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Sudden Unexpected Infant Deaths in Italy, 1996-2023: An Epidemiological Update

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Abstract

Purpose: To provide an updated epidemiological profile of Sudden Infant Death Syndrome (SIDS) and Sudden Unexpected Death in Infancy (SUDI) in Italy from 1996 to 2023.

Methods: Data on causes of death and live births from 1996 to 2023 were obtained from the databases of the Italian National Institute of Statistics (ISTAT). SUDI and SIDS cases were identified using ICD-9 and ICD-10 codes. The analyses included descriptive statistics, non-linear sigmoidal trend models, linear regression, the Mann-Kendall test, and chi-square tests to assess geographic differences.

Results: Between 1996 and 2023, Italy's infant mortality dropped 54.8%, with perinatal conditions, congenital anomalies, and SUDI accounting for 84.8% of all infant deaths. A total of 1,585 SUDI cases were recorded, of which 40% were classified as SIDS. Although SIDS rates declined over time, the reduction in overall SUDI rates was less pronounced. SUDI rates were significantly higher in Southern Italy (7.6 per 100,000) than in Northern (5.3) and Central Italy (3.2). The relative contribution of SUDI to overall infant mortality nearly doubled, increasing from 2.8% in 1996 to a peak of 5.5% in 2022. Between 2016 and 2023, only 8.8% of SIDS cases included a recorded autopsy (ICD-10: R95.0).

Conclusion: Despite the overall decline in mortality, significant temporal changes in the distribution of SIDS and other causes of neonatal death persist. The findings underscore the urgent need to enhance post-mortem investigations and strengthen surveillance systems to improve our understanding of the pathophysiology of SIDS and SUDI.

What is Known:

• Infant mortality in Italy decreased by 54.8% between 1996 and 2023. Perinatal conditions, congenital malformations, and SUDI together accounted 84.8% of all infant deaths.

• Geographic differences in SUDI rates were observed, with higher values in Southern Italy (7.6 per 100,000) than in Northern (5.3) and Central Italy (3.2).

What is New:

• The results suggest a possible shift in the medical coding, with a change from SIDS to other diagnostic categories such as R99 (ill-defined and unspecified causes) or W75 (accidental suffocation).

- According to the ICD-10 coding, only a small proportion of cases included a documented autopsy. The lack of systematic post-mortem investigations may contribute to misclassification and impair diagnostic accuracy and reliable case identification in epidemiological statistics.

Keywords: Sudden infant death syndrome, Sudden unexpected death in infancy, Infant mortality, Autopsy, Epidemiology, Cause of death, Geographical disparities.

Abbreviations

ICD-9/ICD-10 International Classification of Diseases

ISTAT Italian National Institute of Statistics

SIDS Sudden Infant Death Syndrome

SUDI Sudden Unexpected Deaths in Infancy

SUEND Sudden Unexpected Early Neonatal Deaths

Introduction

Sudden Infant Death Syndrome (SIDS) and Sudden Unexpected Death in Infancy (SUDI) represent major public health concerns and a devastating experience for families worldwide [1]. SIDS is one of the leading causes of mortality during the first year of life and remains unexplained even after thorough post-mortem investigations, comprehensive clinical history review and detailed death scene examinations [1].

International public health efforts to promote safe sleeping practices, together with the implementation of the "Back to Sleep" campaigns launched in the 1990s, have resulted in substantial reductions in SIDS rates [1]. However, the extent to which these preventive strategies and standardized diagnostic and management protocols have been implemented varies considerably across different countries and regions [5,6].

In Italy, surveillance of SIDS and SUDI has historically been affected by a lack of homogeneous national guidelines and standardised diagnostic protocols for post-mortem examinations [1,4]. Although international classification systems are used worldwide to code and monitor SIDS trends, with systematic post-mortem investigations aimed at excluding alternative causes of death, Italian official statistics often suffer from underreporting and misclassification [4,8].

To address these gaps and improve the accuracy of SUDI investigations, several regional initiatives have been implemented [2]. Notably, in 2009, the Tuscany Region introduced a project aimed at establishing a multi-agency approach to investigating and managing SUDI cases in accordance with specific regional regulations [3]. This integrated approach was designed to ensure comprehensive and sensitive investigations into the circumstances and causes of death, while also providing structured support for bereaved families. It therefore represents an important example of standardised regional surveillance within the Italian healthcare system [2,3]. Comparison with ISTAT data may help to identify potential discrepancies between regional surveillance and national mortality statistics [3].

This article provides a detailed description of the epidemiologic profile of SIDS and SUDI in order to better characterize the burden of these conditions and to inform prevention and surveillance strategies. The description includes current rates, historical trends, potential changes in the classification of sudden unexpected deaths, regional disparities, and the extent to which post-mortem investigations are documented [6,7, 9]. In particular, examining changes in medical coding over time and the distribution of sudden unexpected deaths among infants and children may provide insights into potential diagnostic and classification shifts.

Materials and methods

Data analyzed in this study were obtained from two national databases maintained by the Italian National Institute of Statistics (ISTAT): the Causes of Death Register and the National Live Births Register. The study period covered 1996–2023. A specific limitation concerns the years 2004 and 2005, during which causes of death were not fully processed or recorded with the same level of detail as in the surrounding years.

Causes of death were coded according to the International Classification of Diseases (ICD), Ninth Revision (ICD-9) for the period 1993–2002 and Tenth Revision (ICD-10) for the period 2003–2023.

Sudden Unexpected Death in Infancy (SUDI) cases were identified using the following codes:

ICD-9 codes: 798.0 (Sudden Infant Death Syndrome), 799.9 (*Other* unknown and unspecified cause), and E913.0 (Accidental mechanical suffocation in bed/cradle);

ICD-10 codes: R95 (Sudden Infant Death Syndrome), R99 (*Other* ill-defined and unspecified causes of mortality), and W75 (Accidental suffocation and strangulation in bed).

From 1996 onward, within the ICD-10 classification, code R95 includes two subcategories: **R95.0**, Sudden Infant Death Syndrome (SIDS) with mention of autopsy; and **R95.9**, Sudden Infant Death Syndrome without mention of autopsy.

A separate analysis was conducted specifically for SIDS cases coded under these two categories in order to examine their distribution over time and across regions.

Cause-specific mortality rates were calculated per 10,000 live births for each study period, and 95% confidence intervals (95% CI) were computed for each rate. Absolute and percentage changes in mortality rates between temporal periods were calculated, together with their corresponding 95% confidence intervals (95% CIs), to assess changes over time.

Data are presented using descriptive statistics, including absolute numbers and percentages.

A sigmoidal (non-linear) trend analysis was performed for SUDI and SIDS to estimate overall mortality rates and corresponding 95% CIs over the period 1996–2023. The fitted model was based on the following four-parameter logistic equation:

$$Y = \text{Bottom} + (\text{Top} - \text{Bottom}) / (1 + 10^{((\text{LogIC50} - X) \times \text{HillSlope})}).$$

Because cause-of-death data for 2004 and 2005 were incomplete, mortality rates for these two years were estimated using the fitted sigmoidal model.

Linear regression and the nonparametric Mann-Kendall test were used to assess temporal trends in mortality rates for SUDI and its components (SIDS and other causes) over the period and within geographical areas.

The χ^2 test was used to assess differences in the distribution of SUDI cases across the main Italian geographic areas.

To assess the completeness and consistency of national SIDS/SUDI mortality data, cases identified in the Tuscany Regional Registry of Sudden Unexpected Infant Death (SUID) between 1 January 2009 and 31 December 2019 were compared with the corresponding official infant mortality data on causes of death reported by ISTAT.

Tuscany was selected because it has a dedicated regional SUID Registry managed by specialized staff at the regional SIDS centre. The registry systematically records both Sudden Unexpected Early Neonatal Deaths (SUEND, occurring in the first week of life) and SUID cases occurring from the end of the first week of life up to one year of age. This provides a comprehensive and centralized dataset that can be used for comparison with national mortality statistics [3].

Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and GraphPad Prism version 10.6.1 (GraphPad Software, San Diego, CA, USA).

As this study was based exclusively on publicly available, anonymized data, ethics committee approval was not required.

Results

Infant Mortality Trends in Italy (1996-2023)

Between 1996 and 2023, the infant mortality rate in Italy decreased by 54.8%, falling from 6.00 to 2.71 per 1,000 live births. The post-neonatal mortality rate (1–11 months), which has remained consistently below 1.00 per 1,000 since around 2010, contributed substantially to the overall low mortality levels. Neonatal mortality (<1 month), which was at 3.90 per 1,000 live births in 1996, remained above 2.00 per 1,000 throughout the study period. Nevertheless, it showed a pronounced downward trend, decreasing by 28.5% between 2006 and 2023. During the study period, the three main causes of infant mortality were perinatal problems, congenital anomalies, and SUDI, accounting for 84.8% of all deaths. During the early and late neonatal periods, deaths were predominantly attributable to perinatal conditions, whereas congenital anomalies represented the main cause during the post-neonatal period. (Table 1)

Table 1 Distribution of causes of death in the infant period (first year of life), early neonatal period (first week of life), post-early neonatal (8th day of life-1 year) and post-neonatal (1-11 months) periods. (Italy, 1996-2023). [Rate per 10,000 and %].

Cause of death	Infant		Neonatal				Post-Neonatal	
			Early		Late			
	Rate per 10,000	%	Rate per 10,000	%	Rate per 10,000	%	Rate per 10,000	%
Perinatal problems	27.97	55.3	19.01	74.3	6.87	63.1	2.09	14.9
Congenital anomalies	13.23	26.2	5.35	20.9	3.01	27.7	4.87	34.6
SUDI	***1.66***	***3.3***	***0.29***	***1.1***	***0.16***	***1.5***	***1.21***	***8.6***
SIDS	0.14	0.3	0.01	0.1	0.02	0.2	0.11	0.8
Diseases of nervous system	1.17	2.3	0.04	0.2	0.09	0.8	1.05	7.4
Diseases of circulatory system	1.13	2.2	0.10	0.4	0.09	0.8	0.94	6.7
Diseases of respiratory system	0.85	1.7	0.04	0.1	0.08	0.7	0.74	5.3
Injuries and poisonings	0.76	1.5	0.04	0.2	0.07	0.7	0.65	4.6
Metabolic diseases	0.71	1.4	0.11	0.4	0.12	1.1	0.48	3.4
Diseases of the digestive system	0.55	1.1	0.01	0.0	0.03	0.3	0.51	3.6
Neoplasias	0.54	1.1	0.07	0.3	0.06	0.5	0.41	2.9
Infectious diseases	0.54	1.1	0.09	0.4	0.05	0.5	0.39	2.8
Symptoms ill-defined causes	0.30	0.6	0.01	0.0	0.01	0.1	0.28	2.0
Other	1.11	2.2	0.43	1.7	0.25	2.3	0.44	3.1
Total	***50.54***		***25.60***		***10.89***		***14.06***	

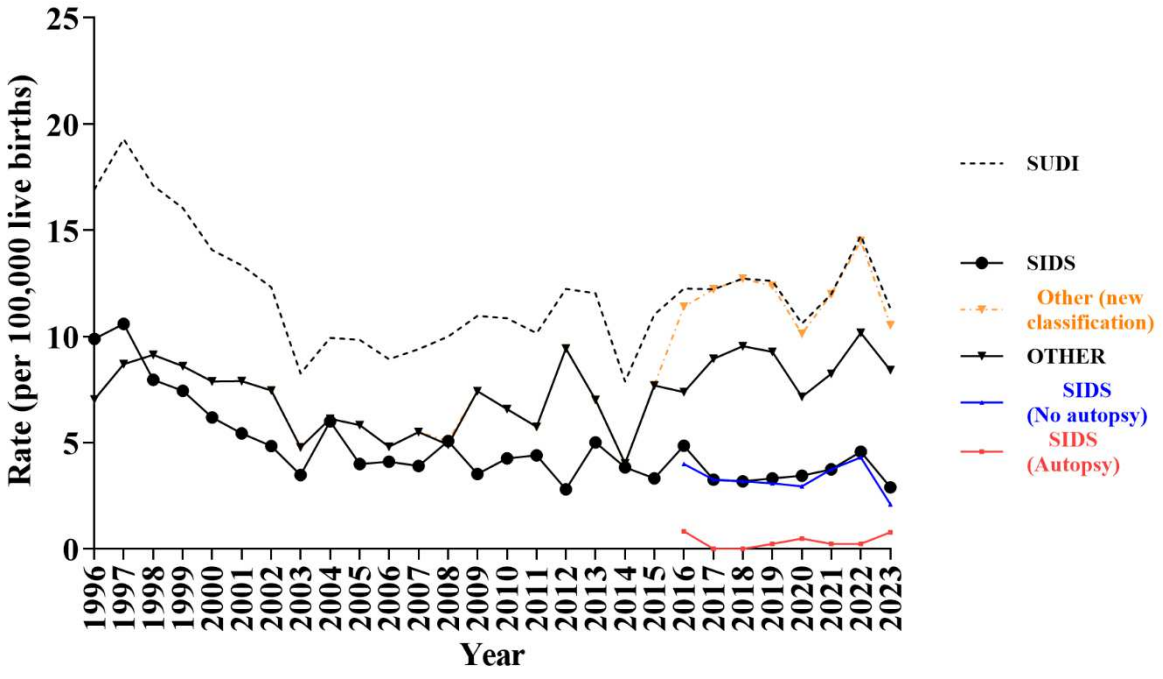
Epidemiology and geographic distribution of SUDI

Over the study period, excluding 2004 and 2005, 1,585 cases of SUDI were recorded, corresponding to an overall mortality rate of 12.27 per 100,000 live births. Of these, 634 cases (40%) were classified as SIDS, whereas 951 (60%) were classified as others causes, including undetermined causes or due to illnesses, accidental suffocation or unnatural causes.

SUDI rates declined markedly in the early years of the study followed by a plateau, resulting in a modest but statistically significant overall downward trend ($p = 0.028$). Time accounted for 18.5% of the variability in SUDI rates ($R^2 = 0.185$).

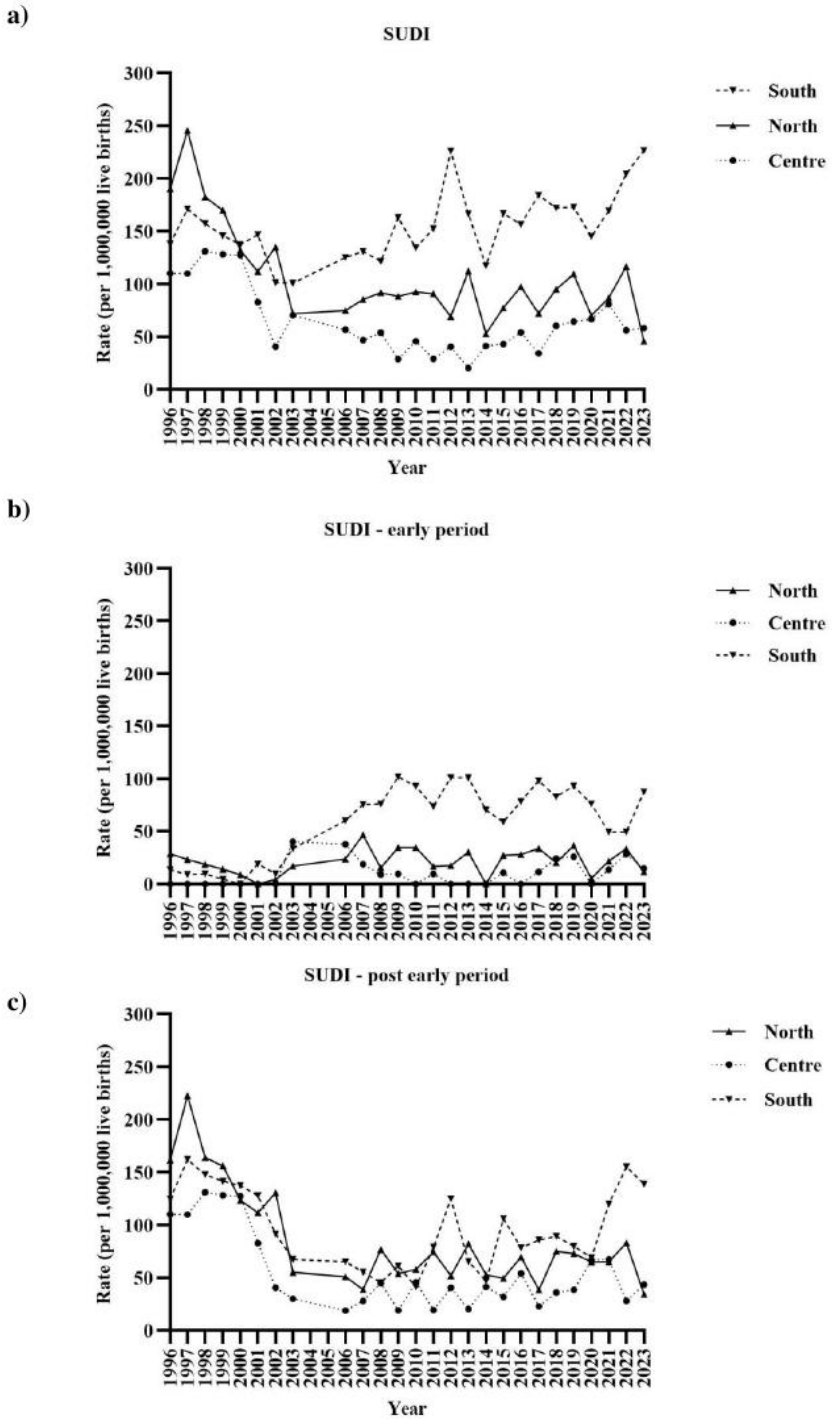
Between 1996 and 2023, the proportion of SUDI cases relative to overall infant death increased. In 1996, SUDI accounted for 2.8% of total infant deaths, decreasing to a minimum of 2.1% in 2003. Thereafter, this proportion followed a progressive upward trend, reaching a peak of 5.5% in 2022 (+96.4% relative to 1996) before settling at 4.4% in 2023. This increase in the relative contribution of SUDI occurred despite a marked decline in both overall infant mortality and the absolute number of SUDI cases over the same period. (Fig 1)

Fig 1 Longitudinal Trend of SUDI, SIDS, and Other Causes (1996–2023)



Geographic analysis revealed significant differences in SUDI rates across the main Italian geographic areas (χ^2= 111.3, $p < 0.0001$). Rates were higher in Southern Italy (7.6 deaths per 100,000 live births; 95% CI: 7.1–8.2) than in Northern Italy (5.3; 95% CI: 4.9–5.7) and Central Italy (3.2; 95% CI: 2.7–3.7). Different temporal patterns were observed across geographic areas. According to the Mann-Kendall trend test, overall SUDI mortality decreased significantly in Northern Italy ($p = 0.0055$), primarily because of a reduction in post-neonatal deaths. In Southern Italy, overall SUDI mortality increased significantly ($p = 0.007$), driven mainly by an increase in early neonatal deaths. In Central Italy, the overall trend was negative but did not reach statistical significance ($p = 0.113$), as an increase in neonatal deaths was offset by a corresponding decline in post-neonatal deaths. (Fig 2: a-c)

Fig 2 (a-c): Geographical distribution of SUDI mortality rates by period (1996–2023).



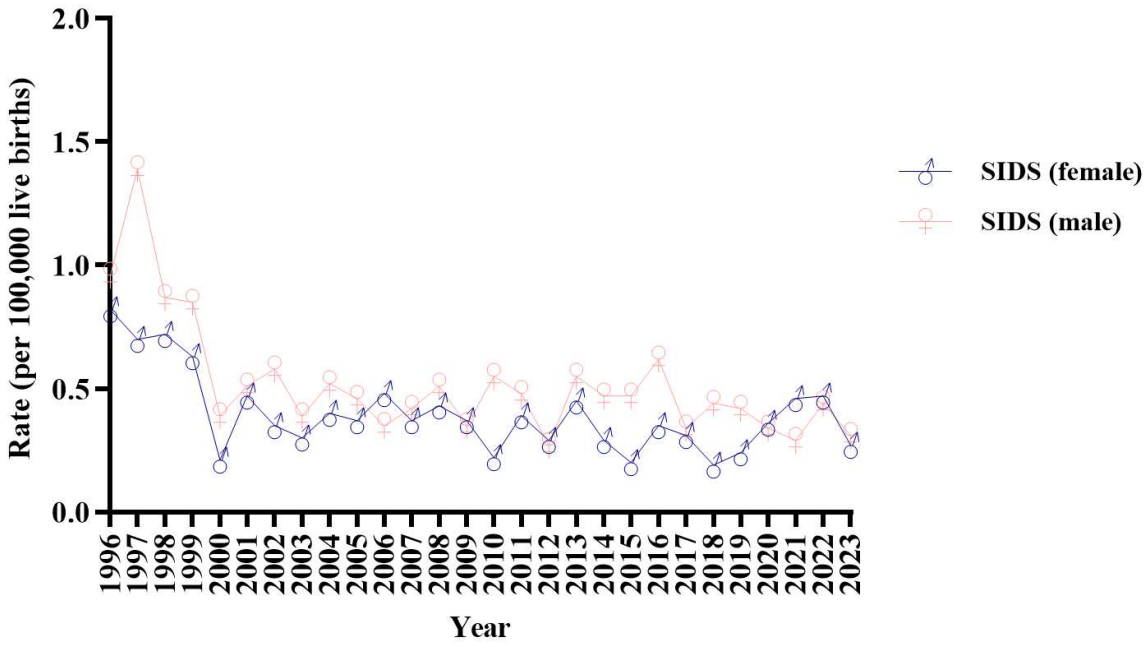
(a) Early period (≤1 month / within the first month); (b) Post-early period (1–11 months); (c) Total/Overall period

SIDS and *Other* deaths

Over the period 1996–2023, the mean mortality rate for SIDS was 4.91 per 100,000 live births, with annual values ranging from 2.81 to 10.59 cases per 100,000 live births and a mean of approximately 24 cases per year. Overall, SIDS accounted for 1.3% of all deaths during the first year of life, with a limited contribution during the neonatal period (0.4%) and a higher contribution during the post-neonatal period (3.3%).

Over the entire study period, SIDS mortality was approximately 1.5 times higher in males than in females. This gender disparity was most pronounced during the initial phase (1996–1999), when male mortality was significantly higher than the female mortality. During the final years of the study, however, male and female mortality rates converged, approaching similar levels. (Fig 3)

Fig 3 SIDS mortality rates by gender (1996–2023)



Between 1996 and 2023, SIDS showed a significant downward trend ($p < 0.001$), with an average annual decrease of approximately one case per 100,000 live births. Time explained 55% of the variability ($R^2 = 0.55$).

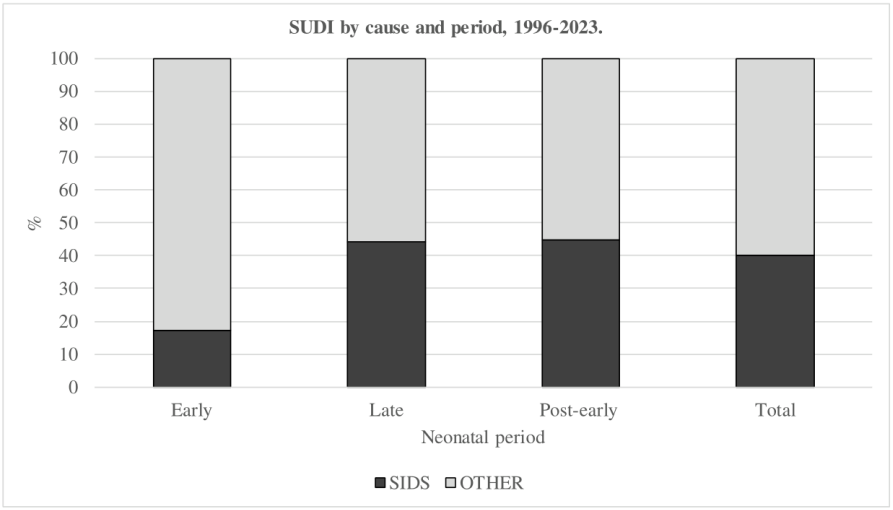
Mortality rates attributed to *Other* causes (including undetermined causes, illnesses, or accidental suffocation) showed greater fluctuations over the study period than SIDS rates. Statistical analysis did not identify a significant temporal trend ($p = 0.457$; $R^2 = 0.02$), suggesting that these rates remained relatively stable overall.

Temporal trends

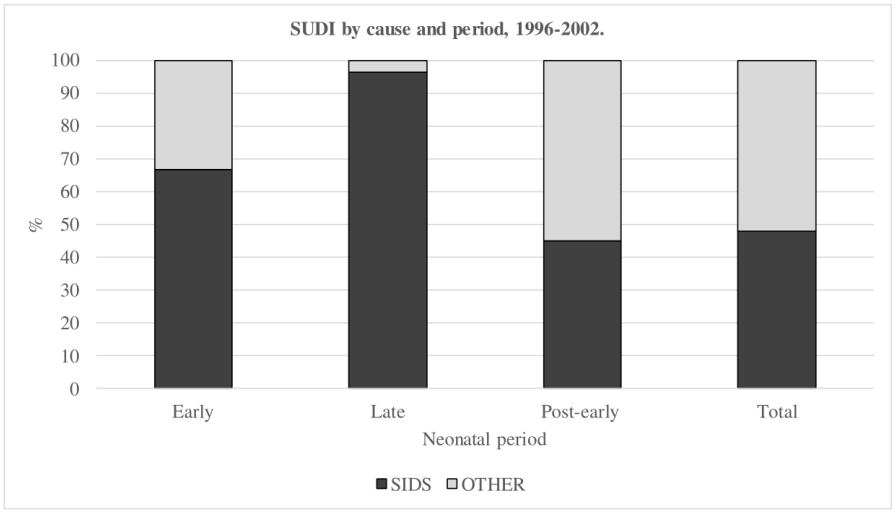
A longitudinal analysis of the two observation periods reveals a significant temporal shift in the distribution of SIDS and other causes of death during the neonatal period (Fig 4: a-c). In the 1996–2002 period, SIDS represented the predominant classification, with high rates in both the early and late neonatal period (66.7 and 96.3, respectively). In the subsequent 2003–2023 period, the distribution changed substantially, with other causes becoming the predominant classification, accounting for 85.0 and 66.9 cases in the early and late neonatal periods, respectively. This redistribution was particularly evident during the neonatal period. In contrast, the post-neonatal period remained relatively stable, with SIDS rates showing only a minimal difference between the two periods (45.1 vs. 44.7).

Fig 4 (a-c): Temporal trends in SIDS and Other Cause mortality cases during neonatal periods (1996–2023).

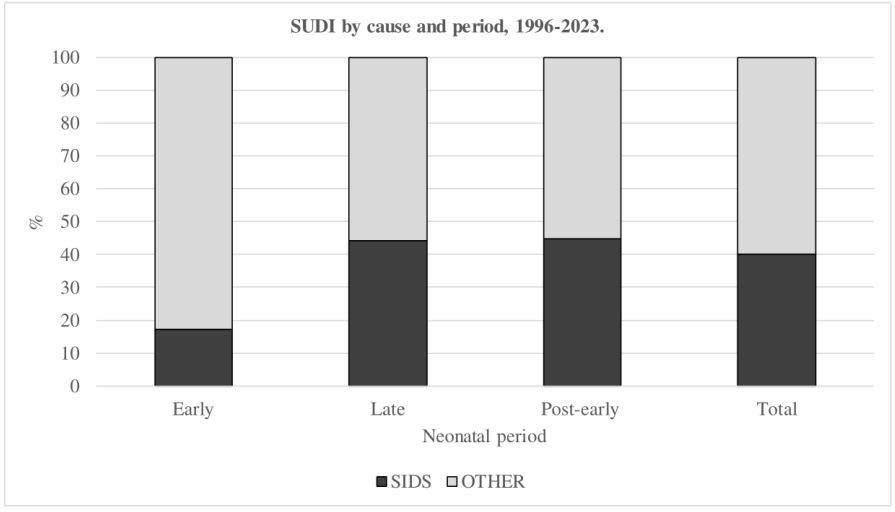
a)



b)



c)



Post-mortem autopsy and reporting (2016–2023)

Between 2016 and 2023, 124 SIDS cases were recorded. Of these, 11 (8.8%) included a mention of autopsy (ICD-10 code R95.0), whereas 113 cases (91.2%) were classified as SIDS without mention of autopsy (R95.9). Cases with a documented autopsy were reported only in limited number of years and were geographically distributed across a small number of regions, including Lombardy, Veneto, Sicily, Abruzzo, and Trentino-Alto Adige. (Table 2)

The Tuscany Study: a comparative analysis

The comparison with the Tuscany Regional Registry identified 66 SUDI cases during the 11-year study period. Autopsies were performed in 91% of cases; 32 cases remained unexplained. Of the autopsies performed, 95% were conducted by three specialized pathology groups using a standardized protocol. The overall incidence of SUDI was 0.21‰ of live births, while SIDS accounted for 48% of cases, corresponding to an incidence of 0.10‰ of live births. Comparison with ISTAT data for the same period showed that the 22 cases identified as SIDS and 24 cases identified as SUDI represent approximately one-third of the total infant deaths reported in Tuscany. This discrepancy may reflect differences in case ascertainment, diagnostic classification, and/or reporting between the regional registry and official mortality statistics, underscoring the potential value of standardized post-mortem protocols and systematic surveillance for epidemiological assessment. (Table 2)

Table 2 Total number of SIDS cases with and without autopsy in Italy, 2016-2023.

Year	SIDS with mention of autopsy (R95.0)	SIDS without mention of autopsy (R95.9)	Total SIDS cases
2016	4 (Trentino Alto Adige, Veneto, Abruzzo, Sicily)	19	23
2017	-	15	15
2018	-	14	14
2019	1 (Lombardy)	13	14
2020	2 (Veneto)	12	14
2021	-	15	15
2022	1 (Lombardy)	17	18
2023	3 (2 Veneto, 1 Sicily)	8	11
Total	**11 (8.8%)**	**113**	**124**

Discussion

Although SIDS mortality declined significantly over the study period, the overall SUDI rate showed a less pronounced reduction. The simultaneous decline in SIDS and the relative stability of other SUDI categories could indicate a shift in cases towards alternative classifications, including R99 (ill-defined and unspecified causes of mortality) and W75 (accidental suffocation and strangulation in bed). However, the available data do not allow us to determine whether this pattern represents a true diagnostic shift, changes in investigative practices, or changes in the underlying epidemiology.

A shift in the diagnosis of sudden deaths in infancy has previously been reported internationally, with some cases previously classified as SIDS increasingly being assigned to categories such as undetermined cause or asphyxia [10]. Beyond its statistical and investigative impact, surveys show that this shift causes severe confusion, psychological distress, and support barriers for bereaved parents, particularly those who receive a non-SIDS diagnosis. To address these human and operational challenges, studies advocate for better public education, enhanced bereavement support, and closer multi-stakeholder collaboration between stakeholders. However, these inconsistencies in classification also pose a broader structural threat, as they may severely hinder SIDS surveillance and research on SIDS [8,11]. In this regard, the small overlap between the number of cases retrieved in the Tuscany

register and those collected in the ISTAT database of causes of death is particularly concerning, as it highlights how local coding discrepancies mirror these wider international challenges.

For the purposes of this study, both R95.0 and R95.9 were included in the definition of SIDS. SIDS represents a specific subset of SUDI and refers to the sudden death of an infant under one year of age that remains unexplained after an investigation, including complete autopsy.

Cases labelled "SIDS" without an autopsy are considered premature or inaccurate, as they lack the evidence needed to confirm the cause of death.

Only a small proportion of SIDS cases reported between 2016 and 2023 included a mention of an autopsy. This suggests that post-mortem investigations were not widely used in the certifying these deaths, which could affect the accuracy of the diagnosis and the reliability of the SIDS classification.

To overcome these limitations and ensure reliable case identification, it is essential to implement standardised classification systems such as the framework established for Sudden Unexpected Infant Death registries. This framework allows for a rigorous distinction between cases that can be explained, such as accidental suffocation in unsafe sleep environments, and cases that are truly unexplained, such as SIDS [15,16].

Systematic autopsy and accurate case identification are important and become necessary. Numerous studies have, in fact, highlighted minute developmental alterations, both and in the expression of various neurotransmitters in SIDS cases. These anomalies could provide a plausible explanation for the pathological mechanism of the deaths that remain unexplained after routine investigations. However, the protocol does not contemplate a thorough neuropathological analysis. Specifically, with regard to examination of the brain, only the search for any macroscopic malformations, haemorrhages, and cerebral infarctions and degenerative or inflammatory conditions through histological examination [7].

Advancements in scientific knowledge make it essential to include an in-depth study of the main structures located in the brainstem, in particular, in existing guidelines for the anatomopathological examination of the brain [7].

Therefore, it is important to consult the latest medical literature or to contact relevant medical professionals to obtain the most up-to-date information on the modalities for examining the centres of the nervous system that control vital activities, particularly respiratory activity, since their normal development is essential for life.

Geographical differences still exist in Italy, with a rate in the 2016-2023 period that was two and a half times greater in the South than in the North and Centre of Italy. Furthermore, an increasing trend in the SUDI rate was observed in Southern Italy. These disparities may be due to several reasons: SIDS has always been associated with a lower adherence by parents to preventive measures (e.g., back sleeping, breastfeeding, room sharing, a firm and bare sleep surface, pacifier use) and with cultural aspects relating to infant care and development (e.g., regular paediatric check-ups, stable childcare services, and a support network to help parents manage socioeconomic and emotional stress). Other contributing factors include sociodemographic differences, low educational attainment, a lack of a smoke, alcohol and substance free environment, and differences in cause of death classification [6,12,13,14].

This study has a limitation regarding the nature of vital statistics data, which does not allow us to trace detailed socioeconomic variables, preventive behaviours (such as infant sleeping position, bed-sharing, or room-sharing), or parental and caregiver attitudes. Consequently, we were unable to fully control for these potential confounding factors in our analysis.

Conclusions

Our study provides an update of the epidemiologic profile of SIDS and SUDI in Italy from 1996 to 2023. Overall infant mortality and SIDS mortality declined substantially during the early years, while SUDI showed a less pronounced reduction. At the same time, a significant temporal change in the distribution of SIDS and other causes of sudden infant death was observed during the neonatal period. This study also identified substantial geographic differences in SUDI rates and a shift in medical coding, indicating that deaths are simply being redistributed into ill-defined and unspecified causes or accidental suffocation and strangulation in bed.

A comparative analysis with the Tuscany Regional Registry highlighted inaccuracies in diagnoses attributed to SIDS. This lack of systematic post-mortem investigation directly causes misclassification, impairs diagnostic accuracy, and compromises reliable case identification in epidemiological statistics. There is a clear need not only to improve death classification, but also to conduct studies investigating the true causes of sudden deaths that are not necessarily attributable to the infant's sleeping position. A thorough investigation is therefore necessary to determine the exact cause of death and absolve mothers of any responsibility. SIDS is still a significant health problem that needs more in-depth investigations to understand its pathogenesis. Consequently, much remains to be done in Italy and in others countries to improve the surveillance of sudden infant deaths during the first year of life.

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Authors' contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Rita Campi. The first draft of the manuscript was written by Rita Campi. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability The data supporting the findings of this study were obtained from the Italian National Institute of Statistics (ISTAT).

Declarations

Ethics approval This study used anonymized vital statistics data provided by the Italian National Institute of Statistics (ISTAT). As the data were anonymized and the study did not involve direct contact with or identification of individuals, ethical approval was not required.

Competing interests The authors have no relevant financial or non-financial interests to disclose.

Declaration of generative AI and AI-assisted technologies in the manuscript preparation process

ChatGPT (GPT-4, OpenAI) was used exclusively for language editing and sentence rephrasing. The authors reviewed and edited all AI-assisted content and take full responsibility for the final manuscript.

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