Physician schedules and patient safety: Critical appraisal

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SUMMARY

This study is a multicentre, randomized, cross-over trial comparing two shift schedules for residents in training. It was conducted from July 2013 to March 2017 in six paedictric intensive care units (PICUs) in the USA. The primary objective was to assess the effect of shorter shift schedules on the rate of serious medical errors by resident physicians.

In 2019, the authors published the design of shift schedules.[1] Briefly, the baseline schedule at each PICU acted as control and consisted of a 5-day cycle, with day shifts of 11–12 hours (6 a.m. to 6 p.m.) on the first 2 days and an extended shift of either 24 hours (11 a.m. to next day 11 a.m.) or 28 hours (6 a.m. to next day 10 a.m.) on day 3 extending to day 4. The restricted hour schedule acted as the intervention arm and eliminated prolonged shifts of >16 hours. It consisted of two day shifts, 11–15 hours long with a 16-hour night shift on the third day. There was a gap of about 24 hours before the night shift started.

The study was conducted in three waves to collect data over a 5-year period, and each site was randomized to either follow the baseline schedule (control) or the restricted hour schedule (intervention). An initial 4-month period was allowed for each PICU to get accustomed to the new schedules, after which 8 months of data collection was done. Subsequently, the sites were crossed over to the alternate schedule, with similar wash in and data collection periods. For instance, site A followed the extended schedule from November 2013 to June 2014 and crossed over to the restricted schedule from November 2014 to June 2015. Residents were posted for an average of 1 month and followed the schedule assigned to each site at the given time. The residents could have multiple rotations in the PICU and were allowed to enrol more than once.

The outcomes were measured by a centrally trained team of chart reviewers and physicians, who followed the residents in the study and noted if any serious errors were made. The primary outcome was the

number of serious medical errors made in both the groups, with a serious error being defined as one that caused patient harm or had the potential to cause harm. A total of 355 residents were contacted for participation, of which 172 were included in the control group and 188 in the intervention group. Nearly 3200 patients were seen by each cohort during the study period, and the patients' median age, duration of stay and chronic condition score were well matched between both the groups. The mean number of patients per resident physician was higher in the intervention group (6.7 *v.* 8.8). The major finding of this study was a higher number of serious medical errors in the intervention group (restricted hours) than the control group (97 *v.* 79/1000 patient-days) with significant variability between different hospitals (sites). Two sites did not show any difference between the arms and one showed the intervention group to have lower errors. This was noted despite documenting better sleep and neurobehavioral performance in the intervention arm. It was also noted that hospitals with highest patient workload had the most negative impact of intervention. The authors cited more frequent handovers as a possible reason for this disparity. It was suggested that better and more objective methods of documenting medical errors are needed, and factors that may hamper physician performance must also be assessed.

COMMENT

Residency is a period of medical postgraduate specialty training, first initiated by Sir William Osler at Johns Hopkins in the last decade of the 19th century. The period of residency can range from 2 to 7 years and is intense, rigorous and characterized by little or no restrictions on work hours, potentially affecting physician well-being and patient safety. Since 2004, a number of studies have assessed the effect of resident duty hours and workload on three major outcomes, i.e. patient safety, resident wellness and resident education.[2] Most studies have shown an improvement in resident well-being with reduction of duty hours, but the effects on patient safety have been equivocal. Other interventions, including introduction of a night 'cover', reduced shift length and protected sleep time, have all shown ambivalent results. Due to contradictory results noted in multiple analyses, it became clear that the correlation between working hours and outcomes was not perfect and better designed studies were required to evaluate this phenomenon.[3] In response to the reports of better resident well-being with duty hour restrictions, a number of regulatory bodies have taken notice and moved to restrict resident duty hours.[4] This study by Landrigan *et al.* is a randomized trial to assess two shift schedules for PICU residents and its effects on patient safety.

Critical appraisal and implications for India

Medical education in India is undergoing a major transformation with the advent of newer course patterns in a background of an increasingly litiginous society and unprecedented scientific advances. For years, residency training has been unregulated with no attention given to resident well-being and its effects on patient outcomes. This is a crucial trial looking at the effect of two resident shift schedules on medical errors and provides a basis on which future policy-changing studies can be designed.

This cluster randomized, cross-over trial has well-matched baseline characteristics in both groups. However, two important aspects of methodology and study design need to be highlighted before we can accept these results *prima facie*.

First, the mean number of patients per physician in the intervention group was higher (8.8 *v.* 6.7), which may act as a possible confounding factor. An increase of two patients per physician on average in an ICU setting can make a considerable difference in the physician workload.[5] Second, medical residency training, especially in a clinical subject with critical care patients, is an intense undertaking, demanding peak performance most of the time. A number of transient and enduring variables can affect cognitive performance and patient care on any given day. It has been shown that reduced sleep,[6] stress[7] and fatigue[8] are important modifiers of self-reported physician performance in the hospital. Occurrence of medical errors can lead to a self-propagating cycle of resident distress, leading to decreased empathy and increased frequency of self-perceived future errors.[9] The resident's previous clinical experience and ability to handle increased pressure is a variable trait that cannot be objectively compared between control and intervention groups. These key 'human' factors are essential modulators of the practice of medicine and can potentially confound the results of this analysis.

The negative results in this study are far more enlightening than a positive result would have been and enable us to dissect obstacles to seeking a perfect solution to this problem. The authors indicate a possible role of more frequent handovers contributing to a higher rate of errors in the intervention cohort. Patient handovers have been previously implicated as possible sources of communication gaps that can increase the risk of events leading to patient harm.[10] However, this effect was noted in only three of the six participating institutions, and previous studies by the same authors have not shown this effect.[11] This is possibly indicative of a system-level problem with hospital functioning and not of individual residents. A printed 'handoff bundle' designed to reduce gaps in communicating patient information has been shown to significantly bring down preventable adverse events, irrespective of physician characteristics.[10]

The association between resident resting hours and medical errors also appears to be imperfect, as the median weekly sleep was higher in the intervention group compared to that of the control group (52.9 *v.* 49.1 hours), along with better neurobehavioural test scores. This is contrary to expectations, and, in the Indian context, hard to explain in the absence of published data. In most teaching hospitals in India, there are little or no restrictions on resident physician working hours, and schedules often run into 48 hours of continuous work.[12] Work-related burnout and stress among residents has been reported to range from 60% to 90% in different Indian hospitals.[13,14] Even after reporting personal adverse effects due to stress, few residents seek help from mental health professionals due to fear of stigma.[15] Nonetheless, most of us can attest that treatment outcomes for most illnesses in India have remarkably improved and even parallel those in western countries. Reducing or modulating resident duty hours almost universally improves resident wellness scores even if the effect on patient errors remains equivocal.

How do we explain these conflicting findings?

These studies only serve to highlight that there is an important, very personal aspect of medicine that cannot be objectified.

This study suggests that more frequent handovers are a source of errors, and once a resident has 'taken over' a particular set of patients, a longer shift might be associated with a lower rate of medical errors. As many physicians and surgeons believe, there is a certain sweet-spot in residency training, when there is just the right amount of work-related stress and one functions at peak performance. It has been shown that highly engaged residents have a lower rate of self-reported errors and

reflect a lower rate of burnout, which is reflected in positive patient outcomes.[16] Any increase in stress, sleeplessness or working hours beyond a point seems to tip the equilibrium and increase the risk of medical errors.

Therefore, it appears that the association between resident working hours and outcomes (patient safety, resident well-being and resident education) is not linear, but a J-shaped curve. An increase in working hours and work-related pressure is beneficial up to a point, beyond which problems increase exponentially.

As William Osler said, '…the education upon which he (trainee physician) is engaged is not a college course, but a life course, for which the work of a few years under teachers is but a preparation'. It becomes apparent that the short period of residency should be as enriching and engaging as possible so that principles and concepts are built for life.

Patient outcomes are a collective result of functioning hospital systems and physician performance, and addressing either one in isolation is ineffective. Blaming all errors on the 'system' is counterproductive and hampers the training process.[17] Blaming the physician hours is reductive and only addresses one aspect of a multifaceted problem. A balance must be struck between both so that patient care is delivered in the most efficient and safe manner possible.

The onus is on policy-makers to identify this J-shaped curve and strike the right balance between responsibilities of the 'system' and individual residents.

Conflicts of interest. None declared

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