

Suffocation Deaths Associated with Use of Infant Sleep Positioners — United States, 1997–2011

Unintentional suffocation is the leading cause of injury death among children aged <1 year in the United States, accounting for nearly 1,000 infant deaths annually. Since 1984, an estimated fourfold increase has been observed in accidental suffocation and strangulation in bed, with many of these deaths linked to unsafe sleep environments (1,2). Infant sleep positioners (ISPs) are devices intended to keep an infant in a specific position while sleeping, yet ISPs have been reported to have been present in the sleep environment in some cases of unintentional infant suffocation (3,4) (Figure). Some specific ISPs have been cleared by the Food and Drug Administration (FDA) for the management of gastroesophageal reflux or plagiocephaly (asymmetry of the skull) (5). However, many unapproved ISPs have been marketed to the general public with claims of preventing sudden infant death syndrome (SIDS), improving health, and enhancing sleep comfort (5). To characterize infant deaths associated with ISPs, FDA, the U.S. Consumer Product Safety Commission (CPSC), and CDC examined information reported to CPSC about 13 infant deaths in the past 13 years associated with the use of ISPs. In this case series, all infants but one were aged ≤ 3 months, and most were placed on their sides to sleep. Many were found prone (i.e., lying on their abdomens). Accompanying medical issues included prematurity and intercurrent respiratory illnesses. When providing guidance for parents of newborns, health-care providers need to emphasize the importance of placing infants to sleep on their backs in a safe sleep environment. This includes reminders about the American Academy of Pediatrics (AAP) recommendations against side sleep position, ISPs and pillows, comforters, and other soft bedding.

A case was defined as an infant death reported to CPSC during January 1997–March 2011 that occurred in the presence of an ISP in the sleep environment. Thirteen cases were identified. Information was abstracted from a CPSC In-Depth Investigation file,* which included medical examiner and police reports made

available to CPSC. This report describes the circumstances of one case and summarizes all 13 cases of infant death.

Case Description

The male victim, aged 7 weeks, was one of twin infants born at 36 weeks' gestation but otherwise was physically and developmentally normal. Five days before his death, he had a well-baby visit that revealed no health concerns. He slept in an ISP in a crib separate from his twin brother. The morning of his death, the victim was fed, uneventfully, at approximately 1:00 a.m. and was placed to sleep on his side in the ISP. At about 4:00 a.m., a care provider prepared the infants for their next feeding and discovered the victim in the ISP, unresponsive, with his face close to one of the ISP's foam pads, which were used in conjunction with swaddling to keep a pacifier in the infant's mouth. The autopsy report listed the cause of death as asphyxia by obstruction of the nose and mouth by a "foam positioning device."

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* Contains data from investigations on death or injury associated with a particular consumer product.



FIGURE. Simulated display using a doll in an infant sleep positioner with two bolsters, demonstrating how an infant's face can get trapped against the bolster, causing suffocation



The ISP was a flat mat with side bolsters, which the mother purchased to prevent SIDS. The device was advertised as helping “position your baby while sleeping or resting” and instructions stated, “This product is to be used if your pediatrician has recommended side sleeping for your baby.”

Summary of 13 Cases

Among the 13 cases of infant death reported to CPSC in association with ISP use, the victims ranged in age from 21 days to 4 months (mean: 9.5 weeks, median: 3 months) (Table). Eight were male. Four victims had been born prematurely, and three of them were one of a pair of twins. One deceased twin had been diagnosed with bronchopulmonary dysplasia

and gastroesophageal reflux. Of the 13 infants, four had recent respiratory symptoms and/or diagnoses of respiratory illness, including respiratory syncytial virus infection and colds.

Infants were most commonly placed on their sides to sleep (nine infants). One infant was placed prone. The position placement was not known for two cases; a discrepancy was noted between parental report and medical examiner assessment for the remaining case. Three families reported using the device in an effort to prevent SIDS. Other reported uses included preventing reflux (two cases), elevating the head (one case), preventing rolling over (three cases), and preventing plagiocephaly (one case). Instructions for use of involved ISPs were available for review for five cases; three indicated that side positioning an infant in the device was an acceptable use of the product. At least three cases involved ISPs with cautionary labeling “once your baby begins to move around during sleep, the sleep positioner should no longer be used.”

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TABLE. Unexplained infant deaths associated with infant sleep positioners, by selected characteristics — United States, 1997–2011

Year	Age	Sex	Race (ethnicity, if noted)	Positioner type	Reported use or <i>Advertised use*</i>	Placement position	Position when found	Medical issues	Comments
1997	2 mos	Male	Unknown	Flat mat with bolsters	"to prevent SIDS by placing infant on side when sleeping"	Side	Prone; after rolling forward, arm trapped between body and wedge	NA	NA
1998	2 mos	Female	White	Flat mat with bolsters	<i>"helps keep sleeping infant on its back"</i> with side position diagram and instructions	Supine	Prone with face in pillow part of positioner	NA	Similar device used with older sibling
1999	4 mos	Female	White	Incline with harness (12 in. incline)	"maintain them in semi-upright position" and "to reduce the incidence of SIDS"	Unknown	Prone; out of harness lying on crib mattress	30 wks gestation; twin; diagnosed with bronchopulmonary dysplasia (on no active medical therapy); gastroesophageal reflux disease	NA
2002	7 wks	Male	White	Flat mat with bolsters	<i>"helps position baby while sleeping or resting"</i> with side position diagram and instructions	Side	On side between bolsters; face close to bolsters	36 wks gestation, twin	Foam pad of device was used to brace pacifier
2004	15 wks	Female	White	Flat mat with bolsters	"to prop baby on left side"	Side	Prone	NA	NA
2006	3 mos	Male	White (Hispanic)	Flat mat with bolsters	<i>"lets baby sleep safer and cooler"</i> with "Side Sleeping Position: (Alternative)" instructions	Unknown	Supine	Recent upper respiratory infection; taking prescribed medication	NA
2006	3 mos	Male	White	Inclined with wedges	<i>"Designed to prevent flat head syndrome and common acid reflux"</i>	Side	Prone	Constipation during 24 hrs prior, vomited once 1–2 hours before bedtime	NA
2008	3 mos	Male	Black	Inclined with bolsters	"elevate head"	Side	Prone; head entrapped between positioner and bassinet	6 wks premature	NA
2009	1 mos	Female	Black	Flat mat with bolsters	<i>"Recommended for use in positioning baby to help reduce the risk of SIDS."</i>	Side	Prone; head on layers of added soft bedding	NA	NA
2009	3 mos	Male	White	Flat mat with pillow attached and side bolsters	"to keep him from rolling over"	Prone	Prone; face in pillow part of positioner	Cold 3 wks prior	NA
2010	7 wks	Male	White	Inclined with wedges	"to prevent the baby from getting a flat head ... and prevent him from rolling over"	Side	Prone; wedged between sleep positioner and crib bumper	Recent viral illness; respiratory symptoms, vomiting, and treatment with antibiotic	Similar device used with an older sibling
2010	3 mos	Male	White	Contains two bolsters; unknown if flat mat or inclined	Not reported	Side	Prone; wrapped in swaddling blanket with arms inside between two bolsters	36 wks gestation; twin; diagnosed 6 wks prior with respiratory syncytial virus	NA
2010	21 days	Female	Black	Inclined with bolsters	<i>"elevates baby's head to help ease breathing and enhance digestion"</i> and <i>"eliminate over-heating"</i>	Side	Prone	NA	NA

Abbreviations: SIDS = sudden infant death syndrome; NA = not applicable or not available.

* Reported use includes information reported by parents on why they were using the device. In the absence of parental report, advertised use (in italics) is provided from the available product packaging or advertisement claim by manufacturer.

What is already known on this topic?

Infant suffocation is a common cause of infant death and often is associated with the sleep environment. The safest sleep environment for infants is in a crib, on their backs (not their sides), without soft objects, loose bedding, or an infant sleep positioner (ISP).

What is added by this report?

Thirteen cases of infant deaths that occurred in the presence of an ISP in the sleep environment were reported to the U.S. Consumer Product Safety Commission during January 1997–March 2011. In this case series, all but one infant were aged ≤3 months, and most were placed on their sides to sleep.

What are the implications for public health practice?

Parents should continue to be made aware of what is the safest sleep environment for infants and reminded that commercial devices are not necessary to keep infants on their backs to sleep.

Editorial Note

This case series summarizes characteristics of the 13 infant suffocation deaths related to ISP use reported to CPSC during January 1997–March 2011. In these cases, ISPs often were used to position infants on their sides. At least nine of the infants were placed on their sides (and one prone), raising the concern that the “back-to-sleep” message to position infants on their backs is either not being heard or not being followed. CDC data from the Pregnancy Risk Assessment Monitoring System CPONDER web-based query system provides an indicator of whether infants most often are positioned on their backs for sleep. Data from reporting states in 2008 suggest that approximately 25% of infants are not being placed supine for sleep (6).

Some infants are at increased risk for SIDS; risk factors include premature birth, twin birth, and male gender (7). This case series raises concerns about ISPs contributing to the risk for suffocation, in the absence of any evidence that ISPs are effective in reducing the risk for SIDS.

Although ISPs have been available since the 1980s, only a few ISP manufacturers have been cleared by the FDA to provide products, by prescription, to manage particular medical conditions (e.g., gastroesophageal reflux). Despite other manufacturers’ claims regarding SIDS prevention or other health benefits, FDA has never cleared or approved an ISP for preventing or reducing the risk for SIDS. Cleared ISPs should only be used by prescription for treatment of specific medical conditions.

After reports of infant suffocation related to ISP use in 2010, CPSC and the FDA launched a joint effort; on September 29, 2010, FDA and CPSC released statements concerning the

danger associated with the use of ISPs (5,8). The agencies urged families to discontinue use of unapproved ISPs, through media messages indicating that “back-to-sleep” is best and ISPs are not necessary to keep infants on their backs (5,8). In addition, they advised health-care providers to continue counseling families on safe sleep practices in accordance with AAP’s recommendations (7). FDA has contacted all manufacturers requesting that all sales be halted until companies submit safety and effectiveness data that not only support the medical claims of their devices but also demonstrate that benefits from use of the product outweigh the risks for suffocation (3).

An additional concern is the “hand-me-down” availability of ISPs. Many products for children, some of which might have been recalled, are passed along by family and friends or purchased from second-hand stores. Public health education and health-care provider counseling are important ways to reduce the inappropriate use of ISPs.

In 2005, AAP definitively recommended against side positioning (9). In 2011, AAP released a comprehensive policy statement on safe sleep environments for infants to reduce the risk for SIDS and suffocation (7). FDA and CPSC also have issued recommendations consistent with the current AAP statements concerning ISPs. First, parents and caregivers should stop using ISPs unless specifically prescribed by their pediatricians. Supine sleeping is safest; use of a device is not necessary in this position and is potentially hazardous. Second, they should never put pillows, comforters, or unprescribed ISPs in an infant’s sleep environment. Finally, they should place infants to sleep on their backs.

The findings in this report are subject to at least five limitations. First, as with many case series, the total number of cases is unknown because the data are from voluntary reporting. Second, because the number of ISPs in use is not known, the risk for suffocation when an ISP is present cannot be directly compared with the risk when no ISP is present. Third, only information on deaths was collected; nonfatal cases are not reported. Fourth, variability was observed in the type and detail of information in each report because no standardized system is implemented consistently. For example, one report used the more recently available Sudden Unexplained Infant Death Investigation reporting form.[†] Finally, this series includes cases reported during 1997–2011; products, instructions, and even recommendations have changed over this 13-year period, which might have influenced use of these devices and reporting of cases.

[†] Additional information available at <http://www.cdc.gov/sids/suidrf.htm#1>.

The need for a safe sleep environment for infants (i.e., in a crib, on their backs [not their sides], without soft objects, loose bedding, or an ISP) is still an important public health message. The original Back-to-Sleep campaign (launched in 1994 by the National Institute of Child Health and Human Development, the U.S. Department of Health and Human Services Child Care Bureau and Maternal and Child Health Bureau, and AAP) did not preclude side sleeping; consequently, manufacturers developed ISPs to keep babies in specific positions. However, ISPs are not necessary to keep a baby supine, and other positions increase the risk for SIDS and/or suffocation. Although some ISPs contained cautionary statements like “discontinue use once baby begins to move around,” these statements are unclear, and caregivers cannot accurately predict when an infant will achieve milestones. Clear, consistent, and frequent reinforcement of the safe sleep messages by public health practitioners and health-care providers is needed to prevent further infant suffocations.

Additional information is available online from FDA at <http://www.fda.gov/forconsumers/consumerupdates/ucm227575.htm>, from CPSC at <http://www.cpsc.gov/cpsc/pub/prerel/prhtml10/10358.html>, and from CDC at <http://www.cdc.gov/sids>.

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