
Patient reported outcomes in respiratory diseases; How to assess clinical success in COPD

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Mr Valette

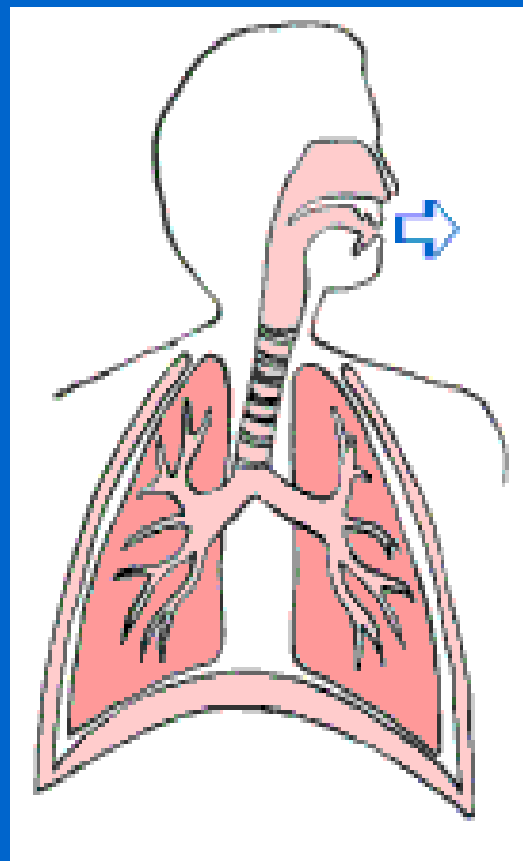




- Smoking is the main cause of the disease
- Smoking cessation is the most effective treatment
- All other treatments are directed to exacerbation frequency, lung function, symptoms and QOL

Chronic Obstructive Pulmonary Disease

- Chronic obstructive pulmonary disease (COPD) is a disease characterized by airflow limitation that is not fully reversible.
- People with severe COPD end up with respiratory failure, hospitalization, and eventually death from suffocation.

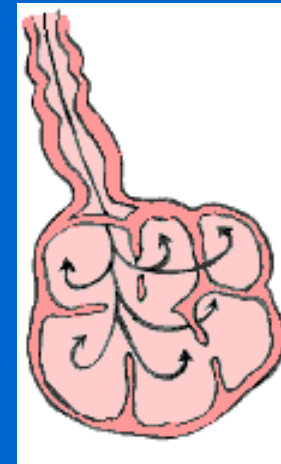


Definition of COPD

- COPD is a disease state characterized by airflow limitation that is ***not*** fully reversible.
- The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases.



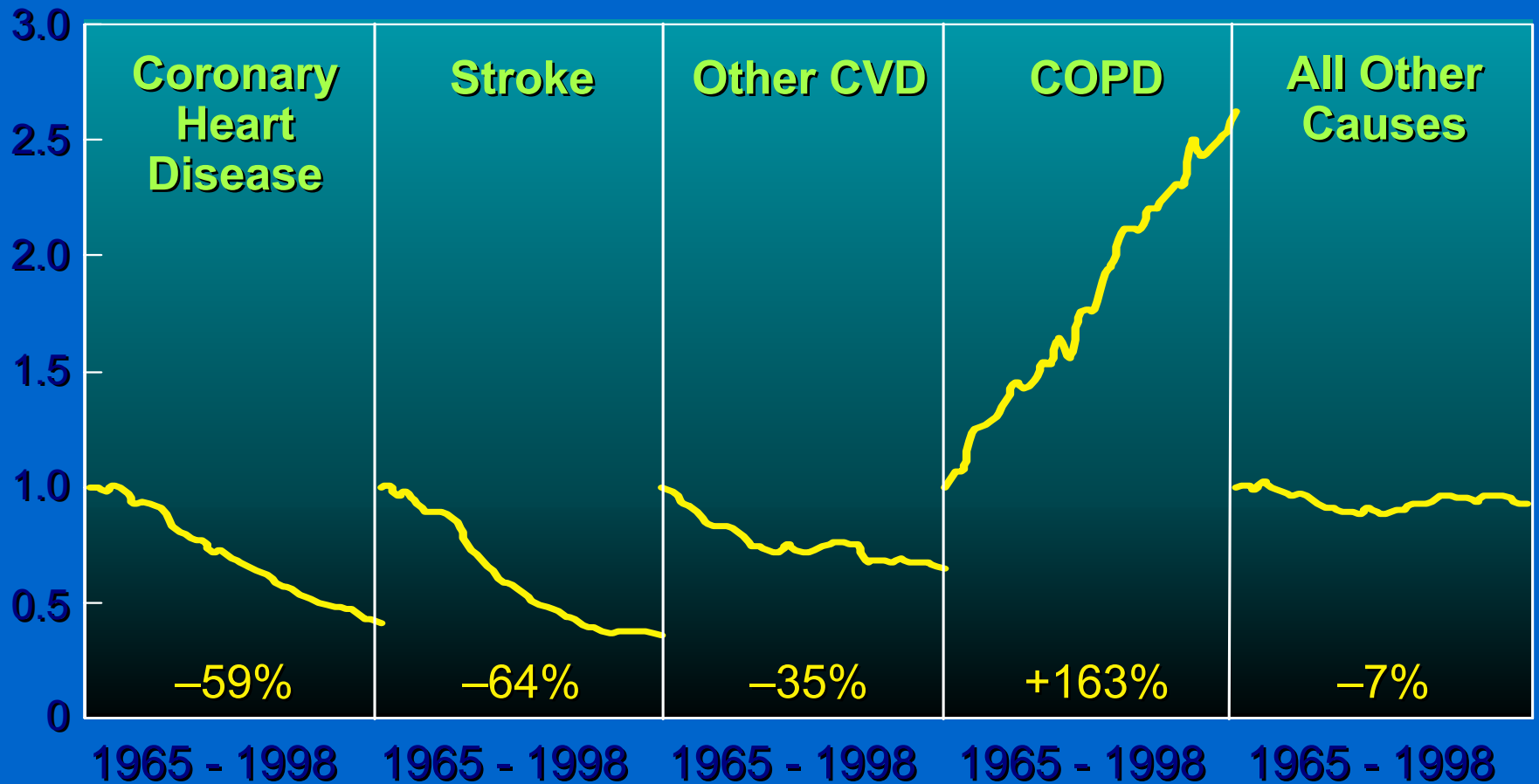
Healthy Alveolus



COPD

Percent Change in Age-Adjusted Death Rates, U.S., 1965-1998

Proportion of 1965 Rate



Impact of Chronic Disease



Impairment

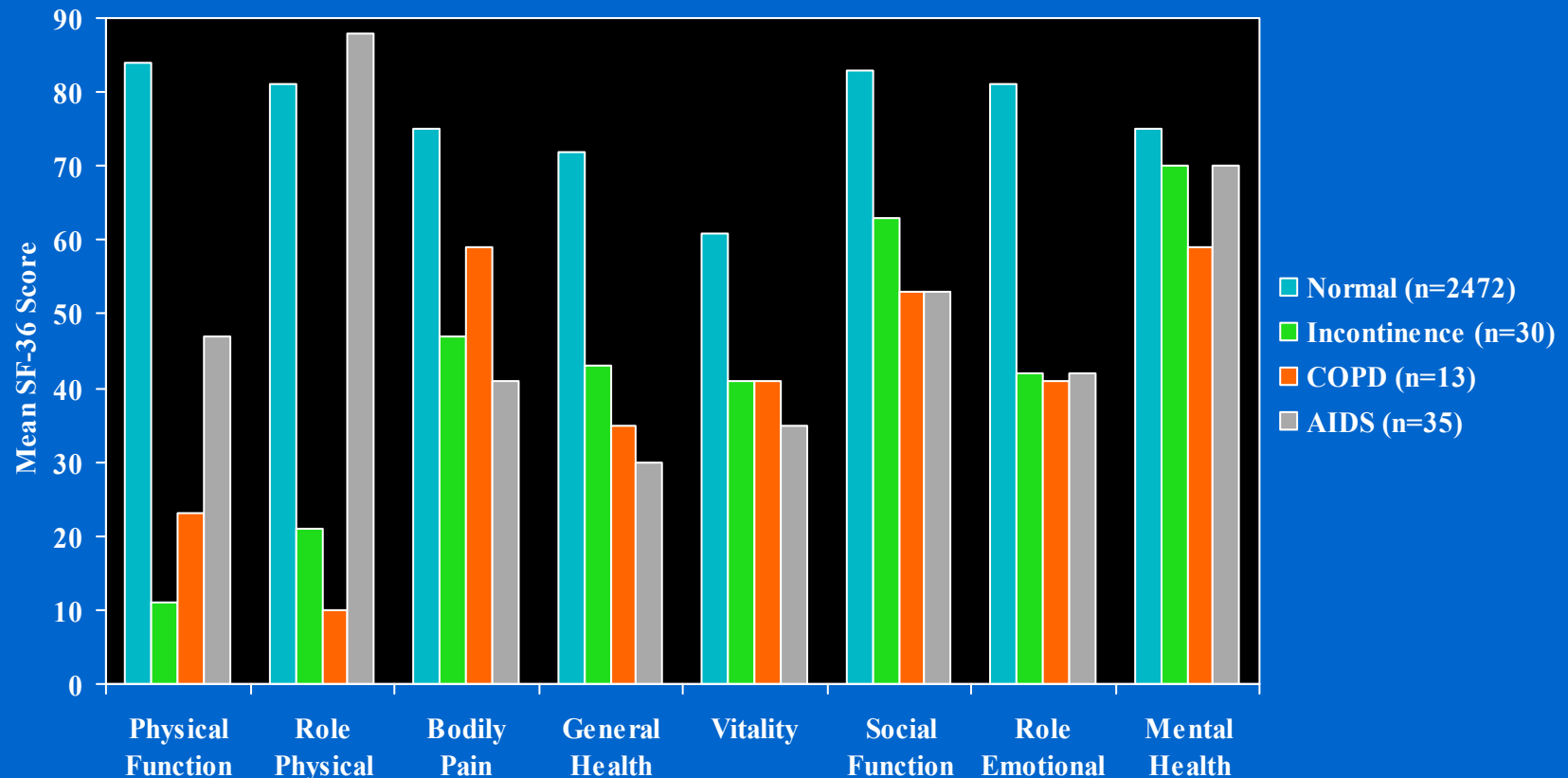


Disability



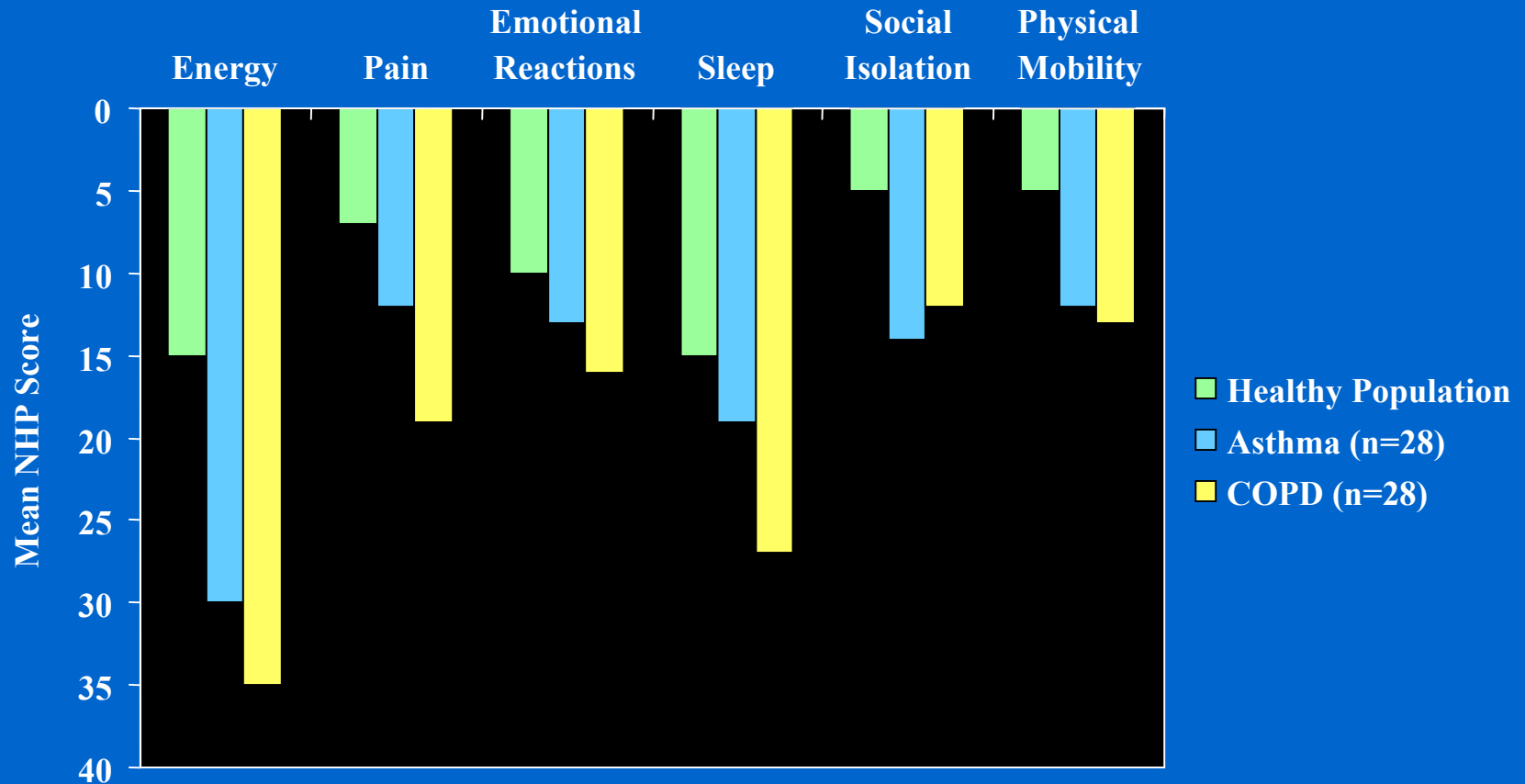
Handicap

Quality of Life: COPD vs Selected Chronic Disorders (SF-36 Scores)



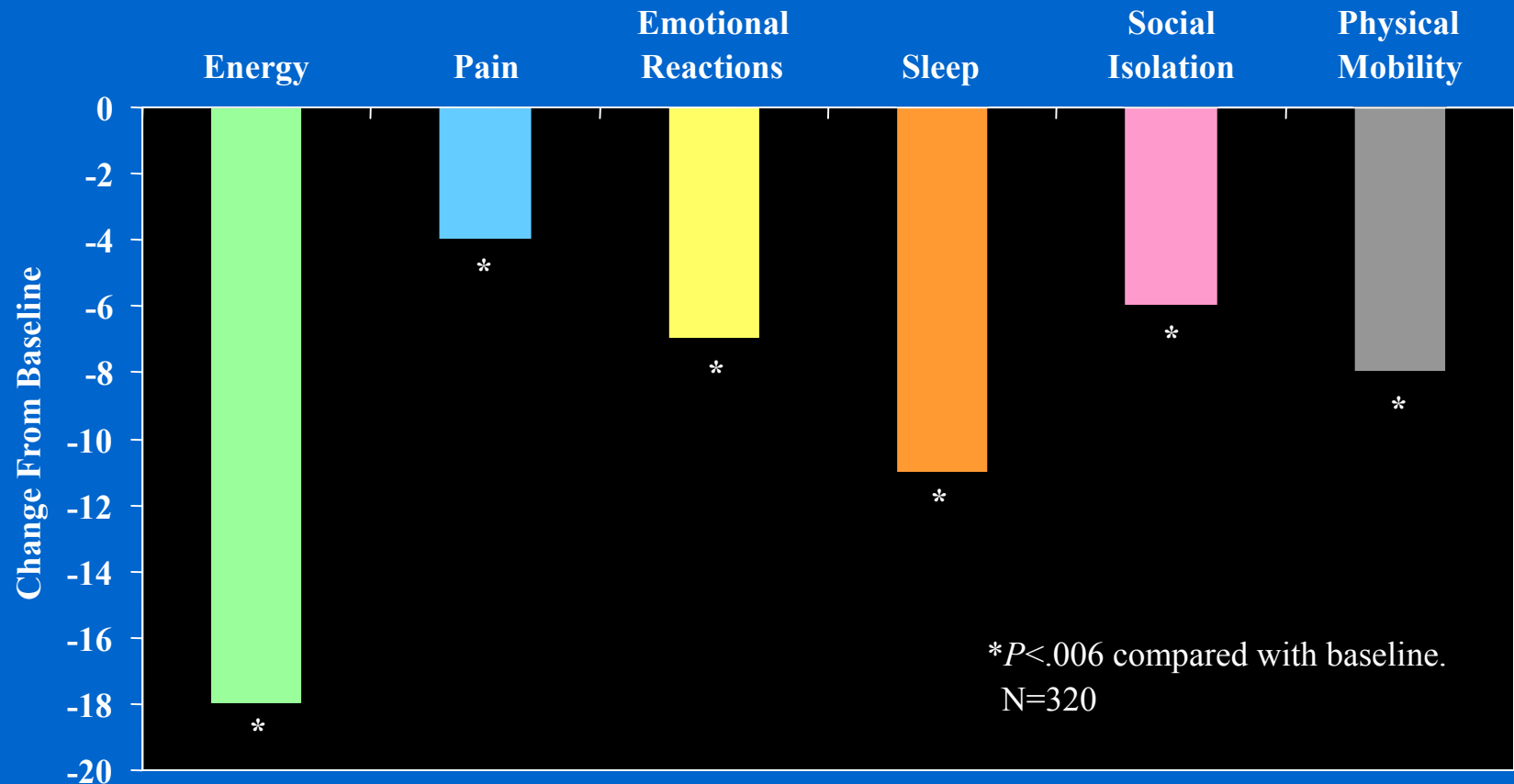
Adapted from Schlenk. *Qual Life Res.* 1998;7:57-65.

Quality of Life: COPD vs Asthma (NHP Scores)



Adapted from Van Schayck. *Chest*. 1995;7:1199-1205.

Quality of Life Deteriorates Further During COPD Exacerbations (Mean Change in NHP Scores)

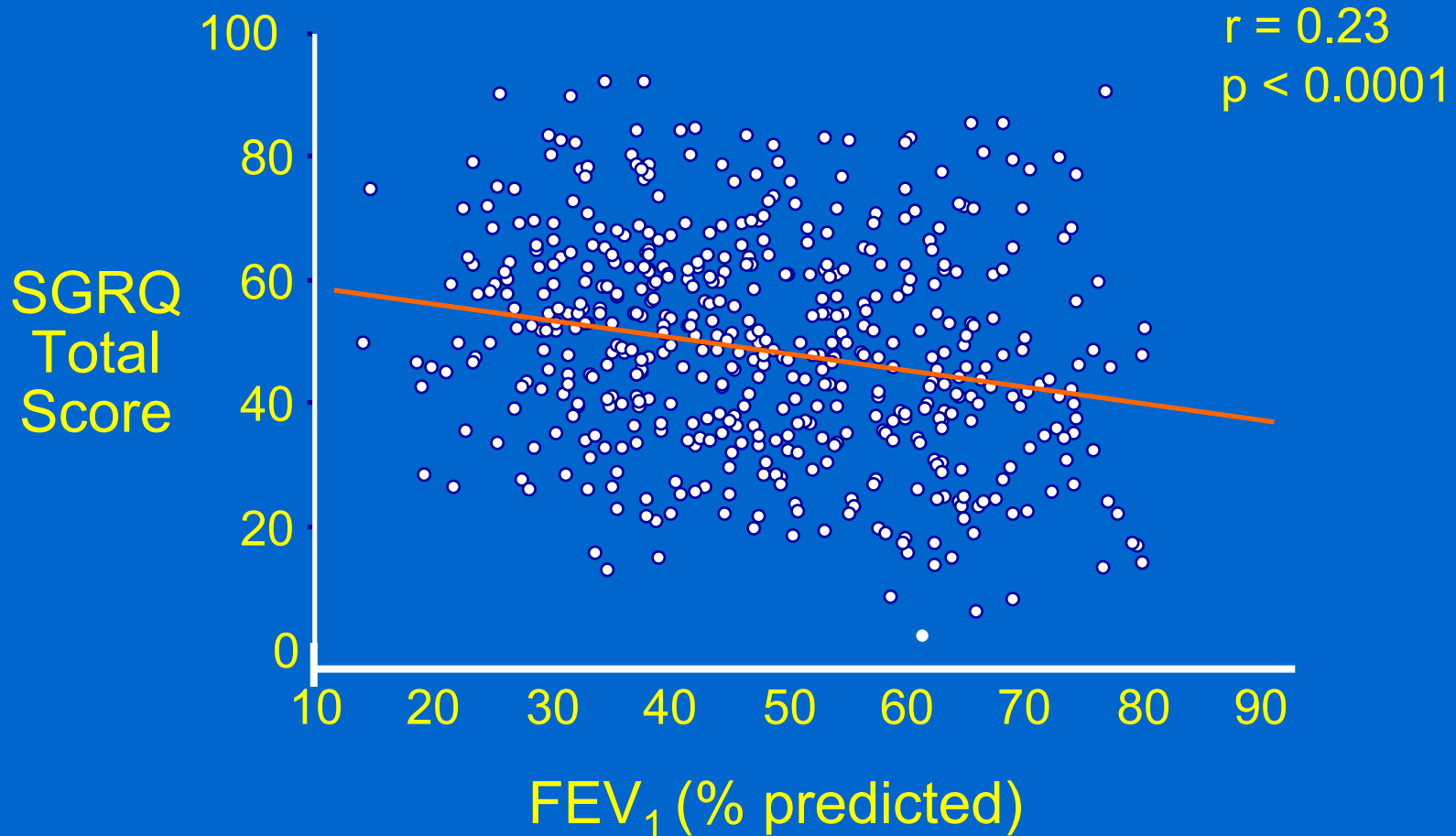


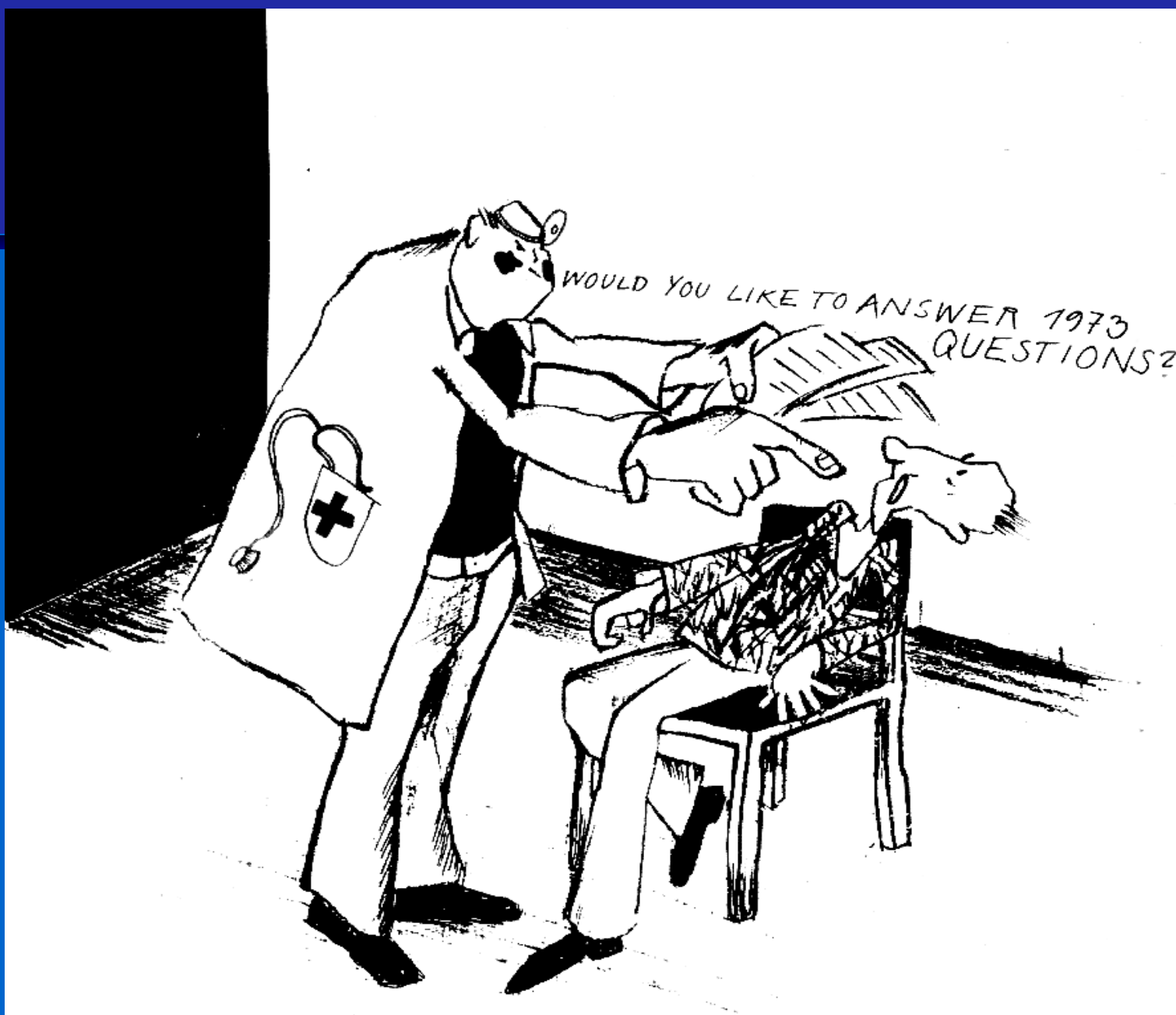
Example SGRQ 76 questions recall period 3 months

Questions about how much chest trouble you have had over the last 3 months. Please tick in one box for each question.

	Most days a week	Several days a week	A few days a month	Only with chest infections	Not at all
1. Over the last 3 months, I have coughed:	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
2. Over the last 3 months, I have brought up phlegm (sputum):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Over the last 3 months, I have had shortness of breath:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Over the last 3 months, I have had attacks of wheezing:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Health Status and Airways Obstruction





Development of the CCQ (I)

- **Evaluative**
- **Domains**
(symptom, functional state, mental state)
- **Short and easy to administer**
- **Weekly / daily**
- **Rolls Royce model**

Development of the CCQ (II)

- **Item generation**
- **Item reduction**
- **Formatting**
- **Pre testing**
- **Validation**

Item generation

- Interview patients with COPD
- Focus groups of patients with COPD
- Discussions with experts

Item reduction

- Item reduction questionnaire
- 77 international clinicians, experts

- Response 87%

Content CCQ

Symptom

- short of breath at rest
- short of breath during physical activity
- cough
- produce phlegm

Functional state

limitation because of breathing problems in:

- strenuous physical activities
- moderate physical activities
- daily activities at home
- social activities

Mental state

- concerned about getting worse or catching a cold
- depressed because of breathing problems

Patient number: _____

Date: _____

CLINICAL COPD QUESTIONNAIRE

Please **circle** the number of the response that best describes how you have been feeling during the **past week**.
(Only **one** response for each question).

age, during the past ow often did you feel:	never	hardly ever	a few times	several times	Many Times	a great many times	almost all the time
rt of breath at rest ?	0	1	2	3	4	5	6
rt of breath doing physical vities?	0	1	2	3	4	5	6
cerned about getting a or your breathing getting se?	0	1	2	3	4	5	6
ressed (down) because of r breathing problems?	0	1	2	3	4	5	6
ral, during the past week , ch of the time:							
you cough ?	0	1	2	3	4	5	6
you produce phlegm ?	0	1	2	3	4	5	6
age, during the past ow limited were you activities because of eathing problems:	not limited at all	very slightly limited	slightly limited	moderately limited	very limited	extremely limited	totally limited /or unable to do
nuous physical activities h as climbing stairs, rying, doing sports)?	0	1	2	3	4	5	6
derate physical activities h as walking, housework, ying things)?	0	1	2	3	4	5	6
ly activities at home h as dressing, washing rself)?	0	1	2	3	4	5	6
ial activities h as talking, being with dren, visiting friends/ tives)?	0	1	2	3	4	5	6

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Validation study (cross sectional)

Study population

N	119
Gender (% male)	58%
Age (range)	54 (42-74)
Pack yr. (range)	30 (2-85)
FEV₁ (%pred) (range)	88 (22-132)

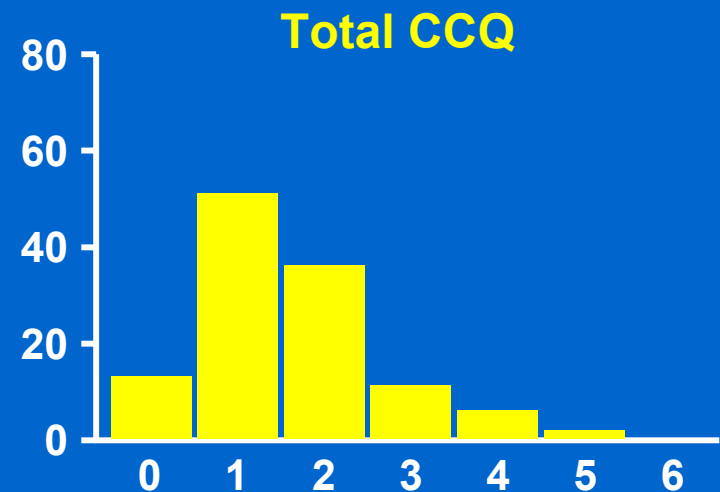
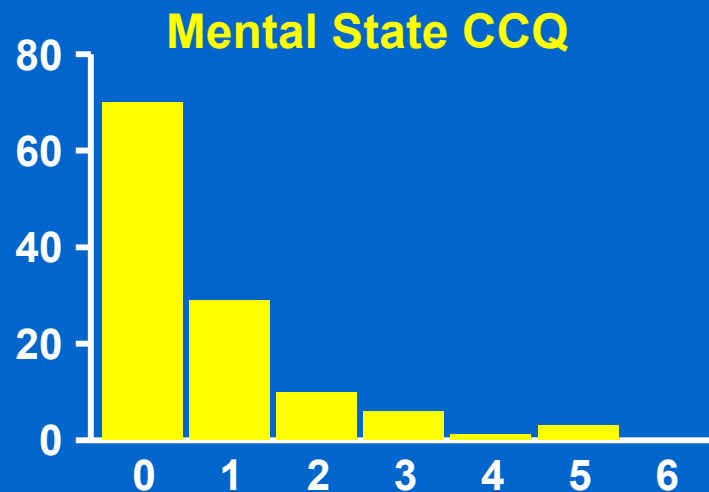
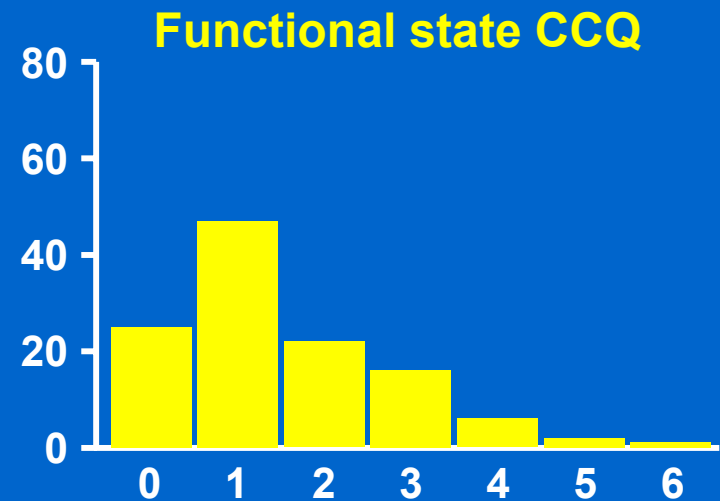
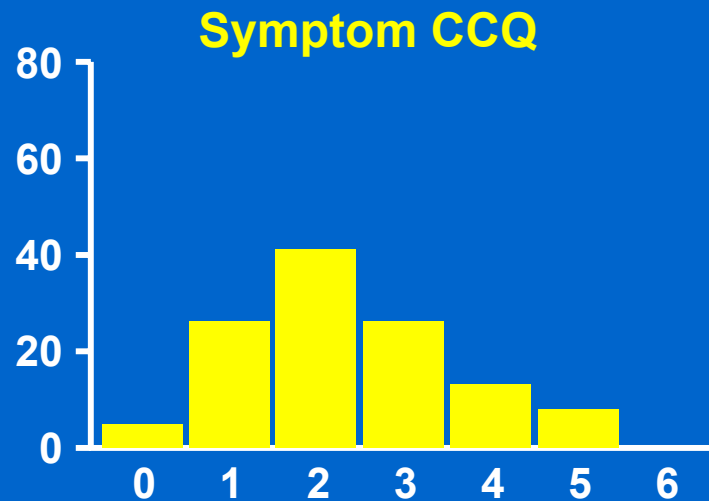
CCQ scores

COPD Stages (GOLD)

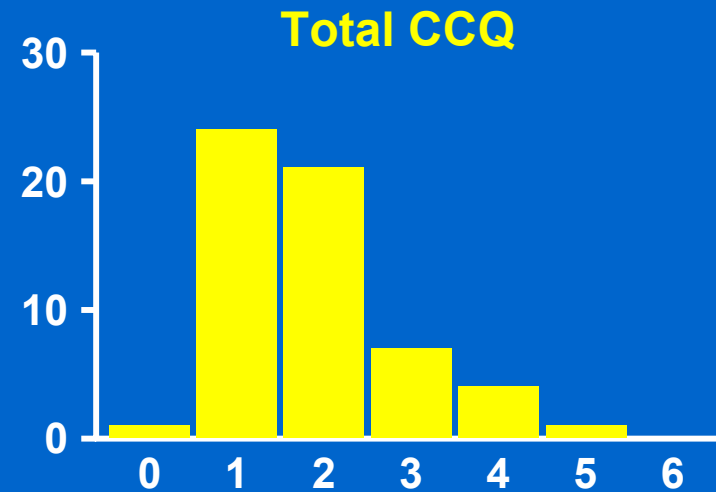
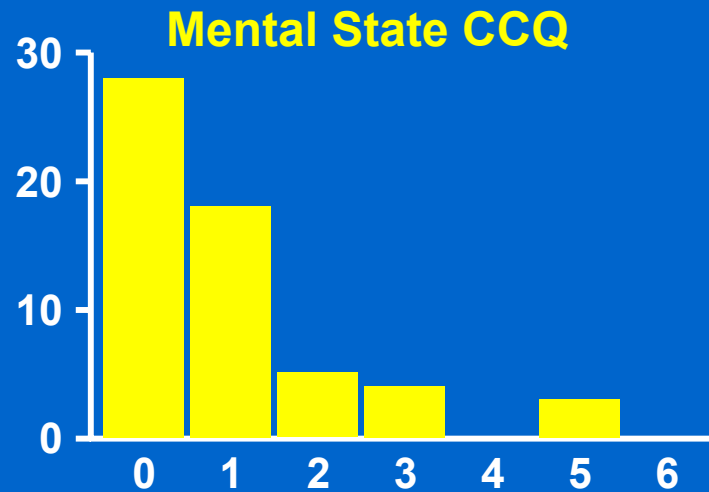
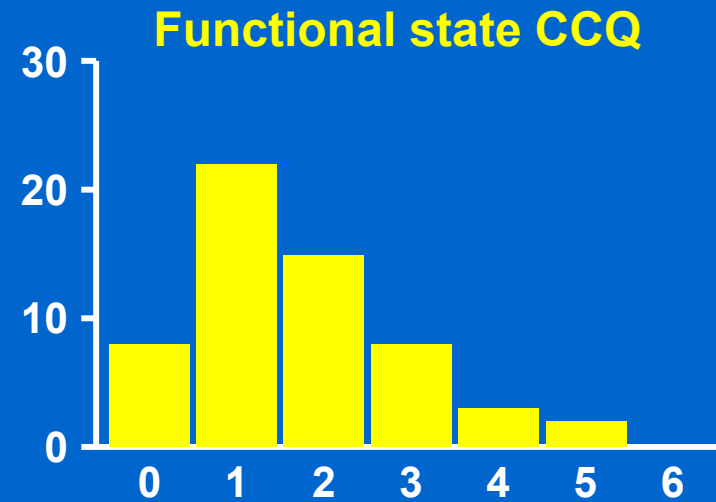
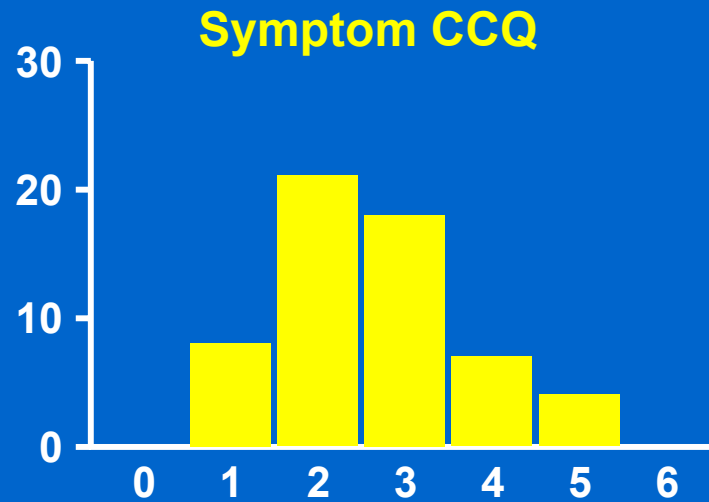
	Healthy (ex)smokers	0 At Risk	I Mild	IIA Moderate	IIB Moderate	III Severe
Symptom	1.5	3.1	1.8	2.0	3.1	2.9
(range)	(0.3-3.5)	(1.8-5.3)	(0.5-5.0)	(0.8-5.3)	(0.8-4.5)	(1.5-4.5)
Functional	0.8	1.5	0.3	1.4	1.5	2.6
(range)	(0.0-3.8)	(0.3-6.0)	(0.0-2.5)	(0.3-4.0)	(0.5-4.8)	(2.0-5.0)
Mental	0.0	0.5	0.0	0.0	1.0	0.5
(range)	(0.0-1.5)	(0.0-3.5)	(0.0-1.0)	(0.0-4.5)	(0.0-5.0)	(0.0-5.0)
Total	0.8	2.2	1.0	1.3	1.9	2.5
(range)	(0.1-2.2)	(0.8-5.2)	(0.2-2.5)	(0.5-4.3)	(0.9-4.7)	(1.7-4.3)



Score distributions for all (n=119)



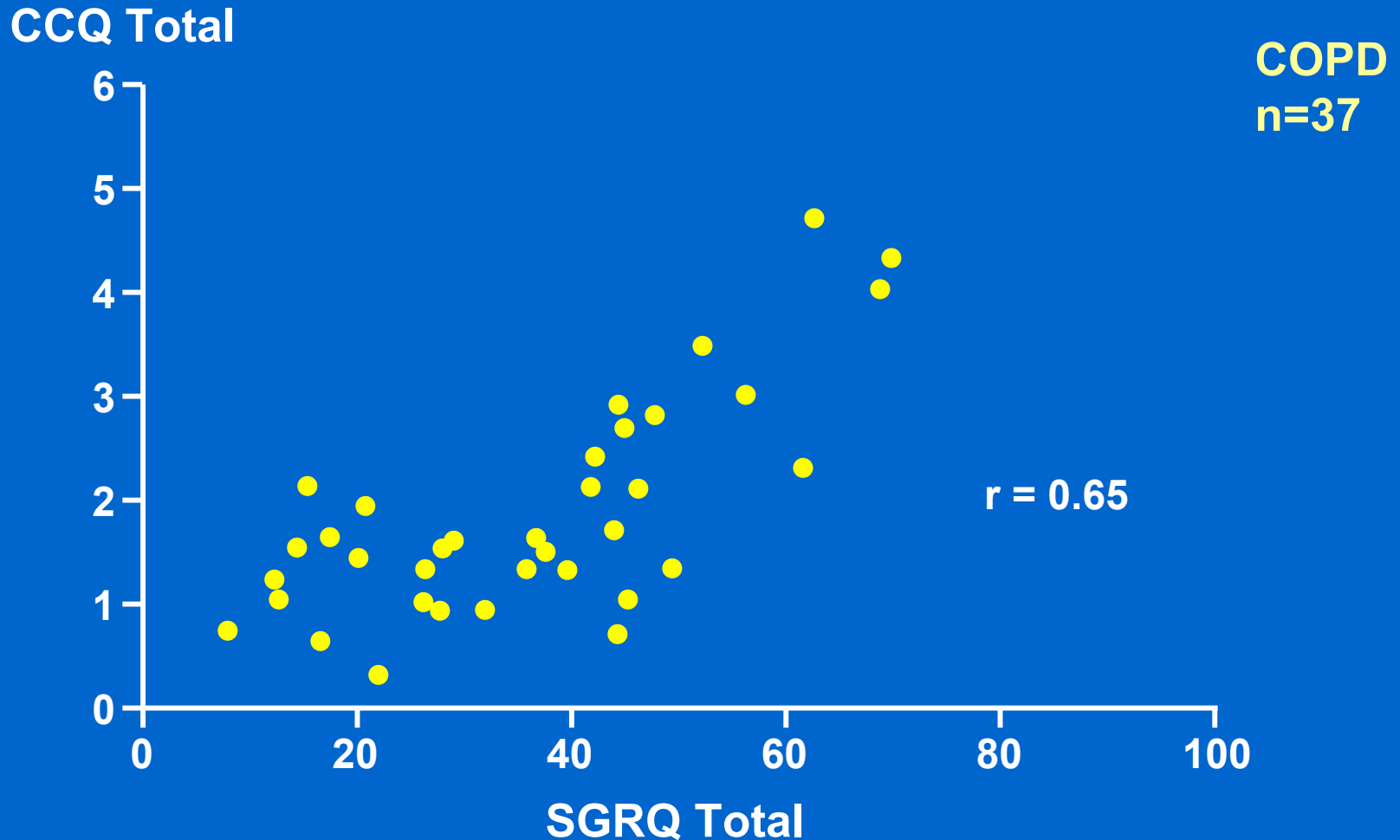
Score distributions for COPD (n=58)



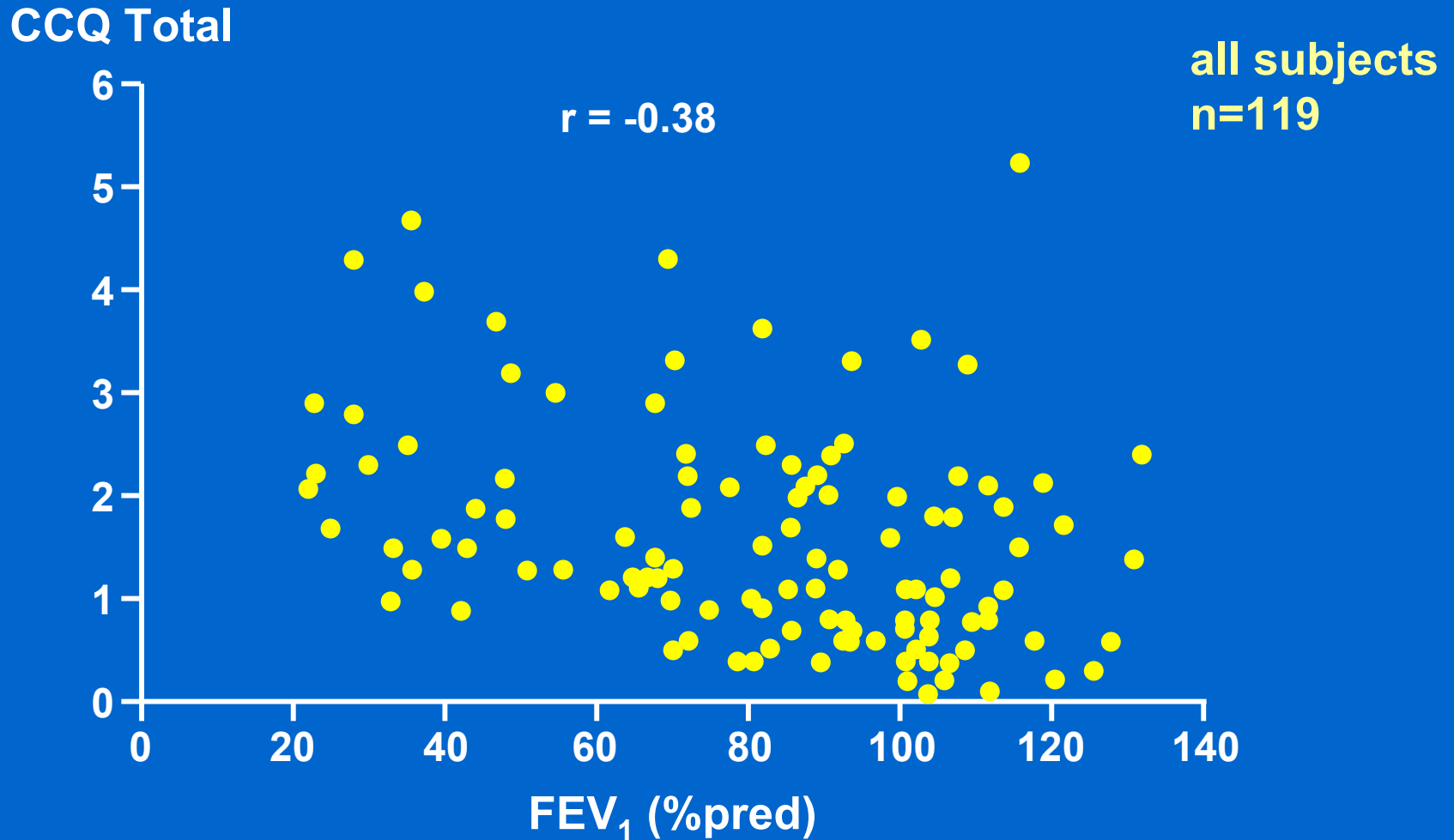
Internal consistency

	Cronbach's α
Symptom	0.78
Functional state	0.89
Mental state	0.80
Total score	0.91

Correlation between CCQ and SGRQ



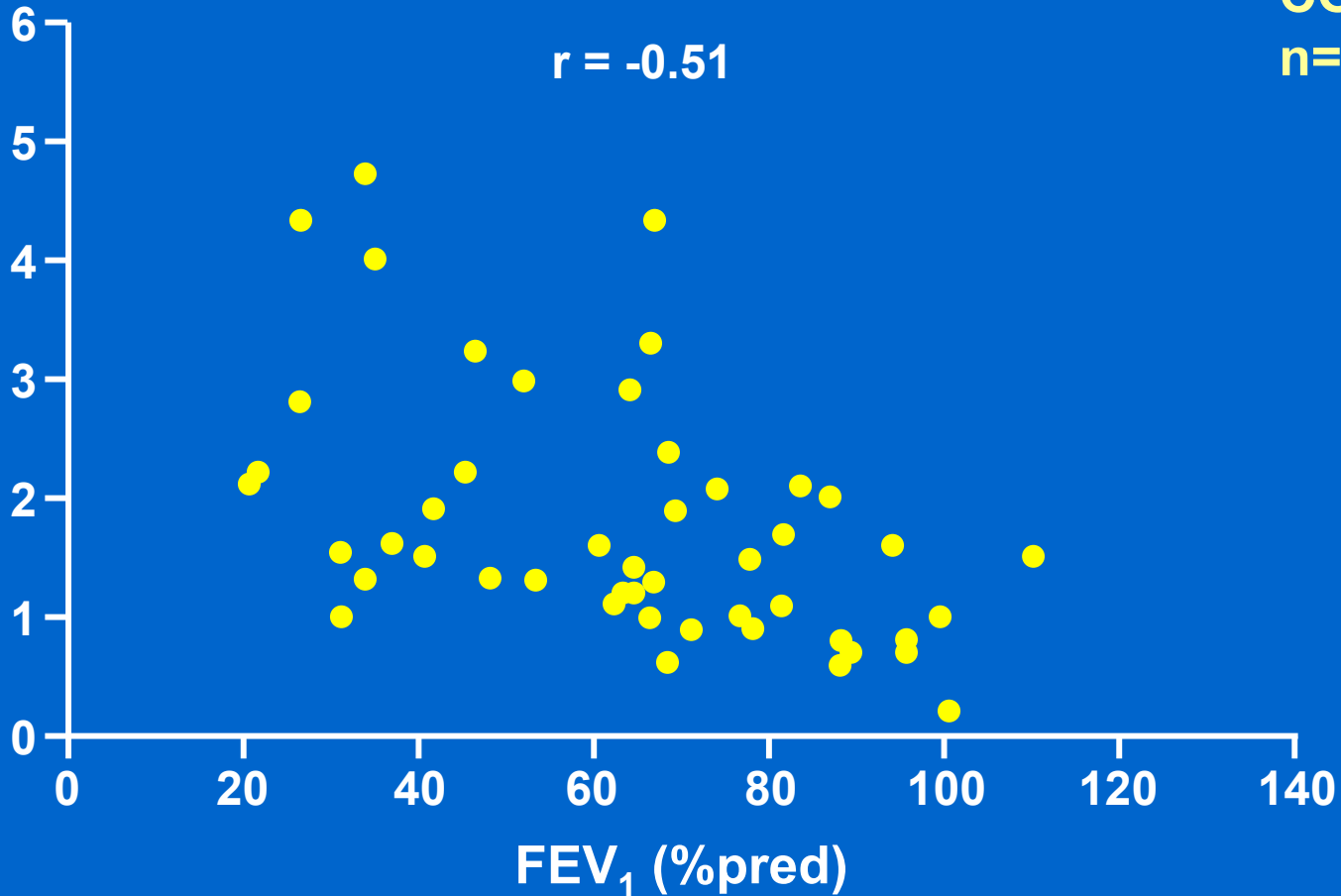
Correlation between CCQ and FEV₁



Correlation between CCQ and FEV₁

CCQ Total

COPD
n=58



Respiratory symptoms after smoking cessation

months	COPD+			COPD-		
	0	2	12	0	2	12
Symptoms (CCQ)	2.1 [#]	1.6	1.1 ⁺	1.5	0.5 [*]	0.8
Symptoms (SGRQ)	66	62	34 ⁺		NA	

Values expressed as medians

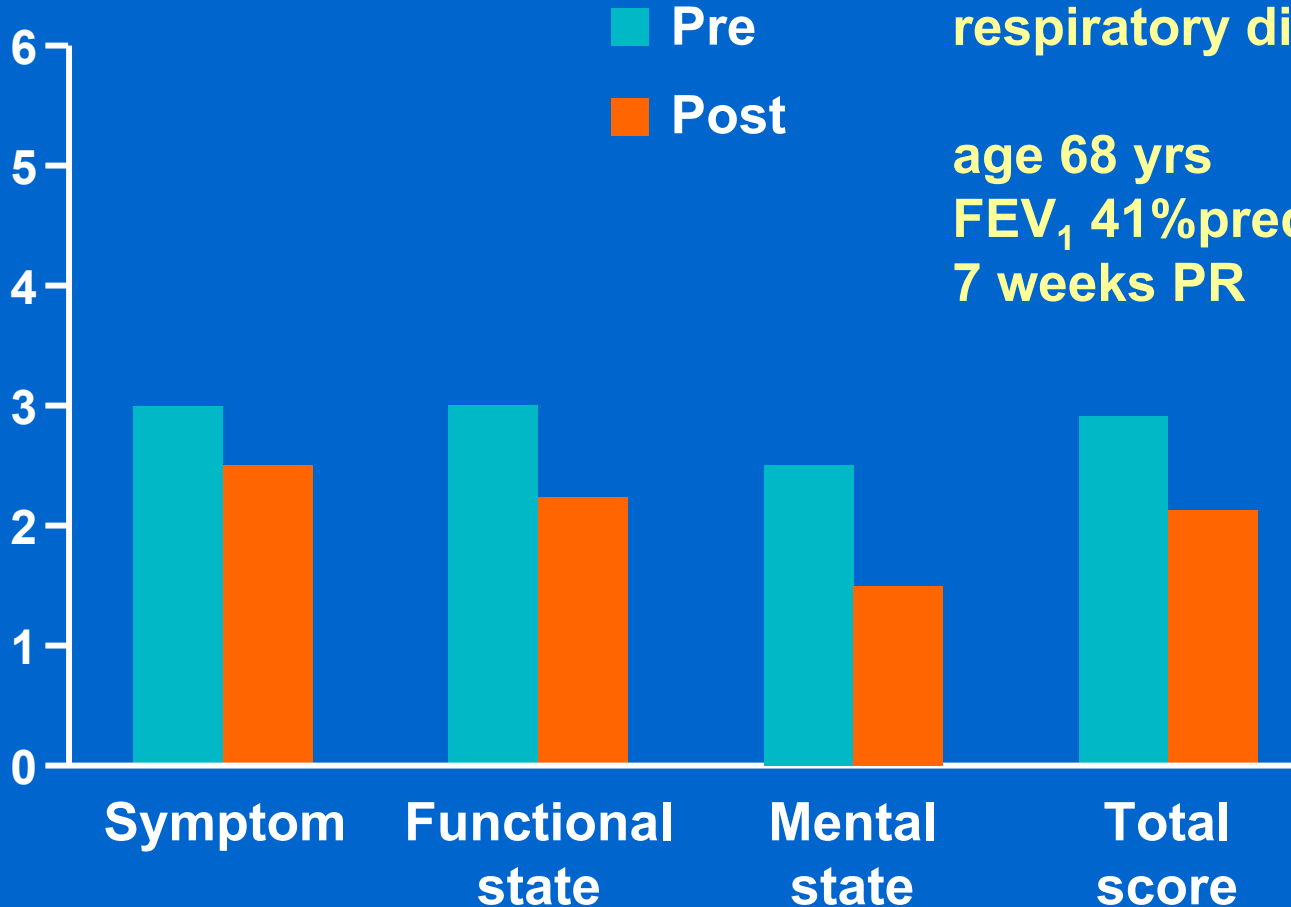
[#] p<0.05 COPD+ versus COPD- at 0 months

⁺ p<0.05 0 versus 12 months within group

^{*} p<0.05 0 versus 2 months within group

Pre/post pulmonary rehabilitation

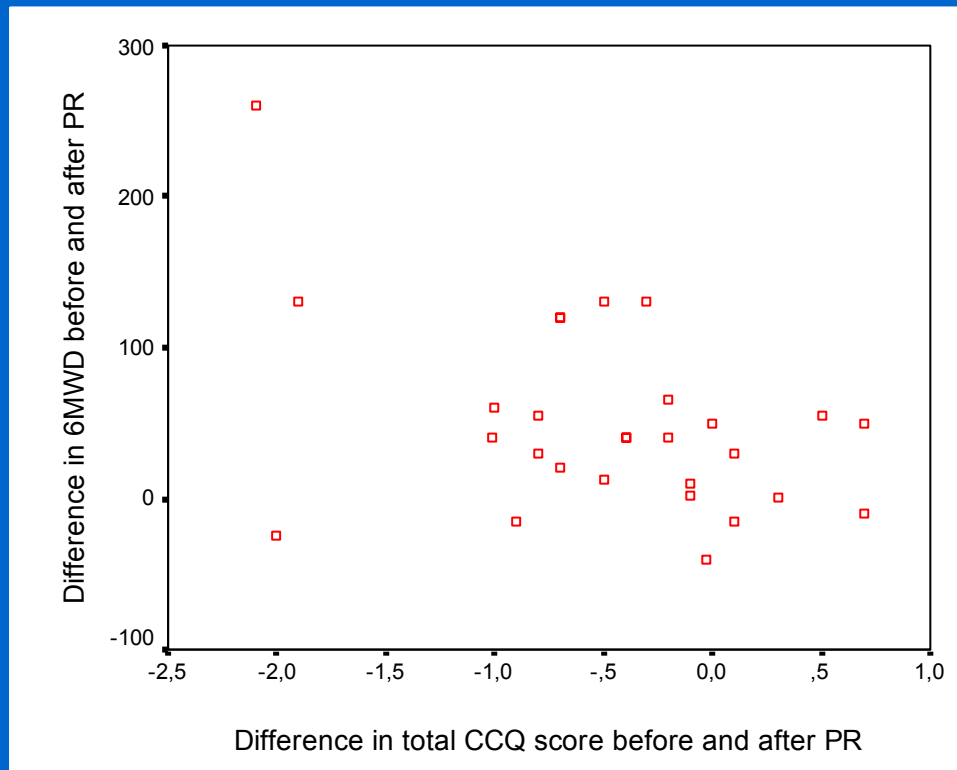
Median



54 patients with chronic respiratory disease

age 68 yrs
FEV₁ 41%pred
7 weeks PR

Pulmonary rehab in outpatient clinic CCQ compared to 6MWD



Health status FEV1 and Borg scores at day 1 and after 7 days of hospitalisation

Parameter	Mean difference day7-day0 (95%CI)	Mean % change (95%CI)
CCQ total score	-1.1 (-1.3; -0.9)	-31.7 (-38.2; -25.1)
FEV ₁ (L)	0.11 (0.06; 0.16)	14.3 (9.1; 19.4)
SGRQ total score	-5.3 (-8.0; -2.5)	-6.0 (-12.1; 0.02)
Borg score	-1.7 (-2.2; -1.3)	-31.1 (-43.1; -19.1)

Conclusion

- Health status assessment will become an essential part of future clinical monitoring of COPD
- For COPD the CCQ might be a valuable tool
- In many other diseases such tools should be developed and validated
- One international questionnaire is preferred above multiple national questionnaires
- Translations (23) are available on www.CCQ.nl