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Validation of a standard set of patient-centered outcomes for lung cancer in Spain

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Introduction

- Lung cancer (LC) and its treatment may affect several aspects of patients' lives [1–3]. Nevertheless, while survival outcomes are frequently assessed, patient-centered outcomes are rarely collected during patient follow-up. Filling this gap, the International Consortium for Health Outcomes Measurement (ICHOM) developed a standard set of variables aimed at following-up of newly diagnosed LC patients [4]. To implement this standard set, different aspects need to be considered:

1. selected variables should be routinely collected in clinical practice or, at least, doctors and patients should be familiarized with them;
2. the technology needed to measure the selected variables should be available;
3. instruments to collect the variables should be available and validated in the language of the country;
4. the target population to which the standard set may apply, should be defined according to each country clinical needs.

The main objective of this project was **to validate and adapt the ICHOM standard set for lung cancer to the Spanish setting.**

Methods

- A scientific committee, consisting of an oncologist specialized in LC, three hospital pharmacists and two patient representatives, led and coordinated the project.

Literature Review
- Objective: to update the literature search conducted by ICHOM [4] amd identify publications related to health outcomes (clinical and PROs), instruments and periodicity, published between 01/01/2015 and 31/12/2017

First scientific committee meeting
- Objective: to propose the main variables to be evaluated during 4 nominal groups based on the ICHOM standard set and a literature review.

Nominal Groups (n=4)
- Objective: to reach consensus (≥75% of participants agreed) on the variables (instrument and periodicity) to include
- Participants: 14 hospital pharmacists, 13 oncologists, 4 hospital managers and 3 patients; from most Spanish

Second scientific committee meeting
- Objective: to review the results obtained during the 4 nominal groups. When consensus was not achieved among 4 nominal groups, the scientific committee determined its inclusion/exclusion.

Results

- **Target population** of the standard set included all Spanish patients with newly diagnosed LC, regardless of the disease stage, type or therapeutic option.
- Table 1 shows the variables selected to be included in the Spanish standard set in LC.

Table 1. Variables included in the Spanish standard set of patient-centered outcomes in LC.

CASE MIX VARIABLES

Patient profile	Variable	Supporting information	Measurement instrument	Timing	Data sources
Demographic factors					
All patients	**Age**		Date of birth	Baseline (before treatment begins)	Clinical
	Gender		Male / Female		Clinical
	Family support	Degree of family support and degree of patient dependence	Yes / No		Patient-reported
	Educational level	Level of schooling completed	(0) Without studies / (1) Primary school level / (2)Secondary school level / (3) Higher education		Patient-reported
Baseline clinical factors					
All patients	**Unintentional weight loss**		Yes / No / I don´t know	Baseline (before treatment begins)	Patient-reported
	Smoking status	Smoking status at diagnosis	(0) Never-smoker (<100 cigarettes in lifetime) / (1) Ex-smoker (stopped >1 year before diagnosis) / (2) Current smoker		Patient-reported
	Performance status		ECOG scale		Clinical
	Patient-reported health status		Tracked via generic questionnaire EQ-5D-5L and lung cancer specific questionnaire LCSS		Patient-reported
	Comorbidities		Charlson index		Clinical
	Pulmonary function	FEV_1	NA		Clinical
Treatment factors					
All patients	**Treatment intent**		(1) Curative/ (2) Palliative	Baseline (before treatment begins)	Oncologist-reported
	Completed treatment		(1) Yes, with dose reduction / (2) No, due to toxicity / (3) No, due to patient´s will / (4) No, due to patient´s death	At treatment ending	Oncologist-reported

NA: not applicable; ECOG: Eastern Cooperative Oncology Group; EQ-5D-5L: EuroQol; LCSS: Lung Cancer Symptoms Scale; FEV_1: forced expiratory volume;

Table 1. Variables included in the Spanish standard set of patient-centered outcomes in LC (Cont.).

CASE MIX VARIABLES

Patient profile	Variable	Supporting information	Measurement instrument	Timing	Data sources
Baseline tumor factors					
All patients	**Clinical stage**		TNM staging system	Baseline (before treatment begins)	Clinical
	Pathological stage		TNM staging system		Clinical
	Histology		NA		Clinical
	EGFR; ALK; ROS-1; PD-L1 *		Yes / No / Undetermined		Clinical

OUTCOMES VARIABLES

Patient profile	Variable	Supporting information	Measurement instrument	Timing	Data sources
Degree of health					
All patients	**Performance status**		ECOG scale	During follow-up visits	Clinical
	Patient-reported health status	Global health status, physical and emotional function	Tracked via generic questionnaire EQ-5D-5L and lung cancer specific questionnaire LCSS	At 3, 6 and 12 months. Later, tracked annually for life*	Patient-reported
		Fatigue, vitality, pain, cough, difficulty breathing, hemoptysis and loss of appetite	Tracked via lung cancer specific questionnaire LCSS		
Survival					
All patients	**Overall survival**		Date of death	NA	Administrative data (death registry)
	Cause of death	Tumor/ treatment related or not	NA		Clinical
Quality of death					
All patients	**Place of death**		NA	Date of birth	Administrative data (death registry)
	Aggressive intervention and palliative care	(1) patient receives antineoplastic therapy in last 14 days of life / (2) initiates a new therapeutic scheme in the last month of life / (3) goes to emergency room more than once in the last month of life or Intensive Care Unit admitted / (4) dies at an oncology unit instead of receiving palliative care / (5) patient does not receive palliative care before passing away / (6) dies while was receiving palliative care in the last 72 hours before hospital admission		30 days before death	Clinical
	Existence or doctor´s knowledge about the living will of patients		Yes / No	NA	Oncologist-reported
Acute complications of treatment					
Patient receiving surgical resection	**Major surgical complications**	(1) Secondary complication related to surgical care; (2) Urgent re-admission after the next 7 days post-discharge, for a cause related to surgical treatment; (3) Death after surgery (in the next 30 days)		NA	Clinical
Patient with systemic therapy or/and radiotherapy	**Major systemic therapy or/and radiotherapy complications**	Presence of grade ≥3	CTCAE	NA	Clinical
			PRO- CTCAE	NA	Patient reported
Others					
All patients	**Time from diagnosis**		Date of hospital admission or non-hospital consultation when data of the histological or cytological confirmation is unknown	At diagnosis	Clinical
	Time from diagnosis to treatment		NA	When treatment begins	Clinical
	Patient productivity loss	Sick leave or disability	Yes / No	NA	Patient reported

NA: not applicable; TNM: Tumor, Nodes, Metastasis; EGFR: Epidermal growth Factor Receptor; ALK: Anaplastic Lymphoma Kinase; ROS-1: ROS proto-oncogene 1 receptor tyrosine kinase; PD-L1: Programmed Death-ligand; *List of Biomarkers annually valuated and updated .ECOG: Eastern Cooperative Oncology Group; EQ-5D-5L: EuroQol; LCSS: Lung Cancer Symptoms Scale; *when treatment is changed, patient-reported health status will be evaluated at 3, 6 and 12 months; CTCAE: Common Terminology Criteria for Adverse events; PRO-CTCAE: Patient-Reported Outcomes version of the CTCAE

Conclusions

- Variables included in the present standard set are the most relevant for the follow-up of patients with LC in the Spanish setting. They can be routinely collected in clinical practice and both the technology and the instruments needed to measure them are available in Spain.
- Validation and adaptation of the ICHOM standard set to the Spanish setting may facilitate its implementation in clinical practice, paving the way to standardize LC variables collection.

References

1. Gralla et al. Thorac Oncol.; 2014;9:1243–8. **2.** Walker et al. Psychooncology. 2017;26:755–62. **3.** Migliorino et al. J Cancer Res Clin Oncol.; 2017;143:783–91. **4.** Mak et al. Eur Respir J 2016; 48: 852–860