Onderzoeksprotocol

(voor aanvraag niet-WMO verklaring)

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Algemene gegevens

Titel	Implementation of a consensus based decision support tool to Improve Nebulization Practices in Mechanically Ventilated ICU Patients: a multi-center study.
Datum	11-08-2025
Versienummer	2
Indiener	S.F.C. Mugge
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Opdrachtgever (verrichter)	Amsterdam University Medical Centers Intensive Care

Onderzoekgegevens

Rationale	Nebulization is a commonly used in Intensive Care Unit (ICU) patients receiving invasive ventilation to manage secretion accumulation resulting from impaired mucociliary clearance, mucosal dehydration and weakened cough reflex. Our previous nationwide survey (yet to be published) revealed considerable practice variation across Dutch ICUs, with difference in indication, frequency and choice of agents. Notably, many currents practice appear misaligned with available evidence, including findings from the NEBULAE trial (1). This trial showed that routine nebulization does not improve clinical outcomes compared to on-indication use, while contributing to adverse effects, increased costs and treatment burden. This variation underscores a persistent gap between evidence-based recommendations and clinical practice, likely driven by the absence of standardized protocols, inconsistent clinical reasoning and organizational barriers. To bridge this gap, we conducted a Delphi study among experts to develop consensus on appropriate indications and best practices for nebulization in invasively ventilated ICU patients. The results are used to develop a pragmatic, consensus based decision tool designed to

	guide ICU professionals in the indication, initiation and evaluation of nebulization therapy. This aims to reduce unnecessary, routine use of nebulization by promoting targeted, need-based application. The next step is to implement this consensus based decision support tool in a selection of ICUs that participated in the original survey. Our aim is to implement the decision support tool, and systematically explore barriers and facilitators to its uptake, using the Measurement Instrument for Determinants of Innovations (MIDI). Insights gained will guide the development of site-specific implementation toolboxes, enhance adherence to best practice and contribute to more effective and efficient nebulization therapy in the ICU. 1. van Meenen DMP, van der Hoeven SM, Binnekade JM, de Borgie C, Merkus MP, Bosch FH, et al. Effect of On-Demand vs Routine Nebulization of Acetylcysteine With Salbutamol on Ventilator-Free Days in Intensive Care Unit Patients Receiving Invasive Ventilation: A Randomized Clinical Trial. JAMA. 2018;319(10):993-1001.
Doel	To implement consensus based nebulization practice for invasively ventilated ICU patients through the use of a decision support tool in selected ICUs and to identify local barriers and facilitators to implementation using the MIDI to develop site-specific implementation toolboxes.
Studie design	This nationwide (the Netherlands) questionnaire-based implementation study to explore implementation barriers and facilitators using the MIDI questionnaire to inform a site-specific implementation toolbox.
Studie populatie	The study population comprises of a selected group of healthcare professionals from 5 selected Intensive Care Units across the Netherlands. This group includes intensivists, ICU nurses and ventilation practitioners. Participating centers are either those that routinely apply nebulization or those lacking structured evaluation moments of nebulization practices.
Beoogd aantal proefpersonen Amsterdam UMC	10
Beoogd aantal proefpersonen in Nederland	Based on the results of 54 completed surveys among the 72 Dutch ICUs, we will purposively select five Dutch centers that indicated willingness to participate in the implementation study. Within the participating centers, we aim to conduct our MIDI assessment in at least ten healthcare professionals per center (5x10 participants)
Inclusiecriteria	Healthcare professionals working in the ICU from centers that participated in our prior survey and indicated willingness to participate in this implementation and feasibility study and either apply

	nebulization routinely or lack structured evaluation moments regarding nebulization use.
Exclusiecriteria	None
Aantal proefpersonen/ sample grootte	50 (10 from each center)
Werving proefpersonen	Within each ICU department, our designated contact person will be asked to inventory which staff members are interested and willing to participate voluntarily, and whether the research team may contact these individuals. Only after the contact person has obtained permission and confirmed interest from staff members will the research team approach these individuals to provide further study information and facilitate participation. This process ensures that the initial approach takes place via the organization and that staff members do not have to actively decline participation, thereby minimizing social pressure. If fewer healthcare professionals participate than expected, this will be accepted without any negative consequences for the department or its staff. Voluntariness and the right to refuse participation will be clearly communicated and guaranteed. The research team will not share with the centers which staff members do or do not participate in the study.
Interventie	Selected ICUs will participate in a phased implementation process. We will introduce and hand over the consensus based nebulization decision support tool to the selected group of healthcare professionals in the participating centers. The decision support tool is presented as a flowchart, available both in paper format and digitally. One to two weeks after this introduction of the decision tool, the MIDI questionnaire is conducted to identify barriers and facilitating factors to the implementation of the decision tool. These findings from the MIDI will be used to develop a site-specific implementation toolbox, guided by the Consolidated Framework for Implementation Research (CFIR), where MIDI domains are mapped to CFIR topics. Subsequently, the consensus based nebulization decision tool will be implemented in clinical practice, supported by the tailored implementation toolboxes.
Standaardzorg / Standaardbehandeling	Not using the toolbox, care as usual.
Studie eindpunten	The primary endpoint are the facilitators and barriers to implementation of this consensus based nebulization tool, assessed through the MIDI. Second endpoint is the site specific implementation toolboxes based on the MIDI results.
Studie parameters	Data will be collected at individual professional level (questionnaire responses) on the MIDI. The following study parameters will be recorded:

	- Responses to the MIDI questionnaire, capturing perceived barriers and facilitators across predefined determinants (e.g. procedural clarity, compatibility, outcome expectations). - Mapping of MIDI findings onto CFIR domains to inform tailoring of the implementation toolbox per ICU. - Characteristics of MIDI respondents (professional role, years of experience (categorized), prior experience with nebulization protocols (yes/no)) - Exposure to the intervention (e.g. participation in education session, reported use of the decision tool or flowchart). The questionnaire will be conducted in Castor EDC.
Statistische analyses	Categorical variables are expressed as number and percentage (%). Continuous data will be expressed as mean with standard deviation (SD) or as median with interquartile range (IQR) as appropriate. Normality of data will be assessed using Q-Q plots. A Chi-square test will be used to compare categorial variables between groups, while ANOVA or Kruskal-Wallis test will be used to compare continuous variables. A p-value of <0.05 will be considered to be statistical significant. All statistical analysis will be performed with RStudio (R version 4.3.2). MIDI questionnaire responses will be analysed descriptively per determinant, calculating mean scores and standard deviations or medians and interquartile ranges as appropriate. Differences in MIDI scores between subgroups (profession, ICU site, years of experience, exposure to the intervention) will be assessed using appropriate statistical test (ANOVA or Kruskal-Wallis).
Belasting voor de proefpersoon	The use of the decision-tool will take place during routine care and is designed to support current airway management and nebulization practices. While the introduction and use of a new tool may temporarily lead to a slight increase in workload, we think this burden is minimal. Participation in the MIDI questionnaire is only for a selected group of healthcare professionals and expected to take approximately 20 to 25 minutes. No additional invasive or time-consuming procedures are required from ICU staff as part of this study.
Risico voor de proefpersoon	None
Voordelen deelname aan het onderzoek	Participation in this study offers several benefits for ICU staff and patient care. The study brings focused attention to mechanical ventilation management, specifically evidence-based practices in airway care and nebulization. Using the nebulization decision-tool itself functions as an educational intervention, increasing knowledge and awareness among healthcare professionals. Additionally, the eventual implementation of the toolbox may lead to a reduction in

	unnecessary nebulization, potentially saving time for the nurses, materials, and reducing workload.
Nadelen deelname aan het onderzoek	There are no disadvantages associated with participation in this study. Choosing not to participate will have no negative consequences for the participant or their work situation. Participants do not need to actively decline; participation only occurs when they actively provide consent ('yes'). The research team will not share with the centers which staff members do or do not participate in the study. This approach ensures there is no pressure to participate and fully guarantees voluntariness.
Vergoeding voor de proefpersoon	None
Administratieve aspecten	Data will be collected in a coded (pseudonymized) form via Castor EDC, ensuring that individual responses cannot be traced back to specific participants. Each participating center will receive aggregated MIDI results only for their own center, in a summarized form that cannot be linked to individual participants. Final analyses and publications will present results per center in coded form, preventing identification of centers or linking results to specific sites. All data will be stored and analyzed within the ICT domain of Amsterdam UMC and retained for a maximum of 10 years.
Publicatiebeleid en amendementen	The results of this study will be published in a scientific, peer-reviewed journal.
Overige punten van belang voor de Niet-WMO toetsingscommissie	All participating centers have provided prospective oral consent to participate in the study. Each center will receive an information letter by email prior to participation, and study activities will only commence after explicit written consent is obtained from the center. The research team is independent from the participating centers and will not share with the centers which staff members do or do not participate. Within each department, a designated contact person from the center will inventory which staff members are interested in participating; only those who actively express interest in volunteering will be contacted by the research team to receive further study information and facilitate participation. Participants will receive clear information about the study's purpose, the voluntary nature of participation, and their right to refuse or withdraw at any time without repercussions. Consent will be obtained via the MIDI questionnaire. The workload is minimal and no invasive procedures are involved, further lowering the threshold to participate. This approach minimizes social pressure, ensures that consent is freely and validly given, and safeguards the privacy and confidentiality of all participants.