



Health Record Banking Alliance

From: William A. Yasnoff, MD, PhD, President, Health Record Banking Alliance
To: ONC
Date: April 3, 2015
RE: Interoperability Roadmap Comments

The Health Record Banking Alliance (HRBA) is a non-profit 501(c)(6) membership organization with the goal of establishing accurate, secure, and comprehensive health records that can be accessed and authenticated by both patients and their health care providers under the control of the individual patient. We advocate for community repositories of electronic health records (health record banks) as an effective and sustainable health information infrastructure solution, support programs that provide assistance to communities building health record banks, and advocate for necessary legislation and regulation consistent with community health record banks (see <http://www.healthbanking.org> for additional information). HRBA members include national, state and community health information exchange organizations, health information providers, physicians, and vendors interested in health information technology, exchange, and services.

We have reviewed the Draft ONC Interoperability Roadmap. We are very disappointed that eleven years after the creation of ONC, we are presented with (yet another) ten-year plan that essentially states many the known problems of health information infrastructure (HII) and then proposes to address them through collaboration of the stakeholders. This is not substantively different that what has repeatedly failed in the past. Furthermore, the focus of this plan on interoperability is misguided, as it is only one element among the many challenges to the development of an effective HII. What we urgently need is a different approach that actually addresses the key problems with a feasible and sustainable architecture that ensures the availability of comprehensive electronic patient records when and where needed. Health record banking, as described in our appended comments, is such an approach and we urge immediate funding of large-scale pilot testing to demonstrate its effectiveness.

Thank you for your consideration.

/s/ William A. Yasnoff

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Executive Summary

A. Purpose of ONC Interoperability Roadmap

The stated purpose of the Roadmap is to encourage interoperability to promote “*a high degree of information sharing between individuals, providers and organizations*” with the ultimate goal of “*a nationwide learning health system.*” ONC has asked for comments on this ten-year plan.

B. Health Information Infrastructure (HII) Challenges

It is self-evident that achieving interoperability will not in itself result in an effective health information infrastructure (HII) that can be the basis for improved care, reduced costs, and serve as the cornerstone of a learning health system. Even with perfect interoperability, how can we assure that all patient data is electronic? How can we assure that all the records for each patient will always be available at any site of care? Most importantly, how can we ensure financial sustainability for HII?

The core purpose of the HII is ***NOT*** interoperability, but rather to assure the availability of comprehensive electronic patient records when and where needed. Over the past decade, the four key challenges to achieving this goal have become clear: 1) privacy, 2) stakeholder cooperation, 3) availability of all medical record data in digital, interoperable formats, and 4) financial sustainability. Interoperability is just one aspect of the problem, and focusing exclusively on this one aspect of the bigger problem neglects the other important challenges. Therefore, even if this plan is successful, the end result will not achieve the overall goals. What is needed is a comprehensive approach that addresses all four of the challenges noted above, rather than just a portion of one of them. Health record banking is such an approach.

C. Health Record Bank (HRB) Approach Solves Problems

A Health Record Bank (HRB) is an organization that stores and protects copies of personal, private health information, including both medical records and additional data that optionally may be added by the patient. The patient controls who may access which parts of the information in his or her account. When patients seek care, they give permission for their health care provider to access some or all of their up-to-date health records. When care is complete, the new records from that encounter are securely deposited into the HRB and securely stored for future use under the patient’s control.

The HRB approach solves the problems of privacy (through ongoing patient control), and stakeholder cooperation (since the patients request their own records, the HIPAA regulations require every stakeholder to provide them electronically if available in that form). It also can facilitate all digital interoperable information by paying providers for deposits (required to be in standardized form) from their EHRs or supplying no-cost Internet-accessible EHRs to outpatient physicians who do not yet have them. Financial sustainability can be achieved through a combination of revenue sources including optional apps for patients, advertising to patients, and research use of the data with patients’ permission (including identified records with specific patient consent).

D. Actions needed

1. Fund large-scale HRB demonstration projects

ONC, in cooperation with the CMS Innovation Center (CMMI), should immediately allocate at least \$50 million to competitively fund at least three large-scale HRB demonstration projects. Properly structured, such projects could be fully functional within six months after initiation.

2. Help HIEs convert into HRBs

ONC should also provide assistance to existing HIEs that wish to convert to HRBs. This conversion requires: 1) engagement with consumers; 2) development of value-added services for consumers; and 3) organizational realignment to ensure consumer trust. A collaborative effort to address these issues among HIEs could rapidly lead to effective transitional strategies.

I. Current Problems with Health Information Infrastructure (HII)

A. Goal

The overarching purpose of health information infrastructure (HII) is to assure the availability of comprehensive electronic patient information when and where needed, allowing providers to have comprehensive and current compilations of a patient's health data upon which to base clinical decisions. This would also allow clinical decision support to be integrated effectively with information delivery so that both clinicians and patients could receive reminders of the most recent clinical guidelines and research results. This would avoid the need for clinicians to have superhuman memory capabilities to assure the effective practice of medicine, and enable patients more easily to adhere to complex treatment protocols and to be better informed. Patients could also review and add information to their compiled records and thereby become more active participants in their care. In addition, the availability of comprehensive compiled records for each patient would enable value-added services, such as immediate electronic notifications to patients' family members about emergency care, as well as patient-authorized queries in support of medical research, public health, and public policy decisions.

B. HII Requirements

An effective HII requires both EHR adoption and the capability to aggregate each patient's records into a coherent whole.

1. Electronic Health Record (EHR) adoption

It is self-evident that health information cannot be electronically exchanged unless the information is in digital form. The information also must ultimately be structured and codified to maximize its value. While creating digitized electronic images of paper records for transmission may be a potentially useful interim "publish and subscribe" strategy, it will not facilitate the processing necessary to automatically integrate records from multiple sources over time. Therefore, universal EHR adoption is necessary to enable a fully functional HII.

2. Aggregation into comprehensive individual records

EHRs alone, even if adopted by all healthcare providers, are a necessary but not sufficient condition for achieving HII. Each EHR simply converts an existing paper "silo" of information into structured electronic form. These provider-based systems manage each provider's information on the patient in question, but do not have all the information that exists among the multiple providers for each patient. To achieve the goal of availability of comprehensive patient information, there must also be an efficient and cost-effective mechanism to aggregate the scattered records of each patient from all their various providers and over time. Major gains in quality and efficiency of care will be attainable only through HII that ensures the availability of every patient's comprehensive record when and where needed.

C. Challenges of EHR Adoption

While medication information and laboratory results are already predominantly electronic, patient records, particularly for office-based physicians, are not. The major obstacle to physician adoption of EHRs is not merely cost, as is often cited, but the very unfavorable ongoing cost/benefit ratios. Most of the benefits of EHRs in physician offices accrue not to the physician, but to other stakeholders. It is unreasonable to expect physicians to shoulder 100% of the cost of systems while receiving only a tiny fraction of the benefits.

D. Challenges to Aggregation of Individual Records

With rare exceptions, most existing HII systems have chosen an institution-centric approach to data storage, leaving patient records wherever they are created and using distributed health information exchange (HIE) to retrieve them when needed (Figure 1 below). Although records are not stored centrally, it is necessary in this architecture to maintain at least a central index of where information can be found for a particular patient; without such an index, finding information about each patient would require queries to every possible source of medical information worldwide -- clearly an impractical approach. When a given patient's record is requested, the index is used to generate queries to the locations where information is known to be stored. The responses to those queries are then simultaneously and immediately aggregated to produce the patient's comprehensive record. After the patient encounter, the new data is entered into the clinician's EHR system and another pointer (to that system) is added to the index so it will be queried (in addition to all the other known prior locations) the next time that patient's record is requested.

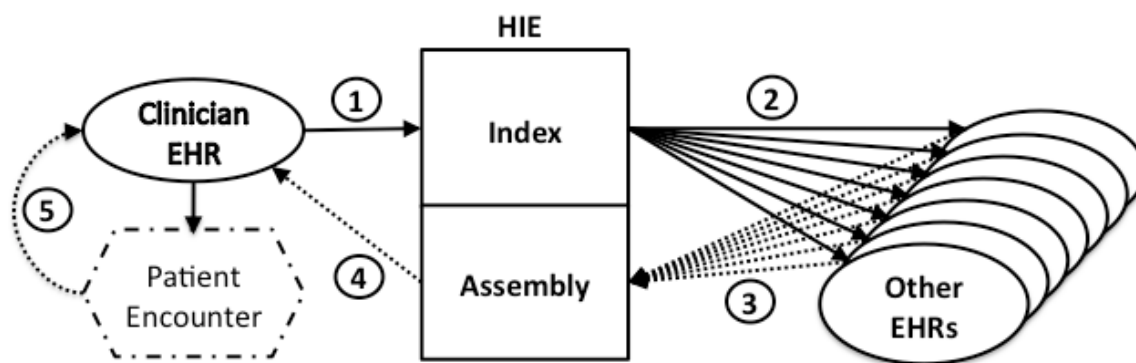


Figure 1. Institution-centric HII Architecture.

1. The clinician EHR requests prior patient records from the HIE; this clinician's EHR is added to the index for future queries for this patient (if not already present)
2. Queries are sent to EHRs at all known sites of prior care recorded in the HIE Index; patient consent is verified at each "other" EHR prior to release of information
3. EHRs at each known prior site of care return records for that patient to the HIE; the HIE must wait for all responses
4. The returned records are assembled and sent to the clinician EHR; any inconsistencies or incompatibilities among records must be resolved immediately
5. After the care episode, the new information is stored in the clinician EHR only

E. Current Path Has Not Been Successful

1. Measurement of progress

Labkoff and Yasnoff described four criteria for the quantitative evaluation of HII progress in communities: (1) completeness of information, (2) degree of usage, (3) types of usage, and (4) financial sustainability (Labkoff SE and Yasnoff WA. A framework for systematic evaluation of health information infrastructure progress in communities. *J Biomed Informatics* 2007;40(2):100-105). Using these criteria, four of the most advanced community HII projects in the U.S. achieved scores of 60-78% (on a 0-100 scale), indicating that substantial additional work was required before their respective HII systems could be viewed as complete. These measures or their equivalent should be used routinely by ONC

to evaluate HII progress. Such evaluation would provide an objective ongoing assessment of the degree of completeness of HII systems in communities and, with aggregation, the nation.

2. Both key tasks not on trajectories towards success

While estimates vary, it is clear that the majority of office-based physicians still do not utilize fully functional EHR systems, despite Meaningful Use (MU) incentives. Furthermore, even the most optimistic estimates of EHR adoption predict that many office-based physicians will still be using paper-based systems after the expiration of the incentive program.

The HIE approach to aggregating records has multiple serious flaws as described in 2013 (Yasnoff W, Sweeney L, and Shortliffe EH. Putting Health IT on the Path to Success. *JAMA* 2013;309(10):989-91):

“1. *Complex and expensive.* It requires that all EHR systems be online 24/7 responding to queries, as well as implementation of new systems for real-time reconciliation of records from multiple sources. It is extremely difficult to accomplish without a unique patient identifier (which is both politically impractical and a privacy threat). Further, an expensive 24/7 network operations center must constantly monitor and ensure availability of all possible sources of information.

2. *Prone to error and insecurity.* A recent simulation study showed that, in comparison with a central repository, the institution-centric approach requires exponentially more transactions and is exponentially more likely to provide incomplete records because of EHR response failures (Lapsia V, Lamb K, and Yasnoff WA. Where should electronic records for patients be stored? *Int J Med Informatics* 2012;81(12):821-7). Decentralization of records also allows more security failure points.

3. *Increased liability.* Because patients have no opportunity to review or annotate data, the burden of data correctness falls on clinicians, institutions, and the HIE. Integration errors and an inability to propagate corrections to those who already received data further compound medical-legal risks.

4. *Not financially sustainable.* This is a widely acknowledged problem. Financial sustainability should not require clinicians and hospitals to underwrite costs (ultimately passed on to patients or insurers).

5. *Unable to protect privacy.* Leaving data at their source makes managing privacy preferences impossibly complex because patients would need to set and maintain permissions separately at each location providing care.

6. *Unable to ensure stakeholder cooperation,* because providing records is totally voluntary; requests for them are not from patients, leaving records incomplete and possibly misleading as a result.

7. *Unable to facilitate robust data searching,* e.g., for research and public health purposes. Because each record must be obtained from all sources and integrated each time it is needed, search becomes sequential, which is prohibitively inefficient. Even with high-speed systems, access to patient information is greatly facilitated by having that information in one place. For instance, although credit reporting systems are admittedly imperfect, they would be much less effective if they had to query all creditors when a report was needed, and it would be much more difficult for consumers to review or attempt corrections if records were not in a single location.”

II. Health Record Bank (HRB) Approach Solves Problems

A. HRB Approach

A Health Record Bank (HRB) is an organization that stores and protects copies of personal, private health information, including both medical records and additional data that optionally may be added by the patient. The patient controls who may access which parts of the information in his or her account. When patients seek care, they give permission for their health care provider to access some or all of their up-to-date health records in the HRB repository. When care is complete, the new records from that encounter are securely deposited into the HRB for future use (Figure 2 below).

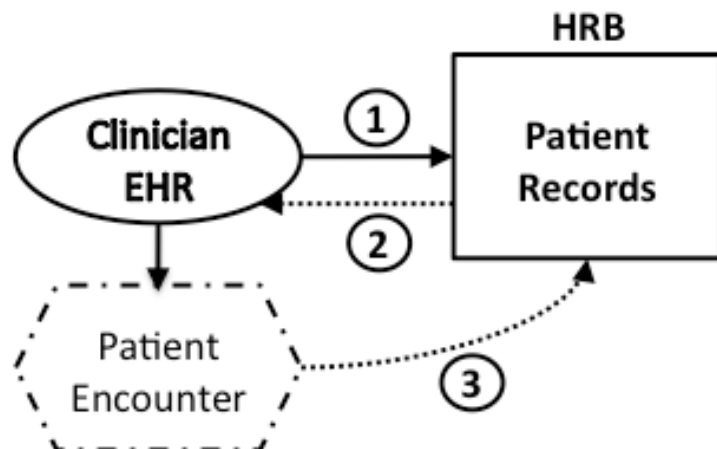


Figure 2. Patient-centric HII Architecture.

1. The clinician EHR requests prior patient records from the HRB
 2. The prior patient records are immediately sent to the clinician EHR
 3. After the care episode, the new information is stored in the clinician EHR and sent to the HRB; any inconsistencies or incompatibilities with prior records in the HRB need to be resolved or flagged before that patient's records are requested again (but not necessarily immediately)
- (Note: This process is repeated whenever care is provided, resulting in the accumulation in the HRB of each patient's records from all sources)

The HRB approach solves the problems of privacy (through ongoing patient control) and stakeholder cooperation (because the patients request their own records, the HIPAA regulations require every stakeholder to furnish them electronically if available in that form). It also can facilitate the transition to all digital interoperable information by paying providers for deposits (required to be in standardized form) from their EHRs or supplying no-cost Internet-accessible EHRs to outpatient physicians who do not yet have them. Financial sustainability can be achieved through a combination of revenue sources, including optional apps for patients, advertising to patients, and research use of the data with permission.

B. Privacy

Privacy is of overriding importance for HII. Clearly, health records are very sensitive – perhaps the most sensitive personal information that exists. In addition to our natural desire to keep our medical information private, improper disclosure can lead to employment discrimination. Furthermore, failure to assure the privacy of health records will naturally result in patients' unwillingness to disclose important personal details to their providers – or even to avoid seeking care at all. In addition to the contents of the records, the very existence of certain records (e.g., a visit to psychiatric hospital) is sensitive even if no other details are available. Therefore, extraordinary care must be taken to ensure so that health information is protected from unauthorized disclosure and use.

Assigning decision-making for disclosure of personal health records to anyone other than the patient or the patient's representative inherently erodes trust. In essence, the patient is being told, "we are going to decide for you where your medical records should go because we know what's in your interest better than you do." A patient may wonder why,

if a given disclosure is in their interest, their consent would not be sought. Furthermore, failing to seek such consent inevitably leads to suspicion that the disclosure is in fact not in the patient's interest, but rather in the interest of the organization deciding that the records should be released. To address the trust issue, all decisions about release of patient records need to be entrusted to the patient (with rare exceptions, such as mental incompetence). Establishing trust is absolutely necessary for an effective and accepted HII. The HRB approach does this by assigning all record access decisions to the patient (or the patient's authorized representative). This need not be inconvenient or burdensome; patients' disclosure preferences may be indicated in advance and stored to avoid the necessity for specific patient approval of each access to their health records.

C. Stakeholder Cooperation

To ensure the availability of comprehensive patient records, all healthcare stakeholders that generate such records must consistently make them available. Assuring long-term cooperation of competing healthcare stakeholders in providing records is problematic. Indeed, only a handful of communities have succeeded in developing and maintaining an organization that includes the active participation of the majority of healthcare providers. Even in these communities, the system could be disrupted at any time by the arbitrary withdrawal of one or more participants. The unfortunate reality is that healthcare stakeholders are often quite reluctant to share patient records, fearing loss of competitive advantage.

Patient control, a key part of the HRB approach, addresses this issue by mandating healthcare stakeholder participation through the HIPAA Privacy Rule. It requires all providers to respond to patient requests for their own records (U.S. 45 CFR 164.524(a)). Furthermore, if patients request their records in electronic form, and they are available in electronic form, this regulation also requires that they be delivered in electronic form. Although not well known, this latter provision is included in the original HIPAA Privacy Rule (U.S. 45 CFR 164.524(c)(2)), and has been reinforced by HITECH. It is also being promoted by ONC's "blue button" initiative.

D. Ensuring Information in Standardized Electronic Form

While the MU incentives are helpful in promoting EHR adoption, they do not cover the majority of costs for physician EHR systems. This is particularly evident when including the substantial conversion costs related to reduced revenue from lost productivity during the transition from paper to electronic records. In addition, the MU incentives are one time only, while the costs of EHRs continue indefinitely for physicians. To encourage EHR adoption by the vast majority of practices, we believe it will be necessary to provide permanent reimbursement and/or other offsetting benefits to allow physicians to recoup their costs. At the very least, any proposed approach to building a sustainable HII will be more effective if it includes mechanisms that result in a favorable cost/benefit ratio for physician EHRs. These reimbursements also serve to ensure standardized data export to the HRB – thereby solving the interoperability problem that is the focus of the Draft ONC Plan.

Hospitals also have not uniformly adopted EHRs. However, hospitals have a more substantial economic incentive to do so, since reducing their costs improves financial performance under the diagnosis-related groups (DRG) reimbursement system that pays a fixed amount for a specific condition. In addition, MU incentives for hospitals have been substantially more effective than for office-based physicians. However, once patients are

admitted to the hospital, coordinating their records is largely an internal problem that cannot be greatly aided by external HII. Furthermore, the large majority of healthcare encounters do not involve hospitals, and therefore HII should focus primarily on the outpatient environment.

E. Financial Sustainability

The most common approach suggested for long-term HII sustainability is leveraging anticipated healthcare cost savings. This is based on the substantial, growing body of evidence that the availability of more comprehensive electronic patient records to providers results in higher quality and lower cost care. Some of the best examples include large, mostly closed healthcare systems such as Kaiser, Group Health and the Veterans Administration, where the conversion of records into electronic form over time has been consistently associated with both cost savings and better care. While the case for HII reducing healthcare costs is compelling, the distribution and timing of those savings is difficult to predict. In addition, cost savings to the healthcare system may mean revenue losses to one or more stakeholders – clearly an undesirable result from their perspective. Finally, the allocation of savings for a given population of patients is unknown, with the result that organizations are reluctant to make specific financial commitments that could be larger than their own expected benefits. The unfortunate reality is that this path to financial sustainability has not been effective, as demonstrated by multiple HIE failures.

HRBs utilize a more promising path to financial sustainability of HII: utilizing the new value created by the availability of compiled, comprehensive electronic information held in a repository with access controlled by each patient. While it is widely recognized that this information will be extremely valuable for a wide variety of purposes, this option has remained largely unexplored.

Perhaps the largest potential HII revenue source is from innovative applications that rely on using the underlying information to deliver compelling value to consumers and other healthcare stakeholders. For example, HII allows the delivery of timely and accurate reminders and alerts to patients for recommended preventive services, needed medication refills, and other medically related events of immediate interest to patients and their families. It also would allow deployment of applications that assist consumers automatically with management of their chronic diseases. Utilizing new value to finance HII avoids the prediction and allocation problems inherent in attempts to leverage expected healthcare cost savings, with the added incentive that any such savings would fully accrue to whoever achieves them.

III. Actions Needed

A. Fund large-scale HRB demonstration projects

ONC, in cooperation with the CMS Innovation Center (CMMI), should immediately allocate at least \$50 million to competitively fund at least three large-scale HRB demonstration projects. Properly structured, such projects could be fully functional within six months after initiation. An RFP soliciting HRB proposals should be issued at the earliest possible time. Proposers should be required to show how they would successfully address the privacy, stakeholder cooperation, fully standardized and electronic information, and financial sustainability issues within a specific targeted population.

B. Assist HIEs in converting to HRBs

ONC should provide assistance to HIEs to convert their operations into HRBs. This would involve at least six steps:

1. Use data from the HIE for the HRB

Whatever data is already being collected or is available from providers by the HIE should be used for the HRB. Existing HIE interfaces should be kept in place. Those interfaces that use a “pull” approach of requesting data only when needed should be converted to a “push” methodology that transmits new data as it created. The Direct protocol being promoted by ONC can be used here.

2. Add central repository (if not already present)

If the HIE does not already have a central repository to store data, this capability should be added. This allows patient information to be immediately available for provider use with a single query authorized by the patient. It also enables efficient searching of the data to facilitate value-added applications and research (see step 5 below).

3. Provide patients with access to and control of their own data

Patients should be engaged to enroll in the HRB to access their data and record their preferences for access to it, which can be stored for ongoing use (and modified by the patient at any time). A default set of preferences might for example allow use by all of a patient’s current providers as well as bona fide emergency providers who certify the patient is present in an emergency situation. Patient enrollment should also include a standing, blanket request for medical records to be deposited in the HRB, thereby invoking the HIPAA requirement for all providers to supply such data.

4. Include patients in HRB governance

To facilitate the trust needed to operate a central repository holding comprehensive, aggregated digital patient records, patient representatives should be included in the governance structure. It may be appropriate for the HRB to be a separate organizational entity from the original HIE. The ideal governance arrangement has not yet been determined, and may vary depending on local circumstances. However, it is essential that patients’ interests be directly represented.

5. Add new capabilities to generate revenue

The HRB should include the ability to deploy applications (“apps”) to patients, advertising to patients, and generate anonymized aggregate reports of patient data for research and public health purposes. All of these activities should require the consent of the patient.

Examples of apps include 1) “Peace of Mind” Alerts -- automatic notifications to a patient’s loved ones when a patient’s information is accessed by emergency medical personnel; 2) Health and Wellness Alerts (“Prevention Advisor”) -- reminders by email or text message of recommended preventive tests and procedures; and 3) Prescription Refill Alerts -- reminders by email or text message when prescriptions are due for renewal coupled with automatic refill requests to pharmacies. In addition, third-party vendors of health-related applications (*e.g.*, Health 2.0 firms) can integrate their “apps” into an HRB. While there are many creative and compelling ideas for such apps, most require the patient’s medical information in order to be effective. Manual input and updating of that data is a huge disincentive for consumer adoption. By offering a direct connection to the HRB, consumers can select and use applications that automatically access their data on an ongoing basis, making them convenient and easy. Vendors will thus be able to benefit by deploying applications that can be rapidly adopted by large numbers of consumers. The

HRB would retain a minority share (*e.g.*, 30%) of third-party application revenue, incentivizing vendors by allowing them to retain the bulk of their own revenue.

Advertising should not interfere with the basic access functions. Patients should be able to opt out of advertising by payment of a small annual fee (*e.g.*, \$5).

Aggregation of data into anonymized reports should include data only from patients who have agreed to such use. To encourage patients to allow this, a material portion of revenue generated from these reports can be shared on a pro rata basis with participating patients (patients who agree therefore would have “interest bearing” HRB accounts).

6. Use revenue to incentivize data deposits

Revenue generated from apps, advertising, and reports may be used to incentivize providers to deposit standardized electronic medical records in the HRB. Although such deposits are required on patient request under HIPAA, the reality is that the EHR systems that generate the data are costly and burdensome, particularly to outpatient physician practices. By paying for deposits, the HRB can incentivize higher levels of EHR adoption leading to more comprehensive patient records (which are much more valuable). Another option to accomplish this is for the HRB to provide no-cost Internet-accessible EHRs to outpatient physicians who do not already have them. Provision of EHRs and/or payments for deposits should also be conditioned on providers enrolling patients for basic HRB accounts (which could be free), as well as compliance with established data standards (the latter requirement addresses the interoperability problem).

IV. Conclusion

A comprehensive health information infrastructure (HII) is a prerequisite for healthcare reform. In essence, healthcare must be “informed” before it can be successfully “reformed.” While much progress toward HII has been made, the end goals still remain elusive. It is clear that we must try new approaches, which by definition are currently unproven. A focus on interoperability alone, as described in the Draft ONC Interoperability Plan, will not be successful as it ignores other critical aspects of the problem.

As we have described, the HRB approach solves the critical problems that have stymied progress thus far. At this time, two key actions are needed: 1) Fund several large-scale HRB demonstration projects; and 2) Assist HIEs to reconfigure their operations and organizations into HRBs.