Policy Issues Relevant to Evaluation of Interactive Health Communication Applications

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This article provides an analysis of policy-related issues associated with the evaluation of interactive health communication (IHC) applications. These include an assessment of the current health and technology policy environment pertinent to public (government, education, public health) and private (medical care providers, purchasers, consumers, IHC developers) IHC stakeholders and discussion of issues likely to merit additional consideration by these stakeholders in the future.

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Introduction

Several externalities may positively or negatively influence the practice of Interactive Health Communications (IHC) evaluation,[1] including legal, regulatory, social, and economic processes. Some of these processes result from the legislative efforts of federal and state governments acting on behalf of the public interest. Others stem from the purchasing decisions of federal, state, and local governments and of private institutions. Still others stem from informal "policies" of private health care enterprises such as what resources they use, and to whom they refer when their patients need health information. All of these factors also influence the marketplace for IHC that others typically follow.

Decision-makers of all types need to understand more about IHC technologies and applications. These individuals need a process that enables assessment of the efficacy, effectiveness, and impact of IHC applications. Of potentially greater importance, however, will be mechanisms by which policy-makers can understand the "value-added" by IHC to the overall mix of public and private investment in the promotion and protection of individual and community health, in disease prevention, and in medical care and rehabilitation. That is, with respect to IHC, "the whole may be greater—or less—than the sum of its parts." Knowing how IHC applications relate to, enhance, and/or potentially detract from other determinants of individual and community health may enable choices to be made, which promote the wisest investment in IHC development and use.

Background

Interactive health communication is expanding at a rapid pace. The information technology industry is now the second largest industry in the United States, trailing closely behind personal health services. Research and development (R&D) in information and communication technologies now represents 37% of total R&D by U.S. companies.[2] Nonetheless, health and medical care are prominent among those business and social sectors considered to be most underdeveloped from an infor-

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mation technology perspective. Investment in information technologies is seen by many as essential to the creation of manageable and cost-accountable medical care and public health systems. To foster development in this area, the federal government's High Performance Computing and Communications Program (HPCC) has targeted the health information infrastructure for improvement.[3] However, several other phenomena—both inside and outside the health arena—are almost certain to accelerate the deployment of IHC technologies and applications. These include:

- The trend away from small-scale cottage industry provision of episodic medical care to delivery by larger integrated medical care systems that address everything from prevention to home care to tertiary hospitalization and long-term care. While this trend may initially hamper the growth of online communication services as size outstrips communication capacity, the need to manage increasingly larger amounts of information will maintain the pressure for expanding information technologies.[4]
- The change from fee-for-service and cost-reimbursed medical care to pre-paid, capitated coverage with the concomitant shift of financial at-risk status from the consumer/purchaser/payer to the provider. Under these funding arrangements economic pressures will increase to provide services to consumers in the least expensive way, including in their homes and workplaces.
- An increasing recognition of the historical imbalance between investments in episodic and end-stage medical care versus investments in prevention and health promotion services at both the individual and community levels.[5] Often based on behavioral, social, and environmental determinants, disease prevention and health promotion interventions are usually "information intensive"—dependent more on information and communication strategies than on procedures or pharmaceuticals.
- Increased access to, and reduced costs of, the infrastructure for interactive information delivery tools and systems. This includes the Internet, home and worksite computers, and the increasingly robust wired and wireless communications infrastructure being developed through private and public investment. Forty-one percent of U.S. households had a personal computer in 1997.[6]
- The increased demand for health information from consumers. One of the most common reasons people use the Internet is to obtain health information.[7]

These phenomena raise some interesting questions for almost everyone involved in public health and medical care. What will the future of personal health care services look like? How will the traditional role of the health care provider change? What new challenges will exist for those who have traditionally paid for health care services? More specifically, as we witness the proliferation of interactive health communication applications, how should those with an interest in health policy respond? For example:

- What policies should be put in place to encourage the wisest investment in IHC in either public or private settings? What objective criteria can be used to assure that IHC purchasers are "getting what they pay for?" From the standpoint of health outcomes, is it better to invest in IHC applications than to invest in other health and medical care inputs? If so, how much better?
- Is a market-driven *laissez-faire* approach appropriate with respect to IHC? If not, what sort of approach is necessary? Is "truth in advertising" an issue, either with respect to core content and/or how IHC applications are marketed as efficacious and effective?
- Will IHC technologies "naturally" evolve to satisfactorily address issues of compelling public health importance? If not, what should be done about it? How can IHC research, development, and use best support attainment of the Healthy People 2000 and 2010 Health Objectives for the Nation?[8]
- Will all Americans be served by IHC? If not, should something be done about it? Should there be an R&D agenda for IHC to ensure that "orphan" issues or populations are served by IHC applications that may not be addressed by applications developed solely for their commercial value? In the context of current major telecommunications reform, are there opportunities to promote the potential benefits of IHC to underserved populations? If so, how is this best done?
- How should privacy rights of citizens be respected in the deployment of IHC? Under what rules for disclosure does the system operate?
- Are there unique issues related to malpractice or other liabilities associated with assumptions or claims of efficacy, effectiveness, and use of IHC?

In the long run, it is not merely the existence of IHC that will be important to policy-makers in the public and private sector. Rather, it is the impact that IHC applications may have on the structure, process and outcomes of medical care and public health. To make qualitative and quantitative judgments about these increasingly important systems of personal and public health communication, policy-makers should become as knowledgeable as possible about them.

Policy Issues

Several areas of health information policy are already undergoing extensive review in the context of expanded use of telecommunications and computer technologies.[9,10] These include health data and information standards, network security issues, and legislative actions at the federal and state levels addressing issues such as medical information privacy, confidentiality, and security. While each of these issues has one or more dimensions relevant to the development and deployment of IHC, the focus of this article is on those aspects of each pertinent to IHC. This list of policy issues is exhaustive neither in scope nor in its description of each issue. The primary aim of this section is to present key issues related to the evaluation and use of IHC and help policy-makers answer the following question: What decisions made now in the broader context of health and communications policy-making will promote optimal development, evaluation and improvement of IHC?

Privacy and Confidentiality

In virtually all assessments of consumer concerns about communication technology-based health information and medical care, privacy and confidentiality issues are paramount. Simply put, individuals wish to keep their health concerns private or, if shared, shared only with a health professional with the capacity and commitment to maintain complete confidentiality.[11,12] Many IHC experts consider the concern about privacy and confidentiality of IHC as out of proportion to the actual risk of disclosure, especially if appropriate safeguards are developed.[13] Nonetheless, considerable effort is being devoted to fail-safe technologies that assure complete privacy and confidentiality both within a given health care organization and in situations where information is shared between and among health care entities.[14,15] This issue will become considerably more complex as IHC applications proliferate and diversify in ownership and location. For example, individuals now seek health information from a variety of sources on the Internet, only a limited number of which are sponsored by mainstream professional health organizations. The Internet enables disseminators of information to know precisely who is seeking that information (or at least their Internet address). Many individuals access the Internet through job-based workstations, expanding even more the potential for others (such as employers monitoring Internet access) to discover both content sought and information source. The implications of these electronic trails for someone seeking, for example, potentially sensitive information on HIV/AIDS, may be profound.[16]

Policy-making now underway in the area of secure, private, and confidential transmission of information via new communication technologies should anticipate more than simply the electronic storage of medical records and the transmission of this information between health care providers in medical environments. Our experience suggests that increasing use is being made of e-mail, transmitted across the Internet, for communication between health care providers and patients. In the future, more and more health information obtained via interactive media will be obtained from many kinds of health professionals in a variety of settings. Safeguards to ensure that individual health information–seeking behavior is treated with maximum privacy and confidentiality will become critical to the specific operation—and evaluation—of IHC. Policy-makers confronted with the decision to pay for or adopt a given IHC should know how well the IHC application protects privacy and/or confidentiality. And, because standards and practices in this arena are likely to evolve and improve, ongoing assessment of this capability should be sought.

Perhaps one of the most complicated areas related to confidentiality and security of health information in the future may relate to the balance between individual rights to control the release of personal health information and the greater community-wide and public health benefits of such things as community health information networks or health data registries.[17–19] One of the most common current uses of registries is to house data on immunization status of infants and children. These data are used to assess and improve levels of immunization in defined communities.[20,21] Use of community-wide data in this way protects not only the health of specific individuals but that of an entire population. IHC applications may emerge in the future that enable the aggregation and analysis of other types of health information, including information gathered from nonclinical sources, that can benefit an entire community. For this to occur, however, new approaches will need to be developed for policies and procedures supporting privacy and consent for release of personal health information.

Oversight, Regulatory, and Legal Issues

These are areas of considerable controversy at present. While it is impossible to predict how each will evolve, some general principles can be articulated.

Content. While first-amendment principles will likely apply to IHC, it is also probable that the tradition of governmental regulation of certain aspects of health care (e.g., pharmaceuticals by the Food and Drug Administration [FDA]) and trade-related issues (e.g., some aspects of advertising by the Federal Trade Commission [FTC]) may impact IHC. For example, consider the case of an IHC application that facilitates the use of either a drug or a device in a disease-management program. Should this IHC tool come under the

domain of existing regulations with respect to product labeling and information provision now required by the FDA? If it becomes "bundled" within a larger suite of IHC applications, will the need for explicit information about its safety and effectiveness disappear? As health-related interventions have the potential to produce harm,[22] several leading health and information technology organizations have outlined a proposed FDA role in the regulation of clinical software systems, including some IHC applications.[23] This may be more likely if private industry doesn't adopt at least a minimum standard of self-evaluation and quality control.

The FTC is well known for penalizing entities engaged in false and deceptive advertising. Recent examples include actions against companies promising near-miraculous results from the use of dietary supplements for weight loss. Developers of an IHC promising the same would change only the venue for false claims, not the content.[24–26] In fact, the FTC is already monitoring the Internet for false claims.[27]

Policy-makers should also be familiar with the potential for persuasion in IHC applications. As these media increase in sophistication to include video, compelling graphics, and sound, their power to persuade may also increase. The emotional impact of a well-produced video may be much stronger than that conveyed by traditional print-based health information. Drawing a line between legitimate product marketing or advertising and false and deceptive advertising may become a difficult thing to do. This is an area that may require scrutiny from independent entities, perhaps in the public sector.

Some oversight of IHC content will probably occur naturally through the extension of existing mechanisms for influencing health care, such as certification, licensure, and accreditation. For example, a Web site maintained by a hospital may come under review by a state licensing agency if it is used to enhance marketing or to justify community service requirements. Because of the newness of IHC applications, and the difficulty in anticipating the kinds of safety and effectiveness problems that might result from their use, it also seems likely that legal challenges, and resulting case law, will influence the policy environment for IHC application development and adoption.

Liability for Information Provider and IHC Developers. Advances in the use of communication technology for the provision of health information also raise some unique questions about liability. In the context of a traditional provider–patient relationship, the provider is responsible for the quality and timeliness of information that is provided to the patient. Although sometimes imprecise, norms and standards of practice have evolved regarding the delivery of health information to patients in clinical situations. Examples of these include informed consent prior to surgical procedures, information about potential side-effects of prescribed medications, and advice about what precautions to take to avoid risk of illness or injury in the face of an established medical condition (e.g., coronary artery disease, osteoporosis, diabetes).

If a health care provider is negligent in anticipating and addressing the information needs of a patient, that provider is at risk for legal action. What rules should apply for IHC applications? These tools may be deployed by a variety of providers, some trained in the traditional biomedical sciences and others with different backgrounds. This issue may become more complex as IHCs become increasingly tailored to the specific needs of users. Interactivity may enable such systems to become influential health counselors for individuals. Through successive use by an individual, the accumulated wisdom that an IHC application could develop about an individual's health status and preferences could rapidly exceed that of the health care provider, whom the same person visits only a few times a year. Will this "wisdom" beg issues of responsibility and, if the responsibility is not addressed by the IHC provider, negligence?

A related issue of liability pertains uniquely to IHC developers. IHC technologies are becoming increasingly sophisticated and are often dependent on complex algorithms, elaborate logic, successively revised software, and sophisticated technology. While they may become easier to use, it is likely that fewer and fewer individuals will truly understand their inner workings. Those who deploy them, for example, in a medical setting for patient-centered disease management, will need to accept that they will perform as intended. In this scenario, if something goes wrong, and it can be traced to a flaw in, for example, the IHC application logic, the developer almost certainly will be drawn into the liability loop.

Will providers be liable for the damaging effects of a flawed IHC application made available by their institution? Or conversely, if an effective IHC application is available, will providers be considered negligent if they don't use it?

Finally, there are legal issues concerning the operation of shared health record systems and data registries. Do patients need to permit providers to add information to their record or can providers add to the publicly-held shared records without a signed release? Patients typically need to sign for release of information to third parties, but there are exceptions to this practice. For example, if the patient is under the care of two clinicians, they can share information with each other without the patient's written consent. Some releases of information require time-specific and purpose-specific consents. Who is liable for a breach in these communication processes? Suppose a public health information registry releases information automatically to a provider who says he or she has the patient's consent.

Who is responsible for keeping written patient consents on file? Answers to these questions will require different approaches and attitudes to personal health information from those now prevalent.[17] As many of these situations already exist, different practices, varying state laws, and potentially conflicting regulations are already evolving. Clearly the IHC field will need to participate in ongoing discussions about these issues.

Given the many unknowns in this arena, policymakers faced with the decision to fund or use IHC applications, or who have the responsibility to safeguard the public interest, should develop mechanisms for assuring that IHC developers have considered these issues and have implemented appropriate processes for quality control and evaluation.

Linking Issues: the Interconnectedness of IHC Content. In the historically "closed" system of health information provision, a health care provider supplies specific information to patients from personally selected sources. Health information, usually in the form of a brochure or similar document, is either produced in-house or purchased or licensed from a health information provider. As interactive media and infrastructure grow, especially on the Internet, developers and deployers of IHC applications have an ever-increasing number of sites where information can be accessed "in real time" to add value to their own efforts. The Internet has become an extremely dynamic environment in which sites link with new sites, and content is revised or changed, on an almost continuous basis. Where does the chain of responsibility begin and end with respect to the quality of that information?

It is not clear if liability for linked information will be as much of a problem as some might think. In part, this may be dealt with by the regulatory, licensure, and certification mechanisms for content noted previously. If norms for appropriate content in health information provision emerge, and if intermediaries become more savvy in their ability to create links, entire "sub-networks" of high-quality health information may emerge as the predominant resource. However, it may take new legislation to protect entities that direct their users to other sources of content over which they have no ongoing control. Absent these developments, mandating explicitly stated disclaimers about linked information might be the standard that policy-makers deploy for IHC they fund or use, or in which they have other legitimate interests. Examples of these disclaimers have been provided by others.[28–30]

Quality Assessment and Improvement

Several models of quality control may be relevant to this emerging field. Placing the development and deployment of IHC applications under the jurisdiction of an entity such as the FDA or an analogous public agency is the strongest mechanism to assure that rigorous evaluation occurs. The FDA's tradition of assuring that drugs and devices meet established standards of safety and efficacy has stood the test of time. For a variety of reasons, however, this approach may not be the best for the kinds of applications addressed in this article. These include the dynamic nature of the underlying technologies, the changing nature of information content, and the "porous" nature of many IHC systems as they are likely to be deployed on the Internet and Web. Therefore, other mechanisms of quality improvement may be preferable, including:

- Adoption of voluntary quality standards and performance measures through an organization of IHC providers, similar to the Health Plan Employer Data and Information Set (HEDIS) established by the National Committee on Quality Assurance. This approach would enable IHC developers and providers to jointly develop and apply evaluation and performance criteria on a systematic basis. As knowledge increases on IHC efficacy and effectiveness, these criteria could be revised. In fact, it may even be possible to build this type of functionality into the existing HEDIS program. Adoption and effective use of IHC applications could become part of an approach to measure the level of involvement in shared clinical decision-making and consumer satisfaction.
- Assessment of IHC by independent entities (e.g., *Consumer Reports*) is another approach to quality assessment and improvement. Some of this is already occurring for such things as health-related Web sites, but early efforts may need to be improved.[31] The long-standing tradition of making this type of independent consumer-oriented information available suggests that no matter what other mechanisms are developed, this process will occur for some IHC applications.
- Development of an accreditation system for IHC developers is another possible approach to increasing the quality of IHC applications. This approach may be preferable to one that assesses individual IHC applications because both the underlying technology and the content of any given application can change frequently. An accreditation system could establish and apply accepted norms for internal quality control; software design; participation of experts in content development; appropriate formative, process and outcome evaluation; and ongoing evaluation after release. However, for such a system to be effective, it too would need to be evaluated to verify that its criteria are linked to desired outcomes for end-users.

As in other health-related areas such as medical education or health care facilities accreditation, an IHC accrediting body could be created with representation from both the IHC developing and IHC-consuming

communities. Independently chartered, and at arms length from entities receiving accreditation, such a group could be supported through a combination of accreditation fees and financial support from IHC stakeholder groups.

- Another approach might be to develop a system of post-marketing surveillance to monitor any potential negative effects of IHC applications. This effort could be undertaken by independent entities or required of those who develop or deploy IHC applications.

Public Versus Private Investment for Research, Development, and Education

With substantial current, and ever-increasing, private R&D in the area of IHC, public policy-makers might legitimately ask whether it is appropriate to "let the marketplace decide" about the future of these technologies or whether they need to influence that market. Public support can take the form of grants or contracts, specific financial incentives, tax relief, or other forms of indirect support.

This merits attention because of the need to address health issues for underserved individuals and populations. The issues associated with R&D of IHC applications are different from those relating purely to access to existing tools. Knowledge about the evaluation of IHC applications is now in its infancy. It is not yet known if special circumstances or conditions apply to enable these tools to benefit economically or socially disadvantaged populations. What is virtually certain, however, is that if there isn't a viable financial market for these products in some settings, the private capital needed to develop them will not be available. Therefore, the safety net that federal or state governments, or philanthropic entities, can provide for IHC R&D to serve these populations will be important.

At a more general level, the issue of public versus private investment becomes more complicated. Many private organizations, large and small, have already entered and abandoned IHC development. Several traditional managed care organizations have introduced online services but have done so without changing the nature of medical care delivery. In some settings, patients can receive modest amounts of information online but cannot make appointments, receive reminders, contact their health care provider, or conduct other necessary managed care services. While some types of networked innovations—such as online information about benefits—have proceeded, others have not.

Is it a function of public investment to encourage innovation in IHC development? Perhaps a reasonable role for government is to assist in demonstrating the utility of these interventions, especially if a convincing case can be made that IHC applications will contribute to the attainment of national health objectives.[8] While many federal efforts focus on infrastructure and/or technology to support application development, the real need may be for demonstration projects to model how health care practices can be improved through the use of IHC applications. These projects may be especially helpful in demonstrating the potential return on investment for health plans and large employers. Also, these technologies are accompanied by major changes in practice, for which clinicians and others in health care may be ill-prepared.[22] The problems associated with implementing IHC are rapidly shifting from technologic to cultural and social. Given this environment, public-sector stimulation of case studies may be a necessary precondition of meaningful progress in IHC development. Once these projects have been completed and their results disseminated, market forces can then facilitate growth and development in the field.

Payment and Reimbursement

Payment and reimbursement are important areas in which policy-makers, public and private, can influence IHC development and evaluation. Ample precedent exists for federal, state, and local government to require that, prior to payment for health-related services, certain criteria are met. These can include requirements for populations served, quality of product, evidence of safety and effectiveness, possessing appropriate accreditation, proof of consumer input into the system, and a host of other requirements. Given that the public share of health care expenditures has been estimated to be 46% in 1995,[32] these requirements can be extremely important to IHC developers.

Access

In addition to the issue of appropriateness of content discussed previously, there is also the question of access to IHC for the economically or geographically disadvantaged. While it is possible that low-cost devices will eventually improve access to IHC, some of these applications are inherently biased against those who are afraid of technology or who cannot read or write. These problems are especially important among the poor, disabled persons and the very elderly. Market-driven interventions are unlikely to address the needs of these relatively small groups of users. Traditionally, it has been the role of governments and private foundations to ensure access to services vital to individual and community health. This dimension of IHC should be kept in mind as evaluation approaches are developed and validated.

IHC, Telemedicine, and Other Electronic Health Information

The relationship between IHC and other electronic health information systems and processes is neither fully developed nor completely understood. From a policy perspective this relationship is critical primarily because of the large amount of current and projected investment in medical information systems and telemedicine applications. Absent other input, these systems often develop along a medical-model approach to health communication. With few current incentives to engage consumer or public health professional input into these systems, they promise simply to replicate past and current models of health care rather than enable future ones. For example, recent FCC regulations stemming from telecommunications reform provide financial support for rural medical clinics, hospitals, and public health agencies to improve their electronic connectivity with one another and with more urban settings. Without adequate oversight, this investment could produce systems that are not compatible with the needs of IHC users.

This problem can, in part, be remedied through the assurance that IHC and other health information systems utilize standardized and common languages and open platform architecture, such that they are scaleable, extensible, and ultimately interoperable with one another. Fortunately, the platform-independent Internet model is rapidly becoming the norm among health entities, although policy-makers should monitor potential changes in these practices.

Recommendations

As with most complex issues facing policy-makers, we believe that there will be no easy way to assure optimal outcomes for IHC-mediated individual and community health. However, it is possible to make several broad recommendations to policy-makers that are likely to improve the climate for favorable progress in this regard.

Monitoring and Evaluation

There is a need for ongoing monitoring and evaluation of IHC applications. As described in the other articles in this series, there is no substitute for explicitly understanding the use, efficacy, effectiveness, and impact of these tools on real-world conditions in actual settings. Through the consistent application of defined evaluation criteria, the value added from these systems can be measured and tracked, and IHC can be systematically and continuously improved in an evidence-based manner.[22] If policy-makers wish to maximize their contributions to improved health outcomes, they should participate in the creation and application of standards of evaluation as advocated by the articles in this series, and in the creation of an environment that encourages and promotes such evaluation.

Financial Support for "Orphan" Populations and Their IHC Applications

Because of the issues outlined previously, it is virtually impossible to outline a scenario in which all will be well served by IHC applications in the immediate future. There is too much financial uncertainty and too little financial incentive to address noncommercially viable and/or controversial public health issues such as prenatal care for indigent women, prevention of tuberculosis, mental health needs of the homeless, immunization assurance for low-income refugees, HIV risk behavior change for incarcerated individuals, and a host of other problems. Policy-makers will need to support the IHC development community in these areas and should apply the same standards of evaluation to tools for these problems that they do for others.

Public Education and Community Awareness

Policy-makers, especially those in state and federal government and individuals associated with voluntary health organizations, are in a unique position to promote public awareness of IHC resources that have demonstrated benefits. As with public awareness campaigns for specific topics or issues such as heart disease, stroke, or diabetes, the promotion of evaluated IHC media themselves may be beneficial. Akin to promoting the use of libraries to increase general knowledge, promoting the adoption and regular use of effective health communication tools can potentially lead to a healthier and more self-reliant populace.

Collaboration Among Stakeholders

Policy-makers in the public and private sectors will need to collaborate with one another to assure optimal outcomes from IHC. As noted previously in this article, most of the challenges of IHC are no longer technical, but rather social and cultural. Community-wide demonstration projects that connect public health programs with private health care providers may be required. New approaches to evaluation research may be needed to assess the impact of IHC on health, functional status, and quality-of-life. Discipline- and tradition-bound perspectives will need to give way to new ways of cooperative R&D efforts if these systems are to realize their potential for improving the health of individuals and communities.

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