



ACCEPT **Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics**

Agenda

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Session Date: Friday, December 18, 2020

Didactic Topic and Presenter:

Using Peer Support Activities to Facilitate Recovery

Michael Miller, MD, DFASAM, DLFAPA

Board-certified General and Addiction Psychiatrist

Past President, Amer Society of Addiction Medicine (ASAM)

Former Director, Amer Board of Addiction Medicine (ABAM)

Former Director, Amer College of Academic Addiction Medicine (ACAAM)

Content Experts:

Ritu Bhatnagar, MD; Lindsey Peterson, MS, CRC; Sheila M. Weix, MSN, RN, CARN

-
- 12:15 PM: Attendance text-in – Introductions
 - 12:25 PM: Case Presentation
 - Presenter: Kellene Eagen, MD - *Assistant Professor, Dept. of Family Medicine and Community Health; Addiction Medicine Fellowship Faculty, UW School of Medicine and Public Health*
 - 1 PM: Didactic Presentation
 - Presenter: Michael Miller, MD, DFASAM, DLFAPA
 - 1:15 PM: End of Session

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ACCEPT
Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics
2020-2022

Using Peer Support Activities to Facilitate Recovery

Friday, December 18, 2020

Michael M. Miller, MD, DFASAM, DLFAPA – Didactic Presenter

Kellene Eagen, MD – Case Presenter

Provided by the University of Wisconsin–Madison Interprofessional Continuing Education Partnership (ICEP)

Intended Audience:

Nurses, Nurse Practitioners, Pharmacists, Physicians, Physician Assistants, Pharmacy Technicians, Psychologists, Social Workers, Patient/Caregivers, Students

Objectives:

As a result of this educational regularly scheduled series, learners will be able to:

1. Implement appropriate opioid prescribing and monitoring practices.
2. Effectively participate in office-based, collaborative management of substance use disorders.
3. Consistently provide in overdose prevention education to appropriate patients.
4. Identify the role of medication assisted therapies, such as methadone, naltrexone, and buprenorphine, and contributions of different members of the healthcare team to the management of substance use disorders.

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Randall Brown, RSS Chair	No relevant financial relationships to disclose	Yes	4/8/2020
Briana Kleinfeldt, RSS Coordinator	No relevant financial relationships to disclose	No	4/8/2020
Kathleen Maher, RSS Coordinator	No relevant financial relationships to disclose	No	4/18/2020
Nada Rashid, RSS Coordinator	No relevant financial relationships to disclose	No	7/1/2020
Ritu Bhatnagar, Planner	No relevant financial relationships to disclose	Yes	4/15/2020
Richard Crawford, Planner	No relevant financial relationships to disclose	No	4/9/2020
Paul Hutson, Planner	No relevant financial relationships to disclose	No	4/9/2020
Susan Mindock, Planner	No relevant financial relationships to disclose	No	4/6/2020
Lindsey Peterson,	No relevant financial relationships to disclose	No	4/6/202

Planner			
Alyssa Tilhou, Planner	No relevant financial relationships to disclose	No	4/13/2020
Sheila Weix, Planner	No relevant financial relationships to disclose	No	4/6/2020
Michael M. Miller, Speaker/Author	Advancing a Healthier Wisconsin Endowment (Contractor) Alkermes (Speakers Bureau) AMITA Health (Honorarium – Conference Keynote) Ammon Labs (Consultant) Aware Healthcare (Contractor) Childrens Community Health Plan (Consultant) JBS International (Contractor) US WorldMeds, LLC (Physician Advisory Board) Waypoint Health Innovations (Contractor)	No	11/24/2020
Kellene Eagen, Speaker/Author	No relevant financial relationships to disclose	No	11/25/2020

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Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics

Patient Case Presentation

***Please do not attach any patient-specific files or include any Protected Health Information.**

1. Date: 12/18/20
2. Presenter Name: Kellene Eagen, MD
3. Presenter Organization: University of Wisconsin-Madison School of Medicine and Public Health
4. ECHO ID: 2084
5. Have you presented this patient during this teleECHO clinic before? **No**

6. Please state your main question for this case:

57y female with COPD, fibromyalgia, anxiety, heroin and alcohol use who was brought in by ambulance to ED with AMS and hypoxia late evening 10/17. Pt's partner called 911 due to patient sedation on 10/17. Pt had used heroin (intranasal) earlier that day. EMS administered naloxone x2 in field with improvement in sedation. Noted to be wheezy and hypoxic and started on duonebs, ab'x and steroids for presumed component of COPD exacerbation. Patient admitted for treatment of hypercapnic/hypoxic respiratory failure in setting of COPD exacerbation and heroin overdose.

Urine drug screen on admission - positive for opiates, negative for cocaine, BZD, barbituates, amphetamines
No BAL checked

10/17 – Presented to ED at 19:30 pm (after having received naloxone x2 in field by EMS). Stable overnight requiring O2 with wheeziness but no ongoing significant sedation.

10/18 (morning after ED presentation):

- 7:42 am – given PO naltrexone (continued inpatient from outpatient med list) as part of morning medications
- 8:15 am – Seen by inpatient team rounding and patient conversant, alert and comfortable
- 8:30 am - RN noted pt to be very anxious, tremulous and restless. Called MD to evaluate.
- Given lorazepam 2 mg x3 at approximately Q10 minute doses.
- Quickly progressed to hallucinations and severe agitation.
- Given haloperidol 4 mg x 1 without improvement.
- Given lorazepam 2 mg without improvement.
- Given lorazepam 4 mg without improvement.
- Transferred to ICU for initiation of dexmedetomidine infusion for severe agitation
- Required dex ggt for < 24 hours.

- After dex ggt discontinuation, managed with lorazepam prn and gabapentin 600 mg TID for alcohol withdrawal syndrome.

The primary team and pharmacy contacted AODA MD to inquire if single oral dose of naltrexone (subsequently discontinued) could be contributor to clinical status including require for ICU transfer?

Patient Demographic Information:

7. Age: 57
8. Sex: Female
9. Education/Literacy: Unknown
10. Income source: Disabled. Medicaid
11. Social Factors/History: Housed in apartment

12. Substance Use History:

Alcohol: Drinks daily, begins in AM. Has AM withdrawal sx daily. 3-4 Steel Reserve per day. Rarely drinks vodka. History of alcohol withdrawal with delirium at St Mary's (9/2020) managed with lorazepam and haloperidol. No history of seizures. Rx'd naltrexone after hospitalization – reports did not help alcohol cravings. Experiences withdrawal sx in the am prompting her to keep drinking.

Began drinking heavily in college, then daily in her 40s. Has not achieved prolonged abstinence since she started drinking daily. Did attend treatment at rehab center a few times and also sought care previously at BH&R (specifics unknown). Tries “self discipline.”

Opioids:

Started using opioids after injuring her foot and receiving rx opioids in 2014. Pain continued and she starting buying pills from friends then switched to intranasal heroin when limited access to pills. In last year approximately \$20 heroin/day. Denies IDU. Would like to stop using heroin because she uses more than she wants to and for her own safety - she has overdosed twice. PO NTX (rx'd for AUD) did block the heroin effect, which she liked. Was on buprenorphine x1 week in the past from friend. Used 8-2 mg films, taking ¼ film Q4h which helped with cravings to a degree. Has never been on methadone.

Stimulants

Past cocaine use, denies current

13. Consequences of Substance Use:

- Social/occupational/educational:
 - Unknown
- Physical (including evidence of tolerance/withdrawal):
 - Opioid overdose requiring naloxone x2
 - Complicated alcohol withdrawal (hospitalized 9/2020)

14. Interventions that have been tried:

Has done some OP treatment at rehab facility and BH&R, details unknown. No BH treatments at time of hospital admission.

• OUD – as above, has tried buprenorphine for about a week from friend with some effect
– found PO naltrexone (rx'd for AUD) helpful for opioid craving

• AUD – PO naltrexone (reports not helpful for alcohol cravings)
(rx'd gabapentin 600 mg TID for neuropathic pain)

15.

Current Addiction and Mental Health-related Medications:	Medical/Behavioral Health Diagnosis:
<ul style="list-style-type: none">• Naltrexone 50 mg daily• Gabapentin 600 mg TID (rx'd for neuropathic pain)• Duloxetine 60 mg daily• Buspirone 10 mg BID	<ul style="list-style-type: none">• OUD, severe• AUD, severe• Nicotine dependence• Chronic pain syndrome• Fibromyalgia• Asthma/COPD• Anxiety• HCV AB - indeterminate

16.

Patient Strengths/protective factors:	Risk factors:
<ul style="list-style-type: none">• Unknown	<ul style="list-style-type: none">• Partner with OUD

17. Labs (as indicated), include summary of urine testing or last urine drug screen results:

ADMISSION: 10/18/2020 UDS positive for opiates
8/31/2020 UDS positive for BZD, opiates, cannabinoids
7/12/2020 UDS positive for cocaine, BZD, opiates

No blood alcohol level checked

AST/ALT – 55/31

18. Patient Goals/Motivations for Treatment:

After medical stabilization in hospital, stated desire to stop using heroin.

19. Proposed Diagnoses:

OD, severe

AD, severe

Complicated alcohol withdrawal (delirium)

Possible opioid withdrawal

20. Proposed Treatment Plan:

Was the clinical picture that required transfer to ICU purely alcohol withdrawal syndrome (AWS)? Purely opioid withdrawal syndrome (OWS)? A mixed picture?

To what degree did the single dose of oral naltrexone precipitate withdrawal syndrome(s)?

Some take-homes:

- Naltrexone would not precipitate AWS
- Naltrexone could precipitate opioid withdrawal (though not with ongoing delirium as was witnessed requiring dexmedetomidine.)
- Patient had received 2 doses of naloxone ~ 12 hours prior with improvement in level of sedation but then no significant evidence of ongoing opioid withdrawal prior to acute onset of delirium.
- Patient had a history of complicated AWS (6 weeks prior) which is a predictor of future complicated AWS.
- RN did not observe that patient had GI complaints, diarrhea, dilated pupils during the period of delirium (which could point to component of OWS).
- There is significant overlap in symptoms from OWS and AWS (anxiety, restlessness, nausea, insomnia, etc) making a definitive and singular diagnosis difficult.

General take-home:

→ If a patient with AD receiving PO naltrexone at home is hospitalized, do not continue until medically stable and treatment plan clear, especially if there is concern patient has used opioids and/or opioids will be needed for treatment.

Follow-up:

After resolution of withdrawal syndromes, patient decided she wanted to initiate buprenorphine for OD. Started on buprenorphine-nx 4-1 mg daily which was continued by new PCP after discharge. At post-hospital follow-up, pt continued to drink alcohol but had abstained from opioids and was taking bup-nx.

By initialing here __KVE__ you have acknowledged that Project ECHO case consultations do not create or otherwise establish a provider-patient relationship between any ECHO clinician and any patient whose case is being presented in a teleECHO clinic.

DSM 5 Criteria for Substance Use Disorder

A use disorder is characterized by maladaptive use resulting in repetitive consequences over the previous 12 months. A minimum of 2-3 criteria is required for a mild substance use disorder diagnosis, while 4-5 is moderate, and 6-7 is severe (American Psychiatric Association 2013)

1. Taking the substance in larger amounts and for longer than intended
2. Wanting to cut down or quit but not being able to do it
3. Spending a lot of time obtaining the substance
4. Craving or a strong desire to use
5. Repeatedly unable to carry out major obligations at work, school, or home due to use
6. Continued use despite persistent or recurring social or interpersonal problems caused or made worse by use
7. Stopping or reducing important social, occupational, or recreational activities due to opioid use
8. Recurrent use in physically hazardous situations
9. Consistent use despite acknowledgment of persistent or recurrent physical or psychological difficulties from using
10. *Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount. (Does not apply for diminished effect when used appropriately under medical supervision)
11. *Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal (Does not apply when used appropriately under medical supervision)



“Using Peer Support Activities to Facilitate Recovery” UW ACCEPT Project ECHO Didactic

**Dept. of Family Medicine and Community Health
Univ. of Wisc. School of Medicine and Public Health**

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Interventions

- Professional Treatment (Clinical Interventions)
 - Pharmacotherapy
 - Psychosocial Interventions/Therapies

- Recovery Activities/Peer Support (Complementary)
 - Alcoholics Anonymous
 - Narcotics Anonymous
 - SMART Recovery
 - Working with a Recovery Coach

Does adding pharmacotherapy to psychosocial treatment in persons with OUD improve outcomes?

- ▶ Medication Assisted Treatment for OUD (methadone, buprenorphine, naltrexone) -- MAT
- ▶ Medications for OUD (MOUD)

Does adding psychosocial
treatment to
pharmacotherapy in persons
with OUD improve outcomes?

Is professional treatment the only path to recovery?

■ Addiction Treatment includes

- Psychosocial Rehabilitation
(various methods of counseling/psychotherapy)
- Pharmacotherapy
- Recovery supports/peer-led/ “self-help” as an adjunct to professional tx

“Using Peer Support Activities to Facilitate Recovery”

- ▶ Does adding peer support to professional treatment improve outcomes?

What are Peer Support Activities?

Often called “Self Help,” but the key is to interact with others (peers)

Humphreys, Kelly, et al. (2020)

- Mutual help groups are non-professional, peer-led sources of fellowship, emotional support, role models, and practical coping strategies for members.

Non-Professional Treatment

- ▶ Peer support / mutual support
 - (Almost always, the misnomer “self-help” is used, but it’s not “yourself”, it’s via others!)

- ▶ Alcoholics Anonymous (AA), et al. (12-step recovery)
 - Narcotics Anonymous (NA)
 - Cocaine Anonymous (CA) and Heroin Anonymous (HA)
 - Gamblers Anonymous (GA)
 - Overeaters Anonymous (OA)
 - Sex Addicts Anonymous (SAA)

- ▶ It is for recovering people, and offered by recovering people, without a trained professional to ‘lead’ the group, without any charges or documentation

Public Policy Statement on the Relationship Between Treatment and Self Help:

A Joint Statement of the American Society of Addiction Medicine, Inc., the American Academy of Addiction Psychiatry, and the American Psychiatric Association

<https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2011/12/16/relationship-between-treatment-and-self-help-a-joint-statement>

<https://www.aaap.org/wp-content/uploads/2018/07/Relat-bw-Treatment-SelfHelp-1997.pdf>

ASAM, AAAP and APA recommend that:

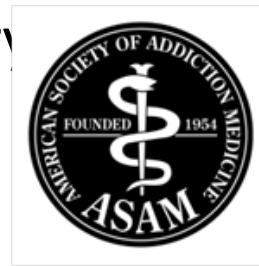
1. Patients in need of treatment for alcohol or other drug-related disorders should be treated by qualified professionals in a manner consonant with professionally accepted practice guidelines and patient placement criteria;
2. Self help groups should be recognized as valuable community resources for many patients in addiction treatment and their families. Addiction treatment professionals and programs should develop cooperative relationships with self help groups;
3. Insurers, managed care organizations and others should be aware of the difference between self help fellowships and treatment;
4. Self help should not be substituted for professional treatment, but should be considered a compliment to treatment directed by professionals. Professional treatment should not be denied to patients or families in need of care.

From *The ASAM Definition of Addiction* (2011)

***[now referred to as the ASAM Description of
Addiction]:***

**As in other health conditions, self-management,
with mutual support, is very important in recovery
from addiction.**

Peer support such as that found in various “self-
help” activities is beneficial in optimizing health
status and functional outcomes in recovery



**From *The ASAM Definition of Addiction (2011)*
*[now referred to as the ASAM Description of Addiction]:***

Recovery from addiction is best achieved through a combination of self-management, mutual support, and professional care provided by trained and certified professionals.



Recovery Coaches (Wikipedia)

- ▶ Recovery coaches do not offer primary treatment for addiction, do not diagnose, and are not associated with any particular method or means of recovery. They support any positive change, helping persons coming home from treatment to avoid relapse, build community support for recovery, or work on life goals not related to addiction such as relationships, work, or education. Recovery coaching is action-oriented with an emphasis on improving present life and reaching future goals.
- ▶ Recovery coaching is unlike most therapy because coaches do not address the past, do not work to heal trauma, and put little emphasis on feelings. Recovery coaches are unlike licensed addiction counselors in that they are non-clinical and do not diagnose or treat addiction or any mental health issues.

Twelve Step Facilitation (TSF)

- ▶ A modality of psychotherapy
- ▶ An evidence-based practice (EBP)
- ▶ A manualized treatment developed in a collaboration between the University of Pennsylvania and NIAAA
- ▶ One of the three therapeutic modalities studied on Project MATCH
 - MET – Motivational Enhancement Therapy
 - CBT – Cognitive Behavioral Therapy
 - TSF – Twelve Step Facilitation Therapy

Twelve Step Facilitation (TSF) Therapy

(from Twelve Step Facilitation Therapy Manual, pp. 99-101)

Termination of Intensive Therapy

Like every session, start with Check in/Review (this is the ESSENSE of TSF)

- Meetings
- Sober Days
- Urges
- Slips
- Readings
 - Phone Calls
 - Sponsor Contacts
 - Working the Steps

Doing TSF

1. Probe for responses to recommendations: are you attending? Why/why not (what are the factors influencing your attending or not)?
2. TSF vs “go to meetings” suggestion
3. Recommend various levels of involvement:
 - Attendance
 - Participation at meetings (speak up)
 - Get a sponsor
 - Work the steps
 - Be involved in clubhouse activities (chores, GSR)
 - Be involved in beyond-clubhouse activities (conventions, retreats, dances, camping)

Research on AA—look for key authors

- ▶ Lee Ann Kaskutas, DrPH (Cal-Berkeley) – 2007 Smithers Award
- ▶ Rudolf Moos, PhD (Stanford) – 2006 Smithers Award
- ▶ John Kelly, PhD (Harvard)
- ▶ Keith Humphreys, PhD (Stanford)
- ▶ Marc Galanter, MD (NYU)

Humphreys, Kelly, et al. “Impact of 12 step mutual help groups on drug use disorder patients across six clinical trials.” Drug and Alcohol Dependence 215: article # 108213 (October 1, 2020)

Abstract:

- ▶ Greater 12 step mutual help group attendance by drug use disorder patients predicted reduced use of and problems with illicit drugs and also alcohol.
- ▶ Facilitating significant and lasting involvement in 12 step groups may be more challenging for drug use disorder patients than for alcohol use disorder patients.

Humphreys, Kelly, et al.

Mutual help groups are non-professional, peer-led sources of fellowship, emotional support, role models, and practical coping strategies for members.

Most of the effectiveness evidence available for 12 step mutual help groups comes from studies of individuals with alcohol use disorder who attend AA. As demonstrated in a new Cochrane Collaboration review of 27 rigorous studies enrolling a total of 10,565 individuals with AUD, AA generates alcohol-related outcomes as good or better than high-quality psychosocial interventions such as CBT.

Twelve step group evaluations focused specifically on individuals with drug use disorder are less common and less rigorous.

Humphreys, Kelly, et al.

- ▶ Moos et al. (2001): number of 12 step groups attended had a strong linear association at 1 year follow-up with rate of abstinence from all substances
- ▶ Weiss and Griffin (2005): greater 12 step group participation (e.g., not just attending meetings but also reading literature, practicing the steps, having a sponsor) predicted reduced cocaine use.
- ▶ Humphreys, Kelly, et al. (2020): pooling clinical trial samples from all existent federally-funded RCTs of TSF for AUD patients (1730 individuals, 62% male); the primary outcome examined was the composite Drug Severity score on the ASI. The key predictor of interest was 12 step mutual help group attendance by drug use disorder patients.

Humphreys, Kelly, et al.

- ▶ Regression models identified a predictive association between greater 12 step group attendance and fewer drug problems.
- ▶ **12 step facilitation (TSF) interventions have limited ability to increase mutual help group participation among drug use disorder patients.**
- ▶ Compared to those with alcohol or cannabis histories, those with primary opioid or stimulant use disorder histories had substantially lower levels of recovery capital and quality of life in the early years of recovery and needed more services to sustain remission.
- ▶ [MMM hypothesis: those with OUD on MOUD may face stigma and discrimination within NA groups not specifically designed for persons on MOUD, and face these even from sponsors]

Monico et al. “Buprenorphine Treatment and 12-step Meeting Attendance: Conflicts, Compatibilities, and Patient Outcomes.” Journal of Substance Abuse Treatment 57:89–95. 2015.

- ▶ Abstract: The number of NA meetings attended in the prior 6 months was associated with a higher rate of retention in BMT and with heroin/cocaine abstinence at 6-month follow-up.
- ▶ Quantitative and qualitative data collected (patient verbatims)
- ▶ “Although leading researchers in the addiction treatment field have argued that 12-step recovery and opioid agonist maintenance are not incompatible the reality is that opioid agonist treatment patients attending NA meetings for support are likely to experience conflicts and pressures to discontinue their medication (Parran et al. 2010).

Harvey et al.

- ▶ In Parran et al.'s longitudinal study of bup-ntx treatment (2010), the most common reason for discontinuation of MOUD was the perceived incompatibility of the treatment with the 12-Step model of abstinence.

Monico et al. “Buprenorphine Treatment and 12 step Meeting Attendance: Conflicts, Compatibilities, and Patient Outcomes.” JSAT 57:89–95. 2015.

- ▶ Participants were 300 opioid-dependent African Americans newly admitted to buprenorphine treatment at one of two participating outpatient treatment programs in Baltimore: one in an FQHC and one in a CMHC.
- ▶ At the 6 month follow-up, among participants who attended NA meetings within the past 3 months, just over two-thirds reported that NA meetings were “quite a bit” or “extremely” helpful to their recovery, while just 5% reported that NA meetings were “not at all helpful.”

Monico et al. “Buprenorphine Treatment and 12-step Meeting Attendance: Conflicts, Compatibilities, and Patient Outcomes.” JSAT 57:89–95. 2015.

- ▶ At 6 months, among participants who reported attending NA meetings while enrolled in BMT, only 33% reported disclosing their BMT status to an NA member.
- ▶ Of participants who disclosed their BMT status, 26% reported that someone at NA encouraged them to stop taking buprenorphine or decrease their dose.
- ▶ Each additional NA meeting attended over the course of 6 months was associated with a 1% increase in the odds of being abstinent at 6 months.

Laura Harvey et al. “Psychosocial intervention utilization and substance abuse treatment outcomes in a multi-site sample of individuals who use opioids.” JSAT Treatment 112:68–75 (2020).

- ▶ Abstract: 570 individual from 8 SUD tx centers enrolled in a RCT testing bup-ntx vs extended-release naltrexone for OUD.
- ▶ Abstract: Hours of individual counseling and 12-Step participation significantly predicted abstinence at follow-up. There was a significant interaction between individual counseling and 12-Step participation.

Harvey et al.

- ▶ Groups such as AA and NA are widely available, free of charge, and provide ongoing support to individuals with SUDs (Galanter 2018).
- ▶ A key distinction of the 12-Step model is its emphasis on complete abstinence from alcohol, drugs, and medications with abuse potential. Therefore, some MOUD treatments challenge this fundamental principle.

Monico et al. “Buprenorphine Treatment and 12-step Meeting Attendance: Conflicts, Compatibilities, and Patient Outcomes.” JSAT 57:89–95. 2015.

- ▶ According to NA World Services, methadone patients are typically asked not to speak at NA meetings, are barred from holding service positions within the abstinence-focused fellowship, and are not recognized for periods of sobriety or “clean time” while in methadone treatment (World Service Board of Trustees Bulletin #29).

Harvey et al.

- ▶ Several studies have demonstrated a beneficial effect of psychosocial interventions when combined with MOUD during OUD treatment (Amato et al., 2011; Carroll and Weiss, 2017; Dugosh et al., 2016).
- ▶ While other studies have not found psychosocial interventions to add a significant treatment effect above medication management (Fiellin et al., 2013; Ling et al., 2013).
- ▶ Dugosh et al. conducted the most comprehensive review of the effectiveness of psychosocial interventions in conjunction with MOUD. This review included 27 studies and 3 reviews....
- ▶ The addition of psychosocial interventions may improve OUD treatment retention and opioid use at follow-up.

Harvey et al.

- ▶ The current study found that greater levels of 12-Step group participation significantly predicted illicit opioid abstinence.
- ▶ Previous studies have shown that participation in 12-Step groups is associated with increased levels of social support (Kaskutas, et al., 2002), which is an established predictor of post-treatment abstinence (citing multiple studies by Humphreys, Moos, Kaskutas, Kelly, and others).
- ▶ The current study found that the interaction between individual and 12-Step intervention hours significantly predicted opioid abstinence. This finding suggests the combination of individual and 12-Step interventions may offer additional benefits above and beyond the direct effects of each treatment alone.

Harvey et al.

- ▶ The American Society of Addiction Medicine (ASAM) and the World Health Organization (WHO) both recommend that MOUD be combined with psychosocial interventions to achieve optimal treatment outcomes.

What can a physician do to promote the benefits than can accrue from N.A.?

- ▶ Regularly advise patients with SUD on the benefits of AA/NA
- ▶ Have resources to share with patients
 - Meeting schedules in communities your practice serves
 - Names of recovering persons who could serve as a “First Friend”
- ▶ Understand that Twelve Step Facilitation is an Evidence Based Practice (EBP) – it works!
- ▶ TSF is a lot more than advising patients to “go to meetings”
- ▶ But the first thing is...be literate about AA, know the language/concepts

How to learn more, if you're a health professional?

- ▶ Experiential learning
- ▶ Attend a meeting yourself
- ▶ “Open Meetings” are usually Speaker Meetings
- ▶ If you're a health professional, see if the General Service Representative (GSR) or other “leader” of a health professionals meeting can get the group's permission for you to come and observe

Thank you!

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Special Section: Defining and Measuring “Recovery” Special article

What is recovery? A working definition from the Betty Ford Institute The Betty Ford Institute Consensus Panel[☆]

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Abstract

There is an unknown but very large number of individuals who have experienced and successfully resolved dependence on alcohol or other drugs. These individuals refer to their new sober and productive lifestyle as “recovery.” Although widely used, the lack of a standard definition for this term has hindered public understanding and research on the topic that might foster more and better recovery-oriented interventions. To this end, a group of interested researchers, treatment providers, recovery advocates, and policymakers was convened by the Betty Ford Institute to develop an *initial* definition of recovery as a starting point for better communication, research, and public understanding. Recovery is defined in this article as *a voluntarily maintained lifestyle composed characterized by sobriety, personal health, and citizenship*. This article presents the operational definitions, rationales, and research implications for each of the three elements of this definition. © 2007 Published by Elsevier Inc.

Keywords: Recovery; Addiction; Substance use disorders; Addiction treatment

1. Introduction

Individuals who are “in recovery” know what it means to them and how important it is in their life. They do not need a formal definition. However, *recovery* is not clear to the public, to those who research and evaluate addiction treatments, and to those who make policies about addiction. Indeed, there is reason to believe that there is no complete consensus on the definition even among those in recovery (see [Laudet, 2007](#); [Laudet, Morgen, & White, 2006](#)).

A commonly accepted and operationally defined measure of recovery could lead to improved research and understanding in the addiction field. For example, we do not definitively know what role formal treatment plays in initiating or sustaining recovery. Many formerly dependent individuals enter recovery without addiction treatment, using only Alcoholics Anonymous (AA) and 12-step activities—

and some without any assistance (see [Humphreys et al., 2004](#); [Sobell, Ellingstad, & Sobell, 2000](#)). In addition, research on therapeutic community and social model forms of treatment over the past 30 years had also produced well-formed theoretical models and explicit methods by which substance-dependent individuals have become abstinent and associated with reduced crime and improved employment rates (see [Borkman, Kaskutas, Room, & Ma, 1998](#); [De Leon, 2000](#); [Flynn, Joe, Broome, & Simpson, 2003](#)).

Despite their importance, these models do not all share the same measures or even the same underlying concepts of what they all refer to as “recovery.” Thus, we have little to tell families, employers, schools, payers, and policymakers about how they can support and extend the recovery process. Also, despite the many successes within the treatment field in helping addicted individuals initiate recovery, it is presently not possible to tell treatment providers the best ways to foster recovery ([McLellan & Weisner, 1996](#)). Without a consensus definition of recovery that will permit systematic measurement, there will likely be no research to inform these issues.

A second reason to define and study recovery is that it may have value beyond addiction (see [American Psychiatric Association \[APA\], 2005](#); [Anthony, Gagne, & White, 2007](#); [Deegan, 1988](#); Department of Health and Human Services,

[☆] Members are listed alphabetically in the Appendix.

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2003). Of course, the word *recovery* has been widely used throughout health care. Individuals suffering from other chronic illnesses also want more than just symptom remission from their health care: They want improved function and a satisfying quality of life (QOL; see Breslow, 2006; Galanter, 1997; Institute of Medicine, 2006; Ware, Hopper, Tugener, Dickey, & Fisher, 2007). This has been recognized within the National Institutes of Health (NIH) in its efforts to include common measures of “wellness” and “quality of life” in clinical trials for many illnesses (see Reeve, 2007; NIH Patient-Reported Outcomes Measurement Information System at <http://www.nihpromis.org>). Thus, the study of recovery in the addiction field may be illuminated by what we have learned from other disorders. For example, maintaining healthy, stress-free, and socially productive lifestyles appears to offer protective factors in other medical and mental health conditions (Breslow, 2006).

1.1. The consensus process

With this as background, the Betty Ford Institute (BFI) invited a group of 12 concerned and experienced individuals (hereafter called the *consensus panel*) representing addiction treatment, policy, and research—several of whom were themselves in stable recovery—to develop a consensus definition that might serve as a starting point for open communication and improved understanding about this important concept. The consensus process started with the commissioning of articles (see this issue) designed to frame some of the important issues in defining this complex concept. These articles were presented to the members of the consensus panel before a 2-day conference, held in September 2006 on the grounds of the Betty Ford Center in Rancho Mirage, California. At that conference, the panel members heard abbreviated presentations of the articles and debated on each of the important components of the definition. The process was professionally facilitated by Erica Goode, a science writer from the *New York Times*, to ensure full coverage of the topic.

By the end of the conference, a working draft definition was formulated and circulated for additional comments from all members of the panel. It was agreed from the outset that there would be no attempt to force a consensus. In the end, there was no issue requiring a minority position and consensus (11 voting affirmative and 1 abstaining) was achieved on the definition subsequently discussed.

We present the three-part consensus definition, which is followed by the orienting premises and rationale for each of the definition's components. It is emphasized that this definition does not necessarily represent the views of the Betty Ford Center, the treatment provider community, and especially the recovering community. Furthermore, the definition is not based on a consensus interpretation of available evidence, as most researchers would wish. That body of scientific evidence does not yet exist—in part because there has been no agreed-upon starting point for the research.

2. The definition

Recovery from substance dependence is a voluntarily maintained lifestyle characterized by sobriety, personal health, and citizenship.

2.1. Sobriety

Sobriety refers to abstinence from alcohol and all other nonprescribed drugs.

This criterion is considered to be primary and necessary for a recovery lifestyle. Evidence indicates that for formerly dependent individuals, sobriety is most reliably achieved through the practice of abstinence from alcohol and all other drugs of abuse.

Early sobriety = 1–11 months; *sustained sobriety* = 1–5 years; *stable sobriety* = 5 years or more.

2.2. Personal health

Personal health refers to improved quality of personal life as defined and measured by validated instruments such as the physical health, psychological health, independence, and spirituality scales of the World Health Organization QOL instrument (WHO-QOL Group, 1998a,b).

2.3. Citizenship

Citizenship refers to living with regard and respect for those around you as defined and measured by validated instruments such as the social function and environment scales of the WHO-QOL instrument (WHO-QOL Group, 1998a,b).

Criteria 2 and 3 extend sobriety into the broader concept of recovery. Personal health and citizenship are often achieved and sustained through peer support groups such as AA and practices consistent with the 12 steps and 12 traditions.

3. General premises guiding the consensus definition process

3.1. Recovery is not simply sobriety

Although sobriety is considered to be necessary for recovery, it is not considered as sufficient. Recovery is recognized universally as being multidimensional, involving

more than simply the elimination of substance use (see De Leon, 2000; Kurtz, 1979; Laudet, 2007; Laudet et al., 2006; Tiebout, 1953; White, 2006, 2007). The additional health and social aspects of recovery are potentially quite important to the prevention of relapse and may be the most attractive aspects of recovery to affected individuals, their families, and society as a whole.

3.2. Recovery as a personal condition, not a specific method

This was a particularly important premise, governing several important decisions on elements of the definition. It would have been easiest to define recovery as “abstinence attained through adherence to 12-step principles.” Such an approach would have the advantage of describing recovery in the most familiar methods presently used to attain it. However, it would essentially freeze the concept in time and stipulate a requirement for full and active participation in AA and 12-step activities as the way to attain recovery. No individual or group has the authority to represent AA or other 12-step organizations on such a position. On conceptual grounds, even the founders of AA recognized that there were many paths to the same position (AA World Services, 1939/2001; Cheever, 2004) and did not suggest that their specific methods were the only means to attain the overall goal. Indeed, one of the important purposes of this initial definition is to promote exploration of different ways to achieve recovery.

3.3. Recovery from addiction, not general recovery

Although the term *recovery* is not unique to the addiction field, the consensus panel decided to focus on recovery from addiction as this was the focus of our interest and experience. It is not known whether recovery from addiction is similar to or different from recovery from other illnesses (see Anthony et al., 2007; APA, 2005; Deegan, 1988; Department of Health and Human Services, 2003). It is hoped that the current definition will promote research in this important area.

In this regard, it should be noted that recovery as it is used here is only intended to apply to those who once met the diagnostic criteria for substance abuse or dependence (see APA, 2000, *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*). Very simply, people cannot be in recovery from a serious substance use disorder if they never met *DSM-IV* criteria for the disorder in the first place.

3.4. A starting point, not a final definition

The consensus panel did not intend or expect to produce the final definition of recovery. As concerned and involved members of the addiction field, the panel participants attempted to represent the best available data, thinking, and accrued wisdom as a starting point for communication,

exploration, and refinement of the recovery concept. Thus, it is expected that this definition will evolve with comments from the recovering community, treatment providers, and policymakers, as well as from new research findings that should follow this definition. Just as *DSM* diagnoses have been changed four times since the original criteria were provided, there may be many future editions of a recovery definition. However, we hope that future definitions of recovery will be informed by research made possible by the initial definition.

4. Rationale for specific elements of the definition

4.1. Voluntary

Although there are many periods of forced abstinence, such as during incarceration or coerced treatment, the consensus panel agreed that one of the key elements of recovery is the willing and voluntary pursuit of behaviors that constitute recovery.

4.2. Maintained lifestyle

The phrase *maintained lifestyle* reflects recognition that recovery is more than just a state of being at a moment in time but that it is also not necessarily a permanent state. Recovery status may change without active management to sustain it (see De Leon, 2000; Simpson, 2004; Scott, Foss, & Dennis, 2005). Most of those in recovery convey this by describing themselves as being “recovering” or “in recovery” rather than “recovered.” Thus, the consensus panel considered recovery to be best represented as a maintained lifestyle.

5. Rationale for the three components of recovery

The consensus panel agreed on three components to capture the overall concept of recovery (i.e., sobriety, personal health, and citizenship) and turned to well-developed and widely used measures to better specify each of these components.

5.1. Sobriety

Sobriety is defined as “abstinence from alcohol and all other nonprescribed drugs.” This was considered as the cardinal feature of a recovery lifestyle. In turn, several underlying issues were negotiated to specify this component.

5.1.1. Time frame

The consensus panel attempted to convey the importance of sobriety stability as a likely indicator of resilience to relapse. However, there is no empirically established or widely agreed-upon time frame for describing the stability of sobriety (see Dennis, Scott, Funk, & Foss, 2005; Moos & Moos, 2006). Adopting and extending some of the language

and concepts from contemporary diagnostic thinking (see APA, 2000, *DSM-IV-TR*) about “remission” from substance use disorders, the panel agreed on the following adjectives as a first effort to describe the duration and perhaps the stability of sobriety:

early sobriety – sobriety (by the current definition) lasting for at least 1 month but less than 1 year;

sustained sobriety – sobriety (by the current definition) lasting for at least 1 year but less than 5 years; and

stable sobriety – sobriety (by the current definition) lasting for at least 5 years.

These adjectives and the suggested time frames were derived in part from the meager research literature on this topic but primarily from the common experience of those in recovery. It remains an open question whether these time frames capture true differences in relative risk for relapse and whether they are associated with different levels of development in the other components of recovery.

5.1.2. Sobriety sustained by medications

There has been no consensus even within the recovering community about the role of “medication-assisted recovery.” There appears to be essentially full agreement that formerly dependent individuals who are abstinent from all drugs of abuse but take, for example, insulin for diabetes or diuretics for hypertension still meet contemporary views about being in recovery. There does not appear to be agreement regarding whether those whose use of alcohol has been blocked by naltrexone, acamprosate, or disulfiram (Rychtarik, Connors, Demen, & Stasiewicz, 2000) are also considered to be in recovery. Finally, it appears that only few of those presently in recovery within the United States consider individuals whose illicit opioid use is blocked by buprenorphine or methadone to be in recovery (Murphy & Irwin, 1992; White & Coon, 2003). However, it should be noted that many persons outside the United States who are maintained on methadone or buprenorphine consider themselves to be in medication-assisted recovery (see Laudet, 2007).

Again, the panel’s intent with this definition was to characterize the condition of recovery, not the method by which one attains it. Thus, it was the consensus that those who are abstinent from alcohol, all illicit drugs, and all nonprescribed or misprescribed medications would qualify for this component of the definition regardless of whether those behaviors were being maintained by a medication, a form of unforced outpatient treatment, support from a recovering peer group, or some alternative lifestyle. To be explicit, formerly opioid-dependent individuals who take naltrexone, buprenorphine, or methadone as prescribed and are abstinent from alcohol and all other nonprescribed drugs would meet this consensus definition of sobriety. Similarly, alcohol-dependent individuals who take acamprosate or naltrexone as prescribed, to reduce cravings for alcohol, but are abstinent from alcohol and all other nonprescribed drugs

would also meet this consensus definition of sobriety. Obviously, those who continue to meet the criteria for a substance use disorder despite taking a prescribed medication would not meet this consensus definition of sobriety.

5.1.3. The special case of tobacco

Although tobacco dependence is among the most pervasive and serious public health problems facing this country and many others (Danaei, VanderHoom, Lopez, Murray, & Ezzati, 2005; Rosner & Stamfer, 2006), many of those who have successfully become abstinent from alcohol and other drugs have not attempted or sustained abstinence from tobacco products (cigarettes, chewing tobacco, and snuff). Indeed, there are significant rates of emphysema, cancer, and other terminal health conditions associated with these products among those otherwise in recovery (Grant, Hasin, Chou, Stinson, & Dawson, 2005).

For these reasons, the consensus panel wanted very much to include tobacco products in the list of substances that are part of the sobriety component of this recovery definition. However, it was recognized that traditional concepts of sobriety and recovery have been silent on tobacco use; thus, including tobacco in the sobriety component would disqualify many of those who now consider themselves to be in recovery. As such, for the time being, the consensus panel considered it best to remain silent on tobacco use within the sobriety component of the recovery definition. It is admitted that there is no clinical justification for this position. This is an aspect of sobriety that the recovering and the addiction treatment communities must embrace on behalf of public health.

5.2. Personal health

The consensus panel understood that these additional components of the recovery definition may be particularly important to the recovering individual and to families and society. There are many other illnesses in which a reduction of presenting symptoms is seen as necessary but not sufficient to produce return of function (see Institute of Medicine, 2006). Indeed, this sentiment has been captured by the WHO in its definition of health as a “...a state of complete physical, mental, and social well-being, not merely the absence of disease” (WHO, 1985, p. 34). More recently, the NIH has incorporated three domains into its working definition of health: physical health (including function and symptoms), mental health (emotional distress, cognitive function, and psychological function), and social health (role participation and social supports; see NIH PROMIS at <http://www.nihpromis.org>; Reeve, 2007).

5.3. Citizenship

The word *citizenship* has not been routinely used in the context of recovery and has sometimes had a political connotation. However, as suggested in Wikipedia (<http://>

www.wikipedia.org/), citizenship “...implies working towards the betterment of one’s community through participation, volunteer work, and efforts to improve life for all citizens.” We believe this captures important traditional recovery elements such as “giving back.”

For the sake of greater specificity, there was the wish to ground personal health and citizenship in previously validated conceptual domains and criteria, with validated assessment tools to measure them. However, there is currently no single instrument in our field to adequately measure all the elements within these two critical constructs. Nonetheless, the panel felt that it was preferable to first disseminate the preliminary consensus definition and stimulate productive debate toward refining that definition.

Outside the addiction field, other areas of health care are increasingly embracing the concept of QOL as a bona fide outcome domain and clinical goal. Quality of life is a multidimensional construct generally measured in terms of physical, mental, and social health—many of the constructs the panel sought to capture in the last two components of the recovery definition. Generic QOL instruments encompass measures of positive health and social functioning as well as life satisfaction.

In this regard, the WHO-QOL is becoming the leading generic QOL measure, increasingly used worldwide in biomedical research, including clinical trials. The full instrument, the WHO-QOL-100 (Murphy, Herrman, Hawthorne, Pinzone, & Evert, 2000; WHO-QOL Group, 1995, 1998a,b), and the abbreviated WHO-QOL-BREF (26 items) offer multidimensional cross-culturally valid assessments of four dimensions: physical health, mental health, social health, and environment (e.g., living context, personal safety, opportunity for leisure and learning, as well as access to and quality of care). The WHO-QOL instruments are in the public domain, with available published norms for healthy and “ill” populations in more than 15 countries (WHO-QOL Group, 1998a,b; also see Skevington, Lotfy, & O’Connell, 2004).

Thus, selected scales from the WHO-QOL may be suitable assessment tools for some aspects of the personal health and citizenship dimensions of recovery as defined in this article. At the same time, there are many other validated instruments and scales that measure the domains making up personal health and citizenship. New measures of these domains are also under development through the NIH PROMIS effort (see NIH PROMIS at <http://www.nihpromis.org>; Reeve, 2007). It is hoped that the specification of these two domains with operational definitions rooted in this generic instrument example will lead the way for testing of additional measures.

5.3.1. Threshold scoring?

Unlike the sobriety component, which has a clear and dichotomous measurement threshold (abstinence as defined: *yes* or *no*), there is no threshold determination of “problem status” with regard to the personal health and citizenship

domains. The consensus panel thus agreed to accept improvement in these domains, measured against a pre-recovery period of substance use. Again, one goal of this definition is to foster the kind of research that will provide empirically derived threshold guidelines for “normal function” on these domains.

6. Discussion

Recovery may be the best word to summarize all the positive benefits to physical, mental, and social health that can happen when alcohol- and other drug-dependent individuals get the help they need. Those who are in recovery are typically sober, working, and tax-paying parents and neighbors. These are the types of personal and social qualities that one might reasonably take pride in and publicly announce if one were seeking elected office or a position of responsibility within a corporation or community. Instead, this term (i.e., *in recovery*) has marginal social status and even more uneasy optimism associated with it than, for example, the term *cancer survivor*.

It is interesting in this regard that there is an operational definition for cancer survivors. Based on prospective follow-up studies of cancer patients, those who are living symptom free for 5 years after a cancer diagnosis appear to have reached a period of significantly reduced risk for relapse and are thus termed *survivors* (Reis et al., 2003; Rowland, 2004). “Survival rates” are now tracked regularly and publicly in professional journals and in the popular press. Improvement in survival rates is part of the national health strategy for 2010 (see *Healthy People 2010*, 2000, Objectives 3–15). The pink ribbon has become a widely used public symbol of support for breast cancer survivors and for increased research and treatment in that field. Perhaps most importantly, public discussion of survival rates has increased the proportion of individuals willing to get early screening for the illness and to take preventive measures (see *Centers for Disease Control and Prevention*, 2004).

6.1. Issues facing the field regarding recovery

Unlike the term *cancer survivor*, the term *in recovery* has not been operationally defined by the addiction treatment and research communities and, consequently, is not well understood by the public. There is as yet no threshold point that conveys significantly reduced levels of relapse risk. It was the hope of the BFI Consensus Panel that the preceding definition of recovery might be the beginning of a similar course of events in the addiction field. If recovery can be effectively captured, distilled, and communicated, it can come to be expectable by those now suffering from addiction. Recovery could then also be studied from an economic perspective, using standard procedures. This could lead to more realistic public perceptions of the true worth of recovery that payers might come to value and invest in.

However, there is much that must occur for this or any definition of *recovery* to have the kind of broad impact that *survivor* has had in the cancer field. Within the current definition, we have simply reached consensus on key concepts. We do not yet have the research evidence to establish the clinical importance of or the parameters for these concepts. For example, do those who have *stable sobriety* have a significantly better chance of remaining sober and productive in the next year than those who have *sustained sobriety*? Is the appropriate threshold 1, 3, 5, or more years? Is medication-assisted sobriety more or less likely to result in stable sobriety than efforts that do not involve medications? Are those who have achieved abstinence from their primary drug problem but are still smoking less likely to sustain that abstinence than those who have also quit smoking? What is the role of personal health and citizenship in sustaining sobriety?

The recovery definition may have special significance for the treatment field. The broad and inclusive definition of recovery might form the basis for unrealistic expectations from a treatment industry that has been severely and adversely affected by budgetary restrictions and managed care (see [Institute of Medicine, 2006](#)). Conversely, there have been suggestions from the many individuals who attained recovery through mutual support groups or other informal methods that treatment is not necessary for recovery. What *are* appropriate expectations for the treatment field in terms of this definition of recovery?

In fact, the consensus panel does not pretend to know the answer to this question. Again, the decision to focus on defining the *state* of recovery rather than the *process* by which one attains that state was quite purposeful. This definition was designed purposely as an operational definition of what we believe is both a desirable and achievable state for those who now suffer from addiction. It is an open but hopefully empirical question as to which kinds of treatments or other interventions delivered for what amount of time and to which “types” of addicted individuals will lead to what level and duration of sobriety, personal health, and citizenship. It is the earnest hope of the BFI Consensus Panel that this initial definition will provide a starting point for more extended research and clinical efforts to answer these and other questions.

Appendix A. Items on the WHO-QOL scales referenced in the definition

The BFI Consensus Panel – The BFI at the Betty Ford Treatment Center is a not-for-profit institute created to conduct and support collaborative programs of research, education, and policy development that lead to a reduction of the devastating effects of substance use disorders on individuals, families, and communities.

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A.1. Level of independence questions

F9.1 (F11.1.1): How well are you able to get around?

F9.2 (F11.2.1): How satisfied are you with your ability to move around?

F9.3 (F11.2.2): How much do any difficulties in mobility bother you?

F9.4 (F11.2.3): To what extent do any difficulties in movement affect your way of life?

F10.1 (F12.1.1): To what extent are you able to carry out your daily activities?

F10.2 (F12.1.3): To what extent do you have difficulty in performing your routine activities?

F10.3 (F12.2.3): How satisfied are you with your ability to perform your daily living activities?

F10.4 (F12.2.4): How much are you bothered by any limitations in performing everyday living activities?

F11.1 (F13.1.1): How dependent are you on medications?

F11.2 (F13.1.3): How much do you need any medication to function in your daily life?

F11.3 (F13.1.4): How much do you need any medical treatment to function in your daily life?

F11.4 (F13.2.2): To what extent does your quality of life depend on the use of medical substances or medical aids?

F12.1 (F16.1.1): Are you able to work?

F12.2 (F16.1.2): Do you feel able to carry out your duties?

F12.3 (F16.1.3): How would you rate your ability to work?

F12.4 (F16.2.1): How satisfied are you with your capacity for work?

A.2. Social relations questions

F13.1 (F17.1.3): How alone do you feel in your life?

F13.2 (F17.2.1): Do you feel happy about your relationship with your family members?

F13.3 (F17.2.3): How satisfied are you with your personal relationships?

F13.4 (F19.2.1): How satisfied are you with your ability to provide for or support others?

F14.1 (F18.1.2): Do you get the kind of support from others that you need?

F14.2 (F18.1.5): To what extent can you count on your friends when you need them?

F14.3 (F18.2.2): How satisfied are you with the support you get from your family?

F14.4 (F18.2.5): How satisfied are you with the support you get from your friends?

F15.1 (F3.1.1): How would you rate your sex life?

F15.2 (F3.1.2): How well are your sexual needs fulfilled?

F15.3 (F3.2.1): How satisfied are you with your sex life?

F15.4 (F3.2.3): Are you bothered by any difficulties in your sex life?

A.3. Environment questions

F16.1 (F20.1.2): How safe do you feel in your daily life?

F16.2 (F20.1.3): Do you feel you are living in a safe and secure environment?

F16.3 (F20.2.2): How much do you worry about your safety and security?

F16.4 (F20.2.3): How satisfied are you with your physical safety and security?

F17.1 (F21.1.1): How comfortable is the place where you live?

F17.2 (F21.1.2): To what degree does the quality of your home meet your needs?

F17.3 (F21.2.2): How satisfied are you with the conditions of your living place?

F17.4 (F21.2.4): How much do you like it where you live?

F18.1 (F23.1.1): Have you enough money to meet your needs?

F18.2 (F23.1.5): Do you have financial difficulties?

F18.3 (F23.2.3): How satisfied are you with your financial situation?

F18.4 (F23.2.4): How much do you worry about money?

F19.1 (F24.1.1): How easily are you able to get good medical care?

F19.2 (F24.1.5): How would you rate the quality of social services available to you?

F19.3 (F24.2.1): How satisfied are you with your access to health services?

F19.4 (F24.2.5): How satisfied are you with the social care services?

F20.1 (F25.1.1): How available to you is the information that you need in your day-to-day life?

F20.2 (F25.1.2): To what extent do you have opportunities for acquiring the information that you feel you need?

F20.3 (F25.2.1): How satisfied are you with your opportunities for acquiring new skills?

F20.4 (F25.2.2): How satisfied are you with your opportunities to learn new information?

F21.1 (F26.1.2): To what extent do you have the opportunity for leisure activities?

F21.2 (F26.1.3): How much are you able to relax and enjoy yourself?

F21.3 (F26.2.2): How much do you enjoy your free time?

F21.4 (F26.2.3): How satisfied are you with the way you spend your spare time?

F22.1 (F27.1.2): How healthy is your physical environment?

F22.2 (F27.2.4): How concerned are you with the noise in the area you live in?

F22.3 (F27.2.1): How satisfied are you with your physical environment (e.g., pollution, climate, noise, attractiveness)?

F22.4 (F27.2.3): How satisfied are you with the climate of the place where you live?

F23.1 (F28.1.2): To what extent do you have adequate means of transport?

F23.2 (F28.1.4): To what extent do you have problems with transport?

F23.3 (F28.2.2): How satisfied are you with your transport?


F23.4 (F28.2.3): How much do difficulties with transport restrict your life?

References

- Alcoholics Anonymous World Services. (1939/2001). *Alcoholics Anonymous: The story of how many thousands of men and women have recovered from alcoholism*, 4th ed. New York: Alcoholics Anonymous World Services Inc.
- American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders*, 4th ed. Text Revision. Washington, DC: Author.
- American Psychiatric Association – Committee on Public and Community Psychiatry. (2005). *Use of the concept of recovery: Position statement*. Approved July 2005. <http://www.psych.org>.
- Anthony, W., Gagne, C., & White, W. (2007). Recovery: A common vision for the fields of mental health and addictions.
- Breslow. (2006). Health measurement in the third era of health. *American Journal of Public Health*, 96, 17–19.
- Borkman, T., Kaskutas, L., Room, J., & Ma, L. (1998). An historical and developmental analysis of social model programs. *Journal of Substance Abuse Treatment*, 27, 123–134.

- Centers for Disease Control and Prevention, & Lance Armstrong Foundation. (2004). A national action plan for cancer survivorship: Advancing public health strategies. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Available at: www.cdc.gov/cancer/survivorship/what_cdc_is_doing.
- Cheever, S. (2004). *My name is Bill: Bill Wilson—His life and the creation of Alcoholics Anonymous*. New York: Simon & Schuster.
- Danaei, G., VanderHooft, S., Lopez, A. D., Murray, C. D. L., & Ezzati, M. (2005). Causes of cancer in the world: Comparative risk assessment of nine behavioral risk factors. *Lancet*, 336, 1785–1793.
- Deegan, P. E. (1988). Recovery: The lived experience of rehabilitation. *Psychosocial Rehabilitation Journal*, 11, 11–19.
- De Leon, G. (2000). *The therapeutic community: Theory, model and methods*. New York: Springer Publishing.
- Dennis, M. L., Scott, C. K., Funk, R., & Foss, M. A. (2005). The duration and correlates of addiction and treatment careers. *Journal of Substance Abuse Treatment*, 28(Suppl 1), S51–S62.
- Department of Health and Human Services (2003). *Achieving the promise: Transforming mental health care in America*. Rockville, MD: Substance Abuse and Mental Health Services Administration.
- Flynn, P. M., Joe, G. W., Broome, K. M., & Simpson, D. D. (2003). Looking back on cocaine dependence: Reasons for recovery. *American Journal on Addictions*, 12, 398–411.
- Galanter, M. (1997). Spiritual recovery movements and contemporary medical care. *Psychiatry*, 60, 211–223.
- Grant, B. F., Hasin, D. S., Chou, P., Stinson, F. S., & Dawson, D. A. (2005). Nicotine dependence and psychiatric disorders in the United States. *Archives of General Psychiatry*, 61, 1107–1115.
- Healthy People 2010 – Volume 1. U.S. Department of Health and Human Services Pub. 2000. <http://www.healthypeople.gov/>.
- Humphreys, K., Wing, S., McCarty, B., Chappel, J., Gallant, L., Haberle, B., et al. (2004). Self-help organizations for alcohol and drug problems: Toward evidence-based practice and policy. *Journal of Substance Abuse Treatment*, 26, 151–158.
- Institute of Medicine. (2006). *Improving the quality of health care for mental and substance-use conditions*. Washington, DC: The National Academies Press.
- Kurtz, E. (1979). *Not God—A history of Alcoholics Anonymous*. Center City, MN: Hazelden.
- Laudet, A. (2007). What does recovery mean to you? Lessons from the recovery experience for research and practice. *Journal of Substance Abuse Treatment*, 33, 243–256.
- Laudet, A., Morgen, K., & White, W. (2006). The role of social supports, spirituality, religiousness, life meaning and affiliation with 12-step fellowships in quality of life satisfaction among individuals in recovery from alcohol and drug use. *Alcoholism Treatment Quarterly*, 24, 33–73.
- McLellan, A. T., & Weisner, C. (1996). Achieving the public health potential of substance abuse treatment: Implications for patient referral and outcome evaluation. In W. Bickel, & R. DeGrandpre (Eds.), *Drug policy and human nature* (pp. 296–324). Philadelphia: Wilkins and Wilkins.
- Moos, R. H., & Moos, B. S. (2006). Rates and predictors of relapse after natural and treated remission from alcohol use disorders. *Addiction*, 101, 212–222.
- Murphy, B., Herrman, H., Hawthorne, G., Pinzone, T., & Evert, H. (2000). Australian WHOQOL instruments: User's manual and interpretation guide. Melbourne, Australia: Australian WHOQOL Field Study Centre.
- Murphy, S., & Irwin, J. (1992). "Living with the dirty secret": Problems of disclosure for methadone maintenance clients. *Journal of Psychoactive Drugs*, 24, 257–264.
- Reeve, B. B. (2007). Special issues for building computerized-adaptive tests for measuring patient-reported outcomes: The NIH's investment in new technology. *Medical Care* (See also <http://www.nihpromis.org/>).
- Reis, L. A., Eisner, M. P., Kosary, C. L., et al. (Eds.). (2003). *SEER cancer statistics review, 1975–2000*. (pp. 233–256). Bethesda, MD: National Cancer Institute.
- Rosner, S. A., & Stamfer, M. J. (2006). The heart-breaking news about tobacco: It's all bad. *Lancet*, 368, 621–622.
- Rowland, J. H. (2004). What's in a name: Who is a cancer survivor? *Journal of the National Cancer Institute*, 96, 1414–1415.
- Rychtarik, R. G., Connors, G. J., Dermen, K. H., & Stasiewicz, P. R. (2000). Alcoholics Anonymous and the use of medications to prevent relapse: An anonymous survey of member attitudes. *Journal of Studies on Alcohol*, 61, 134–138.
- Scott, C. K., Foss, M. A., & Dennis, M. L. (2005). Pathways in the relapse-treatment-recovery cycle over 3 years. *Journal of Substance Abuse Treatment*, 28, S63–S72.
- Simpson, D. D. (2004). A conceptual framework for drug treatment process and outcomes. *Journal of Substance Abuse Treatment*, 27, 99–121.
- Skevington, S. M., Lotfy, M., & O'Connell, K. (2004). The World Health Organization's WHOQOL-BREF quality of life assessment: Psychometric properties and results of the international field trial. A report from the WHOQOL Group. *Quality of Life Research*, 13, 299–310.
- Sobell, L., Ellingstad, G., & Sobell, M. (2000). Natural recovery from alcohol and drug problems: Methodological review of the research with suggestions for future directions. *Addiction*, 95, 749–764.
- Tiebout, H. (1953, September). Surrender versus compliance in therapy. *Grapevine*, 10, 3–8.
- Ware, N. C., Hopper, K., Tugenber, T., Dickey, B., & Fisher, D. (2007, April). Connectedness and citizenship: Redefining social integration. *Psychiatric Services*, 58, 27–38.
- White, W. (2006). Let's go make some history: Chronicles of the new addiction recovery advocacy movement. Washington, DC: Johnson Institute and Faces and Voices of Recovery.
- White, W. (2007). Addiction recovery: Its definition and conceptual boundaries. *Journal of Substance Abuse Treatment*, 33, 229–241.
- White, W., & Coon, B. (2003). Methadone and the anti-medication bias in addiction treatment. *Counselor*, 4, 58–63.
- WHO-QOL Group. (1995). The World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organization. *Social Science & Medicine*, 41, 1403–1409.
- WHO-QOL Group. (1998a). The World Health Organization Quality of Life assessment (WHOQOL): Development and general psychometric properties. *Social Science & Medicine*, 46, 1569–1585.
- WHO-QOL Group. (1998b). Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychological Medicine*, 28, 551–558.
- World Health Organization (1985). Basic documents, 35th ed. Geneva, Switzerland: WHO.

Buprenorphine Treatment for Opioid Use Disorder in Community-Based Settings: Outcome Related to Intensity of Services and Urine Drug Test Results

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Background and Objectives: Variables contributing to the outcome of buprenorphine treatment for opiate use disorder have been studied, including patient characteristics and the treatment approach applied. It is also valuable to study the types of clinical facilities that can affect outcome.

Methods: We evaluated patients (N = 20 993) in 573 facilities where buprenorphine was prescribed. Urine drug test results were analyzed for those (N = 13 281) who had buprenorphine prescribed at least twice in the period January 2015 through June 2017. Facilities were divided into three categories: medication management (MM) only, limited psychosocial (LP) therapy, and recovery-oriented (with more extensive counseling and a 12-step orientation) (RO).

Results: Urine drug tests negative for other opioids at the time of the second buprenorphine prescription were 34% for MM, 56% for LP, and 62% for RO ($P < .001$). A comparison was made between the most recent and the established patients at the facilities. The decrement in urinalyses positive for other opioids in this latter comparison was 3% for MM, 7% for LP, and 23% for RO ($P < .001$).

Discussion and Conclusions: In a large sample of community settings, buprenorphine patients' urinalyses positive for opioids can vary considerably across treatment facilities, and more intensive recovery orientation may yield a better outcome in terms of secondary opioid use.

Scientific Significance: The majority of buprenorphine patients are treated in community facilities. It is important that research be done by facility type in such settings in order to plan for optimal treatment. (© 2020 The Authors. *The American Journal on Addictions* published by Wiley Periodicals, Inc.;00:00–00)

INTRODUCTION

Studies have been published on how the outcome of buprenorphine-based medication-assisted treatment can vary in relation to settings for treatment, such as individual private offices¹; health maintenance organizations²; and home induction.³ When psychosocial adjunctive treatments are applied, such as group counseling and cognitive behavioral therapy,⁴ outcomes may vary as well. The effectiveness of buprenorphine treatment has also been studied in terms of prescriptions for secondary opioids both before and after treatment.⁵

Another option for evaluating outcome in the assessment of misuse of other opioids when buprenorphine is prescribed is the examination of the results of urine drug testing during treatment, and this can be done relative to different community-based programs. We present data here on urinalyses for ongoing opioid use among buprenorphine patients in a large sample of community-based facilities, relative to the nature of the adjunctive counseling provided.

MATERIALS AND METHODS

Data Source

Dominion Diagnostics, LLC, of North Kingstown, RI, is a national toxicology laboratory serving treatment programs and practitioners in 41 US states, specializing in the treatment of substance use disorders and pain management. The institutional review board of Dominion Diagnostics reviewed and approved the use of anonymized urine drug test data for this outcome study without the approval of the original patients. Informed consent of patients was therefore not required. Urine drug testing data are maintained in a database that contains clinical information related to patients' adherence to the prescribed treatment. Laboratory results are

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combined with clinical information obtained at the time of urine collection. Prior to the analysis for this study, the data from the records studied were de-identified and anonymized. Anonymized results were then analyzed for those patients (N = 20 993) who had buprenorphine prescribed during the calendar year 2015. All data, including laboratory results and clinical information, were fully anonymized prior to being accessed by any of the authors of this study.

Inclusion Criteria

Facilities (N = 573) where buprenorphine was prescribed for the treatment of opioid use disorder were studied. The number of patients in the settings where treatment was carried out is given in Table 1. The treatment approach in the facilities selected was characterized on the basis of clinical descriptions given by facilities' staff and on reports of on-site visits by the laboratory's clinical staff at each respective facility. These reports are then reviewed with the laboratory's clinical research staff.

The facilities studied were then divided into three categories defined by the laboratory's clinical research staff, headed by two of the authors (MH and JF). This allows for determining the relative role of counseling in three facility types. The three facility types are: (a) medication management (MM) facilities (138 facilities and 6103 patients) where buprenorphine is prescribed with periodic medication checks, but without an onsite counseling program; (b) limited psychosocial (LP) facilities (9 facilities and 2557 patients), where case management is limited to periodic individual counseling sessions; (c) and recovery-oriented (RO) facilities (109 facilities and 11 589 patients), with case management, and individual therapy takes place along with more extensive counseling (such as family and group treatment), and an orientation towards 12-step referral. The two facility types not included in this study were, therefore, (a) those solely conducting opioid detoxification (5 facilities and 244 patients), and (b) those prescribing medications upon referral from other facilities where counseling was carried out (8 facilities and 586 patients). This study was therefore undertaken to ascertain the association between three facility types, MM, LP, and RO, and urinalyses of the patients treated there.

Data Analysis

The SPSS-V.24 statistical software program was applied to conduct analyses (SPSS, IBM Corporation, Armonk, NY, USA). Descriptive statistics were generated. Group mean differences for continuous outcomes were examined using an analysis of variance and Tukey HSD post hoc test where appropriate. Group differences for categorical outcomes were assessed by the χ^2 statistic.

Analyses Conducted

Patients from each of the three facility types who were prescribed buprenorphine during the calendar year 2015 were studied. Those patients who had buprenorphine prescribed during that calendar year and a second buprenorphine prescription prior to July 1, 2017 (N = 13 281) were subjects for analysis. The period between the first and second prescription for those patients with two buprenorphine prescriptions during the above period was designated as a buprenorphine episode (BE), and results of their urinalyses at the time of the second buprenorphine prescription were analyzed for secondary opioids. This was done in order to ascertain the relationship between a BE and secondary opioid use. Secondary opioids, as the term is applied here, are ones other than the prescribed buprenorphine that were detected on the urinalyses; they reflect ingestion of opioids other than the prescribed buprenorphine at the time that the second prescribed buprenorphine of the BE was detected in the urine. Analysis was also done on the interval between the first and second prescription for buprenorphine of the BE. Urinalyses of patients who had only one buprenorphine prescription in the facilities between January 1, 2015 and July 1, 2017 (N = 7248) were not studied.

Analysis of Secondary Opioid Use

For patients who had a BE (ie, a second buprenorphine prescribed before July 1, 2017), the urine drug tests at the time of the second buprenorphine prescription were studied. They were analyzed for the presence of any other opioids, namely codeine, fentanyl, heroin metabolite, hydrocodone, hydromorphone, methadone, methadone metabolite, morphine, norbuprenorphine, norcodeine, norfentanyl, norhydrocodone, noroxycodone, norpropoxyphene, o-desmethyiltramadol,

TABLE 1. Comparison of urine drug test rates positive for other opioids stratified by any urine drug test prior to the buprenorphine episode

	None		≥ 1		χ^2	Cohen's <i>h</i>
	<i>N</i>	% (+)	<i>N</i>	% (+)		
Medication management only	1587	68	1116	64	4.916*	0.08
Limited psychosocial	394	45	351	42	1.158	0.06
Recovery oriented	1782	42	1063	32	77.756***	0.21
Total	4101	53	2574	44	107.531***	0.18

Cohen's *h* is interpreted as follows: small effect = 0.20 to 0.49; medium effect = 0.50 to 0.79; and large effect = 0.80 or greater.

P* < .05, **P* < .001.

oxycodone, oxymorphone, or tramadol (nubuprenorphine was not included here as a secondary opioid).

Urine testing was performed at the diagnostic laboratory by quantitative immuno-assay and confirmatory analysis by liquid chromatography dual mass spectroscopy (LCMSMS). It was not done at the point of contact. A patient who had other opioids detected in the second buprenorphine prescription was designated as opioid-positive. These other opioids may have been prescribed by a different physician or may represent illicitly obtained opioids. If no other opioids were detected in the urine at the time of the second buprenorphine, the patient was designated as opioid-negative.

Further analyses were done on the patients with a BE (ie, had a second buprenorphine prescription). The mean period of time from their first urine drug test conducted at the facility to their first buprenorphine prescription in 2015 was calculated, serving as a proxy for duration of prior contact with the facility. These findings may clarify whether there is a benefit relative to the likelihood of abstinence from secondary opioids for patients with engagement in any one of the three facility types. This was done to ascertain whether negative urines during the BE were more likely if a patient had prior treatment at the respective facility (ie, MM, LP, or RO).

The patients were then divided into three groups by facility type, MM, LP, and RO. The portion of urine drug tests positive for opioids at the time of their second buprenorphine prescription was calculated for patients in the three respective facility types. For each facility type, a calculation was then made comparing the portion of urine drug tests positive for opioids at the time of the second buprenorphine prescription, comparing those patients who had no previous urine drug tests

reported to those who had prior urine drug tests done (an estimation of new vs established patients). This served as a proxy for estimating the relative impact of prior experience at the respective facilities on changes in opioid positivity. The duration of patients' activity at the facility was estimated as the period between the first urine drug test they ever had at the facility up to the first buprenorphine prescription of their BE. This served as a proxy for how long they had been active in their respective facility.

RESULTS

As indicated in Figure 1, there were 20 993 patients who had buprenorphine prescribed in the calendar year 2015. The mean duration of time from their first urine drug tests at the facility to the buprenorphine prescribed of their BE was 7.36 (SD, 16.26) months, indicating a proxy for the average length of contact with the facility prior to the 2015 buprenorphine prescription; this indicated that many patients were not new to the clinic at the time of their BE. The mean time between the first and second buprenorphines of the BEs was 1.47 (SD, 2.97) months.

Patients who had a second buprenorphine prescription prior to July 1, 2017, were 4088 (68%) of MM patients, 1706 (67%) of LP patients, and 7487 (65%) of RO patients, indicating that the three program types had similar portions of patients studied who had a BE. The mean portion of urine drug tests negative for other opioids where the second buprenorphine was prescribed was calculated. Altogether, 34% (N = 1345) of the samples were negative for MM

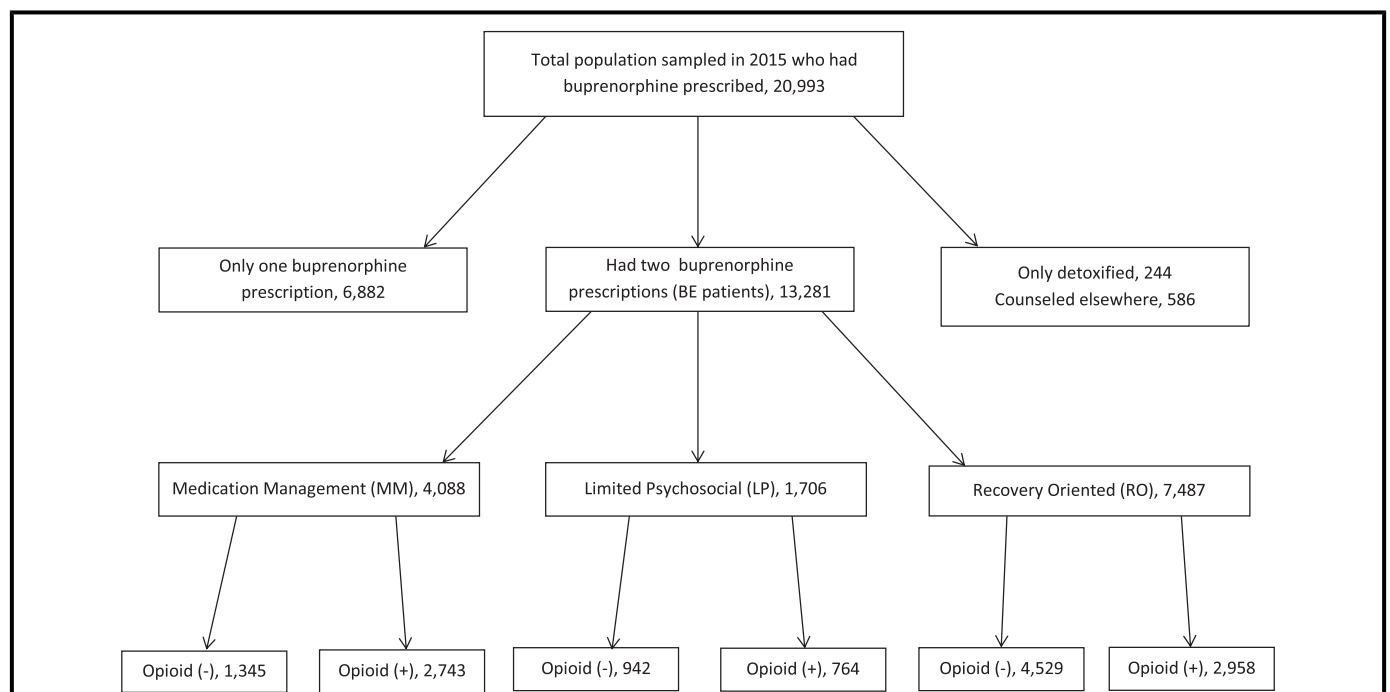


FIGURE 1. Patients who had a urine toxicology positive for buprenorphine. BE = buprenorphine episode.

TABLE 2. Patients studied who had a buprenorphine positive urinalysis in 2015

Characteristics	Medication management (MM) ^a	Limited psychosocial (LP) ^b	Recovery oriented (RO) ^c	χ^2/F	P value	Cohen's <i>h/d</i>			
						MM vs LP	LP vs RO	MM vs RO	
New at first buprenorphine screen									
With buprenorphine episode	1738 (42.5%)	829 (48.6%)	3281 (43.8%)	18.35	<.001	-0.12	0.1	-0.03	
Without buprenorphine episode	698 (36.2%)	319 (37.5%)	1035 (25.2%)	102.5	<.001	-0.03	0.27	0.24	

^a $\chi^2 = 21.8$; $P < .001$; Cohen's $h = 0.13$.
^b $\chi^2 = 28.32$; $P < .001$; Cohen's $h = 0.22$.
^c $\chi^2 = 391.89$; $P < .001$; Cohen's $h = 0.39$.

facilities, 56% (N=961) for LP facilities, and 62% (N=4642) for RO facilities ($X^2 = 849.55$, $P < .001$). A post hoc analysis revealed that there was a significant difference between LP and RO, $X^2(1) = 18.77$, $P < .001$, indicating that RO programs had the highest portion of patients who had urine drug tests free of opiates at the time of the second toxicology of the BE.

As indicated in Table 1, a comparison was made between patients who had no previous urine drug test at the facility at the time of the first buprenorphine prescription to those who previously had a urinalysis performed. During that time, some patients may have had buprenorphine prescribed before their BE was initiated in 2015, while others may not have had buprenorphine prescribed prior to that period. The facilities for which there was a difference in secondary opioid use between those patients with prior urine drug tests and those with none were the RO facilities (42%-32%, a 24% difference) compared with MM (68%-64%, a 6% difference) and LP (45%-42%, a 7% difference). The decrease in urinalyses positive for secondary opioids during the interval from the period before the BE to the first buprenorphine of the BE period itself was measured. Patients in RO facilities showed a greater decrease than the MM and LP facility types in secondary opioids during this interval. This suggests that RO patients may improve more than the MM and LP patients from their first appearance at the facilities. Table 2 gives a comparison for MM, LP, and RO of patients with and without a BE for their recency of arrival at the respective facilities. It includes statistical comparisons both across and (within the footnotes) within the three facilities. The former facilities typically include increased counseling involvement with an orientation toward a 12-step-based recovery.

DISCUSSION

The relative adherence by patients to pharmacotherapeutic regimens is an issue of concern broadly in medical practice.⁶ One report published by the World Health Organization provided an estimate that adherence rates in developed countries to pharmacotherapies overall averaged only about 50%.⁷ Causes for poor adherence may include patient-related factors, such as lack of motivation, inadequate involvement in the treatment decision-making process,⁸ and, in the case of opioid treatment, it may be even more compromised. Doctor-patient communication can be compromised by denial of illness.⁹

The marked increase in opioid-related deaths in recent years has led to an appreciation of the need for medication-assisted treatment (MAT).¹⁰ When buprenorphine was approved for the treatment of opioid use disorders in 2000, it was stipulated that practitioners should have the capacity to refer patients for appropriate counseling.¹¹ Federal guidelines posited that patients should have "reasonable access" to counselors to receive counseling services.¹¹ More specifically, This points to the presumed importance of the availability of attendant

counseling to stabilize the recovery of opioid-dependent patients. This also relates to avoiding misuse of secondary opioids during ongoing buprenorphine treatment.

The outcome of buprenorphine treatment can vary depending on factors apparently independent of counseling services. In one report, the outcome of short-term buprenorphine treatment (16 weeks) with MM alone yielded a better outcome for patients with prescription opioid misuse if they had no history of concomitant heroin use than if they had used heroin as well.¹² A difference is also observed when different buprenorphine preparations were compared; adding of naloxone to buprenorphine resulted in less likelihood of patients injecting or diverting the buprenorphine.¹³ Additionally, patients given buprenorphine implants were found to have less frequent secondary opioid use.¹⁴

There may be limitations in the degree to which added counseling can yield an increment of improvement. Feillin et al¹⁵ reported that over a period of 6 months of treatment, once weekly buprenorphine dispensing along with manualized medical management was found to be as effective as more frequent dispensing or extended weekly counseling. Furthermore, inferences based on unobserved home induction onto buprenorphine have been found to be problematic, as randomization of patients either to other treatments, the intensity of psychosocial services or patient characteristics were not preformed.¹⁶ Weiss et al¹⁷ found that adding counseling to medical management in a 12-week maintenance period did not improve on the outcome of MM alone, but better outcomes were found for those patients who did attend added counseling. A lack of benefit was found with the addition of either cognitive-behavioral therapy or contingency management in a 16-week medically managed maintenance regimen.¹⁸

On the contrary, there are studies that reflect on the incremental benefit of added counseling in certain circumstances. In relation to opioid detoxification, a Cochrane review¹⁹ revealed that when psychosocial treatments were offered in addition to pharmacologic intervention, clinical outcome was improved. For longer periods of maintenance, there are some studies showing benefits in a particular format for counseling. One retrospective study found better retention when patients who were veterans were counseled in a group format rather than individually.²⁰ Additionally, when heroin addicts attended drug counseling in addition to MM, they did better than those who received MM and did not attend the sessions.²¹ One analysis of cost in care-integrated health systems by Lynch et al²² revealed that the addition of counseling to buprenorphine treatment reduced the use of medical visits and emergency services. Furthermore, improved access to counseling along with buprenorphine maintenance has been found to be useful in some settings, such as primary care.² In one study of private practice, 58% of buprenorphine patients reported receiving adjunctive counseling and 75% of the patients were judged to have a positive outcome.²³ Controlled studies on the issue of

counseling are limited in conclusive outcome. Such studies, however, do not specify the randomization or type of counseling provided. Carroll and Weiss²⁴ undertook a review of randomized controlled studies on the relative efficacy of concomitant behavioral interventions, and recommended that physicians consider a stepped care model in which patients can be initiated with relatively non-intensive treatment, with the option of increasing counseling intensity as clinically needed.

Another issue is that medically assisted treatment may not be fully accessible across clinical settings. One recent survey of administrators in privately funded substance abuse treatment organizations revealed that MAT for opioid dependence had been adopted only in 34% of drug treatment programs.¹ This is particularly relevant, since counseling services as part of MAT might become more difficult to sustain relative to the number of patients that practitioners maintain on buprenorphine at any given time, given the fact that the ceiling on buprenorphine patients in treatment by a given physician had been raised from 100 to 275. An increase in patient loads may limit the time for arranging relevant counseling. Additionally, nurse practitioners and physician assistants can now prescribe buprenorphine as well, thereby adding to the volume of patients prescribed for.

The analysis of pharmacy claims, but not patient records, by Daubresse et al⁵ drew on organized, individual-level, all payer pharmacy claims to identify incident users of buprenorphine who filled an opioid prescription during a buprenorphine treatment episode. This was done to ascertain the portion of patients who filled an opioid prescription both during (43%) and after (67%) the treatment episode. (No distinction was made as to the clinical settings where prescriptions were given.) There is, however, utility in quantifying the degree of inappropriate use of opioids, including illicit opioids, concomitant with buprenorphine use, relative to the character of community-based treatment settings. This can be useful clinically, in understanding the relative role of different levels in adjunctive counseling support for medically assisted treatment.

We are reporting on urine drug test results restricted to samples collected when the clinician had prescribed buprenorphine. Urine drug tests for all opioids can lend some clarity to the ecology of buprenorphine use in community settings. There is a literature on misuse of buprenorphine internationally, particularly when it is not combined with naloxone (to prevent self-injection).^{25,26} In the United States, use of buprenorphine to get “high” was reported in one study by 30% to 35% of patients applying for opioid treatment.²⁷ In another study, 46% of physicians certified for prescribing buprenorphine were aware of it being sold on the street.²⁸

The patients studied here are in some measure of active treatment, and the buprenorphine was prescribed by treating physicians. Additionally, involvement in treatment is likely for many of the patients. The mean interval between the two

buprenorphine urinalyses of the BE was 1.47 months, although the SD of 2.97 suggests considerable variability in frequency of the buprenorphine dosing for different community-based patients. The BEs studied were not typically ones that were for patients new to the facilities; since considerable time had passed since the very first urine drug test recorded for many of them at the respective facilities, a mean of 7.36 months. Furthermore, the fact that the patients had agreed to provide urine samples, suggests a measure of engagement. Nonetheless, it is of note, that in all three facility types, about one-third of patients did not have a second prescription for buprenorphine during the 18-month period studied, suggesting that for a significant portion of facility patients there was a lack of active, ongoing buprenorphine management, and benefit from the medication among them may be limited. The majority of patients had a significant difference across facility types as to whether urine samples were negative for other opioids, with the RO facilities showing the largest portion negative for other opioids, with the RO facilities showing the largest portion negative and the MM and LP facilities the smallest.

Table 2 shows the relative portion of patients who were new to the facilities for MM, LP, and RO. A smaller portion of RO patients without a BE was likely to be new to the facility. It is possible that RO facilities treated patients with buprenorphine sooner after arriving at the facility, that is, when they were relatively newer to the clinic. The data reported in this table also underline the significance of the sizeable number of patients who are prescribed one dose of buprenorphine without receiving a second dose within 18 months. Findings such as these also illustrate the multiplicity of variables that reflect on the difficulty of drawing inferences from community-based data. Nonetheless, the large numbers of persons being prescribed buprenorphine in the community is important. This is because it reflects the actuality of the medication's impact on the effectiveness of treatment in the diversity of treatment facilities that are currently addressing the high prevalence (colloquially, epidemic) of opioid use disorder.

There was, however, less opioid positivity among patients with previous records of urine drug tests in the facilities (ie, had previous evidence of enrollment in the facility) than ones who had no previous urine drug tests (ie, no evidence of previous enrollment in the facility). There was no difference between the longer-term and newer enrollees for the MM and LP patients (3% and 7%, respectively), but a sizable difference for the RO patients (23%). This suggests that the RO patients may receive greater benefit over time. It would therefore appear that the patients in facilities that offered the more active counseling, including those with a 12-step orientation, may be more likely to see a decline in the use of opioids after buprenorphine dosing. In an early study by Gossop et al²⁹ the frequency of 12-step attendance was associated with an enhanced outcome following inpatient opioid treatment. This is compatible with the findings of Weiss et al³⁰ in their cohort of patients dependent on

prescribed opioids in a long-term follow-up, where mutual-help group attendance was independently associated with opioid abstinence.

Limitations

Community-based data may vary considerably from findings in well-controlled studies,³¹ but the role of a medication like buprenorphine in the community may be particularly difficult to ascertain. We have attempted here to characterize the role of buprenorphine in a sample of 573 such treatment settings by employing data on urine drug tests conducted there. While useful in approximating the role of buprenorphine among patients being treated, this methodology is subject to certain limitations.

We have characterized facilities based on a description of the counseling applied. Certain data were not available, in particular, doses of buprenorphine prescribed. These may vary considerably across facilities and would bear on outcome. This would require further research in characterizing this important variable. The indications for referral to the facilities, the nature of patients' opioid use, and the socioeconomic status of patients as well were not evaluated. Other issues are important, as well, such as patient demographics, secondary psychiatric and general medical diagnoses, patients' possible attendance at other clinical settings, and misuse of other drugs.

Another limitation is the way a "buprenorphine episode" is characterized. Neither the continuity of treatment nor the possibility of an intervening period of inpatient care between the buprenorphine prescriptions were ascertained. Additionally, our data do not address the overall duration of treatment with buprenorphine, as there is a wide variability in retention rates across different studies,³² and insurance benefits can also impact on retention.³³ Future studies on community-based treatment should, therefore, best include an analysis of physician reporting and patient demographics, as has been done for general pharmacotherapies.³⁴ The indications for referral to the facilities, socioeconomic status of patients, and recovery-oriented services patients actually accessed, were not evaluated. Important, as well, is an understanding of which modalities of psychosocial treatment are most effective, and at what "dose" these should be applied. We only characterized facilities' format, rather than classifying treatment by specifics of modalities applied.

Although the recovery-oriented facilities' urine drug tests suggest a treatment outcome more positive than the ones in the MM and limited psychosocial settings, any of the above factors may be biasing any conclusive inferences regarding an apparent benefit from the enhanced availability of a 12-step orientation and the multiple modalities applied in the RO settings. It may also be that the volume of counseling is a determining factor in outcome. The RO facilities typically include a 12-step orientation, but the relative role of this approach, as opposed to more time invested in counseling was not evaluated. To date, studies of large samples of

community-based patients on opioid medication assisted treatment typically do not have access to all such patient information. This is either because of a lack of systematic recording of this clinical information in facility records, or the unreliability of facilities' data collection. This problem pertains to other studies on treatment outcome with large databases of community-based buprenorphine prescribing, for example, studies published on pharmacy records,⁵ criminal justice,³⁵ changes in the choice of formulary preparation,³⁶ and veteran samples.³⁷ The importance of further access to such information points to the need for systematic and retrievable record-keeping to facilitate further research on treatment outcome in community-based populations.

We acknowledge these limitations but present our findings here in order to introduce issues that are pertinent to community-based treatment of opioid use disorder. Facilities like those studied here represent the majority of settings that provide buprenorphine for opioid use disorder, conducted without the controls and formal protocols applied in published structured studies. Similarly, the study by Daubresse et al⁵ presents prescription data without reference to specific modalities applied. Limitations described here therefore point to other areas that need to be further evaluated for community treatment of this major public health problem.

CONCLUSION

In this study sample, it is notable that many patients (a third of those studied here) did not get a second prescription of buprenorphine from the facility at all during a follow-up period of at least 18 months, reflecting a significant deficit in the utility of the medication for long-term care in those settings. This reflects the difficulty in collecting data from all patients in this study design. However, when a second prescription is given, it appears that regimens of buprenorphine-based medication-assisted treatment with extensive counseling oriented to addiction recovery and a 12-step orientation may be associated with a more positive outcome. Nonetheless, a variety of clinical confounds bear on this observation, and these need to be studied further.

In any case, it is clear that the outcome of buprenorphine treatment can vary considerably across different clinical settings, and can vary as well, depending on the particular clinical modalities applied. This suggests that it would be valuable for research to be conducted on clinical outcome relative to the counseling practices in community-based opioid treatment facilities, not only treatment effectiveness observed in well-controlled settings. From a broader health perspective, this is also important in terms of determining the actual outcome of the buprenorphine based treatment in the population overall.

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Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

REFERENCES

1. Knudsen HK, Abraham AJ, Roman PM. Adoption and implementation of medications in addiction treatment programs. *J Addict Med*. 2011;5: 21-27.
2. Weisner C, Mertens J, Parthasarathy S, et al. Integrating primary medical care with addiction treatment: a randomized controlled trial. *JAMA*. 2001;286:1715-1723.
3. Lee JD, Nunes EV, Novo P, et al. Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicenter, open-label, randomized controlled trial. *Lancet*. 2018;391:309-318.
4. Miotto K, Hillhouse M, Donovan R, et al. Comparison of buprenorphine treatment for opioid dependence in three settings. *J Addict Med*. 2012;6:68-76.
5. Daubresse M, Saloner B, Pollack HA, et al. Non-buprenorphine opioid utilization among patients using buprenorphine. *Addiction*. 2017;112: 1045-1053.
6. Brown MT, Bussell JK. Medication adherence: WHO cares? *Mayo Clin Proc*. 2011;86:304-314.
7. Sabaté E, ed. *Adherence to Long-Term Therapies: Evidence for Action*. Geneva, Switzerland: World Health Organization; 2003.
8. Haynes RB, McDonald HP, Garg AX. Helping patients follow prescribed treatment: clinical applications. *JAMA*. 2002;288:2880-2883.
9. Williams AR, Olfson M, Galanter M. Assessing and improving clinical insight among patients "in denial". *JAMA Psychiatry*. 2015;286-297.
10. Volkow ND, Friedan TR, Hyde PS, et al. Medication-assisted therapies: tackling the opioid-overdose epidemic. *N Engl J Med*. 2014;370: 2063-2066.
11. Substance Abuse and Mental Health Services Administration (SAMHSA). Federal Guidelines for Opioid Treatment Programs. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2015.
12. Nielsen S, Hillhouse M, Mooney L, et al. Buprenorphine pharmacotherapy and behavioral treatment: comparison of outcomes among prescription opioid users, heroin users and combination users. *J Subst Abuse Treat*. 2015;48:70-76.
13. Larance B, Degenhardt L, Lintzeris N, et al. Post-marketing surveillance of buprenorphine-naloxone in Australia: diversion, injection and adherence with supervised dosing. *Drug Alcohol Depend*. 2011;118: 265-73.
14. Rosenthal RN, Ling W, Casadonte P, et al. Buprenorphine implants for treatment of opioid dependence: randomized comparison to placebo and sublingual buprenorphine/naloxone. *Addiction*. 2013;108:2141-2149.
15. Fiellin DA, Pantalon MV, Chawarski MC, et al. Counseling plus buprenorphine-naloxone maintenance therapy for opioid dependence. *N Engl J Med*. 2006;355:365-374.
16. Bhatraju EP, Grossman E, Tofighi B, et al. Public sector low threshold office-based buprenorphine treatment: outcomes at year 7. *Addict Sci Clin Pract*. 2017;12:7.
17. Weiss RD. Adjunctive counseling during brief and extended buprenorphine-naloxone treatment for prescription opioid dependence: a 2-phase randomized controlled trial. *Arch Gen Psychiatry*. 2011;68: 1238-1246.
18. Ling W, Hillhouse M, Ang A, et al. Comparison of behavioral treatment conditions in buprenorphine maintenance. *Addiction*. 2013;108:1788-1798.
19. Amato L, Minozzi S, Davoli M, et al. Psychosocial and pharmacological treatments versus pharmacological treatments for opioid detoxification. *Coch Data Syst Rev*. 2011;9:CD005031.

20. Berger R, Pulido C, Lacro J, et al. Group medication management for buprenorphine/naloxone in opioid-dependent veterans. *J Addict Med*. 2014;8:415-420.
21. Weiss RD, Griffin ML, Potter JS, et al. Who benefits from additional drug counseling among prescription opioid-dependent patients receiving buprenorphine-naloxone and standard medical management? *Drug Alcohol Depend*. 2014;140:118-122.
22. Lynch FL, McCarty D, Mertens J, et al. Costs of care for persons with opioid dependence in commercial integrated health systems. *Addict Sci Clin Pract*. 2014;9:16.
23. Finch JW, Kamien JB, Amass L. Two-year experience with buprenorphine-naloxone (suboxone) for maintenance treatment of opioid dependence within a private practice setting. *J Addict Med*. 2007;1:104-110.
24. Carroll KM, Weiss RD. The role of behavioral interventions in buprenorphine maintenance treatment: a review. *Am J Psychiatry*. 2017; 174:738-747.
25. Yokell MA, Zaller ND, Green TC, et al. Buprenorphine and buprenorphine/naloxone diversion, misuse, and illicit use: an international review. *Curr Drug Abuse Rev*. 2011;4:28-41.
26. Eiden C, Nogue E, Diot C, et al. Three complementary approaches to characterize buprenorphine misuse. *Subst Use Misuse*. 2016;51:1912-1919.
27. Cicero TJ, Surratt HL. Use and misuse of buprenorphine in the management of opioid addiction. *J Opioid Manag*. 2007;3:302-308.
28. Johanson C, Arfken CL, di Menza S, et al. Diversion and abuse of buprenorphine: findings from national surveys of treatment patients and physicians. *Drug Alcohol Depend*. 2012;120:190-195.
29. Gossop M, Stewart D, Marsden J. Attendance at narcotics anonymous and alcoholics anonymous meetings, frequency of attendance and substance use outcomes after residential treatment for drug dependence: a 5-year follow-up study. *Addiction*. 2008;103:119-125.
30. Weiss RD, Griffin ML, Marcovitz DE, et al. Correlates of opioid abstinence in a 42-month posttreatment naturalistic follow-up study of prescription opioid dependence. *J Clin Psychiatry*. 2019;80:18m12292.
31. Wang SV, Schneeweiss S, Gagne JJ, et al. Using real world data to extrapolate evidence from randomized controlled trials. *Clin Pharmacol Ther*. 2018;105:1156-1163. <https://doi.org/10.1002/cpt.1210>
32. Timko C, Schultz NR, Cucciare MA, et al. Retention in medication-assisted treatment for opiate dependence: a systematic review. *J Addict Dis*. 2016;35:22-35.
33. Saloner B, Daubresse M, Alexander GC. Patterns of buprenorphine-naloxone treatment for opioid use disorder in a multistate population. *Med Care*. 2017;55:669-676.
34. Blum K, Han D, Femino J, et al. Systematic evaluation of “compliance” to prescribed treatment medications and “abstinence” from psychoactive drug abuse in chemical dependence programs: data from the comprehensive analysis of reported drugs. *PLoS One*. 2014;9:e104275.
35. Robertson AG, Easter MM, Lin HJ, et al. Associations between pharmacotherapy for opioid dependence and clinical and criminal justice outcomes among adults with co-occurring serious mental illness. *J Subst Abuse Treat*. 2018;86:17-25.
36. Soper R, Appajosyula S, Deximo C. Decline in buprenorphine/naloxone prescriptions in a state medicaid population following formulary conversion from suboxone to buprenorphine. *Adv Ther*. 2018;35:457-466.
37. Wyse JJ, Robbins JL, McGinnis KA, et al. Predictors of timely opioid agonist treatment initiation among veterans with and without HIV. *Drug Alcohol Depend*. 2019;198:70-75.

The Effects of Psychosocial Services in Substance Abuse Treatment

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Objective.—To examine whether the addition of counseling, medical care, and psychosocial services improves the efficacy of methadone hydrochloride therapy in the rehabilitation of opiate-dependent patients.

Design.—Random assignment to one of three treatment groups for a 6-month clinical trial: (1) minimum methadone services (MMS)—methadone alone (a minimum of 60 mg/d) with no other services; (2) standard methadone services (SMS)—same dose of methadone plus counseling; or (3) enhanced methadone services (EMS)—same dose of methadone plus counseling and on-site medical/psychiatric, employment, and family therapy.

Setting.—The methadone maintenance program of the Philadelphia (Pa) Veterans Affairs Medical Center.

Subjects.—Ninety-two male intravenous opiate users in methadone maintenance treatment.

Results.—While methadone treatment alone (MMS) was associated with reductions in opiate use, 69% of these subjects had to be "protectively transferred" from the trial because of unremitting use of opiates or cocaine, or medical/psychiatric emergencies. This was significantly different from the 41% of SMS subjects and 19% of EMS subjects who met the criteria. End-of-treatment data (at 24 weeks) showed minimal improvements among the 10 MMS patients who completed the trial. The SMS group showed significantly more and larger improvements than did the MMS group; and the EMS group showed significantly better outcomes than did the SMS group. Minimum methadone services subjects who had been "protectively transferred" to standard care showed significant reductions in opiate and cocaine use within 4 weeks.

Conclusions.—Methadone alone (even in substantial doses) may only be effective for a minority of eligible patients. The addition of basic counseling was associated with major increases in efficacy; and the addition of on-site professional services was even more effective.

(*JAMA*. 1993;269:1953-1959)

WITH the rapid spread of the acquired immunodeficiency syndrome (AIDS) among intravenous drug users, public health officials have called for an expansion of treatments, particularly methadone maintenance. The weight of eval-

uation evidence indicates that the majority of opiate addicts remain in methadone maintenance treatment for a significant period (usually 1 year or more) and show important reductions in opiate use, use of other drugs such as cocaine and alcohol, and illegal activity during their treatment.¹⁻³ However, perhaps the only component of methadone maintenance treatment that has been conclusively evaluated is the dose level of the medication itself.⁴ While it is true that some patients show favorable responses at doses below 40 mg/d, it is also true that this dose level is usually less

effective than doses of 60 mg/d or more (as indicated) to achieve maximum reductions in opiate use and thereby, the attendant threat of human immunodeficiency virus infection.¹⁻⁵

While the dose of methadone is clearly an "active ingredient" in methadone maintenance treatment, questions remain regarding the efficacy and value of the support services such as medical/psychiatric care, drug abuse counseling, urine monitoring, and social work services that are commonly offered by most methadone maintenance programs and by all other forms of substance abuse treatment. Virtually none of these common "ingredients" of treatment has received rigorous evaluation,⁶⁻⁹ especially under conditions in which the methadone treatment was held at a constant and potent dose. In fact, a recent study by Yancovitz et al¹⁰ in an "interim methadone clinic" found that methadone treatment without counseling or other services produced significant reductions in opiate use compared with patients' pretreatment levels and with patients on a "wait list" comparison group.

For editorial comment
see p 1995.

If methadone treatment alone were sufficient to effect patient improvement it would be possible to remove unnecessary and expensive psychosocial services, and more patients could be medicated. At the same time, it may be that only when methadone is administered with supportive services can it achieve its potential therapeutic value. Because these are important public health policy issues, we thought that a randomized, controlled study of three levels of medical and psychosocial services, under conditions in which the dose of methadone was maintained at a proven potent level

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would be the most rigorous and direct test of the efficacy and value of these services in the treatment of opiate-dependent patients.

Three treatment groups were studied over 6 months: (1) minimum methadone services (MMS)—a minimum dose of 60 mg/d but no regular counseling and no extra services; (2) standard methadone services (SMS)—a minimum dose of 60 mg/d plus regular supervised counseling, but no extra services; and (3) enhanced methadone services (EMS)—a minimum dose of 60 mg/d plus regular counseling, plus on-site medical/psychiatric care, family therapy, and employment counseling.

METHODS

Subjects

Subjects (92 male intravenous opiate-using veterans) were drawn from patients admitted to the methadone maintenance clinic of the Philadelphia (Pa) Veterans Affairs Medical Center during 1991. The only exclusion criteria were a diagnosed need for medical or psychiatric hospitalization at the time of admission to the study, or plans for an imminent move from the Philadelphia area. The study protocol was approved by the institutional review board of the University of Pennsylvania.

Program

The methadone maintenance program of the Philadelphia Veterans Affairs Medical Center has an active census of approximately 320 opiate-dependent patients. The clinic is open from 7 AM to 6 PM Monday through Friday and from 8 AM to noon on the weekends. There is no charge for receiving methadone or other services. Urine screenings for drug detection are taken weekly on a random schedule and are observed to ensure validity. The staff consists of the medical director (a psychiatrist), two full-time physicians, a pharmacist, two nurse-practitioners, two psychologists, two social workers, a counselor supervisor, nine drug counselors, and three secretaries. A research and program evaluation staff perform intake interviews and outcome evaluations as a regular part of the program. Five of the counselors have master's degrees, two have bachelor's degrees, and the remainder have high school diplomas. Two of the counselors were formerly opiate-dependent (each with more than 10 years' sobriety). All counselors have a minimum of 5 years' counseling experience.

PROCEDURE

Orientation Week

Patients were recruited during the first week of treatment by a technician

using a standard introduction. All patients received a standard intake/orientation procedure consisting of an assessment battery, a physical examination, an AIDS information package, and a supervised period of methadone dose adjustment during the first 5 to 7 days following admission. Patients were told that the duration of the study could last as long as 6 months but could be less depending on the needs of the study and that they would return to standard treatment when the study was completed.

The initial dose of methadone was approximately 30 to 40 mg/d. The dose was subsequently adjusted upward to a minimum of 60 mg/d during the orientation week. All patients achieved the 60-mg/d dose and there were no complaints of sedation or side effects at this level. The AIDS information package consisted of two films and two pamphlets supplied by the National Institutes of Health, Bethesda, Md, followed by a 10-item quiz that the prospective subject had to pass with a score of at least 90% in order to continue. During this 5- to 7-day orientation period, no program counselor assignment was made. One counselor was responsible for providing the AIDS information, explaining the program rules, and recording the attendance and dosage, but was instructed to withhold extra services. Following the orientation period, consenting subjects were randomly assigned to one of the three interventions. All were paid \$25 for their time and effort involved in the evaluation battery.

The Interventions

All interventions were performed for 6 months, after which all subjects were referred back to standard treatment.

Minimum Methadone Services.—The MMS treatment procedure was designed to provide the lowest level of supervised care possible under current Food and Drug Administration standards. Methadone, given at 60 to 90 mg/d, was the only therapeutic component provided on a regular basis. No ancillary medications, counseling, or other professional services were provided except in emergency circumstances (see "Protective Transfer" below).

The Counselor.—The orientation counselor continued as the MMS counselor for the 6 months of the intervention. The counselor was asked to satisfy routine requests such as providing treatment verification to employers and/or probation officers and to enforce the program rules and regulations. Contacts with the patients in this group were designed to be infrequent (once per month) and usually less than 15 minutes per session.

Methadone Dose.—This initial dose of 60 mg/d was increased when either the patient requested an increase (usually due to withdrawal symptoms), or when opiate-positive urine samples were detected (pending the subject's approval). In each case the counselor recommended the dose change to the project physician, who virtually always concurred with the recommendation. This procedure for adjusting the methadone dose was exactly the same for all groups throughout the course of the study.

Take-Home Doses.—Patients were automatically eligible for up to two take-home doses per week after they had completed 4 weeks of treatment and had shown verification of employment.

Urinalysis.—Urine specimens were collected under observed conditions once each week on a random schedule. Results were not reported to either the patient or the counselor. Specimens were analyzed by an accredited laboratory using the enzyme multiplication immunoassay technique (EMIT) procedure to test for 10 drugs likely to be abused. No service or counseling contingencies for the MMS patients were based on the results of their urine tests.

Protective Transfer.—Because the MMS condition involved less care than is standard within the program and because the risks of continued intravenous drug use were considered life-threatening, there were expressed concerns regarding the ethics of conducting this study. To address these concerns we instituted a set of patient safeguards that would cause premature transfer from the project to "treatment as usual" (standard treatment) with a standard program counselor who was not involved with the project. In fact, treatment as usual was approximately equivalent to the SMS condition. Patients were not aware of this project contingency and when patients did meet criteria for protective transfer, they were told only that the project had collected all necessary data and that they would be transferred back to the standard clinic treatment. Two conditions were considered serious enough to warrant transfer from the MMS condition: (1) unremitting drug use as defined by eight consecutive opiate- or cocaine-positive urine samples during the course of the 24-week intervention, or (2) three emergency situations requiring immediate health care, as defined by the medical director (who was blind to group) and reviewed each week at the project meeting.

Subjects from either the SMS or EMS groups who met the criteria for protective transfer were recorded as such, but not removed from the study since they

were already receiving standard or enhanced levels of service.

Standard Methadone Services.—In the SMS treatment group, regular counseling sessions were required including a series of behavioral interventions contingent on the weekly random urine sample test results. No other services were provided within the program for the 6 months of the trial.

The Counselor.—The goal of counseling in both the SMS and EMS groups was to change patients' behaviors with regard to drug use, employment status, illegal activity, and family/social relations. This was more than simply policing the patient or maintaining the program rules. This type of counseling involved application of rewarding and punishing contingencies to achieve positive behavioral change. The counselors' duties with regard to the SMS patients were based on the counselor training manual that we have used in prior studies^{8,11} and on the schedule of counseling contingencies used by Stitzer et al.⁷ First, the counselor was required to monitor the patient's alcohol and other drug use through weekly urine and Breathalyzer screening results. Failure by the patient to reduce illicit drug or alcohol use resulted in suggestions (but not demands) for increases in the methadone dose (when continued opiate use was seen), and/or a requirement for additional counseling visits (when continued cocaine, alcohol, or other nonopiate drug use was observed).

During the first month of treatment the patient was required to meet once each week with the counselor. This period was used for establishing and continuing the treatment plan, further stabilizing the patient's methadone dose, and helping with the various problems that were common to most patients in treatment. In the second through sixth months of treatment, if the number of drug-positive urine test results was reduced and if the patient showed signs of positive social change (eg, reduction of criminal behavior or seeking employment), the patient could meet on a less intensive (biweekly) basis. When urinalysis results showed no decrease in drug use, the patient was asked to attend sessions twice each week or more, until the problematic behavior was reduced.

Methadone Dose.—Doses were exactly the same as in the MMS group.

Take-Home Doses.—As in the MMS treatment group, up to two take-home doses per week were available after the fourth week of treatment but were contingent on negative urine sample test results and verifiable employment.

Urinalysis.—Urinalysis was exactly

the same as in the MMS group except that these urine sample test results were reported to the counselor as the basis for most counseling contingencies.

Enhanced Methadone Services.—The EMS treatment procedure was designed to provide the highest level of care possible using the standard components of methadone and counseling plus extended on-site medical/psychiatric, employment, and family therapy services. Methadone dose, take-home doses, and urinalysis were the same as in the SMS treatment group.

The Counselor.—The counselors' duties were identical to those described under the SMS condition except that the counselors referred all patients in this group to the extra professional resources that were available within the program. These resources included a full-time psychiatrist, a half-time employment counselor, and a half-time family therapist. The psychiatrist was involved in the physical evaluations and the general medical and psychiatric care for the EMS patients as needed. The employment counselor conducted a series of workshops and group sessions designed to teach reading and prepare for a general equivalency diploma, as well as job-seeking and job-holding skills. The family therapist provided couples and family therapy toward the development of a mutually supportive life-style. These therapy sessions were available even if families and/or partners did not attend, with the idea that even the discussion of a patient's family problems would be helpful and might lead to later involvement of the families. In fact, this was the case in a significant proportion of patients. Patients were required to attend at least one session with each professional involved. Additional professional appointments were scheduled at the discretion of the particular professional and the patient.

MEASURES

Pretreatment and Posttreatment Patient Status Measures

The pretreatment and posttreatment evaluations were performed by project technicians who were independent of the treatment process. All subjects were assessed using a baseline Addiction Severity Index (ASI) during the orientation week and again at the end of treatment (at 24 weeks). The ASI is a reliable and valid interviewing instrument measuring the lifetime and recent (within the previous 30 days) status of patients in seven problem areas commonly experienced by substance abusers.¹² All patients were contacted 24 weeks after initiation of treatment, regardless of

completion; 95% were successfully reached at that point. At the end of treatment, research technicians collected urine and Breathalyzer samples and requested proof of employment (eg, a pay stub), and city, state, and federal arrest records were checked to validate patient self-reports. Subjects were paid \$20 for completing the evaluation.

During-Treatment Patient Status Measures

During-treatment patient status measures consisted of (1) urine and breath screening—all patients received weekly, random, observed urine screening via the EMIT system for 10 different drug classes. Breathalyzer evaluations of alcohol use were also performed at each urine screening and at follow-up; and (2) treatment services review (TSR)—all treatment services actually received by the patients were recorded weekly by the study technicians using a 5-minute structured interview, the TSR.¹³ This quantitative summary of the types and amounts of treatment provided measured the extent to which the three conditions were carried out in the manner intended.

RESULTS

Pretreatment Results

One hundred forty-four patients were contacted to participate in the study over the 1-year course of recruitment. Twenty-nine of these patients (20%) refused to participate, most because of perceived interference with work and/or other responsibilities. Thirteen (11%) of the remaining 115 patients were screened out during the orientation phase because of serious medical or psychiatric conditions (n=6) or failure to follow through with the initial study procedures (n=7). Thus, 102 (71%) of the 144 patients contacted completed the orientation phase of treatment, signed the informed consent form, and accepted random assignment to the three groups: 35 to MMS, 32 to SMS, and 35 to EMS.

One patient dropped out of methadone treatment in the MMS condition and two others dropped out from each of the other groups prior to 2 weeks' participation in the study. We thought that this level of participation was not meaningful and all five were dropped from the data analyses. We were unable to follow up on five additional subjects (95% contact rate). Thus, the presented data are based on 92 male veterans (32 in the MMS group, 29 in the SMS group, and 31 in the EMS group) who completed at least 2 weeks of the protocol and who were contacted at 24 weeks.

The average subject was approximate-

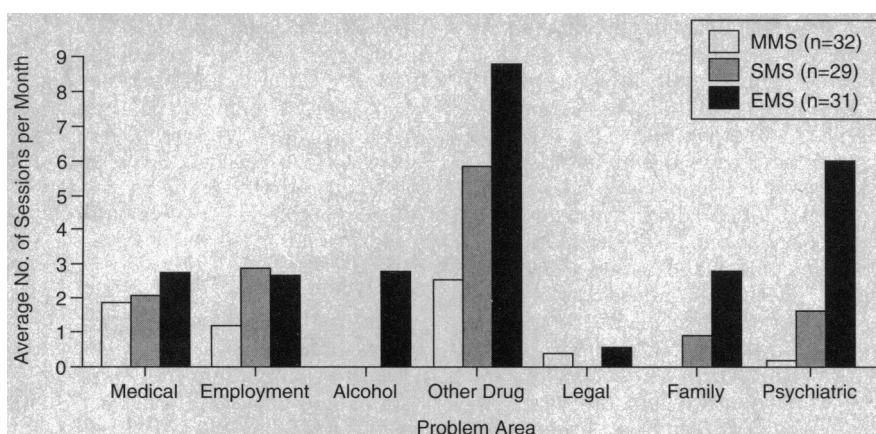


Fig 1.—Types of professional services (divided into treatment groups) and average number of discussion sessions provided to patients per month, by problem area. The treatment groups are as follows: minimum methadone services (MMS), standard methadone services (SMS), and enhanced methadone services (EMS).

ly 41 years old, black (74%), and had 12 years of education (77%). Approximately 27% were married, almost one third had never been married, and approximately one fifth were divorced. Subjects averaged 11 years of opiate use, 7 years of problematic alcohol use, and 3 years of cocaine use at the start of the study. While a majority of these patients had reasonably good employment histories, a majority also had significant criminal histories and most reported periods of serious psychiatric problems. The general demographic descriptions and prestudy histories of these patients are quite similar to those of the multisite study of methadone treatment recently completed by Ball and Ross.³

Subjects in the three groups were compared on 36 variables assessing past and recent (within the previous 30 days) status in medical, legal, family, psychiatric, and employment status as well as alcohol and other drug use patterns, and previous treatments for medical, substance abuse, and psychiatric conditions. Only three of the 36 comparisons showed statistically significant differences and there was no pattern to these differences. Thus, the random assignment procedure produced three groups that were quite similar at the start of treatment and at least generally comparable to other samples of methadone-maintained patients treated in northeastern cities.^{3,10}

During-Treatment Results

We used the TSR to summarize the professional services (eg, physician appointments, medications, and family therapy sessions) and discussion sessions (eg, counseling and education sessions and Alcoholics Anonymous/Narcotics Anonymous meetings) provided each

week in each of the seven problem areas. The TSR has shown evidence of reliability and validity¹³ and offers a general picture of the number and pattern (but not the quality) of treatment services provided to the three groups. The professional services and discussion sessions provided to each patient in each of these problem areas were totaled and averaged for each group in Fig 1 to compare actual service utilization over the course of the study. Results of multiple analysis of variance (MANOVA) indicated an overall difference among groups in total services provided (F test, 18.76; df , 6, 118; $P < .001$) and that each of the groups differed significantly from the other two ($P < .05$). Given this overall difference, we were at liberty to compare the groups in each of the specific service areas. The three groups differed significantly and in the expected direction ($P < .05$) in all but the legal area. Minimum methadone services patients received significantly fewer services than did SMS subjects ($P < .05$) in the medical, employment, drug, family, and psychiatric problem areas. Standard methadone services patients received significantly fewer services than did EMS patients ($P < .05$) in all problem areas except employment and legal.

As can be seen in Fig 1, all groups received very few services or discussion sessions in the legal area. Surprisingly, the EMS group received no more services in the employment area than did the SMS group, despite the intended addition of this intervention. Further, although the three groups did differ as intended on most of the treatment-service categories, the MMS subjects received generally more services than planned. This was generally because 90% of this group required at least one emer-

gency medical or social service at some time. In contrast, the EMS group received fewer employment and family sessions than originally planned. Reasons for this included lack of available personnel, incomplete monitoring of treatment plans, and refusal of some services by some patients. Thus, while the three groups did receive significantly different levels of psychosocial services as intended, not all services were provided in the amounts originally intended.

As discussed above, it was considered ethically, medically, and legally prudent to provide an appropriate level of services for patients who showed continuation of potentially life-threatening behaviors (eg, continued intravenous drug use) via taking the action of protective transfer. As indicated, only the MMS patients were actually transferred to standard treatment (essentially SMS services), but we recorded all patients who met the criteria. Sixty-nine percent (22 of 32 patients) of MMS subjects, 41% (12 of 29 patients) of SMS subjects, and 19% (six of 31 patients) of the EMS subjects met the protective transfer criteria. The difference in proportions was statistically significant (χ^2 , 30.31; df , 2; $P < .001$). Eighteen of the MMS patients met the termination criterion through consecutive weekly positive urine samples (the majority were for cocaine), while the remaining four patients had three or more serious medical/psychiatric emergencies requiring sustained levels of care. In fact, all of these patients required transfer within the first 12 weeks of the study. Patients in the SMS and EMS groups who met the protective transfer criteria did so exclusively through continued cocaine use.

Figure 2 presents the percentage of subjects from each group who had opiate-positive (Fig 2, top) and cocaine-positive (Fig 2, bottom) urine samples over the 24 weeks of the study. Only 3 months of data are presented for the MMS group since 69% of these subjects had terminated the intervention by that point in the study. The MMS subjects showed more cocaine and opiate use than did the other two groups ($P < .0001$) throughout the first 3 months of the study. The proportions of opiate-positive and cocaine-positive urine samples were compared between the SMS and EMS groups using repeated-measures analysis of variance (ANOVA) (across weeks). The between-group difference was only statistically significant for opiate use (F test, 5.67; df , 1, 5; $P < .05$). There was a significant reduction over weeks in the proportion of both opiate-positive and cocaine-positive urine samples for the EMS subjects ($P < .05$) but not for the SMS subjects ($P > .10$).

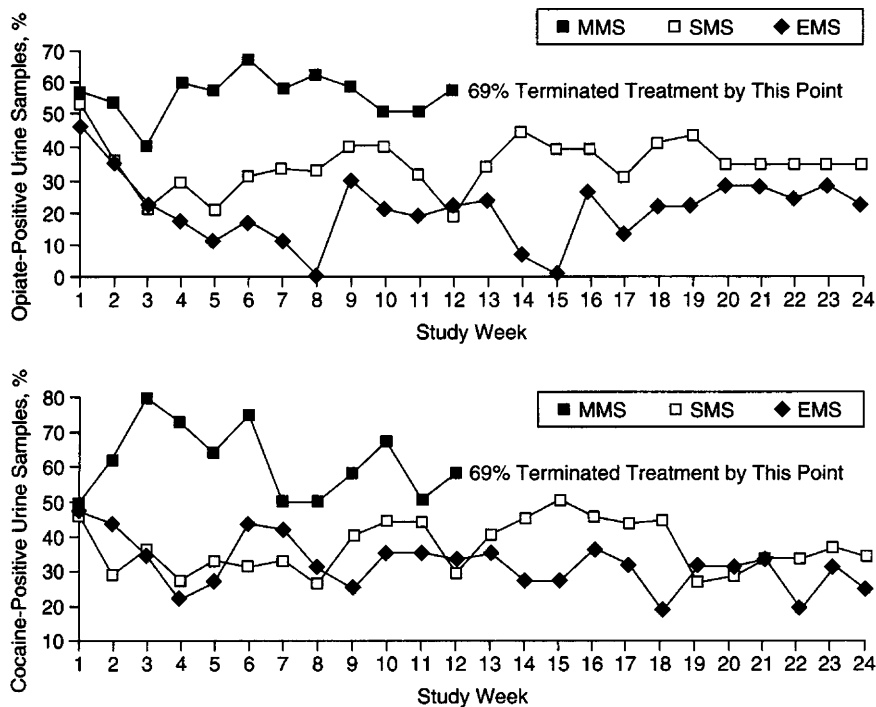


Fig 2.—Percentages of opiate-positive (top) and cocaine-positive (bottom) urine samples, per treatment group, by study week. See legend for Fig 1 for explanation of treatment groups.

Thirty-one percent of MMS patients were able to achieve 8 consecutive weeks of opiate-free urine samples, 22% were able to achieve 12 consecutive opiate-free weeks, and none was able to achieve 16 or more weeks of opiate-free urine samples. Corresponding statistics for the SMS group were 100% for 8 weeks, 59% for 12 weeks, and 28% for sixteen weeks. Data for the EMS group were 94% for 8 weeks, 74% for 12 weeks, and 55% for 16 weeks. These proportions differed significantly across groups (χ^2 , 21.18; df , 4; $P < .01$).

Similar data were also available to describe the cocaine abstinence patterns of these patients. Thirty-one percent of MMS patients achieved 8 consecutive weeks of cocaine-free urine samples, 25% had 12 consecutive cocaine-free weeks, and 22% had 16 weeks of cocaine-free urine samples. Corresponding data for the SMS group were 89% for 8 weeks, 59% for 12 weeks, and 34% for 16 weeks. Corresponding data for the EMS group were 94% for 8 weeks, 74% for 12 weeks, and 45% for 16 weeks. Again, these differences were statistically significant (χ^2 , 9.66; df , 4; $P < .05$).

End-of-Treatment Results

Addiction Severity Index composite scores were calculated in each of the seven problem areas and compared between the start of treatment and the

end of the intervention, 24 weeks later (Table). These composite scores range from 0 (no problem) to 1.00 (extreme problem) and are mathematically weighted combinations of items that give reliable, valid, and sensitive measures of problem severity during the 30 days prior to each of the assessment points.¹² Additional items from the ASI were analyzed to provide a more intuitive picture of improvement and outcome by the 6-month point. Paired Student's *t* tests were used to calculate the significance of improvements within each of the groups and analysis of covariance (ANCOVA) was used to determine if there were outcome differences at the 24-week point among the three groups, adjusting for differences in the criteria at admission. Power calculations using various examples from the ASI data indicated that within-group improvements of 12% to 15% and posttreatment between-group differences of approximately 15% to 18% (depending on the measure) could be detected at the $P < .05$ level with at least 80% power. Differences of this magnitude are considered clinically significant.

The patients who completed MMS treatment showed improvement in the drug-use factor score and a decrease in the number of days of opiate use but no significant changes in any of the other measures examined (Table). It is im-

portant to note that data in the Table for the MMS group excludes the 22 patients who were protectively transferred, since their end-of-treatment data reflect a different treatment condition than MMS. Although the small number of remaining subjects in this group and their non-representative status make their data difficult to interpret, we present the data because they are arguably the best responders from the original MMS group.

The SMS patients showed significant decreases in illegal drug use (both opiate and cocaine use) with some additional changes in alcohol, legal, family, and psychiatric problem area status measures. For example, SMS subjects showed a 79% reduction in the number of days of opiate use, a 75% reduction in the number of days of cocaine use, and a 67% reduction in the number of days of illegal activity. There were no significant improvements in medical or employment status.

The EMS patients showed significant improvement in employment status, decreases in alcohol and other drug use and illegal activity, improved family relations, and improved psychiatric status. Specifically, EMS patients showed a 30% increase in number of days of employment, a 57% decrease in cocaine use, and 67% reductions in the numbers of days of alcohol use, opiate use, illegal activity, and psychological problems.

The fact that 69% of the MMS subjects had to be transferred to standard treatment within the first 3 months of the trial required separate analyses for that group. Thus, in the last column of the Table we compare just the SMS and EMS groups. We first performed a multiple analysis of covariance (MANCOVA) across the seven ASI factor scores. The MANCOVA adjusts for baseline differences between the two groups on the criterion scores. The results showed a significant overall difference in 24-week outcomes between the two groups (*F* test, 9.76; $P < .01$), favoring the EMS group and permitting more detailed comparisons. The EMS group showed better outcomes than did the SMS group on 14 of the 21 measures (Table). Results of ANCOVA on each of the individual outcome criteria (Table) indicated significantly better outcomes ($P < .05$) among the EMS patients in the areas of employment, alcohol use, and legal status with a trend toward better status ($P < .08$) in the psychiatric area. No significant group differences ($P > .10$) were observed in the areas of medical condition, drug use, or family relations.

Posttermination Results

We continued to follow up on the 22 protectively transferred MMS patients after

Variable	Minimum Methadone Services†			Standard Methadone Services			Enhanced Methadone Services			P at 24 wk Using ANCOVA‡
	Baseline (n=10)†	P Using Student's t Test	24 wk (n=10)	Baseline (n=29)	P Using Student's t Test	24 wk (n=29)	Baseline (n=31)	P Using Student's t Test	24 wk (n=31)	
Medical factor	.315	NS§	.286	.304	NS	.320	.306	NS	.343	NS
No. of days with medical problems	8	NS	6	7	NS	8	7	NS	9	NS
Patients hospitalized by 6 mo, %	NA	NS	40	NA	NS	21	NA	NS	0	<.05
Employment factor	.685	NS	.659	.543	NS	.585	.641	NS	.549	<.05
No. of days worked in past 30 d	8	NS	10	12	NS	10	10	NS	13	<.05
Employment income, \$	360	NS	461	606	NS	552	505	NS	580	.06
Welfare income, \$	116	NS	124	84	NS	90	87	.08	63	<.05
Patients working, %	100	NS	70	55	NS	69	68	NS	77	NS
Drug factor	.300	<.05	.229	.318	<.01	.181	.339	<.01	.233	NS
No. of days of opiate use	14	<.05	3	14	<.01	3	15	<.01	5	NS
No. of days of cocaine use	4	NS	3	4	<.05	1	7	<.05	3	NS
Patients abstinent from opiates and cocaine, %	0	NS	30	0	NS	55	0	NS	68	<.05
Legal factor	.099	NS	.061	.105	.08	.094	.158	<.05	.076	<.05
No. of days on which a crime was committed	1	NS	1	3	NS	1	6	.08	2	<.05
Illegal income, \$	89	NS	15	179	<.05	39	289	<.05	28	<.05
Patients arrested by 6 mo, %	NA	NS	10	NA	NS	0	NA		0	NS
Psychiatric factor	.144	NS	.157	.199	.08	.135	.212	<.01	.113	<.05
No. of days with psychological problems	5	NS	6	7	NS	6	9	<.05	3	<.05

*Variables reflect the 30 days prior to baseline and 24-week evaluations. Factor scores vary from 0 to 1. Larger values equal greater severity. Paired Student's *t* tests were used within groups; analysis of covariance (ANCOVA) was used between groups; and χ^2 was used for percentage comparisons.

†Because only 10 subjects (31%) completed this type of treatment, interpret with caution. See "End-of-Treatment Results." Data under this column were not considered in the ANCOVA.

‡Only standard methadone services and enhanced methadone services groups were compared using ANCOVA or χ^2 . All significant differences favor enhanced methadone services.

§NS indicates not significant.

||NA indicates not applicable.

their transfer from the study, collecting the TSR data and the clinical urinalysis screening weekly throughout this period. In fact, the TSR data indicated that standard treatment was similar to the types and amount of services provided in the SMS group. After the transfer, these patients immediately received more medical attention, alcohol and other drug counseling sessions, and employment discussions than during their last month of MMS treatment. There were no appreciable changes in methadone dose following transfer, as their dose had been continuously adjusted throughout the trial in the same manner as in the other groups.

Urinalysis results from random, weekly urine screenings by the program were available on 19 of these 22 patients for 4 weeks prior to and 4 weeks following their transfer to standard treatment. Opiate use decreased from a weekly high of 69% during the month prior to transfer to 34% during the fourth week following the transfer. Similar results were seen for cocaine use, decreasing from a weekly high of 59% prior to transfer to 34% during the fourth week following transfer. These patients also reported a decrease of 10% in the number of days of alcohol use and a 25% increase in the number of days worked over the 4 weeks following the transfer. These results are

impressive considering that these patients had demonstrated at least 8 weeks of virtually continuous drug use and poor social adjustment during the first 3 months of the study.

COMMENT

Randomly assigned patients who received the same dose of methadone but also received contingency-based counseling (the SMS patients) showed more, faster, and greater improvements than did the MMS patients. The inclusion of on-site professional psychosocial services in addition to the counseling (the EMS patients) produced significantly more improvements than did the SMS in the problem areas of employment, alcohol use, criminal activity, and psychiatric status. An interesting additional finding was that those MMS patients who were protectively transferred to standard care showed significant reductions in opiate and cocaine use within 4 weeks after the transfer, and at approximately the same dose of methadone.

Qualifications to the Study Results

It is reasonable to question whether 6 months was an appropriate amount of time to study the three interventions. Based on our research,¹¹ 6-month interventions appear adequate to show be-

havioral changes in a methadone-maintenance population. In fact, there was substantial change in the SMS and EMS groups even during the first 4 weeks of the trial; and the transferred MMS patients also showed rapid improvements in the 4 weeks following their transfer.

While it is true that the concurrent provision and evaluation of the three different types of interventions by this study's staff members was complex, we felt that this would allow the most rigorous design strategy possible (prospective, random assignment) and would enable the best test of whether the different interventions could actually be applied as intended. Our experience and that of Bale and colleagues¹⁴ indicate that patients will not accept random assignment to programs outside their geographic location; thus, random assignment to different programs did not seem feasible. Further, had these interventions been tested in different programs, any differences in outcomes could have been interpreted as a failure of one of the program environments rather than a legitimate difference in the efficacy of the interventions themselves.

Although the findings from this study, which was conducted in a well-funded, stable, hospital-based, university-affiliated setting and used all male veterans

as subjects, may not generalize to other populations and settings, it was important to test the effects of the added psychosocial services in a setting in which they could actually be provided as planned.^{15,16} The demonstrated efficacy of the EMS and even the SMS groups depends on administrative and clinical conditions that are conducive to the delivery of these levels of care. We are aware of the significant range in administrative and clinical conditions among methadone and other substance abuse treatment programs.²⁻⁵ We are in the process of conducting a replication study in a community methadone program and these data will be the subject of a separate report.

Conclusions

These data offer evidence that psychosocial interventions can be measured and evaluated for scientific study in much the same manner as pharmacological or other medical interventions. Also, the provision of additional counseling, medical, and psychosocial services produced dramatic enhancements to the efficacy of treatment with methadone alone.

These findings are consistent with a growing body of work showing that those substance abuse patients who receive the most services during treatment have the best outcomes^{3,8,17-19} and that those substance abuse treatment programs that provide the most services to their clients have the best programmatic results. We have seen that specialized professional services can be particularly

cost-effective with the more severely impaired clients.^{15,16} The present data indicate that the expansion of methadone availability may be a necessary but not a sufficient medical response to the multiple problems of opiate dependence, psychiatric illness, AIDS, and other infectious diseases that make this group of individuals such a public health concern. The research of Ball and Ross³ and the data provided here argue convincingly that the quantity and quality of medical and psychosocial services in existing methadone clinics should be significantly enhanced to address the serious public health problems associated with opiate and cocaine dependence.

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References

- Cooper JR. Methadone treatment and acquired immunodeficiency syndrome. *JAMA*. 1989;262:1664-1668.
- Hubbard RL, Marsden ME, Rachal JV, Harwood HJ, Cavanaugh ER, Ginzburg HM. *Drug Abuse Treatment: A National Study of Effectiveness*. Chapel Hill, NC: University of North Carolina Press; 1989.
- Ball JC, Ross A. *The Effectiveness of Methadone Maintenance Treatment*. New York, NY: Springer-Verlag NY Inc; 1991.
- D'Aunno T, Vaughn TE. Variations in methadone treatment practices: results from a national study. *JAMA*. 1992;267:253-258.
- Newman RG. Methadone treatment: defining and evaluating success. *N Engl J Med*. 1987;317:447-450.
- Dolan MP, Black JL, Penk WE, Robinowitz R, Deford H. Predicting the outcome of contingency contracting for drug abuse. *Behav Res Ther*. 1986;17:470-474.
- Stitzer ML, Bickel WK, Bigelow GE, Liebson IA. Effect of methadone dose contingencies on urinalysis test results of polydrug-abusing methadone maintenance patients. *Drug Alcohol Depend*. 1986;18:341-348.
- McLellan AT, Woody GE, Luborsky L, O'Brien CP. Is the counselor an 'active ingredient' in substance abuse treatment? *J Nerv Ment Dis*. 1988;176:423-430.
- LoSciuto L, Aiken LS, Ausettes MA, Brown BS. Paraprofessional versus professional drug abuse counselors: attitudes and expectations of the counselors and their clients. *Int J Addict*. 1984;19:232-252.
- Yancovitz SR, Desjarlais DC, Peyser NP, et al. A randomized trial of an interim methadone clinic. *Am J Public Health*. 1991;81:1185-1191.
- Woody GE, Luborsky L, McLellan AT, et al. Psychotherapy for opiate addicts: does it help? *Arch Gen Psychiatry*. 1983;40:639-645.
- McLellan AT, Luborsky L, Cacciola J, et al. New data from the Addiction Severity Index: reliability and validity in three centers. *J Nerv Ment Dis*. 1985;173:412-423.
- McLellan AT, Alterman AI, Woody GE, Metzger D. A quantitative measure of substance abuse treatments: the treatment services review. *J Nerv Ment Dis*. 1992;180:100-109.
- Bale RN, VanStone W, Kuldau J. Therapeutic communities vs methadone maintenance. *Arch Gen Psychiatry*. 1980;37:1436-1449.
- Woody GE, McLellan AT, Luborsky L, O'Brien CP. Severity of psychiatric symptoms as a predictor of benefits from psychotherapy: the Veterans Administration-Penn Study. *Am J Psychiatry*. 1984;141:1172-1177.
- McLellan AT, Luborsky L, Woody GE, Druley KA, O'Brien CP. Predicting response to alcohol and drug abuse treatments: role of psychiatric severity. *Arch Gen Psychiatry*. 1983;40:620-625.
- Allison M, Hubbard RL. Drug abuse treatment process: a review of the literature. *Int J Addict*. 1985;20:1321-1345.
- Joe GW, Simpson DD, Hubbard RL. Unmet service needs in methadone maintenance. *Int J Addict*. 1991;26:1-22.
- McLellan AT, Luborsky L, O'Brien CP, Woody GE, Druley KA. Is treatment for substance abuse effective? *JAMA*. 1982;247:1423-1428.