Harnessing Openness to Transform American Healthcare

A Report by the Digital Connections Council of the Committee for Economic Development

Committee for Economic Development

The Digital Connections Council (DCC) of the Committee for Economic Development (CED) has been developing the concept of openness in a series of reports. It has analyzed information and processes to determine their openness based on qualities of "accessibility" and "responsiveness." If information is not available or available only under restrictive conditions it is less accessible and therefore less "open." If information can be modified, repurposed, and redistributed freely it is more responsive, and therefore more "open."

This report looks at how "openness" is being or might usefully be employed in the healthcare arena. This area, which now constitutes approximately 16-17 percent of GDP, has long frustrated policymakers, practitioners, and patients. Bringing greater openness to different parts of the healthcare production chain can lead to substantial benefits by stimulating innovation, lowering costs, reducing errors, and closing the gap between discovery and treatment delivery.

The report is not exhaustive; it focuses on biomedical research and the disclosure of research findings, processes of evaluating drugs and devices, the emergence of electronic health records, the development and implementation of treatment regimes by caregivers and patients, and the interdependence of the global public health system and data sharing and worldwide collaboration.

Biomedical Research

Biomedical research is being transformed by the success of the Human Genome Project (HGP). By mapping the human genome, the HGP demonstrated the possibilities of mass collaboration and the beneficial results of allowing data to be accessed immediately and manipulated by researchers around the world. The progeny of the HGP have adopted this open model and are flourishing by sharing data, applications, and even network resources. The Council recommends that the federal research agencies push further by enunciating clear policies favoring openness, funding further work on standards for protocols, formats, terminology and nomenclature that allow the sharing and manipulation of data, and supporting experiments with differing levels of openness to determine the optimal level for research under various scenarios.

Clinical Trials

Questions about the openness of clinical trials have been raised vigorously over the last decade. Although the Food and Drug Administration (FDA) had long required the registration of clinical trials involving life-threatening interventions, there have been disputes as to the completeness of these registrations—and about the lack of registration of other clinical trials. Advocates of greater openness have been concerned not only about registrations, but also about access to trial results and, perhaps more important, to the data that underlie the results—and whether the data will be available in a computable form.

Because clinical-trial populations do not fully reflect the broader populations that will later use the intervention—or the length of time that they will use it—many adverse effects may not be discovered through clinical trials, raising questions about drug safety and the processes for monitoring drug impacts after approval. Amendments to the FDA's enabling legislation in 2007 addressed these issues in part, but there are additional ways in which greater openness can improve clinical trials and post-approval surveillance. Most important for improved healthcare research is to make the trial results and the data underlying trials more accessible more quickly in a form that is searchable and computable using common standards. In addition, applicants for FDA approval should be required to submit all studies they have conducted on the intervention with any safety-related results being made publicly available.

The system would also be improved by strengthening the protections for trial participants, ending split federal oversight of trials, and clarifying the laws regarding tissue donations. The Council joins others recommending far more comparative testing of drugs to supplement clinical trials that simply compare an intervention's effects with those of a placebo.

Disclosure of Results and Underlying Data

Common to both basic research and clinical trials are issues surrounding what results and what data are made public and when? Of concern is how data will be published or disclosed, given the rise of new disclosure models, ranging from the filing of human genome sequences in the open GenBank to new open-access scientific and technical journals and open-access archives.

The Council recommends federal support for earlier and expanded accessibility to results and data, and the passage of legislation that would mandate public access to results of most unclassified government-funded research. Major government funders of research should also be receptive to requests for funding for the publication of research results in open-access journals.

Electronic Health Records

The emergence of electronic health records (EHRs) raises new openness issues. Utilizing such records, caregivers at any location would have access to a patient's medical history. Results of tests and treatments could be added easily as they become available, thereby improving treatment, preventing duplicative testing, and

reducing medical errors. Eventually, EHRs could be constructed including family medical histories, genomic and pharmacogenomic data, environmental exposures, lifestyle and other information, easing the way toward the "personalization" of treatment. The aggregation of such records and others could then facilitate the achievement of a genuine "evidence-based" medical system. Such records provide far richer data than clinical trials, and could serve as the basis for predictive models similar to those used in other scientific domains.

Privacy and Security

But the openness of the EHR that allows more efficient collection of more data and permits improved caregiver access raises fundamental issues of privacy and security that will tend to limit openness. Who will have access to these records and under what circumstances? How will the information be used? Who will make these decisions?

New rules will need to be extended to any entity that handles patient-identifiable healthcare information, and new resources will be needed to support vigorous enforcement of privacy and security rules. To foster comparative testing of drugs and treatments, strengthen drug and device safety monitoring, and spur development of evidence-based medicine and the generation of clinical-practice guidelines that would bridge the gap between discovery and treatment, the Council calls for a public-private partnership to create large databases made up of EHRs, health-insurance-claims data, and clinical-trial data, etc., appropriately de-identified to protect patient privacy.

New Sources of Information for Patients and Caregivers

Patients are now able to search through a vast store of health-related information on the Internet and even provide their caregivers with current research. They can customize their own treatment through shared decision making with their caregivers, and continuously contribute data through the use of remote-monitoring equipment. With greater access to information about the quality and costs of procedures and practitioners, patients can become more responsible healthcare consumers; good caregivers should benefit as poorer performers are weeded out. But information can be used in harmful ways such as the adverse selection of sicker patients or of talented, but less cost-conscious, caregivers.

The Council recommends that the federal government move aggressively to disclose data on the cost and quality of healthcare providers and procedures, and to monitor and provide financial incentives for compliance with evidence-based, clinical-practice guidelines. Given the explosion of caregiver-affiliated enterprises that provide patient testing or treatment, conflicts of interest by caregivers need to be disclosed. To avoid disincentives for the use of remote monitoring and telemedicine, the federal government should review its reimbursement policies and work with the states to address conflicting state licensing and malpractice rules.
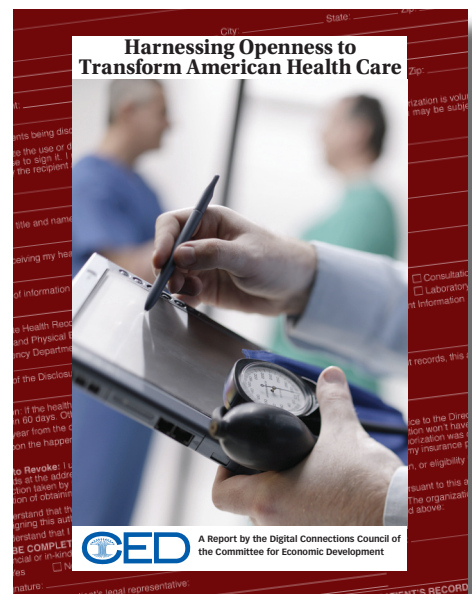
Public Health

The global public health system depends on data sharing and worldwide collaboration; without it, as seen in the Severe Acute Respiratory Syndrome (SARS) experience, the lives of millions are threatened. With lower-income countries showing reluctance to share data and physical evidence, the Council recommends greater attention to ensuring that all countries benefit from discoveries that result from the global sharing of data related to the emergence of new diseases. Better electronic linkages among public health agencies, both globally and locally, and a willingness to develop new detection methods, are also necessary.

Medical Devices

Greater openness in software-controlled medical devices creates new opportunities and challenges. The history of practitioner innovation in scientific instruments and the infinite malleability of software suggest the potential for a dramatic increase in practitioner-driven customization of such devices. At the same time, the FDA continues to have responsibility for assuring the safety and efficacy of these devices and has justifiable concerns about post-approval changes made to them. The Council recommends that the FDA begin an examination of how to benefit from the user-driven innovation while maintaining appropriate oversight for safety and efficacy.

Conclusion

Greater openness is likely to become increasingly important in areas driven by the relentless progress of information and communications technology. We expect that modest changes based on greater access to information by more people, and more possibilities for them to contribute based on their own expertise and energy, will help improve healthcare in the United States and around the world.

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The full statement is available at www.ced.org.