The Impact of a Quality Improvement Collaborative for the Care of Patients With HIV Infection: The Evaluation of Quality Improvement for HIV (EQHIV) Study

Running Title: The EQHIV Study

Word Count: 4,529

March 12, 2003

Bruce E. Landon, M.D., M.B.A.

Ira B. Wilson, M.D., M.Sc.

Keith McInnes, M.A.

Mary Beth Landrum, Ph.D.

Lisa Hirschhorn, M.D., M.P.H.

Peter V. Marsden Ph.D.

David Gustafson, Ph.D.

Paul D. Cleary, Ph.D.

Institutional Affiliation:

From the Division of General Medicine, Beth Israel Deaconess Medical Center (B.E.L.) and the Department of Health Care Policy (B.E.L., P.D.C., M.B.L., K.M.), Harvard Medical School; the Division of Clinical Care Research and the Department of Medicine, New England Medical Center (I.B.W.); Dimock Community Health Center (L.H.); all in Boston, MA; The Department of Sociology, Harvard College (P.V.M.), Cambridge, MA; and The University of Wisconsin (D.G.), Madison, WI.

Supported by a grant from the AHRQ (R-01HS10227). Address reprint requests to Dr. Landon at the Department of Health Care Policy, Harvard Medical School, 180 Longwood Avenue, Boston, MA 02115. Telephone: 617-432-3456. Fax: 617-432-0173. email: landon@hcp.med.harvard.edu

ABSTRACT

BACKGROUND: Multi-institution collaborative quality improvement programs are a well-established and broadly applicable quality improvement strategy that has been applied in numerous health care settings for many conditions, but there is little systematic assessment of their effectiveness.

OBJECTIVE: To evaluate the effectiveness of a quality improvement collaborative (the "Breakthrough Series") in improving the quality of care for underserved patients with HIV infection.

DESIGN Controlled pre/post intervention study. Changes over time for intervention and control clinics were examined using hierarchical regression models that controlled for patient and clinic characteristics.

SETTING: Clinics receiving funding under the auspices of Title III of the Ryan White Care Act.

PARTICIPANTS: We assessed changes in care quality in a sample of 44 intervention clinics and 25 control clinics matched by location (urban/rural), region, size, and clinic type.

INTERVENTION: A Multi-institutional quality improvement collaborative (the "Breakthrough Series").

MEASUREMENTS: Changes in quality of care measures abstracted from medical records of pre- and post-intervention samples of patients at each study clinic. Measures examined included use and effectiveness of anti-retroviral therapy, screening and prophylaxis, and access to care.

RESULTS: Overall, 9,986 patients were studied (6,406 from the intervention clinics and 3,580 from the control clinics) for an average of 72 patients per clinic in the pre- and post-intervention time periods. Most clinical and sociodemographic characteristics of the intervention and control

patients were similar (p>.05). There were no statistically significant differences in changes in the quality of care between intervention and control clinics, although some trends favored the intervention group. The proportion of patients with a suppressed viral load increased by 11.0% from 40.1% to 51.1% in the intervention group as compared with 5.3% from 43.6% to 48.8% in the control group, but this difference was not statistically significant (p=.17). Rates of HAART use for appropriate patients were high in both the pre and post-intervention periods with a slight decrease in the second period. There was no difference between the intervention and control sites. There were also no differences between intervention and control sites in rates of appropriate screening tests and prophylaxis.

CONCLUSIONS: In this prospective matched study of a quality improvement collaborative that included almost 10,000 patients, the collaborative did not significantly affect the quality of care. Further research is needed to improve methods of teaching and implementing quality improvement programs in order to achieve better results.

Key Words: HIV/AIDS, Quality Improvement, Quality of Care

Introduction

In the last decade, there have been tremendous improvements in measuring and monitoring the quality of medical care in the United States. Despite these advances, striking problems with quality persist.(1) The quality of care for patients with HIV-infection is of particular concern. There is substantial evidence that getting medical services and treatment for patients with HIV infection may lead to longer survival and better quality of life,(2, 3) yet serious quality of care problems and striking disparities in quality by race and social class have been documented.(3-5)

In the 1980s, continuous quality improvement techniques began to be used in health care.(6, 7) These strategies emphasize that most quality problems in health care are a result of "system" failings rather than problems with individual practitioners.(8) In 1995, the Institute for Healthcare Improvement (IHI) introduced the concept of the "breakthrough series", which brings together health care organizations dedicated to improving the quality of care in particular clinical areas through the application of continuous quality improvement techniques.(9) These techniques involve identifying deficiencies in quality and then repeatedly implementing small-scale interventions, measuring changes, and then refining and expanding interventions in an effort to improve processes of care (called "Plan, Do, Study, Act or PDSA Cycles, Figure 1).(10, 11) (Figure 1) Typically, each Breakthrough series collaborative is comprised of between 20 and 40 participating health care organizations and a faculty with expertise in the clinical area and quality improvement methods.(12) To date, IHI has conducted collaboratives with over 700 teams working on 23 clinical conditions or treatment processes including improving asthma care and reducing medication errors. While some evaluations of quality before and after a

collaborative support the validity of this approach, only a few limited controlled trials have been conducted.(13, 14)

An important source of funding for HIV care is the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which is administered by the HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA). Title III of the CARE Act supports comprehensive primary health care for HIV-infected individuals and currently supports primary care services for more than 150,000 patients being cared for in over 200 community health centers, hospital based clinics, and city/county health services.(15) In 1999, HRSA required all clinical sites that were first receiving funding under Title III of the Care Act participate in a quality improvement collaborative conducted by IHI. Existing sites receiving funding were also invited to participate. In this study, we evaluate the impact of the collaborative by collecting pre and post implementation quality of care information on samples of patients from both participating and matched non-participating clinics.

Methods

Study Site Selection and Controls

Of the 199 Title III sites in the continental United States in 1999, we excluded 16 sites that reported caseloads of less than 100 cases per year and 12 sites that were initially slated to participate in the Breakthrough collaborative but elected not to do so.**[Keith, I don't have the breakdown of how I got from 208 to 185 so you probably have more accurate data—please let me know]** Of the remaining 171 sites, 62 participated in the collaborative. Among these sites, 54 agreed to participate in the study and 44 (including 11 mandatory participants and 33 voluntary participants, 71% of collaborative participants) provided chart review data. The 109 non-participating sites were eligible to be selected as control sites and 65 of these sites provided

information needed for matching. The potential control sites were matched with intervention sites based on the type of site (community health center, community based organization, health department, hospital, or university medical center), location (rural, urban), number of care sites, region, and number of active HIV cases. Using these criteria, 42 potential sites were selected as controls and 37 of these (88%) agreed to participate in the study. Of these, 25 (60% of potential control sites) participated in the chart review portion of the study. The Committee on Human Studies of Harvard Medical School approved the study protocol.

Quality Improvement Intervention

Each participating clinic selected a team, usually consisting of at least one administrator and one or more clinicians, and a "population of focus" on which the team's interventions would be tested. Usually, the population of focus consisted of all of the HIV infected patients in a particular site but sometimes participants chose to focus on a subset of patients, such as those cared for by a particular group of clinicians. The collaborative was designed to have a "kickoff" meeting and two subsequent two-day meetings called learning sessions over 12 months that were attended by all of the improvement team members. The kickoff learning session focused on instruction in the theory and practice of quality improvement by first identifying problems in HIV care and then introducing the techniques of continuously implementing, measuring, and refining changes (the Plan/Do/Study/Act cycles)(10, 11) to improving the care of HIV-infected patients. Each learning session included additional instruction in quality improvement techniques and breakout sessions that focused on improving specific aspects of care, developing an information infrastructure to track progress, and specific aspects of quality improvement theory. In addition, teams exchanged ideas and presented "storyboards" of their progress to date. At each session, teams reported on activities, methods, and results. Towards the end of the

collaborative, HRSA decided to extend it by 4 months and add a third learning session. Between the sessions ("action periods"), team members implemented concepts and ideas. Each site had access to a collaborative list-serve, participated in monthly conference calls with the collaborative faculty, and submitted monthly reports of their improvements, which included charts tracking their improvements to date in the required key quality measures noted above. Detailed descriptions of the Breakthrough series collaboratives are available elsewhere.(9, 16-18)

Quality of Care Monitors

The quality of care measures (see Table 1) were selected to coincide with required and optional quality measures selected by the collaborative faculty as areas for improvement. These measures were selected by the faculty after reviewing the literature to identify areas of quality deficiency in the delivery of HIV care, particularly for underserved populations targeted by the Ryan White Care Act. Because of the paramount importance of antiretroviral therapy to the treatment of HIV, the faculty focused on measures related to ARV treatment including the percentage of patients on HAART therapy, the percentage of patients with a controlled viral load, and the percentage of patients that received adherence counseling as required key measures for the collaborative. Measures were then developed based on consensus guidelines appropriate for the period of care.(19) Our primary measures were rates of highly active anti-retroviral therapy (HAART) use and control of HIV viral load for appropriate patients. Eligible patients for HAART included those with CD4 counts less than 350, those with CD4 counts between 350-500 and viral load >5000 copies/ml, all patients with viral load>30,000 copies/ml, and patients already on HAART, as per the guidelines. We also assessed the use of HAART for those with CD4 counts <350 copies/ml to reflect recommendations that were published after the end of the collaborative.(20) Because of the variability in viral load assays available at the time, viral load

was considered controlled if it was undetectable or if the total viral load was less than 400 copies/ml. We also assessed the use of screening and prophylaxis as well as access to care. The only key measure being followed for the collaborative that we were unable to assess was one related to adherence counseling because this information is not reliably available from medical records.

Quality of Care Data Collection

In order to identify pre- and post- intervention samples of patients, we requested lists of all HIV-infected patients in care at each of the sites during the two time periods. For the first sample, sites were asked to provide encrypted lists of all HIV infected patients ages 18 years or older by June, 2000 seen at the site between January 1 and June 30, 2000 and for the second sample, sites were asked to provide a similar list of active patients ages 18 years or older by December 2001 seen at the site between July 1 and December 31, 2001 (the first six months of the "post" study period). From each of these lists, we randomly selected 75 patients from the first list and 75 from the second list for the chart review portion of the study. In addition, we selected 5 additional patients for each review period to be substituted for cases in which the chart could not be located or was otherwise unavailable. In the 11 intervention sites that had focused their improvement efforts on a subset of patients, we asked the sites to indicate such patients on the lists they gave us and we randomly selected half of the patients from the population of focus and the remaining half from the other patients. Each site selected 1 or 2 medical records reviewers (typically nurses). Data were then collected from each sampled patient's medical record covering a one-year period of care. The first period was selected to end just as the collaborative began while the second period of care extended approximately 6 months beyond the originally scheduled end of the collaborative (2 months past the extended time) to assure

maximal overlap with the end of the collaborative. The data abstracted included socio-demographic information (e.g. age, sex), history of HIV related illnesses, comorbid medical or psychiatric conditions (current substance abuse or psychiatric illness), screening and prophylaxis for HIV related conditions, number and timing of visits, CD4 counts, and viral loads, and antiretroviral medications prescribed.

Descriptions of Changes

In addition to the quality of care data, we also coded and tracked all of the interventions attempted as noted in the monthly reports submitted by each of the participating clinics. Finally, both control and intervention sites were surveyed at the beginning and the end of the intervention to ascertain their quality improvement activities and environment.

Statistical Analyses

We compared characteristics of the intervention and control sites to each other and to all Titile III sites in the continental United States. Based on initial power calculations, we designed our study to include 15 intervention clinics and 15 control clinics with a total of 50 patients selected per clinic per round. We estimated power for our two-level model using standard formulas for two group comparisons where the total variance of changes in quality was assumed to be equal to the sum of the average within clinic variance plus the between clinic variance. Assuming that the standard deviation in changes in quality across clinics ranged from 7.5% to 15%, the original design would have resulted in 80% power to detect a difference in the rate of change of 13 to 16 percentage points in the main outcome measures. We subsequently decided to increase our sample size to 44 intervention clinics and 25 control clinics and examined 75 patient/clinic per round in order to increase our power to detect differences of approximately 10%, which we thought would have been clinically significant.

Mean changes from baseline to follow-up in quality measures within each of the two groups were compared using chi-square tests for discrete variables and t-tests for continuous variables. Assessments of relative change over time were examined using hierarchical regression models that controlled for both patient clinical and socio-demographic characteristics and clinic characteristics. These models included a random intercept and period term to account for correlation among patients within a clinic and allow for differential changes in outcomes across sites. We tested for differences in changes in outcomes between intervention and control sites. Patient control variables included age, sex, stage of disease based on lowest recorded CD4 count over the period of care, active psychiatric or substance abuse problem, history of HIV related diagnoses, and other comorbid medical conditions. Because we thought that change might be different for Title III clinics that were required to participate in the program, we compared the effectiveness of the intervention for newly funded clinics and those with ongoing funding. None of the newly funded clinics were new to providing HIV care. All but one had been providing HIV care for 5 or more years. We also stratified clinics at baseline as poorly performing (the bottom 50%) and examined the effectiveness of the intervention for this group of clinics separately. We also assessed the relative effectiveness of the intervention among patients in the population of focus. Because new guidelines for the initiation of antiretroviral therapy were released in the year after the collaborative, we also reassessed the performance on the HAART and viral load indicators after restricting the eligible population to those already on HAART or those with CD4 counts < 350 copies/ml.(20) Finally, to test the sensitivity of our conclusions to modeling assumptions, we refit models assuming fixed site effects.

Role of the Funding Source

This research was funded by the Agency for Healthcare Research and Quality (AHRQ). The funding source had no role in the design, conduct, or reporting of the study.

Results

Study Sites

Characteristics of the collaborative participants and control sites are presented in Table 2. None of the differences between the intervention and control sites were statistically significant and the sites were representative of Title III clinics nationally. The majority of clinics were located in urban areas (77% of intervention clinics and 84% of control clinics, p=.5) and the clinics were well distributed throughout the country. Even after matching, more collaborative clinics were in the South, while more control clinics were located in the West but these differences were not significant (p=.06). Thirty percent of intervention clinics and 40% of controls were community health centers and approximately 15% were hospital-based clinics (p=.41). Most clinics were HIV specialty clinics and they were approximately evenly split between large (>400 HIV patients) and small (<400 HIV patients) size.

Among the 25 control sites, 4 (16%) reported that they had previously participated in a breakthrough series collaborative for a different disease and none were currently participating in a different collaborative. As another test of the impact of the collaborative on participating clinics, we interviewed clinic directors from both the intervention and control sites after the end of the collaborative. While both intervention and control directors reported that they had undertaken quality improvement initiatives for HIV care, there were many more reported in the intervention clinics. Twenty-seven percent of the intervention directors reported implementing 6 or more initiatives as compared with 0 control clinics. Conversely, 64% of control clinic

directors reported attempting between 0-2 initiatives as compared with 27% of intervention clinics.

Participation in the Collaborative by Sites and Types of Interventions attempted.

All of clinics attended at least three of the four learning sessions and 75% submitted monthly reports 7 or more times (mean=10.6). All clinics also participated in conference calls and the collaborative listserve but we have no way of quantifying the level of participation in these activities. We identified 1,479 interventions attempted at 43 of the intervention clinics that submitted monthly reports, with a mean of 33.6 interventions per clinic. Table 3 demonstrates the number of interventions tried in specific clinical areas. The most common targets of interventions were access to care and antiretroviral therapy with an average of 9.1 and 6.9 identified interventions per clinic, respectively. Fewer interventions, however, reached the stage where they were either being refined in preparation for being institutionalized across the clinic or were actually institutionalized. On average, there were 1 or fewer of these later stage interventions per clinic in each of the target areas we examined, although at least 50% of clinics reported interventions at this stage in the areas of antiretroviral care and access to care.

Demographics and Clinical History

Overall, 9,986 patients (6,406 from the intervention clinics and 3,580 from the control clinics) were studied representing 96% of the requested sample. There were few significant differences in the clinical and socio-demographic characteristics between the intervention and control patients (Table 4). There were also few significant differences between the pre- and post-intervention samples. The average patient was approximately 40 years old and about two thirds of the patients were male. Patients in the post intervention period were slightly older ($p<.01$ for both the intervention and control group). Eighty percent were cared for primarily by

a physician. About 13% of patients had any HIV-related diagnoses, with the most common of these being *Pneumocystis carinii* pneumonia, *Candida* esophagitis, and AIDS wasting syndrome (each present in approximately 4-5% of the sample). Those with any HIV diagnosis had an average of 1.3 HIV-related conditions. Similarly, the patients in the study had 1.3 other comorbid conditions with cardiovascular conditions being the most common (present in about 15% of the sample). Approximately 30% of the patients had a psychiatric comorbid condition and 15% were current substance abusers.

Change in Performance: Impact of the Breakthrough Series

The proportion of patients with a suppressed viral load increased by 11.0% (from 40.7% to 51.7) in the intervention group as compared with 5.4% (from 44.1% to 49.5%) in the control group but this difference in trends was not statistically significant (p=.18) (Table 5). Rates of HAART use for appropriate patients were high in both the pre and post-intervention periods (approximately 80%) with a slight decrease in the second period. There was not a significant difference between the intervention and control sites.

Differences between the pre- and post-assessment periods for screening and prophylaxis were small for both the intervention and control clinics. Tuberculosis screening tests were conducted for half of the patients and the difference between the intervention and control sites was small. Flu shots and documentation of hepatitis C exposure status increased for both study groups (7.3% and 6.8% for flu shots for the intervention and control clinics respectively, p=.92 and 5.5% and 6.2% for hepatitis C screening, p=.89). Papanicolaou (PAP) smear rates increased by 4.6% in the intervention clinics from a baseline level of just 60.4% and decreased by 4.2% in the control clinics from a baseline level of 66.4% (p=.06).

Finally, both the intervention and control clinics showed a slight increase in the number of patients with visits in at least 3 of the last 4 quarters. From a baseline rate of approximately 65%, the collaborative clinics improved by 5.4 % as compared with 2.7% for the control clinics (p=.29).

There was not a significant difference in the effectiveness of the intervention for any of the outcomes for new Title III (n= 11) versus ongoing Title III clinics (n=33) nor was the intervention more effective for clinics that were poor performers at baseline. Finally, in models that compared improvement in the population of focus (applicable for 11 intervention clinics), only the increase in the number of visits in 3 or 4 quarters was marginally significant (p=.04). The results also did not change when we used fixed effect models or when we repeated the analyses for HAART use and viral load control based on the new guidelines for antiretroviral use released in 2002.

Discussion

This is the first national controlled evaluation of a breakthrough collaborative that we are aware of. In a prospective matched trial including almost 10,000 patients in 69 clinics, we found that the quality improvement collaborative did not have a significant impact on virologic outcomes or process measures, such as screening, prophylaxis, and access to care (Table 6).

Quality improvement methods of various types have been widely adopted throughout the health care system and there are numerous reports of successful interventions.(16, 21, 22) However, there are few rigorously controlled trials of the implementation of such programs.(13, 22-28) Furthermore, publication bias favors the dissemination of successful interventions.(29, 30) Thus, the evidence on the success of such efforts is mixed and dramatic improvements in quality have generally not been demonstrated.(22)

Multi-institution collaborative quality improvement programs such as the Breakthrough Series are particularly important because of their well established and documented methodology, broad applicability, and potential for widespread adoption (Table 6).(17) There are notable examples of quality improvement collaboratives that demonstrated improvements in small numbers of sites (13, 31) and other anecdotal or less rigorously evaluated examples that have shown dramatic improvements.(14) These studies suggest that selected institutions can achieve significant improvements in quality in collaboratives. Many previous studies of collaboratives, however, have suffered from selection bias, relied on pre-post designs without being able to account for secular trends, have used self report measures rather than medical record reviews, or have included only selected populations from self-selected sites.(13, 14, 18, 22, 31, 32) For instance, Horbar and colleagues evaluated quality improvement in a collaborative that focused on neonatal care. They demonstrated improvements relative to a set of control clinics, but the two intervention groups were small (6 and 4 sites) and self-selected.(13) Other evaluations such as one of a collaborative to reduce cesarean section rates have used historical controls that make accounting for secular trends difficult and these have usually not incorporated a control group.(14, 18, 33, 34) Thus, our evaluation is the most rigorous assessment of a collaborative that we are aware of. To illustrate the importance of this, if we had conducted an uncontrolled study, we might have attributed the 11% improvement in viral load control and the 7.3% increase in the percentage of patients receiving a flu shot to the intervention whereas our trial showed that these increases did not differ significantly from those observed in the control clinics.

There were several study limitations. First, we were not able to perform a pure randomized trial of the intervention. Instead, we relied on rigorous matching and statistical models to further adjust for potential confounding variables. Lack of randomization, however, is

of less concern when examined in the context of our results. Typically, a major concern of this type of evaluation is that clinics that are more amenable to quality improvement or more familiar with the concepts of continuous improvement would be more likely to participate in this type of intervention. Consequently, one would expect that the resulting bias would be in the direction of finding positive results. Second, while we assessed important markers of HIV quality that were the main focus of the collaborative, some clinics might have improved in areas of care that we did not measure, such as adherence. If that were the case, however, we would expect to see improvements in these areas reflected in some of the other important measures tracked by each clinic in the collaborative such as the proportion of patients with a controlled viral load. Third, Hawthorne effects could have led to improvements in the control clinics just by virtue of their being observed. Fourth, HRSA mandated participation for some clinics and the collaborative was larger than most prior collaboratives. There are, however, several other collaboratives that have used similar approaches and our subgroup analysis failed to show any differences between mandated and voluntary clinics.(35) Finally, a small number of the control clinics might have been "contaminated" by participation in prior quality improvement collaboratives aimed at different clinical conditions. While we cannot say if prior participation might have resulted in improved performance in these clinics, there are currently no data to suggest that organizations have been able to spread these methods either throughout the organization or to other clinical conditions.

For some of the measures that we studied, such as the use of HAART therapy, quality of care was excellent in both intervention and control clinics, thus leaving little room for improvement. Interestingly, our results demonstrated that both intervention and control patients were on HAART therapy less frequently in the second period than the first. This is likely due to

secular trends in the use of HAART.(19, 20) Other measures, however, such as the screening, prophylaxis, and access to care measures also did not show any improvement and performance on these measures was not as good. All of these process measures are widely accepted as beneficial and their implementation is not complex. In addition, we expected that these types of measures would be good candidates for improvement since parts of the quality improvement intervention focus on the use of registries of patients and other automated processes that can be used to identify and intervene upon patients that are in need of particular services, such as screening exams or immunizations. Some of the trends, however, did favor the intervention group and the difference approached statistical significance for one of the measures (p=.06 for Pap smears).

Our study, like other evaluations of quality improvement programs, is only generalizable to the disease we studied, a chronic medical condition. Different clinical areas might be more amenable to the improvement methods we studied. For instance, other collaboratives have focused on a particular procedure or process of care such as rates of cesarean sections or successful extubations, which are process measures that might be more amenable to collaborative improvement processes. Improving care for patients with chronic medical conditions, however, has become a major focus of collaborative improvement programs.(35)**[this ref does not seem correct currentlycan you recheck what I sent previously?]** Currently, collaboratives are being conducted for such conditions as asthma, diabetes, and depression. While not generalizable to all chronic medical conditions, this is the first rigorously controlled trial that examines the effectiveness of this well known type of collaborative for a chronic medical condition that we are aware of. Nonetheless, because each targeted disease and each breakthrough program have idiosyncratic components, we would not conclude that all

breakthrough series collaboratives for chronic medical conditions are ineffective. Our results, however, should give pause to those considering implementing similar collaboratives and, if, additional evidence from similar studies supports our findings, a different approach should be advocated. Alternatively, in the spirit of continuous improvement, similar results from additional evaluations might prompt a redesign in the Breakthrough Series process to potentially improve the effectiveness of the intervention.

A strength of our study is that, unlike most published studies of quality improvement interventions, we used statistical techniques that account for clustering of patients within clinics. Accounting for such clustering is even more important when the level of the intervention is at the institution as opposed to individual patients.(36, 37) We also conducted several post-hoc analyses to test the robustness of our results. In addition, our study was powered to detect clinically significant differences even prior to expanding the sample of clinics. Given the nature of quality improvement collaboratives, it is unlikely that future studies will have this many participants.

Finally, we do not know whether the collaborative failed because participants were not engaged actively enough, because of the types of changes that were implemented, or because of the way that they were implemented. Our impressions from attending the learning sessions and post intervention site visits, is that most participants were actively engaged in the improvement processes. It is possible that some interventions were more effective at some sites than at others and that different sites may have improved in different areas. However, if that were the case, the fact that there was not significant improvement over all the clinics means that some clinics would have had to experience declines in quality in order to balance out any selective positive effects. Future research should address this issue in more detail.

In conclusion, in this national controlled trial of a quality improvement collaborative aimed at improving care for patients with HIV infection, we did not find a significant difference in rates of improvement between participating and control sites. Our findings suggest that further research is needed to improve methods of teaching and implementing quality improvement programs in order to achieve better results.

Acknowledgements

We thank our colleagues at the HIV AIDS Bureau of the Health Resources and Services Administration for their efforts and expertise. We are indebted to Lin Ding, Ph.D. for assistance with expert statistical programming; to Deborah Collins for assistance with manuscript preparation; to Carol Cosenza and Trish Gallagher of the Center for Survey Research for assistance with survey administration; and to Barbara J. McNeil, MD, Ph.D. for comments on an earlier version of this manuscript.

References:

1. **Kohn LT, Corrigan JM, Donaldson MS**, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: Committee on Quality in Health Care in America, Institute of Medicine; 2000.
2. **Palella FJ, Delandy KM, Moorman AC, et al.** Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. *N Engl J Med*. 1998;338:853-860.
3. **Stein MD, Piette J, Mor V, et al.** Differences in access to zidovudine (AZT) among symptomatic HIV-infected persons. *J Gen Intern Med*. 1991;6(1):35-40.
4. **Shapiro MF, Morton SC, McCaffrey DF, et al.** Variations in the care of HIV-infected adults in the United States. Results from the HIV Cost and Services Utilization Study. *JAMA*. 1999;281:2305-2315.
5. **Moore RD, Stanton D, Gopalan R, Chaisson RE.** Racial differences in the use of drug therapy for HIV disease in an urban community. *N Engl J Med*. 1994;330(11):763-768.
6. **Shortell S, O'Brien J, Carman J, et al.** Assessing the impact of continuous quality improvement / total quality management: concept vs implementation. *Health Serv Res*. 1995;30(2):377-401.
7. **Chassin MR, Galvin RW.** The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. *JAMA*. 1998;280(11):1000-1005.
8. **Berwick DM.** Continuous improvement as an ideal in health care. *N Engl J Med*. 1989;320:53-56.
9. Institute for Healthcare Improvement. http://www.ici.org/collaboratives/. Accessed December 12, 2003.

10. **Berwick DM, Nolan TW.** Physicians as leaders in improving health care: a new series in Annals of Internal Medicine. *Ann Intern Med*. 1998;128(4):289-292.

11. **Edwards W.** (Massachusetts Institute of Technology Center for Advanced Engineering Study). Out of the Crisis. 1986 June 1986.

12. **Langley G, Nolan K, Nolan T, et al.** *The Improvement Guide* San Francisco: Jossey Bass; 1997.

13. **Horbar JD, Rogowski J, Plsek PE, et al.** Collaborative quality improvement for neonatal intensive care. *Pediatrics*. 2001;107(1):14-22.

14. **Flamm BL, Berwick DM, Kabcenell A.** Reducing cesarean section rates safely: lessons from a "breakthrough series" collaborative. *Birth*. 1998;25(2):117-24.

15. 2001 Ryan White CARE Act Title III Early Intervention Services. http://hab.hrsa.gov/reports/titleiii2001/titleiii2001.htm. Accessed March 1, 2003.

16. **Kilo C.** A framework for collaborative improvement: lessons from the Institute for Healthcare Improvement's Breakthrough Series. *Qual Manage Health Care*. 2001;6:1-13.

17. **Wilson T, Berwick DM, Cleary PD.** What do collaborative improvement project do? Experience from seven countries. *Jt Comm J Quality Improve*. 2003:In press.

18. **Leape L, Kabcenell A, Gahndi T, et al.** Reducing adverse drug events: lessons from a breakthrough series collaborative. *Jt Comm J Quality Improve*. 2000;26:321-331.

19. **Carpenter CC, Cooper DA, Fischl MA, et al.** Antiretroviral therapy in adults: updated recommendations of the International AIDS Society-USA Panel. *JAMA*. 2000;283(3):381-390.

20. **Yeni PG, Hammer SM, Carpenter CC, et al.** Antiretroviral treatment for adult HIV infection in 2002: updated recommendations of the International AIDS Society-USA Panel. *JAMA*. 2002;288(2):222-35.

21. **Blumenthal D, Kilo CM.** A report card on continuous quality improvement. *Millbank Q*. 1998;76(4):625-648.

22. **Shortell SM, Bennett CL, Byck GR.** Assessing the impact of continuous quality improvement on clinical practice: what it will take to accelerate progress. *Millbank Q*. 1998;76(4):593-624.

23. **Mehta RH, Montoye CK, Gallogly M, et al.** Improving quality of care for acute myocardial infarction: The Guidelines Applied in Practice (GAP) Initiative. *JAMA*. 2002;287(10):1269-76.

24. **Holman WL, Allman RM, Sansom M, et al.** Alabama coronary artery bypass grafting project: results of a statewide quality improvement initiative. *JAMA*. 2001;285(23):3003-10.

25. **Wells KB, Sherbourne C, Schoenbaum M, et al.** Impact of disseminating quality improvement programs for depression in managed primary care. *JAMA*. 2000;283(2):212-220.

26. **O'Connor GT, Plume SK, Olmstead EM, et al.** A regional intervention to improve the hospital mortality associated with coronary artery bypass graft surgery. The Northern New England Cardiovascular Disease Study Group. *JAMA*. 1996;275(11):841-6.

27. **Soumerai SB, McLaughlin TJ, Gurwitz JH, et al.** Effect of local medical opinion leaders on quality of care for acute myocardial infarction: a randomized controlled trial. *JAMA*. 1998;279(17):1358-1363.

28. **Shafer MB, Tebb KP, Pantell RH, et al.** Effect of a clinical practice improvement intervention on chlamydial screening among adolescent girts. *JAMA*. 2002;288(22):2846-2852.

29. **Agema WR, Jukema JW, Zwinderman AH, van der Wall EE.** A meta-analysis of the angiotensin-converting enzyme gene polymorphism and restenosis after percutaneous transluminal coronary revascularization: evidence for publication bias. *Am Heart J*. 2002;144(5):760-8.

30. **Stern JM, Simes RJ.** Publication bias: evidence of delayed publication in a cohort study of clinical research projects. *BMJ*. 1997;315(7109):640-5.

31. **Pronovost PJ, Jenckes M, To M, et al.** Reducing failed extubations in the intensive care unit. *J Qual Improve*. 2002;28(11):595-604.

32. **Kerr D, Bevan H, Gowland B, Penny J, Berwick DM.** Redesigning cancer care. *BMJ*. 2002;324:164-166.

33. **Oldham R, et al.** How to spread good practice to 7 million patients. 7th European Quality Forum. Edinburgh; March 2002.

34. **Bate S, Robert G, McLeod H.** (Health Services Management Centre, University of Birmingham). Report on the 'Breakthrough' collaborative approach to quality and service improvement within four regions of the NHS. A research based investigation of the orthopaedic services collaborative within the Eastern, South & West and Trent regions. 2001.

35. Health Disparities Collaborative. http://www.healthdisparities.net. Accessed December 12, 2003.

36. **Divine GW, Brown JT, Frazier LM.** The unit of analysis error in studies about physicians' patient care behavior. *J Gen Intern Med*. 1992;7:623-629.

37. **Whiting-O'Keefe QE, Henke C, Simborg DW.** Choosing the correct unit of analysis in medical care experiments. *Med Care*. 1984;22(12):1101-1114.

Table 1. Quality of Care Indicators

Quality Indicator	Eligible Population	Meets Quality measure
Tuberculosis screening during review period *	All patients	All patients that received a *Tuberculosis* screening test or were known to be *Tuberculosis* screening test+ in the past
Flu shot	All patients	Documentation that the patient received a flu shot during the review period.
Hepatitis C Status	All patients	All patients with hepatitis C status documented during the review period**
Pap smear	All women	PAP smear performed or offered and refused at least once during the review period or note of a PAP smear done elsewhere.
Pneumocystis carinii pneumonia prophylaxis	All patients with CD4 count <200 at any point during the review period.	Receipt of PCP prophylaxis*
HAART last visit for appropriate patients	All patients with CD4 count <500 or VL >10,000 or already on HAART	Receipt of 3 drug HAART regimen
Viral Load Controlled last visit (VL<400 or undetectable)	All patients on or eligible for HAART	Viral load undetectable or less than 400 copies/ml
Proportion with	All patients with initial CD4 count less	CD4 count >200 on last CD4 count

increased CD4 count	than 200 and at least one other CD4 check.	
Visits in 3 or 4 quarters	All patients	Visits in at least 3 of 4 quarters

* Patients with documentation of a prior positive Tuberculosis screening test were counted as being screened. Those with missing values were counted as not being screened.

** Includes those with documentation of a prior positive test for Hepatitis C.

Table 2. Description of All title III sites , EQHIV Intervention, and EQHIV Control Sites

	All title III	Intervention	Control	p value *
	Sites n=208	(n=44)	(n=25)	
Location				
Urban	79.3%	77.3%	84.0%	.50
Region				
South	27.7%	36.4%	16.0%	.06
West	17.5%	6.8%	24.0%	
Midwest	15.0%	15.9%	28.0%	
Northeast	39.8%	40.9%	32.0%	
Clinic Type				
CHC	38.9%	29.5%	40.0%	.41
Hospital	11.1%	13.6%	16.0%	
Other	50.0%	56.8%	44.0%	
# HIV patients (S.D)	623 (733)	657 (695)	490 (295)	.17
Clinic Size				
Small (<400 HIV pts)	49.0%	45.4%	44.0%	.91
HIV Specialty Clinic				
Yes	74.3%	81.8%	84.0%	.82

Note: p value is for testing the differences between intervention and control sites.

+ Other includes Community Based Organizations, University Medical Centers, and Public Heatlh Clinics.

Table 3. Description of Specific Interventions Attempted by Individual Sites*

Intervention Target	Average number of interventions per site	Average number of interventions per site that were being refined or institutionalized (Mean per site)	Number of sites with at least one intervention	Number of sites with at least 1 intervention that was being refined or institutionalized
Antiretroviral Therapy	6.9	1.1	41	22
Screening	3.5	.6	39	18
Access to Care	9.1	1.5	42	27
Prevention	1.3	.1	27	4
Women	1.7	.5	27	16

*n=43 sites with at least one report

Table 4. Description of the Patient Population by Time Period and Intervention/Control

	Pre assessment		Post Assessment	
	Intervention	Control	Intervention	Control
	n=3,190	n=1,761	n=3,216	n=1,819
Age (mean (S.D.))	39.6 (8.7)	40.0 (8.9)	41.5 (8.9) ++	41.7 (9.1) ^^
Male (%)	66.4%	71.3% ##	65.8%	71.2% $$
Primary Provider				
Physician	81.7%	80.3%	80.0% ++	79.5%
PA/NP/Other *	18.4%	19.7%	21.0%	20.5%
HIV Related Diagnoses**				
Any HIV related Diagnosis	13.3%	13.8%	12.9%	13.7%
Number of HIV Diagnoses	1.31 (0.59)	1.30 (0.58)	1.32 (0.67)	1.21 (0.42) $
Pneumocystis carinii Pneumonia	3.7%	4.9% #	3.5%	4.2%
Candida Esophagitis	4.3%	3.8%	5.0%	3.5% $
AIDS wasting Syndrome	4.6%	4.6%	4.2%	4.6%
Co-Morbid Conditions±				
Number (S.D.)of conditions	1.30 (0.59)	1.42 (0.69) ##	1.33 (0.57)	1.39 (0.63)
Cardiovascular	15.5%	12.7% ##	16.9%	16.2% ^^
Endocrine	5.3%	5.5%	6.0%	5.6%
Gastrointestinal	4.0%	5.3%	4.1%	5.7% $
Lipid Disorders	12.6%	14.2%	16.4% ++	16.6%

Psychiatric Disorders#	30.4%	32.0%	30.7%	35.2% $$ ^
Substance abuser†	15.7%	18.0% #	14.1%	18.2% $$
Lowest CD4 counts		##		$
0-49	11.0%	8.6%	11.0%	8.7%
50-199	21.3%	21.4%	20.9%	19.0%
200-499	43.9%	42.8%	42.0%	45.4%
500	23.9%	27.3%	26.1%	26.9%

'#' or '##' indicates comparison between column 2 & column 3, for p<.05 or p<.01 respectively.

'$' or '$$' indicates comparison between column 4 & column 5, for p<.05 or p<.01 respectively.

'+' or '++' indicates comparison between column 2 & column 4, for p<.05 or p<.01 respectively.

'^' or '^^' indicates comparison between column 3 & column 5, for p<.05 or p<.01 respectively.

*NP= Nurse Practitioner, PA= Physician's Assistant

**HIV related diagnoses include *Pneumocystis Carinii* Pneumonia, Mycobacterium Avium Complex Infection, Candidal Esophagitis, Kaposi's Sarcoma, AIDS Wasting Syndrome, Cytomegalovirus Retinitis and Enteritis, and HIV Encephalopathy,

±Cardiovascular comorbid conditions include hypertension and coronary artery disease, Endorine comorbid conditions includes diabetes, GI comorbid conditions include active Hepatitis B or Active other chronic liver disease, Lipid disorders includes elevated cholesterol or lipodystrophy.

#Psychiatric disorders include depression, schizophrenia, bipolar, or anxiety disorder

†Substance Abuse includes documented current use of heroin, cocaine, infection drug use, other illegal drugs, or alcholol.

Table 5 Adjusted Quality of Care Indicators for Intervention and Control Clinics*

	Pre assessment		Post Assessment		Difference		
	Int. n=3,190	Control n=1,761	Int. n=3,216	Control n=1,819	Int. n=6,406	Control n=3,580	p
Anti-retroviral Therapy							
HAART last visit for appropriate patients	83.5%	80.4%	80.5%	77.5%	-3.0%	2.9%	.85
Viral Load Controlled	40.7%	44.1%	51.7%	49.5%	11.0%	5.4%	.18
Screening and Prophylaxis							
Tuberculosis Screening	52.2%	54.2%	52.3%	52.3%	0.1%	-2.1%	.65
Flu shot	45.8%	52.7%	53.1%	59.5%	7.3%	6.8%	.92
Hepatitis C Status	84.4%	83.5%	90.0%	89.7%	5.5%	6.2%	.89
Pap smear	60.4%	66.4%	65.0%	62.2%	4.6%	-4.2%	.06
PCP prophylaxis	74.7%	67.9%	75.1%	71.4%	0.4%	3.5%	.54
Access to Care							
Visits in 3 or 4 quarters	68.0%	64.7%	73.4%	67.4%	5.4%	2.7%	.29

P>.05 for all tests between intervention and control clinics. Adjusted rates calculated using hierarchical linear regression models controlling for patient age, sex, HIV-related diagnoses, comorbid conditions, and lowest CD4 count over the review period as well as for clinic location, region, type, site size, and specialty status.

Table 6. Key Summary Points

Unlike other quality improvement interventions, multi-institutional quality improvement collaboratives such as the Breakthrough series have a well-established and documented methodology, broad applicability, and potential for widespread adoption.

Prior evaluations of QI collaboratives have been limited by the use of pre/post designs, self-reported data, lack of a concurrent control group, and the failure to include analytic methods that account for the clustering of patients within sites of care.

The HIV quality improvement collaborative did not have a significant impact on virologic outcomes, or measures of prevention, screening, or access to care.

Real world quality improvement evaluations face numerous challenges including:

- An inability to perform randomized evaluations in most cases.
- Possible contamination from other quality improvement activities.
- The difficulty of assessing all potential important outcomes that might be affected.
- The difficulty in defining the exact nature of specific interventions attempted by individual clinics.

Quality improvement methods need to be developed further in order to achieve measurable improvements in quality.

Figure 1 Theoretical Construct of Continuous Quality Improvement (adapted from Berwick and Nolan, Annals of Internal Medicine, 1998)

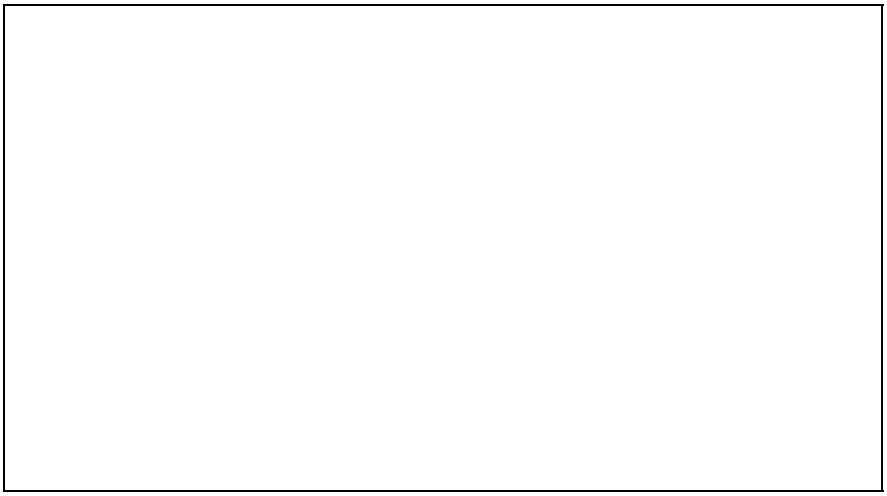
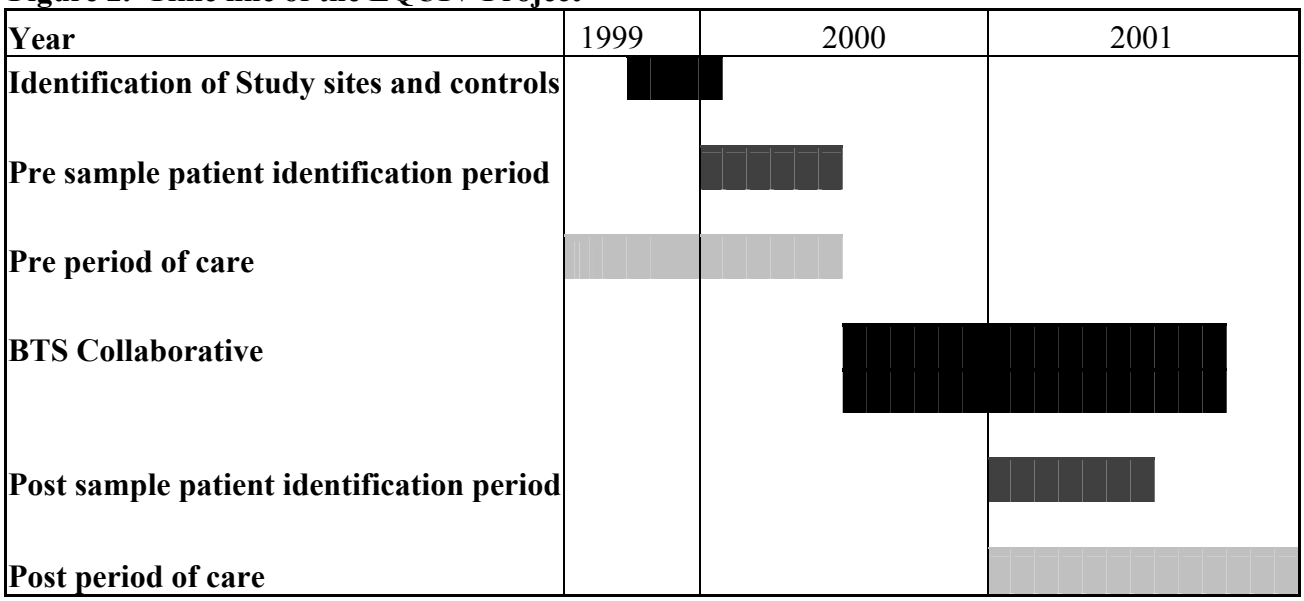


Figure 2. Time line of the EQUIV Project



***Note. The collaborative was extended 3 months past its originally scheduled end date midway through the process.**