DGIM Project Summary

Name of Project: Decisional Quality in Patients with Stable Coronary Artery Disease (DeQCAD)

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)

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<tr>
<th>Principal Investigator</th>
<th>R. Adams Dudley, MD, MBA</th>
<th><a href="mailto:adams.dudley@ucsf.edu">adams.dudley@ucsf.edu</a></th>
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<tr>
<td>Co-investigator &amp; Primary contact</td>
<td>Grace Lin, MD</td>
<td><a href="mailto:glin@medicine.ucsf.edu">glin@medicine.ucsf.edu</a></td>
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Research question(s): The objective of the DeQCAD study is to measure the quality of the decision-making process for patients with stable coronary artery disease (CAD) who are making treatment decisions. In particular, this study is seeking to answer:

1. How informed are patients about their treatment choices (optimal medical therapy, PCI, or CABG)?
2. Are patients participating in the decision-making process as much as they would like to?
3. Do the treatment decisions made match patients’ preferences?

Brief Background/Significance: For patients with stable CAD, the three foci of clinical management are symptom control, risk factor modification, and making optimal decisions about whether and when to revascularize. Since the decision about revascularization often does not involve clear survival advantages, the choice of therapeutic approach (optimal medical therapy, PCI, CABG) should be sensitive to the preferences of a well-informed patient. However, data suggest that patients often make treatment decisions without understanding the full benefits and risks of the available options.

There are currently no tools available for physicians to assess whether patients with CAD have sufficient knowledge and are making good quality decisions (i.e., informed, participates in decision as desired, decision consistent with preferences). Therefore, we propose to develop and validate the first patient-reported, comprehensive measure of decision quality that could be implemented into routine practice to determine whether patients are making well-informed, high quality decisions about treatment for CAD. This tool could be used to routinely: a) improve physician understanding of their patients’ knowledge about revascularization benefits, risks, and symptoms and b) help physicians assess whether they are providing enough assistance and information to their patients to ensure high quality decisions are made about treatment options. The proposed decision quality tool could also be used in future studies and by physicians in clinical practice to assess whether interventions to improve decision-making are effective, and if improving decision quality improves outcomes and adherence to risk factor modification.

Inclusion/exclusion criteria (list)
Inclusion criteria: All patients ≥ 18 years old, English speaking, no significant cognitive deficits, referred to cardiology for evaluation of coronary artery disease.

Exclusion criteria: Patient with acute ST-elevation myocardial infarction, positive biomarkers, referred for an emergent cardiac procedure.

Method of contact/recruitment (be specific): Our goal is to recruit patients being referred from DGIM to UCSF cardiologists for the purpose of evaluation and treatment for CAD (e.g., having symptoms consistent with angina and/or positive stress test). We are targeting
patients being referred to cardiology as these patients are the mostly likely to be at or near a
treatment decision point. Our recruitment procedures will be:

1. Send letter to all DGIM providers familiarizing them with the study and our intention
to recruit DGIM patients (see attached letter).
2. Request that DGIM referral coordinators keep a list of patients who are being referred
to UCSF cardiology for any reason.
3. Study staff will then screen the referrals for eligible patients and contact eligible
patients by letter first then follow-up telephone call to assess interest in enrolling in
the study. We also request to post fliers in the clinic waiting area to inform patients
about the study.

Benefits/burden for participants (clearly identify potential for harm): A potential benefit
from this project for patients with CAD is that they will have a heightened awareness of the
importance of physician communication and education about CAD, as well as have the
opportunity to consider their preferences for treatment and involvement in the decision-
making process.

Patients will be asked to answer survey questions on 1-3 occasions, depending on the
phase of the study. Phase 1 will include cognitive testing of a preliminary survey (see
attached survey). Phase 2 will consist of recruiting patients for pilot testing of the survey to
establish preliminary psychometric measures and further refine the survey. Phase 3 will be
field testing of the final survey to establish validity and reliability of the items. We estimate
the time to answer survey questions as 15 minutes or less for each administration. There are
minimal risks to participants in any of the study activities. The participants risk loss of
privacy if identifiable data are revealed; however, we have taken steps to mitigate the risk.
There is a risk that patients and physicians may perceive a disruption to their relationship;
however, participation in the study will be voluntary and participants are free to stop
participating at any time with no penalty. Participation in the study will require informed
consent. Participating or declining to participate in the study will in no way affect the
services provided to the patients at each clinical site. There will be no physical risks to
participants and no costs. Participants will be informed that they do not have to respond to
any question that they do not want to, and that responses are confidential.

Any benefits or burden to DGIM practitioners? DGIM providers do not need to do anything
beyond filling out APeX referrals to cardiology as usual. Study staff will take care of
identifying and recruiting patients into the study.

Timeline for recruitment (projected start and stop dates): We anticipate starting recruitment
April 7, 2014, for the first phase of the project (cognitive testing of the survey). We will
recruit patients through July 2016.

Funding source: National Heart, Lung, and Blood Institute

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in
particular) Yes.

Do you agree to notify us when recruitment is completed? Yes

Date form completed: March 24, 2014