

HOW ACADEMIC HEALTH SYSTEMS CAN TRANSFORM MEDICINE

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Introduction:

The world's population faces unprecedented challenges to its health. Put in stark, familiar terms: the US spends over \$2 trillion dollars on healthcare annually, while leaving 47 million individuals uninsured, and ranking poorly on important health metrics relative to our peer nations, including life expectancy.^{1,2,3} The outlook turns even more grim when one considers the developing world. For example, sub-Saharan Africa has 11% of the world's population, but 24% of the world's burden of disease and only 3% of the world's healthcare workers to combat that burden.⁴ Such dangers and challenges demand the radical transformation of healthcare.

The transformation will require sociopolitical reform, system and technology improvements, which will not be easy. However, transformation can be accomplished through functional integration of innovation with clinical care and with efforts in community and global health. It requires aligning discovery and translational research to sustainable care delivery in the community – whether local or global. Central to this transformation is the creation of a continuum across discovery, translation, adoption, community implementation and global extension through major organizational restructuring, alignment of incentives and creation of public-private partnerships. Although Academic Health Systems (AHSs) historically have not been major players in addressing these global issues, we believe that they are now uniquely positioned to contribute to and to lead this transformational effort.

The Challenges Facing Healthcare

Drivers of escalating health care costs include: greater demand for services, aging population, increased service utilization, lack of evidence-based medicine and an excessive treatment and research emphasis on late disease. The United States has a fragmented healthcare delivery and financing system in which the incentives of providers, insurers, regulators and industry are misaligned. For example, providers are not reimbursed for maintaining their patients' health. Inherently, we have a healthcare model that focuses on late-stage illness, with as little as 1 % of our healthcare expenditures directed at prevention, the vast majority of our resources directed at treating post-symptomatic illnesses, and our R&D incentivized to develop products for late-stage disease.⁵ This narrow focus may not make the best use of our technological potential to improve health. Furthermore, it has been said that it takes an average of 10-15 years to move a discovery to the bedside.⁶ It can take even longer to get technologies adopted and part of the standard of care.⁷ It is clear that our innovation engines are not aligned to move discoveries swiftly to patient application or to implement population-wide

strategies using cheaper, simpler, faster technologies. The situation is further aggravated by inability of the economically disadvantaged to access care.

This health discrepancy apparent within the U.S. is even greater worldwide. Poor environment, poor hygiene, poor economic development and poor access to healthcare have led to a dramatic increased disease burden and shortened life expectancy in 5 billion of the world's 6 billion citizens.⁸ Such burden and instability reduces opportunities for economic growth in the developing world and can threaten to destabilize global economics and politics, making our efforts abroad both an economic and moral imperative.

A Radical Transformation Needed and the Time is Now

It has been stated that the major advances in research and technology, such as the sequencing of the human genome, will change the face of medicine.⁹ To date, we have not realized even a fraction of these potential breakthroughs. For instance, the genomic revolution is creating explosive growth in knowledge of molecular mechanisms and biomarkers, and neuroscientists and behavioral researchers are elucidating the complexity of individual and societal decision-making processes, especially as they relate to health and health care. At the same time, society is demanding faster and more cost-effective implementation of new technologies, at least in part, one could argue, because consumers/patients have greater direct access to information about such technologies.¹⁰

While biomedical research and publications grow at an increasing rate, the fraction of these that are applied to actual clinical practice remains small and the time required for such applications remains very long. The challenge is to find ways in which the tremendous wealth of emerging clinical and biomedical information can be applied more rapidly within the different contexts and environments of health care spanning the world. Ultimately, population-based strategies using faster and cheaper innovative technologies and targeting environmental factors will give the greatest yield from a public health perspective, and bold innovation, if properly incentivized and executed, can transform health and health care.

Transforming the healthcare system will require both top-down and bottom-up approaches. In other words, it will need both national policy changes and reform of the care delivery system, enabled through innovative and transformative technologies and new approaches. Universal health care coverage should be reconsidered for the United States, for example. However, we cannot wait for policy makers to act. As leaders and innovators in medical research, education, care delivery and policy, academic health systems (AHSs) must play a more proactive role to transform medicine.

The Role of the Academic Health System: a Driver of Transformation Through Integration Across Silos and the Innovation to Clinical Care Continuum

The Silos Problem:

Achieving the desired innovation and subsequent transformative impact requires overcoming the current fragmentation of the biomedical and health care industry, in which each sector functions as an independent silo.

The disconnect between sectors is compounded because each step of the continuum from innovation to clinical care is housed in separate entities, including universities, industries, clinical research organizations, medical centers, hospital and community practices, epidemiological cohorts, public and private organizations, and others.

Each of the silos and entities has its own incentives, which are often misaligned with those of others, resulting in a highly inefficient research, health care delivery and financing system.

Filling Gaps:

To succeed we must fill the gaps in the “innovation to clinical care continuum”. The innovation-care continuum consists of research and development, commercialization, clinical care delivery/patient care, community and public health, policy, and payers/insurers. (Figure 1 – the continuum slide) Two major gaps, or translation points, in this continuum have been identified,¹¹ and AHS’s have a unique ability to fill both. The first gap is between basic discovery and development of clinical application, and the second gap is between clinical application and adoption of clinical advances in local and global communities – essentially between proving a clinical advance and subsequently impacting health.

Traditionally, AHSs have handed off discoveries to industry at the first translation gap, and it has been largely up to industry – through licensing technologies or through start-ups – to pursue a discovery’s potential. However, we and others¹² believe that academic health systems are uniquely positioned to house the full spectrum of activities to fill both translational gaps, which could eliminate significant time from discovery to global adoption. The Roadmap Initiative^{13,14,15} and the resulting Clinical and Translational Science Awards (CTSA) of the National Institutes of Health (NIH) support this very perspective.

AHSs have an opportunity to be a leader in changing this fragmentation and creating this seamless continuum since they have the full spectrum of research and care delivery: from intellectual and innovative activities to community health. If properly organized, restructured, incentivized, AHS can be engines of health care transformation. AHS are uniquely positioned to lead as models and bastions of translational medicine whereby new discoveries, devices, practices or drugs are rapidly and efficiently introduced into clinical application and can be expertly translated and adapted to the local and global community with demonstrable benefit to the community health status.

However, for AHSs to lead the transformation of health care through innovation and translational medicine, they need to change dramatically the way they conduct research and clinical care and how they engage with the local and global community.

What must AHSs do to transform health care?

Organizational Structures to Break Through Silos:

AHSs must create a bold, seamless, facilitated and integrated organizational infrastructure that quickly moves innovative discoveries (whether a new device, drug or method) through to clinical research, to adopted standards of practice, to application in the local population, and eventually, to the application in the global population. To help achieve this goal, AHSs should create unique functionally integrated centers and institutes that transcend traditional academic departmental structures and promote greater interdisciplinary collaboration and more efficient utilization of common resources.

New Research Priorities:

While continuing to support fundamental scientific investigation, they should also support new research priorities in that first translational gap in order to spearhead development of new technologies that are value added, cheaper, faster and adoptable, such as biomarkers, diagnostic imaging, devices, surgery and information technology. Research focus cannot continue to be development of highly reimbursed, late-disease incremental improvements. This new research focus should accelerate discovery of opportunities to practice “P5 Medicine” – Preventive, Predictive, Preemptive, Personalized and Prospective – such as utilizing customized therapy for particular patients or sub-populations.

Put another way, AHSs need to do a better job of creating disruptive technologies – technologies that change the way medicine is practiced. These technologies must be practical, translatable and adaptable, measurable, affordable, and cost-effective.

New Models of Care:

AHSs also have the capacity to utilize these new technologies to help create a more efficient care continuum. In the future, measurements and testing might be conducted in the community, allowing non-physician providers and/or lay persons to make quick and early assessments. Patients could be followed by remote monitoring, telemedicine and other technologies.

“P5 Medicine” requires greater attention to preventive health and investment in “integrated medicine” that pays close attention to risk assessment, lifestyle, holistic care, environment, early diagnosis and intervention. Such an approach stands the best chance to limit development of the expensive, debilitating late-stage diseases and reduce health care costs. Furthermore, new models of care delivery that are patient-centered, community-based, and team-oriented must be developed and have available effective information technology for patient-monitoring and decision support.

Although true transformation of care delivery is difficult if financial incentives remain unaligned and reimbursement policies reinforce fragmentation of the health care system, AHSs can begin the process by piloting new models of care delivery. Through successful modeling, one could define approaches that provide better access, greater cost efficiency,

increased effectiveness and better outcomes and thereby justify appropriate reimbursement. Such models could then be adopted and expanded systemically forming the foundations of new ways of organizing and delivering care globally.

Investments in IT:

All of these changes will require AHSs' major investment in information technology (IT). For this vision of a continuum of innovation and health care, conversion of vast amounts of information into meaningful, accurate and applicable knowledge is essential. If properly developed, new technologies should improve efficiency and reduce costs of care.¹⁶ Raw clinical and biomedical data must be available to and be assimilated by health care professionals and health care systems in a manner transparently understood and supported by the global community. In short, AHSs must invest in IT so that “a deluge of raw and turbulent information streams can be turned into much clearer fonts of decisional wisdom.”¹⁷ The development of “mega-knowledge,” “mega-databases” and real-time analysis of interventions should allow AHSs to evaluate the outcomes of research and care and help inform decisions. Examples of IT investments for clinical care and research include electronic medical record, monitoring at remote sites, and telemedicine.

Example of Organizational Transformation: the Duke Model

To lead the effort to transform medicine and health care, we are developing the infrastructure and support systems as well as the cultural, academic and clinical alignment to bridge traditional barriers in order to move technological and scientific discoveries through the pipeline to clinical delivery in local and global populations. We have established two interrelated institutes: Duke Translational Medicine Institute (DTMI) and the Duke Global Health Institute (DGHI) that are system-wide and integrate the traditional organizational structures.

The DTMI, funded in part by an NIH CTSA award, provides leadership and resources for clinical and translational research, as well as evaluating approaches to these investigations. It consists of three pillars, each of which emphasizes a translational point and provides connections that bridge traditional gaps. (Figure 2) The Duke Translational Research Institute (DTRI) is intended to transform how fundamental discoveries are translated into clinical or commercial applications, while the longstanding Duke Clinical Research Institute (DCRI) is devoted to improving medical care by carrying out well-designed clinical trials and analyzing data, as well as by educating diverse professionals in the methods of translational and clinical research. Finally, DTMI is developing best practices for community-based and outcomes research through the Duke Center for Community Research (DCCR).

This tightly interlinked infrastructure provides a more rapid and efficient horizontal movement of translating discoveries to clinical application and of translating clinical application to widespread community adoption through project management. No longer will investigators have to navigate the many handoffs associated with the fragmented

structures and processes of the current system: here the move from discovery to community practice is all under one roof--“one stop shopping.” Furthermore, DTMI’s administrative infrastructure supports faculty and aligns incentives to encourage translation.

The new infrastructure acknowledges that it is not uncommon for advances that clearly demonstrate greater clinical and financial value to fail to be adopted by the local or global community. Take for example, the decades of delay from discovery of benefit to widespread use of ASA, ACE inhibitors, beta blockers or statins as preventive measures in high-risk cardiac patients.

An integrated electronic health record is one opportunity to improve adoption of evidence-based medicine in the community. This repository of information quickly reveals any adverse outcomes in clinical trials, perhaps removing some barriers that may be preventing full adoption of the new information. The repository could also provide information on breadth of adoption, potentially providing ways to address barriers on a more personal level.

Linking Translational Medicine and Global Health

Medicine transformed promises to turn innovative and novel discoveries into meaningful treatments for humankind with appropriate and creative models to engage communities. However, such efforts must allow health care advances to reach all populations in both developed and developing nations. In the past, innovation spent years gestating in universities followed by an agonizingly slow clinical investigation and regulatory process that only Western economies could afford to fund.

But in fact, the problems and solutions of global health are an extension on the continuum of AHSs’ local and national activities, both in research and clinical care. The Duke Global Health Institute includes the study of the drivers of health inequalities, such as political, economic, social and environmental factors, as well as approaches to improving health and health care in select sites locally and overseas.

It is also critically important to understand the societal, environmental and cultural context when new discoveries are introduced to communities to improve the chances of early adoption. DCCR, within DTMI, and the Duke Global Health Institute both offer contributions in this realm. Whether speaking of local or global communities, involvement of community advocates and leaders in the early adoption phase of new practices and products will facilitate more widespread and efficacious practice.¹⁸

Technologies and interventions that prove successful in the local community can be translated and adapted for global application, a win-win situation for the AHS and the foreign community. Novel diagnostic tools or therapies may be made available within a community for the first time through a global partnership, while the AHS gains the opportunity for service-learning within a different population, culture or geographic location. Through such bi-directional service-learning investigators can refine and

improve their discoveries, and their partners have opportunities to spread their knowledge globally as well. Partnerships can lead to identification of new opportunities to address unmet needs, as well as additional inquiry and discovery. Global partnerships also offer opportunities for training and educating the local population to generate a sustainable effect from the collaboration.

For example, we can learn important lessons from community health programs established in other nations. Much is to be learned, for example, from the ability of resource-limited countries like Botswana, plagued by AIDS, to dramatically increase its rate of AIDS testing in just a year through an “opt-out” program.^{19,20} Models formed and executed in one nation can be modified and adapted to suit the needs of communities in other nations.

The challenge

AHSs have an important role to play in transforming medicine, improving health and reducing health disparities globally, as well as a responsibility to act. The first step, and a key to success, is through internal reorganization and realignment to enhance innovation’s swift passage from bench to bedside to population. AHSs can develop public-private partnerships for community-based education, clinical care and research, particularly bi-directional service-learning, in the U.S. and around the world, and be of particular use in developing nations.

REFERENCES

1. Centers for Medicare and Medicaid Services. National Health Expenditures Data Fact Sheet. http://www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp#TopOfPage Accessed May 12, 2008.
2. DeNavas-Walt C, Proctor BD, Smith J. U.S. Census Bureau Current Population Reports P60-233: Income, Poverty, and Health Insurance Coverage in the United States: 2006. Washington, DC: U.S. Government Printing Office, 2007. <http://www.census.gov/prod/2007pubs/p60-233.pdf> Accessed May 12, 2008.
3. Organisation for Economic Co-Operation and Development. OECD Health Data 2006. <http://www.oecd.org/dataoecd/29/52/36960035.pdf> Accessed May 12, 2008.
4. World Health Organization. Fact Sheet No. 302: The global shortage of health workers and its impact, April 2006. <http://www.who.int/mediacentre/factsheets/fs302/en/index.html> Accessed May 12, 2008.
5. Matson Koffman DM, Lanza A, Campbell KP. A purchaser’s guide to clinical preventive services: a tool to improve health care coverage for prevention. *Prev Chronic Dis* 2008;5(2). http://www.cdc.gov/ped/issues/2008/apr/07_0220.htm. Accessed May 12, 2008.

6. Berndt ER, Gottschalk AH, Philipson TJ, Strobeck MW. Industry funding of the FDA: effects of PDUFA on approval times and withdrawal rates. *Nat Rev Drug Discov*. 2005;4(7):545-54.
7. Lee TH. Eulogy for a quality measure. *N Engl J Med*. 2007;357(12):1175-1177.
8. Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJL, eds. *Global Burden of Disease and Risk Factors*. New York: Oxford University Press, 2006.
9. Subramanian G, Adams MD, Venter JC, Broder S. Implications of the human genome for understanding human biology and medicine. *JAMA*. 2001;286(18):2296-2307.
10. Block AE. Costs and benefits of direct-to-consumer advertising: the case of depression. *Pharmacoeconomics*. 2007;25(6):511-521.
11. Sung NS, Crowley WF Jr, Genel M, et al. Central challenges facing the National clinical research enterprise. *JAMA*. 2003;289(10):1278-1287.
12. Partners Healthcare System, Millenium Pharmaceuticals. National Centers for Clinical Discovery (NCCD) Proposal – A White Paper, January 7, 2004.
13. Zerhouni EA. Translational and Clinical Science – Time for a New Vision. *N Engl J Med* 2005;353(15):1621-1623.
14. Zerhouni EA. U.S. Biomedical Research: Basic, Translational, and Clinical Sciences. *JAMA*. 2005;294(11):1352-1358.
15. National Institutes of Health. NIH Roadmap – Overview. Bethesda, MD: NIH Office of Portfolio Analysis and Strategic Initiatives. 16 August 2006. <http://nihroadmap.nih.gov/overview.asp> Accessed May 12, 2008.
16. Hillestad R, Bigelow J, Bower A, et al. Can electronic medical record systems transform health care? Potential health benefits, savings, and costs. *Health Aff (Millwood)*. 2005;24(5):1103-1117.
17. Castell W. Proposition for a New and Better Model for Healthcare. Genetic Engineering & Biotechnology News. 2005;25(17). <http://www.genengnews.com/articles/chitem.aspx?aid=719&chid=4> Accessed May 12, 2008.
18. Michener JL, Yaggy S, Lyn M, et al. Improving the health of the community: Duke's experience with community engagement. *Acad Med*. 2008;83(4):408-413.
19. Seipone K, Ntumy R, Smith M, et al. Introduction of Routine HIV Testing in Prenatal Care—Botswana, 2004. *JAMA*. 2005;293(2):152-153.
20. Creek TL, Ntumy R, Seipone K. Successful introduction of routine opt-out HIV testing in antenatal care in Botswana. *J Acquir Immune Defic Syndr*. 2007;45(1):102-107.