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# **Original Research**

# A study to develop episiotomy care bundle (ECB) for postnatal mothers with episiotomy admitted in the selected hospitals of Ludhiana, Punjab with a view to improve the wound healing and nursing care

<sup>1</sup>Heena Rakwal Rana, <sup>2</sup>Manjot Kaur, <sup>3</sup>Prabhjot Saini

<sup>1</sup>Nursing Tutor, Department of Nursing Obstetrics and Gynaecology, BEE ENN College of Nursing, Chak Bhalwal, Jammu, Jammu and Kashmir, India;

<sup>2</sup>Assistant Professor, Department of Nursing Obstetrics and Gynaecology, Shaheed Kartar Singh Sarabha College of Nursing, Ludhiana, Punjab, India;

<sup>3</sup>Professor cum Principal, Department of Medical Surgical Nursing, Shaheed Kartar Singh Sarabha College of Nursing, Ludhiana, Punjab, India

#### ABSTRACT:

Background: Episiotomy is indicated during the first and second stages of childbirth; however consistent care during the second stage minimizes the occurrence of episiotomy and perineal damage. The present study was conducted to develop Episiotomy Care Bundle (ECB) for postnatal mothers with episiotomy with a view to improve the wound healing and nursing care. Methodology: A Methodological study was conducted involving modified Delphi technique. 11 experts were selected from the field of Obstetric and Gynaecological nursing. From the pool of items, a preliminary draft of ECB was prepared. The draft was given to experts to evaluate content and face validity in 3 Delphi rounds. Reliability was calculated by inter-rater method and Cohen's Kappa. Internal consistency was checked by Cronbach alpha. Usability of ECB was tested by obtaining responses from 10 staff nurses on the basis of 16 evaluatory parameters. Results: The validity of the tool was assessed by calculating CVR (Content Validity Ratio) and CVI (Content Validity Index). The mean I-CVI (Item-CVI) scores of ECB after Delphi round 2 increased from 0.91 to 0.98, S-CVI/Avg (Scale CVI/Average) increased from 0.91 to 0.98, and S-CVI/UA (S-CVI/Universal Agreement) improved from 0.44 to 0.88. Reliability of final developed ECB was calculated as r=0.8 and Cohen's Kappa as 0.88. Cronbach alpha value was 0.99. Therefore the developed tool was highly consistent and reliable. Usability of ECB revealed that it was highly beneficial, reduced communication errors and improve postnatal mothers care. Conclusion: The study concluded that the developed Episiotomy Care Bundle is a valid & reliable tool for usage on postnatal mothers with episiotomy. It is very effective in improving documentation, postnatal mothers care and reduces communication errors. Therefore, it is recommended for immediate use in the episiotomy care procedure. Keywords: Episiotomy Care Bundle, Methodological, Content Validity Index, Reliability

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**Corresponding author**: Heena Rakwal Rana, Nursing Tutor, Department of Nursing Obstetrics and Gynaecology, BEE ENN College of Nursing, Chak Bhalwal, Jammu, Jammu and Kashmir, India

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#### INTRODUCTION

Childbirth, often known as labour or delivery, is the process by which one or more babies escape the uterus through the vagina. The most common method of childbirth is vaginal delivery. For a healthy normal delivery, vaginal and cervical growth should be progressive, and the tissue should be allowed to develop adequately. Throughout the first and second phases of labour, episiotomy is needed; however, constant care during the second stage reduces the frequency of episiotomy and perineal injury. Spontaneous tears may ensure rapid descent during episiotomy, particularly during foetal head drop and vaginal dilatation formation. According to Fernando, they most often affect the perineal skin and mucosa (1st degree), but they may also affect the perineal muscle (2nd degree), the anal sphincter complex (3rd degree), and the anal mucosa (4th degree). <sup>1</sup> During

the second stage of labour, an episiotomy is a medically planned incision in the perineum and posterior vaginal wall (perineotomy). It is a very frequent obstetric operation.<sup>2</sup> Episiotomy, which is a controlled and well-created perineal incision done at the end of the second stage of labour to help parturition by extending vaginal diameter, is another cause of vaginal tears after birth.<sup>2</sup> The four different forms of episiotomies are as follows: The incision is made downwards and outwards from the midpoint of the fourchette, either to the right or left; it is oriented diagonally along a line about 2.5 cm away from the anus.<sup>2</sup> The third form of incision is lateral, which begins around 1 cm out from the centre of the fourchette and extends laterally. It has various drawbacks, including the risk of damaging the Bartholin's duct. The fourth and final incision is a 'J' shape that starts in the centre of the fourchette and runs posteriorly along the midline for approximately 1.5 cm before turning downwards and outwards along the 5 or 7 o'clock position to avoid the anal sphincter.<sup>1</sup> The most often reported side effects of an episiotomy include post-operative discomfort and pain during intercourses.<sup>3</sup> Inability to control bladder or bowel causes urinary and faecal incontinence. Inflammation is the body's response to infection, irritation, or injury, and it causes redness, swelling, pain, and, in some circumstances, a burning feeling in the affected area.<sup>4</sup> The present study was conducted to develop Episiotomy Care Bundle (ECB) for postnatal mothers with episiotomy with a view to improve the wound healing and nursing care.

### **MATERIAL & METHODS**

The "Quantitative Research Approach" was used to create the "Episiotomy Care Bundle" for postnatal moms with episiotomy who were admitted to chosen hospitals in Ludhiana, Punjab.

Design of Research. A methodological research approach with a multistep development (nonexperimental) methodology was used. The proposed tool's dependability and usefulness were tested in the postnatal wards of Sapling Hospital, Ludhiana, a primary care autonomous facility. The tool's validity was tested by professionals at many North Indian institutions, including DMCH, SMVDU, RGCN, Sapling Hospital, GMCH Rajasthan, and SMGSH Jammu. Experts in the field of obstetric and gynaecological nursing, postnatal moms with episiotomy, staff nurses working in certain sections of postnatal wards are among those being studied.

Purposive sampling approach was utilised to pick specialists and staff nurses based on selection criteria, whereas convenience sampling technique was employed to select postnatal moms.

#### SAMPLE SIZE

Experts  $(n_e)$ : 11 experts working in the field of obstetric and Gynaecological. Postnatal mothers  $(n_p)$ : 10 postnatal mothers with Episiotomy.

Staff Nurses  $(n_s)$ : 10 staff nurses working in postnatal wards.

#### **RESEARCH VARIABLE**

Episiotomy Care Bundle

# INCLUSION & EXCLUSION CRITERIA FOR EXPERTS

Inclusion criteria:

- Experts who are :
- Working in the field of obstetric and gynaecological nursing
- Teaching professionals in the field of obstetric and gynaecological

Nursing

 Experts having >3 years of experience in the field of obstetric and gynaecological nursing

Exclusion criteria:

- Experts not willing to participate
- Not available during the period of Delphi rounds.

For Postnatal mothers

#### Inclusion criteria:

 All the postnatal mothers with episiotomy admitted in postnatal wards of Sapling hospital, Ludhiana

Exclusion criteria:

- Postnatal mothers who were non- consenting
- Postnatal mothers with cesarean section

## For Staff Nurses

Inclusion criteria:

All the staff nurses available during the study working in postnatal wards of sapling hospital, Ludhiana.

Exclusion criteria:

- Staff nurses non-consenting to participate
- Staff nurses having less than 2 year of working experience in postnatal wards of sapling hospital, Ludhiana.

### **Description of Tool**

It consists of 4 parts-

Part A: Socio-demographic profile of experts

Part B: Validity of Episiotomy Care Bundle preliminary draft Part C: Reliability of Episiotomy Care Bundle draft.

Part D: Usability of Episiotomy Care Bundle.

Part A: Experts' socio-demographic profile -

It comprises the following: age (in years), gender, occupation, professional qualification, length of experience (in years), and involvement in the establishment of standards/protocols/patient care.

# Part B: Episiotomy Care Bundle Validity Draft preliminary

The degree to which a tool measures what it aims to measure is characterised as its validity. The strength of a collection of several sorts of evidence is used to determine validity. There are four types of validity: content validity, construct validity, criterion-related validity, and face validity. The content validity of the Episiotomy Care Bundle was developed first in this research study, and then the face validity was examined, as mentioned below.

#### Likert scale for Delphi round 1

a) A three-point scale was utilised to identify crucial elements in the instrument from a pool of items, as measured by the content validity ratio (CVR).

The experts were asked to rate each item from 1 to 3 on a scale of "important," "helpful but not necessary," and "not essential."

b) A four-point relevance scale was distributed to selected experts, who picked one answer (not relevant, slightly relevant, relevant, highly relevant) to evaluate the CVI for each item. The following things were included, modified, and deleted using the Lawshe criteria<sup>5</sup>:

<b>CVI Score</b>	Interpretations
0.9-1	No modification
0.62-0.8	Desirable with modifications
< 0.62	Deleted

With the relevance scale, views of experts were also collected regarding kind of modification.

a) Likert scale for Delphi round 2

After completion of Delphi round 1<sup>st</sup>, the Episiotomy Care Bundle draft was sent for Delphi round 2<sup>nd</sup>. Total 17 items in Episiotomy Care Bundle was again rated on 4 point relevance scale (not relevant, somewhat relevant, relevant, and veryrelevant).

b) Face validity of Performa for Delphi round 3 For third Delphi round 3<sup>rd</sup> face validity of Episiotomy Care Bundle was finalized.

# Part –C: Reliability of Episiotomy Care Bundle draft

It was established with use of proportion of agreement and computing Cohen"s kappa. Interpretation of Kappa, according to Landis and Koch (1977).

Cri	t <u>eria</u>	for	kap	pa

Value of kappa	Strength of agreement
>0.74	Excellent
0.6 - 0.74	Good
0.40 - 0.59	Fair

#### Part –D: Usability of Episiotomy Care Bundle

The Likert scale was used to assess the utility of the Episiotomy Care Bundle, which will be introduced in postnatal wards. The usefulness of the Episiotomy Care Bundle was evaluated using 16 evaluative characteristics on 10 staff nurses. i.e. simple to understand, highly beneficial for postnatal mothers, reducing communication errors, time consuming, not interfering with daily work, providing complete and concise information, practically feasible, improving patient and staff satisfaction, improving documentation, improving patient care, raising awareness among nursing staff, reducing serious complications/emergencies, emphasising all important points, authenticating the work, not increasing work load, providing written guide.

### **Ethical Consideration**

- The research study was conducted after getting a written permission from the Principal and ethical committee of Shaheed Kartar Singh Sarabha College of Nursing, Ludhiana.
- A written permission was taken from Sapling Hospital, Ludhiana.
- The written consent was also taken from the postnatal mothers.

### **Data Collection Procedure**

- Data was collected in the month of June 2022.
- Written permission was taken from the Hospital to conduct the researchstudy
- Written consent was taken from the study subjects.
- Episiotomy Care Bundle was given to the staff nurses for the application on 10 postnatal mothers.
- Usability was checked based on 16 parameters by staff nurses of sapling hospital
- At last data was collected and analyised by descriptive and inferential statistics.

### **Plan for Data Analysis**

Analysis of the data was done in accordance with the objectives of the research study. The descriptive and inferential statistics was used for analysis. Calculation was done manually with calculator, Microsoft excel, Statistical Package for Social Sciences (SPSS 16.0). The level of significance was  $\leq 0.05$  level of significance.

#### RESULTS

**Table 1: Sociodemographic profile of experts** 

Characteristics	f (%) ne=11				
Age (in	years)				
31-40	08(73)				
<u>&gt;41</u>	03(27)				
Gen	der				
Male	00(0)				
Female	11(100)				
Profession					

Doctor	06 (54)					
Nursing personnel	05 (46)					
Professional	qualification					
Post graduation	08 (73)					
Super-specialization	03 (27)					
Duration of professiona	ll experience (in years)					
5-10	04(36)					
11-15	04(36)					
<u>&gt;16</u>	03(28)					
Participation in developme	ent of standards/protocols					
Yes	07(64)					
No	04(36)					
Any in-service education program attended						
Yes	11(100)					
No	00(0)					

## Mean age = 38.22

Table 1 shows the socio-demographic characteristics of 11 experts (6 Doctors and 5 from nursing personnel). According to age (in years), the majority of specialists, i.e. 8 (73 percent), were aged  $\geq$ 41 years, and 3 (27 percent) were aged 31 to 40 years. According to gender, all 11 experts chosen were female (100 percent). According to professional qualifications, the majority of specialists (8(73%) were postgraduates, and 3(27%) had super specialization qualifications (i.e. MD. DNB). According to professional experience, only 4 (36 percent) experts had 5 to 10 years, 11 to 15 years, and 3 (28 percent) experts had  $\geq$ 16 years. According to past engagement in the formulation of standards/protocols, the majority, 7(64%), had previous participation and 4(36%) had no previous participation. All 11 experts (100%) have attended inservice education sessions, according to the in-service education programme attended.

Table 2: Content validity ratio (CVR) of each item for preliminary draft inphase 1  $n_e$ = 11

S. No.	Items	No. of experts rated	Expert	CVR	Interpretation	
		essential (Ne)	opinion			
1.	Use aseptic technique for routine	11		1	Remained	
2	Inspect for:-	11		1	Remained	
	Redness					
	• Edema					
	Ecchymosis					
	• Discharge					
	Amount of discharge					
	4 Color					
	🕌 Odor					
	• Approximation of the wound					
3	Assessment of Pain by numeric pain	10		0.8	Remained	
	rating scale:-					
	• Mild(1-4)					
	• Moderate(5-7)					
	• Severe (more than 8)					
4	Appropriate Positioning:-	09		0.63	Remained	
	Left lateral position with legs closed					
	together					
5	First 24 hours after delivery:-	10		0.8	Remained	
	Cold compresses					
	Use ice packs in the first 24 hours after					
	birth					
6.	After 24 hours of delivery:-	02	9/10	-0.63	Eliminated	
	Infra red lamp therapy		experts said			
	• Distance (12 -16 inches away)		that this			
	Timing (10 min for 3 times/day for 3		therapy is			
	days)		not used in			
			current			

			practices and also not feasible		
7.	<b>Perineal cleaning (Peri cleaning)</b> Timing (One week or as long as mother	9		0.63	Remained
8.	Advice on nutrition and hydration:- Drink at least two liters of water every day, plan healthy balanced diet	11		1	Remained
9.	Perform postnatal exercises Initial After 24 hours	10		0.8	Remained
10	Provide sit's bath to the mother. (approx 20 mins) after 24 hours	0		-1	Eliminated
11	Apply antiseptic cream to the wound daily as prescribed by the obstetrician.	11		1	Remained

**CVR criteria**: <0.59: Eliminated Average CVR = 0.54 >0.59: Remained

The CVR calculations proved to be useful in eliminating unnecessary items and retaining only highly reliable items for Episiotomy Care Bundle. Therefore, 9 items were finalized out of total 11 items after phase 1 of preliminary round.

nd	[]
n	1

ne=11

S.	Items	No. Of experts	I- CVI	Expert	Remarks
No.		agreeing on value 3&4		opinion	
1.	Use aseptic technique for routine	11	1		No modification
2	Inspect for:-	11	1		No modification
	Redness				
	• Edema				
	<ul> <li>Ecchymosis</li> </ul>				
	Discharge				
	Amount of discharge				
	🖊 Color				
	🖊 Odor				
	• Approximation of the wound				
3	Assessment of Pain by numeric	10	0.90		No modification
	pain rating scale:-				
	• Mild(1-4)				
	• Moderate(5-7)				
	• Severe (more than 8)				
4	<b>Appropriate Positioning:-</b>	09	0.80	2/11	Desirable with
	Left lateral position with legs closed			experts	modification
	together			said that	
				this	
				statement	
				needed	
				change by	
				adding	
5	First 24 hours often delivery	10	0.00	iew points	No modification
5	Cold compresses	10	0.90		needed
	Use ice packs in the first 24 hours				needed
	after birth				
6	Perineal cleaning (Peri cleaning)	09	0.80		Desirable
-	Timing (One week or as long as				modification
	mother feel comfortable)				needed
7	Advice on nutrition and	11	1		No modification
	hydration:-				
	Drink at least two liters of water				

	every day, plan healthy balanced diet			
8	Perform postnatal exercises	09	0.80	Desirable
	Initial			modification
	After 24 hours			needed
9	Apply antiseptic cream to the	11	1	No modification
	wound daily as prescribed by the			needed
	obstetrician.			

**I-CVI**<0.62: Deleted **Mean I-CVI= 0.91** 

0.62-0.8: Desirable with modifications

0.9-1: No modifications

The I-CVI calculations and Lawshe criteria proved to be helpful in refining the preliminary draft of Episiotomy Care bundle. Based on item level content validity index (I-CVI), 9 items were finalized and kept in the second draft of Episiotomy Care Bundle.

Table 4:	Values	of p	orobability	y of	chance	occurrence	( <b>P</b> <sub>c</sub> ) a	and	Kappa	value	<b>(K)</b>	for each	item	of I	Delphi
round 1															
n <sub>e</sub> =11															

S.	Items	No. of experts agreeing	I-CVI	Pc	K
No.		on value3&4			
1	Use aseptic technique for routine	11	1	0.00048	1
2	Inspect for:-	11	1	0.00048	1
	• Redness				
	• Edema				
	<ul> <li>Ecchymosis</li> </ul>				
	• Discharge				
	Amount of discharge				
	📥 Color				
	🖊 Odor				
	<ul> <li>Approximation of the wound</li> </ul>				
3	Assessment of Pain by numeric pain rating	10	0.90	0.0053	0.89
	scale:-				
	• Mild(1-4)				
	• Moderate(5-7)				
	• Severe (more than 8)				
4	<b>Appropriate Positioning:-</b>	9	0.8	0.026	0.79
	Left lateral position with legs closed together				
5	First 24 hours after delivery:-	10	0.90	0.0053	0.89
	Cold compresses				
	Use ice packs in the first 24 hours after birth				
6	Perineal cleaning (Peri cleaning)	9	0.8	0.026	0.79
	Timing (One week or as long as mother feel				
	comfortable)				
7	Advice on nutrition and hydration:-	11	1	0.00048	1
	Drink at least two liters of water every day,				
	plan healthy balanced diet				
8	Perform postnatal exercises	9	0.8	0.026	0.79
	Initial				
	After 24 hours				
9	Apply antiseptic cream to the wound daily	11	1	0.00048	1
	as prescribed by the obstetrician.				

**Note:** I-CVI: Item-level content validity index,  $P_C$ (Probability of chance occurrence) was computed using formula [N!/A!(N-A)!] x .5<sup>N</sup>, N is no. of experts in panel=11, A=experts who agree that the item is relevant, K=I-CVI -P<sub>C</sub>/1-P<sub>C</sub> Interpretation criteria for kappa using, Landis & Koch (1977)

Out of 9 items, only 4 items  $(1^{st}, 2^{nd} 7^{th} \text{ and } 9^{th})$  had Kappa value= 1 had excellent. Only two items  $(3^{rd} \& 5^{th})$  had Kappa value = i.e.0.89 had excellent. Also item no. 4<sup>th</sup>, 6th and 8<sup>th</sup> scored Kappa value=0.79 had excellent.

Expert	Items rated 3or 4 on a 4 point relevance scale	Expert proportion relevant (SCVI-e)
1	9	1
2	8	0.88
3	8	0.88
4	9	1
5	8	0.88
6	8	0.88
7	9	1
8	8	0.88
9	9	1
10	8	0.88
11	7	0.77

# Table 5: Scale Content Validity Index for each expert(S-CVI- e) of Delphi round 1 $n_e\!\!=\!\!11$

# S-CVI/UA = 0.44; S-CVI/Avg = 0.91

Criteria for I-CVI: <0.62: Deleted, 0.62- 0.8: Desirable with modifications, 0.9-1: No modifications;

It was concluded that the calculations of scale content validity index for each expert (SCVI-e) proved to be useful in depicting the high validity index of entire scale. Also the SCVI /UA (SCVI/Universal Agreement) helped in depicted the universal agreement for 04 items out of 09 items.

<b>Table 6: Content</b>	validity index of eac	ch item (I-CVI) (	of Delphi round 2
n₀= 11			

Sr.	Items	No. of experts agreeing	I- CVI	Expert	Remarks
1	Use esentic technique for routine	11	1	opinion	No modification needed
2	Inspect for:	11	1		No modification needed
4.	Bodnoss	11	1		No modification fielded
	• Edoma				
	• Edellia				
	Ecclivitions				
	• Discharge				
	• Allount of discharge				
	- Coloi				
	+ Oddi				
3	Assessment of Pain by numeric	11	1		No modification needed
5.	Assessment of 1 am by numeric	11	1		No mounication needed
	■ Mild(1 4)				
	Moderate(5,7)				
	• Severe (more than 8)				
4	• Severe (more man 8)				
4.	I ving suping or side lying position	10	0.00		No modification needed
7.1	to rest	10	0.09		No mouncation needed
4.2	Avoid squatting and crossing of	11	1		No modification needed
	legs.		-		
4.3	Breast feeding in correct position	11	1		No modification needed
5.	Use ice packs in the first 24 hours	10	0.09		No modification needed
	after the birth				
6.	Pad cleaning				
6.1	Change perineal pad, when soaked	11	1		No modification needed
6.2	Wash hands before and after	11	1		No modification needed
	changing pad.				
7.	Perineal cleaning(Peri care)				
7.1	Use savlon/Betadine for perineal	11	1		No modification needed
	cleaning				
7.2	Clean from vagina towards anus and	. 11	1		No modification needed
	one swab for one time.				

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	-				
7.3	Duration(7-10 days)	11	1		No modification needed
				-	
7.4	Clean the wound everyday	11	1		No modification needed
			1		The mounternois needed
				-	
8.	Advice on nutrition and	11	1		No modification needed
	hydration:-				
	Drink at least two liters of water				
	every day, plan healthy balanced				
	diet.				
9.	Ambulation of the patient				
01	Early ambulation of the nationt	11	1		No modification needed
7.1	Earry amoutation of the patient	11	1		no mouncation needed
				-	
9.2	After 3 weeks start with post-natal	11	1		No modification needed
	exercises.				
10	Apply antiseptic cream to the	11	1		No modification needed
	wound daily as prescribed by the				
	obstetrician.				
I-CV	/I <0.62: Deleted			Ν	1ean I-CVI= 0.98

0.62-0.8: Desirable with modification

0.9-1: No modifications

It was concluded that the I-CVI calculations and Lawshe criteria proved to be helpful in refining the draft of Episiotomy care bundle. Based on item level content validity index (I-CVI) out of 17 items, all 17 items were finalized and kept in the final draft of Episiotomy care bundle.

Table 7: Values of probability of chance occurrence (Pc) and Kappa value (K) for	each item of Delphi
round 2	
n – 11	

S.	Items	No. of experts agreeing	I-CVI	Pc	K
No		on value 3&4			
1.	Use aseptic technique for routine	11	1	0.00048	1
2.	Inspect for:-	11	1	0.00048	1
	Redness				
	• Edema				
	<ul> <li>Ecchymosis</li> </ul>				
	• Discharge				
	Amount of discharge				
	4 Color				
	📥 Odor				
	<ul> <li>Approximation of the wound</li> </ul>				
3.	Assessment of Pain by numeric pain rating scale:-	11	1	0.00048	1
	• Mild(1-4)				
	• Moderate(5-7)				
	• Severe (more than 8)				
4.	Positioning				
4.1	Lying supine or side lying position to rest.	10	0.90	0.0053	0.89
4.2	Avoid squatting and crossing of legs.	11	1	0.00048	1
4.3	Breast feeding in correct position	11	1	0.00048	1
5	Use ice packs in the first 24 hours after the birth	10	0.90	0.0053	0.89
6	Pad cleaning				
6.1	Change perineal pad, when soaked	11	1	0.00048	1
6.2	Wash hands before and after changing pad.	11	1	0.00048	1
7	Perineal cleaning(Peri care)	11	1	0.00048	1
7.1	Use savlon for perineal cleaning	11	1	0.00048	1
7.2	Clean from vagina towards anus and one swab for	11	1	0.00048	1
	one time.				
7.3	Duration(7-10 days)	11	1	0.00048	1
7.4	Clean the wound everyday	11	1	0.00048	1
8.	Advice on nutrition and hydration:-	11	1	0.00048	1
	Drink at least two liters of water everyday, plan				

	healthy balanced diet.				
9.	Ambulation of the patient				
9.1	Early ambulation of the patient	11	1	0.00048	1
9.2	After 3 weeks start with post-natal exercises.	11	1	0.00048	1
10	Apply anteseptic cream to the wound daily as	11	1	0.00048	1
	prescribed by the obstetrician.				

**Note:** I-CVI: Item-level content validity index,  $P_C$ (Probability of chance occurrence) was computed using formula [N!/A!(N-A)!] x .5<sup>N</sup>, N is no. of experts in panel=11, A=experts who agree that the item is relevant, K=I-CVI -P\_C/1-P\_C Interpretation criteria for kappa using , Landis & Koch (1977)

The calculations of probability of chance occurrence ( $P_c$ ) and kappa value (K) show a high degree of agreement among the experts. These calculations helped in eliminating any probability of chance agreement among the experts.

Table 8: Scale Content	Validity Index for	r each expert(S-CVI-	e) of Delphi round 2
$n_e=11$			

Expert	Items rated 3-4	Expert proportion relevant(SCVI-e)
1	17	1
2	17	1
3	17	1
4	17	1
5	17	1
6	17	1
7	17	1
8	16	0.94
9	17	1
10	17	1
11	16	0.94

S-VI/UA=0.88; S-CVI/Avg=0.98

Criteria for I-CVI: <0.62: Deleted, 0.62- 0.8: Desirable with modifications, 0.9-1: No modifications; S-CVI/UA=0.9

Thus the calculations of Scale content validity index for each expert (SCVI-e) proved to be useful in depicting the high validity index of entire scale. Also the SCVI /UA (SCVI/Universal Agreement) helped in depicting the universal agreement for 15 itemsout of 17 items. Therefore, it was concluded that the SCVI-e Avg and universal agreement increased in Delphi round 2

Values of Content Validity Index	Delphi round 1	Delphi round 2
Mean I-CVI	0.91	0.98
S-CVI/Avg	0.91	0.98
S-CVI/UA	0.44	0.88

### Table 9: Comparison of Content Validity Index (CVI) of Delphi round 1 and 2

It was concluded that the target of high content validity was successfully achieved after Delphi round 2. The scores of Mean I-CVI, S-CVI/Avg and S-CVI/UA were improved after Delphi round 2.

# Table10: Inter-rater Reliability of Episiotomy Care Bundle (ECB) $n_p=10$

Item No.	Agreements	Disagreements
1	10	0
2	10	0
3	10	0
4	9	1
5	10	0
6	8	2
7	0	10
8	9	1
9	10	0
10	6	4
11	10	0
12	0	10

13	10	0
14	10	0
15	10	0
16	8	2
17	10	0
Total	140	30

Daliahilitar -	Agreement	
Reliability -		

Agreement + Disagreement

r = 0.82

As a result, based on Inter-rater Reliability (degree of agreement) and Cohen's Kappa calculations, it was determined that the produced Episiotomy Care Bundle was highly trustworthy. Based on Cronbach alpha calculations, it was also shown that the produced Episiotomy Care Bundle was extremely consistent, demonstrating good internal consistency.

Table 11:	Testing	usability	of Episiotomy	Care	Bundle

ns=10			
S. No.	Parameters	Mean ±SD	f(%)
1.	Clear and concise information	3.0±0.00	10(100)
2.	All the items in ECB are practically feasible	3.0±0.00	10(100)
3.	Improve staff satisfaction	3.0±0.00	10(100)
4.	Reduce communication errors	3.0±0.00	10(100)
5.	Improve patient care	3.0±0.00	10(100)
6.	Helpful in reducing complications/emergencies related to episiotomy	3.0±0.00	10(100)
7.	Highlight all important points related to episiotomy care	3.0±0.00	10(100)
8.	Authenticate the work done by nursing staff	3.0±0.00	10(100)
9.	*Interrupt routine work	3.0±0.00	10(100)
10.	Highly beneficial for postnatal mothers	3.0±0.00	10(100)
11.	Provide written guidelines for episiotomy care	3.0±0.00	10(100)
12.	Improve Documentation	2.8±0.63	9(90)
13.	*Increase workload of nursing staff	$2.6 \pm 0.84$	8(80)
14.	*Time consuming	$2.6 \pm 0.84$	8(80)
15.	Increase awareness among nursing staff about	$2.6 \pm 0.84$	8(80)
	importance of Episiotomy care		
16.	Easy to understand	$2.6 \pm 0.84$	8(80)

Max score=3Min score=1

It was concluded that the developed Episiotomy Care Bundle would behighly beneficial, effective in improving documentation, patient care and reduces communication errors. Therefore it is recommended for immediate use for episiotomy care.

### DISCUSSION

The socio-demographic profile of 11 specialists was examined in this research study (6 Doctors and 5 from nursing personnel). According to age (in years), the majority of specialists, i.e. 8 (73 percent), were aged  $\geq$ 41 years, and 3 (27 percent) were aged 31 to 40 years. According to gender, all 11 experts chosen were female (100 percent). According to professional qualifications, the majority of specialists (8(73%)) were postgraduates, and 3(27%) had super specialization qualifications (i.e. MD. DNB). According to professional experience, only 4 (36 percent) experts had 5 to 10 years, 11 to 15 years, and 3 (28 percent) experts had  $\geq 16$  years. According to past engagement in the formulation of standards/protocols, the majority, 7(64%), had previous participation and 4(36%) had no previous participation. According to the in-service education

programme attended, all 11 experts (100%) had participated.

In this research, a first draught of an episiotomy care bundle was constructed from a pool of things culled from a thorough assessment of the literature. Eleven professionals in the area of obstetric and gynaecological nursing were chosen. Experts evaluated a total of 11 episiotomy care bundle products. For each of the 11 items, the content validity ratio (CVR) was determined. The critical allowable CVR value for 11 experts is 0.59, according to the Lawshe critical value table. Experts evaluated a pool of objects including 11 things. Two of the eleven items received CVR=1, i.e. > 0.59. Total of two items got CVR 0.59 and were therefore removed.<sup>6</sup>

These results were corroborated by Aguero SD et al, (2017)'s research paper, "Content Validity of Food Quality Survey of Elderly (FQSE)," in which a

questionnaire with 23 items was constructed to examine the FQSE. The computation of the Lawshe Content Validity Ratio was used to determine content validity. The validation procedure included 28 specialists. In terms of content, 23 items were verified across two subscales of the instrument.<sup>7</sup>

Another study, "Design and Implementation Content Validity Study: Development of an Instrument for Measuring Patient-Centered Communication," by Zamanzadeh V et al, (2014), created a preliminary instrument with 188 questions. This preliminary instrument was evaluated by 15 specialists. Following the first round of judging, 108 of the 188 instrument components were eliminated. According to Lawshe criterion, the content validity ratio of the items that were eliminated was less than 0.49.<sup>5</sup>

The first draught of the Episiotomy care bundle was then put to Delphi round 1, which determined the content validity index and scale content validity index. The content validity index was computed using I-CVI (Item content validity) and S-CVI (Content validity of scale).

Minimum acceptable value for CVI-I to include the items is 0.62 according to Lawshe criteria for a panel of 11 experts. Mean I- CVI/average was calculated using formula: I- CVI Avg. =  $\sum$ CVI-I / Total no. of items and was 0.91. Out of 9 items, 6 items scored I-CVI = 0.9-1, thus these items were retained as such in Episiotomy Care Bundle (ECB) without any modification .3 items (i.e. 4<sup>th</sup>, 6<sup>th</sup> and 8<sup>th</sup> item) out of 9 items scored I-CVI=0.80), item no.6 (I-CVI= 0.80) and item no.8 (I-CVI= 0.80) and were therefore desirable with modification.

For item no. 4, 2/11 experts said that this statement needed change by adding few points. As this item was desirable, so it was retained with some modification. According to CVI calculations no modification was needed but as per expert's suggestion, statement was rewritten.

Hence, the I-CVI calculations and Lawshe criteria proved to be helpful in refining the preliminary draft of EPISIOTOMY CARE BUNDLE (ECB). Based on item level content validity index (I-CVI), 9 items were finalized and kept in the second draft of episiotomy care bundle (ECB).

The SCVI /UA (SCVI/Universal Agreement) was calculated using formula, SCVI/ UA = No. of items having UA/ Total no. of items and is 0.60 which reveals that out of 9 items, all the 11 experts had universal agreement (100%) for only 4 items .

Therefore, it was concluded that the calculations of Scale content validity index for each expert (SCVI-e) proved to be useful in depicting the high validity index of entire scale. Also the SCVI /UA (SCVI/Universal Agreement) helped in depicting the universal agreement for 4 items out of 9 items.

Therefore desired modifications were done and 2<sup>nd</sup> ECB draft was prepared and subjected to 2<sup>nd</sup>Delphi round to achieve higher universal agreement among

the experts for all the items.

In the second Delphi round, based on the modifications done, a  $2^{nd}$  draft of ECB was prepared and given to experts for content validation. Minimum acceptable value for CVI-I to include the items is 0.62 according to Lawshe criteria for a panel of 11 experts. Mean I- CVI/average was calculated using formula: I-CVI Avg. =  $\sum$ CVI-I / Total no. of items and was 0.98. Out of 17 items, 17 items scored I- CVI = 0.9-1

As a result, it was determined that the I-CVI calculations and Lawshe criteria were useful in revising the design of the Episiotomy Care Bundle. Based on the item level content validity index (I-CVI), all 17 items were finalised and included in the final edition of the Episiotomy care bundle.

The ECB draught was presented to experts for face validity. All experts provided their opinions on the face validity of the ECB, and a final draught of the ECB was developed based on their ideas, i.e. qualitative data.

A research by Caruso R et al, "Italian Version of Dyspnoea-12: Cultural- Linguistic Validation, Quantitative and Qualitative Content Validity Study," validated these results (2016).

This was a methodological research in which the quantitative content validity of expert panellists' responses was analysed using the Content Validity Ratio (CVR) and index (I-CVIs & S-CVI). CVR, I-CVI, and S-CVI scores were all good in this investigation for all translated items. <sup>8</sup> Similar investigations using the Delphi approach and estimating CVI were reported by Devi R et al, (2017)<sup>9</sup>, Bijarania SK et al, (2017)<sup>10</sup>, and Kaur J et al, (2012)<sup>11</sup>.

After completing the final edition of the Episiotomy care bundle, the reliability was computed to indicate homogeneity or unanimity in the observer ratings. The Episiotomy care bundle was used on ten Episiotomy patients. The dependability was assessed using the agreements and disagreements of independent observers. The reliability rating is (r = 0.8), indicating a high level of agreement. As a result, the tool was judged to be trustworthy. Cohen's Kappa was 0.88, while Cronbach alpha was 0.99. As a result, the tool was very consistent and dependable.

Three independent assessors examined 55 scar and normal skin sites using subjective and objective instruments in a research titled "Investigating the intra- and inter-rater reliability of a panel of subjective and objective burn scar measuring tools" by Lee KC et al, (2016).<sup>12</sup> The intra-class correlation coefficient (acceptable >0.70) was used to assess dependability. The intra- and inter-rater reliability of the Derma scan ultrasonography (dermal thickness, intensity) was outstanding (>0.90).<sup>12</sup> Similar studies were published by Kaur J et al,  $(2012)^{11}$  and Sirajudeen MS et al,  $(2012)^{13}$ , in which the tool's reliability was assessed using the inter rater reliability technique and the Cohen's Kappa coefficient.

The usability of the Episiotomy care Bundle was

tested with the help of 10 staff nurses on the basis of 16 evaluatory parameters, which included easy to understand, highly beneficial for postnatal mothers, reducing communication error, time consuming, not interfering with daily work, providing complete and concise information, practically feasible, improving patient and staff satisfaction, improving documentation, improving patient care, raising awareness among nursing staff, and reducing serious complications. The Episiotomy Care Bundle was deemed highly beneficial by 100 percent of staff nurses. It reduces communication errors, is not time consuming, provides complete and concise information, is practically feasible, improves patient and staff satisfaction, improves patient care, reduces serious complications/emergencies, highlights all important points, authenticates the work, and provides written guidelines.

Burchett HAD et al. conducted a research titled "Assessing the adaptability of public health intervention evaluations from one environment to another: a methodological investigation of the usability and utility of assessment methods and frameworks" (2017). References were screened using predetermined criteria. The tools were put to the test by determining the adaptability of a Swedish weight control intervention to the English environment. No tool was deemed appropriate for determining applicability.<sup>14</sup>

#### CONCLUSION

# On the basis of results of data analysis the following conclusion were reached

According to the findings of this study, the designed Episiotomy care bundle has an adequate degree of content validity.

Despite the fact that the overall content validity index of the ECB employing the universal agreement technique is excellent and may be supported by a high value of S-CVI/AVG.

#### LIMITATIONS

- The Delphi approach was modified.
- The target population was chosen using a purposeful and convenient sampling strategy, which limited the study's generalizability to the specific environment.
- Because expert input in content validity research is subjective, the study is susceptible to bias that may occur among the experts.
- The Episiotomy Care Bundle developed is not relevant to other kinds of wounds in postnatal moms.
- Only one nursing expert was able to continue responding until the last Delphi round.
- Usability was restricted to just ten patients.
- · Several observers were present during the

administration of the episiotomy care package.

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