

# Three versus seven day circuit changes of humidified oxygen circuitry: a feasibility study

## AUTHORS

### Joan Webster

RN, RM, BA

Associate Professor, Nursing Director Research, Centre for Clinical Nursing, Royal Brisbane and Women's Hospital, Brisbane, Australia

joan\_webster@health.qld.gov.au

### Laurie Hall

RN, BNSc (Hons)

Project Officer, Centre for Clinical Nursing, Royal Brisbane and Women's Hospital, Brisbane, Australia

### Di Goodwin

BAppSci (Nursing)

Clinical Nurse Consultant, Department of Thoracic Medicine, Royal Brisbane and Women's Hospital, Brisbane, Australia

### Susan Bligh

BN

Clinical Nurse, Department of Thoracic Medicine, Royal Brisbane and Women's Hospital, Brisbane, Australia

### Fiona Coyer

RM, PhD

Associate Professor, School of Nursing, Queensland University of Technology, Brisbane, Australia

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## KEY WORDS

Oxygen inhalation therapy, humidity, pneumonia, humidifier circuitry

## ABSTRACT

### Objective

The study compared the rate of humidifier acquired pneumonia between patients in whom humidifier circuitry is changed every three days with patients in whom circuitry is changed every 7 days in order to assess the feasibility of conducting a large scale randomised controlled trial to test the safety of extending the period between humidified circuit changes from three to seven days.

### Design

The study was a randomised controlled trial.

### Setting

The setting for the study was a 942 bed general teaching hospital in Queensland, Australia.

### Subjects

The subjects of the study were patients receiving humidified oxygen in surgical, medical and infectious diseases units of the hospital.

### Interventions

Consenting subjects were randomly allocated to either 3-day (control) or 7-day (intervention) circuit changes.

### Main outcome measures

The primary outcome measure was nosocomial pneumonia and the secondary outcome measures were death and length of humidification therapy.

### Results

Of the 51 eligible patients, 32 were included in the study (17 patients were randomised to the control group and 15 patients to the intervention group; recruitment rate 63%). During the study, four cases of nosocomial pneumonia occurred; two in the intervention group (13.3%) and two in the control group (11.8%) ( $\chi^2 = 0.018$ ,  $p = 0.894$ ). No patients died during the study period.

### Conclusion

No high quality evidence exists to assist nurses to make a decision about how frequently to change humidifier circuitry. Potential cost savings involved in extending the time frame between humidifier circuitry changes indicate that a large scale randomised controlled trial is both feasible and important.

## INTRODUCTION

Modern health care demands both cost effectiveness and positive patient outcomes. In pursuit of these goals, many hospitals have focused on evaluating high volume practices, such as routine equipment changes, as these present significant recurrent costs. In the hospital where this research took place, humidified oxygen circuits are changed every three days to prevent nosocomial pneumonia however the policy is based on traditional practices, not on evidence. Consequently, a systematic review of the literature was conducted to identify the optimal length of time for humidifier circuitry changes. No research studies were found that answered this question. The Guidelines for the Prevention of Nosocomial Pneumonia recommend following the manufacturers' instructions for use (Tablan et al 2004) however manufacturers' information leaflets that accompany humidification equipment have instructions on how to set up the equipment but not on how often equipment should be changed.

Pneumonia remains an important cause of hospital mortality (Bowton 1999) and increases a patient's length of stay by an average of 5.9 days (Mehta et al 2007). Although no information could be found to guide a decision about how often to change humidifier circuitry, frequency of changes to circuitry used for mechanical ventilation has been studied and, as the two systems are related, this literature was reviewed.

## LITERATURE REVIEW

In the 1960's ventilator circuits were changed at short intervals to prevent ventilator associated pneumonia (VAP) (Phillips and Spencer 1965) which is generally defined as 'nosocomial pneumonia in a patient on mechanical ventilatory support for >48 hours after intubation' (Mayhall 2001). In 1983 the Centres for Disease Control and Prevention recommended changing ventilator circuits every 24 hours (Simmonds and Wong 1983). This was amended in 1994 to >48 hours (Tablan et al 1994) and more recently to "do not change routinely on the basis of duration of use" (Tablan et al 2004

p.3). It was also thought that the cause of ventilator associated pneumonia (VAP) primarily originated from exogenous contamination of the ventilatory circuitry. Studies now suggest that contamination of the circuit may be from the patient rather than vice versa; that is, respiratory tract infection is often the result of aspiration of pharyngeal secretions rather than aerosolisation from the ventilator circuit (Heyland and Mandell 1992).

Increased frequency of circuitry changes may itself contribute to an increased incidence of VAP. For example, Craven et al identified a two fold increase in the rate of pneumonia among patients who underwent 24 hourly circuit changes when compared with those in whom circuitry was changed less frequently. They hypothesised this was a result of increased manipulation which may have led to inadvertent flushing of contaminated condensate into the patients airway (Craven et al 1986). Patient factors such as age, underlying diseases, medications, number of intubations, use of positive end expiratory pressure, presence of a nasogastric tube, neutropenia, nasal intubations and sinusitis are also important issues.

Several recent reports have compared outcomes between short and longer term circuitry changes. The first group of studies used a 'before/after' design (comparing extended time between circuitry changes with historical controls). None of these studies identified a greater risk of VAP when extending ventilator circuit change intervals beyond 2 days (Han et al 2001; Lien et al 2001; Fink et al 1998; Kotilainen and Keroak 1997; Hess et al 1995). One of the problems with before/after studies is the difficulty in replicating exact conditions between the two time frames, introducing the potential for bias. However results in this case are strengthened by the consistency of findings between studies. A randomised controlled design is more appropriate when testing an intervention and four investigations have been reported using this approach. The first was published in 1991 and compared ventilator circuit changes every 48 hours with no changes at all. Levels of tubing colonisation, types of organisms

recovered, and the incidence of VAP were similar in the two groups (Dreyfuss et al 1991). This was a small study with results from only 35 subjects in the '2 day' group and 28 subjects in the 'no change' group analysed. The mean length of ventilator days in the 'no change' group was also unclear. In a separate study which compared one versus three circuit changes per week in patients ventilated for no more than seven days, the 'one change per week' group had a VAP rate of 5.9 per 1,000 ventilator days compared with 9.0 for the 'three per week' group. However in patients ventilated for longer than seven days the 'one change per week' group had a VAP rate of 13.2 per 1,000 ventilator days compared with 9.6 for the 'three per week' group. The results were not statistically significant (Long et al 1996). In an Australian study, '2 day' changes were compared with '4 day' changes and again the rate of VAP remained unaffected (Boots et al 1997).

The final investigation in this group was a multi-site randomised controlled trial comparing 'seven day' circuit changes with 'no changes'. The mean length of ventilator days in the 'no change' group was 14.9 days. Even over this longer timeframe, length of time between changes was not associated with VAP (24.5% in the 'no change' group and 28.8% in the 'seven day' circuit change group) and the length of hospital stay was not affected (Kollef et al 1995).

There are also significant cost savings associated with extending the time between ventilator circuit changes (table 1); presumably similar savings may be realised if the humidifiers were changed less frequently. In the financial year ending 30 June 2007, the hospital where the research took place used approximately 4,000 humidifier circuits in non ICU wards at a cost of \$152,400. Assuming a policy change to seven day circuit changes, a recurrent annual cost saving of \$87,086 could be made in equipment alone.

**Table 1: Savings associated with extending the time between circuit changes**

Intervention	Time between changes	Cost savings
Hess et al 1995	2-day versus 7-day intervals	76.6% reduction in cost (\$111,530/year)
Kollef et al 1995	7-day versus no change	\$30.00 per circuit change
Kotilainen et al 1996	3-day versus 7-day intervals	\$26.46 per circuit change
Fink et al 1998	2-day versus 7-day and 30 day intervals	\$4231/year for each ventilator
Lien et al 2001	2-day versus 7-day intervals	\$80,000/year

In summary, the literature shows that in intensive care settings, although the optimal schedule for the frequency of ventilator circuit changes remains unknown, the first change may be safely delayed until the end of one week of mechanical ventilation. However it may be inappropriate to base humidified oxygen protocols on research pertaining to ventilator circuitry because the configuration, purpose and patient population of humidified oxygen circuits are inherently different from mechanical ventilation circuits. Humidified oxygen circuits are open circuits, usually ending in a tracheostomy mask or a face mask. Patients are often disconnected from the circuit, for example, to attend an x-ray, and the circuit is left open and uncovered for periods of time.

In light of the differences between humidifier and ventilator circuits and the lack of supporting research for humidifier circuit changes, the purpose of the current study was to compare rates of nosocomial pneumonia between patients whose humidified oxygen circuitry was changed every three days with those changed every seven days.

## METHODS

### Design

A randomised controlled trial was used. The study was approved by the study hospitals' Human Research Ethics Committee.

### Setting and sample

All patients receiving humidification in the surgical,

medical and infectious diseases units of a 942 bed general tertiary referral teaching hospital in Queensland, Australia were assessed for eligibility. Exclusion criteria were age <18 years; an inability to give consent, (for example, the patient was mentally incompetent and relatives were either unknown or unable to be contacted); or cessation of humidification prior to 48 hours after admission to the ward. Patients entered the trial only after 48 hours had elapsed since arriving in the ward. This 'window period' was allowed so that pre-existing but undiagnosed infections could be detected prior to commencement in the trial.

## PROCEDURE

### Randomisation process

The randomisation schedule was generated by a researcher otherwise uninvolved with the implementation of the trial. A project officer was responsible for enrolling participants, gaining consent, and collecting data. An a priori research hypothesis was proposed that participants from intensive care would be more likely to develop nosocomial pneumonia so groups were stratified according to whether or not patients had been admitted to the ward from the intensive care unit.

### Intervention

Participants allocated to the intervention group had their circuitry changed every seven days. In all other respects they received usual routine care.

For all study patients, the following characteristics were prospectively collected: age, sex, smoking history, prior location before admission to the ward (eg intensive care unit, home), diagnosis at hospital admission, ward in which the patient was being treated, indication for humidification therapy, presence of chronic obstructive airways disease, number of circuitry changes done and reasons for the changes, duration of humidification therapy prior to pneumonia, total duration of humidification therapy (until death or weaning), and peak temperature.

Changing the humidifiers after patients were enrolled in the trial remained the responsibility of the registered nurses employed in the clinical area.

Stickers were placed on the patients' humidifiers and in the patients' bedside charts to alert the nurses that the patients they were caring for were part of the study group and advising the date on which the humidifier circuit should be changed. Both nurses and participants were aware of the participant's allocation. The nurses changed circuits at any time if visible soiling appeared, irrespective of the patients' study group.

The treating physician was not blinded to the patients' study group but was also not part of the research team. The treating physician diagnosed pneumonia using the following criteria: a new localised chest radiographic infiltrate; fever; white cell count of  $<4 \times 10^9/L$  or  $>11 \times 10^9/L$ ; isolation of a pathogenic organism  $>3+$  on semi-quantitative culture of a tracheal aspirate or sputum sample and clinical signs such as changes in sputum (increased production, changed appearance or increased quantity); and increased respiratory rate. The diagnosis of pneumonia was extracted from the patients' medical records by the project officer. Any ambiguity about the patients' diagnoses was clarified with the patients' treating physician.

### Sample size calculation

The sample size for the study was based on the reported nosocomial pneumonia rate of 18% for patients in the intensive care unit of the hospital where this investigation took place. It was assumed that the pneumonia rate would be less among patients receiving humidification therapy rather than mechanical ventilation, so an arbitrary rate of 10% was applied. Using an  $\alpha = 0.05$ ,  $\beta = 0.02$  (ie power = 0.8) and a change in pneumonia rate from 10% to 5% as clinically significant, an estimated sample size of 430 patients in each group would be required for a full study. To test the feasibility of conducting such a study, the researchers aimed to recruit a 5% sample of approximately 43 patients.

### Outcome measures

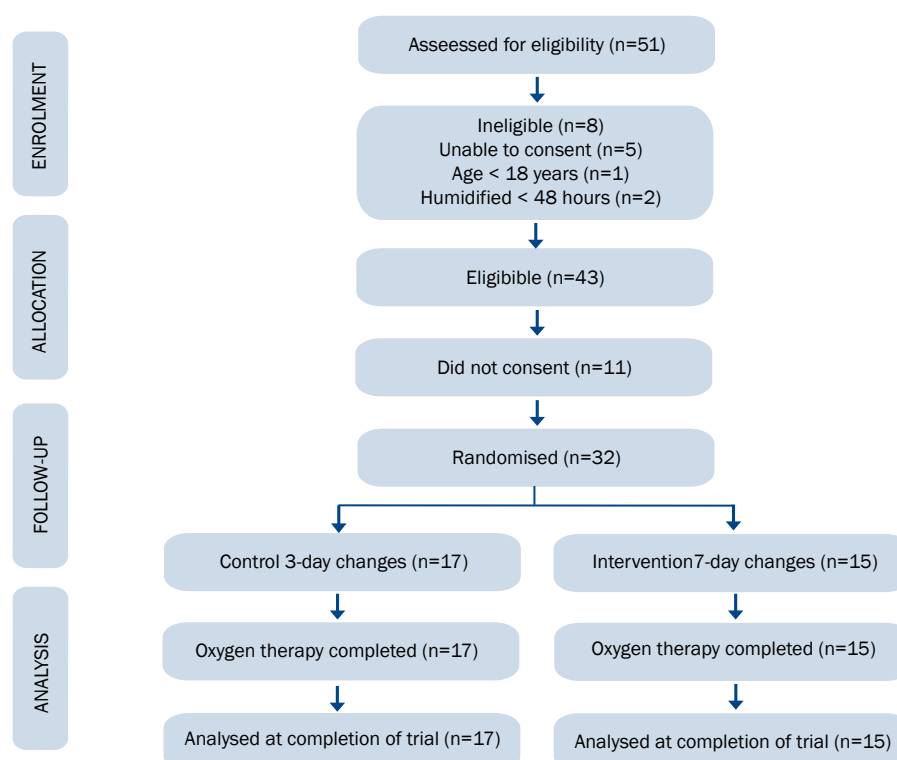
The primary outcome measure was nosocomial pneumonia and the secondary outcome measures were death and length of humidification therapy.

## Analysis

Patients were monitored until 48 hours after the cessation of humidification therapy. Outcome analysis was by original allocation and is expressed as the number of patients with the outcome of interest in each group (%). Baseline characteristics

such as age and weight were not normally distributed and were compared using the Mann-Whitney test and were summarised using the median (range). Categorical variables were compared using the chi-square statistic with Yate's correction and were summarised as proportions (%).

**Figure 1: Flow of participants through each stage of the study**



## RESULTS

During the study period, 51 patients were approached to participate in the study. Of these, sixteen patients were ineligible for inclusion (the reasons for exclusion are shown in figure 1). This left 43 eligible patients, eleven of whom did not consent; a recruitment rate of 63%. Of the 32 patients recruited into the study, seventeen patients were randomised to the '3 day' change group and fifteen patients were randomised to the '7 day' change group. Baseline characteristics for patients in the two groups were comparable at randomisation (table 2).

### Primary outcomes

During the study, four cases of nosocomial

pneumonia occurred; two in the intervention group (13.3%) and two in the control group (11.8%) ( $\chi^2 = 0.018$ ,  $p = 0.894$ ).

### Other outcomes

Both groups were similar in terms of the mean number of humidified days per patient: Intervention 13.7 days (SD 23.5 days), Control 12.9 days (SD 12.3 days),  $p = 0.89$ . There was a non-statistical difference in the mean number of circuits used per patient: Intervention 2.1 (SD 3.5), Control 3.1 (SD 3.9),  $p = 0.2$ . No patients died during the study period. Due to insufficient numbers of participants the effect of previous ICU admission on the primary and secondary outcomes was not able to be investigated.

**Table 2: Demographics of patients in a pilot randomised controlled trial of 7-day versus 3-day changes of humidified oxygen circuitry**

	7-day change (n=15)	3-day change (n=17)
Age in years	63.3 [31 to 78]	67.2 [23 to 90]
Number of males	13 (86.7%)	14 (82.4%)
Weight in kilograms	70.3 [42 to 122]	75.5 [50 to 120]
Admitted from ICU	10 (66.7%)	10 (58.8%)
Patient type:		
Medical	7 (46.7%)	5 (29.4%)
Surgical	6 (40.0%)	8 (47.1%)
Infectious diseases	2 (13.3%)	4 (23.5%)
Smoking history: current or within last 12 months	4 (26.7%)	5 (29.4%)
Presence of COAD	6 (40.0%)	7 (41.2%)
History of pneumonia	6 (40.0%)	11 (64.7%)
Presence of tracheostomy	9 (60.0%)	15 (88.2%)
Antibiotics on admission	10 (31.3%)	15 (46.9%)

NB: The data are median [range] or proportions (%)

## DISCUSSION

The purpose of the current study was to compare rates of nosocomial pneumonia between patients whose humidified oxygen circuitry was changed every three days with those changed every seven days in order to assess the feasibility of conducting a large scale randomised controlled trial to test the safety of extending the period between humidified circuit changes from three to seven days. While the study recruited 63% of eligible patients, only 32 patients were recruited over a seven month recruitment period. A number of issues prevented a larger sample being obtained: for example funding was only received to employ a project officer for one day each week for a period of 12 months. It was originally planned that the project officer would manage data and that nurses on the study wards would recruit participants. This plan was based on an understanding that two

nurses from each of the six study wards who had expressed an interest in the research would act as resource persons for the study and would assist other nurses on the ward with recruiting patients. Although the recruitment process was explained to the resource nurses and a resource folder for the study was left on the ward, it soon became clear that nurses on the study wards were unable to recruit patients into the study because of work pressures. As a result, recruitment was left to the project officer and occurred on only one day each week; hence many potential participants were missed. Although these problems meant the study was under powered to show real differences, the high recruitment rate indicates that recruitment would not be an issue in an adequately funded study.

Four patients (12.5%) developed nosocomial pneumonia while enrolled in the study. This was lower than the 18.8% rate reported in a recent large epidemiological study of pneumonia which included a classification of 'hospital acquired pneumonia' (Kollef et al 2005). All patients diagnosed with pneumonia in this study were admitted to their respective wards from the intensive care unit (ICU), all had received enteral feeding and all remained in hospital for extended periods; all factors associated with increased risk of nosocomial pneumonia (Tablan et al 1994). One of the participants was an elderly victim of a motor vehicle accident and later died after re-admission to the intensive care unit. After an extended stay of more than 98 humidified days, another participant was later transferred to another hospital for a double lung transplant. The third patient to have developed nosocomial pneumonia attended the speech pathology department for the ongoing management of swallowing difficulties, hence this patients' pneumonia was most likely due to aspiration. The fourth patient, although now well, was also an elderly victim of a motor vehicle accident and was fully nursing care dependent and immobile when enrolled in the study. Therefore all of the patients who developed nosocomial pneumonia had in common a number of factors known to be associated with a higher incidence of pneumonia such as: critical



illness and endotracheal intubation; enteral feeding; extended length of stay and immobility (Brooks 2001) and were more likely to have developed the pneumonia as a result of these factors rather than from contaminated humidified oxygen tubing.

While not statistically significant, an important clinical finding of the study was the difference between groups in the number of circuits used per patient. Patients in the control group used almost twice the number of circuits per patient when compared with the experimental group. This difference between groups seems more important when converted into cost savings. The hospital where this investigation took place spends \$98,733 on 3,098 humidifier circuits per year for non-ICU wards. A practice change to 7-day humidifier circuit changes could reduce current expenditure by almost one half, for a potential cost saving of approximately \$45,000 per annum. During the study the usage of humidified circuits for 15 patients during the data collection period was halved, resulting in an actual cost saving of \$930.

Although the study was unable to recruit sufficient participants to meet the sample size required to show a difference in the primary outcome between the two groups, it has shown that further study comparing 7-day and 3-day changes of humidified oxygen circuits would be feasible. Recruitment processes are now quite lengthy and involve specialised knowledge particularly of consent procedures. Expecting clinical nurses to undertake this role is no longer an option in busy clinical settings.

## CONCLUSION

Potential cost savings involved in extending the time frame between humidifier circuitry changes indicate that a large scale randomised controlled trial is both feasible and important.

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