EHR Challenges & Solutions for Genomic / Proteomics Personal Medical Data

MI 403: Group 4 Homework #2

Introduction & Vision

As personalized approaches to the medical diagnoses and treatment of patients are becoming more of an integral part of patient care due to the advancements in genomics and proteomics, secure solutions must be recommended of how to handle, store, reference, and utilize highly sensitive and confidential patient information. If confidential and sensitive patient information is not handled appropriately or properly, the recent advances in genomic and proteomic science may be offset by the growing chorus of scientific, ethical / legal, and technical concerns. The ethical / legal issues that are building in the public domain are specific to the inappropriate use and misapplication of individual patient data in insurance or patient coverage decisions (information misuse which can lead to patient discrimination and bias to satiate financial needs). The technical issues that arise are largely related to how to appropriately store and integrate the genomic and proteomic information (without risk of inappropriate access), and how to inform optimal patient care by linking the patient’s phenotypic findings and historical data to new results. The risk to patients, with genomic and proteomic data populated in EHR’s today, is linked directly to the insurance and long-term care industries having open access to highly sensitive information that can be used to discriminate.

As insurance at its most fundamental level a math exercise of risk and probability, today’s insurers are constantly seeking for new and novel ways to manage costs and minimize expensive care -- to avoid adverse financial medical expenses. The motivation of insurers and other health coverage companies today is so intense that pilots are now being run by U.S. insurers to even mine the vast wealth of data on-line (e.g., shopping behavior, purchases, subscriptions, and information from social-networking sites) with the hypothesis that on-line information can reveal as much about a patient as any lab analysis of blood and medical results. All of this is being done by life insurers today to predict people's longevity. With the U.S. office of British insurer Aviva PLC and Deloitte Consulting LLP building the predictive models, predictive tests are being run on 60,000 recent insurance applicants. As insurers may go to no end to manage expenses, populating an EHR with genomic and proteomic personalized patient data only increases the chances that this sensitive medical data may also be used against the patient. (Scism, 2010)

Accordingly, as the genomic and proteomic fields are still nascent and developing rapidly, the patient data yielded by this new field of medicine puts the patient at great risk if the raw genetic data is stored where it can be used to profile and segment patient populations (e.g., identifying generational traits and avoiding insurance coverage of related family members). While it is our belief that the developing field of genomics and proteomics is promising in the improvement of patient care, due to laws not yet developed and regulations not yet codified to protect sensitive patient data, we believe patient data should be held in anonymous DNA biorepositories vs. patient data storage in the today’s EHR system. Compounding the ethical /
legal risk is the technical EHR challenge today, where few EHR systems are prepared to adequately utilize genomic and phenotypic correlated data due to the underlying architecture of the systems. Different approaches to storing this correlated data include storing all raw genotype and phenotype data in the EHR, or storing the genomic study result in the EHR with a pointer to the raw genotype data stored in a different data warehouse or clinical data repository type system.

**Hypothesis & Specific Aims**

As personalized approaches to diagnoses and treatments will become an integral part of the practice of medicine due to the advancements in genomics and proteomics, secure solutions must be recommended of how to handle, store, reference, and utilize this patient information. Our paper will leverage current research to assess and address: the advancement of personalized medicine enabled by genomics and proteomics, the developing ethical and legal issues related to genomic and proteomic advancements and recommendations for improvement, implications of genomics-based registries, how EHR systems will grow with the fields, and technical solutions to support EHR development.

**Current State of Personalized Care**

The recent advances in genomics and proteomics sciences enabled the addition of more personalized approaches to patient care to the traditional methods of clinical medicine. The new methods are based on individual characteristics of patients in predicting onsets of, diagnosing, testing for, and treating diseases. This “tailoring of medical treatment to the individual characteristics of each patient” is known as personalized medicine. “It does not literally mean the creation of drugs or medical devices that are unique to a patient but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not.” (Bates, 2009)

The main targets of personalized medicine are complex diseases and conditions such as cancer, heart disease, diabetes, AIDS, Parkinson’s, Alzheimer’s, tuberculosis, etc. These diseases are a result of interactions, and sometimes errors, between multiple genes as well as environmental factors, such as diet. For this reason these conditions require studies of entire genome, rather than individual genes only. (US News Health, 2010; Guttmacher & Collins, 2002)

The expansion of traditional patient care workflow to include methods of personalized medicine has a potential of improving quality of patient care because it enables physicians to make medical decisions more suited to the individual patient, start with or modify treatments earlier in the process, improve outcomes with better targeted treatments and reduce undesirable side effects, and be more proactive in disease prevention. (US News Health, 2010)
The two case examples below show the difference the availability of genomics data can make in preventing a condition, i.e. first case, and treatment of a disease, i.e. second case.

“Thirty-four-year-old Kathleen becomes pregnant and sees a new physician for her first prenatal visit. Her medical history is remarkable for an episode of deep venous thrombosis five years earlier while she was taking oral contraceptives; her mother had had deep venous thrombosis when pregnant with Kathleen. Her physician suspects that Kathleen has a hereditary thrombophilia and obtains blood tests to screen for a genetic predisposition to thrombosis. Kathleen proves to be among the approximately 4 percent of Americans who are heterozygous for a mutation in factor V known as factor V Leiden that increases the risk of thrombotic events. On the basis of this knowledge and her history of possibly estrogen-related thromboembolism, she is treated with prophylactic subcutaneous heparin for the balance of her pregnancy. She remains asymptomatic and delivers a healthy, term infant.

Four-year-old John has acute lymphoblastic leukemia and tolerates induction and consolidation chemotherapy well, with minimal side effects. As a key part of his maintenance-treatment protocol, he begins to receive oral mercaptopurine daily, but because a genetic test shows that John is homozygous for a mutation in the gene that encodes thiopurine S-methyltransferase, an enzyme that inactivates mercaptopurine, he receives a greatly reduced dose. Only a few years ago, about 1 in 300 patients had serious, sometimes lethal, hematopoietic adverse effects during mercaptopurine therapy. Although John is in this at-risk minority, a simple genetic test, which is now routine for patients beginning mercaptopurine therapy, alerts his physicians to this genetic predisposition. They reduce his dose of mercaptopurine and carefully monitor his blood levels, ensuring that the drug levels remain therapeutic, rather than toxic. John subsequently has an uneventful several-year maintenance period and achieves complete remission.” (Guttmacher & Collins, 2002)

Integration of genomic data into EHR systems can make the details of individual variations available to physicians at the point of care, and some EHR vendors are working on incorporating genetic data into their solutions. For example Cerner, one of the leading EHR vendors, is incorporating the inclusion of genetic test results into its EHR system. (Atoji, 2008)

The current trend is that the EHR can be a starting point for integration of genomic data with clinical details, medical history, socio/environmental and other patient data, as well as with other data in systems that cover functions such as clinical decision support, diagnostic testing, and medications, etc. These systems can include genetic-based data specific to their function. Specific personalized combinations of clinical facts, genomic, proteomic/pharmacogenomic and other genomic-based types of information help evaluate individual’s predisposition to contract a disease, measure states of disease, predict responses to medication, and ultimately help influence clinical outcomes. The picture below is an example of required data integration to supports personalized medicine. (West, 2006)
Storing complete patient data in an EHR system can make it a comprehensive source of targeted population data for genomic-based research and a tool in advancing genomic science. One of the first studies to use targeted group of patients created out of an EHR is the recent "genome-wide association study on 2334 European American patients with normal ECGs without evidence of prior heart disease from the Vanderbilt DNA databank, BioVU, which accrues subjects from routine patient care. Subjects were identified by combinations of natural language processing, laboratory queries, and billing code queries of de-identified medical record data. Subjects were 58% female, of mean (±SD) age 54±15 years, and had mean PR intervals of 158±18 ms." (Denny & Crawford, 2010)

The implementation of advances in genomic science and incorporating genomic data into established patient care practices come with some challenges. The National Institute for Health (NIH) and Food and Drug Administration (FDA) are taking steps in supporting and regulating the advances of personalized medicine methods and services. Listed below are some of the challenges in developing and using genetics-based diagnostic tests and the use of results to optimize patients' responses. (Hamburg & Collins 2010)

- **Scientific research**: Various studies use different genetic markers; the challenge is to determine the most significant genetic markers and introduce some standardization. Conduct clinical studies to understand correlations between genetic characteristics and effects of specific medication.
- **Diagnostic testing**: Regulate genetic testing to protect patients and not hinder scientific progress. Provide a single source for over 2000 known genetic tests available through clinical laboratories along with their FDA approval status.
- **Therapies**: Set acceptable limits for effects of new therapies.
- **Path to implementation**: Define processes for review, assessment, documentation and coordinated approval of new diagnostics and therapies for clinical use. The FDA's “Critical Path Initiative aims to develop better evaluation tools, such as biomarkers and new assays.” (Hamburg & Collins, 2010)
The Developing Ethical & Legal Issues

As personalized diagnoses and treatments are projected to become an integral part of the practice of medicine in the future due to the advancements in genomics and proteomics, solutions must be recommended now to ensure robust EHR data security as well as solutions to address the ethical and legal issues that arise with the advancement of personalized medicine enabled by genomics and proteomics. The significant issues that arise with the availability of this type of personalized genetic patient information include: patient privacy & confidentiality, use & access of patient genetic information, patient testing & results interpretation, clinical issues related to data & testing, and commercialization & product property rights.

With the developing fields of genomics and proteomics (e.g., protein biomarkers), one key area is related to patient privacy & confidentiality, specifically who should be able to access patient genomic data and how the data may be used. The current law passed in May of 2008 called the Genetic Information Nondiscrimination Act (GINA) prohibits U.S. insurance firms and companies / employers from accessing private patient data and discriminating on the basis of the patient data and test results. The solution of GINA was robust from an outcomes perspective, meaning U.S. citizens are protected from discrimination based on genomic and genetic test results from adverse insurance or employment decisions. The 2008 law also prevents insurers and employers from demanding any genomic tests, particularly as earlier in the decade a U.S. company survey revealed a majority required medical exams for new employees (some companies included tests for breast and colon cancer screening), and a small portion included gathering of patient family medical history which introduced the potential of bias. Patient privacy & confidentiality ensured that researchers would stay focused on developing disease therapies and treatments with genetic linkages. The recent GINA law ensured that personal genomic information, even if it is stored in EHRs, would be protected to some degree from inappropriate access and usage. (Genetic Information Nondiscrimination Act of 2008, 2008)

While GINA was a strong first step to protect patient EHR data and information, a major gap as related to use & access of patient genetic information was not fully covered by GINA. Specifically, EHRs with genomic or proteomic information, while GINA protects the patient from health insurers and employers, the law does not prevent patient bias when applying for life insurance, long-term care, or disability insurance. GINA covered the basics, however did not go as far as fully protecting the patient -- thus creating reasons for patients to want to keep their genomic information out of their EHR. Besides these compelling reasons for patients to minimize their exposure to inappropriate use & access of patient genetic information, the federal GINA law may not be clear how it supersedes any state statutes or regulations regarding patient data and discrimination. All of these potential state-level issues have not yet been addressed and are to be determined. The solution of preventing patient bias on these additional life / disability insurance and long-term care fronts is to amend the current 2008 GINA law. (Keim, 2008)

For the EHR and genomic data issue of patient testing & results interpretation, there are currently tests on the market today that have markedly improved patient lives, without much
downside of patient privacy breach or risk. These tests include the colon growth testing (familial adenomatous polyposis) which has saved lives. Other genetic tests used on the market which have proved beneficial also include prenatal diagnostic / newborn testing (e.g., Down's syndrome) and preimplantation genetic diagnosis (the detection of embryo genetic flaws used for in-vitro fertilization, used to select mutation-free embryos for implantation). However, there are many tests on the market today that target healthy patients seeking prognostication for Alzheimer's disease or some cancers. The issue is that some of these pre-symptomatic tests only give probabilistic results with no certainty, and may have serious limitations as some people may carry genomic mutations never develop the tested disease. In these situations, as genomic and proteomic testing is probabilistic and can be prone to lab testing errors (e.g., contamination, misidentification, mix-up), there are many uncertainties in robust patient testing & results interpretation. The negative outcomes for questionable test results where medical options are limited include unnecessary anxiety, risks for discrimination if the data is included in the EHR and accessed by life / disability insurers, and discrimination on close relatives / children. These negative outcomes, given the current issue where little to no regulations are in place to evaluate the performance of genomic testing as the FDA considers these tests "services", for many clinicians and for the informed patient are another reason not to pursue personalized testing or include the data in EHR or any other medical records. (Human Genome Program, 2008)

For the ethical, legal and social challenges for clinical issues related to data & testing, the challenge as detailed above is that as the FDA has little federal regulation. Accordingly, the challenges become how do clinicians become experts for all of the new genomic and proteomic testing continually being developed, how do the same clinicians vouch for the robustness or utility of certain tests when the science may be questionable, or how do clinicians help their patients understand the current limitations of genomic and proteomic science and educate on the risks to privacy and confidentiality? All of these issues are highly relevant in a developing field where GINA only provides some protections -- as tests aren't regulated, results can be questionable, and the field continues to develop rapidly. The biggest question is how patients should make informed choices, and the best solution is for the FDA to begin regulating the current testing services and Congress to amend GINA to close the known patient risk loopholes that may be exploited. (Human Genome Program, 2008)

As related to companies accessing and commercializing products based on genomic EHR data, as discussed, there is currently very little oversight of how personal genomic data is controlled or used. The deeper detail is that depending on the contractual fine print, some personal genetic testing companies have the ability to sell patient genomic data to outside groups, with little oversight of how the information is being used. With these loopholes, the challenge of the GINA law is that it doesn't fully comprehend the needed patient privacy protections and further highlights how patients may be reluctant to populate EHRs with data not covered by any law. As patients don't know how their genomic and proteomic data is being used, the solution to ensure patient privacy and confidentiality from having companies access and commercialize products is to enhance the GINA law to build privacy protections and regulations to specifically to cover the genomic and proteomic testing companies. This additional solution and amendment to GINA can cover and privatize patient genomic data (the
same data that also potentially gives medical information about close relations or children). (Keim, 2008)

The challenges of including genomics and proteomics information in patient EHRs is significant. As personalized approaches to diagnoses and treatments become more integral to the practice of medicine, patient rights and confidentiality haven’t fully kept pace with the advancements in genomics and proteomics. The solutions required to ensure EHR data is secure and robust includes expanding GINA, engaging the FDA in regulatory oversight of testing, ensuring that federal regulations supersedes state level legislation, and driving full protection of patient privacy against discrimination or bias. The future regulation and law needs to encompass: patient privacy & confidentiality, use & access of patient genetic information, patient testing & results interpretation, clinical issues related to data & testing (including data exchange), and commercialization & product property rights. The development of these protections are critical to ensure new technology developments in genomics and proteomics (including genomics-based registries) fully benefit patients and society.

**Utilization of the EHR for Genotypic & Phenotypic Association Studies**

With the emerging studies and focus on genomics, a number of challenges are being posed from an informatics standpoint in the recording and utilization of this data in conjunction with the phenotypic patient information. Because we still do not know the function of many genomic regions, it is important to store not only the results of genomic tests but also the raw data because the future re-analysis of this data could yield different results as the field matures. Few EHR systems today are prepared to adequately utilize genomic and phenotypic correlated data due to the underlying architecture of the systems. EHRs generally store and correlate a relatively small number of observations compared to the quantity of raw data produced by genomic sequencing. Different approaches to storing this correlated data include storing all raw genotype and phenotype data in the EHR, or storing the genomic study result in the EHR with a pointer to the raw genotype data stored in a different data warehouse or biorepository. The Health Level 7 (HL7) Clinical Genomic Special Interest Group (cgSIG) proposed a new Reference Information Model based genotype model to represent the data as a new observation class in an EHR. European projects such as PICNIC and SCIPHOX successfully leveraged the clinical documentation architecture level one for storage and interoperability of genomic data. Utilizing HL7 clinical documentation architectures for genomic data in EHRs has the benefit of building upon existing standards, but it is not entirely clear as the architecture migrates to version 2 how much backward compatibility will be emphasized for the integrity of early genomic data. (Sax, 2010)

The “Electronic Medical Records and Genomics (eMERGE) network [is] a consortium of biorepositories linked to electronic medical records data for conducting genomic studies.” (“The eMERGE Network”) eMERGE was formed by the National Human Research Genome Institute and subsequently funded by the National Institute of General Medical Sciences. Specifically, eMERGE combines DNA biorepositories with EHR data to develop and disseminate research methods for genome wide association studies (GWAS). The eMERGE consortium is comprise
of Group Health in Seattle, Washington, Marshfield Clinic in Marshfield, Wisconsin, Mayo Clinic in Rochester, Minnesota, Northwestern University in Chicago, Illinois and Vanderbilt University in Nashville, Tennessee. Figure 1 below describes the characteristics of the respective DNA biorepositories. (Denny & Kho, 2010)

<table>
<thead>
<tr>
<th>Institution</th>
<th>Biorepository Overview</th>
<th>Recruitment Model</th>
<th>Repository Size</th>
<th>EMR Summary</th>
<th>Phenotype</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Health (Seattle, WA)</td>
<td>Alzheimer's Disease Patient Registry and Adult Changes in Thought Study</td>
<td>Disease specific</td>
<td>2,800</td>
<td>20+ years pharmacy data</td>
<td>1: Alzheimer's Disease &amp; Dementia, 2: White Blood Cell Counts</td>
</tr>
<tr>
<td>Marshall Clinic (Marshfield, WI)</td>
<td>Personalized Medicine Research Project Marshfield Clinic, an integrated regional health system</td>
<td>Geographic</td>
<td>21,000</td>
<td>98% Caucasian</td>
<td>1: Cataract &amp; Low HDL, 2: Diabetic Retinopathy</td>
</tr>
<tr>
<td>Mayo Clinic (Rochester, MN)</td>
<td>Mayo Clinic Non-Invasive Vascular Laboratory &amp; Exercise Stress Testing Lab</td>
<td>Disease specific</td>
<td>3,300</td>
<td>98% Caucasian</td>
<td>1: Peripheral Arterial Disease (PAD), 2: Red Blood Cell Counts</td>
</tr>
<tr>
<td>Northwestern University (Chicago, IL)</td>
<td>Nugene Project: Northwestern affiliated hospitals and outpatient clinics</td>
<td>Clinic &amp; Hospital</td>
<td>10,000</td>
<td>12% AA, 9% Hispanic</td>
<td>1: Type 2 Diabetes, 2: Lipids &amp; Height</td>
</tr>
<tr>
<td>Vanderbilt University (Nashville, TN)</td>
<td>BioVU: Vanderbilt Clinic, diverse outpatient clinics</td>
<td>Outpatient lab draws</td>
<td>90,000/200,000</td>
<td>11% AA</td>
<td>1: CRS &amp; PR Duration, Other: PreVAP</td>
</tr>
</tbody>
</table>

Figure 1: eMERGE Biorepository Characteristics (Denny, Kho, 2010)

To delve deeper into the methods of collection for a DNA biorepository, greater detail is provided into the Vanderbilt biorepository, called BioVU. BioVU extracts DNA from discarded blood samples and links them to a de-identified image of the EHR, calling this combined information the synthetic derivative. The DNA is extracted only from blood samples that remain left over from routine clinical testing that has been retained for three days and is scheduled to be disposed of. The resulting information is de-identified in accordance with Title 45 Code of Federal Regulations part 46, which sets criteria for research investigation on nonhuman subjects. Exclusion criteria include patients less than 18 years of age, insufficient DNA samples, samples absent of a consent form, and samples from individuals who have opted out, duplicate samples as well as a randomly selected 2% of samples. The random 2% is intended to eliminate any certainty regarding inclusion in the sample biorepository, increasing the anonymity of the de-identified data. (Denny & Crawford, 2010)

One of the most critical pieces of data necessary for genetic association studies and population stratification is ancestry. Early work on the genetic association studies using EHR linked biorepositories began to call into question the accuracy of self reported versus observer reported ethnicity as stored in the EHR. “Although self-reported race / ethnicity is common in
genetic association studies, many clinics and hospital-based studies use observer reported ancestry rather than self-report.” (Dumitrescu, 2010) A study using Vanderbilt’s BioVU DNA biorepository sought to use genetic markers to determine the accuracy of the reported ancestry in the EHR and in so doing concluded that observer reported ancestry approximates the genetic inferred ancestry as well as self reported ancestry. The study endorsed the validity of observer reported ethnicity as being of comparable accuracy to genetically determined ancestry for future studies. (Dumitrescu, 2010)

Studies performed against the DNA biorepositories still face a number of technical challenges when trying to ensure the validity and discreteness of particular phenotypic clinical observations harvested from the EHR. Furthermore, challenges exist in continually performing such validation as one study reported in Circulation states in reference to the Vanderbilt BioVU biorepository: “The synthetic derivative is refreshed regularly to add new clinical information from the EMR as it is accrued.” (Denny & Crawford, 2010) A number of approaches have been taken to reduce the manual, human-based methods for validation and abstraction including extensive use of natural language processing, Systematized Nomenclature of Medicine – Clinical Terminology (SNOMED-CT) mapping, aggregation based on International Classification of Disease (ICD) codes and may more.

One study on genomic predictors of atrioventricular conduction posited that patient sets can be rapidly generated using DNA biorepositories linked to large health system EHRs because the electronic data are already in place, and further suggested the data may be far more valid for retrospective research due to the volume of data drawn from a complete patient population versus a subset identified for clinical trials or based on a specific diagnosed disease state. This particular study was able to utilize phenotypic and genotypic data from a myriad of diverse data sources including unstructured text, through natural language processing, billing and diagnostic codes, laboratory data, and the PR interval captured electronically, directly from an ECG machine. The methods of this study demonstrate that a population selected by interrogation of the collected synthetic derivatives, which have been organized for research, can be efficiently used to identify genomic determinants. A note of caution however, is to understand any potential bias in the biorepository such as the data having been collected from a population with a non-representative prevalence for a given disease state. This study went on to recommend that further attention and research should be focused on developing algorithmic approaches to selecting non-biased, relevant subsets for the purpose of genomic research. (Denny & Crawford, 2010)

Another study using Vanderbilt’s BioVU set out to determine whether or not biorepositories linked to EHR data is a robust platform to accelerate research in genome-driven diagnostics and therapeutics. The methods employed by this study include genotyping approximately 10,000 samples for single nucleotide polymorphism sites associated with five common diseases: atrial fibrillation, Crohn's disease, multiple sclerosis, rheumatoid arthritis, and type 2 diabetes. For each disease, the researches consulted content experts to develop algorithms to separate the de-identified EHR data into four categories: definite cases, possible cases, exclusions for matching potentially overlapping diseases, and insufficient data for classification. Cases were selected based on data from billing codes, encounter information,
laboratory data, and through the natural language processing of unstructured patient record data. “Accruing, defining and accessing samples presented multiple technical challenges, so establishing appropriate quality-control checks was vital to the success of this experiment and to the use of any biorepository.” (Ritchie, 2010) The findings of this study conclude that biorepositories linked to EHRs form a robust toolset that will indeed accelerate genome-driven diagnostics and therapeutics and that further study of larger populations may permit the discovery of new genetic associations. (Ritchie, 2010)

A study on leveraging informatics for genetic studies echoed the findings from the previously mentioned studies, but further relied on the application of technology to reduce cost and improve quality of its findings. This study, based on the biorepository and EHR at the Mayo clinic noted that genotyping and sequencing is getting less expensive, while phenotyping patients continues to grow in cost and effort. “When matched to biorepositories, the electronic medical record can be leveraged for high throughput phenotyping of large numbers of patients for genomics research, thereby substantially reducing the effort and time required to identify genetic variants that influence disease susceptibility.” (Kullo, 2010) This study utilized phenotype specifying algorithms to mine data from disparate sources that had collected in the EHR, which efficiently extracted the appropriate data into a database to be used for genetic / biomarker analyses. Abstraction of data from free text areas of the EHR was performed using the Clinical Text Analytics and Knowledge Extraction System (cTAKES), which is a natural language processing system developed by the Mayo Clinic. Architecture of the data was built upon the SNOMED-CT framework and used to codify signs / symptoms, anatomical sites, diseases / disorders, and procedures; RxNorm was the chosen terminology for drugs. The study concluded that manual abstraction and review of medical records can produce high quality data for large genetic association studies, but it is cost prohibitive. This study demonstrated through the use of EHR and a cadre of complementary technologies, that a research database built upon standard terminologies can be produced quickly, less expensively, and with fewer logistical challenges. A final note in this study was the acknowledgement that future work will now be done in the ongoing development of the EHR to improve the information structure to be more usable for clinical research. (Kullo, 2010)

Our Recommendations

As the genomic and proteomic fields are evolving today and the early genotypic / phenotypic findings and clinical associations are being re-evaluated dynamically, our position is that the EHR should not currently hold detailed or raw patient data, but rather have a secure bio-repository system. This type of system could hold the blinded raw patient data sets to enable and enhance medical research, while at the same time limit the risk to patients of industry profiling and bias. As new laws and regulations still need to be put in place to secure patient data given the growth of personalized medicine, the other significant EHR technical issues related to architecture, storage and access should be farther along and further developed, and better prepared to grow with the genomic and proteomic fields.
References


