Introduction to human factors and systems thinking in medicines and device development: There really is a Plan B!

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What does the system rely upon for safety/quality/compliance?

- Regulators
- Organization
- Customer

‘Requirements’
Incentives and Expectations

DRIVE

Metrics
Measurement
Monitoring

Human Performance
CHFG is an excellent resource

Clinical Human Factors Group
Working with clinical professionals and managers to make healthcare safer

What is Human Factors?

Human factors encompass all those factors that can influence people and their behaviour. In a work context, human factors are the environmental, organisational and job factors, and individual characteristics which influence behaviour at work.

The Institute of Ergonomics and Human Factors (UK) definition for human factors is:

“Ergonomics (or Human Factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimise human well-being and overall system performance.”

What is Clinical Human Factors?

Dr Ken Catchpole, a Human Factors expert who has done much work in healthcare has provided this brief definition:
The Concordat

We, the undersigned, believe that a wider understanding of Human Factors principles and practices will contribute significantly to improving the quality (effectiveness, experience and safety) of care for patients.

We commit to supporting the National Health Service to optimise its leadership, systems and processes, design, education and training, regulation and quality assurance, to build a high performing, resilient and efficient healthcare system which protects patients by minimising human errors in healthcare delivery and is constantly aspiring for excellence through quality improvement. So, supporting the NHS to do the right thing first time, every time.

Our principles

We acknowledge that much of the activity to embed Human Factors in healthcare sits with frontline providers; although commissioners, regulators and other organisations have key enabling roles.

In supporting the NHS to understand and adopt Human Factors principles and practices, we commit
PharmaHuF: set up by S Mott and C Seal (chair UK Air Safety group) May 2014...all are welcome!
What about the pharmaceutical sector in the UK?
The reason why we have failed to change the system is simple.
Pharmaceutical Human Factors and Ergonomics Special Interest Group

A new horizon

Find out about ergonomics and human factors, look for help and expertise, join our community or become a member. We're here to help.

What is ergonomics?  Find expertise  Join in

What is ergonomics and human factors?  Find out now
Pharmaceutical Human Factors and Ergonomics Special Interest Group

The Vision:
Our vision is of a healthcare product system that places an understanding of human and other organisational factors at the heart of improving clinical, managerial and organisational pharmaceutical practice leading to significant improvements in safety and efficiency across the lifecycle of a pharmaceutical product (this includes the active medicine, excipients and all associated labelling).

The Primary Goal:
To optimise human performance within the pharmaceutical sector for patient safety and efficiency by systematically applying evidence from organisational and human factors science.
Pharmaceutical Human Factors and Ergonomics Special Interest Groups

Objectives

• Stimulate dialogue across the healthcare product sector

• Provide a non-judgmental forum for pharmaceutical professionals to explore how the culture, the beliefs, incentives, motivation of individuals, teams and organisations can impact both system and healthcare product safety

• Demonstrate through concrete action and examples the role and impact
Human Factor studies of Medical devices

- Understand user requirements
- Design/engineer for consistent performance: fit for intended purpose
- Minimize likelihood of user-related errors
- Much less experience with pharmaceuticals
- Even less knowing whether they actually help pharmaceuticals

http://www.chi-med.ac.uk/
Thinking about how Human Factor studies will be performed in the EU

The stages of human factors studies

What and Why and When And How and Where and Who

Determine focus

Develop Protocol (usability/attitudinal)

Recruit subjects

Conduct study

Analyze data (task analysis)
Case study with Epipen

The problem: in the UK, there was a seven fold increase in hospital admissions due to anaphylaxis between 1990/1 and 2003/4

The approach: 15 patients were asked about their perceptions and use of prescribed epinephrine auto-injectors.

The findings: Some patients were reluctant to carry Epipen because its design made it ‘weapon-like’. Some were confident that the emergency services would help them and therefore did not carry the device in urban areas.

The MATCH team. University of Nottingham. UK
http://www.nrls.npsa.nhs.uk/resources/?EntryId45=74930
Regulatory framework/pre-market (first thoughts)

- How will HF/usability/simulation studies interact with GCP?
- How do we measure safe performance in trials?
- Information is captured but how should this become data?
- Risk management plans seen as for ‘post-marketing’ not clinical trials
- Representativeness of investigators compared to those who will use product
Regulatory framework/post-marketing surveillance: place of human factors studies

• Who will perform usability studies?
• Will they be a post-authorisation commitment or a PASS?.....QPPVs not part of the discussion
• Will these studies be a barrier to market access and give unfair advantage to older products?
• Will there be retrospective studies or will these studies just be for new chemical entities?
• How should real-time performance data be captured by vigilance processes?
• Commercial teams of companies already support their customers: how can such activities be adapted?
• What will be the role of UK medication safety officers?
• Are there regulatory constraints such as labelling?
• How does PIL testing fit into this?
• What are plans to learn from international experience such as the US?
• What are the plans for capacity building?
Organisational science has developed, grown and is being applied

We now have more evidence about why systems fail

- Simple, linear, chain of events
- Complicated, interdependent
- Complex, nonlinear, coupling, resonance, emergence
So what is the Plan B?...

System – Theoretic Process Analysis

- Identify the hazards
- Construct the control structure

STPA Hazard Analysis

STAMP Model

Step 1: Identify Unsafe control actions

Step 2: Identify causes of unsafe control actions
COST (CO-operation in Science and Technology) ACTION
PROPOSAL FOR CLINICAL RESEARCH

COST is dedicated to networking activities for European researchers.
COST Actions are implemented through a set of networking tools.
Participants are free to develop their own ideas and new initiatives across all scientific disciplines.
Participants should be from COST Member Countries, Cooperating States and Near Neighbor Countries a.k.a. Europe

Led by Ass. Prof. Ioannis M. Dokas
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Thank you.

Let’s get this party started

If you want to know more contact......

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Drug Safety 2010; 33 (10): 1-10

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The Pharmaceutical Journal 2009; 282: 743-744

Embedding ‘Speaking Up’ into Systems for safe healthcare product development and marketing surveillance