

SUPPLEMENTAL MATERIAL

Defining a standard set of patient-centered outcomes for patients with pulmonary sarcoidosis

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Appendix 1. Pulmonary sarcoidosis project group members and institutional affiliations.

Country	(Clinical) Speciality	Name	Institutional Affiliation	Expert group member
Belgium	Pulmonologist	Wim Wuyts, MD, PhD, Prof	University Hospitals Leuven, Belgium	Y
Belgium	Nurse	Els den Dycker, RN	University Hospitals Leuven, Belgium	N
The Netherlands	Pulmonologist	Jan Grutters, MD, PhD, Prof	St. Antonius Hospital, Nieuwegein, The Netherlands	Y
The Netherlands	Pulmonologist	Frouke van Beek, MD	St. Antonius Hospital, Nieuwegein, The Netherlands	Y
The Netherlands	Senior Researcher	Philip van der Wees, PhD, Prof	IQ Healthcare, Radboudumc, The Netherlands	Y
The Netherlands	Senior Advisor	Paul van der Nat, PhD	St. Antonius Hospital, Nieuwegein, The Netherlands IQ Healthcare, Radboudumc, The Netherlands	Y
The Netherlands	Chairman of the Board of Directors	Douwe Biesma, MD, PhD, Prof	St. Antonius Hospital, Nieuwegein, The Netherlands	N
The Netherlands	PhD Candidate	Nynke Kampstra, MPH	St. Antonius Hospital, Nieuwegein, The Netherlands	Y
The Netherlands	Pulmonologist	Marlies Wijsenbeek, MD, PhD	Erasmus Medical Center, Nederland	Y
The Netherlands	Pulmonologist	Bernt van den Blink, MD, PhD	Erasmus Medical Center, Netherlands	Y
The Netherlands	Senior researcher	Wim van den Bosch, PhD	St. Antonius Hospital, Nieuwegein, The Netherlands	Y
UK	Pulmonologist	Elizabeth Renzoni, MD, PhD	Royal Brompton Hospital, Imperial College, London, UK	Y
UK	Pulmonologist	Vasillis Kouranos, MD, PhD	Royal Brompton Hospital, Imperial College, London, UK	Y
USA	Pulmonologist	Robert P. Baughman, MD, Prof	University of Cincinnati Medical Center, Cincinnati, USA	Y
USA	Oncologist	Elyse E. Lower, MD	University Hospital, Cincinnati, USA	Y
USA	Pulmonologist	Daniel Culver, DO	Cleveland Clinic, Cleveland, USA	Y

Appendix 2. Care delivery value chain for pulmonary sarcoidosis.

INFORMING AND ENGAGING	* Stop smoking program	* Stop smoking program	* Stop smoking program	* Stop smoking program	* Stop smoking program	
	* Counseling patient and family on diagnostic procedures	* Counseling patient & family on diagnosis	* Counseling on treatment process	* Counseling on rehabing options/pr	* Counseling on chronic nature disease recurrence of disease	
	* Brochures on diagnostic procedures	* Brochure on disease	* Inform on diagnostic procedures	* Brochure on side effects		
		* Explaining treatment options/ shared decision making (SDM)	* Brochures on diagnostic procedures			
	* Brochures on treatment modalities	* Psychological counseling patient and family				
MEASURING	* Questionnaires by patient Environmental exposure questions Family history Medical Research Council Disproe Score (MRC) CIS20r Checklist Individual Strength Quality of Life (SF36) WPAI GH Work Productivity	* Laboratory (eg. liver, kidney, ...) * Consultation ophthalmologist * ECG	* Questionnaires: SF36, VAS5, CIS, M and WPAI GH * Laboratory (ppILD, ACE, sIL2R) * RR (blood pressure) * BMI * Pulmonary function * X-thorax	* Questionnaires: SF36, VAS5, CIS, M and WPAI GH * Laboratory (ppILD, ACE, sIL2R) * RR (blood pressure) * BMI * Pulmonary function * X-thorax	* Questionnaires: SF36, VAS5, CIS, MRC and WPAI GH * Laboratory (ppILD, ACE, sIL2R) * RR (blood pressure) * BMI * Pulmonary function * X-thorax * DEXA (bone scan)	
	* Laboratory (CRP, LDH, calcium, ACE, ACE genotype, sIL2R, PP-ILD, Quantiferon-TB)					
	* Pulmonary function (bodybox, spirometric, diff cap)	Optionally:	Optionally:	Optionally:	Optionally:	
	* Bronchoscopy and >=3 mucosal biopsies	* 6 minutes walk test	* 6 minutes walk test	* 6 minutes walk test	* 6 minutes walk test	
	* BAL: broncho alveolar lavage	* FDG - PET	* FDG - PET	* FDG - PET	* FDG - PET	
	* Pathology (histology, cytology)	* Neurologist/LEP/MRI cerebral	* Neurologist/CEP/MRI cerebral	* Neurologist/CEP/MRI cerebral	* HRCT	
	* Maximal oxygen consumption VO2max	* Cardiologist MRI cor/Echo cor/24 h Holter	* Cardiologist MRI cor/Echo cor	* Cardiologist MRI cor/Echo cor		
	* High Resolution CT with contrast (HRCT)		* HRCT	* HRCT		
	* Skin biopsies	other specialist measurements if indicated				
	* Lymf node biopsies	* Indications & Contraindications for specific treatment				
	Optionally					
	* FDG - PET					
	* EUS - FNA/EBUS - FNA					
	* Lung biopsy (VATS)					
* Echo kidney: nefrocalcinose?						
ACCESSING	* Outpatient visit	* Outpatient visit	* Outpatient visit	* Outpatient visit	* Outpatient visit	
	* Laboratory	* Laboratory	* Laboratory	* Laboratory	* Laboratory	
	* Radiology	* Radiology	* Pharmacy	* Pharmacy	* Pharmacy	
	* Nuclear	* Nuclear	* Radiology		* Radiology	
	* Pulmonary function test room	* Pulmonary function test room	* Pulmonary function test room		* Pulmonary function test room	
STEPS	1. DIAGNOSING	2. PREPARING	3. THERAPY	4. RECOVERING/REHABING	5. MONITORING/MANAGING	PATIENT VALUE
CARE DELIVERY ACTIVITIES	* Anamnesis	* Multidisciplinary consult	Combination of options:	* Management of side effects	* Follow-up anamnesis/	PROVIDER MARGIN
	* Physical examination	* Determining extrapulmonary involvement	* Pain medication (self care)	* Controlled medication tapering	physical examination	
	* Multidisciplinary meeting/discussion suspected cardio-pulmonary disease suspected cardiac disease suspected other organ involvement	* Choice of treatment modality: - farmaceutical yes/no check absolute criteria check relative criteria - fysiotherapy yes/no - watchful waiting yes/no	* Pain relief team * Inhalation therapy * Amitryptiline, pregabaline, ritalin, methylfenidaat... * Immuno suppressive therapy corticosteroides, or methotrexaat, or TNF-alfa block (biological) * Fysiotherapy * Dietary advice * Psychologist	* Dietary advice * Case management * Helen Downing Institute; learn patient to cope with chronic disease	* Treatment for persistent disease activity * Monitor for reactivation or progression of sarcoidosis	
	* Determining specific nature of disease					

Legenda

Medical Specialist

Other provider entity

Appendix 3. Reference guide and data collection.

FINAL INDICATOR SET

➤ Mortality

Variable: date of death

Definition: Provide the date of the death.

Timing: update every 6 months

Reporting Source: clinical

Response Options: DD/MM/YY

➤ Pulmonary function

Variable: pulmonary function

Definition: absolute and % predicted of FEV1, FVC and DLCOc (depending on severity of sarcoidosis)

Abbreviations:

DLCO= diffusing capacity for carbon monoxide

FEV1= forced expiratory volume in the first 1 second of expiration

FVC= forced vital capacity

Timing: every 3 to 6 months

Reporting Source: clinical

Response Options: DD/MM/YYYY

Absolute PFT in

% predicted PFT in mmol/min/kPa

➤ Activity marker in blood reduction: sIL2R

Variable: Soluble Interleukine 2 receptor

Definition: Absolute and predicted FEV1, FVC and DLCOc

Timing: every 3 to 6 months

Reporting Source: clinical

Response Options: DD/MM/YYYY

sIL2R measured at each presentation.

1. Date measurement
2. sIL2R (measured in pg/ml, limit >3000)

➤ Weight gain

Variable: weight gain

Definition: The weight in kilogram (kg) of a patient

Timing: Every visit to the clinic

Reporting Source: clinical

Response Options: weight in kg

➤ **Quality of Life**

Variable: Quality of Life; physical functioning

Definition: quality of life measured with:

- King's Sarcoidosis Questionnaire (KSQ), appendix 5.
- Fatigue Assessment Scale (FAS), appendix 6.

Timing: every 6 months

Reporting Source: patient reported

Response Options:

- KSQ: five modules (General health status, Lung, Skin, Eye, Medications) 29 questions
- FAS: 10 questions (on 5-point hedonic scale)

➤ **Osteoporosis**

Variable: osteoporosis

Definition: condition in which the bones become brittle and fragile from loss of tissue.

Timing: update every 6 months

Reporting Source: clinical

Response Options:

1= Normal >-1.0

2= Osteopenia $<-1.0, >-2.5$

3= Osteoporosis <-2.5

4= Severe osteoporosis <-2.5 plus fragility fractures

5= not indicated

Diagnosis T-score based on WHO Osteoporosis Classification

➤ **Clinical Outcome Status (COS)**

Variable: Clinical Outcome Status (COS)

Definition:

The definition of clinical phenotypes of the disease based on the clinical outcome status (COS).

- 2 years after initial diagnosis from the new patient cohort (+/- 6 months).
- Diagnosis date:
 - Diagnosed at the clinic: date of the multi-disciplinary meeting.
 - Diagnosed somewhere else: date letter lung physician when the diagnosis is announced.
- The retrospective patients which are still being treated will also be taken into account 5 years after initial diagnosis.

Timing: 2 and/or 5 year after diagnosis.

Reporting Source: clinical

Response options:

1: resolved never treated

2: resolved, no therapy >1 year

3: minimal disease never treated

4: minimal disease no therapy > 1 year

5: persistent-no current therapy, never treated

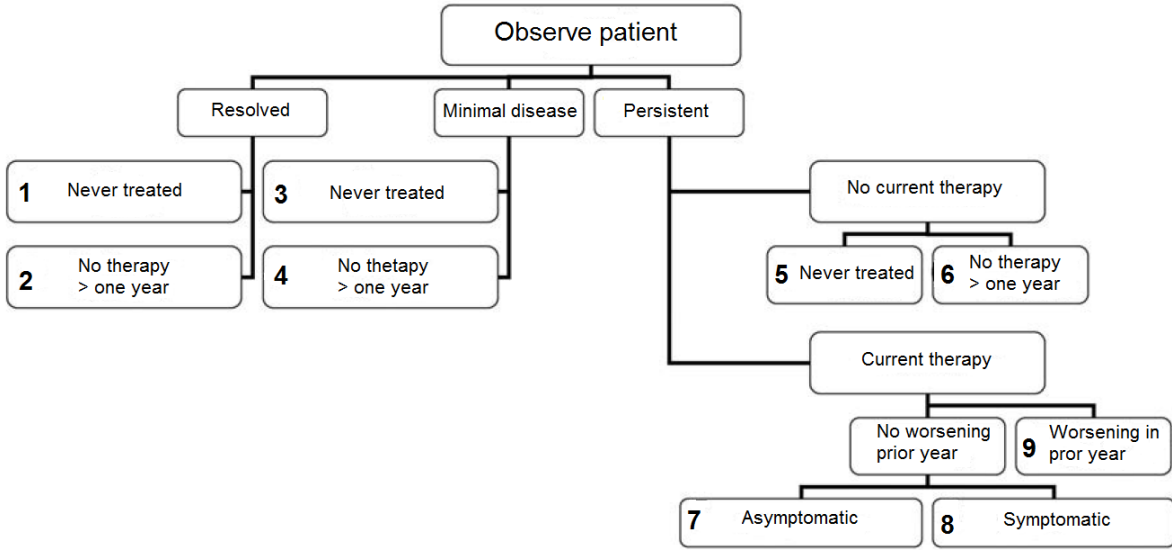
6: persistent-no current therapy, no therapy > 1 year

7: persistent-current therapy, asymptomatic

8: persistent-current therapy, symptomatic

9: persistent-current therapy, worsening prior year

999 = unknown



Baughman, R. P., Nagai, S., & Balter, M. (2011). Defining the clinical outcome status (COS) in sarcoidosis: results of WASOG Task Force. *Sarcoidosis vasculitis and diffuse lung disease*, 28(1), 56-64.

CASE MIX VARIABLES

➤ Patient ID

Variable: Patient ID

Definition: Indicate the patient's medical record number

Timing: Baseline

Reporting Source: Administrative or clinical

Response Options: According to institution

Demographic Factors

➤ Gender

Variable: Gender

Definition: Please indicate your sex at birth:

Timing: Baseline

Reporting Source: Patient-reported

Response Options:

0 = female

1 = male

➤ Age & Date of birth

Variable: Date of birth

Definition: date patient was born

Timing: Baseline

Reporting Source: Patient-reported

Type: Date by DD/MM/YYYY

➤ Ethnicity

Variable: Ethnicity

Definition: Varies by country and should be determined by country (not for cross country comparison)

Timing: Baseline

Reporting Source: Patient-reported

Response Options:

1= Black

2= White

3= Asian

or:

4 = Caucasian

5 = non-Caucasian

999= unknown

For Royal Brompton Hospital the categories Caucasian and non-Caucasian will be used as this is the only available information.

Clinical Factors & Information

➤ Length

Variable: Height

Definition: height in centimeters

Supporting Definition: Height and weight are used to calculate BMI

Timing: Baseline

Reporting Source: Clinical

Response Options: Numerical value of height in cm

➤ Date of diagnosis

Variable: Date of diagnoses of pulmonary sarcoidosis

Definition:

- Diagnosed at the clinic: date of the multi-disciplinary meeting.

- Diagnosed somewhere else: date letter lung physician when the diagnosis is announced.

Timing: Baseline

Reporting Source: Clinical

Response Options: DD/MM/YYYY

➤ Recorded history of (comorbidities)

Variable: Comorbidities

Definition: presence of one or more additional diseases or disorders

Timing: Baseline

Reporting Source: Patient-reported

Response Options: Multiple options possible:

1 = no comorbidity

2 = myocardial infarction

3 = congestive heart failure

4 = coronary artery disease

5 = cerebrovascular disease

6 = dementia

7 = COPD

8 = connective tissue disease

9 = peptic ulcer disease

10 = diabetes mellitus

11 = chronic kidney disease

12 = hemiplegia

13 = systemic hypertension

14 = liver disease mild

15 = liver disease moderate to severe

16 = other cancer (within last 5 years)

17 = peripheral vascular disease

18 = sleep apnoea

999 = unknown

*The assumption here is that most important comorbidities are registered in the electronic patient record.

➤ **Multi organ involvement**

Variable: multi-organ involvement

Definition: multi-organ involvement regarding sarcoidosis, based on the WASOG multi-organ involvement in patients with confirmed sarcoidosis (Table 1).

Timing: every 6 months

Reporting Source: clinical

Response Options:

lungs

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

neurologic

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

non-thoracic lymph node

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

renal

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

cardiac

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

skin

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

eyes

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

liver

1= Highly probable/ at least probable

2= Possible/not probable

3= Unknown

bone marrow

1= Highly probable/ at least probable

2= Possible/not probable
3= Unknown

spleen

1= Highly probable/ at least probable
2= Possible/not probable
3= Unknown

bone/joints

1= Highly probable/ at least probable
2= Possible/not probable
3= Unknown

ear/nose/throat

1= Highly probable/ at least probable
2= Possible/not probable
3= Unknown

parotid / salivary glands

1= Highly probable/ at least probable
2= Possible/not probable
3= Unknown

muscles

1= Highly probable/ at least probable
2= Possible/not probable
3= Unknown

hypercalcemia / hypercalcuria / nephrolithiasis

1= Highly probable/ at least probable
2= Possible/not probable
3= Unknown

Table 1. Multi-organ involvement

Definition of organ involvement:

- 1) Positive biopsy is of the organ or is one of the following conditions
- 2) Assumes no other cause identified (such as infection, trauma, pre-existing condition, or co-existing disease).
- 3) Other situations may be specified.

ORGAN	HIGHLY PROBABLE	AT LEAST PROBABLE	POSSIBLE
LUNGS	CXR: bilateral hilar adenopathy Chest CT: perilymphatic nodules Chest CT: symmetrical hilar/mediastinal adenopathy PET/Gallium-67: mediastinal/hilar enhancement	CXR: diffuse infiltrates CXR: upper lobe fibrosis Chest CT: peribronchial thickening BAL: lymphocytic alveolitis BAL: elevated CD4/CD8 ratio PET/Gallium-67: diffuse parenchymal lung enhancement TBNA: lymphoid aggregates/giant cells	CXR: localized infiltrate PFT: obstruction
NEUROLOGIC	Clinical syndrome consistent with granulomatous inflammation of the meninges, brain, ventricular (CSF) system, cranial nerves, pituitary gland, spinal cord, cerebral vasculature or nerve roots And An abnormal MRI characteristic of neurosarcoidosis, defined as exhibiting abnormal enhancement following the administration of gadolinium or a cerebrospinal fluid exam demonstrating inflammation	Isolated facial palsy, negative MRI Clinical syndrome consistent with granulomatous inflammation of the meninges, brain, ventricular (CSF) system, cranial nerves, pituitary gland, spinal cord, cerebral vasculature, nerve roots but without characteristic MRI or CSF findings	Seizures, negative MRI Cognitive decline, negative MRI
NON-THORACIC LYMPH NODE		Multiple enlarged palpable cervical or epitrochlear lymph nodes without B symptoms Enlarged lymph nodes identified by imaging in at least 2 peripheral or visceral lymph node stations without B symptoms	
RENAL		Treatment-responsive renal failure with no other risk factors. Treatment-responsive renal failure in patient with diabetes and/or hypertension.	Renal failure with other potential risk factors
CARDIAC		Treatment responsive CM or AVNB Reduced LVEF in the absence of other clinical risk factors Spontaneous or inducible sustained VT with no other risk factor Mobitz type II or 3rd degree heart block Patchy uptake on dedicated cardiac PET Delayed enhancement on CMR Positive gallium uptake Defect on perfusion scintigraphy or SPECT scan T2 prolongation on CMR	Reduced LVEF in the presence of other risk factors (e.g., HTN, DM) Atrial dysrhythmias

SKIN	Lupus pernio	Subcutaneous nodules or plaques Inflammatory papules within a scar or tattoo Violaceous or erythematous annular lesions Violaceous or erythematous macular, papular lesions around the eyes, nose, or mouth	Atypical lesions: ulcerative, erythrodermic, alopecic, ichthyosiform
EYES	Uveitis Optic neuritis Mutton fat keratic precipitates Iris nodules Snowball/string of pearls (pars planitis)	Lacrimal gland swelling Trabecular meshwork nodules Retinitis Scleritis Multiple chorioretinal peripheral lesions Adnexal nodularity Candle wax drippings	Cataract Glaucoma Red eye
LIVER		Abdominal imaging demonstrating hepatomegaly Abdominal imaging demonstrating hepatic nodules	
BONE MARROW	PET displaying diffuse uptake		
SPLEEN		Low attenuation nodules on CT PET/gallium-67 uptake in splenic nodules Splenomegaly on imaging or physical examination	
BONE / JOINTS	Typical radiographic features (trabecular pattern, osteolysis, cysts/punched out lesions)	Dactylitis Nodular tenosynovitis Positive PET, MRI, or gallium-67 bone imaging	Arthralgias
EAR / NOSE / THROAT		Granulomatous changes on direct laryngoscopy Consistent imaging studies (e.g. sinonasal erosion, mucoperiosteal thickening, positive PET scan)	Chronic sinusitis
PAROTID / SALIVARY GLANDS	Positive gallium-67 scan ("Panda sign") Positive PET scan of the parotid glands	Symmetrical parotitis with syndrome of mumps Enlarged salivary glands	Dry mouth
MUSCLES		Positive imaging (MRI, Gallium-67) Palpable muscle masses	Myalgias
HYPERCALCEMIA / HYPERCALCURIA / NEPHROLITHIASIS	Hypercalcemia plus all of the following: a) a normal serum PTH level; b) a normal or increased 1,25-OH dihydroxy vitamin D level; c) a low 25-OH vitamin D level Hypercalciuria plus all of the following: a) a normal serum PTH level; b) a normal or increased 1,25-OH dihydroxy vitamin D level; c) a low 25-OH vitamin D level	Nephrolithiasis plus all of the following: a) a normal serum PTH level; b) a normal or increased 1,25-diOH vitamin D level; c) a low 25-OH vitamin D level hypercalciuria without serum PTH and 25 and 1,25 vitamin D levels Nephrolithiasis with calcium stones, without serum PTH and 25 and 1,25 vitamin D levels	Nephrolithiasis, no stone analysis

From: as defined at WASOG congress 2014 (unpublished)

➤ **Opinion stage**

Variable: opinion stage

Definition: opinion stage to the clinic

Timing: baseline

Reporting Source: clinical

Response Options:

1= first opinion
2= second opinion
3 = third opinion
999 = unknown

➤ **Smoking history**

Variable: smoking history

Definition: smoking habits throughout live

Timing: baseline

Reporting Source: patient-reported

Response Options:

1 = never
2 = ever
3 = active
999 = unknown

➤ **Socio-economic status**

Variable: postal code

Definition: socio-economic status through postal code

Timing: baseline

Reporting Source: administrative

Response Options: depending on the country

XXXX
or
XXXXX

➤ **Stadium X-thorax**

Variable: Scadding stage

Definition: stadium based on Scadding-classification

Timing: baseline

Reporting Source: clinical

Response Options:

1 = Scadding stage 0 normal chest radiograph
2 = Scadding stage I hilar or mediastinal nodal enlargement only
3 = Scadding stage II nodal enlargement and parenchymal disease and III parenchymal disease only
4 = Scadding stage IV significant fibrotic lesions/end stage disease
999 = unknown

Appendix 4. Prioritizing outcome indicators for the treatment of pulmonary sarcoidosis.

		Impact		Control		Volume	
		Average	Stand. Dev	Average	Stand. Dev	Average	Stand. Dev
1	TIER 1 - SURVIVAL						
	Mortality 1y after diagnosis	10,0	0,0	4,8	1,7	3,4	2,4
	Mortality 3y after diagnosis	10,0	0,0	4,7	1,2	4,4	1,8
	Mortality 5y after diagnosis	9,9	0,3	4,9	1,4	5,9	1,7
2	TIER 1 - DEGREE OF RECOVERY/HEALTH						
	Number of days lost from school/work due to sarcoidosis	7,9	1,1	4,7	1,2	8,4	0,7
	Number of days per year in the hospital due to sarcoidosis	6,9	1,1	5,4	1,7	5,9	1,5
	Number of emergency room visits due to sarcoidosis	6,4	1,0	4,4	2,2	4,7	1,6
	Activity marker in blood reduction: ACE	3,3	0,8	3,9	1,0	6,5	2,3
	Activity marker in blood reduction: sIL2R	3,3	0,8	3,9	1,0	7,1	1,8
	Pulmonary function improvement: FEV1	6,8	1,6	5,1	2,0	8,0	1,5
	Pulmonary function improvement: forced vital capacity (FVC)	7,0	1,6	5,6	2,1	8,3	1,6
	Pulmonary function improvement: diffusion capacity of lung (DLCO)	6,9	1,7	5,6	2,1	7,9	1,5
	QoL RAND-36	6,8	1,4	4,9	1,6	8,6	1,3
	QoL: % of patients having sleeping problems 1y after diagnosis	6,8	1,5	4,4	2,1	6,9	1,6
	Radiological changes	4,8	2,9	5,3	1,8	6,8	1,8
3	TIER 2 - TIME TO RECOVERY/ NORMAL ACTIVITIES						
	% of patients with remission within 2y after diagnosis	8,4	1,3	4,3	1,7	7,7	1,4
4	TIER 2 - DISUTILITY OF CARE OR TREATMENT PROCESS						
	Early side effects (< 12 mo after diagnosis) due to medication						
	Bone thinning (osteoporosis)	6,8	1,6	7,2	1,0	4,9	2,0

	Cataract	7,3	1,6	5,1	1,8	5,6	1,0
	Diabetes	8,0	1,3	5,9	1,6	6,6	1,2
	Gastro-intestinal complaints	7,0	1,3	5,5	2,1	6,3	1,8
	Hypertension	4,1	1,5	5,1	1,7	5,9	1,1
	Liver function impairment	4,3	2,0	5,0	2,0	5,3	1,7
	Weight increase	8,1	1,0	6,1	1,7	8,6	1,0
5	TIER 3 - SUSTAINABILITY OF RECOVERY OR HEALTH OVER TIME						
	Clinical Outcome Status (COS) 5y after diagnosis	7,8	0,7	5,3	1,4	8,1	1,1
	Incidence of second organ involvement 1, 3 or 5 y after diagnosis	7,1	1,1	4,1	1,2	6,6	1,4
	Percentage exacerbations (readmissions)	7,9	0,9	5,2	2,0	6,6	0,7
	Relapse rate	8,3	0,5	4,7	1,8	7,6	0,7
6	TIER 3 - LONG-TERM CONSEQUENCES OF THERAPY						
	Late side effects (> 12 months after diagnosis) due to medication						
	Bone thinning (osteoporosis)	7,4	1,0	7,4	0,8	6,6	1,4
	Cataract	7,0	1,2	5,3	2,4	5,8	1,5
	Diabetes	7,9	0,7	5,7	2,1	6,4	1,9
	Gastro-intestinal complaints	6,4	1,3	5,0	1,8	5,6	1,7
	Hypertension	4,8	1,3	4,9	1,4	5,8	1,5
	Liver function impairment	4,3	1,5	4,4	1,2	5,1	2,1
	Weight increase	8,0	0,9	6,2	1,7	7,4	1,9
	Percentage of patients developing lung fibrosis	8,2	0,8	4,7	1,9	6,5	1,9

Guidance provided to participants:

- Impact on patient

2: outcome hardly has impact on well-being of patient

4: outcome has somewhat impact on well-being of patient

6: outcome has a moderate impact on well-being of patient

8: outcome has a strong impact on well-being of patient

10: outcome has an extreme impact on well-being of patient

you can also use the intermediate scores 1, 3, 5, 7, 9

- Influence of quality of delivery

2: outcome is hardly determined by quality of care delivery value chain (CDVC)

4: outcome is somewhat determined by quality of care delivery value chain (CDVC)

6: outcome is moderately determined by quality of care delivery value chain (CDVC)

8: outcome is strongly determined by quality of care delivery value chain (CDVC)

10: outcome is extremely determined by quality of care delivery value chain (CDVC)

you can also use the intermediate scores 1, 3, 5, 7, 9

- Volume of negative events

2: negative event only impacts very few patients (0,1-0,2%)

4: negative event impacts few patients (0,5 -1%)

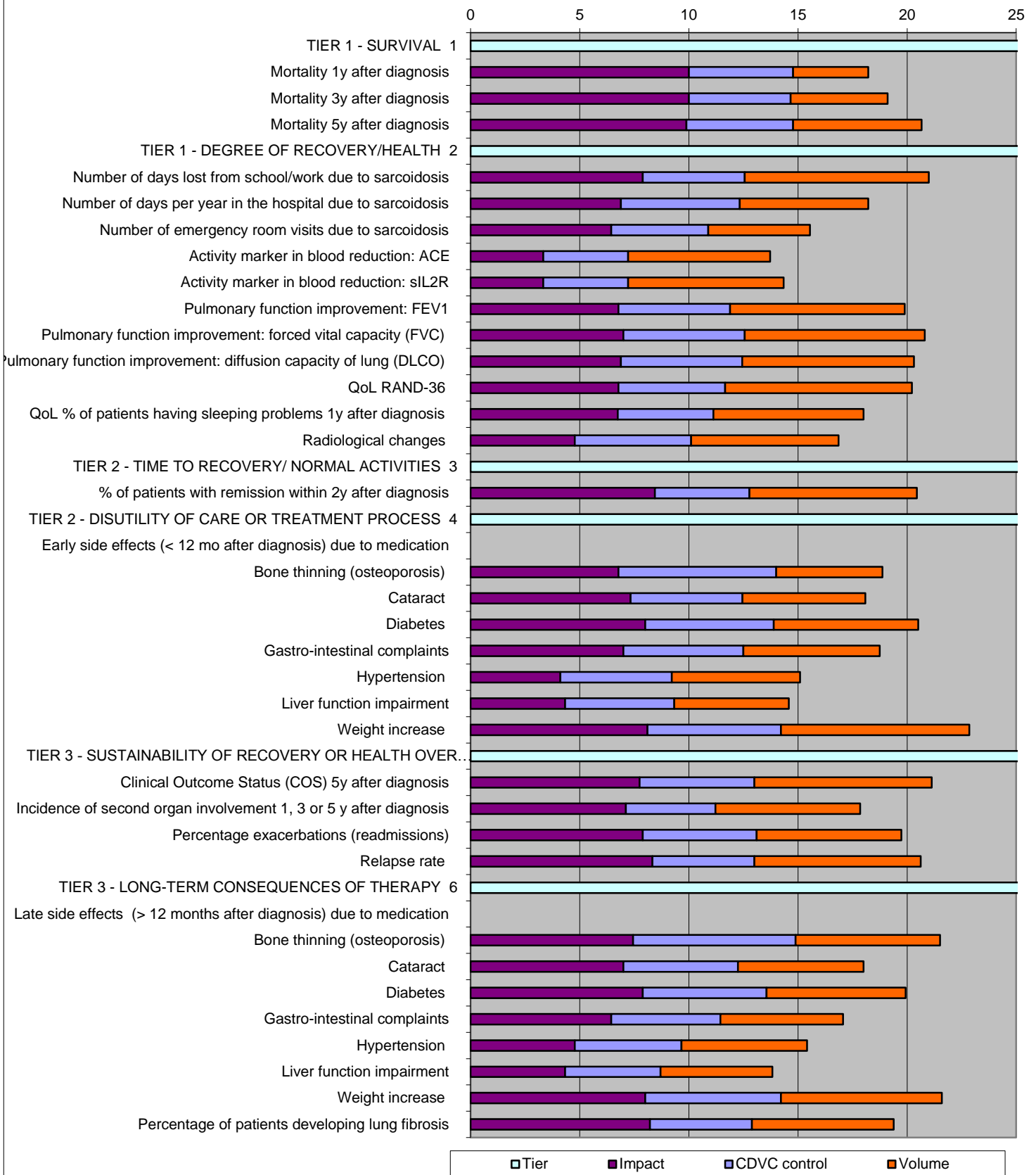
6: negative event impacts some patients (2-5%)

8: negative event impacts substantial percentage of patients (10-25%)

10: negative event impacts many of our patients (>50%)

you can also use the intermediate scores 1, 3, 5, 7, 9

SARCOIDOSIS - Outcome Indicators prioritized



Appendix 5. King's sarcoidosis questionnaire ©

This questionnaire is designed to assess the impact of sarcoidosis on various aspects of your life. Read each question carefully and select the answer that best applies to you. Please answer ALL questions, as honestly as you can. This questionnaire is confidential. All questions relate to how **sarcoidosis** has affected your health.

General health

In the last 2 weeks ...	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly of the time	None of the time
1. I have felt frustrated	1	2	3	4	5	6	7
2. I have had trouble concentrating	1	2	3	4	5	6	7
3. I have lacked motivation	1	2	3	4	5	6	7
4. I have felt tired	1	2	3	4	5	6	7
5. I have felt anxious	1	2	3	4	5	6	7
6. I have felt aches and pains in my muscles/joints	1	2	3	4	5	6	7
7. I have felt embarrassed	1	2	3	4	5	6	7
8. I have worried about my weight	1	2	3	4	5	6	7
9. I have worried about my sarcoidosis	1	2	3	4	5	6	7
In the last 2 weeks...	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly of the time	None of the time
10. Tiredness has interfered with my normal social activities such as going out with friends/family	1	2	3	3	5	6	7

Lung

Does sarcoidosis affect your lungs? If not, go to next section.

In the last 2 weeks...	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly of the time	None of the time
11. My cough has caused pain/discomfort	1	2	3	4	5	6	7
12. I have been breathless climbing stairs or walking up slight inclines	1	2	3	4	5	6	7
13. I have had to take deep breaths, also known as 'air hunger'	1	2	3	4	5	6	7
14. My chest has felt tight	1	2	3	4	5	6	7
15. I have had episodes of breathlessness	1	2	3	4	5	6	7
16. I have experienced chest pains	1	2	3	4	5	6	7

Medication

Are you taking any medication for sarcoidosis? If not, go to next section.

In the last 2 weeks...	A huge amount	A considerable amount	a moderate amount	A modest amount	A small amount	A tiny amount	None at all
17. I have worried about side effects of my medication for sarcoidosis	1	2	3	4	5	6	7
18. I have felt worse because of my medication	1	2	3	4	5	6	7
19. I have gained weight because	1	2	3	4	5	6	7

of my medication							
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Skin

Does sarcoidosis affect your skin? If not, go to next section.

In the last 2 weeks...	A huge amount	A considerable amount	a moderate amount	A modest amount	A small amount	A tiny amount	None at all
20. I have been bothered by my skin problems	1	2	3	4	5	6	7
21. I have been concerned about changes in colour of my skin lesions	1	2	3	4	5	6	7
	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly of the time	None of the time
22. I have been embarrassed about my skin	1	2	3	4	5	6	7

Eyes

Does sarcoidosis affect your eyes? If not, go to next section.

In the last 2 weeks...	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly of the time	None of the time
23. I have had dry eyes	1	2	3	4	5	6	7
24. I have had difficulty with bright lights	1	2	3	4	5	6	7
25. My eyes have been red	1	2	3	4	5	6	7
26. I have had pain in/or around the eyes	1	2	3	4	5	6	7
27. I have had difficulty reading	1	2	3	4	5	6	7
28. I have had blurred vision	1	2	3	4	5	6	7
29. I have been worried about my eyesight	1	2	3	4	5	6	7

Appendix 6. Fatigue assessment scale (FAS)

The following ten statements refer to how you usually feel. Per statement you can choose one out of five answer categories, varying from Never to Always.

Please circle the answer to each question that is applicable to you. Please give an answer to each question, even if you do not have any complaints at the moment.

1 = Never, 2 = Sometimes (about monthly or less); 3 = Regularly (about a few times a month); 4 = Often (about weekly) and 5 = Always (about every day).

	Never	Sometimes	Regularly	Often	Always
1. I am bothered by fatigue	1	2	3	4	5
2. I get tired very quickly	1	2	3	4	5
3. I don't do much during the day	1	2	3	4	5
4. I have enough energy for everyday life	1	2	3	4	5
5. Physically, I feel exhausted	1	2	3	4	5
6. I have problems to start things	1	2	3	4	5
7. I have problems to think clearly	1	2	3	4	5
8. I feel no desire to do anything	1	2	3	4	5
9. Mentally, I feel exhausted	1	2	3	4	5
10. When I am doing something, I can concentrate quite well	1	2	3	4	5

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