Fit-For-Purpose and Scalable Strategy to Address Mortality Completeness for Oncology Research: Comparison of Multiple Real-World Sources with the National Death Index

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Background

- Evaluation of clinical outcomes, particularly for oncology studies, requires capturing patients' vitality status at the conclusion of the observation period.
- Researchers must have accurate and comprehensive dates of death, as well as have confidence that the remaining patients are alive, as patients who can neither be confirmed alive nor deceased are deemed lost to follow-up.
- If a high proportion of patients are lost to follow-up, the validity of the study is threatened, and the results may not be accurate or meaningful.
- While lost to follow-up can occur across study design types, the proportion may be higher in real-world studies because it is frequently not possible to contact patients who transition care settings.
- Sourcing mortality information from multiple sources may increase the capture of death dates, thus reducing the proportion of patients lost to follow-up and improving the precision of outcome assessments.

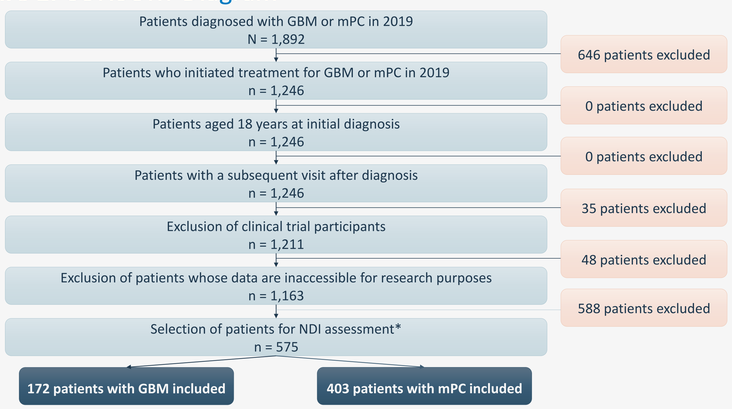
Objective

To examine mortality/vitality completeness across multiple real-world sources among patients with high mortality burden conditions, glioblastoma multiforme (GBM) and metastatic pancreatic cancer (mPC).

Methodology

- **Study Design:** Retrospective, observational cohort study.
- **Population:** Adult patients diagnosed with GBM or mPC between 01 January 2019 and 31 December 2019 in The US Oncology Network were followed through 31 December 2022.
- **Data sources:** The iKnowMed electronic health record (EHR) database, US Oncology's Financial Data Warehouse (FDW), a commercially-available mortality dataset linked by Datavant tokens that included claims data, obituary data and the Limited Access Death Master File (LADMF), as well as the National Death Index (NDI). A selection strategy was used to request NDI records for patients with mPC.
- **Analyses:**
  - The overall capture rate was defined as the proportion of patients with a death date in any of the sources.
  - The concordance and sensitivity across the sources were assessed among patients with a record of death from at least 2 sources. Concordance was defined using two approaches: 1) as death dates that are an exact match between sources and 2) as death dates that occurred within 30 days of each other.
  - Overall survival (OS) with and without NDI data was estimated with Kaplan-Meier methods; censoring patients without a death record on their last contact date.

Figure 1. CONSORT Diagram



Abbreviations: GBM, glioblastoma; mPC, metastatic pancreatic cancer.

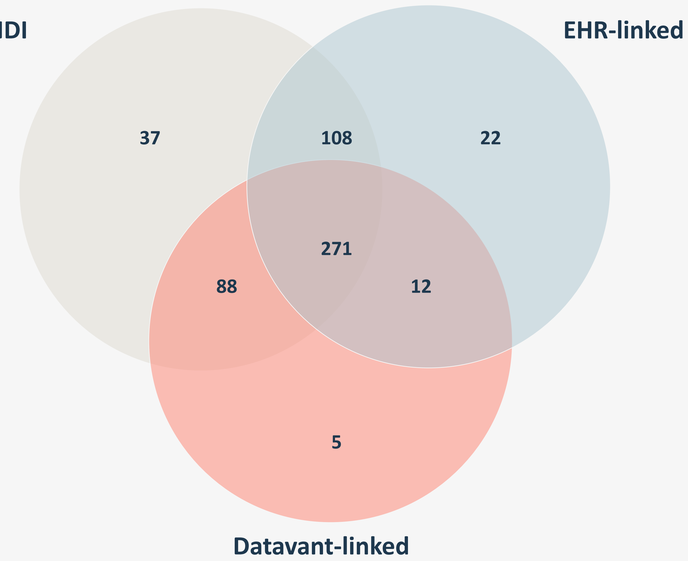
*One patient with multiple cancer diagnoses was excluded from the final analyses. Additionally, a sampling technique was used to request NDI records for patients with mPC to ensure adequate capture of patients with and without known mortality status prior to the NDI request.

Table 1. Baseline Characteristics of the Sample Population

	GBM (n=172)	mPC (n=403)
Median age, years (range)	65 (18,86)	68 (32,90+)
Sex – n (%)		
Female	71 (41.3)	179 (44.4)
Male	101 (58.7)	224 (55.6)
Race – n (%)		
White/Caucasian	121 (70.3)	264 (65.5)
Black/African American	14 (8.1)	33 (8.2)
Asian	2 (1.2)	7 (1.7)
No information	33 (19.2)	93 (23.1)
Other	2 (1.2)	6 (1.5)
Practice location - n (%)		
Midwest	32 (18.6)	81 (20.1)
Northeast	32 (18.6)	27 (6.7)
South	82 (47.7)	166 (41.2)
West	26 (15.1)	129 (32.0)

Abbreviations: GBM, glioblastoma; IQR, interquartile range; mPC, metastatic pancreatic cancer.

Figure 2. Overlap Of Death Records by Source



Abbreviations: EHR, electronic health records; NDI, National Death Index.

Results

- For the final analysis, 172 patients with GBM (median age 65 years, 41.3% female)) and 403 with mPC (median age 68 years, 44.4% female) were included (**Figure 1**/**Table 1**).
- With and without NDI, 155 (90.1%) and 137 (79.7%) of patients with GBM and 388 (96.3%) and 369 (91.6%) of patients with mPC, respectively, had a death record in at least one source (**Table 2**).
- Among the 479 with death records from multiple sources (n=479), 100% of death dates were an approximate match (within the same month or 30 days), and 96.9% (n=464) were an exact match (same day; **Table 2**).
- **Figure 2** presents the overlap of death records across sources.
- Among patients with GBM, median OS was 13.2 months (95% confidence interval [CI] 10.4-14.0) and 13.5 months (95% CI 10.9-14.7) with and without NDI data, respectively (p=0.3727; **Figure 3a**).
- Among patients with mPC, median OS was 7.1 months (95% CI 6.2-8.0) and 7.6 months (95% CI 6.6-8.7) with and without NDI data, respectively (p=0.5789; **Figure 3b**).

Table 2. Capture, Concordance, and Sensitivity Of Death Dates

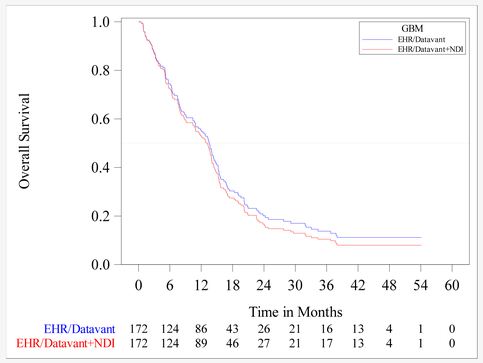
	GBM (n=172)	mPC (n=403)
Death record by source – n (%)		
EHR-linked	106 (61.6)	307 (76.2)
Datavant-linked	95 (55.2)	281 (69.7)
NDI	140 (81.4)	364 (90.3)
EHR- and/or Datavant-linked	137 (79.7)	369 (91.6)
Any source	155 (90.1)	388 (96.3)
Concordance across sources* – n (% of 479)		
Exact	127 (100.0)	337 (95.7)
Approximate	127 (100.0)	352 (100.0)
Sensitivity (%)	87.1	94.8

Abbreviations: GBM, glioblastoma; EHR, electronic health records; IQR, interquartile range; mPC, metastatic pancreatic cancer; NDI, National Death Index.

Concordance was assessed among patients with a record of death in at least two sources (in total, 479; 127 among patients with GBM and 352 among patients with mPC). Exact concordance was defined as the same day, month, and year across sources; approximate concordance was defined as dates within 30 days of each other.

Figure 3. Kaplan-Meier Survival Curve Among Patients With (a) GBM and (b) mPC

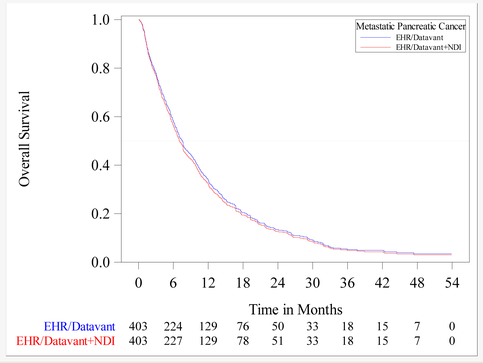
(a)



Median OS (95%CI):
13.2 months (10.4-14.0) with NDI

13.5 months (10.9-14.7) without NDI (p=0.3727)

(b)



Median OS (95%CI):
7.1 months (6.2-8.0) with NDI

7.6 months (6.6-8.7) without NDI (p=0. 5789)

Discussions & Implications

- Mortality data completeness across all data sources was over 90% in this study, with strong agreement across sources.
- Among two malignancies with high mortality burdens, the addition of NDI data to other real world data mortality sources did not affect estimates of OS.
- As a high proportion of death records were captured without chart abstraction or the NDI, survival estimation without these sources can be a fit-for-purpose and scalable option for oncology research.

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