

## A methodological study to develop standard operational protocol for feeding preterm neonates with expressed breast milk

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### ABSTRACT

**Objectives:** The objectives of this study were to assess the current practices, to identify barriers and facilitators for feeding preterm neonates with expressed breast milk (EBM), and to develop standard operational protocol (SOP) and checklist for feeding preterm neonates with EBM. **Materials and Methods:** The methodological research design was used in the present study, and it was conducted in a tertiary level neonatal unit, North India. Sample population was nursing staff, preterm neonates, and their mothers, admitted in neonatal unit. To enroll nursing staff and preterm neonates, total enumeration sampling technique was used, whereas purposive sampling technique was used to select mothers of preterm neonates. Research project was carried out in five phases. **Results:** After assessment of the current practices, focus group discussions were conducted with nursing staff and mothers to know the barriers and facilitators. Findings of discussions were used to develop SOP and checklists. Three Delphi rounds were conducted to finalize the content and calculate content validity index (CVI). After the 3<sup>rd</sup> round, the CVI was 0.99 for SOP and 1.00 for checklists. Cronbach's alpha for the checklist on health education to mother on EBM feeding and technique of milk expression was 0.723 and 0.740, respectively. **Conclusion:** This study provided valid SOP and checklists on feeding preterm neonates with EBM.

**Key words:** Content validity index, Neonatal unit, Standard operational protocol

Preterm neonates include babies who are born alive before 37 weeks of pregnancy [1]. Among them, the babies born between 32 and 36 weeks, 28–31 weeks, and <28 weeks are referred as mild preterm, very preterm, and extremely preterm, respectively [2]. These preterm babies have a wide variety of limitation associated with their premature birth. The preterm babies who are born before 32 weeks of gestation have difficulty in coordinating suck and swallow reflex and are at increased risk of aspiration. Their morbidity and mortality were enhanced by respiratory distress, necrotizing enterocolitis, shock, hypoglycemia, hypothermia, and infection. In addition to that, preterm babies require mechanical ventilation that interferes with normal feeding pattern and this further complicates their situation. This is the reason that preterm babies require intensive supervision and careful administration of nutrition-related interventions. Henceforth, need was felt to develop a standard operational protocol (SOP) for feeding preterm neonates with expressed breast milk (EBM) with an aim to provide guidelines for nursing staff and to improve the practice of EBM feeding in neonatal unit of tertiary hospital.

Focus group discussions (FGDs) conducted with staff and mothers revealed that there are many barriers related to the expression of breast milk and feeding of a preterm baby with EBM. The barriers include difficulty in tracking the mother

of neonates admitted in neonatal intensive care unit (NICU)/step-down nursery, nonexistence of SOP for feeding preterm neonates with EBM, lack of knowledge among mothers related to importance of colostrum and breast milk in preterm neonates, and lack of standard teaching content for nurses to teach the mothers how to express breast milk and how milk output decreases due to increased level of stress and decreased rest period as verbally reported by mothers. The mothers further reported that 2 hourly and many of them hourly milk expression schedules make them to exert as they have to come to NICU/nursery many a times in a day.

### MATERIALS AND METHODS

SOP for feeding preterm neonates was developed by adopting methodological research design in neonatal unit, tertiary care unit, North India. Ethical clearance was obtained from the ethical committee of institute. The research project was carried out in five phases.

The first phase (preparation phase) involves assessment of current practices regarding feeding preterm neonates with EBM. Preparation phase was completed in four steps. First step was the assessment of information and current practices related to the expression of breast milk among mothers, second was audit

for EBM feeding, third step was assessment of feeding details of preterm neonates, and fourth step was to conduct FGDs with nursing staff and mothers to know barriers and facilitators of feeding preterm neonates with EBM. On the basis of findings of current practices, SOP and checklists were developed.

The second phase (validation phase) includes the content validity of SOP and checklists. The Delphi technique was used. A panel of committee experts was formulated from the fields of obstetrics, gynecology, pediatric, and nursing. The content validity index (CVI) of SOP and checklists was 0.99 and 1.00, respectively.

In the third phase (pilot study), feasibility of protocol was assessed by conducting a pilot study. Sample was bedside nurses and mothers of preterm. Sample was selected using purposive sampling technique, and the sample size was 5 in number. Results of the pilot study conclude that developed research protocol for feeding preterm neonates with EBM was complete, feasible, and practicable. The language and sequence of the content were clear and easy to understand and implement.

In the fourth phase (training phase), bedside nurses were trained with developed SOP using lecture cum discussion and Mamma breast to teach the technique of breast milk expression. The sample was bedside nurses and mothers of preterm. Sample was selected using purposive sampling technique, and the sample size was 5 in number. This phase was conducted to see whether the developed research protocol was complete, feasible, and practicable and the language and sequence of the content were clear and easy to understand and implement.

In the fifth phase (checking the reliability), reliability was calculated using Cronbach's alpha on the data collected by tryout using protocol and checklists. These data were collected by observation of nursing staff with the help of observational checklist at time of health education. Mothers were also observed for technique of breast milk expression with the help of observational checklist. SPSS (version-20) was used to analyze the data. Internal consistency of the checklists was checked by calculating Cronbach's alpha.

## RESULTS

Table 1a-c depicts that there were a total of 34 items in the technique of breast milk expression checklist. The overall Cronbach's alpha value of checklist developed in current study was calculated as 0.723, and the item score to total correlation was between 0.2 and 0.81, whereas for few item, the item score to total correlation was <0.2 showing their incompatibility with overall tool. When the individual item was deleted, Cronbach's alpha value of the most of items did not increase except for 10 items. When results were discussed with Delphi Panellists, they were agreed to retain these points as all of them were essential.

Table 2 depicts that the overall Cronbach's alpha value of checklist developed in the current study was 0.740 and the item score to total correlation was between 0.2 and 0.71. However, for few items, the item score to total correlation was <0.2, showing their incompatibility with overall tool. When the individual item

was deleted, Cronbach's alpha value of the most of items did not increase that meant all items were internally consistent and contributed to the total reliability of checklist, but the value for four items increased when that individual item was deleted. It indicates that item was not contributing to the total reliability of tool and could be discarded. When results were discussed with Delphi Panellists, they were agreed to retain these points as these are important points.

## DISCUSSION

SOP is a set of written guidelines to ensure uniformity in the procedures performed by health-care professionals. SOP explains the material required, purposes, and steps of procedure [3]. In addition to this, they reduce the error, improve professional skills, reduce variation, and increase the efficiency services [4]. Every hospital should have a SOP for all the nursing procedures and there were no such guidelines in our hospital; henceforth, the current study has been taken up to develop SOP for feeding preterm neonates with EBM.

FGD is a process, to gather people from same background and experience with the purpose to discuss specific topic [5]. It can provide insight into the issues, perspectives, and attitude of people and generate hypothesis that cannot be identified by observation [6,7]. A number of discussions depend on the point of saturation means conducting the discussions until the point where no new information is gained [8]. Size of group for FGD should be between 6 and 12 people [9]. In the present study, saturation occurred after 16 discussions with nursing staff and after 4 discussions with mothers. In each FGD, only 4–6 members per discussion were included as more nurses could not spare time altogether in any area of neonatal unit. In most of the studies conducted to develop SOP, the same technique has been adopted [10-12].

The validity of SOP and checklist was established by item CVI. According to Lynn, in case of 5 or fewer experts, all experts must be agree (CVI-1.00), but if there are more than 5 experts, the modest amount of disagreement is acceptable, (CVI-0.83) [13]. In the present study, the calculated CVI of protocol and checklists is 0.99 and 1, respectively, which indicates that individual item is valid. Another methodological study conducted by Kumar *et al.* to develop a protocol on drug administration for children calculated CVI 99.7% [10]. A study "nursing care protocol for patients with a ventricular assist device" Machado *et al.* considered item relevant with CVI >0.75 [14]. A study by Santos *et al.* "validation of nursing care protocol for patients undergoing palliative care" estimated CVI 0.9 [15].

Reliability is the measure of the consistency of recorded observations. Reliability of checklists was established by Cronbach's alpha. In the present study, the value of Cronbach's alpha for observational checklists on health education for mother on EBM feeding and technique of breast milk expression was 0.72 and 0.74, respectively. Similar findings were reported by Bandana *et al.* on internal consistency of "audit tool." An audit tool was developed for auditing the family health records; the

**Table 1: Reliability of observation checklist for health education to mother on EBM feeding**

Item	Scale mean if item deleted	Corrected item- total correlation	Cronbach's Alpha - if item deleted
Importance of colostrum			
It is easy to digestion	20.50	-0.043*	0.731
Prepares digestive system	20.50	0.088*	0.724
Protect baby against respiratory infections such as pneumonia, bronchitis, as well as stomach and ear infections	20.45	0.027*	0.725
Reduces the chances of jaundice	20.45	-0.326*	0.738
Helps for growth and development of preterm neonates	20.45	0.209	0.719
Provides energy required by baby's growing body	20.55	-0.297*	0.747
Essential for the growth of baby's nervous system	20.65	0.099*	0.727
Enabling baby to sleep longer	21.30	0.285	0.714
Strategies to support EBM feeding			
Manual expression of breast milk	21.10	-0.424*	0.764
Inform feeding plan of neonate	20.70	0.690	0.680
Skin-to-skin contact	20.75	0.764	0.672
Adequate rest	20.80	0.815	0.666
Technique of expression of breast milk			
Before expressing breast milk			
Wash your hands with soap and water	-	-	-
Use boiled utensils for collection of milk	20.50	0.044*	0.726
Calm and relax at time of milk expression	-	-	-
Spend 20-30 min for full expression	20.65	0.454	0.701
Method of back rub	20.45	0.270	0.717
Preparation of articles			
Select wide mouth katories	20.75	0.601	0.687
Wash katori with water and soap	20.45	0.087	0.723
Immerse katori in water	20.75	-0.075*	0.741
Bring to the boil and continue to boil rapidly for 20 min uninterrupted	20.75	-0.75*	0.741
Take out katori from water with Cheatle Forceps	20.65	0.099*	0.727
Procedure of milk expression			
Wash hands	21.30	0.285	0.715
Hot fomentation	21.10	-0.424*	0.764
Massage of breasts			
Rolling	20.70	0.690	0.680
Striking	20.75	0.764	0.672
Shaking	20.80	0.815	0.666
Sit comfortably and lean forward	-	-	-
Hand formed the letter "C"	20.50	0.044*	0.726
Finger pads are at 6 and 12 o'clock in line with the nipple	-	-	-
Position fingers over the milk reservoirs on breast (half to one inches above areola)	20.65	0.454	0.701
Keep fingers together	20.45	0.270	0.717
Press thumb and index finger directly back into the breast tissue, into the wall of the chest	0.75	0.601	0.687
Repeat these steps at all parts of the breast	20.45	0.087*	0.723

Overall scale mean is 21.40, overall reliability is 0.723 (standardized Cronbach's alpha), \*Items in the tool which shows item to total correlation < 0.2

internal consistency of the tool was checked with Cronbach's alpha coefficient. Value of alpha was 0.73 which indicated the reliability of the protocol [16]. In another methodological study to develop protocol on drug administration for children, by Kumar

*et al.*, the value of alpha 0.96 was calculated [10]. Similarly in a methodological study to develop protocol regarding specific nursing procedures, Rani A *et al.* (2016) also reported increased value of chronbach's alpha 0.81, 0.85, 0.84 [11].

**Table 2: Reliability of observational checklist for technique of breast milk expression**

Item	Scale mean if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Preparation of articles			
Selected wide mouth bowl (Katori)	13.20	0.168*	0.738
Bowl (Katori) washed with soap under running water	13.22	-0.080*	0.730
Bowl (Katori) immersed in water for boiling	13.16	0.008*	0.744
Boiled for 20 min uninterrupted	13.16	-0.190*	0.750
Cheatle's Forceps is being used to take Katori from container	13.16	0.058*	0.742
Procedure of milk expression			
Preparation of milk expression			
Hands washed	13.20	-0.215*	0.735
Hands dried with sterile tissue paper	13.38	-0.184*	0.728
Hot fomentation is done for 2-3 min	14.06	0.232	0.735
Breast cleaned with wet cotton	13.82	-0.221*	0.783
Massaging of breast is being done by			
Rolling	13.54	0.626	0.693
Striking	13.62	0.651	0.689
Shaking	13.66	0.656	0.689
Hand/manual expression of breast milk			
Sit up and leaned forward	13.22	0.716	0.704
Hand formed the letter "C"	13.30	0.478	0.714
Finger pads are at 6 and 12 o'clock in line with nipple	13.22	0.716	0.704
Fingers are positioned over the milk reservoirs on breast (half to one inches above areola)	13.42	0.473	0.712
Fingers kept together	13.26	0.667	0.701
Thumb and index finger pressed directly back into the breast tissue, into the wall of the chest	13.58	0.529	0.705
Steps repeated at all parts of the breast	13.34	0.499	0.711

Overall scale mean is 14.14, overall reliability is 0.740 (standardized Cronbach's alpha), \*items in the tool which shows item to total correlation < 0.2

Kaur *et al.* studied the reliability of developed birth preparedness tool. The value of Cronbach's alpha of their tool was 0.81 which determined the reliability of the tool [12]. Another study by wood was on the development of "initial psychometric evaluation of patient perspective of arrhythmia questionnaire" [17]. In this study, Cronbach's alpha coefficient was used which was 0.84 that determines the internal consistency of the tool. Similarly, in a study on reliability and validity of "sexual pressure scale for women," Jones *et al.* also used Cronbach's alpha to find the internal consistency of their tool and value of alpha was 0.88 which suggested the reliability of tool [18]. In a methodological study by Kaur *et al.* on the development of nursing checklist for cardiac catheterization, the value of Cronbach's alpha was 0.86 [19]. Katz *et al.* reported almost similar findings on the internal consistency of "the dynamic occupational therapy cognitive assessment for children" [20]. The reported alpha value was 0.77. Benson and Koomar also reported Cronbach's alpha similar findings [21]. They assessed the internal consistency of the "gravitational insecurity," and the alpha value was 0.71. Alpha was developed by Lee Cronbach in 1951 to provide a measure of the internal consistency of test or scale, and the value of Cronbach's alpha ranges from 0 to 1. Items with zero variance should be deleted. Higher value of Cronbach's alpha indicates the high correlation

between items and value of Cronbach's alpha 0.70 or greater is acceptable [22].

In the current study, for most of the items, the value of Cronbach's alpha did not increase when individual item was deleted which means that all items were internally consistent and were contributing to total reliability of the checklists, whereas in some items, the value of Chronbach's alpha increased when individual item was deleted. It indicated that these items were not contributing to the total reliability of tool and could be discarded. When the results were discussed with Delphi panellists, all members suggested that all items in checklists were important and should be retained; therefore, these items were not deleted. Iso reported an increased value of Cronbach's alpha when few items were deleted, and they also retained these items in tool as those were basic points of tool [10-12, 16].

Hence, a valid and feasible SOP for feeding preterm neonates with EBM along with valid and reliable checklist to assess the implementation of SOP was developed. The SOP in the form of booklet and pamphlet was made available for ready references to nurses in neonatal unit, tertiary level hospital, North India. Posters of milk expression technique and daily activity schedule of mothers were being displayed in all areas neonatal unit. It is recommended to use this SOP as daily routine to give health

education to mothers for feeding preterm neonates with EBM, admitted in neonatal unit. It is recommended for supervisors to assess the implementation of SOP by using checklists.

## CONCLUSION

We developed a valid and feasible SOP for feeding preterm neonates with EBM along with valid and reliable checklist to assess the implementation of SOP. The SOP in the form of booklet and pamphlet was made available for ready references to nurses in neonatal unit. It is recommended to use this SOP as daily routine to give health education to mothers for feeding preterm neonates with EBM, admitted in neonatal unit.

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