

The Global Usability Score: A Novel Comprehensive Tool for Assessing, Ranking, and Compare Usability of Inhalers in Patients Requiring Airway Treatments

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Abstract

Introduction: The inhalation route is the best choice for respiratory drug delivery, but benefits to patients are strictly related to the proper use of inhalers. The role of patients' view point (such as: their intuitivity, preference, acceptance, and satisfaction) were extensively investigated, even if other factors, unrelated to their personal beliefs, can further affect inhaler usability.

Aim: to define a specific tool for easily assessing, ranking, and comparing the real usability of whatever inhaler by a single, comprehensive score, also based on objective measurements.

Methods: A specific, anonymous questionnaire was validated. The Questionnaire consists of four main sections (Introductory; Assessing Track; Global Score calculation, Patient's personal data). Questions are twenty-seven, all scored: twenty-two addressed to the patient, and five to the expert nurse, who has to conduct the independent assessments. The sum of the eight sub-scores of the Assessing Track will represent the final Global Usability Score-GUS, which ranges 0-50 points for each inhaler; higher the GUS value, higher the real usability will be.

Results: the comprehension of all questions at their first reading was >97% in the final version of the GUS Questionnaire, for both patients and nurses participating to the questionnaire development.

Discussion: usability of inhalers is a complex and multifaceted issue. When assessing usability, it should be taken into account that the role of patients' beliefs differently integrates the role of other objective determinants which are unrelated to the sole patients' viewpoint. Terms like intuitivity, preference, acceptability, or satisfaction should not be used as synonyms for usability, because too related to the patients' subjectivity only.

Conclusions: the Global Usability Score represents the first comprehensive score for assessing, ranking, and comparing objectively the contribution of all main components of inhaler usability, and then provide an effective and motivated standard of choice.

Keywords: Inhalation devices; Inhalation therapy; Usability; Patient preference; Patient acceptance; Usability score

Introduction

The need of increasing patients' awareness and empowerment in inhalation therapy of persistent airway obstruction (such as: Bronchial Asthma and Chronic Obstructive Pulmonary Disease (COPD) raised powerfully in the last decade, together to the increasing attitude in favour of the personalized strategy of treatment. Increasing evidence were suggesting that patients cannot use all inhalers equally well, and then the training with inhalers should have been regarded as a priority challenge [1,2]. On the other hand, further data emphasized that the inhalers represent *per se* a critical factor as they are able to affect the therapeutic outcomes substantially and independently of the drug used [3-6].

In the past, several aspects of patients' adherence to inhalation treatments had been extensively investigated. In particular, the determinants of patients' incorrect inhalation procedures [7,8] and those of patients' preference, acceptance, and satisfaction focused the attention of the majority of researchers [9-15]. The primary role of patients' viewpoint was then highly valued in recent years, even if the attempts to quantify objectively the correspondence between patients' beliefs and real usability in real life by means of specific instruments were only episodically pursued [11,16-19].

Actually, if some factors strictly involve the patients' personal conditions and beliefs (such as: their age, cognition, psychological

profile, socio-economic status, educational level, criteria of preference), further determinants of usability are as much related to other factors which are independent of the patients' role (such as: the intrinsic structure of the prescribed device which affects the drug emitted; the real difficulty in handling the inhaler; the quality and the duration of the educational training received; etc.). In other words, if the patients' opinion has to be valued much more than in the past, nevertheless further indices, less dependent of the personal viewpoint, should be taken into account, in order to provide a more comprehensive and objective evaluation of the overall usability of inhalation devices

Aim

The aim was to define a specific tool for easily assessing, ranking and comparing the real usability of whatever inhalation device (i.e.

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MDIs; DPIs; SMIs) by means of a single and comprehensive score (such as : the Global Usability Score-GUS), and to provide an effective and convenient standard of choice, based on quantitative and objective measurements.

Methods

A specific, anonymous questionnaire able to investigate and assess the role of main determinants of global usability for whatever inhalation device was designed and validated: the Global Usability Score Questionnaire (GUSQ) (Supplementary File 1). The project was approved by the Ethical and Scientific Commission of the National Centre for Respiratory Pharmacoeconomics and Pharmacoepidemiology in the session of January 4th, 2016 (n.001/2016).

In general terms, the GUS Questionnaire, which was planned for assessing and comparing the usability of a maximum of four inhalers together (generically indicated with A, B, C, D, in capital letters), represents the further development of the New Handling Questionnaire, already published in a previous paper [20], to which the algorithm for calculating the final global score was implemented.

The final version of the GUS questionnaire consists of four main sections. The first one is the Introductory section (I), where the previous patient's experience and familiarity with inhalers is generically investigated, and related information collected. The second one is the Assessing Track section (AT), which consists of five items where usability is investigated and assessed analytically, and where the results of both the patients' beliefs and the results of nurse's direct checks and measurements are pooled. The third one is the Global Score section (GS), dedicated to the simple calculation of the global score, which is produced by summing up all the eight partial scores included in the AT sections. Finally, the fourth section is dedicated to collecting some anonymous information on the patient surveyed, such as: age, gender, educational degree, and region of living (Supplementary File 1).

All questions had been worded on a single line in order to facilitate both their reading and their comprehension. The GUS Questionnaire consists of 27 questions. In particular, 22 questions require the patients' direct involvement and response: 18 of them are closed, while the remaining 4 are descriptive questions. After their informed consent, subjects are requested to point out their response by checking with an X, or to describe their opinion in the appropriate spaces: this procedure is easily visible and clearly reported on the top of the questionnaire, in the second line, just under the name of the questionnaire.

In the AT section, some questions (items 1-4) are aimed to grade the patients' opinions on each inhaler. This assessment is carried out before; after the explanation and demonstration of the corresponding inhalation procedure required for achieving the proper actuation, and also after the patients' practicing with each device, such as when their judge is expected to be much more aware and objective. Moreover, other five questions are uniquely addressed to the nurse and are aimed to obtain some motivated opinions and precise measurements of specific practicalities (such as: the real time spent; the corresponding n. of attempts for achieving the first proper actuation with each device; the objective grading of the real difficulty encountered by the patient during the inhalation procedure; the description of that particular step which causes the patient's incapability). In other words, the patients' subjective opinion is strictly checked and compared to the corresponding nurse's objective report. Finally, the patients' preference is further graded by means of ten specific questions (item 5).

Differently from the New Handling Questionnaire [20], each question of the GUS Questionnaire is provided of a graded score to

assign to each device, based on the patient's or nurse's responses. The specific indication of the respondent to whom each question is addressed (such as: the patient rather than the nurse) is reported in brackets immediately below the line of each question, together with the different weight (such as: points) to assign to each patient's or nurse's response. These scores are not reported in the questionnaire administered to patients in order to not influence their opinion.

Eight sub-scores should be calculated within the AT section: four by the patients', and four by the nurse. The sum of these eight sub-scores easily calculates the final global score of usability for each inhaler investigated. The GUS final score ranges 0-50 points, and it should be reported for each inhaler in the dedicated third section; higher the value of the GUS, higher the usability will be.

Finally, as it is a good practice to make individuals aware that their contribution is extremely important to the project, a short thanking sentence was included at the end of the questionnaire.

The nurses involved in the assessing track were professional experts in the educational field since at least five years. Nevertheless, they were further trained specifically on the technical and the psychological aspects of the GUS Questionnaire use.

The cultural and the linguistic validation of the GUS Questionnaire has been carried out between September and November 2016 according the usual procedures which were described elsewhere [20], and the comprehension of each question was >97% in its final version. The English version of the validated GUS Questionnaire was realized using the technique of translation and back-translation, thanks to the contribution of expert professionals of U.S.A. native language.

Discussion

Inhalation is the preferred route for delivering and assuming respiratory drugs, but the choice of the most convenient inhalers to prescribe still represents a critical issue in respiratory medicine, mainly because patients cannot use all inhalers equally well [1,2].

Nevertheless, even if inhalers can differently affect *per sé* the therapeutic outcomes independently of the drug used, their choice is frequently empiric in real life, and the reasons for possible differences in their performance is often underestimated or neglected in real life [14,21,22].

Usually, the patients' skill in the device practicality, as well as their knowledge of the operational manoeuvres consenting the proper and effective inhalation of the drug emitted are inadequate [13]. As a consequence, the causes of patients' incorrect inhalation procedures and the determinants of patients' preference and acceptance had been extensively investigated, mainly being the patient's confidence and beliefs highly valued and regarded as the very crucial steps of the process to improve [9,15].

However, usability of inhalers is a much more complex issue and also depends on other, more objective factors operating in different domains, which are independent of the sole patient's opinion. Actually, if inhalers presently available are highly effective, nonetheless their sophisticated constructive technologies require the contribution of health professionals for supporting patients with a higher education and training level than in the past [23]. The careful quantitative assessment of these aspects represents a crucial, unavoidable contribution to a more comprehensive concept of usability, which should then not be merely limited to that of preference or acceptance by an unaware or untrained patient.

Some investigational instruments have been developed in this field, but many of them are uniquely or mainly oriented to assess patients' intuitiveness, preference, and satisfaction. In 2005, the Patient Satisfaction and Preference Questionnaire (PASAPQ), such as a multi-item measure tool to be administered to asthma and COPD patients, was designed and validated in order to assess both the performance and the convenience of inhalers, together to the overall patients' satisfaction [17]. Even if the questionnaire proved to be a practical and reliable instrument of investigation, it should be pointed out that it only consents to measure the patients' personal beliefs on the inhalers to compare [17,24,25], being unfortunately the objective check and the control of responses by an independent third-part expert observer (i.e. the expert nurse) lacking.

Another self-administered questionnaire was used for assessing the performance of a novel DPI [17]. This questionnaire consists of twenty questions belonging to four different domains of patients' beliefs (confidence; ease-of-use, preference, and satisfaction of the device). Responses are asked before and after demonstration of the proper inhalation procedure by the investigator, who also has to register the time taken to achieve three consecutive correct attempts, together to the number and types of errors done. Even if some quantitative assessments have been included in this questionnaire, all the questions are exclusively addressed to the patients, and then corresponding responses only consent the assessment of their personal confidence and opinions. Furthermore, the assessment of patients' opinions results partially biased because obtained by means of a Likert scale (ranging 1-6; 1-5 only for the satisfaction domain) which patients were asked to respond after two separate training sessions. The major intrinsic criticism to this questionnaire is that the Likert scaling assumes that distances between each item are equal, such as that all items are valued of the same weight and power in contributing to the four different scores of the questionnaire [26,27].

The Feeling of Satisfaction with Inhaler Questionnaire (the SFS-10 questionnaire) was also adopted for comparing different inhalers in COPD patients at different severity. This questionnaire consists of ten simple questions only addressed to the patient, but the assessment of an objective, independent, and graded score is once more lacking [19].

The New Handling Questionnaire-2 (NHQ-2 Questionnaire) has been recently developed and validated with the aim to provide an investigational instrument for assessing acceptance, handling, but also usability of different inhalers in asthma and COPD patients, in a setting strictly supervised by an independent controller. Patients are asked to fill this self-administered questionnaire before; after instruction on the proper use of inhalers, and also after their direct practicing. Patients' opinion are then compared to those of an expert nurse who have to carefully check and register all steps of the patients' behaviour and difficulties, and also to collected quantitative data on usability (such as: the duration of demonstration/instruction for each device; the most difficult step in actuation of each inhaler; the overall n. attempts for the 1st proper actuation and the time spent for the 1st proper actuation with each device) [20]. The NHQ-2 Questionnaire proved reliable and sensitive.

When this questionnaire was adopted for comparing usability of different inhalers, substantial discrepancies clearly appeared among the patients' perception and beliefs (also after instruction), and their real usability of inhalers after direct practicing [28]. These results were confirmed in the elderly by another study which mainly investigated the patients' acceptance, but also performed some measurements of the time required to actuate the proper inhalation [28].

Furthermore, these discrepancies proved to correspond strictly to relevant differences in cost-of-usability for each inhaler [29-31]. This clear evidence supports the concept that "usability" (when stemming from patients' and nurses' controlled information) is a more complex issue than expected. In other words, usability should be regarded as a much more multifaceted concept than those of "intuitivity", "preference", "acceptability", or "satisfaction", respectively, which should not be used as synonyms in the comparison of inhalers' performances. This suggestion is confirmed by the evidence that usability can also affect health care resources and the health technology assessment of different inhalers substantially [29-31].

All these assumptions were analytically weighted and ranked by means of the GUS Questionnaire where, for the first time, the unique comprehensive score calculated (the Global Usability Score) reflects objectively the quantitative contribution of the main components of inhaler usability.

At present, further studies are in progress in order to assess the GUS specificity and sensitivity within multiple inhaler comparisons and the ability to predict the "switch ability" between different devices, such as to define the best inhaler that could be substituted with another in case of therapy interruption or for other medical reasons.

Conclusion

Usability of inhalers is a multifactorial and complex issue. The availability of specific instruments for assessing analytically the real usability of different inhalers is a quite important topic, not only for research purposes, but also in real life.

From this point of view, the availability of a comprehensive index which might quantitatively and easily inform on the role played by the most relevant components affecting inhaler usability is a further crucial need: in other words, the need of a single and global score which may work as a reliable "measuring system", common to all inhalers, and allowing their objective characterization in terms of usability.

This was the aim of the Global Usability Score Questionnaire, which proves fitting to both patients' and nurses' different roles, and provides graded and differently weighted responses to all the specific questions included.

Even if further studies are needed to cover all the usability domains exhaustively, the implementation of a unique and comprehensive score (the Global Usability Score-GUS) highly supports and facilitates the assessment, the ranking and the comparison of usability of whatever inhaler device (i.e.: MDI; DPIs, SMIs), and provides an effective and motivated standard of choice.

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