

# Usage of inhalation devices in asthma and chronic obstructive pulmonary disease: a Delphi consensus statement

Vincent Ninane<sup>1</sup>, Guy G Brusselle<sup>2</sup>, Renaud Louis<sup>3</sup>, Lieven Dupon<sup>1</sup>, Giuseppe Liistro<sup>5</sup>, Wilfried De Backer<sup>6</sup>, Marc Schlessler<sup>7</sup> & Walter Vincken<sup>8</sup>

<sup>1</sup>Centre Hospitalier Universitaire Saint-Pierre, Department of Pneumology, Brussels, Belgium

<sup>2</sup>Universitair Ziekenhuis Gent, Clinic of Respiratory Medicine, Gent, Belgium

<sup>3</sup>Centre Hospitalier Universitaire de Liège, Department of Pneumology, Liège, Belgium

<sup>4</sup>Universitair Ziekenhuis Leuven, Department of Pneumology, Leuven, Belgium

<sup>5</sup>Cliniques Universitaires Saint-Luc, Department of Pneumology, Brussels, Belgium

<sup>6</sup>Universitair Ziekenhuis Antwerpen, Department of Pneumology, Edegem, Belgium

<sup>7</sup>Centre Hospitalier de Luxembourg, Department of Pneumology, Luxembourg, Luxembourg

<sup>8</sup>Universitair Ziekenhuis Brussels, Department of Pneumology, Brussels, Belgium

## Abstract

**Objectives:** The study aimed to assess usage of inhalation devices in asthma and chronic obstructive pulmonary disease (COPD).

**Methods:** In this two-round Delphi survey, 50 experts in asthma and COPD completed a 13-item, Internet-based, self-administered questionnaire about choice of inhalation device, training and monitoring of inhalation techniques, the interchangeability and the role of costs in the selection of inhalation devices. For each item, the median (central tendency) and interquartile ranges (degree of consensus) were calculated.

**Results:** Experts considered that the choice of inhalation device was as important as that of active substance (very good consensus) and should be driven by ease of use (good to very good consensus) and teaching (very good consensus). Experts recommended giving oral and visual instructions (good consensus) and systematic monitoring inhalation techniques. Pulmonologists and paramedics have predominantly educational roles (very good consensus). Experts discouraged inhalation device interchangeability (good consensus) and switching for cost reasons (good to very good consensus) without medical consultation (good consensus).

**Conclusions:** The results of this survey thus suggested that inhalation devices are as important as active substances and training and monitoring are essential in ensuring effective treatment of asthma and COPD. Inhalation device switching without medical consultation should be avoided.

**Keywords:** asthma, chronic obstructive pulmonary disease, consensus, Delphi survey, inhalation device, questionnaire

## 1. Introduction

Inhalation devices (IDs) are widely used to administer treatment to patients with asthma and chronic obstructive pulmonary disease (COPD) because they ensure high level of drug delivery to the airways with only low concentrations into the systemic circulation, resulting in a lower risk of adverse events [1]. In the coming years, generics of existing drugs for obstructive airway diseases treatment will become available, while patents for IDs will remain in place. Active substances that are currently available with one device will be launched with different types of devices in Europe, potentially leading to more opportunity for switching a patient's ID.

In this context, important questions concerning the impact of IDs on asthma and COPD treatment are raised: what is the respective importance of active compounds and IDs? Which criteria should be taken into account in ID choice? Is it needed to teach and check the patients' inhalation technique and how often is it needed? What is

the potential impact of ID switching and who should initiate the switching procedure? The consideration of these questions is important because incorrect treatment delivery may adversely affect the benefits gained from the therapy [2-4], dramatically change the side effects [5] and induce substantial cost increases associated with asthma and COPD [6,7].

Only limited guidance on the choice, use and interchangeability of IDs is provided in treatment guidelines for asthma and COPD, except for teaching and testing inhalation techniques [8-11]. To address this lack of evidence, the authors (Delphi development committee [DDC]) decided to conduct a Delphi survey to explicitly summarize the opinion of Belgian experts in asthma and COPD on ID usage. This survey was designed to develop a consensus of opinions concerning the choice of IDs, the training and monitoring of inhalation techniques, the role of costs in the selection of IDs and the interchangeability of IDs.

## **2. Methods**

### *2.1 The Delphi method*

The Delphi technique is based on the use of questionnaires, which are delivered using multiple iterations to collect data from a panel of selected experts and is typically used when evidence is limited [12]. The major characteristics of the Delphi method are anonymity, controlled feedback and group responses [12]. Anonymity results from the absence of direct interaction between participants, who respond independently to the questionnaire and do not know the specific answers given by any other participants. Controlled feedback occurs during the different rounds, since the group responses obtained during one round are returned to the participants during the next round in the form of statistical summaries. Group responses are expressed using scores that quantify the level of consensus obtained by the group [13-15].

### *2.2 Development of the questionnaire*

In October 2012, the authors prepared a 13-item questionnaire and reviewed the statements (Figure 1 and supplementary material: French and Dutch questionnaires and English translation). The authors comprised eight representatives from major hospitals in Belgium and Luxembourg. For questionnaire preparation, a review of ID recommendations in clinical guidelines was performed by hand-searching major asthma and COPD guidelines. These guidelines were identified by searching the National Center for Biotechnology Information, US National Library of Medicine (PubMed) database for publications with titles containing the terms 'COPD' or 'asthma' and 'guideline' or 'guidelines'. Before administering the questionnaire to the experts, the project was tested and validated by four external reviewers, who checked the formulation of the questions and whether the questionnaire was in line with the study objectives. The questionnaire was Internet-based, self-administered and designed to have a maximum duration of 10 min per round.

The questionnaire included closed questions to allow quantification of the results. The majority of the questions used 11-point Likert scale (from 0 to 10, whereby zero = I do not agree at all and 10 = I fully agree) to evaluate the appropriateness of each response. The questionnaire also included multiple choice questions, for which the option 'other' was added to the response list to minimize the risk of bias. All questions contained an open space to allow respondents to explain or specify their answers during the first round. Comments were mandatory for questions in the sections about the interchangeability of IDs and the role of costs in the selection of IDs and were optional in the sections about the choice of IDs and the training and monitoring of inhalation techniques.

### *2.3 Selection of the experts*

Six members of the DDC received a list of chest physicians in Belgium (about 480) and were asked to designate those that they considered as experts in the use of IDs and in asthma and COPD prevention and treatment who could be eligible for selection (Figure 1). In each Belgian hospital, only one expert was selected; the objective was to represent as far as possible a variety of different hospitals. If more than one expert was identified within a given hospital, the expert designated by the greatest number of DDC members was selected.

### *2.4 Phases of the consensus*

In November 2012, the questionnaires were sent via email to the selected experts (Figure 1). They received reminders by email and telephone to complete the questionnaires by the end of the month.

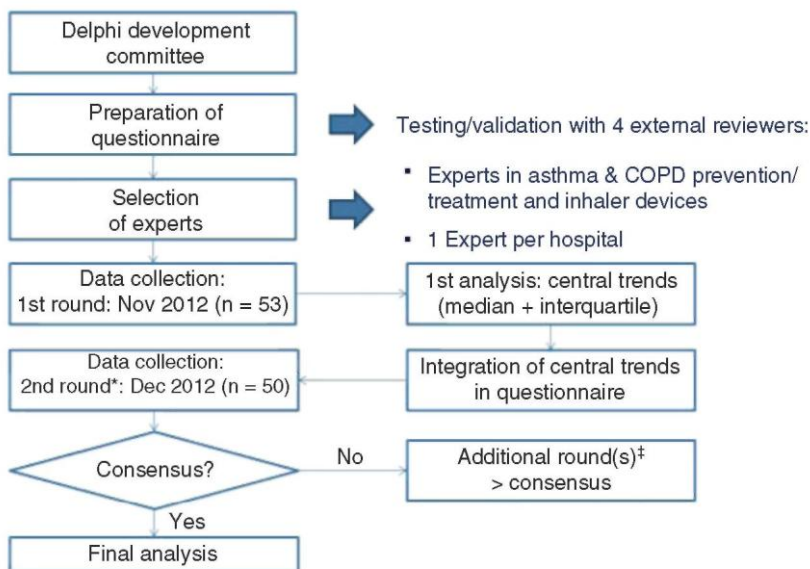
For the second round, the experts' responses were analyzed and trends (median and interquartile) were integrated in the questionnaire with a sample of the experts' comments for each question. The comments were selected to avoid repetitions and explain answers that were close to the central trends, since the objective of a Delphi survey is to obtain a consensus. In December 2012, the same questionnaires were again sent via email to the same experts, who were asked to confirm or modify their answers, which had been individually integrated into the questionnaire. For the second round, there was no possibility to post a comment for each question, but experts could add some comments at the end of the questionnaire.

## 2.5 Analysis and interpretation of the results

The data were analyzed using descriptive statistics and presented as median (Q2), quartiles and interquartile range (Q1 - Q3) for each answer. This provided information on the central tendency of the responses and the extent of dispersion of the data, together giving an indication of the degree of consensus: Q1 = lower quartile (the lowest 25% of data); Q2 = median (50%) and Q3 = upper quartile (75%).

The definitions of the different levels of consensus were based on those given in a previous publication, in which the Delphi method was used by the American College of Chest Physicians to give recommendations on pneumothorax treatment (Table 1) [11]. The statistical analyses were performed by Medi-info scrl-cvba (Rixensart, Belgium) using SPSS (Statistical Program for the Social Sciences).

**Figure 1.** Study design is shown. \*In the second round, the central trend of the previous round was shown to the respondents, who were asked to confirm/review their answers. †No third round was required because adequate consensus was always reached before.



## 3. Results

In the first round of the survey, of the 106 expert pulmonologists contacted, 53 participated from 53 different Belgian hospitals (Figure 1). Of these, 25 French-speaking and 25 Dutch-speaking experts responded to the second round and were included in the analyses. The degree of consensus increased in the second round of the Delphi process for all questionnaire items.

### 3.1 Choice of IDs

When experts were asked to compare the respective impact of IDs and active substances on obstructive lung disease treatment, 58% considered that both choices were equally important (response = 5 on an 11-point [0 - 10] Likert scale). A very good degree of consensus was reached; the responses of 78% of experts ranged between 4

and 6 (Table 2). A good to very good consensus was achieved in the first round and only 7 of the 50 experts modified their answer in the second round.

Among different criteria for the choice of ID, the highest scores ( $Q2 \geq 8$ ) were observed for those that were likely to optimize the correct use of the ID by the patients: easy to teach and use, patients' ability to use the device correctly and practical aspects (Figure 2). For these criteria, the levels of consensus were good or very good and a maximum of 5 of 50 experts modified their answer in the second round.

The criterion of choice of IDs with the highest observed score was the patients' ability to use the device correctly (Figure 3). This criterion had received the highest rating based on individual evaluations from 47 of the 50 experts and the maximum rating based on the top 2 evaluations (response = 9 or 10 on the 0-10 scale) from 40 of 50 experts.

### 3.2 Training and monitoring of the inhalation technique

Most experts considered that, when patients were trained on the correct use of IDs, it was more important to give oral instructions and visual demonstration than written instructions only; the responses of 78% of experts ranged between 8 and 10 (Table 2). The degree of consensus was good; the responses of 64% of experts ranged between 7 and 9. In the second round, 10 of the 50 experts modified their answer.

The majority of experts considered that patients should be prescribed an ID only after having received training on the inhalation technique (Table 2). The degree of consensus was very good; the responses of 80% of experts ranged between 8 and 10. In the second round, 9 of the 50 experts modified their answer. The majority of experts also agreed that patients should be prescribed an ID only after having demonstrated satisfactory technique when using it; the responses of 80% of experts ranged between 7 and 10 (Table 2). The degree of consensus was good; the responses of 52% of experts ranged between 7 and 9. In the second round, 7 of the 50 experts modified their answer.

The experts considered that the most appropriate people for training patients on the use of IDs were, in descending order, pulmonologists ( $Q2 = 10$ ), paramedics (nurses, physiotherapists, pulmonary function technicians working in the pulmonologist's centre;  $Q2 = 9$ ), general practitioners (GPs;  $Q2 = 8$ ), parents ( $Q2 = 8$ ) and pharmacists ( $Q2 = 7$ ) (Figure 4A). A maximum of 6 of the 50 experts modified their answer in the second round. The experts considered that the most appropriate persons to monitor the adequacy of inhalation technique of the patients were, in descending order, pulmonologists ( $Q2 = 10$ ), paramedics ( $Q2 = 10$ ), GPs ( $Q2 = 8$ ) and pharmacists ( $Q2 = 6$ ) (Figure 4B).

The majority of experts declared that checking patients' inhalation techniques should not be limited to the first few visits: 48% considered that this should be monitored at each visit; 28% suggested checking it regularly (every month) after initiation and 34% recommended checking it in the event of exacerbation or patient complaints in addition to the initial appointment ( $n = 2$ ), the first two visits ( $n = 5$ ), the first three visits ( $n = 4$ ), each visit ( $n = 5$ ), or regular monitoring after initiation ( $n = 5$ ). In contrast, 12% of experts suggested checking it only during the first three visits, 14% during the first two visits and 6% once at the initial appointment (data not shown). None of the experts considered that inhalation monitoring should only be done in case of exacerbations or patients' complaints. In the second round, 3 of the 50 experts modified their answer.

**Table 1.** Consensus definitions based on the 11-point Likert scale (0/10) used in this Delphi survey.

Term	Definition
Perfect consensus	All respondents agreed on an answer
Very good consensus	Median and 45 - 55% of respondents at one integer* or 75 - 85% of respondents within one integer of the median <sup>‡</sup>
Good consensus	45 - 55% of respondents within one integer of the median or 75 - 85% of respondents within two integers of the median
Some consensus	45 - 55% of respondents within two integers of the median or 75 - 85% of respondents within three integers of the median
No consensus	All other cases

\*Median and 45 - 55% of respondents give the same rating (e.g., 5).

<sup>‡</sup>For example, median is 5, 75 - 85% of respondents are from 4 to 6.

**Table 2.** Central trends and degree of consensus reached after the second round of the Delphi survey.

	Q1	Q2	Q3	Consensus
Respective impact of ID versus active substance choice*	4	5	5	Very good
importance of written versus oral instructions <sup>‡</sup>	8	8	9	Good
Patients should receive ID prescription only after having received training by an appropriate person on the ID use <sup>§</sup>	8	9	10	Very good
Patients should receive ID prescription only after having demonstrated satisfactory technique when using it <sup>§</sup>	7	8	10	Good
ID are easily interchangeable when the active substances are kept the same <sup>§</sup>	1	2	3	Good
Switching of the prescribed ID can be made by the pharmacist if the active substance is kept the same <sup>§</sup>	0	0	1	Very good
The physician should prescribe the least costly ID for the collectivity <sup>§</sup>	2	4	5	Good
The pharmacist should deliver the least costly ID, which contains the active substance prescribed by the physician <sup>§</sup>	0	0	1	Very good

\*Expert responses: 0 = ID choice is the most important; 5 = both choices are equally important; 10 = active substance choice is the most important

<sup>‡</sup>Expert responses: 0 = written instructions are the most important; 5 = both choices are equally important; 10 = oral instructions and visual demonstration are the most important

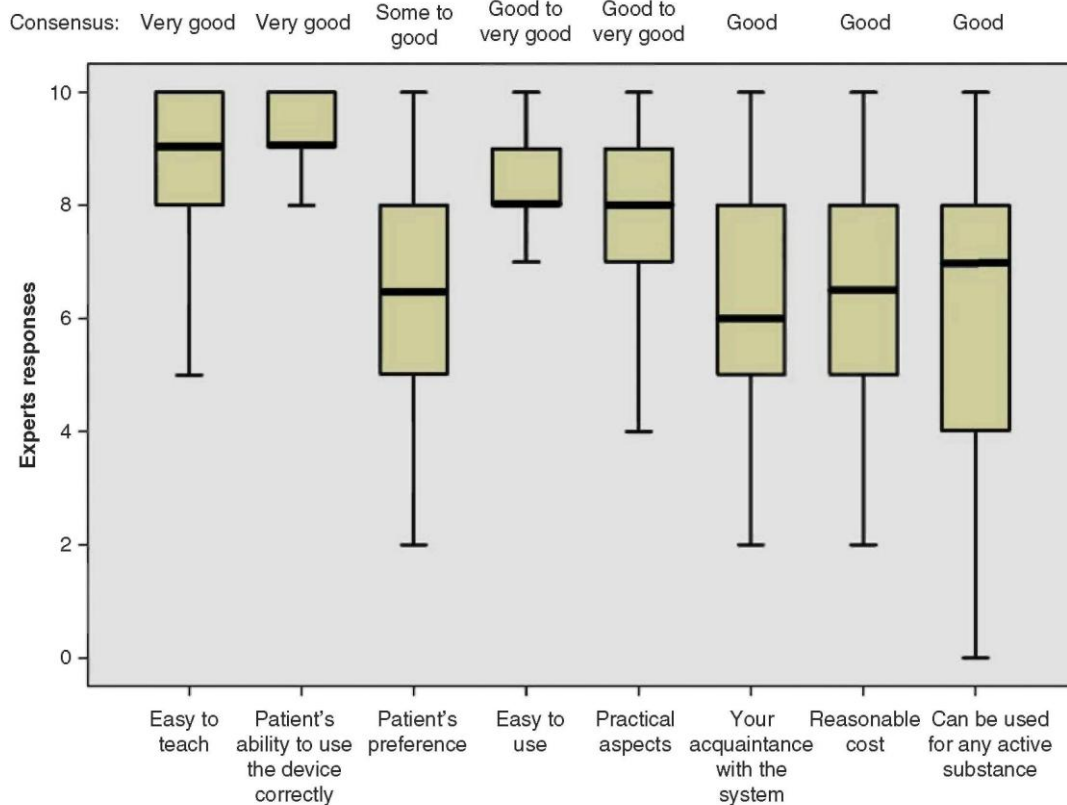
<sup>§</sup>Expert responses: 0 = does not agree at all; 10 = entirely agree  
 ID: Inhalation device; Q2: Median; Q1, Q3: Interquartile range.

**Figure 2.** Importance of different criteria of choice of IDs when prescribing inhalation treatment for obstructive lung disease is shown.

Responses: 0 = 'the criterion is not important at all' and 10 = 'the criterion is very important'.

The boxplot: the central box shows the interquartile range (Q1 - Q3), with the thick horizontal line representing the median (Q2) and the whiskers (above and below the box) the maximum and minimum (calculated as  $Q3 + 1.5 * [Q1 - Q3]$  and  $Q1 - 1.5 * [Q1 - Q3]$ , respectively).

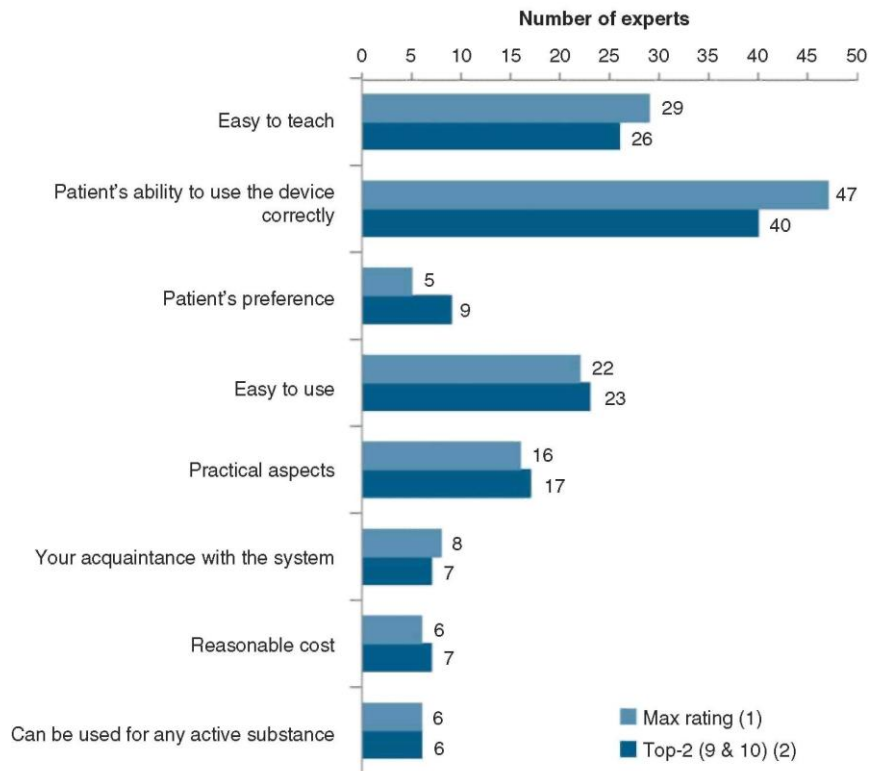
Outliers have been removed from the data sets since they have no impact on the data presented (central trends being presented as median values).



**Figure 3.** Rating level of different criteria of choice of IDs when prescribing inhalation treatment for obstructive lung disease is shown.

Max rating = Number of experts having chosen, for a given criteria, the highest rating among the individual evaluations. Note that similar rating on the 0-10 scale could be given to different criteria.

Top-2 = Number of experts having given a rating of 9 or 10 on the 0 - 10 scale.



### 3.3 Interchangeability of IDs

Most experts disagreed with the idea that IDs were easily interchangeable, even if active substances and dosages were kept the same; the responses of 80% of experts ranged between 0 and 4 (Table 2). The degree of consensus was good; the response of 54% of experts ranged between 1 and 3. In the second round, 10 of the 50 experts modified their answer; more experts disagreed with the idea that IDs were easily interchangeable.

A large majority of experts disagreed with the suggestion that ID switches could be made by pharmacists, even if active substances were kept the same (Table 2). The responses of 94% of experts ranged between 0 and 1 and the degree of consensus was very good. In the second round, 6 of the 50 experts modified their answer; more experts disagreed with the idea that ID switches could be made by pharmacists.

All experts agreed ( $Q2 \geq 9$ ) with all the proposed potential consequences of ID switching without medical consultation (Figure 5). A Q2 value of 10 was achieved for four proposed consequences: misuse, low adherence, lower pulmonary disposition and more exacerbations/poorer control of the respiratory disorder. There was a high degree of agreement and consensus between responses for all suggested consequences.

The consensus was very good for the following consequences: misuse of IDs, patients' doubts about prescriptions and/or the physicians' diagnoses and patients questioning the new IDs upon encountering the slightest problems. A maximum of 4 of the 50 experts modified their answer in the second round.

### 3.4 Costs

Experts tended to disagree with the idea that physicians should prescribe the least costly ID for the community, although this disagreement was rather moderate (the responses of 54% of experts ranged between 0 and 4). The degree of consensus was good: the responses of 54% of experts ranged between 3 and 5 (Figure 6). In the second

round, 13 of the 50 experts modified their answer.

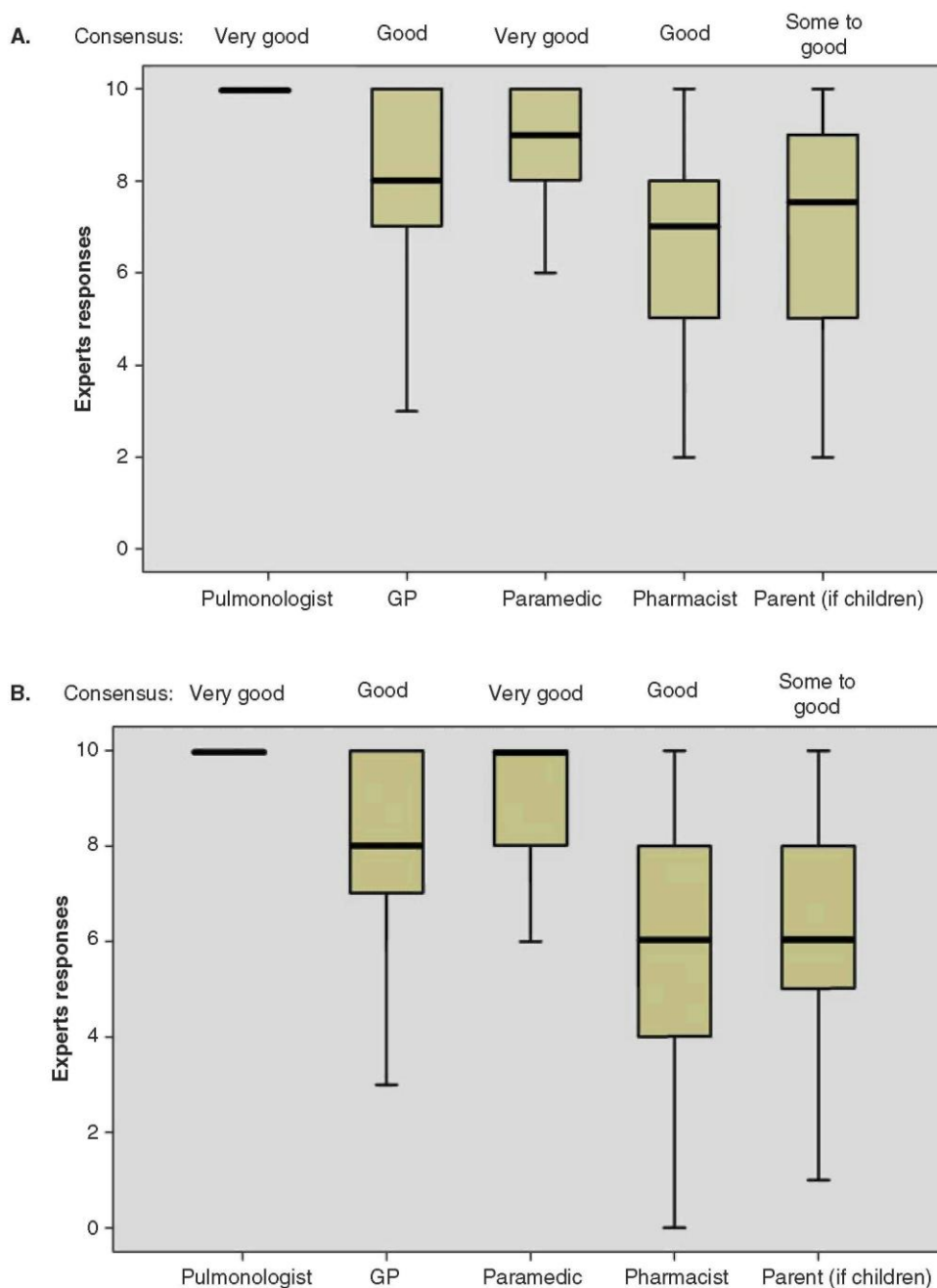
The large majority of experts clearly disagreed with the statement that pharmacists should deliver the least costly ID for the community, even if this device contained the active substance prescribed by the physician; the responses of 94% of experts ranged between 0 and 2. The degree of consensus was very good: the responses of 80% of experts ranged between 0 and 1 (Figure 5). In the second round, 7 of the 50 experts modified their answer.

**Figure 4.** The most appropriate person for (A) training patients in the use of an ID and (B) monitoring of patients' inhalation technique is explained.

Responses: 0 = 'not at all appropriate' and 10 = 'entirely appropriate'.

The boxplot: the central box shows the interquartile range ( $Q1 - Q3$ ), with the thick horizontal line representing the median ( $Q2$ ) and the whiskers (above and below the box) the maximum and the minimum (calculated as  $Q3 + 1.5 * [Q1 - Q3]$  and  $Q1 - 1.5 * [Q1 - Q3]$ , respectively).

Outliers have been removed from the data sets since they have no impact on the data presented (central trends being presented as median values).



#### **4. Discussion**

In this Delphi survey, experts considered that the ID choice was as important as the active substance choice in the treatment of asthma and COPD and important factors to take into account in the ID choice included ease of use and teaching. According to them, IDs were not easily interchangeable and switches should not be made without medical consultation and should not be based primarily on cost rationale. These results highlighted the fact that in many countries, where the guidelines from the Global Initiative for Asthma (GINA) and the Global initiative for chronic Obstructive Lung Disease (GOLD) are used, additional practical recommendations on ID choices are needed [1,16]. These recommendations should be in line with the guidelines from the American College of Clinical Pharmacy and the American College of Allergy, Asthma, and Immunology [17].

The Delphi method is a structured group communication process by which experts in their field can assess issues where relevant knowledge or information is lacking [18]. The present questionnaire addressed questions on the role of costs in the selection of IDs, and the interchangeability of IDs where there is presently no efficient method for decision making. In such conditions, Delphi is a widely used and accepted method for achieving convergence of opinion concerning real-world knowledge in a given topic area. It consists of sequence of questionnaires or 'rounds', interspersed by controlled feedback, in order to obtain consensus of opinion of a group of individuals with expert knowledge in the field evaluated. In order to select the experts in the present study, chest physicians were recruited on the following criteria: they were identified by academic chest physicians to be mainly involved in their own hospital in the management of airway obstructive lung diseases such that they were likely to have major interest and involvement with the questions being examined [18]. This selection was easy to perform since members of the DDC are representative of Belgian academic hospitals and are aware of the organization of chest services in non-academic hospitals. It must be stressed, however, that only one representative per hospital was recruited since anonymity is one of the features that characterizes the Delphi process and that selection of additional experts within the same hospital could lead to face-to-face reaction and bias [18]. Sequential rounds were performed and in the present study, good to very good convergence was already reached after two rounds. A small minority of participants (between 6 and 26% allowing to questions) changed their views in line with the group's responses, mainly in the form of small changes in rating on the scale, which seems reasonable given the absence of knowledge in the field.

The GINA and GOLD guidelines mention that patients should be instructed on ID use, but give very few recommendations on the way this should ideally be performed [1,16]. This survey provided further information on how and by whom this training should be performed. Experts recommended that patients should only receive prescriptions for IDs after receiving training by an appropriate person on their use, which is in line with the results of a previous Delphi survey conducted among Spanish experts [19]. In the present survey, pulmonologists recommended providing oral and visual rather than written instructions to the patients and systematically monitoring their inhalation technique at each visit.

In Belgium, there are only a limited number of healthcare givers, and no asthma or COPD nurses paid by the Health System, who can provide comprehensive instructions for correct handling of IDs and regularly review patients' inhalation technique. Therefore, patients often learn how to correctly use their ID when they are hospitalized due to an exacerbation event [20]. The experts considered that pulmonologists, followed by paramedics and GPs, were the most appropriate healthcare providers to teach and monitor patients' inhalation technique, which is in line with previous observations [2,21]. In the Delphi survey conducted previously in Spain, experts also stated that healthcare professionals should have detailed knowledge on IDs and inhalation techniques, although physicians were often unaware of their correct usage in practice [19]. Pharmacists could assist pulmonologists by providing information and training to the patients, but the experts in our study felt that paramedics were more appropriate to fulfill this, which may be due to the fact that paramedics work with the pulmonologists as part of their team on a daily base [22]. A closer collaboration between pulmonologists and pharmacists may have a positive impact on patients' follow up, as suggested by findings from previous studies [23,24]. Pharmacists could indeed enhance therapeutic outcomes in patients with asthma or COPD, but studies emphasize the importance of training for this purpose [25]. At present, however, most pharmacists are not trained to perform this education and are not familiar with the numerous devices and this factor has probably driven the opinion of the experts in the present study.

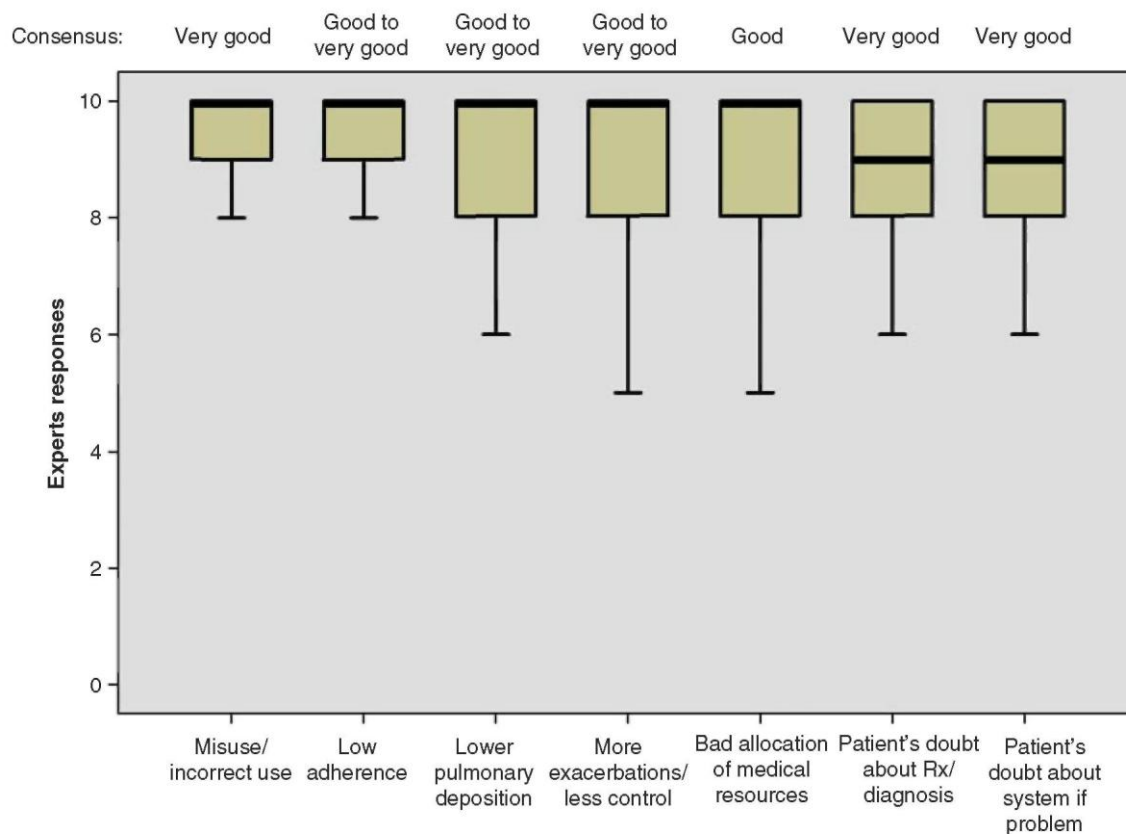
This survey also evaluated the level of concern of experts with regard to ID switches without medical consultation (unconsented switches) or for pure cost reasons. A very good level of consensus was reached between experts, who discouraged unconsented switches of IDs. In previous studies, ID switches have been associated with reduced disease control, and healthcare professionals have suggested that patients should be involved in the choice of their ID [24-28]. Moreover, the US FDA recently pointed to significant safety problems



related to the use of different IDs for the same drug [5]. There was also a good consensus against the choice of the least costly ID, provided that there was a technical difference, in particular when the choice was made by pharmacists. A previous study showed that, when ID switches were implemented as cost-saving procedures, the potential for worsened disease control and the subsequent associated costs may outweigh the cost savings from the switches [26].

This survey also evaluated the level of concern of experts with regard to ID switches without medical consultation (unconsented switches) or for pure cost reasons. A very good level of consensus was reached between experts, who discouraged unconsented switches of IDs. In previous studies, ID switches have been associated with reduced disease control, and healthcare professionals have suggested that patients should be involved in the choice of their ID [24-28]. Moreover, the US FDA recently pointed to significant safety problems related to the use of different IDs for the same drug [5]. There was also a good consensus against the choice of the least costly ID, provided that there was a technical difference, in particular when the choice was made by pharmacists. A previous study showed that, when ID switches were implemented as cost-saving procedures, the potential for worsened disease control and the subsequent associated costs may outweigh the cost savings from the switches [26].

**Figure 5.** The consequences of switching ID without medical consultation are shown. Responses: 0 = 'ID switches without a medical consultation cannot lead to the suggested consequence' and 10 = 'ID switches without a medical consultation can lead to the suggested consequence'. The boxplot: the central box shows the interquartile range (Q1 - Q3), with the thick horizontal line representing the median (Q2) and the whiskers (above and below the box) the maximum and the minimum (calculated as  $Q3 + 1.5 * [Q1 - Q3]$  and  $Q1 - 1.5 * [Q1 - Q3]$ , respectively). Outliers have been removed from the data sets since they have no impact on the data presented (central trends being presented as median values).



It should be noted that several other factors, specific to the device and patient, may preclude the decision to switch ID. These factors include particle size of the drug substance, airflow resistance of the ID and related generated inhalation profiles and upper and lower airway anatomy. Such factors underlie some of the difficulties faced in demonstrating bio-equivalence between different IDs containing the same active substance [29].

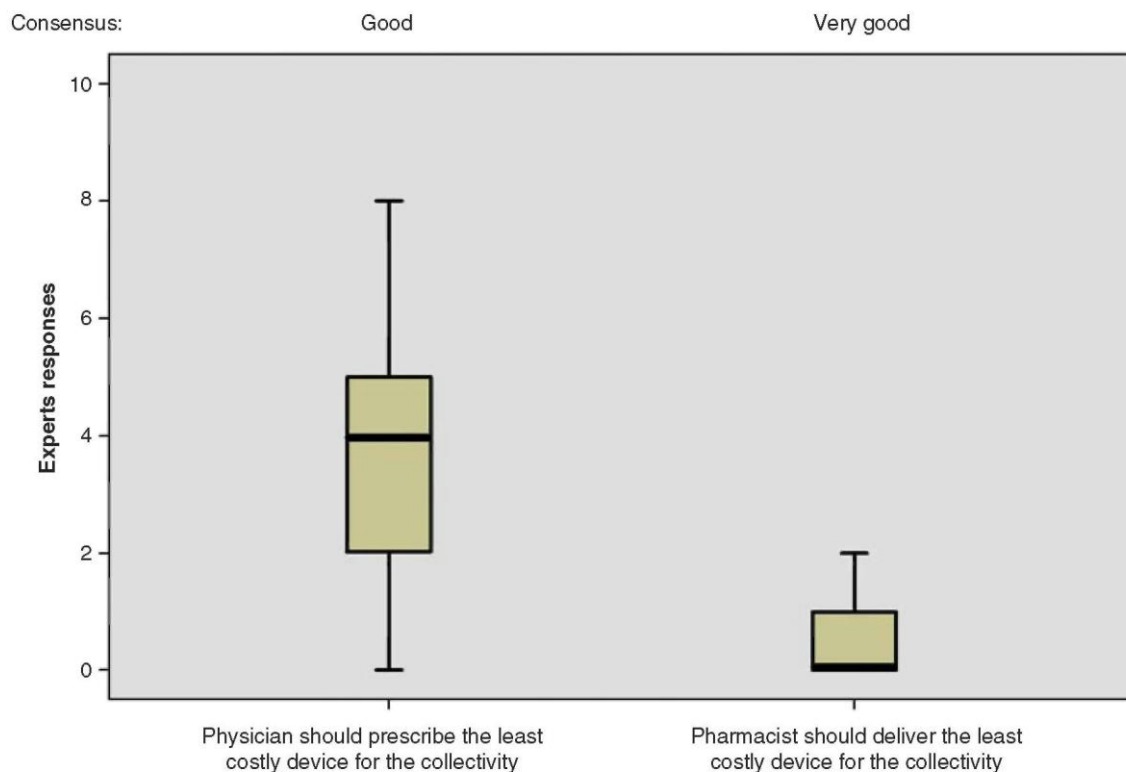
The members of the DDC, who came from Belgian and Luxembourg academic centers, selected the experts to whom the questionnaire was sent. The strengths of this study included the facts that the number of experts who responded to the questionnaire was large enough for a Delphi process, they were clearly identified as being mainly involved in asthma and COPD management, their local context was homogeneous and the level of consensus was systematically elevated. In addition, it is essential that participants who begin a Delphi process maintain involvement until completion [18]. With regard to this, the expert selection in the present study allowed easy reminders by telephone and email: ultimately 50 of the 53 participants who initially agreed to participate effectively completed the process. An alternative approach could have been to select international, preferably world experts as it is the case for the GOLD or GINA guidelines panel [1,16] on the basis of publications in the field, but this option was not retained by the DDC, mainly because the number of published research papers on ID management was limited. This was expected since the present study, according to Delphi inherent indications, addressed issues with limited knowledge. It is also unlikely that a similar good response rate could have been achieved with an international selection of experts.

**Figure 6.** The prescription of the least costly ID for the community is given.

Responses: 0 = 'I do not agree at all' and 10 = 'I fully agree'.

The boxplot: the central box shows the interquartile range ( $Q1 - Q3$ ), with the thick horizontal line representing the median ( $Q2$ ) and the whiskers (above and below the box) the maximum and the minimum (calculated as  $Q3 + 1.5*[Q1 - Q3]$  and  $Q1 - 1.5*[Q1-Q3]$ , respectively).

Outliers have been removed from the data sets since they have no impact on the data presented (central trends being presented as median values).



## 5. Conclusion

In conclusion, the experts included in this Delphi survey considered that the choice of the ID was as important as that of the active substance in the treatment of asthma and COPD, they strengthened the central role of the training and monitoring of the patients' inhalation techniques and they highlighted major concerns about unconsented switching of IDs. The high level of consensus that was observed for nearly all questions after two rounds suggests that our findings may closely represent the overall opinion of the Belgian pulmonologists. The consensus opinions generated by this Delphi survey could be valuable in developing practical guidelines for ID use in the treatment of asthma and COPD.

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## Declaration of interest

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### **Supplementary material available online**

Supplementary material: French and Dutch questionnaires and English translation.