Healthcare Innovation: whose job is it anyway?

Dr Gabriella Spinelli, Reader in Design Innovation,
Brunel Design School, Brunel University London
E: Gabriella.spinelli@brunel.ac.uk

There is a plethora of reasons as to why healthcare is changing in the UK and globally. Causes of changes span from funding issues, consequences of the global Covid-19 pandemic, comorbidity due to an increasing ageing and obese population, to the application of digital technology. The quality of healthcare services depends on economic resources; this causality has been discussed by previous research and reports (Mosadeghrad 2014; Kaye et al 2021 OECD, 2010; Bloomfield and Logan 2003), and captured succinctly in a public media interview to the previous NHS CEO when Stevens stated "when the economy sneezes, the NHS catches a cold" (BBC, 2016).

This reflection argues that to envision, plan and manage a modern and inclusive healthcare system, it is appropriate to consider the impact that approaches developed in a broad set of disciplines may have on the healthcare system and its reform. This piece discusses healthcare innovation through the lens of products' design, specifically the relevance of patient-centred products for the improvement of patients' care outcomes, and for enhancing patients' and staff experience. Most importantly, but uncommonly, this reflection wishes to lay the foundations for considering the contribution of design innovation in enabling a new relationship between the economy and the healthcare system whereby innovation in medical products may stimulate the economy, namely revitalising manufacturing and diversifying the rather oligopolistic market of medical and assistive products. This may somehow mitigate the causal relationship described by Stevens, help to dispel the idea that the healthcare sector wastefully uses resources (OECD, 2017), and strengthen the NHS's agency to reset the UK economy post-pandemic (Claridge et al 2020). The following considerations pivot around three points: i) the opportunity afforded by intuitive and personalised medical products through User-centred Design and Advance Manufacturing, ii) the barriers to products innovation in healthcare, and iii) the conditions for innovation.

Intuitive and personalised medical products

Mobility and prosthetic devices provide an exemplar domain where person-centred requirements can be defined collaboratively between clinical staff and patients, leading to fast, effective and patients' endorsed products that are more likely to be adopted. Poor patients' adherence caused by unrealistic and generic assessment services and lack of custom-made devices, often cause escalating costs to the NHS, as well as significant consequences to the patients' quality of life. Understanding user needs and capitalising on advanced materials and additive manufacturing processes are key design engineering contributions that can enhance the quality of medical products, their speed to market, and may also improve overall patients' adherence.

As materials availability increases, advanced manufacturing methods are no longer limited to thermoplastic resins and their properties to produce medical and assistive devices. The application of 3D printing methods to an extended list of viable materials such as metals,

ceramics, biological inks, glass and composites, enables the creation of implantable products, soft tissues and artificial organs.

Beside functional requirements such as biocompatibility, durability, tensile strength and non-toxicity, advanced manufactured products provide a degree of customisation that was unimaginable at commercial scale only a decade ago. Customisation of personal aids such as prosthetic and mobility devices is a key element in products adoption since these products are charged with emotional investment due to their proximity to one's body (Rozin & Fallon 1987; Spinelli et al 2019). Often prosthetic and mobility devices play an important role in social acceptance too: running blades are a prime example of the significant step-change in public perception and acceptance they have facilitated. The non-functional personalisation of assistive devices, though may seem secondary to the patients' care outcomes, is instrumental to reduce abandonment and to facilitate a stronger emotional bond between the user and the device, ultimately, enabling choice and independence.

A further point that results from the powerful combination of User-centred Design and advanced manufacturing, consists in rapid prototyping and consequent iterative user evaluations. Through an early physical rendering of the user requirements in the design process, rapid prototyping allows multiple evaluation iterations at low cost. This, in return, assures that users/patients actively participate in the design process, leading to patients' preferences fully embedded in the final design, and resulting in higher chances of acceptance and adoption.

Moreover, rapid and bespoke prototyping has a significant economic benefit as it shortens the manufacturing process by reducing the gap between user research and initial product design, and evaluation. Having initially identified a set of solid set of user and product requirements, further customisation of devices, required to follow the patients' recovery trajectory or the increasing needs caused by degenerative conditions, is also feasible and cheaper. Custom-made devices have already been recognised as medical aids by the UK Medical Devices Directives of 2002, however the full integration of advance manufacturing methods in the medical products' provision chain has yet to be realised.

Barriers to products innovation in healthcare

Following on from this latent innovation, a second point this reflection raises is concerned with the resistance to innovation in healthcare systems, and, consequently, a persistence of approaches that instate the *status quo* (Forman 1981). Whilst new therapies are rightly introduced only after rigorous evidence of their efficacy has been obtained, medical resistance, often entrenched in the healthcare systems' administration, hinders true transformation in product innovation (Bergsland 2014). Often this conservatism is caused by two key factors: a lack of exchange between the medical and multidisciplinary communities, and pressing clinical needs overlaid with organisational administration.

Traditional product innovation pathways in healthcare include incubator and accelerator programmes that respectively nurture internal medical staff's inventions and speed up the pilot application of commercial technological innovations in the clinical environment. Whilst both routes can lead to success, in other words to viable products, they both may be limited in their own distinctive ways.

Usually only large medical establishments that double as major teaching institutions have the capacity to establish and resource these innovation pathways: this representing a first limitation of these innovation routes. Large institutions are hardly agile, and the administration required to foster innovation is taxing and adds on to already heavy clinical workloads. Moreover, if administrative processes are not established, medical staff need to laboriously collate and align the required expertise to spur off their ideas.

A similar administrative overburden may be placed on companies who wish to partner with clinical establishments to trial innovation. These *accelerating* programmes are resource-intense and lengthy. Most SMEs do not have the capacity to engage and sustain such effort. Normally only large corporations have the means to finance a clinical trial and, if successful, to expend the additional assets necessary to navigate the complex medical devices' certification process.

This set of circumstances tend to make the exchange between the medical and the engineering communities only possible between large clinical and commercial actors, perpetuating a *status quo* where barriers to entry in clinical product innovation are high. In addition, due to resource-intense processes required to bring new medical devices to the market, needed products' improvements don't take place as often as they should. A lack of market competition also justifies this sluggishness. This results in a market that is stale, where the quality of medical products is underwhelming, and very limited choice is available.

Conditions for Healthcare Innovation

Having discussed the challenges in medical products innovation, I would now like to highlight some of the conditions that may favour it, with a particular attention to the UK context. One of the premises of what is set here is that healthcare innovation should not be a mere function of the size of the participating actors, as this may reduce speed to market, delay existing products' improvement, and precludes access for a wider group of organisations to a market in much need of change.

A second premise for innovation in healthcare is that digitalization should not be portrayed as a response suitable to all challenges in the sector. It must be said that digitalisation, combined with data harvesting and machine learning, provides great opportunities for patients' care improvements, and public health. A digital strategy may also enable personalised health pathways and may improve patient-clinician communication; however digital healthcare strategies are often embedded in product-service systems that require the same User-centred Design effort as medical products to be usable, integrated, and effective.

Substantially, care and the training of staff to deliver it occur through products and devices: myriads of them from pacemakers to hospital beds and catheters. This is a market of *every day medical objects* that is irreplaceable, needs improvements to satisfy its end-users, and that may provide the opportunity to refuel the economy.

To improve the quality of medical products, the disruptions and challenges met by the end-users, both clinical staff and patients, must be studied in their actual practice context. Access to and participation of clinical staff and patients is equally strategic to generate and evaluate solutions that, through design iterations, lead to advanced and improved final prototypes. Decoupling, spatially and organisationally as it currently happens, the studying of the healthcare challenges from their potential design solutions, has contributed to the depleted market we currently experience. Thus, a first characteristic for healthcare innovation is that it must be embedded in the practice context, where healthcare challenges could directly instigate product innovation.

Currently the initiation of new medical products is led by incumbent commercial companies who can assert a technological advancement on the market. They seldom have clinical expertise or design skill sets available in-house, and these are normally outsourced for specific, and limited, parts of the design innovation process, to reduce externalities. Due to the limited involvement of hired clinical or design expertise, the ownership and control of medical products lay predominantly with the manufacturers. For similar reasons, this is a market where manufacturers have the lion's share in terms of intellectual properties rights and royalty allocation. Thus, a rebalancing act must take place to recognise the clinical, design, and manufacturing knowledge bases contributing to effective, intuitive, and technology advanced medical products. This should result in a collaborative stewardship of the medical products' specifications and lead to a shared intellectual property rights allocation, recognising the necessary multidisciplinary efforts that create good medical products.

The picture emerging from these reflections is one suggesting new forms of collaborative structures, able to engage, educate and directly instruct the commercial sector to make medical products, designed to respond to real clinical staff' and patients' requirements at the highest possible standards, and representing value for money. Moreover, commercial enterprises must acknowledge the buying power of the national health system and, as in any other markets, respond to its demands, not simply its needs. New forms of collaborations between clinical units, academic and research establishments, and commercial actors can provide the joint resources to deliver advanced design engineering curricula preparing new healthcare design specialists and defining much needed new career pathways.

To enact innovation in healthcare means more than improving the national healthcare services, and to produce better and more competitive medical products entails more than diversifying the current market. The responsibility to transform such a critical sector for our society is distributed: it is an upstream strategic effort and a design project in its own rights. It cannot rely on single sector's contribution, but it should occur through multidisciplinary partnerships and collaborative

processes that realise innovative national and international opportunities whilst being guided by sensible and accessible regulatory frameworks.

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