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Incident severity in children and young patients versus adults in intensive care: a nationwide cross-sectional analysis of spontaneously reported adverse events in Japan

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Abstract

Background

Safety incidents in intensive care can progress rapidly to permanent disability or death, and children are considered vulnerable to medication- and device-related events. Whether age itself is associated with incident severity, independent of care setting and incident type, remains unclear. We examined this question in a nationwide sample of Japanese intensive-care incident reports.

Methods

We analyzed publicly available adverse-event reports submitted to the Japan Council for Quality Health Care, 2013–2024, from neonatal, general, and cardiac intensive care units (NICU, ICU, CCU). Severe outcome was defined as death, or a high or low likelihood of residual disability accompanied by intensive treatment, derived from recorded harm and treatment grades. A NICU-excluded ICU/CCU subcohort served as a PICU-equivalent proxy. Modified Poisson models estimated relative risks (RR) for ages 0–19 versus 20–59 years, adding care setting, incident category, and the full covariate set sequentially. Pediatric death-associated reports underwent a structured review of apparent incident attribution.

Results

Of 54310 reports, 2835 occurred in these settings, and 2822 with a known age group were analyzed. Pediatric reports were concentrated in the NICU (431/688, 63%) and involved drain/tube-related (250/688, 36%) or medication-related (127/688, 18%) incidents, whereas adult reports were mainly ICU-based (444/491, 90%) and treatment/procedure-related (196/491, 40%). Crude severe-outcome rates (26% vs 38%) and reports recording death as the harm grade (4.8% vs 14%) were lower in children than in adults. The pediatric RR for a severe outcome was 0.71 (95% CI 0.59–0.84) in the crude analysis and 1.07 (0.87–1.30) after full adjustment; corresponding values in the NICU-excluded subcohort were 0.93 (0.76–1.15) and 1.08 (0.87–1.33). Of 33 pediatric death-associated reports, 8 were classified as having a definite or probable incident contribution.

Conclusions

The lower crude severity of pediatric reports was largely explained by NICU-predominant case-mix rather than by a protective association with young age. After adjustment, age was not independently associated with severe outcome, and PICU-equivalent reports showed no clearly lower severity risk than adult reports. Pediatric intensive-care safety should be prioritized by care setting, treatment intensity, and incident type rather than by age alone.

Background

Intensive-care settings, including the neonatal intensive care unit (NICU), the general intensive care unit (ICU), and the cardiac care unit (CCU), concentrate high-risk processes such as invasive device management, mechanical ventilation, high-alert medication use, and time-critical multidisciplinary decision-making. In these environments, a safety incident can progress rapidly to permanent disability or death. Children and neonates are considered particularly vulnerable to medication- and device-related adverse events because of weight-based dosing, the need to dilute and compound adult-strength preparations, developmentally changing pharmacokinetics, a limited ability to communicate distress, and frequent exposure to tubes and invasive devices [1]. In a US prospective study of 10778 medication orders in pediatric inpatients, the rate of potential adverse drug events was three times that reported in a comparable adult population and was highest among neonates in the NICU, although the rates of medication errors and of preventable adverse drug events were similar to adult rates [1]. In a national Korean incident-reporting registry of 57340 reports, children and young adults aged 0–19 years had higher odds of a medication-related incident than adults aged 20–60 years in the emergency room (odds ratio 1.60) and in the intensive care unit (odds ratio 2.06) [2]. Unplanned extubation has recognized pediatric risk factors including young age, male sex, agitation, and intubation duration, as well as environmental factors such as night-shift occurrence and fixation method [3–5].

However, comparisons of pediatric and adult intensive-care incidents are complicated by large differences in care setting and case-mix. Pediatric reports may be concentrated in the NICU, whose population includes not only critically ill neonates but also stable preterm or convalescent infants receiving relatively low-acuity support, whereas adult ICU and CCU populations more often comprise patients with reduced physiological reserve. A crude comparison by age may therefore reflect where incidents were reported and which types of incidents were reported, rather than an age-related difference in susceptibility to a severe outcome. Moreover, spontaneous reporting captures only a fraction of clinical errors, and reporting behavior itself varies [6].

Whether the severity of reported intensive-care incidents differs between pediatric and adult age groups after accounting for care setting and incident category remains unclear. We therefore performed a nationwide cross-sectional analysis of spontaneously reported safety incidents in Japanese NICUs, ICUs, and CCUs. Our aims were, first, to characterize how pediatric incidents differ from adult incidents in where they occur and what they are (the composition of care setting, incident type, and care processes); second, to examine whether age itself is associated with a severe outcome once care setting, incident type, and care processes are held constant by sequential adjustment; and third, to explore whether, in critically ill children cared for in the ICU/CCU after excluding the NICU (a PICU-equivalent proxy), the structure of severity differs from that in adults.

Methods

Study design and data source

This retrospective cross-sectional study used the publicly available incident-report database from the Japan Council for Quality Health Care (JCQHC) Project to Collect Medical Near-Miss/Adverse Event Information [7]. This national program collects reports from both legally mandated reporting institutions and voluntarily registered participating institutions via a dedicated web-based reporting system. Participating institutions are therefore not limited to tertiary hospitals; in addition to mandated institutions defined by Japanese regulations, the program also accepts voluntary participation from hospitals or clinics. As of March 31, 2025, the project listed 4176 registered institutions.

Study population

We analyzed all adverse-event reports submitted between 2013 and 2024 (N = 54310). We defined the intensive-care cohort as reports flagged as occurring in a neonatal intensive care unit (NICU), an intensive care unit (ICU), or a cardiac care unit (CCU); reports not flagged for any of these settings were excluded (n = 51475), leaving 2835 incidents. For age-stratified analyses we further excluded 13 reports with a missing age group, yielding 2822 incidents with a known age group. The derivation and counts at each step are shown in Fig. 1. Patient age was recorded in 10-year coded bands; we grouped reports as children/young (0–19 years) versus adults (20–59 years) for the primary comparison, with older adults (60–79 and 80 + years) retained as additional categories.

Outcome

The primary outcome was incident severity, operationalized to approximate the JCQHC Patient Impact Severity Levels (PISL) ≥3b. Because the database does not record PISL directly, severity was derived from the recorded degree of harm and degree of treatment: a report was classified as severe if the recorded harm grade was death, or if the harm grade indicated a high or low likelihood of residual disability and the treatment grade indicated intensive treatment. The secondary outcome was death recorded as the harm grade (hereafter recorded death). This indicates that death was documented on the incident report and is not equivalent to a patient-level in-hospital mortality rate. Among the 2835 intensive-care incidents, 1049 met the severe definition and 430 involved death.

Exposure and covariates

The primary exposure was age group (children/young 0–19 years versus adults 20–59 years; reference = adults). Pre-specified covariates, defined on subject-matter grounds, comprised the care setting (NICU/ICU/CCU), incident category (drain/tube, medical devices, treatment/procedure, medication, other), time of day (day vs night/off-hours), day type (weekday vs weekend/holiday), the first involved staff member's occupation (nurse [reference], physician, other) and years of experience, the number of on-call/night shifts in the previous week, the number of involved staff, patient sex, patient category (inpatient versus outpatient/emergency-routed), predisposing patient status before the event, and pre-specified contributing-factor flags (verification/observation lapse, coordination failure, skill/technique

immaturity, high workload). Variables coded as “unknown” in the data dictionary (e.g., on-call shift count) were set to missing.

Exploratory review of pediatric death-associated reports

We conducted an exploratory structured review of pediatric reports with death recorded as the harm grade. Reports were stratified by care setting and classified into four levels of apparent incident attribution: Definite, Probable, Indeterminate, and Non-definite. The classification was based on structured fields and narrative descriptions and was intended to describe the apparent contribution of a safety-process problem, not preventability. Reports classified as definite or probable were summarized as having a relatively clear or suggested incident contribution, whereas indeterminate and non-definite reports were summarized as having no definite incident contribution. All reports were classified by a pediatrician (KH), who applied the pre-specified four-tier scheme to the structured fields and the free-text description of each report. All classifications were then reviewed by a second physician, a pediatrician and intensivist (HT), and disagreements were resolved by discussion. Because the second physician verified rather than independently rated the classifications, an inter-rater agreement statistic was not calculated.

Statistical analysis

We first described patient characteristics, incident type, and incident-related characteristics using counts and proportions; descriptive tables do not include p values. To estimate the association between each covariate and the primary (severe) outcome, we fitted modified Poisson regression models (Poisson family with a log link, fitted by generalized estimating equations with an independence working correlation and robust [sandwich] standard errors) [8], which yield relative risks (RR) with 95% confidence intervals (CI) for a binary outcome. Because a severe outcome was common in this cohort, odds ratios would overestimate risk ratios; models that directly estimate a risk (prevalence) ratio are therefore preferred for cross-sectional data with a common binary outcome [9]. Age group was entered as a single covariate, with adults (20–59) as the reference.

We used a pre-specified sequential adjustment strategy adding covariate blocks in a fixed order to assess confounding through change-in-estimate: M1 (age only), M2 (+ setting), M3 (+ incident category), and M4 (+ the full a priori covariate set).

We tested three pre-specified effect-modification hypotheses (age × medication, age × unplanned extubation, age × night) with multi-degree-of-freedom Wald tests of the interaction terms added to M4. In a NICU-excluded ICU/CCU subcohort, used as a strict PICU-equivalent proxy for pediatric reports, we additionally compared pediatric ICU/CCU reports with adult ICU/CCU reports using the same sequential adjustment strategy.

The complete-case set for the fully adjusted model comprised 2758 incidents (1025 severe events); missing values were handled according to the analytic role of each variable. Reports with missing age group were excluded from age-stratified analyses. Variables with missing values that precluded model inclusion were handled by complete-case analysis. For on-call/night-shift count, missingness was retained as an explicit category because it was common and was included in the a priori covariate structure. No multiple imputation was performed. Regressions for the death outcome were unstable given few pediatric events and are reported descriptively.

All analyses were performed with the geepack package (version 1.3.12) in R version 4.5.2 (R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was defined as a two-sided p value < 0.05.

Results

Study cohort

Of 54310 adverse-event reports submitted between 2013 and 2024, 2835 were recorded as occurring in a NICU, ICU, or CCU and constituted the intensive-care cohort. After excluding 13 reports with a missing age group, 2822 reports with a known age group formed the primary analytic set (Fig. 1).

Age-specific incident profile and crude severity

The analytic set comprised 688 reports for children/young patients (0–19 years), 491 for adults (20–59 years), 1175 for those aged 60–79 years, and 468 for those aged 80 years or older. Among children/young patients, NICU reports accounted for 431 (63%), whereas among adults (20–59) ICU reports accounted for 444 (90%). The incident-category distribution also differed by age group: drain/tube-related (250; 36%) and medication-related (127; 18%) incidents were more frequent among children/young patients, whereas treatment/procedure-related incidents predominated among adults (196; 40%) (Table 1). The crude severe-outcome rate was 181/688 (26%) among children/young patients and 185/491 (38%) among adults (20–59), and the recorded-death proportion was 33/688 (4.8%) and 67/491 (14%), respectively (Table 1).

Table 1
Characteristics of intensive-care reports by age group.

Characteristic	Overall, N = 2822	0–19, N = 688	20–59, N = 491	60–79, N = 1175	≥ 80, N = 468
Setting					
NICU	432 (15.0%)	431 (63.0%)	1 (0.2%)	0 (0.0%)	0 (0.0%)
ICU	2165 (77.0%)	244 (35.0%)	444 (90.0%)	1081 (92.0%)	396 (85.0%)
CCU	225 (8.0%)	13 (1.9%)	46 (9.4%)	94 (8.0%)	72 (15.0%)
Incident category					
Drain/tube	651 (23.0%)	250 (36.0%)	95 (19.0%)	210 (18.0%)	96 (21.0%)
Medical devices	174 (6.2%)	45 (6.5%)	41 (8.4%)	67 (5.7%)	21 (4.5%)
Treatment/procedure	1115 (40.0%)	120 (17.0%)	196 (40.0%)	580 (49.0%)	219 (47.0%)
Medication	324 (11.0%)	127 (18.0%)	64 (13.0%)	95 (8.1%)	38 (8.1%)
Other	558 (20.0%)	146 (21.0%)	95 (19.0%)	223 (19.0%)	94 (20.0%)
Report year					
2013	142 (5.0%)	46 (6.7%)	27 (5.5%)	49 (4.2%)	20 (4.3%)
2014	138 (4.9%)	39 (5.7%)	17 (3.5%)	62 (5.3%)	20 (4.3%)
2015	204 (7.2%)	40 (5.8%)	30 (6.1%)	102 (8.7%)	32 (6.8%)
2016	183 (6.5%)	36 (5.2%)	42 (8.6%)	77 (6.6%)	28 (6.0%)
2017	214 (7.6%)	53 (7.7%)	43 (8.8%)	83 (7.1%)	35 (7.5%)
2018	237 (8.4%)	69 (10%)	35 (7.1%)	87 (7.4%)	46 (9.8%)
2019	239 (8.5%)	73 (11%)	33 (6.7%)	92 (7.8%)	41 (8.8%)
2020	266 (9.4%)	66 (9.6%)	48 (9.8%)	115 (9.8%)	37 (7.9%)
2021	274 (9.7%)	59 (8.6%)	48 (9.8%)	125 (11%)	42 (9.0%)

Values are n (%) or median (interquartile range). This table is descriptive; no hypothesis testing was performed. Percentages were calculated using non-missing denominators unless otherwise indicated.

Characteristic	Overall, N = 2822	0–19, N = 688	20–59, N = 491	60–79, N = 1175	≥ 80, N = 468
2022	286 (10.0%)	69 (10.0%)	44 (9.0%)	110 (9.4%)	63 (13.0%)
2023	318 (11.0%)	66 (9.6%)	61 (12.0%)	132 (11.0%)	59 (13.0%)
2024	321 (11.0%)	72 (10.0%)	63 (13.0%)	141 (12.0%)	45 (9.6%)
Sex					
Male	1777 (63.0%)	389 (57.0%)	302 (62.0%)	796 (68.0%)	290 (62.0%)
Female	1045 (37.0%)	299 (43.0%)	189 (38.0%)	379 (32.0%)	178 (38.0%)
Patient category					
Inpatient	2810 (99.6%)	688 (100.0%)	491 (100.0%)	1166 (99.0%)	465 (99.0%)
Outpatient	12 (0.4%)	0 (0.0%)	0 (0.0%)	9 (0.8%)	3 (0.6%)
Patient status before event					
Missing	564 (20.0%)	212 (31.0%)	83 (17.0%)	202 (17.0%)	67 (14.0%)
Predisposing state present	2258 (80.0%)	476 (69.0%)	408 (83.0%)	973 (83.0%)	401 (86.0%)
Time of day					
Day (08:00–15:59)	1275 (46.0%)	320 (47.0%)	227 (47.0%)	524 (46.0%)	204 (45.0%)
Night (16:00–07:59)	1483 (54.0%)	358 (53.0%)	254 (53.0%)	618 (54.0%)	253 (55.0%)
Missing	64 (0.2%)	10 (0.1%)	10 (0.2%)	33 (0.3%)	11 (0.2%)
Day type					
Weekday	2245 (80.0%)	536 (78.0%)	388 (79.0%)	942 (80.0%)	379 (81.0%)
Weekend/holiday	577 (20.0%)	152 (22.0%)	103 (21.0%)	233 (20.0%)	89 (19.0%)

Values are n (%) or median (interquartile range). This table is descriptive; no hypothesis testing was performed. Percentages were calculated using non-missing denominators unless otherwise indicated.

Characteristic	Overall, N = 2822	0–19, N = 688	20–59, N = 491	60–79, N = 1175	≥ 80, N = 468
Involved staff occupation (1st)					
Nurse	969 (34.0%)	344 (50.0%)	153 (31.0%)	333 (28.0%)	139 (30.0%)
Physician	1769 (63.0%)	313 (45.0%)	320 (65.0%)	815 (69.0%)	321 (69.0%)
Other	84 (3.0%)	31 (4.5%)	18 (3.7%)	27 (2.3%)	8 (1.7%)
Years of experience (1st)	10 (5–17)	9 (4–15)	10 (5–16)	11 (5–18)	10 (5–16)
On-call/night shifts (prev. week)					
0	680 (24.0%)	120 (17.0%)	107 (22.0%)	305 (26.0%)	148 (32.0%)
1–2	1255 (44.0%)	333 (48.0%)	212 (43.0%)	506 (43.0%)	204 (44.0%)
≥ 3	130 (4.6%)	44 (6.4%)	21 (4.3%)	44 (3.7%)	21 (4.5%)
Missing	757 (27.0%)	191 (28.0%)	151 (31.0%)	320 (27.0%)	95 (20.0%)
No. of involved staff	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)
Verification/observation lapse	1289 (46.0%)	389 (57.0%)	227 (46.0%)	472 (40.0%)	201 (43.0%)
Coordination failure	490 (17.0%)	133 (19.0%)	91 (19.0%)	193 (16.0%)	73 (16.0%)
Skill/technique immaturity	499 (18.0%)	112 (16.0%)	74 (15.0%)	220 (19.0%)	93 (20.0%)
High workload	280 (9.9%)	102 (15.0%)	36 (7.3%)	105 (8.9%)	37 (7.9%)
Severe outcome					
Non-severe	1774 (63.0%)	507 (74.0%)	306 (62.0%)	690 (59.0%)	271 (58.0%)
Severe	1048 (37.0%)	181 (26.0%)	185 (38.0%)	485 (41.0%)	197 (42.0%)
Death recorded as the harm grade					

Values are n (%) or median (interquartile range). This table is descriptive; no hypothesis testing was performed. Percentages were calculated using non-missing denominators unless otherwise indicated.

Characteristic	Overall, N = 2822	0–19, N = 688	20–59, N = 491	60–79, N = 1175	≥ 80, N = 468
Not recorded	2393 (85.0%)	655 (95.0%)	424 (86.0%)	952 (81.0%)	362 (77.0%)
Recorded	429 (15.0%)	33 (4.8%)	67 (14.0%)	223 (19.0%)	106 (23.0%)

Values are n (%) or median (interquartile range). This table is descriptive; no hypothesis testing was performed. Percentages were calculated using non-missing denominators unless otherwise indicated.

Setting-level case-mix and treatment-intensity metrics

Across settings, we compared the severe-outcome rate, the recorded-death proportion, and a complementary treatment-intensity metric, defined as the proportion of reports requiring intensive treatment. For all ages, NICU reports showed the lowest observed values across these metrics (severe-outcome rate: NICU 21.1%, ICU 39.5%, CCU 43.6%; recorded death: NICU 4.3%, ICU 17.0%, CCU 18.7%; intensive-treatment proportion: NICU 50.9%, ICU 74.1%, CCU 80.0%), and pediatric incidents were concentrated in NICU reports with lower observed severity metrics than ICU/CCU reports in this dataset (Fig. 2). When the analysis was restricted to ICU reports, the severe-outcome rate was similar between children and adults (34.8% vs 36.7%). However, the recorded-death proportion was lower in children (5.7% vs 12.8%), as was the proportion involving intensive treatment (60.1% vs 73.0%). Thus, even among incidents reported in the same ICU, children reached a severe outcome at a rate comparable to that of adults but were less often recorded as having died (Fig. 2). The distribution of harm grades was likewise skewed toward the milder end for NICU reports (Table S1).

Severe outcome by care setting and incident category

Severe-outcome rates by setting and incident category are shown in Fig. 3 and Table S2. Among children, the severe-outcome rate for drain/tube-related incidents was 17.5% in the NICU and 31.0% in the ICU, and for medication-related incidents 7.4% and 17.5%, respectively, whereas severe-outcome rates for treatment/procedure-related incidents were higher (NICU 46.6%, ICU 42.9%). Among adults (20–59), the ICU severe-outcome rate was 46.4% for treatment/procedure-related and 29.1% for drain/tube-related incidents (Fig. 3 and Table S2).

Sequential and fully adjusted analysis in the whole cohort

Under the pre-specified sequential adjustment, the relative risk of a severe outcome for children/young patients (0–19 years) versus adults (20–59 years) was 0.71 (95% CI, 0.59–0.84) in the age-only model (M1), 0.93 (0.75–1.14) after adding care setting (M2), 1.06 (0.86–1.30) after adding incident category (M3), and 1.07 (0.87–1.30) in the fully adjusted model (M4) (Fig. 4A).

In the fully adjusted model, the adjusted RR was 1.07 (95% CI, 0.87–1.30) for age 0–19, 1.03 (95% CI, 0.90–1.17) for 60–79, and 1.03 (95% CI, 0.89–1.20) for ≥ 80, none of which showed an independent association relative to adults (20–59) (Table 2). NICU setting was associated with a lower relative risk of a severe outcome (RR, 0.73; 95% CI, 0.57–0.92), as were drain/tube-related (RR, 0.72; 95% CI, 0.61–0.85) and medication-related (RR, 0.54; 95% CI, 0.42–0.71) incidents. In contrast, a physician as the first involved staff member (RR, 1.65; 95% CI, 1.41–1.93), an outpatient/emergency-routed patient category (RR, 1.76; 95% CI, 1.16–2.65), and ≥ 3 on-call/night shifts in the previous week (RR, 1.25; 95% CI, 1.01–1.55) were associated with a higher relative risk. A verification/observation lapse was associated with a lower relative risk (RR, 0.74; 95% CI, 0.66–0.83) (Table 2).

Table 2
Fully adjusted modified Poisson model for severe outcome in the whole intensive-care cohort.

Variable group	Covariate	RR	95% CI	p
Age group	Children/young patients, 0–19 years	1.07	0.87–1.30	0.528
	Older adults, 60–79 years	1.03	0.90–1.17	0.678
	Very old adults, ≥ 80 years	1.03	0.89–1.20	0.688
Care setting	NICU setting	0.73	0.57–0.92	0.009
	ICU setting	1.42	0.74–2.73	0.291
	CCU setting	1.51	0.79–2.86	0.209
Incident category	Drain/tube-related incident	0.72	0.61–0.85	< 0.001
	Medical-device-related incident	0.87	0.68–1.12	0.289
	Treatment/procedure-related incident	0.93	0.83–1.04	0.208
	Medication-related incident	0.54	0.42–0.71	< 0.001
Timing	Night/off-hours occurrence	1.02	0.93–1.12	0.601
	Weekend/holiday occurrence	1.01	0.91–1.14	0.803
Staff characteristics	Physician as first involved staff member	1.65	1.41–1.93	< 0.001
	Other staff as first involved staff member	1.34	0.95–1.90	0.097
	Years of experience of first involved staff member	1.01	1.01–1.02	< 0.001
Work schedule	1–2 on-call/night shifts in previous week	0.96	0.86–1.07	0.463

Modified Poisson regression with robust standard errors was used to estimate relative risks. Reference categories were adults aged 20–59 years, nurse as the first involved staff member, no on-call/night shifts in the previous week, male sex, and absence of each contributing factor, unless otherwise specified. RR indicates relative risk; CI, confidence interval.

Variable group	Covariate	RR	95% CI	p
	≥ 3 on-call/night shifts in previous week	1.25	1.01–1.55	0.036
	Missing on-call/night-shift data	0.70	0.61–0.80	< 0.001
Patient characteristics	Female sex	0.97	0.88–1.06	0.500
	Outpatient/emergency-routed patient	1.76	1.16–2.65	0.007
	Predisposing patient condition present	1.09	0.97–1.24	0.158
Contributing factors	Verification/observation lapse	0.74	0.66–0.83	< 0.001
	Coordination failure	1.09	0.95–1.25	0.220
	Skill/technique immaturity	0.99	0.87–1.12	0.843
	High workload	0.91	0.74–1.12	0.360
Event characteristics	Number of involved staff members	1.01	0.97–1.04	0.762

Modified Poisson regression with robust standard errors was used to estimate relative risks. Reference categories were adults aged 20–59 years, nurse as the first involved staff member, no on-call/night shifts in the previous week, male sex, and absence of each contributing factor, unless otherwise specified. RR indicates relative risk; CI, confidence interval.

In a supplementary analysis, reports with a physician as the first involved staff member had a higher severe-outcome rate than those with a nurse in every incident category (Table S3). The physician-versus-nurse relative risk attenuated from 2.30 (2.01–2.63) in the crude analysis to 2.14 (1.87–2.45) after adjustment for setting and age, 1.81 (1.56–2.10) after adding incident category, and 1.65 (1.41–1.93) in the fully adjusted model, but remained above 1 (Table S4). The occupation-by-incident-category interaction was not significant (multi-degree-of-freedom Wald test: df = 8, $\chi^2 = 10.74$, $p = 0.217$); the elevated relative risk associated with physician involvement was therefore not explained by incident-category composition alone and was broadly consistent across categories (Table S5). None of the three pre-specified interactions with age group was supported: medication-related incident (df = 3, $\chi^2 = 2.89$, $p = 0.410$), unplanned extubation (df = 4, $\chi^2 = 2.90$, $p = 0.575$), and night/off-hours occurrence (df = 3, $\chi^2 = 2.42$, $p = 0.490$) (Table S5).

NICU-excluded ICU/CCU subcohort

In the ICU/CCU subcohort excluding the NICU, the relative risk of a severe outcome for PICU-equivalent pediatric ICU/CCU reports versus adults aged 20–59 years was 0.93 (95% CI, 0.76–1.15) in the crude analysis and 1.08 (95% CI, 0.87–1.33) in the fully adjusted model (Fig. 4B; Table 3). In this subcohort, medication-related incidents were associated with a lower relative risk of severe outcome (RR, 0.54; 95% CI, 0.35–0.84), whereas a physician as the first involved staff member was associated with a higher relative risk (RR, 1.53; 95% CI, 1.16–2.03). A verification/observation lapse was again associated with a lower relative risk (RR, 0.68; 95% CI, 0.53–0.87). After excluding NICU reports, PICU-equivalent pediatric ICU/CCU reports no longer showed a clearly lower risk of severe outcome than adult ICU/CCU reports.

Table 3

Fully adjusted modified Poisson model for severe outcome in the NICU-excluded ICU/CCU subcohort.

Variable group	Covariate	RR	95% CI	p
Pediatric group	PICU-equivalent children	1.08	0.87–1.33	0.487
Care setting	CCU setting	1.15	0.82–1.60	0.417
Incident category	Drain/tube-related incident	0.83	0.62–1.12	0.232
	Medical-device-related incident	0.89	0.58–1.38	0.603
	Treatment/procedure-related incident	0.82	0.65–1.05	0.112
	Medication-related incident	0.54	0.35–0.84	0.006
Timing	Night/off-hours occurrence	1.00	0.83–1.20	0.974
	Weekend/holiday occurrence	0.86	0.68–1.09	0.227
Staff characteristics	Physician as first involved staff member	1.53	1.16–2.03	0.003
	Other staff as first involved staff member	0.77	0.36–1.67	0.514
	Years of experience of first involved staff member	1.02	1.00–1.03	0.006
Work schedule	1–2 on-call/night shifts in previous week	0.95	0.75–1.18	0.625
	≥ 3 on-call/night shifts in previous week	1.17	0.79–1.74	0.442
	Missing on-call/night-shift data	0.70	0.53–0.92	0.010
Patient characteristics	Female sex	0.88	0.73–1.07	0.203
	Predisposing patient condition present	1.25	0.96–1.63	0.094

The NICU-excluded ICU/CCU subcohort was used as a strict PICU-equivalent proxy for pediatric reports. The reference group for the pediatric-group variable was adult ICU/CCU reports from patients aged 20–59 years. RR indicates relative risk; CI, confidence interval.

Variable group	Covariate	RR	95% CI	p
Contributing factors	Verification/observation lapse	0.68	0.53–0.87	0.002
	Coordination failure	0.99	0.77–1.25	0.905
	Skill/technique immaturity	1.20	0.92–1.56	0.187
	High workload	1.15	0.78–1.70	0.484
Event characteristics	Number of involved staff members	1.06	1.00–1.11	0.049

The NICU-excluded ICU/CCU subcohort was used as a strict PICU-equivalent proxy for pediatric reports. The reference group for the pediatric-group variable was adult ICU/CCU reports from patients aged 20–59 years. RR indicates relative risk; CI, confidence interval.

Exploratory comparisons of selected contributing factors across pediatric, PICU-equivalent, and adult report groups did not show a consistent pattern and are shown in Figure S1.

Exploratory review of pediatric death-associated reports

Thirty-three pediatric reports recorded death as the harm grade; all were in the 0–9-year stratum, with none in the 10–19-year stratum (Table S6). These reports were distributed across the NICU (18) and non-NICU pediatric ICU/CCU (15) settings, with treatment/procedure-related incidents most common by category (Table 4; Table S7). In an exploratory structured case-level review using a four-tier attribution scheme based on structured fields and narrative descriptions, 8 reports were classified as Definite or Probable, whereas 25 were classified as Indeterminate or Non-definite (Table 4). Reports classified as Definite or Probable documented apparent safety-process problems, including medication concentration/dose errors, device disconnection, catheter-tip malposition, extracorporeal membrane oxygenation (ECMO) circuit malfunction, and delayed electrolyte recognition and management, whereas reports with no definite incident contribution predominantly involved severe underlying disease, perinatal emergencies, severe birth asphyxia, postoperative circulatory failure after complex congenital heart surgery, severe infection, or unpredictable acute deterioration (Table S7).

Table 4
Pediatric reports with death recorded as the harm grade by care setting, incident category, and incident-attribution category.

Setting	**NICU**		**ICU/CCU**		**Total**
Incident attribution*	Definite and Probable	Indeterminate and Non-definite	Definite and Probable	Indeterminate and Non-definite	
Treatment/procedure	2	7	0	6	15
Medication	0	0	1	3	4
Medical devices	1	0	1	0	2
Drain/tube	1	1	0	0	2
Other	1	5	1	3	10
Total	5	13	3	12	33

*Incident attribution

Definite: a medical-process deviation is documented (e.g., medication dose/concentration error, contraindicated drug, circuit disconnection, or clear device malfunction) with a strong temporal and pathophysiological link to death (Incident-attributable death report).

Probable: a process vulnerability is documented, with a plausible contribution to death, although disease severity is also substantial.

Indeterminate: a safety concern is present, but the contribution to death cannot be judged from the free text alone (Indeterminate).

Non-definite: severe underlying disease, perinatal emergency, unavoidable complication, or an unpredictable acute deterioration predominates, with no documented clear process deviation (Non-definite incident attribution).

Values are counts of pediatric reports with death recorded as the harm grade. Incident attribution was classified using an exploratory four-tier scheme based on structured fields and narrative descriptions. This classification was intended to describe the apparent contribution of a safety-process problem and should not be interpreted as preventability or as proof that the incident caused death.

Discussion

This study has three principal findings. First, pediatric intensive-care incidents formed a distinct profile that differed both in where incidents occurred and in what they were: they were concentrated in NICU-based care and in drain/tube-related, medication-related, and bedside care processes, whereas adult incidents were mainly ICU/CCU-based and treatment/procedure-related. Second, although pediatric incidents appeared less likely to be severe in the crude analysis, this was not a protective association with young age: once care setting, incident type, and care processes were held constant, the age difference disappeared (crude RR 0.71, 95% CI 0.59–0.84; adjusted RR 1.07, 95% CI 0.87–1.30), and

whether an incident became severe was more strongly related to the care setting, incident type, treatment intensity, and markers of clinical complexity captured in the report than to age itself. Third, after excluding NICU reports, critically ill, PICU-equivalent children no longer showed a clearly lower severe-outcome risk than adults.

Comparison with previous work and interpretation

Prior patient-safety research has emphasized the vulnerability of children to medication errors, device-related incidents, and unplanned airway or tube events. In a US prospective study, the rate of potential adverse drug events among pediatric inpatients was three times that of a comparable adult population, with the highest rate among neonates in the NICU, whereas the rates of medication errors and of preventable adverse drug events were similar to adult rates [1]. A national Korean incident-reporting registry likewise reported higher odds of medication-related incidents among children and young adults than among middle-aged adults in intensive-care settings (odds ratio 2.06) [2]. The higher proportion of medication- and drain/tube-related events among pediatric reports in our data is consistent with the Korean registry findings on incident composition. Our analysis addressed a different question: it separated the frequency and composition of reported incidents from the severity of an incident once it has been reported. After accounting for care setting and incident category, chronological age was not independently associated with a severe outcome. The principal interpretation is that the lower crude severity among pediatric reports reflected the structure of reported incidents, particularly the concentration of pediatric reports in NICU reports with lower observed severity metrics, rather than a protective association with young age. Tube- and device-related events, including unplanned extubation, were observed among the small number of death-associated reports with a relatively clear incident contribution, consistent with recognized setting-specific safety concerns in NICU-type and ICU-type reports [3–5].

The finding that the low crude severity in pediatric reports reflects case-mix (the concentration of reports in NICU reports with lower observed severity metrics) rather than a protective association with young age is supported by several complementary analyses. A complementary treatment-intensity metric, namely the proportion of incidents involving intensive treatment, showed that NICU reports had lower observed treatment intensity and severity metrics than ICU/CCU reports, and that pediatric reports were concentrated in this setting. A lower observed severity among NICU reports does not imply that neonatal intensive care is a low-risk environment: neonates remain at high risk of adverse events, and a multicenter cluster-randomized trial reduced the adverse-event rate in neonatal intensive care units from 33.9 to 22.6 per 1000 patient-days [10]. The distribution of harm grades likewise showed a benign skew for NICU reports, with fewer deaths and high-disability outcomes and more no-harm events. Within the ICU, the severe-outcome rate was similar for children and adults. The recorded-death proportion within the ICU was lower in children, but this likely reflects residual differences in treatment intensity and case-mix (the lower intensive-treatment proportion in children). After excluding NICU reports, PICU-equivalent pediatric ICU/CCU reports no longer showed a clearly lower severe-outcome risk than adult ICU/CCU reports.

The pattern of covariate associations likewise indicated that severity related more closely to clinical context than to chronological age. Several covariates associated with higher severity, including a physician as the first involved staff member, an outpatient/emergency-routed patient category, and a heavier recent on-call burden, are more plausibly interpreted as markers of unmeasured clinical acuity, procedural invasiveness, emergency response, and workflow complexity than as direct causal effects of staff category or work schedule [11].

The exploratory review of pediatric death-associated reports further illustrates that pediatric incidents should not be interpreted as a single homogeneous group. Among the 33 pediatric reports with death recorded as the harm grade, a minority (8 reports) had a relatively clear or suggested incident contribution, whereas most (25 reports) occurred in critically ill children with severe underlying disease, perinatal emergencies, or unpredictable acute deterioration. Therefore, the reported death count should not be equated with incident-attributable deaths. This exploratory classification suggests that the number of deaths directly attributable to a discrete safety incident is likely smaller than the number of death-associated reports, although independent adjudication is required [12, 13]. Judgements of this kind are themselves reviewer-dependent: in a structured implicit review of hospital deaths, agreement between two reviewers was modest, and the proportion of deaths judged preventable decreased from 6.0% to 0.5% once short-term prognosis and between-reviewer variability were taken into account [14]. Importantly, the nature of reports with a relatively clear incident contribution differed by setting: catheter, tube, and device management predominated in NICU-type reports, whereas medication dilution or dosing errors, electrolyte management, and ECMO/continuous renal replacement therapy (CRRT)-related device events predominated in ICU/CCU-type reports. These setting-specific patterns suggest that pediatric intensive-care safety challenges are heterogeneous, and that safety designs may need to be tailored to the care setting and clinical context rather than adapted from adult ICU programs.

Clinical implications

These findings have several implications for intensive-care safety. Safety efforts should not be decided by the broad pediatric-versus-adult label alone; priorities should instead be set by the combination of care setting, incident type, invasive-device exposure, workflow complexity, and the clinical context and treatment intensity captured in the report, rather than by age alone. Neonatal and pediatric intensive-care safety measures should not be designed simply as scaled-down versions of adult ICU programs; they require specific attention to medication compounding and dosing, tube and device fixation, bedside observation, nursing workload, and escalation pathways for early deterioration. At the same time, the low crude severity in NICU-predominant pediatric reports should not be used to underestimate risk in critically ill children: the NICU-excluded analysis suggests that severe incident outcomes in children cared for in the ICU/CCU may be comparable to those in adults. High-reliability interventions should therefore be prioritized for clinically unstable children under invasive management, regardless of chronological age.

The priorities may differ by setting. In NICU-type reports, the most actionable targets include line and tube securement, catheter-tip confirmation, medication dilution and compounding, bedside observation,

and escalation pathways for subtle deterioration. In pediatric ICU/CCU-type reports, priorities include postoperative circulatory management, ECMO/CRRT circuit safety, emergency medication preparation, electrolyte monitoring, and structured communication during acute deterioration. These setting-specific priorities may be more useful for clinicians than a broad pediatric-versus-adult classification.

Strengths

This study has several strengths. It used a nationwide safety-incident database spanning more than a decade; it focused on the intensive-care setting, where adverse events are clinically important and age comparisons are particularly susceptible to case-mix differences; it applied a pre-specified sequential adjustment strategy to examine how the age estimate changed after accounting for setting and incident category; and it provided a clinically grounded, NICU-excluded sensitivity analysis separating NICU-predominant reports, which had lower observed severity metrics, from reports occurring in more directly comparable ICU/CCU settings.

Limitations

This study has several limitations. First, the data are spontaneously reported and reflect reporting behavior rather than true incidence; under-reporting and variation in reporting culture may bias the observed associations, and only a fraction of clinical errors is captured [6, 15]; incident reporting is therefore better regarded as a mechanism for learning than as a measure of incidence [16]. This bias is unlikely to be symmetric across age groups: more complete reporting of low-harm events in neonatal and pediatric units would bias the crude pediatric relative risk downward, whereas preferential reporting of severe pediatric events would bias it upward. Because the database provides no denominator of admissions or device-days, the magnitude of this bias cannot be quantified, and the adjusted estimate should be interpreted as conditional on the population of reported incidents rather than as a patient-level risk ratio. Reporting practice also changed during the study period: in Japanese acute care hospitals, the proportion systematically reviewing all inpatient deaths rose from 25.0% in 2015 to 70.5% in 2023, so the increase in annual report counts over time may partly reflect improved detection rather than a change in event occurrence [17]. Second, the database lacks patient denominators, baseline severity scores, device-exposure time, and unit-level admission data, precluding estimation of patient-level incidence or true risk. Third, severity was operationalized from recorded harm and treatment grades rather than a directly recorded patient-impact severity level. Fourth, a dedicated PICU identifier was unavailable, so the PICU-equivalent definition (NICU-excluded ICU/CCU report) is subject to misclassification, and this small subcohort was underpowered. Fifth, the four-tier attribution of death-associated reports was assigned by one physician and verified by a second rather than by independent, blinded duplicate rating, so no inter-rater agreement statistic is available and the classification remains provisional; formal blinded double adjudication would be required before confirmatory use. It is also a descriptive case review without a denominator; incident attribution should not be equated with preventability. Finally, residual and unmeasured confounding may persist, and the cross-sectional design supports descriptive association rather than causal inference.

Conclusions

This nationwide analysis supports three conclusions. First, pediatric intensive-care incidents have a distinct profile (NICU-based care, drain/tube- and medication-related events, and bedside workflow factors) that differs both from adults and between NICU-type and ICU/CCU-type settings; pediatric safety therefore requires purpose-built design rather than a scaled-down adult ICU program. Second, severe outcomes were more closely associated with care setting, procedural invasiveness, treatment intensity, markers of clinical complexity, and incident type than with age itself; the apparent low severity in children reflects case-mix, so safety resources should be allocated by severity and care setting rather than by an age label. Third, in critically ill, PICU-equivalent children with the NICU excluded, severity risk may be comparable to that in adults, so adult-level high-reliability safeguards should extend to critically ill children. In practice, pediatric intensive-care safety should be targeted by where care is delivered, the clinical context and treatment intensity captured in the report, and what type of incident is involved. Concrete priorities include weight-based medication dilution and preparation, tube and device fixation with tip-position checks, nursing workload, and early recognition of deterioration with prompt escalation, designed specifically for children.

Abbreviations

CCU, Cardiac care unit

CI, Confidence interval

CRRT, Continuous renal replacement therapy

ECMO, Extracorporeal membrane oxygenation

ICU, Intensive care unit

JCQHC, Japan Council for Quality Health Care

NICU, Neonatal intensive care unit

PICU, Pediatric intensive care unit

PISL, Patient Impact Severity Level

RR, Relative risk

Declarations

Ethics approval and consent to participate

This study analyzed anonymized, publicly released secondary data from the Japan Council for Quality Health Care. The dataset contains no personally identifiable information, and no data were newly collected from individuals. Under the Ethical Guidelines for Medical and Biological Research Involving Human Subjects, issued jointly by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry of Japan, research that uses only anonymized information that has already been made publicly available does not require review by an institutional research ethics committee or informed consent from individual participants. Ethics approval and consent to participate were therefore not required for this study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets analyzed during the current study are publicly available from the Japan Council for Quality Health Care, Project to Collect Medical Near-Miss/Adverse Event Information, at https://www.med-safe.jp/. The data were accessed and used in accordance with the terms of use of the project. The analysis code is available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

KH conceived and designed the study, curated the data, classified the death-associated reports, and drafted the manuscript. HT contributed to the study design, reviewed and verified the classification of the death-associated reports, and contributed to the interpretation of the data. YK performed the statistical analysis, provided methodological and statistical supervision, and contributed to the design of the analysis and to the interpretation of the data. KS contributed to writing – review & editing, supervision and interpretation/clinical framing. TW contributed to the interpretation of the results and to the clinical framing of the findings. All authors critically revised the manuscript for important intellectual content, and all authors read and approved the final manuscript.

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Figures

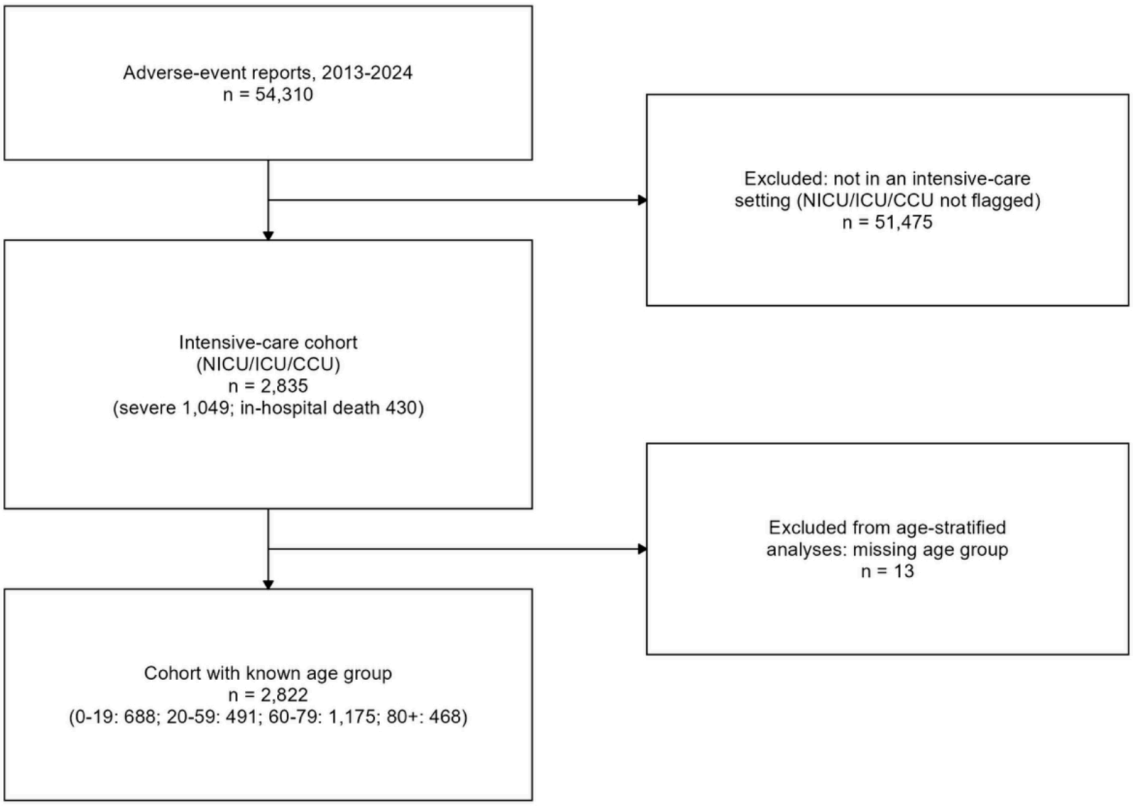


Figure 1

Derivation of the intensive-care study cohort.

The intensive-care cohort comprised reports flagged as occurring in a NICU, ICU, or CCU. Age-stratified analyses excluded reports with missing age group. Severe-outcome and death counts shown in the intensive-care cohort box refer to the full NICU/ICU/CCU cohort before exclusion of reports with missing age group.

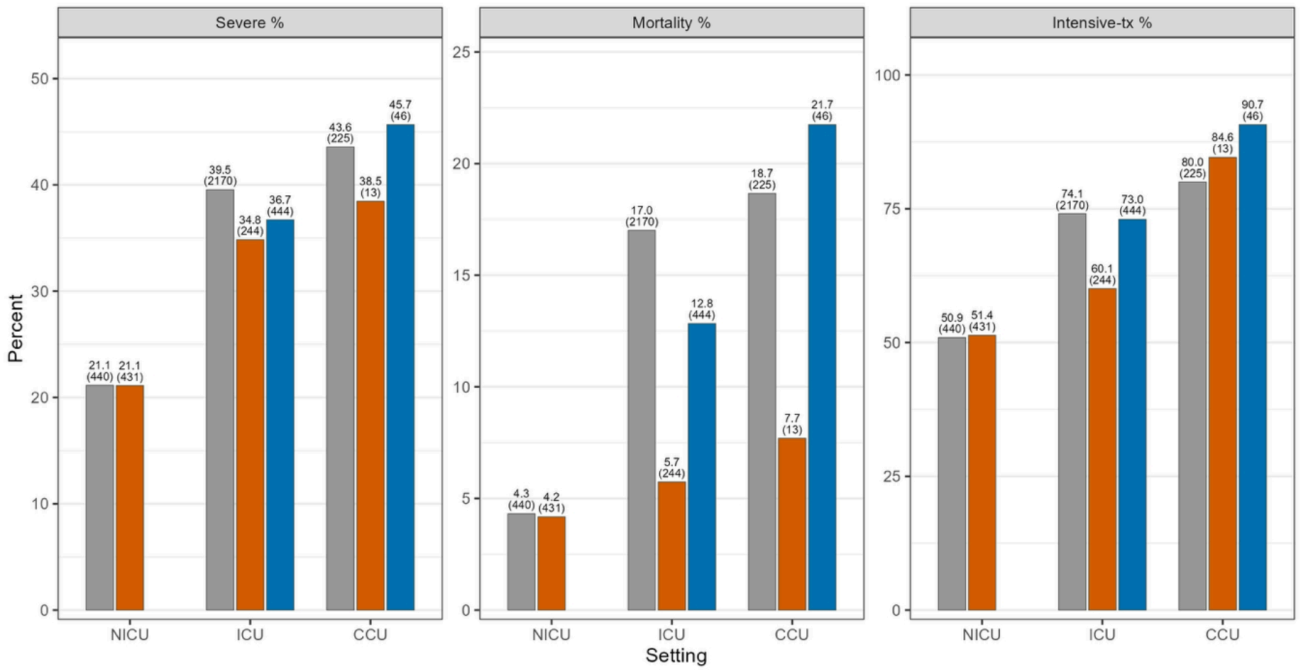


Figure 2

Observed severity and treatment-intensity metrics by care setting and age group.

Bars show the severe-outcome rate, the recorded-death proportion, and intensive-treatment proportion by care setting and age group. Children were defined as 0–19 years and adults as 20–59 years. The intensive-treatment proportion was used as a complementary treatment-intensity metric, not as an independent severity measure. NICU reports showed lower observed severity metrics than ICU/CCU reports in this dataset.

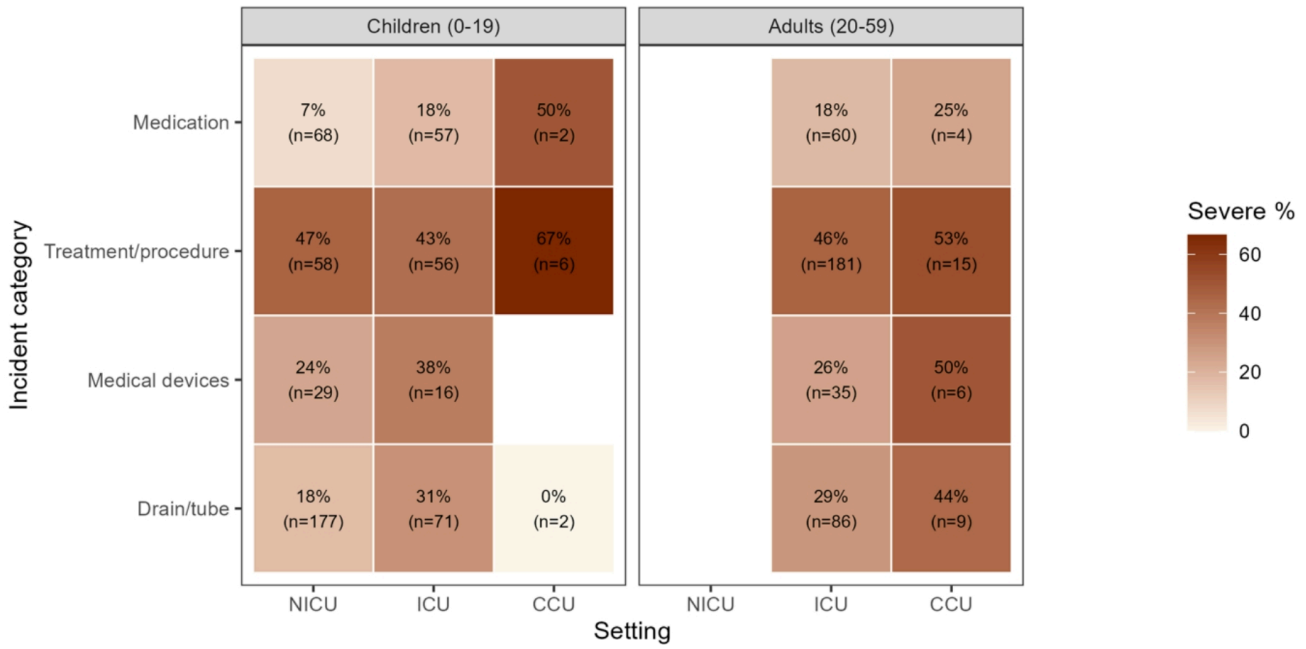


Figure 3

Severe-outcome rate by care setting and incident category in children and adults.

Heatmap cells show the observed severe-outcome rate, with the number of reports in each cell. Children were defined as 0–19 years and adults as 20–59 years. Sparse cells, particularly pediatric CCU cells, should be interpreted cautiously.

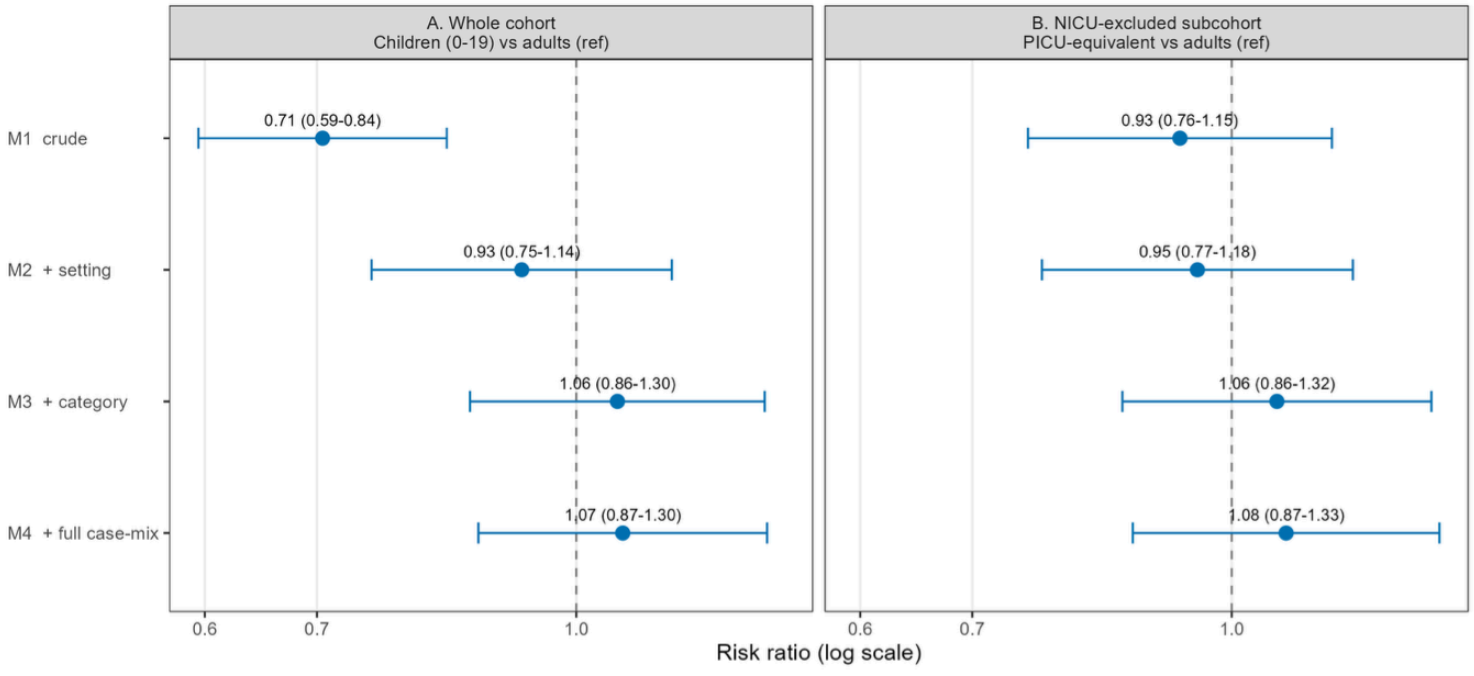


Figure 4

Sequential adjustment of pediatric-versus-adult relative risks for severe outcome.

Panel A shows the relative risk for children/young patients aged 0–19 years versus adults aged 20–59 years in the whole intensive-care cohort. Panel B shows the relative risk for PICU-equivalent pediatric ICU/CCU reports versus adult ICU/CCU reports after excluding NICU reports. M1 included age group only; M2 additionally adjusted for care setting; M3 additionally adjusted for incident category; and M4 was the fully adjusted model. Points indicate relative risks and horizontal bars indicate 95% confidence intervals. The vertical dashed line indicates RR = 1.

Supplementary Files

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