IntNSA Webinar Series

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objectives

• Review introductory and background information regarding the design, implementation, and evaluation of a multidisciplinary outpatient buprenorphine clinic for opioid maintenance therapy
• List and describe essential features of the Buprenorphine Clinic
• Provide demographic and clinical characteristics of the initial patient population
• Describe process measures, outcomes, and patient satisfaction survey results
• Discuss treatment implications and potential adaptability to other settings

for those who are further interested...


extent of the problem

- Prescription drug abuse is the nation’s fastest-growing drug problem.
- Nearly one-third of people aged 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically (SAMHSA, 2010).
- Among young people, prescription drugs are the second most abused category of drugs after cannabis (University of Michigan, 2009).
- The prevalence of prescription opioid abuse now greatly exceeds that of illicit opioids, such as heroin, and prescription opioid dependence has come to dominate the profile of opioid dependence in the United States (Sullivan & Pfieller, 2008).
buprenorphine

- authorized through the Drug Administration Treatment Act of 2000 (DATA 2000) to provide office-based treatment of opioid dependence
- can be used for detoxification and/or opioid maintenance therapy
- to be administered in conjunction with psychosocial treatment
- requires special education or training, and a modified DEA number, currently limited only to physicians

progressive movement

- legislative efforts underway to include qualified advanced practice nurses as prescribers
- HR 1729, Opiate Addiction Treatment Act, introduced by Congressman Dutch Ruppersberger (D-MD)
- Fact sheet: “Advanced practice nurses should have the ability to prescribe buprenorphine”
- www.intnsa.org (publications, position papers)

the medication

- buprenorphine a partial mu opioid agonist
  - both agonist (mu) and antagonist (kappa) properties
  - high binding capacity, clinical implications
  - decreased subjective euphoria
  - limited increased tolerance
  - dosing ceiling, neuroreceptor “saturation”
- sublingual tablets or film (injectable, or transdermal) with or without naloxone (Suboxone or Subutex)
controversy: then and now

- capacity to “revolutionize” treatment of opioid dependence
  - increased access
  - decreased stigma
  - abstinence vs. harm-reduction
  - treatment facilities
  - “real” recovery
  - expense vs. methadone
  - availability (e.g., Medicaid)
  - lack of long-term experience
  - various forms of misuse
  - prescribing to younger patients

buprenorphine clinic: introduction

- Buprenorphine has been shown to be a relatively safe and effective form of pharmacotherapy for the treatment of opioid dependence (Orman & Keating, 2009).
- While protocols and algorithms have been developed for induction, detoxification, and stabilization with buprenorphine (CSAT, 2009), few have described specific programs or approaches to long-term opioid maintenance therapy, and fewer still have examined this phenomenon from the perspective of patient satisfaction.
- Here we describe the initial design, implementation and evaluation of a small pilot project (initiated in 2007) for a monthly buprenorphine clinic for opioid maintenance therapy in an outpatient addictions treatment program, including demographic and clinical characteristics of the participants, process measures, and patient satisfaction survey results.
- Caveat: We are describing a model for a buprenorphine clinic, not the model. WE INVITE YOUR COMMENTS AND CLINICAL EXPERIENCES, either during the webinar, or via e-mail to strobbe@med.umich.edu

background: default vs. design

Anecdotal evidence, within our own clinic, pointed to opportunities to improve services to patients receiving buprenorphine in an outpatient addictions treatment program:
- patients were being seen by various prescribing psychiatrists, who were also providing psychotherapy
- frequency of visits, methods for monitoring progress (e.g., use of urine drug screens), means of addressing missed appointments, varied
- these patients did not have their own dedicated group (tension)
- lacked clear, consistent mechanism to transfer patients from more acute levels of care to ongoing opioid maintenance therapy
quality improvement project

- Prompted us to create a specialized clinic to better meet the needs of this important and emerging population
- Based on principles of
  - continuous quality improvement
  - drug addiction treatment
  - group psychotherapy
  - contingency management
- Obtained IRB waiver as clinical quality improvement activity, allowing data collection, presentations, publications, dissemination

essential features

- A multidisciplinary work group convened to define the problem and to offer potential solutions.
- From this collaboration, the concept of a buprenorphine clinic emerged, which included several essential features:
  - participation
  - psychosocial treatment
  - multidisciplinary team
  - medication visits
  - urine drug screens

participation

- Patients receiving ongoing buprenorphine therapy would be required, at a minimum, to participate in a monthly buprenorphine clinic to
  - provide increased structure, support, and accountability
  - enhance patient satisfaction and outcomes
  - lead to more efficient use of resources, including staff time and patient benefits
  - Intended to expand and complement an array of treatment options
  - Referred only after achieving a certain level of clinical stability
**psychosocial treatment**

- Importance of psychosocial treatment, in conjunction with pharmacotherapy, a well-established standard
  - DATA 2000, “appropriate counseling and other non-pharmacologic therapies”
  - Educational materials provided by Rickett Benckiser (2007, 2008)
  - Technical Assistance Publication (TAP) for nurses, “ensure…psychosocial counseling is delivered concurrently with pharmacological interventions (CSAT, 2009)
- Decided that each session of the buprenorphine clinic would include a dedicated psychosocial group for patient education and support.

**multidisciplinary team**

- Team members:
  - Medicine: addiction psychiatrist
  - Nursing: certified addictions registered nurse (CARN)
  - Social work: master’s prepared addictions therapist, with previous experience working in a methadone clinic
- For patient convenience, clinic scheduled during evening hours
- With a single, monthly visit, patients could schedule an individual appointment with the physician for prescription review and renewal, provide a urine drug screen, and participate in a dedicated group therapy session.

**medication visits**

- Brief individual medication appointments available in conjunction with monthly clinics
- Limited to buprenorphine, i.e., psychiatric evaluations and other issues scheduled at other times
- Consistent with principles of contingency management, prescriptions provided for 1 to 3 months, based on attendance and participation
Purpose of UDS monitoring
- encourage treatment adherence
- corroborate progress
- allow for earlier identification and intervention in the event of relapse

Upon enrollment, patients agreed to provide contact information and urine drug screens upon request, including on a random basis.

Implementation, participants
- Letters were sent to current, established buprenorphine patients describing the clinic, explaining the rationale, requirements for participation, and the option to receive assistance, referral out
- Invited to attend an informational session with refreshments (pizza, soft drinks)
- Consent forms provided
- Of 15 eligible patients, 13 (87%) choose to participate, and an additional patient enrolled during the initial evaluation phase (n=14)
- At 5 months, of 14 active patients, 12 (86%) were present and completed the survey
- Demographic and clinical characteristics
- Feedback regarding buprenorphine clinic, quantitative and qualitative

Demographics
<table>
<thead>
<tr>
<th>Demographic</th>
<th>Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years: mean (range)</td>
<td>43.0 (20-59)</td>
</tr>
<tr>
<td>Race:</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>92%</td>
</tr>
<tr>
<td>African-American</td>
<td>8%</td>
</tr>
<tr>
<td>Gender:</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>75%</td>
</tr>
<tr>
<td>Female</td>
<td>25%</td>
</tr>
<tr>
<td>Married</td>
<td>50%</td>
</tr>
<tr>
<td>Single</td>
<td>25%</td>
</tr>
<tr>
<td>Divorced</td>
<td>25%</td>
</tr>
<tr>
<td>Employed</td>
<td>58%</td>
</tr>
<tr>
<td>Full-time</td>
<td>42%</td>
</tr>
<tr>
<td>Part-time</td>
<td>17%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>42%</td>
</tr>
<tr>
<td>Education, years: mean (range)</td>
<td>15.5 (8-20)</td>
</tr>
</tbody>
</table>
clinical characteristics

<table>
<thead>
<tr>
<th>Item</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid problems: years mean (range)</td>
<td>13.9 (0.7-35)</td>
</tr>
<tr>
<td>Introduction to opioids:</td>
<td></td>
</tr>
<tr>
<td>Pain management</td>
<td>58%</td>
</tr>
<tr>
<td>Primary substance use disorder</td>
<td>42%</td>
</tr>
<tr>
<td>History of other substance dependence</td>
<td>75%</td>
</tr>
<tr>
<td>Episodes of addictions treatment: mean (range)</td>
<td>4.9 (1-15)</td>
</tr>
<tr>
<td>Concurrent psychiatric diagnosis</td>
<td>83%</td>
</tr>
<tr>
<td>Other prescribed psychiatric medications</td>
<td>75%</td>
</tr>
<tr>
<td>Current cigarette smokers</td>
<td>50%</td>
</tr>
<tr>
<td>Goal of abstinence (except buprenorphine, nicotine)</td>
<td>90%</td>
</tr>
<tr>
<td>12 Step (e.g., AA, NA) meeting attendance</td>
<td>92%</td>
</tr>
<tr>
<td>Last use of opioids except buprenorphine, years mean (range)</td>
<td>1.9 (0.3-4.8)</td>
</tr>
<tr>
<td>Daily dose of buprenorphine, mgs/day: mean (range)</td>
<td>13.8 (4-40)</td>
</tr>
</tbody>
</table>

results: attendance, urine drug screens

- attendance: in total, patients attended 52 of 58 (90%) of all regularly scheduled clinic sessions, with more than half (7 of 12, or 58%) attending all available sessions once enrolled

- urine drug screens: of urine drug screens obtained at the clinic, 37 of 40 (93%) were negative for recent alcohol (ethyl glucuronide, n = 3) and/or other drug use (n = 1 positive screen, which was not an opioid)

patient satisfaction: quantitative

<table>
<thead>
<tr>
<th>Item</th>
<th>Statement</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I have received clear information and instructions about how to take buprenorphine (Suboxone).</td>
<td>92%</td>
</tr>
<tr>
<td>2.</td>
<td>Staff members at the Buprenorphine Clinic are concerned with my safety and comfort.</td>
<td>83%</td>
</tr>
<tr>
<td>3.</td>
<td>I know how to obtain prescription refills through the Buprenorphine Clinic.</td>
<td>92%</td>
</tr>
<tr>
<td>4.</td>
<td>I have found the psychosocial treatment sessions (therapy and education) to be helpful to me.</td>
<td>75%</td>
</tr>
<tr>
<td>5.</td>
<td>The frequency of the Buprenorphine Clinic sessions (once a month) makes sense to me.</td>
<td>75%</td>
</tr>
<tr>
<td>6.</td>
<td>The members of the Buprenorphine Clinic team (medicine, nursing, social work) work well together.</td>
<td>100%</td>
</tr>
<tr>
<td>7.</td>
<td>Participation in the Buprenorphine Clinic has been helpful to my treatment and recovery.</td>
<td>83%</td>
</tr>
</tbody>
</table>

Percentages reflect positive responses, i.e., “Agree” or “Strongly Agree” on 5-point Likert scale.
patient satisfaction: qualitative

- Patients were asked to provide written feedback to two open-ended questions:
  - What was most helpful to you during your participation in the Buprenorphine Clinic?
  - What suggestions would you make to improve the Buprenorphine Clinic?
- All respondents (12/12 = 100%) provided positive written feedback regarding their clinical experiences, with most offering comments in more than one area.

qualitative feedback: positive themes

- group identification and membership (8/12, or 67%)
  - “Getting to know a group of people to have a similar background (e.g., are sober and in recovery, but taking Suboxone) has been invaluable.”
  - “Listening to other people’s stories, their experience with the medication.”
  - “The group sessions have always been a plus in getting myself to express my feelings and adjust with my shyness.”
- the medication (5/12, or 42%)
- multidisciplinary treatment team (4/12, or 33%)

qualitative feedback: suggestions

- 8 of 12 (67%) provided suggestions for improvement
  - Responses tended to be specific to a given individual, and no readily identified themes emerged
  - Topics of concern included physical distance to the clinic; schedule conflicts; structure, content, or frequency of the sessions; and the cost of urine drug screens for a private pay patient.
    - “I hope that as we progress, we would need to be here less often.”
    - “More structure and content in monthly meetings.”
- 4 of 12 (33%) stated “none,” or countered with another positive response. For example, one respondent wrote, “Keep up the program. It has saved my life!”
a representative summary

“The combination of medication, individual therapy and group is important. The support of [the nurse], especially, and all other staffers is excellent. The therapy of using Suboxone as a basis for treating my disease makes sense to me. Having (ab)used opiates over a period of 35 years, off-and-on, I know that I am not "normal" without the chemical readjustment that buprenorphine provides. With it, I am relaxed, creative, energetic, and free of cravings and the FEAR of withdrawal.”

discussion

Summary: respondents showed high levels of patient satisfaction, attendance, and adherence in a monthly buprenorphine clinic for opioid maintenance therapy in an outpatient addictions treatment program.

Strengths:
- identified and addressed deficiencies in a continuum of care
- principles of continuous quality improvement were employed
- essential features included patient participation, psychosocial treatment in conjunction with pharmacotherapy, and a multidisciplinary approach
- results were fed back to patients
- review and approval sought and obtained prior to release of results
- success led to the addition of a second monthly clinic

Limitations:
- small sample size
- considerable selection and self-selection bias (may be desirable for treatment matching)
- relatively short evaluation period
- highly specialized treatment setting, with capacity to diagnose and treat concurrent psychiatric disorders
- relatively homogeneous patient population
- predominantly male, Caucasian, well-educated, employed, current mutual help group involvement
- in contrast, considerable range in relation to number of years of opioid problems, and total daily doses of buprenorphine
- patient satisfaction survey generated for quality improvement, not formally tested for psychometric properties
- together, these factors may limit the ability to generalize findings
Certain principles and procedures inherent in the design and implementation of the Buprenorphine Clinic may have merit and applicability across various addiction treatment settings.

In light of mounting evidence that substance dependence is a chronic, medical illness, and the “long-term strategies of medication management and continued monitoring produce lasting benefits” (McLellan et al., 2000, p. 1689), even modest advances in the treatment of opioid dependence can hold promise for the future.

Remember, you can also share your clinical experiences and suggestions via the webinar and/or by e-mailing strobbe@med.umich.edu and your contributions will be added to, and posted on the IntNSA web site www.intnsa.org.