# Title page

TITLE: Spanish translation of the ABC taxonomy for medication adherence

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# Spanish translation of the ABC taxonomy for medication adherence

**Background.** The Ascertaining Barriers to Compliance (ABC) taxonomy was developed aiming at systematizing definitions and operationalizations of medication adherence. Its translation is crucial to improve the generalizability, application and comparison of study findings.

**Objective.** To provide a consensus translation of the ABC taxonomy from English to Spanish.

Methods. A two-phased approach was used, according to the Preferred Methods for the Translation of the ABC Taxonomy for Medication Adherence. Two literature reviews were conducted: to identify Spanish synonyms and definitions of the ABC taxonomy, and to identify a panel of Spanish-speaking experts in medication adherence. A Delphi survey was designed based on the synonyms and definitions found. The experts previously identified were invited to participate in the Delphi. A consensus of ≥85% was established for the first round. A moderate consensus (50-75%), a consensus (75-95%) or a strong consensus (>95%) were considered to be necessary in the second round.

Results. Forty potential synonyms of the ABC taxonomy terms were identified from a total of 270 papers. The response rate during the first Delphi round was 32% (63/197) and in the second round 86% (54/63). A strong consensus was reached for the term "inicio del tratamiento" (96%) and consensus for the term "implementación" (83%). A moderate consensus was obtained for "adherencia a la medicación" (70%), "interrupción del tratamiento" (52%), "manejo de la adherencia" (54%) and "disciplinas relacionadas con la adherencia" (74%). No consensus was reached for the term persistence. Five out of the seven definitions reached a consensus in the first round, and two definitions a moderate consensus after the second round.

**Conclusion**. The adoption of the Spanish taxonomy will increase transparency, comparability and transferability of results in the field of medication adherence. This may facilitate data comparison and benchmarking of adherence strategies between Spanish-speaking researchers and practitioners, and other language speakers.

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Results. Forty potential synonyms of the ABC taxonomy terms were identified from a total of 270 papers. Given that the search did not provide any valid translation of the original definitions into Spanish, these were forward translated and reviewed by a linguist. The response rate during the first Delphi round was 32% (63/197) and in the second round 86% (54/63). A strong consensus was reached for the term "inicio del tratamiento" (96%) and consensus for the term "implementación" (83%). A moderate consensus was obtained for "adherencia a la medicación" (70%), "interrupción del tratamiento" (52%), "manejo de la adherencia" (54%) and "disciplinas relacionadas con la adherencia" (74%). No consensus was reached for the term persistence. Five out of the seven definitions reached a consensus in the first round, and two definitions a moderate consensus after the second round.

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# Introduction

Medication adherence is an important indicator of the quality of disease management, as it affects both the clinical- and cost-effectiveness of medications. The measurement, estimation and improvement of medication adherence are a priority for health systems worldwide<sup>1</sup>. There is a growing number of studies which aim to provide evidence on patients' medication-taking-behaviour in relation to different therapies and settings. However, inconsistencies in adherence conceptualization severely limit the generalizability, application and comparison of study findings, as a high variability in adherence estimations reduces the reliability and validity of the findings<sup>2</sup>.

The Ascertaining Barriers to Compliance (ABC) taxonomy was proposed with the aim of systematizing terms and definitions of medication adherence<sup>3</sup>. It was based on the consensus of international experts and adopted by the International Society for Medication Adherence (ESPACOMP). Seven English terms and their definitions constitute the ABC taxonomy: 1) medication adherence, 2) initiation, 3) implementation, 4) persistence, 5) discontinuation, 6) management of adherence and 7) adherence-related sciences. In order to gain routine utilization in non-native English-speaking regions, its translation into different languages is crucial to ensure an elevated uniformity in adherence conceptualization and operationalization and consequently, a higher usefulness of research findings.

In 2019, Haag & Lehmann published the French and German translation of the ABC taxonomy<sup>4</sup>. Subsequently, a working group comprising ESPACOMP members was established to undertake robust translations of the ABC taxonomy into other languages. In this sense, the Portuguese<sup>5</sup> and the Czech<sup>6</sup> translations have recently been published. Regarding the Spanish language, it is the second worldwide mother tongue by number of speakers and the official language in 21 different countries<sup>7</sup>. Similarly to other languages, differences exist in a wide range of words and terms used in these countries. However, the nuances between Castilian Spanish and South American Spanish are more noticeable in everyday life than in professional environments where scientific terms are widely used. The routine utilization of terms related to medication adherence in these countries, as well as the number of adherence studies published in Spanish, are of importance. For these reasons, having unique medication adherence terms and definitions in Spanish may help native speaking researchers, healthcare professionals and policymakers to conduct, analyse and interpret scientific evidence in a more transparent manner.

The ESPACOMP working group agreed to a consistent translation process for all languages based on a review and synthesis of the literature on the topic to identify possible synonyms and definitions similar to those conforming to the original taxonomy, followed by an experts' consensus to decide the most appropriate elements<sup>8</sup>. This paper aims to provide the translation of the ABC taxonomy of medication adherence from English into Spanish.

# Methods

This research involved two phases: a literature review followed by a Delphi panel, in accordance with the Preferred Methods for Translation of the ABC Taxonomy for Medication Adherence published by the ESPACOMP<sup>8</sup>.

#### Phase 1. Literature reviews

Two non-systematic literature reviews were undertaken aimed at: (1) identifying Spanish synonyms of the terms and definitions included in the ABC taxonomy, and (2) identifying key Spanish-speaking researchers in the field of medication adherence. A publication date filter of ten years was applied in the first review to obtain an updated but high number of synonyms, while in the second review, the preference was to identify panellists with a current activity and expertise on the topic, so a five years filter was applied. Two searches were conducted in PubMed during November 2020. These were undertaken using a combination of MeSH terms related to medication adherence (Appendix 1).

The titles and abstracts of identified articles were assessed for their eligibility. Obviously irrelevant records were excluded. Full-text papers not discarded during the screening phase were considered for inclusion. The exclusion criteria applied for the identification of Spanish synonyms of the ABC Taxonomy terms and definitions were: study not focused on medication adherence; article not available in the usual sources or channels of access to scientific papers (open-access, public or institutional repositories to which the authors had access).

The exclusion criteria applied for the identification of key Spanish-speaking researchers being corresponding authors of at least one paper in the field of medication adherence were: study not focused on medication adherence; corresponding author with an affiliation not located in a Spanish-speaking country; authors of the paper VGC or SM.

Two researchers (SM and VGC) discussed each article and extracted relevant data using a pre-designed and piloted data extraction form. This included the following information: adherence-related terms used, term definitions, year of publication and study location (for the terms and definitions review) and corresponding author, affiliation, e-mail address and location (for the Spanish-speaking researchers review).

#### Phase 2. Delphi method

#### 2.1 Survey design

The Delphi method is a systematic and reliable methodology often used to obtain consensus. It can be performed with online questionnaires administered in successive rounds that collect the group's opinion, until consensus is reached<sup>9,10</sup>. In this research, a survey was developed in the RedCap platform, a secure web application for managing online surveys and databases. The survey was based on the data gathered through the literature review process. It included all seven ABC taxonomy terms for which the Spanish

terms and definitions were to be agreed by the participant experts. Since no translations of the original ABC taxonomy definitions were identified, the original definitions were forward translated into Spanish, reviewed and confirmed by a professional linguist. In the survey, the experts had to choose an answer among all the possible translations proposed for each term and definition. The survey also included an optional free text field, allowing the experts to propose new Spanish terms and definitions. Specific questions to collect demographic characteristics of the experts were included at the beginning of the survey. The survey was pilot-tested for clarification and comprehensibility with 10 junior Spanish and Latin American researchers. The final version of the survey can be found in Appendix 2.

#### 2.2 Experts identification and survey distribution

Potential panellists for the Delphi survey were initially identified and their identity remained hidden to other participants. All panellists identified were invited to participate in the study. A snowball sampling approach was also used, with participant panellists being asked to propose further experts in medication adherence. The survey was distributed, with up to two reminders sent 10 days apart to non-respondents.

## 2.3 Delphi rounds and data analysis

The Delphi survey was undertaken in two rounds. The consensus on the translated terms and definitions was defined according to the following criteria, applied in the other translation processes conducted<sup>4-6</sup>.

- Round 1: Panellists were asked to select their preferred term and definition for each ABC taxonomy term. An agreement cut-off ≥85% (i.e., selection of the same term or definition by at least the 85% of experts) was established for the first round. Those reaching an agreement below 10% were discarded. Thus, all terms and definitions that reached an agreement between ≥10% and <85% as well as all those newly proposed were included in the second round.</p>
- Round 2: The second round of the survey was distributed to all the panellists who participated in round one. Terms and definitions were presented according to their descending order of acceptance in round one, with their corresponding acceptance rate being visible for panellists. As in round 1, panellists were asked to select their preferred term and definition for each ABC taxonomy term. A three-level consensus cut-off was established, which included moderate consensus (50-75%), consensus (75-95%) and strong consensus (>95%).

A descriptive statistical analysis of the panellists' characteristics and the results on adherence terms was undertaken. Categorical variables are presented as frequencies and percentages.

#### 2.4 Ethical considerations

The survey administered to researchers was not considered by regional ethics organisation (i.e. Comité de Ética de Investigación Clínica de Aragón) to require ethical approval. Nevertheless, a consent form was incorporated in the survey.

# Results

The literature review was performed in October 2020 and resulted in 270 studies. After applying the inclusion and exclusion criteria, 150 studies were included. Upon reviewing, 40 synonyms of the ABC taxonomy terms were identified: adherence to medication (11), persistence (10), discontinuation (9), management of adherence (3), adherence-related sciences (3), initiation (2) and implementation (2). All Spanish synonyms of the English terms of the ABC taxonomy identified in the review, together with the forward-translated definitions into Spanish of the ABC taxonomy were included in the questionnaire designed to conduct the Delphi survey. The flowchart is detailed in Figure 1.

#### Selection of the panellists and survey administration

A total of 473 articles were reviewed and 148 experts in medication adherence were identified for participation as panellists. Of them, 108 (73%) were from Spain and 40 (27%) from a Latin American country. Additionally, these panellists proposed 49 further experts in medication adherence (29 Spain and 20 Latin American countries), resulting in 197 invitations being distributed. Two consecutive Delphi rounds were performed through online surveys during April-May and September-October 2021, respectively. Response rate in the 1<sup>st</sup> round was of 32% (63/197). Among the respondents, a total of 45 (71%) were from Spain and 18 (29%) from a Latin American country. In the 2<sup>nd</sup> round, the response rate was of 86% (54/63). There were 42 (78%) from Spain and 12 (22%) from a Latin American country. Twenty-four were females and 30 males. Most (85%) held a PhD degree and had a professional background of pharmacist (44%) or physician (35%). The number of panellists with a different training (on social sciences, nursery, psychology or chemistry) was ≤3. In this way, the 12 Latin American panellists showed the following professions: pharmacist (5), physician (4), social sciences (1), nursery (1) and psychology (1). All of them held a PhD degree (11) or a master (1).

### Evaluation of the results on adherence terms

No term reached consensus (≥85%) after the 1st round. After the 2nd round, a strong consensus was reached for the term *inicio del tratamiento* (96%) [initiation] and a consensus for the term *implementación* (83%) [implementation]. A moderate consensus was obtained for: *adherencia a la medicación* (70%) [medication adherence], *interrupción del tratamiento* (52%) [discontinuation], *manejo de la adherencia* (54%) [management of adherence] and *disciplinas relacionadas con la adherencia* (74%) [adherence related sciences]. No consensus was reached for the ABC term persistence, for which *persistencia* obtained a 39% agreement, followed by *continuidad del tratamiento* which obtained a 30%. In all the cases, the level of consensus increased from the 1st to the 2nd round, except for the term implementation that showed a negligible reduction, and all the initially preferred Spanish terms remained favourites during the process (**Table 1**).

A more detailed description of the Delphi study results after the 2<sup>nd</sup> round can be found in Appendix 3. No differences in the terms and definitions agreed were identified when the nationality of the expert was considered (Spanish vs Latin American countries; data not shown).

**Table 1.** Summary of the Delphi study results. The number of proposed Spanish <u>terms</u> for each English term as well as the level of consensus obtained (%) by round are indicated in the different columns.

	Round 1		Round 2	
	Synonyms	Consensus	Synonyms	Consensus
	presented	obtained	presented	obtained
Medication adherence	11	No (29%)	6	Yes (70%)
Initiation	2	No (83%)	3	Yes (96%)
Implementation	2	No (84%)	4	Yes (83%)
Persistence	10	No (22%)	7	No (39%)
Discontinuation	9	No (22%)	6	Yes (52%)
Management of adherence	3	No (49%)	7	Yes (54%)
Adherence related sciences	3	No (51%)	5	Yes (74%)

Consensus level was defined as ≥85% for the 1st round. The new terms proposed by the panellists were included in the 2nd round, while terms reaching agreement <10% were discarded. In the 2nd and final round, all terms reaching agreement 50-75% were classified as moderate consensus (light grey), 75-95% as consensus (dark grey) and >95% as strong consensus (black).

## Evaluation of the results on adherence definitions

Five out of the 7 initially proposed definitions reached a consensus in the 1st round, with agreement rates of 89-90%. The 2 other definitions reached a moderate consensus in the 2nd round, with agreement rates of 72 and 74% (**Table 2**).

**Table 2.** Summary of the Delphi study results. The number of proposed <u>definitions</u> for each term as well as the level of consensus obtained (%) by round are indicated in the different columns.

	Rou	Round 1		Round 2	
	Definitions presented	Consensus obtained	Definitions presented	Consensus obtained	
Medication adherence	1	Yes (89%)			
Initiation	1	Yes (90%)			
Implementation	1	Yes (90%)			
Persistence	1	Yes (89%)			
Discontinuation	1	Yes (90%)			

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Management of adherence	1	No (73%)	3	Yes (74%)
Adherence related sciences	1	No (81%)	4	Yes (72%)

Consensus level was defined as ≥85% (dark grey) for the 1st round. Definitions meeting this criterion were not integrated into the 2nd round. The new definitions proposed by the panellists in 1st round were included in the 2nd round, while definitions reaching agreement <10% were discarded. In the 2nd and final round, definitions reaching agreement 50-75% were classified as moderate consensus (light grey).

#### The Spanish ABC Taxonomy

The final list of terms and definitions conforming the Spanish taxonomy are shown in **Table 3**.

Table 3. Spanish terms and definitions obtained in the translation of the ABC taxonomy.

English term	Spanish term	Spanish definition
Medication	Adherencia a la medicación	El proceso a través del cual los pacientes toman sus medicamentos tal y
adherence	[70%, 2nd]	como fueron prescritos. [89%, 1st]
Initiation	Inicio del tratamiento [96%,	El proceso comienza con el inicio del tratamiento, cuando el paciente toma
	2nd]	la primera dosis de un medicamento prescrito. [90%, 1st]
Implementation	Implementación [83%, 2nd]	Medida en la que la pauta seguida por el paciente se corresponde con la
		prescrita, desde el inicio del tratamiento hasta la última dosis. [90%, 1st]
Persistence	Persistencia [39%, 2nd]	Es el periodo de tiempo transcurrido entre el inicio del tratamiento y la toma
		de la última dosis, que inmediatamente precede a la interrupción. [89%, 1st]
Discontinuation	Interrupción del	Marca el final de la terapia, cuando el paciente deja de tomar el
	tratamiento [52%, 2nd]	medicamento prescrito, por la razón que sea. [90%, 1st]
Management of	Manejo de la adherencia	Es el proceso de monitorización y apoyo para la adherencia del paciente al
adherence	[54%, 2nd]	medicamento por parte de los sistemas sanitarios, prestadores, pacientes y
		sus redes sociales. [74%, 2nd]
Adherence	Disciplinas relacionadas con	Este elemento incluye las disciplinas que tratan de entender las causas o
related sciences	la adherencia [74%, 2nd]	consecuencias de las diferencias entre la exposición al medicamento tal y
		como fue prescrita (es decir, la deseada) y la real. La complejidad de este
		campo, así como su riqueza, resultan del hecho de que traspasa los límites
		entre muchas disciplinas incluyendo, pero no únicamente restringido a, la
		medicina, farmacia, enfermería, ciencias comportamentales, sociología,
		farmacométrica, bioestadística y economía de la salud. [72%, 2nd]

The level of consensus (%) at the corresponding Delphi-round (1st or 2nd) are indicated among brackets.

# Discussion

The results of the present study propose a Spanish version of the ABC taxonomy for medication adherence, to be used in research environments. It is intended to facilitate the dialogue and comparison of results among researchers speaking Spanish, independently of their country, which may positively impact clinical practice. This study adds to other translations of the taxonomy to other languages,

including French, German<sup>4</sup>, Portuguese<sup>5</sup> and Czech<sup>6</sup> and to the best of the authors' knowledge, it is the first study to systematically develop a taxonomy for medication adherence in Spanish.

Since the development and dissemination of the original ABC taxonomy<sup>3</sup> in 2012, it has been extremely successful, resulting in a wide adoption within the scientific community in English-speaking settings. It also triggered additional initiatives including the creation of the ESPACOMP Medication Adherence Reporting Guideline (EMERGE)<sup>11</sup> and the development of a framework for constructing operational definitions of medication adherence (TEOS)<sup>12,13</sup>.

Following the recommendations by ESPACOMP8 this research adopted a two-phased approach. . The literature review was an essential step to inform the development of the Delphi survey14. A high level of agreement among the participating experts was reached for all seven definitions proposed. Consensus was reached in round 1 for five out of the seven definitions proposed, and during phase 2 for the remaining two definitions. Given that no appropriate Spanish definitions for the ABC taxonomy terms were found during the literature review process, all proposed definitions during round 1 were those elaborated by a professional linguist after the forward translation of the original definitions in English. This fact could have increased their acceptability by the participant experts and might explain the level of consensus obtained. It should also be highlighted the simplicity of the definitions that reached consensus after the first round, compared to the terms "management of adherence" and "adherence related sciences" which involve more complex definitions. In contrast, two rounds were conducted for the terms of the ABC taxonomy. High consensus was reached in the second round for the terms inicio del tratamiento and implementación, with the latest showing a minor decrease in the level of agreement from round 1 (84%) to round 2 (83%). This could be due to the fact that a very similar term (i.e. implementación terapéutica) was suggested by the experts to be included in the second round, slightly decreasing the level of agreement for the preferred term. Moderate consensus was reached for the terms adherencia a la medicación, interrupción del tratamiento, manejo de la adherencia and disciplinas relacionadas con la adherencia during the second round. However, no consensus was reached for the term persistencia, with continuidad del tratamiento (treatment continuity) being the second most suggested term by 30% of experts. Reasons for this lack of agreement could be that some participants could have considered the term persistencia as a potential anglicism. Additionally, it could be postulated that resistance may develop across experts when a theoretical term not aligning with current practice is proposed. Similarly to other languages, many linguistic variations exist across Spanish-speaking countries and it was also hypothesized that the experts' nationality could have influenced the lack of consensus. However, no differences were observed when these two groups were analysed separately, which supports the development of a single translation of the ABC taxonomy into Spanish. Following the ESPACOMP guidelines8, the objective was to translate the ABC taxonomy into Spanish without revisiting the meaning of the original terms and definitions. A plausible explanation for differences on consensus obtained after the 1st round with definitions versus terms could be the fact that a definition represents a unique concept, while a synonym usually shows multiple choices, sufixes and nuances. Under this premise, these two processes were not strictly related and reaching a consensus in the case of definitions seems an easier process than in the terms. Nevertheless, these findings were not replicated in the French<sup>4</sup>, German<sup>4</sup>, Portuguese<sup>5</sup> and Czech<sup>6</sup> ABC taxonomy translations, where no consistent trend seems to be observed across the four studies.

Some limitations were apparent. First, the literature review to identify potential synonyms was only performed using PubMed (the widest search tool for biomedical and life sciences literature), due to the high number of studies on adherence found in initial searches. Additionally, a pragmatic approach is accepted by ESPACOMP<sup>8</sup> and has been reported in previous translations of the taxonomy<sup>4-6</sup>. Second, the literature review performed to identify experts in the field of medication adherence attempted to search from all countries in which Spanish is an official language, with 21 countries being included in the search. Despite the efforts, more than 70% of the sample were from Spain, which is consistent with the distribution of the published literature in the area. Nevertheless, imbalances in the number of experts across different same language speaking countries have been reported in previous translations of the taxonomy including French, German<sup>4</sup> , Portuguese<sup>5</sup> and Czech<sup>6</sup>. Third, only two Delphi rounds were conducted, and further rounds could have been undertaken. Considering that the level of consensus reached for most terms and definitions after the round 2 was acceptable and that none of the new terms suggested by the experts during the round 1 reached the 10% cut-off point during the second round, a third round was not deemed necessary. This decision was reinforced by the stability of the responses obtained for the only term that reached no agreement (i.e. persistence) and the even distribution of the two preferred terms across the two Delphi rounds. It is therefore unlikely that a third round may have influenced the results.

# Conclusion

This study proposes a consensus-based translation of the ABC taxonomy into Spanish. Stakeholder consensus was reached for all the definitions and six out of the seven adherence-related terms included in the taxonomy. The proposed terms and definitions can be adopted across all Spanish speaking countries, increasing the transparency, comparability and transferability of results in the field of medication adherence.

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Victoria Garcia-Cardenas: conceptualization, methodology, investigation, project administration, writing-original draft. Dyfrig Hughes: conceptualization, methodology, writing-original draft, writing-review & editing. Isabel Aguilar-Palacio: investigation, writing-original draft, writing-review & editing. Shalom Isaac Benrimoj: investigation, writing-original draft, writing-review & editing. Maria Jose Rabanaque: investigation, writing-original draft, writing-review & editing. Fernando Martinez-Martinez: investigation,

writing-original draft, writing-review & editing. **Sara Malo:** conceptualization, methodology, formal analysis, investigation, project administration, writing-original draft.

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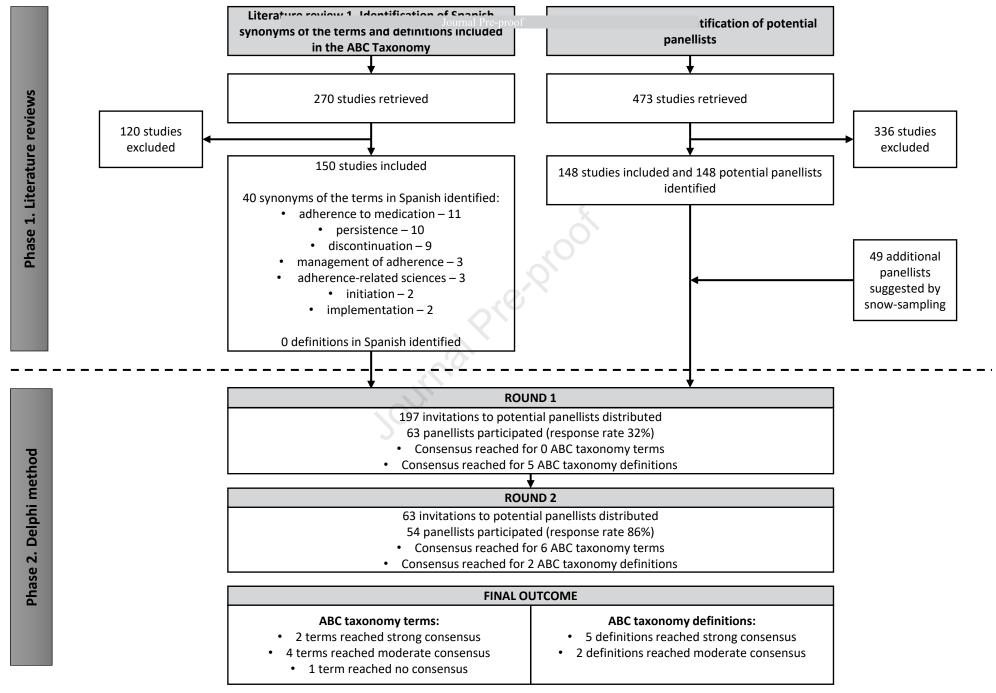


Figure 1. Study Flowchart

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