



## Implementation Protocol

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### Introduction – History of the Program

In 2003, the International Scientific Advisory Board of the National Center on Shaken Baby Syndrome (NCSBS) challenged our organization to invest in, design, develop and test a prevention program that was based on evidence and could be offered to other jurisdictions throughout North America and the world. To do this, the program had to meet the criteria of completing extensive trials; be published in respected, peer reviewed journals; and be economical and easy for others to use.

The NCSBS's evidence based prevention program is called the *Period of PURPLE Crying*. It is a program that gives parents a new way to understand their baby's crying which is based on three lines of evidence that they may not have known about before. It is a skill building program that approaches shaken baby syndrome/abusive head trauma (SBS/AHT) and infant physical abuse prevention by using a child development approach. It helps parents and caregivers to better understand the features of crying in normal infants that can be frustrating and can lead to shaking or abuse. The program is designed to create a cultural change in the way parents and others think about infant crying, especially inconsolable crying which is based on decades of research, by many scientists, on normal infant crying. If parents can understand and handle this normal early crying period, they are less likely to feel stressed to the point where they shake their baby out of frustration and anger.

Many programs tell parents that crying is normal, but this program is very different. This program provides the opportunity for parents to learn about the crying characteristics they are experiencing during this unique period in the first few months of life and gives this period a name. Our understanding of these normal crying characteristics and the research on the crying curve are the result of more than 25 years of research on normal infant crying conducted by Ronald G. Barr, MDCM, FRCPC along with other scientists worldwide. Their research has contributed to the understanding that these patterns of early crying, although frustrating, are a part of normal infant development.

Dr. Barr created the concept of the *Period of PURPLE Crying* to help describe these characteristics of early infant crying in normal, healthy infants. The crying begins at about two weeks of age and usually ends by four or five months of age, and often earlier. The letters in the *PURPLE* acronym describe these normal characteristics of infant crying:

- Peak of Crying** – Crying peaks during the second month, decreasing after that
- Unexpected** – Crying comes and goes unexpectedly, for no apparent reason
- Resists Soothing** – Crying continues despite all soothing efforts by caregivers
- Pain-like Face** – Infants look like they are in pain, even when they are not
- Long Lasting** – Crying can go on for 30-40 minutes at a time, and often for much longer
- Evening Crying** – Crying occurs more in the late afternoon and evening

The word "Period" is used to let parents know that this experience of increased frustrating crying is temporary, and eventually does come to an end.

The program has completed randomized controlled trials, the gold standard of research. In 2003-2006 the NCSBS, the Harborview Injury Prevention and Research Center of the University of Washington, and the University of British Columbia conducted parallel trials in two countries, Canada and the United States. New materials including an education video and booklet were produced as a result of collected data. These trials

successfully determined that the messages in the materials resonated with parents and could change their knowledge and behavior. The program was tested through four different types of delivery systems: maternity services, pediatric offices, prenatal classes and nurse home visitor programs. More than 4,400 parents participated in the research and 75 parents in two countries participated in focus groups to develop the 10-minute *Period of PURPLE Crying* video and 10-page booklet. The research was later published in two high rated, peer reviewed journals; the *Canadian Medical Association Journal* (CMAJ) and *Pediatrics*. The results were statistically positive and therefore the program was made available for implementation in June 2007.

The NCSBS, USA and Prevent SBS British Columbia, Canada have conducted and coordinated 37 focus group testings on the *Period of PURPLE Crying* program materials. In 2004, Dan Jones & Associates of Salt Lake City, Utah, USA were hired to conduct the United States Parent Focus Groups on the *PURPLE* program materials. The primary purpose of the research was to obtain in-depth understandings about attitudes regarding infant crying, what people know about SBS/AHT, and how new parents cope with incessant crying by their infants. In 2004, Prevent SBS British Columbia also coordinated the evaluation of the *PURPLE* program educational materials from the NCSBS for their suitability to the Canadian culture. Samsara Communications was hired to facilitate the focus group process. MTM Research was hired to analyze the results and report the key findings. Participants in the groups included males and females, multicultural, broad range of socioeconomic groups and races. Again the purpose of these focus groups was to determine if the initial *PURPLE* program materials resonated with the parents; was easily understood, was meaningful and of value. The program has been and continues to be tested to see if it can reduce SBS/AHT.

Prevent SBS British Columbia coordinated focus groups for the translation of the *PURPLE* program materials into ten languages. The goal of the translation projects for the *Period of PURPLE Crying* program is to offer a culturally sensitive, accurately translated product that keeps the clarity and cohesiveness of the message. The objective was to utilize a professional translation company that could provide the most comprehensive service that would meet the criteria necessary for academic publishing. To date, 20 translation focus groups have taken place.

## **Protocol for Implementation**

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### **Minimum Requirements When Using the *Period of PURPLE Crying* Program**

#### **1. Each Family Needs to Receive Their Own Set of Materials**

The tested model requires that the parent(s) of a new infant receives their own set of program materials; either booklet with DVD or booklet with web and mobile application (App). There are some very good reasons why the *Period of PURPLE Crying* program makes this requirement. For instance, when parents initially receive the materials, they may not realize how relevant they are until after when their baby is actually going through the *Period of PURPLE Crying*. They will want and need to review the content again. It is understood that people learn in different ways, some through reading and some through viewing a video. The *PURPLE* program messages are given in both video and written formats to address learning style differences. Additionally, parents who have the *PURPLE* program materials can easily share the materials with others who may be caring for their baby rather than attempting to transmit the content of the program themselves. Often it is far easier for a parent to tell a temporary caregiver to watch the 10-minute *PURPLE* video or read the 10-page booklet than try to explain it themselves; while telling the caregiver is the ideal method, this is sometimes difficult for some parents to do. This gives the parent(s) a way to educate their other caregivers in a simple and easy way. Since many babies are shaken by temporary caregivers, it is critical these people receive the program in addition to parents.

#### **2. Consistent Messages and Fidelity of the Program**

It is critically important that consistent, clear and correct (evidence based) messages are given to the parents and the public. The *PURPLE* program is committed to only offering information that meets this criterion. The tested program will not be effective if those delivering the program create their own version of the presentations or change the training materials in any way. Further, the *Period of PURPLE Crying* program

materials should not be distributed with other educational materials that express a conflicting message (e.g. all infant crying can be soothed if only parents respond in the correct way).

### 3. Ideal Delivery of the *Period of PURPLE Crying* Program

The NCSBS strongly recommends delivering the *PURPLE* program in accordance with the three dose approach outlined below. The NCSBS can be helpful in supporting any organization in this effort by providing; 1) free online training modules for all organizations; 2) free downloadable posters and supplemental items; 3) free print and broadcast media ads for communities implementing the program.

## Triple Dose Strategy

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### Dose One: Delivery of the *PURPLE* Program Materials to Parents

The first “dose” of the program is the delivery of the intervention materials to parents of all newly born infants via a demonstration of the materials by a trained educator or provider. This would replicate current “best practice” on the basis of available studies. The timing of each Dose delivery depends on a number of factors; however, the first Dose of the program needs to take place within the first two weeks of the baby’s life before the baby’s crying increases. For example, a maternity delivery setting is ideal because it is universal, meaning most babies are delivered at hospitals. Home visiting programs, pediatric well baby visits and public health, to name a few, have also been a good fit for Dose One.

### **Delivery:** Parent Presentation and Providing the Program Materials to Families:

In short, the following steps are ideal:

- Go through the booklet, page by page, with parent(s) pointing out the important messages:
  - PURPLE Acronym
  - Early Increased Crying is Normal
  - Ways to Comfort Your Crying Baby
  - Important Action Steps
  - Why Crying is Frustrating
  - Why Shaking a Baby is Dangerous
  - Be Sure to Tell others
- In a non-threatening way, as parent(s) to describe in their own words what they think are the important *PURPLE* program messages, or describe what they may say when they share the program with others. It is recommended that the professional(s) teaching the program use the “[TeachBack](#)” model that asks the parent to repeat back what they believe the important messages are. This way the person delivering the materials knows if the parent(s) have really understood the correct messages.
- Tell parent(s) that there are two videos for the program. The first video is about the *Period of PURPLE Crying* and the second video offers specific ways to soothe their baby and strategies for coping when soothing doesn’t work.
- The *PURPLE* program video should be shown to the parent(s), whenever possible, following the presentation of the booklet
  - The provider can leave the room while the *PURPLE* video is playing, but should return shortly after to answer any questions.
- Provide the parent(s) with the *PURPLE* program materials and encourage them to review the materials again and to share the information with others who cares for their baby
  - The activation code for the web and mobile application can be used on up to five personal devices and is available for nine months after activation.
- Allow an opportunity for parents to ask questions

- **Prenatal and other classes for parents** can be offered; however, if these are optional, poor attendance can occur. An advantage of classes is that presenters can take the time to organize a longer presentation, answer questions and show the video(s). The NCSBS has complementary visual aids for these class situations. Additional materials for demonstration purposes are also available for purchase through the NCSBS including a life size doll and an audio CD of infant crying. This method is helpful but not universal and it is better to use it as an enhancement option rather than the only method of distribution.

### **Dose Two: Reinforcing the Message**

Public health nurses, home visitors, pediatricians, family doctors or public health clinics should 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) should provide materials to parents who were missed and did not receive the *PURPLE* program materials at the hospital after having their baby. It is important not to duplicate the materials in the distribution process as, ideally, most parents should have received the materials at their birthing hospital. If the program materials are not being distributed through the hospital then home visiting, prenatal and postnatal programs and/or public health departments are ideal for Dose One if they have contact with the parents within the first two-weeks after the baby is born. These health care professionals need to comply with the Dose One training and distribution requirements that the maternity nurses use, outlined above.

Other groups who serve parents should be specifically targeted to facilitate complete community coverage about the *Period of PURPLE Crying* program messages. Pediatricians, family practice physicians, childcare providers, foster care workers, midwives, nurse help line personnel, hot line personnel, emergency room personnel and others serving parents should be given the opportunity to receive training on the *Period of PURPLE Crying* program. This will ensure that the parents get the same information wherever they go for help and advice.

**Delivery:** Reminding parents about program messages and resources.

In short, the following steps are ideal:

1. Ask parent(s) if they received the *PURPLE* materials and education after the birth of their baby
  - a. If parent(s) responds, “yes”, continue into Dose Two reinforcement
  - b. If parent responds, “no”, follow the Dose One delivery described above
2. Remind parents:
  - Infant crying is normal in the first 4-5 months
  - Crying increases at about 2 weeks, peaks at 2-3 months and declines by 5 months
  - Some normal babies may cry as long as 5 hours a day, some less
  - Call your doctor if you are worried about the crying
  - Shaking is very dangerous, can cause brain damage and even death
  - If the crying becomes too frustrating, put your infant in a safe place, walk away and take a break for 5-10 minutes. And remember, the second video provided offers advice about ways to soothe your baby
  - Be sure to tell everyone who cares for your infant about the *Period of PURPLE Crying* program

### **Dose Three: Public Education and Media Campaign**

A public education campaign provides this information to everyone, and especially to all those who did not receive it through the previous two methods. This is an important part of bringing about a cultural change in our understanding of the normality of early increased crying, as it is necessary to educate grandmothers, temporary caregivers, significant others, neighbors and relatives about the *Period of PURPLE Crying*. Understanding of the *Period of PURPLE Crying* among the general population can help ease the stress, and even criticism, of parents dealing with the inconsolable crying. It also enables mothers and fathers to receive support and reinforcement from those who understand the *Period of PURPLE Crying* concept. A public education campaign, including ads and a user’s guide, downloadable at no cost are available from the NCSBS to those communities implementing the *PURPLE* program in their jurisdiction.

# Training Requirements

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The NCSBS recognizes the limited time available for managers to educate providers and for providers to educate parents. With these time limitations in mind, the online training modules were developed for fast and efficient use and are provided at no cost. The NCSBS coordinates a unique account for each implemented organization to log on to as many times as necessary to train existing and new staff.

## Recommended staff training procedures for the *PURPLE* program's Dose One and Two:

- Read the *Period of PURPLE Crying* program Protocol for Implementation (this document);
- Watch the 10-minute *PURPLE Crying* Video and read the 10-page *PURPLE* booklet;
  - Recommended: watch the 17-minute *Crying, Soothing, Coping: Doing what Comes Naturally* video
- Watch the narrated "Lines of Evidence and Rationale for the *Period of PURPLE Crying*" presentation
- Take and pass the 10 question quiz
- Complete "Feedback Form 1"

## Other supplemental tools located on the training module:

- Program Overview, Implementation Protocol, Fidelity Agreement, FAQs for parents, FAQs for Professionals, 3-Minute Talking Points, 10-Minute Talking Points, Reinforcement Talking Points, TeachBack, Dose 1 and Dose 2 Checklists, Dose 2 Materials, etc.
- 17-minute soothing video titled *Crying, Soothing, and Coping : Doing What Comes Naturally*
- How to Access the *PURPLE* Program App Presentation

## Dose Three: Public Education Campaign

As described above in the triple dose strategy, a public education campaign helps disseminate *PURPLE* program messages to society generally. It is available upon request and is at no cost. The components listed below are part of a media tool kit with additional items continuously being added as developed:

- Normal [campaign] Print Advertisement (various sizes)
- 30 and 60-second radio Public Service Announcements (PSAs)
- 5, 10, and 30 second video Public Service Announcements (PSAs)
- Outdoor Ads

## In-Service Training

In some areas NCSBS personnel are able to go directly to provide training. Arrangements and special circumstances will be given full consideration upon request. In other cases, a provider educator from the implementing organization needs to be trained to deliver the training presentation to other staff. If this is the case then the NCSBS will provide a "train the trainer" session online or in-person (if possible) to prepare the appropriate person.

## Parent website

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This *PURPLE* program website ([PURPLEcrying.info](http://PURPLEcrying.info)) was designed for parents and conveys information in a unique and easy to understand format. It is very different from most other child development websites in that:

1. It is based on scientific studies,
2. The articles are written by authors who are the leading experts in their field,
3. It is designed to be a comfortable place for parents and caregivers to get more information about their baby, especially the baby who is crying a lot, and
4. It is interactive with short videos and lots of images throughout. Parents will be directed to the website through public education campaigns and on the *PURPLE* program materials they get at the hospital.

# Fidelity Agreement

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For the purpose of program fidelity, the NCSBS asks all Dose One: Delivery partners to sign and return a Fidelity Agreement after reading this Implementation Protocol. It is not intended to be a legally binding document, but rather a good faith measure to ensure that the program is being implemented per the evidence-based model.

The Fidelity Agreement outlines the training and support that comes with the purchase of the *PURPLE* program. It also asks that the Dose One organization agree to provide each family with their own copy of the program materials to take home and share with anyone else who will be caring for their infant. Please read and sign the [Fidelity Agreement](#).

- Fax to: (801) 447-9364
- Email to: [PURPLE@dontshake.org](mailto:PURPLE@dontshake.org)

## Conclusion

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The NCSBS is very proud to offer this evidence based program to hospital personnel, home visitors and others serving parents of new babies. It is our intent to make it easy to offer and affordable. The only cost associated with this program is the cost of the program materials. The NCSBS recognizes that hospitals and other organizations have limited budgets for many educational programs. That is why the cost for this program is as low as \$2 a family. Everything else is complimentary. We feel it is very important that this program be complimentary to parents so that all families can benefit from it. It has been designed to be attractive to parents, user friendly, economical and evidence based. The NCSBS has invested many years of development and testing, and millions of dollars to offer this program to other jurisdictions. It is our goal to make it easy to use, affordable and a program that both parents and professionals find desirable and valuable.

### Ongoing Consultation and Support

The NCSBS *PURPLE* program staff is available to guide organizations through the implementation process, provide full access to complimentary online staff training, and keep a shared Fidelity Agreement on file stating an understanding of the program protocol, purchasing procedures, program updates, ongoing support and overall guidance.

### Assistance with Fundraising Strategies

The NCSBS developed a grant template for the *PURPLE* program with the research, lines of evidence and program development information for organizations seeking funding support. The information in the template was designed to be copied and pasted into grant applications found by the participating organization seeking funding. The template is shared upon request from *PURPLE* program staff.

### Contact Us

For assistance with the *PURPLE* program, contact the NCSBS by email at [PURPLE@dontshake.org](mailto:PURPLE@dontshake.org), visit the website at [www.dontshake.org](http://www.dontshake.org), call the Center at 801-447-9360 or write to 1433 North 1075 West Suite #110, Farmington, Utah, 84025.