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PGY-1 Internal Medicine
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Effect of Resident Communication Abilities on Patient Safety

I. Study Purpose and Rationale1

A. Rationale: We are in the midst of a patient safety movement in the United States. Reducing medical errors is the focus of much energy, and spirited debate, in the medical community as well as among politicians in Washington. Although ACGME duty hour regulations were enacted in part to reduce medical errors among residents, research studies have yet to show any positive effects on patient safety[i]. In fact, some fear that the new duty hour limits may lead to more medical errors given an increase in patient hand-offs and transfers among residents[ii]. Resident interpersonal and communication skills are even more important in a fragmented medical care model and have not yet been adequately studied as targets for intervention to improve patient safety.

B. Background: In 2000, the Institute of Medicine (IOM) published its seminal report on medical errors, "To Err is Human: Building a Safer Health System", which estimated that up to 98,000 preventable deaths and 1,000,000 excess injuries occurred annually in U.S. hospitals[iii]. Although the exact figures and accounting methods in the report were later disputed, the IOM report jumpstarted a vigorous debate in the medical community over how best to reduce medical errors and improve patient safety.

This focus on reducing errors played a significant role in spurring the Accreditation of Council for Graduate Medical Education (ACGME) in 2003 to enact new duty hour regulations for residents. Average weekly hours were reduced to 80 hours and continuous duty was limited to 24 hours[iv]. ACGME revised its regulations in 2011 by further limiting continuous duty for PGY-1 to 16 hours. ACGME pointed to the growing public perception that long duty hours were compromising patient safety as one of its main reasons for introducing new regulations.

However, recent studies have called into question whether these and other safety initiatives have made any real progress on reducing medical errors[v][vi][vii][viii]. A study among pediatrics residents showed that total work hours, sleep hours, and medical error rates did not change after ACGME duty hours were enacted[i].

II. Study Design and Statistical Procedures

A. Study Design: This is a retrospective study that will use a comprehensive surveillance method that includes chart reviews (medication orders, physician notes, nursing notes, nursing flow sheets, formal incident reports) by a team of 6 nurse and physician data extractors trained in medical error detection methods.

These methods have been shown to have higher sensitivity and reliability than traditional incident reporting systems[ix]. The team will examine charts of patients on inpatient ward services from June 2010 to June 2011, which include Gen Med 1, Gen Med 2, Allen wards, Cardiology, and ID/Oncology. The team will identify any suspected errors and adverse events at any stage in the medication delivery process (ordering, transcription, pharmacy dispensation, administration, or monitoring). Only those medication errors actually ordered by interns or residents will be counted. If a patient was seen on multiple services, the resident primarily responsible for the patient at the time of the error will be charged with the error.

Medication errors will be further classified for secondary analysis into:

1) Little potential for harm
2) Intercepted potential adverse drug events
3) Nonintercepted potential adverse drug event

4) Preventable adverse drug event

B. Study Population: All 88 categorical Columbia internal medicine PGY-2 (44) and PGY-3 (44) residents from June 2010 to June 2011 will be included in the study. Residents will be separated by communication ability based on their mean interpersonal/communication scores on all previous evaluations by attending physicians and housestaff. The top third will be in the high performance group, middle third in average performance group, and the bottom half will be in the low performance group.

C. Inclusion/Exclusion Criteria: Residents who did not begin as interns and transferred in the middle of residency will be excluded given decreased number of evaluations leading to possible bias (i.e. residents may receive higher scores later in residency as they self improve). Residents who discontinued their training in the middle of the year will be excluded.

D. Study outcomes:
Primary outcome will be medication error rates measured as: # of *medication errors per 100 medication orders.*

Secondary outcome will be adverse error rates measured as: # of *adverse drug events (ADE) per 100 medication orders.*

E. Statistical analysis: A t-test will be used to compare mean medication error rates between the high performance and the low performance groups. The average performance group will be excluded from the statistical analysis. $P<0.05$ will be used for statistical significance. STATA software will be used.

We estimate 80% power to detect an effect size 0.74 of standard deviation in medication error rates (based on estimated sample size of 30). Based on previous studies that have shown medication error rates to have a standard deviation of 2, the detectable effect size would be 1.5.

III.Study Procedures: N/A

IV.Study Drugs or Devices: N/A

V.Study Questionnaire: The evaluation form that is filled out for all residents by attending physicians and other residents is attached below (Exhibit A)

VI. Recruitment: Permission will be obtained from all residents to aggregate their performance evaluations and medical error rates.

VII.Confidentiality of Study Data: All individual evaluation scores and medication error rates will be kept confidential for purposes of the study. Only aggregate scores will be used for analysis. Necessary precautions will be taken to keep individual evaluation scores and medication error rates confidential such as encrypting data files and discarding data once study is finished.

VIII.Potential Risks: N/A

IX.Potential Benefits: This study will shed light on the role of interpersonal and communication ability as a source of medical errors. If this study shows a positive correlation, further research is warranted to see if interventions to improve resident communication skills and can reduce medical errors.

X.Potential Risks: N/A

XI.Exhibit A:

Patient Care: Data Gathering (H&P, Labs, Radiology) *(Question 1 of 11 - Mandatory)*

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

Patient Care: Record Keeping *(Question 2 of 11 - Mandatory)*

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

Patient Care: Clinical Judgment *(Question 3 of 11 - Mandatory)*

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

Patient Care: Procedural Skills *(Question 4 of 11 - Mandatory)*

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

Medical Knowledge *(Question 5 of 11 - Mandatory)*

Knowledge of Basic and Clinical Sciences

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

PRACTICE BASED LEARNING AND IMPROVEMENT *(Question 6 of 11 - Mandatory)*

Effectively learns from patient cases and evaluates own performance, incorporates feedback and strives for improvement

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

INTERPERSONAL AND COMMUNICATION SKILLS *(Question 7 of 11 - Mandatory)*
Demonstrates caring and respectful behaviors when interacting with patients, patients' families and hospital staff

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

PROFESSIONALISM *(Question 8 of 11 - Mandatory)*
Demonstrates respect, compassion, integrity and honesty

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

SYSTEMS-BASED PRACTICE *(Question 9 of 11 - Mandatory)*

Understands the roles of other health care professionals (consultants, social services, dietary, PT, OT, unit assistant and other hospital staff) and appropriately utilizes these resources

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

TEACHING AND TEAMWORK *(Question 10 of 11 - Mandatory)*

Is willing to teach and assist others: medical students, peers, nurses, techs, patients, and patients' family

N/A Did Not Observe	Needs Improvement		Meets Expectations		Far Exceeds Expectations
0	1	2	3	4	5

XII. References:

[i] Landrigan C, Fahrenkopf A, et al. Effects of the Accrediation Council for Graduate Medical Education Duty Hour Limits on Sleep, Work Hours, and Safety. Pediatrics 2008; 122; 250

[ii] Petersen L, Brennan T, O'Neil A, Cook E, Lee T. Does housestaff discontinuity of care increase the risk for preventable adverse events? Ann Intern Med 1994;121:866 –72.

[iii] Kohn L, Corrigan J, Donaldson M, McKenzie D. To err is human: Building a Safer Healthcare System. In: Committee on Quality and Healthcare in America, Institute of Medicine, Washington, DC: National Academy Press, 2000.
[iv] *Report of the ACGME Work Group on Resident Duty Hours*. Chicago, Ill: Accreditation Council for Graduate Medical Education; 2002.
[v] Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med 2010;363: 2124-34. [Erratum, N Engl J Med 2010;363: 2573.]
[vi] Jha A, Classen D. Getting moving on patient safety – harnessing electronic data for safer care. NEJM 365; 19; 1756-58
[vii] Levinson D. Adverse events in hospitals: national incidence among Medicare beneficiaries. Washington, DC: Office of the Inspector General, Department of Health and Human Services, 2010.
[viii] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Aff (Millwood) 2011;30:581-9. [Erratum, Health Aff (Millwood) 2011;30:1217.
[ix] Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. JAMA. 2001; 285(16):2114–2120