

Evaluation Report on 9 Funded CCBH Projects

Final Report

January 12, 2006

Prepared for
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This report was made possible by grant number 1D1BTM00095-01 and 02, through the Health Resources and Services Administration HRSA Office of the Advancement of Telehealth (HRSA/OAT). The contents are solely the responsibility of the authors and do not necessarily represent the official view of HRSA/OAT.

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1.0 Background

Communities across the country are mobilizing information across organizations through multi-stakeholder collaboratives made up of a broad range of constituencies. The Foundation for eHealth Initiative (FeHI), in cooperation with the Health Resources and Services Administration (HRSA) Office for the Advancement of Telehealth (OAT), launched a program in 2003 called Connecting Communities for Better Health (CCBH). The main purpose of the CCBH program is to develop, share and disseminate knowledge, resources and tools to facilitate and support community-based health information exchange.¹

The CCBH Program includes an online resource center and nine funded projects (additional projects may be funded in the future). These nine projects are dynamic and have undergone a variety of changes in scale, scope and schedule in the months since their FeHI awards. The CCBH also convenes a national Learning Forum and fields an annual survey of health information exchange organizations. The program's overall objectives include: learning from the efforts of early programs, sharing successes (and avoiding the repetition of unproductive approaches), and generally moving the field forward.

The CCBH evaluation activities are focused on the overall goals of the CCBH Program, which are to:

- provide input and guidance from community-based collaboratives to the strategic goals, objectives, and outputs of the eHealth Initiative and its Foundation.
- develop practical, actionable work products and strategies, with special focus on connectivity and interoperability, to improve the value proposition of community-based health information exchange (HIE).
- increase adoption of HIE products and services to support community-based collaboratives' efforts to improve the quality, enhance the safety, and increase the efficiency of healthcare delivery.
- create a forum and engage in dialogue with existing and newly forming community-based collaboratives to share best practices and lessons learned.
- help develop the core body of knowledge about HIE successes, failures, and lessons learned to further more widespread adoption of HIE approaches and associated HIT tools and technologies.

FeHI expects that several outcomes will emerge from the Program including: an assessment of the current state of HIE initiatives and organizations; the documentation of lessons learned and best practices from a wide range of states, regions and communities; a set of common principles, policies, standards and supporting guides to help stakeholders address the organizational, legal, financial and technical aspects of HIE (including evaluation tools); and insights that will support the development and enhancement of policies by leaders within the public and private sectors.

It is important to recognize that every "seed money" program like the CCBH attempts to identify projects with strong prospects for success, but that not every project will in fact succeed. Some will engage in a careful planning process and conclude that the time is not right or the project not feasible – this recognition could itself be considered a successful conclusion of the planning process. Other projects may conclude that their vision is feasible, but they cannot consummate the relationships

¹ <http://ccbh.ehealthinitiative.org/>

required to make it happen, particularly in today's competitive health care environment. It is therefore to be expected in a field as new as HIE, there are likely to be projects that cannot proceed to their intended conclusion and others that can, and timeframes are likely to vary considerably. FeHI staff recognize these challenges and work closely with their nine CCBH communities to appraise the realism of plans and, when necessary, realign objectives and schedules. In addition, FeHI's own funding mechanisms require that their CCBH awards are fairly short (12 months), which is a realistic timeline for progress for some HIE initiatives but not for others.

1.1 Report Organization

This report is organized as follows:

1. Background
2. CCBH Project Progress and Status mid-2005
3. CCBH Project Designs, Objectives and Vision
4. CCBH Evaluation Plans

Attachment A: Evaluation Tools and Guidance

Attachment B: Checklist for Evaluations

Attachment C: Summaries of Nine CCBH Projects

Summaries of each of the CCBH projects, which reflect a snapshot in mid-2005, appear in the appendix to this report. Chapters 2-3 of this report discuss the current status (mid-2005) of the nine CCBH projects and their plans for the future.

1.2 Scope of Work

It is important to evaluate CCBH activities, especially the progress to date of the nine funded projects. Most of the nine are in an early or formative stage of development and in some cases FeHI funding was essentially for planning;² these young projects have not undertaken evaluation of their successes to date because no data sharing is yet occurring (or was expected to have occurred), and they are therefore just beginning to design evaluation strategies for the future. Others of the nine are sharing data and have more robust evaluation strategies in place. FeHI contracted with Abt Associates to assess the CCBH projects' evaluation work to date, and to develop evaluation tools and guidance for these projects and others like them that FeHI may fund in the future.

From an evaluation standpoint, FeHI recognized that it is also critical that the nine programs lay the groundwork for successful individual evaluation of their contributions/impact in terms of improving the delivery of efficient and high quality medical care. This groundwork includes measuring the scale and parameters of problems each of the nine is trying to address, so that progress and change can be documented in the future.

Abt was asked to work with the funded communities to help them identify their evaluation plans based on project goals and objectives and measurement of short-term impacts. Abt's efforts were to:

² The appendix to this report contains summaries of the nine CCBH projects.

- Advise FeHI regarding evaluation design, baseline data collection, and measuring non-monetary benefits.
- Help specify the questions that the projects could/should ask; how the communities could answer these questions; and identify proposed measures for success, as well as the correct data collection strategies for this success measurement.
- Assist in developing indicators of long-range impact, extending beyond the scope and timing of the FeHI projects.
- Build tools that can be applied by communities undertaking activities and projects similar to those of the 9 CCBH funded communities as well as a tool to help communities decide which evaluation tools to use based on their project objectives and level of (HIE) development and maturation.
- suggest tools and guidance that addresses the varying stages of HIE development, to provide communities working in this field a starting point for creating formative and impact evaluations.

1.3 Methodology

Materials about the nine current CCBH projects were assembled by FeHI and forwarded to Abt Associates for review. Telephone conversations were scheduled with each of the nine and an email was sent to them in advance, posing the following questions to be discussed:

1. What specifically do you expect your project to accomplish, in terms of improving care, reducing costs or other benefits? What are your project's benefits likely to be? (This should be the 'big picture' vision for your work, not limited to the portion funded by FeHI.)
2. Given these anticipated benefits, how will you know if you are successful – what objective changes do you expect to see (e.g. faster referrals, fewer drug-drug interactions, fewer 'unread' radiographs, reduced costs for photocopy and transcription)?
3. How quickly would you expect to see these anticipated benefits – one year, two years, more?
4. What stage are you at today? Have all the necessary participants agreed to perform their roles on the project? Has your system been installed and tested? Has outreach to providers begun?
5. Do you have an evaluation plan that details how you plan to measure the benefits you anticipate?
6. Are there any 'pre' data against which improvement can be measured? For example, if you are aiming for faster referrals, do you know the current referral lags? If not, can these data be collected? Or are there any benchmarks from other places that could be used for comparison purposes?

7. To what extent can clinicians choose to use your system (or not)? Will clinician reluctance/acceptance make or break the system? How do you plan to demonstrate value to clinicians to get their buy-in?
8. How quickly can clinicians be trained and brought online – will some groups/facilities start using the system before others? Could the early-adopters be considered an ‘experimental’ group, to be compared with others who have not yet begun using the system?
9. Does your system use technology (software especially) that already exists and is somewhat standardized, or are you creating new technology essentially from scratch? If the latter, why did you find this necessary and what additional functionality is being added that improves on standardized, off-the-shelf products?

Telephone conversations were held in May and June 2005 with each of the nine project directors, sometimes with several CCBH project staff attending, to discuss these issues. Each CCBH project director was asked about the ultimate vision and objectives for their project (not limited to the specific funding provided by FeHI), how far along they were as of mid-2005, and how they planned to measure progress toward their objectives. Specific evaluation plans were discussed when appropriate, as were operational plans and activities for the coming months.

1.4 CCBH Project Summaries – Spring 2005

Summaries of the discussions with the nine projects were created by Abt and forwarded to each for their review and comment; several made minor edits or offered comments and the summaries were revised and appear in the Appendix to this report. The status of each of the nine is shown briefly here, to indicate the diversity among these programs in terms of their visions and status in mid-2005:

Wisconsin Health Information Exchange – NIMI: NIMI’s vision is that their HIE, while not being the main care-improvement agent, will “empower” improvements in care. Phase 1 is a demonstration/pilot aiming to create common access for a few users from three HIT user groups: emergency departments, public health officials, and primary care practices. There won’t be any applications tested in the pilot; they’re testing the access and user interface. Phase 2 will be implementing HIT projects on an incremental pay-as-they-go basis (i.e. not funded by the user fees); each project will need separate funding and a separate evaluation.

Regenstrief: This HIE uses a 2-stage model: Stage 1) The entire state was included all at once in electronic interface for state laboratories, PBMs and third party electronic claims; some of this has already been completed. Stage 2) The HIE will roll out clinical applications to providers over the next few years. They want to make clinical messaging and lab results available to physician practices, whether or not they have an EHR. The HIE staff do want to bring clinical messaging and lab results to all practices, but they do not plan to try to bring EHRs into physician offices – they will supply the connectivity/interface to the data, not the EHR itself.

Santa Barbara County Care Data Exchange (SBCCDE): This HIE intends to improve patient care by offering data to providers at point-of-care; they hope to reduce costs at the same time by eliminating redundant lab tests that often result from delays in information transfer (clinicians repeat tests because it takes too long to get results from one provider to another). SBCCDE has recently completed work on myriad complicated legal and contractual issues, licensing and relicensing vendor products, etc. They have completed the technology design, testing, security, data validation audits, etc. and really don’t see technology/connectivity as an important barrier. In the fall of 2005 they expected to begin deployment, starting with 10 physicians and their office staff. They are not creating

a full EHR, but rather are pulling clinical measures (lab results, radiology, discharge summary notes, etc.) from existing electronic systems. They'll be creating provider-specific data repositories, and these in turn will be linked to share clinical measures.

Whatcom County Health Information Exchange - St. Joseph Hospital Foundation: This HIE has been working for over 10 years to create a model of seamless care across Whatcom County. It began with the technical infrastructure (Intranet based) which connects hospitals, SNFs, physician practices, health departments, labs, the medical society and emergency services. Applications/Services to date include:

- Hospital electronic medical record
- Patient chronic disease registries
- Transcription
- Electronic Medical Records (EHRs) for some specialties (geriatrics, nephrology, OB/GYN)
- Medical journal subscriptions via hospital libraries
- Digital images online.
- Hospital-Skilled Nursing Facility data shared for discharge planning/SNF placement.
- Helpdesk and LAN consultation
- They expect to add E-prescribing in the fall of 2005.

Maryland/D.C. Collaborative for Healthcare Information Technology: The Maryland/DC Collaborative includes providers who normally consider themselves competitors, or as not serving the same market. Community physicians have been seeking faster turn around of hospital information so that when patients are discharged the community PCPs know what happened in-hospital (what drugs the patient was on at discharge, lab results, etc.) The system they are designing is not a linked EHR; instead they intend to make providers' existing data systems interoperable so the HIE can quickly pull a core set of data from a provider's existing EHRs when a patient moves from one care setting to another. At this point, the biggest effort is to define exactly what measures will be included, balancing reporting burden and clinical utility.

Tri-Cities TN / VA CareSpark: This HIE is working to improve care of diabetes, heart disease, asthma, COPD (chronic disease management), and to improve screening and immunizations. By meeting the data needs of payers and providers, they hope to encourage full use, with the downstream benefit of being able to access complete data on health indicators and encourage adherence to clinical guidelines. Phase 1 will be data collection about care indicators/quality (e.g. HgA1C testing) and QA efforts. Phase 2 will offer decision support tools that go beyond providing information and bring in 'reminders' to clinicians about what needs to happen when a patient comes for care. Phase 3 would permit querying of records to target efforts for health improvement. If patients in a particular county or a particular physician practice are not getting care consistent with guidelines, there may be need for enhanced clinician educational efforts.

Massachusetts Simplifying Healthcare Among Regional Entities (MA-SHARE): The initial pilot project was to automate the transmission and communication of prescription history to emergency departments. The pilot was too small to detect a clinical impact, but did succeed in demonstrating that the capability of prescription information in EDs is too limited to be of "stand-alone" value and a much broader tool will have greater potential for clinical care improvements. The HIE therefore revised its plans for the future. In the short-term, the HIE will be the community's centralized governing entity with IT resources, vision, and contracting expertise for all interested health plans and providers in the region. They will bring together the various vendors, technologies, etc. into an interoperable gateway so that the individual providers will not have to embark on their own "one by

one” time consuming and varying levels of expertise decision making. The HIE will provide the clinical connectivity “grid” to link existing disparate EHRs and clinical information.

Colorado Health Information Exchange (COHIE): COHIE is a statewide coalition that will eventually create a non-profit entity to establish business rules, technology standards and governance for Colorado’s health information exchange. Their vision is to share clinical data among providers across their entire rural state. They want to build a viable prototype to test technology and clinical utility, in four initial institutions. The prototype (fall 2005) will establish a master patient index where the four partner institutions will test and refine secure messaging protocols and methods to assure confidential demographic data exchange. Statewide they expect to start with hospitals and rural community clinics, as well as payers, laboratories and pharmacies that already have electronic data systems in place that can be readily interfaced.

Taconic Health Information Network and Community: This program has a community-wide data exchange that interfaces hospitals, labs, physician practices and pharmacies. They are active in 2 counties at this time, working with 4 of the 5 hospitals, 1 national reference lab, 500 physicians (250 daily users). The goal is to eventually scale up to 4-7 counties to address the following constituencies:

- Small physician practices without electronic health records or much technology. Will introduce them to technology, help them get connected and started. E-prescribing and clinical messaging will be the first step, and then an EHR will be offered.
- Practices that are ready for EHRs, but don’t yet have them. The small physician groups will be offered a subscription model with a monthly fee and lower up-front costs. This should begin in 2006, and will be offered by MedAllies, a sister company of Taconic IPA.

Next steps include:

- Move toward EHRs for all providers with low fees to minimize costs to each practice
- Develop incentive program.
- Explore Eprescribing.

1.5 Project Management Feedback and Evaluation: A Continuum

During discussions with the nine CCBH projects in mid-2005, many project directors reported that they were in the early planning and coalition-building phases of their projects. At this early stage they saw evaluation as being premature and anticipated focusing on evaluation when data sharing begins and there are changes or interventions to study. Some have held preliminary discussions with academic colleagues regarding future evaluation of their HIE initiatives, but most do not see a role for evaluation in the planning, coalition-building, and IT development/testing phases of their projects.³

Abt researchers believe that meaningful evaluation begins at the very start of a project. A comprehensive evaluation strategy involves articulating specific goals for each step of a project – including the planning phase – and measuring effectiveness in reaching each goal. Evaluating the effectiveness of planning and early testing is sometimes referred to as formative evaluation: collecting information to guide program development and improvement. For example, project staff may have a clear concept or vision of what they hope to accomplish (and for which they’ve been funded). An early planning task could be achieving consensus about this concept among all relevant participants and may want to know whether in fact all participants agree (“buy in”) to the main concept of the HIE. To be sure that this is the case, project managers could explicitly ask relevant participants

³ This may be a matter of terminology – the meaning of ‘evaluation’ may not be the same for all the CCBH projects.

whether they agree with the basic concept or vision for the HIE – and identify any who do not. Even at a very early stage, this sort of feedback could help to identify areas of disagreement and lead to rethinking of the HIE concept and purpose, to align it more closely with the needs and objectives of all constituents. Early information gathering and explicit feedback can also be helpful as projects approach funding agencies for additional resources. Having concrete evidence that an HIE concept is accepted and supported by all relevant constituencies is a good foundation for success; the absence of such evidence weakens the case for additional funding.

Measuring impact, also referred to as summative evaluation, is the rigorous measurement of program performance to determine if specific objectives were met. This usually involves a formal research design, baseline and repeated data collection, and statistical analysis.⁴ This in turn implies that the nature and scale of problems have been measured before any data sharing occurs (e.g. frequency of redundant lab tests) so that change can be documented. This is the part of evaluation that many projects see as an end-product of their work, to be considered only after data sharing begins.

We see the evaluation process as a continuum, beginning with project planning and concept testing (formative evaluation), and culminating with measuring impact (summative evaluation) of key outcomes like cost, timeliness and quality of care. Project managers benefit by applying a disciplined approach to setting objectives and gathering data at every phase of a project; at each step they will have specific metrics of success to aim for, and can base decisions on concrete information. It is also important to emphasize that the process of stating objectives and measuring success is dynamic. As objectives are revisited and perhaps altered or scaled back, metrics of success may also need to be revised. Both for the sake of project staff, and for accountability to funding agencies, it is important to acknowledge change and adhere to current objectives and measurement plans.

The CCBH project directors appear to be planning (eventual) impact evaluations; it is not clear that they are equally focused on stating objectives and gathering data to measure success in the planning and testing phases of their projects. Perhaps they are in fact gathering information that reflects on the success of their planning activities, but not in a systematic way. Only one of the nine CCBH projects, for example, is explicitly querying participants about the success of the planning process. To help project directors build data gathering and success metrics into all phases of their projects, Attachments A and B of this report have been developed and ask a series of feedback and evaluation questions that start at the earliest planning phase.

1.6 Evaluation Matrix

During discussions with the nine CCBH projects, it became clear that there are at least two important dimensions to be considered when evaluating projects like these: the ultimate vision each project has for its eventual role, and each project's current stage of development or maturity.

We created the following Evaluation Matrix as a structural framework showing two dimensions of HIE projects: their phase of development (columns) and their "vision" of for their unique role in promoting health information sharing in their communities (rows). The developmental phases go in sequence and it does not appear that any CCBH projects intend to skip any of the stages. Some are working through the early planning stage of their projects while others have been sharing data for years. The vision/role rows are also somewhat sequential, although it is not necessary to move through each before tackling the next. Some projects have a vision that extends only as far as creating the legal, business and IT infrastructures necessary for a Health Information Exchange

⁴ See Rossi, Freemant and Lipsey Evaluation: A Systematic Approach, 6th Edition, Sage Publications 1999, page 36.

(HIE); they do not see their role as creating or promoting specific clinical tools. Others eventually intend to offer clinical tools for data sharing (e.g. electronic health records or prescription information that span the hospital-to-community continuum of providers) to improve the quality and continuity of care. Some expect to drive change in clinical care processes through pay-for-performance or other means, and improving population health status is the vision of others. Note that this dimension of the matrix describes the eventual vision each of the nine holds for itself, not what they expected to accomplish with their one year of FeHI funding. For example, a project that plans to eventually use pay-for-performance leverage to promote clinical process change could have been funded by FeHI for their early planning phase; in 2005 they would be in the last row of the matrix, and the first column.

In each cell in the matrix, an appropriate level of evaluation activity is suggested, ranging from needs assessments and concept testing, to feedback on project planning, small scale impact evaluations of pilot tests, and complete evaluations of changes in key measures of outcomes of care after projects are fully implemented. As this matrix indicates, regardless of where in its life cycle a project is (or how far it gets with its early funding cycles), managers can specify metrics for success and measure whether they have achieved the objectives relevant for their phase of development.

Evaluation Matrix⁵

		Project Phases		
		Planning Phase	Pilot/Early Implementation Phase	Full Implementation Phase
Project Vision/Objectives	Creating Collaboratives and Business Models (Partners, Governance, Vendors, Financing, Legal Issues)	Needs Assessment, Consensus Development, Planning Feedback		
	Planning and Building IT Infrastructure (security, connectivity, distributed technology, unified IDs, services)	Existing Functionality & Needs Assessment, Consensus Development, Planning Feedback	User Testing and Feedback, Planning for Technical Support	Measuring Ongoing User Needs and Adequacy of HIE Support
	Creating/Offering Centralized Clinical Tools , e.g. EHRs, eRx	Concept Consensus Development, Planning Feedback	Small Scale Impact Evaluation and Baseline Data Collection	Impact Evaluation
	Changing Clinical Processes/Efficiency (pay-for-performance, other incentives)	Concept Consensus Development, Planning Feedback	Small Scale Impact Evaluation and Baseline Data Collection	Impact Evaluation
	Measuring Improvements in Clinical Outcomes, Population Health	Outcome definition, Planning Feedback	Small Scale Impact Evaluation, and Baseline Data Collection, Redefinition of Outcomes	Impact Evaluation

⁵ Needs assessments involves identifying problems and barriers, and the specific needs of participants, so that the HIE is creating a solution that meets real needs.

Concept testing means developing a solution and working with participants to determine whether it is likely to meet their needs. This can be an iterative process.

Planning feedback creates two-way communication and a feedback loop between the HIE planners and the participants in the community, so keep planners focused on addressing community needs before undertaking system implementation.

Small scale tests of impact begins with baseline data collection and then implements the solution(s) on a small scale, to determine whether the expected changes do in fact occur.

Full impact evaluation employs a rigorous evaluation design to test for statistically significant changes in the previously-identified problem areas.

2.0 CCBH Projects' Progress and Status, mid-2005

FeHI was the first and only funding source for a few of these nine projects; others had previous funding (some for a decade or more) or received additional funds from other sources during the year of their FeHI contracts. As a result, several projects' priorities and plans – and their progress – were driven by the requirements of their other funding sources, in addition to FeHI requirements. Some of the nine projects did not expect to share data within the first year of FeHI funding; their FeHI funds were explicitly intended for planning and organizational development. Others were already sharing data or expected to do so within the year. At the time of their interviews with Abt in mid-2005, the nine CCBH projects were therefore in various stages; those that received their initial funding from FeHI were in the earliest phase and those that existed previously and were already sharing data when they received FeHI funding, were more advanced.

2.1 Planning Phase

As of mid-2005, four of the nine CCBH projects can be described as being in, or nearly finished with, the planning/design phase of their projects (column 1 in the matrix). The planning phase for these projects included developing governance structures, arranging contracts among community stakeholders and participants and with vendors, addressing legal and risk issues, addressing privacy and confidentiality concerns (which were substantial for several projects) and in at least one case, working with regulators (i.e. the Maryland Community Services Reimbursement Rate Commission). Planning also began on IT/infrastructure development and assessing end-users' hardware and software capabilities; working with vendors to achieve interoperability so that all end-users could participate regardless of their hardware and software systems; and trying to make system use as simple and straightforward as possible for end-users. Some projects began considering specific clinical applications, tools or data elements to be shared within their HIE initiatives.

Some, but not all projects in the planning phase were developing business plans with the potential to be self-sustaining. Others were not yet ready to create business plans and intended to continue their planning using additional start-up funds (public and private) with the intent to develop sustainable business plans in the future. At least two of the nine projects had created very detailed business plans that involve payers sharing some anticipated gains in order to expand technology and connectivity to remote providers. Most of the projects, however, had not yet begun working with payers or others who have a financial interest in HIE as a tool to enhance productivity or reduce costs.

In terms of gathering feedback on the planning phase, one project is assessing participants' satisfaction with various planning activities, using a Likert-scale survey. The other projects did not mention any formal feedback on their planning activities such as systematically measuring participants' acceptance of planning activities, and instead will be relying on informal feedback from participants.

2.2 Pilot/Early Implementation Phase

Four of the CCBH projects are in the early implementation or pilot phase (column 2 in the matrix). They are early in the process of rolling out technology and data sharing to a limited number of participants and their first users are essentially test sites. Testing IT systems and interfaces is being pursued first by some projects, which prefer to work out any IT issues before initiating actual data sharing. Other projects see the IT issues as straightforward and are combining testing of their IT systems with testing of clinical applications and data sharing. With one exception, the projects do not appear to be contemplating collecting systematic feedback on users' satisfaction/concerns regarding

IT interfaces or early data sharing; most will use anecdotal information from users to work through any problems end-users experience with the systems or data sharing. At this stage, most are concerned with making sure the interfaces and data sharing “work”, rather than measuring what users like or dislike about their interactions. Again, most are relying on informal feedback from early (pilot) users to detect IT problems.

It is important to acknowledge that planning does not always yield a design for a successful program and a decision to move forward. Sometimes the result of careful planning may be a decision that the initial vision is unrealistic, the intended participants are unlikely to cooperate, or barriers (privacy, confidentiality, competition, technology, cost) are insurmountable. In these circumstances, a careful planning process and early testing can limit fruitless expenditures or redirect efforts in new directions. For example, one of these four projects completed a pilot and based on a qualitative evaluation decided to change their focus and future plans. They are essentially going back to the planning stage with a very different vision and set of objectives, rather than proceeding to implement their original plan. This illustrates the value of a pilot test, not as merely a small version to be later scaled up, but as a test of the entire concept of the HIE. In this case, although the pilot was successful – in the sense that data sharing worked – the data collected demonstrated that the original concept required revision.

Another of the four projects plans to collect baseline data during the pilot phase. That project is focusing first on ePrescribing and will collect data using standard paper scripts first, before implementing electronic features. A comparison group is planned as well, yielding a strong 4-way evaluation design that will measure changes over time and between intervention and comparison groups.

The two remaining projects in the early implementation/pilot phase have specified the nature of the problems they are trying to address, but have not measured the scale/scope of these problems or assembled baseline data against which to measure change. Thus it is not clear how they will measure the success of their pilot efforts. It is important that all projects gather data to measure the scope and parameters of the “problem” they expect to address before implementing HIE solutions, so that they will be in a position to measure progress and change. (The same data that would likely be useful as a baseline should also be persuasive to providers, funders, regulators, etc. in demonstrating the nature and scale of problems that HIE can address.)

2.3 Full Implementation Phase

Full implementation means different things for each CCBH project, depending on their vision for their eventual HIE. Some intend to implement data sharing and let participants decide how to best use the shared data, while others intend to implement specific clinical tools and pay-for-performance productivity changes. Considering their ultimate objectives or vision, one CCBH can be considered nearly ready for full implementation and data sharing in mid-2005. Another is already in full implementation mode (column 3), has many participants involved, is adding additional participants, and is continuing to expand the range of data being shared and the clinical tools being offered. This latter project has been in operation years before getting FeHI funding and is implementing increasingly sophisticated clinical applications; they intend to undertake impact evaluations of clinical applications as each is rolled out, in some cases with pre/post surveys. Where no baseline data exist for measuring the impact of these clinical applications, this project is considering bringing providers online with each new application in a staged approach – an early/late comparison rather than pre/post.

3.0 CCBH Projects' Designs, Objectives and Vision

Each of the nine CCBH projects has a different vision for its eventual role and those that intend to promote specific clinical applications have differing objectives – as a result, each will have different metrics for success. Projects whose vision/role at present is simply to enable data sharing rather than to accomplish specific clinical objectives may well evolve into larger roles in the future, but the following is based on the vision they articulated in mid-2005. This is not limited to the objectives of their FeHI funding, but rather the vision each has for their entire effort, combining all their funding sources, when their HIE is (eventually) fully operational. Their visions for their roles are not limited to the year of their FeHI awards.

None of the nine projects see their purpose and objectives as being limited to forming functional collaboratives. The collaboratives are necessary for subsequent work, but are not the final objective. (Several did not expect to progress beyond forming these collaboratives in the first year of funding and with FeHI agreement have made this their priority for 2005.)

Of the nine projects, 2-3 see their ultimate role as being testing, deploying and supporting information exchange systems. Their vision is to become the centralized information interchange, contracting with hardware and software vendors to interface participants, and offering training and technical support to participants. They believe that if they are able to streamline and simplify participation, so that each provider finds participation easy, the HIE will enjoy widespread acceptance. With widespread acceptance and data sharing capabilities, they expect that many participants will develop creative ways to use the health information exchange for a variety of purposes. They do not, however, see it as their role to encourage/promote particular clinical tools, to encourage specific changes in the process of clinical care, or to promulgate any particular pay-for-performance or quality assurance programs. Rather, they see their roles as enabling any of these activities that participants may wish to undertake.

Four of the nine projects have very specific quality of care or cost reduction objectives, or plan to offer clinical tools that are expected to generate quality improvement.⁶ In some cases, the vision is to offer clinical tools with the expectation that users will find the tools helpful and improvements in care processes and outcomes will follow. Others are pursuing much more directive action, using pay-for-performance or other incentive schemes to drive change and improve quality or costs. For example, one project is making data about hospitalized patients nearing discharge accessible to local SNFs, and making SNF bed availability information accessible to hospital discharge planners. Both ends of the hospital-to-SNF discharge process share data, enabling faster and more complete planning for patient transfers. There was no need to offer incentives to get hospitals and nursing homes to share and use data in this manner – everyone involved is able to do their jobs better and more quickly through this data sharing. Another project is aiming to reduce redundant lab tests; to motivate compliance they are working with third-party payers to deny payment for redundant tests. Thus in some cases, a perceived problem is expected to diminish in the presence of data sharing without additional pressures or incentives, while other problems are seen as more intractable/entrenched and requiring of strong incentives to drive change.

⁶ A fifth is reassessing their goals and objectives. After evaluating a pilot clinical tool-sharing initiative they have reassessed their objectives and are now focusing more on the infrastructure that will enable widespread data sharing rather than any particular clinical applications. The pilot was therefore extremely useful, both in terms of measuring the success of the first HIE activity, and in terms of revising the projects objectives for the future.

Finally, the two remaining projects are aiming for individual patient and population improvement in chronic disease management. One project is aiming to improve health indicators for patients with diabetes, CHF, asthma and other chronic conditions, as well as improving immunization rates. They are creating an HIE and “lite” EHR that will meet many needs expressed by providers; in the process the system will assemble data that will allow the HIE to identify those providers who are not meeting clinical guidelines, in order to target remedial educational efforts. The second project is focusing on patient self-management of chronic conditions, with an electronic portal to a medical record shared with their providers, which includes a health log, individual goal setting, etc.

4.0 CCBH Projects’ Evaluation Plans⁷

Most of the CCBH projects are currently focused on building their collaboratives and establishing business/legal relationships, as well as overcoming privacy and confidentiality issues, and are not yet considering how to measure the dimensions of the problems they hope to address or how to measure change resulting from their HIE initiatives. Two projects that are a little further along plan to design innovations (new clinical applications); they expect to create impact evaluations around these innovations one at a time, but so far the planning and testing is all about the innovation – there has been little or no effort to measure the baseline state, jeopardizing their ability to document improvement.

Although many of the CCBH funded communities included impact evaluation components in their original proposals, most scaled back these plans when the full amount of funding they requested (from FeHI and other funding sources) was not awarded. Their progress is necessarily slower than desired and hence they will not have sufficient time to deploy data sharing and measure impact before their FeHI contracts expire. Since most are focused in 2005 on planning, the appropriate evaluative work would be to gather systematic feedback on their planning efforts, to be sure that all participants are in agreement. (It is not appropriate to expect these programs to measure clinical or cost impact, since there has as yet been no data sharing.) However only one of the projects in the planning phase seems to be undertaking systematic data collection to gather feedback about their early planning activities, and one other project has a clear design and data collection plan for evaluating the impact of their pilot clinical initiative (ePrescribing).

It appears that none of the nine projects has created a comprehensive evaluation plan, starting with systematic feedback for project managers on the planning process, and culminating with impact evaluation of changes in quality, timeliness or cost of care. It is possible that a few are engaging in gathering systematic feedback on the planning process (or plan to do so), but only one explained such plans. Few of the nine CCBH projects have specified an impact evaluation design for their HIE work; they have not collected baseline data to quantify the scale/scope of problems to be addressed and have not created a plan for measuring change. While one might not expect a project in the planning stage that is still working on collaborative relationships to specify impact measures, even those projects that are nearing the point of rolling out data sharing do not appear to have collected baseline data against which to measure change (with one exception). There is thus reason to be concerned about the ability of these HIE initiatives to measure the improvements/changes stemming from their efforts. Every project should be encouraged to collect baseline data before starting data

⁷ The Appendix to this report contains extensive suggestions for measuring progress at every stage of HIE development, including steps to prepare for and conduct evaluations of clinical impact, cost, etc. In addition, FeHI staff have provided the nine CCBH programs with guidance regarding reporting their activities and progress to date.

sharing, even if the next year or more will be spent entirely in planning, so that they will be able to measure progress in the future when data sharing does commence.

Attachments A and B

Attachments A and B that follow are intended to help the nine CCBH projects, and future similar projects, as they implement both formative and summative evaluations to generate information and evidence to support their work. Examples are offered of the sorts of questions HIE project managers might ask as they proceed from planning to pilot testing to full implementation.

Attachment A is the Evaluation Matrix, filled with key evaluation questions for each cell. Subsequent sections work through each row in the Matrix, suggesting evaluation steps and offering examples that may help initiatives like the nine CCBH projects to evaluate their achievements at each stage of progress. These tools are all aimed at making the information collection and evaluation process systematic so that planning is based on concrete information and at the end of the day each CCBH will be able to demonstrate its accomplishments. Needs assessments, systematic project management and planning feedback, baseline data collection, selection of appropriate evaluation designs, and other issues are addressed.

Attachment B presents the same information in a ‘check list’ format, for easier use by HIE project directors.⁸

Readers of both appendices should not try to read through from start to finish. Rather, locate the cell in the matrix that seems appropriate for your HIE, and turn to that section for guidance that may be immediately relevant for your project

⁸ In all of the sections that follow, it is assumed that the relevant Institutional Review Boards will be included at the appropriate time, prior to data collection or data sharing, and that all IRB concerns have been addressed.

Attachment A: Evaluation Matrix (by Project Developmental Stage and “Vision”)⁹

		Project Developmental Stage		
		Planning	Pilot/Early Implementation	Full Implementation
Project Vision/Objectives	Creating Collaboratives and Business Models (Partners, Governance, Vendors, Financing, Legal Issues)	Are all necessary partners/participants involved; are the objectives of each clear; have all agreed to a common vision; has a level of mutual trust been established; is there a practical, sustainable business plan? What are the ‘deal killers’; how can these be addressed? What risks (privacy, security, liability, contracting) will each partner take? Have workgroups/roles been established for IT, clinical leadership, etc.? Have all stakeholders agreed to common set of principles, policies, and procedures and signed a data sharing agreement?	Have all stakeholders agreed to changes in principles, policies, procedures, and business plans made necessary by practical implementation issues discovered? Are the changes still consistent with the original common vision?	
	Planning and Building IT infrastructure (security, connectivity, distributed technology, unified IDs, services)	Are network and distributed hardware/software and connectivity realistic; do all parties agree on security, IDs, etc.; what services will be supported by the infrastructure (authentication, encryption keys, message translations, repositories for provider data)?	System tests for various users; estimates of helpdesk, training, and other support functions; standard conformance testing of messages? Have all users been authenticated and signed data protection agreements? Have all vendors agreed to service levels required?	Infrastructure is in place for participants to use as they wish; can measure what participants use it for?

⁹ In all of the sections that follow, it is assumed that the relevant Institutional Review Boards will be included at the appropriate time, prior to data collection or data sharing, and that all IRB concerns have been addressed.

	<p>Creating/Offering Centralized Clinical Tools, e.g. EHRs, eRx</p>	<p>Are clinical problems clearly identified; do proposed solutions match the problems? Have all users groups been involved in specifying tools? Are correct vendors in place?</p>	<p>Proof of concept – are these the right tools; will people use them? Was certification available for the tools that were implemented?</p>	<p>Tools are built and offered; use and reactions can be measured?</p>
	<p>Changing Clinical Processes/Efficiency (pay-for-performance, other incentives)</p>	<p>What problematic clinical processes require change; is this system/tool likely to foster desired change; are financial incentives aligned with desired change?</p>	<p>Proof of concept – any indication that clinical processes are amenable to change and that change can be attributed to the system/tools? Are incentives working as anticipated?</p>	<p>Measure changes in care processes and outcomes before and after implementation, testing for statistical significance; account for other factors that could affect these changes; identify any unanticipated problems.</p>
	<p>Measuring Improvements in Clinical Outcomes or Population Health</p>	<p>Are baseline data available for clinical indicators, population health measures; are cost/efficiency data available? Is research design clear; have size, bias and other threats been estimated? Is clinical data in electronic form available to support measures?</p>	<p>Proof of concept – are these important and measurable clinical outcomes; can changes be attributed to the system/tools? Is ROI likely, who pays and who gains? Can change be attributed to the system/tools?</p>	<p>Measure clinical indicator and/or efficiency measures (costs) before and after; comparison group or other quasi-experimental design?</p>

A.1 Creating Collaboratives and Business Models

The following expands on the first row in the Evaluation Matrix:

	Planning	Pilot/Early Implementation	Full Implementation
Creating Collaboratives and Business Models (Partners, Governance, Vendors, Financing, Legal Issues)	Are all necessary partners/participants involved; are the objectives of each clear; have all agreed to a common vision; has a level of mutual trust been established; is there a practical, sustainable business plan? What are the 'deal killers'; how can these be addressed? What risks (privacy, security, liability, contracting) will each partner take? Have workgroups/roles been established for IT, clinical leadership, etc.? Have all stakeholders agreed to common set of principles, policies, and procedures and signed a data sharing agreement?	Have all stakeholders agreed to changes in principles, policies, procedures, and business plans made necessary by practical implementation issues discovered? Are the changes still consistent with the original common vision?	

There are a host of issues that planners consider in creating an HIE, ranging from participation and governance to privacy and security, to data standards and conventions. Planners might use the following sections to structure their self-evaluations.

Planning Phase

- 1) Organization and Governance
- 2) Privacy, Security and Standards
- 3) Business/Financial Planning

Early Implementation/Pilot Phase

- 4) Revisions based on early experiences

Each of these considerations is discussed below.

A1.1 Planning Phase

1) Organization and Governance

The first set of issues relate to participation, governance, and the goals and objectives of the HIE. An HIE might wish to ascertain the following sorts of information at the end of the planning phase and before moving forward with implementation.

Have all participants (or individuals representing the interests of each type of participant) been included in the planning and design phase? Those who should be involved include:

- Patients
- Clinicians
- Other Providers (e.g. hospital execs, pharmacies)
- Payers/insurers
- Health Departments (if relevant)
- Clinical Laboratories
- Others

Is there a written statement of the goals and objectives of the HIE and do all participants/representatives agree with this statement?

Is there a written set of policies and procedures, particularly concerning data sharing, privacy and liability and do all participants/representatives agree with these policies and procedures

Have all participants (providers, pharmacies, etc.) signed data sharing agreements?

Is the role of each participant clearly defined/described?

Are all important constituencies (including patients and clinicians) involved in the governance structure of the HIE? Who decides the governance structure? Is the HIE led by the technology side or the clinical side?

Is there a history of collaboration among most of the intended participants? Are any of the key participants in direct competition with one another, so that one's gain is another's loss?

2) Privacy, Security and Standards

On July 21, 2004 DHHS released a report called *Framework for Strategic Action, the decade of Health Information Technology*, and requested public comment; over 500 comments were received and were summarized in June 2005 in another DHHS report: *Summary of Nationwide Health Information Network Request for Information Responses*. The organization and business framework section of the original RFI asked about the type of governance models and policy objectives, financial models, and privacy/security considerations of which a national health information network should be cognizant. Many of these issues are equally true for regional Health information exchanges (HIEs) like those funded by eHI. Some of the relevant issues include creating business rules for data use and disclosure policies, security, patient and provider identification and authentication systems, creating a sustainable financial model, and assuring consumer control of the exchange of their identified health data.

Respondents to the RFI also commented about the manner in which covered entities implement the HIPAA privacy and security regulations and noted that exchange of information could be impeded within and across state lines, due to a lack of uniformity and consistency of Federal and state privacy and security laws. Many respondents suggested that Health Information Exchanges should be responsible for creating the infrastructure for privacy and security compliance among their participants, not only to ensure adherence to HIPAA regulations, but also to more foster more uniform business policies and procedures, interoperability standards, etc. and suggested that an HIE certification process could increase public confidence and provide an enforcement mechanism should it be needed.

Issues around patient identifiers and risks to privacy were raised by respondents to the RFI, as were other privacy considerations such as ownership and control of health records, consumer opt-in vs. opt-out models, disclosure limitations, user authentication schemes, and the use of identified vs. de-identified data.

In the absence of a National Health Information Network, these and many other legal and regulatory issues must be addressed by each HIE individually. The following is a checklist which HIEs might want to use, to assure that they have addressed most/all of these issues:

- Does the HIE have policies that ensure patient access to their health information, including the right to review and annotate electronic health information and to review a log of who accessed their records? Is there a mechanism for patients to opt-out and prohibit sharing of their health information?
- Has the HIE defined categories of users for which different levels of access are authorized (i.e. access to identified vs. de-identified patient data)?
- Has the HIE established standards for patient and provider identification and authentication, both to ensure accuracy of shared data and to prevent unauthorized access to identified health information?
- Has the HIE articulated sanctions for unauthorized use/sharing of identified health information?
- Is the system architecture open and non-proprietary? If not, are the required hardware/software /connectivity already widespread in the provider/participant community or will providers need to make substantial investment to participate?
- Are existing standards used whenever possible? For example, is Clinical Document Architecture being used for document-structured data?
- Were bids sought from multiple vendors for system design and implementation?
- Are vendors working under a defined standard for reliability and system availability? What contractual arrangements exist if vendors fail to meet these standards?
- Is there a plan for continuity of operations and recovery in emergency situations?
- Do communication protocols ensure security? Are standard security measures in place (ASTM standards, PKC standards, HML encryption, etc.)?
- Are standard medical coding/terminology nomenclature being used (CPT4, HCPCS, etc.)?

3) Business/financial Planning

Perhaps the most challenging aspect of planning an HIE is developing a sustainable and realistic business plan. Such a plan needs to be inclusive, so that important provider sectors are not left out, and needs to take advantage of the differing incentives of various participants. For example, those who benefit financially from the HIE should bear some/most of the operational costs of the system. Even if “soft” funding is to be relied upon for the planning phase, it is important to envision a sustainable plan that does not rely on funding. Subscription services are an option many HIEs consider, if they feel they can make a real ROI argument for those being asked to subscribe. Contributions from payers whose costs are reduced through data sharing are another option many HIEs explore. By the end of the planning phase, the following questions should be answered, before moving forward:

- Has an ROI analysis been conducted (or will one be conducted) that identifies who gains, and how much, for the major initiatives the HIE intends to complete?
- Do some participants stand to gain more financially than others through data sharing (e.g. payers gaining while labs lose)? Are some likely to suffer financial losses? Have these divergent financial interests been discussed? Resolved?
- Does the business plan include greater contribution from those who stand to gain the most?
- Does the business plan include mechanisms to assist participants who lack adequate technology and connectivity to acquire these, or are those who cannot afford the necessary technology “left out” of the HIE?
- Does the business plan rely on a “critical mass” of participation in key sectors – if that level of participation does not happen quickly, is the plan in jeopardy?
- How much does the business plan rely on “soft” funding for the future survival of the HIE, beyond the initial planning phase? Is there a way to reduce this reliance on soft funding?
- Has the HIE investigated the willingness of participants to pay subscription fees (if these are part of the plan) and is there any important participant-constituency that would be unwilling to pay such fees?

This list of issues above is not exhaustive, but planners should be able to answer these and similar questions before moving forward.

A1.2 Early Implementation/Pilot Phase

When an HIE is nearly ready for operations, it may be very instructive to start and circulate a test data set, which includes all the data elements (e.g. hospitalization dates, prescription histories, etc.) and some may wish to create a data document that can be exchanged for test purposes (e.g. clinical notes). The purpose of such a data set would be to test various connectivity and interface functions. If both document driven and structured data are to be shared, both types of data should be included in the pilot test.

If the pilot test results in recommended changes, or new issues arise that were not previously considered, the HIE needs a mechanism for making/approving changes. Some changes can probably be handled by technical staff but others will require input from all/most participants, and written changes to policies and procedures may be needed. The pilot therefore will test not only technical

capabilities, but also the ability of the organization itself to be responsive to new issues and make changes as needed.

A.2 Building IT infrastructure

The following expands on the second row in the Evaluation Matrix:

	Planning	Pilot/Early Implementation	Full Implementation
Planning and Building IT infrastructure (security, connectivity, distributed technology, unified IDs, etc.	Are network and distributed hardware/software and connectivity realistic; do all parties agree on security, IDs, etc.; what services will be supported by the infrastructure (authentication, encryption keys, message translations, repositories for provider data)?	System tests for various users; estimates of helpdesk, training, and other support functions; standard conformance testing of messages? Have all users been authenticated and signed data protection agreements? Have all vendors agreed to service levels required?	Infrastructure is in place for participants to use as they wish: can HIE measure what participants use it for?

Technology and connectivity have improved in recent years; many of the CCBH project directors believe that these are no longer substantial barriers, while others (particularly those serving more rural areas) still face challenges related to technology, connectivity, bandwidth, etc. All programs continue to face issues around user training and support, which are difficult to estimate in advance. Most also face data sharing issues related to consistent identifiers (for providers and patients), security, data verification/authentication, selection of vendors, and general agreement on these issues among widespread collaborators. It is important to be fully aware of these challenges before creating IT infrastructures, so that planners can anticipate user needs.

In terms of planning, building and supporting the IT infrastructure required for successful data sharing, HIEs might consider the following steps:

Planning Phase

- 1) Assess the hardware and connectivity of users
- 2) Assess users' existing software systems (electronic medical records, electronic billing, electronic lab/pharmacy ordering)
- 3) Specify technology specifications – minimum requirements; identify users lacking in otherwise widespread technology and connectivity and develop plans to overcome their deficits
- 4) Determine number of staff at user locations who will need to be trained/supported
- 5) Determine needs to be filled by vendors and assess competing vendors' offerings; develop vendor contracts

Early Implementation/Pilot Phase

- 6) Identify first/pilot users, including a range of those most/least prepared in terms of technology and connectivity
- 7) Connect first users and train their staff; identify early problems or glitches, training and support needs, and general problem solving

Full Implementation Phase

- 8) Continue with phased roll-out of technology, training and support; identify ongoing user needs and plan for permanent support and continuity

Each of these steps is discussed below.

A2.1 Planning Phase

1) Assess the hardware and connectivity capabilities of potential users

Before beginning any initiative with many sites or users, it is important to assess the readiness of users to participate and any needs users have that must be fulfilled before they are able to participate. In the case of Health Information Exchanges, needs assessment begins with computer technology and connectivity. What are the minimum hardware requirements and do all anticipated users meet these minimum requirements? What connectivity is required to make good use of the planned HIE, without undue delays and frustrations? For example, is dial-up access adequate or is broadband capability required?

All potential users, or at least a large and diverse sample, should be contacted to obtain this information, so that planners have a realistic picture of how prepared users are to participate. If, for example, the HIE is to include both hospitals and physician practices, and broadband connectivity is necessary to fully make use of the HIE, it will be important to know whether physician practices have this connectivity. If broadband connectivity is spotty or lacking, planners may need to design the system so that some functions can be accessed via dial-up, even if more sophisticated applications available via broadband remain out-of-reach for some physician practices.

The goal of this needs assessment is to begin IT infrastructure planning with full awareness of what users will/will not be able to do. If a substantial portion of users do not have the minimum required technology and connectivity, planners might consider subsidizing the purchase of equipment, ISP contracts, etc. to bring more of the user base up to the minimum requirements. This in turn will require creative financing, may imply the inclusion of payers or additional soft (grant) funding, and may delay implementation.

2) Assess users' existing software systems (electronic medical records, electronic billing, electronic lab/pharmacy ordering)

Similarly, it is important to assess users' existing software capabilities, to understand what legacy systems may need to be integrated, and to understand how much user training and support will be needed. Again, all potential users – or at least a large, diverse sample – should be queried regarding their current capabilities. Do they have an EHR (which one)? Do they do electronic billing (what system do they use)? Do they use computerized order entry for labs and/or prescriptions (what system)? Are any of these systems “home grown” rather than commercial products?

3) *Specify technology specifications – minimum requirements; identify users lacking in otherwise widespread technology and connectivity and develop plans to overcome their deficits*

Based on needs assessments and HIE design goals, planners must determine the minimum technology and connectivity requirements for HIE participants – the basic capabilities they will need in order to fully participate. Some CCBHs have taken the stance that anyone who cannot meet minimum requirements for technology and connectivity will be unable to participate; they have no plans to assist in technology acquisition or financing. Others are working with specific users who do not meet minimum requirements, to understand their needs and help them acquire the necessary technology.

The assessments above will provide planners with a good sense of the technological challenges they (and their vendors) will face in creating an HIE. It will also help to identify which specific users will require assistance in obtaining the necessary technology to participate in the HIE. (This is the reason for assessing the capabilities of all potential users and not just a sample.)

4) *Determine number of staff at user locations who will need to be trained/supported*

It is important for planners to understand the scale of the training and support they will need to provide to users. As part of the assessment process above, each potential user site could also be asked about the size/composition of their staff who will need to be trained to use the HIE. Some user sites (e.g. hospitals) will have dozens or perhaps hundreds of potential users; others (e.g. physician practices) may have only 2-3.

5) *Determine needs to be filled by vendors and assess competing vendors' offerings; Develop vendor contracts*

Some CCBHs are working with vendors to merge legacy EHRs that participants have already invested in, so that these systems can continue to function while providing data to the HIE for sharing purposes. Some CCBHs are working with vendors to create/tailor new clinical applications like EHRs to be rolled out to all HIE participants. Some vendors are being asked to provide training and support, while other CCBHs are taking on these tasks themselves. Planners at each HIE must decide exactly what functions they want vendors to fill, and then select the most appropriate vendors. The eHealth Initiative's CCBH resource center has guidance for evaluating and selecting vendors, particularly EJHR vendors.

A2.2 Early Implementation/Pilot Phase

6) *Identify first/pilot users, including a range of those most/least prepared in terms of technology and connectivity*

The purpose of a pilot or early roll-out and testing phase is to recognize unanticipated problems that users are likely to face, so that planners can be prepared to meet these needs during full implementation. To accomplish this critical step it is important not to start with those best able to comply with technological and connectivity requirements – little will be learned from a pilot test among the most advanced users. A pilot will be far more valuable if a full range of participants is included, both those that are most advanced and those that are new to electronic information systems and data sharing. The assessments conducted during the planning phase will help to identify a range of potential pilot/early users for this purpose.

7) *Connect first/pilot users and train their staff; identify early problems or glitches, training and support needs, and general problem solving*

As the first/pilot users begin sharing data, a variety of issues are likely to arise. HIE staff should develop methods to identify and keep track of the types and frequencies of these problems; those that

are very common will need to be addressed systematically, possibly through IT redesign, while those that are unique to one user may not require system changes. Training and support needs should also be tracked so that reliable planning is possible for final/full implementation.

Many important functions can be tested in the pilot. For example, a fictitious patient could opt-out and forbid data sharing; the pilot test would then confirm the inability of providers and clinicians using the system to access that patient’s data. Or participants with various interfaces and legacy systems could test their ability to share data (in both directions) with each other.

A2.3 Full Implementation Phase

8) *Continue with phased roll-out of technology, training and support; identify ongoing user needs and plan for permanent support and continuity*

Based on results of the pilot, and following any necessary system redesign, full roll-out will commence. Again it will be important to track the types and frequency of problems users encounter, and their training and support needs. Users will experience staff turnover, for example, making training an ongoing service need. And as the HIT offers additional and more complex applications, new waves of training and support will be needed.

A.3 Creating/Offering Centralized Clinical Tools

The following expands on the third row in the Matrix:

	Planning	Pilot/Early Implementation	Full Implementation
Creating/Offering Centralized Clinical Tools, e.g. EHRs, eRx	Are clinical problems clearly identified; do proposed solutions match the problems? Have all users groups been involved in specifying tools? Are correct vendors in place?	Proof of concept – are these the right tools; will people use them? Was certification available for the tools that were implemented?	Tools are built and offered; use and reactions can be measured?

Several of the CCBHs are planning to offer clinical tools through their HIEs, which participants can use if they wish. The CCBHs expect that these tools will be useful for clinicians and will therefore be widely adopted. While some of these tools would imply changes in clinical processes, the entire effort is voluntary; when clinicians adopt these tools they will find that their care processes change as a result. For example, ePrescribing will be offered by several CCBHs in the near future. They expect that many/most physicians will adopt ePrescribing and come to rely on it. The challenges for the HIE will be to develop tools that clinicians wish to use, and then to measure the degree to which clinicians in fact adopt these tools.

In terms of designing, implementing and tracking use of clinical tools, HIEs might consider the following steps:

Planning Phase

- 1) Specify the clinical problem or inefficiency that is to be addressed through the planned clinical tool

- 2) Specify potential solution(s) and decide which is most practical
- 3) Determine participant interest in using the intended tool to solve the perceived problem

Early Implementation/Pilot Phase

- 4) Demonstrate potential gains for both clinicians and pharmacists
- 5) Specify how HIE will support desired change – role of the HIE
- 6) Specify an evaluation design
- 7) Implement and evaluate early/pilot program

Full Implementation Phase and P4P

- 8) Evaluate impact/change among users

Each of these steps is discussed below.

A3.1 Planning Phase

1) Specify the clinical problem or inefficiency that is to be addressed through the planned clinical tool.

When new clinical tools or applications are created and offered to HIE participants, it would be wise to first elucidate the problem to be solved, and assure that participants agree that the problem requires correction. Most participants should ideally be in agreement about what the clinical process is that requires change – what’s problematic about it.

Example Problem: Errors related to pharmacist inability to read illegible hand-written prescriptions, and occasional errors in these prescriptions, can be avoided through the use of electronic prescribing. Calls from pharmacists to physicians to clear up confusion/illegibility in hand-written prescriptions are an inefficient use of time for both pharmacists and physicians.

2) Specify potential solution(s) and decide which is most practical.

There may be several different approaches to solving a problem, some having obvious advantages over others. If the best solution is not obvious it may be necessary to solicit input from HIE participants. If, however, the best solution is clear, HIE planners may feel comfortable moving forward.

Example Solution: ePrescribing would eliminate legibility problems. In addition, ePrescribing systems can be designed to link directly to pharmacy drug utilization review systems, to check for dosage errors, drug-drug interactions, patient allergies, etc. The amount of calling between pharmacists and physicians should decline when illegible prescriptions are eliminated.

3) Determine participant interest in using the intended tool to solve the perceived problem.

Even if the advantages of the planned tool/application seem obvious, that does not necessarily mean that participants will adopt it. Physicians in particular tend to be reluctant to alter their standard care processes and any new tool or application will be most acceptable if it fits seamlessly into their accustomed processes and procedures. A tool that requires clinicians to learn new software is

especially likely to meet with resistance, unless it demonstrably saves time/effort. The advantages to the individual clinician will need to be quite compelling, if voluntary adoption is to succeed.

To determine at least the general interest in considering a new tool or application, it may be helpful to convene a panel that includes a wide range of the types of intended users, explain the intended tool or application (learning issues, immediate advantages, long term advantages), and gauge reactions. It may also be useful to approach clinical ‘opinion leaders’ first, who are in a position to encourage their colleagues to adopt the new tool/application. A carefully designed pilot test, whose results will be persuasive to the broader audience of potential users, will most likely be essential to successful implementation and widespread adoption.

A3.2 Early Implementation/Pilot Phase

4) Demonstrate the potential gains for both clinicians and pharmacists.

The most persuasive proposition is one that a) does not threaten any participants and b) offers efficiencies or improvements to all participants. If there are multiple stakeholders who each are involved in the care process that needs to change, each will need to be persuaded that his/her individual responsibilities will be aided – whether or not there is also greater good for the health system or patients in general.

Example:

- Collect baseline data about frequency of calls between pharmacists and prescribing clinicians to clarify illegible or problematic prescriptions, select alternative drugs that are within the patient/payer formulary, etc.
- Share data about the nature and extent of the problem with all participants (clinicians, pharmacists) and explain how ePrescribing will eliminate much of the back-and-forth related to unclear prescriptions. Also explain how electronic prescriptions feed seamlessly into DUR systems, so pharmacists understand that few/no additional steps will be needed on their part.

5) Specify how HIE will support desired change – role of the HIE.

While it is probably obvious to HIE staff exactly what they need to do to support the solution to the specified problem, others will benefit from a clear specification of the role of the HIE – what is it about the HIE that will make this change process possible?

Example:

- HIE will involve all/most local clinicians and laboratories; the same system will be used for all to avoid having multiple competing/confusing systems in use in different places.
- The HIE will assure that the ePrescribing system is interoperable with at least the most common DUR systems in use among local pharmacies.
- The HIE will also assure that the ePrescribing system is interoperable with at least the larger insurers’ automated formulary systems.
- All electronic prescriptions will be sent to the patient’s pharmacy immediately and can be run through the appropriate pharmacy DUR system and patient/payer automated

formulary systems. Any that is flagged for verification/change can be electronically returned to the physician immediately (real time) for verification/change.

6) Specify an evaluation design.

The ability to demonstrate improvement rests on a) baseline data, and b) an evaluation design that permits measurement of change. The gold standard of a randomized design is often not possible for social “experiments” but there are reasonable alternatives.

Options include:

- pre/post (requires baseline or early data)
- random assignment to early vs. late inclusion (compares the early starters with those not yet started);
- comparison group of very similar entities who will not be involved in the HIE; or
- some other design that involves a comparison (over time, against others, etc.)

The strongest design for social experiments is often a combination of pre/post and either early/late starters or some other comparison group, where data are collected for both groups at baseline and again several months after implementation. This 4-way design accounts for changes in the larger environment that affect everyone and permits accurate attribution of effects to the HIE itself.

This is especially true in terms of collecting data that will lay the groundwork for a subsequent evaluation – it will not be possible to demonstrate the results of everyone’s hard work, without a starting point (baseline) against which to measure change. If baseline data do not exist, an alternative will be needed (early/late rather than pre/post).

7) Implement and Evaluate early/pilot program

Example (pre/post):

- Determine the desired level of change or the threshold for declaring success (i.e. what would be considered ‘success’, in terms of reducing back-and-forth between physicians and pharmacists?)
- Collect baseline data on the extent of this back-and-forth among a small number of prescribing clinicians and pharmacists.
- Assure baseline and subsequent data are accurate. Assure that data collected after system implementation are measured/collected/assembled in the same way as baseline data, so no biases are introduced by data collection modality.
- Collect data again after a few months to measure continuing frequency (if any) of the back-and-forth between prescribing clinicians and pharmacists.

A3.3 Full Implementation Phase and P4P

8) Evaluate fully implemented program

Continue with pre-selected evaluation design.

Example (pre/post):

- Collect more complete baseline data on back-and-forth between prescribing clinicians and pharmacists, prior to bringing full array of participants online for ePrescribing. Collect data again after several months (using same measures as at baseline). Or if a comparison group design is being employed, collect the same data for the comparison group that are not using ePrescribing.
- Compare two data sets to determine total reduction in calls between prescribing clinicians and pharmacists. Also examine clinician-level and provider-level reductions so each can see how much they individually have benefited.

A.4 Changing Clinical Processes/Efficiency

The following expands on the fourth row in the Evaluation Matrix:

	Planning	Pilot/Early Implementation	Full Implementation
Changing Clinical Processes/Efficiency (pay-for-performance, other incentives)	What problematic clinical processes require change; is this system/tool likely to foster desired change; are financial incentives aligned with desired change?	Proof of concept – any indication that clinical processes are amenable to change and that change can be attributed to the system/tools? Are incentives working as anticipated?	Measure changes in care processes and outcomes before and after implementation, testing for statistical significance; account for other factors that could affect these changes; identify any unanticipated problems.

Care processes are unlikely to change without clear and unassailable evidence as to the nature and extent of the problem, which in turn requires measurement capability. Each clinical process that seems problematic will require specific data collection in order to: a) prove to all participants that there is a problem, b) prove the scale/extent of the problem, and c) measure change/improvement. It is critical that data be collected at baseline (or at least *before* system changes and incentives/sanctions are implemented) and shared with all participants, to achieve consensus that there is a problem that needs correction and the scale/scope of the problem.

The key to changing clinical care processes is to carefully specify the problem or behavior that needs correction, identify whose behavior needs to change, identify who stands to gain and who stands to lose if the problem is corrected, attempt to align incentives if at all possible, and if necessary create incentives (e.g. Pay-for-Performance or P4P) that encourage change.

Opposition may more readily be overcome if participants are given the opportunity to start with a voluntary program of information sharing, to determine whether improved information alone can affect change, before imposing financial sanctions/incentives. If financial incentives are needed to significantly change the process of care, the most leverage is likely to come from insurers/employers, and the most change is likely to be required of providers; thus all participants are not equal. It is also

important to acknowledge that change is not necessarily a win-win proposition, given the way care is provided and financed in the U.S. More efficient care processes may well have winners and losers, and the gains/losses may be financial and substantial.

This section of the report involves an example that is presented in extensive detail, including all steps in the process of understanding incentives, implementing pay-for-performance (P4P) if necessary. These same considerations apply for efforts to improve health outcomes and population health status (below) although they are not covered in the same extensive detail in subsequent sections of this report. For example, the discussion here about specifying who gains and who loses, understanding incentives, applying new incentives (P4P) all apply equally to efforts to improve health outcomes.

In terms of promoting change in the process of delivering care, and setting the stage for effective evaluations, HIEs might consider the following steps:

Planning Phase

- 1) Specify the clinical process that is problematic or requires change
- 2) Specify potential solution(s) and decide which is most practical
- 3) Specify who wins and who loses if the solution is implemented, and whether gains/losses are financial
- 4) Is there a way to align incentives so that all/most participants gain?
- 5) Specify risks facing the plan for change
- 6) Design system to support a voluntary program first.

Early Implementation/Pilot Phase

- 7) Specify Action Steps
- 8) Specify how HIE will support desired change – role of the HIE
- 9) Specify an evaluation design
- 10) Evaluate early/pilot program

Full Implementation Phase and P4P

- 11) Specify action steps for implementing P4P incentive program (if needed)
- 12) Evaluate fully implemented voluntary program or P4P

Each of these steps is discussed in great detail below, with a full-developed example, to help the reader operationalize the process.

One example of an inefficient clinical care process that requires change, and was mentioned by several of the CCBH communities, is repeated lab tests and diagnostic images ordered for a patient on the same day, by multiple providers. This example is used in each step, to work through the process, focusing on evaluation issues. The participants in this example include the “first” provider who orders a test or image, the “second” provider who repeats the order (possibly because s/he isn’t aware that it was already ordered), the lab(s) that processes both tests, the first and second radiologists who read repeated images, the insurer/employer/patient who pays for both tests/images/readings, and the patient who experiences the pain, inconvenience or risk of having two samples drawn (or images taken) on the same day.

A4.1 Planning Phase

1) Specify the clinical process that is problematic or requires change.

In most cases, all relevant participants should be in agreement about what the clinical process is that requires change – what’s problematic about it. Any discrepancies, where one or more participants see the problem differently than others, need to be identified and addressed. It is also advisable to collect

baseline data that indicates the scale/scope of the problem, so that all participants can see how important the problem is.

Example Problem: Repeated lab tests/images too often ordered, on the same day, by different providers. Measure baseline frequency of this undesirable pattern. Identify which providers are ordering the second (i.e. repeat) test/images most. For example, community-based providers may most commonly be the “first” providers ordering images/tests, while hospitals may most commonly be the “second” provider issuing the repeat orders.

2) Specify potential solution(s) and decide which is most practical.

Relevant participants should also be in agreement about what the desired end state is – how they will know that the “fix” worked, and what solutions will achieve that end state. Again, discrepancies in specifying the solution and how to recognize it need to be identified.

Example Solution: make test/image orders and results available online so second provider can see that the test/image was already ordered and does not need to be re-ordered.

3) Specify who wins and who loses if the solution is implemented, and whether gains/losses are financial. Also specify key players whose cooperation is essential for change to occur.

While sometimes a solution is a win-win and everyone gains, often this is not the case. If it is possible to measure magnitude of gains and losses in dollars or other consistent measures (e.g. time to treatment) this might be considered. Quantifying loss is most necessary if the business plan is going to try to address these losses.

Example:

- lab will process fewer tests (substantial financial loss)
- second provider won't draw sample for processing, or take radiographic image (modest financial loss)
- second radiologist won't be paid for reading second image (substantial financial loss)
- insurer/plan/employer only pays for one test, one image, or one radiologist's interpretation (substantial financial gain)
- second provider can provide care faster, perhaps see more patients (minimal financial gain)
- patient avoids pain/inconvenience/risk of second sample or second image (modest quality gain)
- patient may have only one test/image/radiologist copay, depending on insurance plan (modest financial gain)
- no change for first provider, first radiologist

Key player is the lab – if they don't share data about tests ordered, the system cannot be redesigned to share this information.

4) Is there a way to align incentives so that all/most participants gain?

Could incentives be implemented to encourage cooperation, even among those who stand to lose? Are insurers/employers interested in creating P4P incentives? What case can be made to “winners” that they should at least partially/temporarily subsidize “losers”, in order to encourage participation? This is especially important if a “loser” is key to the success of the project – if that key player's

refusal to cooperate causes the whole project to fail, it will probably be necessary to devise a compensatory strategy.

Example:

- Insurer/employer has most to gain. Insurers (with employer agreement) could refuse to cover second test/image on the same day, giving lab and second provider/radiologist incentive not to repeat the test/image. This approach benefits insurers/employers and patients, and sanctions providers.
- If the lab's data are essential to driving the new system, their cooperation is necessary. Is there a way (other than coercion) to reward their cooperation. For example, insurers could offer bonus incentive to labs and/or second providers if repeat tests/images decline. This approach rewards providers and lab, and some cost to insurers/employers.

5) *Specify risks facing the plan for change.*

Any effort to change long-entrenched processes, especially clinical care processes, faces challenges and risks. It is useful to recognize and itemize these risks up front, and try to address them if at all possible.

Example: The plan will not succeed in reducing redundant testing/imaging if:

- Insurers/employers do not agree to impose sanctions/incentives
- The HIE system cannot generate data to convince providers that the problem exists and to support accurate application of sanctions/incentives
- Providers do not understand sanctions/incentives or strenuously oppose them
- Quality of care is jeopardized (e.g. need to exclude tests where results are volatile within a day and where fluctuations in <1 day drive treatment decisions; perhaps allow providers to 'override' with subsequent review of medical necessity.)

6) *Design system to support a voluntary program first.*

In some instances, information sharing alone can achieve sufficient improvements and no incentives or sanctions are needed. In other cases data sharing alone will be virtually ignored by busy clinicians, absent a sound reason to take these newly-available data into account, and without incentives to change behavior. It is worthwhile designing a system that begins with voluntary data sharing, rather than assuming that incentives and sanctions will be necessary; it is realistic to also recognize that data sharing alone may not suffice.

Example: Data sharing alone could yield reduction in repeated lab tests, without incentives/sanctions, simply because the second provider can see that a test has already been ordered. If the voluntary reduction achieved through data sharing alone is not sufficient (define threshold), prepare a P4P plan to drive change.

By the end of the planning phase, and before implementing any changes, the HIE should together:

- Assure that all relevant participants agree about the nature of the problem to be solved, and collect baseline data demonstrating the scale/scope of the problem.

- Assure that all relevant participants agree about the solution, and what changes will indicate that the solution is successful.
- Specify how each participant is likely to gain or lose when the solution is implemented and change occurs.
- Try to find a way to align incentives, especially if a key player is likely to “lose” – strategies to ameliorate loss (at least partially/temporarily) may be necessary to induce cooperation.
- Specify risks facing the plan.
- Design the solution so that it begins with voluntary data sharing, but with a back-up plan that includes incentives (positive and negative) to encourage participation.

A4.2 Early Implementation/Pilot Phase

7) Specify Action Steps.

Who must act, and in what ways, to make the solution work? Each participant probably has a role to play, whether in providing data, receiving data, acting upon data, or paying for care provided. It is worth specifying the sequence of events and sharing this, so that everyone knows what to expect.

Example:

- Collect baseline data about frequency of repeat tests by multiple providers on same day (See 1 above). If baseline data do not exist, begin the pilot and collect data via the HIE *before* any incentive scheme is implemented.
- Share data about the nature and extent of the problem with all participants (providers, labs, insurers) and explain planned changes and requirements for each.
- Begin with a voluntary program, to determine whether information alone will reduce repeated testing. Voluntary program would share data and encourage provider to wait for first test results, rather than repeating the test. Inform providers and labs that voluntary change will be tried first; if change is not sufficient, full implementation will include incentives for change and sanctions (non-coverage) for redundant test orders.
- Work with insurers/employers to determine P4P incentives, should P4P be necessary.

8) Specify how HIE will support desired change – role of the HIE.

While it is probably obvious to HIE staff exactly what they need to do to support the solution to the specified problem, others will benefit from a clear specification of the role of the HIE – what is it about the HIE that will make this change process possible?

Example:

- Data collected and shared via HIE on number of repeat tests, by provider, and cost of repeated tests to insurers.

- All lab tests ordered need to be immediately available online with time of day, ID of provider ordering test, type of test, patient ID, indication of medical necessity ‘override’ ordered by provider.
- If a test has already been ordered for a patient on a given day, any second provider who logs on and enters patient ID will see list of tests ordered that day (and other data elements as well).
- If P4P is implemented and a repeat test is ordered, system would immediately notify provider that the test was already ordered that day and the repeat test will not be covered. Notice also sent to lab that a test is about to be ordered that will not be covered. (Exceptions being designated tests where results are volatile within a day and where fluctuations in <1 day drive treatment decisions).
- Permit providers to ‘override’ and order the second test for reasons of medical necessity, after being notified that it may not be covered.
- If repeat test is ordered, insurers’ systems need to flag it so the second test is not covered unless medical necessity criteria are met.

9) Specify an evaluation design.

The ability to demonstrate improvement rests on a) baseline data, and b) an evaluation design that permits measurement of change. The gold standard of a randomized design is often not feasible for social “experiments” but there are reasonable alternatives.

Options include:

- pre/post (requires baseline or early data)
- random assignment to early vs. late inclusion (compares the early starters with those not yet started);
- comparison group of very similar entities who will not be involved in the HIE; or
- some other design that involves a comparison (over time, against others, etc.)

The strongest design for social experiments is often a combination of pre/post and intervention/comparison groups, where data are collected for both groups at baseline and again several months after implementation. This 4-way design accounts for changes in the larger environment that affect everyone and permits accurate attribution of effects to the HIE itself.

This is especially true in terms of collecting data that will lay the groundwork for a subsequent evaluation – it will not be possible to demonstrate the results of everyone’s hard work, without a starting point (baseline) against which to measure change. If baseline data do not exist, an alternative will be needed (early/late rather than pre/post).

To the extent that others things are changing at the same time (insurance initiatives, new managed care networks, epidemics or natural disasters) it is important that these influences affect both the intervention and comparison group equally; if these external changes affect one group more than the other it will be difficult to separate impact due to the HIE intervention and impact due to external events.

10) Implement and Evaluate early/pilot program

Example (pre/post):

- Determine the desired level of change or the threshold for declaring success (i.e. what would be considered ‘sufficient’ reduction in repeat testing?)
- If baseline data do not exist, collect data as soon as the data sharing is implemented, before most participants have made any changes or reduced test ordering.
- Assure baseline and subsequent data are accurate. Assure that data collected after system implementation are measured/collected/assembled in the same way as baseline data, so no biases are introduced by data collection modality.
- Implement voluntary program.
- Collect data again after a few months of the voluntary program, regarding frequency of repeat tests by multiple providers on same day. Determine whether reduction in repeat testing is sufficient. If change is minimal, but at least in the right direction, prepare to implement incentives/sanctions.

By the end of the pilot or early implementation phase, the HIE should together:

- Specify who must act, and in what ways, to implement the planned solution.
- Specify how the HIE itself will support the solution, whether through data sharing, incentives, or other means
- Specify an evaluation design, focusing on how change/improvement will be measured
- Collect early pilot data and compare against baseline data (Step 1 above), to evaluate whether the initial attempts appear to be yielding desired change, at least in the right direction if not of great magnitude.

At this point, a decision will be needed as to whether the voluntary program is sufficient or needs to be enhanced with incentives.

A4.3 Full Implementation Phase and P4P

11) Specify action steps for implementing P4P incentive program (if needed).

If sufficient change has occurred through the voluntary data sharing program alone, and if all participants are willing to continue (including “losers”), there may be no needed for an incentive system. If, however, change has been minimal/inadequate, some sort of incentives or sanctions may be necessary, particularly to encourage the cooperation of the key player that stands to lose the most.

Example:

- Notification by insurers/plans to all participants that repeat tests on same day by two providers will not be covered (exceptions being tests where results are volatile within a day and where fluctuations in <1 day drive treatment decisions)

- Providers need to check online to see if a test was already ordered that day and if results are available.
- If voluntary program did not yield appreciable/significant reduction in repeated tests, implement incentives/sanctions.
- Insurers' systems need to flag repeat test to assure that it is not paid unless medical necessity criteria are met.
- Insurer appeal process in cases where 'override' was used, to determine medical necessity (those deemed necessary would be covered). Patient should not be liable for provider decision to 'override' – provider and lab should be at risk for overriding when medical necessity criteria are not met.
- Insurers access information to award bonuses (bonuses to those who reduce redundant testing most, to labs, etc.). Eventual phase-out of bonuses.

12) Implement and evaluate full implemented voluntary program or P4P

Continue with pre-selected evaluation design.

Example (pre/post):

- Collect data after several months of P4P regarding frequency of repeat tests by multiple providers on same day (using same measures as at baseline and pilot evaluation).
- Compare baseline repeated tests, by provider, with subsequent repeated measurement, to determine total savings to insurers and which providers reduced repeated tests most.
- Implement incentive awards. For example, insurers might award X% of savings as bonuses to providers who reduce repeat tests (proportionate to the change, by provider); insurers might award X% of savings as bonus to labs, in part to (temporarily) compensate for losses.
- Work with insurers to examine tests ordered through 'override' that were not covered, to determine medical necessity that would warrant a coverage 'exemption'. Examine appeals of medical necessity. If necessary, revise list of tests that are excluded due to medical necessity.

A.5 Measuring Improvements in Clinical Outcomes or Population Health or costs

Please see section A.4 above for complete discussion and detailed example concerning incentives and P4P. Sections that follow should be interpreted to include all of those section A.4 considerations, as well as focusing on issues related to measuring health status and evaluation study design, which are discussed below.

The following expands on the fifth and last row in the Matrix:

	Planning	Pilot/Early Implementation	Full Implementation
Measuring Improvements in Clinical Outcomes or Population Health	Are baseline data available for clinical indicators, population health measures? Is research design clear; have size, bias and other threats been estimated? Is clinical data in electronic form available to support measures?	Proof of concept – are these important and measurable clinical outcomes; can changes be attributed to the system/tools?	Measure clinical indicators before and after; comparison group or other quasi-experimental design?

Some of the CCBHs intend to go beyond simply offering clinical tools, or encouraging changes in clinical processes – some want to instigate change that leads to improved health outcomes for individuals and/or communities. This implies that the HIE will be created and successfully implemented, clinical tools will be offered that lead to changes in the process of care, which will eventually accumulate into observable changes in health outcomes or health status.

In addition to all of the steps and issues raised in previous sections, measuring changes in health outcomes/status involves a number of issues that researchers routinely grapple with: what are the indicators of improved health? Are these measurable? Are baseline or comparison data available? Are changes/improvements universal or only seen in some clinicians’ practices or only for certain patients? Can change be unambiguously attributed to information sharing and clinical tools via the HIE? Planners and evaluators might consider the following steps to answer these questions:

Note: All of the considerations of incentives and P4P apply to evaluating interventions intended to produce changes in Health Status or outcomes, and are not repeated here.

Planning Phase

- 1) Specify expected changes and how the HIE’s data sharing and tools drive these changes
- 2) Specify the indicators of improvement
- 3) Specify the data collection that will be needed to measure change
- 4) Specify an evaluation design that will allow attribution of change to the HIE while controlling for other factors/biases
- 5) Specify the magnitude of change and the size of the population required (power analysis)

Early Implementation/Pilot Phase

- 6) During pilot phase, collect baseline data before implementing the HIE or the particular tools that are supposed to drive change
- 7) Determine whether data collection omits important variables, important providers, certain patient groups, etc. and adjust to achieve complete data collection
- 8) If a randomized design is used, test randomization procedures to assure that they are not being subverted by well-intentioned clinicians/patients.

- 9) Given patterns in the pilot and the anticipated degree of change in outcomes, review how many cases are needed for tests of statistical significance, and how many months of data collection will be needed to accumulate this many cases – this will determine the evaluation timeframe

Full Implementation

- 10) All of the considerations of incentives and P4P apply to evaluating interventions intended to produce changes in Health Status or outcomes.

These steps are described in detail in the sections that follow.

A5.1 Planning Phase

1) Specify expected changes and how the HIE's data sharing and tools drive these changes.

It is important to link anticipated changes directly to HIE data sharing and tools, so that change can be attributed to the HIE. Each anticipated change should be linked to the HIE activity that supports it.

Example 1: HIE will implement self-management tools for diabetes management, which are expected to yield improved diabetic control.

Example 2: HIE will implement immunization reminders at point-of-care for patients who are not age-appropriately immunized, which is expected to yield improved immunization rates throughout the community.

2) Specify the indicators of improvement

The before and after (or intervention vs. comparison) measures be specified in advance, so that everyone is in agreement about what is expected to change.

Example 1: Several sequential HgA1C test results for diabetic patients before any HIE tools are implemented; tests results should be for all diabetics in the entire community or all those in participating physicians' practices. The percent of diabetics "in control" should be calculated, either for the entire community or for each physician's diabetic patient panel (perhaps divided by type of diabetes and/or age).

Example 2: Age-appropriate immunization rates for all required pediatric immunizations and for elderly patients, for the entire community. If this is a statewide HIE or one that covers an entire large city, these rates may be available through the National Immunization Survey.

3) Specify the data collection that will be needed to measure change.

Data collection should be the same pre and post HIE; if the data collection mechanism changes it will not be possible to attribute change to the HIE.

Example 1: Search records of all diabetic patients in participating physician practices (or perhaps a careful sample of practices) and assemble data on HgA1C test results. If there is an EMR in widespread outpatient use, the test results in the EMR could be used. The same data sources should be used for collecting post-implementation data.

Example 2: There are several options for data collection related to age-appropriate immunization; the key is that the same data collection must be used for pre/post or intervention/comparison groups:

- Search records of all children and elderly in participating physicians’ practices (or perhaps a careful sample of practices) to assemble immunization rates
- If there is an EMR in widespread outpatient use, the test results in the EMR could be used.
- If the community is an entire state or a large city, the National Immunization Survey may have data on pediatric age-appropriate immunizations. Whenever possible external sources like this are the best, since data collection won’t change over time and the results are likely to be viewed as more reliable.

4) Specify an evaluation design that will allow attribution of change to the HIE while controlling for other factors/biases.

The ability to demonstrate improvement rests on a) baseline data, and b) an evaluation design that permits measurement of change. It is also important to select an evaluation design that minimizes external influences so that attribution is as clear as possible. The gold standard of a randomized design is often not feasible for social “experiments” but there are reasonable alternatives.

Options include:

- pre/post (requires baseline or early data)
- random assignment to early vs. late inclusion (compares the early starters with those not yet started);
- comparison group of very similar entities who will not be involved in the HIE; or
- some other design that involves a comparison (over time, against others, etc.)

The strongest design for social experiments is often a combination of pre/post and an intervention/comparison group, where data are collected for both groups at baseline and again several months after implementation. This 4-way design accounts for changes in the larger environment that affect everyone and permits accurate attribution of effects to the HIE itself.

This is especially true in terms of collecting data that will lay the groundwork for a subsequent evaluation – it will not be possible to demonstrate the results of everyone’s hard work, without a starting point (baseline) against which to measure change. If baseline data do not exist, an alternative will be needed (perhaps early/late rather than pre/post).

To the extent that others things are changing at the same time (insurance initiatives, new managed care networks, epidemics or natural disasters) it is important that these influences affect both the intervention and comparison group equally; if these external changes affect one group more than the other it will be difficult to separate impact due to the HIE intervention and impact due to external events.

5) Specify the magnitude of change and the size of the population required (power analysis).

If the HIE tools and data sharing are expected to yield an immediate and dramatic change in health outcomes, a small population and short timeframe will be adequate for the evaluation. If, however, change is expected to be incremental, or fairly small, then either a larger population or a longer timeframe (or both) will be needed to have confidence that any observed change is not due to chance.

A statistician should do a power analysis so that planners know how large and long the data collection period must be before analysis begins.

A5.2 Early Implementation/Pilot Phase

6) During pilot phase, collect baseline data before implementing the HIE or the particular tools that are supposed to drive change.

Baseline data must be collected before the new initiatives are rolled out, and a very small pilot can be used to test data collection protocols. If all goes well, full baseline data can be collected during this phase as well.

7) Determine whether data collection omits important variables, important providers, certain patient groups, etc. and adjust to achieve complete data collection.

Often it is not until after initial data collection that problems become apparent, such as problems with provider compliance, incomplete or inconsistent data, poorly defined variables, inexact instructions, etc. After pilot data collection begins it is important to interview users to understand what confusions or problems they are facing in compiling and reporting data. For example, patient self-management tools for diabetes control could suffer if some providers decide that the tools are too complicated for their elderly patients. If patients are supposed to login and use these self-management tools, only those with computers and Internet access will be able to participate – and outreach to even this segment will need to be done well or there will be no uptake. A pilot test that seems to get only young people, or only patients from certain physician practices, would be an indicator of problems that require some investigation.

8) If a randomized design is used, test randomization procedures to assure that they are not being subverted by well-intentioned clinicians/patients.

If a randomized design is used to randomize either physician practices or patients, it is important that the randomization “works” and the two groups are in fact identical in all important respects. For example, if diabetic patients are randomized to have access to the self-management tools, but only the younger patients login to use the tools, then the two groups must have a nearly identical age distribution and the analysis should be stratified by age. Of if physician practices are randomized so that some get a list of under-immunized patients and the those do not, but male physicians tend to ignore these lists, then the two sets of physician practices need to be nearly identical in terms of sex distribution and the analysis should be stratified by sex. These sorts of important factors can be elucidated in a pilot test and the randomization procedures refined, so that any parameters that are likely to be important are accounted for during randomization (race and sex, in these two examples).

9) Given patterns in the pilot and the anticipated degree of change in outcomes, determine how many cases are needed for tests of statistical significance, and how many months of data collection will be needed to accumulate this many cases – this will determine the evaluation timeframe.

The initial power analysis may need to be revised based on findings from the pilot phase. If the change in health status is expected to be large but in the pilot turns out to be much smaller, then either a longer data collection period or a larger study population will be needed in order to be confident that observed change is “real”.

A5.3 Full Implementation

11) Conduct the evaluation and if change is much less than anticipated, consider incentives and P4P.

See section A.4 above that discusses these issues in detail.

Attachment B: Suggested Evaluation-Oriented Instrument

Attachment A (above) walks through the Evaluation Matrix of CCBH project goals and phase, describing many issues that planners should consider. This discussion was not intended to be exhaustive, but should serve as a guide that will help HIEs prepare to evaluate their processes and outcomes.

The following Evaluation Tool works through these same considerations, in a “fill in the blanks” format that HIE planners can use as they proceed. Planners should first locate their project in one of the five rows of the matrix, and then find the corresponding section in the Evaluation Tools below.

This entire document and the tools that follow are in a preliminary phase of development. We advise that these tools should be tested and validated, or at least carefully reviewed by knowledgeable experts, before being implemented by HIE initiatives.

Row 1: Creating Collaboratives and Business Models

Planning Phase

1) Structure and Governance:

_____ Have all participants (or individuals representing the interests of each type of participant) been included in the planning and design phase? Those who should be involved include:

- Patients
- Clinicians
- Other Providers (e.g. hospital execs, pharmacies)
- Payers/insurers
- Health Departments (if relevant)
- Clinical Laboratories
- Others

_____ Is there a written statement of the goals and objectives of the HIE and do all participants/representatives agree with this statement?

_____ Is there a written set of policies and procedures, particularly concerning data sharing, privacy and liability and do all participants/representatives agree with these policies and procedures

___ Have all participants (providers, pharmacies, etc.) signed data sharing agreements?

_____ Is the role of each participant clearly defined/described?

_____ Are all important constituencies (including patients and clinicians) involved in the governance structure of the HIE? Who decides the governance structure? Is the HIE led by the technology side or the clinical side?

_____ Is there a history of collaboration among most of the intended participants? Are any of the key participants in direct competition with one another, so that one's gain is another's loss?

_____ Does the HIE have policies that ensure patient access to their health information, including the right to review and annotate electronic health information and to review a log of who accessed their records? Is there a mechanism for patients to opt-out and prohibit sharing of their health information?

2) Privacy, security and standards

_____ Has the HIE defined categories of users for which different levels of access are authorized (i.e. access to identified vs. de-identified patient data)?

_____ Has the HIE established standards for patient and provider identification and authentication, both to ensure accuracy of shared data and to prevent unauthorized access to identified health information?

_____ Has the HIE articulated sanctions for unauthorized use/sharing of identified health information?

_____ Is the system architecture open and non-proprietary? If not, are the required hardware/software /connectivity already widespread in the provider/participant community or will providers need to make substantial investment to participate?

_____ Are existing standards used whenever possible? For example, is Clinical Document Architecture being used for document-structured data?

_____ Were bids sought from multiple vendors for system design and implementation?

_____ Are vendors working under a defined standard for reliability and system availability? What contractual arrangements exist if vendors fail to meet these standards?

	<p>_____ Is there a plan for continuity of operations and recovery in emergency situations?</p> <p>_____ Do communication protocols ensure security? Are standard security measures in place (ASTM standards, PKC standards, HML encryption, etc.)?</p> <p>_____ Are standard medical coding/terminology nomenclature being used (CPT4, HCPCS, etc.)?</p> <p>_____ Has an ROI analysis been conducted (or will one be conducted) that identifies who gains, and how much?</p> <p>3) Business/Financial Plan</p> <p>_____ Do some participants stand to gain more financially than others through data sharing (e.g. payers gaining while labs lose)? Are some likely to suffer financial losses? Have these divergent financial interests been discussed? Resolved?</p> <p>_____ Does the business plan include greater contribution from those who stand to gain the most?</p> <p>_____ Does the plan include mechanisms to assist participants who lack adequate technology and connectivity to acquire these, or are those who cannot afford the necessary technology “left out” of the HIE?</p> <p>_____ Does the business plan rely on a “critical mass” of participation in key sectors – if that level of participation does not happen quickly, is the plan in jeopardy?</p> <p>_____ How much does the business plan rely on “soft” funding for the future survival of the HIE, beyond the initial planning phase? Is there a way to reduce this reliance on soft funding?</p> <p>_____ Has the HIE investigated the willingness of participants to pay subscription fees (if these are part of the plan) and is there any important participant-constituency that would be unwilling to pay such fees?</p> <p>_____</p>
<u>Early Implementation/Pilot Phase</u>	Is the HIE able to test itself, identify changes that need to be made, and implement these changes (including the involvement and agreement of all relevant participants/constituencies)?

Row 2: Planning and Building IT infrastructure

Planning Phase

- 1) Assess the technology and connectivity of users. For each user ask (at a minimum):
- What sort of computer technology do you use?
 - individual (un-networked) personal computers
 - networked personal computers
 - shared CPU or mainframe with desktop workstations
 - What operating system do your computers use?
 - Microsoft windows
 - Unix
 - Other (specify)_____
 - Do you have a contract with an internet service provider?
 - Yes
 - No
 - What type of connectivity do you currently have (or expect to soon have)?
 - dial-up modem over standard telephone lines
 - ISDN
 - DSL
 - Cable Modem
 - T1 or T3 line
 - Satellite link
 - Other
 - What Internet browser do you use?
 - Microsoft Internet Explorer (what version_____)
 - Netscape (what version_____)
 - Other (specify)_____
 - Do you have a network security firewall and/or virus protection software on all your computers?
 - Yes
 - No
- 2) Assess users' existing software systems (electronic medical records, electronic billing, electronic lab/pharmacy ordering). For each user ask:
- Do you currently use an electronic health record? Y N (If Yes, which one_____)
 - Do you currently do electronic billing? Y N (If yes, what billing system_____)
 - Do you currently use electronic ordering for lab tests? Y N (If yes, what system_____)
 - Do you currently use electronic prescriptions? Y N (If yes, what system_____)
- 3) Specify technology specifications – minimum requirements; identify users lacking in otherwise widespread technology and connectivity and develop plans to overcome their deficits
- Minimum requirements:_____
 - Number/% of potential users meeting these requirements:_____

	<p>4) Determine number of staff at user locations who will need to be trained/supported. For each user location ask: How many individuals at your location will need to be trained to use a data sharing system? _____ If you have satellite offices, where are they and how many people will need to be trained at each? _____</p> <p>5) Determine needs to be filled by vendors and assess competing vendors' offerings; develop vendor contracts</p>
<p><u>Early Implementation/Pilot Phase</u></p>	<p>6) Identify first/pilot users, including a range of those most/least prepared in terms of technology and connectivity. Which users will be included in early/pilot phase (for each, check technological maturity)? # users at each pilot location who are: Advanced, Moderate, Inexperienced</p> <p>7) Specify the role of the HIE – purchaser, vendor contractor, training support HIE functions, in chronological order _____ _____</p> <p>8) Connect first users and train their staff; identify early problems or glitches, training and support needs, and general problem solving.</p> <p>Type of IT problem _____ Frequency month 1 ____ Frequency month 2 ____ Frequency month 3 ____</p> <p>Type of IT problem _____ Frequency month 1 ____ Frequency month 2 ____ Frequency month 3 ____</p> <p>Requests for additional training _____ Month 1 ____ Month 2 ____ Month 3 ____</p> <p>Technical assistance/helpdesk requests Month 1 ____ Month 2 ____ Month 3 ____</p>
<p><u>Full Implementation Phase</u></p>	<p>3) Continue with phased roll-out of technology, training and support; identify ongoing user needs and plan for permanent support and continuity. Same data collection as (8) above, on a larger scale, to assist future planning.</p>

Row 3: Creating/Offering Centralized Clinical Tools

<p><u>Planning Phase</u></p>	<ol style="list-style-type: none"> 1) Specify the clinical problem or inefficiency that is to be addressed through the planned clinical tool? 2) What is the scale of this problem? In what % of cases does it occur _____? How many providers are involved _____? How many patients _____? 3) Who stands to gain when the problem is solved? Who stands to lose? Specify scale of gains/losses: Physicians gain/lose: a lot, some, little, none Patients gain/lose: a lot, some, little, none Payers gain/lose: a lot, some, little, none Vendors/suppliers gain/lose: a lot, some, little, none Others? (regulators, health department): a lot, some, little, none 4) Do important stakeholders agree about the size and nature of the problem? ___Yes ___No 5) What is the objective - what threshold is being aimed for? Objective is ___% reduction /improvement 6) Determine interest among a sample of potential participants in using the planned tool to solve the perceived problem.
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<p><u>Early Implementation/Pilot Phase</u></p>	<p>7) Demonstrate potential gains for both clinicians and pharmacists</p> <p>8) Specify how HIE will support desired change – role of the HIE.</p> <p>9) Specify an evaluation design (choose one of the following):</p> <p><u>randomized intervention/comparison</u></p> <ul style="list-style-type: none"> - Have all parties agreed to randomization? ___Y___N - If No, will those who don't agree be excluded from analysis? ___Y___N - Are there financial gains/losses for those in either comparison or intervention group (is there something to be gained by being randomized into one group or the other)? ___Y___N - Who will conduct randomization (HIE, somebody else?) -What are the randomization parameters? (e.g. size of clinician practice, types of patients in the practice, type or size of pharmacy) - How long will the randomized trial last? ____ months <p><u>pre/post</u></p> <ul style="list-style-type: none"> - Are baseline data available? ___Y___N - If No, can baseline data be collected? ___Y___N - If No, other options for “pre” data (early/late instead of pre/post)? <p><u>external comparison area/group</u></p> <ul style="list-style-type: none"> - How will the comparison area/group be selected? (demographics, diagnoses, provider attributes)? -Are the same data available for both intervention and comparison areas/groups? ___Y___N If No – how will comparable information be collected? _____ <p><u>4-way Design with pre/post and intervention/comparison</u></p> <ul style="list-style-type: none"> - see items above <p>10) Regardless of evaluation design specify data collection and timing: What data elements will be collected, from whom? _____ _____</p> <p>How often will data be collected/reported? _____ How many providers will be involved and reporting data for the pilot? _____ How many patients/cases/tests do they have in a given month? _____ Given the size of the pilot providers and their caseloads, how long will data collection need to last in order to have enough observations to test for statistically significant differences? _____</p> <p>11) Collect baseline data, begin pilot, and collect follow-up data.</p> <ul style="list-style-type: none"> - Was there a significant change and in the anticipated direction? ___Y___N If No, any idea why not? (Insufficient time, insufficient number of cases, little impact from data sharing, and other external influences dampened effect?) - If the pilot continued longer or became larger, might effects be observable? ___Y___N - If there was significant change in the anticipated direction, are the findings from the pilot persuasive enough to go forward with full, voluntary implementation? ___Y___N If No, what additional information is needed? _____
<p><u>Full Implementation Phase</u></p>	<p>12) Proceed with planned evaluation design and data collection strategy</p>

Row 4: Changing Clinical Processes/Efficiency

Planning Phase

- 1) What is the problem or inefficient care process that needs correction (specify)?
- 2) What is the scale of this problem?
 In what % of cases does it occur _____?
 How many providers are involved _____?
 How many patients _____?
- 3) Who stands to gain when the problem is solved? Who stands to lose? Specify scale of gains/losses:
 Physicians gain/lose: a lot, some, little, none
 Patients gain/lose: a lot, some, little, none
 Payers gain/lose: a lot, some, little, none
 Vendors/suppliers gain/lose: a lot, some, little, none
 Others? (regulators, health department): a lot, some, little, none
- 4) Do all of these stakeholders agree about the size and nature of the problem?
 ___ Yes
 ___ No
 If No, who does not agree (or has not been consulted)? Why?
- 5) Is there a way to align incentives so that all/most participants gain?
 ___ Yes
 ___ No
- 6) What changes will be implemented? Are there costs to implement? Who bears these costs?
 Specify Changes _____
 Implementation costs and who pays:
 No implementation costs _____
 estimated \$ _____ costs paid by _____
 estimated \$ _____ costs paid by _____
- 7) What is the objective - what threshold is being aimed for?
 Objective is ___% reduction /improvement
- 8) Do all of the stakeholders agree with the intended solution?
 ___ Yes
 ___ No
 If No, who does not agree (or has not been consulted)? Why?
- 9) If this stakeholder does not participate, is the planned solution in jeopardy? Y/N
 What can be done to bring this stakeholder on board?
- 10) Is a voluntary program going to be tried first?
 ___ Yes
 ___ No
 If No, why not?
- 11) If the voluntary program fails to elicit sufficient change, are incentives of P4P going to be employed?
 ___ Yes
 ___ No
 If No, what other options are under consideration?
- 12) What are the greatest risks for the plan – what/who could prevent its successful implementation? (specify)

Early Implementation/Pilot Phase

13) How HIE will support desired change – role of the HIE

14) Specify Action Steps – who does what, in what order

Step 1 _____

Step 2 _____

Etc.

15) Specify an evaluation design (choose one of the following):

randomized intervention/comparison

- Have all parties agreed to randomization? ___Y___N

- If No, will those who don't agree be excluded from analysis? ___Y___N

- Are there financial gains/losses for those in either comparison or intervention group (is there something to be gained by being randomized into one group or the other)? ___Y___N

- Who will conduct randomization (HIE, somebody else?)

-What are the randomization parameters? (e.g. size of clinician practice, types of patients in the practice, patient diagnoses and demographics)

- How long will the randomized trial last? ____ months

pre/post

- Are baseline data available? ___Y___N

- If No, can baseline data be collected? ___Y___N

- If No, other options for "pre" data (early/late instead of pre/post)?

external comparison area/group

- How will the comparison area/group be selected? (demographics, diagnoses, provider attributes)?

-Are the same data available for both intervention and comparison areas/groups? ___Y___N

If No – how will comparable information be collected? _____

4-way Design with pre/post and intervention/comparison

- see items above

16) Regardless of evaluation design specify data collection and timing:

What data elements will be collected, from whom?

How often will data be collected/reported? _____

How many providers will be involved and reporting data for the pilot? _____

How many patients/cases/tests do they have in a given month? _____

Given the size of the pilot providers and their caseloads, how long will data collection need to last in order to have enough observations to test for statistically significant differences? _____

17) Collect baseline data, begin pilot, and collect follow-up data.

- Was there a significant change and in the anticipated direction? ___Y___N

If No, any idea why not? (Insufficient time, insufficient number of cases, little impact from data sharing, and other external influences dampened effect?)

- If the pilot continued longer or became larger, might effects be observable? ___Y___N

- Did the pilot fail because it was voluntary, without incentives? ___Y___N

- If there was significant change in the anticipated direction, are the findings from the pilot persuasive enough to go forward with full, voluntary implementation? ___Y___N

If No, what additional information is needed?

<p><u>Full Implementation Phase and P4P</u></p>	<p>18) Proceed with planned evaluation design and data collection strategy</p> <p>19) If voluntary program is not likely to realize sufficient gains, plan and implement P4P</p> <p style="padding-left: 40px;">What positive incentives would foster change, whom do these incentives affect?</p> <p style="padding-left: 40px;">What negative incentives would foster change, whom would they affect?</p> <p style="padding-left: 40px;">How large do the positive/negative incentives need to be, in order to foster sufficient change?</p> <p style="padding-left: 40px;">What system alterations, payment alterations, etc. are needed for P4P? Who gains and who loses if these incentives are implemented?</p> <p>20) After P4P implemented, proceed with planned evaluation design and data collection strategy</p>
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Row 5: Measuring Improvements in Clinical Outcomes or Population Health or costs

Planning Phase

In addition to all of the considerations listed above:

1) Specify expected changes and how the HIE's data sharing and tools drive these changes.

Specify expected changes in health outcomes or population health status and how the HIE data sharing and tools is expected to drive each of these changes.

2) Specify the indicators of improvement

For each expected change in health outcome or population health status, specify the precise indicators that will be measured to demonstrate change.

3) Specify the data collection that will be needed to measure change.

For each indicator, specify the data collection that will be needed, including:

_____ Data Source (e.g. patient charts, immunization registries)

_____ Data collector (e.g. physician office staff, HIE staff, health department staff)

_____ Frequency of data collection

4) Specify an evaluation design that will allow attribution of change to the HIE while controlling for other factors/biases. (choose one of the following):

randomized intervention/comparison

- Have all parties agreed to randomization? ___Y___N

- If No, will those who don't agree be excluded from analysis? ___Y___N

- Are there financial gains/losses for those in either comparison or intervention group (is there something to be gained by being randomized into one group or the other)? ___Y___N

- Who will conduct randomization (HIE, somebody else?)

-What are the randomization parameters? (e.g. size of clinician practice, types of patients in the practice, patient diagnoses and demographics)

- How long will the randomized trial last? ____ months

pre/post

- Are baseline data available? ___Y___N

- If No, can baseline data be collected? ___Y___N

- If No, other options for "pre" data (early/late instead of pre/post)?

external comparison area/group

- How will the comparison area/group be selected? (demographics, diagnoses, provider attributes)?

-Are the same data available for both intervention and comparison areas/groups? ___Y___N

If No – how will comparable information be collected? _____

	<p><u>4-way Design with pre/post and intervention/comparison</u> - see items above</p> <p>5) Specify the magnitude of change and the size of the population required (power analysis). For each indicator, what is the expected degree of change in health outcomes/status between baseline and post-intervention measurement (or between intervention and comparison groups _____%) How many cases will be needed (or how big must the population be) to observe this degree of change during the time period specified? _____ Or, how long must the data collection period be to observe this degree of change in the specified patient group or population size? _____</p>
<p><u>Early Implementation/Pilot Phase</u></p>	<p>In addition to all of the considerations listed above:</p> <p>6) During pilot phase, collect baseline data before implementing the HIE or the particular tools that are supposed to drive change. Were baseline data collected and reported from all relevant participants? __Y__N If not, which relevant participants did not collect/report data? _____</p> <p>7) Determine whether data collection omits important variables, important providers, certain patient groups, etc. and adjust to achieve complete data collection. If these participants are excluded, is the evaluation design still valid? _____ If not, what steps can be taken to complete data collection and reporting? Are incentives of funding needed? Additional assistance from HIE staff? _____</p> <p>8) If a randomized design is used, test randomization procedures to assure that they are not being subverted by well-intentioned clinicians/patients. Did all groups/individuals participate in the pilot as expected __Y__N If not, what are the implications for the randomized groups? _____</p> <p>9) Review power analysis based on findings from the pilot test. Was the anticipated degree of change achieved (indicating power analysis for full evaluation is accurate)? __Y__N If not, revise power analysis to either enlarge the study population or lengthen the data collection period.</p>
<p><u>Full Implementation Phase</u></p>	<p>See evaluation considerations in previous sections.</p>

Attachment C: CCBH Project Summaries

Wisconsin Health Information Exchange - NIMI

NIMI is in the beginning of a staged approach to their HIE; their vision is that the HIE, while not being the main care-improvement agent, will “empower” improvements in care – the HIE will be a necessary but not sufficient change agent. Patient safety could improve, if appropriate tools can be found/developed and made available through the HIE. Administrative costs may also be reduced – for example if ED physicians need fewer interfaces (phone calls, etc.) to assemble patient information and provide care. And improved surveillance could eventually improve public health. But these are all hypotheticals – there is no guarantee that the HIE can make this happen. Rather, these improvements may not be possible without the HIE. NIMI feels that clinical acceptance will be the critical issue. Clinicians’ perceptions of value – either clinical improvement or cost reduction – will be important. The use of information over the HIE must be integrated into clinicians’ work processes, and this isn’t something the HIE can drive; only clinicians themselves can decide whether to make use of available information.

Phase 1 (the current grant) is a demonstration/pilot aiming to create common access for a few users from three HIT user groups: emergency departments, public health officials, and primary care practices. The evaluation will focus on how well users accept/approve of the interface. There won’t be any applications tested in the pilot; they’re testing the access and user interface.

Other aspects of Phase 1 include: developing a governance structure, incorporating, and articulating members’ needs and priorities. And Stage 1 also includes development of a business plan/model for a regional HIE (writing grants, setting up the staffing structure, etc.) NIMI’s vision is that the HIE will be member-supported. Each user will have to fund their own technology purchases but the HIE is working to attract outside funding as well and trying to get payers involved as supporters. WHIE has very recently won an RFP competition organized by the state hospital association to implement a system specifically to provide past medical history information on Medicaid patients that present to emergency departments for care in Milwaukee County. This will provide funding for an initial instantiation of the WHIE technical design and an opportunity to define the benefits of the HIE.

Phase 2 will be implementing HIT projects on an incremental pay-as-they-go basis (i.e. not funded by the user fees); each project will need separate funding and a separate evaluation. The first project will link emergency departments and large primary care practices (who don’t all have base technology as yet) and will probably focus on Eprescribing and making patient information available in EDs. They are interested in gaps in patient records that doctors must work with in EDs, how much time ED staff spend trying to fill in the critical gaps (calling PCPs, etc.), how much this delays ED care, and quality repercussions.

Evaluation

NIMI has engaged evaluators at the University of Wisconsin and together they have written two ROI papers. But at this point they do not have sufficient funding to make much more progress and are working hard to secure additional funds.

They would like a first study to explore data missing from patient records that is required for clinical decision-making. The design would be for ER physicians to record data they need that is not available to them in the ER, and how long it takes to get the information (how many calls, time elapsed trying to assemble information). NIMI intends to use the methodology in a recent JAMA publication as the basis for this design.

Regenstrief

This HIE uses a 2-stage model: some things are available to participants across the entire state, such as certain lab results, claims, PBM and state labs; a geographic model is used for providers, where they're adding users over time, working out from Indianapolis into rural areas.

Stage 1) The entire state was included all at once in electronic interface for state laboratories, PBMs and third party electronic claims; some of this has already been completed.

Stage 2) The HIE will roll out clinical applications to providers over the next few years. In 2005 they will extend to all providers within a 30 miles radius of Indianapolis. Beyond that perimeter they will continue to expand over the following two years. They want to make clinical messaging and lab results available to physician practices, whether or not they have an EHR. The interface will be web-based. 20% of physician practices across the state have no Internet access. For any practices that can't connect to the web-interface, they will fall back on faxes to deliver electronic labs. But the goal is to have everyone connected electronically and reduce the reliance on phone/mail.

The HIE staff do want to bring clinical messaging and lab results to all practices, but they do not plan to try to bring EHRs into physician offices – they will supply the connectivity/interface to the data, not the EHR itself. They see potential economics of EHRs in the physician office, although acceptance is evolutionary and many practices may feel unable to cover the cost of approximately \$2000/year for computer technology and \$60-\$80/month for system access and ISP.

The applications they expect to roll out in the first 30-mile radius-cohort this year will include:

- Clinical messaging – especially lab results. The goal is to get lab results back to physicians as fast as possible
- Claims data and quality metrics to physicians and the health plans interested in pay-for-performance programs
- Disease/outbreak surveillance (although evidence of an outbreak is hard to establish and the cost for surveillance is high)
- Integrated view of patient's clinical data in all emergency rooms and hospitals

An example of public health reporting would be a lead report on a child from a lab, which generates a message to the physician, and links the physician to the health department for lead abatement. Currently these steps all happen separately, via phone/fax/paper, and there is the potential for delay and for cases slipping through the cracks. With the linkages and clinical messaging, time-to-treatment should be reduced and follow-up should happen faster. The improved efficiency should save time for physicians and their staff, and ultimately reduce costs.

In 2006 they plan to add claims submission and clinical quality report cards, as part of a planned Pay-for-Performance initiative.

Evaluation

This HIE plans to do evaluations that are limited to ROI studies in the physician offices and data source. Other planned evaluation studies, done as part of Regenstrief's work, include using a modified randomized trial design to evaluate whether time-to-treatment is reduced, and to measure treatment changes (different/faster Rx, tests, etc.).

Santa Barbara County Care Data Exchange (SBCCDE)

This HIE intends to improve patient care by delivering relevant, timely information to providers at point-of-care, and they hope to reduce costs at the same time by eliminating redundant tests that often result from delays in information transfer (clinicians repeat tests because it takes too long to get results from one provider to another). Staff expect clinician satisfaction to be a positive by-product.

They are working with three major hospital chains which together have 5-6 hospitals, the health department, a large staff model HMO with approx. 150 physicians, and Quest Diagnostics. There is interest from the large IPA in the northern part of the county as well. (There are perhaps 500 additional physicians in small practices throughout the county, some or all of whom could eventually participate.) They would like to reach out to every provider in the community.

SBCCDE has recently completed work on myriad complicated legal and contractual issues, licensing and relicensing vendor products, etc. They have completed the technology design, testing, security, data validation audits, etc. and really don't see technology/connectivity as an important barrier. They believe that most physician offices will have a PC and an ISP, with some sort of high-speed access (they won't support dial-up). Those are the minimal 'entry' requirements and they believe even solo practices probably are at this point already, except in outlying areas where DSL isn't yet available.

Over the next 60 days they expect to have all contracts in place and will begin slow and careful deployment this fall. The first pilot will be 10 physicians and their office staffs (perhaps 40 users); 6 of whom are leaders/champions and four who are "literate" but new to the HIE. There is much they expect to learn from these 10 practices: issues with sign-up and getting user logins/IDs handled, demands on the helpdesk, training needs of physician office staff, etc.

After 45 days they expect to add 10 more practices, and continue adding slowly through the rest of the year.

They are not creating a full EHR, but rather are pulling clinical measures (lab results, radiology, discharge summary notes, etc.) from existing electronic systems. Although they'd like to see open-source architecture with peer-to-peer data queries, that isn't possible with most of the providers' existing technology. Instead, they'll be creating provider-specific data repositories, and these in turn will be linked to share clinical measures. Unique patient identifiers are an issue, since there is no common rubric in use.

They do not yet have payers involved in helping to support the system financially, although payers stand to gain if redundant lab tests are reduced. SBCCDE agreed that reduced lab tests could negatively affect a key participant (Quest Diagnostics). The various (competing) financial incentives for different sectors have not been addressed in a business plan as yet. There have been no pay-for-performance discussions with payers related to quality, and this HIE isn't focusing directly on quality indicators, or on provider performance monitoring against clinical guidelines.

Evaluation

The California Healthcare Foundation funded SBCCDE's early development, and has hired Dr. Robert Miller to evaluate the program. Dr. Miller and SBCCDE have discussed baseline data collection and measures. Unfortunately, Quest data are not patient-specific but rather provider/practice-specific, so it isn't possible to identify duplicate lab tests for a baseline. At this time the evaluation discussions are centering on provider satisfaction, reduced phone calls to Quest (from providers looking for lab results), and patient testimonials, which together should indicate at

least the potential of the HIE. Since baseline data may be unavailable, they might consider early/late repeated data collection, which should show improvement over time.

Whatcom County Health Information Exchange - St. Joseph Hospital Foundation
Washington State

This HIE has been working for over 10 years to create a model of seamless care across Whatcom County. It began with the technical infrastructure (Intranet based) which connects hospitals, SNFs, physician practices, health departments, labs, the medical society and emergency services.

Applications/Services to date include:

- Hospital electronic medical record
- Patient chronic disease registries
- Transcription
- Electronic Medical Records (EHRs) for some specialties (geriatrics, nephrology, OB/GYN)
- Medical journal subscriptions via hospital libraries
- Digital images online so that radiographs are visible across the system.
- Hospital-Skilled Nursing Facilities (SNFs) discharge planning for SNF placement (getting patient data to SNFs before the patient arrives so they can do timely care planning; and alerting discharge planners as to which SNFs have beds available)
- E-mail and internet access
- Helpdesk and LAN consultation

They expect to add E-prescribing this fall.

The hospital has an EHR for inpatient care and for some elements of ancillary outpatient services (e.g. labs). Access to applications varies, depending on job roles – physicians have access to more tools and applications than do labs, for example. They provide technology services (training, helpdesk, etc.) for smaller physician practices and have developed a shared, patient-designed, personal health record including diagnoses, medication lists, procedures, allergies, dietary preferences, etc. and a health log and goal setting tool for patients, to facilitate self-management.

They are currently working on issues like unique patient identifiers. The hospital lab also does a majority of the lab work in the area, so any patient with a lab test (almost everybody in the community) has an identifier from the lab – they may use that ID scheme and bring in the other local labs, then promulgate these IDs as the system-wide unique identifiers.

Since the infrastructure is essentially in place, this HIE is now rolling out applications and tools. With funding from AHRQ, RWJ and HRSA, they are creating a patient record portal for patients and their caregivers. The purpose is to enhance self-management for those with chronic disease. It includes a health log, individual goal setting, etc. but does not yet contain results of lab tests. Savings are expected through reduced hospitalizations, as patients better-manage their chronic conditions. This project has an advisory board, which includes a statistician and analysts from the hospital, who will conduct the evaluation.

With eHI funding they are pursuing another project to create a single, integrated Rx list for each patient, across all providers in the community. They want physicians to be able to access patients' insurance formularies before prescriptions are written, so that docs know which drugs a patient's insurance will pay for. As a pilot they're starting with three practices (8 physicians), each of which has different existing software that must be linked.

Other initiatives include:

- Extending personal health records for self-management to more patients
- CPOE pilot at hospital (starting with just one specialty and expanding to others)

Evaluation

Each of the planned initiatives will have its own work plan, data measures, and analytic team, largely based at the hospital or via contracted surveys. Evaluations of the various initiatives will include outcomes such as patient experiences/satisfaction; quality measurement; and Rx error reduction.

Some of their efforts use a pre/post survey for data collection. For example, with AHRQ funding they are surveying patients at baseline about medication reconciliation, and plan to repeat the survey a few months later, after the integrated Rx list is implemented.

Beyond survey data, baseline data are difficult/costly to collect. It might be possible to bring providers on at a slow pace, collecting data before they really use the system, and measuring repeatedly as they become more familiar with it and use it more.

Maryland/D.C. Collaborative for Healthcare Information Technology

The Maryland/DC Collaborative has been four years in the making and includes providers who normally consider themselves competitors, or as not serving the same market – hence they had very little prior experience collaborating with each other.

The main benefit from providers' perspective will be faster access to more complete data. Community physicians have been pressuring hospitals to turn around information on hospital stays so that when patients are discharged the community PCPs know what happened in-hospital (what drugs the patient was on at discharge, lab results, etc.) The push is really coming from the independent physicians.

The main institutions involved are MedStar Health, Johns Hopkins Medicine, and University of Maryland Medical System. Over 35 other organizations participate in the Collaborative, including: community hospitals, payers, primary care and specialist provider practices, medical societies, government healthcare agencies, and ancillary service providers (radiology and labs).

Care First Blue Cross Blue Shield, the major payer in the area, is offering access to its claims database (30-40% market share for the <65 population in the community) and will be a major financial supporter. CareFirst is eventually interested in pay-for-performance, as is the state's Health Service Cost Review Commission (HSCRC), another potential funder of the initiative. The HSCRC has launched a new quality initiative that can't move forward without consistently-reported data (not available via claims). The Collaborative will try to build in the data elements that the HSCRC is looking for.

The first objective was to educate all these participants about the value that an HIE could bring to the region, and overcome the political sensitivities and competitive histories of many participants. The next goals were to incorporate and seek start-up funding. The three main academic medical centers are providing financial and in-kind support.

The HIE initiated six work groups and have had considerable volunteerism in working on these groups:

- Tech Work group – mainly hospital CIOs, working on architecture design, selecting a vendor, etc.
- Financial group – mainly hospital CFOs, concerned with measuring ROI
- Steering group – 3 main institutions, CareFirst and a variety of others
- Provider group – working with the Tech Work Group on the architecture design and associated work flow
- Patient privacy and security group – working on legal issues, HIPAA, etc.
- Outcomes research group – academic researchers defining measures for patient safety and quality, care efficiency (duplicative tests, readmits); focusing now on baseline data that can be obtained from claims.

The system they are designing is not a linked EHR, but rather making existing systems interoperable. Rather, it can pull a core set of data from a provider's existing EHR (or adds electronic functionality for core data reporting, for those who have no EHRs) so that consistent data are available for all patient encounters/stays

The core data set may include:

- Diagnoses
- Demographics
- Medications
- Allergies
- Visit Notes
- Lab results and radiology
- Procedure reports
- Specialty Consult Notes
- Eprescribing

At this point, the biggest effort is to define exactly what measures will be included, balancing reporting burden (for PCPs without EHRs) and clinical utility. Research funds (grants) are needed to continue this work.

Another priority is to ask the various EHR vendors active in the area to match standards for data storage, access, etc. so physician practices don't each have to deal separately with all these vendors. The HIE would like to be the central technology location, to ease physicians acceptance (lower the entry burden for physician practices).

They intend to move forward with both the technology/vendor work and the core data set definitions. Funding will drive the timeline for getting an operational system up and running.

Evaluation

Since the core measures have not been defined, and they have little funding to continue, they have not yet addressed evaluation, other than to begin work through the outcomes research group described above. They do expect to collect baseline data before implementation, but there is considerable conceptual work needed before they are in a position to define baseline data collection.

Tri-Cities TN / VA CareSpark

This region has extremely poor status as measured along many dimensions. They are working to improve care of diabetes, heart disease, asthma, COPD (chronic disease management), and to improve screening and immunizations for kids and adults, but they are still among the worst in the nation on such measures. The area also has lots of abuse/misuse of prescription drugs and very high Rx drug use in general across the four state lines. Medicaid (especially TennCare) imposes no limits on Rx use due to court order, so recipients are free to get/fill many prescriptions for brand name drugs. The HIE could make some noticeable change in terms of disease management, appropriate prescription use, and immunization rates.

This HIE is designed to appeal to payers and providers, but with the underlying motivation being improving public health. By meeting the needs of payers and providers, they hope to encourage full use, with the downstream benefit of being able to access complete data on health indicators and encourage adherence to clinical guidelines. The potential benefits include:

- Reduced callbacks among physicians/pharmacies/labs for test results and Rx corrections
- Reduced number of duplicate tests
- Increased number of patients receiving treatment in accordance with recommended, evidence-based guidelines
- Increased number of patients receiving preventive screenings and immunizations
- Improved health outcomes for patients with diabetes, cardiovascular disease, hypertension and asthma
- Reduced number of adverse drug events related to errors in medication
- Improved ability to detect and prosecute fraud and abuse

Phase 1) making patient information available to clinicians (e.g. percent of diabetics in glucose control, immunization rates) so clinicians can see where care is not meeting guidelines. They do not intend to build/create new clinical applications, but will use existing tools and experienced vendors.

So far they have 4 identified cohorts of users:

Hi-tech EHR users	250 physicians involved	Online in 6-12 months
Hi-Interest/Medium technology capability	13 clinics involved	Online in 6-12 months
Medium-Interest/Medium technology capability		Office EHRs very quickly, added to HIE when it is up and running
Low-Interest/Low technology		Need to demonstrate ROI in first three groups in order to persuade this last group

The last two groups are where most emphasis needs to be targeted during Phase 1, to get them started. The HIE must get technology into physician offices, link existing diverse systems, create clinical applications/tools that encourage workflow change and QA efforts, and build in some financial incentives.

Phase 2) offering decision support tools that go beyond providing information and bring in 'reminders' to clinicians about what needs to happen when a patient comes for care.

Phase 3) enabling querying of records to target efforts for health improvement. If patients in a particular county are not getting care consistent with guidelines, there may be need for enhanced clinician educational efforts.

In terms of schedule, they plan to have 30% of all physicians with an EHR-lite in their offices in year 1, along with Eprescribing. Diagnostic information will be added next, along with another 30% of practices in year 2. By year 3, the first cohort will have moved through phase 3 and the rest of the practices will be on-board. (projecting out, everybody will have moved to/through phase 3 by the fifth year.)

The HIE will be connecting multiple existing EHR systems – what they call “peer-to-peer” connections. The existing systems range from a few home-grown systems to the major vendor systems, and HealthVision has an interface to link them all together. The architecture isn’t really an issue – it’s getting technology into physician practices that are still entirely paper-based. They also need to get pharmacies on-line (not all have the necessary technology) and are working on that now, to identify those that don’t have the technology and need assistance.

Some large payers and employers are participating. They are not interested in paying for use alone, but are interested in paying for performance. Payers would like to increase the use of generic drug substitution for branded drugs, and reduce redundant lab tests. They are willing to kick much of the savings back in to the program. (Although there has been no agreement reached yet about payment levels – they’re trying to estimate ROI for payers. One concept is that if payers/investors pay for 50% of the functionality/technology to get all physicians into the system, they would get 50% of the savings generated. But it’s not clear that this is what payers will agree to.) Getting the ball rolling is critical. The business plan depends on savings being generated very quickly, so the payer/employer funds start flowing into the system. But generating savings fast requires that clinicians get up and running fast. (The plan is thus somewhat circular).

Evaluation

HIE staff created a Likert-scale survey instrument that allows participants to rate the planning process to date. They will be forming an outcomes/evaluation committee this summer to define metrics and processes for monitoring, tracking and reporting on outcomes.

The states in the area have disease management and screening systems but not in this rural area. Some baseline data do exist, from studies conducted by local universities, so they have some trend data on chronic disease incidence and prevalence in their counties. Similar data can be captured once the system is up and running, and they plan to compare these data with the baseline data from the university studies. One issue for this evaluation design is that the data sources and data collection mechanisms are quite different between baseline and intervention periods. It might be difficult to compare rates (e.g. immunization rates, glucose control rates) because the data sources differ. An alternative might be to use the system to collect baseline data (phase 1) before any clinical applications/tools are implemented – that way the data collection mechanisms and sources will be the same when they take another look at the data a few years out.

Massachusetts Simplifying Healthcare Among Regional Entities (MA-SHARE)

This HIE will complete its pilot phase December 31, 2005. MA-SHARE sees its role as providing and supporting the system to allow providers and payers to share data, and to act as the convener to determine the Privacy and Security requirements for the initiatives. How users choose to participate with the system is part of the value proposition that must also be communicated by MA-SHARE.

MA-SHARE doesn't see its role as offering any particular clinical applications or inculcating consistent quality indicators or care guidelines. It will certainly assist if users want to automate disease management, for example, but they don't see it as their role to decide which disease management software tools are "best", what outcome indicators should be tracked, etc. The sense is that many creative ideas and uses will evolve, once everybody is linked and sharing data.

The first generation MA-SHARE MedsInfo-ED pilot project was a patient safety initiative to automate the transmission and communication of prescription history to emergency departments. The pilot included a live clinical data exchange that identified patients from six (6) disparate health plan data sources and delivered prescription history available from those data sources to five (5) selected hospital emergency departments, when a patient presents at the ED. The technology and business requirements were successfully accomplished. A qualitative assessment took place examining experiences with the HIE through surveys of clinical staff at the three EDs. Hospital staff were asked about their perceptions of the completeness and accuracy of the data available through the system, as well as the value of the system. The qualitative evaluation of the prescription history pilot intervention was completed June 30, 2005.

The pilot was too small to detect a clinical impact, and in fact there might be little demonstrable clinical impact even from larger efforts to make Rx information available in EDs. Hospital staff generally thought that the prescription information provided improved accuracy and completeness – when and if data were available – and thus improved their ability to care for patients. However, currently there is inherent incompleteness of prescription history due to patient payment options, drug benefit coverage, and health plan regulations. It also became clear that this capability of prescription information in EDs is too limited to be of continued "stand-alone" value and a much broader tool will have greater potential for clinical care process improvements. Based on a year of activity, results, and lessons learned, MA-SHARE revised plans for the future to rely on the scalable accomplishments of the pilot, but to step-up to projects that provide broader clinical applications and business cases.

Through considerable attention to community collaboration on the pilot system, a core coalition of healthcare information technology executives has re-committed to moving forward. In addition the Mass eHealth Collaborative (MAeHC) three-community EHR projects complement MA-SHARE work, as each explore the coincident and interoperable points where working together will fulfill many HIE objectives. (As a separate project, MAeHC is interested in eventually extending the HIE to 40 or more communities across the state.)

What the community wants is to fully demonstrate the HIE value proposition. MA-SHARE will focus on projects with more extensive functionality such as an ePrescribing Gateway that will support end-to-end ePrescribing. This is viewed as a first critical step to physician adoption of electronic health records, and thus more closely linked to a fully interoperable EHR that will eventually be offered through MAeHC. MA-SHARE envisions adding other clinical data to the Gateway such as lab results, images, and diagnostic reports.

MA-SHARE sees its role in the near-term as the community's centralized governing entity with IT resources, vision, and contracting expertise for all interested health plans and providers in the region. They will bring together the various vendors, technologies, etc. into an interoperable gateway so that

the individual providers will not have to embark on their own “one by one” time consuming and varying levels of expertise decision making. There will be a single central entity taking care of the business and technology requirements necessary to make the HIE work. MA-SHARE will provide the clinical connectivity “grid” to link existing disparate EHRs and clinical information. This won’t be easy but providers/users won’t see any of the complexities in the background.

Evaluation

Given this near-term vision, an evaluation would be entirely descriptive and might focus on user satisfaction, usage (what do they use it for), and whether the architecture/technology created is meeting users’ needs. Since MA-SHARE does not plan to build or encourage use of any particular clinical applications at this time, it would not make sense to evaluate clinical outcomes. If users decide to proceed with particular clinical applications, those users might wish to evaluate efficacy, quality improvement, cost reduction or other outcomes; but that is not a near-term goal, so currently outside the role MA-SHARE sees for itself.

Colorado Health Information Exchange (COHIE)

COHIE is a statewide coalition that will eventually create a Colorado Regional Health Information Organization (CORHIO); a non-profit entity to establish business rules, technology standards and governance for Colorado's health information exchange. Their vision is to share clinical data among providers across their entire rural state. They want to build a viable prototype to test technology and clinical utility, in four initial institutions. This will be the first effort in their state; as such they need to build community support and collaborative relationships.

The first steps are to design, build and test a prototype for a statewide health information exchange system, including both technical aspects (i.e., prototypes and a statewide blueprint) and business-legal aspects (i.e., business case, operational relationships, and governance). The first year was spent planning and forming a legal entity, governance structure, etc. and laying out the technology architecture for their system. The work they've accomplished re: legal agreements and the architectural model may be useful for others. (They've found that HIPAA actually helps a great deal, as it sets the framework for the necessary business relationships.) No massive data repository will be built, rather data will reside at the source where it was generated and then be shared in a secure and confidential manner. The absence of IT standards has meant creating their own – the Markle Foundation's work on standards will help others in the future but they feel they must move forward in the meantime, knowing that the standards COHIE develops may become obsolete.

The prototype (fall 2005) will establish a master patient index where the four partner institutions will test and refine secure messaging protocols and methods to assure confidential demographic data exchange. Statewide, as they roll out beyond the prototype, they expect to start with hospitals and rural community clinics that already have reasonable information infrastructures. They will add payers, laboratories and pharmacies that already have electronic data systems in place that can be readily interfaced.

The lack of funds to fully build out the technology/prototype is the biggest challenge. The four participating institutions are among the largest and most influential in the state with good relationships; the relevant IT departments are working well together and have designed a workable system using the limited available funding. To date the state has contributed no resources. Much of the collective work has been through volunteerism – especially with community clinicians, organizations and the public who have received no funding. This project will need to find additional funds to support the governance structure, adequate staffing (operations, logistics) and physical environment to house the needed IT staff going forward beyond the prototype.

Realistically, there is uncertainty that the system will save money – in the short term it will certainly add costs, and it isn't clear that payers/employers will want to buy-in. In the absence of compelling data (e.g., unquestionable return on investment) funding will be an uphill battle. COHIE must be able to show that the interoperability service prevented some hospitalizations and significantly reduced testing. Demonstrating ROI will only be possible after a functional normalized health information exchange is established.

Evaluation

A Research and Evaluation Work Group is investigating the impact of missing data and its affect on quality of care. At the request of physicians, they are first going to focus on emergency departments (ED) and sharing of EKG results. Another early application requested by pediatricians is bi-directional radiology results to flow between the ED and primary care providers. Starting in the emergency departments with these data elements, COHIE expects visible success with limited burden, which in turn should help build support for more advanced applications. A pilot analysis to

learn about the extent of missing data will begin at The Children's Hospital, in Fall of 2005 and should provide insight into designing a broader study across all of the COHIE participants.

They have engaged evaluators from the University of Colorado to design and conduct future evaluations related to quality, cost, etc. but without funds to complete the prototype, there won't be anything to test. They have not attempted to evaluate the planning phase; they don't really see a role for evaluation until there are clinical applications up and running.

Taconic Health Information Network and Community

This program has a community-wide data exchange that interfaces hospitals, labs, physician practices and pharmacies. They are active in 2 counties at this time. In the 2 counties they are working with 4 of the 5 hospitals, 1 national reference lab, 500 physicians (250 daily users). The goal is to eventually scale up to 4-7 counties where the large local IPA is heavily enrolled. They are trying to address the following constituencies:

- 1) Small physician practices without electronic health records or much technology. Will introduce them to technology, help them get connected and started. E-prescribing and clinical messaging will be the first step, and then an EHR will be offered.
- 2) Practices that are ready for EHRs but don't yet have them. The small physician groups will be offered a subscription model with a monthly fee and lower up-front costs. This should begin in 2006, and will be offered by MedAllies, a sister company of Taconic IPA.

Next steps include:

- Move toward some version of EHRs for all with low fees to minimize costs to each practice
- Develop incentive program.
- Interoperability project (still in design phase)

Eprescribing has some ROI potential, through increased generic substitution, and this has generated some interest among payers. Taconic expects to spend the next year building tools for this application, focusing on reducing the use of brand name drugs (currently 46% of all drugs prescribed).

HIE staff recognize the potential value of bringing payers into the HIE, both in terms of financing and in terms of encouraging clinician participation. Discussions with one health plan indicate that this payer is willing to pay a bonus just for usage: docs log on, see data electronically, and get a bonus every time – the health plan really wants to encourage participation.

Evaluation

Medication errors. Three groups: 1) Paper, 2) e-Prescribing, 3) EHR.

Six practices in each group number about 20-25 doctors. Duplicate prescription pads will be used in all three groups in phase I (baseline). In phase II, data will be collected electronically from the e-Rx group and the EHR group, while the paper group continues with the standard prescription pads. This enables a 4-way evaluation design, which is perhaps the strongest design possible in these circumstances:

	'Baseline' Paper Scripts - 2005	'Intervention' Electronic Scripts - 2006
Practices New to EPrescribing		
Legacy HER Practices		

Outcomes will focus on prescription problems (misreads, requests for revision, outright errors, etc.). The challenge will be in getting the paper scripts for the baseline period, since some practices have already abandoned them and others will be soon.

In 2006-2007 they plan to examine quality. Again, they would be using a baseline/intervention design but there may not be equivalent paper records for the baseline period to compare much more than HEDIS measures. And in 2007 they want to examine costs - which are of special interest to the health plans. They want to look at budget line items before and after widespread adoption of the HIE. Neither of these studies has been designed.