Academy of Master Educators – Task Force on Virtual EBM Center

Progress Report: 26 May 2009

The primary update over the last six months consists of the collaborative development of an application to the NIH Challenge Grant Program in the category of Science, Technology, Engineering, and Mathematics Education (STEM) for faculty development in the area of evidence-based medicine. The application involves members of the Task Force as well as Drs. S. Kanter, J.B. McGee, and J. Chang. A copy of the application begins on the next page. A decision from the NIH is expected by September.

Goutham Rao, MD
Chair, AME Task Force on Virtual EBM Center
Specific Aims:

The skills necessary to practice evidence-based medicine (EBM) include (1) clearly defining a sound clinical question; (2) efficient and effective searching for evidence to answer the question; (3) critical appraisal of the evidence; (4) gaining a complete understanding of study results; and (5) integration of the evidence into patient care. The proposed research addresses the interpretation of results and integration of evidence into patient care (4 and 5). These two skills require some understanding of research design, biostatistics, and how to combine research evidence with clinical experience, knowledge of the availability of resources, and patient preferences. Unfortunately, physicians are unskilled in these areas, particular with the quantitative aspects of study design and analysis. There is evidence, for example, that physicians have a poor understanding of risk and probability. Over the past decade, evidence-based medicine has been incorporated into undergraduate and graduate medical education in the form of courses, seminars, and journal clubs. It is also part of one of the six core competencies for medical education (practice-based learning and improvement) put forth by the Accreditation Council for Graduate Medical Education (ACGME). Greater emphasis on EBM and the lack of understanding of physicians, including those in academic programs, of the quantitative aspects of study design and analysis, have uncovered a serious need for faculty development in this area. The proposed research is designed to meet the following specific aims:

1) Refinement and dissemination of a web-based course for physicians that addresses basic quantitative aspects of clinical epidemiology and biostatistics, hereby referred to as “physician numeracy.”

It is hypothesized that a high quality web-based course featuring streaming video lectures, multiple self-assessments, and the ability to interact with course faculty and other students can be created and easily disseminated free of charge to any physician or other interested party.

2) Evaluation of the impact of the web-based course upon knowledge acquisition, self-efficacy of physicians in the course content, ability to interpret new research evidence, and self-reported incorporation of content into teaching.

It is hypothesized that physicians who complete the course will be much more knowledgeable, confident, and skillful in their ability to interpret new research evidence compared to those who do not.
Research Plan:

I. Research Area: The proposed research falls under the Science, Technology, Engineering, and Mathematics (STEM) broad challenge area and the Teacher preparation development programs to support STEM teaching (12-OD-102) specific challenge topic.

II. The Challenge and Potential Impact: Practice-based learning and improvement is among the six core competencies described by the Accreditation Council for Graduate Medical Education (ACGME). Residents must demonstrate skill in “locating, appraising, and assimilating evidence from scientific studies related to their patients’ problems and apply knowledge of study designs and statistical methods to the appraisal of clinical studies.” These skills are similar to those described as necessary to practice evidence-based medicine (EBM) by Guyatt et al: (1) recognition of a patient problem and construction of a structured clinical question, (2) efficient and effective searching for information resources to retrieve the best available evidence to answer the clinical question, (3) critical appraisal of the evidence, (4) gaining a full understanding of the study results, and (5) integration of the evidence into patient care.

Teaching evidence-based medicine is becoming widespread both at the undergraduate and graduate levels. Medical schools and residency programs have incorporated EBM into journal clubs, seminars, and formal courses. Teaching EBM is still relatively new and the necessary skills are unfamiliar to many medical educators. It is not surprising that the most common teaching format is journal club, for which students and residents themselves are primarily responsible and which requires minimal preparation on the part of faculty and other participants. Journal clubs focus excessively on critical appraisal skills and little upon achieving a quantitative understanding of the study results and how to integrate these results into patient care. This is not surprising since there is evidence that physicians in various settings, including medical educators, are especially uncomfortable with key concepts of clinical epidemiology and biostatistics needed to practice EBM. These key concepts make up physician numeracy, defined as the ability to understand the quantitative aspects of medical research and practice. This includes, for example, identifying the advantages and disadvantages of different study designs, interpretation of p values and confidence intervals, and explaining concepts such as risk and probability to patients in a way they understand. Though physician numeracy is generally poor, there is evidence that physicians and trainees regard it as important. A survey of Massachusetts physicians, for example, revealed that 76% felt that understanding and communicating risk in quantitative terms is important. In another survey, 95% of residents believed it was important to understand key biostatistics concepts used in original research papers, though 75% reported low confidence in this area, and answered a mean of only 41% of biostatistics questions correctly on a knowledge quiz.

In summary, medical educators have a responsibility to teach EBM to students and residents, including teaching physician numeracy. Unfortunately, this aspect of EBM has long been neglected since medical educators, like physicians in general, are uncomfortable with key numeracy concepts. Furthermore, opportunities to improve physician numeracy are extremely limited. Few faculty development or continuing
education programs emphasize numeracy. A large number of medical educators, therefore, are in need of physician numeracy education, so that they can incorporate a full range of skills into EBM teaching, and improve their own practice of EBM. The proposed research includes a plan to educate medical educators through a web-based course and, as an integral part of the project, to assess the impact on those educators.

The breadth of impact of the proposed research is very large. The primary targets are physicians involved in teaching at the undergraduate or graduate level. The secondary targets, of course, are the students and residents who benefit from this teaching. In 2007, the American Medical Association (AMA) identified 10,471 physicians in the U.S. whose primary activity is medical teaching. This is undoubtedly a gross underestimate of the number of physician medical educators, many of whom teach part-time. Even so, a potential population of more than 10,000 physicians is very significant. A web-based course on physician numeracy can be easily disseminated free of charge to any interested physician. Its potential impact upon how evidence-based medicine is incorporated into training is therefore major.

III. The Approach:

Overview: Web-based continuing medical education (CME) has several advantages over “traditional” (live) CME. Learners have control over the time and place of learning. Web-based courses are easy to access and update. Recent evidence has shown that web-based learning is comparable or superior in promoting measured changes to physician behavior and sustained changes in knowledge to live CME.

The approach to meeting the unmet need for physician numeracy education is first to refine an existing set of video lectures on key topics and incorporate these into a comprehensive web-based course that features pre and post-lecture quizzes, clinical vignette problems that require interpretation of research data, links to additional resources, and creation of an online community for sharing of resources and ideas. The impact of the course will be determined by recruiting physician educators from the Pittsburgh area who represent a broad range of specialties and practice settings. Half will be randomized to first complete the course and then a set of online clinical vignette problems. The other half will first complete the clinical vignette problems, and will then be asked to complete the course afterwards. Clinical vignette problems will be scored by five physicians (evaluation panel) who are blinded to participants’ group assignment. The primary outcome will be performance on these assignments. Key secondary outcomes will include knowledge acquisition as measured by difference in performance on pre and post-lecture quizzes and self-efficacy of physicians with key concepts as measured through pre and post course surveys. All research participants will be surveyed 6 months after course completion to determine the extent to which they have incorporated course content into their teaching.

Specific Aim #1:

A web-based course will be developed using an existing educational learning management program available from the Laboratory for Educational Technology at the University of Pittsburgh. Refinement of video lectures and supplemental content will be completed by the PI, Dr. McGee, and laboratory staff, all of whom have considerable experience in developing web-based programs for teaching physicians and continuing
education courses. This team has also designed and executed a number of academic studies on web-based learning by physicians.

**Content for Web-Based Course:**

Course Platform: The Navigator Learning Management system is a web-based platform that has supported all medical student courses, resident training programs, and many continuing education programs at the University of Pittsburgh since 2002. It was developed internally at the University of Pittsburgh and is being improved on a regular basis. It now includes over 300 courses and 7000 regular users. The system features course management and assessment tools and integrates features such as videos, quizzes, blogs, and discussion boards.

Video Lectures: The web-based course will be entitled *Physician Numeracy*. Its core content will be a series of ten video lectures, each roughly forty-five minutes in duration. The video lectures have already been recorded as a supplement to a mandatory course for first year medical students entitled, *Introduction to Medical Decision Making*. Their technical quality, however, is at times poor. The original lectures were not specifically intended for medical educators. For these reasons, the lectures will be re-recorded in a high quality format at the Laboratory for Educational Technology, and will include specific teaching tips that are useful for medical educators. Lectures will feature high quality video and audio, and easy navigation, such that participants can stop, pause, and rewind the video as needed using Mediasite technology (Sonic Foundry, Madison WI).

The content for the lectures is based upon the book *Rational Medical Decision Making: A Case-Based Approach*. Content is organized according to a standard EBM paradigm, whereby studies are categorized according to the type of problem they address or their general design. Key numeracy topics in each study category are included. Statistical topics have been selected based upon those that appear most commonly in the general medical literature. These topics are discussed in enough depth to allow physicians to understand research articles, but not to the degree necessary to perform advanced statistical analysis or to design research studies from scratch. For example, for the $\chi^2$ test, physicians will be expected to do the following:

- Describe the basic rationale behind the test.
- Describe the types of data to which the test is applied.
- Describe how to determine if a $\chi^2$ value is statistically significant.
- Describe the advantages and limitations of the test.

The specific content for each lecture is described in Table 1.

<table>
<thead>
<tr>
<th>Module or General Topic Area</th>
<th>Lecture</th>
<th>Specific Lecture Topics</th>
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<tbody>
<tr>
<td>Common Descriptive and Statistical Analysis</td>
<td>1. <em>Descriptive Statistics</em></td>
<td>Types of data, normal distribution, mean, median, standard deviation.</td>
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<tr>
<td>Comparative Statistics</td>
<td>2. Comparative Statistics, Correlation, and Regression</td>
<td>Analysis of variance, t tests, Chi-square test, overview of non-parametric tests. Introduction to concepts and types of correlation and regression, Pearson’s correlation coefficient, how to interpret regression analyses.</td>
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<td>Diagnostic Reasoning</td>
<td>3. How Doctors Think about Diagnosis</td>
<td>Inductive and deductive reasoning, pattern recognition, definition and purpose of screening.</td>
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<td></td>
<td>4. Quantitative Evaluation and Interpretation of Diagnostic Tests</td>
<td>2x2 tables and test characteristics (sensitivity, specificity, predictive values, likelihood ratios). Origin and applicability of Bayes theorem to use of diagnostic tests, odds vs. probability, calculation of post-test odds and probability, errors that influence estimate of pretest probability of disease (e.g. “conjunction fallacy”).</td>
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<td>Studies of Therapies</td>
<td>5. Design of Studies of Therapies</td>
<td>Types of study design to evaluate new therapies, definitions of confounder, internal validity, external validity, bias, sampling, type 1 error, type 2 error, power, randomization, allocation, allocation concealment, and general principles of sample size estimation.</td>
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<td></td>
<td>6. Interpretation of Studies of Therapies</td>
<td>Intention-to-treat, relative risk reduction (RRR), numbers needed to treat/harm (NNT/NNH). Interpretation of p values and confidence intervals, p value fallacy.</td>
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<td>Etiology</td>
<td>7. Essential Concepts in Interpretation of Studies of Etiology</td>
<td>Cohort &amp; case-control studies and advantages of each, relative risk (RR), odds ratios ORs), why RR cannot be used for case-control studies, 95% confidence intervals for ORs and RR.</td>
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<tr>
<td>Systematic Reviews</td>
<td>9. Overview of Systematic Review</td>
<td>Definitions of systematic review, meta-analysis, narrative review, overview of key steps in development of a systematic review, Definitions of heterogeneity, Cochran’s Q statistic, inconsistency, fixed and random effects models, Interpretation of forest plots, General description of sensitivity analysis, bias in development of systematic reviews, and funnel plots.</td>
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Pre and Post Lecture Quizzes:
Course participants will be required to complete pre and post lecture quizzes for each video lecture to measure knowledge acquisition. Each quiz will consist of ten multiple choice questions. Pre and post lecture quizzes will not be identical but will include questions of similar difficulty. All questions will be obtained from a large bank of questions developed over the course of several years by the PI.

Pre and Post Course Surveys:
A survey instrument developed and used by Windish, Huot, and Green to measure statistical attitudes and confidence will be administered to all course participants before and immediately after completing the course. Upon registration, course participants will also be asked basic demographic information as well as questions about practice specialty, practice type, years in practice, and previous experience and education in the fields of statistics and epidemiology.

Links to Additional Resources:
The course will include a number of links to outside resource including other related courses, recommended online papers, online calculators, etc. These links have already been compiled by the PI for the undergraduate course he directs.

Online Community:
Course participants will become part of an online community. Should they wish, their demographic, contact, and other information will be stored in a database which can be searched by other participants. Participants will also have the opportunity to share ideas and resources through an online messaging board.

Clinical Vignette Problems:
Clinical vignettes are a valid tool for measuring physician practice behavior and quality of care. Course participants will be asked to complete a set of five clinical vignette problems, either immediately after registration (if assigned to the control group intervention in the proposed randomized trial) or immediately upon completion of the course. Vignettes will not require additional knowledge that is specific to any specialty or subspecialty. Vignette problems will be based upon problems previously developed by the PI as part of an undergraduate course and are designed to evaluate the following:
- The ability to accurately interpret quantitative and other information about research design or analysis.
- The ability to apply this information to a simulated patient problem in a way that not only takes into consideration the evidence, but also other aspects of the patient or patient’s condition.

A sample clinical vignette problem is shown below. Vignette problems each include three questions, to which course participants are expected to provide free text answers. Responses to each question will be graded in the following manner:
- Answer is complete and accurate (2 points).
- Answer is incomplete or only partly accurate (1 point).
- No answer is provided or the answer provided does not address the question or is wholly inaccurate (0 points).

Sample Clinical Vignette Problem:

Patricia Hansen is a sixty-one year old woman who was diagnosed with osteoarthritis of both knees approximately two years ago. Since that time, she has been treated with
short courses of non-steroidal inflammatory (NSAID) medications. She also attended three physical therapy sessions when she was first diagnosed, after which she was advised to carry out exercise therapy at home. She comes to see you for increasing pain and increased need for medication. She is able to carry out her usual activities, but with some difficulty. Mrs. Hansen is obese, but apart from osteoarthritis, has no other medical problems. Your physical examination is consistent with moderately severe osteoarthritis. Mrs. Hansen asks you if she would benefit from arthroscopic knee surgery, which her sister had a few years ago. You search for evidence and retrieve the following paper:


An intervention group that underwent surgery was compared with a control group that underwent intensive physical and medical therapy. Groups were compared with respect to the WOMAC score, a validated measure of disability from osteoarthritis (higher scores are associated with greater disability) over the course of two years. Mean WOMAC score for the surgical group was 874 ± 624. The mean score for the control group was 897 ± 583. Difference = -23, 95%CI (-208 to 161). Baseline scores were 1187 ± 483 and 1043 ± 542 in the surgery and control groups respectively.

Question 1:
Assuming Mrs. Hansen resembles patients in the trial described above, what recommendation would you make to her regarding surgery versus intensive medical therapy?

Question 2:
WOMAC scores are continuous and normally distributed. The investigators estimated that 186 patients would be required for the study to provide 80% statistical power to detect a 200 point difference between the two treatment groups. The standard deviation of WOMAC scores was estimated to be 452. Roughly how many patients would be needed to detect a 100 point difference between the two treatment groups?

Question 3:
The investigators measured several different outcomes, including a measure of quality of life using a “standard-gamble utility score.” Scores range from 0.0 (death) to 1.0 (perfect health). Describe how you might use a standard-gamble method to determine Mrs. Hansen’s utility score prior to either surgical or intensive medical and physical therapy.

Educational Strategy:
The strategy underlying the Physician Numeracy course is consistent with the strategy for EBM education based upon adult learning theory described by Green and Ellis. Table 2 summarizes the assumptions underlying adult learning theory and the features of the course which satisfy these assumptions.

Table 2: Adult Learning Theory and Physician Numeracy Course

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<tr>
<th>Assumption</th>
<th>Course Feature(s)</th>
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<td>Adults need to learn why they need to learn something.</td>
<td>The importance or rationale for learning each topic in the curriculum will be described at the beginning of each video lecture.</td>
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<td>Adults prefer responsibility for their decisions and prefer self-directed learning.</td>
<td>The only requirement for course participants is to complete the quizzes, surveys, and clinical vignette problems. Learners may view all or part of any of the</td>
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</table>
video lectures at their discretion for preparation. They are encouraged to explore links to other sites to enhance their learning.

**Adults accumulate a greater volume of experience than children – a resource for learning and which necessitates individualized learning strategies.**

When disseminated widely, learners will be encouraged to complete only the parts of the course they believe they need. Furthermore, several strategies for learning are built into the course such as viewing lectures, viewing only PowerPoint slides separately, listening to audio only, or only studying recommended paper resources.

**Adults become ready to learn things when they need to know them to cope with real life situations.**

The course will be easy to navigate making it simple to review or complete parts of the course as needed.

**Adults are life-centered rather than subject-centered.**

Clinical vignette problems have been designed to simulate real life problems that require physician numeracy.

**Adults’ most potent motivators are internal rather than external.**

The course has been designed to meet a very specific educational need among medical educators with an interest in EBM. It will be distributed and evaluated among physicians with a genuine need for and interest in EBM.

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**Specific Aim #2:**

**Usability Assessment:**

The course evaluation panel that will score clinical vignettes will also participate in usability assessment of the course. A usability specialist will observe and record how physicians navigate the course, and suggest technical improvements that will be made prior to enrollment of main research participants.

**Recruitment of Research Participants:**

Participants will be recruited by the PI and Dr. Kanter through email and through formal information sessions to be held in April and May 2010. The primary targets for recruitment will be volunteer medical educators who are affiliated with the University of Pittsburgh School of Medicine and provide invaluable education to medical students, residents, and fellows in community hospitals and private practices. This group was selected because they have less access to continuing education and other activities available or sponsored by the medical school than full time faculty members. Enrollment in the proposed research and participation in *Physician Numeracy* will be offered in appreciation for their efforts. An email will be sent to all volunteer medical educators in March 2010 briefly describing the course and research project. Interested physicians will be able to contact a research coordinator for more details, and to attend one of three formal, evening information sessions led by the PI. The purpose of the research and the content of the course will be described in detail, together with requirements for
participation. The PI will be available to answer any questions. A light dinner will be provided at each session. The PI will also personally encourage faculty members to inform others about the study (See Barriers/Challenges). The goal will be to recruit approximately 100 participants. Participants will be required to provide written informed consent.

Randomization:
The research coordinator will use a simple, block randomization sequence to allocate participants to either a control arm or intervention arm. Control group participants will only have access to the pre-course survey and clinical vignette problems upon registration for the online course. They will be given one month to complete these problems. Intervention group participants will have full access to the course and will be required to complete the pre-course survey, view the video lectures and finish pre and post video quizzes, and complete the clinical vignette problems in that sequence. They may access the online community or additional resources at any time, but will not be required to do so. All participants will be encouraged to complete the clinical vignette problems on their own, without consulting experts, other web sites, books, etc. Intervention group participants, however, will be able to review any part of the video lectures or quizzes as they complete the vignette problems. All participants will begin the study at the same time. This is to minimize the contamination that may occur if participants start the study immediately after recruitment. Under such circumstances, participants who complete the clinical vignette problems and/or course early may relate their experience or knowledge to colleagues who have not yet completed the course and bias the results. Some degree of contamination by subjects who complete the vignettes and/or course early is, of course, unavoidable.

Course Completion:
Intervention group participants will have four months to complete the course including clinical vignette problems. The PI and research coordinator will be available throughout this period by email and telephone to address any questions regarding course content or the research study. A technical support professional from the Laboratory for Educational Technology will be available to respond to technical issues. All participants will periodically receive email reminders from the PI to complete the course on time. Once they have completed the clinical vignette problems, control group participants will have full access and may complete any or all parts of the course. Clinical vignette problems will be scored by a panel of five physicians (course evaluation panel), with experience in teaching EBM. The panel will be blinded to participant group assignment. Suggested responses to problems will be provided to panel members by the PI.

Follow-Up Survey:
All study participants will be surveyed through email six months after course completion. They will be asked whether or not (yes/no response) they had incorporated key numeracy concepts into their teaching since completion of the course. Furthermore, the survey will include the following open-ended questions, the responses to which can be of any length and will be reviewed and summarized by the research team:

- How has your experience with the physician numeracy course impacted your practice of medicine in general?
- How has your experience with the physician numeracy course impacted your teaching in general?
Data from pre-course surveys, clinical vignette scores, and follow-up surveys for control group participants will be recorded. Data from pre and post-course surveys, pre and post-lecture quizzes, clinical vignette scores, and follow-up surveys for intervention group participants will be recorded. Follow-up survey data will be summarized with descriptive statistics and summaries of open-ended responses. Between group and before-after statistical analysis will be completed with the help of Dr. Joyce Chang.

Dissemination:
All participants will receive individual feedback in the form of reports sent by email about their performance on clinical vignette problems and pre and post-lecture quizzes. Reports will be prepared by the PI and research coordinator and will be sent between April and July 2011. In addition, the PI and co-investigators will prepare a manuscript suitable for publication in a leading medical education journal based on the results of the study between July and October 2011. The course will be introduced to a broad spectrum of medical educators through MedEdPORTAL, a free peer-reviewed publication and repository service for medical education materials sponsored by the Association of American Medical Colleges (AAMC) in the fall of 2011.

Barriers/Challenges:

1. Technical Quality of the Course
To be useful and well accepted by medical educators, an online course must be easy to view and navigate with a standard high speed internet connection. The technical quality of the course will be systematically evaluated by a usability specialist who will work closely with the course evaluation panel and the Laboratory for Educational Technology.
to suggest feasible technical changes. It is expected that this preliminary step will prevent serious technical problems which may hinder successful participation by course participants.

2. **Recruitment:**
In addition to informing and recruiting participants by email and evening sessions, the PI will use his relationship with medical faculty to disseminate information about the study. The PI is director of a mandatory course in clinical epidemiology and biostatistics that includes approximately twenty-five faculty members who have served as small group facilitators for the course, in some cases, for more than ten years. The PI will ask each of these faculty members to inform any volunteer faculty they may know personally about the study and the course. Dr. Kanter has committed the resources of the Office of the Senior Associate Dean to the recruitment effort. His office will send out detailed information by email about the study and reminders of upcoming information sessions. It is expected that an approach that involves personal contact, email, and formal sessions will result in recruitment of a large enough number of participants to demonstrate a significant impact of the course upon physician performance in completing clinical vignette problems.

3. **Retention:**
Completion of the course by intervention group participants requires a significant commitment of approximately 15 hours over the course of four months. Though there will be no cost for participation, and participation in the course qualifies for elective continuing education credits for most physicians, it is acknowledged that an additional incentive will help retain participants and encourage course completion. Upon completion of the clinical vignettes, all participants (i.e. control and intervention groups) will receive a gift certificate worth $150, valid for use at select businesses in the Pittsburgh area.

4. **Complexity of Course Content:**
The content of the course is undoubtedly unfamiliar and will be perceived as complex to many participants, who may have little or no prior training in clinical epidemiology, statistics, or EBM in general. Moreover, the course covers broad range of topics in a limited number of video lectures. Some participants may be concerned about the density of the course. The course, is however, based on an existing undergraduate course which the PI has taught for nine years, and which has consistently received excellent reviews by students. Lectures will also closely follow a widely used textbook written especially for physicians. As noted above, complex statistical topics will be covered only in enough depth to provide physicians with the knowledge and skills necessary to become skilled interpreters of original research literature.

**IV. Timeline**
Below is a timeline for research activities that includes important milestones. Also included is a list of alternate paths to be followed if specific milestones are not met.

Figure 3: Timeline
Alternate Paths if Milestones are not Met:

1. **Completion of retaping of video lectures by 01/05/2010:** In case the PI is unable to complete retaping of video lectures by 01/05/2010 in a high quality format, the physician numeracy curriculum will not be modified. Instead, the PI will rely upon previously taped lectures in the old format to provide a complete course.

2. **Completion of website features, usability testing, and refinements by 06/15/2010:** The website’s technical features described in this proposal are well within the developmental capabilities of the Laboratory for Educational Technology.
However, usability testing may result in suggestions for improvements that are not technically feasible or that may require too much time. The priority under such circumstances will be to adhere to the research timeline as closely as possible. Technical improvements that are too difficult or time consuming will be foregone in favor of beginning the evaluation phase of the study (Specific Aim #2) on time.

3. **Inability to recruit 100 participants by 06/15/2010:**
   The research team will make every effort to recruit 100 participants. Should the team fall short of this goal, however, they will proceed with the evaluation phase only with the subjects recruited by 06/15/2010. (I.e. The recruitment phase will not be extended.)

4. **Participants unable to complete clinical vignettes by 7/15/2010 or 10/15/2010 (control and intervention groups):**
   Participants will receive multiple reminders to complete required components by the deadlines by the research coordinator. Furthermore, they will be advised to contact the PI or research coordinator at any time with problems in completing activities on time. Subjects who cannot complete clinical vignettes on time will not be given additional time. All clinical vignette problems will be scored and analyzed, regardless of whether individual participants complete all five problems.

**Protection of Human Subjects:**

**Risks to Human Subjects**

a. **Human Subjects Involvement and Characteristics:**
   The primary subjects are volunteer physician educators affiliated with the University of Pittsburgh School of Medicine. They will participate in completion of the physician numeracy course including its evaluative components, and also in an email survey six months later. An evaluation panel, consisting of five faculty physicians, will be involved in usability testing and in scoring clinical vignette problems completed by the primary subjects. The evaluation panel is part of the research team. Approximately 100 volunteer physician educators will be enrolled, ranging in age from roughly 30 to 75. No exclusion criteria will apply to the population from which they will be recruited.

b. **Sources of Materials**
   The material collected from the primary research subjects will include responses to the pre and post course surveys, responses to pre and post lecture quizzes, responses to clinical vignette problems, and responses to a follow-up survey. In addition, basic demographic information and information about current specialty and prior experience with clinical epidemiology and biostatistics will be collected as part of the physician numeracy course. All information will be collected online. Individually identifiable information will be accessible only to the PI, Drs. Kanter and McGee, the research coordinator, and staff from the Laboratory for Educational Technology. The physician evaluation panel will only have access to responses to clinical vignette problems that have been de-identified.

c. **Potential Risks**
The only foreseeable significant risk to research subjects is frustration, inconvenience or both in having to complete the physician numeracy course. Data collected online will be accessible only to the research team, but there is a small risk of it being exposed to parties outside the research team.

Adequacy of Protection Against Risks:

a. Recruitment and Informed Consent

The research subjects will be recruited through email, through personal contact, and through evening information sessions. All participants will be required to provide informed written consent, which will be obtained by the research coordinator after participants express interest in the study. The research coordinator will speak with potential participants either by phone or in person to explain the study in more detail including its purpose, the time commitment, the risks, and the benefits. Potential participants will then be given a detailed written consent form which they may sign and return to the research coordinator anytime during the recruitment period. The research coordinator and PI will be available during the recruitment period to answer any questions or address concerns from potential participants.

b. Protections Against Risk

The research team will have password-protected administrative access to the physician numeracy course for collection of data which will minimize the risk of exposing individual physician data to outside parties. The research coordinator and a technical support person will be available to assist participants in completing the course and help minimize any frustration experienced due to technical problems. The time commitment and course requirements will be explained in detail to all potential participants prior to obtaining consent, so that participants are clear about the expectations of the study. This will help minimize frustration they may experience due to the length of the course. Participants may withdraw from the study at any time.

Potential Benefits of the Proposed Research to Human Subjects and Others:

Research subjects will have the opportunity to learn a great deal about a key element of evidence-based medicine and fulfill a significant faculty development need. They will have the opportunity to improve their understanding of original medical literature, and will be better able to incorporate research evidence into their patient care and teaching. All research participants will also be able to claim elective continuing education credit for completing part or all of the physician numeracy course.

Importance of the Knowledge to be Gained:

Should the proposed research demonstrate a significant impact upon participants in terms of knowledge, self-confidence, and incorporation of physician numeracy into teaching, the course will constitute a valuable and easily disseminated resource for medical educators and physicians in general.

Data and Safety Monitoring Plan:
The PI will be primarily responsible for data and safety monitoring. He will meet with the research coordinator and Laboratory for Educational Technology personnel on a weekly basis to discuss participants’ concerns, including technical problems that may interfere with participants’ participation. He will also periodically remind the research team and Lab personnel to maintain the privacy of all data collected by not sharing administrative passwords with outsiders. A routine data and safety monitoring plan will also be submitted to the University of Pittsburgh IRB. The PI will report any adverse events to the IRB within 24 hours.

**Inclusion of Women and Minorities:**

No specific inclusion or exclusion criteria will be applied to the population of volunteer medical educators from which research subjects will be recruited. It is anticipated that research subjects will be representative of volunteer educators at the University of Pittsburgh in general, and will consist of roughly 35% female physicians, and roughly 25% racial minority physicians. (Targeted/Planned Enrollment Table.)

**References:**