



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

February 5, 2007

John Agwunobi, M.D., M.P.H., M.B.A.
Assistant Secretary for Health
U.S. Department of Health and Human Services
Room 434E
200 Independence Avenue S.W.
Washington, D.C. 20201
Attention: Personalized Health Care RFI

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Dear Dr. Agwunobi:

On behalf of the Blue Cross and Blue Shield Association (BCBSA) – which is made of 39 independent locally-owned and operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage to 98 million Americans – I am pleased to respond to the Request for Information on incorporating genomic information in electronic health records (EHRs) to advance personalized health care [Federal Register: November 1, 2006 (Volume 71, Number 211).]

The vision of personalized health care relies on the ability to associate personalized genomic data with clinical data to support clinical decision making at the point of care for the individual patient. This ability is difficult to realize in today's extremely fragmented information world. Creating a nationwide health information network that supports the exchange of clinical and administrative information among providers, payers, consumers and the government will have enormous favorable implications for personalized medicine. Aggregating these data and correlating them with outcomes or other relevant findings from multiple sources, could greatly expand our capacity for personalized health care.

However, since as the RFI acknowledges we are only in the early stages of introducing personalized healthcare, and have yet to define the utility of genetic information isolated from environmental and other factors, we urge taking a careful, modulated approach to the issues raised in the RFI. As prudent managers of consumers' healthcare dollars, health plans must base coverage decisions for genetic tests on the knowledge that the test results are useful for timely and accurate diagnosis and clinical management. Therefore, we would recommend that before any genomic test information is accumulated in an electronic medical record (EMR), that test should:

- Be a reliable predictor of what it measures and not merely represent normal or unexplained variation.
- Be supported by evidenced-based literature as “medically necessary.”
- Have a clear impact on clinical decision-making.

- Be associated with effective interventions that result in improved clinical outcomes.
- Be familiar to clinicians who are trained in the use of genomic test and demonstrate competency in appropriate counseling on testing and interpretation of results.

As you are probably aware, the Evaluation of Genomic Applications in Practice and Prevention (EGAPP), a nonfederal independent panel that includes a representative from BCBSA's Technology Evaluation Center, is currently compiling a list of outcomes from which to select specific outcomes to be addressed in assessments of pilot topics over the next two years. The experience gained from the EGAPP initiative will lead to an enhanced dialogue among stakeholders as to which specific endpoints are important for assessing specific genetic tests rather than a "one size fits all" evaluation of the utility of genomic applications.¹

In this spirit of taking a careful, modulated approach to the issues raised in the RFI, we offer the following comments to the seven specific RFI areas of greatest relevance to health plans.

RFI Area: *Concepts on anticipated approaches for the use of EHR and population- and community-based health care system databases for longitudinal data collection in addressing disease susceptibility, clinical course and outcomes, treatment response, evidenced-based clinical decision support, and optimal healthcare delivery systems*

BCBSA Comment:

The adoption of EHRs will be vital to the success of personalized medicine. Robust clinical risk, treatment, test, and outcome data from EHRs and disease registries will significantly accelerate health services research and clinical research and the development of evidence-based guidelines. Yet integration of clinical data with genomic data will be a challenge because the currently available genetic tests are generally very expensive and of unproven utility; their value is therefore unknown. Reliable models to assess cost-effectiveness are in an early stage. Models that provide evidence of clinical value are needed to manage these new technologies rationally over time.

At this point, it is difficult to recommend what tests should be included for use in electronic medical records because the requisite conditions necessary to rationally and effectively use genomic-based medicine do not exist. Physicians and patients are arguably not ready today for widespread use of genomic medicine especially when one considers that preventable causes of illness such as tobacco use and obesity remain widespread. As Kohane and others have warned, if practitioners pursue unexpected genomic findings without thought, there may be untoward consequences. Specifically, physicians will be overwhelmed by the complexity of pursuing unexpected genomic measurements, patients will be subject to unnecessary follow-up tests, causing additional morbidity, and the cost of genomic medicine will increase substantially with little benefit to patients or physicians, thus casting into question the benefit of genomic-based

¹ Gross S, & Khoury M. (2006). What is the clinical utility of genetic testing? *Genetics in Medicine*, Vol. 8, No. 7.

² Kohane IS, Masys DR, & Altman RB (2006). The incidentalome: a threat to genomic medicine. *JAMA*, 296(2).

medicine.²

RFI Area: Anticipated applications of genomic-based clinical testing in medical decision-making, safety assessment, and risk management

BCBSA Comment:

As evidence and guidelines develop – and evidence of value is established – we support integrating genomic data into medical decision-making when value can be demonstrated. However, attempts to apply these principles across populations should not be generalized prematurely without the ability to prove significant and definitive positive effects on outcomes. To do so could result in an unfortunate erosion of acceptance of such a strategy (see comments below on social implications).

If, as we hope, the field of genomics uncovers the etiologic and patho-physiological mechanisms of disease, we will gain a greater understanding of the causes of disease, leading to preventive interventions, early diagnoses and new and improved treatments. Although understanding the specific roles of environment and genetics in disease onset and development will most likely improve health outcomes, the impact of this information for the individual and public remains to be seen. Understanding what factors influence individual and public perceptions and behavioral consequences related to genome-based disease labels and attributions will be critical to a successful transition for personalized medicine. Therefore, as Haga has cautioned, to better understand the impact of genomic-based disease labeling and attribution, social scientists need to be involved in clinical genomics studies to assess the consequences of the use of and response to new personalized diagnoses and treatments.³

RFI Area: Establishment of biospecimen resources obtained from clinical medical services for application in research, clinical trials, health services planning, clinical effectiveness, and health outcomes evaluations.

BCBSA Comment:

BCBS Plans are interested in promoting data collection to support evidence-based medicine (EBM) and to guide this field with data. The alternative is many years of uninformed promotion of tests without clear outcomes or value.

RFI Area: Organizational or institutional practices to address ethical, legal, and social implications regarding the use of patient information, including genetic data, to support

³ Haga SB (2006). Genomics-based labeling and attribution: a case for integrating social sciences into personalized medicine research. *Personalized Medicine, Vol. 3, No. 3.*

personalized health care.

BCBSA Comment:

To realize fully the benefits of personalized medicine, people must be reassured that the existence of these programs with access to such specific personal information will not be used in ways that would disadvantage individuals, such as denying employment. Grimson is correct in calling for carefully designed protocols to ensure confidentiality; equally, however, the individual's (and their family's) right to know must also be considered. In one sense genetic data are no different from any other kind of confidential medical data, but in another sense they are profoundly different since they can, in some instances, indicate with certainty that an individual will develop a genetic disease (Huntingtons, for example, or Tay-Sachs) – while perhaps offering no treatment.⁴ This information can also indicate that an individual has a high or increased likelihood of developing some diseases. Genetic information is also different from non-genetic data because it gives provides information about family members as well as the index patient.

Special care must be taken with any research and clinical intervention based on ethnic/genetic differences, because these may be perceived with suspicion and apprehension by populations with a history of suffering discrimination and exclusion – they will not necessarily assume that such targeted programs will benefit them.

From a consumer perspective several requirements should be satisfied before genomic information should be accumulated into an electronic medical record – consumers should be willing and able to:

- Participate in counseling associated with testing.
- Participate in recommended interventions to reduce risk such as lifestyle modification.
- Accept uncertainty.
- Participate in research.
- Understand the potential harm from false positive test results.

Health plans have an interest in joining with others to advocate for protections to ensure access to aggregate and de-identified data. However, it is also important to preserve access to patient-specific results when relevant to medical necessity decisions (e.g., confirming test results for prior authorization for a medication or treatment); this should come through the physician not directly from the patient.

RFI Area: Needs for community-wide standards or best practices that will facilitate large-scale

⁴ Grimson, J (2001). Delivering the electronic healthcare record for the 21st Century. *International Journal of Medical Informatics*, 64.

data integration and exchange to benefit personalized health care.

BCSBA Comment:

BCBSA is committed to a health care system that delivers safe, efficient, and high-quality care for consumers – giving consumers greater value for their health care dollars – as well as increased administrative efficiency for providers, payers, government, and consumers.

Achieving this goal requires nationwide adoption of health information technology (IT) that is based on interoperability standards that support the exchange of clinical and administrative information among providers, payers, government, and consumers, and that includes the tools providers need to deliver higher-quality, evidence-based health care. Sharing of information across a community will be key to the future of integrated health care and should ultimately lead to less waste due to redundant or unnecessary testing, more rapid access to information that may impact the course of care selected, etc. Standards must be established so the information is shared securely and can be accessed by the appropriate users of the system

In the context of this RFI, it is not clear that genetic test data are more relevant than other data revealing risk (i.e., family history, LDL levels, BP, etc.) and, therefore, why genetic data should be especially elevated for integration and exchange. The driver for prioritizing for such standards for interchange should be proven predictive value (e.g., top priorities might include blood pressure and LDL results).

RFI Area: Models for prioritizing analyses to fill gaps in evidence of effectiveness of therapeutic interventions for different populations.

BCBSA Comment:

We have a strong interest in promoting a system that prioritizes research in areas that have significant clinical opportunity for improving treatment, increasing knowledge, or reducing costs (e.g., cancer, premature birth, neurodegenerative diseases, stroke). Test and drug development in such areas, supported by use of the databases discussed, would add value for our members. Health services research, looking at the value of tests or treatments released to the market is especially important. A quasi-government body or collaborative organization on a national level could set such priorities and direct and/or fund such efforts. It would conduct comparative clinical and cost-effectiveness research on new and existing procedures, therapies, drugs, medical devices and other technologies, but not have any role in setting coverage or reimbursement policies. Such a body could also develop genetic tests that identify why different population groups respond differently to health risks and to therapies.

RFI Area: Strategies for accumulating patient data necessary for research that may not be available through EHRs.

BCBSA Comment:

Health plans have tremendous amounts of clinically relevant data through claims, and through such care management tools as health risk appraisals, disease management, care coordination, and on-the-job wellness programs. Indeed, many BCBS Plans offer electronic personal and medical records based on claims data to consumers and to providers. Moreover, working with America's Health Insurance Plans, BCBSA has developed standards to ensure the portability of core clinically-relevant information from one health plan's personal health record system to another.

In addition to individual Plan efforts, BCBSA has launched Blue Health Intelligence (BHI). Blue Health IntelligenceSM (BHI) brings together the claims experience of 79 million Blue Cross and Blue Shield members nationwide with all personal details removed. That makes BHI the broadest, deepest pool of claims information ever created – more than twice the size of the next largest database with a proportionate advantage in accuracy. BHI's data also will provide future opportunities for health services research. The depth and scope of the ever-growing database will provide a rich repository of data to mine.

Thank you for the opportunity to have provided these comments. We look forward to participating in additional discussion with other key stakeholders – government, providers, other payers, consumers – on the appropriate next steps.

If you have questions about BCBSA's comments, please contact Inger Saphire-Bernstein (312.297.5529/ inger.saphirebernstein@bcbsa.com) or Joel Slackman (202.626.8614/joel.slackman@bcbsa.com).

Sincerely,



Allan M. Korn, MD, FACP

Senior Vice President and Chief Medical Officer