

RESEARCH CONNECTIONS

LINKING THE RESEARCH COMMUNITY

APRIL 2009

Digital Program, eCVD-II, Helps Patients Manage Health

Geisinger patients at risk for cardiovascular disease (CVD) soon will be able to participate in their own care. In a process that uses information technology-based tools and builds on information generated by Geisinger's advanced electronic health records (EHR) system, patients will understand their choices with a new clarity and be able to work with their physicians in directing a course of action.

"The patient is one of the most critical but most overlooked members of the healthcare team," explained J.B. Jones, PhD, MBA, a research investigator at Geisinger who is shepherding the new system. "Healthcare providers can, for example, prescribe a medication for the patient, but it will only be effective if the patient chooses to fill the prescription and take the medication as prescribed. This system helps the patient and his or her physician individualize care consistent with steps a patient is willing to take to reduce risk."

The model, which is being implemented at two Geisinger clinics, is called eCVD-II (i.e., the second iteration of an electronic methodology for managing CVD). The eCVD-II system, which is a prototype for similar approaches being developed for diabetes, migraine and other common conditions, was developed by Dr. Jones and Drs. Walter Stewart and Nirav Shah in collaboration with physicians at Geisinger's Scenery Park, Gray's Woods and Lock Haven clinics.

The first step in the eCVD-II process in-

volves the use of software that automatically scans the Geisinger EHR system to identify patients with risk factors for CVD. If patients have been identified but factors affecting their risk assessment are incomplete, the software automatically coordinates collection of the missing data. For example, when an at-risk patient has not had a recent test for cholesterol, an order is placed automatically so

that the test is performed the next time the patient has a blood sample taken.

When the risk assessment is complete and a patient is determined to be a candidate in need of management, the next step in the eCVD-II process begins. In the clinic, prior to meeting his or her physician, the patient is guided through

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HMORN's 15th Annual Conference

The HMO Research Network (HMORN) will hold its annual meeting this month at Geisinger's Henry Hood Center for Health Research. The network brings together a consortium of research centers from integrated delivery systems throughout the United States.

This year's meeting, "Leadership in Comparative Effectiveness and Translational Research," provides investigators - both within and outside the network - the opportunity to share ideas and seek collaborations for health services and population-based research.

"The studies we're going to present have immediate consequences for clinicians, and are of direct relevance to virtually every major medical problem in the country," said Eric Larson, MD, chair of the HMORN Board of Governors.

Founded 15 years ago, the HMORN is

composed of 15 of the nation's largest integrated care delivery systems, including host-site Geisinger, Kaiser Permanente and Boston's Harvard Pilgrim Health Care as well as some international members such as Israel's Maccabi.

"We realized that researchers in these settings had a lot in common in terms of challenges and interests," said Dr. Larson, also executive director of the Group Health Center for Health Studies in Seattle. By fostering collaboration across institutions, the HMORN has developed working groups in several areas, including cancer care, long-term study of drug-related adverse events, and the epidemiology and treatment of cardiovascular problems.

In carrying out these studies, the network mobilizes resources from multiple health systems, leveraging the availability of electronic health records that provide data on more than 11 million patients.

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New Technology Ushers in Substantial Evolution in Rheumatologic Care

A new approach for collecting and analyzing data from patients with rheumatologic disorders is expected to yield a favorable impact on nearly every factor worth measuring, including patient satisfaction, physician productivity, the efficacy and safety of prescribed therapies, and outcomes. The technology-based approach is called Rheum-PACER (PATient-Centric Electronic Redesign), and it has the potential to yield an important evolution in the orientation of care.

"The electronic health record is very efficient for collecting and storing information, but the information is not collected in a way that physicians can easily evaluate the disease course over time. We are trying to change that in a way that allows information to be applied in the context of the needs of the individual patient," explained Eric Newman, MD, director of the Department of Rheumatology at Geisinger.

Rheum-PACER consists of two major components. The first is a touch-screen questionnaire that permits patients to record disease history since the last patient visit by evaluating their own level of function and clinical course. The software elicits information about 10 specific probes or events of note since the last visit. When responses identify clinical issues, a nurse uses a separate data-collection tool to gather more information. This information, collated for physician review, expedites a focus on patient concerns and needs during the clinic visit.

The second component is Rheum-PACER's sophisticated software program that produces patient data over time in a format that has immediate relevance to treatment decisions. For example, functional outcome measures can be displayed in the context of medication exposure over a recent period. Previously, this type of information was difficult to pull out of the patient's record quickly or easily.

The screenshot displays the Rheum-PACER software interface for a patient named Mary Red. The interface is organized into several panels:

- Header:** Patient name (Mary Red), gender (Female), age (62), insurance (Medicare), physician (MATTHEWS, DAVE B), and date (1/28/2014).
- Navigation Tabs:** OUTCOMES GENERAL, OUTCOMES COMPOSITE, MONITORING, DEMOGRAPHICS, BEST PRACTICE, TODAY'S VISIT CONSTRUCTION, TODAY'S VISIT NOTE, TODAY'S VISIT AVS.
- Diagnosis:**
 - Rheumatic:**

Rheumatic	Date of DX	Duration
734.0 Rheumatoid Arthritis	1999	9 years
 - Other:**
 - HYPERLIPIDEMIA NECROS
 - SENILE OSTEOPOROSIS
 - TETANUS-DIPHTHERIA (TDL) (DT)
 - TOBACCO USE DISORDER
- Medication:**
 - Current Meds:**
 - IBUPROFEN 200 MG TABS
 - ASPIRIN 81 MG PO TABS
 - IBUPROFEN 200 MG PO TABS
 - MULTIVITAMIN PO TABS
 - TYL PRN ASTHENTIN PAIN 650 MG PO TABS
 - Current Meds Other:**
 - CATORACEP
 - Previous DMARDs:**
 - HYDROXYCHLOROQUINE
 - ASPIRIN 325 MG PO TABS
 - AVODART 0.5 MG PO CAPS
 - ASPIRIN 81 MG PO TABS
- History:**
 - Med/Surg History:**

History	Mvalue
GI Bleed/PUD	no
Renal Insufficiency	no
Malignancy	yes
Joint Replacement	no
Gastric Bypass	no
 - Social History:**
 - Work Status: working
 - Occupation: pilot
 - Home Status: Spouse
 - Exercise: 1-2 times per week
 - Education Level: 20
 - ETOH: NO
 - Smoking: NO
- Rheumatic Status & Tests-Safety:**
 - Rheumatic Status:** Meet Acr Criteria For It? Yes No
 - Test Results:**

Test	Result	Date
Ccp	20	06/01/2008
Rf	20	06/01/2008
Nodes	20	06/01/2008
Erosion	20	06/01/2008
 - Rheumatic Tests - Safety:**

Test	Result	Result Date
Hep C ab		
Hep B sag	NEGATIVE	06/11/2002
ppd		
- Rheumatic Labs - Immune:**

Test	Result	Result Date
ANA	9.9	09/03/2008
DNA	1.23	09/04/2008
RNP	9.88	09/04/2008
Sm	1111	09/05/2008
SSA	2.229999	09/05/2008
SSB	6.66	09/04/2008
Jo-1	5.55	09/04/2008
PR3	3.333	09/04/2008
MPO	2.222	09/04/2008
- Xrays and Ancillary Tests:**

Test	ResultDate
DXA	07/07/2013
CXR	07/10/2014

"Compared with the time-consuming process of flipping through a traditional chart, or clicking through an electronic health record and searching for the relevant information – while the patient is waiting, the software allows a physician to much more efficiently review a disease course. Rheum-PACER saves a significant amount of time in reviewing the medical record because the data is presented in a far more useful way. The software is designed to display the specific information physicians are interested in when managing a patient," Dr. Newman reported.

When the two components – patient-provided data and information from the electronic health record - are combined, the result is a display for the physician that is easy to use, interpret and discuss with a patient. The tool encourages the

physician to focus on the patient's newly reported problems, and provides the physician with a history that reveals persistent issues and the impact of past management decisions. Relatively versatile, the software allows access to information in several formats through multiple tabs and multiple displays.

"At the same time that this system increases physician productivity, we think it will also provide patients with more reassurance that their issues are being addressed in a systematic way. In turn, we expect patients to be more active in their own care and more adherent to management choices," Dr. Newman said. "I am a data guy and excited about the technology, but this is a very practical system that I think will be a benefit to patients and physicians."

ARBs vs. ACE Inhibitors: New Methodology Plumbs Geisinger's Patient Data

An observational study using data gathered from Geisinger's electronic medical records system is comparing the safety and efficacy of two types of drugs used to treat hypertension and congestive heart failure. Employing biostatistical technology developed over the past decade, the research, led by Nirav Shah, MD, illustrates the potential of comparative effectiveness studies, an area in which the U.S. government is significantly expanding research funding.

Dr. Shah aims to compare angiotensin-converting enzyme (ACE) inhibitors and angiotensin-II receptor blockers (ARBs). Whereas ACE inhibitors are generic and cheap, ARBs are mostly still under patent and, therefore, are more costly.

"We know that [ARBs] are better for some people," Dr. Shah explained, "but in their marketing, drug makers are promoting them as better for just about everyone. And, I believe, they don't have the data for that."

Developing and conducting randomized controlled trials (RCTs) to compare the two drugs would require years of study, Dr. Shah explained, adding that "no pharmaceutical company is going to risk doing a head-to-head trial against a generic ACE inhibitor."

But a comparative effectiveness study affords another way to gather information, using already existing data to compare drugs. "At Geisinger, we have a phenomenal electronic health record system that captures all outpatient care data since 2001. So that provides us with a natural experiment," Dr. Shah said. "There are tens of thousands of patients on ACE inhibitors and thousands on ARBs. Why not compare those patients carefully and see if we can detect differences or benefits for one versus the other?"

Underpinning the research are recently developed biostatistical methods that can control for confounding variables. These novel tools grew out of a recon-

sideration of earlier epidemiologic studies, Dr. Shah explained. "We looked at large data sets and began to understand what mistakes we had made. We became much better at modeling data," Dr. Shah said. "It's easy to get a spurious answer if studies are poorly done," Dr. Shah added.

"In 2008, the Agency for Healthcare Research and Quality [responsible for funding these studies] had a budget of \$30 million. Since the stimulus bill was signed, they've already allocated \$400 million in funding."

Dr. Shah noted that a requirement for developing a well-designed study using existing data is to formulate a clinical question that is answerable by the data at hand. Data may be less complete

when captured in routine clinical care settings than in formal trials, he noted, so researchers who use already-existing clinical records must "select what [they are] studying carefully."

As part of the 2009 stimulus bill, the U.S. Congress allotted \$1.1 billion for comparative effectiveness research. "In 2008, the Agency for Healthcare Research and Quality [responsible for funding these studies] had a budget of \$30 million. Since the stimulus bill was signed, they've already allocated \$400 million in funding," Dr. Shah said. Because much of the stimulus money must be spent within two years, the schedule favors work using already-existing data, as is the case at Geisinger.

Human clinical trials testing one drug against another remain the gold standard of research and are required for the approval of all new drugs and devices by the FDA. But comparing the effectiveness or side effects of already approved drugs using these trials is not always feasible because of lack of funding, ethical issues or time requirements. "That's when we should do comparative effectiveness studies using pre-existing data," said Dr. Shah.

HMORN's 15th Annual Conference

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"The scale at which we can do research is hard to compete with," noted Walter Stewart, PhD, vice chair of the HMORN board of governors, associate chief research officer and director of the Geisinger Center for Health Research.

The breadth of the network's research will be on display at this year's conference. Dr. Stewart, chair of this year's conference, noted that the focus on comparative effectiveness highlights an area of tremendous value to clinicians and patients. The American Recovery and Reinvestment Act of 2009

set aside \$1.1 billion for comparative effectiveness research, promising to open new vistas for creating medical evidence.

This "will pay enormous dividends," noted Dr. Stewart. "Investment in comparative effectiveness research will accelerate our understanding of what treatments work best for whom."

If you are interested in attending the conference, please refer to the HMO Research Network Conference website at: <http://www.hmoresearchnetwork.org/confpgs/conf.htm>.

Staff Publications

These publications feature Geisinger employees as authors and have publication dates spanning December 2008 – February 2009

Publications by Geisinger authors only have no special markings; for publications with authors from other institutions, an author with an asterisk after his name is Geisinger staff and the other author(s) is/are not. The listing below is in the format of the National Library of Medicine; it was compiled using RefWorks.

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Digital Program, eCVD-II, Helps Patients Manage Health

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a customized decision-making process by a Web-based application. The software presents the patient with his or her specific risk profile and a menu of possible treatment options. It then explains the degree to which these risks can be reduced with specific treatments. Using easy-to-interpret graphs, patients can observe how their risk for heart attack would be altered by adhering to specific lifestyle changes or medications. Based on the degree of anticipated benefit, patients can identify which actions they are willing to take and, just as importantly to clinicians attempting to develop a meaningful treatment plan, which actions they are not willing to pursue to reduce risk.

The last step in the eCVD-II process is the use of software that aids physicians when patients are evaluated in the clinic. This software presents physicians with the patients' choices and automatically provides treatment recommendations based on current guidelines, such as those developed for hypertension or elevated cholesterol.

"(As a result), the clinic visit starts at a much more advanced point in the process. The patients are now armed with information about their options and have considered what steps they are willing to take, and the physician has some insight into the orientation of the patients and has guideline-based information at his or her fingertips," Dr. Jones said. "The guidelines are not displayed to promote cook-

book medicine but to allow physicians and patients to discuss an optimal course of care for reducing disease-related risk. Patients become invested in the process and participate in their own care."

Ultimately, Dr. Jones expects that the eCVD-II system will translate to better outcomes, such as greater reductions in blood pressure and cholesterol.

"One of the benefits of this system is that we do not expect it to increase the workload in the clinic. Rather, physicians will have a lot more information in front of them in order to make better decisions. However, physicians actually have to do less work to obtain this information. We will be evaluating the impact of the program over the next year or so.

Recent External Awards

This list includes new awards and competitive renewals from external agencies, as well as those from the Clinical Research Fund, competitively awarded by the Administrative Committee in December 2008 and January, February and March 2009. To protect the sponsor's confidential information, some clinical trials are not listed as well as dollar amounts for clinical trials and industry-sponsored agreements. If an award is overlooked, please forward the information to Shawna Seger (smseger@geisinger.edu) for inclusion in the next issue.

Peter Berger, MD

Serum Proteomic Profiles for Prediction of Coronary Heart Disease Events - Feasibility
Aviir Inc

\$13,600

A Phase 3, Randomized, Double-Blind, Double Dummy, Parallel Group, Multi-Center, Multi-National Study for Evaluation of Efficacy and Safety of DU-176B vs. Warfarin in Subjects with Atrial Fibrillation – Effective Anticoagulation W/Factor XA (ENGAGE) Quintiles, Inc

A Clinical Outcomes Study of Darapladib versus Placebo in Subjects with Chronic Coronary Heart Disease to Compare the Incidence of Major Adverse Cardiovascular Events (STABILITY)

Glaxo Smith Kline

James Elmore, MD

Cardiovascular Outcomes in Renal Atherosclerotic Lesions
University of Toledo/National Institutes of Health

Robert Langer, MD, MPH

Cancer Research Network Across Healthcare Systems
Group Health Cooperative/National Institutes of Health

\$114,849

Chatla Reddy, MD

A Multicenter Randomized Double-Blind Placebo-Controlled Study to Evaluate the Safety and Efficacy of SCH 530348 in Addition to Standard of Care in Subjects with Acute Coronary Syndrome (TRACER)
Schering Corporation

Kimberly Skelding, MD

Xience V Everolimus Eluting Coronary Stent System (EECSS) USA
Post-approval Study
Abbot Cardiovascular Systems

Adele Spegman, RN, PhD

Nursing Shortage Initiative
Commonwealth of Pennsylvania - CPWDC
\$93,710

Walter Stewart, PhD, MPH

GHP Diabetes Bundle Assessment
Geisinger Health Plan
\$100,000

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