
Old, Sick And No Health Insurance. Will You Need A Permit To Use Your Home-made Health Wearable?

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Abstract

We posit that as aging populations grow, so too will the demand for wearable devices that help people manage their chronic health conditions autonomously, at home, without medical supervision. Although healthcare providers are now integrating wearables into frontline services, the regulatory journey from *consumer use* to *patient use* for these devices is complex and oft protracted due to strict legislation. Through the creation of a design fiction – *HealthBand* - we explore how open source and crowd-funded wearables might impact future health product legislation. We argue that the generated artefacts co-construct a world in which *HealthBand* could plausibly exist, and in turn can help audiences engage more explicitly with the fiction's broader debates. Further, if future health wearables are to be adopted, HCI and design researchers must not focus solely on creating prototypes but also engage with regulatory change. We assert design fictions that build worlds like *HealthBand* have a role in highlighting the changes required.

Author Keywords

Wearables; Design Policy; Health Product Legislation; Design Fiction

ACM Classification Keywords

I.m. Computing Methodologies: Miscellaneous.



Figure 1: A selection of pages from the HealthBand digital campaign document

Introduction

The term *wearable* denotes a portable Internet-connected device that is operational while worn in contact with a user's body or attached to their clothing. 'Always on' and able to monitor the user's current context, wearables display real-time data whilst sharing information with other connected devices [1]. Mann describes wearables more formally as a computer that is at once *eudaemonic*: users consider it part of him/herself; *existential*: users have complete control of it, and, *ephemeral*: it is always operational [2].

With consumer fitness and activity wearables like *Nike+*, *Garmin* and *FitBit* helping to make self tracking everyday and routine amongst wider publics, and *quantified self* research giving academic credence to capturing such data [3], designers and manufacturers are now identifying opportunities for devices that specifically monitor serious health conditions. Indeed, the popular fitness brand *Jawbone* has recently ceased its customer-facing operation in favour of developing wearables and accompanying digital services directly for health providers working with patients [4].

From Digital Fitness To Digital Health

New health wearable *Kardia Band* detects *atrial fibrillation* (AF) by taking an ECG of its wearer's heart [5]. AF presently costs the UK's National Health Service more than £2.2bn a year. Consequently, "health authorities are interested in simple wearable devices that could significantly increase early diagnosis of [various] problems before they become life-threatening - and more costly to treat" [6].

Simon Stevens, head of NHS England, has recently allocated funding to ensure several wearables including *Kardia Band* can be adopted throughout UK health services in the next few years: "In the rest of our lives we're seeing the difference that innovative tech makes... now the NHS will have a streamlined way of getting ground-breaking and practical new technologies [to] frontline nurses [and] other staff. By doing that, we can transform people's lives" [7].

Legal Issues

Despite the 'streamlining' rhetoric, the route for wearables into the NHS, and other nations' health systems, remains protracted and expensive. As Gundotra stresses, it is imperative that doctors have "clinically proven products whose data they can use to make clinical decisions" [6]. Resultantly, "the rigorous testing process... for a health product to receive regulatory approval can take years," laments Wall [6].

Kardia Band's designers state that the device can identify and help users' manage a variety of heart conditions, yet it is presently only clinically approved for AF use. If it detects any other symptoms, it merely prompts its wearer to visit their doctor for a check up [5]. In light of all the above, we argue that, in its current form, health product legislation will likely hinder the design and development of future wearable health devices. We contend that such legislation must be revised to accommodate changes in both *how people will access healthcare*, and, *how people will access health technologies* in the near future.



Figure 3: Front cover/page from the NDHS 'Home-made Health Wearable Certification' leaflet

Democratised Health: The Next Frontier for Wearables

Ageing populations is perhaps the most critical issue facing health systems across the world. As Triggles explains, medical advances "have come at a cost. People are living with a growing number of long-term chronic conditions - diabetes, heart disease and dementia. These are more about care than cure - what patients usually need is support. By the age of 65, most people will have at least one of these illnesses" [8].

We argue that as aging populations increase, so too will the demand for wearables that help them manage chronic conditions. Further, we posit that the future of healthcare lies not so much in national or local governmental run health services, but directly with patients themselves. As self-diagnosis wearables become more simplified and habitual, and social care provisions diminish further, we envision people will be compelled to manage their health autonomously, at home, without trained medical supervision. Health product legislation would thus need to reflect this shift to heterogeneous healthcare. Accordingly, we have sought to consider such a future through a design fiction entitled *HealthBand*.

HealthBand: An Open Source Wearable

HealthBand offers a vision for a decentralised health wearable. Born in a near future where public health services are increasingly privatised, the device is the culmination of crowd-sourced design and production capital - an open source health product. Citizen empowerment sits at the forefront of its design and it can be regarded as a bottom up, 'do it yourself' netizen-led response to chronic health issues. Extrapolating the contemporary trend for *quantified self*

devices alongside the nascent field of *digital health*, the fiction seeks to highlight the role that emerging social innovation design practices and technologies like the Maker Movement, 'hacking' and open hardware, could potentially play in the creation of future self-made and personalised health devices [9].

Figure 1 depicts pages from the fictional campaign document for the wearable. The document explains the motivations behind the device and describes the crowd-funding call that led to the production of the first three designs - a diabetes monitor, dementia memory aid and hand stabiliser for Parkinson's disease. Also discussed is how others can become involved in developing the project further - by donating funds, creating new modules or simply purchasing the device.

Building A World For HealthBand

A key tenet of early design fiction practice has been the creation of a prototype that is 'situated', that is, the prototype exists within a world where it 'makes sense' [10][11][12]. In such a near future world for *HealthBand*, patients are taking ownership of their health themselves. They are sharing knowledge and expertise regards the design and development of home-made health devices. The wisdom of the crowd is reducing the expense and time of conventional health wearable research and development, and regulatory approval for such devices now comes about through patient-led trials and testing. As a result, the production and use of open source and crowd-funded wearables has led to changes to UK health product legislation. The UK Government has produced guidelines for health device certification while the netizen developers of *HealthBand* have created an app for use in patient trials. Once a device is certified by the



Figure 4: Screenshot of *HealthBand Patient Trial App* interface

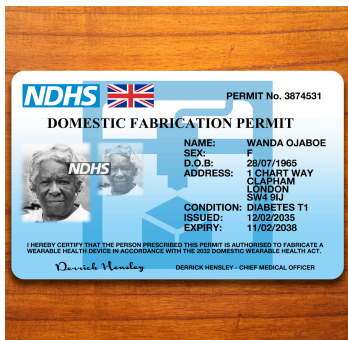


Figure 5: A *Domestic Fabrication Permit* granted by the NDHS

UK's *National Digital Health Service*, patients' wishing to construct it themselves at home – for example using 3D printing and open software – must still apply for a *Domestic Fabrication Permit*.



Figure 2: Extract from the 2028 UK Government white paper

With this in mind, to help 'concretise' this world we have generated several additional artefacts to accompany the initial campaign document:

- Figure 2 - An extract from the 2028 UK Government White Paper entitled
- Figure 3 – Pages from the UK's *National Digital Health Service's* (NDHS) '*A Patient Guide To Gaining Home-made Heath Wearable Certification*' leaflet.
- Figure 4 – The interface for the *HealthBand Patient Trial App* including a patient profile, their wearable usage data and feedback diary entries.
- Figure 5: – A 2035 *Domestic Fabrication Permit*, as supplied by the NDHS, granting construction of a

personalised health wearable at home.

When viewed together, this collection of artefacts build the fictional world for *HealthBand* and once created, this world acts as the prototyping platform for the very designs that define it [13]. Each artefact is designed to provide an alternate entry point to the world and serve to engage different audiences with the wider debate it aims to facilitate.

Conclusions

Although the *HealthBand* prototype and accompanying artefacts are intended to appear realistic and plausible, the focus of the fiction is not to promote the creation of such devices, rather it is to provoke a debate that considers the changes to health product legislation that would be required to enable open health wearables to exist at all. Further, if such products are produced what would be the potential impacts on society that these said devices would create.

If future wearable health products and services are to be adopted, it is important that HCI and design researchers do not merely focus on creating novel prototypes using new technologies. If they truly believe in the value of their prototypes, they must also lobby for the regulatory change required so that such devices can be approved for use. We argue that design fictions that build worlds like *HealthBand* can, to a certain extent, begin to provide designers and researchers with a method for conceiving what is required to move their prototypes from interesting technological experiments to ones that have a tangible societal impact through wide-scale adoption. Further, they then provide a potential means of highlighting such needs to the authorities responsible for facilitating such change.

Acknowledgements

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