

COMMENT

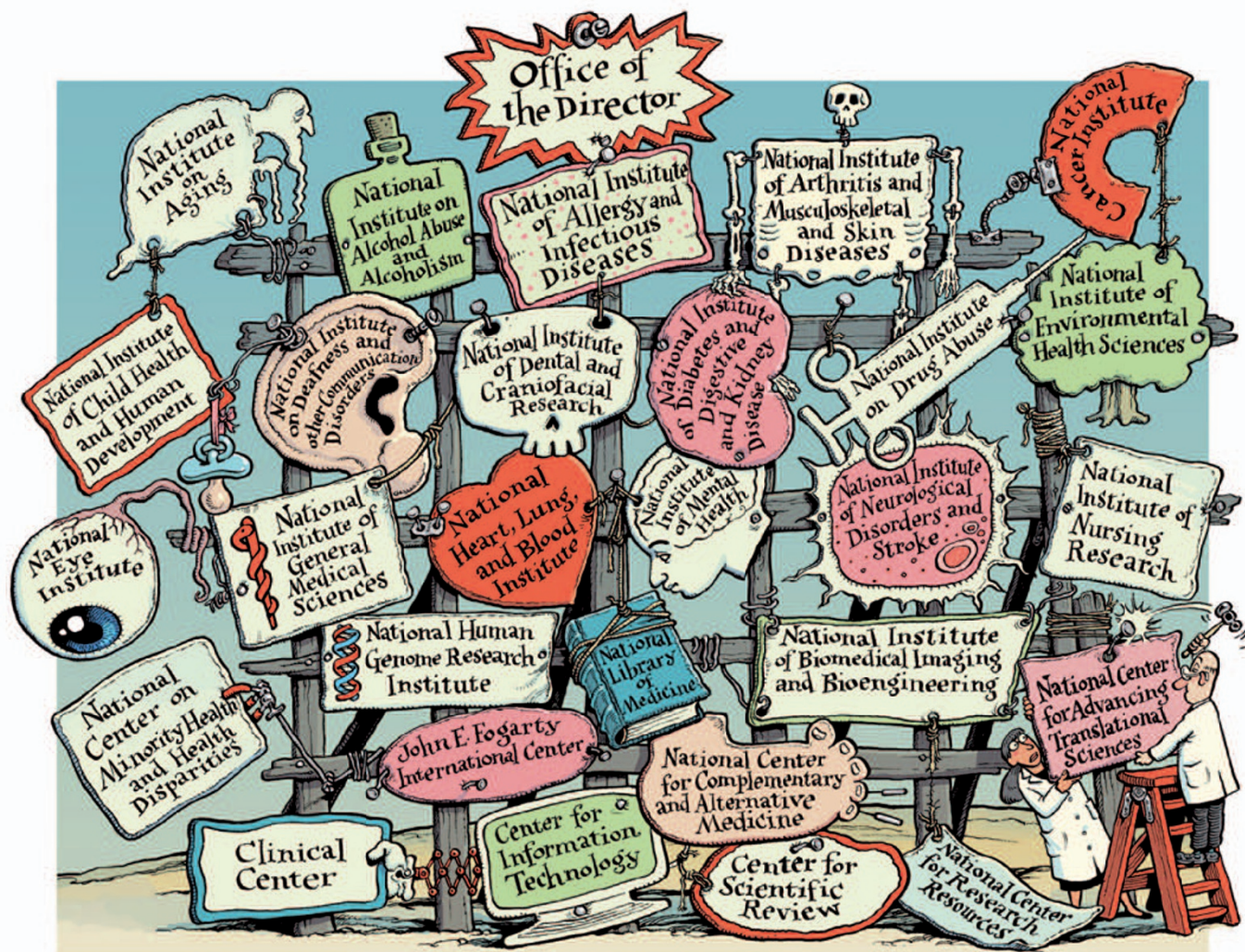
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Time to rethink the NIH

A radical restructure is the only way to solve the systemic problems of the world's biggest funder of biomedical research, argues **Michael M. Crow**.

The United States bets around US\$30 billion a year that advances in basic research will yield improvements in national health care. Yet the nation's global leadership in biomedical science spending has not translated into leadership in health.

Francis Collins, the director of the US National Institutes of Health (NIH) in

Bethesda, Maryland, recently determined that a new centre will help the agency's numerous other institutes and centres better convert 'blue-sky' research into treatments and diagnostics¹.

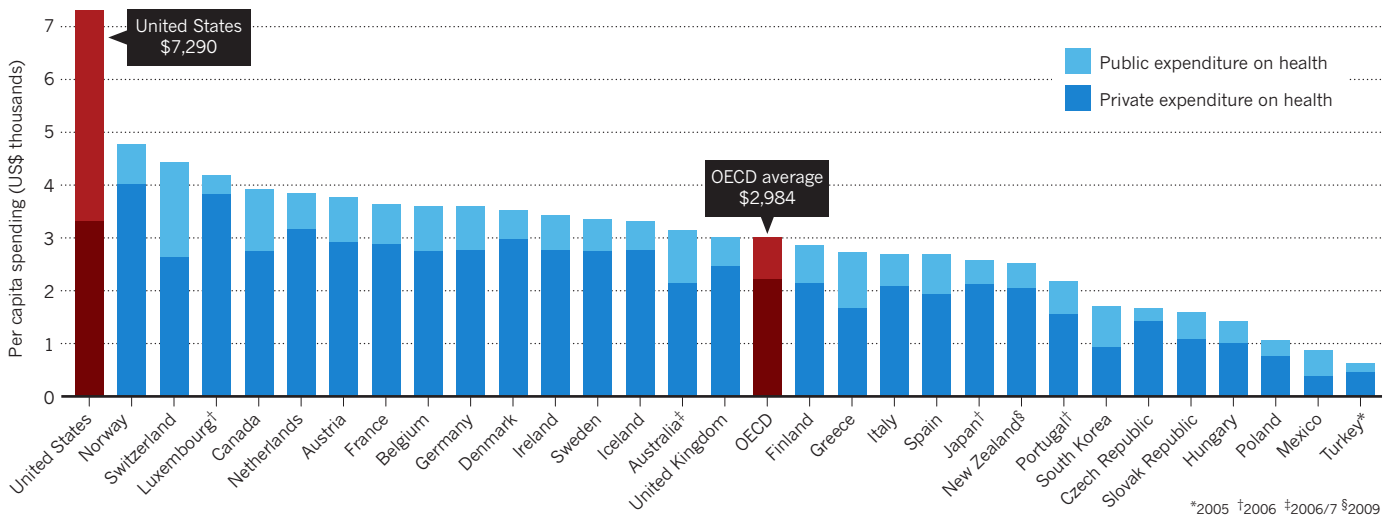
A firestorm of discussion has erupted since Collins announced his plans for the National Center for Advancing Translational Sciences (NCATS) in December^{2,3}.

Much of the debate reflects concerns about what the move will mean for existing programmes and budgets. In my view, Collins's NCATS plan perpetuates the same outmoded beliefs that have led to the current disconnect between the laboratory and the clinic, and sidesteps an opportunity to address the fundamental limitations of the NIH. Therefore I ►

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BIG SPENDER

The US health spend is almost 2.5 times the average for Organisation for Economic Co-operation and Development (OECD) countries, but the country scores middling to poor on a range of health measures including infant mortality and cancer survival rates (data from 2007 unless otherwise stated).



SOURCE: REF. 4

▶ shall not weigh in on the debate about NCATS.

Instead, I propose a thought experiment. If the United States were to start from scratch, what institutional arrangement would do a better job of improving the health and well-being of its citizens for \$30 billion of annual expenditure? I base this experiment on three decades of experience designing large-scale knowledge enterprises — such as the Earth Institute at Columbia University in New York City and the recently reorganized Arizona State University.

Researchers, policy-makers and the government have failed to recognize that progress in health care results from a complex integration of scientific advances with technological, behavioural, social and cultural shifts. To improve clinical outcomes, the NIH needs to be reconfigured around the many determinants of health — with fundamental research as an important component, but integrated and co-equal with others.

THE ROAD TO HERE

In 1945, Vannevar Bush, the director of the Office of Scientific Research and Development under US presidents Franklin Roosevelt and Harry Truman, issued his science policy manifesto *Science: The Endless Frontier*, which set the stage for US government support of science in exchange for scientists securing national defence, economic prosperity and a healthy life for the American people. Influenced by this, and especially by the success of the scientific contribution to victory in the Second World War, the government expanded its investment in all forms of science but mainly in defence and health.

NIH funding in 1939 totalled less than

\$500,000 a year, a sum that supported just one institute. Adjusting for inflation, the budget has since increased nearly 4,000-fold — and now funds a Byzantine array of 27 institutes and centres, most of which focus on a particular group of diseases. That the NIH budget has grown at such a rate reflects the strong belief of political supporters, including scientists, activist groups and other constituencies, that more science inevitably leads to more social good.

This model for discovery and application in health care is failing to deliver. A 2009 report⁴ found that the United States ranked highest in health spending among the 30 countries that made up the Organisation for Economic Co-operation and Development (OECD) in 2007, both as a share of gross domestic product and per capita. In fact, the country spent 2.5 times the OECD average (see ‘Big spender’). Yet life expectancy in the United States ranked 24th of

the 30 countries⁴ (see ‘Poor returns’). And on numerous other measures — including infant mortality, obesity, cancer survival rates, length of patient stays in hospital and the discrepancy between the care of high-versus low-income groups — the country fares middling to poor.

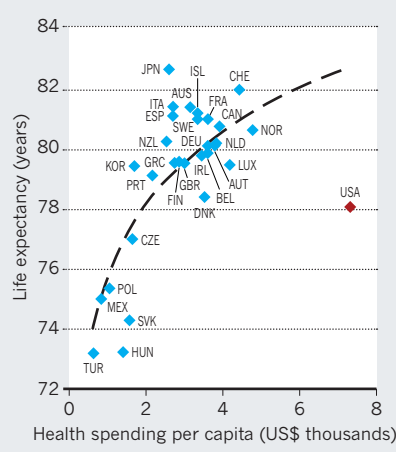
What is missing is not ‘translational’ research, but stronger links between all types of knowledge-generating activities related to health, and a focus on outcomes beyond science.

A cluster of studies from public-health and research-and-development economists indicates that progress in treating diseases results from complex feedbacks between a range of academic disciplines, technological innovation and clinical practice⁵. Take, for example, the advances in treating and preventing cardiovascular disease, which account for most of the gains in life expectancy in the United States during the past half-century. About one-third of the reduction in mortality has been traced to high-tech invasive treatments, such as coronary bypass surgery; one-third has been linked to medications that treat conditions such as hypertension; and one-third to behavioural changes — shifts in smoking habits, diet and exercise — achieved through education and clinical trials revealing the risks of, say, a high-fat, high-salt diet⁶.

Another example illustrates the cost of letting scientific momentum alone drive research strategies. According to the NIH’s National Cancer Institute, more than 220,000 people in the United States were diagnosed with cancer of the lung and bronchus last year. Between 80% and 90% of lung cancers have been linked to smoking tobacco. Yet of the \$2.45 billion that the NIH has spent on trying to find a cure during the

POOR RETURNS

In 2007, US life expectancy was ranked 24th of the 30 member countries of the OECD.



SOURCE: REF. 4

past decade, most has been directed towards the discovery of molecular and genetic causes and treatments rather than on establishing how to modify people's behaviour. Thirty-two years of data⁷ show that lung-cancer death rates overall are worse than they were in the early years of the 'war on cancer', initiated by US president Richard Nixon in the early 1970s.

THE ROAD AHEAD

What if the NIH were reconfigured to reflect what we know about the drivers of innovation and progress in health care?

This new NIH should be structured around three institutes. A fundamental biomedical systems research institute could focus on the core questions deemed most crucial to understanding human health in all its complexity — from behavioural, biological, physical, environmental and sociological perspectives.

Take, for instance, the 'obesity pandemic'. In the United States, medical costs related to obesity (currently around \$160 billion a year) are projected to double within the decade. And by some estimates, indirect spending associated with obesity by individuals, employers and insurance payers — for example on absenteeism, decreased productivity or short-term disability, exceeds direct medical costs by nearly threefold⁸. The NIH conducts and supports leading research on numerous factors relevant to obesity, but efforts are fragmented: 27 NIH components are associated with the NIH Obesity Research Task Force, a programme established to speed up progress in obesity research.

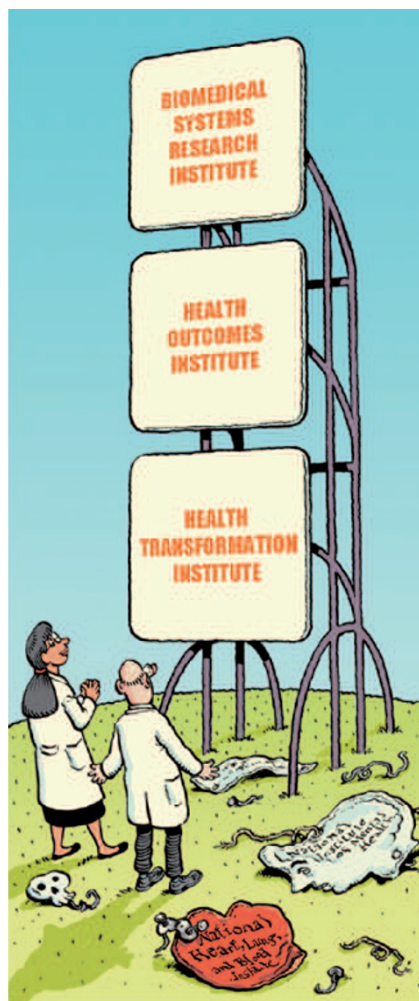
Within a systems research institute, scientists could better integrate investigations of drivers as diverse as genetics, psychological forces, sedentary lifestyles and the lack of availability of fresh fruit and vegetables in socioeconomically disadvantaged neighbourhoods.

A second institute should be devoted to research on health outcomes, that is, on measurable improvements to people's health. This should draw on behavioural sciences, economics, technology, communications and education as well as on fundamental biomedical research. Existing NIH research in areas associated with outcomes could serve as the basis for expanded programmes that operate within a purpose-built organization. If the aim is to reduce national obesity levels — currently around 30% of the US population is obese — to less than 10% or 15% of the population, for example, project leaders would measure progress against that goal rather than according to some scientific milestone such as the discovery of a genetic or microbial driver of obesity.

The third institute, a 'health

transformation' institute, should develop more sustainable cost models by integrating science, technology, clinical practice, economics and demographics. This is what corporations have to do to be successful in a competitive high-tech world. Rather than be rewarded for maximizing knowledge production, this institute would receive funding based on its success at producing cost-effective public-health improvements.

This kind of tripartite reorganization would limit the inevitable Balkanization that has come from having separate NIH units dedicated to particular diseases.



Indeed, such a change would reflect today's scientific culture, which is moving towards convergence — especially in the life sciences, where collaboration across disciplines is becoming the norm, advances in one field influence research in others, and emerging technologies are frequently relevant across different fields.

What remains unclear is how to bring about the change in mindset that is needed to focus scientific research and technological innovation on outcomes that benefit society. A committee of the National Research Council considered the question

of whether to rethink the organization of the NIH in 2003. This committee concluded⁹ that despite its "theoretical attractiveness", restructuring would be difficult because the structure of the NIH is the "result of a set of complex evolving social and political negotiations among a variety of constituencies including the Congress, the administration, the scientific community, the health advocacy community and others interested in research, research training and public policy related to health."

Shifting the mindset of scientists and policy-makers alike must begin with trans-

"A new NIH should be structured around three institutes."

disciplinary undergraduate and graduate curricula that stress the importance of societal outcomes. The US Mayo Clinic and Arizona State University, for instance, are jointly developing a master's degree in the 'science of health-care delivery' — a concept initiated by the Mayo Clinic, whose Center for the Science of Health Care Delivery designs and evaluates best practice in areas such as health maintenance.

As Harold Varmus, former director of the NIH, put it in 2001, the perception that the NIH represents the "jewel in the crown of the federal government" has led to "new facets being added without much thought to overall design"¹⁰. Especially in these recessionary times, spending \$30 billion effectively requires that the accretions of the past be replaced with a framework that better addresses the health-care priorities of the twenty-first century. ■

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