A novel collaborative practice model for treatment of mental illness in indigent and uninsured patients

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Purpose. The implementation and evaluation of a collaborative practice model (CPM) of mental health care at a free clinic are described.

Summary. Since 2004, the mental health clinic of the Cape Fear Clinic in Wilmington, NC, has provided pharmacotherapy and psychotherapy services to a mostly female population of poor and uninsured patients (average age, about 45 years) under a CPM that includes a state-licensed Clinical Pharmacist Practitioner with prescribing privileges. Spanish is the primary language of about 28% of the clinic’s patients. At patient intake and (when possible) six months later, three measures of physical and mental health are administered: the Short-Form Health Survey (SF-12), the physical and mental component summaries of the Patient Health Questionnaire for depression (PHQ-9), and the Alcohol Use Disorders Identification Test (AUDIT); psychological counseling, psychotropic medications, and laboratory monitoring are provided as appropriate. In 2009, the clinic’s volunteer health care providers served 56 patients (a total of 316 office visits), providing about 165 hours of free clinical services valued at more than $15,000 and free prescription medications valued at about $123,000. Although the clinic’s experience has demonstrated the feasibility of CPM-based mental health care for the indigent and uninsured, a comparison of pretest and posttest data on a sample of clinic patients did not show significant changes from mean baseline SF-12, PHQ-9, and AUDIT scores, possibly due in large part to sampling challenges resulting from the loss of many clinic patients to follow-up.

Conclusion. A CPM that includes a pharmacist with prescribing authority and psychologists was implemented to provide care for a low-income, uninsured, partly Spanish-speaking patient population.

Background

The Cape Fear Clinic Health Clinic (referred to as the clinic...
hereafter) is a nonprofit clinic that has served low-income and uninsured patients in southeastern North Carolina for 20 years. The clinic’s mission is to provide quality health services at no cost to those who have no form of health insurance and whose income is below the federally defined poverty threshold (at the time of writing, $21,954 for a household of four people).11

Since its inception, the clinic has expanded its service offerings from the provision of basic primary care services one night per week to providing both primary care and specialty services on several weekdays during both daytime and evening hours. In addition to providing medical services, the clinic provides dental services and operates an onsite pharmacy to ensure clinic patients’ access to prescribed medications. The pharmacy stocks a comprehensive formulary of inexpensive medications and medications obtained for individual patients through medication assistance programs. Under an affiliation agreement between the clinic and a local health system, patients receive referral-based laboratory, radiology, and other diagnostic services.

The clinic’s budget consists entirely of grants, donations, and money collected through fundraising. In 2010, 316 volunteers worked a total of 14,668 hours at the clinic. All services and medications provided by the clinic and its affiliates are free of charge to all of the clinic’s patients.

In 2004, it was determined that the clinic’s patient population had an increasing need of mental health care services not available in the community. There were no services available to enable basic interventions (e.g., psychotherapy, medication therapy) for mild-to-moderate anxiety, depression, and other mental health disorders among indigent, particularly Spanish-speaking, patients. State funding for community-based outpatient treatment of anxiety, depression, and other mental health disorders in the indigent and uninsured patient population of southeastern North Carolina had been lost over the prior decade due to budget cuts, resulting in a widening of gaps in care. As a result, the clinic sought out mental health professionals to assist with patients’ mental health care needs and founded the mental health clinic program in 2004 to ensure that mental health was addressed as a vital component of comprehensive health care.

The mental health care clinic was founded by a clinical psychologist. The initial stages of the clinic’s operation were tedious and time-consuming, as mental health providers were required to consult with the clinic physicians and nurse practitioners to obtain prescription medications for their patients. In an effort to increase the efficiency and quality of care, a pharmacist volunteering in the clinic’s pharmacy proposed the development of a CPM to better meet the mental health needs of the clinic’s patients.

Clinic description

In 2006, a collaborative practice agreement was established between the volunteer pharmacist and the clinic’s medical director (a practicing physician). In accordance with state laws, the pharmacist obtained a Clinical Pharmacist Practitioner (CPP) license from the state boards of pharmacy and medicine.12 Licensure as a CPP allowed the pharmacist to participate in patient interviews with the clinic’s psychologist and prescribe medications based on the physician’s diagnosis and the psychologist’s assessment. Under the terms of the collaborative practice agreement (henceforth “CPP protocol”), the overseeing pharmacist was required to review all clinic notes and endorse the pharmacist’s medication recommendations (appendix). At the time of writing, there were 83 actively practicing CPPs in North Carolina, and the CPP protocol discussed here was the only such agreement in the specialty area of outpatient mental health13; to our knowledge, the pharmacist at the Cape Fear Clinic Mental Health Clinic was one of only 3 CPPs in North Carolina practicing in the area of mental health (the other two were working in an inpatient setting).

The mental health clinic, which has now been in operation for more than nine years, is run solely by volunteers and currently provides services on the first and third Wednesdays of each month. The staff includes two doctorate-level psychologists, one residency-trained doctor of pharmacy, and the physician who oversees the CPP protocol. Several non-doctorate-level counselors provide various forms of psychotherapy. The supervised and nonlicensed volunteer staff of the mental health clinic includes graduate and postgraduate psychology students, pharmacy students, pharmacy residents, and psychology practitioners in need of supervised clinical practice hours. The clinic’s administrative staff is composed of undergraduate and graduate psychology students. All services provided by the clinic are offered in both English and Spanish, as most of the practitioners and support staff are bilingual.

Program description

The clinic’s mental health program is structured to provide four major service types: initial evaluation, psychotherapy only, medication management only, and psychotherapy plus medication management (Figure 1). Once a referral is made and acceptance to the clinic is established, patients participate in a comprehensive initial interview conducted jointly by a doctorate-level clinical psychologist and the clinical pharmacist. Initial interviews generally last one hour and conclude with a suggested diagnosis followed by discussion and initial implementation of the most feasible treatment.
plan. Patients with difficult-to-diagnose conditions or disease states with unclear etiologies receive a more comprehensive evaluation, which includes psychological or neuropsychological testing if deemed appropriate by the psychologist who conducts the initial interview.

Current evidence suggests that the optimal management of many mental health conditions includes both psychotherapy and medication management.\textsuperscript{14-16} Most patients referred to the mental health clinic receive psychotherapy in conjunction with pharmacotherapy. Psychotherapy is provided by licensed psychologists and counselors. The medications most commonly prescribed to clinic patients include selective serotonin-reuptake inhibitors, serotonin-norepinephrine-reuptake inhibitors, and atypical antipsychotics. Medications are selected according to American Psychiatric Association (APA) treatment guidelines and drug availability.\textsuperscript{17}

Patients receiving pharmacotherapy attend periodic visits with the pharmacist and psychologist for ongoing evaluation of the efficacy of the chosen medication regimen (as determined via laboratory testing, patient interviews, and reference to the APA guidelines); these visits occur every two weeks after the initiation of medication therapy and continue through the acute phase of treatment. Once the patient has transitioned to the maintenance phase of therapy, follow-up visits occur every three to six months.

Patients receiving medications that require laboratory monitoring (e.g., assessment of valproic acid levels during divalproex therapy, lipid analysis during the use of an atypical antipsychotic) are referred to a local health system for appropriate testing in accordance with treatment guidelines and medication package inserts. The results of the laboratory tests are transferred to the mental health clinic and included in the patient’s medical records for interpretation by the pharmacist, psychologist, and supervising physician.

**Patient population.** Since the implementation of the CPM in 2006, over 120 indigent and uninsured patients have received services provided by the mental health clinic staff. All patients seen in the mental health clinic must undergo the standard intake process at the medical clinic, where specialists conduct interviews and review financial documents and insurance information to verify eligibility for clinic services. Uninsured patients who meet certain financial criteria are qualified to receive care at the clinic.

In addition to the qualifications described above, some patients must meet other criteria before receiving services at the mental health clinic. Patients with active substance abuse disorders are required to participate in a substance abuse treatment program at one of several local agencies in order to be eligible for mental health clinic services. Patients who are actively suicidal or psychotic are ineligible for mental health clinic services because they need immediate high-level services the clinic is
unable to provide; these patients are immediately referred to the local health system's inpatient psychiatric hospital or emergency department.

All patients are required to sign an informed-consent contract with the mental health clinic before their first appointment. The contract discusses patient confidentiality in addition to outlining patient and provider expectations. Patients must also agree to participate in pretesting and posttesting and the inclusion of collected data in the research study described below; agreement to be included in research is not necessary for the provision of care. Patients who break their contract by missing appointments or refusing treatment are dismissed from the mental health clinic and sent back to the medical clinic for reevaluation.

**Psychological testing.** The purpose of the testing conducted at the mental health clinic is twofold. First, testing is used for diagnostic purposes. Psychological testing and neuropsychological testing are done to facilitate diagnosis and to acquire standardized data for the patient's records and research purposes. Testing is done by graduate psychology students or testing technicians. The tests used at the clinic include those typically used in an outpatient psychology practice, such as the Wechsler Adult Intelligence Scale, Trail-Making Test, Mini-Mental State Examination, and Minnesota Multiphasic Personality Inventory. In addition, clinic providers often administer the 12-item Short-Form Health Survey (SF-12), the Alcohol Use Disorders Identification Test (AUDIT), and the Patient Health Questionnaire for depression (PHQ-9). In each case, a report is generated by the student or testing technician and reviewed by a doctorate-level provider.

Second, testing is used as a means of monitoring and documenting treatment outcomes. Pretest data are gathered during the initial clinic appointment to provide an overall picture of the patient's current physical and mental health status. All pretest data on individual patients are compiled to provide a general description of the clinic population. Posttest data are gathered approximately six months after the start of therapy to enable the evaluation of the patient's response to therapy. Data quantifying the cost of services provided and the associated staff time demands have also been compiled.

**Psychotherapy.** Psychotherapy is provided by staff members fluent in English and Spanish, as well as Portuguese. There are male and female therapists, as well as doctorate- and master's-level clinicians; each offers a blend of expertise in areas such as brain injury and dementia, pediatrics, depression, family therapy, and substance abuse. In most cases, therapy is provided in 30-minute increments. On average, each individual is seen once or twice per month. Each evening psychotherapy service is offered, 15–20 patients are seen at the clinic. The typical intervention is cognitive-behavioral therapy, though some of the master's-level clinicians prefer client-centered interventions. Every effort is made to ensure that the responsible clinician's skills and personality are well suited to addressing an individual patient's problems. Each patient is seen every two to three months for therapy and medication management. Medication consultations are also provided on a more or less frequent basis as necessary.

**Program evaluation.** In order to determine the efficacy of the program, pretest and posttest measures were administered. The three measures used (AUDIT, PHQ-9, and SF-12) were chosen due to their established validity, ease of use and scoring, and previous use in other studies. The project was submitted to the institutional review board at the University of North Carolina at Wilmington.

**Measures.** The patient outcome data for program evaluation are collected in a standardized manner that accommodates both English- and Spanish-speaking patients. After patients give consent to the regulations and procedures of the clinic regarding patient conduct, attendance, and testing, a psychology student administers three questionnaires. The first test administered is the AUDIT, which includes questions about the quantity and frequency of adult alcohol use designed to detect dependence, as well as harmful and hazardous drinking behaviors. AUDIT scores range from 0 to 40, with higher scores indicating more serious alcohol-use problems. The second questionnaire administered is the PHQ-9, which is used to assess and monitor the severity of depression. PHQ-9 scores range from 0 to 27, with higher scores indicating more severe depression.

The third questionnaire routinely administered to patients at the mental health clinic is the SF-12, which is used to assess quality of life by quantifying overall physical and mental health relative to two population-based scores: the physical component summary (PCS) and the mental component summary (MCS). Scores on the SF-12 range from 0 to 100, with 100 indicating the highest level of health. Individual scores on both the PCS and the MCS can be compared to a national norm (mean ± S.D. score, 50 ± 10).

**Inclusion criteria.** All adult patients (≥18 years of age) of the mental health clinic who received pretest and posttest evaluations during the designated study period (January 2007–February 2010) were eligible for inclusion in the analysis described here. Pediatric and adolescent patients received the same testing, but their data were not included in the study because the questionnaires have not been validated in these populations.

All sets of pretest and posttest data collected more than 12 months apart

**Practice Reports**  Collaborative practice model
were excluded from the study. Data from any incomplete questionnaires (unanswered items or illegible writing) were also excluded.

Information on the age, sex, and languages of the mental health clinic patient population, as derived from pretest data, is displayed in Table 1.

**Pretest assessment results.** Pretest data were gathered on 81 patients who ranged in age from 18 to 65 years (mean ± S.D., 44 ± 11.2 years. Approximately 78% \((n = 63)\) of the patient population were women. Spanish-language testing was conducted for approximately 28% \((n = 23)\) of the patients.

As indicated by the mean pretest AUDIT score of 2.4, the majority of patients did not have alcohol dependence and did not report harmful or hazardous drinking behaviors during the year before their initial interview (Table 2). AUDIT scoring indicated that six patients had engaged in harmful or hazardous drinking behavior at some time during the prior year, and two patients were identified as likely alcohol dependent; those eight patients were permitted to receive care from the clinic after an oral agreement to stop abusing alcohol and enroll in substance abuse treatment.

Pretest PHQ-9 assessments identified 32.1% of the patients \((n = 26)\) as having severe depression (mean ± S.D. overall score, 15.0 ± 7.6; mean ± S.D. score on items pertaining to depressive symptoms, 6.7 ± 2.5). On the pretest SF-12 assessments, the mean ± S.D. MCS score was 34.9 ± 13.1, and the mean ± S.D. PCS score was 38.2 ± 11.6.

Approximately one third of the evaluated patient population had major depression, as evidenced by PHQ-9 scores. SF-12 testing indicated that the mean MCS and PCS scores were several points below the national norms.

**Posttest assessment results.** Posttest data were collected on 36 patients, or about 44% of the patient population. Seven sets of pretest and posttest data were excluded from the analysis due to an assessment interval of >12 months; therefore, data sets from 29 patients met the study inclusion criteria. However, AUDIT or SF-12 data from 9 of those 29 data sets were incomplete and thus excluded from the analysis. Data obtained from October 2007 to November 2010 were included in the analysis. Patient demographics for the posttest population are listed in Table 2. A comparison of pretest and posttest results indicated no significant changes in mean AUDIT, PHQ-9, and SF-12 scores.

The mean ± S.D. age of patients included in the analysis was 46.7 ± 9.3 years. Approximately 72% of the patients were women. Spanish-language testing was conducted in approximately 28% of the patients. The mean ± S.D. elapsed time from pretest to posttest assessments was 7.0 ± 1.8 months.

**Comparison of pretest and posttest data.** Table 2 lists the results of pretest and posttest AUDIT, PHQ-9, and SF-12 scoring. The mean pretest and posttest AUDIT scores were 1.59 and 1.72, respectively. Before receiving treatment, two of the patients reported having engaged in harmful or hazardous drinking behavior in the prior year; one was likely alcohol dependent. AUDIT scores obtained after treatment services were initiated indicated that one patient was engaged in harmful or hazardous drinking and one was alcohol dependent. A paired-sample \(t\) test was conducted to assess if there was a significant difference between mean pretest and posttest AUDIT scores. Results showed no significant difference \((t_{28} = 0.190; 95\% \text{ confidence interval (CI)}, –1.62 to 1.35; p = 0.851)\).

Pretest PHQ-9 assessments identified 11 patients as having severe depression; the mean test score was 15.7, and the mean number of depressive symptoms was 7.3. Posttesting indicated that 10 patients remained severely depressed; the mean posttest score was 14.4, and the mean number of depressive symptoms was 6.8. A paired-sample \(t\) test indicated no significant difference between pretest and posttest PHQ-9 scores \((t_{28} = 0.925; 95\% \text{ CI}, –1.55 to 4.1; p = 0.363)\).

Pretest SF-12 assessments yielded a mean ± S.D. MCS score of 30.9 ± 12.1 and a mean ± S.D. PCS score of 35.3 ± 11.7. The mean ± S.D. posttest MCS and PCS scores were 36.7 ± 37.4 and 37.4 ± 12.5, respectively. A paired-sample \(t\) test indicated no significant difference between mean pretest and posttest scores on either the PCS \((t_{19} = 0.641; p = 0.529; 95\% \text{ CI}, –0.73 to 3.04)\) or the MCS \((t_{19} = 1.75; p = 0.095; 95\% \text{ CI}, –1.24 to 1.24)\).

**Economic impact.** Financial data for the designated study period were analyzed to determine the economic impact of the free mental health clinic. In 2009, the mental health clinic served 56 patients during a total of 316 visits. Table 3 quantifies the amount of free health care provided that year by estimating the hourly cost of each service provided. A total

| Table 1. Demographics of Pretest and Posttest Samples of Mental Health Clinic Patients |
|-----------------------------------------------|-----------------|-----------------|
| Variable                                      | Pretest \((n = 81)\) | Posttest \((n = 36)\) |
| Mean ± S.D. age, yr                           | 44.4 ± 11.2      | 46.7 ± 9.3      |
| No. (%) women                                 | 63 (77.8)        | 21 (72.4)       |
| Testing language, no. (%)                     | English 58 (71.6) | 21 (72.4)       |
|                                              | Spanish 23 (28.4) | 8 (27.6)        |
of 165 hours of free health care, with an estimated value of $15,581, were provided by practitioners at the mental health clinic.

Prescription data for the year 2009 were collected from the pharmacy computer system and analyzed (Table 4). A total of 775 prescriptions were issued by clinic pharmacists, with total associated patient cost savings of $123,699.

Discussion

The implementation of an innovative CPM in the mental health clinic was not associated with significant improvements in PHQ-9 depression scores, SF-12 quality-of-life scores, and AUDIT alcohol-abuse scores during the study period despite clinic patients’ increased access to mental health care and medications. Several aspects of the study design and data collection methods limited the usefulness of the pretest and posttest data, and the lack of demonstration of statistically significant results could be due to a number of factors.

First, it is possible that the measures used were not sensitive enough to allow for the detection of significant differences between mean pretest and posttest scores. Second, the amount of time that transpired between the collection of pretest and posttest data on some individuals varied considerably because the testing interval was not standardized to six months, as specified in the original study design. Third, due to the combination of the clinic’s limited hours of operation and the testing workload, several patients were lost to follow-up; in other patients, follow-up assessments were conducted several months past the six-month goal. Fourth, the small number of patients for whom both pretest and posttest data were available for comparison might have precluded the demonstration of significant results.

Although documentation of the reasons why some patients were lost to follow-up was not maintained, there are several likely explanations. Some patients might have become employed or otherwise obtained health insurance after initial evaluation, thus becoming ineligible for the clinic’s services. In some cases, patients transitioning to another health care program did not schedule an exit interview with the clinic’s mental health staff to discuss future care plans. Moreover, it appears that some patients moved out of the area. Finally, the clinic staff was unable to reach some patients using available contact information in order to determine why they were no longer attending regular clinic appointments.

Another factor that might have hindered the demonstration of significant results was that a response to treatment actually did not occur. However, anecdotal evidence does not support that conclusion. The biopsychosocial well-being of the patients was the primary reason for termination of treatment. Therefore, it can be assumed that clinical effects were evident to clinical staff. The sample size used was small, and this variable considerably reduces the possibility of demonstrating a statistically significant result. Given the anecdotal evidence of improvement in treated patients’ symptoms, it is possible that an analysis involving a larger sample size would yield significant results.

The clinic staff is investigating alternative means of testing to help ensure that patients receive testing at shorter and more regular intervals. Additionally, four (rather than three)
students now conduct testing to help ensure that all patients are tested on schedule. The clinic’s support staff plans to track patients who miss appointments and document the reasons why they are no longer attending clinic appointments.

Although the implementation of a CPM in the mental health clinic was not associated with significant improvements in PHQ-9, SF-12, and AUDIT scores, clinic patients were provided access to mental health care and medications that were previously unavailable to them within the community. In 2009 alone, clinic patients received over $139,000 in free mental health care and medications that were previously unavailable to them within the community. In 2009 alone, clinic patients received over $139,000 in free mental health care and prescription medications. The most common diagnosis was depression; the most commonly prescribed medications included bupropion, citalopram, escitalopram, fluoxetine, paroxetine, quetiapine, trazodone, and venlafaxine. Psychotherapy and pharmacotherapy together have been shown to be an effective treatment method in the literature.26–28

Many of the patients who visit the mental health clinic are Hispanic. As the U.S. Hispanic population increases, it is vital that clinics provide Spanish-language services. The U.S. Census Bureau has projected that the Hispanic population will grow from about 48 million in 2010 to 102.6 million in 2050, increasing its representation from 16% to 24%.24 The Cape Fear Clinic Mental Health Clinic remains one of the few institutions in the state providing free medical care, including mental health care, to uninsured Hispanic patients.

**Conclusion**

A CPM care model that includes a pharmacist with prescribing authority and psychologists was implemented to provide care for a low-income, uninsured, partly Spanish-speaking patient population.

**References**


Appendix—Clinical Pharmacist Practitioner (CPP) Protocol

The CPP Agreement shall be approved and signed by both the supervising physician and the CPP, and a copy shall be maintained in each practice site for inspection by agents of either Board upon request. Refer to 21 NCAC 46.3101(6)(b). If practice occurs in an institution, attach appropriate documents from the Pharmacy and Therapeutics Committee or its equivalent. If the P&T practice is followed, then completion of items I through VI is unnecessary: 90-18.4(c).

I. Patients and Diseases

Patients who will receive care from the CPP will meet the following criteria:

- Be active patients of the Tileston Outreach Health Clinic under the supervision of Dewey Bridger, MD
- Be receiving mental health counseling from Antonio Puente, PhD under the supervision of Dewey Bridger, MD
- Be referred to CPP, Dr. Askew, for drug therapy management per protocols

II. Diagnosis or Diagnoses; Drug Therapy or Therapies; Dosage Forms and Schedules; Tests; and Modifications Permitted

- Dewey Bridger, MD will determine the appropriate diagnosis for mental health therapy, monitoring parameters, and duration of therapy per clinic policy and procedure, in consultation with Antonio Puente, PhD.
- Drug therapies authorized for management by the CPP include those found in the Tileston Outreach Health Clinic Mental Health Formulary.
- This formulary will be reviewed, modified, and updated semiannually by Drs. Bridge, Puente, and Askew.
- Examples of medications included in this formulary are:
  - Antidepressants
  - Anxiolytics
  - Antipsychotics
  - Stimulants
  - Mood Stabilizing Medications
- The CPP authorized drug therapies will be managed according to:
  - Tileston Outreach Health Clinic Mental Health Clinic Policy and Procedure (see Attachment 2)
  - Approved by Tileston Outreach Health Clinic Board of Directors
  - Approved by supervising physician, Dewey Bridger, MD
- Current guidelines and standards of care for the management of:
  - Anxiety (such as ICD-9: 293.84, 300.00, 300.02, 300.09, 300.20, 300.4, 308.0)
  - Depression (such as ICD-9: 296.20, 296.21, 296.22, 296.23, 296.24, 296.25, 296.26, 300.4, 311.00)
  - Alzheimer’s Disease (such as ICD-9: 331.0)

III. Plan for Emergencies (per clinic policies and procedures)

- The supervising physician will be notified of any emergent condition
- In the event the supervising physician is not immediately available, the CPP will contact the physician on-duty at the Tileston Outreach Health Clinic or the covering physician for the day within the office of New Hanover Medical Group.
IV. Weekly Plan for Quality Control and Review and Countersignature of All Orders
- The CPP will record all patient encounters in the outpatient medical record. The supervising physician will review and sign all outpatient patient encounters.
- The CPP and supervising physician will meet monthly to review and discuss patient-specific issues, pertinent issues related to mental health, and clinic operations, as this clinic will be held one to four times monthly.
- The supervising physician will be notified of adverse reactions, abnormal labs, and failures of therapy.

V. Patient Notification
- Patients will be informed by the CPP that they are receiving care from a clinical pharmacist practitioner under the supervision of Dr. Dewey Bridger and in conjunction with Dr. Anthony Puente.
- Informed consent for participation in the Tileston Outreach Health Clinic Mental Health Program will be obtained.

VI. Termination Provision
- If the patient receiving care from the CPP transfers to another clinic/physician for management of their mental health therapy, the previously established agreement for the CPP to provide care to that patient will be terminated.
- If the CPP or supervising physician ceases activities with the Tileston Outreach Health Clinic, the agreement between the CPP and supervising physician will be terminated.