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# Evidence Based Practice for POCT Coagulation

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# Where is POC Coag used?

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## ◆ Operating Rooms

- Cardiac surgery

  - » ACT; Heparin Level

    - ◆ Thrombin time based tests; PT, aPTT, TEG

- Vascular surgery

  - » ACT; PT; aPTT

## ◆ Interventional Cardiology and Radiology

- ACT

# Where is POC Coag used?

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- ◆ Critical Care
  - ACT; aPTT
    - » TEG
- ◆ ECMO ACT
- ◆ Dialysis ACT
- ◆ Oral Anticoagulation Clinics
  - PT

# Where is POC Coag used?

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Given the wide array of clinical areas which use POC coag,

1. Is there any evidence of efficacy of POC coagulation testing?
2. Where did the “standards of care” originate?

# EBM POC Coag Focus Group

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- ◆ Valerie Bush, Ph.D.
  - Director, Clinical Laboratory, Bassett Healthcare
- ◆ Stanley Cernosek, Ph.D.
  - Director, Corporate Business Development, Beckman Coulter
- ◆ Vandita Johari, MD
  - Director, Hematology Laboratory, Baystate Medical Center
- ◆ Srikanth Rao, MD
  - Assistant Professor of Anesthesiology, Penn State College of Medicine
- ◆ Marcia L. Zucker, Ph.D. - Chair
  - Director, Clinical Research, ITC

# Assumptions / Caveats

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- ◆ Limit review to 3 most common assays
  - ACT; aPTT; PT
- ◆ Exclude specialty assays
  - Heparin level
  - Heparin / Protamine titrations
  - Heparin neutralization verification
  - TEG
  - Thrombin based assays

# Assumptions / Caveats

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- ◆ All available POC coagulation systems are equivalent for precision and accuracy
  - Exclude papers that are strictly correlation analyses
    - » Each site must perform their own, independent correlation against local “reference” method
- ◆ No recommendation will be made as to choice of system for a given application
  - Studies comparing different systems generally fall into correlation analyses

# Assumptions / Caveats

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- ◆ Studies performed on any given system may or may not be applicable to other systems
  - Many systems have been removed from the marketplace
  - Others have been replaced by newer versions
    - » Some retain disposables, other require new disposables
- ◆ Therapeutic ranges and target values will differ
  - Between multiple POC systems
  - Between POC systems and lab
  - Excluding INR, there is no standardization for coagulation
    - » Even the INR is imperfectly standardized



# Questions - ACT

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## ◆ Target times:

- Where did currently accepted target times originate?
- What evidence exists for efficacy of targets?
- Have studies been performed to optimize target times?

## ◆ Clinical settings:

- CVOR
- Cath Lab
- Critical Care
- ECMO
- Vascular surgery
- Electrophysiology
- Dialysis (routine vs CRRT)

# Questions - PT

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- ◆ Is there evidence that POC can improve patient outcome?
  - Patient self-testing
  - Clinics

# Questions - aPTT

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- ◆ Is POC as effective as laboratory aPTT for monitoring heparin therapy?
  - Comparison to anti-Xa assays
    - » Dose adjustment NOT correlation analyses
    - » Sensitivity / Specificity
- ◆ Can POC aPTT lead to improved clinical outcomes?

# Progress

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- ◆ Split into teams to perform searches
- ◆ Included all papers on POC coag in 1<sup>st</sup> pass
  - Sort for outcome studies
- ◆ Reviewed abstracts
- ◆ Reviewing papers

# Challenges

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- ◆ Limited publications
  - More than half of the identified articles are correlation analyses
- ◆ Few controlled trials
  - Almost no blinded studies

# Schedule

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- ◆ Complete initial review of papers by 9/04
- ◆ Complete rough draft of guidelines for focus group review 11/04
  - Four additional individuals have agreed to assist in first revision
- ◆ Post for comment on NACB website 12/04