June 28, 2022

To: Rochelle Walensky, MD, MPH, Director, Centers for Disease Control and Prevention (CDC)
Robert Anderson, Ph.D, Chief, Mortality Statistics Branch, National Center for Health Statistics (NCHS), Chiquita Brooks-LaSure, Administrator, the Centers for Medicare and Medicaid Services (CMS), Xavier Becerra, U.S. Secretary, Health and Human Services (HHS)
Christi Grimm, Inspector General (HHS)

We are writing to you as governmental agencies, organizations and individuals who have the power to ensure that death certificate data and statistics are accurate and not missing important causes and contributing factors. The problem we are working to address is the omission of patient harm from medical injuries, accidents and healthcare acquired infections (often referred to as 'complications') in national health statistics' leading causes of death.[1]

Health data gathered from death certificates is critical in quantifying public health threats, drawing media attention, and informing the public. Statistics gathered from death certificates are used to develop national health agenda priorities and for funding research on prevention. In the case of medical harm deaths, this national public health issue not only remains silent in vital statistics, but contributes to the inflation of death counts from more general disease categories like heart disease and organ failure.[2]

On a more individual level, death certificates are important legal documents for families' understanding of their health histories, in settling estates, and in getting closure to the 'what, how and why' questions that help them move forward in their grief.

As our country mourns the horrific loss of 10 African-Americans in Buffalo, NY, and 19 precious children and 2 teachers from yet another gun massacre in Uvalde, TX, we are reminded of the essential role that national death statistics play in convincing the public and lawmakers to act and provide accountability for preventable deaths. To quote a Pew Research report[3]:

'In 2020, the most recent year for which complete data is available, 45,222 people died from gun-related injuries in the U.S., according to the CDC. That figure includes gun murders and gun suicides, along with three other, less common types of gun-related deaths tracked by the CDC: those that were unintentional, those that involved law enforcement and those whose circumstances could not be determined. **The total *excludes* deaths in which gunshot injuries played a contributing, but not principal, role. (CDC fatality statistics are based on information contained in official death certificates, which identify a single cause of death.)'**

For medical injuries, accidents and healthcare acquired infections that result in death, we are left to arrive at mere estimates based on retrospective studies of medical records, done years apart. The most recent Office of Inspector General (OIG) Study on medical harm in Medicare

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[1] https://www.cdc.gov/nchs/data/nvsr/nvsr69/nvsr69-13-508.pdf

[2] https://www.bmj.com/content/353/bmj.i2139

[3] https://www.pewresearch.org/fact-tank/2022/02/03/what-the-data-says-about-gun-deaths-in-the-u-s/

beneficiaries published in May 2022 estimated that for patients who experienced an adverse event (AE), 10% resulted in death (14,800 patients in one month).[4] This is comparable to the 2010 OIG study estimating that AEs resulted in 15,000 Medicare patient deaths in one month.[5] A 2013 evidence-based estimate of the true number of all premature deaths associated with preventable harm to patients was in excess of 400,000 per year.[6]

Significant resources are being invested in patient safety by organizations such as CMS, The Agency for Healthcare Research and Quality (AHRQ), Patient Safety Organizations (PSOs), Regional CMS Quality Improvement Organizations (QIOs), Institute for Healthcare Improvement (IHI), The Leapfrog Group, The Joint Commission and many others. Yet, according to these retrospective studies, medical harm continues to be a leading cause of death in America. Without an accurate death toll, we lack a coordinated national effort for prevention and accountability.

Americans and their elected officials can't demand action to prevent a health threat that is invisible to them. We believe adding queries to death certificates about medical injuries, accidents and infections will result in medical harm finally be included in the CDC's leading causes of death. In light of the recent OIG report on Medicare patient harm and deaths mentioned above, as well as recent CDC reports that healthcare associated infections have increased significantly [7], we feel an even greater urgency. It is clear the Pandemic has exposed our fragile system of quality and safety. We feel strongly that failing to accurately report and track these deaths on death certificates is a major contributor to this long standing lack of progress.

We applaud recent improvements to death certificates the CDC's National Center for Health Statistics (NCHS) has implemented by adding queries related to pregnancy/birth. Policies and queries adopted on COVID-related deaths have helped to identify the full impact of the Pandemic.[8]

The undersigned are part of a death certificate reform workgroup committed to bringing greater accuracy to death certificates by including medical injuries, accidents, infections and complications. We want to partner with leaders such as yourselves to bring about the changes needed to ensure death certificates reflect the often undocumented patient harm that contributes to a person's death.

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[4] https://oig.hhs.gov/oei/reports/OEI-06-18-00400.asp

[5] https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

[6] https://s3.amazonaws.com/s3.documentcloud.org/documents/781687/john-james-a-new-evidence-based-estimate-of.pdf

[7] https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/impact-of-coronavirus-disease-2019-covid19-on-healthcareassociated-infections-in-2020-a-summary-of-data-reported-to-the-national-healthcare-safety-network/8197F323F4840D233A0C62F4726287E1

[8] https://www.cdc.gov/nchs/covid19/coding-and-reporting.htm

Below is a list of actionable steps that can provide the attention this issue so urgently needs and deserves:

1. Include a query on death certificates that asks, “Was a medical accident, injury, health care acquired infection or complication present before this death, a cause or contributing factor? If yes, please indicate here.” (Allow for a list of possible causes and a line for ‘other’). In other words, as was used for querying COVID-related deaths, “*Why did the patient die when they did?* “
2. Hire NCHS staff to audit death certificates, using trigger tools in medical record review.
3. Give the CDC’s NCHS federal regulatory authority over state vital statistics departments for standardization of death certificates.
4. Add a brief section to death certificates for caregiver/health care Power of Attorney comment. An example would be, “Do you feel the cause and contributing factors to death are accurate? If not, please explain.” (Allow for a limited narrative summary and section for their contact information.)This could be used to initiate an audit of the medical record. Currently, there is no workable process for family members to have serious inaccuracies and omissions on a death certificate corrected.
5. Require that all death certificate reform committees include patient safety advocate members.
6. Require autopsies for unexpected deaths in a hospital and for those deaths reasonably suspected to be due to medical injuries.
7. Require that hospitals/doctors inform family members when the cause of death is unknown and their right to an autopsy.
8. Make death certificate completion training mandatory for doctors.
9. Require that the doctor certifying and signing the death certificate has had direct experience with the patient.
10. Require that a doctor *and* a facility administrator sign off on each death certificate.

We appreciate your consideration of this letter and our recommendations, and we look forward to hearing from you about how we can work together.

Respectfully submitted,

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