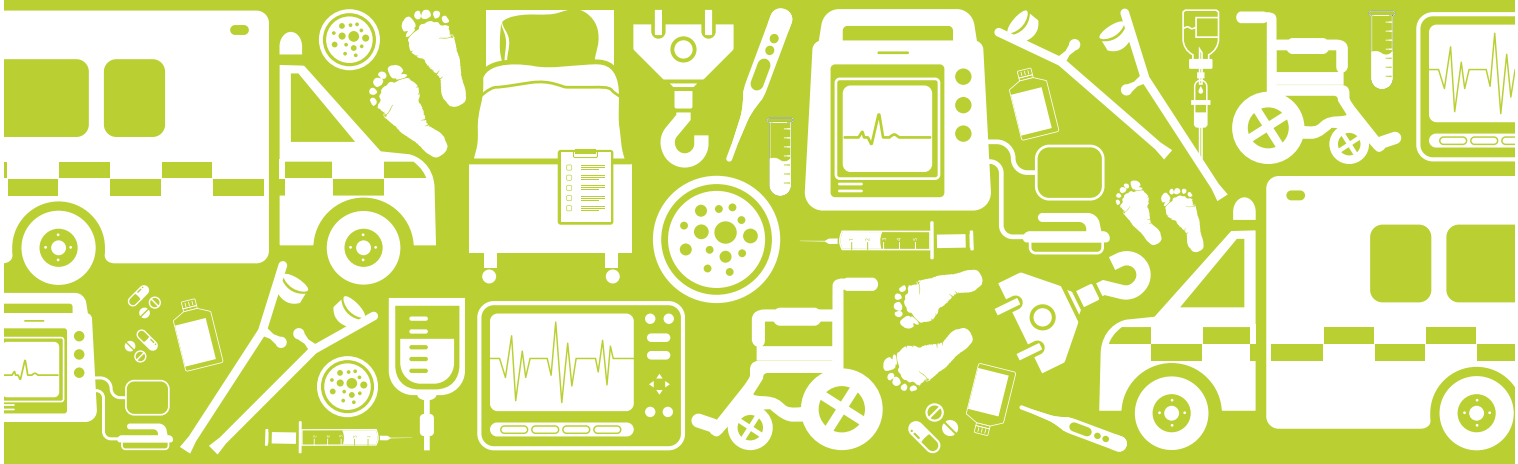
HUMAN FACTORS

FOR HEALTH & SOCIAL CARE



WHITE PAPER

Chartered Institute
of Ergonomics
& Human Factors

Acknowledgements
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Contents

A vision for integrating Human Factors in Health & Social Care

Human Factors input in any industrial sector often follows a major incident or change in legislation. In the 1990s, the removal of Crown Immunity from prosecution under the Health and Safety at Work etc Act 1974 meant that the NHS had to comply with safety legislation as hospitals and other care locations were considered to be places of work. From the 1980s to 2000s, Human Factors input focused on occupational health[1], building design[2], and systems approaches to embed Human Factors as part of the health care organisational culture[3].

In 2004 the National Patient Safety Agency (NPSA) recommended the use of Human Factors as part of the 'Seven Steps to Patient Safety'[4]. There has been much good progress since then including a National Concordat[5] bringing together 16 organisations. Health and Social Care has already started to benefit from Human Factors approaches.

Our vision is to:

- build on this good work
- broaden the scope of Human Factors understanding
- guide understanding of shared aims and offerings from partner organisations
- promote the integration of Human Factors to optimise human (patients and staff) wellbeing and overall system performance
- raise awareness of the discipline as an accredited, professional career
- ensure and maintain the standard of Human Factors practice through demonstration of competence and experience
- encourage the contribution of professional (qualified) Ergonomists & Human Factors Specialists via consultation and employment
- champion an accessible, user-focused approach.

Through ongoing collaboration, co-creation and discovery involving Health and Social Care providers, Human Factors experts and other professionals, this approach will contribute towards developing and embedding sustainable system-level improvements.

1 Straker, L. M. 1990. "Work-Associated Back Problems: Collaborative Solutions." *Occupational Medicine* 40: 75–79.
2 Hilliar, P. 1981. "The DHSS Ergonomics Data Bank and the Design of Spaces in Hospitals." *Applied Ergonomics* 12 (4): 209–216.
3 Hignett, S. 2001. "Embedding Ergonomics in Hospital Culture: Top-down and Bottom-up Strategies." *Applied Ergonomics* 32: 61–69.
4 http://bit.ly/7stepstopatientsafety
5 https://www.england.nhs.uk/wp-content/uploads/2013/11/nqb-hum-fact-concord.pdf

The case for a White Paper

The purpose of this White Paper is to provide the authoritative guide to aid understanding of how Human Factors can and should be used, and the competence and experience needed to manage effort, solve problems and make decisions. It describes how Human Factors can bring a depth and clarity of understanding to Health and Social Care issues.

RECOGNISING THE NEED

In 2016, the Care Quality Commission recommended that skilled analysis was needed for serious incident investigations to "move the focus of investigation from the acts or omissions of staff, to identifying the underlying causes of the incident" and "use Human Factors principles to develop solutions that reduce the risk of the same incidents happening again."[6]

There are national initiatives to embed Human Factors, for example, in medical device and equipment design and purchasing, together with systems and service design. This has been led by Health Education England "to ensure that the practices and principles of Human Factors are integrated into all training and education ... to develop the future healthcare workforce by ensuring it contains individuals with the right skills, attitudes, behaviours and training to enable the delivery of excellent healthcare and drive improvements for the quality of care provided and the safety of our patients."[7]

Of all the sectors in which Human Factors can deliver a contribution to safer and better life, the Health and Social Care sector is arguably the one that currently stands to benefit the most. There have been local successes in introducing improvements using risk management, quality improvement and patient safety methods. Human Factors can act as the integrating discipline to ensure that a system-wide approach is taken. The participative nature of Human Factors can ensure collaboration by all stakeholders.

It has been recognised by a range of people and organisations in healthcare that Human Factors has a critical and fundamental part to play in patient safety by providing methods and approaches which address known issues of integration, impact and sustainability of change. Qualified Human Factors specialists (also known as Ergonomists) help bring the knowledge, skills and expertise to ensure these approaches are used effectively and appropriate interventions are implemented.

TARGET AUDIENCE

This White Paper is aimed at Health and Social Care service managers, leads, commissioners, regulators and Human Factors champions in care settings, as well as anyone interested in ensuring Health and Social Care is the best it can be.

ABOUT THE CIEHF

The Chartered Institute of Ergonomics Human Factors (CIEHF) holds a Royal Charter, which recognises the unique value of the discipline and places obligations on the Institute to bring about changes for the better for society. This also means that the CIEHF is the only body in the world able to award Chartered status in Human Factors.

The CIEHF has grown to become the fourth-largest community of Ergonomists and Human Factors Specialists in the world, from its beginnings as the first UK professional society in 1949. It is part of a global community of over 50 similar, affiliated organisations who provide events, networking, knowledge and greater visibility for Ergonomics and Human Factors.

If you are interested in finding out more about Human Factors go to the CIEHF website for free, up-to-date information: **www.ergonomics.org.uk**

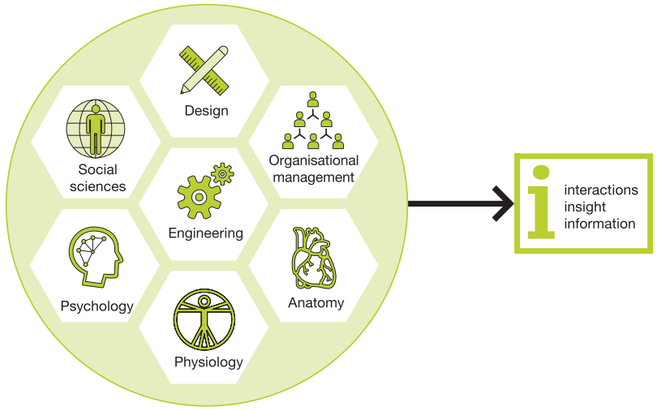
6 http://www.cqc.org.uk/content/briefing-learning-serious-incidents-nhs-acute-hospitals
7 https://hee.nhs.uk/our-work/human-factors

What is Human Factors?

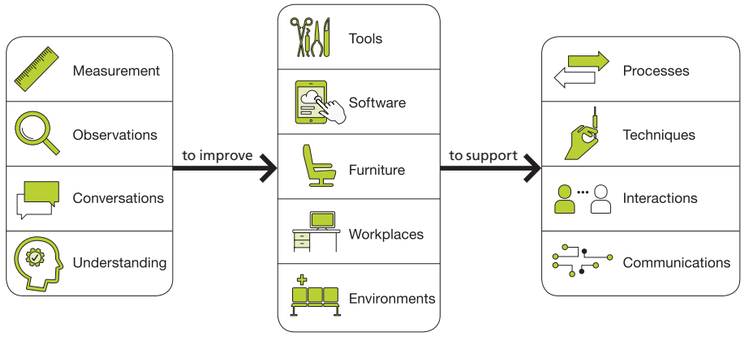
AN EVIDENCE-BASED DISCIPLINE

Human Factors, also called Ergonomics, is an evidence-based scientific discipline and profession that uses a design-driven systems approach to achieve two closely related outcomes of performance and wellbeing.

Human Factors applies elements of other disciplines such as psychology, anatomy and physiology, social sciences, engineering, design and organisational management, and combines them to better understand the nature of human-technology-systems interactions. These systems, and the context within which they operate, include people, products, technology, organisations and environments.



Human Factors uses measurements, observations, conversations and understanding about human physical and cognitive capabilities to make practical improvements to tools, software, furniture, workplaces and environments to initiate and support change for processes, techniques, interactions and communications.



Human Factors uses the systems approach to see design as the priority, only using selection and training of people to overcome design deficiencies when design adaptations are not possible.

TERMINOLOGY

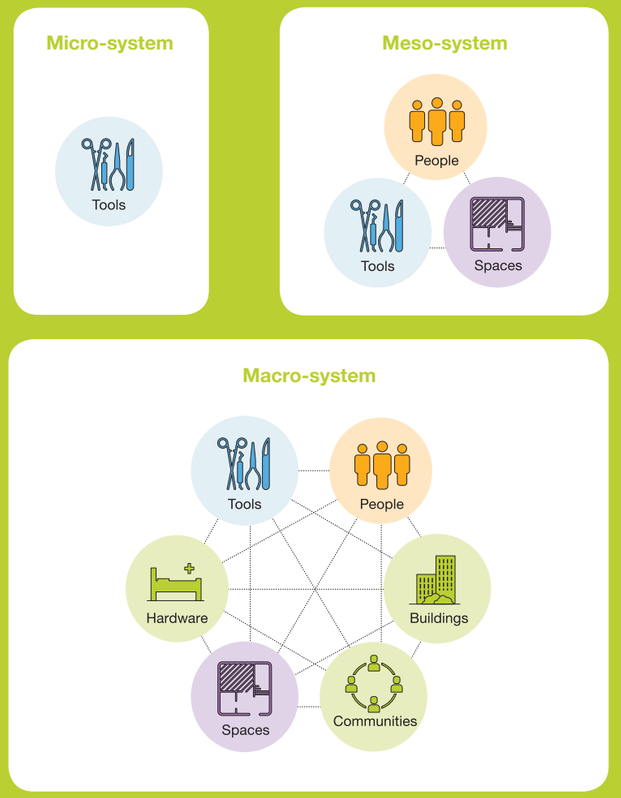
Human Factors is also known as ergonomics and the two terms are used interchangeably to mean the same thing, especially in countries such as UK, USA and Australia. Most non-English speaking countries just use the term 'ergonomics'.

Terms associated with the discipline include Human Factors engineering, human-centred design, user-centred design, usability and user experience. These are often used in relation to certain aspects of Human Factors such as product design or website design.

THE SYSTEMS APPROACH

Systems can be defined as a set of inter-related activities or entities such as hardware, software, buildings, spaces, communities and people, that all have a common purpose. There are links between these activities and entities which can change both the state and interactions in the system within a given set of circumstances and events.

Understanding and applying a systems approach is a fundamental Human Factors concept and must be the starting point for embedding human factors. Systems will range from individuals performing single tasks or using a tool (a micro-system), through to people working as part of a team (a meso-system), and on through to complex socio-technical systems (a macro-system).



"Human Factors is concerned with the understanding of interactions among humans and other elements of a system. It's the profession that applies theory, principles, data and methods to design to optimise human wellbeing and overall system performance. Practitioners contribute to the design and evaluation of tasks, jobs, products, environments and systems to make them compatible with the needs, abilities and limitations of people."
International Ergonomics Association, 2001

Using Human Factors

TO INVESTIGATE INCIDENTS

Where human error or 'user error' may seem at first to be the cause of an incident, a Human Factors approach takes a wider view to encompass root causes such as poor product design. In this case, it may then be termed a 'use error', but there are invariably many other factors that play a part in bringing about an incident. Investigations involving Human Factors experts and clinicians can uncover these factors and lead to an understanding of the relevance and importance of each one and how they combine to bring about a particular outcome at a particular time in a particular set of circumstances.

TO THINK ABOUT SYSTEMS

It may be tempting to consider a short-term fix, but this will rarely involve a systems approach and could therefore introduce unexpected and unfavourable outcomes in other parts of the system. A Human Factors intervention may focus on optimisation of a micro-system, but there will be clear mapping of the relationship of the micro-system with the larger meso- and macro-systems. It is through understanding these interactions and taking a true systems approach that effective solutions can be found. The skill is in developing approaches that are appropriate to the scale of the project and its context and to consider potentially undesirable consequences.

The Systems of Systems in healthcare have been described as nested and overlapping systems; "*A bed in a hospital is a system, the patient monitoring equipment is a sibling system, the two together plus the patient's room comprise another system, …whereas the radiology or scanning equipment, the drugs dispensary, the beds, the ambulances are all systems, but together can be seen as a system of systems when looking at maintenance and replacement regimes.*"[8]

TO THINK ABOUT DESIGN

Human Factors is relevant to all stages of the life-cycle of equipment, environment and services, from early stages of planning and design, right through to implementation and evaluation, and re-design. Initial approaches should define the scope of the project or intervention, establishing the high-level values and goals relevant to the specific context.

Healthcare is starting to recognise the benefits of Human Factors where the systems view of safety and an inclusive, human-centred design process can be applied in nearly all work situations.

Getting the design right can help to safeguard against such factors as high workload, fatigue and stress which can make it difficult for people to succeed.

IMPLEMENTING HUMAN FACTORS

Health and Social Care organisations face challenges in embedding and sustaining improvement initiatives. Successful implementation often relies on individuals having sufficient knowledge, time and resources to effectively play their part.

Our vision for Human Factors implementation is:

- **Human Factors good practice is common across all Health and Social Care processes** including audit, new and redesigned services, investigation and procurement.
- **Human Factors good practice informs all areas** from local pharmacy services and medical devices to national inter-agency information communication systems across all service providers (public and private), and sectors (primary, secondary, mental health, ambulance, community, intermediate, social and home care).
- **Proven strategies and frameworks exist** and are used for Human Factors implementation, such as integration with Quality Improvement, including a sector-specific competency matrix to which all practitioners adhere.
- **International standards for Ergonomics and Human Factors are embedded** in healthcare design and systems for planning, acquisition and safety.
- **The underlying culture is a learning culture**, keen to drive continuous improvement in human performance and wellbeing.

8 Wilson, J. R. 2014. Fundamentals of Systems Ergonomics/Human Factors. *Applied Ergonomics* 45: 5–13.

Brilliant basics

STRATEGIES FOR EFFECTIVE HUMAN FACTORS INTEGRATION

There are a number of strategies[9] to be followed to give Human Factors in Health and Social Care the best chance of success:

- **Manage the Human Factors process** by providing a strategic framework for how it is planned and deployed within projects and investigations.
- **Take full account of Human Factors activities** from start to finish in projects and in ongoing surveillance; ensure that Human Factors is embedded in design and development, testing and installation, commissioning and procurement, operating and maintenance.
- **Formalise the Human Factors process** by understanding and planning the needs of the project or investigation, identifying criteria which evidences competency and outcomes, and by documenting and reporting on Human Factors work streams.
- **If people within the system have developed 'workarounds', explore them in a positive way**; they can be a signpost to 'work as done' (as opposed to 'work as imagined') with alternative ways being taken around challenging interactions. Bear in mind that these alternative ways won't necessarily be considered in the context of the system.
- **Ensure Human Factors practice is design-led, proactive and implemented early**, to maximise safety and efficiency and minimise the potential for risk and error within the system; this will then benefit risk management processes.
- **If Human Factors practice is reactive, ask why an action made sense at the time** or why someone does something a certain way; this can be valuable when looking at clinical systems.
- **Utilise Human Factors expertise** to not only understand what can be done better but also to examine and understand where, how and why the system is working safely and efficiently.
- **Create inclusive solutions** so products or services are accessible to, and usable by the intended users – staff, patients (and family/carers) and sometimes the public. This mitigates the need for special adaptation, extensive training and/or additional information because the design is not intuitive.
- **Test risk mitigation interventions** in context of the wider system before implementation to flush out any unforeseen consequences.

WHAT 'GOOD' LOOKS LIKE

When Human Factors is done well, it can help to:

- **Recognise human needs** and provide for them.
- **Provide effective integration** of human, technological and organisational capabilities.
- **Design out the potential for people to make mistakes**, helping them succeed in what they set out to do.
- **Design work and workplaces** that enable people to perform tasks in a sustained manner with minimum need for training or frequent recourse to instruction.
- **Enable people to work in ways that maximise system safety** and reduce risk.
- **Standardise terminology** and encourage consistency in interactions (with people, places and equipment) to improve safety and performance.
- **Develop systems** that are fit for purpose.
- **Optimise human capabilities** and mitigate physical, cognitive, psychological and social limitations.
- **Identify multiple root causes** of an incident where they exist so a solution does not focus on behaviour change to accommodate poorly-designed systems.
- **Enable everyone to be involved** in the successful operation of a system.
- **Support any industry** in meeting statutory safety requirements.

9 http://orr.gov.uk/__data/assets/pdf_file/0011/22160/human-factors-integration-orr-evidence-principles.pdf

Increasing competence and capacity

As with most safety sciences and improvement strategies in healthcare and other safety-critical industries, Human Factors approaches can provide more impact when expertise is embedded in the system. It enables proactive and reactive Human Factors responses to be quickly and easily initiated to highlight resilience and share improvements in working practices.

Embedding Human Factors expertise provides the opportunity for an effective combination of a person-centred approach and the process optimisation view of Quality Improvement, for example. Interventions are likely to be more effective and sustainable if a multi-disciplinary approach is taken, using specialist knowledge and experience to ensure all aspects of a system have been considered. This ensures that people's skills are used cost-effectively to greater benefit.

Human Factors awareness already exists for a range of professionals in healthcare including among psychologists, occupational therapists, physiotherapists, medical device designers and engineers.

So, part of our vision is to increase Human Factors competence so that:

- Sufficient and relevant Human Factors education is included in clinical curricula[10].
- Sufficient competence and experience exists to fill the roles required for effective Human Factors implementation.
- Professional bodies and regulators seek support from qualified Human Factors professionals in the delivery of Human Factors training.
- Every Health and Social Care organisation has an identified Human Factors advisor at a senior level.
- Sufficient Human Factors capability exists to deliver a resilient system that encompasses safety culture and acceptable workloads for all healthcare providers.

10 Vosper, H., Bowie, P., Hignett, S. (2017) Twelve tips for embedding Human Factors and Ergonomics principles in healthcare educational curricula and programmes *Medical Teacher* https://www.tandfonline.com/doi/abs/10.1080/0142159X.2017.1387240

EXPECT THE BEST

Many healthcare disciplines must adhere to requirements set by regulators such as the Health & Safety Executive, General Pharmaceutical Council, General Medical Council, Nursing and Midwifery Council and the Medicines and Healthcare products Regulatory Agency. The Chartered Institute of Ergonomics & Human Factors (CIEHF) sets standards for professional behaviour in Human Factors through proficiency in its set of competencies and its Code of Professional Conduct.

CIEHF peer-reviews applications for professional membership, including Chartered status.

Practically, those carrying out Human Factors activities are not required in a legal sense to join the CIEHF in order to practice, but those seeking the delivery of Human Factors expertise in Health and Social Care are:

- Strongly advised to seek out and work with qualified Human Factors practitioners.
- Actively encouraged to join CIEHF as an Associate to keep informed and to access its communities and networks of Human Factors professionals.

ACCREDITED QUALIFICATIONS

The CIEHF accredits university-run postgraduate level educational courses, several of which specifically target the upskilling of healthcare professionals in Human Factors.

Those with evidence of successful completion of these courses will be able to demonstrate a level of competence in Human Factors, which includes an in-depth knowledge of Human Factors theory and its role in the workplace. Competence will also include performance elements such as systems approaches to requirements capture, analysis, understanding risk management and developing robust Human Factors interventions to improve systems performance and human wellbeing.

Case studies

FIT-FOR-PURPOSE EQUIPMENT

THE PROBLEM: Carpeted floors in a newly-built hospital prevented easy use of a mobile patient hoist. The hoists were a control measure implemented to reduce the risk of manual handling injuries to staff. The hoist's rubber wheels worked well on smooth or hard floors but not on carpet. When a patient was in the hoist, the wheels sank into the carpet, making it difficult to move so nurses stopped using them, increasing the risk of injury to staff and patients.

THE SOLUTION: A systems approach would have considered all equipment and user requirements in clinical areas before the flooring specification was agreed. In this case, a detailed assessment was carried out with the result that the hoist manufacturer changed the wheels on the hoists, using larger ones made of harder material.

THE IMPACT: Pushing and pulling forces required to move the hoist were reduced by 40%. Nursing staff could use the hoists again, reducing the risk of manual handling injury and increasing the safety of the patient.

Reference: HSE, Case study 2 - Health services, equipment fit for purpose www.hse.gov.uk/msd/healthservice.htm

DESIGN FOR PATIENTS

THE PROBLEM: Birth in water gained momentum in the early 1990s however birthing pools at that time had not been designed with users in mind. Mothers found it difficult to get into the birthing pool and almost impossible to get out of in an emergency. Midwives had to adopt poor posture when monitoring and examining mothers in the pool.

THE SOLUTION: User needs were identified and incorporated into a new design which included steps and rails to assist entry and exit, shaped edges to support the mother, knee room to allow the midwife easier access for monitoring and a seat that allowed the mother to be evacuated rapidly in an emergency.

THE IMPACT: The work revolutionised the design of birthing pools with resultant improvements in safety and wellbeing of the mother, baby and midwife. Support staff carrying out maintenance, cleaning and infection control also benefited from the improved design.

Reference: Case Study 18: Improving birthing pool design. The Human Connection. CIEHF 2015

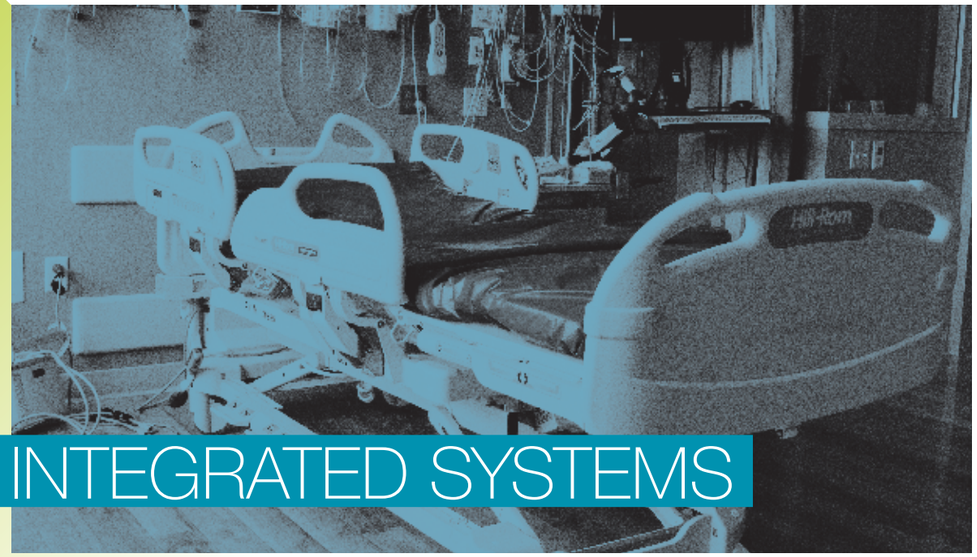
STANDARDISED DESIGN

THE PROBLEM: Before 2006, NHS Ambulance Trusts around the UK produced their own vehicle specifications, resulting in over 40 different designs for emergency ambulances in the UK. This posed a risk to patient safety due to confusion about the interior layout and location of equipment by those working in vehicles operated by different Trusts.

THE SOLUTION: Projects were carried out by ergonomists working alongside paramedics which looked at design of vehicles, equipment, working systems, clinical protocols and patient pathways. Prototypes were developed to validate design recommendations and were presented to CEOs of the UK's ambulance services.

THE IMPACT: Tangible benefits have been provided not only to paramedics but also to those assisted by the UK's ambulance fleet every day. These include improved working conditions and patient safety, financial savings of £2.5m over three years and UK-wide adoption of standardised interior and exterior design.

Reference: Case Study 16: Design for Patient Safety. The Human Connection. CIEHF 2015.



INTEGRATED SYSTEMS

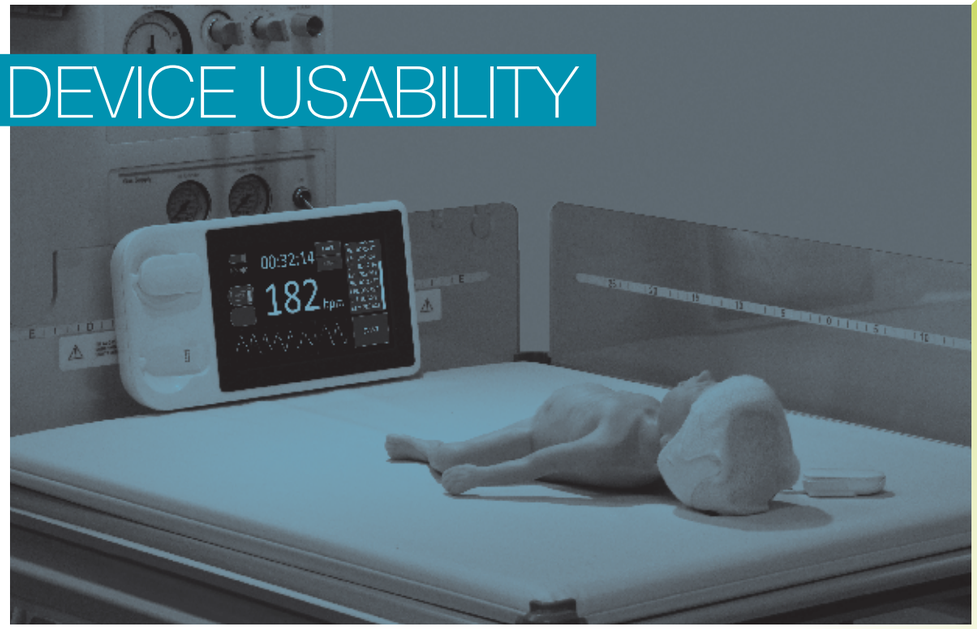
THE PROBLEM: A study in a large acute NHS Trust identified that equipment was often in poor condition or it was not suitable for the task. There were issues of compatibility with different types of equipment that needed to be used together to provide treatment. The study found that rental costs for dynamic mattresses were overspent by £15-20,000 a month but there was still an incidence rate of 11% for pressure ulcers.

THE SOLUTION: A project examined the risks in clinical areas associated with this equipment. A working group consisting of a senior Back Care Advisor, a Trust board member, a finance manager, a tissue viability nurse, a nurse manager, an infection control nurse and representatives from estates, therapies and portering was established. The group specified equipment performance criteria and trialled equipment before drawing up a tender specification.

THE IMPACT: Following the approval and tender processes, the Trust bought 500 electric profiling beds and mattresses, a range of chairs and other equipment. One year on from implementation the benefits included 69% saving in nursing time assisting or moving patients, equating to £1.4m; musculoskeletal injuries fell from 28 to 4; pressure ulcer incidence fell from 11% to 3%.

Reference: HSE. Electric profiling beds (EPBs) in hospitals: Case studies www.hse.gov.uk/healthservices/epb-case-studies.pdf

DEVICE USABILITY



THE PROBLEM: A new device had been developed to assess heart rate during resuscitation of new-born babies, to ensure clinicians are provided with accurate information in a timely and precise manner, without the need to stop resuscitation for manual heart rate assessment with a stethoscope. What information is needed for such as device and how should it be displayed and controlled?

THE SOLUTION: A user-centred design approach called Applied Cognitive Task Analysis (ACTA) was used to investigate and understand the cognitive requirements of clinicians carrying out the task of neonatal resuscitation. This method provided understanding of the tasks involved, the cognitive requirements and the potential for error during a neonatal resuscitation scenario. These findings were then translated into design requirements for system designers.

THE IMPACT: The study and its outputs have been used to develop an interface which prioritises simplicity of use whilst optimising performance and minimising error, and which fits into the current clinical pathways for neonatal resuscitation.

Reference: Resuscitating New Born Babies. The Human Connection II. p12. CIEHF 2018.

UNDERSTANDING ERRORS IN CONTEXT

THE PROBLEM: Intravenous infusion safety is a recognised concern internationally. There is limited evidence about infusion practices in England and how they relate to prevalence and types of error. Further, smart pumps have been advocated to reduce errors but their effectiveness is not known.

THE SOLUTION: Sixteen hospitals engaged in a mixed method study. The study found large variability in practices and in discrepancies and errors. Many deviations were observed but little harm. Not all deviations were bad, and people were a source of system resilience. Policy and practice need better alignment in this area. Smart pumps were found to have little impact in reducing everyday errors.

THE IMPACT: The work suggests that intravenous infusion therapy is a complex system, and technology is not a panacea. Some sites are already reviewing policy and training in response to site specific feedback. This raises debate about where investment should be made to improve infusion safety.

Reference: Lyons I, Furniss D, Blandford A, et al. (2018) Errors and discrepancies in the administration of intravenous infusions: a mixed methods multihospital observational study. *BMJ Quality and Safety*. doi:10.1136/bmjqs-2017-007476.

Signposts to further information

MORE ABOUT HUMAN FACTORS

Scientific discipline and profession

Dul, J, Bruder, R, Buckle, P, Carayon, P, Falzon, P, Marras, W. S, Wilson, J R, and van der Doelen, B, 2012. A Strategy for Human Factors/Ergonomics: Developing the Discipline and Profession. Ergonomics 55:4:377-395 **https://doi.org/10.1080/00140139.2012.661087**

IEA, 2001. International Ergonomics Association. Core competencies. **www.iea.cc/project/PSE%20Full%20Version%20of%20Core%20Competencies%20in%20Ergonomics%20Units%20Elements%20and%20Performance%20Criteria%20October%202001.pdf**

CIEHF Code of Professional Conduct (p20) **https://www.ergonomics.org.uk/Public/About_Us/CIEHF_Documents.aspx**

CIEHF Professional Competencies **https://www.ergonomics.org.uk/Public/Careers_Jobs_CPD/CPD.aspx**

In Health and Social Care

Health Education England in the North East. 2017 Introduction to Human Factors. **https://youtu.be/aGZz3w5Hy8Y**

Health Education England. 2016. Improving Safety through Education and Training. **http://www.hee.nhs.uk/sites/default/files/documents/FULL%20report%20medium%20res%20for%20web.pdf**

Hignett, S, Carayon, P, Buckle, P & Catchpole, K, 2013. State of science: Human Factors and ergonomics in healthcare. Ergonomics 56:1491-1503 **https://doi.org/10.1080/00140139.2013.822932**

Hignett, S, Jones, E, Miller, D, Wolf, L, Modi, C, Shahzad, MW, Banerjee, J, Buckle, P, Catchpole, K. 2015. Human Factors & Ergonomics and Quality Improvement Science: Integrating Approaches for Safety in Healthcare. BMJ Quality and Safety 24:250-254 **http://dx.doi.org/10.1136/bmjqs-2014-003623**

National Quality Board, 2013. Human Factors in Healthcare: A Concordat from the National Quality Board. **www.england.nhs.uk/wp-content/uploads/2013/11/nqb-hum-fact-concord.pdf**

Russ A L, Fairbanks R J, Karsh B-T et al., 2013. The Science of Human Factors: Separating Fact from Fiction. BMJ Quality and Safety 22:802–8 **http://dx.doi.org/10.1136/bmjqs-2012-002036**

PATIENT SAFETY AND HUMAN FACTORS

Berwick, D. 2013. A promise to learn– a commitment to act: Improving the Safety of Patients in England **https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf**

Care Quality Commission, 2016. Learning from serious incidents in NHS acute hospitals. **www.cqc.org.uk/content/briefing-learning-serious-incidents-nhs-acute-hospitals (accessed 10/12/17)**

Cavendish, C. 2013. The Cavendish Review: An Independent Review into Healthcare Assistants and Support Workers in the NHS and social care settings **https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf**

Department of Health, 2000. An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS. London: Department of Health **https://www.aagbi.org/sites/default/files/An%20organisation%20with%20a%20memory.pdf**

Department of Health, 2002. Learning from Bristol. The Department of Health's response to the report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. London: The Stationary Office **https://www.gov.uk/government/publications/the-department-of-healths-response-to-the-report-of-the-public-inquiry-into-childrens-heart-surgery-at-the-bristol-royal-infirmary**

Francis, R. 2013. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry **http://www.midstaffspublicinquiry.com/report**

Hignett, S, Lang, A, Pickup, L, Ives, C, Fray, M, McKeown, C, Tapley, S, Woodward, M, Bowie, P, 2018. More Holes than Cheese. What prevents the delivery of effective, high quality, and safe healthcare in England? Ergonomics 61, 1, 5-14 **https://doi.org/10.1080/00140139.2016.1245446**

Kohn, L T, Corrigan, J M & Donaldson, M S, (Eds), 2000. To Err Is Human: Building a Safer Health System. National Academy Press, Washington, DC **https://www.nap.edu/catalog/9728/to-err-is-human-building-a-safer-health-system**

WHO, 2011. World Health Organisation: The Multi-Professional Patient Safety Curriculum Guide. **www.who.int/patientsafety/education/curriculum/en/**

WHO, 2009. Patient Safety Curriculum Guide for Medical Schools **http://www.who.int/patientsafety/education/curriculum/EN_PSP_Education_Medical_Curriculum/en/**

IMPLEMENTING HUMAN FACTORS

Bowie, P, Watson, P, Gillies, A, Pickup, L, 2017. A Scoping Review of Human Factors and Ergonomics Issues, Interventions and Resources in Primary Health Care. **https://learn.nes.nhs.scot/1601/patient-safety-zone/human-factors/a-scoping-review-of-human-factors-and-ergonomics-issues**

Carthey, J and Clarke, J, 2009. Patient Safety First. The 'How to Guide' for Implementing Human Factors in Healthcare. **www.weahsn.net/wp-content/uploads/Human-Factors-How-to-Guide-v1.2.pdf**

Holden, R J Carayon, P, Gurses, A P, Hoonakker, P, Schoofs Hundt, A, Ant Ozok, A, & Rivera-Rodriguez, A J, 2013. SEIPS 2.0: a Human Factors framework for studying and improving the work of healthcare professionals and patients. Ergonomics 56:11:1669-1686 **https://doi.org/10.1080/00140139.2013.838643**

McKay, J, Pickup, L, Atkinson, S, McNab, D & Bowie, P, 2016. Human Factors in general practice – early thoughts on the educational focus for speciality training and beyond. Education for Primary Care 3, 162-171, **https://doi.org/10.1080/14739879.2016.1181533**

Pickup, L, Lang A, Atkinson S & Sharples S, 2018. The dichotomy of the application of a systems approach in UK healthcare: the challenges and priorities for implementation. Ergonomics, 61, 1, 15-25 **https://doi.org/10.1080/00140139.2017.1306632**

Royal Academy of Engineering, 2017. Engineering better care: a systems approach to health and care design and continuous improvement. **www.raeng.org.uk/publications/reports/engineering-better-care**

MEDICAL DEVICE DESIGN

ANSI/AAMI HE75:2009(R) (2013). Human factors engineering—Design of medical devices, **www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=926#sthash.z3tHlcCS.dpuf**

FDA, 2016. Applying Human Factors and Usability Engineering to Medical Devices. Food and Drug Administration **www.fda.gov/downloads/MedicalDevices/.../UCM259760.pdf**

FDA (2003). GHTF/SG2/N31R8 Medical Device Post Market vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorised Representative, **www.fda.gov/ohrms/dockets/98fr/04d-0001-bkg0001-08-sg2_n31r8.pdf**

FDA (2010). Medical Device Home Use Initiative. Centre for Devices and Radiological Health. **www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/UCM209056.pdf**

FDA (2014). Design Considerations for Devices Intended for Home Use. Guidance for Industry and Food and Drug Administration Staff. Centre for Devices and Radiological Health. **www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM331681.pdf.**

IEC, 2006. IEC 62304:2006 - Medical device software – Software life cycle processes. Geneva: International Organization for Standardization

IEC, 2007. ISO 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. Geneva: International Organization for Standardization

ISO, 2007. ISO 14971: Medical devices - Application of risk management to medical devices as a methodology for assessing and documenting product safety and effectiveness. Geneva: International Organization for Standardization

MHRA, 2016. **www.gov.uk/government/news/human-factors-and-usability-engineering-guidance-for-medical-devices-including-drug-device-combination-products**

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