Author's response to reviews

Title: Patient Severity Matters for Night-shift Workload for Internal Medicine Residents in Taiwan

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Version: 6  Date: 22 August 2014

Author's response to reviews: see over
Cover letter

Dear editor and reviewers:

Attached please find our revised manuscript entitled “Clinical Severity Matters for Night-shift Workload for Internal Medicine Residents in Taiwan.” that we are submitting to be considered for publication in the your prestigious Journal.

We appreciate the reviewer's sincere comments on our work, and we are pleased to respond to each point and try our best to revise the manuscript.

Reviewer: Lena Y Ansmann

#Major Compulsory revisions:

1. Certainly, we should point out that the "patient factor" tested in our study is "Clinical severity" of admitted patients. Therefore, we revised the title to “Patient Severity Matters for Night-shift Workload for Internal Medicine Residents in Taiwan.”

2. Because residents were the frontline manpower at night shifts to receive phone calls from nurses, they were candidates in our study. In our study, the term "physician" always meant resident physician while "attending physician" was used for in-charge visiting staff
(hospitalist). To be less confusing, we were willing to rephrase "physician workload" to "resident workload" and "on-call physician" to "on-call resident" in the revised manuscript. In the discussion section and literature review, we adopted the original author's terminology.

3. In reference 12 (Evaluating the performance of a hospitalist system in Taiwan: A pioneer study for nationwide health insurance in Asia. *J Hosp Med.* 2011;6:378-82), details of our hospitalist setting and daily activity have been depicted. We are also pleased to add a brief definition of "hospitalist" as well as the current role of hospitalist in caring for hospitalized patients to make it more explicit to the readers.

→Section Method, Subheading study setting, Paragraph 1: We add: "Hospitalists, who had general internal medicine background, served as the in-charge attending physicians for hospitalized patients."

4. We are willing to revise and make our study objective more clearly, both in the abstract and introduction section.

→Abstract, Background section: Revised "Even though the topic of work hour restrictions for resident physicians has been highlighted, other contributing factors, with regards to resident workload have been scarcely studied." to "Although work hour is an important factors for resident workload, other contributing factors, such as patient severity, with regards
to resident workload have been scarcely studied."

Section Introduction, Paragraph 4: We add "By comparing the reasons of calls and workload produced after calls, our hypothesis that different patient produced different resident workload could be tested."

5. In this study, nurses communicated with on-duty residents by cell phones, rather than by paging. In every phone call, the nurse could directly report the event to the resident. Therefore, the reason of call were never missed. However, the resident's responses, recorded by night shift nurses, were missed up to 20%. It was probably because other parameters in the night call record form, except for resident's responses, could be recorded right away after calling the resident. After resident's order and management, nurses could record resident's response. Since the recording process was two-phase, one done while calling and the other done after resident's behavior, the later recording process carried higher rate of missing. When the clinical condition was emergent, the possibility of missed recording would be even higher because the nurses would be busy in their nursing activities. In the subsequent study, we will find ways to mitigate the rate of missing.

6. Do-not-resuscitate registration in Taiwan is based on patient's own will, or based on relatives' decision if the patient could not advocate his or her own will. Anyone can registered
DNR in his or her own IC card, but the registration rate is low (less than 10%) currently. In the hospital, when a patient faces irreversible catastrophic events, two physicians can query the patient or the relatives' choice for aggressive treatment or DNR. Currently, DNR orders for old, co-morbid patients are not uncommon in Taiwan, especially when these patients face acute illness [1]. Older patients preferred conservative care in their end of life. In our study, the study patients were averagely aged 69.1, were all admitted from emergency department, with a 18.1% DNR rates, and a 7% in-hospital mortality. It was typical for acute internal medicine department in tertiary referral medical centers in Taiwan.

→Section Discussion, Paragraph 7: We added a brief introduction: "DNR orders for old, co-morbid patients are not uncommon in Taiwan, especially when these patients face acute illness." with the same literature.

Reference:

7. Although the abstract has word count limitation, we have tried our best to revise the conclusion section of abstract to :"Beyond work hours and patient census, patients with different clinical severity and palliative goal produce different workload for on-call residents." We think it would be much more relevant to our study objective and study result.
8. Studies done by Rollinson SC et al. (Reference 3) showed decrease in Visual Memory Capacity test and decreased performance of Delayed Recognition Span Test of ED interns during their 12-hr night shift. The authors, who were concerned about patient safety, concluded that the result might provide valuable insight into ways to improve intern performance during night shifts. In this study, intern's health was not the interest of study.

9. In Meretoja's article (reference 8), health of a night worker was discussed in a subheading. Night work had been shown to adversely affect health for anesthesiologists and even medical students. Therefore, the author advocated that we should reduce night shift workload by several approaches. These studies motivated us to do night shift workload research. We believe that reasonable night shift workload can be designed when determinants of workload are revealed.

10. Some studies, although published in high impact journals, were in 1980s. Libby's work (Reference 9) can be reviewed on-line by free PMC article. All calls were classified into 3 level, and the authors found that 59.1% of calls were not relevant to patient care. These calls was perceived "relayed no relevant patient-related information" by interns who received the calls. These calls did not affect patient management but interrupted doctor-patient interaction
and teaching activity. In the other study published in NEJM, Katz et al. (Reference 10) reported that 26 percent of pages neither resulted in a change in clinical management nor were clinically indicated. Therefore, the authors concluded that reducing the number of unnecessary pages could result in 42 percent decrease in disruptions of patient care and more rest for interns. These authors had similar conclusions on decrease unnecessary calls at night.

→Page 5, Line 3: We added: "Some authors therefore advocated that unnecessary calls at night should be reduced."

11. In our study, the "reasons of calls" were classified into six categories, while the "patient sources of call" means stable, unstable and DNR patients. To our knowledge, studies that focused on "which kind of patient calls" or "patient in which status calls" is never seen in the literature.

12. To avoid observation effect to the on-call residents, the research ethics committee agreed with blinding the residents. The night shift nurses did daily night call recording as a routine practice in our ward, and we retrospectively analyzed the two-year night call recording. We agreed that "the nurses were blinded to the study design" was likely misleading, and decided to delete this sentence.
13. The night call recording aimed to monitor and improve night shift care. The nurse's satisfaction score was used to reflect the quality of resident's response. Although it was not an endpoint in our study, we presented the satisfaction score to demonstrate that the on-call residents responded with similar and acceptable performances to all three kinds of patients.

14. Pearson Chi-square test was used mainly in Table 3 for comparing dichotomous (such as gender) and categorical variables (such as reason of calls). Pearson correlation coefficient was not used in our statistics. For continuous variables, one-way ANOVA test was used.

15. That's why reasons of calls were important in this study. According to the study definition (Page 8, line 5-8), patients who met the 10 criteria of clinical alert system were classified as "unstable". Although they were labeled as unstable, the nurses may call on-call residents just to clarify an order or request a sleep pill. Of 95 calls from unstable patients, it has been shown that only 62.1% of calls were related to abnormal vital signs. It may explain why only 50.6% calls required bedside visit by on-call residents. In addition, our record showed that residents usually gave simple telephone orders to fever (when they felt no need to change current antibiotics), coma scale reported by nurses (when they felt observation was enough), and titration of vasopressors (when hypotension status had been treated with vasopressor pump). Compared to "stable" patients who only required 33.8% bedside visits by residents,
patients labeled as "unstable" produced higher workload.

16. Although nurses felt slightly more satisfied with residents' management for unstable patients as compared to stable and DNR ones, statistical analysis showed no significance (p=0.147m shown in Table 3). In my opinion, this slightly higher satisfaction might result from more bedside visits for unstable patients by residents as compared to stable ones, and more effective management for unstable patients as compared to DNR ones. However, we could not confirm this since no qualitative survey to night shift nurses was done. Therefore, we will revised this sentence (Page 12, line 2-3) to "their level of satisfaction was slightly higher for unstable patients (91.3%) than for stable (83.4%) and DNR ones (80.9%), but did not reach statistical significance (p=0.147)."

17. Thanks for this sincere comment. We are pleased to not overstate our finding and clinical implication in the discussion section. The first sentence about achieving reasonable workload could be our study objective rather than clinical implication, and it was completely removed from our revised manuscript.

18. Actually, our study design could only sample night calls and night shift workload for residents. We should express our finding more explicitly. In revised manuscript, we removed
the previous statement of "However, patient factors such as clinical severity and treatment goal have been scarcely reported.", and added: "However, clinical severity of patient, which is an important patient factor in Horner's framework, has been scarcely taken into consideration in workload studies."

19. In the discussion section, reference 7, 9, 10, and 11 had been mentioned in the introduction section, but required more detailed explanation. Reference 15 was a study on protected sleep time intervention for intern. Since we did not measure the fatigue intensity of resident, we did not consider to remove it to introduction section. Reference 16 was a study on a new paging system, which was not relevant to our study objective. In Table 4, we summarized six important studies on night shift call, five of which had been mentioned already in the introduction section. Efforts we have made are to revise the introduction more explicitly using the previous relevant literature. We hope the revised manuscript can meet your requirements.

20. We are pleased to remove this citation in the discussion section.

→Page 14, Line 1-3. Delete the sentence of "A later study performed in Canada recorded 309 calls that were placed between 7pm and 7am to 10 interns in medical wards.\textsuperscript{11} " and revise the next sentence to: "The study included only medical patients, however it had the
21. Some of the previous studies about night shift paging sampled both medical and surgical internors even pediatric interns for analysis, and focused on how many times interns were paged and interrupted. Some later studies enrolled only medical interns and residents. In our study, we highlighted that different patients produce different workload. Thus we just wanted to remind the targeted patient population in different studies. We have removed the questionable terms "pure medical population" and revised it as follows: "The study included only medical patients, however it had the limitations of covering relatively short time periods and performing in 1980s."

22. In page 18 (line 4-5), we presented the study limitation that patient-nurse communication had not been recorded. We could only sampled nurses' calls to on-call residents. In our study, it was an important limitation. However, all previous studies on paging or call to on-duty interns had similar limitations. Our work in this study is to identify which kind of patients made the nurses place the calls, which was not investigated in previous studies. We completely agree that future study should simultaneously sample both patient-nurse interaction and nurse-doctor communication to mitigate this limitation.
23. Unfortunately, we did not have data of time spent on managing each patient. First, it was not designed in our night shift record form. Second, time spent on managing the patient's call is highly related to the resident's training and personality, which has been classified into "provider factors" in Horner's framework. We agree that time should be an important endpoint in assessing physician workload, but we could not address it based on our data.

24. The sentence was: "In our patients in the three different clinical states, the proportion of the calls based on their reasons was significantly changed, but not for the leading ones." We pointed out that abnormal vital signs were the leading reason of call in stable, unstable and DNR patients, although the proportion of call reasons was different.

To be more clearly presented, we revised the original sentence (page 13, line 14) to: "In our study, abnormal vital signs were the leading reason of call in stable, unstable and DNR patients, although the proportion of call reasons was different."

25. We agreed with your comment and try not to overstate the advantage of using mobile phone in our setting. The original statements (page 15, line 2-7) are reduced with a neutral discussion.

→ Page 15, line 2: "Calling via mobile phones may shorten the time lag compared to traditional paging systems, but has been criticized by residents as being highly disruptive for
the patient care activity.\(^{17}\) It calls for more study to prove the advantage of using mobile phones in clinical settings."

26. In Table 3, only "Age" was a continuous variable using ANOVA. Gender (3 by 2), call reasons (3 by 6), residents' response (3 by 3), and Nurse's satisfaction using 5-level Likert scale (3 by 5) were categorical variables and Chi-square test was used. Therefore, only 5 p-values were generated respectively.

# Minor essential revisions:

27. Yes, we should pointed out ACGME's location.

→Page 4, Line 8: Revise the original sentence to: "The Accreditation Council for Graduate Medical Education (ACGME) in the United States mandated limits on resident work hours in 2003, including a 30-hour limit on continuous shifts."

28. We are pleased to introduce more of Horner's framework in the introduction.

→Page 3, line 12: We inserted a brief introduction of Horner's framework: "In Horner's framework, patient factors, provider factors and practice-based factors were three essential confounders for clinical work demand, which in turn contributed to physician work intensity and influenced physician health and patient outcomes."
29. We agreed that generalizability should be a limitation for our study. In the limitations already discussed, we have pointed out that workload sampled at night could not be generalized to day and evening directly. Besides, we are willing to add the forth limitation as follows.

→ Page 19, line 9: "Forth, the study was conducted in single academic medical center in Taiwan. The generalizability of our results to other settings has not been proved."

30. Thanks. "Emergency department (ED)" has been revised in Page 6, line 16 in edited manuscript.

31. In two years, 45 residents were observed in this study. Thanks for your comments and we should provided this number in the Result section (subheading: On-call residents' responses).

→Page 11, line 13: We added the number: "Forty-five residents were observed, and their responses were recorded on 670 (79.7%) forms."

32. According to your above comments, the study hypothesis is provided in the introduction section in our revised manuscript (page 5, line 12).
33. After consideration, we merged three subheadings together, but still keep remaining important subheadings which are relevant to our study objectives. The final subheadings are "Night shift calls" and "On-call Resident’s Responses".

34. We tried to revised the sentence (page 20, line 3) to: "Both the cause and effect of the night calls differ among patients in different clinical states." We hope it will be easier to understand for readers.

35. I am sorry for our inconsistent naming and thanks for being recognized by your careful reviewing. We have rephrased "general" to "stable" in Figure 1.

36. Thanks for your comment. We have separated the value into two columns to present n(%) and mean(SD) in Table 2.

# Discretionary revisions:

37. As your suggestion, we added our country name, Taiwan, in the title.

38. As your suggestion, the subheadings of Method section have been rephrased.

→Page 7, line 8: revise "Night-shift physician workload sampling" to "Study design"
39. We agree that the nurses’ workload is even important for patient safety and should be studied. When performing literature review for our study, we were surprised that there were already many nurse workload studies, which extensively addressed their work hours, shift design, nursing activity level, manpower prediction, patient classification, mental stress, and so on. However, studies for resident's workload were relatively limited. That why we made an effort on this issue.

40. Table 4 provided a brief literature review including only 6 important studies. We noticed that some of these studies were done decades before, and there was actually a window of rare ongoing research on night call/paging from 1995 to 2008. The table may reveal important aspects that previous researcher did not address, and current researchers can do. I sincerely hope to keep this table.
Reviewer: Christiane Degan

# Major compulsory revisions:

Introduction:

1. Yes, we are pleased to briefly introduce Horner's framework in our introduction section. It helped reader's to capture our motivation and objective of this study.

→Page 4, Line 12-15: We added: "In Horner's framework, patient factors, provider factors and practice-based factors were three essential confounders for clinical work demand, which in turn contributed to physician work intensity and influenced physician health and patient outcomes."

2. Thanks for this sincere comment. In our revised manuscript, we have tried to specify that the independent variable were "patient severity" to replace the original term "patient factor" (which, although consistent with Horner's model, was less specific).

→Page 5, Line 11-14: We added: "Although workload is usually measured by census of patient encounter, we hypothesized that resident workload is associated with patient severity. By comparing the reasons of calls and workload produced after calls, our hypothesis that different patient produced different resident workload could be tested."

3. We agreed that nurse satisfaction score was not an important endpoint we looked at. The
night call recording aimed to monitor and improve night shift care. The nurse's satisfaction score was used to reflect the perceived quality of resident's response. Although it was not an endpoint in our study, we presented the satisfaction score to demonstrate that the on-call residents responded with acceptable performances to all three kinds of patients (without statistical difference). Besides, in the method section (original: page 9, line 19 / revised page 9, line 17) we have explained that we used a five-level Likert scale for satisfaction, as shown in Table 3.

Section Method, subheading "On-call Resident’s Responses and Nurses’ Satisfaction".

We avoid mentioning of satisfaction and revised the subheading to "On-call Resident’s Responses".

4. Thanks for your sincere comment which is helpful in our further work. Unfortunately, in this study we did not measure the length of patient visit or sleep quality for residents. In further study, we may consider using video to measure each time spent for managing a patient's event. Besides, sleep quality can be also assessed by actigraphy in the further study.

5. (1) Sentence 3 was "Regarding the direct patient care workload of on-duty residents, from 289 bedside visits, 40.5%, 14.9%, and 44.3% were from stable, unstable, and DNR patients, respectively." We tried to depict that from residents' view, they went for stable patients in
40.5% of all bedside visits. Since stable patients was a larger population than unstable patients, workload from stable patients was inevitably larger. This finding was not discussed later because it was a common phenomenon.

(2) Sentence 4, "Of all the 187 immediate bedside visits, stable, unstable, and DNR patients accounted for 43.9%, 16.0%, and 39.6%, respectively" had the same implication, and we decided to avoid redundancy. This sentence has been deleted in revised manuscript.

6. We agreed that "simple demographics" was misleading and revised this sentence as follows.

→Page 14, Line 9: "In the future, we may predict on-call workload by analyzing the clinical status of responsible patients."

7. Yes, our study patients were all acute general medicine patients admitted from emergency department. We are pleased to provide this explanation in discussion. Thanks.

→Page 14, Line 7-9: "All patients in this study suffered from acute illness and were admitted from ED, and the picture was typical for an acute general medicine unit."

8. Yes, an interesting finding in our study is that DNR patients produced higher workload than was expected. Both unstable and DNR patients had serious health condition, and they
had higher probability of abnormal vital signs that made nurses place calls to residents. We should not consider DNR patients as low-workload patients in any setting.

9. Thanks for this sincere comments for future study. Calls for new admission was mandatory for nurses to get prescription and orders from residents. However, calls for floor patients depended on patient's medical demand and condition. Workload after calls may also be different for both.

#. Minor Essential Revisions:

1. In abstract with limited word count, we tried our best to revised the background as follows.

"Although work hour is an important factors for resident workload, other contributing factors, such as patient severity, with regards to resident workload have been scarcely studied."

2. We agreed that "after-hours" was less specific and are pleased to rephrase with "night-shift" in the revised manuscript.

3. Thanks for this important comment. We should presented the statistics in the result section.

→Page 11, Line 1: we added: "The call reasons were statistically different by Pearson Chi-square test (p<0.001)."
Page 11, Line 9: We revised as: "The percentage of bedside visits was 33.8%, 50.6%, and 56.1%, and that of immediate (within 15 minutes) visits was 23.7%, 35.3%, and 32.5% after calls received from stable, unstable, and DNR patients, respectively (p<0.001 by Chi-square test for immediate visit, delayed visit, and no visit)."

4. We agreed with your comment and are willing to revise this sentence.

Page 17, Line 16: The sentence was rephrased as "Our study focused on inpatients’ calls at night, rather than on calls for managing admission process. Therefore, the previously admitted patients and new admitted patients should be considered separately."

Our original manuscript had been edited by ATS Medical Editing and Review Solutions. However, if further language editing to our revised manuscript is needed, we are willing to send for a professional language editing service again.

All of the authors have read and approved the final revised manuscript. We hope that our manuscript will meet your standards for review and publication. Thank you very much and we look forward to hearing from you soon.

Best Regards,
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Title: Beyond Work Hours: A Two-year Cohort Study of Night-shift Physician Workload

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This is to certify that the document listed above has been edited to the standards of the industry.