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Improvement of Nurses' Clinical Practice in Neonatal Pain Management: A Protocol of Evidence-Based Intervention

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Abstract

Background: Despite the expansion of knowledge of neonatal pain assessment and management, there is still a considerable gap between nurses' clinical practices in Iran and available evidence. The aim of this study was to develop an evidence-based protocol for neonatal pain management and to evaluate its effectiveness on nurses' clinical practice.

Methods: The present study will be based on the Johns Hopkins nursing evidence-based practice (JHNEBP) model and the three stages of practice question and project planning, evidence, and translation (PET). In this way, after forming an interprofessional team, clinical practice questions will be defined, and the main stakeholders will be identified. Then, the types, levels, and quality of evidence will be assessed to summarize their final strength using the proposed tools of the model, and finally, recommendations will be developed. In the translation phase, the recommendations will be implemented during a stepped wedge cluster randomized trial, and its implications for nursing practices in the management of pain in hospitalized neonates will be evaluated.

Results: The results of this study will lead to the production of an operational and applicable protocol in the management of pain in hospitalized neonates. It can provide the basis for improving the clinical practice of nurses and subsequently improving the quality of neonatal care.

Conclusion: One of the strengths of this study is the use of an interprofessional team approach, considering the clients' priorities, and the improvement of organizational culture in order to endeavor for knowledge translation and change in clinical practice.

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Highlights:

What is current knowledge?

Despite the expansion of the nursing best practice knowledge, there is a considerable gap between available evidence and nurses' clinical practices in neonatal pain management.

Preventive and palliative measures by pharmacological and non-pharmacological methods are neglected by nurses.

What is new here?

The results of this study would be an evidence based protocol to guide the neonatal pain management.

Implementation of the protocol will improve the clinical practice of nurses in neonatal pain management.

Introduction

Neonates admitted to neonatal intensive care unit (NICU) are frequently subjected to painful procedures for diagnostic and therapeutic purposes (1). Pain-induced stress in neonates, even if brief, can lead to problems such as hypermetabolic state, heart and lung failure, cardiac arrhythmias, increased risk of infection, prolonged hospitalization, and increased mortality (2). However, studies show that painful procedures in neonates are performed frequently and often with inadequate pain management (3).

Lack of pain relief in preterm infants can also lead to significant early and long-term consequences (4,5) such as changes in physical-sensory processing, hypersensitivity to painful stimuli, and developmental disorders as well as neuroanatomical, behavioral, emotional, and learning disabilities (6, 7). For this reason, the necessity of pain prevention and management has been emphasized by various international organizations, including the World Health Organization (8). Achieving the above goals requires utilization of the highest level of evidence available and strengthening of necessary skills in the management of neonatal pain. However, despite the advance in knowledge of pain management and its ease of access, clinical practice in the prevention, evaluation, and management of neonatal pain still faces many challenges (9). In fact, there is a gap between research evidence and translation of knowledge into clinical practice (10), and clinical guidelines and recommendations in this field are not used properly nor fully (8). One of the effective strategies to fill this gap in order to improve decision-making in nursing care is to move towards evidence-based practice (11), which is an important component for improving patient outcomes through the provision of high quality and cost-effective care (12). An evidence-based approach should improve decision-making processes, increase the capacity to learn new knowledge, and provide an organizational environment for accepting innovation and promoting organizational readiness (13). Studies on the effect of context on the successful implementation of evidence in clinical settings show that contextual factors such as prevailing culture, leadership model, and evaluation are effective in the successful use of evidence and the continuation of the resulting changes (14). Therefore, recognizing and evaluating underlying factors such as organizational culture, management and leadership, approaches to gaining trust, and employee participation can be used as essential drivers and empowering factors for an evidence-based practice change (15). The Johns Hopkins nursing evidence-based practice (JHNEBP) model provides an organized approach to implementing evidence-based practice, which facilitates evaluation of results while making better use of resources (16). The use of this model provides an opportunity to collect and implement the best evidence in the field of applied neonatal pain management.

In Iran, the use of evidence-based approach in nursing practice is generally low (17). A study by Rahimi et al. showed that the level of evaluation and management of pain in NICU is generally moderate, and it is necessary to improve the performance of nurses in the field of neonatal pain management (18). In addition, Asadi Noghabi et al. reported that nurses have moderate knowledge of pain physiology and its effects and complications and very poor knowledge of pain measurement tools (19). Addressing underlying challenges such as development of protocols and instructions, appropriate training for neonatal pain management, and appropriate control and monitoring of the situation will

facilitate the management of pain in newborns (20). In line with these studies, our research shows that pain management in newborns is not a uniform and structured process. In teaching hospitals, especially in the NICU, only the level of neonatal pain is measured and recorded, while preventive and palliative measures by pharmacological and non-pharmacological methods are not clear nor properly documented. Therefore, due to the need for improving nurses' practice in the field of neonatal pain management by using the best available evidence, appropriate to the characteristics of the patients (21-24), the present study aimed to design an evidence-based protocol and evaluate its effectiveness on quality of nursing practice in neonatal pain management according to the JHNEBP model. In addition, nurses' adherence to applying the evidence-based protocol in neonatal pain management will be investigated.

Methods

This study is an evidence-based intervention based on the JHNEBP model (Table 1), consisting of three phases: practice question and project planning, evidence, and translation (PET) (30).

1 Development of nursing practice questions

At this stage, an interprofessional team (6-8 people) consisting of neonatologists, NICU nurses, research team members, and faculty members with enough experience in the field of neonatal pain management was formed. During the first meeting with the interprofessional team, the importance of pain management in infants and its effects, the current state of clinical practice of nurses in this field, the reason for changing the current practice, and improvement of quality and safety in this regard were discussed. Then, the following clinical practice question was developed and used as the basis for the next steps of model implementation:

"Will applying the evidence-based protocol improve nurses' practice compared with the current approach to managing neonatal pain in newborns aged ⩾34 weeks at neonatal wards?"

Then, based on the study objectives and the clinical question, a working group consisting of all stakeholders including parents, head nurses of intermediate care unit and NICU, educational supervisor, and matrons of hospitals under the study will be formed to participate in the development and implementation of the protocol.

Table 1. JHEBP process: Practice Question and project planning, Evidence, and Translation (PET)

Phase	Activities
Practice Question &Project Planning	1-Recruit interprofessional team
	2-Define the problem
	3-Develop and refine the evidence-based practice question
	4-Identify stakeholders
	5-Determine responsibility for project leadership
	6- Schedule team meetings
Evidence	7-Conduct internal and external searches
	8-Appraise the level and quality of each piece of evidence
	9-Summarize the individual evidence
	10-Synthesize overall strength and quality of evidence
	11-Develop recommendations for change based on evidence synthesis
Translation	12-Determine fit, feasibility, and appropriateness of recommendation(s) for translation pathway
	13-Create action plan
	14- Secure support and resources to implement action plan
	15-Implement action plan
	16-Evaluate outcomes
	17-Report outcomes to stakeholders
	18-Identify next steps
	19-Disseminate findings

2 Evidence collection

First, a search will be carried out to find "the best available evidence to improve nurses' neonatal pain management practices."

2.1 Searched databases

Since these evidences are found in articles, guidelines, protocols, and professional standards in the field of neonatal pain management, a thorough search on the following databases will be conducted: Iran's Research Information System, SID, Irandoc, Elmnet, PubMed/Medline ،Web of Science ،Scopus ، Cochrane Library (CDSR and CENTRAL), TRIP database, Google Scholar, National Guideline Clearinghouse, New Zealand Guidelines Group, Scottish Intercollegiate Guidelines Network (SIGN), National Institute for Health and Care Excellence (NICE), Guidelines International Network (GIN), Institute for Clinical Systems Improvement (ICSI), Organizations of the Office of Neonatal Health, and the Office of Compilation of Clinical Practice Guidelines of the Ministry of Health.

2.2 Keywords and search strategy

Search keywords/phrases and their synonyms will be determined using a combination of article extraction and the Medical Subject Headings (MeSH) thesaurus. First, a list of keywords extracted from the MeSH system of the PubMod database will be prepared. Then, the initial list will be completed by reviewing related articles and obtaining new keywords. The followings are the keywords/terms selected for the search: (Infants AND Newborn), Newborn Infant*, Newborn*, Neonate*, (Infant AND Premature), (Infant AND Low Birth Weight), (Management* AND Pain*), (Pain Management*), Analgesia, procedural pain*, pharmacological, and Non-pharmacological. The search strategy based on these keywords were as follows: ((Infants [tiab] AND Newborn[tiab]) OR "Newborn Infant*"[all] OR Newborn*[tiab] OR Neonate*[tiab] OR (Infant[all] AND Premature[all]) OR (Infant[all] AND "Low Birth Weight"[all])) AND ((Management*[all] AND Pain*[tiab]) OR "Pain Management*"[tiab] OR Analgesia[all] OR "procedural pain*"[all] OR (Management*[all] AND Non-pharmacological[all]) OR (Management*[all] AND Nonpharmacological[all]) OR (Management*[all] AND pharmacological[all])) AND 1994/01/01:2021/03/31[dp].

This strategy has been tested in PubMed and its precision has been confirmed (Numbers needed to read (NNR) =13). In the study process and evidence search, this strategy will be exclusively tailored to each international database.

2.3 Inclusion and exclusion criteria

In this study, all clinical guidelines and protocols related to pain management in hospitalized infants ≥34 weeks, review articles including systematic reviews and meta-analysis, integrated, traditional, and clinical trials on pain management in hospitalized infants ≥34 weeks that have been published between 01/01/1994 and 31/03/2021 will be retrieved and reviewed without language restriction. Irrelevant articles and the results of descriptive or observational studies will be excluded. Next, the full-text of the eligible documents will be prepared and entered the evidence evaluation stage. In this step, the level and quality of research evidence (primary and secondary studies) or non-research (clinical guidelines, quality control reports, and expert opinions) will be evaluated using specific tools for evaluating the research and non-research evidence appraisal proposed by the John Hopkins model. After summarizing the evidence, their overall strength and quality will be determined based on the guidelines provided in tables 1 and 2.

Table 2. Evidence strength levels in the JHNEBP model

Level 1	Randomized clinical trials, systematic reviews, and meta-analysis of randomized clinical trials
Level 2	Quasi-experimental studies
Level 3	Non-experimental and qualitative studies
Level 4	Opinions of nationally recognized experts based on scientific evidence or consensus panel including systematic reviews and clinical practice guidelines
Level 5	Experts' opinion based on experiential evidence including case studies, literature reviews, organizational experiences, clinical expertise, quality improvement, financial data, or the opinion of a nationally recognized expert based on personal experience

Table 3. Evidence quality levels in the JHNEBP model

High quality	Scientific	Consistent results with sufficient sample size, adequate control, and definitive conclusion; Consistent recommendations based on an extensive literature review that includes thoughtful reference to scientific evidence.
	Summative reviews	Well- defined , reproducible search strategies; consistent results with a sufficient number of well-defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; Definitive conclusion
	Experimental	Expertise is clearly evident.
Good quality	Scientific	Reasonably consistent results, sufficient sample size, some control, and fairly definitive conclusion; reasonably consistent recommendations based on a fairly comprehensive literature review that includes some references to scientific evidence
	Summative reviews	Reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well-defined studies; Evaluate the strengths and limitations of the included studies; fairly definitive conclusion
	Experimental	Expertise appears to be credible.
Low quality or major flaws	Scientific	Little evidence with inconsistent results, insufficient sample size; conclusions cannot be drawn
	Summative reviews	Undefined, poorly defined, or limited search strategies; Insufficient evidence with inconsistent results; conclusions cannot be drawn.
	Experimental	Expertise is not discernable or is dubious

Next, the recommendations of the protocols will be established during meetings with members of the expert panel (neonatal physician and NICU nurses) and its main stakeholders (head nurses, supervisors, matrons, and parents) in the hospitals under study. In these meetings, in addition to formulating recommendations based on research evidence, decisions will be made regarding the maintenance, removal, or modification of the recommendations within the recovered clinical protocols. Moreover, the aspects of feasibility and appropriateness of the developed recommendations will be discussed and evaluated. Finally, in order to reach a consensus, the final version of the recommendations will be reviewed and finalized during a meeting attended by

members of the expert panel and the neonatal department of Golestan University of Medical Sciences.

3 Translation

At the beginning of this stage, the translation path will be specified and executed. For this purpose, 1) if the type of available evidence is strong and the results are consistent, it means that they can be used to change practices. In this case, it will be implemented through a systematic process as described below and its effectiveness will be evaluated. 2) If the type of evidence is good, the results are consistent, and there are different sources of evidence, it will be necessary to fully evaluate the risks and benefits of practice change by conducting a pilot study by the interprofessional team. 3) In case of good evidence without consistency of results or 4) absence or insufficiency of evidence, practice change is not recommended. Although the initial review indicated that there was sufficient and consistent evidence to develop protocols, a comprehensive review would indicate the need for a pilot study.

After approving the final version of the recommendations, existing organizational infrastructure, resources, actions required to implement the change, and ways to provide them will be identified during a meeting with key stakeholders. The action plan will then be presented in the form of protocol, which will include recommendations for prevention, pharmacological/non-pharmacological pain management, and evaluation and documentation of neonatal pain. After the approval of this final protocol by the expert panel and stakeholders, and the provision of the required resources, the implementation process will begin. For this purpose, the impact of the applying the protocol on nurses' practices in managing neonatal pain will be investigated via a stepped wedge randomized cluster trial (Figure 1).

Evidence-based intervention

In this trial, the purpose of evidence-based intervention is to implement a neonatal pain management protocol developed according to the JHNEBP model. This protocol will include recommendations on prevention and limitation, evaluation, pharmacological/non-pharmacological pain management interventions for infants, and documentation of the pain management process. In terms of successful implementing, participated head nurses in protocol development and also trained nurses (3-5 nurses from each ward), will be used as mentors. This means, they will be responsible for facilitating and evaluating the process of implementation and educating other nurses.

Research setting

The present study will be carried out in the neonatal wards and NICU of two teaching hospitals affiliated to the Golestan University of Medical Sciences including the Taleghani Children's Hospital (average bed occupancy rate 85%) and Shahid Sayad Shirazi educational and medical center (average bed occupancy rate 75%), as well as a center managed by the Social Security Organization, i.e. Hakim Jorjani Hospital (average bed occupancy rate 80%) in Gorgan, Iran. A total of five wards, including three neonatal wards and two NICUs will be studied in the form of three clusters.

Participants

The research units related to the initial outcome of nurses working in the intermediate care and NICU of the hospitals will be studied. Criteria for inclusion of nurses will include having at least a bachelor's degree in nursing, presence in the wards during the study period, and providing nursing care to hospitalized infants. In addition, pain management in neonates with gestational age of 34-42 weeks hospitalized in the NICU or the intermediate care unit who require at least one painful procedure will be considered. Painful procedures include procedures such as heel-stick method for drawing capillary blood samples, venous/arterial blood sampling, central venous catheter insertion, intramuscular/subcutaneous injection, suctioning, nasogastric intubation, retinopathy of prematurity screening, dressing change, removing sticking plaster, insertion of urinary catheter, and insertion of peripherally inserted central catheter.

Infants under treatment with sedatives or analgesics or those with neuromuscular disorders, cardiopulmonary instability, perinatal asphyxia, birth trauma, drug withdrawal syndrome, a history of cardiopulmonary resuscitation, an Apgar score below 7 at birth, and mechanical ventilation in the last seven days will be excluded from the study.

Sample size

Since the initial outcome is defined as binary (optimal/unfavorable practice), and statistical analysis will be performed using generalized linear mixed model (logistic regression) method, in order to determine the sample size, the general rule of 10 events per variable (EPV) will be used for each variable. Considering five independent variables (knowledge: sufficient/insufficient; attitude: positive/negative; education: bachelor's degree/higher; work experience: less than 5 years, 5-10 years, and more than 10 years), the minimum sample of 50 people will be required. Due to the clustering of the study plan, the design effect of 1.5, and 5% drop-out rate, the minimum sample size of 80 people will be required per measurement. Given the difference in the number of nurses in the neonatal wards of the three hospitals under study, the sample size will be divided proportion to size. Thus, 24 nurses from the Taleghani Hospital (30% of the total), 47 nurses from the Sayad Shirazi Hospital (59% of the total), and nine nurses from the Hakim Jorjani Hospital (11% of the total) will enter the study.

Implementation method

The hospitals will be included in the study in the form of three clusters. Random allocation will be done at the level of clusters (medical centers), and considering that there are three medical centers with neonatal wards in Gorgan and all centers enter the intervention stage in a step-by-step manner, the order of entry of the centers to the intervention stage will be random. In this way, different entry modes of the centers (six modes: 1-2-3 / 1-3-2 / 2-1-2 / 3-3-3 / 1-1-2- / 3-2-1) are written separately on cards and placed in six envelopes. By selecting a random number between 1 and 6, one of the envelopes is selected, and the order of entry of the centers into the intervention phase is determined, while the other two centers will be considered as control centers. In this study, blinding will be possible only at the level of outcome assessor.

At first, the clusters (all centers) will be entered into the basic evaluation stage including, assessing nurses' knowledge, attitude, and practice in pain management. In order to determine the nurses' knowledge, attitude and practice, a validated questionnaire and a researcher-made checklist based on the protocol will be used, respectively. In addition, the recording practice of nurses will be evaluated through assessing the reports and other documents in neonates' medical records.

Then, the mentors (head nurses and nurses in charge in the evening and night shifts) of the first cluster (intervention cluster) will be invited to a two-weeks training course on the protocol content, implementation program and evaluation methods. After fulfilling the workshop, the protocol content and the pain management algorithm will be available to everyone and training of the rest of nursing staffs in each ward will be carried out by trained mentors. It means, the implementation of the pain management protocol will be begun. During this process, the mentors of each ward will facilitate and evaluate the implementation process and support nurses by answering their questions and solving the problems and doubts in practice. After three weeks of intervention (seventh week post-baseline), data on the quality of nurses' practices in managing neonatal pain in all three clusters will be collected again. In addition, during individual interviews with the nurses in the first cluster, their experiences regarding the implementation of the intervention will be heard and if necessary, the executive process will be modified for the next intervention cluster. The implementation of the intervention for the second center is similar to the first center, and data will be collected during the tenth week. At this stage, the third centers will be considered as the control centers and will be evaluated simultaneously. Finally, in order to determine the sustainability of the changing in nurses' practice and their adherence to apply the neonatal pain management protocol, the outcome assessment will be re-evaluated at weeks 18 and 26 post-baseline. At the end of the evaluation, the same intervention and training will be provided to nurses in the neonatal wards of the third center, which were considered as the control cluster throughout the study.

Outcome evaluation

The quality of nurses' clinical practice in managing pain of hospitalized infants will be assessed using a checklist designed based on the pain management protocol and by reviewing reports and documents recorded in medical records. Validity of the checklist will be assessed using the item impact, calculation of content validity ratio (based on the Lawshe table), and S-CVI/UA (minimum acceptable value 0.8) based on the opinion of at least ten faculty members specialized in the field of neonatology, and inter- and intra-evaluator reliability will be determined using Fleiss' kappa.

Data will be collected by observing practices by an evaluator unaware of the research objectives.

In order to measure the amount of pain in infants following painful procedures, a revised version of the premature infant pain profile will be used, which scores the physiological, behavioral, and contextual responses of infants from zero to 21. Scores of 0 to 6, 7 to 12, and greater than 12 indicate no pain, moderate pain, and severe pain, respectively (25). The Persian version of this tool has been validated in Iran (26). In this study, the inter- and intra-evaluator reliability will be measured by the intracluster correlation coefficient. Neonatal physiological and behavioral responses will be recorded using a video camera 30 seconds before the painful procedure, immediately after the procedure, and at 1, 2, and 5 minutes after the procedure. Then, the videos will be viewed independently by two evaluators unaware of the study objectives and scored based on the tools. Disagreements will be resolved by asking the opinion of a third party expert.

A researcher-made tool will be used to assess nurses' knowledge and attitudes regarding neonatal pain management. For this purpose, a pool of items will be formed according to the developed protocol. Then, to perform face validity, first the item impact method will be performed with the participation of the target group (nurses), and for items with an impact score of less than 1.5, a qualitative interview will be conducted. In order to determine content validity, content validity ratio (based on the Lawshe table) and S-CVI / UA (minimum acceptable value 0.8) will be calculated based on the opinion of at least ten faculty members specialized in the field of neonatology. In order to evaluate the reliability of the instruments, Cronbach's alpha coefficient method will be used (acceptable value 0.7-0.9).

Statistical analysis

Data will be analyzed using the STATA software (version 14). The primary statistical analysis method in this trial will be the Mixed Model GLM (logistic regression). Results of hypotheses testing will be reported based on P-values, effect size indicators of risk ratio, and risk difference, and their confidence intervals. The interpretive areas of the risk ratio effect size according to the prevalence of the outcome will be as follows (27):

	α	$OR\ min$	OR_{mid}	OR	OR_{max}
Small	0.1	1.22	1.31	1.32	1.49
Medium	0.3	1.86	2.27	2.38	3.45
Large	0.5	3.00	4.20	4.70	9.00

Secondary statistical analysis will also be performed using the aforementioned method to control potential confounders/covariates for the primary outcome, including the level of knowledge, attitude, education level, and work experience of nurses, and the nurses' adherence to use the protocol will be assessed over time. Due to the confirmatory nature of this study, the Bonferroni correction method will be used to correct the P-value to decide the results of the primary objective. Therefore, considering the sum of multiple comparisons equal to five pairwise comparisons, the level will decrease significantly from the nominal threshold of 0.05 to 0.005. In addition, due to the cluster design of the study, survey data analysis will be performed.

Following the translation phase and the implementation of the protocol, the outcome evaluation will be reported during a meeting with the interprofessional team members, nurses, managers, and officials of the departments. The purpose of this meeting is to decide whether to continue implementing, amending, or suspending the protocol. In the final step, the results of the study will be published in form of an article.

Discussion

In the last three decades, information and knowledge related to neonatal pain have increased dramatically. It is well established that infants can identify, process, and respond to painful stimuli (28). However, interventions to reduce neonatal pain are insufficient and applied inconsistently (29). Gaps in knowledge, evidence, and practice related to neonatal pain assessment and management have made pain management challenging. Therefore, training and applying research results along with improving communication is recommended to help pain management in neonates (28).

Evidence-based practice is an effective way to reduce the gap between knowledge and clinical practice, which increases effectiveness (ability to achieve the desired result) and efficiency (achieving the desired result with the least cost, time and effort), and evaluates the risks, benefits, and costs along with patient preferences. This approach can lead to desirable outcomes, provide similar care at a lower cost and in a shorter time, improve patient satisfaction, and increase health-related quality of life (30).

In addition to producing evidence-based knowledge, evidence-based models provide the basis for the effective application and implementation of the best evidence on a particular topic by involving stakeholders, improving individual and organizational communication, and paying attention to the characteristics of the context. Several studies have shown the effectiveness of the JHNEBP model in successful implementation of evidence in clinical setting, modifying routine practices, and improving patient outcomes (31, 32).

Conclusion

The results of this study will lead to the development of a viable protocol for the management of pain in inpatient neonates that can be used both to train nurses in the neonatal wards and NICUs and to provide a resource for the production of a national clinical protocol. Moreover, the implementation of this evidence-based approach in clinical settings, not only creates opportunities for interprofessional cooperation and promoting the independence of the nursing profession, but also motivates employees and improves organizational culture to strive for knowledge translation and change clinical practice. In this study, the experiences of the participating team members in developing the protocol have been considered. Since, no evidence-based nursing practice based on this model has been implemented in Iran, understanding the experiences of our subjects can provide positive results and facilitate the use of this model in the clinical setting.

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Ethical statement

The study received approval from the research ethics committee of Golestan University of Medical Sciences (ethical code: IR.GOUMS.REC.1400.039).

Conflict of interest

The authors declare that there is no conflict of interest regarding publication of this article.

Author contributions

All authors contributed in research design and refinement of the study protocol and approved the final manuscript.

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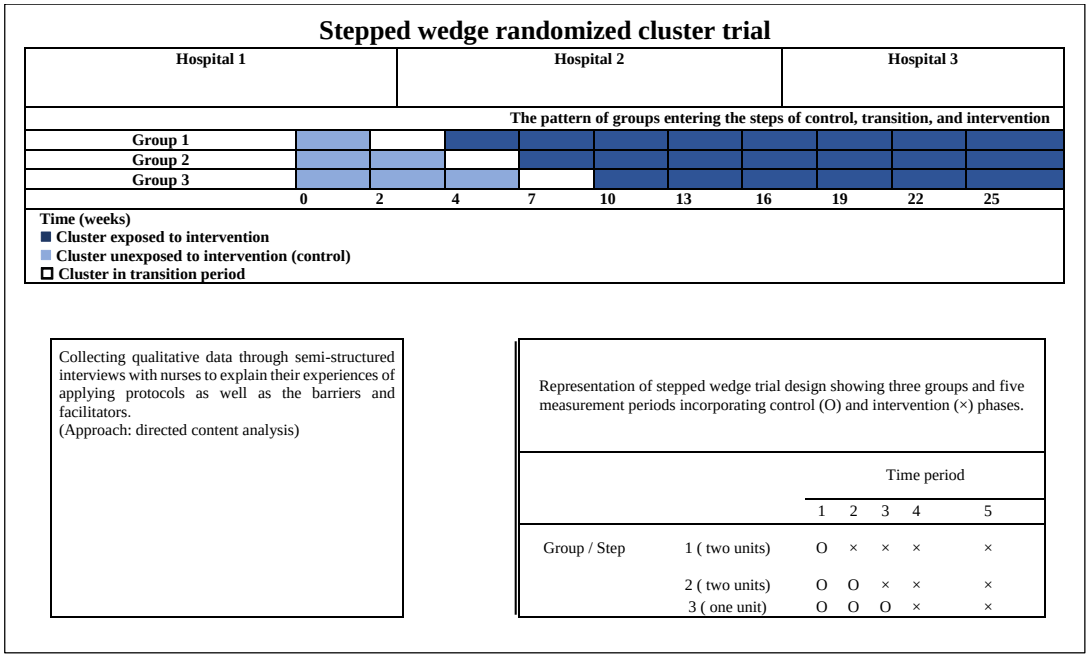

Figure 1. Schematic view of stepped wedge randomized cluster trial

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