knowledge, the only one that examined multiple regions of the country. It showed that 17% of coronary angiographies, 32% of carotid endarterectomies, and 17% of upper gastrointestinal tract endoscopies were performed for clearly inappropriate indications in a nationally representative sample of Medicare beneficiaries in 1981.[20] No data have been published subsequently that suggest significant improvements have occurred. Other studies have found that 16% of hysterectomies in a group of 7 health maintenance organizations were inappropriate, with individual plans rates varying between 10% and 27%[21]; that 23% of children were proposed for tympanostomy tube insertion (the most common surgical procedure in childhood) for inappropriate reasons[22]; and that 20% of cardiac pacemakers were inserted for clearly inappropriate indications.[23]

Misuse problems (that is, the preventable complications of treatment) also occur with great frequency. Misuse is not the same as error because not all errors result in adverse events or injury. Many errors, such as the wrong dose of medication or misdiagnosis, may be identified before harm occurs. If not identified and corrected, however, many errors do cause injury. Recent research indicates that patient injuries resulting from the administration of medications occur at the rate of about 2,000 per year in each large teaching hospital; about 28% are preventable given current knowledge.[24] Each of these preventable injuries adds nearly $5,000 to the cost of the hospital stay during which it occurs.[25] The Harvard Medical Practice Study estimate that more than 27,000 patient injuries due to negligent care occurred among patients hospitalized in New York State in 1984.[26] The RAND study of prospective payment for hospitals showed that Medicare patients who received poor-quality care for congestive heart failure, as judged by adherence to objectively defined criteria, experienced a 74% greater mortality rate within 30 days of hospital admission compared with patients who received good-quality care.[27]

This tripartite classification of quality problems illuminates the relationship between quality and cost. It also helps answer the question of whether improving quality leads to increased or decreased costs. Reducing overuse improves quality (by sparing patients the unnecessary risk that attends to inappropriate health services) and reduces costs at the same time. Solving misuse problems also improves quality (by reducing the number of complications) and decreases costs (by eliminating the cost of treating complications). Fixing underuse problems, however, nearly always results in both increased costs and increased quality. This relationship arises from the fact that, except for immunizations and prenatal care, effective health care services generally do not save money.[28] If they are effective, they improve health and result in increased quality, but only at increased cost. The principal exception to this rule arises when services are narrowly targeted at very high-risk subgroups of people for whom expensive complications of disease are prevented with high frequency.[29] Such circumstances are unusual because we typically cannot predict with accuracy which individuals will suffer particular complications in the short term (e.g., which patients with hypertension will suffer strokes in the next year).

These relationships also identify the most effective ways to improve the value of health care services, which may be defined as the health benefit per dollar spent. The largest improvements in value occur when the same action increases the numerator of the ratio while decreasing the denominator. If we

improve quality by fixing overuse or misuse problems, we have exactly this impact on value. The impact on value of remedying underuse problems is less clear because both the numerator and the denominator of the ratio increase.

The evidence is compelling. Millions of Americans are not reached by proven effective interventions that can save lives and prevent disability. Perhaps an equal number suffer needlessly because they are exposed to the harms of unnecessary health services. Large numbers are injured because preventable complications of medical treatment are not averted. These problems exist in managed care and fee-for-service systems, in large and small communities, and in all parts of the country. Substantial opportunities exist to increase quality and decrease cost simultaneously by ameliorating problems of overuse and misuse.

OTHER QUALITY-OF-CARE ISSUES

In discussing quality problems in terms of overuse, underuse, and misuse, this statement does not attempt to address all the issues that might relate to quality. Such issues include geographic variations in the rates of use of health care services, generalist and specialist physician training, the makeup of the nonphysician health care workforce, and the effect of organization of medical services as a determinant of quality, for which there is an emerging literature.[30–32] These and other relevant issues may be causal or explanatory factors leading to a better understanding of quality problems; that is, they will be related to specific overuse, underuse, or misuse problems.

CURRENT APPROACHES TO QUALITY IMPROVEMENT ARE INADEQUATE

The statement that our health care system faces quality problems of serious magnitude should not be taken as an indictment of the skill or motivation of the men and women who provide those health care services. Indeed, these people, who represent a host of different disciplines, are among the most highly trained, technically proficient, and best motivated of professionals. In the vast majority of specific instances of problems in health care quality, individuals are not to blame. The answers are not simple and often involve shortcomings in the complex systems in which health care is delivered.

In part, the problems we face represent the obverse side of an extraordinary success story. In the past 25 years, we have generated an immense amount of new knowledge about what works to improve health and what does not. One crude index of the pace of this change is illuminating. The randomized controlled trial has become the “gold standard” for evaluating the efficacy of health care interventions of all sorts. Yet it is a relatively recent phenomenon; the first one was published in 1952. In the 30 years from 1966 through 1995, more than 76,000 journal articles were published from randomized controlled trials (as registered in the automated database MEDLINE). The first 5 years of that period contributed less than 1% of the total, whereas the last half decade contributed more than the previous 25 years combined. In the face of this avalanche of rigorous data on efficacy, our methods of training physicians and other clinicians and our systems for supporting them in the delivery of health care services have not kept pace. Their rigorous clinical training has not equipped them to make maximal use of a variety of methods to assess and improve their own practices. Principles of quality measurement and improvement could be included in the education and training of future practitioners to better prepare them for this ongoing responsibility.

Whether they are organized in solo practice, in small single-specialty partnerships, or in large multispecialty groups, too few physicians have ready access to all the data that would be useful to them as they care for patients. Too few hospitals take maximum advantage of all of their data in facilitating efficient patient care while systematically avoiding preventable complications. One hospital has given us a glimpse of what may be possible. Researchers at LDS Hospital in Salt Lake City, Utah, published their experience in reducing the frequency and impact of adverse drug events due to antibiotics. They assisted physicians in prescribing prophylactic antibiotic regimens in surgery and therapeutic treatments using a

powerful set of computer-assisted guidelines. The results were impressive: a 30% decrease in the frequency of patient injuries due to antibiotics, a 27% decrease in the mortality of antibiotic-treated patients, and a 58% decrease in antibiotic costs per treated patient.[3] However, this example stands out starkly, however, because it is so exceptional compared with the experience of the vast majority of other institutions.

A notable constraint to quality improvement is posed by the lack of an information infrastructure to support it in almost all health care delivery settings and the substantial investment needed to build such an infrastructure. Engaging clinicians actively and enthusiastically in quality improvement requires providing them with timely and detailed clinical information they believe and can use to judge quality of care. Collecting and analyzing these data, whether manually by record review or by sophisticated automated systems, is extremely expensive.[33]

At present, quality improvement efforts are sporadic at best. They are typically limited to single, large institutions, usually hospitals. Long-term, multi-institutional quality improvement programs are infrequent, and regional attempts to improve quality across an entire delivery system are very rare. However, the exceptions are, however; noteworthy. New York State's program of collecting standardized clinical data for coronary artery bypass surgery (CABS) patients, producing and publishing risk-adjusted mortality rates for hospitals and surgeons, and using these data to facilitate quality improvement efforts has resulted in lower statewide mortality following this procedure.[34,35] This ongoing program now also produces risk-adjusted mortality data on percutaneous transluminal coronary angioplasty. The 5 hospitals in northern New England at which CABS is performed have used continuous quality improvement techniques to achieve reductions in mortality as well.[5] Pennsylvania has published data on risk-adjusted mortality following CABS and acute myocardial infarction, but their impact on inducing improvement is not clear.[36,37] Some other states are beginning to experiment with compiling and publishing less complicated data on hospital performance.[38] The large majority of these efforts, including a few regional efforts to publish performance data for managed care plans, consist only of compiling and reporting data. Improvement is left to individual hospitals or plans and is rarely documented.

The Joint Commission on Accreditation of Healthcare Organizations, the National Committee for Quality Assurance, and the Peer Review Organizations of the Health Care Financing Administration are encouraging organizations to use methods of continuous improvement; but the effectiveness of these efforts remains to be documented.

Four major strategies have been advocated to move the health care delivery system toward improving quality. Whether one believes in regulation, continuous quality improvement, marketplace competition, or payment incentives as the most effective way to improve quality of care, evidence and experience to date suggests that none of these taken alone will prove up to the challenges we face. The challenges may be stated simply: (1) to always provide effective care to those who could benefit from it, (2) to always refrain from providing inappropriate services, and (3) to eliminate all preventable complications.

Although regulation is not currently fashionable, states are pursuing it vigorously as a means to control perceived abuses in managed care. Regulation is the only mechanism we have to protect the public from egregiously poor providers. Another of its advantages is that it can reach every corner of the delivery system as compared with improvements made by a single hospital or health plan. Although it can establish minimum standards of performance reasonably well, uniform enforcement of those standards has proved far more problematic. In addition, regulation is inflexible, difficult to modify quickly as knowledge changes, and not well suited to motivate those already performing well to strive for even greater achievement.

Continuous quality improvement emerged from the industrial sector as an effective package of theory and practical tools to reduce errors in the production process. Although widely praised in business circles, it is far less widely adopted. As applied to health care, it has been similarly praised but has also spread slowly. Its most exemplary practitioners, who have achieved notable successes,[3–5] emphasize that it is most effective when used as an integral part of a scientific approach to improving clinical practice. Very few data document the effectiveness of continuous quality improvement, however,[39] and even exemplary practitioners have had difficulty in disseminating its benefits uniformly throughout their institutions. Among its potential strengths are an ability to motivate good performers to excel and an emphasis on generating new methods for achieving improvement. Among its limitations are a too narrow focus on administrative (as opposed to clinical) aspects of care and a lack of attention to problems of overuse or underuse. Future experience may yield increased effectiveness. Current experience in both health care and other sectors of the economy suggests that its impact will be useful but may be limited.[40]

Marketplace competition is the engine driving many changes in health care. Market advocates believe that providing more information about quality to the public will induce provider health plans, hospitals, and physicians to compete by improving the quality of their care in the expectations of increasing market share. Skeptics point out that no health care market currently competes on the basis of improving quality, and that there is little theoretical basis in economics to predict that this change will occur.[41]

Many experts believe that payment incentives (to health plans, hospitals, or physicians) can be powerful forces to drive improved quality. Unfortunately, the dominant methods of payment in use today do not achieve this goal. Unadorned fee-for-service payments encourage overuse, whereas capitation payments encourage underuse. No current payment system systematically rewards excellence in quality. The immediate prospects for change are not bright, although some health plans have begun to develop performance-based payment systems as an incentive to improve quality. These efforts have yet to be evaluated. In another area, the difficulties of assembling sufficient data with which to construct risk-adjustment methods have hobbled efforts to counteract the powerful incentives health plans now face to avoid sick individuals and market their services only to healthy people.

Furthermore, and perhaps most important, even if the right set of strategies could be devised to encourage quality improvement, there are no clear role models of exemplary delivery systems to emulate. Whether one examines hospitals, medical groups, health plans, or integrated delivery systems, no institution in any of these categories can provide a blueprint for solving the multitude of current quality problems. Neither has academic medicine met its part of the challenge to modernize its education and training methods so young physicians can begin practice with an understanding of health care quality and the tools needed to engage in a career-long effort to improve the quality of care they provide.

AN URGENT NEED FOR RAPID CHANGE

Who should be concerned about health care quality problems and who should be involved in their solution? The answer is everyone: health care professionals, patients and their families, consumer advocates, health care administrators (whether serving in health care plans, hospitals, medical groups, nursing homes, or other facilities), private and public purchasers of health care services, and policymakers at the national, state, and local levels.

The roundtable believes that health care professionals should take the lead in improving quality, and it strongly urges leaders in the health care professions as well as practicing clinicians to actively do so. Leadership in quality improvement is also a joint responsibility of all who serve in health care organizations including, managers, data and information specialists, laboratory technicians, housekeeping staff, dietary personnel, nurses, and physicians. Individual patients must have the opportunity and the information they need to participate in their own care and to take responsibility, where necessary and appropriate, for their own health. Consumer advocates and purchasers can press to keep quality of care at

the top of the agenda as an issue of concern throughout the health care system and to seek effective ways for health care professionals, administrators, and others to be accountable to patients and to society for the quality of care. Policymakers at all levels of government can foster opportunities for communication of best practices and other innovations, increase research on quality measurement and improvement, facilitate organizational change, assist the development of more effective information and delivery systems. We should all strive for such fundamental improvement that health care becomes not only technologically dazzling but also compassionate, reliable, appropriate to a patient's needs, and safe.

The burden of harm conveyed by the collective impact of all of our health care quality problems is staggering. It requires the urgent attention of all the stakeholders: the health care professions, health care policymakers, consumer advocates and purchasers of care. The challenge is to bring the full potential benefit of effective health care to all Americans while avoiding unneeded and harmful interventions and eliminating preventable complication of care. Meeting this challenge demands a readiness to think in radically new ways about how to deliver health care services and how to assess and improve their quality. Our present efforts resemble a team of engineers trying to break the sound barrier by tinkering with a Model T Ford. We need a new vehicle or perhaps, many new vehicles. The only unacceptable alternative is not to change.

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NATIONAL ROUNDTABLE ON HEALTH CARE QUALITY

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Mark Chassin is professor and chairman of the Department of Health Policy at the Mount Sinai School of Medicine. He is also senior vice president for clinical quality at the Mount Sinai Hospital and Health System. Before coming to Mount Sinai, Dr. Chassin served as commissioner of the New York State Department of Health from 1992 to 1994. He is a board-certified internist and practiced emergency medicine for 12 years. He is a member of the Institute of Medicine. He is a member of the Boards of the National Committee for Quality Assurance and the Association for Health Services Research.

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Robert Galvin started his career at Motorola in 1940. He held the senior officership position in the company from 1959 until January 11, 1990, when he became chairman of the Executive Committee. He continues to serve as a full-time officer of Motorola. Motorola is the first large company-wide winner of the Malcolm Baldrige National Quality Award. Galvin attended the University of Notre Dame and the University of Chicago and is currently a member and was the recent chairman of the Board of Trustees of the Illinois Institute of Technology. He has been awarded honorary degrees and other recognitions, including election to the National Business Hall of Fame and presentation of the National Medal of Technology in 1991.

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Kathleen Angel has over twenty-five years experience in the field of healthcare benefits. In her capacity as Vice President for Digital, Ms. Angel is responsible for Benefit and Work Life programs covering 55,000 active employees plus their families worldwide. Ms. Angel is a member of the Board of Directors of the Washington Business Group on Health and the National Committee for Quality Assurance. She also on the Steering Committee for the Affiliated Health Information Networks of New England.

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Marcia Angell is the executive editor of the New England Journal of Medicine and lecturer in the Department of Social Medicine at Harvard Medical School. Dr. Angell writes frequently for the Journal and other publications on a wide range of topics, and has particular interests in health policy, the ethics of biomedical research, the nature of medical evidence, and care at the end of life. She is a member of the Institute of Medicine of the National Academy of Sciences and the American Association of Physicians. She served as a Director of the Council of Biology Editors and is a member of the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R), the Board of Visitors of the Boston University School of Public Health, and the Robert Wood Johnson Health Policy Fellowships Advisory Board.

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Robert A.Berenson is a board-certified internist who practiced in Washington D.C. for twelve years. Prior to starting his medical practice in 1981, Dr. Berenson spent three and a half years on the Carter White House Domestic Policy staff, initially as a Robert Wood Johnson Foundation Clinical Scholar. Dr. Berenson also served as co-chair to two working groups as part of the Clinton White House

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Brent James is Vice President for Medical Research and Executive Director of the Institute for Health Care Delivery Research at Intermountain Health Care. Dr. James presently holds an Adjunct Professorship in the University of Utah's Department of Family and Preventive Medicine. He is a Visiting Lecturer in the Department of Health Policy and Management at the Harvard School of Public Health. Dr. James also serves on the Institute of Medicine's Board on Health Care Services.

Stephen C.Joseph, M.D., M.P.H.

Stephen Joseph was confirmed as assistant secretary of defense for health affairs by the Senate on March 22, 1994. As Assistant Secretary of Defense for Health Affairs ASD(HA), Dr. Joseph was responsible for overall supervision of the health and medical affairs of the Department of Defense (DOD). He served as the principal staff assistant and advisor to the secretary of defense for all DOD health policies, programs, and activities and, subject to the direction of the secretary of defense, exercised oversight of all DOD health resources. Prior to his appointment, Dr. Joseph served as dean of the School of Public Health, and professor of public health and pediatrics at the University of Minnesota. He previously served as the commissioner of health in New York city. Dr. Joseph has received numerous awards and honors, including the Outstanding U.S. Alumnus Award for Public Health Leadership from the Johns Hopkins School of Hygiene and Public Health. He is an elected member of the Institute of Medicine and the Johns Hopkins University Society of Scholars, and a fellow of the American Academy of Pediatrics and the American Public Health Association.

Rhoda H.Karpatkin

Since 1974, Rhoda Karpatkin has been president of the Consumers Union of the United States, Inc., which publishes *Consumer Reports* and other consumer information. Before joining Consumers Union, Ms. Karpatkin was a lawyer specializing in consumer and education law. She had been Consumer Union's legal counsel for 16 years. Ms. Karpatkin

recently served two terms as president of Consumers International, and now serves as its vice president.

Kenneth W.Kizer, M.D., M.P.H.

Kenneth Kizer was confirmed by the U.S. Senate as the Department of Veterans Affairs (VA) under secretary for health on September 28, 1994. In this capacity, Dr. Kizer functions as the chief executive officer of the Veterans Health Administration. Since assuming his position, Dr. Kizer has become the chief architect of re-engineering the veterans health care system. He has held senior academic positions at the University of California, Davis, and continues as an adjunct professor of public policy at the University of Southern California. Among his state government positions, Dr. Kizer was director of California's Department of Health Services for over six years.

Gerald D.Laubach, Ph.D.

Gerald Laubach was formerly the president of Pfizer, Inc., and is a retired director of CIGNA and several biotechnology companies. He is a member of the Institute of Medicine and the National Academy of Engineering, served on the former IOM Council on Health Care Technology and is the former chair of the Institute of Medicine (IOM) Committee on Technological Innovation in Medicine.

David M.Lawrence, M.D., M.P.H.

David McK. Lawrence was named Chief Executive Officer in 1990 and Chairman of the Board of Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals in 1991. He began his career with Kaiser Permanente with the Northwest Permanente Medical Group in 1981. Dr. Lawrence currently serves on the Boards of Hewlett-Packard, Pacific Gas and Electric Company, Raffles Medical Group of Singapore, the Conference Board, the Bay Area Council, and the Bay Area Economic Forum among others. He is Board Certified in General Preventive Medicine. Dr. Lawrence is a member of the Alpha Omega Alpha Society and the Institute of Medicine.

William L.Roper, M.D., M.P.H.

William L.Roper is Dean of the School of Public Health, The University of North Carolina at Chapel Hill (UNC). Before joining UNC in July, 1997, Dr. Roper was senior vice president of Prudential HealthCare. Before coming to Prudential, Dr. Roper was director of the Centers for Disease Control and Prevention (CDC), served on the senior White House staff, and was administrator of the Health Care Financing Administration. Dr. Roper is the immediate-past president of the Association for Health Services Research, and is Chairman of Partnership for Prevention. He is a member of the Institute of Medicine.

O.David Taunton, M.D.

David Taunton is Clinical Professor of Medicine at the University of Alabama Medical Center and a practicing internist and endocrinologist in Birmingham, Alabama. Prior to entering private practice in 1977 spent eleven years in research in endocrinology and metabolism while at the N.I.H., the U.S. Army Medical Research and Nutrition Laboratory at Fitzsimons General Hospital and Baylor College of Medicine in Houston, Texas. Dr. Taunton has served on the Board of Governors of the American Board of Internal Medicine (ABIM), the Task Force for Recertification and the Subcommittee on Self Assessment Examination for ABIM. He is past president of the medical staff at Baptist Medical Center Montclair and is currently a trustee of the Baptist Health Systems Division Board and serving on the Board of Director of Baptist Health Centers.

Bruce C.Vladeck, Ph.D.

Bruce C.Vladeck is Professor of Health Policy a the Mt. Sinai Medical Center in New York. He is the former Administrator of the Health Care Financing Administration. In this position he also served as a key health policy advisor to the Secretary of the U.S. Department of Health and Human Services and other top administration officials. In July, 1995, Dr. Vladeck received the 1995 National Public Service Award for his outstanding contributions to public service. Dr. Vladeck is a nationally recognized expert in health policy and financing. He has been a member of the Prospective Payment Assessment Commission, the New York State Council on Health Care Financing, and the New York State AIDS Advisory Council. He has also been a member of the board of directors of the New York City Health and Hospitals Corp. and a trustee of the Henry J.Kaiser Family Foundation. In addition, he is a member of the Institute of Medicine.