

Diversion, risk management and the principle of “Balance”

Opioid Risk Management Conference

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Aims

- **What is a “balanced” approach to diversion and risk management?**
 - National policy framework
 - Outcomes of a balanced approach
 - Roles of clinicians and law enforcement
- **Are aiming in the right direction?**
 - All sources of diversion?
 - A public health approach?

Consequences of diversion

- **Illicit availability of prescription drugs**
- **Secondary crime**
- **Misuse, abuse, addiction/drug dependence**
- **Morbidity and mortality**

- **Reduced confidence in medications**
- **Reluctance to prescribe**
- **Reduced patient access to care**
- **Exacerbation of pain**

National Policy Framework

- States-regulate professional practice; diversion inv.
- FDA-regulates drug approval
 - ✓ Efficacy and safety
- CSA
 - ✓ Control system; registration; penalties; diversion inv.
 - ✓ Necessary for public health
 - ✓ Not for addiction; OK for ‘intractable’ pain
 - ✓ Availability ensured
 - ✓ HHS medical and scientific decisions binding on DEA scheduling

The Principle of “Balance”

- **Opioids safe and effective; necessary**
- **Potential for abuse; control system**
- **Medical value of approved drugs unchanged**
- **Controlled substance policy not to conflict with medicine**
- **Efforts to address abuse and diversion must not interfere with medical practice and patient care**

Recognition of need for Balance

- **Institute of Medicine**
- **American Cancer Society**
- **National Cancer Institute**
- **Federation of State Medical Boards**
- **American Medical Association**
- **Drug Enforcement Administration**
- **International Narcotics Control Board**
- **World Health Organization**
- **European Union**

Outcomes of a “balanced” approach

- **Sources of diversion are identified and resolved**
- **No interference in medical practice or patient care**

Roles of clinicians and law enforcement

| | CLINICIANS | LAW ENF./REG. |
|------------------|--|---|
| Primary | <ul style="list-style-type: none">• Evaluate patients' pain• Relieve pain | <ul style="list-style-type: none">• Evaluate sources of diversion• Stop diverters |
| Secondary | <ul style="list-style-type: none">• Know about diversion• Avoid contributing to diversion | <ul style="list-style-type: none">• Know about pain management• Avoid interfering in medicine and patient care |

Balanced Approaches

- **Educate clinicians about risk assessment**
- **Stop internet availability of opioids**
- **Stop pharmacy crime**
- **Identify doctor-shoppers**
- **Identify prescribers who divert**
- **Reduce demand**

Are we doing this?

Unbalanced approaches

- Don't stock it
- Reduce the dose
- Discontinue patients
- Refer pain patients to specialists
- Contracts and urinalysis for all patients?

Are we doing this?

Are we doing this?

Do all states use Medicaid data to detect diversion?

Pharmacy theft in the USA

1984: Congress makes pharmacy theft a federal crime

2002: > 45 pharmacy thefts in Boston area

00-03: 2,494 thefts of Oxycontin

631 armed robberies

707 night break-ins;

1,369,667 dosage units diverted

2004: “the number of pharmacies reporting drug losses due to breaking and entering has increased.”

We need a public health approach to diversion

- Evaluate all the sources (“vectors”)
- Examine existing data bases and their uses
- Prioritize according to severity
- Plan interventions
- Use appropriate authority
- Avoid unintended consequences
- Evaluate outcomes

Are we there yet?