Human Factors Considerations in Inhaler Innovation

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Terminology

HF: human factors – the field
ergonomics – another name for a similar field

HFE: human factors engineering – the activity
usability engineering – another name for the same activity

IFU: instructions for use
Just for today
I’m going to try to not mention regulatory agencies,
their expectations
or their issued guidance
How can a human factors (HF) perspective contribute to inhaler innovation?
Disclaimer

I do not wish to claim that HF has *exclusive* ownership of any topic.

HFE in inhaler development works at the interface of many disciplines. One perspective amongst many.
Innovating to support the inhaler user ...

... by designing easy to use inhalers.

Drug Delivery System

- formulations
- primary packaging devices

reduce cognitive & emotional demands on users
reduce physical demands on users
reduce use-related risk
improve fit with lifestyle

... by supporting competence.

Technique Training

- instructional materials
- training devices
- competence monitoring tools

support competence

... by supporting disease management.

Behaviour Change Interventions

- reminders
- self monitoring tools
- educational interventions
- gamification

support adherence to dosing regimen
enable and support disease management
Innovating to support the inhaler user ...

... by designing easy to use inhalers.

**Drug Delivery System**

- Formulations
- Primary packaging
- Devices

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Innovating to support the inhaler user ...

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**Technique Training**

- Instructional materials
- Training devices
- Competence monitoring tools

- Support competence

**Trainhaler**
Trainhaler Trainer with Flo-Tone (mechanical trainer)

**Noble**
Noble Trainer (electronic trainer)

**3M**
3M ICI (on-board technique training) (technique logging and app support)
Innovating to support the inhaler user ...

... by supporting disease management.

**Behaviour Change Interventions**

- reminders
- self monitoring tools
- educational interventions
- gamification

- support adherence

enable and support disease management

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**Various SMS interventions**

**Various Apps**

- Propeller, Adherium, Gecko, Cohero, etc.

**Inhaler Usage Monitors**

- 3M ICI (adherence monitoring)

**Clickhealth**  
*Packy and Marlon*  
(educational video game)

**Funhaler**  
(fun spacer)

**Cohero**  
Connected Spacer
A lot of great innovation in the inhaler field preceded any focused engagement with HFE
What is human factors (HF)?
“Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system”

*International Ergonomics Association*
“HF is a marriage of psychology and engineering: the application of a scientific body of knowledge about human strengths and weaknesses to the design of technology.”

Human Factors MD Inc.
Understanding the interaction between humans and technology

Understanding both the human and the engineering

Understanding user interfaces
What characterises the HF perspective?
Warning!
Due to a shortage of robots, some of our staff are human and therefore react unpredictably when abused or under pressure.
Warning!
Due to a shortage of robots, our users are human and will make predictable errors and not always behave perfectly rationally.
human biology
in reality
in vitro
in vivo
human behaviour
engaging with **what is really going to happen** when our users use the inhalers we develop
focused on the usability of user interfaces

focused primarily on how the user administers doses
The HF Perspective?

evidence-based inclusion of the human factor in inhaler development

conscened with real world performance: technical and therapeutic
The HF Perspective?

evidence-based, scientific
HF methods

focus on real world performance
HF objectives: different trade offs
HF objectives: different trade offs
An HF perspective on inhaler instructions for use (IFUs)

- Boy: “Stick it in your mouth and push down. Right?”
- Nurse: “Well, then the medicine would end up in your mouth and not in your lungs.”

  “It needs to go to your lungs.”
  “It’s very important to breathe in and squeeze your inhaler at the same time, so that it gets all the way into your body.”
An HF perspective on choice of primary packaging
HF methods
HF methods

analytical
e.g. task analysis, state space analysis, PCA analysis

empirical
e.g. simulated-use studies, HF challenge on the bench
“democracy is the worst form of government except for all those other forms that have been tried from time to time ...”

Winston Churchill
a small-scale, qualitative, simulated-use, observational study is the worst research method we have, except for all those others that have been tried from time to time....
One-way observation mirror
formative work should be formative
How can a human factors (HF) perspective contribute to inhaler innovation?
Yes, HF will contribute as one perspective illuminating the *potential promise* of inhaler innovations
But, HF contributes primarily by providing a *mindset* and a *toolkit* that supports *delivery* of the promise of that innovation.
HFE will help the development of inhalers meant for humans. Not least, by testing during development.
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