

Written Testimony Submitted by the Public on the Health Research Priorities for 2011-2012

The Pennsylvania Department of Health solicited written testimony on health research priorities for state fiscal year (SFY) 2011-2012 using the form contained on pages 2-7. This document provides a copy of all of the written testimony submitted to the Department by June 15, 2010. To conserve space, instructions for each item on the form and the responses to item 5 were removed from the individual testimonies. See table below for the list of persons who submitted testimony. Note that testimony is ordered by date and time submitted to the Department.

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* Testimony was submitted by more than one person. This table shows only the name of the first person listed on the form. See form for the names of other persons.



HD01323F

Invitation to Submit Written Testimony on Health Research Priorities Commonwealth Universal Research Enhancement (CURE) Program

The Pennsylvania Department of Health is inviting the public to submit written testimony to recommend health research priorities for the CURE Program for state fiscal year 2011-2012. Please use the form below to prepare and submit your recommendations regarding the research priorities. *Before proceeding please review background information on the last page of this form.*

This form must be submitted in MS Word via email no later than June 15, 2010, to: ra-healthresearch@state.pa.us. Only testimony that is submitted to the ra-healthresearch mailbox by the deadline will be accepted. All testimony submitted by the deadline will be posted on the Department's CURE Web site under the *CURE Health Priorities* link. The Department will not correct the testimony for spelling, grammatical or other errors. Any text that exceeds the page and size limitations specified on this form will be deleted, including any appendices. The Health Research Advisory Committee will review the testimony that has been submitted and then recommend persons who will be invited by the Department to make presentations to the Committee and answer Committee members' questions. The Committee is not interested in receiving proposals for specific research projects. After you submit written testimony, if you want to request a revision to your testimony, that request for revision must be submitted no later than June 15, 2010.

Questions? Contact: John Koch at 717-783-2548.

1. Contact Information – please complete the information requested below.

PERSON SUBMITTING TESTIMONY		
NAME (First Name MI Last Name)	DEGREE(S)	<input type="checkbox"/> Ms. <input type="checkbox"/> Mr. <input type="checkbox"/> Dr.
POSITION TITLE	MAILING ADDRESS (Street, City, State, Zip Code)	
NAME OF ORGANIZATION		
TELEPHONE (Area code, number and extension)	E-MAIL ADDRESS:	

2. Health Research Priority - Only the following types of research may be funded by the CURE Program: biomedical, clinical and health services research. These are defined as follows:

- Biomedical research is comprehensive research pertaining to the application of the natural sciences to the study and clinical practice of medicine at an institution, including biobehavioral research related to tobacco use.
- Clinical research is patient-oriented research which involves direct interaction and study of the mechanisms of human disease, including therapeutic interventions, clinical trials, epidemiological and behavioral studies and the development of new technology.
- Health services research includes any of the following: (1) research on the promotion and maintenance of health including biobehavioral research, (2) research on the prevention and reduction of disease, (3) research on the delivery of health care services to reduce health risks and transfer research advances to community use.

Please describe the health research priority – which disease, disability, injury or health problem is the research designed to prevent or control? Do not exceed the space provided. Any text that exceeds the space provided will be deleted. Use Times New Roman font size no smaller than 12-point.

TITLE (IN 60 CHARACTERS OR LESS, INDICATE THE HEALTH ISSUE THAT THE PROPOSED RESEARCH PRIORITY WILL ADDRESS):
DESCRIPTION OF THE PROPOSED HEALTH RESEARCH PRIORITY:

3. Hypothesis-driven Research Questions - What are the specific hypothesis-driven research questions that need to be addressed? *At least 50% of research to address the selected research priorities must be clinical and/or health services research. Please list the specific biomedical, clinical and health services research hypotheses and questions that need to be investigated. **If there are no questions or hypotheses that need to be investigated for a particular type of research, enter "none" in the appropriate box.** See definitions of biomedical, clinical and health services research in Question 2. Responses should not exceed the space provided. Any text that exceeds the space provided will be deleted. Use Times New Roman font size no smaller than 12-point.*

Biomedical research questions and hypotheses:

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Clinical research questions and hypotheses:

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Health services research questions and hypotheses:

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4. Impact on Health of Pennsylvanians – Describe the impact of the health-related issue on Pennsylvanians. What is the health impact of the problem on the statewide population? Are there health disparities – vulnerable segments of the population that are disproportionately affected by the health-related issue? Please provide data or statistics to support your statements. For Pennsylvania health statistics, please visit the Department of Health’s Web site: <http://www.health.state.pa.us/stats>. *Responses should not exceed the space provided. Any text that exceeds the space provided will be deleted. Use Times New Roman font size no smaller than 12-point.*

5. Availability to Testify before the Health Research Advisory Committee – Copies of the written testimony will be provided to the Health Research Advisory Committee. Committee members will review the testimony and determine whether persons should be invited to attend the Committee’s fall meeting. During the Committee meeting those persons who are invited to testify will be asked to summarize the critical research questions related to their written testimony and then answer Committee members’ questions. If invited by the Department to do so, would you or your representative be willing to present testimony and answer questions about your proposed research priority at the Committee meeting in the fall of 2010?

Yes No

Process Used by the CURE Program to Establish Research Priorities and Select Health Research Projects for Funding

Act 2001-77, the Tobacco Settlement Act, authorized the Pennsylvania Department of Health to establish the Health Research Program, known as the Commonwealth Universal Research Enhancement (CURE) Program. Each year, CURE awards two types of health research grants: (1) health research **formula** grants, which are awarded only to hospitals, universities and non-profit organizations that have received three consecutive years of funding from the National Institutes of Health; and (2) **nonformula** grants, which are awarded competitively in response to a Request for Application (RFA) that is issued once a year. Any person or organization located in Pennsylvania is eligible to apply for the nonformula health research grants in response to the RFA.

The nonformula health research grants fund biomedical, clinical and health services research projects that are consistent with specific research priorities. Once a year, the research priorities for both formula and nonformula grants are reviewed and revised as needed. The research priorities are established by the Department in conjunction with a Health Research Advisory Committee, which is chaired by the Secretary of Health.

Prior to establishing the research priorities, the public is invited to submit written testimony on research needs. Copies of the written testimony are provided to the Health Research Advisory Committee. Committee members review the testimony and determine which persons should be invited to attend the Committee's fall meeting. During the fall meeting those persons who were invited to testify are asked to summarize the critical research questions related to their written testimony and then answer Committee members' questions.

After the research priorities are finalized for the year, a RFA is issued to solicit research projects that address the priorities. Typically, the RFA is issued during late summer or early fall.

The research priorities for the competitive nonformula health research grants have changed each year. They were: bioinformatics related to cancer or infectious diseases (2001-02) and reducing disparities related to cardiovascular disease and mental disorders (2002-03), lung disease and pregnancy outcomes (2003-04), neurodegenerative disease and tobacco use and cessation (2004-05), obesity (2005-06), vaccine development and gene-environment interactions (2006-07), violence prevention and regenerative medicine (2007-08), autism spectrum disorders and antibiotic resistance (2008-09), and cancer vaccines and blindness and visual impairment (2009-10), and substance abuse (2010-2011). Current and past state fiscal year priorities for both formula-funded and nonformula-funded health research are posted on the Department of Health's CURE website (<http://www.health.state.pa.us/cure>). See *CURE Health Research Priorities* for a complete description of the priorities.

The Health Research Program maintains: (1) a public testimony mailing list of persons who want to receive invitations to submit testimony on health research needs; and (2) an RFA mailing list of persons who want to receive copies of the RFA electronically when released. If you would like to be placed on either or both of these lists (public testimony mailing list or RFA mailing list), please email the following information to ra-healthresearch@state.pa.us: your name and professional degree(s), organization, mailing address, email address, and telephone number.

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Health Research Priority Title and Description

Translation of genomics into clinical practice

Advances in genomics have the potential to improve the delivery of health care by targeting interventions to individuals who will receive the greatest benefit and experience the lowest risk of adverse events. The promise of this approach, often termed personalized medicine, for improving health outcomes is widely recognized. Perhaps less well recognized is that more effective targeting of interventions will also reduce health care costs, a critically important goal for the US economy today. Because of this promise, the nation has invested billions of dollars in the sequencing of the human genome and the identification of genetic markers for disease and disease outcomes. However, this investment is currently at risk because of a lack of information about how to translate these discoveries into clinical practice. The number of potential tests is overwhelming but knowledge about how to use these tests is almost non-existent. Without evidence to guide the use of these tests, genomics risks becoming another example of a new technology that increases health care costs without improving the health of the US population. We propose to develop a multidisciplinary initiative to generate the evidence needed to ensure the effective translation of genomic tests into improvements in disease prevention and treatment. This initiative will focus on the use of genomics in cancer because of the significant cancer burden in Pennsylvanians and the potential for genomics to transform cancer prevention, diagnosis and treatment in the immediate future.

Biomedical Research Questions and Hypotheses

This initiative builds upon basic science discoveries in genomics to answer research questions about how these discoveries should be used in clinical practice to improve health outcomes and increase health care value. However, the results of these studies will also increase understanding of the mechanisms linking genetic markers to outcomes, thereby informing the basic biomedical research in cancer. For example, one of the areas of investigation is the use of EGFR/KRAS testing to determine treatment for non small cell lung cancer (NSCLC). This testing has the potential to target treatment and improve outcomes in a disease where 5 year survival is currently under 20%. Studying the use of personalized therapy in NSCLC will provide important evidence about how to improve outcomes in this disease today but will also provide insight into the mechanisms by which EGFR and KRAS influence cancer initiation and progression, thereby supporting the development of new therapies that may improve disease outcomes in the future.

Clinical Research Questions and Hypotheses

The initiative will answer important clinical questions about the use of personalized and genomic strategies to improve outcomes of cancer prevention, treatment and survivorship. These questions fall into three main areas: (1) whether pharmacogenetic testing can improve treatment effectiveness and reduce treatment related side effects; (2) whether genomic risk panels (i.e. SNPs) can be used to improve the accuracy of cancer screening to

reduce the risk of false positive and false negative tests; (3) whether tests of somatic genetic changes in tumors can be used to tailor cancer treatment to improve treatment effectiveness and reduce treatment related side effects; and (4) whether genetic tests for cancer susceptibility can improve adherence to cancer prevention behaviors and interventions among high risk individuals. For each of these areas, there are novel genomic strategies that need to be tested in multiple different cancer types, including breast, colorectal, lung, melanoma, prostate and leukemia.

Health Services Research Questions and Hypotheses

This initiative will also address important health services research questions about the cost-effectiveness of personalized and genomic strategies. These questions include the relative value of different strategies (i.e. how much benefit is achieved at what cost) and whether the use of personalized and genomic strategies save health care dollars by reducing utilization of unnecessary and often highly expensive therapies (e.g. adjuvant chemotherapy in a patient who has an extremely low risk of recurrence). Given the current economic climate and the economic burden created by rising health care costs, understanding the value of these new technologies and how they impact the cost of prevention and treatment is necessary to inform effective health policy in Pennsylvania. Furthermore, by providing evidence to support the development of policy in these areas, these research questions help to reduce disparities in access created by uneven insurance coverage policies or inadequate investment in the delivery systems for high value interventions.

Impact on Health of Pennsylvanians

The potential impact of genomics on cancer prevention, diagnosis, treatment and survivorship in Pennsylvanians is staggering. In 2006, 73,895 Pennsylvanians were diagnosed with invasive cancer and 28,955 died from their disease. Cancer is the second leading cause of death among Pennsylvanians. The burden of cancer is particularly great among minority populations with African-American men being 37% more likely to die from cancer than white men and African-American women 17% more likely than white women. Furthermore, the adverse impact of cancer treatment is enormous, both for the long-term health consequences for cancer survivors and the costs for the population as a whole. The cost of cancer care in the US is estimated to be 219 billion dollars a year. However, translational research in cancer genomics remains underfunded, with only 1.8 % of NCI's 2007 grant portfolio going to mid and late-phase translational research. It is difficult to overestimate the potential impact of improved strategies for the prevention, diagnosis and treatment of cancer on the health of Pennsylvanians.

While new genomic approaches to cancer are continually being developed, there are currently many examples that have the potential to dramatically impact the burden of cancer in Pennsylvania. For each example, investigators at the University of Pennsylvania and other institutions in Pennsylvania are poised to conduct the clinical studies necessary to move these discoveries into clinical practice. These include:

(1) Pharmacogenetic tailoring of nicotine addiction treatment: Cigarette smoking causes 80-90% of lung cancer deaths, and increases the risk of several other cancers. Current approaches are limited because of variability in response to the FDA approved therapies (nicotine replacement, bupropion and varenicline), side effects and high rates of relapse. Use of information about individual variation in nicotine metabolism (based upon the nicotine metabolism ratio) to optimize therapy may result in greater rates of sustained abstinence with fewer side-effects and lower costs.

(2) Genetic susceptibility and breast cancer screening and prevention: Breast cancer remains the most common cancer among women in Pennsylvania with 9,739 new cases in 2006. Breast cancer risk assessment has the potential to decrease morbidity and mortality from breast cancer through improved prevention and screening strategies but current risk prediction models are inadequate for use in clinical practice. Genome wide association studies have identified multiple genetic markers that may dramatically improve risk prediction and screening and prevention decisions. Tests using these markers are currently available and studies are needed to determine their effectiveness in breast cancer risk stratification.

(3) Personalized treatment for NSCLC: In 2009, 45% of all newly diagnosed lung cancer cases will be advanced stage NSCLC. Standard treatment involves empiric, relatively toxic therapy given with little distinction between histologic subtypes and virtually no input based on molecular typing. However, developments in cancer genomics over the last five years suggest that both pathologic analysis and molecular typing (particularly EGFR and KRAS mutation testing) may be important in determining appropriate therapy for patients with NSCLC and improving disease outcomes and reducing toxicity.

(4) Genetic testing in melanoma families: Adherence to sun protection behaviors remains one of the major challenges in cancer control, particularly for individuals with a personal or familial history of melanoma. The impact of genetic testing for p16 mutations on adherence is promising but currently unknown.

The development of evidence to support the translation into clinical practice is particularly important to ensure that these approaches are able to benefit all segments of the population, including traditionally disadvantaged groups. Disparities in the use of health care advances are an important problem and evidence based guidelines for these advances are an important step to addressing these disparities.

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Health Research Priority Title and Description

Early Intervention to Prevent Obesity

The childhood obesity epidemic elevates risk for adult obesity and its co-morbidities, and has the potential to overwhelm our healthcare system. The fetal and infant periods play critical roles in the development of obesity, but there has been little focus on preventing obesity during these periods. The need for early intervention is obvious: Over 20% of US children aged 2-5 years are overweight and over 10% of infants less than 2 years are already obese. Early intervention is critical because overweight infants and toddlers have elevated risk for obesity, diabetes, and cardiovascular disease later in life when attempts to prevent and treat obesity have had limited success. In contrast, the prenatal period and infancy are opportune times to begin obesity prevention; they are periods of rapid growth, developmental plasticity, and learning, which can have both immediate and long-lasting metabolic and behavioral consequences. Recognizing that early obesity increases risk for obesity and the metabolic syndrome later in life, the Institute of Medicine's expert committee wrote "the prenatal period, infancy, and early childhood may be stages of particular vulnerability to obesity development because they are unique periods for cellular differentiation and development. This unique vulnerability might make it possible for actions taken at these stages to determine the future course of adiposity." Fortunately, basic research findings suggest numerous perinatal interventions with great potential for providing lifelong benefit.

Biomedical Research Questions and Hypotheses

None

Clinical Research Questions and Hypotheses

1) Can childhood obesity be prevented or moderated by delivering interventions to pregnant women?

We hypothesize that maternal characteristics that are associated with obesity in offspring are modifiable and can be moderated through intervention. Such characteristics include maternal obesity, diabetes, pregnancy weight gain, and diet during pregnancy. Each of these can be positively influenced through evidence-based interventions that include education, healthy diet, and exercise.

2) Can childhood obesity be prevented through interventions delivered during infancy?

We hypothesize that various aspects of an infant's life are ripe for interventions that can prevent obesity in the long term. Such areas include promoting breastfeeding, promoting healthy sleep habits, promoting other methods to soothe infants instead of feeding, establishing healthy food preferences early in life, and improving parental understanding of healthy growth patterns when their children are infants. Each of these can be

improved by evidence-based interventions shown to improve parent-infant interactions surrounding feeding and weight gain early in life.

Health Services Research Questions and Hypotheses

None

Impact on Health of Pennsylvanians

Acknowledging the high prevalence of overweight and obesity in the United States, Healthy People 2010 sought to improve the proportion of Americans that have healthy weights. A target of 60% of Americans living at healthy weights was established, but unfortunately, as of 2006 only 37% of adults in Pennsylvania were not overweight or obese. Stated another way, 63% of Pennsylvanians are living at an unhealthy weight. This problem disproportionately affects minorities as 69% of Black adults and 73% of Hispanic adults in Pennsylvania are overweight or obese.

Because maternal health and weight status during pregnancy are key factors in determining the health and future weight status of their offspring, it is particularly concerning that nearly half (46%) of women between the ages of 20 and 39 are overweight. This fact puts the next generation of Pennsylvanians at risk for even worse health than our current generation where obesity has reached epidemic proportions.

Given the prevalence of overweight and obesity among adults, it is not surprising, but still quite concerning that 32% of children aged 2-19 are overweight or obese in the U.S. Minorities are again disproportionately affected with 35% of Black and 38% of Mexican American children characterized as overweight or obese.

These data are particularly troubling given the known associations of obesity with conditions such as heart disease, hypertension, and diabetes as well as poor emotional health. As a result, the Institute of Medicine has estimated that nearly 10% of all medical costs in the U.S. currently can be attributed to overweight and obesity. Further, between the late 1970s and the late 1990s, the costs related to obesity related hospital care for children tripled.

Since few strategies have proven effective in treating obese children, these troubling figures point toward an alternate solution - prevention. Prevention through early intervention to reduce weight gain and childhood obesity can make an essential contribution to addressing the health care problems arising from obesity by stemming the rising prevalence of childhood obesity, which tracks from infancy to childhood to adulthood. Further, since there is evidence that becoming obese as a child leads to more serious complications during adulthood, probably due to longer exposure to obesity's adverse metabolic effects, the cumulative effect of obesity plus its comorbidities of diabetes, hypertension, hypercholesterolemia, and sedentary life style will likely overwhelm the healthcare system in Pennsylvania and the United States in the near future. In fact, it is estimated now that one out of every three children born in the U.S. will have diabetes during their lifetime. Therefore, before another generation exceeds its predecessor and escalates the obesity epidemic, evidence-based prevention efforts must be developed, tested, and implemented.

Contact Information

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Health Research Priority Title and Description

Preventing Harmful Drug-Drug Interactions

Pennsylvania is home to the second-highest number of senior citizens in the US. Because many seniors take multiple medications, they are at greatest risk for harmful drug-drug interactions. Although several medical compendia provide doctors, pharmacists, and patients with advice about which drug-drug pairs to avoid, these compendia disagree with one another to a surprising and dramatic degree. This disturbing disagreement is because most of the information contained in the compendia are based on are anecdotes rather than controlled scientific data. Not surprisingly, electronic prescribing software based on these compendia also disagree markedly. This leaves patients at risk for receiving harmful drug-drug interactions, and also prevents co-administration of medicines that would actually benefit patients if given together, but are avoided because of unnecessary fear of harmful interactions.

Biomedical Research Questions and Hypotheses

None

Clinical Research Questions and Hypotheses

We propose to use known and hypothesized pharmacologic mechanisms to predict which drug-drug pairs will result in clinically important harmful drug-drug interactions, and test these predictions in very large, epidemiologic, population-based studies using administrative (i.e., health insurance) databases. We have used such databases for many years and are well acquainted with their advantages and limitations. Such studies will provide crucial mechanistic insight into interactions between drugs and provide crucial evidence to physicians, pharmacists, and patients.

Health Services Research Questions and Hypotheses

Using the results of these large, population-based epidemiologic studies, we will then design, implement, and evaluate evidence-based health care interventions, for example, using information technology (e.g., computerized physician order entry programs) to reduce the risk of harmful drug-drug interactions while at the same time permitting co-administration of drug combinations that have been shown to be safe. Such interventions can be implemented on a widespread basis throughout the Commonwealth of Pennsylvania and beyond. We will further rigorously evaluate the effectiveness of such interventions, including looking for potential unintended consequences of such interventions.

Impact on Health of Pennsylvanians

Pennsylvania is home to 1.9 million senior citizens (over 15% of the Commonwealth's population), second in number and percent only to that of Florida. Not surprisingly, the elderly population, and in particularly the frail elderly population, is both at highest risk of receiving multiple interacting medications and experiencing adverse effects of those medications. In addition, Medicaid beneficiaries, who include low-income and disabled persons and a disproportionate number of minorities, are also among the highest risk individuals for harmful drug-drug interactions. Another high-risk population is the low-income senior population served by the Pharmaceutical Assistance Contract for the Elderly (PACE) program, which is administered by the Pennsylvania Department of Aging. Among community-dwelling elderly individuals, harmful drug-drug interactions account for 13% of all adverse drug reactions, and are responsible for nearly 3% of all hospitalizations. Harmful drug-drug interactions are the source of a great deal of concern among health professionals and the general public alike. A public opinion poll conducted in 2002 found that fully 70% of respondents indicated that, if hospitalized, they would be "concerned about receiving two or more medicine that interact in a negative way."

Thus, a rigorous, science-based program to reduce harmful drug-drug interactions would have enormous impact within the Commonwealth of Pennsylvania and beyond.

Contact Information

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Health Research Priority Title and Description

Overweight, Obesity and related complications

Overweight and obesity have become one of the most important threats to human health worldwide. In the United States of America more than 50% of the population is overweight and almost 1/3 is obese. Regardless of the efforts made to address this public health issue, the prevalence of obesity continues to rise.

Multiple lines of scientific evidence support the associations between overweight/obesity and various disease including diabetes mellitus, hypertension, coronary artery disease, cancer, and sleep apnea. In addition, the consequences of obesity extend beyond physical ailment and into the psychosocial and economic aspects of life. Thus, overweight and obesity and related complications should be prioritized for the next round of CURE program.

Biomedical Research Questions and Hypotheses

1. Epidemic analysis of overweight and obesity.
2. Establishment of the causal relationship between factors and overweight/obesity.
3. Identification of better and simple parameters in determination of overweight and obesity.
4. Lifestyle and overweight/obesity.

Clinical Research Questions and Hypotheses

1. Development of therapeutic strategies in prevention and treatment of overweight and obesity.
2. Development of therapeutic strategies in treatment of the complications derived from overweight and obesity.

Health Services Research Questions and Hypotheses

None

Impact on Health of Pennsylvanians

The prioritized subject will apply to globally, nationally as well as state wise.

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Health Research Priority Title and Description

Health Monitoring & Management for Successful Aging in Place

Pennsylvania is a largely rural state with one of the largest elder populations in the nation. National surveys report that 85% of elders prefer to remain in their own homes, as they grow older. Key to "successful aging in place" is effective monitoring and management of chronic disease. Nationally, 75% of elders have one and 50% two or more chronic health conditions. If not monitored on a timely basis or managed correctly, chronic conditions can lead to severe, immediate, and preventable disabilities, such as hip fractures and stroke—resulting in unnecessary acute care and long-term care service use. Comorbid mental illness, such as depression, can exacerbate physical health conditions, lead to increased health care utilization and place substantial burden on family caregivers. Given the growing numbers of elders who wish to remain at home in their community, there is a need to better understand the effectiveness of different technological applications (e.g., sensors for remote health monitoring and real-time health data collection), adaptive home and community environments, and integrative care models on chronic disease management. Improving the elder, family member, or health professional's ability to monitor and manage chronic disease at home could enhance coordination and communication between care providers (and between providers and care recipients), reduce the already extensive health care costs associated with unnecessary acute care use or nursing home placements, and foster "successful aging in place."

Biomedical Research Questions and Hypotheses

(1) How do(es) communication and information-focused interventions minimize chronic disease risk factors associated with loss of functional independence and social participation? (2) How can technology be used to provide more accurate monitoring of chronic physical and mental health conditions and deliver 'just-in-time' interventions to prolong independence and delay morbidity?

(H1) Direct, timely access to health information by formal and informal caregivers using instant in-home communication devices will enhance care and prevent acute care visits to physicians - including emergency departments and hospitalization. (H2) In-home teaching regarding medication use, disease prevention, symptom management and injury prevention will reduce unnecessary acute care interventions.

Clinical Research Questions and Hypotheses

(1) How does geographic location (urban/rural), ethnicity, age, family, or socioeconomic status across chronic diseases influence the types of self-management strategies chosen, the effectiveness of different approaches for health monitoring, and the transfer of information between elder, families, and health care providers? (2) How can technology be used to empower family members with the information and communication tools necessary to help identify elders in the community who suffer from undiagnosed or inadequately treated physical and mental health problems?

(H1) Technology can reduce the distance barriers for timely care in rural populations. (H2) Rural elders who use interactive communication technologies will report enhanced social networks and reduced symptoms of social isolation. (H3) Including the family caregiver(s) to report their observations will enhance the amount of patient information available to health care providers to make clinical decisions and result in timely interventions with significant cost savings and improved quality of life for each elder.

Health Services Research Questions and Hypotheses

(1) Which health care provider roles/approaches and care coordination systems are most effective in providing seamless, continuous care that promotes self-management across chronic diseases and successful aging in

place? (2) How can family members facilitate an elder's initial engagement in, and adherence to, treatment of chronic health conditions?

(H1) Using an expanded Chronic Care Model approach increases elder independence and quality of life. (H2) Family involvement in monitoring of frail elders with the ability to contact primary care physicians will result in diminished need for acute care visits, emergency evaluations, and hospitalizations.

Impact on Health of Pennsylvanians

Pennsylvania currently ranks third in the United States in the percentage of people over the age of 65 and fourth in the number of people over the age of 85. It is projected that by 2030, 22 percent of Pennsylvanians will be age 65 or older, and the number of those 85 and older will increase by over 50 percent. The majority of these elders will prefer to remain in their own home as they age. Some will enjoy good health and ample opportunities for continuing and expanding social interactions, while for most advanced age results in physical and mental decline and an increased risk of chronic diseases. Chronic diseases are the leading cause of death and disability in Pennsylvania. For Pennsylvania elders, chronic disease may result in loss of function, and increased dependence on family and friends for support, and health care and long term care providers for essential services.

Nationally, 75% of elders have at least one chronic illness and 50% have two or more chronic illnesses. In Pennsylvania, chronic disease patients account for 80% of all health care costs and hospitalizations, 76% of all physician visits and 91% of all filled prescriptions. Not managed properly, chronic diseases can lead to severe and immediate disabilities (e.g., stroke, hip fracture) as well as progressive disability that slowly erodes the ability of elders to care for themselves. Unmanaged comorbid mental health problems (e.g., depression) can negatively impact the resilience of elders to manage and recover from medical conditions. Effectively managing chronic diseases requires daily decision-making by the elder (and sometimes their family) and timely interactions with health care and long-term care providers. However, elders (and their families) often lack the knowledge and information resources to self-manage their health effectively. In addition, the support efforts of family and friends are not well connected with health care and long-term care providers. Existing research suggests that providing informal caregivers with better, more timely information and improving integration with the formal health care system leads to significantly better overall health for the elder.

An additional challenge is that Pennsylvania is also largely a rural state, with 48 of its 67 counties classified as rural. Among rural Pennsylvanians, 16 percent are currently age 65 or older. Devising technological innovations, supportive environmental designs, and care models that enhance the ability of formal and informal health care providers to monitor and support elder health management (whether they are urban or rural residents) will foster successful aging in place and reduce health care costs associated with unnecessary acute care use or nursing home placements.

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Health Research Priority Title and Description

Promoting wellness for people with chronic conditions across the disease spectrum

Almost half of US adults have one or more chronic conditions (e.g., diabetes, asthma, heart disease). Chronic conditions (CCs) account for 70% of all U.S. deaths annually and are among the most costly and preventable health problems. These figures do not include behavioral health conditions-mental health and substance use disorders- that are also associated directly and indirectly with high expenditures. Though biology plays a part, CCs all have a strong behavioral component, i.e., they are in part determined by one's behavior choices. Behaviors such as substance use (including smoking), diet and activity level contribute to the development, course and severity of all CCs. Nearly every biomedical field spends significant resources to identify effective interventions to initiate and maintain behavior changes believed to minimize the risks and consequences of CCs. Though these strategies all target the same behavior change processes, intervention efforts are not integrated, resulting in duplication of costs and fragmentation of services. A potentially high impact yet unexamined question centers on identifying commonalities (a) among proven behavior change interventions across fields and (b) among successful 'behavior-changers' across chronic conditions. Framing this question is the premise that there is likely a finite number of strategies and of individual psychosocial profiles that effectively promote the initiation and especially the maintenance of behavior change.

Biomedical Research Questions and Hypotheses

None

Clinical Research Questions and Hypotheses

- Are there are similar "success" and "relapse" rates among individuals with one or more CCs across a range of CCs?
- What are the similarities among the individuals who successfully manage to maintain behavior change in the context of a chronic condition?

Health Services Research Questions and Hypotheses

- What are the similarities across behavior change strategies that have proven effective to manage various chronic conditions?
- How information culled from answering the preceding questions can inform the development of a general health behavioral change strategy that can then be adapted for a given condition or individual to maximize the likelihood that health behaviors are adopted and maintained?
- Are integrated behavioral change maintenance programs more effective for individuals with multiple CCs concurrently than interventions delivered in parallel by different medical teams?

Impact on Health of Pennsylvanians

In 2007, 28% of adult Pennsylvanians reported having high blood pressure (hypertension), 40% screened for high blood cholesterol, which puts them at greater risk for developing heart disease and stroke, 32% reported being diagnosed with arthritis, 8% with non-pregnancy related diabetes and 63% were overweight or obese. Of the five most common causes of death in PA in 2005, four were linked to chronic conditions (heart disease, cancer, strokes and respiratory illnesses). Heart disease alone accounted for 28% of deaths; stroke caused 6% deaths. Examining and integrating proven elements of successful behavior change strategies across disciplines and understanding how to effectively manage, prevent and/or arrest the progression of chronic disease will inform health service providers across Pennsylvania, increase quality of life and life years for Pennsylvanians, and minimize disease-related costs to the state. Answering the proposed research questions will represent a first step toward that goal and also position Pennsylvania as a leader nationwide in the ongoing efforts to keep health care's cost down while improving the nation's health.

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Health Research Priority Title and Description

Diabetes

Diabetes incidence is rising exponentially, with most experts indicating that diabetes has reached epidemic proportions. In 2010, there are > 23 million people in the US with diabetes, with some 1.2 million in PA. This accounts for some 8% of the PA population. The complications of diabetes are extensive and expensive. These include coronary artery disease, kidney failure and dialysis, stroke, and blindness. According to a recent report, diabetes cost the nation \$174 billion in both direct cost and productivity losses. The report also showed that approximately half the people with diabetes are covered by publicly funded health care and that routine diabetes care is relatively low cost, with most of the cost as a result of poor chronic management of the disease. Although diabetes is one of the most pressing state health care priorities, PA ranked 47th out of 50 states in accomplishing adequate glycemic control. In the Commonwealth, 70.9% of Pennsylvanians with diabetes had a hemoglobin A1c (HbA1c) (measure of glucose control) > 6.5%, only 0.2% above the State of Mississippi. Very troubling is the economic impact where in PA there are four times the rate of diabetes hospital admissions as the best-performing states. There are recent attempts to address chronic disease with improved health system approaches being delivered across the Commonwealth. Despite these good efforts, the associated escalating health care costs continue to stress state employers and health systems.

Biomedical Research Questions and Hypotheses

Customized treatment of type 2 diabetes: Development of tailored treatment strategies. Research Question: 1) How do the age of the patient and length of diabetes duration affect diabetes treatment response to lifestyle intervention or pharmacologic therapy? Lifestyle modification with diet and exercise is accepted to be a cornerstone in the first-line treatment of type 2 diabetes. Likewise, the benefits of specific anti-diabetic drugs to improve insulin sensitivity or insulin secretion are generally well described. Little objective data exists, however, regarding how the age of the patient, ranging from adolescents to the elderly, as well as the duration of disease may influence response to treatment. For example, little data is available to suggest whether or not those patients respond as well to diet and exercise due to their dwindling pancreatic reserve to secrete insulin, i.e., whether increasing insulin sensitivity is sufficient to treat their diabetes. We hypothesize that diabetes in old age and long-standing diabetes are both more likely to be more resilient to lifestyle and pharmacologic treatment of insulin resistance. This research could directly translate objective data into better evidence-based medicine in the treatment of diabetes.

Clinical Research Questions and Hypotheses

Rural and Minority Outreach. Research Question: 1) What are the specific determinants that affect diabetes care in high risk rural dwelling and minority populations? 2) What culturally sensitive and behavioral approaches are most effective in improving outcomes in underserved populations with diabetes?

Implementing and evaluating diabetes interventions with comprehensive approaches is particularly critical in rural and minority communities, since this population experiences particularly increased rates of diabetes and its complications. Rural residents and minorities have a poorer perception of overall health, lower income, and do not receive the same number and type of chronic care services, such as annual HbA1c measures, eye exams, cholesterol and blood glucose measurements. Investigators at the University of Pittsburgh have extensive experience in deploying programs for underserved rural and minority communities. Thus, we propose to support research to elucidate the determinants of gender, social, and disparities in diabetes care and treatment outcome, and to develop culturally sensitive interventions and behavioral approaches that are tailored to the needs of these under-served populations.

Health Services Research Questions and Hypotheses

Alternate Care Delivery and Telehealth. Research Question: 1) What alternative systems are most effective in providing access to team based care and improved patient outcomes? Team care is shown to be the most positive predictor of improved diabetes outcomes. There is a severe shortage of endocrinologists and primary care physicians (PCP) in the US. In the face of the epidemic, innovative alternate ways to support team care are imperative. 90% of diabetes care is provided by Primary Care Physicians (PCP). They are overwhelmed and often unprepared to provide comprehensive care for optimal management, resulting in poor outcomes. Thus, examining alternative strategies are essential, like engaging nurse practitioners, pharmacists, educators, etc. Several diabetes technology programs that improve access to team-based care have been designed by PA investigators. Exciting new advances include internet technology to enhance team communication and ongoing behavioral support. Specialists visits can be facilitated through teleconsultation where patients in outlying communities have access to a specialist miles away. Expansion and evaluation of these alternative and telehealth efforts are needed.

Impact on Health of Pennsylvanians

Diabetes in the US, and particularly Pennsylvania, has reached epidemic proportions. As further hard evidence, the Centers for Disease Control has recently acquired the topic of Diabetes as one of its central themes; and one in three children born in 2004 will develop diabetes during his/her lifetime. The CDC also recently reported that the incidence of diabetes has increased by 70% in the 1990's in the 30-40 yr age group, the group most likely to lose time and productivity in the workforce. Recent statistics suggest that the prevalence of diabetes will double between 2000 and 2030 with the most important demographic change in those >65 y.o.

Pennsylvania will experience at least a doubling in diabetes prevalence given its high rates of obesity and old age. Given the overwhelming increase in the prevalence, it is inevitable that an increase in the complications associated with diabetes will follow. Unless efforts are initiated to take evidence-based treatment strategies into high risk communities, this path will lead to enormous health care costs and decreased quality of life. PA has the largest rural population of any state. 42 of its 67 counties are classified as rural, accounting for 30% of PA's population. Remarkably, Fayette County has the highest amputation rate in the US. Fortunately, PA is beginning to recognize the magnitude of the diabetes problem, and to formulate health policy reforms directed against diabetes. Stakeholders from across the Commonwealth have joined forces to address the very deficiencies described above with a PA Diabetes Action Plan and through work on PA Chronic Care Commission.

Extensive evidence shows that both diabetes and its complications - blindness, cardiovascular disease, kidney failure/dialysis, and neurological disease - can be substantially delayed, or even prevented by tight glycemic control and other interventions. As national examples, the Diabetes Control and Complications Trial (DCCT) and the Diabetes Prevention Program (DPP), (facilitated at the University of Pittsburgh DPP Lifestyle Resource Core that developed the successful Intensive Lifestyle Intervention) showed that if people at risk for developing diabetes make lifestyle changes, they can decrease their chance of progressing to diabetes and for those with diabetes, complications can be prevented with proper treatment and education. To date, however, findings from

these national trials have not been effectively translated into real-world communities, particularly in underserved communities far from academic hub sites.

The University of Pittsburgh and its health system the University of Pittsburgh Medical Center (UPMC) have a long tradition of excellence in diabetes care and prevention. At present, over 150,000 people with diabetes in western Pennsylvania receive care annually at UPMC facilities, and 30% of patients hospitalized at UPMC facilities annually have diabetes. With its network of academic, community hospital, and primary care practices, UPMC affords the opportunity to translate the findings from trials into diverse communities and practices. There is extensive evidence that both diabetes and its complications can be substantially delayed or even prevented, yet translating findings from the major trials has not been done.

Pitt has been very active in these areas on a local as well as a national level. We have already joined forces with other renowned PA academic institutions and communities. To translate the programs described above from the research to community setting, novel methods for testing the effectiveness of these programs need to be put into place.

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Health Research Priority Title and Description

Biomarkers and Rehabilomics Research and Infrastructure Network for Traumatic Brain Injury (BRAIN: TBI)

A research center to enhance rehabilitation science in the area of biomarkers for traumatic brain injury (TBI) is compelling from a public health perspective. Despite many TBI patients having similar injury factors and clinical care, recovery and outcomes can widely vary. This variability in response to injury and treatments may be attributable to genetic variation and differences in molecular profiles that patients bring to the recovery process. Biomarker research translation to the development of point of care (POC) assays is critical to identify individual data for injury/treatment response, prognosis, and degree of risk for complications (Theranostics). The neurorehabilitation community needs to emphasize translational research to identify the neural substrates underlying mechanisms of injury, recovery, complications, and treatment intervention. Rehabilomics research incorporates unique study designs to systematically evaluate rehabilitation relevant phenotypes in conjunction with biomarkers to better understand the biological mechanisms associated with function, prognosis, complications, treatments, adaptation, and recovery for persons with disabilities. Within this view, our Biomarkers and Rehabilomics Research and Infrastructure Network for TBI (BRAIN: TBI) can partner with other entities to span from bench to bedside to community by addressing common problems and issues that occur within our target population and incorporating a rehabilitation focused model enablement.

Biomedical Research Questions and Hypotheses

The biomedical research questions proposed incorporate the use of molecular techniques in addition to in vitro cell culture models of injury and protein function for identifying the functional/molecular correlates of genetic associations with specific complications identified in our clinical populations with TBI. Additionally, we use in vivo models of TBI for the identification and exploration of novel biomarkers associated with TBI. Additionally in vivo models can be used with well characterized biomarkers to study the impact of rehabilitation relevant treatments and therapies.

***We hypothesize that we can functionally characterize genetic variants, and their resulting concomitant protein expression/function, associated with common and rehabilitation relevant complications after TBI, such as seizures, depression, agitation, heterotopic bone formation, and headaches.

***We hypothesize that in vivo TBI models can be used in conjunction with TBI biomarkers and behavioral outcomes to study the neurobiological influence and assess the therapeutic effects of rehabilitation relevant treatments such as exercise, anti-convulsants, anti-psychotics, and neurostimulants.

Clinical Research Questions and Hypotheses

Clinical research questions involve the use and expansion of our clinical research databases and biosample repositories which contain serum, CSF, and DNA for 200-350 adults with severe TBI and contain an array of multimodal clinical outcomes. Additionally, we are tracking several key TBI complications including seizures, depression, heterotopic ossification, and agitation. We also have an extensive pediatric BI repository that

includes both serum and CSF for children across a range of injury severity and also for children with inflicted TBI. Biosample data can be compared to healthy and non-TBI polytrauma controls.

***We hypothesize that we can use a systems biology based biomarker approach to generate informative models for prognosis, complication risk (e.g. seizures/depression), cognitive function, and clinical research treatment effects after TBI.

***We hypothesize that we can use both mechanistic and exploratory based approaches to identify novel biomarkers for evaluating prognosis, cognition, complication risk assessment, and treatment monitoring for children and adults with TBI.

Health Services Research Questions and Hypotheses

The health services research questions involve the development of generalizable statistical algorithms for real time and dynamic monitoring individual risk and prognosis using contemporary data modeling and prediction approaches. Additionally, these questions will include collaboration with small business and other partnerships to develop and test POC assays for community use and with the goal of improving clinical care and reducing the health care burden of TBI.

***We hypothesize that we can use information derived from the biomedical and clinical research areas described above to develop reliable and generalizable algorithms that accurately predict general outcome and survival, risk for complications, and functional impairments.

***We hypothesize that sensitive, reliable, and cost effective POC assays can be created and used with these data modeling algorithms to provide real time feedback to enhance healthcare delivery, guide therapeutic strategies, and reduce clinical risks for complications after TBI.

Impact on Health of Pennsylvanians

Over 2% of the US population, currently lives with disabilities resulting from TBI, and the national cost to society is estimated to be over \$60 billion per year. Over 8,600 people in Pennsylvania (PA) each year sustain TBI that results in life long disability. These statistics show that TBI is, in fact, a silent epidemic in this country. Despite these large numbers and cost to society, NIH funding for TBI remains disproportionately low when compared to the number of people affected. Thus the scientific and public health need for TBI research and infrastructure is great. In PA each year, there are 245,621 people living with TBI, and over 10,000 are hospitalized each year. TBI is a common injury from the Gulf Wars, with 25,000 of the combat casualties in 2008 sustaining a TBI and many of these veterans returning to civilian life in PA. TBI is also common in the pediatric population, and unfortunately, inflicted TBI is one of the most common forms of child abuse. In fact 25,975 children in PA sustain TBI each year. TBI also afflicts the nation's elderly, with the majority of older patients sustaining TBI from falls. PA has a large population of senior citizens, and over 25% of persons hospitalized with TBI in PA over 75 years of age. Each of these groups represent particularly vulnerable populations within the general population with disabilities with regard to diagnosis, research, treatments, advocacy, and community supports. These are also populations for which there is unique pathology and by which distinct approaches for diagnosis, risk assessment, care, and prognosis are required. Moreover, TBI often requires specialized care and monitoring from rehabilitation specialists. TBI rehabilitation care is challenging and complex, and biomarker and Rehabilomics focused research has the potential to enhance rehabilitation care and optimize recovery. (Sources: <http://www.biapa.org>; <http://health.state.pa.us/stats>.)

Biomarkers have tremendous potential to assist researchers in developing rehabilitation relevant treatments for TBI that attenuate secondary injury and minimize complications. Transomic profiles have the potential to assist practitioners in following long term outcome that can be linked to neuroplasticity and natural recovery. Biomarkers studies can also serve as dynamic and manipulable endophenotypes that reflect treatment response. Key to these concepts is the development of advanced statistical modeling approaches that can be used to predict a broad range of phenotypes, including complications, using advanced biomathematical methods that incorporate time series data, and machine learning algorithms.

Much of biomarkers research is exploratory in nature, and the tools and processes by which to conduct biomarker measurements are similar across disciplines. However, the integration of Rehabilomics in biomarkers research enables the incorporation of rehabilitation structured bioinformatics tools, rehabilitation technologies and engineering devices, and multidisciplinary rehabilitation research design into a unique theranostic approach for individualized treatments and optimized outcome. Although Rehabilomics research has not taken full advantage of the tremendous potential that biomarker research tools and platforms can provide, our center's research program has been focused on these concepts and leads the field. We are leaders in the area of preclinical and clinical Rehabilomics research for TBI, and our work can and does have a direct impact on the welfare and recovery of persons with TBI, including those residing in PA. Our ultimate goal is to develop and implement rapid, accurate, and clinically practical POC assays that can be linked with ancillary devices and software and brought to the patient bedside and/or home setting for effective data analysis and patient management as rehabilitation practitioners monitor and manage patient progress from the bedside to the community.

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Health Research Priority Title and Description

Pathophysiology and treatment of abdominal aortic aneurysms

Abdominal aortic aneurysm (AAA) is a common, late-onset and often fatal disease. The US Surgeon General has identified AAA and lung cancer as the only two diseases definitely caused and related to smoking. AAA rupture is a leading cause of death in the elderly, and is the thirteenth leading cause of death in the US (15,000 deaths annually). With the progressive aging of the US population the impact of AAA disease on public health will increase. The underlying causes of AAA formation are not known, but recent investigations suggest remodeling of the extracellular matrix and inflammation as important mechanisms. At the present time there are no simple laboratory tests to diagnose AAA and no non-surgical treatments. AAA is strongly associated with smoking. There is also a strong genetic risk for AAA.

Basic, translational and clinical research is needed to improve the diagnosis, treatment and long term outcomes of patients with AAA. Advances in these areas would have a substantial positive impact on both individual patients and overall public health.

Biomedical Research Questions and Hypotheses

What are the cellular and molecular mechanisms that cause AAA formation?

What are the genetic variants that affect inherited risk of AAA?

Are there common molecular mechanisms for all types of aneurysm (e.g. abdominal aortic aneurysm, thoracic aneurysm, intracranial aneurysm)?

Clinical Research Questions and Hypotheses

Discovery of AAA-associated biomarkers; development of novel ways to diagnose AAA-disease based on these biomarkers.

Identification of novel therapeutic targets based on knowledge of the molecular mechanism of AAA formation and/or AAA-associated biomarkers.

Clinical trials of non-surgical treatments for AAA.

Clinical trials of new devices to treat AAAs.

Screening programs to detect AAAs.

Health Services Research Questions and Hypotheses

Can genetic AAA risk variants be used to identify at-risk patients and increase diagnosis and treatment?

Does population screening reduce mortality from AAA rupture?

Can new non-surgical or surgical treatments of AAA improve the health of the population of the Commonwealth of PA?

Impact on Health of Pennsylvanians

The incidence of AAA has been estimated between 30 and 66 cases per 1000 persons. More than 15,000 people die in the U.S. each year from aneurysm rupture, making AAAs the thirteenth leading cause of death in the U.S. overall. The frequency of AAA increases significantly with age. In persons between 65 and 84 years of age AAAs account for nearly 1% of all mortalities (CDC/NCHS National Vital Statistics System, 2002). Men are affected more than women by a ratio of approximately 4:1. The incidence of AAA has been increasing over the past several decades. This trend is likely to accelerate with the progressive aging of the U.S. population. This is a major health disparity with the adverse impact on the older population.

The risk of aneurysm-related mortality is exacerbated by the fact that most AAAs are asymptomatic. Because there are no simple laboratory tests for AAA many aneurysms are undiagnosed. Many AAAs are detected incidentally from ultrasound, CT scan or other radiographic imaging of the abdomen during testing for other medical conditions. At the present time there are no medical treatments for AAA. Surgical or endovascular repair before aneurysm rupture is generally safe and effective, but not all patients are candidates for these procedures. In addition, undiagnosed patients will go untreated and at risk of death from AAA rupture. Earlier and more widespread identification of patients with AAA and the introduction of non-surgical therapies would lead to a significant decrease in AAA-related mortality.

This project when funded would lead to a better understanding of the basic mechanisms of abdominal aortic aneurysms which will lead directly to better testing and prevention of aneurysmal degeneration. The discovery at the basic science level would lead to better screening procedures to identify aneurysms and in the future ideally limit the number of patients that require surgical treatment.

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Health Research Priority Title and Description

Improving Diabetes Care with Transformed Care

Primary care is underperforming in Pennsylvania and nationwide, resulting in significant quality gaps in chronic illness care. Diabetes care is a prime example where only 7% of patients are at goal for the key indicators of morbidity and mortality: hemoglobin A1c, blood pressure and cholesterol. Diabetes also has high associated costs of care (\$174 billion annually in the US and \$1 billion in avoidable hospitalizations in PA alone) and is the leading cause of adult blindness, kidney failure and lower-extremity amputations. Thus, the Pennsylvania Chronic Care Commission (CCC) has chosen diabetes as the chronic disease target for a major initiative to transform primary care to improve diabetes care and reduce costs. This initiative is based on the Patient-Centered Medical Home (PCMH) and Chronic Care Model (CCM), which have been embraced nationally as a health care models that facilitate partnerships between individual patients, their physicians and, when appropriate, the patient's family. Because transforming primary care for diabetes is critical to controlling costs and improving the health of the Commonwealth, these transformations warrant study to determine their success and to identify critical facilitating and barrier elements, while giving special attention to the impact on health disparities among Pennsylvania's frequently underserved minority and rural patients.

Biomedical Research Questions and Hypotheses

None

Clinical Research Questions and Hypotheses

Better diabetes patient outcomes can be provided by establishing true Patient-Centered Medical Home (PCHM) practices that support the essential patient self-management, decision support and community resource elements of the Chronic Care Model (CCM). With the Internet now accessible to 72% of Pennsylvanians ([/pasdc.hbg.psu.edu/](http://pasdc.hbg.psu.edu/), 2009), telemedicine and web-based resources are increasingly effective approaches to meet the challenge of supporting this large patient population. Websites engage and empower patients through access to self-management programs and community resource information with personalization now possible through "tailored messaging." As numerous websites are developed, assessment is needed to optimize their effectiveness in producing better diabetes care. Questions to be researched include: 1) What kind of online resources provide the greatest impact on patient outcomes, satisfaction, and cost of care? 2) How are patients motivated to use online resources? 3) What demographic factors need to be considered in designing content and ensuring access to these resources to make them most effective and to reduce disparities among underserved populations?

Health Services Research Questions and Hypotheses

The Patient-Centered Medical Home (PCHM) and Chronic Care Model (CCM) are theoretical models of a constellation of evidence-based components having the potential to reform healthcare delivery and reduce health risks. Combined PCHM-CCM models of primary care redesign are becoming widespread across Pennsylvania, including but not limited to the PA Chronic Care Commission's initiative involving over 100 providers, 17 payers and over 10,000 patients. Additional demonstration sites are needed and each component of the theoretical models (patient experience, care quality, practice organization, information management) must be assessed. Research hypotheses to be tested include: 1) Will PCHM-CCM improve the clinical effectiveness in practice, including diabetes health outcomes of hemoglobin A1c, blood pressure and cholesterol, as well as care quality and the quality of patient/provider interactions? 2) Will members of the system realize increased resource utilization and lower costs? 3) Will patients and providers realize care improvement? 4) What contextual variables might serve as barriers and facilitators of successful PCHM-CCM transformations? and 5) How can telemedicine be leveraged for better care?

Impact on Health of Pennsylvanians

Current epidemics of diabetes and obesity are overcoming Pennsylvania healthcare systems in tsunami-like fashion. Worldwide, 250 million people live with diabetes, yet these individuals receive only a fraction of the attention as the 33 million living with HIV/AIDS. Total costs of diabetes care in the U.S. reached \$174 billion in 2007, and diabetes spending accounts for one in eight spent healthcare dollars. It is the 6th leading cause of death and simultaneously contributes significantly to heart disease, which is the leading cause of death in the U.S. The cost of medical care for patients with diabetes averages 2.3 times higher than similar patients without diabetes, translating to additional medical expenses of \$6,649 per person with diabetes. Over-weight is the single greatest predictor for developing Type 2 Diabetes. Obesity costs our nation \$147 billion annually, accounting for one tenth of all medical costs. With two third of the U.S. population now overweight, one in three individuals born after the year 2000 are expected to develop diabetes in their lifetime. Pennsylvania ranks 13th in the nation in states with the highest rates of diabetes (8.2%).

This now-looming Pennsylvania healthcare disaster predicted by the combined burdens of diabetes and obesity must be addressed immediately to be prevented. The first necessary step is to redesign primary care. The Patient Centered Medical Home (PCMH) and Chronic Care Model (CCM) models for primary care redesign offer hope. Multiple implementations of the PCMH-CCM have recently been initiated in Pennsylvania based upon a recommendation of the Pennsylvania Chronic Care Commission. Multiple insurers, including IBC, Highmark and UPMC, established incentives for PCMH implementation that include enhanced payments for infrastructure and resources. More than one hundred providers are now receiving significant financial infrastructure and incentive payments for the implementation of the PCMH, as defined by the National Committee on Quality Assurance's (NCQA) Physician's Practice Connection (PPC)-PCMH certification program.

What remains to be organized for this essential transformation is an independent systematic statewide formative assessment, development of an extended dissemination plan, and development of web-based resources to meet the extensive information access patient self-managements needs of these programs.

Thus, this testimony is in support of research to determine which program delivery approaches involving the Patient Centered Medical Home (PCMH) and Chronic Care Model (CCM) maximize program sustainability, minimize barriers to the implementation of evidence-based practices, and demonstrate how evidence-based practices can be implemented most effectively through all phases of prevention and treatment, including diagnosis, intervention, and long-term follow-up. At the same time, this research will identify and eliminate those healthcare practices that lead to disparities in care for traditionally-underserved populations such as minority and rural patients.

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Health Research Priority Title and Description

Cancer Pain: Epidemiological Assessment and New Therapeutics

Pain is one of the most frequent and often most feared symptoms in patients diagnosed with cancer. The prevalence of cancer pain remains unacceptably high and, in many cases, is unremitting and unresponsive to treatment with existing pharmacological therapies. Breast, lung and prostate cancers account for approximately 80% of all bone metastases and over half of all metastatic cancers will be associated with pain. Often, chemotherapeutic treatments produce neuropathic pain that persists once treatment has been discontinued. Chemotherapeutic-induced neuropathies are often limiting factors in cancer treatment and preclude a patient's ability to tolerate higher - and potentially more effective - doses. There is a need for systematic epidemiological studies incorporating the powerful tools of bioinformatics and health informatics to examine potential biomarkers and outcomes in patients with regard to the type of cancer pain, the type of treatment for the cancer, as well as the effectiveness and duration of treatment for the cancer-related pain. Additionally, there is a corresponding need for the development and integration of animal models of cancer pain to parallel this clinical assessment to evaluate of emerging novel drug targets that compare current treatments and evaluate the effectiveness of new drugs for cancer pain management. A combination of the powerful tools and expertise available within the Pennsylvania biomedical research community promises many novel opportunities for developing new treatment approaches to cancer pain.

Biomedical Research Questions and Hypotheses

The emphasis of this recommendation is to pursue a bold, comprehensive, and integrated approach to cancer pain management. The fundamental tenet behind this proposal is that there is a pressing need for multiple approaches within the biomedical community to be directed towards developing a better understanding of cancer pain syndromes, current treatment methods, and innovative model systems that will generate new hypotheses designed to discover and provide better treatments for this significant unmet need. The research would focus on the following questions: i) how closely aligned are the current animal models to the pathophysiology and progression of the disease in humans; ii) what animal models provide the opportunity to evaluate current therapeutic approaches to different types of cancer pain (e.g., metastatic bone cancer, chemotherapy-induced neuropathic pain); iii) what new molecular targets can be evaluated for the treatment of cancer pain; iv) is there a relationship between cancer progression and pain therapy; and v) using the technology of microRNA, what biomarkers can be identified to evaluate treatment biomarkers and outcomes? The outcome is more effective treatments that improved existing therapies.

Clinical Research Questions and Hypotheses

A major emphasis of this research would be to employ and align the powerful methods of clinical and epidemiological assessment of cancer pain and treatment with the pharmacological research efforts to better

understand and treat cancer pain. Epidemiological studies will address the following questions: i) what are the current treatment approaches and outcomes assessments for different types of cancer pain, modalities and efficacy of treatment; ii) what are the major liabilities and shortcomings of current approaches to the management of cancer pain and where are there the greatest unmet needs; iii) are there valid and reliable biomarkers that can distinguish responders from non-responders to various pain therapy approaches among different cancer populations; iv) can these methods predict side-effect profiles, the development of tolerance, and other characteristics that might also inform basic research studies and be useful in the identification of new targets; and v) can these biomarkers be used as translational tools to inform the use of animal models to better predict efficacy and side-effect profiles that would permit more rapid introduction and assessment of new therapeutics into the clinic?

Health Services Research Questions and Hypotheses

None

Impact on Health of Pennsylvanians

The Pennsylvania Department of Health has estimated that over 70,000 Pennsylvanians would be diagnosed with cancer in 2008, with over 28,000 patients expected to die in cancer-related deaths (Pennsylvania Cancer Registry, Bureau of Health Statistics and Research, Department of Health). This report also indicates that between 1995 and 2005, the annual age-adjusted cancer mortality rates in Pennsylvania were consistently higher than comparable U.S. mortality rates. It is estimated that on average, an estimated 97 male residents were expected to be diagnosed with invasive cancer each day during 2008; for females this figure is 96. The majority of these patients will have cancer-related pain that is directly related to the cancer or is associated with the chemotherapy used to treat the cancer. Pain is often most severe and intractable at the end of life for these patients.

One major objective of this proposed approach would consist of a systematic and careful epidemiological assessment of cancer pain within the State of Pennsylvania. The plan is to utilize the combined strengths of epidemiology, the tools of contemporary biomedical science, such as bioinformatics and health informatics, together with the discipline of pharmacology to develop a thorough characterization of cancer pain within the State and to integrate this information into a basic research program. The ability to use this information to address the impact of cancer pain on the health of Pennsylvanians will not only provide a rigorous evaluation of the current approaches to the treatment of cancer pain but will also be valuable in helping to design optimal treatment strategies with existing modalities. A second major objective is the development of a systematic, innovative and integrated basic research program that is focused on the identification of new pharmacological targets and treatments for cancer pain, the development of new preclinical model systems, the development of biomarker in both animal and humans using microRNAs to assess treatment efficacy and to distinguish individual patterns of response depending on the type of pain. The capacity to move these basic research outcomes into patient benefit will be done in partnership with biopharmaceutical companies in the Philadelphia area and the State to establish the infrastructure for drug discovery and development to address this critical unmet need. These efforts will yield new discoveries, new tools for clinical assessment and prescribed therapies, as well as new investigators and grant applications. Importantly, it will provide a detailed analysis of cancer pain and treatment approaches within the State of Pennsylvania designed ultimately to provide more effective cancer pain management for its citizens. Furthermore, this effort will potentially yield new partnerships and entrepreneurial opportunities that will help build the State's workforce as well as alleviate a serious debilitating impediment to comfort at a time when the major focus should be on cancer treatment not associated pain.

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Health Research Priority Title and Description

Towards a better understanding and treatment of diabetes

The prevalence of diabetes and obesity is increasing. Currently, it is estimated that 18 million people in the United States (6.2 percent of the population) has diabetes. The rate is higher among the elderly and Hispanics, Native Americans, and African-Americans. The cost of diabetes is estimated at \$147 billion per year in the U.S. The Centers for Disease Control has projected that one out of three children born in the United States in the year 2000 will develop diabetes in their lifetime. Much of this is type 2 diabetes, which represents 90-95% of the epidemic, though type 1 diabetes is also on the rise, and the complications both type 1 and type 2 diabetes are devastating, including heart attack, stroke, blindness, infection, and kidney disease. Although progress has been made, there is still much to be learned about diabetes and its complications. For example, recent large randomized controlled studies disappointingly did not observe improved cardiovascular outcomes with better control of blood sugar. This raises fundamental questions about our current approach to the treatment of diabetes.

Biomedical Research Questions and Hypotheses

- 1) What causes the complications of diabetes?
 - We hypothesize that this is due to factors related to fat cells, as well as to inflammation, which are found in man as well as other mammals.
- 2) What are the effects of different diabetes therapies on cardiovascular risk factors?
 - We hypothesize that different therapies, including bariatric surgical procedures, have different effects.
- 3) Can personalization of disease understanding guide therapy?
 - We hypothesize that genetic differences, including Single Nucleotide Polymorphisms (SNPs) in the human genome, underly the variation in outcome and complications, and that linkage of particular SNPs to outcome would personalize care for diabetes, leading to improved outcomes.

Clinical Research Questions and Hypotheses

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Health Services Research Questions and Hypotheses

None

Impact on Health of Pennsylvanians

The epidemics of diabetes and obesity are a major threat to health of Pennsylvanians and Americans in general. The problem is global, with 250 million people worldwide having diabetes, yet these individuals receive only a fraction of the attention as the 33 million living with HIV/AIDS. Total costs of diabetes care in the US reached \$174 billion in 2007, and diabetes spending accounts for one in eight spent healthcare dollars. It is the 6th leading cause of death and simultaneously contributes significantly to heart disease, the leading cause of death in the US. The cost of medical care for patients with diabetes averages 2.3 times higher than similar patients without diabetes, translating to additional medical expenses of \$6,649 per person with diabetes. Over-weight is the single greatest predictor for developing Type 2 Diabetes. Obesity costs our nation \$147 billion annually, accounting for one tenth of all medical costs. With two third of the U.S. population now overweight, one in three individuals born after the year 2000 are expected to develop diabetes in their lifetime. Compared with other states, Pennsylvania ranks 13th worst in the nation with its high rate of diabetes (8.2%).

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Health Research Priority Title and Description

Use of Health Information Technology to Improve Patient Outcomes in the Commonwealth

Optimizing patient outcomes is essential for the health of all Pennsylvania's citizens. By 2015, Pennsylvania will move into the era of e-health as it responds to the Federal mandate to demonstrate "meaningful use" of the data contained in electronic health records (EHR) as indicated in the Prescription for Pennsylvania. To reap the benefits of e-health for providers and patients, Pennsylvania must determine how best to generate, manage, preserve and exchange this data to stimulate evidence-based clinical practice and behavioral health to improve outcomes. A research program focused on the impact of EHRs on clinical medicine and public health will:

- overcome health disparities on key measures of health status
- develop incentives to promote healthy behaviors by citizens and evidence-based practice by providers
- securely exchange data to coordinate care so that critical information is available to patients and providers at the point of care.

Significant benefit from the investment in technological infrastructure can be realized only through concerted efforts across all relevant sectors—providers, purchasers, and patients. Research efforts must therefore be aimed at identifying policy and practice to ensure the optimal use of Pennsylvania's investment in e-health.

Biomedical Research Questions and Hypotheses

How can the gap between basic research and clinical practice be closed?

How can genomic data be incorporated into personalized medicine to improve clinical outcomes?

Clinical Research Questions and Hypotheses

Which incentives are most effective in reducing unwarranted variations in care delivery across regions and population groups?

What are the best practices associated with clinical adoption of e-health systems?

How can clinicians incorporate e-health data to improve patient-physician communication?

Health Services Research Questions and Hypotheses

What are the most effective outcomes measures to determine the performance of health providers (physicians, nurses, hospitals and clinics)?

As reimbursement becomes aligned with best practices in clinical care and public health, what are the outcomes measures that will be used to evaluate performance?

What is the most effective way for these measures to be designed so they will be adopted and result in better health outcomes for Pennsylvania citizens?

How can Pennsylvania best harness its resources so that high quality health care is delivered to all citizens regardless of location or economic status?

What is relationship between EHRs and health behaviors—both of patients and providers?

Does providing feedback to patients about the impact of their personal choices encourage positive changes in health behavior?

Impact on Health of Pennsylvanians

The greatest untapped resource in our health system today is the patient. To fully benefit from the transformation to e-health, research is needed to explore the role of e-health in supporting patients in managing and improving their health. This is especially urgent in managing the chronic diseases which affect minority populations disproportionately. Health disparities among minority groups will continue to grow in importance and impact as Pennsylvania's minority populations increase. While the total population of Pennsylvania is projected to increase by 6.7% between 1990 and 2025, the total minority population is projected to increase by 76.7% and with it, the likelihood of increased burden of chronic disease. According to the U.S. Department of Health and Human Services' (DHHS) minority groups experience differential health outcomes in these six areas: diabetes, health disease and stroke, cancer, infant mortality, immunizations, and HIV/AIDS. For example, rates of death from heart disease were 30% higher among African Americans than among whites, and death rates from stroke were 41% higher. Although death rates from breast cancer declined significantly during 1992-1998, they remain higher among black women than among white women. African American, American Indian, and Puerto Rican infants continue to have higher mortality rather than white infants. E-health interventions have the potential to create better outcomes in each of these areas; illustrations appear below.

- As Pennsylvania's population ages, the burden of chronic disease will increase, as will the demand for services and the need to make personal and social treatment choices. Pennsylvania's hospitalization rates for four chronic diseases—diabetes, asthma, chronic obstructive pulmonary disease (COPD) and heart failure—were higher than the corresponding national rates in both 2004 and 2007, and the Commonwealth's hospitalization rates for diabetes, asthma and COPD increased from 2004 to 2008.
- PA death rate per 100,000 people is greater than US (790.7 versus 760.3); PA heart disease death rate is higher than US rate. PA cancer incidence is 503.4 versus 461.8 for US; PA prevalence of diagnosed diabetes is higher (8.0/100 versus 5.5/100 for US); PA asthma prevalence for adults is higher than US prevalence. The advent of e-health will enable Pennsylvania to better track data and outcomes in order to better understand the factors that contribute to better outcomes, lower cost, and higher quality of life.
- Through e-health tracking, data on disease manifestations between health encounters helps providers and patients understand disease trajectories and promote compliance with treatment, especially among the elderly and those with chronic diseases. Additionally, clinicians can use remote electronic monitoring devices to enable the elderly to remain in their homes longer and with a better quality of life.
- Providers, too, can leverage e-health advances to understand and improve their practice. Through decision support and reminders built into EHRs, providers can improve through practice, while through data analysis and feedback, they can benchmark their outcomes. Even more important, these activities can be extended to patients so they can participate more fully in their health decisions.
- Throughout the transition to e-health and beyond, balancing preservation of privacy while enabling access to health information any time, anywhere, is a complex problem that must be examined to avoid unintended consequences and social harm.

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Health Research Priority Title and Description

Aortic and cerebral aneurysm disease

Cardiovascular disease is the No. 1 worldwide killer of men and women, including in the United States. It is responsible for 40 percent of all the deaths in the United States, more than all forms of cancer combined. The various diseases that fall under the umbrella of CV disease include coronary artery disease, heart attack, heart failure, aneurysms, high blood pressure and stroke. An aneurysm is a bulge or weakness in a blood vessel (artery or vein) wall, which usually increases in size over time, having the potential to rupture and cause life-threatening bleeding. Aneurysms can occur in arteries in any location in the body, but the most common sites include the abdominal aorta and the arteries at the base of the brain. The formation of an aneurysm represents the loss of structural integrity of the vessel wall. The abdominal aortic aneurysm (AAA) is a socially relevant cardiovascular health disease. The prevalence of AAA disease is 8.8% in the population above 65 years of age and men are affected more often than women by a ratio of 4:1. Intracranial aneurysms are lesions of the arterial wall commonly located at branching points of the major arteries coursing through the subarachnoid space, predominantly at the circle of Willis in the base of the brain. The incidence of reported ruptured aneurysm is about 10 in every 100,000 persons per year (about 27,000 patients per year in the U.S.), most commonly in people between ages 30 and 60 years.

Biomedical Research Questions and Hypotheses

What are the underlying mechanisms by which aneurysms (aortic and cerebral) rupture? How can rupture be predicted and prevented? How does the blood vessel expand and remodel over time leading to continuous aneurysm growth and eventual rupture? We hypothesize that (a) individual-specific geometry and shape of the diseased blood vessel influence the at-risk status of an aneurysm at any stage of the disease; (b) biomechanical determinants of aneurysm rupture include flow-induced elevated forces and strains on the blood vessel wall, which can be evaluated non-invasively by medical image-based and computational methods; (c) there is a positive correlation between subject-specific geometry and the biomechanical determinants of rupture potential, which places certain "categories" of aneurysm shape at a higher risk of rupture, regardless of the initial size of the aneurysm at the time of diagnosis. The assessment of rupture of aortic and cerebral aneurysms can be performed incorporating these geometry-based indices and biomechanical determinants in a non-invasive manner by means of computational (software) tools that can be used by the vascular surgeon or interventional radiologist in a clinical setting.

Clinical Research Questions and Hypotheses

The optimal strategy in the clinical management of cardiovascular disease as it relates to aneurysms is clear: prevention of aneurysm rupture is the primary goal. Currently, the assessment of aneurysm rupture is conducted on the basis of measuring the size (diameter) of the aneurysm. However, there are many large

aneurysms that are detected at an advanced stage of the disease that have not ruptured at the time of diagnosis. Likewise, 10% to 24% of ruptured aneurysms are considered "small", typically less than 5 cm in maximum diameter in the case of aortic aneurysms. There is need for a more reliable indicator of aneurysm rupture potential. Once an aneurysm is diagnosed, what is the at-risk status of this vascular disease and what quantitative parameters can be measured to evaluate the risk of rupture on an individual basis? We hypothesize that there are fundamental differences in the wall stress, size, tortuosity, asymmetry, wall thickness, aspect ratio, and thrombus content between ruptured and non-ruptured aneurysms. These and other factors must be evaluated accurately for subjects placed under surveillance to assess aneurysm rupture potential.

Health Services Research Questions and Hypotheses

Can shape-based geometric analysis be used to identify at-risk patients and improve treatment strategies? Can non-surgical treatments and non-invasive AAA rupture risk assessment improve the health of the overall population in the Commonwealth of PA?

Impact on Health of Pennsylvanians

Abdominal aortic aneurysm rupture kills about 15,000 Americans each year. This statistic is believed to be an underestimation as the disease is asymptomatic and many deaths related to aortic aneurysm rupture may be classified under a different cause. Cerebral aneurysm rupture occurs in about 27,000 Americans each year. The Commonwealth of Pennsylvania is no stranger to these statistics, given the elderly population residing here. The Pennsylvania Department of Health's EpiQMS online data system reveals out of the 379,509 deaths in the period 2004-2006 for Pennsylvania, 136,180 (36%) deaths were attributed to cardiovascular disease. Of these, 117,190 (86% of all CV disease related deaths) occurred in patients 65 years of age and older. The African-American population accounted for 9% of the death toll, well aligned with its statistical participation of the states' total population (10.5%). The major health concern with aneurysms is the high mortality and morbidity rates when the aneurysms rupture. For aortic aneurysms, mortality rates are reported up to 80%; for cerebral aneurysms, up to 60%. Given that risks factors for aneurysm disease include smoking, hypertension, chronic obstructive pulmonary disease, atherosclerosis, familial history, and advanced age, the Commonwealth of Pennsylvania, with its everly increasing elderly population, is particularly affected in a disproportionate manner for cardiovascular disease.