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Editorial

How hard are the hard outcomes reported in national transplant registries?



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Obtaining information to determine patient death would seem to be an uncomplicated process. However, survival estimates can vary widely depending upon the data source and method of death ascertainment. For transplant candidates and recipients in the United States, deaths recorded in the Organ Procurement and Transplantation Network (OPTN) were dependent on transplant center reporting until 2004, when records from the Social Security Administration Death Master File (DMF) were incorporated to supplement transplant program reporting. In the OPTN, patients are assumed to be alive in the absence of a death record.

In 2011, the Social Security Administration conceded that the Social Security Act could not supersede state laws limiting public disclosure, meaning information from state death certificates could no longer be included in the public version of the DMF. This resulted in the removal of 4 million (5%) records and the annual exclusion of 1 million (40% of new deaths) new files. The full DMF is still provided to the OPTN, but public reporting is restricted to deaths that are independently verified. Beginning in 2013, the OPTN began a verification process for deaths in the first 3 posttransplant years and in the first year after waitlist removal. Deaths were considered verified if reported by the transplant center, captured by the Centers for Medicare and Medicaid Services, captured in claims data recorded in Accuprint, a proprietary data-linking tool (Lexisnexis data), or identified in manual searches of obituaries. In 2022, manual verification was outsourced, and the verification process was expanded to include all

deaths, resulting in the addition of 35,000 additional deaths to OPTN records in 2022.

So, what does this mean for transplant programs, researchers, and patients? In the September edition of the journal, Noreen et al¹ reported survival estimates using the publicly released Standard Transplant and Analysis (STAR) and Scientific Registry of Transplant Recipients (SRTR) standard analysis files (SAFs) that include only verified deaths and compared these to estimates based on all deaths in the full DMF that are not available in the public SAFs. Unsurprisingly, there were negligible differences in short-term survival estimates but significant discrepancies in 10-year survival, especially for kidney transplant recipients. Differences in the 10-year survival estimates were attenuated after enhanced death verification in 2022: 12% to 15% of deaths at 10 years in deceased donor kidney transplant recipients were unverified prior to 2022 compared with 5% after 2022.

Reported survival data may impact program assessment and funding, comprehension of outcomes by clinicians, patients, and providers, and research agendas. As a program metric that may impact funding, the findings of Noreen et al¹ are reassuring as regulatory oversight is based on short-term outcomes, and these were unlikely to be compromised by the exclusion of unverified deaths. However, providers, clinicians, and patients are equally interested in longer-term outcomes, and here, analyses utilizing US data sampled between 2011 and 2022 may have underestimated mortality, thereby providing false reassurance.

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Several challenges exist in reporting death within registries. First, death reporting is a local rather than a national responsibility, and only states have the authority to collect death data. As a result, national data are only as timely and accurate as the latest and least accurate state, and state laws may limit national reporting. Similar considerations have led to incomplete reporting of transplant outcomes in Canada, where data from Quebec have been excluded from national data reports. Second, accuracy and granularity of reporting of the cause of death is a major issue. Who certifies the death, how much they understand the antecedent causes of death, and what primary cause is reported when death is multifactorial are all areas of uncertainty. One linkage study of dialysis and transplant patients between the Australia and New Zealand Dialysis and Transplant Registry and the National Death Index of Australia revealed > 99% capture of deaths by the registry, but only 36% agreement as to the primary cause of death.²

The challenges with outcome reporting reviewed by Noreen et al¹ highlight the importance of robust registries outside the United States and the need for registries to report their methods of outcome event ascertainment, validation, and completeness. This is required to enable robust international comparisons to inform patients, policy, and practice globally. International comparisons of transplant outcomes are not a routine activity of the SRTR but have been performed in collaboration with other registries.³ The United States Renal Data System (USRDS) annual data report does include an international chapter; however, the use of USRDS SAFs for independent researchers outside the United States was recently prohibited. Given the data limitations in the United States and the restrictions on the use of USRDS data, the advancement of regular international data reporting whereby insights from multiple countries could be used to improve understanding of long-term transplant outcomes is needed.

The detailed description of the death verification process by Noreen et al¹ illuminates potential limitations of existing publications, persistent data gaps, and limitations of OPTN public analytical files. Because unverified deaths cannot be included in public files, it is likely that some analyses should only be undertaken with direct United Network for Organ Sharing or SRTR involvement (ie, analyses involving rare outcomes, such as death and kidney failure in living donors).⁴ Although the limitations on the use of the full DMF are not unique to transplant, some data restrictions are difficult to understand (ie, the exclusion of Centers for Medicare and Medicaid Services-End-Stage Renal Disease deaths from OPTN SAFs), especially when these deaths are included in public USRD SAFs. Although Noreen et al¹ focused on deaths, the fact that kidney allograft failures are not validated against USRDS dialysis records is an obvious concern for the ascertainment of allograft survival in the public OPTN data files. Interagency cooperation could rectify these issues.

How the lack of rigorous outcome ascertainment might limit innovation, including the advancement of registry-based pragmatic clinical trials or potential solutions to improve future outcome ascertainment, is scarcely discussed by Noreen et al.^{1,5} Given that most transplant recipients are Medicare beneficiaries,

the Medicare Master Beneficiary Summary File would be an option for obtaining death data. This file includes death information received from Medicare claims, family member online date of death edits, and Medicare benefits information collected from the Railroad Retirement Board and the Social Security Administration. A subgroup analysis of long-term survival among Medicare beneficiaries could be a useful addition to the SRTR annual data report to inform long-term outcomes.


In sum, we applaud Noreen et al¹ for their transparent reporting of the challenges with death reporting in the OPTN. The information should motivate strategies to enhance OPTN outcome ascertainment as well as international data efforts to inform long-term transplant outcomes.

Declaration of competing interest

The authors of this manuscript have conflicts of interest to disclose as described by the American Journal of Transplantation. S. Chadban has served as Steering Committee Chair and Member of the Executive Committee of the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA). J.S. Gill serves as a member of the USRDS external expert advisory board.

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