NIH Clinical Center

Report to Hospital Board on Behalf of Medical Executive Committee

July 15, 2016

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OUTLINE

Patient Research at NIH compared to Academic Institutions

Organization and Membership of MEC

Responsibilities of MEC

Responsibilities of Clinical Directors

Current Challenges for MEC

Clinical Practice Committee: Red Team Recommendation

Suggestions

PATIENT RESEARCH AT NIH COMPARED TO ACADEMIC INSTITUTIONS

- All patients are on research protocols
- Large number of healthy volunteers are studied
- Large number of natural history studies
- No emergency room
- Non-departmental structure: For example medical and surgical subspecialists are spread across different ICs
- Oversight of clinical research by
  - Scientific review
  - CD
  - IRB/ Office of human subjects research and protection
  - Data and safety monitoring board/ Independent medical examiner
  - FDA

MEDICAL EXECUTIVE COMMITTEE (MEC) MEMBERSHIP

Voting members:

- **the Clinical Directors of Institutes and Centers with intramural clinical research programs;**
- **the Deputy Director for Clinical Care and Chief Nurse Officer, CC;**
- **the CC Surgeon in Chief;**
- **the Chief of the Critical Care Medicine Department; and**
- **an Institute, Center or CC pediatrician.**

Physicians, licensed independent practitioners and others may serve on the Committee, regardless of discipline or specialty.

Upon the recommendation of the MEC Chair, the Director, CC, may appoint up to two Junior Staff members nominated by the Clinical Fellows Committee to serve on the MEC, with vote.

Ex officio, non-voting members:

- **the Director, CC;**
- **a Clinical Center administrative representative designated by the Director, CC;**
- **the Director, NIH, or his/her designee;**
- **a representative of the Office of General Counsel, NIH;**
- **the Deputy Director for Intramural Clinical Research; and**
- **the Executive Secretary of the MEC.**

2015 MEC MEMBERSHIP

Front Row (left to right): Dr. Avindra Nath (Chair), Dr. John I. Gallin, Dr. William L. Dahut (Vice Chair)

Second Row (left to right): Dr. David Goldman, Dr. William A. Gahl, Dr. Janice S. Lee, Dr. Maryland Pao

Third Row (left to right): Dr. Janet E. Hall, **Dr. Neal S. Young,** Dr. Frederick L. Ferris, Dr. Deborah P. Merke, **Ms. Valerie H. Bonham**

Fourth Row (left to right): Dr. Suzanne J. Wingate, **Dr. Agnes O. Coffay**, Dr. H. Clifford Lane, **Dr. Sidharth P. Kerkar,** Ms. Laura M. Lee, Dr. Forbes D. Porter

Back Row (left to right): Dr. Josephine M. Egan, Dr. Carter Van Waes, Dr. James E. Balow

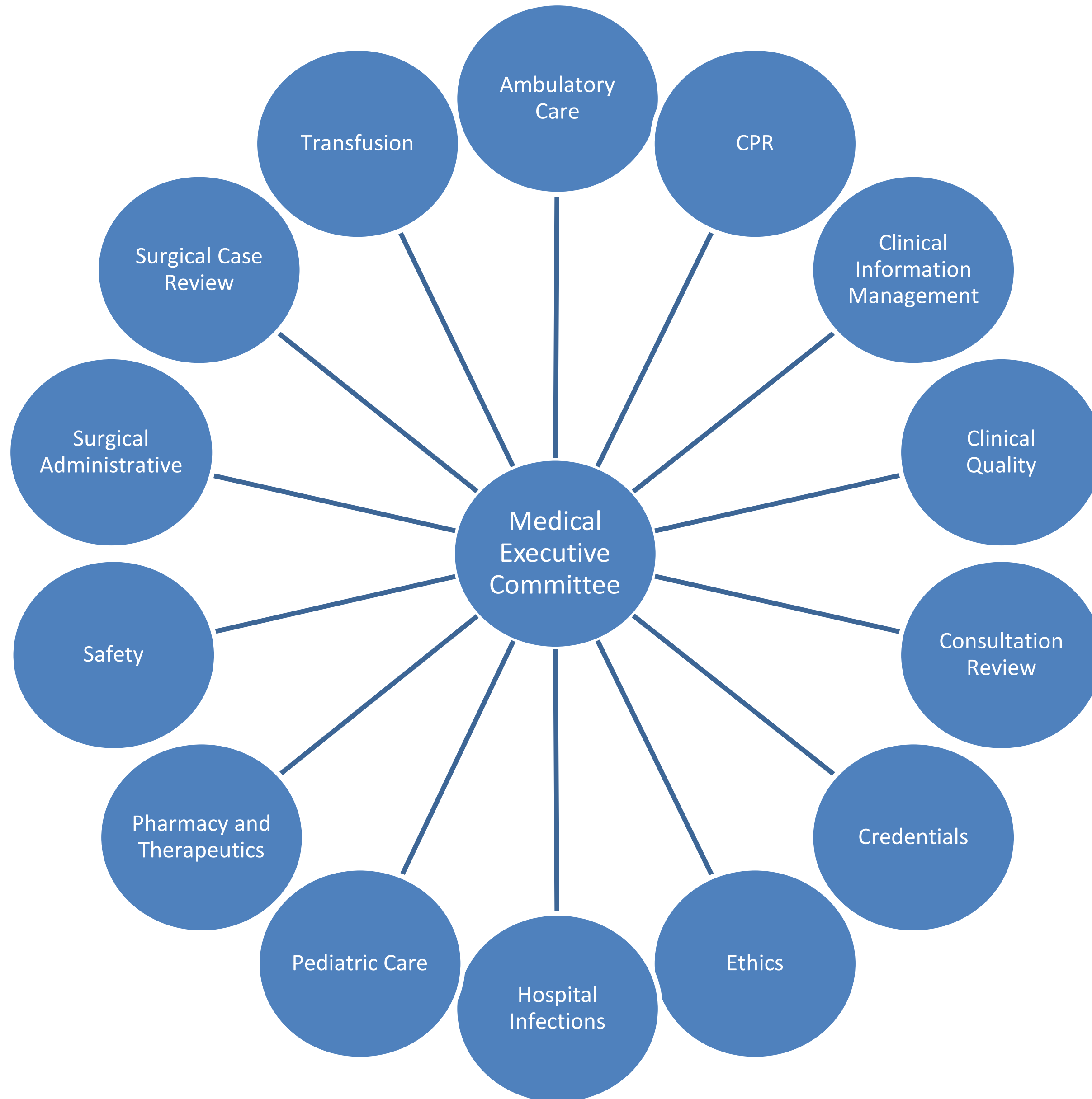
Absent from Photo: **Dr. Natalia I. Chalmers,** Dr. Kevin L. Gardner, **Dr. Clare E. Hastings,** Dr. David K. Henderson, **Dr. Steven M. Holland,** Dr. Henry Masur, **Dr. Steven A. Rosenberg,** Dr. Richard M. Siegel, Dr. Richard G. Wyatt

CURRENT MEC MEMBERSHIP

- Avindra Nath, MD
- William L. Dahut, MD
- Frederick L. Ferris, III, MD
- William A. Gahl, MD, PhD
- Richard Childs, MD
- Josephine Egan, MD
- David Goldman, MD
- H. Clifford Lane, MD
- Richard M. Siegel, MD, PhD
- Forbes D. Porter, MD
- Karran Phillips, MD
- Carter Van Waes, MD, PhD
- Janice Lee, DDS, MD, MS
- James E. Balow, MD
- Stavros Garantziotis MD (Acting CD represented by Janet Hall, MD)
- Maryland Pao, MD
- Kevin Gardner, MD (Acting CD)
- Suzanne J. Wingate, PhD
- David K. Henderson, MD (ex officio)
- W. Marston Linehan, MD (Surg in Chief)
- Deborah P. Merke, MD, MS (Pediatrician)
- Henry Masur, MD* (Intensivist)
- Laura Wake, MD (Clin Fellow)
- Agnes N. Mwakingwe, MD, PhD* (Clin Fellow)
- Gwenyth R. Wallen, PhD, RN
- John I. Gallin, MD (ex officio)
- Carrie Kennedy, JD (ex officio)
- Steven M. Holland, MD/ Andrew Griffith MD (ex officio)
- Richard G. Wyatt, MD (ex officio)
- Laura Lee, RN, MS (Exec Sec)

Meetings are open to the whole community except for occasional executive sessions

STANDING COMMITTEES OF MEC



FUNCTIONS OF MEDICAL EXECUTIVE COMMITTEE

POLICIES AND PROCEDURES

- Develops and enforces medical practice and patient safety policies
- Reviews clinical research policies
- Receives and acts upon various committee reports
- Policies recommended by the MEC are transmitted to CC Director for approval that then become operating policies of the CC

QUALITY OF PATIENT CARE

- Assesses quality of patient care
- Recommends to the Director, CC, programs to establish maintain, improve and enforce standards for health care

CREDENTIALING

Recommends

- Medical Staff appointment
- Clinical privileges
- Corrective action

CLINICAL DIRECTORS: RESPONSIBILITIES WITHIN ICs

- **Conduct scientific review of all clinical protocols, approve all protocol amendments, oversee research coordinators and monitor NIH-sponsored clinical protocols**
- **Evaluate Quality of patient care**
- **Disseminate and implement improvements in quality and safety**
- **Evaluate resource utilization**
- **Corrective actions**
- **Educational activities for clinical privileges**
- **Voting member on MEC**
- **Transmit information and implement policies of MEC at ICs**

CLINICAL DIRECTORS: CHALLENGES

- **Reporting structure and resources available to CD are highly variable: Often report to Basic Scientists**
  - **As per Read Team: CDs should report to Institute Directors**

- **No control over performance, budget or resources for clinical programs in ICs**
  - **As per Red Team: Clinical competency element in PMAP**
  - **Low volume of procedures and patients**

CURRENT CHALLENGES FOR MEC

- No oversight of facilities
- No role in recruitment of clinical faculty
  major vacancies:
  - Chief of Stroke
  - Chief of Neurosurgery
  - Interventional radiologist/ neurosurgeon
- Pediatric Care
- No Neuro-ICU (part time neurointensivist), Pediatric or Neonatal ICU
- Reporting structure and resources available to CD is highly variable

RED PANEL RECOMMENDATION: CLINICAL PRACTICE COMMITTEE

1. Rec: 6-8 members:
   Issue: Very large commitment to conduct all tasks
   Suggestion: Consider several smaller groups/subcommittees

2. Rec: Report to CEO/Board:
   Issue: Close interaction with MEC is critical since CDs implement all policies
   Suggestion: CPC could be a subcommittee of the MEC or have a defined mechanism of interaction

3. Rec: Lists a large number of tasks/functions
   Issue: Many tasks overlap with current functions of MEC
   Suggestion: Restructure the functions of MEC or pare down role of CPC

SUGGESTIONS

- As recommended by Red Team, develop clear lines of authority and communication
- Participation by CDs in decision making for hiring of CEO, CMO and others
- Participation by CDs in organization of CPC organization and develop mechanisms of interactions with MEC
- Budgetary authority to CDs within their IC
- PMAP evaluation of clinical performance by CDs
- Development of Clinical Practice Groups /Departments
  - For establishing practice parameters
  - For teaching
  - Salary structure
  - Department Chair