

September 13, 2016

www.citizen.org

Bipartisan Consensus: The Public Wants Well-Rested Medical Residents to Help Ensure Safe Patient Care

National Public Opinion Poll Shows Overwhelming Majority of Americans Oppose Any Loosening of Medical Resident Duty-Hour Restrictions

Acknowledgments

This report was written by Sammy Almashtat, MD, MPH, Michael Carome, MD, and Sidney Wolfe, MD, of Public Citizen's Health Research Group; Christopher P. Landrigan, MD, MPH, Director of the Sleep and Patient Safety Program at Brigham and Women's Hospital, Research Director of the Inpatient Pediatrics Service at Boston Children's Hospital, and Associate Professor of Pediatrics and Medicine at Harvard Medical School; and Charles Czeisler, PhD, MD, FRCP, Chief of the Division of Sleep and Circadian Disorders at Brigham & Women's Hospital and Baldino Professor of Sleep Medicine and Director of the Division of Sleep Medicine at Harvard Medical School. The report is based, in part, on a poll conducted by Lake Research Partners (LRP), with data analysis performed by LRP's David Mermin, Zoe Grotophorst, and Pooja Patel.

About Public Citizen

Public Citizen is a national nonprofit organization with more than 400,000 members and supporters. We represent consumer interests through lobbying, litigation, administrative advocacy, research, and public education on a broad range of issues including consumer rights in the marketplace, product safety, financial regulation, worker safety, safe and affordable health care, campaign finance reform and government ethics, fair trade, climate change, and corporate and government accountability.

About Lake Research Partners

Lake Research Partners is a nationally recognized qualitative and quantitative research firm with over 24 years of experience in all phases of consumer and public opinion research. It has designed and conducted more than 3,000 opinion surveys for its network of partners, including nonprofit groups, government agencies, elected officials, associations, ballot measures, and political campaigns in every state and region of the country. LRP has especially deep expertise in public health research, working on topics as diverse as hospitals and medical residents, childhood obesity, mental health, chronic diseases, substance abuse, long-term care, and women's health.



Executive Summary

Background

In 2009, the Institute of Medicine (IOM) issued a comprehensive report documenting the risks to both medical residents (also known as resident physicians or simply residents) and patients when residents work shifts longer than 16 hours and recommended that, among other things, no resident be permitted to work for more than 16 hours straight without sleep.

A national opinion poll conducted in 2009-2010 assessed the public's attitudes toward the IOM's recommendations. The overwhelming majority (90%) of the public favored restricting all medical resident work shifts to no more than 16 straight hours without sleep.

In response to the IOM's report and concomitant public pressure to revise its duty-hour rules, the Accreditation Council for Graduate Medical Education (ACGME) in 2011 restricted first-year residents (interns) to shifts of no more than 16 hours — but allowed all other residents to work shifts of up to 28 straight hours without sleep. The 16-hour work-shift cap for interns was put in place because the ACGME concluded, after an exhaustive evidence review, that interns “make more errors when working longer consecutive hours.”

In recent years, two recent cluster-randomized clinical trials — known as FIRST and iCOMPARE — are purporting to investigate the effect of medical residents' shift length on patient safety and resident education. The trials randomly assigned resident physicians' hospitals to either a control arm that was supposed to adhere to the ACGME's current duty-hour rules, where interns were limited to shifts of no more than 16 hours, or an experimental arm that removed all limits on shift length. These trials are being conducted without the voluntary informed consent of the residents or their patients.

In September 2015, as part of the ACGME's commitment to review its resident duty-hour restrictions every five years, the ACGME Board of Directors established a task force to develop recommendations for revising these restrictions. Dozens of physician organizations have advocated lifting the 16-hour cap in order to allow interns to work for 28 or more hours in a row without sleep. The ACGME is expected to publicly release a draft proposal for revision of its resident duty-hour limits and solicit comments from stakeholders in the coming months.

New Public Opinion Poll

In July 2016, in response to the potential loosening of the ACGME's resident duty-hour restrictions, Public Citizen commissioned Lake Research Partners (LRP), an independent public opinion research firm, to conduct a new national opinion poll to assess the public's current attitudes toward the existing restrictions and proposals to modify them.

On July 20-24, 2016, a randomly identified representative sample of 500 likely voters nationwide participated in a 10-minute telephone survey that was conducted by professional interviewers from LRP. The margin of error for the poll is +/- 4.4%.

Key findings from the poll include the following:

- A total of 86% of respondents opposed a proposal to eliminate the ACGME's current 16-hour shift limit for first-year residents. This opposition holds across party lines — with 84% of Democrats, 83% of independents, and 88% of Republicans in opposition. Providing respondents with additional information on the reasons to support or oppose the proposal did not affect the level of opposition.

- Most respondents (80%) also supported decreasing the shift limit from 28 hours to a maximum of 16 hours for residents in their second year and above, with Democrats (84%) and Republicans (84%) supporting the measure slightly more than independents (72%).
- Most respondents (77%) said that hospital patients should be informed if a medical resident treating them has been working more than 16 hours without sleep.
- Regarding the iCOMPARE and FIRST trials, 84% of respondents wanted to be informed if they were admitted to an experimental hospital where first-year residents were allowed to work 28 or more consecutive hours without sleep, with 78% “strongly” feeling this way.

Evidence on the Dangers of Long Shifts to Residents and Their Patients

The public’s marked apprehension about resident shifts beyond 16 consecutive hours comports with the evidence on the risks of long resident work shifts without sleep to the safety of both residents themselves and their patients. A substantial body of literature shows that sleep deprivation due to excessively long work shifts increases residents’ risk of motor vehicle accidents, depression, and needle-stick and other injuries that can expose residents to bloodborne pathogens. Depriving medical residents of sleep for more than 16 hours also impairs performance and exposes their patients to an increased risk of medical errors, which can lead to patient injury and death.

One of the primary arguments against reducing the length of residents’ work shifts is that this would increase the number of handoffs necessary to transition patient care from one resident to another and thus interfere with the continuity of care. However, handoffs must occur no matter the length of a resident’s shift, and it is not primarily the number but the quality of handoffs that is crucial in ensuring the safe transfer of patients between physicians. Numerous studies published in recent years point to the potential for implementing standardized handoff systems to minimize errors during the handoff process. Furthermore, all else being equal, a resident handing off a patient after a 16-hour shift will undoubtedly be more alert than will a sleep-deprived resident at the end of a 28-hour or longer shift.

Conclusion

This new poll makes clear that the American public’s opinion on resident duty hours has not changed since a similar poll was conducted in 2009-2010. The public is overwhelmingly opposed to lifting the 16-hour maximum shift length for interns, and favors, by similar margins, the implementation of a new similar cap for all other medical residents. The public strongly feels that patients should be informed if the doctor treating them has worked for more than 16 hours in a row. Similarly, members of the public would want to be informed were they admitted to an experimental-arm hospital in the FIRST or iCOMPARE clinical trials where interns are allowed to work shifts of 28 hours or longer. The results were bipartisan across the board, with Democrats and Republicans expressing nearly identical preferences in response to all questions. Thus, this is not a partisan political issue, but one of public safety.

As detailed in this report, the science is clear: Residents, like any other human beings, are unable to avoid the cognitive and motor limitations that inevitably accompany prolonged sleeplessness, and both residents and their patients are put at risk once residents’ shifts exceed the 16-hour mark. Furthermore, 16-hour or shorter shifts are feasible and have already been implemented, in some cases for all residents, through the night float systems adopted by many residency programs across the country. The ACGME acted counter to public opinion when it allowed second-year-and-above residents to work 28 hours consecutively without sleep in its 2011 rules, and it risks continuing to do so should it disregard the latest poll’s results.

I. New National Public Opinion Poll on Medical Resident Duty Hours

Background

In 2003, the Accreditation Council for Graduate Medical Education (ACGME) set a series of limits on the duration and frequency of duty hours for medical residents (also known as resident physicians or simply residents). These limits included a maximum shift duration of 30 consecutive hours for all residents. However, in 2009, the Institute of Medicine (IOM) issued a comprehensive report documenting the risks to both residents and patients of such long shifts and recommended that, among other things, no resident be permitted to work for more than 16 consecutive hours without sleep.¹

That same year, Public Citizen, the Committee on Interns and Residents of the Service Employees International Union, and the American Medical Students Association commissioned Lake Research Partners to conduct a national opinion poll assessing the public's attitudes towards the Institute of Medicine's recommendations.² The overwhelming majority (90%) of the public favored restricting all medical resident work shifts to no more than 16 straight hours without sleep.

In response to the IOM's report, concomitant public pressure to revise its duty-hour rules, and its own internal reviews, the ACGME in 2011 restricted first-year residents (also known as interns) to shifts of no more than 16 hours — but allowed all other residents to work shifts of up to 28 straight hours without sleep.³ The 16-hour work-shift cap for interns was put in place because the ACGME concluded, after an exhaustive evidence review, that interns “make more errors when working longer consecutive hours.”⁴ Notably, most residency program directors opposed the ACGME's 16-hour shift cap for interns, both before⁵ and soon after⁶ implementation.

In recent years, two recent cluster-randomized clinical trials purported to investigate the effect of medical residents' shift length on patient safety and resident education. The trials randomly assigned resident physicians' hospitals to either a control arm that was supposed to adhere to the ACGME's current duty-hour rules, where interns were limited to shifts of no more than 16 hours, or an experimental arm that removed all limits on shift length. The Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) trial, which began in July 2014 with partial funding from the ACGME, involved general surgery residents at approximately 160 hospitals and hospital systems,⁷ while the National Institutes of Health (NIH)-funded Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) trial, which began in July 2015, involved residents at 63 internal

¹ IOM (Institute of Medicine). *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. Washington, DC: The National Academies Press; 2009. <http://www.nap.edu/catalog/12508/resident-duty-hours-enhancing-sleep-supervision-and-safety>. Accessed September 1, 2016.

² Blum AB, Raiszadeh F, Shea S, et al. US public opinion regarding proposed limits on resident physician work hours. *BMC Med*. 2010 Jun 1;8:33.

³ 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/acgme/web/Portals/0/PDFs/jgme-monograph%5B1%5D.pdf>. Accessed September 1, 2016.

⁴ *Ibid.*

⁵ Antiel RM, Thompson SM, Reed DA, et al. ACGME duty-hour recommendations — a national survey of residency program directors. *N Engl J Med*. 2010;363(8):e12.

⁶ Drolet BC, Khokhar MT, Fischer SA. The 2011 duty-hour requirements — a survey of residency program directors. *N Engl J Med*. 2013;368(8):694-697.

⁷ Flexibility in Duty Hour Requirements for Surgical Trainees Trial — “the FIRST trial.” Study Overview. <http://www.thefirsttrial.org/Overview/Overview>. Accessed September 1, 2016.

medicine residency programs across the U.S. and their affiliated hospitals.⁸ The ACGME granted waivers of many of its duty-hour limits, including all limits on shift duration, to the hospitals and residency training programs randomized to the experimental arm in the two trials. Neither trial could have proceeded without the ACGME's waivers. The researchers are assessing whether patients treated by residents at the experimental hospitals are more likely to die or have serious complications than patients treated at control hospitals. These trials are being conducted without the voluntary informed consent of the residents or their patients.

Of note, before the FIRST trial began, the investigators signaled that one of their primary goals for conducting the study was to have the ACGME rescind its 2011 resident duty-hour requirements that placed more restrictive limits on maximum work-shift duration for all residents, but particularly those affecting interns.⁹

In September 2015, as part of the ACGME's commitment to review its resident duty-hour restrictions every five years, the ACGME Board of Directors established a task force to develop recommendations for revising these restrictions.¹⁰ In late December, the ACGME formally requested statements from its member organizations, constituent organizations, and other stakeholders regarding current ACGME resident work-hour requirements.¹¹ Dozens of physician organizations submitted statements,¹² and gave oral testimony at the ACGME's March 2016 National Congress on Resident Duty Hours in the Learning and Working Environment in Chicago,¹³ advocating lifting the 16-hour cap in order to allow interns to work for 28 or more hours in a row without sleep. Some physician groups also urged the ACGME to allow shifts of longer than even the current 28-hour maximum for second-year-and-above residents and to allow training programs some "flexibility" in determining appropriate shift length.¹⁴ The ACGME is

⁸ iCOMPARE trial information: Executive summary. September 2014.

[http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Design%20Summary%20\(20140908\).pdf](http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Design%20Summary%20(20140908).pdf). Accessed September 1, 2016.

⁹ Flexibility in Duty Hour Requirements for Surgical Trainees Trial – "the FIRST trial": Webinar PowerPoint presentation.

<http://www.thefirsttrial.org/Documents/Flexility%20In%20duty%20hour%20Requirements%20for%20Surgical%20Trainees%20Trial-the%20FIRST%20trial%20webinar.pptx>. Accessed September 1, 2016.

¹⁰ Accreditation Council for Graduate Medical Education. Letter to Members of the Graduate Medical Education Community. January 6, 2016. http://www.acgme.org/Portals/0/PDFs/NascaLetterCommunity_1_7_16.pdf. Accessed September 1, 2016.

¹¹ *Ibid.*

¹² Accreditation Council for Graduate Medical Education. 2016 Position Statements on Duty Hours and the Learning and Working Environment. <http://www.acgme.org/What-We-Do/Accreditation/Duty-Hours/2016-Position-Statements-on-Duty-Hours-and-the-Learning-and-Working-Environment>. Accessed September 1, 2016.

¹³ Accreditation Council for Graduate Medical Education. Letter to Members of the Graduate Medical Education Community. January 7, 2016. http://www.acgme.org/Portals/0/PDFs/NascaLetterCommunity_1_7_16.pdf. Accessed September 1, 2016.

¹⁴ Accreditation Council for Graduate Medical Education. 2016 Position Statements on Duty Hours and the Learning and Working Environment. <http://www.acgme.org/What-We-Do/Accreditation/Duty-Hours/2016-Position-Statements-on-Duty-Hours-and-the-Learning-and-Working-Environment>. Accessed September 1, 2016. For example, see statements from the following physician groups in response to the ACGME's call for comments on the duty hour rules and the resident learning and working environment before the March 2016 congress: a) American Association for Thoracic Surgery. February 9, 2016. <http://www.acgme.org/Portals/0/PDFs/Position%20Papers/American%20Association%20for%20Thoracic%20Surgery.pdf>; b) American College of Physicians. February 22, 2016. <http://www.acgme.org/Portals/0/PDFs/Position%20Papers/American%20College%20of%20Physicians.pdf>; c) American College of Surgeons. January 22, 2016. <http://www.acgme.org/Portals/0/PDFs/Position%20Papers/American%20College%20of%20Surgeons.pdf>; and d) American College of Cardiology. February 17, 2016.

expected to publicly release a draft proposal for revision of its resident duty-hour limits and solicit comments from stakeholders in the coming months.

In July 2016, in response to the potential loosening of the ACGME's resident duty-hour restrictions, Public Citizen once again commissioned Lake Research Partners (LRP), an independent public opinion research firm, to conduct a national opinion poll to assess the public's current attitudes toward the existing restrictions and proposals to modify them.

Methodology

On July 20-24, 2016, a randomly identified representative sample of 500 likely voters nationwide participated in a 10-minute telephone survey that was conducted by professional interviewers from LRP.

Participation was strictly voluntary, and no personal identifiers were recorded. No financial incentives were provided for participation. The sample was stratified geographically to reflect the expected voter turnout of the 2016 general election. The survey was designed jointly by Public Citizen and Lake Research Partners.

Respondents were asked questions about the following topics:

- (a) the duration of resident work shifts;
- (b) a proposal to increase the ACGME's 16-hour limit on work shifts for interns to 28 hours;
- (c) a counter-proposal to lower the ACGME shift limit for all other residents from the current 28 hours to 16 hours;
- (d) whether hospital patients should be informed if a medical resident who is treating them has been working for more than 16 hours without sleep;
- (e) whether the respondents would feel anxious about the safety of their medical care or want to be treated by a different doctor if a doctor treating them had been working for more than 16 consecutive hours; and
- (f) whether the respondents would want to be informed if they were admitted to a hospital participating in the experimental arm of either of two ongoing clinical trials that allowed interns to care for patients after working for 28 consecutive hours or longer without sleep.

Information was also obtained on demographics,¹⁵ recent hospital employment by the respondent or a member of the respondent's household, and recent emergency room visits or hospitalization by the respondent or a member of the respondent's household. A copy of the complete survey instrument is provided in **Appendix A**.

The margin of error for the poll is +/- 4.4%.

Results: Key Findings

The demographic characteristics of the 500 poll respondents were similar to those of the U.S. adult population (see **Appendix B**).

<http://www.acgme.org/Portals/0/PDFs/Position%20Papers/American%20College%20of%20Cardiology.pdf>. All links accessed September 1, 2016.

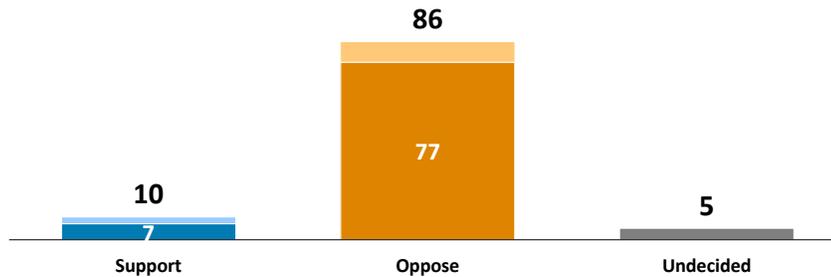
¹⁵ Respondents were queried as to their partisan affiliation. Respondents identifying as "independent" but whose political views leaned towards either Republicans or Democrats were classified, for the purposes of the analyses, as Republicans or Democrats, respectively.

Proposal — Eliminate the ACGME’s 16-Hour Shift Limit for First-Year Residents

- Respondents overwhelmingly opposed a proposal to eliminate the ACGME’s current 16-hour shift limit for first-year residents.

**Proposal – Eliminate the ACGME’s 16-hour Shift Limit for First-Year Residents:
Initial Ballot**

Currently, a private organization called the ACGME — the Accreditation Council for Graduate Medical Education — is responsible for setting limits on the number of hours worked by medical residents. In 2011, the ACGME capped shifts for first-year residents, physicians who just graduated from medical school, at a maximum of 16 hours in a row. Before 2011, first-year residents were allowed to work shifts of 28 hours in a row without sleep. The ACGME now is considering a proposal to eliminate the 16-hour shift limit for first-year residents, allowing them to work shifts of up to 28 hours in a row without sleep. Do you support the proposal to increase the shift limit for first-year residents from 16 to 28 hours in a row without sleep?

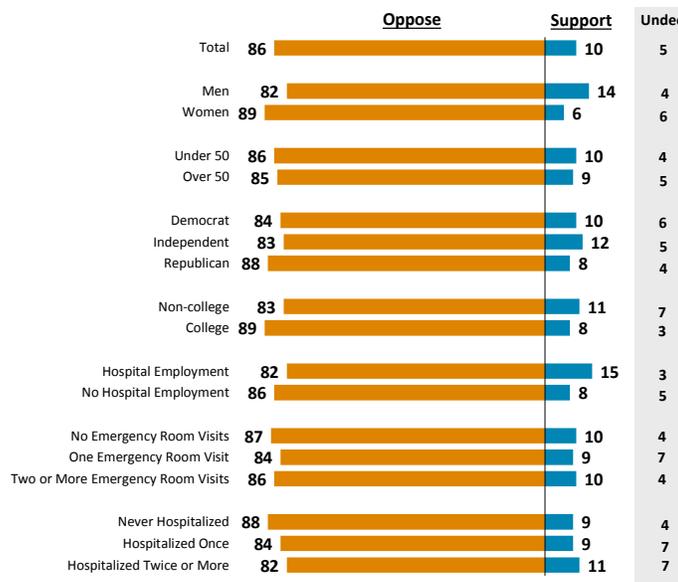


Legend:
 Strongly support: Dark blue (7%)
 Support: Light blue (3%)
 Oppose: Light orange (9%)
 Strongly oppose: Dark orange (77%)
 Undecided: Gray (5%)



- This opposition holds across party lines, with 86% of the overall sample in opposition, 84% of Democrats, 83% of independents, and 88% of Republicans. It also holds across all other analyzed subgroups.

Proposal – Eliminate the ACGME’s 16-hour Shift Limit for First-Year Residents: Initial Ballot

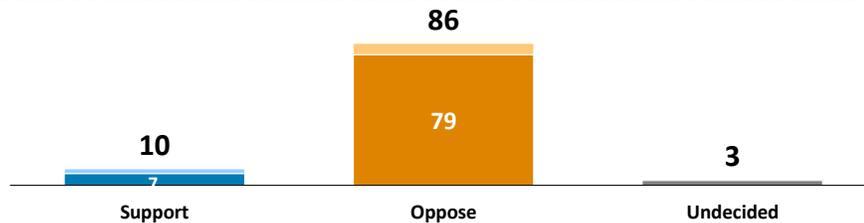


- Providing respondents with additional information on the reasons to support or oppose the proposal did not affect the level of opposition.

Proposal – Eliminate the ACGME’s 16-hour Shift Limit for First-Year Residents:
Informed Ballot

The 16-hour cap was imposed for several reasons, including evidence that residents working shifts of 24 or more hours make more medical errors when treating patients than residents working 16 hours or less. Residents working longer hours are also more likely to accidentally injure themselves when treating patients, have car accidents, and become depressed.

Many in the medical community oppose the 16-hour cap. They point out that shorter shifts lead to more transitions in care between doctors, which also could contribute to medical errors. Opponents of the shorter shifts also argue that they interfere with the training and education of residents.



Legend:
 Strongly support: Dark blue (7%)
 Support: Light blue (3%)
 Oppose: Light orange (7%)
 Strongly oppose: Dark orange (79%)
 Undecided: Gray (3%)

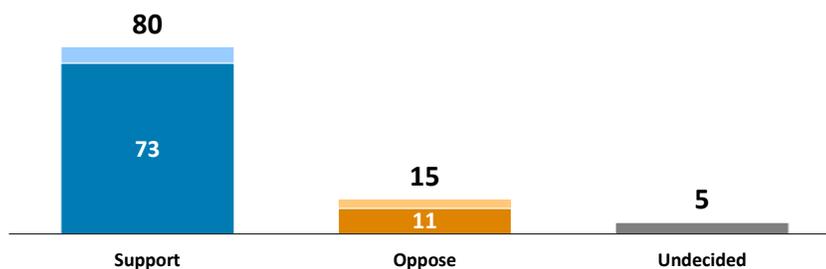


Decrease Shift Limit From 28 to 16 Hours for Second-Year Residents and Above

- Most respondents (80%) also supported decreasing the shift limit from 28 hours to a maximum of 16 hours for residents in their second year and above, with Democrats (84%) and Republicans (84%) supporting the measure slightly more than independents (72%) (see **Appendix C**).

Proposal – Decrease Shift Limit from 28 to 16 Hours for Second-Year Residents and Above

The ACGME currently caps shifts for medical residents in their **second year and above** at a maximum of 28 hours without sleep. Some have proposed reducing this cap from 28 hours to a maximum of 16 hours in a row. Do you support the proposal to decrease the shift limit for 2nd year and above residents from 28 hours to a maximum of 16 hours in a row?



Legend:
 Strongly support: Dark blue (73%)
 Support: Light blue (7%)
 Oppose: Light orange (4%)
 Strongly oppose: Dark orange (11%)
 Undecided: Gray (5%)



Perception About Typical Medical Resident Shift Length and Ideal Maximum Shift Length

- Respondents had different ideas about how long medical residents actually work on a typical shift, but a plurality (31%) believed the typical shift is about 12 hours long. A large majority of respondents (78%) also believed that these shifts should last no more than 12 hours. These preferences held across party lines.

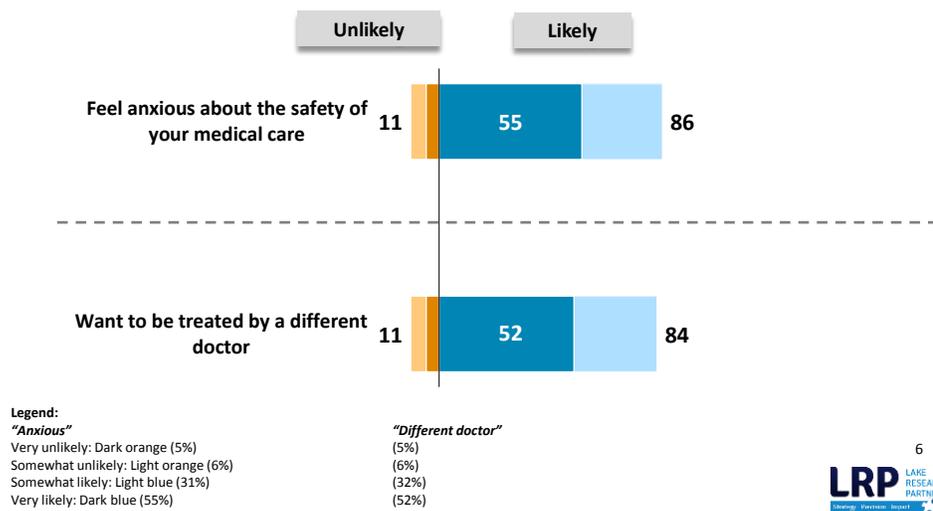
Informing Patients If a Medical Resident Who Is Treating Them Had Been Working for More Than 16 Hours

- Most respondents (77%) said that hospital patients should be informed if a medical resident treating them has been working more than 16 hours without sleep.

Reaction to Knowing That a Doctor Treating Patients Had Been Working for More Than 16 Hours

- When it comes to their personal care, 86% of respondents would feel anxious about the safety of their medical care knowing that the doctor treating them had been working for more than 16 consecutive hours, and 84% would want to be treated by a different doctor.

Reaction to Knowing Doctor Had Been on Duty for More than 16 Hours

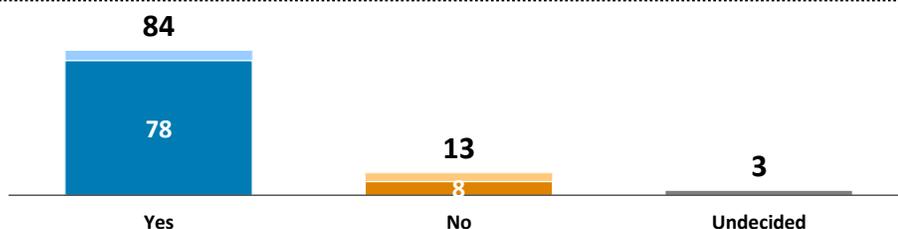


Desire to Be Informed If Admitted to a Hospital Participating in the Experimental Arm of Ongoing Clinical Trials

- Regarding the iCOMPARE and FIRST trials, 84% of respondents would want to be informed if they were admitted to an experimental hospital where first-year residents were allowed to work 28 or more consecutive hours without sleep, with 78% “strongly” feeling this way.

**Desire to Be Informed If Admitted to an Experimental Hospital That Allows
First-Year Residents to Work 28+ Hours**

Researchers are conducting an experiment at more than 100 hospitals in the U.S. The hospitals were randomly divided into two groups: In one group, first-year residents are working shifts lasting no more than 16 hours in a row, as currently required by the ACGME. In the other group, first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep. The researchers want to find out whether patients treated at the hospitals where first-year residents are allowed to work for 28 or more hours in a row are more likely to die or have serious complications compared with patients treated at hospitals where first-year residents work no more than 16 hours in row. **If you were admitted to one of the hospitals participating in this experiment, would you want to be informed if that hospital was assigned to the group where first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep?**



Legend:
 Strong yes: Dark blue (78%)
 Yes: Light blue (6%)
 No: Light orange (5%)
 Strong no: Dark orange (8%)
 Undecided: Gray (3%)



- Eighty-one percent of those who had been employed (or had a household member employed) in hospitals in the past five years stated that they would want to be so informed, as did 83-88% of people who had been hospitalized or visited the emergency room (or had a household member hospitalized or visit the emergency room) at least once within the previous three years.

Other Subgroup Results (Appendix C)

Poll responses were evaluated according to the following demographic characteristics: gender, age, race, political party affiliation, years of schooling, and region of residence. Respondents also were classified based on the following levels of experience with the health care system, by either the respondent or someone in the respondent's household: hospital employment within the previous five years, or a visit to the emergency room or hospitalization within the previous three years. In every subgroup examined, with two exceptions,¹⁶ a majority of respondents responded in line with the overall results presented above.

Conclusions

This new poll makes clear that the American public's opinion on resident duty hours has not changed since a similar poll was conducted in 2009-2010. The public is overwhelmingly opposed to lifting the 16-hour maximum shift length for interns, and favors, by similar margins, the implementation of a similar cap for all other medical residents. The public strongly feels that patients should be informed if the doctor treating them has worked for more than 16 hours in a row. Similarly, members of the public would want

¹⁶ Both exceptions applied to question #2, which asked: "On average, if you had to guess, how many hours in a row do you think medical residents actually work on a typical shift?" More than 50% of people in every subgroup thought that residents worked 12 hours or less on a typical shift except for: 1) people 50 years of age and older living in the West (49%); and 2) people who had visited the emergency room twice within the previous three years (50%).

to be informed were they admitted to an experimental-arm hospital in the FIRST or iCOMPARE clinical trials where interns are allowed to work shifts of 28 hours or longer.

The results were bipartisan across the board, with Democrats and Republicans expressing nearly identical preferences in response to all questions. Thus, this is not a partisan political issue, but one of public safety. The ACGME acted counter to public opinion when it allowed second-year-and-above residents to work 28 hours consecutively without sleep in its 2011 rules, and it risks continuing to do so should it disregard the latest poll's results. Furthermore, as detailed in the remainder of the report, the public's marked apprehension about resident shifts beyond 16 consecutive hours comports with the evidence on the risks of long resident work shifts without sleep to the safety of both residents themselves and their patients.

II. Discussion of the Adverse Impact of Depriving Medical Residents of Sleep

Risks of Long Shifts to Residents

There is a substantial body of evidence that an increased duration of duty shifts and the resulting sleep deprivation pose significant risks to medical residents' health and well-being. Three serious outcomes have been studied extensively: motor vehicle accidents, percutaneous injuries and exposure to bloodborne pathogens, and depression.

Motor Vehicle Accidents

A 1996 study found that 23% of pediatric residents at Johns Hopkins Hospital reported falling asleep while driving, with 71% of the incidents happening after shifts averaging 33 hours.¹⁷ Forty-four percent of pediatric residents reported falling asleep while stopped at a traffic light, with all such incidents occurring post-call. One resident reported that she "routinely used her emergency brakes when stopped at a light because of her sleepiness post-call."

In a 2005 *New England Journal of Medicine* study, the Harvard Work Hours, Health, and Safety Group collected monthly data from 2,737 interns across the U.S. to investigate the relationship between hours worked and motor vehicle accidents, near misses, and incidents involving involuntary sleeping while driving.¹⁸ Interns' risk of a motor vehicle crash increased more than twofold (odds ratio [OR] 2.3; 95% confidence interval [CI]: 1.6-3.3) and the risk of a near-miss driving event increased nearly sixfold (OR 5.9; 95% CI: 5.4-6.3) after shifts of 24 hours or greater compared with shifts of less than 24 hours. Interns were also significantly more likely to fall asleep while driving during months with one to four (OR 1.82; 95% CI: 1.73-1.93) and five or more (OR 2.39; 95% CI: 2.31-2.46) extended shifts than during months with no extended shifts. Every extended shift scheduled per month increased the monthly rate of any motor vehicle accident by 9.1% (95% CI: 3.4-14.7%) and increased the monthly rate of an accident on the commute from work by 16.2% (95% CI: 7.8-24.7%). The study authors concluded that "scheduling physicians to work such extended shifts, which our group has recently shown to increase the risk of failures of attention and serious medical errors, poses a serious and preventable safety hazard for them and other motorists."

A 2006 study of 19 residents' performance on a driving simulator found that male residents displayed greater impairment, as measured by increased lane deviations and crash frequency, after a 15-hour

¹⁷ Marcus CL, Loughlin GM. Effect of sleep deprivation on driving safety in housestaff. *Sleep*. 1996;19(10):763-766. Survey response rate: 87% of residents.

¹⁸ Barger LK, Cade BE, Ayas NT, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med*. 2005;352(2):125-134. Survey response rate: 80% of interns who volunteered to participate.

overnight call shift and an extra four hours of patient-care duties, compared with driving simulation testing after a night spent at home without call responsibility.¹⁹ The authors concluded that “[c]ollectively, results of this study and others suggest that medical residents are at risk when driving after a night on call.”

Percutaneous Injuries and Exposure to Bloodborne Pathogens

A 2000 retrospective review analyzed 745 accidental exposures (involving both percutaneous injuries and superficial skin or mucous membrane contact from splashes) to bloodborne pathogens reported by residents and medical students while on duty.²⁰ The rate of such incidents was 50% higher during night shifts than during day shifts ($p < 0.04$), and first- and second-year residents reported considerably more such incidents than more-senior residents. The authors concluded, “Presumably, the fatigue of the 24h–36h work schedules with little or no sleep for on-call medical students and residents plus circadian rhythms in human cognitive performance and eye-hand coordination contribute to the observed day-night pattern in accidental exposures to bloodborne pathogens described herein.”

A 2006 prospective cohort study analyzed reported percutaneous injuries in 2,737 interns from July 2002 through June 2003.²¹ Interns most commonly reported lapses in concentration (64% of injuries) and fatigue (31%) as contributing factors for the injuries. Injuries were significantly more likely to occur during extended shifts than non-extended shifts (OR 1.61; 95% CI: 1.46-1.78). Injuries following extended shifts occurred after an average of 29 consecutive hours of work, while those occurring on days not preceded by an overnight shift occurred after an average of six hours of consecutive work. The authors concluded, “The association of these injuries with extended work duration is likely due to the adverse cognitive effects of the sleep deprivation associated with such extended work.”

Depression

The first year of medical residency is known to be a time of high stress, and such residents are at a higher risk for major depression than the general population.²² A 1991 study of 61 pediatric residents (34 first-year residents and 27 second-year residents) found that scores on mood and anxiety questionnaires were significantly worsened following a 24-hour call shift compared with residents completing the questionnaires following 24 hours without a call shift.²³ A 1993 study found that internal medicine residents working 32-hour shifts every fourth night reported significantly higher rates of depression symptoms than those working 16-hour shifts under a night float system, as indicated on a post-shift questionnaire (although scores on anxiety and hostility questionnaires did not differ between the two groups).²⁴

¹⁹ Ware JC, Risser MR, Manser T, Karlson KH. Medical resident driving simulator performance following a night on call. *Behav Sleep Med*. 2006;4(1):1-12.

²⁰ Parks DK, Yetman RJ, McNeese MC, et al. Day-night pattern in accidental exposures to blood-borne pathogens among medical students and residents. *Chronobiol Int*. 2000;17(1):61-70.

²¹ Ayas NT, Barger LK, Cade BE, et al. Extended work duration and the risk of self-reported percutaneous injuries in interns. *JAMA*. 2006;296(9):1055-1062.

²² Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry*. 2010;67(6):557-565.

²³ Berkoff K, Rusin W. Pediatric house staff's psychological response to call duty. *J Dev Behav Pediatr*. 1991;12(1):6-10.

²⁴ Gottlieb DJ, Peterson CA, Parenti CM, Lofgren RP. Effects of a night float system on housestaff neuropsychologic function. *J Gen Intern Med*. 1993;8(3):146-148.

A 2010 prospective cohort study administered depression questionnaires to 740 first-year residents at 13 U.S. hospitals.²⁵ Surveys were administered at one to two months prior to beginning their first year of residency training and at months 3, 6, 9, and 12 of the first year. A total of 58% (740 of 1271) of the interns who could be contacted agreed to participate and, of these, 88% (651 of 740) completed at least one follow-up study survey. Just 4% of interns met the criteria for major depression at the beginning of their internship, but 27% reached this threshold both at month 3 and at the end of the year. The prevalence of moderately severe depression increased from 0.7% at baseline to 7.6% by the end of the year. A greater number of hours worked was significantly associated with an increase in depressive symptoms ($p < 0.001$).

A 2016 online survey of 1,888 medical residents conducted by Medscape found that 69% reported that they were “always, mostly, or sometimes too tired to function well owing to long shifts.”²⁶ Disturbingly, 10% of residents reported feeling depressed always or most of the time (compared with 6.7% of all U.S. adults), 33% reported depression sometimes, and 9% reported having considered suicide (compared with 2.9% of all adults 18 years and older who had completed college).²⁷ These findings prompted family physician Dr. Pamela Wible, author of *Physician Suicide Letters—Answered*, to note: “We must confront the system issues that lead so many doctors in training to suffer and offer nonpunitive on-the-job mental healthcare as the norm in all medical institutions.”²⁸ The response rate was not reported; therefore, it is difficult to determine to what extent these findings are generalizable to the broader resident population.

Risks of Long Shifts to Patients

Medical Errors During Shifts Greater Than 16 Hours

The long shifts that second-year-and-above residents are allowed to work also put their patients in danger. A number of studies have confirmed that tired residents make more medical errors the longer they go without sleep, which can lead to patient injury and death.

The Intern Sleep and Patient Safety Study, published in 2004 by experts in patient safety and sleep medicine at Harvard, remains the most rigorous study of the effects of different resident shift lengths on the rate of medical errors.²⁹ Over the course of the 2002-2003 academic year, the authors randomized interns working in intensive care units to one of two arms: a) maximum workweeks of 60-63 hours, with maximum shift lengths of 16 consecutive hours; or b) average workweeks of 77-81 hours, with shifts of up to 34 consecutive hours. The study included 634 admissions and 2,203 patient-days. Interns working shifts of 24 hours or longer made 36% more serious medical errors, including 21% more serious medication errors and 460% more serious diagnostic errors, than interns working shifts of 16 hours or less.

In 2010, Reed et al. published a systematic review of all studies published up to May 2010 that examined the association between shift length and patient health, among other outcomes.³⁰ The review found that, of the six studies evaluating the relationship between shift length and medical errors, all showed

²⁵ Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry*. 2010;67(6):557-565.

²⁶ Medscape. Residents Lifestyle and Happiness Report 2016. August 17, 2016.

http://www.medscape.com/features/slideshow/residentslifestylereport2016?src=wnl_physrep_160817_mscpedit_md_V2&uac=126316PN&impID=1180021&faf=1#page=12. Accessed September 1, 2016. See slide 12.

²⁷ *Ibid.* See slides 5-6.

²⁸ *Ibid.* See slide 6.

²⁹ Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med*. 2004;351(18): 1838-1848.

³⁰ Reed DA, Fletcher KE, Arora VM. Systematic review: Association of shift length, protected sleep time, and night float with patient care, residents' health, and education. *Ann Intern Med*. 2010;153(12):829-842.

statistically significant decreases in error rates with shorter shifts. The Intern Sleep and Patient Safety Study was the only randomized trial and therefore deemed the highest-quality study. Of the other five studies, one showed a decreased rate of potentially serious medication errors by residents working 16-hour shifts (plus two additional hours after the shift ends to finish work) once per week compared with those working 32-hour shifts every fourth (interns) or eighth (second-year-and-above residents) day.³¹ A national survey study found that interns who worked between one and four extended-duration shifts of 24 hours or longer within a one-month period were 3.5 (95% CI: 3.3-3.7) times more likely to report at least one significant medical error due to fatigue compared to interns who did not work such long shifts, and residents working five or more extended-duration shifts in a month were 7.5 (95% CI: 7.2-7.8) times more likely to report such incidents.³²

Post-2011 Studies and the FIRST Trial's Methodological Flaws

An updated systematic review of the effect of duty-hour restrictions on patient safety, resident well-being, and resident education, published in 2015 by Bolster et al., claimed that the 2011 duty-hour reforms had no significant impact on patient outcomes.³³ The review encompassed 27 studies published since the cutoff date for the 2010 Reed et al. review. Seven new studies on shortened shift duration and patient outcomes were analyzed; three were deemed by the authors of the systematic review to show a positive effect,^{34,35,36} one a negative effect,³⁷ and three no effect.^{38,39,40} The studies were of varying quality and design, and none were prospective, randomized trials. Two studies involved focus groups or surveys that did not directly measure patient outcomes.^{41,42}

The largest study by far included in the Bolster et al. review that attempted to examine the effect of resident shift length on patient outcomes was published in 2013.⁴³ Cohorts of interns in 51 residency training programs were surveyed in 2009 (714 interns), 2010 (772 interns), and 2011 (837 interns). The interns were asked in quarterly surveys, among other questions, whether they were concerned that they

³¹ *Ibid.* Citing: Gottlieb DJ, Parenti CM, Peterson CA, Lofgren RP. Effect of a change in house staff work schedule on resource utilization and patient care. *Arch Intern Med.* 1991;151(10):2065-2070.

³² *Ibid.* Citing: Barger LK, Ayas NT, Cade BE, et al. Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. *PLoS Med.* 2006;3(12):e487.

³³ Bolster L, Rourke L. The effect of restricting residents' duty hours on patient safety, resident well-being, and resident education: An updated systematic review. *J Grad Med Educ.* 2015;7(3):349-363.

³⁴ Emler LL, Al-Khafaji A, Kim YH, et al. Trial of shift scheduling with standardized sign-out to improve continuity of care in intensive care units. *Crit Care Med.* 2012;40(12):3129-3134. Note that this study was of fellows, not residents.

³⁵ Rosenbluth G, Fiore DM, Maselli JH, et al. Association between adaptations to ACGME duty hour requirements, length of stay, and costs. *Sleep.* 2013;36(2):245-248.

³⁶ Stroud L, Oulanova O, Szecket N, Ginsburg S. "The benefits make up for whatever is lost": Altruism and accountability in a new call system. *Acad Med.* 2012;87(10):1421-1427.

³⁷ Sen S, Kranzler HR, Didwania AK, et al. Effects of the 2011 duty hour reforms on interns and their patients: A prospective longitudinal cohort study. *JAMA Intern Med.* 2013;173(8):657-662.

³⁸ Choma NN, Vasilevskis EE, Sponsler KC, et al. Effect of the ACGME 16-hour rule on efficiency and quality of care: duty hours 2.0. *JAMA Intern Med.* 2013;173(9):819-821.

³⁹ Yaghoubian A, Kaji AH, Ishaque B, et al. Acute care surgery performed by sleep deprived residents: Are outcomes affected? *J Surg Res.* 2010;163(2):192-196.

⁴⁰ Yaghoubian A, Kaji AH, Putnam B, de Virgilio C. Trauma surgery performed by "sleep deprived" residents: Are outcomes affected? *J Surg Educ.* 2010;67(6):449-451.

⁴¹ Stroud L, Oulanova O, Szecket N, Ginsburg S. "The benefits make up for whatever is lost": Altruism and accountability in a new call system. *Acad Med.* 2012;87(10):1421-1427.

⁴² Sen S, Kranzler HR, Didwania AK, et al. Effects of the 2011 duty hour reforms on interns and their patients: A prospective longitudinal cohort study. *JAMA Intern Med.* 2013;173(8):657-662. Survey response rate: 58% of interns.

⁴³ *Ibid.*

made any major medical errors in the preceding three months. Significantly more interns in the 2011 cohort — the first group subject to the ACGME's 16-hour shift limit — reported concerns about making major medical errors than interns in the combined 2009-2010 cohort (23.3% vs. 19.9%; $p = 0.007$). However, the study had several weaknesses. First, there was no objective assessment of actual medical errors. Second, self-reports by interns of concern about making medical errors may have been biased by the fact that most residency program directors had opposed the ACGME's 16-hour shift cap for interns, both before⁴⁴ and after⁴⁵ implementation, a view that filtered down to, and was shared by, nearly half of residents in a 2012 national survey.⁴⁶ Finally, the study was restricted to just the first year of the new 2011 duty-hour limits, possibly before many programs had adjusted adequately to the new rules by, among other measures, reducing interns' workload to accommodate the shortened 16-hour shift. The study authors alluded to the lack of such adjustment as a possible reason for the finding of increased concern about medical errors.

The central flaw in the seven studies included in the Bolster et al. 2015 systematic review that examined the effect of resident shift length on patient outcomes is that none used objective patient outcome measures specific to the residents working varying shift lengths, such as medical errors committed by the residents.

A 2014 systematic review of the effect of 16-hour shifts for surgery residents included just one study that assessed the impact of such shifts on objective patient measures.⁴⁷ The 2013 randomized, crossover trial compared the effects of assigning interns on general internal medicine teams at a single university hospital to either 16-hour or 30-hour shifts on length of stay and 30-day readmissions.⁴⁸ Shift length was not associated with a significant effect on either outcome. However, the study was not adequately powered to assess such outcomes, with just 834 hospital admissions.⁴⁹ Nor did it utilize an objective, rigorous procedure for detecting medical errors, as was used in the Intern Sleep and Patient Safety Study, further diminishing its ability to detect any actual change.

A 2014 observational study found that, compared with the two years (2009-2011) prior to implementation of the 2011 ACGME resident duty-hour restrictions, there was no increase in patient mortality or serious morbidity during the two years after the rules took effect (2011-2013) among more than 204,000 surgical

⁴⁴ Antiel RM, Thompson SM, Reed DA, et al. ACGME duty-hour recommendations — a national survey of residency program directors. *N Engl J Med.* 2010;363(8):e12.

⁴⁵ Drolet BC, Khokhar MT, Fischer SA. The 2011 duty-hour requirements — a survey of residency program directors. *N Engl J Med.* 2013;368(8):694-697.

⁴⁶ Drolet BC, Christopher DA, Fischer SA. Residents' response to duty-hour regulations—a follow-up national survey. *N Engl J Med.* 2012;366(24):e35.

⁴⁷ Ahmed N, Devitt KS, Keshet I, et al. A systematic review of the effects of resident duty hour restrictions in surgery: Impact on resident wellness, training, and patient outcomes. *Ann Surg.* 2014;259(6):1041-1053.

⁴⁸ Desai SV, Feldman L, Brown L, et al. Effect of the 2011 vs 2003 duty hour regulation-compliant models on sleep duration, trainee education, and continuity of patient care among internal medicine house staff: a randomized trial. *JAMA Intern Med.* 2013;173(8):649-655.

⁴⁹ By way of reference, the 2004 Intern Sleep and Patient Safety Study (Landrigan et al.), detailed above, did not find a significant difference in patient outcomes (serious adverse events, patient length of stay, or overall mortality) in 634 admissions between intern shifts of 16 hours or less and shifts of up to 34 consecutive hours, despite a significantly increased rate of serious medical errors. This demonstrates that the number of admissions necessary to detect an effect of serious medical errors by residents (which, as demonstrated by Landrigan et al., increase with increased shift length) on patient outcomes is likely far higher than the number included in either the 2004 (Landrigan et al.) or 2013 (Desai et al.) randomized trials. Citation for 2004 study: Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med.* 2004;351(18): 1838-1848.

patients in 54 hospitals.⁵⁰ In addition, the concern raised by some residency directors in 2011⁵¹ that duty-hour limits could lead to less knowledgeable residents was countered by the study's finding that resident examination performance did not decrease following implementation of the duty-hour restrictions.⁵²

Since 2015, two randomized controlled trials have attempted to assess the effect of resident shift lengths on medical errors and patient outcomes. In 2015, Parshuram et al. published a randomized controlled trial that assessed the effects of three different resident work schedules on adverse events, medical errors, and other patient outcomes at two academic medical-surgical intensive-care units in Toronto.⁵³ Blocks of residents were randomly assigned to schedules with 12-hour, 16-hour, or 24-hour maximum shift durations and included 807 patients and 971 admissions, totaling 5,894 patient-days. The study found no significant differences in the rates of adverse events, preventable adverse events, medical errors, mortality, or other patient outcomes among the three work schedules.

However, this study had three critical flaws. First, the authors did not monitor whether residents were compliant with the shift limits to which they had been assigned. Second, the study did not directly monitor individual residents to see whether they made serious medical errors, nor were adverse events attributed to individual residents. Failing to do so would dilute out any differences among the three groups in the rates of adverse events or medical errors directly resulting from the residents' different work schedules. Third, the authors identified only eight preventable adverse events during 971 patient admissions (1.4 per 1,000 patient-days), which is a small fraction of what would be expected, indicating that the study lacked adequate procedures for detecting such events. By way of comparison, the Intern Sleep and Patient Safety Study, which did use rigorous procedures for detecting preventable adverse events, found 39 such events per 1,000 patient-days.⁵⁴

In contrast to the Parshuram et al. trial, the Intern Sleep and Patient Safety Study⁵⁵ monitored residents' compliance with the assigned shift limits through daily sleep logs, validated by third-party observers.⁵⁶ Furthermore, interns were directly observed by a physician "continuously, day and night" in order to detect serious medical errors that they made. This ensured that the study was measuring the direct effects of sleep deprivation in individual interns on patient care.

The FIRST trial, published in 2016, is the latest study to claim that a 16-hour limit on interns' work shifts has no impact on patient outcomes.⁵⁷ The trial found no significant difference in the rate of death or serious complications between patients cared for by residents randomized to the ACGME's 2011 duty-hour restrictions and residents assigned to a "flexible" duty-hour schedule that did away with caps on shift

⁵⁰ Rajaram R, Chung JW, Jones AT, et al. Association of the 2011 ACGME resident duty hour reform with general surgery patient outcomes and with resident examination performance. *JAMA*. 2014; 312(22): 2374-2384.

⁵¹ Antiel RM, Thompson SM, Hafferty FW, et al. Duty hour recommendations and implications for meeting the ACGME core competencies: Views of residency directors. *Mayo Clin Proc*. 2011;86(3):185-191.

⁵² Rajaram R, Chung JW, Jones AT, et al. Association of the 2011 ACGME resident duty hour reform with general surgery patient outcomes and with resident examination performance. *JAMA* 2014; 312: 2374-2384.

⁵³ Parshuram CS, Amaral AC, Ferguson ND, et al. Patient safety, resident well-being and continuity of care with different resident duty schedules in the intensive care unit: A randomized trial. *CMAJ*. 2015;187(5):321-329.

⁵⁴ *Ibid*.

⁵⁵ Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med*. 2004;351(18): 1838-1848.

⁵⁶ Lockley SW, Cronin JW, Evans EE, et al. Effect of reducing interns' weekly work hours on sleep and attentional failures. *N Engl J Med*. 2004;351(18):1829-37.

⁵⁷ 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.

duration. We have previously detailed the serious flaws in the trial's design that undermine its findings and conclusions,⁵⁸ but briefly summarize them here:

- The following factors resulted in a minimization of differences between the control and experimental arms of the FIRST trial, making it unlikely that any significant differences in the measured patient outcomes would be detected:
 - The trial assessed patient outcomes related to the care received by the entire patient care team, even though interns were the only members of the typically sizable team in whom there was any substantial difference in work schedules between the two groups;
 - General surgery interns are almost never the primary surgeons in the operating room, spend the least amount of time in the operating room compared to other residents, and never operate unsupervised; and
 - Experimental-arm programs were not required to implement all of the permitted changes from the 2011 rules.
- No intern-specific patient health care outcomes — most importantly, medical errors made by interns — were measured in the trial.

Thus, there has yet to be a post-2011 study as rigorous as the 2004 Intern Sleep and Patient Safety Study that assessed the effect of the reduced, 16-hour shifts on *resident-specific* patient outcomes. In the absence of such new data, the pre-2011 evidence of the deleterious effects of sleep deprivation resulting from shifts of longer than 16 hours on serious medical errors still stands.

The Handoff, Workload, and Feasibility Questions

Handoffs

One of the primary arguments against reducing the length of residents' work shifts is that this would increase the number of handoffs necessary to transition patient care from one resident to another and thus interfere with the continuity of care. This concern is, of course, valid, but the notion that shorter shifts must come at the expense of patient safety due to the increased number of handoffs represents a zero-sum mentality that fails to account for the fact that it is not primarily the number but the quality of handoffs that is crucial in ensuring the safe transfer of patients between physicians. Handoffs still occur at the end of a long resident shift, but residents handing off patients at the end of a 28-hour or longer shift are exhausted and more prone to omitting or erring on critical information than residents who are more alert after a 16-hour or shorter shift.

A 2009 systematic review of studies on physician handoffs found that “very little research ha[d] been done to identify best practices” and that there existed “a great need for high-quality handoff outcomes studies focused on systems factors, human performance, and the effectiveness of structured protocols and interventions.”⁵⁹ Since then, an updated 2015 systematic review (Mardis et al.) identified a number of higher-quality studies in medical residents that attempted to address these shortcomings and arrive at effective means of handing off patients at shift transitions.⁶⁰

⁵⁸ Public Citizen and the American Medical Student Association. Letter to OHRP Regarding the FIRST Trial Comparing Standard and Long Work Schedules for General Surgery Residents. November 19, 2015. <http://www.citizen.org/documents/2284.pdf>. Accessed September 2, 2016.

⁵⁹ Riesenber LA, Leitzsch J, Massucci JL, et al. Residents' and attending physicians' handoffs: A systematic review of the literature. *Acad Med*. 2009;84(12):1775-1787.

⁶⁰ Mardis M, Davis J, Benningfield B, et al. Shift-to-shift handoff effects on patient safety and outcomes: A systematic review. *Am J Med Qual*. 2015 Oct 30. pii: 1062860615612923. [Epub ahead of print]

One of these was a very large prospective cohort study published in 2014 in *The New England Journal of Medicine*.⁶¹ This study was conducted to assess the effectiveness of a standardized handoff system in pediatric residents across nine different residency programs. The intervention involved a bundle of interventions that included extensive resident training in how to conduct handoffs, changes to the verbal handoff process, changes to the written handoff process, and a faculty development and sustainment campaign, all organized around the handoff procedure using a mnemonic known as I-PASS (illness severity, patient summary, action list, situation awareness and contingency plans, and synthesis by receiver). The primary outcome was the rate of medical errors and preventable adverse events before and after implementation of the new system.

In 10,740 patient admissions, the rate of medical errors decreased by 23% (24.5 vs. 18.8 per 100 admissions; $p < 0.001$), the rate of preventable adverse events decreased by 30% (4.7 vs. 3.3 events per 100 admissions; $p < 0.001$), and the rate of near misses and non-harmful medical errors decreased by 21% (19.7 vs. 15.5 per 100 admissions; $p < 0.001$) from the pre-intervention to the post-intervention period, respectively. There was no significant change in the rate of *non-preventable* adverse events. The inclusion of key information in written and oral handoffs significantly increased after the intervention, even though residents spent the same amount of time preparing for, and conducting, the handoffs as before.

Three handoff studies published since the 2015 Mardis et al. systematic review are summarized below. All were prospective cohort studies that compared outcomes before and after the implementation of a standardized handoff system:

- A 2016 study evaluating outcomes in 5,407 patients on general medicine and general surgery wards demonstrated that training on and use of a web-based standardized handoff procedure, incorporating a checklist for the most important points to be relayed, significantly reduced overall medical errors by 51%, medical errors resulting from a failure in communication by 60%, and medical errors due to mistakes in the handoff by 62% in the year after the procedure was implemented ($p < 0.001$ for all comparisons).⁶²
- A 2016 study in psychiatric residents involved the implementation of a handoff system known by the mnemonic PSYCH (patient information/background, situation leading to the hospital visit, your assessment, critical information, and hindrance to discharge).⁶³ The standardized handoff system significantly reduced the mean number of omissions from handoffs, while increasing residents' rating of the clarity of expectations and confidence in the handoffs.
- A 2016 study in pediatric residents found that implementation of the I-PASS system, including the integration of I-PASS into the electronic medical record system, resulted in significantly fewer omissions of important information, as well as improvements in identification of disease severity and other measures of handoff efficiency.⁶⁴

Thus, the implementation of best practices and standardized, validated handoff protocols has the potential to decrease medical errors resulting from poorly conducted handoffs.

⁶¹ Starmer AJ, Spector ND, Srivastava R, et al. Changes in medical errors after implementation of a handoff program. *N Engl J Med*. 2014;371(19):1803-1812.

⁶² Mueller SK, Yoon C, Schnipper JL. Association of a web-based handoff tool with rates of medical errors. *JAMA Intern Med*. 2016 Aug 1. doi: 10.1001/jamainternmed.2016.4258. [Epub ahead of print]

⁶³ Mariano MT, Brooks V, DiGiacomo M. PSYCH: A mnemonic to help psychiatric residents decrease patient handoff communication errors. *Jt Comm J Qual Patient Saf*. 2016;42(7):316-320.

⁶⁴ Walia J, Qayumi Z, Khawar N, et al. Physician transition of care: Benefits of I-PASS and an electronic handoff system in a community pediatric residency program. *Acad Pediatr*. 2016;16(6):519-523.

Supervision of interns' handoffs by senior residents or attending physicians is another element that might ensure that the necessary information is conveyed. As the ACGME noted in its report related to the 2011 revisions to the duty-hour rules, "transitions of care and handoffs are complex clinical acts, which benefit from supervision and coaching, particularly for junior learners."⁶⁵ Studies, including one randomized trial, have found significant improvements in various aspects of handoff efficiency after the implementation of retrospective feedback from faculty to residents regarding their handoff procedures.^{66,67}

"Intrateam" handoffs offer further potential for reducing critical omissions, as explained in a 2012 letter to the editor in *JAMA Internal Medicine*:⁶⁸

Finally, one must consider that it is not only the number but the quality of handoffs. More importantly, not all handoffs are created equal. Systems can be designed to maximize continuity despite handoffs through the use of intrateam handoffs by having team members work serially so that someone from the team is always present and has both knowledge of and professional responsibility to the patient. This is in contrast to interteam handoffs, when all members on a team work in tandem; when they leave and handoff, no one who has primary knowledge of the patient is left.

Ultimately, handoffs must occur no matter the length of a shift. But, all else being equal, a resident handing off a patient after a 16-hour shift will undoubtedly be more alert than will a sleep-deprived resident at the end of a 28-hour or longer shift. The best way to minimize critical omissions or errors during transitions of care is to ensure that handoffs are (a) conducted by alert, well-trained residents using standardized, validated procedures; (b) supervised by senior residents or attending physicians; and (c) intrateam.

Resident Workloads

The debate over resident duty hours has largely sidestepped the question as to whether hospitals have adjusted interns' workloads sufficiently in order to accommodate the interns' shortened 16-hour duty shifts. Failing to do so not only would require interns to rush through much of their work during the shortened shift, thus attenuating the intended benefits of reduced work hours, but would force senior residents within the care team who are allowed to work shifts of up to 28 hours to complete any unfinished work after the intern leaves; this latter phenomenon was reported as having occurred by 66% of residents in a 2012 national survey.⁶⁹

It would also increase the chance that interns would work beyond the 16-hour maximum in order to complete their work and then falsify their self-reported hours to their residency program. In a national survey published in 2013, nearly half (43%) of 6,202 residents stated that they had falsely reported their duty hours at some point, including 19% who did so at least once or twice a month.⁷⁰ It is perhaps not

⁶⁵ 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>. Accessed September 2, 2016.

⁶⁶ Martin SK, Farnan JM, McConville JF, Arora VM. Piloting a structured practice audit to assess ACGME milestones in written handoff communication in internal medicine. *J Grad Med Educ*. 2015;7(2):238-241.

⁶⁷ Bump GM, Bost JE, Buranosky R, Elnicki M. Faculty member review and feedback using a sign-out checklist: Improving intern written sign-out. *Acad Med*. 2012;87(8):1125-1131.

⁶⁸ Farnan JM, Arora VM. The "new normal". *JAMA Intern Med*. 2013;173(19):1845.

⁶⁹ Drolet BC, Christopher DA, Fischer SA. Residents' response to duty-hour regulations — a follow-up national survey. *N Engl J Med*. 2012;366(24):e35.

⁷⁰ Drolet BC, Schwede M, Bishop KD, Fischer SA. Compliance and falsification of duty hours: Reports from residents and program directors. *J Grad Med Educ*. 2013;5(3):368-373. Survey response rate: 23% of interns.

surprising that more than twice as many residents disapproved (48%) than approved (23%) of the 2011 ACGME rules in a 2012 national survey.⁷¹

Sen et al., in reporting the results of their survey study of three large cohorts of interns in 2009, 2010, and 2011, pointed out that work compression may have been at play in the first year of implementation of the 16-hour shift limit for interns:⁷²

In addition, for many hospitals, the new duty hour restrictions were not accompanied by funding to hire additional clinical staff. As a result, the duty hour restrictions may have exacerbated the problem of work compression, with residents expected to complete the same amount of work as previous cohorts but in less total time. Increased work compression has been associated with poorer clinical performance and decreased satisfaction among residents.

It has now been more than five years since the 16-hour shift limit was first implemented. We are not aware of any comprehensive study assessing to what extent academic hospitals have adjusted to the 2011 duty-hour rules by making appropriate reductions to intern workloads and hiring the additional health care practitioners necessary to compensate for the reduction in intern labor. But it is clear that there is an ample and rapidly growing supply of physician assistants and nurse practitioners who could considerably reduce interns' (and other residents') workloads.⁷³ Academic hospitals genuinely interested in reducing residents' burdens while minimizing medical errors committed by overstretched residents would be wise to invest in these and other health care workers.

Night Float and the Feasibility of a 16-Hour Shift Limit for All Residents

Arguments against a 16-hour shift limit for residents on grounds of feasibility are belied by the reality that numerous residency programs across the country already have implemented night float systems, in which residents work day shifts and go home at night, to be replaced by other residents who work only at night, usually for a few weeks at a time. Under such a system, residents work shifts lasting 16 hours or less (often as short as 12 hours) for much of each training year. According to the American Medical Association, 391 (90.7%) of the 431 ACGME-accredited internal medicine residency programs and 219 (83.9%) of the 261 ACGME-accredited general surgery residency programs have a night float system.⁷⁴ Furthermore, in some programs, such schedules have been instituted for upper-level residents.⁷⁵

Conclusions

A substantial body of literature shows that sleep deprivation due to excessively long work shifts increases residents' risk of motor vehicle accidents, depression, and needle-stick and other injuries that can expose residents to bloodborne pathogens. Depriving medical residents of sleep for more than 16 hours also impairs performance and exposes their patients to an increased risk of medical errors, which can lead to patient injury and death.

⁷¹ Drolet BC, Christopher DA, Fischer SA. Residents' response to duty-hour regulations — a follow-up national survey. *N Engl J Med*. 2012;366(24):e35.

⁷² Sen S, Kranzler HR, Didwania AK, et al. Effects of the 2011 duty hour reforms on interns and their patients: A prospective longitudinal cohort study. *JAMA Intern Med*. 2013;173(8):657-662.

⁷³ Salsberg E. The Nurse Practitioner, Physician Assistant, and Pharmacist Pipelines: Continued Growth. Health Affairs Blog. May 26, 2015. <http://healthaffairs.org/blog/2015/05/26/the-nurse-practitioner-physician-assistant-and-pharmacist-pipelines-continued-growth/>. Accessed September 9, 2016.

⁷⁴ Personal communication with the American Medical Association (AMA) on September 8, 2016. Data are based on the AMA's FREIDA residency database. Of the programs with a night float system, 349 of 391 (89.3%) internal medicine and 195 of 219 (89.0%) general surgery programs reported that first-year residents participate in the night float system.

⁷⁵ *Ibid*.

The arguments against shorter shifts represent a zero-sum mentality that claims that shorter shifts must necessarily result in poorer continuity of care and diminished resident well-being. Although shorter hours increase the frequency of handoffs, numerous studies published in recent years point to the potential for implementing improved, standardized systems to minimize errors during the handoff process. Furthermore, handoffs must occur no matter the length of a resident's shift, and, all else being equal, a resident handing off a patient after a 16-hour shift will undoubtedly be more alert than will a sleep-deprived resident at the end of a 28-hour or longer shift. As for the purported increased workload on some residents resulting from a 16-hour shift limit, hiring more health care practitioners is necessary in order to reduce residents' workloads and ensure that residents do not work beyond the 16-hour limit to finish their work and falsify their reported hours.

Ultimately, the science is clear that residents, like any other human beings, are unable to avoid the cognitive and motor impairment that inevitably accompany prolonged sleeplessness, and both residents and their patients are put at risk once residents' shifts exceed the 16-hour mark. Furthermore, 16-hour or shorter shifts are feasible and have already been implemented, in some cases for all residents, through the night float systems adopted by many residency programs across the country. Were all residency programs to adopt such schedules, for all residents, resident and patient safety would be greatly enhanced, while finally bringing residents' work schedules in line with the long-standing public consensus on this issue.

Appendix A – Complete survey instrument

500 likely voters
Timing: 10 minutes

Hello. My name is _____. May I please speak with (VOTER NAME FROM FILE)?
I'm calling from National Opinion Surveys. We are conducting a public opinion survey and I would like to ask you some questions. We are not selling anything, and I won't ask you for a contribution or donation.

1. Before we begin, I need to know if I have reached you on a cell phone, and if so, are you in a place where you can talk safely? [IF NOT ON A CELL PHONE, ASK:] "Do you own a cell phone?"

- Yes, cell and can talk safely 1
- Yes, cell and cannot talk safely 2 **TERMINATE**
- No, not on cell, but own one..... 3
- No, not on cell, and do not own one..... 4
- (Don't know/Refused)..... 5 **TERMINATE**

Now I'm going to ask you some questions about medical residents who work in hospitals. As you may know, medical residents are licensed doctors who have recently completed medical school and are practicing under the supervision of more experienced doctors.

2. On average, if you had to guess, how many hours in a row do you think medical residents actually work on a typical shift?

3. And what do you think should be the maximum number of hours in a row medical residents should work on any given shift?

4. Currently, a private organization called the A-C-G-M-E — the Accreditation Council for Graduate Medical Education — is responsible for setting limits on the number of hours worked by medical residents. In 2011, the A-C-G-M-E capped shifts for first-year residents, physicians who just graduated from medical school, at a maximum of 16 hours in a row. Before 2011, first-year residents were allowed to work shifts of 28 hours in a row without sleep. The A-C-G-M-E now is considering a proposal to eliminate the 16-hour shift limit for first-year residents, allowing them to work shifts of up to 28 hours in a row without sleep. Do you support the proposal to increase the shift limit for first-year residents from 16 to 28 hours in a row without sleep?

[IF YES/NO ASK: Is that strongly or not so strongly YES/NO?]

- Yes - strongly 1
- Yes - not-so-strongly 2
- Undecided..... 3
- No - not-so-strongly 4
- No - strongly..... 5
- (Don't know)..... 6

5. Now I would like to give you some additional information about this proposal. [ROTATE STATEMENTS]

The 16-hour cap was imposed for several reasons, including evidence that residents working shifts of 24 or more hours make more medical errors when treating patients than residents working 16 hours or less. Residents working longer hours are also more likely to accidentally injure themselves when treating patients, have car accidents, and become depressed.

Many in the medical community oppose the 16-hour cap. They point out that shorter shifts lead to more transitions in care between doctors, which also could contribute to medical errors. Opponents of the shorter shifts also argue that they interfere with the training and education of residents.

Do you support the proposal to increase the shift limit for first-year residents from 16 to 28 hours in a row without sleep?

[IF YES/NO ASK: Is that strongly or not so strongly YES/NO?]

- Yes - strongly 1
- Yes - not-so-strongly 2
- Undecided..... 3
- No - not-so-strongly 4
- No - strongly..... 5
- (Don't know)..... 6

6. The A-C-G-M-E currently caps shifts for medical residents in their **second year and above** at a maximum of 28 hours without sleep. Some have proposed reducing this cap from 28 hours to a maximum of 16 hours in a row. Do you support the proposal to decrease the shift limit for 2nd year and above residents from 28 hours to a maximum of 16 hours in a row?

[IF YES/NO ASK: Is that strongly or not so strongly YES/NO?]

- Yes - strongly 1
- Yes - not-so-strongly 2
- Undecided..... 3
- No - not-so-strongly 4
- No - strongly..... 5
- (Don't know)..... 6

7. Do you think hospital patients should be informed if a medical resident who is treating them has been working for more than 16 hours without sleep, or should patients not be informed?

[IF YES/NO ASK: Is that strongly or not so strongly YES/NO?]

- Yes, informed - strongly 1
- Yes, informed - not-so-strongly 2
- Undecided..... 3
- Not informed - not-so-strongly..... 4
- Not informed - strongly 5
- (Don't know)..... 6

8. If you knew the doctor who was treating you had already been on duty for more than 16 hours without sleeping, would you be very likely, somewhat likely, somewhat unlikely, or very unlikely to:

ROTATE

	Very likely	Smwt likely	Smwt unlikely	Very Unlikely	(Don't know/Refused)
a. Feel anxious about the safety of your medical care	1	2	3	4	5
b. Want to be treated by a different doctor	1	2	3	4	5

9. Researchers are conducting an experiment at more than 100 hospitals in the U.S. The hospitals were randomly divided into two groups: In one group, first-year residents are working shifts lasting no more than 16 hours in a row, as currently required by the A-C-G-M-E. In the other group, first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep. The researchers want to find out whether patients treated at the hospitals where first-year residents are allowed to work for 28 or more hours in a row are more likely to die or have serious complications compared with patients treated at hospitals where first-year residents work no more than 16 hours in row.

If you were admitted to one of the hospitals participating in this experiment, would you want to be informed if that hospital was assigned to the group where first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep?

[IF YES/NO ASK: Is that strongly or not so strongly YES/NO?]

- Yes - strongly 1
- Yes - not-so-strongly 2
- Undecided..... 3
- No - not-so-strongly 4
- No - strongly..... 5
- (Don't know)..... 6

The remaining questions are for statistical purposes only.

10. Generally speaking, do you think of yourself as a Republican, a Democrat, an Independent or something else? [IF REPUBLICAN/DEMOCRAT:] Do you consider yourself a strong or a not-so-strong (Republican/Democrat)? [IF INDEPENDENT:] Would you say you lean more towards the Republicans or more towards the Democrats?

- Strong Democrat..... 1
- Not-so-strong Democrat 2
- Independent - lean Democrat..... 3
- Independent 4
- Independent - lean Republican 5
- Not-so-strong Republican..... 6
- Strong Republican 7
- (Other) 8
- (Don't know)..... 9
- (Refused) 10

11. How old are you? **[IF REFUSED, ASK:]** Well, would you tell me which age group you belong to? **(READ LIST.)**

18-24.....	1
25-29.....	2
30-34.....	3
35-39.....	4
40-44.....	5
45-49.....	6
50-54.....	7
55-59.....	8
60-64.....	9
65-69.....	10
70-74.....	11
75 and older.....	12

12. What is the last year of schooling that you have completed?

1 - 11th Grade.....	1
High School Graduate.....	2
Non-College Post H.S.	3
Some College.....	4
College Graduate.....	5
Post-Graduate School.....	6
(Refused).....	7

13. Have you or anyone in your household worked in a hospital within the past five years? **[IF YES]** Is that you or someone in your household?

Yes, self.....	1
Yes, household member.....	2
Yes, self AND household member.....	3
No.....	4
(don't know).....	5

14. Just to make sure we have a representative sample, could you please tell me whether you are from a Hispanic, Latino, or Spanish-speaking background? **[IF "NO", ASK:]** What is your race - white, black, Asian, or something else?

Select one

White.....	1
Black/African American.....	2
Hispanic/Latino.....	3
Asian/Pacific Islander.....	4
Native American/American Indian.....	5
(Other).....	6
(Don't know / Refused).....	7

14. How many times in the last 3 years have you or anyone in your household:

- a. Gone to the emergency room for care?
- b. Been hospitalized for at least one night?

15. What is your zip code?

Thank you and have a nice day/evening.

Appendix B – Characteristics of the survey respondents (n = 500)

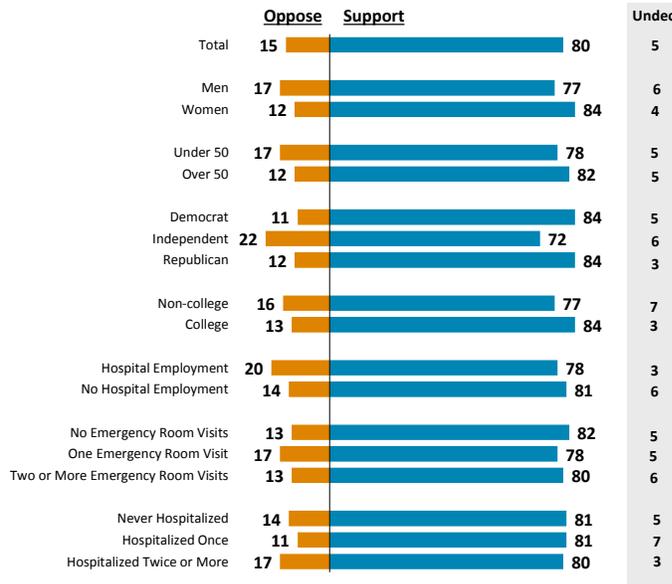
Variable	Percentage
Gender	
Female	52
Male	48
Age, range	
Under 30	15
30-39	14
40-49	16
50-64	29
65 & over	25
Region	
Northeast	18
Midwest	24
South	37
West	22
Party Affiliation	
Democrat	35
Republican	31
Independent	25
Race/Ethnicity	
White	70
Black	12
Latino	11
Asian/Pacific Islander	3
Native American/American Indian	0
Other/don't know/refused	4
Education	
Non-high school graduate	2
High school graduate	19
Non-college post-high school	3
Some college	29
College graduate	33
Post-graduate school	14
Health care system exposure*	
Emergency room visit	56
Hospitalization	38
Employed by a hospital	15

* All health care system exposure questions asked about either the respondent or someone in his or her household. The question about hospital employment applied to the previous five years. Questions about emergency room visits and hospitalization applied to the previous three years.

Appendix C – Additional poll results by subgroup

Proposal to decrease shift limit from the current 28 hours to 16 hours for second-year residents and above

Proposal – Decrease Shift Limit from 28 to 16 Hours for Second-Year Residents and Above

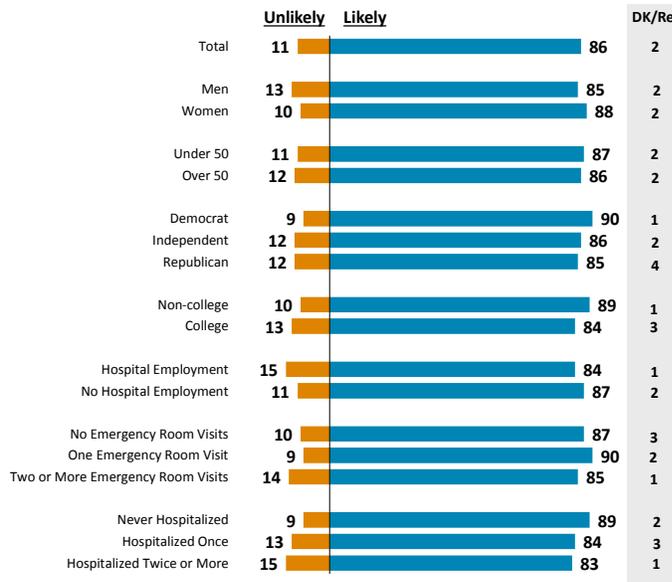


Q6: The A-C-G-M-E currently caps shifts for medical residents in their **second year and above** at a maximum of 28 hours without sleep. Some have proposed reducing this cap from 28 hours to a maximum of 16 hours in a row. Do you support the proposal to decrease the shift limit for 2nd year and above residents from 28 hours to a maximum of 16 hours in a row? [IF YES/NO ASK: Is that strongly or not so strongly YES/NO?]



Reactions to knowing that a resident treating the respondent had been on duty for more than 16 hours

Feel Anxious About the Safety of Your Medical Care

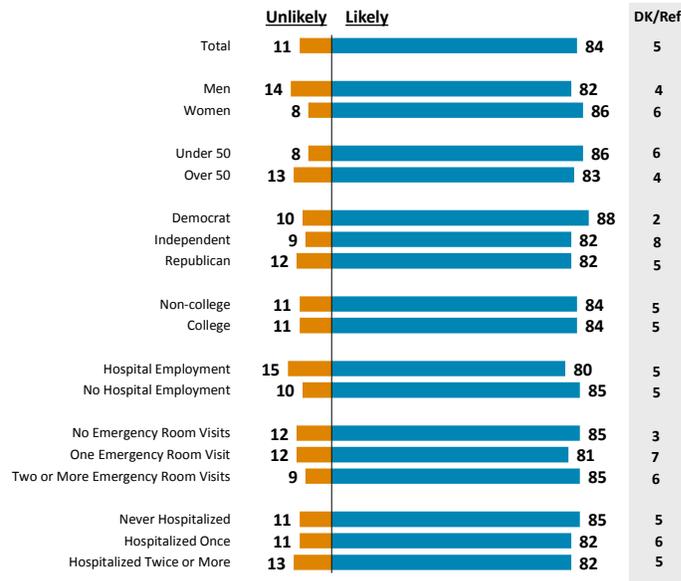


Legend:
DK/Ref (don't know/refused)

Q8: If you knew the doctor who was treating you had already been on duty for more than 16 hours without sleeping, would you be very likely, somewhat likely, somewhat unlikely, or very unlikely to feel anxious about the safety of your medical care?



Want to Be Treated by a Different Doctor



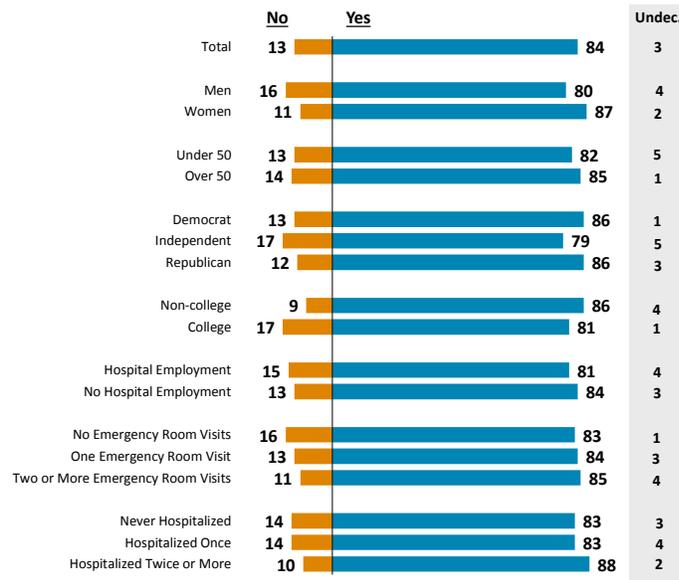
Legend:
DK/Ref (don't know/refused)

Q8: If you knew the doctor who was treating you had already been on duty for more than 16 hours without sleeping, would you be very likely, somewhat likely, somewhat unlikely, or very unlikely to want to be treated by a different doctor?



Desire to be informed if admitted to an experimental hospital, in the iCOMPARE or FIRST trials, which allows first-year residents to work 28 hours or longer

Desire to Be Informed If Admitted to an Experimental Hospital That Allows First-Year Residents to Work 28+ Hours



Q9: Researchers are conducting an experiment at more than 100 hospitals in the U.S. The hospitals were randomly divided into two groups: In one group, first-year residents are working shifts lasting no more than 16 hours in a row, as currently required by the ACGME. In the other group, first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep. The researchers want to find out whether patients treated at the hospitals where first-year residents are allowed to work for 28 or more hours in a row are more likely to die or have serious complications compared with patients treated at hospitals where first-year residents work no more than 16 hours in row. If you were admitted to one of the hospitals participating in this experiment, would you want to be informed if that hospital was assigned to the group where first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep?

