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The Unethical iCOMPARE and FIRST Trials

- In 2011, the Accreditation Council for Graduate Medical Education (ACGME) set a 16-hour limit on the number of consecutive hours a first-year medical resident (intern) can work.
- Subsequently, two clinical trials were initiated, in nearly 190 hospitals and residency programs nationwide, that allowed hundreds of interns to work shifts of 28 consecutive hours or more — nearly twice the 16-hour ACGME maximum.
- The Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) trial involved general surgery residency programs and affiliated hospitals, while the National Institutes of Health (NIH) - funded Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) trial involved internal medicine residency programs.
- In both trials, the interns in half of the residency programs were allowed to work shifts of 28 or more hours (experimental arm), while those in the other half of the programs were limited to 16-hour shifts (control arm). In order for the trials to proceed, the ACGME granted the experimental-arm residency programs a waiver from its 2011 consecutive-hour limits on residents' work shifts.
- The trials were highly unethical:
 - Informed consent was not obtained from the residents, with the FIRST trial investigators claiming that the trial did not even involve human subjects research. Residents could not avoid participating in either trial, unless they left their residency programs, an exceedingly rare occurrence and one that would jeopardize their careers.
 - Interns were forced to work shifts of 28 hours or longer despite well-established findings from numerous studies that working such lengthy shifts significantly increases the risks for motor vehicle accidents, depression, and needle-stick injuries and exposure to blood-borne pathogens. The trials lacked rigorous plans for measuring adverse events in residents.

Patients enrolled in both trials were not informed about the trial, meaning all patients in the experimental-arm hospitals were unaware that they were being treated by interns allowed to work shifts of 28 hours or more. This is especially egregious given that a) the ACGME's reasoning for reducing interns' work shift limits to 16 hours in 2011 was, in part, that "interns make more errors when working longer consecutive hours;"¹ and b) the hypothesis being

¹ Accreditation Council for Graduate Medical Education. *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*. 2011. <https://www.acgme.org/acgmeweb/Portals/0/PDFs/jgme-monograph%5B1%5D.pdf>.

tested was whether patients treated by residents working longer hours *were more likely to die* than those cared for by residents working the currently mandated hours.

- Documents obtained from NIH revealed that 56 of 63 internal medicine residencies participating in the iCOMPARE trial did not have adequate review by their institutional review boards. In addition, the trial's protocol did not specify rigorous procedures for monitoring, or mitigating hazards to, residents' or patients' safety in real time. Finally, the trial's data and safety monitoring board, which is responsible for monitoring the safety of subjects while the trial is ongoing, didn't convene for the first time until more than three months after the trial began.
- The trials have not, and will not, yield any useful information, as the trials were designed in such a way as to virtually guarantee that no significant difference in patient outcomes would be seen between the experimental and control groups:
 - Experimental-arm programs were not required to implement all of the permitted changes from the 2011 rules, thereby minimizing differences between the two study groups.
 - Interns are just one of many members of the care team, yet were the only members in whom there was any substantial difference in work schedules between the two groups. This therefore resulted in the two groups being very similar and therefore unlikely to yield different patient outcomes. This is especially true of the FIRST trial, as surgery interns are almost never the primary surgeons in the operating room and never operate unsupervised.
 - No intern-specific health care outcomes — most importantly, medical errors by interns — were measured in either trial.
- Public Citizen and American Medical Student Association (AMSA) actions:²
 - Public Citizen and AMSA have repeatedly demanded that the Department of Health and Human Services' Office for Human Research Protections (OHRP) open an investigation into both trials' lack of compliance with the most basic federal requirements for the protection of human subjects and immediately stop the ongoing iCOMPARE trial.
 - The FIRST trial's initial experimental phase was completed in June 2015 and results were published in February 2016.³ However, the surgical residency programs in the experimental arm retain their ACGME waivers until at least June 2016 and are therefore still permitted to work their interns for shifts of 28 hours or longer.
 - The iCOMPARE trial is still ongoing. OHRP has not only refused to stop the trial, it has not even initiated a formal investigation into the NIH-funded trial's conduct.

² Public Citizen and AMSA. iCOMPARE and FIRST Trials. <http://www.citizen.org/icompare>.

³ Bilimoria KY, Chung JW, Hedges LV, et al. National Cluster-Randomized Trial of Duty-Hour Flexibility in Surgical Training. *N Engl J Med*. 2016;374(8):713-727.