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ORIGINAL ARTICLE

Use of Informatics and Information Technologies in the Clinical Research Enterprise Within US Academic Medical Centers: Progress and Challenges From 2005 to 2007

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■ ABSTRACT

Background: Data on the state of information systems infrastructures used in the clinical research enterprise of academic medical centers are limited and mostly anecdotal. What has been published is slowly beginning to make important distinctions, such as clinical trials as a specialized form of clinical research and between "Informatics" in an academic setting from health care information technology. However, this field continues to undergo fundamental changes, accelerated by the National Institutes of Health's creation of Clinical and Translational Science Awards to build a new "home" for biomedical research.

Methods: We surveyed all Clinical Research Forum member institutions regarding their enterprise infrastructure and use of information systems in support of clinical research. The questions in this on-line study expanded on one first done in 2005. Of the 52 sites invited, 19 (37%) responded. We analyzed the responses and also made matched comparisons for those organizations that participated in both surveys.

Results: Although there continues to be conceptual agreement on information system elements for the clinical research enterprise, no single institution achieved the ideal, a similar result to the 2005 survey. Indeed, little progress was made over the past 2 years at most locations other than in information technology planning, strategy, and governance.

Conclusions: There is increased recognition of the importance of information systems infrastructure and expertise for biomedical research, but the needs are accelerating much faster than institutions can build or pay for. A much greater realization of and innovative solution for this growing chasm is urgently required.

Key Words: biomedical research, academic medical center, information systems, research support, informatics, computerized medical records systems

■ INTRODUCTION

Starting as early as 1999, organizations such as the American Medical Association, Association of Academic Medical Colleges, and the Clinical Research Forum have been analyzing the clinical research operations within their member institutions.[1] Initially, the work was done via opinion surveys that showed general complacency with the current situation. However, these surveys did identify problems with the availability of research data and low levels of process discipline and efficiency, especially in comparison to similar industry-sponsored clinical trials. As the National Institutes of Health (NIH) budget nearly doubled over the period of 2000–2005, other studies began to look more carefully at the increasing funding inefficiencies that were beginning to delay study completion or medical product approvals.[2]

The NIH Roadmap was created to reengineer the collective clinical research enterprise and communicate a new strategy that would require process and efficiency changes across broad groups of stakeholders.[3] Information technology was a core component of this strategy and the expected improvements. Several new studies again (one by this team) looked more closely at the clinical research infrastructure within academic medical centers (AMCs) and especially at the information systems that were installed.[4,5] These publications were increasingly used to highlight this specialized area of research informatics and technology that was now in synchrony with unfolding NIH initiatives. Overall, the findings

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indicated that IT, to support clinical research, was poorly structured, governed, and funded, with limited leadership around a future vision or strategy for development and sustainability over time.

The launch of the Clinical and Translational Science Awards (CTSA) by the NIH in late 2005 elevated the urgency of this situation, presenting it as an opportunity for arguably the best AMCs in the country to solve. Dr Elias Zerhouni challenged CTSAs to create a "home" for clinical research and to solve the inefficiencies and funding problems that were being increasingly identified. A critical component, again, was information technology, not just within the organization but as the tool for data sharing, research data analysis, and research collaboration. Along with the heightened need for IT, a new professional disciple is emerging, known as biomedical informatics. Although no widespread agreement exists yet on a precise definition, this evolving discipline incorporates a number of research and information technology areas such as information systems, computer science, medical informatics, application development, systems biology, data and process modeling, standards, and health care information exchange.

In light of these challenges, members of the IT Roundtable, a subcommittee of the Clinical Research Forum, voted to again survey its members about the use of information technology. The goals for this survey were to identify the current status, learn about the impact of the aforementioned challenges on progress and decision making, and determine trends based on the initial 2005 survey results.

■ METHODS

A small group of IT Roundtable members volunteered to spearhead this effort, including some of the original people who worked on the 2005 study. This group started with the 2005 survey instrument and solicited input from the entire IT Roundtable membership for suggested additions and improvements. Challenges identified from 2005 prompted these recommendations:

- Reduce the heavy reliance on one-on-one dialogue for data gathering.
- Expand the response format beyond a dichotomous yes/no choice.
- Reword and update some questions that would be essentially repeated for 2007.
- Add new questions based on evolving information systems interests and activities.

To address the first issue, the team decided to gather information via an on-line survey tool, ultimately choosing the Web-based tool from Advanced Survey. All questions used in the 2005 survey were reviewed by the work team and updated, with an expanded interval data response format created for 2007 that, in most cases, could reflect a degree of progress for each item rather than just whether something had been accomplished or not. This approach was selected to better understand where organizations were in the journey of implementing systems and infrastructure and was received well by the 2007 respondents.

Pilot testing proved that the revised 2007 survey was too long and difficult for any 1 person to complete. After careful review, the number of questions was decreased. The second draft was validated on-line across 5 institutions. The final questionnaire had 55 questions, categorized as follows:

- Demographics (10 questions)
- Research Data Sharing (2 questions)
- Administrative Applications (9 questions)
- IT Infrastructure/Services (7 questions)
- Clinical Study Applications (8 questions)
- Research Repositories (6 questions)
- Collaboration/Connectivity (5 questions)
- Governance/Vision/Planning/Budget (8 questions)

The 2007 survey took approximately 45 to 60 minutes to complete once on-line entry was ready and the responses to the questions were determined. Because of the decentralized nature of many organizations' research facilities and services, collecting the responses, especially at the new level of granularity being asked, was particularly challenging. Often, the survey respondent had to interview and collect information from individuals working in Research, Information Systems, and IT and Administration, which typically took weeks. The additional work placed on recipients to complete the survey reduced our response rate significantly from the approach used during 2005 (ie, originally one-on-one phone interviews). This year, we sent out invitations to all 52 Clinical Research Forum members and received 19 usable responses (37% for 2007 vs 78% for 2005). Although our sample size was smaller, the makeup of those respondents generally reflected the overall membership, considering size, funding level, geographic location, and the like, and is therefore reflective of the broader group. The possibility of ascertainment bias is not addressed in this report because of the confidential nature of the responses.

The survey was available on-line for 2 months to accommodate the time and effort to gather the data. Once the survey was officially closed, data was compiled and manipulated with on-line tools, then MS Excel, and finally SAS/JMP for analysis of both the responses and nonresponses.

■ RESULTS

As in the 2005 survey, the logical structure of the 2007 survey built on a conceptual model used by the IT Roundtable to illustrate common components required to conduct clinical research. Such conceptual models were illustrated in the earlier publication by Turisco et al.[5] and have also been described in much greater detail by others more recently for health care information systems in general.[6] Various other institutions, national and international organizations, and trade associations have created similar frameworks, but there still is no single approach that is generally accepted as a standard. Results for the 2007 survey are presented in the next sections, followed by specific matched comparisons between 2005 and 2007 where 14 institutions replied to both surveys (although not necessarily the same person responded in each case). Most respondents (71%) in the comparison analysis between 2005 and 2007 received a CTSA award or planning grant in 2006 or 2007.

Demographics

The technical point of contact that provided information from the Clinical Research Forum member institutions typically (63.2%) had the term *director* in their job title in 1 form or another. Most of them (52.6%) answered all of the 2007 questions themselves based on their own knowledge and experience of the local research informatics enterprise, whereas some others (36.8%) did indicate that they needed to seek information from additional people. Ostensibly, all organizations do the same thing, that is, to support clinical research activities through the use of technology and informatics. Making process or architectural comparisons, however, between the textual descriptions that were provided to describe their internal environments were next to impossible, as we had anticipated. Even when we asked for specific numeric answers to questions, there was often no precise and complete response. For example, when asked for the number of full-time equivalent (FTE) personnel that worked in research informatics, the average response was 25.6. However, the range between the lowest and the highest number of FTEs was 195, making the average less helpful as a general statistic to characterize our target population. Ten locations of the 17 that responded to this question qualified their numeric answer depending on how FTEs were accounted for, 6 saying that it was difficult to estimate or that they were merely approximating. One respondent even said that it was, for all practical purposes, impossible to determine a true answer for their institution.

When asked if there was an NIH/National Center for Research Resources (NCRR)–funded General Clinical Research Center located at the institution, 84.2% responded that they had at least one. For reference, this survey was completed in early 2007. The relevance of this point and its respective survey question was to monitor the speed of conversion of General Clinical Research Center sites to CTSAs; only 12 of which had actually been awarded at the time this survey was completed. Table 1 illustrates the strong interest of a majority of the responding member institutions to pursue this award.

Administrative Applications

There is unanimous agreement among survey respondents that software applications are needed to facilitate the application and approval process for research studies and to manage the various other administrative and reporting obligations that are required. For on-line grant proposal development, 11 (57.9%) of 19 had system implementations in progress, with 26.3% of locations having fully implemented a major installation. Similarly 52.6% of responding sites had fully implemented postaward grants management software, although 5 (26.3%) were just planning this, and 2 (10.5%) had no current plan in place yet to do so.

As expected, where there were financial or regulatory requirements, there were more examples of fully implemented administrative applications or ones that were in progress. Such was also the case for software that did: electronic institutional review board (IRB) applications (85.2% either fully implemented or in progress), budgeting and resource tracking (57.9%), effort reporting (68.4%), research billing (57.9%), and even providing research investigator portals (52.6%).

IT Infrastructure and Services

A common challenge for people providing informatics support for clinical research is having both limited funding and funding that comes in a disaggregated manner with specific obligations or limitations for how the money is used. Thus, research informaticians must rely on the central health care information technology (HIT) group to provide needed infrastructure, such as network or Internet connectivity, and possibly technical support for investigators. This is often the case where research investigators are also the physician providing patient

TABLE 1. Clinical and Translational Science Award (CTSA) Application Status

Response	*No. Responses*	*%**
Applied for a CTSA planning grant in 2006	3	15.8
Applied for the full CTSA grant in 2006	3	15.8
Did not apply in 2006	1	5.3
Applied for the full CTSA grant in 2007	11	57.9
Did not apply in 2007	1	5.3

*Multiple responses were possible.

care or where study managers are also nurses providing care in addition to having data collection responsibilities. Thus, it was no surprise that desktop support and helpdesk services, whether for Windows or Mac operating systems, generally came from some combination of research and HIT resources (79.0%), whereas only 15.8% had this need met exclusively by HIT.

Conversely, and as an important distinction between "information technology" and "informatics" services for clinical research, most custom programming and database development (63.2%) came from research-specific funded resources versus from a central HIT group. Unfortunately, there were even investigators at 15.8% of responding sites where no HIT or informatics support was available at all. These studies had to find whatever support they could, often through department discretionary funds that paid for informal but necessary assistance to conduct research activities. Not surprisingly, such studies are often completed with Excel spreadsheets on laptop computers with little or no security or backup services in place, which would not be the case if more professional informatics or IT resources were used.

Another sharp contrast between HIT and dedicated research informatics resources was that, in most cases (52.6% of the time), computing facilities and research-specific servers ran somewhere outside a central data center. It was more common for research hardware to be operated in a much less formal space, including modified closets or under desks. This disparity is partly due to the fundamentally different missions of an HIT group versus a research informatics group. The former focuses on complex high-cost patient care systems that are highly available, typically through standardized hardware configurations that change very little on a day-to-day basis. Research data collection and information management demand that things change frequently and run on a wide array of hardware that may have been specified by a nontechnical investigator as part of a grant application submitted a year before start-up with little way of knowing where that device would eventually be housed. Finally, regarding statistical software, 63.2% is acquired, operated, and/or supported by dedicated research informatics resources rather than central HIT.

Clinical Study Applications

Once a research study is approved, another type of information system is used to actually conduct it. These are generally known as clinical trial management systems (CTMS), which were in place at a majority of the AMCs surveyed. Responses to questions in this section of the survey were very similar to each other. Enrollment tracking capability through a CTMS of some kind was available at 57.9% of the sites. Similarly, on-line protocol development and submission systems were in progress at 42.1% of sites; informed consent forms could be collected electronically now (21.1%), or this capability was in progress (36.8%); and the capability to collect electronic case report forms was in progress at 47.4% of locations.

In contrast, but as expected because of both safety and regulatory requirements, the capability to electronically report on adverse events or serious adverse events was collectively at 73.6% for being either in place already or in progress.

Although many of the questions already discussed had been asked in both the 2005 and 2007 surveys, the following question was new. The Clinical Research Forum's IT Roundtable, made up of individuals working at AMCs and people working in the associated vendor community, has seen more interest and technical experimentation around using electronic medical record (EMR) systems (now becoming more generally referred to nationally as electronic health record systems [EHRs]) to directly support clinical research. This is a complicated topic beyond the scope of this report, but the response to the survey question that was asked helped clarify where the state of the art is for both suppliers and users of EMR/EHR systems. As Table 2 illustrates, no institution has an EMR/EHR capable of conducting all necessary aspects of clinical research. However, the data also suggest that many locations are working on this problem, as the spectrum of responses to the question was built to illustrate if this were the case. A similar response pattern was seen for questions regarding research information archives and research knowledge bases, although a few of the more advanced AMCs (21.1% and 10.5%, respectively, for these 2 areas) have already completed and are using such systems.

Research Funding and Budgets

Based on quantitative and qualitative input to questions asked concerning research informatics funding, the best estimate for this survey was that the average AMC spent $2.1 million per year, with a range between $100,000 and

TABLE 2. Electronic Medical Record (EMR) System Integration With Clinical Research Data Management

Response	*No. Responses*	*%**
No integration	0	0.0
Discussion or planning underway	12	63.2
Research data can be pulled from EMR	10	52.6
Data fields in EMR exist or can be created to capture research data directly	4	21.1
Research data can be pushed to the EMR	1	5.3
Some 2-way interoperability exists	1	5.3
All aspects of research studies can be fully conducted within the EMR	0	0.0

*Multiple responses were possible.

TABLE 3. Estimated Change in Research Informatics Budget From 2006 to 2007

Response	*No. Responses*	*%*
Will be lower than that in 2006	0	0.0
Will be essentially the same as that in 2006	4	21.0
Will increase by up to 3% above that in 2006	1	5.3
Will increase by 3.1%-10% above that in 2006	3	15.8
Will increase by more than 10% above that in 2006	6	31.6
Not sure	2	10.5
No response	3	15.8
Total responses	19	100.0

$6 million. This statistic was challenging to estimate with any accuracy because of the following:

- Financial information was not available easily or at all.
- Confusion exists on what expenses to allocate for research.
- Research activities are not being methodically accounted for outside central IT.
- Institutional commitments to research were changing because of CTSAs.

Most locations did, however, respond to the questions regarding what the expected change in their funding would be for the upcoming year. The greatest response (Table 3) was that overall spending would increase by more than 10% at 31.6% of the sites.

■ SPECIFIC COMPARISON BETWEEN 2005 AND 2007 SURVEY RESULTS

Fourteen organizations completed both the 2005 and the 2007 surveys. This subset was used as the basis for comparison to understand progress, trends, and new challenges.

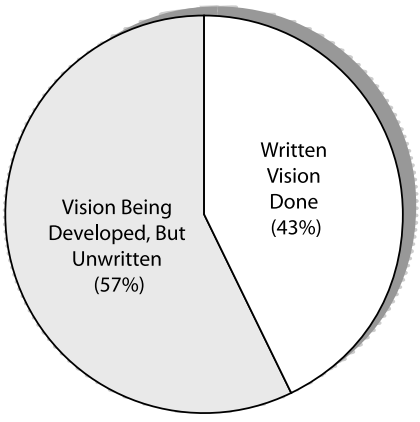

FIGURE 1. Extent of a clinical research informatics vision or strategy existed in 2007.

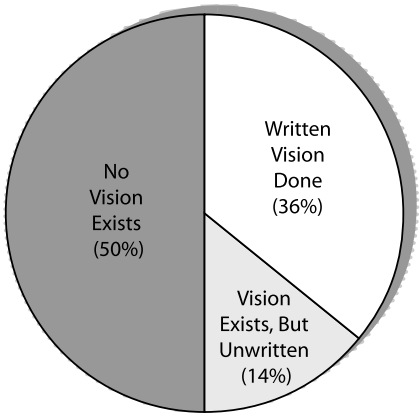

FIGURE 2. Extent of a clinical research informatics vision or strategy existed in 2005.

The comparison was focused on the top priority areas from the first survey that included governance, strategy, key clinical research applications, data integration with health care delivery systems, and future priorities. The 2005 survey results, as originally reported, were recalculated for comparison purposes to include only those organizations that also responded in 2007 to be valid.

Strategy and Governance

The 2007 results identified a dramatic increase in attention to developing and documenting an information technology strategy for clinical research. Forty-three percent of 2007 respondents have a written vision and strategy for IT, and the remaining 57% are currently developing one (Fig. 1). Of those organizations with a written vision and strategy, 83% of them are CTSA applicants or awardees (full award or planning grant). In comparison, half of the organizations did not have a vision or strategy for clinical research IT in 2005. Of the remaining 50%, 14% had a vision, but it was not formally documented, and only 36% had a written vision and strategy (Fig. 2). It is important to

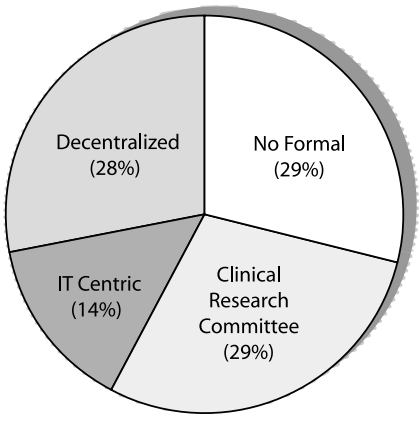

FIGURE 3. Governance structures in 2005 for clinical research informatics and health care information technology (IT).

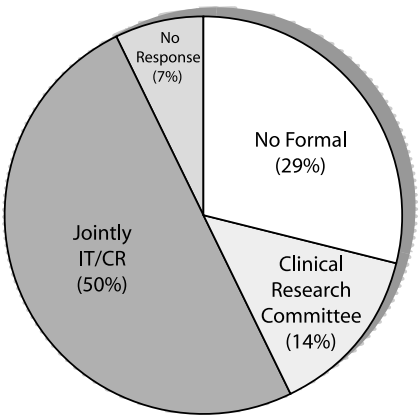

FIGURE 4. Governance structures in 2007 for clinical research informatics and health care information technology (IT). CR, clinical research.

note that several organizations cited that the CTSA application was the impetus for developing and documenting a written vision and strategy.

Similarly, the trend in governance structures for clinical research and IT has been toward a more collaborative and centralized approach between Research and Information Services. In 2005, more than 50% of the respondents had either no formal governance for IT (29%) or a decentralized one (28%). The centralized governance approaches were either IT-centric (14%) or Clinical Research–centric (29%) with cross-representation (Fig. 3). The trend identified by the 2007 study is to jointly govern IT, with 50% of the organizations now following this approach. Fourteen percent have a centralized governance structure led by Clinical Research, and almost 30% still do not have a formal approach of any type (Fig. 4).

This progress in terms of building a vision and strategy for IT supported by a jointly sponsored governance body represents important first steps toward implementing applications and infrastructure that span the local research enterprise and could connect with others.

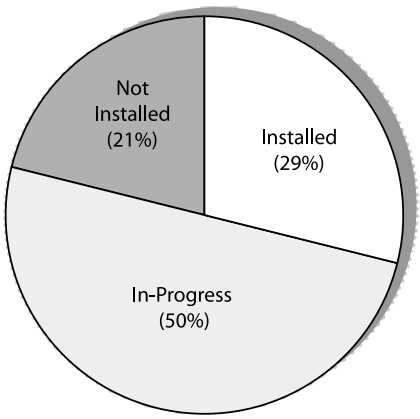

FIGURE 5. Institutional review board application implementation in 2005.

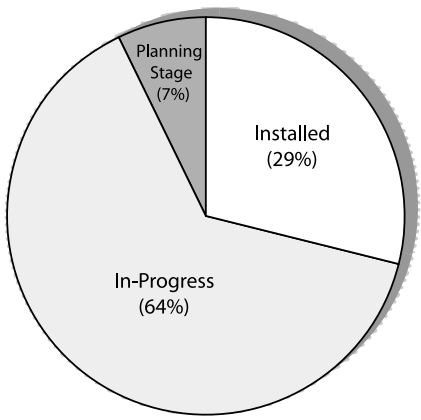

FIGURE 6. Institutional review board application implementation in 2007.

Applications and Integration

The focus of the application comparison was the number 1 priority from the 2005 survey—implementing an IRB application. At that time, only 29% of the organizations had installed it, with 50% in progress and 21% not started (Fig. 5). Unfortunately, 2 years later, it is still a high priority, but there is very little progress. In 2007, still only 29% have implemented an IRB electronic information system. Sixty-four percent are in progress, and the remaining 7% are now in the planning stages (Fig. 6). Survey comments and follow-up discussions with the respondents helped to identify the reasons for this lack of progress. Clearly, implementing an IRB application is a piece of a much larger and complicated process and workflow redesign project involving many departments and researchers. As such, it can take years to be fully implemented and is an area where collaboration and information sharing among members remain an extremely important topic.

An interesting applications-specific finding from this comparison was the apparent backward progress for some of the applications and organizations. Upon further

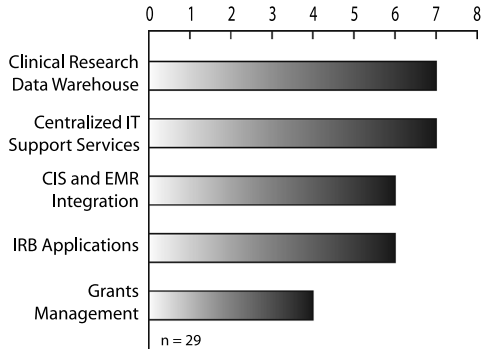

FIGURE 7. Top priorities for the future of clinical research informatics in 2005. CIS, computer information systems; EMR, electronic medical records; IRB, institutional review board; IT, information technology.

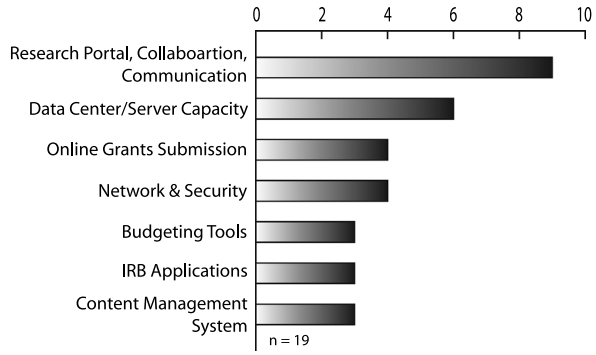

FIGURE 8. Top priorities for the future of clinical research informatics in 2007. IRB, institutional review board.

investigation, there were several reasons why an application was paradoxically identified as being "installed" in 2005 and yet was "in progress" in 2007. These included moving from homegrown systems to a commercial product, switching systems to be able to meet new requirements such as submitting grants on line, and changing applications to participate in cross-organization research programs such as caBIG.

Another high-priority initiative for many organizations is to integrate clinical research and patient care data, both in delivery of care and to advance research. The 2005 survey identified only a small number of organizations (7%) that currently share data. From the 2007 survey, the responses provided 2 important findings. First, there has been progress by organizations on integrating clinical research and patient-based clinical data, with the response rate increasing to 14%. The added granularity in responses with the 2007 survey also identified several approaches where organizations have made progress in extracting or displaying data and embedding clinical research functionality in hospital systems that demonstrate real progress but did not meet the definition of integration used in the survey.

Top Priorities for the Future

In this final analysis step, the decision was made to include all of the responses from the 2005 survey against all those from the 2007 findings (Figs. 7 and 8) to determine overall trends for future projects. What the comparison uncovered was a significant shift toward IT solutions that support collaboration, communications, and data sharing, such as full-function researcher portals to provide wider access and finer administrative control to research data, such as through an honest broker process. Administrative workflow continues to be important in general concerning grant applications for funding, scientific review, and IRB approval. Finally, there is an increased desire for centralized and upgraded IT infrastructure products and services with particular interest in a central data center, more reliable and secure network access, and a huge need for data storage and associated services such as backup and recovery.

■ DISCUSSION

Our investigation indicates that some progress has been made by AMCs over the past 2 years to help develop and support data and information management systems for clinical research. Prior Federal programs and funding, such as the Human Subject Research Enhancement Awards (HSREA S07 awards), have specifically targeted improving such education and oversight for increased patient protection during study participation at research institutions, including database and information systems usage. The relative differential, however, between existing systems and the growing bodies of biomedical science has expanded even faster. It could thus be argued that we have lost ground, relatively speaking, by not keeping pace. However, our data, along with a careful review of the qualitative statements made by respondents, nevertheless, were upbeat. This suggests a cautious optimism that, although there is no dramatic success to report over the past 2 years, an inflexion point indicating fundamental improvement and progress for clinical research informatics is now unfolding.

There is, in most cases, no single organizational unit that provides clinical research informatics and IT support to investigators in even the best AMCs. We can therefore reliably estimate that this situation is even worse for other institutions where research is conducted. The current state of clinical research informatics is, in general, a reflection and manifestation of research funding over past decades, an evolutionary amalgamation of highly individualized but typically underfunded seedling efforts that are rarely expected to meet longer-term generalized institutional needs. Researchers are funded because they are going to do things differently than what is currently being done, an essential element of research. They use whatever resources they can find or obtain through grant applications and other funding efforts, often making technology choices independently or based on what has been used and funded in the past, whether it is the best way to use hardware or software to solve increasingly complex information management problems. Investigators are not necessarily responsible for creating this state of affairs. Responsibility is shared by informaticians who have not provided, or not been asked to provide, leadership to secure more well-developed clinical research infrastructures.

Some AMCs are consistently pioneering new ground in this area. The primary challenge is to begin to think about how to develop an enduring research infrastructure with necessary technology and informatics resources to meet current and future needs. The survey questions concerning

vision and mission statements explored this dimension. There is certainly progress being made in this area, which we view as a fundamental antecedent to future progress and the ability to articulate an inspirational yet realistic vision. The secondary challenge is to build, buy, or adopt and adapt necessary elements of an overall clinical research information system to meet operational needs of investigational processes. Many of the other questions in this survey explored the status along these dimensions, again, with progress being evident, although more AMCs were challenged at this phase of progress than could claim accomplishments. A third challenge we see is to integrate all of the information and data management systems once they are in place, so they operate seamlessly—sharing data when and where appropriate (ie, at the often cited "point of care"). A fourth challenge is to begin to leverage such an information system to interoperate with other institutions—first, locally, then regionally, across the State, and eventually, nationally or internationally with other locations where scientific partnerships and collaborations enable new levels of biomedical exploration that could not be accomplished any other way. We believe that this road map, as just described, is consistent with what Dr Zerhouni hopes the CTSA program will do to help facilitate exchange of data, knowledge, and resources among NIH-funded organizations and to create the required "home" for clinical research in the future that leverages biomedical informatics as an essential element for success.

Our survey also highlighted an interesting confusion between the information technology group, usually governed and funded under a Chief Information Officer as institutional HIT resources, and people working in clinical research informatics who, in many cases, are not part of the HIT group. Both groups involve programmers, analysts, database developers, technicians, and systems engineers and administrators and thus can easily be seen as being redundant resources. The 2 groups have fundamentally different missions, however, as mentioned earlier. It could be an easy mistake to assume that one of these groups could do the work of the other. However, when those responsibilities are mixed, usually asking the IT group to take on responsibilities for clinical research support, this may be problematic for both groups, ultimately being inefficient and ineffective at meeting research investigators' needs. Ideally, these 2 groups would coexist and share resources as appropriate (ie, be interdependent). Several surveyed sites gave illustrations where this was the case, or was being changed, so that the informatics needs of research can leverage the significant technical depth and professionalism that central IT resources have already been built to achieve. The central IT organization has, in most cases, been carefully engineered, and funded, to meet patient care and institutional information systems needs, whereas research resources have not been, but rather is a "problem-rich" environment that can benefit from such a strong association with IT. Although all AMCs arguably do the same thing when it comes to research, no two do it similarly enough to be directly comparable or to be able to easily share what they have learned with another location. Although there is no single "best practice" that has been authoritatively qualified, rough comparisons such as the one performed by this survey help each institution to see where they are relative to other organizations who may be achieving similar results, although by very different means.

Based on results from questions asked concerning technical experiments to integrate EMR/HER systems with clinical research processes, we anticipate that efforts along these lines will continue to progress, including being led by some of the more visionary EMR/EHR and CTMS commercial providers who will begin to offer integration capabilities and professional services as differentiating features to increase the value that they can contribute to customers.

Somewhat surprisingly, a number of surveyed institutions indicated that even the application process for a CTSA had caused their senior leadership to begin a dialogue to rethink how they were managing research and how to view those investments differently, relative to capital and operational budgeting priorities. Based on ongoing semiannual meetings of the Clinical Research Forum's IT Roundtable, those locations that have received a CTSA already have been working at an increased pace and across a broader spectrum of biological science than has ever been done previously despite best efforts. How continued awards from the NIH will benefit others, whether a CTSA is already located at the institution, is to be seen. The future does not look promising right now. National Center for Research Resources will fund no more than 60 total CTSA sites over the upcoming 3 years. Budget cuts are already happening for the first 2 rounds of "winners." An upcoming administration change in Washington may call for tougher scrutiny of the overall CTSA game plan if greater returns on this investment are not seen beginning in 2008. Researchers have recognized this squeeze, and their opinions have been voiced loudly regarding the potential adverse impact to biomedical research.[7,8]

For people working in clinical research informatics, the challenges are certainly increasing, but so are the opportunities. For those individuals who have advanced degrees and enough years of technical, research, and managerial skills, they are beginning to see new positions being created in leadership roles that offer another level of advancement to their careers. For others, the sometimes midcareer effort required to pursue an advanced certification or degree in biomedical informatics or computer science looks much more appealing and worth the time and

effort it would take. However, keeping up with information across these various intellectual realms can be challenging, with conferences to attend nearly every month on 1 topic or another or professional associations to stay involved with and keep up with technology or colleagues' activities. Despite the benefits of technology being used by technical professionals, the travel schedule of most people in this field has increased. Thus, the energy level required to succeed in an informatics role in the future has increased dramatically.

Recommendations for the Future

The landscape of AMCs involved with clinical research informatics in the future may inevitably become polarized into the "haves" and "have nots," especially being the case for industry-sponsored clinical trials.[9,10] Those institutions that receive a CTSA may be inspired to rethink their clinical research enterprise in fundamental ways to their benefit, despite what the NIH does in the future. Others seem to have a wait-and-see posture. Additionally, CTSA sites may qualify for new major NIH or NCRR funding opportunities where other institutions cannot apply, thus obtaining a sustainable differential advantage for future growth. However, even for research organizations in general, whether AMCs, or where a CTSA award will never exist, a high-level commitment may be made with significant new funding because of the strategic fit with overall organizational direction. Either way, clinical investigators should benefit from these improvements and expanded infrastructure.

With such improvements, investigators may also begin to expect that enterprise-grade IT and informatics services are provided as a matter of course for research studies. Informatics groups need to be positioned with the necessary resources and infrastructure to meet demands, including such things as the following:

- Seamless integration of protocol application, review, and approval with IRBs;
- CTMS to conduct research, integrated with EHRs;
- High availability for research information systems;
- The latest security measures, on the network and for an investigator's device(s);
- Full backup and recovery services that do not interfere with performance;
- Disaster recovery services for both data and applications;
- Web-enabled data collection across many types of wired and wireless devices;
- Interoperability of study data with any institutional or patient care system;
- Standards-based information models, regardless of the uniqueness desired;
- Long-term storage, archival, and warehousing of study data;
- "Secondary uses" of study and EHR data beyond what was originally intended while also meeting privacy obligations to research participants per terms agreed to in informed consents.[11]

Many members of the Clinical Research Forum have already made innovative steps in the directions bulleted above. All but one of the current CTSA awardees are members of the Forum. Many of these institutional thought leaders have already created new Departments of Biomedical Informatics or other such units to augment their current resources and extend into new ventures (eg, Oregon Health and Science University, University of Pittsburgh, Vanderbilt University, Columbia University Health Sciences, Partners Healthcare, Johns Hopkins University, Ohio State University, University of Texas Health Science Center at Houston, Stanford University, University of Washington (in Seattle), University of Wisconsin at Madison (CTSA winning site), and University of Rochester). Likewise, exceptional commitments and ongoing efforts have been put forth by Clinical Research Forum Information Technology (IT) Roundtable member companies to modify their products for the future of research and to help AMCs to overcome institutional gaps in system interoperability. Thanks to Siemens, Velos, Click Commerce, Computer Sciences Corporation, Huron Consulting, and StudyManager for their collaboration. The IT Roundtable affords a unique opportunity for this kind of academic-commercial dialogue.

This survey heightened our team's awareness of the importance to enable and then require broader use from NIH-funded informatics initiatives, such as the caBIG collaboration for cancer research[12] or the Biomedical Informatics Research Network network for imaging research. We applaud the NCRR's efforts and additional R01 grant funding to provide incentives for institutions to do just that.[13] Finally, we have seen evidence that the most sophisticated organizations are now extending their reach to act more as data coordinating centers for multicenter clinical trials—a potentially profitable endeavor. This includes expanding clinical research informatics responsibilities for outsourcing arrangements, with contract research organizations and with offshore international affiliations in partnership with growing informatics organizations around the world (eg, Singapore, India, United Kingdom, Germany, Japan, China).[14]

If the survey is repeated in 2009, it would be useful to further explore the unexpected variability received on some questions. There may have been confusion on the wording or the underlying concepts or terminology, some of which are known to also be changing through time. Similarly, the diversity of responses may be due

more to a lack of good organizational understanding for how research systems and efforts are governed, especially given the differences in accounting for these activities by either the IT or research informatics resources. Finally, further investigation around the ongoing convergence of research and health care IT systems is warranted, including testing of new concepts being proposed for comprehensive research infrastructures of the future.[15]

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■ REFERENCES

1. Breaking the Scientific Bottleneck—Clinical Research: A National Call to Action. Report of the AAMC and AMA. November 1999. Available at: http://www.umassmed.edu/uploadedfiles/NationalCalltoAction.pdf. Accessed November 18, 2007.
2. Sung NA, Crowley WF, Genel M, et al. Central challenges facing the national clinical research enterprise. *JAMA*. 2003;10:1278–1287.
3. Zerhouni E. The NIH roadmap. *Science*. 2003;302:63–72.
4. Mallon WT, Bunton SA. Characteristics of Research Centers and Institutes at U.S. Medical Schools and Universities. AAMC. June 2005.
5. Turisco F, Keogh D, Stubbs C, et al. Current status of integrating information technologies into the clinical research enterprise within US academic health centers: strategic value and opportunities for investment. *J Investig Med*. 2005;8:425–433.
6. eHealth Initiative Blueprint: Building Consensus for Common Actions. 2007 Oct. Available at: http://www.ehealthinitiative.org/blueprint/eHiBlueprint-BuildingConsensusForCommonAction.pdf. Accessed October 30, 2007.
7. Nathan DG, Schechter AN. NIH support for basic and clinical research: biomedical researcher angst in 2006. *JAMA*. 2007;22:2656–2658.
8. Mitka M. Scientists warn NIH funding squeeze hampering biomedical research. *JAMA*. 2007;17:1867–1868.
9. Rubin E, Lazar D, Gaich N, et al. The clinical trials landscape: limitations, strengths, and promise. October 23, 2007. Available at: http://www.aahcdc.org/policy/reddot/AAHC_Limitations_Strengths_and_Promise.pdf. Accessed November 20, 2007.
10. The Food and Drug Administration's Oversight of Clinical Trials. September 2007. DHHS OIG Report OEI-01-06-00160.
11. Secondary Uses and Re-Uses of Healthcare Data: Taxonomy for Policy Formulation and Planning. September 12, 2007. Available at: http://www.amia.org/inside/initiatives/healthdata/2007/amiataxonomyncvhs.pdf. Accessed November 25, 2007.
12. The caBIG Pilot Phase Report: 2003–2007. National Cancer Institute. November 2007.
13. Sharing Data and Tools: Federation using the BIRN and caBIG Infrastructures. NIH R01 Grant PAR-07-426, 2007 Aug 3. Available at: http://grants.nih.gov/grants/guide/pa-files/PAR-07–426.html. Accessed November 25, 2007.
14. Wartman SA. The multinational academic health center. Association of Academic Health Centers. Available at: http://www.aahcdc.org/policy/reddot/AAHC_Multinational_AHCenter.pdf. Accessed November 15, 2007.
15. Research Rewired* (Connected Thinking): Merging Care and Research Information to Improve Knowledge Discovery. PricewaterhouseCoopers' Health Research Institute. 2008. Available at: http://www.pwc.com/extweb/pwcpublications.nsf/docid/519641BEDF3C7F78852573FA00199288. Accessed March 10, 2008.