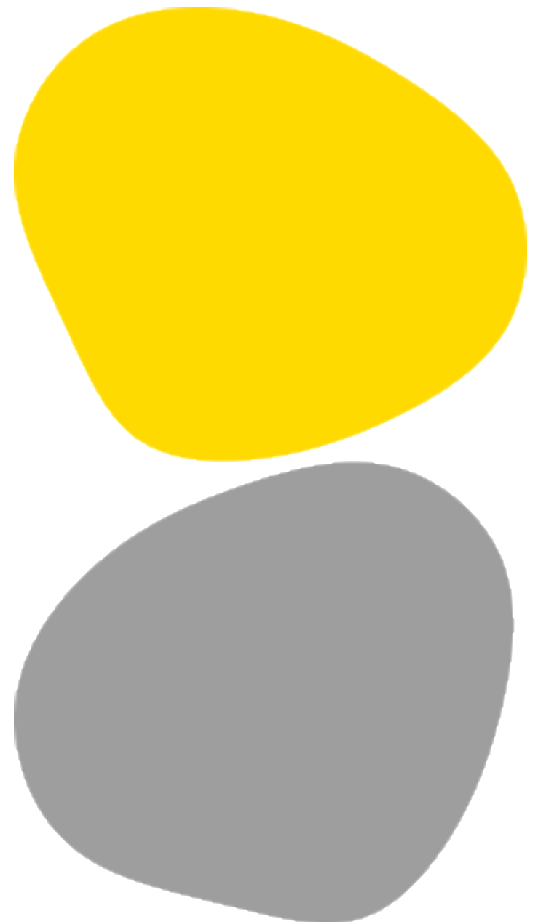




# Predicting exacerbations in patients with chronic respiratory failure and home mechanical ventilation using telemonitoring platforms: A prospective observational study

Rui Oliveira





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**Predicting exacerbations in patients with chronic respiratory failure and home mechanical ventilation  
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**Author**

Rui Oliveira, PT

**Supervisors**

PT, MSc, PhD, Rui Vilarinho, Universidade Fernando Pessoa

PT, MSc, PhD, Andreia Noites, Escola Superior de Saúde do Porto, Instituto Politécnico do Porto

PharmD, MSc, PhD, Cátia Caneiras, Faculdade de Medicina da Universidade de Lisboa

PT, MSc, Rita Santos, Escola Superior de Saúde do Porto, Instituto Politécnico do Porto

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Politécnico do Porto.*



## Resumo

A ventiloterapia é o principal tratamento para doentes com insuficiência respiratória crónica hipercápnica sendo que atualmente se discute a pertinência da telemonitorização nestes doentes. O objetivo principal deste estudo é avaliar se a telemonitorização consegue prever a exacerbação, pretendendo-se também analisar o padrão de prescrição e desenvolver um template de análise dos relatórios.

O estudo foi dividido em três fases: (1) análise descritiva da tendência na prescrição de ventilação em doentes com insuficiência respiratória crónica referenciados para uma empresa de cuidados respiratórios domiciliários; (2) análise descritiva das plataformas de telemonitorização com uma sugestão de análise dos reportes ventilatórios, realizando um focus group; (3) análise observacional prospetiva dos parâmetros ventilatórios na previsão precoce de exacerbações.

A maioria dos doentes (99%, n=1089) foram ventilados por pressão (1). O focus group comparou as duas plataformas e desenvolveu um template com as principais variáveis ventilatórias cruciais para uma boa adesão e adaptação à terapia (2). Por último, os resultados não foram estatisticamente significativos em nenhuma das variáveis independentes avaliadas (3).

A prescrição em Portugal parece manter o padrão de modos de pressão. Adicionalmente, aumenta a necessidade de desenvolver um template universal para analisar destes reportes. Estudos adicionais são precisos para avaliar potencial da telemonitorização.

**Palavras-chaves:** Telemonitorização; Ventiloterapia; Cuidados respiratórios domiciliários, Exacerbação, predição



## Abstract

Ventilotherapy is the main treatment for patients with hypercapnic chronic respiratory failure and nowadays, there has been discussion on how telemonitoring can benefit these patients. With that, the main objective of this study is to analyze if telemonitoring platforms can predict exacerbation of these patients and additionally analyze the prescription pattern of ventilotherapy and develop a template for the ventilatory report analysis.

The study was divided into 3 phases: (1) descriptive analysis of current ventilation prescription practices in patients with chronic respiratory failure referred to a Portuguese home respiratory healthcare company; (2) descriptive analysis of telemonitoring platforms with a template suggestion of ventilation report, using a focus group; (3) prospective observational analysis of ventilation parameters to predict early exacerbations.

Majority of patients (99%; n=1089) patients were ventilated by pressure modes (1). The focus group compared both platforms and developed a template with the most important ventilatory variables to assure a good adherence to the treatment (2). Lastly, results showed no statistical significance in all the independent variables (3).

Prescription in Portugal might remain pressure-based. Additionally, there is an increased need for development of a universal layout to analyze ventilatory reports. Additional studies are needed to evaluate the potential of telemonitoring.

**Keywords:** Telemonitoring; Ventilotherapy; Homecare; Exacerbation; Prediction



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## 1. Introduction

Home mechanical ventilation (HMV) has been used to treat patients with hypercapnic chronic respiratory failure (CRF) for decades (Antón et al., 2021), and its use has increased over time (Biggelaar et al., 2023).

In this field of medicine, technology is also advancing at a rapid pace, and there has been recent discussion on how telemedicine can benefit both the healthcare professional and these patients (Ambrosino et al., 2016). First, however, it is important to distinguish telemedicine from telemonitoring and the many other classifications with different applications.

In 2016, the European Respiratory Society issued a statement in which they defined these terms and pointed out the differences between them (Ambrosino et al., 2016). Telemonitoring, defined as the online transmission of physiological and other non-invasive data (Ambrosino et al., 2016), is expected to become more widespread, especially in the wake of COVID-19 pandemic. This was primarily due to a lack of face-to-face and routine contact with patients, but also because healthcare providers urgently needed to keep track of their patients' health status (Onofri et al., 2021; Shah et al., 2022). This enables the review of data primarily related to patient ventilatory function (Ambrosino et al., 2016). However, this subject has its advantages and disadvantages, as well as raising unanswered questions (Biggelaar et al., 2023).

In terms of its impact on the economic burden, telemonitoring could be a cost-effective strategy for reducing the strain on emergency services, urgent clinical visits and hospital admissions (Ackrivo et al., 2021). While some studies state that telemonitoring is cost-effective for certain populations (Almeida et al., 2012) or may be cost-effective overall (Vitacca et al., 2009), others disagree, stating that it is not possible to conclude whether or not it is cost-effective (Ambrosino et al., 2016).

For its overall use, more evidence is needed to have a definitive statement (Ambrosino et al., 2016; Borel et al., 2019).

As of today, the two main online telemonitoring platforms used in Portugal are: *Airview* (Resmed, 2025) and *Care Orchestrator Online* (Philips, 2025). Both platforms are known to transmit daily information about various ventilatory parameters, including unintentional



leaks, daily use, compliance, among others. However, they present these parameters using different measures and scales. This can lead to redundancy and difficulty when analyzing ventilator reports (Ackrivo et al., 2021). To resolve that, a standardized method, template or layout to analyze ventilatory reports is needed.

It is extremely important to assess the objective information provided by the reports without overlooking the subjective analysis. Over the phone, patients can provide verbal cues that help healthcare professionals understand the cause of their complaint. With that, adverse effects caused by ventilator prescriptions or treatments can be identified early, allowing for immediate adjustments to prevent exacerbations. Additionally, nowadays, almost all equipment's don't rely on modems, or patients' collaboration to transmit ventilatory information daily (Jiang et al., 2021). Ideally, the implementation of telemonitoring in ventilated patients, with addition of remote follow-up by a specialized team, could prevent exacerbation and ultimately reduce hospitalization and overall cost. Additionally, exacerbation in COPD patients is related to faster disease progression, increased mortality risk and poor prognosis (Jiang et al., 2021).

According to the 2005 Eurovent survey, the majority of Portuguese patients relied on pressure ventilation modes, while a small proportion used volume modes. The updated data reflects both continuity and evolution in practice (Antón et al., 2021). This underscores the need to assess whether this pattern represents improved patient outcomes or simply aligns with technological advancements and clinical preferences since 2005 (Lloyd-Owen et al., 2005).

The primary objective of this study was to analyze whether exacerbations or hospitalizations in patients with CRF can be predicted based on detectable changes in continuously monitored ventilatory parameters. These parameters will be tracked through online platforms, and the goal was to evaluate the predictive potential of these monitoring systems for clinical deterioration in order to support earlier and more effective intervention strategies.

The secondary objectives of this study were to assess current ventilation prescription practices and trends within a domiciliary respiratory care company, and to develop a standardised ventilatory report template. The investigation team hypothesizes that, during acute exacerbation, some ventilatory parameters could suffer a significant deviation,



especially respiratory rate (RR), % of spontaneous breaths (%spont breaths) and daily use of the ventilation.

## **2. Methods**

### **2.1. Study Design**

This study was divided into 3 different phases, answering the objectives stated above.

#### **2.1.1. Phase 1**

Descriptive analysis of current ventilation prescription practices in patients with CRF, referred to a Portuguese home respiratory healthcare company– Nippon Gases Healthcare. To accomplish this, a percentage of Nippon Gases Healthcare patients were selected. The exact percentage could not be provided due to legal and company policies. The inclusion criteria were patients that had ventilation prescription, telemonitored ventilators and lived in the Northern or Center area of Portugal. Data collection was in December 2024. Initially, the descriptive analysis involved the subdivision of ventilatory prescription according to ventilation mode (Volume or Pressure). Data was provided in an absolute and percentual value. Afterwards, the included patients were characterized in terms of gender, age, Inspiratory positive airway pressure (IPAP), Expiratory positive airway pressure (EPAP), Backup respiratory rate (bRR) and tidal volume (Vt) – when applicable. Data is presented as median and interquartile range (IQR) 25–75%.

#### **2.1.2. Phase 2**

Descriptive analysis of telemonitoring platforms with a subsequent template suggestion of ventilation report. To fulfill the second phase of the study, a focus group, composed by healthcare professionals from 3 different areas (3 physiotherapists, 1 rehabilitation nurse and 2 cardiopulmonologist technicians) was created. Initially it was debated and highlighted the advantages, disadvantages, differences and unanswered questions between the 2 most used online telemonitoring platforms in Portugal (Airview from Resmed and CareOrchestrator Online from Philips). No guidelines or checklists to develop Focus groups were used. No registers, both written and recorded were made during the interview



Afterwards, a template suggestion regarding ventilatory reports was created. The Focus Group was performed in a one-time meeting at Nippon Gases headquarters and aimed to answer questions such as: What are the advantages and disadvantages of each online platform? Which functionalities should be added to these platforms to promote adherence by the users? Which ventilatory parameters should be part of any ventilatory report? To avoid redundancy, which measure, or scale should be used and why? Which values should be registered and why? The main research led the meeting and did not interfere in the topic's discussion.

### **2.1.3. Phase 3**

Prospective observational analysis of ventilation parameters to predict and detect early exacerbations. Participants' recruitment protocol was divided in 2 parts. Firstly, an informed consent was sent, via mail to every patient that had a ventilation device, were Nippon Gases Healthcare clients already, and were included in the first phase. All participants were fully informed about the study and could voluntarily withdraw at any time during the study. All information was given, and if they agreed to participate, they were instructed to sign the letter and send it back to Nippon Gases Healthcare headquarters. The second phase of recruitment was through a telephone call, where all the information and objectives of the study were reminded, indicating that they had received information about the study, clarified any doubts, and agreed to participate. After agreeing to participate via phone call, data collection began. Data collection began in January 2025. Patients were asked if there was an exacerbation event in the prior month. For this study, exacerbation was event-based and not symptom-based. Event-based was considered when the patient had to visit, urgently, a primary care facility, emergency department, change medication, contact Portuguese healthcare line "Saúde24", or be admitted in the hospital. All these scenarios had to be related to the respiratory failure condition and excluded any other reasons. To avoid investigation bias, the research team did not perform the phone calls. These were assured by Nippon Gases Healthcare CallCenter, who was blinded to this study. To guide and prevent heterogeneity in the questions and dialogue with participants, a written guide was created (attachment 1). This telephone call was performed once a month, for 3 months straight. Phone calls for each participant had at least a 30-day interval between them. If



participants did not answer the phone call, after 3 tries (1 per day) the participant would be excluded and considered lost during follow-up. Patients that died or did not have an average use of ventilation for at least 4 hours during data collection, were also excluded. Concurrently, in the same day as the phone call, a ventilatory report was extracted from the respective online platform by the main investigator. If in the first question, the patient answer was "NO", a report from the past 30 days counting from the day of the phone call was created. If the answer was "YES", a report from the past 4 days counting from the day of the exacerbation (date which the patient provided through the phone) was extracted from the online platform. After data collection, ventilatory report data was compared between the exacerbation period with the clinically stable phase and analyzed if there were any variances in the ventilatory parameters, such as: RR, Percentage of spontaneous breaths (%spont breaths), Unintentional leaks, Inspiratory time (Ti), Vt, Adherence to treatment and Apnea / Hypopnea Index (AHI).

### **3. Ethic considerations**

As for ethic commission, the development of this study was approved (process number CE00105E). All participants received full information about the study and could withdraw voluntarily at any time. Informed consent was signed and also recorded during the initial phone call (indicating that participants had received information about the study, had clarified any doubts, and had agreed to participate). All data was collected in accordance with the General Data Protection Regulation. This means that the collected information was confidential and anonymous. The data was stored on a private desktop to which only the main researcher had access. The audio-recordings of the follow-up phone calls were erased after the study was completed. Codes consisting of letters and numbers were used provided to identify each patient. No private information regarding the participants was made public.

### **4. Data analysis**

To store and analyze data, the statistical Package for Social Sciences (SPSS) was used. Regarding the first phase of the study, to assess normal distribution, Kolmogorov-Smirnov



test was used. Afterwards, comparisons were performed using the Mann–Whitney test for non-normally distributed variables. The second phase is purely descriptive. No statistical analysis was included. For the third phase, a binary logistic regression analysis was conducted to evaluate whether the independent variables could predict the occurrence of exacerbations. The dependent variable was the presence or absence of exacerbation (yes/no). Independent variables included respiratory rate, percentage of spontaneous breaths, unintentional leaks, inspiratory time, tidal volume, adherence to treatment, and apnea/hypopnea index. Data was collected through continuous monitoring at 1, 2, and 3 months. Accordingly, three separate logistic regression models were constructed – one for each time point – to assess how predictive factors may vary over time. Statistical analyses were performed using IBM SPSS Statistics, version 29. Before model fitting, all variables were assessed for multicollinearity, and key assumptions of logistic regression were tested, including the linearity of continuous predictors with the logit of the dependent variable. Variables that did not meet statistical significance thresholds or exhibited high collinearity were considered for exclusion or adjustment. Each final model was developed using the LR forward selection method. Model fit was assessed using the Hosmer–Lemeshow goodness-of-fit test, and explanatory power was evaluated using the Cox & Snell  $R^2$  and Nagelkerke  $R^2$  coefficients.

## **5. Results**

### **5.1. Phase 1**

Of the 1090 patients, 1089 patients were ventilated by pressure and only 1 by volume with assisted control ventilation (ACV) mode. From the 1089, 1019 were prescribed Spontaneous timed (ST) mode (93,5%), and 70 (6,4%) with Spontaneous (S) mode (Table1). Regarding gender distribution, 559 (51,3%) were male and 531 females (48,7%) (Table2). All variables (age, IPAP, EPAP and bRR) were not normally distributed when compared with gender. As in age, male participants had a median of 70 [IQR;60–78] compared to female that had a median of 75 [IQR;65–82] ( $p$ -value  $<0,001$ ). Regarding ventilatory prescription pattern, the median IPAP for the entire sample was 18 [IQR;16–20] ( $p$ -value = 0,057). Median EPAP 7 [IQR;6–8] and EPAP 7 [IQR;6–9] for female and male participants, respectively ( $p$ -value = 0,167). Concerning bRR a median of 14 [IQR;14–16] ( $p$ -value = 0,617).



bRR comparison included ST and ACV mode patients only. The patient ventilated by ACV was a man that had prescription of 900ml Vt, EPAP of 5 and bRR of 16. This patient was not included in table 2.

Table1- Ventilatory modes

Ventilation mode	n (%)
S	70 (6,4%)
ST	1019 (93,5%)
ACV	1 (0,1%)
Total	1090 (100%)

The values are expressed as absolute (N) and as percentual value (%).

Abbreviations: S- Spontaneous mode; ST- Spontaneous Temporized

Mode; ACV- Assisted Control Volume Ventilation Mode

Table 2 - Characteristics of ventilatory prescription (n=1089).

	Total Sample n=1089	Men n=558 (51,2%)	Women n=531 (48,7%)	Maximum value	Minimum value	p-value
IPAP	18 [16-20]	18 [16-20]	18 [16-20]	40	8	0,057
EPAP	7 [6-8]	7 [6-9]	7 [6-8]	18	4	0,167

The values are righten as median [interquartile range 25%-75% ] unless otherwise indicated. P-value corresponds to the comparison of values between genders. Abbreviations: IPAP- Inspiratory Positive Airway pressure; EPAP- Expiratory Positive Airway Pressure;

## 5.2. Phase 2

The focus group characterized both platforms individually and stated advantages, disadvantages, differences and recommendations (Table 3.) As for the template suggestion, the group created a table that was believed to be the most important and crucial ventilatory parameters to be analyzed (Table 4.). The written layout of the interview is also available (attachment 2.)

Table 3 - Telemonitoring platform comparison and Focus Group opinion

Topic	Airview	CareOrchestrator Online	Focus group comment/decision
Usability	User-friendly and intuitive layout; main page uses three colors (Green = therapy going well, Yellow =	Intuitive and easy to understand overall data. The front page shows first an overview of the average value of different ventilatory parameters.	Both platforms are user friendly and easy to learn. No suggestions made by the Group



	high leaks and/or AHI, Red = low compliance).	Afterwards, a temporal line with 2 colors depending on the compliance (Green = good compliance, Red = poor compliance) is shown.	
Parameters Data	Quantitative values shown as median, 95th percentile, and maximum for the selected period.	Quantitative measures are shown as average, minimum and maximum	Group decided that the more important measures are the Percentile 95 <sup>th</sup> and median, and both should be analyzed combined.
AHI Characterization	No differentiation between central and obstructive apneas	Differentiation between central and obstructive apneas is provided.	AHI differentiation should be added to guide clinician in the objective examination
Inspiratory Time (Ti)	Calculated as median, 95th percentile, and max (thanks to TiControl™ technology (Resmed, 2018)	Since inspiratory time is fixed, no values are calculated.	Both technologies should be integrated. A backup, fixed inspiratory time for the cycles triggered by the ventilator and also a window for the patient to decide the inspiratory time during patient-triggered ventilation.
Rise Time	Expressed in milliseconds (ms)	Rise time is numerically programmed (1 to 6), with 1 being fast rise time and 6 being a slow rise time.	Group believes that it is easier if the rise time is expressed in milliseconds rather than numeric values in order to avoid redundancy and uncertainty between users.
Trigger and Cycle sensibilities	Shown qualitatively (low, medium, high, very high)	Since Philips has Auto-Trak technology, there is no need to program both triggers and cycling sensibilities. Although, depending on the ventilator used, it can be changed, for instance in the A40 pro and Trilogy Evo the trigger can be adjusted by flow.	Trigger and cycle sensibilities should be able to be changed. The group suggests that both qualitative and quantitative measures should be provided Example: Cycling set high (70% of inspiratory flow).
Inspiratory and Expiratory Correlation	Expressed as a ratio (I:E).	Not available on the platform (except for some ventilators like Trilogy Evo; otherwise via SD card download).	Expression of this parameter as ratio (I:E) is easier to understand and avoids mistakes and redundancy by users.
Flow curves analysis	Not available; only accessible via ResScan.	Flow curves can be reviewed for the last 7–14 days, depending on the modem used.	Flow curves analysis is fundamental to correctly ventilate any patient.
Alarm programming	Only possible via "AirView Ventilation Expert," which is not commonly used in Portugal	Alarms can be freely programmed by the healthcare provider.	Alarms are just as important as programming any other parameter. Pop-ups and messages should appear in the front page of the patient's profile.
Clinical notes	Notes can be added by professionals and are	Includes a specific tab for clinical notes, visible to other users.	Notes are important for healthcare professionals to communicate. No suggestions added.



	visible to all with access to the patient's profile.		
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Abbreviations: AHI – Apnea hypopnea index;

Table 4- Ventilatory report template suggestion by the Focus Group

Parameter	Scale and/or value suggestion
Adherence to treatment	Percentage (%): Days used divided by Total report days
Adherence $\geq$ 4h/night	Percentage (%) of nights with $\geq$ 4 hours of usage
Median usage per night	Time (hours:min) per night
Median restarts per night	Number of therapies restarts per night (mean)
AHI (Apnea-Hypopnea Index)	AHI per hour value + Breakdown by type (central, obstructive, hypopnea)
Tidal Volume	Percentile 95 and Median (ml)
Unintentional Leaks	Percentile 95 and Median (l/min)
Respiratory Rate	Percentile 95 and Median (breaths/min)
% of Spontaneous Breaths	Percentage (%) of spontaneous triggered breaths
% of Spontaneous Cycles	Percentage (%) of spontaneous cycled breaths
Inspiratory time	Percentile 95 and median (seconds)
Inspiration and expiratory relation	Ratio format (I:E) with percentile 95 and median

Abbreviations: ml- milliliters; breaths/min- breaths per minute; l/min: liters per minute

### 5.3. Phase 3

From the 65 patients included, 18 were lost in the follow-up, 16 for not answering the telephone call and 2 died during the data collection time, leaving 47 participants for data analyzes. From the 47 participants, times 3 calls made for each one, a total of 17 exacerbation episodes were registered (Figure1). Table 5 summarizes the descriptive statistics of the independent variables across all observations. Table 6 expresses the binary logistic regression for predicting monthly exacerbation. In the first month, the final model included unintentional leaks as the sole predictor. The model was statistically non-significant ( $\chi^2(1) = 2.75, p = 0.097$ ), indicating that unintentional leaks did not significantly contribute to predicting exacerbations. The odds ratio for this variable was 1.03 (95% CI: 0.99–1.08), with a p-value of 0.096, suggesting a non-significant positive association with experiencing exacerbations. In the second month, the final model included respiratory rate



as the sole predictor. The model was statistically non-significant ( $\chi^2(1) = 2,86, p = 0,091$ ), indicating that respiratory rate did not significantly contribute to predicting exacerbations. The odds ratio for this variable was 1.53 (95% CI: 1.07–2.17), with a p-value of 0.09, suggesting a non-significant positive association with experiencing exacerbations. In the third month, the final model included respiratory rate as the sole predictor. The model was statistically non-significant ( $\chi^2(1) = 3,75, p = 0,052$ ), indicating that respiratory rate did not significantly contribute to predicting exacerbations. The odds ratio for this variable was 1.46 (95% CI: 1.01–2.08), with a p-value of 0,052, suggesting a non-significant positive association with experiencing exacerbations.

Figure1: Participants included in phase 3

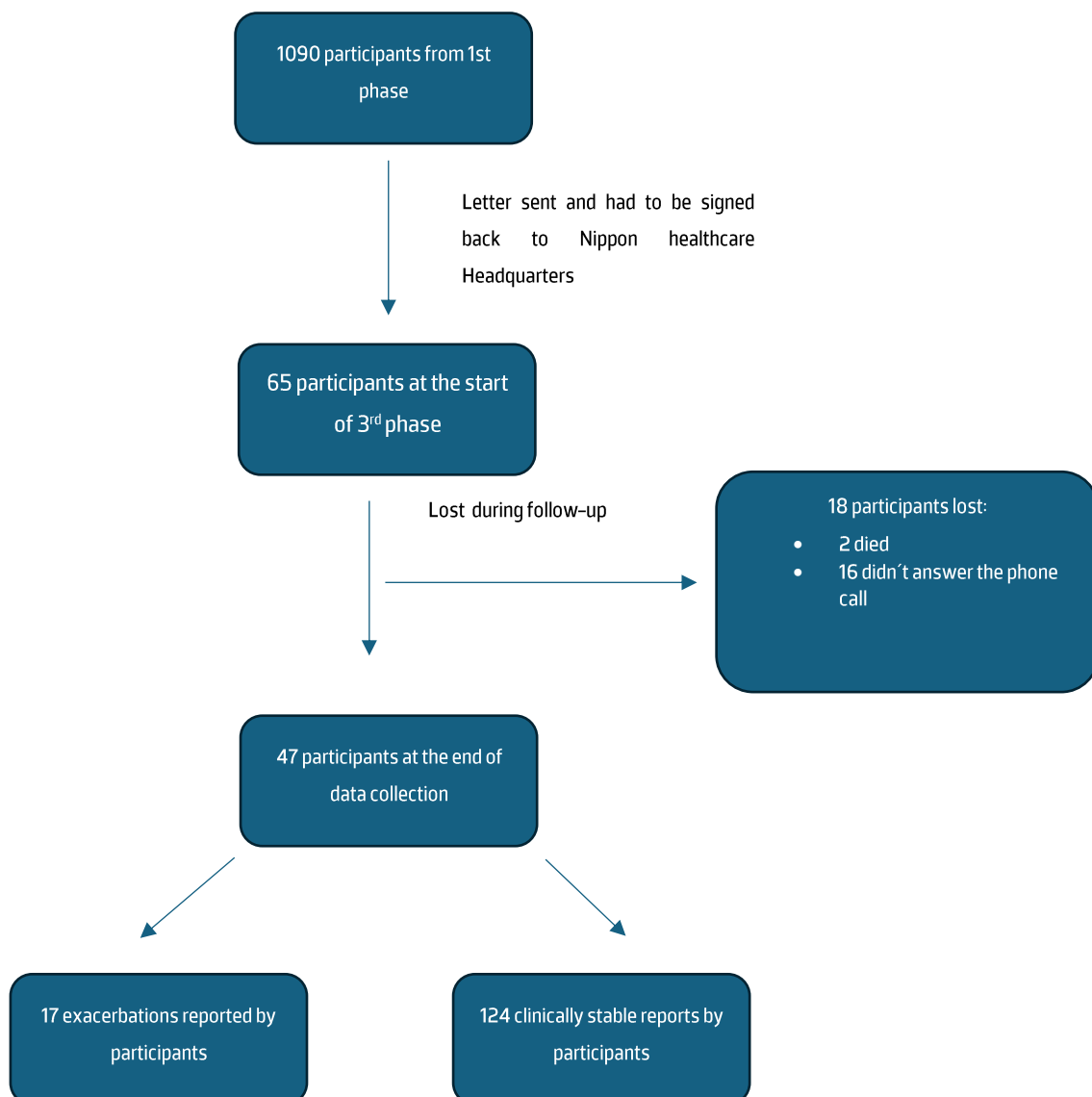




Table 5: Descriptive statistics of the dependent and independent variables

Variables	First month (n=65)		Second month (n=53)		Third month (n=47)	
		Range		Range		Range
Exacerbations, n (%)	4 (6,1%)		7 (10,6%)		6 (9,1%)	
Respiratory Rate (breaths/min)	16,90±2,30	[13,50; 26,30]	17,14±2,79	[14; 27,64]	16,95±2,25	[14; 24,90]
Spontaneous Breaths (%)	42,90±31,77	[0; 100]	43,08±31,41	[0; 100]	46,22±29,55	[0; 100]
Unintentional leaks (L/min)	8,75±15,87	[0; 92,50]	6,60±10,54	[0; 51]	6,08±9,6	[0; 51]
Inspiratory Time (s)	1,21± 0,22	[0,9; 1,8]	1,19± 0,23	[0,8; 1,70]	1,18±0,23	[0,9; 1,70]
Tidal Volume (mL)	498± 163	[142; 1150]	526,9± 167	[228; 1147]	539,5±163,7	[214,8; 977,8]
Adherence (% <4h nights used)	95,93± 11,1	[38; 100]	96,93±8,9	[55,0; 100]	95,3±12,3	[47; 100]
Adherence (mean time used in hours)	7,94±2,84	[1,59; 15,58]	8,40± 2,75	[1; 16,17]	8,52±2,70	[1,24; 15,58]
Apnea-Hypopnea index	2,7± 5,9	[0; 43,20]	3,2±6,1	[0; 36,7]	2,7±6,1	[0,1; 39,7]

Abbreviations: ml- milliliters; breaths/min- breaths per minute; l/min: liters per minute; s- seconds

Table 6: Binary logistic regression for predicting monthly exacerbation

Variables	First month (n=65)		Second month (n=53)		Third month (n=47)	
	OR (95% CI)	p value	OR (95% CI)	P value	OR (95% CI)	p value
Unintentional leaks	1,03 (0,99-1,08)	0,096				
Respiratory rate			1,53 (1,07-2,17)	0,09	1,46 (1,01-2,08)	0,052

First month: Cox and Snell  $R^2=0,038$ ; Nagelkerke  $R^2=0,099$ ; Hosmer-Lemeshow test=0,449. Second month: Cox and Snell  $R^2=0,113$ ; Nagelkerke  $R^2=0,204$ ; Hosmer-Lemeshow test=0,326. Third month: Cox and Snell  $R^2=0,093$ ; Nagelkerke  $R^2=0,174$ ; Hosmer-Lemeshow test=0,917.

## 6. Discussion

For phase 1, our results are aligned with the current literature. As for phase 2, our team created a template focused on available evidence and chose variables and respective scales that we believed would benefit both the patients and all the healthcare providers. For phase 3, results are not allied with the scarce evidence available.



The 2005 Eurovent survey (Lloyd-Owen et al., 2005) estimated a prevalence of 0.1 to 6.6 per 100 000 people for patients undergoing home mechanical ventilation. More recent studies showed a higher prevalence. An estimation of 9.9 and 12.0 per 100 000 habitants in Australia and New Zealand respectively (Garner et al., 2013), and 12,9 in Canada (Rose et al., 2015). Additionally, in Geneva Lake Area, between France and Swiss, the calculated prevalence reached 38 per 100 000 habitants (Cantero et al., 2020).

To keep up with the higher demand of home mechanical ventilation, telemonitoring usage has been increasing (van den Biggelaar et al., 2023). Costs and effectiveness of ventilation in hospital admission initiation and follow-up versus home initiation is not yet established. Besides, studies show different stands regarding telemonitoring. A study showed telemonitoring did not change the time to the next exacerbation, increased home visits and didn't improve quality of life in patients with CRF (Chatwin et al., 2016). On the other hand, a study with amyotrophic lateral sclerosis patients shows decreased hospital utilization, and that survival, cost and functional status could be improved with telemonitoring (Pinto et al., 2010)

A better understanding and investigation of the potential benefits of telemonitoring should be developed.

Regarding prescription patterns, the 2005 Eurovent (Lloyd-Owen et al., 2005) showed an overall higher percentage of positive pressure ventilators compared to volume preset ventilators. Countries like Portugal, Ireland and the United Kingdom had a residual use of volume mode ventilators, where some countries like the Netherlands, Poland, Spain and Belgium almost reached a 50/50 prescription pattern. More recently, a study developed both in Portugal and Spain showed that the prescription pattern is also predominantly ST mode (Antón et al., 2021). Compared with our results, the Portuguese reality prescription may remain the same. This might be because pressure modes are safer than volume modes, since in the first one, it is programmed a maximal inspiratory pressure, while in others, this parameter is not controlled, and might end up causing barotrauma (Campbell Robert, 2002). Besides, in pressure modes, the flow curve has a decelerating pattern, which may improve gas exchange and is more physiological, compared to the squared flow pattern represented by volume modes (Burns, 2008). Some studies have shown that pressure ventilation improves survival, higher rates of weaning and lower barotrauma incidents when compared



with volume-cycled ventilation in acute respiratory distress syndrome (Amato et al., 1998) and another one showed that higher volume ventilation was associated with ventilator induced pulmonary edema and not with higher airway pressures (Dreyfuss & Saumon, 1998). Additionally, pressures modes are considered more comfortable (Betensley Alan et al., 2008) and may decrease more work of breathing when compared to volume modes in patients with higher respiratory demands (Campbell Robert, 2002).

Regarding the use of online platforms to analyze ventilatory reports it is important to understand that, firstly, depending on the manufacturer and model, telemonitoring might need an external device to transmit data to the cloud, for example, Resmed Astral 150 and Stellar 150, or can already be intrinsically lodged in the device, like the Lumis 150 VPAP. For this extra cost in external modems, and logistics reasons at the patient's home, the ventilator has to be wisely chosen. Depending on the ventilator used, for instance, if using Trilogy Evo, with the external telemonitoring device, it is possible to access data 8 hours after. When using Dreamstation, it is 24 hours (Ackrivo et al., 2021).

Secondly, when it comes to reliability and accuracy of data transmitted to the cloud, it is crucial to analyze with caution. High, uncontrolled, unintentional leaks are, without a doubt, the major culprit for decreased accuracy and reliability of ventilatory parameters values (Borel et al., 2019; Luján et al., 2013; Sogo et al., 2013). Especially Vt and minute ventilation, since those are calculated indirectly through flow measurement (Ackrivo et al., 2021).

There are no standardized values to consider data reliable or not, however, healthcare professionals should take caution if values are above 40L/min of unintentional leaks (Ackrivo et al., 2021). However, most of the manufacturer's guidelines assure that ventilators compensate for leaks up to 60L/min (Mansell et al., 2018).

A study stated that 10-12 l/min or 20-24 l/min of median and percentile 95 unintentional leak respectively is acceptable (Arnal et al., 2023).

Another important aspect of leak analysis is the metrics used. They are different between manufacturers. Some display unintentional leaks, while others present only overall leaks, which may difficult data interpretation (Arnal et al., 2023).

Regarding time used per night, median should be preferred over mean, since median is not affected by outliers (Arnal et al., 2023).



As for the adherence superior to 4 hours of use in 70 % of the nights, it is already studied the impact of this cut-off. Besides, it is the Portuguese prescription criteria according to the national guidelines (Direção Geral Saúde, 2015)

To our team knowledge, the median of times the therapy was restarted per night is not available. In our perspective this value is very important. Even though overall usage might be good, if the patients restart therapy many times throughout the same night, it might indicate discomfort, ventilator-patient asynchronism or an undetected side-effect.

Relatively to the Apnea Hypopnea Index (AHI) Care Orchestrator Online differentiates obstructive and central apnea. On the other hand, Airview detects apneas and hypopneas only. This division is important to adjust pressures, the IPAP increase in case of hypopneas, and the EPAP in case of obstructive apneas (Kushida et al., 2008).

As for the importance of RR and % of cycles triggered by patients, they will be discussed later on this chapter on phase 3.

When it comes to inspiratory time, ResMed developed the TiControl, which allows healthcare professionals to establish both a Minimum (Ti Min) and Maximum (Ti Max) inspiratory time. This is extremely helpful when trying to prevent premature and late cycling respectively (Khirani et al., 2023; Resmed, 2018).

As for Philips, the fixed inspiratory time programmed is only for the mandatory breaths (Philips, 2019), which means, during spontaneous breath, the exact inspiratory time is unknown, since CareOrchestrator Online platform does not provide a median, mean or percentile 95 of both inspiratory time and I:E ratio for the spontaneous breaths.

Lastly, regarding I:E ratio, the physiological ratio is 1:2 (Frownfelter & Dean, 2012). In case of obstructive disease, the ratio should be closer to 1:3, while in restrictive disease the ratio should be closer to 1:1 (Berry et al., 2010). With that, clinicians should aim for a I:E ratio according to the baseline condition.

With all these independent variables, with different scales, measures and interpretation bias, coupled with different manufactures with different nomenclatures, redundancy might occur between users. With a focus group, having input from different healthcare professionals, with different background and experience might lead to a complete, standardized and summarized key-points. Besides, focus group main goal is to generate



new ideas (Breen, 2006) , in this case, template suggestion. For future studies, Delphi method could be developed.

A standard definition of exacerbation, in patients with CRF, is hard to achieve and is yet not established. Depending on the diagnosis etiology, obstructive, restrictive or both, different criteria should be developed to consider, or not, an exacerbation. As for COPD patients, for instance, a scoping review (Machado et al., 2023) takes into consideration various definitions. Some symptom-based, others event-based, others both. For diagnosis of asthma exacerbation, the Global Initiative for asthma (GINA) takes a more functional approach, using lung function worsening rather than symptoms (Global Initiative for Asthma – GINA, 2022). As for idiopathic pulmonary fibrosis, a case report was published in 2009, defining exacerbation as the “severe worsening of dyspnea, hypoxemia and new or progressive opacities on imaging studies” (Melo et al., 2009). Lastly, for bronchiectasis, the definition of exacerbation is symptom based, with worsening of 3 key symptoms for more than 48 hours (Hill et al., 2017). For this study, event-based criteria was used, since the investigation team considered harder for the patient to recall when he was feeling worse compared to when he had to visit an emergency department or had to change medication. This consideration reduces the recall bias, even though it is still present. As for the analysis of the ventilatory report during the development of exacerbation, 4 days seemed enough time to flag the deterioration of patients’ ventilatory function. We believe that, according to some evidence stated above, 48 hours could be a small window to detect exacerbation, turning the report prediction ineffective, and not long enough to detect ventilatory differences.

The forces between the chest wall and lung are unbalanced in patients with CRF. Consequently, more energy and work of breathing are required to maintain respiratory demands (Frownfelter & Dean, 2012).

During exacerbation, especially a type I hypoxemic, minute ventilation is increased in response to the decreased of PaO<sub>2</sub> (Frownfelter & Dean, 2012).

Minute ventilation can be augmented either by increasing V<sub>t</sub> or RR. In terms of energy costs, due to the lung elastic component, it is more efficient to increase RR instead of V<sub>t</sub> (Natalini et al., 2005) . Studies have shown increased RR prior exacerbation of COPD patients.



(Blouet et al., 2018; Borel et al., 2015; Jiang et al., 2021). However, concerning % spontaneous breath, results are contradictory (Blouet et al., 2018; Borel et al., 2015). During exacerbation, ventilatory asynchronies may be more recurrent, thus affecting %spont breath results. As for therapy daily use, the number of days with abnormal values (abnormal values being days with >75th or <25th percentile of individual baseline parameters) was higher in the exacerbation group compared with the control (Jiang et al., 2021). Another study showed an increased risk of exacerbation in patients with higher standard deviation results (Blouet et al., 2018). As reported above, regarding these 3 independent variables, our study showed different results. Our team did not find statistically significant results. All the results from the independent variables used each month as potential predictor were limited. For all the other independent variables, the results were also not statistically significant. Compared to other studies, different methodologies were used. For instances, (J. Borel et al., 2015) used a stratified conditional logistic regression model and (Jiang et al., 2021) a multivariate logistic regression analysis. Different methodology approaches might have led to different results between studies.

As for unintentional leaks, the tendency for increased values might have led to patient-ventilator asynchronies, which could have led to the ineffective therapeutic effect, which ultimately could have caused exacerbation episodes. More studies correlating ventilatory parameters and exacerbations are required.

Separating the limitation for each phase of the study, for the first one, regarding participants recruitment, the underlying condition diagnosis was not achievable. As a home respiratory healthcare provider, our company does not have access to the participant healthcare hospital records. Hence, the more vague and redundant term chronic respiratory failure was used. Moreover, only the telemonitored patients were included in the study, excluding patients without telemonitored devices, acknowledging a selection bias. However, this percentage trends to be small, as these devices are gradually being replaced by telemonitored ones.

As for the second phase, our team believes that a broader range of healthcare professionals should have taken part of the Focus Group, especially medical practitioner, as they are the ones who have authority to prescribe ventilotherapy, following Portuguese Health



Regulation. Besides, a checklist of guidelines to develop Focus Groups should have been used, for instance, COREQ, in order to augment methodology quality.

As in the last phase, the biggest limitation is related to recall bias. Patients had to remember if they had or not an exacerbation the prior month, leaving uncertainty to whether that was true or not. Moreover, the small number of exacerbations registered during data collections could have led to the not statistically significant results. The lack of exacerbation might indicate that the sample is stable and well adapted to ventilation, which ultimately shows the benefits of home mechanical ventilation.

For future studies, full access to medical records for the patients should be provided, but also a longer data collection time, 6 months to 1 year. Also, patient selection should be disease-specific, so that a prediction value can be created depending on the CRF etiology. Lastly, more studies regarding the cost-effectiveness of telemonitoring are required.

## **7. Conclusions**

Telemonitoring usage has been increasingly used in patients with CRF, undergoing HMV. In Portugal, ventilatory prescription pattern may remain pressure based, especially the ST mode. Telemonitoring platforms are useful to healthcare professionals track their patients' health status, although it's cost-effectiveness remains unclear. To guide and to avoid redundancy, a standard template should be used when analyzing ventilatory reports. Additionally, this study did not find any patterns or prediction values for exacerbation of patients with CRF. More studies are needed in order to establish a prediction formula to prevent exacerbation episodes.



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## 9. Attachments

### Attachments 1.

#### Guião chamada

1. “Bom dia, o meu nome é Xxxxxxx, sou da Nippon Gases, do aparelho do sono que o Sr/Sra Xxxxxx utiliza para dormir. Estou a falar com o próprio?” **(Caso a resposta seja sim, passar para ponto 2)**

#### Caso a resposta seja Não

- 1.1. “Sendo assim tenho o prazer de falar com ..?”
- 1.2. “Sr/Sra Xxxxxx, será possível falar diretamente com o Sr/Sra Xxxxx?”

#### Caso a resposta seja não

- 1.3. “Tem um contacto para o qual possamos ligar agora para falar com o Sr/Sra. ou com alguém que esteja com ele/a?”

#### Caso resposta seja não

- 1.3.1. “Muito bem, desta forma explico-lhe a si o motivo desta chamada”.

#### Caso a resposta seja sim

- 1.3.2. “Pode-me indicar o contacto telefónico por favor?”

#### Anotar contacto telefónico e usar esse para a chamada do mês seguinte

2. “Estamos a entrar em contacto consigo por causa do estudo que aceitou participar, lembra-se? Mantém o seu interesse? **(Caso a resposta seja sim, passar para ponto 3)**

#### Caso o doente negue a participação

- 2.1. “Permita-me que lhe explica muito rápido em que consiste, não lhe vou ocupar mais que 2 minutos, pode ser?”

#### Doente mantém negação

- 2.2. “Seria importante para nós que aceitasse, para melhorar ainda mais os serviços que lhe prestamos. Permita-me que explique por favor?”

#### Doente mantém negação

- 2.3. “Agradecemos o tempo que disponibilizou e muito obrigado”

#### Doente aceita

“Este estudo é anónimo, ou seja, ninguém saberá o seu nome nem nenhuma informação que o identifique. A qualquer momento pode desistir sem qualquer justificação.”



3. “Apenas vamos precisar de lhe ligar 1 vez por mês durante 3 meses, e realizar 1 pergunta, para saber como se sente e como tem andado de saúde, nada mais.”

4. “Desta forma, aceita participar?”

Sim (Caso a resposta seja sim, passar para ponto 6)

Não

Doente nega participação.

4.1. “Como referi, certificamos confidencialidade e anonimato e seria muito importante para nós que participasse.”

Doente nega participação.

4.2. “Agradecemos o tempo que disponibilizou e muito obrigado”

Doente aceita participação

5. “Muito obrigado pela sua contribuição. Passo então às perguntas:”

5.1. “**Neste último mês, contactou a saúde 24, ou teve de ir com urgência ao médico de família/ urgências hospitalares/ ou até mesmo internado por causa do seu problema dos pulmões?**”

Sim

Não

Doente responde sim

5.2. “Preciso que me indique o dia ao certo desse acontecimento por favor.”

Doente não sabe especificar dia

5.3. “É importante que nos indique o dia exato em que teve de ir ao hospital/urgência/médico família/internado. Estará alguém consigo que possa ajudar?”

Caso responda que não, registar apenas Não no ficheiro.

5.4. “ Já está, muito obrigado pela sua participação. Voltaremos a ligar-lhe para o próximo mês para repetir as questões. Tenha um bom dia, muito obrigado”.



Focus group meeting

**Tema:** Plataformas de Telemonitorização e template reporte ventilatório

**Materiais:** Mesas, cadeiras, computador

**Facilitador:** Rui Oliveira

**Escriba:** Rui Oliveira

**Descrição da atividade:**

Devemos começar por dar as boas-vindas aos participantes e agradecer-lhes pela sua ajuda. Iniciamos com a nossa apresentação e de algumas regras básicas de participação no *focus group* (por exemplo, pedir que não se mantenham conversas privadas e desligar os telemóveis);

Explicar o objetivo desta entrevista – avaliar o ponto de vista dos participantes em relação às Plataformas de telemonitorização e template reporte ventilatório);

A entrevista terá início às 8h30 e termina, por volta das 9h40 com uma duração estimada de 60 minutos.

Faixa etária: 25-39 anos

Ambos os géneros;

1 grupo de 6 participantes



Início da atividade	Duração	Atividade	Facilitador	Escriba
Questões de abertura 8h30	5 minutos	Qual é o vosso nome?  Qual a vossa categoria profissional?	Rui Oliveira	Rui Oliveira
Questões introdutórias 8h35	10 minutos	Cada vez mais temos doentes com diagnóstico de insuficiência respiratória crónica e inevitavelmente usamos cada vez mais plataformas de telemonitorização.  O que acham acerca das duas plataformas que usamos no nosso dia a dia e como nos podem ajudar?	Rui Oliveira	Rui Oliveira
Questões de transição 8h45	20 minutos	Na vossa perspetiva, quais as vantagens e desvantagens que aportam cada uma das plataformas?	Rui Oliveira	Rui Oliveira
Questões-chave 9h05	30 minutos	a) Que parâmetros acham que deviam estar presentes em qualquer reporte ventilatório? Sem adição de exames externos (oximetria noturna, oxicapnografia). b) Dos parâmetros selecionados, que escala, medida e valor deve de estar presente?	Rui Oliveira	Rui Oliveira
Questão final 9h35	5 minutos	Algum "gadget", funcionalidade extra que gostariam que as plataformas tivessem?	Rui Oliveira	Rui Oliveira

**P.PORTO**

ESCOLA  
SUPERIOR  
DE SAÚDE



**M**

**MESTRADO**

DESIGNAÇÃO DO MESTRADO