CHAPTER 3

Methodology

This chapter describes the methodology of the study. The contents consist of a description of the research design, participants and samples including sampling methods, research instruments, data collection procedures, data analysis, and human rights protections. Each aspect of the methodology is presented in detail to the relevant step of the instrument development process.

3.1 Research Design

The instrument developmental research design was used to develop a clinical pain assessment scale for preterm neonates in NICU. The study was carried out at two NICUs of Maharaj Nakorn Chiang Mai Hospital, Chiang Mai, Thailand. The development of the clinical pain scale for preterm neonates included three phases (see Figure 3.1). In the first phase, the construction of initial scale followed a guideline of scale development mainly based on DeVellis (2012) to achieve the goal of the study. In the second phase, implementation of the clinical pain scale with a target group was performed for validation and reliability testing. In the third phase, the clinical utility of the clinical pain scale was evaluated using a multi-dimensional model of clinical utility as stated by Smart (2006). The following contents included the detail of participants and samples, research instruments, data collection and statistical analysis in each step of scale development (see Table 3.1).

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3.1.1 Phase I Construction of Initial Scale

The development procedure of the clinical pain assessment scale consisted of four steps including 1) analyzing pain concept in preterm neonates to determine clearly what it was to be measured, 2) generating a list of pain indicators by clinical observations, 3) determining the format for measurement by clinical experts' interview, and 4) having the initial clinical pain scale reviewed by content experts. The detail of each step is described as follows:

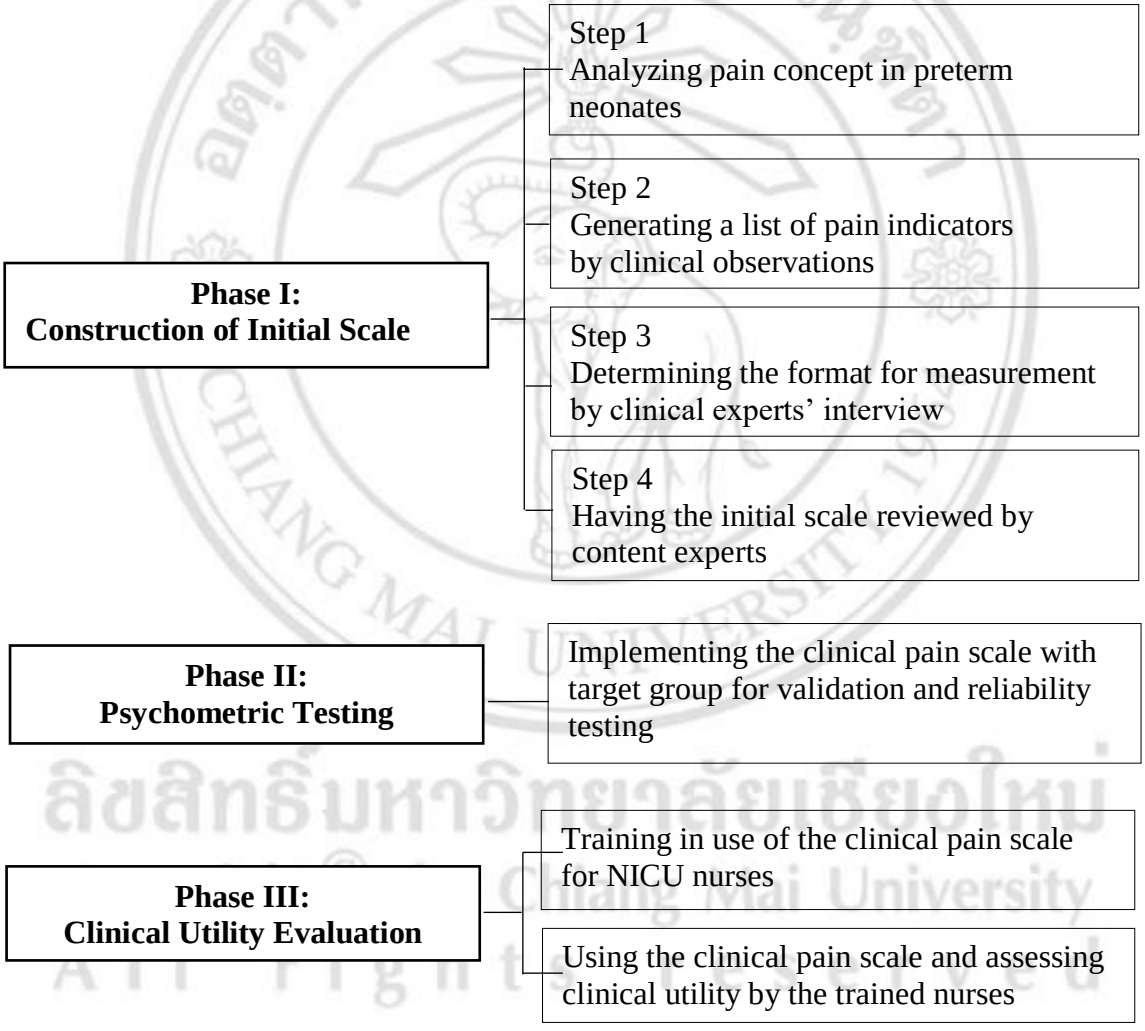

Figure 3.1 The process of clinical pain scale development

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Table 3.1

The participants, samples, and instruments in each phase

Development process	Participant and Sample	Instrument
Phase I: Construction of the Initial Scale		
Step 1 Analyzing pain concept in preterm neonates	Participant: none Sample: none	None
Step 2 Generating a list of pain indicators by clinical observations	Participant: one nurse educator Sample: 15 occasions	Structured observation checklist of pain indicators
Step 3 Determining the format for measurement by clinical experts' interview	Participant: five clinical experts Sample: none	1. Checklist of seven pain indicators 2. Open-ended questions of interview guide (15 questions)
Step 4 Having the initial scale reviewed by content experts	Participant: six content experts Sample: none	1. Initial clinical pain scale 2. Indicators evaluation form
Phase II: Psychometric Testing		
Implementing clinical pain scale with target group for validity and reliability testing	Participant: one registered nurse Sample: 53 occasions	1. Clinical Pain Scale (6 indicators) 2. PIPP-R Scale (7 indicators)

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Table 3.1 (continue)

Development process	Participant and Sample	Instrument
Phase III: Clinical Utility Evaluation		
Using clinical pain scale and assessing clinical utility by the trained nurses	Participant: 30 NICU nurses Sample: 150 occasions	Clinical utility questionnaire (17 items)

1) Step 1 Analyzing pain concept in preterm neonates

In this step, the concept of pain in preterm neonates was selected for the analysis based on the principle of a manageable concept selection. The purposes of this analysis was to clarify the pain concept in preterm neonates and to identify indicators of pain in preterm neonates. According to the purpose of concept analysis, antecedent, attributes, consequences, and empirical referents were identified. The researcher determined the defining attributes of pain in preterm neonates and determined both pain reactivity and specific factors associated with pain response. However, any types of case (model case, contrary case, related case, and borderline case) were not necessary to be identified in this study. At the end of this step, the operational definition of pain in preterm neonates was stated and both pain reactivity and specific factors affecting pain reactivity were summarized.

2) Step 2 Generating a list of pain indicators by clinical observations

Due to the purpose of a clinical scale, direct observations of preterm neonates in relevant situations was a good way to find applicable indicators. In this step, clinical observations and literature review were used for generating a pool of pain indicators. Prior to direct observations, a structured observation checklist of pain indicators was developed.

A Participant

For the clinical observation, one nurse educator was invited to observe preterm neonates simultaneously with the researcher at the bedside using a structured observation checklist of pain indicators. Inclusion criteria of this participant were having earned a master's degree in nursing and having expertise in caring for preterm neonates in NICU over five years. She is a faculty member of Faculty of Nursing, Chiang Mai University with

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experience of being a research assistant, research instrument reviewer and also familiar with the research process. The curriculum vitae of this participant is in Appendix A-1.

Samples

Regarding to samples for observation, 15 occasions of painful procedures in preterm neonates were observed at the bedside by two observers, a researcher and another nurse educator. Fifteen observations provided enough information due to prior exploratory studies existence (Bozzette, 1993; Walden et al., 2001). Equal numbers of preterm neonates were planned for selection from each gestational age group of ELGA, VLGA, and late preterm infants as possible. Inclusion criteria of preterm neonates were 1) being hospitalized in the NICU, 2) having ≥ 24 to $36^{6/7}$ weeks' gestational age at birth, 3) being scheduled to receive a painful procedure within a 24 hour period, and 4) being permitted by their parent(s) or legal guardian(s) to participate in this study indicated by their written informed consent. Exclusion criteria were showing signs of life-threatening malformation, having undergone any type of operation or being treated with continuous neuromuscular blocking agents, and receiving analgesics or sedative within 72 hours.

Parents of nine preterm neonates were approached, and eight of preterm neonates met the inclusion criteria for observation. The other infant was not permitted by her parents for video recording. Data of 15 occasions were obtained from those eight preterm neonates (six females, two males) (see Table 3.2). These infants were in NICUs (five cases in NICU I, three cases in NICU II). Under standard and usual nursing care of the NICUs, each infant was observed by nurse educator and the researcher for only one to four occasions depending on the clinical requirement for blood collection, none of them for research purposes. All infants needed respiratory support and supplemental oxygen via endotracheal tube (ETT), CPAP, and cannula. The gestational age at birth ranged from 27 to 29^{+4} weeks and the mean postnatal age on the study day was 17.20 days (*SD* = 5.66). Gestational age of the infants did not vary as planned because there was no infant with > 30 weeks of gestational age admitted in the NICUs during the time of this step. However, the data from those eight preterm neonates were saturated and enough for gathering data in the next step.

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Table 3.2

Characteristics of eight preterm neonates who were observed during painful procedures in Phase I

Case	Sex	Respiratory support on each occasion	GA at birth (weeks)	Number of observed occasions	Data of each occasion	
					Postnatal day at each occasion (days)	Number of pain exposures prior to each occasion
1	F	ETT	27	2	23,27	77,81
2	F	ETT	28	1	11	7
3	M	ETT	28	2	15,22	47,74
4	F	ETT	28	2	11,12	48,49
5	M	ETT/	28	2	16	47
		CPAP			24	54
6	F	ETT	28^{+}	4	11,15,19,25	46,56,64,75
7	F	NPCPAP	28^{+4}	1	12	33
8	F	Cannula	29^{+4}	1	15	27

Note. F=female, M=male, ETT= endotracheal tube, CPAP= Continuous Positive Airway Pressure, NPCPAP= Nasopharyngeal Continuous Positive Airway Pressure

Research instrument

A structured observation checklist of pain indicators, one instrument in this step, had been developed by the researcher according to literature reviews and findings of concept analysis in previous step. It consisted of two parts including the personal data profile of preterm neonates (i.e., sex, gestational age at birth, postnatal age or length of NICU stay, respiratory support, and number of prior pain exposures) and a list of pain indicators (see Appendix B). The list of pain indicators included brow bulge, eyes squeeze, nasolabial furrow, vertical mouth stretch, sleep-wake states, and heart rate.

A digital video recorder (SONY NEX-C3) with a tripod stand, which provided close up view of the infant' facial image, was mounted on the bedside for continuous monitoring for all 15 occasions. The interval timer application in a smart phone (iPhone 6 Plus) was set and connected to earbuds for two listeners.

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Data collection

Data collection of Step 2 was performed as follows:

1) After receiving ethical approval from and permission of the hospital director, the researcher contacted another observer and informed her about the purpose of the study and observation process. The researcher also clarified all pain indicators in the structured observation checklist with the observer. On the day before naturalistic observation, the researcher selected both painful events and infants with as much heterogeneity as possible.

2) On a day shift of the observation day and after routine clustered nursing care was completed, an infant was immediately prepared (i.e., supine positioning, stabilized and calmed, sensor placement of heart rate monitoring, removal of eyes pad, shut off phototherapy). Then, a timer started for a washout period, a 10-minute-period which an infant received no handling to ensure that previous condition affecting pain reactivity were eliminated (or assumed to be eliminated). However, in real situation, some activities that interrupted the washout period were performed including X-ray, echocardiography, and turning off all lights for the eye examination and performing laser. The other example of episodes that delayed washout period were parents' visiting. The camera was set to obtain a full view of the entire body of a preterm neonate before any painful procedure. Video recording ran continuously from the end of the washout period to the end of recovery.

3) After the washout period, the observer and the researcher simultaneously, but independently, observed preterm neonates using the structured observation checklist of pain indicators for three phases including baseline (30 seconds interval of ten-minute observation), puncture (30 seconds interval until needle removal), and recovery phases (30 seconds interval of 10-minute observation).

4) The completed and rechecked data from two observers as well as from the video clip were coded with case number for subsequent recheck. All data obtained from two observers were compared and summarized. In addition, comments from two observers were noted. Discrepancies were rated and resolved by going back to the video recording.

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Data analysis.

The researcher calculated frequencies of occurrence of each pain indicator during baseline, puncture, and recovery phases. The data from the structured observation checklist of pain indicators was put in order and then formed the checklist of seven pain indicators that were used for the next step.

3) Step 3 Determining the format for measurement by clinical experts' interview

In this step, five clinical experts were interviewed individually to determine the format of pain assessment scale. Determining the format for measurement includes revising the indicators, selecting a response format, and scoring of each indicator.

Participants

Five clinical experts participated in an individual interview. Inclusion criteria of those clinical experts had expertise in caring for preterm neonates in NICU for at least ten years and currently worked closely with preterm neonates, being able to identify indicators related to pain, and willing to participate in this study. Five clinical experts were composed of one neonatologist, one bachelor's prepared nurse, and three master's prepared nurses. Their curriculum vitae are in Appendix A-2.

Research instrument

Two instruments including the checklist of seven pain indicators and the 15 open-ended questions of the interview guide (see Appendix C-1) were developed by the researcher to explore a construct of pain in preterm neonates in this step. The checklist of seven pain indicators was based on data from the clinical observations in Step 2. The 15 open-ended questions of interview guide related to four topics including meaning and characteristics of pain in preterm neonates, pain indicators in preterm neonates, scoring of each indicator, and use of pain scales to assess pain in preterm neonates in clinical setting.

Data collection

Data collection of the third step was performed as follows:

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1) After receiving permission from the supervisor of the clinical experts, the researcher contacted each clinical expert and arranged an appointment with them. The researcher informed each clinical expert about the purpose of the study and an individual interview process.

2) The researcher conducted a personal interview with each clinical expert following the interview guide. After receiving their permission, the researcher took notes and audio recorded communicating sound. The face-to-face interview with each person was conducted during the working-time on a working-day in a conference room of their NICU and lasted approximately 60 minutes. The researcher checked completeness of the obtained data.

Data analysis

All comments from audio recording and the researcher's notes regarding the four topics as mentioned were recorded and the content was analyzed. Based on the comments from the five clinical experts, the indicators of the scale were revised and scoring of each indicator was identified, and then called "The Initial Clinical Pain Scale". Discrepancies were resolved by returning to the expert and discussion with the thesis advisory committee.

4) Step 4 Having the initial scale reviewed by content experts

In this step, the initial scale was reviewed by a panel of content experts to obtain content-related validity evidence, especially the relevance of pain indicators and appropriateness of the scale format.

Participants

Six content experts who are specialists in preterm infant care in NICU, not the same persons as the clinical experts in the earlier step, were invited. Inclusions criteria of those experts were 1) having experience working directly with preterm neonates for at least five years, 2) currently working closely with preterm neonates, and, 3) being able to identify indicators related to pain, and 4) willing to participate in this study. Two nursing educators, two advanced practice nurses (APN) in pediatric nursing, one neonatologist, and one neurologist validated content of the initial scale in this step. With regard to their education, two have master's degree in nursing, two have a degree of Doctor of Medicine (MD.) and two have a PhD in nursing (see Appendix A-2).

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Research instruments

One instrument in this step was an indicator evaluation form for experts which was developed by the researcher. It was composed of two parts. Part 1 included the relevance of indicators to pain in preterm neonates (7 items) and the relevance of indicator scoring (14 items) and part 2 was the appropriateness of the scale format (10 items) (see Appendix C-2). In the first part, the experts were asked to rate the relevance of each indicator and relevance of each indicator scoring on a four-point Likert scale. The answer choices included 4 = very relevant, 3 = quite relevant, 2 = somewhat relevant, and 1 = not relevant. In the second part, the experts were asked to rate the appropriateness of the scale format on a four-point Likert scale. In addition, the experts were asked to give comments and suggestions for indicators and/or scoring revisions.

Data collection

Data collection of the forth step was performed step by step as follows:

1) After contacting each expert, the researcher delivered the same documents to six experts. Documents included the cover letter, the initial clinical pain scale and the indicator evaluation form. The purpose of the cover letter was to explain the objective of the study, instrument development process, especially how to obtain pain indicators on the initial clinical pain scale. The experts were asked to independently review the initial clinical pain scale and evaluate its indicators and scoring. The researcher requested permission to come back to receive the document within one month. All experts returned the questionnaires with their comments and suggestions.

2) Two parts of the indicator evaluation form were summarized. Regarding the relevance of indicators to pain and indicator scoring, the researcher calculated the content validity index from the returned indicator evaluation form. Item-level content validity index (I-CVI) related to relevance of pain indicators and scoring of each indicator were calculated. Since the indicator of heart rate change was judged with CVI, the second-round review of experts was performed. All experts returned the second-round review questionnaires with their comments and suggestions. With regard to the appropriateness of the scale format, the researcher summarized all comments and then revised the initial scale format for the following phases.

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Data analysis

Regarding the relevance of indicators to pain, the I-CVI was calculated to indicate content validity of each indicator. The number of content experts giving items a relevance rating of three or four was divided by six which was the total number of raters to calculate I-CVI. The indicator with lower values would be discarded. In addition, the scale-level content validity index, averaging method (S-CVI/Ave) was calculated by summarizing of all I-CVIs and then dividing by the number of indicators. Polit, Beck, and Owens (2007) recommended that for a scale, I-CVI being .78 or higher and S-CVI/Ave being .90 or higher indicates a very good content validity. With regard to the appropriateness of the scale format, the number of experts rated in each item was summarized as well as additional comments and suggestion for indicator and/or scoring revision.

3.1.2 Phase II Psychometric Testing

In this phase, the newly developed clinical pain scale was implemented with the target group of preterm neonates who were having ≥ 24 to $36^{6/7}$ weeks' gestational age at birth in the NICUs. The reliability and validity of the clinical pain scale for preterm neonates were examined.

Reliability testing was performed with two approaches.

1) Internal consistency testing was performed to determine whether all indicators in the scale consistently measure pain in preterm neonates.

2) Inter-rater reliability testing was performed to examine the degree of agreement between two observers.

Construct validity testing was performed with two approaches.

1) Based on previous research findings, hypothesis was stating that the total pain scores of the puncture phase were higher than those of baseline and recovery phases. The comparison of total pain scores obtained from the clinical pain scale during three phases of painful procedures was conducted with hypothesis testing approach. In this study baseline and recovery phases are known to be a non-pain situation, whereas puncture and squeezing phase

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are known to be a painful situation; therefore, comparing between scores of those situations can test these hypotheses.

2) The comparison of total pain scores obtained from the clinical pain scale and from the PIPP-R scale as another measure of pain was performed to examine convergence evidence.

Participant

A registered nurse was recruited to serve as an observer for assessing pain in preterm neonates. Inclusion criteria of this participant were having earned a master's degree in nursing, having expertise in caring for preterm neonates in NICU over five years, and having experience in using PIPP-R in clinical setting. She is a registered nurse of NICU, Maharaj Nakorn Chiang Mai Hospital who's having experience of being research assistant and knowing research process as well as familiar with using the PIPP-R in English version. Curriculum vitae of the registered nurse is in Appendix A-1.

Sample

Preterm neonates were recruited from two NICUs in Maharaj Nakorn Chiang Mai Hospital. A purposive sampling method was employed to recruit eligible subjects who met the following inclusion criteria: 1) being hospitalized in the NICU, (2) having ≥ 24 to $36^{6/7}$ weeks' gestational age at birth (3) being scheduled to receive a painful procedure, and (4) being permitted by their parent (s) or legal guardian (s) to participate in this study indicated by their written informed consent. An equal number of preterm neonates were selected from each gestational age group of ELGA, VLGA, and late preterm infants as possible. Exclusion criteria were preterm neonates who showed signs of life-threatening malformation, had undergone any type of operation or treated with continuous neuromuscular blocking agents, and received analgesics or sedative within 72 hours.

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Concerning the sample size estimates for test of difference between mean scores of three phases, eta-squared was used. Polit and Hungler (1999) suggested that if no estimates of eta-squared could be developed on the basis of prior study, then the researcher would predict whether effects are likely to be small, medium, or large. In this study, a medium effect (eta-squared .06) was chosen. Assuming an α of .05 and power of .80, a sample of 53 events per

group was required. The data of 53 occasions that clinically required blood collection were obtained from 19 neonates (11 males and 8 females). Their age was between 24 to 36^{+1} weeks' gestational age at birth and 26^{+6} to $36^{6/7}$ weeks of postconceptional age on the day of the study (see Table 3.3). Thirty three occasions were obtained from 11 preterm neonates age ≥ 32 to $36^{6/7}$ weeks of gestational age at birth and 20 occasions were obtained from eight preterm neonates aged < 32 weeks of gestational age at birth. Thirty-nine occasions were performed in NICU II and the rest of them in NICU I. The preterm neonates that needed respiratory support via ETT, cannula, and nasopharyngeal continuous positive airway pressure (NPCAP) were 36, 11, and 6 occasions, respectively. The average number of previous pain exposures after birth was 20.27 times (*SD* = 29.30, range 1 to 137).

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Table 3.3

Characteristics of 19 preterm neonates who were observed during painful procedures in Phase II

Case	Sex	Respiratory support	GA at birth (weeks)	Number of observed occasions	Data of each occasion	
					Postnatal day at each occasion (days)	Number of pain exposures prior to each occasion
1	M	ETT	24	2	23,50	78, 116
2	M	ETT	27^{+}	2	64,66	133,137
3	F	ETT	28	4	11,17,24,30	5,17,29,38
4	F	ETT	30	4	10,12,17,18	11,13,18,19
5	F	ETT	30	3	16,18,19	28, 32, 33
6	M	ETT	31	3	1,2,3	7,14,16
7	F	Cannula	31	1	22	21
8	M	ETT	31^{+2}	1	35	56
9	M	ETT	32	3	1,2,3	4,8,14
10	M	ETT	33^{+}	4	3,6,7,8	23,35,39,41
		Cannula		1	28	52
11	F	Cannula	33^{+2}	2	4,5	14,17
12	F	Cannula	34	1	1	4
13	M	Cannula	34	3	3,5,6	6,9,11
14	M	NPCAP	34^{+3}	5	2,3,4,5,8	1,6,10,11,17
		Cannula		1	9	18
15	F	NPCAP	35	1	2	7
16	M	ETT	35^{+}	6	3,4,7,10,11,12	20,21,31,35,38,40
17	F	Cannula	36	1	1	3
18	M	ETT	36	2	1,4	7,24
19	M	ETT	36^{+1}	2	2,5	13,20
		Cannula		1	6	25

Note. F=female, M=male, ETT= endotracheal tube, NPCPAP= Nasopharyngeal Continuous Positive Airway Pressure

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Research instruments

Two instruments including the newly developed clinical pain scale for preterm neonates and the PIPP-R scale (see Appendix C-3) were used to examine convergence validity of the newly developed scale. The PIPP-R scale has been used widely to assess acute pain in preterm infants in research studies. In the recent study, its inter-rater reliability was .92 (Gibbins et al., 2014). A PIPP-R score is the sum of points for all seven indicators and the presence of pain is defined as its score ≥ 7 (Stevens et al., 1996). Prior to implementation for 53 occasions, inter-rater reliability of the PIPP-R scale was tested by the registered nurse and the researcher in five preterm neonates which yielded a reliability coefficient of 1.00.

Data collection

Data collection of the phase II was performed step by step as follows:

1) All parents of hospitalized preterm neonates who met the inclusion criteria were approached to allow their child participate in the study.

2) On a morning shift and after routine clustered nursing care was completed, the observer and the researcher simultaneously, but independently without discussion, observed each occasion of clinically required blood collection using the clinical pain and PIPP-R scales for three phases including baseline, puncture, and recovery phase. To meet the objective of using the scale in real world clinical conditions, a specific point of time for scoring was to be regularly and constantly used. Baseline, puncture, and recovery of the PIPP-R scale were performed at 15 seconds, 30 seconds, and 30 seconds, respectively, based on the PIPP-R instruction. While the baseline, puncture, and recovery of the clinical pain scale were performed at 30 seconds, 60 seconds, and 60 seconds, respectively, based on literature review and the observations in previous step.

3) The researcher completed and rechecked data which were coded with a case number for subsequent rechecks. The same process was repeatedly conducted for all 53 occasions. All data obtained from two observers were compared and analyzed. At the end of Phase II, the researcher printed the clinical pain scale results to prepare to test for clinical utility.

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Data analysis

1) Internal consistency and inter- rater reliability were analyzed.

1.1) According to estimations of the relations between and among the pain indicators for internal consistency testing, Cronbach's alpha coefficient was calculated. Scores obtained from six indicators of the clinical pain scale during procedures (n = 53) were used to compute Cronbach's alpha coefficient, inter-items correlation matrix among them, corrected item-total correlation, and Cronbach's Alpha if items were deleted.

1.2) Regarding observations from two observers, the inter-observer reliability was determined to assess the degree of agreement between two observers using intraclass correlation coefficient. The total pain scores assessed with the clinical pain scale by the observer and the researcher in baseline, procedures, and recovery phases were computed for intraclass correlation coefficients.

2) Construct validity were tested with two evidences, hypothesis testing and convergence examination.

2.1) To determine the differences of total pain scores measured by using hypothesis testing approached across three phases of observations, ANOVA was planned for use. The assumptions of one way ANOVA including homogeneity of variance, independence of observations, normal distribution of the populations from which the samples were drawn or random samples, interval-level data were examined. The assumption of normality and homogeneity of variance have not been met for the given samples, thus, Kruskal-Wallis test, the non-parametric alternative to ANOVA, was used instead.

2.2) To determine how closely the clinical pain scale measured the same construct as the PIPP-R scale, Pearson's correlation coefficients was planned to be used. But the assumption of normality was not met for the given samples; therefore, Spearman rank correlation, non-parametric statistics were used instead.

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3.1.3 Phase III Clinical Utility Evaluation

Most of the scales developed for measuring health are used within the context of research; however this clinical pain scale was developed not only for research but also for clinical use. Therefore, clinical utility of the clinical pain scale from Phase II was tested with neonatal nurses in the clinical setting.

Participants

Participants in this phase were general professional nurses in NICU who were users of a pain assessment scale. Inclusion criteria was nurses who were currently working full time in the two NICUs of Maharaj Nakorn Chiang Mai Hospital and willing to participate in this study. The entire 32 licensed nursing staff of two NICUs were invited to participate in this phase, but one nurse has been promoted to be a supervisor of the pediatric nursing division and was not currently working fulltime as a pain assessment scale user. Another nurse was previously invited to be the observer in the development process. Therefore, only 30 nurses participated and were trained to use the scale. With regard to their education, three had earned a master's degree and 27 had earned a bachelor's degree. The average age of nurses was 39.39 years (*SD* = 9.92, range 24 to 56) and their average NICU experience was 9.69 years (*SD* = 7.12, range 10 months to 33 years).

Sample

Regarding samples for using the clinical pain scale, 150 occasions of painful procedures in preterm neonates were conveniently observed at bedside by the 30 trained nurses (five occasions per each nurse). To fulfill this process, preterm neonates with ≥ 24 to $36^{6/7}$ weeks' gestational age at birth were recruited through the admission of two NICUs. Inclusion and exclusion criteria were the same as those infants in Phase I and II.

Research instrument

A clinical utility questionnaire was developed by the researcher based on the multi-dimensional model of clinical utility (Smart, 2006) (see Appendix C-4). Seventeen questions to explore nurse opinions regarding use of the clinical pain scale in terms of appropriateness (5 items), accessibility (2 items), practicability (6 items), and acceptability (4 items). Each question was rated on a four-point Likert scale. The answer choices include 4 = very good, 3 = good, 2 = fair, and 1 = poor. An additional open-ended question was utilized for comments and suggestions.

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Data collection

Data collection of Phase III was performed step by step as follows:

1) The 30 NICU nurses who met the inclusion criteria were invited to participate in this phase and arranged an appointment for group training after signing consent form.

2) Six group training sessions were organized for preparing all 30 nurses before using the scale at bedside. Each nurse was required to participate in only one session. The training session included a lecture regarding use of the new clinical pain scale with video case scenarios and practice of scoring from video case scenarios. Video case scenario of both preterm infants < 32 weeks and ≥ 32 weeks of gestational age at birth were used.

3) Each trained nurse used the clinical pain scale at bedside with five observations. After five observations were completed, the nurse answered the clinical utility questionnaire and returned it to the researcher. The researcher checked for completeness of data and gave them a gift.

Data analysis

The mean scores of four clinical utility dimensions of the questionnaire were calculated and qualitative data obtained from open-ended questions were analyzed using content analysis.

3.2 Human Rights Protections

Permission for the study and ethical approval were obtained from the Research Ethic Review Committee of the Faculty of Nursing and the Faculty of Medicine, Chiang Mai University (see Appendix D1-3). Human right protections of two groups of people including samples and participants was described as follows:

With regard to samples, subjects were recruited from preterm neonates who were admitted to the NICUs. The parents or legal guardians of any preterm neonates who met the stated criteria were asked to allow their infants to participate in the study. The researcher explained the purpose of the study and the research procedures including video recording, benefits and risks, and expected time needed for the study to parents of preterm neonates. Then, parents or legal guardians of all preterm neonates were given written informed consent form

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and had enough time to read all information with understanding before signing. The information given to the parents of selected infants and the informed consent form they signed were shown in Appendix E 1-2.

All preterm neonates routinely undergo procedures multiple times during the day. Pain assessment is a part of daily care and is nonvasive and only observe characteristics. The infant's environment was altered and no procedure was added for observation. Usual care for pain prevention and alleviation of infant pain was continued. A minimum standardized protocol was still employed for all infants ensuring at least a minimum level for known comforting strategies such as positioning support, swaddling and providing some regulatory support to infants. All parents or legal guardians of preterm neonates were informed that they have the right to withdraw from the study anytime without any prejudice or negative effect. The demographic data of preterm neonates involved collection of data from existing medical and nursing records. No information identifying patient was collected on the data collection forms. No names or hospital number were used. Confidentiality was maintained for all study observations. The demographic information sheets and all score sheets were stored in a locked file at the nursing faculty office, shared only with the dissertation committees, and was destroyed after the completion of the study.

Participants including two nurse observers, five clinical experts, six content experts, 30 NICU nurses, were invited to participate in this study with respect to ethics the rights-based approach. The researcher explained the purpose of the study, the research procedures and the right to withdraw from the study anytime without any prejudice or negative effect. The curriculum vitae of all participants were provided by themselves and allowed for citation in the study.

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