RESEARCH ARTICLE

VALIDATION OF INDIA EBUS AMONG PROFESSIONALS PRACTICING IN NICU

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Manuscript Info

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Abstract

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Background-INDIA EBUS is a cloud-based software aimed at supporting optimal neurodevelopmental outcomes in NICU. INDIA is an acronym for Individual New-born Developmental Intervention Application which is based on the available evidence. It includes various aspects like Neurodevelopmental, Neurophysiological, Neurobehavioral, developmentally supportive and Trauma informed care, Splinting, Occupational Therapy intervention, etc., which helps in clinical assistance, interpretation and documentation for professionals. The objective of the study was to check the content validity of the INDIA EBUS. Prospective online survey was used.

Methods- The professionals were contacted and a letter of request was sent to them. An online process was used to select the participants. For the online survey, 30 people were chosen using a convenient sampling method. Request letter was sent to the professionals. After that investigator briefly introduced the INDIA EBUS. Later software access was given for seven to ten days to the participant. After sending google form online recruitments of the participants, if they click to 'I agree' as per google form, data was collected. The main inclusion criteria were that the participants had at least one year of clinical experience in the NICU.

Results-INDIA EBUS uses the combination of different models aimed at neuroprotection by the multidisciplinary team in NICU and post discharge follow up as a theoretical framework. The literature review & expert-based panel supported the Content Validity of the INDIA EBUS. Content Validity Index for the Components relating to the Developmentally supportive care and neuromotor assessment was 0.87. The neurodevelopmental assessment and intervention had a CVI greater than or equal to 0.78. For the Trauma informed care, chest physiotherapy, and neurobehavioral assessment, it was below 0.50. The health care workers confirmed the understandability, completeness & credibility of the INDIA EBUS. The different stakeholders in the study considered the software would be helpful for the brain-oriented care in NICU (neuroprotection) & beneficial for neurodevelopment. Negative ratings referred to the time required for the use of data entry and the use of digital devices.

Conclusion- There was substantial evidence supporting the content validity of the INDIA EBUS. Despite the substantial length & time requirement, software was considered helpful for comprehensive

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neurodevelopmental care in NICU. Further research on psychometric qualities, implementation and effectiveness is needed.

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Introduction:-
Perinatal mortality has radically decreased in recent years. [1] Various factors have been consistently related to morbidity for long term problems occurring in the babies. A few of them are gestational age, birth weight, sex, etc. The effect of environmental factors on neurodevelopmental outcomes has been pointed out. Most studies have focused on the family, educational, and economic background but the NICU environment and early practices need more attention than previously granted. Various approaches are used: control of environmental factors known to cause physiological and behavioural disorganization, e.g., light and sound, scheduling of caregiving, swaddling and general motor containment, kangaroo mother care. Also, neuro physiologically based occupational therapy intervention is found to be useful.

Recently INDIA EBUS is offered as ''Digital Approach to Neurodevelopmental Care in NICU''. INDIA is an acronym for Individual Newborn Developmental Intervention Application. In EBUS 'EB' is evidence based and 'US' for ultra-smart [ultra is very early and SMART represents Specific Measurable Accountable System Realistic solution and all is done in a timely manner]. It is cloud-based software.

A pilot study of software was done regarding the professional perception of the newly developed software [2]. The concept behind INDIA EBUS is to get individualized neuroprotective and neurodevelopmental Newborn care. In this approach, Individual intervention is based on the cues given by the baby and aimed at preventing stress on the immature developing brain. Technology is used for reliable, consistent care by all the team members and facilitates professional communication in NICU. It is based on existing evidence. INDIA EBUS is an effort/ venture to organize all the evidence in one place. It serves different purposes, including documentation analysis of the enter data, clinical assistance for grading various scales, report generation, and referencing the related literature.

It consists of software and interfaces training for the professionals. The software is in agreement with the various categories of WHO Digital Health Intervention [3]. Interface training includes lectures for the orientation and hands-on training to gain mastery over the software.

Method:-
The protocol was prepared and submitted to the Institutional Ethics Committee at Seth G.S. Medical College and King Edward Memorial Hospital in Mumbai, where it was approved.

Design-
Psychometric design using cross sectional survey

Participants and Recruitment-
Informed consent was obtained from all individual participants included in the study. We conducted the study online. We enrolled various professionals with a minimum of one year of clinical working experience in NICU. They were neonatal nurses, neonatologists, neonatal therapists, paediatricians, speech therapists, occupational therapists, physiotherapists, developmental paediatricians, paediatric neurologists, a paediatric surgeon from diverse institutions globally. These individuals come from a variety of professional backgrounds, but they are all regular members of the NICU team. They were all included in the study because they all have a role to play in ensuring that each child receives individualized developmentally appropriate care throughout their expert intervention.

We selected the participants by convenient sampling. We recruited 30 different professionals [Occupational therapist, Neonatal nurse, Neonatologist, Paediatrician, Paediatric surgeon, Physiotherapist] to check the content validity. The content validity form was prepared and validated by experts to check the content validity.

The approach described by Lynn was used to test the new software's content validity. Two stages are advocated in this method. Stage I of development involves creating the instrument's items, while stage II assesses the software's performance (judgment and quantification). These two stages were supplemented in this study by a third stage

(evaluation), in which the new software's feasibility and practicability were tested in an evaluation study. An expert panel evaluation was conducted based on this approach.[4]

Stage I -Development
INDIA EBUS software was developed mainly to provide neurodevelopmental care of the newborns. For developing this software, various opinions regarding the digital approach towards treatment, requirements in neurodevelopmental care were collected from 91 different professionals through online surveys. After this, with different collective opinions, software was developed.

We have different sections like
1. Basic demographic data for the registration purpose
2. Developmentally supportive care
3. Neurophysiologically based intervention
4. Neuromotor assessment
5. Neurodevelopmental assessment
6. Growth monitoring
7. Hand washing
8. Neurobehavioral assessment
9. Trauma informed Care
10. Splinting & Taping

We began developing software in response to the survey's suggestions. We created various parts, which were then grouped together with relevant forms. Also decided were the required output and analysis. The dynamic graph was used, for example, to track the temperature, pulse, and breathing rate. Colour coding was also utilized for input that needed to be interpreted. A red background was utilized if the observed behaviour was abnormal. The rules were set for totalling the score, interpretation. For convenience of access, all of the assessment forms and reports were placed on the dashboard. The group headings were also added to the taskbar.

Stage II- judgment and quantification
The Judgement and Quantification phase included two evaluations. The first evaluation comprised a workshop with the experts that focused on the understandability and operation of the software. The second assessment consisted of an expert panel that focused on the relevance and clarity of the content as well as the significance and completeness of software. This was done through the questionnaire.

The content validity questionnaire for the second stage was created using various aspects of the INDIA EBUS software. A questionnaire was created to gather opinions on the relevance of the digital approach to neurodevelopmental care in the Neonatal Intensive Care Unit [NICU]. Later, different professionals with experience working in the NICU field peer validated the questionnaire. Changes in content and grammatical presentation of questions were made as needed. The Institutional Ethics Committee later granted ethical approval based on this.

Stage III Evaluation - Expert panel
Experts in the expert panel were defined as individuals who worked in practice as a practitioner or in science in the NICU. The criteria for inclusion in the study was having a minimum of one-year clinical experience in NICU, understanding the field of assessment instruments. This served as the study's operational criteria. We focused on various professionals to obtain the multi-dimensional perspective about the software.

Measurement of content validity-
As the INDIA EBUS was composed of various assessments and interventions, the content validity index was also calculated at scale and item levels.

Each domain of the software was evaluated by the rating for
a) its relevance to the software aims and
b) its understandability/clarity. Each answer was assessed regarding its
c) comprehensiveness/completeness and
d) meaningfulness/significance for the domain
e) not applicable.

The five attributes (a-e) of the questions and answers were rated on a 5-point scale [5-strongly agree/4-agree/3-neutral/2-disagree/1-strongly disagree]

In addition, the experts were asked to evaluate whether the domain covered all important aspects of Neurodevelopmental care or if there were missing components. The experts could also comment on every domain or an overall aspect.

Measurement of the content validity index –
A content validity index was calculated at the item level - Content Validity Index (I-CVI) and scale level - Content Validity Index (S-CVI) for all domains. The I-CVI was calculated as the number of experts providing a score of 5 or 4 divided by the total number of experts. With more than five experts, the I-CVI should not be lower than 0.78 [5].

To calculate the S-CVI, two different indices were calculated:
1) the proportion of the items on one scale that the experts scored as valid (ratings of 5 or 4) (universal agreement by experts = S-CVI/UA) and
2) the average proportion of the items on one scale rated 4(moderate agreement by experts = S-CVI/Ave) [4]. The SCVI/UA is sensitive to the number of experts: the more experts are included, the greater the possibility of generating a low S-CVI. The S-CVI/Ave is more liberal and is preferred by Polit and Beck [5]; however, they recommend presenting both indices.

The acceptable standard for the S-CVI/UA and the S-CVI-Ave is 0.8 [5]; values up to 0.9 indicate an excellent average [6].

Sample
A convenient sample of 30 different professionals from various regions participated in the study. From which, seven Occupational therapists, three neonatologists, two paediatric surgeons, one NICU nursing staff, two paediatricians were enrolled in the study. All these healthcare professionals were briefly introduced to the app and its content. Later for 7-10 days, access was given to explore.

Data Collection And Analysis
To evaluate the validity of INDIA EBUS software self-developed validated questionnaire on each domain was used. The questionnaire included rating about its contents. One open ended question was also included to collect any suggestions about the software. Data were analysed using inferential statistics.

Results:-
Results obtained from 30 different professionals were evaluated. Table no 1 shows professional participants of study. In the 30 study participants 10 are occupational therapists ,10 Neonatologist, 2 paediatric surgeon, 5 Neonatal nurses, Paediatric neurologist 1, and 1 Physiotherapist. They were from different regions of India (Maharashtra, Madhya Pradesh, Karnataka, Chennai, Kerala, Delhi) and abroad (USA, Portugal, Switzerland, Germany)

Table no 1:- Professional participants of study.

Sr. No	Professional Background	Number of participants
1	Neonatologist	10
2	Neonatal Nurse	5
3	Physiotherapist	1
4	Occupational Therapist	10
5	Paediatric neurologist	2
6	Paediatric surgeon	2

Thirty experts were identified and contacted. Later, the INDIA EBUS app was introduced through video conferencing (Google Meet, Zoom). After the first meeting, the trial access was also given to the participants for one week to 10 days. Some participants used it for a month. They sought a longer period of exploration due to the Covid - 19 and other factors. After the exploration for a sufficient duration, the validation form was introduced to be filled with different stockholders. Though one professional was invited, many others in the unit explored the software. The

collective feedback from the unit followed it. Despite the fact that the full unit was not invited, the participants involved the entire unit on their own initiative. This action earned no disapproval from us.

Time constrained is the major issue while conducting this study due to the busy schedule of different health care professionals.

Content validity index at different items level [I-CVI] mentioned in Table 2

Table no 2:- Content validity index at item level-

ITEMS	CVI
Developmentally Supportive Care	0.93
Neuro-behavioural observational assessment	0.50
Dubowitz neonatal neurological examination	0.93
NeoSWAT i.e., sleep wake assessment	0.87
AmeilTison battery	0.87
Test of infant motor assessment	0.93
INFANIB	0.78
Pain assessment	0.93
Growth monitoring	0.93
Trauma informed care	0.40

S- CVI /Ave [scale – level content validity index based on the average method]
The average of the I-CVI scores for all items on the scale or the average by all experts. The proportion relevant is the average relevance rating by individual experts.
S-CVI/Ave= Sum of I-CVI scores/ Number of items
8.17/10= 0.80

So, based on the average method, the Content **Validity index at scale level is 0.80**, which indicates that this software got a valid accepted content validity index.

Discussion:-

This study aimed to validate the content of the INDIA EBUS software, which will help in the neurodevelopmental care and ultra-early intervention of the Newborn. INDIA EBUS has different domains which are included in the software. Few of them are different aspects of Developmentally supportive care, Neurophysiologically based intervention, Neuromotor assessment, Neurodevelopmental assessment, Growth monitoring, Hand washing, Neurobehavioral assessment, Splinting & Taping. The software assists with its artificial intelligence to different professionals practicing in NICU. Presently there is no mobile application which is dedicated for the neurodevelopmental care in NICU.

We utilized Lynn's technique, which has been widely employed in health care and nursing research. In the methodological literature, the two-stage technique is widely acknowledged. It is regarded as a prerequisite for the creation of new instruments.

To assess the content validity of the INDIA EBUS, it was important to assess different attributes of both the questions and the answer options. The experts perceived the majority of the questions as relevant. The experts' judgments, together with the comments, provided detailed information about the strengths and weaknesses of each item and led to well-reasoned modifications. Suggestion or any changes from various professional were done accordingly. Very few answered to open ended questions. But some of them commented that the Digital approach based on Neurodevelopmental care is a need of the current situation, which states that in the developing medical faculty ultra-early intervention helps prevent future complication.

INDIA EBUS promotes individualized Newborn neurodevelopmental care. Als H claims that this strategy shows greater progress in the development of preterm infants in his paper effectiveness of individualized neurodevelopmental care in NICU. NIDCAP encompasses a wide range of developmental services and places a strong emphasis on individualized, family-centered treatment. NIDCAP has the ability to promote mental and

psychomotor development clinically and statistically, according to L Fazilleau's study NIDCAP in preterm infants. Both this article and even INDIA EBUS advocate for personalized Newborn care.[7]

According to the opinions of various professionals such as neonatologists, paediatricians, physiotherapists, occupational therapists, and NICU nurses. The item level validity score for the Trauma Informed Care aspect was lower because many NICU working professionals were unaware of its impact on neurodevelopment.

In this study, professionals prioritized the neuromotor aspect. As a result, various assessment scales such as the AmeilTison battery, the Test of Infant Motor Performance, and INFANIB have a higher item-level validity index. This could be due to the clear nature of the motor impairment seen in newborns. Another reason could be familiarity with the tool and regular use of the tool in one's own ecosystem.

The ultra-early intervention based on the neurobehavioral assessment and intervention will have an impact on this kind of cognitive outcome. Expected cognitive behaviour, with academic impairment becoming apparent only after 5-10 years. This, in turn, will help to improve the mental health of infants. The cognitive or psychological domain were given a low priority by professionals during regular practice because of its non-obvious nature in the early years. This must have influenced their decision when rating the INDIA EBUS content.

From health economics point view, if we spend enormous amounts and care in the 1st thousand days of life, the spending money will be lesser. Individuals should comprehend that the future cost burden will be lessened if the current expenditure is more for the right purpose. Even the professionals, families, administrators should also be thoughtful about it. Heckman's curve states that if we spend more money on acute care, the future cost burden will be reduced. Heckman proved in his curve of Early childhood is a smart investment that if we invest in the prenatal period at the highest level, then the cost-effective burden will go on decreasing day by day, least in the post school and job training phase of life then. As a result, experts, parents, and hospital administrators should recognize the necessity of ultra-early intervention in an acute care situation through neurobehavioral assessment. This indicates that there is a need for stakeholders to be aware of and educated about neurobehavioral assessment.

The development and maturation of an infant's brain require a long period of uninterrupted sleep. Everyone seems to believe this, as evidenced by the content validity score.

All of the professionals agreed on the inclusion of the pain assessment and its interpretation. In her article Neurodevelopmental Care in the NICU, Susan Aucott states that pain management is a critical aspect of neurodevelopmental care. [8].

According to the study participants, chest physiotherapy does not appear to be necessary for Newborn neurodevelopmental care.

Growth monitoring is part of routine in NICU. Everyone needs to do it on regular basis. It might be convenient to have in the application. This might be the reason for

According to research, if we spend a lot of time and effort in the first thousand days of their lives, we will spend less money later on. Individuals should understand that if current expenditures are more for the correct goal, future cost burdens will be reduced. Professionals, families, and administrators should all think about it. According to Heckman's curve, if we spend more money on acute care, the cost burden will be lessened in the future. Heckman demonstrated in his Early Childhood is a Smart Investment curve that if we invest the most in the prenatal period, the cost-effective burden will decrease day by day, with the least in the post-school and work training phase.

As a result, experts, parents, and hospital administrators should recognize the necessity of ultra-early intervention in an acute care situation through neurobehavioral assessment.

Content validity refers to how the construct of interest represents currently available information. Despite its low position in the validity hierarchy, content validity is a significant quality indicator of an instrument's validity and gives information about its feasibility and practicability. The derived content validity index of INDIA EBUS is used in the development of the software in this study.

Conclusion:-

As per the opinion of various professionals, INDIA EBUS got a valid accepted content validity index at a scale of 0.80. So, INDIA EBUS can be incorporated in multiple multidisciplinary NICU settings to promote neurodevelopmental care at the early stages of life.

Limitations-

This study has some limitations.

As per the feedback from the different participants there are lacunae in the present system of NICU. In a multidisciplinary NICU setting we have limited trained manpower to incorporate the digital approach in current practice. For better monitoring of particular NICU setup daily entry of the record is required, which was hampered due to various reasons during the trial sessions.

Even our country is also lacking in infrastructures in many settings. Because of that, there is an unavailability of networks in NICU settings. It will automatically hamper the digital approach behind this software.

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