Supplemental Written Information Improves Prenatal Counseling: A Randomized Trial

**Authors:** Anbu Durai Muthusamy, MD, Steven Leuthner, MD, MA, Charlene Gaebler-Uhing, MD, MHPE, Raymond G. Hoffmann, PhD, Shun-Hwa Li, PhD, and Mir Abdul Basir, MD, MS

**Affiliations:**
- Scott and White Healthcare, Temple, Texas
- Medical College of Wisconsin, Milwaukee, Wisconsin

**Key Words:** counseling, communication, parent, premature infant, physician

**Abbreviation:**
- STAI—State-Trait Anxiety Inventory

Dr Muthusamy contributed to the study design, data collection, analysis, and writing of the manuscript; Drs Leuthner and Gaebler-Uhing contributed to study design and writing of the manuscript; Drs Hoffman and Li contributed to study design and data analysis; and Dr Basir is the principal investigator and contributed to the study design, data collection, analysis, and writing of the manuscript.

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Address correspondence to Mir Abdul Basir, MD, Medical College of Wisconsin, CCC 410, 8701 Watertown Plank Rd, Milwaukee, WI 53226. E-mail: mbasir@mcw.edu

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**What’s Known on This Subject:** During prenatal counseling for prematurity, information is provided to expectant parents to empower them to participate in the medical-care decision-making regarding their child. However, numerous studies have shown that providing information effectively during preterm labor is challenging.

**What This Study Adds:** The current study provides evidence that effectiveness of counseling can be improved by providing written information to parents before the face-to-face verbal counseling. Appropriately presented, detailed information improves knowledge and decreases maternal anxiety.

**Abstract**

**Objective:** To determine if maternal knowledge of prematurity is improved when verbal gestational age-specific counseling is supplemented with written gestational age-specific information.

**Methods:** Prospective, randomized study of 60 pregnant participants assessed to be at risk for premature delivery between 23 and 34 weeks gestation. Counseling in the control group consisted of gestational age-specific verbal information, and counseling in the intervention group consisted of written gestational age-specific information 1 hour before the verbal gestational age-specific information. Both groups completed a Prematurity Knowledge Questionnaire after counseling and the State-Trait Anxiety Inventory before and after counseling. The Prematurity Knowledge Questionnaire consisted of questions regarding short-term problems (immature lungs, intraventricular hemorrhage, retinopathy, feeding problems, infection, apnea, and jaundice), long-term problems (chronic lung disease, postdischarge respiratory infections, visual impairment, hearing impairment, brain damage, and learning and behavior problems), and numerical outcome data (probabilities of survival, survival without significant morbidity, severe intraventricular hemorrhage, severe retinopathy, and chronic lung disease).

**Results:** Knowledge of short-term problems was not statistically different between the intervention (82%) and control groups (67%). Knowledge of long-term problems was better in the intervention (71%) than the control group (45%). Knowledge of numerical data was better in the intervention (48%) than the control group (29%). State-Trait Anxiety Inventory scores decreased after counseling in the intervention group.

**Conclusions:** Supplementation of face-to-face verbal counseling with written information improved knowledge of long-term problems and knowledge of numerical outcome data, and it also decreased anxiety in women expecting a premature delivery. Pediatrics 2012;129:e1269–e1274
Knowledge of problems and outcomes of premature infants is necessary for women with threatened premature delivery to make informed medical-care decisions regarding mode of birth, neonatal resuscitation, and neonatal intensive care. Previous studies have shown that it is challenging to provide complex information effectively to women in preterm labor. Maternal factors specifically related to threatened preterm delivery that contribute to this challenge include stress, anxiety, pain, influence of medications such as magnesium sulfate, and teenage pregnancies. Low health literacy of the general population and, specifically, poor knowledge of prematurity increase the challenge.

The American Academy of Pediatrics Committee on Fetus and Newborn recognizes the need to improve communication of complex neonatal outcome information to parents expecting a premature delivery. Kaempf et al recommended providing written information to parents during prenatal counseling. No studies have measured the effectiveness of providing written information to improve knowledge of problems of prematurity in women with threatened premature delivery, and no studies have been conducted to determine what effect this knowledge may have regarding a woman’s anxiety.

A prospective, randomized trial was designed to study the hypothesis that providing gestational age–specific written information for review before face-to-face verbal counseling will improve knowledge of problems and complications of prematurity in women admitted with threatened preterm delivery and will not increase anxiety.

**METHODS**

**Subjects and Institutional Review Board Approval**

The study was conducted in 2 area hospitals between April 2009 and December 2009. Both hospitals have labor and delivery units and level 3 NICUs. The institutional review boards of the respective hospitals approved the study.

**Inclusion Criteria**

Eligible participants included ≥18-year-old English-speaking pregnant women of all ethnic groups admitted to labor and delivery between 23 and 34 weeks’ gestation who were assessed by the obstetrician to warrant counseling for prematurity by a neonatal medical professional.

**Exclusion Criteria**

Pregnancies with known birth defects were excluded, because counseling may differ in these situations. Participants who gave birth before completion of the study were excluded because after delivery they are likely to be exposed to additional sources of information. Participants who were approached for study enrollment during a previous admission were also excluded.

**Gestational Age–Specific Written Information**

Written information was prepared for each gestational week from 23 to 34 weeks. Information was compiled at the lowest reading level possible, which was difficult with the use of medical terms. A previous study has shown that a reading level less than ninth grade is acceptable. The final handout was written at an 8.6-grade reading level and was 5 to 7 pages in length. It contained information on parental rights to refuse NICU treatment, delivery room care and resuscitation, anticipated problems, common treatments and complications, anticipated residual morbidities, and incidence rates of select problems. On each page, space was provided for the participants to write down any questions that they may have wanted to ask during the face-to-face verbal counseling. The last page of each handout consisted of a data sheet that summarized the gestational age–specific survival rate and incidence rates of common short- and long-term problems. The information included in the written handout was obtained from neonatal text books, Vermont Oxford Neonatal Network data, and National Institute of Child Health and Human Development data. To standardize information presented to all participants during verbal counseling, the counselors were asked to reference the handouts before their face-to-face meeting with the parents. In addition, the counselors carried pocket cards with similar gestational age–specific outcome data.

**Parental Knowledge Questionnaire**

A 54-item postcounseling questionnaire was designed to assess parental knowledge of problems of prematurity. The content was based on the American Academy of Pediatrics Clinical Report, which outlines recommended information that parents expecting a premature infant should know, which includes gestational age–specific problems of prematurity, common treatments, and complications. Participants were asked to respond in a yes/no/don’t-know format to indicate if a specific problem, treatment, or complication would apply to their infant. In addition, participants were instructed to write a number indicating the probability of 7 select outcomes to assess their knowledge of these occurrences. The Parental Knowledge Questionnaire was tested for readability, face validity, and content validity by a sample of neonatal intensive care parents, nurses, and physicians. If needed, study personnel could help participants read the questionnaire or write down answers provided by the participants. The participants were told not to refer to the written handout while answering the questionnaire.
State-Trait Anxiety Inventory

The State-Trait Anxiety Inventory (STAI) is validated in pregnant women and used in several studies to detect change in state of anxiety. Each participant's general level of anxiety (ie, state) was assessed by answering 20 short questions that required 5 minutes to complete. A lower score indicates less anxiety.

Study Design

A study flow diagram is shown in Fig 1. Study personnel were notified when a prenatal consult was requested. If study eligibility requirements were met and consent provided by the parents, the neonatal charge nurse determined the study assignment by opening the next consecutively numbered opaque envelope containing the assignment slip. Randomization was computer-generated. Study instruments were administered by the study personnel. Study personnel did not counsel any of the participants. This was an open label study.

Statistical Methods and Data Analysis

In a previous study (submitted for publication) using a similar questionnaire, we found knowledge of long-term outcomes after face-to-face verbal counseling to be 52%. Sample size was calculated to detect a 20% difference in knowledge. To achieve power of 90% and \( \alpha \) of .05, sample size was calculated as 30 participants in each group. Vermont Oxford Neonatal Network outcome data were used as the standard to assess the 7 items requiring knowledge of numerical data. To not be too stringent on the participants’ memory, answers in \( \pm 20\% \) range were accepted as correct responses. The items requiring yes/no/don’t know responses were assessed based on general neonatal knowledge. The “don’t know” response was assessed as an incorrect response.

Categorical variables were analyzed by using \( \chi^2 \) or Fisher exact tests. Continuous variables were analyzed by using \( t \) test, \( t \) tests with log-transformed variables, or nonparametric Mann-Whitney, as appropriate. Paired \( t \) test was used to compare preintervention and post-intervention STAI scores.

RESULTS

Women who presented to labor and delivery and in whom a prenatal consult was requested were screened and consented until the goal of 30 participants in each arm was reached (Fig 2). Participant characteristics are shown in Table 1. The gestational age distribution for study participants was similar in each group. Maternal knowledge of short-term problems is listed in Table 2. Overall, 68% of the participants in the control group and 82% of the participants in the intervention group had knowledge of gestational age—specific short-term problems after counseling; this difference was not statistically significant. Maternal knowledge of long-term problems is shown in Table 3. Overall, 47% of the participants in the
TABLE 1 Baseline Characteristics of Study Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control(^a)</th>
<th>Intervention(^b)</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age (wk), mean ± SD</td>
<td>30 ± 0.5</td>
<td>30 ± 0.5</td>
<td>NS(^c)</td>
</tr>
<tr>
<td>Maternal age (y), mean ± SD</td>
<td>28 ± 1</td>
<td>28 ± 1</td>
<td>NS(^d)</td>
</tr>
<tr>
<td>Married, %</td>
<td>53</td>
<td>50</td>
<td>NS(^e)</td>
</tr>
<tr>
<td>Education, %</td>
<td>≤ High school</td>
<td>20</td>
<td>33</td>
</tr>
<tr>
<td>Maternal Race, %</td>
<td>White</td>
<td>70</td>
<td>60</td>
</tr>
<tr>
<td>Health Insurance, %</td>
<td>Uninsured</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Primigravida, %</td>
<td>White</td>
<td>40</td>
<td>27</td>
</tr>
<tr>
<td>Previous preterm infant, %</td>
<td>13</td>
<td>23</td>
<td>NS(^j)</td>
</tr>
<tr>
<td>Magnesium sulfate/opioids, %</td>
<td>43</td>
<td>40</td>
<td>NS(^k)</td>
</tr>
<tr>
<td>Counselor, %</td>
<td>Attending</td>
<td>7</td>
<td>10</td>
</tr>
</tbody>
</table>
| NNP, neonatal nurse practitioner; NS, not significant. \(^a\) Control group, received only verbal counseling. \(^b\) Intervention group, received written information before verbal counseling. \(^c\) Mann-Whitney test. \(^d\) \(t\)-test. \(^e\) \(x^2\) test. \(^f\) Fisher's exact test.

Recall of Incidence Rates: Percentage of Correct Responses After Counseling

<table>
<thead>
<tr>
<th>Problems</th>
<th>Control Group, n = 30</th>
<th>Intervention Group, n = 30</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premature lungs</td>
<td>20</td>
<td>53(^*)</td>
<td></td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>3</td>
<td>30(^*)</td>
<td></td>
</tr>
<tr>
<td>Brain bleed</td>
<td>10</td>
<td>37(^*)</td>
<td></td>
</tr>
<tr>
<td>Retinopathy</td>
<td>17</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>20</td>
<td>47(^*)</td>
<td></td>
</tr>
<tr>
<td>Survival to discharge</td>
<td>83</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>No significant morbidity</td>
<td>52</td>
<td>58</td>
<td></td>
</tr>
</tbody>
</table>

* \(P < .05\).

Fifty-one percent of all participants did not report using any other source of information, others reported getting information from the Internet (20%), books (15%), family or friends (15%), and television (5%). Twenty-seven percent of the participants reported that labor and delivery nurses or the obstetrician provided them with the most information regarding premature infants.

**DISCUSSION**

The current study shows that face-to-face counseling supplemented with the simple and inexpensive intervention of providing written information to women with threatened premature delivery improves both maternal knowledge of long-term outcome and recall of incidence rates. Interestingly, provision of detailed written information helped to reduce maternal anxiety. These findings support the practice of supplementing verbal face-to-face counseling with written information. It is important to realize that more than half of the participants reported the counseling to be their only source of information regarding outcome of premature infants, and 27% reported a member of the obstetric team as the person who gave them the most information regarding prematurity.
The ethical principle of autonomy suggests that patients should always be fully informed, and most physicians in the United States value this principle. However, there are circumstances when physicians consciously or unconsciously withhold information from patients. In the setting of threatened preterm delivery, the barriers that may result in provision of limited information to the parents by the clinician include lack of established patient-counselor relationship, concern that too much information may increase anxiety and reduce clarity, time constraints of the counselor, patient-counselor race discordance, and avoidance of controversial aspects of care. Providing predetermined gestational age–specific written information can to some extent help overcome some of these barriers. In the current study, participants who received written information had more knowledge of long-term outcomes and better recall of incidence rates even though they were not allowed to reference the materials as they completed the questionnaire. Knowledge in both of these domains is important for decision-making and enhances autonomy. There was an improvement trend in the knowledge of short-term outcomes in the intervention group; however, the change did not reach significance. This is likely due to a type 2 error, and a larger sample size is needed to evaluate the effect of written information on short-term outcomes. Although it is beyond the scope of this study to assess decision-making, one would imagine in clinical implementation that parents would repeatedly reference their gestational age–specific written handouts as they were faced with making decisions, thus potentially providing a greater impact than that appreciated in this study.

Kemp et al studied the psychological impact of parental antenatal counseling for prenatally diagnosed surgical anomalies; they used the STAI to identify a significant decrease in the parental median anxiety score after counseling. In the current study, the change was measured from the preintervention anxiety score in each participant; a significant decrease was found in those who received written information. It is encouraging that appropriately provided and more detailed information did not increase the psychological burden of the mothers. Uncertainty is known to lead to emotional distress and a sense of loss of control. Uncertainty occurs when one perceives treatment and outcome as random and unpredictable. Uncertainty is an important burden for the parents with a threatened preterm delivery. It is possible that the information contained in the written handout helped the women better manage uncertainty, leading to less anxiety. In very low birth weight infants, controlling for maternal education and neonatal morbidity, early maternal anxiety has been shown to be a significant and independent predictor of cognitive development at 24 months of age.

It has been recognized that magnesium sulfate therapy affects attention and working memory in women undergoing preterm labor. In the current study, 43% of the women admitted with threatened preterm delivery received magnesium sulfate. The study was not designed to look at the effectiveness of written information in this subgroup; however, the trend of data suggest that this mode of supplementing information may not be as effective in this subgroup of patients because they have difficulty reading the written information. This significant subgroup identifies the need for additional study to determine if education on preterm deliveries should occur as part of high-risk obstetrical care or if there may be other educational tools to consider in this group.

**CONCLUSIONS**

Supplementing verbal face-to-face counseling with gestational age-specific written information is an effective method to improve transfer of information to women with threatened preterm delivery. Addition of written information improves knowledge of long-term outcome and numerical outcome data, and, after counseling, it decreases maternal anxiety.

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