

UNIVERSAL PRECAUTIONS
FOR PRESCRIBING
CONTROLLED SUBSTANCES

Mary G. McMasters, MD, FASAM

- Board Certified Addiction Medicine
- Board Certified Hospice and Palliative Care
- Co-Medical Director Project REMOTE
- Expert Witness USDOJ
- Old Country Addictionologist

CONTACT INFORMATION

- 540-941-2500
- mcmaste1@msu.edu
- 57 N. Medical Park Dr. Box 105
Fishersville, VA 22939
- Physician Clinical Support System Mentor,
SAMHSA, www.PCSSmentor.org

Why be concerned about your
controlled substance prescribing
practices?

- Epidemiology- we have a staggering epidemic of prescription substance misuse
- Lethality- many people are dying due to substance abuse
- Cost- the price of substance misuse is a major contributor to the national debt
- Legality- prescribers are being scrutinized regarding their prescribing practices
- Pain continues to be poorly managed
- Prescriber Burn-Out

Epidemiology

- While there are more opioid deaths in SW Virginia, no part of the state is immune to the Substance Abuse Epidemic
 - Equal amounts of abuse throughout the state
 - More lethal substances being used in SW Virginia

Lethality

- In 2006, 12.5/100,000 Virginians died in MVAs*
- In 2007, 11.3/100,000 Virginians aged 35-54 died due to drug poisoning (most polypharmacy deaths involving opioids)**
- opioid dependent patients 13x more likely to die than their age- and sex- matched peers in the general population***
- "Among people age 35 to 54 years old, unintentional poisoning surpassed motor vehicle crashes as the leading cause of death in 2005"****

*Kaiser State Health Facts <http://www.statehealthfacts.org/profileind.jsp?cat=2&sub=35&rqn=48>

**DAWN https://dawninfo.samhsa.gov/files/ME2007/ME_07_state.pdf

*** Gibson A, Degenhardt L, Mattick RP, et al. (2008). Exposure to opioid maintenance treatment reduces long-term mortality

****Reuters, "Prescription Drug Overdoses on the Rise in U.S." Tuesday, April 06, 2010, Associated Press FOX News Network



Cost

- Treated and untreated substance use including ETOH: 62 Billion dollars in 2008 for healthcare alone (more in crime and welfare costs)*
- Audit of five large states 2006-7 found 65,000 Medicaid recipients improperly obtained potentially addictive drugs- \$65 million dollars**
- 938,586 urine drug screens from over 500,000 patients prescribed chronic opiates showed only 25% taking their medications as directed***

*Chalk, Mady, "Medical Costs of Unrecognized, Untreated substance Dependence: A Case for Health Reform", Behavioral Health Central, 2009

**Kiely, Kathy, "GAO report: Millions in fraud, drug abuse clogs Medicaid, 2009. <http://www.usatoday.com/news/health/2009-09-29-Medicaid-drug-abuse-fraud.htm>

***Leider, Couto, Population Health Management 9/3/2009

Legality

- The DEA **IS NOT** out to get you.
- The State Board of Medicine **IS NOT** listening outside your door

HOWEVER

You **CAN** get into trouble for failing to practice good medicine when prescribing controlled substances

From a VA Board of Medicine's Order of Summary
Suspension 8/19/2009

- Dr. X prescribed BNZs and narcotics...without an adequate medical indication or diagnosis, developing and adequate treatment plan, performing urine drug tests... commenced prescribing narcotics without obtaining prior treatment records to verify.....
- Dr. X failed to appropriately respond to signs that the patient was misusing or abusing his medications (controlled substances)
- Failure to refer for substance abuse treatment
- Dr. X prescribed Suboxone to treat the patient's narcotics addiction even though he was not qualified or registered to dispense narcotic drugs for addiction treatment as required by Federal law and regulation (Controlled Substance Act of 1970, 21 U.S.C.801 et.seq. and Federal Regulations 21 C.F.R. 1306.04 and 1306.07).

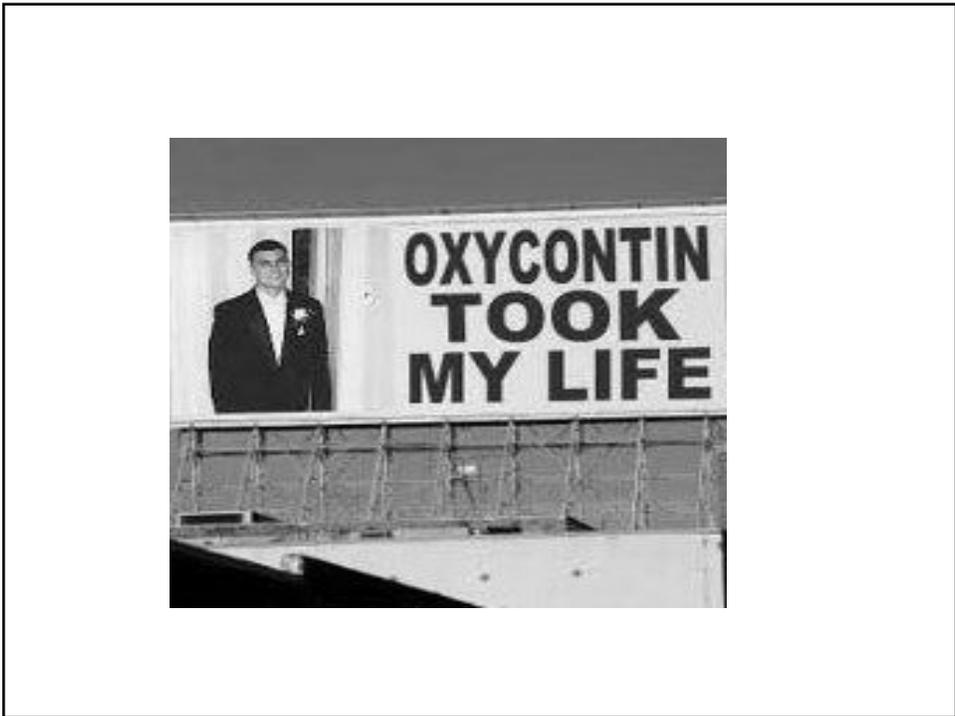
THE GOOD NEWS

- Substance Abuse and Diversion are preventable
- Addiction is treatable
- Health Care Reform includes measures to address the Addiction epidemic

OUR COMMUNITY...OUR RESPONSIBILITY

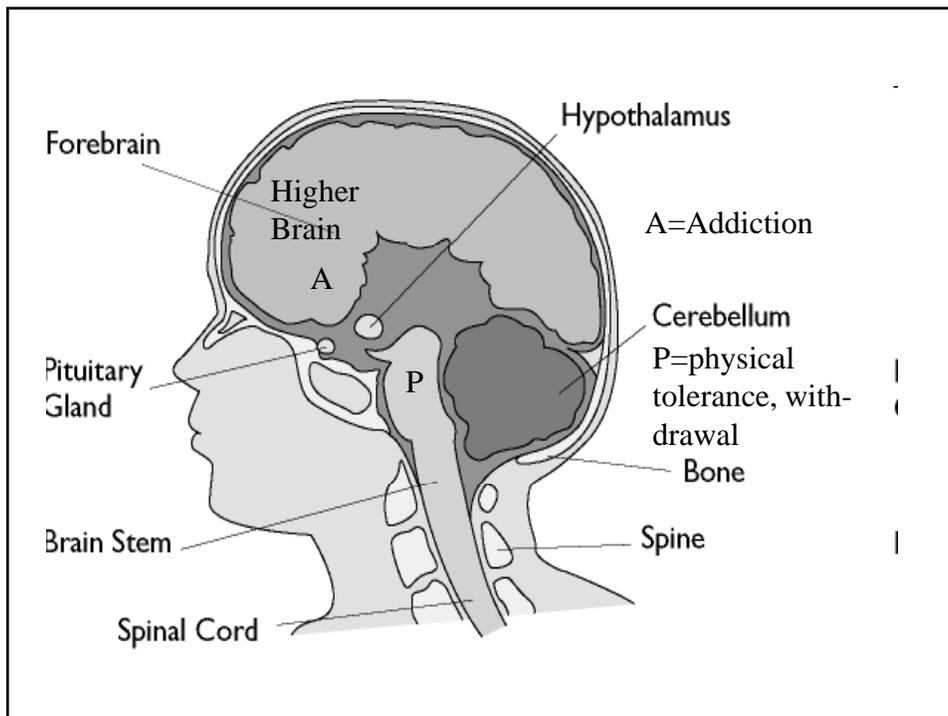


Appalachian Substance Abuse Coalition for Prevention & Treatment



DEFINITIONS

- Physiological Adaptations to Medications
 - Tolerance
 - Withdrawal
- Substance Misuse Disorders
 - Diversion
 - Substance Abuse
 - Addiction



Physical Adaptations

- Tolerance and Dependence
 - PHYSICAL
 - Physiological adjustment to MANY medications
 - Anti-depressants
 - Anti-hypertensives
 - NOT the same thing as addiction

Factoid

- It is ***AGAINST THE LAW*** to detoxify a patient addicted to opioids by using other opioids (unless the reason is to treat a separate medical condition).
- Detoxification only treats the physical dependence, NOT the Addiction
- Patients who are detoxified lose their tolerance to respiratory depression
- When they resume substance use, they are likely to die

*Heit HA; Dear DEA, Pain Medicine Vol 5 #3, 2004, 303-308

Substance Misuse Disorders

DIVERSION

- Obtaining mood altering substances under false pretenses and diverting them to other people
 - To get high
 - FOR PROFIT.
- **DIVERSION IS BIG BUSINESS!!!!**

SUBSTANCE ABUSE

- “the substance use is continued despite knowledge of having a persistent or recurrent physical or psychological (or social or occupational) problem that is likely to have been caused or exacerbated by the substance.”

ADDICTION

- “the substance use is continued despite knowledge of having a persistent or recurrent physical or psychological (or social or occupational) problem that is likely to have been caused or exacerbated by the substance.”
 - » *AND*
- “persistent desire or unsuccessful efforts to cut down or control substance use.”



THERE WAS A LOT OF
DIVERSION GOING ON DURING
THESE RIOTS:

- Underaged drinking (people over 21 were selling alcohol to minors)
- Ketamine was in use (diverted from veterinary use)
- Diverters (dealers) were making a lot of money (methadone is \$1/mg on the street)
- Drug dealers VERY SELDOM have the disease of addiction



THERE WAS A LOT OF
SUBSTANCE ABUSE GOING ON

- Fines
- Jail time
- Expelled from MSU
- ANGRY parents

These are effective in convincing substance abusers to quit or to be more responsible.



Some of these students have the
disease of ***ADDICTION***
(they cannot stop abusing mood
altering substances without help)

What Makes a Substance
Addictive or Psychoactive or
Reinforcing or Abuseable???

Natural Rewards

Food
Water
Sex
Nurturing



What is needed to trigger the natural reward center (elevate Dopamine) in the Forebrain?

- The substance must get into the blood
- The substance must cross the blood-brain barrier and get into the brain
- The substance must elevate Dopamine in the forebrain

How Quickly can you get chemicals into the blood?

- Swallowing- VERY Slow
- Rub on Mucosa- Slow
- Inhale- Fast
- Inject into Blood- VERY Fast

Well, This Is One Way Around That Pesky "Slow Release"

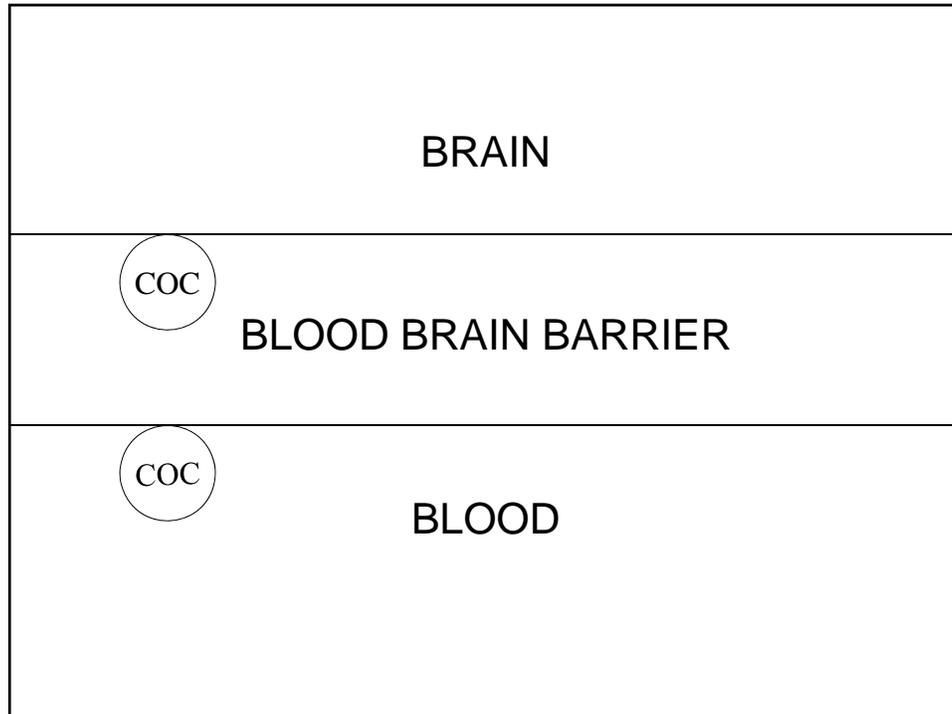


BRAIN

BLOOD BRAIN BARRIER

PCN

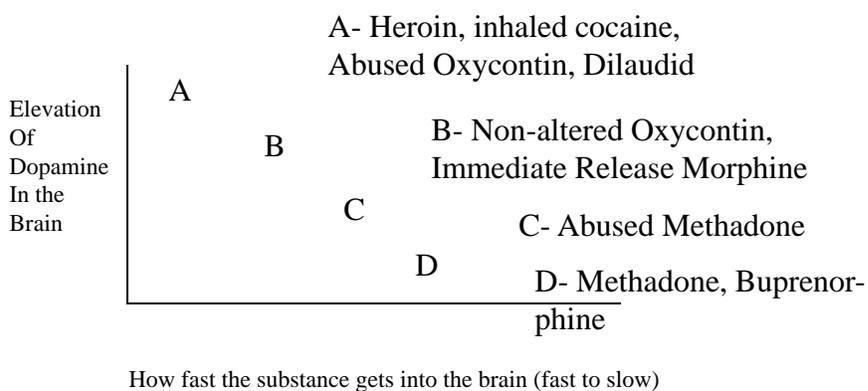
BLOOD



Once Inside the Brain, What do Substances of Abuse DO?

- Trigger the Natural Reward System
 - Increase Dopamine in the Forebrain
 - The FASTER
 - The HIGHER
 - THE MORE ADDICTIVE
- MANY more things than Abused Substances can trigger this system

Which Substance, A B C or D, is the most Addictive?



Street Value

- 100 Vicodin \$500-\$800
- 100 Xanax 2mg \$1,000
- 4 Fentanyl patches 100ug \$400
- 100 Dilaudid 8mg \$4-8,000
- 100 Oxycontin 80mg \$8-16,000
- Methadone 1\$ per milligram

* Beard, J Tobias, "Coke is the Real Thing: Fifty bucks and you're in with Charlottesville's favorite powder", C'VILLE CHARLOTTESVILLE NEWS & ARTS, 2/11/2008

Non-controlled substances with street value

- Muscle Relaxants
- Remeron
- HIV medications
- Prednisone

***It's not about the Substance.
It's about the Brain.***

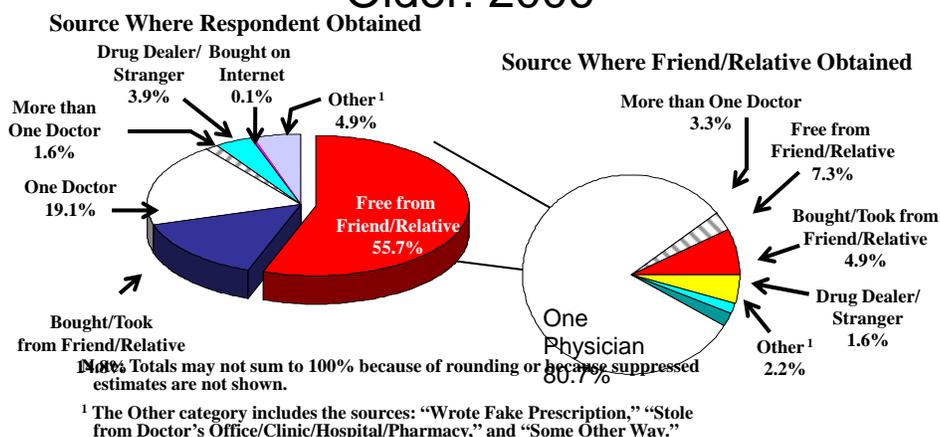
TRAMADOL

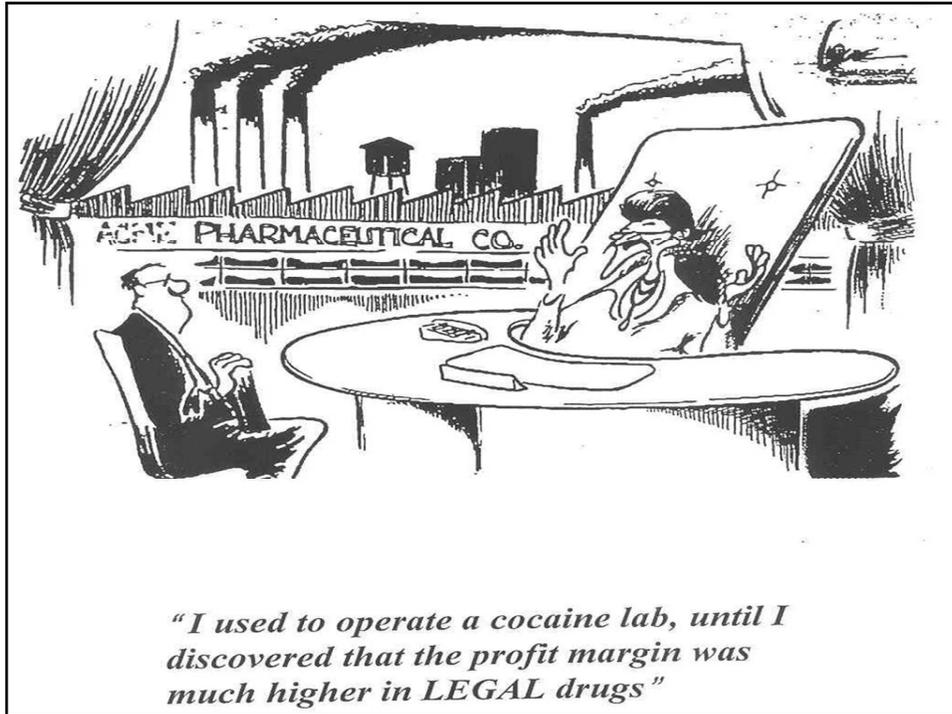
- **Hamas burns recreational drugs**
Associated Press 4/20/2010
- GAZA CITY, Gaza Strip
- GAZA CITY, Gaza Strip (AP) — Gaza's Hamas rulers on Tuesday burned nearly 2 million pills of a painkiller many Gazans take recreationally

Quality of Pain Control DOES NOT equal abuse-ability!!!!

- Vicodin- lousy for pain, great for abuse
- Methadone- great for pain, harder to abuse
- Cocaine and stimulants exacerbate pain

Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2006





What Changes Does Addiction
Make to the Brain?

Cops: Drunken horseman rides into crowd on Mule Day Updated 4/14/2010 1:03 PM ET
 COLUMBIA, Tenn. (AP) — A Middle Tennessee horseback rider was jailed after being charged with running into a crowd of people at the Mule Day festivities in Columbia. The man, 32, was charged with two counts of reckless endangerment and public intoxication.

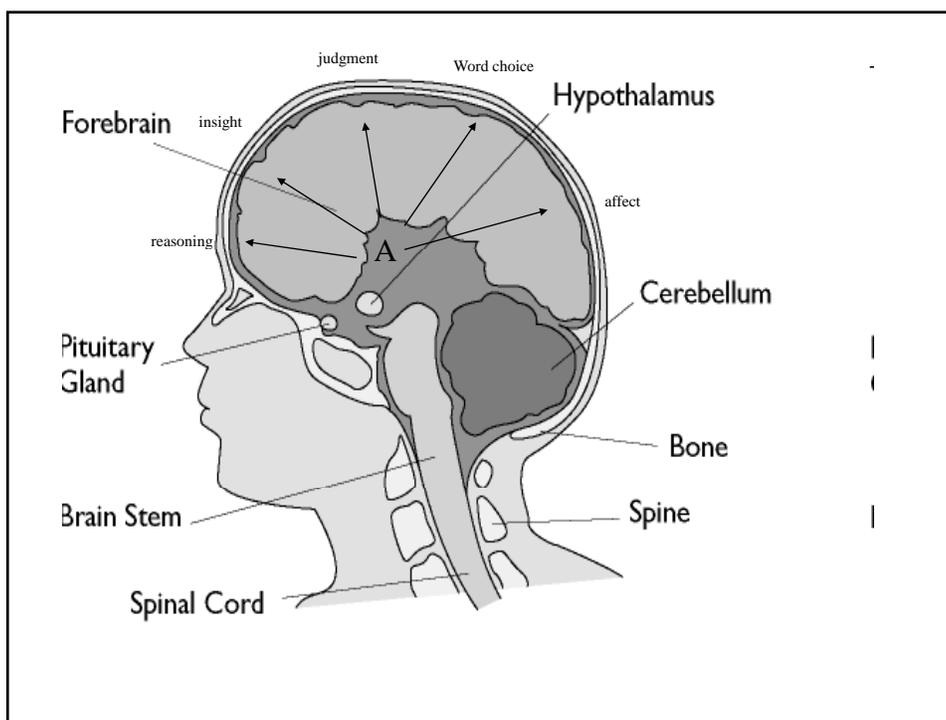
Cops: Man drove drunk to prison for DUI sentence

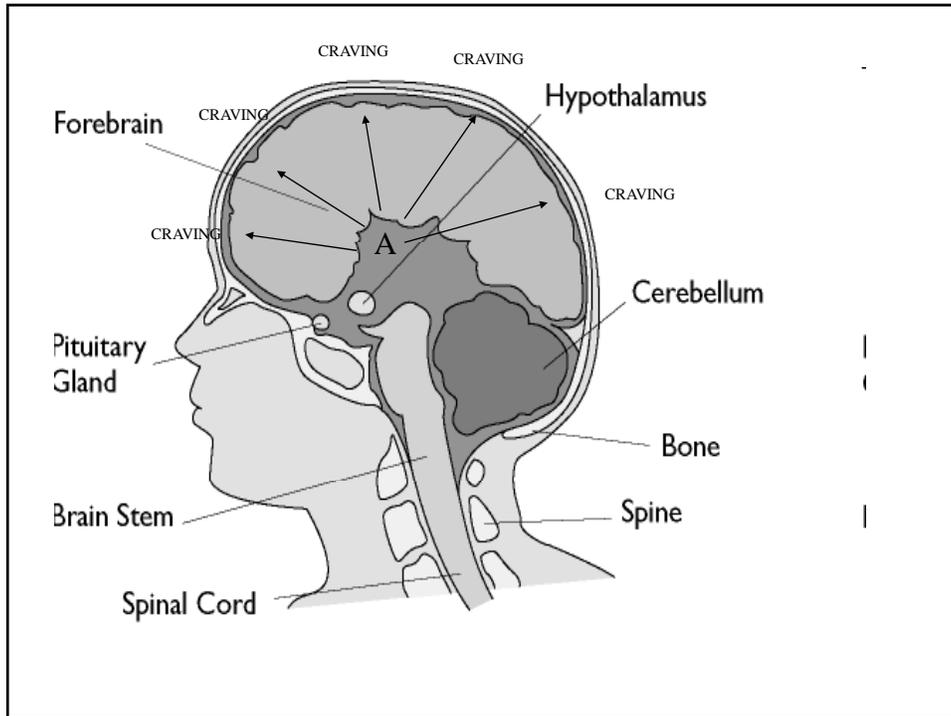
AP

SPRINGFIELD, Vt.

SPRINGFIELD, Vt. (AP) — Police said a Massachusetts man headed to a Vermont prison to serve a two-day sentence for driving under the influence was intoxicated when he drove himself to prison.

Man on mower charged with DUI, fishing pole theft Posted 4/14/2010 12:29 PM ET
 ATHENS, Tenn. (AP) — An East Tennessee man driving a lawn mower in the road has been charged with DUI. Athens police said 30-year-old Jimmy Graham Jr. smelled like alcohol and failed a sobriety test Monday after an officer spotted him on the lawn mower. He told the officer he had consumed a beer and taken a stress reliever prescribed to him.





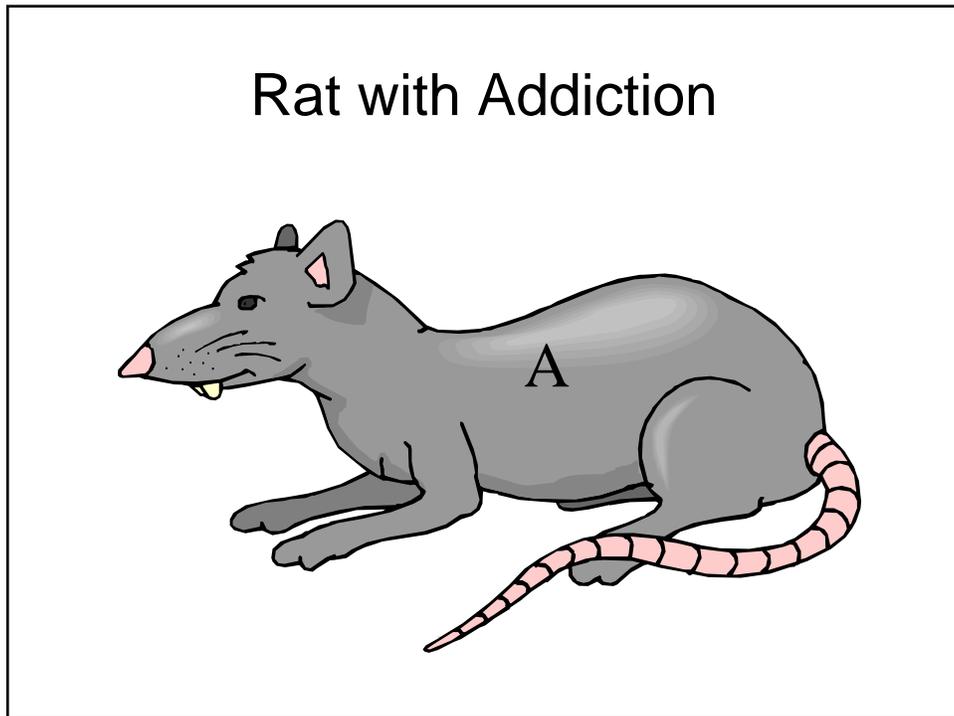
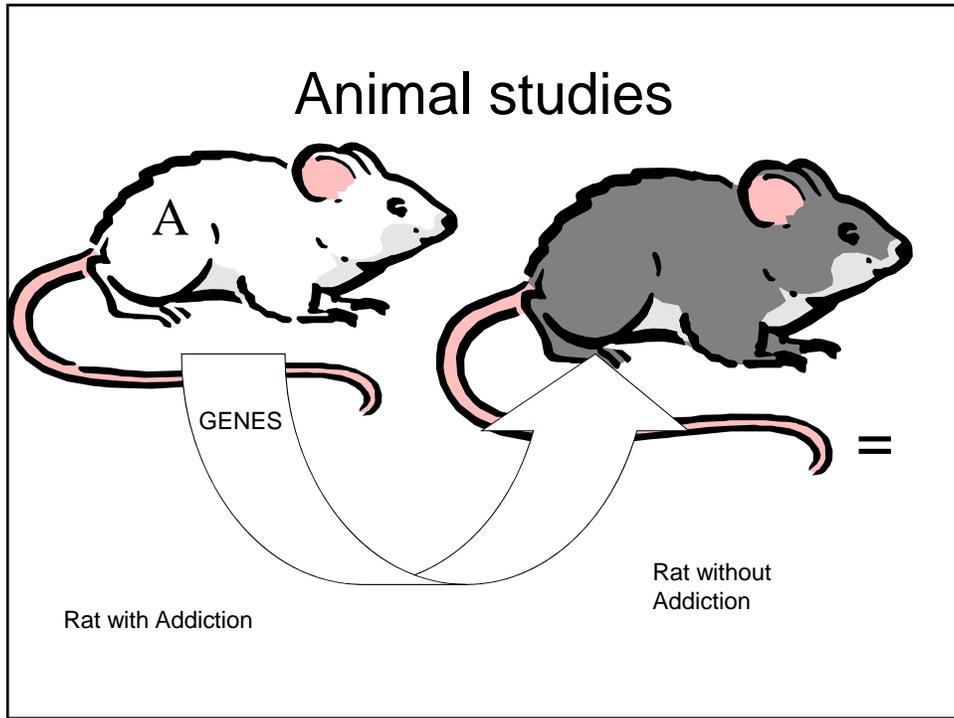
ADDICTION IS NOT
SUBSTANCE SPECIFIC!!!

In Animals AND Humans

- Addiction IS NOT Substance Specific
 - Preferences
 - Can't get one, will abuse the other
- Stereotypical patterns of behavior
 - Stimulant “runs”
 - Picking
 - Constant Use Patterns
 - Subtypes
 - Alcohol
 - Constant Use
 - Binge

What do you need to develop the disease of addiction?

- Genetic Predisposition
AND
- Exposure to Psychoactive Substances



Genetic Predisposition

- Some people get **a lot** of genetic predisposition
 - Some American Indian nations
 - 60% inherited
- Some people don't have any genetic predisposition
 - CANNOT become addicted
 - CAN become physically dependent

Exposure to Psychoactive Substances

- Long exposure to substances with low addictive potential
 - Many years of social drinking
 - Usually progresses from social to problem to addiction
- Short exposure to substances with high addictive potential
 - Snort cocaine, shoot heroin (or altered oxycontin)



Can people given pain medications for “real” pain develop the disease of Addiction?

YES!!!

Does that mean you shouldn't treat patients with Addiction, or the genetic predisposition to develop Addiction, opioid pain Medication?

NO!!!

Where to start?

**“It’s what you learn
after you know it all
that counts”**

Attributed to Harry S. Truman

- First: KNOW WHAT YOU DON'T KNOW!!!
 - Pain
 - Virginia Department of Health Professions
http://www.dhp.state.va.us/dhp_programs/pmp/default.asp
 - AMA
 - Diversion, Substance Abuse and Addiction
 - American Society of Addiction Medicine
 - Buprenorphine Waiver course (you don't have to prescribe to take the course)
 - SAMHSA
 - Federation of State Medical Boards

P	C	P	C	Physician Clinical Support System
S	S	S	S	
BUPRENORPHINE		METHADONE		
<p>PCSS...</p> <ul style="list-style-type: none"> ▪ answers questions about opioids, including methadone, for treatment of chronic pain ▪ answers questions about use of buprenorphine for treatment of opioid dependence 				

P	C	P	C	Physician Clinical Support System
S	S	S	S	
BUPRENORPHINE		METHADONE		
<p>PCSS...</p> <ul style="list-style-type: none"> ▪ is free, for interested physicians and staff ▪ is supported by SAMHSA through the Center for Substance Abuse Treatment (CSAT) and administered by the American Society of Addiction Medicine (ASAM) 				

P	C	P	C
S	S	S	S
BUPRENORPHINE		METHADONE	

Physician Clinical Support System

Ask a clinical question...

- get a response from an expert PCSS mentor
 - on line by email PCSSproject@asam.org
 - by phone 877-630-8812

From www.PCSSmentor.org...

- download clinical tools, helpful forms and concise guidance's (like FAQs) on specific questions

Where to start?

Second: Universal Precautions for Prescribing Controlled Substances (not just opioids, but ALL Controlled Substances)

- Every Patient
- Every Time
- No Exceptions
 - Not even your grandmother



Universal Precautions for Prescribing Controlled Substances

1. Have a “real” diagnosis: check the labs, look at the xrays, read the consultant reports
2. Try the less risky interventions first: PT, NSAIDS, etc. *TREATING PAIN WITH NON-NARCOTIC INTERVENTIONS IS TREATING PAIN.*

Con't

3. Get informed consent: Controlled Substance Agreement
 - Include Prescription Monitoring Program
4. UDS
 - Protects the patient AND YOU
 - Every patient
 - See Algorithm for frequency

Con't

5. Assess Risk Factors for Substance Misuse Disorders

- Family History
 - Addiction is a GENETIC disease
- Current Addiction
 - Smoking
- Behaviors symptomatic of a Substance Misuse Disorder
 - Legal problems, MVAs, DUIs, etc

Con't

6. Assess Functioning

7. Time limited Trial

- Expectations
 - No problematic behavior
 - IMPROVED FUNCTIONING

8. Exit Strategy

- See Algorithms

9. Periodic Reassessment

Con't

10. Prescribe the fewest number of pills possible with the lowest abuse potential

- DOCUMENT, DOCUMENT, DOCUMENT

THE BOTTOM LINE:

FUNCTIONING

- IF YOU ARE TREATING PAIN,
FUNCTIONING GETS BETTER
- IF YOU ARE FEEDING AN ADDICTION,
FUNCTIONING GETS WORSE

Urine Drug Screens

- For the BENEFIT of the patient, the physician and society
- NOT to “catch” people doing bad things
- Provide a “teachable” moment
 - Risks of substance abuse
 - Diagnose addiction and refer for treatment

UDS

- A few details about UDS:
 - Each laboratory is different
 - ALWAYS call and clarify unexpected results
 - They are very seldom WRONG
 - It never hurt anyone to pee in a cup

UDS

- WOULD YOU PRESCRIBE COUMADIN WITHOUT CHECKING AN INR?
- WOULD YOU PRESCRIBE INSULIN WITHOUT CHECKING A BLOOD SUGAR?
- THEN **DON'T** PRESCRIBE CONTROLLED SUBSTANCES WITHOUT DOING UDS

TREATING ADDICTION

- THE MAINSTAY OF ADDICTION TREATMENT IS ABSTINENCE COUNSELING
- 12 STEP PROGRAMS **ARE** EFFECTIVE AND COST EFFECTIVE
 - FREE
 - WIDELY AVAILABLE
- MEDICATIONS AS ADJUNCT

MEDICATION ASSISTED ADDICTION TREATMENT- primarily **decrease cravings**

- Medication- (FDA approved)
 - Nicotine
 - Varenicline
 - Nicotine Replacement
 - Alcohol
 - Acamprosate
 - Antabuse
 - Naltrexone (pills and injections)
 - Opioids
 - Methadone (Methadone Maintenance Therapy- MMT)
 - Buprenorphine

Barriers to Treating Opioid Addiction (some of many)

1. DEA Record Keeping and Inspections
2. Confidentiality
 - Employer provided insurance
3. Reimbursement
 - Discrimination
 - Now illegal, but it happens
4. It is MUCH easier to get drugs than to stop using them

REMEMBER THAT ADDICTION IS A CHRONIC LIFELONG DISEASE

If your “recovering” patient
isn’t utilizing abstinence
counseling, s/he ISN’T
recovering.

From a VA Board of Medicine’s Order of Summary Suspension 8/19/2009

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- Dr. X failed to appropriately respond to signs that the patient was misusing or abusing his medications (controlled substances)6,7,9
- Failure to refer for substance abuse treatment 8
- Dr. X prescribed Suboxone to treat the patient’s narcotics addiction even though he was not qualified or registered to dispense narcotic drugs for addiction treatment as required by Federal law and regulation (Controlled Substance Act of 1970, 21 U.S.C.801 et.seq. and Federal Regulations 21 C.F.R. 1306.04 and 1306.07).

FACTOID

References

- Anton et al, Combined Pharmacotherapies and Behavioral Interventions for Alcohol Dependence, The COMBINE Study: A Randomized Controlled Trial, JAMA 2006;295:2003-2017
- Federation of State Medical Boards
 - Report of the Center for Substance Abuse Work Group
 - Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office
- Buprenorphine in the Treatment of Opioid Dependence, www.aaap.org

More References

- Slides 8 & 9 courtesy of Brian H. Reise, Diversion Group Supervisor
DEA, Greensboro Resident Office
(336)-547-4219, Ext. 30
- The Economic Costs of Drug Abuse in the United States
1992–2002 Office Of National Drug Control Policy
http://www.whitehousedrugpolicy.gov/publications/economic_costs/

More References

- USDHHS, Office of the Surgeon General, “At a Glance, Suicide in the United States”, <http://www.surgeongeneral.gov/library/calltoaction/fact1.htm>
- Source: Mokdad, Ali H., PhD, James S. Marks, MD, MPH, Donna F. Stroup, PhD, MSc, Julie L. Gerberding, MD, MPH, "Actual Causes of Death in the United States, 2000." Journal of the American Medical Association, March 10, 2004, Vol. 291, No. 10, pp. 1238, 1241.

More References

- Hojsted J, Sjogren P; European Journal of Pain 11 (2007) 490–518 2006 European Federation of Chapters of the International Association for the Study of Pain. Published by Elsevier Ltd. doi:10.1016/j.ejpain.2006.08.004
- <http://www.facebook.com/asacpt>
- <http://www.youtube.com/watch?v=aYygjK9A5CM&feature=related>

**UNIVERSAL PRECAUTIONS FOR
PRESCRIBING CONTROLLED
SUBSTANCES^[i]:
EVERY PATIENT, EVERY TIME**

- IDENTIFY: Ask for picture identification. Confirm the diagnosis
- Try the less risky interventions for pain first: PT, NSAIDS, etc. *TREATING PAIN WITH NON-NARCOTIC INTERVENTIONS IS TREATING PAIN.*
- Get informed consent: Controlled Substance Agreement. This should always include permission to query the Virginia Prescription Monitoring Program.
- Do a UDS. This protects the patient AND YOU.
- Assess Risk Factors for Substance Misuse Disorders
 - Family History (Addiction is a GENETIC disease)
 - Current Addictions (This includes smoking)
 - Behaviors symptomatic of a Substance Misuse Disorders (Legal problems, MVAs, DUIs, etc)
- Assess Functioning
- Do a Time limited Trial (Expectations: No problematic behavior, IMPROVED FUNCTIONING)
- Have an Exit Strategy (know how to wean what you start; know where to refer patients with substance misuse problems)
- Periodic Reassessment
- Give the fewest number of pills possible with the lowest abuse potential
- DOCUMENT, DOCUMENT, DOCUMENT

THE BOTTOM LINE:

FUNCTIONING

IF YOU ARE TREATING PAIN, FUNCTIONING GETS BETTER
IF YOU ARE FEEDING AN ADDICTION, FUNCTIONING GETS WORSE

[i] Adapted from Gourlay

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