



ENGINEERING VALUE-EFFECTIVE HEALTHCARE SOLUTIONS: A SYSTEMS DESIGN PERSPECTIVE

Patou, François; Maier, Anja

Technical University of Denmark, Denmark

Abstract

Our modern healthcare systems commonly face an important dilemma. While they depend on innovation to provide continuously greater healthcare value, they also struggle financially with the burden of adopting a continuous flow of new products and services. Although several disruptive healthcare models, i.e. decentralised, personalised, pervasive, connected, and stratified, promise to relieve some of this tension, they do not per se guarantee optimal value generation. We argue that systems thinking and engineering design can remedy this limitation. We support this claim by making the case of Design for Evolvability and by elaborating on two examples: MRI systems and Point-of-Care in-vitro diagnostics solutions. We specifically argue that Design for Evolvability can realign the agendas of various healthcare stakeholders, serving both individual and national interests. We finally acknowledge the limitations of current engineering design practices and call for new theoretical and empirical research initiatives taking a systems perspective on healthcare product and service design.

Keywords: Design for X (DfX), Large-scale engineering systems, Biomedical design, Innovation, Healthcare

Contact:

Dr. François Patou
Technical University of Denmark
Department of Management Engineering
Denmark
frpato@dtu.dk

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1 INTRODUCTION

Pressured by an increasing prevalence in chronic diseases, constrained by limited budgets and hindered by severe systemic issues, many modern healthcare systems are struggling (Rouse and Serban, 2014). Among the many challenges they must address, one tension stands out: on the one hand, healthcare depends on continuous progress in medical science and on the exponential technological developments of the information age to improve the value of healthcare delivery. These advances are key in determining our ability to prevent, diagnose, treat, and manage medical conditions with continuously increasing safety and efficacy. On the other hand, healthcare systems suffer under the financial burden of adopting such continuous flow of innovative solutions. They also need to cope with operational disruption, risks, and process inefficiencies that often accompany the integration of new products or services.

This position paper argues for the potential of engineering design to release this tension innovation imposes on healthcare systems. We strive to show that systems thinking, and adapted engineering design principles (such as evolvability), applied to novel frameworks and methodologies can support the development of cost-effective innovative healthcare solutions reconciling the short-term best interests of individuals with the long-term economic sustainability objectives of nations.

We elicit from the literature some of the key trends currently prevailing in healthcare, including decentralisation, personalisation, connectivity, pervasiveness, and stratification and discuss their prospects for remedying the aforementioned tension. We then present a brief summary of the evidence of the complex and adaptive nature of national healthcare systems. We then reason that, in such context, an engineering design perspective is essential for new technology-based care models to deliver on their expectations. More specifically, we reason that the transformation of national healthcare systems can be partly addressed from the bottom-up: we argue that the engineering design of healthcare products and services, according to context-appropriate design principles, may reconcile all healthcare stakeholders' interests (e.g. user, payer, supplier, etc.) from the individual to the international scale. We support this position by elaborating on a particular example: the case of Design for Evolvability. We discuss the relevance of the latter design principle in certain contexts and illustrate its legitimacy for both the design of well-established healthcare technologies, with MRI systems, and for the design of new, decentralised healthcare solutions, with direct-to-consumer in-vitro diagnostics devices.

2 TECHNOLOGY-ENABLED EMERGING HEALTHCARE MODELS

Although the cost of innovation often burdens healthcare systems, most of the envisioned corrective strategies also propose to capitalise on technological progress. This apparent paradox is resolved by distinguishing the nature, purpose and operation of various technologies: when expenditures on advanced solutions for acute or chronic conditions is soaring (e.g. MRI systems), many technology-based concepts have shown great potential for delivering increased healthcare value at limited costs in less critical and more manageable cases.

A system perspective in design is yet needed for both cases. Before we exemplify how a specific design principle can support durable healthcare-value delivery to all stakeholders, we give a brief overview of the key macro-trends and emerging health care models made possible by exponential technologies. The derivation of these trends follows an extensive literature review with core references listed from both clinical and technical journals. We observe that the vision of an effective, efficient and cost-sustainable healthcare system includes a decentralised, pervasive, personalised, connected, and perhaps stratified approach to care (Figure 1). We argue that the application of appropriate engineering design strategies will determine the extent to which these models reach their full potential.

2.1.1 Decentralised healthcare

The decentralisation of healthcare in the Western world started as a socio-political process, essentially promoting the transfer of political decision-power and financial accountability from central institutions to local structures (Regmi, 2014; Saltman et al., 2007).

Today, this decentralisation process is still central to the remodelling of our healthcare system. It yet involves aspects extending way beyond financial and authoritative autonomy.

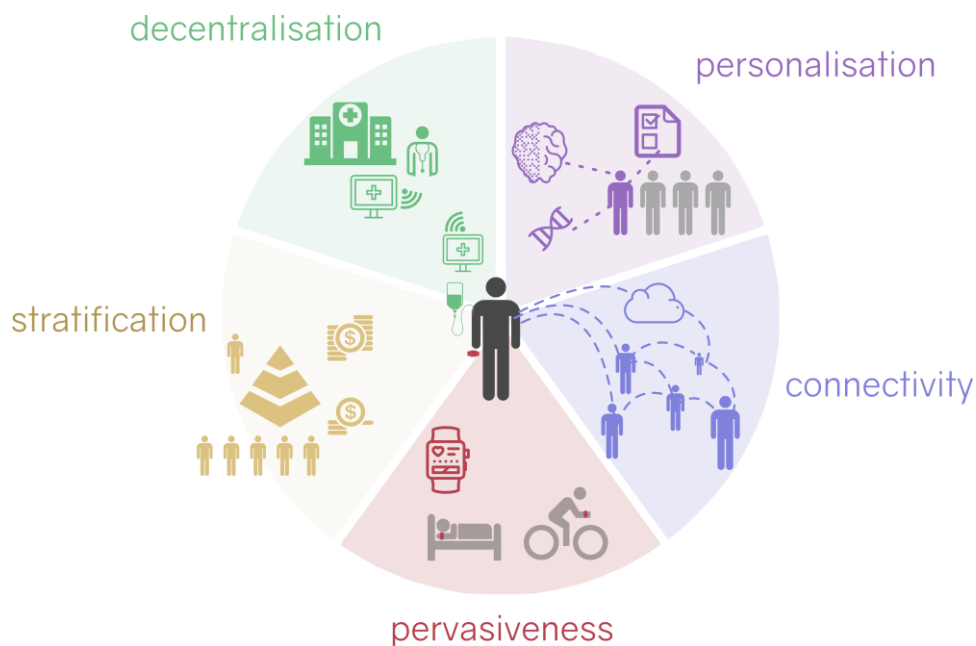


Figure 1. Macro-trends in healthcare

It aims at pushing the geographical and organisational boundaries of traditional hospital-care, advocating in particular the comprehensive and integrated delivery of a number of chronic- and palliative-care services in a decentralised, sometimes home-based setting. This model relies of course on medical-grade products such as vital-signs monitors and other assistive bedside technologies (e.g. end-of-life support), but it also increasingly incorporates a variety of connected eHealth and telemedicine services, enabling the extension of the scope of decentralised care to less critical applications (e.g. e-Consultations).

In low- and middle-income countries, the decentralisation of healthcare systems has long been considered an essential strategy for coping with the scarcity of healthcare resources and infrastructures. In-vitro Point-of-Care (POC) diagnostic testing for instance, supports the screening and diagnosis of many infectious diseases in remote locations with minimal assistance from medical or technical staff (Drain et al., 2014).

The decentralisation of healthcare delivery therefore manifests throughout a variety of applications, all aiming at diminishing the cost of healthcare labour and reducing the inequities of access to care, while offering individuals the comfort of a proximity of service.

2.1.2 Pervasive and preventive healthcare

The vision of a decentralised healthcare system has long been advocating the geographical translation of a few strategic traditional healthcare services from central infrastructures to our personal living spaces. Recently, this vision has been complemented by what is often referred to as a pervasive care model: a patient-centric model contributing to the creation of healthcare value everywhere, at all time. The implications of continuous and ubiquitous care are significant: pervasive healthcare intends to extend the realm of current healthcare applications. One of its main objectives is to anticipate and react promptly to risks or signs of health degradation before they progress and require central interventions (e.g. hospitalisation). Prevention is considered by many as key for limiting or reversing the issues associated with the increasing prevalence of chronically ill patients. Pervasive healthcare also proposes an ubiquitous technological assistance model, for individuals dealing with chronic conditions limiting their autonomy or quality of life (Thorpe et al., 2016).

This vision is becoming more and more realistic as novel technologies - a great number of which are consumer-grade - enable the pervasive and continuous monitoring and interpretation of our physiological status, behaviour and environment. Our smartphones, wearable, ingestible, and implantable-devices, supported by advances in big-data analytics, should eventually flip our vision of health care from a sparse and episodic service to a constant, life-spanning care delivery process (Andreu Perez et al., 2015).

2.1.3 Personalised healthcare

The "personalisation of care" may somehow seem an elementary and almost tautological notion, since humankind has for a long time attempted to attend to the specific needs of those in poor health. Yet only recently has personalisation become a comprehensive, strategic and actionable item for the delivery of higher healthcare value. Increased knowledge in medical sciences and technological innovations are to thank for that. Recent and dazzling advances in life-science for instance, in particular in genomics, transcriptomics, and other -omics disciplines, have generated considerable hope in our near-future ability to cure or prevent diseases by designing drugs adapted to each individual's very own biological profile (Collins and Varmus, 2015). Personalised or "precision" medicine, as it is referred to, only represents one of many possible paths for the personalisation of care. Progress in stem cell research, synthetic biology, medical imaging, brain-machine interfaces, 3D printing and augmented reality have opened up astounding possibilities for applications ranging from personalised cancer treatment to regenerative medicine, implants, prosthetics or cognitive rehabilitation. These technologies can readily be harnessed to provide innovative products and services that better match individuals' needs and expectations (Hayes et al., 2014).

2.1.4 Connected healthcare

The aforementioned emerging care models require a large degree of connectivity and integration to reach their full potential. First, the vertical integration of multimodal health information, from implantable-devices and genome sequencers to the cloud is an obvious and necessary feature for supporting patients and clinicians with integrated, information-rich, personalised decision-making tools. Electronic and Personal Health Records (EHRs/PHRs), the health-information repositories of hospitals and individuals respectively should constitute the articulating nodes of this vertical integration silo.

On top of relying on vertical integration, a variety of novel health-related services also thrive on a massive horizontal connectivity. The surge of personalised medicine for instance, greatly depends on our ability to leverage large networks of individual health information repositories. For instance, the aggregation of a large number of human genome sequences, coupled with their associated phenotypes (e.g. symptoms associated with a specific disease) is essential for unravelling the influence of rare gene variants in the development of certain genetic diseases. Patient community platforms, social networks and mobile-health in general also promise disruptive applications: from tracing the epicentre of infectious disease outbreaks, to offering patients the possibility to determine which specialised clinic to go for, or even for generating new medical knowledge in a bottom-up fashion. The availability of the Apple ResearchKit Application Programming Interface (API) is a good illustration of this latter opportunity. It constituted a steppingstone for the promotion of crowd-sourced clinical research, enabling the collection of Apple products' users own health information, and offering revolutionary ways to conduct clinical trials (Schork, 2015).

2.1.5 Stratified healthcare

The inequity of individuals towards healthcare is a fact, globally at least, but also often enough nationally. This inequity fuels abrasive societal debates and profound moral, ethical and economical questions. In countries such as the US, it has led governance, healthcare providers and insurers to enact policies or offer healthcare services targeting specific segments of the population, based on what they can afford. Healthcare technological innovations are often at the centre of this stratification strategy since, as we mentioned before, they usually represent a significant share of total healthcare costs. These technological solutions and specific drugs have for long been emblematic of the "Inverse-Care Law": the advances that can foster better health will benefit those who need it the least (Tudor Hart, 1971). The Inverse-Care Law has driven a number of healthcare suppliers (e.g. medical device manufacturers) to design specific solutions offering slightly reduced utility for a fraction of the costs of a parent, higher-end solution. Frugal innovation, as it is often referred to, has become a key driver of innovation for the low- and middle-income countries, where the "base of the pyramid" is in need for health care more than anyone else (Allen and Christiel, 2016).

3 PRODUCT AND SERVICE DESIGN FOR VALUE-EFFECTIVENESS IN HEALTHCARE

3.1 Complexity and adaptiveness in healthcare systems

In a country such as the United States, where growth in healthcare spending has increased beyond the growth in Gross Domestic Product, the inadequacy of the national healthcare system to deal effectively with current needs is alarming. Although necessary, the rethinking of national healthcare policies and incentives is unlikely to alone correct the current trajectory (Rouse, 2006; Rouse and Serban, 2014). Healthcare systems are complex socio-technical systems (De Weck et al., 2011). They are composed of manifold interdependent parts interacting in complex ways. The healthcare delivery process depends not only on patients and healthcare practitioners but also on families, services, nurses, medical devices and equipment, reimbursement policies, drugs, regulatory agencies, patient support groups, etc. This complexity makes the central control of national healthcare systems unrealistic, let alone their simple decomposition as hierarchies of sub-systems and components. Healthcare human agents are driven partly by their own values and agendas, and thus often interact and behave in non-linear and non-deterministic ways. This, in many instances, hinders the efficacy of governance policies and limits the effectiveness of high-level, e.g. institutional control mechanisms. These characteristics prevent the application of methodologies commonly supporting prescriptive modelling, design and implementation of safe, effective and efficient systems. Those features reflect the complex and adaptive nature of healthcare systems (Rouse, 2008).

Two main interrelated factors have been aggravating the inadequacies of the American healthcare system and of those based on a similar model. First, the prevalence of chronic diseases in the Western world is increasing. Accounting for almost 3 trillion US dollars, or about 84% of all healthcare expenditures in the US, the increasing costs incurred by chronic diseases dramatically stretch the US healthcare budget. This increase in prevalence, in turn, stems mostly from our ageing population and from an inadequate lifestyle including diet, smoking, etc.

Second, and central to our discussion, the products and services healthcare systems depend on are costly, especially those related with the acute- and chronic care required by the increasing segment of the population in need for them. In many instances, medical imaging, in-vitro diagnostic tests, chemotherapeutic treatments, medical devices, intensive care units, etc., together with their associated service costs, account for the majority of observed increases in healthcare expenditures.

3.2 Product and service design in healthcare

How to transform the potential of innovative technologies into solutions that will present high odds of systemic benefits? Or, reformulated from an engineering design perspective: How to design solutions that will leverage technological advances while meeting durably all of the healthcare system stakeholders' objectives?

Yukich et al. (2010) provide a good illustration of the intricacies of transforming a promising solution into systemic success. The authors discuss a rapid diagnostic testing (RDT) strategy for detecting malaria in Dar es Salaam, Tanzania, with the perspective of a cheaper, simpler and more accurate solution particularly fitting the needs of a low-income country. Against all odds and all initial investigations, the empirical field evaluation of the RDT strategy revealed increases in healthcare provider costs and a disappointingly limited reduction in patient costs even though the test itself generated fewer false-positives (thus avoiding the costs of unnecessary treatment) and required less specialised medical oversight (Yukich et al., 2010). The Dar es Salaam case highlights the scoping challenges, and the intricacy of systems thinking that often arise in healthcare product or service design. Together with many other examples it reveals more generally the increasing need for using adapted heuristics and formal engineering design practices if one is to develop innovative solutions wary of their integrative environment. As Clarkson puts it: "The design of the product and the system must be integrated, as knowledge about the system should affect the product, and vice versa" (Clarkson et al., 2004).

4 EXAMPLE CASES: DESIGN FOR EVOLVABILITY IN HEALTHCARE

Whether for the traditional or any of the emerging care models discussed above, the adoption of appropriate engineering design principles, frameworks and methodologies is essential for harnessing the

potential of new technologies to the fullest and for promoting both individual and systemic value-effectiveness while limiting expenses. We support this claim in the next sections by discussing the specific case of Design for Evolvability, for which we present two different design cases: the first in a well-established hospital setting, with Magnetic Resonance Imaging, and the other in a decentralised care context, with Point-Of-Care (POC) in vitro diagnostics.

4.1 System Evolvability

We argued in the previous sections that the design of innovative healthcare solutions (e.g. products, services) must take into consideration the specificities of the encompassing complex and adaptive socio-technical healthcare system in which they must integrate. In many instances, the anticipation of manifold interactions between the envisioned solution and other sub-systems, people, or contextual elements will bring a significant degree of uncertainty to the design process. The technological dynamism animating the healthcare technology marketplace may challenge that process even more. A constant flow of innovation means that solutions rapidly become obsolete. Two main alternatives are then usually available: One, frequently replacing the solution in place, with the full-expenses associated with purchasing and implementing the new system, as well as the disruption of current practices and the operational challenge this sometimes entails. Two, continuing to deliver sub-optimal care value in comparison to what the new technological gold standard could offer.

Uncertainty and technological dynamism therefore challenge decision-makers (e.g. end-user, payer) to resolve issues spanning from the financial to the ethical domain. Luckily, uncertainty and dynamism have been addressed by the design community. Among the many approaches available to handling them, we discuss the case of Design for Evolvability or "*the design characteristic that facilitates more manageable transitions between system generations via the modification of an inherited design*" (Beesemyer et al., 2011). Abstracting from the semantic and ontological variations appearing in the engineering systems and design literature, we assume that system evolvability translates above all to the ability of a system to be successively upgraded or reengineered in a cost- and time-efficient manner. Design for Evolvability should therefore drive system affordability, acceptance and innovation, reconciling the agendas of the various healthcare system stakeholders. We elaborate on these points: First, if Design for Evolvability *facilitates the cost-efficient reengineering or upgrading* of an existing product or architecture, it should translate into more affordable product upgrades or replacements, to the benefit of the payer (third row of Figure 2). Second, beyond facilitating system upgrades, it may *extend the scope* of possible upgrades or reengineering endeavours, for instance by allowing the incremental integration of radically new technologies (e.g. at the component level) that would otherwise have required rethinking the overall system architecture. Design for Evolvability may therefore *prolong the system's life expectancy*, or at least the life expectancy of the system architecture. This attribute can in turn reconcile multiple stakeholders' agendas: first, by appeasing the payer, who would only be required to provide for the limited costs of system upgrades over time, rather than for full capital expenses of a new system (first row of Figure 2). Arguably, now, it may also benefit the system designer/supplier. Although it may appear that a supplier would be primarily interested in capitalising on new products as often as possible (first row of Figure 2), this strategy may not hold in a constrained economy where the payer is increasingly cautious of their expenses. Instead, as the payer or any policy-enforcing body might impose direct or indirect restrictions on the rate of technology and service renewals, the supplier may have greater incentives to offer evolvable systems. By doing so the supplier may encourage the initial purchase of his product or service (since advantageous from the payer's perspective), while *safeguarding his position and revenues* for an extended period as the product or service is anchored in the client's organisation or is now part of the user's environment.

Finally, these attributes of evolvability can have a *positive impact on the uptake, acceptance and learning curve* of the system use and its upgrades (bottom row of Figure 2). It can be harnessed to *facilitate the adaptation* of the various healthcare system stakeholders to innovation through controlled, incremental changes of the product or service rather than afflicting the abrupt transition often accompanying a new disruptive solution. The possible benefits of system for evolvability are illustrated in Figure 2.

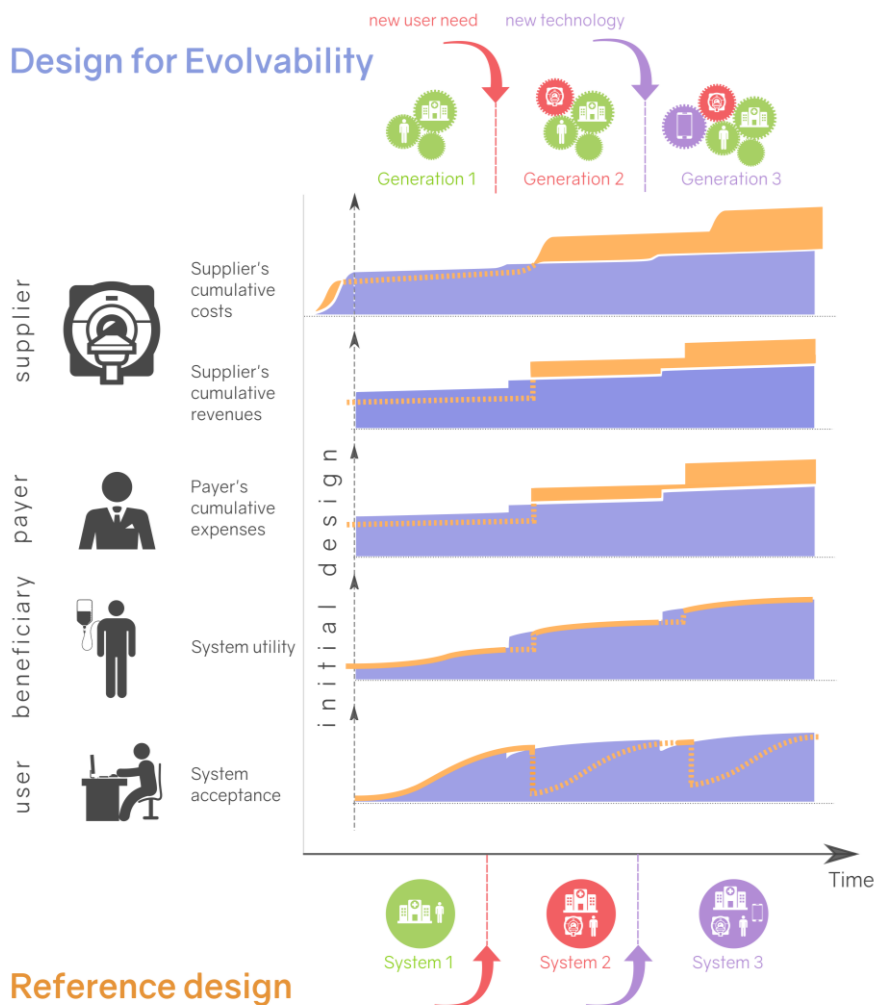


Figure 2. Impact of Design for Evolvability on the various stakeholders' agendas. For the supplier, an evolvable architecture means lower reengineering or upgrading costs and a durable position within the user's infrastructure. For the payer, an evolvable solution can translate into limited upgrade expenses for gaining superior utility. For the beneficiary, utility is here considered maximal, a function of what state-of-the-art technology makes possible. Finally, for the user, who might be different from the beneficiary (e.g. nurse) an evolvable system should ease the learning curve when transitioning between various system upgrades.

4.2 Applications: Magnetic Resonance Imaging and Point-of-Care diagnostic testing

Van De Laar and Punter presented an extensive case for system evolvability in Magnetic Resonance Imaging (MRI) equipment (Van De Laar and Punter, 2011). MRI machines are complex Cyber-Physical Systems (CPS). They are central to numerous well-established clinical applications as they allow the assessment of structural, functional and even chemical properties of the human body's soft-tissues. State-of-the-art MRI machines originate from years of incremental open and proprietary developments and are likely to continue evolving in that manner. The appeal of enabling an MRI system with the capacity to evolve (or rather being evolved) is unequivocal. The blank-canvas design of an MRI system is a tremendous enterprise and its development and hence purchasing costs are significant. Likewise, the disruption caused by the installation of a MRI system in a radiology service is considerable, necessitating weeks of preparation followed by significant training efforts, and often steep learning curves for its users. Evolvability is thus key to enable cost-effective incremental developments and non-disruptive field upgrades over the relatively long life expectancy of most MRI systems (> 3 years).

While Design for Evolvability makes a lot of sense for massive, costly and internally complex systems, we recently also made the case for its adoption for a less conventional application: for the design of Point-of-Care (POC) in-vitro diagnostics solutions targeting direct-to-consumer (i.e. home-based)

applications (Patou et al., 2016). These solutions aim principally at detecting molecular markers from biological samples (e.g. blood) in a decentralised and ideally fully automated manner. The rationale supporting our design strategy were the following: despite the promises offered by POC technologies for translating in-vitro diagnostics to the consumer-market, home-based finger-prick blood analyses are still far from becoming a standard of care. A systems perspective on the issue revealed that unlike glucose monitoring, many home-based in-vitro POC tests may need only be performed sporadically depending on the biological processes under scrutiny. As POC systems mainly rely on an instrument/consumable business model, such low frequency-of-use translates into low consumable sales volumes, which in turn may drive the average cost-per-test to increase beyond acceptable limits for the payer. This tendency alone questions the justifiability of designing POC systems for sporadic, home-based applications as it could discourage system adoption and hence success. This latter risk is itself reinforced by the fast pace of innovation driving in-vitro diagnostic testing, which could well limit the life expectancy of a POC system, decreasing even more its life-long cumulative perceived value in the eyes of the end-users or payers.

We thus undertook the Design for Evolvability of a POC system mostly by relying on a Platform-Based Design framework, and searched for the incorporation of change-enablers in our system architecture, such as modularity, non-hierarchical integration, or redundancy. Our systems architecting endeavours meant to promote the fast and easy upgrade of system specifications should new biological targets or new biosensor technology become available. By translating most of the reengineering efforts at the mobile-software layer, we provided biological assay developers a platform to streamline the development of new in-vitro diagnostic applications, potentially reducing costs and delivery-time of system upgrades. Our attempt also meant to decrease the risk of fast system architecture obsolescence by allowing for the interfacing of a growing variety of testing-chips. We argued that our design strategy could increase value perception in the eye of both users and payers, therefore favouring the decentralisation of in-vitro diagnostics testing (Patou et al., 2016).

5 SYSTEM DESIGN CHALLENGES

While we argue that systems thinking and novel engineering design frameworks can benefit healthcare value generation for the many healthcare system's stakeholders, we concede that significant issues remain to be addressed before one can guarantee design optimality in any given scenario. For instance, although we highlighted the potential benefits of Design for Evolvability with our two examples, we acknowledge that only a set of contexts are appropriate for it to allow mutual benefits among medical suppliers, end-users and payers. Obviously, uncertainty, complexity, dynamism and an expected long system life expectancy should reinforce the legitimacy of Design for Evolvability, but the formal assessment of these properties is not trivial, which could mislead designing teams.

More generally, various contexts and requirements will call for different design approaches, some fitting best to particular classes of healthcare products and services. Various tools, reference models and frameworks, borrowed from other domains or conceived specifically for healthcare, are therefore needed in order to determine the adequacy of given design approaches to various cases.

If answering the question of *when* particular engineering design approaches can be profitable is challenging, answering the question of *how* is obviously just as difficult. Design for Evolvability is a particularly good example. Although relatively clear semantics for evolvability are available, as well as metrics for its quantitation and incorporation in cost-utility assessment methods (Ross and Hastings, 2006), its ontology is somewhat unclear. Even though it can be considered as an overarching change-enabling *-ility*, its enabling principles are not fully consensual, in turn complicating the design process (De Weck et al., 2012). Principles such as modularity constitute the foundation of changeable systems and by extension of Design for Evolvability. Modularity is arguably a mature design principle, which can be promoted and evaluated in systems, for instance using Design Structure Matrices and Change Propagation Analysis. Other principles are unfortunately not as clearly mastered; scalability or autonomy for instance, both of which are also deemed to favour overall system evolvability (De Weck et al., 2012). If the underlying principles of a design approach are misleading then the frameworks and methodologies supporting their application should also suffer from imprecisions.

Our approach to Design for Evolvability for the POC system we referred to (Patou et al., 2016) mainly relied on Platform-based design, which we strove to complement with the adoption of a few of the architectural *-ilities* suggested by others (Fricke and Schulz, 2005; Ross, 2006; Steiner, 1998; De Weck

et al., 2012), including non-hierarchical integration and redundancy. Even though promising, our model-based approach for the POC system needs a tighter formalism. It could for instance have benefited from the application of a quantitative assessment method, fostering a metric of how evolvable our product was. Likewise, frameworks for Design for Evolvability must address the specificities of designing for an evolvable *architecture*, in which case the design instantiations of inherited products need to be replaced after each design upgrade. Such framework will surely differ from those for the design of evolvable *system instances*, in which case the product (e.g. an MRI system) is upgraded or changed while it is in operation, without necessitating its dismissal and the introduction of a new inherited design instance.

The systems thinking tools and the engineering design frameworks and methodologies that can maximise value delivery in healthcare therefore need further theoretical and empirical research. Only then will specific design approaches have a very direct positive impact on the remodelling of our complex and adaptive healthcare systems.

6 CONCLUSION

We argued in the present paper that systems thinking and the application of selected engineering design principles support the development of products and services enabling the bottom-up transformation of our healthcare systems. This appears to us as particularly important against the background of emerging healthcare models such as decentralisation, personalisation, connectivity, pervasiveness, and stratification. We demonstrated specifically that engineering design could help relieve the tension healthcare systems experience, as they are currently dependent on innovative solutions that however strain their financial and organisational abilities. We supported our argumentation by exemplifying the case of Design for Evolvability. We showed that the latter could, for a set of specific scenarios, help realign the many healthcare stakeholders' agendas and favour the adoption, acceptance and durable success of cost-effective innovative solutions in healthcare. We illustrated the relevance of system evolvability for two applications: MRI systems and Point-of-Care in-vitro diagnostics. We finally reckon that further theoretical and empirical healthcare design research is needed on the modalities facilitating the translation of innovative concepts within our existing healthcare systems. Such research findings should ensure that design practice steadily supports the effective, efficient, and equitable delivery of care.

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