



Mission: Eradicating Heart Attacks

The SHAPE Trial Advisory Meeting – Part II

A satellite event in conjunction with
2015 Annual Scientific Sessions of American Heart Associations

November 9th, 7-9PM, Rosen Plaza Hotel, Orlando, FL

AGENDA

7:00 PM

Opening: **Morteza Naghavi, M.D.**
Founder and Executive Chairman of SHAPE, Houston, TX

Chairmen:

Daniel Berman, M.D.
Director of Cardiac Imaging and of Nuclear Cardiology at Cedars-Sinai,
Los Angeles, CA

Mathew Budoff, M.D.
Professor of Medicine and Director of Preventive Cardiology, UCLA Harbor, Los
Angeles, CA

Summary of Part-I SHAPE Trial Advisory Meeting
(Design and Fundraising)

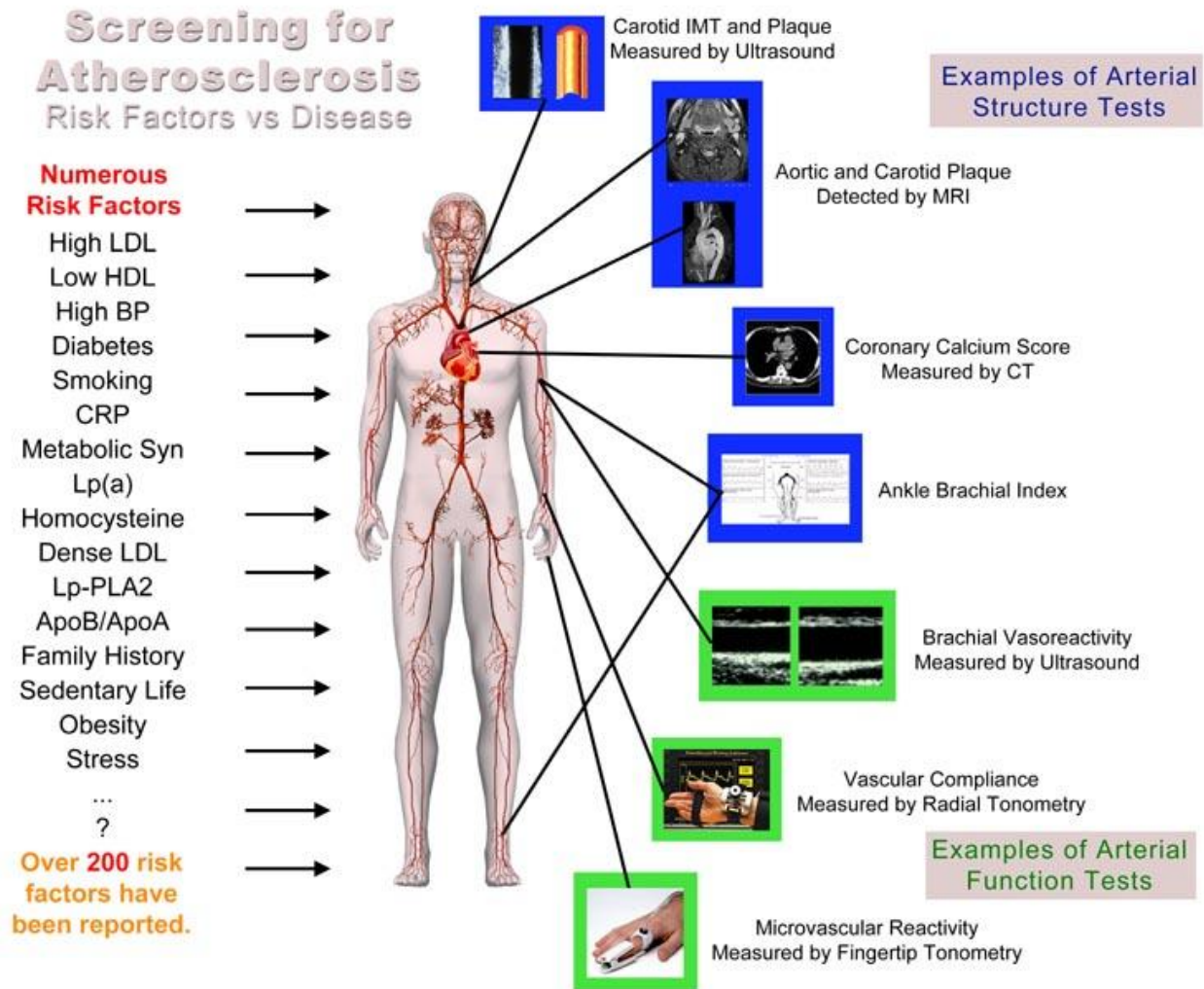
David Maron, M.D. Morteza Naghavi, M.D.

- 1- ROBINSCA original www.robinsca.nl
- 2- Modified ROBINSCA with a CAC zero subgroup to test "Power of Zero"
- 3- PRECISION
- 4- Modified PRECISION with a CAC zero subgroup to test "Power of Zero"
- 5- HRP / BioImage? Google Baseline? VIEW? or a completely new study design?

Design and Implementation of ROBINSCA
(Risk of Benefit in Screening for Cardiovascular Disease www.robinsca.nl)

H.J. de Koning, M.D., Ph.D. and Matthijs Oudkerk, M.D., Ph.D.

**A New Paradigm in Coronary Risk Stratification Based on Assessment of Arterial Structure and Function
Screening for the Disease Not Risk Factors**



Source: SHAPE Guidelines: American Journal of Cardiology, VOLUME 98, NUMBER 2, July 2006

The SHAPE Trial Advisory Meeting Part-I

August 21-23, 2015

Los Angeles -Marina del Ray

Ritz-Carlton Hotel, Marina Vista Conference Room

Topics

Day 1:

Necessity, Feasibility, Design, Implementation, and Fundraising for a Longitudinal Outcome Study to Compare SHAPE Guidelines with the Status Quo

Day 2:

Public Healthcare Policies and Regulatory Initiatives, SHAPE Centers of Excellence

Attendees

(Alphabetic Order)

Sameer Bansilal, M.D.

Assistant Professor Medicine, Cardiology
Mount Sinai Hospital
New York, NY

Daniel Berman, M.D.

Director of Cardiac Imaging and of Nuclear
Cardiology at Cedars-Sinai,
Los Angeles, CA

Mathew Budoff, M.D.

Professor of Medicine and Director of
Preventive Cardiology, UCLA Harbor, Los
Angeles, CA

Jeff Fine, Ph.D.

President/CEO of J&J Medical, LLC
SHAPE Centers of Excellence

Brenda Garrett-Superko, RN, CCA

CVD Nurse Researcher and
SHAPE Executive Board Member
Stanford, CA

Hattie Rees Hanley, MPP,

Director, Right Care Initiative,
UC Berkeley & DMHC
Berkeley, CA

Harvey Hecht, M.D.

Director of Cardiac CT Imaging Laboratory
Mount Sinai School of Medicine
New York, NY

Howard Hodis, M.D.

Director, Atherosclerosis Research Unit,
Division of Cardiovascular Medicine
Keck School of Medicine USC,
Los Angeles, CA

Sanjay Kaul, M.D.

Director of Cardiology Fellowship
Cedars-Sinai, UCLA
Los Angeles, CA

Dan Keeney, A.P.R.

Principal, KeenerPR
Director of SHAPE Public Relations
Dallas, TX

David Maron, M.D.

Professor and Director, Preventive
Cardiology Stanford University School of
Medicine, Stanford, CA

Michael McConnell, M.D.

Professor of Medicine (Cardiovascular) and,
by courtesy, Electrical Engineering,
Director, Cardiovascular Health Innovation;
Stanford University, Stanford, CA

Jessica Mega, M.D., M.P.H.

Associate Professor at Harvard Medical
School and Director, Google Baseline Study
Boston, MA

James Min, M.D.

Professor of Medicine and Radiology
Weill Cornell Medical College, Cornell
University
New York, NY

Morteza Naghavi, M.D.

Founder and Executive Chairman of the
SHAPE Task Force, President of MEDITEX
Houston, TX

Tasneem Naqvi, M.D., M.M.M.

Professor of Medicine and Director of
Echocardiography, College of Medicine,
May Clinic, Scottsdale, AZ

P.K. Shah, M.D.

Professor and Director, Atherosclerosis
Research Center, Cedars-Sinai Medical
Center, UCLA
Los Angeles, CA

Henrik Sillesen, M.D.

Professor and Head of Dept. of Vascular
Surgery, Rigs Hospitalet, University of
Copenhagen, Copenhagen, Denmark

Robert Superko, M.D.

Professor of Medicine and President at
Cholesterol, Genetics, and Heart Disease
Institute, Stanford, CA

JoAnne Zawitoski, J.D.

Chairwoman, SHAPE
Principal, Semmes, Bowen & Semmes LLC,
Attorneys at Law, Baltimore, MD



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AGENDA

Friday Aug 21, 2015: Arrival in Los Angeles and Check-in @ Ritz-Carlton Marina del Rey

8:00 PM Kick Off Dinner at Ritz-Carlton, Marina Vista Room

Welcome: **Morteza Naghavi, M.D.**
Executive Chairman of SHAPE Task Force

JoAnne Zawitoski, J.D.
Chairwoman, SHAPE Board of Directors

Saturday August 22, 2015

6:30-7:30 AM Breakfast

7:30-7:45 Introduction and Review of the Agenda
Morteza Naghavi, M.D.

Moderators: **PK Shah, M.D. and David Maron, M.D.**

Session I 7:45-9:45 AM

Why do we need a SHAPE Outcome Trial? Isn't the existing evidence enough?

Moderators comment followed by presentations on CAC and CIMT (the two SHAPE-approved testing modalities). The following will be addressed by presenters:

- superior predictive value over risk factors and risk scores (including CRP and other non-traditional serum markers)
- correlates with the progression and regression of the disease
- increases compliance to therapy
- and is cost effective

Coronary Artery Calcium Imaging

Presenters: **Mathew Budoff, M.D. (Dan Berman, M.D. will present as needed)**

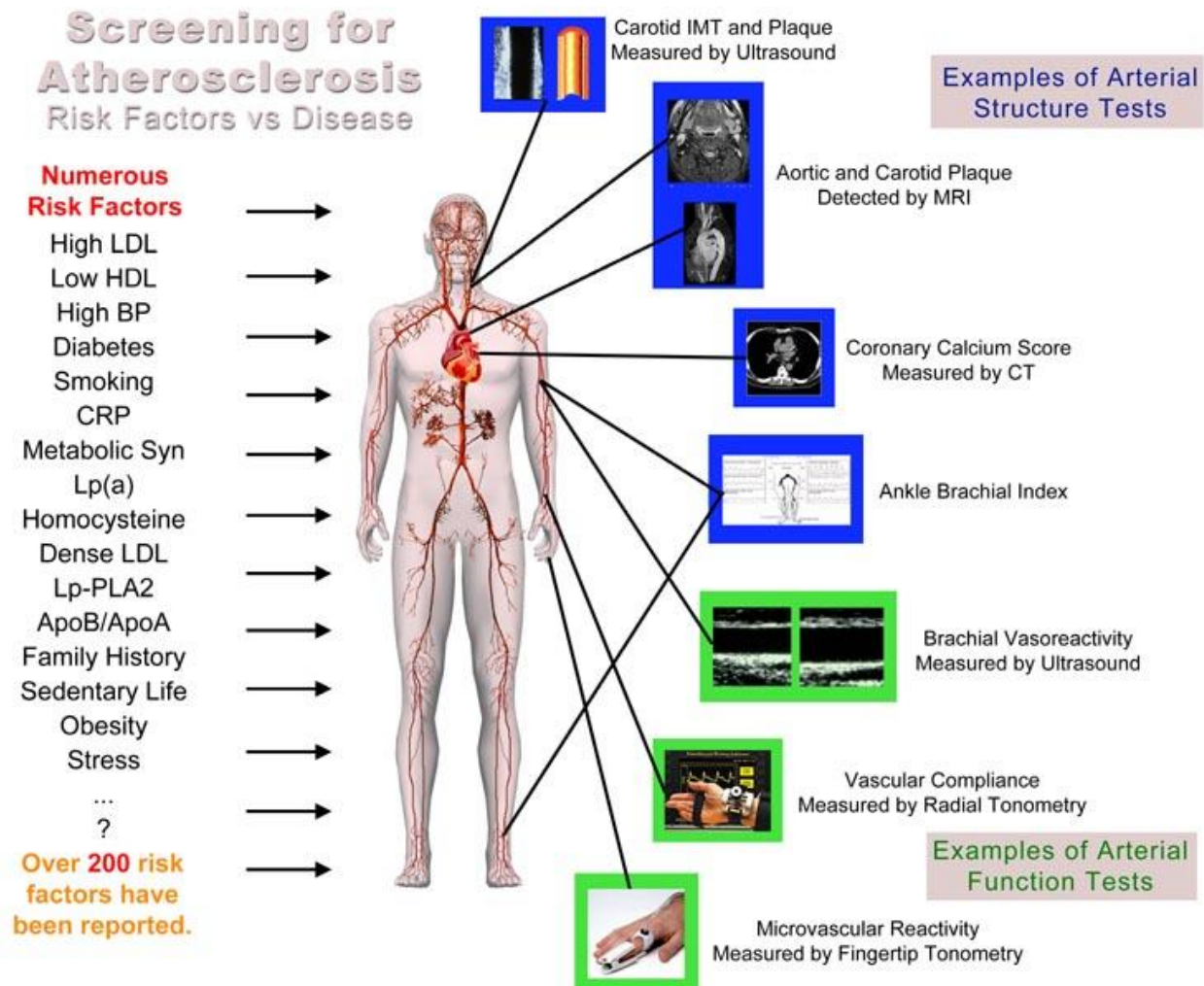
30 Minutes

Carotid CIMT and Plaque Imaging

Presenters: **Tasneem Naqvi, M.D. (Henrik Sillesen, M.D., and Howard Hodis, M.D. will present as needed)**

30 Minutes

**A New Paradigm in Coronary Risk Stratification Based on Assessment of Arterial Structure and Function
Screening for the Disease Not Risk Factors**



Source: SHAPE Guidelines: American Journal of Cardiology, VOLUME 98, NUMBER 2, July 2006

Where Do We Stand on Genetic, Proteomic, and Functional Testing?

Presenters: **Robert Superko, M.D., Jessica Mega, M.D., Morteza Naghavi, M.D.**
30 Minutes (10 minutes each)

30 Minutes Moderated Discussions. All attendees please prepare to comment.

9:45-10:00 AM

REFRESHMENT BREAK

Session II 10:00 AM -12:00 PM

Why bother testing? Treat all at-risk population. (Unconditional Therapy) vs. (Testing + Therapy) and discussions on Polypill in primary and secondary prevention.

Presenter: Sanjay Kaul, M.D.

30 minutes

Discussions on SHAPE II Guidelines – is it time to update? 3D Carotid and Polypill are not ready, what’s new?

-Discuss “de-escalation” based on zero CAC and no-plaque in carotids.

-Discuss Dr. PK Shah’s approach; starting with carotid ultrasound imaging, if found no plaque then proceed with coronary calcium imaging.

60 Minutes Moderated Discussions. All attendees please prepare to comment.

12PM **WORKING LUNCH (Discussions continue during Lunch)**

Session III 12:00 – 4:30 SHAPE Trial

12:00-2:00 PM

Brainstorming on the Design and Implementation of a SHAPE Trial

Review of Phil Greenland’s Proposal to NIH: **Design of the Value of Imaging in Enhancing the Wellness of Your Heart (VIEW) Trial**

Presenter: Mathew Budoff, M.D.

15 Minutes

What can we learn from HRP / Bio-Image Study?

Presenter: Sameer Bansilal, M.D.

15 Minutes

What can we learn from the new mobile health studies?

(e-Heart of USCF <https://www.health-eheartstudy.org> and MyHeart Counts of Stanford <https://med.stanford.edu/myheartcounts.html>) particularly for rapid recruitment and cost reduction.

Presenter: Michael McConnell, M.D.

15 Minutes

What is Google Baseline Study and can we collaborate with Google?

Presenter: Jessica Mega, M.D.

15 Minutes

30 Minutes Discussions. All attendees please prepare to comment.

1:30-2:00 PM

REFRESHMENT BREAK



2:00-2:30 PM Skype presentation on SHAPE trial design by Jim Min from Cornell University

2:30-3:00 PM David Maron discusses key questions:

- What is the study question?
- Primary endpoint?
- Selection criteria?
- What is the intervention?
- How many patients?
- How long a period of follow-up?
- Approximately how much will it cost?

60 Minutes Moderated Discussions. All attendees please prepare to comment.

4:00-4:30 PM REFRESHMENT BREAK

Session IV

Moderators: **JoAnne Zawitoski, J.D. and Brenda Garrett-Superko, RN, CCA**

4:30-6:30 PM Part I -How to Fund the SHAPE Trial; Fundraising and Public Relations

Presenter: Daniel Keeney

- A review of potential sources of funding
 - o Philanthropic Donors
 - o Charitable Organizations Offering Research Grants
 - o Crowdfunding / Public Fundraising
- ALS “The Ice Bucket Challenge”
- SHAPE’s “The Up” Campaign (10 push-ups, sit-ups?)

Review successful public fundraising campaigns and brainstorm on funding based on milestones.

6:30 PM Adjourn and Plan for Sunday Morning
Morteza Naghavi, M.D.

7:00-9:30 PM [Enjoy The Hornblower!](#)

“Watch the sun going down before enjoying a romantic three-course dinner prepared fresh on board by our chefs. Then dance to live music or watch the sights drift by from the outdoor decks...”

Sunday August 23, 2015

6:30-7:30 AM Breakfast

Moderators: **David Maron, M.D. and Morteza Naghavi, M.D.**

7:30 - 9:00 AM **Public Healthcare Policies (Challenges and Promises)**

- Lessons learned from Texas SHAPE Law (HB1290)
- California Initiative presented by **Hattie Hanley, MPP**
- Federal Initiative
 - Legislative – Obama Care
 - USPSTF Guidelines

9:00 - 10:00 AM **SHAPE Centers of Excellence**
Presenter: **Jeff Fine, Ph.D.**

- **What exactly do we provide?**
- **How do we measure success?**
- **How can we enhance it?**
- **What can you do to help?**

10:00- 10:30 AM **Conclusions by Moderators**

11:00 AM **Adjourn and Plans for AHA 2015 SHAPE Symposium**
Morteza Naghavi, M.D.