

Liu Y¹, Diakun D¹, Prinic N¹, Palmer L¹

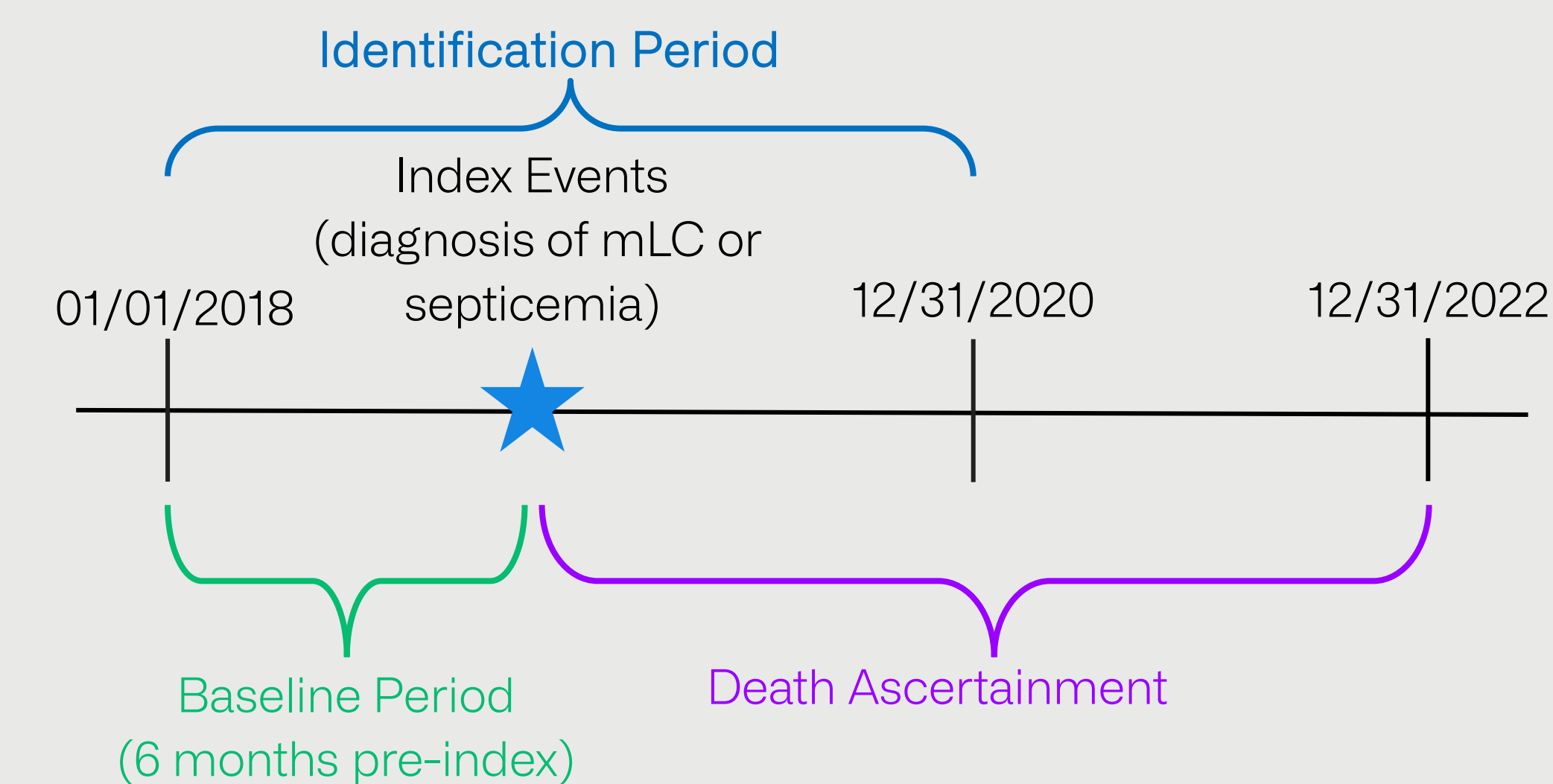
¹Merative, Real World Data Research & Analytics, Ann Arbor, MI, USA

Study Summary

Research Question

Can cross-referencing multiple sources be employed to enhance the accuracy and robustness of mortality data in real world evidence (RWE) research?

Study Design



Study Results

Among 119,370 patients with metastatic lung cancer (mLC) or septicemia, 22,800 deaths (19.1%) were identified. Using both administrative claims (inpatient death) and deaths from the Social Security Administrations (SSA) Death Master File, it was found that a notable portion of deaths were exclusively in one source (overlap of deaths reported in both sources was $\leq 11\%$). Using the National Death Index (NDI) as the gold standard, the positive predictive value (PPV) of identification of deaths using administrative claims or SSA was 98.6%.

Conclusion

Administrative claims data with enrollment status and government databases are complementary for capturing mortality data. Utilizing both sources is essential to improve death ascertainment in RWE research.

Background

- The 21st Century Cures Act of 2016 emphasizes the important role of RWE in pharmacoepidemiology studies by providing insights into disease burden, drug effectiveness, safety, and treatment patterns in real-world settings¹.
- Mortality is an important outcome in pharmacoepidemiologic research yet is often missing or incomplete in RWE sources.
- While NDI is often considered as the gold standard for mortality data in the United States for RWE studies², administrative claims and the SSA Death Master File serve as practical sources of mortality data given their accessibility and relative cost-effectiveness.
- There are limited studies evaluating the validity of mortality data in administrative claims databases.

Objectives

- This study evaluated mortality capture across administrative claims and government databases, aiming to evaluate death reporting and provide options for enhancing mortality data capture in RWE.

Methods

Data Sources

- This retrospective analysis utilized administrative claims data from the Merative™ MarketScan® Commercial and Medicare Database and the SSA Death Master File.
- Patients with a death were linked to the NDI. The NDI, maintained by the National Center for Health Statistics at the Center of Disease Control and Prevention (CDC), has death information derived from death certificates provided by vital records offices.

Study Design

- Adult (18+) patients with ≥ 1 non-diagnostic claim with an ICD-10-CM diagnosis code of metastatic lung cancer (mLC) or septicemia between 01/01/2018 –12/31/2020 were identified (earliest date=index date).

- mLC and septicemia were selected as they have high mortality rates and death is expected to occur in a variety of settings (mLC deaths more likely to be outpatient; septicemia deaths more likely to be in the hospital).

- Death from administrative claims was captured using inpatient death, identified using discharge status.
- Inpatient death and death documented in the SSA were identified using data from index through 12/31/2022 (both presence of death and date of death were captured).
- Occurrence of end-of-life care (e.g., hospice, cardiac arrest) and disenrollment status within 6 months of death were measured among those with an identified inpatient death.
- Patients with an inpatient death or SSA documented death were linked to the NDI (gold standard) for death and the PPV was calculated.

Results

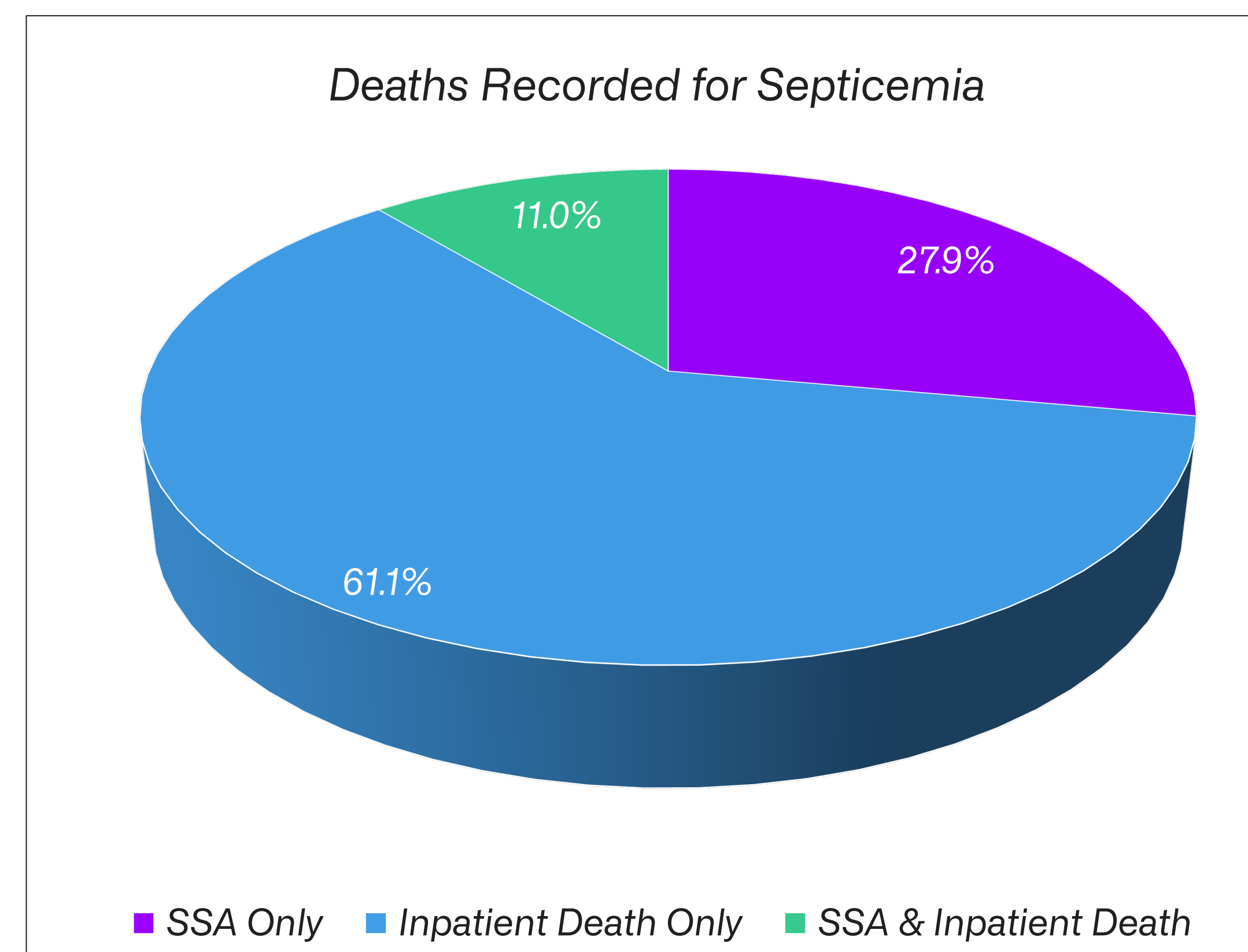
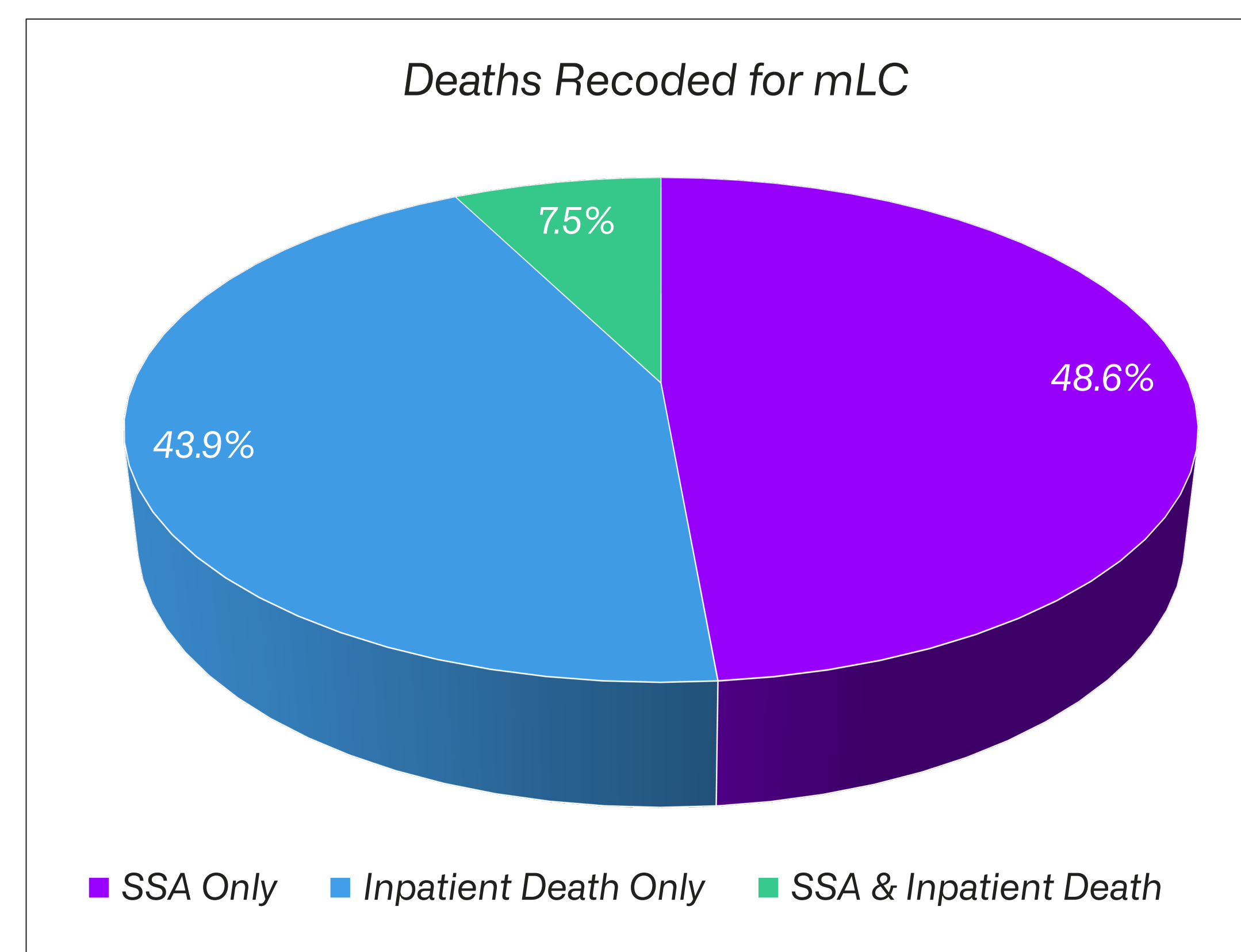
- A total 119,370 patients were identified (mLC: 13,558; septicemia: 105,812), with a mean age of 65.1 years for mLC and 61.4 years for septicemia.
- There were 22,800 patients (19.1%) with an inpatient death or a death documented in the SSA (mLC: 2,857 [21.1%], septicemia: 19,943 [18.8%]) (Table 1).

Table 1. Death Captured by Data Sources

	mLC	Septicemia
Total patient counts (N)	13,558	105,812
Total number of deaths (N)	2,857	19,943
Proportion of patients with any death (%)	21.1%	18.8%
Proportion of deaths from SSA (%)	56.1%	38.9%
Proportion of deaths from claims (%)	51.4%	72.1%

- Among patients with septicemia, a condition where death is more likely to occur in a hospital, 72.1% of deaths were identified by inpatient discharge status, while 38.9% of deaths documented in the SSA (Table 1).
- Conversely, for patients with mLC, where death is more likely to occur in outpatient settings, 51.4% of deaths were identified by inpatient discharge status and 56.1% of deaths were documented in the SSA (Table 1).

Figure 1. Overlap of Inpatient Deaths and Deaths Documented in SSA Death Master File



- The overlap of reported deaths in both sources (inpatient death and SSA death) was minimal (7.5% for mLC and 11.0% for septicemia) with most deaths reported exclusively in one source (Figure 1).
- Of patients with an inpatient death, >95% had at least one end-of-life care event and >80% disenrolled in the administrative claims database within six months of death.
- Using the NDI data as the gold standard, it was found that the PPV of identification of deaths was 98.6% overall (98.4% for mLC and 98.7% for septicemia) (Table 2).
- For inpatient and SSA documented deaths, the dates of death were highly consistent with the NDI with $\geq 98\%$ occurring within one day (Table 2).

Table 2. Death Validation with NDI (Gold Standard)

	mLC			Septicemia		
	Inpatient Death	SSA	Both	Inpatient Death	SSA	Both
PPV, %	98.4%	97.8%	98.4%	98.7%	97.6%	98.7%
Death date concordance (% within 0 days)	89.0%	97.6%	93.2%	89.9%	97.2%	91.9%
Death date concordance (% within 1 day)	98.6%	98.9%	98.8%	97.7%	98.9%	98.1%
Death date concordance (% within 15 days)	99.9%	99.5%	99.7%	99.4%	99.7%	99.5%

Conclusions

- Results from this study provide insights into options for enhancing mortality capture in RWE, using a substantial patient sample size from a large administrative claims database with a geographically diverse US Commercial and Medicare population.
- Administrative claims data can be used to identify deaths in the inpatient setting, while deaths documented in SSA can augment this by identifying deaths outside of inpatient settings.
- The high PPV of death and the concordance of the death date with the NDI provides validation that deaths reported in both administrative claims and documented in the SSA Death Master File are accurate.
- The high proportion of patients with an end of end-of-life event or disenrollment status within the six months of inpatient death in the administrative claims suggests these factors could potentially be used to develop an algorithm to identify death in administrative claims databases in the absence of data available from an external government source.

Limitations

- The number of patients and deaths included in the study were limited to patients with mLC or septicemia and may not be generalizable to all conditions.
- Only patients with relevant personal identifier information could be linked to SSA and NDI, which may affect the representativeness of the findings.

References

- US Food and Drug Administration: Framework for FDA's real-world evidence program. <https://www.fda.gov/media/120060/download>.
- Lash TL, Silliman RA. A comparison of the National Death Index and Social Security Administration databases to ascertain vital status. *Epidemiology*. 2001 Mar;12(2):259-61

Disclosure

All authors are employees of Merative. This study was funded by Merative.