

# STAIR VIII

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

## Accelerating the Evolution of Stroke Therapy

March 9 - 10, 2013

Sheraton Pentagon City Hotel  
Washington D.C

Session I  
UPDATE ON  
ENDOVASCULAR  
REPERFUSION TRIALS

Session II  
STROKE IMAGING  
RESEARCH ROADMAP  
STIR

Session III  
NEW ORAL  
ANTICOAGULANTS:  
UNRESOLVED ISSUES  
& NEXT STEPS

Session IV  
REGULATORY ISSUES  
RELEVANT TO STROKE  
& PREVENTION TRIALS

Consensus  
Recommendations  
Workshops

- Endovascular Therapies
- Imaging Research Roadmap
- New Oral Anticoagulants

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# New Oral Anticoagulants



Workshop Facilitators/Co-chairs

***Karen Furie***

***Robert Hart***



# Redefining the Approach to Stroke Prevention in NVAF

- Direct oral anticoagulants (DOACs) comparable in efficacy
- Similar benefit for primary and secondary stroke prevention
- Strengthen message in Guidelines
  - Transition from more conservative recommendation for VKA to stronger rec for DOACs
  - CHADS2 score of 1 may be better threshold
  - Need to emphasize lower ICH rates



# Selecting Patients

- Those at higher risk for ICH may benefit from DOACs, but more research is needed
  - Microhemorrhages, WMH, CAA, may impact risk/benefit
- Stroke and death rates similar for VKA and DOACs when there is good INR control
  - Lower benefit for thromboembolism to switch patients stable on warfarin, but potentially no benefit for reducing ICH



# Needs

- Assay to measure drug effect/level
  - For now aPTT
  - POC Factor Xa assays may not all be reliable; may give information about compliance
  - Kodachrome assay recommended
- Need method of verifying levels/effects to verify compliance
  - Switch mechanisms for “failures”



# Antidotes

- Preventing the event vs. trying to ameliorate the damage
- Having an antidote may sway perception and increase utilization esp amongst non-neurologists
- Concern that abrupt reversal could increase risk of thrombotic events
- Unclear when antidotes will be available
- Using PD endpoints for FDA approval may expedite



# Research Directions

More discussion/phase 4 data collection for patients with renal dysfunction

- CrCl before DOAC initiation (specific method unclear- Cockcroft Gault, MDRD, CKD-epi) and reassess annually
- Field needs to look at how renal function affects risk/benefit over time
- Converting the renal parameters into modern indices would be very useful



# Research Priorities

- Post marketing surveillance
  - Mini-sentinel: FDA has links to databases with use and can correlate with outcomes
- Industry collaboration to collect data on utilization





# Research Priorities

- Study early vs. late initiation of DOACs
- Secondary stroke prevention of cryptogenic stroke: DOAC vs. antiplatelet- partnership between NIH and industry
- Antiplatelet vs. DOAC in other cerebrovascular conditions: dissection, intracranial disease, low ejection fraction (stroke as primary outcome)
- Safety with IV tPA
  - Currently heterogeneous practice
  - Area of uncertainty
  - Registry will help



# Do we need more drugs?

- Further exploration should not be discouraged
- Emphasis should be on detecting AF and treating patients with effective agents

# Thank You

