Moving Toward Electronic Health Information Exchange:

Interim Report on the Santa Barbara County Data Exchange

Prepared for:

CALIFORNIA HEALTHCARE FOUNDATION

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Acknowledgments

The California HealthCare Foundation (CHCF) is an independent philanthropy committed to improving California's health care delivery and financing systems. Our goal is to ensure that all Californians have access to affordable, quality health care. CHCF's work focuses on informing health policy decisions, advancing efficient business practices, improving the quality and efficiency of care delivery, and promoting informed health care and coverage decisions.

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ISBN 1-932064-49-4

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Executive Summary

Santa Barbara County is like many other health care markets in the United States. Health care in Santa Barbara is delivered by numerous physicians, some solo practitioners and others in large groups, along with ancillary clinicians. These include several hospitals, public health facilities and various pharmacies, laboratories, and imaging centers. The residents of Santa Barbara receive their care from a personally crafted set of these caregivers, depending on their location, illnesses, family situation, and insurance coverage. Some people are cared for exclusively by one provider and remain loyal to this caregiver for many years, but most construct a panel of caregivers and move from one to another over time. As is the case elsewhere in the United States, the clinical information about Santa Barbara residents rarely moves with them, between caregivers or across time.

The Santa Barbara County Care Data Exchange (SBCCDE) is demonstrating how a patient's clinical information can be readily accessible by any authorized person, including the patient. This project was supported by a \$10 million grant from the California HealthCare Foundation and seeks to determine whether regional health information exchange: (a) is feasible (i.e., can it be accomplished at all), (b) is sustainable (i.e., is there a financial case for it and does it fit within technology plans of provider organizations), and (c) can improve the quality of care. The project began in 1998 and has evolved over the past four years to develop the legal, organizational, financial, technical, and operational mechanisms to foster health information exchange. SBCCDE is a public-private collaboration of providers across the county and is operated as a public utility—available to all comers—for the secure exchange of patient-specific clinical information. The organizational and operational model of the SBCCDE has been in place for 18 months, and the technical model is now in the final phase of pilot testing.

To date, SBCCDE has shown that secure patientspecific health information exchange is legally, organizationally, and technically feasible. The idea of health information exchange in Santa Barbara County has gained support because of its potential to simplify workflow in physician offices and maintain flexible organization and technology. Adoption has been slowed by the complexities of developing and deploying a region-wide technical architecture and by security and privacy concerns. Modeling shows that health information exchange in Santa Barbara is sustainable because it creates a positive financial return both overall and for each participant, including physicians, hospitals, laboratories, imaging centers, and payers. Studies are underway to determine the degree to which health information exchange improves quality of care delivery.

Santa Barbara is a laboratory for other regions and for national policy discussions about health information exchange. While this project is still underway, it has highlighted a variety of areas in which federal policy could be altered to promote health information exchange. Potential policy initiatives include financial incentives for regional exchange of health information, clear safe harbors in federal health care regulations, operating standards for health exchange organizations, stepwise pathways to technical interoperability, regional implementation support organizations, and promotion of a variety of health information exchange technologies.

I. Introduction

BECAUSE HEALTH CARE IN THE UNITED STATES is so fragmented, every health care delivery organization shares clinical data about its patients with many others. This mostly occurs through faxing, teleprinting, or shipping paper records through a laborious and inefficient process. Hospitals, large medical groups, and other ancillary care providers each employ dozens of people who request, collate, and store clinical data supplied by other providers or who collect, copy, and ship clinical data as a fulfillment of another party's request.

Despite these efforts, timely and efficient access to a patient's complete medical information ranks among the most longstanding challenges faced by physicians. Physicians rarely have access to clinical test results ordered by other physicians on shared patients, causing expensive and sometimes risky tests to be reordered or critical facts to be missed in evaluating a patient's health. Even when physicians can get access to relevant data about their patients, it is often achieved through laborious manual efforts and rarely keeps pace with the tempo of diagnostic decisions or treatment actions. Preventable sentinel events (Balas et al, 1996; Ioannidis and Lau, 2001), medical errors after discharge (Beers et al, 1992; Dvorak et al, 1998; Parkin et al, 1976; Smith et al, 1997), readmissions (Flyer et al, 1988; Oddone et al, 1996; Paterson and Allega, 1999; van Walraven et al, 2001), hospital treatment delivery (Himmel et al, 1996; Katz et al, 1996), ambulatory prescribing (Kuehl et al, 1999; Laswsila et al, 1997; Rupp, 1992) and redundant treatments (Stair, 1982) can occur because lab results, prescription data, and other information are not moved among sites of care in a timely manner.

Consumers cannot access their clinical information easily, leading some to collect and store their medical records on their own initiative. When they can access their information, it is usually from a small subset of the physicians or organizations from which they receive care, giving them an incomplete, and potentially misleading picture of their health status. Consumers do not have a way to transport their clinical data among physicians or hospitals, and cannot determine what data are available to which physicians. Consumers also do not know how their clinical information is being used or who is using it, or when their data is relevant and is not being used.

These problems occur because the current health care information environment consists of a wide variety of semi-compatible software applications and disparate data sources spanning both inpatient and ambulatory settings. In essence, the organization of health information reflects the fragmented organization of the industry, and may be even more pronounced because many health systems are unable to produce a single set of information about the patients under their care. This reality has impaired the systematic application of clinical data in meaningful ways to support clinical decision making, health system management, care process improvement, health policy analysis, and health services research.

Recognizing these weaknesses, many health care organizations are making investments in information systems to provide their clinical data to physicians, and some are making clinical records available to patients. As enterprise-based efforts, these change the medium of information from paper to electronic, and thereby increase the convenience of accessing clinical information and allow for interaction between data and rules of medical evidence or other decision-making guidance. However, these efforts do not provide the physician with all the information about the patient's treatment experience because each organization is creating access to its information on a stand-alone basis. Without a viable means of pooling clinical information about a single patient into one view, physicians cannot gain access to patient's complete medical information, and cannot determine how much information is missing from what they do see.

Over the past 20 years, there have been many attempts to organize and exchange clinical data for a whole region or population. Health plans were expected to create useful and comprehensive patient- and population-specific clinical data repositories. However, with rare exception, such potential has not progressed beyond demographic and financial claims data about health plan members. Community Health Information Networks (CHINs) were formed in the mid-1980s to support data sharing through the creation of regional databases as central points of access. This approach was hindered by data ownership conflicts, competitive and confidentiality issues, large up-front costs, and data control concerns. Integrated delivery systems had among their founding goals the compilation of complete and longitudinal clinical information about patients to improve clinical quality and efficiency. But operational, financial, and cultural barriers limited realization of this benefit, and, in the end, the viability of integrated systems themselves. Even systems with a high degree of integration, such as the Veterans Health Administration or Kaiser Permanente, face ongoing challenges in assembling the entirety of information about their patients—whether from within the network or from outsourced care providers—in a clinically meaningful manner. These efforts reflect the evergreen interest in organizing complete information about the patient care experience. At the same time, the fact that many of these efforts have failed highlights the substantial barriers to change that continue to exist in the health care industry

Information exchange has been most successful in the administrative arena because of privacy, security, and administrative simplification rules under the Federal Health Insurance Portability and Accountability Act (HIPAA) along with concerns about reducing billing-related paperwork. A variety of states and regions have organized quasi-public clearinghouses for eligibility, claims adjudication, referrals, and other administrative transactions (e.g., New England Healthcare EDI Network—NEHEN). However, it should be noted that these investments in information exchange are for administrative data, and are tightly controlled and system-specific, and none has bridged into the clinical environment. Clinical health information exchange requires more complex data (e.g., test results), point-of-care users (e.g., physicians), and more stringent security.

Many recent developments, mostly at the national level, have focused significant attention on the exchange of clinical and administrative information. These include broad use of the Internet, evolution of HIPAA privacy and security rules, and widespread concerns about patient safety. These drivers raise the potential benefits of health information exchange and also the potential of reducing the cost of sharing clinical data. Likewise, recent bioterrorism concerns have made real-time data sharing an imperative for early outbreak detection and response. Despite these stimulants, however, physicians and patients have yet to see much change in how clinical data is communicated or shared.

II. The Santa Barbara County Care Data Exchange

The Santa Barbara County Care Data Exchange (SBCCDE) was formed in 1998 by health care leaders in Santa Barbara County to enable health information exchange in the region. The SBCCDE is a county-wide initiative that has instituted the technical, financial, organizational, and legal infrastructure for sharing clinical data among regional physicians, hospitals, ancillary centers, and consumers. This project was recently referred to in an IOM report as "Perhaps the best-known example of a data exchange platform for patient information" (Corrigan et al, 2002).

The SBCCDE is demonstrating how a patient's clinical information can be readily accessible by any authorized person, including the patient. The SBCCDE operates as a public utility that will be available to all physicians, caregivers, and consumers for the purposes of increasing the quality and efficiency of care delivery. The exchange has brought together leading public and private health care organizations throughout Santa Barbara County. These organizations work closely together to ensure that a secure, valid, and useful data asset is available to all, and that these data are protected so they cannot be used inappropriately or for proprietary advantage.

The SBCCDE was supported by a \$10 million grant from the California HealthCare Foundation (CHCF) and seeks to determine whether regional health information exchange: (a) is feasible (i.e., can it be accomplished at all), (b) is sustainable (i.e., is there a financial case for it and does it fit within technology plans of provider organizations), and (c) can improve the quality of care. In particular, this effort seeks information about whether health information exchange can be a positive contributor to patient safety, efficiency, and access to care, and whether it could be replicated elsewhere. In addition, the project seeks to add to what is known about how physicians use information, how competitive organizations collaborate to achieve common goals in the interests of their patients, and how interoperability works in a real-world setting. This is an interim report on this effort, reflecting the past four years of experience and learning in Santa Barbara County.

In addition to financial support from CHCF, the design and implementation of the SBCCDE has been supported by the investment of local health care organizations. A six-month feasibility study, funded by CHCF and performed by David J. Brailer, M.D., Ph.D., evaluated the general potential for regional data sharing in the post-Internet era, and the specific potential for forming a datasharing network in Santa Barbara County. Based on the findings of this study, CHCF awarded a grant to Dr. Brailer, through CareScience, Inc., to establish a program management office to oversee the implementation of the technical, governance, legal, and regulatory mechanisms required for health information exchange. CHCF also provided grant funds to various organizations in Santa Barbara County to support their involvement in the project, including system purchasing and application enhancements, integrating data sources into the central technology, implementing common information technology solutions with trading partners, developing the legal model that makes health information exchange compliant with state and federal regulations, and working with physicians and consumers to support their use of the technology.

Starting in 2001, as the business framework for the SBCCDE became operational and the technology went into beta testing, CHCF began a three-year phase-down of its funding under an explicit plan for full community financing by the end of 2003. At this point, CHCF funds constitute less than half of the SBCCDE budget and will continue to diminish as the SBCCDE technology becomes fully operational and gains broad use by physicians and consumers

Organization and Operation

Providers across the entire county of Santa Barbara, not just in the municipality of Santa Barbara, are involved in the SBCCDE. The county has diverse health care delivery settings, ranging from large group practice and hospital-based delivery in south county to small office and IPAbased care delivery in the north. It is also economically disparate, with a large proportion of high-income earners in the south and a large proportion of low-income and migrant workers in the north. While there is no major metropolitan area in the county, there are strong urban influences and care delivery dependencies from Los Angeles in south county and heavy rural and agricultural influences in the north. It is a county that is representative of the diversity of care across California and much of the United States.

The SBCCDE is a collaboration of competing, unaligned, and semi-aligned organizations, such that each organization agrees to a minimal set of requirements for interoperability but otherwise pursues its organization's own strategic priorities. The business framework for the SBCCDE was designed to take this into account, granting a minimal set of powers to a central oversight body while decentralizing much of the operational decision making. The first two years of the project were focused on establishing the foundation for health information exchange. This apparatus has been in place since the summer of 2000, and includes the following components:

Governance Model

The broad goal of a care data exchange is to allow collaboration among organizations without encumbering the participants with unnecessary overhead or legal risks, or requiring inter-organization commitments that are not feasible. A variety of legal mechanisms for creating the SBCCDE were explored. A collaborative publicprivate partnership was selected because it was least expensive to implement and minimized up-front, inter-organizational legal risks such as malpractice, antitrust, and financial liability. More formalized organizational models are currently under consideration.

Under this model, participating organizations, detailed in Figure 1, elect to participate by entering into a Care Data Exchange User Agreement with the other participants in a hub-and-spoke model. This agreement sets forth obligations, responsibilities, and rights of the participants and limits the range of business behaviors in which SBCCDE participants can engage. These agreements include language consistent with HIPAA's data use and disclosure requirements for business associates. To support these agreements, substantial effort was put into legal review and formulation of legal opinions addressing potential ambiguities in federal or state law or outright misunderstandings about specific regulations.

Figure 1. SBCCDE Participants

- The Santa Barbara Regional Health Authority (SBRHA)
- Santa Barbara Department of Public Health
- Sansum-Santa Barbara Medical Foundation
- Cottage Health System
- Catholic Health Care West Marion Medical Center
- MidCoast IPA
- The Lompoc Valley Community Healthcare Organization
- Santa Barbara Medical Society
- Pueblo Radiology
- UNILAB Corporations
- University of California Santa Barbara (UCSB)
- Veterans Health Administration

Multi-level oversight and decentralization of decision making was deemed essential for the SBCCDE's success, and was achieved by formation of the following oversight bodies, depicted in Figure 2:

Care Data Exchange Council—the overall governing body, comprised of a senior leader from each organizational participant. Each organization on the council gets one vote and meets monthly to determine the business and operating policies of the SBCCDE, set priorities for SBCCDE expansion, develop communication strategies, and address legal and business issues.

Care Data Alliances—composed of multiple organizations that are information trading partners working together to implement common solutions under the guidance of the SBCCDE. Each alliance coordinates data sharing goals and facilitates overall technology deployment and implementation with one another more closely than with other participants in the Care Data Exchange.

Technical Advisory Committee (TAC)—

includes technical representatives, chief information officer-level or equivalent from each care data alliance and many other contributing organizations. It meets regularly to review functional and technical requirements for data sharing, sets integration strategies to optimize existing systems, and assesses implementation priorities based on system capabilities.

Clinical Advisory Committee (CAC)—

includes physician leaders from each care data alliance plus at-large members. It develops functional usability requirements and strategy for adoption by physician offices.

Figure 2. SBCCDE Governance **SBCCDE Council Committees Technical Advisory Clinical Advisory Committee** Committee (TAC) (CAC) Lompoc Sansum Midcoast **SBRHA Alliances** Sansum-SB Medical Midcoast IPA SBRHA (Anchor) Lompoc Valley Community Health Foundation Clinic (Anchor) Lompoc Valley Organization (Anchor) Marian Medical Community Health (Anchor) Unilab Center Care Organization Federal Correction **UCSB** Meridian Health Care Sansum-SB Medical Complex Management Foundation Clinic Cottage Health Lompoc Hospital System Unilab SBC Health Dept District Local pharmacies SBC Medical Society Lompoc Public Health SB Neighborhood Dept Health Clinics **SBRHA** Valley Medical Group Vandenberg

In establishing the governance model for the SBCCDE, organizers considered whether to establish an organization and technology solution that was tightly coupled and top-down or one that was loosely coupled and flexible. On the one hand, there was a fundamental respect for the autonomy of the community and its ability to solve problems. However, there were substantial concerns about how something implemented in one community could be deployed elsewhere and how the lessons could be made meaningful to others. Early project efforts had a tendency

Airforce Base

toward tightly coupling—corporate structures binding constituents together, strict adherence to inoperability standards, stringent requirements for data formats, etc.

However, at nearly every step along the way, a loosely coupled solution was selected. And as it turned out, tightly coupled solutions would have failed on many occasions. There is currently no corporate structure in Santa Barbara that binds SBCCDE participants to each other. However, the organizations work together with the discipline and rigor of corporate shareholders.

Although there are published integration standards (e.g., those recently adopted by the federal government) for accessing the data-sharing technology, any willing source of data that physicians want can be integrated into the SBCCDE, regardless of how it complies with published standards. Data is made available in the most granular form, such as from a LOINC (Logical Observation Identifiers Names and Codes)-compatible database, but also from jpeg images of older scanned laboratory reports that have no discrete data elements. In short, the flexibility of the organizational and technical model has helped this project leap long-standing barriers, and has set in motion an organic mode of operation for the SBCCDE.

A flexible and open-ended process was not intended for Santa Barbara, but has come to be fundamental to the SBCCDE. It is possible, however, that this results from the philanthropic origins of the project and will not be observed in future deployments. Since the SBCCDE was initiated with grants from CHCF, the financial infrastructure for the effort was created outside the SBC-CDE—it had no mechanism for centralizing budget, cash receipts, disbursements, or financial reserves. These functions were performed by the program office on behalf of the SBCCDE. As the SBCCDE takes full responsibility for its operations, it is creating a fiscal infrastructure and relieving the program office of this duty. Other regions considering health information exchange are instituting the financial tools up front. It is possible that fiscal discipline will carry with it tighter control over governance, technology, integration, and other project aspects.

The organic nature of the SBCCDE's evolution makes it difficult to produce a recipe for how other regions should implement data sharing. The lesson of Santa Barbara may be that the particular sequence of deployment depends on the characteristics of the region and its stakeholders. If this observation is true under further scrutiny, then it

raises significant questions about the degree to which health information exchange can be fostered from a national perspective, either through federal policies or from national data-sharing collaboratives.

Access Control

To safeguard patient privacy, the SBCCDE adopted and enforces strict access control policies. These policies determine who can see what data under what circumstances, and what happens when these rules are not followed. The rules comply with HIPAA and the more stringent California Medi-Cal (Medicaid) regulations. The policies are embedded in the SBCCDE technology so that users are forced into compliance with the access control policies. These policies include the rules for authentication, informed consent, data holder over-rides, and other elements such as logging and auditing. In general, the policies "presume access" to data when the established rules are met, which is to say that any physician who can electronically identify him or herself, has patient consent, and has not had their access over-ridden by a data holder, can get access to his or her patient's data.

Insiders know that there has been little control over clinical data in the past. It has been accepted that there is a high degree of risk, but a low cost of failure, although some more recent studies have demonstrated that fears of improper disclosure have changed care-seeking behavior by consumers in harmful ways. Health information exchange changes this equation considerably. There is undoubtedly better control over data, particularly with peer-to-peer technology, and detailed auditing of data access that reveals where confidentiality has been compromised. But at the same time there is a much higher consequence of failure because so much data is available in a specific location.

Despite the strong technical protections designed into the SBCCDE, a technical error or intentional break-in that results in a breach of privacy or confidentiality is inevitable. This is why the SBCCDE has identified the most important component of its security apparatus to be the business processes that surround the technology. Issues such as reviewing requests for urgent or emergent access to data, policing complaints about improper data use, or setting and enforcing access control policies that are practical will rely on the SBCCDE's central governance to act in a judicious manner.

The SBCCDE encountered other forms of privacy concerns as well. Public health entities in Santa Barbara have an ongoing interest in being able to analyze care delivered to specific populations (e.g., children with asthma) whose care process is difficult to put together from piecemeal data. Physicians note that examining physician practices is just one step beyond this, and have expressed concern about whether the SBCCDE data can be pooled together and be used to profile or evaluate their practices. While this assumes the data will be more complete, standardized, and archived than the exchange can manage, it does represent a fundamental conflict that will take some time to resolve. There has rarely been a longitudinal and complete record of care on a population assembled outside research settings, and many recognize the enormous benefits in care improvement and disease management that this could bring. On the other hand, the very success of regional health information exchange arises from physician adoption, and if physicians are reticent to participate in something that may be used against them (or simply fear that it could be used against them), then this benefit of physician practice evaluation may have to be foregone for the foreseeable future.

Consumers will probably raise privacy and confidentiality issues as well. Consumers who examine the audit trails of access to their data may be surprised by how many different people and entities access their data. These are not security violations, but routine clinical and business uses of identified clinical data. As Santa Barbara moves toward full disclosure of clinical data and access logs to consumers, consumers will have to be educated about the realities of how their personal health information is used. Likewise, consumers have expressed fears about their employers having access to their data (now prohibited by HIPAA), which have only been slightly less vocal than employers' fears about gaining access to this data by accident. These issues are on the cutting edge of the consumer movement in health care, and therefore may change over time.

Physician Adoption

Since physician support for regional health information exchange is essential for success of the project, the Clinical Advisory Committee worked with local physicians and physician organizations to develop requirements for SBCCDE technology. The high-level technology requirements that were identified are:

- 1. The underlying technology must be able to access patient information from multiple sources (office, clinic, lab, hospital, ER, home, etc.);
- 2. Views of information must be patient-centric, complete, accurate, and timely;
- 3. The information must be available at the point of care where it is needed most;
- 4. Physicians must have access to this information in different practice locations;
- 5. The solution must improve physician office workflow; and
- 6. Information about both physicians and patients needs to be protected and access to it controlled.

These requirements have been continually reviewed and updated by the Clinical Advisory Committee during deployment of beta and pilot solutions, creating an interactive process for requirements development that has become a key piece of its success with physicians. Physicians have also overseen the process of designing and implementing the user interface that they will use. This process will continue as testing goes on and new data-sharing features are considered for deployment.

It could be argued that physicians have worked with information access fragmentation for years, so the change from paper and fax to electronic access should not pose new problems. However, there is substantial process change in converting a physician's office to electronic reporting, as the requirements for using these types of technology are highly specified for reasons such as security, user process, HIPAA, and intra-office communication. Therefore the switch to electronic access, a risky proposition to start with, is made even more risky by the tenuous ability and willingness of physicians' offices to change their processes. This is further complicated by the simultaneous conversion of multiple reporting systems to proprietary technology, requiring physician offices to operate in a more complex environment.

In many ways, Santa Barbara is like other regional markets in which multi-dimensional competition occurs among players of various sizes. The largest players, such as hospital networks or laboratories, have the capacity to invest in proprietary tools for engaging physicians and getting information out to them efficiently. Indeed, in Santa Barbara, there are at least nine proprietary reporting efforts that are trying to gain physician adoption. However, this growth in proprietary information tools—or, more precisely, in stand-alone results reporting tools—is of concern to physicians, who do not want the task of integrating a variety of proprietary systems. Unless they practice exclusively with a specific health system or in a fixed setting, they may reject the added work of supporting multiple proprietary solutions in their offices.

Physician hesitation limits technology leaders' ability to move forward with their plans, so they may view participation in regional data sharing as a way of hedging their proprietary investment. For a small premium over their own investment, they can participate in a public solution for sharing data with physicians. If the public solution does not work or yield benefits, then their bets are hedged by the proprietary investments. On the other hand, if the public solution gains acceptance, proprietary investments can be scaled down to lower costs. It seems likely that reduced health system margins will pressure their leaders to hedge their results-reporting bets on regional solutions, and maybe modify their approach to proprietary solutions altogether.

There are many technology followers in Santa Barbara, and in every other market, that cannot mount proprietary investments but still want technical parity with the leaders. These technology followers see regional data sharing as a means of closing the gap or gaining technology, or even gaining access to expertise or to subsidies that flow from public solutions. Both technology followers and leaders have reasons—albeit different reasons—for supporting a shared regional solution. These reasons go beyond the financial returns and speak directly to how technology is affecting the fundamental relationships among physicians and hospitals and ancillary providers. In the end, both leaders and followers are trying to maximize the returns they get from their information technology investments, although the ways they deem benefits to accrue are quite different.

Physicians may be more likely to adopt regional results-reporting solutions to simplify the change process in their offices. When this physician preference is brought to bear on the regional market, information architecture becomes more regionalized among the institutional players. This push for regionalization is likely to increase as physicians face more proprietary systems from their labs, radiology providers, hospitals, pharmacies, and health plans. For the same reasons, it is possible that health information exchange will increase physician interest in adopting computer-based medical records.

Technology and Data

Health information exchange is a vague term and is inadequately defined for technology development. This is caused in part by the unique needs of different stakeholders, each of which has different data needs. In developing the SBCCDE, health information exchange was defined by characterizing the interaction between each data holder (e.g., a laboratory) and each data user (e.g., a physician), constituting a many-to-many interaction. Each interaction determines the unique requirements for health information exchange. Figure 3 summarizes 25 potential use cases for health information exchange among six general types of data holders and users.

Figure 3. Health Information Exchange Use Cases

TO ►	Physicians	Consumers	Hospital	Ancillary Providers	Health Plans	Public Health
Physicians	Referrals and consultations	Findings and treatment advisories	Admission information, reports	Test orders	Authorization, medical necessity, claims	Case reporting
Consumers	Personal health information		Personal health information		Authorization	
Hospital	Reports, results reporting	Personal health records			Authorization, medical necessity, claims	Case reporting
Ancillary Providers	Reports, results reporting	Results reporting	Results reporting			Results reporting
Health Plans	Eligibility, enrollment, formularies		Eligibility, enrollment	Eligibility, enrollment		
Public Plans	Treatment advisories	Treatment advisories	Treatment advisories	Reporting requests		Population reporting

Each of these 25 use cases represents a potentially different business function that requires some degree of technology specialization and unique data. Each of these involves different combinations of participants, and each would be expected to have unique implementation and operating costs and unique benefits.

The SBCCDE determined it wanted to support the physician as the primary data user and the consumer as secondary data user. Given this, and the priority given to data that are readily available in electronic format, primary data suppliers were hospitals, ancillary health organizations (lab, pharmacy, imaging), large medical groups, and public health. These were chosen because of the large amount of electronic information that these organizations possessed and their relatively high degree of technical sophistication. Physician-held data was not prioritized because of the low degree of information system penetration in physician offices, and the low degree of usability of data that does not show up elsewhere as electronic transactions (e.g., patient symptoms, physician findings, and differential diagnosis are potentially of less use to other physicians than lab results or drug lists). Hence, the SBCCDE focused on an institutionto-physician and an institution-to-consumer health information exchange, which narrowed product requirements to the sharing of reports, results, and personal health information.

During the feasibility study, several potential vendors of data-sharing technologies were identified and evaluated for their potential to develop the technology needed to meet the data-sharing requirements. The evaluation criteria included the following technology attributes: (a) inexpensive, both in upfront and ongoing costs; (b) lightweight in both bandwidth and computational demands; (c) secure, including the ability to implement access control policies; (d) decentralized so there is little or no central data storage; (e) usable in

physician's offices and remotely by physicians; and (f) application-neutral such that any vendor could access the technology. None of the products on the market at the time met these criteria, so the feasibility study recommended that the technologies to support data-sharing be built de novo for this project. Notably, several vendors described concerns about the negative impact of interoperability and seamless health information exchange on their consulting revenue streams and customer retention strategies.

The original plan was to deploy technology in early 2002, but this deadline was not met because of the vague requirements for—and inordinate complexity of-unique patient identification, user interface design, latency management (delays in data access), and data availability control. However, the iterative nature of the design continued to refine the requirements, and sequential beta testing incrementally simplified technology functional needs. Despite the overly aggressive expectations for the initial technology deployment, the requirements for the technology have become highly specific and have now been through three rounds of testing by physician offices. The SBCCDE technology is now is pilot use in 17 provider offices, and is slated for county-wide deployment in late 2003.

At this stage, the following technology components, depicted in Figure 4, are deployed in the SBCCDE. Each component of this technology is described in the following sections.

Figure 4. SBCCDE Technology **Data Integration Central Infrastructure User Access SBCCDE** Hospital **Physician Patient** Demographics Radiology Records **Physician Portal Information Location** ■Clinical Records Service Access ■ Links to patient clinical Pharmacy ■ Browser-based records in participants' Records ■ Retrieve records systems from anywhere in ■ No clinical records stored system at CDE central site ■Only allowed to Lab Records ■ Demographic data of all access records of patients in system own patients **Payor Access & Security** Policy Holder Management Demographics ■ Controls login **Patient** ■ Monitors and records access requests ■ Enables access only to allowed data Eligibility and Authorization **Consumer Portal** Lab ■ Medical Information ■ Browser-based ■ Information on **Identity Correlation** Patient hospitals, clinics, Demographics ■ Correlates patient physicians identities from different ■ Consumer medical sources

information

guidelines

■ Pharmacy listings

■ Health care plan

■Intelligently matches

similar records (e.g.,

similar names, SSNs,

addresses)

Lab Records

Data Integration

Regional surveys during the feasibility study mapped out the data that could be integrated for physician and consumer access, and priorities were set for the sequence of data integration by the clinical and technical advisory committees. Particular attention was given to the regional and specialty-based clusters of data that could provide a minimally sufficient set of information for groups of physicians users. The integration work was performed by third-party vendors and local organizations using a published set of data integration requirements. At this point, more than 29 interfaces are operational in the SBCCDE. Data sources by organization are shown in Figure 5.

Figure 5 implicitly reveals a question about implementation that posed a substantial challenge for the SBCCDE. Should the exchange first select

physicians and then find the data they need, or should it choose data sources and then find the physicians who need that data? The original implementation scheme in the SBCCDE was to choose physicians and then get the data they need. However, for each physician, there is a minimal amount of information that is needed for an information tool to be useful, and any given data source supports only a fraction of each physician's needs. Therefore, some number of data sources needs to be assembled before the first physician is introduced. Because of this, implementation evolved to choosing data sources and finding the physicians who could make use of the data.

Figure 5 also shows the variety of data formats that are accessed by the SBCCDE. Because of the lack of data standardization among (and within) providers in Santa Barbara County, and also the broad variety of data sources that physi-

Figure 5: SBCCDE Data Sources

Organization	Lab Reports	Radiology Reports	Radiology Images	Clinical Notes	Pharmacy Detail	Eligibility/ Enrollment
Cottage Hospital	1	1	1	1	1	
Marian Medical Center						
Lompoc CHO						
Sansum SBMF Clinic	/	/	1	/	/	
UniLab	/					
SBRHA	/				/	/
Local Pharmacies					/	
Pueblo Radiology		/	1			
Public Health Dept.	/	1		/		

cians wanted to view, emphasis was placed by the SBCCDE Technical Advisory Committee on flexibility in data formats. In the SBCCDE, data formatted by well-defined methods such as LOINC can be presented alongside an image of a lab report, voice clips, still images from DICOM or other format, or text. The most common data formats in the SBCCDE are HL-7, DICOM, and ASCII text.

Central Infrastructure

A brokered peer-to-peer technology was selected for the SBCCDE because of the low cost of operation and its superior security features ("brokered" in this case referring to centralization of master patient index, identity resolution, and security management). The Care Data Exchange keeps a central index of patients and pointers to secure Web sites enrolled in the SBCCDE that house data about that patient. This index controls access to patient-specific data by authorized users by accessing Web-enabled data from behind the data holder's firewall. These data include patient demographics; transcriptions; laboratory, radiology and pharmacy data; and eligibility and referral information. When data are sought on a particular patient, all sources for those data are identified and hyperlinks are presented to the physician user through a browser portal. A variety of unrelated information systems and applications generate the data that are viewed by the user, making the SBCCDE a 'system of systems' with a common list of patients and shared access, viewing, and security technologies.

The security of highly sensitive clinical data and the privacy of the patients and providers was a requirement of great concern for the SBCCDE. By eliminating central data storage with peer-topeer technology, control of data was maintained with organizations that already had responsibility for its security. Within the peer-to-peer architecture, a set of security tools was implemented that

provides access to confidential information under highly controlled circumstances, which include:

- All clinicians' identities are confirmed through authentication and digital certificates;
- Only authorized users can access data according to rules established by the data holder;
- Patient consent is required and logged by the data requester in order to view data;
- The data holder can override an authorized request and withhold data if directed by the patient; and
- Access and consent are logged for patient review or routine auditing.

There is a dualism in Santa Barbara about security that has little to do with health information exchange. Both the Clinical Advisory Committee and Technical Advisory Committee outlined detailed and stringent specifications for how the technology should handle security. Although these stringent requirements were met in technology design and implementation, many of the clinicians asked to be exempted in their own practices. For example, the advisory committees were adamant that users have a digital credential when logging on. Because many clinicians find certificates unwieldy, particularly in multi-site practices, many have asked that certificates be made optional. Optional authentication is an interesting dilemma in the health information exchange environment. In the CPOE environment, digital credentials pose a benefit to the physician user (electronic signatures) and for the data holder (protection). However, in the health information exchange environment, digital credentials present disadvantage to the user (hassle, lack of portability) but benefits to the data holder (protection). Hence, there is a free-rider authentication effect in health information exchange. This and a variety of other issues about the realities of security are currently under consideration by leaders of the SBCCDE.

User Access

A browser-based user interface was created for physicians and their staff to allow search and retrieval of data. This interface was designed to resemble a search engine, albeit one with stringent security, highly specified data, and limited search breadth. Users can access the SBCCDE interface or access SBCCDE data through other CCOWintegrated applications. Features have been added to allow users to 'subscribe' to a set of patients and then have new information about those patients forwarded to themselves whenever it is released.

The SBCCDE includes access for consumers as well as physicians, although consumer deployment will happen after physicians are set up. In pilot testing, consumers are testing how they can: (a) gain access to their information in accordance with the HIPAA patient privacy regulations; (b) review usage logs detailing what personal health information (PHI) was seen by others; (c) update and make comments on their PHI; and (d) communicate with physicians, provided that physicians allow this to occur. Recent California law limits the electronic release of some results until those results have been authorized for patient access by physicians, so the implementation of consumer access to certain information will be limited and dependent on willing physicians to gain widespread use.

III. Benefits Analysis

SANTA BARBARA IS ONE EXAMPLE OF HOW A region's health care leaders came together to address fragmentation of care. They committed themselves to improving care delivery by working collaboratively and this commitment contributed to the support they received from CHCF and other entities trying to foster health information exchange. Whether Santa Barbara would have succeeded without this support will not be known, but the fact that Santa Barbara has overcome many obstacles and is now at the cusp of widespread deployment of health information exchange raises the important questions of whether it is beneficial and sustainable. Can it actually change the information used by physicians in the treatment of patients and reduce or eliminate duplicative testing and the erroneous decisions made with improper or incomplete information? Even if beneficial to patient care, can information exchange be implemented in a way that reflects the real world of health care's hyper-competitive, capitalstarved and low-margin operation?

To address these questions, a rigorous benefits analysis has been undertaken in Santa Barbara. This analysis includes detailed financial modeling by an independent consultancy to objectively assess the economic impact of health information exchange. Also, a quality and service analysis is underway by academic investigators that will determine the degree to which health information exchange in Santa Barbara improves patient safety and physician workflow.

Problem Definition

Like many innovations that can affect the delivery of care to patients, health information exchange addresses a problem that has been poorly defined in the past but which, on closer examination, is a potentially significant obstacle to high quality and efficient care delivery. Health information exchange has the potential to remedy the fragmentation of care delivery and the communication, knowledge, and decision-making problems fragmentation creates. The degree of fragmentation in a market is determined by a variety of factors, including the degree of specialization of physician groups, the size of physician offices, the degree of integration of delivery systems, and by patient preferences (e.g., how they choose physicians or hospitals). In general, these factors can be summarized along

two dimensions. First is the degree of dispersion of care across providers (e.g., how concentrated they are). Second is the degree of "closedness" of any provider (e.g., the share of patients who are treated exclusively by a given provider). These dimensions were used to create testable scenarios, summarized in Figure 6.

Clearly, more dispersed markets are less likely to have closed systems, but even in highly consolidated environments, patients still select care 'a la carte' from competing systems because of personal preferences, network design, or access to specialized expertise. Moreover, while there are some organizations that are highly closed and limit patient access outside their network, such as Kaiser Permanente or the Veterans Health Administration, these organizations still purchase substantial amounts of services from outside providers, requiring them to share data with others. Many of these large, national networks face data-sharing challenges within their own organizations as well.

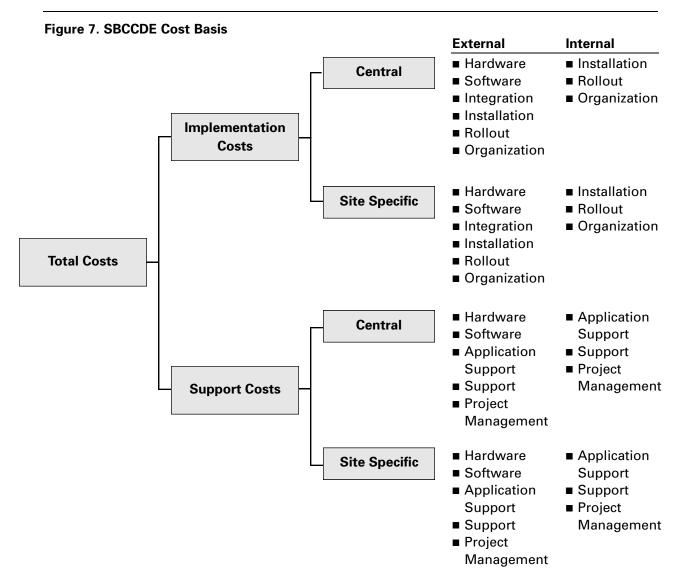
Most health systems are not closed and provide care in tacit, and occasionally intentional, collaboration with a variety of other competing or allied providers. In some cases, these relationships are pre-determined by network design. Increasingly, however, patients are shaping these collaborations as they customize care delivery to their own needs. The consequence of this uniquely American care delivery environment is that the care for a typical patient is delivered by an array of unrelated providers. Under this arrangement, no single provider is able to estimate the fraction of care provided to any given patient, nor determine who else is providing care or whether any treatments given by others are overlapping or conflicting. Because of this, the provider can uncover only the treatments that have been given elsewhere by inducing patient recall or through a slow, unreliable paper process. Most organizations cannot measure the consequences of missing information on their decisions or actions, nor the impact of fragmentation on the quality or efficiency of the services they provide.

jure 6. Finar	ncial Analysis Scenarios	Total Number	Penetration	
	Constituent type	in Region	Low	High
Large	Major hospital	10	3	7
	Diagnostic imaging center	5	2	4
	Independent laboratory	3	1	2
	PBMs	5	1	3
	Major physician groups	5	1	3
	Physicians	5,000	750	1,750
Medium	Major hospital	6	2	4
	Diagnostic imaging center	2	1	2
	Independent laboratory	1	1	1
	PBMs	5	1	3
	Major physician groups	2	1	2
	Physicians	1,000	150	350
Small	Major hospital	1	1	1
	Diagnostic imaging center	1	1	1
	Independent laboratory	1	0	1
	PBMs	5	0	3
	Major physician groups	0	1	0
	Physicians	200	30	70

Financial Analysis

Starting in January 2002, CHCF established an assessment team supported by McKinsey & Company to examine the financial case for health information exchange in Santa Barbara. A set of models was developed that can be extrapolated to other regions. Six scenarios were evaluated, as summarized in Figure 6, including high and low penetration in each of small, moderate, and large regions. These models were tested with decisionmakers in Santa Barbara.

In performing the cost side of this analysis, each scenario included the cost of setting up a health information exchange apparatus, including integration of systems, deployment of central data sharing services, development and validation of a set of algorithms to generate and maintain a master patient list, training and support of physicians and their offices for gaining access to data, and supporting the implementation and operation of the central oversight entities. These cost bases are summarized in Figure 7.

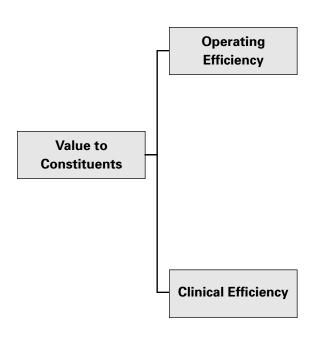


There are two classes of benefits that were considered in this analysis. First are the benefits that can be directly realized through improved operating efficiency, mostly in the form of labor cost reductions. These are determined by the cost of managing the paper-based data-sharing process and the degree to which automated data exchange can lower the use of these inputs. These are relatively easy to define and are understandable to most decisionmakers. Second are the benefits gained through changes in clinical efficiency—the outputs of care. These benefits are more difficult to measure and are somewhat opaque, but are potentially quite large. These classes of benefits are

summarized in Figure 8. To generate the most conservative estimates possible, only operating efficiencies were used in subsequent analysis.

Figure 9 summarizes the financial analysis, considering only operating efficiencies, for the six test scenarios. The analysis shows that there are positive returns to health information exchange in all except small communities (e.g., one hospital and less than 100 physicians), even when ignoring improvements in clinical efficiency. In one-hospital markets, there is little difference between enterprise-data access and regional data sharing, so it is not surprising that these markets do not have a business case for sharing data beyond the enterprise.

Figure 8. Constituent Value Framework



Quantifiable Benefits

- Labor savings in laboratory and radiology
 - Lower cost of result delivery
 - Less staff time spent handling test results
- Radiology Savings
 - Lower cost of radiology results delivery -Less staff time spent handling radiology results
- Less time spent fulfilling external requests for information
- Less time spent requesting information
- Payor transaction costs
- Fewer admissions from the ED
- Fewer readmissions
- Fewer medical errors
- Shortened hospital length of stay
- Enhanced revenue from proper coding
- Test duplication avoidance

In Santa Barbara, which is similar to the mediumsized, high-penetration scenario, the net financial benefit to the community is more than \$1 million per year in excess of the fully laden cost of deployment and operation of regional data sharing. Again, this does not take into account any financial benefits from clinical efficiency changes, nor any service or quality benefits.

At face value, there is a moderate return on investment on health information exchange, but two considerations should be noted. First is that the financial returns are completely related to lowering the volume of manual data handling. This benefit is determined by the rate of physician adoption and use. Hence, in health information exchange, as in every other clinical information technology in health care, the key variable is

physician adoption. The workflow simplification in physician offices induced by health information exchange creates a strong and unique adoption factor that may spill over to other information tools destined for the physician office.

Another consideration that should be noted is that the overall magnitude of returns is relatively low. A net benefit of \$1 million is a small fraction of the percentage of health care expenditures in Santa Barbara or any other region. However, Santa Barbara decisionmakers required that health information exchange be self-funded, and did not require it to be a net money maker for them. The ability of the SBCCDE to be net positive at all results from the ultra-low cost of deployment and operation of the SBCCDE, resulting from the use of peer-to-peer technology, which scales the benefits to the cost of operation and carries little overhead.

Figure 9. Returns to Size and Penetration

		Penetration				
Annual Results		L	.ow		High	Value
	Large	Costs Benefits Net	\$1,000,000 \$1,300,000 \$300,000	Costs Benefits Net	\$2,200,000 \$7,900,000 \$5,700,000)
Region Size	Medium	Costs Benefits Net	\$800,000 \$900,000 \$100,000	Costs Benefits Net	\$1,400,000 \$2,600,000 \$1,200,000)
_	Small	Costs Benefits Net	\$490,000 \$180,000 (\$310,000)	Costs Benefits Net	\$780,000 \$600,000 (\$180,000)

Note: Excludes Clinical Efficiency Benefits

The breakdown of returns by constituent tells a more complicated story, as summarized in Figure 10, which shows a breakdown of benefits for one scenario, the large high-penetration region. The findings in this analysis are similar to those observed for all other scenarios. It demonstrates that each constituent bears some cost for implementing and operating data sharing. These costs include all of the internal costs for data integration and implementing data sharing as well as an allocated share of the central infrastructure costs. Central costs are allocated to constituents other than physicians on the basis of the number of unique lives for which data are made available by them. Physicians are allocated a small training fee based on an assumption about willingness to pay determined by the SBCCDE Clinical Advisory Council.

Looking only at changes in operating efficiency, each constituent derives two types of benefits. First are benefits of providing data to any set of physicians on an enterprise level without "regionalization" (i.e., stand-alone Web-enablement, or

one-to-one interaction). Each organization derives a benefit from this form of data provision, with only the hospital yielding a net benefit over its investment. It should be noted that the assumptions for the cost of stand-alone Webenablement were determined using the SBCCDE cost as a basis, although these costs are markedly lower than the actual investments reported for enterprise-only Web-enablement in Santa Barbara. Even given the low cost of Web-enablement in this project, there is still a significant first mover disadvantage, in that there is a strong financial disincentive for investing in enterprise-based data provision without investing in health information exchange at the same time.

Each organization also gains benefits from participation in the regional network, which arises from having a single place for physicians to get all relevant data for their patients (i.e., many-to-many interaction). Physicians get a very high rate of return in the form of office efficiencies and imaging centers have a slightly negative return. Overall, however, every organization

Figure 10. Net Returns by Constituent

Annual Results

Organization

Imaging Center

Physician Group
Solo Physician

Hospital

Laboratory

Per Constituent

Stand-alone

\$90,000

\$0

Costs	Web Enablement	Network	Individual Benefits
\$120,000	\$180,000	\$110,000	\$290,000
\$110,000	\$44,000	\$(15,000)	\$29,000
\$110,000	\$70,000	\$170,000	\$240,000

\$280,000

\$2,400

Total

\$370,000

\$2,400

Note: Excludes Clinical Efficiency Benefits

\$120,000

\$40

Total for all Constituents

Number of Constituents	Total Costs	Total Benefits
7	\$840,000	\$2,000,000
4	\$440,000	\$120,000
2	\$220,000	\$480,000
3	\$360,000	\$1,100,000
1,750	\$70,000	\$3,500,000
	\$2,200,000	\$7,300,000

has positive overall returns from regional data sharing, as shown in the right-most two columns in Figure 10. These returns exhibit strongly positive network externalities (not shown), such that they rise with increasing adoption of regional data sharing by physicians. Physicians are essentially free riders in the SBCCDE, but this is the result of a business choice to not charge physicians for access rather than an intrinsic economic characteristic of health information exchange. Indeed, if physicians paid up to their \$2,400 marginal benefit, this would itself double the return on investment for the community in addition to the other financial and non-financial benefits.

Just as the costs of the current manual approach to data sharing are fragmented across every type of organization, the benefits are spread among constituents as well. This is likely to be both an advantage and a disadvantage, and the net effect will likely be determined by the dynamics of any given market. The benefit dispersion is advantageous because each organization gets a net benefit from regional data sharing (i.e., there are no losers). Yet, it is disadvantageous because there is no single entity with a strong incentive to drive regional data sharing. It could be that the latter is fallacious since the more advantage any single organization gets, the more likely it would be to take a proprietary approach, thus undermining the basis for regional collaboration that gets the results in the first place.

While health plans have formed or been involved in a number of administrative health information exchange efforts, their role in clinical health information exchange remains unclear. There is no doubt (although not modeled) that these organizations derive a large share of the financial benefits created by regional data-sharing efficiencies and that the clinical efficiency benefits-which are likely to be much larger than the direct financial benefits—also accrue largely to health plans, and ultimately perhaps to employers or Medicare. However, there are limits imposed by law, common practice, or competitive concerns on the amount of person-specific clinical information that these entities may access. Moreover, some providers see data sharing as a way to shift leverage in the market away from plans and toward providers; meanwhile, provider revenue increases that arise from clinical data sharing's improved billing yield come at the cost of payers. Further experience with how employers and payers regard clinical health information exchange, and how providers regard their participation in turn, is needed.

Quality and Service Analysis

Nearly every clinician in Santa Barbara views the potential quality and service benefits of the SBC-CDE to be their primary motivation for participation, and see the benefits they derive from improving clinical quality and service as more significant bases for returns than the direct financial benefits. Physicians see the costs of missing data, duplicative data and erroneous data affecting their practice and their patients in harmful ways. More broadly, concerns about fragmentation and repeated efforts to achieve closedness of health care delivery suggest that many institutions recognize that the burden imposed by this problem is very large, and that solving it will produce equally large returns. These beliefs have been corroborated in numerous studies documenting the inefficiencies that arise from missing, incomplete, and erroneous information. However, there are relatively few well-designed studies that measure the degree to which health information exchange can yield benefits.

As the SBCCCDE becomes operational, various aspects of how health information exchange affects clinical quality and service quality in care delivery will be tested. There are six sets of questions that will be addressed, including:

- Who uses health information exchange and how frequently is it used? Which clinicians and/or staff are using health information exchange directly, indirectly, or not at all?
- How are clinicians and staff using health information exchange? What information are users obtaining from health information exchange? Are users obtaining needed clinical data more quickly than they did prior to health information exchange?
- What is the net contribution of health information exchange, beyond what clinicians and staff could have obtained from their own laboratory or radiology systems? That is, how much data accessed by data-using organizations was produced by some other data-producing organization?
- What are the effects of health information exchange on productivity, utilization, patient quality, and satisfaction? How do they vary among type of organization and region?
- Do direct physician "users" (e.g., those who view laboratory results on their monitors) realize different benefits than "indirect users" (e.g., the staff who look up results, print them out for the physicians to read) when engaging in health information exchange?
- What are the actual costs and benefits to users and potential users of health information exchange? What individual factors affect which clinicians will be direct users, indirect users, and non-users? What factors determine frequency of use, among users? What are the characteristics of each type of user and nonuser?

As a field demonstration project, Santa Barbara has no control group, and the project is still evolving organically. Therefore, no scientific conclusions are likely to emanate from this work. However, given the absence of rigorous research on this topic, the investigation in Santa Barbara is focused on refining hypotheses and giving direction to future work. These questions are of sufficient complexity and importance that evaluations of health information exchange outside Santa Barbara will have to be conducted to fully understand the potential role for health information exchange.

IV. Implications for Public Policy

THE SBCCDE PROJECT IS UNDERWAY AT A critical point in the national dialogue about a health information infrastructure. While a single experiment cannot be extrapolated with great confidence to public policy, and the SBCCDE is still evolving, this project stands as one of America's few laboratories for understanding health information exchange. Based on learnings to date in the SBCCDE and other regions, the following issues should be considered in public policy discussions on interoperability and health information exchange.

Because of strongly positive network externalities that accrue as operational and clinical efficiencies, health information exchange can transform care if widely adopted. However, paradoxically, the first-mover disadvantage penalizes any organization that takes the first steps toward interoperability. Therefore, the broad policy question is how to address this market failure where collective short-term enterprise good is a barrier to the long-term common good.

Explicit Financial Incentives

The SBCCDE has shown that there is a moderate-to-strong business case for health information exchange. However, benefits are widely spread among participants and there is a first-mover disadvantage in making health information interoperable. For many care delivery organizations, multiple payment schemes (e.g., case-based payment mixed with feefor-service) obscure realization of the implicit financial benefits of health information exchange. Hence, in any given organization, health information exchange competes with many other possible means of improving quality and efficiency, many of which may have a more explicit (albeit weaker) business case. Because regional collaboration is needed to institute health information exchange, these intra-organizational barriers are compounded across organizations. Given these factors, it is likely that, without catalysts, adoption of health information exchange will be incremental despite technology advances and other environmental adjuvants.

There is significant attention being given today to quality-based payment strategies and this is perceived by some to be a step toward incentivizing behaviors such as health information exchange. Certainly health information exchange will be rewarded to the degree that it improves demonstrable quality in a way consistent with the payment scheme. However, the slow movement toward reimbursement reform, the nonspecific reward for interoperability, and the simpler means of achieving the reward (e.g., guideline compliance within an organization) make "pay-for-quality" a very weak and indirect means of driving the critical goal of health information exchange.

There may be a role for explicit incentives for health information exchange if they can help reduce fragmentation of care, lower the lag time in clinical information availability, or improve health status and care delivery quality. Even a small incentive that hedges an organization's upfront investment or an incentive that causes an organization to document its current cost of fragmentation would help many regions take the first steps toward health information exchange. Policy discussions should examine carefully whether, and how, explicit incentives can be used to promote health information exchange.

Clear Safe Harbors

A noteworthy lesson from the SBCCDE and other regions is the significant concern about whether health information exchange is consistent with federal rules, particularly HIPAA, antitrust regulations, and Stark anti-inurement laws. Since HIPAA has stabilized, it has become less of a concern, but concerns about antitrust and Stark persist, and these concerns appear to slow consideration of health information exchanges. These issues were examined in-depth for the SBCCDE, and legal opinions and related analyses were used

to design the legal framework so that the SBC-CDE could operate in accord with existing laws in all ways possible. However, these analyses were very complicated, required extensive knowledge of arcane federal and state regulation and case law, and were quite expensive. Moreover, the complicated and highly technical nature of these laws led to numerous contentious discussions in the formation of the SBCCDE.

Unfortunately, these analyses and the operating frameworks they imply have not proved to be adaptable from exchange to exchange. This is because of a need to determine what rules are changing over time, concerns about regional differences in application of rules, and fear about regulatory exploitation of ambiguities in federal rules. In short, many health care executives reflexively fear the legal risks of health information exchange despite strong opinions by highly technical experts that health information exchange is legal if operated in a certain way and governed by a certain set of bylaws and agreements.

Because ambiguity in federal rules that affect health information exchange is a barrier to its use, clear guidelines about health information exchange should be established. Particular attention should be given to health information exchange among groups of provider organizations that constitute more than a majority of care delivery in a region and to how providers can offer joint access to health information for physicians. Beyond this, identifying and promulgating clear limitations and restrictions that health information exchanges must follow would be beneficial.

It should be noted that many legal concerns affecting health information exchange are controlled by states or are purely matters of case law. For example, peer-review protections, professional liability exposure via health information

exchange, and Medicaid privacy rules vary significantly from state to state. Also, for example, California recently passed a law prohibiting release of certain patient information on the Internet without the physician reviewing it in advance, but few other states have such a law. This inter-state variability will require that, without intervention, the operations and bylaws of health information exchanges will vary from state to state. There may be a role for federal rationalization of state rules affecting health information exchange. At a minimum, federal policy considerations should be aimed at reducing federal ambiguity regarding health information exchange.

Regional Implementation Support

The competitive nature of regional markets makes it very difficult for health information exchanges to form spontaneously. In past CHIN efforts, the participant with the largest market share often played a lead role. While these organizations could induce involvement of others, their motives were—or were perceived to be—contrary to formation of a public utility and this is one reason they failed. In the case of the SBCCDE, local health care leaders coalesced because of the involvement of a trusted party, the California HealthCare Foundation. In other regions, other philanthropies have played this role as well. As health information exchange moves toward broad adoption, it will necessarily move away from philanthropic sponsors, but the need for independent and locally trusted third parties as catalysts is likely to continue.

There is also a need in many regions for outside technical expertise that is necessary for health information exchange, such as security, business management, legal contracting, information standards, and physician training. While many large

providers have some of this expertise, it is a precious asset within their organizations and difficult to access. Many organizations simply lack these capabilities and lack the funds to hire it from consultants or other external agents. Regional third parties that can go beyond supporting formation of health information exchange and actually advance their implementation and operation would be useful assets in many regions.

Currently, there is a wide variety of local entities forming to support health information exchange under the rubric of so-called regional exchange management organizations (REMOs). Some REMOs are formed by institutional providers, some by business coalitions, some by physicians, and others by health plans. There does not appear to be a single entity around the United States that can become a REMO in every market. However, these REMOs have one strong common characteristic: They are locally driven, reflecting the local nature of care delivery, the overwhelming role of locally held information in day-to-day practice, and sensitive intra-regional trust issues.

Policy consideration should be given to the required characteristics and capabilities of REMOs and how they can be fostered in a replicable manner across regions of the United States. Given the organic, grass-roots nature of the health information exchange movement and the potential urgency of this topic to national health care reform, it may be necessary to set operating standards and to accredit organizations to be REMOs. However it is done, if policy leaves the support and implementation of health information exchange to natural forces, few regional efforts will form and fewer will succeed.

Stepwise Pathways Toward Interoperability

Interoperability is envisioned in health care as an intrinsic feature of information systems, an "outof-the-box" capability. This is undoubtedly an ideal for a frictionless health information exchange that the industry should strive toward. However, the state of the art in the industry is far behind this, and the installed base of legacy systems in health care organizations is further behind still. In Santa Barbara, after instituting the legal, governance, and operational framework for health information exchange, the SBCCDE faced the fundamental challenge of how information technology would be used to foster exchange of health information. Originally, regional leaders conceived of a "community EMR" in which all organizations would group-purchase the same product, thus forcing top-down interoperability in a highly controlled manner. This plan, however, was abandoned because of the high cost of purchasing an EMR, lack of agreement on which product to buy (and for some corporately owned organizations, requirements to follow a corporate information technology plan rather than a regional one), and lack of synchronization in implementation readiness and their accompanying budgets. Integrating a small set of different EMRs was also considered, but vendors offered meager support for making their products interoperable with competing products.

Based on these experiences, the SBCCDE moved away from seeking a big leap and chose instead to seek incremental progress towards full interoperability. The SBCCDE decided to overlay its information systems with a separate exchange technology so that data, rather than software, were made interoperable, buffering the user from the specific information systems and the change in systems over time. To accomplish this, trade-offs were certainly made, notably in standardization of content and completeness of integration with existing

EMRs (e.g., order writing requires switching over to an EMR). However, Santa Barbara now has a group of leaders who are highly educated about interoperability, a business framework to evaluate the costs and benefits of uniform standards adoption across the region (as in the case of LOINC, which is now under consideration), and is planning several further steps toward a broad health information exchange capability that builds upon current capabilities.

The particular question is how to foster pathways—stepwise movements for a region from non-interoperability to full interoperability that either do not increase short-term costs to government, employers, or providers or that create benefits along the way that compensate for higher costs.

Particular attention needs to be given to fostering a portfolio of information tools that support all levels of information exchange sophistication that are available, establishing a framework for regions to assess their readiness and business case for health information exchange, developing tool kits to plan exchange implementation, and identifying case studies or demonstrations that illuminate possible pathways. Also, attention should be given to how to incentivize vendors to offer health information exchange and interoperability capabilities. If vendors can see it is in their selfinterest to offer this capability, and maybe even competitively differentiate on it, health information exchange will be advanced dramatically.

V. Conclusion

Santa Barbara set out to determine whether the emergence of the Internet and the failure of assetbased integration would drive cost-effective data exchange that can remedy some of the egregious errors and waste that arise from the fragmented American care delivery model. This effort had the benefit of strong leaders and physicians in a relatively protected health care market, sufficient funding and nationally talented expertise. However, it also faced challenges with the technology development complexity and also the social context of privacy as HIPAA was debated and ultimately adopted.

Santa Barbara has shown that health information exchange is feasible, and a set of hypotheses have been generated to explain why this it true. It has not shown, however, that health information exchange is replicable, although independent financial modeling has given reason for optimism. The many efforts underway across the United States today will address this with their very success or failure. There is reason to believe that health information exchange will deliver substantial and reproducible benefits to care delivery and has the potential to become part of the accepted practice of medicine. If it does, it will change the reality of care for many physicians and patients in the future.

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