**INFORMATION STATEMENT**

# Implementation Trial of a Coaching Intervention to Increase the Use of Transradial PCI

# Researchers:

Christian Helfrich, PhD, MPH, Principal Investigator, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA, (206) 277-1655, Christian.Helfrich@va.gov

Sunil Rao, MD, Co-Principal Investigator, Durham VA Medical Center, Durham, NC, (919) 286-0411, Sunil.Rao@duke.edu

Mladen Vidovich, MD, FACC, FSCAI, Co-Investigator, Jesse Brown VA Medical Center, Chicago, IL, (312) 569-6129, Mladen.Vidovich@va.gov

Adhir Shroff, MD, MPH, Co-Investigator, Jesse Brown VA Medical Center, Chicago, IL, (312) 569-6129, Adhir.Shroff@va.gov

Meg Plomondon, PhD, MSPH, Co-Investigator, VA Eastern Colorado Health Care System, Denver, CO, (303) 370-7572, Meg.Plomondon@va.gov

Steve Waldo, MD, Co-Investigator, VA Eastern Colorado Health Care System, Denver, CO, (303) 399-8020 x2808, Stephen.Waldo@va.gov

Javier Valle, MD, Co- Investigator, HSR&D COIN, VA Eastern Colorado Health Care System, Denver, CO, (303) 266-4157, Javier.Valle@va.gov

Edwin Wong, PhD, Co-Investigator, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA, (206) 277-4703 , Edwin.wong@va.gov

George Sayre, PsyD, Co-Investigator, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA, (206) 277-4187, George.Sayre@va.gov

Arnold Seto, MD, MPA, FACC, FSCAI, Co-Investigator, Long Beach VA Medical Center, Long Beach, CA, (562) 826-8000 x 8115, Arnold.Seto@va.gov

Rajesh Swaminathan, MD FACC, FSCAI, Co-Investigator, Durham VA Medical Center, Durham, NC 919-286-0411, Rajesh.Swaminathan@va.gov

Samir Pancholy, MD, FAHA, FACP, FACC, FSCAI, Co-Investigator, Wilkes-Barre VA Medical Center, Wilkes-Barre, PA (507) 824-3521, samir.pancholy@va.gov

Jacob Doll, MD, Co-Investigator, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA, (919) 286-0411, [Jacob.Doll@va.gov](file:///%5C%5CVHAPUGFPC30.v20.med.va.gov%5CProjectsAdmin%24%5CrPCI-SDP-Admin%5C02%20CIRB%20and%20R%26D%5CCIRB%5C07a%20Modification%5CJacob.Doll%40va.gov%20)

Sara Jensen, RN, Nursing Coach, Durham VA Medical Center, Durham, NC (919) 286-0411 Sara.Jensen@va.gov

Charles Maynard, PhD, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA, (206)277-6496, [Charles.Maynard@va.gov](file://VHAPUGFPC30.v20.med.va.gov/ProjectsAdmin%24/rPCI-SDP-Admin/02%20CIRB%20and%20R%26D/CIRB/07%20Modification/Recruitment/Charles.Maynard%40va.gov)

Diana Naranjo, MPH, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA (206) 762-1010 Diana.Naranjo@va.gov

Emily Neely, MPH, Research Coordinator, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA, (206) 277-5176, Emily.Neely@va.gov

Christine Sulc, BA, Research Coordinator, HSR&D COIN, VA Puget Sound Health Care System, Seattle, WA, (206) 277-5173, Christine.Sulc@va.gov

Decebal (Sorin) Griza, Research Coordinator, Jesse Brown VA Medical Center, Chicago, IL , (312) 569-6129, [Decebal.Griza@va.gov](file:///%5C%5CVHAPUGFPC30.v20.med.va.gov%5CProjectsAdmin%24%5CrPCI-SDP-Admin%5C02%20CIRB%20and%20R%26D%5CCIRB%5C09%20Modification%5CTo%20Upload%5CDecebal.Griza%40va.gov)

Candice Mueller, BA, Research Coordinator, VA Eastern Colorado Health Care System, Denver, CO, (303) 202-8387

# Researchers’ Statement:

We are asking you to participate in a research study. The purpose of this statement is to give you the information you will need to help you decide whether to take part in the study. Please read this form carefully. You may contact us with questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you decide if you want to participate in the study or not. This form is yours to keep for your records.

# PURPOSE AND BENEFITS

The purpose of this study is to test the effectiveness of a training program on transradial approach cardiac catheterizations (TRA). Previous research has demonstrated the safety, efficacy, and improved outcomes associated with the use of TRA); however, TRA accounts for just over 20% of PCIs in the U.S. One identified barrier to the use of TRA is a scarcity of training opportunities. Little is known about what type of training method is the most effective, safest, and results in the lowest number of associated complications. Based off of our successful pilot study conducted in 2012 and 2013, this study aims to determine the effectiveness, safety and cost-effectiveness of a comprehensive training program compared to a more conventional workshop presentation of the TRA approach. Ultimately, we hope this implementation project will increase the proportion of TRA performed in VA cardiac catheterization laboratories (or cath labs).

This study has several additional parts. Study components will include data analysis of the use of routinely collected clinical data to assess rates of total cardiac catheterizations and associated complication rates and costs. Other study components will include: pre- and post-training individual interviews with cath lab staff, and pre- and post-training surveys of VA cath lab staff about items including, but not limited to, experience with TRA barriers to PCI use and facility cath lab capabilities.

We are asking you, as a cath lab director, interventional or invasive cardiologist, cath lab nurse or technician, to participate in this implementation study.

# PARTICIPATION

Participation in this study is voluntary. Six to nine VA cath labs sites will be recruited to participate. The goal is to include two to three staff members per cath lab site: at least one interventional or invasive cardiologist (or cath lab director), at least one nurse manager, and one other cath team member (such as a cath lab technician or an additional nurse or interventional or invasive cardiologist). Even if other members of your cath lab decide to participate, your individual participation is voluntary. If you do not wish to participate we will remove you from our list and not contact you again about this project.

You have the right to decline to participate in the interviews and/or surveys, and may still complete the training course.

# PROCEDURES

If you volunteer for this study, you will be asked to:

1. Participate in **pre- and post-training online surveys.** There are three surveys: one pre-training and two post-training (approximately 6 months apart). Questions asked during this survey may include, but are not limited to,perceptions of and barriers to TRA at your facility, organizational readiness to change and demographic information. Completing each survey will take approximately 15 minutes. Completing all surveys should take about 45 minutes of your time, and you are free to answer only the questions that you feel comfortable answering.
2. Attend and participate in a **day-long educational training program** at the Jesse Brown VA Medical Center in Chicago, IL or the Durham VA Medical Center in Durham, NC, tentatively scheduled for summer, winter, spring, of 2018-2019. Cath labs will be randomized to one of three of these trainings, and all participating members of a given lab will attend together. This program will include education on the benefits of transradial over transfemoral cardiac catheterizations, safety procedures, practice of TRA techniques, and viewing of live cases. All travel and course costs will be covered by the study.
3. Participate in **pre- and post-training program telephone interviews.** There are three interviews: one pre-training two post-training (approximately 6 months apart). Questions asked during this interview may include, but are not limited to,perceptions of and barriers to TRA at your facility, individuals you may go to for advice, or your opinion of the study training program. All answers will be kept anonymous. Completing the interviews should take about 40 minutes, and you are free to answer only the questions that you feel comfortable answering. Interviews will be recorded using Microsoft Skype for Business or a secure VA issued recording device. Interviews will be kept on a secure network folder available to a limited qualitative subset of the study team.
4. Receive a post-training program **coaching visit** at your cath lab approximately one month after the training. Members of the research team, including an experienced TRA interventionalist and nurse, will travel to your facility to follow up on the training program, assist with overcoming any material and technical challenges to implementing TRA at your facility, and request feedback about the training program. The coaching visit will last approximately one day.

# RISKS, STRESS, OR DISCOMFORT

The study intervention is an educational training program, and there is minimal risk for participating. Even though this is a research project, this study also takes place in the context of clinical operations and dissemination of medical knowledge and practices. As a result, if you choose to participate, your identity and participation will be known by your cath lab director and possibly other supervisors and co- workers. While we will make every effort to keep any data collected from you for the study confidential, no system for protecting your confidentiality can be completely secure. You may choose to share with others the fact of your participation or your opinions about the training program and interviews; however, we will not disclose your responses to any questions to anyone outside our research team.

There is an associated risk to patients when providers start utilizing a new procedural technique that has not been practiced before. The magnitude of the risk and the length of learning curve are both unknown, but by participating in this study you will help researchers begin to assess this risk.

# OTHER INFORMATION

If you choose to participate, the cost of your travel to Chicago or Durham and the training program will be covered by the VA Health Services Research & Development research study (IIR 15-362) as part of this project to test the effectiveness of this innovative training program on TRA.

We will be using routinely collected clinical data maintained in the CART-CL database to determine the effectiveness of the comprehensive training program.

With your permission, we will audiotape the telephone interviews so they can be transcribed for analysis. If you agree to be interviewed but do not wish to be audiotaped, we will only take notes to record your responses.

The results of this study, aggregated at the facility level, will be published in academic journals and distributed in project reports that will be available to VA administrators. We will recode facility identifiers to retain geographic groupings but will not identify individual facilities in any report or publication. Nor will individual responses be reported. We will not identify you as a participant.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you.

Additionally, the following people or groups may know that you are participating in the study:

* the cath lab director and/or the chair of the cardiology department or other supervisors and co-workers at your facility
* the research team members
* VA (to monitor studies)
* government agencies that regulate research such as the Food and Drug Administration (FDA) or the Department of Health and Human Services (HHS)
* the VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
* Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors

Again, participation in this study is voluntary. If you agree to participate you are free to refuse to complete any part of the procedures or answer any individual questions that you may not wish to answer.

*If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.*

*In the event of a research related injury, please immediately contact Dr. Helfrich at 206-277-1655 or Dr. Rao at 919-286-0411 ext. 6942.   If you have any questions, comments or concerns about the research, please contact the study team at* pugtrastudy@va.gov*.*

We very much appreciate your consideration of this study. Thank you for your assistance.

Christian D. Helfrich, PhD, MPH \_\_\_\_\_\_\_\_\_\_

Printed name of researcher Signature of researcher Date

Sunil V. Rao, MD \_\_\_\_\_\_\_\_\_\_

Printed name of researcher Signature of researcher Date