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The above letter was referred to the author of the article in question, who offers the following reply.

### **Response: Re: Parental Acceptance of a Mandatory Human Papillomavirus (HPV) Vaccination Program**

*To the Editor:* We appreciate the comments from Dr. Schneider<sup>1</sup> and concur with her observations about the human papillomavirus vaccines. It seems that German health care providers are confronted with many of the same issues we face in the United States. Given the robust efficacy and excellent safety profile of these cancer prevention vaccines, we too are extremely frustrated by the poor rates of vaccination that are documented in many parts of the world. Furthermore, a high number of individuals do not complete the entire 3-dose series. There is great room for improvement to help reduce the morbidity and mortality associated with human papillomavirus infection. A mandatory HPV vaccination program is one means of ensuring maximum coverage and protection.<sup>2</sup> All health care providers should encourage their patients to receive the vaccine. Dr Schneider's comments about making the vaccines widely available to all inhabitants of our globe are certainly appropriate. My response actually comes from our cervical cancer prevention clinic in Cusco, Peru ([www.theincca.org](http://www.theincca.org), [www.cervicusco.org](http://www.cervicusco.org)) where we see women with cervical cancer too often. To think that we now have a vaccine to prevent the horrid suffering associated with cervical cancer is simply a wonderful gift to mankind. Although secondary cervical cancer prevention efforts with cervical cytology have reduced the rates of disease, particularly in developed countries, the developing world does not have the capacity to derive the same benefits. Yet, I believe this same gift of life-saving vaccination will be shared with all one day. In fact, Merck, Sharp and Dohme Corp. has been very generous in sharing their vaccine with the developing world. We are extremely grateful to them and hope that this effort can be expanded in the future.

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### **Re: A Randomized, Controlled Trial of a Behavioral Intervention to Reduce Crying among Infants**

*To the Editor:* I applaud McRury and Zolotor<sup>1</sup> for attempting to add a validation study of The Happiest Baby on the Block (THB) video to the growing evidence base evaluating this popular approach to calming babies.

Unfortunately, as the authors state, their study has several critical flaws that weaken any conclusions. There was a small study population and a 30% drop-out rate; there was contamination by advising both the control and intervention group about the use of swaddling; a video was used instead of a digital video disc (DVD; a more user-friendly interface); and parents received no instruction in THB video techniques. The factor that most undermined the reliability of this report is that there was little confidence that the intervention was even viewed or used (mothers said they watched, but they did not refer to THB video in their comments and did not swaddle as was demonstrated in the video).

THB<sup>2,3</sup> is a novel synthesis of several steps that have been shown to calm infant crying and promote sleep. It is based on the hypothesis that babies are born with a suite of previously overlooked neonatal reflexes (the “calming reflex”) that can quickly soothe most fussing during the first months of life.

The goal of finding an effective approach to crying reduction is not trivial. Infant irritability, and the parental exhaustion that it provokes, are primary triggers for many serious problems (eg, child abuse, failure of breastfeeding, marital stress, postpartum depression, excessive visits to an emergency room or doctor, excessive treatment for acid reflux, disturbed bonding, and perhaps sudden infant death syndrome/suffocation).<sup>4</sup>

Numerous peer-reviewed studies<sup>4</sup> have confirmed the effectiveness of the interventions used in THB video (ie, swaddling, white noise, rhythmic motion, sucking). In addition, a growing body of pilot studies is finding benefits of THB video on early parent–infant interactions.

In 2007, the Department of Public Health in Boulder, CO, reported a study about reducing infant crying. Home-visiting nurses taught THB techniques to 42 at-risk families (teens, drug users, etc) who had fussy babies. Each family was given a THB DVD, compact disc of white noise, and a swaddling blanket. Most families (41 of the 42) reported an immediate, dramatic, and continuing improvement in their ability to calm crying. Many families also reported more than one additional hour of sleep.<sup>5</sup>

A recent randomized controlled trial, funded by the National Institute of Health, was done at Penn State University.<sup>6</sup> Nurses taught THB techniques to breastfeeding mothers and gave each a THB DVD, a white noise compact disc, and a swaddling blanket. Intervention babies slept an extra ½ to 1 hour per night ( $P < .05$ ).

A University of Arizona survey ( $n = 225$ ) showed THB classes significantly boosted parental reports of self-efficacy ( $P < .001$ ). Before the class, 40% of expectant parents reported moderate, marked insecurity about being able to calm their baby's crying. After the class that dropped to 0.5%.<sup>7</sup>

Today, more than 2000 certified educators teach THB techniques in hospitals and clinics across the United States (including more than 1000 educators in the departments of health of Pennsylvania, Minnesota, Wyoming, Connecticut, and Massachusetts and in numerous regional shaken baby prevention programs). Another 2000 educators are currently in training.

The need to discover an effective intervention to reduce infant crying is especially pressing in light of the recent failure of the highly promoted anti-Shaken Baby Syndrome intervention, Period of PURPLE Crying.<sup>8</sup> In a large randomized controlled trial, babies whose parents were taught PURPLE reported a 10% increase in irritability. That is of great concern because crying is a primary risk factor for Shaken Baby Syndrome.

Although McRury and Zolotor's<sup>1</sup> study is seriously flawed, other well-designed studies are being planned and conducted to evaluate THB techniques. Hopefully they will yield sufficient information to allow further evaluation of this approach.

Simple, scalable, inexpensive interventions that can reduce infant crying are urgently needed to spare human suffering and reduce the billions of dollars of expenditures resulting from the numerous serious health risks that this stressful experience can trigger.

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*Conflict of Interest:* The author developed The Happiest Baby video and profits from the sale of books and DVDs.

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The above letter was referred to the author of the article in question, who offers the following reply.

## Response: Re: A Randomized, Controlled Trial of a Behavioral Intervention to Reduce Crying among Infants

*To the Editor:* We appreciate the thoughtful letter written by Dr. Karp<sup>1</sup> in response to the recent randomized controlled trial of The Happiest Baby on the Block (THB) video techniques,<sup>2</sup> a proprietary program which he has designed.<sup>3</sup>

We find his critiques mostly fair and fully acknowledged in our publication. Early trials of new interventions are often small and subject to the risk of a type II error. However, small trials can help identify unforeseen consequences and determine the appropriate sample size for larger trials. The only significant finding of the article was that mothers in the intervention group reported more stress at 12 weeks compared with parents in the control group ( $P = .01$ ).<sup>2</sup> There was a tendency toward more crying by the babies in the intervention group at every time point (ie,  $P = .04$  at 8 weeks), but this did not reach our a priori level of statistical significance.<sup>2</sup> Given that this study showed more crying at every time point among babies whose mothers received the THB video intervention, these findings are not useful for supporting a larger trial of THB techniques as delivered.

A drop out rate of 30% is a concern, but not out of the ordinary. We did compare participants that remained to those that dropped out and found little important difference.

We are puzzled by Dr. Karp's concern about contamination. We did not advise mothers in the control group to swaddle their babies. Many mothers in both groups reported the use of swaddling, bouncing, swinging, and pacifiers to calm their babies. It is possible that an intervention such as THB technique will be of little use if such behaviors are either culturally normative or hard wired.

We appreciate Dr. Karp's concern about the lack of “use” of the intervention. This is akin to the ever-present