Institution:
Royal College of Art

Unit of Assessment:
32 Art and Design: History, Practice and Theory

Title of case study:
Inclusive design for healthcare: creating impact in clinical practice and commercial investment by addressing barriers to innovation

Period when the underpinning research was undertaken:
2004-2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Jonathan West	Senior Research Fellow	2004–present
Anna Wojdecka	Research Associate	2014–2017
Indira Knight	Research Associate	2018–present
Paul Eliasz	Research Associate	2018–2020
Hawys Tomos	Research Associate	2013–2016
Gabriele Meldaikyte	Research Associate	2015–2017
Thea Swayne	Research Associate	2004–2005
Gianpaolo Fusari	Senior Design Associate	2012–present
Ed Matthews	Reader in Healthcare Design	2014–2018

Period when the claimed impact occurred:
2014-2020

Is this case study continued from a case study submitted in 2014?
N

1. Summary of the impact

RCA research led by Jonathan West and a team in the Helen Hamlyn Centre for Design expanded the use of inclusive design techniques to address procurement and regulatory factors that constrain innovation in hospital and community health design. Building on the RCA's participatory design approach with patients and frontline staff, the work resulted in significant impact in *clinical practice* (10,000 'Wee Wheel' pocket guides produced by Public Health Wales enabling nurses to assess urine output easily and accurately); in *clinical trials* (362 people with paranoia in three NHS areas participated in the 'SlowMo' digital platform clinical trial); and in *commercial development* (the 'Flomark' redesign of the hospital drip has raised over £400,000 from investors). This research also enabled the HHCD team to work with hospitals and Public Health Wales to address challenges during the Covid-19 pandemic.

2. Underpinning research

Since 2004, the Helen Hamlyn Centre for Design (HHCD) has undertaken research in inclusive design for patient safety in hospitals, which has developed into collaborative studies with frontline clinical staff addressing broader healthcare challenges. Building on the work described in the related REF2014 impact case study, techniques and models of inclusive design research for healthcare have been further developed during the REF2021 period to address a broader range of factors and clinical settings.

Overall, this research has not only investigated how inclusive design techniques can be applied effectively to the clinical environment, but has also addressed improvements in collaboration across clinical and design disciplines to maximise effectiveness, and broadened the clinical context to include mental as well as physical health. The most recent development in this research has involved including regulatory and procurement stakeholders in projects in order to maximise the likelihood of research findings being adopted and achieving the envisaged impact on clinical practice, as these were identified as significant constraints to implementing design-led innovation in hospital and community healthcare.

Research undertaken with the National Patient Safety Agency (2006) (3.1) resulted in a series of publications addressing user error with infusion devices and drug labelling and packaging. The

EPSRC-funded 'Designing Out Medical Error' project (2008-12) built on this (3.2), defining a collaborative co-design methodology for design for patient safety which incorporated the 'Double Diamond' framework for the design method, as well as specific tasks shared across the collaborative clinical/design team, such as process mapping and Failure Mode and Effect Analysis.

More recently, the 'Safety = Design' project (2015) (3.3) with Betsi Cadwaladr University (BCU) explored how inclusively designed interventions can help clinical and care staff in detecting a patient's deterioration on a hospital ward. BCU provided clinical access for the RCA designers, identified staff and patients to participate in the research, and championed the design outputs. HHCD researchers led the co-design of early-stage concepts with clinical staff and patients, and rapid user testing and iterative refinement of the most promising designs resulted in two final interventions.

These methods were developed further in the 'SlowMo' project (2014) (3.4) with King's College London (KCL) to include inclusive design for interventions in mental health. The project explored how inclusively designed materials can support the uptake of Cognitive Behavioural Therapy (CBT) for people with paranoid and suspicious thoughts. KCL provided clinical access for the RCA designers, identified staff and patients to participate in the research, and trialled the design outputs. HHCD researchers conducted the research and co-design, involving observations, interviews and mapping with therapists and with people with lived experience.

This approach was further refined in 2020 with the gameChange project, which combined a transdisciplinary approach with participatory design to create interventions for mental health (VR for psychosis).

West expanded the traditional inclusive design research methodology (focusing primarily on end-users) to include addressing commercial, procurement and regulatory constraints in the design-led innovation process in response to his observations of the barriers to successful implementation in previous projects (3.5). This resulted in his development of the Flomark, a redesign of the hospital drip (3.6), a demonstration of how inclusive design methods combined with consideration of clinical, procurement and regulatory factors can produce a commercially viable device to improve the safety of infusion on hospital wards. The knowledge and networks established through this research meant the HHCD team was well placed to develop a number of rapid and effective design interventions for frontline healthcare during the Covid-19 pandemic.

3. References to the research

3.1 Helen Hamlyn Research Centre, National Patient Safety Agency Design for patient safety: 'A guide to the graphic design of medication packaging' (second edition) (2007): available in the Helen Hamlyn Centre for Design research repository http://collections.rca.ac.uk:8085/helen_hamlyn_centre_for_design_archive/#/

3.2 West, J., Davey, G., Anderson, A., Brodie, A., Norris, B. and Myerson, J. (2014) 'Designing out medical error – an interdisciplinary approach to the design of healthcare equipment', *The Design Journal*, 17 (3), pp. 238-266. Related to Designing Out Medical Error: Establishing Performance Requirements for Equipment Use on Hospital Wards, funded by EPSRC (EP/F064802/1, £1.3m, Myerson PI).

3.3 Subbe, C. (2015) 'Safety = Design – Driving safety and signposting risk', Shine 2014 final report, Bangor, Wales and London: Betsi Cadwaladr University Health Board and The Health Foundation: https://www.health.org.uk/sites/default/files/Betsi%20Cadwaladr%20final%20report_website%20version.pdf (accessed 25 September 2020).

3.4 West, J., Meldaikyte, G., Wojdecka, A., Hardy, A. and Garety, P. (2017) 'SlowMo / Mo – digital technology to provide support in coping with daily life', Design 4 Health Conference, Melbourne, Australia. Related to The effects of targeting reasoning on paranoia for people with non-affective psychosis: the SLOWMo blended digital therapy RCT, funded by NIHR and MRC (Award ID 15/48/21, £1.4m, Garety PI).

3.5 West, J. (2020) 'Design in healthcare: the challenge of translation', Design for Health, DOI: 10.1080/24735132.2020.1783880.

3.6 'Flomark' granted patents in Europe, US, China, Japan (WO2016170296A1 (2019)) for a new design of intravenous infusion flow meter. **Submitted to REF2014**.

4. Details of the impact

The research has resulted in demonstrable impact on clinical practice.

Clinical practice impact

The 'Safety = Design' research resulted in two design outputs: the 'Wee Wheel', a pocket guide for nurses to assess urine output; and the 'KidneySafe' bracelet for patients to self-assess urine output. More than 10,000 'Wee Wheels', paid for by Public Health Wales, are now in use across Wales, with further units in use internationally. Frontline staff and patients have noted the benefits, with the Programme Lead for Acute Deterioration at Public Health Wales confirming that: ''The Wee Wheels have been extremely popular with participants… [and] have been an important factor in raising awareness of acute kidney injury' (5.2). The 'KidneySafe' bracelets are in use in community health settings, gaining particular traction in care homes. Further clinical research has shown that patient engagement with self-assessment increased after deployment of the bracelets (5.1).

The 'SlowMo' digital platform to support the uptake of Cognitive Behavioural Therapy (CBT) for people with paranoid and suspicious thoughts has now completed clinical trials (5.3) involving 362 people from three NHS areas (London, Sussex and Oxford), funded by the National Institute for Health Research (NIHR) and the Medical Research Council (MRC). The results were positive in terms of clinical outcomes, with excellent indicators of usability (adherence, acceptability, usefulness, enjoyment) (5.4). These results are of particular significance given the widely acknowledged lack of evidence of the quality and efficacy of currently available mental health apps.

Commercial development impact

The research has led to commercial impact. The 'Flomark' redesign of the hospital drip has been developed to improve fluid management: one in five patients suffer complications or morbidity due to inappropriate administration (NCEPOD, 1999); 24% of incidents relate to flow rate errors, and 15% involve harm. The clinical benefits of the Flomark are primarily that it reduces error in drip set-up. It has been subject to extensive bench tests, which proved its reliability and its accuracy across different viscosities, and to user testing on a hospital ward, which showed statistically significant improvements in set-up time. Thirteen frontline staff (doctors and nurses at a London teaching hospital) were asked to set a flow rate using the Flomark prototype, without any prior training in the product: they were found to have set an accurate rate 69% faster (25 seconds v 80 seconds) than with standard drips. Flomark not only reduces set-up time, but also increases reliability, maintaining a prescribed rate for twice as long as standard drips (a series of head-to-head infusions over 12 hours). Flomark would thus save the NHS an estimated £20 million per annum in nursing time (based on 50s/rate setting, band 5 nurse = 20p/use, 100 million drips used in UK NHS per annum).

West, as lead researcher, has established a spin-out company (Flowmark Ltd.) to commercialise the Flomark innovation. It has been granted patents in Europe, US, China and Japan, with further territories pending and further patents filed, and secured £55,000 investment from Venrex Investment Management in 2017. The spin-out company has had licensing offers from two multinationals, with a licensing deal now agreed (5.5), and leading figures in the industry have confirmed that the innovation has both commercial merit and demand. A further £350,000 has been pledged from angel investors, and £200,000 from a commercial investor, which will support progress towards obtaining a CE mark, further clinical testing, and final design for manufacture and tooling. The pre-company valuation of Flowmark Ltd. is [text removed for publication] (5.5).

COVID-19 design interventions

The insights into healthcare design and deliver gained through these inclusive design research projects (Section 2) built up a knowledge base and a network of designers and clinicians on

which the HHCD team was able to draw to create rapid and highly effective design-led interventions which impacted directly on clinical practice during the first wave of the Covid-19 pandemic.

For example, noting that innovations in visor design were proliferating early in the pandemic, the HHCD team, working with Great Ormond Street Hospital, coordinated efforts in the design community to produce one single version, which was approved for use.

When University College Hospital had to convert its theatre suites into a Covid-19 recovery complex, the altered layout and function of the space, combined with redeployed staff working in unfamiliar settings, meant that there was an urgent need to establish an agreed layout that would be immediately comprehensible to all users. Engaging over Zoom with clinical staff, the HHCD team led by West designed layout posters detailing where the PPE zones, defibrillator, and other vital equipment was located. An anaesthetist at UCH stated that the maps 'were really helpful… and helped us visualise the space as a whole and work out where best to place our emergency equipment' (5.6). These remained in use at UCH during the second wave of the pandemic.

Public Health Wales was required to assemble Covid-19 testing kits for both drive-through locations and the home mailing. A high level of accuracy by the user in the swabbing and packing procedures was essential, and while Public Health Wales had a variety of photographs and internet-sourced images available to use, it had no agreed steps for the user to follow. The HHCD team converted these materials into two user-friendly sets of instructions, which were also translated into Welsh, and were rolled out for us in the testing sites (5.7).

5. Sources to corroborate the impact

(5.1) Ahmed, M, Ajakiye, A, Butt, U, Cooper, D, Ibrahem, A, Holmes, J, Hancock, C and Subbe, CP (2017) 'AKI – PRO: Patients as partners in Recording Output', poster presentation at Society for Acute Medicine National Conference, Cardiff.

(5.2) Programme Lead for Acute Deterioration at Public Health Wales (26 February 2020), email correspondence: 'The Wee Wheels have been extremely popular with participants in the NHS Wales RRAILS Acute Deterioration Programme; we have printed and distributed approximately 10,000 of them. I believe that their presence and branding have been an important factor in raising awareness of acute kidney injury (AKI) as a cause of avoidable harm in Wales, as it is internationally.'

(5.3) SlowMo Clinical Trial number ISRCTN32448671: http://www.isrctn.com/ISRCTN32448671 (accessed 24 January 2020).

(5.4) Professor of Clinical Psychiatry at King's College London and PI for the NIHR-funded SlowMO project (2021), letter on confidential results from SlowMo Clinical Trial.

(5.5) Director of InnovationRCA (2021) letter on licensing and investment agreement with Flomark Ltd.

(5.6) Anaesthetist at University College London Hospitals Trust (3 December 2020, 21:49), COVID Design WhatsApp group (used for remote design research with ICU clinicians, which they had requested as the easiest medium): 'Seeing the empty map was really helpful (especially the distinction between "clean" and "not clean" areas), and helped us visualise the space as a whole and work out where best to place our emergency equipment. Also having to think and explain what was in all our different stations (e.g., airway trolley vs difficult airway trolley) helped us simplify what we kept in each station.'

(5.7) Director, Screening Division, Public Health Wales (1 December 2020) email correspondence: 'We did use the bilingual and photo instructions towards the end of the time we were running the testing site at the Cardiff site. That was mostly, I recall, as they needed to be amended to show double bagged samples and there was a delay in getting the leaflets approved via Gold.

I don’t think we had any specific feedback on them but they seemed fit for purpose and some anecdotal feedback was that the clinical support could see the Welsh side being used when patients read the leaflet.

When we handed the site over to Cardiff and Vale, they use a staff administered test so leaflets would not have been required.’