

Original Research

COPD Exacerbation Recognition Tool: Translation, Linguistic, and Cross-Cultural Validation

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Abstract

Background: The Chronic Obstructive Pulmonary Disease (COPD) Exacerbation Recognition Tool (CERT) was developed to improve patients' recognition of COPD exacerbations. This validation study concerned the cross-cultural and linguistic validation of 46 CERT translations across 25 countries and 6 continents.

Methods: This study employed a rigorous, certified (International Organization for Standardization-17100) methodology. Dual forward translations for each language were developed by independent translators who were native speakers of the target language and then reconciled by a linguistic validation consultant (LVC). Independent linguists provided a back translation of the reconciled translation, which was reviewed by the LVC and project manager. Linguistic validation was performed for each language through cognitive debriefing interviews with at least 5 participants with COPD who were native speakers of the target language. These participants also reviewed 7 sets of images produced for different global regions to reflect patients from a diversity of cultures, countries, and religions, to determine if the images were representative of themselves and/or other people living with COPD. The images were amended as needed and reshown to the participants for approval.

Results: The translations were found to be conceptually equivalent to the original CERT and harmonized with each other. Participants found the CERT easy to use and understand and confirmed that the images were representative of themselves and/or other people living with COPD.

Conclusions: CERT translations were created using a patient-centric approach and appear to be easily understandable and valid across many languages and cultures.

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Abbreviations:

CERT=COPD Exacerbation Recognition Tool; **CERT-J**=COPD Exacerbation Recognition Tool-Japan; **COPD**=chronic obstructive pulmonary disease; **FDA**=Food and Drug Administration; **GAAPP**=Global Allergy and Airways Patient Platform; **LVC**=linguistic validation consultant; **PACE**=Predictors of Acute COPD Exacerbation study

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COPD; education; exacerbation; patient-centered

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Introduction

Chronic obstructive pulmonary disease (COPD) is one of the leading causes of morbidity and mortality worldwide and has a considerable economic burden.^{1,2} COPD exacerbations have been shown to increase health care resource utilization and costs and to negatively impact patients' quality of life.³ Exacerbation frequency is an important determinant of lung function decline⁴; as exacerbation frequency and severity increases, the risk of future exacerbations and mortality also increases.⁵ Despite this, patients experience difficulty recognizing an exacerbation,⁶ and approximately 40% of COPD exacerbations are not immediately reported by patients.⁷⁻¹⁰ Additionally, patients have been shown to report exacerbations in some instances, but not in others.¹⁰ Opportunities for treatment changes can, therefore, be missed, and this may have a subsequent impact on health status.^{11,12}

The COPD Exacerbation Recognition Tool (CERT) was first developed in China to help patients recognize when they are experiencing a COPD exacerbation and to encourage them to seek prompt medical assessment.¹³ The development study aimed to identify the words and phrases used by patients in China to describe symptoms associated with the onset of a COPD exacerbation.¹³ The key symptoms identified were worsening cough, increased sputum volume, shortness of breath, labored breathing, and limitation of activity.¹³ Moderate or severe worsening in at least 2 of these symptoms relative to the patient's usual state had good sensitivity (91.8%) and specificity (100%) for an exacerbation.¹³ A recent study conducted in China in a different population of patients with COPD has shown that the CERT has high sensitivity (92.4%) and specificity (72.1%) for moderate and severe exacerbations.¹⁴ A second developmental study took place in Japan, independently of the development of the CERT in China.¹⁵ Using similar methodology to the original CERT study, this Japan-specific CERT identified the same symptoms as those listed in the original CERT, with the addition of a sixth symptom (change in sputum color) that was added at the request of physician advisors.¹⁵

Another recent study, conducted in Germany, used

a German translation of the CERT items in the form of a daily diary to determine whether the tool could identify the onset of a COPD exacerbation.¹⁶ Patient responses to the CERT when it was used in this way were shown to predict exacerbations one day before the clinical diagnosis was made and showed good sensitivity and specificity (70% and 91%, respectively).¹⁶

To improve the accessibility of the CERT, it has been translated into over 60 languages, taking care to ensure that the translations were conceptually equivalent to the original, comparable across languages, culturally relevant to the context of the target country, and easily understood by patients. To this aim, we conducted a cross-cultural and linguistic validation of 46 CERT translations. In this paper we focus the results on 5 translation languages from 5 different regions that represent a broad range of cultures and geographic scope: Indonesian, Korean, Norwegian, Spanish for use in Latin America, and Universal Arabic (Modern Standard).

Materials and Methods**COPD Exacerbation Recognition Tool Translation**

The original version of the CERT, written in Simplified Chinese (Mandarin), was translated into English.¹³ The translations and cultural and linguistic validation of the CERT employed rigorous, certified (International Organization for Standardization-17100) methodology and were performed in accordance with Food and Drug Administration (FDA) guidance¹⁷ and industry standards.^{18,19} This ensured that the translation was conceptually equivalent to the original English translation and harmonized with other translations. A total of 46 CERT translations across 25 countries and 6 continents were linguistically and culturally validated in this study (Table 1). An overview of the CERT translation process is shown in Figure 1.

Preparation and Concept Definitions:

An overview of the preparation of CERT translations and concept definitions is included in the online supplement. The concept elicitation guide is presented in Supplemental Table 1 in the online supplement.

Dual Forward Translations:

Two forward translations were developed by independent translators who were native speakers of the target language, fluent in English, and experienced in the translation of clinical outcome assessment measures.

Reconciliation of Forward Translations:

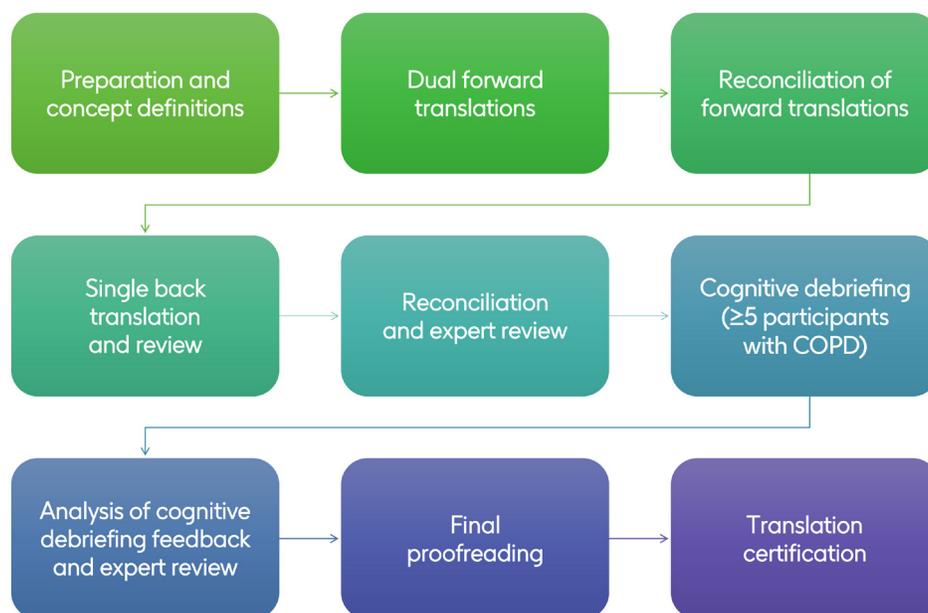
A linguistic validation consultant (LVC) reconciled the 2

Table 1. COPD Exacerbation Recognition Tool Translations That Were Culturally and Linguistically Validated

Country	Language
Australia	English
Belgium	Dutch, French, German
Brazil	Portuguese
Canada	English, French
Cuba	Latin-American Spanish ^a
Denmark	Danish
Egypt	Universal Modern Standard Arabic
Finland	Finnish, Swedish
France	French
Germany	German
India	Assamese, Bengali, Gujarati, Hindi, Kannada, Malayalam, Marathi, Oriya, Punjabi, Tamil, Telugu, Urdu
Indonesia	Indonesian
Korea	Korean
Mexico	Latin-American Spanish ^a
Netherlands	Dutch
Norway	Norwegian
Philippines	Cebuano, English, Hiligaynon, Ilocano, Tagalog
Saudi Arabia	Universal Modern Standard Arabic
Spain	Spanish
Sweden	Swedish
Taiwan	Traditional Chinese
Thailand	Thai
Turkey	Turkish
United Kingdom	English
United Arab Emirates	Universal Modern Standard Arabic
United States	English, ^b Latin-American Spanish ^a

^aLinguists from these Latin-American countries reviewed the forward translation prior to cognitive debriefing interviews, but the forward translator was not debriefed with participants from these countries.

^bTranslation from Traditional Chinese used as a source

Figure 1. COPD Exacerbation Recognition Tool Translation Process

COPD=chronic obstructive pulmonary disease

forward translations into a third translation by comparing, choosing, and combining the most appropriate translation and/or wording from the 2 initial translations, while ensuring that the reconciled version was conceptually equivalent to the English translation.

Single Back Translation and Review:

A back translation of the reconciled translation was provided by independent linguists in the source language. In each case, the back translator was fluent in the target language and English, and had no prior knowledge of the original CERT. The back translations were reviewed against a U.S.-English translation of the Simplified Chinese source

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CERT by the project manager, who directed any queries to the LVC. The LVC then refined the translation to correct any discrepancies or errors based on recommendations and comments from the back review.

Reconciliation and Expert Review:

The translation was submitted to the expert reviewers, who reviewed the decisions that had been made throughout the translation process up to this point. Any comments or questions that arose from this review were discussed between the project manager and the LVC until they were resolved.

Cognitive Debriefing:

Linguistic validation was achieved through a series of individual interviews with at least 5 participants with COPD, conducted by the LVC. To be included in this study, participants needed to be diagnosed with COPD, aged ≥ 18 years (ideally ≥ 45 years as COPD is more prevalent in mature individuals²⁰), and native speakers of the target language. We aimed to include participants of a mix of genders (ideally 2 males and 3 females, due to expected increase in prevalence of COPD in females compared with males²¹), educational backgrounds, and socioeconomic statuses. An overview of the interview process is included in the online supplement.

Analysis of Cognitive Debriefing Feedback and Expert Review:

An overview of the analysis of cognitive debriefing feedback and expert review is included in the online supplement.

Proofreading:

An overview of the proofreading process is included in the online supplement.

Cultural Adaptation of the Images

In addition to the creation of culturally appropriate wording, 7 sets of images were produced for different global regions, including Mexico, the United States (Spanish-speaking population), the Philippines, Central and South America, Western Europe and Australia, India and Asia-Pacific, the Middle East, and Turkey. These images were tested in the same participants who were involved in the linguistic validation of the CERT, to determine if the participants thought that the images represented them. Prior to interviewing the participants, the questions were developed using a single forward translation of the questions from English into the target language. Participants were asked the following questions:

1. Do you feel these images (skin color, eye color, hair color, hair texture, hair length, hair style, facial features, clothing, accessories, apparent age, etc.) represent you?
2. Do you feel these images (skin color, eye color, hair color, hair texture, hair length, hair style, facial features, clothing, accessories, apparent age, etc.) represent patients with your condition?
3. How do these images make you feel?
4. Anything else you would like to share about these images?

The images were then updated based on the feedback according to different cultures, demographics, and countries via an iterative process.

Ethics Approval and Informed Consent

As this study exclusively involved translations, no personally identifiable information or protected health information was collected, and there was no drug intervention. Therefore, institutional review board approval was not needed. Additionally, study results were in tabular form, and aggregated analyses omitted participant identification. Prior to involvement in the linguistic and cultural validation of the CERT, participants were given a standardized form in their native language that explained the nature of the linguistic validation, how the cognitive debriefing interviews would be conducted, and how their feedback would be used. Details concerning privacy and data protection were also included. Informed consent was obtained from all participants who contributed to the linguistic and cultural validation of CERT translations. This study complied with all applicable laws regarding participant privacy, as described in the Declaration of Helsinki.

Results

Examples of the CERT translated into different languages, along with representative images, are shown in Figure 2.

A total of 212 participants with COPD were involved in the whole translation program across all 46 CERT translations. An overview of the demographics and characteristics of participants included in the cognitive debriefing interviews for 5 CERT translations are included in Supplemental Table 2 in the online supplement.

During the cognitive debriefing stage (when participants were asked to reword the instructions, items, and responses in the CERT to confirm their understanding), most participants demonstrated good comprehension of the tool (Table 2; Supplemental Table 3 in the online supplement). In instances where phrases in a CERT translation were interpreted slightly differently than intended by a majority of

Figure 2. Examples of the COPD Exacerbation Recognition Tool in Different Languages

Select the most accurate description for you today compared with your usual state.

<p>English (UK)</p>	 <p>Worsening cough</p> <p>As usual <input type="radio"/></p> <p>Mild <input type="radio"/></p> <p>Moderate <input type="radio"/></p> <p>Severe <input type="radio"/></p>	 <p>Increased volume of sputum</p> <p>As usual <input type="radio"/></p> <p>Mild <input type="radio"/></p> <p>Moderate <input type="radio"/></p> <p>Severe <input type="radio"/></p>	 <p>Shortness of breath</p> <p>As usual <input type="radio"/></p> <p>Mild <input type="radio"/></p> <p>Moderate <input type="radio"/></p> <p>Severe <input type="radio"/></p>	 <p>Laboured breathing</p> <p>As usual <input type="radio"/></p> <p>Mild <input type="radio"/></p> <p>Moderate <input type="radio"/></p> <p>Severe <input type="radio"/></p>	 <p>Limitation of activity</p> <p>As usual <input type="radio"/></p> <p>Mild <input type="radio"/></p> <p>Moderate <input type="radio"/></p> <p>Severe <input type="radio"/></p>
<p>Arabic translation</p>	 <p>محدونية النشاط</p> <p>كالمعتاد <input type="radio"/></p> <p>خفيف <input type="radio"/></p> <p>متوسط <input type="radio"/></p> <p>شديد <input type="radio"/></p>	 <p>صعوبة في التنفس</p> <p>كالمعتاد <input type="radio"/></p> <p>خفيف <input type="radio"/></p> <p>متوسط <input type="radio"/></p> <p>شديد <input type="radio"/></p>	 <p>ضيق تنفس</p> <p>كالمعتاد <input type="radio"/></p> <p>خفيف <input type="radio"/></p> <p>متوسط <input type="radio"/></p> <p>شديد <input type="radio"/></p>	 <p>زيادة كمية البلغم</p> <p>كالمعتاد <input type="radio"/></p> <p>خفيف <input type="radio"/></p> <p>متوسط <input type="radio"/></p> <p>شديد <input type="radio"/></p>	 <p>تفاقم السعال أو زيادة شدة الكحة</p> <p>كالمعتاد <input type="radio"/></p> <p>خفيف <input type="radio"/></p> <p>متوسط <input type="radio"/></p> <p>شديد <input type="radio"/></p>
<p>Chinese translation</p>	 <p>咳嗽恶化</p> <p>和平常一樣 <input type="radio"/></p> <p>輕度 <input type="radio"/></p> <p>中度 <input type="radio"/></p> <p>重度 <input type="radio"/></p>	 <p>痰量增加</p> <p>和平常一樣 <input type="radio"/></p> <p>輕度 <input type="radio"/></p> <p>中度 <input type="radio"/></p> <p>重度 <input type="radio"/></p>	 <p>呼吸急促</p> <p>和平常一樣 <input type="radio"/></p> <p>輕度 <input type="radio"/></p> <p>中度 <input type="radio"/></p> <p>重度 <input type="radio"/></p>	 <p>呼吸費力</p> <p>和平常一樣 <input type="radio"/></p> <p>輕度 <input type="radio"/></p> <p>中度 <input type="radio"/></p> <p>重度 <input type="radio"/></p>	 <p>活動受限</p> <p>和平常一樣 <input type="radio"/></p> <p>輕度 <input type="radio"/></p> <p>中度 <input type="radio"/></p> <p>重度 <input type="radio"/></p>
<p>French translation</p>	 <p>Aggravation de la toux</p> <p>Comme d'habitude <input type="radio"/></p> <p>Légère <input type="radio"/></p> <p>Modérée <input type="radio"/></p> <p>Sévère <input type="radio"/></p>	 <p>Augmentation du volume des expectorations</p> <p>Comme d'habitude <input type="radio"/></p> <p>Légère <input type="radio"/></p> <p>Modérée <input type="radio"/></p> <p>Sévère <input type="radio"/></p>	 <p>Essoufflement</p> <p>Comme d'habitude <input type="radio"/></p> <p>Léger <input type="radio"/></p> <p>Modéré <input type="radio"/></p> <p>Sévère <input type="radio"/></p>	 <p>Respiration laborieuse</p> <p>Comme d'habitude <input type="radio"/></p> <p>Légère <input type="radio"/></p> <p>Modérée <input type="radio"/></p> <p>Sévère <input type="radio"/></p>	 <p>Limitation des activités</p> <p>Comme d'habitude <input type="radio"/></p> <p>Légère <input type="radio"/></p> <p>Modérée <input type="radio"/></p> <p>Sévère <input type="radio"/></p>
<p>Hindi translation</p>	 <p>बिगड़ती हुई खासी</p> <p>हमेशा की तरह <input type="radio"/></p> <p>हल्की <input type="radio"/></p> <p>मध्यम <input type="radio"/></p> <p>तीव्र <input type="radio"/></p>	 <p>अधिक मात्रा में बलगम</p> <p>हमेशा की तरह <input type="radio"/></p> <p>हल्का <input type="radio"/></p> <p>मध्यम <input type="radio"/></p> <p>तीव्र <input type="radio"/></p>	 <p>सांस फूलना</p> <p>हमेशा की तरह <input type="radio"/></p> <p>हल्का <input type="radio"/></p> <p>मध्यम <input type="radio"/></p> <p>तीव्र <input type="radio"/></p>	 <p>सांस लेने में कठिनाई</p> <p>हमेशा की तरह <input type="radio"/></p> <p>हल्की <input type="radio"/></p> <p>मध्यम <input type="radio"/></p> <p>तीव्र <input type="radio"/></p>	 <p>गतिविधि की सीमा</p> <p>हमेशा की तरह <input type="radio"/></p> <p>हल्की <input type="radio"/></p> <p>मध्यम <input type="radio"/></p> <p>तीव्र <input type="radio"/></p>
<p>Spanish translation</p>	 <p>Empeoramiento de la tos</p> <p>Como es habitual <input type="radio"/></p> <p>Leve <input type="radio"/></p> <p>Moderado <input type="radio"/></p> <p>Grave <input type="radio"/></p>	 <p>Mayor volumen de esputo</p> <p>Como es habitual <input type="radio"/></p> <p>Leve <input type="radio"/></p> <p>Moderado <input type="radio"/></p> <p>Grave <input type="radio"/></p>	 <p>Falta de aliento</p> <p>Como es habitual <input type="radio"/></p> <p>Leve <input type="radio"/></p> <p>Moderada <input type="radio"/></p> <p>Grave <input type="radio"/></p>	 <p>Respiración fatigosa (o dificultosa)</p> <p>Como es habitual <input type="radio"/></p> <p>Leve <input type="radio"/></p> <p>Moderada <input type="radio"/></p> <p>Grave <input type="radio"/></p>	 <p>Actividad limitada</p> <p>Como es habitual <input type="radio"/></p> <p>Leve <input type="radio"/></p> <p>Moderada <input type="radio"/></p> <p>Grave <input type="radio"/></p>

If you choose at least two items in red, you are probably experiencing a COPD exacerbation, and should visit your doctor.

The actual CERT consists of a single row of images in a single language

CERT=COPD Exacerbation Recognition Tool; COPD=chronic obstructive pulmonary disease; UK=United Kingdom

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Table 2. General Participant Feedback on the COPD Exacerbation Recognition Tool Obtained During the Cognitive Debriefing Interviews

Language	Participant Responses
Indonesian Translation (Indonesia) (N=5)	R1: Well understand. R2: Well understand. R3: Well understand. R4: Well understand. R5: Well understand. LVC general comments: The questionnaire is well understood by the respondents.
Korean Translation (South Korea) (N=5)	R1: Easy, clear. No difficulty in choosing 1 answer among the 4; the answer choices are clearly differentiated. R2: Nothing's difficult; clear. R3: Generally easy, clear; Answer choices are distinct and no difficulty in choosing 1 answer. R4: It's simple. No difficult words, and clear to understand. But I wonder what are the criteria of the answer choice severities, whether it's from patients' position or healthy people's position. It would also be different for people of different ages. So, you need to add a clause giving that information. R5: It's about the symptoms COPD patients have. The symptoms are severe for some, and mild for others. So, this questionnaire is asking to know if a patient's symptoms are mild or severe. Nothing's difficult and all are clear. No difficulty in choosing the answer among the answer choices. The answer choices are clearly different between each other. LVC general comments: Respondents didn't find any item, question items or answer choices, difficult or unclear by itself. But I'm not sure of their distinction between "shortness of breath" and "labored breathing," and their understanding of answer choices are not in line with the author's intention as can be presumed from the composition of the questionnaire. These 2 issues are those that I think require checking with the author with him being given the report of respondents' suspected lack of clear and accurate distinction between 2 question items and the discrepancy in their reasonable understanding the answer choices from the suspected intention of the author.
Latin-American Spanish Translation (N=9; U.S.=3, Argentina=3, Colombia=3)	R1: It is an easy survey to answer, the images fit perfectly to each of the symptoms. A relatively short survey. R2: It's short and easy to fill out. No problem at all. R3: It's a survey about this illness and I think all the terminology is clear and easy to follow and understand. R4: The questionnaire is perfect. I look at it and it is perfect. I selected "moderate" in 3 options. "Serious" none. The instructions are clear. The only option I would change is "mild." I don't like that one. To me "mild" is "a little." The only thing I understand is that it is less than "moderate." There are no options to choose from if I improved. Because I improved this symptom, but I can't choose any option here. I would add 1 more option. R5: It is simple, easy to understand, the drawings are fine ... Maybe item 3 and 4 sounds quite similar. The disease characteristics are fine. R6: I think it is very good. The number of options is correct. It shows the progression of the disease. R7: Very easy questionnaire. Easier and more amiable with the illustrations. R8: The questionnaire is easy, to understand the questions and to answer them. R9: The images shown are clear and help to imagine the symptoms and answer the questionnaire. LVC general comments (U.S.): All respondents understood and paraphrased correctly. LVC general comments (Argentina): They all understood well the questionnaire. I noticed that none of them were struck by the physical appearance of the drawings. I insisted on commenting something about it, but they limited themselves to talking about the symptoms they represented. I understand that they did not notice anything that shocked them enough to comment and, therefore, they feel represented, with the exception of the age comment. As for the suggestion to change "leve" (mild) to "un poco" (a little), I think it is acceptable. Maybe "leve" is too abstract, while with "un poco" the respondent can imagine a degree of quantity of the worsening of the symptom. LVC general comments (Colombia): The questionnaire was well-received and easily answered by the 3 participants.
Norwegian Translation (Norway) (N=5)	R1: The questionnaire was fine. The questions made sense to me in my situation, and they were easy to understand. R2: This was fine. I had no problems with it. R3: Everything was easy to understand. No problems whatsoever. R4: It was all fine. I didn't find anything to be confusing or anything. R5: This was pretty easy to understand, and the instructions helped. I had no problems with any of this. LVC general comments: All respondents were clear as to what was being asked here, and we had no issues with any of this.
Universal Modern Standard Arabic Translation (N=9; Egypt=3, Saudi Arabia=3, UAE=3)	R1: The questionnaire is about a serious illness that deserves to be studied to see how it affects the entire family. R2: A useful medical questionnaire that sheds light on the symptoms of the disease in a brief and interesting way. R3: Despite this being a short questionnaire, it provides valuable information about the disease. R4: Easy and understood survey. R5: The questionnaire is quite good and easy to fill. R6: The questionnaire is well worded and uncomplicated. R7: Questions and responses were clearly understood. R8: Questions and responses were clearly understood. R9: Questions and responses were clearly understood. LVC general comments (Egypt): Answers and comments are in English. LVC general comments (Saudi Arabia): Short and straightforward. LVC general comments (UAE): The wording is direct and understandable to the subjects.

COPD=chronic obstructive pulmonary disease; LVC=linguistic validation consultant; R=respondent; UAE=United Arab Emirates; U.S.=United States

participants, the wording was updated and retested among the participants. For example, in the Norwegian translation, most participants interpreted the translation of "shortness of breath" as "kortpustethet" to mean "difficulty breathing." However, when this was updated to "åndenød," participants interpreted this as feeling like there is not enough air, which was closer to the original meaning. The final wording was subsequently updated to "åndenød."

Overall, the CERT was well received by participants, and

the translations were judged to be conceptually equivalent to the English source CERT and harmonized with each other (Table 2; Supplemental Table 3 in the online supplement). Most participants found the tool easy to use, with 54.5% of participants specifically describing the tool as clear, simple, and/or easy, and an additional 24.2% of participants commenting that the tool was well understood (Table 2).

Of the 30 participants who provided responses to all questions in the cognitive debriefing interviews of the

Table 3. Participant Responses to the Cultural Adaption of the COPD Exacerbation Recognition Tool Images in 5 Different Translations

Language	Responses			
	Do you feel these images (skin color, eye color, hair color, hair texture, hair length, hair style, facial features, clothing, accessories, apparent age, etc.) represent you?	Do you feel these images (skin color, eye color, hair color, hair texture, hair length, hair style, facial features, clothing, accessories, apparent age, etc.) represent patients with your condition?	How do these images make you feel?	Anything else you would like to share about these images?
Indonesian Translation (Indonesia) (N=5)	R1: Yes. R2: Yes. R3: Yes. R4: Yes. R5: Yes.	R1: Yes. R2: Yes. R3: Yes. R4: Yes. R5: Yes.	R1: I feel sick. R2: I think about the cough with phlegm that I have. R3: I saw pictures of complaints from sick people that I experienced. R4: Coughing and shortness of breath like I experienced. R5: Picture of complaints of coughing and shortness of breath.	R1: Nothing more. R2: Nothing more. R3: Nothing more. R4: Nothing more. R5: Nothing more.
Korean Translation (South Korea) (N=5)	R1: Yeah, it looks similar to my expressions when I'm having a hard time. R2: They look younger than me, and they have short hair. R3: Yes, they are similar (to my image), like the coughing image. R4: They look younger than me. R5: Yeah, they seem to look similar to me. They have broad faces like ordinary Korean people.	R1: Yeah, the same. Asian skin color, the depiction of having a hard time, spitting out phlegm. It's the same as the image of me having a hard time. R2: Not similar. Those in the pictures look healthy. And their expressions are bright, though their actions represent coughing and things like that. R3: The expressions having a hard time looks similar to those of patients. R4: They are in a different age group from us, and their complexions are good while patients are usually pale. R5: The people in the images have big heads and plumpy faces, but COPD patients are gaunt. COPD patients are generally older and have more wrinkles than those in the images. The images don't look like they are having a hard time, out of breath, or having difficulty breathing. The last image of activity restriction looks like out of breath.	R1: It's the same as when I'm really sick and have a hard time with this chronic disease. R2: They generally look young and have bright expressions, not particularly having a hard time. In the 4th and 5th pictures, though, they seem to look like having a hard time with the sweats. R3: They depict sick people. R4: They are just cartoon pictures. R5: [No response]	R1: The images mostly fit the conditions. R2: Nothing. R3: Nothing. R4: They look young and pretty. We don't actually look at these images when answering the questionnaire. R5: Nothing.
Latin-American Spanish Translation (N=9; U.S.=3, Argentina=3, Colombia=3)	R1 (U.S.): You can see that they represent a person who is sick, probably with COPD. Their age is not clear; they look like children but in the facial features you can see that they have like wrinkles, so it is a little hard for me to determine their age, skin, hair, eye color, and everything. They seem to represent a person who is suffering and each of the images perfectly shows each of the symptoms they are asking about at the moment. I would not say that they represent me in particular, but they do represent a person who is having COPD symptoms. R2 (U.S.): The images represent what it says below. It seems that they indicate that you're coughing a lot and you're going to have to self-medicate or go to the hospital. Short of breath, not able to breathe properly. An old lady somewhere in her 50s and 60s. It's okay for the age it seems. I guess they would represent a person, not necessarily myself, but a COPD patient. R3 (U.S.): Yes, I think they do. The features listed, like skin color and so forth can vary from person to person, but overall, I see they show brown people and that is fine. R4 (AR): Yes, from the physical point of view, I feel identified. I think they are fine. Honestly, when I see them, I don't pay attention to the appearance, but they are ok. R5 (AR): The thing I don't feel identified with is that these 5 are young people, I'm much older than that. Then, except for the phlegm theme [LVC: because he/she doesn't have this symptom], I do feel identified with all the drawings. Any person with COPD, in this case me, suffers from what the picture shows. That is why I feel identified; the physical aspect is secondary. There is nothing that catches my attention to comment on.	R1 (U.S.): The images do perfectly represent the disease of each of them. R2 (U.S.): Yes, they represent very well a person who is having COPD symptoms. R3 (U.S.): Yes. For example, the one who is sweating, and the color of her skin is somewhat strange, the child also represents the same thing. They seem to be coughing too much and having to cover their mouth; he's coughing too much. So, overall, they do work as a good representation of a person with my illness. R4 (AR): Yes, yes because I get red like this, I start sweating. I get red when I can't breathe and everything swells up down here, in my neck, and I start sweating. Yes, these images represent me. I also see them sad. One feels that way. R5 (AR): Yes, of course they represent the disease. And they are represented very well. Yes, perhaps not individually, but all the images together clearly represent the disease. If you take the drawing in isolation, you may not realize that it is trying to represent COPD, but all the drawings together are the disease. They identify the disease very well. In general, patients may look like this. R6 (AR): These are all symptoms that patients with more severe or moderate COPD have. I can say that the pictures represent the patients suffering from this disease. R7 (CO): If these images with the features really illustrate a person who like me suffers symptoms related to COPD. – Yes, any person with a respiratory disease like COPD. R8 (CO): If what the images show, meaning also the gestures and what they are doing represent my disease: coughing, sneezing, etc. – Yes, they represent any general patient with COPD.	R1 (U.S.): Each one makes you feel the symptoms; for example, the first one makes me feel like I'm coughing too much and the last one makes me look like I am straining, like when you're climbing stairs or walking a long distance. R2 (U.S.): It makes me feel like these people in the images, who are having quite a few difficulties with COPD, and they are also short of breath, they are not able to breathe. R3 (U.S.): They make me feel like I am having lots of COPD symptoms. R4 (AR): When I see these images, they make me feel really bad because I see that I am like this. R5 (AR): If you are referring to how it affects me psychologically, we are all touched differently. I have a way of being that ... I don't feel like a victim, I don't worry about my health, I just take care of it, that's why I go to the doctors. I am not affected by these drawings. I have what I have, period. R6 (AR): I feel like I don't want my situation to get worse, because I wouldn't want to get to any of those 5 states. R7 (CO): My personal feelings when looking at the images. – Ok, they are nice ("divertidas"). R8 (CO): What these images make me feel like, if I can relate to them or reject them. – Well, I can accept them as general representations. R9 (CO): The feeling I experience in	R1 (U.S.): Maybe define the face a little more so that the person can identify the patient's age. R2 (U.S.): No. R3 (U.S.): No. I think they match the answer choices well. R4 (AR): No, nothing. Because here I see the boy who has a hard time climbing the stairs and it's the same as me. I have to hold on, wait, and then go up. Or I have to hold on to my daughter's arm and walk like that. They reflect very well what happens to me. R5 (AR): No, I think I just said everything. R6 (AR): No, I have nothing further to comment. The colors of the options are well represented, because green is like softer and red is always linked to something more intense, more alert, caution. R7 (CO): If I have something else to add about the images. – No. R8 (CO): Any additional comment about the images, if I want to share it. – No. R9 (CO): I am asked about giving another comment about how I perceive the images. – No.

(continued on the next page)

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	<p>R6 (AR): They don't represent me because luckily, I don't have any symptoms now. The pictures are fine. They are like standard people.</p> <p>R7 (CO): If I can identify with the images shown, illustrating the color of a person's eyes, his skin and hair color and how long is the hair and the style (i.e. pushed back or how it is parted now), and also his physical characteristics, like long nose, shape of the lips, the age he seems to have and the clothing, jewelry. – Yes, I can identify with these images.</p> <p>R8 (CO): How do I personally relate to and feel, about the images, if they depict a person correctly. They are including a possible color of the skin and the eyes and the hair, with a texture (thick) the style, like if it is parted-side or in the middle, and longer (women) or shorter (men), and the clothes they are wearing and other characteristics like the size of the mouth and gestures ... and how old or young they are looking. – The images are ok, represent people in general.</p> <p>R9 (CO): If I feel that these images represent a person like me or like a person in general, man or woman. How I feel when looking at the hair, at the eyes, the skin, the color and shape, if the hair is longer or shorter and the hairstyle meaning the type of cut, layered and not too short or long, and the shape of the face, the clothes, and what age they seem to have in the images. – Yes they do.</p>	<p>R9 (CO): How accurately the 4 images are showing the symptoms that I usually or sometimes have. – Yes, they depict well the COPD symptoms in the questionnaire.</p>	<p>general when looking at each one of the 4 images and what they are trying to show about the symptoms. – They add something light to the questions.</p>	
<p>Norwegian Translation (N=5)</p>	<p>R1: Yes, they were representative and fine.</p> <p>R2: I think they were ok, I had no problem with them, and they represent me.</p> <p>R3: The images were ok, I can see them representing me in a way.</p> <p>R4: They were ok. No problem with them, they are representative, I think.</p> <p>R5: The pictures represent me fine.</p>	<p>R1: Yes, they do.</p> <p>R2: Sure, they can represent us, as we are probably of higher age.</p> <p>R3: Yes, I guess most of us are older.</p> <p>R4: Yes, they can represent someone with my condition.</p> <p>R5: I think they can, yes.</p>	<p>R1: I don't really feel anything in particular. Neither negative nor positive, this is just the way it is.</p> <p>R2: I can't say I have any feelings about them in any form, I guess I feel fine.</p> <p>R3: They make me feel ok, I don't always struggle as hard as some of the images.</p> <p>R4: The pictures don't really affect my emotions in any way. The way they struggle resembles how I sometimes feel, so I guess that makes me a bit sad, but not very much.</p> <p>R5: I have no particular feelings about this either way.</p>	<p>R1: Not really.</p> <p>R2: They are fine, I've got nothing more to say, really.</p> <p>R3: No.</p> <p>R4: No.</p> <p>R5: No, I don't have any more comments.</p>
<p>Universal Modern Standard Arabic Translation (N=9; Egypt=3, Saudia Arabia=3, UAE=3)</p>	<p>R1: Yes, I possess specifications that are close to those in the images in general, with a slight difference in skin color, freshness, and apparent age.</p> <p>R2: I feel like these images do not represent me well because my condition is much worse than the situations shown therein.</p> <p>R3: Yes, these images are good to some extent as examples of my medical condition where I suffer from the same attacks due to shortness of breath.</p> <p>R4: [No response]</p> <p>R5: [No response]</p> <p>R6: [No response]</p> <p>R7: No, I do not feel these pictures represent me such as (skin color, eyes, hair, hair touch, hair length, face traits, accessories, age, etc.).</p> <p>R8: No, I do not feel these pictures represent me.</p> <p>R9: No, I do not feel these pictures represent me.</p>	<p>R1: Yes, these images represent them to a great extent, and depict their reaction to coughing, shortness of breath, and sweating, with slight differences in skin color and apparent age.</p> <p>R2: Yes, I feel these images can generally represent patients suffering from my condition, with varying degrees of severity of the disease and apparent age.</p> <p>R3: Yes, they represent other patients who suffer from my condition in one way or another, but not in terms of general appearance, clothing, accessories, and apparent age.</p> <p>R4: [No response]</p> <p>R5: [No response]</p> <p>R6: [No response]</p> <p>R7: Yes, I do feel these pictures represent other people with the same sickness (skin color, eyes, hair, hair touch, hair length, face traits, accessories, age, etc.).</p> <p>R8: Yes, I do feel these pictures represent other sick people with the same disease (skin color, eyes, hair, hair touch, hair length, face traits, accessories, age, etc.).</p> <p>R9: Yes, I do feel these pictures represent other sick people with the same disease (skin color, eyes, hair, hair touch, hair length, face traits, accessories, age, etc.).</p>	<p>R1: These images make me feel that I'm not alone, but that there are many others who are suffering from the same illness and condition as me. Thus, makes me feel supported.</p> <p>R2: These images stir a feeling of sadness in me, because they reflect conditions that seem better than my current situation.</p> <p>R3: These images make me feel optimistic.</p> <p>R4: [No response]</p> <p>R5: [No response]</p> <p>R6: [No response]</p> <p>R7: Nothing, how do these pictures make me feel?</p> <p>R8: Nothing, how I feel when I see these pictures?</p> <p>R9: Nothing, how do these pictures make me feel?</p>	<p>R1: No thanks.</p> <p>R2: In my opinion, the images cannot reflect the medical condition 100% accurately.</p> <p>R3: No thanks.</p> <p>R4: [No response]</p> <p>R5: [No response]</p> <p>R6: [No response]</p> <p>R7: No, I don't like to add anything about the pictures.</p> <p>R8: No, I don't like to add anything about the pictures.</p> <p>R9: No, I don't like to add anything about the pictures.</p>

R=respondent; COPD=chronic obstructive pulmonary disease; U.S.=United States; AR=Argentina; CO=Colombia; LVC=linguistic validation consultant; UAE=United Arab Emirates

Universal Arabic, Korean, Indonesian, Norwegian, and Latin-American Spanish translations of the CERT, 24 (80.0%) agreed that the images were representative of themselves (Table 3). In particular, participants commented that the presentation of the symptoms in the CERT corresponded to how they and/or other people with COPD usually appear when experiencing the same symptoms. A total of 4 (13.3%) participants who did not find the images to be representative of themselves responded that the images were likely to represent other patients with COPD instead. However, 4 participants (13.3%) commented that people in the images looked younger than themselves and/or other people with COPD.

Discussion

COPD exacerbations are often under-reported by patients.^{6,11} Possible reasons may include lack of patient awareness early in their diagnosis of what an exacerbation is, and inadequate provision of information on how to identify exacerbations (Supplemental Tables 5A and 5E in the online supplement). Therefore, access to tools like the CERT is important if patients are to better recognize the early signs of an exacerbation and seek prompt assessment and treatment. This study linguistically and cross-culturally validated 46 CERT translations across 25 countries and 6 continents and found that they appeared to be conceptually equivalent to the original CERT and harmonized with each other. Participants found the CERT easy to use and understand and confirmed that the images were representative of themselves and/or other people living with COPD. This was the largest of several translation projects for the CERT to date and brings the total number of translations to over 60, which are all now available on the Global Allergy and Airways Patient Platform (GAAPP) website²² (Supplemental Table 4 in the online supplement).

Images included alongside the text in the CERT can aid patient understanding of medical terminology (Supplemental Table 5C in the online supplement), and the addition of pictures in health care communications has been shown to improve comprehension and adherence to health instructions.²³ The images were culturally adapted according to participant input to ensure that they reflected patients from a diversity of cultures, countries, and religions, aiming to improve global accessibility and health literacy. The majority of participants specifically commented that the CERT is easy, clear, and/or simple, or commented that the tool was well understood. The tool may be particularly useful in helping newly diagnosed people with COPD or people who are unable to access care easily (Supplemental Tables 5B and 5D in the online supplement). However, 13.3% of participants who provided responses in the cognitive debriefing interviews regarding the Universal Arabic, Korean, Indonesian, Norwegian, and Latin-American

Spanish translations of the CERT found that the images of the people in the tool appeared younger than themselves and/or people with COPD. This may be due to the cartoon nature of the images. As the majority of participants found the images representative of themselves and/or other participants with COPD, no changes were made.

Although subtleties had to be captured when translating the CERT, the tool contains only a small number of symptoms that are universally experienced by patients with COPD. Participants who reviewed the CERT during the cognitive debriefing stage would have been able to recognize the symptoms that they experience during a COPD exacerbation and to think of appropriate words that they themselves would use. This is particularly important as a previous study identified a disconnection between patients' experiences of exacerbations and the language and definitions for exacerbations used in clinical practice.⁶

While the CERT is now accessible to patients in over 60 languages, it is necessary to continue the process of translation and validation into as many languages and regional dialects as possible. The alternative of producing a CERT in every country would require extensive research and the close similarity between the original CERT developed in China and the CERT-J developed in Japan suggests that similar items would be identified in other countries.^{13,15} We argue that the process of translating and validating the tool, as described here, is a proven methodology that is in accordance with FDA guidance and industry standards.¹⁷⁻¹⁹ Furthermore, using translated versions derived from a single original version ensures a consistent approach across countries. In this context, it should be noted that the Predictors of Acute COPD Exacerbation (PACE) study, which demonstrated that the tool can reliably identify the onset of an acute exacerbation of COPD one day before clinical diagnosis with good sensitivity and specificity, was performed using a German translation of the CERT.¹⁶

One potential limitation of the translation and cultural and linguistic validation of the CERT is that the participants included in the cognitive debriefing stage may have had a respiratory disease other than COPD; therefore, in the cultural and linguistic validation of the Korean CERT translation, the terms “chronic bronchitis” and “emphysema” were used. However, the results of the cultural and linguistic validation of the Korean CERT translation were consistent with other translations, so we do not think that this will have affected the results. Another potential limitation of the study is that when participants were interviewed to determine if the images included in the tool had been sufficiently culturally adapted, they were not asked whether the images also aided their understanding of the tool. Future translation and linguistic validation studies of patient education tools should consider including a question in the participant interviews to determine if imagery improves participants'

comprehension of the tool as previous research suggests.²³

While there is scope to expand the translation and linguistic validation of the CERT by testing the items included in the tool in each individual country, the results of our study and the recent PACE study¹⁶ indicate that this is unnecessary. Additional languages for CERT translation continue to be considered and country-specific implementation programs are in progress; it is anticipated that these translations and programs will further facilitate patient accessibility to the tool.

Conclusions

This study cross-culturally and linguistically validated 46 CERT translations across 25 countries and 6 continents. The CERT is easy for patients to understand, and the translations can be considered to be equivalent regardless of country or language. These translations may support health care professionals in multiple global regions in educating patients to recognize and act upon early signs of a COPD exacerbation.

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Declaration of Interest

Rainer Gloeckl is a member of the CERT governance board which is led by GAAPP. Ruth Tal-Singer is a retiree and shareholder of GSK and reports share options from ENA Respiratory, and personal fees from AstraZeneca, Boehringer Ingelheim, the COPD Foundation, ENA Respiratory, GAAPP, Global Skin, GSK, ImmunoMet, ItalyAndBeyond, Janssen, Renovion, Roche, Samay Health, Teva, and Vocalis Health. Peter Deussen has received fees from Biomedical Research Group Oxford and GAAPP for public and patient involvement. Russell Winwood is a patient consultant for Inogen Global. Tharishini Mohan, Megan Turner, Mohamed Hamouda, and Mandeep Moore are employees of and/or hold financial equities in GSK. Paul Jones is a contractor to and holds financial equities in GSK.

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