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Project Narrative

Three major health care providers—Columbia-Presbyterian Medical Center (CPMC), the New York City Department of Health (NYCDOH), and Visiting Nurse Services of New York City (VNS)—and three major information technology vendors—IBM, Cellular Telecommunications Industry Association (CTIA), and PI Systems—propose to collaborate to create the information infrastructure necessary to provide coordinated, effective care to patients in the home, doctor's office, and hospital. This project will demonstrate that the NII is essential to providing coordinated health care.

CPMC, which comprises Columbia University and The Presbyterian Hospital, is one of the nation's largest medical centers (50,000 admissions and 800,000 outpatient visits per year). It is a leader in health information standards for knowledge (Arden Syntax), vocabulary (Medical Entities Dictionary), and data exchange (HL7 Toolkit). NYCDOH, the nation's largest health department, is responsible for the effective treatment of tuberculosis patients in New York City, and has published a 300-page protocol guide for tuberculosis. VNS, the nation's largest non-profit home care corporation, receives over 5000 referrals from CPMC per year, and has begun to investigate the use of portable hand-held computers by nurses visiting patient's homes. IBM provides a clinical database and an automated decision-support system. CTIA's members provide connectivity at many levels, including wireless cellular links. PI Systems supplies hand-held computer devices, specializing in visiting nurse systems.

While the communications infrastructure to be developed in this proposal will be useful for all types of health care, we have chosen a particular disease, tuberculosis, to demonstrate its usefulness. In the U.S., 10 million people have quiescent tuberculosis infections and 2000 die of tuberculosis each year. After a long decline in mortality rate from tuberculosis, the rate has recently begun to climb, due to HIV infection, social conditions, and health care factors. Tuberculosis is difficult to treat because the therapy (several simultaneous medications) must be taken reliably over a long period (6 months to 2 years). Partial compliance with the therapy not only fails to treat the patient's tuberculosis, but also induces the development of tuberculosis strains that are resistant to known medications. To reduce the spread of tuberculosis and to reduce the development of drug-resistant strains, Directly Observed Therapy is recommended for all patients—patients are observed by a qualified health care provider for every medication dose they take.

For Northern Manhattan (north of 145th Street), CPMC is the major provider of primary, secondary, and tertiary care. When a patient with tuberculosis is discharged from the hospital, care is typically transferred to NYCDOH, which has a Public Health Clinic adjacent to CPMC. Patients attend the clinic or are visited in the home by NYCDOH Public Health Assistants (non-tuberculosis care is still provided by CPMC). VNS is the major supplier of home care for patients who require intravenous therapy and patients with severe illness. The area is populated by 240,000 people, of which two thirds are Hispanic, fifteen percent are African-American, and the rest are mainly white immigrants; most of the residents are of lower social and economic status. Over 3000 new cases of tuberculosis are seen in New York City each year, and over 100 cases are detected at CPMC (the largest number reported of all the N.Y. City private hospitals). One hundred cases represents about 15,000 clinic or home visits in a year.

The objective of the project is to use automated decision-support systems, networks, interactive wireless hand-held computers, and natural language processing in order to (1) coordinate the many providers of care for tuberculosis patients; (2) respond better to patient needs; (3) ensure that appropriate tuberculosis protocols are followed, thus reducing treatment failures and drug-resistant tuberculosis; (4) provide an infrastructure that will be used for the treatment of other diseases; (5) demonstrate how electronic medical records can achieve the high standards of privacy and confidentiality advanced by the NTIA, Congress, and the ACLU; and (6) evaluate and disseminate the results of the demonstrations.

We envision the following scenario. An elderly patient arrives at the CPMC emergency room complaining of chronic cough. The preliminary result of a sputum sample reveals evidence of tuberculosis infection and a chest X-ray reveals lesions in the lung indicative of tuberculosis. An automated tuberculosis protocol (NYCDOH protocol #VI-1) recommends the appropriate antibiotics, further tests, and an isolation room. A message is sent over the network to NYCDOH, reporting that a likely case of tuberculosis has been found. After about two weeks, the patient's fever and cough have subsided. The physician contacts NYCDOH electronically to arrange for the patient to be followed by the NYCDOH for Directly Observed Therapy; with the patient's permission, relevant clinical data are transferred from CPMC to NYCDOH electronically. Since the patient is unable to attend the NYCDOH Public Health Clinic, the patient is visited in the home (for each medication dose) by a NYCDOH Public Health Assistant, who carries a hand-held computer. During one visit, the patient reports numbness of the hands. The NYCDOH Assistant uses the hand-held computer to query whether this might be caused by tuberculosis or one of the medications. An automated tuberculosis protocol (#V-23) indicates that the cause might be the medication isoniazid, and asks the NYCDOH Assistant whether the patient has predisposing factors such as diabetes, alcoholism, etc. The

patient reports having mild diabetes, and the protocol indicates that the patient should stop isoniazid and follow-up with the physician immediately. Electronic mail is sent to the CPMC physician, and an appointment is scheduled. The NYCDOH Assistant completes the computer entry of routine visit data, and the patient soon visits the physician for adjustment of therapy. Several weeks into therapy the final results of the original sputum sample are completed. An automated tuberculosis protocol (#VII-11) notes that the infection is resistant to one of the patient's medications, and an alert is sent to the physician and NYCDOH. An intravenous medication (which must be given by a nurse rather than a Public Health Assistant) is recommended. The physician completes an electronic form to order visiting nurse services from VNS. With the patient's permission, the form and relevant clinical data are transferred electronically from CPMC to VNS. Subsequent home visits are made by a VNS nurse, who also carries a hand-held computer. Eventually, the patient is well enough to attend the NYCDOH Public Health Clinic for the remainder of the treatment. The patient uses the tuberculosis information kiosk in the waiting area to ask whether it is safe for a grandchild to visit the patient's home. The kiosk accesses an automated protocol (#IX-8) that indicates that the visit is, in fact, safe at this stage.

The project consists of five technical components (more details are provided under Optional Materials):

1. Connectivity. Basic connectivity is the essential first step to carry out this project. We will link the three major providers of health care in Northern Manhattan—CPMC, NYCDOH, and VNS—by exploiting existing networks and standards, and by using the most economical links that offer sufficient bandwidth, security, and potential for future expansion.

Initially, CPMC, NYCDOH, and VNS will be linked directly to each other; in this way, programs can be tested and security measures can be validated before placing confidential data on public networks. CPMC already has a 1500-workstation network from which physicians and nurses can access clinical data and Internet resources. This network will be extended into the NYCDOH Public Health Clinic, which is contiguous with CPMC; four IBM-compatible PCs will be placed in the patient examining rooms, and one, outfitted with touch-based multimedia interaction, will serve as an information kiosk in the waiting area. CPMC will be linked to the NYCDOH central office via a leased T1/56kbps line connecting two IBM RS/6000 Unix computers. Mainframe to RS/6000 connections will use SNA and TCP/IP protocols, and inter-RS/6000 connections will use TCP/IP protocols. CPMC will be linked to VNS in the identical fashion.

Once programs and security have been validated, each of CPMC, NYCDOH, and VNS will be linked to the centralized, public NYSERnet (available via services from PSInet), thus making them part of the NII. Because standard protocols and hardware have been chosen, this switch will require only a change in phone numbers without additional hardware or resources.

Wireless hand-held devices from PI Systems will be given to eight NYCDOH Public Health Assistants (this covers all Northern Manhattan field workers) and eight VNS nurses (this covers one sixth of all Northern Manhattan field workers). The devices support pen- and forms-based data entry. The devices' PCMCIA slots will hold a modem device compatible with a cellular telephone system. Through a collaboration with CTIA, packet switching will be investigated, since it may provide a cheaper alternative to cellular links by the time the project is under way.

2. Clinical Data Transfer and Applications. The project requires a complex flow of data (shown schematically in the Visual Documentation section). CPMC will send NYCDOH notification of new tuberculosis cases, discharge plans, test results, clinical data, medication orders, readmissions, and access to information sources such as Medline. NYCDOH will send CPMC clinical visit information on CPMC-treated tuberculosis patients. CPMC will send VNS orders for nursing care, discharge plans, medication changes, and access to information sources such as Medline. VNS will send CPMC clinical observations and more emergent notifications from field nurses. VNS will send NYCDOH clinical observations and information on cases lost to follow-up.

All data transfer will use the HL7 data transfer protocol. CPMC's Medical Entities Dictionary (a clinical vocabulary based on the National Library of Medicine's UMLS standard) will provide transparent mappings of vocabulary terms among the three organizations. Applications for querying and receiving data will be written for each of the three central database repositories. Applications for displaying and entering data will be written for th network workstations and the hand-held devices.

3. Automated Clinical Protocols. The automated clinical protocols are essential to the project, since th direct the flow of information: they decide when, where, and who needs what clinical data. An automated clinical protocol is a set of guidelines, criteria, and actions that have been coded in electronic form. They are triggered by clinical events (visits, admissions, discharges, transfers, storage of test results, recording of diagnoses, etc.) and check the condition of the patient. If a clinically important situation is found, then an appropriate action is take (send electronic mail over the network to a provider, store an alert in the electronic patient record, etc.). For example, if the drug ethambutol is ordered for a patient, and it was noted previously in the record that the pati allergic to the drug, then an alert will be sent to warn the physician of the allergy. An extensive set of tubercul

protocols has been developed by NYCDOH, and a related set has been tailored for use at CPMC. These will be used to coordinate care for tuberculosis patients, and to demonstrate the use of automated clinical protocols over the information infrastructure.

The protocols will be implemented using a computer program called a clinical event monitor. CPMC has such a monitor running today. It contains a set of rules called Medical Logic Modules (MLMs) written in an international standard called the Arden Syntax (ASTM E1460-92). The use of this standard will allow the electronically-coded protocols to be disseminated among other organizations with clinical event monitors.

In the first year, we will run all protocols on the CPMC monitor. In the second year, a commercial clinical event monitor made by IBM will be installed on a unix computer at NYCDOH. This will permit NYCDOH to run protocols for all of its tuberculosis patients (not just those seen at CPMC), and it will allow us to demonstrate the ability to transfer the Arden Syntax-based protocols among organizations.

4. Security and Privacy. Our proposed model for the electronic patient-oriented medical record is not one central database, but a set of database repositories administered by separate organizations and linked over information infrastructure. For this model to succeed, strict security and privacy procedures must be achieved.

We will follow the general guidelines for privacy and confidentiality advanced by the NTIA, Congress, and the ACLU. Proper user and machine authentication will be required for each data transfer. Authorization to access data will be determined by patient consent, patient responsibility (e.g., CPMC will access NYCDOH data only for patients treated at CPMC), data type (HIV results will not be transferred), type of provider (physicians may access different data than clerks), and time limitations (the authorization to see a patient's data will need to be renewed after a period). Data send over public connections will be encrypted. All data access will be audited; the three organizations will receive periodic summaries of data access, and there will be random checks in which patients and their providers will be given a list of who accessed their record. Security standards, such as MIT's kerberos, will be the preferred mechanism for implementing security procedures.

5. Evaluation and Dissemination. Both formative and summative program evaluation will be used. Psychometric testing will be completed on the evaluation instruments prior to project implementation. All data will be available for those wishing to replicate the program.

All instruments will be devised in Likert Scale format and developed in scannable form. Pre- and post-measures, as well as monthly process measures, will be developed to evaluate progress in the domains of communication, confidentiality, efficacy, cost savings, satisfaction, and technical feasibility.

The automated tuberculosis protocols will be donated to Columbia University's Health Sciences Library, which manages a collection of Arden Syntax protocols. Outside organizations are free to use the protocols in their own regions.

Criteria. We believe that this project is an excellent match to the NTIA's General and Specific Criteria. Just as the National Information Infrastructure (NII) is a "network of networks," our model of the national electronic medical record is a set of clinical repositories, linked by the NII. By exploiting the NII, rather than creating a monolithic clinical database, and by adhering to standards like TCP/IP, HL7, and the Arden Syntax, the participant organizations will produce a model that can be expanded easily, and they will gain access to national resources over networks like the Internet. All designs and purchases will make economic and efficient use of scarce resources. For example, by exploiting existing machines, networks, and applications ("reuse"), this project will leverage a vast investment in clinical information resources. Furthermore, the evaluation and documentation will be performed by an experienced evaluation team.

Interoperability is an overriding concern. Both external and internal interoperability are provided through the use of standards (TCP/IP, HL7, Arden Syntax, vocabulary, kerberos, etc.) that conform with "open system architecture." Each of the three organizations will have access (with appropriate security) to the resources that the others possess. Through the internet (both before and after the connection to NYSERnet) outside organizations will have access to such resources.

The system is scalable in several ways. Additional hand-held devices can be added to the system seamlessly after the prototype is ended. Additional institutions that follow established standards will be able to join the three organizations will minimal equipment (approximately $20,000). Their tuberculosis patients will have automated protocols run via the NYCDOH clinical event monitor, once that connection is established.

The project represents a partnership among very different providers—a medical center, a local health agency, and a private non-profit home care corporation; this is a model of collaboration that can be copied in other regions. The joint agreements with three information vendors will not only leverage the NTIA investment, but also provide a mechanism for distributing the fruit of this project. IBM's clinical event monitor will allow others to use the tuberculosis protocols developed in this project. CTIA will use this project as a demonstration of the capabilities attained through wireless communications. PI Systems will be able to improve upon their own software, extending their reach further into the health care market.

This project employs innovation and experimentation in several critical areas ("new use"). Clinical event monitors and automated protocols are just beginning to make inroads in health care. The use of monitors and protocols to bridge disparate health care organizations has not been done before, and it represents a novel approach that we feel will be critical to the future success of organizing health care. The protocols insure that all patients, regardless of social and economic status, receive treatment in harmony with established standards.

Privacy (described above) is a key component in this project. CPMC's security initiative (the result of a successful partnership with the Digital Equipment Corporation) for authentication, authorization, encryption, and auditing will be extended for use among the three participant organizations.

This project is aimed at eliminating disparity of access. The proposed area is a minority community, and ordinary Americans will benefit directly from the information infrastructure. The control of tuberculosis in the community will not only benefit those who have contracted the disease, but also the many others who are at risk for contracting the disease. By outfitting NYCDOH and VNS field workers with interactive hand-held devices, we are empowering them to respond to patients needs and questions immediately and in an informed fashion. The information kiosk will give patients direct access to information about their disease.

For this project, the existing information infrastructure includes the Internet, land leased lines, cellular access, the CPMC network, and the NYCDOH and VNS information centers, all of which will be exploited.

The project addresses the accommodation of future technology and flexibility in several ways. (1) The land-based connections can be augmented (e.g., increase number of lines) as needed to accommodate increased usage. (2) Wireless hand-held devices can be added modularly as required by NYCDOH and VNS. (3) By providing NYCDOH with the IBM clinical event monitor and by providing a communication channel between NYCDOH and VNS, care can extend beyond the confines of Northern Manhattan to all of N.Y. City. Links with other hospitals and medical centers can be accomplished. (4) While the treatment of tuberculosis is being demonstrated in this project, it is intended to be extended to many other diseases. Investigations on using the system for the treatment of diabetes mellitus are already underway.

This project will contribute to the NII. Although CPMC is already on the Internet, the project will add the vast resources of NYCDOH and VNS to the Internet. With proper privacy measures, other N.Y. City agencies will be able to coordinate care through the network, and broader regional agencies will be able to collect data on health care. Furthermore, the Arden Syntax-based automated protocols can be exploited by groups in any region. The evaluation plan, which is outlined above, is a critical part of the project.

Coordinated health care, improved education about their disease, and certain community services will be provided to patients. A number of knowledge sources (for example, Medline for bibliographic retrieval) will be provided over the hand-held devices, enabling health care workers to answer patient's questions in the home in an informed fashion, and the information kiosk will provide direct education in the NYCDOH Clinic. As demands for these services increase, field workers in other regions will be outfitted with devices.

This project offers a chance to demonstrate that the NII is essential to providing coordinated health care. Because it leverages existing investments, and because it relies in part on industry donation and cooperation, it represents an efficient use of NTIA resources. The technology chosen is appropriate because it conforms to existing standards, thus facilitating dissemination and future expansion. CPMC, NYCDOH, and VNS are all stable health care providers with budgets to maintain network and computer resources; the system funded by NTIA will be maintained within this structure. This type of system is critical to the proper function and future of health care providers, so maintenance is assured. The value of the project lies in the demonstration of coordinated health care, the definition of a security specification appropriate to health care, the creation of a library of tuberculosis protocols, and a demonstration of the use of wireless hand-held devices. As particular networks or devices become obsolete, the knowledge gained in this project can be transferred forward easily, especially given the compliance with standards. The role of commercial services, outlined above, is an important component of the project.

End user support will depend on the organization. NYCDOH and VNS have few workers (about 20 each) who will use the system constantly, while CPMC has many workers (about 2000 physicians and nurses) who will use it intermittently. The computer applications will be user-friendly, and applications will include self-instruction tutorials. Nevertheless, a NYCDOH and a VNS team member will provide training for their workers. CPMC physicians and nurses already use the CPMC network workstations; they will require only minor additional instruction, which will be provided on-line. The ultimate end-users are the patients, and they will receive access in the home mediated through the CPMC, NYCDOH, and VNS providers. In the clinic, patients will have direct access to the information resources through the computer-based information kiosk. The kiosk, which will use touch-based multimedia interaction, will be designed for direct patient use without formal training.