Increasing participation in and improving outcomes from pressurised metered dose inhaler training

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Summary

**Background:** There is a continued requirement for the effective use of inhaler devices, and the undeniable importance of training. Many patients remain unable to use their inhaler correctly owing to their inability to understand the instructions and/or a perverse ability to use their device in an incorrect manner, or as a result of misguided lay advice. Inhaler technique training, specifically pressurised metered dose inhaler (pMDI) technique training, remains a significant issue for the industry and for healthcare professionals.

**Methods:** Two new training aids, the Trainhaler® and Flo-Tone® respectively simulate pMDI use and help the patient co-ordinate pMDI actuation with the inspiratory manoeuvre. Following instruction based solely on user comprehension of the product Patient Instruction Leaflets for placebo pMDI and these training devices, pMDI technique was assessed before training, during use-training with Trainhaler plus Flo-Tone, and after training. The ability to carry out five tasks—[1] breathe out all the way, [2] put the inhaler into the mouth, over teeth and seal the lips around the mouthpiece, [3] start to inhale gently, [4] press canister, and [5] continue inhaling for about 5 seconds—was scored 0 (poor), 1 (average), or 2 (good). Data were analysed using McNemar's test.

**Results:** Twenty-four subjects completed the assessments. Tasks 3, 4 and 5 demonstrated significant improvement (P<0.05) following training with Trainhaler plus Flo-Tone. The overall score (mean of the sums of all scores for each subject) before (7.2) and after training (8.5) improved significantly (P<0.01). Prior to training three subjects achieved a maximum score of 10, increasing to 11 subjects after training.

**Conclusions:** These are preliminary findings, and there are goals to achieve beyond new training aids. Training *per se* and outcomes from that better training should be improved. We should investigate the benefits of formal record keeping, promote patient self-support, and explore regular versus intermittent use of training tools.

Introduction

The mission statement of this Anniversary Conference is 'Shaping the next 25 years of Nasal and Pulmonary Drug Delivery' with session themes focussing on disease, devices, regulation and pharmaceutical development. All are highly relevant and promote immensely valuable knowledge-sharing and peer discussion. We are all aware, however, from the recent National Review of Asthma Deaths, and its moving foreword by Martyn Partridge, that despite the medical and pharmaceutical communities' best efforts, asthma remains a killer. This seems, or should be, impossible in the 21st century in the UK. The Report contains many recommendations, one of which reads "Parents and children, and those who care for and teach them, should be educated about managing asthma. This should include emphasis on 'how', 'why' and 'when' they should use their asthma medications, recognising when asthma is not controlled and knowing when and how to seek emergency advice." Another major 2014 report, from the Global Initiative for Asthma (GINA), repeatedly draws attention to inhaler technique, citing up to 80% of patients unable to use their inhaler correctly, and makes the sensible point to check technique before stepping up medication. GINA suggests a Choose, Check, Correct and Confirm strategy (Box 3-11) for effective use of inhaler devices that includes demonstration by both patient and physician. Inhaler technique training, specifically pressurised metered dose inhaler (pMDI) technique training, remains a significant issue, and has an impact not only on patients but on healthcare professionals (HCPs) and therapy costs. Many will be familiar with my interest in all things inhaler-historical, and so cannot resist citing an 1844 text: "...and a medical man, when he orders a patient to inhale vapours, must give his personal attention to the manner in which it is performed, if he wishes to have his intentions efficiently carried out.". 170 years later, and we are still trying to achieve this goal for our patients.

**Methods and Materials**

A review of the literature refreshed in our minds the key pMDI training issues and highlighted particular aspects for attention. Within the context of device development at Clement Clarke International, this exercise has served as a spark to creativity, and to the conduct of question-answer research. The self-posed questions have included: why are there no devices that do more than check inspiratory flow rate but would (1) simulate patient use and not involve a placebo pMDI, and (2) help the patient to co-ordinate the actuation of the pMDI with the inspiratory manoeuvre?

**Results**

Mark Everard’s influential and provocative 2000 paper introduced the concept of the three Cs with regard to pMDI use: compliance (the ability to adhere to a regimen), competence (the ability to understand an instruction) and contrivance (the seemingly perverse ability, despite understanding, to use a device in an incorrect manner).
These are distinct problems, but are frequently confused and/or amalgamated. Effective pMDI training focuses mainly on competence and seeks to reduce contrivance. Training is acquired by a variety of routes; ideally it is a combination of product Patient Instruction Leaflet (PIL), pharmacist, and HCPs, with demonstration and frequent reinforcement. Patients also have access to other sources such as the Internet and copying family/friends who also self-administer pMDI treatments. These latter, more readily available, resources can engender poor technique under the guise of ‘authority’ – with an element of contrivance clearly coming into effect. The one person who is best-placed to impact pMDI training is the HCP. Unfortunately, absent specialised training tools, the HCP can be hamstrung by circumstance: they may not have a lung disease and have therefore never used a pMDI, and are understandably reluctant to inhale repeatedly from a placebo product; time is tight, training budgets low, and the patient Q&A is uninformed. HCP-delivered training can fall far short of the ideal. 8

The instructions and explanations for correct pMDI technique are reproduced in Table 1, and the mistakes commonly seen include: not exhaling fully to begin with; nearly completing the inhalation before depressing the canister; inhaling too quickly; failing to coordinate depression of the canister with the inhalation manoeuvre, and stopping the inhalation too soon.

The benefit of training has been clearly demonstrated from the Isle of Wight Respiratory Inhaler Project. 7 With a high prevalence of long-term respiratory conditions, the Primary Care Trust recognized the issue of poor pMDI technique. Poor HCP pMDI competence was improved, and patient training was carried out. The higher than average treatment-spend and a greater number of respiratory emergency hospital admissions within the Trust were reduced within one year of the initiative.

Simple pMDI training aids are available (for example, 2-Tone Trainer™, Canday Medical and In-Check Dial®, Clement Clarke), and Mag-Flo® (Fyne Dynamics) for dry powder inhalers, plus complex instrumented devices more suited to clinic/research use.

The self-posed questions have resulted in two further simple training aids, the Trainhaler® and the In Check Flo-Tone® (Figure 1); tools which aim, per the title of my presentation, to increase participation in and improve outcomes from pMDI training. I would like to take you through some of the findings from our research and the early human volunteer work that is nearing completion. In brief, the Trainhaler is a true simulator of pMDI use. It contains no propellants (using only air to fuel the ‘whoosh’ sound of an actuated canister), and its appearance and functionality are that of a regular pMDI (Figure 1). The HCP can repeatedly practise, for themselves, and demonstrate to the patient, pMDI use without concerns relating to placebo. Interchanging mouthpieces means this can be a multi-user tool. Ideally, the Trainhaler is used in combination with the Flo-Tone; an attachment whose whistle begins to sound when the user is inhaling at the appropriate flow rate to actuate the canister (Figure 1) and to guide duration of inhalation. This is therefore a single-user tool.

Initial research with Flo-Tone has shown (1) user competence from age 7 years, 8 (2) the effect on pMDI technique, determined from a questionnaire-survey of a largely adult group of asthma/COPD patients, is significant for overall technique and the ability to generate and maintain an adequate inspiratory flow rate, and (3) it is without effect on the in vitro proportion of respirable particles. 10 As the Trainhaler is essentially a mechanical copy-me training tool that can have no impact on drug delivery per se, aerosol performance studies are neither necessary, nor have been conducted. We have, however, received preliminary results from two clinical handling studies, conducted in the UK and USA. The former addresses the acquisition of pMDI-use skills, and the latter

<table>
<thead>
<tr>
<th>Table 1. Correct pMDI technique</th>
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<tbody>
<tr>
<td><strong>pMDI Instruction</strong></td>
</tr>
<tr>
<td>Check pMDI for debris and shake before use</td>
</tr>
<tr>
<td>Exhale fully</td>
</tr>
<tr>
<td>Put inhaler into mouth, over teeth and seal lips around mouthpiece</td>
</tr>
<tr>
<td>Inhale gently</td>
</tr>
<tr>
<td>Press canister</td>
</tr>
<tr>
<td>Continue inhaling for about 5 seconds (5)</td>
</tr>
<tr>
<td>Hold breath for 10 s</td>
</tr>
<tr>
<td>Wash mouth out with water - spit out</td>
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</tbody>
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Figure 1. Trainhaler (non-electric pMDI training) plus Flo-Tone (co-ordination) devices
has compared participation-training with PIL-training in healthy volunteers.\(^{11}\) A third Western Asia study is underway to determine any effect that use of the Trainhaler plus Flo-Tone has on drug use, asthma exacerbations and hospitalisations.

The UK study is a questionnaire-based comparison of the effect of Trainhaler plus Flo-Tone on pMDI technique, based solely on user comprehension of the PIL for the pMDI and for Trainhaler plus Flo-Tone, i.e. with no instruction or coaching. Technique was assessed on three occasions: placebo pMDI before training, use-training with the Trainhaler plus Flo-Tone, and placebo pMDI after training. The ability to carry out five tasks (Table 3) was scored 0 (poor), 1 (average), or 2 (good).

### Table 3. Assessments and scoring

<table>
<thead>
<tr>
<th>Task</th>
<th>Good (Score=2)</th>
<th>Average (Score=1)</th>
<th>Poor (Score=0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Breathe out all the way</td>
<td>Full exhalation</td>
<td>Medium exhalation</td>
<td>Minimal exhalation</td>
</tr>
<tr>
<td>2 Put inhaler into mouth, over teeth and seal lips around mouthpiece</td>
<td>All correct</td>
<td>Incorrect mouth placement or seal</td>
<td>Both incorrect</td>
</tr>
<tr>
<td>3 Start to inhale gently</td>
<td>Correct</td>
<td>Too fast</td>
<td>Much too fast</td>
</tr>
<tr>
<td>4 Press canister</td>
<td>Pressed promptly</td>
<td>Pressed after 1 s</td>
<td>Pressed after ≥2 s</td>
</tr>
<tr>
<td>5 Continue inhaling for about 5 seconds</td>
<td>Duration ≥3 s</td>
<td>Duration &lt;3 s</td>
<td>Duration &lt;1 s</td>
</tr>
</tbody>
</table>

The 24 subjects who completed the assessment were mainly adult: six were recorded as 'adult' and the remaining 18 ranged in age from 7 to 82 years (mean 25), of whom six were less than 15 years old. Fourteen subjects had no history of asthma (10, inhaler-naïve), and the remaining 10 reported asthma (9) or hay fever. Data are displayed in a shift table format which shows how each subject's task score altered with training (Figure 2). Data were analysed using McNemar's test for matched pair data (see also Figure 2).

Three of the five tasks (Nos. 3, 4 and 5) demonstrated significant improvement (\(P<0.05\)) following training with Trainhaler plus Flo-Tone. The second task was not appropriate for McNemar's test owing to the high number rated as "good" both before and after training.

The scores assigned to each task have been summed to provide an overall score for each subject for before and after training. The mean score before training was 7.2 with a statistically significant improvement to 8.5 after training (\(P<0.01\)). Prior to training only three subjects achieved a maximum score of 10 indicating correct technique for all aspects. This was increased to nine subjects during the Trainhaler plus Flo-Tone phase, and to 11 subjects after training.

These preliminary findings are particularly pleasing as they provide an early demonstration that the initiation of a gentle inhalation, canister co-ordination and an appropriate duration of continued inhalation can be better achieved following training with specific tools.

### Discussion and Conclusions

There are goals to achieve beyond new training aids. To increase participation in pMDI training, training aid companies need to extend their collaborations with pharmaceutical companies to encourage their uptake of training devices. All interested parties need to engage with regulators to look at the wider provision of training tools - both via prescription-type reimbursement and reimbursement for delivering training.

We should strive to improve training per se and to improve outcomes from better training. It should be possible to build on the Isle of Wight findings, and to build the recognition of inhaler training – via collaborations such as
GINA. We should investigate the benefits of formal record keeping of training, promote patient interest in self-support, and explore daily/regular versus intermittent use of training tools.

References


6. Baverstock M, Woodhall N, Maarman V. Do healthcare professionals have sufficient knowledge of inhaler techniques in order to educate their patients effectively in their use? Thorax 201; 65 Suppl 4:A118.


