Understanding the OPO performance metric is key to public trust in our organ donation system

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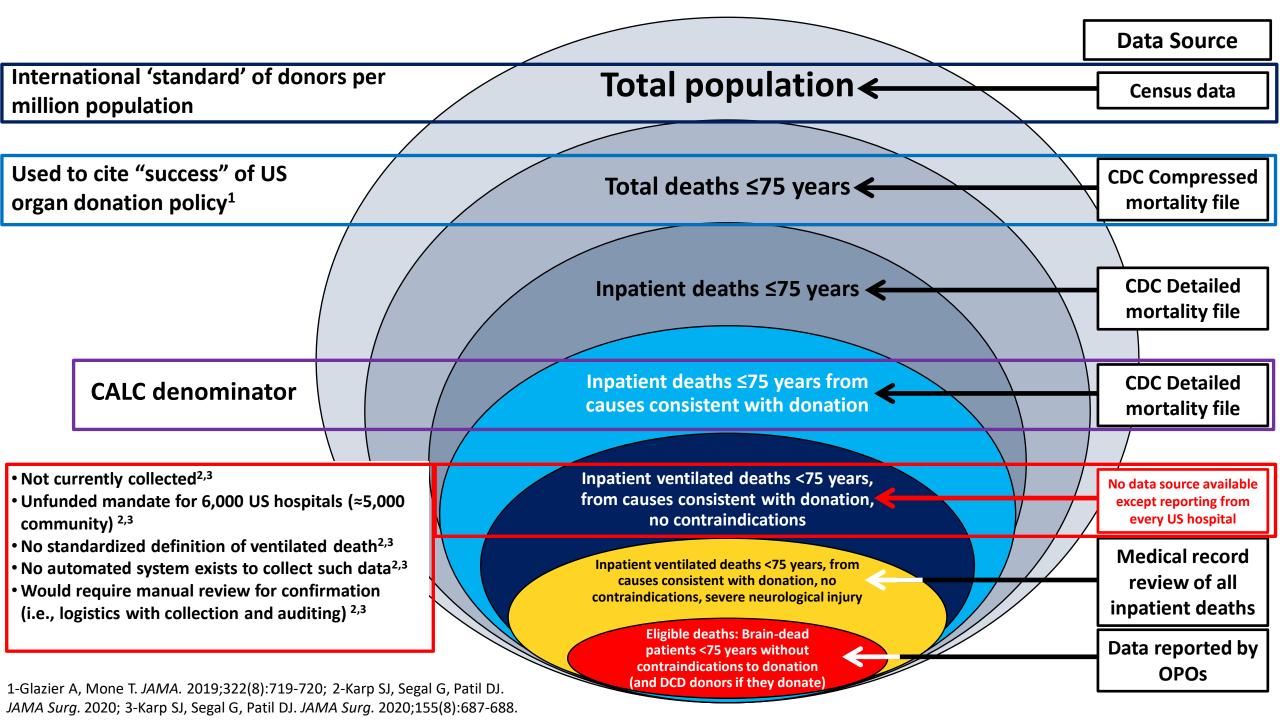
What is the purpose of the OPO performance metric

- Compare OPO performance for re-certification
- Identify
 - High-performers to serve as model OPOs
 - Intermediate-performers who may benefit from quality-improvement initiatives (i.e., SIAs) and/or increased local competition
 - Low-performers that should be considered for decertification
- Similar to 2006 (eligible death metrics)
 - Define: "A lowest common denominator measure of a portion of donor potential oin order for CMS to assess OPO performance for redesignation."
 - Caveat: "It was never intended to be a complete measure of donor potential..." 1

Potential sources of denominator for OPO metric¹

Data Source Total population ← Census data **CDC Compressed** Total deaths ≤75 years ← mortality file **CDC Detailed** mortality file **Inpatient deaths ≤75 years from CDC Detailed** causes consistent with donation mortality file Inpatient ventilated deaths <75 years, No data source available from causes consistent with donation, except reporting from no contraindications every US hospital **Medical record** Inpatient ventilated deaths <75 years, from causes consistent with donation, no review of all contraindications, severe neurological injury inpatient deaths Eligible deaths: Brain-dead Data reported by patients <75 years without contraindications to donation **OPOs** (and DCD donors if they donate

1-Goldberg D, Karp S, Shah MB, Dubay D, Lynch R. Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation. *American Journal of Transplantation*. 2019;19(11):2973-2978; 2-Glazier A, Mone T. Success of Opt-In Organ Donation Policy in the United States. *JAMA*. 2019;322(8):719-720; 3-Karp SJ, Segal G, Patil DJ. Using Data to Achieve Organ Procurement Organization Accountability-Reply. *JAMA Surg*. 2020; 4-Karp SJ, Segal G, Patil DJ. Fixing Organ Donation: What Gets Measured, Gets Fixed. *JAMA Surg*. 2020;155(8):687-688.



What is the CALC metric?

- CALC=Cause Age Location Consistent with donation¹
- Cause: Underlying causes of death included in >98% of all donations (e.g., cardiovascular, stroke, trauma, overdose)
- Age: Age at death ≤75 years of age (>99% of all donors)
- Location: Inpatient (in a hospital; >99.5% of all donors)
- Underlying cause of death data from CDCs' National Center for Health Statistics (NCHS)

What are the NCHS underlying cause of death data?

- Data based on death certificates¹
 - Mortality information collected by state registries
- Underlying cause-of-death
 - "The disease or injury which initiated the train of events leading directly to death, or the circumstances of the accident or violence which produced the fatal injury."
 - Selected from conditions entered by physician on cause of death section of the death certificate
 - https://wonder.cdc.gov/wonder/help/CMF/TechnicalAppendix1999.pdf
- NCHS established data source for researchers, UNOS scientists, and OPO leaders:
 - Estimate organ donor potential to impact policy, regulatory, and practice changes²
 - Evaluating geographic variability in organ donation³
 - Examine racial and ethnic difference in donation over time in the US⁴

Concerns about death certificate "errors" unfounded

- JAMA Surgery Letter to the Editor from OPO Board Member¹:
 - "The problem is that the data sources are death certificates, which are known to be error-ridden, with significant errors in 50% of cases."²
 - "It might not matter if the errors were uniformly distributed, but it is known that this is not the case, neither region to region³ nor hospital to hospital."⁴

Truth

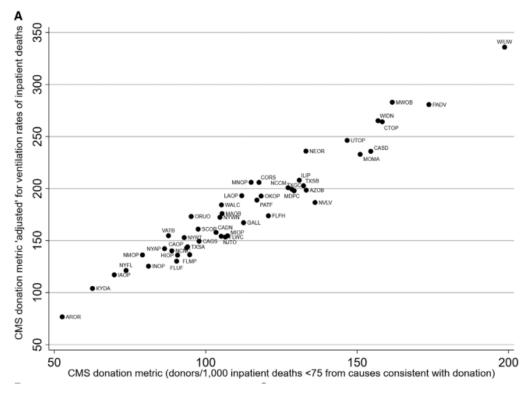
- Most death certificate errors involve death chain of events and not final cause, or refer to small populations⁵
- "Significant errors": Pulmonary hypertension instead of pulmonary hypertension from systemic sclerosis²
- "Region-to-region"³
 - Single-state (Florida)
 - Errors related to type of drug involved in overdose deaths, not overdose themselves
- "Hospital-to-hospital"^{4:} 95% of death certificates accurate for underlying cause of death for most common causes
- Death certificate data accurate for stroke and type of stroke⁶
 - PPV for all stroke: 100%

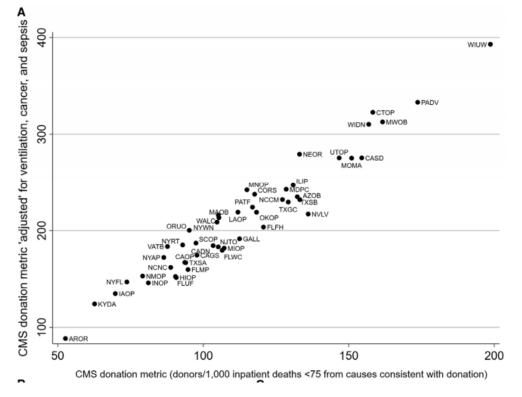
More data (if available) are not better

- Adding data on ventilation, cancer, and/or sepsis (available in a subset of states) changes denominator (CALC deaths), increase absolute value of metric (CALC donation rate) but does not change among-OPO comparisons.¹
 - "These data should provide confidence that the current CALC metric is an objective, standardized, and verifiable metric of OPO performance. Despite critiques, these empirical data highlight that data on ventilation, cancer, and/or severe sepsis may decrease the metric denominator but would not alter the interpretation of among-OPO performance using inpatient death data to be used as the denominator of an OPO performance assessment tool. As such, the cost, delays, and reporting burden of a ventilation-dependent metric would not seem justified from the sole perspective of improving the proposed CMS metric as a tool to compare OPOs. These conclusions should provide CMS, and the transplant community, with confidence that the CALC metric using CDC inpatient death data alone does not compromise the proposed CMS metric as a tool to compare OPOs, and that calls to require collection of increased data will not affect the tool's ability to compare OPOs."²

More data (if available) are not better

 Comparing CMS metric to CMS metric using adjustments for ventilation (ever in hospital), cancer, and severe sepsis: Absolute value of donation rate changes but not among-OPO comparisons





NCHS data valid tool to compare donation rates across different groups

- JAMA Surgery study comparing donation rates across racial/ethnic groups using NCHS data
 - "The CDC Detailed Mortality File includes data based on death certificates, which have a single underlying cause of death for each US resident... The overestimation of potential donors is unlikely to threaten our inference, given that our definitions were not differentially applied across racial/ethnic groups."

Going straight to the source: Robert Anderson, NCHS Chief of Mortality Statistics

- January 2021 STATCAST discussion (https://www.cdc.gov/nchs/pressroom/podcasts/2021/20210201/20210201.htm)
- How has CDC Mortality data guided public health in the past: "They've been used to surveil influenza mortality for quite a long time and also to document and track deaths due to epidemics including HIV, drug overdoses, and most recently COVID-19."
- What are the steps to completing the death certificate: "The death certificate is really designed to elicit an underlying cause of death and the underlying cause of death is defined as the disease or injury that started the chain of events leading to death. And this is considered to be most useful information from a public health standpoint..."