

**Center for Health Insurance Reform, Cardiovascular Outcomes, and Disparities**  
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**Specific Aims for the Center**

One of the central policy assumptions in the U.S. today is that expanding health insurance coverage will improve access to health care, improve health outcomes, and make each more equitable for all Americans. Indeed, the evidence is clear that lack of health insurance is associated with poor health outcomes and increased mortality,<sup>1</sup> and results from policy studies, including the RAND Health Insurance Experiment,<sup>2,3</sup> indicate that when individuals have health insurance coverage, they are more likely to utilize preventive and other medical care. Health insurance increases use of physician services, preventive services, self-reported health status, and decreases mortality.<sup>2</sup> Limited access to care is associated with poor cardiovascular (CV) disease management, likely adversely affecting outcomes.<sup>4</sup> In addition, reduced access to health care among racial/ethnic minorities, low-income persons, and persons with limited English proficiency is of great concern, and is thought to be one of the most important causes of disparities<sup>1</sup> in health outcomes, as noted by the Agency for Healthcare Research and Quality (AHRQ) in its 2007 Healthcare Disparities report.<sup>5</sup>

Massachusetts (MA) is the site of a key policy-relevant natural experiment, whereby recent legislation has resulted in nearly all (97%) of the state's residents obtaining health insurance; it is thus the ideal setting in which to monitor and evaluate CV health outcomes, and disparities in such outcomes, associated with this policy change. Research to examine the impact of this natural experiment is needed to understand its effects on patient outcomes, including access to and use of care for CV conditions, clinical events, mortality, quality of life and costs associated with such use of care. Integral to the MA legislation was a goal to reduce racial and ethnic disparities in health; racial/ethnic, gender, language, and socioeconomic disparities in CV care and outcomes have been well documented by us and others.<sup>6,7</sup> They are cause for great public health concern, and reducing disparities while improving outcomes has been proposed as a crucial goal for CV outcomes research,<sup>8</sup> and indeed, for the national health promotion and disease prevention agenda.<sup>9</sup>

Thus, in response to RFA-HL-10-008, we propose a Center for Cardiovascular Outcomes Research (CCOR), entitled the "**Center for Health Insurance Reform, Cardiovascular Outcomes, and Disparities**". This Center will be based in the Health/Care Disparities Research Program within the Department of Medicine of the Boston University School of Medicine (BUSM), and at Boston Medical Center (BMC), New England's largest urban safety net hospital, which serves a largely poor and impoverished population, including many immigrants and minorities. Center investigators will capitalize upon the extensive clinical data available on these patients, with one of the proposed research projects using the new "MA Health Disparities Monitoring System" data registry created through NHLBI/RC2/GO grant funding to the proposed Center PI.

Within MA, the primary focus among policy makers has been on maximizing the proportion of the population who are now covered by insurance, and less on whether or how having insurance will affect individuals' use/receipt of care, or on health outcomes related to insurance or use of care. We seek to understand the effects of MA health reform on CV care and outcomes, and in disparities in each, through two research projects which share a common underlying question: *Is expanded insurance coverage in MA associated with improved CV outcomes?* The first study will evaluate whether expanded insurance coverage (with an attendant improved access to primary and CV care, and greater choice of care setting) will be associated with fewer preventable inpatient admissions for ambulatory care sensitive CV conditions (those thought to be preventable with the receipt of adequate outpatient care) and readmissions for CV conditions. This project will also assess rates of referral-sensitive cardiac procedures, and the use of safety-net hospitals by racial/ethnic minority patients. In Project 2, we will examine care and outcomes of care for venous thromboembolism (VTE) both pre- and post-reform, examining whether expanded coverage (with increased access to primary and home care, and to outpatient pharmacy services), will be associated with better clinical outcomes (e.g. fewer recurrent VTEs, major hemorrhages, and deaths), as well as improved health related quality of life, survival and cost-effectiveness. **The specific aims of our Center are:**

- 1) To conduct two research projects, by multidisciplinary teams, to evaluate the effects of health reform in MA, examining whether increased access to health care, through provision of insurance to a majority of state residents, leads to improved CV outcomes, and reduced disparities in them. We will focus on patients especially vulnerable to CV disease and poor access – low-income minority patients.
- 2) To complement and collaborate with other existing centers in CV outcomes research.
- 3) To develop three Early Stage Investigators into seasoned CV outcomes researchers who are well versed in the issues, topics and methods in the field, and who, upon the completion of the center activities, will be poised to make substantial future contributions to the field of CV outcomes research.

<sup>1</sup>Throughout this proposal, we use the term 'disparities' as an umbrella term for unequal care, which may arise as a function of patients' race/ethnicity, income or language preference.

## **Project #1: The Effects of Massachusetts Health Reform on Cardiovascular Outcomes and Disparities**

### **1. Specific Aims**

Cardiovascular (CV) disease is the leading cause of death in the US, and it disproportionately affects racial/ethnic minorities, and the poor.<sup>20</sup> Lack of health insurance is associated with increased mortality, and is often cited as the main reason for racial and ethnic health disparities.<sup>1, 2, 21-27</sup> Prior studies suggest that when individuals have insurance, they are more likely to have a usual source of care and to utilize medical care. Receipt of such care can prevent unnecessary and costly hospitalizations.<sup>2, 25, 28-34</sup>

Massachusetts (MA) is the setting of a landmark experiment in health care reform that has sharply lowered the percent of uninsured state residents over the past 3 years and now has an uninsurance rate far below all other states (2.6%).<sup>35</sup> It thus provides a unique opportunity to evaluate whether a major coverage expansion has improved access to care, and reduced disparities in such care, for CV conditions. Most previously uninsured patients in MA now have a portable insurance card, rather than being tied to safety-net institutions where they previously could receive "Free Care." Because of this, patients now have **more choice regarding their care setting**. Patients who received care in safety-net hospital settings, where quality of care may be lower,<sup>36</sup> have, since MA reform, been able to transfer care to other locations potentially providing higher quality care. Newly-insured patients may also now have **expanded access to outpatient care and to referral-sensitive procedures** (non-emergent procedures where failure to obtain a referral can be a barrier to obtaining the procedure; e.g. CABG) only available at selected hospitals. Thus, MA health reform could potentially reduce disparities in CV outcomes through greater choice of care setting, increased access to primary and specialty care, and improved access to procedures.

Only one prior published study has examined changes in access to care under MA health reform, finding that access improved.<sup>37</sup> However, this study relied on patient survey responses rather than utilization or outcome data. While assessment of outpatient utilization is not feasible due to a lack of all-payer outpatient data, changes in access to outpatient care under the reform can be examined indirectly, by using all-payer inpatient discharge data to examine changes in **ambulatory care sensitive (ACS) hospital admissions**, hospitalizations which are believed to be preventable by access to ambulatory care within the weeks before admission.<sup>38</sup> **30-day hospital readmissions** are another indirect measure of access to outpatient care, as post-hospital discharge access to follow-up outpatient care is critical to avoiding re-hospitalizations.

We propose to use inpatient administrative data on adults age 21-64 (using state inpatient discharge databases) from six states, including MA, which have nearly-complete race and ethnicity indicators, sizable minority populations, and diagnosis and cost data for each admission. We will analyze data from 2004-2010, encompassing the years before and after 2006 MA health reform implementation. All analyses will control for potential confounders such as area-level socioeconomic status, economic indices, regional variation in health resources, and baseline insurance rates among states. We have the following aims:

**Aim 1: Compare changes in admission rates, and racial/ethnic disparities in such rates, and associated changes in inpatient costs in MA vs. other states for CV ACS conditions including congestive heart failure (CHF), angina, and hypertension.**

Hypothesis 1. Following the implementation of health reform, CV ACS admissions and disparities in such admissions will decline in MA relative to states without reform; thus there will be decreased net inpatient costs.

**Aim 2: Compare changes in 30-day readmission rates, and racial/ethnic disparities in such rates, and associated changes in inpatient costs for CHF and Acute Myocardial Infarction (AMI), in MA vs. other states.**

Hypothesis 2. Following the implementation of health reform, 30-day readmission rates and disparities in such admissions will decline in MA relative to states without reform; thus there will be decreased net inpatient costs.

**Aim 3: Compare changes in rates, and disparities in such rates, of referral-sensitive cardiac procedures, such as pacemaker implantation, CABG, and percutaneous coronary interventions (PCI), in MA vs. other states.**

Hypothesis 3. Following the implementation of health reform, MA will have increased use of referral-sensitive cardiac procedures and reduced disparities in access to such procedures relative to states without reform.

**Aim 4: Compare changes in utilization of safety-net vs. non-safety-net hospitals by racial and ethnic minorities for all outcomes included in aims above in MA to other states, pre- and post-reform.**

Hypothesis 4. The concentration of minority hospital inpatients using safety-net hospitals will decline and those using non-safety-net hospitals will increase in MA, relative to states without reform.

## **Project #2: Did Massachusetts Health Reform Reduce Disparities in Outcomes after Venous Thromboembolism, and at What Cost?**

### **1. Specific Aims**

Venous thromboembolism (VTE) is a spectrum of cardiovascular (CV) disorders encompassing deep venous thrombosis (DVT) and pulmonary embolus (PE). VTE is common, costly, and often fatal; it is the third most common CV disease, affecting 300,000 Americans annually.<sup>117</sup> After the initial episode, VTE is associated with hundreds of dollars in monthly costs for warfarin monitoring and education<sup>118</sup> and thousands to treat the early complications of VTE – recurrent VTE and major hemorrhage.<sup>119</sup> 30-day case fatality rates for VTE range between 5-9% for DVT and 8-15% for PE.<sup>120, 121</sup> This burden is not shared equally across racial/ethnic groups: Blacks have higher rates of VTE and worse prognosis,<sup>122-127</sup> with a higher rate of mortality following PE<sup>128</sup> and higher rates of complications<sup>129</sup> and readmissions<sup>130</sup> following VTE. Although previous work has primarily focused on outcomes from the acute phase (e.g., 30-day case fatality rates) and subacute phase (3 to 12 month recurrent VTE and hemorrhage rates), VTE is a chronic disease with additional important long-term clinical sequelae (post thrombotic syndrome (PTS) and pulmonary hypertension). VTE is also associated with long term reductions in health-related quality of life (HRQOL), reduced survival, and high costs.

Warfarin anticoagulation is the mainstay of VTE therapy, but limitations in accessing quality care likely contribute to disparities in outcomes. Enhanced access to community-based pharmacies, dedicated anticoagulation clinics with phlebotomy and nutrition education, primary care, and home care services may contribute to improved outcomes, and comprehensive insurance coverage is likely associated with differential access to these important elements of care. We propose to use VTE as a test case by which we will evaluate the effect of health insurance reform in MA upon a specific CV condition, and disparities in that condition, for which we posit that initial, intermediate and long-term outcomes will improve with a hypothesized improvement in access to care following health reform.

With NHLBI RC2/GO grant funding to establish a clinical data infrastructure with which to monitor CV health disparities from 2000 to the present, we are amassing an extensive clinical database of over 2 million patients in Eastern MA seen at New England's largest safety-net hospital, Boston Medical Center (BMC), and its network of community health centers. This database, the MA Health Disparities Registry ("MHDR"), covers the pre- and post-health insurance reform periods, and includes many variables not typically available in administrative databases, including rich detail on insurance status over time as well as race, language preference, processes of care, laboratory values and comorbid conditions. The large number of patients provides sufficient power to study the effects of these factors on a single disease condition: VTE.

We will use this dataset, comprised of an unusually diverse and high-risk population, to examine outcomes (recurrent VTE, major hemorrhage, and mortality), and disparities in outcomes, before and after health insurance reform. We will compare outcomes among the newly insured (i.e. patients with Commonwealth Care) with historical controls without insurance coverage (i.e. Free Care or Self-Pay) prior to health reform. Then, we will evaluate longer-term outcomes including HRQOL, survival and costs, as well as the cost-effectiveness of the reform in improving VTE outcomes, using disease simulation, an integrative analysis technique which can synthesize acute phase and subacute phase outcomes in subpopulations tracked by our clinical database with long-term sequelae data from longitudinal studies of VTE. Disease simulation can also integrate cost data from payer reimbursement schedules and HRQOL information from population-based surveys. *We will address the following aims:*

**1. Measure one-year outcomes (recurrent VTE, major hemorrhage, and death), and disparities in outcomes (related to race, language preference, and income), among patients with incident VTE newly insured following MA health reform, relative to patients uninsured prior to reform.**

Hypothesis 1: Following MA health reform, one-year outcomes after incident VTE will be better among newly insured patients relative to patients uninsured prior to health reform.

Hypothesis 2: Following MA health reform, race, language preference, and income disparities in one-year VTE outcomes will be fewer among newly-insured patients relative to patients uninsured prior to health reform.

Hypothesis 3: Better outcomes post-reform will be related to improved intermediate outcomes (retention in anticoagulation care and adequate anticoagulation control).

**2. Measure long term HRQOL, survival and cost for a cohort of patients with incident VTE newly insured following MA health reform, relative to patients uninsured prior to reform, and determine the cost effectiveness of MA health reform for patients with incident VTE.**

Hypothesis 4: Following MA health reform, there will be better long-term HRQOL, survival and lower cost following incident VTE among newly insured patients relative to patients uninsured prior to health reform, and MA health reform will be cost-effective for patients with incident VTE.