Summit Report

Reimbursement for Clinical Information Technologies (CIT)

Duke University
February 2001

Medical Technology Leadership Forum

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Duke University
The Fuqua School *of* Business

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MTLF Summit Report

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Duke University
February 2001

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Introduction

The Medical Technology Leadership Forum (MTLF) convened a Technology Summit at Duke University in February 2001. The Summit focused on the policy issues facing Clinical Information Technology (CIT), defined as a system of technology that allows a remote interface to collect and transmit data between a patient and provider.

The Summit's CIT focus brought together two themes that MTLF has explored in the previous sessions. Since its founding in 1996, MTLF has studied Evidence of Value—the challenge of designing scientific standards of evidence to show value in the fast paced and technologically diverse field of medical technology innovation. MTLF also identified information technology (IT) as one of the emerging medical technology issues at a Stanford University Forum in 1999. The following year, our Indiana University Forum opened the door to the public policy implications of the information revolution on therapeutics and diagnostics. (A list of MTLF publications and ordering information can be found at the back of this Report.) CIT is a burgeoning subset of information technology developments in health, and it is challenged to provide evidence of value to all stakeholders.

MTLF members represent the broad spectrum of the medical technology community, including clinicians, inventors, manufacturers, providers and patients. The Duke Summit brought together experts from multiple perspectives, including government officials, to dialogue with MTLF members in an exploration of these CIT policy issues. The Summit was organized and moderated by Dan Mendelson of the Health Strategies Consultancy and Professor Kevin Schulman of Duke University's Fuqua School of Business. (See Appendix A for the Duke Summit agenda.)

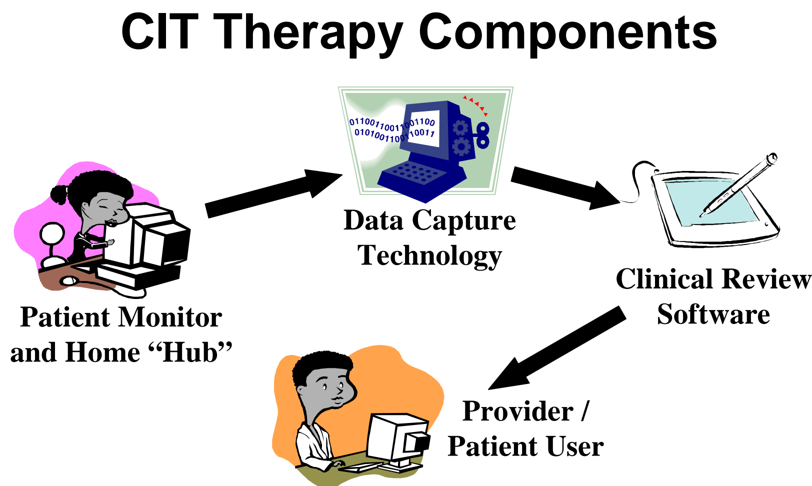
This document captures the salient points of discussion at the Summit. Part I provides perspectives on CIT including examples of CIT technologies, analysis of CIT's impact on the practice of medicine and patient care, and a look at how commercial payers view CIT. Part II discusses the challenges that CIT faces in the Medicare program and considers a range of public policy options.

The promise of CIT is clear. CIT allows for information to be electronically collected, stored, analyzed and transmitted to the physician and, as appropriate, to the patient. CIT can lead to economic efficiencies, faster and more accurate responses to data, and improved outcomes for patients. We need a better understanding of concerns in the marketplace and the policy community to ensure that CIT developers provide appropriate evidence of value and that inappropriate barriers to adoption and diffusion do not limit CIT's benefits for patients.

Part I - Perspectives on CIT

A. *Examples of CIT Technologies*

CIT technologies have been developed for a range of high cost, chronic conditions, such as diabetes and congestive heart failure (CHF). They can be invasive or non-invasive technologies. CIT can collect objective data, such as heart rhythms, or subjective data, such as patient responses to closed-ended wellness questions ("do you feel well today?"). CIT can transfer and/or synthesize data electronically, and the data can be fixed or manipulated. Our focus is on patient-provider interaction, not provider-provider consultations. CIT may replace face-to-face data collection or can add to it.



To date, the CIT market has focused on a subset of costly chronic conditions and can be characterized by dividing technologies into the conditions they address, as follows:

- **Chronic heart failure (CHF)** is a chronic, debilitating condition that affects millions of Americans, primarily in the Medicare age range. Monitoring technology provides a new way to manage CHF to prevent emergency room visits and frequent hospitalizations. Some technologies are non-invasive, and have the capacity to collect data on such measures as pulse, ECG, blood pressure and weight on a daily basis. They can use wireless or telephonic data transfer for analysis by health care practitioners. Some technologies can also ask the patient questions, such as "did you take your medicine today?" allowing trained

personnel to follow up with patients who meet certain risk profiles. In addition, there are implantable monitoring devices for CHF that serve as stand alone implants for the specific diagnosis, or as adjuncts to implanted cardioverter-defibrillators (ICDs) that can collect patient data chronically, providing a more comprehensive picture of the patient's condition.

- ▷ **Diabetes management** is basically information management. For many years patients have used home blood glucose measurement devices to monitor their condition. However, CIT offers sophisticated blood glucose monitors that have increased memory capacity and/or the ability to download data for physician review. For example, there is an FDA-approved device worn like a watch that continuously monitors blood glucose for a 72-hour period without a needle stick. Other technologies include built-in blood glucose monitoring capabilities as a component of their broader disease management technologies.

- ▷ Other technologies measure **general vital signs**, making them applicable to many chronic disease conditions, including hypertension or asthma. One example includes a close-fitting shirt embedded with over forty sensors to monitor a wide range of vital signs.

A detailed matrix describing representative technologies in each category is provided as Appendix B. A glossary of terms appears in Appendix C.

B. Impact of CIT on the Practice of Medicine and Patient Care

Technologies embedded with information systems that can monitor, analyze, and report information can profoundly change the nature of the physician-patient relationship.

From a patient perspective, monitoring can provide information in a more convenient and timely fashion and make the patient feel more involved and empowered in relationship to his or her medical condition. Those benefits can translate into greater patient satisfaction and improved outcomes. Technologies that have shown promise include patient monitors for those with diabetes and heart disease, where ongoing monitoring can help patients feel in control of their diseases and better manage their conditions.

While physicians express interest in the benefits of CIT, they also have significant concerns. First, many physicians are concerned that these new technologies will not improve their ability to care for patients, but instead will disrupt their current practices. Increasingly, patients challenge health professionals with Internet-generated information. In some cases, the information is not clinically sound or appropriate. Physicians have also expressed concerns that CIT will overload them with extraneous data points with no clinical value. Health professionals are left with the time-consuming task of sorting through the

electronically gathered data looking for relevant information.

Both patients and health professionals also are aware of confidentiality issues associated with telephonic and wireless transfer of information about specific patients. CIT brings the medical technology community into the ongoing privacy debate. Many CIT products incorporate significant layers of security and protection into software algorithms. While the publication of the final privacy rule will improve protections for patients in some environments, many basic questions remain unresolved, with further regulation and possibly legislation likely in the coming year. (See the back of this Report for information on ordering the MTLF report on privacy issues associated with medical technology.)

Finally, deployment of CIT will require fundamental changes in the economics of medical practice. Physicians are wary of technologic change that is not associated with appropriate reimbursement and clear coding convention. Currently, Medicare and many other payers lack appropriate mechanisms through which to pay for many information-based innovations. In the current environment, CIT has the potential to decrease billable interactions by heading off visits through remote monitoring, providing inadequate reimbursement to physicians for services provided via the new technologies, and leaving the sickest patients to be treated in the office without an increase in reimbursement rates. Many technologies also require providers to make a significant up-front investment in capital equipment and software.

It is critical that the Medicare program and other insurers address these issues to ensure that physicians have economic incentives to adopt technologies proven to improve care, as well as those that can decrease costs while maintaining quality.

C. Response of Commercial Payers

Managed care organizations (MCOs) are interested in technologies that provide cost-savings in the care of their enrollees. Because many chronically ill patients are costly to treat, there has been interest on the part of MCOs in managing chronic care more efficiently. Commercial MCOs often work with the assistance of benefit managers and consultants to evaluate innovative technologies for this purpose.

Experimentation with technologies that transmit basic vital signs and patient self-report data has become relatively common in managed care settings. Many MCOs have begun to integrate these technologies into existing disease management (DM) programs. Much of the initial focus has been on diseases such as CHF, where near term (*i.e.,* within 6-12 months) cost savings can be realized. Several CIT firms have been successful in establishing pilot programs in CHF disease management.

While data from these “demonstrations” provide useful insights into the potential benefits of remote technologies, the studies tend to be non-randomized, with pre/post or historical

comparisons only. The results often are compared to no intervention, rather than to an existing DM program, making the results appear more favorable. There is little published in the peer-reviewed literature to date. Payers want to see controlled studies in patient populations similar to their enrollees. They also want to see evidence of the benefit of new technologies from both a clinical (utility) and economic (cost-effective) perspective, which unfortunately, for new technologies is often insufficient.

Some payers may also have an interest in direct cost savings, rather than savings for outcomes improvements (i.e., cost effectiveness). Some may be unwilling to measure savings over the long term, seeking only the short-term benefit of direct savings. This perspective may create expectations not easily realized by CIT.

Despite these barriers, many commercial payers are now offering limited coverage for specific types of remote technologies, including telephonic pacemaker monitoring and holter monitoring. Aetna U.S. Healthcare also recently published a policy offering limited coverage for ambulatory blood pressuring monitoring.[1] However, for the most part, coverage of CIT in the commercial payer setting is limited to inclusion of CITs in existing DM programs primarily on a limited basis. Furthermore, payment levels for CIT tend to be very low.

Even a positive coverage decision and payment does not guarantee physician adoption. The ability to ensure widespread utilization for covered CIT is limited primarily to the small number of staff model MCOs where physicians are employees, or in some way share risk for high cost chronic care with the payer.

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[1] Aetna U.S. Healthcare, Automated Ambulatory Blood Pressure Monitoring (CPB 25) (copy on file with MTLF).

Part II - Public Policy Implications

A. Medicare and CIT

The Medicare program enrolls nearly 40 million elderly and disabled Americans. Medicare patients represent a large portion of the market for many CITs. For example, Medicare enrollees make up almost all of the CHF patients. In addition, Medicare policy serves as a bellwether for commercial payers, who often follow Medicare's lead on coverage and payment policy.

There are several significant structural barriers to the diffusion of CIT in the Medicare program. First, and most importantly, the traditional fee-for-service (FFS) payment system is encounter-based, and pays based on the input costs of services and products delivered to patients. Thus, if new information technology can improve care while reducing the number of physician or hospital visits, it cannot be adopted without reducing revenues to providers. These problems may be addressed, even in the context of the current system, through legislation ensuring that remote visits are reimbursed and provided for in bundled payments for the care of chronically ill patients in the Medicare program.

The Medicare+Choice program, which is the managed care alternative to FFS Medicare, does not share the rigidity of the FFS payment structure. However, relatively few Medicare enrollees participate in this system, and a number of major managed care plans have stopped providing service to Medicare beneficiaries, further reducing the scope of this program. Policy makers cannot pin their hopes on the Medicare+Choice program as it is currently designed, as FFS parity is necessary to ensure that these technologies diffuse.

A second challenge to widespread CIT adoption in the Medicare program involves the coverage process. Under the Social Security Act, Medicare may not cover any services that are not "reasonable and necessary for the diagnosis or treatment of injury or to improve the functioning of a malformed body member."[2] This provision is critical to maintain fiscal discipline and program integrity, but is difficult to implement while also ensuring that beneficiaries can access needed technology. Congress delegated to the Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration, or HCFA) the authority to implement this provision. There are currently two avenues to coverage in Medicare: a national process that has been under revision for the last three years, and a local process administered by the 54 carriers and fiscal intermediaries.

CIT faces challenges in both the national and the local processes. All new technologies that represent departures from traditional services must provide some level of evidence of value. As previously discussed, CIT developers do not always provide scientifically controlled studies that an evaluator might require for coverage. Additionally, in recent years, Medicare has been vigilant against fraud and abuse in the program. Technologies used in remote

settings, such as the home, raise concerns among officials about the potential for misuse or overuse. For example, Medicare has withheld a coverage decision for a home monitoring device to measure coagulation time due, in part, to concerns about over-utilization of the device.

Those developing CIT typically assert that their systems are an economical alternative to traditional treatments. However, many have argued that Medicare does not have the legal authority to use cost as a criterion for coverage. Dating back to a 1989 proposed rule,[3] the Congress and a string of CMS administrators have wrestled with this issue. Subsequent criteria with the potential to measure economic factors, such as comparability or added value, have also been unsuccessful to date.[4] (A listing of the MTLF reports on aspects of Medicare's efforts to design coverage criteria is provided at the back of this Report.) While Medicare's coverage process remains in flux, career officials contend that the program remains interested in technologies that reduce costs while maintaining or improving quality.

A final challenge involves the difficulty that government has in keeping up with the rapid pace of change in technology, and particularly with the effects of information technology and its perpetually changing terminology in health care public policy creation. The sheer potential volume of CIT makes the challenge of picking "winner" and "loser" technologies particularly daunting. In this regard, the regional coverage process has actually been quite helpful in diffusing innovative technologies, as they have generally been able to ensure moderately paced diffusion as the new technologies are accepted in local geographic areas.

B. Current Medicare Policy on CIT

It comes as no surprise that Medicare has a patchwork set of approaches to rapidly evolving CIT. These approaches include policy on telemedicine (a term which, in Medicare, has generally been used to describe teleconsultation), local policies on specific technologies (such as holter monitors), and current demonstrations. As we will describe, the program has clearly been evolving towards providing more coverage for proven CIT, a trend that we expect will accelerate over the coming years as technologies mature.

1. **National Telemedicine Policy**

Congress has shown a strong interest in the promise of telemedicine, particularly in rural America. In the Balanced Budget Act of 1997, Congress included some telemedicine provisions to encourage the use of and payment for these technologies.[5] A broad definition of telemedicine could include CIT and provide CMS with greater flexibility in coverage and payment. However, to date, federal coverage on telemedicine is strictly limited in scope to health professional shortage areas.

Furthermore, CMS needs to clarify persisting ambiguity in the telemedicine terminology. When the implementing provisions of the BBA telemedicine provisions

were published in the Federal Register, the rules limited how some important CIT would be defined. The regulations state:

> A teleconsultation is equivalent to a traditional, face-to-face consultation only if it permits the consultant to control the examination of the patient as the examination is taking place. With store-and-forward technology, the consultant is reviewing an examination that has already occurred and is limited to whatever information was recorded at that time. We believe that a teleconsultation instead must be an interactive patient encounter. (June 22, 1998)[6]

Similarly, in September 2000 Congressional testimony, Acting CMS Administrator Robert Berenson, M.D. limited telemedicine services to "consultations" for which Medicare will pay. "Therefore, a Medicare teleconsultation is a medical examination under the control of the consulting practitioner, in lieu of an actual face-to-face encounter, that must take place via an interactive audio-video telecommunications system."[7]

This interpretation appears to limit coverage to "real time" patient-provider interactions and exclude store-and-forward technologies (technologies that can be stored and held until the receiving party opens the data and analyzes it). This definition is a significant limitation on one aspect of CIT.

However, subsequent policy suggests that, in limited circumstances, store-and-forward technologies qualify for coverage under Medicare telemedicine regulations. In the recently enacted Beneficiary Improvement and Protection Act of 2000 (BIPA), the following language appears:

> The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician … to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing telehealth service is not at the same location as the beneficiary. . . In the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.[8]

This language appears to extend coverage for store-and-forward technologies if they are provided in a specific telemedicine demonstration project.

Though congressional telemedicine legislation had the potential to open the door to widespread coverage of CIT in Medicare, subsequent interpretations by CMS officials and in regulation, do not welcome that opportunity. Although Congress

appears to be inching toward a broader embrace of CIT, in the near term, federal telemedicine policy continues not to provide incentives for widespread utilization in the Medicare program.

2. Local Policies on Specific Technologies

As discussed above, Medicare has both a national coverage process and over 50 local carriers and intermediaries who make coverage decisions that apply to their local jurisdictions in the absence of federal policy. Medicare carriers issue local medical review policies (LMRPs) governing Medicare coverage in their regions. Telephonic pacemaker monitoring and holter monitoring have received a range of coverage options. The following are representative examples of the Medicare carrier LMRPs that exist for these two forms of CIT:

- **Telephonic Pacemaker Monitoring:** Blue Cross Blue Shield of Alabama, the carrier for that region, issued an LMRP stating that trans-telephonic pacemaker monitoring services are covered if they consist of a minimum 30 second readable strip of the ECG and pacemaker in the free-running and magnetic modes. Monitoring services require an annual physician prescription for each patient in order to file claims for trans-telephonic monitoring. The coverage policy also includes frequency guidelines that describe accepted intervals depending on the type of pacemaker system used.[9]

- **Holter Monitoring:** Under an LMRP issued by Triple-S of Puerto Rico, holter monitoring can be paid under Part B for EKG services if provided by a physician, approved laboratory or approved supplier. EKG is not covered as a screening or routine function, so the claim must indicate a clinical reason—such as angina, vertigo, or atrial fibrillation—to justify the service.[10]

- **EKG Monitoring:** Palmetto in South Carolina covers EKG monitoring for a 24-hour time frame. If the monitoring period is longer, it must be accompanied by documentation to justify it because use of long-term EKG for routine assessment of pacemaker function is not covered. Holter monitoring for a patient with an internal pacemaker is covered only when symptoms are present that suggest arrhythmia not revealed by a standard EKG.[11]

These local coverage policies have generally been consistent across carriers and have enabled the adoption of a number of important technologies. However, they may pose challenges for innovative technologies that do not have clearly defined benefit categories. Also, particularly for new technologies developed by smaller companies without a strong local presence, navigating the local coverage process can be quite cumbersome.

3. Disease Management Demonstrations

As previously addressed, Medicare is dominated by a fee-for-service payment system and lacks many managed-care style tools used to coordinate care for chronic diseases. The Medicare demonstrations described below are notable because they represent a divergence from the traditional resource-based payment of chronic disease management. A sampling of DM demonstrations includes:

- **CMS Telemedicine:** With the Agency for Healthcare Research and Quality (AHRQ), CMS will study the cost-effectiveness of store-and-forward technology, patient self-monitoring, and potential applications for non-surgical services.[12]

- **Diabetes Assessment in New York:** Led by Columbia University, this demonstration project uses advanced computer and communications technology to improve the quality of health care to diabetics living in isolated rural areas.[13]

- **Coordinated Care:** Models of coordinated care for chronic conditions such as CHF, heart disease, diabetes, etc., will be tested to assess cost-effectiveness and delivery and payment models to determine clinical outcomes, patient satisfaction, and quality of life in 9 sites.[14]

- **Medicare+Choice CHF DM:** M+C organizations will receive extra payments to reflect the costs of managing the treatment of CHF patients outside the hospital. Payment for outpatient care for CHF patients will begin in 2002 for M+C plans that provide high quality care based on quality indicators.[15]

- **BIPA-Mandated DM:** Three organizations will be selected to demonstrate the impact on costs and outcomes of applying DM to 30,000 beneficiaries with advanced stage CHF, coronary heart disease or diabetes.[16]

These selected demonstrations are evidence that CMS is interested in the potential of CIT. However, it is important to recognize that demonstrations can be complicated and time-consuming. It is not uncommon for Medicare demonstrations to span 5 years from inception to completion. Given the speed of technological change, it is unclear how lengthy demonstration projects can assist in rapid diffusion unless Medicare provides preliminary coverage and payment for promising technologies prior to the final evaluation at the demonstration’s conclusion. Given the breadth of CIT applications, selected demonstrations will clearly be insufficient at providing adequate data to inform a comprehensive policy approach to CIT.

C. Policy Recommendations

The issues described in this Report have been used by some to advocate for fundamental healthcare reform. However, many of the impediments we have described could and should be addressed through modest changes in federal policy. In this final section, we focus on those modest changes that could be adopted without legislation, and also those that could be attached to CMS reform or any other Medicare legislation.

1. **Focus on producing strong clinical and economic evidence from trials to demonstrate the value of new CIT**.

   Managed care payers expect to see comparisons relative to current practice (i.e., existing DM or case management programs) and prefer well-controlled studies. In addition, payers need to see data from patient populations that are representative of their beneficiaries/members. Because CIT is still relatively untested, payers also will look to the peer-reviewed literature as validation of research results, and companies should develop a clear publication plan for the studies they undertake. Congress needs to allow CMS to maintain the expertise necessary to make critical coverage evaluations of new technology, which will require the hiring of additional individuals with expertise in CIT.

2. **Explore managed care as a vehicle for data collection.**

   MCOs provide opportunities for studies on CIT because they facilitate data collection relative to existing "low tech" disease management programs. Managed care trials also can potentially generate product revenues while data is being assembled and will provide reimbursement benefits if the plan ultimately covers the technology. However, the experience of current CIT manufacturers underscores the importance of sound study design and peer-reviewed publications to demonstrate broader value from study results, as well as expand market opportunities beyond commercial managed care plans. Congress should continue to fund demonstrations in managed care settings, but should focus on CIT applications in the FFS environment, where most Medicare patients will continue to receive their care.

3. **Work collaboratively with providers and patients.**

   While patients are increasingly willing to embrace information technologies, health care professionals have shown some reluctance to adopt CIT. Provider and patient acceptance of CIT will ultimately drive acceptance by payers. Companies should involve key provider groups in their clinical research design and should work with specialty societies to address coding limitations that affect payment. Manufacturers should also involve patients in their technology development process. Developers must be particularly sensitive to the potential disruption these technologies present to traditional healthcare relationships and the implications on provider compensation. The Department of Health

and Human Services needs to encourage dialogue among stakeholders, through available vehicles including AHRQ.

4. Improve Knowledge of Government Officials.

It is critical for public officials to keep current on the pace of technology development. Given the key role that Medicare plays in the health care system, it is particularly important that policymakers with a role in that program understand CIT's potential. This educational role will continue to be served by both public and private entities. However, it is particularly helpful when members of Congress lead by example, as Senators Jay Rockefeller [D-West Virginia] and Bill Frist [R-Tennessee] have in supporting the National Health Policy Forum, and as others have in participating in relevant MTLF Forums.

5. Allow for Administrative Flexibility within CMS.

If appropriate studies on evidence of value are produced, CMS should show receptivity to CIT by establishing a record of positive coverage decisions. CMS staff can also advocate through the AMA's CPT for broader coding flexibility, make positive coverage decisions for technologies that are proven to improve the quality of care for Medicare beneficiaries, and push for equity in payment between remote and face-to-face visits.

6. Enact Minor Legislative Changes to Facilitate the Diffusion of Needed Technologies.

Three primary legislative changes would assist in the diffusion of useful CIT: (1) Payment parity for face-to-face and remote services, assuming comparable outcomes; (2) bundled payments for routine treatments associated with chronic disease to facilitate use of CIT (e.g., in CHF); and (3) coding reform to facilitate accurate service description and payment. To the extent that CMS lacks the authority or inclination to make changes administratively, the Congress may have to set the framework in legislation.

These six relatively modest steps would dramatically improve the climate for CIT. Of course, consideration of these suggestions, particularly the legislative changes referenced above, also raises fundamental questions about the nature of Medicare FFS payment. If the Congress does pursue more fundamental programmatic reforms it should address that our current system is based around reimbursing resource costs, not the value delivered to patients. This issue should be addressed to ensure that rapid diffusion of current and future CIT applications proven to improve quality and efficiency is encouraged.

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[2] Social Security Act, sec. 1862(a)(i)(A), 42 U.S.C. 1395y(a)(i)(A).
[3] 54 Fed. Reg. 4302 (Jan. 30, 1989).
[4] 65 Fed. Reg. 31124 (May 16, 2000) (notice of intent to publish a proposed rule).
[5] Pub. Law No. 105-33, sec. 4206 (Aug. 5, 1997).
[6] 63 Fed. Reg. 33882 (June 22, 1998) (proposed rule).
[7] Testimony of Robert A. Berenson, M.D. before the House Committee on Commerce/Subcommittee on Health (Sep. 7, 2000) (available at http://www.hcfa.gov/testimony/2000/090700.htm).
[8] H.R. 5661, sec. 223(b), as incorporated into the Omnibus Consolidated & Emergency Supplemental Appropriation for FY2001, Pub. Law No. 106-554 (Dec. 21, 2000) (codified at Social Security Act, sec. 1834 (m), 42 U.S.C. 1395m(m)).
[9] Blue Cross Blue Shield of Alabama, Transtelephonic Monitoring of Pacemakers (LMRP 97-29) (1998) (available at http://www.lmrp.net).
[10] Triple-S, Inc., Holter Monitoring (1994) (available at http://www.lmrp.net).
[11] Palmetto, Holter and Real Time Monitoring (LMRP 91-0020-M) (rev. 1996) (available at http://www.lmrp.net).
[12] Evidence Report/Technological Assessment No. 24, Telemedicine for the Medicare Population (AHRQ Publication No. 01-E012).
[13] Balanced Budget Act of 1997, *supra* note 5, sec. 4207: Informatics, Telemedicine, and Education Demonstration Project (Aug. 5, 1997)
[14] *Id.*, sec 4016: Medicare Coordinated Care Demonstration (Aug
[15] Medicare Benefits Improvement and Protection Act of 2000, *supra* note 8, sec. 607. *See also* HCFA Operational Policy Letter #129 (Nov. 22, 2000).
[16] Medicare Benefits Improvement and Protection Act of 2000, *supra* note 8, sec. 121.

Appendix A

SUMMIT ON REIMBURSEMENT FOR CLINICAL INFORMATION TECHNOLOGIES (CIT)

February 26-27, 2001

Washington Duke Inn and Golf Club
Duke University
Durham, North Carolina

Summit Agenda

--------------------------------Monday, February 26--------------------------------

Reception 6:30 p.m. – 7:00 p.m.

Location: Ambassador Ballroom, Center Room
Hosted by the Fuqua School of Business, Duke University – Rex D. Adams, Dean

Dinner Meeting 7:00 p.m. – 8:30 p.m.

Location: Ambassador Ballroom, Center Room
Keynote Address: William L. Roper, MD, MPH
Dean of the School of Public Health
University of North Carolina at Chapel Hill
Former Administrator, Health Care Financing Administration

--------------------------------Tuesday, February 27------------------------------

Location: All sessions will be held in the Ambassador Ballroom, Allen Room

Welcome/Introductions 8:00 – 8:15 a.m.

▷ Kenneth Keller, Ph.D.
Charles M. Denny, Jr., Professor of Science and Technology
Hubert H. Humphrey Institute of Public Affairs, University of Minnesota

▷ Kevin Schulman, M.D.
Director of the Health Sector Management Program
Fuqua School of Business, Duke University

Meeting Purpose/Background Materials 8:15 – 8:50 a.m.

▷ Dan Mendelson
Managing Director, The Health Strategies Consultancy LLC
Adjunct Professor, Fuqua School of Business, Duke University

The development of the Internet has enabled the development of many information-focused health-monitoring devices and systems; however, there is uncertainty over coverage and reimbursement of these products. The purpose of this conference is to discuss possible coverage options and to identify key issues from several perspectives, including the technology industry, government payers, patient groups, providers, and commercial payers.

The Introduction will cover the following issues:

- What types of technologies are likely to emerge?
- What are the coverage / payment precedents for CIT?
- What terminology best describes the new technology?
- What barriers or impediments hinder development and coverage?
- Is there an imperative for better coverage?

Background materials distributed included a summary of the structure of the industry, a review of the published literature and/or legislation relevant to the CIT industry (e.g., coding and payment policies, restrictions on the marketing of CIT devices, privacy).

Technology Perspective 8:50 a.m. – 9:50 a.m.

Many new technologies that collect, analyze, and transmit information are approaching the market for both professional and consumer use. These include pure monitoring technologies as well as others that offer a treatment component. There is considerable uncertainty regarding the coverage and payment environment for these technologies, particularly related to valuing non-traditional service components (e.g., e-mail, telephonic, data interpretation,

store/forward technology, etc.), which complicates key clinical development and commercialization decisions.

This panel discussion features representatives from three diverse types of companies, and will be facilitated by Dan Mendelson. Speakers include:

- ▷ Bob Thompson
  Medtronic, Inc.

- ▷ Steve Brown
  CEO, Health Hero Network, Inc.

Points of discussion:

- What kinds of challenges have CIT companies met in gaining reimbursement for their products?
- What initiatives have been undertaken to optimize or minimize?
- What additional new concerns emerge for CIT that is marketed directly to the consumer with no medical provider oversight?
- What are the reimbursement advantages and disadvantages seen in packaging CIT services within a disease management program approach?
- How should the value of the service be viewed, through a package approach or be valued separately?
- What evidence is there that consumers value clinical information technologies, and that they would want them covered or be willing to pay for the technologies themselves?
- What future capabilities might increase demand for these types of technologies such as:
    - Managing multiple diseases?
    - Downloadable software?

Break 9:50 a.m. – 10:00 p.m.

Government Payer Perspective 10:00 a.m. – 11:30 a.m.

- ▷ Sean Tunis, M.D., M.Sc.
  Director of the Coverage and Analysis Group
  Health Care Financing Administration

- ▷ Parashar Patel
  Center for Health Plans and Providers
  Health Care Financing Administration

Points of discussion:

- What kind of opportunities do you see for beneficiaries? What types of concerns do you have?

- How is the political environment likely to affect HCFA's decisions regarding coverage and payment for CIT?
- How does the existing coverage language or payment mechanisms assist or preclude payment for the many aspects of CIT such as data transmission, physician reading, frequency of patient download vs. physician read? (e.g., How will HCFA assign each component to a benefit category? How does CIT relate to current policies on telemedicine?)
- What types of clinical and economic studies will be required to support specific payment decisions in this area, and should the study requirements differ from other assessments? What specific study outcomes requirements are required?
- If different components of a given technology fall into distinct coverage categories, how can payment rates be made rational and consistent?
- How will HCFA value components of the technology (e.g., e-mail) within existing resource-based payment systems?
- If HCFA begins to cover these new CIT technologies, are there existing technologies that could also be affected (e.g., reimbursing physicians when diabetic patients fax/phone in/e-mail their blood glucose values)?
- What are HCFA's views on the need for "Quality Standards" for CIT?
- What are your impressions of CIT facilitating the management of a patient's multiple diseases or using software to upgrade a current implantable to accommodate a patient's newly diagnosed co-morbidities?
- Is inappropriate billing or over-utilization a concern, and if so, how can it be addressed?

Patient/Provider Perspective 11:30 a.m. – 12:30 p.m.

Technologies that monitor, analyze, and report information on disease states can be expected to profoundly change the nature of the physician / patient relationship. Physicians are already spending an increasing amount of time working with patients to sort through new publicly available information (e.g., internet resources) on disease. Some technologies that give patient-specific information should be more useful, but will require more time and effort to help patients understand the information. Further, the different business models for bringing CITs to market raise important questions about role of the physician in interpreting and delivering information to the patient.

▷ Yank Coble, M.D.
Secretary-Treasurer
AMA Board of Trustees

▷ Robert Levine, M.D.
Chairman, Clinical Affairs
Juvenile Diabetes Foundation

▷ Eric D. Peterson, M.D., M.P.H.
Director, Cardiovascular Outcomes and Research
Duke Clinical Research Institute

Points of discussion:

- Should patients have direct access to clinical information – including data analyses of their vital statistics? Are there some observations that should be available only to the physician?
- How may the payment for the technology affect patient access to CIT?
- What evidence is there that consumers value clinical information technologies, and that they would want them covered or be willing to pay for the technologies themselves?
- What effect will chronic information of CIT data and vital statistics have on patient compliance?
- What effect will payment approaches have on the frequency of office visits (e.g., physician concerns that patients relying on remote devices may not return to the office)?
- How will CIT affect the amount of time physician spend with the patient? How will physician time and other resources be recognized (e.g., Relative Value Units)?
- How might future capabilities increase demand, by patients or physician, for these types of technologies such as:
- Managing multiple diseases?
- Downloadable software?

Lunch 12:30 p.m. – 1:30 p.m.

Hon. Richard Burr
United States House of Representatives, North Carolina

Commercial Payer Perspective 1:30 p.m. – 2:30 p.m.

Payers have been, and will continue to critically evaluate these technologies to determine whether they should be covered, and if so, how they should be reimbursed. They often work with the assistance of benefit managers (e.g., Mercer, Hay Group), and are increasingly requesting more sophisticated data on health outcomes.

▷ Mitchell Sugarman
Director, Medical Technology Assessment
The Kaiser Permanente Federation

▷ Linda Bergthold, Ph.D.
Research Associate
Center for Health Policy, Stanford University

▷ Kathy King
Vice President
Washington Business Group on Health - Insurance Industry Representative

Points of discussion:

- What kind of opportunities do you see for subscribers? What types of concerns do you have?
- How does the existing coverage language or payment mechanisms assist or preclude payment for the many aspects of CIT such as data transmission, physician reading, frequency of patient download vs. physician read? (e.g., How will HCFA assign each component to a benefit category? How does CIT relate to current policies on telemedicine?)
- What are options for payment (e.g., monthly monitoring fees, capitated disease management fees)?
- What types of clinical and economic studies will be required to support specific payment decisions in this area, and should the study requirements differ from other assessments? What specific study outcomes requirements are required?
- When there are competing perspectives within a plan, how do you resolve the conflicts that arise between realizing short-term and long-term goals?
- How should patient preferences be balanced against costs and other considerations in making coverage and payment decisions?
- What are your impressions of CIT facilitating the management of a patient's multiple diseases or using software to upgrade a current implantable to accommodate a patient's newly diagnosed co-morbidities?

Wrap-Up/Next Steps 2:30 – 3:00 p.m.

Dan Mendelson / Kevin Schulman

Appendix B

Technology Matrix

Please Note: The following tables do not provide a comprehensive list of companies that manufacture devices for each disease area. The tables contain a select list of companies that are representative of the different types of products available or in development.

Table 1: Devices used for CHF/CAD

Companies	Products	Product Description	Level of Invasiveness			Type of Data Provided			Manipulable Data?	
			Impl.	Sub-Q	Non-Inv.	Subj.	Obj.	Combo	Yes	No
Agilent	Zymed’s EasyView Telemetry System; AEDs: Heartstream FR2; Holter Monitors: Zymed’s MultiTrak, DigiTrak; Event Recorders: Zymed’s HomeTrak, HomeTrak Plus	Zymed: Digital telemetric monitoring in the clinical setting provides continuous waveform displays AED: Portable lightweight automatic external defibrillator	☐	☐	☑	☐	☑	☐	☐	☑
Alere	AlereNet System	Patients step on digital scales and use DayLink Monitors to answer questions about symptoms each day.	☐	☐	☑	☐	☐	☑	☐	☑

Cardiocom, LLC	Cardiocom System: Cardiovisor, Telescale	A scale that transmits data to alert staff through a phone line regarding a patient's weight and asks12 wellness questions that could indicate signs of an impending CHF crisis	☐	☐	☑	☐	☐	☑	☐	☑
HeartMasters	LifeMasters Online Qmed, Inc. ECG monitor: Monitor One, nDx model; ohms|cad® system	Online disease management program offers self-care tools for patients to track disease-specific measures, and a "virtual coach" sends customized email messages to encourage appropriate behavior	☐	☐	☑	☐	☐	☑	☐	☑
HomMed	HomMed System: HomMed Sentry and HomMed Observer	A home unit measures vital signs for chronic disease patients (e.g., weight, BP, blood glucose, heart rate, temp., lung function) and sends data wirelessly to clinician.	☐	☑	☑	☐	☑	☐	☐	☑
Inovise Medical	Cardiovise Software, Cardiovise Online	Software that runs an algorithm with criteria that determine which region of the heart has an infarction and the size of the infarct(s) in each region	☐	☐	☑	☐	☑	☐	☐	☑

Medtronic	Chronicle	Continuously captures real-time data from devices implanted in CHF patients and transmits it via a secure Internet-based connection to clinics investigating and using the technology	☑	☐	☐	☐	☑	☐	☑	☐
Nexan	The Nexan System	Provides continuous wireless 24 hour physiological measuring of cardio-respiratory activity monitoring through skin patches containing sensors.	☐	☐	☑	☐	☐	☑	☐	☑

Table 2: Devices Used for Diabetes

Companies	Products	Product Description	Level of Invasiveness			Type of Data Provided			Manipulable Data?	
			Impl.	Sub-Q	Non-Inv.	Subj.	Obj.	Combo	Yes	No
Bayer	Blood Glucose Monitor: Glucometer Dex		☐	☑	☐	☐	☑	☐	☐	☑
Cygnus	Glucowatch Biographer	Worn like a watch, this non-invasive meter measures glucose collected through the skin, not from blood, and calculates, displays and stores glucose readings.	☐	☐	☑	☐	☑	☐	☐	☑

Integ	LifeGuide System	Non-invasive meter uses interstitial fluid (ISF) taken from the outermost layers of the skin to measure glucose	☐	☐	☑	☐	☑	☐	☐	☑
Lifescan	Blood Glucose Monitors: OneTouch series: FastTake, SureStep, Basic, Profile	OneTouch system allows blood collection from the fingertips or arm	☐	☑	☐	☐	☑	☐	☐	☑
Medisense	Blood Glucose Monitors: Precision QID, ExacTech	QID monitor uses biosensor technology (G2 electrode test strip design) to read glucose level; ExacTech does not require cleaning	☐	☑	☐	☐	☑	☐	☐	☑
MiniMed	508 Insulin Pump	Worn outside of body, delivers basal and bolus rates of insulin throughout the day, adjusted by user	☑	☐	☐	☐	☑	☐	☐	☑
Roche Diagnostics	Blood Glucose Monitors: Accu-Chek series	Blood glucose meters; also has voice synthesis meters for visually impaired	☐	☑	☐	☐	☑	☐	☐	☑

Table 3: Devices Used for General Vital Sign Monitoring

Companies	Product	Product Description	Level of Invasiveness			Type of Data Provided			Manipulable Data?	
			Impl.	Sub-Q	Non-Inv.	Subj.	Obj.	Combo	Yes	No
American Telecare	AVIVA Home Telemedicine System	A monitoring system that incorporates both live audio and video with integrated, electronic medical peripherals to allow a physician or nurse to conduct remote examinations of patients in their homes.	☐	☑	☑	☐	☐	☑	☐	☑
Health Hero	Health Buddy	A two-way, Net-based communications service and appliance to aid daily communication between health-care providers and patients at home.	☐	☐	☑	☐	☐	☑	☐	☑
LifeChart	AirWatch	Asthma monitor records data for two key asthma parameters and uploads the data via modem to LifeChart.com, which graphs the data to highlight asthma triggers and trends.	☐	☐	☑	☐	☑	☐	☐	☑

Lifeshirt	LifeShirt	A vest fitted with six types of sensors that continuously monitor 40 indicators based on heart activity and breathing patterns; data uploads to data center.	☐	☐	☑	☐	☑	☐	☐	☑

Appendix C

Glossary

1. Capture:

The acquisition/collection of a patient's medical data or other healthcare information through remote technologies or any of the following means: electronic, wireless, telephonic, satellite.

2. Clinical Information Technology (CIT):

A system of technology that allows a remote interface to collect and transmit data between a patient and provider.

3. Clinical Review:

The analysis or evaluation of health data by a physician or practitioner.

4. Combined Subjective-Objective Patient Data:

Self-reported patient data and data measured by a medical device or diagnostic (e.g., a device that will ask health status questions and electronically gather information on weight from a scale)

5. Connectivity:

The ability of a system or device to link with other systems or devices (e.g., via telephone, wireless, satellite, etc.).

6. Continuous Capture:

Acquisition/collection of the patient's medical data/information by a remote technology occurs on a constant basis, often requiring daily (or more frequent) downloading.

7. Data Aggregation:

The collection, consolidation, processing and presentation of data for modeling, decision-making and implementation of those decisions.

8. Device Guided Therapy:

Clinical information technology that aggregates patient data, which is utilized by the provider to make treatment decisions.

9. Disease Management:

A process of managing a specific disease in a patient population. Disease management entails identification of patients at risk and then working systematically to either prevent the illness or provide interventions to decrease complications, manage exacerbations and optimize health.

10. e-health:

Employing the internet and other advanced networking technologies to improve on the development, delivery and evaluation of health care products and services.

11. Episodic payment:

Describes a reimbursement system in which payments would be made at measured intervals of time, regardless of the number of transactions of health services rendered within each period.

12. Event Initiated Capture:

Medical data from the patient is only recorded by the remote technology when triggered by a medical event, or symptoms of a medical event, experienced by the patient (e.g., heart palpitations, dizziness).

13. Objective Patient Data:

Data gathered/measured from the patient via a medical device or diagnostic (e.g., scale, holter monitor, event recorder, etc.).

14. Real Time:

Data transferred remotely from a patient or provider is reviewed by another provider in a synchronous manner (i.e., "virtual face-to-face" interaction between a provider and patient or between two providers).

15. Routine Capture:

Acquisition/collection of the patient's medical data/information by a remote technology is scheduled/programmed to occur at specific measured intervals (e.g., once every month).

16. Store/Forward:

Data transferred remotely from a patient or provider is reviewed by another provider in an asynchronous manner (e.g., review of an x-ray film by a radiologist in a remote location).

17. Subjective Patient Data:

Health data gathered from the patient by means of self-reporting (e.g., Device: “Are you feeling more shortness of breath today?”; Patient: “Yes”; Symptom: Slight dyspnea)

18. Technical Standards:

Methods, protocols, and terminologies agreed on by an industry to allow information systems to communicate successfully with one another (e.g., data transmission formats, standards for interoperability, etc.).

The American National Standards Institute (ANSI) provides a private sector based national accreditation mechanism to Standards Developing Organizations (SDO) for conformity assessment programs (e.g., products and quality management systems) that facilitates sectoral approaches to satisfy U.S. needs for products and services to flow freely in the marketplace (domestic, and foreign).

Health Level Seven (HL7) is an ANSI-accredited SDO whose members—providers, vendors, payers, consultants, government groups and others—develop specifications that enable healthcare applications to exchange key sets of clinical and administrative data.

19. Teleconsult:

The remote delivery and provision of consultative services between physicians in lieu of an actual face-to-face encounter, with information related to care transmitted remotely.

20. Telehealth/Telemedicine:

A broad term used to describe the remote delivery and electronic provision of health care and consultative services for the direct benefit of individual patients and their families. It traditionally described physician-physician interactions over distance, but now includes physician-patient interactions over distance using telecommunications technology and the provision of education and information services designed to increase awareness of (and where applicable, compliance with) diagnoses and medical conditions, treatments, and good health practices.

21. Transactional payment:

Describes a system of reimbursement in which payment is made for each health service rendered by a provider or practitioner to a patient.

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