

controlled trials were neither feasible nor ethical. Fortunately, it was considered safe and acceptable to reduce or eliminate aspirin use in children because there was a widely used alternative—acetaminophen (often used as the brand name Tylenol)—that was not implicated in the studies of Reye's Syndrome.

As early as 1980, the CDC cautioned physicians and parents about the potential dangers of aspirin. In 1982, the U.S. surgeon general issued an advisory on the danger of aspirin for use in children. By 1986, the U.S. Food and Drug Administration required a Reye's Syndrome warning be placed on all aspirin-containing medications. These efforts were coupled with public service announcements, informational brochures, and patient education by pediatricians and other health professionals who cared for children. The use of the term "baby aspirin" was strongly discouraged.

In the early 1980s, there were over 500 cases of Reye's Syndrome per year in the United States. In recent years, there have often been fewer than 5 per year. The success of the efforts to reduce or eliminate the use of "baby aspirin" and the subsequent dramatic reduction in the frequency of Reye's Syndrome provided convincing evidence that aspirin was a contributory cause of the condition and its removal from use was an effective intervention.

## Discussion Questions

1. How does the Reye's Syndrome history illustrate the use of each of the steps in the P.E.R.I.E. process?
2. What unique aspects of Reye's Syndrome made it necessary and feasible to rely on case-control studies to provide the evidence to help reduce the frequency of the syndrome?
3. What types of methods for implementation were utilized as part of the implementation process? Can you classify them in terms of when, who, and how?
4. How does the Reye's Syndrome history illustrate the use of evaluation to demonstrate whether the implementation process was successful?

## SUDDEN INFANT DEATH SYNDROME (SIDS)

Sudden infant death syndrome, or SIDS, was first recognized as a distinct public health problem in the late 1960s when over 7,000 infants each year were found to die suddenly and unexpectedly. "Crib deaths" have been recognized for centuries, but until they were formally recorded and investigated, little was known about their cause, leading some to conclude that intentional or unintentional suffocation by parents or caregivers played an important role.

Data from the investigations of SIDS indicated that the syndrome was very rare before babies' first month of life, increased during the second month, and peaked during the third month, before rapidly declining in frequency to again become rare after the fourth month of life. The timing of SIDS suggested that the condition occurs after infants begin to sleep for extended periods but prior to the time in which children can raise themselves up and roll over on their own. Additional evidence suggested a seasonal trend, with more cases of SIDS occurring during cold weather months than during warm weather months.

In the 1980s, several case-control studies of SIDS cases and similar infants without SIDS established that infants who slept on their stomachs were at substantially increased risk of dying from SIDS. The studies indicated that the chances increased four to seven times, suggesting that if a cause-and-effect relationship exists, a clear majority of SIDS cases could be prevented if infants slept on their back. Many parents and clinicians remained skeptical because the traditional teaching emphasized sleeping prone, or on the stomach, to reduce the possibility of choking on regurgitation and vomit. Despite the lack of evidence for this hazard, generations had been raised on this practice and belief.

Additional evidence of the effectiveness of a "back-to-sleep" intervention was provided by the experience of New Zealand, which was the first country to begin a program to encourage caretakers to put infants to sleep on their backs. The rates of SIDS in New Zealand declined rapidly in parallel with the increased rate at which infants were put to sleep on their back. Similar declines in SIDS did not occur in other countries that had not yet instituted similar back-to-sleep programs.

In 1992, the American Academy of Pediatrics made a recommendation that infants be placed on their back to sleep. The initial recommendations also endorsed side sleeping. In 1994, with the support of the American Academy of Pediatrics, the National Institutes of Health (NIH), and the U.S. Public Health Service, the Back-to-Sleep campaign was launched. The educational campaign included public service announcements, brochures and other publications, including information accompanying new cribs, plus efforts for pediatricians and others who care for infants to educate parents and caretakers about the importance of having infants sleep on their backs.

The frequency of infants sleeping prone in the United States was found by survey data to be reduced from approximately 70% to less than 15% during the years immediately following the initiation of the Back-to-Sleep campaign. During these years, the rates of SIDS fell by approximately 50%, an impressive change but less than expected by the initial data. The rate of prone sleeping among African