



Recent epidemiologic studies have found that most patients with mental illness are seen exclusively in primary care medicine. These patients often present with medically unexplained somatic symptoms and utilize at least twice as many health care visits as controls. There has been an exponential growth in studies in this interface between primary care and psychiatry in the last 10 years. This special section, edited by Wayne J. Katon, M.D., will publish informative research articles that address primary care-psychiatric issues.

## Using nurse practitioners to implement an intervention in primary care for high-utilizing patients with medically unexplained symptoms

Judith S. Lyles, Ph.D.<sup>a</sup>, Annemarie Hodges, MA<sup>a</sup>, Clare Collins, R.N., Ph.D.<sup>b</sup>, Catherine Lein, R.N., M.S., F.N.P.<sup>b</sup>, C. William Given Ph.D.<sup>c</sup>, Barbara Given, R.N., Ph.D.<sup>b</sup>, Dale D'Mello, M.D.<sup>d</sup>, Gerald G. Osborn, D.O.<sup>d</sup>, John Goddeeris, Ph.D.<sup>e</sup>, Joseph C. Gardiner, Ph.D.<sup>f</sup>, Robert C. Smith, M.D., Sc.M.<sup>a,\*</sup>

<sup>a</sup>Department of Medicine, Michigan State University College of Human Medicine, East Lansing, MI 48824, USA

<sup>b</sup>College of Nursing, Michigan State University, East Lansing, MI 48824, USA

<sup>c</sup>Department of Family Practice, Michigan State University College of Human Medicine, East Lansing, MI 48824, USA

<sup>d</sup>Department of Psychiatry, Michigan State University College of Human Medicine, East Lansing, MI 48824, USA

<sup>e</sup>Department of Economics, Michigan State University, East Lansing, MI 48824, USA

<sup>f</sup>Department of Epidemiology, Michigan State University College of Human Medicine, East Lansing, MI 48824, USA

### Abstract

Patients with medically unexplained symptoms (MUS) often are a source of frustration for clinicians, and despite high quality biomedical attention and frequent diagnostic tests, they have poor health outcomes. Following upon progress in depression treatment approaches, we developed a multidimensional treatment protocol for deployment by primary care personnel. This multi-faceted intervention for MUS patients emphasized cognitive-behavioral principles, the provider-patient relationship, pharmacological management, and treating comorbid medical diseases. We deployed it in an HMO using nurse practitioners (NP) to deliver the intervention to 101 patients, while 102 controls continued to receive medical care from their usual primary care physician. Successful deployment of the intervention required training the NPs, continuing support for the NPs in their management of this difficult population, and establishing strong communication links with the HMO. This paper addresses the practical considerations of using primary care personnel to implement a complex intervention in primary care, and it includes a discussion of special challenges encountered as well as solutions developed to overcome them. © 2003 Elsevier Science Inc. All rights reserved.

**Keywords:** Randomized controlled trial; Somatization; High utilizing patients; Medically unexplained symptoms; Nurse practitioners; Mental health; Primary care

### 1. Introduction

Medically unexplained symptoms (MUS) are physical complaints for which there is no documented organic disease explanation [1]; these symptoms occur commonly among the general patient population [1–8]. Indeed, in primary care it is estimated that only 16% of new symptoms prove to have an organic disease basis [9]. When combined

with high-utilization, MUS can become debilitating for patients and costly to the health care system [10–16]. Depression, anxiety and impaired mental and physical functioning often accompany the physical symptoms MUS patients experience [17–20]. MUS is one of medicine's great challenges at many levels [21].

In the context of a randomized control trial (RCT), we developed and implemented a twelve-month intervention to address the needs of MUS patients and to manage their symptoms in a primary care setting. We tested hypotheses that intervention patients would show significantly more improvement on mental and physical health function mea-

\* Corresponding author. Tel.: +1-517-355-6516; fax: +1-517-432-1326.

E-mail address: robert.smith@ht.msu.edu (R.C. Smith).

asures twelve months after entry into the study as compared to control patients.

The intervention exemplified integrated biopsychosocial principles by focusing on: 1) common comorbid medical conditions; 2) psychological distress – by screening patients for depression and anxiety, prescribing standard pharmacological treatment if indicated, and by weaning patients from any addicting medications; 3) cognitive behavioral treatment (CBT) to help patients manage their physical symptoms and reframe their attitudes toward them [22–26]; and 4) the patient-provider relationship (PPR) and communication by using a recently reported evidence-based patient-centered method [27–31].

We chose nurse practitioners (NPs) to deploy the intervention for several practical reasons. First, nurse practitioners are educated with a biopsychosocial orientation that is conducive to effective management of MUS patients [32–36] and NPs are known to be effective with medical [33,37] as well as psychological problems [36]. In contrast, numerous studies show that the biomedical disease emphasis of physician training does not prepare many of them to manage either difficult mental health problems or MUS patients whose predominant physical symptoms have no disease origin [38–42]. Second, training for the intervention required over eighty hours of experiential learning that would have been difficult to schedule with practicing physicians. Third, the HMO employed three nurse practitioners that, if used to deploy the intervention, could ensure continuity of care at the end of the study and/or ease the transition to usual care for the intervention patients. We report here how we addressed key design and implementation issues, particularly those surrounding deployment of the intervention.

## 2. Collaborating with the HMO

The intervention was conducted at three staff model sites of a nonacademic, not-for-profit HMO. When the project started, a total of 28,000 adult primary care patients received care from 21 primary care physicians, 3 NPs, and 4 physician assistants. We had previously worked with the HMO on the pilot study of this intervention [43] and were fortunate to have had the opportunity to learn not only about its operations and information systems, but also the importance of involving and informing all HMO personnel of project activities that would affect their work. Support and cooperation at all staff levels were critical to the success of the clinical trial.

## 3. Training for nurse practitioners

We recognized that we were placing NPs in a unique role that goes beyond the better-established role of case manager for mental health patients [35,44]. Assuming the challenging role of primary provider was unusual and difficult

enough, but our intervention called for NPs, in addition, to treat some of the most difficult patients known to primary care—and to integrate the skills of case manager and primary care provider in one person. Our NPs, like many, had little training or experience that prepared them for this task.

Four certified NPs were trained for this project. Three were employed by the HMO and one by Michigan State University's (MSU) College of Nursing. Screening interviews were conducted with the eligible NPs to determine previous experience in primary care and their interest and experience in working with MUS patients. The faculty NP had deployed the intervention for the pilot study. In the RCT, she assisted in training, was an on-site supervisor for the other NPs in the early stages of deployment, and was a clinician for a panel of the intervention patients.

Prior to seeing their first patient, the NPs completed an 84-hour training program that was conducted over seven weeks by the PI, a nursing faculty member trained in psychological counseling and mental health nursing, and the MSU NP. These sessions involved intensive training in the evidence-based patient centered interviewing method [27,28] developed and tested by the PI and colleagues [29–31]. They also included didactic presentations, role-play, interviews with simulated patients, and review of audiotaped interviews until proficiency in patient-centered interviewing was attained. Equally prominent attention was accorded cognitive-behavioral approaches and the specific model used in the intervention. Role-playing the model for new and follow-up patients helped NPs gain familiarity with what was a new approach for them. Weekly seminars focused on treatment of MUS, diagnosis and treatment of commonly occurring psychiatric disorders in primary care (e.g., depressive disorders, anxiety disorders), and a review of diagnosis and treatment of commonly occurring medical symptoms and illnesses in primary care. The training syllabus is available upon request.

## 4. Subject identification and recruitment

### 4.1. Screening and recruiting candidates

The intervention for this study was developed for chronic high-utilizing patients with MUS. The challenge was to identify them from the clinical picture presented in their charts. Clinical criteria required that patients have a minimum of one physical symptom with an incomplete or absent organic disease explanation, and that it be of at least six months duration (intermittent or continuous) during the preceding 12 months [45,46].

Identification of potentially eligible subjects required a three-phase screening process. First, we screened patients between the ages 18 and 65 for high-utilization through the HMO's management information system. Patients needed to have eight or more outpatient visits to primary care providers, consulting physicians, urgent care, or emergency

Table 1  
Recruitment mailings, contact points, and retention strategies

Recruitment	Mailing 1	From patient's primary care physician, introduces study and encourages patient to participate; includes fact sheet
	Mailing 2	From HMO's medical director, expresses support for study; includes fact sheet
	Mailing 3	From principal investigator, thanks patients for their interest and previews upcoming recruitment call; includes interview response & information card, 2 consent forms, & return envelope
	Recruitment Call	From project staff, asks final eligibility screening questions, answers patients' questions about the study, secures verbal consent
Month 1	Assignment call	From project staff, informs patient of study assignment; for STP group members, first appointment scheduled.
	Assignment letter	From project manager, thanks patient for participation & confirms assignment made by phone; for STP patients, provides first appointment information/instruction
	WHO-CIDI letter & response card	from project staff (interviewing staff), provides guidance for intake interview part II
	Payment letter #1	From project manager, expressing thanks for participation and recognizes time and effort in completing study interviews
	Patients also potentially receive . . . Non-Contact letter (known/unknown)	From project manager, informs patients that attempts to reach them have been unsuccessful, provides a return postcard to indicate correct phone/address, and STP staff contact information for questions
	Non-Consent letter	From project manager, informs patient that records indicate verbal consent has been given, but no written consent received; provides STP contact information for questions
Month 2		
Month 3	NO CONTACT	
Month 4		
Month 5	Reminder letter #1	From project staff, letter thanking patient for participating, reminds patient of upcoming 6-month interview.
Month 6	6 month interview	Call from interviewer staff (whenever possible this was the same interviewer from intake interviews)
Month 7		
Month 8	NO CONTACT	
Month 9		
Month 10		
Month 11	Reminder letter #2	From project staff, letter thanking patient for continued participation, upcoming 12 month interview
Month 12	12 month interview	Call from interviewer staff (again, all attempts made to have the same interviewer as previous interviews)
	Payment letter #2	From project manager, expressing appreciation for completing study; includes an invitation to receive preliminary study results by calling or writing project office; This letter also contained an invitation for a select group of control or "usual care" patients to participate in a separate but related study supported by a minority supplement.

rooms for a minimum of two years to meet the high-utilization criterion. Next, the charts of those patients were reviewed to ensure that a high utilization rate was sustained until the time of recruitment and that there was a sufficient proportion of MUS reported at the primary care visits for the twelve months preceding recruitment. The chart audits were performed by trained physicians using a systematic, objective review procedure that was developed especially for this project [47]. The chart review method derives from an earlier, simpler version developed on a different population of somatizing patients [43]. Finally, patient charts that met the criterion for medically unexplained symptoms were reviewed a final time by the PI to ensure continued high utilization and that predominant organic disease was not the basis for high utilization. Subjects were not excluded for

commonly occurring comorbid medical or psychiatric conditions.

Table 1 summarizes our recruitment process. An important part of the recruitment procedure was keeping track of potential candidates. The dates for each letter, the completion of screening, and receipt of written consent were recorded in the recruitment database. In addition, each of the recruitment stages and scheduled interviews was represented in the database as a unique status code, as were dispositions; e.g., "unable to contact," "refusal," or "not eligible." Development and use of the database streamlined the recruitment process, ensured that each record was pursued to a final disposition, and that as few delays as possible occurred in the progression of each potential participant to final disposition. Reports could be generated from any sta-

Table 2  
Baseline measures in treatment and control population

Characteristics of Participants at Intake			
Characteristic	Mean or Percent		<i>p</i> -value
	Intervention ( <i>n</i> = 101)	Control ( <i>n</i> = 102)	
Age	49.4	47.5	0.14
Gender (% Female)	82.2	76.5	0.32
CIDI/DSM-IV diagnosis (% Positive)	50.5	40.0	0.14
MUS (% of total complaints that are medically unexplained)	64.2	62.4	0.47
Mean visits in past 12 months	14.0	13.1	0.17
Baseline Scores on Physical and Mental Health Functioning			
Scale	Mean Score		<i>p</i> -value
	Intervention ( <i>n</i> = 101)	Control ( <i>n</i> = 102)	
CES-D TOTAL—depression	15.97	15.25	0.677
PSC—physical symptom list	22.65	23.65	0.641
MCS—mental summary	46.26	48.71	0.146
PCS—physical summary	37.37	35.35	0.165
SSAS—anxiety	39.87	38.33	0.585

CIDI = World Health Organization-Composite International Diagnostic Interview (58) to produce DSM-IV diagnoses (59). MUS = Medically Unexplained Symptoms, regarded as a continuous, percent of total complaints that are medically unexplained.

CES-D = Center for Epidemiological Studies-Depression scale (60); PSC = Psychosomatic Symptom Checklist (61); MCS = Mental Component Summary of the SF-36 (62-65); PCS = Physical Component Summary of the SF-36 (62-65); SSAS = Spielberger State Anxiety Scale (66).

tus code. For example, we could prepare a list of potential participants who had been unreachable for eligibility screening and ask the HMO for verification of the telephone numbers.

#### 4.2. Recruitment results

Table 2 summarizes our baseline findings and shows effective randomization. From 28,000 adult primary care patients, the HMO identified 4016 (14.3%) as high utilizers (8 or more visits/year). We identified 1646 (5.9%) of these patients who had at least 2 consecutive years of high utilization (most had 3 or more). Our means of identifying subjects was a reliable chart review method [47] where raters had 97% agreement with the PI for entry into study. We found that 904 (54.9%) had predominant organic disease symptoms and 742 (45.1%) had predominant MUS. These 742 predominant MUS patients then entered the recruitment process. Because chart ratings could have occurred as much as 9–12 months prior to entry into recruitment in some patients and because the chart scoring system was very sensitive (high false positive rate), the PI reviewed and cleared charts immediately prior to recruiting: 240 sub-

Table 3  
Reasons for refusing to participate in the study; *N* = 160

Not interested/no reason elaborated	74
Too busy	56
Don't need an intervention	11
Satisfied with doctor	5
Have begun other treatment (e.g., pain clinic)	4
Not comfortable with idea of program	3
Don't want to pay co-pay for visits needed	2
Interview questions too personal	1
Hate going to the HMO	1
Unreachable after eligibility interview	3

jects were deemed ineligible at this review point due to predominant organic diseases or recent low utilization. Of the remaining 502 eligible candidates actively recruited, 206 subjects enrolled in the study; recruitment rate=41%. Of the 296 subjects not enrolled, 125 were determined ineligible during the interview screening (e.g., changed residence, no longer in HMO, physically unable), 11 were unreachable by telephone, and 160 refused. Table 3 summarizes the reasons for refusal. There was no statistically significant clinical or demographic difference between those enrolled and those subjects who refused on the following measures obtained from the MIS and chart review procedure: age, gender, co-pay status, mean number of visits, and percentage of MUS symptoms.

#### 4.3. Retaining subjects

Remunerating participants in recognition of their time commitment helped to maintain interest. However, consistent, clear communication from project staff and persistence in contacting participants were also important factors in enrolling and retaining subjects. We maintained a communication link with participants at intervals throughout the project. After initial enrollment, we sent letters to each subject to reiterate the meaning of the group assignment and the importance of both groups to the success of the study. Conveying the latter clearly was essential since most subjects had expressed a preference for assignment to the intervention. A letter of thanks also accompanied the first incentive payment. Later, participants received reminder letters a week before their six-month and twelve-month interviews to once again express appreciation for continued participation and underscore their contribution to the project. See Table 1. To date, our retention rate is 98%; three participants have declined to continue (2 of whom are in the treatment group), and one participant is no longer reachable by telephone.

#### 5. Intervention overview

The NPs systematically deployed the four-point CBT treatment plan within the usual primary care clinic appoint-

ment times. Points of treatment were integrated into all patient encounters and involved: 1) Identifying achievable long-term goals with the patient and negotiating achievable short-term goals to work toward actualizing the former. 2) Achieving patient understanding by first determining the patient's explanatory model for symptoms followed by helping the patient develop an awareness of the role that anxiety, stress, and depression play in illnesses. 3) Obtaining a commitment from the patient to work with the NP on a jointly negotiated program. 4) Negotiating a specific treatment plan tailored to the patient's needs that typically included the following: exercise, relaxation training, physical therapy, antidepressants, reduction/elimination of addicting medications, appropriate use of nonaddicting medications. Table 4 summarizes some CBT components of the treatment. In addition, active cognitive re-orientation occurred at many visits and was based upon the NP's elicitation of the patient's explanatory model [48], often facilitated by using symptom diaries [49]. Further, behavioral approaches based upon operant mechanisms [50] were employed [49]; e.g., regular visits and medication schedules independent of symptoms.

We integrated CBT activities with management of comorbid organic diseases. NPs managed ongoing chronic medical problems, such as hypertension and diabetes mellitus, and also handled new medical problems from chest pain to sore throats. NPs sought back-up from the usual care physician when necessary and, more often, relied upon informal, curbside consultations during their daily work together in the HMO clinics seeing nonstudy patients. Physicians were actively informed of patients' clinical status and they provided significant input in what we viewed as an active, ongoing collaboration between NP and physician.

We integrated throughout all the above activities the mainstay of the intervention: establishing the provider-patient relationship (PPR). NPs used the evidence-based 5-step patient-centered method summarized in Table 5 [27–31]. We find only rare mention in previous interventions for MUS patients of a focus on the PPR [51] and believe that this is the first treatment to recommend an explicit approach to establishing the PPR in these patients where poor PPRs are notorious.

Treatment entailed twelve patient visits over a twelve-month period. The intervention timetable specified visits in weeks 1, 2, 3, 5, 8, 12, 16, 22, 28, 36, 44 and 52, but additional visits could be scheduled and were often necessary. The mean number of nurse visits was 14.55 during the 12-month intervention; SD 2.7; range 11–24. Contact was purposely frequent early in the intervention to foster establishment of the relationship and a treatment plan; the intervals between visits progressively increased over the year. Telephone contact (5–10 min conversations) was scheduled in between visits to avert problems. The scheduled visits and telephone calls occurred whether or not patients were experiencing symptoms at the time of the contact. This

Table 4  
Four-point cognitive-behavioral treatment

- 
- I. Facilitate realistic goals
    1. Long-term goals; e.g. better work/school record, improved relationships with spouse and others, reduction in addicting medications, and reduction in pain.
    2. Short-term goals; e.g., what the patient wants to achieve prior to the next visit.
  - II. Educate patient to produce understanding of her/his illness
    1. Learn patient's explanatory model and underlying health assumptions.
    2. Ensure a realistic understanding.
      - a) State that problem is real, somatic, and not "all in your head."
      - b) Emphasize that, following medical record review and thorough history and physical evaluation, no life-threatening diseases have been found, there is no need for surgery, that no further tests or consultation are required, and that the continued close clinical observation to be made is sufficient to detect any organic disease that might develop.
      - c) Give MUS a specific name in somatic terms and explain its mechanism in lay terms; e.g., irritable bowel syndrome.
      - d) Show confidence that diagnosis is correct, explain that the provider has considerable experience with it, and emphasize that the diagnosis is common.
      - e) Note that stress, depression, and anxiety are important contributors to the symptoms, but that the patient is not a "psychiatric case," an issue of concern to almost all patients.
      - f) Make a point that cure is unlikely but that treatment leads to improvement for most patients. With every new treatment, the patient is reminded that improvement is expected but cure is not.
  - III. Obtain informed commitment to treatment
    1. Present an overview of planned treatment to allow the patient to make an informed decision.
    2. The patient must take the responsibility to commit to conduct the treatment.
  - IV. Negotiate a specific treatment plan
    1. Use antidepressants in full doses for depression, always beginning with SSRIs
    2. Use SSRIs for generalized anxiety and panic disorders.
    3. Taper and discontinue addicting drugs. Do not initiate treatment with addicting drugs.
    4. Use appropriate nonaddicting, symptomatic medications on a scheduled basis.
    5. Use individualized physical therapy activity without consultation.
    6. Use individualized physical exercise program without consultation.
    7. Use relaxation exercise program without consultation.
    8. Establish agreement to see no other caretakers (i.e., no self-referral) without prior discussion and to take only medications prescribed by the NP.
    9. Involve significant family member or other.
- 

helped patients to shift their thinking toward managing symptoms rather than reacting to them.

Treatment group participants understood that the NP would coordinate all care over the next year, that they would have access to their primary care physician as needed or desired, and that the physician would be regularly updated and involved in their care, albeit less directly. Appointments were scheduled directly with the NP at the time of the visit, and patients were asked to contact the NP if they needed to

Table 5  
Evidence-based patient-centered interviewing method

---

Setting the Stage for the Interview (Step 1)

1. Welcome the patient
2. Use the patient's name
3. Introduce self and identify specific role
4. Ensure patient readiness and privacy
5. Remove barriers to communication
6. Ensure comfort and put the patient at ease

Chief Complain/Agenda Setting (Step 2)

1. Indicate time available
2. Indicate own needs
3. Obtain list of all issues patient wants to discuss; e.g., specific symptoms, requests, expectations, understanding
4. Summarize and finalize the agenda; negotiate specifics if too many agenda items

Opening the HPI (Step 3)

1. Open-ended beginning question
2. 'Nonfocusing' open-ended skills (Attentive Listening): silence, neutral utterances, nonverbal encouragement
3. Obtain additional data from nonverbal sources: nonverbal cues, physical characteristics, autonomic changes, accouterments, and environment

Continuing the Patient-Centered HPI (Step 4)

1. Obtain description of the physical symptoms
2. Develop the more general personal/psychosocial context of the physical symptoms
3. Develop an emotional focus
4. Address the emotion(s)
5. Expand the story to new chapters

Transition to the Doctor-Centered Process (Step 5)

1. Brief summary
2. Check accuracy
3. Indicate that both content and style of inquiry will change if the patient is ready

---

Used by permission: RC Smith: *Patient-Centered Interviewing—An Evidence-Based Method*; Lippincott Williams and Wilkins, 2001.

change an appointment, needed a prescription refill, or had other health concerns.

Approximately 1.5 h were allocated for the first (new patient) visit to obtain an adequate intake evaluation and 30 min for each return visit. An additional 2 h for each new patient visit and 1.5 h for each return visit were allocated for research documentation and meeting time to allow record keeping about the process and content of care. NPs collected no hypothesis-testing research data.

Nurse practitioners gave the patients' primary care physicians formal patient summaries at intake, three months, and at the end of the study. As part of the protocol, NPs also discussed the patient with the primary care physician under the following circumstances: 1) diagnosis of any new organic disease, even a minor one; 2) any change in symptoms or other problems or failures of any treatment whether somatization or organic diseases; and 3) any untoward reactions to medications or nonpharmacological interventions. The primary care physicians directly evaluated patients where needed and remained actively involved in care plans throughout.

Psychiatric comorbidities were a significant concern be-

cause primary care physicians would not be able to provide effective back-up. NPs were trained to recognize depression and dysthymia, generalized anxiety disorder, post-traumatic stress disorder, and panic disorder (with and without agoraphobia) and were assisted by the PRIME-MD [52–54] as well. NPs systematically observed and recorded the symptoms of these disorders when present, and treated them. The project faculty also included a psychiatrist for routine and emergency consultation. NPs contacted the PI and/or project psychiatrist (and the primary care physician) if any of the following occurred: 1) presence of suicidal or homicidal thoughts whether judged serious or not; 2) evidence of psychosis; 3) failure to reduce depression and anxiety in spite of treatment; 4) worsening dysfunctional behaviors (deteriorating relationships, work problems); 5) request from a patient for consultation with a mental health professional; and 6) suspicion of a psychiatric problem. These indications for seeking help from a mental health professional are similar to those expected for primary care providers in managed care settings.

## 6. Supervising and supporting the intervention

When formal intervention training ended, supervision, support and monitoring systems were implemented that met not only the scientific requirements of the project, but also the needs of the NPs. Prior to this project, the HMO NPs had neither managed a panel of patients, nor had they managed chronic biomedical or mental health problems. They also faced the challenge of using new skills and treatments in a health care environment where biomedical solutions and speedy results were valued.

From a research perspective, it was essential that they be able to shift the emphasis of their patient encounters and consistently deliver the intervention to patients. From a clinical perspective, it was equally important that the NPs felt confident about all aspects of managing MUS patients.

Subjects for the RCT were recruited over an 18-month period with the heaviest enrollment occurring during the middle twelve months. The intervention continued over a 30-month period with the number of patients in each NP panel gradually building during the first four months and then slowly diminishing during the last year. The following are highlights of the support and supervision activities that we developed:

### 6.1. Pilot training

Before official subject enrollment began, a pilot patient was recruited for each NP to begin supervised implementation of the Special Treatment Project (STP) (the name we used to identify the research study to the public). The first three to five visits with the pilot patient were attended by the PI or supervising NP.

### 6.2. Protected STP time for NPs

To facilitate concentration on the intervention, NPs were scheduled for the STP project a minimum of a half day at a time; their STP hours ranged from 4 to 20 h a week during the 30-month intervention period. This also had the advantage of not interfering with routine clinic operations for other patients.

### 6.3. Supervised patient appointments

For the first two months of the intervention, either the supervising NP or PI attended all patient appointments as observers only. Following the appointment, they provided feedback to the NPs on management of biomedical issues and application of patient centered interviewing skills and the STP intervention.

### 6.4. Weekly meetings

Initially, each NP met weekly for 1.5 h with the PI to review cases. In addition, the NPs met as a group for two hours weekly to discuss and resolve procedural difficulties and to share case issues of mutual concern. The PI and other study faculty or staff attended these meetings to facilitate problem-solving. In the last year of the intervention, group meetings were held twice a month, and individual meetings with the PI every three to four weeks.

### 6.5. Addressing self awareness issues

The individual meetings with the PI and the group meetings, to a lesser degree, were opportunities to raise and discuss personal feelings about working with this patient population. We used our prior research and teaching experiences to address and work with NPs' self-awareness issues [31,55,56].

### 6.6. Continuing education

After a few months of subject enrollment, we asked the NPs to complete a survey about their level of confidence in implementing components of the intervention and their training needs. The results were used to identify additional areas of focus for the group meetings. Periodically a consulting psychiatrist or psychologist was invited to present a seminar or workshop.

## 7. Estimating the costs of the intervention

The costs of training an NP include primarily the value of the NP's time and the time of the supervisor physician. We assume an hourly rate for the NP of \$36, based on our actual costs, including benefits. The value of NP time de-

voted to training then includes: 1) 72 h training – \$2592; 2) 6 h with pilot patient and 6 h supervision – \$432; 3) weekly meeting with supervisor @ 1.5 h/week for final 44 weeks – \$2376; 4) weekly 2-h group meeting for 44 weeks – \$3168. Items #1 and #2 are one-time-only costs. Also, when NPs become confident after 6–12 months, supervisory time is reduced, on average, to about 1.5 h every 3 weeks. Likewise, group meetings can be decreased. Considering supervision in the first year as training, an NP's time devoted to training in the first year for cost  $\$2592 + \$432 + \$2376 + \$3168 = \$8568$ .

Using a supervisor physician's salary at \$75/h (\$150,000/year), we estimate the following costs: 1) 72 h of training + 28 h of preparation = 100 h = \$7500; 2) supervising pilot training (12 h) = \$900; 3) weekly 1.5 h supervisory meetings for 44 weeks = 66 h = \$4950, 4) the 2-h weekly group meeting for 44 weeks would require 88 h = \$6600. When more than one NP is trained, only items #2 and #3 increase. As above, supervisory time decreases after the first 6–12 months but does not end. Thus, total first year supervisory training costs are \$19,950 for one NP. Most supervisory costs are nonrecurring. For year 2, estimating 18 supervisory sessions (27 h) and 18 group sessions (36 h) per subsequent year, the cost would be only \$4725. We have calculated this based upon one physician (likely, a psychiatrist), but multiple supervisors can be used, sometimes for lower salaries; one supervisor/session is sufficient. Thus, total training costs (NP and supervisor) for one NP in the first year =  $\$8568 + \$19,950 = \$28,518$ .

*Actual care* for one patient with the mean of 14.55 visits/year using a 90 min allotment of time for intake visits and 30 min for follow-up visits = 8.3 h/patient/year; 5–10 min/telephone calls between each visit adds about 1.5 h. Thus, for 9.8 h of patient contact, the cost is \$353/patient/year (9.8 X \$36). The number of patients an NP can carry is determined by her (his) confidence and stress level; our NPs each handled about 25 patients total, seldom more than 15 at one time.

These figures treat the patient's visits to the NP as additional services, implicitly assuming that the patient's other care is unchanged. They thus do not address cost offsets from substituting less costly services from NPs for those of physicians who otherwise would be managing these patients, nor do they include hypothesized offsets from reduced laboratory investigations and hospitalizations. These issues are being addressed in the analysis of the trial. Nor is it possible to address the "leakage" impact of this training on NPs' interactions with patients not in the study and, usually, not having unexplained symptoms. Similarly, it will be difficult if not impossible to measure the cost offset, over time, from the trained NP's impact upon the primary care physician with whom she works closely on these and other patients; we believe that significant learning can occur.

## 8. Documenting and monitoring the intervention

NPs audiotaped all encounters with their third, sixth, ninth and eighteenth patients as a straightforward “spot check.” The tapes were used to systematically review the fidelity of administering the treatment and using the relationship-building skills.

To ensure that we had a way to comprehensively quantify the elements of the intervention that were deployed for each patient, we developed a second tool that could be used for both monitoring the intervention and compiling data for later analysis—an electronically readable nursing documentation form. NPs completed the documentation form after every patient encounter. The form took only a few minutes to complete, yet it captured all of the necessary aspects of the contact relevant to the intervention, including at the intake visit the names, dosage, and frequency of prescription pain medications, sedatives/hypnotics, antidepressants and anti-anxiety medications that the patients were taking when they entered the study. At the last visit, NPs updated information on the medications originally listed (current dosage, frequency, and final status; e.g., discontinued, decreased frequency, etc.). NPs also listed any new medications that had been prescribed and were still current at discharge.

### 8.1. Quality assurance

We also used the documentation form data to initiate a quality monitoring process. The purpose was two-fold: 1) to review all treatment cases to determine if the elements of the treatment protocol were being consistently implemented; and 2) to verify the accuracy of the coding of the nursing documentation form by comparing the forms to the patient record.

Each case was reviewed administratively between the fourth and twelfth STP visit. Prior to a scheduled weekly meeting, the NP and PI were given a summary profile for each treatment patient to be reviewed that week. The summary was compiled from data generated by the nursing documentation form and included: number, type and frequency of visits to date, psychotropic, sedative/hypnotic and pain medications on intake, nursing interventions implemented across study visits. NPs reviewed the actual patient record and ascertained the accuracy of the data coded on the nursing documentation form. During the meeting, the NP and PI reviewed each case to determine if all nursing interventions were being consistently implemented, and recorded. Similarly, the adequacy of dosage of antidepressant medications was reviewed for each case. Less than 1% of the nursing documentation forms contained discrepancies between the patient record and the nursing documentation file, indicating a high level of accuracy of coding of the nursing documentation forms.

### 8.2. Final documentation and quality check

After the last visit with each patient, NPs completed two nursing documentation forms: one to record the final visit as usual, and one to record the whole intervention in summary form. This summary documentation form was coded to distinguish it from others, and NPs recorded the six predominant symptoms/complaints treated over the course of the study, and all interventions deployed.

Nurse practitioners also completed a qualitative summary of each case. The case summary form required NPs to provide some objective information (number of scheduled and unscheduled encounters), but focused primarily on their impressions of the relative success or failure of the intervention with each patient. The form also captured their perceptions of specific challenges encountered in treating each patient, life events that may have had an impact on the effectiveness of the treatment, and determinations of what would be their ongoing goals should they continue to treat the patient. By reviewing this last document, interoffice patient records, and data available from processed documentation forms, project staff were able to take a final accounting of each case and resolve any documentation issues.

## 9. Discussion

### 9.1. Making it work clinically

There is no question that patients with the magnitude of medically unexplained symptoms like those in this study are challenging to treat. The challenge is increased by having a panel of them for a 12-month intervention. Often, along with their medically unexplained symptoms, the patients had organic disease and psychological problems as well. It was the treatment of the latter two that was initially most troublesome for the NPs. Most of their previous clinical work had been dealing with acute symptoms, procedures, and routine physical examinations, and they had little experience managing chronic medical or psychological problems. The additional medical management training and consultation provided in the NP meetings, particularly in the early stages of the intervention, were critical to the NPs' effectiveness with their patients and to the success of the project. Similar training and support were provided for treatment and understanding of psychological symptoms; e.g., depression, anxiety. With psychologically distressed patients, there was also a component of personal discomfort that was addressed openly in both group and individual sessions. Raising the NPs' self-awareness about their feelings helped to prevent their discomfort from interfering with care.

Among the greatest challenges was trying to help patients who, though verbally committing to a treatment plan, would neither work nor comply. Although they rarely

missed an appointment, the deep seated resistance in some of these patients made them almost unmovable. Careful attention to developing the provider-patient relationship (PPR), negotiating undemanding short-term goals, involving relatives, and counseling referrals were attempted, but with limited clinical success. Similar strategies were used and were somewhat more effective with patients whose resistance manifested in “reactions” to antidepressants [57]. A testament to the power of the PPR was the patient, who after more than six months refusal to try an SSRI because of “nausea” with the most minimal dose, successfully began and maintained regimen that improved her depression.

A small number of patients became very demanding and time-consuming, reflecting their underlying dependency features. These patients provided a good learning opportunity for the NPs and in all instances the excessive demands resolved, largely due to well established PPR and structure. Indeed, the PPR was relied upon by the NPs particularly in the first and last months of treatment. CBT assumed equal prominence with the PPR between weeks 3 and 15 and continued to be important throughout, but it was less relied upon as patients’ discussions of psychosocial issues increased and their talk of somatic symptoms diminished. The support provided to the NPs in the weekly meetings from the PI, nursing faculty, and consultants was essential to their ability to develop and sustain the PPR.

### 9.2. Making it work administratively

Administratively, the clinical trial was complex and involved several physically separated groups that required consistent coordination of effort and communication. The project office became the hub of the wheel maintaining links between and among HMO personnel, NPs, study participants, chart raters, data collection staff, data analyses staff, and the research faculty. Having two full time project staff (and two part-time students) in a central location made it possible to recognize, respond and resolve problems rapidly and to disseminate needed information.

The project staff worked with HMO personnel from administrators to receptionists on a first name basis. These relationships, for example, facilitated arrangements with medical records staff for chart rating on weekends and evenings, development of the NP schedules with HMO administrative staff, and a smooth transition when one of the HMO sites closed during the intervention period.

Project staff were equally important in facilitating the communication between NPs and intervention patients. For example, when it became clear that the HMO switchboard system could not accommodate the type of communication needed for the intervention, the project office became the daytime message center and communication link to the NPs for STP patients. Patients could leave messages for the NPs, convey needs to change appointment times, or ask that an NP contact them and project staff relayed the message. NPs contacted the office to change their schedules, to ask ques-

tions about documentation procedures, to check for patient messages, and to change meetings with the PI. Similar links were maintained between chart raters, data collection interviewers and subjects, and data analyses staff and research faculty.

### 9.3. Acceptability of the clinical trial in the HMO

Throughout the project we have monitored its acceptability with the NPs, the HMO primary care physicians, and the HMO administration. The NPs, in spite of their adjustments to the increase in responsibility, frustration with the paperwork demands of research, and struggles with difficult patients, have uniformly expressed appreciation for the ongoing education and the opportunity to work on the project, saying in one way or another, “It has been a privilege.” Overall, NPs agreed that it was hard work, but that they would do it again, especially now that they have training, confidence, and experience. All have continued to follow study patients after completion of study.

The usual care physicians appreciated the project for different reasons. Not only did they receive welcome assistance in caring for difficult patients, but they remained actively involved and saw patients improve. The HMO administration was equally supportive and pleased to be part of a research endeavor. There appeared to be little burden for the HMO as a result of its participation and hiring the HMO NPs for the project was mutually beneficial to the HMO and project. The medical director related numerous occasions when STP patients approached him while shopping, thanked him, and proclaimed the value of the program for them.

In summary, we believe interventions for MUS patients by primary care personnel are feasible and will become important for the field (mental health in primary care). They will focus upon brief training of primary care physicians, nurse practitioners, or physician assistants. We report here the key design and implementation issues involved when using nurse practitioners without previous psychological training to deploy a complex, multi-modal treatment. We propose the work presented here as a beginning template to guide others along what is a difficult path.

### Acknowledgments

We thank Blue Cross Network of Michigan for their active collaboration with this study.

This work was supported by National Institute of Mental Health grant MH57099.

### References

- [1] Lipowski ZJ. Somatization: the concept, and its clinical application. *Am J Psychiatry* 1988;145:1358–68.

- [2] Ford CV. The somatizing disorders: illness as a way of life. New York, Elsevier Biomedical, 1983.
- [3] Culpan R, Davies B. Psychiatric illness at a medical, and a surgical outpatient clinic. *Compr Psychiatry* 1960;1:228–35.
- [4] Barsky AJ. Hidden reasons why some patients visit doctors. *Ann Intern Med* 1981;94:492–8.
- [5] Katon W, Ries RK, Kleinman A. The prevalence of somatization in primary care. *Compr Psychiatry* 1984;25:208–15.
- [6] Stoecle JD, Zola LK, Davidson GE. The quantity, and significance of psychological distress in medical patients. *J Chron Dis* 1964;14: 959–65.
- [7] Roberts BH, Norton NM. The prevalence of psychiatric illness in a medical outpatient clinic. *N Engl J Med* 1952;246:82–6.
- [8] Katon W, Russo J. Somatic symptoms, and depression. *J Fam Pract* 1989;29:65–9.
- [9] Kroenke K, Mangelsdorff AD. Common symptoms in ambulatory care: incidence, evaluation, therapy, and outcome. *Am J Med* 1989; 86:262–6.
- [10] Smith GR Jr, Monson RA, Ray DC. Psychiatric consultation in somatization disorder. *N Engl J Med* 1986;314:1407–13.
- [11] Cherkin D, Deyo RA. Nonsurgical hospitalization for low back pain: is it necessary? *Spine* 1993;18:1728–35.
- [12] Hoffman RM, Wheeler KJ, Deyo RA. Surgery for herniated lumbar discs: a literature synthesis. *J Gen Intern Med* 1993;8:487–96.
- [13] Deyo RA, Ciol MA, Cherkin DC, Loeser JD, Bigos SJ. Lumbar spinal fusion: a cohort study of complications, reoperations, and resource use in the Medicare population. *Spine* 1993;1:1463–70.
- [14] Fink P. Surgery, and medial treatment in persistent somatizing patients. *J Psychosom Res* 1992;36:439–47.
- [15] Bass C, Benjamin S. The management of chronic somatization. *Brit J Psychiatry* 1993;162:472–80.
- [16] Lightfoot J RW, Luft BJ, Rahn DW, et al. Empiric parenteral antibiotic treatment of patients with fibromyalgia, and fatigue, and a positive serologic result for Lyme disease. *Ann Intern Med* 1993;119: 503–9.
- [17] Escobar JI, Waitzkin H, Silver RC, et al. Abridged somatization: a study in primary care. *Psychosom Med* 1998;60:466–72.
- [18] Bass C, Murphy M. Somatisation disorder in a British teaching hospital. *British Journal of Clinical Practice* 1991;45:237–44.
- [19] deGruy F, Columbia L, Dickinson P. Somatization disorder in a family practice. *J Fam Pract* 1987;25:45–51.
- [20] deGruy F, Crider J, Hashimi DK, Dickinson P, Mullins HC, Troncale J. Somatization disorder in a university hospital. *J Fam Pract* 1987; 25:579–84.
- [21] Lipsitt DR. Challenges of somatization: diagnostic, therapeutic, and economic. *Psychiatric Medicine* 1992;10:1–12.
- [22] Sharpe M, Bass C, Mayou R. An overview of the treatment of functional somatic symptoms. In: Mayou R, Bass C, Sharpe M, editors. *Treatment of Functional Somatic Symptoms*. Oxford, Oxford University Press, 1995. pp 66–86.
- [23] Sharpe M, Hawton K, Simkin S, et al. Cognitive behaviour therapy for the chronic fatigue syndrome: a randomised controlled trial. Used comparison of % improved vs. not improved > ES or MCID. *Brit Med J* 1996;312:22–6.
- [24] Warwick HMC, Clark DM, Cobb AM, Salkovskis PM. A controlled trial of cognitive-behavioural treatment of hypochondriasis. *Brit J Psychiatry* 1996;169:189–95.
- [25] van Dulmen AM, Fennis JFM, Bleijenberg G. Cognitive-behavioral group therapy for irritable bowel syndrome: effects, and long-term follow-up. *Psychosom Med* 1996;58:508–514.
- [26] Speckens AEM, van Hemert AM, Spinhoven P, et al. Cognitive behavioural therapy for medically unexplained physical symptoms: a randomised controlled trial. *Brit Med J* 1995;311:1328–32.
- [27] Smith RC. *Patient-Centered Interviewing: An Evidence-Based Method*, 2nd ed. Philadelphia, Lippincott Williams, and Wilkins, 2002.
- [28] Smith RC. Videotape of Evidence-Based Interviewing: 1) Patient-centered interviewing, and 2) Doctor-centered interviewing. Produced by Michigan State University Broadcasting Services, Eric Schultz, Producer—Available from Marketing Division, Instructional Media Center, Michigan State University: 1) PO Box 710, East Lansing, MI 48824; 2) 517-353-9229(tel); 3) 517-432-2650(fax); 4) <http://www.msuvmall.msu.edu/imc>.
- [29] Smith RC, Lyles JS, Mettler J, et al. The effectiveness of intensive training for residents in interviewing. A randomized, controlled study. *Ann Intern Med* 1998;128:118–26.
- [30] Smith RC, Marshall-Dorsey AA, Osborn GG, et al. Evidence-based guidelines for teaching patient-centered interviewing. *Patient Education and Counseling* 2000;39:27–36.
- [31] Smith RC, Dorsey AM, Lyles JS, Frankel RM. Teaching self-awareness enhances learning about patient-centered interviewing. *Acad Med* 1999;74:1242–8.
- [32] Ethridge P, Lamb GS. Professional nursing case management improves quality, access, and costs. *Nursing Management* 1989;20: 30–5.
- [33] Horrocks S, Anderson E, Salisbury C. Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors. *Brit Med J* 2002;324:819–23.
- [34] Munding MO. Twenty-first-century primary care: new partnerships between nurses, and doctors. *Acad Med* 2002;77:776–80.
- [35] Ziruras SJ, Stuart GW, Jackson AC. Assessing the evidence on case management. *Brit J Psychiatry* 2002;181:17–21.
- [36] Mead N, Bower P, Gask L. Emotional problems in primary care: what is the potential for increasing the role of nurses? *J Adv Nurs* 1997; 26:879–90.
- [37] Aubert RE, Herman WH, Waters J, et al. Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization: a randomized, controlled trial. *Ann Int Med* 1998;129: 605–12.
- [38] Sullivan MD. Psychosomatic clinic or pain clinic: which is more viable? *Gen Hosp Psych* 1993;15:375–80.
- [39] Goldberg D, Gask L, O'Dowd T. The treatment of somatization: teaching techniques of reattribution. *J Psychosom Res* 1989;33:689–95.
- [40] Jones RL, Badger LW, Ficken RP, et al. Inside the hidden mental health network: examining mental health care delivery of primary care physicians. *Gen Hosp Psychiatry* 1987;9:287–93.
- [41] deGruy FV. Mental healthcare in the primary care setting: a paradigm problem. *Families, Systems, Health*; 1997;15:3–26.
- [42] Lin E, Katon W, Simon G, et al. Achieving guidelines for the treatment of depression in primary care: is physician education enough? *Med Care* 1997;35:831–42.
- [43] Smith RC, Gardiner JC, Armatti S, et al. Screening for high utilizing somatizing patients using a prediction rule derived from the management information system of an HMO: a preliminary study. *Med Care* 2001;39:968–78.
- [44] Katon WJ, VonKorff M, Lin E, Simon G. Rethinking practitioner roles in chronic illness: the specialist, primary care physician, and the practice nurse. *Gen Hosp Psychiatry* 2001;23:138–44.
- [45] Smith RC. A clinical approach to the somatizing patient. *J Fam Pract* 1985;21:294–301.
- [46] Smith RC. Somatization disorder: defining its role in clinical medicine. *J Gen Intern Med* 1991;6:168–175.
- [47] Smith RC, Korban E, Kanj M, et al. A method for rating charts to identify, and classify patients with medically unexplained symptoms (under revision) 2003.
- [48] Kleinman A. Explanatory models in health-care relationships: a conceptual frame for research on family-based health-care activities in relation to folk, and professional forms of clinical care. In: Stoecle JD, editor. *Encounters between patients and doctors*. Cambridge, The MIT Press, 1987. p 273–83.
- [49] Sharpe M. Cognitive behavioural therapies in the treatment of functional somatic symptoms. In: Mayou R, Bass C, Sharpe M, editors.

- treatment of functional somatic symptoms. Oxford, Oxford University Press, 1995. p. 122–43.
- [50] Fordyce WE. Behavioral methods for chronic pain, and illness. Saint Louis, CV Mosby, 1976.
- [51] Heymann-Monnikes I, Arnold R, Florin I, et al. The combination of medical treatment plus multicomponent behavioral therapy is superior to medical treatment alone in the therapy of irritable bowel syndrome. *Am J Gastroenterol* 2000;95:981–94.
- [52] Spitzer RL, Williams JBW, Kroenke K, et al. Utility of a new procedure for diagnosing mental disorders in primary care: the PRIME-MD Study. *JAMA* 1994;272:1749–56.
- [53] Kroenke K, Spitzer RL, deGruy FV, et al. Multisomatoform disorder: an alternative to undifferentiated somatoform disorder for the somatizing patient in primary care. *Arch Gen Psychiatry* 1997;54:352–8.
- [54] Spitzer RL, Kroenke K, Williams JBW. Validation, and utility of a self-report version of the PRIME-MD. *JAMA* 1999;282:1737–44.
- [55] Smith RC. Teaching supplement for “The patient’s story—integrated patient-doctor interviewing”. B306 Clinical Center, Michigan State University, East Lansing, MI 48824: Robert C. Smith, 1996.
- [56] Marshall AA, Smith RC. Physicians’ emotional reactions to patients: recognizing, and managing countertransference. *Am J Gastroenterol* 1995;90:4–8.
- [57] Barsky AJ, Saintfort R, Rogers MP, Borus JF. Nonspecific medication side effects, and the nocebo phenomenon. *JAMA* 2002;287:622–7.
- [58] Sartorius N. Composite International Diagnostic Interview (CIDI)—Core Version 1.1. Copyright World Health Organization.
- [59] American Psychiatric Association. Diagnostic, and statistical manual of mental disorders, 4th ed. Washington, DC: American Psychiatric Association, 1994.
- [60] Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. *Appl Psychol Measur* 1977;1:385–401.
- [61] Chibnall J, Tait R. The Psychosomatic Symptom Checklist revisited: reliability, and validity in a chronic pain population. *J Behav Med* 1989;12:297–307.
- [62] Ware J JE, Snow KK, Kosinski M, Gandek B. SF-36 health survey - manual, and interpretation guide. Boston: The Health Institute, New England Medical Center, Box 345, 750 Washington St., 1993.
- [63] McHorney CA, Ware J JE, Raczek AE. The MOS 36-item short-form health survey (SF-36): II. Psychometric, and clinical tests of validity in measuring physical, and mental health constructs. *Med Care* 1993; 31:247–63.
- [64] Ware J JE, Kosinski M, Bayliss MS, et al. Comparison of methods for the scoring, and statistical analysis of SF-36 health profile, and summary measures: summary of results from the Medical Outcomes Study. *Med Care* 1995;33:AS264–79.
- [65] Ware JE Jr, Kosinski M, Keller SD. SF-36 physical, and mental health summary scales: a user’s manual. Boston, The Health Institute, New England Medical Center, 1994.
- [66] Spielberger CD, Gorsuch RL, Lushene PR, Jacobs GA. State-trait anxiety inventory (Form Y) (“Self-evaluation questionnaire”). Palo Alto, CA 94303, Consulting Psychologists Press, Inc, 1983.