

White Paper

Shaken Baby Syndrome/Abusive Head Trauma Prevention

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Introduction

Shaken baby syndrome (SBS) and abusive head trauma (AHT) continue to be the most common causes of mortality and morbidity due to physical child abuse in the United States. Despite being recognized for nearly 40 years, there are only a couple of valid studies about how often shaken baby syndrome (abusive head trauma) happens. Both of these studies report the incidence for only the most serious hospitalized and/or fatal abusive traumatic brain injury cases and are estimates for infants younger than 1 year of age. The figure ranges from about 25 to 30 cases for 100,000 person years in and around Edinburgh, Scotland, and in North Carolina, respectively.

A significant proportion of cases of SBS/AHT, about 25%, die during the initial phase of hospitalization. The survivors do very poorly as shown in a number of studies. In a study done in Canada, only 7% of the survivors were reported as “normal,” 12% were in a coma or vegetative state in the hospital, 60% had a moderate or greater degree of disability, 55% had lasting neurologic deficits, 65% had visual impairments, and 85% would require ongoing multidisciplinary care for the rest of their lives. The negative effects following hospital discharge are likely to be underestimated, because it often takes several months or even years before neurologic and developmental difficulties become apparent.

Clearly, the best response to this major harm to the health and safety of infants and young children is to devise programs that prevent inflicted brain injury from happening in the first place. The development and validation of effective programs for prevention have proven to be challenging because of a number of factors.

The first of these factors is a counting problem. In order to count the cases of a medical condition, a good and acceptable definition of that condition must be *established* and *accepted* by those doing the counting. All diseases require such definitions. In abusive head trauma, for a number of reasons, this is not always easy since this condition is a collection of signs, symptoms, clinical and X-ray findings, and in fatal cases, autopsy findings. A second factor is establishing a baseline incidence rate across large populations. Since the US is divided into states and counties, there are counting practices that vary widely from jurisdiction to jurisdiction and a lack of uniformity in tabulating the results. So establishing the baseline- the starting point of measurement- is difficult, but essential to determining the effectiveness of any intervention to change the

incidence of abuse. A third factor is economic. Many communities simply do not have the resources to keep detailed statistics on all conditions. Another economic factor is the fiscal support needed to design and implement a sustained program for intervention.

Rigorous Scientific Testing

Any prevention strategy must be validated by rigorous scientific evaluation to determine whether the intervention itself or numerous other factors are responsible for any measured change in incidence. This requires comparing families who receive a particular experimental intervention to others who do not receive the experimental intervention (a control group.) Since abusive head trauma is a relatively low incidence phenomenon, intervention must occur in a very large population of families with comparable control groups.

The Approaches to Prevention

Prevention efforts in child abuse may be divided into three categories: primary, secondary and tertiary.

Primary Prevention has all parents as its target population and seeks to prevent the occurrence of the problem. Examples of primary prevention include public service announcements, pamphlets and brochures given away at stores, hospital and clinic waiting rooms, and doctor's offices.

Secondary Prevention or prevention that short circuits or ameliorates abusive head trauma as it occurs may be most successful by targeting "at-risk" populations such as single parents, young parents, drug- and alcohol- dependent parents, persons with demonstrated impulse control problems, poverty-ridden parents, and isolated parents. These are parents under unusual stress for any number of reasons.

Tertiary Prevention, also known as rehabilitation, targets the populations who have already abused their children to restore child function and prevent recurrence.

What are the elements of sound prevention programs?

1. The intervention strategy must be studied and validated before being widely implemented. This requires a scientifically rigorous testing of the elements of the intervention, using study populations and control groups to gauge the effectiveness of the strategy.
2. The benefits should be measurable. The effects of whatever intervention is given must be able to be quantified. This means establishing baseline numbers, applying the intervention, and then measuring the change in the baseline numbers.
3. The intervention should be easily accepted by clients. In order for any intervention to be effective, it has to be easily understood and embraced by the parents of the infants. They have to understand how this will benefit them and their baby.
4. Goals should be broad. If the expected outcome of the intervention is too narrow the measurement may fail to demonstrate any effectiveness.

5. Variables affecting outcomes should be considered and controlled to the extent possible.
6. Scientific research on effectiveness should be conducted in order to assure that the intervention is working when the intervention is implemented as well as later on.
7. Continuing education of providers. Those administering the intervention must be updated about the progress of the whole program and given new information as it becomes available about how to improve the application of the intervention.

What prevention programs for SBS/AHT have been studied?

Dias and his colleagues are well-known for their programs in western New York and Pennsylvania.¹ They used a geographically defined area around Buffalo New York for their first study on SBS prevention. The goals of the program were to:

1. Educate every parent of every newborn child before the child leaves the hospital
2. Secure commitment statements from both parents that they have received and understand the materials before leaving the maternity ward
3. Monitor regional incidence of AHT using historical controls

There were seven key elements in the program. The program was to be:

1. Universal (all parents of newborn children)
2. Administered at a consistent time during the perinatal period
3. Administered by nurses
4. Targeted to both parents, especially fathers
5. Presented in a multimedia format
6. Inclusive of a commitment statement signed by both parents
7. Separate from other information given to parents of newborns before discharge

They gave educational materials to the parents of all newborns in an eight-county region around Buffalo in western New York State during the years spanning 1993 through 1998. Nurses were trained to ask parents to read a single page of information and look at an 11-minute video describing the dangers of shaking a baby and suggesting other responses to a crying baby. Both parents were also asked to sign a paper that they had received and understood the materials and that they were committed to not shaking their infant. When the infants turned 7-months old, ten percent of the sample was surveyed by phone about the content of the material. Twenty-seven percent spontaneously recalled receiving SBS information, but when asked specifically about the SBS material, 94% said they had gotten the materials. Nurses estimated that the vast majority of the parents received the leaflet, but that less than two-thirds viewed the videotape. Sixty-nine percent signed the commitment paper.

In the 9.5 years of the intervention program in western New York, they had 16 participating regional hospitals. They obtained commitment statements from over 150,000 families representing over 80% of the region's live births. Ninety-six percent of the commitment statements were signed by mothers and 76% by fathers. On the follow-up survey, 98% of the participants recalled written material, 94% recalled the commitment statements, 61% recalled a poster on SBS, and 30% recalled the video.

In the six years before the prevention program was introduced, there were 49 cases of SBS/AHT reported in this region. This translated into 41.6 cases/100,000 live births, or 29.7 cases per 100,000 person-years. During the years in which the program was administered, there were 21 cases, a rate of 22.2 per 100,000 live births. This represents a 47% reduction.

Dias and colleagues initiated an identical program in Pennsylvania in May 2002. Forty-two hospitals in central Pennsylvania initially participated and it was then expanded and supported by the Pennsylvania Department of Health.

The cost of the New York program was \$10 per infant. This study showed that prevention can work and that parents' recall was excellent for written materials about abusive head trauma. The act of signing a commitment statement vowing to abstain from shaking of infants was recalled in the overwhelming majority of participants. Interestingly, only one-third recalled the video "*Portrait of Promise*." The results of the Dias programs have implications for the future of such prevention programs. Its goals of using nurses in the newborn period to provide educational materials about SBS to all parents of all newborn children, coupled with a commitment statement signed by both parents were effective in seeing a reduced rate of SBS in the region studied.

Do the educational materials used in a prevention program matter?

Without citing an enormous literature about testing of educational materials, the common-sense answer is yes. The entire advertising industry is devoted to getting "the message" into the thinking patterns of the general public. Effective presentations to any audience depend not only on *what* information is transmitted, but *how* it is presented.

The importance of form and content of educational materials in AHT/SBS prevention programs was shown to make a difference to observers by a study done by Russell and her colleagues.² This study sought to compare interventional materials intended to raise public awareness of care-giving practices connected to SBS. Two hundred sixty-four adults were recruited for participation. Participants fell into two groups: those who regularly cared for children (46%) and those who did not (54%)

SBS awareness was surveyed (using a specifically designed instrument) prior to an educational intervention and three times afterwards (at two, six and 12 weeks). Four items relevant to SBS prevention were measured:

1. Attitudes towards adults' emotion regulation
2. Attitudes towards soothing
3. Attitudes towards discipline
4. Basic caregiver knowledge

Three interventions were presented to the participants: these educational materials included "*Portrait of Promise*" video, the "*Shaking, Hitting, Spanking: What to do instead*" video, and the brochure "*Never, Never Shake a Baby*." Both videos are approximately 10 minutes long and have similar information on the risks connected to shaking of infants. The second one, however, offers several alternative behaviors that might help soothe a crying infant and help the caregiver to remain calm during the frustration.

This study used a rigorous scientific approach to determine the effectiveness of the three types of educational materials. This “evidence-based” approach to validating materials is essential, since many untested approaches to soothing babies, based on anecdotes and opinion, are available in multimedia formats without ever having been subjected to scientific evaluation. Russell and her colleagues found that the highest likelihood of increased awareness was derived from the teaching video intervention (“*Shaking, Hitting, Spanking: What to do instead*”) followed by the testimonial video (“*Portrait of Promise*”); the lowest probability of increased awareness was from the use of only a brochure. The authors’ conclusion was that addition of video materials increased significantly the likelihood of positive changes in SBS awareness over interventions using only brochures. In other words, the manner of delivery of the information does matter.

The *Period of Purple Crying*- A Program for Prevention of Shaken Baby Syndrome (AHT) that emphasizes the educational approach

The acronym ‘*PURPLE*’ stands for the characteristics of infant crying in the first few months of life:

- P: Peak of crying
- U: Unexpected
- R: Resists soothing
- P: Pain-like face
- L: Long lasting
- E: Evening and late afternoon

There is evidence that infant crying is the most important stimulus for AHT/SBS. The *Period of Purple Crying* program approaches SBS prevention by educating parents about normal infant development and, specifically, about crying patterns to be expected in normal infants based on scientific evidence about infant crying. It uses positive messages for parents rather than negative warnings about detrimental consequences of shaking. The authors of this program recommend a “triple-dose” approach:

Dose One: Maternity Wards

The *PURPLE* program is given to families of new babies, both mothers and fathers, in the hospital after the birth of their baby. Maternity nurses are trained and provided with a script to use when presenting the materials to families of new babies and the *PURPLE Crying* materials themselves. Each family receives the 10-minute DVD and 11-page booklet about *PURPLE Crying* to take home with them. When possible, the parents should watch the film in the hospital and be able to ask the nurse questions. It is very important that the parents receive the program from a person in a position of authority or influence, like a maternity nurse or health educator. It is equally important that the person delivering the *PURPLE* program recommends its use to the parents, encourages them to review the materials, and recommends sharing the materials with other caregivers of their baby.

Dose Two: Pre- and Postnatal Primary Health Care Units, Public Health Visiting Nurses or Primary Care Physicians

Health nurse home visitors, pediatricians, family doctors or public health clinics can reinforce the message by talking to parents about the concepts taught in the *Period of PURPLE Crying* program. If needed, the physician (or office personnel) can provide materials to parents who were missed at the hospital after having their baby and did not receive the *PURPLE* materials. It is important not to duplicate the materials in the distribution process as, ideally; most parents should have received the materials at the hospital.

Dose Three: Public Education and Media Campaign

A public education campaign provides this information to the general public, including all those who did not receive the program through the previous two methods. This is an important part of bringing about a cultural change as it is necessary to educate grandmothers, boyfriends, neighbors and relatives about the *PURPLE* program. Understanding of the *Period of PURPLE Crying* among the general population can help ease the stresses of parents dealing with the inconsolable crying of their babies.

Reinforcers and Enhancers

Other groups who serve parents are specifically targeted to facilitate complete community coverage about the *Period of PURPLE Crying* program. Childcare providers, foster care workers, midwives, advice and hot line personnel, family practice physicians, emergency room personnel and other groups serving parents should be contacted and receive training on the *Period of PURPLE Crying*. This ensures that parents get the same information wherever they go for help and advice.

Scientific Testing of the Program

The efficacy of these educational materials has been studied in two randomized controlled trials—the most stringent designs for such studies—and reported on in 2009. One study was done in the state of Washington³ and the other in Vancouver, BC, Canada.⁴ In the Washington study, the population consisted of a study group of 1374 mothers of newborns. The control group consisted of 1364 mothers of newborns. In the Vancouver study, the study group had 913 mothers of newborns with a control group of 920 mothers of newborns. The aim of these studies was to investigate the effect of the *Period of Purple Crying* materials on the mother's knowledge and behavior relevant to the prevention of SBS.

Both study groups received the *PURPLE* materials: an 11- page booklet and a 12- minute DVD, both of which identified the association between crying and SBS. In the US the control group received a DVD about infant safety and safe sleep. In Canada, they received the Canadian Pediatric Society's brochure on sleep position, a brochure on SIDS and a DVD with clips from the National Institute of Child Health and Human Development Back to Sleep campaign and the Safe Start program of BC Children's Hospital in Canada.

The eight main outcome measures were:

1. Crying knowledge
2. Shaking knowledge
3. Responses to crying generally
4. Responses to inconsolable crying
5. Self-talk responses to inconsolable crying
6. Sharing information with a temporary caregiver on crying
7. Sharing information on walking away if frustrated, and
8. Sharing information on the dangers of shaking.

Secondary outcomes were derived from the mothers' entries of infant and caregiver behaviors in a Baby's Day Diary for four days.

Results from both studies were similar but not identical. Among the USA mothers there was increased knowledge about crying and the dangers of shaking after receiving the *PURPLE* materials, and they shared more information about walking away if frustrated and the dangers of shaking. The Canadian mothers who received the *PURPLE* materials showed greater knowledge about infant crying and were more active in sharing information about crying, walking away if frustrated and the dangers of shaking with other caregivers. Of note is that, in the Vancouver study, the diary results also indicated that caregivers were more likely to lay the infant down and walk away if they were frustrated by inconsolable crying.

It is important to understand that these studies were not designed to determine whether the *Period of PURPLE Crying* materials reduced the incidence of shaken baby syndrome or infant abuse. Much larger population-based studies are required to do that. Rather, they were designed to assess whether the materials changed knowledge (especially about infant crying characteristics that are frustrating) and behaviors (such as sharing information with temporary caregivers) that are relevant to reducing shaken baby syndrome.

To have an idea about the effectiveness of the materials, the authors reported an index referred to as an "effect size," a standardized measure that allows results to be compared across studies of similar types. On the most important knowledge change (the increase in knowledge about frustrating crying characteristics), the parents who received *PURPLE* materials showed a change with an effect size of 0.46. This compares to an average effect size change of .23 for similar kinds of studies which are attempting to change parental knowledge (0.18 for randomized trials like this one). In other words past research on changing the beliefs that people hold about health is extraordinarily difficult. The *PURPLE* program study has demonstrated these positive changes.

What are the differences between the Dias trials and *Period of PURPLE Crying* trials?

The Dias trials and the *Period of PURPLE Crying* trials are examining different aspects of the strategy for prevention. The Dias trial tested a process model and describes how to implement a SBS prevention program. The Dias published model is an "open source" model amenable to the use of different materials than were originally used in that study. The *PURPLE* program tested the content of prevention materials for

changes in knowledge and behaviors. The two positive sets of findings suggest that combining the *PURPLE* materials with the Dias process could make the resulting program greater than the sum of its parts.

Ongoing Research on Shaken Baby Syndrome Prevention Programs

The Period of PURPLE Crying: Keeping Babies Safe in North Carolina-2007-2012

After the completion of the studies conducted in British Columbia and the state of Washington, a five year follow up study was launched in 2007 in the state of North Carolina. The *PURPLE* program had previously been tested (see above) to determine if the materials changed knowledge and behavior of mothers after learning about the *Period of PURPLE Crying*. The study implemented in North Carolina includes the state-wide implementation of the *Period of PURPLE Crying* program to determine if the program could reduce the incidence of SBS and infant abuse generally. The current implementation is being done as a universal prevention program for all of the approximately 125,000 births a year in North Carolina over a five-year period. The program is designed to be an improvement on current best practices by combining the *PURPLE* materials with the Dias distribution in maternity wards, but adding a second “dose” of reinforcement by public health and physician practices, and by including a public education and media campaign for the general public as the “third dose.” It is targeted both at mothers and fathers of newborns and society generally with the aim of bringing about a cultural change in society’s understanding and approach to infant crying, shaking and infant abuse generally.

The State of North Carolina was selected because Drs. Heather Keenan, Desmond Runyan, and colleagues had previously conducted the only North American study to date on the incidence of Shaken Baby Syndrome in North Carolina ⁶which is being used to help determine the effectiveness of the program. This prevention program is conceptualized and designed as a primary, universal, community education prevention program.

The program will be evaluated by; 1) Program Fidelity.; 2) Parental Recall of Program; 3) Parental Use of Shaking as Discipline; 4) Reduction in the Rate of Abusive Head Trauma (Shaken Baby Syndrome) 5) Hospital Specific Effectiveness of the Program; and 6) Economic Impact of the Prevention Program. The research program funded by CDC, The Doris Duke Charitable Foundation and The Duke Endowment will go on from 2007 to 2013.

The Period of PURPLE Crying: British Columbia, Canada-2007-2012

Similar to the model being used in North Carolina the *PURPLE Program* is also being tested in the province of British Columbia. The lead investigator is Dr. Ronald Barr and implementation is administered by Marilyn Barr. Dose One will include the delivery of the program by maternity nurses in all birthing hospitals. Dose Two will be given by public health nurses who in British Columbia reach 97% of all mothers in the first week after the birth of their baby. A public education campaign will be conducted as Dose Three. The project is funded by the Provincial Government and will be completed during 2007 to 2011.

The program will be evaluated by; 1) whether it reached the targeted groups; 2) reduction of shaken baby syndrome and abusive injury in infants generally; and 3) whether it achieves a cultural change in the community's understanding of early crying and its relationship to shaking.

Pennsylvania Shaken Baby Syndrome Prevention and Awareness Program

Starting in 2007 this five year study will continue the hospital based program completed in the previous study and expand parent education into pediatric care providers' offices in 16 randomly selected central Pennsylvania counties and will be compared to 15 counties not offering the program through pediatric care providers. This expanded program provides the opportunity for further parent education about infant crying and violent shaking at the 2, 4 and 6 month well child visits (during which immunizations are given). This includes asking both parents to read a "crying card" called "*Take a Break Don't Shake*" that reviews 1) normalcy of infant crying, 2) ways to handle caregiver frustration about infant crying, 3) ways to calm the infant, and 4) how to select other infant caregivers. Parents sign a commitment statement affirming their receipt and understanding.

The program will be evaluated by; 1) Effectiveness in reducing abusive head injury; 2) cost-effectiveness of the hospital based program alone and in combination with the primary care based program; 3) feasibility of repeated exposure both immediately postnatal in the hospital as well as later in a medical offices.

Conclusion

The programs to prevent child abuse, to be effective, need to be easily understood by the population for which they are intended. They need to be easily administered and universally applied. They must use validated educational materials as was shown by the study by Russell and colleagues. They need to be measurable in terms of the received knowledge as well outcome measures of reduction of cases of abuse. They need to be inexpensive in terms of time and actual cost.

The two approaches described here could be combined, using the best aspects of both. The materials of *PURPLE*, incorporated into the Dias delivery model, is likely to produce both objectives-an effective teaching moment in the newborn period to equip new parents with better understanding about how to deal with infant crying and the consequent decrease in abuse.

Reference List

1. Dias MS, Smith K, deGuehery K, et al. Preventing abusive head trauma in infants and young children: a hospital-based parent education program. *Pediatrics* 2005;115:470-477.
2. Russell BS, Trudeau J, Britner PA. Intervention type matters in primary prevention of abusive head injury: event history analysis results. *Child Abuse & Neglect* 2008;32:949-957.
3. Barr RG, Rivara FP, Barr M, et al. Effectiveness of educational materials designed to change knowledge and behaviors regarding crying and shaken-baby syndrome in mothers of newborns: a randomized controlled trial. *Pediatrics* 2009;123:972-980.
4. Barr RG, Barr M, Fujiwara T, et al. Do educational materials change knowledge and behaviour about crying and shaken baby syndrome? A randomized controlled trial. *CMAJ* 2009;180:727-733.
5. Layzer JI, Goodson BD, Bernstein L, et al. National evaluation of family support programs. Final report volume A: the meta-analysis. Cambridge, MA: Abt Associates Inc.; 2001.
6. Keenan HT, Runyan DK, Marshall SW, et al. A population-based study of inflicted traumatic brain injury in young children. *JAMA* 2003;290:621-626.