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Mortality and Disability Attributable to Adverse Medical Treatment Effects in India: Insights from the 2019 Global Burden of Disease Study

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ABSTRACT

Patient harm due to unsafe medical care can result in hospitalization, long-term disability, or death. In India, where access to tertiary healthcare varies widely across its large and heterogeneous population, there is limited research evaluating the burden of adverse medical events. This study assessed the impact of adverse effects of medical treatment (AEMT) in India between 2010 and 2019 using data from the Global Burden of Disease (GBD) 2019 study. We estimated national-level deaths and disability-adjusted life years (DALYs) associated with AEMT, further analyzing differences across age groups and genders. Findings indicate that AEMT accounts for less than 0.01% of all-cause deaths and DALYs. From 2010 to 2019, the death rate showed a marginal decline from 2.34 (1.75–2.66) to 2.33 (1.73–2.86) per 100,000 population. The 50–74-year age group and females experienced the highest burden in terms of both deaths and DALYs. Although AEMT contributes minimally to overall mortality, its potential underreporting and effects on public confidence in healthcare merit further research.

Keywords: Disease burden, Disability, Death, Pharmacotherapy, Adverse effects

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Introduction

The fundamental ethical principle in healthcare, “do no harm,” obliges medical professionals to take precautions to prevent avoidable harm during treatment. When patient care is unsafe, it can lead to adverse events resulting in hospitalization, long-term disability, or death [1]. Even when serious outcomes do not occur, such events may diminish patients’ trust in their care or healthcare providers, particularly when communication between doctors and patients is insufficient. In low- and middle-income countries, lapses in patient safety are estimated to cause approximately 134 million adverse events and 2.4 million deaths annually [2]. A systematic review examining the incidence of adverse events in hospitalized patients reported a median rate of 9.2% (interquartile range [IQR], 4.6%–12.4%), with 7.4% of these events resulting in patient death [3].

A meta-analysis across multiple healthcare settings—including hospitals, various specialties, and primary care—found that preventable patient harm occurred in 6% of cases, with 12% (IQR, 9%–15%) leading to disability or death [4]. The most common sources of preventable harm were errors in drug management and other therapeutic interventions, followed by surgical procedures, healthcare-associated infections, and diagnostic errors [4]. Data from the U.S. Department of Health and Human Services indicate that treatment-related adverse events remain a significant concern despite measures implemented to reduce their occurrence [5].

In many countries, including India, medical treatment-related adverse events have yet to be recognized as a major public health issue, as attention is often focused on the growing burden of non-communicable diseases. Accurately assessing the magnitude of adverse effects of medical treatment (AEMT) within a country is a critical first step toward addressing this problem. To improve healthcare standards, the Government of India established the National Accreditation Board for Hospitals & Healthcare Providers under the Quality Council of India [6].

Surveillance programs such as the Adverse Events Following Immunization (AEFI) and the Pharmacovigilance Program of India monitor adverse outcomes from immunization and drug therapy, respectively, providing insights into the nature, incidence, and causes of such events nationally [7].

Despite these efforts, there remains a lack of comprehensive studies quantifying the burden of adverse events specifically related to medical treatment in India. Annual vital statistics at state and national levels offer some data, and the National Patient Safety Implementation Framework (2018–2025) by the Ministry of Health and Family Welfare aims, in part, to identify and report the frequency and characteristics of adverse events in healthcare [8]. On a broader scale, the Global Burden of Disease (GBD) study compiles data from government records, surveys, and published literature to generate country-specific estimates of mortality and disability [9]. Using the GBD 2019 dataset, this study aimed to evaluate the burden of AEMT in India over the period 2010–2019.

Materials and Methods

This study employed a retrospective, descriptive design to assess AEMT in India from 2010 to 2019 using the GBD database. The GBD 2019 study provides estimates of incidence, prevalence, deaths, and disability-adjusted life years (DALYs) for numerous causes of death and disability between 1990 and 2019, stratified by age, sex, country, region, and, in some cases, subnational units [9]. Causes of diseases and injuries are organized hierarchically, from broad level-1 categories (communicable, non-communicable, and injury-related conditions) to specific level-4 causes (totaling 301 causes). This study focused on the level-3 cause, "Adverse effects of medical treatment," encompassing death or disability resulting from exposure to medical interventions, whether occurring in hospital or community settings.

DALYs are calculated as the sum of years of life lost and years lived with disability, with one DALY representing a single year of healthy life lost [10]. The GBD estimates are derived from diverse sources including census data, disease registries, government-published vital statistics, health surveys, and published reports. In cases where data were missing or incomplete for certain states or years, the GBD methodology applied statistical modeling that incorporated available regional data and relevant covariates to produce approximate estimates [11]. This approach ensures that policymakers have at least an approximate understanding of the burden, rather than excluding areas with incomplete data and potentially overlooking the problem.

The data on adverse effects of medical treatment (AEMT) were coded using the International Classification of Diseases, ICD-9 and ICD-10 [9]. The GBD study used these codes to identify deaths attributable to AEMT. Specifically, the level-3 cause "Adverse effects of medical treatment" in the GBD 2019 process included the ICD-10 codes N30.4, Y40–Y84.9, and Y88–Y88.3.

Using the GBD dataset, we extracted estimates for incidence, mortality, and disability related to AEMT at both national and state levels, further stratified by age and gender (https://vizhub.healthdata.org/gbd-results/) [12]. To evaluate differences between reported and modeled estimates, we compared annual mortality rates from the GBD database with those from the Medical Certification of Cause of Death (MCCD) reports for India and the state of Karnataka, published by the Office of the Registrar General & Census Commissioner, India [13]. MCCD data are derived from medical professionals in selected hospitals, mostly in urban areas, and therefore represent only a subset of registered deaths. Notably, the ICD-10 codes used for AEMT in MCCD reports differ slightly from the GBD codes, as they exclude N30.4 and Y88–Y88.3. Additionally, we compared India's GBD estimates with those of the United States for 2019, which are based on more comprehensive data coverage [9]. Comparisons were also made according to sociodemographic index (SDI) categories, which combine fertility rates under age 25, mean educational attainment among individuals aged ≥15 years, and lag-distributed income per capita (10-year average GDP per capita) to reflect correlations with health outcomes [14]. SDI classifications include high, high-middle, middle, low-middle, and low, with India falling in the low-middle category.

The study protocol received approval from the Kasturba Medical College Institutional Ethics Committee (IEC KMCMLR-12/2022/497).

Statistical analysis

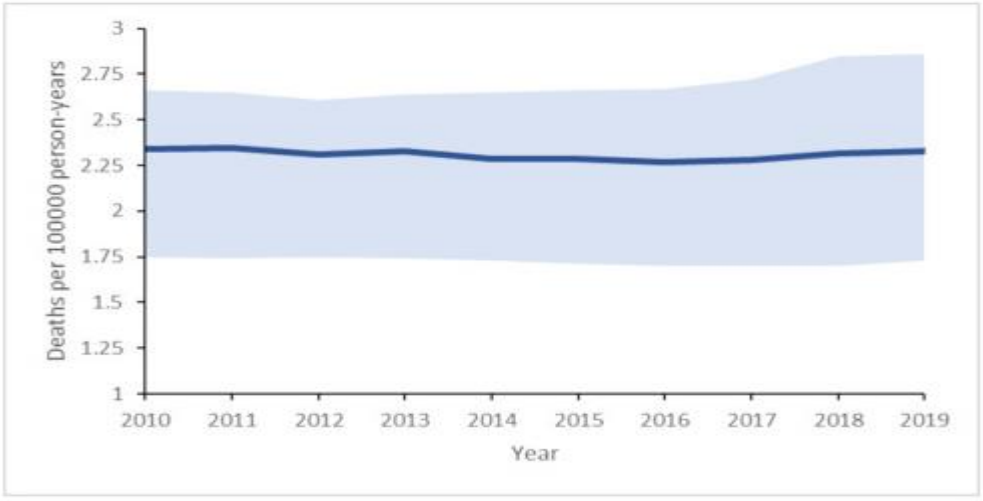
Estimates for incidence, deaths, and DALYs related to AEMT in India (overall and by age and gender), the United States, and across SDI categories were downloaded from the GBD database as Microsoft .csv files (Microsoft Corporation, Redmond, WA, USA). These data were imported into Microsoft Excel for further analysis and

visualization. Rates are presented per 100,000 person-years and are age-standardized. Changes in estimates from 2010 to 2019 are reported, along with point estimates and 95% uncertainty intervals (UI). The UI represents a range likely to contain the true population value, calculated by sampling 1,000 draws, with the 2.5th and 97.5th quantiles forming the interval [9]. Data from the MCCD reports were manually entered into Excel for comparison.

Results and Discussion

National-level AEMT incidence, mortality, and disability

In India, the incidence rate of AEMT increased from 140.89 (114.03–167.92) per 100,000 person-years in 2010 to 162.40 (131.14–195.95) per 100,000 person-years in 2019. The estimated number of deaths due to AEMT rose from 28,830 (21,491–32,707) in 2010 to 32,464 (24,076–39,747) in 2019, while the death rate remained largely stable, changing from 2.34 (1.75–2.66) to 2.33 (1.73–2.86) per 100,000 population. DALYs showed a decline both in absolute numbers (1,058,375 [792,000–1,194,384] in 2010 to 1,020,453 [761,309–1,230,656] in 2019) and in rate (85.95 [64.32–97.00] to 73.38 [54.74–88.49] per 100,000). **Figures 1a and 1b** display the year-wise trends in death and DALY rates, respectively. Overall, AEMT contributed to less than 0.01% of deaths and DALYs from all causes. The GBD data incorporated MCCD reports from 2009–2012 (national), Odisha 2009–2013, Karnataka 2014–2015, and Delhi 2013.



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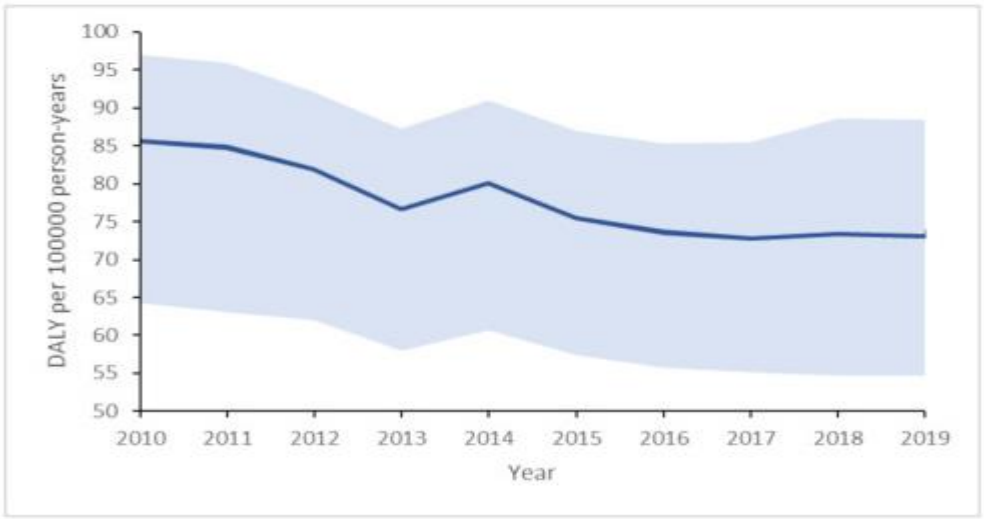

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Figure 1. Changes in a) mortality and b) DALY rates from adverse medical treatment in India between 2010 and 2019. Rates are age-standardized per 100,000 person-years. The solid dark line shows the central estimate, while the shaded area indicates the 95% uncertainty interval. DALY: disability-adjusted life years.

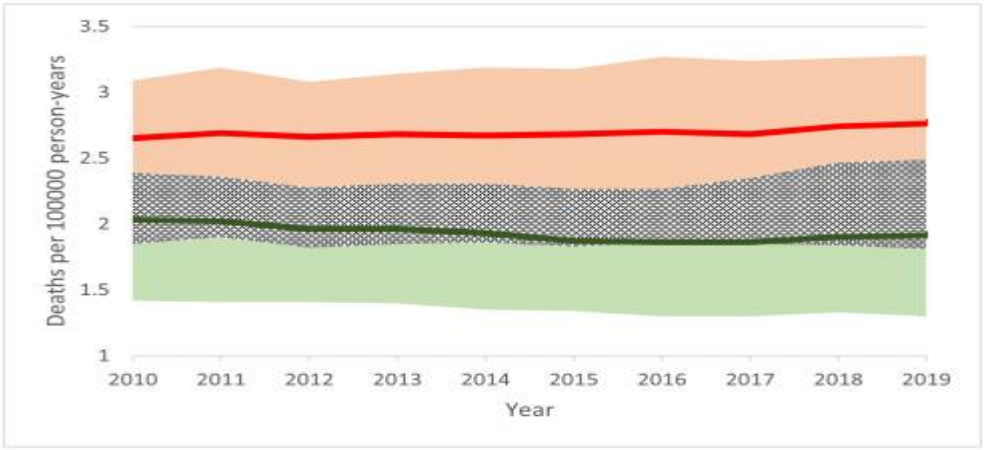
Age-specific burden of AEMT

Analysis of 2019 data shows that the impact of adverse medical events was greatest among older adults. Individuals aged 50–74 years accounted for the largest absolute number of deaths (approximately 14,877, range: 10,684–18,666), whereas those aged 75 years and above experienced the highest death rate, reaching 29.71 per 100,000 (21.86–37.10). In terms of disability, the 50–74-year age group also contributed the most DALYs (388,668; 278,699–490,352), but the rate per 100,000 was highest among the ≥75 age group (243.10; 178.48–304.38).

Gender differences in AEMT burden

Females bore a larger share of the burden of AEMT compared with males in 2019, both in absolute numbers and per capita rates **(Figures 2a and 2b)**. Women represented 58% of all deaths linked to AEMT. Male deaths rose modestly from around 12,967 (8,997–15,161) in 2010 to 13,704 (9,260–17,771) in 2019. Female deaths increased from 15,862 (11,051–18,625) to 18,760 (12,244–24,263) over the same period. DALYs in men decreased from 444,344 (313,297–512,253) to 408,139 (282,433–517,872), while in women the figures declined slightly from 620,050 (430,890–719,537) to 612,314 (406,869–774,798). Although mortality rates were largely stable across genders, DALY rates showed a general downward trend over the decade.

Regarding incidence, males consistently experienced higher rates than females, with increases noted for both sexes from 2010 to 2019. Male incidence rose from 151.50 (120.13–184.73) to 167.52 (132.71–205.68) per 100,000, whereas female incidence increased from 129.64 (105.58–156.26) to 157.01 (126.85–188.72) per 100,000.



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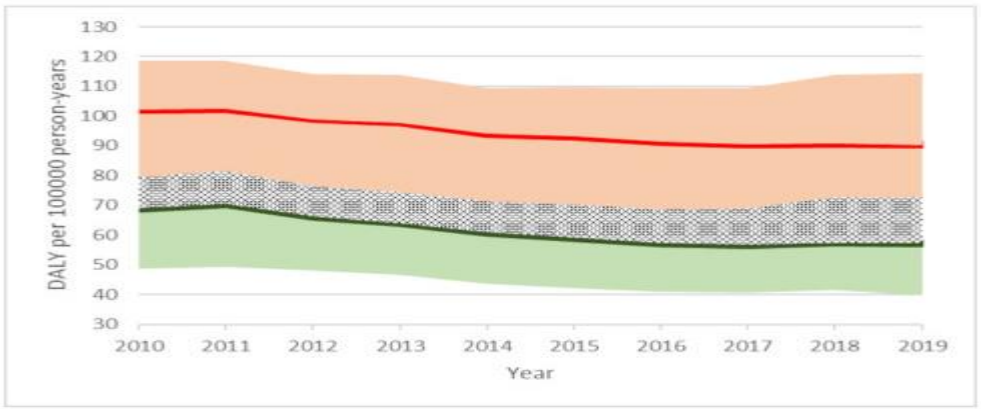


b)

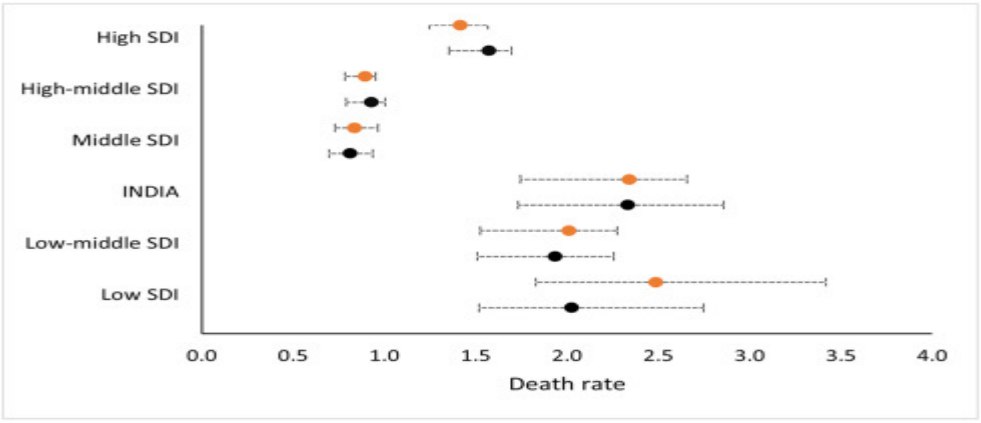
Figure 2. Trends in a) mortality and b) DALY rates from adverse effects of medical treatment by gender. Rates are age-standardized and expressed per 100,000 person-years. Solid green and red lines indicate point estimates for males and females, respectively. The light-colored shaded areas reflect the 95% uncertainty intervals for each gender, with overlapping regions shown by dotted shading. DALY: disability-adjusted life years.

Mortality and disability by SDI categories

Figures 3a and 3b present comparisons of India's death and DALY rates from AEMT with estimates across different sociodemographic index (SDI) categories. India's mortality exceeded the average for low-middle SDI countries and was higher than middle and high-middle SDI groups, but remained lower than low SDI countries in 2010, though not in 2019. DALY trends showed a similar pattern, except that India's DALY rates in both 2010 and 2019 were below those of low SDI countries.

Table 1 compares modeled GBD estimates of AEMT-related deaths with figures reported in the Medical Certification of Cause of Death (MCCD) reports by the Office of the Registrar General, India. Reported deaths were substantially lower than modeled estimates, with discrepancies ranging from 10- to 200-fold. This discrepancy was also observed when analyzing data from the state of Karnataka.

Table 2 contrasts India's 2019 AEMT estimates with those of the United States. While India had higher mortality and DALY rates, the U.S. exhibited higher incidence and prevalence. Additionally, India experienced a slight decline in death rates from 2010 to 2019, whereas the United States showed an increase over the same period.



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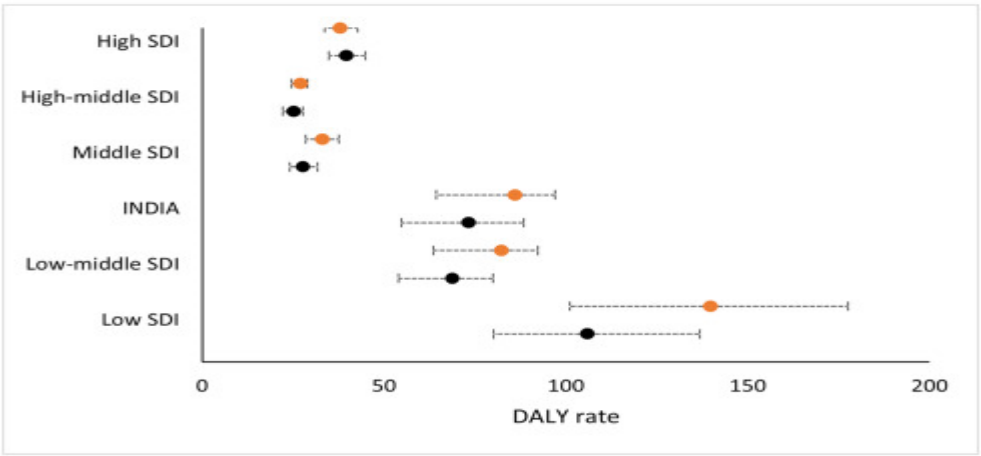

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Figure 3. Age-standardized rates of deaths (a) and DALYs (b) associated with adverse medical treatment in India compared to countries classified by sociodemographic index (SDI) levels. Circles in orange indicate estimates for 2010, while black circles indicate estimates for 2019. The dashed horizontal lines represent the 95% uncertainty range. Rates are reported per 100,000 person-years. DALY: disability-adjusted life years.

Table 1. Number of deaths due to adverse effects of medical treatment based on GBD 2019 study and MCCD report.

Year	Number of deaths due to AEMT			
	In India		In Karnataka	
	GBD	MCCD	GBD	MCCD

2010	28830	142	1108	8
2011	29416	584	1159	14
2012	29382	489	1185	39
2013	30018	1209	1234	NA
2014	29963	556	1255	16
2015	30284	700	1291	8
2016	30977	870	1329	16
2017	30470	851	1348	7
2018	31935	1469	1374	19
2019	32464	3245	1365	10

AEMT, adverse effects of medical treatment; GBD, global burden of disease; MCCD, medical certification of cause of death.

Table 2. Comparison of AEMT statistics in India and the United States for 2019.

Variable[a]	India	United States of America
Incidence rate	162.40 (131.14–195.95)	1934.95 (1594.02–2356.44)
Prevalence rate	12.41 (9.05–16.18)	147.35 (108.78–190.68)
Death (Number)	32464 (24076–39747)	5016 (4556–6232)
Death rate	2.33 (1.73–2.86)	1.53 (1.39–1.9)
Percentage of all deaths	0.35 (0.26–0.41)	0.17 (0.15–0.21)
DALY rate	73.38 (54.74–88.49)	53.83 (45.34–65.79)
% change in death rate (2010–2019)	−0.033%	1.21%

AEMT, adverse effects of medical treatment; DALY, disability-adjusted life years.
[a] Rates are expressed per 100000 person-years.

Our analysis revealed that the incidence of adverse effects of medical treatment (AEMT) in India rose between 2010 and 2019. Although the absolute number of deaths increased during this period, the overall death and DALY rates showed a slight decline. Overall, AEMT contributed to less than 0.01% of the total disease burden in India. Age-wise, individuals aged 75 years and older experienced the highest mortality rates, whereas the largest number of deaths occurred in the 50–74-year age group. Gender differences were evident, with females experiencing a higher burden in terms of deaths, which also increased over time. Despite higher incidence rates in males, the rate of annual increase was greater among females. Studies from other countries report mixed gender trends: for instance, Lunevicius *et al*. in the UK found a higher burden in males [15], whereas Sunshine *et al*. in the US observed no significant gender difference [16]. By 2019, both death and DALY rates due to AEMT in India exceeded the average estimates for low-middle SDI countries.

To our knowledge, this is the first study providing a comprehensive assessment of AEMT burden in India, alongside a comparison with official MCCD-reported data. While Nauman *et al*. have described the global AEMT burden using GBD 2017 data [17], our study emphasizes the most recent India-specific trends, elaborates on data sources, and situates India's burden in an international context. Comparisons by SDI reveal that India's death and DALY rates are higher than those in middle, high-middle, and high SDI countries, as well as above the average for low-middle SDI nations. Between 2010 and 2019, high-middle and high SDI countries experienced increases in mortality, with high SDI countries also showing a rise in DALY rates, whereas low SDI countries had the greatest reduction in these measures.

Several Indian studies have quantified adverse drug reactions (ADRs) as a source of hospitalization and mortality. In a Gujarat hospital, 5.42% of patients admitted to an internal medicine ward were hospitalized due to ADRs, with 4.25% fatal, 29.79% life-threatening, and 62.83% requiring hospitalization or prolonged stay [18]. Among 6,026 pediatric admissions in Maharashtra over one year, ADRs were observed in 182 patients (3.02%), of which 25 cases (13.7%) were severe and 2 fatal [19]. At a North Indian tertiary hospital, 167 of 1,033 patients (16.2%) experienced ADRs, with 15 (7.5%) of 199 events classified as severe [20]. Sunshine *et al*. reported that in the US, surgical and perioperative events accounted for 63.6% of deaths due to AEMT [16]. A scoping review by

Schwendimann *et al*. analyzed 25 retrospective hospital studies across 27 countries, showing that a median of 10% of patients experienced at least one adverse event (range: 2.9%–21.9%), with fatal events in 7.3% (0.6%–30%), and nearly half of all adverse events deemed preventable. Common categories included surgical, medication- or fluid-related, and healthcare-associated infections [21].

Underreporting remains a major challenge in India, as reflected in ADR statistics. Voluntary reporting systems result in widespread under-reporting due to patient factors, such as inability to recognize ADRs or link them to medications, and provider-related factors, including fear of litigation, guilt, inadequate training, lack of awareness, or difficulty correlating clinical findings with ADRs [22–24]. Reporting rates vary across ADR monitoring centers, with a small fraction contributing the majority of reports [22]. Recognizing that these challenges are not unique to India, fostering a culture of reporting is crucial. The 2019 World Health Organization resolution on 'Global Action on Patient Safety' underscores the need to address healthcare-related harm even in the absence of complete data [25].

A review of systematic reviews highlighted that the most frequent cause of medication errors is flawed clinical decision-making, such as overlooking patient-specific risk factors, followed by organizational issues like staff shortages and environmental distractions [26]. Various strategies have been explored to reduce adverse medical events, but many have shown limited effectiveness, and very few have consistently demonstrated clear benefits [27, 28]. Technology-driven interventions offer potential in minimizing medication errors, including automated dispensing systems, pharmacy computer platforms, computerized physician order entry, and renal dosing alerts [29]. The Beers criteria are commonly employed to prevent or correct prescriptions of potentially inappropriate medications, thereby enhancing medication safety in elderly patients [30]. Artificial intelligence (AI) has also been applied to automate adverse event reporting during drug development; for instance, a study in Spain found that AI could significantly reduce the occurrence of adverse incidents by assessing clinical case data [31].

The ISTOP-ADE system in Canada, which uses an interactive voice response to monitor patient issues and connect them with pharmacists, identified 10 of 26 primary non-compliance events and 56 of 125 (45%) adverse drug events, demonstrating improvements in medication adherence and reduction in ADE duration [32]. In France, an intensive care unit study utilized a multidisciplinary committee applying the Orion methodology to examine event reports, evaluate root causes, review standard-of-care practices, and determine corrective measures. However, this approach was limited by the small number of incidents per category and high staff turnover, reducing its overall effectiveness [33].

Given the widespread underreporting, incomplete medical certification of deaths, and evidence that hospital-based studies report a high proportion of treatment-related hospitalizations and deaths, it is crucial to strengthen systems for identifying and reporting adverse medical events within healthcare facilities. There is also a pressing need to review and implement evidence-based, cost-effective safeguards for preventing AEMT in India. Key measures include establishing robust policies, restructuring patient care delivery, providing comprehensive patient safety training for healthcare personnel, enforcing individual accountability through clear and transparent documentation, and fostering a culture that supports feedback and continuous improvement, all aligned with the goals of the World Health Organization's patient safety strategy.

In interpreting our findings, it is crucial to acknowledge the limitations inherent in the GBD modeling approach and the potential shortcomings of the MCCD data. GBD estimates are derived from available source data, and when such data are sparse or of low quality, the resulting estimates carry wide uncertainty intervals. This is particularly relevant for AEMT in India, where the underlying data were drawn from MCCD reports covering 2009–2012, Odisha reports from 2009–2013, Karnataka reports from 2014–2015, and the Delhi report from 2013. The modeling framework extrapolates from these data to generate estimates for regions without direct reporting. Consequently, many states showing no reported AEMT deaths still have modeled estimates, which likely explains why GBD-generated numbers are substantially higher than those in MCCD reports. The underlying assumption is that even a rough estimate is more informative than no estimate, aiding health planning and resource allocation. For comparison, GBD estimates for the United States in 2019 indicated 5,016 AEMT deaths, whereas a 2018 DHHS study of a representative sample of Medicare users suggested that 14,800 deaths occurred per million, with 121,089 serious adverse events [5]. This discrepancy highlights that even with robust underlying data, GBD estimates may underestimate actual deaths.

The phased implementation of MCCD also limits the comprehensiveness of reported deaths. In 2019, medically certified deaths accounted for only 20.7% of all deaths [13]. Regarding AEMT specifically, one state contributed 83% of reported deaths, while 18 states/union territories reported none; in 2010, three states accounted for 81%

of the total with 18 states/UTs reporting zero deaths [13]. This suggests either misclassification of AEMT-related deaths under other causes or underdiagnosis of treatment-related mortality. Additional discrepancies arise because GBD includes ICD-10 code Y88–Y88.3 ("sequelae with surgical and medical care as external cause") under AEMT, whereas MCCD categorizes these under "Late effects of external causes" (Y85–Y89), partially explaining but not fully accounting for the differences.

Conclusion

Over the past decade, India has experienced a rising incidence of AEMT, yet the associated death and DALY rates have declined. The burden is disproportionately higher in females and in individuals aged 75 years and older. Although AEMT contributes to only a small fraction of total deaths, the potential underreporting of cases and the influence of treatment-related deaths on public trust in healthcare warrant further investigation.

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Conflict of Interest: The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The corresponding author is an advisory board member of Heliyon.

Financial Support: None

Ethics Statement: The study protocol was approved by the Kasturba Medical College Institutional Ethics Committee (IEC KMCMLR-12/2022/497). Informed consent was not required for this study because the study used data from databases accessible to the public.

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