National Cluster-Randomized Trial of Duty-Hour Flexibility in Surgical Training

Reference:
Bilimoria KY1,2, Chung JW1, Hedges LV3, Dahlke AR1, Love R1, Cohen ME2, Hoyt DB2, Yang AD1, Tarpley JL5, Mellinger JD4, Mahvi DM1, Kelz RR4, Ko CY2,8, Odell DD1, Stulberg JJ1, Lewis FR7. National Cluster-Randomized Trial of Duty-Hour Flexibility in Surgical Training. The New England Journal of Medicine. 2016 Feb;[ePub ahead of print]

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Tags
Clinical domain
General

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(Post)graduate
(Residency training)

Background

Wait for it... wait for it. a New England Journal RCT on a #meded topic. The KeyLIME paper this week is a love child of EBM and education psychology. Also it’s political. Buckle up!

Resident duty hours is a hot topic in North America. The Royal College tackled this issue via a national steering committee report, found here. With an acknowledgement of the dangers of condensing complex topics into headlines, the report states that “traditional duty periods present risks to the physical, mental, and occupational health of residents,” yet, “a tired doctor is not necessarily an unsafe doctor,” and “there is no conclusive data to show that restrictions on consecutive resident duty hours are necessary for patient safety.” Yep, pretty bold and contentious statements.
The perception is that a restriction in duty hours leads to less clinical exposure to patients, which impedes the development of experience. We tackled this perception among general surgery program directors on KeyLIME Episode 55.

Subsequently, Episode 62 suggested that duty hour restrictions had NO impact on written exam scores among US internal medicine trainees.

Despite the FIRST trial label, this is NOT the first trial to look at the effects of the ACGME duty hour reform. A 2007 study of registry data of 1.2M internal medicine pts found a 0.25% reduction in absolute mortality rates, yet in 240k surgical patients there was no significant difference in mortality.

So, how do we parse the data? How about a multicenter, prospective, randomized trial?

**Purpose**

“We conducted the Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) Trial30-32 to test whether surgical-patient outcomes under flexible, less-restrictive duty-hour policies would be no worse than outcomes under standard ACGME policies. Resident satisfaction and perceptions of patient care, resident education, and resident wellbeing were also assessed.”

**Type of paper**

Research: RCT

**Key Points on the Methods**

- Prospective, cluster-randomized, pragmatic, non-inferiority trial
  - 1.25% non-inferiority margin **
- n=117 (of 136 eligible) general surgery residency programs 2014-15
- Both control and experimental arm
  - Max 80 hrs/wk
  - 1 in 7 off
  - 1 in 3 call
- Control
  - PGY1 max 16 hr shift
  - PGY2+ max 28 hr shift
  - 14hrs off post 24hrs call
  - 8-10hrs off post shift
- Experimental
  - None of the above CGME restrictions required
- Patient outcomes via Am Coll Surg Nat Surg Qual Imp Program database
- Resident outcomes MCQ survey added to 2015 boards
Key Outcomes

Analyzing ~139k pts, no difference in 30 day rate of death or serious complication (CVA, MI, need for CPR, PE, PPV, ARF, blood tx, sepsis, surgical-site infection, wound dehiscence)
- 9.0% standard policy v 9.1% flexible; p = 0.92

Analyzing ~4300 residents with response rate of 84-87%:

No difference between groups regarding:
- overall education quality
  - 10.7% standard policy v. 11.0% flexible; p = 0.86
- well being
  - 12.0% v. 14.9%; p = 0.10

Residents in flexible policy are less likely to perceive negative impact on patient safety, continuity of care, professionalism BUT more likely to perceive negative effects on personal activities.

Residents in flexible policy were less likely to report leaving during an operation (7.0% v 13.2%; p = <0.001)

Key Conclusions

The authors conclude...
“As compared with standard duty-hour policies, flexible, less-restrictive duty-hour policies for surgical residents were associated with noninferior patient outcomes and no significant difference in residents’ satisfaction with overall well-being and education quality”

Spare Keys – other take home points for clinician educators

This manuscript is an important reminder to Clinician Educators that the education design we wrestle with has important system and patient implications. While we may tend to live and think within the #meded literature, our work often has much broader implications.

And a quick side note… Northwestern University REB deemed the trial to be non-human-subjects research 😊

Shout out

Big shout out to the authors for including all of their data. I think. With 30 supplementary tables, they provide an overwhelming look at the raw data of their
findings. Rather than “piecemeal-ing” their data into multiple manuscripts, they provide a coherent and rich narrative.