Drug-Involved Mortality (DIM) Project

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FDA/CDER/OSE/OPE/DEPI II

CDC/OPHSS/NCHS/DVS/MSB

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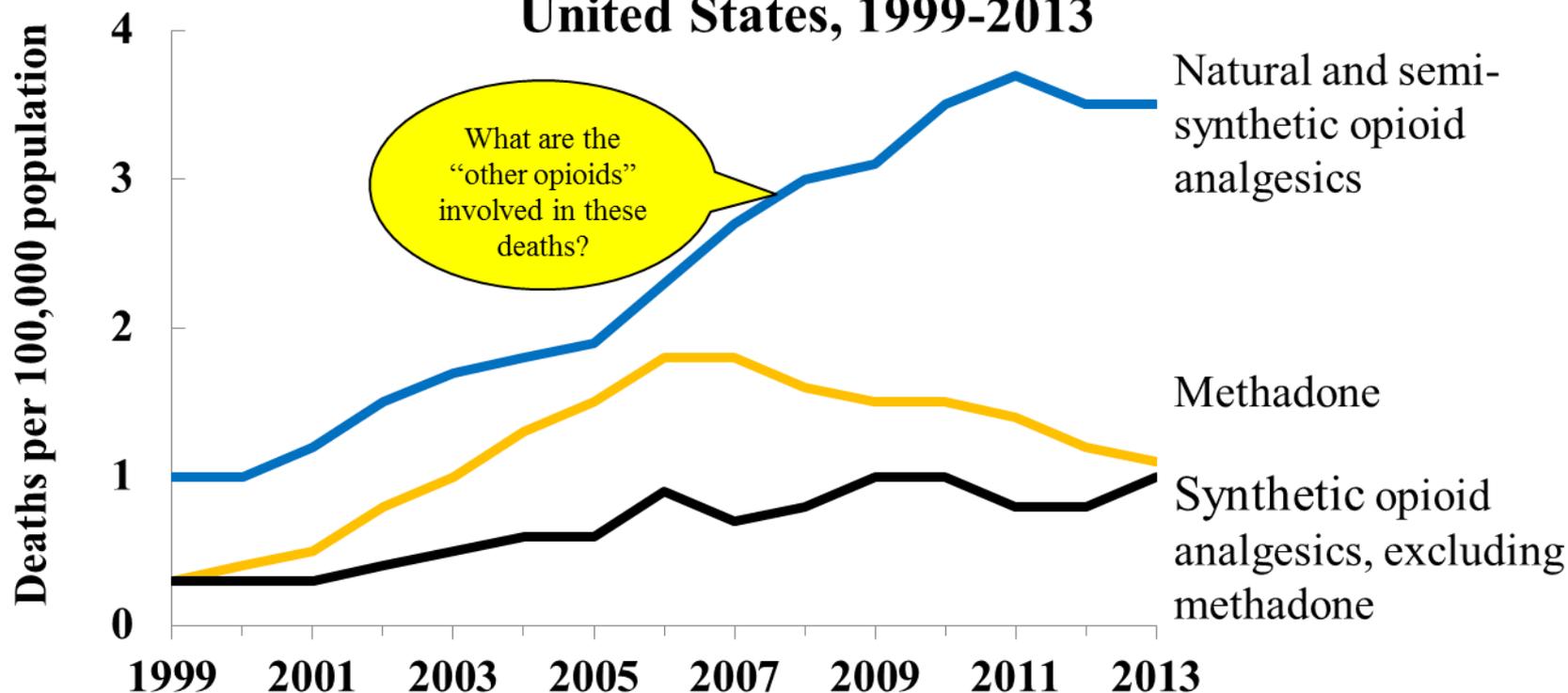
2015 National Conference on Health Statistics

Scientific Session: "From Health to Harm: The Burden of Drug Poisoning in the U.S."

Increase in drug poisoning deaths due to "other opioid analgesics"

Age-adjusted drug poisoning death rates, United States, 1999-2013

NOTES: Decedents' exposures may not be mutually exclusive (i.e., concomitant exposure).
SOURCE: CDC/NCHS, National Vital Statistics System, Mortality File

Death certificate text:
Better drug specificity than ICD

- Data on drug-specific mortality could enhance understanding of benefit-risk profile for FDA-regulated drugs

- Limited drug specificity in ICD-10 coded mortality data

- Information written by medical certifiers on death certificates could provide better specificity

- Similar efforts utilizing literal text analysis
  - Prions (Creutzfeldt-Jakob Disease)
  - Not-in-traffic surveillance
  - State-specific drug poisoning deaths

DRUG-INVOLVED MORTALITY (DIM) PROJECT: AN INTERAGENCY COLLABORATION

DIM Project: An interagency collaboration

- Memorandum of Understanding (FDA and CDC)
  - Coordinate and collaborate by utilizing expertise, resources, and relationships to increase capability and readiness to respond to emergency situations

- Letter of Agreement (CDER and NCHS)
  - Agreement to leverage information on DIM written in death certificates
  - CDER provides 1 on-site FTE
  - NCHS provides training, resources, and relevant data access

Project aim: Surveillance of DIM

- To explore the utility of National Vital Statistics System – Mortality data (NVSS-M) linked with SuperMICAR literal text to provide data needed for public health surveillance of deaths associated with specific drugs

Scientific objective:
Develop methodology for identifying DIM

- Evaluate the ability to identify specific drugs in literal text
  - Quantify the number of cases associated with specific drugs

- Understand how drugs are portrayed in literal text

- Assess strengths and limitations of using death certificate literal text vs. ICD-10 codes for research and surveillance

Programmatic objective:
Optimize collaboration

- Recommend methods for routine sharing of DIM data between NCHS and CDER --- for example:
  - Standardized processes for data requests
  - Development of request forms
  - Automation of simple searches and analyses
  - Establishment of roles/responsibilities for FDA and CDC personnel

- Maintain interagency collaboration for projects of mutual benefit

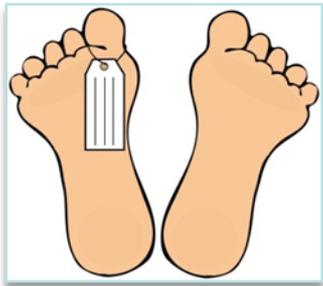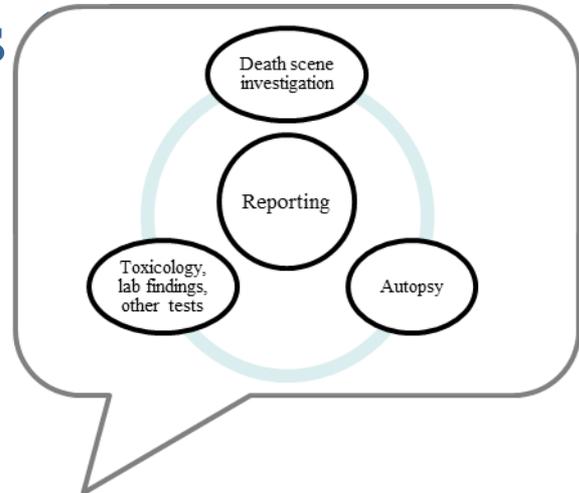- Optimize project by using physical, intellectual, and data resources in NCHS and CDER

DEATH CERTIFICATE DATA WITH FOCUS ON DIM

CDC death certificate data file:
A subset of death investigation data
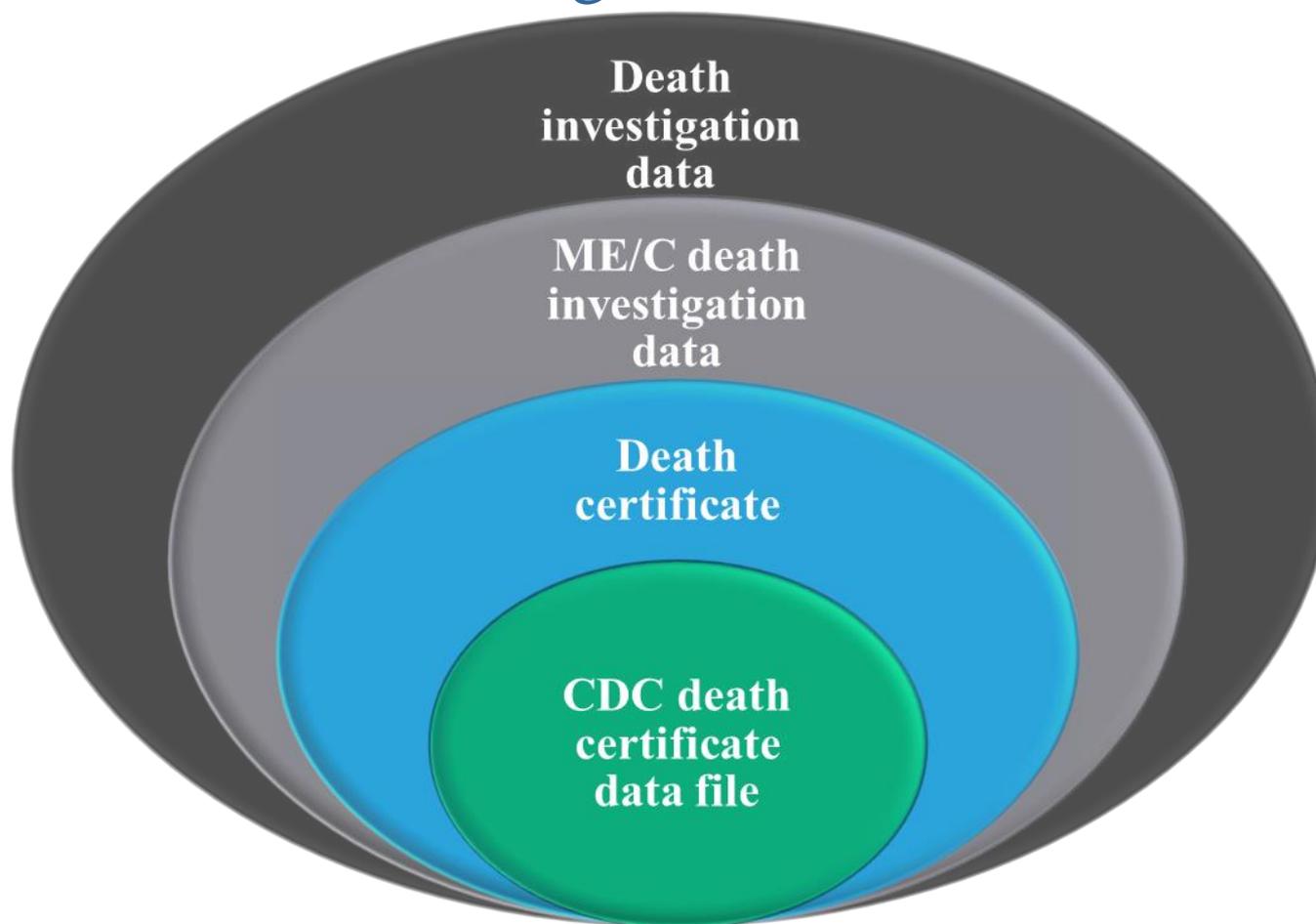
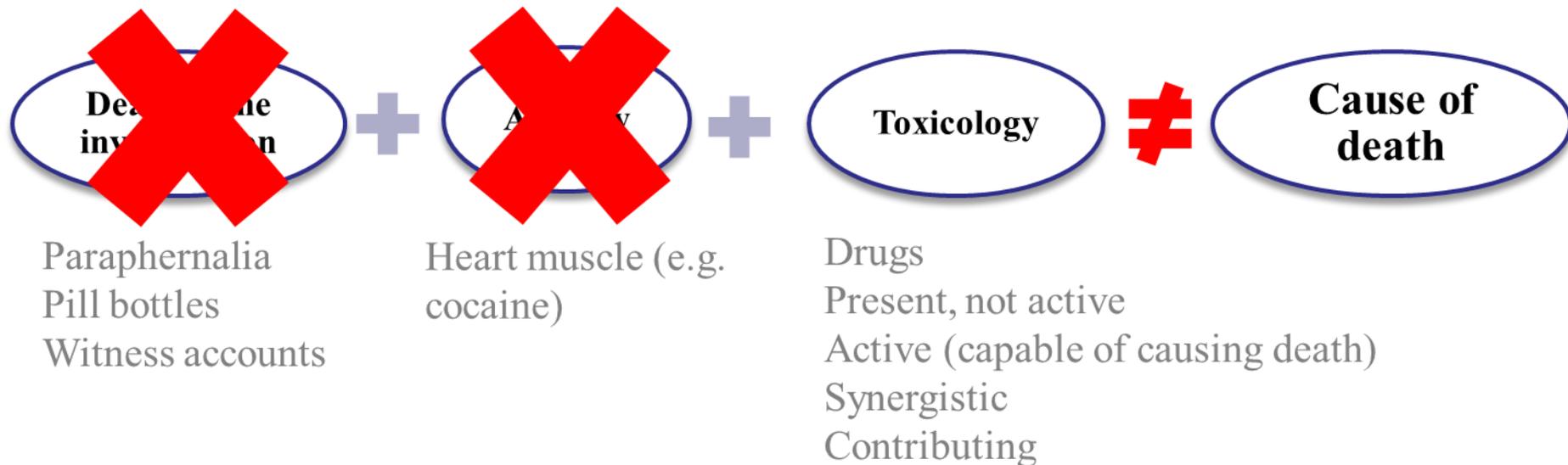# Death investigation data from medical examiners and coroners

Death investigation data encompasses multiple data sources

Death scene investigation + Autopsy + Toxicology = Cause of death

Paraphernalia
Pill bottles
Witness accounts

Heart muscle (e.g. cocaine)

Drugs
Present, not active
Active (capable of causing death)
Synergistic
Contributing
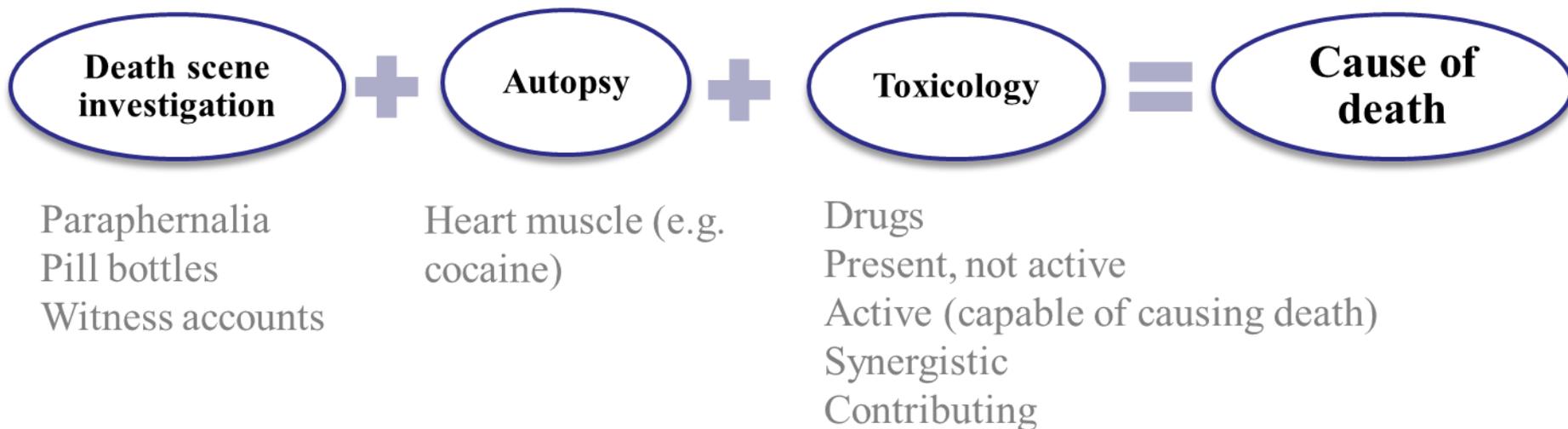
DIM investigation is more than toxicology

Dea... he inv...on ✗ + A...y ✗ + **Toxicology** ≠ **Cause of death**

Paraphernalia
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Death certificate text fields → electronic literal text → ICD codes

Multiple cause of death files

Mortality Medical Data System

Super-MICAR literal text → **Process data** → **ICD-10 coded MCOD**

Specific drug mentioned in Parts I and Part II of death certificate

IDENTIFICATION OF MENTIONS OF DRUGS/SUBSTANCES IN LITERAL TEXT

Automated identification of drug mentions and classification of involvement

- SAS programs were developed to automate the identification of mentions of drugs and substances from literal text and ascertain their involvement (if any) in death

- Steps (in general)
  - Identify mentions of drugs and substances
    - Based on investigator-defined list of drugs/substances
  - Use contextual words surrounding drug mentions to classify involvement

DIM programs consider death certificate text characteristics

- Punctuation and letter case (upper case)

- Drug name variations and descriptive words
  - Generic, brand, metabolites, abbreviations, misspellings, other
  - Descriptive words may appear, e.g., "*RX AND ILLICIT* DRUGS"

- Phrasal syntax
  - Generally no sentences
  - Interchangeability of words in phrase
    - E.g., "_____ OVERDOSE" may refer to oxycodone, alprazolam ,or both
  - Phrases help classify DIM vs. non-DIM cases
    - E.g., "Insulin overdose" vs. "Insulin-dependent diabetes"

DIM PROJECT: STRENGTHS, LIMITATIONS, AND FUTURE ENDEAVORS

Literal text analysis has inherent limitations

- Incompleteness of data
    - Drugs not written on death certificates
    - Other information missing (e.g., routes of administration)

- Non-specificity: Mentions of drugs not otherwise specified

- Hurdles to understanding validity of literal text analysis
    - Temporal/geographic variation: Missingness, lack of specificity
    - Appreciation of toxicology (e.g., morphine is metabolite of heroin)

- Context may be important

DIM project can address major knowledge gap

- Better identification of specific drugs

- DIM encompasses
  - Poisoning
  - Adverse effects (e.g., anaphylaxis)
  - Drugs 'on board'
  - DIM in other external injuries (e.g., motor vehicle accidents)
  - Other

- Many potential research opportunities with national scope
  - Retrospective research
  - Prospective surveillance

FDA and NCHS pursuing pilot projects driven by specific questions

- Currently developing research/surveillance questions

- Results will further help appreciate strengths and limitations of literal text analysis