Research Protocol

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Nursing Section

Comparative Efficacy of Ventilator Nursing Clinical Pathway versus Paediatric Ventilation Guidelines in Paediatric Intensive Care Unit: A Research Protocol

KHUSHBU MANOHAR MESHRAM[1], BIBIN KURIAN[2], ARCHANA TAKSANDE[3], SHALINI LOKHANDE[4]

ABSTRACT

Introduction: Many critically ill children in the Paediatric Intensive Care Unit (PICU) require mechanical ventilation. Despite lung-protective strategies, ventilation-related complications remain common, emphasising the need for effective management and prevention.

Need of the study: Through constant observation and intervention, nurses are essential to the care of children on mechanical ventilation. However, organised, nurse-led care is not given much attention in the current paediatric ventilation recommendations, and inconsistent nursing practice, expertise, and protocol execution may result in less-than-ideal patient outcomes.

Aim: To compare the efficacy of the Ventilator Nursing Clinical Pathway (VNCP) versus paediatric ventilation guidelines for children on mechanical ventilators at the PICU for improvement in clinical outcomes.

Materials and Methods: The present two-arm parallel superiority randomised controlled trial will be conducted at Smt Radhikabai Meghe Memorial College of Nursing, Sawangi (Meghe), Wardha, Maharashtra, India, from June 2026 to June 2027. There will be two stages to the study: In Phase I, the VNCP will be developed and validated by experts; in Phase II, the VNCP's efficacy will be compared with standard nursing care for children on mechanical ventilation between the ages of one month and twelve. Random assignment will be used to place eligible individuals in either the intervention group (VNCP) or the control group (routine care). Continuous variables will be compared using the independent *t*-test or Mann-Whitney U test, categorical data using the Chi-square test, and longitudinal data using repeated measures Analysis of Variance (ANOVA). A p-value of <0.05 will be deemed statistically significant.

Keywords: Artificial respiration, Critical care, Patient care planning, Treatment outcome

INTRODUCTION

About 20-64% of hospitalised children in the PICU require mechanical ventilation, a commonly employed intervention. Seasonal variations, PICU environment, illness severity, and patient characteristics all affect its indications and management [1]. Advances in paediatric intensive care have led to markedly improved survival rates in critically ill children. About 70% of those children make it through with some complicated chronic illness or disability [2].

Even with the extensive use of lung-protective ventilation techniques, children nevertheless frequently have difficulties from mechanical ventilation. Improving healthcare outcomes requires early detection, prevention, and effective management [3]. It takes specific training, ongoing observation, infection control, and careful evaluation to care for kids on a mechanical ventilator [4]. To increase the quality of paediatric ventilatory treatment, healthcare personnel must get thorough education and training. This is because safe and effective practice depends on sufficient knowledge and expertise [5]. Children have smaller airways, higher metabolic and oxygen demands, and less functional residual capacity than adults, making them more prone to rapid hypoventilation during illness. Mechanical ventilation helps in maintaining oxygenation and ventilation [6].

Combining predictive markers, Extubation Readiness Tests (ERTs), and thorough clinical evaluation is essential for the successful release from mechanical ventilation. To reduce difficulties in PICU patients, early identification of risk variables is crucial because weaning failure can still happen [7].

By providing comfort, contact, and vocal reassurance, parental presence is an effective non pharmacological intervention that lessens dread, anxiety, and the need for sedatives. Including parents in regular care promotes children's physical and mental health and accelerates their recovery [8]. Mechanical ventilation is necessary for 17-64% of children admitted to PICUs, and these patients are more likely to die than children who are not ventilated. Co-morbidities, the severity of the illness, and treatment-related complications all affect mortality [9].

The current study indicated a fatality rate of 59.1%, compared to studies conducted in the Czech Republic (3.5%), Italy (6.7%), Sri Lanka (27.6%), Pakistan (30.3%), India (43.8%), and Egypt. In a similar vein, a multicenter study by Farias JA et al., including 36 PICUs across seven nations, found a fatality rate of 15.6%. Previous data indicate that mortality rates in prosperous countries have varied from 1.6% to 15%. According to the current investigation, the most common causes of mortality were sepsis (26.8%) and Acute Respiratory Distress Syndrome (ARDS) (13.6%). Similar findings were also reported by Dahlem P et al., [10].

Primary objectives:

- To develop and validate the VNCP.
- To evaluate the efficacy of paediatric ventilation guidelines among children on mechanical ventilators to improve clinical outcomes in the control group.
- To evaluate the efficacy of the VNCP among children on mechanical ventilators to improve clinical outcomes in the experimental group.

Secondary objectives:

- To compare the effectiveness of the VNCP with standard paediatric ventilation guidelines in improving clinical outcomes among children on mechanical ventilation in the PICU.

Hypotheses:

Null Hypothesis (H_0): There will be no significant difference between the VNCP and the paediatric ventilation guidelines in terms of clinical outcomes among mechanically ventilated children admitted to the PICU.

Alternate Hypothesis (H_1): There will be a significant difference between the VNCP and the paediatric ventilation guidelines in terms of clinical outcomes among mechanically ventilated children admitted to the PICU.

REVIEW OF LITERATURE

The Fiji Paediatric Ventilation Guideline (2010) outlines key doctor and nurse-led interventions for mechanically ventilated children, including infection prevention, airway management, proper positioning and humidification, skin care, acid-base and Partial pressure of carbon dioxide in arterial blood ($PaCO_2$) regulation, fluid and electrolyte balance, prevention of hospital-acquired infections, and comfort measures to improve clinical outcomes [11].

According to Sharma B et al., the nursing care protocol greatly enhanced nurses' clinical practice and understanding about the care of children on mechanical ventilation. The mean practice score improved from 8.57 to 11.87, and the mean knowledge score rose from 18.6 to 27.5. Both improvements were statistically significant ($p<0.05$), indicating the protocol's efficacy [12].

To assess a multidisciplinary ventilator liberation intervention among children on mechanical ventilation, Blackwood et al. carried out a pragmatic stepped-wedge cluster randomised study in United Kingdom (UK) PICUs. The intervention enhanced extubation success and considerably shortened the time to effective extubation by a median of 6.1 hours in children who needed extended ventilation. Reintubation rates and PICU duration of stay did not alter, but it was linked to an increased frequency of unexpected extubation and a higher usage of non invasive ventilation following extubation. Nonetheless, there were fewer respiratory problems and a somewhat longer hospital stay, indicating a moderate but clinically beneficial benefit of the intervention [13].

Ineffective communication in PICUs is linked to worse patient outcomes and more medical mistakes, according to Hallman ML et al., [14]. The study did not assess standardised communication within ventilator nursing pathways or its influence on clinical outcomes, highlighting the need for more research. Nevertheless, structured multidisciplinary and nurse-led communication techniques enhanced patient safety and quality of care [14].

In a systematic study, Hill C et al., discovered that parents appreciated active participation in PICUs, courteous communication, and involvement in care. Their Family-Centred Care (FCC) experience was similarly impacted by the care environment, underscoring the necessity of increasing parental participation and including the care environment in FCC criteria [15].

According to Hollingsworth T et al., a nurse-driven sedation and analgesia strategy promoted standardised sedation procedures in the PICU by increasing nurses' understanding of and adherence to Richmond Agitation-Sedation Scale (RASS) documentation. However, the results' generalisability was restricted by the single-centre design, small sample size, and absence of patient acuity data, underscoring the necessity of multicenter trials to assess long-term clinical outcomes [16].

In a similar vein, Poletto E et al., examined the data on extubation readiness and ventilator weaning in paediatric critical care units and discovered no conclusive evidence favouring one weaning approach over another. The study urged more research to build evidence-based weaning techniques and highlighted the lack of standardised protocols, with clinical judgment being crucial to decision-making [17]. Individual strategies such as Ventilator-Associated Pneumonia (VAP) prevention, sedation control, extubation preparedness, nurse education, and communication have been the main focus of earlier research on paediatric ventilator care. Nevertheless, there is little data on comprehensive nurse-led VNCPs that incorporate standardised assessment, ventilator liberation, post-extubation care, handover, and FCC, and randomised controlled trials have not sufficiently assessed their impact on clinical outcomes. To enhance nurse care quality and patient outcomes, the current study attempts to create, validate, and assess an evidence-based VNCP.

MATERIALS AND METHODS

The present randomised, two-arm, parallel interventional study will be conducted at Smt Radhikabai Meghe Memorial College of Nursing, Sawangi Wardha, Maharashtra, India, from June 2026 to June 2027. Ethical Approval was obtained from the Institutional Ethics Committee with Ref. No. DMIHER(DU)/IEC/2025/596. The study was registered with the Clinical Trial Registry of India CTRI/2026/02/104444. Informed consent is obtained from all patients, willing to participate in the study before enrolling them in the procedure.

Inclusion criteria:

Nurses:

- Registered Nurses (RNs) working in the PICU;
- Minimum six months of continuous clinical experience;
- Directly appointed as a PICU nurse;
- Willingness to participate and provide informed consent.

The children:

- Expected duration of ventilation >24 hours;
- Whose parents give written consent;
- Who are one month to 12 years.

Exclusion criteria:

Nurses:

- Nurses currently on extended leave or rotating out of the PICU during the study period;
- Nurses who have recently undergone training on a mechanical ventilator.

Children:

- With pre-existing congenital anomalies;
- Accidental chest injuries;
- Children with tracheostomy before the current admission;
- Children on chronic home ventilation before admission.

Sample size calculation:

Formula: $n=\{(Z_{\alpha/2}\sqrt{(2P(1-P))} + Z_{\beta}\sqrt{(P_1(1-P_1) + P_2(1-P_2))})^2\} / (P_1-P_2)^2$

Where:

P_1=anticipated event proportion in the control group

P_2=anticipated event proportion in intervention group

$P=(P_1 + P_2)/2$

$Z_{\alpha/2}$=1.96 for 95% confidence

Z_{β}=0.84 for 80% power

P_1=0.384

P_2=0.134

Difference=$P_1 - P_2$=0.384 – 0.134=0.25

P=(0.384 + 0.134) / 2=0.259

$n=\{(1.96\sqrt{(2\times0.259\times0.741)} + 0.84\sqrt{(0.384\times0.616 + 0.134\times0.866)})^2\} / (0.25)^2$

n ≈ 46.2, rounded up to 47 children per group before attrition

Adding 5% attrition: 47×1.05=49.35

Rounded up sample size=50 children per group (total sample size=100) [18].

Study Procedure

Participants will be randomised using a computer-generated random sequence prepared by an independent statistician not involved in participant recruitment or outcome assessment [Table/Fig-1]. Allocation concealment will be ensured using opaque, sealed, sequentially numbered envelopes prepared by an independent research assistant. The principal investigator will screen and enrol eligible participants. Following enrollment, the next sequential envelope will be opened to assign participants to either the control group (standard nursing care) or the intervention group (VNCP).

Before initiation of the intervention, baseline data will be collected using a structured proforma. Participants will be monitored until they are successfully extubated, released from the PICU, or the study results are available. The efficacy of the intervention will be assessed by collecting and analysing data on mechanical ventilation duration, length of PICU stay, extubation success, incidence of ventilator-associated problems and death.

Blinding of participants and caregivers is not feasible due to the nature of the intervention; however, outcome assessors and the data analyst will remain blinded to group allocation to minimise assessment bias.

Development of the Ventilator Nursing Clinical Pathway (VNCP)

- **Step 1: Determining the Critical Care Theme**

A thorough examination of the literature, clinical observations in the PICU, the prevalence of ventilator-related problems, gaps in conventional ventilator nursing care, and expert advice in paediatric critical care will all be taken into consideration when choosing the critical care subject.

- **Step 2: Identify a nursing intervention within the theme**

Nursing care domains for children on mechanical ventilation, such as assessment and monitoring, airway and ventilator care, sedation management, infection prevention, nutritional support, FCC, weaning and extubation, and post-extubation monitoring, will be arranged into intervention clusters after theme identification.

- **Step 3: Literature Search**

A comprehensive literature search will be conducted to identify relevant evidence related to each intervention and nursing practice. Electronic databases including:

PubMed, Scopus, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Google Scholar, etc., Search keywords will include: paediatric mechanical ventilation, ventilator nursing care, PICU nursing interventions, Ventilator-Associated Events (VAE), extubation care, and evidence-based ventilator care.

- **Step 4: Extraction of Research Evidence**

A standardised evidence extraction form will be used to obtain data once pertinent research has been reviewed using predetermined inclusion and exclusion criteria. To guide the creation of pathways, the gathered evidence will be combined and arranged into important ventilator nursing care domains.

- **Step 5: Categorise the available research according to its quality.**

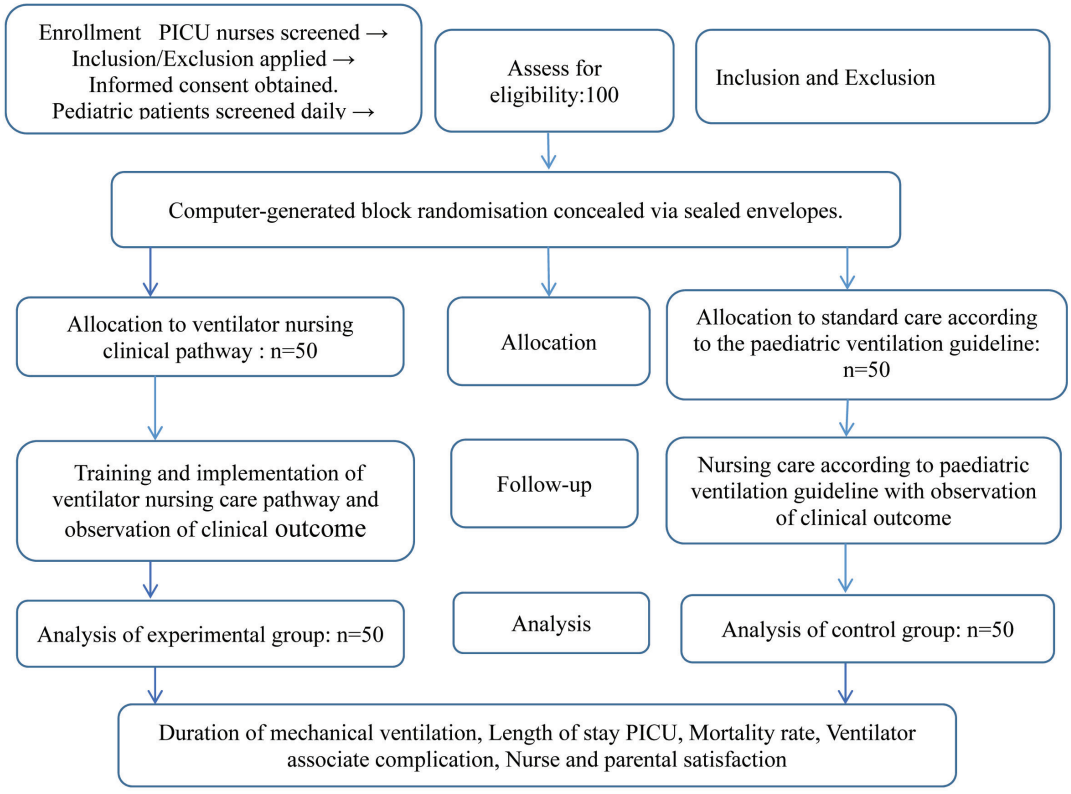
High-quality evidence, such as systematic reviews, meta-analyses, and randomised controlled trials, will be given precedence when the relevant literature is critically evaluated and categorised using the hierarchy of evidence. The ventilator nurse care route will be developed based on this evidence.

- **Step 6: Development of evidence-based interventions.**

Based on the synthesised evidence, the VNCP will be developed by organising evidence-based nursing interventions into a standardised sequence. The pathway will be guided by established paediatric ventilation guidelines and recommendations from international organisations and evidence-based PICU protocols.

The VNCP includes components shown in [Table/Fig-2] [11].

A panel of specialists in paediatric nursing, paediatric critical care medicine, and nursing research will validate the VNCP content when it has been developed. The pathway will be evaluated by a panel of



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow chart.

S. No.	Component	Nursing intervention	Standard care Paediatric ventilation guideline [11]	Ventilator Nursing Care Pathway (VNCP)
1.	Initial Assessment Adequate oxygenation, ventilation and supported work of breathing	Assessment of the child receiving mechanical ventilation, ABCDE Monitoring (Airway, Breathing, Circulation, Disability and exposure) and Family orientation	✓	✓
2.	Correct positioning and patency of artificial airway	Placement of artificial airway; airway is secure and stabilised in desired position	✓	✓
3.	Adequate humidification, mobilisation and removal of secretion	Adequate humidification of ventilation, suctioning of ET tube,	✓	✓
4.	Adequacy of pH and PaCO2	Monitor PH and $PaCO_2$ through periodic sampling of arterial or capillary blood gases	✓	✓
5.	Haemodynamic stability	Maintain optimal cardiovascular status, hourly assess vital signs, ensure continuous ECG monitoring with alarms limit, monitor and optimise perfusion	✓	✓
6.	Fluid and electrolyte balance	Calculation and monitoring of fluid intake to reduce fluid retention, Monitor urine output, Routine evaluation of lab results, optimise nutrition through initiation of feeding via NG tube	✓	✓
7.	Free of nosocomial infection	VAP prevention bundle (e.g., oral care, HOB elevation, suctioning protocols). Minimise ventilator sources of infection, keep HOB elevation 30 deg, mobilise patient as able, and additional source of hospital infection like CVL, Foley catheter	✓	✓
8.	Skin integrity	Assess skin integrity every 2 to 4 hour, keep skin clean and dry, Reposition every 1 to 2 hour	✓	✓
9.	Oral care	A thorough oral assessment should be done at least every 2 hours	✓	✓
10.	Acceptable level of comfort	Assess the patient's pain and sedation level 1 to 4 hours, using MAPS and State Behaviour scales. Titrate pain and sedation modification as per protocol Provide noninvasive comfort measures parental presence, favourite blanket or toy, ear plugs to reduce noise level, dim lights and distraction techniques	✓	✓
11.	Spontaneous breathing Trial) /Extubation readiness assessment screening bundle and monitoring	Adequate respiratory drive Spontaneous breathing Cough/gag present SBS=0 Airway bundle completed (for potential reintubation) Ability to manage secretions Referring (https://www.chop.edu/clinical-pathway/picu-ventilator-weaning-clinical-pathway)	×	✓
12.	Communication and handover	Handover consistency (IPAS Tool) illness severity, patient summary, action list, situation awareness and contingency planning, synthesis by receiver (standardised handover tool)	×	✓
13.	Family centered care, counselling and referral	Include families in rounds, education, shared decision-making if needed refer for counselling	×	✓
14.	Evaluation and escalation: paediatric early warning score, escalation protocol	Use of PEWS, and structured escalation protocol by nurses	×	✓
15.	Key symptom assessment	Pain, sedation, agitation and anxiety, delirium, dyspnoea, discomfort/ thirst, sleep disturbance and communication difficulty	×	✓
16.	Post-extubation assessment and ongoing monitoring	Nurse-driven assessment post-extubation monitoring	×	✓

[Table/Fig-2]: Comparison of standard nursing care in practice of children on mechanical ventilator vs VNCP for children on mechanical ventilator [11].
ET: Endotracheal tube; pH: Potential of hydrogen; ECG: Electrocardiogram; NG: Nasogastric; HOB: Head of bed; CVL: Central venous line; MAPS: Mean arterial pressure; SBS: State behavioural scale; IPAS: Illness severity, patient summary, action list, situation awareness and contingency planning, and synthesis by receiver; PEWS: Paediatric early warning score

experts for its clinical applicability, comprehensiveness, relevance, clarity, and feasibility.

Outcome Measures

1. **Duration of ventilator stay** by Electronic Health Records (EHRs) for ventilator settings and usage.
2. **Length of stay at PICU after post-extubation:** Total number of days the child remains in the PICU.
3. **Incidence of Ventilator-Associated Complications (VAE):** Includes VAP, VAC, IVAC
   a. VAP rate=(Number of VAP cases ÷ Ventilator days)×1000
   b. VAE rate=(Number of VAE cases ÷ Ventilator days) ×1000
   c. **Clinical Pulmonary Infection Score (CPIS):** This tool helps in diagnosing VAP based on clinical criteria, including temperature, leukocytosis, tracheal secretions, oxygenation, and chest X-ray findings.

      CDC/NHSN VAE (Centers for Disease Control and Prevention / National Healthcare Safety Network Ventilator-Associated Event) Surveillance Form /Clinical Pulmonary Infection Score (CPIS) [19].

   d. **Mortality rates:** The Paediatric Risk of Mortality (PRISM) and Paediatric Index of Mortality (PIM) are widely used scoring systems for predicting mortality in critically ill children. Their updated versions, PRISM III and PIM III, are commonly used in PICUs worldwide for mortality prediction and quality assurance [20]. The mortality rate (%) will be used as the actual outcome variable for evaluating the effectiveness of the Comprehensive Ventilator Nursing Care Pathway [21].

      Mortality Rate (%)=Number of deaths among mechanically ventilated children/ Total number of mechanically ventilated children X 100 [22].

      Mortality data can be collected from EHRs and death registers [21].
4. **Parental satisfaction:** Measures perceptions of FCC in paediatric settings. It assesses aspects such as communication, respect for family preferences, and the involvement of families in care decisions. Empowerment of Parents in The Intensive

Care (EMPATHIC) 30 scale includes Information, Care and treatment, Organisation, Parent participation, and Professional Attitude. Scoring each item: 1-6 [23]

Total=Mean score. Interpretation: Higher score=better FCC

A qualified research assistant who is not involved in patient treatment will deliver the EMPATHIC 30 questionnaire to gauge parental satisfaction.

5. **Nurses' satisfaction with care:** Nurse Satisfaction with Quality-of-Care Scale (NSQCS) or Nursing Work Index-Revised (NWI-R)

The NSQC is a self-administered 5-item scale designed to measure nurse satisfaction with quality of care that they provide to their patients. Nurses rate their satisfaction for each item on the NSQC from 1 (very dissatisfied) to 5 (very satisfied), with higher scores indicating higher levels of satisfaction. A demographic questionnaire was also used to gather descriptive information about the study participants [22].

Outcome assessments will be performed by trained independent assessors blinded to the VNCP. Clinical outcomes, including duration of mechanical ventilation, PICU length of stay, and mortality, will be obtained from EHRs. VAP and VAE will be independently assessed by two qualified clinicians using the CDC/NHSN surveillance criteria and Clinical Pulmonary Infection Score (CPIS), with a third reviewer resolving disagreements. All assessors will receive standardised training before data collection to ensure consistency.

STATISTICAL ANALYSIS

Data analysis will be done using Statistical Package for Social Sciences (SPSS) 29.0. Continuous variables will be expressed as mean ± Standard Deviation (SD). The independent t-test or Mann-Whitney U test will be used to compare continuous variables, which will be reported as mean±SD. The Chi-square test will be used to assess categorical data. For longitudinal data, repeated measures ANOVA will be employed. Confounders will be controlled via multivariate regression. $p<0.05$ will be regarded as significant, and intention-to-treat analysis will be used.

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Child Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing DMIHER (DU), Wardha, Maharashtra, India.
2. Associate Professor, Department of Child Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing DMIHER (DU), Wardha, Maharashtra, India.
3. Assistant Professor, Department of Child Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing DMIHER (DU), Wardha, Maharashtra, India.
4. Assistant Professor, Department of Child Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing DMIHER (DU), Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Khushbu Manohar Meshram,
Assistant Professor, Department of Child Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing DMIHER (DU), Wardha-442001, Maharashtra, India.
E-mail: khushbupande86@gmail.com

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