Exploring the feasibility of remotely monitoring breathing rate, heart rate and physical activity levels to detect and manage exacerbations of Chronic Obstructive Pulmonary Disease

Supplementary information

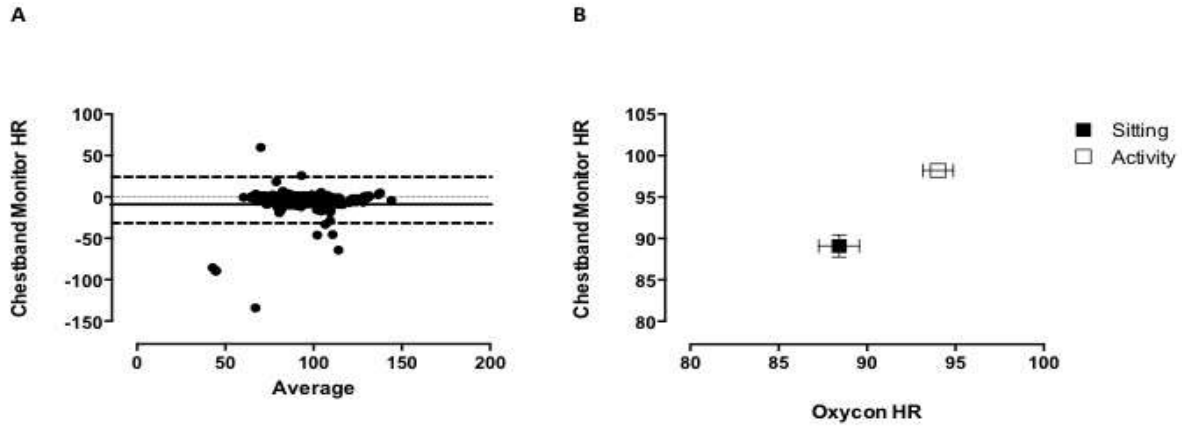
Section 1: Validation of HR and PAL on Monitor 5 Chest-band

HR from the Oxycon was used as a criterion measure for HR and was compared with Monitor 5 Chest-band. Monitor 5 Chest-band also provided data on PAL.

To validate PAL provided by the Monitor 5 Chest-band, Oxycon VO_2 values were divided by participants' body weight and converted to Metabolic Equivalents of Task (METs)[19]. This energy expenditure estimates from the portable metabolic system (METs) was used as a criterion measure for energy expenditure to validate PAL provided by Monitor 5 Chest-band.

Bland & Altman plots were used to assess bias and limit of agreement between the gold standard and Monitor 5 Chest-band to determine the level of accuracy in detecting changes in HR. Monitor 5 Chest-band has a high level of accuracy detecting HR (Bias= -3.88 LoA= -30.83 to 23.06) **Figure 1A**. Moreover, the ability to capture changes in HR was tested between HR data obtained at rest (sitting immediately before the activity) (88.416 SD 2.3 bpm) and different activities (94.02 SD 1.71 bpm) and showed good consistency with the data obtained by the gold standard measure (**Figure 1B**).

Figure 1: Validation of HR in a laboratory setting for Monitor 5 Chest-band.

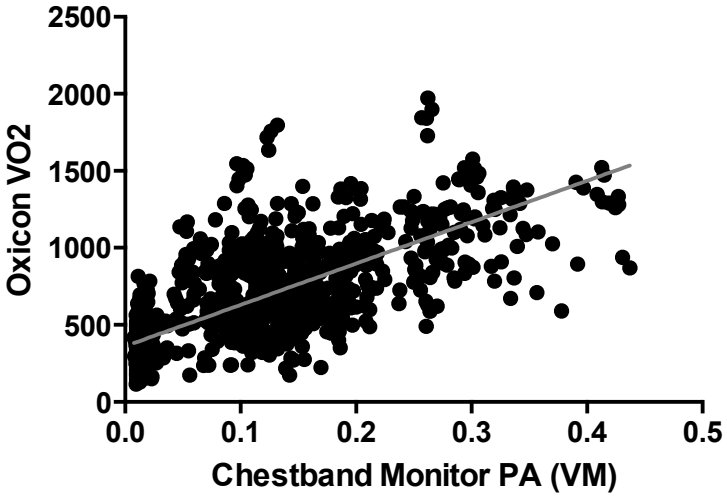


PAL was also validated for the Monitor 5 Chest-band. **Figure 2A** shows minute-by-minute correlations between metabolic cost (METs) and activity monitor output for Monitor 5 Chest-band. Strong correlations were found with Monitor 5 Chest-band and the gold standard (R.0.77). **Figure 2B** shows strong correlations between Oxicon-metabolic cost (VO_2 and METs) and Monitor 5 Chest-band PAL output (VM) in individual patients.

As expected, the change from resting (sitting) to combined activities (Fast 6MWT, Slow 6MWT Sweeping, Lifting), produced increments in PA that were shown by the Oxycon (1.25 SE 0.05 *vs* 3.53 SE 0.46), which were reproduced by Monitor 5 Chest-band (1.0 SE 0.02 *vs* 3.62 SE 0.51) (**Figure 2C**).

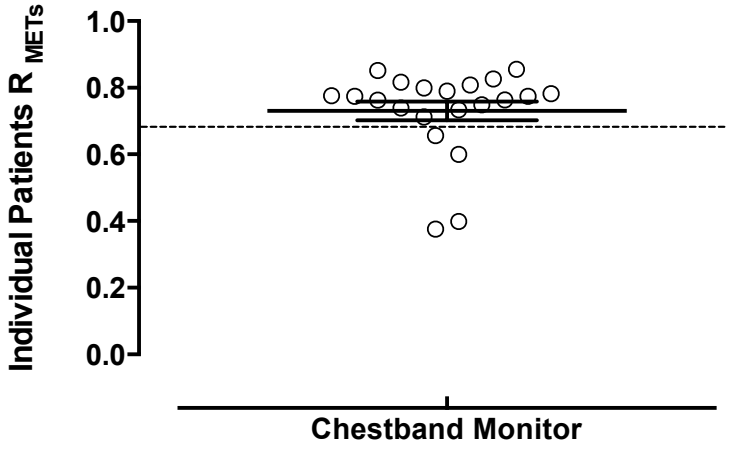
Figure 2. **Validation of PAL in a laboratory setting Monitor 5 Chest-band.**

A

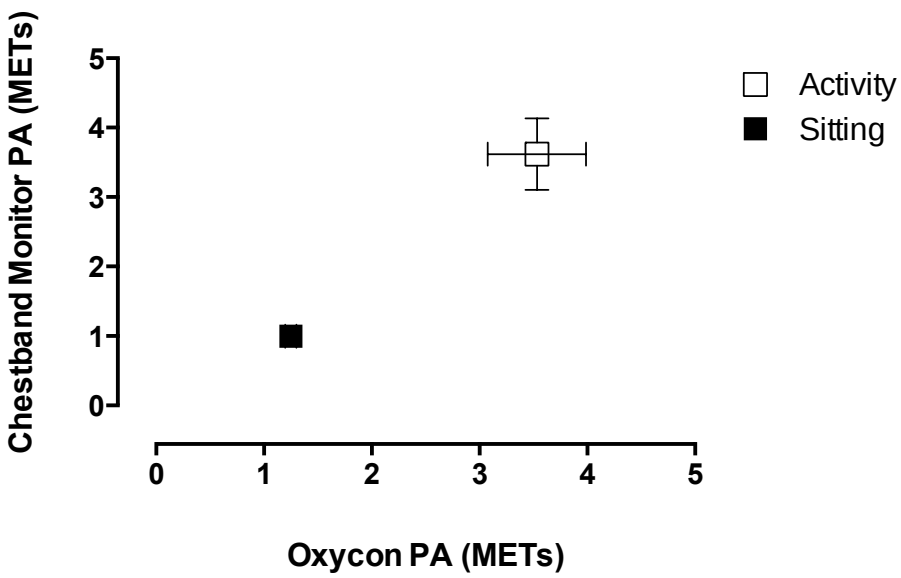


r=0.75
p=0.0001

B



C



Section 2: Phase 2 analysis results

2.1 Data Completeness

374 resting respiratory rates out of a possible total of 644 (58%) were recorded using Monitor 5 $_{\text{Chest-band}}$ compared to only 237 out of 644 (37%) for the Monitor 4 $_{\text{Accel}}$. However, 23 of the 374 Monitor 5 measurements (6%) were regarded as not accurate and indicative of a poorly fitting device due to very low respiratory rate measurements of less than 9 breaths per minute, whereas no values recorded by the Monitor 4 $_{\text{Accel}}$ device were less than 9. After removing the extreme Monitor 5 $_{\text{Chest-band}}$ values, 351 resting respiratory rates remained for Monitor 5 $_{\text{Chest-band}}$ (55%) compared to 237 for the Monitor 4 (37%). The analyses in this section are based on the 351 and 237 resting respiratory rates for Monitor 5 $_{\text{Chest-band}}$ and Monitor 4 $_{\text{Accel}}$ devices respectively.

2.2 Respiratory rate descriptive statistics

Measured breaths per minute ranged from 9.55 to 45.68 using the Monitor 5, and from 9.05 to 30.15 using the Monitor 4. The mean respiratory rate was 18.83 (SD 4.91) for Monitor 5 $_{\text{Chest-band}}$ compared to 21.50 (SD 3.79) for the Monitor 4 $_{\text{Accel}}$

2.3 Exploratory assessment of the within-patient variances

The following table shows the within-patient variances of breathing rate (BR) per patient as measured by Monitor 4 $_{Accel}$ and Monitor 5 $_{Chest\text{-}band}$ devices when the patient was at rest. Recall that these variances are calculated across all the occasions that were recorded by the patient as being "at rest" (maximum 28).

Table 2: Patient-level variances and 95% confidence interval half-width of the limits of at-rest reference ranges:

	Monitor 4				Monitor 5			
Patient	**Variance**	**N**	**Half-width***	**Number of days §**	**Variance**	**N**	**Half-width***	**Number of days §**
1	13.20	20	2.8	38		0		
2		0			10.63	25	2.2	31
3		0			1.34	19	0.9	4
4		0			13.32	5	6.0	38
5	7.31	12	2.7	21	7.58	17	2.3	22
6	1.45	7	1.6	4		1		
7	10.50	7	4.4	30	13.60	12	3.7	39
8	8.48	25	2.0	24	5.92	24	1.7	17
9	15.03	16	3.4	43	9.11	23	2.2	26
10		0			12.02	28	2.3	35
11	2.68	4	3.1	8	37.07	18	5.0	107
12	12.14	19	2.8	35	7.92	22	2.1	23
13	19.56	23	3.2	56	25.67	25	3.5	74
14	2.62	3	3.7	8	13.05	8	4.5	38
15		0			7.84	20	2.2	23
16	0.01	2	0.3		10.80	7	4.4	31
17		0			3.21	24	1.3	9
18	3.04	25	1.2	9	17.68	24	3.0	51
19	5.92	26	1.6	17	8.40	7	3.9	24
20	4.29	26	1.4	12	6.82	6	3.9	20
21	2.21	18	1.2	6	3.01	20	1.3	9
22	9.49	4	5.8	27	8.39	15	2.6	24
23		0				1		
Average	7.37	10.30	2.6	23	11.17	15.26	2.9	32

* Half width of 95% confidence interval of the limit of the reference range.
§ Approximate number of days needed for the half-width of the 95% confidence interval of the limit of the reference range to be 2 breaths per minute or below.

An average of 5.0 more measurements were taken by Monitor 5 $_{\text{Chest-band}}$ per patient (95% CI -0.8 to 10.7). For Monitor 4 $_{\text{Accel}}$ device, the device was not used or no data recorded for 7 out of 23 patients compared to only 1 out of 23 patients for Monitor 5 $_{\text{Chest-band}}$

Among those patients who used both devices at least once, resting respiratory rate was measured on an average of 15 occasions for the Monitor 4 $_{\text{Accel}}$ compared to an average of 16 occasions for Monitor 5 $_{\text{Chest-band.}}$ The mean difference was calculated to be 1.3 with a 95% CI of -4.3 to 6.9.

2.4 Establishing the "at rest" reference ranges

In the previous section, the at-rest measurements taken on Monitor 4 $_{\text{Accel}}$ appeared to be less variable on average per patient compared to those taken on Monitor 5 $_{\text{Chest-band}}$. However, these variances were calculated based on fewer measurements on average and therefore this may bias the comparison between the two devices. A better method is to compare the within-patient variances calculated from random effects models which take into account the number of measurements per patient. Two separate random effects models were fitted: one for Monitor 5 $_{\text{Chest-band}}$ and one for the Monitor 4; both with patients included as random effects. The results are shown in the table below.

Table 3: Results based on random effects models of the "at rest" respiratory rate data for the Monitor 5 and Monitor 4 devices

	Within-patient SD	Between-patient SD	Intra-class correlation coefficient (ICC)	Approximate number of days needed for confidence interval of limit to be +/- 2 breaths per minute
Monitor 5	3.364	3.768	0.556	33
Monitor 4	2.920	2.549	0.432	25

The Monitor 4 had a slightly lower within-patient standard deviation. This means that for the Monitor 4 data there was less uncertainty about the limits of the respiratory rate reference range compared to Monitor 5 $_{\text{Chest-band}}$. This may indicate that the Monitor 4 is slightly better at identifying an at-rest reference range. However, the within-patient SDs are close to each other.

Furthermore, we must interpret the above findings with caution because:

(i) The number of patients is fairly small.

(ii) There was a high proportion of missing data.

(iii) There were differences in patients and numbers of measurements between the devices.

For example, for patient 11, some relatively high breathing rates were recorded at some time points suggesting that the patient may not have been at rest at those time points which contributed to the high variance for Monitor 5 $_{\text{Chest-band}}$ observed in the table. In contrast, no Monitor 4 $_{\text{Accel}}$ data was recorded for patient 11 except on the first day of measurement.

Monitor 5 $_{\text{Chest-band}}$ identified a greater level of between-patient variability compared to Monitor 4 $_{\text{Accel}}$ and produced a slightly higher ICC indicating greater relative agreement within patients when compared to the variability between patients. However, it is noted that these findings may have been at least partly due to a poorly fitting device in some patients.

Using the within-patient standard deviation as calculated by the random effects models, the expected 95% reference range for a COPD patient was estimated to be Mean ± 6.594

for Monitor 5 $_{\text{Chest-band}}$ and Mean ± 5.724 for Monitor 4 $_{\text{Accel}}$ device. Using the overall estimate of the mean respiratory rate from the random effects models, the expected 95% reference ranges became (11.7 to 24.9) for Monitor 5 $_{\text{Chest-band}}$ and (15.9 to 27.3) for the Monitor 4 $_{\text{Accel}}$. However, please note that these reference ranges, though wide, do not take into account the between-patient variability which was quite substantial. The relatively high between-patient variability observed for the respiratory rates suggests that calculating individualised reference ranges is most appropriate. Using the *observed* means and within-patient standard deviations, the individualised reference ranges (with 95% confidence intervals around the limits) were as follows:

Table 4a: Individual 95% reference ranges for the Monitor 5

Patient	Mean	Within-patient SD	N	95% reference range		95% CI of LOWER limit of reference range		95% CI of UPPER limit of reference range	
				Lower limit*	Upper limit	Lower	Upper	Lower	Upper
1			0						
2	21.48	3.26	25	15.09	27.87	12.85	17.34	25.63	30.12
3	11.04	1.16	19	8.77	13.31	7.85	9.69	12.39	14.22
4	14.73	3.65	5	7.57	21.88	1.59	13.56	15.90	27.86
5	16.78	2.75	17	11.39	22.18	9.07	13.70	19.86	24.49
6	10.94		1						
7	15.67	3.69	12	8.45	22.90	4.72	12.17	19.18	26.62
8	20.89	2.43	24	16.12	25.65	14.41	17.83	23.94	27.36
9	19.13	3.02	23	13.21	25.04	11.04	15.38	22.87	27.21
10	19.00	3.47	28	12.21	25.80	9.96	14.46	23.55	28.05
11	25.84	6.09	18	13.91	37.77	8.94	18.87	32.81	42.74
12	23.84	2.81	22	18.32	29.35	16.25	20.39	27.28	31.42
13	16.83	5.07	25	6.90	26.76	3.42	10.39	23.28	30.25
14	24.63	3.61	8	17.55	31.71	13.01	22.09	27.17	36.25
15	18.92	2.80	20	13.43	24.41	11.27	15.59	22.25	26.57
16	16.16	3.29	7	9.71	22.60	5.27	14.16	18.16	27.04
17	22.64	1.79	24	19.13	26.15	17.87	20.39	24.90	27.41
18	14.18	4.21	24	5.94	22.43	2.99	8.90	19.47	25.38
19	15.75	2.90	7	10.07	21.43	6.15	13.99	17.51	25.35
20	20.25	2.61	6	15.13	25.37	11.27	18.98	21.51	29.22
21	18.15	1.73	20	14.75	21.55	13.41	16.09	20.21	22.89

22	15.85	2.90	15	10.17	21.53	7.57	12.77	18.93	24.13
23	14.83		1						

Table 4b: Individual 95% reference ranges for the Monitor 4

Patient	Mean	Within-patient SD	N	95% reference range		95% CI of LOWER limit of reference range		95% CI of UPPER limit of reference range	
				Lower limit	Upper limit	Lower	Upper	Lower	Upper
1	21.50	3.63	20	14.38	28.62	11.57	17.18	25.81	31.43
2			0						
3			0						
4			0						
5	17.74	2.70	12	12.44	23.04	9.71	15.17	20.31	25.77
6	20.13	1.20	7	17.77	22.50	16.14	19.40	20.87	24.13
7	21.76	3.24	7	15.40	28.11	11.02	19.79	23.72	32.49
8	21.99	2.91	25	16.28	27.70	14.28	18.29	25.69	29.70
9	16.18	3.88	16	8.58	23.77	5.22	11.94	20.41	27.14
10									
11	22.70	1.64	4	19.50	25.91	16.43	22.57	22.84	28.98
12	26.63	3.48	19	19.80	33.46	17.04	22.56	30.69	36.22
13	21.80	4.42	23	13.13	30.47	9.95	16.31	27.29	33.64
14	24.61	1.62	3	21.44	27.78	17.77	25.10	24.12	31.45
15			0						
16	21.64	0.10	2	21.44	21.84	21.12	21.75	21.52	22.15
17			0						
18	19.69	1.74	25	16.28	23.11	15.08	17.48	21.91	24.31
19	23.13	2.43	26	18.36	27.90	16.72	20.00	26.26	29.54
20	22.61	2.07	26	18.55	26.67	17.15	19.95	25.27	28.07
21	19.52	1.49	18	16.61	22.44	15.40	17.82	21.22	23.65
22	25.40	3.08	4	19.36	31.44	13.58	25.14	25.66	37.22
23									

The reference ranges for some patients (e.g. patient 13) are very wide, and hence they may not be useful in practice. This is because the daily variability in respiratory rates for these patients is very high. Other patients such as patient 21 gave sensible reference ranges using both devices.

2.5 Investigation of the association between respiratory rate and other variables

The association between respiratory rate and each of oxygen saturation, heart rate and perception of breathlessness as measured using the Borg scale and the MRC Dyspnoea scale were assessed using normal linear mixed models fitted to respiratory rate as the outcome variable. The results are shown in the table below:

Table 5: Results from linear mixed models for the association between respiratory rate and other variables

Variable	Monitor 4			Monitor 5		
	Estimated coefficient	**95% CI**	**P-value**	**Estimated coefficient**	**95% CI**	**P-value**
SpO2 Oxygen Saturation	0.062	-0.067 to 0.191	0.345	0.059	-0.068 to 0.187	0.362
Heart rate	0.003	-0.040 to 0.046	0.896	0.006	-0.032 to 0.045	0.752
Borg scale	0.615	-0.186 to 1.416	0.134	0.227	-0.601 to 1.056	0.591
MRC Dyspnoea scale	0.743	-0.224 to 1.710	0.134	0.069	-0.813 to 0.951	0.878

There were no statistically significant associations between respiratory rate and oxygen saturation, heart rate, the Borg scale, or the MRC Dyspnoea scale. This suggests that respiratory rate, as measured by the Monitor 4 and Monitor 5 devices, is poorly associated with other variables used to assess breathlessness.

2.6 Conclusions

More respiratory rate data was collected using the Monitor 5 than the Monitor 4, although the data did suggest some occasional problems with the Monitor 5 recording impossibly low values, perhaps due to a poorly fitting device. The Monitor 4 device was estimated to

have a slightly lower within-patient standard deviation compared to the Monitor 5 on average, but the difference was only small. For most patients, the within-standard deviations were large so that it made the resulting individual reference ranges too wide to be practically useful. Also, the respiratory rate measurements were found to be poorly associated with oxygen saturation, heart rate, and perception of breathlessness scales.

Section 3: Phase 3 analysis results using all “at rest” data (determined using physical activity data from Monitor 5)

3.1 Introduction

19 patients in total were recruited into the study. One patient died during follow-up. 6 other patients dropped-out from the study early; one of whom had no data recorded because they withdrew from the study before any monitoring was done. Therefore, there were 18 patients with at least one valid observation recorded.

Two patients (3 and 4) had a second AECOPD event during their monitoring period; and so we have data from two exacerbation cycles for these patients.

By examining the physical activity data measured by the Monitor 5, we were able to exclude those respiratory rate observations where the patient was evidently not at rest.

Therefore, in this sensitivity analysis we only use respiratory rate data for which we are confident that the patient was “at rest”.

Very low respiratory rates of below 10 breaths per minute or very high values of 40 or above were regarded as implausible and excluded from the analysis. These were most likely due to a poorly fitting device.

In total, 109,686 respiratory rate observations were recorded as valid. The average number of observations per patients was 6094. The minimum number was 135 while the maximum was 28836.

3.2 Descriptive Statistics of resting respiratory rate

The mean overall resting respiratory rate was 17.7 breaths per minute (SD 4.61), based on 109,686 observations. Further descriptive statistics are shown below:

Min.	1st Qu.	Median	Mean	3rd Qu.	Max.	SD
10.00	14.32	17.15	17.68	20.18	39.99	4.61

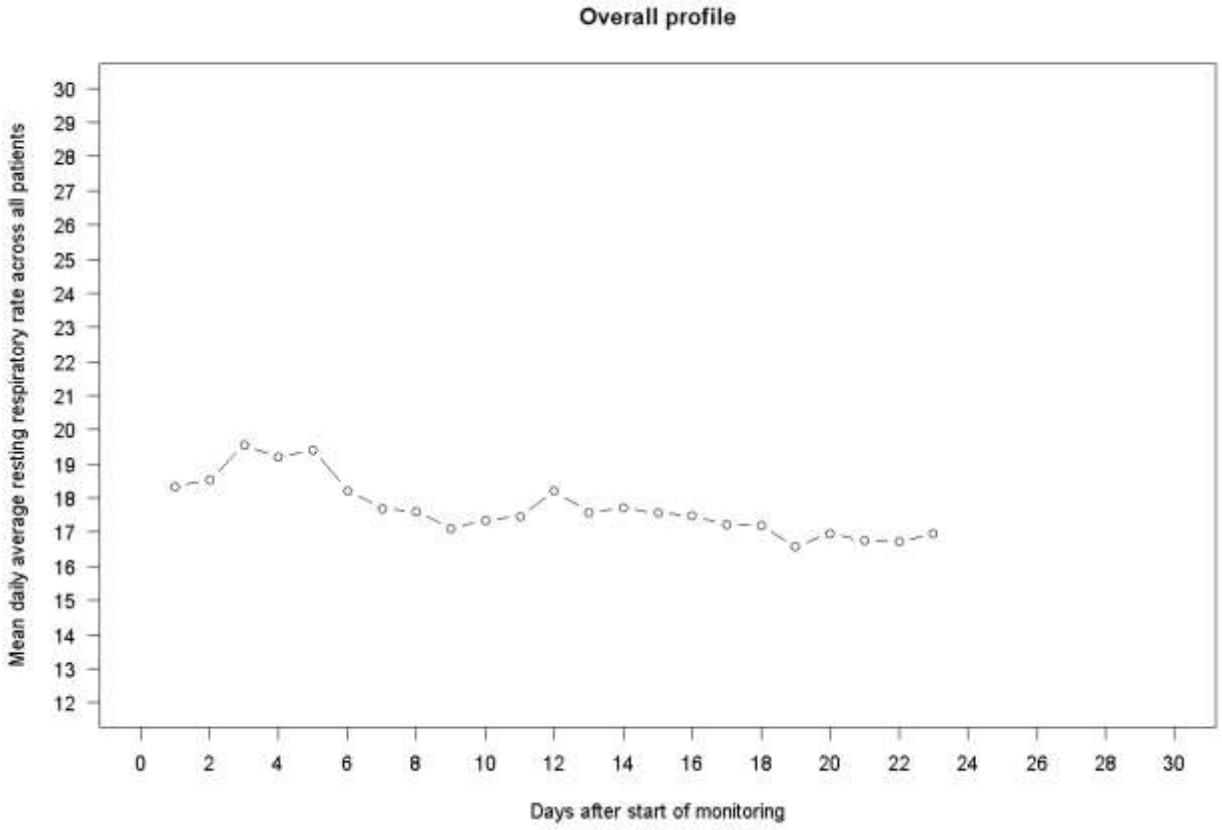
3.3 Variation in resting respiratory rate measurements

To determine the between-patient and day-to-day within-patient variation in respiratory rate measurements as recorded by the Monitor 5, a normal linear mixed effects model was

fitted, including a fixed effects term for number of days post-exacerbation (explanatory factor variable), and with patients included as a random effect. **The within-patient standard deviation was estimated to be 3.99 and between-patient standard deviation 2.98**. The intra-class correlation coefficient (ICC) was calculated to be 0.36. The within-patient variability in resting respiratory rate appears to be slightly higher than the between-patients variability in COPD patients recovering from an exacerbation.

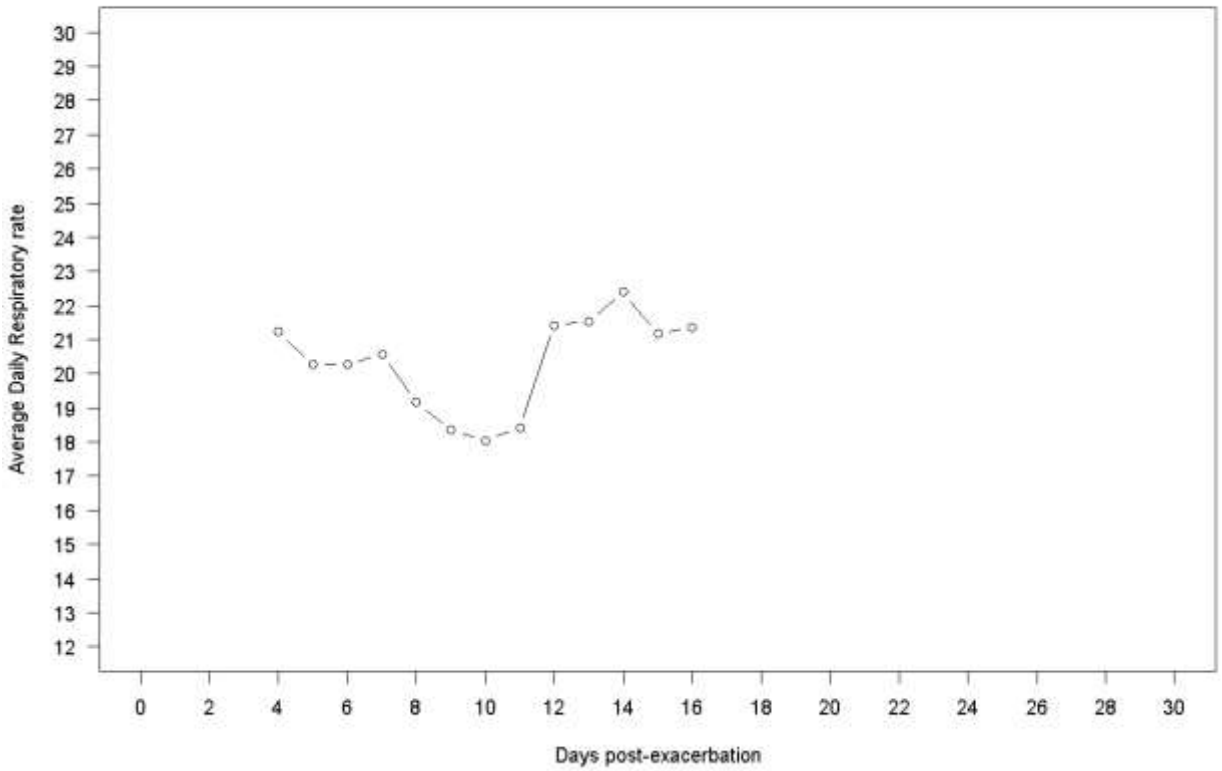
3.4 Evolution of average daily resting respiratory rate over time following an exacerbation

Firstly the average respiratory rate was calculated for each day, and then these daily averages were used in a graphical method to investigate the relationship between days post-exacerbation and mean daily respiratory rate. The evolution of daily average respiratory rate over time was summarised graphically for all the patients in a mean overall profile (see below).

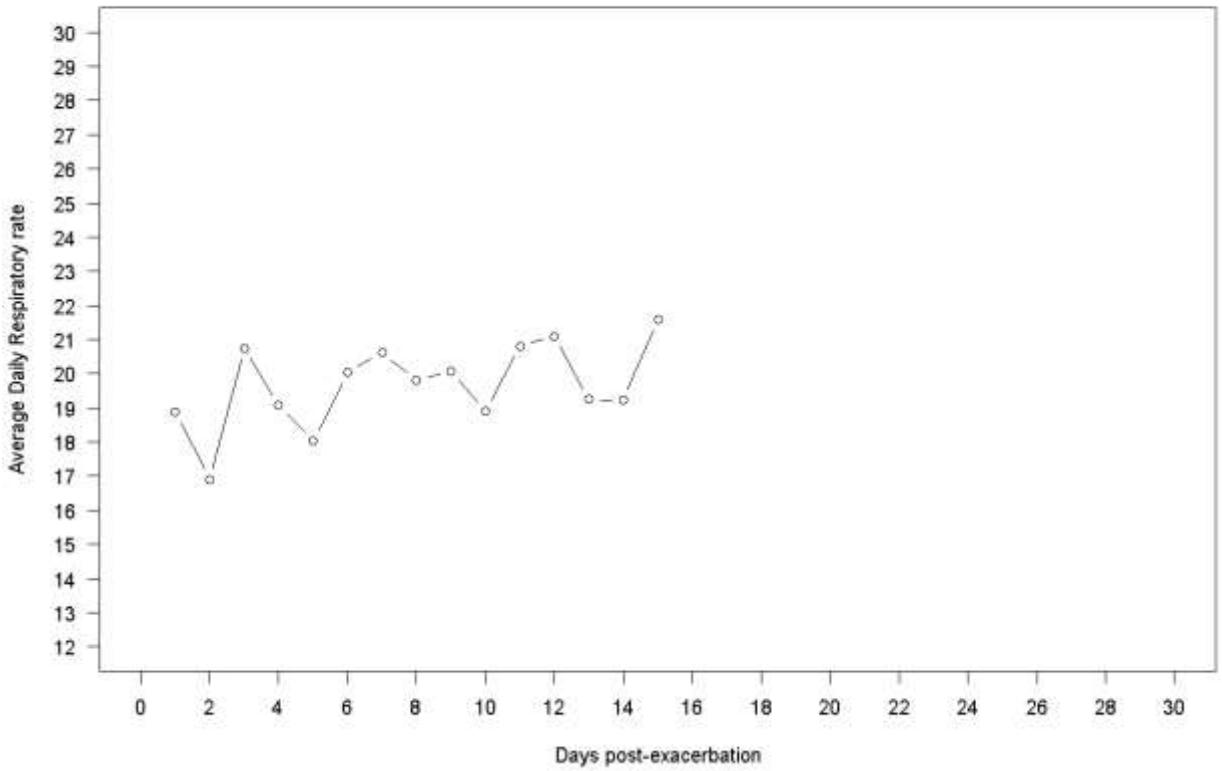


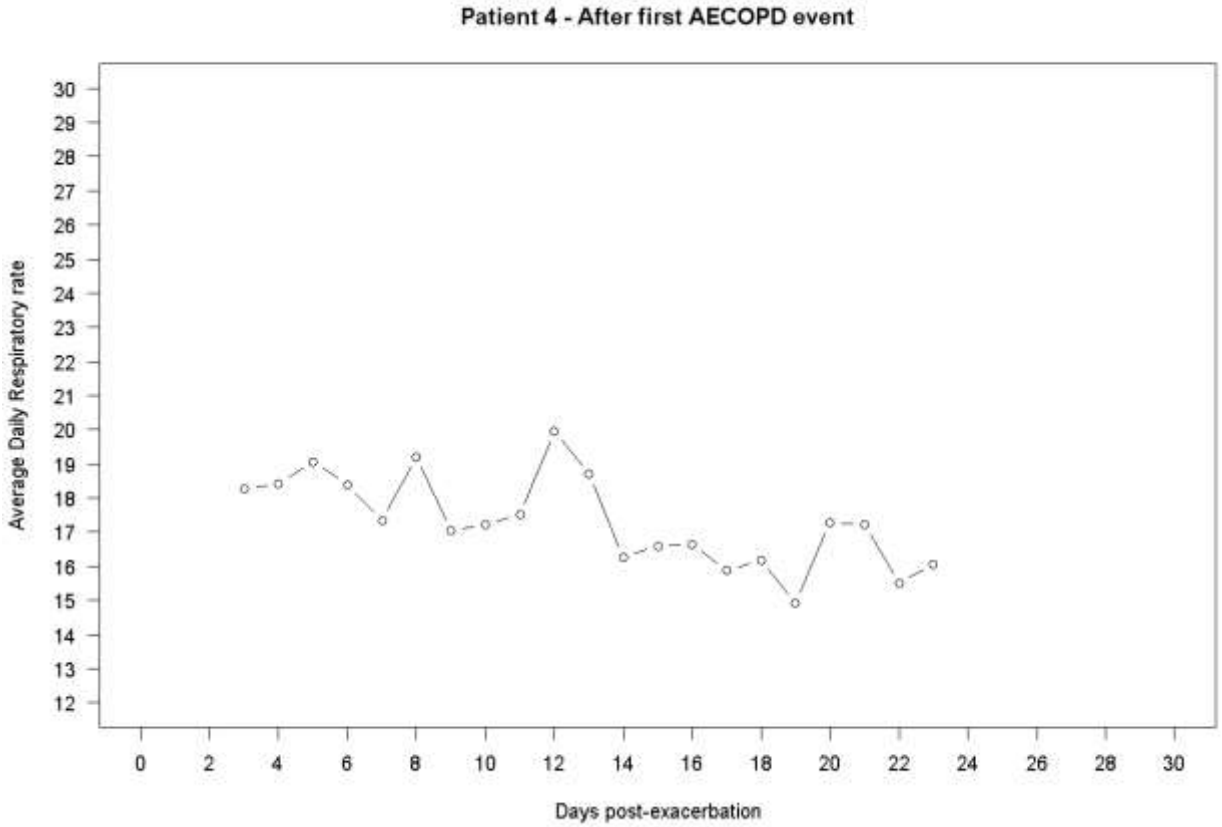
The line plot suggests a gradual decrease in resting respiratory rate over time following an exacerbation. However, there is considerable variation in what is shown in the individual patient plots (see below).

Patient 3 - After first AECOPD event



Patient 3 - After second AECOPD event




Patient 4 - After first AECOPD event
Average Daily Respiratory rate
30
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28
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16
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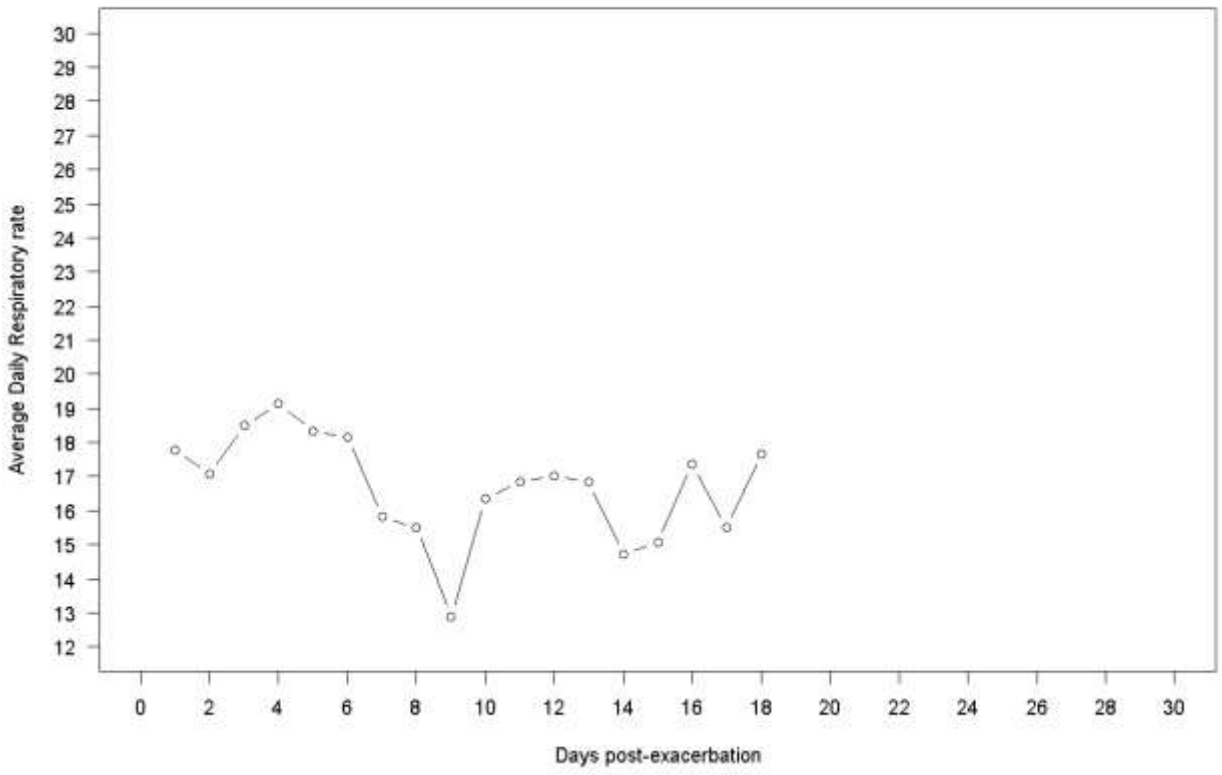
28
30
Days post-exacerbation


Patient 4 - After second AECOPD event
Average Daily Respiratory rate
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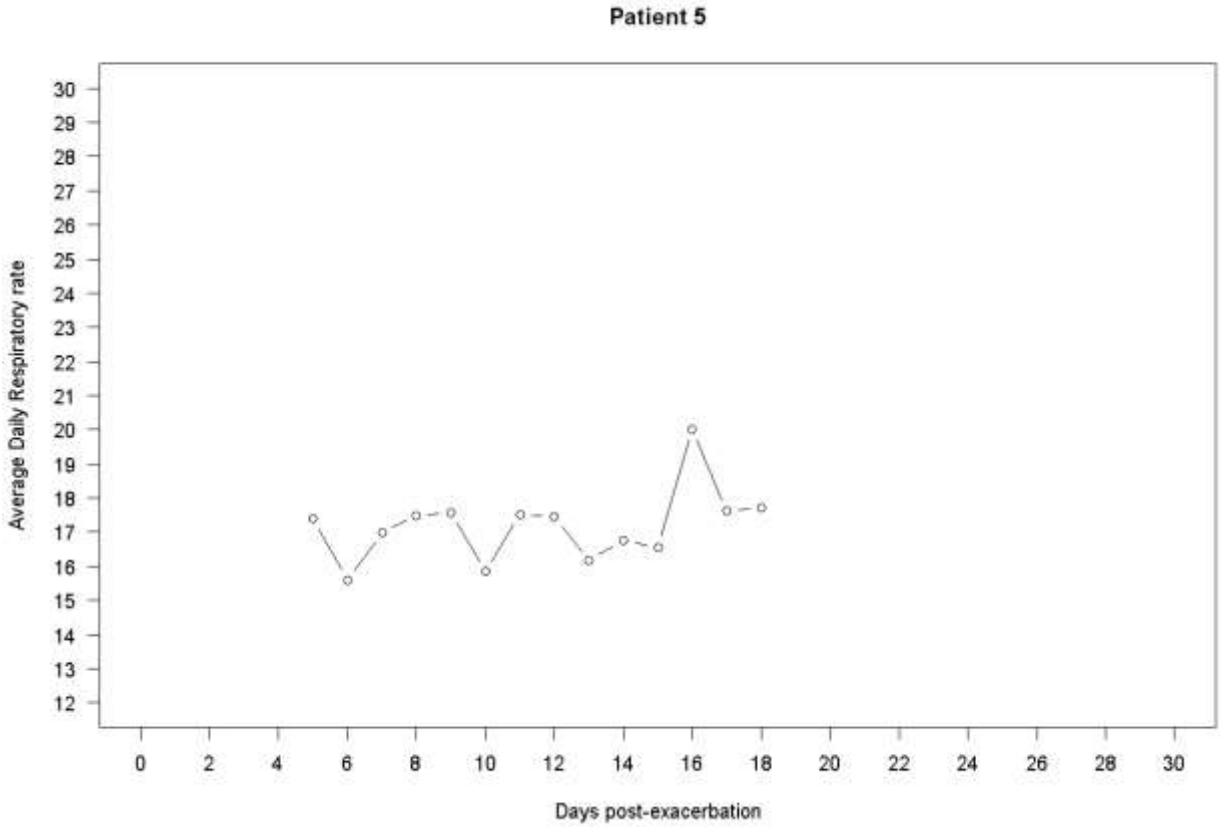
Days post-exacerbation


Patient 5
Average Daily Respiratory rate
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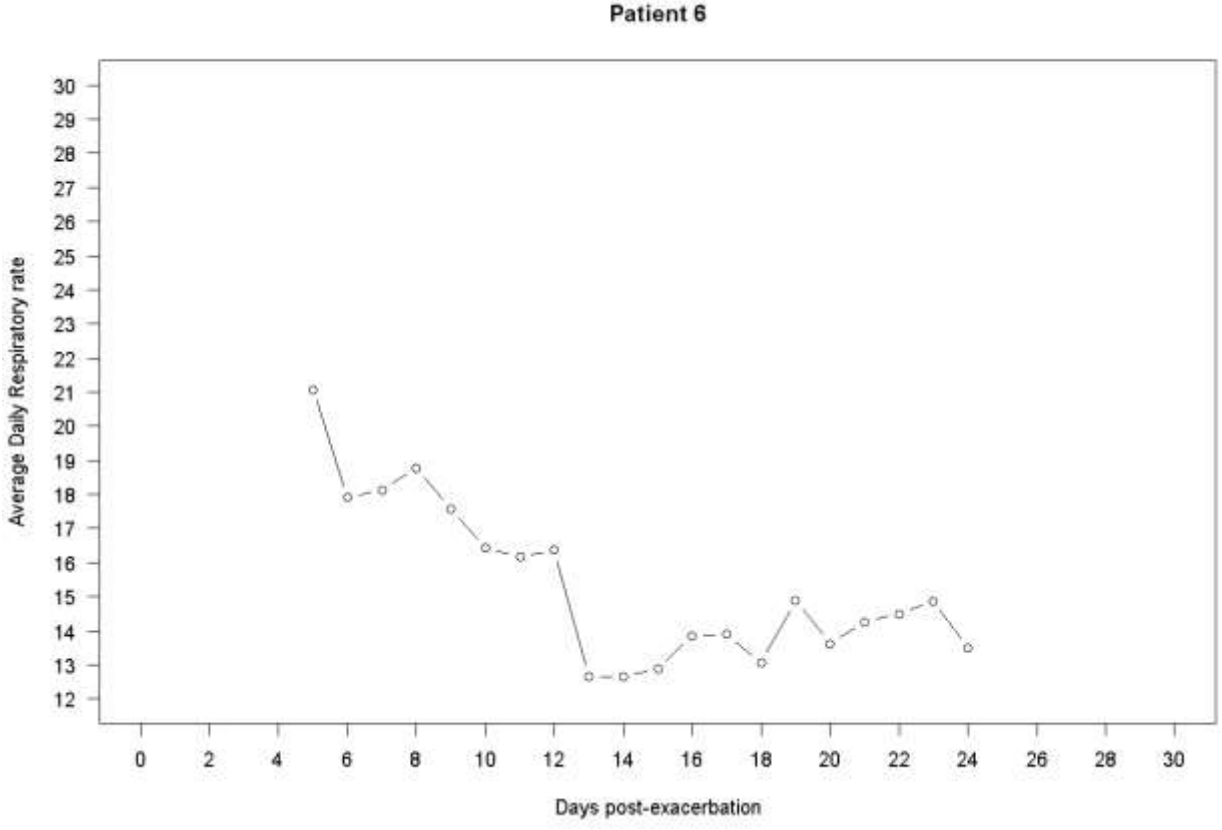
30
Days post-exacerbation


Patient 6
Average Daily Respiratory rate
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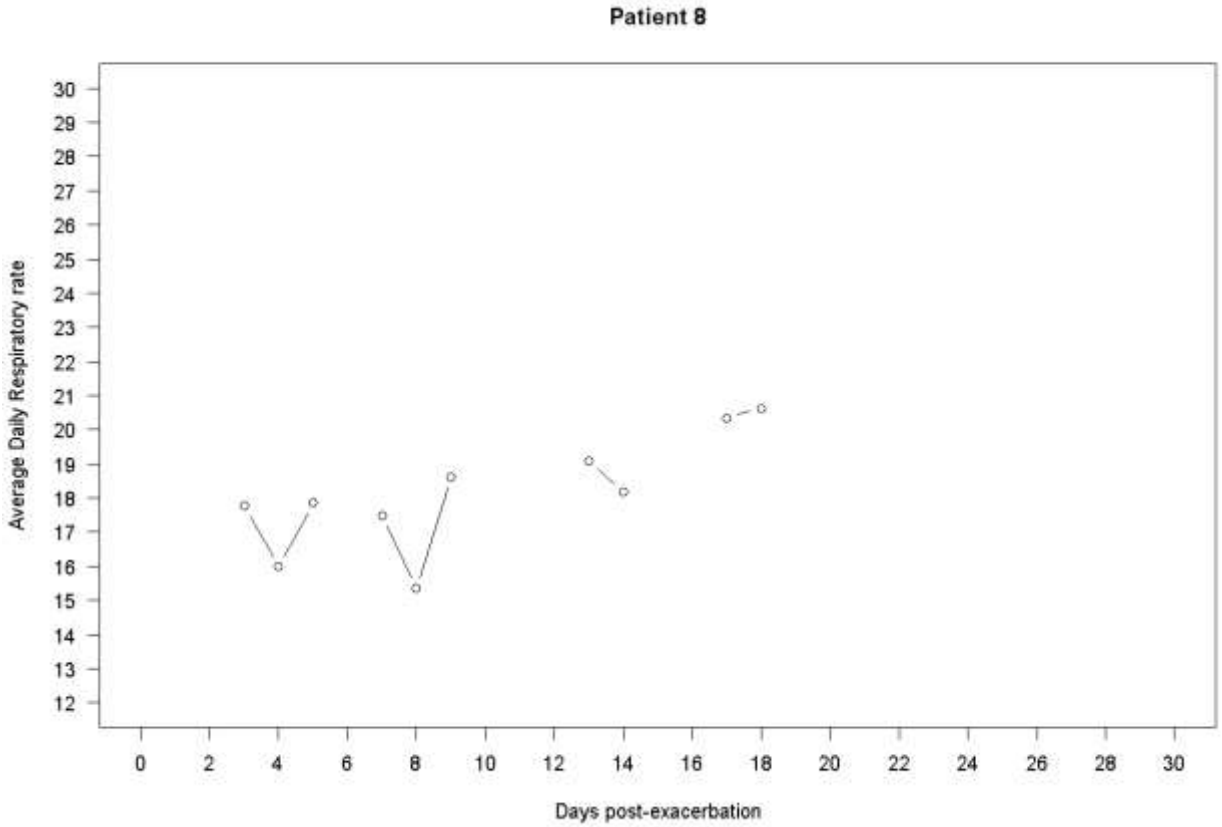
30
Days post-exacerbation


Patient 8
Average Daily Respiratory rate
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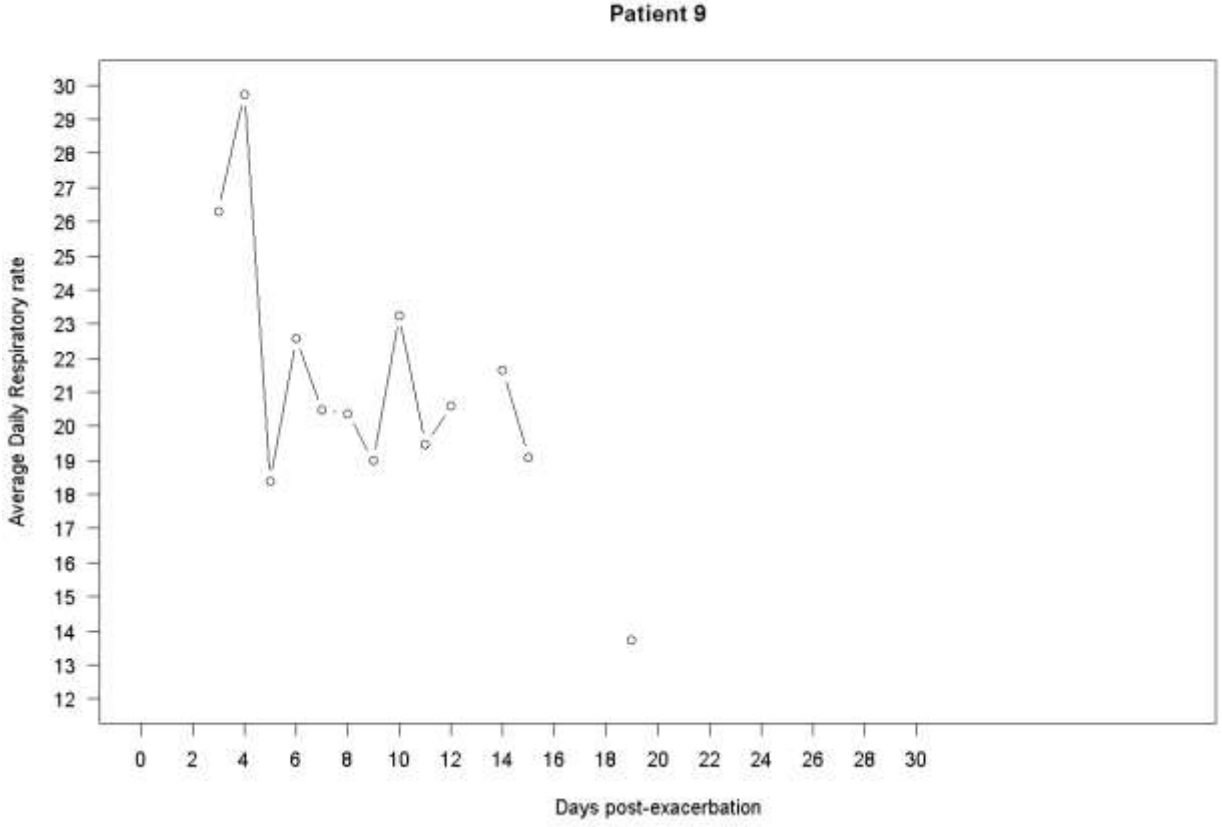
30
Days post-exacerbation


Patient 9
Average Daily Respiratory rate
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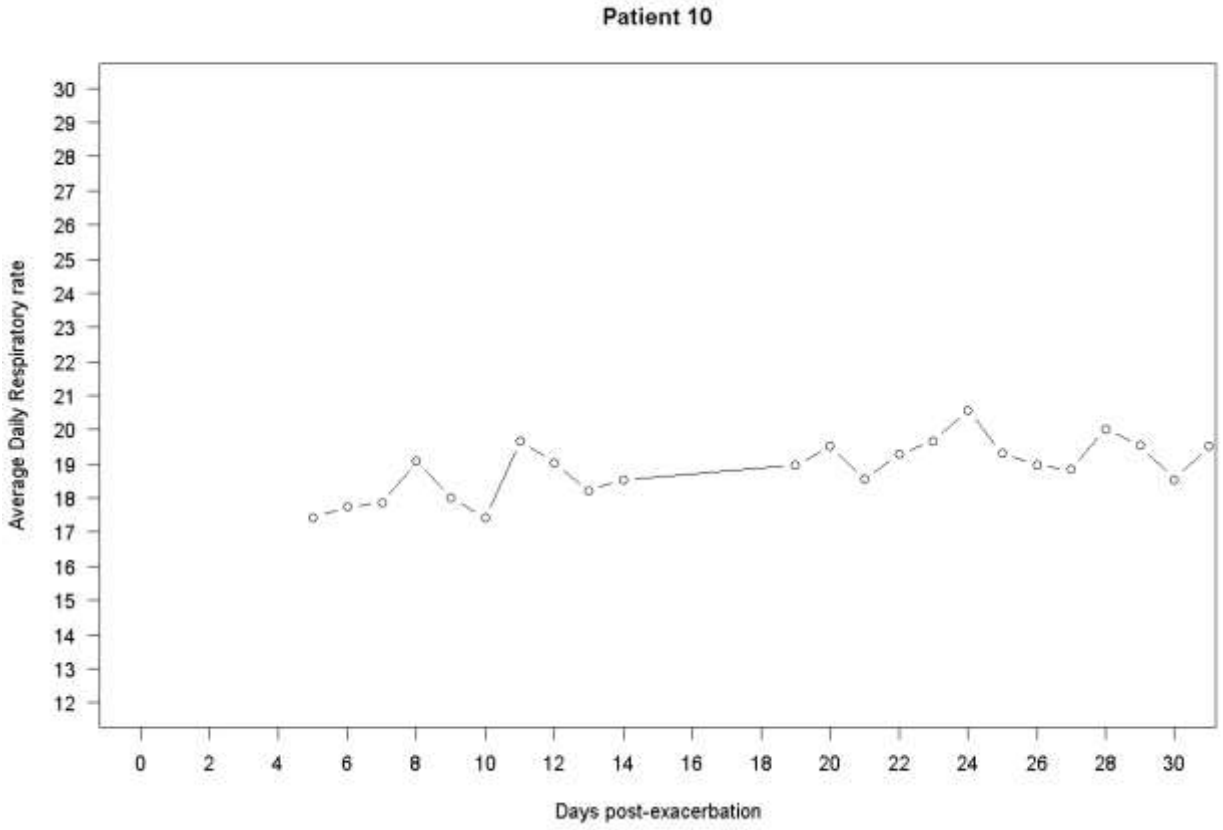
30
Days post-exacerbation


Patient 10
Average Daily Respiratory rate
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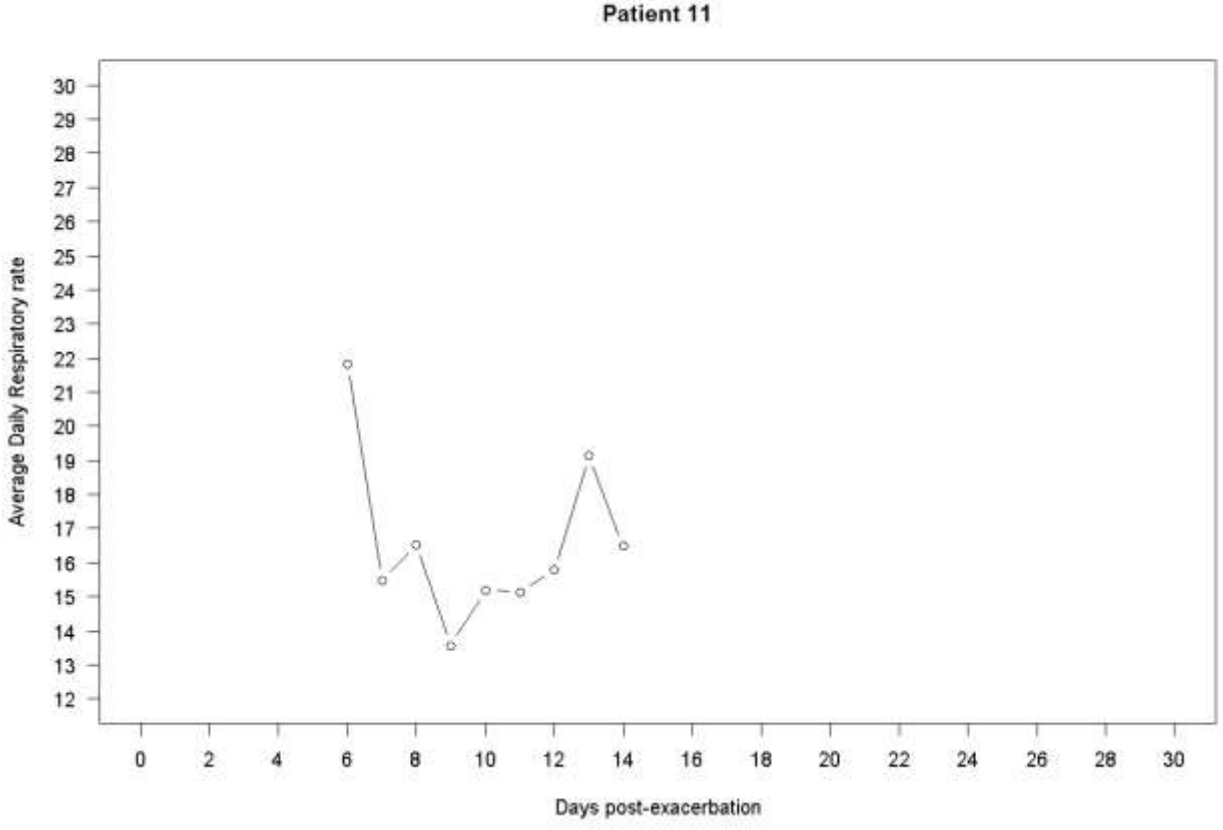
28
30
Days post-exacerbation


Patient 11
Average Daily Respiratory rate
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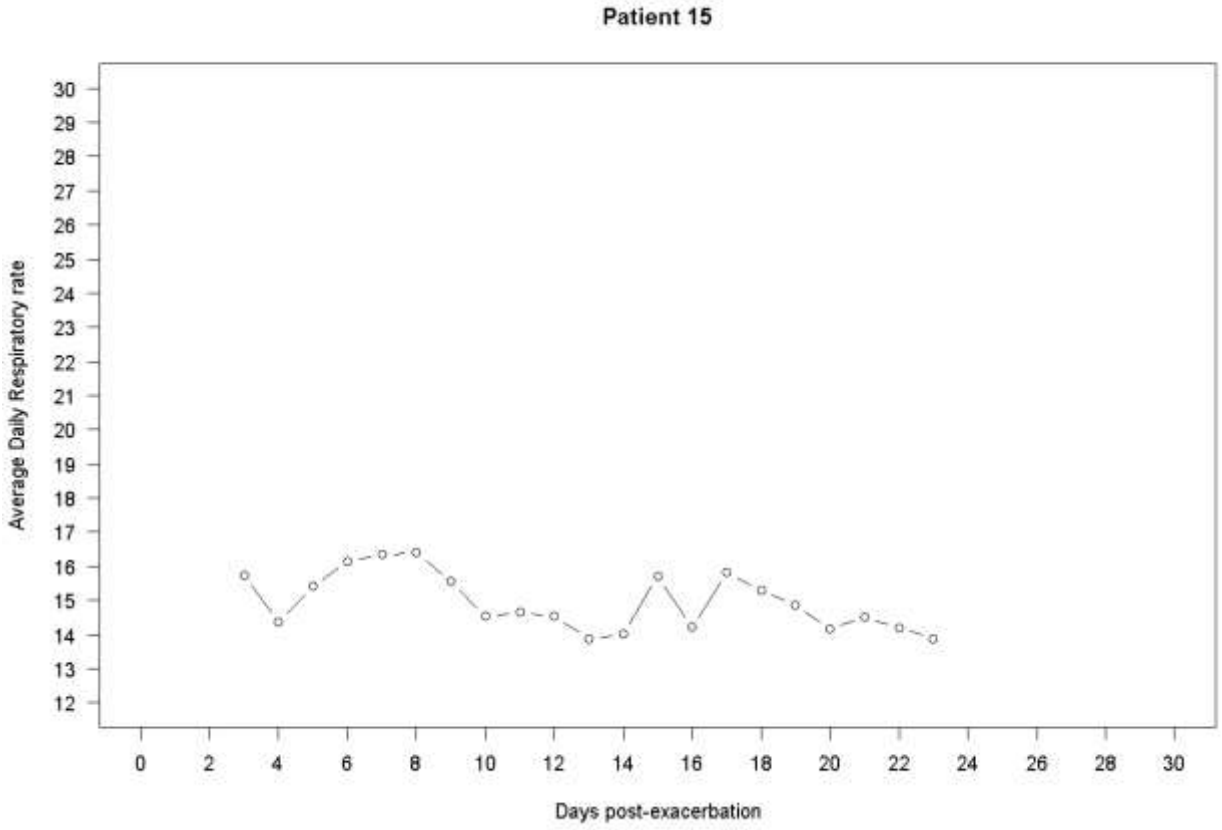
Days post-exacerbation


Patient 15
Average Daily Respiratory rate
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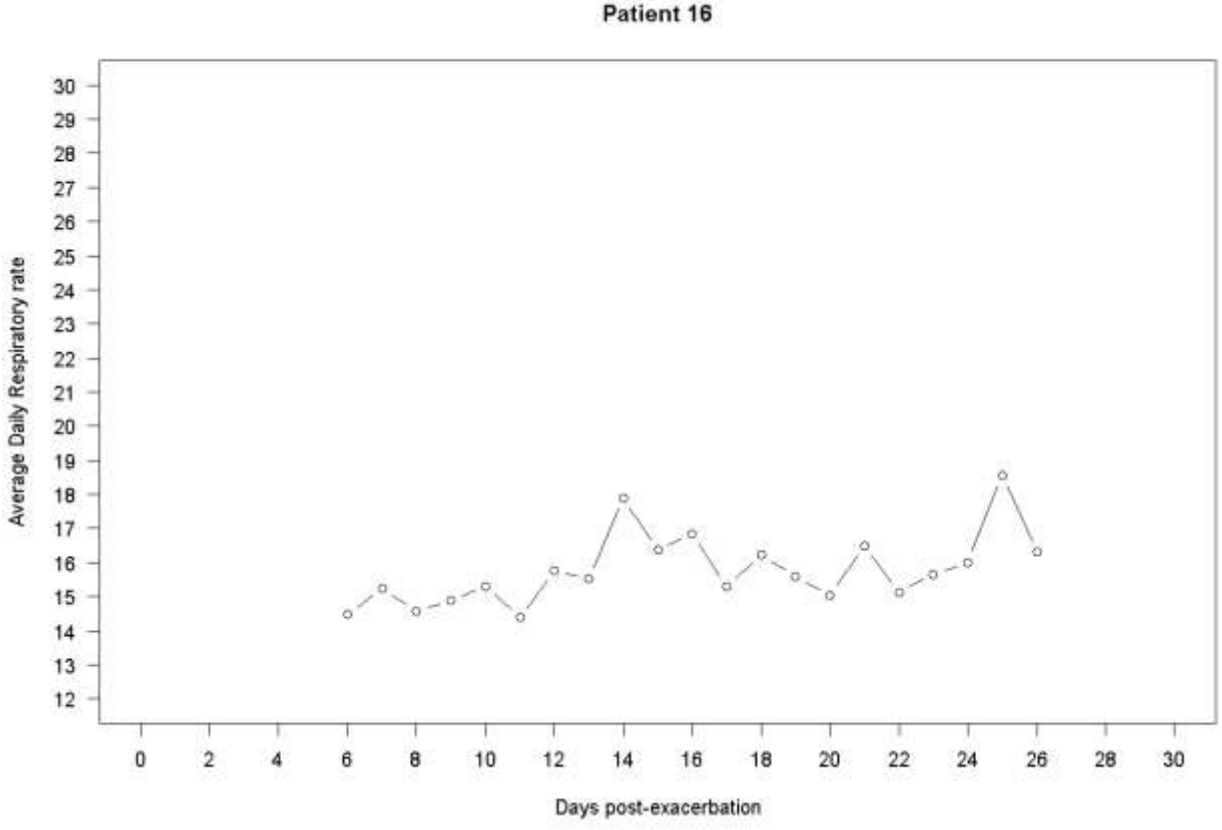
Days post-exacerbation


Patient 16
Average Daily Respiratory rate
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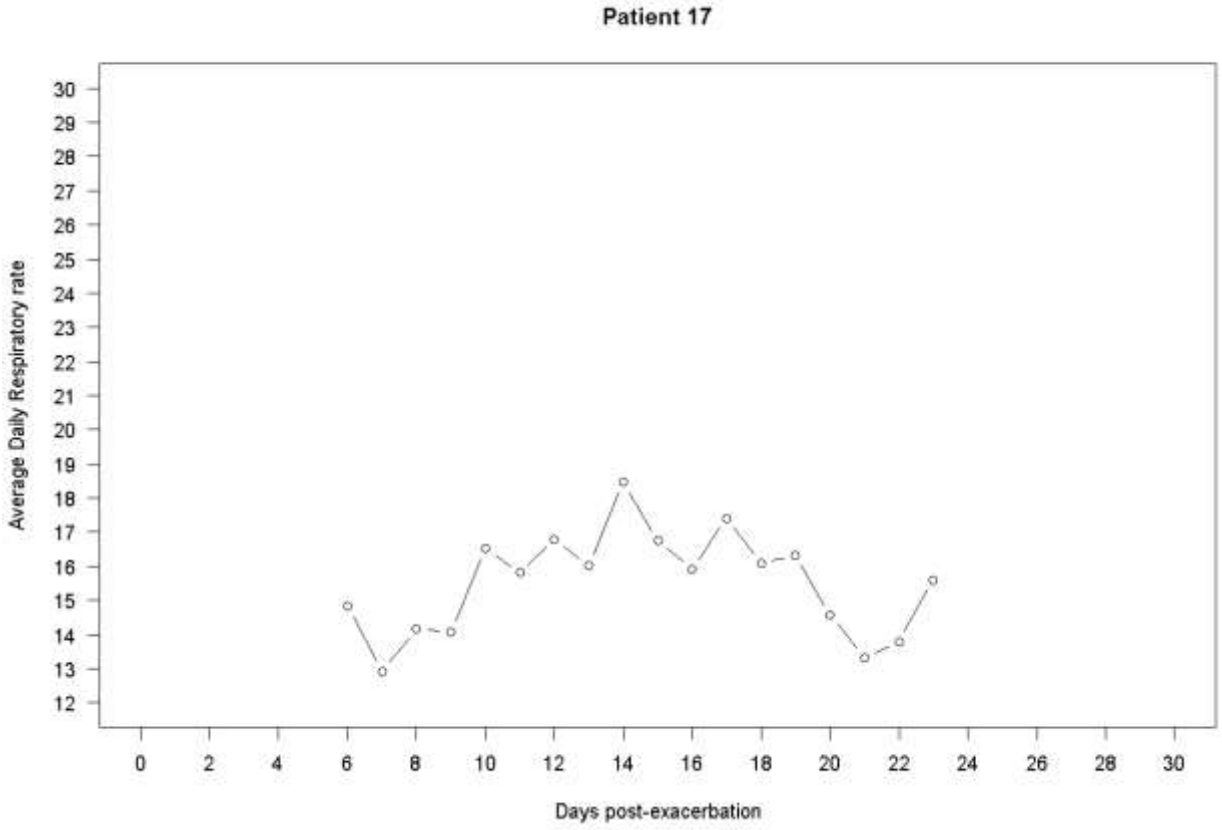
Days post-exacerbation


Patient 17
Average Daily Respiratory rate
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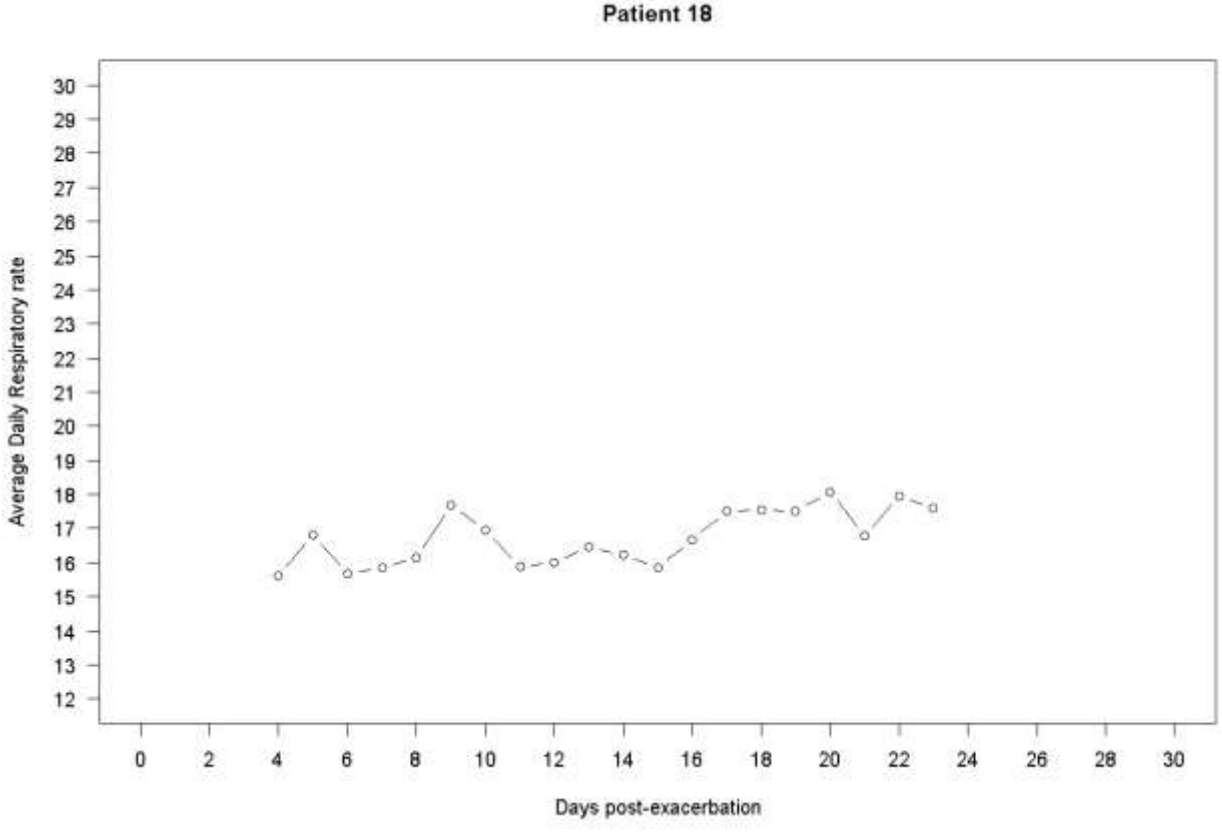
Days post-exacerbation


Patient 18
Average Daily Respiratory rate
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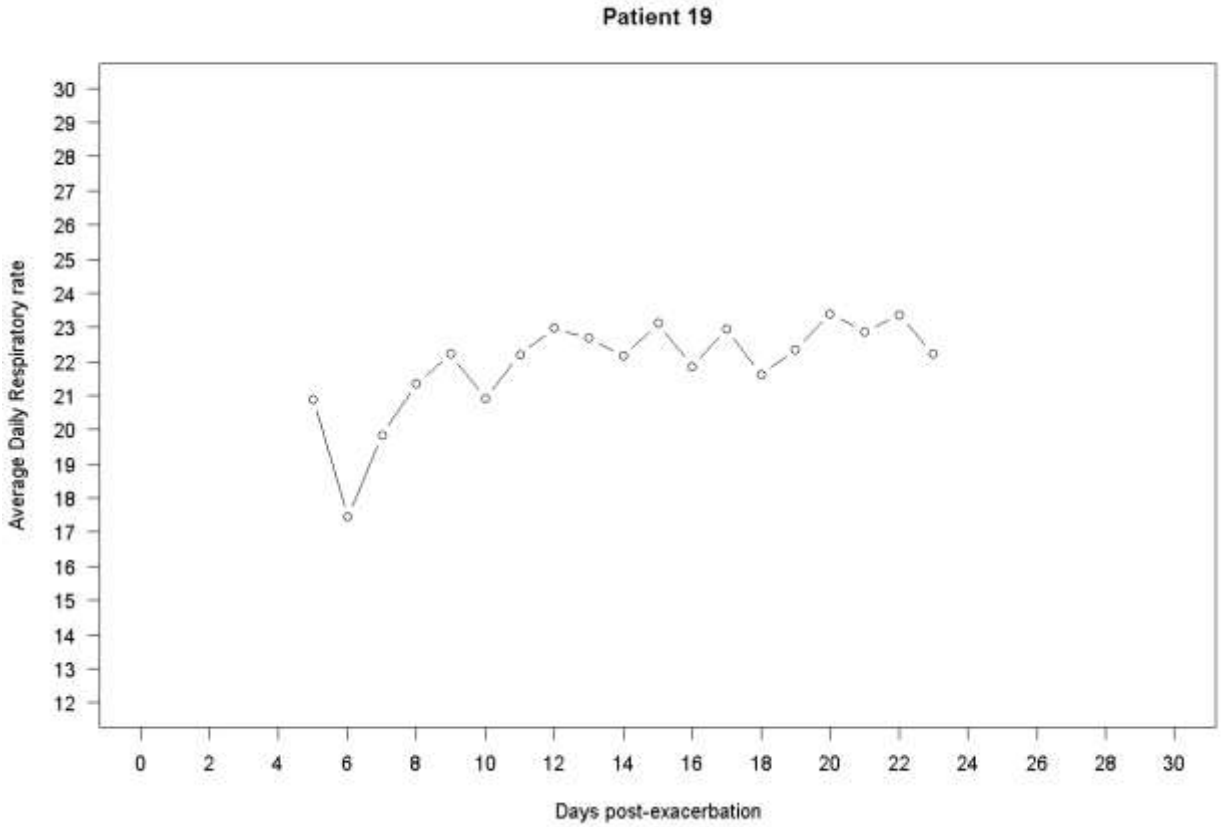
Days post-exacerbation


Patient 19
Average Daily Respiratory rate
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Days post-exacerbation

General Discussion Guide for Interviews

Personal Instructions to Interviewer:

- Introduce yourself and what you do
- Tell the patient that you are participating in a team that is exploring the feasibility of using remote respiratory rate monitoring to detect and manage exacerbations of COPD
- Advise that this may not help them directly in their immediate treatment, but that it may help to develop better treatment in the future
- Ask whether it is ok to record the interview and start the recording

Patient number xxx

- Thank you for taking the time today for this interview. This interview is part of a Scottish Government funded project, called the COPD and Respiratory Rate Monitoring study, to explore the use of remote respiratory monitoring to detect and manage exacerbations of COPD. In this second phase of the study, that you are kindly participated in, the aims are to learn about:
  - also your **experience** of using the devices: your willingness to use them in future and how long each day you would be happy to be monitored
  - how reliably the devices **measure and store data** in the home setting
  - **how long or frequently monitoring** of respiratory rate needs to be carried out
  - how it relates to **breathlessness symptoms, oxygen saturation and pulse rate**

- I will have some general questions and then we'll discuss the use of each monitor in turn

- All of the information you provide will be used for the purpose of this research project only. You do not have to answer any questions you don't want to. We are interested in your thoughts and opinions. ***There are no right or wrong answers***.

General:
Have you had any experience of using ZEPHYR, RESPECK, pulse oximetry previously?

Have you had any experience of Tele-health before (remote monitoring & assessment of your COPD)?

How did you find wearing the two monitors?
Was wearing the two monitors too much?
Can you tell me your normal day from when you put them on in the morning, if you took them off during the day, the 2 quiet periods…?
Were any days easier/more difficult? (weekend/ why?)

Did you stop using any monitor?

- What were the issues if stopped, why?

- Any technical problems?

We'll now discuss your experience of each monitor in turn:
First of all, the **Zephyr**

How did you find putting it on?
Did you have to adjust the belt?
Do you think everyone would find it easy?
How did you find wearing it?
How did you find taking it off?
Do you think everyone would find it easy?

Did you wear it all day, every day? – If you took it off during the day– when/why/how long?
Did you wear it outside?

How did you find charging it? – How did that go?
How did you find removing the device from the belt?
The data is transferred automatically, were you aware of it?

Would you be willing to use the ZEPHYR over a longer period of time?
Would you use it over a longer period of time:

- If you were doing so for only a period every day?
- If the data was of clinical benefit to your care?
- If you were able to use it to monitor your health, with the availability if help?
- Or would you prefer someone to monitor the data?

If you could see a reading, would you use it if you were not feeling well to check for a change from your norm, and then contact someone for help?

What if someone was more severe than you & in hospital regularly, do you think this monitor would benefit them then (when at home)?

Is there anything we haven't covered?

We'll now discuss your experience of the **RESPECK**

How did you find putting it on? - do you think everyone would find it easy?
How did you find wearing it?
Did it stay on/any problems with sticking it to your skin?
Did it cause any pain or rash?
How confident were you in positioning it?
Do you think it would be suitable for all people?
How did you find taking it off? - do you think everyone would find it easy

Did you wear it all day, every day? – If you took it off during the day– when/why/how long?
Did you wear it outside?

Did you find charging it? – How did that go?

Would you be willing to use the RESPECK over a longer period of time?
Would you use it over a longer period of time:

- If you were doing so for only a period every day?
- If the data was of clinical benefit to your care?
- If you were able to use it to monitor your health, with the availability if help?
- Or would you prefer someone to monitor the data?

If it produced a reading, would you use it if you were not feeling well to check for a change from your norm, and then contact someone for help?

What if someone was more severe than you & in hospital regularly, do you think this monitor would benefit them then (when at home)?

Is there anything we haven't covered?

We'll now discuss your experience of the **pulse oximeter**

Have you used one before?
Did you have any problems using it (cold fingers/variable)?
How did you find putting it on? - do you think everyone would find it easy?

Did you check the reading?
How did you use the reading? (use it more?)
Was the reading helpful?
Did you record the data? – How did you find that?

Did you need to charge it? – How did that go?

Would you be willing to use the pulse oximeter over a longer period of time?
Would you use it over a longer period of time:

- If the data was found to be valuable?
- If you were doing so for only a period every day?
- If you were doing it for your own monitoring of your health, with the availability of help?
- Would you like someone to monitor the data?

Would you use it (with the data reading) if you were not feeling well to check for a change from the norm, and then contact someone for help?

What if someone was more severe than you & in hospital regularly, do you think this monitor would benefit them then (when at home)?

Is there anything we haven't covered?

General

In general, how has your health been over the last 2 weeks?
How did wearing the monitors make you feel?

Do you have any further comments?

THANK YOU!