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Impact of the iCODEX tool in routine clinical practice in Spain

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ABSTRACT

Introduction: The prognosis of COPD patients can be calculated using multidimensional indexes that improve the predictive capacity of the individual variables. The CODEX index can be calculated using iCODEX, a digital support tool available on the web and in an app. The aim of this study was to evaluate how the usefulness and applicability of iCODEX and its recommendations in routine clinical practice are perceived by specialists in internal medicine, pneumology, and primary care.

Methods: A cross-sectional study was conducted from November 2019 to February 2020 with the participation of specialists in internal medicine, primary care, and pneumology. All respondents completed a survey consisting of 104 questions on their perception of the iCODEX tool.

Results: Overall, 335 physicians responded. Of these, 95.2% had no difficulty accessing the tool and 83.1% were quite or very satisfied with it. Regarding the applicability and implementation of iCODEX recommendations in routine clinical practice, respondents reported that the recommendations were generally applicable: most questions obtained a median score of ≥ 4 out of 5. The recommendations with the greatest expected clinical benefit are listed.

Conclusions: Our study shows that the iCODEX tool is easy for participating specialists to use and identifies the recommendations that have the greatest clinical impact in areas such as lung obstruction, severe exacerbations, exercise, smoking, and patient follow-up.

Introduction

Chronic obstructive pulmonary disease (COPD) is defined as a preventable disease characterized by persistent respiratory symptoms and chronic airflow limitation, mainly caused by exposure to harmful particles or gases, such as tobacco smoke[1,2]. According to the Global Burden of Disease Study, the worldwide prevalence of COPD in 2016 was 251 million cases[3]. In Spain, according to data from the IBEREPOC, EPISCAN and EPISCAN II studies, the prevalence of COPD in the general population aged 40–69 years was 9.1%, and 10.2%–11.8% in individuals aged between 40 and 80 years[4–6]. Projections suggest that prevalence will increase in the coming years due to the aging of the population[3].

The prognosis of COPD patients is associated with a number of variables, such as degree of airflow limitation, frequency and severity of symptoms, number and severity of exacerbations, and co-existence of comorbidities. The use of multidimensional indexes improves the predictive capacity of the individual variables.

One of these multidimensional indexes is CODEX[7,8]. This tool, introduced in 2014, combines comorbidity measured with the age-adjusted Charlson index with other widely accepted prognostic variables, such as dyspnea, airflow obstruction, and severe exacerbations. The CODEX index has been validated externally in different populations and is used to predict mortality and the risk of hospital readmission[9–12].

Since 2017, it has been possible to calculate the CODEX index using iCODEX, a digital support tool available on the web and as an app. In 2019, this tool was extended to include, in addition to the CODEX score, a series of recommendations for clinicians treating COPD patients. These recommendations were developed by consensus and aim to improve the treatment of patients, not only by calculating their CODEX index but also by designing a personalized control and follow-up strategy for each individual[13]. The aim of this study was to evaluate how the usefulness and applicability of iCODEX and its recommendations in routine clinical practice are perceived by internal medicine, pneumology, and primary care professionals.

Methodology

A cross-sectional study was conducted over a 3.5-month period, from November 2019 to February 2020, with the

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participation of specialists in internal medicine, primary care, and pneumology.

The main objective was to evaluate the applicability in routine clinical practice of the expert recommendations reached by consensus using the iCODEX tool, and the secondary objectives were:

a. To evaluate the usability of the iCODEX tool.
b. Identify possible barriers to using the iCODEX tool.
c. Evaluate user satisfaction with the iCODEX tool.
d. Categorize the recommendations based on their clinical significance.
e. To assess the perception of the possible impact on readmissions and mortality.

All respondents completed a survey on their perception of the iCODEX tool. The questionnaire consisted of 104 questions and collected data on the demographic and professional characteristics of the respondents (19 items), iCODEX usability and user satisfaction (23 items), and applicability of the recommendations derived from the CODEX index (62 items). Recommendations were grouped into 5 blocks: recommendations on general care and patient follow-up, lung obstruction, dyspnea, comorbidities, and exacerbations. General recommendations referred to diet, exercise, smoking, vaccines, and disease monitoring, and addressed cardiovascular disease, renal impairment, diabetes, osteoporosis, and dementia. All questions on the recommendations were answered using a Likert-type scale of 0–5 points, with 0 being never, 1 very rarely, 2 rarely, 3 occasionally, 4 very frequently and 5 always.

Both the research protocol and the web questionnaire were developed in collaboration with a scientific advisory committee. Specialists were then invited to participate voluntarily in the survey by distributing flyers containing the access link, and physicians who had used the tool in at least 5 patients were selected. The study was conducted in routine clinical practice and was approved by the research ethics committee of the Hospital Mutua de Terrassa.

Statistical analysis

For both the main and the secondary objectives, a series of Likert-type questions were used to assess the degree of consensus among study respondents. For each of the different recommendations provided by iCODEX, a descriptive analysis of their applicability and expectations in terms of clinical benefit and patient follow-up was performed using bar diagrams and the proportions of "negative" and "positive" scores were calculated by splitting the scale into two halves. Mean and median scores per interval were also estimated.

We determined the existence of statistically significant differences in the score obtained for the items expected to have the clinical benefit that achieved a consensus of less than 90% according to the specialty of the participating physician and their age.

The data recorded in the study CRF were stored in a database and periodically reviewed by the monitor responsible for the study to detect missing information. This database included ranges and internal consistency rules to control the quality of the data entered.

The statistical analysis was conducted on a series of 335 evaluable respondents, comprising all respondents who met the selection criteria. Categorical variables were expressed as absolute and relative frequencies (percentages). Mean, standard deviation, median, minimum, and maximum values were used for the description of continuous variables, including the total number of valid values. Data analysis was performed using R, version 3.3.2 or later[14].

Results

Out of a total of 443 specialists who were invited, 335 specialists (76% of the total) from 15 different autonomous communities of Spain ended up participating in this study (Andalusia, Aragon, Asturias, Balearic Islands, Basque Country, Canary Islands, Cantabria, Castilla-La Mancha, Castilla-Leon, Catalonia, Community of Madrid, Extremadura, Galicia, Region of Murcia, and Valencian Community). Respondents were selected by the sponsor and they were remunerated. Overall, 51% of the respondents were specialists in internal medicine, 31% in primary care, and 18% in pneumology. Fifty-five percent (55%) were men, 45% were women, and the median age was 43.0 years. The median of years as a specialist was 13 years, and the approximate number of COPD patients visited in the last month was a median of 20 patients, being the pneumologists those who visited the higher number of COPD patients (median of 50) (Table 1).

Usability and satisfaction with the iCODEX tool

Overall, 319 (95.2%) respondents reported no difficulty in accessing the tool (95.3% internal medicine (IM); 100% pneumologists (P); 92.2% primary care (PC)). Scores were ≥ 4 for ease of use (86.6% of the respondents; 90.6% IM; 88.5% P; 78.6% PC), clarity of instructions (83%; 86% IM; 83.6% P; 77.7% PC), color choice (80%; 80.7% IM; 80.3% P; 78.6% PC), and usefulness for generating a simplified report (84.5%; 83.3% IM; 86.7% P; 85.4% PC).

Possible barriers to the use of the iCODEX tool were identified as follows: lack of time: 127 respondents (38.7% of respondents; 36.9% IM; 49.2% P; 33.0% PC); lack of diffusion: 27 (8.1%; 9.9% IM; 4.9% P; 6.8% PC); computer problems: 25 (7.5%; 8.8% IM; 1.6% P; 8.7% PC); lack of integration in computer systems: 16 (4.8%; 2.9% IM; 6.6% P; 6.8% PC); physicians who did not use new technologies: 11 (3.3%; 3.5% IM; 1.6% P; 3.9% PC); and difficulties encountered in use: 10 (3.0%; 2.9% IM; 1.6% P; 3.9% PC); and others.

Respondents' satisfaction with the tool was high; 274 (81.8%; 84.2% IM; 75.4% P; 81.6% PC) reported being quite or very satisfied. The average level of satisfaction with the CODEX index calculator was 4 and 278 respondents (83.0%; 87.1% IM; 77.0% P; 79.6% PC) were quite or very satisfied. The recommendations report received a score of 4 out of 5, and 246 (73.4%; 87.1% IM; 77.0% P; 79.6% PC) of the respondents stated that they were quite or very satisfied.

Table 1. General characteristics of the different specialty clinicians (internal medicine, pneumology and primary care).

	[ALL] N = 335	Internal medicine N = 171	Pneumology N = 61	Primary care N = 103	p. overall	N
Age, Median (P25, P75)	43.0 (35.0, 51.0)	42.0 (35.0, 49.0)	38.0 (32.0, 47.0)	47.0 (40.0, 56.0)	<0.001	335
Sex, n (%):					0.625	335
Men	184 (54.9%)	95 (55.6%)	36 (59.0%)	53 (51.5%)		
Women	151 (45.1%)	76 (44.4%)	25 (41.0%)	50 (48.5%)		
Year of specialty obtained, Median (P25, P75)	2007 (1999, 2015)	2008 (2001, 2016)	2012 (2003, 2016)	2003 (1994, 2010)	<0.001	335
Number of years as a specialist, Median (P25, P75)	13.0 (5.00, 21.0)	12.0 (4.50, 19.0)	8.00 (4.00, 17.0)	17.0 (10.5, 26.0)	<0.001	335
Approximate number of COPD patients visited in the last month, Mediana (P25, P75)	20.0 (12.0, 30.0)	15.0 (10.0, 25.0)	50.0 (25.0, 65.0)	20.0 (10.0, 30.0)	<0.001	335
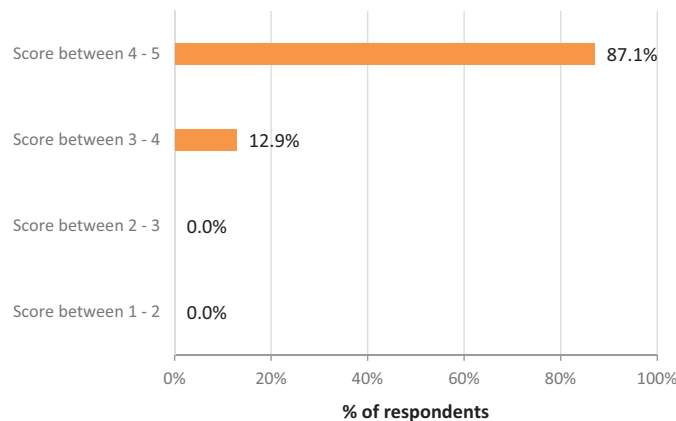
Figure 1. iCODEX tool recommendation applicability, median score.

Applicability and implementation of iCODEX in routine clinical practice

In terms of the main objective, respondents generally reported that the consensus expert recommendations reflected in the iCODEX tool are applicable in routine clinical practice, with a median score of 4 or more being obtained in most questions (maximum score of 5) (Figure 1). Only a few questions in the sections on exercise, patient follow-up, and severe exacerbations obtained a median score of 3 (Table 2). More than 40% of respondents also stated that they did not implement any of the consensus recommendations before using the iCODEX tool (Table 3) and they believed that these recommendations would be useful in the future.

The recommendations that respondents expected to yield greater clinical benefit (100% positive opinion) are listed in Table 4 in order of clinical importance. Recommendations that respondents expected to yield less clinical benefit (opinion <90% positive) are listed in Table 5.

It should be noted that for some of the issues for which the positive opinion of the respondents was less than 90%, there were statistically significant differences among the different specialties and the age of the respondents. Thus, pneumology specialists considered recommendations on the use of metformin in the treatment of diabetes and on the management of cognitive impairment to be less relevant. Internal medicine specialists, for their part, implemented the recommendation on the use of roflumilast and mucolytics to a lesser extent, whereas primary care specialists found the age criteria

recommendation for chest CT screening for lung cancer the least applicable. By age, respondents aged 36–50 believed that the recommendation on the use of calcium and vitamin D supplements to prevent osteoporosis was less applicable, compared to respondents in the other age groups (Table 6).

In assessing the perception of the potential impact on readmissions and mortality of the iCODEX recommendations, 96.7% of respondents considered that their implementation could influence the assessment of these risks in COPD patients. Finally, it is remarkable that 9% of respondents use the iCODEX tool in more than 20 patients. Among the barriers to the use of the tool, 38.7% of the respondents identified a lack of time. Most of them use it after the visit (48%) and more than 22% use it prior to the visit.

Discussion

The implementation of any type of new tool in daily clinical practice is often complicated, even if it has proven benefit or utility. There are various reasons for these difficulties, but they may include the burden of care, entrenched behavior, and distrust or resistance to innovation. There is no universal solution; instead, the implementation process must be gradual and dynamic, and adapted and realigned in response to the results of ongoing evaluations.

The CODEX index was developed and validated in 2014 as an easy-to-use tool for predicting survival and hospital readmission at 3 and 12 months after hospital discharge following an exacerbation of COPD, with a prognostic capacity greater than previously published indexes[7].

The iCODEX, introduced as a digital tool in 2019, not only facilitates the use of this index in the routine clinical practice of physicians, it also includes recommendations based on the different components of the index, aimed at personalizing patients' therapeutic management, thus adding value beyond the prognosis for survival and hospital readmittance at 3 and 12 months after hospital discharge after a COPD exacerbation[13]. The iCODEX tool is now available, and this study seeks to understand how its usefulness and applicability are perceived in clinical practice. The study respondents reported a high level of satisfaction with the tool, including both the CODEX index calculator and the recommendations: 81.9% indicated that they were quite or very satisfied.

The fact that most respondents use the tool prior to or after the visit indicates that it can provide useful information

Table 2. Recommendations with the lowest median score (between 3 and 4) for the question on applicability of the iCODEX tool recommendations in routine clinical practice.

General
- Annual lung cancer screening with low-dose computed tomography (CT) is indicated in smokers aged 55–74 years with a pack-year index of 30 or more.

Physical exercise
- In patients with COPD, the risk of osteoporotic fractures must be estimated with the FRAX tool and a lateral chest X-ray should be performed to rule out osteoporotic vertebral compression fractures.
- Bone densitometry is required in postmenopausal women and men over 55 years of age weighing <70 kg or with a body mass index <21.

Patient follow-up
- The regular physician of patients hospitalized for an exacerbation should be informed by email of their admission and, in particular, their planned date of discharge, 24–48 hours in advance to facilitate patient follow-up after they return home. Medication reconciliation should also be performed prior to discharge, and information on any changes in the chronic treatment of patients should be provided in writing.
- Patients who are not institutionalized and/or do not have mobility problems and who are discharged from hospital after an exacerbation should be assessed in a face-to-face visit by their primary care team within 72–96 hours to assess clinical status and therapeutic adherence, with special emphasis on a correct inhalation technique.
- After discharge from the hospital after a severe exacerbation, patients should be seen in the specialist outpatient clinic of the hospital within 1–2 months to review their progress, adjust their medication and check their inhalation technique, except for patients with difficulties travelling to the site.

Exacerbations
- Respiratory rehabilitation is recommended to prevent acute exacerbations in patients with moderate or severe COPD who have had a recent exacerbation.
- In a highly selected group of patients with advanced COPD (patients with FEV1 ≤45% and bilateral emphysema on chest CT), lung volume reduction surgery to reduce exacerbations will be assessed.

Table 3. Recommendations not implemented by experts before using the iCODEX tool.

General
- CT screening for lung cancer should not be performed in asymptomatic individuals under 55 or over 74 years of age, in patients who stopped smoking more than 15 years previously, or who have severe comorbidities that would potentially prevent curative treatment and/or have a limited life expectancy. *Not implemented by 42.3% of respondents; median 3; CI 2–4*

Physical exercise
- In patients with COPD, the risk of osteoporotic fractures must be estimated with the FRAX tool and a lateral chest X-ray should be performed to rule out osteoporotic vertebral compression fractures. *Not implemented by 42.2% of respondents; median 3; CI 2–3*
- Bone densitometry is required in postmenopausal women and men over 55 years of age weighing < 70 kg or with a body mass index < 21. *Not implemented by 45.3% of respondents; median 3; CI 2–3*

Diet
- A high-calcium, high-vitamin D diet should be recommended for all patients to prevent osteoporosis. *Not implemented by 44.9% of respondents; median 3; CI 2–3*

Table 4. Recommendations expected to yield the greatest clinical benefit according to experts.

Lung obstruction
- In patients with FEV1 < 50% and dyspnea mMRC grade 0–1, the initial treatment should be a long-acting bronchodilator (BD) (preferably a LAMA), if not previously prescribed. If symptoms or exacerbations persist, a second BD should be added and the response should be evaluated. Since many patients do not report dyspnea due to decreased activity, patients with persistent exacerbations should be directly questioned about dyspnea, and the combination of LABA + ICS may be considered as an alternative to dual BD or triple therapy (TT) with LABA + LAMA + ICS. *Positive opinion 100% of respondents; median 4; CI 4–4*
- Patients with FEV1 ≥ 50% and high-risk criteria (mMRC ≥ 2 despite treatment and ≥ 2 moderate exacerbations or 1 exacerbation requiring hospitalization in the last year) should receive LAMA + LABA combination as the first choice, except for mixed asthma-COPD overlap phenotypes, for whom the combination LABA + ICS is indicated. If control is insufficient, the phenotype should be identified and new drugs should be added accordingly. *Positive opinion 100% of respondents; median 4; CI 4–4*

Severe exacerbations
- Long-acting bronchodilators (LAMA/LABA) reduce the number of exacerbations. *Positive opinion 100% of respondents; median 4; CI 4–4*
- In patients with frequent exacerbations despite optimal BD treatment, the addition of an ICS is indicated. *Positive opinion 100% of respondents; median 4; CI 4–5*
- Both LABAs and LAMAs reduce the risk of exacerbations, although, in monotherapy, LAMAs are superior. *Positive opinion 100% of respondents; median 4; CI 4–5.* In exacerbations:
  - If the patient has exacerbations with a LABA or a LAMA, dual BD therapy should be initiated.
  - If the patient's exacerbations persist, the addition of an ICS is indicated (LABA + LAMA + CI).
  - If exacerbations persist despite treatment, roflumilast may be added if FEV1 is less than 50% and the patient has criteria for chronic bronchitis.
  - Long-term macrolide treatment may be initiated in selected patients with chronic bronchitis.
  - Mucolytics can also decrease exacerbations.

Smoking
- Non-pharmacological measures, such as smoking cessation, should be reevaluated in all patients. *Positive opinion 100% of respondents; median 4; CI 4–5*

Physical exercise
- Non-pharmacological measures, such as physical exercise, should be reevaluated in all patients. *Positive opinion 100% of respondents; median 5; CI 4–5*

Patient follow-up
- In patients with criteria for chronic bronchitis, the presence of bronchiectasis should be investigated in a chest CT scan, especially in the case of exacerbators. *Positive opinion 100% of respondents; median 4; CI 4–5*

for preparing for the patient visit and for making recommendations to patients. The use of the tool after the visit may be the result of a lack of time during the visit.

The applicability of the recommendations made by the iCODEX tool received a high score, while the scores for recommendations on physical exercise, patient follow-up, and severe

Table 5. Recommendations expected to yield less clinical benefit according to experts.

Diabetes
- All patients with diabetes should be treated with metformin unless contraindicated. *Positive opinion 88.4% of respondents; median 4; CI 4–5*

Dementia
- Patients with cognitive impairment should be treated similarly to patients without COPD. *Positive opinion 87.9% of respondents; median 3; CI 3–4*

Severe exacerbations
- The addition of roflumilast to bronchodilator treatment will be assessed in patients with FEV1 < 50% with at least one exacerbation in the last year despite treatment and chronic bronchitis phenotype. *Positive opinion 87.9% of respondents; median 3; CI 3–4*
- Mucolytics may be used to prevent exacerbations in patients with moderate-severe COPD and 2 or more exacerbations in the last year. *Positive opinion 72.7% of respondents; median 3; CI 3–3*
- In a highly selected group of patients with advanced COPD (patients with FEV1 ≤ 45% and bilateral emphysema on chest CT), lung volume reduction surgery to reduce exacerbations will be assessed. *Positive opinion 84.8% of respondents; median 3; CI 3–4*

General
- CT screening for lung cancer should not be performed in asymptomatic individuals under 55 or over 74 years of age, or in patients who stopped smoking more than 15 years previously or who have severe comorbidities that would potentially prevent curative treatment and/or have a limited life expectancy. *Positive opinion 84.4% of respondents; median 4; CI 3–4*

Diet
- A high-calcium, high-vitamin D diet should be recommended for all patients to prevent osteoporosis. *Positive opinion 88.9% of participants; median 4; CI 4–4*

Table 6. Analysis of the recommendations expected to have the lowest clinical benefit. Statistically significant differences according to specialty and patient age.

Pneumology specialists
- Pneumologists gave the lowest score to the recommendation "All patients with diabetes should be treated with metformin unless contraindicated".
  - What is your expectation of clinical benefit if this recommendation is applied to all patients in whom it is indicated? ($p = 0.00012$)
  - To what extent do you consider this recommendation to be applicable? ($p = 0.00016$)
  - Before using iCODEX tool, did you implement this recommendation in your patients? ($p = 0.00053$)
  - Do you think that having the iCODEX tool might make it easier for you to implement this recommendation in patients in whom it is indicated? ($p = 0.00087$)
- They considered to a lesser extent that using the iCODEX tool effectively facilitated the implementation of the recommendation "*Patients with cognitive impairment should be treated similarly to patients without COPD*" in patients in whom it is indicated. This difference is statistically significant ($p = 0.01085$).

Internal medicine specialists
- Internists indicated that before the iCODEX tool was available, they implemented the recommendation "*The addition of roflumilast to BD treatment will be assessed in patients with FEV1 < 50% with at least one exacerbation in the last year despite treatment and chronic bronchitis phenotype*" to a lesser extent than the other specialists. This difference was statistically significant ($p = 0.01277$).
- They implemented the recommendation "*Mucolytics may be used to prevent exacerbations in patients with moderate-severe COPD and 2 or more exacerbations in the last year*" to a lesser extent before using the iCODEX tool.
  - To what extent do you consider this recommendation to be applicable? ($p = 0.04513$)
  - Before using the iCODEX tool, did you implement this recommendation in your patients? ($p = 0.03847$)

Primary care specialists
- Primary care specialists found the following recommendation most applicable: "*Mucolytics may be used to prevent exacerbations in patients with moderate-severe COPD and 2 or more exacerbations in the last year*" (Primary care mean score: 4.11; Pneumologists mean score: 3.73; Internists mean score: 3.41).
- Before using the iCODEX tool, primary care specialists found the following recommendation least applicable: "*CT screening for lung cancer should not be performed in asymptomatic individuals under 55 or over 74 years of age, or in patients who stopped smoking more than 15 years previously or who have severe comorbidities that would potentially prevent curative treatment and/or have a limited life expectancy*" (Primary care mean score: 3.21; Internists mean score: 3.71; Pneumologists mean score: 3.79).

Age
- Respondents aged 36–50 years were those who believed that the recommendation "*A high-calcium, high-vitamin D diet should be recommended for all patients to prevent osteoporosis*" was less applicable ($p = 0.01752$).

exacerbations were lower (see Table 2). This is possibly due to the scant implementation of respiratory rehabilitation and the limited access to services of this type. In the area of exacerbations, recommendations related to treatments other than bronchodilators, such as mucolytics or lung volume reduction surgery for preventing exacerbations were scored lower, perhaps because the beneficial effect of these approaches is often questioned. Difficulties surrounding the applicability of the recommendations for patient follow-up reported by some of the respondents are likely to be attributable more to the burden of care than to the appropriateness of their implementation. It has to be noted that as the study only included respondents who used the iCODEX in at least 5 patients, respondents included in the sample were likely to have a more favorable perception of the iCODEX and may not be representative of the general physician population.

It is worth noting that 40% of respondents did not implement certain recommendations before using the iCODEX tool, and this tool can help physicians increase their use of the consensus recommendations. Many of the recommendations that would be implemented with the use of the tool address comorbidities, such as osteoporosis or cardiovascular disease, pathologies that are common in COPD patients, but still under-recognized and undertreated. We believe that the recommendations of the iCODEX tool are especially useful in managing comorbidities in COPD patients, and this approach will lead to a better quality of life and prognosis for our patients. We also believe that the dissemination of the usefulness that we found in its use by reviewing all the recommendations that should be reviewed for comprehensive management of the COPD patient will stimulate the use of it. It will also be necessary to demonstrate the clinical benefit that COPD patients obtain by applying the iCODEX recommendations, which will emphasize the use of this tool, and which will be the subject of other work.

Limitations

This study has some limitations. Firstly, although the sample size was calculated at 385 eligible cases with a margin of error of ±5%, and, assuming 18% of ineligible cases, 470 physicians had to be recruited. Finally, a sample of 335 eligible cases was obtained, resulting in an ±5.4% error in the estimated proportions, so the study findings were not affected. Secondly, participation was voluntary, and the 3 groups of medical specialties that participated in the study were not balanced.

Conclusions

This study showed that iCODEX is a user-friendly tool for internal medicine, primary care, and pneumology specialists that helps them implement recommendations that were previously overlooked in routine clinical practice. The study also defined the recommendations that have the greatest clinical impact in areas such as lung obstruction, severe exacerbations, exercise, smoking, and patient follow-up.

The aim of this survey was to conduct an initial assessment of the perception of the usefulness and applicability of the iCODEX tool and its recommendations in the clinical practice of internal medicine, primary care and pneumology specialists involved in the care of COPD patients. It would be of interest in the future to design a study to evaluate the clinical benefit obtained by the patients in whom the recommendations suggested by the tool have been implemented.

Transparency

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Author contributions

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