La rilevanza del device nella scelta della strategia terapeutica e criteri di scelta del device in relazione al paziente

Federico Lavorini

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Firenze, Italia

Presenter Disclosures

F.L. has received in the last 5 years fees for lectures, advisory boards and reimbursements for attending meetings from the following pharma companies:

- AstraZeneca,
- Boehringer Ingelheim,
- CIPLA,
- Chiesi,
- Menarini International,
- TEVA.

The content of this talk represents the personal opinion of the presenter and does not necessarily represent the views or policy of the A.O.U. Careggi.

Inhaler Devices & Drugs >250 = confusion!

Devices

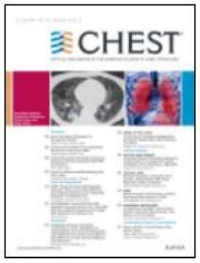
- pMDI
- Spacers
- DPI
- Nebulisers

Inhaled Drugs

- **SABA**
- **SAMA**
- LABA
- **LAMA**
- ICS
- **ICS/LABA**
- **LAMA/LABA**

Too many devices!

"That's a puffer. If you want to blow a house down, you'll also need a huffer."



Systematic Review of Errors in Inhaler Use

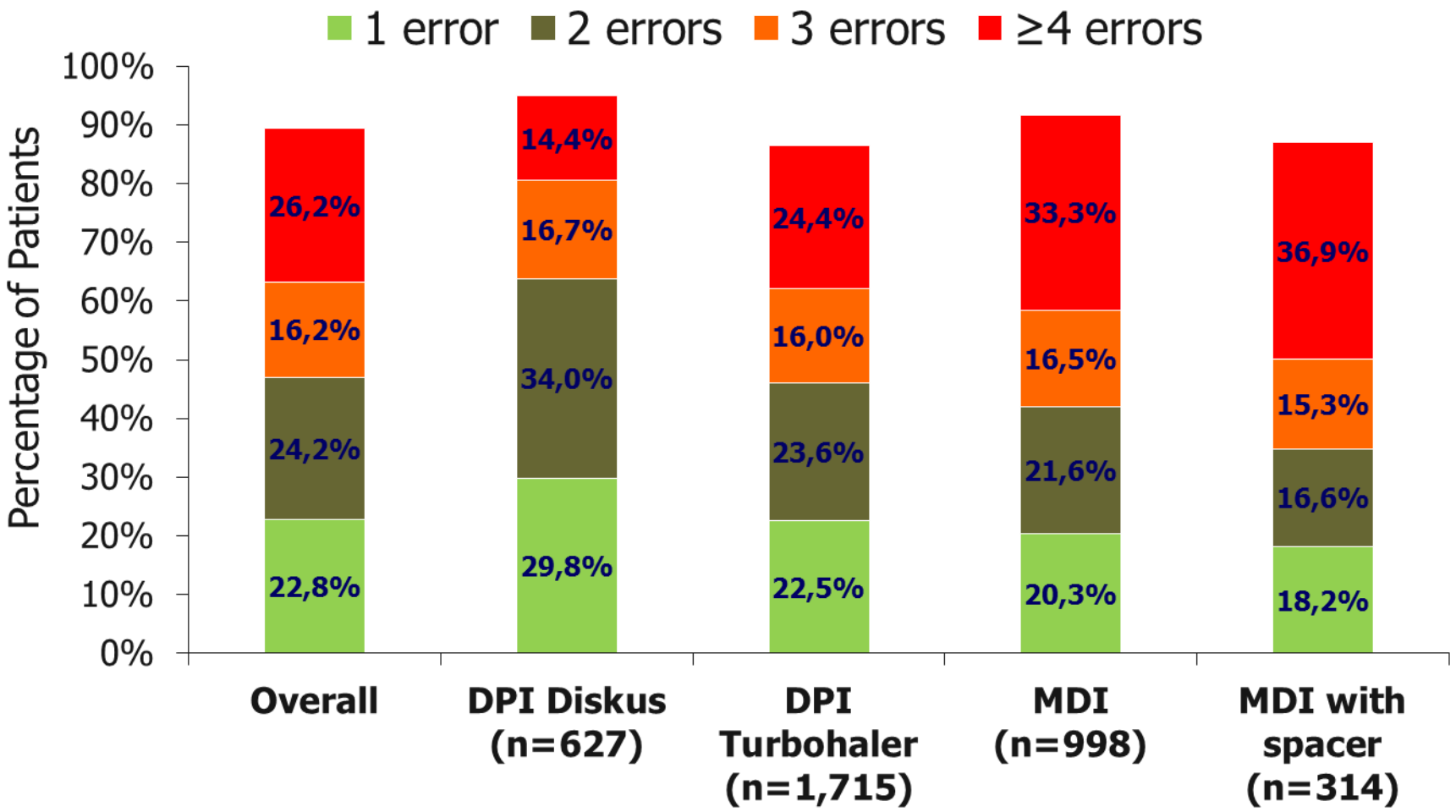
Has Patient Technique Improved Over Time?

Joaquin Sanchis, MD, PhD; Ignasi Gich, MD, PhD; and Soren Pedersen, MD, PhD, Dr Med Sci;

2016; 150(2):394-406

Inhalers use by patients over the past 40 years

Inhaler-specific serious error



n=3.654 asthma patients

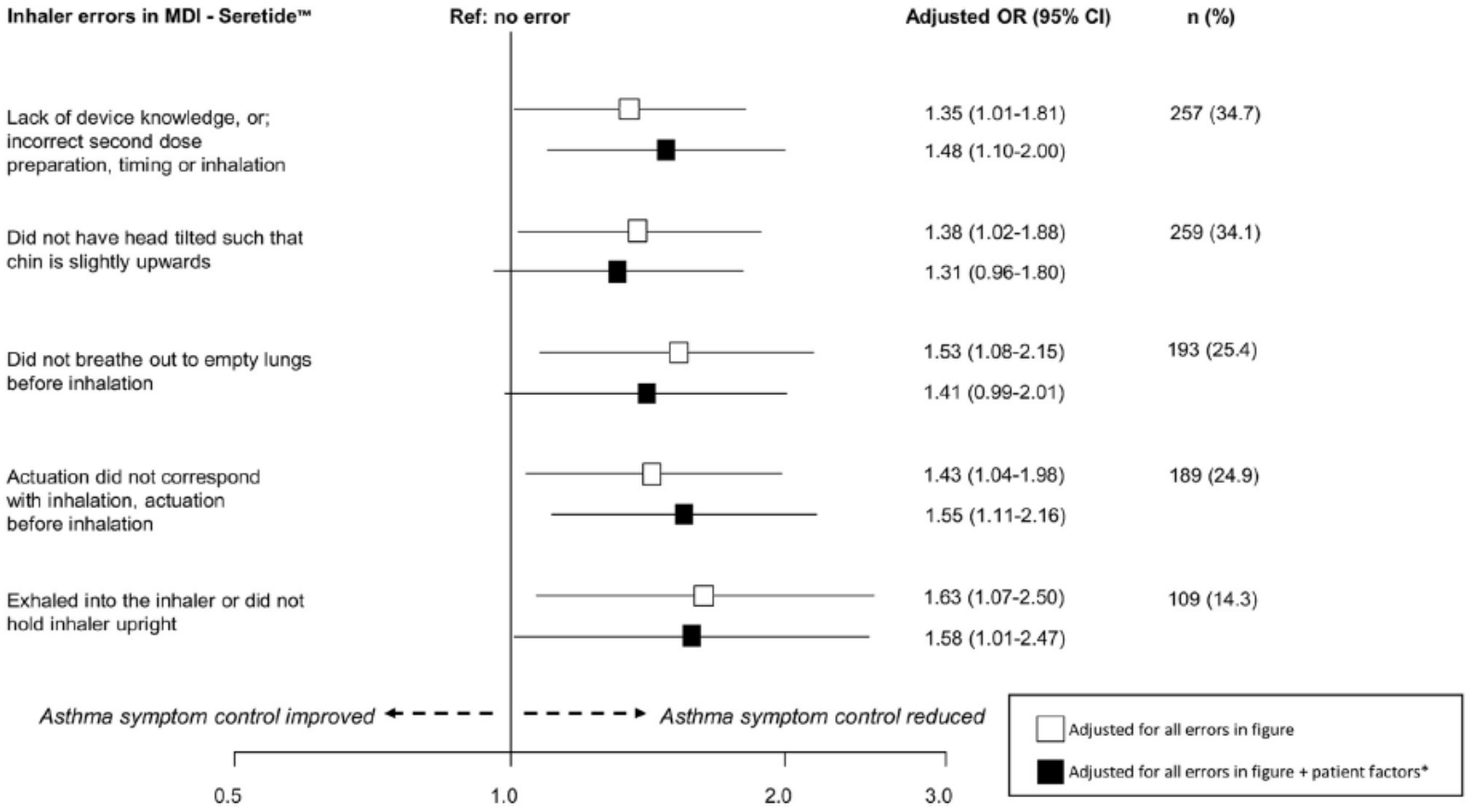
Price D, Roche N, Lavorini F et al IPCRG meeting 2014

Inhaler Errors in the CRITIKAL Study: Type, Frequency, and Association with Asthma Outcomes

The Journal of Allergy and Clinical Immunology: In Practice
An Official Journal of AAAAI American Academy of Allergy Asthma & Immunology

David B. Price, FRCGP[a,b], Miguel Román-Rodríguez, MD[c], R. Brett McQueen, PhD[d], Sinthia Bosnic-Anticevich, BPharm (Hons), PhD[e,f], Victoria Carter, BSc[g], Kevin Gruffydd-Jones, BM BCh, FRCGP[h], John Haughney, FRCPE, FRCGP[a], Svein Henrichsen, MD[i], Catherine Hutton, BA[b], Antonio Infantino, MD[j], Federico Lavorini, MD, PhD[k], Lisa M. Law, MSc[b], Karin Lisspers, MD, PhD[l], Alberto Papi, MD[m], Dermot Ryan, MD[g,n], Björn Ställberg, MD, PhD[l], Thys van der Molen, MD, PhD[o], and Henry Chrystyn, Phd, FRPHarmS[b,p] *Aberdeen, Cambridge, Box, Edinburgh, and Plymouth, United Kingdom; Singapore, Singapore; Palma de Mallorca, Spain; Aurora, Colo; Sydney, Australia; Oslo, Norway; Bari, Florence, and Ferrara, Italy; Uppsala, Sweden; and Groningen, The Netherlands*

Association between pMDI errors and uncontrolled asthma



Inhaler Errors in the CRITIKAL Study: Type, Frequency, and Association with Asthma Outcomes

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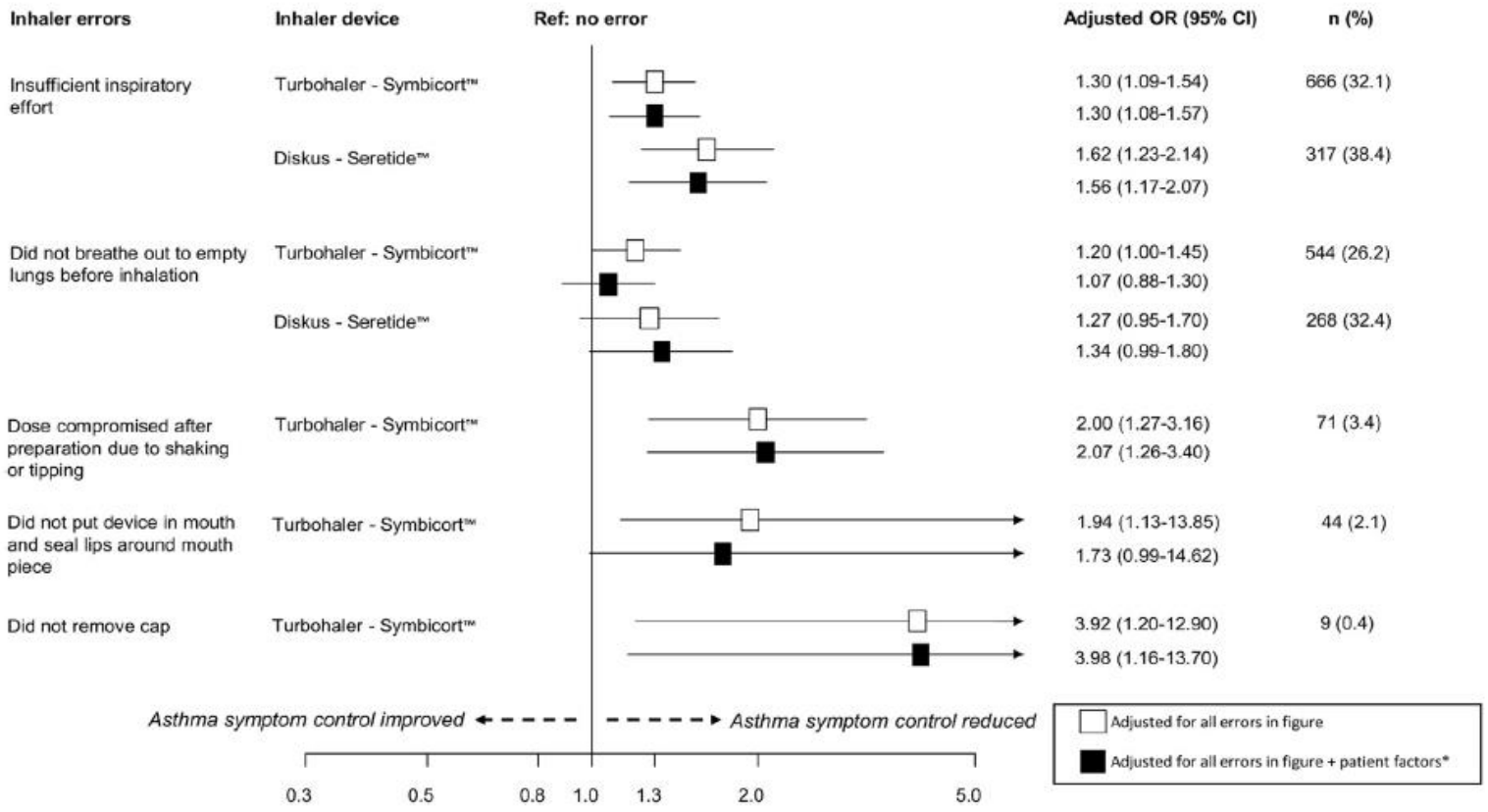
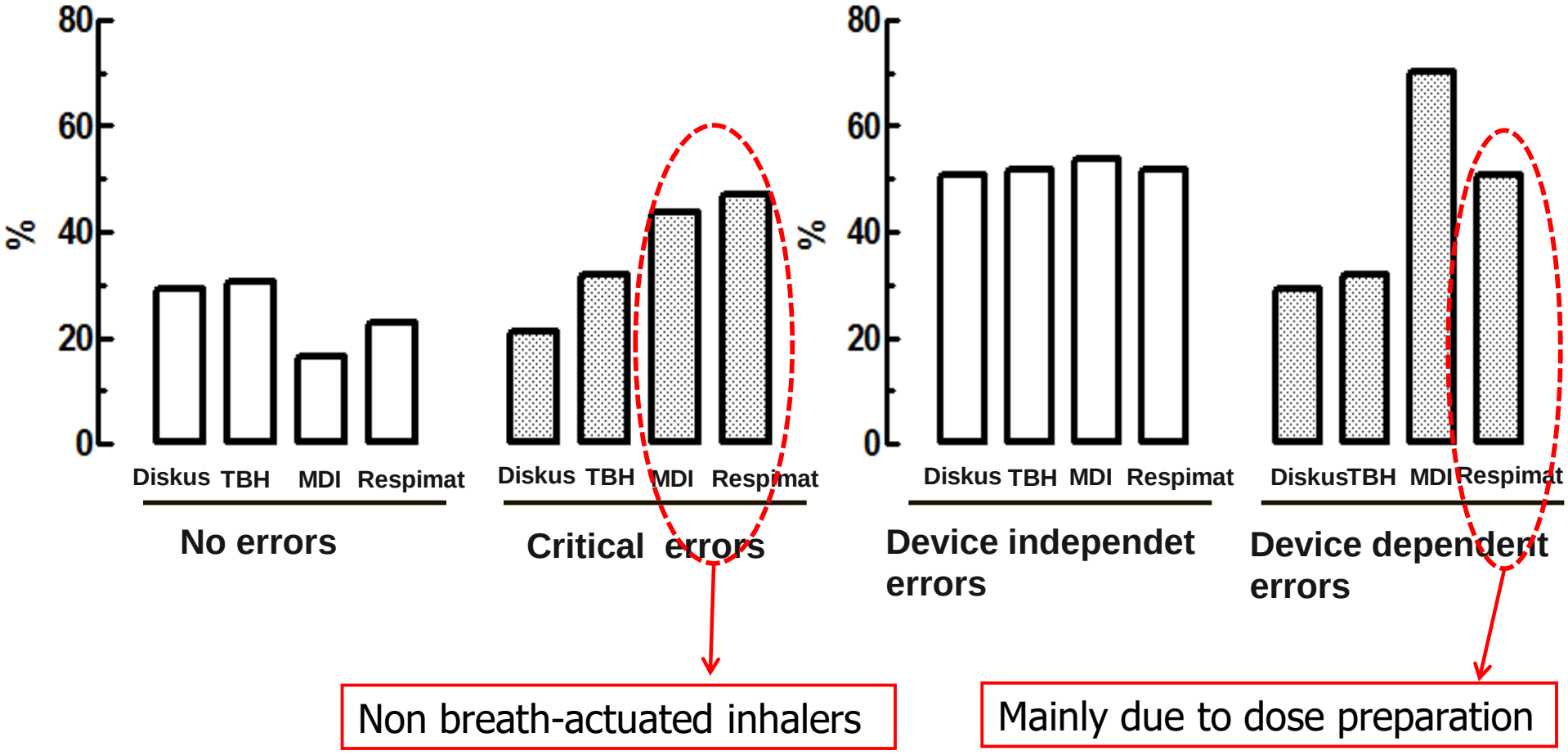
Association between DPI errors and uncontrolled asthma



Chronic obstructive pulmonary disease exacerbation and inhaler device handling: real-life assessment of 2935 patients

Mathieu Molimard[1,2], Chantal Raherison[2,3], Severine Lignot[1,4,5], Aurelie Balestra[1,4,5], Stephanie Lamarque[1,4,5], Anais Chartier[1,4,5], Cecile Droz-Perroteau[1,4,5], Regis Lassalle[1,4,5], Nicholas Moore[1,2,4] and Pierre-Olivier Girodet[1,4]

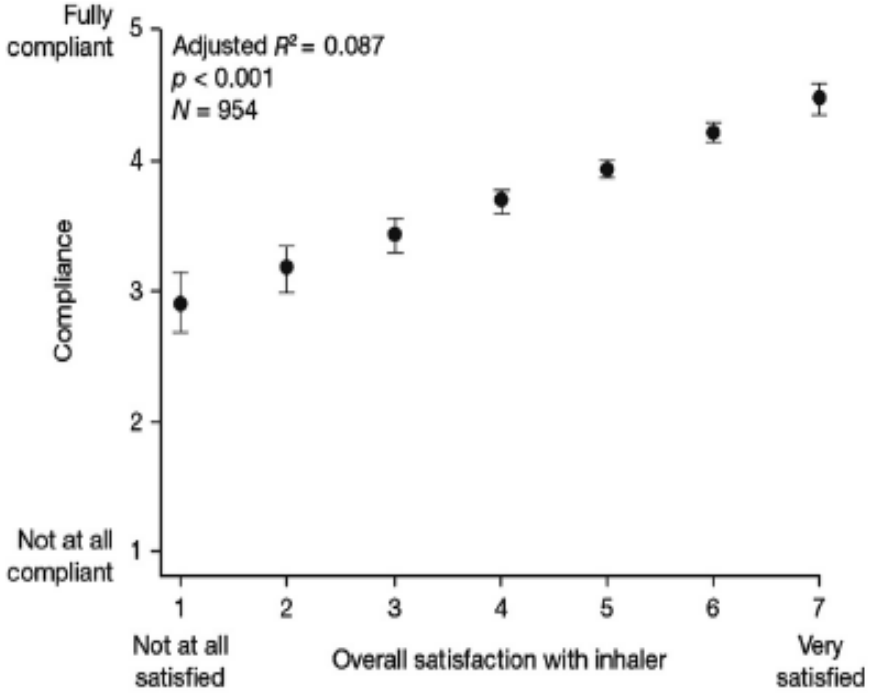
2017

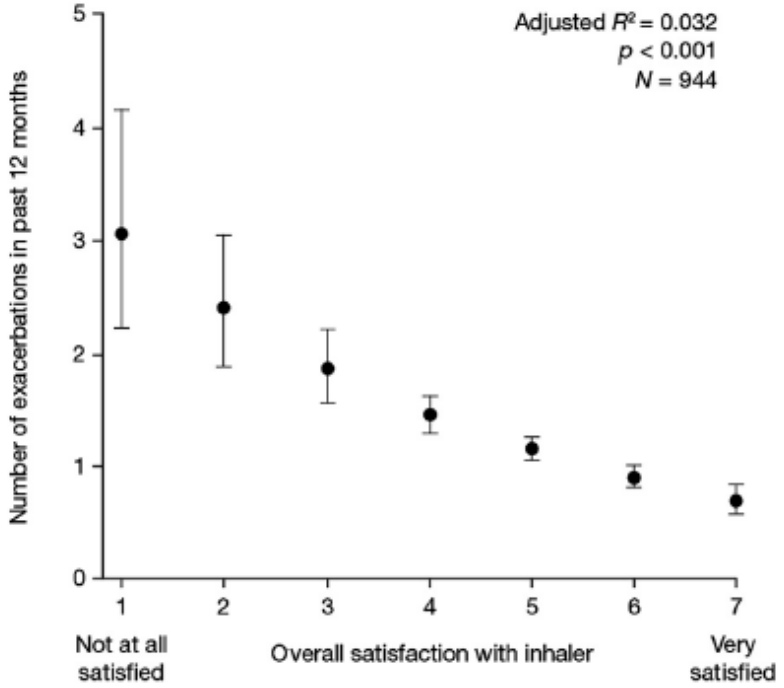


Impact of patients' satisfaction with their inhalers on treatment compliance and health status in COPD

Respiratory Medicine (2014) 108, 358–365

Henry Chrystyn [a,*], Mark Small [b], Gary Milligan [b], Victoria Higgins [b], Esther Garcia Gil [c], Jordi Estruch [d]





Patients satisfaction with their inhaler is an important factor driving treatment compliance in COPD

Problems with All Inhaler Types

pMDIs:

High oropharyngeal deposition, slow inhalation, coordination with inhalation.

DPIs:

Different device preparation, fast inhalation from the beginning, storage.

Nebulisers:

- Bulky, noisy, poor lung deposition, expensive.

So, which inhaler is right for your patient?

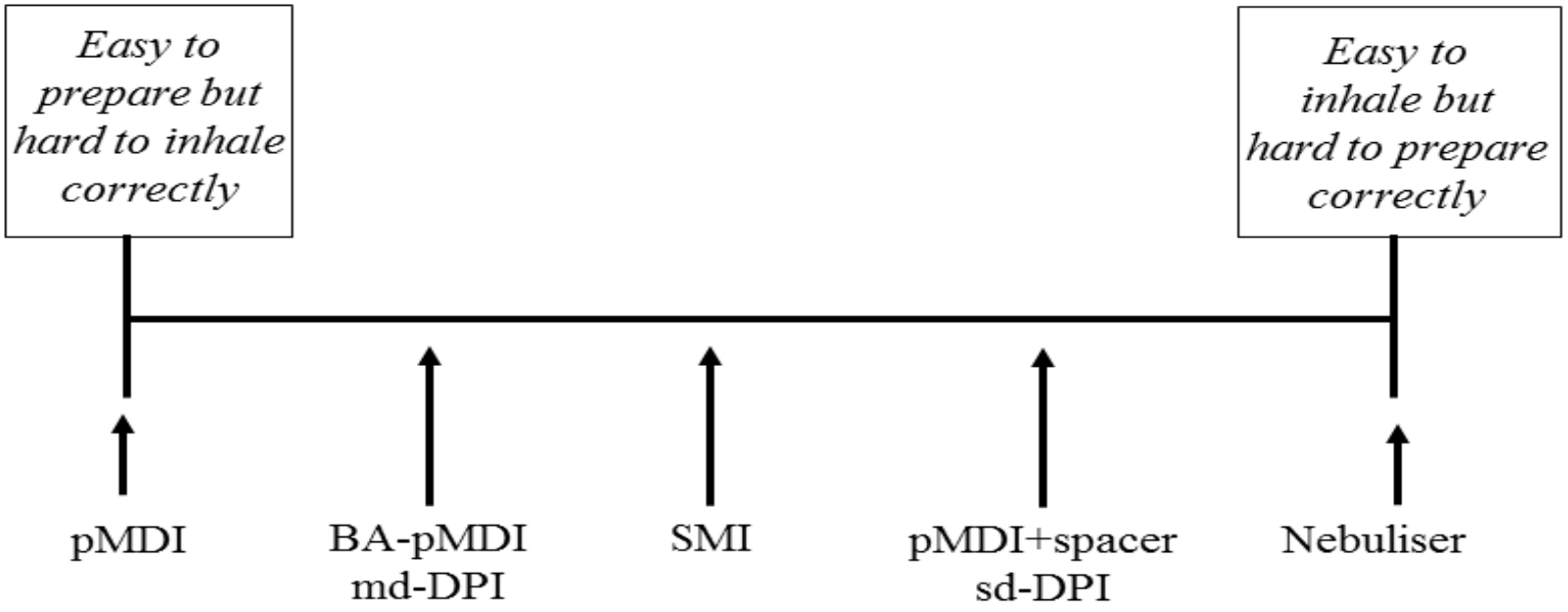
- Inhaler’s features;
- Patient’s characteristics.

REVIEW ARTICLE

2016

Optimising Inhaled Pharmacotherapy for Elderly Patients with Chronic Obstructive Pulmonary Disease: The Importance of Delivery Devices

Federico Lavorini[1] · Claudia Mannini[1] · Elisa Chellini[1] · Giovanni A. Fontana[1]



Correct drug delivery from inhalers is dependant on the patient: a) Preparing the device correctly;

b) Inhaling correctly.

Advantage of pMDIs: familiarity

DPIs on the other hand…..

What the pulmonary specialist should know about the new inhalation therapies

B.L. Laube, H.M. Janssens, F.H.C. de Jongh, S.G. Devadason, R. Dhand, P. Diot, M.L. Everard, I. Horvath, P. Navalesi, T. Voshaar and H. Chrystyn

ERS/ISAM TASK FORCE REPORT Eur Respir J 2011; 37: 1308–1331

Crucial differences between device types

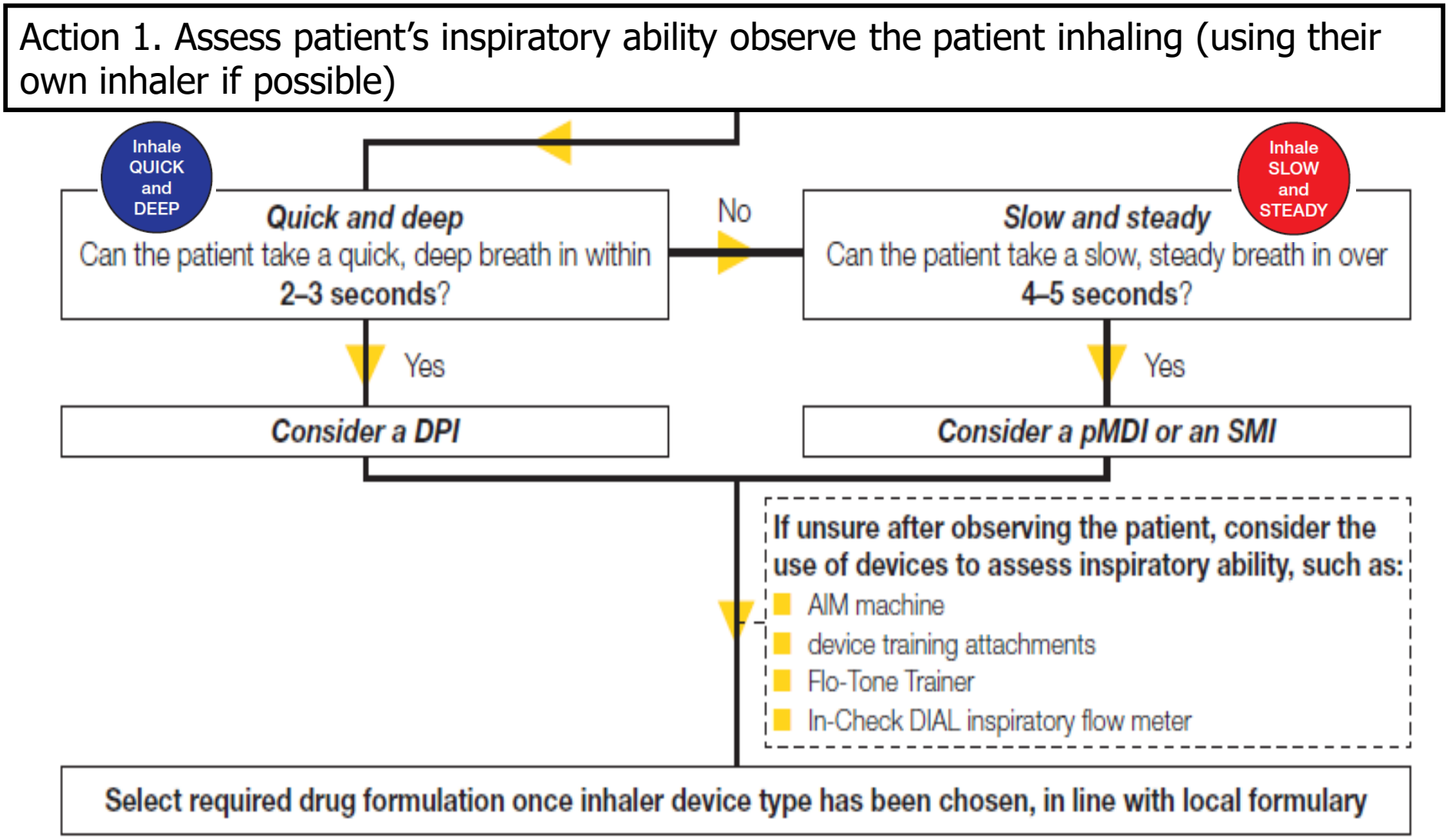
MDI

- Shaking (+/-)
- Actuation
- Coordinated with inspiration, except
  - BAI
  - MDI + Spacer
- Slow inhalation

DPI

- Device preparation
- No actuation, i.e. no need to coordinate
- No manipulation during inhalation
- Fast inhalation from the beginning

Inhaler choice: the UK perspective (i)



Usmani, Capstick, Chowhan & Scullion. www.guidelines.co.uk

Inhaler choice: the UK perspective (ii)

Action 2. Patient engagment and inhaler technique

When selecting a specific inhaler device, and at every patient review, reinforce the following seven steps for correct inhaler technique:

- **Preparation:**
  - Check dose counter (where present)—to confirm sufficient doses are remaining, and when replacement may be needed
  - Shake inhaler (if applicable—refer to manufacturer's instructions)
- **Priming:**
  - Prime the device ready for use—refer to manufacturer's instructions for details on how to prime specific devices and how often they may need re-priming
  - Open inhaler/remove cap
- **Exhaling:** Exhale fully and away from mouthpiece
- **Mouth:** Place mouthpiece in mouth and close lips around it to form a tight seal
- **Inhalation:**
  - DPI: quick and deep inhalation (within 2–3 seconds)
  - pMDI/SMI: slow and steady inhalation (over 4–5 seconds)
- **Breath holding:** Remove inhaler from mouth and hold breath for up to 5 seconds, then breathe out slowly
- **Closing and repeating:**
  - close inhaler/replace cap
  - repeat as necessary

After review of inhaler technique, patient and healthcare professional agree that chosen device is appropriate?

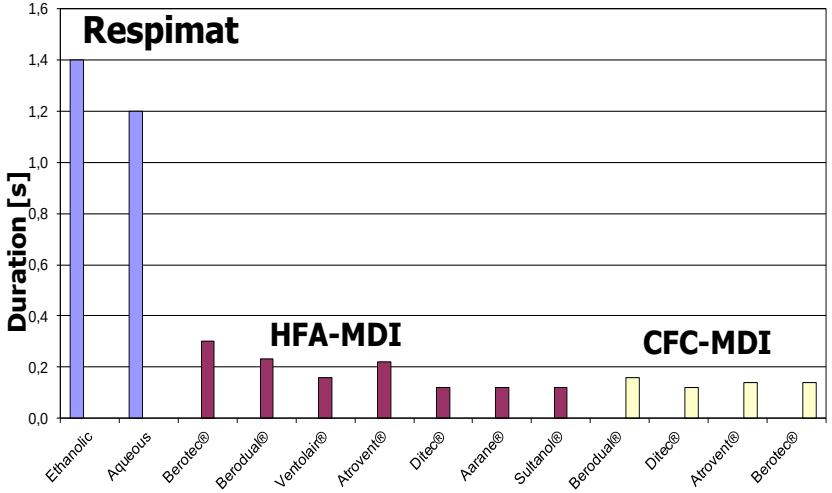
Yes → Prescribe chosen device

No → Consider alternative device → (repeat from Action 2)

Usmani, Capstick, Chowhan & Scullion. www.guidelines.co.uk

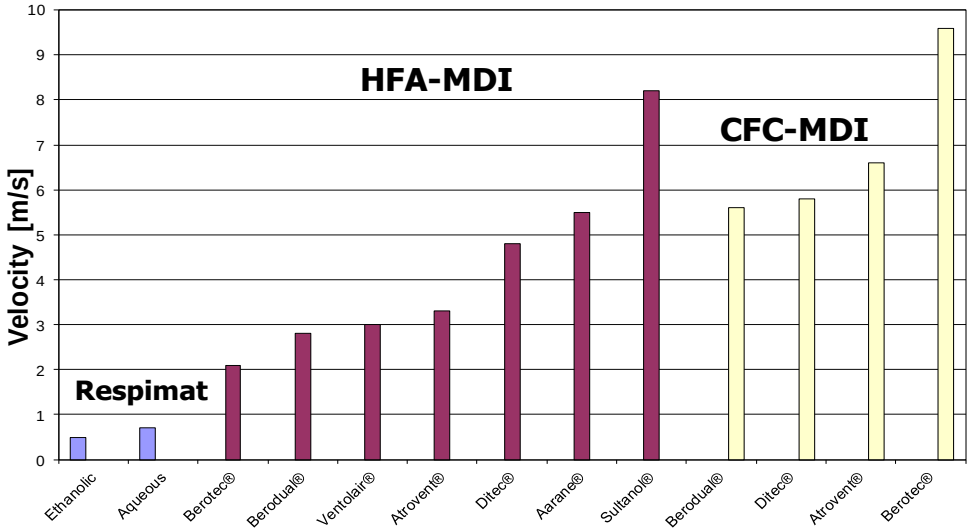
Respimat: aerosol cloud characteristics

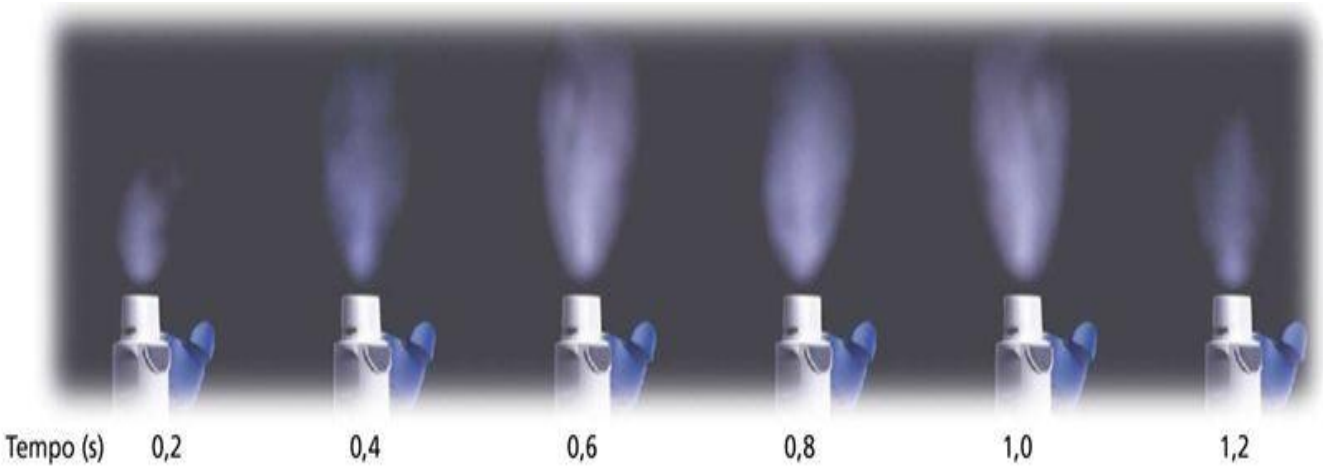
Cloud duration



Hochrainer *et al* J Aerosol Med 2005

Cloud velocity



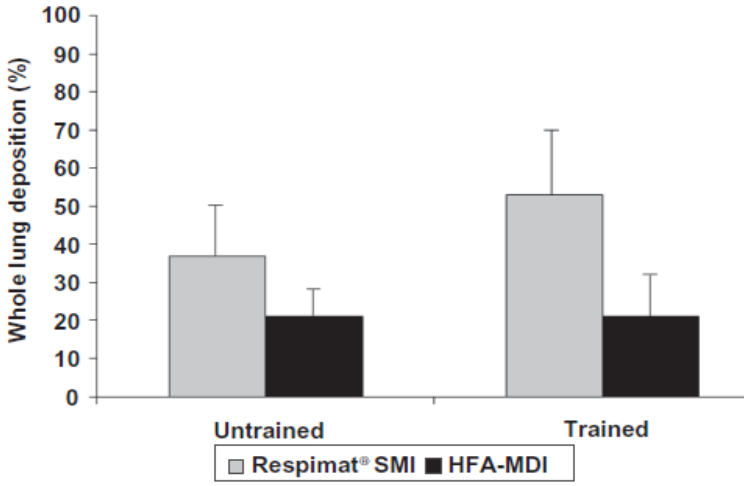


Respimat may reduce the need of hand-breath coordination !

Higher lung deposition with Respimat® Soft Mist™ Inhaler than HFA-MDI in COPD patients with poor technique

Peter Brand[1]
Bettina Hederer[2]
George Austen[3]
Helen Dewberry[3]
Thomas Meyer[4]

2008:3(4) 763–770
International Journal of COPD



	Lung region		
	Central	Intermediate	Peripheral
Respimat® SMI: untrained	17.9 (10.0)	11.7 (3.9)	7.80 (2.3)
Respimat® SMI: trained	25.0 (9.9)	17.7 (6.1)	9.9 (3.4)
pMDI: untrained	11.1 (5.0)	6.1 (2.3)	3.6 (1.2)
pMDI: trained	11.0 (6.6)	6.5 (2.7)	3.8 (1.8)

Drug delivery to the lungs with Respimat is more efficient than with HFA-pMDI..

Dry Powder Inhalers

- Practical advantages similar to pMDIs; no propellants
- Contain micronised drug attached to larger carrier particles;
- Actuated and driven by patient's inspiration; no hand-breath coordination required

Pre-metered Single Dose Unit

Pre-metered Multiple Dose Unit

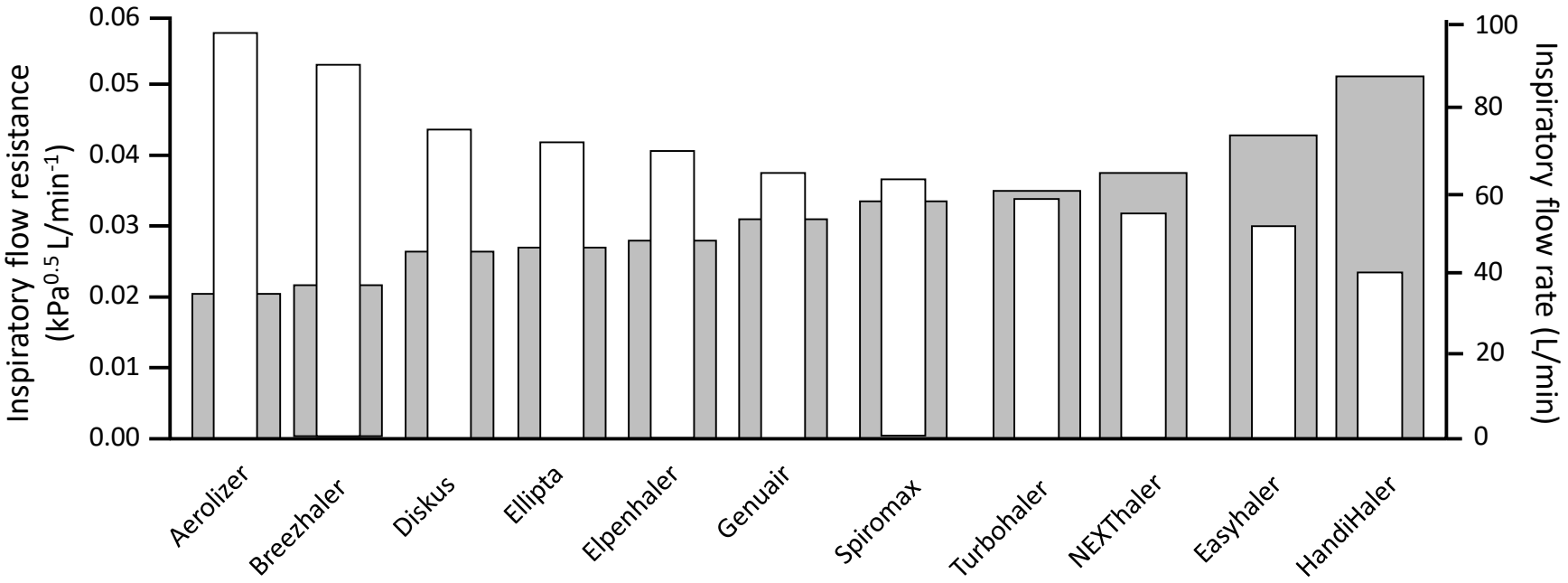
Drug reservoir

Drugs Aging
DOI 10.1007/s40266-016-0377-y

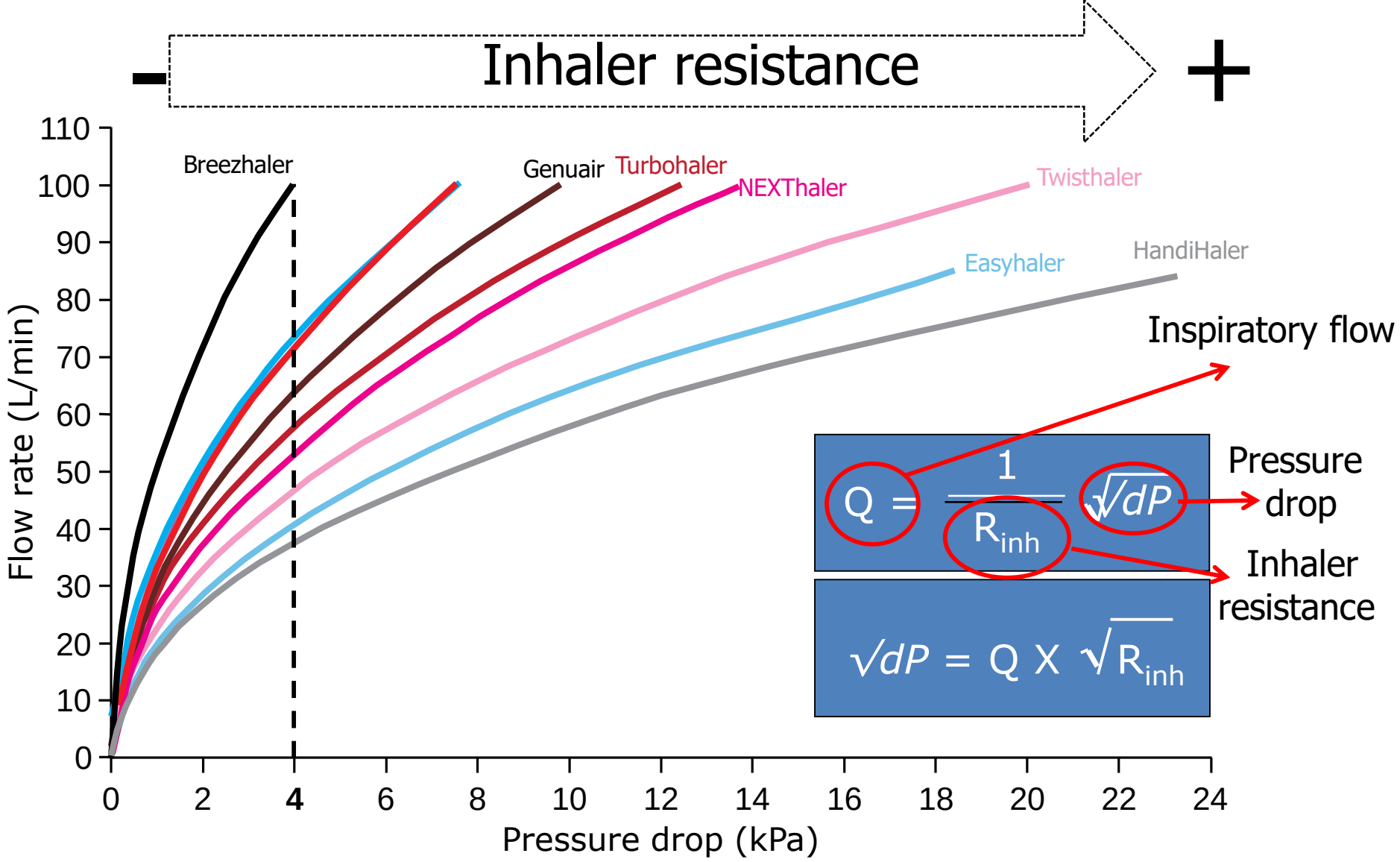
REVIEW ARTICLE

Optimising Inhaled Pharmacotherapy for Elderly Patients with Chronic Obstructive Pulmonary Disease: The Importance of Delivery Devices

Federico Lavorini[1] · Claudia Mannini[1] · Elisa Chellini[1] · Giovanni A. Fontana[1]

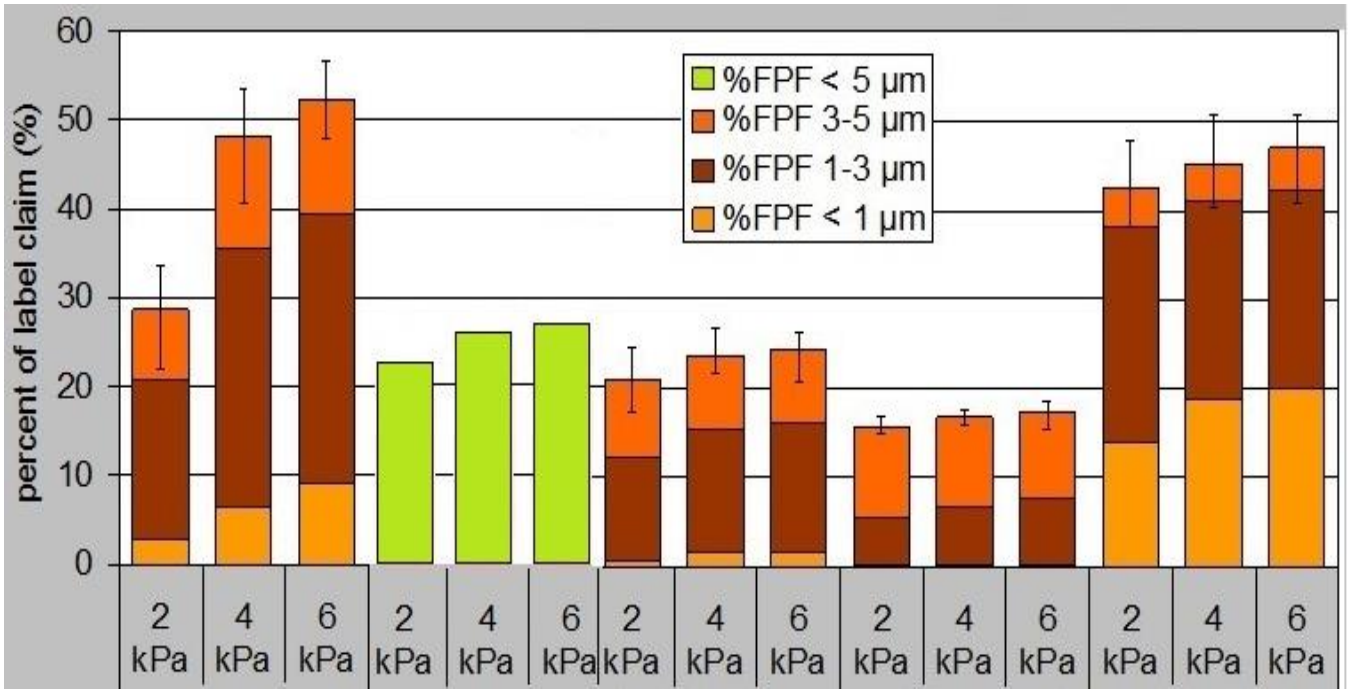


Inhaler resistance and the corresponding flow to achieve 4 kPa pressure drop



"..with a low resistance inhaler you need a higher inhalation flow than with a high resistance inhaler."

Mean delivered ICS fine particle fraction (FPF) as function of kPa *(in vitro)*



DPI	Resistance ($kPa^{0.5}$.min. L^{-1})	Flow rate (4 kPa) (L/min)
Turbuhaler	0.0340	58.8
NEXThaler	0.0339	59.0
Ellipta*	0,0286	72,5
Diskus	0.0293	73.3
Elpenhaler	0.0273	68.3

#, data from 1;* , data from 2

In vitro data do not necessarily correlate with clinical effectiveness

Similar results for β_2-agonist

Adapted from:
1 De Boer et al. *Eur J Pharm Biopharm* 2015;
2 Grant A et al *JAMPDD* 2015.

REVIEW Open Access

Recent advances in capsule-based dry powder inhaler technology

Multidisciplinary Respiratory Medicine

Federico Lavorini[1*], Massimo Pistolesi[1] and Omar S. Usmani[2]

Lavorini *et al. Multidisciplinary Respiratory Medicine* (2017) 12:11
DOI 10.1186/s40248-017-0092-5

- The single-unit, capsule-based DPI requires the patient to load a single hard gelatine capsule containing the powder formulation into the device before each use
- Capsule piercing by needles is essential to release the powder from the capsules.
- The capsule motion under inhalation airflow essentially governs the powder emission, whereas the airflow around the capsule in the turbulence inhaler chamber reinforced the disaggregation and dispersion of the powder.

International Journal of Pharmaceutics 487 (2015) 197–204

Contents lists available at ScienceDirect

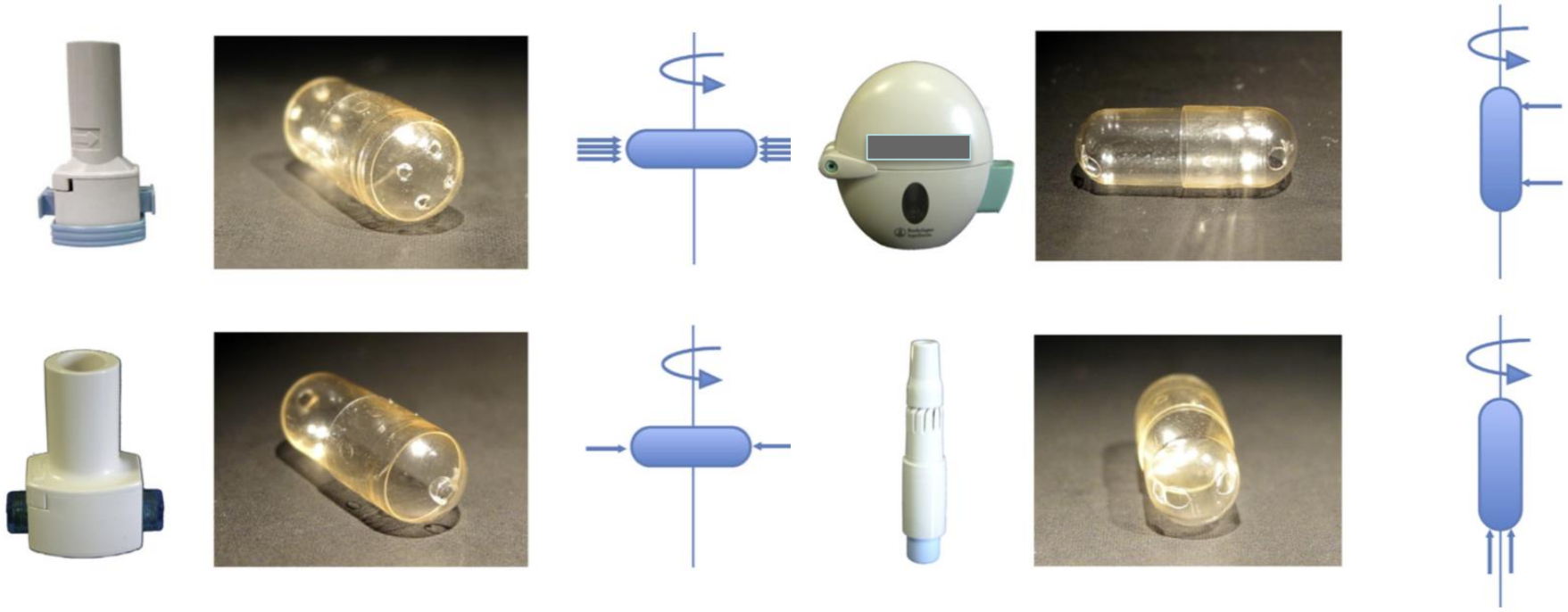
International Journal of Pharmaceutics

journal homepage: www.elsevier.com/locate/ijpharm

Capsule-based Device selection

"Pierce and inhale" design in capsule based dry powder inhalers: Effect of capsule piercing and motion on aerodynamic performance of drugs

Francesco Martinelli [a], Anna Giulia Balducci [b], Alessandra Rossi [a], Fabio Sonvico [a], Paolo Colombo [a], Francesca Buttini [a,c,*]



The spinning motion of capsule is the most powerful mechanism for improving the overall aerodynamic performance.

Courtesy by F. Buttini

Capsule-based Device selection

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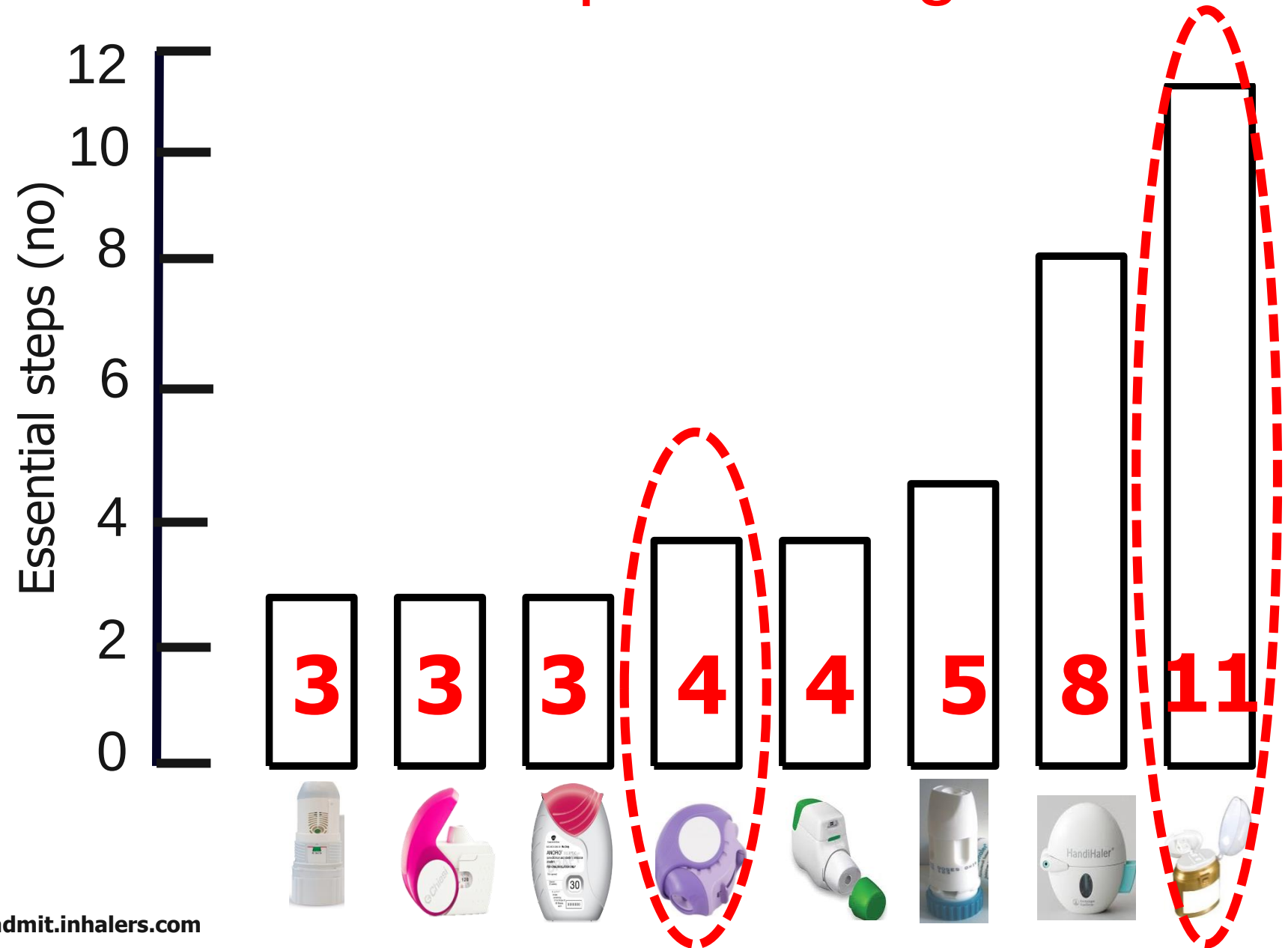
Table 3
Ranking of the different combinations between the inhalers on the base of the respirable fraction (RF), *i.e.*, the ratio between the fine particle dose (FPD<5 μm) and the labeled dose.

Aerosolizing Device	Piercing Device	RF (%)
RS01	RS01	34.6 ± 0.1
RS01	HandiHaler	34.6 ± 1.1
RS01	Turbospin	31.5 ± 0.3
Aerolizer	Aerolizer	30.9 ± 0.4
Turbospin	Turbospin	28.0 ± 0.1
HandiHaler	Turbospin	26.6 ± 1.5
Turbospin	HandiHaler	26.4 ± 0.6
HandiHaler	HandiHaler	26.1 ± 1.8
Turbospin	RS01	22.2 ± 0.2
HandiHaler	RS01	19.8 ± 0.2

Courtesy by F. Buttini

DPIs: essential steps for drug inhalation



Diskus = 4 steps

1. Open the inhaler
2. Push lever back completely
3. Inhale
4. Close the inhaler

A randomised cross-over trial investigating the ease of use and preference of two dry powder inhalers in patients with asthma or chronic obstructive pulmonary disease

Expert Opin. Drug Deliv. [Early Online]

Job van der Palen†, Paul van der Valk, Martijn Goosens, Karin Groothuis-Oudshoorn & Marjolein Brusse-Keizer

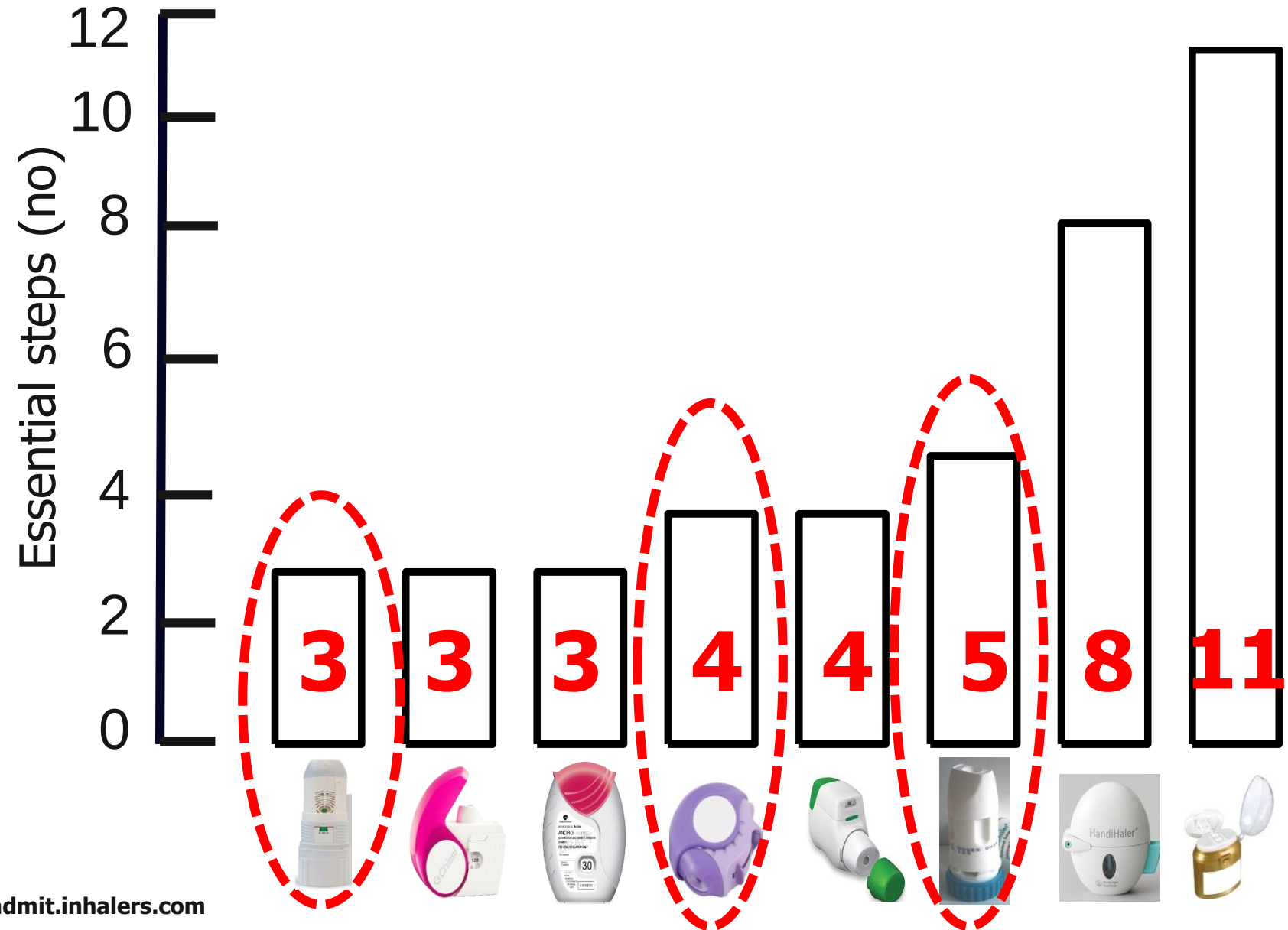
Elpenhaler = 11 steps

1. Open the storage compartment
2. Take blister strip
3. Close the storage compartment
4. Open protective cap
5. Push back mouthpiece to reveal supporting surface
6. Place blister strip correctly on supporting surface
7. Close mouthpiece correctly
8. Gently pull the protruding end of the strip
9. Inhale
10. Remove the strip
11. Close the inhaler

Objectives: to compare critical errors with the Diskus (4-steps DPI) and with the Elpenhaler (11-steps DPI).

Results: 17% of patients made at least 1 critical error with the Diskus ; **40%** with Elpenhaler (P<0.01).

DPIs: essential steps for drug inhalation



Comparison of serious inhaler technique errors made by device-naïve patients using three different dry powder inhalers: a randomised, crossover, open-label study

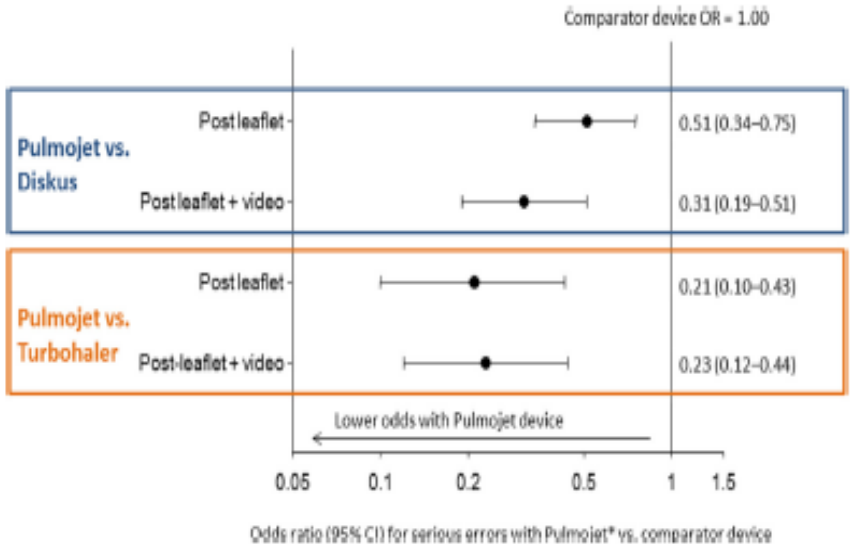
Henry Chrystyn[1,2], David B. Price[2,3*], Mathieu Molimard[4], John Haughney[3], Sinthia Bosnic-Anticevich[5], Federico Lavorini[6], John Efthimiou[7], Dawn Shan[2], Erika Sims[2,8], Anne Burden[2], Catherine Hutton[2] and Nicolas Roche[9]

BioMed Central
The Open Access Publisher

BMC Pulmonary Medicine

BMC Pulmonary Medicine (2016) 16:12

Odds ratio (≥1 serious errors) with Pulmojet vs Diskus or vs Turbohaler

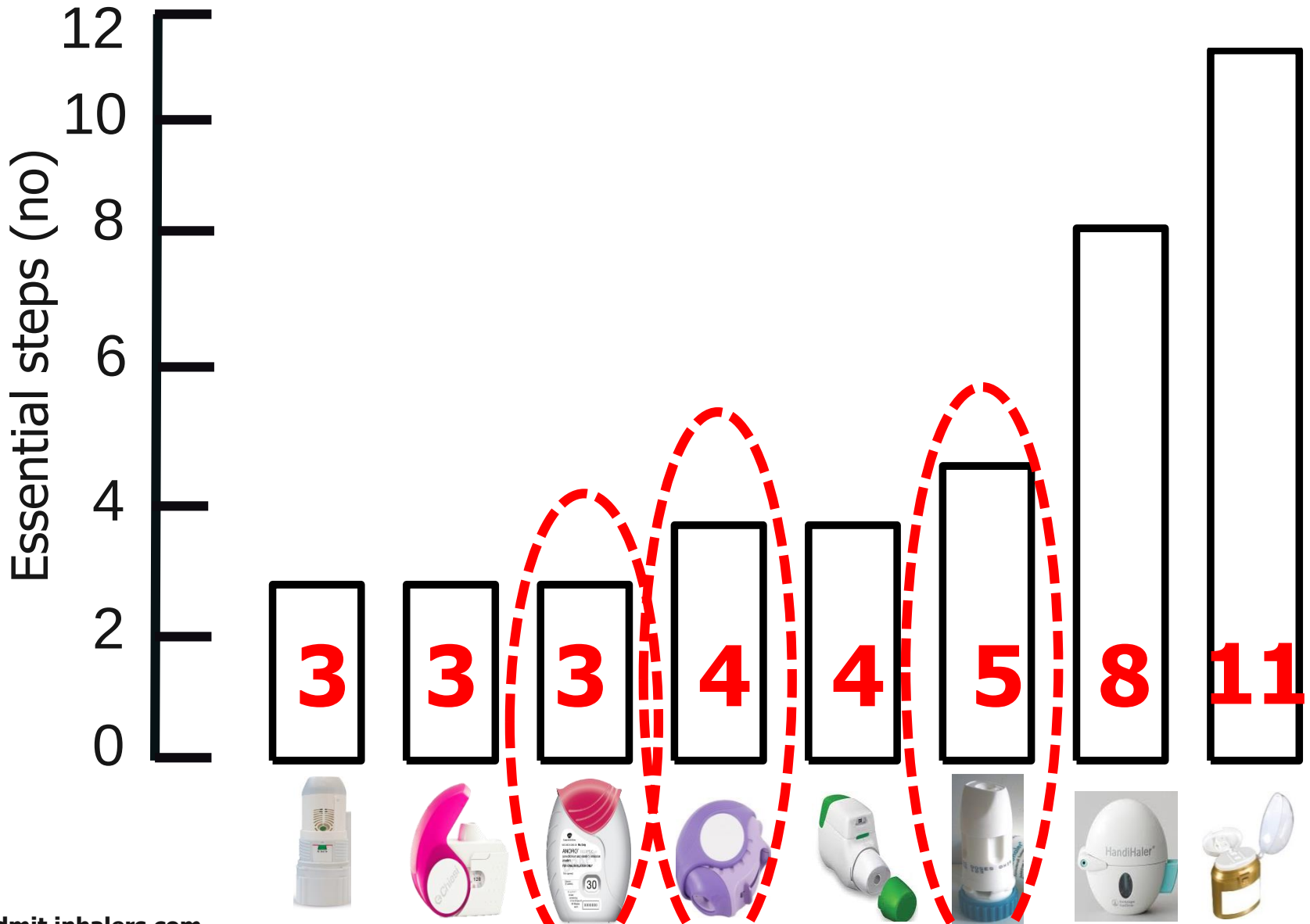


Number of patients making 0, 1, ≥2 serious errors

	First randomised device			
	Pulmojet vs. Diskus		Pulmojet vs. Turbohaler	
	Pulmojet (*n* = 277)	Diskus (*n* = 277)	Pulmojet (*n* = 144)	Turbohaler (*n* = 144)
Post-patient information leaflet alone				
0 errors, n (%)	110 (39.7)	74 (26.7)	59 (41.0)	25 (17.4)
1 error, n (%)	82 (29.6)	76 (27.4)	40 (27.8)	24 (16.7)
≥2 errors, n (%)	85 (30.7)	127 (45.8)	45 (31.3)	95 (66.0)
Post-patient information leaflet and instructional video				
0 errors, n (%)	215 (77.6)	170 (61.4)	106 (73.6)	69 (47.9)
1 error, n (%)	43 (15.5)	64 (23.1)	26 (18.1)	36 (25.0)
≥2 errors, n (%)	19 (6.9)	43 (15.5)	12 (8.3)	39 (27.1)

The less the operation steps, the less the probability of serious errors in the DPI use.

DPIs: essential steps for drug inhalation

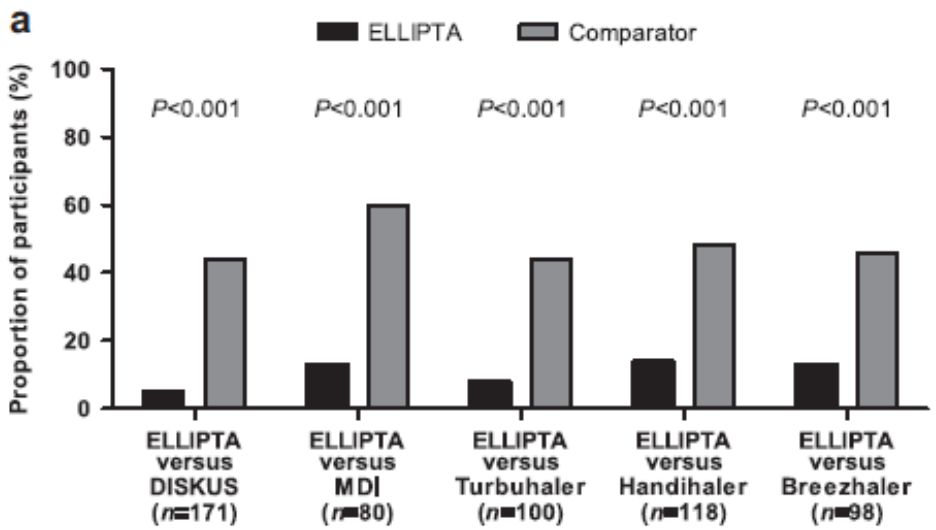


A randomised open-label cross-over study of inhaler errors, preference and time to achieve correct inhaler use in patients with COPD or asthma: comparison of ELLIPTA with other inhaler devices

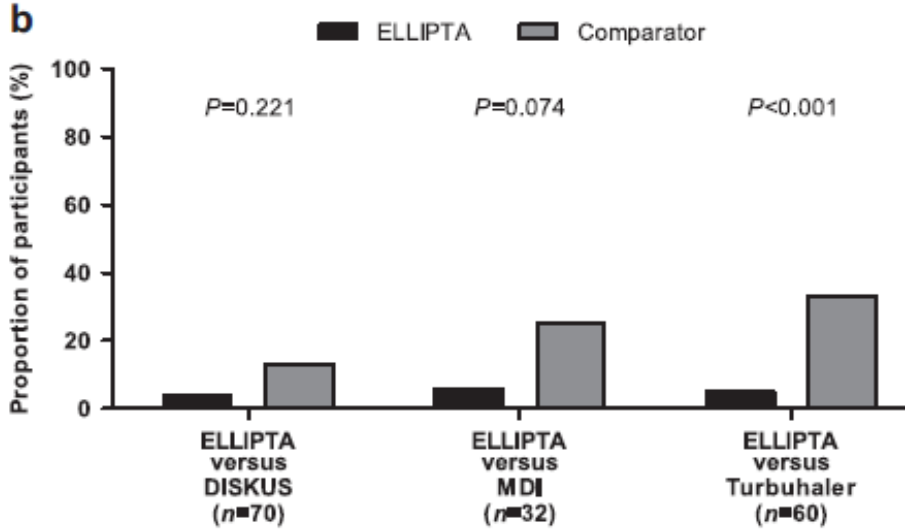
npj | Primary Care Respiratory Medicine 2016

Job van der Palen[1,2], Mike Thomas[3,4], Henry Chrystyn[5], Raj K Sharma[6], Paul DLPM van der Valk[1], Martijn Goosens[7], Tom Wilkinson[8], Carol Stonham[9], Anoop J Chauhan[10], Varsha Imber[11], Chang-Qing Zhu[12], Henrik Svedsater[13] and Neil C Barnes[6]

COPD patients (n=567)



Asthma patients (n=162)



The less the operation steps, the less the critical errors in inhaler use

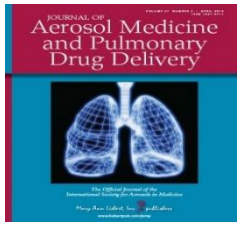
Teaching and learning data obtained in asthma ad COPD patients

Inhaler	Steps (no)	Time (sec.) for nurse's teaching and patient's learning	Successful inhaler technique at 1st attempt	Attempts before achieving proper actuation
		mean ± SD	(%)	**mean ± SD**
Breezhaler	7	615 ±301	18	2.6 ± 1.1
Turbuhaler	6	350 ± 85	9.5	2.5 ± 1.0
Respimat	4	150 ± 95	62.4	1.6 ±0.8
Diskus	4	155 ± 35	45.5	1.5 ± 1.0
Genuair	3	170 ± 40	55.7	1.6 ± 1.0

Adapted from Dal Negro R and Povero M. MRM 2016

- Inhaler’s features
- Patient’s characteristics

Determinants of inhaler use



		OR	*95% CI*
Age (years)	<60	1.00	
	≥60	1.40	0.67–2.94
Educational level[a]	low	2.01	0.67–4.61
	middle	1.84	0.73–4.61
	high	1.00	
FEV_1/VC[b]	<0.6	1.15	0.55–2.41
	≥0.6	1.00	
Received inhalation instruction[c]	yes	1.00	
	no	2.22	1.02–4.80
Device	single	1.00	
	multiple	2.23	1.07–5.02

Rootmensen, JAMPDD 2010

Optimising Inhaled Pharmacotherapy for Elderly Patients with Chronic Obstructive Pulmonary Disease: The Importance of Delivery Devices

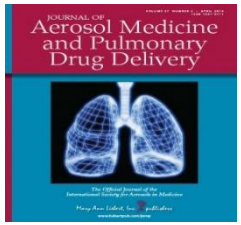
Federico Lavorini[1] · Claudia Mannini[1] · Elisa Chellini[1] · Giovanni A. Fontana[1]

Drugs Aging
Published online: 23 May 2016

Potential issues that may prevent elderly COPD patients from using inhaler devices properly

Factors	Mechanism
Cognitive function	Cognitive function determines the ability to acquire and retain techniques needed for competent use of inhalers. Cognitive impairment is often related to worsening of hypoxia and/or hypercapnia, as well as to co-morbidities such as Alzheimer's disease, Parkinson's disease, cerebrovascular diseases
Tremors	Intention tremors or tremors due to overuse of β-adrenergic agonists or Parkinson's disease can make proper inhaler loading or twisting the inhaler difficult or even impossible
Hand–eye coordination	Some older patients may have difficulties in locating their mouth for delivering the spray from a pMDI
Dexterity and hand strength	Inhaler manipulation requires manual dexterity and strength, which may be affected by osteoarthritis, joint pain and neurological conditions such as Parkinson's disease. Impairment in manual dexterity may affect preparation of capsule-based DPIs, which require loading, puncturing and inserting the capsule into a small holding chamber. Inadequate hand strength may lead to an inability to press the pMDI canister for releasing the dose
Vision	Visual deficits may affect the patient's ability to see the dose counter, leading some patients to believe the device still holds medications when it is empty. Visual deficits may affect proper loading of the inhaler, particularly for capsule-based DPIs
Hearing	Poor hearing may prevent patients from hearing the 'click' indicating readiness to inhale some DPIs or the discharge from a pMDI into a spacer
Chest wall and respiratory muscle strength	Stiffening of the thoracic cage from calcification of the rib cage and age-related kyphosis from osteoporosis may reduce the ability of the thoracic cage to expand during inspiration and places the diaphragm at a mechanical disadvantage to generate effective contraction. Respiratory muscle strength decreases with age due to muscle atrophy and age-related decrease in fast twitch fibres. All these age-related structural changes may reduce the patient's ability to generate the minimum flow and volume needed to correctly operate some inhaler devices

Determinants of inhaler use



		OR	*95% CI*
Age (years)	<60	1.00	
	≥60	1.40	0.67–2.94
Educational level[a]	low	2.01	0.67–4.61
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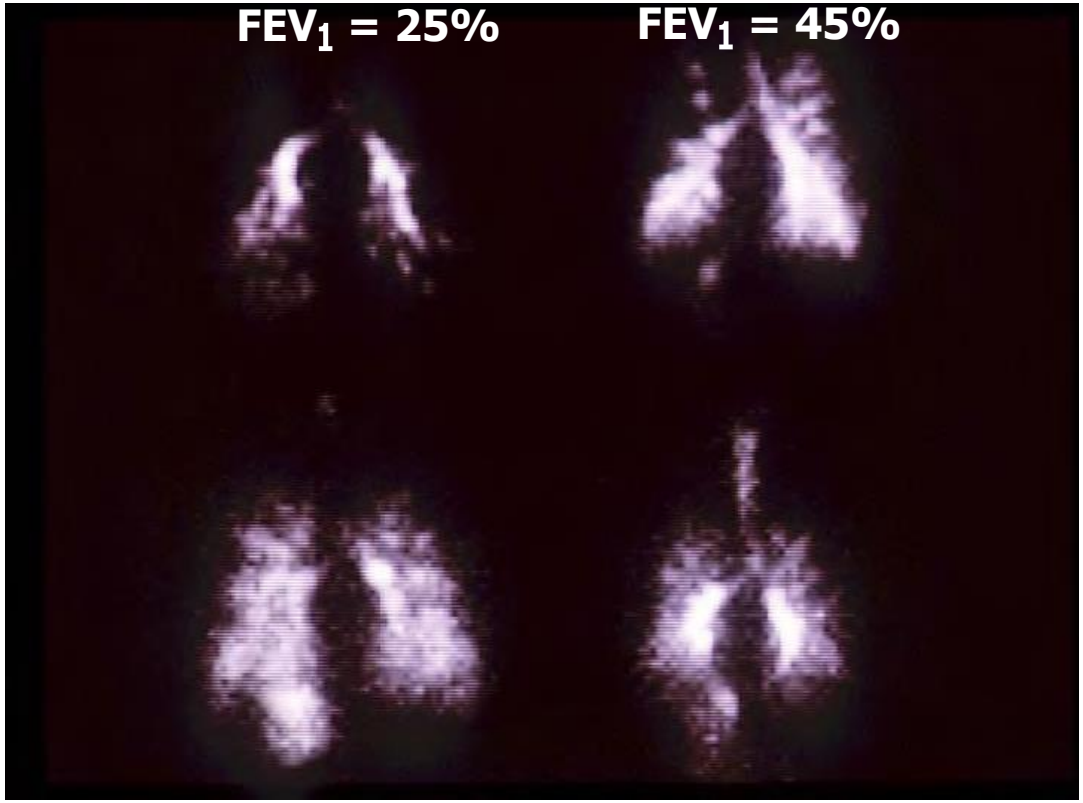
Rootmensen, JAMPDD 2010

Lung deposition is altered with increasing severity of airway obstruction

Healthy subject

Patients with various degrees of airway obstruction



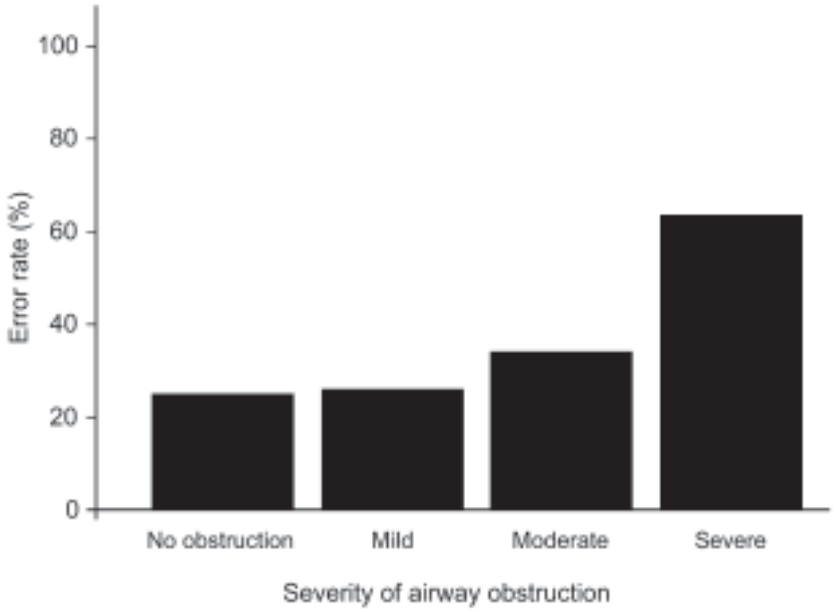
Laube BL et al *Respiratory Care* 2005

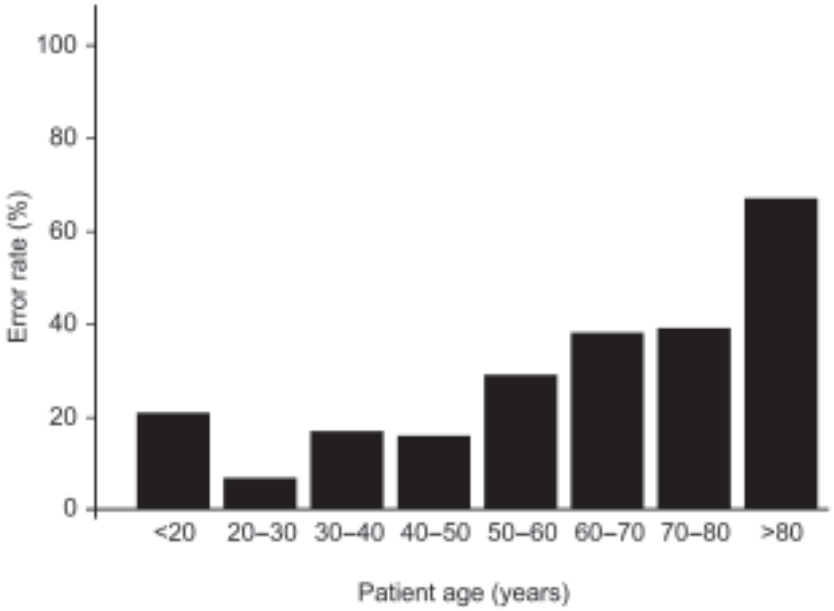
Dry Powder Inhalers: Which Factors Determine the Frequency of Handling Errors?

Siegfried Wieshammer[a] Jens Dreyhaupt[b]

Respiration

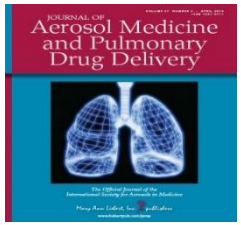
Respiration 2008;75:18–25
DOI: 10.1159/000109374





Inhaler error rate increases with the degree of airway obstruction and with patient's age

Determinants of inhaler use



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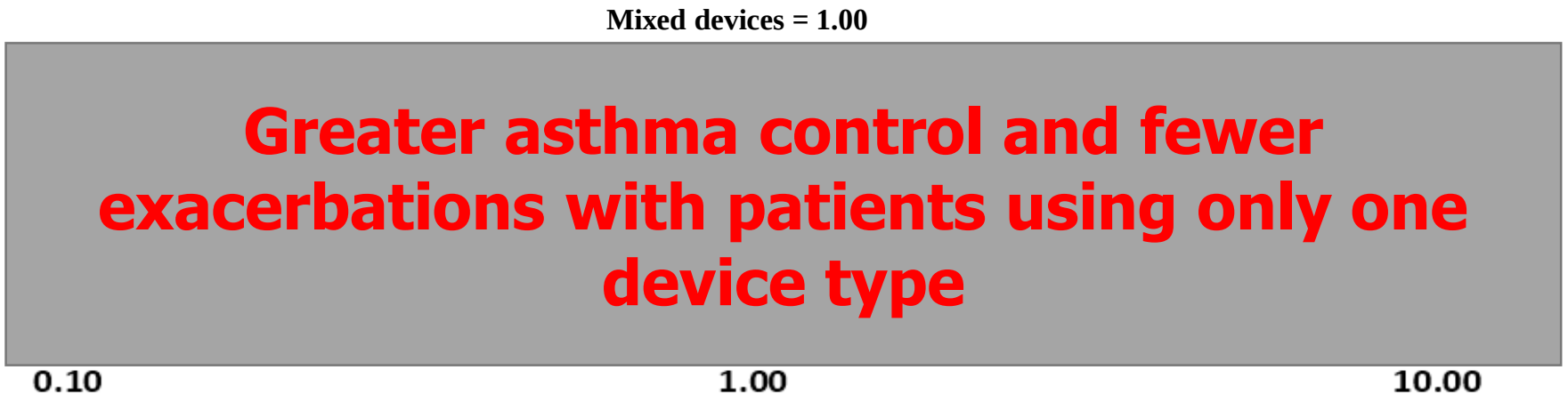
Allergy, Asthma & Immunology Research

Effectiveness of Same Versus Mixed Asthma Inhaler Devices: A Retrospective Observational Study in Primary Care

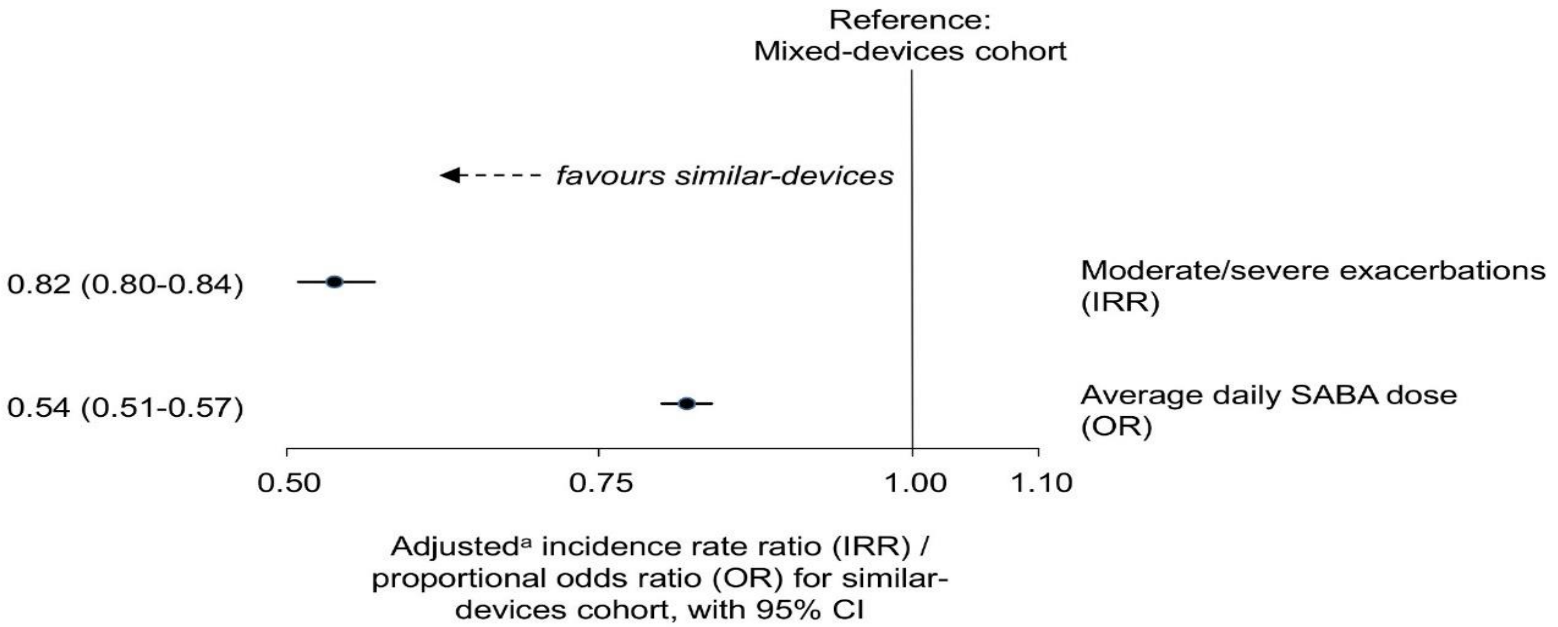
David Price,[1,2*] Henry Chrystyn,[3] Alan Kaplan,[4] John Haughney,[1] Miguel Román-Rodríguez,[5] Annie Burden,[2] Alison Chisholm,[2] Elizabeth V. Hillyer,[2] Julie von Ziegenweidt,[2] Muzammil Ali,[2] Thys van der Molen[6]



Sinthia Bosnic-Anticevich[1]
Henry Chrystyn[2]
Richard W Costello[3,4]
Myrna B Dolovich[5]
Monica J Fletcher[6]
Federico Lavorini[7]
Roberto Rodríguez-Roisin[8]
Dermot Ryan[9,10]
Simon Wan Yau Ming[2]
David B Price[2,11]

The use of multiple respiratory inhalers requiring different inhalation techniques has an adverse effect on COPD outcomes

Aims: To compare clinical outcomes of COPD patients who use devices requiring similar inhalation technique with those who use devices with mixed techniques.



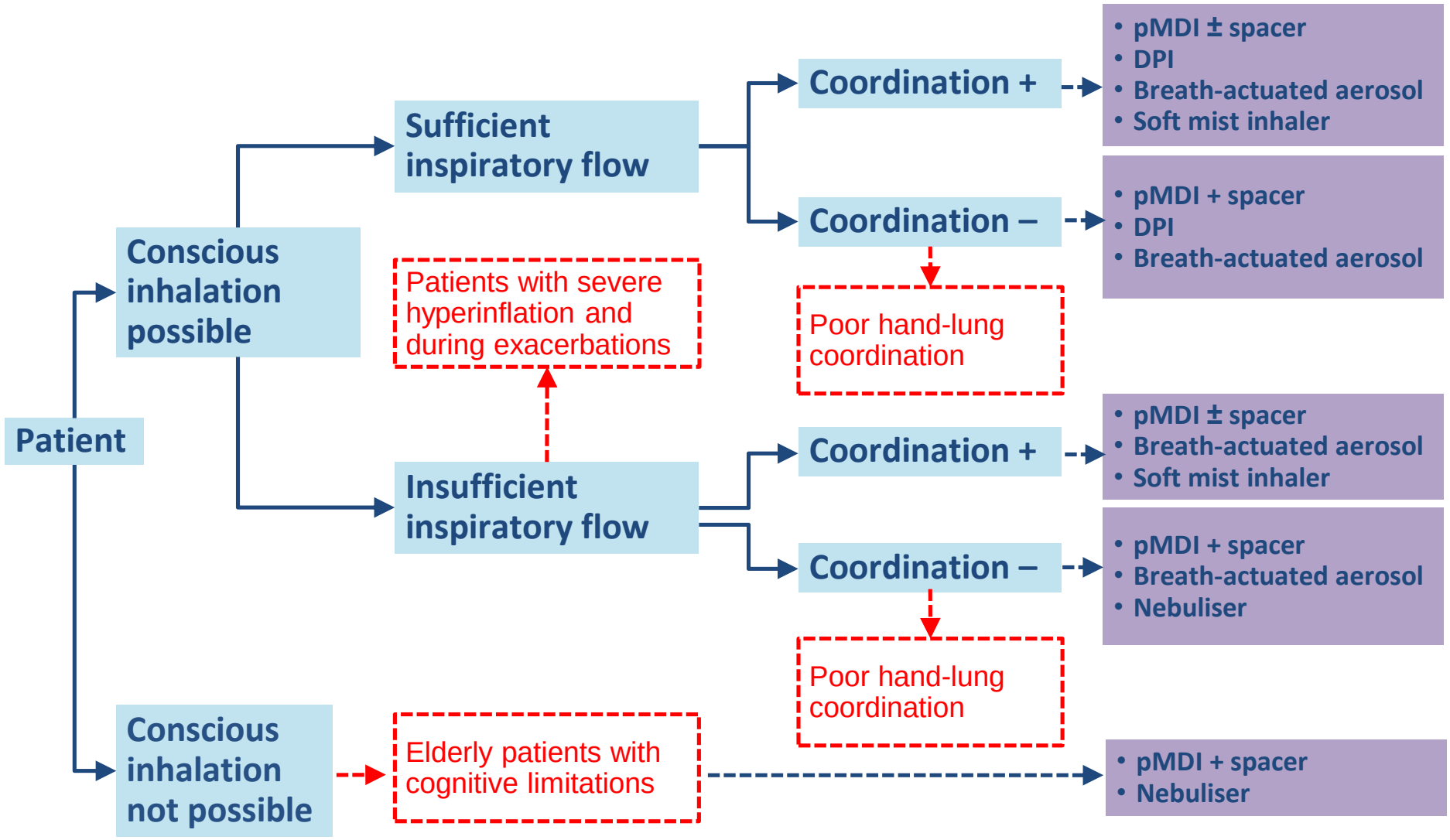
Better COPD outcomes and fewer exacerbations with patients using only one device type

International Journal of COPD 2017:12 59–71

Suggested hierarchy for best match

P.N.R. Dekhuijzen[a,*], W. Vincken[b], J.C. Virchow[c], N. Roche[d], A. Agusti[e], F. Lavorini[f], W.M. van Aalderen[g], D. Price[h]

Respiratory Medicine (2013) 107, 1817–1821



The Global Inhaler Effectiveness Score (GIES): a novel comprehensive tool for assessing and ranking in vitro properties, intrinsic characteristics and real lifeusability of dry powder inhalers.Rationale and Methodology

Francesca Buttini[1],Federico Lavorini[2],Ruggero Bettini[1], Giovanna Pisi[3],
Søren E. Pedersen[4];Richard P.N. Dekhuijzen[5], Mark L. Levy[6], and Omar S. Usmani[7]

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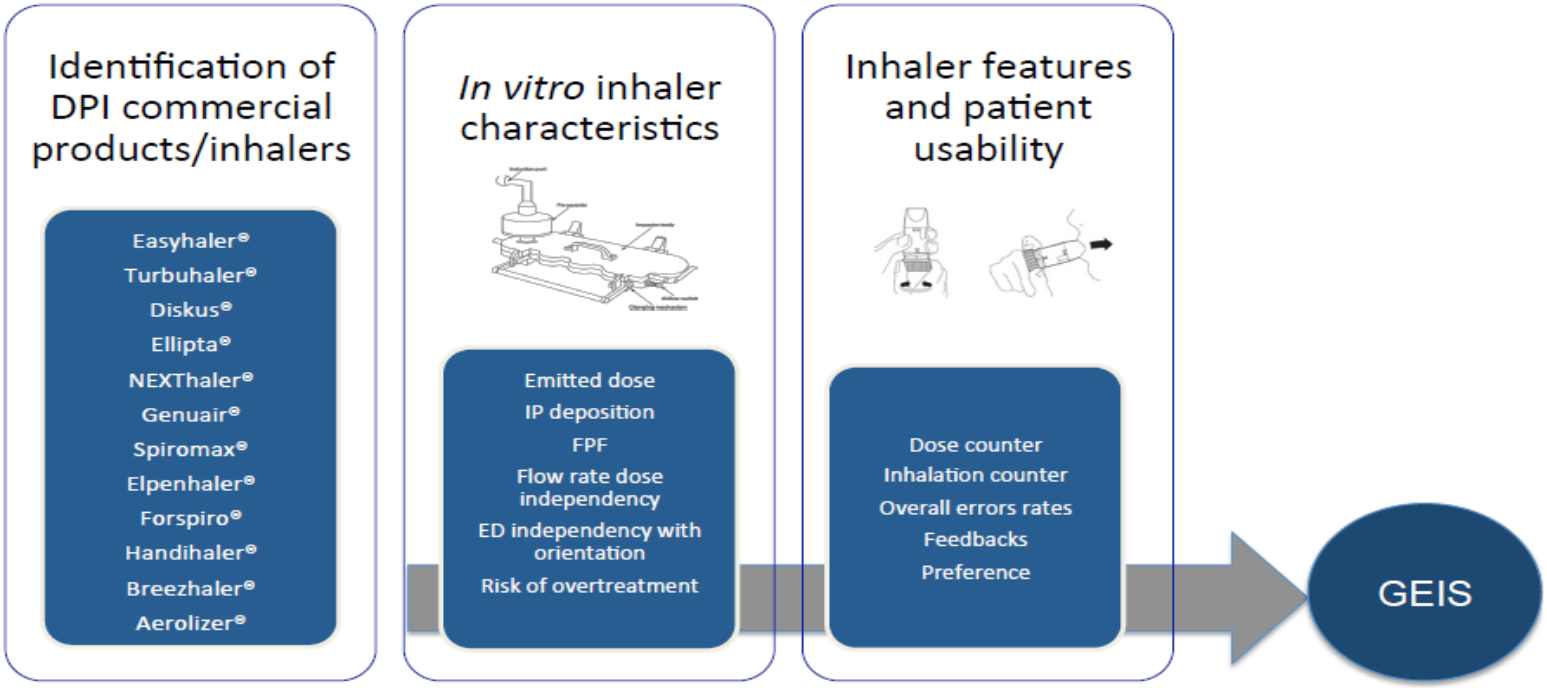
[7]Imperial College London and Royal Brompton Hospital, London, UK



The Choice of Inhaler Device: Summary

- Several delivery systems are currently available but many more are in clinical development.
- The choice of inhaler device should be based on an evidence-based awareness rather than on empirical basis.
- Inhalers' features as well as patients' characteristics should be considered in the choice of inhaler devices and development of future delivery systems.

Thanks for your kind attention !

Questions ?