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The Pittsburgh Health Information Network (PHIN) Summary Report

Submitted for the AMA-led

"Effecting Change in Chronic Care: The Tipping Point"

AHRQ Grant

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Executive Summary

From late 2001 to the end of 2003, the Pittsburgh Regional Healthcare Initiative (PRHI) designed and began to build an electronic infrastructure called the Pittsburgh Health Information Network (PHIN). The PHIN was intended as a response to a crisis in the care of people with chronic illnesses, particularly diabetes and depression, and to the overwhelming lack of information technology being used in outpatient practices of southwestern Pennsylvania. Fewer than 10% of these practices have Electronic Medical Record systems and can track their chronically ill populations.

The PHIN was designed as a chronic disease registry for the region that would function as a partial EMR for every diabetic and depressed patient in Southwestern Pennsylvania and that would be available to any registered physician via secure web interfaces. Hosted by a neutral platform in the region, Pennsylvania's Quality Improvement Organization (QIO) "Quality Insights," the central database would receive data from insurance plans and laboratories. Using a Master Patient Index program, it would collate data from all sources and make three different kinds of reports available to physician practices and one report available to patients.

This report details the process of introducing this model to the community of stakeholders, and identifying barriers to implementing the PHIN with their help. Working to resolve these barriers led to important demythologizing of assumptions around HIPAA and patients' rights and indicated that a system like PHIN, designed to overcome the fragmentation of patient data and fragmentation of care across different physicians, locations and insurance plans, would indeed be possible both legally and technically.

Ultimately, the PHIN did not progress past the beginning stages of a technical feasibility pilot using live data from a small handful of data providers (two health plans and two commercial diagnostic labs) due to a lack of committed participation from key data holders in the region.

We believe that a major reason for hesitation among some of the data holding stakeholders was an immature policy environment when it came to data sharing across competing institutions for community benefit. HIPAA was untested in the courts and organizations preferred to err on the side of caution. And there were no national standards for electronic data sharing. It was only after the PHIN had been conceived and designed that President George Bush appointed David Brailer to the position of National Health Information Technology Coordinator in order to lead a coherent national policy toward electronic medical data networks.

The story of the PHIN is one example of how a powerful network of parties committed to improving the health of a region was nevertheless unable to make headway in a data-sharing endeavor due to the uncertainties of the national policy environment. It highlights the grave need for speedy development of clearly delineated legal safeguards around data sharing in order to provide the integrated ongoing care from a team of caregivers that is so critical for the chronically ill.

PRHI and the AMA-led "Tipping Point" Grant

The Pittsburgh Regional Healthcare Initiative (PRHI) is a nonprofit organization with the goal of perfecting the delivery of evidence-based care to all patients in SW Pennsylvania.

Established in 1998 under the leadership of Alcoa Chairman Paul O'Neill (former U.S. Treasury Secretary), PRHI is a unique regional laboratory pursuing improved patient outcomes through improved health system performance. PRHI has assembled over 200 clinicians, 41 hospitals, 8 insurers and dozens of purchasers and employers to work together towards the PRHI mission to achieve the world's best patient outcomes, through superior health system performance, by identifying and solving problems at the point of patient care.

In 2001, PRHI commissioned two reports from the Pennsylvania Health Care Cost Containment Council (PHC4) on diabetes (DM) and depression (MDD) in Southwestern Pennsylvania. The PHC4 analyses documented that in spite of the existence of evidence-based treatment guidelines for these two conditions, the kind of care patients receive varies widely across county and health insurance plan. In response, PHRI convened two Working Groups including local opinion leaders (physicians, other healthcare professionals, employers, patient advocates, etc.) to develop a plan to improve the care of persons with diabetes or depression.

In exploratory visits to physician practices, PRHI staff asked doctors what barriers made it difficult for physicians

to give the recommended treatment to their patients every time. One of the things they heard consistently was "lack of data". At the time less than 10% of physician practices in the Pittsburgh region had an Electronic Medical Record (EMR) and most remained dependent on keeping paper files updated with information coming in from multiple sources. Data "lived everywhere" in these offices. Lab reports and insurance company aggregate reports arrived asynchronously with patient visits, and all too often, precious minutes of a 12-15 minute visit with a patient was spent tracking down lab results and other information vital to the effective treatment of the patient, particularly if the patient was being cared for by multiple physicians.

Members of both the Diabetes and Depression groups soon realized that the need for timely data was a common issue for both diseases. If a doctor could not easily tell whether or not a patient had had the recommended 3 follow-up visits within 12 weeks of prescribing an anti-depressant, or whether or not a patient's glucose levels were under control and being tested every 3-6 months, then he or she would not be able to prescribe appropriate ongoing treatment. Doctors' and patients' time was being wasted and often tests were reordered for lack of data, or patients were given treatment instructions with no mechanisms to find out if the instructions were carried out. Physicians needed help with data management and with tracking how

evidence-based care was being delivered to their patients.

Initial discussions for a solution called for creating shared practice improvement tools among a network of up to 50 primary care physician practices, employers representing up to 90,000 employees and their dependents, the region's four commercial health insurers representing 85% of the Southwestern Pennsylvania market (including Highmark Blue Cross Blue Shield), and two laboratories (representing 68% of the market). The initiative would provide patient tracking tools, performance data, and laboratory test results to physicians.

At this point, the PRHI Working

> All too often, precious minutes of a 12-15 minute visit with a patient are spent tracking down lab results and other information vital to that patient's effective treatment.

Groups reviewed and endorsed the newly released AMA Consortium performance measures for the treatment of diabetes and depression, and planned to disseminate these Consortium tools to practices participating in the initiative. PRHI then joined with the AMA as a partner in the AHRQ-funded "Effecting Change in Chronic Care: Tipping Point Grant" to test methods for integrating these performance measures into physician treatment processes in clinically useful ways that would actually improve

Evolution of the PHIN Model

The initial model at the time that the AHRQ grant proposal was submitted in July 2002 focused on providing physicians with partially populated templates of data for their diabetic and depressed patients. The model called for health plans and laboratories to identify patients with diabetes and to pre-populate the Consortium tools with information available from claims data, thus providing physicians with baseline data (see Figure 1). Physicians would then prospectively add data to the Consortium tools to assemble a more complete picture of patient care. The tool would also serve as an intervention, reminding physicians of the guidelines for management of diabetes. The proposed model for depression would differ; health plans would only identify patients diagnosed with MDD by the physician participating in the project via claims data, but would not pre-populate the tools with any patient specific data to protect patient confidentiality. Physicians would be encouraged to use the tools for those identified patients as well as prospectively for any new patient who presented with symptoms of MDD.

PRHI identified 70 potential physician practice participants at the request of PRHI's employer partners. These 70 practices provided care for 50% of the employees and dependents of these partners (Employer partners included Bayer, Giant Eagle, Highmark, Kirkpatrick Lockhart, Mercy Hospital, Mellon Bank, Nova Chemical, PPG, United States Steel, UPMC Health System, and West Penn Hospital).

At the time of the grant proposal, PRHI was also considering a regional chronic disease registry that would aggregate relevant data from both claims data and physicians to provide
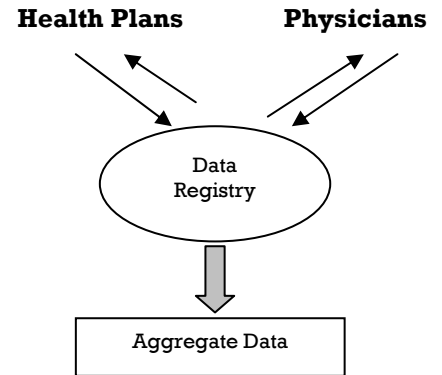
Figure 2: Proposed Regional Data Registry for benchmarking and regional quality improvement assessment

benchmarking data back to physicians and health plans. Such a registry could also provide aggregate reports for assessment of regional progress (see Figure 2).

In January 2003, the PRHI Depression and Diabetes Working Groups began meeting together to test and refine this model for getting outpatient physicians the data they needed about their patients on demand at the time of
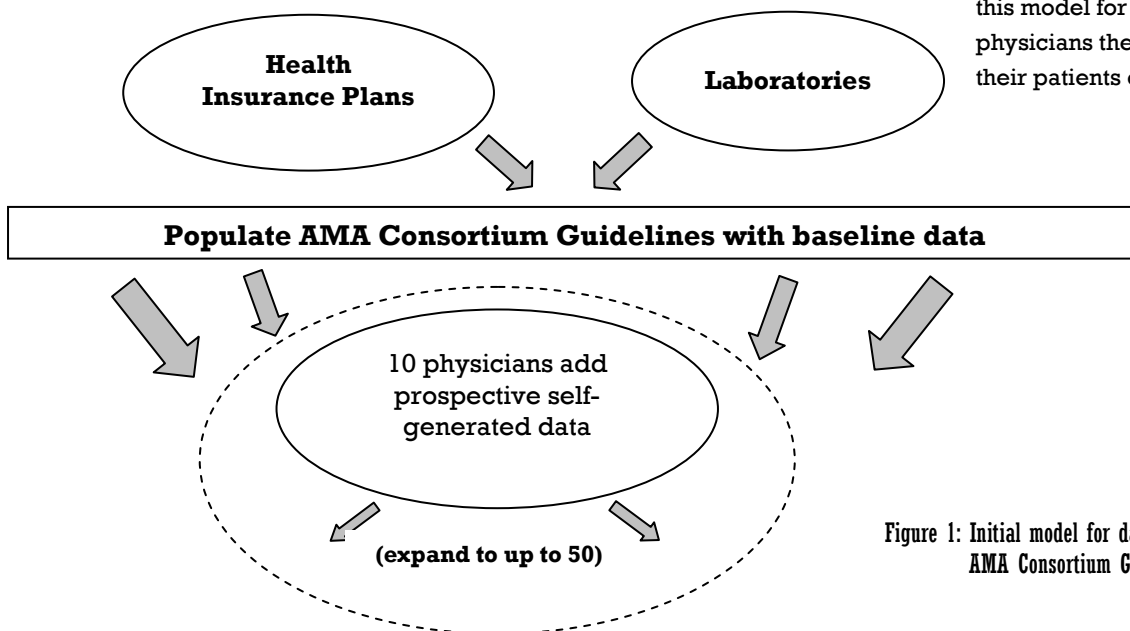
Figure 1: Initial model for data-sharing and integrating AMA Consortium Guidelines

the patient visit.

This combined Chronic Care Working Group yielded important feedback that changed some of the fundamentals of the proposed model:

1) **Keep the design time-neutral for physicians:** Physicians in the group pointed out that they were already strapped for time, were working with extremely thin or nonexistent profit margins, and would not have resources available for data reporting or for significant data compilation in their own offices. PRHI therefore resolved to design a model that would be time neutral for participating physicians, or that would actually save office staff time. This meant working with data that were already available in electronic form outside physician offices—namely lab reports and claims data, and relinquishing expectations that physicians would feed data into a regional registry.

2) **Allow for data-sharing between physicians:** Another problem with the lack of necessary data at the time of a patient visit was traced to the current fragmented system of care; a specialist who needed to know what a PCP was doing to treat a disease would have to pick up the phone and request information. There was no simple system for patient information to become portable across different caregivers. PRHI needed a model that would help reduce this fragmentation of patient data across different physician offices by populating tools for each patient with relevant data from multiple treating physicians.

PRHI also received feedback from co-founder Paul O'Neill who urged the design of a model that could be rolled out to the entire community rather than a handful of physicians at a time. By asking the question "How will this model impact the average health of southwestern Pennsylvanians?" he challenged PRHI to think more broadly about data sharing.

PRHI therefore began to discuss a model that would create a central

> **PRHI began to discuss a central regional database for care of diabetes and depression.**

regional database with available data relevant to the care of diabetes and depression (i.e. claims data and lab results) that would collate and package data in a clinically useful format, patterned after the AMA Consortium performance measures. In this way, any interested physician could contract to access the database, no physician reporting was required, and the registry could combine data from multiple treating physicians on a single patient. PRHI, however, did not have the resources at the time to host such a registry.

Quality Insights of Pennsylvania partners with PRHI

By March 2003, PRHI discovered a partner in the Pennsylvania's Quality Improvement Organization, Quality Insights of PA, and its parent company, the West Virginia Medical Institute (WVMI). WVMI had a CMS mandate to improve the care of diabetics and an interest in contributing to region-wide efforts for quality improvement. It soon became clear that they would be a logical host for a regional chronic disease registry. First, they represented a neutral party who could hold data from competing labs and health plans. Second they had an impressive track record for storing, managing and securing high volumes of sensitive patient medical data for CMS, the Department of Defense and the Veterans' Administration. PRHI also believed at this point that the QIO would automatically bring both Medicaid and Medicare data to the registry. Given the age of the population in Allegheny County (the second oldest county in the nation) and the increased incidence of diabetes with age, we knew that Medicare would be one of the most critical datasets for a regional registry.

Chronic Care Summit I: Introducing the PHIN Model to the Community

By April 2003, the PHIN model had taken shape and was ready to be presented to the community. It was named the Pittsburgh Health Information Network or PHIN (pronounced "fin"), patterned after similar data sharing projects in Utah (the UHIN) and Delaware (the DHIN).

On April 23, 2003 PRHI hosted the first regional Chronic Care Summit. Representatives from all identified stakeholders in the PHIN were invited to attend. These included physicians, patient advocates, employers, as well as decision-makers (CEOs or Regional Managers) from all six major commercial health plans in the region

(Highmark, UPMC, HealthAmerica, Aetna, Gateway, Three Rivers) and from the two commercial diagnostic laboratory companies, Quest and LabCorp.

The description that follows is the basic model that was presented to this Summit, with about 60 stakeholders in attendance.

Goals of the PHIN

➢ **Make it easy for physicians** to access the data they need about a patient with a chronic condition at the point of care, by organizing data from multiple sources into single-format reports.

➢ **Improve the coordination of care** between multiple physicians treating a patient by allowing physicians to access each other's data with patient consent.

➢ **Promote evidence based best practices** in the care of chronic diseases by incorporating AMA-consortium guidelines and prompts to physicians into PHIN reports.

➢ **Give patients greater access to their medical data** as a step toward becoming more educated and active in their own chronic disease management.

➢ **Reduce disparities** in how patients with different insurance plans receive treatment for chronic illness by standardizing the availability of data on all patients, regardless of health plan.

➢ **Bring all payers** (including Medicare and Medicaid) and laboratories in the region together to support this community resource that will benefit ALL residents with chronic illness.

> In April 2003 PRHI hosted the first regional Chronic Care Summit, where the PHIN model was introduced.

➢ **Promote principles of a chronic care model** (as opposed to the dominant acute care model) in the care of patients with chronic illness.

➢ **Begin with data related to diabetes and depression** with the long-range goal of expanding to other chronic diseases (i.e. asthma, coronary artery disease, congestive heart failure, etc.)

Visual Model of the PHIN
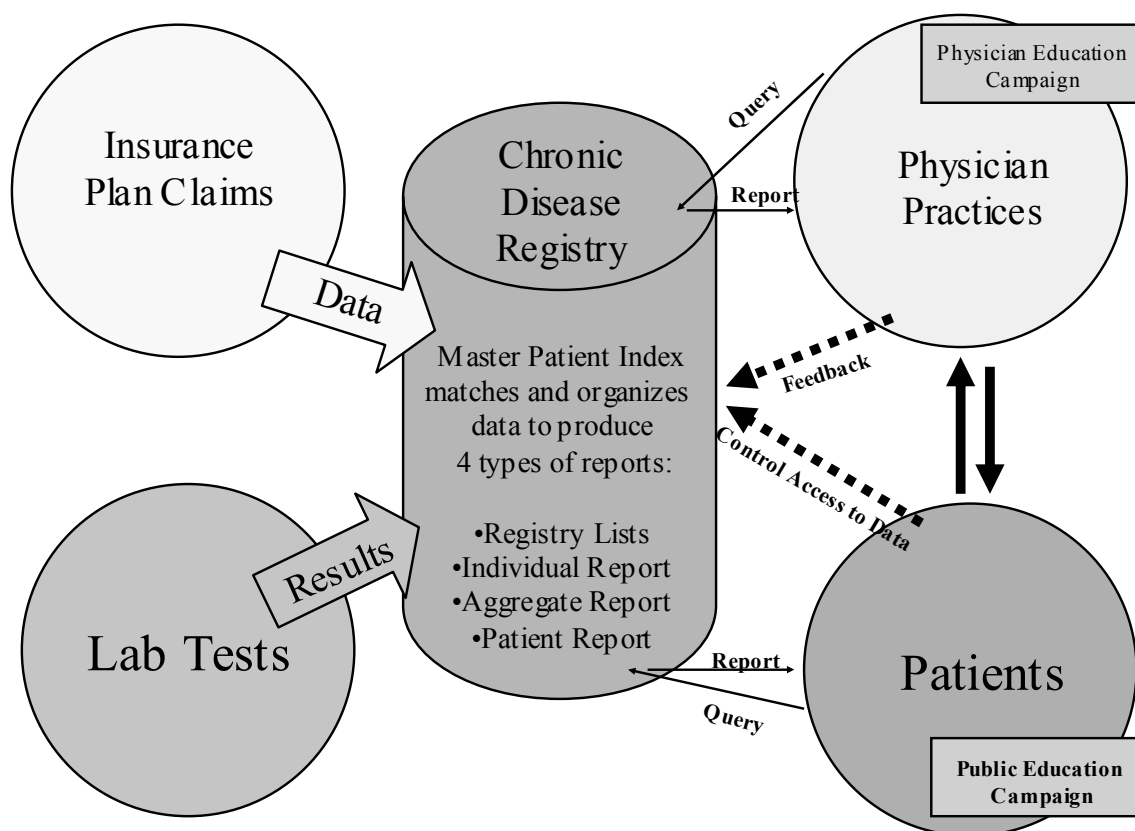
How the PHIN works

The Central Database

Hosted by a neutral platform in the region, Pennsylvania's Quality Improvement Organization (QIO) "Quality Insights", the central database would receive data from insurance plans and laboratories. Using a Master Patient Index program, it would collate data from all sources and make three different kinds of reports available to physician practices and one report available to patients through a secure website.

These four reports would include:

1. A patient registry (physician practices could pull up a list of all their diabetic or depressed patients).

2. Individual Patient Reports (these reports, based on AMA consortium performance measures for best practices in managing diabetes and depression, would provide at-a-glance summaries of office visit histories, lab results trended over time, and medication histories as

well as prompts for other data that should be tracked for evidence-based care but would not be provided by the PHIN).

3. Aggregate Reports (for interested practices to monitor their own progress against themselves and against other PHIN-using practices).

4. Patient-Accessed Reports (for patients to see their own data and become more active and educated in their own disease management).

How the PHIN works, continued

Health Plans (Payers)

Commercial health plans as well as those intermediaries handling Medicare and Medicaid data would first run an algorithm on their claims data to identify lists of probable diabetic patients and probable depressed patients. Each plan would then send a monthly data transmission to the PHIN with a limited set of relevant data on each of these identified patients, namely:

For Diabetes (DM)	For Depression (MDD)
• Date of last office visit	• Date of last office visit
• Date of last eye exam	• Date of new Rx for antidepressants
• List of all medications (based on pharmacy claims)	• Date of last Rx refill for antidepressants
	• List of all other medications

Diagnostic Laboratories

Laboratories would send a monthly data report to the PHIN with the following seven diabetes-related lab results (basic elements of evidence-based treatment guidelines):

- HbA1C
- Micro-albumin
- Fasting Lipid Profile (Y/N)
- Total Cholesterol
- HDL-C
- LDL-C
- Triglycerides

Physician Practices

Physician practices would not need to submit data in order to receive PHIN reports. The only technical requirement would be access to the internet.

There would also be a feedback mechanism for physicians to correct erroneous data. For example, practices would probably want to review the patient registries generated by PHIN via claims data in order to confirm diagnoses and keep a "clean" updated list. Physicians would also be able to correct any errors detected in a patient's individual report.

Practices with EMR systems would eventually be able to populate their own system directly with data from the PHIN, saving significant time on data entry and multiple interfaces with different data providers.

Once the pilot were successfully completed, part of rolling out the PHIN to the broader community would involve a Physician Recruitment Campaign designed to inform physician practices of the purposes and benefits of PHIN:

- An on-demand tool to help physicians give more effective care to their patients;
- NOT a tool for regulation or punishment;
- Collates and tracks chronic disease data for physician practices without the tools to do so on their own.

Note: At the time of the first Chronic Care Summit, PRHI had recruited 12 willing physician practices (primary care, psychiatric, and endocrinology) to pilot the PHIN.

Patients

Once the PHIN were running smoothly for physicians, patient reports would become available to patients themselves. This would help interested individuals learn more about the standards for best treatment of their disease and work together with their physicians to ensure follow up on these best practices.

When the PHIN were ready to go on-line for the entire community, PRHI would launch a Patient Education Campaign designed to inform Pittsburgh area residents of the purposes and benefits of the PHIN.

This campaign would include media coverage, letters from health plans, as well as notification and brochures in physician offices.

PHIN's Benefits to Physicians

Organized Data at the Point of Care

Under the current system, physicians receive different reports with different formats from each insurance carrier in their office. They also receive test results for their patient pool from multiple labs which arrive out of synch with individual patient visits. The PHIN pulls similar data together into a single format report for ALL patients, no matter what their health insurance carrier, and makes it available on demand to be retrieved when a patient comes in for a visit.

The patient registry report enables practices to better track patients with targeted chronic illnesses, and creates opportunities to engage in better preventive care (i.e. calling patients who have fallen through the cracks and are not coming in for treatment).

Individual patient reports contain both organized data and prompts to help reinforce a minimum standard of care that has been established for depression and diabetes through evidence-based, nationally recognized measures.

In short, PHIN reports:

- Are available in a single format from a single source;

- Are pulled as needed rather than pushed at physicians;

- Cover all patients regardless of insurance carrier;

- Create opportunities to track patients who have fallen through the cracks of chronic care;

- Reinforce a minimum standard of care established by nationally recognized measures.

PHIN's Benefits to Patients

Better coordinated care among physicians

Patients could also access their data as a step toward becoming more educated and active in their own chronic disease management. By establishing a link between physician practices though the patient, care can be coordinated between involved practices. Redundant unnecessary procedures and tests can be eliminated while visits that are not completed can be made apparent to all practices involved in care.

Patients who are then lacking particular treatments or tests can then be contacted by the practices for any necessary follow up.

Better record-keeping for many patients

Observations made in several busy practices has shown us that data tend to live "everywhere" in paper-based systems. By capturing as much data as possible in electronic form and repackaging it in a single document available on demand, many patient files will be more complete and will include at-a-glance histories of past treatment for a chronic illness.

added" in that it more closely relates to searching for information or material needed for patient care rather than actually providing patient care. By providing physicians and patients with real time tools necessary to support chronic disease care, we hope to increase the quality of the time spent with physicians without an increase in overall time for the physician or their staff.

Restoring actual patient care time is one objective of efficient information retrieval systems.

More time with doctor during visit

Much of the time spent in healthcare may be classified as "non-value

PHIN's benefits to the community

Closes disparities between health plan services

Because the PHIN will solicit data from every health insurer, both public and private, all patients in SWPA will reap the same benefits of having their chronic disease data compiled and readily accessible.

Raises regional awareness of standards for chronic care

By putting a report in the hands of both patients and physicians that include prompts for the best known practices for treating specific chronic illnesses (based on the AMA consortium guidelines), the PHIN can increase awareness of how diseases can and should be managed.

Can we all agree that physicians should have the data they need for a patient, at the time of the patient visit, every time? If so, let's remove the barriers that keep us from that goal.

PHIN's Limitations

The utility of the PHIN to physicians and patients would depend on the completeness of its database. This means that the more health plans and laboratories who participate, the more powerful community resource the region would create.

Because the PHIN would not require physician practices to submit data, it is limited to events (office visits, lab tests, and medications) that are paid for by a third party and therefore go through the claims process. Events or products paid for in cash would not be captured in the database.

For the same reasons, critical data for treatment gathered in physician practices would not be captured or reported by the PHIN: i.e. weight, blood pressure, foot exams, etc. The PHIN is designed to supplement a patient's record, not replace it.

Because we would be dealing with claims data and monthly transmissions, the PHIN could only post data as fast as claims are filed. PRHI estimated that the PHIN should be able to post data within a 3-month maximum time lag (with lab data coming faster than office claims data); however this means that a patient's individual report would rarely include relevant data from the previous 3-4 weeks. It would not be a fully real-time tool, but it would allow physicians to trend most data over time to monitor the overall progress of a chronic illness.

Committing the Stakeholders

Paul O'Neill, former Treasury Secretary and PRHI co-founder, keynoted the April summit. He led the 60 attendees through the PRHI approach to community problem solving:

1) Does everyone agree that this is a community need? "Do you agree that physicians should have the data they need for a patient, at the time of the patient visit, every time?"

2) Assuming this project (the PHIN) is a basic value we can all agree on, then we need to identify and work to resolve the barriers to achieving it.

Upon achieving consensus around the value of making data available for improved patient care, Mr. O'Neill challenged the stakeholders, namely those who would be asked to provide data to the registry (insurers and labs), to identify and list the barriers they see to achieving this goal. We resolved to hold a second summit in three months time to discuss those barriers and move ahead.

Revealing and Resolving Barriers

The concerns and barriers that were submitted to PRHI in the ensuing weeks fell primarily into two categories: legal and operational. In response, the Chronic Care Working Group formed two task forces to research answers and resolutions to these issues: a Legal Team and a Clinical/Technical Team.

Legal Issues

How to Organize the PHIN

With assistance from WVMI's legal counsel, Alex Brittin, we identified two options for organizing under HIPAA:

➢ Form an Organized Healthcare Arrangement (OHCA) To Use And Disclose PHI for Healthcare Operations [under 45 CFR 164.506(c)(5)] or

➢ Organize under the stipulations for Use And Disclosure Of PHI For Healthcare Operations Of Another Entity [45 CFR 164.506(c)(4)]

PRHI adopted the second approach primarily because it overcame the barrier of requiring participating entities to reprint their current privacy and disclosure of information statements (whereas forming an OHCA would require public disclosure of the arrangement). Language in existing privacy statements already covered data sharing under the umbrella of healthcare operations. The second approach would simply require every participating entity (health plan, laboratory and individual physician practices) to enter into a Business Associate Agreement with Quality Insights (the registry host).

Business Associate Agreements

Business Associate Agreements define the roles of the covered entities as they relate to sharing protected health information (PHI). Covered entities expect their associates to perform in the ways stipulated, but the covered entities are not liable for their associates' behavior. If there is a breech of protection, the covered entity should notify the associate and secretary, and should not provide any further protected health information (PHI) until the breech has been repaired.

Generally liability associated with HIPAA falls into two categories

➢ If the covered entity does not adhere to its standard of due care – (i.e. becoming aware of legal violations in a partner entity without reporting it);

➢ The Federal Trade Commission can site the covered entity for consumer fraud if it is in violation of its own notice of information policy. The notice is considered a public advertisement and violation of the policy it publishes would be false advertising.

Business associate agreements do not require an indemnification clause, but legal reviewers do not object to the clause as long as both parties are mutually indemnified.

For the basic text of the Business Associate Agreements that the PHIN used for both data providers (Health Plans and Labs) and data users (Physician Practices), see Appendix A.

Liability Issues for Stakeholders

Liability of participating entities providing data to the PHIN is limited to what is described in the section above under Business Associate Agreements.

Question: Will physicians' liability

Myth-Buster: Contrary to many assumptions about HIPAA (which was only just being implemented at the time of the Chronic Care Summit), HIPAA has actually reduced liability by establishing an industry standard of due care.

increase if they do not draw on the available data in PHIN?

Answer: Physicians are already liable for providing a minimum standard of care. PHIN is designed as a tool to help them provide that care more easily and effectively.

For a more detailed analysis of liability issues, see Appendix B: Legal Opinion from Alex Brittin (legal counsel to WVMI) on Liability.

Revealing and Resolving Barriers, cont'd.

Mental Health Data

To review, the PHIN was designed only to report office visits and prescription data from **outpatient mental health claims data** for MDD patients. The Legal Team learned that in terms of mental health data, the only additional protections from HIPAA concern psychiatric notes (which are not involved in PHIN). State laws, however, often stipulate more stringent requirements.

With the assistance of Kimberly Gray, legal counsel to Highmark and a member of the PHIN Legal Team, PRHI learned that **in PA state law, the only additional protections on mental health data are for (A) Involuntary Outpatient care and (B) Inpatient care.** PRHI then confirmed that the PHIN could easily separate inpatient data from outpatient data through coding, and that involuntary outpatient data are so rare, it did not constitute a barrier to the existing PHIN model.

PRHI did not find any state laws providing additional protections to voluntary outpatient mental health claims data—the target data for PHIN. For more detailed legal analysis, please see Appendix C: Legal Opinion from Highmark's legal department on state law protections for mental health data.

Patient Authorization

To overcome the current fragmentation of care across multiple physicians and specialists, the PHIN was designed to populate reports with data from all the treating physicians of each patient. Thus, for example, a PCP could pull down an Individual Report on a diabetic patient and see all office visits, lab results, and prescriptions ordered by the patient's endocrinologist as well as by him- or herself.

Question: Under what conditions can such data be shared across multiple physicians? Is individual patient authorization necessary?

Answer: Legally, individual patient authorization is not required. Because PHIN is sharing personal health information (PHI) under permissible disclosures (i.e. healthcare operations for quality improvement) patients are already being informed and giving authorization for this use in existing disclosure of information notices.

For a more detailed legal analysis, see Appendix D: Legal Opinion from Kirk Nahra (outside legal counsel to Highmark) on the need for patient authorization.

However, in a desire to comply not only with legal requirements but also with reasonable expectations of privacy from practitioners and patients—especially as the PHIN would include some mental health data— the Legal Team recommended allowing patients to "opt out" of the PHIN if they would not want their physicians to have access to all their data related to their chronic disease(s).

Operational Issues (Clinical and Technical)

Access to Medicaid and Medicare Data

It soon became clear that although Quality Insights of PA (and its parent company WVMI) warehoused Medicare and Medicaid data for quality improvement purposes, these data would not be adequate for the PHIN. Whereas the PHIN model called for a maximum lag time of 3 months on posting data in order to be clinically useful to physicians, QIOs generally experienced a 12-month lag time before receiving data from Medicare and Medicaid administrative intermediaries.

PRHI therefore began exploring who processed Medicare and Medicaid claims for the region and how to secure permission from the right authorities to

Myth-Buster: **Many assumed that heavy legal protections for mental health data would make it impossible to design a network that would include data on MDD. Upon a close reading of HIPAA and state law this assumption** *did not hold up.*

include these data in the PHIN registry.

Medicaid:

Medicaid data are managed by the state of PA and mental health data are managed at the county level. Pat Valentine, Deputy Director of Allegheny County Department of Human Services indicated to PRHI that permission at the state level would probably cover the release of all county level data. PRHI therefore sent a letter to State Secretary of Public Welfare, Estelle Richman, requesting the release of Medicaid (both Health Choices and

fee-for-service) and county level mental health data, accompanied by a letter of support from Pat Valentine. A similar request for CHIP and adultBasic data were sent to Deputy Insurance Commissioner, Pat Stromberg. We received prompt replies indicating strong support and the PA State Dept of Public Welfare was the first entity to sign a Business Associate Agreement with Quality Insights.

Medicare:

Highmark Blue Cross Blue Shield is the fiscal intermediary for Medicare data in the PHIN's 6-county target region. Although willing to cooperate with the PHIN, Highmark had no authority to release data to the registry. PRHI then began working through WVMI to secure permission from CMS for the release of relevant Medicare data.

PRHI also learned of a newly circulated CMS memo stipulating web access to Medicare data must include a two-step authorization process; for example, a login/password AND an electronic authentication step of some kind. WVMI estimated that this security requirement would add an additional $150,000 cost to the basic

infrastructure of the PHIN. On the other hand, it would also ensure an unusually secure system.

Data Transmission

What is a diabetic patient? What is a depressed patient?

Health plans have highly compatible algorithms already in place for identifying patients as diabetic or depressed. PRHI agreed it would be preferable to err on the side of a wider capture rather than a narrower capture as it would be easier to identify false positives than missing data. PRHI also decided to capture only newly-diagnosed depressed patients in our model. A list of depressed patients could then be sorted into a newly diagnosed category and a continuing care category (as the treatment requirements for those two populations are very different).

Transmission Volume

- ➢ **Plans** would run an algorithm to send claims data only for identified diabetic and depressed patients.

- ➢ **Laboratories** would send all data on 7 diabetes-related test results for any patients in the 6-county target region.

Physician to PHIN Feedback Loop

Physician practices would be able to confirm that a patient on its chronic disease list is in fact in a current relationship with the practice. Patients would remain on a list until (1) a practice removed it via the

confirmation mechanism or (2) no data were submitted on that patient for 36 months.

Lab Data Transmission Format

PRHI planned to meet with Information Systems staff at a number of commercial and hospital labs in order to build on existing reporting formats.

Timeliness

PRHI working group members agreed that physicians would want at least monthly updates in order to find the registry a useful and accurate tool. In order to post available data immediately while still capturing straggling data for the same time period, Quality Insights would request overlapping time captures from plans and labs. PHIN would begin with a 12-month retrospective capture of data on the target population and would then accept

> **Health plans have compatible algorithms already in place for identifying patients as diabetic or depressed.**

monthly updates of 3-month retrospective data. Any duplicated data would be eliminated.

Expected lag time: From the two plans represented on the Clinical/ Technical Team, it was determined that about 80% of HbA1c claims hit within 30 days (and 60% of office visit claims); another 25 days elapse before analytical data becomes available from the warehouse, although this delay was expected to

Revealing and Resolving Barriers, cont'd.
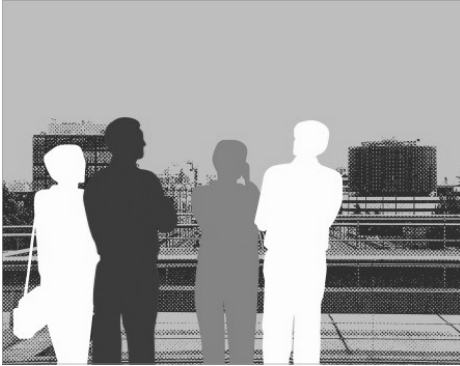
be eliminated within another six months via technological upgrades. PRHI therefore expected to be able to post over 80% of relevant data within the target maximum of 3 months.

Managing Unique Patient Identifiers

In order to handle unique patient identifying systems from each participating organization, Quality Insights would need to develop a Master Patient Identifier program (similar to programs in place for blood banks and other companies handling multiple data feeds) which use about 20 weighted demographic variables to match patients across different systems. QI would need the cooperation of each plan and lab in order to understand each organization's identifier system.

Ensuring Patient Privacy and Security

The security system of Quality Insights has been federally validated as a requirement of their federal Center for Medicare and Medicaid Services (CMS) contracted service.

A PHIN user (i.e. physician office) could never gain access to a patient's data unless a clinical relationship had been established between user and patient

via at least one office visit claim. Patients would be identified as diabetic or depressed and included in the database based on claims forms which would always have a practice identifier. Only practices who submitted a claim on a patient would gain automatic access to the patient's data. In the event that a patient wanted a new physician practice to have access to his or her PHIN data before a claim is processed to establish the link, Quality Insights could set up a mechanism for physician practices to indicate that they have permission from patient to access the records.

At this stage of the PHIN model, PRHI planned to go forward with an opt-out design: any physician with a clinical relationship to a patient would be able to access ALL of the patient's relevant data generated through any other treating physician unless the patient opted out of the PHIN.

A patient's history would follow a patient across physicians via the PHIN as soon as the new practice established a relationship with the patient (via a claims form for a visit, for example) to gain access to the patient's history.

At this stage of the PHIN model, PRHI planned to go forward with an opt-out design, with patients presumed to participate unless they specifically refused.

Chronic Care Summit II: Deeper into the Details

On July 30, 2003, PRHI convened a follow up summit as planned. The findings of the Legal and Clinical/Technical task forces were presented for discussion. Several action points came out of this meeting including the decisions to:

1. Go forward with implementing the initial pilot phase of the PHIN;

2. Secure a written statement of intention to participate in PHIN from health plans and laboratories by the end of August, 2003;

3. Form additional task forces to address more specific aspects of the pilot design (i.e. Finance Team; Report Design Team; Evaluation Criteria Team; Data Transfer Protocol Team.)

Securing Laboratory Participation

As it turns out there are well over 3000 registered diagnostic laboratories in the PHIN's 6-county target region. In order to identify a reasonable starting point for engaging these stakeholders while still capturing a critical mass of data, representatives in our working group from Highmark and Gateway health plans helped to identify which labs collectively processed at least 80% of their HbA1c tests. From this analysis, PRHI identified 32 labs that handled the vast bulk of the kind of tests most critical to the PHIN. Of these labs, two are commercial (Quest and LabCorp), one is independent, and the remaining 29 are hospital affiliated.

On July 22, PRHI held a Laboratory Summit for these 32 key labs: over 25 were represented by attendees. At this forum we engaged Lab Managers in a discussion of what PHIN could offer the community and asked what we would need to do to secure their participation. We learned that most hospital labs were resource poor and would find it difficult to dedicate staff time to long hours of programming to meet PHIN reporting requirements. We agreed to follow up with IT staff at each lab or parent health system to establish actual technical requirements for PHIN reports (see section on Data Transfer Protocols).

Securing Health Plan and CMS (Medicare) Participation

PRHI staff followed up with representatives of each health plan in the region (see columns below) to resolve concerns and invite a written commitment to the PHIN.

Highmark and Gateway agreed immediately to participate and signed a written letter of intent to submit data.

Commercial Plans	Medicaid Plans	Medicare
• Highmark Blue Cross Blue Shield • UPMC Health Plan • HealthAmerica • Aetna	• Gateway Health Plan • Three Rivers Health Plan • UPMC for You	• Center for Medicare and Medicaid Services

Aetna and Three Rivers indicated in writing that they would not participate in the PHIN at this time due to other resource priorities. Since these two plans held a relatively small percentage of market share we did not consider their withdrawal to be lethal to the PHIN.

UPMC and HealthAmerica continued to meet with PRHI representatives and to raise questions and concerns about PHIN's design and potential for success.

Efforts to identify current CMS policy on sharing data for regional quality improvement purposes met with difficulty. Via several channels, PRHI learned that there were only two circumstances under which CMS would grant the release of Medicare data for our purposes:

1) As a special project under WVMI's QIO contract, or

2) As a research or demonstration project.

WVMI's application to have PHIN considered as a special project was denied. And conversations with CMS directors in the demonstration division indicated that the PHIN probably would not fulfill the criteria for a successful demonstration project. Nevertheless, we were advised that what we sought was a policy issue, not a technical or legal issue and therefore the possibility for a pilot project with CMS remained a possibility as we continued working on other aspects of the PHIN pilot. For a more detailed history of PRHI's interaction with CMS on this issue, please see Appendix E: Memo Re: Background for CMS and PHIN, June 2004.

Chronic Care Summit II: Deeper into the Details, continued

Finance Team

The Finance Team began working on pricing elements of the PHIN and on exploring cost-effective ways to implement it. For

> **Concerns over patient privacy persisted among physicians, despite legal reassurances. Would "opt out" be visible enough for patients who might not want all their doctors to know of all their conditions?**

example, at one point we discussed the possibility of subcontracting part of the data management to MedPlus, a subsidiary of Quest Diagnostics. Although MedPlus had extensive experience in interfacing data and had already built an expensive Master Patient Index, Quest's competitors would opt out of the PHIN if it required sending data to Quest, no matter what safeguards were promised. We therefore resolved to remain with Quality Insights and WVMI as the platform for data processing.

WVMI estimated that a 6-month pilot would cost about $500,000 and that a full 3-year roll-out, including the pilot phase, could be accomplished for about $1.2 million. Ongoing maintenance costs for the PHIN, once established, were estimated at a modest $100,000 a year. For a breakdown of this estimated budget, please see Appendix J.

Report Design Team

A team of clinicians sat down with the AMA Consortium Performance Measures for diabetes (DM) and depression (MDD) and adapted their elements into a compact Individual Patient Report for physicians.

These report templates included graphing HbA1c values over team for at-a-glance assessment of glucose levels. They also included shaded data elements that the PHIN would not be able to populate (i.e. blood pressure, weight, etc.) but that would serve as prompts to physicians in providing consistent evidence-based care.

For final drafts of these individual patient reports for diabetes and depression please Appendices F and G.

A second team met to design a system of Aggregate reporting patterned loosely after Highmark's Smart Registry. This team did not produce a final product before the end of the PHIN project.

Evaluation Criteria Team

This team established two sets of criteria for evaluating the success of the PHIN. One set was designed for short term evaluation and focused on issues of functionality. The second set was designed for the long term impact of the PHIN and focused on issues of physician work processes and clinical outcomes.

To see the final products of the Evaluation Criteria team's work, please see Appendices H and I.

Data Transfer Protocol Team

This team consisted of stakeholder representatives with expertise in Information Technology. WVMI set up and hosted two electronic listservs: one for IT reps from participating health plans and one for reps from participating labs.

The listservs offered forums for identifying data transfer protocols already in use for other reporting requirements and helped to discuss and identify the best protocols to use in transmitting the date requested by PHIN.

# Ongoing Issues and Design Changes

Patient Authorization

One of the most common concerns PRHI heard from health plans revolved around the issue of patient authorization for sharing data across multiple treating physicians. In spite of the legal reassurances we had acquired (see Appendix D), many data providers felt that the "opt out" design was not a powerful enough protection against patients who would not want their PHIN data seen by all treating doctors (i.e. perhaps a patient who sought psychiatric counseling would not want his or her PCP to know of this condition; or perhaps a patient seeking a second opinion or wishing to change physicians would not want this known to his or her original doctor).

However, the PHIN designers in our working group also asserted that to require individual authorization from each patient for his or her data to be included in the PHIN represented prohibitive design problems. First, data providers would have to maintain records of who had opted in adding to the burden of participating in the PHIN. Second, the difficulty of acquiring active consent from every patient in the region would reduce the data flow into the PHIN to a trickle. This in turn would discourage physicians from drawing on the tool.

As a compromise that would satisfy both functional demands and constituent concerns, we developed an "opt-in" model which asked for patient consent at the point of data extraction (as opposed to data submission). In other words, no patient consent would be required to submit patient data to the PHIN. However, explicit patient consent would be required before a physician could pull down data from other physicians.

The default design is that data will enter the PHIN and be sorted by the master patient index (MPI). If a physician user calls up a patient's data without gaining consent from the patient, he or she will only be able to pull down the data already generated by his/her own practice (i.e. his/her own office visits, tests ordered, medications prescribed). In this form,
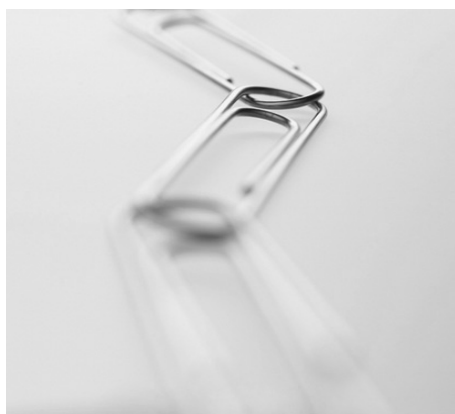
the PHIN simply repackages data already available to the physician in an organized easy-to-access format.

The PHIN becomes a much powerful tool of coordination if a patient gives his or her physician permission to access data from other physicians providing treatment. Under the revised design, patients would be able to fine-tune this consent to some extent: for example they could choose to release their diabetes data for sharing among physicians, but not their depression data. More

sophisticated options could be developed in time where patients could go on-line themselves and specifically direct which data they wish which physicians to see.

In the PHIN's revised design, physicians requesting a patient's individual data would encounter a screen asking if patient consent has been given. The PHIN would track keystrokes to maintain records of who has accessed each patient's data. Physician offices would have the responsibility to keep their own records on patient consent. WVMI legal counsel assured us that verbal consent is sufficient under HIPAA, but PHIN would recommend that physicians keep a written record for added security. In the future, patient consent could be given via health "ATM" cards with pin numbers.

Once a patient in the region opted in to data sharing at the point of care, the confidentiality switch on their record in the PHIN's Master Patient Index would be de-activated and other treating physicians would not encounter the screen requiring patient consent. Thus a patient would only need to opt in once to the PHIN, rather than at each of his/her physician's offices.

A public education campaign would inform patients of PHIN, its purpose, and its intention to improve coordination of care by allowing physicians to access other physicians' data. This campaign would include media coverage, advertisements, notices from health plans, and notices in physician practices. PRHI would

Ongoing Issues and Design Changes, continued

also provide participating physicians with talking points to explain aspects of the PHIN directly to patients.

Lab Data

Another design change in how the PHIN planned to solicit lab data came in response to a discussion on the lab Data Transfer Protocol listserv.

We had assumed that it would be easiest for labs to simply dump all of the seven diabetes-related test results requested by the PHIN and let Quality Insights match the data to identified diabetics and delete the remaining lab data. However, one lab representative pointed out that this could be seen as contrary to HIPAA guidelines in that it involved sharing more than the necessary data.

We therefore adjusted our design to query each lab for data on a list of identified diabetic patients furnished by the PHIN from claims data. Although this would require more programming work for labs and would add a small delay to the posting of lab data, it satisfied stakeholders' desires to stay strictly HIPAA compliant.

Centralized versus Distributed Models

As PRHI developed a working model for the PHIN, staff paid close attention to developing models in other regions. Some of the areas in the United States publicizing work on regional or statewide data networks included Delaware, Santa Barbara County, Indianapolis and others. We also encountered the Patient Safety Institute (PSI), a nonprofit trying to establish a viable scalable model for the nation based on the organizational premises of

the VISA corporation.

We soon realized that none of the other models included a central database like ours. Out of concern for compatibility with national networking efforts (i.e. the federally supported National Health Information Infrastructure), we carefully evaluated the pros and cons of our centralized model versus other's "distributed" models. (See table, opposite page.)

We concluded that the PHIN had many advantages and that it would not be incompatible with distributed models that would likely emerge to connect greater pools of medical data in the future of SW PA. The PHIN could simply become a data source alongside hospitals, labs and other data providers in a broader distributed network.

Funding

PRHI explored several avenues for grant funding to launch the PHIN. However, co-founder Paul O'Neill discouraged pursuing these outside infusions of capital until we had established a model for fiscal sustainability: our community should invest in and "own" this resource. We needed to work out a model for maintaining the PHIN on an annual basis or the PHIN would likely lose steam when the initial grant expired. We planned to convene the principle stakeholders and find a way to distribute the cost of the PHIN across the beneficiaries of the PHIN. We hypothesized that many constituents in the region stood to benefit from the PHIN (health plans could see reduced health care costs with improved preventive care, laboratories could see an increase in lab tests as more patients receive consistent chronic care, employers could see an increase in

productivity among employees with chronic conditions and reduced health care costs, and SWPA residents could enjoy better health and well-being outcomes).

We began plans for a stakeholder meeting to develop this model but never convened it due to critical questions over CMS and other health plan participation in the PHIN.

A "Technical Feasibility Pilot"

While we worked on resolving the ongoing concerns of CMS and UPMC engagement, other aspects of the PHIN pilot were well under way. In June 2004, we decided to move ahead with a modest small-scale pilot designed to test the technical feasibility of our design with committed data providers: the two health plans of Highmark and Gateway and the two commercial labs, Quest and LabCorp.

WVMI staff had by now designed a web interface for the PHIN that was ready to go live with real data. We successfully fine tuned the necessary data transfer protocols and transmitted data into the PHIN. We also secured the cooperation of three physician practices to query the PHIN and help debug the system as well as fine tune it for user friendliness and clinical utility.

PRHI invested about $30,000 of its own operating funds to purchase a dedicated server and to pay for initial programming. WVMI had already invested many hours in designing the PHIN and the web interface. For a detailed budget of this technical feasibility pilot, please see Appendix J.

Medical Data Exchange
Centralized versus Distributed Model Comparison

Centralized Model (current PHIN design)	Distributed Model (Patient Safety Institute design)
Discrete data amounts = lower liability risk and lower cost investment required for data providers	Comprehensive data requires greater commitment from data providers; may slow down their rate of commitment
Discrete data amounts make it a less powerful tool for physicians who will have to look elsewhere for non DM and MDD data; slows likely rate of adoption among user	Comprehensive data make it a much more powerful tool to physician users; increases likelihood of adoption and dissemination among users in the long run
Data can be centrally collated and presented in uniform format to physician users regardless of data source	Some models (i.e. Indianapolis) require normalized standards to feed data through central hub which creates more work for data providers; models which do not require normalization (i.e. PSI) can be established more quickly but leave user with disparate data reports from multiple sources
Patient registries and aggregate reports can be queried very quickly from central repository	Queries for registries and aggregate reports would be slower
Easier to run quality improvement analyses on central database; easier system to evaluate progress and success	Data analyses for evaluation of quality improvement would be slower/more complex; less accessible to public health research
Can be integrated into a PSI model eventually as a chronic disease report data source feeding reports to users through central hub	In keeping with national trends for community data exchange programs; would be poised to eventually integrate into national health information infrastructure (NHII) called for by HHS
Can probably implement a pilot project in a few months	Time for implementation dependent on multiple other organizations; likely to take another year of planning/negotiating

Intransigent Barriers

Incompatible Policy Environment

When we began the PHIN project in 2003, it gradually became clear that CMS had not yet developed a coherent policy on releasing Medicare data to regional data sharing projects designed for quality improvement. Not until mid-2004 did CMS policies begin to emerge moving away from regional registries and toward the adoption of individual EMR technology in each physician practice.

This is of course a sound policy. The PHIN was always intended as a temporary fix for a region with very little Information Technology in physician offices. If every practice managed its own database, it would be more powerful and complete than what the PHIN could offer. PRHI understands the value of disseminating EMRs to every practice, but also recognized the long timeline involved in achieving this goal and designed the PHIN to improve the care of devastating chronic diseases in the interim years.

We believe that a major reason for hesitation among some of the data holding stakeholders in our region was

an immature policy environment when it came to data sharing across competing institutions for community benefit. HIPAA was untested in the courts and organizations preferred to err on the side of caution. And there were no national standards for electronic data sharing. UPMC, for example, had already invested over half a billion dollars in its own standardized electronic network for its sprawling health system—a significant and challenging undertaking—and was exploring options to market what they had developed.

It was after the PHIN had been conceived and designed that President George Bush appointed David Brailer to the position of National Health Information Technology Coordinator in order to lead a coherent national policy toward electronic medical data networks.

Pulling the Plug

By January 2005, it was increasingly clear that CMS and UPMC would not be engaged in the PHIN, leaving a critical shortfall in Medicare and laboratory data. Rather than investing any further resources in a "technical feasibility" pilot that was unlikely to become actively used in the community for patient care, PRHI decided to shut down the pilot and end the PHIN project.

> The PHIN was always intended as a temporary fix for a region with very little Information Technology in physician offices.

The PHIN Legacy and the Future of Regional Data Networks

The learnings from and relationships forged during this two-year process are nevertheless extremely valuable. PRHI has already consulted with other organizations seeking to connect medical databases for clinical use.

Much of the groundwork that was laid by PRHI and WVMI in building the PHIN is now being parlayed into an even more comprehensive and powerful Information Technology effort currently under way in the state

of Pennsylvania: the Pennsylvania eHealth Consortium.

AHRQ 15 Grant

In early May 2004, with only a six week lead time until the deadline,

AHRQ issued an RFP (#15) for "State and Regional Demonstrations in Health Information Technology". AHRQ planned to contract with only 5 states (or regions with state-wide support) who could demonstrate:

"evidence of a significant and statewide planning process in health information technology and data exchange. The planning process must have included multiple stakeholders, addressed technology needs (including infrastructure and data exchange), identified methods to improve safety and quality of care, and designed a strategy to ensure sustainability of the data exchange enterprise… It is expected that the resulting contracts will build upon ongoing state/regional interoperability efforts. These contracts are intended to leverage on-going efforts and investments of multiple partners in states and regions to create data sharing and interoperability health information systems."

PRHI understood that this AHRQ solicitation was designed specifically to bypass the usual academic review process for grants and to channel funds directly into building the infrastructure of 5 key states from which at least one successful and viable national model could emerge. Given the design work and relationships that were already built around inter-system data exchange issues in Pittsburgh, PRHI and WVMI believed that Pennsylvania would be competitive in an extremely small field of likely applicants. We also recognized that it would be advantageous to PA to build this electronic infrastructure sooner with (1) federal funding support and (2) a

chance to shape the design of the model the nation is likely to adopt, rather than later when seed funding would no longer be available and a viable model developed by other states would already be in place.

A core number of organizations joined PRHI in developing a proposal, including Quality Insights of PA, the Patient Safety Institute (PSI), the Hospital and Healthcare Association of PA (HAP), and the PA Medical Society.

We proposed Pittsburgh as the region to host the first data exchange hub, with the goal of rolling out the model to other regions of PA as soon as possible in subsequent years.

We also endorsed Quality Insights of Pennsylvania (QIP) with its statewide presence and its quality improvement mandate to be designated the "agent of the state" and act as prime contractor with AHRQ.

We began talks with State Secretary of Health Calvin Johnson and Director of the OHCR, Rosemarie Greco, to explain the opportunity we saw and sought the participation and support of other key organizations and data providers (i.e. PHC4, the Patient Safety Authority, Business Groups on Health, major hospital systems, commercial laboratories, etc.) around the state.

Finally, in conversations with sources close to the AHRQ RFP process, we came to understand that our state networks had not yet reached the level of maturity that this grant was designed to leverage and decided not to pursue the grant further.

Our efforts to launch a statewide network capacity based on what we

learned with the PHIN, however, laid the groundwork for an exciting current initiative.

The Pennsylvania eHealth Initiative

In March 2005, Quality Insights of PA and the PA Medical Society co-hosted an initial stakeholder meeting for something informally called the Pennsylvania e-Health Technology Consortium. At this meeting in Harrisburg, 28 health-related organizations affirmed a desire to launch a statewide data network or Regional Health Information Organization (RHIO) as called for by David Brailer and the national IT initiative. For the press release issued on this first meeting please see Appendix L.

If this consortium is successful, then the goals of the PHIN will be accomplished and patients can expect to receive more consistent, coordinated evidence-based care for their chronic conditions.

Appendices A-L

The appendices to this report are attached as a separate document.

Pittsburgh Regional Healthcare Initiative

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WHO WE ARE...

PRHI is a consortium of the institutions and people who provide, purchase, insure and support healthcare services in the region. Our partners include hundreds of clinicians, 42 hospitals, four major insurers, dozens of large-and small-business healthcare purchasers, corporate and civic leaders, and elected officials. Our goals are:

* Achieving the world's best patient outcomes by

* Creating a superior health system, by

* Identifying and solving problems at the point of care.

Through our efforts, we believe we will address many of the challenges facing health care across the country. These challenges—rising costs, frustration and shortage of healthcare workers, financial distress, the malpractice crisis, overcapacity, and lack of access to care—share a common cause and can be addressed when the healthcare system begins to focus solely on the needs of each patient.

WHAT WE'RE TRYING TO ACHIEVE...

We are working to achieve perfect patient care in more than a dozen counties in the Pittsburgh area using the following, patient-centered goals:

* Zero medication errors.

* Zero healthcare-acquired (nosocomial) infections.

* Perfect clinical outcomes, as measured by complications, readmissions, infections and other patient outcomes, in:

    -- Coronary artery bypass graft surgery.

    -- Critical care and emergency medicine physicians.

    -- Chronic conditions: depression and diabetes.

OUR GUIDING PRINCIPLES

PRHI emerged out of the community, based on a few fundamental principles upon which everyone can agree:

* Respect and dignity for everyone.

* The opportunity for healthcare workers to succeed in doing meaningful work and to have it acknowledged.

* Neutral collaboration among all stakeholders.

* Improvement based on scientific methods, applied to every patient every day.

Through PRHI, we are beginning as a region to track:

* Which processes of care are most likely to propel patients to complete recovery.

* Whether our system allows us to learn from problems, improving healthcare delivery processes quickly, frequently and at low cost.