

The Opioid Crisis: "It's all in how you spin the Data"

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Disclosures

- Janssen Pharmaceuticals: Consultant
- YourEncore: Consultant

Case Study

Case Study

- 70 year old female
 - Found dead laying on her back in the kitchen.
 - Dish washing gloves, water running in sink, cup of coffee on the sideboard.
 - No evidence of foul play or head trauma.
 - History of heart disease.

Thanks to Dr. Josh Gunn for this case

Case Study

- Past History:
 - Patient had been on Morphine 30 mg twice a day for over 6 years.
 - Stable dose for over 5 years.
 - Had a history of trauma with multiple vertebral fractures
 - Morphine kept her comfortable.
- No personal or family history of SUD.
 - Same pain physician for 6 years, no issues.
- Long history of CAD
 - Past history of myocardia infarction.
- Death Certificate: Myocardia Infarction due to CAD.

Case Study

- Coroner (non-MD) reviewed the case
 - Central Heart Chamber blood was drawn:
 - Morphine found.
 - "Toxic Levels"
 - Death Certificate changed to "Morphine Overdose".
- Secondary Outcomes
 - Family lost the life insurance
 - Family reputation, patient now a "drug addict"
 - Other issues:

Case Study

- Issues:
 - Coroner Qualifications.
 - Death Certificate date and data entry.
 - Misunderstanding of opioid drug levels.
 - What is toxic and what is not.
 - Questionable post-mortem blood draw.
 - Lack of understanding of this process

Death Certificates

Death Certificates

- Success at life prolongation = "age-adjusted mortality rates"
 - Primary tool = Death Certificate (DC)
 - Helps Set National, Regional, Statewide policies.
 - Local funding, disease research and interventional approaches
- Settling estates, bank accounts, stocks & bonds, etc ..
- Evidence in court cases.
- Data for major research studies.

Swain, (2005)

Death Certificates

- Who fills out DCs:
 - Funeral directors, attending physicians, medical exam-iners, coroners, and others.
 - Does not have to be a medical professional

Death Certificates

- Mortality statistics derived from DC
 - Most widely used health data source at the national, state, and local levels.
- Data from the National Vital Statistics System
 - Collaboration with NCHS and state vital statistics offices
 - DCs are reported to state vital statistics offices.
- WHO
 - WHO plays a major role in data collection, classification and tabulation
 - International agreement, US is signatory, ICD system

Death Certificates

- Cause of death traditionally presented in terms of one underlying cause
 - Data can be augmented
- Each state is required to comply with NCHS rules to receive federal funding
- CV Death is significantly over represented as a COD.

Death Certificates

“In an ironic twist, probably no document has as much impact on the health of a population as does the death certificate. ... But recent studies have found many inaccuracies in these certificates, and their reliability has come under increasing criticism in medical journals and among health officials.”

Altman, 1988

Death Certificates

- “Death certificate inaccuracy is a well-recognized problem at both the national and international levels.” (Carter, 2017)
 - Errors in identifying cause and manner of death
 - ICD-10 codes
 - illegibility and incompleteness.
- “If enhanced surveillance can be incorporated into the death certificate process, national data on overdoses may better reflect the contribution of heroin to the opioid crisis.” (Horon, 2018)

Death Certificates

- “The Cause-of-death (COD) statement, which is vulnerable to various errors, is the vital part of a DC that has the potential to mislead policy makers and statisticians.” (Maharjan, 2015)

Death Certificate-Physicians

- National
 - Pritt, et. al., 2005: Multiple errors identified in 82%
 - Aung, 2010: Educational interventions shown to improve error rates
 - Wexelman, et. al. 2013: 46.5% knowingly inaccurate reporting, only 33% believed that cause of death data is accurate.
 - Brooks, 2015: Only 15.5% could correctly identify cause of death
- International
 - Myers, 1998: 32.9% Errors in DC in Canada
 - Maharjan, 2015: The study found errors in 78.4 % of DCs in Nepal.

Death Certificate-Physician and Political

- Physician ignorance
 - Lack of training in filling in the DC
 - Understanding Drug Overdose Deaths
 - Understanding Polysubstance Overdose
 - ICD-10
- Little data on others who fill in DC data
- Political Pressures on Death Statistics
 - Kishore, et., al., 2018: Hurricane Maria:
 - Puerto Rico Official mortality 70 times less than survey results
 - Similar issues in Kentucky with the opioid crisis

Coroners and Medical Examiners: Oh My!

Coroner/Medical Examiner

- Coroner:
 - States with laws specifying training requirements for coroners: 16
 - States that require coroners to be physicians: 4 (Kansas, Louisiana, Minnesota, and Ohio)
- Coroners frequently elected officials
 - No health care or medical requirements.
 - If an autopsy needed, coroner consults a pathologist or forensic pathologist, if available (not required).
- Medical examiners
 - Most appointed and must be physicians.
 - Most states no requirement to be pathologists or forensic pathologists.

Georgia Coroner Qualifications

- Elected Position
 - Registered Voter
 - Over 25 years old
 - No felony Convictions
 - High School diploma or equivalent
 - Attest to the above by affidavit
 - 1 week of annual training.

Opioid Overdose as a Cause of Death

- Oxycontin Deaths frequently Polypharmacy
 - "Majority of cases involved multiple drugs." (Cone, 2003; Cone, 2004)
- 2015 NH opioid deaths 72% - Fentanyl (Costantini, 2016)
- When opioid prescription detected, "prescription OD". (Hannah, 2017)
- 2018 CDC data: Fentanyl/heroin > prescription deaths (CDC, 2018)
- Do we have a prescription opioid problem or a polypharmacy problem?

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Opioid Overdose as a Cause of Death

- Relies primarily on opioid blood concentrations compared to pre-determined fatal cutoffs. (Miron, 2018)
 - Ranges frequently obtained from drug development PK/PD Studies.
 - Healthy, non-tolerant, study subjects.
- Medical Examiner, forensic pathologist, Funeral Home Director, Coroner, Others. (Gunn, 2019; Molina, 2013)
 - Peripheral Blood, Urine, Vitreous collections.
 - Frequently it is central Heart Chamber Blood.
 - Notorious for postmortem redistribution effects.
 - Falsely elevated levels antemortem, can be significant elevations

Opioid Overdose as a Cause of Death

- Example: Methadone
 - Numerous fatal ranges stated:
 - 220-3040 micrograms/liter; 320-2980 micrograms/liter; 600-3000 micrograms/liter
 - 400-1800 micrograms/liter Baselts (Baselt, 2000)
 - Studies on patients taking Methadone
 - 20-1308 micrograms/liter (Loimer, 1992)
 - 585-2700 micrograms/liter (Gagajewski, 2003)

Opioid Overdose as a Cause of Death

- Methadone Therapy:
 - No difference between methadone blood concentration "caused" by methadone toxicity, and when methadone was incidental finding (Karch, 2000)
- Morphine concentrations in current heroin users and heroin overdose death, found substantial concentrations overlap (Darke, 1997)
 - 1/3 had morphine concentrations double the "fatal" level.
- Morphine concentrations in deaths ruled morphine toxicity compared to those homicide with incidental morphine in the body. (Darke, 2007)
 - No difference between the two groups.

Opioid Overdose as Cause of Death

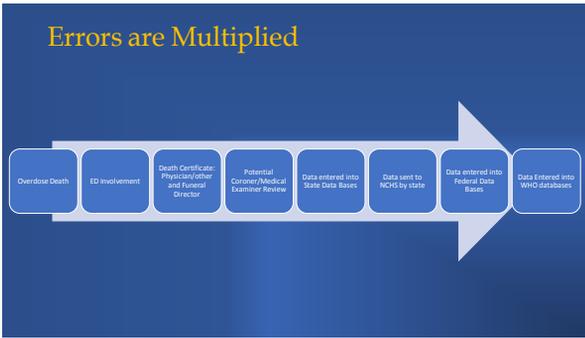
- "With fatal toxic concentration levels being so broad and overlapping, with ranges that many addicts live with, a toxicology report is of little help with determining the cause of death." (Miron, 2018)

California Death Certificate Project

- "This increase in enforcement activity has been driven in part by the Board's Death Certificate Project."
 - "The project utilizes California death record data to identify physicians that may be inappropriately prescribing opioids to their patients."
 - "The Medical Board of California, in collaboration with the California Department of Public Health, has been using the project as an additional tool to investigate physicians who may have violated the law."

California Death Certificate Project

- "On "All Things Considered"
 - KQED's April Dembosky reports on the California medical board's Death Certificate Project.
 - Collected 3,000 death certificates due to "opioid overdoses"
 - Cross-referenced with state's PDMP.
 - Sent letters to more than 500 doctors.
 - "The board has filed formal charges against 25 doctors, and left hundreds more,... waiting to learn their fate."



- ### Recommendations:
- Required Education for Medical Boards on:
 - Understanding the use of Blood/serum levels of opioids in "opioid over dose deaths."
 - Pain Medicine
 - Standardized requirements for Medical Examiners:
 - Not Coroners
 - Physicians with expertise in toxicology and forensics.
 - Elimination of non HCPs drawing blood/serum for toxicology in death reviews.
 - Training on where, what and where to draw these samples.
 - Updating of Death Certificates to allow of more than one cause of death.

Thank You.
