Prescribing Controlled Drugs During a RXDA Epidemic: *Balancing SAFE Practice Principals*

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Disclosures

None

Terms

- Tolerance
  - The development of a need to take increasing doses of a medication to obtain the same effect; tachyphylaxis is the term used when this process happens quickly
- Dependence
  - The development of substance specific symptoms of withdrawal after the abrupt stopping of a medication; these symptoms can be physiological only (ie, absence of psychological or behavioral maladaptive patterns)

Terms: Addiction (Substance Use Disorder: moderate or severe)

- The development of a maladaptive pattern of medication use that leads to clinically significant impairment or distress in personal or occupational roles. This syndrome also includes *a great deal of time used to obtain the medication, use the medication, or recover from its effects; loss of control over medication use; continuation of medication use after medical or psychological adverse effects have occurred*

Substance Use Disorder DSM-V

- Tolerance*
- Withdrawal*
- More use than intended
- Craving for the substance
- Unsuccessful efforts to cut down
- Spends excessive time in acquisition
- Activities given up because of use
- Uses despite negative effects
- Failure to fulfill major role obligations
- Recurrent use in hazardous situations
- Continued use despite consistent social or interpersonal problems

* ? not counted if prescribed by a physician

Severity measured by number of symptoms; 2-3 mild, 4-6 moderate, 7-11 severe

Substance abusing or addictive brains = High Risk Brains **(I am sorry but they just are!!!)**

- Substance use disorder mild (Substance Abuse) = planned binge – type use patterns
  - Higher risk
  - Phase or time of life
  - Behavior not a disease
- Substance use disorder moderate or severe = intermittent, inconsistent, unpredictable, repeated loss of control over the use of a euphoria producing drug / "high risk" drug / controlled prescription drug; resulting in repeated adverse consequences
  - Highest risk
  - With craving for the drug when absent
  - Disease, 60% genetic, 20% environment, 10-14% life time prevalence
  - Higher in some groups (trauma / *psychiatric patient populations)*

Substance Use Disorder Moderate to Severe: predictable natural history

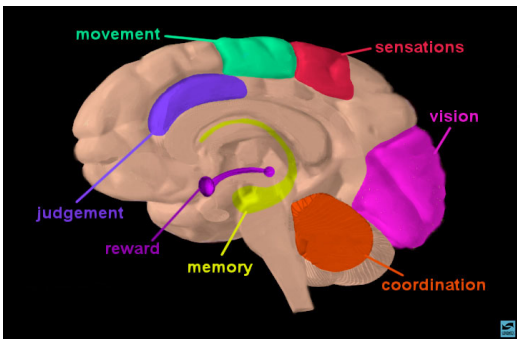
- A cascade of increasing dysfunction and disability in the following domains:
  1. ***Self image***
  2. ***Interpersonal***
  3. ***Social***
  4. ***Financial***
  5. ***Legal***
  6. ***Work***
  7. ***Physical***

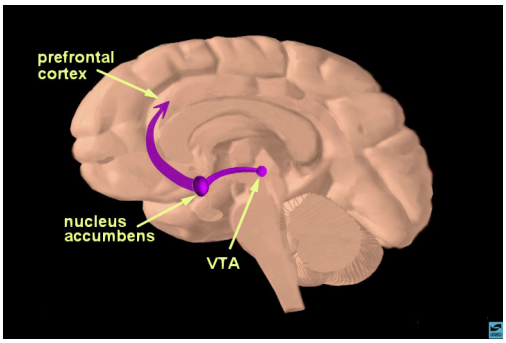
SUD: from natural history to morbidity and mortality: the unspeakable toll

- Tobacco dependence – contributes to 20% USA annual mortality
- Tobacco dependence kills 1/3 and maims 1/3 of users
- Other addictions-
  - ***DEATH***: 700% increased annual mortality risk
  - ***FAMILIES***: 50% divorce, 70% domestic violence, 75% child abuse/neglect, >80% childhood sexual abuse.
  - ***SELF HARM***: 40-50% of successful suicides, 40-80% of level I trauma
  - ***FINANCIAL***: productivity
  - Not to mention all of the other medical complications / organ damage

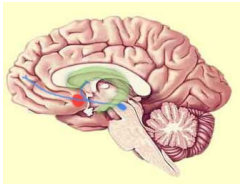
Euphoria Producing Drugs = EPD's

- EPD's include: opioids, stimulants, sedative-hypnotics, cannabinoids, and PCP / ketamine /etc
- Very different substances
- Totally different primary brain effects
- ALL produce an acute surge of dopamine from the mid brain to the fore-brain
- ***Dopamine surges mediate addictive disease***
- High Risk Medications (***sorry***, but they just are!)



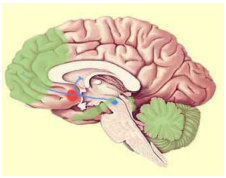


The Pleasure Centers Affected by Drugs: Cocaine and ALL stimulants



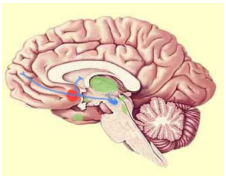
- Cocaine and amphetamines concentrate in the central link of the reward circuit (the ventral tegmental area and the nucleus accumbens). These areas contain especially high concentrations of dopaminergic synapses, which are the preferred target of these drugs.

The Pleasure Centers Affected by Drugs: Alcohol, Benzos and Barbs



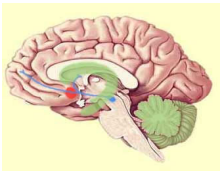
- Alcohol and other sedative-hypnotic drugs affect not only the basic structures of the reward circuit, but also several other structures that use GABA as a neurotransmitter. GABA is one of the most widespread neurotransmitters in several parts of the brain, including the cortex, the cerebellum, the hippocampus, the amygdala, and the superior and inferior colliculi.

The Pleasure Centers Affected by Drugs: Opioids

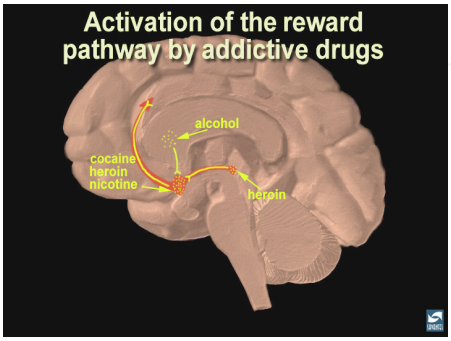


- Opioids act not only on the central structures of the reward circuit (the ventral tegmental area and the nucleus accumbens), but also on other structures that are naturally modulated by endorphins. These structures include the amygdala, the locus coeruleus, the arcuate nucleus, and the periaqueductal grey matter, which also influence dopamine levels, though indirectly. Opiates also affect the thalamus, which would explain their analgesic effect.

The Pleasure Centers Affected by Drugs: Cannabis

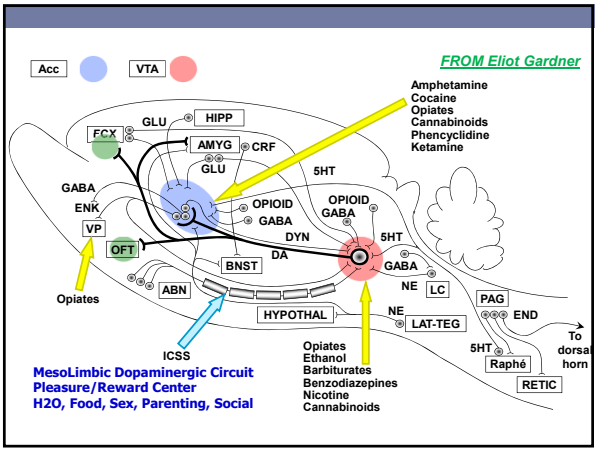


- The active ingredient in cannabis is THC, which concentrates chiefly in the ventral tegmental area and the nucleus accumbens, but also in the hippocampus, the caudate nucleus, and the cerebellum.
- THC's effects on the hippocampus might explain the memory problems that can develop with the use of cannabis, while its effects on the cerebellum might explain the loss of coordination and balance experienced by people who indulge in this drug.



Controlled drugs ARE Euphoria Producing Drugs: **CRx = EPD's**

- So why do you have to put your DEA # on it?????
- So why do controlled drug RX cause such a high risk of relapse of addictive disease?
- So what does this mean for clinical practice … … …
  - High Risk Brains + High Risk Drugs = ***High Risk Behaviors***
  - SUD patients + *chronic* CRX = high risk of problem patient behaviors and patient / family / community / Rxer ***harm***.



So isn't this just ***obvious***?
(and why spend a lovely day going over it)

- "Like … don't prescribe long term outpatient addictive and abuse-able medications to patients who are abusers or addicted"
- Perhaps it is obvious … but haven't you seen it done?
- Several data points: 1992 / 1998 / 2007 / 2016

1992 Inner City Medical Clinic

- "Physician Failure to Record Alcohol Use History When Prescribing Benzodiazepines."

Graham AV, Parran TV: Journal of Substance Abuse 1992. 4:179-185

- Little evidence of SUD screening in medical records prior to initiating long term benzodiazepine prescription

1998 University Affiliated Large County Teaching Hospital

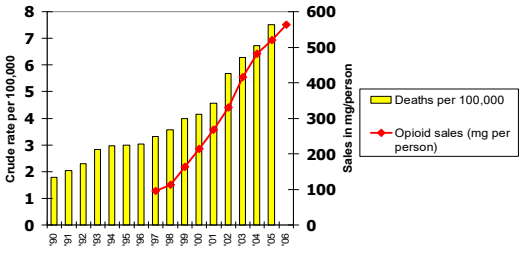
1. > 7000 Out Patients interviewed for SUD (alcohol problems)
2. Inpatient & Outpatient Medical Record Review for SUD documentation
3. Outpatient Medical Record Review for prescribing of CRX

- **Second strongest predictor of receiving a CRX = having SUD documented in the medical record and having a Resident Physician as the doctor**
- ***Strongest predictor* of receiving a CRX = having a SUD documented in the medical record and having an Attending Physician as the doctor**

2007

Deaths per 100,000 related to unintentional overdose and annual sales of prescription opioids by year, 1990 - 2006

Source: Paulozzi, CDC, Congressional testimony, 2007



January *2016 – Annals of Int Med*

- *90% of patients **continued to receive** prescription opioids **after** an accidental overdose was recorded in the chart*
- >20% received a higher dose within 6 months
- Opioid discontinuation after overdose was associated with lower risk for repeated OD

Annals of Internal Medicine • Vol. 164 No. 1 • 5 January 2016

March 2016 - JGIM

- Benzodiazepines are Prescribed More Frequently to Patients Already at Risk for Benzodiazepine-Related Adverse Events in Primary Care.
- J Gen Intern Med. 2016;31(9):1027-1034 March 2016

Controlled drug prescribing trends 1989 - 2019

- 1985-2013 > 500% increase in opioid prescribing in the US
- 2014 – 2019 ~ 40% decrease in opioid prescribing from peak in 2013 in Ohio
- 2013-2019 ~ 30% increase in benzodiazepine prescribing in Ohio
- 2013-2019 ~40% increase in psychostimulant prescribing in Ohio

Controlled Drug Presribing Trends: 2021-2022

- Current Rumors and Assertions:
  - Use of Adderall or Vyvanse to "treat" stimulant addiction
  - Prescribing of benzodiazepines and/or psychostimulants to patients on buprenorphine or methadone OTP
  - "Medical MJ" to treat opioid addiction
  - "Little evidence for the abuse of or addiction to prescribed psychostimulants in weight loss"
- Beware: The prescriber who forgets history is likely to repeat it!!! (and may get into trouble)

HOW COULD THIS BE? Perpetuation of status quo

- **HRB's** REALLY REALLY REALLY **want** high risk drugs: RXer-Pt relationship / communication challenge
- Screening for HRB **poorly & rarely** done
  - Good Screens are incompletely / rarely used
- Un-appreciated contraindications (death/jail/etc)
- Blurring of basic ethical tenants of doctoring
  - Above all, first do no harm … **then** comfort always
- Lack of knowledge of *SUD dopamine surge nexus*

CRx Prescribing Decisions:
Avoid High Risk Drugs with High Risk Brains

- Any prescribing decision involves:
  - Indications – establishing the reason to RX
  - Contraindication – screening for reasons not to RX
  - Clinical reasoning – comparing risks v. benefits
- Contraindication screening requires K,A,S.
  - K=clinically understanding contraindications
  - A=respecting the gravity of contraindications
  - S=using screening tools to ID contraindications **and** communication skills to maintain your boundaries
- K,A,S are ***ALL*** needed for safe CRx prescribing

Chronic OPT Prescribing of CRX

- Who **TO** prescribe to?
  - **Presence** of **Indications** – patient specific and disease specific
    AND
  - **Lack** of **Contraindications**
- Who **NOT TO** prescribe to?
  - Lack of **indications**
    OR
  - Presence of **contraindications** **(even if indications exist)**

Contraindications to chronic CRX TX

- Highest Risk Brains (HRB)***:
  - **Current addictive disease = strong contraindication**
  - **Past addictive disease = strong contraindication**
  - **History of diversion = strong contraindication**
- Risky Brains (SUD MILD) = relative contraindication
- Significant nonadherence = relative contraindication
- Substantial psychiatric co-morbidity = relative contraindication
- COPD &/or Obst Sleep Apnea = relative contraindication

***** Prescribe chronic C RX to HRB's only with expert advice and support (i.e. a methadone or buprenorphine clinic)**

Indications for *possible* ***chronic*** CRX
Use Universal Precautions
ASK THE 5 QUESTIONS OF Ted Parran

1. Is there a clear diagnosis? (in your scope of practice?)
2. Is there documentation of an adequate work-up?
3. Is there impairment of function?
4. Has non-CRX multi modal therapy been tried & failed?
5. Are contraindications to CRX therapy ruled out?

- IF "yes to ALL 5" then ***consider*** CRX TX …
- **Always** use an Informed Consent Form!
- Be sure to **Document** & **Monitor**!
- Avoid poly-pharmacy *of controlled substances*

Prescribing Controlled Drugs: ruling out addiction (**Team** WORK)

- Perform an AUDIT (questionnaire) and CAGE-AID with pt
- Ask family or sig. other the f-CAGE (Informed Consent)
- Do an initial toxicology test
- Inquire of prior prescriber re: use of controlled prescriptions, general adherence patterns, etc.
- Check the PMP report, *and* local pharmacy print out

If screen is + for current or prior addiction = High Risk Brain … so the decision *should* be obvious!

The "Family / Significant Other Interview"

- Requires a **TEAM** and **Systems** approach:
  - Somebody gets consent to call (Informed Consent Form)
  - Somebody calls and asks the "6 Functional Assessment ?'s"
    1. What can __ do now?
    2. What could ___ do before this DX (pain/anxiety/insomnia/ADD)?
    3. What does the family hope ___ will be able to do if we can help?
    4. Has ___ **C**utback on use of alcohol or other drugs?
    5. Has ___ been **A**nnoyed by comments re: alc / drug use?
    6. Has ___ felt **G**uilty or embarrassed about actions/words when using?

Monitoring strategy when prescribing OPT CRx – **Team** Work = ***"universal precautions"***

- Informed Consent Form – require adherence with TX Plan
- Document functional improvement – pt and family
- ROI for ANYONE you think is needed (What if they say NO?)
- Titrate RX to improved function
- Monitor medications (pharmacy profile printout, OARRS)
- Avoid non-planned escalation – "nonadherence"
- Monitor for scams (***NO early refills***)
- Perform occasional toxicology tests
- Document, document, document! (**Flow sheet**)

Diagnosing Aberrant Prescriber - Pt Relationships: the Heart Sink Patient!!!!

- The ***"HEART SINK"*** Patient
- Differential Diagnosis
  - Borderline personality disorder
  - Somatiform disorder
  - ******* **Addiction** *******
  - Family disturbances / Chemical Coping
  - Criminal intent – "a true capitalist!"

Passik SD, et al. *Oncology*. 1998;12:517-22.
Portenoy RK, Savage SR. *J Pain Symptom Manage*. 1997;14:S27-35.
Passik SD, Weinreb HJ. *Adv Ther*. 2000;17:70-83.
Portenoy RK, Payne R. In: *Substance Abuse: A Comprehensive Textbook*. 3rd Edition. Baltimore, MD: Williams & Wilkins; 1997:563-89.

Prescribing Controlled Drugs
Mechanisms of **PRESCRIBER** Involvement of CRxDA

- AMA mechanisms re: RxDA – "the 6-D's" & others
  - **D**ated
  - **D**uped
  - **D**isabled
  - **D**ishonest
  - **D**efiant
  - **D**istracted
  - *Medication Mania / Confrontation Phobia / Hypertrophied Enabling*

Prescription Drug Abuse
Scams

- Strategies to increase frequency, number, potency of controlled prescriptions
- Efforts to increase drug supply by stressing/pressuring the doctor-patient relationship
- "You know Dad … I really love you Dad!"
- You know Doc … I really love you Doc!"

Prescription Drug Abuse
Scams #1

- Spilled the bottle
- The dog ate it
- Lost the prescription
- Washed in laundry
- Medications stolen
- Left somewhere
- The Pharmacist "shorted" me

Prescription Drug Abuse
Scams #2

- Lost my luggage
- No generics
- Multiple medication sensitivities
- Allergic to Kappa agonists
- This cough calls for…
- It's the only thing that works…
- House burned down

Prescription Drug Abuse
Scams #3

- Physician heal thyself
- Oh, by the way
- You are the only one who understands...
- Rx lifting/altering
- Late calls/cross coverage
- John Hancock/"Dear Doctor"

- (almost) NONE of these are true

Dealing with Scams
Principles of Universal Precautions

- **TEAM WORK** (Informed Consent avoids mixed messages)
- Cops v. Docs attitudes
- No offense but … … … (please don't fire me)
- Learn to recognize common scams
- Just say no and mean it – "say no when you mean no and yes when you mean yes" – INFORMED CONSENT FORM
- Avoid being "coy" – when "no becomes yes"
- Turn the tables, but be kind (no offense right?)

Giving Bad News

- Prepare the patient to receive the news:
- Tell the Bad News (no early refill, need to change RX etc)
- Use the ***OPEN*** mnemonic:
  - **O**ptimism Statement
  - **P**artnership Statement
  - **E**licit the Patient's Response
  - **N**o More talking, just listen
- Allow space / time for reaction / emotion
- Use ***PEARLS*** statements
- Close

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Giving Bad News: The Words "I am *SO* sorry … but no"

- *"Unfortunately, I have some difficult news for you."*
- "Based on what you have been nice enough to tell me, and your PMP report, I can not continue to RX …"
- THEN Use PEARLS Statements: **P**artnership / **E**mpathy / **A**pology / **R**espect / **L**egitimization / **S**upport
- Then "this can be really hard to hear I am wondering what your thoughts are?"
- Allow space / time for reaction / emotion
- Answer questions, use more PEARLS statements
- Then close

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Additional "**words that make a difference**"

- "I wish things were different … and I know that you do too, but they aren't …"
- I thought you had one DX, but now I know you have two DX (including SUD) … and I ***must*** change the TX plan.
- I don't want you sick … but I ***must*** have you safe, and continued prescribing is not safe

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Avoid Common Pitfalls

- "But I really, really need the _____"
- "Don't you trust me?" / "I thought we had a good relationship" / "I thought you cared about me?"
- "If you don't give them to me, I will drink / use drugs / hurt myself."
- "Can you just give me enough to find a new doc?"
- "You did this to me" / "I will go into withdrawal"
- ***Remember*** … it is unsafe and thus not allowed … and "I am so sorry … and still want to work with you"

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Giving Bad News **REVISITED**
"I am *SO* sorry … but no"

- Prepare the patient to receive the news:
  - *"Unfortunately, I have some difficult news for you."*
- Tell the Bad News (no early refill, stopping prescribing CRx)
- THEN Use PEARLS Statements:

Partnership / **E**mpathy / **A**pology / **R**espect / **L**egitimization / **S**upport

- Allow space / time for reaction / emotion
- Answer questions, use more PEARLS statements
- Then close

Emergency contraindications to continued prescribing: (above all, first do no harm)

- Altering a prescription = FELONY
- Selling Rx. drugs = DRUG DEALING
- Accidental/intentional overdose = DEATH
- Threatening staff = EXTORTION
- Too many Scams = OUT OF CONTROL

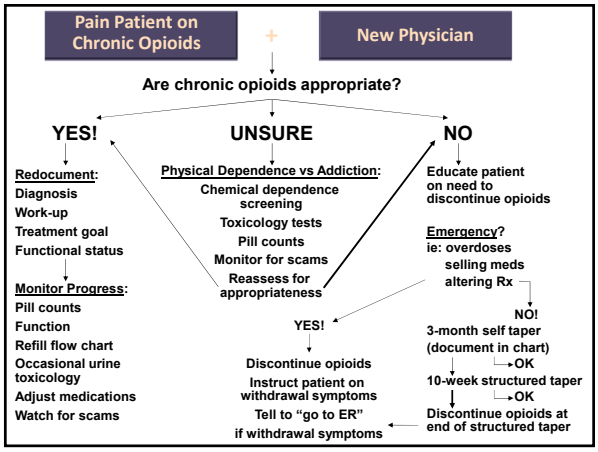
Emergency contraindications to continued prescribing (above all, first do no harm)

- What is a prescriber to do?

1. Identify the contraindicated behavior.
2. State that ongoing prescribing is not safe.
3. Educate about withdrawal symptoms.
4. Instruct to go to the E.R. if withdrawal.
5. Offer care with out CRx (or referral if threatned).

But but but … what about the patients I ***inherited*** on CRx X, Y, or Z?????

- Is the CRx in you area of expertise?
  - If "no", then refer out immediately or refer to detox
- Are there CLEAR indications AND no Contra-indications?
  - If "yes", then is the Type of CRx and Dose OK? Adjust if needed
  - If "no" then stop CRx via: slow taper / fast taper / or DC
- Which approach to stopping is needed?
  - Non-urgent reason to stop v. urgent reason v. emergency reason
- What is X, Y and Z? (opioids / benzos / stimulants of course)



Prescribing Controlled Drugs
Solutions

- Improve skills to identify SUD mod-severe (current or past)
- Approach affected patients as if they have a relative, if not absolute, contraindication to controlled prescriptions … DON'T RX ADDICTIVE / ABUSEABLE MEDICATIONS TO PEOPLE WHO ARE OR HAVE BEEN ADDICTED!!!!!
- Aggressively pursue skills in DDx and management of:
  - Acute vs chronic pain
  - Anxiety vs depression
  - Insomnia

Prescribing Drugs
Solutions (cont'd)

- Carefully document in progress note the rationale, diagnosis, anticipated time course, and symptom endpoint when initiating a controlled drug prescription
- Implement a team based monitoring strategy
  - Just like in DMII or Coumadin anticoagulation therapy
- USE a CRX Flow Chart / refill flow chart
- Establish a cross coverage prescription policy

Prescribing Controlled Drugs
Solutions (cont'd)

- Know the pharmacology and abuse potential of all drugs prescribed
- Medical letter, AHFS > PDR, industry reps
- Careful prescription writing and management habits
- Recognize and deal with scams

Prescribing Controlled Drugs
A Question of Balance

- Implementing RxDA solutions can
  - Increase comfort with prescribing controlled drugs
  - Markedly decrease inappropriate prescribing
  - Improve documentation and monitoring
  - Achieve better balanced and improved patient care

Symptoms of opioid withdrawal

- dilated pupils, rhinorrhea (runny nose)
- tachycardia, hypertension
- nausea, vomiting, diarrhea, abdominal cramps
- goose bumps, sweats, muscle/bone/joint aches.
- insomnia, anxiety, headache

Benzodiazepine Withdrawal Symptoms

Tremors

Diaphoresis (sweats)

Anxiety

Insomnia

Nausea

Hallucinosis (seeing or feeling things, not hearing voices)

Dosage of selected benzodiazepines roughly equivalent (anxiolytic-hypnotic effect) to 10 mg of DIAZEPAM	
Agent	Equivalent Dose (mg)
Alprazolam (Xanax)	1
Chlordiazepoxide (Librium)	20
Clonazepam (Klonopin)	0.5
Clorazepate (Tranxene)	15
Estazolam (ProSom)	4
Flurazepam (Dalmane)	30
Halazepam (Paxipam)	40
Lorazepam (Ativan)	2
Oxazepam (Serax)	30
Prazepam (Centrax)	20
Quazepam (Doral)	30
Temazepam (Restoril)	30
Triazolam (Halcion)	0.5