A Human Factors review of "the Blue Puffer" asthma reliever inhaler

Deborah Stratford[1] & Susan Whalley-Lloyd[1,2]

[1]School of Health, Science and Wellbeing, Staffordshire University, UK, [2]Lloyds Risk Services Ltd, UK

SUMMARY

The literature reports that Asthma Inhaler technique has not improved during the last forty years, despite improvement strategies focused on educating users to improve their technique and compliance. This is particularly critical for reliever inhaler users when 'use error' may result in a full asthma attack and possible death. This paper presents a pilot study Human Factors design review of the standard UK reliever inhaler, commonly referred to as 'the blue puffer'. The results indicate a mismatch between 'work as done' and 'work as imagined' and that this mismatch appears to be influenced by the design of the inhaler. Conceptually it appears possible to improve the design of technical components of the inhaler system to reduce use errors and hence improve patient safety. This would require appropriate scenario and user testing, with any changes being integrated into the system as a whole.

KEYWORDS

Patient Safety, Inhaler Design, Human Factors, Human-Centered Design, Sociotechnical systems

Introduction

Asthma related deaths have increased in the UK over the last decade with over 1,400 deaths from asthma attacks in 2018 alone, including a 42% increase in people aged 35 to 44 years (Asthma and Lung UK, 2019).

Self-administered drug delivery through inhalation is the primary method for treatment of respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD) (Schreiber 2020). This is via Preventer inhalers. In addition to using a preventer, most of these patients will be prescribed a Reliever inhaler to use during an acute episode of breathing difficulty or when they have signs of an asthma attack. Reliever inhalers can also be prescribed for short term use for those with temporary breathing difficulties. In the UK the current most common asthma reliever is the Ventolin Evohaler pressurized metered-dose inhaler (PMDI), this is blue in colour and commonly referred to as 'the blue puffer'.

Inhaler technique has not improved during the last forty years despite improvement strategies. These strategies have largely focused on improving human action by providing additional education to improve technique and compliance (Sanchis et al, 2016). Furthermore, it has been shown that as few as 9% of healthcare professionals tasked with educating patients in inhaler use had adequate knowledge of all prescribed steps. Healthcare professionals were unable to demonstrate the correct technique required to ensure effective medication dose delivery (Baverstock et al, 2010).

Aim

The aim of this study was to identify aspects of the reliever inhaler system that appear to impact user performance and to consider Human Factor improvement opportunities with the potential to reduce 'use error' and improve optimal drug dose delivery.

Method

This pilot study was conducted between January and April 2022 by a cohort of Human Factors postgraduate students from Staffordshire University, all currently working within the healthcare system.

The overall method was based on the Human Centered Design Process (Gilero, 2022). The first four steps were used to provide a framework for reviewing the reliever inhaler sociotechnical meso system, see Figure 1. The system comprised of; inhaler users, medical professionals, the inhaler device plus spacer, instruction leaflet, packaging and an educational video provided by Asthma and Lung UK (Asthma and Lung UK, 2021)

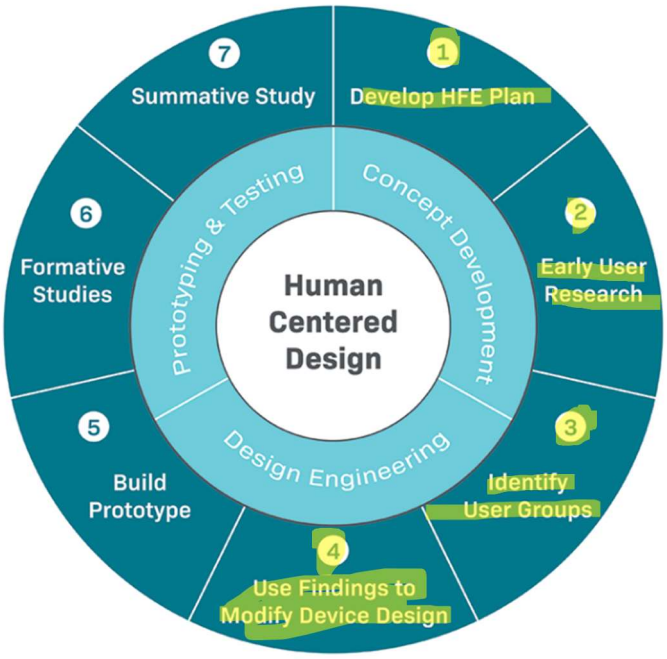

Figure 1: The Human Centered Design process

Phase One: Develop HFE Plan

Step 1: Select the Reliever inhaler for review

An initial literature review identified use problems associated with reliever inhalers and which Reliever inhaler was predominantly used within the UK. A photograph of the Blue Puffer inhaler and Spacer is provided in Figure 2. Note that Spacers are often recommended for use with a reliever inhaler to help ensure the full dose of medication reaches the lungs.

Step 2: Compile Study Brief and key dates

The brief provided an overview of patient safety issues associated with Reliever inhalers, photographs of the components, links to manufacturer patient instruction sheets and links to the

patient training videos available on the Asthma and Lung UK website (Asthma and Lung UK, 2021). The pilot study ran from 5th March – 8th April 2022

Figure 2: The Ventolin, Blue Puffer Inhaler and associated Spacer (photographs by C Saunders, 2022)

Phase Two: Early User Research undertaken by Student Group

Step 1: Full group brainstorming session

An initial live virtual group brainstorming session was conducted. The purpose was to facilitate a shared understanding of the reliever inhaler system and to prompt consideration of the range of users, their capabilities and limitations and why these may impact effective system interaction.

Step 2: Interviews and Observations

Two separate sessions were conducted live virtually. Each Interview session included Task Observation and walk-through-talk-through with a reliever inhaler user. Each participant had used a reliever and preventer inhaler for more than twenty years. One participant was male aged 55 and one female aged over 60.

Phase Three: Identify User Groups and their needs

Each reviewer was responsible for identifying likely users based on the initial brainstorming session, user interviews, task analysis and their own personal research.

Phase Four: Use findings to modify device designs

Phase four comprised the Human Factors review and suggestions for Design Modifications. To support Phase Four, the Inclusive Design Wheel was used as a prompt, see Figure 3 (unknown author). This covers the basic human sciences applied during design.

The review of each technical element was based on the concept of 'use error' to focus attention on any mismatch between design and user capabilities. It also recognised that poor design can create 'stressed' users who then have an increased potential for error (Wears et al, 2016). Conversely user-centred design can minimise training needs (Wears et al, 2016).

Figure 3: The Inclusive Design Wheel

Results

Figure 4 presents the results of the initial Brain Storming Activity which was used to help understand the different elements of the system from a micro and meso system level. This is followed by an example of the tasks as imagined and as done.

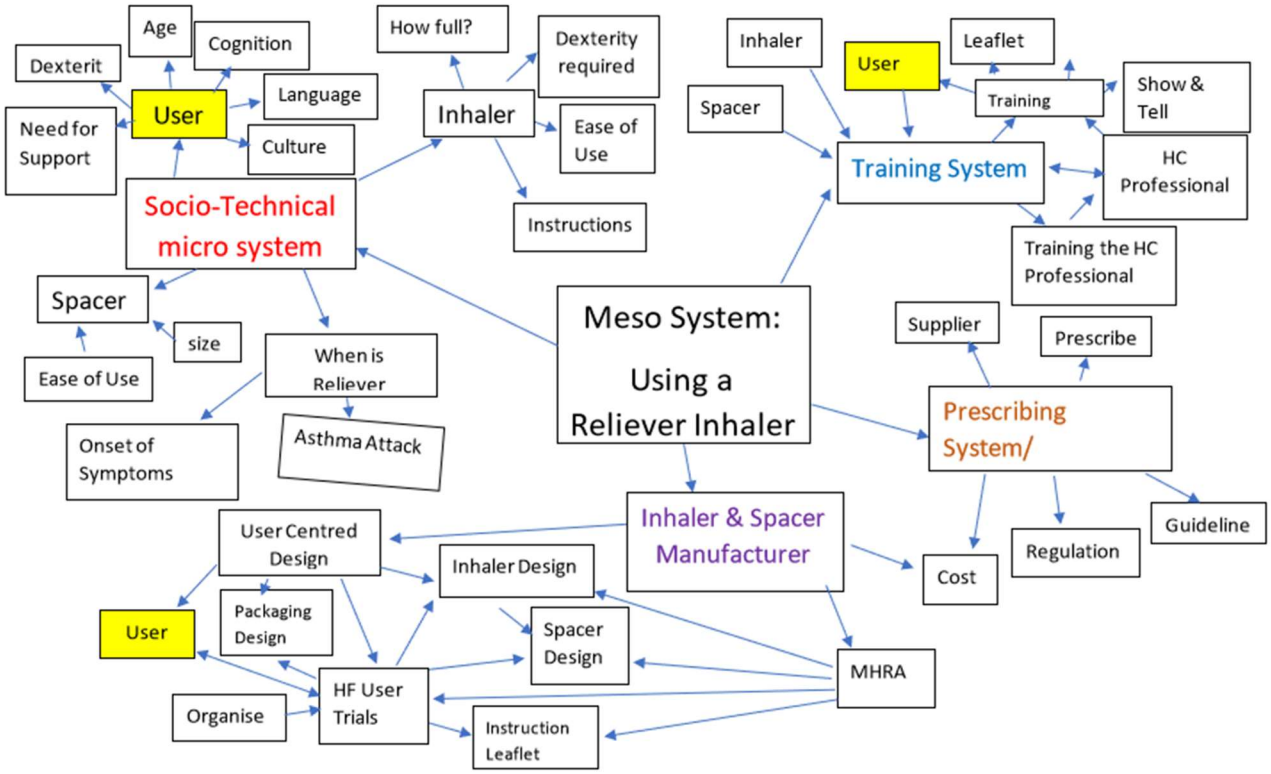

Figure 4: Reliever Inhaler Sociotechnical System Network

In terms of the specific results, this paper focuses on the reliever inhaler and its Patient Instructions Leaflet.

Instructions for using the Ventolin reliever inhaler

Figure 5 provides an example of generic user instructions provided by a Ventolin Inhaler supplier-Work as Imagined (https://www.ukmeds.co.uk/ventolin).

In order to use your Ventolin inhaler correctly you should follow this step-by-step guide:

1. Take the cap off the mouthpiece.
2. Hold the inhaler upright and shake it very well.
3. Exhale and tilt your head a bit.
4. Place the mouthpiece in your mouth and enclose your lips on the mouthpiece.
5. Breathe in slowly and deeply with your mouth, press down the canister firmly and let out one puff of Ventolin. Continue inhaling slowly.
6. Take the inhaler off your mouth; hold your breath for about five seconds. Exhale with your nose.
7. Place the cap back.

Should you need to take another puff, wait around 60 seconds before you repeat steps 2-7 above.

Figure 5: User Instructions

This example does not match the user video instructions ((Asthma and Lung UK, 2021), the available instruction leaflets (PILS) within inhaler packaging, nor the tasks identified during the user task observations, Figure 6. This demonstrates some of the problems encountered by front-line healthcare professionals who first instruct the inhaler user and the inhaler users themselves as they try to determine how to use their inhaler. Recall of instructions is in any case an issue over time without use and in stressful situations e.g. experiencing the start of an asthma attack or difficulty with breathing.

1. Inhaler grasped in palm of hand using fist grip
2. Other hand removes the dust cap from mouth piece
3. User Shakes inhaler up and down in vertical position twice
4. Mouthpiece placed in mouth between lips (no head tilt)
5. Top of the inhaler canister is depressed with thumb whilst slowly breathing in
6. Inhaler is immediately re-pressed and user breaths in again due to insufficient dose
7. Dust cap not replaced on mouth piece (this increase the risk of mouthpiece damage, contamination and foreign objects becoming lodged in the mouthpiece preventing its use

Figure 6: Observed Task Sequence

Specific Results for the Inhaler Device

Anthropometric Considerations

The Users in the pilot study did not use the recommended pinch grip. One reason may be that the length of the reliever inhaler at 85mm is difficult for most users to comfortably and securely hold in a pinch grip. The lack of contact points between the inhaler and the hand may also be an issue. The observation sessions showed that users grasped the inhaler in their fist (grasp grip) and used the thumb to activate it – rather than their index finger.

Biomechanical interaction

Device contours were suboptimal with raised edges and corners creating tissue hotspots which Pheasant and Haslegrave (2006) recommend should be eliminated. The radial shape of the PMDI was not a consistent cylindrical or elliptical shape which prevented even points of contact with the anatomy of the human hand (see Figure 7). This also prevented an optimal compression grasp grip (Pheasant and Haslegrave, 2006; Matuszek and Drobina 2018) which was the users grip of choice.

The device cross sectional diameter was 25mm at its widest point and 15mm at its narrowest point, which was below an “optimal diameter of 30-50mm” as suggested by Pheasant and Haslegrave (2006 pp.153) for optimal grip strength. A ridged zone was located on the bottom of the Reliever inhaler to aid a pinch grip, see Figure 8, which did not reflect Work as Done (WAD) and therefore, both users were unaware of this design feature.

The surface material was smooth plastic which may reduce grip when interacting with the viscoelasticity and lubrication of human skin (Pheasant and Haslegrave, 2006).

The observed user's shoulder and arm position, necessary to comply with the prescribed head tilt (see the Asthma and Lung UK (2021) video), involved a significant forward arm and shoulder flexion this reduces effective usability for users with comorbidities and upper limb injuries.

Figure 7: Radial Contours + Hands

Figure 8: Ridged Area

Figure 9: Inhaler differences

Sensory Interactions

The shape of the reliever inhaler matches those that are perceived to be associated with a typical grasp grip.

Visually, the reliever inhaler was the exact size and shape as the preventer inhaler, the only differences were colour plus a 'V' shaped raised area detectable visually and by touch on some Ventolin reliever inhalers, see Figure 9. There were no visual or physical markings on the preventor inhaler device. Note: the mouthpiece protection cap for the preventor inhaler in this photograph has been lost.

Specific Results for Patient Information Leaflet (PIL)

The PIL (Cardill, 2022) revealed a Fog Index readability score of 10.89. A score of 7-8 is considered ideal, whereas above 12 is too complex (EDUTAS, 2019). No alternate language options were provided. Copies of the leaflet are available in Braille, large print or audio but need to be requested by phoning a designated number and this opportunity may be missed by the user.

Physically the Patient Instruction Leaflet (PIL) was difficult to open as the leaflet was tightly folded and paper was thin which meant it could tear easily (Cardill 2022). In any case, Bix (2016) reported that written patient information has a negligible impact on user adherence and that leaflets may be lost or discarded. Both participants stated that they threw away the PIL without reading it.

Discussion and Recommendations

Cognitive Considerations

The affordance priming effect (APE) of the reliever inhaler design appears to have been a potential reason for the identified gap between work as imagined and work as done in terms of user grip choice, fist rather than pinch grip. The affordance priming effect (APE) states that the visual stimuli of design and shape significantly influences the neural to physical pathway mechanisms and subsequent physical hand and arm interactions with an object (Makris et al 2013). This indicated a possible ambiguity in device design (Natraj et al, 2013) it looks to the user as though a fist grip would be the best choice.

In terms of task steps the differences between the Patient Insert Leaflet supplied with the inhaler and the basic instructions provided on the internet demonstrate inconsistencies in work as imagined. Given this situation, there can be no surprise that actual work as done does not comply. The users within this pilot study did not read their instruction leaflets and did not know that training videos existed. They were therefore reliant on Health care workers to train them and they then had to remember what they were shown. The Literature suggests that older people with airway diseases have a high prevalence of cognitive deficits such as reduced information processing, memory, attention and concentration levels which can result in poor competence and compliance in inhaler techniques (Jin Song et al, 2022). Regardless of cognitive defects, Long Term memory and recall degrade over time, which places additional importance on good design rather than training.

Physical Considerations

Dexterity and grip can be impacted by room temperature and humidity with hand skin temperature being the most significant factor; grip strength has been shown to decrease by 16% after two minutes of environmental exposure to 5^{o}C (Prasetyo, 2020; Vincent and Tipton, 1988). Given that one trigger of breathing problems can be moving into cold temperatures, this may increase the likelihood of needing to use a reliever inhaler in these conditions. Age and gender also impact physical ability and dexterity and the average grip strength declines in both men and women (Viana et al, 2007). The range of shoulder mobility has been found to significantly decline with age, including active flexion and abduction movements with external rotation ranges particularly declining in females (Gill et al, 2020) this is important given that the inhaler is expected to be used with a recommended backwards head tilt.

Suggested integrated System changes

Any changes to one element of the system needs to be followed through into the rest of the system technical components in order to achieve a robust system that supports the user. For example: A QR code could be included on the Inhaler and PIL that takes the user to an Instruction Video (Kenyon, 2022); An inhaler design that supports the grasp grip should be shown on PIL infographics and the instruction video. Combined concept design adaptations need to be user centered and incorporate Human Factors theory. User trials should consider how to mimic actual use scenarios to appreciate the impact of stress on use errors and to ensure that the design can cope with the actual conditions a user is faced with.

Conclusions

The current design of the PMDI device inhaler system provides inadequate support to typical users, such as those involved within this pilot study. Users had to make significant adaptations from techniques that they were not even aware of, despite regular asthma reviews with healthcare staff. Both users made identical adaptations.

There are numerous resource disincentives for healthcare providers to invest in human centred design (Bix, 2016; Wears et al, 2016). It is therefore important to assess whether a change in one or more elements of the Reliever Inhaler meso socio-technical system is cost beneficial. To do this it is necessary to consider the whole patient journey. At the start, improved technical design is likely to reduce the amount of patient training required, reducing health carer contact time. In addition, an improved design that reduces use error should offer lifecycle cost benefits including a reduction in ambulance journeys, hospital inpatient stays and ultimately a reduction in patient deaths. It is

inappropriate to concentrate on the unit price of the inhaler device itself without placing this in context with a full cost benefit analysis.

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