## ORIGINAL ARTICLE

# Medical records as screening tools for child death review in Japan

<sup>1</sup>Department of Emergency and Intensive Care Medicine, Nagoya University Hospital, Nagoya, Japan

<sup>2</sup>Department of Pediatrics, Graduate School of Medicine, Nagoya University, Nagoya, Japan

<sup>3</sup>Department of Legal Medicine and Bioethics, Graduate School of Medicine, Nagoya University, Nagoya, Japan

<sup>4</sup>Department of Developmental Disability Medicine, Graduate School of Medicine, Nagoya University, Nagoya, Japan

<sup>5</sup>Department of Pediatrics and Neonatology, Graduate School of Medical Science, Nagoya City University, Nagoya, Japan

<sup>6</sup>Department of Forensic Medicine, Graduate School of Medical Science, Nagoya City University, Nagoya, Japan

<sup>7</sup>Department of Pediatrics, Graduate School of Medicine, Fujita Medical University, Toyoake, Japan

<sup>8</sup>Department of Legal Medicine, Graduate School of Medicine, Fujita Medical University, Toyoake, Japan

<sup>9</sup>Department of Pediatrics, Graduate School of Medicine, Aichi Medical University, Nagakute, Japan

<sup>10</sup>Department of Legal Medicine, School of Medicine, Aichi Medical University, Nagakute, Japan

#### Correspondence

Atsushi Numaguchi, Department of Emergency and Medical Intensive Care Medicine, Nagoya University Hospital, 65 Tsurumai-Cho, Showa-Ku, Nagoya City, Aichi Prefecture 466-8550, Japan. Email: nummer@med.nagoya-u.ac.jp

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#### **Abstract**

**Background:** Although many child death review (CDR) systems have been developed in Japan, the optimal system is still being identified. The aim of this study is to identify the etiologies of child deaths and to propose a screening method for initiating the CDR process in Japan.

**Methods:** Clinical medical records (CMRs) in hospitals and autopsy records were surveyed for cases of deaths of children aged less than 15 years between 2014 and 2016 in Aichi Prefecture, Japan. The data were analyzed in three steps, and the findings were compared with the vital statistics.

**Results:** Of the 695 children whose death certificates were submitted to Aichi Prefecture, 590 could be traced to pediatric care hospitals. The distribution of causes of death was slightly different from the vital statistics, with 11.5% dying of extrinsic causes and 19.7% dying of unknown causes. Maltreatment was suspected in 64 cases, which was much higher than that in government statistics. Overall, 158 (26.8%) deaths were considered preventable. The number of unnatural deaths, which might be screened in, was calculated as 172 (29.2%) in the vital statistics, whereas the survey of CMRs revealed that 241 (40.8%) to 282 (47.8%) should be screened in.

**Conclusions:** Surveying CMRs in hospitals may be a suitable method to detect and screen deaths to start the CDR process in Japan.

#### KEYWORDS

autopsy, causes of death, child death review, clinical medical records, death certificate

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## INTRODUCTION

Child deaths have been decreasing, especially in developed countries. In Japan, children (under 15 years old) account for 12.6% of the total population, and approximately 4500 children die annually, accounting for about 0.3% of all deaths. Although the number of child deaths is small, the impact of each death is substantial, and clarification of the facts surrounding each death, including the use of the findings to prevent child deaths in the future, is of great significance for the bereaved family.

Child death review (CDR) systems operate in several countries, including the UK and the USA. They aim to "sufficiently discuss each case of the unfortunate death of a child as a minimum courtesy for the child who died as well as one of the greatest forms of grief care for the bereaved family." Information on child deaths is shared among multiple institutions, and a multi-institutional review of these data is conducted to obtain specific measures to avoid preventable deaths. The World Health Organization (WHO) also emphasized the importance of CDR systems and issued guidance for developing such systems. The targets of CDR are often selected by methods such as extraction of deaths attributable to external causes, including those caused by abuse; however, many deaths caused by intrinsic causes have preventable factors. As such, all child deaths are evaluated by CDR in the UK. Irrespective of whether the CDR system evaluates cases identified by specific criteria or assesses all the cases, processes to analyze all child deaths are an essential part of this system. Although vital statistics include all deaths and reveal important aspects of the epidemiology of deaths, these statistics are only released after a certain interval. Moreover, the detailed status of some deaths may be unknown<sup>9</sup> in evaluations based on death certificates, which are the source of vital statistics. In Japan, vital statistics are currently the only source for investigating child deaths. Thus, a system that can provide a bird's-eye view of child deaths with minimal selection bias while investigating the causes in detail from a professional point of view is essential.

The Japan Pediatric Society conducted retrospective observational studies using the medical records of approximately 20% of child deaths, including preventable deaths of intrinsic causes, which are common in Japan. The studies<sup>10</sup> reported several important findings, such as the finding that 25% of all deaths were preventable, and that the system for investigating the causes of death could be insufficient. Cases involving maltreatment, including abuse and neglect, were also potentially greater than those reported in the statistics. 11 Most child deaths occur in hospitals and are diagnosed by clinicians (mainly pediatricians) based on various medical examinations performed during treatment. A thorough investigation of this process may facilitate retrospective assessments of the various causes of death. On the other hand, although physicians are responsible for diagnosing death medically, for deaths that occur outside the hospital, medical examinations are limited, and physicians are not involved in such death-scene investigations at all. In cases where unnatural death is suspected, the police are notified to take over subsequent criminal investigations.

The Japanese medical examiner system is very limited locally and qualitatively compared to the coroner/ medical-examiner system in the UK and the USA.<sup>12</sup> Forensic doctors, who are limited in number, undertake forensic autopsies on behalf of the law-enforcement agencies and compare the findings obtained with the information acquired during the death-scene investigation, which contributes to the investigation of the cause of death. However, this only applies to cases for which an autopsy is deemed essential for criminal investigation by police officers. Moreover, the autopsy results are treated as investigation information and not shared outside the police. For these reasons, forensic doctors do not currently have a legal basis for actively providing their findings to CDR systems. Despite investigating the causes of death, the current systems do not include any effective mechanism to analyze and verify the analysis of events surrounding death and propose preventive measures. Several forms of death, such as deaths caused by confirmed abuse, bullying-related suicides, or school accidents, are reviewed by multiple institutions. Still, there is no system covering all aspects of child deaths.

Similar to its role in other countries, a CDR system is expected to solve many of these problems in Japan and the establishment of such a system is already under way. Several issues remain to be addressed, including real-time identification of child deaths and appropriate processes for selecting the cases. However, at present there is no basis for tackling these issues.

Within this context, this study aimed to clarify the status of child deaths in Japan through a population-based survey and to use the data obtained to propose and verify the effectiveness of screening methodologies that would serve as the launchpad for the clinical medical record-based processes for pediatricians, particularly for the construction of the CDR system in Japan.

## **METHODS**

## Data collection and analysis

The deaths of the residents of Aichi Prefecture under 15 years of age between January 1, 2014 and December 31, 2016 were enrolled. Data were collected from three sources, and analyzed in three steps.

Step 1: Study of vital statistics. The death certificates and vital statistics were browsed in compliance with the procedures stipulated in the Statistics Act. Those whose death certificates were submitted outside Aichi Prefecture were excluded from Step 1 and after. As the preliminary analysis, the causes of death were reclassified into 10

categories from "1.Deliberate" through "10.Unexpected/ unexplained," according to the data obtained (Table 1). All the cases of unnatural deaths—deaths with an external cause (categories 1–3) or unknown cause (category 10)—were screened in as suitable for CDR, whereas the natural deaths (categories 4–9) were automatically screened out.

Step 2: Study of clinical medical records (CMRs) in the hospital. A questionnaire survey on the target cases was conducted at 301 hospitals in Aichi Prefecture that might handle the target cases. The survey sheet included age, sex, direct cause of death, situation at death, pre-existing disease, past history, and patient and family background. Those whose CMRs were not identified were excluded from Step 2 and after. Responses were handwritten by the director of the pediatric department or a board-certified pediatrician designated by the director of the respondent facilities. The respondents assessed three items as the initial analysis. The cause of death were classified in the same manner as in Step 1. The possibility of maltreatment (Supporting Information, Table S1) and its preventability (Supporting Information, Table S2) were also assessed. If any

of each item is positive (unnatural death, involvement of maltreatment, preventability, or any other concerns raised by respondents or investigators) the case was assigned to be screened in as suitable for the CDR, whereas the others were screened out.

Step 3: Study of autopsy records. The results of pathology autopsies were extracted from the annual database of the Japanese Society of Pathology. Autopsy records were also obtained from the four forensic centers. These data were carefully combined with the information obtained in Step 2. Reviewal analysis against these merged data was done separately by two members of the Japan Pediatric Society CDR Committee, who are considered experienced. They carefully reviewed each case and validated each analysis item in Step 2 to screen whether the case was "mandatory," "hopeful," or "not necessary" to be reviewed in the CDR, according to Table 2.

Descriptive statistics were presented with numbers and percentages, and a  $\chi^2$  test was performed using IBM SPSS Statistics software (ver. 29.0.1.0, IBM) if applicable.

**TABLE 1** Reclassification of the cause of death while focusing on preventive intervention (taken from reference 18, box 1).

Category	Name and description of the category					
1	Deliberate: Deliberately inflicted injury, abuse or neglect					
	This includes suffocation, shaking injury, knifing, shooting, poisoning, and other means of probable or definite homicide; deaths from war, terrorism or other mass violence, and severe neglect leading to death					
2	Suicide/self-harm: Suicide or deliberate self-inflicted harm					
	This includes hanging, shooting, self-poisoning with paracetamol; death by self-asphyxiation, solvent inhalation, alcohol or drug abuse, or other forms of self-harm. It will usually apply to adolescents rather than younger children					
3	Other extrinsic: Trauma and other external factors					
	This includes isolated head injury, other or multiple trauma, burn injuries, drowning, unintentional self-poisoning in preschool children, anaphylaxis and other extrinsic factors. <b>Excludes</b> deliberately inflicted injury (category 1).					
4	Malignancy:					
	Solid tumors, leukemias and lymphomas, and malignant proliferative conditions such as histiocytosis, even if the final event leading to death was infection, hemorrhage, etc.					
5	Acute conditions: Acute medical or surgical conditions					
	For example, Kawasaki disease, acute nephritis, intestinal volvulus, diabetic ketoacidosis, acute asthma, intussusception, appendicitis; sudden unexpected deaths with epilepsy					
6	Chronic conditions: Chronic medical condition					
	For example, Crohn's disease, liver disease, neurodegenerative disease, immune deficiencies, and cystic fibrosis, even if the final event leading to death was infection, hemorrhage, etc. Includes cerebral palsy with a clear post-perinatal cause					
7	Chromosomal/congenital: Chromosomal, genetic, and congenital anomalies					
	Trisomies, other chromosomal disorders, single-gene defects, and other congenital anomalies, including cardiac anomalies.					
8	Perinatal: Perinatal or neonatal event					
	Death ultimately related to perinatal events, such as sequelae of prematurity, antepartum and intrapartum anoxia, bronchopulmonary dysplasia, and posthemorrhagic hydrocephalus, irrespective of age at death. It includes cerebral palsy without evidence of cause and includes congenital or early-onset bacterial infection (onset in the first postnatal week)					
9	Infection:					
	Any primary infection (i.e., not a complication of one of the above categories), arising after the first postnatal week or after discharge of a preterm baby. This would include septicemia, pneumonia, meningitis, HIV infection, etc.					
10	Unexpected/unexplained: Sudden unexpected, unexplained death					
	Where the pathological diagnosis is either sudden infant death syndrome or unascertained, at any age. Excludes sudden unexpected death in epilepsy (category 5)					

**TABLE 2** Screening of cases to be reviewed.

	Step 1	Step 2	Step 3
Person in charge	Central investigator	Respondents in the institutes (Board-certified pediatrician) (mainly)	Two external reviewers (Members of the CDR committee, Japan Pediatric
		Central investigator (if any empty field)	Society)
Source	Governmental Statistics	Clinical Medical Records	All information collected, including the results of autopsies
Criteria			
Screen-In			
Mandatory	Unnatural death (death from external cause or death from unknown cause)	Satisfy any of the four criteria below:  1. Cause of death: unnatural death (death of external cause or death of unknown cause)  2. Involvement of maltreatment: "suspicious" or "possible"  3. Preventability: Other than "low"	<ol> <li>Satisfy any of the criteria below:</li> <li>Any challenge or concern was seen in any information collected.</li> <li>The result of Step 2 may be inappropriate.</li> <li>Cases that should be reviewed multi-institutionally with priority.</li> </ol>
Hopeful		Any other concerns raised by respondents or investigators.	<ol> <li>Satisfy criteria 1–3 below:</li> <li>No problem was pointed out in the information collected.</li> <li>The results for Step 2 were almost appropriate.</li> <li>Some issues might be pointed out that should be reviewed multi-institutionally.</li> </ol>
Screen out	Natural death (death of internal cause)	Satisfy all of the four criteria below:  1. Cause of death: natural death (death of internal cause)  2. Involvement of maltreatment: "less possible" or "NOT possible"  3. Preventability: "Low"  4. No concerns raised by respondents and investigators.	<ol> <li>Satisfy all of the criteria below:</li> <li>No problem was pointed out in the information collected.</li> <li>The result of Step 2 is completely appropriate.</li> <li>No issues could be pointed out that should be reviewed multi-institutionally.</li> </ol>

Sensitivity and specificity were also calculated for the relevant items.

#### **Ethical considerations**

This study was conducted with the approval of the ethics review board of Nagoya University (approval numbers 2016-0037-5 and 2017-0163). Approval for data provision was also obtained from the respective ethics review boards of each facility. As this study only handled anonymous data, written informed consent from the bereaved family was not obtained. Instead, participants were guaranteed the opportunity to opt out.

## RESULTS

Figure 1 provides an outline of the cases evaluated in this study. According to government statistics, 718 Aichi residents under the age of 15 died during the target period, of whom 23 (box 1 in Figure 1) were excluded because their death certificates were submitted outside Aichi Prefecture and could not be reviewed. The remaining 695 cases were included in Step 1 of this study and examined.

Of these, 53 residents (7.6%, box 2 in Figure 1) who died outside Aichi Prefecture could not be identified because

the hospital was not identifiable. The remaining 642 cases (the total of boxes 3 and 4 in Figure 1) were targeted for Step 2, of which 590 cases (total of boxes 5–9 in Figure 1) could be verified and subjected to verification in Step 3. The remaining 52 (total of boxes 10–13) cases could not be included in Steps 2 and 3 because the respondents could not identify the cases or their medical files in the hospital. Table 3 shows the profiles of the 590 cases in which Steps 2 and 3 were performed, and compares them with the 105 cases (total of boxes 2 and 10–13 in Figure 1) that were targeted in Step 1 but were not included in Steps 2–3.

Overall, 57 pathological and 85 forensic autopsies were performed on Aichi residents under 15 years during the target period. All of these records were carefully combined with data from matching cases among the targets of Step 3.

#### Causes of death

The results of the preliminary analysis of the 590 cases included in Steps 2 and 3 were not significantly different from those for the 105 cases included only in Step 1. The reclassification for Steps 1 through 3 are compared for the cases incorporated after Step 2 (Table 4).

The reclassification under "1. Deliberate" including abuse and neglect increased significantly up to reviewal analysis. In particular, in the three age groups of

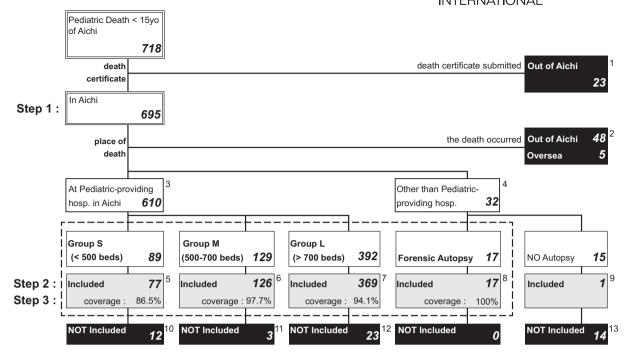


FIGURE 1 Case evaluation protocol.

**TABLE 3** Profiles of the cases included in the three steps.

	Step 1 only	Steps 2 and 3	
Total number	105	590	
Males (%)	46 (43.8)	328 (55.6)	$p = 0.025 * \chi^2 \text{ test}$
Age (%)			
<1 month	25 (23.8)	150 (25.4)	n.s.
1–11 month	24 (22.9)	189 (32.0)	n.s.
1–4 year	21 (20.0)	118 (20.0)	n.s.
5–9 year	19 (18.1)	62 (10.5)	n.s.
≥10 year	16 (15.2)	71 (12.0)	n.s.
Cause of death (%)			
Natural (intrinsic causes)	78 (74.3)	403 (68.3)	n.s.
Place of death (%)			
Pediatric-providing hospital	38 (36.2)	572 (96.9)	$p < 0.001 * \chi^2 \text{ test}$

newborns (<1 months), infants (1–11 months), and young children (1–4 years), there were many changes from the examples of "3. Other extrinsic factors" and "10. Unexpected/unexplained" in the preliminary analysis. On the other hand, the number of cases classified under "3. Other extrinsic factors" decreased significantly, mainly due to the change in "10. Unexpected/unexplained." As a result, the agreement between the preliminary and reviewal analyses results was 64.7% (382 of 590 cases).

In the pathological autopsies, "7. Chromosomal/congenital" and "8. Perinatal" cases were common, and in the forensic autopsies, "10. Unexpected/unexplained" including sudden infantile death syndrome and "1. Deliberate" were common.

### **Involvement of maltreatment**

The results of initial analysis and reviewal analysis regarding the possibility of maltreatment were compared in Table 5. In the initial analysis, maltreatment was involved in 11 "definite" cases (1.9%), eight "suspicious" cases (1.4%), and 24 "possible" cases (4.1%). In contrast, in the reviewal analysis, maltreatment was involved in 17 "definite" cases (2.9%), 10 "suspicious" cases (1.7%), and 37 "possible" cases (6.3%). Thus, the involvement of maltreatment equal to or more than possible was significantly greater in Step 3 than in Step 2 (p<0.05,  $\chi^2$  test). When adding up the cases with possible or greater involvement of maltreatment and comparing them by

**TABLE 4** Comparison of causes of death in preliminary, initial, and reviewal analyses.

	Preliminary analysis (Step 1)	Initial analysis (Step 2)	Reviewal analysis (Step 3)
Death of external causes (%)			
1. Deliberate	5 (0.8)	9 (1.5)	20 (3.4)
2. Suicide/self-harm	11 (1.9)	6 (1.0)	10 (1.7)
3. Other extrinsic	51 (8.6)	43 (7.3)	38 (6.4)
Death of internal causes (%)			
4. Malignancy	62 (10.5)	63 (10.7)	61 (10.3)
5. Acute conditions	44 (7.5)	30 (5.1)	29 (4.9)
6. Chronic conditions	25 (4.2)	12 (2.0)	24 (4.1)
7. Chromosomal/congenital	150 (25.4)	172 (29.2)	184 (31.2)
8. Perinatal	94 (15.9)	90 (15.3)	88 (14.9)
9. Infection	43 (7.3)	35 (5.9)	20 (3.4)
Death of unknown causes (%)			
10. Unexpected/unexplained	105 (17.8)	130 (22.0)	116 (19.7)
(sum)	590	590	590

TABLE 5 Comparison of initial and reviewal analysis for possibility of involvement of maltreatment.

	Initial analysis	Reviewal analysis					
		(sum)	<1 month	1-11 month	1–4 year	5–9 year	≥10 year
Definite	11	17	2	5	1	4	5
Suspicious	8	10	2	3	3	1	1
Possible	24	37	3	19	8	3	4
Less Possible	103	103	4	57	24	5	13
Not possible	444	423	139	105	82	49	48
(sum)	590	590	150	189	118	62	71

age group, the 1–11 month group was the largest (27/64 cases), whereas the group aged below 1 month was the smallest (seven cases).

## Preventability

The results of initial analysis and reviewal analysis regarding preventability are compared in Table 6. In the reviewal analysis, the preventability was "high" in 12.7% (75 cases), "moderate" in 14.1% (83 cases), and "low" in 65.6% (387 cases) of the cases. These results showed no significant difference from the results of the initial analysis.

## **Screening for CDR**

Figure 2 represents the comparison of preliminary, initial, and reviewal analyses of the 590 cases that completed Steps 1–3. Initial analysis screened in more cases than the preliminary analysis—282 (47.8%) versus 172 cases (29.2%), respectively; p < 0.001 using the  $\chi^2$  test. In the reviewal analysis, 14 cases (2.4%) were classified as

**TABLE 6** Comparison of initial and reviewal analysis for preventability.

	Reviewal analysis (Step 3)				
	High	Moderate	Low	Unknown	(sum)
Initial analysis	(Step 2)				
High	66	4	1	0	71
Moderate	6	65	10	0	81
Low	0	9	372	6	387
Unknown	3	5	4	39	51
(sum)	75	83	387	45	590

"mandatory" by two reviewers, 92 cases (15.6%) were classified as "mandatory" by one reviewer, and 135 cases (22.9%) were classified as "hopeful" by at least one reviewer. Thus, the sum of these 241 (40.8%) were considered screen--ins.

Assumed that the gold standard for case screening is the reviewal analysis, the sensitivity and specificity of initial analysis were calculated as 0.85 and 0.78. The sensitivity and specificity of preliminary analysis were 0.56

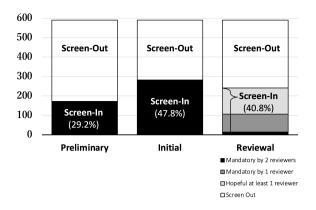


FIGURE 2 Comparison of screening results in the preliminary, initial, and reviewal analyses.

and 0.89, respectively. Out of the 418 screened-outs in the preliminary analysis, 106 could potentially be false negatives, subsequently screened-in during the reviewal analysis. Among these were included 38 deaths of external or unknown causes, 15 categorized more than 'Possible' maltreatment, and 29 more than the 'Moderate' preventability cases (allowing for item duplication).

### DISCUSSION

This study showed that a survey of CMRs in hospitals in Japan had high sensitivity and specificity to identify child deaths that should be targeted for CDR. This measure should be the first step in the upcoming CDR system, and this is an important finding in designing the CDR system in Japan. The limitation of this method is that it is not always possible to confirm CMRs of all deaths. The cases that died or for which death certificates were submitted outside Aichi prefecture could not be included, and those whose CMRs was not identified could not be included either. This was partially because this study was designed to survey only in pediatric departments at hospitals in the Aichi Prefecture. This limitation may be overcome if broader engagement is achieved in the future.

This study also revealed the limitation of using vital statistics. The sensitivity and specificity of the preliminary analysis to identify those who needed to be reviewed were low. In particular, the preliminary analysis could detect only 25% (five out of 20) deliberate deaths including abuse-related deaths, which is essential in CDR.<sup>6</sup> In other words, government data could not be reliably used alone to screen CDR targets appropriately, even if the screening was performed by experts. The CDR system in the UK covers all child deaths, and recommendations in the USA also support the development of an approach to reviewing all child deaths because "there are elements of preventability in many natural deaths." In Japan, although local governments can identify all cases of child deaths

based on death certificates, this document only contains a minimal amount of information necessary for the generation of vital statistics. The death details are therefore unclear, and the rules governing selection may result in some arbitrary assumptions.<sup>8,9</sup>

Moreover, Japan's medical examiner system is too limited to adequately supervise pediatric death for CDR, in contrast with the coroner/medical examiner system in the UK and the USA.<sup>12</sup> An autopsy has the potential to reveal the cause of death<sup>11</sup> and the presence of maltreatment, <sup>12</sup> and provides one of the most sufficient medical records if available. However, forensic doctors in Japan only deal with unnatural deaths reported to the police, resulting in their autopsy coverage of as low as 14.4% [85/590] for all deaths. Moreover, most of the forensic autopsies are treated as confidential information in Japan, and the results are not shared with institutions outside of law enforcement. Thus, the coroner/medical examiner system is not appropriate for overviewing and screening all the children's death in Japan.

In Japan, most dying pediatric patients would have been treated in hospitals, whereas most cases of death at home (sudden infant death syndrome, etc.) would have also involved transfer to a hospital to confirm death. If careful interviews are done at the emergency department, the background events leading up to death can be recorded in the CMRs to a certain extent. Therefore, a survey of hospital-held CMRs could cover 84.9% [590 /695] of child deaths and provide access to the information needed for screening. Despite the limitations of this approach, conducting screenings based on the records of hospitals by pediatric medicine experts appears to be an appropriate method.

To the best of the authors' knowledge, this study is the first detailed population-based investigation of child deaths in Japan. The results suggested that child deaths in Japan, especially those due to extrinsic causes, may be fewer than those in other countries. According to reports from other countries, 50.2-60.6% of the death among those aged 1-19 years were injury related, which is considered to be the result of a significant reduction in internal cause of death.<sup>13,14</sup> When the data for children aged 1 year or older were extracted from the results of this study, the percentage of deaths due to extrinsic causes was 20.6% (52 out of 252). This study did not clarify whether the infrequent occurrence of injuries results in a reduction of deaths from external causes, or if successful treatments prevent fatalities from external causes even in the presence of frequent injuries. In the future, by reviewing both survival and fatal trauma cases, it will be possible to accurately assess the impact of injuries on children in Japan.

Next, using CMRs, this study revealed, for the first time, that maltreatment, including abuse and neglect, is significantly involved in the death of children in Japan, especially in the 1–11 months group. In the government

statistics report, abuse-related death, including forced homicide, accounts for less than 2% of all child deaths each year, with the highest number noted in the group aged less than 1 month. 11 In the reviewal analysis of this study, inappropriate care was involved in 2.9% of cases when only "definite" cases and 10.8% when "possible" cases were added, indicating a significant difference from the findings based on government statistics. In government statistics abuse is determined based on the judiciary's judgment whereas in this study it was based on the clinical diagnosis by medical professionals; therefore, differences in judgment criteria<sup>15</sup> may be a major factor. Alternatively, only a portion of the cases involving inadequate care may have been revealed to date. In the future, we would like to review child deaths multi-institutionally, based on the CMRs at the moment of death and any other information available from child welfare, law enforcement, and so forth.

Finally, the results concluded that almost onequarter of the child deaths in Japan are preventable, which is very similar to the results of previous studies conducted in Japan and overseas. <sup>11,16,17</sup> Modifiable factors<sup>5</sup> can be found to the same extent in Japan, although the number of deaths due to intrinsic causes is higher than in other countries. These findings suggest that all cases, including natural deaths, should be targeted for CDR. <sup>6,7</sup>

## Limitations

The study had multiple limitations. First, as mentioned above, despite being a population-based survey, some cases could not be surveyed; therefore, selection bias cannot be ruled out. As CDR systems emphasize comprehensiveness, these omissions cannot be overlooked. Child death reviews for deaths outside the region are difficult, indicating the need for a system that allows access to CMRs outside the region. In addition, because some of the missed cases occurred in the hospitals surveyed, a standard guideline for collecting mortality statistics is needed across hospitals.

Second, the method for the classification of the cause of death adopted in this study is not commonly used in Japan and some investigators were unfamiliar with it. This classification reduces miscellaneous classifications and accounts for preventive measures; however, it requires adequate training to ensure proper application. Nevertheless, both preliminary and reviewal analyses in this study were conducted by skilled researchers and their judgments can be expected to have been accurate. The slight discrepancy between initial and reviewal analysis can be covered by investigator training or expert overview.

Third, medical records constitute a content-restricted source for CDR. Clinicians are extremely busy, especially when resuscitating cardiopulmonary arrest; they are likely to overlook or mishear information that is not essential for ongoing treatment. Information on the history of growth (i.e., vaccination history, history of involvement in child guidance centers and health administration, and history of police involvement) are not likely to be included; therefore, to supplement the information from medical records, integration of information on child welfare and maternal and child health is essential.

Finally, the most important limitation is that this study did gather information, screened the target cases of CDR, and proposed the contents to be verified, but did not include further reviews. The purpose of CDR is not to audit deaths but to find measures that would prevent death. In the future, such surveys should be designed and conducted not as a medical study by researchers but as an administrative measure involving multiple institutions to reflect the measurements conducted in actual practice. Despite these limitations, this study provides important information about deaths of Japanese children as well as the ideal approach for verifying these deaths.

In conclusion, hospital surveys on CMRs effectively screen for almost all child deaths and identify cases that should be targeted for CDR in Japan. This approach is appropriate as the first step in the upcoming CDR system. We hope that the results of this study will facilitate the formulation of a CDR system in Japan.

## **AUTHOR CONTRIBUTIONS**

Atsushi Numaguchi conceptualized and designed the study, collected the data, carried out the initial analyses, drafted the initial manuscript, and reviewed and revised the manuscript. Akira Ishii, Shinji Saitoh, Yasuhiro Aoki, Tetsushi Yoshikawa, Ichiro Isobe, Akihisa Okumura, Hiroshi Seno, and Yoshiyuki Takahashi collected the data, conducted initial analyses, and reviewed and revised the manuscript. Jun Natsume critically reviewed the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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#### CONFLICT OF INTEREST STATEMENT

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#### ORCID

Atsushi Numaguchi https://orcid.
org/0000-0003-4875-6037

Jun Natsume https://orcid.org/0000-0002-2081-9449

Shinji Saitoh https://orcid.org/0000-0001-6911-3351

Tetsushi Yoshikawa https://orcid.
org/0000-0002-2847-7682

Akihisa Okumura https://orcid.
org/0000-0003-2447-2857

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#### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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