December 31, 2006

To: Walter Anderson

From: Lloyd Etheredge[1]

Re: How the UN Can Foster a Rapid-Learning International Health System

Proposal:

The UN convene three regional planning conferences (Asia; Europe (incl. Africa and the Middle East; Western Hemisphere) to discuss emerging opportunities for a rapid-learning international health system. Participants will include leading biomedical research scientists, government officials, and private sector representatives.

Background:

Two developments have created the foundation for fresh thinking and a global, rapid-learning system to accelerate biomedical research and improve health in all countries: 1.) Genome mapping, which (among other benefits) creates the potential for the development of new drugs well-targeted to specific individuals and conditions; 2.) Electronic health records (EHRs), which allow rapid feedback from millions (eventually, billions) of patients about the safety and efficacy of new drugs and optimal treatments. (And, soon, the inclusion of individual-level genome information from each patient.)

In the US, the Institute of Medicine convened a working conference in July 2006 (agenda attached) to articulate a vision to integrate these emerging technologies and create a new US rapid learning system for biomedical research and health. (One major challenge in the US, which does not have a national healthcare system, is to achieve a rapid shift to electronic health records. These must include all of the information that biomedical researchers will want to have, and different EHR systems must use standard definitions and

[1] Lynn Etheredge is responsible for the basic ideas discussed in this paper, in a field where he has taken the lead in the US.

be translatable/interoperable to permit research projects that will draw upon different systems of many different healthcare providers. (The US government also is developing a new system to approve drugs "with learning" - i.e., reimbursing for the additional costs of monitoring results from all patients.)[2] In late January 2007 a special issue of a leading journal, Health Affairs, based on the IOM proceedings, will be published and accompanied by a special symposium for members of Congress and their staffs, with the Secretary of Health and Human Services as the keynote speaker. The government of Great Britain has already announced its own national initiative.[3]

There is an exciting opportunity to get an international system underway. An international system:

a.) Quickly increases the N of the world's databases available for learning (a highly desirable step, given the complexity of the human genome and requirements for very large scale computing);

b.) Assures that medical conditions and diseases affecting UDCs, or relatively small

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[2] In the US, new drugs are approved when they are safe and effective, beyond chance, in randomized clinical trials. Later, many drugs only work for a minority of the patients for whom they are eventually prescribed - with no way of knowing, hit-or-miss, the right match. New drugs also typically are tested on relatively healthy under-65 populations with only the relevant condition - but they are often prescribed, later, to many over-65 patients with multiple health conditions, taking a range of additional medications, without any rigorous or rapid feedback system about effects of drugs under these conditions. It is notable that a recent million-patient study in Great Britain discovered evidence that hormone replacement therapy actually has caused cancer deaths in tens of thousands of women (i.e., including Americans) to whom it was widely prescribed. Such needed discoveries can be made sooner with the new EHR systems: Gina Kolata, "Hormones and Cancer: Assessing the Risks," The New York Times, December 26, 2006, online.

[3] Ben Hirschler, "Half a Million Britons Set for DNA Disease Quest." Reuters online, August 21, 2006.

numbers of people, also will be included for rapid learning.[4] And (honoring appropriate privacy requirements) that patients who can benefit from new discoveries can be identified and informed rapidly by their physicians.

c.) Accelerates learning about environmental health - with data from a wider range of sites, potential early detection of the cumulative health effects of small contaminations in local water supplies, etc.

d.) Makes it more likely that researchers and the biomedical companies in less developed countries will have equal access to research resources and data from all countries.

Implementing a Bold Vision

This is a bolder vision than anyone has yet articulated, internationally, in biomedical science. The key step to create an international rapid learning system is simply for the UN to articulate a vision and bring together specialists from major stakeholders (academic, government, private sector) who can assure common definitions and build the interoperable data and computing systems. (The UN-activated planning process also might address high priority projects and government policies and investments that can accelerate learning.)[5]

- The possibility of international leadership by the US government has been discussed. However this is unlikely to be available, at least for several years. There are perhaps 50 million EHR patient records in the US (including military records in the Veterans

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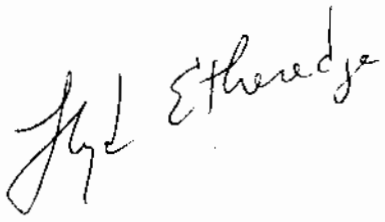
[4] Learning can extend beyond drug- and treatment-efficacy questions. Research already suggests that, in the US, children with chronic conditions and disabilities, especially from poorer families, often receive disjointed and sub-optimal care. These conditions include autism, asthma. cerebral palsy, cystic fibrosis, hemophilia, HIV/AIDS, sickle cell anemia, spinal bifida, muscular dystrophy, mental retardation, etc.

[5] Large countries with capable and visionary governments (e.g., India, China), and/or any countries with an interest to develop their own biomedical research companies also might wish to participate actively.

Administration system). Given the pluralism of the US system, senior government officials believe they must give full time to the priority of developing the US EHR system.[6]



Contact: Dr. Lloyd S. Etheredge
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[6] The Gates Foundation (letter attached) believes this is a bit ahead of where they are.

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THE LEARNING HEALTHCARE SYSTEM

A WORKSHOP OF THE IOM ROUNDTABLE ON EVIDENCE-BASED MEDICINE

July 20-21, 2006

DRAFT Agenda

OBJECTIVE: To characterize the key features of the Learning Healthcare System, to identify the most important hindrances to its evolution, and to posit some remedies.

DAY 1: THE LEARNING HEALTHCARE SYSTEM

8:30 WELCOME: ***Harvey V. Fineberg, Institute of Medicine***

OPENING REMARKS: ***Darrell Kirch, American Association of Medical Colleges***
What would be the features of a healthcare system designed *not* to learn; how might it be corrected?

9:00 SESSION 1: HINTS OF A DIFFERENT WAY - CASE STUDIES IN PRACTICE-BASED EVIDENCE: LEARNING FROM EXPERIENCE

CHAIR: ***Carolyn Clancy, Agency for Healthcare Research & Quality***

What *best practices* might be spotlighted to illustrate ways to use the health care experience as a practical means of both generating and applying evidence for health care? Are there lessons from certain examples that can help identify the most promising approaches?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- Coverage with evidence development: lung volume reduction surgery: ***Peter Bach/CMS***
- Use of large system databases: Cox-2 inhibitors: ***Jed Weissberg/Kaiser Permanente***
- Quasi-experimental clinical trials: drug coverage policy: ***Steve Soumerai/Harvard Pilgrim***
- Practical clinical trials: ***Sean Tunis/HealthTech***

10:30 SESSION 2: THE EVOLVING EVIDENCE BASE—METHODOLOGIC AND POLICY CHALLENGES

CHAIR: ***Don Steinwachs, Johns Hopkins University***

What challenges confront methodologically rigorous learning from experience? How can alternatives to RCTs and innovative approaches to generating evidence be used to confront emerging challenges: broader post marketing surveillance; linking phase 3 and coverage requirements; increasingly complex patterns of co-morbidity; subgroup

analysis and heterogeneity in treatment outcomes? How might learning that is more nimble also foster innovation and discovery?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- Alternatives to large RCTs: ***Rob Califf/Duke***
- Refined subgroup analysis: heterogeneity in treatment outcomes, methods for engaging genetic variation and interpreting data for specific patients: ***David Goldstein/Duke***
- Broader post marketing surveillance for insights on risk and effectiveness: ***Harlan Weisman/J&J***
- Evaluating interventions in a rapid state of flux (e.g. procedures, devices) ***Telba Irony/FDA***

12:00 LUNCH

1:00 SESSION 3: NARROWING THE RESEARCH-PRACTICE DIVIDE—SYSTEM CONSIDERATIONS

CHAIR: ***Cato Laurencin, University of Virginia***

What system changes are needed for the healthcare delivery environment to facilitate the generation and application of better evidence? What are the needs and implications for structuring *built in* study designs, managing the data burden, and defining appropriate levels of evidence needed? What's needed to turn clinical data into an *epidemiologic utility*, a public good?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- Feedback loops to expedite study timeliness and relevance: ***Brent James/IMHC***
- Clinical data system structure and management for better learning: ***Walter Stewart/Geisinger***
- Implications for standards of evidence: ***Steve Pearson/AHIP***
- Implications for innovation acceleration: ***Bob Galvin/GE***

2:30 SESSION 4: PANEL DISCUSSION—KEY BARRIERS AND PRIORITIES FOR ACTION

CHAIR: ***Denis Cortese, Mayo Clinic***

- ***Members: IOM Roundtable on Evidence-Based Medicine***

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DAY 2: ACCELERATING THE PROGRESS

8:30 AM OPENING REMARKS: ***Denis Cortese, Mayo Clinic & IOM Roundtable Chair***

What are some of the key challenges and opportunities if the development of a sustainable capacity for real-time learning is to be accelerated?

9:00 SESSION 5: HINTS OF A DIFFERENT WAY—LEARNING SYSTEMS IN PROGRESS

CHAIR: ***Jonathan Perlin, Department of Veterans Affairs***

What experiences of healthcare systems highlight the opportunities and challenges in integrating the generation and application evidence for improved care? What's needed to take to scale?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- Veterans Health Administration: ***Joel Kupersmith/Department of Veterans Affairs***
- AQA (Ambulatory Care Quality Alliance): ***George Isham/HealthPartners***
- Practice-Based Research Networks: ***Bob Phillips/American Academy of Family Physicians***
- Rapid Learning Health Systems: ***Lynn Etheredge***

10:30 SESSION 6: DEVELOPING THE TEST-BED: LINKING INTEGRATED DELIVERY SYSTEMS

CHAIR: ***Helen Darling, National Business Group on Health***

How can integrated healthcare delivery systems be better engaged for structured real-time learning? How can the organizational, logistical, data system, reimbursement and regulatory issues be addressed?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- NIH & Re-engineering Clinical Research : ***Steve Katz/National Institutes of Health***
- AHRQ's Action network: ***Cynthia Palmer/Agency for Healthcare Research & Quality***
- HMO research network: ***Eric Larson /Group Health Cooperative***
- Council of Accountable Physician Practices: ***Michael Mustille/Kaiser***

12:00 LUNCH

12:30 SESSION 7: THE PATIENT AS A CATALYST FOR CHANGE

CHAIR: ***Andy Stern, Service Employees International Union***

What is the changing role of the patient in an age of the Internet and the personal health record? Reengineering a system focused on patient needs and built around best care requires improved communication of evidence. How does patient preference fit into evidence development?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- The Internet, eHealth and patient empowerment: ***Janet Marchibroda, eHealth Initiative***
- Joint patient-provider management of the EHR: ***Andy Barbash/PHR***
- Evidence and shared decision making: ***James Weinstein/Dartmouth***

1:45 SESSION 8: TRAINING THE LEARNING HEALTH PROFESSIONAL

CHAIR: ***Nancy Nielsen, American Medical Association***

What are the educational needs for the health professional in the Learning Healthcare System? How must qualification exams and CE be adjusted? What approaches can bring the processes of learning and application into sync?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- Health professions education and teaching about evidence: ***Mary Mundinger/Columbia***
- Providers and the EHR as a learning tool ***William Stead/Vanderbilt***
- Redefining continuing education around evolving evidence: ***Mark Williams/Emory***

2:30 SESSION 9: STRUCTURING THE INCENTIVES FOR CHANGE

CHAIR: ***Steven Udvarhelyi, Independence Blue Cross***

What policies can provide the incentives for the developments necessary to build learning—evidence development *and* application—into every healthcare encounter?

15 MINUTE PRESENTATIONS FOLLOWED BY DISCUSSION SESSION

- Opportunities for private insurers: ***Alan Rosenberg/ Wellpoint***
- Opportunities for CMS: ***Barry Straube/ CMS***
- Opportunities for Manufacturers ***Cathy Bonuccelli/Astra Zeneca***
- Opportunities for standards organizations: ***Peggy O'Kane/ NCQA***

4:00 CONCLUDING SUMMARY REMARKS

Denis Cortese, Mayo Clinic

J. Michael McGinnis, Institute of Medicine

4:30 ADJOURN

BILL & MELINDA GATES *foundation*

August 24, 2006

Dr. Lloyd S. Etheredge
Director
International Scientific Networks Project
The Policy Sciences Center, Inc.
7106 Bells Mill Road
Bethesda, MD 20817

Dear Dr. Etheredge,

Bill Gates Sr. forwarded me your recent letter in my role as the Deputy Director for Access and Delivery of the Bill and Melinda Gates Foundation's Global Health Strategies program, which coordinates programs related to health systems strengthening. Thank you for the information on the new national rapid learning system. The contributions of the Institute of Medicine and Robert Wood Johnson Foundation are exciting developments.

The work you're involved with is obviously significant, and we are grateful that you are working on this important health system issue. Our current priorities are focused on a relatively small number of diseases and conditions that cause the greatest mortality in the poorest people in the poorest countries in the world. As such, we have invested in strengthening health information e.g. vital records, disease surveillance and other important health information systems in the developing world through an alliance of stakeholders called the Health Metrics Network (HMN). I will share this information with HMN as they work on developing health data for the developing world. We are pleased to know of the commitment of you and your colleagues. Thank you for this opportunity to review your program information and we wish you every success in your future efforts.

Sincerely,

Kathy Cahill

Kathy Cahill

Cc: Mr. Bill Gates Sr.
Dr. Tachi Yamada
Dr. David Fleming

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