

The California Clinical Data Project: A Case Study in the Adoption of Clinical Data Standards for Quality Improvement

Walter Sujansky, MD, PhD; and Sophia Chang, MD, MPH

ABSTRACT

The California Clinical Data Project is a statewide initiative to remove barriers to the widespread and effective use of information technology to improve chronic disease care. The project is a case study in the development and widespread adoption of clinical data standards by varied and often competing stakeholders. As an initial step, the project defined precise data standards for the batch reporting of pharmacy claims data and laboratory results data. These uniform standards facilitate the flow of existing electronic clinical information into disease registries and electronic health record systems. Pharmacy and lab results data now are being exchanged electronically with this standard among the largest health plans, medical groups, and clinical laboratories participating in California's pay-for-performance programs. Lessons from this project may apply to the development and adoption of data standards for other states and locales and for the emerging national health information infrastructure.

KEYWORDS

- Data standards
- Data integration
- Disease registry
- Clinical data warehouse
- Quality improvement
- Chronic disease care
- Disease management
- Pay for performance

During the last several years, the goal of quality improvement and the supportive role of information technology have taken center stage in national healthcare policy discussions. Launched with the Institute of Medicine's Quality Chasm report,¹ there has been a call for greater focus on quality and safety in the care delivery system and greater accountability for the quality of care delivered.

Academics and politicians alike have pointed to informa-

tion technology as an important and underutilized tool in measuring and improving healthcare quality. Specifically, there is growing consensus and interest in the potential for information technology to provide key clinical information to busy clinicians. The synthesis of patient data, best-practice recommendations, and payer requirements enabled by information technology can support timely clinical decisions and improve the quality of care.

In California, as elsewhere, discussions have focused on chronic disease care in the ambulatory setting. In this domain, the clinical and economic stakes are high, and there is significant room for improvements in quality.² Electronic data sharing and computerized decision support can play an important role in improving chronic disease care, but certain technical and logistical barriers exist that have prevented the broad and effective application of such technologies.

These barriers include the absence of widely adopted data-exchange standards for clinical information, the challenges of integrating electronic data from disparate sources, and the difficulty of building or buying effective decision-support systems that leverage clinical data to improve care.

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The California Clinical Data Project (CCDP) is a multi-stakeholder initiative sponsored by the California HealthCare Foundation that seeks to address these barriers on a large scale in California. In its initial phase, the CCDP worked in 2004 and 2005 with major provider organizations, health plans, and clinical laboratories to define effective data exchange standards for pharmacy claims and laboratory result data. The goal was to streamline the collection and integration of clinically relevant information already available in electronic form (lab and pharmacy data), thereby facilitating the use of disease registries and other information systems to improve chronic disease care. The CCDP focused from the outset on promoting the rapid and widespread adoption of these standards, not simply their development.

This paper describes the CCDP as a case study in defining and achieving rapid adoption of clinical data standards by a large and varied stakeholder group. We first briefly describe the healthcare environment in California, an important quality improvement initiative already under way and a past effort to standardize clinical data exchange. We then describe the CCDP’s structure and processes, its successes and challenges, and lastly, the lessons learned and how they may apply to larger, more complex data standardization efforts under way at the national level.

Background

Care for patients with chronic diseases, such as diabetes, asthma, and congestive heart failure, is provided not at a

single facility, but at various primary care sites, specialists’ offices, laboratories, pharmacies, emergency departments, and hospitals. Optimal care requires coordination and information sharing among these providers, which is difficult to achieve in the largely decentralized care delivery system of the United States. As a result, suboptimal care is unfortunately the norm for chronic disease patients.²

Information technology can integrate and analyze clinical data generated across many sites and provide clinicians with prompts and reminders that improve chronic disease care.^{3,4,5} The integration of clinical data across treatment sites remains difficult, owing to the use of disparate information systems and the absence of widely adopted standards for clinical data exchange.^{6,7}

The majority of California’s citizens receive their healthcare in a decentralized way. Their care is paid for by a number of commercial and government-sponsored health plans with a menu of coverage and payment options—HMO, PPO, and fee-for-service—delivered through contracted networks of independent physicians, laboratories, pharmacies, and hospitals. In other words, there is a multitude of data sources and no single market driver to promote standards adoption. In light of the challenges to quality improvement posed by this environment, two initiatives are under way in California to help bring information technology to bear.

The first is a robust pay-for-performance program that directly and indirectly incentivizes provider organizations to use clinical information technology. Six large commercial insurers are offering financial incentives to provider organizations for improved performance on certain quality measures, as well as for the adoption of clinical information systems.⁸ Providers, in response, are increasingly interested in information technologies, such as disease registries and electronic health record systems, to assist in tracking and improving their performance on quality measures.⁹

In light of the slow uptake of EHRs in the ambulatory setting^{10,11} and the variable acceptance of structured data entry among physicians,¹² most of the available health information technology solutions rely on existing electronic data generated outside of the clinical documentation process, primarily claims encounter, pharmacy utilization, and lab result data. Provider groups in California obtain these data from health plans, clinical laboratories, and internal financial systems. The data are sent in a variety of data formats and at variable, often lengthy, intervals, making it difficult to provide timely, relevant, and useful data to clinicians.

Recognition of these difficulties led to the second initiative, the California Clinical Data Project (CCDP), a program initiated in 2004 by the California HealthCare Foundation, a philanthropy dedicated to improving access to and quality of healthcare in California.¹³ The overall goal of the CCDP is to increase the use of information technology to improve the quality of chronic disease care in California. The project

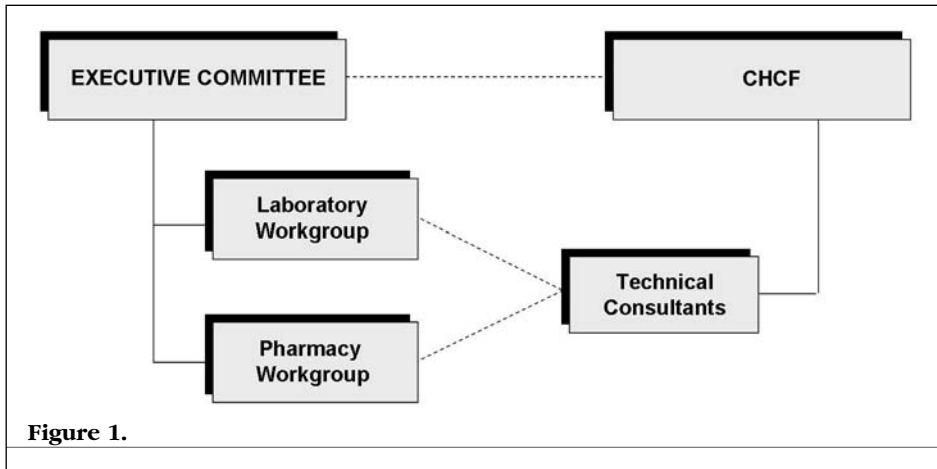


Figure 1.

Exchange, or CALINX,¹⁴ had defined standard formats for exchanging pharmacy claims and lab result data in 2000, but that program did not achieve widespread and consistent use of standards. Specifically, insufficient incentives, assistance, and oversight were provided for the technical implementation of the original CALINX standards, and stakeholders were focused on, and distracted by, Y2K preparedness. The CCDP sought to update these earlier

standards in a way that would maximize adoption throughout California.

CCDP Project Description

The project started in early 2004 with a planning phase and the creation of an organizational structure, as depicted in Figure 1. The structure itself established processes, incentives, and resources intended to promote the adoption of the CALINX standards.

Executive Committee. An executive committee was formed to represent key stakeholders, which included large health plans participating in California’s pay-for-performance program; representative provider organizations

<p>Provider Organizations</p> <ul style="list-style-type: none"> Alameda Health Consortium Brown & Toland Medical Group Buenaventura Medical Group California Association of Physician Groups Greater Newport Physicians HealthCare Partners Medical Group Hill Physicians Medical Group Kaiser Permanente LA County Dept. of Health Services Sharp Community Medical Group Sutter Health System <p>Employer Groups</p> <ul style="list-style-type: none"> Pacific Business Group on Health 	<p>Health Plans</p> <ul style="list-style-type: none"> AETNA Blue Cross of California Blue Shield of California Medi-Cal, California Department of Health Services CIGNA HealthCare of California Health Net PacificCare Health Systems <p>Laboratories</p> <ul style="list-style-type: none"> Laboratory Corporation of America (LabCorp) Quest Diagnostics/Unilab
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Table 1.

“After the standards were approved, the firm worked closely with stakeholder organizations to support the accurate implementation of the data formats and compliance with procedural rules for data exchange.”

began with an investigative phase to identify a set of common barriers to the effective use of information technology for quality improvement. This phase included extensive interviews with payers and providers; research on technical, business, and regulatory issues related to clinical information sharing; and input from national experts on quality improvement and information technology. Prominent among these barriers was the absence of common data formats and procedural rules for exchanging pharmacy claims and lab results data among health plans, clinical laboratories, and provider organizations. CHCF chose to address these infrastructure barriers as an initial step.

A previous project called the California Information

affected by pay-for-performance; representative payers and providers serving California’s underserved populations through Medicaid and community clinics; major commercial laboratories contracted by payer and provider organizations; and employers with a collective interest in improving quality of care.

The purpose of the executive committee was to provide oversight of the data specifications and rules of exchange; to ensure that appropriate technical staff within the stakeholder organizations participated in the development of the standards; and to provide a mechanism for the adoption of the standards by stakeholder organizations, particularly the incorporation of the standards in their normal business operations. A list of the specific organizations represented appears in Table 1.

Sponsoring organization. CHCF funded all aspects of this project, including the communication, travel, and facility costs; the technical consulting to the workgroups; and the development of software tools to facilitate implementation and use of the standards. CHCF also leveraged its credibility and track record as an “honest broker” in the California healthcare system to convene the large group of prominent stakeholders needed for success. Lastly, CHCF provided strategic leadership for the project, leveraging its relation-

ships and knowledge of the California payment and delivery systems.

Lab and pharmacy workgroups. These two workgroups specified the data formats and procedural rules for exchanging laboratory result and pharmacy claims data. The membership of the groups, which operated independently, consisted of data analysts and technical personnel from the stakeholder organizations on the executive committee. Participants were asked to commit to full active participation. All specifications were opened to public comment before being finalized by the workgroup.

The tasks of these workgroups were to analyze the requirements of data exchange standards for use in quality improvement activities; to develop standard data formats and data exchange policies that met these requirements and were feasible to adopt in the short run; and to support the implementation and testing of the standards within their organizations, culminating in the incorporation of the standards in their routine business practices. The groups met biweekly, usually via conference call.

Technical consultants. CHCF engaged a consulting firm to provide full-time technical leadership for the project. The consultants organized and facilitated biweekly meetings of the workgroups. They staffed the meetings, documented and presented relevant issues, solicited input from the varied participants, and mediated technical disagreements. The consultants also prepared the specifications drafts for review by the workgroups. After the standards were approved, the firm worked closely with stakeholder organizations to support the accurate implementation of the data formats and compliance with procedural rules for data exchange. The engagement of a professional firm with health data standards expertise offloaded documentation tasks from the volunteer members of the group, optimized the technical content of the standards, and helped members meet project timelines amidst the competing priorities of their day jobs.

Technical Development of the Standards

The CCDP benefited from the previous work of the CALINX project, which provided early versions of pharmacy utilization and lab result data standards. The pharmacy utilization data standard was a derivative of the NCPDP Telecommunication Standard v5.1 and specified the batch transmission of post-adjudicated claims records in a flat file, fixed-width format. The lab result data standard was based on the HL7 v2.3 ORU message type and specified the batch transmission of laboratory test results in the hierarchical structure of HL7 messages. Each of the working groups began with these existing standards and introduced changes and additions as required.

The work consisted of the following steps:

- A field-by-field discussion of the standards, specifically focused on the use case of data exchange for quality improvement purposes.

- Consideration of whether each field definition met the business requirements of the organizations that receive and use the data and whether the organizations could consistently and correctly provide the data. The group used a consensus resolution process to resolve discrepancies.
- Consensus approval of a complete draft specification by the workgroup, with the formal documentation of each member's assent or grounds for dissent.
- Distribution of the draft specification to a wider stakeholder audience in California for public comment, and consideration of all comments and incorporation of suggested changes as agreed by the workgroup.
- Final approval of the standards specifications and rules of exchange.

Several aspects of this process are noteworthy. First, the technical work was firmly based on the business needs of the participating organizations rather than on purely technical or academic considerations. Second, the ability of participating organizations to implement the resulting standard was elevated above the ideal requirements of any stakeholder. Third, the public comment period provided an opportunity for the larger stakeholder community to weigh in on the standards and review the products of the workgroups.

The completion of the seven steps required six months for the pharmacy utilization standard and nine months for the lab result standard. Additional time was required for the lab result standard because the data structures of the HL7 messaging format were less familiar to workgroup members and there was very little implementation experience with the previous CALINX lab standard.

Endorsements of the Standards

After approval by the working groups of the standard data formats and rules of exchange, the member organizations of the executive committee were asked to formally endorse the standards. These endorsements constituted a specific commitment to implement the data formats and abide by the rules of exchange.

The endorsement process required organizations to align their management decisions with the input of their workgroup representatives. This alignment helped to assure that adequate resources would be available to implement the standards within each organization. In addition, the process took advantage of the competitive commercial relationships among executive committee organizations to urge timely adoption of the standards.

The implementation and testing phase consisted of two steps. The first was the implementation and internal testing of the standard formats by health plans, pharmacy benefit management companies and laboratories responsible for sending data encoded in the CALINX standards. After that, test files were transmitted to the provider organizations and

health plans that would be receiving and processing data encoded in the CALINX standards.

It is not uncommon for standards development projects at this point to hand off specifications and implementation guidelines to the healthcare industry, hoping that independent entities will implement and use the standards correctly and consistently. In practice, however, even formal commitments and best-faith efforts to implement complex data exchange standards can fail to achieve correct and consistent technical implementations. Recognizing this challenge, the CCDP planned from the outset to assist and monitor organizations that were implementing the CALINX formats to ensure widespread conformity.

“Provider organizations and health plans are applying these data, through disease registries and data warehouses, to improve chronic disease care.”

This assistance took three forms. First, organizations could obtain extensive documentation of the standards at various levels, including detailed specifications, tutorials, FAQs, and sample data files. These resources were publicly available from the project Web site. Organizations also could use software tools to systematically verify the accurate formatting of CALINX data files and to facilitate the processing of data received in these files. These tools were developed specifically to meet the CALINX standards and provided free of charge to any interested party. Finally, organizations could get consulting time to help them understand the details of the CALINX data specifications and resolve errors encountered in the generation or processing of CALINX data files.

These tools and resources are available for review at www.calinxstandards.org. Collectively, they proved critical in achieving the goals of the project.

First, before using the software tools, most of the organizations generating CALINX files had residual errors in their test files of which they were unaware. The rigor of these tools helped identify these remaining errors, some of which occurred in only a few hundred records of multi-megabyte files.

Second, the tutorials, the sample data files and the data-conversion capabilities of the software tools helped many provider organizations make the transition to the updated standards. These resources helped receiving organizations fully understand the CALINX formats, assure that the formats would meet their business needs, and prepare their internal systems to process these formats. This assistance was particularly helpful for lab result data because the complex HL7-based structure of the format was unfamiliar to many data

recipients. For example, many provider organizations used the lab import tool to convert the nested and repeating structures of HL7 messages into equivalent flat-file representations for database loading, obviating the need for HL7 interface engines.

Lastly, the technical assistance and general oversight provided by CCDP enabled participating organizations to remain focused on timely and correct implementations despite competing priorities over a multi-month implementation period. The project staff frequently monitored progress, encouraged rigorous testing via the tools, provided technical information needed to resolve issues, and, in the few cases, escalated problems and delays to appropriate executives of the participating organization.

The implementation and testing phase required three months for the pharmacy claims standard and six months for the lab result standard. At the conclusion of these phases, the health plan and laboratory participants in the CCDP were able to generate pharmacy and lab files in a CALINX format that was verifiably correct.

Transition to Production Use

Before the work of the CCDP, many provider organizations, health plans, and labs in California were already routinely exchanging pharmacy claims and laboratory results data to support quality improvement programs.

These legacy data exchanges used a variety of nonstandard formats and supported ongoing business practices that could not be disrupted by the transition to uniform data standards. Also, the health plans and labs providing data preferred not to support both the CALINX standard and legacy data formats for a lengthy period of time while waiting for their numerous trading partners to make the transition to the new standards.

To meet this important practical need, the CCDP designated a discrete date to switch over to the new standards, at which time both senders and recipients of data agreed to begin using the CALINX standards. To some extent, the objective was comparable to switching a society from driving on the left side of the road to driving on the right side, a transition that is best achieved quickly and universally to avoid adverse events. The switchover process for the pharmacy and lab standards was planned separately.

For the pharmacy standard, the concept of having a transition at a single point in time worked relatively well. Because only six health plans were sending batch pharmacy claims data to provider organizations in 2004, and because health plans and provider organizations already had experience with a flat file data format similar to the new CALINX standard, a relatively rapid and orderly transition to the new standard was possible.

In the end, the complete transition to the pharmacy standard took place over a period of three months, rather than the one month that had been planned. Although a

three-month time frame may have been disastrous for a left-to-right switch in roadway travel, it created relatively minor inconveniences for the health plans and provider organizations participating in the CCDP; the biggest disruption was primarily a temporary interruption in the transmission of pharmacy data by one or two of the health plans.

For the lab standard, the transition required considerably more time because the HL7 standard was much less familiar to the organizations receiving lab result data. These organizations required a longer time to develop capability with the technical specifications, during which time they requested parallel data feeds encoded in both the CALINX format and their legacy format. Also, there is greater fragmentation among the providers of lab result data in California than among the health plans that provider pharmacy claims data—more than 100 laboratories perform outpatient testing for provider organizations. Although two large commercial laboratories (Quest Diagnostics and LabCorp) perform approximately 60 percent of the ambulatory testing for the insured non-Kaiser-Permanente population in California, dozens of hospital, clinic and specialty labs perform the remaining 40 percent.

There is limited aggregation of the state's smaller labs at a managerial and technology level, with the exception of a few hospital chains. The result was that few of the labs overall could be represented on the executive committee of the CCDP, which precluded many of them from making commitments to the CALINX lab standard at an early point in the process. Also, because most of the smaller labs operate independently, it meant that the CCDP had to foster their awareness and implementation of the CALINX standard on a gradual basis. As a result, most of the smaller labs in California have not yet implemented the CALINX lab standard.

Results

By December 2004, the CCDP defined a set of consensus-based standards and achieved adoption of these standards by six large health plans, two major clinical laboratories, and numerous provider organizations in California. Today, these organizations use the CALINX standards to routinely exchange data on more than 6 million patients, facilitating data integration and analysis.

Provider organizations and health plans are applying these data, through disease registries and data warehouses, to improve chronic disease care. For example, a provider of data integration services recently reported that its medical group clients are requesting database queries to identify patients in need of chronic care interventions, such as diabetics in need of their annual lipid studies or HgB A1c levels, specifically to meet pay-for-performance measures.¹⁵ This suggests that the use of information technology, incentivized by pay-for-performance and facilitated by data standards, is resulting in improved care for chronically ill

patients. Until EHR systems are widely adopted, healthcare organizations seeking to improve care will continue to depend on the effective integration and analysis of pharmacy claims and lab result data.

Despite the level of standardization achieved through the CCDP to date, the effective use of the CALINX standards cannot be sustained without continued focus on and support for the standards process. Recognizing this, the California HealthCare Foundation has created certain support resources and is helping to implement a long-term support infrastructure. This plan includes the ongoing availability of the software tools to prevent variations in the standard implementations, as well as an annual update of the standards to ensure that they continue to meet stakeholders' needs as business practices change.

The goals of the California Clinical Data Project extend beyond the establishment of data exchange standards to include the following.

- Application of the CALINX standards to patient populations beyond the commercially insured HMO patients addressed by the California pay-for-performance program. These populations include those covered by state Medicaid plans and commercial preferred provider organizations.
- Acceleration of the frequency with which pharmacy claims and laboratory result data are transmitted to disease registries and other disease management systems. Over time, the goal is to move from the monthly data feeds that currently occur to weekly, daily, or near real-time feeds.
- Expanded use of electronic clinical data at the point of care so that real-time clinical decision support is more widely available to improve chronic disease care. This goal will entail the concurrent promotion of disease registries with point-of-care interfaces and EHR systems with population-based disease management features.

Lessons Learned

The experience of the CCDP yielded a number of lessons that may be useful to others engaged in similar projects.

It is beneficial for standards development projects that involve numerous and diverse stakeholders to be sponsored by an organization that is financially and politically independent of the stakeholders, and has credibility as an effective change agent and a proponent of system-wide improvement. Ideally, the sponsoring organization can provide both independent funding and technical leadership, which best enables it to balance the needs of various stakeholders to benefit the entire system.

If correct implementation and widespread adoption are the ultimate goals of a standards development project, then these goals should be factored into every aspect of the project from its inception. Leveraged properly, competitive and commercial dynamics in a healthcare market can accelerate the adoption of data-exchange standards. In the case

of the CCDP, the endorsement and implementation of the standards was probably accelerated by the composition of the executive committee, which included competitors and commercial partners, such as health plans, provider groups, and laboratories. Although all of these organizations now benefit individually through improved efficiencies from widespread adoption of the CALINX standards, such benefits did not accrue until a critical mass had implemented the standards. The competitive and commercial dynamics among these organizations and the visibility of their project support likely accelerated the rate of organizational adoption of the new standards.

To achieve widespread support for and adoption of interoperability standards, efforts should be made to leverage existing data standards, such as those developed by NCPDP and HL7. For organizations to use these standards effectively in business practice, however, more detailed requirements with fewer options must be specified. It is possible for a less formal, consensus-based process to achieve these specifications if a sufficiently impartial and knowledgeable third party mediates the process and if adequate transparency and opportunity for public comment is provided.

It is best to ground the development of clinical data standards in the specific business practices and use cases of the stakeholders rather than in abstract technical or informatics considerations. This approach provides clear guidance for design decisions and maximizes the chance that the results will be useful to and adopted by the wider number of stakeholders. At the same time, technical rigor cannot be overlooked; it is important to produce logical, internally consistent, and well-documented standard specifications. The quality of the technical content affects both the credibility of the project and the ability of stakeholders to implement the standards correctly and expediently.

Mechanisms to objectively verify the compliance of stakeholders' standards implementations are critical. At a minimum, software tools should be available that enable stakeholders to internally test their implementations because even the best-intentioned efforts result in errors in the absence of systematic verification tools. Ideally, verification of standards compliance by an independent third party should be made available.

Although it is possible for the development and adoption of clinical data standards to occur relatively quickly with appropriate planning and execution, sponsors and participants should be aware that the process will take longer than

expected. Even in the case of the CCDP, where similar standards had earlier been defined and partially implemented, widespread adoption still required 12 months for the pharmacy claims standard and more than 18 months for the lab result standard. Sponsors and participants should plan to be involved for a sustained period of time and allocate resources accordingly.

Transition time is required for a community of interoperating organizations to change their business practices to use new standards, and this process also must be managed. A coordinated switch to a new standard over a short period of time is the most efficient way to achieve the transition, but it may not always be possible. In the latter case, stakeholders must be prepared to support new and legacy processes concurrently during an interim period.

Many of these lessons are relevant to efforts currently under way to establish clinical data standards at the national level. Specifically, sponsoring organizations, such as the Health Information Technology Standards Panel,¹⁶ should recognize that adequate funding and competent technical leadership on their part, independent of the participating stakeholders, are important to effective standardization. Additionally, all of the stakeholders should recognize that the process will take a long time—on the scale of five to 10 years—and they should anticipate long-term commitments and plan realistic transition strategies.

It is encouraging that the federal government is putting important drivers of health IT standards adoption into place, such as mechanisms for verifying standards-compliant implementations^{17,18} and commercial incentives for implementing EHRs that conform to standards.¹⁹ As the CCDP has demonstrated on a much smaller scale, appropriate organizational structures, technical oversight, market-driven incentives, and implementation support can achieve the widespread use of clinical data standards and the realization of their benefits.

About the Authors

Walter Sujansky, MD, PhD, is president of Sujansky & Associates, LLC. His firm specializes in clinical information system design and has collaborated with the California HealthCare Foundation on several information technology projects.

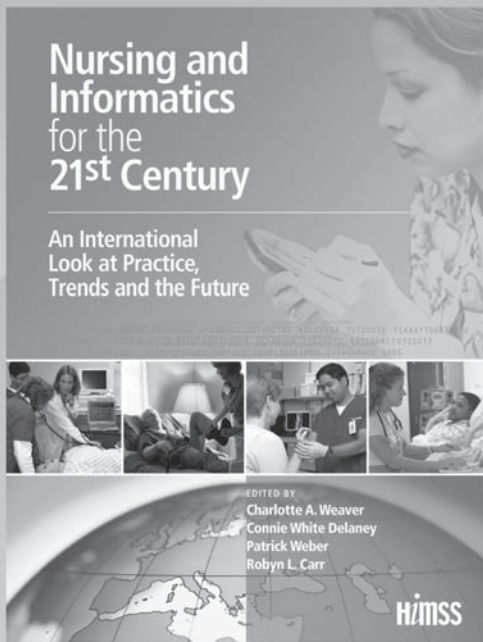
Sophia Chang, MD, MPH, is the director of chronic disease care at the California HealthCare Foundation. She is leading several initiatives to improve clinical care through information technology and clinical process re-engineering.

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