



Issues in the Surveillance of Pharmaceutical Health Effects in the United States

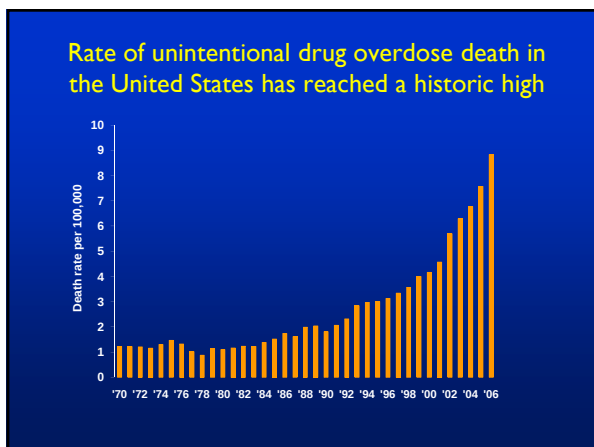
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Centers for Disease Control and Prevention
National Center for Injury Prevention and Control



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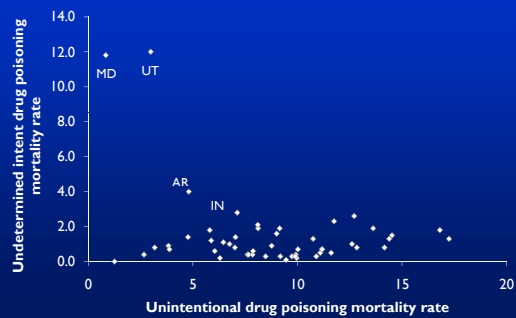
Overview of issues

- I. Case definition
- II. Sensitivity
- III. Risk measurement
- IV. Timeliness
- V. Conflict of interest

I. Case definition issues

- Intent
- Acute versus chronic: mental disorders
- “Licit” versus “illicit”
- Definition of nonmedical use
- Definitions of drug categories

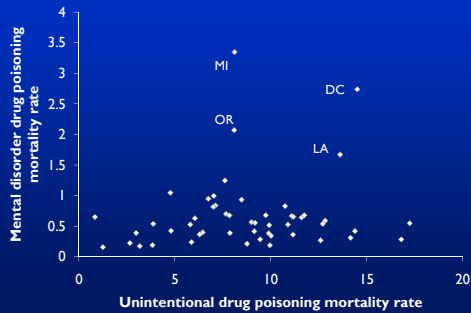
Undetermined vs. unintentional drug poisoning crude mortality rates by state, 2006



Recommendation

- Undetermined (Y10-I4) resemble unintentionals (X40-44) more than drug suicides (See Donaldson, Inj Prev, 12:338, 2006)
- Undetermined in states with high undet rates are too numerous to be suicides (5-6 times greater)
- Therefore, best to combine undetermined with unintentional to negate this source of variability in geographic comparisons.
- Look for such outliers on county/city level, too.

Mental disorder (2000-2006) vs. unintentional drug poisoning (2006) crude mortality rates by state



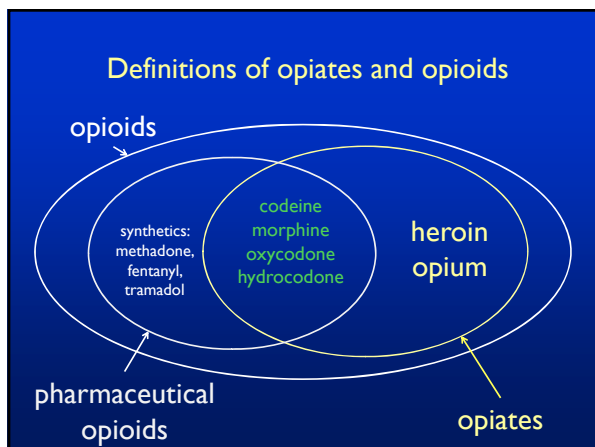
“Licit” versus “illicit” drugs

- “Licit” drugs, eg, oxycodone, are used illicitly
- “Licit” drugs, eg, fentanyl and amphetamines, are also manufactured illicitly
- Some “illicit drugs,” eg, marijuana, have approved uses in some states.
- “Prescription” drugs are used without prescriptions.
- Therefore, distinguish between legal status of drug and use to which it is made.

Toxicology footnote to licit/illicit issue

- Morphine and codeine can be both “licit” prescription opioid analgesics and by-products of the metabolism of the “illicit” drug heroin.
- Be aware of the data used to identify drugs. Lab identifications will not always tell you the legal status of the drug taken.

Definitions of “nonmedical use” of pharmaceuticals by SAMHSA		
Feature	DAWN ED system	NSDUH
Drugs included	Prescription, OTC or dietary supplement	Pain relievers, sedatives, stimulants, and tranquilizers.
Types of use	Taking a drug prescribed for someone else OR	Use without a prescription OR
	Substance abuse involving pharmaceuticals	Use “simply for the experience or feeling it causes”
	Malicious poisoning, including tampering	<i>Not explicitly included</i>
	Withdrawal from drugs	<i>Not explicitly included</i>
	Taking more than prescribed or more OTC than recommended, also known as “overmedication”	<i>Not explicitly included</i>
Timing of use	Drug use must be “recent” to qualify.	Lifetime, past year or month
Exclusions	Suicide attempts, “accidental” ingestions, adverse effects, and seeking detoxification	<i>No explicit exclusions</i>



II. Sensitivity issues

- Reporting biases
- Laboratory testing issues

Reporting biases

- Drug overdose is one of the few types of unintentional injuries where a felony charge is possible.
- Insurance companies might refuse to pay for injuries resulting from abuse of drugs or alcohol.
- Drug misuse is socially undesirable behavior.
- Therefore, failure to report both overdoses and drug misuse is common.
- Suggest using more than medical history to determine whether misuse/abuse was involved in an overdose, e.g., nonmedical route of administration or co-use with street drugs.

Laboratory testing insensitivities

- Not all coroners/MEs test for all drugs because of cost issues.
- Immunoassay is cheap and highly sensitive but misses some drugs entirely, eg, fentanyl
- Identifying specific drugs in classes requires more expensive GC/MS testing.
- Testing done long after exposure may miss some drugs because of short detection times.

III. Risk measurement issues

- Denominators
- Partitioning responsibility among multiple drugs

Denominator options

- Population
 - Consider populations at high-risk for illicit use, eg, people 15-54 years old
- Patients treated with drugs
- People using drugs nonmedically
- Prescriptions issued
- Units of weight or potency

Sources of denominators by jurisdiction

Type	Patient Counts	Prescription Counts	Units of weight or potency
Nation	Commercial, eg, IMS; NAMCS of NCHS	Commercial or NAMCS	DEA ARCOS
State	Commercial or Prescr. Drug Monitor Program	Commercial or PDMP	DEA ARCOS or PDMP
County	?	PDMP	ARCOS (custom), PDMP
Zip	?	PDMP	ARCOS (3-digit), PDMP
Beneficiaries	Medicaid/Insurance, HMO members, Workers' compensation	Medicaid/Insurance, HMO members, Workers' compensation	Medicaid/Insurance, HMO members, Workers' compensation

Approaches to partitioning responsibility among drugs

- Mentions: cite every occurrence (e.g., DAWN, multiple cause mortality data)
- Break out single-drug-related events
- Give each drug a fraction of an event that equals 1 over the number of drugs in the event?
- First-listed drug?
- Use of lethality cutoff levels to identify causal versus present drugs (eg, Florida ME's report)
- Expert opinion

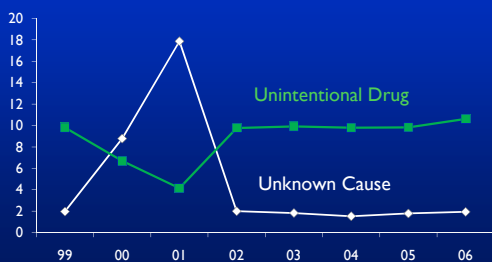
IV. Timeliness issues

- Cases finalized after deadlines: the unknown cause issue
- Lags in major reporting sources

The problem of unknown cause deaths

- Deaths with pending cause are given placeholder codes, such as R99 in ICD10 mortality data.
- Poisoning events take longer to get final cause determination because of lag in toxicology.
- Poisoning events are more likely to miss cutoff dates for file closure.

Unintentional drug poisoning and unknown-cause (R99) death rates, 15-54 years old, California, 1999-2006



Lag Times for Pharmaceutical Surveillance Sources

Source	Lag time (year available)
National mortality file	3 years (2007)
State mortality file	1-3 years (varies by state)
Hospital discharge data/HCUP	2-3 years (2007)
Emergency department (ED) data, DAWN	1-2 years (2008)
ED data, DAWNLive!	Rolling, data from past month
DEA ARCOS	3+ years? (2006)
Prescription Drug Monitoring Program	1-3 months

V. Conflict of interest issues

- Private sector surveillance systems
 - RADARS, funded by Purdue, maker of OxyContin
 - NAVIPPRO, funded by Endo and Alpharma, makers of Endocet and other opioids.

Thank you

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