

ETHICS AND THE LAW

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The ASAM Board Exam Study Course in Addiction Medicine

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Financial Disclosures

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Agenda



1. Ethical Principles
2. Informed Consent
3. Privacy and Confidentiality
4. Ethical Prescribing
5. Special Topics



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Ethical Principles

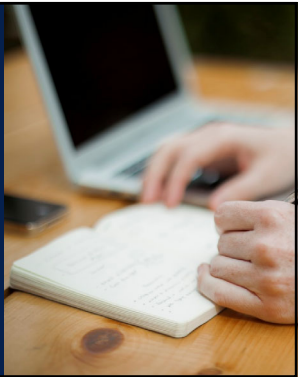

- **Autonomy:** self-determination, self-governance, moral independence
 - Example: Patient with recurrent upper GI bleed refusing voluntary inpatient addiction psychiatry admission

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Ethical Principles


- **Beneficence:** actions should promote patient well-being
 - Example: A patient with a severe heroin use disorder sees PCP who refers him to inpatient detox and community recovery resources

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Ethical Principles

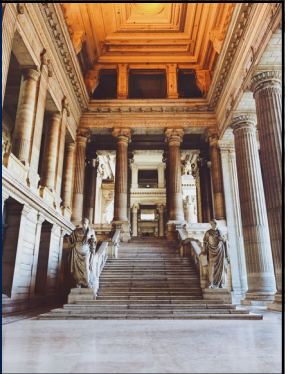
- **Non-maleficence:** do no harm (or as little as necessary)
 - Example: Providing comfort measures for a patient undergoing heroin detoxification



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Ethical Principles


- **Justice:**
 - Fairness in decisions
 - Equal distribution of resources and new treatments
 - Medical practitioners uphold laws
 - Example: Advocating for a patient rejected from inpatient addictions treatment when the insurance provider deems it "not clinically indicated"



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Ethical Principles

- **Respect for people:** treating people in a manner that acknowledges their intrinsic dignity
- **Truth-telling:** honesty, sharing information



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Complex Ethical Scenario

- 40-year-old female anesthesiologist
- Taking opioid medications meant for patients, replacing with saline
- Has used oral opioids on the job but denies problems
- Asks you to notify nobody




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Audience Response Question #1

Which of the following is NOT true regarding informed consent?


- It must be given voluntarily.
- An individual must possess decisional capacity.
- Patients with psychosis cannot give informed consent.
- It involves the disclosure of information between the physician and the patient.



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Informed Consent

- Voluntariness
- Information disclosure
- Decisional capacity



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Voluntariness

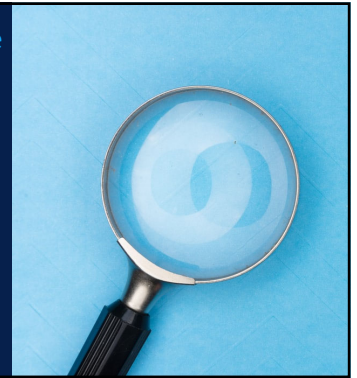
- Freely given
- Coercion: punishment or excessive rewards
- Persuasion
- Influence
- Context-dependent
- Risk of infringing
 - SUDs treatment in custody
 - Drug court
 - Inpatient treatment



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Information Disclosure

- Nature of illness and proposed treatment
- Risks/benefits
- Alternatives
- Consequences of foregoing treatment
- "Reasonable person" standard
- High standard of disclosure
 - Addictive medications (opioids)
 - Harmful medications (disulfiram)
 - Dangerous medications (methadone)



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Decisional Capacity

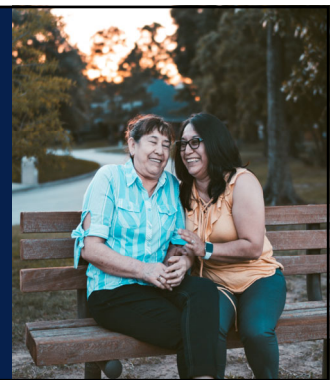
- Communicate a choice
- Understand the relevant information
- Appreciate the situation and its consequences
- Reason about treatment options
- "Sliding scale" approach
- Potentially impaired
 - Intoxication
 - Substance-related neurocognitive problems
 - Dual diagnosis



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For Those Lacking Capacity

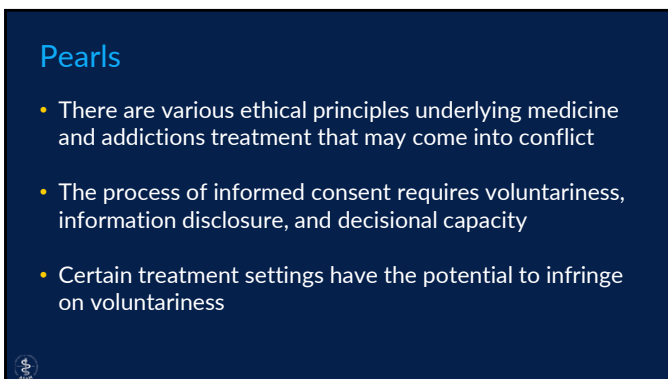
- Durable power of attorney for healthcare decisions (DPOAHC): form identifying surrogate decision-maker if one becomes incapacitated
- Advanced directive/living will: written statement expressing specific wishes, does not designate health care POA
- Guardian/conservator of the person: person appointed to make care decisions when patient is incapacitated



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Pearls

- There are various ethical principles underlying medicine and addictions treatment that may come into conflict
- The process of informed consent requires voluntariness, information disclosure, and decisional capacity
- Certain treatment settings have the potential to infringe on voluntariness



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Privacy and Confidentiality

- Privacy: patient's right to protection of sensitive information
- Confidentiality: clinician's obligation to protect sensitive information
- 42 CFR Part 2: Confidentiality of Alcohol and Drug Abuse Patient Records
- HIPAA



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42 CFR Part 2 – Covered Programs

- Individual, entity, or identified unit within a general medical facility that provides SUDs diagnosis, treatment, or referral for treatment
- Medical personnel/staff in a general medical facility whose primary function is provision of SUDs diagnosis, treatment, or referral for treatment



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42 CFR Part 2 – Federal Assistance

- Conducted in a federal department or agency
- Supported by federal funds
- Carried out under a license or registration from federal government
 - Medicare providers
 - Authorization to conduct maintenance treatment or withdrawal management
 - Registration under Controlled Substances Act to dispense a substance used in treatment of SUDs



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Disclosure

- Part 2 programs may only release patient information with the patient's consent
- Exceptions include:
 1. Medical emergency
 2. Error in manufacture, labeling, or sale of a product under FDA jurisdiction
 3. Research
 4. Valid court order with subpoena
 5. Crimes committed on part 2 program premises
 6. Reporting suspected child abuse or neglect
- Failure can result in criminal penalty (a fine)



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HIPAA ('96), Privacy Rule ('00)

- All PHI protected
- Exceptions related to medical operations and public interest/benefit
- SAMHSA working to revise 42 CFR Part 2

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Controlled Substance Act (1970)

- Classification and regulation
- Manufacturing
- Distribution
- Exportation and sale

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CSA Regulation/Classification

- DEA licensure requirement
- Schedule I: illegal, no medical use (cannabis, MDMA, methaqualone)
- Schedules II-V: addictive potential
 - II: cocaine, meth, methadone
 - III: ketamine, testosterone
 - IV: benzos, zolpidem
 - V: diphenoxylate, gabapentin

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Ethical Prescribing

- Patient risks
 - SUDs
 - Diversion
 - Exacerbation of comorbid medical or psychiatric illness
- Practices to address
 - Urine drug testing
 - Medication contract
 - PDMPs

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Universal Precautions

1. Make a diagnosis with appropriate differential
2. Psychological assessment (risk of addictive disorders)
3. Obtain informed consent
4. Treatment agreement
5. Pre- and post-intervention assessment of pain level and function
6. Appropriate trial of opioid therapy +/- adjunctive medication
7. Reassess pain score and level of functioning
8. Regularly assess 4 A's: analgesia, activity, adverse effects, aberrant behavior
9. Periodically review diagnosis and comorbid conditions
10. Documentation

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Audience Response Question #2

Which of the following is NOT an example of misprescribing?

- A. Providing a patient opioids at a dangerously high dose.
- B. Providing a prescription for 3 months of opioids following an uncomplicated outpatient surgical procedure.
- C. Providing a friend a prescription for Ativan for no medical purpose.
- D. Providing a patient a prescription for Ativan for short-term treatment of anxiety, only to later learn via your state's PDMP that she had received multiple prescriptions in the last week from different providers.

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Legal Consequences

- Misprescribe: inappropriate rationale, dose, quantity
- CSA: "unlawful for any person to knowingly or intentionally... manufacture, distribute, or dispense, or possess with intent... a controlled substance"
 1. Knowingly
 2. Without legitimate medical purpose
 3. Outside the course of professional practice
 - State medical board sanctions
 - Civil: malpractice
 - Criminal: CSA, murder



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Recent Case

- Joel Smithers, D.O.
- Opened practice in 2015, made 500,000 Schedule II prescriptions
- Led to death of WV woman
- 800 federal drug charges (unlawful distribution)
- Given 40-year sentence in 09/2019 and \$86K fine



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Prescription Drug Monitoring Programs

- 49 states (MO pending), D.C., Guam
- Mitigate abuse/diversion
- Models
 - Non-mandated use
 - Proactive reporting
 - Mandated use
- Criticisms
 - Inadequate information collection
 - Ineffective utilization in clinical settings
 - Limited interstate sharing
- Mixed data on effectiveness, differs by state

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Pearls

- Confidentiality of substance abuse treatment is governed by 42 CFR Part 2, HIPAA, and the Privacy Rule
- The Controlled Substances Act of 1970 established the DEA regulation and classification of addictive drugs and criminal penalties for distribution of drugs
- There are various models of ethical prescribing that generally involve informed consent, regular assessment and dose planning, and appropriate clinical documentation
- PDMPs, though potentially helpful, differ in their implementation and effectiveness

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Addiction & the Law: Special Topics

- Adolescents
- Pregnant patients
- Justice-involved populations
- Civil commitment & substance use
- Americans with Disabilities Act (ADA)
- Impaired Physicians

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ADOLESCENTS, ADDICTION & THE LAW

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Audience Response Question #3

A 15-year-old patient comes to you requesting treatment for alcohol use disorder. Which of the following scenarios most likely requires guardian informed consent before initiating treatment?

- A. She is a mature minor
- B. She is married
- C. She is serving in the military
- D. She has run away from home
- E. She is experiencing severe withdrawal

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Legal Standards: Minor Informed Consent

- Age of majority
- Minor's ability to consent
 - General medical care
 - Mental health
 - Substance use disorders
- Emancipation
 - Legal
 - Marriage, military
 - Other forms
 - Mature minors
 - Have children
 - High school graduate

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Mature Minor Doctrine

- Definition
- Assessment of maturity:
 - Age & maturity
 - Emotional capacity
 - Intelligence
 - Risk of procedure/treatment
 - Benefit to minor
- Informed consent assessment:
 - Risks of forgoing treatment
 - Long term consequences
- Brain development, impulsivity & "charged" environments

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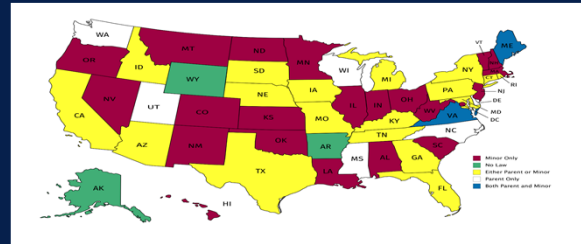
Minor Consent for SUD Treatment

- Laws vary by state
- Minimum age of consent can range from age 12-16
- May be able to consent to some services but not others
 - Detox
 - Outpatient
 - Inpatient
- Parental notification may still be required



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Consent for Inpatient Substance Treatment Lallemont et al. (2009)



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Adolescent Autonomy, Privacy & Confidentiality

- Parental involvement
- Confidentiality can be preserved
- Insurance & privacy



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Pearls

- State laws vary regarding minor consent requirements and may allow for a mature minor to consent
- Adolescents usually have the greatest autonomy to consent for substance use disorder treatment compared to other medical treatments
- When treating an adolescent patient, involve parents if possible while preserving the adolescent's confidentiality



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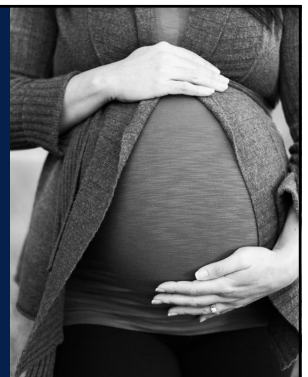
PREGNANCY, SUBSTANCE USE & THE LAW



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Legal Consequences Of Substance Use In Pregnancy

- Criminal
 - Feticide laws (38 states)
 - Chemical endangerment of a child (Amnesty)
 - Direct criminalization of use during pregnancy
- Civil
 - Child welfare (23 states + DC)
 - Civil commitment (3 states)



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Reporting Requirements to Child Welfare

(Jarlenski, Guttmacher. Org)

- Mandated reporting of child abuse/neglect
 - Standard: Reasonable belief or suspicion for abuse
 - Prenatal drug use & Substance Exposed Newborns
- Clinical & ethical problems
- Guidelines
 - Inform of any mandated reporting requirements & limits of confidentiality
 - Obtain informed consent before drug testing (ACOG)

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Pearls

- A person who uses substances during pregnancy can be subjected to civil or criminal penalties in many states
- Mandated reporting requirements of perinatal substance use vary across states
- Obtain informed consent before drug testing, including notification of reporting requirements

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JUSTICE-INVOLVED POPULATIONS

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Audience Response Question #4

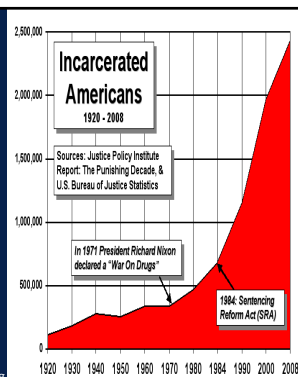
Approximately what percentage of women who are incarcerated in jail have a substance use disorder?

- A. 25%
- B. 33%
- C. 50%
- D. 75%
- E. 90%

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Statistics

- 6.8 million under supervision or incarcerated
- History of incarceration in the U.S.
- SUDs & incarceration
 - Over 50% with active SUD
 - >75% of women have SUD
 - ~10- 15% receive treatment



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MAT IN CORRECTIONS

The Need

- 75% will relapse within 3 months of release (SAMHSA)
- 100x more likely to die of overdose within 2 weeks of release (BJS, Binswanger)

Barriers

- Lack of education
- Substituting "one drug for another"/abstinence mentality
- Diversion concerns
- Cost
- Lack of community providers to start or continue MAT

BUT, more pilots across the U.S.

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Problem Solving (Treatment) Courts

- Drug, mental health, DUI, veteran's courts
- Therapeutic Jurisprudence
- Judge plays critical role
- Entry & Eligibility
- Structure & sanctions
- Efficacy (Logan)
 - Recidivism decreases
 - Future drug use reduced
- Treatment provider can be in dual role
- Some do not allow MAT (Matusow)



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FINAL TOPICS

- Civil commitment
- The Americans with Disabilities Act (ADA)
- Impaired Physicians

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Civil Commitment

- Standards
 - Mentally ill (or substance disorder, below) AND
 - Dangerous to self/others OR
 - Gravely disabled
- Substance use disorders
 - 37 states + DC (NAMSDL)
- Legal process
 - Due process required
 - Hearing occurs in timely manner
 - Committed for specified time by the judge



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The Americans With Disabilities Act (ADA)

- Disability: Physical or Mental impairment which:
 - Limits in one or more major life activities
 - History of impairment
 - Regarded as having an impairment
- Substance use
 - Alcohol use disorder
 - Other substance use disorders
 - Protected: Not using now but is or has been in treatment for addiction or regarded by others as using drugs
 - Not protected: "Currently using drugs" or casual user
- Exceptions



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Physician Regulation & Impaired Physicians

- Medical practice acts & state medical boards
- Physician health programs & impaired physicians
 - Exist in nearly every state
 - Goals
 - Voluntary vs. mandated treatment
 - High success rates
- Duty to report impaired physicians?
 - Impairment: physical, mental or substance-related disorder that interferes with abilities to safely and competently perform professional duties
 - Legal standards (have knowledge of or reason to believe) & options
 - Ethical and professional duties

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QUESTIONS?

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- Complete bibliography available on request

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REFERENCES

1. Geppert CMA, Bogenschutz MP. (2009). Ethics in substance use disorder treatment. *Psychiatric Clinics of North America* 32:283-297.
2. Appelbaum PS. (2002). Privacy in psychiatric treatment: Threats and responses. *American Journal of Psychiatry* 159(11):1809-1818.
3. Dennis M, Rieckmann T, Baker R, McConnell KJ. (2017). 42 CFR part 2 and perceived impacts on coordination and integration of care: A qualitative analysis. *Psychiatric Services* 68(3):245-249.
4. Schwartz HI, Mack DM. (2003). Informed consent and competency. In "Principles and practice of forensic psychiatry, 2nd edition." Edited by Rosner R. Boca Raton: CRC Press.
5. Preuss CV, Kalava A, King KC. (2019). Prescription of controlled substances: Benefits and risks. *StatPearls*.
6. D'Souza RS, Eldrige JS. (2019). Prescription drug monitoring program. *StatPearls*.
7. Gourlay DL, Heit HA, Almahrezi A. (2005). Universal precautions in pain medicine: A rational approach to the treatment of chronic pain. *Pain Medicine* 6(2):107-112

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REFERENCES

8. Jarlenski M, et al. Characterization of U.S. state laws requiring health care provider reporting of perinatal substance use. *Womens Health Issues*. May-June 2017, 27(3): 264-70.
9. Guttmacher Institute. Substance use during pregnancy. February 202. Accessed at: <https://www.guttmacher.org/state-policy/explore/substance-use-during-pregnancy>.
10. Parental Drug Use as Child Abuse. Child Welfare Information Gateway. Access at: <https://www.childwelfare.gov/pubPDFs/drugexposed.pdf>.
11. Matusow, H., Dickman, S., Rich, J., Fong, C., Dumont, D., et al. (2013). Medication assisted treatment in US drug courts: Results from a nationwide survey of availability, barriers, and attitudes. *Journal of Substance Abuse Treatment*, 44, 473-480.
12. National Alliance for Model State Laws. Involuntary commitment of individuals with a substance use disorder or alcoholism. (2016). Accessed at: <https://www.mass.gov/files/documents/2018/11/15/Involuntary%20Commitment%20for%20Individuals%20with%20a%20Substance%20Use%20Disorder%20or%20Alcoholism%20%28August%202016%29.pdf>

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REFERENCES

13. Medication-assisted treatment (MAT) in the criminal justice system: brief guidance to the states. SAMHSA. https://store.samhsa.gov/sites/default/files/d7/priv/pep19-matbriefcjs_0.pdf
14. Drug Use, Dependence and Abuse Among State Prisoners and Jail Inmates, 2007-2009. BJS (2017). <https://www.bjs.gov/index.cfm?ty=pbdetail&iid=5966>.
15. APA Resource Document on recommended best practices for physician programs. (2017).
16. Fact Sheet: Drug Addiction & Federal Disability Rights Laws. At: <https://www.hhs.gov/sites/default/files/drug-addiction-aand-federal-disability-rights-laws-fact-sheet.pdf>

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