A MIXED METHOD APPROACH TO DEVELOP AND VALIDATE A MULTIDISCIPLINARY FRAMEWORK FOR EVALUATION OF BARRIERS AND FACILITATORS TO AWARENESS, IMPLEMENTATION, INITIATION AND CONTINUITY OF EXCLUSIVE, BREASTFEEDING IN NEWBORN STAGE IN SAUDI ARABIA

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Abstract

Background: Exclusive breastfeeding has been a major international health initiative as regulated and launched by the World Health Organization and UNICEF since 1992. As a vital component of the reproductive process, exclusivity in breastfeeding for at least 6 months has shown implications for the well-being of the infants as well as the mothers. It has been observed that in Saudi Arabia, few hospital new born units practice exclusive breast feeding leading to design a well-structured approach in solving issues and concerns. As such, still there is no strong and unique multidisciplinary theoretical framework with a family-centred service delivery and sustainable quality health outcome philosophy seen in the hospitals in the country. Aim: This study aims to provide a more efficient multidisciplinary research method for collecting and analyzing both quantitative and qualitative focus group data in developing and validating a framework to evaluate the barriers and facilitators to awareness, implementation, initiation and continuation of exclusive breastfeeding practices in new born stage in Saudi Arabia. Methods: Quantitative-qualitative research methods were utilized to design and validate a framework for barriers and facilitators to exclusive breastfeeding. For the quantitative methods, previously published multidisciplinary international standards, guidelines and evidence based research and practice were reviewed, analyzed, tabulated and coded into systems, constructs and themes resulting in 257 comprehensive items. A coding criteria and ranking was used for validating the framework. The developed framework was validated by six session's focus groups of

multidisciplinary experts in the fields of speech pathology, rehabilitation, pediatrics, neonatology, obstetrics and nursing for consensus' verification and re-verification of the classifications and codes of the pre-classified framework. Another team of co-researchers re-read, reviewed and reclassified the focus group re-verification data with > 90% reliability. Results: A focused and quantifiable consensus and validation was obtained from the focus groups discussions. Focus groups consensus revealed a high (> 85%) content validity and reliability. All statements in each category were rated from 9 to 10 as highly important. The literature referenced pre-determined framework and coding criteria helped focus group participants and researchers to design and focus a valid standard framework with modification of less than 15% of the original. Conclusion: This study provides a validated mixed methodology in medical research to design and validate frameworks with results informing modification of the framework and identification and organization of appropriate exclusive breast feeding constructs and themes. Establishing a framework is hoped to lead to the development of tools to evaluate barriers and facilitators to breastfeeding to sustain the nutritional needs of the infant and likewise the health of the mother. Utilization of the mixed method design is recommended as a focused and efficient research tool to elicit process and validate reliable data.

Keywords: mixed research design, quantitative-qualitative, focus group, exclusive breastfeeding, mother-child-health care.

1 INTRODUCTION

Exclusive breastfeeding has been a major international health initiative as regulated and launched by the World Health Organization (WHO) and UNICEF since 1992. As a vital component of the reproductive process, exclusivity in breastfeeding for at least 6 months has shown implications for the wellbeing of the infants as well as the mothers. Breastfeeding is an integrated process as the source of nutritional secretion by the mother and intake by the new born; it is a mechanical process where the mother learns how to feed her new born and the new born needs to develop how to suck and swallow and breathe. As a physiological process, both the mother and new born benefit from breastfeeding to regulate their body functions. As for the new born, breastfeeding supports her neurodevelopmental and neurobehavioral growth. It is a family centered function as well as community involved, and at a macro level breastfeeding has a socioeconomic impact as a national health issue. Hence, a multidisciplinary approach is best fit to examine this health issue.

It has been observed that in Saudi Arabia, few hospital new born units practice exclusive breastfeeding. Factors and environment that establish breastfeeding at healthcare settings were inconsistent with several gaps. AlJuaid and others (2014) in a review study reported that "there is insufficient data available on breastfeeding in Saudi Arabia to monitor progress and develop promotion programs. The WHO does not report any breastfeeding data in the country profile because there are no national data on breastfeeding." (p.12) According to AlJuaid and others (2014), most studies about breastfeeding in Saudi Arabia were incomplete, inconsistent and lack research uniformity. Breastfeeding has declined to half in the last 25 years (AlJuaid, et.al, 2014). This observation leads to design a well-structured approach in solving issues and concerns. As such, still there is no strong and unique multidisciplinary theoretical framework with a family-centred service delivery and sustainable quality health outcome philosophy seen in the hospitals in the country.

The concept of this project arises from the great need of mothers and babies in the local community for better care. To provide an improved standardized and regulated care, according to international standards that is measurable and evaluated for improvement and sustainability, a scientific approach is required to evaluate the status quo of this issue and assess the needs. A review of the international models and standards of mother-baby health care as well as factors and characteristics of breast feeding is part of the study framework. Data from both sources provide a good designed model that is verified by sound methodologies to provide a valid and reliable best fit model for mother-baby health care.

This study reports results of the first phase of the research about validating a multidisciplinary framework with mixed quantitative-qualitative method. At this phase, the study focuses on the end of the trimester and the first month of the new born to establish factors facilitating or hindering breast feeding.

1.1 Breastfeeding factors and characteristics for programs

A significant part of a breastfeeding framework is the program established for service delivery at a healthcare setting. Several factors and characteristics were reviewed that were considered based on the literature important to include in a program. Programs may be divided into two: a program for the mother and one for the neonate.

1.1.1 The Mother Program

Based on the mother program literature review, the multidisciplinary team collected all constructs and themes necessary toward the development of a framework from several sources. According to the literature reviews of the mother program relevant factors and characteristics were noted, such as quality of the program specifically accreditation and strategic plan. Another factor is administration of a program including vision, mission, objectives, policies and procedures. In a program, evidence-based practice and evidence based outcome is considered as a main theme. Patients' registries and documentation are necessary factors in a program. Multidisciplinary team approach is an effective characteristic of a program. Health Education with the main theme of family centered support is necessary features of a program framework. The midwife/nurse and the family play as a key role in the support, encouragement, assistance and education of new mothers in relation to breastfeeding. Also, health professionals should possess the appropriate information on lactation methods and its mechanisms, including skills to help women solve problems associated with breastfeeding after birth and helping to increase the lactation rates among these mothers. The practice of breastfeeding should be encouraged and suggestions should be given to ensure the mother is comfortable with breastfeeding and is able to do so correctly. Health professionals, including obstetricians, midwives, nurses and lactation consultants should make new mothers aware of skin-to-skin contact and early bonding resulting to commencement of breastfeeding. It is also important that mothers are aware of lactation strategies to promote self-confidence and that fathers are encouraged to help mothers care for the baby. WHO and UNICEF recommend breastfeeding exclusively for the six months post-birth to promote infant health, development and growth, after which breastfeeding should be supplemented with appropriate food until the child is 2 years of age. It is recommended not to allow the use of bottles, teats or pacifiers. However, despite the benefits of breastfeeding and the support from practitioners the rate of breastfeeding remains low which has a negative health impact in both developed and developing countries (Imdad, Yakoob & Bhutta, 2011, WHO 2011). Breastfeeding has a number of advantages such as reducing the risk of postpartum haemorrhage, faster uterine involution and faster weight loss of the mother after delivery, especially caesarean (CS) mothers (Erlandsson, Dsilna, Fagerberg & Christensson, 2007). According to WHO 2014, it is obvious that early sucking for a baby, whether by vaginal or caesarean delivery (CS), is a key factor in the longer duration of lactation, which is recommended for at least from 1 to 6 months. Also, most medical organizations and public health hospitals, with the WHO, the Obstetricians and Gynaecologists Associations and the American Academy of Paediatrics documented the benefits of long-term breastfeeding for women who had had either a vaginal and caesarean delivery, recommend breastfeeding be initiated immediately after birth as well as to be continued for at least six months (Maternal and Child Health Journal, 2010, WHO 2011). In general, women who have had a normal or a CS delivery show low rates of breastfeeding. Thus, to enhance breastfeeding rates, women who delivered may be a target group for increased education and support. To improve the duration of breastfeeding, researchers have suggested that health professionals need to clarify and manage the factors that affect the self-efficacy of breastfeeding. However, no evidence has been identified as to whether increased breastfeeding self-efficacy among mothers who have had a normal birth and CS delivery would increase and improve breastfeeding outcomes (McQueen, 2009). According to the Baby-friendly Hospital Initiative (BFHI) that was launched in 1992 and concerned to support breastfeeding and to strengthen maternity practices, the "Steps to Successful Breastfeeding" served as a foundation for the BFHI. This initiative has been documented, evidenced and summarized in its effectiveness within the scientific review (WHO 1998). The Australian Breastfeeding Association (ABA) is a community breastfeeding service and Australia's leading source of support and information for breastfeeding mothers. The ABA is an association of people intensive to protect and promote breastfeeding (Towle, 2009, ABA 2012). This group includes breastfeeding mothers; fathers; and health professionals-for example, physicians, lactation consultants, health practitioners, and midwives. The ABA was established in 1964 in Melbourne, Victoria as the Nursing Mothers' Association (ABA, 2007). It is supported by specialists in the health and nutrition of new born infants and children, and by a health organization, involving a panel of the ABA voluntary counsellors. The aim of this service is to provide mother-to-mother support and breastfeeding resources, and to promote babies' and mothers' health and well-being in Australia. Its values are to support breastfeeding mother-to-mother, to promote a love of parenting; to increase qualification and innovativeness for breastfeeding education; to protect mothers and babies wellbeing; cooperative teamwork-based values, obvious principles, respect and honesty during communication (ABA, 2012). The skin-to-skin contact and bonding immediately after birth shows a positive impact from the mother's or father's perceptions of their infant's crying behaviors, suckling and rooting. This technique can facilitate breastfeeding behavior. In addition, babies who receive immediate breastfeeding and experience skin-to-skin contact are protected from many health issues such as physiological jaundice, hypoglycaemia and will have a better immune system (Erlandsson, Dsilna, Fagerberg & Christensson,

2007). Hence, it is clear that the relationship between the mother and her newborn immediately after a birth, including attachment, skin-to-skin care will be closer if she is given assistance to breastfeed immediately after birth (Kuguoglu, Yildiz, Tanir & Demirbag, 2012). Also, studies have shown that fathers' support has an impact on initiation, exclusivity and continuity of breastfeeding (Mitchell-Box and Braun, 2013). With the aforementioned constructs, supporting literatures and studies were searched to make it valid for preparing the framework for the mother's program.

1.1.2 The Neonate Program

Neonate program factors and characteristics inductive of breastfeeding were reviewed across international and national accredited organizations (e.g. Joint Commission International (JCI, 2016) and Central Board for Accreditation of Healthcare institutions (2016) (CIBAHI). One of the main factors of quality of a program is measured by whether the program is accredited by international and national health organizations. Compliance with Baby-Friendly Hospital Initiative (BFHI) is also an important factor (UNICEF, 1993). Use of breastfeeding definitions consistent with World Health Organization (WHO) terminology or the American Academy of Pediatrics (AAP) is a crucial feature of a program (AlJuaid, et.al. 2014) with verified and consistent translation into Arabic. A program should have a clear mission and measureable objectives that assures outcome measurements of breastfeeding (e.g. the Academy of Breastfeeding Medicine, 2014; AAP, 2016; JCI, 2016). Existing and updated internal policy and procedures that standardize health care of breastfeeding is a fundamental feature of a program where guidelines, procedures and roles and responsibilities are well defined and evaluated for continuous improvement. A crucial factor of a neonate program is patient registries and documentation for optimal service and quality improvement. Staff education and training on evidence based neonate health care, such as neurodevelopment, is a fundamental factor for clinical care efficiency (e.g. Als, Duffy, and Mcanulty, 1996; Hedlund,1998). A multidisciplinary team for neonate health care provision helps standard quality care. Likewise, a program must be family centered where the parents are educated, supported and involved in every decision making (Neifert and Bunik, 2013). Standard features of the physical plant of neonate intensive care unit equally impact a neonate health condition. For example, monitoring of ambient auditory and visual environment is crucial. A program should also promote breastfeeding and skin-to-skin care with a designated place for the mother.

1.2 System factors and characteristics of the mother and neonate

An equally significant part of a breastfeeding framework is factors and characteristics of the mother and neonate systems. Several factors and characteristics were reviewed that were considered based on the literature important to include as system variables for the mother and the neonate.

1.2.1 The mother system

For breastfeeding to be effective, the mother should be prepared holistically in all aspects. Based on the mother system literature review, the multidisciplinary team categorized important factors and characteristics that can facilitate or hinder continuity of breastfeeding are the prenatal/antenatal, intrapartum and postpartum phases. One of the major factors that can have an impact on the promotion of breastfeeding is awareness among mothers as well as society and decision of implementation and type of birth (Alexander, LaRosa, Bader, Garfield, Alexander, 2010). Breastfeeding promotion has been a worldwide effort to raise the awareness about the extensive benefits of breastfeeding. Researches have been focusing on reduction of barriers to encourage the initiation and continuing breastfeeding (U.S. Department of Health and Human Services, 1984). Each year, exclusive breastfeeding can save 1.3 million lives globally (UNICEF, 2004). During the prenatal phase, breastfeeding support should be started during pregnancy. Multidisciplinary team or peer support is significant to change maternal attitudes positively toward breastfeeding, therefore, increase mother's confidence in her decision to initiate and sustain breastfeeding (Caulfield et al., 1998, Grummer-Strawn, et. al., 2006). Planning to breastfeed for only a short period of time was less likely to initiate breastfeeding after birth (DiGirolamo, et. al., 2005). Also, demographic characteristics should be assessed such as, minority and low-income women as it influences breastfeeding duration (Sikorski, 2004). According to Horta and Victora (2013), recall of how long the breastfeeding was practiced by the mothers is also vital as well as with some socio-demographic characteristics in terms of exclusivity and non-exclusivity of the method. The mother's diet aside from the baby's diet is also a factor where the health practitioner can educate about the importance of breast milk and the risks of alternative intake to baby (UNICEF/WHO, 2010). The identified labor facilitators are educating the mother about moving and walking, educating on the importance of breastfeeding exclusively and if deciding for mixed with formula substitute, or non-breastfeeding at all ; and how often to breastfeed like when the baby is hungry, every hour or every 2-3 hours; and how long to suckle after discharge, hospital provides suggestions for help on breast feeding if

problems arise (UNICEF/WHO 2009) and increase the rate of exclusive breastfeeding in the first 6 months up to at least 50% (WHO, 2014). Intrapartum care is a very crucial time to initiate breastfeeding as this period focuses on immediate breastfeeding. Appropriate latching and positioning, support, skin-to-skin care, stability of the neonate, and comfort of the mother was noted. One of the main factors that make it difficult to establish breastfeeding is intrapartum analgesia. Although inhalational analgesics are excreted quickly unless fentanyl (an opioid) to epidural analgesia (Ransjo-Arvidson, et.al. 2005). Therefore, mothers should be encouraged to know their pain management options and alternatives best for the baby and her condition. Positioning and latching are identified themes in the mother system tool where the healthcare practitioner needs to help the mother on how to do both correctly before discharge. Latching helps also in the initial attachment of the baby to the mother especially when breastfeeding is to be started (UNICEF/WHO, 2009). Identifying the mother's breast by smell by the newborn is encouraged while avoiding frequent washing or cleaning of the breasts can interfere with spontaneous breastfeeding initiation (Kruse et.al., 2005). The medical condition of the mother is important to assess her labor progress and the factors contributing to the difficulty initiating and sustaining breastfeeding. These include "prolonged labor, maternal medical problems, use of medications during labor, cesarean birth and maternal perception of breastfeeding problems" (Riordan, 2005). In postpartum care, first hours after delivery are vital to continue breastfeeding. Therefore, rooming-in, continues to skin-to-skin care, nipple care and avoid using pacifier and formula in the hospital increased breastfeeding motivation (Righard, L., & Alade, M. O. 1997, Riordan, J. 2005). Other factors to the facilitation of mother care are lactation and preparation of the mother to breastfeed. According to Sisk, et.al (2006), "Breastfeeding promotes health and development of very low birth weight (VLBW) infants, lactation initiation among mothers of VLBW infants is low." According to the study of Venancio and de Almeida (2004), Kangaroo mother care reduces severe infant morbidity without any harmful effect and still being recommended for use routinely in the hospitals (Venancio, S., de Almeida, 2004). On the one hand, skin-to-skin care (UNICEF/WHO, 2009) is still part of attachment of the baby to the mother after birth (UNICEF/WHO, 2010). In their study, they were able to identify the importance of counseling toward breast milk, formula and the stress and anxiety the mothers will experience (Sisk, et.al.2006). As mentioned, based on critical appraisal of the studies, factors have been classified into three parts: prenatal, intrapartum and postpartum. Information gathered to provide insight might improve breastfeeding initiation.

1.2.1 The neonate system

The neonate system is closely integrated to neurodevelopmental and neurobehavioral system (Als, 1986) As well as the craniofacial growth and jaw development compared to bottle-feeding which may affects oral-facial development negatively (Howard CR et al 2003,Camurdan AD et.al 2008) The neonate autonomic, motor and state subsystems are closely integrated and clinical indicators of a neonate's self-regulation and feeding condition including sucking According to Macias and Meneses (2011), any defect to digestive, respiratory, cardiovascular and nervous systems can causes problems in the neonate sucking.

For breastfeeding to be effective in the initiation and continuation, a neonate sucking, swallowing and breathing cycle is considered a major element that directly impacts a successful breast feeding process (Browne and Ross, 2011; Gewolb, and Vice, 2006). Sucking for breastfeeding is impacted by initiation of feeding immediately after birth (Als and Duffy, 1989) which could be hindered by multiple barriers (e.g. Neifert and Bunik, 2013; Kakute, et.al., 2005; Agunbiade and Ogunleye. 2012). Association was also observed between reduced breastfeeding duration(<6 months) and higher prevalence of non-nutritive sucking habits during neonate phase which will in turn increases the prevalence of developing malocclusions (defined as an unacceptable deviation either and/or functionally from the ideal relationship of the upper and lower teeth) (Heasman, 2003).

1.3 Quantitative-qualitative Focus Group Method

For initial investigation of a phenomenon, researchers have used focus group as a qualitative research method to simultaneously collect open-ended data in medical research from a group of participants (Onwuegbuzie, et.al. 2009). Data is transcribed, classified and coded by researchers with a descriptive data outcome reported. This method has been conducted in studies on breast feeding (e.g. Avery and Magnus, 2011; McFadden and Toole, 2006; Moore and Coty, 2006). Krueger and Casey (2000) highlighted the main benefit of focus groups research as helping researchers to collect data with efficient time and cost from multiple participants. In certain world regions and with national medical issues, medical researchers need to collect data within a short period of time to develop intervention programs and inform health policy makers. Furthermore, interactions in focus groups among participants with diverse background experiences yield significant outcome data for research (Morgan, 1988). However, such a classical method is somewhat time consuming post data collection as researchers transcribe, analyze and classify open-ended texts. Reliability

has to be conducted for all the open-ended data processing which may render it resources cost effective. Furthermore, more transcribing, classifying and coding errors may occur. Descriptive qualitative data is reported.

There is a need for a focused, efficient and cost effective focus group method that yields online reliable and quantifiable data. In this study, we adapted an innovative method for focus groups that has been developed by a group of medical researchers (AlAbdulkarim, et.al. 2016) to validate a framework for the evaluation of barriers and facilitators to breastfeeding. This method was creatively developed as a simple solution to the classical focus group method to validate data classification in a more reliable, focused and readily quantifiable process. This new method is explained fewer than 2. Methods.

1.4 Aims of the study

This study aims provide a more efficient multidisciplinary qualitative-quantitative research method for collecting and analyzing focus group data in developing and validating a framework in healthcare. The current focus group method yields focused and quantifiable qualitative data that is more reliable, focused and cost effective for researchers. This mixed method study also aims to develop and validate a framework of internationally recognized and locally fit systems, constructs and themes to evaluate barriers and facilitators to awareness, implementation, initiation and continuity of exclusive breastfeeding practice in new born stage in Saudi Arabia.

2 METHODS

The study question about what is a valid breastfeeding framework to evaluate barriers and facilitators to breastfeeding and the qualitative research design guided the construction of the focus groups (Onwuegbuzie, et.al. 2009). Local experts with international experiences discussed in depth information about the fitness of the framework for the evaluation of breastfeeding barriers and facilitators. In the following subsections, the focus groups methods are detailed.

2.1 Planning and organization of the focus groups

A plan for stimuli, target participants and structure was developed prior to the focus groups workshop conducted to validate the framework for the evaluation of barriers and facilitators to breastfeeding. A team of expert multidisciplinary researchers planned the methods in multiple phases. After thorough review of the relevant literature discussed under introduction, a focus groups stimuli was designed. A pool of multidisciplinary experienced participants was selected. A focus groups workshop was conducted for data collection.

2.1.1 Stimuli of the Focus Groups

The focus groups stimuli consisted of three major variables: a pre-classified framework of systems, constructs, themes, and items; predetermined closed validation codes and an item ranking code. The three were the focus groups norms and guidelines for data analysis. For the framework, a thorough review of published literature on international best practice models of policies, standards, guidelines and clinical protocols for breastfeeding as well as on national guidelines and international and national studies on breastfeeding was conducted and supervised by two national and international experts in breastfeeding related health care. The multidisciplinary review group of nine members was divided into two teams to review the factors and characteristics of breastfeeding programs and systems of the mother and the neonate. Each team searched and reviewed multiple published references on breastfeeding including accredited health organizations and associations (World Health Organization, American Pediatric Association, WHO-Eastern-Mediterranean-Regional-Office (EMRO) and published studies on breastfeeding for factors and characteristics of breastfeeding. The factors and characteristics were then classified into systems, constructs, themes and items. Each reviewer wrote each item in a meaningful statement. Items were then numbered and classified into types of a policy, a standard, a guideline or a clinical protocol. Four frameworks were developed. The mother's program included 10 constructs, 12 themes and 35 items. The neonate's program consisted of 12 constructs, 33 themes and 87 items. The mother's system had 11 constructs, 34 themes and 68 items whereas 6 constructs, 9 themes and 24 items were for the neonate system. All classifications were entered into Excel© spread sheets with reference citation for each item. The four spread sheets of classifications for the mother's and neonate's programs and mother's and neonate's systems were validated by two inter-examiner expert researchers and health practitioners. The content of each spread sheet was represented in matrices in tables format on word doc© which were reviewed by two expert researchers for the focus groups discussions. Each table has a "comments" section for open ended data by

the focus groups. A coding system was used to collect and code note-based data of the focus groups developed by AlAbdulkarim and others (2016). The codes represented closed coding of the data (e.g. Onwuegbuzie, et.al., 2009) with six coding categories: keep, modify, delete, merge, move and add. Definitions of the codes are provided in Table 1 The "Add" code also yields open ended data. The codes are used by the focus groups to reclassify and validate the content of the framework.

Table 1. Coding of the focus groups for reclassification of the framework.

No	Coding	Definition
1	**Keep**	The construct, theme and/or item is appropriate to keep for the study topic and objectives.
2	**Modify**	The construct, theme and/or item needs modification for the study topic and objectives.
3	**Delete**	The construct, theme and/or item is inappropriate for the study topic and objectives.
4	**Merge**	The construct, theme and/or item needs to be merged with other constructs, theme and/or item to avoid redundancy.
5	**Move**	The construct, theme and/or item should be moved to another construct, theme and/or item for appropriate classification.
6	**Add**	The construct, theme and/or item should be added as a necessary factor.

A ranking system of each item was also used with (1) as not important to (10) as very important item to include in the framework. The stimuli were carefully designed to facilitate and focus discussions leading to the target outcome of reaching consensus on the proposed framework. Thus, descriptive and interpretive validity would be increased for the themes and help researchers focus the framework to a better fit for further studies. A focus groups guide was developed for the focus groups discussions.

This innovative efficient mixed method of eliciting and analyzing the focus groups data allows the focus groups participants to focus on task (Morgan, 1997; Kruerger, 2000) and to simultaneously analyze, classify and code the focus groups information on each system, construct and theme.

2.1.2 Selection of the Focus Groups Participants

A purposive sampling technique of maximum variation sampling was used to select participants of the focus groups (Onwuegbuzie, et.al., 2009). Focus groups represented a multidisciplinary health backgrounds related to breastfeeding with specialized knowledge and national and international experiences and of mixed gender. From this large group, small focus groups of 7 to 8 participants were planned for in depth discussions and ideas sharing in a comfortable environment (Krueger, 1994). As recommended in the literature (Morgan 1997) to avoid missing participants, participants were recruited by 20% more of the total number planned for the focus groups. Candidate participants who fit the selection criteria were first recruited by mobile calls, followed by invitations emailed to the candidates. A mobile message reminder was texted three days and one day before the focus groups date to all participants. They included a mix of faculty and health practitioners of neonatologists, family physicians, maternity and gynecological registered nurses, midwifery registered nurses, neonate intensive care unit registered nurses, pediatric registered nurses, nurses in health management, speech pathologists, audiologists, occupational therapists and physical therapists with experience in neonate intensive care units and or maternity, doulas and health educators. All members voluntarily participated. There were 2 groups of 8 to 9 participants with diverse backgrounds. A total of 18 participated in the focus groups.

2.1.3 Conducting the Focus Groups Sessions

Stimulus materials with instructions on the framework under investigation were emailed as PDF files to all participants. A focus groups workshop with six sessions was conducted all day at King Khalid University Hospital, College of Medicine. The focus groups supervisor explained the topic background, the purpose and objectives of the study, the study framework, the coding matrix, the ranking system, the focus groups ground rules and finally the schedule of the focus groups day all presented on PowerPoint© slides. An expert researcher supervised the focus groups sessions. At the beginning of each session, the supervising moderator guided the moderators who were trained before the workshop and groups on the stimuli and methodology of the focus groups discussions. The supervising moderator supervised all group discussions; facilitated transitions into each session, data interpretation, classifications and reclassifications, item ranking and created a conductive environment for group discussions and helped group moderators facilitate their small group discussions. Each small focus group was assigned a group moderator who presented the

stimulus materials, facilitated and encouraged group discussions using structured format including verifying and documenting group consensus (Krueger, 1994; Krueger & Casey, 2000). The group dynamics were monitored and observed to be coherent (Morgan 1997).

The first focus groups had three sessions. The length of each session lasted 60 minutes of focus group discussions and consensus feedback as recommended in published research of a well-designed focus group (Morgan, 1997). The structure of the first three sessions was that each focus group reviewed, verified, classified, coded and ranked the items under the themes of each construct and system after exchanging and discussing common values, understandings and experiences (Krueger, 1994). During session four to six, large focus groups verified the reclassifications and validated the coding and ranking of data from sessions one to three. When there were disagreements on an item, a consensus was reached following discussions. When no further information added value and the framework were adequately validated, researchers evaluated whether the group has reached data and framework (Morgan, 1997). A note taker at each group synchronically documented focus groups discussions, disagreements and resulting consensus and validations in prepared tables which were uploaded to dropbox© files for co-researchers validation and reliability.

2.2 Source of Focus Group Data

Documented focus groups discussions and consensus of the focus group stimuli were the main source of the focus group data used for the analyses (Kreuger, 1994). The data constituted note-based reclassification codes, rankings and comments taken by each group moderator on data tables. The closed coding matrix and ranking helped researchers focus on the research question and develop accurate interpretation of the framework under study in addition to documented focus groups comments and additions to the framework as well as summary comments from the moderators. The type of the focus group data in this study was group and group interaction data which was used as the unit of analysis (Morgan, 1997). Data of the fourth to sixth large groups sessions were the result of the focus groups reviewing and refining of the closed coding technique during the first small groups sessions. Groups refined coding through consensus until groups reached agreed on each code and ranking. The inter-group reliability was > 85%.

2.3 Data Analysis

Data analyses used classical content analysis as a qualitative data analysis technique to analyze the focus groups data. In classical content analysis, a researcher evaluates which codes the focus groups used and how frequent. Data on ranking of importance of items were analyzed. Interpretive descriptions of the group use of codes and comments were included. This yielded a mixed method contents analysis (Morgan, 1997; Onwuegbuzie, et.al., 2009). The unit of analysis was the group. Limitations of individual focus group data (Onwuegbuzie, et.al., 2009) was corrected by the multiple group consensus and validation sessions and the predetermined framework. No dissenting views among group members were observed. For further validating and completing reliability of the note-based coding data and ranking of the focus groups validation data, two co-researchers and six research assistants reviewed the data. They re-read the reclassifications, codes, rankings and comments. Co-researchers reliability was greater than 85%.

3 RESULTS

Focus group consensus data of coding constructs, themes and items as well as item rankings were cross tabulated to reveal validation patterns and important relevance of items.

Table 2. Percentages of focus group validation codings for the two small groups and the large consensus group for the neonate program

Codes	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
1 (Keep)	65	74.7	67	77.0	59	67.8
2 (Modify)	15	17.2	15	17.2	24	27.6
3 (Delete)	4	4.6	0	0	2	2.3

4 (Merge)	3	3.4	1	1.1	0	0
5 (Move)	0	0	0	0	0	0
6 (Add)	0	0	4	4.6	0	0
Total	8787	1100	87	100	87	100

Table 2 above shows a focused and quantifiable consensus and verification from pool of experts of the developed framework for neonate program. Both groups (n=59 out of 87; 67.8%) have an equal positive consensus, majority (n=65, 74.7%) from group A, while (n=67, 77.0%) from group B to keep the developed framework. With regard modification, 15 out of 87 (17.2%) from both groups; whereas only 4.6%, 2.3% from groups A and B, respectively agreed to delete some items. About 3.4% and 1.1% from groups A and B, respectively agreed to merge some items. There was only a 4.6% (n=4) members from group B who decided to make some additions in the items. Collectively, the table above yielded a positive result of keeping the items.

Table 3. Percentages of focus group validation ranking of items for the two small groups and the large consensus group for the neonate program.

Rank for importance	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
0 **(deleted items)**	4	4.6	0	0	4	4.6
1 **(not important)**	0	0	0	0	0	0
2	1	1.1	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	1	1.1	0	0	0	0
6	2	2.3	1	1.1	1	1.1
7	0	0	0	0	1	1.1
8	2	2.3	1	1.1	3	3.4
9	2	2.3	0	0	6	6.9
10 **(Most important)**	75	86.2	75	86.2	72	82.8
Total	8787	1100	87	100	87	100

Table 3 depicts the percentages of focus group validation ranking of items for the two small groups and the large consensus group for the neonate program. 72 out of 87 (82.4%) for the large group gave a consensus of high importance with regard neonate program. 3.4% and 6.9% of the group of expert validators gave a ranking of 8 and 9, respectively. There was no significant difference in the responses of between the 2 groups, as both groups yielded a positive consensus ranking.

Table 4. Percentages of focus group validation codings for the two small groups and the large consensus group for the mother program.

Codes	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
1 (Keep)	30	85.7	30	85.7	27	77.1
2 (Modify)	5	14.3	4	11.4	7	20.0
3 (Delete)	0	0	1	2.9	1	2.9
4 (Merge)	0	0	0	0	0	0
5 (Move)	0	0	0	0	0	0
6 (Add)	0	0	0	0	0	0
Total	35	100	35	100	35	100

Table 4 above shows a focused and quantifiable consensus and verification from pool of experts of the developed framework for mother program. It has shown a collective majority's (n= 27 out of 35, 77.1%) decision to keep the items for the Mother Program. with 87.7 % from group A and 85.7 % from group B. It is followed by only 20% (n=7) to modify and 1% to delete from both groups. Collectively, both groups' consensus validation yielded positive results.

Table 5. Percentages of focus group validation ranking of items for the two small groups and the large consensus group for the mother program.

Rank for importance	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
0 (deleted items)	0	0	1	2.9	1	2.9
1 (not important)	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	1	2.9	0	0	1	2.9
6	0	0	0	0	0	0
7	0	0	0	0	2	5.7
8	1	2.9	0	0	0	0
9	0	0	0	0	2	5.7

10 **(Most important)**	33	94.3	34	97.1	29	82.9
Total	35	100	35	100	35	100

Table 5 depicts the percentages of focus group validation ranking of items for the two small groups and the large consensus group for the mother program. 29 out of 35 (82.9%) for the large group gave a consensus of high importance with regard mother program. 2% and 5.7% of the group of experts gave a consensus ranking of 5 and 7 respectively. There was no significant difference in the responses of between the 2 groups, as both groups yielded a positive consensus ranking.

Table 6. Percentages of focus group validation codings for the two small groups and the large consensus group for the mother system.

Codes	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
1 (Keep)	65	74.7	67	77.0	59	67.8
2 (Modify)	15	17.2	15	17.2	25	287
3 (Delete)	4	4.6	0	0	2	2.3
4 (Merge)	3	3.4	1	1.1	1	1.1
5 (Move)	0	0	0	0	0	0
6 (Add)	0	0	4	4.6	0	0
Total	87	100	87	100	87	100

Table 6 shows a focused and quantifiable consensus and verification from pool of experts of the developed framework for Mother System. It has shown a collective majority's (n= 59 out of 87, 67.8%) decision to keep the items for the Mother System. With 74.7 % from group A and 77 % from group B. It is followed by 26.7% (n=25) to modify and 2.3% (n=2) to delete the items from both groups. Collectively, both groups' consensus on the Mother System validation yielded positive results.

Table 7. Percentages of focus group validation ranking of items for the two small groups and the large consensus group for the mother system.

Rank for importance	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
0 **(deleted items)**	4	4.6	0	0	4	4.6
1 **(not important)**	0	0	0	0	0	0
2	1	1.1	0	0	0	0
3	0	0	0	0	0	0

4	0	0	0	0	0	0
5	1	1.1	0	0	0	0
6	2	2.3	1	1.1	1	1.1
7	0	0	0	0	1	1.1
8	2	2.3	1	1.1	3	3.4
9	2	2.3	0	0	6	6.9
10 (Most important)	75	86.2	85	97.7	72	82.8
Total	87	100	87	100	87	100

Table 7 depicts the percentages of focus group validation ranking of items for the two small groups and the large consensus group for the Mother System. 72 out of 87 (82.9%) for the large group gave a consensus of high importance with regard mother system. 3.42% and 6.9% of the group of experts gave a consensus ranking of 8 and 9 respectively. There was a significant difference in the responses of between the two groups, where group B have the most numbered with 97.7% who gave the high importance. Both groups still yielded a positive consensus ranking.

Table 8. Percentages of focus group validation codings for the two small groups and the large consensus group for the neonate neurodevelopmental and neurobehavioral system.

Codes	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
1 (Keep)	12	100	9	75.0	12	100
2 (Modify)	0	0	1	8.3	12	100
3 (Delete)	0	0	0	0	0	0
4 (Merge)	0	0	1	8.3	0	0
5 (Move)	0	0	0	0	0	0
6 (Add)	0	0	1	8.3	0	0
Total	12	100	12	100	12	100

Table 8 shows a focused and quantifiable consensus and verification from pool of experts of the developed framework for Neonate Neurodevelopmental and Neurobehavioral System. It has shown a 100% (n=12) decision to keep the items for the neonate system for group A while 75% for group B. Only 8.3 % decided to modify some items and 8.3% to merge some items coming from group B. On the one hand, there are an 8.3% of experts from group B decided to add in some items.None from the group suggested to delete all items. Collectively, both groups' consensus on the Neonate System validation yielded positive results.

Table 9. Percentages of focus group validation ranking of items for the two small groups and the large consensus group for the neonate neurodevelopmental and neurobehavioral system.

Rank for importance	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
0 (deleted items)	0	0	0	0	0	0
1 (not important)	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	2	16.7	0	0	0	0
7	0	0	0	0	0	0
8	1	8.3	0	0	2	16.7
9	0	0	0	0	1	8.3
10 (Most important)	9	75.0	12	100	9	75.0
Total	12	100	12	100	12	100

Table 9 depicts the percentages of focus group validation ranking of items for the two small groups and the large consensus group for the Neonate System. 9 out of 12 (76%) for the large group gave a consensus of high importance with regard neonate system. 16.7% and 8.3% of the group of experts gave a consensus ranking of 8 and 9 respectively. Both groups still yielded a positive consensus ranking.

Table 10. Percentages of focus group validation codings for the two small groups and the large consensus group for the neonate oral motor and nutrition system.

Codes	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
1 (Keep)	31	86.1	31	86.1	28	77.8
2 (Modify)	5	13.9	4	11.1	7	19.4
3 (Delete)	0	0	1	2.8	1	2.8

4 (Merge)	0	0	0	0	0	0
5 (Move)	0	0	0	0	0	0
6 (Add)	0	0	0	0	0	0
Total	36	100	36	100	36	100

Table 10 shows a focused and quantifiable consensus and verification from pool of experts of the developed framework for Neonate Oral Motor and Nutrition System. It has shown that majority, 77.8% (n=28) of the experts came up with a decision to keep the items for the neonate oral motor and nutrition system for group. Whereas, 19.4% (n=7) recommended for a modification and only 2.8% (n=1) suggested to delete some items. None from the group of experts suggested merging move and adding any items. Collectively, both groups' consensus on the neonate oral motor and nutrition system validation yielded positive results.

Table 11. Percentages of focus group validation ranking of items for the two small groups and the large consensus group for the neonate oral motor and nutrition system.

Rank for importance	Small Group A		Small Group B		Large Consensus Group	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
0 (deleted items)	0	0	0	0	0	0
1 (not important)	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	1	2.8	0	0	1	2.8
6	0	0	0	0	0	0
7	0	0	0	0	2	5.6
8	1	2.8	0	0	0	0
9	0	0	0	0	2	5.6
10 (Most important)	34	94.4	36	100	31	86.1
Total	36	100	36	100	36	100

Table 11 depicts the percentages of focus group validation ranking of items for the two small groups and the large consensus group for the Neonate Oral Motor and Nutrition System. 31 out of 35 (86.1%) for the large group gave a consensus of high importance with regard neonate oral motor and nutrition system. Equal ranking of 7 and 9 was given to both groups. Both groups still yielded a positive consensus ranking.

4 DISCUSSIONS

The literature referenced pre-determined matrix and coding and ranking criteria helped focus group participants and researchers to design and focus a valid standard framework with modification of less than 15% of the original matrix. Results have shown that the mixed methods implemented in this study was effective in eliciting focused and valid data that could be reliably quantified and tabulated for best interpretation of the framework. Focus groups consensus data supported the appropriateness of the content of the proposed framework developed by reference to international and national standards and guidelines as well as published studies. Furthermore, the focus group validated the framework against the specificity of the local culture.

5 CONCLUSION

This study provided a validated mixed methodology in medical research to design and validate programs and tools with results informing modification of the framework and identification and organization of appropriate exclusive breast feeding constructs and themes. The results of this first phase of the study through a focus groups validation of framework correlated with factors and characteristics to evaluate the barriers and facilitators. Such results will serve as a guide in the development of tool towards the initiation, implementation and continuation of breastfeeding in the newborn stage. Further, the results can be used in hospital units at a national or regional level in Saudi Arabia, and the framework can set as a standard protocol guideline whether administrative or clinical with a goal to improve health outcomes of both mothers and neonates.

Establishing a framework is hoped to lead to the initiation and full continuation of breastfeeding to sustain the nutritional needs of the infant and likewise the health of the mother. Further, it is highly recommended that breastfeeding case management monitoring programs can be created by the Ministry of Health (MOH) towards a more efficient preventive care in hospitals in Saudi Arabia. Utilization of the tool is recommended as an effective multidisciplinary assessment to improve exclusive breastfeeding rates in Saudi Arabia.

Whether and how the results are to be used at a national or regional level in Saudi Arabia, it will depend whether the items can be set as a standard protocol guideline (administrative, clinical) for assessment/re-assessment /screening/ evidence based outcomes. It would be a positive strategy for the MOH in the implementation and utilization of the tool with its framework to promote the continuity of breastfeeding initiative in Saudi Arabia. This can also become an offshoot to the improvement of all hospitals in maintaining standards with policies and guidelines properly disseminated to all stakeholders as initiated by the multidisciplinary team.

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