

Flexibility In duty hour Requirements for Surgical Training Trial

“The FIRST Trial”



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Changes in Duty Hour Requirements

- 2003:
 - 80 hours
 - 1 in 7 days off
 - 1 in 3 call
 - 8-10 hours off between shifts
- 2011 Changes
 - 16 hours for interns
 - Intern supervision
 - 14 hours off after 24h call

Evidence in Surgery

- Unclear
- Patient outcomes: trend to worse
- Resident wellbeing: inconsistent
- Certification exams: trend to worse

Widespread Concern

- New regulations may go too far
- Adverse consequences
 - Continuity of care
 - Patient ownership
 - Shift work mentality
 - Decreasing certification exam scores
 - Decreased preparedness for fellowship/practice
- Need evidence to support changes

Opportunity

- Equipoise
 - Increasing flexibility in duty hour regulations
 - Better outcomes: ↑↑ continuity of care
 - Worse outcomes: tired residents make mistakes
- Discussions between ABS and ACGME
- Willingness to eliminate some duty hour requirements if evidence based

Study Proposal Vetting

- ABS
- ACS
- ACGME
- APDS

Funding



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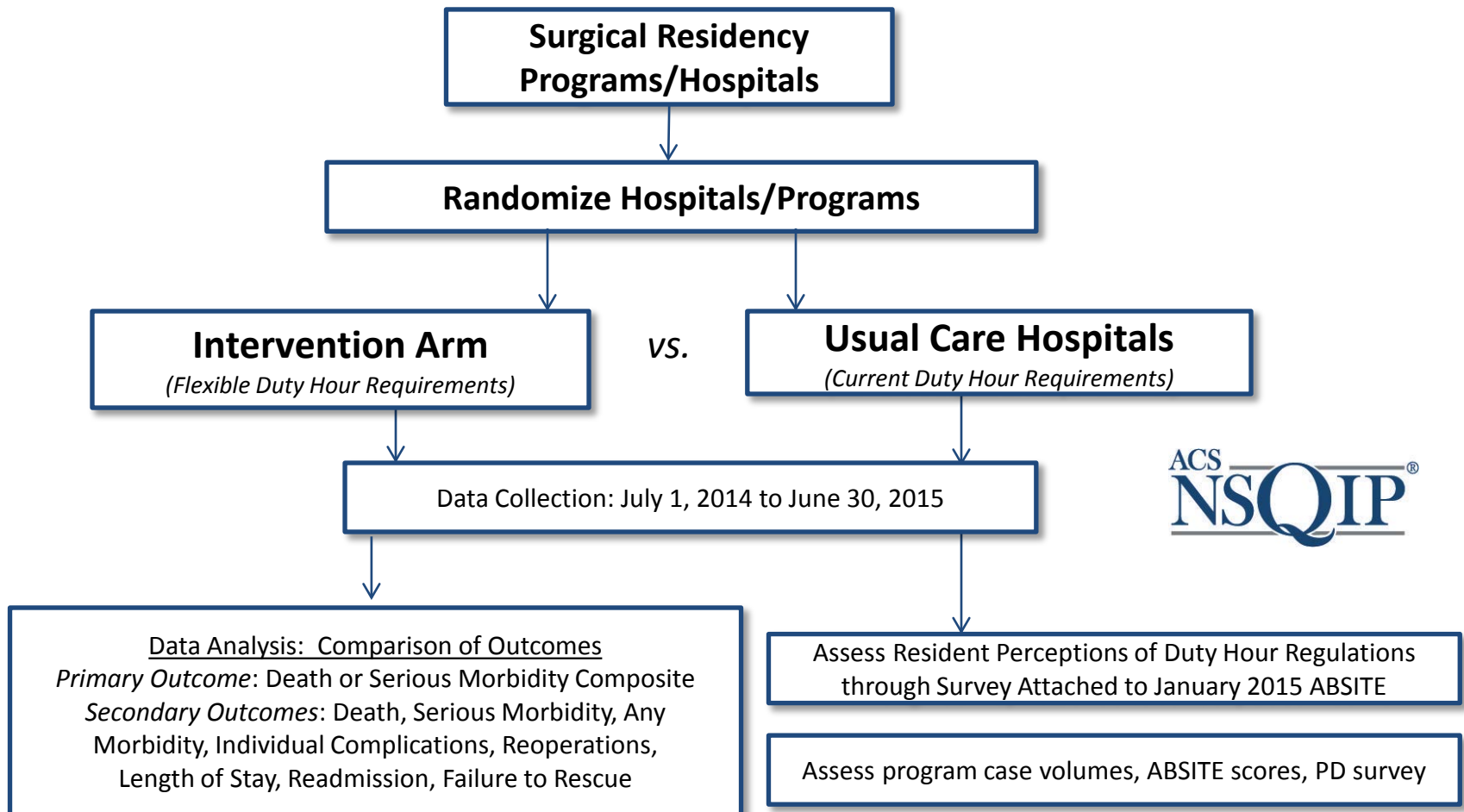
Highest Standards, Better Outcomes



ACGME

**Accreditation Council for
Graduate Medical Education**

Pragmatic Cluster Randomized Trial



Current Resident Duty Hours USUAL CARE/CONTROL ARM	Flexible Resident Duty Hours INTERVENTION ARM
Duty hours limited to 80 hours/week averaged over 4 weeks	Same
Minimum of one free day (no duty)/week averaged over 4 weeks	Same
May not take in-house call more frequently than every 3 rd night, averaged over 4 weeks	Same
PGY-1 resident duty periods must not exceed 16 hours	Eliminated
PGY-2 residents and above may work a maximum of 24 hours duty with an additional 4 hours for transitions in care	Eliminated
Residents must have 14 hours off after 24 hours in-house duty and at least 8-10 hours off after a regular shift	Eliminated
<p>*Chief Residents are to be given flexibility to manage their own hours without duty hour logs to maximize continuity of care for patients and to maximize this invaluable time for developing their decision making, technical skills, autonomy, dedication to patient care, and professionalism as they transition into independent practice.</p>	

ACGME Waiver

- Awaiting formal approval next week
- Waiver of common program requirements for 2 years
- Applies to all services and all residents on services overseen by General Surgery Residency Program
 - Rotators are included
- All hospitals included and can follow same rules

Intervention Arm: Recommend Changes

Eliminated Rule	Recommended Change
PGY-1 resident duty periods must not exceed 16 hours	PGY-1 residents should take call longer than 16 hours in a fashion similar to all other residents in the program.

Intervention Arm: Recommend Changes

Eliminated Rules	Recommended Change
<p>All residents may work a maximum of 24 hours duty with an additional 4 hours for transitions in care</p> <p>Residents must have 14 hours off after 24 hours in-house duty and at least 8-10 hours off after a regular shift</p>	<p>Focus on maximizing continuity of patient care rather than simply exiting at the end of the shift. For example and not limited to:</p> <ol style="list-style-type: none">1. Unstable patients should be attended to by the admitting on-call resident until stabilized2. Patients admitted by the on-call resident needing a surgery should be operated on by that resident.3. Residents that begin an operation should complete the procedure irrespective of whether their “shift” is over and any duty hour requirements4. Residents should complete ongoing urgent patient evaluations5. Residents should ensure proper handoffs and transitions in care

Analyses



- End points
 - Death or serious morbidity
 - Other clinical outcomes
 - Resident perceptions
 - PD perceptions

- Subset Analyses
 - Critically ill patients
 - Inpatients only

IRB Approval

- Waiver obtained from Northwestern University IRB
- Intervention at hospital level
- No patient- or resident-identifiable data being collected
- Analysis of data already being collected for ACS NSQIP

Additional IRB Approvals

- Analyze the ACS NSQIP data
- Analyze the ABSITE survey data
- Analyze the ACGME caselog data

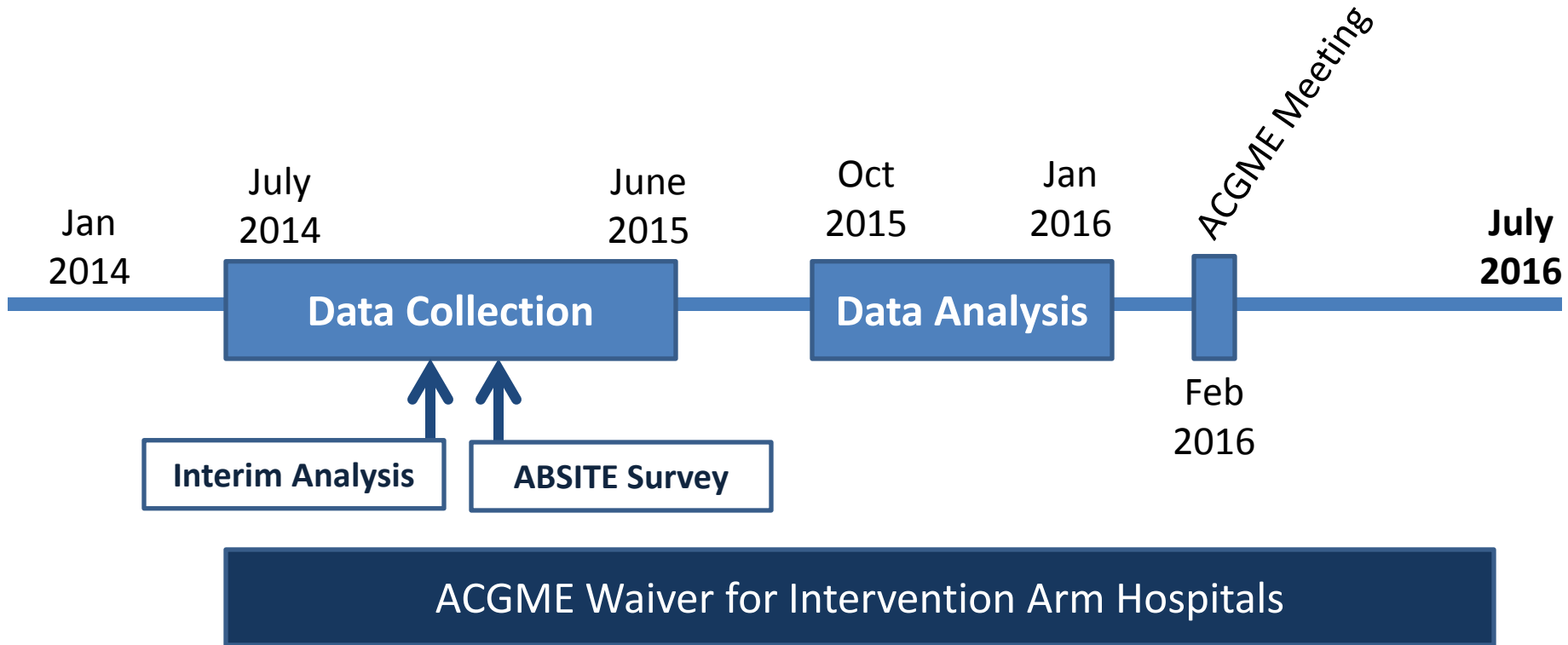
What Are You Agreeing To?

- Randomization to a study arm
- Access to duty logs, call schedules, and rotation schedules
- Access to de-identified ACGME Resident Caselog totals and ABSITE scores
- Access to de-identified hospital ACS NSQIP data
- ABSITE Survey
- Complete data abstraction of all study period cases (general surgery CPTs only) by October 1, 2015 (allows 8 weeks beyond the 30 day postoperative period to close out the final cases of the study period).

Expected Results

- No difference in outcomes
- Return to more flexible resident duty hours
- Culture change: Emphasize continuity of care, not clocking in/out

Timeline



iCOMPARE Study

- Internal medicine study
- 60 programs
- Only addresses intern 16-hour rule
- Allows interns to work 28 hours with 4 hour nap
- Uses Medicare data for outcome measurement
- Focus on sleep measurements/analyses
- Expected to run July 2015 to June 2017

FAQs

- Residency program with multiple hospitals
 - If Residency Program approves, any hospital can enroll if in ACS NSQIP
 - All hospitals randomized to same study arm
 - Waiver applies to Residency Program so non-enrolled hospitals subject to same rules
- Rotators from other services and hospitals
 - Same rules apply

FAQs

- DIO approval needed
- Only ACS NSQIP
- VA and children's hospitals excluded
- New York eligibility?

Advisory Committee

- Karl Bilimoria MD MS (ACS, Northwestern)
- Frank Lewis, MD (American Board of Surgery)
- David Hoyt, MD (American College of Surgeons)
- Christine Kinnier, MD (MGH, resident)
- Clifford Ko, MD MS MSHS (American College of Surgeons, UCLA)
- David Mahvi, MD (American Board of Surgery, Northwestern)
- John Mellinger, MD (APDS, SIU)
- Ajit Sachdeva, MD (American College of Surgeons)
- Bill Scanlon (patient/public representative)
- John Tarpley, MD (APDS, Vanderbilt)

Why Should You Join?

- Minimal work for you
- Huge opportunity to influence resident duty hour requirements
- Need everyone to participate if we are to generate high-level, compelling evidence

Enroll ASAP!

- Enrollment forms sent to Chairs, PDs, and NSQIP Surgeon Champions
 - Request application by emailing rlove@nmff.org
- Additional form will be sent in mid February
- DEADLINE: **February 28, 2014**
- Notification of study arm assignment by end of March

Questions

- Karl Bilimoria kbilimoria@facs.org
- Frank Lewis flewis@absurgery.org
- Any of the other study team members

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