Final Report
National Heart, Lung, and Blood Institute
Level 1 Strategic Planning Working Group
July 19-20, 2006

Cardiovascular Program – Theme # 9: Translation, Implementation, and Community Research

Introduction:

Transforming cardiovascular disease (CVD) science to improve human health requires not only innovation in CVD research but translation to the health care system and the community. In recent decades, population studies have identified major risk factors such as smoking and unfavorable blood pressure and blood lipid levels, and large long-term trials have evaluated behavioral and pharmacologic approaches that reduce CVD incidence. The obesity epidemic can benefit from the same approaches, focusing on individuals, communities, and populations.

Systems for the timely assessment of patterns of care are lacking, and the implementation of evidence-based care is incomplete and inadequate. Research on translating validated interventions from the investigation phase to widespread application within the health care system and in the community has a tremendous capacity to reduce the burden of CVD in the US. To improve the health of the public, new treatments and emerging risk factors from the wealth of genomic, proteomic, and metabolomic efforts will also require careful translational evaluation to identify those that truly reduce risk, improve care, or lower costs. All of these strategies need to incorporate health disparities. The ultimate measure of success is the health outcomes achieved in the population, and the planning group envisions a society that reaps the full benefits of scientific advances in diverse populations across the lifespan in the prevention and treatment of CVD.

Recommendations:

1. Develop community strategies that involve the community to enhance prevention of CVD events and risk factors across the lifespan, with special attention to high risk and vulnerable populations.

a) Understand the determinants of healthy lifestyle behaviors ranging from genetics to the environment to social norms and develop and evaluate innovative strategies for changing these determinants and, thereby, promoting healthy behaviors
b) Develop and evaluate policy, environmental, and other strategies in community settings, such as workplaces, schools, faith-based organizations and neighborhoods, to encourage and support lifestyle changes such as weight control, healthy diet, physical activity, and smoking cessation
c) Develop and evaluate effectiveness of alternative strategies to screen for and assure follow-up for risk factors (smoking, hypertension, dyslipidemia, obesity, and diabetes) in community settings
d) Develop and evaluate innovative strategies, such as computer games and tailored health messages, to encourage and support healthy lifestyle change, particularly among children and adolescents and their families
e) Develop and evaluate methods for accelerated dissemination, adoption, implementation, and institutionalization of successful evidence-based strategies

2. Develop strategies within the health care system to improve evidence-based care for prevention, diagnosis, and treatment of CVD events and risk factors across the lifespan, with special attention to high risk and vulnerable populations.

a) Understand current factors influencing patient, provider, organizational, and health system behavior and performance
b) Develop and evaluate interventions influencing patient, provider, organizational, and health system behavior and performance, including information technology, in order to enhance quality of care and health outcomes
c) Develop and evaluate interventions to reduce inappropriate use of diagnostic tests and treatments and to determine incremental benefit when used appropriately
d) Develop and evaluate appropriate methods to elicit and incorporate patient preferences in clinical decision-making
e) Develop and evaluate methods for accelerated dissemination, adoption, implementation, and institutionalization of successful evidence-based strategies

3. Implement systems to assess current status and trends in CVD risk factors, lifestyle behaviors, treatment patterns, and outcomes to characterize the status of the population's health and health care in diverse populations. Such systems will serve as a broad resource to the scientific community; identifying research opportunities, tracking impact of scientific innovation, and supporting translational, clinical, population, and policy research.

a) Initiate partnership opportunities with existing public and private sector organizations with electronic health information (insurers, large health care systems, professional societies, other federal agencies, etc.) to create integrated databases that can serve as ongoing CV surveillance systems
b) Enhance and promote the use of existing data collection systems such as NHANES
c) Develop and evaluate new approaches to capture key data and diverse populations not currently available in existing systems
d) Develop and evaluate new approaches to measure and monitor policies and environmental characteristics related to cardiovascular risk
e) Use these systems for timely evaluation of the impact of natural experiments (such as rapid adoption of unproven diagnostic tests or financial incentives to physicians for meeting quality of care goals) on population health and health care delivery
f) Promote the broad-scale use of such systems and data for cross-cutting translational, clinical, population and policy studies

4. Develop studies to evaluate the full range of risks and benefits of diagnostic tests and treatments, alone and in combination, in representative populations and settings.

a) Evaluate the utility and impact of existing and new diagnostic tests (biomarkers, imaging studies, -omics, etc.) on risk measurement, clinical decision-making, individualization of care, patient compliance, behavioral change, and outcomes
b) Evaluate the impact of prevention and treatment strategies on clinical and functional outcomes and costs, including in patients with multiple risk factors and co-morbidities
c) Develop and evaluate new instruments to improve risk assessment by such enhancements as encompassing both short-term and long-term risk, incorporating new risk markers, and accounting for risk factor-reducing treatments (such as for hypertension, dyslipidemia, and diabetes)
d) Develop new statistical methods to determine best predictive models for risk assessment, incremental value of new tests added to standard tests, and patients who will benefit most from new testing strategies

5. Encourage development of research design, measurement and analytic methods for CVD prevention and treatment in health care and community settings across populations and the lifespan.

a) Develop and promote methods for quasi-experimental designs, group randomized trials, qualitative, and participatory approaches
b) Improve and validate methods to measure behaviors, environmental and psychosocial characteristics, quality of care, health-related quality of life, patient preferences, and satisfaction with care
c) Promote data standardization and integration among disparate data sets to facilitate clinical and population studies
d) Advance methods for analysis of complex data, including modeling techniques for natural history of disease and long-term effects of interventions

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Business Operations
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Recommendations:

	High	Medium	Low	Priority Rank[1]
1a. Create streamlined procedures for renewing grants for established investigators	3	3	7	7
1b. Include a briefer application and greater emphasis on prior productivity	9	7	2	1
2. Funding and Award Mechanisms	11	8	1	3
3. Create incentives and mechanisms for cross-Institute and interagency funding of large projects	10	8	2	4
4. Review the NHLBI pre-approval process for investigator-initiated grants with direct costs >$500K in any year and the process for Institute-initiated programs (RFAs, RFPs):	8	10	2	5
5. Create a mechanism to provide infrastructure support for large observational studies to facilitate addition of ancillary studies. Create mechanisms to assure that the data and samples from the core studies are made available to the wider scientific community as a resource for further research	11	7	2	6
6. Issues related to CSR and study sections	12	7	1	2
7. Dissemination and communication of advances and discoveries and resources made by NHLBI-Supported Investigators	1	14	5	8

Additional Business Operations Areas and Recommendations

a. Strongly encourage NHLBI-supported research systems to adopt the same federal recommended standards (such as those from Health Level 7, Inc. and the National Council for Prescription Drug Programs) that clinical systems use day-to-day. This would allow research systems to obtain registration, appointment, lab, medication, and other data as appropriate automatically, easing research use of data stored in clinical computer systems within health care organizations

b. To more rapidly generate knowledge based on high quality data and methods, develop multidisciplinary networks with population, social, clinical, and basic science expertise that emphasize teamwork in addressing issues of cardiovascular health, including patient perspectives

c. Shorten length of grant application research design and methods section to 10-15 pages

d. For grant application resubmissions, allow an option for investigators to submit an expanded response (5-7 pages) to reviewers' concerns in lieu of a full application resubmission

e. Designate "emergency" funds readily available to support acute or time-sensitive opportunities

[1] We used the actual assigned priority ranking at the meeting to generate the priority rank rather than the high to low scoring.

for research, with a mechanism in place for expedited reviews of applications to use these funds
f. Shorten the turnaround time for application reviews
g. To encourage participation in study sections from senior investigators, offer shorter terms (2 years) and attendance at 2 meetings/year
h. Create graded levels of review and approval of ">$500K" grant application requests, with those nearer the $500K limit (for example, ≤ $800K to $1M in direct costs per year) undergoing a more streamlined review and approval process for submission than those applications with substantially higher annual direct costs.

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