Session 4 Panel Discussion

Questions:
• How do we fill evidence gaps in care and prevention using epidemiology?
• What is the role of observational epidemiology in a "data rich" environment where randomized clinical trials may not always be feasible?

Moderator: Sheri D. Schully, Ph.D., EGRP, DCCPS, NCI

Panelists:
• Barnett Kramer, M.D., M.P.H.
  Division of Cancer Prevention, NCI
• Michael Lauer, M.D.
  Division of Cardiovascular Sciences, National Heart Lung and Blood Institute (NHLBI)
• Jeffrey A. Meyerhardt, M.D., M.P.H.
  Harvard Medical School
• Olufunmilayo I. Olopade, M.D. F.A.C.P.
  University of Chicago
Barnett Kramer, M.D., M.P.H.

Division of Cancer Prevention, NCI
Description of Evidence in PDQ: Five Domains

1. Study design: ranked by design strength

2. Internal validity: “quality” of execution within study design (good, fair, poor)

3. Consistency (coherence)/volume of evidence
   • One vs. multiple studies
   • Small vs. large studies
   • Consistent direction of outcomes

4. Magnitude of effects: prefer absolute vs. relative effects
   • Change from 1% to 0.5%, or from 4/1000 to 2/1000
   • Not: 50% decrease

5. External validity (good, fair, poor)
   • Applicability in usual practice with same effect?
Michael Lauer, M.D.

Division of Cardiovascular Sciences
National Heart Lung and Blood Institute
Trends in Epidemiology (M. Lauer, NHLBI)

All primary PCI:s

Randomized

Cost (incremental) = US $300,000 ($50 per patient)
Jeffrey A. Meyerhardt, M.D., M.P.H.

Harvard Medical School
Integrating Epidemiology into Randomized Clinical Trials

HOST FACTORS

Eligible Patient

Physical activity

Smoking status/hx

Diet

Comorbidities / Age

Adiposity

Vitamin D

Vitamin intake

Complementary meds

Drug X

Drug Y

Molecular Markers

Overall Survival

QOL Costs

Toxicity

Other endpoints
New cancers
New precursors
Other diseases

QOL

Costs

Overall Survival
Olufunmilayo I. Olopade, M.D. F.A.C.P.
University of Chicago

Huo D, Ikpatt OFR et al. JCO 27:4515-21, 2009
Data abstracted from Adeniji et al. ASCO Proceedings 2010, Yang et al 2007, Kurebayashi et al. 2007