

Lung function assessed by home Forced Oscillation and self reported symptoms during COPD exacerbations



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on behalf of CHROMED consortium

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CHROMED is an EU-funded, multicenter, randomized trial aimed at evaluating the socio-economic impact of a home-monitoring platform on the quality of life of COPD patients with comorbidities.



Fig. 1: CHROMED home monitoring platform

- Population:** Elderly (>65yrs) COPD patients (GOLD stage ≥2), with at least one comorbidity and ≥ 1 exacerbation in the previous year, randomly assigned to an interventional or control group.
- Protocol:** For 9 months, monitored patients performed daily self-assessment of lung mechanics with a FOT (Forced Oscillation Technique) device and completed a symptom diary card (see Table 1). Any detected worsening in lung mechanics generated an alert triggering a phone interview directed at verifying the patient's status and optimizing treatment.

Table 1: Symptom diary card. Major symptom (M), minor symptom (m)

Please select any WORSENING of symptoms ABOVE YOUR USUAL daily level:	No changes
	increased BREATHLESSNESS (M)
	increased SPUTUM COLOUR (M)
	increased SPUTUM AMOUNT (M)
	increased COUGH (m)
Do you have one or more of the following ?	increased WHEEZE or CHEST TIGHTNESS (m)
	a COLD such as a runny or blocked nose (m)
	FEVER (m)
	SORE THROAT (m)

Partners of the consortium:

RESTECH SRL ITALY (RES)	HOSPITAL OF SEŽANA SLOVENIA (SHO)	BARCELONA UNIVERSITY SPAIN (UB)
ELETTRONICA BIO MEDICALE ITALY (EBM)	UNIVERSITY OF LIVERPOOL UK (ULIV)	TALLINN UNIVERSITY OF TECHNOLOGY ESTONIA (TUT)
UNIVERSITY OF UPPSALA SWEDEN (UUPP)	UNIVERSITY OF LINCOLN UK (ULIN)	UNIVERSITY HOSPITAL OF NORTH NORWAY NORWAY (UNN)

Methods

- Data from 70 patients in the monitoring arm.
- Patient compliance:** number of measures received/number of scheduled measures.
- A **worsening event** has been defined as a cluster of persistent alarms generated within 7 days.
- A **symptom-based exacerbation** was identified using diary cards if at least one major and one minor symptom were present for at least 2 consecutive days (Seemungal et al., Am J Respir Crit Care Med 1998).
- Association between a worsening event, a prescribed treatment and the presence of a symptom-based exacerbation was investigated for the week preceding and the week after the date of generation of the first alarm.

Results

Population

Table 1 – Baseline data	
Nr of patients (M/F)	57/13
Age	71,6 ± 5,9
BMI (Kg/m ²)	27,4 ± 5,2
Smoking history (pack/years)	42,8 ± 25,5
%FEV1 postBd	47,8 ± 15,5
%FVC postBd	72,0 ± 19,0
%FEV1/FVC postBd	67,8 ± 18,3
Exacerbations last yr	2,1 ± 1,2
Hospitalizations last yr	1 ± 0,9

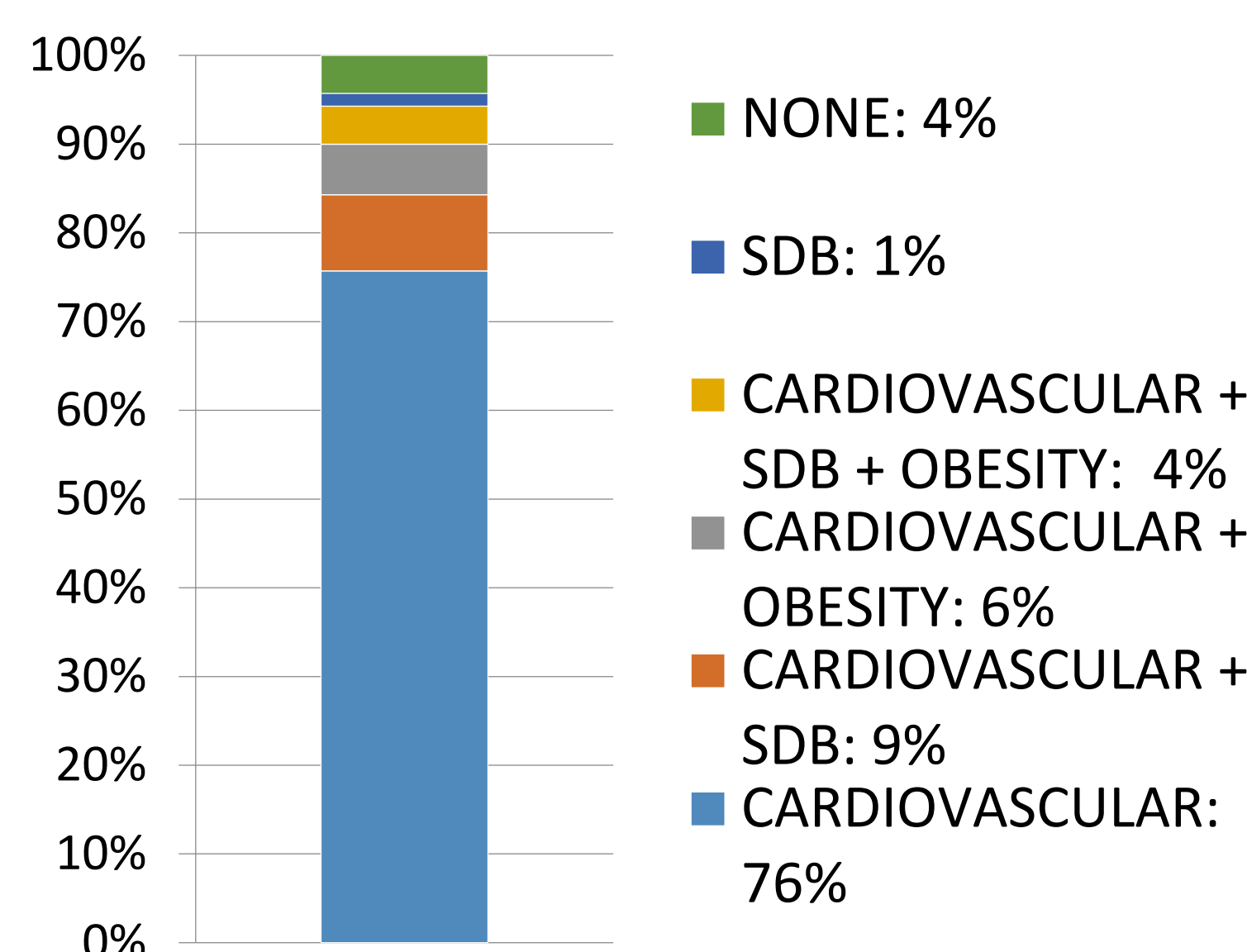


Fig. 2: Comorbidities distribution. Cardiovascular diseases: Congestive heart failure, hypertension, ischaemic disease, hyperlipaemia. SDB: Sleep disordered breathing.

Patients' compliance

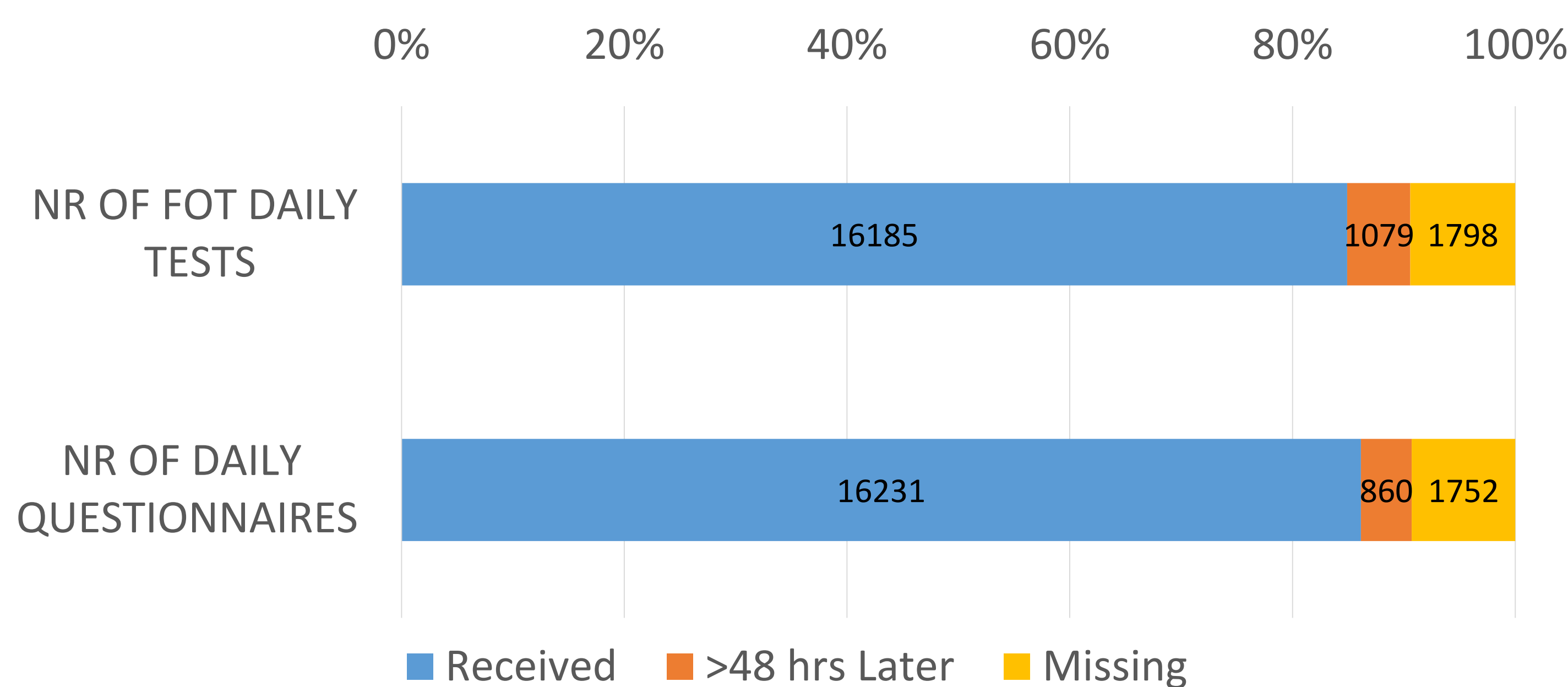
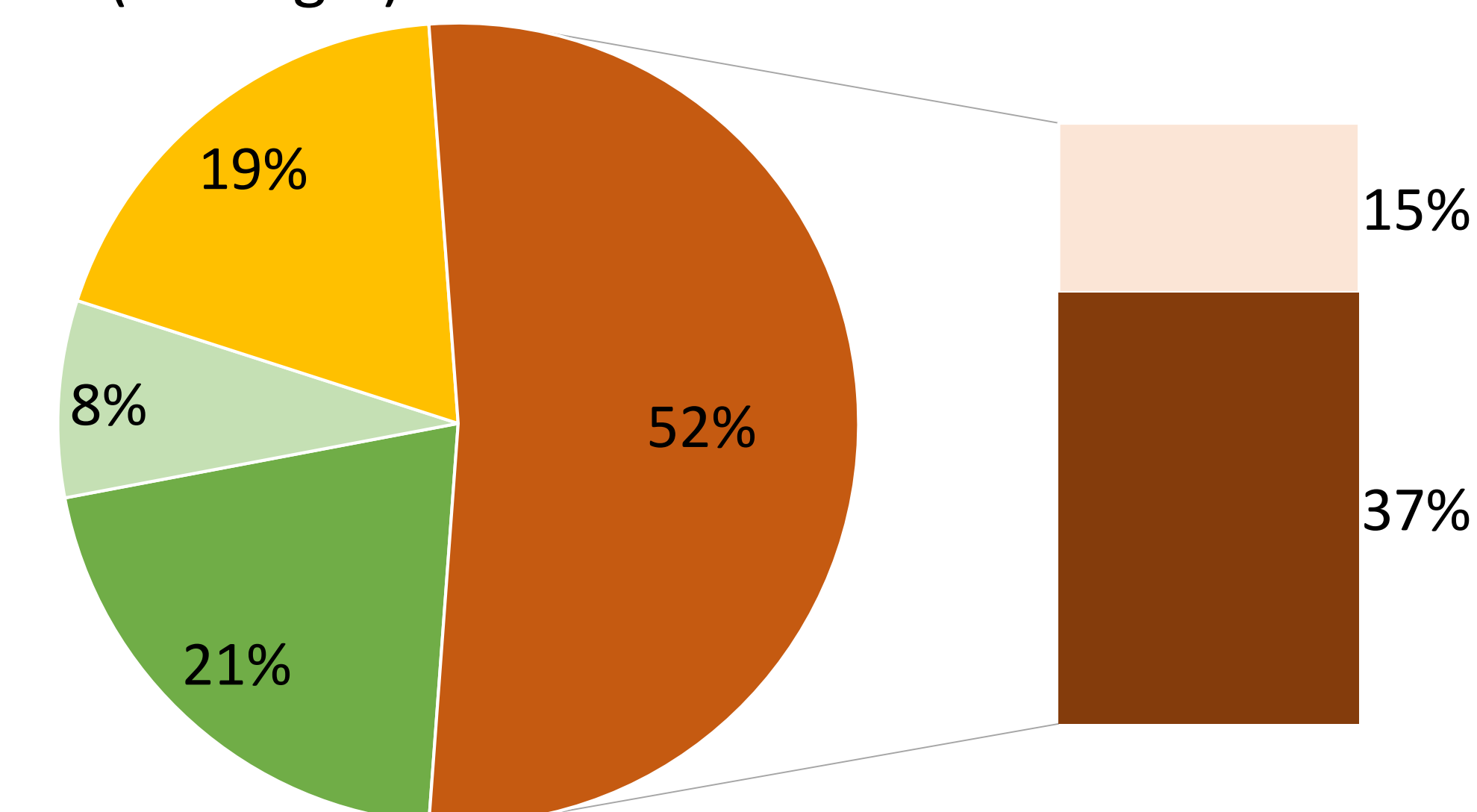


Fig. 3: FOT measurements and completed questionnaires

Worsening events

- 381 Alarms have been generated in the whole period resulting in 311 worsening events.
- Rate of worsening events per patient was 0,65±0,3 per month.
- 48% of the CHROMED worsening events¹ were associated with a treatment and/or a symptom-based exacerbation. An additional 15% of events was associated with worsening of one major symptom. (see Fig.4)



Treated events¹:

- with symptom-based exacerbation
- without symptom-based exacerbation

Untreated events¹:

- with symptom-based exacerbation
- without symptom-based exacerbation:

with a worsening of one major symptom

Fig. 4: Percentages of worsening events generated by the monitoring platform and associated with a treatment and/or an exacerbation or worsening in a major symptom. ¹ 101 alarms were excluded since handled more than 48 hours after their generation

- Eight (11% of the population) patients generated 48% of the asymptomatic untreated worsening events.

Conclusions

- Patients' compliance to the study protocol was high, confirming the suitability of FOT as an unsupervised monitoring tool in a community setting.
- The majority of CHROMED events were associated with a treatment and/or a worsening in lung perceived symptoms.
- In a small group of patients, a worsening in lung mechanic was neither associated with a worsening in symptoms nor with a prescribed treatment.