



**Fifth Annual eHealth Developers' Summit
Summary Report**

**eHealth:
Achieving Mainstream Acceptance**

Presented by



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Suggested Citation:

Beauchamp N, Eng TR. eHealth: Achieving Mainstream Acceptance. Seattle, Washington: eHealth Institute, May 2005.

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This entire report and additional information about the eHealth Developers' Summit are available at: www.ehealthinstitute.org/summit/.

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Acknowledgments

First and foremost, the authors thank the speakers, moderators, team leaders, and other participants of the Fifth Annual eHealth Developers' Summit who were the generators of the ideas in this report. We also thank the following colleagues who reviewed and provided valuable feedback about the contents: David Ahern, Health e-Technologies Initiative; Deborah Burns, iMetrikus, Inc.; Nathan Cobb, QuitNet Inc.; and Steve Downs, Robert Wood Johnson Foundation.

The success of the Summit was largely attributable to the work of the Planning and Advisory Committees. The Planning Committee members included David Ahern, Health e-Technologies Initiative; Darrell Atkin, The Launch Pad; Beth Bock, Brown Medical School; Deborah Burns, iMetrikus, Inc.; Gwendolyn Doebbert, California Department of Health Services; Sue Ebbers, Florida State University; Kerry Evers, Pro-Change Behavior Systems, Inc.; Hank Fanberg, CHRISTUS Health; Susan Martin Gould, Colorado State University; Diana Laurent, Stanford School of Medicine; Madhu Nair, Ansya Enterprise Solutions; Tom Young, Consumer Health Interactive.

The Advisory Committee members included Wendy Angst, Bio-Imaging Technologies, Inc.; Kenneth Brier, Purdue Pharma, L.P.; Royer Cook, ISA Group; Connie Dresser, National Cancer Institute; Verle Harrop, National Research Council, Canada; William Avery Hudson, Memorial Sloan-Kettering Cancer Center; Tom Lee, California HealthCare Foundation; Armando Valdez, Valdez & Associates; Ken Yale, Health Solutions Network.

This report and the Summit would not have been possible without the funding provided by the Summit sponsors. We extend special thanks to Sam Karp, David Ahern, and Marie Smith for their generous support.

eHealth: Achieving Mainstream Acceptance

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May 2005

Summary Report of

The Fifth Annual eHealth Developers' Summit
November 10–12, 2004
Huntington Beach, CA

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Executive Summary

This report summarizes the discussions at the Fifth Annual eHealth Developers' Summit, held November 10–12, 2004, in Huntington Beach, California. A major focus of the Summit is to foster business relationships and collaboration among developers from commercial entities, academia, government agencies, and nonprofit organizations. More than 110 eHealth leaders from a range of disciplines, including health care and medicine, business, public health, and computer science and technology participated. Participants represented more than 100 organizations, including commercial eHealth companies, health care organizations, academic institutions, government agencies, technology corporations, pharmaceutical and medical device companies, nonprofit organizations, foundations, and investors.

eHealth is evolving from what was once a niche enterprise to baseline practice. There is increasing recognition by health care organizations, employers, the government and consumers that eHealth is an essential tool for improving quality and reducing costs.

As health care organizations increasingly implement eHealth technologies such as electronic health records (EHRs) and computer-based physician order entry (CPOE), physicians are beginning to overcome their initial resistance to these technologies. It has been difficult for many eHealth products to gain a foothold among physicians, but health systems are increasingly receptive to eHealth products, especially if research studies can demonstrate the technology's ability to reduce costs, decrease errors, and provide oversight for physician practice. Once EHRs are an established part of clinical practice, it is anticipated

that a convergence of technologies will offer eHealth developers a tremendous market opportunity.

Within the past year, the federal government has very visibly promoted the widespread adoption of IT in health care. The administration's recent establishment of the Office of the National Coordinator for Health Information Technology to promote widespread adoption of interoperable EHRs within 10 years highlights the increasing interest among political leaders in the role of information technology (IT) in health care. Although Summit attendees were largely optimistic about the outlook for generic eHealth adoption, they did not agree that widespread adoption of interoperable EHRs was likely within the next decade. The government has recently funded more than 100 health IT initiatives designed to improve provider education, expand health informatics, and hasten the diffusion of research results into practice. However, some critics contend that these efforts are only a fraction of what is really needed.

With escalating health insurance premiums, employers have a vested interest in technologies that can reduce costs, and they expect their health plans to lead the way in providing such capabilities. The growing interest of employers in consumer driven health plans, health savings accounts, and disease management will drive growing demand for eHealth products that promote informed health consumerism.

Ethics are often a primary consideration in product development. They may be the motivator of an idea or pose technical challenges. Small legal or ethical

errors can have a disproportionately large impact that may delay or doom product development and marketing. Developers can make ethics central to their business by including ethical standards in their mission, establishing a code of conduct, training new employees in ethical procedures, and enforcing accountability for lack of compliance.

Research in the effectiveness of eHealth products is only in its infancy. Nevertheless, eHealth developers are increasingly developing their products in close relationships with universities and researchers. In growing numbers, developers are conducting evaluation research, including randomized control trials, to verify outcomes and reveal unintended consequences.

The evolution from a great idea to a successful commercial product was a major topic of discussion at the Summit. The Small Business Innovative Research (SBIR) program is a valuable resource for seed R&D funding. With regard to eHealth commer-

cialization, developers must keep in mind that a commercially viable product must meet a recognized need, have a sufficient potential market, and provide enough economic justification for its purchase. A product does not have to be a radical innovation to achieve commercial success. In fact, some of the best products involve using existing and accepted methods in a new or different context. Developers are not always the best at marketing and distribution; they often need to find strategic partners to fill in these gaps.

Momentum for eHealth adoption is growing. This is made evident by the public proclamations of the value of IT in health care and public health voiced by the current administration, Congress, and private industry groups. However, it is also clear that sufficient movement toward eHealth adoption will not be attained unless considerably more public and private funding and financial incentives for eHealth development and implementation are available, especially for smaller organizations.

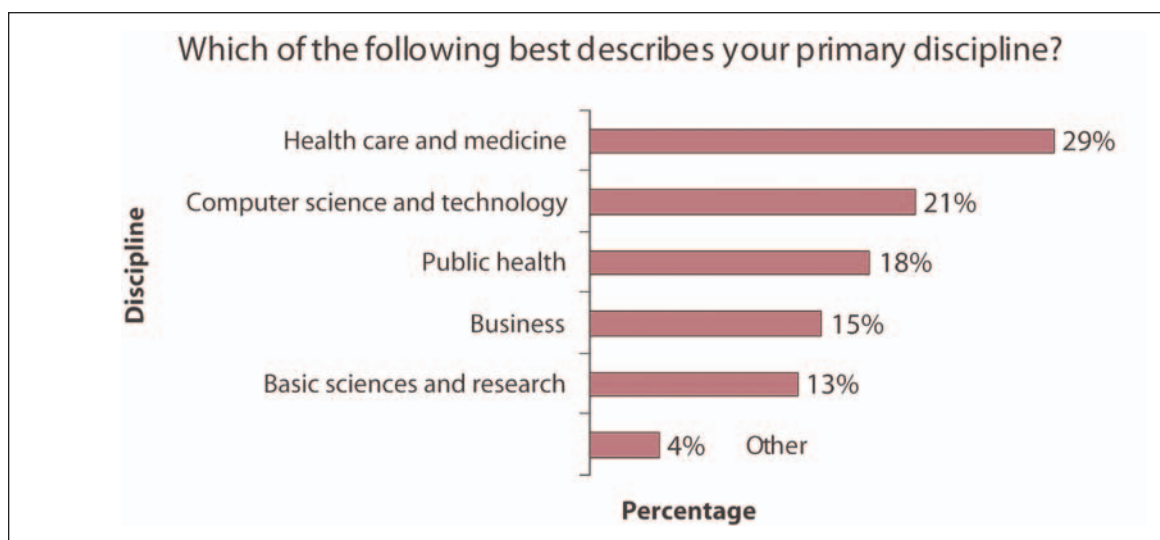
Introduction to the Summit

Convened by the eHealth Institute, the Annual eHealth Developers' Summit (the Summit) is a national forum for eHealth developers and funders. The Summit promotes synergistic efforts to improve the quality, effectiveness, and availability of eHealth products by catalyzing business relationships and collaboration among developers, funders, and other stakeholders in the business, health, research, and technology fields. A major activity at the Summit is the exchange of ideas and experiences among peer developers from various sectors (e.g., commercial, academia, government, nonprofit organizations).

Attendees are invited on the basis of their direct involvement and leadership in some aspect of eHealth R&D (e.g., application or technology developer, funder, investor, purchaser).

The Fifth Annual eHealth Developers' Summit was convened November 10–12, 2004, in Huntington Beach, California. More than 110 eHealth leaders participated, from a range of disciplines that included health care and medicine, business, public health, and computer science and technology (Figure 1).¹ More than 100 organizations were represented,

Figure 1. Results of audience poll regarding primary discipline (N = 68).



¹ Data presented in the figures in this report are from polls of meeting attendees using wireless audience response devices. "N" refers to the number of people responding to the question posed; some attendees chose not to respond to some questions. Percentages may not add to 100 due to rounding error.

Figure 2. Results of audience poll regarding primary affiliation (N = 67).



including eHealth companies, health care organizations, academic institutions, government agencies, technology corporations, pharmaceutical and medical device companies, nonprofit organizations, philanthropies, and investors (Appendix A). About 37 percent of attendees were from small eHealth or technology companies, while 21 percent were from academia, 19 percent from nonprofits, and 12 percent from government agencies (Figure 2).

A major objective of the Summit is to foster business relationships and collaboration among developers from commercial entities, academia, government agencies, and nonprofit organizations. Summit participants reported that they made a median of six (range was one to 15) new contacts during the meeting that may eventually result in a collaborative activity, partnership, investment, funding, a business deal, or other valuable relationship.

The purpose of this summary report is to convey the rich discussions and insights of this distinctive

gathering of leading eHealth developers and to share the lessons learned with the larger eHealth community. Consistent with the target audiences of the Summit, this report is primarily intended for eHealth developers and funders. For the purposes of this report, eHealth is defined as “the use of emerging technologies, especially the Internet, to improve or enable health and health care.”

The authors attempted to capture the major perspectives that seemed to be shared among Summit participants. However, because no attempt was made to form consensus during the meeting, this report does not necessarily represent the views and perspectives of most or all Summit participants. The opinions of Summit participants about a variety of issues were collected throughout the meeting using wireless polling technology and are presented in this document. Readers should be aware that most of the data and statistics cited in this report were based on materials provided directly by various Summit presenters and were not independently verified.

The State of eHealth

Take Home Messages

- eHealth comes of age as health systems, employers, the government, and consumers all look to IT to improve healthcare quality and reduce healthcare costs. What was once a niche enterprise is becoming baseline practice.
- Forty-three percent of this year's Summit attendees selected health care organizations and providers as the most influential driver/player in eHealth.
- As many health care systems prepare to launch technologies such as electronic health records (EHRs)² and computer-based physician order entry (CPOE), physicians are beginning to overcome their resistance and incorporate these procedures into their workflow.
- With the administration's support for EHRs to be in widespread use 10 years from now, EHRs will be high on the list for actively adopted eHealth products.
- With continuing double digit annual increases in health insurance premiums, employers have a vested interest in technologies that can reduce costs, and they expect health plans to lead the way in providing such options.
- The growing interest of employers in consumer driven health plans, health savings accounts, and disease management will drive growing demand for eHealth products that promote informed health consumers.

- The federal government has recently funded more than 100 health IT initiatives designed to improve provider education, expand health informatics, and hasten the diffusion of research results into practice.

Achieving Mainstream Acceptance

eHealth has come of age. Although the dot-com bust occurred less than five years ago, eHealth is enjoying a remarkable comeback. As employers and health plans embrace Web portals for the dissemination of insurance information, the government looks to health IT to improve quality of care and speed the adoption of research findings into daily practice. EHRs are now entering mainstream practice. On the horizon are secure messaging between patients and providers, home computer medication reminders and home monitoring for persons with chronic conditions. In addition to improving care and

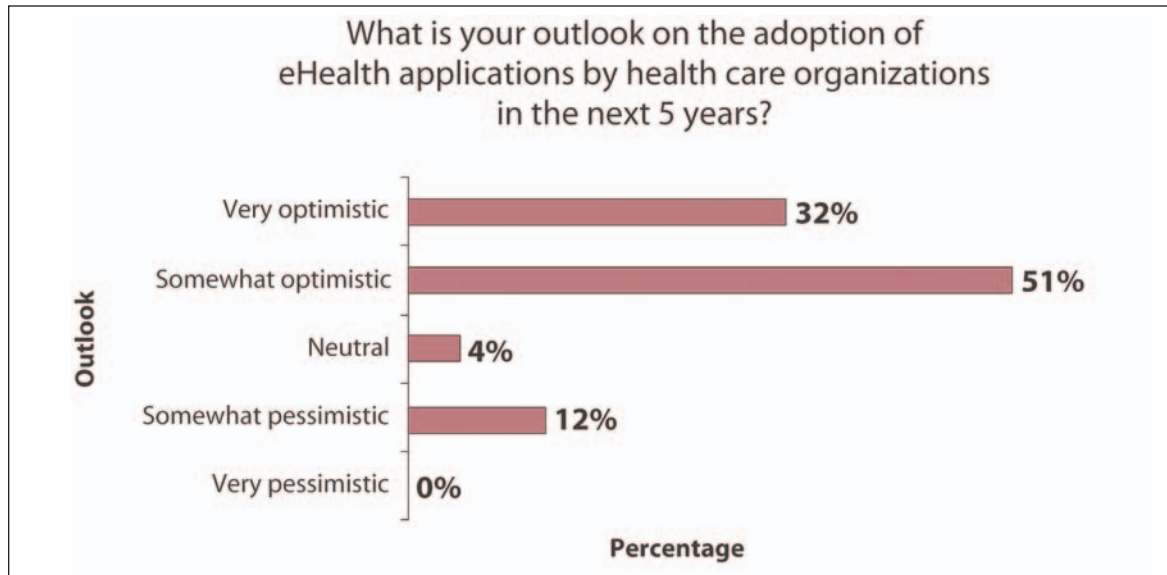
Participant Perspectives

"If you don't consider yourself in eHealth, watch out! It was once a niche, but it is now baseline."

— *Christine Paige, Senior
VP of Marketing and Internet Services,
Kaiser-Permanente*

² The term "electronic health records (EHRs)" rather than "electronic medical records (EMRs)" is used in this report because the former term more accurately reflects the growing consensus that electronic records for health should be available for shared access among clinicians and patients/consumers and that such records should capture data across health-related organizations and settings.

Figure 3. Results of audience poll regarding outlook for eHealth adoption (N = 68).



relieving a congested medical system, many of these IT solutions appear to offer significant cost savings.

According to participants in this year's Summit, the outlook for eHealth adoption is bright. Eighty-four percent are optimistic concerning health plan adoption of eHealth applications in the next five years (Figure 3). This is an increase from two years ago when 78 percent of Summit participants had an optimistic outlook.

As for who will drive adoption of eHealth technologies, 43 percent of Summit attendees thought that health plans and providers were likely to be the most influential drivers (Figure 4). This number reflects a growing trend: 28 percent of participants in 2002 and 34 percent in 2003 considered health plans and providers to be the primary driver. In 2004, the perceived impact of consumers continued its descent: only 11 percent of Summit participants identified consumers as the most influential driver compared with 29 percent in 2002 and 24 percent in 2003. Participant perception of government influ-

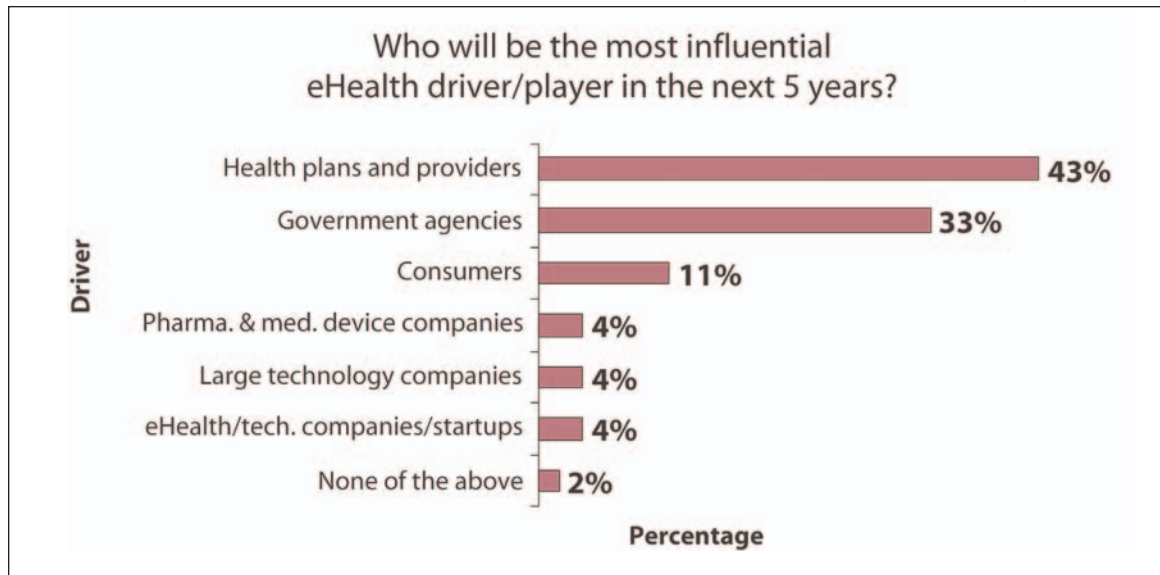
ence in eHealth has varied. In 2002, 24 percent of attendees felt the government would be the primary driver. In 2003 this figure dropped to 19 percent, but this year it bounced back to an all time high of 33 percent. Pharmaceutical companies continue to be perceived as less of a force. This year only 4 percent of Summit attendees considered the drug companies to be major players, generally consistent with the perception two years ago of 6 percent and 8 percent. Interestingly, in 2001, after the "bubble burst," pharmaceutical companies were one of the few sectors still willing to invest in eHealth. At that time, 20 percent of attendees rated the pharmaceutical industry as a primary driver. The drop to only 4 percent in three years represents a substantial shift.

Health Care Providers and Organizations

It has been difficult for many eHealth products to gain a foothold among health care providers.³ There are certainly some notable exceptions such as PDA appli-

³ The data and information in this section are largely based on presentations by Christine Paige, Senior Vice President of Marketing and Internet Services, Kaiser Foundation Health Plan; Debra Sleight, Director of eHealth & Integration Solutions, Sutter Health; and Jeff Tangney, Vice President of Subscription Business and Product Development, Epocrates, but this section does not necessarily represent their views.

Figure 4. Results of audience poll regarding perceptions of the most influential eHealth drivers/players (N = 60).



cations that allow clinicians to look up drug information at the point of care. Practical reasons include concern about having to focus attention on a monitor while in the room with a patient, and having too much information to sort through on a screen. There is some movement toward “heads up” applications that can easily be referred to at the point of patient contact, but which do not require in depth scanning and numerous click-throughs—just the right information at just the right time.

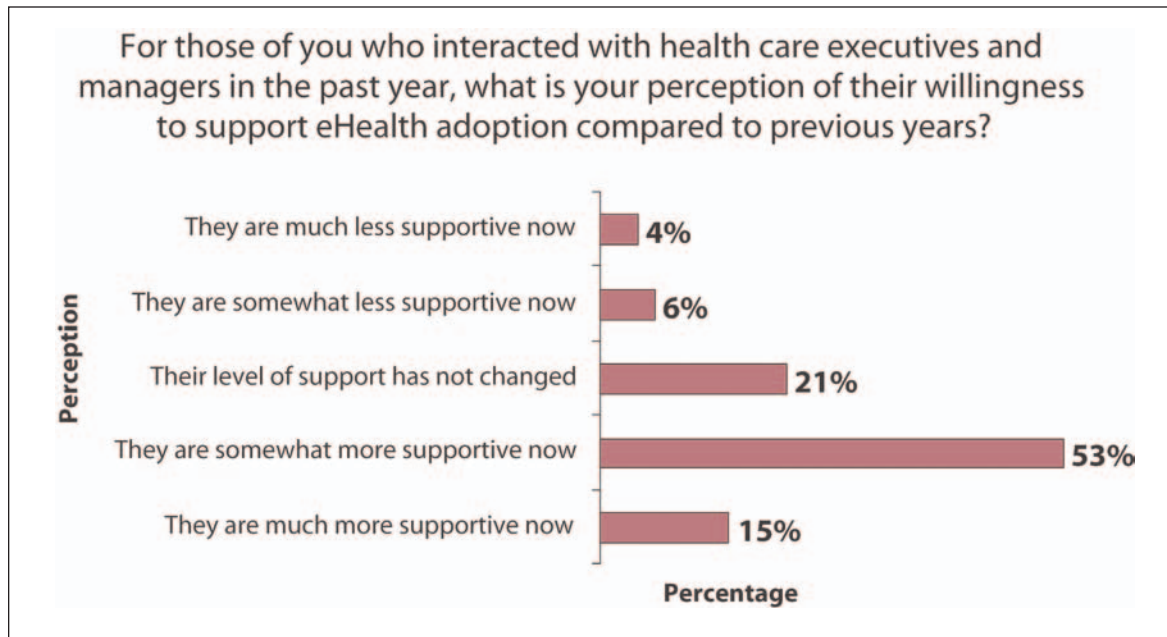
In situations with great clinician resistance to eHealth, how should health care organizations promote eHealth adoption? Some staff-model health organizations simply send out a memo and insist that clinicians adopt the new technology. Others go through lengthy processes to increase buy-in, including forming committees of physicians, nurses, pharmacists, and others so they can implement a fully integrated system. Research studies reveal that physician concerns about being flooded with patient emails are unfounded. In fact, a surprising proportion of physicians who are initially pessimistic, change their minds after a trial period using EHRs and secure messaging. Some even say that they now prefer it over conventional procedures. Nevertheless, eHealth adoption moves slowly in the health care system.

In general, health systems appear to be increasingly receptive to eHealth products, especially as studies consistently demonstrate technology’s ability to reduce costs, decrease errors, and provide oversight for physician practice. When asked to rate health care executives’ level of support for eHealth implementation, 68 percent of Summit participants said that managers were more supportive than they had been in previous years (Figure 5).

EHRs are high on the priority lists of health care organizations. Kaiser-Permanente has earmarked \$3 billion to create one, with plans to make a version available for other health plans to purchase. Similarly, Sutter Health—a prominent health system of 33 hospitals in northern California—plans to implement an EHR for both inpatient and outpatient services in the next two years. The goal is to have medical records available anytime and from anywhere using a single sign-on for both patients and providers. With an eye to making their facilities more accessible, Sutter Health’s Internet system is expected to also allow administrative transactions such as online registration and credit card payments.

What data are included in the EHR and when and how information is released to patients are critical

Figure 5. Results of audience poll regarding perceived health care executive/managers' willingness to support eHealth implementation now, compared with previous years (N = 47).



issues that have yet to be resolved. Privacy and authentication are primary concerns. Can or should spouses be able to see each other's records? What if a partner is getting an HIV test? With online access, will practitioners be convinced that they can protect patient confidentiality at least as well as they have in the past?

In addition, there are questions about what information is appropriate to share with patients online. For instance, should a patient have real-time access to lab results concerning biopsy of a potentially cancerous tumor? If not, when should this information become part of the "shared" record? Do we rely upon physicians to actively release lab results (in one study only 3 percent remembered to mark test results for release to the patient)? But if release is automated, what are the ethics of potentially distressing information getting to the patient without immediate access to medical advice and counseling?

While the details remain to be worked out, the White House recently issued an executive order promoting EHRs to be in widespread use within the next 10

years. The government's strong support of eHealth has resulted in five to ten companies vying for position as primary EHR providers. With numerous patients switching health plans in any given year, portability and interoperability rise to the forefront. Because health care systems typically seek an integrated solution, selection of EHR vendors will be based on the products' abilities to further organizational goals at an appropriate price. As with all eHealth technologies, there must be a strong business rationalization for the product chosen.

In terms of innovations, once EHRs are an established part of clinical practice, it is anticipated that a convergence of technologies will offer eHealth developers a tremendous opportunity. With central or linked repositories for patient data, other innovations—such as biomedical and surgical technologies or transmission from home monitoring devices—will become more realistic. Other eHealth applications gaining substantial attention include CPOE, bedside scanning to track inpatient medications, secure provider-patient messaging, and e-visits.

Lessons from the Field

“Sometimes free isn’t cheap enough. You also have to factor in funds for promoting adoption.”

Dr. Randy Mauffray, Director of the Center of Excellence for Medical Multimedia, described the lengths they had to go to get a multimedia patient education CD-ROM about pregnancy accepted by providers as a regular part of patient education. This example illustrates the importance of developing a communications strategy to encourage product adoption.

In any given year, medical staff in a nationwide set of worksite clinics provides care for approximately 18,000 pregnancies. Because information is key to maintaining prenatal health, avoiding premature labor, and preventing low birth weight, the Center of Excellence for Medical Multimedia created an award winning CD-ROM for free disbursement to all pregnant personnel and their dependents. A thorough marketing campaign was executed, and sample CD-ROMs were sent to all clinics with order forms to obtain more free copies for patients. Dr. Mauffray related, however, that the outcome was a classic case of defying the axiom “If you build it, they will come.” Very few orders were received.

Further inquiry revealed major misunderstandings. Many facilities assumed that the CD-ROM was going to cost money, so they did not even look at it because they thought that ordering

copies would require them to cut back on more-critical medical supplies. One clinic thought the CD-ROM was a single issuance giveaway and held a lottery and presented it to the lucky patient who won the drawing. Another facility didn’t have time to look at it, and put it in the closet for later review and simply forgot it was there.

Despite national recognition of the program, providers did not seem to be adopting this free technology. Determined to see the CD-ROM get into the hands of pregnant women, Dr. Mauffray went on a blitz of visits to their medical facilities around the country. He met face to face with administrators to demonstrate the CD-ROM, discuss optimal ways to incorporate it into prenatal care, and to reiterate that it was available for free. Although it took an average of 90 minutes at each facility, orders have grown to 16,000 per year.

A motivated champion or change agent is needed at each site to drive usage. Once administrators were given the tour, knew what was inside, and were provided with simple suggestions on how to easily incorporate the program, orders soared. It simply took setting aside time and money in addition to the costs of production to promote—in person—technology adoption in the real world. Always reserve some resources to ensure user adoption.

Although large health care systems usually look to large companies for EHR products, they appear to recognize that the more creative applications of eHealth are likely to come from smaller companies. A primary concern with small vendors, however, is whether they will be around long enough to support the product during an extended period of time. Health care organizations looking to venture into more-innovative technologies rely upon analysis by independent

technology evaluation organizations to help them make purchasing decisions. They also evaluate the financial status of the small company and engage in careful contract negotiations. Some even use an escrow account to safeguard the disbursement of payments throughout the length of the project. Strategic partnerships are also a possibility, but they may require more time and money than the health care organization wants to invest.

Working models

Elizabeth Waterman, U.S. Programs Benefits Manager at Intel, describes the company's eHealth vision: access to benefits information anytime, anywhere. "Intel's philosophy is 'one generation ahead,'" says Waterman. "Our mission is to lead the market in the use of world-class technology. We need our health plan to share this mission so we can be a 100 percent eHealth corporation for our employees." Faced with 15–20 percent annual increases in health benefit costs, Intel is pioneering an effort to offer a health savings account plan as its base coverage for all employees. Their strategy is to implement cost controls and cultivate informed, engaged, healthy and productive health consumers. As such, Intel is looking for health plans that will offer online decision support tools, health education materials, methods for tracking costs, and tools to help employees find more cost-efficient alternatives. "Quality and cost transparency are important drivers for us," notes Waterman.

Although the digital approach is considered optimal at Intel, the company also is committed to "high touch." eHealth applications presented

by health plans are expected to also facilitate real-time communication, including voice contact and work with a personal coach. The thrust of their eHealth strategy is to enhance the value of the benefits program to Intel employees and their families by embracing technology designed to improve quality of care, expand product offering and access to care, and to enhance marketing and communications.

In addition, Intel's U.S. Programs Benefits plans to make more-informed benefits decisions by performing analysis through their data warehouse, which integrates Intel's medical claims. The data will not be tied to personal identifiers, but will allow Intel to track the types of services their employees and dependents use. For instance, because they have a young employee base that is about 73 percent men, spousal expenses are high relative to other companies due to a disproportionate use of obstetrical services. By having blinded access to claims history information, Intel expects to be able to make data-driven strategic decisions without having to rely upon the health plan for information.

Employers

Although health plans appear to pay for medical care, employers are the real purchasers.⁴ With double digit annual increases in insurance premiums, employers have a vested interest in technologies that can reduce costs and expect their health plans to lead the way in providing such options. Employers have become increasingly vocal and visible about reducing health care costs. Large employers, in particular, are seeking to empower patients by providing Web information portals to help employees stay healthy and be informed health care consumers.

The growing popularity of consumer-driven health plans and health savings accounts offers eHealth developers numerous opportunities for meeting employer needs in this regard. Major issues with the Web portal approach center on privacy and authentication. If a portal is sponsored by the employer or the health plan, some employees have concerns that management may gain access to individually identifiable health information. Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance is also a significant consideration.

⁴ The data and information in this section are largely based on a presentation by Elizabeth Waterman, U.S. Benefits Program Manager, Intel, but this section does not necessarily represent her views.

Disease management is another area that appeals to employers. With 50 percent of health care claims stemming from 15 chronic, mostly preventable, conditions, employers are attracted to eHealth applications that involve risk assessment, regular tracking, promotion of health behavior change, and the support of a coach. They don't, however, necessarily want to run these programs themselves. Many employers are willing to offer incentives for employees to enroll in such programs, but large employers are looking for health plans to be proactive and provide disease management services themselves.

Government

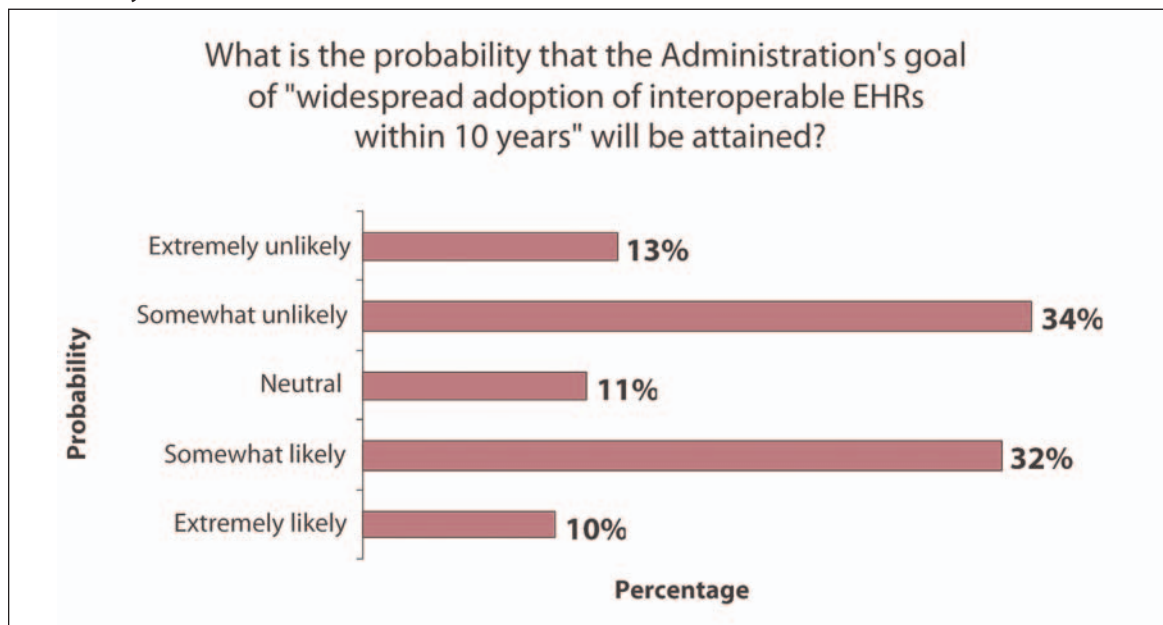
With the White House executive order to promote national adoption of EHRs within the next 10 years, eHealth appears to be front and center on the federal radar.⁵ Dr. David Brailer has been appointed the

National Coordinator for Health IT to improve safety, reduce costs, and speed the incorporation of research results into daily practice. Summit participants were polled regarding the likelihood of the EHR goal coming to fruition. Forty-two percent thought it was likely to happen, while 47 percent were pessimistic (Figure 6).

One of the lead agencies to support the White House initiative is the Agency for Healthcare Research and Quality (AHRQ). The mandate of AHRQ has changed in recent years. Given the interest in accelerating eHealth adoption and the Institute of Medicine report on medical errors, the agency is shifting its focus from research to being accountable for the provision of better and safer medical care throughout the country.

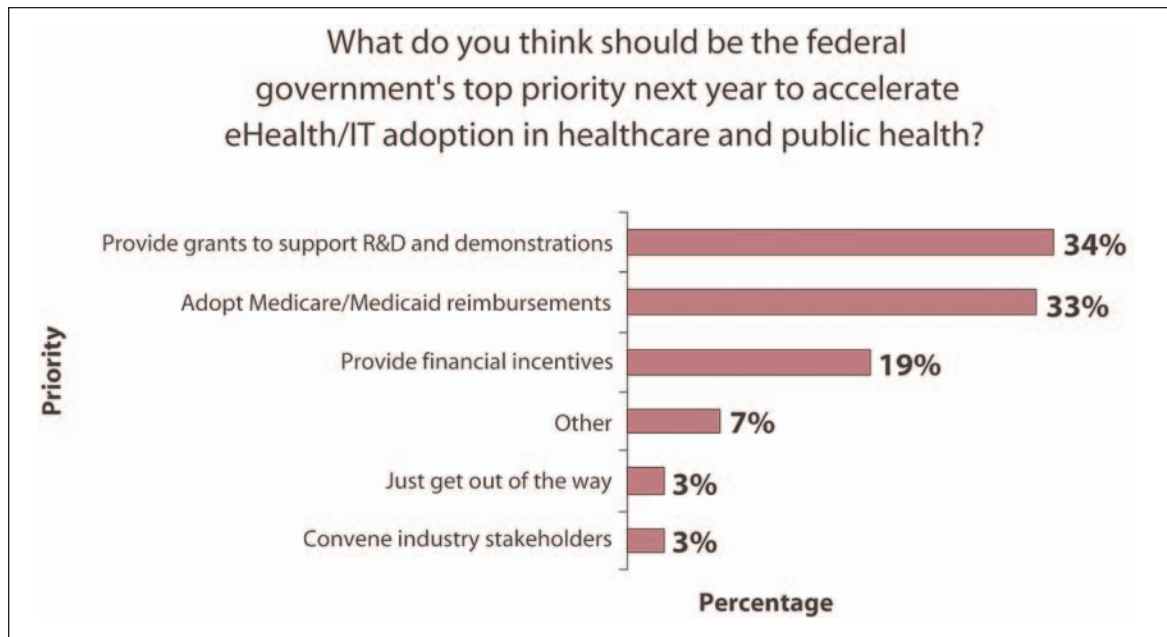
According to the Institute of Medicine's 2001 report, "There must be renewed national commitment to building an information infrastructure to support

Figure 6. Results of audience poll regarding the likelihood of widespread adoption of interoperable EHRs within the next 10 years (N = 62).



⁵ The data and information in this section are largely based on a presentation by Lisa Dolan-Branton, Senior Advisor for Community-based Health IT, Agency for Healthcare Research and Quality, but this section does not necessarily represent her views.

Figure 7. Results of audience poll regarding the top priority for the government to accelerate eHealth adoption (N = 67).



health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education.” AHRQ’s priorities include improving provider education, expanding health informatics, and hastening the diffusion of research results into practice. EHRs, e-prescribing, CPOE and decision support are some of the initiatives AHRQ is exploring, as well as efforts toward connectivity and interoperability.

Over a three year period, AHRQ has budgeted \$96 million in grants that have been awarded to more than

100 organizations across 38 states. A National Health IT Resource Center has been established to provide technical support for grantees and a repository of best practices. Recently funded projects target improving health IT penetration in small and rural communities; furthering the development of clinical standards and interoperability; and creating, implementing, and evaluating new technologies focused on improving safety and quality of care in diverse settings. Future emphasis will be on regional collaborations; enhancing technical and resource support for stakeholders; synergizing medication and therapeutic initiatives; and expanding the use of health IT to integrate clinical, patient-focused care and research. However, some critics contend that current government expenditures are only a fraction of what is really needed.

Thirty-three percent of Summit attendees perceived the government to be the primary driver in eHealth (Figure 4). When asked what the government’s top priority for accelerating eHealth adoption should be, 34 percent said grant funding for R&D and demonstration projects. Thirty-three percent endorsed the

Participant Perspectives

“The eHealth sector is like a giant jigsaw puzzle without the picture on the cover of the box. It is the government that has the ability to help us fit the pieces together.”

— Gayle Wilson-Steele, CEO, MedSeek

suggestion that Medicare and Medicaid reimburse for eHealth services. Tax breaks, loans, and other financial incentives for health care organizations came in as the third choice (Figure 7).

Consumers

Only 11 percent of Summit participants identified consumers as the primary drivers of eHealth throughout the next five years. Certainly consumers are well ahead of health professionals in relying on the Internet for health information and decision support. Health plans report that consumers readily accept Web portals as a convenient way to interact with their insurance carriers. One health plan representative said that 20 percent of their interactions with subscribers occurred online, and that persons buying individual plans were highly likely to use the Internet for their research and purchase. In the future, this plan expects to use the Web portal to

deepen its relationships with subscribers. Consumers are the customers of the health plans and the employers. They are starting to use eHealth to better manage their personal and family situations. It is generally recognized that the baby boomer generation will continue to adopt new tools and technologies that will benefit them. Developers are encouraged to pay attention to this trend.

Consumers continue to express some privacy concerns about eHealth. Privacy issues commonly involve insurance companies and employers gaining access to medical records, possibly compromising the individual's coverage or employability. Fueled by recent news about medical errors and iatrogenic deaths, patient safety is also of concern. Adoption of eHealth technologies may relieve some consumer anxiety as technologies such as point-of-use medication checking become more prevalent, ensuring that the right person is getting the right medications at the right time.

Ethics and Legal Considerations

Take Home Messages

- Ethics are often a primary consideration in product development. They may be the motivator of an idea (e.g., to reduce health disparities) or pose technical challenges (e.g., protecting patient confidentiality in an electronic health record).
- Developers can make ethics central to their business by including ethical standards in their mission, establishing a code of conduct, training new employees in ethical procedures, and enforcing accountability for lack of compliance.
- Regulatory compliance is not only the law, but it also makes good business sense. Small legal or ethical errors can have a disproportionately large impact that may delay or doom product development and marketing. Noncompliance can also result in financial and criminal penalties.
- Those receiving federal funding to research the effectiveness of their products must go through an institutional review board process to ensure that people participating in the study (even just sharing their health information) are being adequately informed of the benefits and risks, that all risks are minimized wherever possible, and that the confidentiality of participants is protected.
- HIPAA privacy and electronic security regulations have been the federal government's regulatory response for protecting the privacy and confidentiality of patient infor-

mation. The electronic security regulations must have been implemented by April 20, 2005.

Ethics and the law

Ethics are often a primary driver in product development. They may be the motivator of an idea (e.g., to reduce health disparities) or pose technical challenges (e.g., protecting patient confidentiality in an EHR).

Much as everyone likes to think of themselves as ethical, situations frequently arise in which the line becomes blurred and there is no one “right” answer.⁶ As professionals involved in health care, eHealth developers may be obligated to higher ethical standards than most other professions.

Participant Perspectives

“When it comes to the law and ethics, there are three rules:

- Just because it's legal doesn't mean you should do it.
- If the law mandates it, do it.
- Ethics may require you do more than the law mandates.”

— Rodney Johnson, Senior Medical Center Counsel, Stanford University

⁶ The data and information in this section are largely based on presentations by Allan Frankel, CEO, ChartScape, LLC; and Rodney Johnson, Senior Medical Center Counsel, Stanford University, but this section does not necessarily represent their views.

Figure 8. Results of audience poll regarding the current level of safeguards protecting the privacy and security of health information (N = 59).

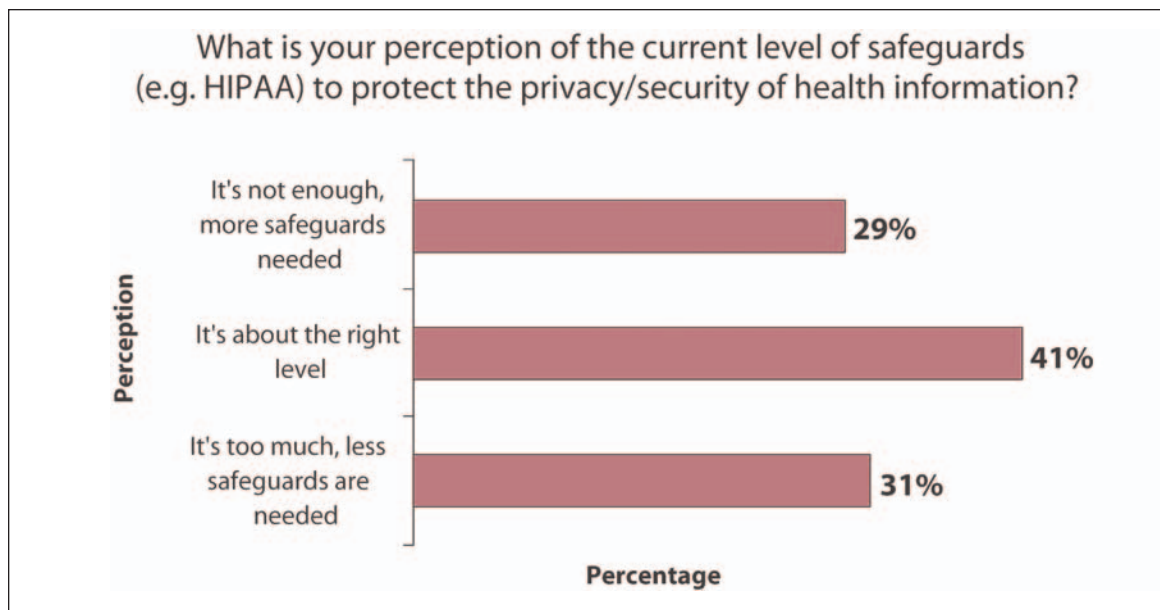
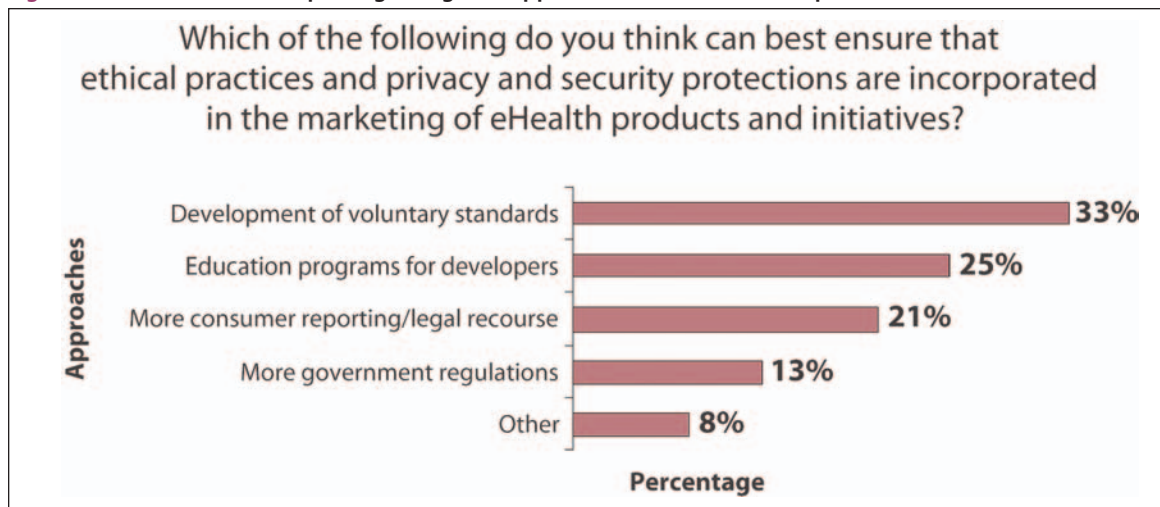


Figure 9. Results of audience poll regarding best approaches to ensure ethical practices (N = 63).



When asked if there are enough legal safeguards to protect the privacy and security of health information, 41 percent of Summit participants said there were. Interestingly, the remaining participants were nearly evenly divided on this issue, with 31 percent saying there are too many safeguards and 29 percent saying there are too few (Figure 8).

Summit participants overwhelmingly favored the development of voluntary standards over government regulation (33 percent to 13 percent) to ensure ethical practices (Figure 9). Other approaches to promote ethical practice included education programs for developers (25 percent) and improved consumer reporting and legal recourse (21 percent).

Lessons from the Field

“To be or not to be: the decision to shut down a support group Website.”

Robert Pretlow of eHealth International described his research with bedwetters, who number in the millions of children and adults. Given the embarrassing nature of the problem and the anonymity of the Web, Robert felt that an online chat room and message board might be an ideal format for helping people overcome this problem. Much to his surprise, the site turned into a gathering place for people who *like* wearing diapers. Ninety percent of visitors—and the site eventually had 60,000 hits a month—had no interest whatsoever in treating their bedwetting problem. Calling themselves “diaper lovers,” most of the conversation revolved around types of diapers and brand comparisons. Sixty-percent of visitors liked wearing diapers to the point that they anticipated wearing them the rest of their lives.

Concerned that the site was inadvertently promoting diaper use among children and teens, who should resolve rather than perpetuate their bedwetting problem, Robert blocked the use of the word “diaper” in the chat dialogue. Visitors simply found ways around the barricade. In the end, Robert decided the ethical thing to do was to shut down the site. Paradoxically, he received a communication from a former visitor who expressed disappointment at the site’s closure, remarking that if Robert thought he was stopping the promotion of diaper use, he was in error.

Regulatory compliance is not only the law; it also makes good business sense. Small legal or ethical errors can have a disproportionately large impact that may delay or doom product development and marketing. For instance, health care providers and consumers will not use a product if they do not trust it and its developers. In addition, noncompliance can result in stiff financial and criminal penalties.

Developers can set a tone in their business that makes support of ethical actions and legal compliance quite visible. For instance, ethical standards should be included in the mission statement and

code of conduct. Training of new employees should include a review of the code of conduct, legal requirements, and the company compliance plan. The budget should reflect allocations for training and legal compliance. As well, accountability must be built into the system—even a compliance officer for large companies—with consequences elucidated and enforced in the case of violations. Finally, in decision-making, management should always address the question, “What is the right thing to do?”

For examples of guidelines created for the pharmaceutical industry, which often juggles ethics in health care, developers might look to the Office of the Inspector General (OIG) of Health and Human Services (<http://oig.hhs.gov/fraud/complianceguidance.html>). For more useful links, see the Further Resources section at the end of this chapter.

Ethical Concerns in Research

To protect against ethical lapses in research that involve people and personal information, the federal government has created the Office of Human Research Protection, which enforces a series of regulations known as the “Common Rule.” All recipients of federal research dollars, or organizations conducting Food and Drug Administration (FDA)–related trials, must comply with these regulations if they are doing research on human subjects. In addition to Department of Health and Human Services regulations, the FDA and individual states also have statutes and procedures to protect persons engaging in health research studies.

To maximize protections, the definition of human subject research is intentionally broad: “Human subject research involves the collecting of identifiable information about a living person, or an intervention or interaction with an individual.”

To verify that a study is in compliance with the Common Rule, it must get approval from an Institutional Review Board (IRB). Most universities and many hospitals have an IRB in place to review the risks and benefits of a study, plans to minimize risks, and efforts to maintain confidentiality. In addition, the IRB ensures that informed consent forms appropriately describe the risks and benefits to research participants, and that there is a reasonable plan for addressing any adverse events/consequences that occur during the research. While IRB approval indicates that unbiased professionals and community members agree that the research design and plans for implementation are not unduly injurious to human subjects, the onus is on the researcher to make sure that participants are continually aware of their rights—including the right to quit the study—and that risks are in fact being minimized at all times.

Another intersection of ethics and research concerns the fair reporting of results. For instance, adverse effects have not always been publicly disclosed in reports regarding health interventions. To offset this problem, the Public Health Service and the FDA have implemented regulations regarding falsification and fabrication of data. In addition, 11 international journals—including the *Journal of the American Medical Association* and the *New England Journal of Medicine*—have made it a publication requirement that researchers also submit their full results to a public access Website.

Security, Privacy, and Confidentiality

The right of patients to decide who has knowledge about their medical conditions is central to health care delivery. Each state may have its own confidentiality regulations concerning basic medical information and special situations such as HIV/AIDS. The federal government has stringent “super-confidentiality” laws in two areas: substance abuse and mental health treatment.

As much as companies may strive to maintain privacy protection, lapses do occur. In an audience

poll of Summit attendees, 16 percent admitted that violations of privacy and security had occurred on a regular basis in their organizations during the past year (Figure 10). Eighteen percent said they knew of a few occasions, while 35 percent reported one or two violations in the past 12 months. Thirty-one percent indicated that their company never had violations of privacy or security.

As one Summit participant observed, “We all know that the conventional paper record system has flaws: entries are illegible, paperwork gets lost, et cetera. But because hackers and unauthorized persons have the potential for easy access to digital information, electronic medical records are being held to a higher standard.”

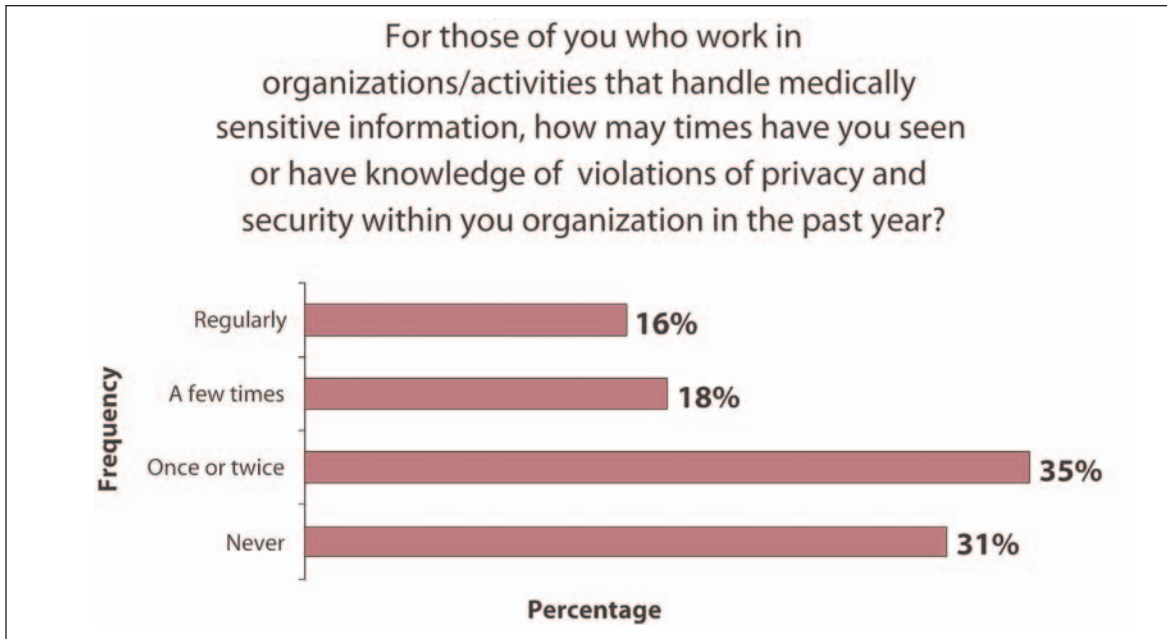
HIPAA reflects the federal government’s effort to ensure the privacy and security of patient information. For “covered entities,” the privacy regulations promulgated under this federal law have greatly restricted the flow of personal medical information without the express consent of the patient. “Covered entities” are health care providers, health plans (including employers with Employee Retirement Income Security Act of 1974 employee benefit plans), and health care clearinghouses. As one participant noted, “If you yourself are not a covered entity, your customer probably is. You need to be aware of the HIPAA regulations.”

The HIPAA initiatives are generally based on the fundamental principles of fair information practices. Individuals must be able to

- determine what information about them is in a record and where and how it is used
- correct or amend a record of identifiable personal data
- prevent information obtained for one purpose from being used for other purposes without their consent.

The electronic security regulations must have been implemented by April 20, 2005. These rules focus on electronic transmission of medically sensitive information and require password protection, firewalls, and the creation of an audit trail of who has accessed

Figure 10. Results of audience poll regarding violations in privacy and security of medically sensitive information (N = 51).



which files—including databases and payment and billing spreadsheets.

Issues of privacy and confidentiality may be challenging in the context of eHealth products such as shared EHRs. For instance, even though information probably should not be concealed from the patient, some physicians may withhold information from the chart; for example, information that might jeopardize a patient’s insurability. Or, a physician might wish to document the possibility of a psychiatric condition on the record but might not be ready or willing to bring up this possibility with the patient.

Another challenge in the creation of EHRs involves the responsibility of the organization that is creating, maintaining, using, or disseminating identifiable personal data to ensure reliability of the data for their intended use and to take reasonable precautions to prevent misuses of data. The advantage of computerization is that large amounts of data can be stored quite efficiently in a relatively small, centralized location. Separating personally identifiable informa-

tion from medical data is one way to hinder exploitation. However, as documented by recent episodes, even the best security features are susceptible to employee misuse.

Conflict of Interest

Clinicians must ensure that their professional duties are not unduly influenced by financial gain or remuneration from a third party. State and federal laws prohibit kickbacks; however, such conflicts of interest are not always immediately evident. In addition, eHealth developers should become familiar with the conflict of interest regulations for research created by the OIG and may need to develop a conflict of interest policy for research, development, and distribution of products. For example, there are new accreditation laws concerning continuing medical education courses for physicians. To legitimately provide continuing education credits, a course cannot be a veiled advertisement for a specific product but must objectively present the range of treatment options.

Serving the Underserved

Ideally, eHealth should serve all people, not only the affluent “worried well.” It is possible that the trend toward increasing consumer responsibility will increase disparities. eHealth tools may be of more value to underserved populations when they are developed with those populations in mind, rather than targeted for higher income and more highly educated audiences.

Ensuring that the underserved will benefit from eHealth solutions requires the cooperation of industry, government, and advocacy organizations. Major needs include eHealth solutions to address health disparities and unequal access. Examples include the development of telemedicine tools for rural areas and virtual “home visits.” Patients can be empowered by means of eHealth products to take better control of their health through self-care, behavior change interventions, and informed decision support. Reducing health care costs by creating more-efficient processes can also increase accessibility, while quality of care can be addressed by enhancing professional online access to evidence-based information.

Further Resources

- Research bioethics resources on the Web, including Public Health Service conflict of interest and misconduct:
<http://www.nih.gov/sigs/bioethics/index.html>
- Office of the Inspector General — Guidance for Pharmaceutical Manufacturers:
<http://oig.hhs.gov/fraud/complianceguidance.html>
- Pharmaceutical Research and Manufacturers:
<http://www.phrma.org>
- Office of Human Research Protections:
<http://www.hhs.gov/ohrp/> — 45 *CFR* Part 46
- FDA IRB Reg’s 21 FDA Part 50, Information Sheets For IRBs:
<http://www.fda.gov/oc/ohrt/irbs/default.htm>
- Office for Civil Rights: HIPAA Privacy Rule:
<http://www.hhs.gov/ocr/hipaa/> — Regs 45 *CFR* Parts 160, 164:
<http://www.hhs.gov/ocr/hipaa/finalreg.html>
- National Institutes of Health: HIPAA Privacy Rule and Research:
<http://privacyruleandresearch.nih.gov/>
- Centers for Medicare and Medicaid: HIPAA Security Rule, 45 *CFR* Parts 160, 162:
<http://www.cms.hhs.gov/hipaa/hipaa2/regulations/security/default.asp>
- Accreditation Council for Continuing Medical Education: <http://www.accme.org/>
- 2004 standards for Commercial Support:
http://www.accme.org/whatsnew/sec_new_nw1_255.asp

eHealth Research and Dissemination

Take Home Messages

- It may take more than a decade to move a proven research innovation into the mainstream of health care. In order to improve the quality of health care, the speed of the diffusion of innovation must be accelerated.
- It seems that eHealth developers are increasingly building their products in close relationships with universities and researchers.
- In growing numbers, developers are conducting evaluation research, including randomized control trials, to verify outcomes and reveal unintended consequences.
- The Small Business Innovative Research (SBIR) program of the National Institutes of Health is a valuable resource for commercial enterprises seeking seed R&D funding.

eHealth Research

Each year the eHealth Developers' Summit solicits eHealth research abstracts for a peer-review competition, with four to five selected for presentation at the Summit. Out of 25 submitted abstracts, four projects were invited to present their findings. A panel of judges evaluated the four presentations and presented an award and \$1000 to the project that showed the most originality, overall quality, scientific rigor, methodology, design and analysis, and potential impact on health and eHealth. All the developers who presented their findings at this year's Summit worked extensively with academics in their field, and some received grant funding from the Small Business Innovative Research program of the National Institutes of Health.

Sponsored by the Health e-Technologies Initiative of the Robert Wood Johnson Foundation, the goal of the "Best eHealth Research Paper" session is to encourage and improve the quality of eHealth research and speed the diffusion of innovations into daily practice. On average, it takes more than a decade for research findings to become mainstream medicine practice. In contrast, the four Summit research presenters expected to begin distributing their evaluated products within three months to three years.

By supporting applied research, the Health e-Technologies Initiative and the eHealth Institute hope to encourage developers to engage in rigorous evaluations, not only to demonstrate positive outcomes, but also to reveal unintended consequences. As providers, health systems and the government move toward evidence-based practice, and developers have both an incentive and a responsibility to assess the efficacy, risks, and benefits of their products.

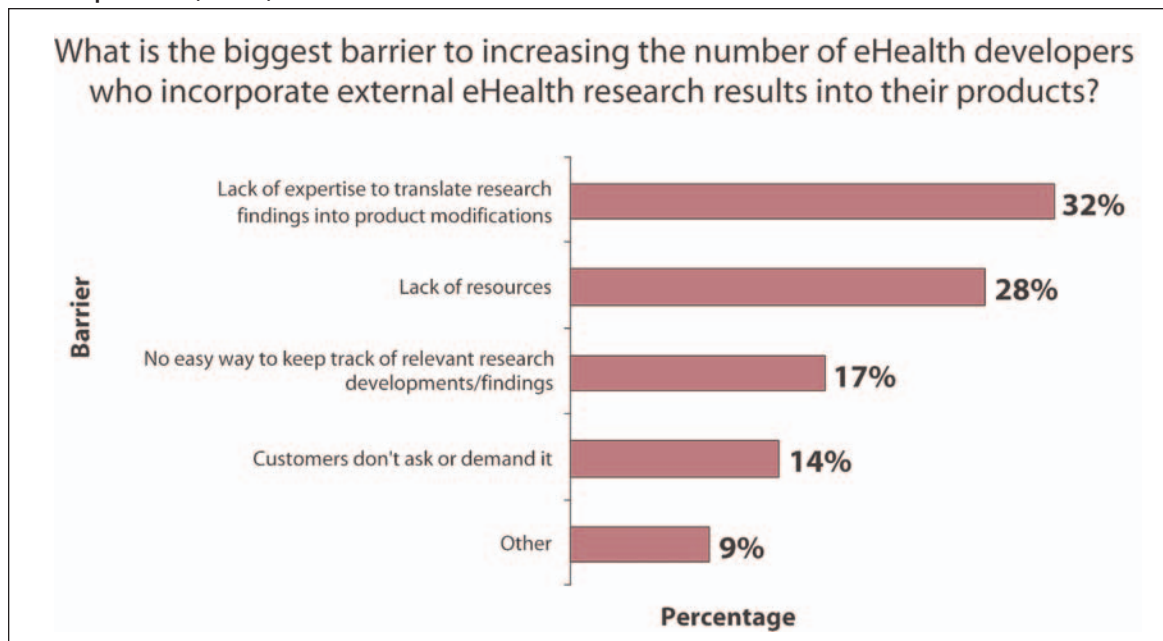
When Summit participants were asked about barriers to developers increasing their use of external research results, 32 percent cited lack of expertise in translating findings to practical products (Figure 11). Twenty-eight percent identified lack of resources as their biggest barrier, while 17 percent attributed the problem to difficulty tracking relevant research. Lack of consumer demand for integration of research was also a factor.

The four research projects presented at the Summit are summarized as follows:

Armando Valdez of Valdez and Associates developed a touchscreen kiosk program to promote mammography and early detection of breast cancer among Hispanic women. While 90 percent of Caucasian women diagnosed with breast cancer make it to the five-year survival point, only half of Hispanic women are so fortunate. Hispanic women are often not diagnosed until late in the disease, diminishing their chances of recovery and reinforcing cultural fears that a positive diagnosis of breast cancer means certain death. Topics covered in the touchscreen program were derived from focus group input and included a description of detection methods, risk factors for breast cancer, the advantages of early detection, a description of treatment options, and an explanation of survival rates. The intervention was created to be linguistically and culturally competent; the touchscreen and multimedia format allowed for self-paced learning and minimum literacy to use the program. In addition, the program tailored information to the circumstances of the user (e.g., previous experience with mammography).

Kiosks were placed in several community clinics and a large HMO. Participants were screened to include only women who were 40 years old or older, who self-identified as Latinas, had no personal history of breast cancer, had no more than a high school education, and had household incomes of less than \$510 per week. Most (83 percent) of the participants were immigrants, and 45 percent had not had a mammogram within the recommended time period for their age and risk factor(s). The research design involved a randomized control trial of 1197 users who completed a pre- and post-intervention assessment with a four-month follow-up. Half the participants were assigned to the treatment group and received immediate access to the kiosk. The other half were in a waitlist control condition and were not given access until four months later. Comparisons were made between the treatment group's immediate post-test assessment and the control group's assessment four months after the baseline. Measures included mammography status, access to health care, and demographic characteristics, as well as assessment of breast cancer knowledge, attitudes, beliefs, and intentions concerning mammography.

Figure 11. Results of audience poll regarding developer barriers to incorporating external research results into eHealth products (N = 65).



As compared with those who did not see the program, participants in the treatment group demonstrated significant improvements in knowledge about breast cancer, attitudes and beliefs about early detection, and the benefits/risks of mammography. In addition, of the 541 participants who were overdue for mammograms at the pretest, 36 percent actually had a mammogram and 15 percent made appointments to do so four months after exposure to the program. Responding to requests from interested clinics, Valdez and Associates are working on a similar multimedia program regarding Pap smears and screening for cervical cancer. Plans are to bundle the two programs and sell them as a female reproductive health program.

Vesta Brue of Lifetechniques, Inc. evaluated the efficacy of a computerized, portable medication dispenser (MedSignals) for HIV patients that facilitates adherence to complicated treatment regimens. Persons with HIV frequently suffer from cognitive impairment, making it difficult to track and monitor adherence to their antiretroviral regimens. The MedSignals team designed a handheld device that could handle four distinct medications. To overcome diminished sensory perception, each of the four compartments on the device was equipped with both visual and audio reminder alerts that flashed or beeped according to the number of pills to be taken. Opening the compartment lid allowed the medication to be dispensed and recorded as “taken.” In addition to delivering the correct number and type of pills, with a push of a button, the device displayed how long since the last pill was taken, how long until the next one was to be taken, and how many had been taken so far on a given day. This information can be uploaded via a telephone line to a central database.

Evaluation participants used the device for two months in a counterbalanced crossover design study. Half of the participants were randomly selected to receive the full functioning device first, with alerts and pill dispensing. After one month, the alerts were disabled and the device only recorded when pills were taken. The remaining half of the participants used the device in the opposite order, with

recording-only during the first month and the reminder alerts during the second month. Out of 51 initial participants, 32 men and 12 women completed the study.

User satisfaction and feedback was an essential facet of the study. On a seven-item satisfaction measure, participants agreed or strongly agreed that the device was easy and convenient to use, provided useful feedback, helped them remember to take their pills, and that they would recommend it to a friend. The researchers defined “timing compliance” as taking a pill within 15 percent of the recommended time interval between doses. By that definition, 64 percent of participants using the alerting features were timing-compliant. Those who had the alerting disabled and were using the device only to record when they actually took their pills had a significantly lower (48 percent) compliance rate. Since dosage timing is critical to successful management of HIV, the 16 percent improvement with reminders is important. A treatment order effect was observed during the study; those who received the alert functions first had better timing compliance in the second record-only month than those who had the device set to record-only in the first month. Unfortunately, methodological issues appear to have confounded assessment of actual pill counts (whether participants took the right number of pills). The MedSignals dispenser is being modified for use in other countries such as Uganda.

Alice Ray of Ripple Effects evaluated a Website for adolescents that provided multimedia cognitive-behavioral therapy support for adaptive coping responses to life stressors. The program was implemented in high school settings. The program addressed dozens of problems common to adolescents such as substance abuse, pregnancy, STDs, bad grades, disputes with friends, and divorcing parents. Viewers could log on and explore these problems, including interactive activities for identifying intrinsic and extrinsic causes of the problem as well as personal strengths for managing the situation. Users could also view video clips of onscreen characters handling similar problems—with varying levels of success depending on the wisdom of their

“choices”—and analyze the range and efficacy of possible coping responses. The program also offered journaling capabilities, multiple choice games, opportunities to role play and rehearse situations, and the ability to add new topics to the “Situations Library.”

The goal of the program was to increase protective factors in teens facing adversity and to decrease risk of drug use. In addition, Ripple Effects sought to measure whether the product could increase academic performance while reducing truancy and discipline problems. In a quasi-experimental pre-post test design, 523 students spanning six schools were randomly assigned to treatment and control conditions. The schools included four in an urban setting with predominantly African-American and Hispanic populations and two in a rural setting.

Those students who viewed the program were asked to visit at least 21 topics throughout the seven week evaluation. Participants were requested to use the program outside of classroom hours with no adult assistance. On average, they spent 14 hours with the program. Computers were available in a variety of locations, including computer labs, school libraries, disciplinary settings (e.g., the principal’s office), and the back of a classroom. Measures included validated instruments concerning locus of control and fatalistic thinking, as well as attitudes and beliefs concerning the risks of alcohol and drug use/abuse. A review of school records to assess academic performance, school attendance, and discipline referrals was also included.

The treatment group exhibited significant improvements compared with those who had not yet viewed the program. Grade point averages (i.e., A = 4 points; B = 3 points) increased by more than one point. Discipline referrals dropped by two thirds, absenteeism was cut in half, fatalistic thinking decreased by 10 percent, and disapproval of alcohol use increased by 20 percent. However, disapproval of marijuana use—when compared with the use of Ecstasy, methamphetamines, and crack cocaine—decreased. The Ripple Effects program is currently in use in 350 school districts throughout the country.

CT Lin of the University of Colorado at Denver presented a descriptive study of usage patterns and satisfaction with a secure patient-provider messaging system in a family practice setting. In this study, patients in the waiting room of a university affiliated family practice were recruited into the study if they had Internet access. Six hundred and six people agreed to participate and were randomized to treatment and control conditions. The control group was given usual telephone access. Treatment participants were allowed to use the telephone but were also provided access to a commercial secure messaging system for communicating with their physician’s office. Approximately one-third of those assigned to the treatment group used the online system during the course of the six month study. In addition to secure messaging, which was a direct conduit to the physician with no intermediaries, the Web-based program offered online appointment requests, online prescription refills, and online specialist referral requests. Users could also provide and edit personal and insurance information as well as access other online information resources from this page.

Overall, patients who used the online system were very pleased, rating their experiences significantly higher than did the control group who had only telephone access. In terms of practice communication, for instance, 44 percent of the treatment group rated the practice as better or a lot better, whereas only 12 percent of the control group gave the practice that rating. Eighty-one percent of the treatment group patients said that the online system saved a phone call to the clinic; 33 percent noted that it saved a visit. Eighty-six percent said that they preferred the online system to the phone for nonurgent communications. Forty-seven percent stated that they would be willing to pay an average of \$4.10 per completed online message with their physician.

From the physicians’ point of view, far from the deluge they had expected, they received an average of eight messages per day (roughly one for every 250 patients), which took a daily total of 12–15 minutes of their time. Only 27 percent of messages were sent during clinic hours (8:00 am–5:00 pm, Monday–Friday). Put differently, nearly three-

quarters of the communications were initiated at times when the clinic was closed. As a result of this analysis, the clinic shifted staffing ratios to accommodate “after hours” needs.

The University of Colorado is extending its research into usage patterns by investigating online disease management programs and exploring the workability of a shared EHR.

Commercializing eHealth

Take Home Messages

- To move from great idea to a commercially viable product, a concept must meet a recognized need, have a sufficient potential market, and provide enough economic justification for its purchase.
- A product does not have to be a radical innovation to achieve commercial success. In fact, some of the best products involve using existing and accepted methods in a new or different context.
- It is important to be early, but “first to market” is not always the wisest course.
- “Building buzz,” even before a product is ready, can lead to unexpected benefits such as strategic partnerships, or attracting key personnel to join the company.
- Developers are not always the best at marketing and distribution; they often need to find strategic partners to fill in these gaps.

From Inspired Idea to a Viable Business

Many Summit attendees who have made it through the gauntlet of the critical early years of a venture graciously shared their insights.⁷ On the basis of their experience, it appears that several key questions must be addressed if an idea is to evolve from a great concept to a successful commercial product. These

questions include the following:

- Is there a recognized need for the product?
- How big is the market?
- Is there economic justification for the customer to purchase the product? (Does it save money, save time, or make money? How long will it take for the buyer to recoup the initial investment?)

eHealth developers often get caught up in the societal benefits of their product and forget that it also must fit into the current economic framework of our health care system.

Participant Perspectives

“In the war between socialism and capitalism, socialism lost. So, if you don’t want to become a cultural asterisk in a capitalist society, you need to find a way to create economic value while doing good. This is the definition of social entrepreneurship and as developers, it must be our beacon.”

— Alice Ray, CEO, Ripple Effects

A product idea does not have to be a radical innovation to achieve commercial success. In fact, some of the best products involve using existing and accepted methods in a new or different context. This is evidenced by a generally slow diffusion of change that seems to proceed best when people are asked to

⁷ The data and information in this section are largely based on presentations by Susan Brink, Principal, Healthmark Multimedia; Ezra Davidson, Chairman of the Board, Blue Shield Foundation; Manish Singh, Director, California Technology Ventures, LLC; Jim Wittmack, Director of Transactions, JWC Capital Advisors; Kevin Woods, Co-founder, iCAD, Inc., but this section does not necessarily represent their views.

Lessons from the Field

"You have to be early, but first to market is not always the wisest course."

Kevin Woods, co-founder of iCAD, described the evolution of his business. He and his partner developed software designed to identify suspicious areas in a mammogram that warranted further investigation by the radiologist. When they began, another company was ahead of them by about two years. "They say you can tell the true pioneers," Woods noted, "because they are the ones with the arrows in their backs." Indeed, this

was the case with Woods' competitor. The more established company blazed the trail, but had to spend huge sums of money softening a new market and getting the procedure accepted for reimbursement. The iCAD product was developed with a fraction of the investment capital. When the IPO market collapsed the competitor could not go public and was too expensive to be acquired, while iCAD was quickly scooped up by a public company providing an exit for the investors. iCAD has since assumed a leadership role in the market.

make only small alterations to existing systems. For example, when the World Wide Web became open to commerce, most people were initially very hesitant to buy merchandise online; it was too big of a leap. Writing letters online, however, was not such a big change; thus, email was easily embraced. Then people evolved to Web surfing, exchanging ideas in real time (i.e., chat rooms), and e-commerce. Who could have foreseen that those who were hesitant to buy online from even name brand companies 10 years before, now readily buy used goods sight unseen from strangers as is routinely done on eBay? Large, system-wide changes occurred over time as each activity built on the functionality of the previous process in small palatable increments.

Similarly, just as a good idea does not have to be a radical departure from current practice, so too a developer does not have to be the very first to market. In fact, sometimes being the first can actually be a disadvantage.

Given that health care is driven in many ways by insurance reimbursement, several developers spoke to the need to have their product/procedure qualify for reimbursement. In fact, when selling to providers or health systems, clearing this hurdle is paramount.

It may be beneficial to publicize information about products, even before the product is ready to launch. "Building buzz" is integral to product success and can lead to unexpected benefits. One developer described the advantages of going to conferences and venture forums even though the company did not have a finished product. "We never raised a dime," he said, "but we got great feedback and fantastic contacts." Trade shows also offer opportunities to create strategic partnerships with companies selling ancillary products. One developer found a distributor among the other companies exhibiting in a trade show. After presenting at a venture forum, one company was turned down for investment by the group, but it gained a CEO who has taken the business to new heights.

With regard to product distribution, an innovator does not a marketer make. Developers are not always the best at marketing and distribution; they often need to find strategic partners to fill in these gaps. One presenter suggested that a new business pursue any distribution possibility as long as it didn't cost money or time: "Respond when opportunity knocks. You never know which one is going to turn out. If it requires little investment on my part, why not let someone take the product and see what they can do with it? I've been surprised many a time." Similarly, if a potential distributor or sales partner says "no" or

Working models

Ezra Davidson, Chairman of the Blue Shield Foundation (BSCF) and Chair of the California Technology Assessment Forum (CTAF), which BSCF co-sponsors with the HealthCare Technology Center and the California Healthcare Association, spoke about the rigorous process used to determine which products and services they will recommend for clinical use. The Blue Shield of California Health Plan in general adopts these recommendations for reimbursement policy.

CTAF wants patients and physicians and health plans to make decisions on the basis of scientific evidence. Technology is one of the largest drivers of increasing health costs. While there is promise in the use of technology, there is also potential for abuse, misuse, and actual harm. Before approving a technology, therefore, Blue Shield wants to be sure the product/procedure is both safe and clinically useful.

To evaluate innovations, CTAF has developed a forum panel of research and practicing physicians, a public advocate, and an ethicist to review relevant data about the technology under consideration. The hope is that this forum will contribute to a dialogue and be able to make its findings available to the public, providers, and other health plans.

A product or procedure is recommended for forum review when providers begin requesting it. The review process has a firewall between the evidence and the cost of a product/procedure, thus all decisions are made only in the best

interest of the patient. To gain acceptance for reimbursement, five criteria must be met:

- 1) The technology must have government approval by the appropriate agency (e.g., the FDA).
- 2) Studies on the technology must be available in peer-reviewed journals.
- 3) Studies must show that the technology improves health outcomes.
- 4) The literature must also indicate that the efficacy of this technology is superior to current methods.
- 5) Research findings must be generalizable, demonstrating that the technology will work and deliver the same results in the real world as it did in the testing environment.

Once a product/procedure has met these criteria, then it is recommended for clinical use; otherwise it is determined that it did not meet the criteria and /or is still considered to be investigational.

The process involves a detailed review of the peer reviewed published literature and an open public hearing with invited and other interested experts who will comment on the readiness of the technology for routine clinical use. The positions of the professional and medical specialty societies are taken into consideration. The review board then discusses the product/procedure and makes a recommendation. The completed protocol and recommendations are passed on to Blue Shield of California Health Plan, but they also posted on the CTAF Website so providers and the public can have access to the findings.

does not seem to be enthusiastic about the product, take the “no” gracefully and bow out. There is no use in spending precious time and effort on a prospect that isn’t biting.

Another topic of discussion at the Summit was internationalization. Several participants had devel-

oped their products for the U.S. market and were now finding foreign companies or governments interested in purchasing their goods. There are many challenges involved in international business, including trade issues, coding standards, intellectual property rights, and cultural and language translation.

Lessons from the Field

“How NOT to get lost in translation.”

Zorianna Hyworon of InfoTech spoke about her experience taking an online health risk assessment and adapting it for use in 11 languages across 30 countries. Her first recommendation was never to use translation software and to be very cautious of using professional translators who do not have a practical health background in interacting with consumers. Translation software can be useful for understanding the gist of the meaning of a foreign word or phrase, but it probably would not be accurate for translating English phrases, sentences, and paragraphs into foreign language passages that would be easily understood and accepted by native speakers. InfoTech’s experience is that translations done by professional translators usually had to be redone at a substantial cost after it was found to be unacceptable when delivered to the client. Instead, Zorianna recommends using local people who work as front line health personnel. Local people know best how fellow citizens refer to specific conditions or treatments.

Beyond translation issues, those considering global markets must be careful about localized idioms. For example, the Spanish word “tortilla” means a flat pancake in Mexico and the United States, while in Spain it means “omelet” and would be a typical example of foods rich in eggs. In the Asian Pacific region, soya, not milk, is a major source of calcium.

Technology issues can differ among regions. In order to use the accents in central European languages such as Polish, an application must be in Unicode, the same standard as required for Asian and Arabic languages. A seemingly simple accent over a recognizable letter can lead to a major set of unanticipated technical issues if an application was developed using the standard western character sets. Proofing languages can also be very tricky; an error in the use of an accent mark may not seem significant to us, but to the local user it can totally discredit an application.

Compatibility of standards can also be a significant concern. In the United Kingdom, weight is expressed as “stones and pounds,” in which one stone equals 14 pounds, and drinks of alcohol are expressed in units (two units are roughly the same amount of alcohol as one drink elsewhere in the world). In Mexico, men know their waist measure in inches but their height and weight in metric measures (centimeters and kilograms). Preventive screening guidelines may also vary from country to country, and even within a country. Legal limits for blood alcohol can range from 0.02 (Poland) to 0.10 (some states in the United States). Furthermore, there are regulatory considerations that are not trivial. For instance, the British equivalent of Section 508 compliance for persons with disabilities resulted in a complete rewrite of InfoTech’s software. As a developer, it is important to investigate these types of issues before jumping into international markets.

Funding

Most new businesses fail predominantly because they are underfunded. A new business is risky, and most entrepreneurs try to minimize that risk by limiting their financial indebtedness. But by not asking for enough money, they can only get part way toward their goals and thereby set themselves up for failure.

The desire to limit risk is understandable, even wise. But rather than ask for only 20 percent of what is actually needed, some Summit presenters encouraged developers to think longer term and ask for a realistic sum with a step-phased release of funds. They also suggested matching the type of funding to the activities being funded. For instance, long-term capital assets should be financed with long-term money, while immediate and cyclical needs are best

addressed with a line of credit or some other short-term approach. Appropriate strategic management of finances not only builds credibility with funders, but also helps the developer keep financial commitments within reasonable limits.

The usual first funders are personal credit cards and funds from friends and family. This latter method poses a unique set of pressures. Grant funding is another possibility for new ventures. A particularly relevant source is the SBIR program. Created during the Reagan administration, it provides R&D funds for small businesses to pursue new technology development. Ten government agencies, including the National Institutes of Health (NIH), offer SBIR awards. Numerous participants at the Summit have obtained NIH SBIR awards, which typically provide \$100,000 for a Phase 1 feasibility study and as much as \$750,000 for Phase 2 development of the product. SBIR proposals must make a commercial argument for the need and present a development plan, a research/evaluation plan, and a plan for marketing of the program. Marketing and commercialization activities, however, cannot be funded using federal grant money.

The advantages of SBIR funding are numerous, including retaining all intellectual property rights and not having to give up any equity in the business. The peer review process also offers useful feedback. Disadvantages include a long funding cycle as it can take a year or more from the time a proposal is submitted to funding. This situation can be cumbersome and prove difficult for strategic partners. SBIR awardees also must comply with the numerous federal regulations related to funding.

Equity financing is a common way entrepreneurs fund their ventures. Summit participants suggested seeking the advice of a professional before offering a stock or profit-sharing package. A professional can help you calculate a valuation that is appropriate for the current and potential state of the business. Many developers are so anxious to get funding, for instance, that they end up giving away the store, or

Lessons from the Field

Tips for SBIR funded projects

Susan Brink of Healthmark Multimedia developed a set of decision-support programs for cancer patients using SBIR funding. The following are her suggestions for handling the key elements of this useful but niche funding mechanism:

1. Do your homework on your competitors. Reviewers may be very knowledgeable about your field, and you will lose points if you do not address what the competition is doing and why your product is different. Your competitors may have already received SBIR funding or they may be on the review panel.
2. The application for Phase 2 funding is very specific about what must be included in the marketing section. Follow the specifications to the letter, responding to every element.
3. If possible, consider the Fast Track approach in SBIR. Although it is more difficult to get, it shortens the development cycle significantly as there is no gap between the funding of the Phase 1 feasibility study and the Phase 2 development phase.
4. Be up front with strategic partners about the length of the funding cycle and who will own the product once it is developed. This point is especially true if they came to you with the original idea.
5. The skill set needed to write successful grants and develop a product is often not the same as what is needed to market it. You may want to partner with others to do the marketing and distribution, especially since these activities cannot be paid for by the grant.

not offering enough, and wind up unhappy with the results.

At the Summit, developers were strongly encouraged to think ahead about an exit strategy for themselves or for their investors. The dream of an IPO is no longer a reality for most eHealth businesses. It is

more likely that a business will be acquired by or merge with a related business. Some participants advised developers to make business decisions on the basis of a 4- to 5-year plan to sell to a larger company once the venture is on its feet. Exit strategies are certainly of prime importance to angels or venture capitalists. One investor commented that biotech firms make up 95 percent of his organization's portfolio because the exit strategy is clear, whereas eHealth comprises only one percent of their total investment.

When polled about how savvy investors seem to be about eHealth, 26 percent of those Summit participants who had experience with investors felt the investors were fairly advanced in their understanding, while more than half (54 percent) felt the investors' understanding was only at a basic level (Figure 12).

As with past Summits, the watchword when working with investors is "return on investment." Much as an idea might hold tremendous potential for solving an important public health issue and improving the lives of millions, the developer must speak the

Participant Perspectives

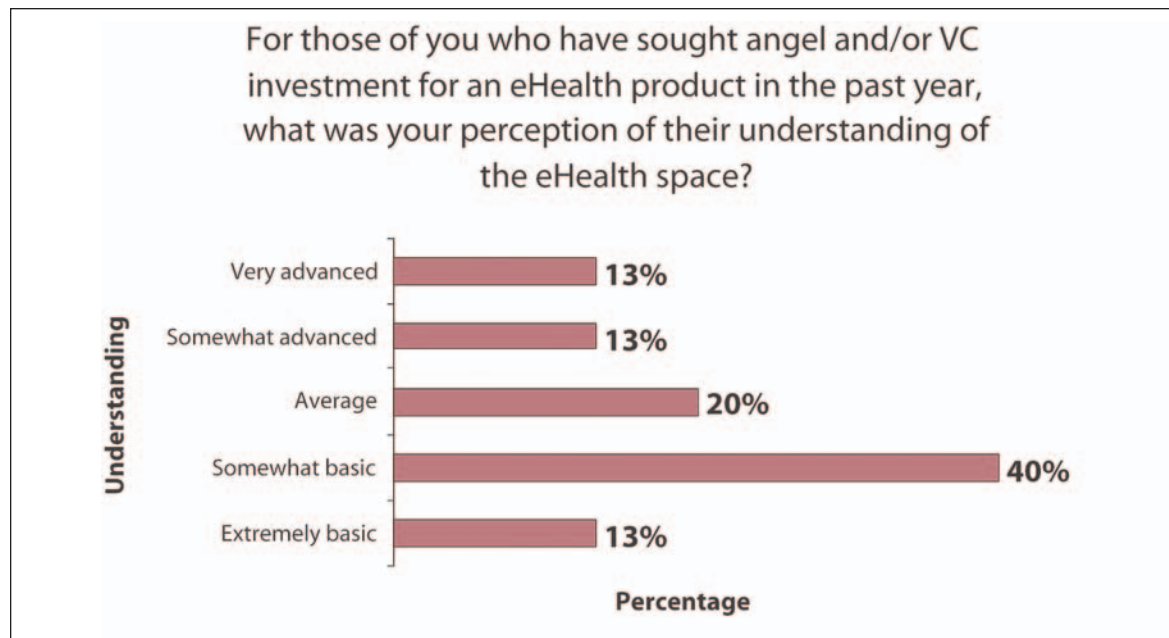
"Your seven-second elevator speech must start with 'I've got an opportunity that will yield an X percent return on investment over Y period of time. It's in eHealth.'"

— Jim Wittmack, Director of Transactions, JWC Capital Advisors

language of the investor and present the idea with the investor's priorities in mind.

To save time, developers are encouraged to qualify their investors before approaching them. For instance, venture capitalists typically engage in large-scale endeavors, while angels and other private investors more often focus on smaller opportunities. Some developers have found it useful to hire consultants to find appropriate investors and to advise about the packaging of their proposal. One venture capitalist revealed that for every 100 applications his organization receives, it asks 30 for a presentation. Of those 30, two or three will be invited back for a "due diligence" review and only one will be funded.

Figure 12. Results of audience poll regarding investor understanding of eHealth (N = 17).



When reviewing an application, investors typically scrutinize the health of the product market, the principal's experience in the market, the strength of the management team, their strategies for success, and the viability of the exit plan. They will also be extremely interested in identifying weaknesses (areas in the venture that are in need of extra support). If an investor is going to ask for some measure of control in the company, for instance, it will be in the areas of perceived vulnerability.

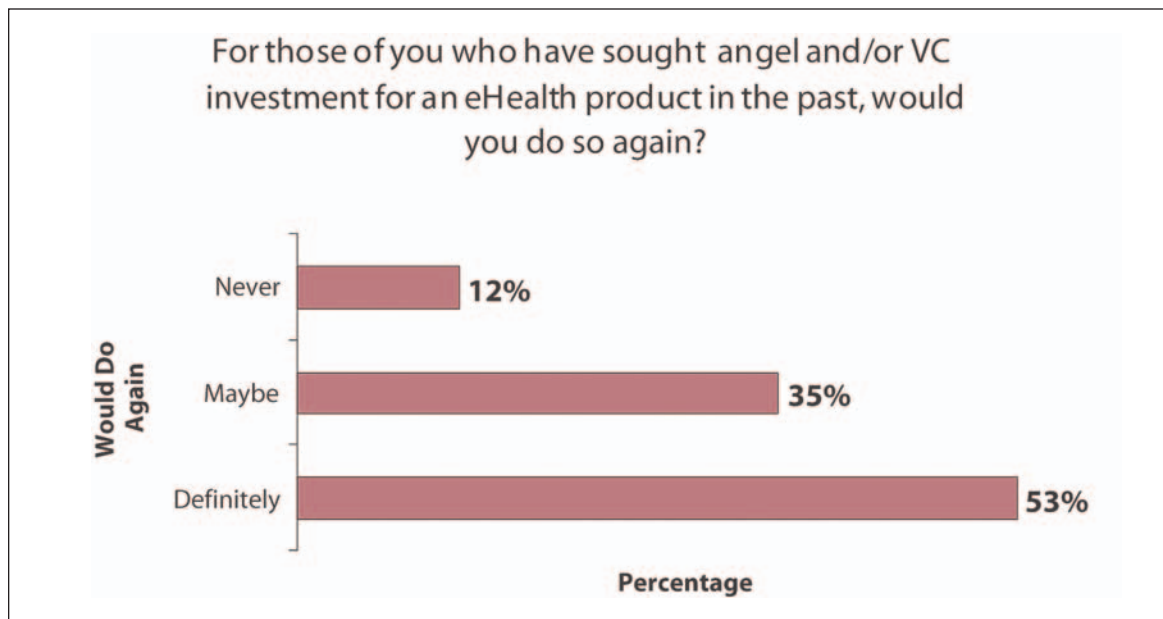
Developers applying for debt financing were advised of the six Cs for loan evaluation:

- **Character.** The principals must demonstrate a willingness and ability to repay the loan.
- **Capital.** The owners must also be personally invested and share the risk.

- **Cash flow.** Realistic figures are critical, with enough money projected to specifically pay off the loan.
- **Collateral.** The company must have high credit rating or significant tangible assets.
- **Coverage.** Life, legal, property insurance must be available to handle unforeseen events.
- **Conditions.** The market (e.g., perceived need of the customer base) must be viewed as being strong enough to support such a venture.

A poll of Summit attendees who have sought private funding revealed that 53 percent would definitely do it again. Thirty-five percent said they might be willing to try, and the remaining 12 percent had no interest in repeating the process (Figure 13).

Figure 13. Results of audience poll regarding willingness to seek private investment among those who have sought it before (N = 17).



Conclusions

Momentum for eHealth adoption is growing. This fact is made evident by the public proclamations of the value of IT in health care and public health voiced by the current administration, Congress, and private industry groups. However, it is also clear that sufficient movement toward eHealth adoption will not be attained unless considerably more public and private funding and financial incentives for eHealth development and implementation are available, especially for smaller organizations.

Summit participants in 2004 were very optimistic about eHealth adoption in the next several years. This sense of optimism has been growing among Summit attendees in the past few years. While Summit attendees largely agreed about the outlook for generic eHealth adoption, they did not agree that widespread adoption of interoperable EHRs was likely within the next 10 years.

There seems to be increased agreement among Summit participants that health plans and providers are likely to be the most influential stakeholders in the near term. It is important to note, however, that much of the activity in eHealth adoption among health care organizations is being driven by large organizations, and that smaller provider organizations and certainly small practices typically do not have the resources or expertise to evaluate and implement current eHealth solutions. eHealth developers should be cognizant of this potentially large untapped market segment.

The growing popularity of consumer-driven health plans, health savings accounts, and disease manage-

ment programs offers interesting market opportunities for eHealth developers. To be successful in these focus areas, developers must address consumer/patient privacy concerns. The need to be attentive to privacy issues was affirmed by a poll of Summit attendees indicating that most attendees were aware of at least one or two violations of privacy and data security in their organizations within the previous 12 months.

Privacy practices are important aspects of the larger scope of eHealth ethics. eHealth developers should ensure that their products and business practices not only comply with relevant laws and regulations, but also reflect ethical standards. In almost all cases, “doing the right thing” will result in commercial success.

eHealth developers, like other entrepreneurs, must focus on market segments that will lead to financial rewards. In the case of consumer eHealth products, the natural market segment may be groups such as the “worried well,” who already have sufficient resources to support a new product entry. Because they work in the health care or public health arena, it can be argued that eHealth developers have a social responsibility to make their products also accessible to those who cannot ordinarily gain access, such as the underserved.

Research in the effectiveness of eHealth products is only in its infancy. There are many instances of commercially successful products that have not been rigorously evaluated before being adopted. The many years that typically elapse between research findings

and their impact on real-world practice is certainly not unique to the health care field. However, this issue may be more relevant in health than for other industries because of the urgency of many health problems and the adverse health consequences that may result from ineffective and poorly designed products.

Rich discussions about eHealth commercialization have been hallmarks of the Summit for many years. Attendees reiterated the fact that products do not have to be radical innovations to achieve commercial success. However, they must meet a recognized need, have a sufficient potential market, and provide enough economic justification for purchase. Few developers are also experts in marketing and dissemination. Developing and leveraging strategic alliances

and partnerships for marketing and dissemination may be the differentiator between product success and failure.

The underlying principle of the eHealth Developers' Summit is that collaborative, transdisciplinary, and multisector approaches to product development and dissemination will result in higher quality and more-effective products. Additional experimentation with trans- and multidisciplinary models for eHealth R&D and dissemination is essential as we move forward. More programs and support for professionals and companies that are interested in the intersection of business, health, and technology are clearly needed to bring health care and public health fully into the twenty-first century.

Appendix A. Organizations Represented at the Fifth Annual eHealth Developers' Summit

ACOR
Agency for Healthcare Research and Quality
Alteer Corporation
Apple Computer
Bibliomed
Bioexpertise, Inc.
Blue Cross Blue Shield Association
Brown University/Miriam Hospital
BTTF
California Department of Health Services
California HealthCare Foundation
California Technology Ventures, LLC
Center for Practical Health Reform
Center of Excellence for Medical Multimedia
Centers for Disease Control and Prevention
Centre for Addiction and Mental Health
ChartScape, LLC
CHI Systems, Inc.
CHRISTUS Health
City of Hope
Colorado State University
Commonwealth Fund
Consumer Health Interactive/Caremark
Cooper Institute
Deschutes Research, Inc.
Digitalmill
eHealth International
Epocrates
Essex Group
Geometric
Harvard Medical School
Health e-Technologies Initiative/Brigham and Women's Hospital
Health Solutions Network
HealthMark Multimedia
HispaniCare (DrTango Inc)
iCAD, Inc.
IDX Systems Corporation
iMetrikus
Ingham County, Michigan
Intel Corporation
ISA Associates, Inc.
JWC Capital Advisors
Kaiser Permanente
Klein Buendel, Inc.
Klieman Spiwak Surgical Associates
LA Tech Coast Angels
LifeMasters Supported SelfCare, Inc.
LIFETECHniques Inc.
LuminEssense Consulting
Madigan Army Medical Center
Maine Medical Center
Mather LifeWays Institute on Aging
MD Anderson Cancer Center
Medical Decision Logic, Inc.
MediMedia USA
MedSeek
MedSignals
Meetup, Inc.
Misys Healthcare Systems
National Cancer Institute
NewSof Group
Polymap Wireless, LLC
Pro-Change Behavior Systems, Inc.
QUALCOMM, Inc.
QuitNet Inc
Ripple Effects
Robert Wood Johnson Foundation
RTI International
Ruder Finn

SAIC-Frederick, Inc.
San Diego Center for Health Interventions
SDA Group, LLC
St. Cloud Communications
Stanford Patient Education Research Center
Stanford University School of Medicine
Sutter Health
SymTrend, Inc.
The Launch Pad
TommyHo! Consulting
U.S. Department of Health and Human Services
UCLA/Center for Community Health
UCSD

University Health Network
University of California, San Diego
University of California, San Francisco
University of Colorado at Denver and Health Science
Center
University of Illinois at Chicago
University of Maryland
University of Washington
USAF/CEMM
VA San Diego Healthcare System
Valdez & Associates
Valley Medical Center
York College, The City University of New York

Appendix B. Summit Awards

Best eHealth Research Paper Award

The annual Best eHealth Research Paper Award, consisting of a plaque and \$1,000, recognizes the best eHealth-related research conducted within the past year. The purpose of the award is to highlight and promote the application of scientific research methods for identifying effective eHealth solutions. A national call for papers was issued for eHealth research studies reporting on work completed during the previous one-year period. The award is sponsored by the Health e-Technologies Initiative, a national program of the Robert Wood Johnson Foundation.

A review panel selected the top four papers for presentation at the Summit. Criteria for paper selection included 1) quality, originality, and timeliness of the study; 2) scientific rigor of the study design, analysis, and interpretation; 3) potential impact of study results to similar applications and the eHealth sector; and 4) clarity of writing and organization of the abstract. In addition to these evaluation criteria, presenters were judged on the quality and clarity of their presentation and their ability to answer questions from the audience.

The four papers selected for presentation at the Summit were

An eHealth Breast Cancer Education Intervention
Armando Valdez (1); Kakoli Banerjee (1); Carol Somkin (2); Lynne Ackerson (2); Maria Fernandez (3). (1) Valdez & Associates, (2) Kaiser Division of

Research, (3) University of Texas Health Science Center.

A Novel Technology to Improve Compliance with HIV Medications

Vesta Brue (1); Jerome Hahn (1); Nancy Haug (2); Richard Olmstead (2); David R. Bangsberg (2). (1) Lifetechniques, Inc., (2) University of California San Francisco.

A Web-based Patient Portal for Patient–Clinic Communication: A Randomized Controlled Trial
Chen-Tan Lin; Stephen Ross; Loretta Wittevrongel.
University of Colorado Health Science Center.

Potential of Comprehensive Prevention Training Software to Reduce Risk and Enhance Protective Factors in Adolescents, a Multi-Site Study
Alice Ray (1); Sarah Berg (1); Michael Roona (2); Peter Ochshorn (2). (1) Ripple Effects, Inc., (2) Social Capital Development Corporation.

The review panel awarded the “Best eHealth Research Paper Award” for 2004 to Armando Valdez of Valdez & Associates.

Review Panel for Best eHealth Research Paper Award

David Ahern (Chair), Director, Health e-Technologies Initiative
Susan Martin Gould, Research Associate/Program Coordinator, Department of Food Science & Human Nutrition, Colorado State University
Nancy Hitzschke, Project Manager, Plan Education, Blue Cross Blue Shield Association.

eHealth WIT (Working Innovation Technology) Teams Competition

The eHealth WIT Teams Competition is held each year in conjunction with the Summit. The purpose of this competition is to promote collaboration and team problem solving among Summit participants from disparate backgrounds and organizations. During the course of the meeting, small group teams develop an eHealth solution to a problem/opportunity in health or health care. The facilitated teams tackled the issue through a series of small group meetings and presented their solution to the entire audience and to a judging panel on the final day of the Summit.

Teams were challenged to develop an eHealth solution related to one of two topics: obesity or aging. Each proposed concept was evaluated by the judging panel on the basis of innovation, feasibility, sustainability/commercial viability, and potential impact on health or health care. The winning team received a \$5,000 grant to support team follow-up activities to further develop the concept. Team winners from the past two years are still active and working as a team to further develop their winning concepts.

The judges selected the Orange Team for their concept to promote healthy shopping habits at grocery stores. The Team's presenters were Nathan Cobb, Kyahn Kamali, and Herb Severson.

WIT Teams Presentation Judges

Majid Abai, President, Seena Technologies Corporation; Member, LA Tech Coast Angels
Steve Downs, Senior Program Officer, Robert Wood

Johnson Foundation
Manish Singh, Director, California Technology Ventures, LLC

“True Confession” Award

This award is given to the person who provides the most useful description of what s/he learned from working with a recent business, application development, or research problem. The audience recognized Robert Pretlow, President, eHealth International, for his presentation on the ethics of closing down a Website.

Summit “eHealth Geek” Award

This award is given to the Summit attendee who demonstrates the broadest knowledge across many subject areas as evidenced by answering the highest number of trivia questions during the Summit. The 2004 “eHealth Geek” is Kim McClung, Valley Medical Center in Renton, Washington.

eHealth Prediction 5K/2M Fun Run/Walk

This award is given to the individuals who come closest to predicting their finishing time for a 5K run or a 2 mile walking course.

Women's Division Winner - Susan Swartz (5-second difference from predicted time)

Men's Division Winner - Allen Tien (37-second difference from predicted time)

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- 1 Data presented in the figures in this report are from polls of meeting attendees using wireless audience response devices. “N” refers to the number of people responding to the question posed; some attendees chose not to respond to some questions. Percentages may not add to 100 due to rounding error.
- 2 The term “electronic health records (EHRs)” rather than “electronic medical records (EMRs)” is used in this report because the former term more accurately reflects the growing consensus that electronic records for health should be available for shared access among clinicians and patients/consumers and that such records should capture data across health-related organizations and settings.
- 3 The data and information in this section are largely based on presentations by Christine Paige, Senior Vice President of Marketing and Internet Services, Kaiser Foundation Health Plan; Debra Sleight, Director of eHealth & Integration Solutions, Sutter Health; and Jeff Tangney, Vice President of Subscription Business and Product Development, Epocrates, but this section does not necessarily represent their views.
- 4 The data and information in this section are largely based on a presentation by Elizabeth Waterman, U.S. Benefits Program Manager, Intel, but this section does not necessarily represent her views.
- 5 The data and information in this section are largely based on a presentation by Lisa Dolan-Branton, Senior Advisor for Community-based Health IT, Agency for Healthcare Research and Quality, but this section does not necessarily represent her views.
- 6 The data and information in this section are largely based on presentations by Allan Frankel, CEO, ChartScape, LLC; and Rodney Johnson, Senior Medical Center Counsel, Stanford University, but this section does not necessarily represent their views.



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