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Developing a methodology for visualising Human Factors in healthcare

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1. Workshop Organizer/s

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Abstract (200 words max)

Design as a catalyst for change can be most potent when informed by insights gained from contextual user research. These insights can enable design to shift paradigms, alter traditional perspectives and create step changes in practice. With national health services around the world under pressure due to increasing, ageing, and less active populations, the ability of design to deliver transformative healthcare products, interactions and services, based on these insights, could not be more opportune.

This workshop poses the question of how human factors related insights can be generated in such a complex socio-technical and safety critical system as healthcare, and how they can be visualised so that all stake holders can understand the subtleties, interactions and inter-dependencies of the various clinical, social, physical, technical and environmental elements.

The workshop will present and seek feedback on proposed methods and the outcome will contribute to the development of a set of tools and systematic methodology that can assist designers, researchers, architects, healthcare professionals and administrators during the research phase of a healthcare design project to uncover user needs, identify potential risks, provide documentation for regulatory adherence and inform the development of a comprehensive design brief and subsequent design process.

2. Context of Workshop

The US Association for the Advancement of Medical Instrumentation (AAMI) defines Human Factors Engineering (HFE) as "the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations" and regards HFE as synonymous with "human factors, ergonomics, human engineering, usability engineering (UE), or human–computer interaction (HCI)".[1] The AAMI currently produces two standards which detail the consideration of Human Factors in the design of medical devices: ANSI/AAMI HE74:2001/(R)2009. Human Factors Design Process for Medical Devices, ANSI/AAMI HE75:2009/(R)2013, Human Factors Engineering – Design of Medical Devices.

The US Food and Drug Administration (FDA) recognises HE75 as a general consensus standard related to human factors and the application of HFE/UE to medical devices.[2] The preparation of a HFE process file is mandatory for any company seeking FDA approval for a medical device. While HE75 presents guidelines on the HFE process and the relevant inputs and outputs, it does not provide methodologies for conducting the Research, Contextual Inquiry and Use Scenario elements of the required process. This workshop aims to contribute of the development of a methodology by which these elements of the HFE process may be satisfied, leveraging expertise developed in the Product Design Department in the National College of Art and Design, Dublin.

The department has run a MSc. programme in Medical Device Design since 2009, during which students work in collaboration with clinicians and industry partners to develop solutions to real world healthcare problems. These projects typically begin with a period of contextual user research in order to understand the environment in which any device will be used and establish the requirements of potential users that will inform the design solution. As a result of this process, a competency in the creation and application of methodologies to conduct contextual research in complex environments and to interpret and visualise its results has developed within the department. This workshop seeks to expand on and develop this existing knowledge and expertise into a formalised system for Human Factors evaluation and visualisation.

The approach of this workshop reflects developments in this area conducted by the Human Factors in Complex Systems Research Group, led by Dr Patrick Waterson in Loughborough University. This group researches how humans manage dynamic situations in complex socio-technical systems created by the interactions between people, products, technologies, services, procedures, policies and culture. The workshop will also draw on the work of the Clinical Human Factors Group (CHFG), an independent UK charity working with clinicians and healthcare managers to deliver safer patient care. Established in 2007, the CHFG applies Human Factors methodologies and risk assessment models developed in aviation and other safety-critical industries to healthcare scenarios.

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[1] Association for the Advancement of Medical Instrumentation. *Human factors Engineering – Design of medical devices.* ANSI/AAMI HE75:2009/(R)2013. Arlington (VA): AAMI, 2013.

[2] US Food and Drug Administration, *Applying Human Factors and Usability Engineering to Medical Devices*, https://www.fda.gov/downloads/MedicalDevices/.../UCM259760.pdf

Cumulatively, the organisers have developed, coordinated and delivered several workshops in Design Thinking and Creative Enterprise both within NCAD and for organisations including the RSCI, The Digital Hub and Bank of Ireland and conducted the workshop activities for Dingle IoTHon, 2017.

3. Planned Activities and Expected Outcomes

This workshop intends to be generative as well as informative by eliciting the experiences and input of participants in a co-creative process to assist the development of a practical, fit for purpose, design research methodology and a framework for the visualisation of research results.

The workshop activities are centred around the creation of a shared understanding of the importance of human factors in the delivery of healthcare, the challenges associated with uncovering research insights in such a complex environment, and visualising the interwoven and layered findings of this research so that it can be understood by all stakeholders.

Building on this understanding, current methods of conducting and presenting this type of research, developed during collaborative projects between NCAD MSc Medical Devices students, healthcare institutions and medical device companies, will be presented, examined and discussed.

Working in small groups, participants are then encouraged to contribute their experiences and knowledge to improve the proposed methodology and suggest alternative approaches and methods. These suggestions will then be mapped and documented as the best practice recommendations of the workshop.

A provisional timetable for the workshop is as follows:

15 mins	Welcome and introduction of workshop aims
15 mins	Brief introduction by each participant to establish background and interests
30 mins	Context of workshop and demonstration of current methods in NCAD
30 mins	Discussion on the methods proposed
15 mins	Coffee break
30 mins	Break into groups to create proposals on methodology and visualisation (Groups may be thematic e.g. Commercial, Clinical, Academic, User, Mixed)
30 mins	Re-group with presentation and charting of findings resulting in generation of best practice recommendations
15 mins	Thoughts on further steps and conclusion.

Expected outcomes are:

- The challenging and/or validation of proposed theories and approaches for the development of a methodology for the discovery and recording of human factors during contextual user research in healthcare delivery scenarios.
- Experienced and informed feedback on proposed methods to present information collated in a visual format.
- Cooperative generation of best practice recommendations for the continued development of the proposed methodologies.

It is intended that participants will leave the workshop with a greater understanding of the impact of Human Factors during clinical procedures and in the usage of medical devices but also the contribution that in-depth contextual user research and the visualisation of its results can make by enabling designers to confidently present transformative concepts based on transparent, traceable and accountable methodology.

4. Intended Audience

The organisers hope to attract a cross-sectoral and interdisciplinary audience composed of health care professionals, medical device designers, educators, design researchers and interaction designers. It is hoped that by having disparate viewpoints we can elicit a wide range of different opinions, experiences and inputs that feed into proposed methods to inform and refine their development. The ideal number of workshop participants is approximately 25 - 30.

5. Length of Workshop

A half-day workshop (approx. 3.5 hours) is proposed as the organisers feel any less would be too short to address the subject coherently and engage in worthwhile reflective activities while a full day might stretch beyond the limit of interest for participants.

6. Space and Equipment Required

Space: Informal studio-like space that can accommodate 25 – 30 participants.

Equipment: Whiteboards, flip-boards (4-5), wall space, projector and screen, video recording equipment, tables and chairs.

7. Potential Outputs

Potential outputs of the workshop are:

- Development of a methodology for the discovery and recording of Human Factors during contextual user research in healthcare delivery procedures.
- Framework for the compilation and visualisation of the information collated.

- Inclusion of the workshop results in a paper describing the creation of the above methodology and framework.
- Inform standards development and policy around the area of Human Factors inclusion in the research of healthcare related products and delivery.
- The main output is a contribution to the development of a set of tools that can assist designers, researchers, architects and healthcare professionals during the research phase of a healthcare design project to uncover user needs, identify potential risks, provide documentation for regulatory adherence and inform the development of a comprehensive and transformative design process.

About the Organizers:

Organizer 1 Donal Healion holds a BDes in Industrial Design and MSc in Medical Device Design. He is engaged in EU and Enterprise Ireland supported design research and commercialisation activity within NCAD and is currently Principal Investigator on a Commercialisation Fund project.

Organizer 2 Enda O'Dowd is course coordinator for the MSc in Medical Device Design in NCAD. With a background in materials and engineering, he specialises in applying science and technology to design questions, helping designers use technology to develop innovative, human-centered products

Organizer 3 Derek Vallence lectures on the MSc in Medical Device Design in NCAD. With a BDes in Industrial Design and MSc in Computer-aided Product Design, he specialises in the realisation of design concepts.