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A Systems-Based Patient Aid Design Artifact for Active Medication Management in Type 2 Diabetes

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BY

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APPROVAL OF THE DISSERTATION COMMITTEE

This dissertation has been duly read, reviewed, and critiqued by the Committee listed below, which hereby approves the manuscript of Hamzah A. Ibrahim as fulfilling the scope and quality requirements for meriting the degree of Doctor of Philosophy in Information Systems and Technology.

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Abstract

In this dissertation, I explore the use of the Abstraction-Decomposition Space (ADS) alongside Hierarchical Task Analysis (HTA) to guide the design of a minimalist patient aid for active medication management in type 2 diabetes. The goal is to address a practical problem, but in addition, this study seeks to address a theoretical problem that is prevalent in design research in Information Systems (IS) today. The practical problem concerns the need for IT-based care delivery models to support patients in the interim period between in-person visits. In this vein, I present a bare-minimum design that focuses on the most essential functionality required to achieve remote insulin titration using the ADS and HTA.

The theoretical problem, on the other hand, pertains to the limitations resulting from taking a tool-focused view in design research which inhibits our ability to produce generalized knowledge about IT systems in their contexts. The study proposes an alternative view based on work systems. The overarching thesis is that a work systems view provides for knowledge at a more abstract and generalizable level, yielding contributions beyond mere software packages. Moreover, the study highlights the artifact-building methodology used to delineate the rationale behind the design and to balance evaluation-dominant design research.

In this vein, I conducted document analysis and semi-structured interviews with patients and care providers to develop the ADS, then used it alongside HTA to develop and test the usability of twelve user scenarios implemented on a large mobile form factor.

Dedication

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To my **father** and my **mother**, Ali and Suhad.
No language has the words. I love you!

&
To Summer, my soulmate, and the apple of my eye. And to Dima and Nasser.

&
To the soul of my late brother, **Mohammad Tantour**, and my late grandmother, **Haifa Alayoubi**.

&
To my dear brother, Hussam and to my beloved sisters Haifa and Suzan, and of course, to the little precious one, Zeina.

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Chapter 1

Introduction

Designing information technology (IT) aids for the elderly patient is a challenging undertaking. In the context of chronic disease, most of the burden of care lies on the patients themselves. Not only do they have to suffer the symptoms, they also must maintain strict compliance with a dynamic and complex self-care regimen in order to keep their condition under control. For many patients, this burden far outweighs their abilities which leads to suboptimal adherence to therapy.

Literature on this topic suggests that chronic disease patients could benefit from additional support. Certainly, IT offers innovative solutions in this vein, but delivering health services via IT entails a degree of interaction between the patient and technology. This added layer of complexity is superimposed on top of the patient's existing self-care demands. Under such circumstances, patients who are already overburdened by their regimens may find it difficult to cope with the additional friction.

With that in mind, an ideal patient-facing IT aid is one which succeeds at encapsulating the complex and domain-specific requirements pertaining to self-care within a simple and low-friction implementation that does not overburden the end user. This places much of the problem within the realm of design research.

Theoretical Background

Previously, design-type studies were often deemed ineligible for publication in many Information Systems (IS) outlets. Recognizing design research (DR) as an independent stream within the IS circles represented a departure from the upheld norms that viewed works rooted in the natural sciences methods as the only type of legitimate research that is suitable for publication. However, this resistance towards DR was not without basis – there surely was, and still is, an expanse of ambiguity surrounding the ability of DR to contribute to generalized knowledge about IT systems (i.e., design theory). Discussions around this issue took place as part of a larger debate around the character and central identity of our discipline. A significant outcome of this debate was the conceptualization of the Information Technology Artifact (ITA) and its coronation as the core subject matter in IS scholarship. And because the purpose of DR is to produce artifacts that provide utility and add value, forging this construct proved to be very useful for design researchers. Not only did it appropriately situate DR within our discipline, but it also created a path through which design researchers can publish their contributions. The recognition that DR enjoys today can be largely attributed to this debate.

Conceptualizing the IT Artifact

March and Smith (1995) noted that the natural science-design science duality is common in fields which encompass both knowledge-producing and knowledge-using activities. In their work, they point to two kinds of scientific interest in IT: descriptive and prescriptive. While descriptive research seeks to theorize about IT in a way that corresponds to the behavioral and natural sciences, prescriptive research is a *knowledge-using activity* that seeks to utilize what is known about IT-related phenomena in order to devise ITAs that can provide utility and/or add value. March and Smith further argued that research efforts which aimed to devise novel and useful ITAs have been more successful and important than traditional IS research that theorizes about them.

To bridge both paradigms, March and Smith proposed a two-dimensional research framework in IS (Figure 1.1) which specifies four research activities and four classes of ITAs. The first two activities are (1) *theorize* and (2) *justify*, both of which correspond to descriptive research rooted in the natural sciences. The other two activities are (3) *build* and (4) *evaluate*, both corresponding to prescriptive and design-oriented research. These four activities are conducted to examine, or devise, ITAs in the form of: (1) constructs, (2) models, (3) methods or (4) instantiations. By intersecting these two dimensions, IS research can fall within one or more of the resulting sixteen square spaces, eight of which are within the DR domain.

		Research Activities			
		Build	Evaluate	Theorize	Justify
Research Outputs	Constructs				
	Model				
	Method				
	Instantiation				

Figure 1.1. March and Smith (1995) Research Framework

They concluded their work by arguing that in order to achieve progress in the IS field, researchers should be engaged in prescriptive DR seeking to devise useful ITAs along with descriptive research intending to theorize about their existence, use, and evolution (March & Smith, 1995). This resonates in many design-type publications today.

Orlikowski and Iacono (2001) expressed concerns that IS scholars have not yet deeply engaged the discipline’s core subject matter – the ITA, and as a consequence, it was vastly under-theorized in IS research. In their commentary, they defined the ITA as a bundle of material and cultural properties that is encapsulated in a *socially recognizable form* such as hardware and/or software (Orlikowski & Iacono, 2001). They further noted that the diverse ways by which ITAs are treated in IS research often led to erroneous assumptions about their nature. For instance, viewing the ITA as a purely technical tool often led to it being treated as a fixed and unproblematic black box independent of the context in which it operates. Similarly, using proxy measures to assess what is perceived to be a property of the ITA can increase the risk of the proxy becoming confused with that which it intends to represent.

Such treatment of the ITA tends to overlook its dynamic nature and how its context influences its structural characteristics, properties and evolution. The authors further showed that the most prevalent treatment of the ITA in IS research tends to invoke technology (i.e., IT) "in name only, but not in fact", thus ultimately oversimplifying, or even ignoring, the discipline's core subject matter – the ITA. They concluded by calling for an explicit attention to and consideration of the ITA in IS research (Orlikowski & Iacono, 2001).

Benbasat and Zmud (2003) attributed the aforementioned to the variety of academic backgrounds from which IS scholars have emerged. As such, researchers in our field tend to engage IS phenomena through their own disciplinary lenses. And while such diversity in perspective is beneficial to a field like ours, it also poses a real problem in the absence of a *set of core properties* or *central character* that distinctively signals its essence.

Reassuringly, Benbasat and Zmud continue to state that such a natural ensemble of entities, structures and processes that can serve to bind together the IS subdisciplines does exist. That ensemble is comprised of the *ITA* and its *immediate nomological net* (Benbasat & Zmud, 2003). They view the ITA as the *application of IT* to enable a *task* which is embedded within a *structure* that operates within a defined *context*. Given that, the hardware/software design of the IT artifact "encapsulates the structures, routines, norms, and values implicit in the rich contexts within which the artifact is embedded" (Benbasat & Zmud, 2003). They illustrated this definition by drawing four concentric circles where information technology sits at the inner core (Figure 1.2).

Benbasat and Zmud added that the boundaries of IS scholarship are not confined to the study of the ITA itself, they also encompass its *immediate nomological net*. This includes (1) research on the ITA's usage, (2) its impact on its environment, (3) the IT methodological and operational practices which influence its construction, as well as (4) the IT methodological and technical capabilities which govern its design and operation. Given that, IS research which treats phenomena that are too distant from the ITA (i.e., commission), or that which excludes phenomena intimately related to it (i.e., omission), threatens to dilute the identity of our discipline by making its boundaries less salient (Benbasat & Zmud, 2003).

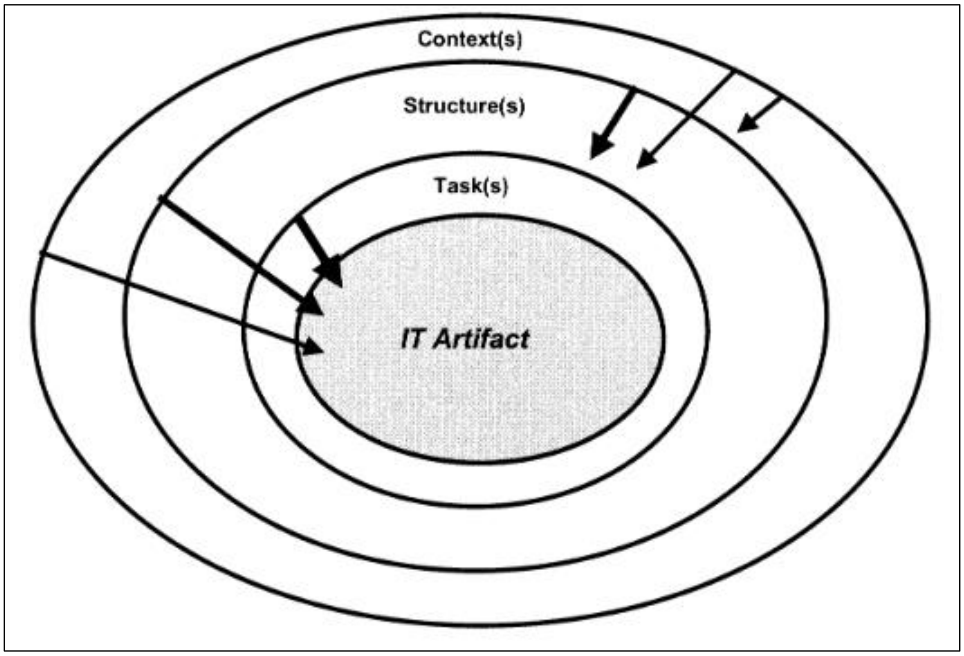

Figure 1.2. Conceptualization of the ITA as articulated by Benbasat and Zmud (2003)

This explicit attention to the ITA influenced the development of design research in many ways. For instance, it served as a basis to legitimize design as an integral part of research in our field. Secondly, and while the application of IT is viewed above as a defining characteristic of the ITA, these scholars did not restrict its definition as an entity of a specific form or flavor. These definitions are quite abstract and can accommodate a variety of artifact types. This includes operating IT systems or even descriptions of these systems encoded external to a computing apparatus. Given that, and in the absence of a one-size-fits-all ITA, design researchers are afforded a great deal of flexibility in constructing the theoretical frame that best suits their particular study (Orlikowski & Iacono, 2001).

The Design Science Research Framework

The aforementioned literature catalyzed the development of frameworks with a deliberate focus on design research. Perhaps one of the most recognizable contributions in this vein is the *Design Science Research* (DSR) framework (Hevner, 2007; Hevner et al., 2004). Fundamentally, DSR is a problem-solving paradigm which is concerned with extending the capabilities of humans and organizations through the creation of ITAs that add value. Hevner and colleagues adopted much of March and Smith's views on DR. In addition to describing it as an iterative process of building and evaluation, they also conceptualized the ITA as an entity that could be presented as constructs, models, methods or running instantiations (Hevner et al., 2004; March & Smith, 1995).

The DSR framework defines three fundamental cycles within design-type research in IS (Hevner, 2007). The first is the relevance cycle in which real-world problems within some application domain (e.g., healthcare) are identified. In software development terms, this can be thought of as akin to gathering requirements. Additionally, the relevance cycle involves identifying the metrics against which emerging design alternatives (i.e., ITAs) are evaluated. The second is the rigor cycle. It depicts tapping into the solution-domain by identifying the theories, methods, practices, experience or meta-artifacts that can be used to generate design alternatives suitable for the *class of problem* in question. The rigor cycle is also the route to enriching the IS knowledgebase by communicating the outcomes of DR (i.e., ITAs) and making them accessible to IS scholars and practitioners through dissemination (Hevner, 2007).

Most importantly, and at the core of the DSR framework, is the design cycle. This cycle encompasses the build/evaluate research activities as described by March and Smith (March & Smith, 1995). Here, Hevner (2007) drew on Simon's description of design as characterized by the *iterative generation of alternatives*, and the subsequent evaluation of these alternatives against a set of criteria defined in problem-domain terms (Simon, 1996). Simon (1996) states that this cycle *perpetuates* until a "satisfactory" design is achieved. In software development terms, this process resembles iterative system prototyping.

Tool-thinking and Generalizability

A cursory review of design studies reveals that ITAs are frequently presented as technical *tools* that the users *use* (i.e., instantiated IT systems). And while many in our discipline state the purpose of design with an emphasis on direct impact in practice (e.g., Hevner et al., 2004; March & Smith, 1995), taking a purely tool-focused perspective to the ITA can be somewhat problematic.

The first problem facing design researchers with a tool-focused perspective is in the domain of *generalizability*. When it comes to the place of theory in IS design research, our discipline is split into two camps (Gregor & Hevner, 2013). The first camp is rooted in pragmatism, placing much of the emphasis in design research on *utility in a practical setting* rather than on the production of generalized knowledge about IT systems in their respective contexts (e.g., Hevner et al., 2004; March & Smith, 1995).

For instance, March and Smith made it clear that DR is a *knowledge using* activity in which artifacts are built and evaluated, and that it is different from the "natural sciences" paradigm which emphasizes theorizing and justification. In their view, design-oriented research is *a-theoretical*, and the notion of science should be broadened to include a-theoretical activities (Vahidov, 2012).

Given that, the pragmatist camp places theory firmly outside the realm of design research, stating that the ITA, in itself, constitutes a contribution to knowledge (e.g., Hevner et al., 2004; March & Smith, 1995).[1] In contrast, the design-theory camp emphasizes the importance of producing generalized knowledge about IT systems (i.e., contribution to design theory). For instance, Vahidov (Vahidov, 2012, p. 104) states that *science* and *theory* are such closely related terms "that a conception of an a-theoretical science sounds almost like an oxymoron."

Another view is that of Gregor and Jones who argued that a theory-based perspective in IS design research helps promote rigor and legitimacy. In addition, it facilitates the development of cumulative knowledge that *rises beyond craftsmanship* and towards developing generalizations about design (Gregor & Jones, 2007). Other scholars argued that the lack of theoretical contribution in IS design research is among the remaining factors that hinder its acceptance as a legitimate scientific exercise (e.g., Weber, 2010).

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[1] Some discussions I had with other researchers always ended with a statement in defense of this approach, stating that "We're interested in theory from the output-side."

The second problem with a tool-focused perspective in design research results from the scarcity in methodological guidance pertaining to *artifact building* activities when compared to those guiding artifact evaluation. March and Smith (1995) described such imbalance, stating that it resembles the problem of theorizing versus justification in the natural sciences where the process of theorizing is far more ambiguous and less prescribed than the process of justifying (e.g., via formal hypothesis testing). In the absence of such guidance, a tool-focused design study can easily become *evaluation-dominant* with little elaboration on the rationale behind the artifact or on the "how" part of its construction.

This issue manifests frequently in literature anchored in IS through the DSR framework. Note that DSR does not prescribe a specific methodology to the act of *designing* itself in its formative sense. In its essence, the framework is hollow at the core, telling one what to do, but not *how* to do it. What is somewhat confusing here is that while many DSR-anchored studies pose research questions about the "how" part of design (i.e., artifact building), they do not sufficiently address that part. Given that, when using the DSR framework without augmenting it with specific methodological guidance on artifact building, researchers often overemphasize evaluation while not elaborating on the rationale behind the artifact's proposed form, function and values.

And so, in the case of design research which is (1) tool-focused, (2) a-theoretical and (3) evaluation-dominant, one is justified to ask: Where is the *design* in design science research? And where is the science? And how can one contribute beyond presenting the community with technical tools that will surely become obsolete sometime in the near future?

Systems View: An Alternative Perspective

An alternative and less prevalent view to the aforementioned is that which perceives and analyzes IS phenomena through a systems lens. Systems thinking entails conceptualizing the phenomena we encounter in terms of hierarchies of interrelated modules and components, working together to achieve a common purpose (Mobus & Kalton, 2015, p. 81).

The notion of systems theory (i.e., generalized knowledge about systems) first appeared in the work of Austrian biologist Ludwig von Bertalanffy, who is credited for the development of General Systems Theory (GST). In his work, he argued that mechanistic models of inquiry that reduce phenomena to low-level interactions do not sufficiently address the presence of a *rational whole* with a dynamic and purposeful organization. Alternatively, he advocated for an *organismic view* of the world, arguing that it is more capable of describing phenomena that cannot be viewed in terms of mechanistic interactions (e.g., homeostasis) (Boulding, 1956; Mobus & Kalton, 2015, pp. 33–35; von Bertalanffy, 1972). The abstract nature of GST led to its adoption in many other fields such as ecology and, business. Furthermore, it contributed to the creation of new fields such as systems analysis and design, systems science and systems engineering.

A number of colleagues advocated for a systems perspective in IS research. For example, Alter (2004) argued that IS scholars have done too little to exploit the *systems nature* of information systems as situated in their respective contexts. In his view, IS research that is rooted in systems thinking is underrepresented, and the balance is slanted towards tool thinking (Alter, 2004). He proposed a systems-based framework for understanding information systems in organizations in which human participants and/or machines perform *work* using information, technologies, and other resources to achieve a common goal (Alter, 1999). More recently, Alter advocated for the retirement of the ITA concept altogether, adding that “it no longer means anything in particular", and that a work systems perspective is better aligned with the character of IS (Alter, 2015).

> While Humpty Dumpty can get away with saying that things mean whatever he chooses them to mean in Lewis Carroll's sequel to Alice's Adventures in Wonderland, that approach is not appropriate for IS researchers, especially because the IS field espouses such great concern about combining rigour, relevance and influence in the real world. (Alter, 2015).

Other examples include proposing the use of GST as a possible framework for conceptualizing the *Information Systems (IS) artifact* in IS research (e.g., Chatterjee et al., 2021; Syynimaa, 2017). The IS artifact is one of the IT artifact's "cousins" that Alter called for carefully using, if not even retiring along with its more celebrated relative, the ITA (Alter, 2015).

Systems-based conceptualizations in IS are also foundational in the sociotechnical perspective (e.g., Baxter & Sommerville, 2011; Bostrom & Heinen, 1977), actor-network theory (e.g., Tatnall, 2005), and in soft systems methodology (e.g., Checkland, 1999; Checkland & Poulter, 2020).

Taking a systems view offers pathways around the aforementioned issues resulting from the adoption of a tool-focused perspective in design research. For example, a systems approach offers a level of abstraction that enables design researchers to make generalizations about IT systems as situated in their respective context. As such, this makes a longer-lasting contribution to design theory. This is especially useful because a design researcher, unlike a designer, is not so much interested in the marketability of gadgets – their interest lies beyond a specific software package. Vahidov (2012) states the goal of design research is to provide *abstract design artifacts* (i.e., meta-artifacts) that can be used in the construction of concrete instantiations. This approach provides for knowledge that remains relevant as specific technologies become obsolete. Work domain models that are rooted in systems thinking are one type of meta-artifact that fulfils such criteria.

Furthermore, many systems-based methods are formative (e.g., Cognitive Work Analysis), and are therefore inherently geared towards artifact building activities. This offers to balance evaluation-dominant research by revealing the rationale behind the proposed artifact. Other benefits to adopting a systems approach are its ability to distinguish between IT and IS, and between manual, semi-manual and computerized operations, thus adding more context that can inform concrete artifact construction (Alter, 2004).

Study Objectives

In this dissertation, I take a systems approach to designing a low-friction patient-facing IT aid for active medication management in the domain of chronic disease care. In particular, I focus on the unique requirements of patients with type 2 Diabetes who are on an insulin regimen.

First, I augment the DSR framework with systems-based formative guidance pertaining to artifact building by utilizing Work Domain Analysis (WDA). The resulting artifact, the Abstraction-Decomposition Space (ADS), captures the functional purpose of the system, its values and priority measures, its purpose-related functions and the physical objects that operate within it. The ADS also depicts the means-ends relationships among these abstraction layers. Furthermore, the ADS captures the structural decomposition of the system by spreading it across a parts-whole dimension and decomposing it into modules and components. When overlayed, these two dimensions depict the *fundamental problem space* of the system.

Next, I transition from model to instantiation using the above-mentioned ADS along with Hierarchical Task Analysis (HTA). The goal of performing an HTA is to elicit task-specific descriptions that can be used to guide the development and subsequent testing of an expository instantiation. HTA also adds an element of procedure to WDA and allows designers to map the specific resources needed to perform work.

Lastly, I conduct a simple heuristic inspection to assess the usability of twelve unique patient scenarios that span the core user tasks I identified. The result is a list of usability violations, ordered by severity.

The overarching thesis in this dissertation is that work system models, such as the ADS, are design artifacts that can be used to instantiate concrete IT systems.

Dissertation Outline

In Chapter 2, I discuss the problem of insulin dose titration in type 2 diabetes and conduct a systematic literature review of a number of IT interventions in that space. The literature review focuses on issues pertaining to clinical efficacy, safety, system architectures and end user experiences.

Chapter 3 discusses the theoretical roots of WDA, demonstrates its augmenting of the DSR framework, and discusses its suitability for the class of problem at hand (i.e., active medication management). In this chapter, I take a systems approach in building a model (i.e., the ADS) that depicts the work system of a patient aid operating as part of a provider-guided remote insulin titration intervention. This part of the dissertation departs from mainstream design research by evaluating the work system first then encoding the results of that evaluation into a design artifact – the ADS.

Chapter 4 shows the transitioning from model to instantiation using the aforementioned ADS along with HTA. In this chapter, I map the specific resources required to perform work as depicted in the ADS with the task hierarchies I developed using HTA. Finally, I run a simple heuristic usability inspection with seven evaluators in order to derive requirements for further iterations.

Chapter 5 provides conclusive remarks that reflect on this study, discuss limitations and provides suggestions for future work.

Chapter 2

Information Technology Interventions for Remote Insulin Titration in Type 2 Diabetes: A Systematic Literature Review

Introduction

Driven by the rapid advances in sensor technology, home health devices and smartphone applications, many healthcare providers are adopting IT-enabled care delivery models capable of providing timely support to outpatients with chronic disease. These systems enable the prompt adjustment of treatment, allow for a closer observation of patients, and provide tailored self-care and adherence support.

The Problem: Type 2 diabetes and Insulin Titration

Patients with type 2 diabetes (T2D) are instructed to follow a daily self-care routine typically comprising behavioral changes and medication. The goal of self-care in diabetes is to maintain a good level of glycemic control in order to avoid, or delay, the onset of irreversible complications such as neuropathy, retinopathy and cardiovascular disease (American Diabetes Association Professional Practice Committee, 2021).

Clinicians rely on a number of indicators to measure glycemic control to assess the progression of their patient's disease and to introduce changes to their care plan. The gold standard measure in this regard is the glycated hemoglobin A1c (HbA1c). A1c tests are conducted routinely in the laboratory, at home, or during a visit to the clinic. Ideally, patients should aim to maintain an A1c between 6.5% and 7.0%, although targets may vary depending on the patient's condition (CDC, 2018; Inzucchi et al., 2015).

In addition to HbA1c, patients conduct multiple capillary blood glucose tests at home using commercially available glucometers. Unlike A1c which gives an average measure of blood glucose concentration over a 90-day period, a home-based glucose test gives an immediate measure of blood sugar. Suggested fasting glucose concentration is between 80 mg/dL and 130 mg/dL, although more or less stringent targets may be appropriate depending on the patient's unique circumstances (American Diabetes Association, 2013).

In the early stages of T2D, behavioral interventions relating to lifestyle such as physical activity, a healthy diet and the frequent self-monitoring of blood glucose (SMBG) may be sufficient to achieve the patient's clinical targets. However, and as the disease progresses, it becomes harder to maintain optimal glycemic control without a pharmacological intervention, further complicating the patient's routine (Inzucchi et al., 2015). Under any circumstance, maintaining a good level of adherence to the prescribed regimen, whether behavioral or medication-based, is key to the success of treatment.

Inzucchi et al. (2015) identify four stages of medication-based management in T2D (Figure 2.1). First, and in addition to the aforementioned behavioral routines, an oral hypoglycemic agent (OHA), Metformin, is introduced. If optimal A1c could not be maintained with Metformin, further escalation up the treatment hierarchy may be required and can include additional OHA as well as injectable medications, possibly including multiple forms of insulin (American Diabetes Association Professional Practice Committee, 2021; Inzucchi et al., 2015). Here, adherence to the care plan becomes even more critical to achieving glycemic targets. However, and with each level up the treatment hierarchy, the complexity of the self-care regimen increases, imposing an additional burden on the patient. For many diabetics, and especially in the elderly, this burden far outweighs the patient's physical, cognitive and emotional capacity. As such, when caring for T2D patients, physicians try to find a balance between treatment complexity and glycemic targets in order to achieve a suitable level of adherence to therapy (Inzucchi et al., 2015).

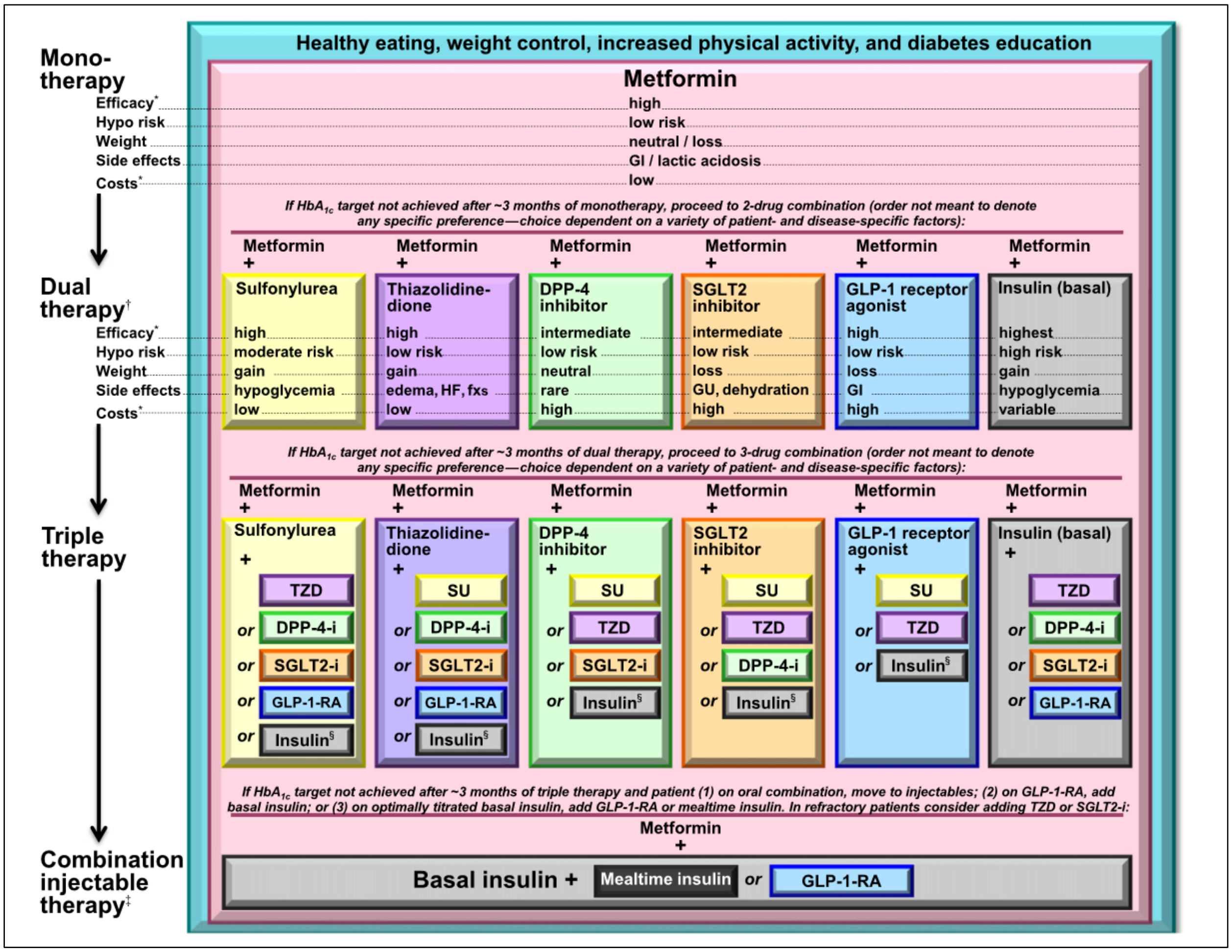

Figure 2.1. The stages of T2DM therapy as described in Inzucchi et al. (2015).

A cursory review of the relevant healthcare literature points to a variety of definitions for the treatment regimen complexity (TRC) construct. For instance, when defined in terms of medication taking, TRC includes the number of prescribed medications (i.e., the pill-burden) as well as the dosing schedule (Muir et al., 2001). Other studies go beyond that to include administration instructions, and the prescribed dosage forms (e.g., George et al., 2004) (Figure 2.2).

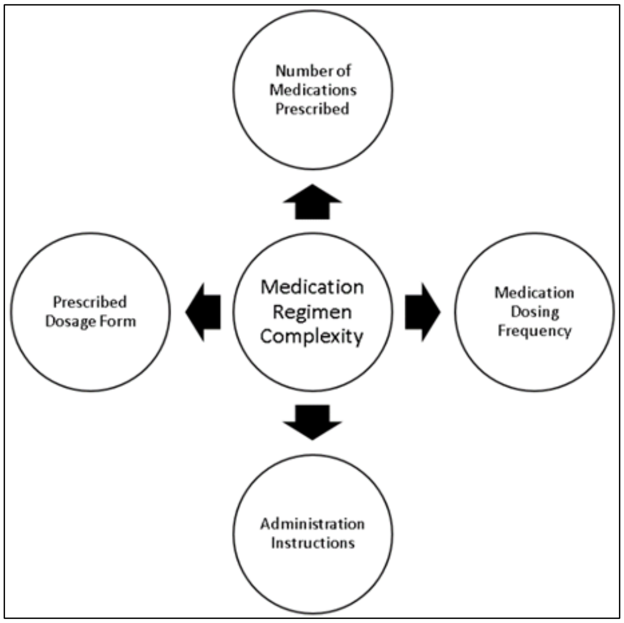

Figure 2.2. Medication Regimen Complexity as described by George et al., (2004)

Several instruments that measure TRC were developed from the above-mentioned definitions. For instance, George et al. (2004) used their definition to develop a 65-item medication regimen complexity index (MRCI) which appraises and quantifies several features of medication regimens. Disease-specific TRC indices also exist. For example, Martin et al. (2007) developed the Antiretroviral Regimen Complexity Index (ARC) to quantify the complexity of viral suppressant regimens in the context of HIV/AIDS. Witticke et al., (2013) measured regimen complexity based on 7 factors including tablet splitting and variable dosing requirements.

These instruments enabled healthcare researchers to investigate the association between TRC and non-adherence to treatment. In this vein, several articles point to a strong link between high TRC and low levels of adherence to therapy. For instance, results from one study show a 15% difference in the average 1-year adherence levels for patients with simple regimens when compared to those with complicated regimens (58% vs. 43%, respectively) (Pollack et al., 2009). Pollack and colleagues used George et al.'s MRCI to measure TRC. In the case of diabetes and hypertension, one study concluded that "… treatment complexity is related with non-adherence to glucose- and blood pressure-lowering drugs…" (de Vries et al., 2014, p. 136). Similar results can be seen in the context of clinical trials where regimen complexity factors were associated with non-adherence to the trial protocol (Robiner, 2005). A systematic review of literature on this matter concluded that focusing on regimen factors by simplifying TRC is key for achieving more satisfactory adherence levels (Ingersoll & Cohen, 2008).

In light of the above, patients with insulin treated T2D are faced with a number of unique challenges arising from the characteristics of their management routine. First, insulin is administered subcutaneously, typically using a syringe or an injection pen/vial apparatus[2]. This requires a sufficient level of skill pertaining to self-injection. Second, and depending on the patient's condition, insulin dosing requirements are variable, and patients rely on their glucometer readings to determine how much insulin they need. This is a safety-critical task where a slight oversight can lead to a potentially life-threatening situation in case of overdosing. Lastly, these patients also deal with matters pertaining to medication and material stock management (e.g., insulin vials, glucometer strips, lancets, etc.), storage requirements as well as matters pertaining to the disposal of medical waste. Given these challenges, the burdens associated with self-care are overwhelming, especially for many elderly patients. As such, IT designers working on this class of problem must be deliberate in accommodating for the unique

[2] Issues pertaining to T2D patients on a continuous subcutaneous infusion regimen are outside the scope of this dissertation.

requirements of these patients from the early stages of design. Interventions which overlook this aspect often risk adding yet another layer of demands on top of an already burdensome routine.

Insulin therapy in type 2 diabetes

Insulin is extremely effective at rectifying severe hyperglycemia in patients with diabetes (Inzucchi et al., 2015). A number of studies estimate that about one third of the diagnosed diabetes population are treated with insulin, the vast majority of whom are patients with T2D (Selvin et al., 2014; Trief et al., 2016). But despite its proven efficacy, initiating or intensifying insulin therapy is often unnecessarily delayed for several years. During that period, many patients remain poorly controlled, causing their condition to progress (Russell-Jones et al., 2018).

There is an abundance of literature pointing to this issue, for instance, one study showed that patients suffered from severe hyperglycemia at the time of insulin initiation (mean HbA1c > 9%), suggesting that an earlier initiation of treatment could have delayed the onset of irreversible diabetes complications (Costi et al., 2010). A retrospective analysis of a large cohort of T2D patients (n=14,824) revealed that the median wait time between starting the last prescribed oral diabetes medication and the initiation of insulin treatment was more than 7 years. Patients included in the analysis were already on two or more oral diabetes medications but still had poor metabolic control at the time of introducing insulin (HbA1c >8%) (Calvert et al., 2007).

Patients and their healthcare providers (HCPs) cite multiple reasons for the aforementioned delay in the initiation of insulin treatment. First, insulin is linked to an increase in the incidents of symptomatic, asymptomatic and nocturnal hypoglycemia. This side effect can be life threatening if not detected and rectified in a timely manner, adding to the patient's anxiety. As such, fear of hypoglycemia is among the top cited reasons for treatment inertia. Other reasons include the lack of care provider time and resources, patient fear of injections, and the patient's inability to comply with a complex and burdensome new regimen (Inzucchi et al., 2015; Russell-Jones et al., 2018). These barriers impact both insulin-naïve patients and patients who are already on insulin but are reluctant to intensify their treatment despite not meeting their glycemic targets.

Care providers help their patients overcome these barriers through self-care education and training. Some of the issues covered during diabetes self-care education include the proper use of glucometers, using blood glucose test results to calculate and adjust insulin doses, insulin self-injection techniques using syringes or insulin pens, injection site rotation as well as recognizing and rectifying hypoglycemia, just to name a few.

A number of studies point to a strong association between diabetes self-care education and improved glycemic control. For instance, a meta-analysis of 118 unique educational interventions concluded that diabetes self-care education is significantly associated with an improvement in HbA1c (absolute average reduction of 0.57%). The same study found that extensive education (total contact hours >10) contributed to an above average improvement in metabolic control (Chrvala et al., 2016).

Patients are expected to incorporate the self-care practices they have learned during patient education into their daily care routine. During that period, patient-provider interaction is maintained through follow-up appointments during which the patient's response to treatment is assessed, and their regimen is modified as needed. Obviously, self-care activities that are carried out by the patients on a daily basis are not performed under HCP supervision. As a consequence, corrective action may be delayed until the next patient follow-up, or until the patient initiates communication (e.g., to report severe hypoglycemia), leaving many patients in need of additional support in the interim period during which access to assistance is not readily available.

Objectives and Review Questions

This review aims to aggregate and synthesize the evidence behind the clinical efficacy and safety of IT-enabled remote insulin dose adjustment (IDA) interventions targeting patients with T2D. In addition, it explores the IT architectural patterns and usability requirements of these interventions. To achieve these objectives, this review is guided by the following research questions:

1. What are the reported clinical outcomes of IT-enabled remote IDA interventions?
2. What are the reported safety considerations associated with the adoption of IT-enabled remote IDA interventions?
3. What architectural features and technologies are used in the construction and deployment of remote IDA systems?
    a. What specific technologies are utilized?
    b. What IT architectural patterns are exhibited?
4. What usability-related considerations were reported by the users of these interventions?

Method and Materials

Data Sources

I conducted an online database search using NIH-PubMed, Scholar and Web of Science to retrieve the relevant literature. Keywords pertaining to the theme of the study were identified (Table 2.1). A number of relevant publications that were not returned by the search string were manually retrieved. The search spanned articles published within the last 14 years (January 1st, 2008, and December 31st, 2021).

Review Scope		
IT-enabled remote insulin dose adjustment (IDA) interventions targeting patients with type 2 diabetes		
Topics	**Search Keywords**	**Scope Description**

Telemedicine	• Telemedicine ○ Mobile Health ○ Telehealth ○ eHealth ○ mHealth	Delivery of health services via remote telecommunications. This includes interactive consultative and diagnostic services.
Apply logical operator "AND"		
Insulin Dose Adjustment (IDA)	• Insulin	Any occurrence of the keyword "Insulin" in the title or the abstract of the publication.

Table 2.1. Search keywords used to identify relevant publications.

Literature Screening

I conducted a title and abstract review of the resulting pool of articles. Studies which evaluate, review or provide a meta-analysis of telemedicine interventions for remote IDA targeting adult patients with T2D were included for full-text review. Any article that is not available in English, or that focuses on continuous subcutaneous insulin infusion (CSII), closed-loop insulin delivery (i.e., artificial pancreas), or that which targets pediatric patients or patients with Type 1 or gestational diabetes was excluded from this review. The reason for excluding these studies is this dissertation's focus on elderly T2D patients on a multiple daily injections (MDI) regimen. Excluding non-English articles was due to translation cost and time barriers. Relevant data was extracted during full-text review using a standardized data extraction form created for that purpose.

Results

Descriptive Summary

The search yielded 210 unique publications, 160 of which (76%) were excluded during title and abstract screening. The top reason for exclusion was for focusing on Type 1 diabetes, gestational diabetes or for studying a pediatric population (n=76, 46%). Non-interventional or off-scope studies came in second (n=54, 34%), followed by studies that feature continuous glucose monitoring (CGM), continuous subcutaneous insulin infusion (CSII) or closed-loop insulin therapy (i.e., artificial pancreas) (n=21, 13%). A small number of studies were excluded for focusing on one or more diabetes-related complications such as retinopathy (n=7, 4%). Only four studies were excluded for being in a language other than English (n=4, 3%) (Table 2.2).

Reason for exclusion	Count, (% of excluded publication)
Type 1, pediatric or gestational diabetes	74, **(46%)**
Non-interventional studies other than systematic reviews and meta-analyses	54, **(34%)**
Studies featuring CSII, CGM or artificial pancreas	21, **(13%)**
Studies focusing on diabetes-related complications	7, **(4%)**
Studies not available in English	4, **(3%)**
Total exclusions	160, **(100%)**

Table 2.2 Excluded studies and reasons for exclusion

Fifty studies from 2008-2021 (n=50, mode=3 per year) met the eligibility criteria and were included for review (Figure 2.3). Nineteen studies (n=19, 38%) were single-group interventional studies, seventeen studies (n=17, 34%) used a randomized controlled trial (RCT) design, four studies (n=4, 8%) were systematic literature reviews, three studies (n=3, 6%) used a non-randomized quasi-experimental configuration, two publications (n=2, 6%) were prescriptive studies providing elaborate IDA system descriptions, two studies (n=2, 4%) were qualitative content analysis studies, two studies (n=2, 4%) performed a formative or summative usability evaluation, and only one study (n=1, 2%) conducted a retrospective analysis of patient health records (Figure 2.4).

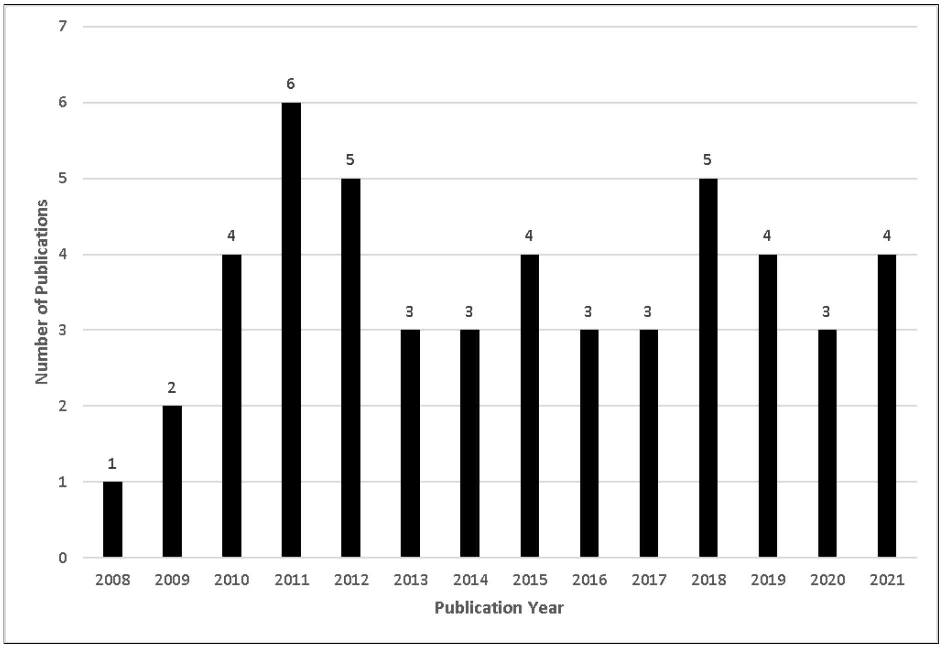

Figure 2.3. Count of included publications by publication year

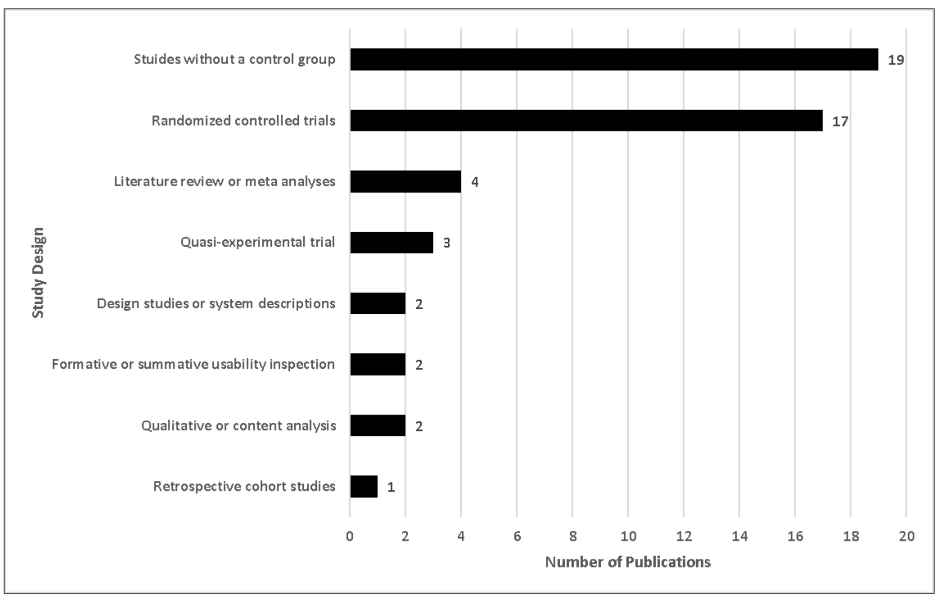

Figure 2.4. Count of included publications by study design

Clinical Outcomes and Patient Safety

Evidence behind the clinical efficacy of remote IDA interventions was reported in twenty-six publications (n=26, 52%) (Figure 2.5). RCT was the most frequently utilized study design (n=15), followed by experiments without a control group (n=7). Other studies used a quasi-experimental configuration (n=3) or conducted a retrospective analysis using patient records (n=1). Standardized measures of glycemic control such as HbA1c and capillary blood glucose were reported in all but one of these publications (n=25). One study measured the proportion of patients achieving their optimal insulin dose by the end of the intervention period (Levy et al., 2015). Other patient health indicators such as systolic blood pressure, weight, and cholesterol levels were also reported (e.g., Tang et al., 2013; Wakefield et al., 2014). A subset of the aforementioned studies discussed issues pertaining to safety by reporting on the incidents of hypoglycemia among their patient cohorts or through post-hoc expert evaluation (n=12).

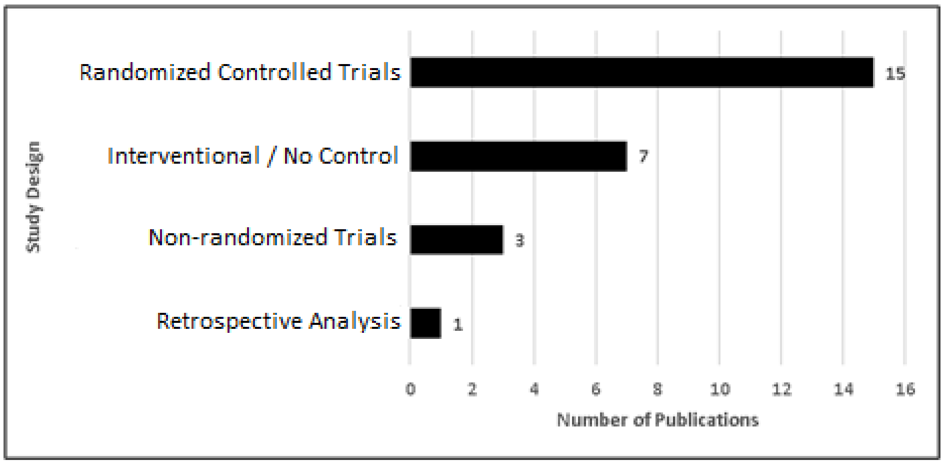

Figure 2.5. Publications reporting on the clinical efficacy of remote IDA interventions by study design

Nineteen publications (n=19) concluded that the adoption of IT-enabled care delivery models for remote insulin dose titration is associated with a significant improvement in health outcomes in patients with T2D. For instance, one study enrolled 101 patients in a telemedicine intervention featuring video teleconsultation and a remote stethoscope. In addition to reporting a significant reduction in HbA1c among their patient cohort, they also noted that the initiation or adjustment of insulin therapy was among the most frequently performed services via their system (Nikkanen et al., 2008). Another study used a smartphone application with a connected glucometer. Their system enabled patients to upload their capillary glucose readings to be reviewed remotely by their HCP. The cohort used the system for 3 months during which an average of 160 blood glucose readings were transmitted per patient. End point results showed a significant improvement in glycemic control with a mean HbA1c reduction of 0.52% (Turner et al., 2009). The same intervention was evaluated in a separate study in which similar results pertaining to glycemic control were reported. The authors further noted that the system enhanced patient support during insulin dose optimization, however, there remained a reluctance to increase doses due to risks of hypoglycemia (Larsen et al., 2010). A retrospective study analyzed the records of 1000 patients with T2D who received care via a telemedicine intervention over a 6-month period and reported a mean HbA1c reduction from 8.5% (±1.4%) at baseline to 6.3% (±0.6%) at endpoint ($p<0.0001$). Additionally, 84% of the patients reported no hypoglycemia, pointing to an acceptable level of safety, especially among patients adjusting insulin therapy. The intervention integrated a confluence of mainstream communication technologies, enabling patients to share their SMBG data with their HCP via email, phone or through a dedicated secured web-portal (Kesavadev et al., 2012). Interventions with less elaborate functionality also yielded similar results. For example, Levy et al. (2018) evaluated the use of Short Message Service (SMS) and telephone for remote IDA in patients with T2D and concluded that the intervention helped patients achieve their glycemic targets without in-person care and with only 9 out of 113 patients not meeting their targets by the end of the intervention period (Levy et al., 2018).

Results from comparative studies investigating the efficacy of remote IDA interventions in comparison with standard care practices coincide with the findings discussed above. For example, 10 out of 15 RCTs concluded that patients receiving remote IDA services demonstrated a significant improvement in multiple measures of glycemic control when compared to those receiving standard care. For instance, Stone et al., (2010) showed that patients with T2D receiving a telemedicine intervention consisting of a monitor with an integrated glucose meter and messaging functionality demonstrated a significant improvement in glycemic control versus those who received a monthly follow-up call. Another smartphone-based intervention with features for supporting SMBG, condition-related actionable messages and patient record integration also demonstrated superior clinical efficacy when compared to in-person follow-up. A significant improvement in measures of patient knowledge and empowerment was also reported in the intervention arm (Greenwood et al., 2015).

A smaller number of studies (n=4) concluded that the efficacy of remote IDA intervention is, at least, comparable to that of standard care. For instance, one study concluded that even though improvement in glycemic control was marginal in the remote IDA group versus standard care, patients who received the intervention reported a significantly higher level of treatment satisfaction (Boaz et al., 2009). Another RCT studied the use of a smartphone-based intervention with a wireless glucose meter to improve diabetes control. Patients enrolled in the 12-month trial exhibited a significant improvement in HbA1c by midpoint, however, a statistically significant difference was not sustained by the end of the intervention period. Still, the study concluded that the intervention was found to be effective at improving glycemic control in patients with T2D (Tang et al., 2013). Only one study reported that patients using their telemedicine intervention, which consisted of a glucose meter connected via a modem, did not show an improvement in health outcomes (Wakefield et al., 2014). The authors argued that the use of such intervention alone is unlikely to contribute to an improvement in patient health, and that the technology should be reserved for patients anticipating a significant change to their care plan, such as the introduction of insulin.

Other articles evaluated the safety risks associated with the adoption of remote IDA via an IT-enabled intervention. In this vein, twelve studies (n=12) discussed the prevalence of hypoglycemia among their patient participants, reporting it as a primary or a secondary outcome measure. For example, Dy et al. (2013) sought to explore the feasibility of telemedicine in reducing the incidents of hypoglycemia and severe hyperglycemia in patients with diabetes. They evaluated standard care augmented with teleconsultations via videoconferencing and observed a decrease in the incidents of hypoglycemia among patients in the intervention arm (Dy et al., 2013). Another intervention using a connected glucometer and support for SMS and email communications was evaluated with insulin-treated diabetics and yielded a reduction in the incidents of both mild and severe hypoglycemia in their intervention group (Fountoulakis et al., 2015). Other studies did not report a significant improvement in patient safety as a result of utilizing such interventions. For instance, one study investigated the impact of using a dedicated telemedicine system featuring a connected glucometer setup. Despite reporting a significant improvement in A1c in the intervention group (from 9.5% ± 1.8% to 8.1% ± 1.2%; $p < 0.01$), the study found no significant intergroup difference in hypoglycemic events (Chen et al., 2011).

The results discussed above suggest that remote IDA interventions can provide a good level of support to patients with T2D during the period in which insulin therapy is initiated or intensified. Studies that did not yield a statistically significant improvement in glycemic control reported other clinical benefits associated with the adoption of IT-enabled care delivery targeting elderly patients with T2D. Section A in Appendix 1 provides a tabulation of the aforementioned 26 publications on clinical efficacy.

Architectural Patterns and Technologies

A large proportion of the articles elaborated on the technical setup of their remote care system to an extent that allowed for deriving specific technologies and architectures (n=32, 64%). At the patient's premises, commercially available home health devices (HHD) such as glucometers, automatic blood pressure monitors (BPM) and weight scales were an integral part of the system in the vast majority of these interventions (n=30). Only two studies did not specify the use of an HHD as part of their setup (i.e., Fatehi et al., 2013; Vluggen et al., 2021). Reports in this vein show that HHD varied in capabilities and features and ranged from basic and self-contained units to ones with more elaborate features and supported data transmission via standardized or proprietary interfaces (e.g., Bluetooth LE).

A variety of methods were used to transmit patient health data to a remote site, whether for HCP review or otherwise. For instance, one intervention described the use of SMS to share SMBG data with a remote server using basic phone functionality (Levy et al., 2015). Another study described the use of a glucometer with an integrated infrared (IR) transmitter that sends SMBG data to an internet-enabled desktop computer which is configured to relay the data to a designated remote site (Bujnowska-Fedak et al., 2011). Other systems used modems or specialized health gateways deployed at the patient's premises. These gateways were configured to relay health data directly to a remote site over the public phone network (PSTN) without the need for an intermediate node such as a desktop computer (e.g., McFarland et al., 2012). One system featured a glucometer equipped with a built-in modem which transmits SMBG data via dial tones (Del Prato et al., 2012). Interventions using companion smartphone applications transmitted SMBG and other health data using the phone's data link (e.g., Baron et al., 2017; Greenwood et al., 2015; Tang et al., 2013). The use of private secured networks was also reported, typically to support videoconferencing and real-time monitoring applications (e.g., Fatehi et al., 2013; Nikkanen et al., 2008; Stone et al., 2010).

The reviewed systems achieved a number of goals at the healthcare provider site. Most essentially, they served as an on-demand source of patient health data, making the timely adjustment of therapy possible (e.g., insulin dose up-titration). Access to health data was implemented in various ways including through the use of dedicated web-based dashboards (e.g., Boaz et al., 2009; Kesavadev et al., 2012; Kim et al., 2010; Turner et al., 2009; Wakefield et al., 2014) or by integrating the telemonitoring system with the provider's electronic health records system (e.g., Greenwood et al., 2015; Ronda et al., 2018; Tang et al., 2013).

In addition, these systems provided a mechanism through which instructions pertaining to regimen changes are communicated. This also was implemented in various ways. In symmetrical feedback designs, the patient received their therapy adjustment instructions via the same channel through which they transmitted their health data. For example, if the intervention involved a glucometer with a companion smartphone application, adjustments to treatment instructions originating from the HCP site would be communicated through that application (e.g., Baron et al., 2017). This occurs either through push notifications, via messaging features, or directly via the patient-facing display. Another example of symmetrical feedback is in videoconferencing applications (e.g., McGloin et al., 2020). Conversely, in asymmetrical feedback designs, changes to the treatment regimen are communicated through a channel other than the one that was used to transmit patient data to the HCP site. This can be seen in designs utilizing a patient's premises modem or a health gateway without a companion interactive device such as a computer or a smartphone (e.g., Chen et al., 2011). Hybrid feedback designs where regimen adjustments are communicated via the same or a different channel were also used. One example of that is the use of SMS to send SMBG data while receiving insulin adjustment instructions either via SMS or via a phone call, depending on the user's preference (e.g., Levy et al., 2015).

I identified 8 archetypal configurations from the reviewed literature. See Figures 2.6 through 2.13. Figure 2.14 shows the most common deployment archetypes found in the literature. See section B in Appendix 1, which summarizes the findings pertaining to technologies and architectures from the aforementioned 32 publications.

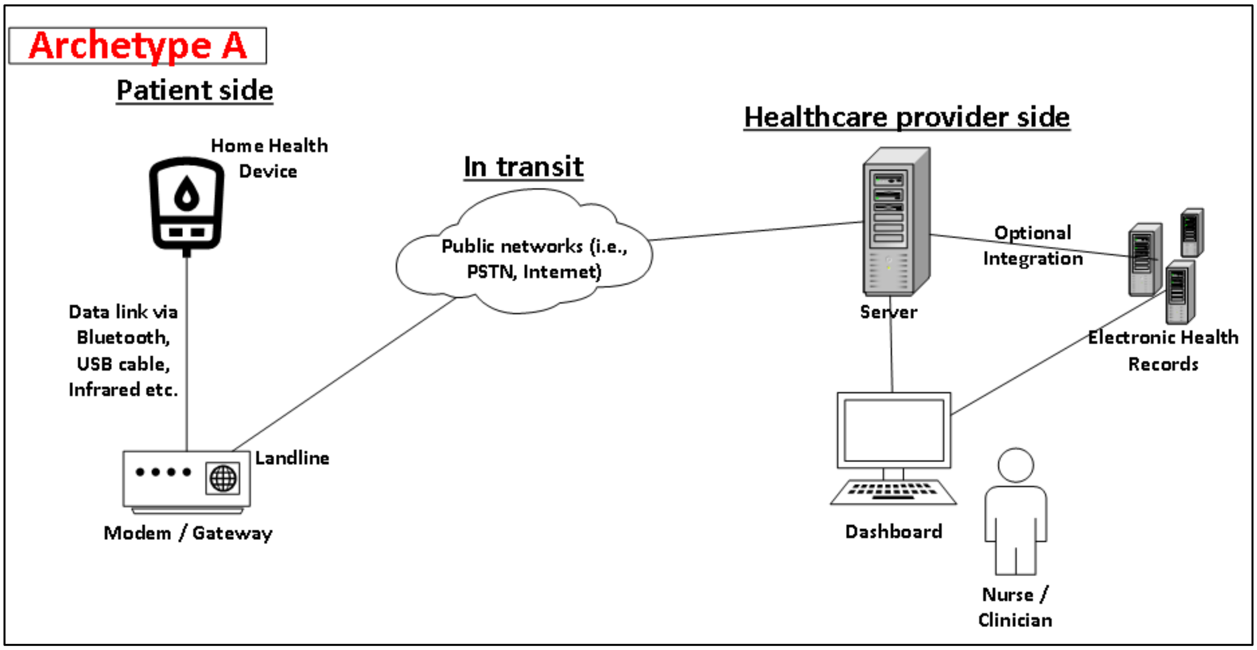

Figure 2.6. Archetype A. Telemedicine via connected health gateways with optional EHR integration.

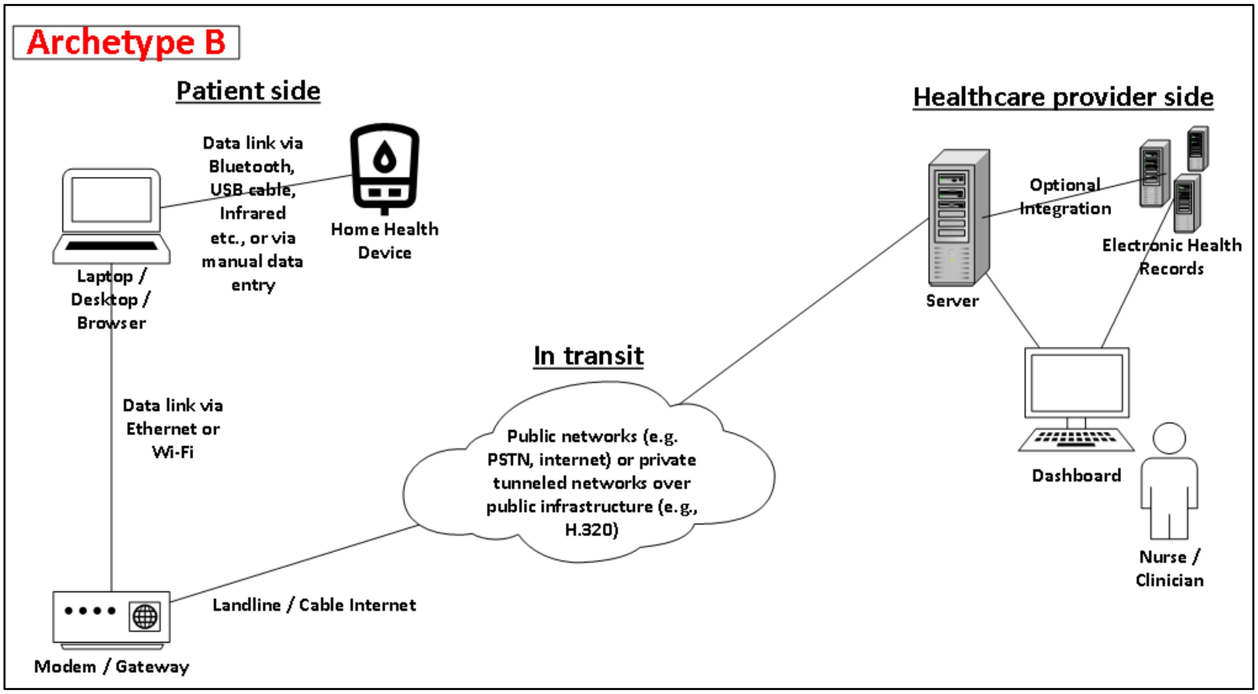

Figure 2.7. Archetype B. Telemedicine via internet-enabled computers at the patient's premises and with optional EHR integration.

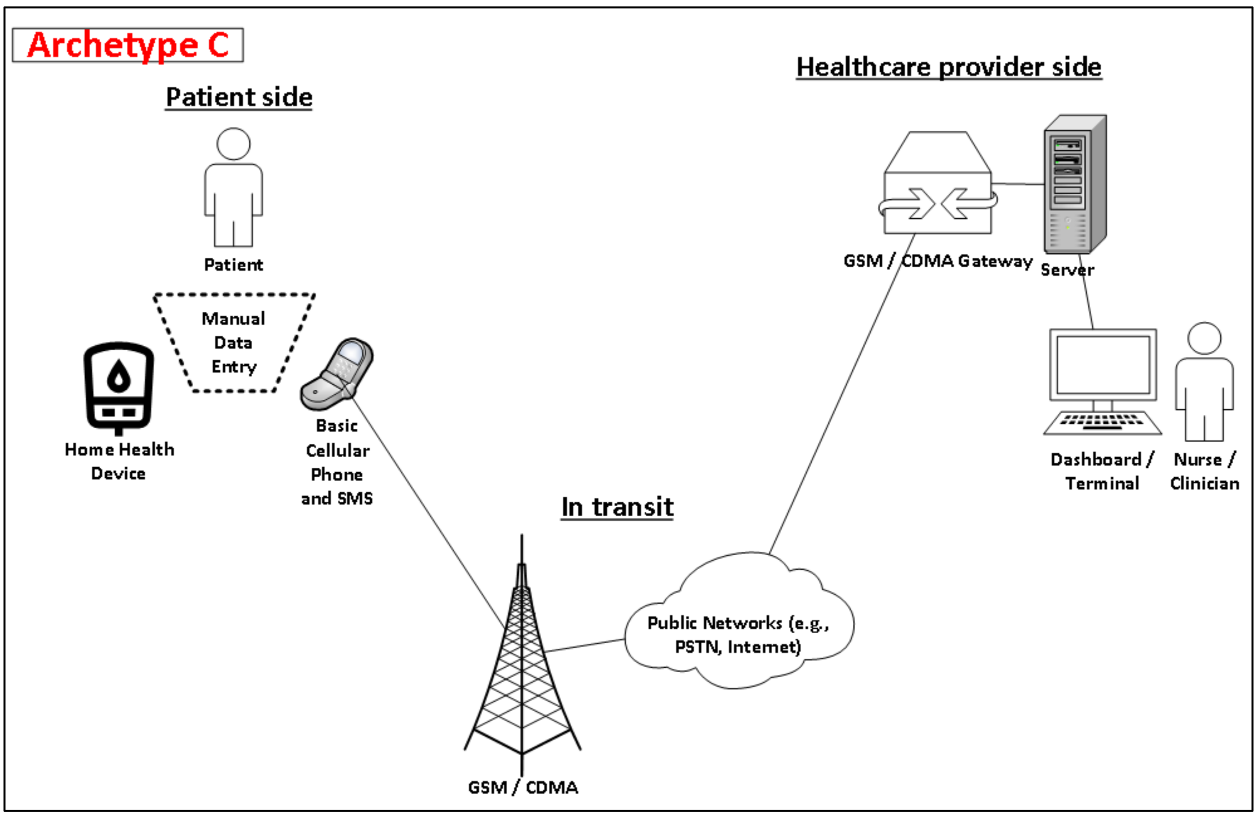

Figure 2.8. Archetype C. Telemedicine via basic cellular phone functionality.

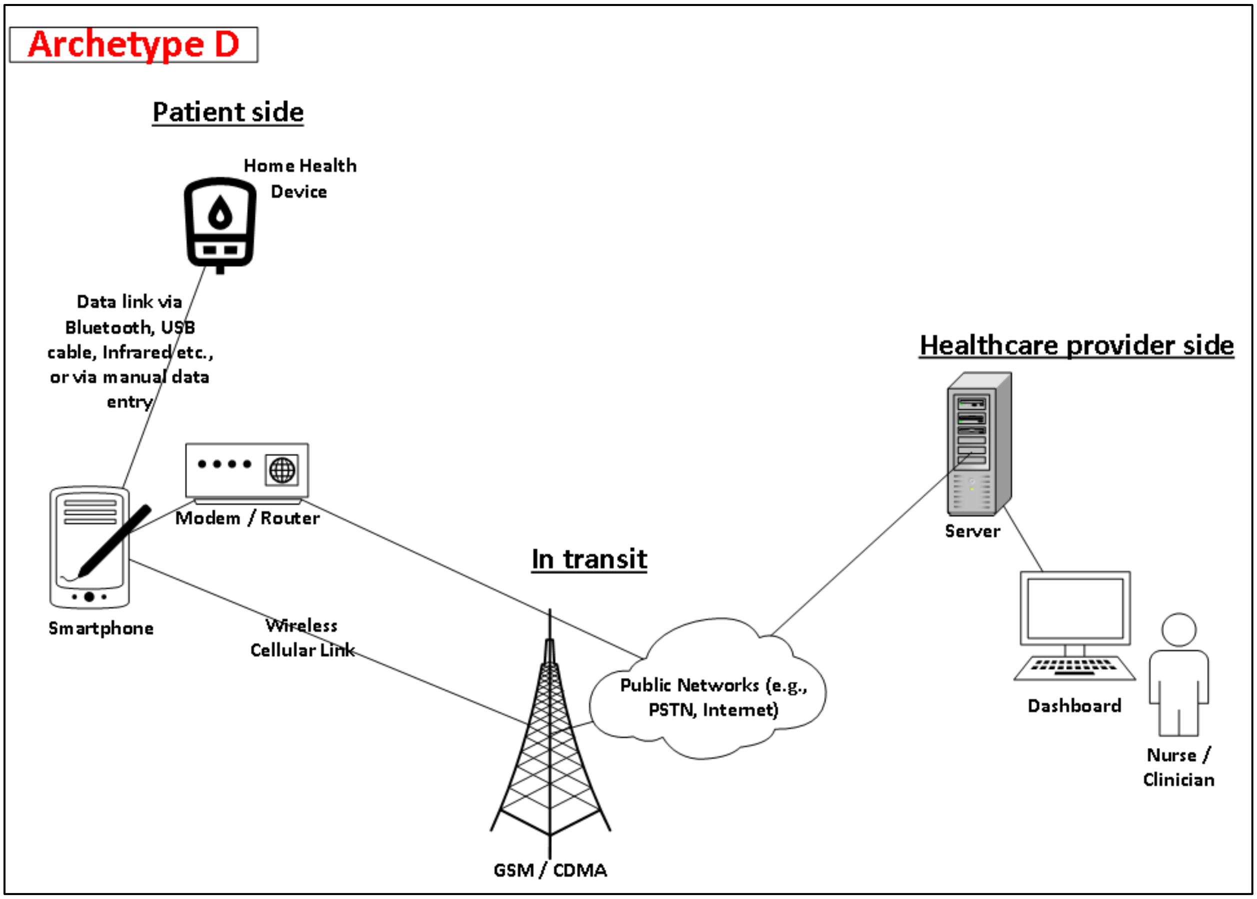

Figure 2.9. Archetype D. Telemedicine via smartphone applications.

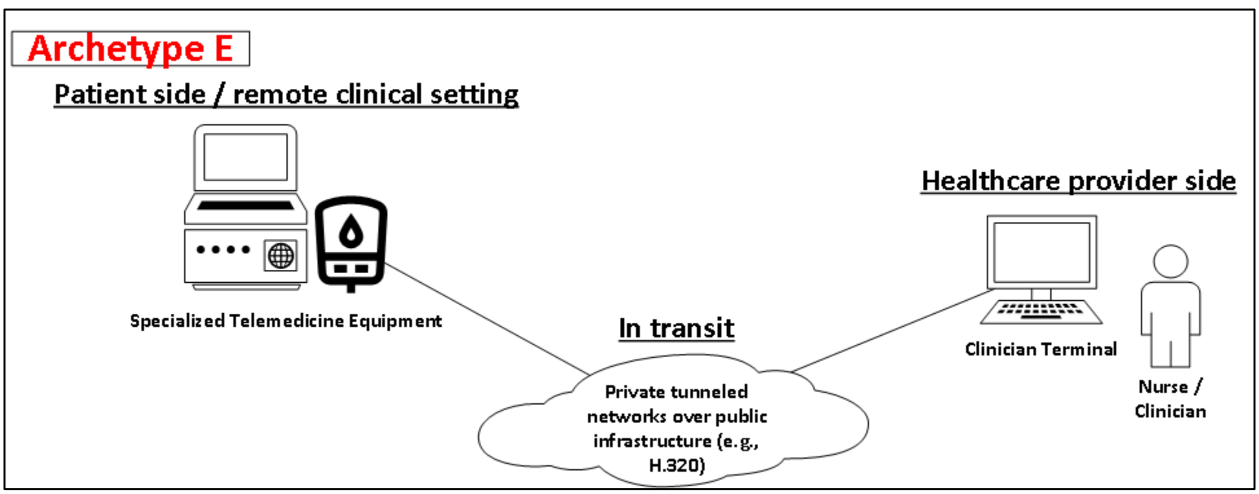

Figure 2.10. Archetype E. Telemedicine via specialized equipment through tunneled networks over public infrastructure.

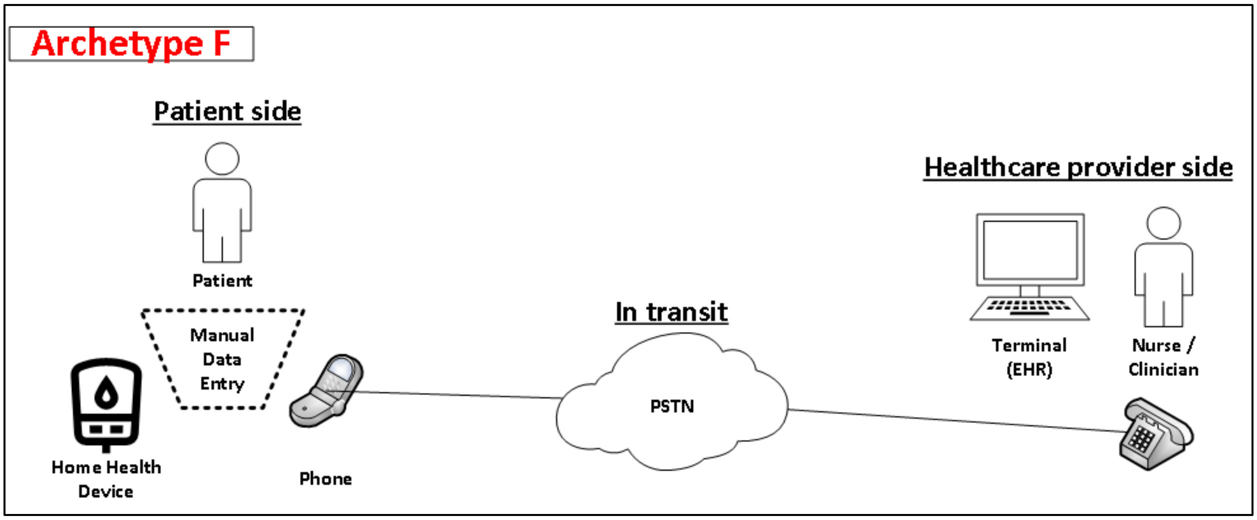

Figure 2.11. Archetype F. Telemedicine via phone calls.

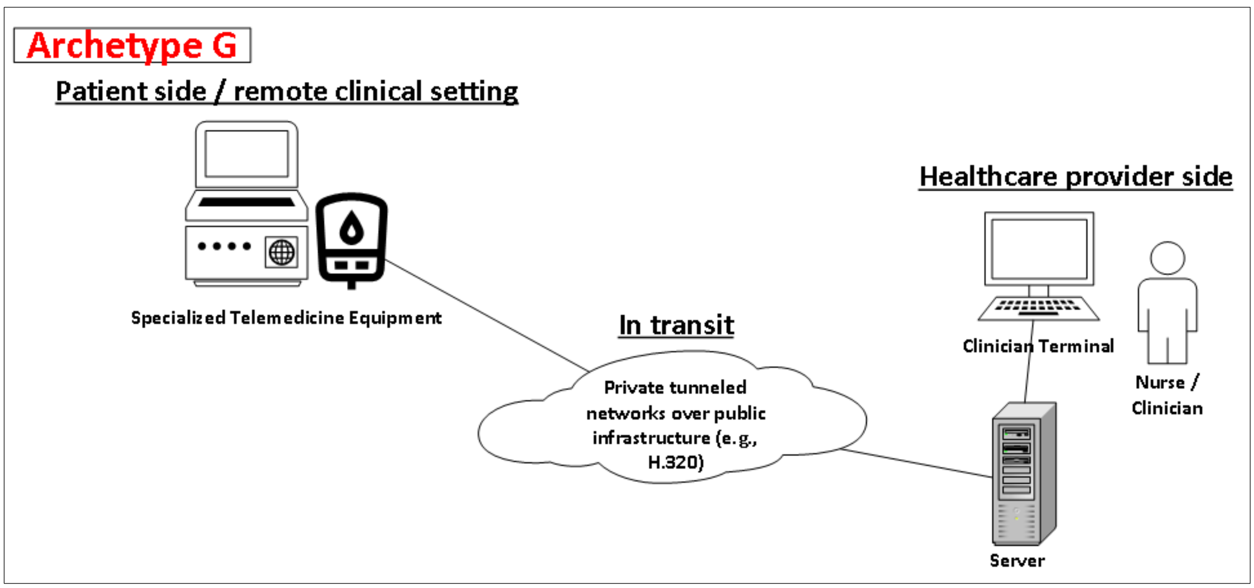

Figure 2.12. Archetype G. Telemedicine via specialized equipment with a provider-premises server.

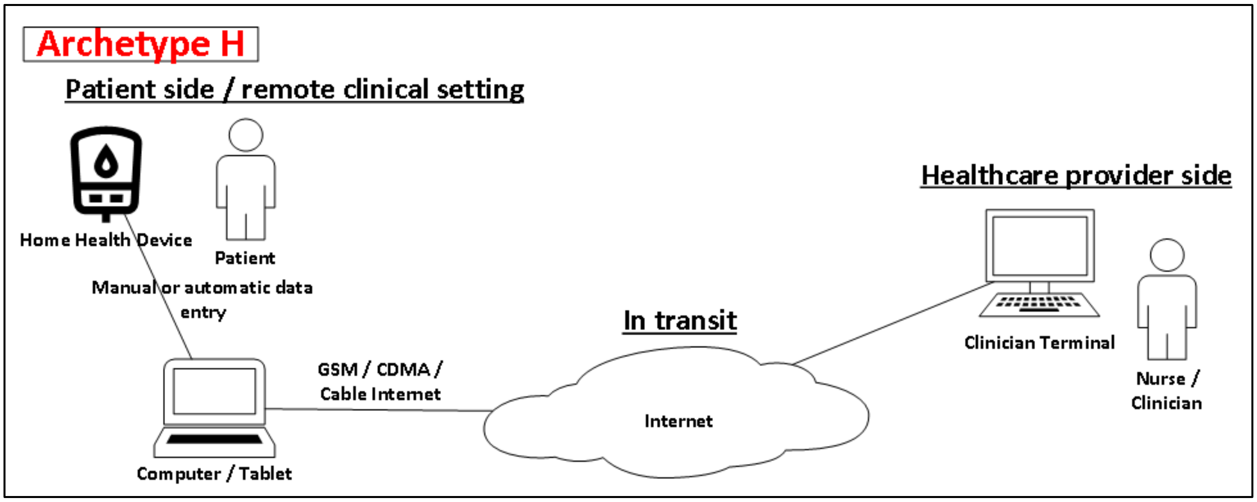

Figure 2.13. Archetype H. Peer-to-peer telemedicine via internet-enabled patient's premises computer.

Table 2.4. Summary of findings on technologies and architectures.

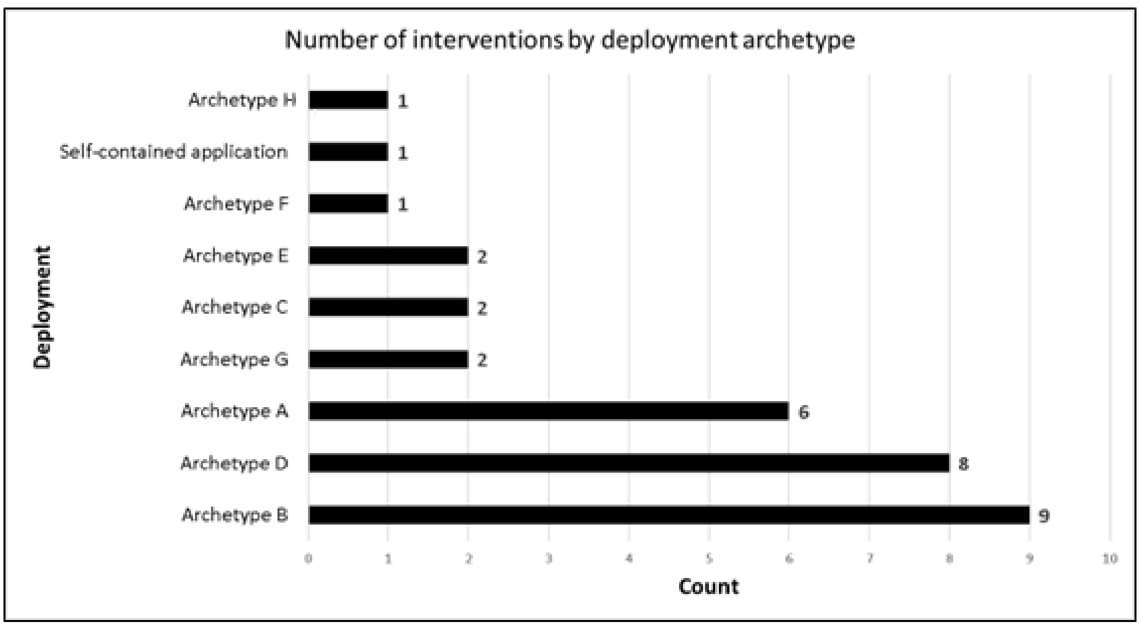

Figure 2.14. Most common deployment archetypes

The most common two archetypes (i.e., B and D) utilized a client-server architecture with an interactive patient-facing aid but only differed in form factor. Interventions classified under Archetype B utilized a web-based system with a full-size patient-side device (e.g., desktop computer), while Archetype D utilized a mobile device form factor. These two may overlap as web-based applications can be used on a mobile browser, but the extent to which designers accommodated for that is not elaborated on in the reviewed studies.

User Experience

A small subset of the publications (n=11) discussed issues pertaining to the user experience (UX) of remote care delivery systems targeting patients with diabetes. Reports in this vein ranged from simple tabulations of usability-related data derived from system usage (e.g., Turner et al., 2009) to more elaborate studies using extensive usability methods such as cognitive walkthroughs (e.g., Gude et al., 2012). In terms of specific platforms, seven studies tested smartphone-based interventions (n=7) and two others tested web applications (n=2). One study reviewed a variety of interventions including both web and smartphone-based systems (n=1), and another study assessed remote care delivery via basic phone (n=1). Table 2.3 provides a summary of the articles that focus on UX.

Reference	Apparatus / Specific Technology	UX Methods / Metrics	Summary
(Turner et al., 2009)	Smartphone application with a connected glucometer	• Informal / List of technical problems	The study discussed the end-user views of the technology. Care providers valued the utility of the system; however, they expressed concerns that such interventions may increase the patient's dependence on technology for daily disease management. In terms of usability, the authors tabulated a list of technical problems that was derived from system usage data and user reports.
(Gude et al., 2012)	Web application	• Cognitive Walkthrough • Expert Evaluation	The authors used a series of cognitive walkthroughs to uncover usability issues with their system and ranked these issues based on their severity. Their method involved identifying a number of

Reference	Apparatus / Specific Technology	UX Methods / Metrics	Summary
			usage scenarios for both HCP and patient user categories. On the patient side, obtaining insulin dosing advice from the system, including blood glucose data entry, had the largest number of usability problems. Such findings highlight the importance of UX-driven design, especially in matters pertaining to patient safety.
(Harrison et al., 2014)	Smartphone and Web-based interventions	• Systematic Review	This literature review concluded that web-based interventions had better overall usability when compared to applications accessed via hand-held devices such as in smartphone-based systems. Poor user interface design, difficulty in manipulating the device and poor sound quality were among the problems reported. The review concluded that future research should work towards tailoring diabetes technology to the unique challenges facing people with diabetes.
(Isaković et al., 2016)	Smartphone Application	• Retrospective Probing • Custom Usability Survey • System Usability Scale (SUS)	The authors featured a self-contained mHealth application with a connected glucometer and pedometer. Their application provided features for SMBG and insulin logging and reminders. A two-phased usability test was performed using retrospective probing along with the System Usability Scale (SUS) as a summative usability index. Results from these tests were used as inputs for redesign. The study concluded that their approach to redesign improved the overall usability score of their product.

Reference	Apparatus / Specific Technology	UX Methods / Metrics	Summary
(Ding et al., 2018)	Smartphone Application with a connected glucometer	• Custom Likert-scale questionnaire	This article tested an mHealth system for remote insulin dose titration with a small sample of older diabetes patients (n=9, mean age 58) using a Likert-scale questionnaire. While many participants had technical problems using the application, their responses indicated a good level of satisfaction with the system.
(Adu et al., 2018)	Smartphone Application	• Online questionnaire • Semi-structured phone interviews	This mixed-method study sought to explore the user-preferred features in mHealth apps for chronic disease care, focusing on patients with diabetes. It used an online questionnaire and ran a series of semi-structured phone interviews. The authors identified a number of preferred features including blood glucose and physical activity tracking. Among the recommendations to foster long-term engagement with mHealth pertained to reducing complexity and improving ease of use.
(Rogers et al., 2019)	Basic Phone (SMS)	• Interviews	The aim of this study was to pinpoint the barriers and facilitators to implementing an SMS-based telemedicine intervention for remote insulin dosing. The authors conducted a series of in-depth interviews with patients and care providers, both of whom concluded that the intervention was easy to use. Being SMS based, the low complexity of the system was among its top valued characteristics.

Reference	Apparatus / Specific Technology	UX Methods / Metrics	Summary
(Menon et al., 2019)	Smartphone Application	• Custom questionnaire	This article assesses the feasibility of an mHealth intervention for remote insulin dose adjustment. A customized user experience questionnaire was used and included items pertaining to the interventions ease of use. While many participants reported that they've had technical problems with the product, there was a degree of consensus on its ease of use, especially in functions pertaining to SMBG data transmission and sharing.
(León-Vargas et al., 2021)	Web Application / Smartphone Application	• System Usability Scale (SUS) • Interviews	This pilot study evaluated a cloud-based diabetes management system with a small sample of Type 1 and 2 diabetics. They used the System Usability Scale (SUS) as part of their evaluation and concluded that most participants found the system easy to use, especially its web interface and data visualization features. Another aspect that promoted a better UX was the fact that the technology was not burdensome or time consuming. Their evaluation yielded new requirements such as matching the web dashboard with the smartphone version of the application, both visually and from a functionality standpoint.
(Fu et al., 2021)	Commercial Mobile Health Applications (Smartphone)	• Field notes • Interviews • Content Analysis	This study argues that the use of diabetes mHealth applications is low, possibly due to design and usability issues. The authors conducted a content analysis of field notes and patient comments obtained during a crossover trial which evaluated two different

Reference	Apparatus / Specific Technology	UX Methods / Metrics	Summary
			commercially available diabetes applications. Their results indicated that problems with data entry, data presentation, readability and overall ease of use were prevalent in the evaluated systems.
(Nguyen et al., 2020)	Commercial Mobile Health Applications (Smartphone)	• Systematic Review • Mobile Application Rating Scale (MARS)	This study generated usability scores for 75 commercially available mHealth applications targeting patients with diabetes using the Mobile Application Rating Scale (MARS). In addition, it provided a list of features supported by the reviewed applications. The authors concluded by stating that an ideal application should support automatic data transmission of glucose meter (e.g., via Bluetooth), a bolus insulin calculator, resources for carbohydrate counting, medication reminders and report sharing with HCP.

Table 2.3. Summary of findings on user experience and usability

Conclusions

This review

Chapter 3

Theoretical Framework

Work Domain Analysis (WDA) is a work system analysis and design method used to model the *fundamental problem space* of actors operating in a dynamic and complex work environment. It is part of a parent framework called Cognitive Work Analysis (CWA) (Figure 3.1), which emerged to fulfill the need for analyzing work systems that place high cognitive demands on their operators (Rasmussen et al., 1990, 1994; Vicente, 1999). And despite it being developed within the domain of industrial process control, the framework's abstract nature allows it to be applied to a variety of problem domains including those in the realm of information systems design (Salmon et al., 2010; Stanton et al., 2017; Vicente, 1999).

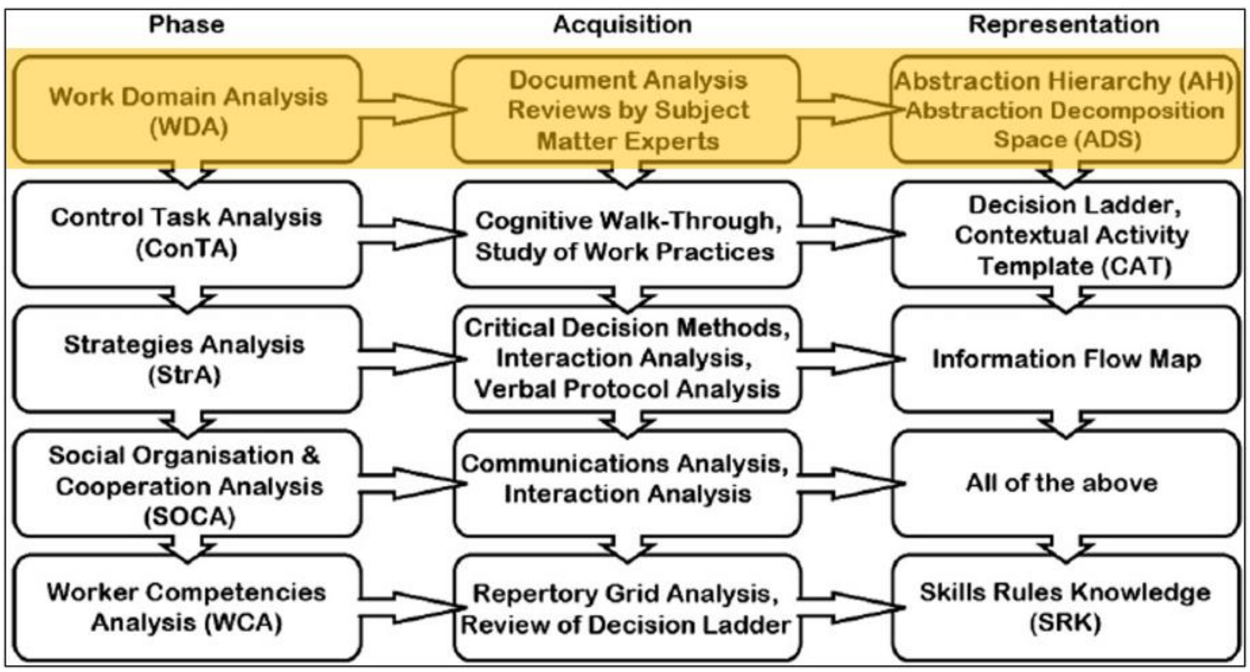

Figure 3.1: The CWA framework. WDA is the first method within the CWA framework. From (Salmon et al., 2010). Highlighting added.

As the first phase in the CWA framework, WDA aims to provide an event, actor and time independent description of the system under analysis, thus allowing analysts to identify the constraints that govern the work system as a whole. As such, and unlike descriptive approaches focusing on *work-as-done* or normative approaches that describe how work should be done, WDA is a formative method that focuses on the *domain of possible action*, i.e., what a system could do (Baxter & Sommerville, 2011).

In CWA, each phase models the constraints governing work from a unique perspective, thus representing *aspects* or *classes* of constraints. In WDA, the focus is on the constraints created by the work domain. Here, the notion of constraints refers to the enablers and possible trajectories of action within some work system as a whole. In other words, they are the parameters within which work is performed to achieve the system's purpose. Taking such a perspective in WDA facilitates the analysis of dynamic and cognitively demanding operational environments while also retaining their complexity. This non-reductionist approach allows designers to model, and possibly account for, new or unexpected situations, thus promoting resilience and design for adaptation (Fidel & Pejtersen, 2004). These features made CWA methods like WDA useful in safety-critical operational environments, such as is the case in healthcare (Rasmussen et al., 1990, 1994; Vicente, 1999).

When used in a design context, CWA methods depart from the norm which follows the *build* then *evaluate* sequence common in IS design research. Alternatively, and by viewing the problem through a systems lens, CWA methods thoroughly evaluate the focus work system first. The evaluation of the human-information interaction, or the *information behavior* in context yields recommendations for design, encapsulated in abstract design artifacts (i.e., meta-artifacts) that can be used in the instantiation and refactoring of concrete technical systems (Fidel & Pejtersen, 2004; Rasmussen et al., 1994; Vahidov, 2012).

WDA uses the Abstraction Decomposition Space (ADS) (Figure 3.2) as its main tool for modeling the problem space of actors. The ADS spreads the work system under analysis across two orthogonal dimensions: the abstraction dimension and the decomposition dimension.

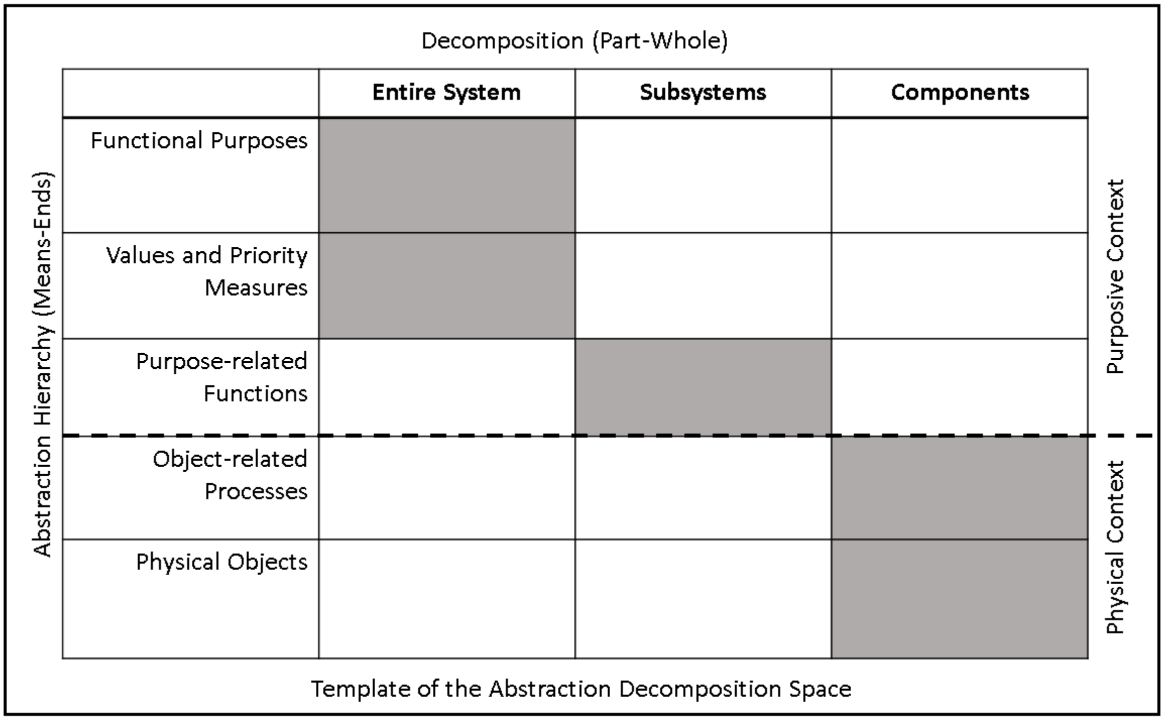

Figure 3.2. An illustration of a typical ADS. Shaded cells depict worker's reasoning trajectories. Adopted with modifications from (Naikar et al., 2005).

The abstraction dimension divides the constraints imposed by the work domain into purposive constraints and physical constraints. *Purposive constraints* are represented in the top three abstraction layers. These capture the functional purpose of the system, the values and priority measures it must keep, and the abstract and generalized functions it must implement to achieve its stated purpose. The work domain's *physical constraints* are depicted in the bottom two abstraction layers. These model the physical objects within the system and their affordances (Naikar et al., 2005; Vicente 1999; Rasmussen et al., 1994).

The decomposition dimension of the ADS (horizontal) models the system at different levels of detail from coarse (left) to fine (right). The left-most level of decomposition is concerned with the focus system as one single entity. Subsequent levels break down the system into sub-systems, modules, components, sub-components, informational content, etc. There is no specific guidance on the number of decomposition layers one can specify in an ADS. The level of detail highly depends on the purpose behind conducting the analysis. However, a typical decomposition hierarchy consists of three levels. Similarly, there is no set prescription on naming the abstraction dimensions as in the original CWA literature (Naikar et al., 2005). Researchers are afforded a good deal of flexibility in this avenue, and instances of such practice in the literature are not hard to come by (e.g., Payyanadan & Lee, 2021).

CWA methods, such as WDA, have been praised for integrating the contributions of several disciplines (e.g., systems engineering, cognitive decision making) in a way that makes their implications for guiding system design more salient (Vicente, 1999). The framework targets research and practical problems that can be characterized as high-risk, safety critical, dynamic and interconnected (Stanton et al., 2017). This is similar to what the DSR framework literature often refers to as “wicked” problems.

Positioning the DSR Framework for Work System Design

In chapter 1, I discussed how using the DSR framework without augmenting it with methodological guidance pertaining to artifact building often yields evaluation-dominant research. When that is combined with a tool-focused perspective to the ITA (i.e., the ITA as an instantiation), it compromises our ability, as design researchers, to contribute to design theory (i.e., generalized knowledge about IT systems). Given that, one is justified to question the ability of design research to contribute to knowledge that remains relevant as specific technologies become obsolete.

Here, I propose a pathway around the above-mentioned limitations. I augment the DSR framework by using CWA at its core – the design cycle. In doing so, I extend its ability to contribute to generalized knowledge about system design by utilizing the meta-artifacts that CWA produces (e.g., the ADS). In addition, I make the process that leads artifact building more transparent. In doing so, I seek to balance the scale towards artifact building activities. The resulting research framework is depicted in Figure 3.3.

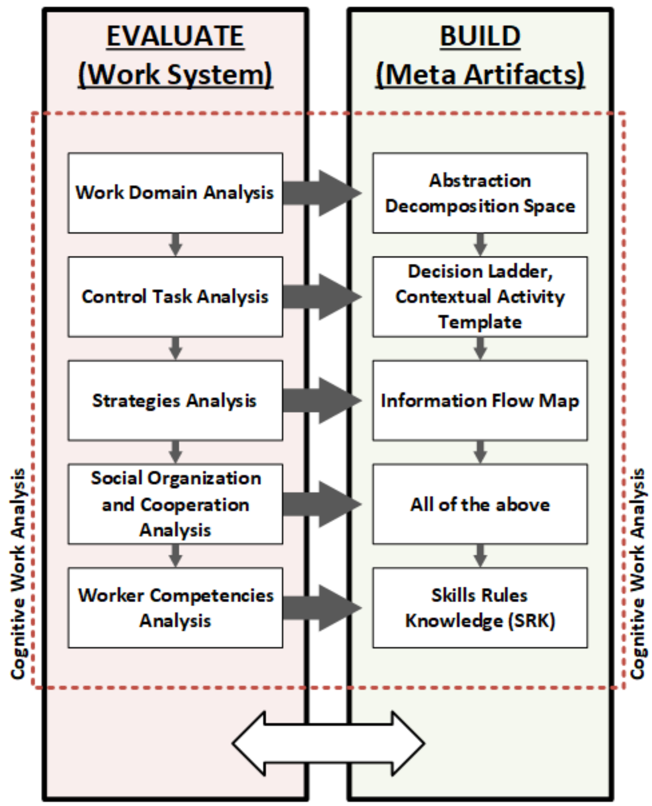

Figure 3.3. The heart of the DSR framework, augmented with CWA.

Study Objectives

The goal of this study is to construct a work domain model of a patient-facing active medication management intervention using WDA. Specifically, the model depicts the operational environment of the intervention in the context of a provider-guided remote care delivery intervention for insulin dose adjustment. Subsequently, the ADS will be used in the next chapter to inform the construction of a minimalist and low-friction instantiation targeting these patients.

Study Protocol

Sources of Information

I used public-domain documents, field notes and semi-structured interviews with patients and healthcare providers (HCP) to develop the ADS in small increments (Table 3.1).

Information Source	Description
Documents	**1.** Patient-facing publications including standard guidelines on self-care from credible sources (e.g., the American Diabetes Association). **2.** Technical manuals of diabetes home health devices (e.g., glucometers, insulin pens) as published by their respective manufacturers. **3.** Fieldnotes collected from two separate diabetes educational classes.
Semi-structured interviews	**1.** Four semi-structured interviews with elderly T2D patients on an insulin regimen administered via injection or insulin pen. **2.** Six semi-structured interviews with healthcare providers specialized in diabetes care, including diabetes nurse practitioners, certified diabetes educators and endocrinologists.

Table 3.1. Data sources used in developing the ADS.

Research Site

Research activities were supported by an outpatient diabetes care facility that is part of a large regional university medical center in southern California. See Appendix 2. The clinic has been accredited by the American Diabetes Association (ADA) for providing recent and accurate patient self-management education to people with diabetes. The clinic staff provides a list of medical and educational services in a number of avenues such as in advanced carbohydrate counting, glucose monitors, meal planning, insulin administration, dose titration, subcutaneous infusion pumps and general diabetes life skills.

Participant Eligibility Criteria and Recruitment

I targeted healthcare providers who are in close functional proximity to insulin dose initiation and adjustment in patients with T2D. This included endocrinologists, advanced diabetes nurse practitioners, registered nurses and certified diabetes educators.

Adult patients with T2D on an at least a once-daily dose of insulin administered via a syringe or pen were eligible for interviewing. Patients on a basal-bolus regimen were also eligible for interviewing. Patients equipped with a continuous glucose monitor, an infusion pump or those with Type 1 or gestational diabetes were excluded.

Ten (n=10) participants were interviewed. First, I recruited six (n=6) healthcare providers through referrals, via email or in person during my recruitment sessions at the diabetes clinic. In addition, I gave a number of brief recruitment presentations to diabetes patients attending the classes offered by the clinic. Recruitment activities took place between April of 2019 and August of 2021. A temporary halt in all human subject research activities occurred at the host institution due to the state and local restrictions imposed by the COVID-19 pandemic. Additional research compliance requirements largely pertaining to conducting safe fieldwork during the pandemic were met after which in-person and online interviews were resumed. Four (n=4) patients meeting the eligibility criteria agreed to participate in the study and were interviewed. The interviews took place in person in a designated office provided courtesy of the diabetes clinic or remotely via audiovisual conferencing. Audio recording was used during the interviews. I transcribed the audio and omitted all identifiers in compliance with the approved research protocol and the associated data transfer agreement with the host institution.

Interview Guide

The interview guide was initially developed using the guidance and suggested prompts provided in (Naikar et al., 2005). Subsequent interviews led me to tune the guide in areas that mainly pertained to language. Additionally, I needed to increase the focus on the purpose-related functions of the system during expert discussions. As such, this part of the interview was given more time after the first two interviews. The interviews followed a semi-structured to open-ended format and lasted between 35 and 55 minutes. There was a slight deviation in execution (i.e., order of topics and topic-time allocation) from one participant to another.

Data Analysis and Coding Structure

Naikar et al. (2015) list a number of keywords that are frequently used to describe the layers of abstraction in an ADS. These keywords were used as guidance to develop the coding structure and in coding the documents, field notes and interview transcripts. I used a combination of tools including NVivo 12, spreadsheets and Voyant Tools to code and analyze the narratives. Table 3.2 contains keywords used to develop the coding structure and to code the data.

Research Funding

Funding for this research, including research equipment, software licenses and research participant compensation was provided by Claremont Graduate University (CGU) in the form of a dissertation grant awarded to PhD candidates who embrace a transdisciplinary approach in their research and develop a compelling and feasible project. The grant application was filed under the supervision of Dr. Brian Hilton and was awarded $7,050 (U.S. Dollar – USD) on May 3rd, 2018, by the office of transdisciplinary studies at the university.

Abstraction Layer (Main Codes)	Keywords
External constraints (EC)	Laws, regulations, guidance, standards, directives, requirements, rules, limits, public opinion, policies, values, beliefs, views, rationale, philosophy, norms, conventions, attitudes, customs, ethics, morals, principles.
Functional Purpose (FP)	Reasons, goals, objectives, aims, intentions, mission, ambitions, plans, services, products, roles, targets, aspirations, desires, motives, values, beliefs, views, rationale, philosophy, policies, norms, conventions, attitudes, customs, ethics, morals, principles.
Values and Priority Measures (VPM)	Priority measures: criteria, measures, benchmarks, tests, assessments, appraisals, calculations, evaluations, estimations, judgements, scales, yardsticks, budgets, schedules, outcomes, results, targets, figures, limits, measures of effectiveness, efficiency, reliability, risk, resources, time, quality, quantity, probability, economy, consistency, frequency, success. Values: laws, regulations, guidance, standards, directives, requirements, rules, limits, public opinion, policies, values, beliefs, views, rationale, philosophy, norms, conventions, attitudes, customs, ethics, morals, principles.
Purpose-related Functions (PRF)	Functions, roles, responsibilities, purposes, tasks, jobs, duties, occupations, positions, activities, operations.
Object-related Processes (ORP)	Processes, functions, purposes, utility, role, uses, applications, functionality, characteristics, capabilities, limitations, capacity.
Physical Objects (PO)	Artificial and natural objects: tools, equipment, devices, apparatus, machinery, items, instruments, accessories, appliances, implements, technology, supplies, kit, gear, buildings, facilities, premises, infrastructure, fixtures, fittings, assets, resources, staff, people, personnel Inventory: names of physical objects, number, quantities, brands, models, types. Material characteristics: appearance, shape, dimensions, color, attributes, configuration, arrangement, layout, structure, construction, make up, design.

Table 3.2 A sample of the keywords. Adopted from (Naikar et al., 2005).

Participant Compensation

Patient participants received a $25 USD prepaid gift card for their participation. Healthcare providers received a $100 USD prepaid gift card for their participation. Compensation was awarded upon interview completion.

Document Review

I conducted document analysis to develop an initial sketch of the ADS based on patient-facing materials available in the public domain (Naikar et al., 2005). The rationale was to explore the problem using readily available information prior to engaging in more resource-intensive data collection activities such as subject matter expert (SME) interviews. I used evidence-based self-care guidelines from credible sources, patient education handouts provided by the diabetes clinic, and user manuals of commercially available glucometers and insulin administration devices as published online by their manufacturers.

There is an overwhelming amount of public-domain information within this problem space. Materials that are topically relevant were selected for review. The retrieved materials had to fulfill a number of criteria (Scott, 2014). First, I verified the *authenticity* of the material by retrieving information directly from a verified domain address that is registered to the publishing entity. Second, the *credibility* of the list of sources I used was discussed with three care team participants. These discussions were off-the-record except for one participant (HCP 1 – see Table 3.4). The final list was reduced to 5 sources (Table 3.3).

Type of Document	Sources	Topics
Patient-facing evidence-based self-care guidelines from credible sources.	1. American Diabetes Association 2. Association of Diabetes Care and Education Specialists (ADCES)	• Type 2 diabetes Self-care guidelines • Medication taking • Lifestyle • Insulin

	3. National Library of Medicine (Medline Plus) 4. Centers for Disease Control and Prevention (CDC) 5. Patient handouts provided by the host clinic	• Self-monitoring • Diabetes skills
Technical manuals and operating procedures pertaining to glucometers, insulin administration devices (e.g., insulin pen).	As published online by the device manufacturer.	• Operating instructions • Maintenance requirements • Medical waste disposal • Features • Compliance

Table 3.3. Document categories, topics and sources

Healthcare Provider Interviews

Healthcare provider interviews (see Table 3.4) were useful for expanding and refining the initial ADS sketch. In particular, a deeper understanding of the external constraints of the work system was gained as will be discussed below. This aided in crafting a better articulation of the system's functional purpose. Furthermore, numerous factually incorrect aspects in the initial model were rectified, including, for example, aspects pertaining to the role of carbohydrate counting in insulin treated T2D.

Handle	Title	Education, Training and Credentials	Specialty	Years in Practice
HCP 1	Adult Nurse Practitioner	DNP, MSN	Endocrinology, Pharmacological Management	25+
HCP 2	Physician	MD	Endocrinology, Diabetes and Metabolism	5+
HCP 3	Diabetes Educator	BSN, RN	Diabetes Care and Education	15+
HCP 4	Certified Diabetes Educator	RN, CDCES	Diabetes Care and Education	5+
HCP 5	Certified Diabetes Educator	PHN, BSN, RN, CDCES	Diabetes Care and Education, Pump Trainer	5+

Handle	**Title**	**Education, Training and Credentials**	**Specialty**	**Years in Practice**
HCP 6	Certified Diabetes Educator	BSN, RN, CDCES	Diabetes Care and Education	5+
Abbreviations: DNP, Diabetes Nurse Practitioner. MSN, Master of Science in Nursing. MD, Medical Doctor. BSN, Bachelor of Science in Nursing. RN, Registered Nurse. CDCES, Certified Diabetes Care and Education Specialist. PHN, Public Health Nurse.				

Table 3.4. Healthcare Provider Participants

Patient Interviews

Patient interviews (Table 3.5) contributed mainly to understanding the end user persona.

Handle	Patient Profile
Patient 1	Age = 65+ 13 years since diagnosis 12 years on insulin / long acting, twice daily (70 units AM, 65 units PM) Oral diabetes medication: metformin / twice daily Last A1c = 6.7% Income (<25,000 USD/year) Insured / No coverage for diabetes equipment. Medicare. Other medications: Yes • Cholesterol • Hypertension Total number of medications: 5 Education: College
Patient 2	Age = 50+ 7 years since diagnosis 4 years on insulin / basal, once daily Last A1c = 9.3% (uncontrolled) Income (>75,000 – household) Insured / Covered / Family Oral Diabetes Medication: Yes • Glipizide / twice daily • Metformin / twice daily Total number of medications: 3 Education: Master's degree
Patient 3	Age = 60+ 5 years since diagnosis 2 years on insulin / Intermediate acting pre-mixed pen, 35 units twice daily, pre-meal. Last A1c: Not recent, was 13%+. Income: 50,000+ Insured / Covered / Employer Oral Diabetes Medication: Yes • Jardiance (Empagliflozin) Education: Master's degree
Patient 4	Through family caregiver. *Omitted upon participant's request*.

Table 3.5. Patient Participants

Work Domain Analysis

The boundaries of the focus work system are drawn around the self-care environment surrounding T2D patients initiating or intensifying insulin under the supervision of their care provider. This includes both the cultural (i.e., purposive) and material (i.e., physical) elements of that work system.

External Constraints and Functional Purposes

I identified **insurer practices** and **healthcare provider resources** as salient external constraints imposed on the work domain. These two interact in such a way that rationalizes the development of the proposed intervention. For instance, insurers utilize a number of evidence-based health metrics to codify coverage for basic diabetes services such as routine follow-up visits. Under these circumstances, caring for those who need additional support in the interim period between covered visits becomes a challenge because provider resource allocation (e.g., patient scheduling) is often shaped by the coverage guidelines of the insurers. A number of healthcare team members acknowledged this issue and further discussed its negative impact on that particular set of patients requiring closer and more frequent attention (e.g., during insulin therapy initiation).

> **HCP 1:** [Insurer] guidelines say [every] three months because you're checking the A1c. So, the challenge becomes when you need to see somebody before the three-month timeframe, you don't usually have the availability to schedule patients because the clinics are booked.

This goes in line with the previously discussed views arguing that the influx of patients seeking treatment can overwhelm conventional care delivery. Both patient and healthcare team participants discussed this issue during the interviews, mostly without prompting. One team member indicated that the clinic was fully booked for the next six weeks. They added that *"*... [the clinic is] only taking risk management patients … because they're so busy.*"* (HCP 6). Risk management patients are those covered under the institution's employee insurance[3]. Another HCP discussed the case of one of their patients, indicating that their next follow-up appointment is in sixteen weeks!

Much of the above can also be derived from the discussions I had with the patients. This was especially the case among those with lower incomes. For example, one patient complained about their insurance not only in terms of coverage for in-person visits, but also in terms of sufficient reimbursement for basic diabetes supplies such as glucose testing strips. When I asked whether they believed this issue has had a negative impact on their health, their response was affirmative.

> **Interviewer**: Do you believe [that] not being sufficiently covered has negatively affected your ability to take care of yourself?
>
> **Patient 1**: I'm going to say yes.

Given this context, there was a good level of agreement among the participants that the proposed IT solution could bridge the gap between the patients and their care provider, especially in the domain of medication titration. Some added that it would also relieve some of the burden on the provider side.

> **HCP 1:** … it would save time if they had some form of technology that we could see [the patient] in between the three-month timeframe, make the changes [to their regimen], and they don't have to physically be in the office.

---

[3] The host institution is a self-insured organization.

Another participant listed a number of channels that they currently use to communicate regimen adjustments to their remote patients, including a cloud-based service.

> **Interviewer:** Do you believe that this process [insulin titration] can be done remotely without the patients being present [in-person]?
>
> **HCP 2:** To a certain extent, yes, I think so. I mean, we do it a lot here in the hospital. For instance, we have a lot of information in the computer and a lot of the patients that are in my list, some of them, I don't really physically see them every day, but I do make adjustments.
>
> **Interviewer:** How are they, exactly, made aware of a change that you've made to their regimen?
>
> **HCP 2:** Right now? Either a message using the My Chart service that I was telling you [about], or over the phone.

The participant proceeded to complain that, despite having these channels in place, many patients fail to reach out when necessary.

> **HCP 2:** I think it's pretty easy to communicate. I'll say most of them don't do that. No. I ask them to do it and not a lot will communicate back. Let's put it this way, you open the door and offer but they don't send you a message.

HCP 2 added that some patients still deposit hand-written notes at the front desk because they cannot use the available web-based system. Another participant stated that not all patients have access to, or know how to use, the available web-based system. When probing for an articulation for the functional purpose of the system, the majority pointed at its potential to bridge the communication gap discussed above.

> **HCP 6:** I think the biggest barrier for them being adherent is, I don't think

that we have that, like I said, that physician-patient closed loop... That would be life changing, because I think that would help prevent re-hospitalization.

> **HCP 5:** If you can get something that captures that and that bridges that gap between providers and patients [with] reminders and things like that, I think it will be very well received.

Given that, I identified **aiding provider-guided remote insulin dose adjustment** as the chief function of the proposed IT intervention.

Values and Priority Measures

First, a number of care providers suggested that offering a degree of **tailoring** is essential and could greatly benefit their patients. A special emphasis was placed on tailoring for tasks that are considered demanding from a cognitive point of view. One recurring example of that was determining insulin dose requirements while on a sliding-scale regimen. For instance, one nurse complained that some patients still executed their insulin regimen incorrectly despite receiving an abundance of instructional materials and training at discharge.

> **HCP 6:** Even when we discharge them from the hospital, we discharge them with <u>this much</u> [gesturing a large stack of] paperwork.

This participant added that providing specific instructions tailored to the patient's individual case could help boost their chances of executing their regimen as prescribed.

> **HCP 6:** If they could open [the application] up and show the color of <u>their</u> [insulin] pen and the name, really big, and then show, "Take this [many] times a day", and the dosing, that would make it much easier for the patient.

The notion of tailoring was also present in the course of discussing the problem of adherence to routine lab tests. Most notably, A1c test reminders were explicitly requested, in addition to reminders for other tests such as kidney function and lipids.

> **HCP 5:** Another thing that will be good is also some notification when their A1c [test] is due.

Less recurring examples of tailoring included providing model-specific glucometer instructions, supporting injection site rotation and providing multi-language support.

Another frequently discussed idea pertained to **supporting patient adherence**. Here, a number of participants argued that providing *actionable cues* to the patient to aid them in the decision-making process is somewhat necessary for this particular demographic.

> **HCP 5:** Then my app also needs to tell me: "Tonight", or: "tomorrow morning, take 16 [units of insulin] instead of 20

Suggestions for the delivery of actionable cues included delivery in textual form (i.e., through messaging), or via interface manipulation. Some even suggested the use of audible cues, including human voice.

> **HCP 5:** For example, we like patients to be between 80 to 180 [capillary BG], right? 70 to 180, if you will. So anytime that they're out of range, it could be if it's under 200, you can make the number yellow, right? Let's say you're 188, the number is yellow. If you are 122, the number is green. And then if you're 250 or above 200, whatever you want to put as capping, that is red. And then if it's above 400, then it can have some sort of alert or something like a sound or something [saying] that you are above 400, you better go call your doctor, go to urgent care, go to the ER, seek some sort of medical attention.

Numerous other participants discussed adherence support for self-care tasks other than medication taking. For instance, many suggested providing aid to the patient in the context of capillary BG sampling. This included both the procedural and the scheduling aspects of the SMBG routine.

> **HCP 4:** I would say the biggest thing with a glucometer is that … they don't talk. There is one glucometer that talks. However, for them to even see which side of the strip they're putting in … you need a magnifying glass or something! Or if they're completely blind, it's really hard, it doesn't say, "Strip in backwards, strip in upside down" or something like that, you know?

Finally, multiple references call for implementing measures to **reduce patient risks**. As such, patient safety emerged as an overarching value in the analyzed information. This was especially the case in the context of insulin titration which is an inherently safety-critical task. Public domain documents, for instance, dedicate a considerable amount of space to instruct patients on recognizing and rectifying hypoglycemia. Care team participants also identify hypoglycemia as the top priority risk to mitigate throughout the medication titration process. For instance, a participant suggested implementing measures to reduce the risk of hypoglycemia by informing patients with such medical history to *withhold the dose* if their capillary blood sugar was closer to the lower bounds.

> **HCP 6:** If they [the patient] plug in their sugar, and their sugar was 80 [mg/dL] and the doctor feels it's not safe because they know that that particular patient already has a history of hypoglycemia, to say: Do not take insulin at this time.

Domain Functions (Purpose-related Functions)

Salient high-level domain functions in this vein include (1) medication management, (2) self-care task support, and (3) patient data tracking. References pertaining to medication management discussed covering insulin as well as other antidiabetic medications. Some also suggested covering medications for associated comorbidities such as hypertension. Ample references to the parameters of interest, such as medication type (e.g., injectable), dosage, timing (e.g., in relation to meal, time of day) and side effects were present in the analyzed information.

> **HCP 6:** Probably having a feature where they can plug in their blood sugars, and then it can tell them how much insulin to take. Because for the sliding scale [regimen], I think you should give them the little calculation dose, five plus three, and give them [the] eight**…** If your audience is type two diabetics, the great majority of them are on pills, so I think it is important that you say, for example, when you click, when you have a little icon that says pills, or something simple.

Support for self-care tasks was also widely suggested. This includes supporting the self-monitoring of vital signs, lancing and injection site rotation as well as supporting routine care activities that are performed in a clinical setting.

> **HCP 2:** We always ask them to feel for any lumps or bumps, if it's tender not to use [that site for injection] ... Also, not to go over maybe a visible vein or rotate the [injection] site.
>
> **HCP 3:** Definitely checking their kidney function. In some cases, it depends on the medication, check the liver function. They should [also] do oral hygiene with a dental hygienist about every three to four months.

While multiple participants tended to favor implementing elaborate features to support numerous routine care tasks, others suggested to avoid overwhelming the typical patient. For instance, one care provider argued that supporting self-care tasks would help *some* patients, but obviously not everyone. In their experience, only a certain type of patient would have the right level of engagement needed to benefit from the system. They cited a number of factors in this context, one of which is rooted in the patient's intrinsic motivation. As such, they suggested that I pursue a *bare minimum* design to avoid overwhelming the *typical* patient.

> **HCP 4:** But for the typical [patient], it's like: I barely want to eat the way you're telling me [to eat].

Patient sentiment does not depart much from the above-mentioned. Narratives in this area reflect a degree of willingness to use an aid to help simplify complicated self-care tasks. One chief concern, however, pertained to learning a potentially complicated new technology.

> **Patient 3:** I would be willing to give it a try as long as somebody can patiently walk me through the technology piece of it. I like to learn new things and if it's something that would help me do a better job of taking care of myself, I would be willing to try it.

Lastly, matters pertaining to the handling of patient data, such as capillary BG and other vital sign logs, along with medication intake, were classified under the theme **patient data tracking**. This covers the data of interest itself along with the requirements pertaining to its storage, transfer, validation and presentation. Multiple previously quoted references point to this area as a core domain function of the system. The following quote shows an example of how participants specified requirements pertaining to the transfer of patient data.

> **HCP 3:** Definitely blood sugar log. This is a must.” They also added “Another thing, a log for insulin … that they can send direct to the doctor.

Staff participants discussed the importance of having an *up-to-date image* of the patient’s health status. In their view, this is essential to the provision of relevant and timely adjustments to their patient’s regimen. Some even suggested tracking the patient in near real-time:

> **HCP 5:** So, if your app can do the [capillary] sugars and the A1c straight to the provider. And for them to be flagged to call the patient and say “Hey, we need to change your Metformin, we need to go ahead and add another medication.” Or “Your A1C is super high we need to start you on insulin. Your insulin is not enough.” Or “Your insulin is too much. We see that you are running 65/50 all the time” …that app will be great!

References to the concrete metrics that must be tracked included both those obtained in a self-monitoring context (e.g., capillary BG, blood pressure, weight) as well as in a clinical setting (e.g., A1c, renal function test results).

> **HCP 2:** For sugar control, there's two main variables: one is the A1c, obviously, everybody tells you that. Then the other one [is] the blood sugar variability.

Another participant explained the importance of having a recent A1c and a capillary BG log available *at a minimum* in order to make decisions pertaining to the patient’s regimen.

> **HCP 6:** I had a patient one day came over, we did his A1c, and it was 6.3. I said, “Mr. So-and-So, I am so excited for you. Your A1c looks great.” He's like, “Oh yeah, but I don't feel very good. My sugars are all over the place.” I said, “Let me see your [sugar] log.” When he gave me his log, I almost fell off my

chair. He had blood sugars in the 300s and 400s and then sugars in the 50s and 40s.

Others discussed tracking metrics that can be derived from the ones mentioned above. For instance, one participant suggested tracking (i.e., instance counting) the incidents of hypoglycemia and hyperglycemia every time a patient BG measurement is recorded. Another participant suggested tracking patient adherence to routine outpatient care requirements such as frequent dental care.

Technical Functions

This is the first set of constraints within the physical domain of the ADS. As such, one will notice how the meaning these labels deliver is somewhat "closer to the metal". Table 3.6 is a list of the salient technical functions that I identified in this vein. WDA literature frequently uses the label *object-related processes* for these functions (Naikar et al., 2005).

By definition, technical functions (TF) depict the specific capabilities supported by the physical resources and materials within the focus system (Lintern, 2016). It is worth mentioning that even though the patient aid itself is not explicitly modeled in the ADS[4], however, the orchestration the functions depicted within it delivers the capabilities of the intervention as a whole. For instance, supporting medication intake and capturing vital signs is a grouping of individual object capabilities orchestrated in such a way that generates value exceeding the mere sum of the parts. This observation will become much clearer in the course of discussing the expository instantiation in Chapter 4.

Function Name	Definition	Decomposition
TF1: Support Medication Intake	A grouping of system object capabilities that	TF 1.1: Dose Calculation TF 1.2: Communicate Changes

[4] This is a design decision. The reason behind not explicitly modeling the aid itself is an effort to be abstract. In doing so, the ADS can be used to guide instantiating aids without regard to specific platform.

	provides support for medication-taking tasks.	
TF2: Capture Vital Signs	A grouping of system object capabilities that provides support for capturing vital signs from patient's premises devices.	TF 2.1: Capture Blood Glucose TF 2.2: Capture Blood Pressure TF 2.3: Capture Weight TF 2.4: Capture Metadata TF 2.5: Report Safety Alerts
TF3: Manage Patient Data	A grouping of system object capabilities that provides support for keeping record of the patient's data and making them available for care provider review.	TF 3.1: Logging TF 3.2: Synchronization TF 3.3: Presentation
TF4: Run Patient Routine	A grouping of system object capabilities that provides support for scheduling, sequencing and actuating the care routine.	TF 4.1: Scheduling TF 4.2: Sequencing TF 4.3: Actuation

Table 3.6. The System's Technical Functions

Material Form

This set encompasses the resources and materials that are necessary, and sufficient, for performing work within the system. This includes both physical and informational resources. A single TF may use a subset, or the entire set of capabilities afforded by these objects. It may also utilize a combination of capabilities from two or more objects. Table 3.7 provides the objects I identified that insulin-requiring patients interact with as part of their self-care routine.

Object	Definition
OBJ 1: Glucose Monitor	Reads, displays and/or transmits capillary blood glucose measurements and measurement metadata.
OBJ 2: Blood Pressure Monitor	Reads, displays and/or transmits blood pressure measurements and measurement metadata.
OBJ 3: Weight Scale	Reads, displays and/or transmits capillary blood glucose measurements and measurement metadata.

Object	Definition
OBJ 4: Insulin Kit	Contains the insulin-related properties such as medication-specific information, administration information, along with the administration kit and its properties.
OBJ 5: Other Medication	Contains the properties related to medication other than insulin. This includes the medication-specific information, what it is used for, and the information pertaining to its storage, disposal and preparation.
OBJ 6: Care Routine	Contains the regimen instructions pertaining to vital sign self-monitoring and medication intake. This includes the procedural and scheduling aspects.

Table 3.7. The system's physical objects and their decomposition.

Discussion

The main product of WDA is the ADS. It is an analytical tool that depicts the system's functional structure across various levels of abstraction and at multiple levels of detail (i.e., decomposition) (Naikar et al., 2005; Vicente, 1999). Within the abstraction dimension, a typical abstraction hierarchy (AH) consists of five layers, each of which can be thought of as a different analytical lens.

The links between the different layers within the AH represent a means-ends relationship where the lower layers provide the means to achieve the ends at the layers above it. This relationship can be read in either direction. Going from the bottom towards the top, the ADS addresses questions relating to the rationale behind performing work (i.e., why-type questions), while going from top to bottom reveals the resources available to perform work (i.e., how-type or what-type questions). See Figures 3.4 and 3.5).

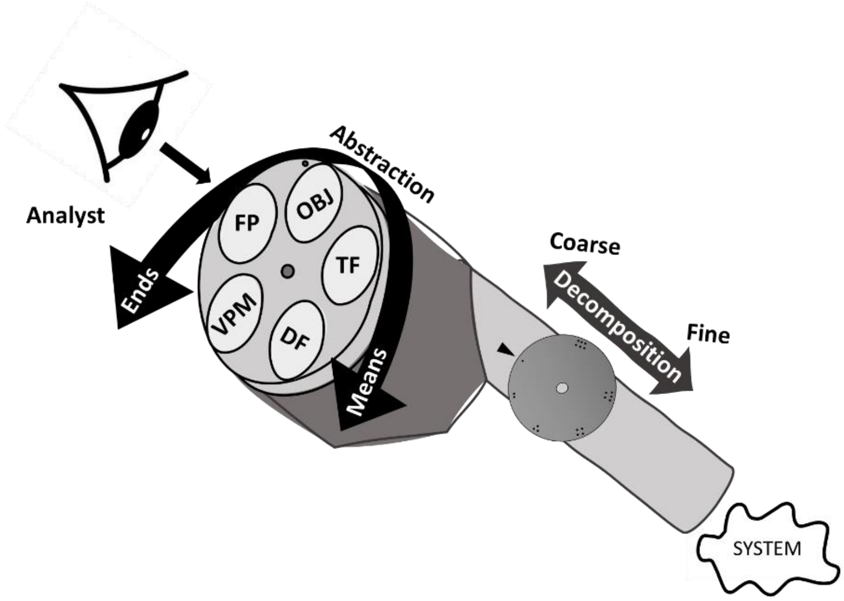

Figure 3.5. Illustration of WDA.

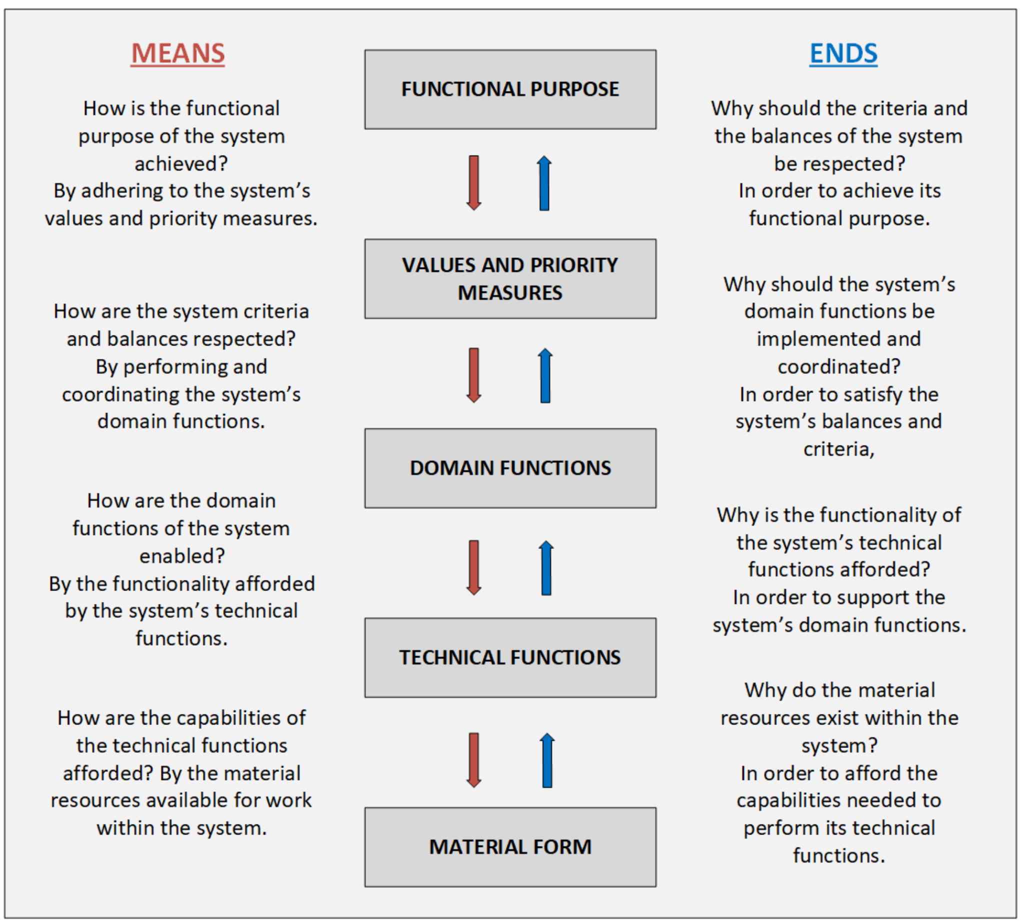

Figure 3.6. Why-type and How-type questions addressed by the ADS

Mounting the first abstraction lens reveals the system's functional purpose (FP) in light of the constraints imposed by the external environment. WDA literature points out that identifying the external constraints that shape work leads to an articulation of the gap that the system intends to bridge. When this gap is defined, it aids in generating an articulation of the system's FP. This process can vary depending on the nature of the system, the purpose from the analysis, and whether the system is actuated by natural laws (i.e., causal) or is less formal and more intentional (e.g., socio-technical systems).

Consider the AH for the proposed remote insulin dosing system (Figure 3.4). The high-level FP of the system is to facilitate remote insulin dose adjustment in a provider-guided environment (FP1). This was reached in the course of discussing the constraints imposed by insurer policies and practices and by healthcare provider capacity (i.e., scheduling and staff availability). These two limitations form the rationale for the system's existence.

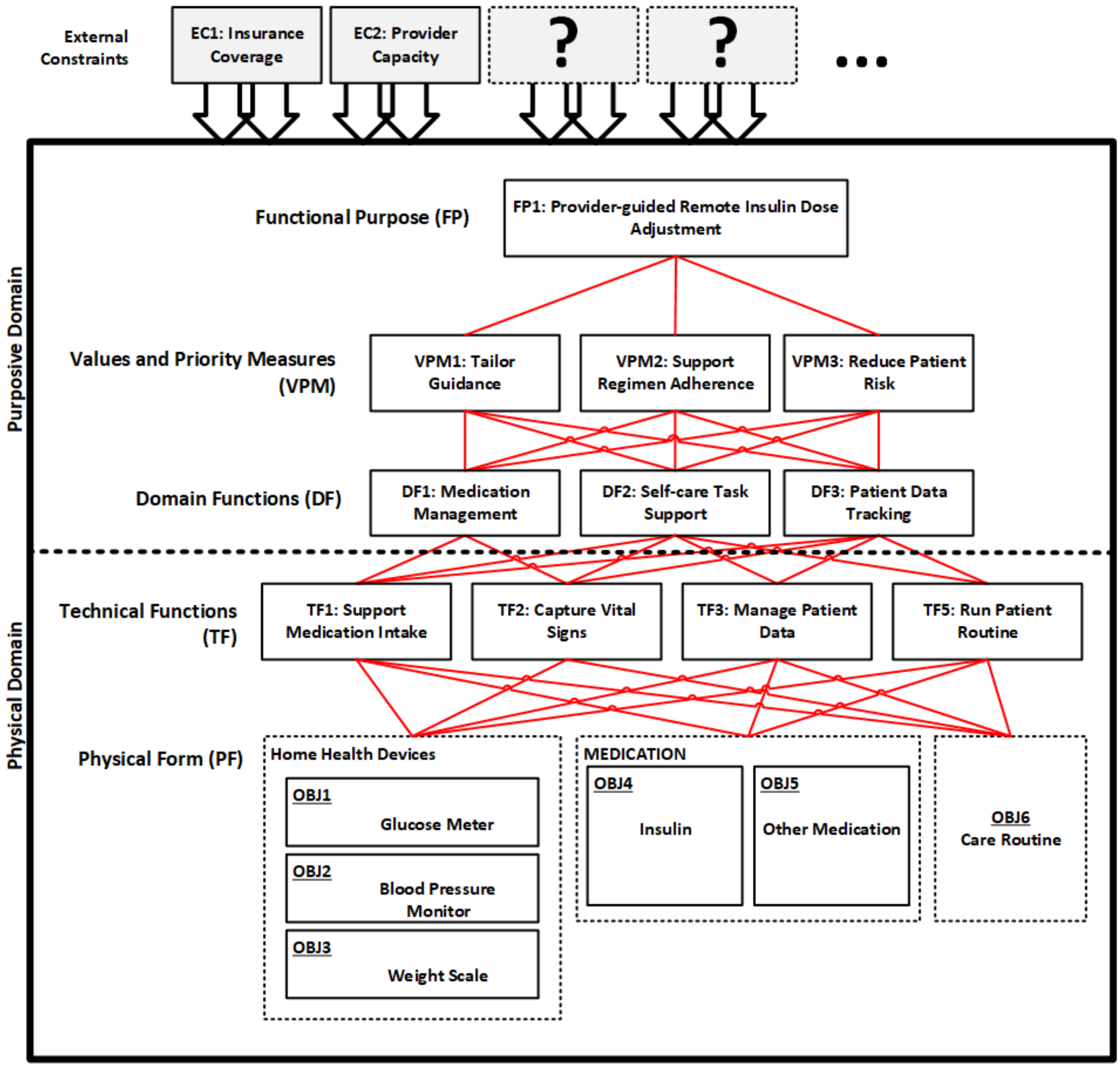

Figure 3.6: High-level abstraction hierarchy of the system

The second lens, *Values and Priority Measures* (VPM) is concerned with the rules, balances and conditions that must be respected by the system in order to achieve its stated FP. As seen in the system's AH, three salient system values must be observed. First, the system must provide tailored guidance (VPM1) that is specific to each patient's unique case. This is key to alleviating the patient's cognitive burden. Second, the system must support the patient's regimen adherence (VPM2). At a high level, this is inclusive of medication taking and self-care routines. It also handles adherence from a procedural perspective (i.e., compliance) as well as from a persistence point of view (Cramer et al., 2008). Third, the system must strive to mitigate and reduce patient risk by observing various safety metrics (VPM3). These mainly pertain to monitoring and mitigating the risk of hypoglycemia and severe hyperglycemia among the target patient population. These three high-level functions delineate the space of acceptable system operation (Figure 3.7).

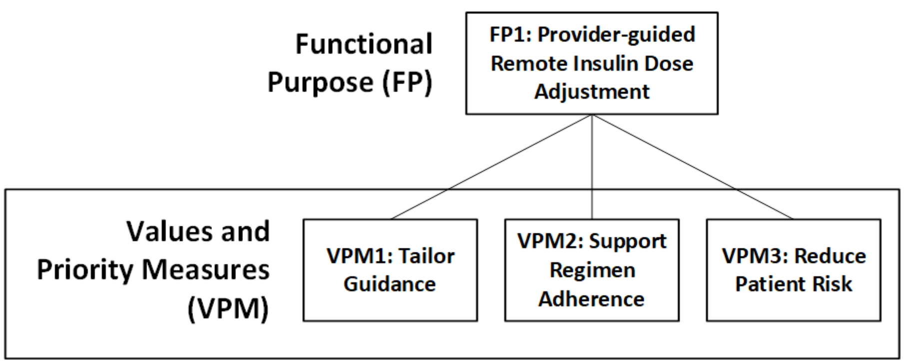

Figure 3.7. System Values and Priority Measures

The third analytical lens, domain functions (DF), depicts the means by which the stated FP is achieved through respecting the system's criteria (i.e., VPM). To qualify under this category, constraints must satisfy two conditions. First, they must carry a specific implication of meaning in relation to the stated purpose of the system. WDA highlights this criterion by frequently using the label *purpose-related functions* (Naikar et al., 2005; Vicente, 1999). Second, domain functions must always be depicted independent of a particular technology or platform (Lintern, 2016). If they contain attributes that are technology dependent, they likely belong in the next layer (i.e., technical functions). Consider, for instance, the **medication management** function (DF1)**.** It is an abstract label that is not explicitly dependent on a particular physical platform. The same can be said about **self-care task support** (DF2) and **patient data tracking** (DF3)**,** both of which carry an implication of meaning at the purpose level yet do not specify the technical and material resources required to achieve it.

The fourth abstraction layer contains the system's technical functions (TF) (Figure 3.8). By definition, these represent the specific capabilities afforded by the material resources within the system (Lintern, 2016). Functions in this category act as a middle layer between the system's purposive domain and its material resources. They do so by laying the means to achieve the system's purposes at a technical level of detail. For instance, the system's AH shows that medication management at a domain level (i.e., DF1) relies on a number of technical functions, one of which is concerned with supporting medication intake (TF1). Here, TF1 represents a logical grouping of capabilities and limitations, organized in such a way that provides the means to achieve medication management at a technical level. Another technical function that is essential to medication management is concerned with capturing the patient's vital signs (e.g., Capillary BG in mg/dL, systolic blood pressure) (TF2). As noted earlier, even though the patient aid itself is not explicitly modeled in the ADS, the orchestration of the ADS functions produces the capabilities of the aid being modeled.

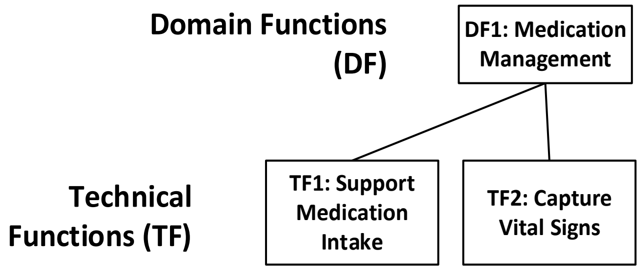

Figure 3.8. Medication management and the technical means to achieve it.

Finally, the materials layer (OBJ) lists the physical resources, objects and materials that are necessary, and sufficient, to perform work within the system. These include material objects (e.g., tools and equipment) and their informational properties. For instance, capturing a patient's vital sign (TF2) utilizes the capabilities afforded by home health devices (OBJ1, 2 and 3) in conjunction with the instructions pertaining to their use as encoded in the patient's self-care instructions (OBJ6).

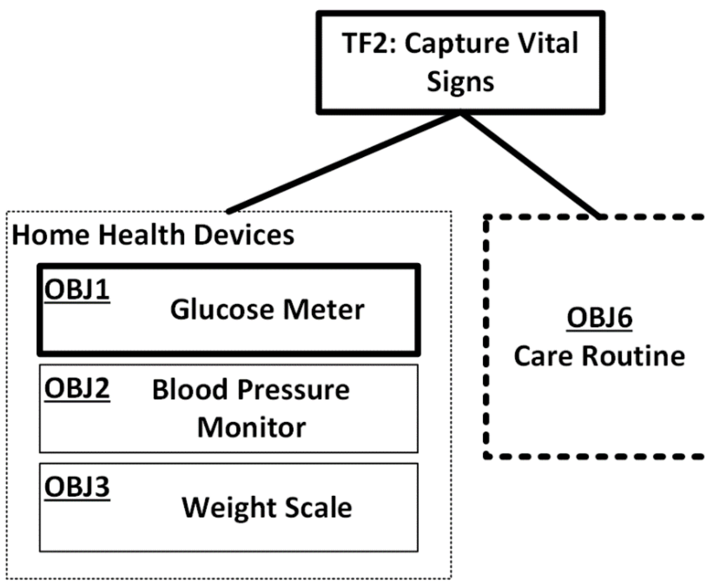

Figure 3.9. Capture vital signs and the resources it consumes (abstract).

Some means-ends links may not be as evident at a coarse level of detail. For instance, the relationship between TF2 and the material resources it uses (see Figure 3.9) becomes clearer when instantiated with a specific patient scenario. Here, decomposing the system aids in making the specific informational content and technical capabilities needed to perform that scenario more salient. See Figure 3.10.

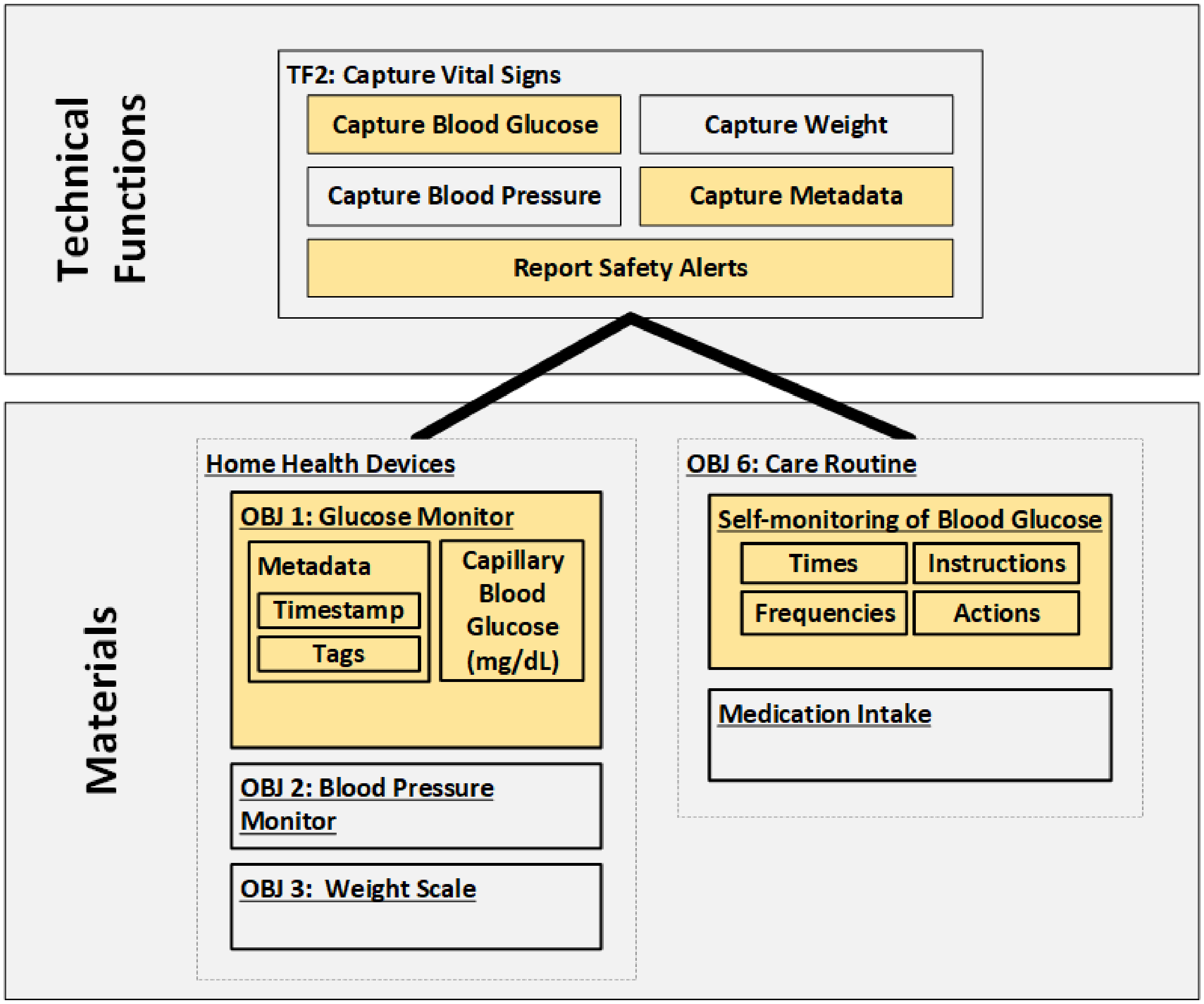

Figure 3.10. An instantiation of ADS showing the blood glucose measurement scenario.

WDA uses the term *function* in reference to a structural property of the system, not to a particular mechanism through which work is produced within it (Lintern, 2016; Naikar et al., 2005). Analysts also use the term *constraint* to denote a grouping of related attributes that enable and govern work in some salient functional area within the domain.

This separation between structure and action is a distinguishing feature of WDA. Indeed, WDA does not explicitly address activity, nor does it intend to do so, yet it serves as an *analytical tool* that can be utilized in the planning of work. It achieves that by identifying the resources available for action along with the constraints imposed on it. This allows system analysts to account for all the possible trajectories of work, including those which are unanticipated.

WDA literature often uses the analogy of a geographic map versus specific turn-by-turn instructions for a route on that map. Unlike route instructions, a geographic map shows all the possible routes of action to get to the final, and hopefully, the intended destination. WDA is often praised for taking such a non-reductionist approach as it is able to bring order into the complexity that characterizes socio-technical systems but without sacrificing any of its details. See Appendix 3 for the full system ADS for the focus system.

Chapter 4

Expository Instantiation

Study Objectives

In this chapter, I use the previously developed ADS to guide the design of a high-fidelity patient aid on a mobile platform. Because WDA does not explicitly focus on activity, I used Hierarchical Task Analysis (HTA) to capture and model the user tasks. This adds an element of procedure to an otherwise static-structural view of the system. I then map the specific ADS resources to their corresponding task structures. Lastly, I conduct a simple usability inspection using a modified version of Heuristic Evaluation (HE) with seven evaluators (Inostroza et al., 2013; Nielsen, 1992; Nielsen & Molich, 1990).

Theoretical Background

Hierarchical Task Analysis

HTA is a simple task modelling technique that was developed in response to the need for analyzing work processes within complex operational environments (Annett, 2004; Stanton, 2006). It describes work (i.e., activity) as a hierarchy of goals, sub-goals, operations and plans. As such, the technique provides for decomposing tasks as far as the analyst deems useful and depending on the purpose of the analysis. The end-node in an HTA tree is always an operation. The *plans* part dictates the sequence by which the operations and subgoals are executed. Sequences can be linear and they can also include loops and conditionals. This process yields an exhaustive description of the task under analysis.

The method has its roots in the control theory of human behavior as described by Miller Miller et al. (1960, 1968). The authors argued that a scientific account of behavior must always begin with defining an *elementary unit of analysis* that can be used to describe complicated phenomena, such as in complex adaptive systems, as lawful compounds (Miller et al., 1960, 1968).

In HTA, the fundamental unit of problem solving is called a TOTE unit (Test-Operate-Test-Exit). TOTE units model the thought pattern of actors as they attempt to achieve some goal (Figure 4.1).

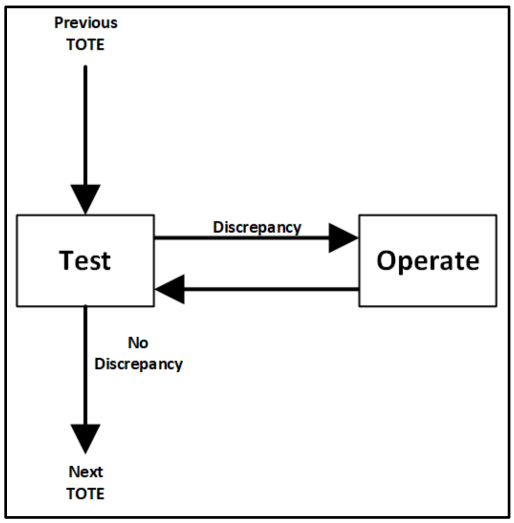

Figure 4.1 A fundamental TOTE unit.

Miller and colleagues illustrate a TOTE unit using the classical example of hammering a nail into a piece of wood (hammer nail process). The goal here is to make the nail flush with the surface of the wood (Miller et al., 1960; Stanton, 2006). The repetitive sequence of striking the nail represent a series of TEST (i.e., check nail) and OPERATE (i.e., strike) actions. When the nail is flush, the goal is achieved, and the procedure is terminated. The idea here is that an operator will continue performing an action until the state of the entity that is being manipulated by their work matches the desired end state from performing the task. Figure 4.2 shows that analysts can go as far as decomposing the **hammer nail** process into a TOTE sequence.

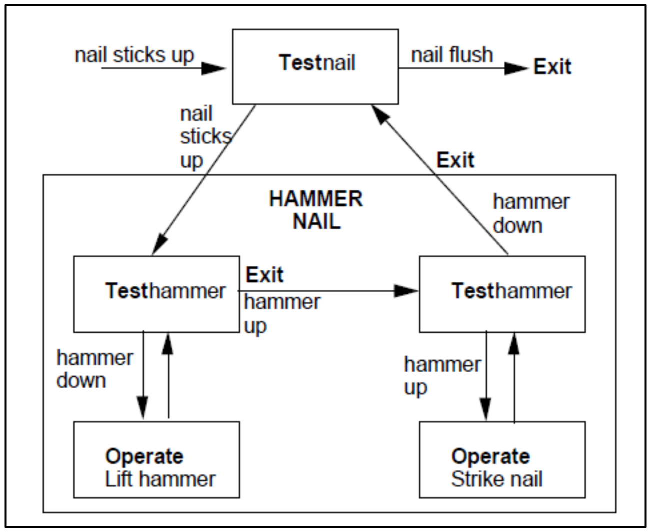

Figure 4.2. Decomposition of the “hammer nail” example as described in (Miller et al., 1968).

Despite it being light-weight and cheap to implement, HTA generates a considerable amount of insight into work. In addition, the technique is generic and can be applied in any domain. In fact, numerous other analysis and design methods list HTA as a starting point in their procedures.

HTA is not without limitations. First, it is strictly descriptive, and may become laborious and time-consuming depending on the set of tasks being modeled. Furthermore, the technique has issues with reliability as different analysts may produce different task descriptions. To overcome some of these limitations, systems analysts may utilize inputs from different data sources and attempt to validate their models using a different technique such as think aloud walkthroughs with subject matter experts (Stanton et al., 2017, pp. 39–45).

Heuristic-based Interface Inspection

HE is a lightweight usability inspection method that relies on expert inspector judgement as a source of evaluative feedback on the usability of user interfaces (UI). The method utilizes a set of best practice design standards (i.e., the heuristics) against which expert participants evaluate the UI. The result is a list of violations of the heuristics, rated by severity (Nielsen, 1992; Nielsen & Molich, 1990).

Nielsen's original work suggested ten heuristics, however, many other researchers attempted to tune them to a specific problem domain. For example, one publication suggested twelve heuristics that, more or less, correspond with Nielsen's original ten (Inostroza et al., 2013). The authors, however, tuned their heuristics to yield better results when inspecting interfaces on touch-based platforms. Table 4.1 compares the original list compiled by Nielsen (1992) to a newer version specifically tuned for touch-based interaction on a mobile platform.

During HE, inspectors are asked to rank the usability problems they uncover on an ordinal scale. Numerous scales are utilized in the literature. Among these is the original scale developed by Nielsen and colleagues (Nielsen, 1992; Nielsen & Molich, 1990) (Table 4.2).

HE has known issues with its reliability and validity. These issues can result from the diversity by which evaluators understand the meaning of the heuristics. As such, it is recommended to use expert evaluators where possible, however, the technique accommodates for recruiting novices as well. Novice pre-training is sometimes recommended in an attempt to raise the level of understanding of the heuristic among the evaluators. These shortcomings may dissuade some from utilizing it in settings where such reliability and validity are key in method selection. However, due to its ability to generate fairly inexpensive feedback that can be directly utilized in the refactoring of the design, HE is widely used in UX\UI research and practice. This is especially the case at the earlier phases of the system development lifecycle (SDLC).

Original List	Inostroza et al., 2013	Definition
Visibility of system status	Visibility of system status	The system should always keep users informed about what is going on through appropriate feedback within reasonable time.
Match between system and the real world	Match between system and the real world	The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms, follow real-world conventions and make information appear in a natural and logical order.
User control and freedom	User control and freedom	Provide a clearly marked "emergency exit" for users to leave unwanted states and support undo and redo.
Consistency and standards	Consistency and standards	Ensure that different words, situations, or actions have the same meaning and follow platform conventions.
Error prevention	Error prevention	Design the system to prevent problems from occurring or check for them and present users with a confirmation option before they commit to the action.
Recognition rather than recall	Minimize the user's memory load	Minimize the user's memory load by making objects, actions, and options visible and accessible.
Flexibility and efficiency of use	Efficiency of use and performance	Allow for both novice and expert users by providing accelerators and options for users to tailor frequent actions.
Aesthetic and minimalist design	Aesthetic and minimalist design	Avoid irrelevant information in dialogues and keep information simple and concise.
Help users recognize, diagnose, and recover from errors	Help users recognize, diagnose, and recover from errors	Provide clear and helpful error messages that suggest solutions in plain language.
Help and documentation	Help and documentation	Make help and documentation easy to search, focused on the user's task, and provide concrete steps to be followed.
n/a	Customization and shortcuts	The system should provide users with options to customize and create shortcuts to frequently used actions.
n/a	Physical interaction and ergonomics	The system should be designed to be physically comfortable and ergonomic to use, considering the device form factor and usage context.

Table 4.1. The original ten heuristics versus one tuned for touch-based interaction on a mobile platform.

Severity	Description
(1) Minor	Minor issue, such as a small cosmetic problem or slight inconvenience.
(2) Significant	Significant issue, such as confusing or inconsistent language, or a feature that is difficult to use.
(3) High Impact	High impact issue, such as an error that prevents the user from completing a task, or a feature that is impossible to use.
(4) Critical	Critical issue that severely impacts the user's experience.
(5) Blocking	Blocking issue that prevents the user from effectively using the system.

Table 4.2. Example of a severity ranking scale of usability problems uncovered in an HE.

Expository Instantiation: A Mobile Patient Aid for Remote Insulin Dose Adjustment in Type 2 diabetes

Design Scope

The Remote Dosing System (RDS) is a client-server IT system consisting of two components. The first component is a web-based dashboard used by healthcare providers. The second component is a patient-facing mobile aid. The purpose of the system is to facilitate remote insulin dose titration for outpatients with type 2 diabetes mellitus. In this study, I focus on the patient-facing component of the RDS – the mobile application.

User Tasks

I analyzed seven user tasks using HTA. These core tasks are: 1) measure blood sugar, 2) measure blood pressure, 3) measure weight, 4) determine insulin dose requirements, 5) administer insulin using an insulin pen, 6) administer insulin using syringes and vials, and 7) take medication (Figure 4.3).

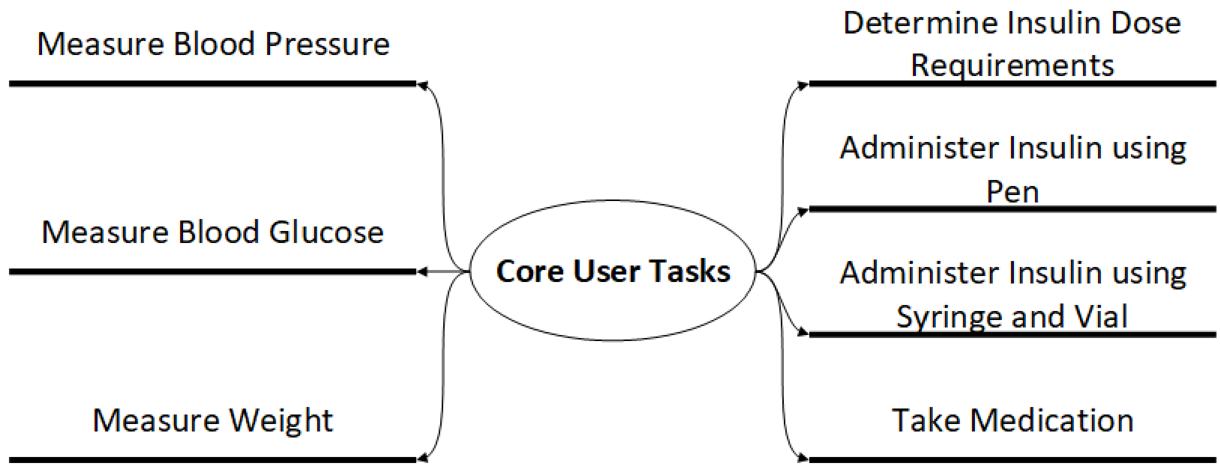

Figure 4.3. The seven core user tasks.

Depending on the unit of analysis, these tasks can be classified into monitoring tasks and control tasks, but in reality, they all contain elements of both. For instance, having an up-to-date blood glucose measurement (a monitoring task) is a prerequisite to determining insulin doses (a control task).

The hierarchies for these seven tasks were derived from the responses to two walkthrough questions I asked during the patient and care provider interviews described in Chapter 3. Whenever conflict between patient and provider narratives occurs, healthcare provider input supersedes patient descriptions in the analysis. As such, these models are for work-as-imagined and do not necessarily depict work-as-done (Blandford et al., 2014; Hollnagel, 2015; Wears & Schubert, 2016)[5]. Tables 4.3-4.9) provide a narrative and instructional description of each task as well as outlines its hierarchy.

[5] It is the proposed system's job to realign these two depictions in situ, but that is beyond the current scope and is just mentioned as a reflection.

Name	**Measure Blood Sugar**
Instructional Description	To measure blood sugar, start by unpacking the glucose test kit and verifying that all items are present. Then, switch the meter on and check its status. Next, insert a glucose test strip into the meter, making sure the strip is oriented correctly and is inserted into the strip receiving port. To obtain a sample, clean the sample site, such as the fingertips, and use a lancing device to get a blood sample. Collect a second drop of blood on the strip. Record the glucose measurement in a glucose diary. When the task is complete, dispose of the medical waste by collecting the strips, swabs, and sharps into an appropriate receptacle, such as a locking biowaste bag. Dispose of the receptacle in an approved container, then check all items and repack the glucose test kit.
Structure	**TASK 1: Measure Blood Sugar** **1.** Prepare Equipment. *1.1.1.* Unpack the glucose test kit and check items. 1.2. Prepare meter. *1.2.1.* Switch meter ON. *1.2.2.* Check meter status. 1.3. Insert glucose test strip into meter. *1.3.1.* Check strip orientation. *1.3.2.* Insert strip into the strip receiving port on the meter. **2.** Obtain Sample. *2.1.1.* Clean sample site (e.g., fingertips). *2.1.2.* Use lancing device to get a blood sample. *2.1.3.* Collect second drop of blood on the strip. **3.** Note glucose measurement. *3.1.1.* Record reading in glucose diary. **4.** Terminate Task. 4.1. Dispose of medical waste. *4.1.1.* Collect strips, swabs, and sharps into an appropriate receptacle (e.g., locking biowaste bag). *4.1.2.* Dispose of receptacle in an approved receptacle. *4.1.3.* Check items and repack the glucose test kit.

Table 4.3. The “Measure Blood Glucose” task.

Name	**Measure Blood Pressure**
Instructional Description	To measure blood pressure using a home blood pressure monitor, first prepare the equipment by unpacking the kit and assembling the unit if necessary. Next, fit the measurement cuff by sitting upright with both feet on the ground and securing the cuff up to your heart level, making sure it's oriented correctly. When ready, take the blood pressure measurement by pressing the ON button on the meter, sitting still with arms resting on armrests, and maintaining the cuff alignment with your chest. Wait for the measurement completion notification from the meter, then record the measurement in your vitals diary. Finally, remove the cuff, disassemble the unit if necessary, and repack the blood pressure measurement kit.
Structure	**<u>TASK 2: Measure Blood Pressure</u>** **1.** Prepare Equipment 1.1.1. Unpack the blood pressure meter kit. 1.1.2. Assemble unit if necessary. **2.** Fit measurement cuff 2.1.1. Sit upright with both feet on the ground. 2.1.2. Check cuff orientation (marked on cuff). 2.1.3. Wear cuff up to the heart level and secure to fit. **3.** Take blood pressure measurement 3.1.1. Confirm correct cuff fitment and orientation. 3.1.2. Press the ON button on the blood pressure meter. 3.1.3. Sit upright with both feet on the ground. 3.1.4. Rest arms on armrests 3.1.5. Maintain cuff alignment with chest. 3.1.6. Remain still and wait. 3.1.7. Receive measurement completion notification from meter. **4.** Note blood pressure measurement 4.1.1. Record measurement in vitals diary. **5.** Terminate Task 5.1.1. Remove cuff. 5.1.2. Disassemble unit if necessary. 5.1.3. Repack the blood pressure measurement kit.

Table 4.4. The “Measure Blood Pressure” task.

Name	**Measure Weight**
Instructional Description	First, prepare your equipment. Place the scale on a hard and level surface and turn it on. The next step is to take the weight measurement. Start by removing your shoes, then step onto the scale and wait for the weight measurement to appear on the display. Once you have your reading, step off the scale. Make not of the measurement and record it in your vitals diary. Finally, if necessary, stow away the scale.
Structure	**<u>TASK 3: Measure Weight</u>** 1. Check equipment 1.1.1. Place scale on a hard, level surface 1.1.2. Switch scale on 2. Take weight measurement 2.1.1. Take off shoes 2.1.2. Step on scale 2.1.3. Wait for measurement to appear 2.1.4. Step off scale 3. Note wight 3.1.1. Record measurement in vitals diary. 4. Terminate task 4.1.1. Stow away scale if necessary

Table 4.5. The "Measure Weight" task.

Name	**Determine Dose Requirements**
Instructional Description	To determine your insulin dose requirements, start by noting your current blood glucose measurement. Next, make sure to use the correct insulin by confirming the insulin type and checking the insulin dose on the label. To calculate the dose, use the appropriate sliding scale formula given your current glucose reading. Note the recommended insulin dose in your patient diary and tag the recommendation with the insulin type and dose.
Structure	**<u>TASK 4: Determine Dose Requirements.</u>** 1. Note current blood glucose measurement 2. Use correct insulin 2.1. Confirm insulin type 2.2. Confirm insulin dose on label 3. Calculate dose 3.1. Use the titration formula 3.2. Note the recommended insulin dose in patient diary 3.3. Tag recommendation with insulin type and dose

Table 4.6. The "Determine Dose Requirements" task.

Name	**Insulin Administration using an Insulin Pen**
Instructional Description	To use your insulin pen, start by preparing the insulin. First, check the label and confirm the insulin type and dose. Make sure the pen contains sufficient insulin. Then, prepare the administration device by mounting a new needle on the pen, uncapping it, priming the pen if necessary, cleaning the needle site with alcohol, and dialing in the recommended dose. For the injection, consult your site rotation routine, determine the injection site, clean it with alcohol, insert the pen into the skin at a 90-degree angle, actuate the plunger to administer the insulin, and then remove the pen. After the injection, keep a record of the insulin type and dose administered, tag the reading (e.g., bedtime, with meal) and record the injection site. Finally, terminate the task by managing the medical waste, ejecting the used needle in an appropriate waste bag, collecting the waste, and sealing the bag, and storing the insulin for the next use by checking its storage requirements and storing it accordingly.
Structure	**TASK 5: Insulin Administration using an Insulin Pen** 1. Prepare insulin. 1.1. Check the insulin label. 1.2. Confirm insulin type and dose. 1.3. Confirm pen contains sufficient insulin. 2. Prepare administration device 2.1. Mount a new needle on pen 2.2. Uncap needle 2.3. Prime pen if necessary 2.4. Clean needle site with alcohol 2.5. Dial in the recommended dose 3. Inject insulin 3.1. Consult site rotation routine. 3.2. Determine injection site. 3.3. Clean injection site using alcohol. 3.4. Insert pen into skin at 90-degree angle (subcutaneous) 3.5. Actuate the plunger to administer insulin. 3.6. Remove pen 4. Keep record 4.1. Record insulin type and dose administered 4.2. Tag reading (e.g., Basal, with food) 4.3. Record injection site 5. Terminate task 5.1. Manage medical waste 5.1.1. Eject used needle in appropriate waste bag. 5.1.2. Collect waste and seal bag. 5.2. Store insulin for next use. 5.2.1. Check insulin storage requirements 5.2.2. Store insulin accordingly

Table 4.7. The “Insulin Administration with Pen” task.

Name	**Insulin Administration using Syringes and Vials**
Instructional Description	To administer insulin using syringes and vials, first, prepare the insulin. Check the insulin label to confirm the type and dose. Ensure the vial contains enough insulin for the required dose. Next, prepare the administration device by mounting a new needle on the syringe and uncapping it. Draw the insulin from the vial and confirm the correct dose. Consult your site rotation routine and determine the injection site. Clean the site with alcohol before inserting the needle at a 90-degree angle, subcutaneously. Slowly push the plunger to administer the insulin, then remove the needle. Record the insulin type, dose, and injection site in your patient diary and tag the reading (e.g., basal, with food). When you have finished, properly manage the medical waste by disposing of sharps and waste in an appropriate receptacle. Seal the bag and dispose of it properly. Finally, check the insulin storage requirements and store the insulin accordingly for future use.
Structure	**<u>TASK 6: Insulin Administration using Syringes and Vials</u>** 1. Prepare insulin. 1.1. Check the insulin label. 1.2. Confirm insulin type and dose. 1.3. Confirm vial contains sufficient insulin. 1.4. Perform special instructions 2. Prepare administration device 2.1. Mount new needle on syringe 2.2. Uncap needle 2.3. Draw insulin from vial 2.4. Confirm correct dose on syringe 3. Inject insulin 3.1. Consult site rotation routine. 3.2. Determine injection site. 3.3. Clean injection site using alcohol 3.4. Insert needle into skin at 90-degree angle (subcutaneous) 3.5. Slowly push plunger to administer insulin. 3.6. Remove needle 4. Keep record 4.1. Record insulin type and dose administered 4.2. Tag reading (e.g., basal, with food). 4.3. Record injection site 5. Terminate task 5.1. Manage medical waste 5.1.1. Dispose of sharps and waste in appropriate receptacle 5.1.2. Seal bag and dispose of appropriately 5.2. Store insulin for next use 5.2.1. Check insulin storage requirements 5.2.2. Store insulin accordingly

Table 4.8. The “Insulin Administration with Syringe and Vial” task.

Name	**Take Medication**
Instructional Description	First, you must identify the correct medication by checking the label to confirm the name and dosage. Once you have confirmed the correct medication, you need to prepare by ensuring that you follow any prerequisites. This may involve confirming the timing in relation to your meals or checking if the medication should be taken with other medications. After preparation, it's time to consume the medication by following the administration instructions, such as whether it's topical, oral, or requires tablet splitting. Make sure to consume the medication as instructed and follow the recommended dosage. Keeping track of your medication intake is important, so make sure to record the medication name, dosage, timing, and any relevant information, such as whether it was taken with food or while fasting. Finally, store the medication as prescribed to ensure its safety and effectiveness for future use.
Structure	**TASK 7: Take Medication** 1. Identify correct medication 1.1. Check medication label 1.2. Check medication dosage 2. Prepare 2.1. Perform prerequisites 2.1.1. Confirm compliance in relation to meal (e.g., with food, fasting) 2.1.2. Confirm compliance in relation to other medication (e.g., take with another medication) 3. Consume medication 3.1. Follow administration instructions (e.g., topical, oral, tablet splitting) 3.2. Consume medication as instructed 4. Keep record 4.1. Record instance (e.g., medication name, dosage, and timing) 4.2. Tag instance (e.g., with food, fasting) 5. Terminate 5.1. Store medication as instructed.

Table 4.9. The “Take Medication” task

The ADS and the Build Cycle

Given that the ADS is grounded in non-reductionist thought, it encodes a wealth of information on the application’s functional, structural and technical requirements. Furthermore, it encodes the application’s information architecture and provides for populating its content. And because it contains a decomposition dimension, it aids in formulating these requirements at multiple levels of detail.

The above-mentioned can be better understood in light of a specific user task. Consider, for instance, the hierarchy for the user task **determine dose requirements** (Table 4.6). The ADS points to the specific resources and *classes of resources* that can be used in designing for that task (Figure 4.4). In the case of developing a smartphone-based aid, this includes the information architecture (i.e., the meaningful groupings of information) and informational content of the application.

Decomposing the above reveals the specific resources used in the task at a lower level of detail (Figure 4.5). Here, designers can extract direct mappings between the resources available in the ADS and the specific task elements that utilize these resources. Table 4.10 shows the HTA-ADS mappings for the user task *"determining insulin dose requirements"*.

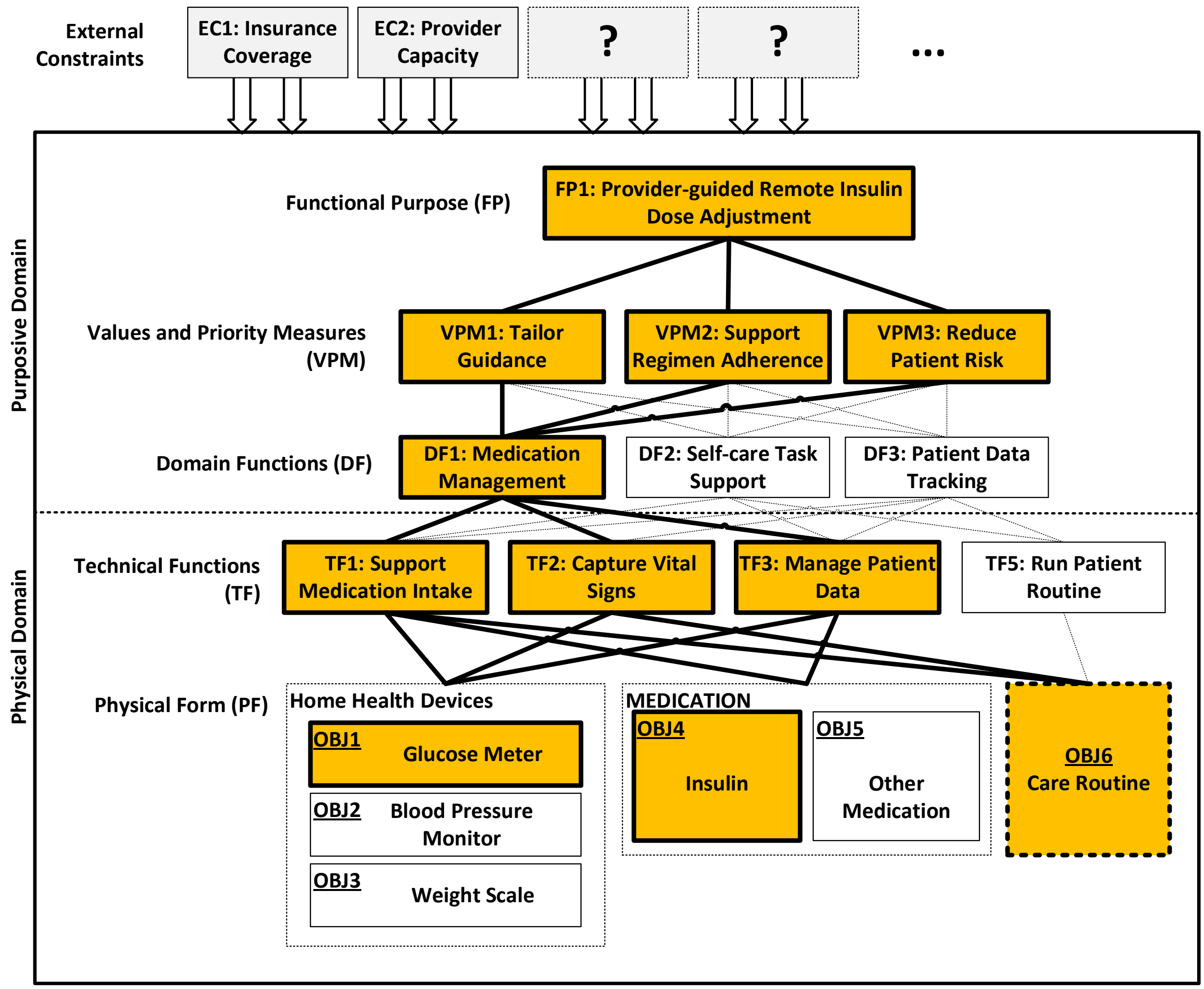

Figure 4.4. Abstraction Hierarchy, highlighting resources for Task 4: *Determine Insulin Dose Requirements.*

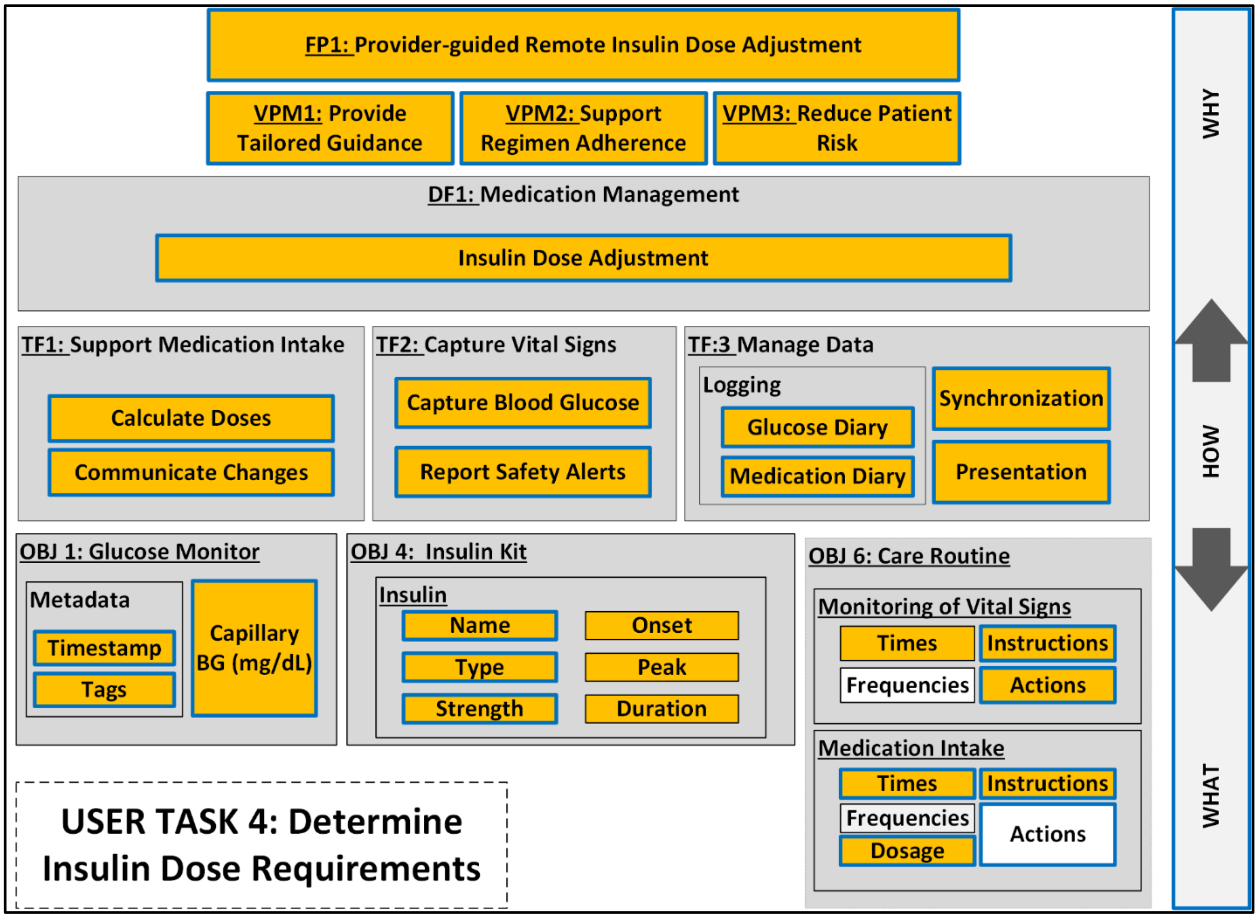

Figure 4.5. The specific ADS resources supporting Task 4: *Determine Insulin Dose Requirements*

Task 4: "Determine Insulin Dose Requirements"	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Note current blood glucose measurement.	**OBJ 1:** BG in mg/dL, timestamp, tags. **OBJ 6:** Blood measurement instructions **TF 2:** Capture blood glucose and capture metadata. **TF 3:** Glucose diary, synchronization and presentation.
2. Use correct insulin. 2.1. Confirm insulin type. 2.2. Confirm insulin dose on label.	**OBJ 4:** Insulin name, insulin type, insulin strength, peak, onset and duration.
3. Calculate dose. 3.1. Use the titration formula. 3.2. Note the recommended insulin dose in patient diary. 3.3. Tag recommendation with insulin type and dose.	**TF1:** Calculate doses and communicate changes. **TF3:** Medication diary, synchronization and presentation.

Table 4.10. ADS-HTA Mappings for Task 4 "Determine Insulin Dose Requirements"

As such, during the early stages in design, the ADS serves as a valuable blueprint that can be directly used in the construction of software systems. Appendix 3 provides the full system ADS, along with a tabulation of the ADS-HTA mappings that I used to build the UI. The UI design and user flows described below were directly derived from these ADS-HTA mappings.

User Interfaces and Workflows

I designed for twelve unique user scenarios that span four out of the seven core user tasks above. The rationale behind this selection is that they depict the core functionality of the system in its most atomic form. Table 4.11 includes a full description of these scenarios.

Scenario Code	Description	User Tasks Covered
A	Enters blood glucose data using a conventional meter. Receiving a high fasting blood glucose.	TASK 1: Measure Blood Sugar
B	Enters blood glucose data using a conventional meter. Receiving a within-range reading.	TASK 1: Measure Blood Sugar
C	Hypoglycemia mitigation. Blood glucose data entry using a conventional meter. Receiving a "Withhold Dose" recommendation.	TASK 1: Measure Blood Sugar TASK 4: Determine Dose Requirements.
D	Sends verified blood glucose data entry from a wireless/connected meter. Receiving meter status errors.	TASK 1: Measure Blood Sugar
E	Sends verified blood glucose data entry from a wireless/connected meter. Receiving a high fasting blood glucose.	TASK 1: Measure Blood Sugar
F	Sends verified blood glucose data entry from a wireless/connected meter. Receiving a result within-range notification.	TASK 1: Measure Blood Sugar
G	Sends verified blood glucose data entry from a wireless/connected meter. Receiving a "withhold insulin" recommendation.	TASK 1: Measure Blood Sugar TASK 4: Determine Dose Requirements.
H	Sends blood pressure manual data entry. Receiving a "within-range" result.	TASK 2: Measure Blood Pressure
I	Sends verified blood pressure data entry from a wireless/connected meter. Receiving a "within-range" result.	TASK 2: Measure Blood Pressure
J	Verified blood glucose measurement from a wireless/connected meter. Receiving a pre-meal "high-reading" result and a rapid-acting insulin recommendation as per tailored sliding scale.	TASK 1: Measure Blood Sugar TASK 4: Determine Dose Requirements.
K	Receives specific rapid-acting recommendation and gets guided to priming a new insulin pen. Primes pen and confirms priming. Dials dose and receives injection guidance. Confirms intake.	TASK 4: Determine Dose Requirements. TASK 5: Insulin Administration using an Insulin Pen
L	Receives specific rapid-acting recommendation and proceeds with a pre-primed pen. Dials dose and receives injection guidance. Confirms intake.	TASK 4: Determine Dose Requirements. TASK 5: Insulin Administration using an Insulin Pen

Table 4.11. The twelve user scenarios, A through L, and the user tasks they span.

I used a high-fidelity application prototyping tool (i.e., Figma) to design the scenarios. Each scenario was made available to the evaluators via a private link. I included snapshots of the UI and flows I designed in Appendix 4.

Heuristic Evaluation

A total of seven (n=7) inspectors evaluated the scenarios. Each evaluator was asked to use the twelve heuristics provided above and record violations (Inostroza et al., 2013). Evaluators were also asked to rank the severity of each problem they uncover using the previously mentioned scale (Table 4.2).

The scenarios were hosted online and were made accessible to evaluators via a private web link. I used convenience sampling and did not collect inspector characteristics beyond expertise with heuristic evaluation. Three out of the seven inspectors were experts, the rest being novices.

A total of (n=219) problem reports were recorded by all evaluators, the majority of which were ranked as minor to significant (n=202). Only (n=3) problems were ranked as blocking. A summary of the usability problem reports is shown in Table 4.12 and Figure 4.6.

Evaluator		**Problem Severity**					
		Minor	**Significant**	**High impact**	**Critical**	**Blocking**	**Total**
EV1	Expert	54	6	-	-	-	60
EV2	Expert	13	19	1	6	3	42
EV3	Expert	18	24	-	-	-	42
EV4	Novice	12	13	-	-	-	25
EV5	Novice	8	8	7	-	-	23
EV6	Novice	16	1	-	-	-	17
EV7	Novice	10	-	-	-	-	10
	COMB	131	71	8	6	3	**219**

Table 4.12. Number of usability problems discovered by each evaluator.

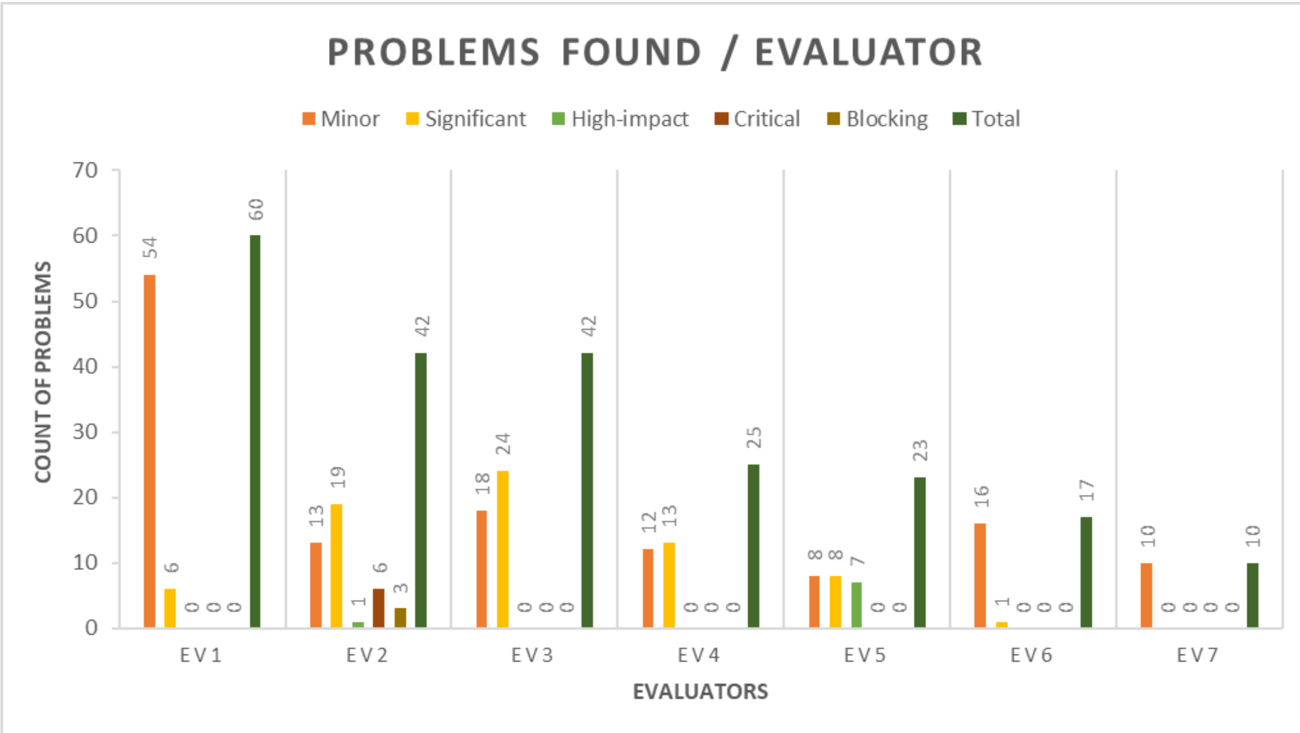

Figure 4.6. Number of usability problems found by each evaluator.

Expert evaluators 1, 2, and 3 recorded noticeably more problems than their novice counterparts. Since these reports included redundancies, I cleaned the data manually to remove redundancies and an invalid report. The inspection yielded (n=125) unique and valid usability problems across all twelve scenarios. See Appendix 5.

To assess the level of agreement among the inspectors as to the problems discovered, I conducted an inter-rater reliability test using Fleiss' Kappa coefficient. I chose this test because it is appropriate for assessing agreement among multiple raters and the data being evaluated is categorical (i.e., found, not found). See Table 4.13.

Scenario	Fleiss κ	Standard Error	95% Confidence Interval		p-Value
			Lower	Upper	
A	-0.11	0.16	-0.43	0.21	.497
B	-0.17	0.22	-0.6	0.27	. 550
C	-0.15	0.19	-0.53	0.22	.575
D	0.02	0.16	-0.29	0.33	.916
E	0.1	0.19	-0.27	0.47	.594
F	-0.02	0.2	-0.41	0.37	.073
G	-0.13	0.22	-0.57	0.3	.445
H	-0.07	0.15	-0.37	0.23	.357
I	***-0.01***	***0.21***	***-0.41***	***0.4***	***.020****
J	0.06	0.18	-0.29	0.4	.744
K	-0.04	0.12	-0.29	0.2	.262
L	***0.33***	***0.15***	***0.03***	***0.64***	***.031****

Table 4.13. Agreement among evaluators per scenario using the Fleiss coefficient test. *p<0.05

For scenarios A, B, C, F, G, H, I and K, the Fleiss Kappa coefficients were negative, indicating a lack of consistency in the evaluators' assessments (i.e., different evaluators found different problems). However, given the small sample size and the diversity of the evaluators (i.e., in terms of their expertise), this result is expected. That is not to mention not meeting the significance threshold.

Scenarios D and E showed slight agreement, but the agreement was not statistically significant. This means that while there appeared to be some consensus about certain usability problems within the scenarios, it is very likely that the agreement occurred completely by chance, especially given the wide confidence interval. The same can be said about scenario J.

Scenario L showed fair to moderate agreement among evaluators, and the agreement was statistically significant (p=0.031). This suggests that the evaluators' assessments were more consistent and reliable compared to the other scenarios. The chief complaint within this scenario was the difficulty to follow instructions the way they are currently being conveyed (i.e., through timers and auto-transitions). This places strong emphasis on refining the way by which instructions are delivered to the patient via a mobile platform. Overall, and in cases where there was no agreement, or even significant agreement, it is imperative to re-evaluate the assessment criteria and the training of evaluators to improve the reliability scores. That is not to say that the recorded problems were not actually problems – they were. It just indicates that different evaluators found different problems, and they rarely reported on the same problems with scenario L being the exception.

As far as the heuristics are concerned, the top violated standard pertained to aesthetics, followed by minimizing user load (Table 4.14 and Figure 4.7). However, given the diversity in the inspector sample and the overlapping definition of the heuristics, this result should not be completely relied on. In fact, developing understandable heuristics that are suitable for the inspector sample is still an active research area in usability studies. The same can also be said about the development of severity scales (Abulfaraj & Steele, 2020; Quiñones & Rusu, 2017).

Violation	**Reports**
Error recovery	1
Efficiency and performance	3
Physical interaction	6
User control and freedom	6
Error prevention	9
Match with real world	11
System Status Visibility	13
Consistency	16
Minimize user memory load	18
Aesthetics	42
Total	**125**

Table 4.14. Frequency of unique problem reports per heuristic.

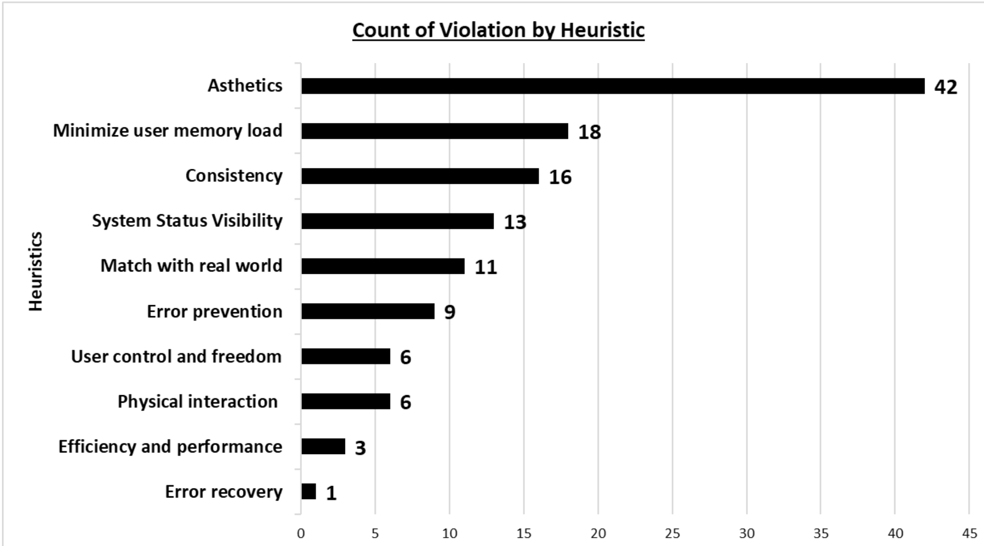

Figure 4.7. Count of violation reports citing each heuristic

Conclusions, limitations, and future work

In this chapter, I demonstrated moving from model to instantiation via utilizing the HTA-ADS mappings. Furthermore, I designed 12 unique user flows on a mobile platform and conducted a simple heuristic evaluation of the prototype. The intention behind the test was not to show that the ADS produces problem-free instantiations. This is evident in the prototype I created, which yielded numerous valid violation reports. The goal behind this chapter was to demonstrate how an abstract design artifact like the ADS can guide the construction of concrete system instantiations, and further guide their evaluation.

This demonstration showed a small proportion of what system designers could extract from the ADS. Because the focus was on the patient-facing intervention, I did not elaborate much on how the ADS aids in extracting the system's functional, structural and operational requirements. These will be better highlighted in conjunction with discussing the entire insulin dose titration solution, inclusive of both the patient-facing aid as well as the care provider dashboard.

Chapter 5

Conclusions, Limitations and Future Work

This research demonstrates the use of the Abstraction-Decomposition Space (ADS) alongside Hierarchical Task Analysis (HTA) to guide the design of a minimalist patient aid for active medication management. One of the goals here was to provide a practical IT-based solution to a real-world problem (i.e., insulin titration in type 2 diabetes). However, and beyond the practical implications, this study has also sought to address a methodological and a theoretical problem that are prevalent in design research in IS today.

On addressing the practical problem

As far as the practical problem is concerned, there is a degree of consensus in the literature about multiple issues. One is that the literature and the interviewees both acknowledge the current inefficiencies in conventional care delivery, specifically in relation to its inability to support that particular set of patients who require close observation in the interim period between in-person visits. Furthermore, the sources agreed that IT has the potential to offer effective solutions in this vein.

However, and beyond these two points, there was less consensus on the demographic that could benefit from this solution. There was also less agreement on the specific form and functionality that should be implemented within that solution as well as on the means to deliver that functionality. While some favored implementing elaborate features to support all the possible aspects of self-care at home, others argued that constructing a more focused solution that targets the titration problem in its most fundamental form would be more effective.

Given that the intention behind proposing this intervention was to benefit the patient with minimal additional complexity and friction, I pursued a bare-minimum design which focuses on the most essential functionality required to achieve remote dose titration. My interview transcripts were filled with suggestions for elaborate features, so one of the challenges was to include what is relevant and exclude the rest. As such, the proposed system, as encoded in the ADS, and in the ADS-HTA mappings, represents my perception of the system in its most irreducibly complex form. In other words, should a more elaborate system be constructed, then it should contain, at its core, the functional structure I present in the ADS.

In terms of the expository instantiation, namely, the scenarios and their usability tests, I elected to design and test atomic scenarios instead of designing a complete application that addresses all the possible scenarios. The rationale was to gain more insight at a finer level of granularity. This way, and instead of assessing the product as a whole, I was able to pin-point which parts of the important scenarios cause the most friction. Such knowledge would have been less readily derivable if I tested the product as a whole. Having said that, one challenge in adopting this approach is that it requires modelling all the possible trajectories of work within the system, then instantiating them in software form. This is much harder to do with just the ADS alone as it lacks a procedural dimension. As such, an intermediate technique is required to map the ADS resources to the specific scenarios that consume these resources. To overcome this challenge, I used HTA to map the individual ADS resources to their corresponding goals and sub-goals. This can be laborious especially when modelling and mapping to complex tasks. As such, designers who pursue a similar approach must consider other project constraints such as cost and time. In a healthcare context, however, the investment is justified given the safety-critical nature of the problem.

On addressing the theoretical and methodological problem

In chapter one, I discussed the potential issues that could result from taking a purely tool-focused view to the artifact in IS design research. First, limiting the contribution of design research to instantiated software packages jeopardizes our ability to produce generalized knowledge about IT systems. Unlike in design in industry, design research is not so much interested in the marketability of a particular package, its interest lies beyond *the tool* (Vahidov, 2012). Design research should be both practical and theoretical because it is both *design* as well as *research* (Cole et al., 2005). Therefore, it should also aim to produce generalized knowledge in the form of abstract design artifacts that can guide the construction of concrete IT systems. In my view, the idea of a systems-based design artifact is better aligned with the character of our field. Other scholars share this point of view (e.g., Alter, 2004, 2015; Chatterjee et al., 2021; Checkland, 1999; Checkland & Poulter, 2020; Vahidov, 2012) not only because the word "systems" constitutes half of its name, but also because a systems-based conceptualization affords us a level of abstraction that cannot be found in studies that are fixated on apps and gadgets. Systems-based conceptualizations provide for knowledge that remains relevant as specific technologies become obsolete. Work system models that are rooted in systems thinking are one type of meta-artifact that fulfils such criteria.

Second, and in light of the scarcity in artifact-building methodology, tool-focused studies tend to overemphasize evaluation but give little elaboration on the rationale behind design in its proposed form, functionality and attributes. This can be seen in studies that anchor in the field via the Design Science Research (DSR) framework but fail to augment it with formative and artifact-building guidance. As such, because design research is both practical and theoretical, it needs methodological grounding in order to bridge both worldviews (Vahidov, 2012; Walls et al., 1992). Figure 5.1 illustrates the components of design theory as described by Walls and colleagues.

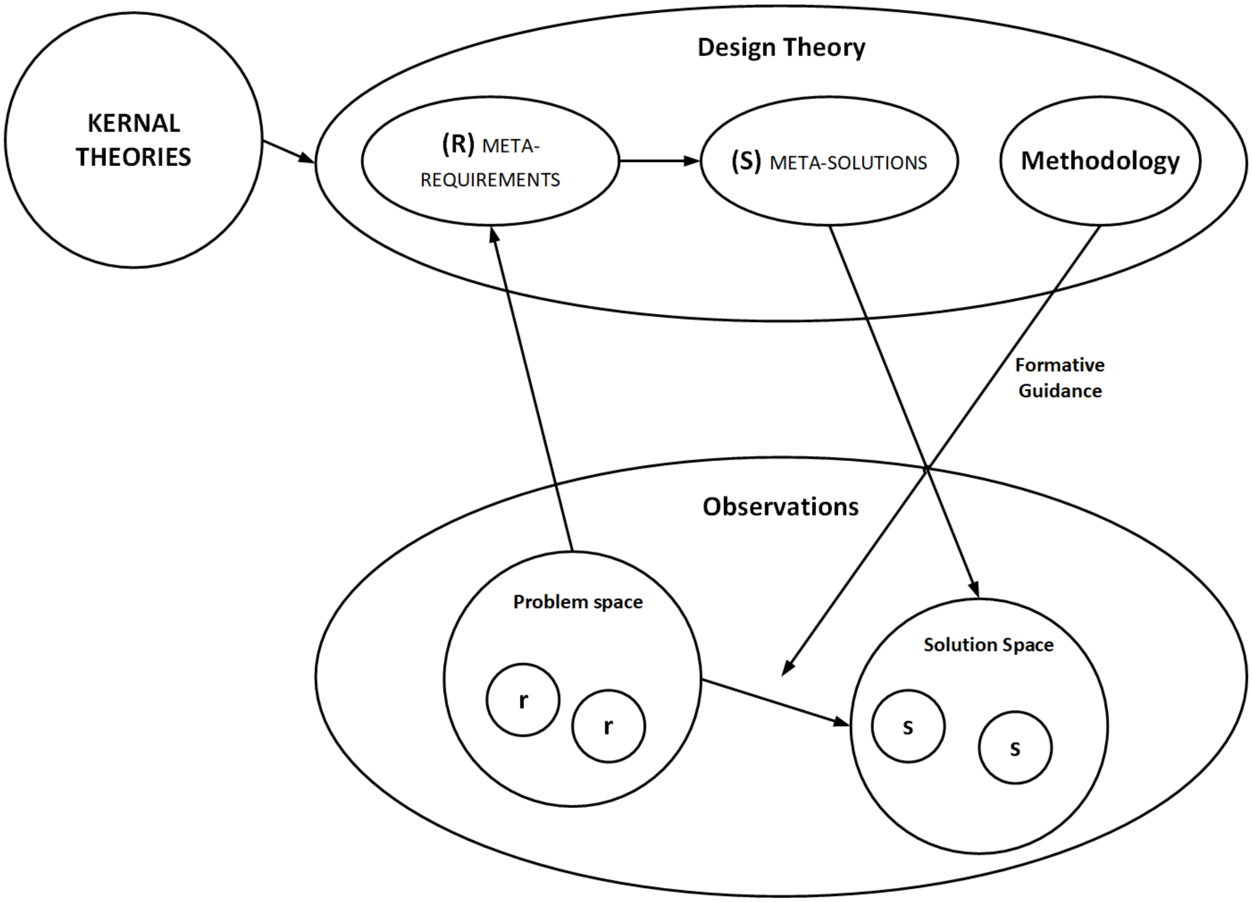

Figure 5.1. The components of design theory and the bridging role of methodology.

Given the above, I proposed one pathway around these problems that can be described in two simple points:

1. By adopting a work systems-based view rather than a tool-centric view of *the artifact*, researchers can contribute at a more abstract and generalizable level, resulting in a longer-lasting contribution that transcends specific IT systems. This allows researchers to go beyond craftsmanship and into contributing to knowledge at a theoretical level. The ADS is an example of a systems-based artifact that fulfils the criteria.
2. By augmenting DSR with guidance specific to artifact building, researchers can highlight the artifact-building process, which is often overshadowed by its evaluation. This balances

evaluation-dominant research and places more emphasis on artifact building activities. WDA as well a other formative CWA methods, are well-geared to fill in this gap.

Concluding Remarks

In this dissertation, I aimed to contribute to the ongoing debates surrounding design research in IS by proposing an approach that balances the practical and theoretical dimensions of design. Specifically, I have used the Abstraction-Decomposition Space (ADS) alongside Hierarchical Task Analysis (HTA) to guide the design of a minimalist patient aid for active medication management in type 2 diabetes. By doing so, I have demonstrated how a systems-based conceptualization of the artifact can contribute to knowledge that remains relevant even as specific technologies become obsolete. Moreover, I have highlighted the importance of artifact-building guidance in design research to ensure that the rationale behind design is properly elaborated upon and to balance an otherwise evaluation-dominant landscape.

Given that the number of interviewees is relatively small, it was difficult to achieve a satisfactory level of saturation in some critical areas within the ADS and within the scenario descriptions (i.e., the walkthrough questions). Similarly, the heuristic evaluation cohort was small and diverse, casting doubt about the validity and reliability of the inspection results. However, heuristic evaluation does not require utilizing input from a large number of evaluators as it is typically used in the earlier stages of design to provide affordable feedback for next design iterations.

The other limitation is that the qualitative data was analyzed and coded by one researcher, thus raising question concerning validity, reliability and bias. As such, the study could be greatly improved with input from two or more investigators. Ideally, these investigators should be familiar with the problem domain (i.e., active medication management) and with the methods utilized herein (i.e., WDA and HTA). Such expertise is harder to find but could be realized with investigator training.

To overcome some of the aforementioned limitations, this study utilized a strategy which involved triangulating across sources of information. Still, this does little to mitigate the risks of experimenter bias.

Future work can build on this study in a number of ways. One avenue for further research is to explore the application of the ADS-HTA method in other design problems beyond patient aids for medication management. In this context, investigators must assess the suitability of the method to their particular problem as it may be laborious and time consuming. As such, if the research problem is characterized as being high-risk, safety-critical, complex and dynamic, the presented method may be suitable for the class of problem at hand.

Another potential area of research would be to explore ways to validate the ADS by utilizing the means-ends statements encoded within it. Literature on validating the results of WDA acknowledges the difficulty of assessing the correctness and completeness of the produced models. Utilizing the means-ends statements in a validation context may be the key to solving that challenge.

In summary, this study highlights the importance of balancing practical and theoretical contributions in design research and proposes an approach that can help achieve this balance. By continuing to refine and develop this approach, we can continue to push the boundaries of design research as a scholarly activity while also contributing to the development of IT solutions that effectively address real-world problems.

It is a statement of consensus among IS scholars that design research is focused on solving real-world problems. However, and for almost any other topic beyond that, there is a vast expanse of ambiguity that occasionally manifests in heated debates. I have been fortunate to witness some of these myself in a number of seminars and conferences. It usually ends with a customary soft landing such as "well, we will have to agree to disagree then. But thank you for your feedback!" You could cut the tension with a knife!

Others wrote about their own experiences. For example, in his book entitled *Design-Type Research in Information Systems,* Vahidov reported on what he claims to be a "hypothetical" dialog between two IS researchers: T-Researcher and D-researcher. The discussion between the two starts somewhat friendly but turns a little sour towards the end. Vahidov, and in a humorous fashion, later states:

> "After the lunch, somewhat upset D-researcher went to his office to start writing this book." (Vahidov, 2012).

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Appendix 1: Systematic Review Tables

(A) – Clinical Efficacy

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Boaz et al., 2009)	**Design** RCT **Length (weeks)** 26 **Sample Size** 35 **Age (mean)** 63	**Intervention (n=17)** A glucose meter integrated with an embedded gateway for data synchronization. **Control (n=18)** Standard Care	**Outcome Measures** Quality of Life: • Unspecified Instrument Glycemic Control: • HbA1c **Results** HbA1c improvement was marginal in the intervention group. However, measures of quality of life significantly improved post intervention.

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Stone et al., 2010)	**Design**	RCT	**Intervention (n=64)** A telemedicine monitor integrated with a glucose meter as well as messaging capabilities.	**Outcome Measures** Glycemic Control: • HbA1c
	Length (weeks)	26	**Control (n=73)** Monthly follow-up via phone call.	**Results** A significant improvement in glycemic control was observed in the intervention group by the end of the observation period.
	Sample Size	137		
	Age (mean)	80+		

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Kim et al., 2010)	**Design**	**RCT**	**Intervention (n=50)** Remote insulin dose titration via SMS supported by a knowledge matrix **Control (n=50)** Standard care	**Outcome Measures** Glycemic Control: • HbA1c • FBG Safety: • Incidents of Hypoglycemia **Results** A1c was significantly improved in the intervention group. Almost 10% more patients reached their A1c target in the intervention group when compared to the control group.
	Length (weeks)	**12**		
	Sample Size	**100**		
	Age (mean)	**48**		

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Bujnowska-Fedak et al., 2011)	**Design** RCT **Length (weeks)** 26 **Sample Size** 100 **Age (mean)** 37	**Intervention (n=50)** A glucose meter integrated with a laptop computer via Infrared. **Control (n=50)** Standard care	**Outcome Measures** Glycemic control: • HbA1c • Capillary BG Quality of life and adherence to therapy: • A custom survey **Results** Difference in A1c between groups was not statistically significant. The intervention group had less incidents of hypoglycemia. Quality of life improvement was best observed in insulin-requiring patients.

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Chen et al., 2011)	**Design**	RCT	**Intervention (n=32)** A telecare system with a glucose meter and equipment needed for data synchronization with the server. **Control (n=32)** Standard care	**Outcome Measures** Glycemic control: • HbA1c Safety: • Incidents of hypoglycemia • Hospitalizations **Results** Telecare can be an effective tool in supporting diabetes control in patients with T2DM on an insulin regimen when compared to standard care. In addition to a significant improvement in A1c in the intervention group, the use of the system was associated with a significantly less risk of hypoglycemia or hospitalizations for any reason.
	Length (weeks)	52		
	Sample Size	64		
	Age (mean)	53		

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Del Prato et al., 2012)	**Design**	RCT	**Intervention (n=115)** Reporting of SMBG via a connected glucose meter which transmits glucose readings to the clinic via PSTN (tone gateway). **Control (n=126)** Conventional SMBG reporting	**Outcome Measures** Glycemic control: • HbA1c Safety: • Incidents of hypoglycemia **Results** Improvement was observed in both groups with no statistically significant difference between groups. The implemented system provides comparable results to conventional methods of SMBG reporting.
	Length (weeks)	12		
	Sample Size	241		
	Age (mean)	58		

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Dy et al., 2013)	**Design**	RCT	**Intervention (n=12)** Standard care augmented with teleconsultation via a desktop or laptop computer with glucose data transfer capability. **Control (n=11)** Standard care	**Outcome Measures** Safety • Basal insulin dose • Incidents of hypoglycemia **Results** The study concluded that the use of telemedicine to improve glycemic control is feasible. Patients in the intervention group were able to optimize their basal insulin intake and thus a reduction in the incidents of hypoglycemia was observed.
	Length (weeks)	26		
	Sample Size	23		
	Age (mean)	83		

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Tang et al., 2013)	**Design**	RCT	**Intervention (n=186)**	**Outcome Measures**
	Length (weeks)	52	A wireless glucose meter connected to a smartphone companion application providing logging features.	Glycemic control: • HbA1c Other health measures: • Blood pressure • Wight • Cholesterol levels • Heart attack risk factors
	Sample Size	379	**Control (n=193)**	**Results**
	Age (mean)	53	Standard care	A significant improvement in A1c was observed at midpoint (6 months), however, a significant difference in A1c was not observed between groups by the end of the intervention period. The authors pointed that such systems can be effective at improving glycemic control in patients with T2D.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Wakefield et al., 2014)	**Design** RCT **Length (weeks)** 12 **Sample Size** 94 **Age (mean)** 60	**Intervention (n=53)** A glucose meter connected to the HCP site via a dedicated modem. **Control (n=55)** Standard care	**Outcome Measures** Glycemic control: • HbA1c Other health measures: • Systolic blood pressure **Results** Remote monitoring of blood glucose and systolic blood pressure did not improve health outcomes. The intervention failed to demonstrate clinical efficacy.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Greenwood et al., 2015)	**Design** RCT **Length (weeks)** 26 **Sample Size** 90 **Age (mean)** 58	**Intervention (n=45)** A smartphone application on a tablet apparatus supporting functionality for SMBG data sharing, HCP review, actionable messaging and integration with electronic health records. **Control (n=45)** Standard care	**Outcome Measures** Glycemic control: • HbA1c Patient-reported measures: • The diabetes knowledge test (DKT) • Summary of Diabetes Self-care activities (SDSCA) • Diabetes empowerment test **Results** A1c significantly improved among patients receiving the intervention by study endpoint. SDSCA sub-items pertaining to SMBG, foot care and carbohydrates also showed a significant improvement.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Levy et al., 2015)	**Design** RCT **Length (weeks)** 12 **Sample Size** 61 **Age (mean)** 46	**Intervention (n=33)** Enrollment in a remote care system for insulin dose adjustment via SMS and phone calls using a basic cellphone **Control (n=28)** Standard care	**Outcome Measures** Glycemic control: • Reaching optimal basal dose by the end of the intervention period Feasibility, cost and satisfaction • System usage data • Copay data • The diabetes treatment satisfaction questionnaire (DTSQ) **Results** Significantly larger proportion of patients achieved optimal long-acting dose by the end of the study (88% vs. 37%). In addition, higher patient satisfaction was observed in the treatment group. The study concluded that SMS is an effective tool for remote insulin dose adjustment for patients with low socio-economic status.

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Fountoulakis et al., 2015)	**Design**	RCT	**Intervention (n=70)** A glucose meter connected via a modem for transmitting SMBG data in addition for SMS and email support. **Control (n=35)** Standard care	**Outcome Measures** Glycemic control: • HbA1c Other health measures • Body Mass Index Safety • Incidents of hypoglycemia **Results** A significant improvement in A1c was observed in the intervention group without a significant change in BMI. Cost savings were achieved for patients living more than 100KM away. The study concluded that remote monitoring of blood glucose can significantly improve patient outcomes and reduce the frequency of hypoglycemic episodes.
	Length (weeks)	52		
	Sample Size	105		
	Age (mean)	55		

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Hsu et al., 2016)	**Design**	RCT	**Intervention (n=20)**	**Outcome Measures**
	Length (weeks)	12±2	A cloud-based mobile application preloaded on a tablet computer with self-tracking, shared decision making, secure messaging and virtual visit capabilities. The intervention also featured the use of a self-titration algorithm.	Glycemic control: • HbA1c Patient satisfaction: • The diabetes treatment satisfaction questionnaire (DTSQ)
	Sample Size	40	**Control (n=20)**	**Results**
	Age (mean)	53	Standard care	The study showed that mHealth interventions can be an effective tool for sharing data, enhancing communication and improving glycemic control. Patients in the intervention group demonstrated a significant reduction in A1c (3.2% ± 1.5%) versus the control group. Higher treatment satisfaction was also observed versus standard care.

Reference	Study Design and Patient Characteristics		Interventions and Allocation	Outcome Measures and Results
(Baron et al., 2017)	**Design**	RCT	**Intervention (n=45)** A health devices kit consisting of a blood glucose meter and a blood pressure monitor connected via Bluetooth to a smartphone application with data logging functionality. The app transmits the data to a nurse dashboard for review. **Control (n=36)** Standard care	**Outcome Measures** Glycemic control: • HbA1c Other health measures: • Systolic blood pressure • Diastolic blood pressure • Insulin dose Patient-reported measures: • Quality of life (SF12v2) • Diabetes health profile (DHP-18) • STAI6 Anxiety Survey **Results** The study found that clinical outcomes associated with the adoption of their system are comparable to those reported in a standard care setting. However, benefits pertaining to patient-reported measures were observed in the intervention group.
	Length (weeks)	36		
	Sample Size	81		
	Age (mean)	55-58		

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Franc et al., 2019)	**Design** RCT **Length (weeks)** 56 **Sample Size** 191 **Age (mean)** 58	**Intervention A (n=64)** Interactive voice insulin dose adjustment guide **Intervention B (n=64)** Mobile application with automated insulin dose adjustment **Control (n=63)** Standard Care	**Outcome Measures** Glycemic control: • HbA1c • Fasting BG Safety: • Frequency of hypoglycemia Patient-reported measures: • DHP-QoL **Results** Both telemonitoring systems improved glycemic control without a significant increase in risk of hypoglycemic episodes when compared to the control arm.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(McFarland et al., 2012)	**Design:** Non-randomized Quasi-experiment **Length (weeks)** 26 **Sample Size** 103 **Age (mean)** 64	**Intervention (n=36)** A messaging device with the ability to transmit of SMBG data via a modem. **Control (n=67)** Standard care	**Outcome Measures** Glycemic control: • HbA1c • % of patients meeting the ADA criteria on A1c **Results** While the intervention did not cause a significant change in A1c between groups at endpoint, other benefits were reported such as time spent with patients and the percentage of patients meeting the ADA criteria for HbA1c.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Bramwell et al., 2020)	**Design:** Non-randomized Quasi-experiment **Length (weeks)** 56 **Sample Size** 92 **Age (mean)** 56-64	**Intervention (n=42)** A smartphone application with an integrated glucose meter. HCP access to patient data via a dedicated dashboard. **Control (n=50)** Standard care (Phone)	**Outcome Measures** Glycemic control: • HbA1c Efficiency • Time to titrate patients **Results** The intervention was associated with better resource utilization versus usual care, including time spent with patients. However, in terms of clinical outcomes, there was no significant difference between groups by the end of the intervention period.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Lemelin et al., 2020)	**Design:** Non-randomized Quasi-experiment **Length (weeks)** 26 **Sample Size** 92 **Age (mean)** 58	**Intervention (n=45)** Access via a browser to a web application supporting health status logging, including a capillary glucose diary as well as incidents of hypoglycemia. **Control (n=47)** Standard care	**Outcome Measures** Glycemic control: • HbA1c Patient-reported measures • Patient empowerment **Results** Improvement in glycemic control was significant in the intervention group, however, nurses reported additional work burdens associated with the use of the system.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Nikkanen et al., 2008)	**Design:** Single group, Interventional **Length (weeks)** 60 **Sample Size** 101 **Age (mean)** 62	**Treatment** Remote consultation via videoconferencing and an integrated remote stethoscope.	**Outcome Measures** Glycemic control: • HbA1c **Results** An improvement in glycemic control was observed. Results show that the most commonly requested service via their telemedicine platform was pertaining to insulin dose adjustment.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Turner et al., 2009)	**Design:** Single group, Interventional **Length (weeks)** 12 **Sample Size** 23 **Age (mean)** 58	**Treatment** A smartphone application with a connected glucose meter and capability of SMBG logging and automated insulin dose calculation via an algorithm under HCP supervision.	**Outcome Measures** Glycemic control: • HbA1c Other clinical outcomes: • Insulin dose **Results** Conclusive remarks indicate that the technology provided an enhanced level of support to patients with T2D commencing insulin therapy. Some healthcare professionals expressed worries about patient overdependence on technology.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Larsen et al., 2010)	**Design:** Single group, Interventional **Length (weeks)** 26 **Sample Size** 23 **Age (mean)** 58	**Treatment** A smartphone application with a connected glucose meter and capability of SMBG logging and automated insulin dose calculation via an algorithm under HCP supervision.	**Outcome Measures** Glycemic control: • HbA1c • FBG Other clinical outcomes: • Insulin dose • Adherence **Results** Using the system was associated with an improvement in glycemic control. In addition, enhanced patient support was reported. There remained a reluctance to increase doses due to hypoglycemia.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Grady et al., 2016)	**Design:** Single group, Interventional **Length (weeks)** 12 **Sample Size** 40 **Age (mean)** 49	**Treatment** A web application for uploading SMBG logs. HCP makes adjustments upon review of SMBG data and communicates new titration instructions via phone.	**Outcome Measures** Glycemic control: • Mean capillary BG Patient-reported measures: • Patient perceptions **Results** The study concluded that similar interventions have the potential to improve glycemic control. 83% of patients reported an enhanced sense of security knowing that they have access to their data. 97% reported the intervention helped them stay motivated.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Mora et al., 2017)	**Design:** Single group, Interventional **Length (weeks)** 26 **Sample Size** 87 **Age (mean)** 58	**Treatment** A wireless glucose meter with a companion smartphone application. The application allows for data sharing with HCPs who can access the system via their own dashboard. Timely treatment adjustment is provided by HCP.	**Outcome Measures** Glycemic control: • HbA1c Patient-reported measures: • Treatment satisfaction **Results** A significant improvement in HbA1c was observed in the patient cohort. The intervention was associated with an improvement in patient satisfaction and better glycemic control. Overall, the ability to share data with clinicians and receive timely guidance improved the patient's perceived treatment satisfaction.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Levy et al., 2018)	**Design:** Single group, Interventional **Length (weeks)** 12 **Sample Size** 113 **Age (mean)** 50	**Treatment** Remote insulin dose adjustment via basic phone using SMS and phone calls.	**Outcome Measures** Glycemic control: • FBG • Insulin dose optimization **Results** The intervention helped patients meet their targets without in-person care. This was particularly useful for those who cannot make a physical appearance due to remote residence. Satisfaction with the intervention was high, and it was found to be generalizable to a clinical setting. Only 9 out of 113 did not meet their indicated clinical targets.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(McGloin et al., 2020)	**Design:** Single group, Interventional **Length (weeks)** 12 **Sample Size** 39 **Age (mean)** 62	**Treatment** A dedicated telemedicine apparatus integrated with a blood glucose meter and a button to enable interviews with HCP via videoconferencing.	**Outcome Measures** Glycemic control: • HbA1c Patient empowerment: • DES **Results** A significant reduction in A1c was observed at end point. This effect commenced post intervention termination. A high level of satisfaction with the intervention was reported. Additional benefits included an increase in patient competence and knowledge.

Reference	Study Design and Patient Characteristics	Interventions and Allocation	Outcome Measures and Results
(Kesavadev et al., 2012)	**Design:** Retrospective cohort review **Span (weeks)** 26 **Sample Size** 1000 **Age (mean)** 53	**Treatment** A confluence of mainstream communication technologies in addition to access to a secured patient portal. The service included active medication management, including insulin.	**Outcome Measures** Glycemic control • HbA1c Safety • Incidents of hypoglycemia **Results** The intervention was cost effective and safe with no incidents of hypoglycemia reported. Improvement in A1c was also observed.

(B) – Technologies and Architectures

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Nikkanen et al., 2008)	**Interactive User Devices** Specialized teleconferencing equipment **Health Devices** Integrated Stethoscope **Access Point** Unspecified	**Application** Video Consultations and Remote Diagnostics **Networking** Private Secured Network (H.320)	**Access** Specialized teleconferencing equipment **Feedback** Real-time, symmetrical	**Archetype E**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Boaz et al., 2009)	**Interactive User Devices** NA **Health Devices** Glucometer **Access Point** Health Gateway / Modem	**Application** Patient Telemonitoring **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Asymmetrical	**Archetype A**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Turner et al., 2009)	**Interactive User Devices** Smartphone **Health Devices** Connected Glucometer **Access Point** GSM / CDMA	**Application** Patient Telemonitoring **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Asymmetrical	**Archetype D**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Stone et al., 2010)	**Interactive User Devices** Specialized telemedicine Equipment **Health Devices** Connected Glucometer Connected BPM Connected Weight Scale **Access Point** Health Gateway	**Application** Patient Telemonitoring **Networking** Tunneled network over public infrastructure	**Access** Proprietary platform for routine report generation from subscribed devices **Feedback** Asymmetrical	**Archetype A**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(West et al., 2010)	**Interactive User Devices** Desktop / Laptop **Health Devices** Glucometer BPM **Access Point** Modem	**Application** Patient Telemonitoring Remote Consultation **Networking** Internet	**Access** Desktop / Laptop, various applications **Feedback** Hybrid	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Kim et al., 2010)	**Interactive User Devices** Basic Phone **Health Devices** Glucometer **Access Point** SMS via GSM / CDMA	**Application** Automatic Insulin Dose Adjustment **Networking** GSM / CDMA	**Access** Web Application / Dashboard **Feedback** Hybrid	**Archetype C**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Simon et al., 2011)	**Interactive User Devices** Browser-enabled computer **Health Devices** Glucometer **Access Point** Modem	**Application** Basal insulin dose titration **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Symmetrical, Automatic with HCP control.	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Bujnowska-Fedak et al., 2011)	**Interactive User Devices** Desktop / Laptop **Health Devices** Infrared Glucometer **Access Point** Modem	**Application** Remote Patient Monitoring **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Asymmetrical	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Chen et al., 2011)	**Interactive User Devices** Specialized platform **Health Devices** Glucometer BPM **Access Point** Modem / Landline	**Application** Remote Patient Monitoring Insulin dose adjustment **Networking** Internet / Phone	**Access** Web Application / Dashboard **Feedback** Asymmetrical	**Archetype G**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Kesavadev et al., 2012)	**Interactive User Devices** Phone Browser-enabled computer. **Health Devices** Glucometer **Access Point** Modem / GSM / CDMA / PSTN	**Application** Remote Patient Monitoring **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Hybrid	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(McFarland et al., 2012)	**Interactive User Devices** NA **Health Devices** Connected Glucometer **Access Point** Gateway / Landline	**Application** Remote Patient Monitoring **Networking** Internet	**Access** Direct integration with electronic health records **Feedback** Asymmetrical	**Archetype A**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Del Prato et al., 2012)	**Interactive User Devices** NA **Health Devices** Connected Glucometer **Access Point** Integrated modem	**Application** Remote Patient Monitoring **Networking** Public Phone Network	**Access** Desktop Computer **Feedback** Asymmetrical	**Archetype A**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Fatehi et al., 2013)	**Interactive User Devices** Dedicated Telemedicine Equipment in a clinical setting **Health Devices** Unspecified **Access Point** Unspecified	**Application** Remote Consultation **Networking** Private secured network over public infrastructure	**Access** Dedicated telemedicine equipment **Feedback** Symmetrical, real-time	**Archetype E**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Tang et al., 2013)	**Interactive User Devices** Smartphone **Health Devices** Connected Glucometer **Access Point** GSM / CDMA	**Application** Remote Patient Monitoring **Networking** Internet	**Access** Direct integration with electronic health records **Feedback** Asymmetrical	**Archetype D**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Wakefield et al., 2014)	**Interactive User Devices** NA **Health Devices** Connected Glucometer Connected BPM **Access Point** Modem / Health Gateway via Landline	**Application** Remote Patient Monitoring **Networking** Internet	**Access** Secured Web Portal **Feedback** Asymmetrical	**Archetype A**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Greenwood et al., 2015)	**Interactive User Devices** Smartphone **Health Devices** Cable-connected glucometer **Access Point** GSM / CDMA	**Application** Remote Patient Monitoring **Networking** Internet	**Access** Secured Web Portal Direct integration with electronic health records **Feedback** Hybrid	**Archetype D**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Levy et al., 2015)	**Interactive User Devices** Basic Cellular Phone **Health Devices** Glucometer **Access Point** SMS via GSM / CDMA	**Application** Remote Insulin Dose Adjustment **Networking** PSTN, GSM/CDMA	**Access** Secured Web Portal **Feedback** Hybrid	**Archetype C**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Fountoulakis et al., 2015)	**Interactive User Devices** NA **Health Devices** USB Glucometer **Access Point** Modem / Health Gateway	**Application** Patient telemonitoring Active therapy management **Networking** Not specified	**Access** Secured Server **Feedback** Asymmetrical	**Archetype A**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Due-Christensen et al., 2015)	**Interactive User Devices** NA **Health Devices** Glucometer **Access Point** PSTN	**Application** Remote consultation **Networking** PSTN	**Access** Patient health records **Feedback** Symmetrical, Real-time	**Archetype F**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Isaković et al., 2016)	**Interactive User Devices** Smartphone / Tablet **Health Devices** Connected Glucometer Pedometer **Access Point** NA	**Application** Generic Diabetes Self-care **Networking** NA	**Access** NA **Feedback** NA	**N/A** **(Self-contained diabetes care application)**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Hsu et al., 2016)	**Interactive User Devices** Smartphone / Tablet **Health Devices** Connected Glucometer Pedometer **Access Point** Wi-Fi, GSM / CDMA	**Application** Remote consultation Shared decision making with shared UI **Networking** Internet	**Access** Desktop / Laptop Unspecified specialized software **Feedback** Symmetrical	**Archetype H**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Grady et al., 2016)	**Interactive User Devices** Browser-enabled computer (Web application) **Health Devices** Glucometer **Access Point** Wi-Fi, GSM / CDMA, Ethernet etc.	**Application** Remote patient monitoring Active therapy management **Networking** Internet, PSTN	**Access** Web Application / Dashboard **Feedback** Hybrid	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Baron et al., 2017)	**Interactive User Devices** Smartphone / Tablet **Health Devices** Connected glucometer Connected BPM **Access Point** Wi-Fi, GSM / CDMA	**Application** Remote patient monitoring Remote insulin dose adjustment **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Hybrid	**Archetype D**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Mora et al., 2017)	**Interactive User Devices** Smartphone / Tablet **Health Devices** Connected glucometer **Access Point** Wi-Fi, GSM / CDMA	**Application** Remote patient monitoring Risk-based therapeutic adjustments **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Asymmetrical	**Archetype D**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Ding et al., 2018)	**Interactive User Devices** Smartphone / Tablet **Health Devices** Connected glucometer **Access Point** Wi-Fi, GSM / CDMA	**Application** Remote patient monitoring **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Asymmetrical	**Archetype D**

Reference	Patient’s Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Ronda et al., 2018)	**Interactive User Devices** Browser-enabled computer **Health Devices** Glucometer **Access Point** Internet via Wi-Fi, GSM / CDMA, Ethernet etc.	**Application** Remote patient monitoring **Networking** Internet	**Access** Direct integration with patient health records **Feedback** Asymmetrical	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Joubert et al., 2019)	**Interactive User Devices** Smartphone / Tablet **Health Devices** Glucometer **Access Point** Wi-Fi, GSM / CDMA	**Application** Remote patient monitoring Remote insulin dose adjustment **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Symmetrical, Automatic, Real-time	**Archetype D**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Bramwell et al., 2020)	**Interactive User Devices** Smartphone / Tablet **Health Devices** Glucometer **Access Point** Wi-Fi, GSM / CDMA	**Application** Remote patient monitoring HCP Messaging **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Asymmetrical	**Archetype D**

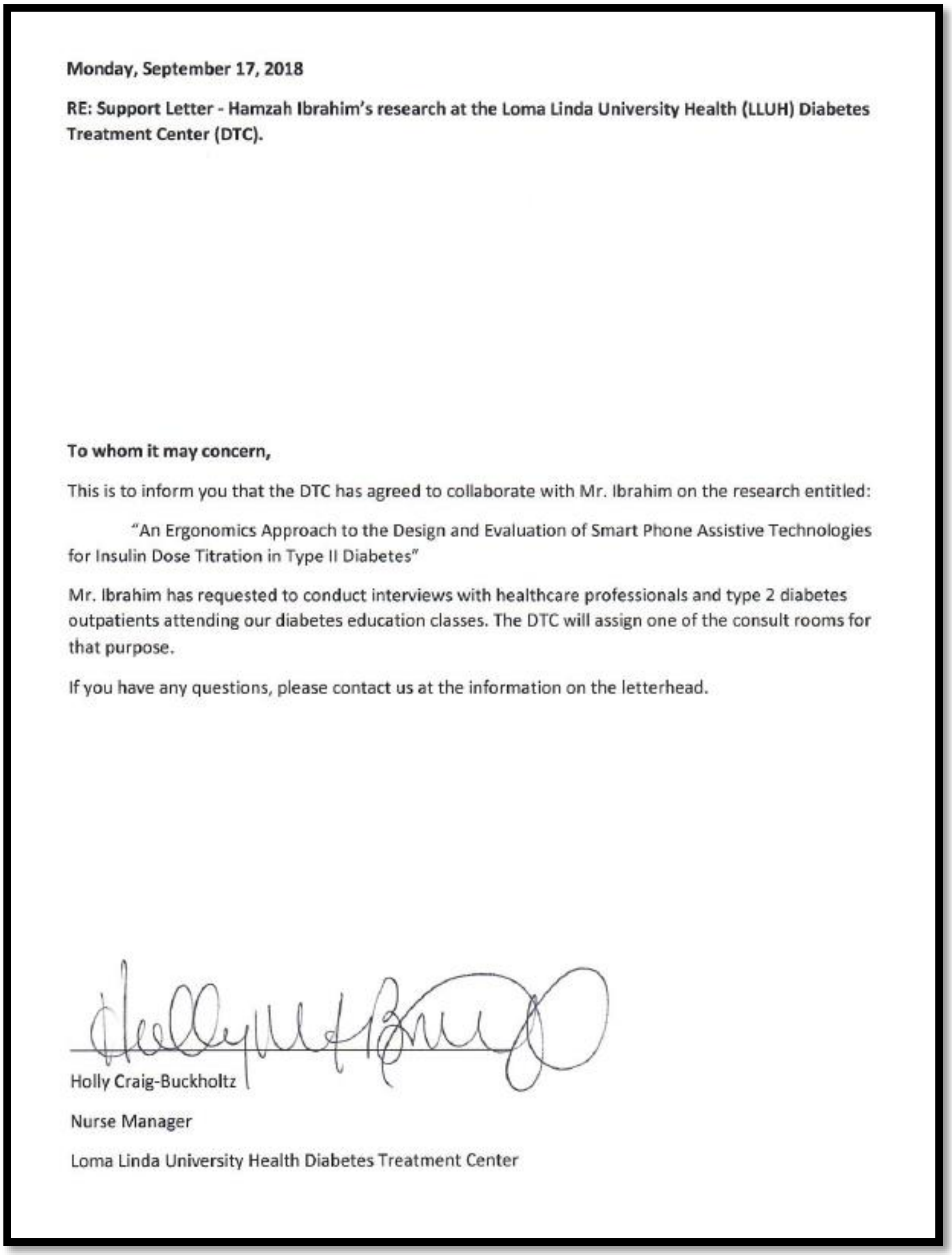
Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(McGloin et al., 2020)	**Interactive User Devices** Specialized telemedicine equipment **Health Devices** Connected glucometer **Access Point** Internet access /Unspecified	**Application** Remote patient monitoring Teleconsultation **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Hybrid	**Archetype G**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Lemelin et al., 2020)	**Interactive User Devices** Browser-enabled computer **Health Devices** Glucometer **Access Point** Wi-Fi, GSM / CDMA, Ethernet etc.	**Application** Remote patient monitoring Hypoglycemia Alerts **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Hybrid	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(León-Vargas et al., 2021)	**Interactive User Devices** Browser-enabled computer **Health Devices** Glucometer **Access Point** Wi-Fi, GSM / CDMA, Ethernet etc.	**Application** Remote patient monitoring **Networking** Internet	**Access** Web Application / Dashboard **Feedback** Unspecified	**Archetype B**

Reference	Patient's Premises	Application and Communication Infrastructure	Healthcare Provider Premises	Deployment
(Vluggen et al., 2021)	**Interactive User Devices** Browser-enabled computer **Health Devices** Unspecified **Access Point** Wi-Fi, GSM / CDMA, Ethernet, etc.	**Application** Glucose logs Tailored feedback messages and videos **Networking** Internet	**Access** Unspecified, report generation **Feedback** Asymmetrical	**Archetype B**

Appendix 2: Research Site and Ethics Approvals



Monday, September 17, 2018

RE: Support Letter - Hamzah Ibrahim's research at the Loma Linda University Health (LLUH) Diabetes Treatment Center (DTC).

To whom it may concern,

This is to inform you that the DTC has agreed to collaborate with Mr. Ibrahim on the research entitled:

"An Ergonomics Approach to the Design and Evaluation of Smart Phone Assistive Technologies for Insulin Dose Titration in Type II Diabetes"

Mr. Ibrahim has requested to conduct interviews with healthcare professionals and type 2 diabetes outpatients attending our diabetes education classes. The DTC will assign one of the consult rooms for that purpose.

If you have any questions, please contact us at the information on the letterhead.

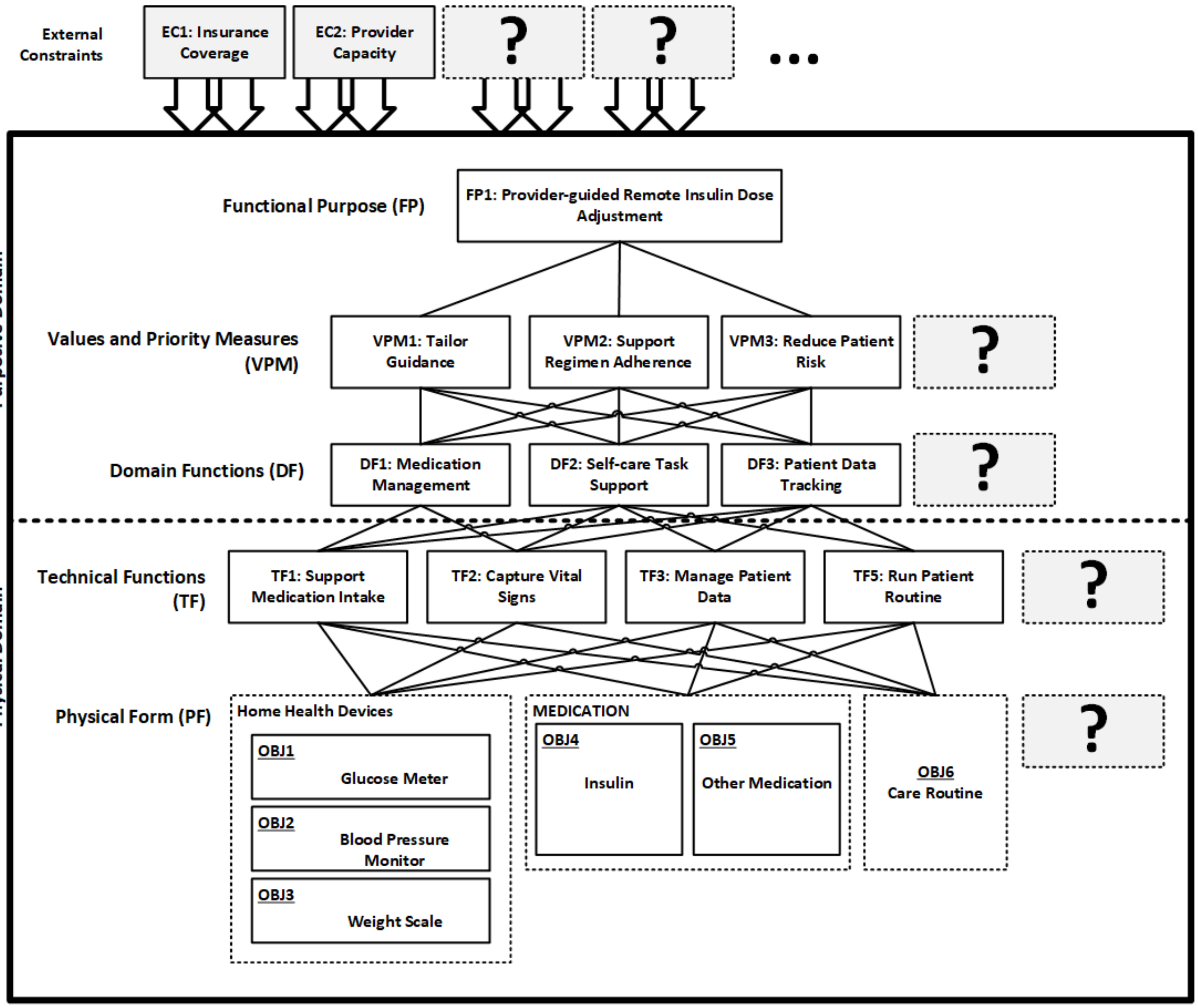
Holly Craig-Buckholtz

Nurse Manager

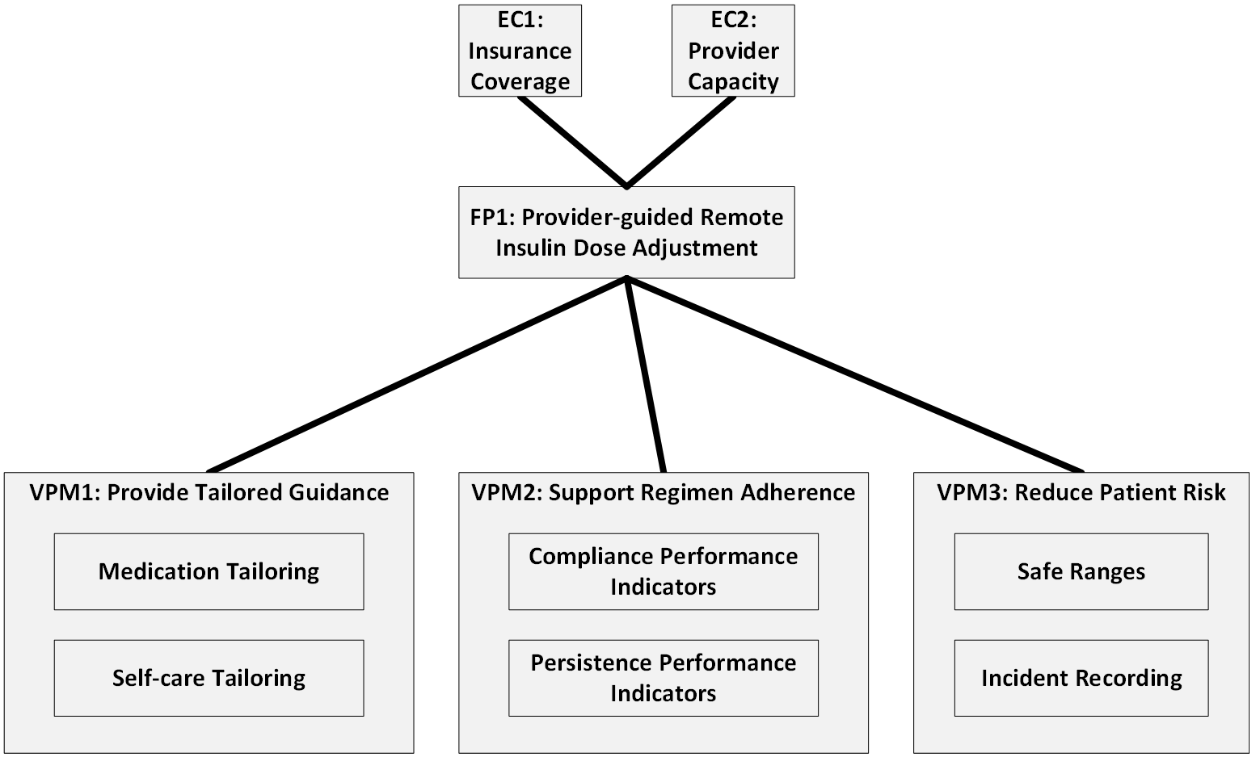
Loma Linda University Health Diabetes Treatment Center

Loma Linda University Diabetes Treatment Center – Letter of Support

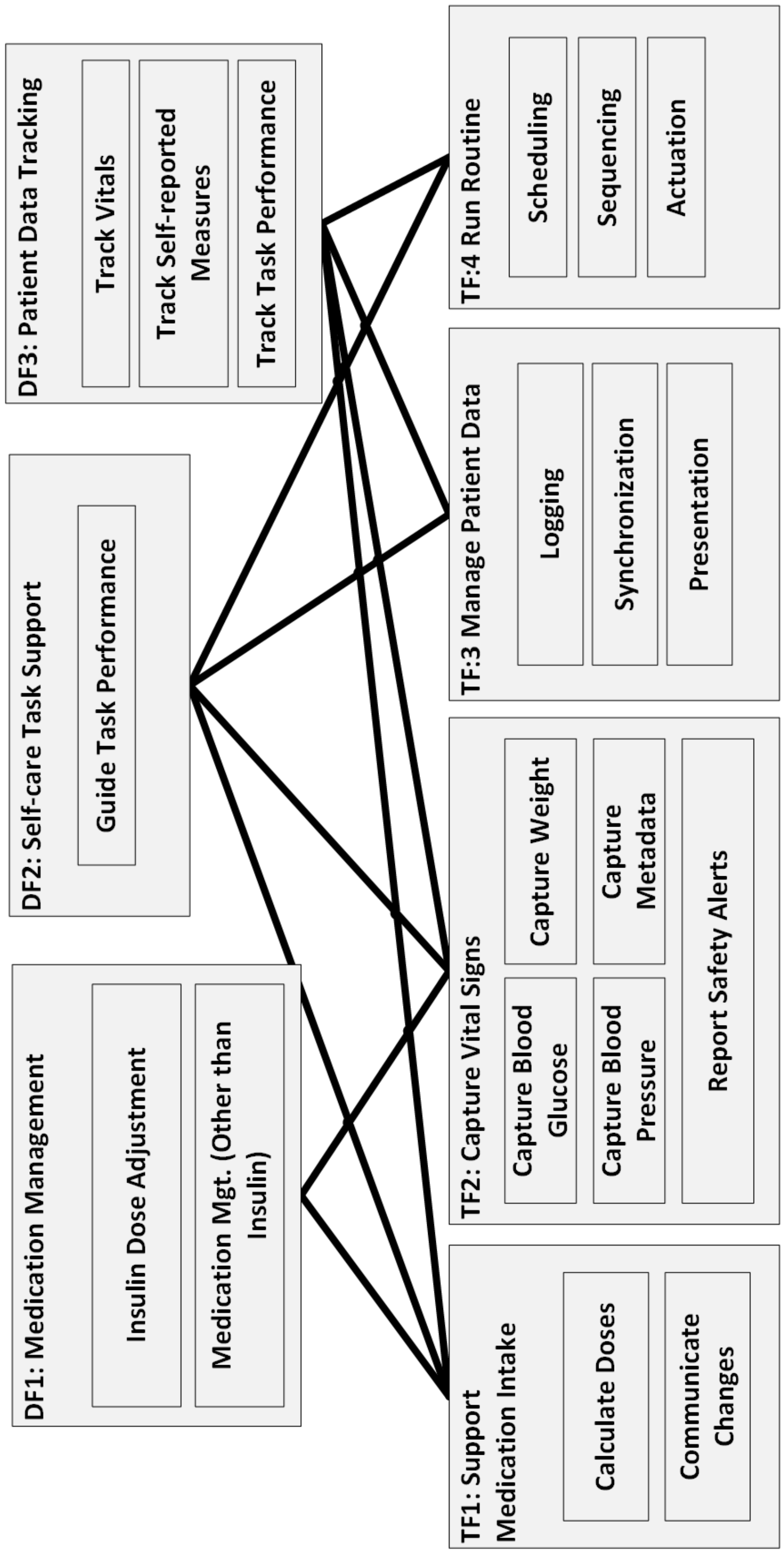
Appendix 3: Full Abstraction-Decomposition Space for the Insulin Dose Titration Aid



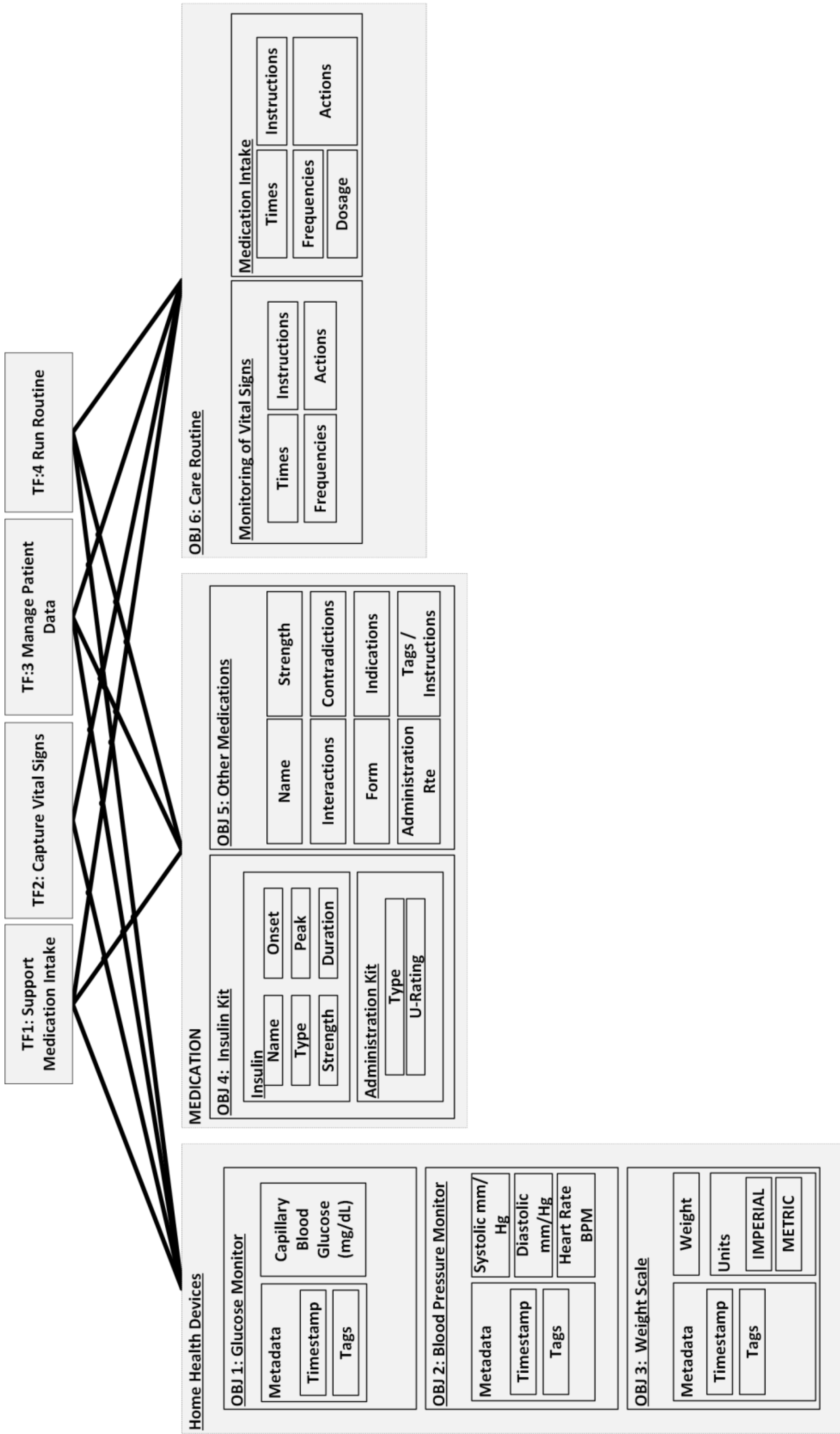
Full Abstraction Hierarchy



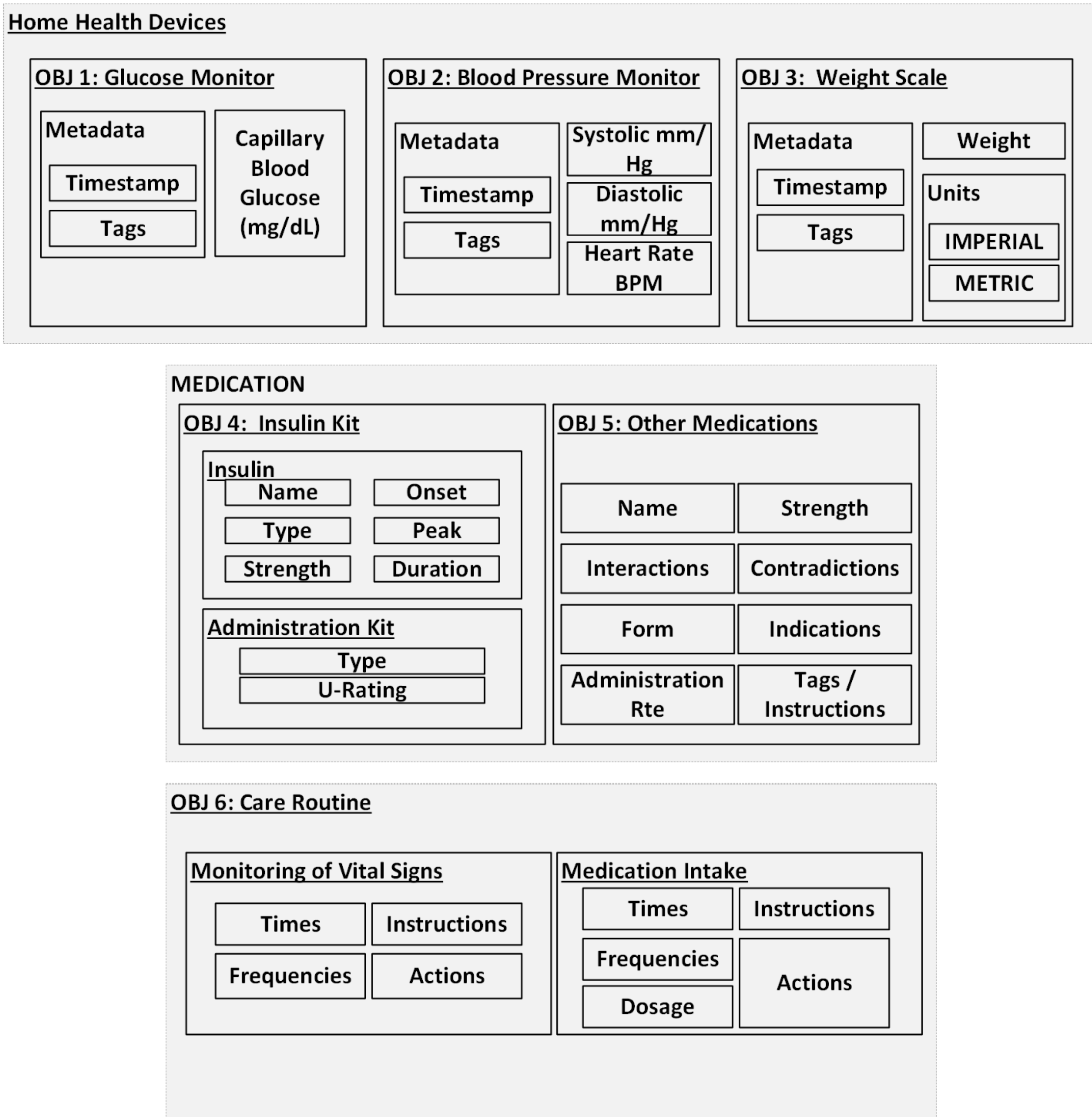
External Constraints (EC), Functional Purpose (FP), and Values and Priority Measures (VPM)



Domain Functions (DF) and Technical Functions (TF)



Technical Functions (TF) and Materials (OBJ)



Materials (OBJ)

ADS-HTA Mappings

TASK 1: Measure Blood Sugar	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Prepare Equipment. *1.1.1.* Unpack the glucose test kit and check items. 1.2. Prepare meter. *1.2.1.* Switch meter ON. *1.2.2.* Check meter status. 1.3. Insert glucose test strip into meter. *1.3.1.* Check strip orientation. *1.3.2.* Insert strip into the strip receiving port on the meter.	**OBJ 1:** Blood glucose monitor **OBJ 6:** Care Routine
2. Obtain Sample. *2.1.1.* Clean sample site (e.g., fingertips). *2.1.2.* Use lancing device to get a blood sample. *2.1.3.* Collect second drop of blood on the strip.	**OBJ 1:** Blood glucose monitor **OBJ 6:** Care Routine **TF 2:** Capture Vital Signs
3. Note glucose measurement. *3.1.1.* Record reading in glucose diary.	**TF 3:** Manage Patient Data
4. Terminate Task. 4.1. Dispose of medical waste. *4.1.1.* Collect strips, swabs, and sharps into an appropriate receptacle (e.g., locking biowaste bag). *4.1.2.* Dispose of receptacle in an approved receptacle. *4.1.3.* Check items and repack the glucose test kit.	**OBJ 6:** Care Routine

ADS-HTA Mappings for Task 1: Measure Blood Sugar

TASK 2: Measure Blood Pressure	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Prepare Equipment 1.1.1. Unpack the blood pressure meter kit. 1.1.2. Assemble unit if necessary.	**OBJ 2:** Blood Pressure Monitor **OBJ 6:** Care Routine
2. Fit measurement cuff 2.1.1. Sit upright with both feet on the ground.	

TASK 2: Measure Blood Pressure	
Goal / Sub-Goal	**ADS Resources Utilized**
2.1.2. Check cuff orientation (marked on cuff). 2.1.3. Wear cuff up to the heart level and secure to fit.	
3. Take blood pressure measurement 3.1.1. Confirm correct cuff fitment and orientation. 3.1.2. Press the ON button on the blood pressure meter. 3.1.3. Sit upright with both feet on the ground. 3.1.4. Rest arms on armrests 3.1.5. Maintain cuff alignment with chest. 3.1.6. Remain still and wait. 3.1.7. Receive measurement completion notification from meter.	**OBJ 2:** Blood Pressure Monitor **OBJ 6:** Care Routine **TF 2:** Capture Vital Signs
4. Note blood pressure measurement 4.1.1. Record measurement in vitals diary.	**TF 3:** Manage Patient Data
5. Terminate Task 5.1.1. Remove cuff. 5.1.2. Disassemble unit if necessary. 5.1.3. Repack the blood pressure measurement kit.	**OBJ 6:** Care Routine

ADS-HTA Mappings for Task 2: Measure Blood Pressure

TASK 3: Measure Weight	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Check equipment 1.1.1. Place scale on a hard, level surface 1.1.2. Switch scale on	**OBJ 3:** Weight Scale **OBJ 6:** Care Routine
2. Take weight measurement 2.1.1. Take off shoes 2.1.2. Step on scale 2.1.3. Wait for measurement to appear 2.1.4. Step off scale	**OBJ 3:** Weight Scale **OBJ 6:** Care Routine **TF 2:** Capture Vital Signs
3. Note wight 3.1.1. Record measurement in vitals diary.	**TF 3:** Manage Patient Data

TASK 3: Measure Weight	
Goal / Sub-Goal	**ADS Resources Utilized**
4. Terminate task 4.1.1. Stow away scale if necessary	**OBJ 6:** Care Routine

ADS-HTA Mappings for Task 3: Measure Weight

TASK 4: Determine Dose Requirements.	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Note current blood glucose measurement.	**OBJ 1:** Blood Glucose Monitor **OBJ 6:** Care Routine **TF 2:** Capture Vital Signs **TF 3:** Manage Patient Data
2. Use correct insulin. 2.1. Confirm insulin type. 2.2. Confirm insulin dose on label.	**OBJ 4:** Insulin Kit.
3. Calculate dose. 3.1. Use the titration formula. 3.2. Note the recommended insulin dose in patient diary. 3.3. Tag recommendation with insulin type and dose.	**TF1:** Support Medication Intake. **TF 3:** Manage Patient Data

ADS-HTA Mappings for Task 4: Determine Insulin Dose Requirements

TASK 5: Insulin Administration using an Insulin Pen	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Prepare insulin. 1.1. Check the insulin label. 1.2. Confirm insulin type and dose. 1.3. Confirm pen contains sufficient insulin.	**OBJ 4:** Insulin Kit **OBJ 6:** Care Routine
2. Prepare administration device 2.1. Mount a new needle on pen 2.2. Uncap needle 2.3. Prime pen if necessary 2.4. Clean needle site with alcohol 2.5. Dial in the recommended dose	**OBJ 4:** Insulin Kit **OBJ 6:** Care Routine
3. Inject insulin 3.1. Consult site rotation routine. 3.2. Determine injection site. 3.3. Clean injection site using alcohol. 3.4. Insert pen into skin at 90-degree angle (subcutaneous) 3.5. Actuate the plunger to administer insulin. 3.6. Remove pen	**OBJ 6:** Care Routine

TASK 5: Insulin Administration using an Insulin Pen	
Goal / Sub-Goal	**ADS Resources Utilized**
4. Keep record 4.1. Record insulin type and dose administered 4.2. Tag reading 4.3. Record injection site	**TF1:** Support Medication Intake **TF 3:** Manage Patient Data **OBJ 4:** Insulin Kit **OBJ 6:** Care Routine
5. Terminate task 5.1. Manage medical waste 5.1.1. Eject used needle in appropriate waste bag. 5.1.2. Collect waste and seal bag. 5.2. Store insulin for next use. 5.2.1. Check insulin storage requirements 5.2.2. Store insulin accordingly	**OBJ 6:** Care Routine **OBJ 4:** Insulin Kit

ADS-HTA Mappings for Task 5: Insulin Administration with Pen

TASK 6: Insulin Administration using Syringes and Vials	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Prepare insulin. 1.1. Check the insulin label. 1.2. Confirm insulin type and dose. 1.3. Confirm vial contains sufficient insulin. 1.4. Perform special instructions	**OBJ 4:** Insulin Kit **OBJ 6:** Care Routine
2. Prepare administration device 2.1. Mount new needle on syringe 2.2. Uncap needle 2.3. Draw insulin from vial 2.4. Confirm correct dose on syringe	**OBJ 4:** Insulin Kit **OBJ 6:** Care Routine
3. Inject insulin 3.1. Consult site rotation routine. 3.2. Determine injection site. 3.3. Clean injection site using alcohol 3.4. Insert needle into skin at 90-degree angle (subcutaneous) 3.5. Slowly push plunger to administer insulin. 3.6. Remove needle	**OBJ 6:** Care Routine
4. Keep record 4.1. Record insulin type and dose administered 4.2. Tag reading. 4.3. Record injection site	**TF1:** Support Medication Intake **TF 3:** Manage Patient Data **OBJ 4:** Insulin Kit **OBJ 6:** Care Routine

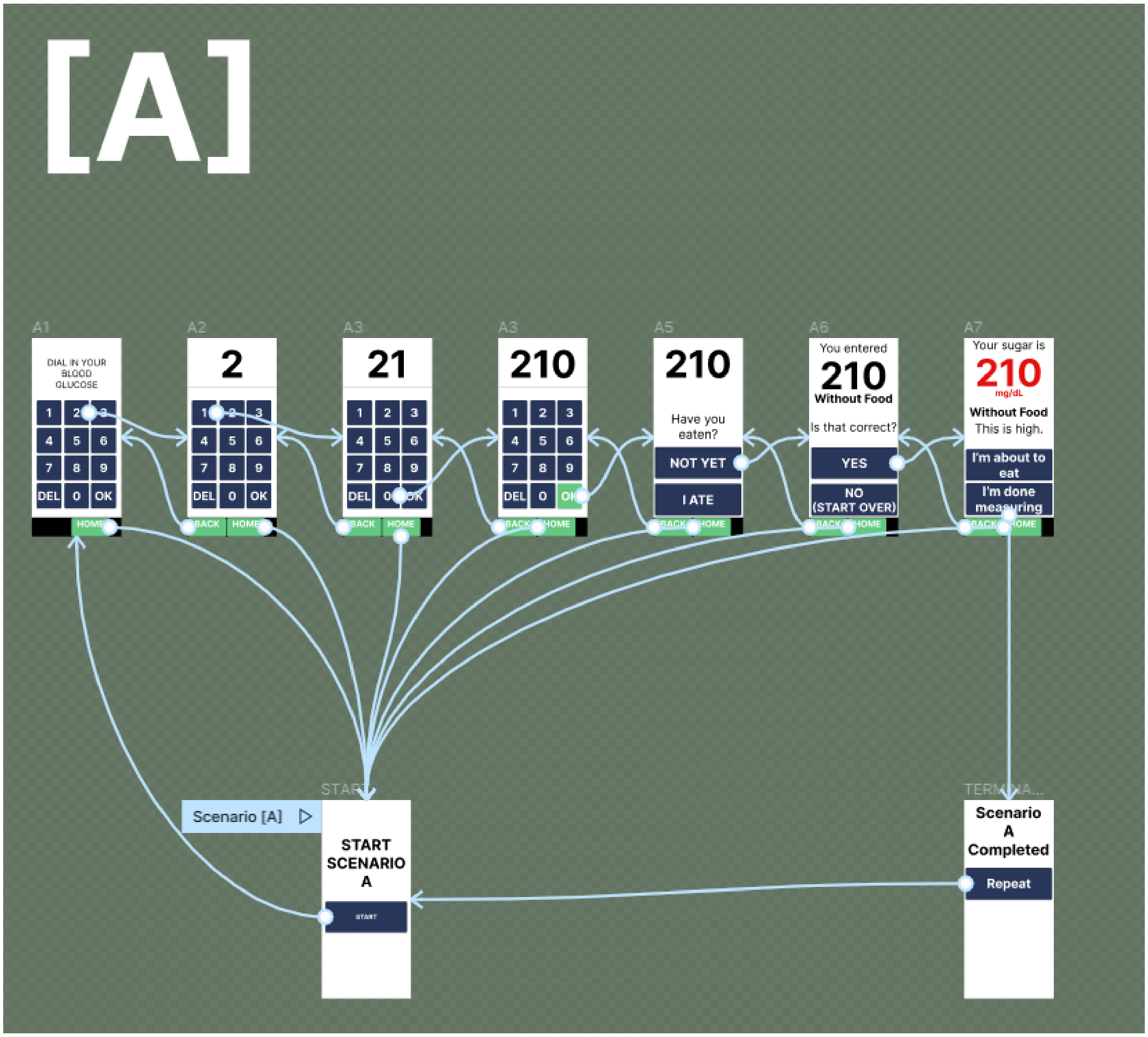
TASK 6: Insulin Administration using Syringes and Vials	
Goal / Sub-Goal	**ADS Resources Utilized**
5. Terminate task 5.1. Manage medical waste 5.1.1. Dispose of sharps and waste in appropriate receptacle 5.1.2. Seal bag and dispose of appropriately 5.2. Store insulin for next use 5.2.1. Check insulin storage requirements 5.2.2. Store insulin accordingly	**OBJ 4:** Insulin Kit **OBJ 6:** Care Routine

ADS-HTA Mappings for Task 6: Insulin Administration with Syringe and Vial

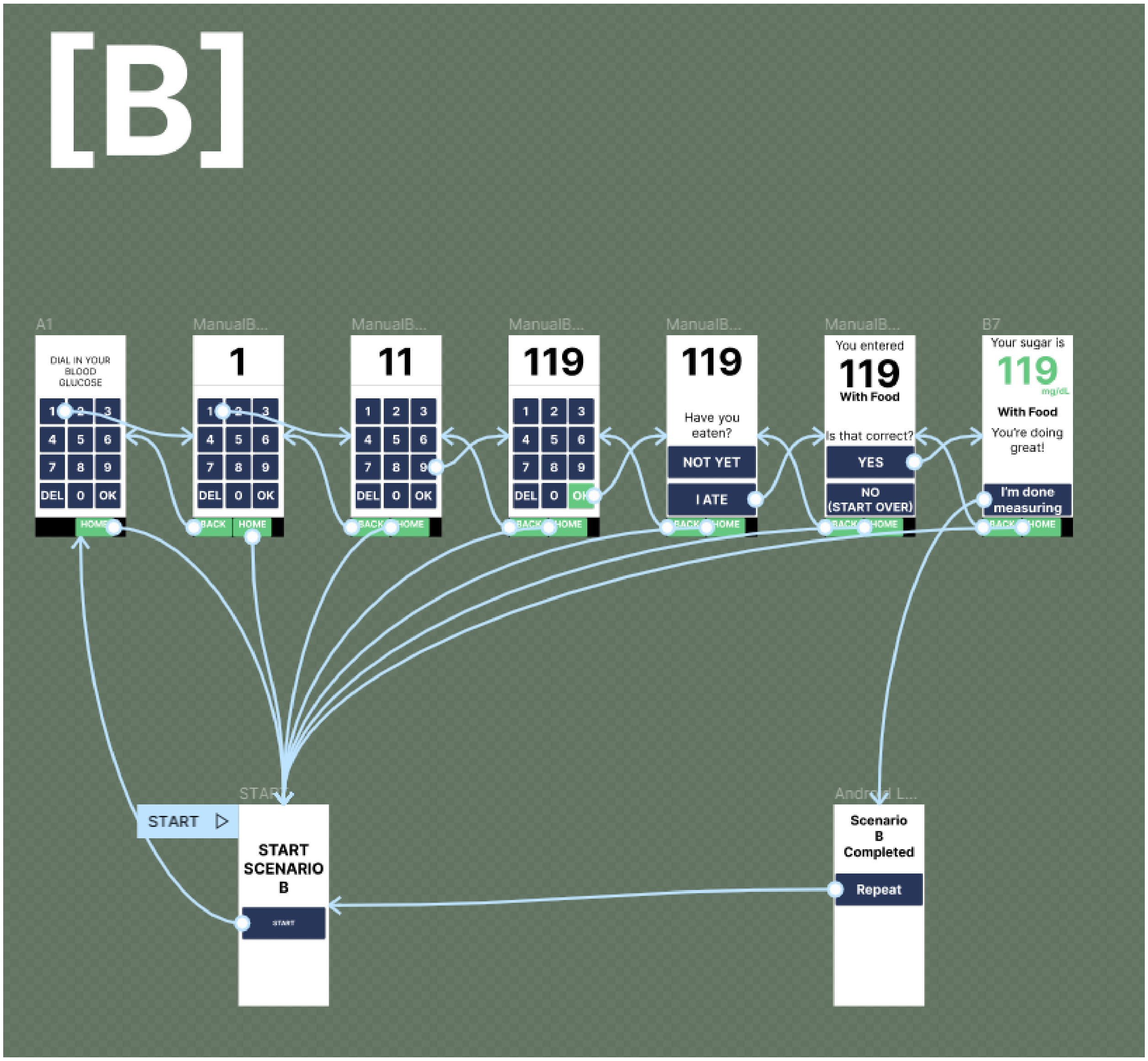
TASK 7: Take Medication	
Goal / Sub-Goal	**ADS Resources Utilized**
1. Identify correct medication 1.1. Check medication label 1.2. Check medication dosage	**OBJ 6:** Care Routine **OBJ 5:** Other Medication
2. Prepare 2.1. Perform prerequisites 2.1.1. Confirm compliance in relation to meal (e.g., with food, fasting) 2.1.2. Confirm compliance in relation to other medication (e.g., take with another medication)	**OBJ 6:** Care Routine **TF 1:** Support Medication Intake
3. Consume medication 3.1. Follow administration instructions (e.g., topical, oral, tablet splitting) 3.2. Consume medication as instructed	**OBJ 6:** Care Routine **TF 1:** Support Medication Intake
4. Keep record 4.1. Record instance (e.g., medication name, dosage, and timing) 4.2. Tag instance (e.g., with food, fasting)	**TF1:** Support Medication Intake **TF 3:** Manage Patient Data **OBJ 5:** Other Medication **OBJ 6:** Care Routine
5. Terminate 5.1. Store medication as instructed.	**OBJ 6:** Care Routine

ADS-HTA Mappings for Task 7: Take Medication

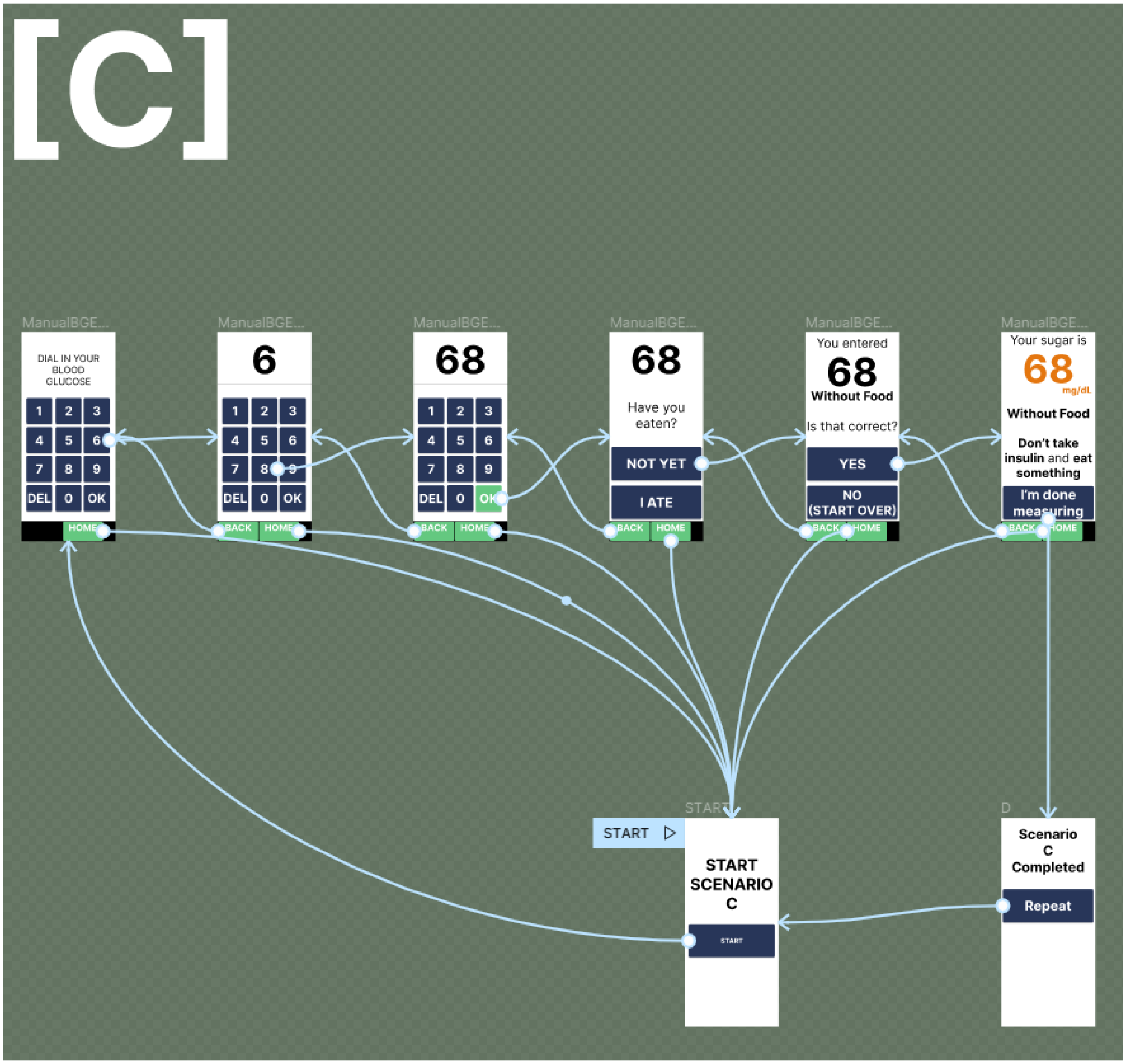
Appendix 4: User Interfaces

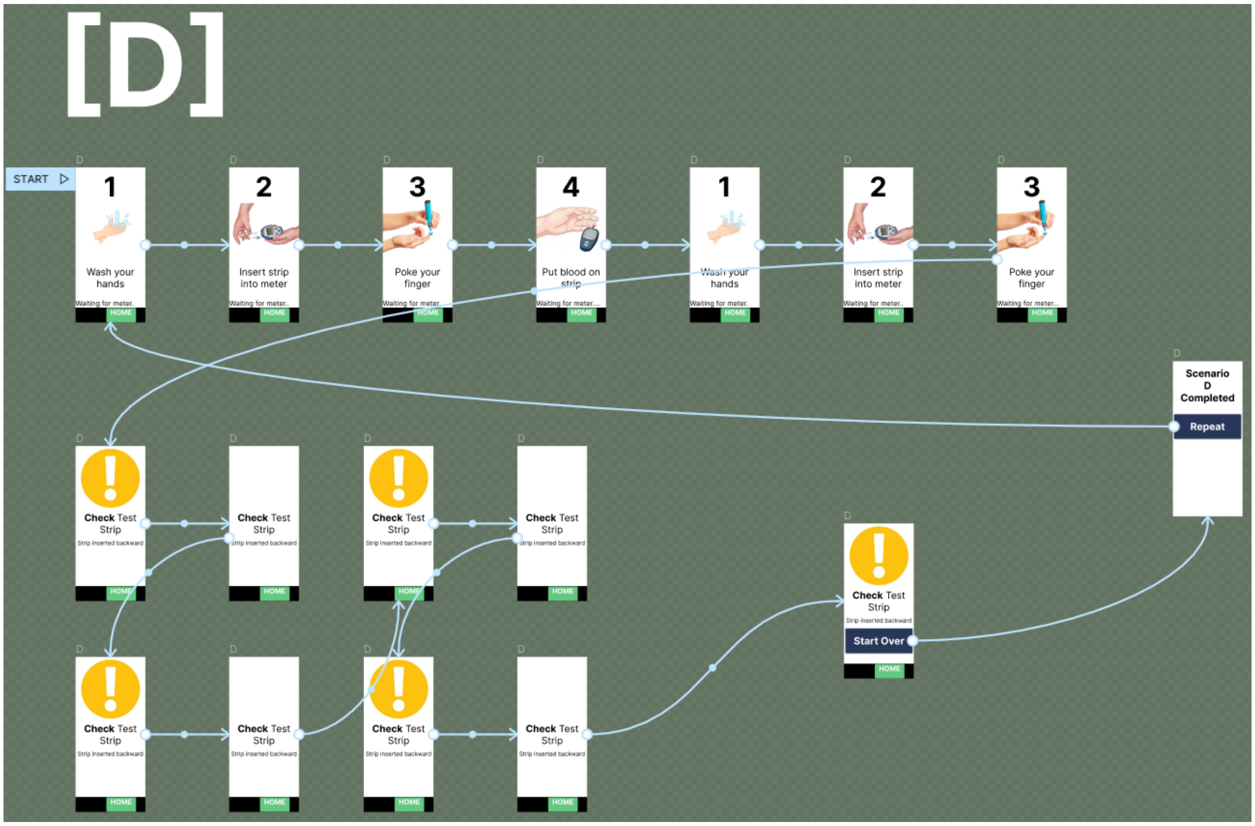


Scenario A.

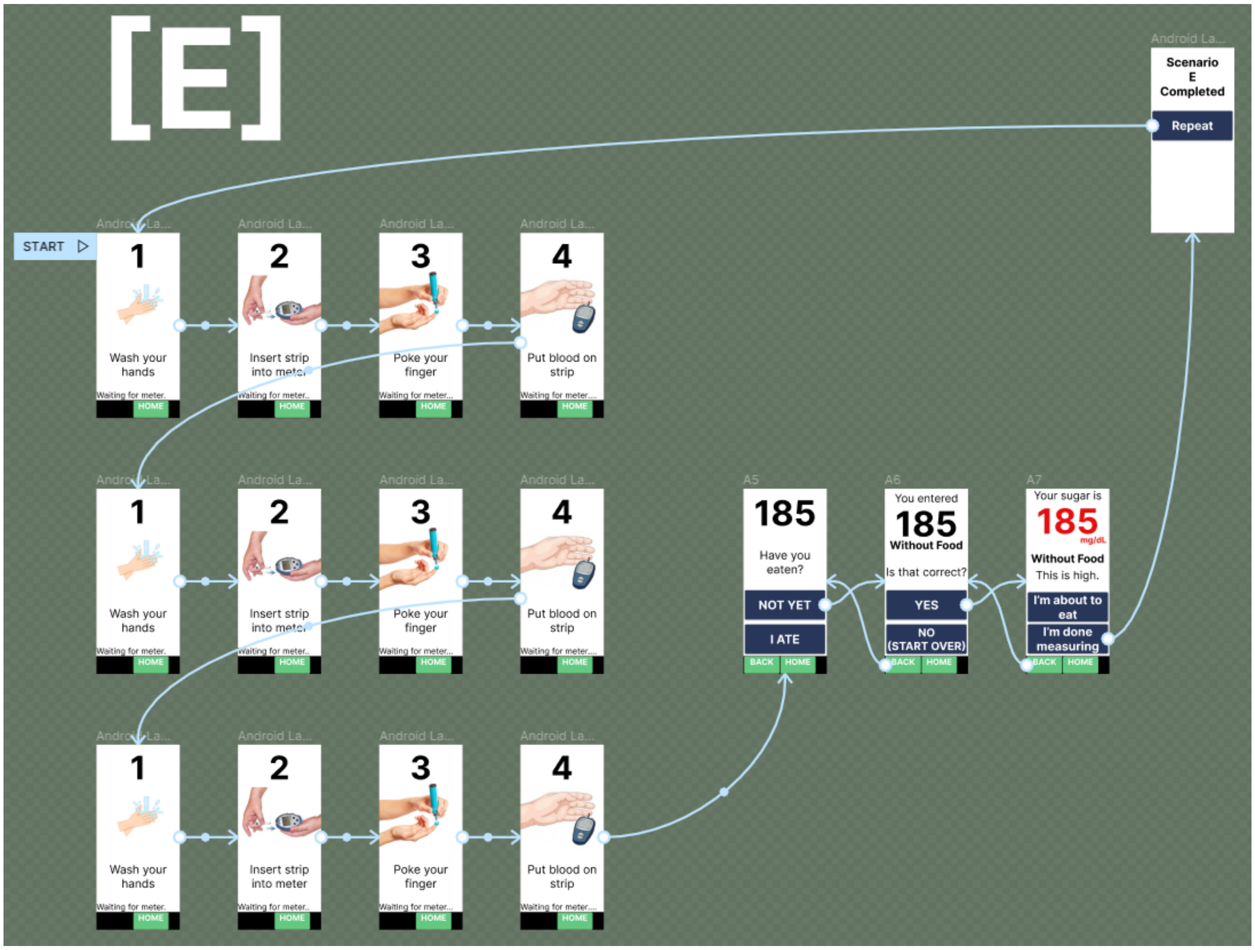

[B]
A1
DIAL IN YOUR BLOOD GLUCOSE
1
11
119
Have you eaten?
NOT YET
I ATE
You entered
119
With Food
Is that correct?
YES
NO (START OVER)
B7
Your sugar is
119
mg/dL
With Food
You're doing great!
I'm done measuring
BACK
HOME
START
START SCENARIO B
Scenario B Completed
Repeat

Scenario B.

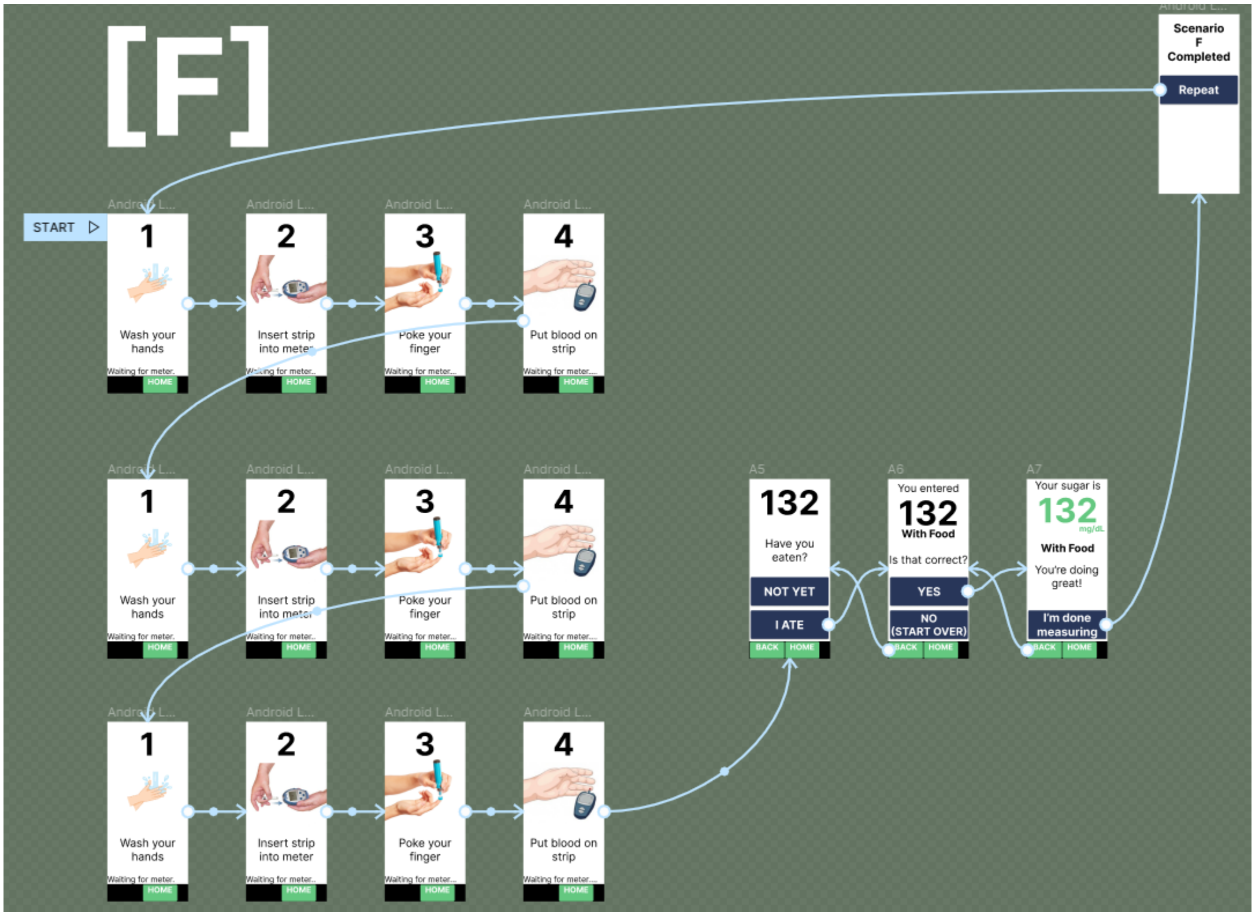

[C]
ManualBGE...
DIAL IN YOUR BLOOD GLUCOSE
1 2 3
4 5 6
7 8 9
DEL 0 OK
HOME
6
BACK
68
Have you eaten?
NOT YET
I ATE
You entered
68
Without Food
Is that correct?
YES
NO (START OVER)
Your sugar is
68
mg/dL
Without Food
Don't take insulin and eat something
I'm done measuring
START
START SCENARIO C
D
Scenario C Completed
Repeat
Scenario C.

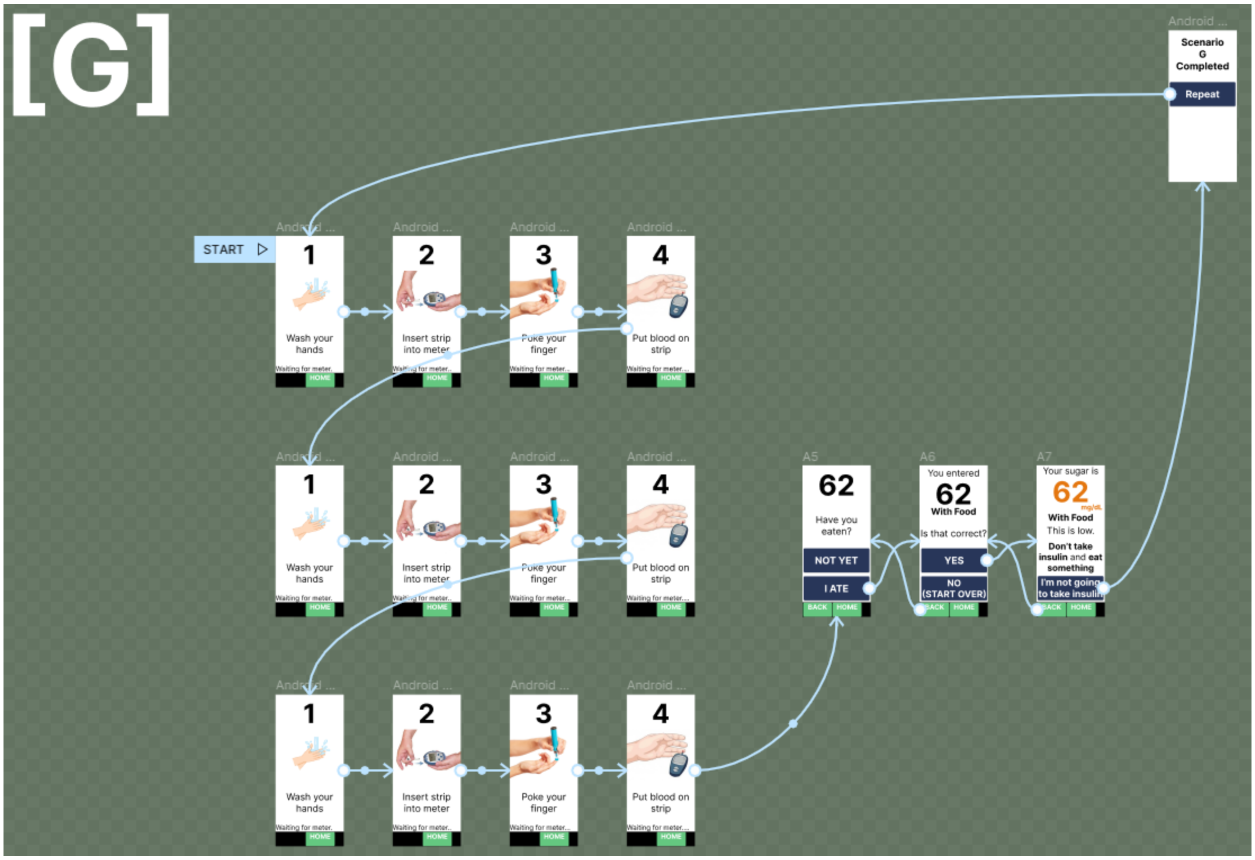

[D]
START
1
Wash your hands
2
Insert strip into meter
3
Poke your finger
4
Put blood on strip
1
Wash your hands
2
Insert strip into meter
3
Poke your finger
Scenario D Completed
Repeat
Check Test Strip
Start Over
HOME

Scenario D.


[E]
Scenario E Completed
Repeat
START
1
Wash your hands
2
Insert strip into meter
3
Poke your finger
4
Put blood on strip
185
Have you eaten?
NOT YET
I ATE
You entered
185
Without Food
Is that correct?
YES
NO (START OVER)
Your sugar is
185
mg/dL
Without Food
This is high.
I'm about to eat
I'm done measuring

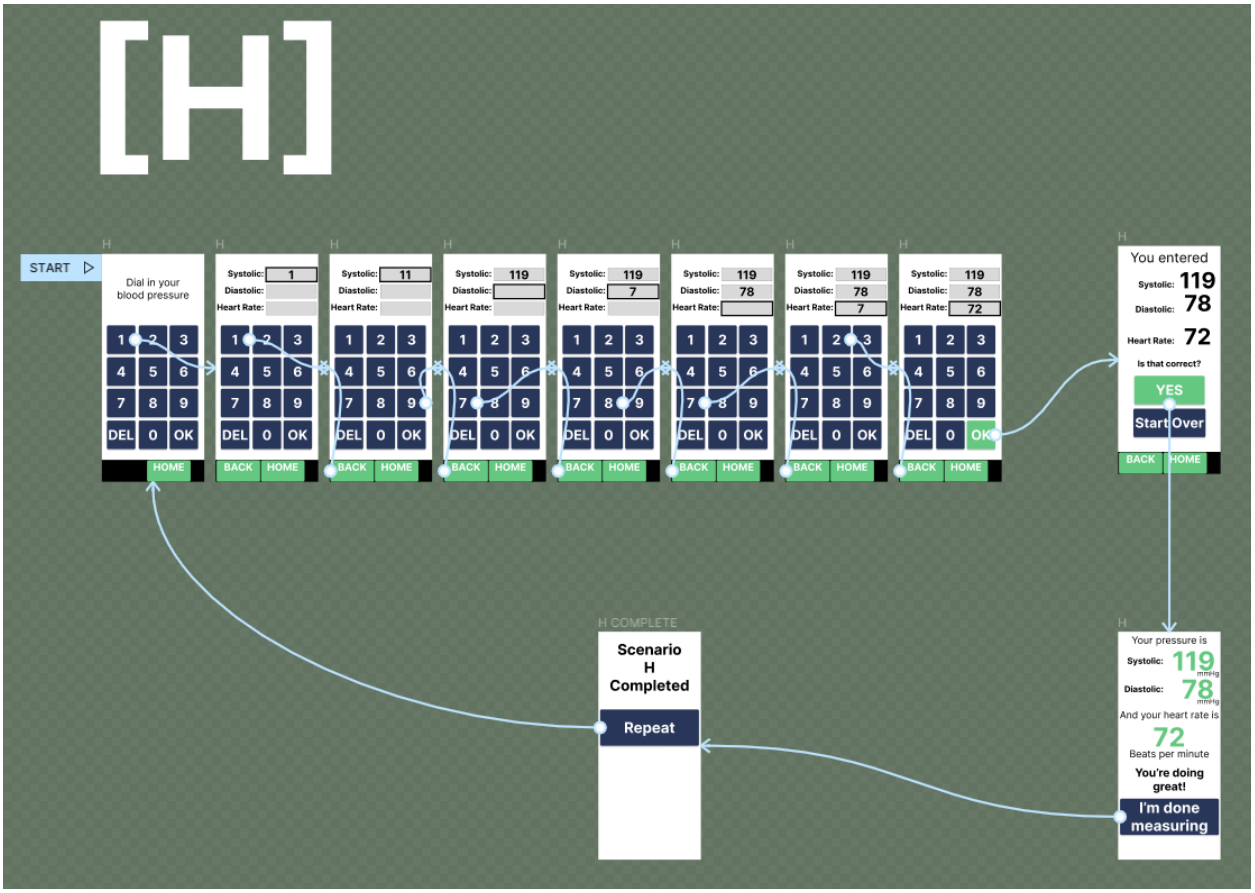
Scenario E.


[F]
START
Scenario F Completed
Repeat
1
Wash your hands
2
Insert strip into meter
3
Poke your finger
4
Put blood on strip
HOME
132
Have you eaten?
NOT YET
I ATE
You entered
132
With Food
Is that correct?
YES
NO (START OVER)
Your sugar is
132
With Food
You're doing great!
I'm done measuring
BACK
HOME
Scenario F.

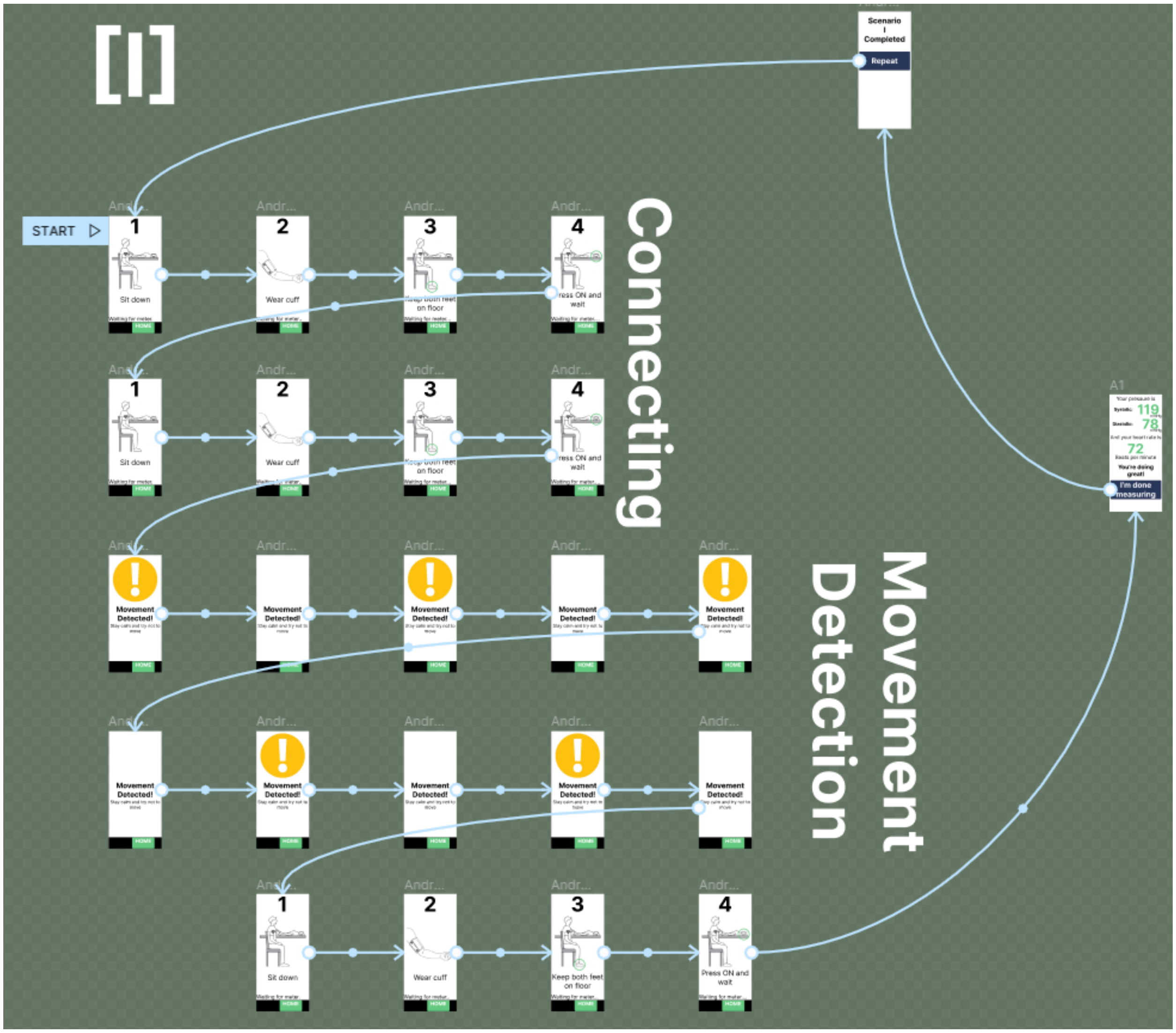


[G]
Scenario G Completed
Repeat
START
1
Wash your hands
2
Insert strip into meter
3
Poke your finger
4
Put blood on strip
A5
62
Have you eaten?
NOT YET
I ATE
A6
You entered
62
With Food
Is that correct?
YES
NO (START OVER)
A7
Your sugar is
62
With Food
This is low.
Don't take insulin and eat something
I'm not going to take insulin

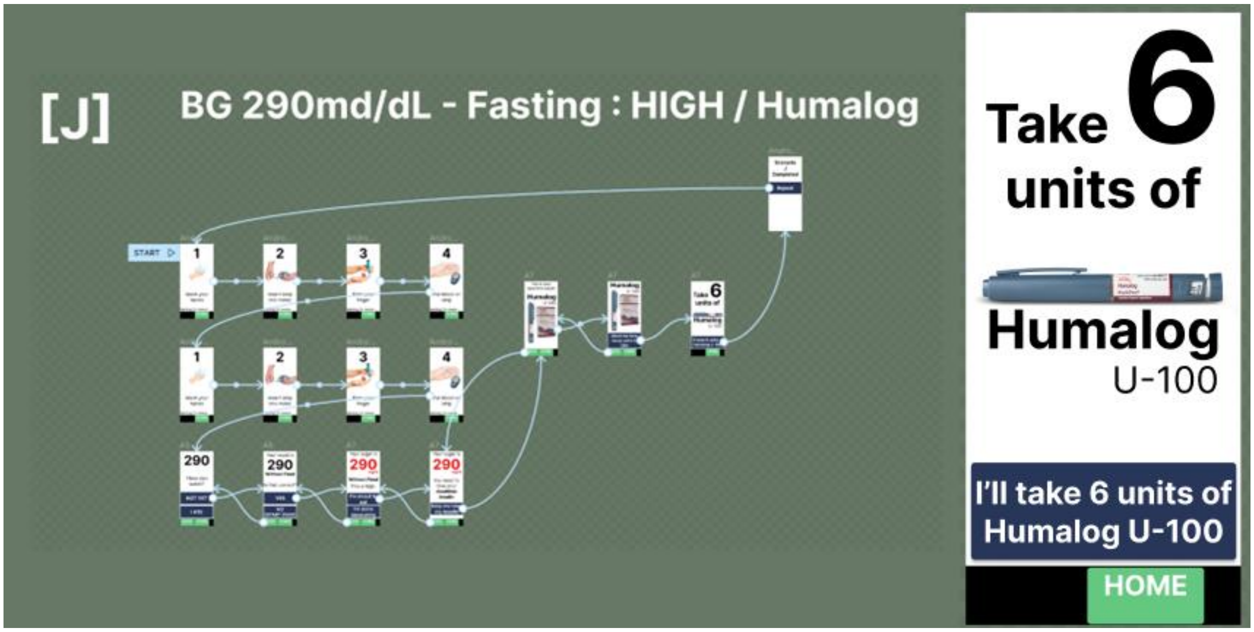
Scenario G.


[H]
START
Dial in your blood pressure
Systolic:
Diastolic:
Heart Rate:
YES
Start Over
You entered
Is that correct?
H COMPLETE
Scenario H Completed
Repeat
Your pressure is
And your heart rate is
Beats per minute
You're doing great!
I'm done measuring

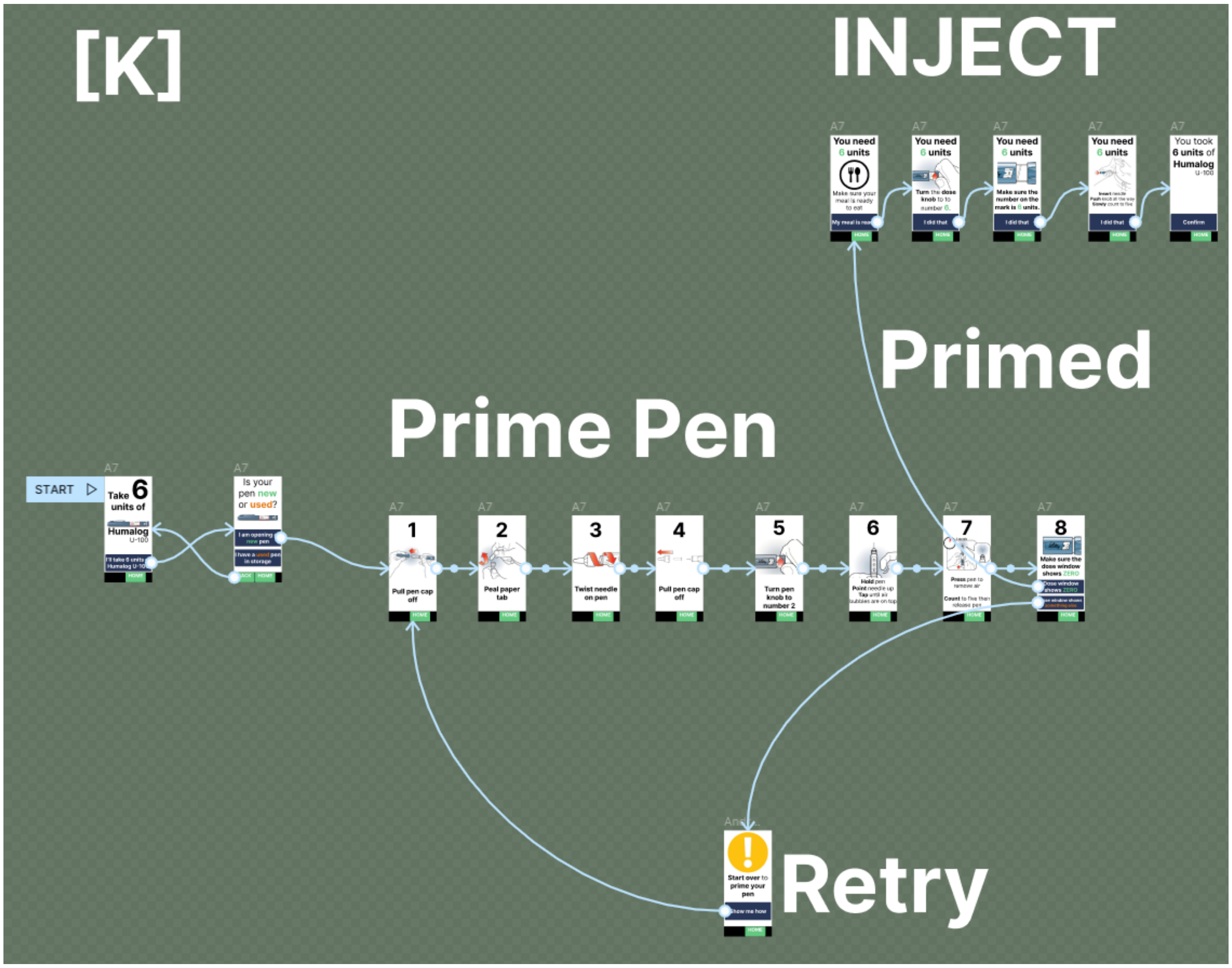
Scenario H.


[I]
START
Scenario I Completed
Repeat
Connecting
Movement Detection
Movement Detected!
Sit down
Wear cuff
Keep both feet on floor
Press ON and wait
I'm done measuring

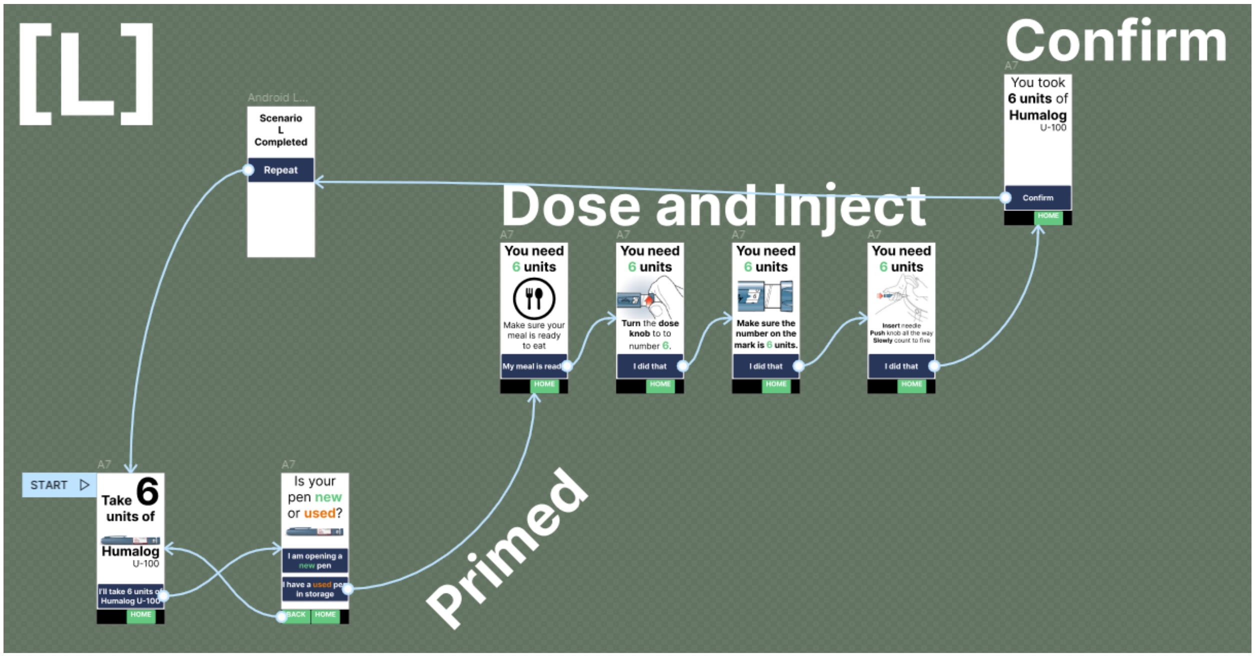
Scenario I.



Scenario J.



Scenario K.



[L]
Confirm
Scenario L Completed
Repeat
You took 6 units of Humalog U-100
Confirm
HOME
Dose and Inject
You need 6 units
Make sure your meal is ready to eat
My meal is ready
You need 6 units
Turn the dose knob to to number 6.
I did that
You need 6 units
Make sure the number on the mark is 6 units.
I did that
You need 6 units
I did that
START
Take 6 units of Humalog U-100
Is your pen new or used?
I am opening a new pen
I have a used pen in storage
BACK
Primed

Scenario L.

Appendix 5. Problems found and inter-rater reliability.

Problem ID	Scenario	Problem	Mode Severity	Violation
1	A	"Have you eaten" is confusing as to the timeframe.	2	Minimize user memory load
2	A	"This is High" must be better highlighted.	2	Match with real world
3	A	Answer is larger than question. Question should be more obvious.	1	Error prevention
4	A	Back and Home button colors are similar and may cause confusion.	2	Error prevention
5	A	Back and Home button placement and spacing	1	Aesthetics
6	A	Choice of word "dial in" is confusing.	1	Match with real world
7	A	Cluttered interface could be cleaned up.	1	Aesthetics
8	A	Data entry UI for blood sugar looks like a phone alphanumeric pad. Feels like application exited.	2	Minimize user memory load
9	A	Inconsistent font styles	1	Consistency
10	A	No feedback from pressing buttons.	1	Aesthetics
11	A	Small button	1	User control and freedom
12	A	Small text in some screens	1	Physical interaction
13	A	Would be better if the reading gets captured without the OK button.	1	Physical interaction
14	B	"Have you eaten" is confusing as to the timeframe.	2	Error prevention
15	B	Answer is larger than question. Question should be more obvious.	1	Aesthetics
16	B	Back and Home button colors are similar and may cause confusion.	1	Minimize user memory load
17	B	Choice of word "dial in" is confusing.	1	Match with real world

Problem ID	Scenario	Problem	Mode Severity	Violation
18	B	Data entry UI for blood sugar looks like a phone alphanumeric pad. Feels like application exited.	2	Minimize user memory load
19	B	Display data in the center and include "You're doing great!" at the top of the screen.	1	Aesthetics
20	B	Recommendation must be more obvious.	2	Match with real world
21	B	Small text in some screens	1	Physical interaction
22	B	Too many steps to obtain the result.	1	Aesthetics
23	B	When 119 goes green it moves up. Keep it in the same place	1	Consistency
24	C	"Have you eaten" is confusing as to the timeframe.	2	Error prevention
25	C	Answer is larger than question. Question should be more obvious.	1	Aesthetics
26	C	Back and Home button colors are similar and may cause confusion.	2	Minimize user memory load
27	C	Choice of word "dial in" is confusing.	1	Match with real world
28	C	Crowded but contains important information	2	Aesthetics
29	C	Data entry UI for blood sugar looks like a phone alphanumeric pad. Feels like application exited.	2	Minimize user memory load
30	C	Distinguish "Do not take insulin" from the color of the reading itself.	1	Aesthetics
31	C	Highlight important information better.	1	Match with real world
32	C	Measurement confirmation screen "68" may leave users wondering what that means!	1	System Status Visibility

Problem ID	Scenario	Problem	Mode Severity	Violation
33	C	No feedback from pressing buttons.	1	Aesthetics
34	C	Reading of 68 should remain in the same position	1	Consistency
35	C	Small text in some screens	1	Physical interaction
36	D	"This is High" must be better highlighted.	2	Match with real world
37	D	Add a loading bar	1	Aesthetics
38	D	Back and Home button colors are similar and may cause confusion.	1	Minimize user memory load
39	D	Confusing choice of language in "Start Over	1	Consistency
40	D	Highlight important information better.	1	Consistency
41	D	Home and Back buttons should be centered.	1	Aesthetics
42	D	Inconsistent writing styles	1	Consistency
43	D	Instructions are confusing.	1	Efficiency and performance
44	D	Instructions too fast to read	1	Minimize user memory load
45	D	Small button	1	User control and freedom
46	D	Small text in some screens	1	System Status Visibility
47	D	Unclear error message	2	Match with real world
48	E	Center your screen for better space utilization	1	Aesthetics
49	E	Emphasize "Too high", like blinking or otherwise.	1	Aesthetics
50	E	Highlight important information better.	1	Match with real world
51	E	Instructions too fast to read	1	Consistency
52	E	No navigation between instruction steps	2	User control and freedom
53	E	Small text in some screens	1	System Status Visibility
54	E	The confirmation screen "Your sugar is high" leaves the user wondering what should be done next.	2	Error recovery

Problem ID	Scenario	Problem	Mode Severity	Violation
55	F	Center your screen for better space utilization	1	Aesthetics
56	F	Important information could be highlighted better.	1	Error prevention
57	F	Instructions are too fast	1	Efficiency and performance
58	F	lacking navigation through instructions	2	User control and freedom
59	F	Buttons are problematic	1	Consistency
60	F	Images could be better	1	Consistency
61	F	Small text in some screens	1	System Status Visibility
62	F	Use of images is inconsistent. Some are realistic and some are drawings.	1	Consistency
63	G	Crowded but contains important information	2	Aesthetics
64	G	Highlight "Do not take insulin" and distinguish it from the result.	1	Aesthetics
65	G	I'm not going to take insulin' could be slightly smaller font	1	Aesthetics
66	G	Instructions are too fast	2	System Status Visibility
67	G	No "done measuring" button.	2	Consistency
68	G	Small text in some screens	1	System Status Visibility
69	H	"The first task-dial n blood pressure is not specific" Which blood pressure the user should insert first.	2	System Status Visibility
70	H	Gap between Diastolic & Heart Rate is too large	1	Aesthetics
71	H	I'm done measuring' could just be 'Finish' as there is no other option to go back here anyway	1	Consistency
72	H	issue with home and back buttons being same as ok	2	Minimize user memory load
73	H	Lots of text . . . Kind of busy	2	Minimize user memory load

Problem ID	Scenario	Problem	Mode Severity	Violation
74	H	Maybe move "You're doing great" feedback to top and center data	1	Minimize user memory load
75	H	mmHg' could be a slightly smaller font	1	Aesthetics
76	H	No home button at the last screen	1	System Status Visibility
77	H	Prefer to see "enter your blood pressure"	1	Match with real world
78	H	Text is out of alignment	1	Aesthetics
79	H	Text is small	1	System Status Visibility
80	H	The buttons may make the user feels he existed the application because the way the user is prompted to insert blood glucose measurement loos like phone dialing screen	2	Minimize user memory load
81	H	The word "dial in" choice is confusing	1	Match with real world
82	H	Users should be able to tap between Systolic and Diastolic to edit	1	Physical interaction
83	H	Yes button has inconsistent color compared to previous scenarios	1	System Status Visibility
84	I	Center your screen for better space utilization	1	Aesthetics
85	I	Crowded but contains important information	2	Aesthetics
86	I	Highlight important information better.	1	Aesthetics
87	I	Instructions are too fast	1	Physical interaction
88	I	Repeated instruction - a bit confusing	2	Aesthetics
89	I	Stressful warning message	1	Aesthetics
90	I	Text is out of alignment	1	Aesthetics
91	J	Center your screen for better space utilization	1	Aesthetics
92	J	Extra unneeded steps	1	Efficiency and performance

Problem ID	Scenario	Problem	Mode Severity	Violation
93	J	Instructions are too fast and hard to follow	2	System Status Visibility
94	J	Maybe a button that shows that the user is ready to move to the next step (insulin pen ready)	1	Minimize user memory load
95	J	No actionable cues as to what to do after unit recommendation	2	Minimize user memory load
96	J	Overlap between screen transitions	2	System Status Visibility
97	J	Use "proceed" instead of helping me take my insulin as it is already clear	1	Aesthetics
98	K	Actionable cue maybe confusing as patient may take insulin before viewing the instructions	4	Error prevention
99	K	Back and Home button colors are similar and may cause confusion.	1	Minimize user memory load
100	K	Bad graphics, could be better	1	Aesthetics
101	K	Confused as to what happens after pen is primed	5	Error prevention
102	K	Crowded but contains important information	1	Aesthetics
103	K	Images look grainy at a very important step of the application. They MUST be high quality here	2	Aesthetics
104	K	Inconsistent emphasis through the use of bold text between action cues and information	1	Consistency
105	K	Instruction auto loading is not preferred and better if < > buttons were used	2	Minimize user memory load
106	K	Instructions are too fast	4	Minimize user memory load
107	K	Instructions may overload memory without freedom of navigating them	2	Minimize user memory load
108	K	Next' instead of 'I did that'	1	Aesthetics

Problem ID	Scenario	Problem	Mode Severity	Violation
109	K	Overlapping screens transitions	2	Consistency
110	K	Should say 'Proceed'/'Next' instead of 'My meal is ready'	1	Aesthetics
111	K	Text typeface inconsistent	1	System Status Visibility
112	K	Transition between instructions screens may cause confusion because the text overlap.	2	Aesthetics
113	K	Typo: "peel", not "peal".	1	Consistency
114	K	Typo: double use of 'to'	1	Consistency
115	K	Unclear as to when to eat vs insulin intake	5	Error prevention
116	K	Use "proceed" instead of “help me take my insulin” as it is already clear	1	Aesthetics
117	K	You took 6 units…' should be in the center of the screen	1	Aesthetics
118	L	The "used" and "new" pen buttons can be replaced by buttons to make it easy navigating through the process	2	Aesthetics
119	L	Green home and back buttons move eyes away from data	2	Aesthetics
120	L	Instructions are long and no way to control speed, prefer to have < > buttons to control flow and speed	2	User control and freedom
121	L	No back button throughout	2	User control and freedom
122	L	Overlapping screens transitions	2	Aesthetics
123	L	Should say 'Proceed'/'Next' instead of 'My meal is ready'	1	Aesthetics
124	L	The button that says take 6 units may have patient immediately taking the dosage without following steps	4	Error prevention
125	L	You took 6 units…' should be in the center of the screen	1	Aesthetics

Inter-rater Reliability for the Usability Problems Reported

For scenario A, the Fleiss Kappa coefficient is -0.11 with a standard error of 0.16, indicating slight disagreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.43 to 0.21, with a p-value of 0.497, suggesting that the level of disagreement may not be statistically significant.

Fleiss Kappa	Standard Error	lower 95% CI	upper 95% CI	p-Value
-0.11	0.16	-0.43	0.21	.497

For scenario B, the Fleiss Kappa coefficient is -0.17 with a standard error of 0.22, indicating slight disagreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.6 to 0.27, with a p-value of 0.55, suggesting that the level of disagreement may not be statistically significant.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
-0.17	0.22	-0.6	0.27	.55

For scenario C, the Fleiss Kappa coefficient is -0.15 with a standard error of 0.19, indicating slight disagreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.53 to 0.22, with a p-value of 0.575, suggesting that the level of disagreement may not be statistically significant. Further investigation is recommended.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
-0.15	0.19	-0.53	0.22	.575

For scenario D, the Fleiss Kappa coefficient is 0.02 with a standard error of 0.16, indicating almost no agreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.29 to 0.33, with a p-value of 0.916, suggesting that the observed level of agreement is likely due to chance. Further investigation is recommended to identify sources of disagreement and improve agreement among the raters.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
0.02	0.16	-0.29	0.33	.916

For scenario E, the Fleiss Kappa coefficient is 0.1 with a standard error of 0.19, indicating slight agreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.27 to 0.47, with a p-value of 0.594, suggesting that the observed level of agreement is likely due to chance.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
0.1	0.19	-0.27	0.47	.594

For scenario F, the Fleiss Kappa coefficient is -0.02 with a standard error of 0.2, indicating almost no agreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.41 to 0.37, with a p-value of 0.073, suggesting that the observed level of disagreement is possibly statistically significant.

Fleiss Kappa	Standard Error	lower 95% CI	upper 95% CI	p-Value
-0.02	0.2	-0.41	0.37	.073

For scenario G, the Fleiss Kappa coefficient is -0.13 with a standard error of 0.22, indicating slight disagreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.57 to 0.3, with a p-value of 0.445, suggesting that the observed level of disagreement is likely due to chance.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
-0.13	0.22	-0.57	0.3	.445

For scenario H, the Fleiss Kappa coefficient is -0.07 with a standard error of 0.15, indicating slight disagreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.37 to 0.23, with a p-value of 0.357, suggesting that the observed level of disagreement is likely due to chance.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
-0.07	0.15	-0.37	0.23	.357

For scenario I, the Fleiss Kappa coefficient is -0.01 with a standard error of 0.21, indicating almost no agreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.41 to 0.4, with a p-value of 0.02, suggesting that the observed level of disagreement is likely statistically significant.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
-0.01*	**0.21**	**-0.41**	**0.4**	**.02**

For scenario J, the Fleiss Kappa coefficient is 0.06 with a standard error of 0.18, indicating slight agreement with a moderate amount of uncertainty. The 95% confidence interval ranges from -0.29 to 0.4, with a p-value of 0.744, suggesting that the observed level of agreement is likely due to chance.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
0.06	0.18	-0.29	0.4	.744

For scenario K, the Fleiss Kappa coefficient is -0.04 with a standard error of 0.12, indicating almost no agreement with a low amount of uncertainty. The 95% confidence interval ranges from -0.29 to 0.2, with a p-value of 0.262, suggesting that the observed level of disagreement is not statistically significant.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
-0.04	0.12	-0.29	0.2	.262

For scenario L, the Fleiss Kappa coefficient is 0.33 with a standard error of 0.15, indicating moderate agreement among the raters. The 95% confidence interval ranges from 0.03 to 0.64, with a p-value of 0.031, suggesting that the observed level of agreement is likely statistically significant.

Fleiss Kappa	**Standard Error**	**lower 95% CI**	**upper 95% CI**	**p-Value**
0.33*	**0.15**	**0.03**	**0.64**	**.031**

Raw Kappa Inputs:

Scenario	Problem	Inspectors						
		1	2	3	4	5	6	7
A	1	0	0	0	0	1	0	1
A	2	0	0	1	0	0	0	0
A	3	0	0	0	0	0	1	0
A	4	1	0	0	0	0	0	0
A	5	0	0	1	0	0	0	1
A	6	0	0	0	0	1	0	0
A	7	0	0	0	0	0	0	1
A	8	0	0	0	0	1	0	0
A	9	0	0	1	0	0	0	0
A	10	0	0	0	0	0	0	1
A	11	0	0	1	0	1	1	0
A	12	0	0	0	0	1	0	0
A	13	0	1	0	0	0	0	0
B	14	0	0	0	0	1	0	0
B	15	0	0	0	0	0	1	0
B	16	1	0	0	0	0	0	0
B	17	0	0	0	0	1	0	0
B	18	0	0	0	0	1	0	0
B	19	1	0	0	0	0	0	0
B	20	0	0	1	0	0	0	0
B	21	0	0	0	0	1	0	0
B	22	0	1	0	0	0	0	0
B	23	0	0	0	0	0	0	1
C	25	0	0	0	0	1	0	0
C	26	0	0	0	0	0	1	0
C	27	1	0	0	0	0	0	0
C	28	0	0	0	0	1	0	0
C	29	1	0	0	0	0	0	1
C	30	0	0	0	0	1	0	0
C	31	0	1	0	0	0	0	0
C	32	0	0	0	0	0	1	0
C	33	0	0	0	0	1	0	0
C	34	0	0	0	0	0	0	1
C	35	0	0	0	0	0	0	1
C	36	0	0	0	0	1	0	0
D	37	0	0	1	0	0	0	0

Scenario	Problem	Inspectors						
		1	2	3	4	5	6	7
D	38	0	0	0	0	0	0	1
D	39	1	0	0	0	0	0	0
D	40	0	0	0	0	0	0	1
D	41	0	0	0	0	0	0	1
D	42	0	0	1	0	0	0	0
D	43	0	0	1	0	0	0	0
D	44	0	0	0	1	0	0	0
D	45	1	1	0	0	1	1	1
D	46	0	0	1	0	0	0	0
D	47	0	0	0	0	1	0	0
D	48	0	0	0	0	1	1	0
E	49	1	0	0	0	0	0	0
E	50	0	1	0	0	0	0	0
E	51	0	0	0	0	0	1	0
E	52	0	1	1	1	1	0	1
E	53	0	0	1	0	0	0	0
E	54	0	0	0	0	1	0	0
E	55	0	0	0	0	1	0	0
F	56	1	0	0	0	0	0	0
F	57	0	0	0	0	0	1	0
F	58	0	1	1	1	1	0	0
F	59	0	0	1	0	0	0	0
F	60	0	0	0	0	0	0	1
F	61	0	0	0	0	0	0	1
F	62	0	0	0	0	1	0	0
F	63	0	0	0	0	0	0	1
G	64	1	0	0	0	1	0	0
G	65	0	1	0	0	0	1	0
G	66	0	0	0	0	0	0	1
G	67	0	0	0	1	1	0	0
G	68	0	0	1	0	0	0	0
G	69	0	0	0	0	1	0	0
H	70	0	0	0	0	1	0	0
H	71	0	0	0	0	0	0	1
H	72	0	0	0	0	0	0	1
H	73	1	0	0	0	0	0	0
H	74	1	0	0	0	0	0	0

Scenario	Problem	Inspectors						
		1	2	3	4	5	6	7
H	75	1	0	0	0	0	0	0
H	76	0	0	0	0	0	0	1
H	77	0	0	0	0	1	0	0
H	78	0	1	0	0	0	0	0
H	79	1	0	1	0	1	1	0
H	80	0	0	0	0	1	0	0
H	81	0	0	0	0	1	0	0
H	82	0	0	0	0	1	0	0
H	83	0	0	0	0	0	0	1
H	84	0	0	0	0	1	0	1
I	85	1	0	0	0	0	0	0
I	86	1	0	0	0	0	0	0
I	87	0	0	0	0	0	0	1
I	88	0	1	0	0	1	1	1
I	89	0	1	0	0	0	0	0
I	90	0	1	0	0	0	0	0
I	91	0	0	1	0	0	0	0
J	92	1	0	0	0	0	0	0
J	93	0	0	0	0	0	0	1
J	94	0	0	0	1	1	0	0
J	95	1	0	0	0	0	0	0
J	96	1	0	0	0	1	0	0
J	97	1	1	1	0	1	1	0
J	98	0	0	0	0	0	0	1
K	99	1	0	0	0	0	0	0
K	100	1	0	0	0	0	0	0
K	101	0	0	0	0	0	1	0
K	102	1	0	0	0	0	0	0
K	103	0	0	0	0	0	0	1
K	104	0	0	0	0	0	0	1
K	105	0	0	0	0	0	0	1
K	106	0	1	0	0	1	0	0
K	107	1	0	0	0	0	0	1
K	108	0	0	0	0	1	0	0
K	109	0	0	0	0	0	0	1
K	110	1	1	1	1	0	0	1
K	111	0	0	0	0	0	0	1

Scenario	Problem	Inspectors						
		1	2	3	4	5	6	7
K	112	0	0	0	0	1	0	0
K	113	0	0	0	0	1	1	0
K	114	1	0	0	0	0	0	1
K	115	0	0	0	0	0	0	1
K	116	1	0	0	0	0	0	0
K	117	0	0	0	0	0	0	1
K	118	0	0	0	0	0	0	1
L	119	0	1	0	0	0	0	0
L	120	1	0	0	0	0	0	0
L	121	0	1	0	0	0	0	0
L	122	0	0	0	0	0	0	1
L	123	1	1	1	1	1	1	1
L	124	0	0	0	0	0	0	1
L	125	1	0	0	0	0	0	0

Problems discovered by raters per scenario:

Scenario A:

	Frequency	%
Rater 5	5	29.41%
Rater 3	4	23.53%
Rater 7	4	23.53%
Rater 6	2	11.76%
Rater 1	1	5.88%
Rater 2	1	5.88%
Rater 4	0	0%
Total	17	100%

Scenario B:

	Frequency	%
Rater 5	4	40%
Rater 1	2	20%
Rater 2	1	10%
Rater 3	1	10%
Rater 6	1	10%
Rater 7	1	10%
Rater 4	0	0%
Total	10	100%

Scenario C:

	Frequency	%
Rater 5	5	38.46%
Rater 7	3	23.08%
Rater 1	2	15.38%
Rater 6	2	15.38%
Rater 2	1	7.69%
Rater 3	0	0%
Rater 4	0	0%
Total	13	100%

Scenario D:

	Frequency	%
Rater 3	4	23.53%
Rater 7	4	23.53%
Rater 5	3	17.65%
Rater 1	2	11.76%
Rater 6	2	11.76%
Rater 2	1	5.88%
Rater 4	1	5.88%
Total	17	100%

Scenario E:

	Frequency	%
Rater 5	3	27.27%
Rater 2	2	18.18%
Rater 3	2	18.18%
Rater 1	1	9.09%
Rater 4	1	9.09%
Rater 6	1	9.09%
Rater 7	1	9.09%
Total	11	100%

Scenario F:

	Frequency	%
Rater 7	3	27.27%
Rater 3	2	18.18%
Rater 5	2	18.18%
Rater 1	1	9.09%
Rater 2	1	9.09%
Rater 4	1	9.09%
Rater 6	1	9.09%
Total	11	100%

Scenario G:

	Frequency	%
Rater 5	3	33.33%
Rater 1	1	11.11%
Rater 2	1	11.11%
Rater 3	1	11.11%
Rater 4	1	11.11%
Rater 6	1	11.11%
Rater 7	1	11.11%
Total	9	100%

Scenario H:

	Frequency	%
Rater 5	7	36.84%
Rater 7	5	26.32%
Rater 1	4	21.05%
Rater 2	1	5.26%
Rater 3	1	5.26%
Rater 6	1	5.26%
Rater 4	0	0%
Total	19	100%

Scenario I:

	Frequency	%
Rater 2	3	30%
Rater 1	2	20%
Rater 7	2	20%
Rater 6	1	10%
Rater 3	1	10%
Rater 5	1	10%
Rater 4	0	0%
Total	10	100%

Scenario J:

	Frequency	%
Rater 1	4	30.77%
Rater 5	3	23.08%
Rater 7	2	15.38%
Rater 2	1	7.69%
Rater 3	1	7.69%
Rater 4	1	7.69%
Rater 6	1	7.69%
Total	13	100%

Scenario K:

	Frequency	**%**
Rater 7	11	39.29%
Rater 1	7	25%
Rater 5	4	14.29%
Rater 6	2	7.14%
Rater 2	2	7.14%
Rater 3	1	3.57%
Rater 4	1	3.57%
Total	28	100%

Scenario L:

	Frequency	%
Rater 7	4	28.57%
Rater 1	3	21.43%
Rater 2	3	21.43%
Rater 3	1	7.14%
Rater 4	1	7.14%
Rater 5	1	7.14%
Rater 6	1	7.14%
Total	14	100%