

**Summary of Report on Biostats/EBM Curricular Thread
Submitted 3/3/15 to MSEC**

Reviewed content standards: USMLE testable content, AAMC’s Medical School Objectives Project, EPAs, MedEd Portal, comparable courses at other schools, American Stastical Association.

Objectives

1. List the top causes of morbidity and mortality in the general population and in selected groups; recognize how these data and other health indicators are measured, reported and accessed
2. Formulate focused clinical questions, and effectively utilize databases and other evidence resources to search for answers
3. Generate differential diagnoses based on probabilities, derived from disease incidences and prevalences
4. Assign the maximum acceptable degree of uncertainty for drawing any particular conclusion from a study, or proceeding with any particular management plan in a given patient scenario
5. Predict the utility of a clinical test based on its predictive value, and select accordingly
6. Identify potential sources of error in a study, including:
 - a. Random chance
 - b. Sampling inconsistencies
 - c. Imperfect randomization
 - d. Selective reporting of outcomes
7. Systematically evaluate published studies of various designs for scientific validity and clinical relevance
8. Interpret graphs and tables of patient characteristics, measurements, and outcomes presented in the literature
9. Determine the clinical implications of evidence presented in journal articles as confidence intervals or p-values.
10. Propose strategies for implementing new knowledge into patient care, accounting for potential barriers to change
11. Describe the basic steps involved in a disease outbreak investigation
12. Explain the roles of Institutional Review Boards, informed consent, and HIPAA in research ethics.
13. Participate in patient and colleague education, effectively utilizing electronic media and handouts as appropriate to effectively support formal and informal oral presentations

Current content with areas for improvement:

Course	Current Content	Short Term Improvements	Long Term Improvements
M1			

Profession of Medicine	Population health measures; EBM; cognitive biases	Introduce Thread with Objectives; stress import of EBM; introduce debiasing strategies	Session on IRB; problems with medical literature, textbooks, etc.
COL	Students do literature searches and present topics	Introduce PICO, etc.	
Intro to PE	None	Introduce predictive values of PE maneuvers	Test knowledge of appropriate use of exam online
Biostats & Epid	Passim	Add content related to outbreak investigation; conditions for assuming causation; ROCs	Examples of OR vs RR; appraisal of drug ads; surrogate outcomes; appraisal of study designs; CITI training, ARR; hazard ratios
Cadaver Cases	Students do literature searches and present topics	Require incidence, prevalence rates, etc for diseases; require data about predictive values of tests, etc	Emphasize PICO searches; encourage info about next steps in treatment and statistics behind them
M2			
Practice of Medicine	Emphasis on incidence, prevalence, risks, df dx	Emphasize probability-driven df dx and testing based on predictive values	Consider statistics behind treatment choices, intended and unintended consequences
Microbiology			Outbreak investigation modules
Pharmacology		Present some drugs in terms of NNT, NNH	Introduce EBM databases re drugs
M3			
Transitions	Overview of EBM databases	Review PICO searches, levels of evidence	Session on probability based Df Dx, predictive values of common tests, etc
Core Clerkships	Various passim	Encourage EBM searches (PICO)	Session presenting EBM issues in speciality

Community	Review of library resources, CDC searches, public health projects		
Specialities	Incidence, etc of diseases in H&P		Require discussion of pretest prob, stats behind tests, etc.
M4			
Inpatient Selective	Dependent on preceptor	Require brief EBM presentation	Participate in Journal Club
Keystone	Session on review journal articles		

Outcomes

- USMLE Step 1 and Step 2-CK subset performance
- Regularly obtained student feedback
- Instructor feedback
- Measured outcomes are attainable also in the first year Biostatistics and Epidemiology Course. Assessments on individual sessions in other courses could be obtained once a year from individual course directors, including student evaluations of individual sessions and possibly performance characteristics on individual questions related to content. Also completion rates of required assignments (such as the EBM presentation on the Ob/Gyn clerkship).
- Question 18 of the GQ (“Critically review published material”) is appropriate to this Curricular Thread. Also Question 19 (“I have the basic skills in clinical decision making and the application of evidence based information to medical practice”) is appropriate to this Curricular Thread.

Report of the Working Group on the Biostatistics and Evidence-Based Medicine Curricular Thread submitted to the Curriculum Integration Subcommittee of MSEC (2/11/15)

Working Group members: Howard Herrell, MD, Antonia Roberts, MS4, in consultation with John Kalbfleish, Ph.D.

Introduction

An understanding of biostatistics and epidemiology are necessary for the practice of evidence-based medicine. Although these subjects are also tested on the USMLE, there are few formal standards regarding how they should be taught to undergraduate medical students. Students at Quillen College of Medicine have in the past consistently performed below the national average on USMLE Step 1 and Step 2 CK in the biostatistics and epidemiology subcategories.

We have identified specific potential areas of improvement in our students' biostatistics and epidemiology education across the standard four-year curriculum, and therefore propose ways to improve them and more deeply integrate these topics into existing courses. Our recommendations rest on the premise that a longitudinal curricular 'thread,' through common oversight of teaching content and methods, will help achieve continuity, fill gaps, and eliminate redundancy in what the students are taught, as well as measure specific outcomes related to the content.

We have set the USMLE testable content, AAMC's Medical School Objectives Project (1998), and a published peer-reviewed biostatistics and epidemiology medical school curriculum as the standards underlying our recommendations. Furthermore, we have incorporated advice from officers of the American Statistical Association's section on Teaching Statistics in the Health Sciences. Finally, each component of the following proposed curriculum is rooted in specific Quillen College of Medicine Institutional Educational Objectives.

Also in context of the EPAs: the following are relevant:

- EPA 2: Prioritize a differential diagnosis following a clinical encounter.
- EPA 3: Recommend and interpret common diagnostic and screening tests
- EPA 7: Form clinical questions and retrieve evidence to advance patient care

Goals of the Curricular Thread

The goals are to foster an evidence-based approach to medical learning and clinical decision-making, through the understanding of:

- a. physicians' roles in measuring, reporting and tracking reportable diseases and other population health indicators
- b. how to use available information resources appropriately and efficiently for lifelong learning and practice improvement
- c. how biologic and random variability are quantified, accounted for, and compared
- d. general study design and data analysis principles utilized in published studies
- e. the necessary conditions for inferring causation from correlation
- f. the distinctions between clinical and statistical "significance"
- g. the role of probabilities in the diagnostic process
- h. biases affecting the interpretation of studies, test results, and patient presentations
- i. economic and ethical considerations implicit in any study involving human or animal subjects

These goals are to be met through the following objectives:

Objectives of the Curricular Thread

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Curricular Thread Organization with Current and Future Opportunities

Rationale:

There is currently a 20-hour biostatistics and epidemiology class taught at the end of the first year at Quillen College of Medicine. In addition to a dedicated introductory course such as this, we recommend a formal and cohesive plan to reinforce and build upon the concepts taught in the introductory course throughout the remainder of the 4 years. This will serve several purposes relevant to the aforementioned goals and objectives:

- 1) to provide timely review of the USMLE –relevant content,
- 2) to guide a rational approach to diagnostic and treatment planning in preparation for and throughout the clinical years,
- 3) to familiarize the students with productive ways to search for and assimilate evidence as they continue to encounter new clinical questions
- 4) to instill professional attitudes that will serve the students throughout their careers, including: critically analyzing new information, aptly implementing evidence that is deemed sufficient, and striving to improve patient care on both the individual and corporate levels.

Structure and timing of proposed content is based on typical course layout at Quillen College of Medicine but is easily modifiable:

M1

Setting and time: “Profession of Medicine” –course, with lectures given by various faculty as an orientation during the first 3 days of M1 and occasionally interspersed throughout the remainder of the year. Includes various cultural, ethical, legal, and social topics in medicine, and required community service project.

Current related content:

- 1 lecture discussing population health status measures and rankings (historically by Dr. Wykoff, School of Public Health)
- 1-2 lectures discussing paucity of evidence behind medical practice; high prevalence and burden of medical errors; introducing and defining “evidence-based medicine” (historically by Dr. Franko, Dept. of Family Medicine)
- 1 video lecture on cognitive biases in general, not specifically applied towards medical decision-making scenarios (historically selected by Dr. McGowan)

Opportunities for improvement: (to be added and/or substituted with current lectures)

- Introductory lectures (as early in timeline as possible)– what is Evidence-Based Medicine, how & why statistics fits in with being a doctor; importance of constantly questioning assumptions and dealing with uncertainty
- Lectures with interactive components: Cognitive biases, including examples in medical decision-making, with specific tools for overcoming them (debiasing strategies)
- Lecture discussing problems with quality of evidence in peer-reviewed literature, textbooks, and anecdotal practice
- Basic discussion of research ethics (involve history of unethical research practices; existence of IRB today; ethical mandate to do statistically valid research)
- Give “syllabus” of expected EBM & biostats skills & learning objectives for the whole 4 years.

Setting and time: Case Oriented Learning (general track only) – 2h sessions once weekly throughout year; common case topics taught in small groups by various faculty (same group and faculty throughout year). Students take turns making short presentation on a case

Current related content: Students variably assigned topics to search and present information to group; no specific instructions regarding search strategy or sources

Opportunities for improvement: (to be incorporated into current sessions and content)

- Introduction to basic literature search (PICO) and appraisal (instructions can be in lecture or at-home reading and/or video watching assignment)
- This information could be shared with Rural Track students, particularly if it is an at-home or video assignment
- Proper citation formats, included with above
 - Incorporate these skills into students’ presentation assignments

Setting and time: Introduction to Physical Exam - physical exam techniques are demonstrated and practiced in SP lab in 2h sessions twice weekly; lectures by physician and occasional physician hands-on guidance; weekly reading and online quizzes; culminates in OSCE

Current related content: No content explicitly regarding statistics (namely, probability, sensitivity, specificity)

Opportunities for improvement: (to be added to current sessions and content)

Lecture and/or handout about predictive values of physical exam maneuvers for associated conditions are presented (i.e. when and WHY these maneuvers are done), with online quiz questions after each session or each week

Setting and time: Biostatistics and Epidemiology course - approximately three weeks late in spring semester, 18h lecture, 3 required hand-in calculation assignments and 2h in-house final exam, accompanying notebook (with blanks to be filled-in during class, and optional at-home review problems added) and statistical analysis software that includes examples and explanations

Current related content:

- Structure of typical medical journal article
- Various study designs defined and compared (observational vs. experimental and their respective sub-categories)
- Biases in medical studies listed
- Device & drug clinical trial phases listed
- Measurement scales compared (categorical vs. continuous and their respective subcategories)
- Descriptive statistics for various types of data
- Normal distribution, Z-scale, standard deviation and standard error of mean
- Graphical data representations
- Confidence intervals of means; comparing means
- Hypothesis testing; type I vs. type II errors
- Comparing proportions; chi-square analysis assignment
- Odds ratio contrasted with relative risk
- Sample size determination and power analysis
- Number needed to treat (and –harm)
- Linear regression and correlation coefficients
- Survival analysis and Kaplan-Meier curves
- Epidemiology: basic terms, common vital statistics measures and various physician roles defined
- Historical pandemics listed
- Leading causes of death listed (overall, by age group, and cancer-specific)
- List of reportable diseases, per CDC
- ICD-9 coding appendix provided
- Sensitivity, specificity, predictive values and likelihood ratios of tests
- Effects of disease prevalence on predictive value

Opportunities for improvement: (to be added to current format, and/or substituted for selected topics)

- Examples of appropriate and inappropriate uses of odds ratios (vs. relative risks) when reporting study results
- Epidemiologic outbreak investigation simulations – CDC website has four free downloadable cases based on actual outbreak investigation, each takes ~3 hours to complete
http://www.cdc.gov/epicasestudies/download_classroom.html
- Critical examination of drug ads
- Discuss pros & cons of using surrogate outcomes
- Critical appraisal of the various study designs described
- Conditions for assuming causation from a correlation, with examples of spurious correlations
- Distinguishing clinical from statistical “significance,” with discussions of:
 - Statistically significant but clinically meaningless findings
 - Clinically important although not statistically “significant” findings

- Assigning various levels of significance needed depending on clinical context (e.g. contrast intervention of benign disease with invasive intervention of serious disease)
 - Discuss ethical mandate of appropriate study design and power analysis
 - Hazard ratio
 - Absolute Risk Reduction
 - Receiver-operator curves
- Whenever possible, give a common in-class calculation or online evidence search assignment, to take roughly 5-10 minutes each. Alter certain parameters of the assignment by row or student group, and go over the various outcomes together as a class. Examples of such assignments might include:
- Calculating a diagnostic test's predictive value → students to judge how informative it is (can alter disease prevalence in one instance, and diagnostic cutoff points - thereby sensitivity and specificity - in another instance)
 - Calculate an intervention's absolute risk reduction/number needed to treat → students to judge how beneficial it is (can alter the clinical context/disease severity)
 - Perform a literature search; compare outcomes and utility of various methods (e.g. PICO vs. blind PubMed search vs. Google)
- Consider optional or non-graded midterm exam consisting of old or similar test questions, to help students identify their weaknesses before final exam

If the above additional content cannot be made to fit into current course, then other opportunities exist through the Curricular Thread for integration.

Setting and time: Cadaver Case Presentation, done at end of M1 year with anatomy group – roughly 10min presentation given to rest of class on chosen topic related to assigned cadaver

Current related content: Student groups present overview of their chosen disease

Opportunities for improvement: (to be incorporated into current requirements and evaluation criteria)

- Incorporate skills of basic literature search (PICO), appraisal, and desired citation format into students' presentation assignments (as in "Case-oriented learning" above)
- Require reporting of disease incidence, prevalence, mortality rates
- Require discussion about diagnosis: pretest probability, predictive values of typical physical exam maneuvers and/or diagnostic tests
- Require brief discussion on prognosis and "next step" after initial diagnosis; can include confirmatory testing and empiric or targeted therapy; give NNT and NNH when available

Future Opportunity (resource dependent): Evidence-based medicine elective open to M1-M2 students

Details:

- Content to consist of topics related to some or all of the following:
 - basics of literature appraisal and journal club primer;
 - statistics without equations;
 - discussion of cognitive biases;
 - misuses of statistics in medicine and science
- To meet one afternoon weekly for a limited number of weeks throughout a semester, similarly to currently offered End-of-Life interdisciplinary elective, Medical Spanish elective, and Healer's Art elective

- Graded as pass/fail, based on participation in in-class assignments; minimal outside-of-class work

M2

Setting and time: Practice of Medicine (general track only) – one full day per week throughout year. Common cases worked in small groups (6-8 students), starting with SP encounter in the morning, afternoon discussion with faculty in the afternoon. Students stay in same group all year; faculty rotate groups every 2-3 weeks.

Current related content: (variable by assigned faculty) individually written patient assessment & plan in SOAP-note format required each week. Online quiz, typically asking about incidence/prevalence, risk factors, and differential diagnosis.

Opportunities for improvement: (to be uniformly incorporated into current setup, including quiz questions and components of weekly SOAP-note assignment. References to best information resources for this content should also be provided)

- Emphasis on probability-driven differential diagnosis
- Testing selection based on predictive values of tests and risk/benefit considerations
- Treatment recommendations based on comparison of projected beneficial vs. deleterious effects, and level of diagnostic certainty desired for proposed treatment course
- These standard approaches would need to be shared with Rural Track preceptors

Setting and time: Microbiology (year-round, roughly 9h lecture per week by various faculty within department)

Current related content: Comprehensive overview of disease pathophysiology and transmission

Opportunities for improvement:

- Explicit review of reportable communicable diseases (incl. how each are transmitted)
- Review of epidemiologic outbreak investigation (this may take the place of or simply reinforce the content provided in the Biostatistics Course)

Setting and time: Pharmacology (spring semester, roughly 8h lecture per week by various faculty within department)

Current related content: Comprehensive overview of drug therapeutic mechanisms and toxicities

Opportunities for improvement:

- Concise risk/benefit profile of selected drugs (such as number needed to treat; number needed to harm)
- Comments on whether drugs are currently used clinically, ideally solicited from clinicians and/or provided as references to information sources for students to look up on their own.

Future Opportunity (resource dependent): Biostatistics & epidemiology USMLE review session

Details: near end of M2 year, 1-hour mandatory session blocked off for giving a brief practice test of USMLE –style biostatistics & epidemiology questions, to be graded immediately by students in-class and followed by Q&A and discussion.

M3

Setting and time: Transition to 3rd year – 1 week prior to beginning first clinical clerkship; covers various topics including gowning & gloving, breast and pelvic exams, suturing, intramuscular injections, complex wound classification

Current related content: Overview of electronic information resources provided by medical library: Epocrates, Micromedex, DynaMed, and others; HIPAA refresher

Opportunities for improvement: (to be added or substituted in with current course content)

- Give interactive lecture on PICO search
- Give lecture and/or handout overview of “levels of evidence” / strength of recommendations
- Interactive lecture reviewing probability-based differential diagnosis, predictive values of common tests, and morbidity/mortality outcomes of common therapies weighed against their risks

Setting and time: Core clerkships (6 weeks each) in rotating order – Family Medicine (general track only), Obstetrics & Gynecology, Surgery, Internal Medicine, Pediatrics

Current related content:

- Ob/Gyn: Biostatistics review (1-hour lecture), Cognitive Biases in clinical medicine (1-hour lecture). Required short EBM-based presentation of selected topic in morning report.
- Family medicine (general track only):
 - Lecture on PICO searches at beginning of rotation; required 10-minute student presentations of best evidence on FM–related topic of student’s choice, utilizing PICO search (at end of rotation)
 - 1-2 informal ‘morning report’ topics assigned to student by attendings’ discretion (roughly 5 minute oral summary, can make handouts or PPT according to preference)
- Internal Medicine: 1-2 informal ‘morning report’ topics assigned to student at attendings’ discretion (roughly 5 minute oral summary, can make handouts or PPT according to preference)
- Surgery: each student assigned 1-2 formal case presentations to group (for weekly didactic day and/or Saturday morning sessions) in which differential diagnosis & management are discussed; mandatory attendance of weekly resident EBM-presentation
- Pediatrics: informal topics assigned to students at attendings’ and residents’ discretion while on wards, involving brief oral summaries after searching for evidence on given topic

Opportunities for improvement: for *each* clerkship:

- a didactic lecture on evidence-based medicine (ideally diverse, complementary to each other, and applied to that particular specialty)
- student EBM-topical presentation requirement utilizing PICO search

Setting and time: Community medicine (general track only) – 6 weeks based in Sevierville at LeConte Medical Center, of which 1 week devoted to health fair at varying rural underserved locations; health fair week does include rural track students

Current related content:

- Review of medical library electronic information resources, given by library personnel (1-2h)
- Interactive tutorial on searching CDC- and related website for various population health statistics and rankings
- Required presentation to group of various assigned community health indicators of given region

- Required tallying of data from patient encounters during health fair (such as chief complaint, smoking status, etc) ultimately combined and compiled into one Health Fair Report

Opportunities for improvement: No changes particular to this clerkship are proposed currently.

Setting and time: Specialties – 3 different 2-week rotations in specialties of student’s choice, covering surgical, medical and primary care fields; required oral presentation of H&P as well reflection and discussion of encountered social issue at end of rotation

Current related content: With H&P presentation, discussion of disease including incidence, diagnosis, and therapy

Opportunities for improvement::

Add formal requirement with H&P presentation to include:

- disease incidence, prevalence, and differential diagnosis
- patient’s pretest probability at presentation for the disease (based on general prevalence and patient’s risk factors)
- predictive values of physical exam maneuvers and diagnostic tests
- morbidity/mortality benefits of treatment options weighed against risk profile
- prognosis

M4

Setting and time: Inpatient Selective, inpatient – 4 weeks required for each student, involves 1 day each week of didactic lectures in-classroom or by video, and 1 morning of procedures in SimLab

Current related content: (variable by assigned team and patient load)

Content proposed:

- As proposed for M3-internal medicine clerkship, prepare one brief presentation on relevant topic, supported by best evidence found from PICO search
- Participate in one resident journal club session

Setting and time: Biostatistics & research design elective, 2 weeks, arranged with biostatistics professor

Current related content: Highly variable, tailored to student’s specialty area of interest; typically focused on data analysis of student’s ongoing research project

Setting and time: Keystone, 3 weeks at end of 4th year, required; wide range of lecture options for students to choose from

Current related content: Variable by year and speaker availability. Previous year included lecture on journal article review with pertinent biostats.

Future Opportunity (dependent on fourth year restructuring): required “transition to 4th year”

Details: if created could include a session focussing on a refresher on biostatistics and literature appraisal (oriented towards preparation for journal clubs)

Future Opportunity (resource dependent): Journal club

Details: run year-round by consistent group of faculty (with or without help from senior residents in various specialties), monthly as practical; requirement for each student to attend 2 of these sessions throughout the year. This has been happening already informally with groups of students in the third and fourth year but is limited to only one faculty member (Dr Herrell).

Future Opportunity (currently in development): Evidence-based medicine –online senior elective
Details: 2-week online elective reviewing cognitive biases and cognitive forcing skills, probabilistic differential diagnosis, basic biostatistics, test selection based on predictive values, dealing with diagnostic uncertainty, critical appraisal of various types of published medical literature, etc.

Outcomes

We recommend tracking each student’s progress in these topics across their time at QCOM. Some specific skills or participation events could be added to the New Innovations tracking of procedures, such as performance of a PICO search or attendance at a Journal Club.

Success of this proposed curriculum should be tracked by:

- USMLE Step 1 and Step 2-CK subset performance
- Regularly obtained student feedback
- Instructor feedback
- Measured outcomes are attainable also in the first year Biostatistics and Epidemiology Course. Assessments on individual sessions in other courses could be obtained once a year from individual course directors, including student evaluations of individual sessions and possibly performance characteristics on individual questions related to content. Also completion rates of required assignments (such as the EBM presentation on the Ob/Gyn clerkship).
- Question 18 of the GQ (“Critically review published material”) is appropriate to this Curricular Thread. Also Question 19 (“I have the basic skills in clinical decision making and the application of evidence based information to medical practice”) is appropriate to this Curricular Thread.

References

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