A REPORT OF THE CSIS GLOBAL HEALTH POLICY CENTER

Information Technology in Health Care E-HEALTH FOR JAPANESE HEALTH SERVICES

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FOREWORD

The Center for Strategic and International Studies (CSIS) in the United States and the Health and Global Policy Institute (HGPI) in Japan launched a joint project to create a dialogue on major health care policy issues and solutions in the two nations in early 2011.

In both nations, new health care policies will clearly be necessary to meet citizens' current and future demands for affordable, available, and quality health. Greater efficiencies in health care will be essential for each nation to renew and sustain economic growth over the long term.

This dialogue among national experts and senior leaders is based on the opportunities to learn from the overall similarities of the two nation's health care systems. Both the Japanese and the U.S. health care systems have multiple insurers, a fee-for-service payment system, and thousands of independent hospitals and physicians.

The project—for the first time—introduces experts and leaders from Japan and the United States to the similarities of the two nations' health care systems' problems and solutions.

The goal of the project is to generate fresh analyses and recommendations in critical areas of health care in Japan and the United States. It provides an opportunity for informed discussion of pragmatic next steps to address priority health care concerns. It aims to generate pragmatic and actionable options in each key policy area that can increase the efficiency and quality of health care.

This project's initial efforts focused on options for health care policies that addressed the development of health care information systems and the design of hospital payment reforms. The CSIS/HGPI report Information Technology in Health care: e-Health for Japanese Health Services was authored by Masanori Akiyama, MD, PhD, and Ryozo Nagai, MD, PhD. This report provides challenges and recommendations for Japan in introducing e-health.

After the Japan-U.S. Health Policy Dialogue was initiated by CSIS and HGPI in January 2011, the Tohoku earthquake, tsunami, and radiation disaster occurred on March 11. It has now been agreed by CSIS and HGPI that the next phase of the Japan-U.S. Health Policy Dialogue will shift the project's focus to collaborative U.S.-Japan efforts to the respond to the health implications of the disaster.

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INFORMATION TECHNOLOGY IN HEALTH CARE E-HEALTH FOR JAPANESE HEALTH SERVICES

Masanori Akiyama and Ryozo Nagai¹

Introduction

As Japan faces rapid aging, a declining birthrate, widening income disparity, expanding fiscal debt, and remarkable hikes in health care costs, the sustainability of its health care system is at stake. Despite the need to allocate limited medical resources optimally, Japan lacks a common platform for sharing medical data, ideally over the Internet. The potential benefits of health information technology, or health IT, are not well known among patients, practitioners, or policymakers. Electronic patient records are not available from one hospital to another and are isolated from the Internet due to privacy concerns. Clinical practitioners have no remote access to patients' information when away from a particular hospital or clinic. Unique medical data, stored individually in each hospital or clinic, is vulnerable to accidents and natural disasters. The Tohoku disaster demonstrated the absence of a reliable backup for health data, the challenge of data management during an emergency, and the dangers of prescribing drugs with insufficient access to medical records.

It is therefore critical to move toward an improved, Internet-ready health IT system. An ehealth system presents an effective and efficient means to reduce costs and improve the quality of health care services. Moving forward on a discrete set of sensible policy and operational reforms is possible and timely, as the Tohoku disaster provides a mandate to change the way the Japanese health system operates.

Why e-Health?

The ultimate measure of medical practice is the health of the patient. Failure to share data not only affects patients' health and quality of life, but also burdens the national economy with immense medical expenditures. Developing a disease registry and sharing data through a comprehensive medical information network would help identify useful trends in serious clinical events, such as stroke and heart failure.

A primary goal of electronic patient records is to collect all essential data. The input forms have required fields, and the electronic format minimizes the risk that information is subsequently

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lost. For example, the electronic records used in primary care include recording templates to ensure that key demographic, clinical, physiological, biochemical, and pharmaceutical variables are collected systematically, in a standardized manner for all patients.

Data integrated across medical centers would enable efficient detection of any adverse effects of drugs and medical devices. The construction of a comprehensive network of electronic records is essential to detect adverse effects as quickly as possible.

At present, Diagnosis-Procedure Combination (DPC) data are used to compare treatment methods and costs for the same disease across medical institutions, with the aim of improved medical decisionmaking. Until DPC data are integrated with electronic patient records, however, it will be difficult to determine the best use of limited medical resources.

Health IT is a solution to many of the challenges Japanese health care faces. In particular, e-health improves patient safety at the point of care: it facilitates better clinical decisions; it saves time for doctors; and it reduces prescription-drug-related error. Health IT makes it easier to evaluate essential data on the patient's identity and medical history, as well as medicines to be used and medical personnel required, every time a new intervention is needed.

New technologies have the capacity to extend and replace existing clinical and administrative processes in health. Technological innovation is one component of a larger process of change, which will ideally represent a new way of working, an attitude and a commitment for networked thinking to improve health care at all levels.

Issues with the current system:

- The current Japanese health care system presents five primary obstacles to effective e-health: No interoperability among different systems: Each manufacturer provides electronic record systems with highly complicated specifications incompatible with other systems. In the interest of privacy, electronic patient records are disconnected from the Internet, making them inaccessible to clinical practitioners outside that particular hospital or clinic and preventing telemedicine. Moreover, storing medical data within each hospital or clinic causes severe difficulties in the case of an accident or natural disaster, in which physical records may be lost or destroyed.
- 2. *Insufficient privacy protections:* Because clinics and hospitals have not sufficiently invested in the security of their own electronic record systems, have not fully understood the benefit of Internet access to electronic records, and have proven unwilling to take any risks of data leakage, connecting electronic patient records to the Internet is not seen as a practical option. Japan lacks practical standards for protecting patient medical data. The government's guidelines remain vague and fail to designate the institutions responsible for ensuring compliance with national privacy law. This lack of clarity deters clinics and practitioners from connecting electronic patient records to the Internet, as they fear potential government penalties.
- 3. *No universal registry of hospital and clinic data:* A comprehensive disease registry is essential to provide data for future clinical studies. Japan lacks a system that would enable hospitals and clinics to share daily treatment data. Insufficient financial support has prevented the development of such a system, as has hesitance to connect patient records and electronic charts to any independent registry. Effective clinical outcomes are possible at less cost if Japan can aggregate sufficient population-based health data to develop new medicine, clinical trials, and other research to improve treatment. Furthermore, the accumulation of such data, knowledge, and

experience will raise the effectiveness of medical practice and prevent harmful side effects by incorporating feedback from clinical practitioners.

- 4. *Bureaucratic divisions:* Jurisdiction over electronic patient records overlaps among the Ministry of Health, Welfare, and Labor, the Ministry of Economy, Trade, and Industry, the Ministry of Education, and the Ministry of Internal Affairs and Communications. Ministries have no incentive for cooperative planning to promote compatibility among electronic record systems. Only after the recent Tohoku earthquake is the MyHospital Project finally underway. The project, run by the Ministry of Internal Affairs and Communications, aims to establish a communication system in which clinical practitioners can check patients' prescriptions from outside hospitals and clinics. The MyHospital Project is only a preliminary trial, however, and the Japanese government needs to promote such a compatible system vigorously and in unity.
- 5. *Potential for clinical error:* Even as new clinical decision support systems are introduced, significant gaps exist in the data on which new tools are based. There is a risk that the increasing sophistication of such tools makes these gaps and potential errors in design less visible.

Furthermore, the impact of incorrect recommendations by clinical decision support systems extends beyond the risk of harm to the patient in question. If clinical decision support systems are perceived to produce unreliable reports, clinicians will be reluctant to use such systems in routine practice, negating their potential benefits. Active quality assurance—such as algorithms that check the consistency of the systems' outputs—will be necessary to assuage these concerns and mitigate the risk of covert, behind-the-screen error. An effective interface that requires active confirmation of inputs can limit user error, but interfaces that are confusing or illogical can induce errors by even the most skilled users. Successful interface design requires a detailed understanding of how a technology will be used and in what work environment to predict errors that might arise and plan for them.

Three Key Principles

What would a comprehensive e-health system look like in practice at the clinical level? Implementation of an effective health IT system would rest on three primary priorities:

1. A shift from a financially oriented system to an integrated one: Although hospital information systems in Japan have long been focused on the financial aspects of health care, efficiency has not been appropriately addressed. The Japanese billing system uses an "insurance disease name" to specify how the practitioner should be reimbursed and therefore pays for whatever tests and operations are performed or resources used, providing little incentive to reduce usage. Ostensibly, the primary role of health information systems is to manage patient information and to centralize ordering. The existing systems, however, have been used primarily for preparing medical payment requests.

As a result, the existing systems cannot handle and do not receive data on clinical activities that are irrelevant to medical insurance payments. In these circumstances, when certain expenses are not covered by medical insurance, it has not been possible to make accurate cost calculations for materials and personnel based on the data in the medical financial systems. The problem is that clinical systems have served primarily as a means of supplying the appropriate billing

information to the health information services, rather than as a means of providing medical practitioners with the clinical information they need.

Therefore, it is necessary to change from a financially oriented system to an integrated architecture that supports billing and medical workflow management. Calculating medical care costs, with all of its difficulties, has become possible with the Point of Action System (POAS), a design feature of a comprehensive medical information system. POAS allows input into logs and inventories as clinical activity unfolds—at the "point of action"—creating a real-time record of which practitioner did what to which patient, when, where, using what, and for what reason. Over the last nine years, a POAS system has been in continuous operation at the International Medical Center of Japan, handling 100 transactions per second, or 360,000 per hour. Such a system improves hospital operation and encourages best medical practices, though its installation requires a complete overhaul of the system design.

- 2. *The introduction of e-prescriptions, as well as electronic identification and tracking of patients and drugs:* Prescription errors are among the most common medical mistakes and risk death or disability for the patient. Although most serious problems originate with the initial prescription order, errors are possible at each stage of the process:
 - Decision errors—failing to account for relevant comorbidities, the patient's use of other medications, previous reactions, and the like;
 - Calculation errors—failing to calculate the appropriate dosage;
 - Communication errors—failing to write the drug and dosage correctly and legibly, prescribing drugs for the wrong patient, providing ambiguous directions to the pharmacy, or processing prescriptions too slowly;
 - Monitoring errors—failing to track drugs for which accumulated toxicity requires timelimited or closely monitored treatment;
 - Slips or attention errors—packaging drugs under the wrong label or at the incorrect dose, or dispensing drugs to the wrong patient.

Electronic systems offer not only to process prescriptions more efficiently but also to inform and enhance the safety of clinical decisions. Like other decision support systems, e-prescriptions record and display relevant details in real time, making essential information more accessible to practitioners and reducing their propensity for mistakes. Increasingly sophisticated tools can integrate relevant history—such as recent laboratory results—with risks and contraindications specific to each medicine. Designed correctly, e-prescription software interprets data, flags potential mistakes, presents prescription information unambiguously, and transmits it electronically to those who need it.

POAS functionality and e-prescriptions go hand in hand with more efficient electronic identification and tracking of patients and drugs. Identification and tracking technologies—typically using bar codes—are pervasive in commercial settings but have yet to realize their potential in health care. The implementation of such a system—labeling prescription drugs with bar codes and asking patients to wear tags with bar codes or radio frequency identification (RFID) chips—makes it easier to provide the right drugs to the right patient and, as part of a broader clinical decision support system, lowers the risk of doctor error. An integrated identification and tracking system also provides extensive data on hospital processes, the flow of practitioners, tests, procedures, and the use of drugs and other resources—creating a natural resource for studies on clinical practice and a forensic tool to reconstruct the journey leading to any clinical incident. Similarly, bar code and RFID provides real-time stock management capabilities, as a central computer system tracks hospital resources.

A potential concern is the current lack of regulatory oversight and consistency among systems. For example, prescribing systems are exempt from federal oversight in the United States and the United Kingdom. While empirical benefits-including a reduction in preventable adverse events—have been shown with in-patient care, these studies have generally been carried out in centers of excellence with home-grown software. A 2000 Cochrane review suggested that dosage advice can decrease adverse drug reactions and can improve performance with drugs that pose a toxicity risk. The efficacy of systems that flag drug interactions and allergies is also unclear. Clinical decision support systems that include drug management appear to improve clinical performance, but have not shown

Adverse Clinical Events

Worryingly, clinical events that risk harm to patients appear to be extremely common. With increasing social demand for the prevention of medical accidents, the Ministry of Health, Labor, and Welfare in Japan began collecting data in 2001 on "medical near-misses and adverse events" in order to analyze case studies and identify measures to improve medical safety. In 2004, the Japan Council for Quality Health Care took over the collection of incident case studies.

Most events have a mixture of latent and active contributory causes, which complicates their analysis and makes it difficult to identify strategies for prevention. Each "fix" has a cost-benefit profile, and changes to established processes present their own safety implications.

Although high rates of reporting have reduced adverse events in other industries, there is significant underreporting in health care, as the process is voluntary. The reasons for this are complex and include fear of blame, organizational culture, lack of reminders, and other demands on time.

Automated post-hoc identification of adverse events holds significant promise to address underreporting issues. Data-mining technology can help identify threats to patient safety, particularly clusters of adverse events or deaths following health care interventions.

concomitant benefits in terms of patient outcomes. When flagging systems are optional, they appear to be used infrequently, while routine flagging may come to be viewed as an unwelcome distraction. In a 2002 survey of UK general practitioners, 28 percent admitted to frequently or very frequently dismissing electronic alerts without reading them. These concerns suggest the need for a comprehensive system that supports decisionmaking in redundant fashion, looking for mistakes at each level of the clinical and drug-dispensing process.

3. *Careful management of the transition to new technology:* The effects of dramatic changes to current practices and familiar tools can be difficult to predict and must be managed carefully. The introduction of new technology can change the behavior of users, who may resist new systems, use them incorrectly, or miscalculate how much time and attention various tasks now require. Introducing new systems too quickly or failing to address these possible effects carries the risk of patient harm. By designing user-friendly systems and making the case to clinicians for the utility of new tools, however, policymakers and leaders in the health care industry can facilitate adoption of e-health technology.

There are a number of methodologies for evaluating new health IT tools. The critical gap between the benefits anticipated from theoretical work and those realized in clinical practice can only be addressed through well-designed evaluation programs. Successful evaluation programs involve systematic planning and oversight throughout the life span of each technology, as the challenge shifts from implementing new tools to maintaining them—training, sustainability, and service-level issues. A robust strategy must also identify and address the unpredicted consequences of new technologies, a task that may extend beyond the implementation phase. Measuring the impact on patient safety should be a recurring and explicit program of work throughout the life cycle of every relevant IT tool.

Policy Recommendations

The implementation of a comprehensive health IT system throughout Japanese health care will necessitate support and e-health-friendly policies at a national level. If Japan is to see cost savings and improved clinical outcomes through health IT, the Japanese government should:

- Adopt a long-term goal and strategy: Japan needs to establish a long-term vision for e-health. The long-term goal is to achieve a sustainable health system with optimal utilization of limited medical and financial resources by making e-health the foundation of Japanese health care. Japan needs a common platform for sharing medical data over the Internet. Designing a standardized system calls for national leadership, perhaps including a National Council for Health IT, established under a cabinet office and chaired by the prime minister.
- 2. *Create incentives for participation:* To make e-health sustainable, Japan needs to create incentives for hospitals and clinics to contribute health and treatment data within the existing insurance structure. It is important to start with a voluntary or opt-in/opt-out mechanism. Eventually, making insurance repayment conditional on participation in a national registry could provide an incentive to keep the database robust and sustainable.

The Japanese government should also look to eliminate the disincentives that deter participation in a national e-health system. Ambiguity about government privacy regulations and concerns about the security of electronic patient records, as discussed above, are sources of concern that can be addressed with policy clarity and well-designed technology.

- 3. *Adopt a national health ID:* The current discussion of national ID—led primarily by the Ministry of Finance—focuses on the introduction of a social security ID for social welfare and taxation purposes. The introduction of a health ID is less controversial, however, and should be discussed separately. The first phase of a health ID system should not be mandatory but should instead offer opt-in or opt-out options. The voluntary contribution of health data tied to personal IDs could establish the basis of a more comprehensive e-health system.
- 4. Standardize electronic patient records: The standardization of electronic patient records has been discussed, but these discussions have so far focused on the convenience of the individual patient and not on using medical information to evaluate the present state and effectiveness of medical practice. Consistent medical records, available electronically and comparable to each other, would allow epidemiological analysis and cost-effectiveness studies in real time, providing data for medical policymaking and guiding medical innovation.

5. *Regulate e-health software:* A recurring theme in health IT is the lack of regulation for medical software. Japanese regulatory authorities have significant scope to exact the same demands for reliability as in other industries in which software tools are mission critical. The complexity of medical systems is often cited as a barrier to regulation; however, simple parameters like system upload time are easily measurable.

Standards in health informatics focus on two main areas: data capture and data exchange. Regulations in both categories hold the potential to address a number of issues. Ensuring that data inputs are comprehensive is essential for many tools with potential clinical benefits, such as e-prescriptions and clinical decision support systems. Facilitating data exchange likewise has direct safety implications: systematic transfer reduces the likelihood of transcription errors and physical loss of data. When patients are receiving care from many different providers, particularly in emergencies, the easy and reliable electronic transfer of their clinical records has clear benefits. Furthermore, disease and intervention taxonomies and terminologies also need to be considered in a process of standardization.

Conclusion

A key lesson from the countries that have successfully implemented health IT is that a commitment from the funders of health care (governments, national insurance schemes, or third parties) to meet the costs of IT solutions is essential to ensuring their rapid and effective adoption. Countries where this is not the case, such as the United States, have had a much lower uptake of essential technologies, such as electronic patient records, than countries—such as many in the European Union—where funders have shown greater commitment.

Although IT solutions have considerable potential to heighten the efficacy of medical practice and improve patient safety, there is currently a gap between the theoretical benefits and those that have been empirically demonstrated. Future e-health applications should be evaluated against a comprehensive and rigorous set of measures at all stages of the application life cycle. Attention must also be paid to professional dynamics and ease of use—the human factors—to maximize the likelihood of successful adoption. It is necessary to make the case for new technologies to clinicians and other professionals and to provide adequate training to allow them to use health IT solutions appropriately.

It is also important that methods for effective data exchange among IT systems are in place, both to realize the full benefits of health IT and to limit the workload and errors that can arise from duplicative and unnecessary data entry. DPC data, electronic patient records, health insurance claims, and a national disease registry for clinical study should be combined into one database system—e-health.

Finally, the implementation of IT solutions in health care should be linked to an effective research, development, and evaluation agenda to ensure that the Japanese health care system adopts only those technologies that have a real impact on the safety, quality, and efficiency of medical care.

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