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Vital Directions for Health and Health Care
Priorities From a National Academy of Medicine Initiative

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IMPORTANCE Recent discussion has focused on questions related to the repeal and replacement of portions of the Affordable Care Act (ACA). However, issues central to the future of health and health care in the United States transcend the ACA provisions receiving the greatest attention. Initiatives directed to certain strategic and infrastructure priorities are vital to achieve better health at lower cost.

OBJECTIVES To review the most salient health challenges and opportunities facing the United States, to identify practical and achievable priorities essential to health progress, and to present policy initiatives critical to the nation's health and fiscal integrity.

EVIDENCE REVIEW Qualitative synthesis of 19 National Academy of Medicine–commissioned white papers, with supplemental review and analysis of publicly available data and published research findings.

FINDINGS The US health system faces major challenges. Health care costs remain high at $3.2 trillion spent annually, of which an estimated 30% is related to waste, inefficiencies, and excessive prices; health disparities are persistent and worsening; and the health and financial burdens of chronic illness and disability are straining families and communities. Concurrently, promising opportunities and knowledge to achieve change exist. Across the 19 discussion papers examined, 8 crosscutting policy directions were identified as vital to the nation's health and fiscal future, including 4 action priorities and 4 essential infrastructure needs. The action priorities—pay for value, empower people, activate communities, and connect care—recurred across the articles as direct and strategic opportunities to advance a more efficient, equitable, and patient- and community-focused health system. The essential infrastructure needs—measure what matters most, modernize skills, accelerate real-world evidence, and advance science—were the most commonly cited foundational elements to ensure progress.

CONCLUSIONS AND RELEVANCE The action priorities and essential infrastructure needs represent major opportunities to improve health outcomes and increase efficiency and value in the health system. As the new US administration and Congress chart the future of health and health care for the United States, and as health leaders across the country contemplate future directions for their programs and initiatives, their leadership and strategic investment in these priorities will be essential for achieving significant progress.

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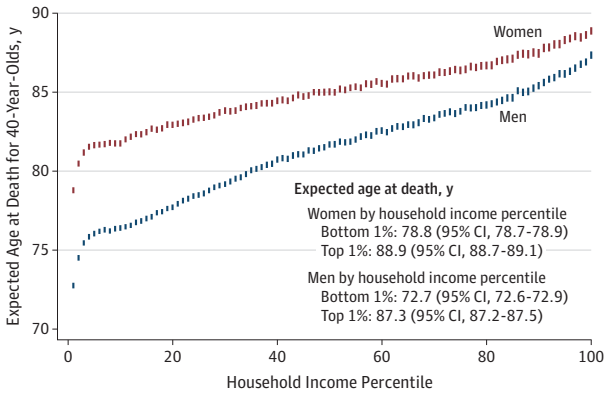
The US health and health care system is at a critical juncture. Discussions about repeal of the Affordable Care Act (ACA) introduce considerable uncertainty into the health care marketplace and for the 20 million people newly insured during the past 6 years,[1] but the range of health and health care challenges spans far beyond the coverage provisions of the ACA. Unparalleled health costs, structural inefficiencies, fragmented care delivery, payment hardships, and proliferating administrative requirements impose burdens on individuals, clinicians, employers, and entire communities. The consequences are especially severe for those who are ill, lack needed medical and social services, and have lower incomes, as indicated by the association of lower incomes with substantially lower life expectancies (**Figure 1**). But inadequate and inappropriate treatment, overdiagnosis and underdiagnosis, medical errors, and excessive costs are also experienced by many other individuals in the United States.

These serious systemwide challenges are complicated by increases in illness and disability from an aging population, emerging infectious diseases, and physical, behavioral, and mental health disorders such as opioid abuse, tobacco use, obesity, depression, and their related chronic diseases. Although US residents with higher incomes have never been healthier, conditions such as these are life-altering threats for many individuals. The most recent data on US life expectancy indicate not only sustained health disparities by income level and by race/ethnicity, but also a decline in overall life expectancy for the first time in nearly 2 decades.[3]

At the same time, compelling opportunities and novel tools are emerging to possibly solve these problems. Insights now underscore the central importance of social, behavioral, and environmental factors for people's health throughout the life span. Technology is reshaping every dimension of health care, from the ability to treat organ system failure and the capacity to visualize metabolic processes in real time to the use of digital systems that can record, inform, connect, and assess care experiences, introducing new possibilities for precision medicine, the creation of evidence, and the delivery of care.[4] Scientific discoveries offer breakthrough potential for greater precision in the prevention, detection, and treatments of illness and disease.

The nation's challenge is to choose priorities and actionable steps to address them that will have the greatest effect in improving the health of the population. Moreover, as indicated in **Figure 2**, it is not only the nation's health but its fiscal capacity that is at risk, as health care spending reduces investments in education, infrastructure, and other arenas important to the daily lives of US residents. In 1974, the United States spent $14.8 billion on major health care programs, $55 billion on Social Security, and an estimated $199.6 billion on all other spending; by 2015, this had changed to $936.5 billion, $881.9 billion, and $1869.9 billion, respectively (note that major health care programs include spending for Medicare [net of premiums and other offsetting receipts], Medicaid, and the Children's Health Insurance Program as well as spending to subsidize health insurance and to stabilize premiums for health insurance purchased by individuals and small employers). The $3.2 trillion spent annually for health care in the United States[6] is far higher than anywhere else in the world,[7] and the magnitude of the nation's excessive expenditures was estimated in 2009 at approximately 30% of health care costs[8] and in 2012 at between 21% and 47%[9]—including unnecessary services, delivery inefficiencies, excess administrative costs, high prices, missed prevention opportunities, and fraud—underscoring the need for better use of resources. Because this trajectory of health care spending is unsustainable, reforms are needed that enable health care organizations, communities, and individuals to redirect resources to uses that achieve better health, promote efficiency, and reduce waste. Given that the leading health determinants are outside of health care,[10] policies must not only encourage more judicious use of health care services, but also ensure supports

Figure 1. Race- and Ethnicity-Adjusted Life Expectancy for 40-Year-Olds by Household Income Percentile, 2001-2014

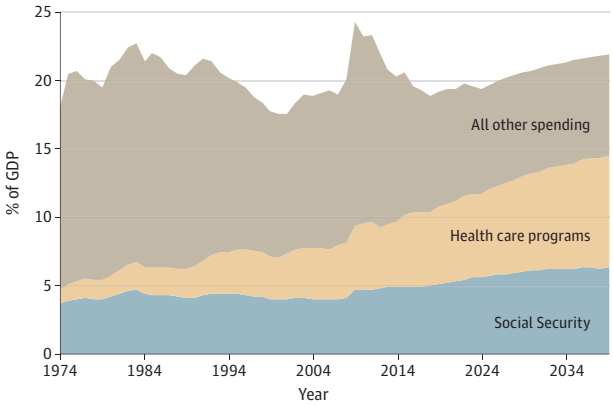


Mean household income in thousands, $[a]					
Women	24	45	71	112	1.9 million
Men	26	50	77	119	2.0 million

Higher income is associated with longer life expectancy across the income distribution. The vertical height of each bar depicts the 95% confidence interval. The difference between expected age at death in the top and bottom income percentiles is 10.1 years (95% CI, 9.9-10.3 years) for women and 14.6 years (95% CI, 14.4-14.8 years) for men. To control for differences in life expectancies across racial and ethnic groups, race and ethnicity adjustments were calculated using data from the National Longitudinal Mortality Survey and estimates were reweighted so that each income percentile bin has the same fraction of black, Hispanic, and Asian adults. Reprinted from *JAMA*.[2]

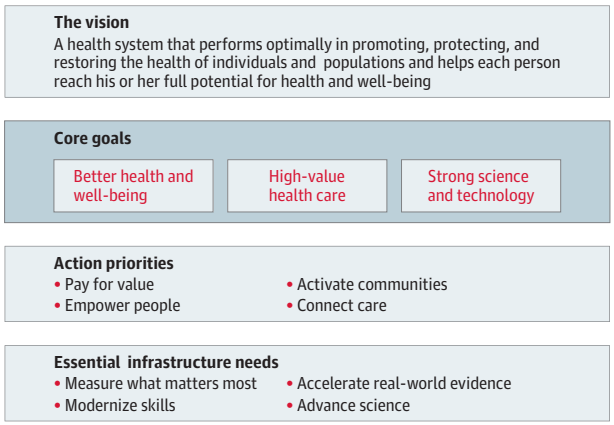
[a] Averaged across years and ages. The data are in thousands unless otherwise indicated.

Figure 2. Historical (1974-2015) and Projected (2016-2039) Federal Spending on Health Care and Other Programs



All other spending includes other mandatory spending and discretionary spending (including defense and nondefense). Data are from the Congressional Budget Office.[5] GDP indicates gross domestic product.

Figure 3. Vital Directions Framework



Achieving the vision of the Vital Directions for Health and Health Care requires focusing on 3 core goals—better health and well-being, high-value health care, and strong science and technology—and pursuing the action priorities and infrastructure needs required for their achievement.

for better health behavior and facilitate integration of health-related social service interventions.[2] Furthermore, by fostering incentives and culture change supportive of proven, value-based models of care payment and delivery as well as connected health care and information, greater efficiency, better results, and more person-engaged care could be achieved.[11]

As the new administration and Congress work to craft the future of US health and health care, this Special Communication is offered by members of a steering committee of experienced nonpartisan experts and opinion leaders assembled by the National Academy of Medicine (NAM). In the spirit of the chartered mandate and long-standing service of the National Academies to provide trusted, independent counsel to the nation, the NAM last year launched an initiative to consider practical and achievable priorities essential to the nation's health and fiscal integrity. Underscoring the importance of the issues, this initiative is named Vital Directions for Health and Health Care.

The Priorities

The Vital Directions initiative is motivated by the vision of a health system that performs optimally in promoting, protecting, and restoring the health of individuals and populations and helps each person reach her or his full potential for health and well-being (**Figure 3**). Attainment of this vision requires focusing on 3 core goals—better health and well-being, high-value health care, and strong science and technology—and, in turn, pursuing the action priorities and infrastructure needs required for their achievement (**Box 1**).

Across the 3 goals of the Vital Directions for Health and Health Care initiative—better health and well-being, high-value health care, and strong science and technology—the Vital Directions Steering Committee identified 19 issue areas to be assessed in expert-written articles. The National Academy of Medicine convened more than 150 of the nation's leading health and policy experts to author the 19 articles, each of which addressed pressing policy challenges and opportunities and offered specific recommendations for achieving progress (**Box 2**). Summarized in this Special Communication are the most potentially transformative crosscutting policy directions identified from those assessments, indicated as action priorities and infrastructure needs essential to addressing these priorities. These strategies and priorities are offered to assist the new administration and others leading change throughout health and health care at national, state, local, and institutional levels. Pursuing these action priorities and essential infrastructure needs as part of major 2017 legislative and executive initiatives can achieve better health and lower costs.

Action Priorities

From across the spectrum of the 19 discussion papers developed through the Vital Directions initiative, 4 crosscutting action priorities emerged: pay for value, empower people, activate communities, and connect care. Whether from the perspective of the need to prevent and control heart disease, cancer, or diabetes; to prevent, identify, and treat people with problems of mental health and addiction; or to streamline and improve access to the range of services needed, these 4 action priorities are vital to progress. Moreover, because these priorities represent a substantial departure from current patterns of health and health care services, their advancement requires strong leadership, commitment, and strategic emphasis.

Pay for Value—Deliver Better Health and Better Results for All

Leaders throughout the United States adhere to the principle that no individual should lack access to basic health services. Central to the realization of this principle is ensuring that those services deliver the greatest possible value and minimize waste. But the nation falls substantially short of that aim. Although contributions vary across population groups, shortfalls in medical treatment have a relatively small effect on the occurrence of early deaths throughout the population—accounting for only about an estimated 10% of

Box 1. Vital Directions for Health and Health Care: The Priorities

Action Priorities

Pay for value—deliver better health and better results for all

Empower people—democratize action for health

Activate communities—collaborate to mobilize resources for health progress

Connect care—implement seamless digital interfaces for best care

Essential Infrastructure Needs

Measure what matters most—use consistent core metrics to sharpen focus and performance

Modernize skills—train the workforce for 21st-century health care and biomedical science

Accelerate real-world evidence—derive evidence from each care experience

Advance science—forge innovation-ready clinical research processes and partnerships

Box 2. Vital Directions for Health and Health Care: Issue Areas

Better Health and Well-being

Systems strategies for better health throughout the life course

Addressing social determinants of health and health disparities

Preparing for better health and health care for an aging population

Chronic disease prevention: tobacco, physical activity, and nutrition for a healthy start

Improving access to effective care for people who have mental health and substance use disorders

Advancing the health of communities and populations

High-Value Health Care

Benefit design to promote effective, efficient, and affordable care

Payment reform for better value and medical innovation

Competencies and tools to shift payments from volume to value

Tailoring complex care management, coordination, and integration for high-need, high-cost patients

Realizing the full potential of precision medicine in health and health care

Fostering transparency in outcomes, quality, safety, and costs

The democratization of health care

Workforce for 21st-century health and health care

Strong Science and Technology

Information technology interoperability and use for better care and evidence

Data acquisition, curation, and use for a continuously learning health system

Innovation in development, regulatory review, and use of clinical advances

Targeted research: brain disorders as an example

Training the workforce for 21st-century science

premature deaths overall—while behavioral patterns, genetic predispositions, social circumstances, and environmental exposures have been estimated to account for approximately 40%, 30%, 15%, and 5% of premature deaths, respectively.[12] Yet the majority of health expenditures are devoted exclusively to treatment. Because payments have not been explicitly linked to the value of the services or evidence of their necessity, per-person health expenditures in the United States are much higher than in other high-income countries.[7]

To advance value-based care for all, policy reforms should do the following:

- **Drive health care payment innovation providing incentives for outcomes and value.** Payment for individual services inherently encourages volume over outcomes. The reward focus adopted by all payers needs to target patient- and population-specific profiles that yield better outcomes at reasonable costs for care for a designated population over a specified period.[13]
- **Help clinicians develop the core competencies required for new payment models.** As new payment models are implemented and tested for their effects on care outcomes and value as well as patient and clinician satisfaction, clinician practices need to develop the adaptive core competencies to succeed.
- **Remove barriers to integration of social services with medical services.** Treatments are frequently prescribed without consideration of the social, behavioral, and environmental factors that are important determinants of health.[14] Integrated arrangement, financing, and delivery of nonmedical social services (eg, food, housing, transportation, and income assistance) with medical services is important to improve outcomes, yield savings, and enhance equity.[15] Integration of this sort could be achieved through virtual integration models such as Medicaid health homes, which use a team-based clinical care approach while connecting care to community resources and supports.[16]

The following are example policy initiatives from the Vital Directions discussion papers:

- Sustain and accelerate the implementation, demonstration, and assessment of alternative payment models supported by public and private health care payers to reward value and improve outcomes and health.
- Reward measurement streamlining that helps identify and reward innovation and outcomes delivering value at systemwide and population levels (population-based payments).
- Support public-private collaborations among industry and government, for example, the Accountable Care Learning Collaborative, which helps clinicians and other health care delivery groups and organizations develop competencies needed for success in the use of alternative payment models.[17]
- Implement successful models for health and social services integration, for example, funding stream integration so that Medicaid managed care plans can coordinate with social and community interventions proven effective in improving outcomes and reducing costs.

Empower People—Democratize Action for Health

Consistently and effectively engaging patients and families is essential to improve health outcomes and efficient use of care. Yet care and care instructions are still too often poorly matched to the personal context of patients' daily lives or their individual goals.[18] Health care must not only be safe and effective, but also be understandable and practical, accounting for patient and family knowledge and

circumstances and linking them with easy access to ongoing information and communication channels. Furthermore, individuals' health data are increasingly siloed and are often in electronic health records that may be impossible to access when needed. Beyond the need for a platform to integrate health data is the need for practical assurance to patients of ownership of their own data, which in most cases are now held by physicians and hospitals.[19]

To empower people, policy reforms should do the following:

- **Link care and personal context.** Clinicians should work together with patients and their families to ensure that care provided matches closely with each individual's goals.
- **Communicate in a way appropriate to literacy.** To foster trust and active patient engagement, policy makers and health leaders should focus on making information more available, understandable, and useful for all. Improving health literacy also stands to have significant economic benefit; low health literacy has been estimated to cost the United States $106 billion to $238 billion annually.[20]
- **Promote effective telehealth tools.** Telehealth technologies—use of internet, telephone, and other methods—have shown some promise in increasing patient access to medical care, particularly in remote or underserved areas, and reducing costs.[21,22] Harmonizing state-specific physician licensure rules and restrictions as well as reimbursement eligibility requirements would help promote their scalability and broader use.
- **Ensure patient data access, ownership, and privacy.** Empowering patients through ownership and protection of their health data would allow patients the opportunity to use, act on, and derive the most (personal) value from their health information.[23] Data ownership combined with better assurance of data privacy and security would increase the likelihood that patients would be willing to share their health information.

The following are example policy initiatives from the Vital Directions discussion papers:

- Promote development of clinical practice guidelines and decision support tools to encourage physicians to engage with each patient on their personal context and goals in making care decisions.
- Support patient communication research on and decision-making strategies to determine the most effective approaches to relaying information on care, cost, and quality, such as the Patient-Centered Outcomes Research Institute (PCORI) Communication and Dissemination Research program focusing on approaches to communicate and disseminate health information and research findings to patients.[24]
- Establish harmonized licensure and reimbursement for telehealth clinicians, so that telehealth clinicians may provide services across state lines.

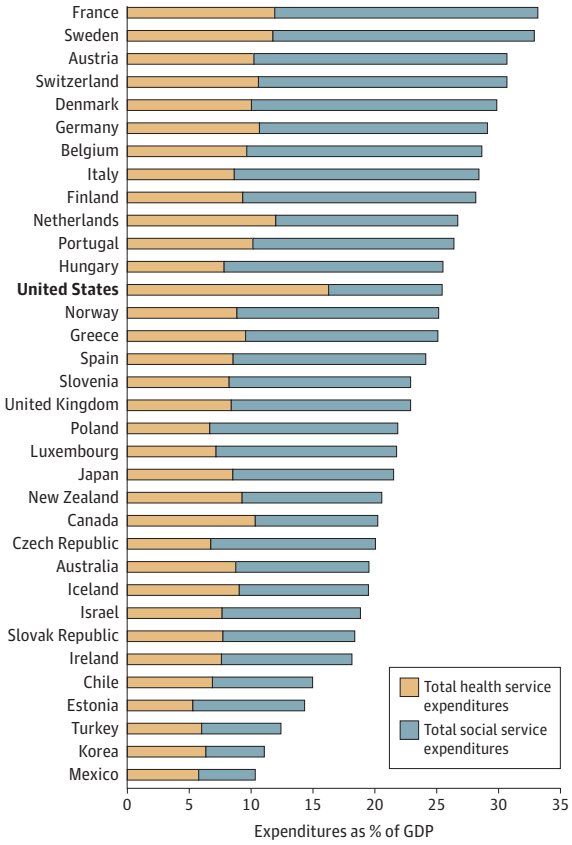
Activate Communities—Collaborate to Mobilize Resources for Health Progress

Health begins in communities, where people live, work, and play. However, as the nation experiences increasing health disparities, the gap in life spans between the rich and the poor has increased[2] and discrepancies between urban and rural health care access and quality persist.[25] In 2015, aggregate population-wide life expectancy experienced a concerning decline. Whether this will continue is unclear. Health disparities are not inevitable; they are a product not only of health care access and quality, but also of community-based social, economic, and environmental conditions that can be changed. Work sponsored by the NAM Culture of Health program assessed the health-related effect from targeting social determinants in 9 communities and found that, altogether, multisectoral community-wide leadership can be effective in reducing the adverse effects of key social determinants on health disparities.[26] Moreover, the United States invests far less than peer nations on community-based social services (**Figure 4**) that are important to health outcomes. Community-wide leadership and capacity are essential not only to reducing disparities, but also to combating the nation's most pressing and costly health threats—such as chronic disease and multiple comorbidities—by promoting healthy environments and behaviors and ensuring that the necessary supports are in place to achieve health improvement.

To activate communities, policy reforms should do the following:

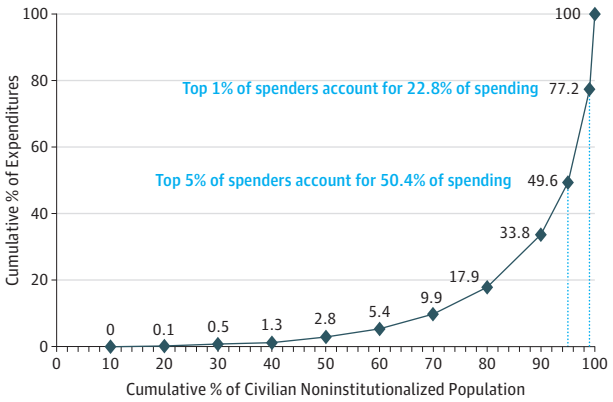
- **Invest in local leadership and infrastructure capacity for public health initiatives.** Transformative change in health and health care requires maintaining and strengthening the capacity to deliver essential public health services, including ongoing collaboration with business, education, housing, and transportation stakeholders.

Figure 4. Health Care and Social Service Spending Across Countries in the Organisation for Economic Co-operation and Development (OECD)



Compared with other high-income countries, the United States spends a greater proportion of health care and social service expenditures on health care services. For every $1 spent on health care, about $2 is spent on social services by countries in the OECD overall but only about $0.50 is spent on social services by the United States.[27] GDP indicates gross domestic product. Data are from OECD countries (n = 30) from 1995 to 2005 according to the 2009 release of the OECD Health Data 2009 Statistics and Indicators and OECD Social Expenditure Database. Adapted from Bradley and Taylor.[27]

Figure 5. Distribution of Personal Health Care Spending in the US Civilian Noninstitutionalized Population, 2014



In 2014, the top 1% of health care spenders accounted for 22.8% of total health care spending and the top 5% of health care spenders accounted for 50.4% of total health care spending. Data are from the Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality.[28]

- **Expand community-based strategies targeting high-need individuals.** High-need patients, often characterized as those with multiple comorbidities, disproportionately drive health care costs, with the top 1% and 5% of spenders accounting for 22.8% and 50.4% of health care spending, respectively (**Figure 5**).[28] The right care for these patients requires close alignment and coordination of medical and social services. Community care (health) teams, typically associated with patient-centered medical homes, can help coordinate these services for complex patients, but they strongly rely on community-based organizations to provide the social supports and services needed (eg, food, housing, income, and care assistance).[29]
- **Provide strong state-based capacity for guidance, assistance, and synergy for local health efforts.** Success in achieving better health at lower cost will depend on strategies implemented at the local level. Resources, flexibility, and insights from successful state innovation models and model Medicaid waivers that encourage and empower local leaders can provide guidance for customizing and scaling community health innovations.

The following are example policy initiatives from the Vital Directions discussion papers:

- Require that tax-exempt health organizations meeting Internal Revenue Service requirements for community benefit work through coordinated community-wide public-private partnerships and multisectoral initiatives.
- Support states' flexible use of grant funds for technical assistance to local leadership and collaborative action working to identify and mobilize action on the most important health challenges.
- Identify best practices from pilot programs from the Center for Medicare & Medicaid Innovation (CMMI) on approaches linking relevant health, education, social service, and legal system activities and resources to address individuals at highest risk and with the greatest needs.
- Give states flexibility to use Medicaid funds to implement best practices in targeting the most effective efforts for high-risk, vulnerable children (eg, prenatal to age 3 years) as well as adults at particular risk with complex, multifactorial conditions.

Connect Care—Implement Seamless Digital Interfaces for Best Care

Health care in the United States is complex and often difficult to navigate—for patients, families, and clinicians—but tools are available. The expanded adoption of health information technology has introduced powerful new opportunities for better health and health care,[30] including the potential for greater accountability and value, enhanced public engagement, improved public health surveillance, and more rapid development and distribution of new therapies. Yet important challenges remain. System incompatibilities and clinician discomfort levels need to be overcome. Clinical data do not consistently follow the patient to inform care across settings and over time. Aggregate clinical data are not available to inform health policy, generate discovery, or improve care efficiency and effectiveness.[31]

To achieve connected care, policy reforms should do the following:

- **Make necessary infrastructure and regulatory changes for clinical data accessibility and use.** The following barriers need to be removed: specifications for data developed but not adopted, commercially protective coding practices, proprietary data ownership and use restrictions, and misinterpretation of control requirements for use of clinical data as a resource for new knowledge. The recently passed 21st Century Cures Act contains provisions to encourage sharing and use of clinical data, but those provisions require local action.
- **Create principles and standards for end-to-end interoperability.** Specific standards are needed for end-to-end (system, clinician, and individual) interoperability. Despite the rapidly progressing technical capacity of digital technology for health, interoperability between and among systems is very limited, leading to serious clinical and administrative inefficiencies and inhibiting more responsive and effective care.[32]
- **Identify information technology and data strategies that support continuous learning.** The technical capacity now exists for continuous communication and learning throughout health care—among organizations, between clinicians, between devices, and between patients and care partners. Comprehensive strategy and action are required to improve data infrastructure, foster public trust around data privacy and security, and resolve inconsistent state and local policies on data use and sharing.

The following are example policy initiatives from the Vital Directions discussion papers:

- Use US Department of Health and Human Services (HHS) regulatory and reimbursement mechanisms to enforce existing standards for interoperability across electronic health records and medical devices.
- Through the HHS, sponsor a public-private standards organization to commission the necessary additional standards, for example, open, standardized application programming interfaces to support continuously improving standardized service-oriented architecture for interoperability and clinical decision support.
- Streamline inconsistent state and local security and privacy policies related to data exchange and use, such as federal guidelines enabling states and localities to harmonize data use policies and reciprocal support agreements.
- Building on the principle of patient ownership of data, foster active patient access and use of their own data for care and evidence improvement.

Essential Infrastructure Needs

To achieve the 4 action priorities, there must be commitment to essential infrastructure needs common across the 19 Vital Directions discussion papers: measure what matters most, modernize skills, accelerate real-world evidence, and advance science. The foundation for progress in any of those 19 areas resides in the availability of accurate information on the central determinants of progress, the skills to address those determinants, the pace at which new approaches can be developed, and the knowledge and tools available to better understand, assess, and improve those approaches.

Measure What Matters Most—Use Consistent Core Metrics to Sharpen Focus and Performance

Measurement is essential to guide progress. Ironically, as measurement tools and skills have advanced, the proliferation of reporting requirements has resulted in clinical measures now numbering in the thousands, raising serious concerns about the time, cost, validity, generalizability, and overall clinician and financial burden of clinical measurement. Results become meaningless if measures are unreliable and inconsistent.

To achieve meaningful measurement, policy reforms should do the following:

- **Focus reliably and consistently on factors most important to better health and health care.** To reduce the burden and increase the utility of measurement, an anchor set of core measures standardized and available consistently over time at national, state, local, and institutional levels can provide baseline reference points and improve the reliability of broader measurement, evaluation, accountability, and research efforts. The National Academies report *Vital Signs: Core Metrics for Health and Health Care Progress*[33] provides a framework for 15 such measures of health, care quality, value, and engagement.
- **Create the national capacity for identifying, standardizing, implementing, and revising core measures.** The *Vital Signs* committee recommended that the Secretary of Health and Human Services identify a lead organization for each of the 15 core measures and, in turn, engage related stakeholder organizations in the refinement process. The committee also recommended creation of an ongoing, independent capacity to steward the revision process over the longer term.
- **Invest in the science of performance measurement.** With the increasing capacity and importance of performance measurement, an ongoing investment is needed for continuous assessment of measures application, proposing and testing improved approaches, and periodic updating of individual measures, their components, and the measure set.[34]

The following are example policy initiatives from the Vital Directions discussion papers:

- Initiate an HHS process to refine and implement the *Vital Signs* core measures nationally, beginning with the federal categorical and health care funding programs, including a variation to be used by states in return for Medicaid management flexibility.
- Provide waivers from Medicare reporting requirements for health care organizations working in multiorganization collaborations to implement and report on core systemwide performance measures.
- Explore the design of an independent, standards-setting body for reports on health care performance measures, possibly modeled after the Financial Accounting Standards Board, which establishes financial accounting and reporting standards for companies and nonprofit organizations.[35]
- Establish a multiagency collaborative research initiative on the science of performance measurement, including how best to develop, test, evaluate, and improve measures.

Modernize Skills—Train the Workforce for 21st-Century Health Care and Biomedical Science

Investing in and strengthening the capacity of the health care and biomedical science workforces is critical to ensuring the health, economic, and physical security of the United States as well as global leadership in research and innovation. This investment must take new directions. The health care workforce of the 21st century must be adept at managing increasingly complex patients and populations, particularly as people live longer and the burden of chronic disease continues to increase, the complexity of medicine increases, and the research tools become more sophisticated. Ensuring a 21st-century biomedical science workforce will require modern education and training approaches; existing pathways are becoming outdated and fragmented[36] and no longer guarantee stable, successful careers.

To modernize the skills of the health care and biomedical science workforce, policy reforms should do the following:

- **Reform health care training to meet the nation's changing health needs and opportunities.** Reorienting training and practice to coordinated team-based approaches is essential to care delivery in today's increasingly complex care environment. This can be done by fostering the skills to work collaboratively in interdisciplinary teams and keep pace with technology advances.[37]
- **Create new education and training pathways for the science workforce.** The science workforce of the future will need to be diverse, multidisciplinary, team oriented, and adept at data analytics and informatics. Attracting and retaining the most talented individuals will require innovative education pathways and programs to create and support a cutting-edge, cross-disciplinary health science workforce.

The following are example policy initiatives from the Vital Directions discussion papers:

- Engage the scientific community, private foundations, state higher education officials, and federal health professions funders in proposing a public-private national initiative on health professions education that is team based, collaborative, multidisciplinary, and skilled in health information technology and informatics.
- Require that organizations delivering care as Medicare alternative payment models have the clinical research, information technology, and systems engineering personnel for continuous learning and improvement.
- Implement a prominent initiative to attract the most talented people to shape and lead the new biomedical research enterprise, a sort of NextGen Opportunity Fund.[38]

Accelerate Real-World Evidence—Derive Evidence From Each Care Experience

The potential to analyze large amounts of health-related data from actual patient care holds immense promise for improving medical

care by better informing care decisions, increasing drug and medical device safety, more accurately evaluating treatment effectiveness, and accelerating scientific discovery.[39] However, progress has been hampered by technical, regulatory, and cultural barriers, including an outdated clinical research model, an inadequate data-sharing incentive structure, and gaps in methods appropriately suited for such data. Randomized clinical trials, while still the gold standard of clinical research, are very expensive and can be limited in their generalizability and ability to reflect results in clinical practice.[40] The prospects now exist for a health system that is constantly learning, adjusting, and improving, and elements of the recently enacted 21st Century Cures Act provide impetus to this work.

To accelerate reliable evidence, policy reforms should do the following:

- **Advance continuously learning clinical research drawing on real-world evidence.** Complementing randomized clinical trials, the ability to collect data from actual clinical practice presents a great opportunity to gain new insights about the efficacy and safety of new drugs and medical devices as well as the relative effectiveness and efficiency of those in use. The National Institutes of Health (NIH), the US Food and Drug Administration (FDA), and other leading research agencies are actively developing strategies in this respect.
- **Foster a culture of data sharing by strengthening incentives and standards.** As with routine clinical data, research participants have presumptive rights to access and share their own health data. Researchers have a responsibility to accept that strong science and good scientific citizenship require individual-level data to be more accessible for evaluation and reuse, with appropriate safeguards.[41]
- **Partner with patients and families to support evidence generation and sharing.** Partnering with patients—and in the process, better ensuring their privacy and improving trust—is a linchpin for effective evidence generation and data sharing for care improvement and learning. Patient engagement throughout the research process can help identify unmet needs and future research priorities as well as improve clinical outcomes.[42]

The following are example policy initiatives from the Vital Directions discussion papers:

- Create public-private partnerships to build on existing pilot studies to assess and expand real-world evidence development in both preapproval and postapproval settings.
- Provide incentives for data sharing, such as a reimbursement benefit for health systems that facilitate data access and sharing between patients and researchers.
- Implement initiatives to build patient skill sets for engagement, better define value in terms that reflect the patient perspective, and determine measures for trustworthiness and participation.

Advance Science—Forge Innovation-Ready Clinical Research Processes and Partnerships

Preeminence in science and technology has driven the nation's health and economic vitality. This requires national investment and unwavering support for science—basic and applied. However, cumbersome and outdated regulatory processes can make it difficult for the pharmaceutical industry to bring promising drugs and devices to market in a timely fashion. With US global investment in biomedical research softening,[43] maintaining leadership in science and innovation will require modernized and adaptive regulatory processes, research partnerships, and commercialization models.

To advance the pace of innovation, policy reforms should do the following:

- **Promote the conditions for scientific innovation.** Science needs investment. Important conditions for success include commitment to funding, support for basic and applied research, and acceleration in translation. Furthermore, taking advantage of data sets rapidly growing to very large sizes, new forms of science, technology, and evidence development can boost clinical care research. Opportunities include making greater use of evidence from actual clinical settings and of cognitive computing to better understand and ensure the most effective and appropriate interventions for the best possible clinical outcomes.
- **Support an adaptive and patient-driven regulatory framework.** Aligning discovery and development with current needs will require patient input and partnership in all stages of research and development; multidisciplinary teams; more efficient clinical trials with adaptive designs; and a blend of real-world and randomized clinical trial evidence.
- **Foster cross-disciplinary and public-private partnerships.** More collaboration among the government, academia, and industry scientists will be necessary to advance innovation, including in the most challenging therapeutic areas such as autoimmune, neurodegenerative, and inflammatory diseases.[44] Exploration of multifocal public-private research partnerships has been the focus of initiatives at the NIH and FDA, including those related to the programs expanding brain and cancer research. Pharmaceutical and device companies are exploring sharing trial data in the interest of advancing very-large-scale clinical databases to facilitate discovery.

The following are example policy initiatives from the Vital Directions discussion papers:

- Ensure research funding for basic and applied sciences.
- Create public-private programs to invest in and advance the science and related applications of big data analysis, such as cognitive computing.
- Facilitate patient support for evidence generation through expanded use of clinical data for discovery and real-time outcomes monitoring (eg, the FDA's National Medical Evidence Generation Collaborative, "EvGen"[45]).
- Implement precompetitive collaborations including industry, government, and academia to achieve needed breakthroughs in the most challenging therapeutic areas that cannot be done by any sector alone (eg, the Accelerating Medicines Partnership led by the NIH).

The Urgency

The opportunities described are real and substantial. As a nation, the United States has the world's largest observable discrepancy between the amount spent on health care and the health status of the population, but it also is positioned with the knowledge needed for improving value and outcomes. Greater involvement of people in their care processes, support for active community-wide initiatives, harnessing transformative connectivity of the digital infrastructure, and accelerating the movement toward a reward system based on results are all possible. Evidence exists on the potential of these priorities and on the steps necessary to deliver better health for all people in the United States at a sustainable cost. Furthermore, there are strong indications that these priorities will garner

broad support, with recent bipartisan legislation in some of these areas, such as the Medicare Access and CHIP Reauthorization Act (MACRA) for payment reform and the 21st Century Cures Act for more efficient drug development and approval.

The urgency is as compelling as the opportunities. Major concerns such as sustained, yet preventable, health disparities and perverse payment system incentives that drive unnecessary services and costs threaten achievement of possibilities for better health, greater equity, and even global economic competitiveness. Importantly, there is no easy fix or simple budgetary adjustment that will resolve excessive health care spending. As noted earlier, the excess costs stem from inefficiencies in multiple components of the health system, and their remediation will require a priori commitment to the priorities indicated. In fact, if even a relatively small portion of the approximately $1 trillion now spent unnecessarily on health care can be redirected to the high-priority investment opportunities described herein, the health and productivity benefits will ripple far beyond the health sector.

The complexity and magnitude of the issues as well as the promise for gain call for vigorous leadership from every quarter, including prominent federal initiatives as well as the state and local levels. At this vital inflection point in health and health care, the challenges are great, but so are the opportunities and knowledge to direct change. Prioritizing the nation's health through strong leadership and strategic investment is both possible and imperative for all Americans to reach their full potentials for health and well-being.

ARTICLE INFORMATION

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