Teaching clinical trials electronically

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SUMMARY *This article discusses the development, delivery and evaluation of an electronic extramural course, 'Fundamentals of Clinical Trials', a CME course designed to reach physicians and health care researchers without easy access to a local university. Ten week-long modules of instruction were developed. These were based on a graduate course in clinical trials, standard textbook topics and additional course materials specifically developed for the course. Questions and course topics were to be discussed by the students, and each participant was encouraged to present an actual or proposed clinical trial to the virtual class. Communication between students and tutors could be either 'one to one' or through a listserve, i.e. an automated mailing list available to all participants which copied and routed any message instantly to all participants. Ongoing evaluation of the course was accomplished by questions monitoring students' attitudes and needs, and a more extensive on-line questionnaire administered at the end of the course. Ten students from four countries were accepted onto the course. Half of the students contributed regularly and extensively, while the others tended to respond only when addressed directly. The students spent on average approximately 6 hours per week on the course. This differed little from regular classroom courses, but the students appreciated the ability to organize the course around their regular schedules. The students preferred topics that encouraged discussion and differing opinions. From the instructors' viewpoint, considerable time was required for course development and communication. This form of distance continuing medical education was preferred by all the students over regular correspondence courses, as it allowed for more immediacy and interaction. However, the time required for developing and teaching courses over the Internet should not be underestimated.*

Introduction

Traditional correspondence courses have long been used for reaching individuals living and working in remote areas. Electronic mail and other forms of electronic communication provide an effective vehicle for distance education and offer a means of uniting learners electronically so they may engage in a shared learning experience (Hiltz, 1994; Donahue, 1996). Electronic distance education has been used in general education, business and industry for two decades (Harasim, 1990; Davie & Wells, 1991), but is just starting to emerge in medical and public health education (Cataldo, 1993; Laporte *et al.*, 1994; Letterie *et al.*, 1994; Friede *et al.*, 1995; Frank, 1996; Tagg & Arreola, 1996), and may prove to be an valuable vehicle for continuing medical education.

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This article outlines the experiences with the delivery of an extramural electronic course, 'Fundamentals of Clinical Trials', designed to reach physicians and health care researchers who do not have easy access to regular university courses, either because of geographical distance or because of work responsibilities that do not allow them to attend regularly scheduled courses.

Methods

Development of the course

A set of ten modules was developed, consisting of directed readings, 'electronic tutorials' and exercise sets. Each module lasted one week. The course was based on a standard clinical trials textbook (Friedman *et al.*, 1996), selected material from an existing graduate course conducted by the Department of Epidemiology & Biostatistics, the University of Western Ontario, and standard textbook topics (Dawson-Saunders & Trapp, 1994; Fletcher *et al.*, 1996; Friedman *et al.*, 1996, Meinert, 1996), and supplemented by material especially developed for the course (Østbye, 1993; Donner & Klar, 1994; Davey *et al.*, 1995). A very basic understanding of biostatistics (equivalent to Leaverton, 1995) was set as a prerequisite for the course to allow the modules to focus instead on conceptual issues.

A series of suitable exercises and other tasks were partly taken from the clinical trials/ epidemiology literature and partly developed specially for the course. These exercises were intended to be simple enough to be completed by a student working relatively independently and at the same time be of sufficient complexity and realism so that an understanding of core clinical trials concepts and issues would ensue. Choice and formulation of appropriate questions proved to be one of the most important aspects of developing the course.

Two graduate students from the University of Western Ontario School of Journalism assisted in the production of an introductory video, presenting the university, the department, the course and the tutors. The video was created to enable the participants to appreciate visually the otherwise 'virtual' classroom.

Recruitment of students

The new electronic course was introduced as a continuing medical education (CME) distance learning offering, but differed from more traditional offerings both in content and scope. The course was advertised in a national general medical journal and via brief electronic postings to several Internet discussion groups frequented primarily by family physicians.

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Interestingly, almost all the initial responses (about 200) resulted from the electronic announcements and originated around the world (North America, rural Africa, Eastern and Western Europe and Southeast Asia). Most of the inquiries for further information were indeed from family physicians seeking to further their clinical trials research knowledge. The course tuition costs (C$650 including all materials) proved prohibitive to many potential participants.

The students

Ten students were accepted into the course in spring 1998: three from Canada, one from Australia, one from South Africa and six from the United States. Five were women. The participants were physicians or other individuals engaged in clinical research. Only two were taking part from truly remote areas.

Teaching the course

The video, the textbook, additional articles and keynotes for each module were sent by regular mail to all participants prior to course start. All communication for the course was based on electronic mail. Table 1 provides an overview of the course. Tasks and exercises, as well as a 'Clinical Trials Definition of the Week' (Last, 1995) were sent out via electronic mail at the beginning of each week. The exercises could be completed at any time during that week.

Like traditional correspondence courses, communication was asynchronous (i.e. the participants do not have to be available for communication at exactly the same time). However, there were major differences. Participants could communicate in two ways: by one-to-one 'private' communication with one of the tutors or through a listserve that copied and routed the message instantly to all participants. Furthermore, the electronic mail format allowed students to communicate with each other. This was important in that it helped to provide a sense of group identity that is usually absent from traditional correspondence education. Finally, the turnaround time was much more rapid; we attempted to answer all questions within 48 hours, and sometimes other students would already have answered a question before the tutors.

In addition to the readings and exercises, individual student 'presentations' added an important and popular dimension to the virtual class. These presentations were miniature essays describing a research idea or a clinical trial already in progress. To foster group identity and a further sense of a virtual classroom, the other students were encouraged to send comments, concerns and questions to the whole group regarding these presentations.

To alleviate privacy concerns, no instructor would re-route to the group a comment made in confidence by an individual student. In situations where a personal comment was deemed to be particularly interesting or relevant, the student's name was removed from the message, and the message re-routed anonymously to the group. While this rule existed to protect all participants, a sense of camaraderie prevailed that made its enforcement unnecessary.

Evaluation

Observations about student interaction, performance and rates of learning were made throughout the delivery of the course. A few simple questions were included among the other weekly tasks to monitor student attitudes and needs, and a more extensive questionnaire was given (also via electronic mail) at the termination of the course to evaluate broader aspects of the course. Comparisons were made with students enrolled in the corresponding lecture-based clinical trials class mentioned earlier.

Table 1. Fundamentals of clinical trials: course outline.

Module	Topic	Description
1	Introduction	– What is a clinical trial?
2	Study design I	– Defining the study population
		– Design types
		– Determining control group
3	Randomization	– Methods of randomization
		– Issues of blindness
4	Sample size	– Sample size calculations for various situations
5	Data quality I	– Baseline assessment
		– Selecting subjects
		– Monitoring for quality control
6	Data quality II	– Assessing adverse effects
		– Using HRQL indices
7	Survival analysis, etc.	– Estimation of survival curve
8	Data analysis & management I	– Ineligibility of participants
		– Dealing with missing data
		– Surrogate or proxy measures
9	Data analysis & management II	– Rationale and issues
		– Statistical analysis
10	Ethical issues	– Ethics of certain designs
		– Research constraints

Observations and discussion

Promotional video

The introductory video, as extraneous as it may have first seemed, was perceived to be an effective tool for fostering comfort in the virtual classroom. One student pointed out, "it was nice to see the faces of the tutors".

Questions and answers

The asynchronous nature of electronic mail communication combined with a permanent written record of all contributions leads to more careful phrasing of questions and answers. Unlike a regular live class in which a teacher may ponder a question briefly, then issue a casual response, an electronic mail response, by virtue of its permanence, must be researched, well phrased and more correct. This became even more crucial when it turned out that several students printed out and saved all messages, thus creating a 'course book' for later reference.

Instruction using graphs and other visuals

Until recently, regular electronic mail supported only ASCII text, so, in the first version of the course, we chose to limit the use of graphics to images that could be created from ASCII characters. With some effort, even relatively complex figures could be transmitted using ASCII characters. This meant that even students with very simple computer equipment and limited computer expertise could take part. However, in the last 2–3 years, the transmission of graphics and other special files as attachments has become much simpler and more standardized, and, in the next version of the course, graphic files (e.g. for survival curves) will be used much more extensively. Other electronic extramural courses have employed multimedia interfaces (Goldberg & Ritenour, 1993) and conferencing systems (Østbye, 1989), but, at least until recently, these have required a higher level of technical and computer literacy.

As the computer literacy of the general population improves, this format can be expanded to included multimedia segments via the World Wide Web or videoconferencing. Until that development, however, the present 'low-tech' electronic mail format seems sufficient to convey the essential information.

Student behaviour

Of the students registered in the course, half contributed extensively, vocally and regularly throughout the course's duration. It seems that a self-started, self-motivated student capable of managing his or her own time effectively is best suited to this type of learning. The other students were considered to be 'lurkers', an Internet term meaning someone who monitors the on-line discussion, but who chooses not to take part actively or let his or her presence be known. The lurkers were happy to respond when addressed directly. The variation in participation we observed has also been found in other courses taught electronically (Harasim *et al.*, 1995). However, it is possible that the 'quiet' participants also benefit from 'listening' carefully to the others (Wells, 1993).

Evaluation

Student time usage

The students reported spending about 6 hours per week on the course. Of this time, more than half was spent reading the textbook. The students in the corresponding 'live' graduate class indicated that they spent 6–8 hours per week on their clinical trials course. The difference appears to be in the way these hours were allocated: the students in the 'live' class spent 30–40% of their time reading the textbook, 30% in the classroom and the rest on practical exercises.

The direct time commitment, then, for a clinician wishing to upgrade his or her skills in this manner is not very different from that for those seeking education via the traditional route. There is, however, a greater control over one's personal time allocation. Indeed, all of the 'virtual' students commented that the ability to organize the course around their personal schedules was a major drawing point. Furthermore, local travel time is of course eliminated.

Resource use

Despite the relatively small number of students, the moderation of discussion, the monitoring of student activities, the answering of student queries and the ongoing curriculum development was a relatively demanding load for the administrative team of one professor and one senior graduate student. All comments had to be typed in, making reasonable keyboard skills essential (for all participants). Furthermore, as answers to questions had to be prompt, comprehensive, well written and well researched, each question demanded much more time and care than would otherwise have been expected. Although subsequent courses can reuse a substantial part of developed material, the maximum number of students per part-time tutor is probably not more than a dozen.

Student comments

The modules attracting greatest participation were those that discussed meta-analysis and ethical issues. These topics lend themselves well to differing opinions and spirited debate, as they tend to generate questions with no definite correct answers. This indicates the appropriateness of an open-ended approach to courses taught via the Internet.

Some students pointed out that even further personal interaction should have been stimulated. At times, interaction was reduced to the posing and answering of questions rather than the actual sharing of ideas. This relates to the desire to foster a comfortable 'virtual classroom' setting. More open-ended topics such as ethics are better suited for such interaction than more technical, biostatistical topics.

Costs

The tuition fee for the course was based on comparative Canadian university tuition rates for graduate courses as well as the actual direct costs of the course. Table 2 summarizes the various cost components of the course. (The listed costs are approximate and in Canadian dollars; the relative importance of the different components would probably be quite different in other settings and in other

Table 2. Overview of costs of teaching electronically.

Textbook (C$50/student)
Video (cassette and duplication) (C$10/student)
Mailing costs (C$10–30/student)
Advertising the course (C$400)
Production of video (C$500)
Salary of teaching assistant (C$1500)
Opportunity costs of faculty members' time
Course development (~200 hours)
Communication time (~50 hours)
Evaluation (~5 hours)
Maintaining Internet server (~C$100)

Note: All costs are approximate and in Canadian dollars.

disciplines.) Most of the overall cost of delivering this course was borne by the university department, especially if the costs of development time and communication time used by the tutors are included. To provide similar courses on a regular and cost-effective basis would require either that tuition fees be increased, or that a larger number of students be recruited. The latter option may decrease the attention and time available for interaction with individual students. However, it should be emphasized that the costliest part of the course is development time the first time such a course is offered. This cost will be much lower when the course is offered again.

Comparison with traditional correspondence courses

Since the primary motivation for providing this course was to take medical education for remote physicians beyond traditional correspondence courses, the final questionnaire was also used to evaluate the electronic medium's competition with the postal medium. One participant responded, "I don't feel so isolated; interaction improves [my] learning, and [there were] quicker response times to questions". All the students listed the electronic forum as either 'better' or 'much better' than traditional correspondence courses. There are even suggestions in the general educational literature that student achievement has been of comparable or higher quality than in face to face courses (Davie, 1988).

Conclusion

Electronic communication allows the participation in new forms of continuing medical education by physicians who, for reasons of geographical remoteness or irregular work schedules, would otherwise be unable to take part. Clinical trials and research methodology can be taught via an electronic distance learning medium; concepts and higher level issues are likely to generate more interesting interaction than more technical and statistical problems. The amount of resources (time) necessary for course development and communication, if such a course is to be of value to the participants, should not be underestimated.

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