

Checklists for the Assessment of Correct Inhalation Therapy

Checklisten zur Beurteilung einer korrekten Inhalation

Authors

V. Knipel¹, S. Schwarz¹, F. S. Magnet¹, J. H. Storre¹, C P Criée²,
W. Windisch¹ on behalf of the German Airway League

Institutions

- 1 Kliniken der Stadt Köln gGmbH – Lungenklinik, Universität Witten/Herdecke, Ostmerheimer Strasse 200, 51109 Köln
- 2 Ev. Krankenhaus Göttingen-Weende gGmbH, Pneumologie, Beatmungsmedizin/Schlaflabor, Bovenden-Lengern

received 28.10.2016

accepted after revision 14.11.2016

Bibliography

- DOI <http://dx.doi.org/10.1055/s-0042-121285>
Pneumologie 2017; 71: 96–105
 © Georg Thieme Verlag KG Stuttgart · New York
 ISSN 0934-8387

Corresponding author

Prof. Dr. Wolfram Windisch, Head of the department of Pneumology, Cologne Merheim Hospital, Kliniken der Stadt Köln gGmbH, Witten/Herdecke University, Faculty of Health/School of Medicine, Ostmerheimer Strasse 200, D-51109 Köln, Germany
 windischw@kliniken-koeln.de

ABSTRACT

Introduction For the long-term treatment of obstructive lung diseases inhalation therapy with drugs being delivered directly to the lungs as an aerosol has become the method of choice. However, patient-related mistakes in inhalation techniques are frequent and recognized to be associated with reduced disease control. Since the assessment of patient-mistakes in inhalation has yet not been standardized, the present study was aimed at developing checklists for the assessment of correct inhalation.

Methods Checklists were developed in German by an expert panel of pneumologists and professionally translated into English following back-translation procedures. The checklists comparably assessed three major steps of inhalation: 1) inhalation preparation, 2) inhalation routine, and 3) closure of inhalation.

Results Checklists for eight frequently used inhalers were developed: Aerolizer, Breezhaler, Diskus (Accuhaler), metered-dose inhaler, Handihaler, Novolizer, Respimat, Turbohaler. Each checklist consists of ten items: three for inhalation preparation, six for inhalation routine, and one for closure of inhalation.

Discussion Standardized checklists for frequently used inhalers are available in German and English. These checklists can be used for clinical routines or for clinical trials. All checklists can be downloaded free of charge for non-profit application from the homepage of the German Airway League (Deutsche Atemwegsliga e.V.): www.atemwegsliga.de.

ZUSAMMENFASSUNG

Einführung Die Inhalationstherapie mit Medikamenten, die als Aerosol direkt in die Lungen gelangen, hat sich als Therapie erster Wahl bei Patienten mit obstruktiven Atemwegserkrankungen etabliert. Fehler von Seiten des Patienten bei der Inhalation sind jedoch häufig und führen zu einer eingeschränkten Kontrolle der Erkrankung. Ziel der Studie war die Erstellung von Checklisten zur Beurteilung einer richtigen Inhalationstechnik, da die Methoden zur Überprüfung von Inhalationsfehlern bis jetzt nicht standardisiert sind.

Methodik Die Checklisten wurden von einem Expertenpanel in deutscher Sprache entwickelt und professionell ins Englische übersetzt nach den Methoden der Hin- und Rückübersetzung. Die Checklisten erfassen vergleichbar drei wesentliche Schritte der Inhalation: 1) die Vorbereitung der Inhalation, 2) die tatsächliche Anwendung sowie 3) die Beendigung der Inhalation.

Ergebnisse Es wurden Checklisten für acht häufig eingesetzte Inhalationssysteme erstellt: Aerolizer, Breezhaler, Diskus, Dosieraerosole, Handihaler, Novolizer, Respimat, Turbohaler. Jede Checkliste besteht aus 10 Items: drei für die Vorbereitung der Inhalation, sechs für die tatsächliche Anwendung sowie ein Item für die Beendigung der Inhalation.

Diskussion Es stehen standardisierte Checklisten für häufig eingesetzte Inhalatoren zur Verfügung. Diese Checklisten sind auf Deutsch und auf English verfügbar und können sowohl in der klinischen Routine als auch für klinische Studien eingesetzt werden. Alle Checklisten können kostenfrei für nicht kommerzielle Zwecke von der Homepage der Deutschen Atemwegsliga e. V. heruntergeladen werden: www.atemwegsliga.de.

Introduction

Asthma and chronic obstructive pulmonary disease (COPD) rank among the most widespread of chronic diseases contributing to morbidity and mortality in the world [1–3]. For the long-term treatment of these diseases, inhalation therapy with drugs being delivered directly to the lungs as an aerosol has become the method of choice as it allows high concentrations of the

drug at the target site at a cost of negligible or acceptable systemic side effects [4–8]. In addition, another advantage of inhalation therapy is the quicker onset of action compared to systemic treatment [4,5,8]. For the purpose of inhalation therapy of asthma and COPD anti-inflammatory agents, primarily inhaled corticosteroids (ICS), and bronchodilators including both beta-2-adrenergic agonist and anticholinergics are currently being used [1,2].

AEROLIZER			AEROLIZER		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Remove the cap and open the inhaler to insert a capsule.	The inhaler is not correctly opened.	V1	Verschlusskappe abnehmen und Inhalator auseinanderklappen, um Kapsel einzulegen.	Inhalator wird nicht korrekt geöffnet.
V2	Remove the capsule from the blister pack according to the instructions, and insert it into the inhaler's capsule compartment.	The capsule is not correctly removed from the blister pack, or inserted incorrectly into the capsule compartment.	V2	Kapsel entsprechend der Gebrauchsanweisung aus der Blisterzelle entnehmen und in das Kapselfach des Inhalators einlegen.	Kapsel wird nicht korrekt aus der Verblisterung entnommen bzw. Kapsel wird nicht oder falsch in das Kapselfach eingelegt.
V3	Pierce the capsule by once pressing the buttons provided for this purpose.	The capsule is pierced incorrectly.	V3	Kapsel anstechen durch einmaliges Drücken der Bedienknöpfe.	Kapsel wird nicht korrekt angestochen.
A4	Inhale in an upright posture (seated or standing).	Inhalation in an unfavourable posture.	A4	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation bei ungünstiger Körperhaltung.
A5	Before inhalation, exhale fully (but not into the mouthpiece).	Before inhalation, exhalation was insufficient or took place into the mouthpiece.	A5	Vor Inhalation tief ausatmen (nicht in das Mundstück).	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet bzw. in das Mundstück hinein.
A6	Tightly wrap the mouthpiece with your lips.	The mouthpiece is not tightly wrapped by the lips, or release takes place against the teeth, lips, or tongue.	A6	Mundstück mit den Lippen dicht umschließen.	Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Inhale vigorously, rapidly and deeply.	Inhalation was not deep or vigorous enough.	A7	Kräftige, rasche und tiefe Inspiration.	Inspiration nicht tief und kräftig genug.
A8	Hold your breath for 5-10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A8	Atem möglichst für 5-10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
A9	Do not exhale into the mouthpiece.	Exhalation took place into the mouthpiece.	A9	Exspiration nicht in das Mundstück.	Exspiration in das Mundstück hinein.
B10	Remove the capsule to check whether it was pierced and fully emptied.	No check is performed as to whether the capsule contains residual powder after inhalation.	B10	Kapsel herausnehmen und prüfen, ob sie durchgestochen und vollständig entleert wurde.	Es wird nicht geprüft, ob die Kapsel nach Inhalation noch Pulverreste enthält.

a

- **Fig. 1** Checklists for proper inhalation technique
- V 1 – 3: Questions about correct preparation for inhalation
- A 4 – 9: Questions about correct inhalation routine
- B 10: Questions about correct closure of inhalation

However, optimal inhalation treatment is essential for deposition of the inhaled drug in the lungs [4, 9 – 15]. This is dependent on the medication itself (type of inhaler device, particle size), but also on performing the inhaling action correctly [4, 9, 10]. Thus, the technique and performance of inhalation including device handling form integral parts of the drug deposition within the lungs [4, 7, 9 – 11, 16, 17].

As a matter of fact, optimal inhalation therapy is hindered by both intentional (patient's beliefs, doubts, fears of adverse effects) and non-intentional (when the patient forgets to use the inhaler device or has no access to it) adherence to treatment [7, 18]. In addition, even if the patient is willing and able to use the inhaler, a number of studies have identified patient-related mistakes in inhalation techniques being common, and this has

BREEZHALER			BREEZHALER		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Remove the cap and open the inhaler to insert a capsule.	The inhaler is not correctly opened.	V1	Verschlusskappe abnehmen und Inhalator auseinanderklappen, um Kapsel einzulegen.	Inhalator wird nicht korrekt geöffnet.
V2	Remove the capsule from the blister pack according to the instructions, and insert it into the inhaler's capsule compartment.	The capsule is not correctly removed from the blister pack, or inserted incorrectly into the capsule compartment.	V2	Kapsel entsprechend der Gebrauchsanweisung aus der Blisterzelle entnehmen und in das Kapselfach des Inhalators einlegen.	Kapsel wird nicht korrekt aus der Verblisterung entnommen bzw. Kapsel wird nicht oder falsch in das Kapselfach eingelegt.
V3	Pierce the capsule by once pressing the buttons provided for this purpose.	The capsule is pierced incorrectly.	V3	Kapsel anstechen durch einmaliges Drücken der Bedienknöpfe.	Kapsel wird nicht korrekt angestochen.
A4	Inhale in an upright posture (seated or standing).	Inhalation in an unfavourable posture.	A4	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation bei ungünstiger Körperhaltung.
A5	Before inhalation, exhale fully (but not into the mouthpiece).	Before inhalation, exhalation was insufficient or took place into the mouthpiece.	A5	Vor Inhalation tief ausatmen (nicht in das Mundstück).	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet bzw. in das Mundstück hinein.
A6	Tightly wrap the mouthpiece with your lips.	The mouthpiece is not tightly wrapped by the lips, or triggering takes place against the teeth, lips, or tongue.	A6	Mundstück mit den Lippen dicht umschließen.	Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Inhale vigorously, rapidly and deeply.	Inhalation was not deep or vigorous enough.	A7	Kräftige, rasche und tiefe Inspiration.	Inspiration nicht tief und kräftig genug.
A8	Hold your breath for 5–10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A8	Atem möglichst für 5–10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
A9	Do not exhale into the mouthpiece.	Exhalation took place into the mouthpiece.	A9	Exspiration nicht in das Mundstück.	Exspiration in das Mundstück hinein.
B10	Remove the capsule to check whether it was pierced and fully emptied.	No check is performed as to whether the capsule contains residual powder after inhalation.	B10	Kapsel herausnehmen und prüfen, ob sie durchgestochen und vollständig entleert wurde.	Es wird nicht geprüft, ob die Kapsel nach Inhalation noch Pulverreste enthält.

b

been shown to be associated with reduced disease control [11–14, 19].

Therefore, inhaler technique training is suggested to be a cornerstone of the care of patients with obstructive airway diseases to ensure optimal treatment. Furthermore, there are a number of strategies to choose the best inhaler device, and this is also aimed at improving the ability of the patient to correctly apply her/his prescribed inhaler [4, 7, 9–11, 15, 20, 21].

Patient-related mistakes in inhalation techniques have been assessed differently in previous studies [11–13]. Typically, questionnaires and checklist have been used for the purpose of assessing correct inhalation. However, these tools differ considerably. In addition, application procedures and pitfalls are

different amongst the various hand-held devices used for daily inhalation treatment. Finally, assessments of patient-related mistakes in inhalation techniques are not standardized. In this regard, it has been clearly established that patient-related mistakes in inhalation techniques might be related to inhalation preparation, inhalation routine, and closure of inhalation [22]. For these reasons, both scientific studies and different devices are not comparable to each other, respectively.

Therefore, the present study was aimed at developing checklists for frequently used hand-held devices used for inhalation treatment. These checklists were required to facilitate the comparison of different devices at least to some degree, but also to allow patients with different devices to be included

DISKUS/ACCUHALER			DISKUS		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Hold the disc horizontal with the mouthpiece facing you and the counter pointing up. Hold the outer housing with one hand. Place the other hand's thumb on the grip provided for this purpose.	The disc is not held correctly.	V1	Diskus waagerecht halten mit Mundstück zu sich und Zählwerk nach oben. Mit einer Hand das Äusengehäuse festhalten. Daumen der anderen Hand auf Daumengriff legen.	Diskus wird nicht korrekt gehalten.
V2	Open the disc by pushing away the thumb grip until the mouth piece and lever appear and a click is heard.	The disc has not been opened correctly.	V2	Diskus öffnen durch Wegschieben des Daumengriffes, bis Mundstück und Hebel erscheinen und ein Klicken zu hören ist.	Diskus wird nicht korrekt geöffnet.
V3	To load a dose, tighten the disc by pushing away the lever until a click is heard.	The disc is not correctly tightened and the dose is not correctly loaded.	V3	Diskus spannen, um Dosis zu laden durch Wegschieben des Hebels, bis ein Klicken zu hören ist.	Diskus wird nicht korrekt gespannt und Dosis nicht korrekt geladen.
A4	Inhale in an upright posture (seated or standing).	Inhalation in an unfavourable posture.	A4	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation bei ungünstiger Körperhaltung.
A5	Before inhalation, exhale fully (but not into the mouthpiece).	Before inhalation, exhalation was insufficient or took place into the mouthpiece.	A5	Vor Inhalation tief ausatmen (nicht in das Mundstück).	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet bzw. in das Mundstück hinein.
A6	Tightly wrap the mouthpiece with your lips.	The mouthpiece is not tightly wrapped by the lips, or triggering takes place against the teeth, lips, or tongue.	A6	Mundstück mit den Lippen dicht umschließen.	Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Inhale vigorously, rapidly and deeply.	Inhalation was not deep or vigorous enough.	A7	Kräftige, rasche und tiefe Inspiration.	Inspiration nicht tief und kräftig genug.
A8	Hold your breath for 5-10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A8	Atem möglichst für 5-10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
A9	Do not exhale into the mouthpiece.	Exhalation took place into the mouthpiece.	A9	Exspiration nicht in das Mundstück.	Exspiration in das Mundstück hinein.
B10	Close the disc after finishing inhalation. Use the counter to check the delivered dose.	The disc is not closed after the end of inhalation. The counter has not been checked or a wrong dose was dispensed.	B10	Diskus schließen nach Beendigung der Inhalation. Überprüfen der abgegebenen Dosis anhand des Zählwerks.	Diskus wird nicht geschlossen nach Beendigung der Inhalation. Zählwerk wird nicht überprüft bzw. falsche Dosis wurde abgegeben.

c

in one study. In addition, it was an aim to standardize the checklists for the different parts of the inhalation manoeuvre, i.e. inhalation preparation, inhalation routine, and closure of inhalation. Moreover, the easy usage of the checklists in clinical practice was a prerequisite. Finally, the checklists were developed in German, but the finalized versions were later profes-

sionally translated into English. For this purpose, a translation and a back-translation by two independent translators were performed. The translated versions were refined to avoid incongruence between the original and the back-translated version where appropriate.

HANDIHALER			HANDIHALER		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Remove the protective cap, pull up the mouthpiece, and open the inhaler to insert a capsule.	The inhaler is not correctly opened.	V1	Schutzkappe öffnen, Mundstück hochziehen und Inhalator auseinanderklappen, um Kapsel einzulegen.	Inhalator wird nicht korrekt geöffnet.
V2	Remove a capsule from the blister pack and insert it into the inhaler's capsule compartment.	The capsule is not correctly removed from the blister pack, or inserted incorrectly into the capsule compartment.	V2	Kapsel aus dem Blister entnehmen und in das Kapselfach des Inhalators einlegen.	Kapsel wird nicht korrekt aus dem Blister entnommen und nicht oder falsch in das Kapselfach eingelegt.
V3	Pierce the capsule by pressing the buttons provided for this purpose.	The capsule is pierced incorrectly.	V3	Kapsel anstechen durch Drücken der Bedienknöpfe.	Kapsel wird nicht korrekt angestochen.
A4	Inhale in an upright posture (seated or standing).	Inhalation in an unfavourable posture.	A4	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation bei ungünstiger Körperhaltung.
A5	Before inhalation, exhale fully (but not into the mouthpiece).	Before inhalation, exhalation was insufficient or took place into the mouthpiece.	A5	Vor Inhalation tief ausatmen (nicht in das Mundstück).	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet bzw. in das Mundstück hinein.
A6	Tightly wrap the mouthpiece with your lips.	The mouthpiece is not tightly wrapped by the lips, or release takes place against the teeth, lips, or tongue.	A6	Mundstück mit den Lippen dicht umschließen.	Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Inhale vigorously, slowly and deeply.	Inhalation was not deep or vigorous enough.	A7	Kräftige, langsame und tiefe Inspiration.	Inspiration nicht tief und kräftig genug.
A8	Hold your breath for 5-10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A8	Atem möglichst für 5-10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
A9	Do not exhale into the mouthpiece.	Exhalation took place into the mouthpiece.	A9	Exspiration nicht in das Mundstück.	Exspiration in das Mundstück hinein.
B10	Remove the capsule to check whether it was pierced and fully emptied.	No check is performed as to whether the capsule contains residual powder after inhalation.	B10	Kapsel herausnehmen und prüfen, ob sie durchgestochen und vollständig entleert wurde.	Es wird nicht geprüft, ob die Kapsel nach Inhalation noch Pulverreste enthält.

d

Methods

Checklists were developed for eight frequently used inhalers:

- Aerolizer
- Breezhaler
- Diskus/Accuhaler
- Handihaler
- Novolizer
- Metered-dose inhaler
- Respimat
- Turbohaler

The checklists were developed by an expert panel of pneumologists familiar with inhalation treatment (author group). Possible inhalation failures were adopted from previous research [7, 11–14, 18, 19]. Accordingly, item formulation was primarily based on previous studies showing main mistakes in inhalation treatment. Ten items were formulated for each checklist. Thereby, three items were formulated for the preparation of the inhalation process; six items were formulated for the inhalation routine; one item was formulated for the inhalation conclusion. Items for preparing and closure of inhalation were device-specific. For items covering inhalation routine the most important six possible mistakes were addressed as agreed

METERED-DOSE INHALER			DOSIERAEROSOLE		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Join the inhalation aid and pressure container together.	The inhalation aid and pressure container are incorrectly joined.	V1	Inhalationshilfe und Druckbehältnis zusammenstecken.	Inhalationshilfe und Druckbehältnis werden nicht korrekt zusammengesteckt.
V2	Remove the mouthpiece's cap.	The cap has not been removed.	V2	Kappe des Mundstücks entfernen.	Kappe wird nicht entfernt.
V3	Hold the metered-dose inhaler between your thumb and middle finger with the thumb pointing down, and shake at least five times.	The inhaler has not been shaken.	V3	Dosieraerosol zwischen Daumen und Mittelfinger mit dem Daumen nach unten halten und mindestens fünfmal schütteln.	Inhalator wird nicht geschüttelt.
A4	Exhale fully before inhaling.	Insufficient or no exhalation before inhalation.	A4	Vor Inhalation tief ausatmen	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet.
A5	Inhale in an upright posture (seated or standing).	Inhalation in a reclining or non-upright position.	A5	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation in liegender oder nicht aufrechter Position.
A6	Hold the inhaler upright during release. Tightly wrap the mouthpiece with your lips.	The inhaler is not held upright. The mouthpiece is not tightly wrapped by the lips, or release takes place against the teeth, lips, or tongue.	A6	Inhalator während des Auslösens senkrecht halten. Mundstück mit den Lippen dicht umschließen.	Inhalator wird nicht senkrecht gehalten. Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Perform release on commencing inhalation. Inhale through your mouth. Use one burst of spray per inhalation.	Release takes place in the middle/at the end of inhalation. Insufficient coordination between inhalation and spray release. Incorrect inhalation (not through the mouth, lips not tightly closed). Multiple triggering of the metered-dose inhaler per inhalation.	A7	Auslösen zu Beginn der Inhalation. Inhalation durch den Mund. Ein Sprühstoß pro Inhalation.	Auslösen erfolgt Mitte/Ende der Inhalation. Unzureichende Koordination zwischen Einatmung und Auslösung des Sprühstoßes. Fehlerhafte Inhalation (nicht durch den Mund, Lippen nicht dicht geschlossen). Mehrfachauslösen des Dosieraerosols pro Inhalation.
A8	Inhale slowly and deeply.	Inhalation is too shallow or fast.	A8	Langsame und tiefe Inspiration.	Zu kurze oder zu schnelle Inspiration.
A9	Hold your breath for 5–10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A9	Atem möglichst für 5–10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
B10	Fit the protective cap.	The protective cap was not fitted.	B10	Schutzkappe aufsetzen.	Schutzkappe wird nicht aufgesetzt.

e

within the expert panel. Thereby, the items for the inhalation routine were also formulated according to each device, respectively, but were closely related to each other according to the general rules of correct and optimal inhalation [22].

The checklists will be used by therapists evaluating the inhalation process of patients. For this purpose, each of the ten steps of inhalation will be rated as “failure” or “no failure”. Accordingly, each item consists of a positive statement (correct)

and one negative (mistake) statement. The therapist must decide for each item if the step of the inhalation process is performed correctly or not. Subsequently, the number of mistakes can be counted in total or depending on the three categories as identified above, i. e. inhalation preparation, inhalation routine, and inhalation conclusion.

NOVOLIZER			NOVOLIZER		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Insert the cartridge before initial use.	The cartridge is not properly inserted before initial use.	V1	Einlegen der Patrone vor Erstgebrauch.	Patrone wird vor Erstgebrauch nicht korrekt eingelegt.
V2	Remove the protective cap.	The protective cap was not removed.	V2	Schutzkappe entfernen.	Schutzkappe wird nicht entfernt.
V3	Press the dispensing button (colour changes in the inspection window).	The dispensing button was not pressed; the colour in the inspection window did not change.	V3	Dosiertaste drücken (Farbwechsel im Kontrollfenster).	Dosiertaste wird nicht gedrückt, kein Farbwechsel im Kontrollfenster.
A4	Inhale in an upright posture (seated or standing).	Inhalation in an unfavourable posture.	A4	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation bei ungünstiger Körperhaltung.
A5	Before inhalation, exhale fully (but not into the mouthpiece).	Insufficient or no exhalation before inhalation.	A5	Vor Inhalation tief ausatmen (nicht in das Mundstück).	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet.
A6	Tightly wrap the mouthpiece with your lips.	The mouthpiece is not tightly wrapped by the lips, or release takes place against the teeth, lips, or tongue.	A6	Mundstück mit den Lippen dicht umschließen.	Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Inhale vigorously, rapidly and deeply.	Inhalation was not deep or vigorous enough.	A7	Kräftige, rasche und tiefe Inspiration.	Inspiration nicht tief und kräftig genug.
A8	Hold your breath for 5–10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A8	Atem möglichst für 5–10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
A9	Do not exhale into the mouthpiece.	Exhalation took place into the mouthpiece.	A9	Exspiration nicht in das Mundstück.	Exspiration in das Mundstück hinein.
B10	Replace the protective cap after finishing inhalation. Use the counter to check the delivered dose.	The protective cap is not replaced after end of inhalation. The counter has not been checked or a wrong dose was dispensed.	B10	Schutzkappe wieder aufsetzen nach Beendigung der Inhalation. Überprüfen der abgegebenen Dosis anhand des Zählwerks.	Schutzkappe wird nicht aufgesetzt nach Beendigung der Inhalation. Zählwerk wird nicht überprüft bzw. falsche Dosis wurde abgegeben.

f

The initial checklists were shared within the board of the German Airway League (Deutsche Atemwegsliga e.V.). Refinements were made where appropriate.

Results

Checklists for all eight inhalers could be sufficiently provided and translated into English. The finalized versions of the eight checklists were then judged to be acceptable for use in clinical trials. The items of both the German and the English version of all checklists are displayed in ▶ Fig. 1.

Discussion

In the present study, checklists for the assessment of correct inhalation were developed by an expert panel of pneumologists working independently of any companies that produce the devices, in order to assure face validity.

The checklists are available in German and in English. They can be downloaded free of charge for non-profit projects from the homepage of the German Airway League (Deutsche Atemwegsliga) [www.atemwegsliga.de]. These checklists can be used for clinical application, but are also appropriate for clinical trials, particularly if different devices are used in one study.

The current project is aimed at stimulating the research in the field of inhalation treatment. Today, more and more drugs, drug combinations, and devices for inhalation therapy are available [4, 6, 8, 15, 23, 24]. In this regard, randomized controlled

RESPIMAT			RESPIMAT		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Insert the cartridge before initial use.	The cartridge is not properly inserted before initial use.	V1	Einlegen der Patrone vor Erstgebrauch.	Patrone wird vor Erstgebrauch nicht korrekt eingelegt.
V2	Load a dose by rotating the housing section in the direction of the arrow. Hold the Respimat inhaler upright while loading a dose.	The housing section is not correctly rotated. The Respimat inhaler is not held upright.	V2	Dosis laden durch Drehen des Gehäuseteils in Pfeilrichtung. Senkrechte Haltung des Respimat-Inhalators während Laden der Dosis.	Gehäuseteil wird nicht korrekt gedreht. Respimat wird nicht senkrecht gehalten.
V3	Remove the protective cap.	The protective cap was not removed.	V3	Schutzkappe öffnen.	Schutzkappe wird nicht geöffnet.
A4	Inhale in an upright posture (seated or standing).	Inhalation in an unfavourable posture.	A4	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation bei ungünstiger Körperhaltung.
A5	Exhale fully before inhaling.	Insufficient or no exhalation before inhalation.	A5	Vor Inhalation tief ausatmen.	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet.
A6	Tightly wrap the mouthpiece with your lips.	The mouthpiece is not tightly wrapped by the lips, or release takes place against the teeth, lips, or tongue.	A6	Mundstück mit den Lippen dicht umschließen.	Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Hold the Respimat horizontally during inhalation.	The Respimat inhaler is not held horizontally.	A7	Respimat waagerecht halten während Inspiration.	Respimat wird nicht waagerecht gehalten.
A8	Inhale slowly and deeply.	Inhalation was not deep enough or too fast.	A8	Langsame und tiefe Inspiration.	Inspiration nicht tief genug bzw. zu schnell.
A9	Hold your breath for 5–10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A9	Atem möglichst für 5–10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
B10	Replace the protective cap after finishing inhalation. Use the counter to check the delivered dose.	The protective cap is not replaced after end of inhalation. The counter has not been checked or a wrong dose was dispensed.	B10	Schutzkappe wieder aufsetzen nach Beendigung der Inhalation. Überprüfen der abgegebenen Dosis anhand des Zählwerks.	Schutzkappe wird nicht aufgesetzt nach Beendigung der Inhalation. Zählwerk wird nicht überprüft bzw. falsche Dosis wurde abgegeben.

g

trials have clearly established the benefits gained by inhalation treatment in obstructive lung diseases [11–13]. However, the evidence gained by randomized controlled trials is typically based on optimal circumstances also concerning correct inhalation. In real life, steadily improved inhalation treatment strategies as established by randomized controlled trials are worthless if high failure rates of the inhalation technique attenuate the treatment success.

Based on this, the current project is in line with a previous project from the German Airway League, where video screens for correct inhalation were provided as an efficient and globally available platform of information for both patients and therapists. Here, correct use of all inhalation devices available in Ger-

many has been videotaped and published via internet and DVD, with video screens, spoken text passages, and the visual insertion of information, all available free of charge on the homepage of the German Airway League [www.atemwegsliga.de] [20, 25–27]. The videotaped information is updated continuously.

As a limitation, the checklists were developed by pneumologists not regularly involved in the treatment of children. Therefore, the checklists are valid for adult patients only. Even though the current authors would not exclude that the checklists could also be successfully used in paediatric patients, specific aspects related to mistakes typically performed by children were not addressed. In addition, direct comparability be-

TURBOHALER			TURBOHALER		
	Procedure for proper inhalation technique	Inhalation fault (checklist)		Vorgehen bei richtiger Inhalationstechnik	Inhalationsfehler (Checkliste)
V1	Remove the protective cap.	The protective cap was not removed.	V1	Schutzkappe entfernen.	Schutzkappe wird nicht entfernt.
V2	Load a dose by rotating the ring located away from the mouthpiece.	The dosage ring was not correctly rotated.	V2	Dosis laden durch Drehen des mundstückfernen Dosierrings.	Dosierring wird nicht korrekt gedreht.
V3	Hold the Turbohaler upright while loading a dose.	The Turbohaler was not held upright.	V3	Senkrechte Haltung des Turbohalers während Laden der Dosis.	Turbohaler wird nicht senkrecht gehalten.
A4	Inhale in an upright posture (seated or standing).	Inhalation in an unfavourable posture.	A4	Inhalation bei aufrechter Körperhaltung (Sitzen od. Stehen).	Inhalation bei ungünstiger Körperhaltung.
A5	Before inhalation, exhale fully (but not into the mouthpiece).	Before inhalation, exhalation was insufficient or took place into the mouthpiece.	A5	Vor Inhalation tief ausatmen (nicht in das Mundstück).	Vor der Inhalation wird nicht oder nicht ausreichend ausgeatmet bzw. in das Mundstück hinein.
A6	Tightly wrap the mouthpiece with your lips.	The mouthpiece is not tightly wrapped by the lips, or release takes place against the teeth, lips, or tongue.	A6	Mundstück mit den Lippen dicht umschließen.	Mundstück wird nicht dicht mit den Lippen umschlossen bzw. Auslösen erfolgt gegen Zähne, Lippen oder Zunge.
A7	Inhale vigorously, rapidly and deeply. Hold the Turbohaler horizontally during inhalation. Do not block the air inlets during inhalation.	Inhalation was not deep or vigorous enough. The Turbohaler was not held horizontally. The air inlets were blocked by fingers.	A7	Kräftige, rasche und tiefe Inspiration. Turbohaler waagerecht halten während Inspiration. Lufteinlassöffnungen nicht verschließen während Inspiration.	Inspiration nicht tief und kräftig genug. Turbohaler wird nicht waagerecht gehalten. Lufteinlassöffnungen mit Fingern verschlossen.
A8	Hold your breath for 5–10 seconds, if possible.	Breath was held too briefly or not at all after inhalation.	A8	Atem möglichst für 5–10 Sekunden anhalten.	Atem wird nach Inhalation nicht oder zu kurz angehalten.
A9	Do not exhale into the mouthpiece.	Exhalation took place into the mouthpiece.	A9	Exspiration nicht in das Mundstück.	Exspiration in das Mundstück hinein.
B10	Replace the protective cap after finishing inhalation. Use the counter (if present) to check the dispensed dose.	The protective cap is not replaced after end of inhalation. The counter has not been checked or a wrong dose was dispensed.	B10	Schutzkappe wieder aufsetzen nach Beendigung der Inhalation. Überprüfen der abgegebenen Dosis anhand des Zählwerks (falls vorhanden).	Schutzkappe wird nicht aufgesetzt nach Beendigung der Inhalation. Zählwerk wird nicht überprüft bzw. falsche Dosis wurde abgegeben.

h

tween different devices is naturally hindered, and this is particularly due to main differences for preparing device-specific inhalation. Nevertheless, as all checklists refer to their main mistakes as established, it appears feasible to figure out what device is individually associated with overall lower mistake rates compared to others. Thus, certain comparability between different devices in terms of device-related failure rates is suggested to be feasible.

Therefore, the currently developed checklists are also suggested as a capable means of identifying patients who could benefit from inhalation training. In this regard, the teaching videos would be helpful, because these screens do not just cover the inhalation routine, but also the process of preparation and closure of inhalation.

Conflict of interest

V. Knipel, F. S. Magnet, J. H. Storre, C. P. Criée, and W. Windisch received speaking fees from companies dealing with inhalation treatment. All authors received financial travel support for attending conferences.

References

- [1] From the Global Strategy for the Diagnosis, Management and Prevention of COPD. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2016: Available from: <http://goldcopd.org>
- [2] From the Global Initiative for asthma. (GINA). 2016: Available from: <http://ginaasthmacopd.org/>
- [3] Burney PG, Patel J, Newson R et al. Global and regional trends in COPD mortality, 1990–2010. *Eur Respir J* 2015; 45: 1239–1247
- [4] Laube BL, Janssens HM, de Jongh FHC. What the pulmonary specialist should know about the new inhalation therapies. *Eur Respir J* 2011; 37: 1308–1331
- [5] Siekmeier R, Scheuch G. Systemische Therapie mit Aerosolen. *Atemw.-Lungenkrkh* 2005; 31: 374–386
- [6] Hoppentocht M, Hagedoorn P, Frijlink HW et al. Technological and practical challenges of dry powder inhalers and formulations. *Adv Drug Deliv Rev* 2014; 75: 18–31
- [7] Newman S. Improving inhaler technique, adherence to therapy and the precision of dosing: major challenges for pulmonary drug delivery. *Expert Opin Drug Deliv* 2014; 11: 365–378
- [8] Virchow JC, Crompton GK, Dal Negro R et al. Importance of inhaler devices in the management of airway disease. *Respir Med* 2008; 102: 10–19
- [9] Broeders ME, Sanchis J, Levy ML et al. ADMIT Working Group. The ADMIT series – Issues in Inhalation Therapy. 2) Improving technique and clinical effectiveness. *Prim Care Respir J* 2009; 18: 76–82
- [10] Broeders ME, Vincken W, Corbetta L ADMIT Working Group. The ADMIT series-Issues in Inhalation Therapy. 7) Ways to improve pharmacological management of COPD: the importance of inhaler choice and inhalation technique. *Prim Care Respir J* 2011; 20: 338–343
- [11] Crompton GK, Barnes PJ, Broeders M et al. The need to improve inhalation technique in Europe: a report from the Aerosol Drug Management Improvement Team. *Respir Med* 2006; 100: 1479–1494
- [12] Melani AS, Bonavia M, Cilenti V et al. Inhaler mishandling remains common in real life and is associated with reduced disease control. *Respir Med* 2011; 105: 930–938
- [13] Lavorini F, Magnan A, Dubus JC et al. Effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD. *Respir Med* 2008; 102: 593–604
- [14] van Beerendonk I, Mesters I, Mudde AN et al. Assessment of the Inhalation Technique in Outpatients with Asthma or Chronic Obstructive Pulmonary Disease Using a Metered-Dose Inhaler or Dry Powder Device. *J Asthma* 1998; 35: 273–279
- [15] Knipel V, Criée CP, Windisch W. Korrekte Inhalationstherapie: Einweisung mittels Internet-verfügbarer Filmsequenzen [Eine Initiative der Deutschen Atemwegsliga e.V.]. *Pneumologie* 2013; 67: 157–161
- [16] Dekhuijzen PN, Vincken W, Virchow JC et al. Prescription of inhalers in asthma and COPD: towards a rational, rapid and effective approach. *Respir Med* 2013; 107: 1817–1821
- [17] Capstick TG, Clifton IJ. Inhaler technique and training in people with chronic obstructive pulmonary disease and asthma. *Expert Rev Respir Med* 2012; 6: 91–101
- [18] Mäkelä MJ, Backer V, Hedegaard M et al. Adherence to inhaled therapies, health outcomes and costs in patients with asthma and COPD. *Respir Med* 2013; 107: 1481–1490
- [19] Wieshamer S, Dreyhaupt J. Dry Powder Inhalers: Which Factors Determine the Frequency of Handling Errors? *Respiration* 2008; 75: 18–25
- [20] Deutsche Atemwegsliga e.V. Homepage [Internet]. Richtig inhalieren (Pulverinhalatoren, Dosieraerosole, Respimat, Feuchtinhalation, CF-Inhalationssysteme). Verfügbar unter <http://www.atemwegsliga.de/richtig-inhalieren.html>
- [21] Dieninghoff D, Knipel V, Criée CP et al. Richtig inhalieren bei Mukoviszidose: Internet-verfügbare Videoclips der Deutschen Atemwegsliga e.V. *Pneumologie* 2015; 69: 583–587
- [22] Deutsche Atemwegsliga e.V. Homepage [Internet]. Richtig inhalieren (Checklisten). Verfügbar unter <http://www.atemwegsliga.de/checklisten.html>
- [23] Zhou QT, Tang P, Leung SS et al. Emerging inhalation aerosol devices and strategies: where are we headed? *Adv Drug Deliv Rev* 2014; 75: 3–17
- [24] Lavorini F, Fontana GA, Usmani OS. New Inhaler Devices – The Good, the Bad and the Ugly. *Respiration* 2014; 88: 3–15
- [25] Deutsche Atemwegsliga e.V. Youtube [Internet]. Inhalationssysteme bei COPD, Asthma, Mukoviszidose. Verfügbar unter <https://www.youtube.com/user/Atemwegsliga>
- [26] Deutsche Atemwegsliga e. V. on Vimeo [Internet]. Richtige Anwendung von Inhalationssystemen. Verfügbar unter <https://vimeo.com/channels/atemwegsliga>
- [27] Deutsche Atemwegsliga e. V. auf Facebook [Internet]. Videos zur richtigen Inhalation. Verfügbar unter <https://de-de.facebook.com/atemwegsliga.de>