Reach of Benchmark Psychiatric Trial Results to Community-Based Providers: A Case Study of CATIE

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Objective: To evaluate the familiarity of front-line clinicians with findings from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), the influence of didactic continuing medical education on provider knowledge about key details of CATIE, and how location-related factors affect rates of pre-event knowledge and intraevent learning about CATIE.

Method: Data derived from the Massachusetts General Hospital Psychiatry Academy (MGH-PA) semester II live symposia provided in different cities nationally between September and December 2006 were analyzed to evaluate providers' self-assessment of their knowledge about CATIE. In addition, participants were also asked a preactivity and postactivity question to assess learning of material presented during the live event psychosis lecture. Descriptive statistics were utilized to characterize participants' self-assessment of knowledge about CATIE, while parametric and nonparametric statistical tests were used to evaluate the degree of observed learning and the effect of lecture location on the results.

Results: 3333 participants (mean attendance: N = 278 per event) attended 1 of the 12 MGH-PA live symposia. Of the subsample of providers who treat schizophrenia, 51% indicated that either they had never heard of CATIE or they were not familiar enough with its results to change their practice. Overall, the proportion of correct answers on the postactivity question was 65%, compared with 24% prior to the lecture ($\chi^2 = 48.68$, df = 1, $p < .001$). Degree of learning did not differ among symposium locations.

Conclusion: In this sample, the CATIE study had very limited dissemination to, and impact on, a geographically and occupationally diverse sample of mental health practitioners. Robust learning of a key methodologic detail of this trial was evidenced across symposium locations.

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Clinical trial data are a key source of information for evidence-based patient care. However, the dissemination of information from clinical trials is suboptimal. Clinical trial findings are often very slowly translated into actual changes in patient care,[1] and, frequently, key findings are not implemented by the majority of practitioners, especially when such findings are not broadly communicated using several sources of information.[2,3] Not only are physicians frequently unaware of core findings from key clinical trials, they also display significant gaps in understanding the details of research studies and applying that information to direct patient care.[4,5] These translational difficulties may be magnified for large pivotal clinical trials, as these trials often have complex methodologies and numerous outcomes. Expert description and discussion of major studies may be required for adequate understanding and implementation by front-line clinicians.

For many years, psychiatry has lacked the large, federally funded, effectiveness-based clinical trials necessary to answer core questions about major mental disorders. However, in the last 5 years, several such trials have been completed. For example, Sequenced Treatment Alternatives to Relieve Depression (STAR*D)[6] and Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD),[7] major multicenter trials investigating unipolar major depressive disorder and bipolar disorder,

respectively, have recently concluded, and their results have been made available to the community.[8–11] A third benchmark clinical trial, the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE),[12] was a federally funded, multisite study designed to compare the efficacy, tolerability, and cost-effectiveness of 4 atypical antipsychotics and a conventional antipsychotic in patients with schizophrenia. This complex trial utilized an "effectiveness" design, was implemented in multiple real-world settings, had few exclusion criteria, and allowed for significant clinician flexibility in an effort to mirror actual clinical practice. Furthermore, it evaluated outcomes that were relevant to clinical practice. Given the fact that there had never been a large federally funded study comparing the effectiveness of the newer atypical antipsychotics in real-world settings using relevant clinical outcomes, the results of this study were critically important in helping practitioners make evidence-based decisions about using these widely prescribed medications. Despite the millions of dollars spent to perform these studies and the many articles published (over 170 at last count) describing the results, there is a substantial risk that the data from these 3 benchmark trials will not be fully understood or implemented clinically.

How can the dissemination and translation of findings from these pivotal psychiatric trials be tracked and improved? Continuing medical education (CME) offerings may be an important method of documenting the impact of major clinical trials as well as for improving knowledge transfer and clinical implementation of the new findings. Clinicians appear to use CME more frequently than primary literature review to learn about clinical trials,[13] and CME in various forms appears to improve knowledge and may influence behavior.[14–16] It has been proposed that CME may be an excellent platform for documenting the initial impact of clinical trials and for dissemination of information about clinical treatment guidelines,[17] and, similarly, CME may have great utility in informing front-line providers about the core details of pivotal clinical trials in psychiatry.

In this study, we evaluated attendees of a Massachusetts General Hospital Psychiatry Academy (MGH-PA) CME event that described the performance and results of a pivotal psychiatric trial (the CATIE study) to investigate 3 major questions. (1) Approximately 1 year after initial publication of the results, how familiar were front-line clinicians with the findings from CATIE? (2) Can didactic CME, provided by national experts in psychotic disorders, influence provider knowledge about key details of the complex CATIE study? (3) Do location-related factors affect rates of pre-event knowledge and intraevent learning about CATIE?

To our knowledge, there has been no prior formal evaluation of the impact of seminal psychiatric studies on clinical practice, nor has there been substantial investigation of the ability of CME participants to learn important methodologic details about such key studies. Answers to these 3 questions would help establish the extent of dissemination of CATIE to front-line clinicians and the *teachability* of key principles of this trial.

METHOD

Overview and Sample

The MGH-PA is a nationwide CME program designed to provide education about core psychiatric disorders. The MGH-PA utilizes several features identified as critical components of educational programs,[18–21] including assessment of learning needs, multimodal teaching methods (live lectures, satellite broadcasts, and e-mail–based content), use of opinion leaders in given topic areas, and sequential linking of topics to build on previously taught content in a module-based system.

The study sample consisted of attendees at 1 of 12 MGH-PA live symposia provided in different cities nationally between September and December 2006 (semester II). These live symposia consisted of 6 consecutive 45-minute lectures on various psychiatric conditions. One of the lectures, entitled "An Update on Treatment of Schizophrenia," focused heavily on the CATIE results and was presented in identical fashion in each of the 12 cities. Two senior faculty members of the MGH Department of Psychiatry, Boston (both Harvard Medical School, Boston, Mass., associate professors), with over 30 years collective teaching and research experience in psychotic disorders, divided speaking duties during the second semester (6 lectures per faculty member). Attendees included a mixture of provider types, including psychiatrists, nonpsychiatrist physicians, psychologists, nurse practitioners, and nurses, as continuing education credits for this program were made available for participants from each of these disciplines.

Instruments and Data Collection

Outcome 1: Dissemination and clinical impact of CATIE data. To evaluate providers' self-assessment of their knowledge about the CATIE trial, we utilized a polling question prior to the beginning of the lecture regarding their knowledge and utilization of data from the CATIE trial: "Which statement best summarizes the impact of the CATIE trial on your treatment of patients with schizophrenia?" The polling question was presented to the audience on a display screen at the beginning of the presentation, and the question and answer choices (Table 1) were read aloud by the lecturer. An electronic audience response system using touch keypads was utilized to capture and record participants' responses to the questions. This polling question was utilized at all 12 program sites.

Outcome 2: Participants' ability to learn a key detail of CATIE. In addition to the polling question, participants were also asked a preactivity and postactivity question to

Table 1. Polling Question (12 cities) and Preactivity and Postactivity Question (10 cities)

Polling question
Which statement best summarizes the impact of the CATIE trial on your treatment of patients with schizophrenia?
A: I've never heard of the CATIE trial.
B: I've heard of the CATIE trial but am not familiar enough with its results to change my practice.
C: I'm familiar with the CATIE trial and its results, but it has not led to any change in my practice.
D: I'm familiar with the CATIE trial and have made changes in my practice based on its results.
E: I do not generally treat patients with schizophrenia in my practice.
Preactivity and postactivity question
In the recent CATIE trial evaluating the various treatment options for schizophrenia, what was the primary outcome measure?
A: Change in PANSS positive symptom score from baseline.
B: Change in total SAPS + SANS score from baseline.
C: Quality of life (self-reported).
D: Physician-rated functional capacity.
E: All-cause treatment discontinuation.

Abbreviations: CATIE = Clinical Antipsychotic Trials of Intervention Effectiveness, PANSS = Positive and Negative Syndrome Scale, SANS = Scale for the Assessment of Negative Symptoms, SAPS = Scale for the Assessment of Positive Symptoms.

assess learning during the event. The pre/post question was chosen from a pool of questions developed by the 2 faculty members responsible for creating and delivering the psychosis module lecture. The pool of questions was evaluated by administering the questions to an internal cohort of 45 MGH faculty in the psychiatry department to ensure that the question and answer choices were clearly written and to establish an internal benchmark of correct response rate. In this case, the selected question asked participants about a key methodologic detail to assess their understanding of the trial, the primary outcome measure: "In the recent CATIE trial evaluating the various treatment options for schizophrenia, what was the primary outcome measure?" The MGH reference sample had a correct response rate of 51% (23 of 45) for this item. For tests of knowledge (achievement tests), item difficulty levels of 0.50 are considered optimal and are potentially the most discriminating.[22]

The preactivity question occurred just prior to the lecture, and the (identical) postactivity question was given immediately after the lecture. As with the polling question, the pre/postquestion and answer choices (Table 1) were presented on a display screen to the audience and read by the lecturer, with the audience response system used to capture participants' responses to the questions. This lecture was 45 minutes in length, and the interval between the preactivity and postactivity question varied between 45 minutes and 135 minutes. For our analyses, we included only data from participants who responded to both the preactivity and postactivity questions.

The same preactivity and postactivity question was used for 10 of the 12 program sites (a different preactivity and postactivity question was used for 2 of the live symposia [Westchester, N.Y., and Chicago, Ill.]). Therefore, we only collected and analyzed preactivity and postactivity question data from these 10 lectures to reduce the number of potential confounding variables. As a secondary analysis, we considered an additional characteristic that may have affected attendees' response to the above questions by examining whether the geographic location of the event was associated with variability in self-reported baseline knowledge and impact of CATIE (as measured by the polling question).

Data Analysis

Data analysis included descriptive statistics for participant demographics as well as responses to the polling question. Parametric and nonparametric tests were used to evaluate the degree of observed learning and the effect of lecture location on the results. All data analysis was carried out using SPSS for Windows.[23]

RESULTS

A total of 3333 participants (mean attendance: N = 278 per event) attended 1 of the 12 MGH-PA live symposia. The majority of program participants were physicians; overall, greater than 60% identified themselves as either psychiatrists or primary care physicians, although there was some significant variation in proportion of physicians between the cities (ranging from 33% physicians in Miami, Fla., to 75% in Los Angeles, Calif.). Nonphysicians, accounting for roughly 40% of the total audience, consisted of physician assistants (≅ 2%), nurse practitioners (≅ 9%), nurses (≅ 9%), pharmacists (≅ 4%), and participants who did not identify their professional discipline (≅ 10%). Of the attendees, a total of 1832 (55%) responded to the polling question for the psychosis module.

Only 10 of the sites used the preactivity and postactivity question shown in Table 1. In these 10 cities, there were a total of 2845 participants. At these sites, 1106 participants (39%) responded to the preactivity psychosis question, and 1618 (57%) responded to the postactivity question; 800 participants (28%) responded to the question both before and after the events. Results are described for these 800 participants in outcome 2.

Outcome 1: Dissemination and Clinical Impact of CATIE Data

Responses to the polling question regarding recognition and clinical impact of CATIE are presented in Table 2. Overall, approximately three quarters of respondents (73%) reported that they treat patients with schizophrenia. Of this subsample of providers, 31% indicated that they had never heard of CATIE; 20% indicated that they had heard of CATIE but were not familiar enough with its results to change their practice; 31% indicated that they

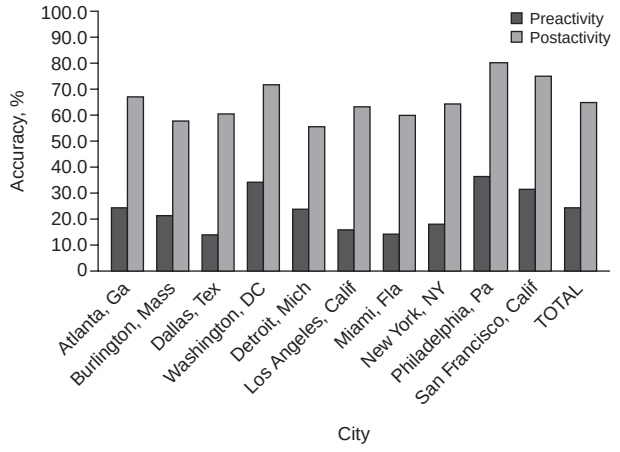
Table 2. Results by Program Site for Psychosis Module Polling Question for Practitioners Who Treat Patients With Schizophrenia (N = 1337)

Which statement best summarizes the impact of the CATIE trial on your treatment of patients with schizophrenia?
A: I've never heard of the CATIE trial.
B: I've heard of the CATIE trial but am not familiar enough with its results to change my practice.
C: I'm familiar with the CATIE trial and its results, but it has not led to any change in my practice.
D: I'm familiar with the CATIE trial and have made changes in my practice based on its results.
E: I do not generally treat patients with schizophrenia in my practice.

Response, %	Atlanta, Ga	Burlington, Mass	Chicago, Ill	Dallas, Tex	Washington, DC	Detroit, Mich	Los Angeles, Calif	Miami, Fla	New York, NY	Philadelphia, Pa	San Francisco, Calif	Westchester, NY	Total
A	35	31	34	43	20	38	28	42	26	26	28	28	31
B	22	26	14	28	20	15	19	21	19	24	12	14	20
C	26	31	33	15	43	22	27	23	35	32	32	36	31
D	17	12	18	14	16	25	26	15	20	18	28	21	19

Abbreviation: CATIE = Clinical Antipsychotic Trials of Intervention Effectiveness.

Figure 1. MGH-PA Attendees' Accuracy on the Preactivity and Postactivity Question (N = 800)



Abbreviation: MGH-PA = Massachusetts General Hospital Psychiatry Academy.

were familiar with the CATIE trial, but it had not led to any change in their practice; and 19% indicated that they were familiar with the CATIE trial and had made changes in their practice based on its results. Rates of unfamiliarity with CATIE results among the attendees who treat patients with schizophrenia ranged from 40% to 71% at the different lecture sites. These location-related differences in polling question responses were not statistically significant after adjusting for multiple comparisons.

Outcome 2: Participants' Ability to Learn a Key Detail of CATIE

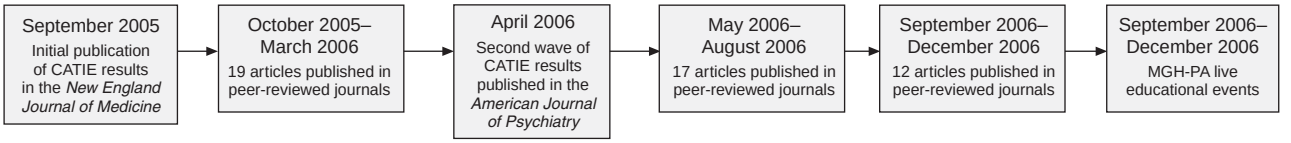
Accuracy on the preactivity and postactivity question (about the primary outcome measure in CATIE) increased from prelecture to postlecture at each of the program sites (Figure 1). Overall, the proportion of correct answers on the question postactivity was 65%, compared with 24% prior to the lecture. This pre/postimprovement in performance was statistically significant ($\chi^2 = 48.68$, df = 1, $p < .001$). Of note, when the larger sample was examined (prelecture: N = 1106 and postlecture: N = 1618), we found similar percentages of correct responses. No significant differences in the degree of learning were found between lecture locations ($p > .05$).

DISCUSSION

The first major finding of this study was that, 1 year after publication of its initial results, it appears that CATIE had very limited dissemination to and impact on a geographically and occupationally diverse sample of mental health practitioners. Figure 2 depicts the timeline from the original publication of the CATIE results to the MGH-PA CME events. More than half of the attendees reported being unfamiliar with the results from the trial prior to the lecture; in fact, approximately one third had never heard of CATIE. This poor dissemination of the trial's findings occurred despite substantial financial investment in the study and the publication of 47 CATIE-related reports in PubMed-indexed journals in the year preceding the CME symposium.

This finding is consistent with prior evaluations of clinical trial dissemination showing publication in academic journals alone to be insufficient to result in widespread knowledge or changes in clinical practice.[1,24,25] Results of important studies often have little practical impact for many years,[26] even when there are multiple studies of the same topic with similar and clinically important implications.[27] As a result, patients commonly do not receive care with efficacious treatments for either general medical conditions[28,29] or psychiatric disorders, such as posttraumatic stress disorder.[30] Fortunately, in the rare cases when there is comprehensive dissemination of information about a clinical trial's findings (for example, the Women's Health Initiative findings related to hormone replacement therapy in postmenopausal women[31]), there can be rapid, widespread, and appropriate changes

Figure 2. Timeline From the Initial Publication of the CATIE Trial to the MGH-PA Continuing Medical Education Events



Abbreviations: CATIE = Clinical Antipsychotic Trials of Intervention Effectiveness, MGH-PA = Massachusetts General Hospital Psychiatry Academy.

in clinical practice.[32] However, at this juncture, our results suggest that there remains suboptimal dissemination of pivotal psychiatric studies to practitioners in the community and that additional methods of dissemination and education (beyond publishing) are required.

The second major finding of this study was that the MGH-PA CME lecture on psychosis, which contained information on CATIE, led to robust improvement in understanding of a key detail about this complex and important study. Despite the complexity of the trial, a diverse group of practitioners was able to learn about CATIE, even when lecturers did not teach specifically to methodology but instead placed the trial in clinical context. This finding is important because practitioners do not appear to change their clinical practice solely through review of scientific literature; instead, in real-world practice, providers appear to require consolidation of the new information through CME programs or colleagues before changes in patient care occur.[33] Fortunately, our study suggests that this common method of learning about clinical trials via CME can result in substantial improvement in knowledge.

Furthermore, CME can play an important role in *translating* the results of trials with complicated designs. Large-scale clinical trials that utilize complicated methodologies are often difficult for providers to fully understand just by reading journal articles. Formal education programs may thus be an important component in increasing the likelihood of providers' understanding of these methodologies. Clinicians report limited confidence in their ability to interpret the findings of research studies,[34] and both medical students and physicians show substantial deficits in applying the results of trials to patient care.[5,35] Therefore, the model applied in this study—using national experts who were involved in the performance of the trial to describe and translate the trial—may be an optimal method of improving front-line providers' ability to use the results of these benchmark trials.

Two other findings in the trial were notable. First, both the low prelecture familiarity with CATIE and the improvement in understanding a key detail about study design cut across locations, suggesting that CME, as used here, is an effective tool for teaching about pivotal clinical trials to a diverse population. There was, however, some potential regional variance in dissemination of trial results, with rates of unfamiliarity with the trial's results ranging from 40% (Washington, D.C.) to 71% (Dallas, Tex.). This is consistent with prior studies finding regional variance in implementation of research findings,[32] although we were not able to account for other potential covariates (e.g., discipline) related to unfamiliarity with CATIE. Further studies of pivotal trial result dissemination and implementation are required and should use methodologies that allow for examining response characteristics at the individual provider level. This would include evaluation of the impact of practice location and professional discipline on degree of familiarity with key elements of pivotal trials.

These results represent only a tentative but promising first step in bridging the gap between clinical trial findings (efficacy) and widespread implementation in practice (effectiveness). It will be important to evaluate the ability of the MGH-PA and other CME programs to influence longer-term learning, changes in clinical practice, and, ultimately, impact on patient outcomes. In addition to assessing details of study design, future studies should also assess the ability to teach more immediately clinically relevant facts. Our results clearly underscore the limitations of current dissemination methods but point to a potential enhancement of these methods via the MGH-PA and other CME programs that utilize similar methods.

The strengths of this study include the fact that it evaluated a large population that was diverse both geographically and by discipline. In addition, this is to our knowledge the first study of dissemination and learning about pivotal clinical trials in psychiatry. This study also had several limitations. Attendees consisted of providers who wanted CME (and may have self-identified knowledge deficits about psychiatric illness), and the proportion of responses to the lecture was relatively low, especially to the pre/post question. These facts may mean that the responders may not represent practitioners as a whole. This relatively low response rate is explained by several factors, including variable levels of participant motivation to take part in the assessment process, coupled with possible eagerness to begin hearing program content (preactivity questions were administered just before the lecture).

Two limitations specific to the pre/post question include the fact that attendees may have been *primed* by the preactivity question to pay more attention to that specific content (potentially artificially elevating rates of improvement on the question) and the fact that this study only measured the short-term learning of a single aspect of CATIE. An additional limitation was our reliance on a single question to test participants' knowledge of CATIE. A greater number of questions covering a broader range of aspects of the trial may have provided more comprehensive coverage of participants' knowledge base and may have better represented both the impact of CATIE on practice and how well participants learned CATIE-related content.

Despite these limitations, our results suggest that dissemination of a benchmark clinical trial (CATIE) was substantially limited 1 year after initial publication of its results, and a specific CME lecture, independent of location, improved practitioners' ability to understand a key methodologic detail about the trial. Future studies should focus on the broader impact of such CME on changes in attendees' clinical practice and on improvement in patient outcomes, as well as assessments of longer-term learning through these methods.

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