Characterizing the Ideal Clinical Office System for Nephrology

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Clinical information technology (IT) systems that support nephrology-specific content can facilitate the coordinated, progressive, and comprehensive care of all patients with renal disease including those with each stage of chronic kidney disease (CKD). The ideal clinical IT system should have flexible features to meet the needs of individualized practice patterns, yet also have tools to enhance continuity, measure performance, and deliver decision support features that assist the nephrologist in providing optimal care for the CKD patient. This article provides insight into the complexities of engaging in the process of technology adoption, including selection, integration, and implementation while emphasizing the utility of using a continuous quality improvement paradigm to identify and achieve positive results from the adoption and integration of a clinical IT system into outpatient clinical practice of nephrology.

Index Words: Health information technology; Nephrology electronic health record; Chronic kidney disease; Electronic health record; Nephrology

In the outpatient setting, health care providers in nephrology are faced with providing care for a large population of chronic kidney disease (CKD) patients with complex medical needs. Recent studies support the need for coordinated outpatient care between primary care providers and nephrologists even at the early stages of CKD. Strategies to treat CKD patients to delay the progression of kidney disease and to improve outcomes at the start of dialysis are known, but they are being underused. Clinical information technology (IT) systems that support nephrology-specific content can facilitate the coordinated, progressive, and comprehensive care of CKD patients. The ideal clinical IT system should have flexible features to meet the needs of the individual practice and also have tools to enhance continuity and measure performance in the care of CKD patients. The purpose of this article is to provide context for nephrology practices to consider when deciding to adopt a technology initiative while providing insight into the complex features of the implementation of such systems.

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The Nephrology Professional Environment

Clinical IT systems will be a necessary and integral part of nephrology care given the scope of the CKD population, the complexity of CKD care, and the limited number of nephrologists. The Centers for Disease Control has adopted CKD as a "public health condition." Schoolwerth and colleagues[1] have documented the 4 conditions that must exist for the Centers for Disease Control to identify a public health condition. These criteria require the disorder to have a large societal burden, an unfair societal distribution, known preventive actions that could reduce the disease burden, and a lack of deployed strategies to affect the societal burden.[1] In the United States, nearly 20 million people have CKD, approximately 11% of the total US population.[1,2] The cost of care for CKD exceeds $25 billion dollars annually, and patients with predialysis CKD access the health care system 2.4 times more frequently than the stage 5 CKD population.[1,3] The United States Renal Data System projects that by the year 2015 there will be 712,290 patients with end-stage renal disease (stage 5 CKD).[4] In addition, the relative risk of stage 5 CKD requiring dialysis or transplantation therapy disproportionately affects certain ethnic groups as described in Figure 1.[5] Clearly, the large number of people with CKD represents a large societal burden, and CKD places a disproportionate disease burden on certain population subgroups.

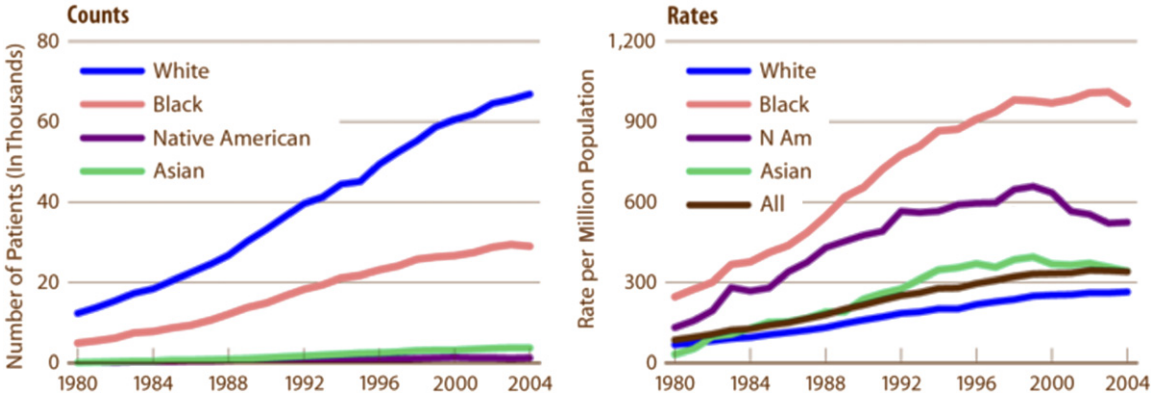

Figure 1. Incident stage 5 CKD patients. Rates adjusted for age and gender (USRDS 2006 Annual Data Report). CKD, chronic kidney disease.

Recent data suggest that early interventions and preventive therapies may postpone the need for renal replacement therapy.[1,2] Early detection of problems such as mineral metabolism abnormalities and anemia associated with CKD may improve patient outcomes and delay the start of dialysis.[2,3] Early recognition of nontraditional risk factors for cardiovascular disease may also improve outcomes in CKD.[6] There is evidence that these CKD issues are currently underdiagnosed and undertreated such that new strategies to detect and treat CKD complications may improve patient outcomes.[1-3]

Most nephrology practices today continue to function as small businesses with an average size of 6 physicians per practice.[7] It is anticipated that the rate of new nephrologists entering private practice from fellowships each year will not meet the demand placed on practices to accommodate the care of more CKD patients.[8,9] The average nephrologist currently cares for about 70 stage 5 CKD patients. By the year 2015, it is projected that each provider will be responsible for over 100 stage 5 CKD patients. The use of clinical guidelines for patient care, the use of nonphysician providers for routine care, and data reporting to participate in the practice measurement process are all expected to increase as the demands of nephrology practice evolve. The expanding CKD population, the limited number of nephrologists, and an increasing demand for clinical practice measurement will drive the need to adopt health IT systems that will provide tools to help meet these patient care and nephrology practice needs.

The scope and scale of the problem of caring for CKD is large. Every resource that allows early identification of the CKD patient and early recognition of unique CKD treatment issues should be mobilized to impact outcomes for these patients. The large CKD patient population, the complexity of care at various stages of CKD, and the importance of clinical and laboratory data in this care make CKD an ideal clinical setting for the utilization of the advanced technology of a nephrology electronic health record (nEHR).

Selecting a clinical system is a process that can be very difficult for practices. Many of the systems commercially available today have recognized the barriers to adoption within the marketplace and have aimed to find ways to assist practices in their decision making and implementation. Such systems as Fresenius Medical Care's CKD Solutions–nEHR (Waltham, MA; www.CKDSolutions-nEHR.com), Sage Health's Intergy (Tampa, FL; www.sagehealth.com), and Allscripts (Chicago, IL; www.allscripts.com) purport to have specific integrations for nephrology and the unique features of nephrology practice. The Renal Physicians Association (www.renalmd.org) has put together in their member site a series of resources that nephrology practices can use that will assist in the process of finding a system that has features specific to the practice of nephrology and renal care.

The Quality of Care Connection

Health information technology (HIT) is recognized as a means to support practices in improving the quality of care delivered by the adoption of best practice standards and the use of disease specific guidelines. The concept of a continuous quality improvement model for evolving a better, more cost-effective, and stable clinical care environment hinges on the ability to look at information across a patient population and measure performance on standard metrics that are understood by all parties involved in the health care process. HIT systems including electronic health records (EHRs), personal health records, and clinical decision support systems must be used to collect this complex clinical information. The American Health Information Community Quality Workgroup envisions that performance measurement in health care is tightly integrated with patient safety and patient care quality.[10,11] Timely reporting and organizational level performance analysis will be used to evaluate national quality care performance and, ultimately, will drive performance expectations through payment.[11] Despite this recognized need, the adoption of IT solutions has been slow because of the high cost of IT systems and the complexity of the work required to implement such systems. The AHIC Quality Workgroup documents an EHR adoption rate among outpatient providers of only 15% to 18%.[10,11] Patient-care information, which can only be obtained through health IT solutions, will not only benefit health care consumers directly but will also provide valuable population-based data to support beneficial health care spending and policy.[11] Given the desire to stimulate adoption of HIT systems, several catalysts have been developed to encourage a more rapid acquisition of HIT systems. These catalysts have been specifically initiated to address the cost barriers to adoption while recognizing that the functional and user barriers are being overcome by advances in the systems and technology platforms that deliver these systems.

Catalyzing Health IT Adoption

Several catalyst efforts have been initiated to stimulate the adoption of advanced HIT systems by health providers. The first is a federal safe harbor for technology adoption that was implemented in October 2006. This safe harbor allows large health organizations that qualify as permitted donors to provide up to an 85% subsidy for certain software licenses and tools for smaller health care providers.[12] This safe harbor program is in effect through 2013 and has rules that will allow smaller practices to implement advanced IT systems. Each system under this safe harbor must meet certain requirements that include standard features of interoperability and e-prescribing. Hardware, staff, and storage of information are not included in the safe harbor, but the intent is to promote system deployment that has been delayed because of the high cost of system licenses and implementation.

The second early catalyst to adoption of HIT systems is a program within the Tax Relief and Health Care Act of 2006, which provides a 1.5% bonus payment for those practices who report clinical data and outcomes under the Physician Quality Reporting Initiative.[13,14] This act is the first true federal pay-for-performance program that is not part of a demonstration project. It is expected that such programs will evolve to include not just reporting but also the implementation of both process and outcome performance measurements that ultimately will be tied to the methods and levels of reimbursement for physician practices for clinical care.[14]

Other catalytic events include the adoption of certain clinical standards for nomenclature that have become an important element in developing ideal clinical systems. HIT clinical systems must ensure quality data collection, integration, and output. To ensure quality data in HIT clinical systems, data standards must be adopted and used. Such standards include the Health Level 7 (HL7), Systematized Nomenclature of Medicine Clinical Terms, and Logical Observation Identifiers Names and Codes (LOINC) standards that identify how systems will interact and interface with each other and determine certain standard data specifications for clinically relevant elements. The HL7 standard is the most widely accepted data format standard in health care information systems. The prevalent use of HL7 standards allows

relatively easy electronic exchange of health care data between IT systems.[15] Systemized Nomenclature of Medicine Clinical Terms is widely accepted as a standardized set of clinical terms.[16] The LOINC standard is a means by which laboratory data can be shared across various labs and analytic platforms for use in reporting and data analysis. The LOINC database can identify not only laboratory data but also vital signs, echocardiograms, and other clinical data. LOINC is used by many large commercial laboratories including Quest and LabCorp. This is a universal database that can facilitate incorporation of this type of laboratory and clinical data directly into an EHR.[16] LOINC is maintained by a nonprofit medical research organization, the Regenstrief Institute.[17]

The HIT Integration Pyramid for Medical Practices

It is important for clinic practices to recognize the complexity and commitment to process change required to fully implement the features of an advanced HIT system. Often the final integrated functionality of an advanced HIT system is clearly identified, but the incremental integration required to achieve this goal is not appreciated. The implementation of a clinical IT solution must proceed through a series of steps that will gradually integrate the IT tools into the workflow of clinical medicine. This integration process provides an opportunity for a practice to enhance clinical care delivery through more efficient workflow and the use of clinical decision support systems. The HIT Integration Pyramid (Fig 2) provides a visual depiction of the pathway of activities that a practice may expect to encounter when implementing an advanced HIT clinical system. Although the depiction is not designed specifically for nephrology, it provides a means of outlining the work that a practice must undertake if they strongly desire a successful integration of an IT system into the practice.

When selecting an HIT clinical system, a nephrology practice must first identify and define practice goals and needs for a nephrology EHR. The articulation of these goals will identify HIT system features that are priorities. Some basic questions to ask about a prospective HIT system might include the following: (1) Is there automated data exchange? (2) Is there system scalability to an expanding practice size? (3) Will there be a need for in-practice IT expertise and support? and (4) How does the system fit into the clinical practice environment? An ideal HIT clinical system should offer network infrastructure and use within the usual clinical practice space. It should be available for use in the patient room, at the nursing desk, at the check-in desk, and wherever the care provider is located. The network infrastructure should support a variety of delivery platforms from fixed to portable to handheld devices and should have the ability to interact in real time with the clinical data from any place that care is

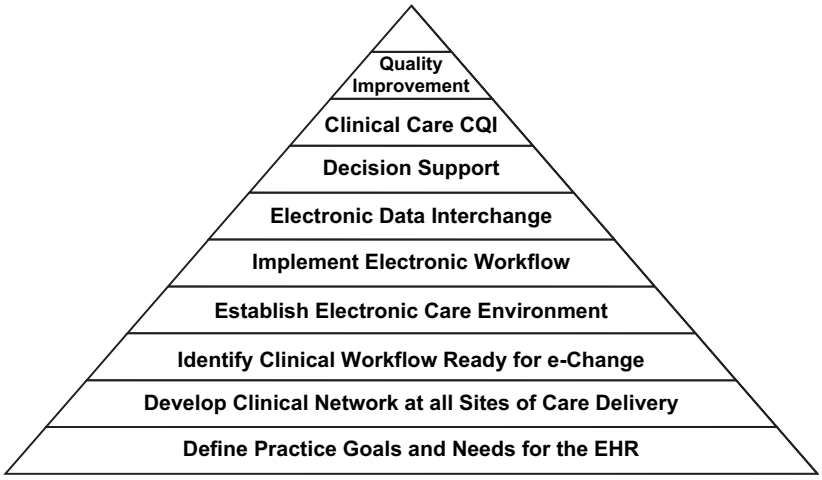

Figure 2. The Technology Integration Pyramid for Medical Practices. (Adapted from CKD Solutions–nEHR, A closer look at CKD solutions. Available at http://www.ckdsolutions-nehr.com/html/closerlook.html. Accessed July 19, 2007). CQI, continuous quality improvement; EHR, electronic health record.

to be delivered. The HIT clinical system should be redundant, reliable, and scalable.

Within the context of the development of a clinical network, the practice must make a sentinel decision about whether the system will be delivered from within the practice environment or over the Internet. A Web-based system will differ from a locally hosted model in a variety of ways including capital investment required, sophistication of the internal practice network security model, redundancy of data, scalability of systems, and disaster recovery processes. For many practices without extensive networking expertise, the delivery of the clinical system through a model of "Software as a Service" over the Internet is preferred because of the simplicity and lack of additional personnel required to support and evolve such a system.

Clinical workflow patterns are unique to each practice, but understanding this workflow is important in identifying those components that will benefit from the change that an advanced HIT clinical system can bring to documentation, decision support, and best practice integration. To fully engage the clinical system, a practice must accept that mere installation of a software system is not enough to ensure that a system will improve productivity; enhance analysis; and make changes that will benefit patient quality of care, productivity of providers, or efficient functioning of the practice.

As an initial step to clarify existing workflow, practices should consider developing a clinical process library. A clinical process library analyzes the practice workflow process including scheduling, gathering patient intake information, the patient check-in process, identification of historic clinical events, clinical encounters with providers, enrollment of patients into appropriate-structured care programs based on their diagnoses and demographics; patient education tools; and billing capture. These are examples of some independent processes that occur in the clinical environment of a practice that should be enhanced by the tools of the HIT clinical system.

One example of a clinical workflow process that can be greatly impacted by a clinical IT solution is the review of laboratory information. A practice must understand the current non-IT laboratory result review process to determine if an IT solution will enhance and improve this daily workflow process. The clinical IT system should offer efficiency and improvement in the laboratory review process because it can automatically present a diagnostic test for review; allow review in the context of the patient's clinical information and previous laboratory results; document a provider response; and disseminate this response and any necessary orders to others including nursing staff, other providers, and the patient.

The more fully a practice makes a transition into the electronic environment the more useful the clinical IT tools and data will be. Clinical information can enter a system in 3 ways: as discrete data elements, as objects of text, or as an image of physically represented data. An IT system will store all clinically relevant data in an electronic format through some combination these methods. Discrete data that can be stored in a relational database offer the best ability to analyze groups of patients and maintain standardization of the nomenclature of clinical information. This type of data typically comes from point-of-care documentation sources commonly known as templates. Other discrete data sources in the world of CKD care include laboratory, pharmacy, dialysis, and hospital data.

The clinical IT solution should allow the documentation of prose or text. Textual data allow the documentation of an individual patient history or care provider assessment without complete reliance on templates or boiler plate information. It allows for the "story" of the patient to be captured and the unique features of an individual patient/provider interaction to be documented. The ability of advanced systems to be flexible enough to capture both normalized, structured discrete data and prose-based text data is essential to having a system that will evolve as the practice of nephrology evolves.

Clinical systems should allow data acquisition through the ability to accept an image of data that is delivered to the practice in a physical representation and must be converted or scanned into an electronic document. This image should have the ability to be routed through the system and "tagged" with appropriate placeholders that will allow the image

to traverse through the system workflow mechanisms for provider review and documentation and, ultimately, be correctly placed in the appropriate patient electronic record. The automated workflow of imaged data should include the capacity for the image to be reviewed and annotated by a care provider. Imaged data cannot be normalized so it does have more limited reporting and research capacity when compared with discrete data elements and even textual clinical information.

The additional data coming from third parties is most efficiently integrated into a system through the use of an electronic data interchange (EDI) between the source of the data and the clinical system. EDI is a real example of high-level interoperability between 2 systems. This level of the HIT Integration Pyramid creates a novel approach to how providers receive new information about their patients and what they can do with that information. It is the first of the levels that provides something that cannot be provided in a nonelectronic environment. The acquisition of information from a related third party in nephrology is typically a laboratory, hospital, or dialysis facility. This information is transported to and from the nEHR in a method that does not require any human data entry and provides a means for routing the information to the appropriate person for review or the specific electronic chart for permanent repositing. EDI's have become progressively more common over the past decade, and many follow the standard of HL7 for exchange of clinical health information. In an EDI, the clinical data are received in a highly structured format through a secure method of transmission. In the most elegant of these interfaces, there is error checking between systems to ensure that the data sent are the data received and the exchange is occurring in real time. Other EDI processes are performed in a batch environment on a near real-time basis but still clearly enhance the timeliness of the delivery of information when compared with traditional printing, faxing, or mailing. The use of an EDI most easily integrates decision support software because it offers the opportunity for clinical systems to analyze information when it is electronically delivered and provide a targeted action based on the electronic analysis as defined by the provider.

Decision support can be implemented in a number of ways, and it represents another feature of IT clinical systems that enhance existing workflow in a way that cannot be duplicated in the nonelectronic environment. The concept of making the provider a more reliable cognitive clinician when analyzing clinical information is 1 goal of the decision support tools that an nEHR can bring to the practice of CKD care. Decision support in the patient care setting provides a set of tools and communication options for the clinician such that the presentation of a patient with a specific condition will trigger a specific set of actions to be considered based on current clinical recommendations. Some examples would be the notification that a CKD patient at stage 4 should have education about dialysis options and vascular access preparation or that a patient with stage 3 CKD and anemia should undergo evaluation for enrollment into an anemia-management program. But decision support extends beyond reminders that make the clinician a "smarter" provider to include also the ability to analyze practice patterns. System analysis of provider attention to timely laboratory data review or highlighting the work in a queue of documents to review and respond to are all part of improving the timeliness of care and the ability of the provider to prioritize the work to be accomplished. This also represents system-driven decision support, which can impact productivity of providers and their efficient workflow.

Decision support is also deeply integrated into how a practice determines which individuals will perform specific functions within the practice. The system can provide coordination of medication refills. It can help patients access the scheduling or triage personnel. These system issues go well beyond the traditional concept of an electronic medical record and extend into the communication of clinical information within the practice environment as well as to referring or consulting providers that share responsibilities for the patient.

Clinical care Continuous Quality Improvement represents a high-level concept in integrating ideal clinical systems. The concept of

driving improvements in the method and the delivery of care with continuous observation of clinical performance and measurement allows providers to recognize that the delivery of care is dynamic and will change over time. The ideal clinical system should become a part of the Continuous Quality Improvement process and help a practice evolve its implementation of best clinical practices. The IT system must have the capacity to capture normalized information and report on the conditions of care for the providers of the practice and their patients.

Finally, the drive toward pay for performance by CMS and other payers is a recognition that the cost of health care remains high and the systems for understanding how to make providers follow best practice standards is complex. Integrating the functional components identified in the pyramid will allow a practice to be in a position to measure, report, and adjust the clinical workflow in the practice. This performance and measurement process is one of the ultimate objectives driving the adoption of HIT in clinical practice. Once integrated to this level, the practice can then engage in the ongoing process improvement methods to persistently streamline and improve the means by which patients receive care. Ultimately, the integration of these methods will cross over practice boundaries and extend directly to the patient. The systems will be both practice specific and patient specific but will integrate across all venues of care for an individual patient.

Nephrology-Specific Functions

Specific functionality for a clinical system in nephrology includes a broad series of features that are specific to the management of patients with renal disease. Nephrology as a specialty is dominated by the collection and analysis of critical laboratory data that is crucial to the decision-making process used by providers caring for the various stages of CKD. Functional elements that have nephrology specificity include those elements that capture, document, and communicate the unique clinical targets in the care of patient with renal disease. Figure 3 provides a list of the primary elements of a nephrology-specific EHR.

Areas of specific note include the tools that are part of the structured, stage-oriented delivery of CKD care. These decision support tools should highlight the conditions understood as core components of care for the CKD patient. These core components include the educational aspects of therapy for stage 5 CKD, vascular access preparation, dialysis options education, recognition and treatment of anemia, bone and mineral management, and

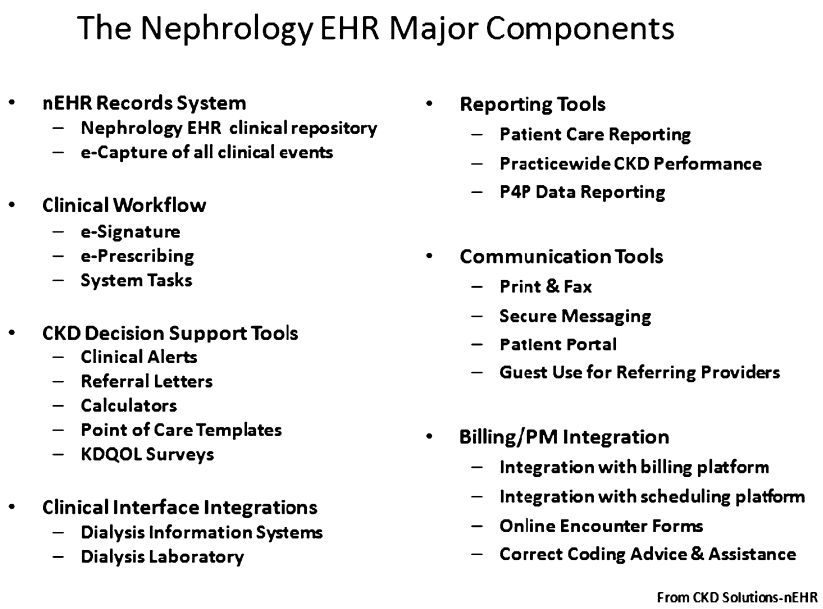

Figure 3. Components of nEHR. Adapted from CKD Solutions-nEHR, which is a joint project between Fresenius Medical Care, Waltham, MA, and HIT Services Group, Nashville, TN. nEHR, nephrology electronic health record; EHR, electronic health record; CKD, chronic kidney disease; P4P, pay for performance; PM, practice management.

unique nutritional issues in advancing CKD. Other nEHR features should support the ability to monitor and optimize care for diabetes, lipid disorders, hypertension, and cardiovascular disease as well as prompt the use of preventive measures such as hepatitis B, Pneumovax, and influenza vaccinations. These elements represent a set of core clinical imperatives as outlined in the National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines.[18] Each represents an area of clinical decision making on the part of the provider during the course of treatment for a CKD patient.

Ideal clinical IT systems should provide a communication link between the patient, all care providers, and ancillary-care services. It should encourage patient compliance with medications, appointments, and educational efforts. Systems should integrate with other entities that also provide care to the patient and coordinate that care with tools that avoid redundant interactions between the patient and the local health system. The incorporation of clinical tools to communicate with referring providers may highlight these core elements and underscore who has responsibility for particular components of care. Integration with pharmacy systems should give a record of an individual's full prescription history for incorporating prescribing from all providers.

Integration of Systems

Nephrology care is delivered from multiple clinical sites including the local hospital, the nephrology clinic, and the dialysis unit. Integration of these multiple sites of care is critical to realizing the full advantage of a clinical system. This integration requires that the systems have a data interchange that shares common information elements. An example of an important integration of data is the nephrology practice oversight of patient care in the dialysis unit. Although, the dialysis facility must note rounding activities the clinical documentation and billing of the services occurs from the nephrology practice. The ideal nEHR system should provide a means of sharing the information that must be obtained by the dialysis facility for compliance with the conditions of coverage while maintaining adequate documentation that dialysis patient oversight care is being provided under the guidance of the monthly capitation payment model for the nephrology practice. Documentation of dialysis rounding activities should be maintained in the nephrology practice record but should contain elements from the dialysis clinical information system such as core dialysis laboratories, dialysis prescription, and intradialytic medications. The most advanced systems would also have the ability to respond to alerts from the dialysis clinical system and initiate orders that flow from 1 clinical system to the other in a secure manner. This level of interoperability represents an advanced degree of system integration that highlights the utility of advanced HIT clinical systems.

Contracting and the Business Model

The ideal clinical system must support a business model that respects a number of tenets that benefit the medical practice. Contracting for a system should provide a combination of licensing, implementation, training, maintenance/upgrade path, and a business associate arrangement between the practice and software provider. The contract should delineate service levels that are acceptable to the practice and response times that are realistic for the vendor. The unique nature of the health care enterprise should ensure that the clinical system and vendor provide adequate security and controls that meet the standards of the Health Insurance Portability and Accountability Act.[19] Practices should look for methods that encourage the vendor to reasonably provide data interchange interfaces with other systems at known pricing expectations. Furthermore, if the practice were to change to an alternative system, then the vendor should be required to provide the practice clinical data in a machine-readable format for the next vendor to incorporate. Although most systems ultimately will be certified to be able to meet certain system and functional requirements, the current certification process under the guidance of Certification Commission for Healthcare Information Technology is progressing with a slow adoption process, changing rules for certification and a substantial expense to software vendors.[20]

Summary

Clinical IT systems offer valuable tools in insuring quality care across an outpatient population. Such systems are necessary for current quality initiative programs and for the collection of clinical data that will ultimately support the best practice guidelines for CKD care. Government, industry, and payer resources now have aligned incentives to support the outpatient medical community in adopting clinical IT systems. These incentives for adoption come at a time when outpatient clinical IT systems are becoming more flexible, portable, and affordable. It is now an opportune time because of the pressure in practice to begin to measure and document the practices performance for a nephrology clinic to consider adoption of an IT system that will support quality care for CKD patients in the outpatient setting.

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