Treatment: The Gold Standard, Past, Present, and Future

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Director of Research and Evaluation
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Overview

- History: Lessons from the past
- Research on effective outcomes
- Research on medication
- Future?
- Recommendations/Discussion

Bayer Heroin 1895



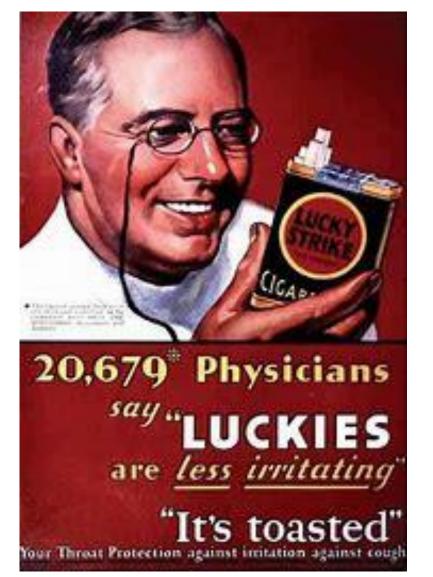


Coca Cola 1900



Cigarettes 1947





Mother's Little Helper: Valium 1966





History 1980

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients' who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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- Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
- Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

NEJM, 1980

History

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

(NEJM, 1978)

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients' who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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 Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

- A 1989 monograph for the National Institutes of Health, which asked readers to "consider the work" of Porter and Jick.
- A 1990 article in Scientific American, where it was called "an extensive study"
- A 1995 article in Canadian Family Physician, where it was called "persuasive"

JANE PORTER

- A 2001 Time magazine feature, which said that it was a "landmark study" demonstrating that the "exaggerated fear that patients would become addicted" to opiates was "basically unwarranted"
- A 2007 textbook, "<u>Complications in Regional Anesthesia and Pain Medicine</u>," which said that it was "a landmark report" that "did much to counteract" fears that pain patients treated with opioids would become addicted.

(Jacobs, 2016)

History

Pain as the Fifth Vital Sign

Pain Scale (English) Escala de Dolor (Spanish)



Oxycontin 2009

• The pain-relieving properties of opioids are unsurpassed; they are today considered the <u>"gold-standard"</u> of pain medications. p106

» Exit Wounds, American Pain Foundation

Pseudoaddiction 2017

...physicians continue to have misconceptions about opioid use including the fear of addiction (confusing addiction with physiological dependence), and fearing opioids hasten death [7]. Evidence by contrast has been shown to refute these misconception [8,9].

McDarby, Evans ad Kiernan, 2017

Opioid pseudoaddiction — an iatrogenic syndrome 1989

 "The term pseudoaddiction is introduced to describe the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."

Weissman & Haddox

Pseudoaddiction 2017

...physicians continue to have misconceptions about opioid use including the fear of addiction (confusing addiction with physiological dependence), and fearing opioids hasten death [7]. Evidence by contrast has been shown to refute these misconception [8,9].

(McDarby, Evans & Kiernan, 2017)

What About Treatment?

Why does one become addicted?

Causes
<u>Biology</u> Genes, Biochemistry, Brains, Autopilot Learning
Relationships with Others Peer Pressure, Family, "Enabling", Isolation, Lies
Relationship with Self Shame, Guilt, Negative Beliefs, "Hate Self"
Relationship with Higher Power Lack of Connection with Personal Values, Anger/Shame with God

Why does one become addicted?

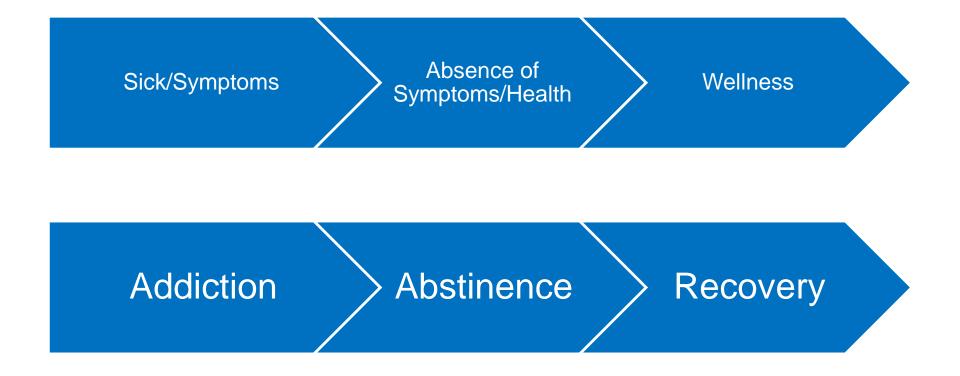
Causes	Solutions				
<u>Biology</u> Genes, Biochemistry, Brains, Autopilot Learning	Medication, Meditation Exercise, Diet, Sleep, Stress Management Decisional Actions				
Relationships with Others Peer Pressure, Family, "Enabling", Isolation, Lies	Limit Setting, Relationship Building, Honesty, Clear Communication Family/Couples Therapy Positive Peer Pressure				
Relationship with Self Shame, Guilt, Negative Beliefs, "Hate Self"	Forgive Self, Gratitude Practice Engage in Healthy Behaviors Today Healthy Coping Skills Training				
Relationship with Higher Power Lack of Connection with Personal Values, Anger/Shame with God	Define Values, Live by Personal Values Pray, Meditate, Other Spiritual Practice				

Why does one become addicted?

Causes	Tools				
<u>Biology</u> Genes, Biochemistry, Brains, Autopilot Learning	Medication				
Relationships with Others Peer Pressure, Family, "Enabling", Isolation, Lies	Family/Couples Therapy Peer Support				
Relationship with Self Shame, Guilt, Negative Beliefs, "Hate Self"	Psychosocial Therapy				
Relationship with Higher Power Lack of Connection with Personal Values, Anger/Shame with God	12-Step Meetings Religious/Spiritual Services				

Other Ancillary Tools: Employment, Housing, Other Medical Treatment

Treatment Goals



Treatment Goals

Addiction Abstinence Recovery Chemical addiction Withdrawal "Addiction" to recovery behaviors Dysfunctional Tension/ distrust/ Trust, partnership, relationships judgment in relationships respect in relationships Negative self image Lack of confidence/ Self respect doubts Questioning of values Lack of values/spiritual Knowing personal values connection and following them Motivation to seek Motivation to use/drink Motivation to stop drinking/avoid pain pleasure/ health

Treatment Goals

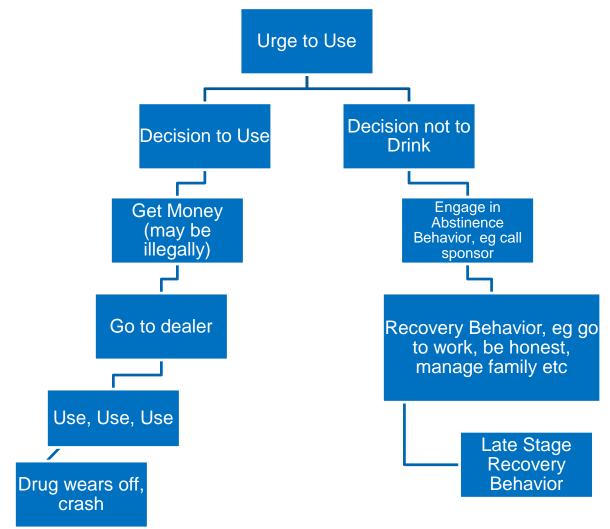
Addiction

Abstinence

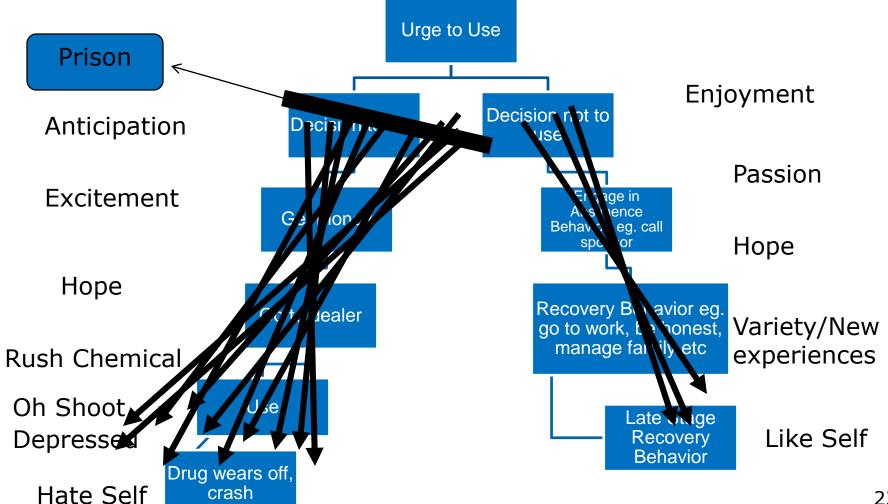
Recovery

Mental health issues	Awareness of mental health as triggers	Management/ remission of mental health issues			
Depression	Boredom, blunted emotion	Happiness, range of emotion			
Avoidance /numbing of feelings	Aware of uncomfortable feelings	Able to tolerate unpleasant feelings as they arise			
Lack of range of coping skills	Novice at identifying coping strategies	Competent at a range of coping strategies			
Unresolved trauma/grief	Aware of losses	Able to "let go" of past			
Personality disorder(s)	Aware of personal issues	Able to reduce negative impact of personality style			
Unmedicated (bipolar, ADHD etc)	Finding proper medication combination	Stable on effective 21 medication			

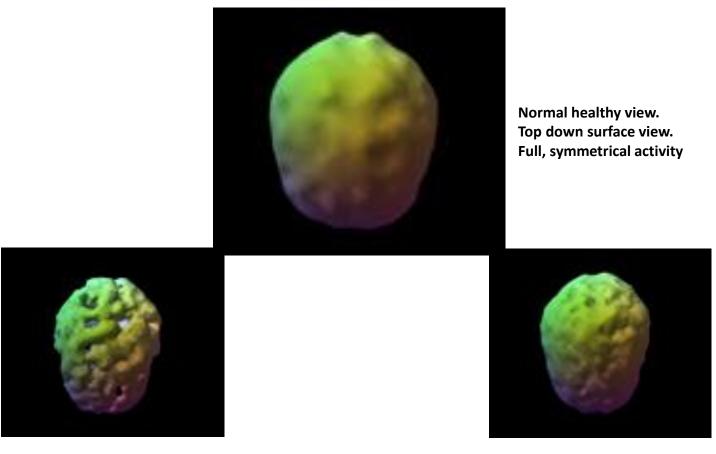
Biology Example of 2 Brain pathways



Biology Example of 2 Brain pathways



Which Brain do You Want?

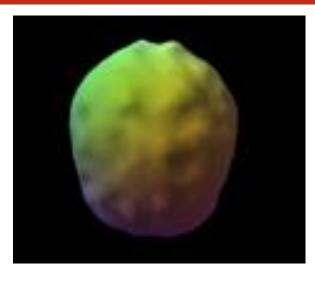


During substance abuse

One year drug and alcohol free

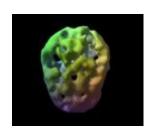
Notice the overall holes and shriveled appearance during abuse and marked improvement with abstinence.

Which Brain do You Want?



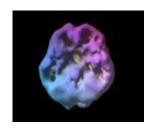
Normal healthy view. Top down surface view. Full, symmetrical activity

Effects of other substances:



abuse

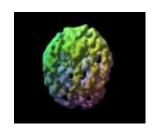
Long term alcohol



57 y/o 30 years marijuana abuse (underside view)

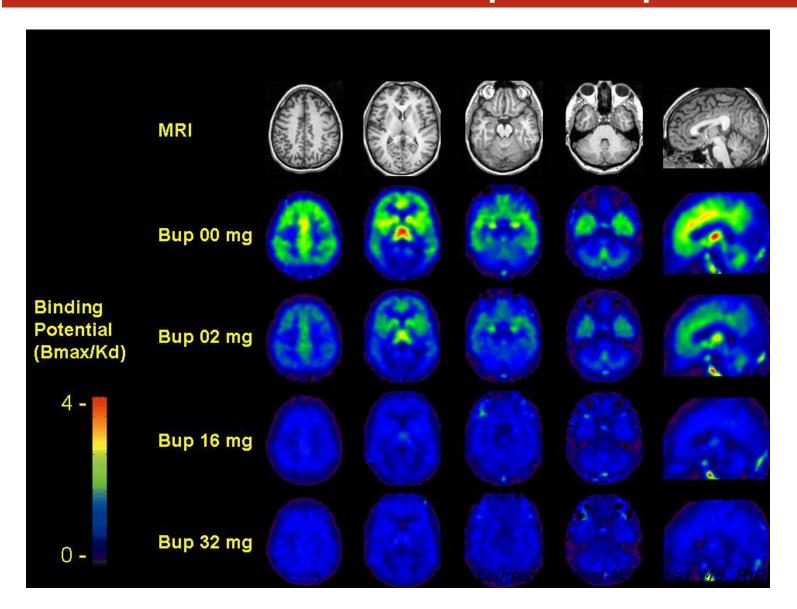


39 y/o - 25 years frequent heroin use



40 y/o, 7 years on methadone. **Heroin 10 years** prior.

Your Brain on Buprenorphine



ASAM Definition of Addiction

ASAM Definition Then	ASAM Definition Now
Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry	Addiction is a <u>treatable</u> , <u>chronic medical disease</u> <u>involving complex interactions among brain</u> <u>circuits</u> , <u>genetics</u> , <u>the environment</u> , <u>and an individual's life experiences</u> .
Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.	People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.
Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response.	
Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.	Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.
	Adopted September 15, 2019

What the Treatment Research Indicates

What (Doesn't) Work?

- Brief Therapy
- Bibliotherapy
- Drug/Alcohol Education
- Detox Only
- Psychoanalytic Therapy
- Any Single "Magic Bullet" Approach



Contents lists available at ScienceDirect

Addictive Behaviors

journal homepage: www.elsevier.com/locate/addictbeh



Residential and outpatient treatment completion for substance use disorders in the U.S.: Moderation analysis by demographics and drug of choice



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HIGHLIGHTS

- Clients in residential treatment (vs. outpatient) were 3 times more likely to complete treatment.
- Treatment completion was particularly moderated by age, race and ethnicity, and drug of choice.
- Opioid users were more likely to benefit from residential treatment than users of other substances.
- Marijuana users were less likely to benefit from residential treatment than users of other substances.

ARTICLE INFO

Article history: Received 6 August 2015 Received in revised form 23 December 2015 Accepted 14 February 2016 Available online 17 February 2016

Keywords: Treatment completion Retention Outpatient Residential Dropout

ABSTRACT

Background: This study investigates the impact of residential versus outpatient treatment setting on treatment completion, and how this impact might vary by demographic characteristics and drug of choice, using a national sample of publicly funded substance abuse programs in the United States.

Methods: This is a retrospective analysis using data extracted from the 2011 Substance Abuse and Mental Health Services Administration (SAMHSA) Treatment Episode Data Set (TEDS-D). A total of 318,924 cases were analyzed using logistic regression, fixed-effects logistic regression, and moderated fixed-effects logistic regression.

Results: Residential programs reported a 65% completion rate compared to 52% for outpatient settings. After controlling for other confounding factors, clients in residential treatment were nearly three times as likely as clients in outpatient treatment to complete treatment. The effect of residential treatment on treatment completion was not significantly moderated by gender, but it was for age, drug of choice, and race/ethnicity. Residential compared to outpatient treatment increased the likelihood of completion to a greater degree for older clients, Whites, and opioid abusers, as compared to younger clients, non-Whites, and alcohol and other substance users, respectively.

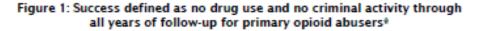
Conclusion: We speculate that for opioid abusers, as compared to abusers of other drugs, residential treatment settings provide greater protection from environmental and social triggers that may lead to relapse and non-completion of treatment. Greater use of residential treatment should be explored for opioid users in particular.

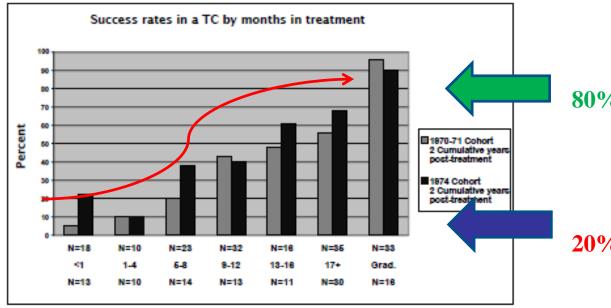
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Research Length of Stay

Almost 50 years of studies consistently find length of stay as the primary predictor of outcomes, along with intensity of treatment, for 90 days minimum and appropriate continuum of care.

1970's





Do we want:

80% success rates?

Or

20% success rates?

Research Length of Stay

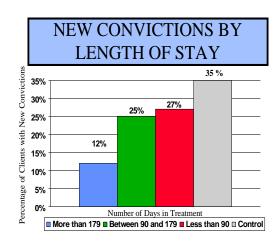
Almost 50 years of studies consistently find length of stay as the primary predictor of outcomes, along with intensity of treatment for 90 days minimum and appropriate continuum of care.

1990's

Overview of 1-Year Follow-Up Outcomes in the Drug Abuse Treatment Outcome Study (DATOS)

Robert L. Hubbard, S. Gail Craddock, Patrick M. Flynn, Jill Anderson, and Rose M. Etheridge
National Development and Research Institutes, Inc.

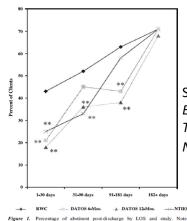
The Drug Abuse Treatment Outcome Study (DATOS) collected 1-year follow-up outcomes for 2,966 clients in outpatient methadone (OMT), long-term residential (LTR), outpatient drug-free (ODF), and short-term inpatient (STI) programs in 1991–1993. LTR, STI, and ODF clients reported 50% less weekly or daily cocaine use in the follow-up year than in the preadmission year. Reductions were greater (p < .01) for clients treated for 3 months or more. Clients still in OMT reported less weekly or daily heroin use than clients who left OMT. Multivariate analysis confirmed that 6 months or more in ODF and LTR and enrollment in OMT were associated with the reductions. Reductions of 50% in illegal activity and 10% increases in full-time employment for LTR clients were related (p < .01) to treatment stays of 6 months or longer. The results replicated findings from 1979–1981 for heroin use in OMT and illegal activity and employment for LTR but not for illegal activity in OMT and ODF.



Source: Pennsylvania Department of Corrections (1997) *Pennsylvania FIR Evaluation*

Research Length of Stay

Almost 50 years of studies consistently find length of stay as the primary predictor of outcomes, along with intensity of treatment for 90 days minimum and appropriate continuum of care.



*Difference from RWC is statistically significant at p<.01

2000's

Source: Greenfield et al, (2004). Effectiveness of Long Term Residential Treatment for Women: Findings from 3

National Studies

Source: Zhang (2002).

Does retention matter?

Treatment duration and improvement in drug use.

(4,005 clients)

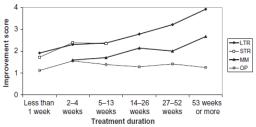


Figure I Overall improvement by treatment duration by modality

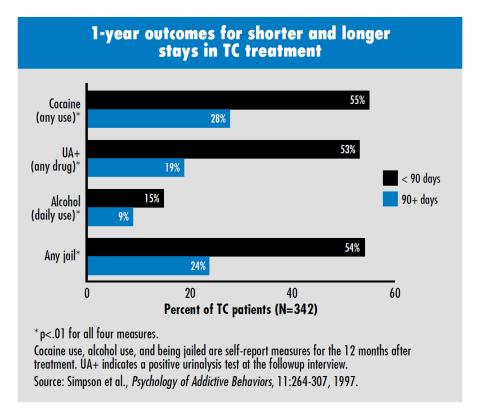
Table 2 Drug use improvement by modality and treatment duration	٦.
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	Methadone mai	done maintenance		Out-patient non-methadone		Short-term residential			Long-term residential			
Improvement	< = 3 months n = 100	>3 months n = 341	Raw P-value	< = 3 months n = 780	>3 months n = 923	Raw P-value	< = 2 weeks n = 229	>2 weeks n = 441	Raw P-value	< = 3 months n = 530	>3 months n = 653	Raw P-value
Specific drugs												
Heroin	0.59	1.12	0.0001***	0.10	0.07	0.25	0.19	0.51	0.0001***	0.11	0.26	0.0004**
Cocaine powder	0.41	0.53	0.37	0.29	0.27	0.62	0.43	0.61	0.07	0.46	0.62	0.01
Crack cocaine	0.16	0.11	0.66	0.52	0.62	0.10	0.73	0.62	0.25	0.99	1.24	0.0009**
Marijuana	0.52	0.39	0.27	0.50	0.39	0.03	0.56	0.74	0.06	0.69	0.97	0.0001***
Overall drug use	1.67	2.33	0.03	1.41	1.33	0.51	1.91	2.47	0.01*	2.24	3.07	0.0001***
Primary drug use	1.02	1.71	0.0005**	0.82	0.79	0.67	1.14	1.38	0.09	1.36	1.83	0.0001***

Significance tests (*P < 0.05, **P < 0.01, ***P < 0.001), ***P < 0.001) were conducted to test the mean difference of the improvement scores between the group with shorter treatment duration and the group with longer treatment duration, for each type of substance within each modality. For the improvements on the five the type of substances used as the components of the general drug use improvement, the significance level symbols reported in this table were adjusted with bootstrap method to control for multiple tests by means of Bootstrap through SAS PROC MULTTEST.

NIDA Research

Decades of studies consistently find length of stay as the primary predictor of outcomes, along with intensity of treatment and continuum of care.



"Therapeutic community treatment shows improvements in recidivism and relapse rates, as well as engagement in employment. These improvements are correlated to length of treatment, with highest rates of improvement among those with 9 months of treatment, and reduced effectiveness for treatment of less than 90 days."

NIDA Research

Decades of studies consistently find length of stay as the primary predictor of outcomes, along with intensity of treatment and continuum of care.

NIDA (2018) Principles of Drug Addiction Treatment

"Research indicates that most addicted individuals need at least 3 months in treatment to significantly reduce or stop their drug use and the best outcomes occur with longer durations of treatment." p. 5

"Research has shown unequivocally that good outcomes are contingent on adequate treatment length. Generally, for residential or outpatient treatment, participation for less than 90 days is of limited effectiveness, and treatment lasting significantly longer is recommended for maintaining positive outcomes. p. 14

"The best known residential treatment model is the therapeutic community (TC), with planned lengths of stay between 6 and 12 months." p. 29

Intensity and Duration of Treatment

Importance of Level of Care

- Under treating can lead to treatment resistance or increased progression of the disease
 - What happens if you take a half dose of antibiotic?
 - What happens if you take a half dose of insulin?
 - What happens if you take a half dose of treatment?

– Answer:

- It doesn't work
- Individuals get sicker
- Individuals and providers "give up" believing that there is no hope

Treatment Works: But what is treatment?

- •Treatment addresses a wide range of clinical issues that cause and exacerbate risks of substance use disorder.
 - •These include the needs for habilitation and rehabilitation, including vocational supports, addressing trauma, learning coping skills, learning relapse prevention skills, improving relationships etc.
- •This is not to be confused with supporting services such as detoxification, medications, peer supports, 12-step programs, housing and other similar approaches which complement the core treatment program.

Integration of MET, CBT and Self Help Approaches Into the TC Model					
TC Model – Phases of Treatment	MET, MI tech and CBT	12 Step and Other Self Help			
Extent of compliance with rules: "Support through evidence of use of House Tools. Completion of ITP for Phase 1. Degree of personal responsibility: a. Support through review of Individual, group notes as well as willingness to use house tools. B. have homework assignments completed Have they demonstrated an understanding of the TC concepts and Components, of Addiction, stages of change and cognitive self-change Have they demonstrated positive management of their identified self Defeating behavior pattern? Have behavioral goals been met?	MET: sessions focusing on: Stages of change, Expectations, Values (discrepancy between personal goals and behavior), Decisional balance and goal setting CBT: sessions focusing on cognitive self-change, understanding ABC and completing thinking reports MI: FRAMES approach	12-step work books -Step 1- powerlessness unmanageability -Step 2 – Insanity (acceptance of) -Step 3 – Surrender (I can't do it alone)			
Extent of compliance with rules Support through evidence of use of House tools? Have they modeled the use of the concepts of the TC community? Completion of ITP for Phase II Degree of personal responsibility – Level of sharing during community meetings Level of sharing and disclosure during therapy group Degree of leadership role in TC – Has there been successful mentoring role i.e. big brother/big sister? Has there been positive crew leadership and positive initiative?	CBT: Reviewing homework, thinking report, social skills and understanding cognitive distortions. MET: Setting a goal and preparing to change, MI: continue empathy, roll with any resistance, avoid arguments, support self-efficacy.	Step 4 – Inventory (self) Step 5 – Disclosure Step 6 – Defects (list of) Step 7 – Id shortcomings God/Spirituality`			
Extent of compliance with rules Degree of personal responsibility Completion of approved aftercare/continuity/transition plan Degree of willingness to follow the plan Degree of leadership in the TC Degree of awareness of relapse setups Completion of Transition/Discharge/Relapse plan	CBT: Role plays (repetitions, practice) problem solving. 30:30:30 MET: new ways to enjoy life, social support, review Continue MI techniques.	Step 8 – Reconciliation (List of persons we had harmed) Step 9 – Make amends (going to person when possible) Step 10 – Daily practice Keep check			
Transition to the next level of care IOP/OP services	Aftercare Outpatient CBT groups	Step 10 – Daily practice Keep check Step 11 – Spirituality Step 12 – Integration			

Gaudenzia's Evidence Based Care: A Community to Take Root and Grow

herapeutic

Community

Biology

Clinically appropriate use of medications

Recovery Management

Tools to manage triggers and urges

Trauma

Trauma informed care

Spiritual

Spiritual services

Beliefs

Address cognitive distortions

Motivation

Engage and increase motivation for success

Emotion

Addressing emotional triggers

Relationships

Group Therapy,





12-Step supports,



Gaudenzia's Evidence Based Care: A Community to Take Root and Grow

Biology

MAT, Diet, Exercise, Healthy sleep habits

Recovery Management

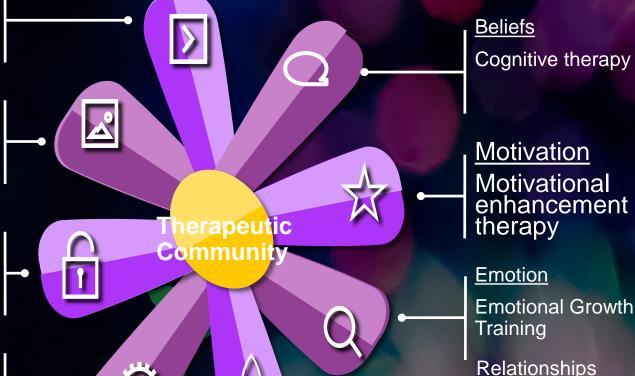
Relapse Prevention Therapy

Trauma

Trauma Reinforcement and Empowerment Model (TREM), Seeking Safety

Spiritual

12-Step supports,



Spiritual services

Group Therapy,

Peer Support



Washington State Institute for Public Policy Cost Benefit Analysis

Program name	Total benefits	<u>Costs</u>	Benefits minus costs (net present value)	Benefit to cost ratio	<u>Program name</u>	Total benefits	<u>Costs</u>	Benefits minus costs (net present value)	Benefit to cost ratio
12-Step Facilitation Therapy	\$4,697	\$320	\$5,016	n/a	Methadone maintenance treatment	\$8,531	(\$3,722)	\$4,809	\$2.29
Relapse Prevention Therapy	\$3,982	\$0	\$3,982	n/a	Buprenorphine/				
Cognitive-Behavioral	\$35,594	(\$263)	\$35,331	\$135.56	Buprenorphine-Naloxone (Suboxone and Subutex) treatment	\$6,201	(\$4,556)	\$1,646	\$1.36
Coping Skills Therapy Motivational					Peer support for substance abuse	\$3,493	(\$2,783)	\$709	\$1.25
Interviewing to enhance treatment engagement	\$6,890	(\$263)	\$6,627	\$26.17	Supportive-Expressive Psychotherapy for Substance Abuse	(\$1,587)	(\$2,015)	(\$3,602)	(\$0.79)
Seeking Safety: A Psychotherapy for Trauma/PTSD and Substance Abuse	\$9,509	(\$391)	\$9,118	\$24.29	Behavioral Self-Control Training (BSCT)	(\$12,642)	(\$156)	(\$12,798)	(\$81.03)

Therapeutic

communities for chemically dependent offenders (community) \$11,503

(\$1,562)

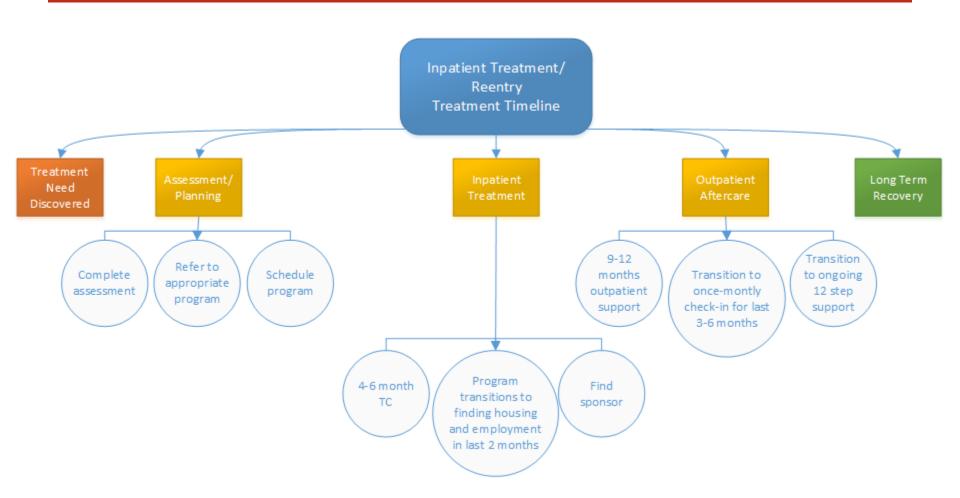
\$9,941

\$7.37

Successful Offender Reentry

A COMPREHENSIVE CONTINUUM OF CARE

Transition Timeline



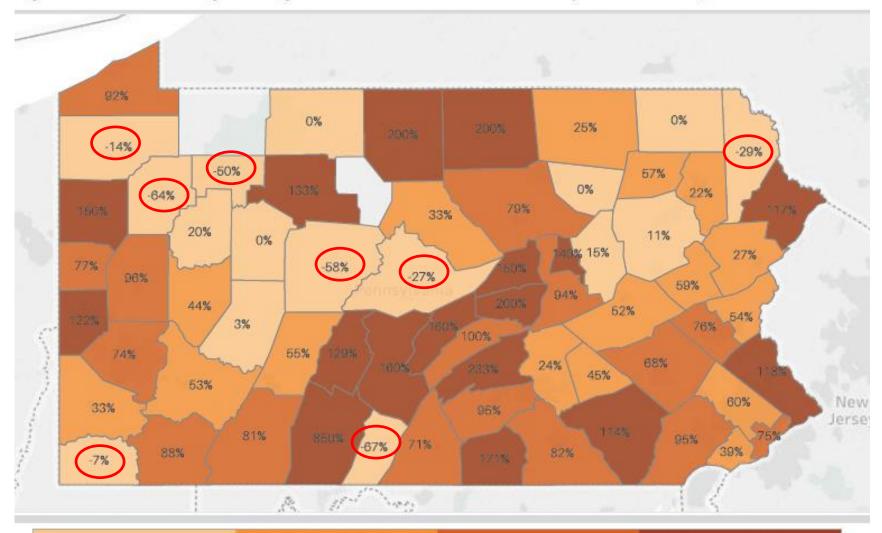
What About Medication Assisted Treatment?

Role of Medication

- Three FDA approved medications and related variations
 - Methadone
 - Buprenorphine
 - Naltrexone
- As of 2017, Medication Assisted Treatment (MAT) has been called the "gold standard" but what does this mean?
 - What works for who?
 - Duration/Dosage issues?
- In 2018, the State Opioid Response grants offered an expansion of funding for OUD treatment. It included the requirement:
 - "All grantees are required to use evidence-based MAT in patients diagnosed with OUD." (p.11)

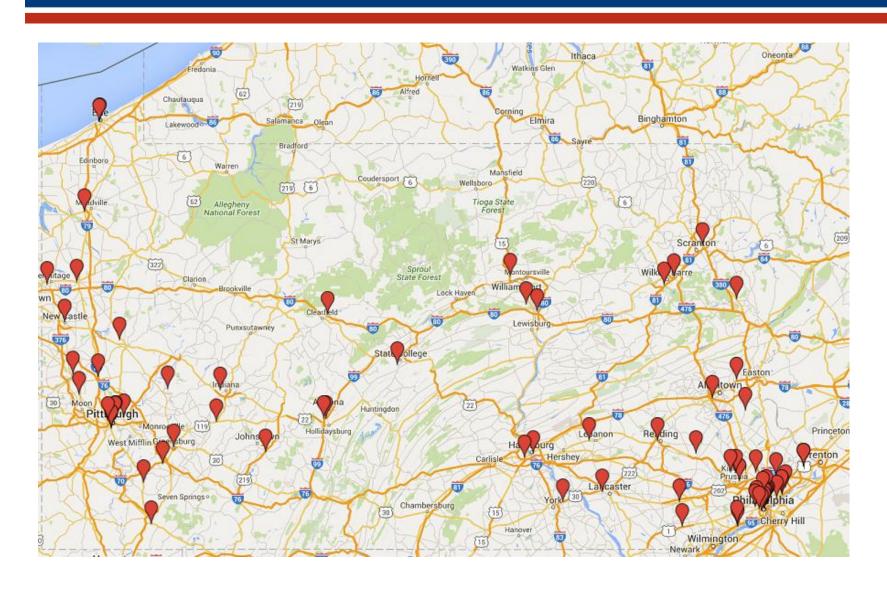
Overdose Deaths in Pennsylvania: Why are these areas improving?

Figure 21. Percent Change in Drug-Related Overdose Deaths in Pennsylvania Counties, 2015-2017



Largest % Decrease Largest % Increase

Map of NTP providers in Pennsylvania



Treatment Benefits

Table 1: Summary of Costs and Benefits Associated with Substance Abuse Treatment (Based on the Social Planner Perspective)

	All Treatment Modalities $(N=2,567)$	Methadone Maintenance (N = 115)	Outpatient Treatment $(N = 1,585)$	Residential Treatment ($N=867$)
Average cost per substance abuse treatment episode (based on weighted per diem prices) Average cost per substance abuse treatment episode (based on unweighted per diem prices) Average benefits	\$1,583 (\$1,506, \$1,660) \$3,336 (\$3,150, \$3,524) \$11,487 (\$9,784, \$13,180)	\$2,737 (\$2,460, \$3,004) \$2,867 (\$2,440, \$3,290) \$5,313 (-\$2,418, \$8,265)	\$838 (\$806, \$871) \$1,505 (\$1,443, \$1,567) \$9,049 (\$0,804, \$11,225)	\$2,791 (\$2,600, \$2,984) \$6,745 (\$6,282, \$7,215) \$16,257 (\$13,482, \$19,078)
Net benefits (benefits minus cost of treatment, based on weighted per diem prices) Cost-benefit ratio (based on weighted per diem cost estimates)	\$9,903 (\$8,205, \$11,592) 7:1	\$2,575 (-\$321,\$5,529) No statistically significant benefits	\$8,211 (\$6,028, \$10,385) 11: 1	\$13,467 (\$10,706, \$16,269) 6: 1

Note: The follow-up period is 9 months. Ninety-five percent confidence intervals (shown in parentheses) were bootstrapped using normal-based methods and 10,000 replicate samples.

Ettner, et al., 2006

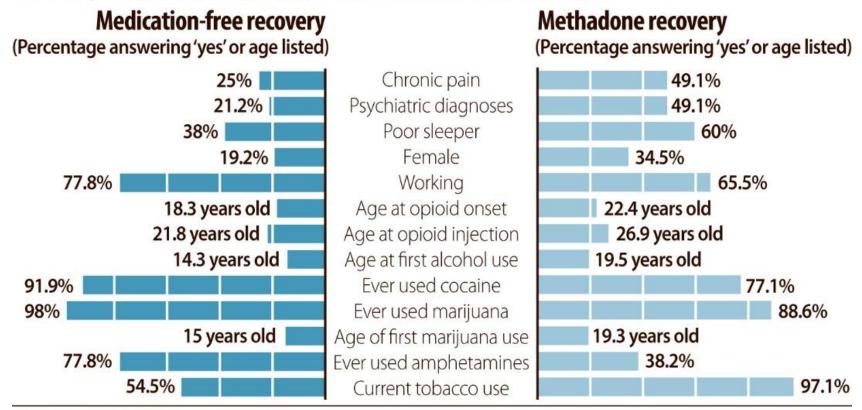
Methadone Outcomes

- In a test of equivalence, subjects randomly assigned to Therapeutic Community (TC) vs TC plus methadone found no significant differences in outcome (Sorensen, et al. 2009)
 - This means that the effective element was the psychosocial treatment, and the methadone added no additional outcome
- In a test of equivalence, at 33 month followup, 33% of those receiving residential rehabilitation were drug free as compared to 11% receiving methadone maintenance (McKeganey et al., 2006).

Methadone Outcomes

Methadone vs. medication-free opiate recovery

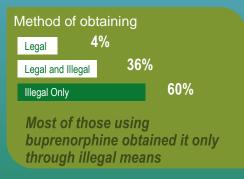
A recent Israeli study compared 10-year recovery rates among opiate addicts who used methadone versus those who went without medication. Notably, the study found longtime methadone users were more likely to report chronic pain, psychiatric conditions and poor sleep.



Experience of buprenorphine among polysubstance users

Findings from real-world conditions of 1,674 individuals...

Buprenorphine is an opioid that, like other drugs can produce effects such as pain reduction, a pleasurable "high", sleepiness, physical dependence and addiction. It has become a street trafficked drug.



2)F

25.2% reported it helped 31.5% reported no effect

Effect of buprenorphine

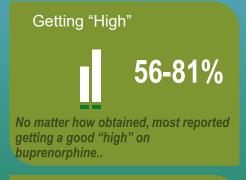
43.3% reported it made problems worse

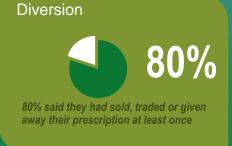
43%

Implications

1)People who report a strong history of polysubstance use may not be good candidates for buprenorphine product MAT.

2)Public policy should address buprenorphine abuse and diversion.





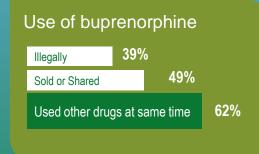
Robert Walker, TK Logan, Quintin T. Chipley & Jaime Miller (2018): Characteristics and experiences of buprenorphine-naloxone use among polysubstance users, *The American Journal of Drug and*

Alcohol Abuse, DOI: 10.1080/00952990.2018.1461876 https://www.tandfonline.com/doi/full/10.1080/00952990.2018.1461876

Edward V. Nunes (2018) "Buprenorphine in the real world: coming to terms with misuse and diversion." The American Journal of Drug and Alcohol Abuse. DOI: 10.1080/00952990.2018.1504952

Published Studies Parallel our Own Findings

Findings from survey of 256 Residential Gaudenzia clients ...



Treatment with buprenorphine



77%

- 20% reported it didn't help
- 39% received treatment with medication
- 77% reported prior MAT

Implications:

1) There is value in listening to the real world experience of those we serve.

2)Public policy should address buprenorphine abuse and diversion.

Fast Facts

- <u>2.5 Times:</u> Average number of Narcan Reversals
- <u>5 Times:</u> Average number of treatment episodes

Treatment Recommendations

Reported the most helpful approaches were:

- Long term rehabilitation
- AA/NA
- Individual/outpatient counseling
- Recommended 6 months minimum treatment time

• Twelve-year trend in treatment seeking for buprenorphine abuse in Finland (Drug and Alcohol Dependence, Uosukainen et al, 2012)

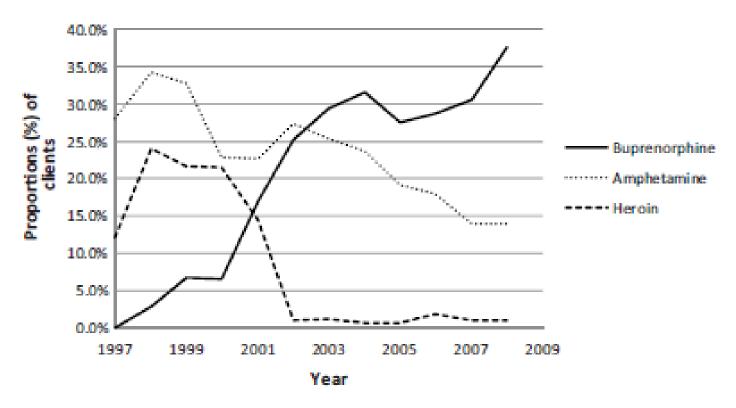
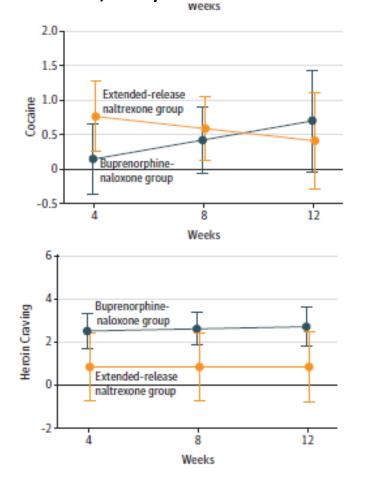
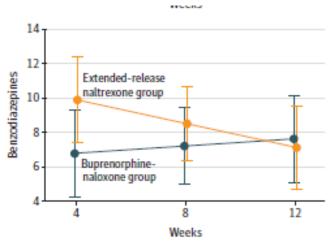


Fig. 1. The proportions of clients seeking treatment for buprenorphine (n=780), amphetamine (n=1249) and heroin (n=598) abuse from all clients (n=4817) seeking treatment from HDI in 1997–2008,

 Effectiveness of Injectable Extended-Release Naltrexone vs Daily Buprenorphine-Naloxone for Opioid Dependence A Randomized Clinical Noninferiority Trial (JAMA, Tanum et al., 2017)

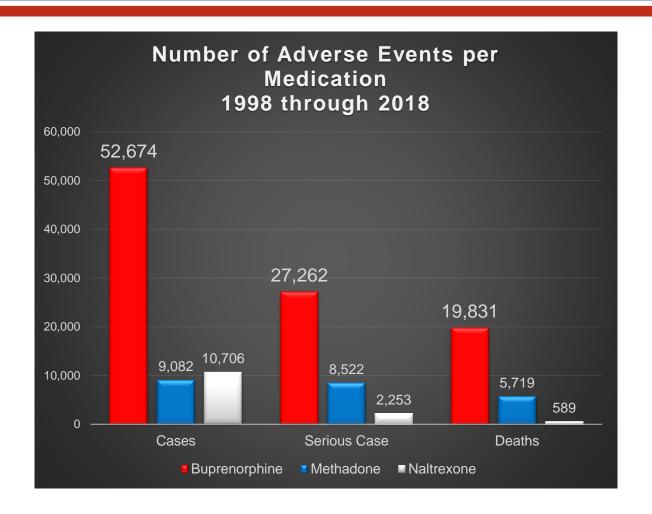




CONCLUSIONS

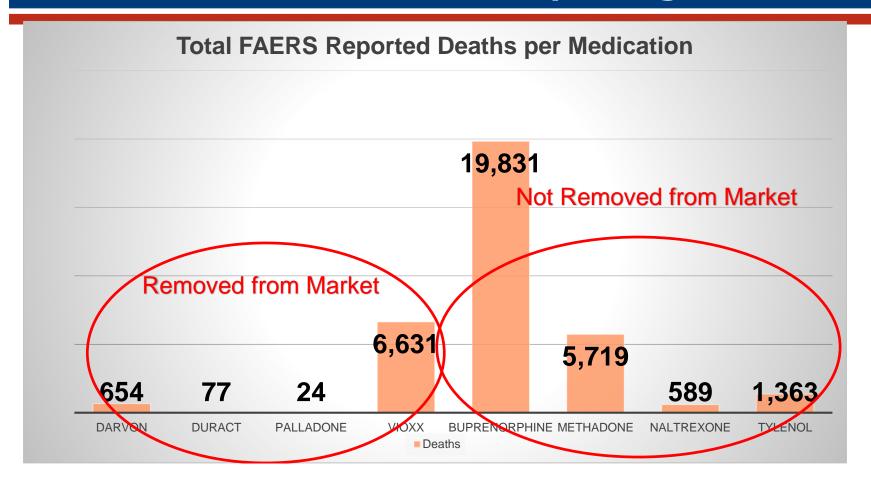
The main clinical implication of these findings is that extended-release naltrexone seems to be as safe and effective as buprenorphine-naloxone treatment for maintaining short-term abstinence from heroin

FDA Adverse Events Reporting



Source:

FDA Adverse Events Reporting



Darvon, Duract, Palladone, Vioxx are pain relievers that have been removed from the market. Source:

Diversion and Abuse

- Relationship between diversion related attitudes and sharing and selling buprenorphine (Journal of Substance Abuse Treatment, Kenney et al, 2017)
 - "50.5% reported they had shared buprenorphine and 28% reported they had sold buprenorphine...Although considered diversion, sharing B-MAT is normative among B-MAT patients" (p. 43)
- Intravenous Misuse of Buprenorphine Characteristics and Extent among Patients Undergoing Drug Maintenance Therapy (Clinical Drug Investigations, Moratti, et al., 2010)
 - In total, 23.12% of patients admitted an IV misuse of buprenorphine, with a significantly greater prevalence among patients currently receiving buprenorphine (35.48%) than those receiving methadone (17.75%; p,001). Younger patients were also more likely to have misused buprenorphine and tended to have done so before coming to the Drug Addiction Centre. (p. 3)

Opioid use and the Brain

 Neuropsychological consequences of chronic opioid use: A quantitative review and meta-analysis (Baldaccino et al, 2012)

This metanalysis suggests that chronic opioid exposure is associated with deficits across a range of different neuropsychological domains.

Robust <u>impairment was found in verbal working memory</u>, risk taking, and verbal fluency.

Long Term SuboxoneTM Emotional Reactivity As Measured by Automatic Detection in Speech

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Abstract

Addictions to illicit drugs are among the nation's most critical public health and societal problems. The current opioid prescription epidemic and the need for buprenorphine/naloxone (Suboxone®; SUBX) as an opioid maintenance substance, and its growing street diversion provided impetus to determine affective states ("true ground emotionality") in long-term SUBX patients. Toward the goal of effective monitoring, we utilized emotion-detection in speech as a measure of "true" emotionality in 36 SUBX patients compared to 44 individuals from the general population (GP) and 33 members of Alcoholics Anonymous (AA). Other less objective studies have investigated emotional reactivity of heroin, methadone and opioid abstinent patients. These studies indicate that current opioid users have abnormal emotional experience, characterized by heightened response to unpleasant stimuli and blunted response to pleasant stimuli. However, this is the first study to our knowledge to evaluate "true ground" emotionality in long-term buprenorphine/naloxone combination (SuboxoneTM). We found in long-term SUBX patients a significantly flat affect (p<0.01), and they had less self-awareness of being happy, sad, and anxious compared to both the GP and AA groups. We caution definitive interpretation of these seemingly important results until we compare the emotional reactivity of an opioid abstinent control using automatic detection in speech. These findings encourage continued research strategies in SUBX patients to target the specific brain regions responsible for relapse prevention of opioid addiction.



Contents lists available at ScienceDirect

Drug and Alcohol Dependence





Methadone patients in the therapeutic community: A test of equivalency

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ABSTRACT

Background: Residential therapeutic communities (TCs) have demonstrated effectiveness, yet for the most part they adhere to a drug-free ideology that is incompatible with the use of methadone. This study used equivalency testing to explore the consequences of admitting opioid-dependent clients currently on methadone maintenance treatment (MMT) into a TC.

Methods: The study compared 24-month outcomes between 125 MMT patients and 106 opioid-dependent drug-free clients with similar psychiatric history, criminal justice pressure and expected length of stay who were all enrolled in a TC. Statistical equivalence was expected between groups on retention in the TC and illicit opioid use. Secondary hypotheses posited statistical equivalence in the use of stimulants, benzodiazepines, and alcohol, as well as in HIV risk behaviors.

Results: Mean number of days in treatment was statistically equivalent for the two groups (166.5 for the MMT group and 180.2 for the comparison group). At each assessment, the proportion of the MMT group testing positive for illicit opioids was indistinguishable from the proportion in the comparison group. The equivalence found for illicit opioid use was also found for stimulant and alcohol use. The groups were statistically equivalent for benzodiazepine use at all assessments except at 24 months where 7% of the MMT group and none in the comparison group tested positive. Regarding injection- and sex-risk behaviors the groups were equivalent at all observation points.

Conclusions: Methadone patients fared as well as other opioid users in TC treatment. These findings provide additional evidence that TCs can be successfully modified to accommodate MMT patients.

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What about Recovery?

The Goal of Treatment

- The Goal of treatment is not only to stop substance use.
- The Goal of the treatment is Right Living
 - This is a higher standard that requires both:
 - Abstinence from substances

AND

- Develop a crime free lifestyle
 AND
- Contributing members of society

Peer Supports

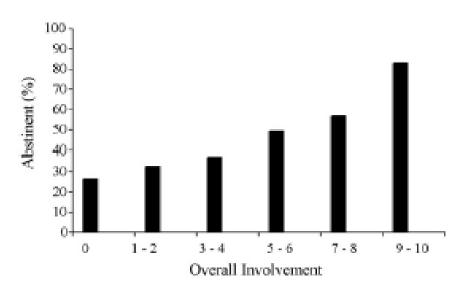


Fig. 2. Percent abstinent from alcohol and drugs at both the first and second six-month follow-ups according to 12-step involvement.

- Increasing attendance at 12-step meetings following treatment are associated with increased rates of abstinence (Timko & DeBenedetti, 2007).
 - This includes a range of activities such as attendance, getting a sponsor, being a sponsor, reading at meetings, calling a 12-step member for help etc.

Recovery Lessons Learned

 Faces and Voices of Recovery Survey of 3,200 individuals with an average of 10 years in recovery.

Personal Descriptions:

- The majority (75%) selected "in recovery";
- 14% chose "recovered,"
- 8% "used to have a problem with substances and no longer do,"
- 3% chose "medication-assisted recovery."

Paths to Recovery:

- 71% professional addiction treatment
- 18% had taken prescribed medications (e.g., buprenorphine or methadone).
- 95% had attended 12-step fellowship meetings (e.g., Alcoholics Anonymous),
- 22% had participated in non-12-step recovery support groups (e.g., LifeRing, Secular Organizations for Sobriety (S.O.S.).

Recovery Lessons Learned

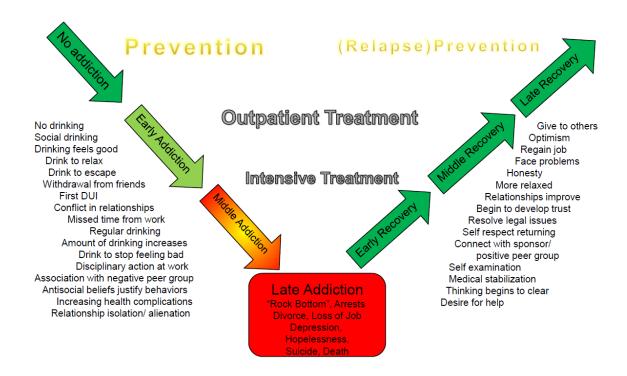
Table 5. What was different on the last quit attempt?

Reason	n (%)
12-Step affiliation (AA/NA/CA)	24
Good support	22
'Tired of the lifestyle'	21
Insight	10
Feeling psychologically prepared	6
Moving away from drug-using peers	5
Benefits of residential rehabilitation	4
Family reasons	3

AA: Alcoholics Anonymous; NA: Narcotics Anonymous; CA: Cocaine Anonymous.

(Best et al. 2008)

Medications and Stage of Addiction



Consider initiation of medications at each stage.

- Antidepressants?
- Opioid Pain Medications?

Future?

Purdue from Commonwealth of Massachusetts v. Purdue, 2019

"Purdue deceived doctors and patients to get more people on dangerous drugs, at higher doses, for longer periods." (p.5)

Quotes:

"Addiction is not caused by drugs"(p.14)

The pain-relieving properties of opioids are unsurpassed; they are today considered the <u>"gold-standard"</u> of pain medications.

(p.18)

"Promoted its drugs for the opioidnaïve patients using the deceptive term "first line opioid"(p.19) Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin <u>as less</u> <u>addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.</u>" (p.61)

Purdue from Commonwealth of Massachusetts v. Purdue, 2019

Project Tango: Buprenorphine

"Kathe and the staff concluded that millions of people who became addicted to opioids were the Sacklers' next business opportunity. ...The team identified eight ways that Purdue's experience getting patients on opioids could now be used to sell treatment for opioid addiction." (p.154)

The team noted the opportunity to capture customers: even after patients were done buying suboxone the first time, 40-60% would relapse and need it again. (p.155)

Commonwealth of Massachusetts v. Purdue, January 31, 2019

On May 15, 2007, this Court entered Judgment ("2007 Judgment") to prohibit Purdue's deceptive conduct in the sale of opioids. This suit addresses Purdue's misconduct since that 2007 Judgment. (p.4) OxyContin's sole active ingredient is oxycodone, a molecule nearly identical to heroin. Purdue later introduced another dangerous drug, Butrans, which releases opioids into the body from a skin patch. Then Purdue introduced Hysingla, which contains yet another opioid.

Almost all of Purdue's business is selling opioids. (p.8)

- Purdue promoted its opioids to Massachusetts patients with marketing
 that was designed to obscure the risk of addiction and even the fact that
 Purdue was behind the campaign. Purdue created a website, In The Face
 of Pain, that promoted pain treatment by urging patients to "overcome"
 their "concerns about addiction." Testimonials on the website that were
 presented as personal stories were in fact by Purdue consultants, whom
 Purdue had paid tens of thousands of dollars to promote its drugs.3 (p.14)
- spend millions of dollars to establish the Massachusetts General Hospital
 Purdue Pharma Pain Program. Similarly, the Sacklers and Purdue pursued
 an intense relationship with Tufts University, which named its School of
 Biomedical Sciences as the Sackler School of Graduate Biomedical
 Sciences, and created an entire degree program, the Master of Science in
 Pain Research, Education, and Policy, funded by Purdue (p.64)

https://flaglerlive.com/wpcontent/uploads/Massachusetts-AGO-Amended-Complaint-2019-01-31.pdf

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, July 11, 2019

Justice Department Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History

- Reckitt Benckiser is not to manufacture, market or sell controlled substances for 3 years. Why?
 - Promoted Suboxone as less-divertable and less abusable even though such claims have never been established.
 - <u>Promoted the sale and use of Suboxone without any counseling</u> or psychosocial support and for uses that were unsafe, ineffective and medially unnecessary.

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, April 9, 2019

Indivior Inc. Indicted for Fraudulently Marketing Prescription Opioid

Company Allegedly Lied to Doctors and Public Health Care Benefit Programs About the Safety and Diversion Risks of Suboxone Film

Dayton Daily News

Local. In-Depth. Always updated.

NATION & WORLD | Oct 22, 2019

By Katie Wedell, Staff Writer

\$260M settlement reached in bellwether Ohio opioid lawsuit

The agreement reached Monday calls for the distributors AmerisourceBergen, Cardinal Health and McKesson to pay a combined \$215 million to the two counties, said Hunter Shkolnik, a lawyer for Cuyahoga County.

Israeli-based drug maker Teva would contribute \$20 million in cash and \$25 million worth of Suboxone, a drug used to treat opioid addiction.

Trending Resurgence in Methamphetamines



Meth Vs. Opioids: America Has Two Drug Epidemics, But Focuses On One

By April Dembosky, KQED • MAY 7, 2019

Drug and Alcohol Dependence 193 (2018) 14-20



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journal homepage: www.elsevier.com/locate/drugalcdep

Full length article

Twin epidemics: The surging rise of methamphetamine use in chronic opioid users

Matthew S. Ellis*, Zachary A. Kasper, Theodore J. Cicero

Washington University, Department of Psychiatry, Campus Box 8134, 660 S. Euclid Avenue, St. Louis, MO 63110 USA

Re-emergence of Cocaine and Methamphetamine Use in the 21st Century

By Richard A.Rawson, Ph.D., UCLA Research Professor, Vermont Center for Behavior and Health Professor Emeritus

Fast Facts:

- Methamphetamine use is on the rise
 - Meth overdose deaths have quadrupled from 2011 to 2017
- Increase in cocaine and other drug use
 - Methamphetamine use is rising among opioid users
 - 82% increase in methamphetamine use among treatment admissions
 - Clients report using meth as an opioid substitute
 - Clients report using meth to balance the effects of opioids
 - Increase in cocaine and other drug use

Stateline

As the Opioid Crisis Peaks, Meth and Cocaine Deaths Explode 73

One Future

Canada Approves Prescription Heroin to Combat Opioid Crisis BY

GILLIAN MOHNEY

Sep 14, 2016, 6:12 PM ET

Sustained-release methylphenidate in methamphetamine dependence treatment: a double-blind and placebo-controlled trial (2015)

Conclusion:

Sustained-released methylphenidate was safe and well tolerated among active methamphetamine users and significantly reduced methamphetamine use, craving and depressive symptoms.

Science News

from research organizations
Cannabis treatment counters
addiction: First study of its kind

Trial shows cannabis replacement therapy can be effective

Date:

July 15, 2019

An Australian study has demonstrated that cannabisbased medication helps tackle dependency on cannabis, one of the most widely used drugs globally. A new article provides the first strong evidence that cannabis replacement therapy could reduce the rate of relapse.

What Works? The Road Less Travelled

Therapeutic dose issues

- Level of care
- Length of stay
- Continuum

Quality issues

- Evidence based practices
- Behavioral practice
- Cognitive restructuring
- Emotion/coping
- Trauma
- Monitoring/ case management/Advocacy

Comprehensive care elements

- Recovery supports/12-step
- Employment
- Housing

Research Literacy Basics

- Seek original sources not third hand data
- Look for trends across theories
- Look for research with decades of support/replications
- Look for long term outcomes (5 years)
- Look for funding source/disclosures of conflicts
- Be cautious of statements without research reference

The Solution

- Comprehensive Treatment
 - Appropriate duration and intensity of care
- Research Literacy
 - Understand basic research principles
- Learn the Lessons from our Past
 - Do not repeat mistakes

Apply it Now

Challenge

Length of SUD

Negative Peer Pressure

Multiple Social Pressures

Trauma

Secrets

External Motivation

Past Negative Behavior

Lack of Safety

No Range of Family Supports

Short Length of Treatment

Stopping Treatment Due to

Funding

Lack of Hope

Opportunity

Length of Recovery

Positive Peer Pressure

Multiple Positive Social Pressures

Trauma Resolution

Trust

Internal Motivation

Developing Positive Behavior

Relative Risks but Safe

Wide Range of Family Supports

Longer Length of Treatment

Stopping Treatment due to Completion of Goals

Hope, Goals, Vision, Drive

Recommendations

Why Treatment Fails	Why Treatment Works
Length of Stay (Less than 90 days)	Length of Stay (More than 90 days)
Undertreating (Giving OP instead of TC)	Appropriate Level of Care
Fragmented care (Detox only, 12-step only)	Full Continuum of Care
Weak Enforcement of Insurance Law	Enforcement of State and Federal Laws
Medicating all Pain	Appropriate Prescribing
Stigma (Seeing individuals as "bad")	Humanizing (Treating those with disease)
Locking up Drug Users	Treating those with Substance Use Disorder
Thinking There is a Silver Bullet	Clinical Integrity

What Works: Clinical Integrity

What Can I Do? 10 Simple Steps

- Are my programs trained in cross-system needs (criminal justice, child welfare, medical etc.)?
- Are my system partner programs trained in drug and alcohol treatment?
- Are we using adequate lengths of stay or terminating based on funding?
- Are we using a continuum of care?
- Are we educating on proper prescribing practices?
- Does our county have medication take back boxes?
- Are we expanding the use of Naloxone to save overdose victims?
- Are we practicing good research literacy?
- Are we learning from our past to create the future we want?
- Are we doing SOMETHING? Pick one and keep moving forward.

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