IRB Proposal

"Determining the Impact of Case-Exposure on Preparedness for Practice"

A. Study Purpose and Rationale
One receives the degree of Medical Doctor upon graduating from a 4 year medical school, but this is not sufficient for independent practice as a physician. In order to achieve a level of proficiency to become licensed, physicians of all specialties are required to complete specialized residency training in the field in which they will practice. Residencies serve as the opportunity to work with faculty, more senior residents, medical students, and other members of the healthcare team to learn the core knowledge and develop the requisite skills to be an independent practitioner. It thus serves a critical role in the development of physicians and preparation for practice.

Given the importance of proper training to provide care that is high-quality, an accreditation body exists, namely the Accreditation Council for Graduate Medical Education (ACGME) to certify and attest to the quality of training at residency training programs in the US. The ACGME has created specialty-specific guidelines (1, 2) for training programs, with a view towards ensuring physicians graduating from accredited programs do so with a breadth and depth of experiences sufficient to ensure that they are prepared to serve our country effectively. These guidelines, which are readily available online, make numerous demands on programs seeking accreditation or re-accreditation, yet they do not universally require that residency programs objectively measure what their residents are being exposed to on the wards.

Each year approximately 20% of all medical school graduates enter internal medicine residencies—double the number who enter any other specialty (3). While many such graduates go on to pursue sub-specialty training (4), implicitly deciding that the area of their practice will be somewhat narrowed, all are presumed to have achieved a level of education in general internal medicine sufficient to be a general internist (1). However, without a formal system for logging case-load, diseases encountered, and educational objectives achieved, there is no way of formally assessing the breadth or depth education that each resident has achieved. Moreover, standardized exam scores—the "gold standard" of assessment of medical knowledge, have been shown to correlate poorly with case load (5); calling into question whether they should serve as the ultimate assessment of competency.

Many medical specialties differ from internal medicine in that they require trainees to document the nature and number of cases that they encounter during their training (2). Surgeons keep a running total of the types of operations they have performed, and the level of involvement they had in the case (lead surgeon, first assistant, second assistant, teacher) and must complete a specified number of cases in order to be eligible to graduate from their program (2). In this manner, surgery residencies have objective criteria on which they base their attestation of competence.

In addition to using data at the individual resident level to evidence an adequate training experience, data on surgical case volume are tabulated and reported at the program and

national level, with reports of the mean number, range, and standard deviation for cases seen during each post-graduate year of training, and the same data also presented as percentiles (6). This enables individual surgeons and training programs alike to asses where they stand with regard to their training.

Given the complete lack of a similar log for internal medicine residents, there is much less certainty and no objective means for assessing the breadth, depth, and quality of internal medicine residents, at the national, program, or individual level. Previous studies have recognized this deficiency and sought to assess internal medicine residency training through a number of means. One type of study that has been pursued has been to give a questionnaire to graduating seniors from internal medicine and other residency training programs and assess their self-perceived preparedness to take care of common diseases (7). This study was taken further by attempts to ask questions not only of IM trainees, but also of senior residents in family medicine training programs, and compare perceived preparedness to take care of diagnoses in the inpatient and outpatient setting (8). While informative, the data are based on self-report, with no attendant description of the experiences residents had and how those correlated with reported competency.

A more mathematically rigorous study here at Columbia sought to provide some objective data on the number of cases seen and diseases encountered during a three-year internal medicine residency (9). The study also attempted to compare what was encountered to published-guidelines of what should be taught in IM (FCIM guidelines, 11, 12). This study, which queried the electronic sign-outs prepared by residents at NYPH-CUMC in the late 1990s, represents the only quantitative, data extraction approach to description of cases encountered in internal medicine. It also benefits from attempting to compare what was seen to a set of priority training areas. However, it is limited in that it only attests to case exposure, and does not provide a measure of knowledge imparted, the data is nearly two decades old, and was collected prior to the ACGME changes in resident work hours, and the electronic medical record at the time was significantly more-limited, meaning the approaches to identifying cases encountered and conditions cared-for were more limited.

Given the limitations of the two types of studies described above, I will seek to update and advance the literature by employing a novel method for querying the electronic medical record at NYPH-CUMC to describe the number of cases seen by residents during their training in internal medicine, and the diseases and chief complaints encountered. I will pair this data with results from questionnaires administered to the same residents, asking about perceived preparedness to care for common conditions; enabling us to ask how variations in case volume impact perceived preparedness for independent practice. Finally, I will attempt to describe how relevant the education of an internal medicine resident is by comparing the diseases we most often encounter in training to published data on causes of morbidity, mortality, and hospitalization in the United States.

B. Study Design and Statistical Analysis
Overview

The study will have two core components; a review of electronic medical record data, collected retrospectively, and questionnaires administered to residents training at NYPH–CUMC in a prospective fashion.

Study Sample
The study will include 80 categorical-internal medicine residents followed throughout their three years of training. Given the 2011 change in work hours, determining which cohorts to follow is complicated. For the purposes of obtaining baseline data regarding case-exposure, the classes of 2009 and 2010—for whom questionnaire data will not be readily available—will first be collected. Those graduating years are chosen because they precede the most recent change in resident work hours. Subsequently, the graduating classes of 2014 and 2015 would be added (an additional 80 residents, all of whom trained after the 2011 change in intern work-hour requirements) along with data collected prospectively from their questionnaires.

Data Collection
1) Determination of resident case-load will be made by looking at both inpatient and outpatient encounters across all three years of residency. In accordance with ACGME guidelines, data collected about patients seen in the emergency room will be considered outpatient visits (1).

For inpatient encounters, the electronic medical record will be queried for the following note types:
 • Medicine Admission Free Text Note
 • Medical ICU Admission Note
 • CCU Admission Note
 • Any relevant notes from the Alan Hospital

For outpatient encounters, the electronic medical record will be queried for the following note types:
 • Amb AIM Primary Provider Structured Note
 • Amb AIM Walk-in Clinic Note

A resident will be considered to have had a "patient encounter" for every patient whom he or she has written one of the above notes. Each time a patient is admitted to the hospital or transferred from one service to another, a resident will be considered to have encountered that patient. This means that *the same resident could have multiple encounters with the same patient, and that the same patient could be considered to have served as a case for multiple residents.*

2) Determination of diagnoses encountered will be made by querying the electronic medical record in each of the following manners. By using the combination of approaches described, assessment of the validity of the data could be made, more diagnoses could potentially be captured, and chief complaints, as well as diagnoses, could be reported.

a) Query diagnoses from EAGLE database (ICD-9 codes, inputted by billing)
b) Query the discharge summary linked to the visit for which the resident made the admission for "discharge diagnoses" (free text, inputted by the resident)
c) Query the free-text of resident admission notes with a Natural Language Processor to look at diagnoses listed in the assessment and plan, as well as chief complaints

Statistical Analysis
Assessing the quality of Extracted Data
Data collected for each resident will be compared to data that is already being collected by the hospital looking at the volume of admissions on each service. This hospital data is currently being collected by an alternative method (looking at the number of patients with "Add to list" orders for each service.) This will enable an assessment of whether all admissions are being captured, as the number of patients admitted on a given service should be equal to the sum of the number of admissions performed by each intern (or resident) on that service. Given that each patient receives an admission note from both the accepting intern and the accepting resident, one would have to sum the number of admissions by looking at residents only at the same level (PGY-1 or non-PGY-1) to avoid double-counting of patients.

Descriptive Statistics for Perceived Preparedness
Similar to the publication of Blumenthal et al JAMA 2001, I will report the number of residents who respond saying they are "Very Unprepared," " Somewhat Unprepared," "Somewhat Prepared," or "Very Prepared" for each of the items in the questionnaire.

Year to Year Changes in Perceived Preparedness
Will be assessed at the individual resident level and the aggregate PGY level, by linear regression analysis. This will enable a quantification of learning year over year.

Descriptive Statistics for Case-Exposure

The mean number of cases seen and standard deviation will be calculated for residents at the PGY-1, PGY-2, and PGY-3 level. This will be reported for inpatients and outpatients. Separately, the number of inpatients encountered across all three years will be tabulated. I estimate the case volume will be as follows:

Year of Training	Mean	Standard Deviation
PGY -1	225	15
PGY-2	275	20
PGY-3	250	20
TOTAL	750	32

Relationship between case load and Perceived Preparedness

The data of Blumenthal et al JAMA 2001 suggest that in most cases, a strong majority of graduating residents describe themselves as feeling very prepared. This means there would be a small n in the other three groups (Very Unprepared, Somewhat Unprepared, Somewhat Prepared), reducing statistical power. To simplify analyses and amplify power, I will group the respondents into only two subsets; those who are "very prepared," and "all others." These groups will be formed for each of the 4 inpatient and 8 outpatient conditions included in the questionnaire, and the mean number of cases seen among respondents in the two groups will be compared by T test. With an initial n of 80 residents (the classes of 2014/15) the statistical power would be as follows:

% Very Prepared	Breakdown (othr/VP)	Detectable Difference in # of Cases Seen
90	8/72	3.32
85	12/68	2.75
80	16/64	2.45
75	20/60	2.23
70	24/56	2.12
60	32/80	1.97
50	40/40	1.9

Comparing case-exposure to causes of morbidity, mortality, and hospitalization
This will be done at both the individual resident level and the aggregate, program level, by chi squared analyses, with the power to detect the following differences as significant.

Aggregate, 80 residents, three years of follow-up, expect 60,000 patient encounters

Expected Prevalence	# Cases Expected	Significance Threshold (low)	Significance Threshold (high)
10%	6,000	5,820	6,208
5%	3,000	2,880	3,180
3%	1,800	1,680	1,920
1%	600	534	660

Individual, 750 patient encounters expected over three years of follow-up

Expected Prevalence	# Cases Expected	Significance Threshold (Low)	Significance Threshold (High)
10%	75	53	98
5%	38	22	56
3%	23	11	38
1%	8	1.2	18

C. Study Procedure

In addition to the above data, which will be collected retrospectively, questionnaires regarding perceived preparedness for practice will be administered to all residents, at every PGY level, beginning in the spring of 2013. Residents will complete the same survey at the start of each PGY year, and upon completion of training (four rounds of surveying over three years.) This will allow for an assessment of perceived-preparedness over time and thus an analysis of the relationship between volume and breadth of cases seen, on the one hand, and preparedness for practice on the other. The questionnaire will be the instrument published by Blumenthal et al. JAMA 2001, which has already been tested and validated, and will enable us to compare our resident's responses to those of residents at other institutions.

D. Study Drugs
N/A

E. Medical Device
N/A

F. Study Questionnaires
See attached

G. Study Subjects
The study subjects will be the categorical residents in the Internal Medicine program at New York Presbyterian Hospital, Columbia University Medical Center, as detailed above.

H. Recruitment of Subjects
All categorical medicine residents at NYPH-CUMC will be automatically-enrolled in the study. Notes they have written in the electronic medical record will be queried. Questionnaires will be administered at departmental gatherings with support of the internal residency program leadership.

I. Confidentiality of Study Data
The data will be de-identified so residents will not be linked to data on the number of admissions they have performed. A unique identifier will be generated to link each resident's data from the electronic medical record to the questionnaires that they will fill out regarding their perceived preparedness.

J. Potential Conflict of Interest
None of the authors have any conflicts of interest regarding the study; financial or otherwise.

K. Location of the Study
NYPH-CUMC

L. Potential Risks

There are minimal to no foreseen risks to study participants, as their data will be collected automatically from the electronic medical record, de-identified, and linked to their questionnaire only by a randomly-generated, unique identifier. The only potential harm would be related to accidental disclosure of a participant's identity, but this would not be anticipated to occur.

M. Potential Benefits

Individual residents are unlikely to benefit significantly from participating in the study. They may derive some insight into their own education and preparedness to practice medicine upon completing the questionnaires they will be given, but the majority of benefit would be to future generations of residents and patients, as well as the program administration, as results of this study could improve the quality of education in our residency training program.

N. Alternative Therapies
N/A

O. Compensation to Subjects
None

P. Costs to Subjects
None

Q. Minors as Research Subjects
N/A

R. Radiation or Radioactive Substances
N/A

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