Management of Unhealthy Alcohol Use:
From Research to Practice

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EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Boston Medical Center is the primary teaching affiliate
of the Boston University School of Medicine.

A 43 year old man presents because he bumped his head after slipping and falling. No loss of consciousness.

Breath alcohol is 210 mg/dL (0.21 g/100mL).

He reports no hematemesis, hematochezia, melena, tremors, past seizures, liver disease, gastrointestinal bleeding, pancreatitis or delirium.

He lives alone and reports drinking all day since he became disabled from lumbar disc disease ten years ago. He takes no medications, has no allergies, and smokes one pack of cigarettes daily.

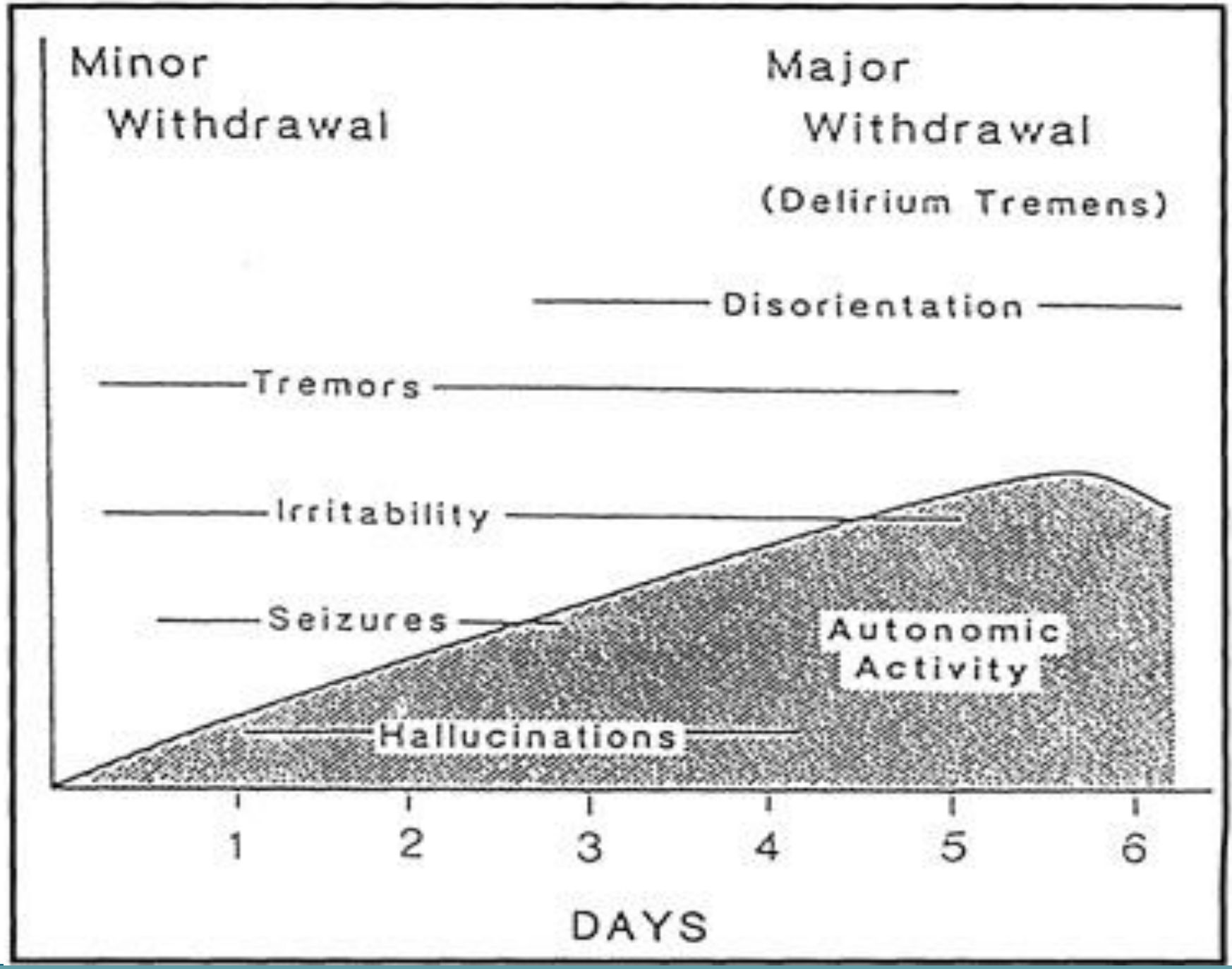
T 98, RR 18, **HR 110** (regular), BP 136/82 standing, 100, 140/70 lying down.

EOMI, supple neck, no tremor; frontal ecchymosis.

He is awake, alert and oriented to place, time and person. Speech is fluent. Gait normal. Sensorimotor exam non-focal.

Four hours later (15-20 mg/dL/hr [1 drink] elimination), the patient becomes tremulous, anxious, and complains of nausea. BP 134/84, HR 90, ethanol level 146 mg/dl.

- What is the diagnosis?
- What is appropriate management?


Minor
Withdrawal
Major
Withdrawal
(Delirium Tremens)
Disorientation
Tremors
Irritability
Seizures
Autonomic
Activity
Hallucinations
1
2
3
4
5
6
DAYS

ALCOHOL WITHDRAWAL TRIAGE

- Outpatient
  - Last drink >36 hrs: symptoms unlikely to develop
  - No other risk factors, responsible other
- Consider inpatient
  - Past seizure, drug use, anxiety disorder, multiple detoxifications, alcohol >150 (risks more severe symptoms)
- Inpatient
  - Older age (>60), concurrent acute illness, seizure, moderate to severe symptoms (risks DTs)
- ICU level
  - DTs

Clinical Institute Withdrawal Assessment, for Alcohol, revised (CIWA-Ar)

Nausea and vomiting. Ask "Do you feel sick to your stomach? Have you vomited?"

Observation:

0—No nausea and no vomiting
1—Mild nausea with no vomiting
2—
3—
4—Intermittent nausea with dry heaves
5—
6—
7—Constant nausea, frequent dry heaves, and vomiting

Tremor. Ask patient to extend arms and spread fingers apart.

Observation:

0—No tremor
1—Tremor not visible but can be felt, fingertip to fingertip
2—
3—
4—Moderate tremor with arms extended
5—
6—
7—Severe tremor, even with arms not extended

Paroxysmal sweats

Observation:

0—No sweat visible
1—Barely perceptible sweating; palms moist
2—
3—
4—Beads of sweat obvious on forehead
5—
6—
7—Drenching sweats

Anxiety. Ask "Do you feel nervous?"

Observation:

0—No anxiety (at ease)
1—Mildly anxious
2—
3—
4—Moderately anxious or guarded, so anxiety is inferred
5—
6—
7—Equivalent to acute panic states as occur in severe delirium or acute schizophrenic reactions

Agitation

Observation:

0—Normal activity
1—Somewhat more than normal activity
2—
3—
4—Moderately fidgety and restless
5—
6—
7—Paces back and forth during most of the interview or constantly thrashes about

Tactile disturbances. Ask "Do you have you any itching, pins-and-needles sensations, burning, or numbness, or do you feel like bugs are crawling on or under your skin?"

Observation:

0—None
1—Very mild itching, pins-and-needles sensation, burning, or numbness
2—Mild itching, pins-and-needles sensation, burning, or numbness
3—Moderate itching, pins-and-needles sensation, burning, or numbness
4—Moderately severe hallucinations
5—Severe hallucinations
6—Extremely severe hallucinations
7—Continuous hallucinations

Auditory disturbances. Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?"

Observation:

0—Not present
1—Very mild harshness or ability to frighten
2—Mild harshness or ability to frighten
3—Moderate harshness or ability to frighten
4—Moderately severe hallucinations
5—Severe hallucinations
6—Extremely severe hallucinations
7—Continuous hallucinations

Visual disturbances. Ask "Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?"

Observation:

0—Not present
1—Very mild sensitivity
2—Mild sensitivity
3—Moderate sensitivity
4—Moderately severe hallucinations
5—Severe hallucinations
6—Extremely severe hallucinations
7—Continuous hallucinations

Headache, fullness in head. Ask "Does your head feel different? Does it feel like there is a band around your head?"

Do not rate for dizziness or lightheadness; otherwise, rate severity.

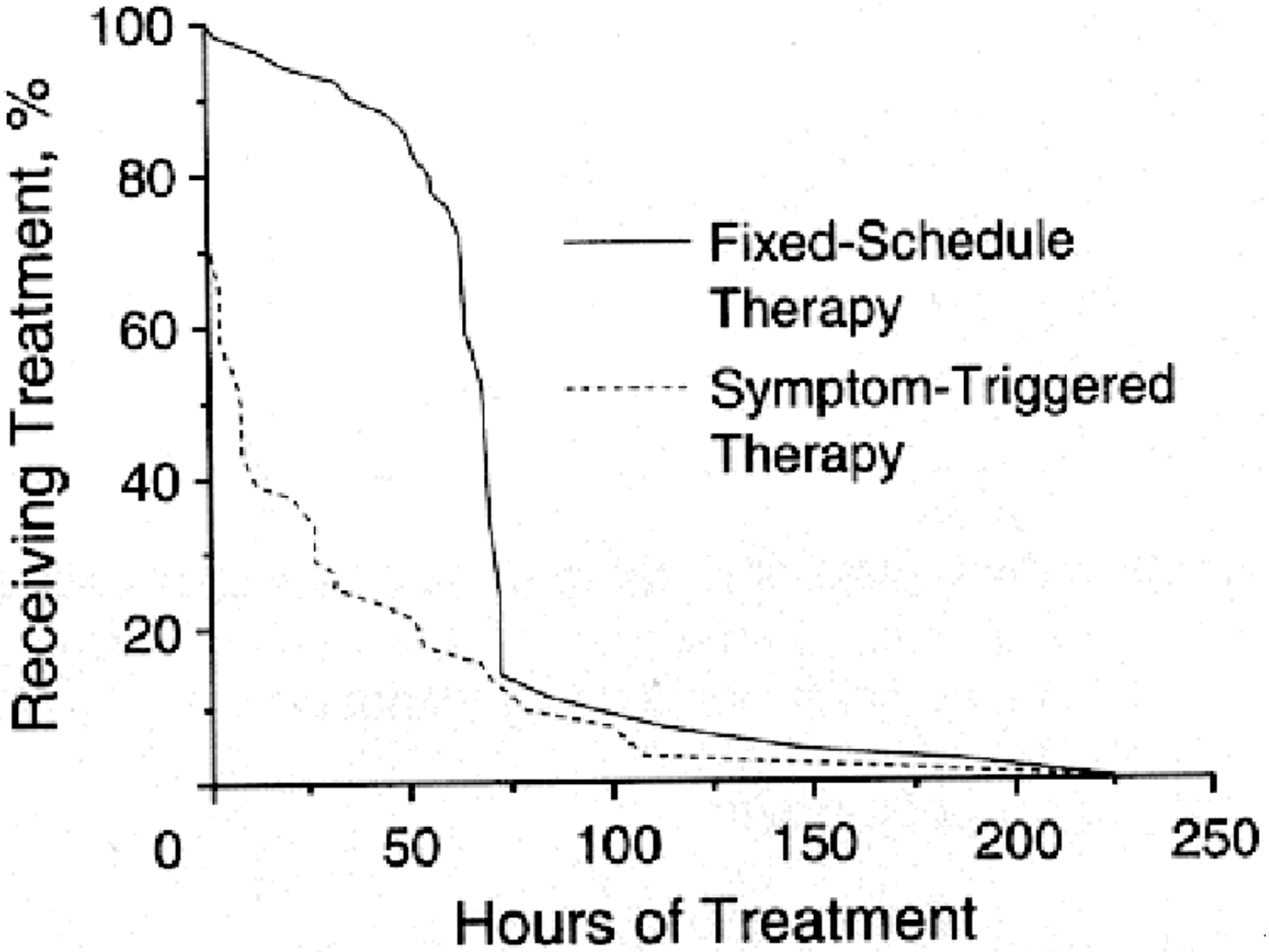
0—Not present
1—Very mild
2—Mild
3—Moderate
4—Moderately severe
5—Severe
6—Very severe
7—Extremely severe

Orientation and clouding of sensorium. Ask "What day is this? Where are you? Who am I?"

Observation:

0—Orientated and can do serial additions
1—Cannot do serial additions or is uncertain about date
2—Date disorientation by no more than two calendar days
3—Date disorientation by more than two calendar days
4—Disorientated for place and/or person

Decreased Duration of Treatment



Saitz R et al JAMA 1994;272:519-23

American Society of Addiction Medicine Practice Guidelines

- **Symptom-triggered** (q 1 when CIWA-Ar≥8)
  - Chlordiazepoxide 50-100 mg
  - Diazepam 10-20 mg
  - Lorazepam 2-4 mg
- **Fixed schedule** (q 6 for 4/8 doses + PRN)
  - Chlordiazepoxide 50 mg/25 mg
  - Diazepam 10 mg/5 mg
  - Lorazepam 2 mg/1 mg

Mayo-Smith and ASAM working group JAMA 1997;278:144-51
Saitz and O'Malley Med Clin N A 1997;81:881-907

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The patient is seen having a generalized tonic-clonic convulsion.

- What is the most likely etiology?
- What is the appropriate work-up?
- Can it be prevented?

Benzodiazepines reduce seizures

ANY 1/188 (0.5%)
Placebo 16/201 (8%)

RRR 93%, p<0.001

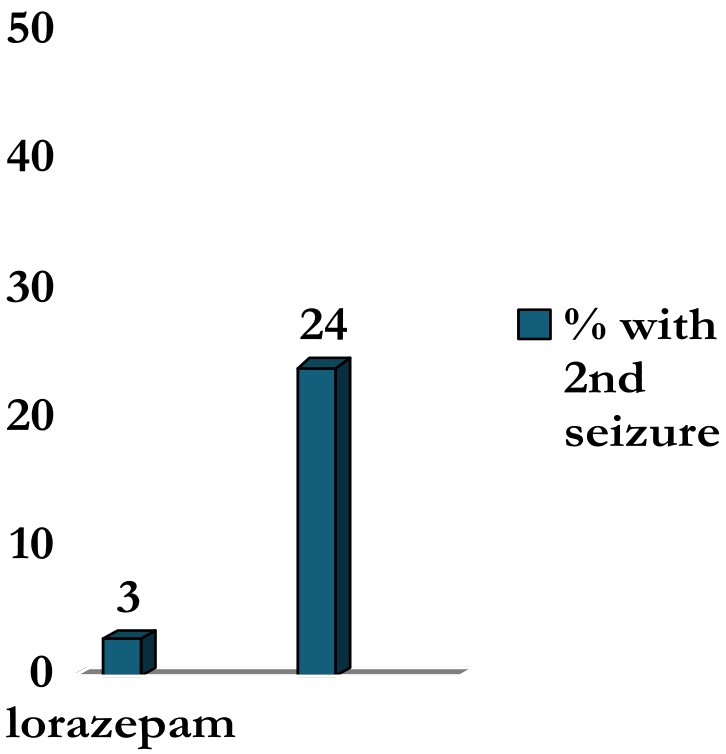
Sereny 1965, Kiam 1969, Zilm 1980, Sellers 1983, Naranjo 1983, summarized in Mayo-Smith MF & ASAM Working Group JAMA 1997;278:144-51

ALCOHOL WITHDRAWAL SEIZURES

- Recurrent detox and prior seizure are risk factors
- Generalized
- Single or a few (79% <3, <3% status)
- 86% in the 1st 6 hrs
- Imaging unhelpful if clinical picture consistent
  - Fever
  - Delirium
  - Focal exam, focal seizure
  - Head trauma
  - 1st or multiple seizures, status

LORAZEPAM PREVENTS RECURRENCE

- 186 subjects with alcohol withdrawal seizures
- RPCDBT
- 2 mg of lorazepam IV
- Also decreased hospital admission



D'Onofrio G et al New Engl J Med

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The patient tells you he is at the racetrack with his friends, BP 170/100, HR 110, Temp 99.

- What is the diagnosis?
- What if he were febrile?
- Can it be prevented? Treated?

DSM-5 DEFINITION: alcohol withdrawal delirium

A. A disturbance in **attention** (i.e., reduced ability to direct, focus, sustain, and shift attention) and **awareness** (reduced orientation to the environment)

B. The disturbance develops over a short period of time (usually hours to days), represents a change from baseline attention and awareness, and **fluctuates** in severity during the course of a day

C. An additional disturbance in **cognition** (e.g., memory deficit, disorientation, language, visuospatial ability, or perception)

Benzodiazepines reduce delirium

Chlordiazepoxide 3/172 (2%)
Placebo 11/186 (6%)

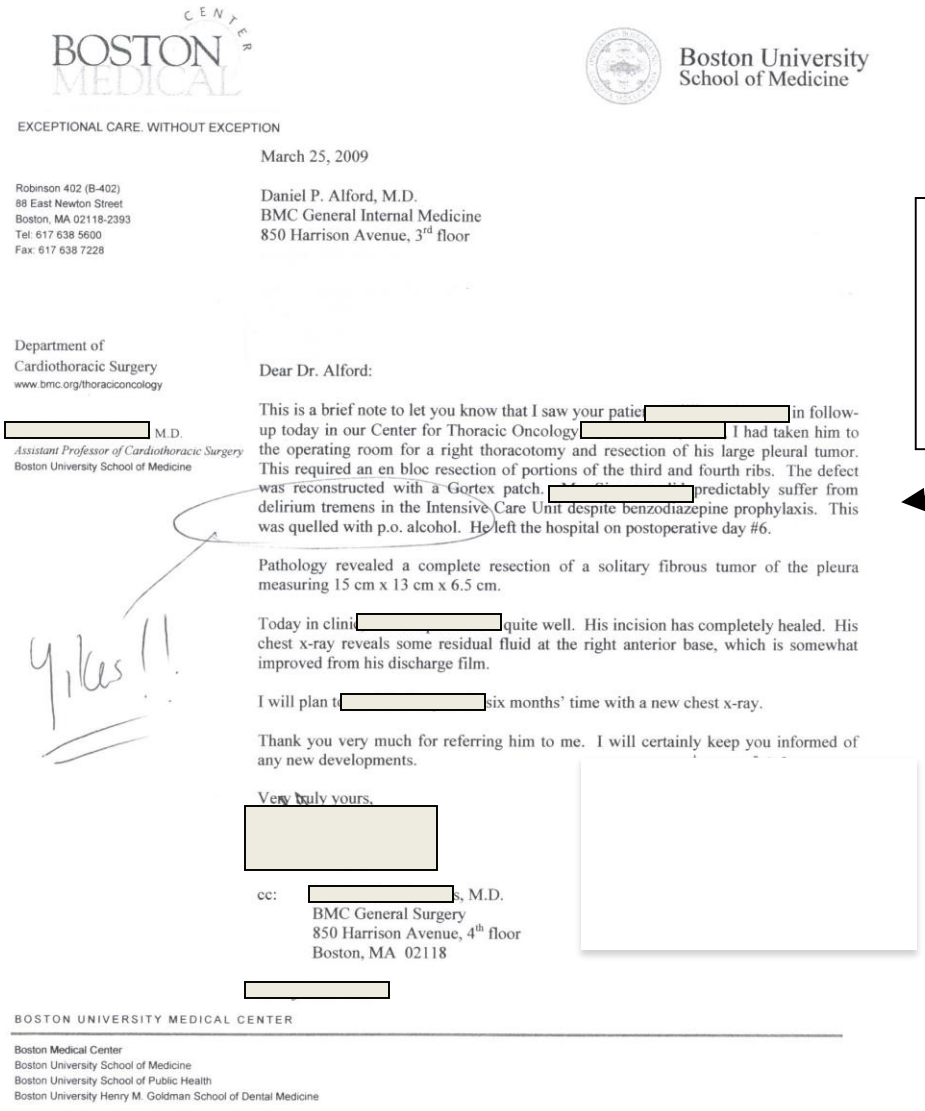
RRR 71%, p=0.04

Rosenfeld 1961, Sereny 1965, Kaim 1969, Zilm 1980,
summarized in Mayo-Smith MF & ASAM Working Group JAMA 1997;278:144-51

DTs: Treatment

- N=34, RCT, Diazepam 10 mg IV then 5mg q 5” (mean 200mg req’d) vs. paraldehyde 30cc PR q 30” until calm but awake
  - Shorter time to light somnolence
  - All complications in paraldehyde group
    - sudden death (2), apnea (2), brachial plexus injury (2), 3rd floor jump attempt (1), bitten nurse (1), bitten intern (1)
- Decreased duration of delirium by 22-90 hours
  - Paraldehyde vs. neuroleptics (4 trials)
- Decreased mortality RR 0.15 (95% CI 0.03-0.83)
  - 5 trials (n=386) sedative hypnotics > neuroleptics, 1 vs. 8 deaths

Mayo-Smith et al. Arch Intern Med, Jul 2004; 164: 1405 – 1412
Systematic evidence review and practice guideline
Thompson, Maddrey, Osler Medical Housestaff. Ann Int Med 1978;82:175



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March 25, 2009

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[redacted] M.D.
Assistant Professor of Cardiothoracic Surgery
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Dear Dr. Alford:

This is a brief note to let you know that I saw your patie[redacted] in follow-up today in our Center for Thoracic Oncology [redacted] I had taken him to the operating room for a right thoracotomy and resection of his large pleural tumor. This required an en bloc resection of portions of the third and fourth ribs. The defect was reconstructed with a Gortex patch. [redacted] predictably suffer from delirium tremens in the Intensive Care Unit despite benzodiazepine prophylaxis. This was quelled with p.o. alcohol. He left the hospital on postoperative day #6.

Pathology revealed a complete resection of a solitary fibrous tumor of the pleura measuring 15 cm x 13 cm x 6.5 cm.

Today in clini[redacted] quite well. His incision has completely healed. His chest x-ray reveals some residual fluid at the right anterior base, which is somewhat improved from his discharge film.

I will plan t[redacted] six months' time with a new chest x-ray.

Thank you very much for referring him to me. I will certainly keep you informed of any new developments.

Very truly yours,

[redacted]

cc: [redacted]s, M.D.
BMC General Surgery
850 Harrison Avenue, 4th floor
Boston, MA 02118

[redacted]

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Boston Medical Center
Boston University School of Medicine
Boston University School of Public Health
Boston University Henry M. Goldman School of Dental Medicine

"He did predictably suffer from delirium tremens. This was quelled with p.o. alcohol"

- Dose/therapeutic index
- Effectiveness
- Toxicities

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DTs: Recommendation

- Parenteral benzodiazepines, prefer long-acting
- Example regimen:
  - Diazepam, 5 mg intravenously (2.5 mg/min)
  - If not effective, repeat in 5 to 10“
  - if not satisfactory, use 10 mg for the third and fourth doses
  - if not effective, use 20 mg for the fifth and subsequent doses until sedation
  - Then 5 to 20 mg q 1h PRN to maintain light somnolence

MANAGEMENT OF UNHEALTHY ALCOHOL USE: BEYOND WITHDRAWAL

- Detoxification is not treatment
- Brief Intervention
- Treatment
  - Counseling, removal from environment/access
  - **Pharmacotherapy**
- Self (online, books) and mutual help (e.g. AA, Smart Recovery)
- Manage comorbidity (medical and psychiatric)

Friedmann PD, Saitz R, Samet JH. JAMA 1998;279(15):1227-31.

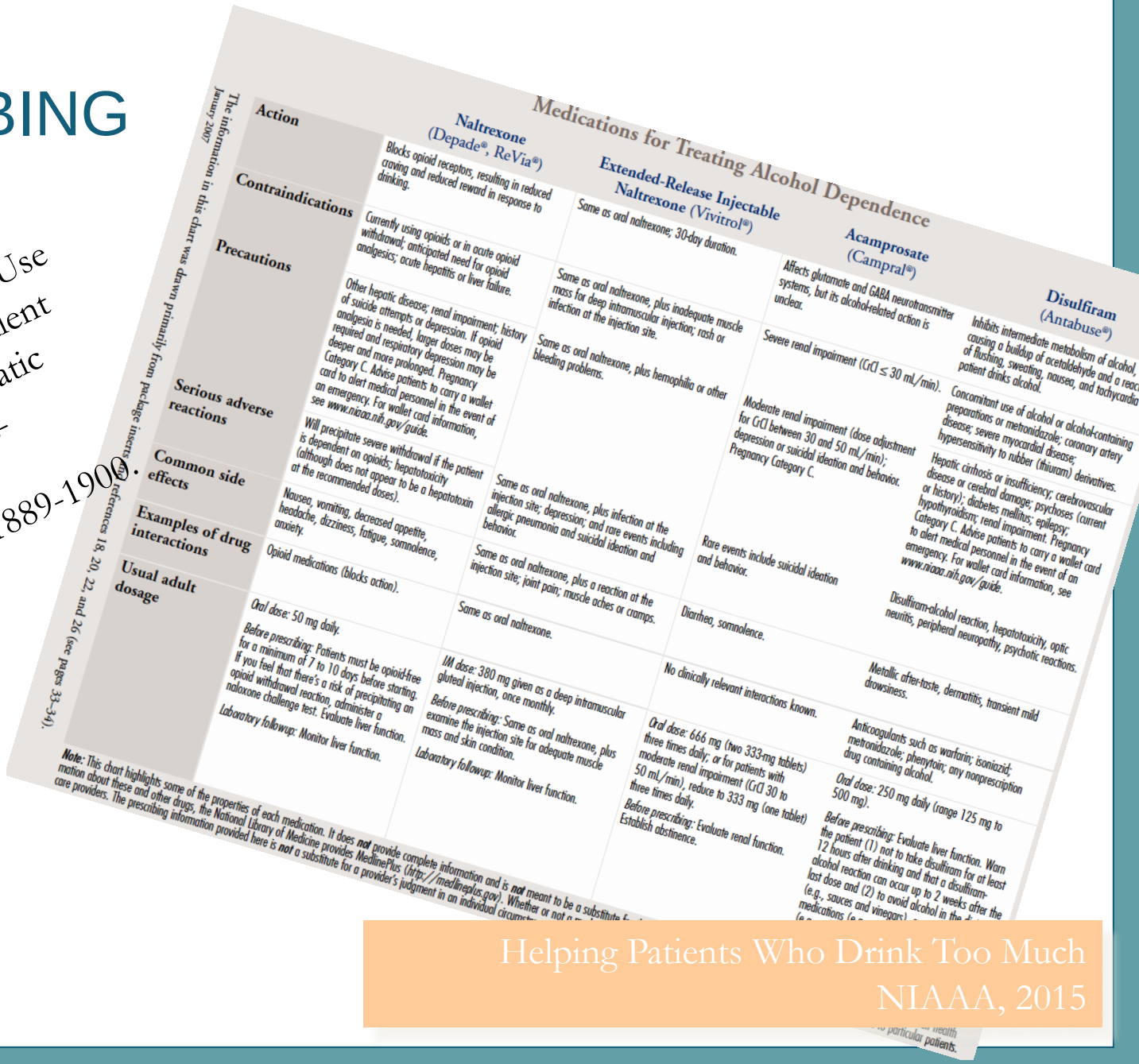
PATIENT SELECTION FOR PHARMACOTHERAPY

- All people with moderate to severe alcohol use disorder who are:
  - currently drinking
  - experiencing craving or at risk for return to drinking
- Considerations
  - Specific medication contraindications
  - Psychosocial support/therapy and follow-up
    - Primary care med mgt (O'Malley; Anton; Oslin*)
      - as effective as specialized behavioral therapy**

*O' Malley SS et al. *Arch Int Med* 2003;163:1695-1704.
*Anton RF et al. *JAMA* 2006 May 3;295:2003-17.
*Oslin DW et al. J Gen Intern Med 2014;29:162-8.
**Latt NC, et al. *Med J Australia* 2002;176:530-534.
RCT: naltrexone effective without obligatory therapy

PRESCRIBING

Jonas DE, Amick HR, Feltner C, et al. Pharmacotherapy for Adults With Alcohol Use Disorders in Outpatient Settings: A Systematic Review and Meta-analysis. JAMA. 2014;311(18):1889-1900.



Medications for Treating Alcohol Dependence

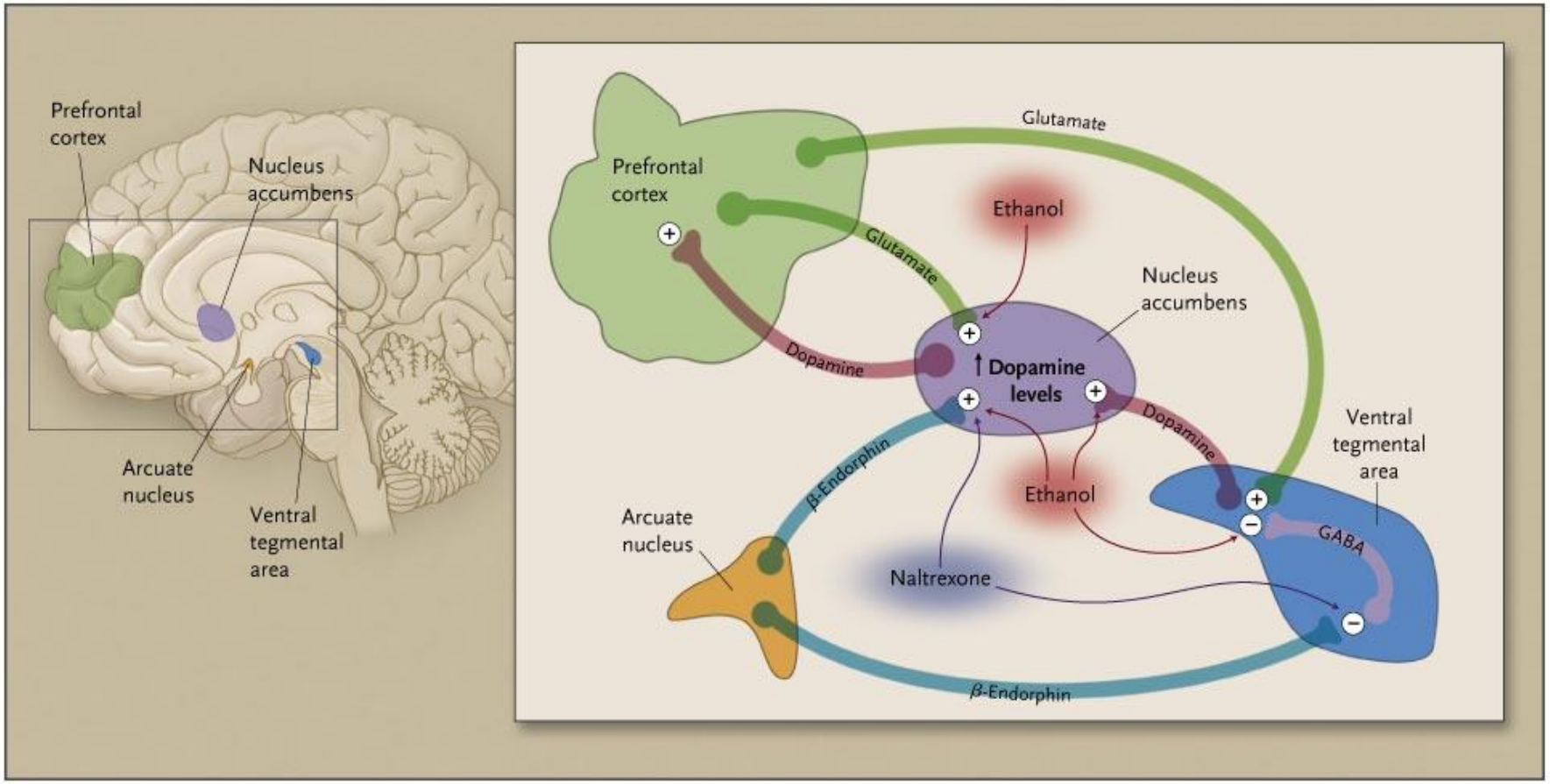
The information in this chart was drawn primarily from package inserts (see references 18, 20, 22, and 26 (see pages 33–34). January 2007

Action	Naltrexone (Depade®, ReVia®)	Extended-Release Injectable Naltrexone (Vivitrol®)	Acamprosate (Campral®)	Disulfiram (Antabuse®)
	Blocks opioid receptors, resulting in reduced craving and reduced reward in response to drinking.	Same as oral naltrexone; 30-day duration.	Affects glutamate and GABA neurotransmitter systems, but its alcohol-related action is unclear.	Inhibits intermediate metabolism of alcohol, causing a buildup of acetaldehyde and a reac of flushing, sweating, nausea, and tachycardia patient drinks alcohol.
Contraindications	Currently using opioids or in acute opioid withdrawal; anticipated need for opioid analgesics; acute hepatitis or liver failure.	Same as oral naltrexone, plus inadequate muscle mass for deep intramuscular injection; rash or infection at the injection site.	Severe renal impairment (CrCl ≤ 30 mL/min).	Concomitant use of alcohol or alcohol-containing preparations or metronidazole; coronary artery disease; severe myocardial disease; hypersensitivity to rubber (thiuram) derivatives.
Precautions	Other hepatic disease; renal impairment; history of suicide attempts or depression. If opioid analgesia is needed, larger doses may be required and respiratory depression may be deeper and more prolonged. Pregnancy Category C. Advise patients to carry a wallet card to alert medical personnel in the event of an emergency. For wallet card information, see www.niaaa.nih.gov/guide.	Same as oral naltrexone, plus hemophilia or other bleeding problems.	Moderate renal impairment (dose adjustment for CrCl between 30 and 50 mL/min); depression or suicidal ideation and behavior. Pregnancy Category C.	Hepatic cirrhosis or insufficiency; cerebrovascular disease or cerebral damage; psychoses (current or history); diabetes mellitus; epilepsy; hypothyroidism; renal impairment. Pregnancy Category C. Advise patients to carry a wallet card to alert medical personnel in the event of an emergency. For wallet card information, see www.niaaa.nih.gov/guide.
Serious adverse reactions	Will precipitate severe withdrawal if the patient is dependent on opioids; hepatotoxicity (although does not appear to be a hepatotoxin at the recommended doses).	Same as oral naltrexone, plus infection at the injection site; depression; and rare events including allergic pneumonia and suicidal ideation and behavior.	Rare events include suicidal ideation and behavior.	Disulfiram-alcohol reaction, hepatotoxicity, optic neuritis, peripheral neuropathy, psychotic reactions.
Common side effects	Nausea, vomiting, decreased appetite, headache, dizziness, fatigue, somnolence, anxiety.	Same as oral naltrexone, plus a reaction at the injection site; joint pain; muscle aches or cramps.	Diarrhea, somnolence.	Metallic after-taste, dermatitis, transient mild drowsiness.
Examples of drug interactions	Opioid medications (blocks action).	Same as oral naltrexone.	No clinically relevant interactions known.	Anticoagulants such as warfarin; isoniazid; metronidazole; phenytoin; any nonprescription drug containing alcohol.
Usual adult dosage	*Oral dose:* 50 mg daily. *Before prescribing:* Patients must be opioid-free for a minimum of 7 to 10 days before starting. If you feel that there's a risk of precipitating an opioid withdrawal reaction, administer a naloxone challenge test. Evaluate liver function. *Laboratory followup:* Monitor liver function.	*IM dose:* 380 mg given as a deep intramuscular gluteal injection, once monthly. *Before prescribing:* Same as oral naltrexone, plus examine the injection site for adequate muscle mass and skin condition. *Laboratory followup:* Monitor liver function.	*Oral dose:* 666 mg (two 333-mg tablets) three times daily; or for patients with moderate renal impairment (CrCl 30 to 50 mL/min), reduce to 333 mg (one tablet) three times daily. *Before prescribing:* Evaluate renal function. Establish abstinence.	*Oral dose:* 250 mg daily (range 125 mg to 500 mg). *Before prescribing:* Evaluate liver function. Warn the patient (1) not to take disulfiram for at least 12 hours after drinking and that a disulfiram-alcohol reaction can occur up to 2 weeks after the last dose and (2) to avoid alcohol in the [illegible] (e.g., sauces and vinegars) [illegible] medications [illegible]

Note: This chart highlights some of the properties of each medication. It does **not** provide complete information and is **not** meant to be a substitute [illegible] mation about these and other drugs, the National Library of Medicine provides MedlinePlus (http://medlineplus.gov). Whether or not [illegible] care providers. The prescribing information provided here is **not** a substitute for a provider's judgment in an individual circumstance [illegible]

Helping Patients Who Drink Too Much
NIAAA, 2015

Neurochemical Circuits Involved in Alcohol Dependence and Craving



The NEW ENGLAND JOURNAL of MEDICINE

Anton R. N Engl J Med 2008;359:715-721

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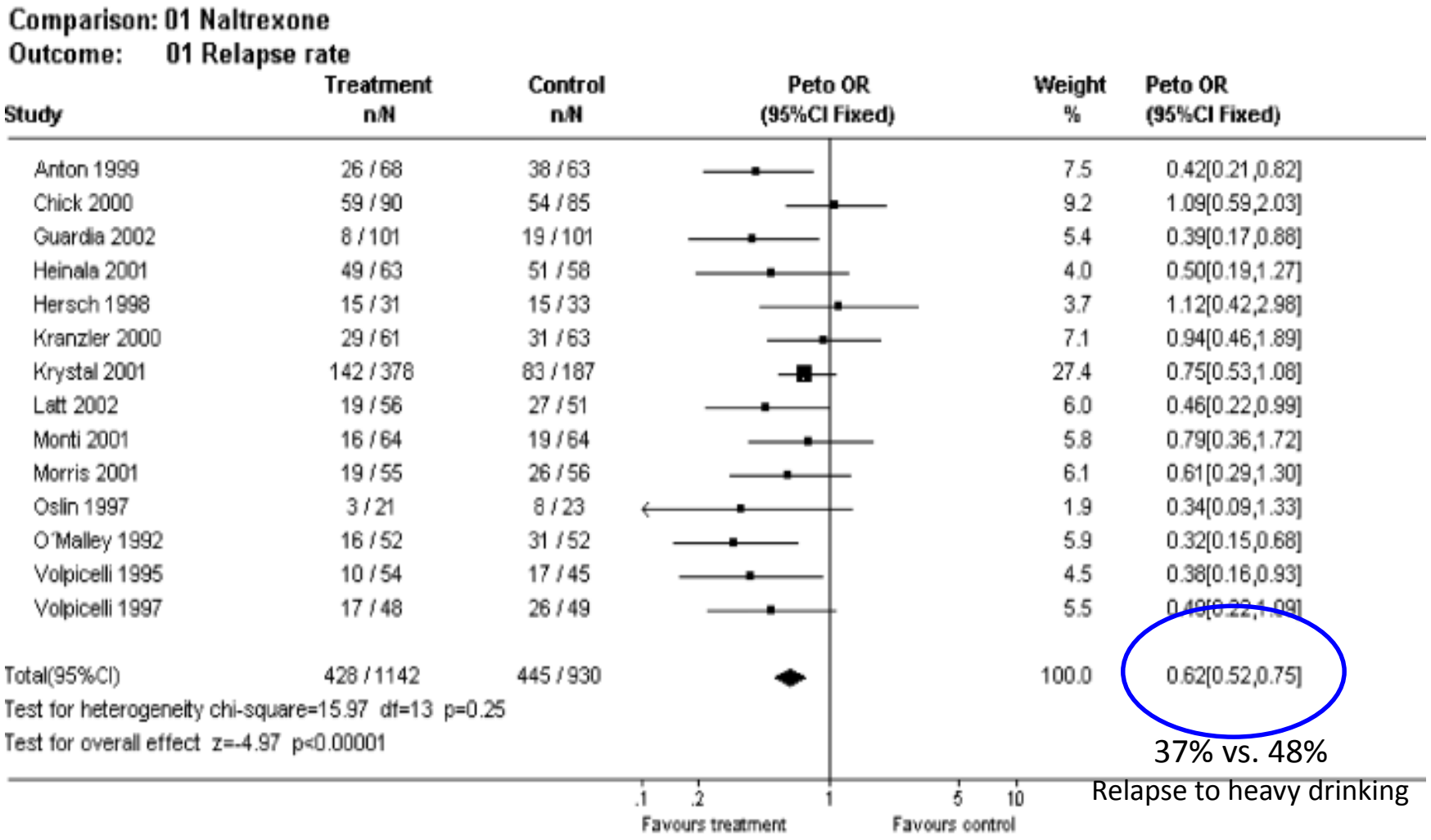
Efficacy of Naltrexone



37% vs. 48%

Relapse to heavy drinking

Bouza C et al. Addiction 2004;99:811

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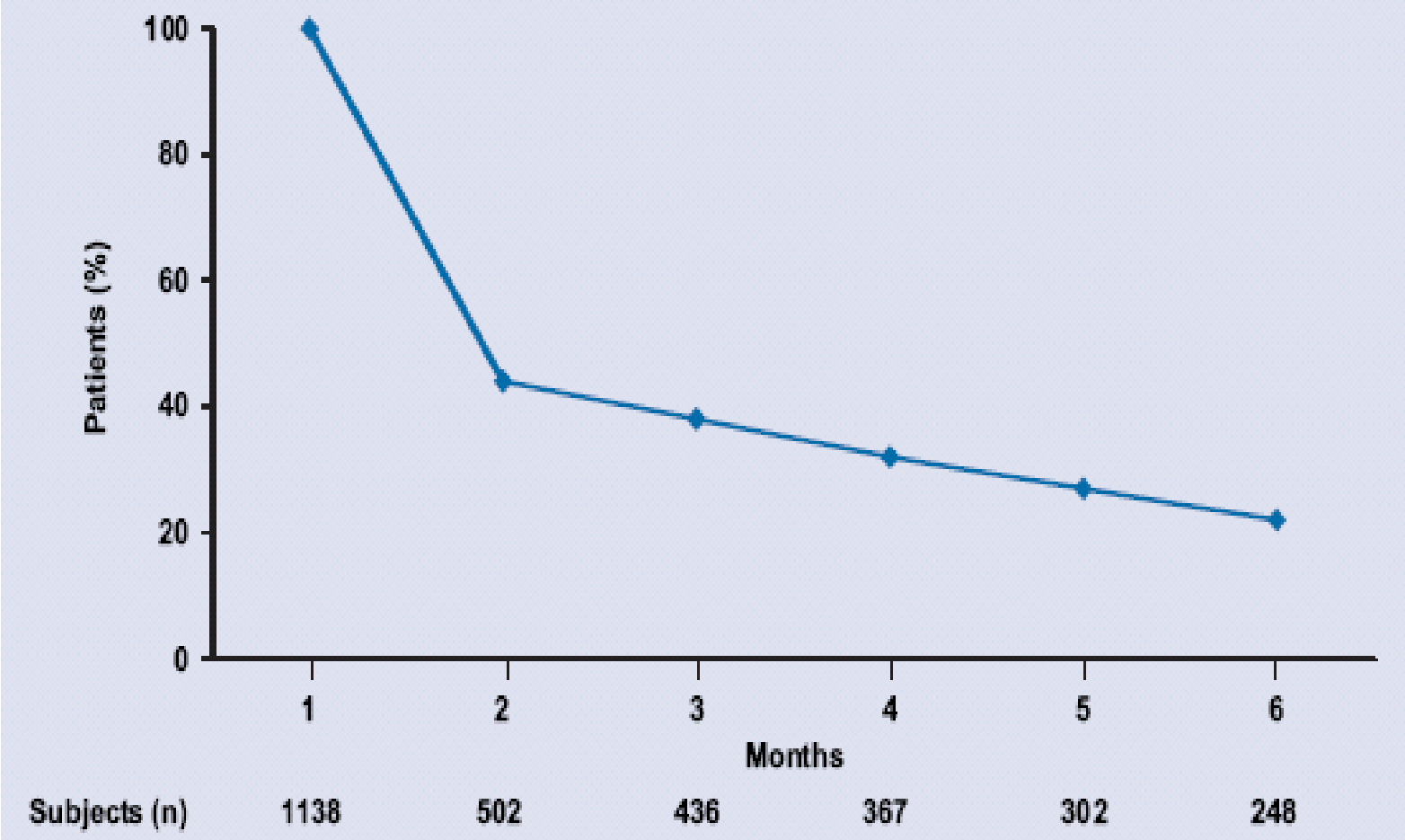
NALTREXONE

- 50 RCTs, 7793 patients, less heavy drinking, fewer heavy drinking days, drinking days, amount of alcohol, GGT, any drinking
  - Heavy drinking NTX RR 0.83 (95% CI 0.76 to 0.90)
  - Drinking days, MD -3.89% (95% CI -5.75 to -2.04)
  - Heavy drinking days, MD - 3.25 (95% CI -5.51 to -0.99)
  - Consumed amount of alcohol, MD - 10.83 (95% CI -19.69 to -1.97)
  - GGT, MD - 10.37 (95% CI -18.99 to -1.75)
  - Any drinking, RR 0.96 (95 CI 0.92 to 1.00)
- Side effects
  - GI (e.g. nausea: RD 0.10; 95% CI 0.07 - 0.13)
  - Sedation (e.g. daytime sleepiness: RD 0.09; 95% CI 0.05 - 0.14)

Rösner S, Hackl-Herrwerth A, Leucht S, Vecchi S, Srisurapanont M, Soyka M. Opioid antagonists for alcohol dependence. Cochrane Database of Systematic Reviews 2010, Issue 12. Art. No.: CD001867. DOI: 10.1002/14651858.CD001867.pub3.

Receipt of Naltrexone

14% got 80% of a 6-mo course



Stephenson JJ et al. (abstract) AAAP 2006.
Medstat MarketScan Commercial Claims data

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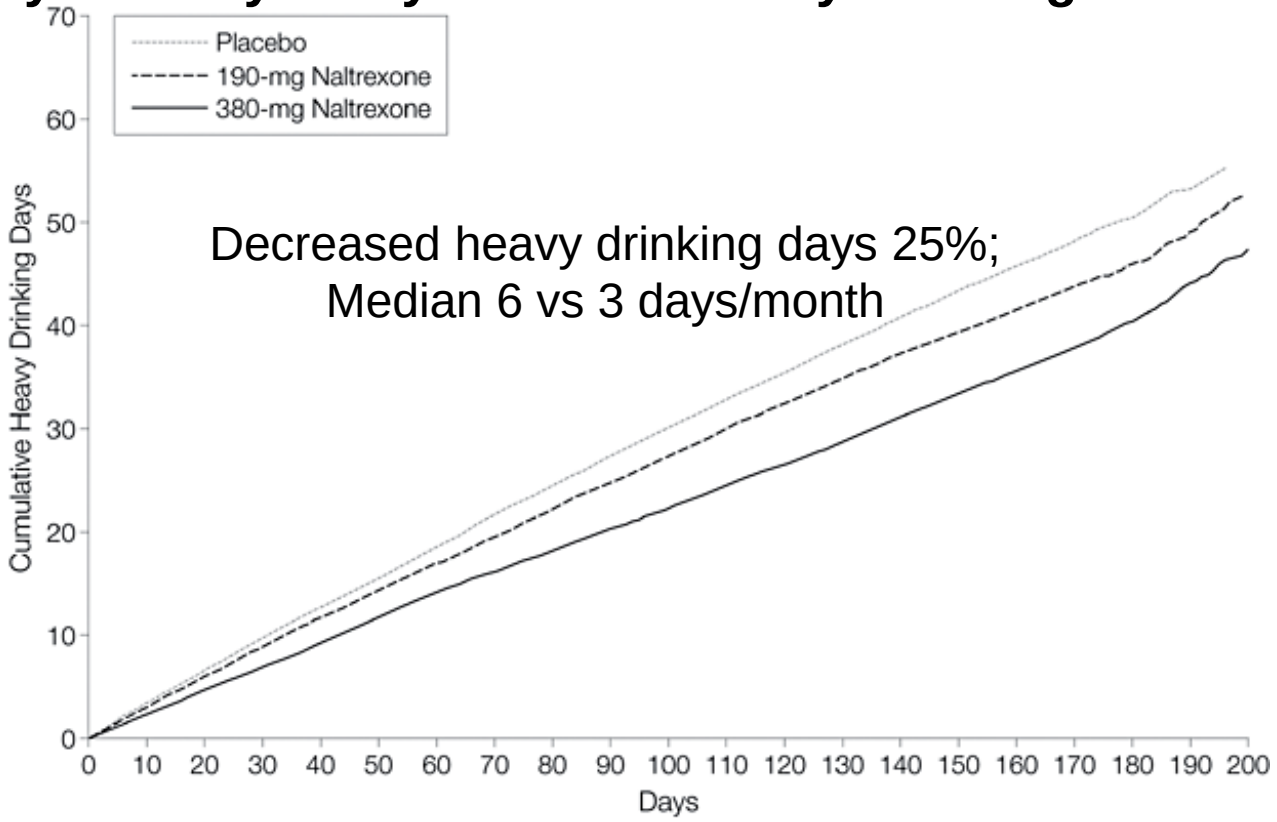
Injectable Naltrexone

Primary Efficacy Analysis: Mean Heavy Drinking Event Rate



Decreased heavy drinking days 25%;
Median 6 vs 3 days/month

Treatment Dose	1	2	3	4	5	6
No. of Patients						
Placebo	209	194	169	160	142	134
Naltrexone						
190 mg	210	187	169	156	144	137
380 mg	205	186	161	147	139	130

JAMA

Garbutt, J. C. et al. JAMA 2005;293:1617-1625.

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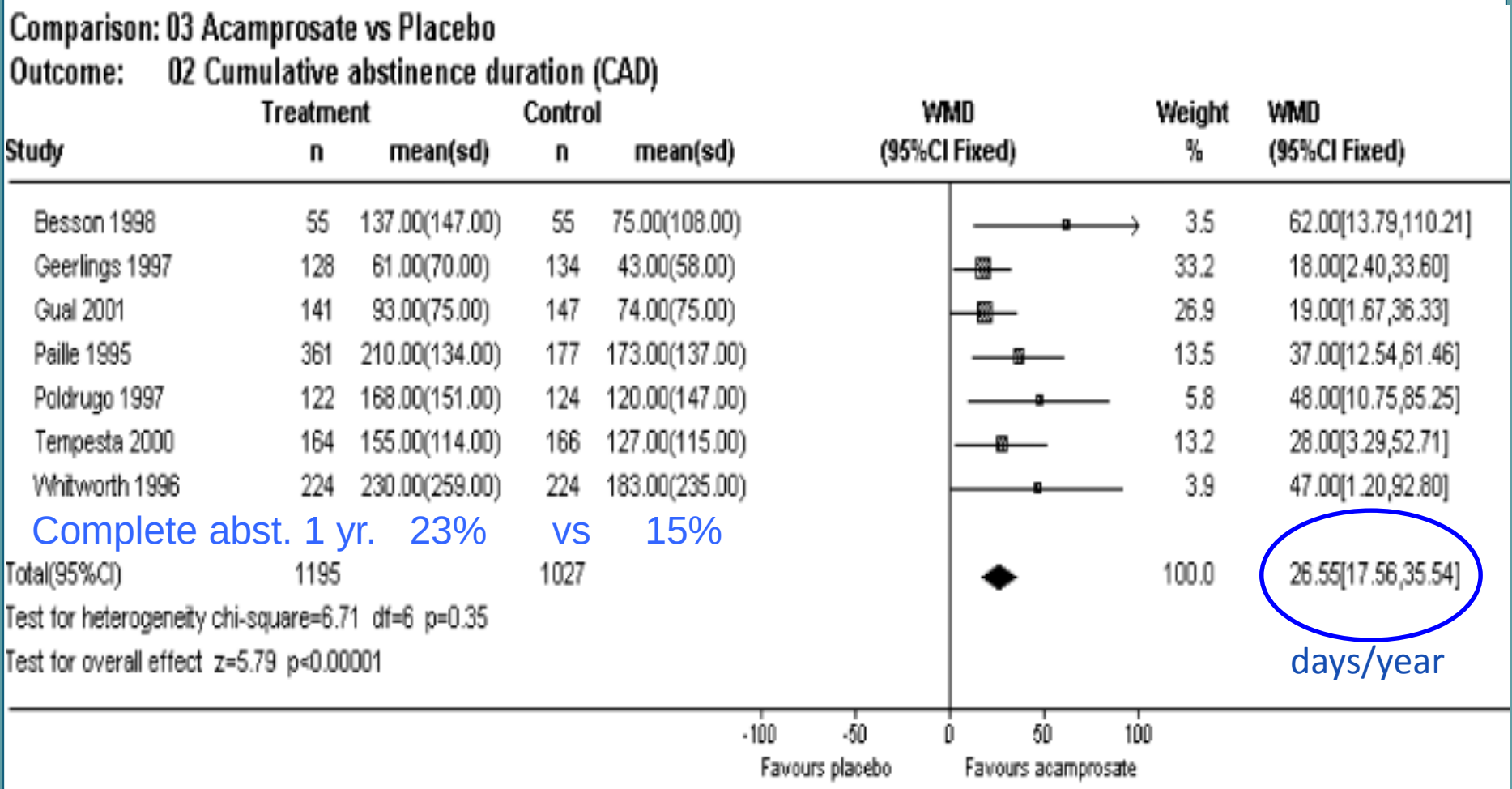
Prescribing Naltrexone

Naltrexone 12.5 mg/d-->25 mg/d-->50 mg/d or 380 mg IM per month

- Main contraindication: opiates, pregnancy
- Main side effects: nausea, dizziness

Efficacy of Acamprosate
"stabilizes activity in the glutamate system"



Bouza C et al. Addiction 2004;99:811

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ACAMPROSATE: COCHRANE REVIEW

- 24 RCTs, 6915 participants, compared to placebo decreased any drinking, cumulative abstinence duration
  - Any drinking RR 0.86 (95% CI 0.81 to 0.91); NNT 9.09 (95% CI 6.66 to 14.28)
  - Cumulative abstinence duration MD 10.94 (95% CI 5.08 to 16.81)
  - Secondary outcomes: GGT and heavy drinking NSD
- Diarrhea was the only side effect more frequent
  - 11% difference (95% CI 9 to 13%)

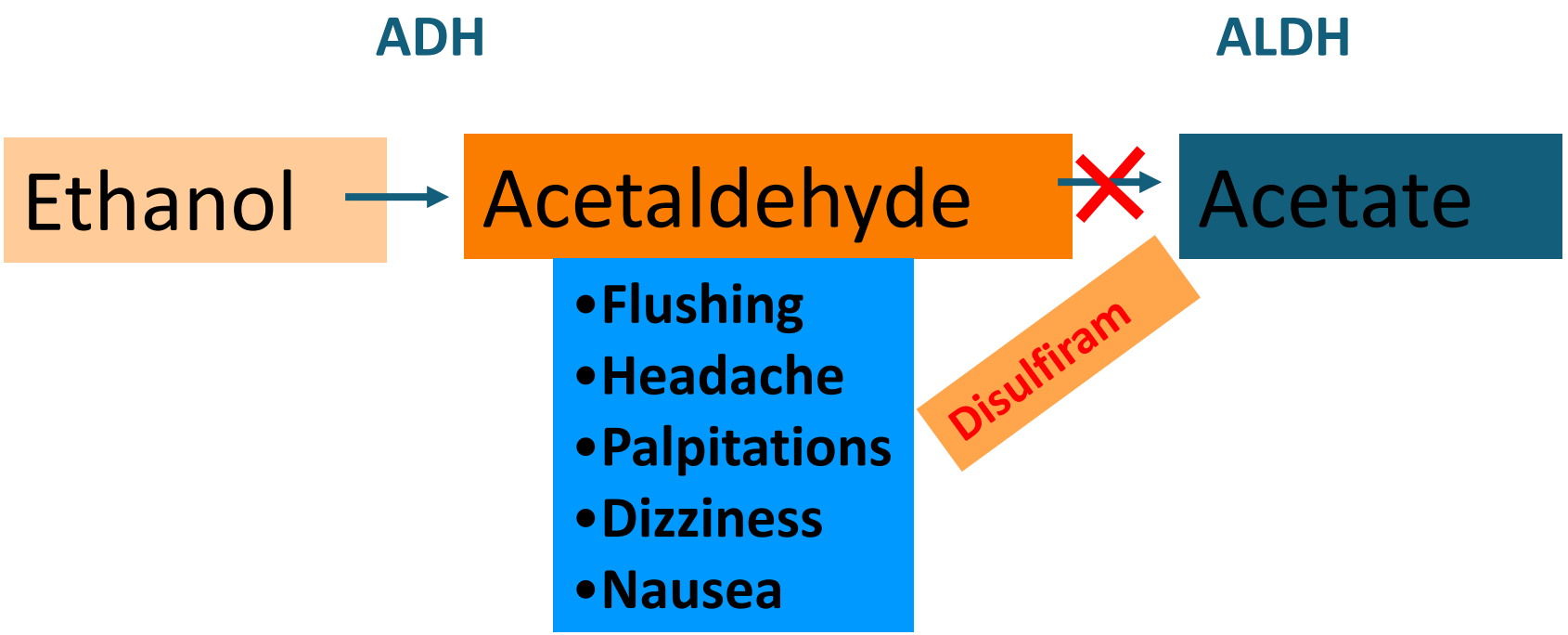
Rösner S, Hackl-Herrwerth A, Leucht S, Lehert P, Vecchi S, Soyka M. Acamprosate for alcohol dependence. Cochrane Database of Systematic Reviews 2010, Issue 9. Art. No.: CD004332. DOI: 10.1002/14651858.CD004332.pub2.

Prescribing Acamprosate

Acamprosate 666 mg tid

- Main contraindication:
  renal insufficiency
- Main side effect:
  diarrhea; pregnancy category C

Disulfiram



Disulfiram (DS)

2 RCTs
DS 250 mg; DS 1 mg (subtherapeutic); or riboflavin (in all).

DS groups informed about the DS-ethanol reaction; riboflavin not.

N = 605
20% adherent (15+ urines positive over a year, weekly/biweekly)
No differences between groups for abstinence

DS 250 mg--Fewer drinking days (subsample who drank, complete assessments)

N = 128 Abstinence:
DS groups 21%, 25%
Riboflavin 12%

Fuller RK & Roth HP. Ann Intern Med. 1979;90(6):901-904.
Fuller RK et al. JAMA 1986;256:1449

Monitored Disulfiram: Small Randomized studies

Author, Yr	Follow-up	Disulfiram	Abstinence
Gerrein, 1973	85%, 39%	Monitored Unmonitored	40% 7%
Azrin, 1976	90%	Monitored Unmonitored	90-98% 55%
Azrin, 1982	100%	Monitored Unmonitored	73%* 47*
Liebson, 1978	78%	Monitored Unmonitored	98% 79%

Length of follow-up: Gerrein 1973: 8 weeks; Azrin 1976: 2 years, Azrin 1982: 6 months; Liebson 1978: 6 months.

*Thirty-day abstinence at 6 months.

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Prescribing Disulfiram

Disulfiram 250 mg/d-->500 mg/d

- Main contraindications:
  recent alcohol use, cognitive impairment, risk of harm from disulfiram--ethanol reaction, drug interactions, pregnancy, rubber, nickel or cobalt allergy
- Main side effects:
  hepatitis, neuropathy

The following medications are not approved by the FDA for the treatment of alcohol use disorder

Likely effective: topiramate (7 RCTs).

May be effective (a few RCTs):
ondansetron, gabapentin, varenicline, buspirone (if anxiety), SSRI (e.g. fluoxetine) if depression*

Not ready for prime time:
baclofen (1 positive, several negative trials), rimonabant (1 trial; not available)

*Systematic review suggests no effect on alcohol in comorbid anxiety, depression

Nunes EV, Levin,FR JAMA. 2004;291(15):1887-1896. doi:10.1001/jama.291.15.1887.

Prescribing Topiramate

25 mg hs, increase by 25-50mg each week and dose bid. Target 200 mg. May respond to lower doses

- Main contraindication: Narrow angle glaucoma, kidney stones, renal or hepatic impairment, severely underweight, use of CNS depressants.
- Main side effects: Paresthesias, taste perversion, anorexia, weight loss, somnolence, cognitive dysfunction; pregnancy category C

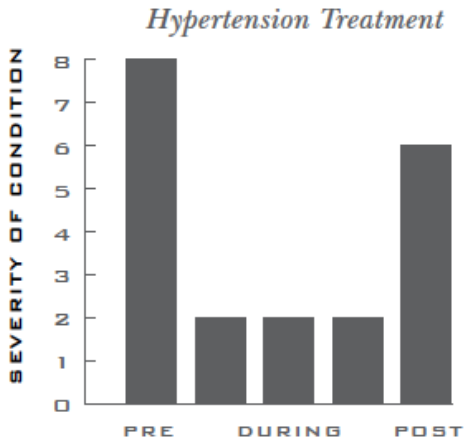
Alcohol use disorder treatment effectiveness

- At one year, 2/3^{rds} of patients have a reduction in
  - alcohol consequences (injury, unemployment)
  - consumption (by 50%)
- 1/3rd are abstinent or drinking moderately without consequences

Miller WR et al. J Stud Alcohol 2001;62:211-20
Anon. Journal of Studies on Alcohol 1997;58:7-29,
O'Brien CP, McLellan AT. Lancet 1996;347:237-240 and JAMA 2000:284:1689-95.

SUMMARY

- Benzodiazepines for withdrawal; individualize
- Pharmacotherapy, for as long as needed (see figure)
  - Efficacious though modest; future promise for individualization
    - Naltrexone
    - Acamprosate tid (renal), disulfiram (monitored), topiramate (SEs)
    - Maybe ondansetron (early onset), gabapentin, varenicline
  - Targeted (prophylactic) may be effective; pharmacogenetics?
  - Psycho-social or medical-type counseling
    - Address depression and anxiety, social needs



HOW DO I TEACH THIS?

INTEGRATE

- Morning report case of WD
- Ambulatory case for pharmacological management
- Journal club re RCTs

TEACHING POINTS

- BZD for WD
- Prescribe pharmacotherapy
- Keep current