Addiction Therapy-2014

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Adherence Monitoring: Minimizing Risk of Substance Use Disorders in Chronic pain Patients receiving Opioid Therapy

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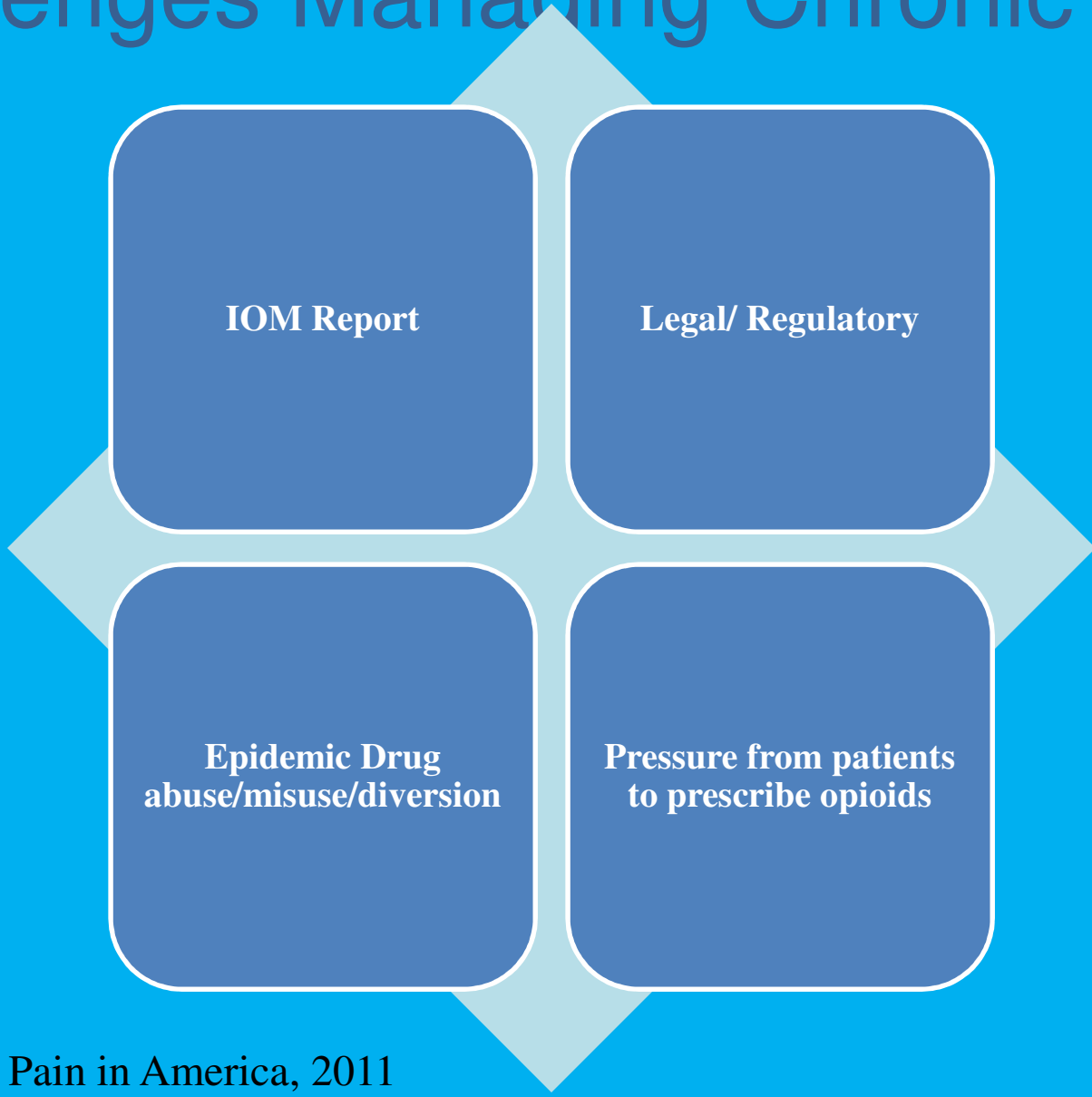
Program of Research

- Risk Mitigation
- Chronic illness model
- Treatment of Chronic Pain including co-morbidities
  - Psychiatric
  - Substance Use Disorders
  - Alcoholism
- Holistic Approach

Challenges Managing Chronic Pain



Relieving Pain in America, 2011

Ethical Tenets

•When opioid therapy is initiated, an ethical imperative is created to monitor the patient regarding risk for inappropriate use and response to treatment throughout the trajectory of care

Definitions

- Iatrogenic opioid addiction
- Aberrant drug related behaviors
- Substance use disorders
- Problematic opioid use

Addiction

- Inability to consistently abstain
- Impairment in behavioral control
- Craving
- Diminished recognition of ones behaviors
- Dysfunctional emotional response
  - (ASAM, 2012)

Therapeutic Tolerance

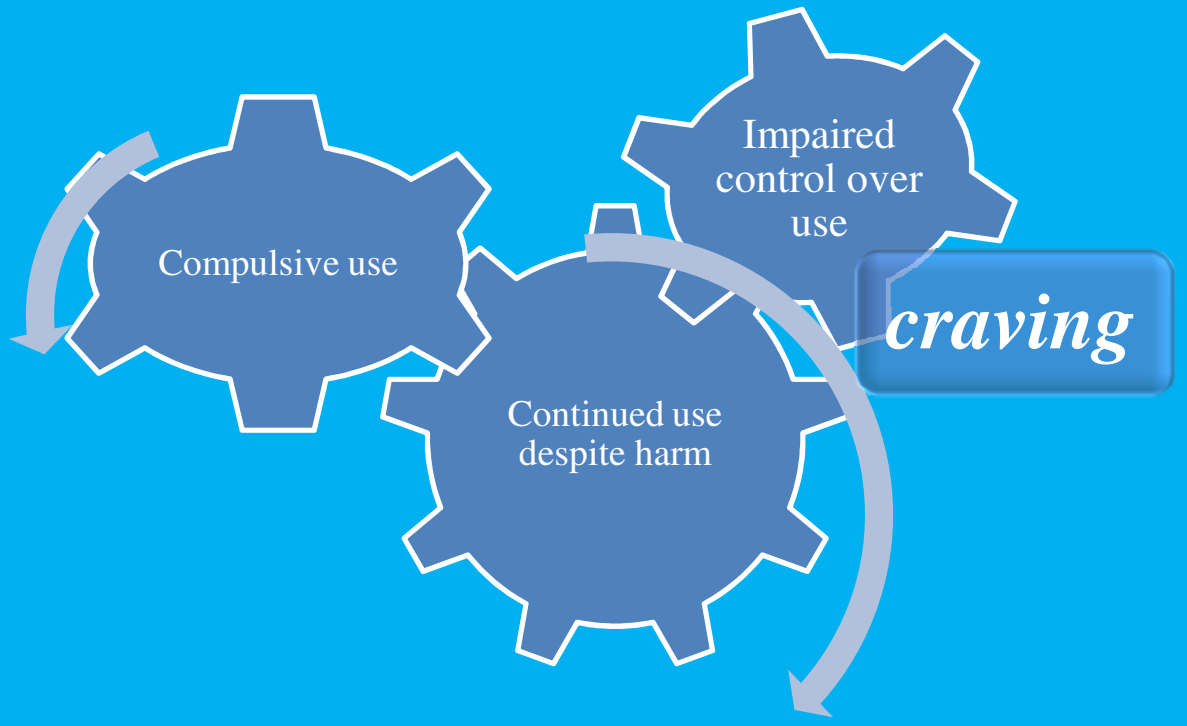
Psuedoaddiction

Physical dependence

Identifying Problematic behavior

- "Addiction is not simply a lot of drug use; it is a disease of the brain that is expressed through behavior"

Leshner, 1996



Universal Precautions

Risk

Benefit

Universal Precautions
Practice Assessment

	Universal Precaution	Date performed
1	Make a Diagnosis with Appropriate Differential	
2	Psychological Assessment Including Risk of Addictive Disorders; including Patient-Centered UDT	
3	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	Reassessment of Pain Score and Level of Function	
8	Regularly Assess the “Five As” of Pain Medicine (Analgesia, Activity, Adverse Effects, Aberrant Behavior, Affect)	
9	Periodically Review Pain Diagnosis and Comorbid Conditions, Including Addictive Disorders	
10	Documentation	

Gourlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. Pain Med. 2005;Mar-Apr;6(2):107-12.
Passik SD, Weinreb HJ. Managing chronic nonmalignant pain: overcoming obstacles to the use of opioids. *Adv Ther*. 2000 Mar-Apr;17(2):70-83.

Universal Precautions for Level of Risk

- Define pain diagnosis
- Assess substance use and mental health
- Informed consent
- Treatment agreement
- Evaluate efficacy of medication pre and post treatment
- Re assessment of pain and level of function
- Documentation

Regular assessment of the Five A's

- Analgesia
- Activity
- Adverse effects
- Aberrant behavior
- Affect

Barriers to identifying risk

- Stigma
- Misconceptions
- Limited access to providers familiar with identifying substance use disorders or other risks

Barriers

- Misunderstanding of indicators that could point to risk
- Lack of understanding of toxicology screening
- Lack of understanding of how to implement a systemized approach to adherence monitoring

Screening

- Pill Counts
- Prescription Drug Monitoring Programs REMS
- Urine Drug Testing

Understand Opiate metabolism

There is much variation in how individual patients respond to different opioids

Pharmacodynamics

What a drug does to your body

Pharmacokinetics

What your body does to a drug

Absorption, Distribution, Metabolism, Elimination

Smith HS. Mayo Clin Proc. July 2009;84(7):613-624.

UDT *Rationale*

UDT provides objective information regarding medication use and patient risk for substance abuse or misuse

- Supports healthcare providers manage medication plan and/or diagnose substance abuse, misuse, or diversion
- Provides objective data for informed decision-making
- Should be used in conjunction with other monitoring tools to optimize outcomes

Only one component of overall risk management plan

Gourlay DL, Heit HA, Caplan YH. Urine Drug Testing in Clinical Practice: the Art and Science of Patient Care. 2010. Stamford, CT: PharmaCom Group, Inc.

Urinary Drug screening (UDT)

- Order UDT with patient consent to answer a clinical question
- know what you are looking “for”
- Seek guidance from experts at the laboratory
- Understand limitations of UDT; design was never intended for use as screening test for chronic pain patients
- Do not base clinical decisions solely on results from UDT

Types of Urine Drug Tests

Immunoassay Screen IA	Laboratory Testing GC-MS or LC-MS/MS
In-office, Point of Care or lab-based IA test	Laboratory highly specific and sensitive
Results within minutes	Results in hours-days
Detects drug classes and few meds, illicit substances	Measures concentrations of all medications, illicit substances and metabolites
Guidance for preliminary treatment decisions	Definitive identification and analysis
Cross-reactivity common: More False positives	False-positive results rare
Higher Cutoff Levels More False Negatives	False-negative results rare

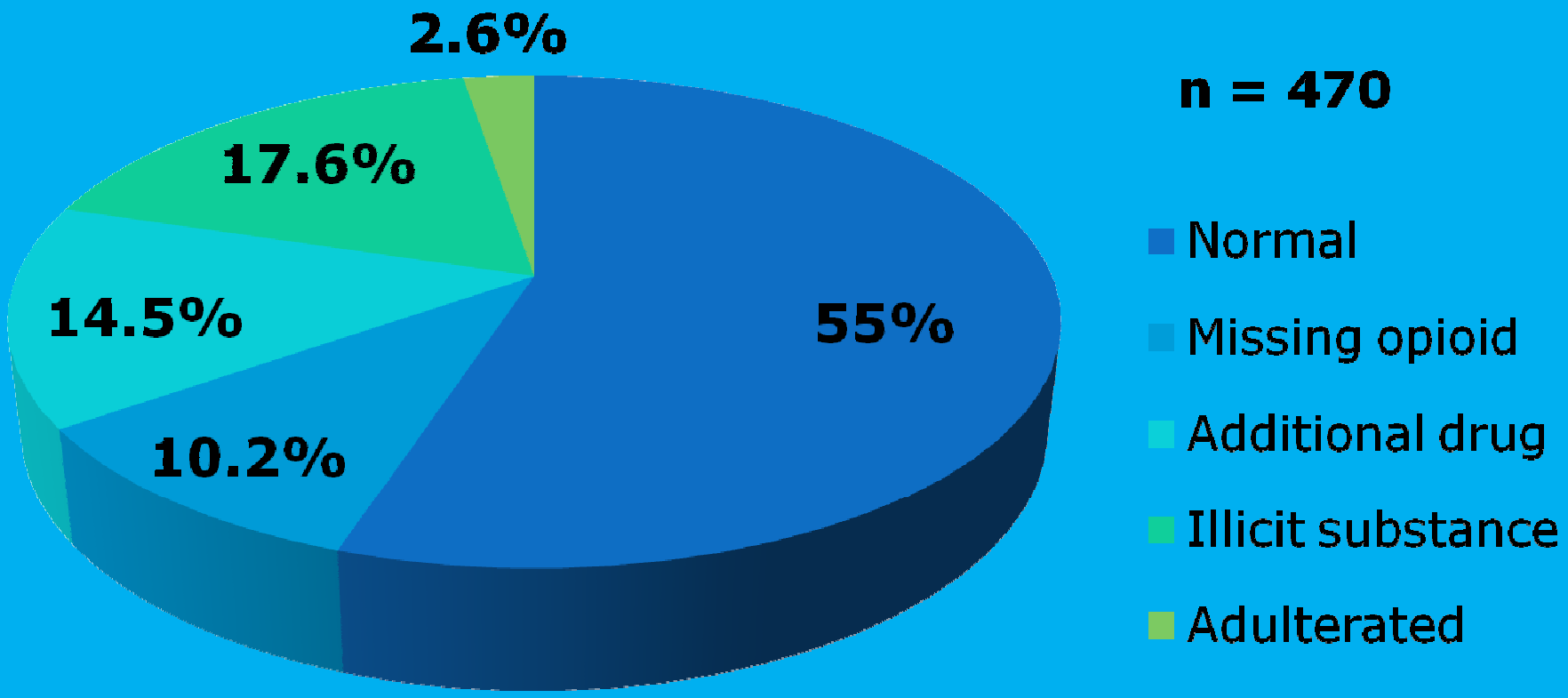
False Negative vs. False Positive Results

With immunoassay based tests - POC

False Negative	False Positive
Occurs when immunoassay is negative for a substance but quantitative identification is positive for same substance	Occurs when immunoassay is positive for a substance but quantitative identification is negative for same substance
Primary reasons include: • Higher cutoffs compared to mass spec. • Immunoassays unable to effectively identify some substances (e.g., lorazepam)	**Primary reason:** • Cross-reactivity
Adverse Impact on Patient: • Accused of drug diversion • Not receive ongoing meds • Drug interactions • Failure to detect addiction • Untreated pain	**Adverse Impact on Patient:** • Discharged from practice • Not having access to care • Legal decisions – loose family, return to jail

Urine Drug Testing:

Frequency of Unexpected Results



Michna E, Jamison RN, Pham LD, et al. Urine toxicology screening among chronic pain patients on opioid therapy: frequency and predictability of abnormal findings. *Clin J Pain* 2007; 23: 173-179.

Initial Assessment and Abuse Screening Tools

Tool	# of Questions	Purpose
ORT[1]	5	Identify risk of prescription drug abuse prior to prescribing
SOAPP-R[2]	5-24	Identify risk of prescription drug abuse prior to prescribing
COMM[3]	17	Identify if patients on opioid therapy are abusing their prescriptions

1. Webster LR, Webster RM. Predicting aberrant behaviors in opioid treated patients: Preliminary validation of the opioid risk tool. *Pain Med.* 2005;6(6):432-442.
2. Butler SF, Fernandez K, Benoit C, Budman SH, Jamison RN. Validation of the revised Screener and Opioid Assessment for Patients with Pain (SOAPP-R). *J Pain.* 2008 Apr;9(4):360-72.
3. Inflexxion, Inc. Current Opioid Misuse Measure. http://www.inflexxion.com/COMM/. Accessed March 7, 2013.

Examples of Risk Factors for Abuse of Pain Medications

- Age
- Family and personal history of substance abuse
- Cigarette dependency (first
- thing in the morning)
- History of preadolescent sex or sexual abuse
- Psychologic stress
- Psychiatric history (anxiety, depression)
- Patterns of impulsive behaviors
- Victimization by others in household such as an abusive
- Spouse, physical abuse

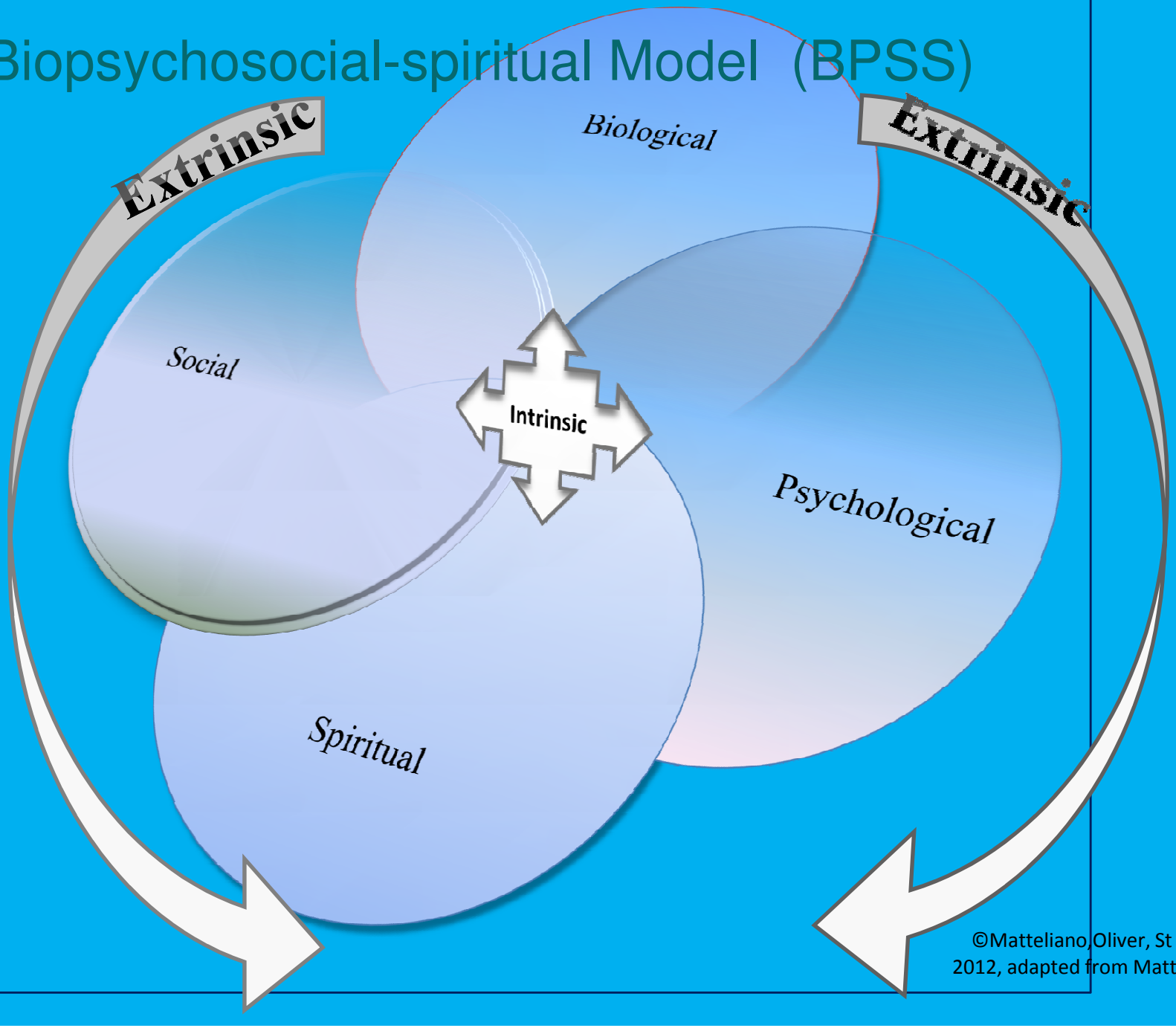
Adapted from Webster and Webster (2005)

Aberrant Drug-related Behaviors

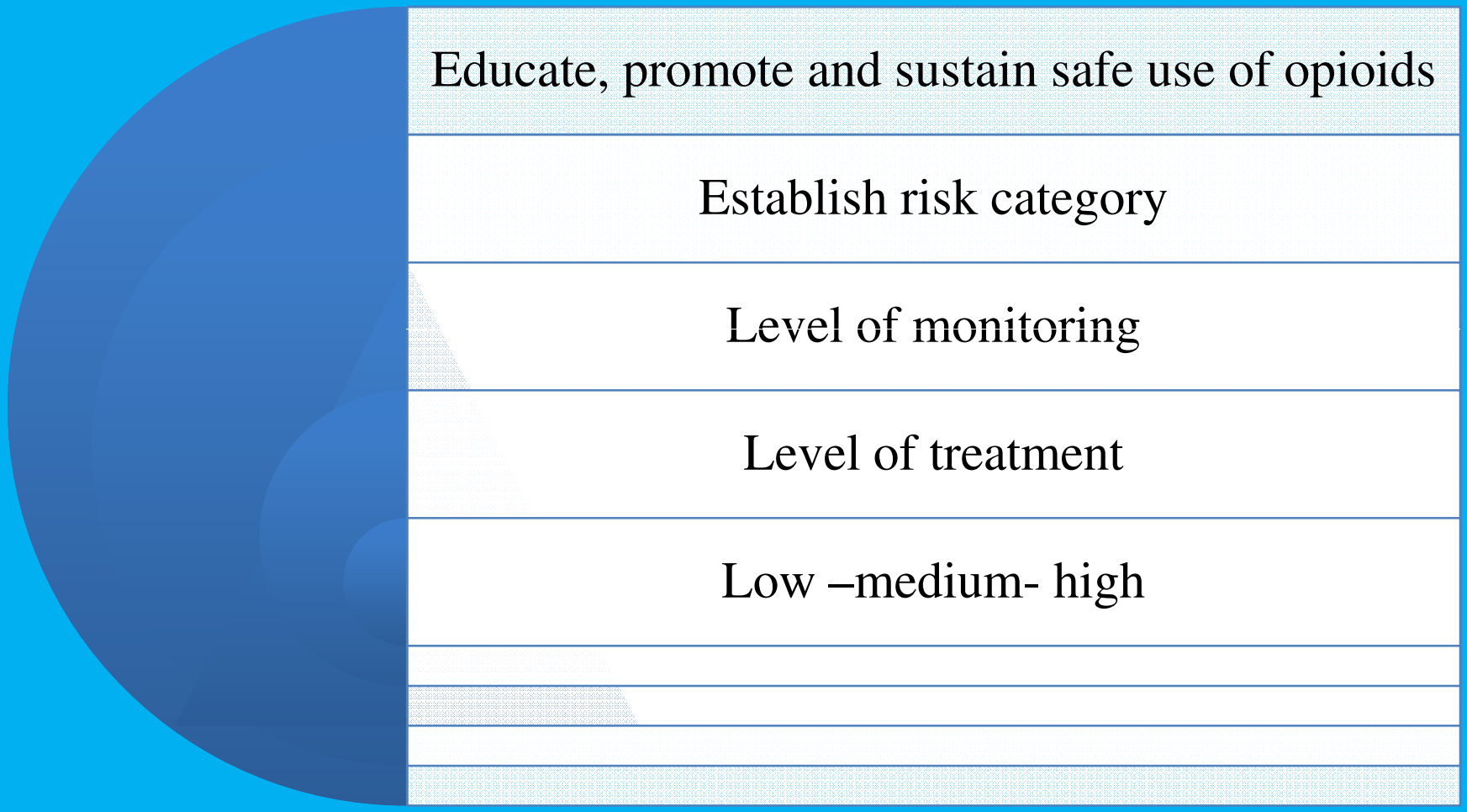
Probably ***MORE*** Predictive of Addiction	Probably ***LESS*** Predictive of Addiction
Selling prescription drugs	Aggressive complaining
Prescription forgery	Drug hoarding when symptoms milder
Stealing or "borrowing" drug(s) from another person	Requesting specific drug(s)
Injecting oral formulation	Acquisition of drugs from other medical sources
Obtaining prescriptions from non-medical sources	Unsanctioned dose escalation once or twice
Concurrent abuse of related illicit drugs	Unapproved use of the drug to treat another symptom

Adapted from: Portenoy RK, et al. Acute and chronic pain. In: Lowinson JH, et al, eds. *Comprehensive Textbook of Substance Abuse.* 4th ed. Baltimore: Williams and Wilkins; 2005:863-903.

Biopsychosocial-spiritual Model (BPSS)



Adherence Monitoring Procedures



Matteliano Pain Management Rehab Protocol

NEW PATIENT: PRE SCREEN for Substance abuse$_1$, Alcohol History$_2$, Quantitative Urine Drug Test (UDT)$_3$. Continuing patient: at least annual documentation of low risk strategies.

1ST visit with Nurse

- Review results of Questionnaires and UDT,
- Psychosocial and smoking history
- Evaluate all medications, pill count if necessary
- Evaluate risk for sleep apnea or other potential risks with COT
- Review patient treatment agreement
- Develop patient goals, document
- Risk stratification as below

Subsequent visits 5 A's document at each visit: Aberrant behavior, Analgesia, Activity, Affect, Adverse side effects. Random UDT

Low risk : *no drug ETOH hx., stable biopsychosocial profile*

- Annual UDT Substance abuse and Alcohol screen
- Annual pill count review of meds
- Regular evaluation for continuation or modification of opioids, review of treatment agreement

Moderate Risk: *active biopsychosocial problems, not following through with referrals for adjuvant pain treatments, Unstable pain, Ambiguous or failed UDT, self report Alcohol/Drug abuse or minor aberrant medication use/behaviors*

- Monthly –Bi-annual tox/Substance abuse and Alcohol Screen
- Support referrals for pain pump, epidural or other modalities
- Frequent med review
- Psychotherapy
- Support group

High risk: *active addiction or evidence of illegal criminal or dangerous behaviors*

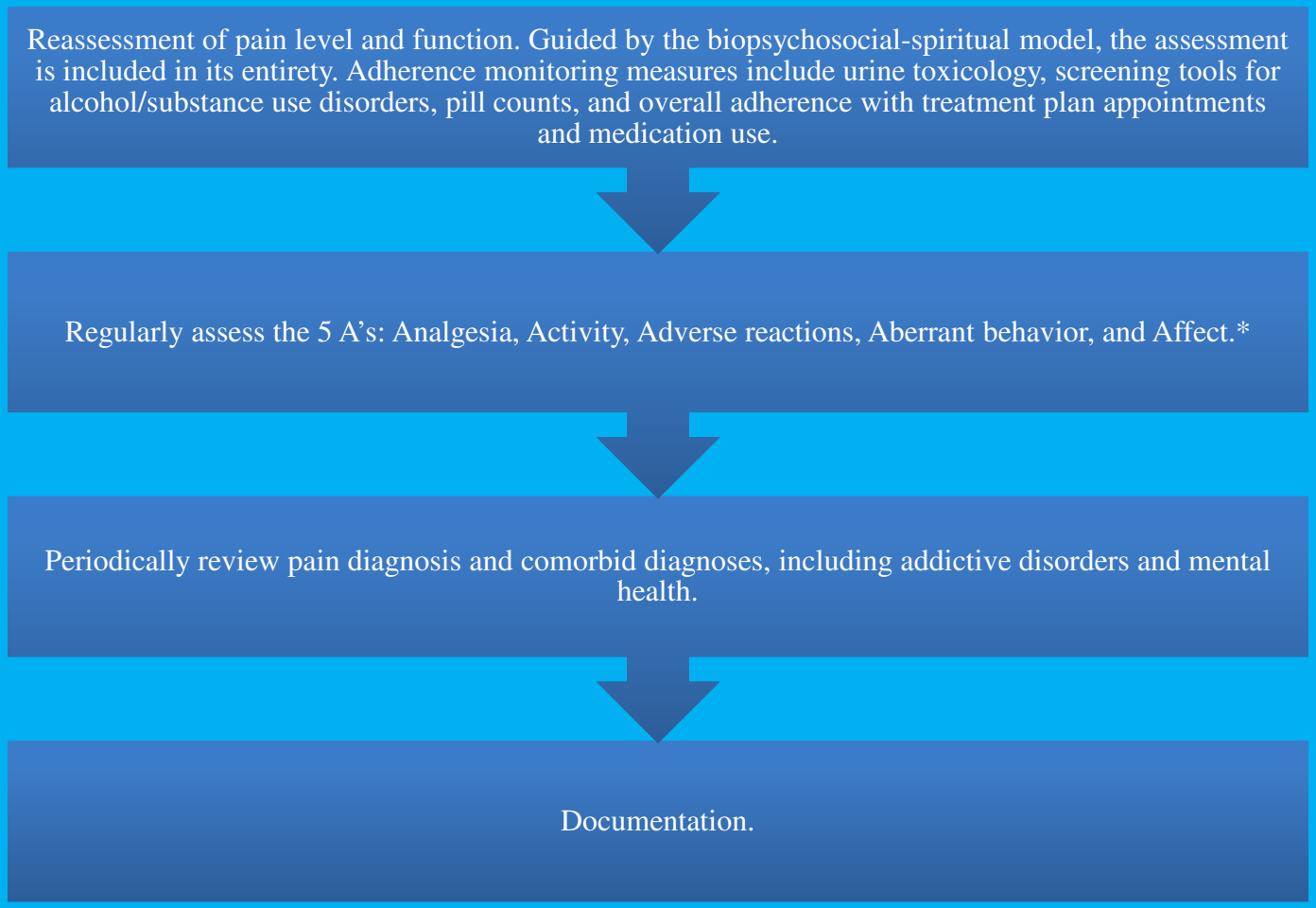
- Shorten dosage interval
- weekly UDT, Substance abuse/ Alcohol screen,
- Refer to or co- manage with addiction care.
- Discontinuation of opioids if interventions are not effective,or evidence of illegal/ dangerous behavior

Establish a therapeutic relationship promoting trust and honesty. Continue to review the Treatment agreement to establish expectations of both the provider and the patient.

This treatment agreement also includes safe storage of medications in the interest of public safety, e.g., Lock Your Meds, as well as rationale for potential opioid discontinuation or discharge from medication treatment.

Appropriate trial of opiate therapy. Integrate cognitive therapy, and support groups

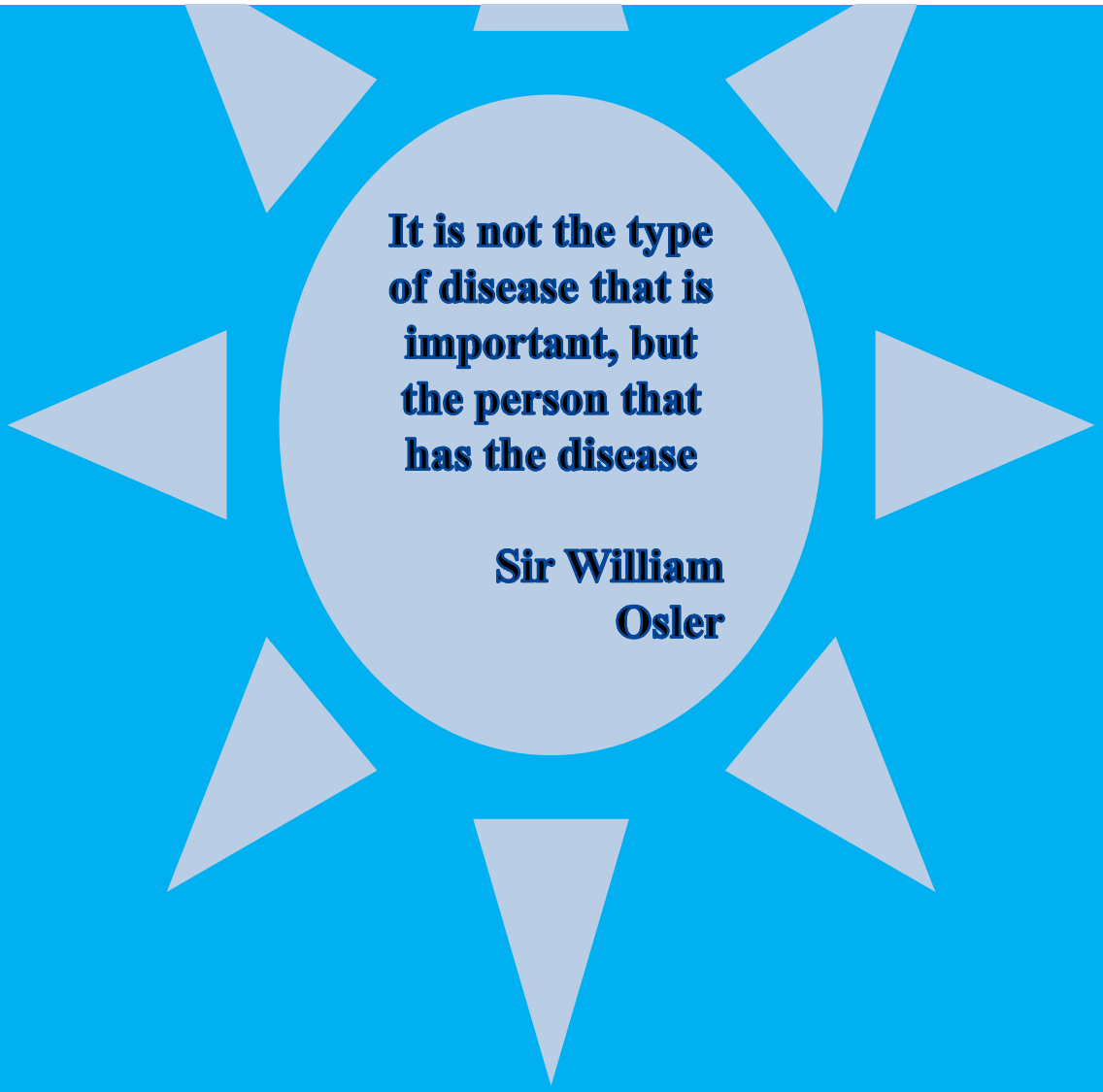
Pre and Post intervention assessment of pain level and function.



*Adapted from "The Four A's of Pain Treatment Outcomes" (Passik & Weinreb, 2000).

Ethical Obligations

- evaluate and treat problems associated with unrelieved pain
- evaluate and treat problems associated with actual or potential risk of a substance use disorder or addiction
- practice without stigmatizing patients
- correct misconceptions in practice
- advocate for holistic treatment of patients with pain and substance use disorders


It is not the type of disease that is important, but the person that has the disease
Sir William Osler

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