Chapter 21 Healthcare System Design

This book includes several design applications in several fields: Energy, Large Systems, Manufacturing, and many more. In this chapter we turn our focus to the design of Healthcare Systems. But first, what exactly do we mean by Healthcare Systems? This chapter will describe the large scale and scope of what is meant by the phrase "Healthcare Systems". A broad definition of Healthcare System Design consequently leads to the recognition of the large number of stakeholders affected by such designs. The need for appropriate, effective, timely, sustainable, and cost-effective healthcare services has been recognized globally, and has led to an increasingly growing healthcare sector. As the healthcare sector continues to expand, there are several unique challenges that have risen due to the many siloed designers of different parts of the healthcare system. ***The goal of this chapter is to orient the reader to the various scale and scope of healthcare systems and to present a structure that allows the reader to thoughtfully consider the design process relative to stakeholders, system boundary, system functions for functional requirement (FR) selection, system form for design parameter selection (DP), and consequently the process variables (PV).***

1. Introduction

1.1 Motivation

As a reader of this book, your career may include designing across multiple sectors or may focus on a single sector. This chapter will focus on health care. While it may seem like a niche service, healthcare is currently the largest employer in the United States. Why is that?

People are living longer today than any time in our history. The aging population along with a continuous growth in medical spending has led to an increased rate of health-care jobs in the United States and globally. Interestingly, although science and technology have allowed for significant advancements in health treatments, humanity is facing an unprecedented chronic disease burden. While we may live longer, most will struggle with many more long-duration chronic diseases – such as diabetes, heart disease, autoimmunity, and cancer. Such a significant disease burden has led the healthcare sector to expand to address the many challenges that arise when treating or managing health conditions today.

1.2 Chapter Outline

Chapter 2 starts with how to define the healthcare system. Healthcare design has many varying levels of scale and scope. Therefore, understanding and identifying the scale and scope of the design is critical to a successful design [Section 2.1]. This includes presenting a framework for thinking about what the healthcare system does (*functions*) and who or what performs these functions (*resources*) [Section 2.2]. While many engineered designs are universal, healthcare designs can vary across regions or countries. Understanding the variation in functional requirements and/or design parameters across cultures and countries will be discussed [Section 2.3].

Chapter 3 discusses the challenges unique to healthcare systems. This includes a discussion of the significant heterogeneity even within a specific country, a specific region, and a specific hospital [Section 3.1]. While many engineered systems are typically defined as technical systems, healthcare is both a technical and non-technical (i.e., social) system. This leads to unique implementation and outcome challenges [Section 3.2]. Given the range in scale, scope, heterogeneity, regional impact, and interconnection with other healthcare services needed, complexity in healthcare is significant and designing for interoperability is a critical consideration for success [Section 3.3]. Finally, healthcare is a legacy system, it is hard to change what has been already designed – be it technical in nature (such as a hospital) or social in nature (such as healthcare education or culture). Therefore, understanding the already designed system, what aspects are flexible and inflexible, and why is a critical consideration to healthcare design [Section 3.4].

Finally, Chapter 4 summarizes the key takeaways and conclusions.

2. Defining a Healthcare System

Defining a healthcare system includes identifying the boundary of the system (*system boundary*), the scale and scope of the problem, and a framework to organize the system. As described in previous chapters on several occasions with a dedicated chapter to the topic (Chapter 5: *Problem Definition*), *accurately identifying the problem* is absolutely critical. This section will help identify to the design reader the importance of *accurately identifying the problem* and consequently the realization of the interconnection of what is designed to the remainder of the healthcare system.

Design Story No. 1:

> In 1951 a Boston cardiologist (heart doctor) is given credit for ushering in the modern era of clinical cardiac pacing, the fitting of a device – a pacemaker – to maintain a regular heart rhythm. Since then cardiac pacemakers have advanced tremendously. One of the primary functional requirements for permanent (internal to the body) pacemakers is their ability to function for very long periods of times and consequently the requirement on their battery life and energy use. Pacemakers are continuously designed to improve on this functional requirement. But what has not been included as a functional requirement that has become a significant problem is the ability to turn off a pacemaker. A classic engineering designer may wonder, "why would you ever need to do that?" In reality, the complexity of the type of patients that now receive these devices have led to this functional requirement becoming more critical and possibly handled by more than just the cardiac surgeon. However, such a requirement arose from failure and heart break rather than identified from stakeholder needs.

As we previously mentioned, people are living longer today, but they are living with chronic and in many cases currently incurable diseases, such as dementia – a progressive condition where the brain deteriorates and the individual loses their ability to remember. Such a condition is emotionally, socially, and physically taxing on both the individual and their family. Many patients with dementia typically in their 60s, 70s, or 80s years of age also tend to have deteriorating heart conditions that would have led them to receive a pacemaker either prior to dementia or during early-onset. Some patients believe that such debilitating conditions come to a late-stage that can cause so much suffering that they would prefer not to prolong their lives with supportive measures such as cardiac devices. Patients in the United States at least have the right to refuse or discontinue treatment, including a pacemaker that keeps them alive. Physicians also have a right to refuse to turn it off. This has raised a significant ethical question of "is it ethical to turn off or deactivate pacemakers – since their use in patients with dementia has significantly extended a patient's life, but with questionable quality of life for both the patient and their family". Many would consider this an ethical or legal issue, rather than technical, but in reality, identifying it as a functional requirement by stakeholders and designing, at least to some degree, for it would have alleviated the ramifications.

2.1 Healthcare System Boundary, Scale, and Scope

A system can be described once a boundary has been identified. Such a boundary can be defined at varying scale and scope. For example, one may be interested in improving knee pain. Creating a system to address this problem can be defined at various scales and scope. This includes – with increasing scope – a system defined as: "a knee implant", "a knee replacement surgical suite", "a knee replacement service – which includes the surgical suite and surgical team", "an orthopedic (i.e., bone) clinic – with several services such as physical therapy", or "a hospital". A designer may be responsible for designing a healthcare system at any of these example levels. This essentially translates to an increasing system boundary and may include a design that could be described as a "product", "software" (See Chapter 16), "both product and software", and "organizations" (See Chapter 20).

Clarity of the system boundary may or may not be specifically defined for the designer. Specification of the system boundary in product and software projects may be typically specified externally, or by the organization, or by politics, or even health care regulation laws. This alleviates the responsibility of the designer in determining the system boundary. However, external designation of the system boundary does not alleviate the burden of ensuring the to-be-designed-system integrates well into the healthcare system providing care and consequently produces the expected health-outcome results.

Design Story No 2:

The company Endologix, Inc. in Irvine, CA manufactures an internal implant called the AFX endograft used in a procedure called an endovascular aortic aneurysm repair (EVR). EVR was developed almost three decades ago as a minimally-invasive alternative to a surgical procedure to address abdominal aortic aneurysms (AAA) – a bulge in the wall of the main blood vessel leading away from the heart to the abdomen. Endologix, Inc. innovatively designed their endograft to have the main body stabilized by resting directly on the aortic bifurcation rather than using hooks for fixation with the fabric of the endograft affixed to the stent skeleton only at the top and bottom of the device. This design created a novel sealing concept that reduces the possibility of device migration and leakage (i.e., reducing the risk of what is considered a type 1 endoleak – flow around the proximal or distal seal zones of the endograft.

At the time of initial manufacturing the graft was a stratra fabric, which upon introduction into the healthcare delivery system yielded increased reports of Type III (defects in the endograft device) endoleaks for patients with significant aortic remodeling contributing to the this issue[1]. Endoleaks are uncommon but serious late complication that lead to high risk of rupture and death. A study found that there was a 24% chance of type 3 endoleaks due to fabric breakdown. Endologix, Inc. consequently provided a safety notice to providers and the Food and Drug Administration (FDA) in the US classified this as a class I recall – the most serious type of recall. Endologix, Inc. has since updated their graft material to a new formulation called Duraply™.

This is an example of how a new and unique design although viewed as completely successful at the time, can have unintended life-threatening consequences if not attributing for, in this case, the key biological factor of aortic remodeling. Furthermore, the novelty of this device created an endoskeleton design that may complicate guidewire and device entry on redo procedures. This also suggests that the device was designed taking into account the biological integrity of an initial procedure and not taking into account the realistic increase of complications for this more recent minimally-invasive EVR procedure.

Now that the importance of identifying a system border and understanding how the system designed will affect and be affected by its introduction into the healthcare delivery system, it is useful to describe a systems framework that formally describes a healthcare from a systems perspective.

2.2 Healthcare System Function and System Form

A system is defined by what the system does (i.e., *functions*) and who or what performs these functions, called form (i.e., *resources*). Consequently, system design requires the identification of *functional requirements* (FR) that describe the functions and *design parameters* (DP) that describe the form.

The healthcare system has historically organized based on form and *not* function. Such an organizational structure has led to departments that address specific body parts (e.g., Rheumatology [Joints], Neurology –[Brain], Cardiology [Heart], Endocrinology [Hormones], etc.). At a higher abstraction, healthcare systems are also defined by the location of resources.

For example: inpatient (location where a patient is admitted staying overnight), outpatient (location where a patient meets with a doctor with no overnight stay).

Interestingly, healthcare is a field that typically describes care provided – a function designation – by who provides it, with a particular focus on resources. This is evident in the way typical clinical models are described by the personnel involved (e.g., behavioral health model, serious illness care). In doing so, such models do not define the needed functions, but instead describe the type of provider that should be performing these non-explicitly stated functions. For example, while it seems intuitive to describe surgery by the resource performing the surgery (e.g., heart surgeon), this leaves much of the details of the functions of surgery undescribed. Furthermore, the Merriam-Webster (medical dictionary) defines surgery as a noun and not a verb. For example, surgery can be defined as "a procedure that involves *cutting* of a patient's tissues or closure of a previously sustained wound".

While, healthcare is not perfect it seems to be functionable. What's the problem with how healthcare describes and defines their system? This is part of why designers and non-medically trained individuals require more time to understand the field, terminology, nomenclature, etc. This has isolated healthcare a bit and is part of the silos of where we find design in healthcare. These silos tend to be focused on biomedical engineering (focused on creating devices focused on measuring or delivering treatment) with growing efforts in health informatics (providing software solutions focused on providing clinical decision-support tools) and fairly new efforts in systems engineering design focused on healthcare delivery (re-designing practice patterns). Intersecting engineering, systems thinking, and formal design methods require practitioners from these different fields to be aware and able to identify these discrepancies to their own field.

In the past, designers remained within the technical realm thus avoiding much of these discrepancies. They could become experts in knees or hearts. However, diseases today tend to be chronic and multifaceted – involving and requiring services from several departments in various healthcare locations. This leads to a more significant need for integration (detailed further in section 3.3) to address the many needs of patients. Therefore, designers are needing to understand how their technology, devices, and software integrate and fit within the full healthcare system. For example, diabetes care typically starts with involving an endocrinologist (a doctor specializing in hormones and their glands) to address the dysregulation of the hormone insulin (which helps glucose enter cells to give them energy). Complications from diabetes include foot damage (requiring the field dealing with feet called podiatry), eye damage (requiring the field dealing with eyes called ophthalmology), kidney damage (requiring the field dealing with kidneys called nephrology). This leads to significant healthcare delivery needs for diabetic patients. They now require care from many types of doctors from different specialties in different types of settings that are not designed to communicate or interact with each other. To address this, Diabetes Centers, places where all care needs for diabetes can be provided have emerged. These centers are not necessarily where most people receive their care today, many patients still receive care in the typical medically silod healthcare environment. It is important to note, that most patients prefer diabetes centers, a healthcare delivery system based on addressing the functional needs of patients rather than one that is organized based on types of healthcare resources.

Design Story No. 3:

Insert MIT Harvard Pilgrim Su project

The remainder of this section will describe a system model architecture for personalized healthcare delivery first described elsewhere[2], to formally define *system function* and *system form* for healthcare. A visual representation is show in Figure 1.

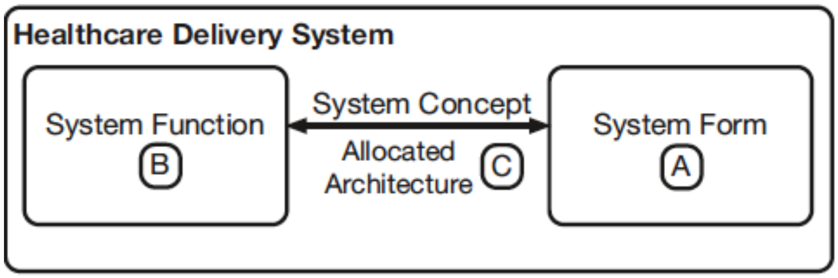

Figure 1. Adapted figure from Khayal et al.[2] showing System Form and system function with an allocation between them called the system concept.

<u>*System Function*</u>

The primary functions in healthcare are described based on how medicine is practiced – the diagnostic model[3] – that first, examines the patient's complaint (measure); second, attempts to determine its cause (diagnose and decide); and, third, applies a treatment regimen to that cause (treat or transform). Sequentially, these are:

(1) measurement: understand, quantify or classify individual health state,
(2) decision: determine what to do for the individual and when,
(3) transformation: perform service(s) for the individual,
(4) transportation: move the individual between any of these processes, if needed.

Measurement is a cyber-physical process that converts a physical property of the operand (i.e., what the system operates on) into a cyber, informatic property to ascertain health state of the individual. Typical healthcare measurement processes acting on individuals include clinical evaluation, diagnostic tests (e.g., blood test, urine test, and stool test) and diagnostic procedures (e.g., medical imaging, endoscopy, and electrocardiography).

Decision is a cyber-physical process occurring between a healthcare system resource and the operand: the individual that generates a decision on how to proceed next with the healthcare delivery system. Several types of decision processes exist in a healthcare delivery system. Planning is defined as the determination of which healthcare system processes need to occur for the individual (e.g., treatment plan and cancer screening plan). Scheduling is defined as who/what is going to perform that process and when (e.g., individual booking). When decision is described in this chapter, the focus is on the planning of an individual's healthcare plan. While most designers may feel that their design development would be focused on measurement or treatment – it is important to understand and design for how the clinician and possibly the patient will decide on using a measurement or technology. For example, the best way to see and address colon and other GI cancers is through preventative colonoscopy. A procedure that uses a device called a colonoscope, a long, flexible, tubular instrument to image the lining of the colon and take biopsy samples if needed. A colonoscope is inserted through the rectum and advanced to the other end of the large intestine, a fairly uncomfortable procedure that many refuse, and decide to forgo this preventative procedure or use an imaging based preventative procedure. Information about cancer risk, family history, reaction to drugs, etc. are all key discussion points when deciding to undergo a procedure.

Transformation is a physical process that transforms the operand: specifically the internal health state of the individual (i.e., treatment of condition, disease, or disorder). A transformation process typically changes the internal health state of the individual. Such processes include surgical procedures (e.g., amputation, ablation, laparoscopic surgery, and endoscopic surgery) and therapeutic procedures (e.g., pharmacotherapy, chemotherapy, physical therapy, psychotherapy, and laser therapy).

Finally, I include the final process, *transportation*, for the sake of completeness. Individuals do not typically need to be moved (unless they are incapacitated). A physical process that moves individuals between healthcare resources (e.g., bring individual to emergency department and move individual from operating to recovery room).

System Form

Similar to system function, system form is defined based on resources that perform the functions described. For each of the resources defined and described below, they include the set union of both human and technical resources. A designer should expect that for every technical resource they design, there will be a human resource that operates the technical resource. The design of the technical resource needs to take into consideration the operation by the human resource. For example, operating a technical resource can be a simple process that can be performed by any adult (e.g., push wheelchair) or a complex process requiring years of specialist clinical training (e.g., operating a surgical robot system). While the design system boundary for many projects may be the technical system, understanding and designing for the non-technical, human resources is essential and invariably making most successful healthcare designs both technical and non-technical systems. The unique implementation and outcome challenges this poses will be discussed in Section 3.2.

Measurement resource is a resource capable of measuring the operand: here the health state of an individual. They include human measurement resources (e.g., MRI technician, sonographer, and phlebotomist) and technical measurement resources (e.g., magnetic resonance imaging scanner, ultrasound machine, and syringe).

Decision resource is a resource capable of advising the operand, an individual, on how to proceed next with the healthcare delivery system. They include human decision resources (e.g., oncologist, general practitioner, and surgeon) and technical decision resources (e.g., decision support systems and electronic medical record decision tools).

Treatment resource is a resource capable of a transformative effect on its operand (e.g., the health state of an individual). They include human transformation (e.g., surgeon, oncology infusion nurse, and physical therapist) and technical transformation resources (e.g., operating theatres, chemotherapy infusion room, and physical therapy room).

Transportation resource is a resource capable of transporting its operand: the individual themselves. They include human transportation resources (e.g., emergency medical technician, clinical care coordinator, and transporter) and technical transportation resources (e.g., ambulance, gurney, and wheelchair).

2.3 Healthcare System Function and System Form vary across cultures and regions

Engineering is typically viewed as imploring universal scientific principles (e.g., of physics, mathematics, chemistry) that allow the field to generally produce designs that can be used universally across cultures and regions. Healthcare system design is unique in that there are several levels of design that are impacted by the biology and culture of people in different regions.

National-Financial Level

While the term medicine elicits a focus on medicine, the financing of healthcare is a significant driver of how, where, when, and what healthcare services are available to a population. For example, Japan faces a significant aging population issue along with a shrinking population of young people. This has led the healthcare industry to focus on creating resources that have a much higher focus on technical resources (e.g., social robots) over human resources (e.g., nursing home staff). This provides a feasible healthcare delivery model and financial focus that supports the resources of the country.

Social Level

The social level also affects several aspects of healthcare services, but most importantly, acceptability of a healthcare service.

With the rise of social media today, there is an increase in designing and developing care treatments that are provided through peer-to-peer support networks (i.e., patient-to-patient support networks). There is a history of success of such networks in the United States (e.g., Alcoholics Anonymous – AA). Such peer networks create a strong bond across individuals with a similar condition. However, some cultures still have a significant stigma for certain diseases, and for others for any diseases at all. Some cultures (e.g., many Asian countries) have social constructs where women have significant difficulty marrying if they are identified as having either certain diseases or any diseases at all.

There are also more typical examples where some societies, cultures, and/or religions have specific acceptability of certain healthcare interventions (e.g., birth control, abortios).

Biological Level
The testing of healthcare treatments today (i.e., clinical trials) require specifically noting the ethnicity of the population in the study. It is well-accepted that biological factors across ethnicity and culture affect study efficacy and effectiveness.

Medical research today has recognized that although we test new treatments across ethnicity, the design of new treatments still follows a one-size-fits-all approach. The latest trend in medicine today is focused on developing therapies tailored to the specific individual (i.e., personalized medicine). The personalized medicine approach takes into account an individual's unique molecular and genetic profile to develop and predict which medical treatments will be safe and effective, and which ones may not be.

3. Challenges Unique to Healthcare Delivery Systems

3.1 Healthcare Delivery Heterogeneity

3.2 Healthcare – a technical and non-technical system

3.3 Complexity in healthcare

3.4 Healthcare as a Legacy System
Stopped here

3.1 Lots of heterogeneity: The system can be large, but can also be small, typically it includes varying levels of stakeholders, and these stakeholders cannot be viewed as the same.

3.2 Healthcare – a technical *and* non-technical system. Variations in Healthcare occur due to the intrinsic decision making that happens at the clinician level, which is not typically the same across clinicians.

3.3 Complexity in healthcare: typical designs in healthcare are for artifacts that are used in combination with other artifacts that are rarely designed taking into consideration interoperability.

3.4 Healthcare is a legacy infrastructure: hard to change what has been designed

4. Key Takeaways and Conclusion

References:

1. https://www.jvascsurg.org/article/S0741-5214(18)31460-5/fulltext
2. Khayal, Inas S., and Amro M. Farid. "Architecting a system model for personalized healthcare delivery and managed individual health outcomes." *Complexity* 2018 (2018).

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