

White Paper ■

Patient-centered Applications: Use of Information Technology to Promote Disease Management and Wellness. A White Paper by the AMIA Knowledge in Motion Working Group

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Abstract Advances in information technology (IT) enable a fundamental redesign of health care processes based on the use and integration of electronic communication at all levels. New communication technologies can support a transition from institution centric to patient-centric applications. This white paper defines key principles and challenges for designers, policy makers, and evaluators of patient-centered technologies for disease management and prevention. It reviews current and emerging trends; highlights challenges related to design, evaluation, reimbursement and usability; and reaches conclusions for next steps that will advance the domain.

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Introduction

Advances in information technology (IT) have introduced new design approaches that support health care delivery and patient education. Such advances enable a fundamental redesign of health care processes based on the use and integration of electronic communication at all levels. Health-care IT has the potential to empower patients and support a transition from a role in which the patient is the passive recipient of care services to an active role in which the patient is informed, has choices, and is involved in the decision-making process.

New IT tools can enhance and supplement communication between health care professionals and patients. As a result, many informatics researchers and system designers who previously focused on designing IT applications that addressed the needs of health care providers and institutions are shifting toward patient-centered applications. Previous data models included episodic patient encounters as one type of health care transaction but did not capture the life

course of the individual patient or consistently take an approach to ensure continuity of care. New technologies and advances in informatics research will enable support of patients as active consumers in a health care delivery system that is evolving from an institution-centric to a patient-centric model.¹

Information technology tools can support interventions focusing on disease management and wellness. A disease management intervention is defined as “a set of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant.”² Disease management programs aim to support patient-specific care plans and the provider-patient relationship via evidence-based guidelines. They focus on prevention of deterioration and/or complications. In the context of consumer empowerment, the paradigm of disease management can be extended to wellness management, where the focus is on the maintenance and improvement of the health status of any individual.

Patient-centered applications are defined as systems that enable a partnership among practitioners, patients, and their families (when appropriate) to ensure that procedures and decisions respect patients’ needs and preferences. Developers should solicit patients’ input regarding the education and support that patients require to make decisions and participate in their own care.³ Such applications bridge clinical and nonclinical sectors and include both individual and population health-oriented tools. They encompass different communication channels such as web-based systems, portable monitoring tools, and mobile devices.

The Knowledge in Motion Working Group of the American Medical Informatics Association coalesced from the merger of three previous working groups: Internet, Telehealth, and Mobile Computing. The working group produced this white paper to define the key principles and challenges for designers, policy makers, and evaluators of patient-centered tech-

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nologies designed for disease prevention and management. The paper reviews current and emerging trends; highlights challenges related to design, evaluation, reimbursement, and usability; and reaches conclusions for next steps that will advance the domain.

Review of Applications

Internet-based Applications

The Internet provides a platform for consumers to access health information. The number of web-based patient education sites that provide access to information related to patients' conditions has been increasing. The web enables patients communication between patients and health care providers⁴ or among patients and/or community members. Internet technologies have been utilized for disease management in many clinical areas, e.g., in asthma and diabetes management, where frequent monitoring can lead to early detection of potentially critical situations and timely intervention. In this context, a distinction needs to be made between applications that support pure self-care (without involvement of a health care provider) and applications that provide IT-enabled provider support of self care or disease co-management (vs. the traditional model of provider-administered and controlled care delivery).

One example of IT-enabled self care is the home asthma telemonitoring⁵ system, which provides patients with continuous individualized help in the daily routine of asthma self-care. Extensive evaluations of the CHESS system (Comprehensive Health Enhancement Support System), an interactive computer system containing information, social support, and problem-solving tools for different patient groups (e.g., breast cancer patients, HIV patients), show the potential of web-based applications to increase disease knowledge, education, and social support.⁶

Most Internet-based health intervention studies have measured immediate, IT-focused nonclinical outcomes of Internet utilization for disease management, including features accessed by the patients,⁷ patient experience and satisfaction,⁸ or general health portal reliability.⁹

In general, it is difficult to characterize the effect of patient-centered applications compared with other interventions due to difficulty in teasing out the independent contribution of the technology. A systematic literature review focusing on the effects on health and social outcomes of computer-based peer-to-peer communities and electronic self support groups¹⁰ came to a similar conclusion, indicating that no robust evidence exists yet for the effects of such communities.

Mobile Devices

Mobile health applications focus on serving the needs of the user by providing widespread access to relevant information and/or remote data capture, thus eliminating the need for the user to be physically linked to a network or restricted to a specific geographic location.

The use of mobile IT devices such as personal digital assistants (PDAs) and cellular phones in health care is increasing. For health care practitioners, the use of mobile IT can bring additional resources to the point of care and can change the location of that point of care. Earlier research into

using mobile IT devices, such as PDAs or cellular phones, emphasized the collection of data from the patient to facilitate clinician decision making.¹¹ There are a few applications that provide real-time decision support to patients as well.¹² Despite the movement toward patient-centric applications, most applications described in the literature follow the old model of decision-making in which the patient is a receiver of instructions rather than a participant in the management process.¹³ In these applications, it is assumed that patients will comply with recommended interventions and there is little follow-up to examine whether and how the patient did so.¹⁴

Patient-centered mobile health care applications have often targeted the areas of asthma,¹⁵ diabetes,¹⁶ and chronic obstructive pulmonary disease (COPD).¹⁷ Mobile health promotion or wellness applications have primarily addressed smoking cessation,¹⁸ nutritional intake,¹⁹ and vaccinations.²⁰ In the popular media but not yet in scientific literature, there have been descriptions of how MP3 players²¹ and iPods²² might promote wellness activities and patient education. As noted by Moen and Brennan,²³ consumers use complex strategies for managing their health information (storing information throughout multiple spaces in their household, recording with different media, and organizing data based on perceived urgency of the information), and technology designers should incorporate these strategies into their mobile IT designs for health management.

Home Telehealth Applications

Home telehealth applications (also known as telehomecare applications) utilize telecommunication and videoconferencing technologies to enable a health care provider at a clinical site to communicate with patients in their homes. Such an interaction via videoconferencing is called a virtual visit. In this context, the term actual visit is used to describe the traditional visit of the health care provider to the patient's home that includes a face-to-face interaction. In addition to the use of videoconferencing to enhance interactions, telehomecare applications utilize vital sign and other reporting devices that allow patients to become more involved and in many cases to oversee the monitoring process.

Johnston et al.²⁴ evaluated the use of remote video technology and monitoring devices in the home and determined that it achieved cost savings and improved access to home care support while producing no differences in clinical outcomes when compared with traditional care. A recent clinical trial at the Veterans Affairs Palo Alto Health Care System explored the use of a simple telephone-based device to ask patients a series of questions related to their health on a daily basis²⁵ and demonstrated a significant decline in readmissions as a result of this simple asynchronous monitoring process.²⁵ Health-related outcomes, including patient compliance, morbidity, and mortality, have been studied less often. Most such studies have had a maximum follow-up of one year and therefore are not able to evaluate long-term outcomes.

Usability and User Acceptance

The usability of mobile health systems is a key factor in the acceptance and diffusion of such technology in disease

management and wellness promotion. In this context, four factors need to be addressed: user-friendliness, usability, user competence, and confidence.²⁶ The first two factors deal mostly with the type of mobile technology (hardware matters such as size, noise, aesthetic presence, and obtrusiveness, and software matters such as user interfaces and device operation), whereas the last two factors relate more to users and their perceptions.

The rate and impact of errors, at all steps, e.g., data acquisition, use of sensors, manual data entry, networking, and support services, must be analyzed. Furthermore, end users need to be confident in the system's performance. The latter involves challenges such as minimizing false positive alerts, protecting data security, maximizing diagnostic accuracy, etc. Special design considerations should apply when developing systems for the elderly or for other populations with functional limitations.²⁷

Data Transmission

Patient-centered applications often require the secure exchange of clinical data via electronic messages from different patient record systems to consolidate the disparate data required for disease management. To allow the correct interpretation of the exchanged information and adequate responses by the receiver, both a semantically sound and technically feasible set of standards are required. Goossen²⁸ defined a framework of relevant standards for using clinical information in IT for five core areas: clinical, vocabulary, messages, work flow, and technical standards. Clinical standards, such as guidelines indicating the professional care that is appropriate for specific conditions, must be reflected in the domain knowledge included in programs for disease management and wellness. A second type of standard concerns terminologies in different formats and usually developed for specific purposes, such as clinical documentation, comparison of data, or statistical reporting. Ultimately, a broader goal of standardized vocabulary is the collection of more accurate and appropriate population and public health data to support decision making. The third type of standards focuses on the electronic exchange of information within and/or between health information systems; the classic example is Health Level Seven (HL7),²⁹ which provides standards for the exchange, management, and integration of data that support clinical patient care and the management, delivery, and evaluation of health care services. Current HL7 v3 message models, e.g., for patient care, can represent the patient as author of health information, thus respecting self-care responsibilities. The fourth type of standard deals with work flow of health care processes. These standards describe the details of the care plan, stakeholders and timeline, required interactions, and transactions. For example, in home care, there is a detailed care plan that dictates the number of home care visits, their goals and who conducts them (registered nurse, nursing aid, social worker, etc.), and rules for specific processes (e.g., capturing of vital signs). Finally, technical standards need to be addressed. Numerous technical standards are available, including infrastructure, networking, and security issues. Particularly relevant for disease management applications are the Internet protocol (TCP/IP) for the infrastructure and

Extensible Markup Language (XML) for the technical expression of messages.

Economic Evaluation

Investments in patient-centered IT-based applications are based in part on expectations of improving interorganizational networks, reducing costs, controlling resource allocation, and achieving a higher standard of quality of services promoting disease management and wellness.³⁰ Innovators face major challenges in meeting increasing demands for health care services with limited resources. A major impediment for investments in IT applications, however, may be a lack of evidence of their economic impacts³¹ on end users, organizations, stakeholders, and society as a whole. Although pilot studies indicate clinical efficacy of patient-centered IT-based applications at the intraorganizational level,³² less is known about the cost effectiveness of such applications. Evaluation studies often are limited to hypothetical discussions, rather than actual analyses, of the potential value of patient-centered applications to consumers and methods for developing business models that transition from a payment-per-visit model (prospective payment principle) to a payment-per-episode-of-care model, or for quantifying the direct cost of the technology in use.³³ Any economic evaluation will need to recognize that the system we are dealing with is not just an information system but an entire grid of interlocking actors and work processes³⁴ whose boundaries must be determined for the sake of the evaluation.

The majority of economic evaluations performed to date provide no conclusive answers about how to combine efficiency, effectiveness, and business process benefits derived from IT implementations involving patient-centered care.³⁵ More recent intraorganizational studies have tried to evaluate savings due to productivity improvement and cost reductions. Other models of transformational benefits of clinical IT³⁶ use frameworks such as return on investment and focus on the health care organization's perspective. However, many such models failed to represent IT-induced benefits apart from direct savings (such as patient empowerment, increased patient satisfaction) and do not include the efforts needed to enable the change, namely, overcoming user resistance, training and technical support, and achieving management support. Solid economic evaluations of patient-centered IT-based applications have to be performed as a comparative analysis of alternative courses of actions in terms of both their costs and their consequences. The main problem in evaluating patient-centered applications today often involves tracing and delimiting the consequences from an IT-based application. Benefits may occur only after a time lag, and sometimes they may arise as unintended consequences of the system.³⁷

Public Policy

The public policy issues related to the use of IT to promote disease management and wellness are the same as those that arise for the use of IT in health care in general and involve several levels (state, federal) as well as numerous stakeholders. Specifically, these issues relate to access to care; the quality, safety, and efficacy of the delivered services; who will pay for that care and how much; and how to maintain the privacy and confidentiality of information. Introduction

of IT adds a new set of cost drivers to these issues and raises questions about the benefits derived from these new technologies.

Although the use of IT for patient-centered management has shown positive benefits for patients in selected experimental settings, the widespread use of IT for disease management might paradoxically reduce access to care via two mechanisms. The first of these reflects the extent to which the use of IT increases the cost of care. For example, a hypertensive patient's blood pressure can be monitored at home with a simple \$50 sphygmomanometer. The same monitoring can also be performed by a home telehealth unit costing 10 to 100 times as much that automatically reminds the patient and transmits the results to a central location for evaluation. Although the latter technocentric approach may lead to higher quality of care and better patient outcomes, it also consumes considerably more financial resources. In a constrained spending environment, fewer patients will have access to this more advanced and potentially more beneficial care. The second way that access to care may be increasingly restricted results from infrastructure requirements becoming more sophisticated. Use of a particular technology may be restricted by the lack of access to high-speed telecommunications at the point of care in the home—the "last mile" problem.

The U.S. federal government has adopted a number of policies and regulations with implications for many of the topics in this report. In the field of telehealth, the U.S. Centers for Medicare and Medicaid Services (CMS) has taken the stance that videoconferencing and related technologies can be used to provide appropriate medical care over geographic distances, but that reimbursement, aside from a small fee paid to the site where the patient is located, will be equivalent to what is provided for a face-to-face visit. There is only a token reimbursement for the costs of the associated technologies when used in a rural setting.³⁸ Similarly, in the field of home care, CMS reimburses for virtual visits (videoconferencing to the home) and remote monitoring at a set amount (Prospective Payment System) that makes no specific provision for the costs of the technologies.³⁹ CMS is moving away from reimbursement for services to payments for outcomes (Pay for Performance),⁴⁰ and it is reasonable to expect that these technologies will have to live up to the same standard.

Another public policy issue arises from concerns about the safety and efficacy of health care devices. The U.S. Food and Drug Administration (FDA) has the responsibility for ensuring the safety and efficacy of all such devices marketed in the United States.⁴¹ Any devices used for monitoring of disease conditions, such as sphygmomanometers, stethoscopes, etc., are subject to FDA oversight. Embedded IT (particularly software) is reviewed as an integral device component. What may have a greater impact is the FDA's evolving position on software that is used for medical purposes, but is not intrinsically bound to a particular device, such as Electronic Medical Record (EMR) systems, decision support systems, and disease management systems.

Telecommunications is a significant public policy issue that is, at the date of this writing (October 2007), undergoing

major review at the national level as Congress considers reauthorization of the Telecommunications Act of 1996. That act governs who can provide such services, what kinds of services are allowed, and in many respects, how much can be charged for those services. It provides for subsidies through the Universal Service Fee to ensure that health care facilities in rural areas, the education system, and public libraries have financially reasonable access to telecommunications services including the Internet. One of the provisions under consideration is to allow the creation of a multitiered Internet where users must pay an additional amount for faster, quality-of-service-controlled access. Although this is perceived as a way to improve quality of services, the concern is that it will also increase the digital divide between people who can afford better infrastructure and the applications that require them and those who cannot. Some argue that this might exacerbate rather than help to eliminate health disparities.⁴²

Another public policy issue relates to delivery of health care across state borders.⁴³ In many health care professions, the site of practice is considered to be where the patient, not the practitioner, is located. In any situation in which reimbursement for direct care is sought and IT is used to bridge geographic distance across state borders, this distinction can become an issue. In the past, it has been a significant barrier to the diffusion of many IT-based interventions. One emerging solution to the state-based licensure may be the National Council of State Boards of Nursing's interstate compact promoting recognition of licensure in one state as effective in all subscribing states.

Ethical Considerations

The literature to date on the subject of patient-centered systems has focused overwhelmingly on technical feasibility matters. Although ethical considerations related to implementation of such systems are equally important and possibly more challenging, there have been far fewer studies or discussions. Ethicists have dwelt on patients' internally competing interests in knowledge of their own health (e.g., knowing one's risk for breast cancer can lead to life-extending changes and/or can have a negative impact on quality of life⁴⁴) as well as externally competing interests between the patients and insurers⁴⁵ and between patients and researchers (or public health officials).⁴⁶ Several organizations have issued guidelines for protecting the privacy of electronic clinical communication.⁴⁷ Privacy is a process that begins with preparations to protect data when they are generated and continues for the lifetime of the patient. While protecting the data they keep with state-of-the-art security, data collectors must become increasingly open about their collection and storage procedures, because it is well known in the data security community that closed security mechanisms, i.e., security mechanisms dependent on keeping a key fact of their operation from the public, are almost always more easily penetrable than open security mechanisms readily amenable to expert review and subsequent strengthening.

When a professional, abetted by modern IT, provides a patient with medications (e-prescribing), advice (teleconsultation), or other services from afar, the propriety of doing so (outside of the bounds of the traditional doctor-patient relationship) is an area ripe for ethics discussions.⁴⁸ The

Spring 2001 *Cambridge Quarterly of Healthcare Ethics*,⁴⁹ together with material in Anderson and Goodman's 2002 volume on health care information technology ethics,⁵⁰ comprise a comprehensive assessment of the broad array of telehealth and mobile health ethics matters. More recently, Terry's⁵¹ exhaustive treatise on e-prescribing details the tremendous complexities in just this one aspect of telehealth. A developing body of work in the mobile device arena addresses issues of data security⁵² but not yet ethics. Recent commercial offerings of mobile technologies at discounted prices to health care providers in exchange for the (disclosed or undisclosed) right to harvest and commercially use information collected thereupon raise ethical questions.

Conclusion

This white paper reviewed some of the system development, evaluative, technical, policy, and ethical issues related to patient-centered disease management applications. Initial clinical investigations show promise and indicate that IT has great potential to contribute to improving patient health. However, more research is needed, including rigorous, large-scale, longitudinal experimental studies and economic evaluations. Existing studies suffer from weak methodology including poor design (e.g., small sample sizes, inadequate follow-up), leading to inconclusive results. Scientific evidence of the effectiveness of patient-centered applications is required to further the field.

Before maximal benefits of reimbursable, IT-enabled care can be realized, the barriers imposed by state-based licensure of health care professionals must be addressed. Further work on standards and interoperability issues will facilitate distributed health applications. Although these issues are important generally, they loom even more critical for patient-centered technologies, which often require data transfer and exchange among a diverse set of hardware and software applications and stakeholders across varied institutional settings. The usability and utility of patient-centered applications and devices should be addressed early in the design phase, taking into consideration patient's needs, limitations, and expectations.

The concept of patient empowerment requires further exploration. For researchers and system designers, the need exists for valid and reliable instruments that can measure patient empowerment or shared decision making. This involves review and synthesis of many existing tools, for example scales that measure patient activation⁵³ and patient empowerment in the context of a specific disease,⁵⁴ as well as the design of new tools. For clinicians the challenge is to design patient education and counseling initiatives that will take advantage of the shift to a patient-centered approach.

A systematic exploration of the issues of clinical data ownership will help to ensure that patient data becomes available to its source—the patient. Finally, the ethical issues involved with the application of mobile IT to health care are many and complex. System designers should consciously incorporate safety and privacy considerations. It is important to consider whether and how ethical issues related to IT should be integrated into the clinical curricula for practitioners.

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