

The effect of admission by night float residents on patient outcomes.

Jessica Cook-Mack

A. Study Purpose

While it has been said that 'to err is human', medical errors can have devastating consequences for everyone involved. The death of Libby Zion in 1984 focused a spotlight on the medical system at teaching hospitals. It was suggested that one of the factors contributing to her death was that the resident admitting her was overworked and exhausted. The Bell Commission created in response to Zion's death, suggested that regulation of resident work hours would reduce medical error by preventing exhausted residents from making life and death decisions. One of the systems developed by training programs in response to this recommendation is known as "night float". Traditionally patients sick enough to require a stay in the hospital were admitted by the "team on call". This team was awake and available to accept patients for 24 hours - from the morning of their call day through until the same time on the following day when the next team on call would take over. Night float systems have been implemented in a variety of ways but all seek to allow the team on call to sleep by relieving them of over-night admitting duties. At Columbia-Presbyterian Medical Center (CPMC), where this study will take place, night floats are second year residents who admit patients to the hospital between 8PM and 6AM. These night floats are responsible for the assessment and care of the patient in the first critical hours of their hospital stay. In the morning, the patients' care is passed on to the team on call who retains primary responsibility for the patient until discharge. Despite the presumed benefit of reducing excessive work hours, there is also continued concern about safety. One study suggested that transfer of care results in an increase in preventable adverse events. Another study showed that complications and delays increased after workhour regulations were implemented. Despite this, no study has looked directly at the effects of admission by night float on patient outcome. This study aims to evaluate whether there are differences in delay of care (as measured by length of stay) and preventable adverse events between patients admitted directly to the team on call and those admitted by night float.

B. Study Subjects and Method of Recruitment

This study will compare the outcomes of patients admitted to the internal medicine department's teaching service. These patients are all adults whose demographics reflect the fact that CPMC effectively serves as both a referral center and a community hospital. Patients to be included are all those admitted via night float between Sunday and Thursday evenings and then transferred to services run by second year residents (oncology, GM2 and AIDS/Tb). The control group will consist of all patients admitted to second year run medicine teams between Monday morning and Thursday evening. Data for this study will be obtained from chart and computer database review. There will not be any direct contact with the patients themselves.

C. Study Procedures

This is an observational study which will collect information without requiring any additional interventions or procedures.

D. Issues

There are no ethical or practical problems anticipated in the performance of this study.

E. Study Purpose and Rationale

In NYC, the Bell commission, convened after the 1984 death of Libby Zion (a death attributed, at least in part, to errors made by an exhausted intern), recommended the reduction of work hours to 80 per week. One of the innovations adopted to comply with these new regulations was the introduction of a night float system. Rather than admitting all night long, primary teams finish admitting in the evening. Patients requiring admission after this time (or after team caps have been reached) are admitted via night float and subsequently passed on to the admitting team the next morning. A survey of residency programs performed by Trontell et al. (1991) found that 30% of residency programs had implemented a night float system. (10) This number may be higher in New York State where work-hour regulations are legislated.

Reduction in resident work-hours continues to be a hotly debated subject. There have been several studies which suggest that extended work-hours result in a decrease in resident capabilities. These studies have examined the effect of sleep deprivation on a range of outcomes from physical tasks to identification of cardiac arrhythmias with outcomes which generally favor the rested groups. (2) Gottlieb et al (1991) looked at length of stay, number of lab tests and medication errors and found that patients admitted after implementation of work-hour regulations had better outcomes than those admitted before regulations began. (2) On the other hand, it has been argued that the decrease in hours can be detrimental to both patient and practitioner decreasing learning for the resident and reducing continuity of care for the patient. One study by Laine et al (1993) found in-hospital complications and diagnostic test delays were more frequent after the institution of work-hour regulations (5) - a direct contradiction of the findings from Gottlieb.

Both Laine and Gottlieb observed outcomes before and after work hour regulations without specifying how these changes were made. Other studies have examined the night float system more directly. Trontell et al (1991) and Lieu et al (1992) suggested that night float systems have improved resident and increased sleep time without impacting on the quality of patient care or patient's perception of their care. (6,10) Despite these findings, others argue that patient outcome has, in fact, suffered. Griffith et al (1997) suggest that patients admitted to shortcall and night float residents were significantly less satisfied with their care. (4) Lofgren et al (1990) looked at length of stay, number of lab tests and mortality in patients admitted by a crosscovering resident (not a night float) and transferred in the morning to the primary team as compared with patients admitted directly by the primary team. Their study suggested that although mortality in the two groups was not different, length of stay and number of lab tests ordered increased in the patients admitted by a cross-covering resident. (7) Petersen et al (1994) suggested that preventable adverse events were more likely to occur when the patient was being cared for by someone other than their primary team. (8) Given these conflicting findings, the prevalence of the night float system and the paucity of data about it, a patient outcome study is badly needed. This study will evaluate two primary outcomes chosen to reflect patient morbidity - length of stay and number of preventable adverse events.

F. Study Design and Statistical Analysis

The proposed study is longitudinal, retrospective and observational. Since it is observational, it is not randomized. Subjects will not be crossed over between groups.

Adverse events will first be identified by computer-driven chart review and review of hospital incident reports for all patients fitting inclusion criteria. Charts to be flagged for further analysis by trained physicians will include those in which the patient had any of the following: an incident report filed by any hospital personnel, intervention by patient relations, risk management or an ethics consult, in hospital mortality, ICU transfer during hospital stay (patients admitted to the ICU directly from the ED will not be flagged unless they required a second admission during the same hospitalization), discharge to place other than home if admission was from home, any tests or labs ordered 'stat', significant medication change or medication addition during hospitalization, head CT, EEG, portable CXR excluding CXR from

day of admission, doppler of an extremity, presence of a type and hold, decreasing Hct, or increasing Cr or LFTs from baseline at admission. Once these subjects are identified by computer, admission by night float or on call team will be identified by a designated investigator who will then remove possible subject identifiers and indications of the means of admission. A panel of three trained physicians will then review the charts for any adverse events. These events will be categorized by the raters on a scale of preventability (1 -6, with 1 being unavoidable and 6 being entirely preventable). If there is disagreement, further chart review and discussion between the three raters will take place and ultimate decisions will be based on a 'majority-rules' scenario.

Length of stay will be defined as number of days from triage in the emergency department (ED) until discharge. If the patient was made ALC or transferred to the rehab service while in the hospital, length of stay will be defined as number of days from triage in the ED to transfer to the ALC or rehab service.

In order to analyze the adverse event outcome, a chi-square test will be used (since the outcome is a proportion in two groups). Based on the findings from Petersen et al, the proportion of preventable events to total events in patients admitted by cross-cover residents was approximately 50% while it was 35% in patients admitted by the on-call team. Using these proportions, a p value of 0.05 (the chance of rejecting the null hypothesis when it is true), a power of 80% (the chance of rejecting the null hypothesis when it is false) and a ratio of 3:1 (three patients admitted by the on call team for every patient admitted by night float), the number of adverse events needed in the night float group was calculated to be 122 while the number of adverse events needed in the on call team group was calculated to be 367. Given that the study found an adverse event rate of 4%, a total of 12406 patients are needed. Given that approximately half of night float admissions are subsequently passed on to GM2, AIDS/Tb or Oncology and NF admits a total of 12 patients per night (or 60 per week), a total of 1560 patients were calculated as meeting admission criteria for subjects per year. Given that there are a total of 8 admitting residents on the GM2, AIDS/Tb and oncology teams and that over 28 days with 7 short calls and seven long calls, each resident might admit 28 patients, a total of 2912 patients were calculated as meeting admission criteria for control subjects per year. With a total of 4472 admissions per year which might be eligible, a total of 3 years of retrospective data are estimated to be necessary to obtain the needed number of events. It should be noted that Petersen et al used resident reporting to flag adverse events. It is unclear whether the difference in method here would result in an increase or decrease in the detection of adverse events.

In order to analyze the length of stay outcome, a unpaired t-test will be used (since the outcome is a continuous variable for subjects in parallel arms). Based on the findings of Lofgren et al, the mean number of days in the hospital was 8.3 for the patients admitted by cross-cover and 7.1 for patients admitted by the on call team. The standard deviation for both means was approximately 5.3. Given these values, a p value of 0.05, power of 80%, and a ratio of 3: 1, the number of patients needed in the night float group was calculated to be 206 while the number of patients in the on call group was calculated to be 618. The other primary outcome requires many more subjects.

Examination of other factors which might contribute to LOS or adverse events (including age, gender, race, primary language, insurance, whether the patient was coming from home or a nursing care institution, means of arrival to the emergency department, number of hours between triage and arrival to the floor, floor of admission, APACHE score on admission, co-morbidities, and DNR status) will be analyzed by multivariate analysis.

G. Study Procedure, Drugs, Devices

This is an observational study. No procedures, drugs or medical devices other than those determined necessary by the primary team responsible for the patient during their hospital stay will be required.

H. Study Questionnaires

This is an observational study, there will be no questionnaires to complete.

I. Study Subjects

Inclusion Criteria:

Study subjects will be patients admitted via the emergency department to CPMC's Department of Adult Internal Medicine for the past four years beginning June 19th 1998 and ending June 18th 2002.

Study subjects will be patients admitted by night float between Sunday at 8PM and Thursday at 6AM and transferred in the morning to teams run by second year residents (general medicine 2, AIDS/Tb and oncology). Control subjects will be patients admitted by the on call teams run by second year residents between Monday at 6AM and Thursday at 8PM. The weekend admissions are excluded as some studies have suggested that patients admitted on the weekends may have increased mortality. (1) Patients admitted to other internal medicine services (cardiology, general medicine 1) are excluded since the resident doing the initial evaluation is a third year resident rather than a second year resident. As all night float residents are second years, it is hoped that by limiting the patients to those initially assessed by a second year resident, errors attributable to level of training will be reduced.

Information regarding age, gender, race, primary language, insurance, whether the patient was coming from home or a nursing care institution, means of arrival to the emergency department, number of hours between triage and arrival to the floor, floor of admission, APACHE score on admission, comorbidities, and DNR status will be collected. Patients will not be excluded on this basis.

Exclusion Criteria:

Patients with an admission to CPMC in the month prior to the admission in question will not be included as this is suggestive of factors which may confound the outcomes being examined in the present study (social situations leading to increased length of stay, diagnoses which were incompletely or incorrectly diagnosed or treated at initial presentation).

Patients transferred within 2 days to another service in the hospital (Surgery, Neurology etc ...) will not be included as practices regarding length of stay and routine testing vary between departments.

Patients admitted directly to the hospital from a doctor's office or admitted to an ICU are to be excluded as night floats are not involved in these admissions. Furthermore, the initial assessment and early care for these patients is not comparable to those admitted by night float and the on call ward teams.

J. Recruitment of Subjects

Subjects will be identified by reviewing information obtained from the admitting office. All admissions which satisfy the above inclusion criteria without meeting any of the exclusion criteria will be considered subjects.

Potential adverse events will be identified by computer review of hospital databases (using criteria given above). The occurrence of an adverse event will be verified by physicians blinded to the patient's means of admission. All other information regarding patients will be obtained via chart and computer database review.

K. Confidentiality of Study Data

All study data will be coded and information which could potentially reveal patient identity (names, initials, medical record numbers, social security and insurance numbers, phone numbers and addresses) will be removed.

Data for this study will be kept in a locked office drawer in the department of medicine. Only members of the research team will have access to the key for this drawer. Medical records are kept confidential by the hospital.

L. Potential Conflict of Interest

No conflicts of interest are foreseen.

M. Location of the Study

The study will be located at Columbia Presbyterian Medical Center (CPMC).

N. Potential Risks

It is hypothesized that there are some risks associated with admission via the night float system. This system, however, is currently the standard of care at CPMC. This study aims to determine if there is risk and further define it so that improvements (if needed) can be implemented.

O. Potential Benefits

There is no direct benefit to the study subjects. Indirectly, however, if differences are found, alteration of the system could bring benefits (i.e. increased safety) to future CPMC patients.

P. Alternative therapies

This is an observational study assessing patient outcomes. The events in question have already occurred and no alternative therapies are therefore available. It should be noted that it is

Q. References:

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