

Development and Validation of Educational Leaflet for Caregivers of Preterm Infants

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ABSTRACT

Introduction: Facilitation of child development is usually emphasized in the form of early intervention classes and practical demonstrations. However, non-adherence to home program for such interventions has been reported due to various reasons.

Aim: To develop and validate an educational leaflet as a supplement guide for caregivers to promote better development of their child during 4-6 months of age.

Materials and Methods: An in-depth literature review and focus group discussion with the experts was conducted to formulate the content of leaflet. Initial framework consisted of introduction, main text with pictorial representation and instructions about facilitation of various milestones, do's-don'ts and disclaimer. Validation was done through a questionnaire consisting of 9 questions pertaining to completeness, understandability, legibility, clarity and utility of educational material for caregivers and a section for comments. Leaflet with enclosed questionnaire was distributed to 14 validators (2 neonatologists, 4 paediatricians and 8 physiotherapists), along with a covering letter

stating the purpose and relevance of this educational material, and the importance of their participation in validation process. Scoring was done on 5 point Likert scale for each item in the material.

Results: Responses from the 14 evaluators were collected and analysed. Item level content validity index (I-CVI) was calculated for individual items which ranged from 0.73 – 1. Scale level Content Validity Index (S-CVI) was calculated for complete nine items and it was found to be 0.91. Validators expressed their views to include a column on normal milestones across 4-6 months of age and also to highlight the significance of performing each activity mentioned in the leaflet. These suggestions were incorporated in consensus with the subject experts and the final draft was made.

Conclusion: Educational leaflet for caregivers of 4-6 months preterm infants has been developed and validated. It can be provided as a supplement guide to the caregivers to facilitate better development of their child.

Keywords: Handout, Milestones, Pamphlets

INTRODUCTION

Recent technological advances and the collaborative efforts of obstetricians and neonatologists have brought a profound increase in the rate and survival of premature births. According to a World Health Organization (WHO) report, approximately 15 million children are born prematurely every year worldwide [1]. Recent trends have revealed that majority of preterm births takes place in moderate (32^{0/7} – 33^{6/7} weeks) and late preterm (34^{0/6} day to 36 week^{6/7} days) category [2]. India, contributes its highest share of moderate to late preterm births to global statistics, entailing to approximately 85% of total preterm births [1,2].

Moderate to Late Preterm (MLP) infants often look equivalent in size and weight of full term peers, but they are biologically immature with underdeveloped organs, especially lungs and brain [3]. Traditionally, these MLP infants were considered as fully developed and were managed like full term babies [4,5]. However recently, it has been reported that these infants belong to a low risk category and the short and long term complications suffered by them cannot be undermined [5]. Late preterm infants are at 3 times higher risk of developing cerebral palsy, 1.5 times more likely to develop intellectual disabilities, commonly diagnosed with developmental co-ordination disorder, behavioural problems, mental retardation and psychological disturbances as compared to full term babies [6,7]. In order to minimize the risks of these complications and its consequences, these babies would need to be kept under continuous surveillance and should be referred for early intervention services if necessary.

Early Intervention (EI) services to promote the overall development of these premature infants are predominantly provided by physiotherapists in India. These services can be initiated as early as Neonatal Intensive Care Unit (NICU) phase and are available at private hospitals in major cities. NICU intervention services at an early stage are proved to be effective, still there is a considerable controversy about the effect of these services at a later stage on the development of preterm infants [8]. In spite of their availability, barriers are noted in terms of accessibility to these services [9]. In a developing country like India, affordability, low accessibility to higher tertiary care centers, lack of insurance coverage, lacking technology and low literacy levels of caregivers are few of the obvious barriers.

Due to the low socioeconomic status of caregivers they are not able to receive these services in hospital settings and lower literacy levels further increases the problem of comprehension of verbal information provided by the healthcare provider [10]. Thus it becomes extremely important to train and educate the caregivers and involve them as active participants in the rehabilitation of their child. Caregivers can be facilitated about the developmental programs through verbal instructions, practical demonstrations, written format, audiovisual resources, computer technology etc., [11]. Studies have documented that verbal teachings and discussions are the least effective teaching strategies for patient education as they can produce a recall of only 14% of the spoken medical instructions provided by the healthcare provider [12-14]. A study done by Houts et al., showed that written information

along with illustrations can be an effective teaching strategy for caregivers' especially from low literacy population [15].

According to Census 2011, Indian literacy rate is 74% but the health literacy level is very low [16]. In a study done by UPR and Belman M et al., to determine the status of health literacy in South India, they found that 77% of the recruited population scored less than 61 scores on REALM Questionnaire which indicates reading skills at or below 7th or 8th grade [17]. Hence the need arises for such a service system which can be understood in local language and can be delivered in their home settings without much professional involvement. Keeping this into consideration, present study was aimed at development and validation of an educational leaflet for the caregivers of MLP infants in English as well as local (Kannada) Language. Its main purpose was to impart knowledge and educate caregivers that simple developmental activities can positively stimulate motor, visual, auditory and vestibular systems of the baby thus leading to better development of their child.

MATERIALS AND METHODS

Preliminary Collection of Content of Educational Handout

An initial content of the leaflet was generated through in-depth literature review. The literature review focused on exploring the already available educational material for MLP infants and need for more contribution in this context. Input from the experts were taken into account for generating the material, on the basis of their day to day clinical practice and caregivers' ability to read, comprehend and perform activities on their child.

Handout Design

Literature review revealed a necessity of educational material to enhance the retention and recall of home program provided to the caregivers. Information regarding the development of infants in these months, vulnerabilities of preterm infants to develop complications and activities on how to promote optimum development were retrieved from the literature. Discussions were carried out with the experts (two physiotherapists, one paediatrician and one neonatologist) who had a minimum experience of 10 years. Framework was divided into four headings (introduction, main text with pictorial representation, do's-don'ts and disclaimer) to extract the age appropriate developmental content. A thorough analysis of each and every activity was done to identify what is expected from a pictorial representation is communicated to the caregivers. Voluntary participants consenting to be photographed in the educational material were identified after explaining in detail about the information regarding public distribution of leaflet. Following this, a written consent was taken to avoid any future conflicts. The photographs were captured using a digital camera. The best photograph for the educational handout was selected by experts after reviewing several photographs for inclusion in the leaflet. The criteria for sorting the photographs was kept in such a way that it should be a best match with the content and should give minimum distraction to the caregiver. It underwent several revisions and resulted in the pre-final draft with the following sections:

- **Introduction:** This section clearly explains the parents about the purpose and utility of leaflet. It also ensures the caregivers that all the activities will be demonstrated to them by physical therapist before handing them the educational material.
- **Main text:** This section constitutes 13 activities with pictorial representation and written instructions about facilitation of global development of their child across 4-6 months of age. While planning, activities were designed to concentrate on all areas -cognitive, motor, language and social milestones without focusing specifically on anyone. Red flags like inability

to make eye contact, scissoring, tightness etc. were also included at the end of this section.

- **Do's and Don'ts:** A general section on the Do's and Don'ts related to promoting general development and safety measures were also included to provide simple but important information especially for lower literacy caregivers.
- **Disclaimer:** This last section of the leaflet was made to inform caregivers that it is a supplement guide and is not a substitute for physical therapist. Moreover, they should not underestimate or overestimate their child's development.

Parents were provided information with the exact address of the hospital, department and contact number of the person to contact, in case of any doubts regarding the educational material or the developmental status of their child.

Assessment of Content Validity

This pre-final draft was sent for content validity to experts. It was a two-stage process requiring validation in the developmental and judgment-quantification stages [18]. During the developmental stage, a panel of four experts including two physiotherapists, a paediatrician and a neonatologist validated the accuracy of information presented and ability to comprehend according to caregivers' point of view.

Judgment-quantification stage of content validation involved validation of both the content of the items and the entire instrument [19]. Rating scales were sent to 14 validators. The panel of experts were having the relevant training, experience and qualification for this validation. Experts were selected from different fields to make the educational material more user friendly and to cater the needs of caregivers appropriately. The panel received specific instructions to determine the content relevance of specific items and of the leaflet as a whole. Validation was done through a questionnaire consisting of 9 items pertaining to completeness, understandability, legibility, clarity and utility of educational material for caregivers and a section for comments. Questionnaire was distributed to - 14 validators (2 neonatologists, 4 paediatricians and 8 physiotherapists), along with a covering letter stating the purpose of this educational material, the reason why they have been chosen for validation and the importance of their participation in validating the educational material. Scoring was based on 5 point likert scale. Results were quantified by applying the Content Validity Index (CVI) [20,21].

Translation & parallel back translation: Standard procedure was followed for translation into local language to enhance its utility and acceptability by local population [22]. After completing the content validity, this leaflet was translated into local language (Kannada) by two independent persons with fluency in both the languages i.e., Kannada and English. Both the versions were discussed with the involvement of third person with bilingual expertise to resolve any identified discrepancies or ambiguity of words. After reaching the final consensus, one single version was prepared. This final copy was sent to another person who was completely blinded for the study to translate it back to English (original language). Once parallel back translation was done, an expert committee meeting consisting of translators, language experts, physiotherapist and paediatrician were held to consolidate the final form with equivalence in both the versions i.e., English and Kannada.

RESULTS

Fourteen responses were collected and analysed. The number of experts required to validate were arbitrary, depending upon the requirement of the educational content, its scope and area of utility and convenience to get a response. Two neonatologists, four paediatricians and eight physiotherapists studied the leaflet and rated the items in the questionnaire. Experts included for validation

had a minimum experience of 3 years with a maximum ranging to 15-20 years in neonatology, clinical paediatrics and physical therapy. Four items were completely agreed by all validators (Q1, Q4, Q7, Q9), whereas remaining 5 items were agreed by about 75% of them (Q2, Q3, Q5, Q6, Q8). 4 questions (Q2, Q5, Q6, Q8) showed a mild disagreement (7% - 15%) and three items (Q2, Q3, Q5) had a neutral opinion (6%-20%) among the validators. Item level content validity index (I-CVI) was calculated for individual items which ranged from 0.73 – 1 and Scale level Content Validity (S-CVI) was calculated for complete nine items and it was found to be 0.91. S-CVI should be minimum 0.80 to be acceptable as content valid [Table/Fig-1] [12,13].

Questions	Item Level Content Validity Index (I-CVI)
Q1. This pamphlet is presented in a simple and understandable language	1
Q2. This pamphlet provides information to the parents about development of their child across 4-6 month of age	0.73
Q3. Introduction column in pamphlet explains about the utility and purpose of the pamphlet	0.80
Q4. Images presented in the pamphlet are legible and clear	1
Q5. Sequence of photos is acceptable for 4 month - 6 month development of a baby	0.86
Q6. Instructions on how to play with the child and at the same time encouraging development are made simple and clear	0.93
Q7. Do's and Don'ts are informative	1
Q8. Conclusion column informs and explain the warning signs about child development clearly	0.93
Q9. This pamphlet serves the objective of guiding and encouraging 4-6 months development of a baby	1
Scale Content Validity Index (S-CVI) = Average of I-CI	8.25/9 = 0.91

[Table/Fig-1]: Items and content validation of an educational handout. Rating scale to assess the completeness, comprehensibility, legibility, clarity and utility of educational material. S-CVI was found to be > 0.80 thus the content of educational leaflet is acceptable.

Validators expressed their views to include a column on expected normal developmental milestones across 4-6 months of age. They also gave comments to highlight the importance of performing each activity mentioned in the educational leaflet. These suggestions were incorporated in consensus with the subject experts in final version of educational leaflet.

DISCUSSION

The objective of the present study was to develop and validate an educational leaflet for caregivers of preterm infants. Literature has reported that educating patients and providing them with structured written information leaflets can enhance the probability that important information will be better attended to, understood, accepted and recalled [23]. Thus the present study was designed with the purpose to educate the caregivers about home program for early intervention services and encourage their active participation in promoting better development of their child.

The present study involved validators from different specialties and while selecting the panel of experts their qualification, training, experience, publication, presentations and research interests were taken into consideration. This was done in consensus with American Psychological Association guidelines which emphasize that these aspects should be considered to make the material more authenticated and operational for target population [24]. Content validation of our study showed I-CVI more than 0.80 for all the items in the questionnaire except item - 2 (I-CVI= 0.70). This item interviewed the validators regarding availability of adequate information to the caregivers about normal development of child across 4-6 months of age. Maximum number of validators

found inadequacy and expressed their views to add a section on the expected normal development across 4-6 months of age. Therefore a table was added on the first page to provide information about the same in the educational leaflet. This was done in line with previous studies which states that awareness of caregivers/parents about their child development is very crucial and it influences their expectations and interactions with their child [25,26].

Another area where experts highlighted the lacunae was lack of clarity on emphasizing each developmental activity in the leaflet. Thus we modified the leaflet to convey information in a simple language regarding the importance of each developmental activity and its effect on motor, sensory, visual, vestibular or auditory development of the child. Understanding the basis for developmental activity enhances the parental participation in promoting normal growth [27]. This is in consensus with previous studies which state that parental perception about the need to participate in infant's care and support is utmost for successful implementation of any home program [28].

In our tertiary care hospital, EI services are provided as a routine care throughout the length of hospital stay and even at follow up. However, non-adherence to home program has always been a major issue. This is in line with previous studies which have documented the non-compliance rate of 30-80 percent [29]. Non-compliance can be attributed to inability to recall and remember the verbal information provided by the healthcare provider, on contrary, if verbal instructions are accompanied with a written format consisting of pictorial representation, the level of recall can be raised to 85% [14]. Written information with pictorial representation improves the comprehension, recall and adherence of health education information, especially patients with low literacy skills, as it helps them to understand the abstract information in a much easier way [15]. Thus considering the above recommendations we have developed this educational leaflet, it will be a good tool to improve adherence to home program. Moreover, the availability of leaflet in local language will further enhance its opportunity to reach to grass root level. This is in line with the previous studies which have shown that providing patients with well-designed information leaflets improves patients' acceptance and satisfaction [30].

In our educational leaflet we made it very clear to the parents that educational handout is an adjunct which contains simplified information. Leaflet is not a substitute for a therapist and caregivers should not pass it on to others by themselves. This is in consensus with the previous studies which states that handouts are not all inclusive, they are supplement guides and should be properly discussed with parents to ensure that they have understood its complete purpose [31].

Present study is a part of ongoing study. Future research will be done to assess the efficacy of this educational handout on improving the adherence to home program and the development of these, for moderate to late preterm infants using pre and post measurement in target population.

CONCLUSION

To the best of our knowledge, there is no published caregiver educational leaflet to promote development of MLP infants. Hence, an educational material covering information regarding the development across 4-6 month of age, activities with pictorial representation on how to promote development and red flags can be extremely useful in this subset. Major advantage of this leaflet is that since MLP belongs to a low risk category so they won't require therapist supervised intervention services, parents can very well play an important role and can report to the therapist if any red flags found.

REFERENCES

- [1] Althabe F, Howson CP, Kinney M, Lawn J, World Health Organization. Born too soon: the global action report on preterm birth [Internet]. 2012 [cited 2015 Oct 21]. Available from: http://www.who.int/pmnch/media/news/2012/201204_borntoosoon-report.pdf
- [2] Blencowe H, Cousens S, Oestergaard MZ, Chou D, Moller A-B, Narwal R, et al. National, regional, and worldwide estimates of preterm birth rates in the year 2010 with time trends since 1990 for selected countries: a systematic analysis and implications. *The Lancet*. 2012;379(9832):2162–72.
- [3] de Jong M, Verhoeven M, van Baar AL. School outcome, cognitive functioning, and behaviour problems in moderate and late preterm children and adults: A review. *Semin Fetal Neonatal Med*. 2012;17(3):163–69.
- [4] Gouyon J-B, Iacobelli S, Ferdynus C, Bonsante F. Neonatal problems of late and moderate preterm infants. *Semin Fetal Neonatal Med*. 2012;17(3):146–52.
- [5] Loftin RW, Habli M, Snyder CC, Cormier CM, Lewis DF, DeFranco EA. Late preterm birth. *Rev Obstet Gynecol*. 2010;3(1):10.
- [6] Petrini JR, Dias T, McCormick MC, Massolo ML, Green NS, Escobar GJ. Increased risk of adverse neurological development for late preterm infants. *J Paediatr*. 2009;154(2):169–76.
- [7] Moster D, Lie RT, Markestad T. Long-term medical and social consequences of preterm birth. *N Engl J Med*. 2008;359(3):262–73.
- [8] Spittle A, Orton J, Anderson P, Boyd R, Doyle LW. Early developmental intervention programmes post-hospital discharge to prevent motor and cognitive impairments in preterm infants. *Cochrane Libr* [Internet]. 2012 [cited 2015 Oct 21]; Available from: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005495.pub3/full>
- [9] Maring J, Croarkin E, Morgan S, Plack M. Perceived effectiveness and barriers to physical therapy services for families and children with friedreich ataxia. *Paediatr Phys Ther*. 2013;25(3):305–13.
- [10] McCarthy DM, Waite KR, Curtis LM, Engel KG, Baker DW, Wolf MS. What did the doctor say? health literacy and recall of medical instructions. *Med Care*. 2012;50(4):277–82.
- [11] Friedman AJ, Cosby R, Boyko S, Hatton-Bauer J, Turnbull G. Effective teaching strategies and methods of delivery for patient education: a systematic review and practice guideline recommendations. *J Cancer Educ*. 2011;26(1):12–21.
- [12] Johnson A, Sandford J. Written and verbal information versus verbal information only for patients being discharged from acute hospital settings to home: systematic review. *Health Educ Res*. 2005;20(4):423–29.
- [13] Theis SL, Johnson JH. Strategies for teaching patients: a meta-analysis. *Clin Nurse Spec CNS*. 1995;9(2):100–5. 120.
- [14] Houts PS, Witmer JT, Egeth HE, Loscalzo MJ, Zabora JR. Using pictographs to enhance recall of spoken medical instructions II. *Patient Educ Couns*. 2001; 43(3):231–42.
- [15] Houts PS, Doak CC, Doak LG, Loscalzo MJ. The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence. *Patient Educ Couns*. 2006;61(2):173–90.
- [16] Ranking of States and Union Territories by literacy rate. Available from: http://censusindia.gov.in/2011-prov-results/data_files/india/Final_PPT_2011_chapter6.pdf
- [17] Kamath A. Evaluation of health literacy status among patients in a tertiary care hospital in coastal Karnataka, India. *J Clin Diagn Res* 2013;7(11):2551-54.
- [18] Leininger M. Culture care theory: A major contribution to advance transcultural nursing knowledge and practices. *J Transcult Nurs*. 2002;13(3):189–92.
- [19] Lynn MR. Determination and quantification of content validity. *Nurs Res*. 1986;35(6):382–85.
- [20] Davis LL. Instrument review: Getting the most from a panel of experts. *Appl Nurs Res*. 1992;5(4):194–97.
- [21] Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health*. 2006;29(5):489–97.
- [22] Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine*. 2000;25(24):3186–91.
- [23] Morris LA, Halperin JA. Effects of written drug information on patient knowledge and compliance: a literature review. *Am J Public Health*. 1979;69(1):47–52.
- [24] Hambleton RK, Arrasmith G, Sheehan DS, Grobe RP, Hathaway W, Doherty V, et al. Standards for educational and psychological testing: six reviews. association aer, association ap, education nc on m in, editors. *J Educ Meas*. 1986;23(1):83–98.
- [25] Reich S. What do mothers know? Maternal knowledge of child development. *Infant Ment Health J*. 2005;26(2):143–56.
- [26] Stevens JH. Child development knowledge and parenting skills. *Fam Relat*. 1984;33(2):237.
- [27] Gravem D, Lakes KD, Teran L, Rich J, Cooper D, Oishansky E. Maternal perceptions of infant exercise in the neonatal intensive care unit. *J Obstet Gynecol Neonatal Nurs JOGNN NAACOG*. 2009;38(5):527–33.
- [28] Dusing SC, Van Drew CM, Brown SE. Instituting parent education practices in the neonatal intensive care unit: an administrative case report of practice evaluation and statewide action. *Phys Ther*. 2012;92(7):967–75.
- [29] Marston MV. Compliance with medical regimens: a review of the literature. *Nurs Res*. 1970;19(4):312–23.
- [30] Gibbs S, Waters WE, George CF. Prescription information leaflets: a national survey. *J R Soc Med*. 1990;83(5):292–97.
- [31] Garcia M, Chismark EA, Mosby T, Day SW. Development and validation of a nutritional education pamphlet for low literacy paediatric oncology caregivers in Central America. *J Cancer Educ Off J Am Assoc Cancer Educ*. 2010;25(4):512–17.

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