Prescribing Boundaries

by
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Disclaimer

- I don't prescribe opiates as part of my clinic practice, with the exception of a buprenorphine waiver
- I don't treat chronic pain
- I do get to deal with the fallout of addiction
- not a criticism of any field of medicine
- talk to exclude discussion of the operations of dedicated pain clinics
- Some will and some will not agree

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"Scope of the Problem"

- **#1 - People die; people get hurt**
- #2 - Big and growing
- #3 - Costly

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Scope of the Problem

- Substance Abuse and Mental Health Services Administration (SAMHSA)
  - Office of Applied Studies http://www.oas.samhsa.gov/
  - 2009 National Survey on Drug Use and Health http://www.oas.samhsa.gov/NSDUH/2k9NSDUH/MH/2K9MHResults.pdf
  - Substance Abuse and Mental Health Data Archive (SAMHDA) http://www.icpsr.umich.edu/icpsrweb/SAMHDA/studies/29621
- National Institute of Drug Abuse (NIDA)
  - Monitoring the Future (MTF) http://monitoringthefuture.org/
  - National Survey Results on Drug Use, 1975 - 2009
    - Vol. 1 http://monitoringthefuture.org/pubs/monographs/vol1_2009.pdf
    - Vol. 2 http://monitoringthefuture.org/pubs/monographs/vol2_2009.pdf

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The Source?

- **#1 - Valid Prescriptions** - *apparently legal* vs. *legitimate*
- *#2* - offshore pharmacy
- #3 - theft, border crossing

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primum non nocere

- often misattributed to Hippocrates or Galen
- debate about the authorship continues to exist, although it is recognized to have originated in the late 19th century
- summarizes the principle of ***nonmaleficence***, which is as much a call to inaction as it is to action.

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Goals

- to present a practical, unapologetic talk on the realities and misconceptions that lead to misprescribing
- to list potential sources of prescribing guidance, with identification of those expected to be most helpful to the prescriber
- to discuss categories of misprescribing and traits which may lead to misprescribing
- to provide a commentary on several particular categories of illness for which controlled substances are routinely prescribed
- to provide several operating parameters which will serve to protect patients and to protect the prescriber's license, livelihood and practice

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What Are The Physician's Guides?

- Hard (yet indeterminate) boundaries
  - DEA - "we won't tell you how to prescribe, just when you're doing it wrong"; rod of punishment for overprescribing
  - FSMB - model policy then threatens punishment for underprescribing
  - Board of Medicine - minimally acceptable standards of practice
- Unreliable sources
  - pharmaceutical industry - still corrupt
  - bad "science" - putting falsehoods in print does not make them true
- Imperfect (yet perfectible) boundaries
  - internal "self" monitoring - quality depends on the individual prescriber
  - stringent policies and procedures - best routine protection

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Hard Boundaries - DEA

- According to the DEA's practitioner's manual, the *DEA remains committed to the 2001 Balanced Policy of promoting pain relief and preventing abuse of pain medications.*
- *Today, more than 6 million Americans are abusing prescription drugs -- that is more than the number of Americans abusing cocaine, heroin, hallucinogens and inhalants combined.*
- *Researchers from the Centers for the Disease Control and Prevention report that opioid prescription painkillers now cause more drug overdose deaths than cocaine and heroin combined.*
- *Today, more new drug users have begun abusing pain relievers (2.4 million) than marijuana (2.1 million) or cocaine (1.0 million).*

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition. 9

Hard Boundaries - DEA

- Balanced Policy?
  - http://www.deadiversion.usdoj.gov/pubs/advisories/newsrel_102301.pdf
  - http://www.painpolicy.wisc.edu/Achieving_Balance/EG2008.pdf
  - *The Central Principle of Balance represents a dual imperative of governments to establish a system of controls to prevent abuse, trafficking and diversion of narcotic drugs while, at the same time, ensuring their medical availability* (Pain & Policies Study Group. Univ. of Wisconsin SOM and Public Health. Achieving Balance in Federal and State Pain Policy. A Guide to Evaluation, 5th ed. 2008.)
  - CRITICISM: the "balance" groups often appear to place disproportionately high emphasis on policing and publishing state laws ensuring *medical availability,* with relatively little emphasis given to identifying and responding to addiction and medication abuse behaviors.

Pain & Policies Study Group. Univ. of Wisconsin SOM and Public Health. Achieving Balance in Federal and State Pain Policy. A Guide to Evaluation, 5th ed. 2008 10

Hard Boundaries - DEA

- established in 1973
- primary federal agency responsible for the enforcement of the CSA
- twofold responsibility:
  - *to prevent diversion and abuse of these drugs while*
  - *ensuring an adequate and interrupted supply is available to meet the country's legitimate medical, scientific and research needs.*
- "closed system" - *all legitimate handlers of controlled substances - manufacturers, distributors, physicians, pharmacies and researchers - must be registered with DEA and maintain strict accounting for all distributions*

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition. 11

Hard Boundaries - DEA

- DEA participates in a *cooperative framework* with state authorities, during investigations into possible violations of controlled substance laws
- when a state board revokes a practitioner's license, the DEA will generally request a surrender of the practitioner's DEA registration; *the DEA may also pursue administrative action to revoke the DEA registration.*
- *The DEA is authorized under federal law to pursue legal action in order to prevent the diversion of controlled substances and protect the public safety. A lack of compliance may result in a need for corrective action, such as administrative action…oir in extreme cases, civil or criminal action.*

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition. 12

DEA Schedule I Substances

- have no currently accepted medical use in treatment in the US
- may not be prescribed, administered or dispensed for medical use
- high potential for abuse
- *e.g.*, heroin, LSD, cannabis, peyote, psilocybin, MDMA, methaqualone

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DEA Schedule II Substances

- high potential for abuse, with severe psychological or physical dependence
- *e.g.*, morphine, codeine, opium, amphetamines, methylphendidate, cocaine, methamphetamine (Desoxyn), hydromorphone, methadone, meperidine, oxycodone, fentanyl

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DEA Schedule III Substances

- potential for abuse less than substances in Schedules I or II
- *e.g.*, combination products containing less than 15mg of hydrocodone per dosage unit (*i.e.*, Vicodin, Lortab), combination products containing not more than 90mg of codeine per dosage unit (*i.e.*, Tylenol w/ codeine), Marinol, ketamine, anabolic steroids, buprenorphine, Butalbital,

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DEA Schedule IV Substances

- lower potential for abuse relative to substances in Schedule III
- *e.g.,* propoxyphene, benzodiazepines, Provigil, Cylert, Talwin, phenobarbital, Ambien, Lunesta

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DEA Schedule V Substances

- lower potential for abuse relative to substances listed in Schedule IV
- *e.g.*, cough preparations containing not more than 200mg codeine per 100mL (*i.e.*, Robitussin AC, Phenergan with codeine), Lyrica, Lomotil

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DEA Schedules (Summary)

- substances in Schedule I have no accepted medical use in treatment in the US; they may not be prescribed, administered or dispensed for medical use
- in general, the abuse potential of Schedule I > II > III > IV > V
- in some cases, however, the placement of a drug in a particular schedule (or in no schedule) does not reflect clinical understanding about the drug. Examples to consider are Xanax, Tramadol, Soma and Lyrica.

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DEA Recommended Safeguards for Prescribers

- *keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use*
- *write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order*
- *use prescription blanks only for writing a prescription order and not for notes*
- *never sign prescription blanks in advance*
- *assist the pharmacist when they telephone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription*
- *contact the nearest DEA field office to obtain or to furnish information regarding suspicious prescription activities*
- *use tamper-resistant prescription pads*

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition.

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DEA Prescription Requirements

- a prescription for a controlled substance must be dated and signed *on the date* when issued.
- must include
  - patient's full name and address
  - practitioner's full name, address and DEA registration number
  - drug name
  - strength
  - dosage form
  - quantity prescribed
  - directions for use
  - number of refills
- written in ink or indelible pencil or typewritten

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition.

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DEA Prescription Requirements

- *to be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice*
- *The practitioner is responsible for the proper prescribing and dispensing of controlled substances* (with a corresponding responsibility on the part of the pharmacist who fills the prescription)
- *An order purporting to be a prescription issued not in the usual course of professional treatment…is not a valid prescription within the meaning and intent of the CSA and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to penalties provided for violations of the provisions of law relating to controlled substances.*
- *A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.*

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition. 21

DEA Prescription Requirements

- schedule II drugs require a written prescription which must be signed by the prescriber.
- no federal time limit for filling of a schedule II prescription after being signed by the practitioner
- no specific federal limits to quantities of drugs dispensed by prescription
- for schedule II, an oral order is only permitted in an emergency situation

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition. 22

DEA Multiple Prescriptions for Schedule II Drugs

- An individual practitioner may issue multiple prescriptions, allowing a patient to receive a total of up to a 90-day supply of a schedule II controlled substance, if
  - *Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice*
  - *The individual practitioner provides written instructions on each prescription indicating the earliest date on which a pharmacy may fill each prescription*
  - *The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse*
  - *The issuance of multiple prescriptions is permissible under applicable state laws*
  - *The individual practitioner complies fully with all other applicable requirements under the CSA and CFR, as well as any additional requirements under state law*

USDOJ. DEA. Office of Diversion Control. Practitioner's Manual, An Informational Outline of the Controlled Substances Act. 2006 Edition. 23

Hard Boundaries - FSMB

- here the indeterminate boundary lies in the direction of underprescribing
  - *Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations…*
  - *The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.*
  - *Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.*

FSMB of the US, Inc. Model Policy for the Use of Controlled Substances for the Treatment of Pain. May 2004. 24

Hard Boundaries - FSMB

- My criticisms…
  - emphasis on pain management should be equally matched with the emphasis placed on addiction, with its cost to the individual and to society
  - physiologic tolerance and dependence ALSO occur in most cases of opiate addiction
  - the basis of *unrelieved pain* is unreliable, both as a principle for treating patients and as a principle for disciplining physicians; bypasses the principle of *primum non nocere*.
  - the assignation of *inappropriate treatment of pain* as a measure of standard of care (and *outcomes of pain treatment* as a measure of physician conduct) is capricious and dangerous
  - this imbalanced threat of punishment does more to encourage wanton prescription of pain meds than it does to reduce the hazards of controlled substance abuse and diversion
  - additional criticism of the term *pseudoaddiction*

FSMB of the US, Inc. Model Policy for the Use of Controlled Substances for the Treatment of Pain. May 2004.

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A *Right* ???

- we have certain *unalienable rights*, but who determined that a right to pain treatment was one of these?
- in some cases, we have a *right* to due process
- identifying pain treatment as a *right* and attempting to translate a perceived natural right to a statutory right is dangerous indeed
- the fact of something being desirable, convenient or even essential (e.g., a proposed right to housing) does not make it a right
- inherent in the naming of a right is the creation of a mandate that someone else either pay the tab or modify their behavior
- if physicians are given a mandate to treat pain, and if pain treatment often involves the use of narcotics, why not make Oxycontin and Dilaudid available in vending machines?
- a right to "medical marijuana"?

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Misprescribing Types

- have been previously categorized as
  - *dated* - not keeping up with educational needs
  - *duped* - mislead by the patient
  - *disabled* - struggling with their own addiction or mental health issues
  - *dishonest* - criminally motivated misprescribing

  (from Voth *et al. Responsible Prescribing of Controlled Substances.* AFP 1991; 44:1673 - 1678)
- some have studied the role of family-of-origin on physician ineffectiveness (Mengel, Mark B., M.D. *Physician Ineffectiveness Due to Family-of-Origin Issues.* Family Systems Medicine, Vol. 5, No.2, 1987.)
- some physician CME courses on misprescribing even undertake an investigation of the participants' family-of-origin dynamics (e.g., Vanderbilt Center for Professional Health, *Prescribing Controlled Drugs: Critical Issues and Common Pitfalls.*, VUMC)

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Sorting Out the Bad Math

Physician ≠ NP, CNS, APRN

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What Makes a Child Psychiatrist?

- 4 years med school + 4 years Ψ residency + 2 years C&A fellowship = **10 years postgraduate** training (greater than full-time)
- Sorting Out More Bad Math:

10 years ≠ 2, 3 or 4 years postgraduate training PT!!!

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Misprescribing Types - The Timid

- unable to tolerate uncomfortable patient interactions; difficulty coping with any perceived rejection/abandonment
- prescribing is unduly influenced by patient's expectations for medication and by the patient's emotional response (either the actual or the anticipated response) to the prescribing decision
- easily intimidated; may become target for a network of drug seekers
- prescriber's avoidance of difficult conversations invariably leads to skewed prescribing

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Misprescribing Types - The Rescuer ("messianic")

- operational creed is "no man cometh to good health but by me."
- often found to have been the rescuer in the family of origin; not to be confused with the *gatekeeper* role of the PCP, the messianic provider is the totality of their patient's care
- generally reluctant to refer out or seek second opinions; often practices outside of scope of practice
- overly self-confident; routinely acts contrary to accepted standards of care; rewrites the textbook; scoffs at any suggestion that prescribing is out-of-bounds
- would often rather concede to patient demands than to lose a member of the "flock"
- prescribing practices unduly influenced by patient's expectations for medication
- while his motivation is usually to help patients; the messianic provider is generally blind to the harm that overprescribing causes his own patients

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Misprescribing Types - The Psychopath

- lacks true regard for the well-being of the patient and prescribes in an opportunistic and predatory manner, generally at the expense of the patient's health
- e.g., "hugs for drugs," "drugs for drugs" and "drugs for dollars" programs. True criminal prescribing.
- represents the most blatant abuses of public trust and of the doctor-patient relationship
- generally recidivistic; a problem with the moral "core," typically without allowances for return to work (to be distinguished from the *lovesick* provider discussed in sexual boundary violation literature).

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The Focus on Adult ADD/ADHD

- describes a syndrome of primary inattention/hyperactivity
- inattention itself is a non-specific sx seen in mood disorders, anxiety disorders, substance use disorders, OCD, thought disorders, sleep disorders, etc. Diagnosis in adults requires systematic evaluation and rule-out of other disorders.
- the criteria for ADD/ADHD do not include patient complaints of "can't focus" or "poor attention"; does not include an anecdotal hx of that dx
- popular screening tools for ADD/ADHD based on patient self report are easily manipulated; paper does not make a diagnosis'
- childhood ADHD estimated to affect **3 to 7%** of elementary school children in the US; in Britain, this estimate is at **< 1%**
- symptoms persist in to adulthood in roughly **50%** of cases
- not every case requires medication
- non-stimulant treatment approaches (*e.g.*, Strattera, Buproprion, Venlafaxine, Tenex, Catapres)
- shameful direct-to-patient waiting room "educational" paraphernalia

Sadock et al. Synopsis of Psychiatry. 10th ed. Lippincott Williams & Wilkins. 2007. 33

Adult Self-Report Scale (ASRS)

- answer as *never, rarely, sometimes, often, or very often*
- 1.) How often do you have trouble wrapping up the details of a project, once the challenging parts have been done?
- 2.) How often do you have difficulty getting things in order when you have to do a task that requires organization?
- 3.) How often do you have problems remembering appointments or obligations?
- 4.) When you have a task that requires a lot of thought, how often do you avoid or delay getting started?
- 5.) How often do you fidget or squirm with your hands or feet when you have to sit down for a long time?
- 6.) How often do you feel overly active and compelled to do things, like you were driven by a motor?

World Health Organization. Adult Self-Report Scale v.1.1 (ASRS) 34

The Buzz About Anxiety

- anxiety comes in different flavors; best to identify specific type to offer more directed treatment
- benzodiazepines are a non-selective "dimmer" on the CNS and may, initially, show efficacy for multiple anxiety types
- when used chronically, tolerance and rebound anxiety may complicate the original anxiety disturbance
- not all BZD's are created equally; clinically, much greater abuse (and corresponding street value) with Xanax; less abuse potential with clonazepam and Xanax XR.
- recommend against using BZD's as a monotherapy for any anxiety disorder
- question chronic, escalating doses, especially when there appears to be no net change in the patient's psychological distress

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The Assault of the Happy Butterflies

- shameful direct-to-consumer advertising of sedative-hypnotic soporifics
- deceptive advertising of "not a narcotic."
- while abuse behaviors and withdrawal syndromes less commonly seen with Ambien and Lunesta, sleep dependence can result from continued usage
- memory disruption and parasomnic reactions!
- alternatives which are generally cheaper and safer for long-term use: Trazodone, OTC soporifics (*e.g.*, diphenhydramine, chlorpheniramine, melatonin)

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Identifying the Drug Abuser

- patient clearly feigning symptoms
- patient transient or "passing through"
- claiming "lost" or "stolen" prescription; doctor shopping
- atypical symptoms or physical exam findings not c/w complaint
- robust understanding of controlled substance(s)
- seeking a specific drug rather than treatment for symptoms; no interest in diagnosis
- unwilling to provide references and/or medical records; resistant to medical workup
- claims that non-controlled or less addictive options are ineffective
- known substance abuse history or external signs of drug use
- no PCP
- assertive, demanding or threatening (including threats to harm self)
- multiple ER visits for pain complaints

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Deterring Drug Seekers

- ask for ID
- confirm medical hx; request outside records
- contact pharmacy for medication list or history of irregular behaviors
- insist upon complete history and examination
- do not prescribe to patients on demand
- create a controlled substance prescription policy for your clinic
- insist on seeing police reports for "stolen" medications
- adopt a policy against replacing "lost" controlled substance prescriptions
- utilize centralized state database (PDMP) for controlled substance prescriptions

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Protecting Yourself

- complete H&P with sufficient documentation (discussed later)
- require patients to sign an *informed consent agreement* for controlled substance medications, prior to prescribing (discussed later)
- one physician - one pharmacy policy
- secure prescription pads
- do not prescribe controlled substances to yourself or to family members
- notify law enforcement for suspected diversion or prescription forgery
- medication choice, prescription duration and prescription intervals should be consistent with legitimate medical treatment
- refer when appropriate

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Documentation

- substance abuse or addiction treatment
- comorbid psychiatric illness
- documented PE, lab test results, results of imaging and other studies
- medication informed consent discussions (discussed separately)
- document pain complaint: nature and intensity, current and past treatments for pain, effect of pain on physical and psychologic function
- document presence of indication for controlled substance
- document attempts to monitor both response to medication and development of addiction (including relevant abuse screens)
- attempts to use non-medication therapies, non-controlled substance medications
- rationale for continuing or modifying therapy
- substance use screenings and all attempts at referrals
- assess not only the patient's reported pain level, but also functional parameters

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Medication Informed Consent Agreement

- a written informed consent agreement recommended for every patient receiving controlled substance medications
- customized for practice type
- statement of the expected benefits, relevant risks, and relevant drug-drug interactions
- statement of the risk of addiction
- directly address consequences of violation (*e.g.*, obtaining controlled medications from other sources, use of illicits, use in a manner other than prescribed, *etc.*)
- allow for on-demand monitoring (*e.g.*, UDS, pill counts, PDMP)
- firm boundaries; use of physician *SHALL* rather than *MAY*

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Alcohol Abuse Screening

- CAGE
  - Have you ever felt that you ought to **cut** down on your drinking or drug use?
  - Do you get **annoyed** at criticism of your drinking or drug use?
  - Do you ever feel **guilty** about your drinking or drug use?
  - Do you ever take an **early-morning** drink (eye-opener) or use drugs first thing in the morning to get the day started or eliminate the "shakes"?
  - 2/4 or greater = POSITIVE = refer for further evaluation

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Alcohol Abuse Screening

- Michigan Alcohol Screening Test (MAST)
  - no training required to administer or score
  - a 22-item self-scored test that the patient can complete on their own time
  - a score of 6 or more suggests problem drinking
  - http://www.ncadd-sfv.org/downloads/mast_test.pdf

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Drug Abuse Screening

- CAGE-AID
  - essentially the CAGE but reworded to include the word "drugs"
- Drug Abuse Screening Test (DAST)
  - the newer DAST-20 is a 20-item patient questionnaire
  - patient can complete on their own time
  - any score greater than 10 warrants referral to addiction specialist
  - http://www.camh.net/publications/camh_publications/drug_abuse_screening_test.html

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Dr. Dodd's Prescribing Risk Stratification

- I - Circumscribed Medical Illness
- II - Malignancy Syndromes
- III - Chronic Nonmalignant Disease
- IV - Medicalization of Social Problems
- V - Somatoform Disorders
- VI - Factitious Disorders
- VII - Chemical Dependence

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Summary

- the modern prescriber is faced with opposing yet indeterminate hard boundaries which are reinforced with a stick and not a carrot
- there is no single algorithm which determines the best course of action for all patients
- treatment decisions and modifications must continue to be made on a case by case basis
- the prescriber must respond definitively to clear abuse and/or diversion behaviors
- the patient and the prescriber are best protected by thorough history collection, investigation, risk stratification and documentation, documentation, documentation.

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Further Reading

- American Pain Society. *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain.*
  - http://www.ampainsoc.org/pub/pdf/Opioid_Final_Evidence_Report.pdf
- Chou, Roger *et al. Opioids for Chronic Noncancer Pain: Prediction and Identification of Aberrant Drug-Related Behaviors.* The Journal of Pain, Vol 10, No 2. February 2009.
  - *http://www.jpain.org/article/S1526-5900%2808%2900832-8/abstract*

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