IMPROVING THE HEALTH OF PEOPLE WITH COLLECTIVE SYSTEM DESIGN

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PREFACE

This thesis represents a product of work during my time as a Graduate Research Assistant with the Center of Excellence in Systems Engineering at Purdue University Fort Wayne under the direction of Dr. David S. Cochran from 2017 to 2019. The work within the Systems Engineering (SE) Center focuses on the design of sustainable enterprise systems. The Collective System Design methodology used in the SE center is applicable to the design and sustainability of health care systems. This research is the result of my interest in sustainable food and farming systems and the health-care field in terms of the management of obesity and diabetes. Although the initial connection of these two entities may not be clear, systemically, they must function together to improve the health of people. I have enjoyed my time spent understanding and developing the body of research presented in this thesis and hope that you will gain a passion for this subject as a result of this research.

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SYMBOLS

PFW	Purdue Fort Wayne
SE	Systems Engineering
CSD	Collective System Design
MSDD	Manufacturing System Design Decomposition
AD	Axiomatic Design
FR	Functional Requirement
PS	Physical Solution
FRm	Measure for Functional Requirement
PSm	Measure for Physical Solution
PDCA	Plan-Do-Check-Act

ABSTRACT

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With the growing number of obese and diabetic individuals, there lies great importance in finding novel ways to reverse the epidemic of diabetes. There are numerous factors that contribute to the health crisis that the world is experiencing. Due to the prevalence of diabetes, optimizing solutions to address only certain aspects of the epidemic will only provide marginal benefits to society. With a systems-level viewpoint, the true pitfalls and areas of improvement can be better recognized.

The current global health crisis is due to three major systemic issues: (i) a food supply chain that results in an overfed but undernourished society; (ii) a medical establishment that mitigates symptoms instead of root causes; and (iii) a widespread research base that is plagued with conflicting information [1]. Together these problems represent system design failures of the current food and medical establishments.

This thesis argues that designing systems to meet customer needs will in fact improve the health of people. Therefore, this thesis explores the possibility of using the Collective System Design Methodology to understand and design health care systems that meet customer needs. There are three main objectives of this thesis: (1) an explanation of the current failures of the food and farming systems and the health care field from a systems-level perspective, (2) a case study of an existing system that improves the health of people by meeting customer needs, and (3) the development of a Collective System Design Map for meeting the needs of obese and type-II diabetic patients to reverse diabetes. By applying Collective System Design to the prevention and reversal of type-2 diabetes, this thesis provides a new approach for chronic disease reversal and care.

CHAPTER 1. INTRODUCTION

1.1 Research Objectives

This thesis is comprised of three main research objectives. The first research objective is to use a systems-level viewpoint to explain why the current diabetes and obesity epidemic is due to systemic problems. This research objective provides the argument for applying system design methodologies to mitigate the epidemic. The second research objective is to describe the logical structure of the Parkview Lagrange Food Pharmacy Program using Collective System Design (CSD). This research objective is used to show that CSD can describe the design of systems that improve the health of people. The third research objective is to apply CSD to create the design of a system that would Prevent, Early Detect, and Reverse Type-2 Diabetes. This research objective provides the argument that CSD can describe new and innovative system designs that improve the health of people.

1.2 Outline of Thesis

This thesis begins by defining what is meant by a system, in general, and to the specific field of systems engineering. Next, the Collective System Design (CSD) Methodology is introduced. CSD is the system design methodology applied in this thesis. To conclude the introduction chapter the Research Hypothesis is presented and discussed.

Chapter 2 provides a literature review that will cover topics such as the Use Cases of Collective System Design, Current Food and Farming System, Development of Abdominal Obesity and Type-2 Diabetes, Reversal of Type-2 Diabetes, and Early Detection of Type-2 Diabetes.

Chapter 3 addresses the first research objective by providing a discussion from a system-level viewpoint of the current health care and food and farming system. This Chapter works to argue that the current health crisis, in terms of chronic disease, is largely due to systemic problems.

Chapter 4 covers the second research objective by providing a case study of the Parkview Lagrange Food Pharmacy Program from a systems engineering perspective. This chapter argues that the Food Pharmacy Program improves the health of its participants because it works to meet customer (participant) needs.

Chapter 5 focuses on the third research objective by building on Chapters 3 and 4 to propose the logical design of system that will improve the health of people. More specifically, this system will prevent, early detect, and reverse type-2 diabetes. Chapter 3 provides the argument for why a systems engineering approach to health care is beneficial to designing systems that improve the health of people, and Chapter 4 provides a real example of a system that is currently improving the health of people. The system design in Chapter 5 proposes a new system design to improve the health of people.

1.3 Introduction to Systems and Systems Engineering

The word "system" represents anything that meets the needs or requirements of the users/customers through the connection and interaction of various parts [2]. Systems Engineering represents a specific discipline of engineering that focuses on the development and sustainment of systems in a methodical manner. This definition is built on the International Council on Systems Engineering's (INCOSE) definition of systems engineering which states that, "Systems Engineering is a transdisciplinary and integrative approach to enable the successful realization, use, and retirement of engineered systems, using systems principles and concepts, and scientific, technological, and management methods [3]." Within the field of systems engineering, there are numerous tools that are actively used including: Collective System Design [4], Axiomatic Design [5], Sprint [6], Strategic Doing [7], and NASA's Handbook on Systems Engineering [8]. These tools are tailored towards the development of specific systems, organizations, or products. The Collective System Design Methodology provides a rigorous approach for system design that is applicable to many diverse systems and is the chosen approach for the health system design applications presented in this thesis.

1.4 Introduction to the Collective System Design Methodology

This thesis focuses on the application of a system design methodology, known as Collective System Design (CSD), in an attempt to understand and design systems that will improve the health of people. The CSD methodology is used because it provides a rigorous approach to understanding customer needs and for designing systems that will meet those needs. The CSD Methodology is from Dr. David S. Cochran's work that began in the mid 2000's [9]. Applications of CSD are noted in many different fields such as manufacturing [10, 11], hospital related design [12, 13], disease reversal [14], course development [15], and organizational development [4]. The methodology of CSD is comprised of a few key components including the Flame Model, the CSD 12 Steps, the Plan-Do-Check-Act Continuous Improvement Cycle, and the CSD Language [13, 15].

The word "collective" in the CSD Methodology represents the most important aspect of the system design process. A system design should be the result of collective agreement regarding why a system exists, what function(s) the system should be capable of performing, and how the system will achieve those functions. The CSD Methodology helps facilitate an environment in which a team can actively understand the "why" and "what" behind a system and ultimately agree on the "how."

The importance of separating the "what" from the "how" needs further discussion as the facilitation of collective agreement relies very much on this point. The Strategic Doing Methodology from the Purdue Agile Strategy Lab facilitates a process to show the importance of separating the “what” from the “how.” This process organically reveals how people can come to a conclusion regarding what a system should accomplish as opposed to how the system will accomplish requirements that have not even been defined.

At a Strategic Doing training session, the participants were asked to write down what the perfect vacation would be for them. Once this answer was written down, the participants were asked to meet with someone else in the room and to work with that person to agree on a vacation that would meet both of their needs. To no surprise, most people wrote down a glamorous and scenic place in the world such as Italy. When individuals met, the participants found out that their ideal vacations were on opposite sides of the world. This difference in locations makes finding a suitable alternative for both of the participants incredibly difficult.

What if the question to the participants was this, "how would you know if you had a perfect vacation?" This question was in fact presented to the participants. Once an answer was written down, they were asked to meet with another individual in the room. This time, the participants wrote down the activities in which they wanted to participate in during their vacations (i.e., hiking, fishing, site-seeing, eating local cuisine, etc...). When the individuals met to come to a common agreement on a vacation it was much easier. They discussed that there are numerous places to go to participate in all of the different activities as cited by the participants.

When the vacation started as a place, the individual’s plan for a perfect vacation represented the “how” behind accomplishing that perfect vacation. Once the participants’ stated “what” they wanted to do on their vacation, it was much easier to find common ground for an alternative vacation. This interplay between the “what” and “how,” the requirement and solution, respectively, made decision making easy because it formed the basis of a taxonomy in which to communicate design ideas/precepts. This taxonomy is the foundation of CSD as it provides a language to communicate the design of systems.

1.5 Collective System Design Flame Model

The Collective System Design Flame Model, as shown in Fig.1.1, provides a viewpoint for diagnosing and designing or re-designing systems [16]. The flame model represents a hierarchy of the different elements that make up and co-exist simultaneously within systems. These elements are expressed as different layers cohesively connected like the different layers within a flame and represent different viewpoints of a system [17]. All elements are present within a system at any given time. The outcome of each layer is either formed intentionally, or becomes unintentional due to the lack of attention given to that element. Prof. Cochran notes that systems evolve based on the way they are measured [18]. The work/actions and structure are the physical elements that we can see, while the thinking and tone are the hidden drivers that ultimately influence what is seen as enterprise structure and the actions and work of people within an enterprise.

Diagnosis and system design, or redesign are both expressed by the flame model [20]. The diagnosis phase looks at determining the root cause of the problem by first understanding the work and actions. This process of looking at the work and actions is often referred to as, "going to the Gemba [21]."

Next, the structure of the organization that drives the work and actions is understood by the redesign team asking questions about “why” a certain undesirable action exists. The word “structure” here is broad and can apply to many different aspects of an organization or system. For example, structure of an organization could mean the actual structure of the facility, the hierarchy of workers, the layout of a work station, or even the reward system that is in place. Adaptations of these structures can result in different work and actions. Consider the common saying in manufacturing, “what gets measured gets done [22].” This notion clearly expresses the idea that structure drives the work and actions of an organization, or of a system [23].

After learning about the structure of the existing system, the thinking layer is considered. The thinking layer often represents where a great deal of assumptions

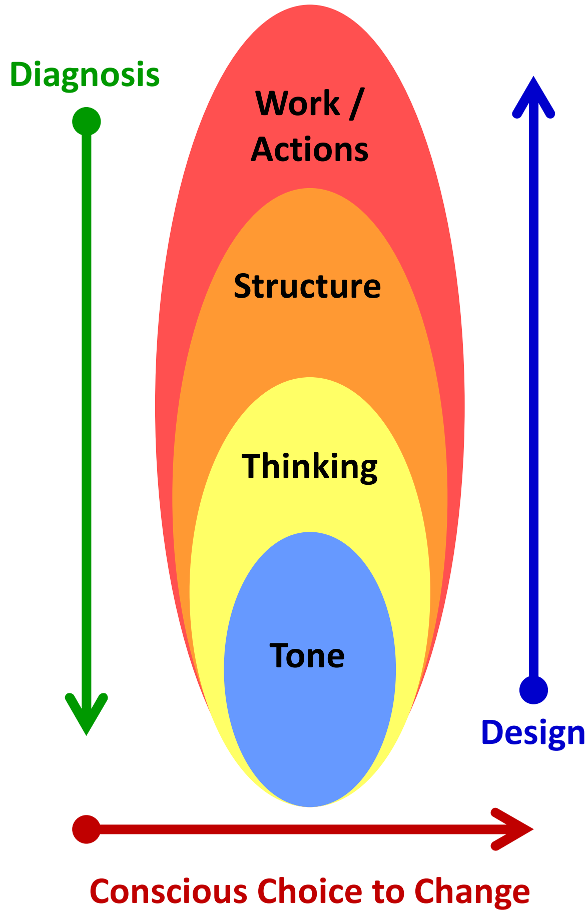

Fig. 1.1. Collective System Design Flame Model [19]

and miscommunication lies in an organization. People may or may not know what the requirements are, or they do not collectively agree on those requirements. A reward system, for example, represents the result of the thinking layer. Consider a reward system that pays a worker more if he/she produces more products per hour. The thinking behind this structure could be as simple as "more products produced equals more profit," but what if there are no customers, or what if the quality is terrible? Thinking, whether consciously defined or not, or just blatantly wrong, will affect the structure of the organization. With the above example, the thinking to maximize production with a reward system drove an undesirable structure that resulted in over production and poor quality.

Finally, the tone represents the attitude of the people or what many individuals refer to as the "culture" of the organization. A proper tone facilitates a respectful environment that allows everyone to be engaged, and the understanding that a system should not let someone fail. Abnormal conditions will inevitably happen and the system should be continuously improved in response to these conditions.

Once the problem is diagnosed and a conscious choice to change is made, the system design process moves from the hottest part, the tone, of the flame outward.

1.6 Collective System Design 12 Steps

The system design process, which is broadly represented with the different layers of the Flame Model, is further detailed in the Collective System Design (CSD) 12 Step Process [16]. The CSD 12 Steps are detailed in Table 1.1. Also provided in Table 1.1 are the key questions that the designers must ask in each step of the process. In addition, the table is color coded to indicate the layers of the Flame Model that relate to specific steps in the design process.

The steps highlighted in green (Steps 1, 2, 11, and 12) are not directly captured in the Flame Model, but represent crucial parts of the system design process. The steps in green represent the key steps of ensuring sustainability by investing in the system design. The approach begins by senior leadership consciously making the decision to change. By then defining the stakeholders and establishing tone and values, an environment is created that fosters collective agreement among the team. The thinking layer, which is represented by the steps highlighted in yellow, codifies the thinking behind a system with the Collective System Design Language. This language further allows for a team to communicate and collectively agree on the design relationships of a system.

Table 1.1.
Collective System Design 12 Steps

Step	Descriptions	Questions
1	Senior Leadership Makes a Conscious Choice to Change	• Why would we make the change? • Are we capable of achieving something greater? • Is continuous improvement important to us?
2	Define Stakeholders & System Boundary / Value Stream(s)	• Who will be affected by the change? • Who should be involved in the process? • What/who can and cannot be controlled? • What information is passed across the system boundary? • What risks exist within the interfaces?
3	Establish Tone and Values	• What attitude is required to get everyone to participate? • What attitude is required to facilitate collective agreement? • How do we convey to our people the tone we desire for our organization? • How do we problem solve together?
4	Identify Customers and Needs	• Who will purchase/use our product(s)? • What will this customer/user need the product to do?
5	Determine Functional Requirements (FRs)	• How do we state the needs of our customers as functional requirements of the system? • What MUST the system achieve to satisfy the customer(s)?
6	Map the Physical Solutions (PSs) to FRs	• What function MUST the system achieve? • Is the design uncoupled/partially coupled, but not fully coupled? • Are the requirements of the leaf PSs sufficiently clear and implementable through standard work?
7	Define Performance Measures (FR_M & PS_M)	• How will we know if the FR is achieved (FR_M)? • How will we know if the PS is implemented correctly (PS_M)?
8	Define Organization Structure based on CSD Map	• What team structure is needed to make the implementation? • What should the value stream look like? • Can we physically simulate the value stream?
9	Establish Standard Work by Continuous Improvement: Plan, Do, Check, Act (PDCA)	• Currently, what is the best practice for completing the work? • How will we implement a PS as standard work? • Does the current standard work achieve the FRs of the system design? • How can the standard work be improved?
10	Evaluate the Cost of Not Achieving the FRs	• What is the result of not achieving each one of the FRs? • What is the cost benefit of achieving, unachieved FRs?
11	Prepare Resource Re-allocation Plan	• What restructuring of resources is required to make and sustain the system design transformation?
12	Feedback for Sustainability and Growth	• What was the result of the implementation? • What are the required continuous improvement efforts that are necessary to sustain and to improve the system?

Table 1.2.
System Design Domain Terminology

Domain	**Terminology**	**Task**
Customer	Customer Needs (CN)	Defines the needs of customers (why)
Functional	Functional Requirements (FR)	Defines "what" the system must achieve
Physical	Physical Requirements (PS)	Defines "how" the FR will be achieved

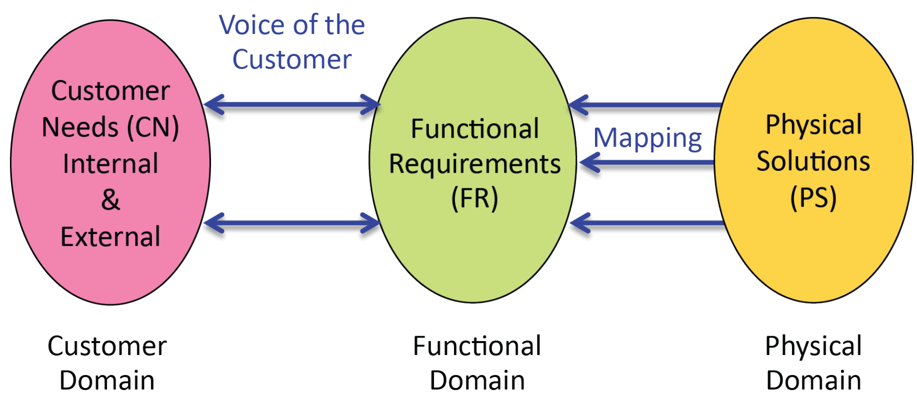

Fig. 1.2. The system design domains(adapted from [5])

1.7 Collective System Design Language

Steps four through seven of the Collective System Design Language provide the terminology required to talk about three different design domains. These steps represent the thinking layer of the flame model. Design domains represent demarcation lines between different kinds of design activities [5]. The three design domains are the customer domain, the functional domain, and the physical domain (see Fig. 1.2). Different terms are used to discuss the information derived from or represented by each domain. A summary of each domain, the related terminology, and the importance of each domain is provided in Table 1.2.

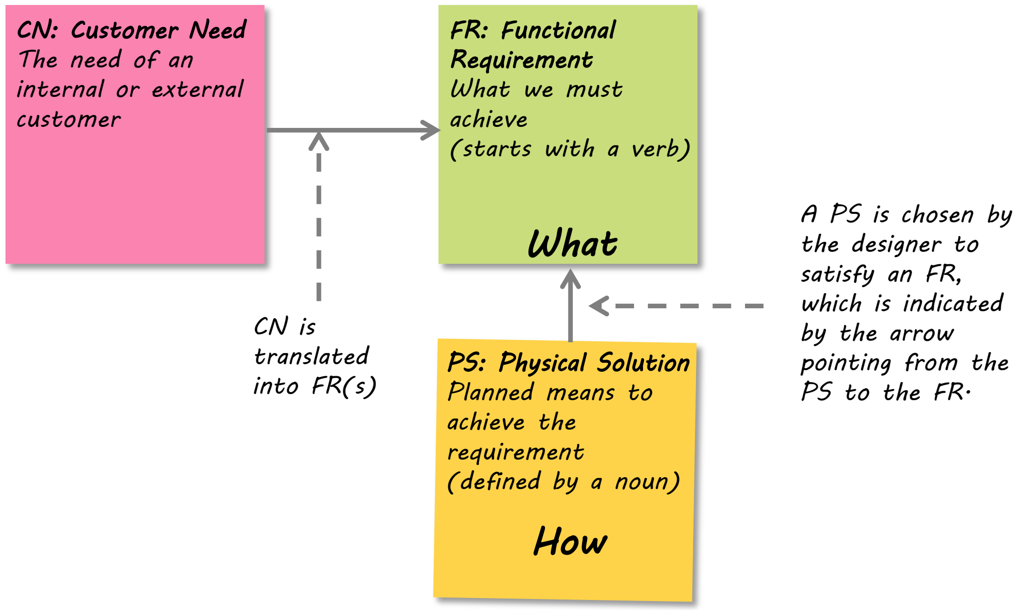

Fig. 1.3. Example of a design relationship

Figure 1.3 further details the Collective System Design Language in the format in which it is commonly used. Often in practice, 3 different colored post-it notes (magenta, green, yellow) are used to actively express design relations. Figure 1.3 depicts a single design relationship. Measures can be applied to both Functional Requirements and Physical Solutions. Please see Fig. 1.4 for more information.

The measure on a Functional Requirement, denoted FR_m, defines when the FR is achieved. When an FR is achieved, then the design intent of the system can be checked to ensure that the customer need is met. This process is commonly referred to a validation. Validation indicates to the designer that a system is meeting customer needs.

The measure on a Physical Solution, denoted PS_m, defines when the PS is implemented correctly. When a PS is implemented correctly, this information can be used to determine if the corresponding Functional Requirement was achieved. This process is commonly referred to as verification. Verification indicates to the designer that the system is functioning as designed, but it may or may not be meeting customer needs.

1.8 Collective System Design Map

A Collective System Design Map represents a hierarchy of design relations as discussed above. A CSD Map is the consequence of a design decomposition process that results in an implementable sequence of design relationships. The decomposition process is best defined through the series of steps presented below. The first 4 steps are depicted in Fig. 1.4 and the last 2 are in Fig. 1.5.

1. Map Customer Needs to Functional Requirements
2. Choose Physical Solutions to satisfy Functional Requirements
3. Define a performance measure for the FRs (abbreviated FRm) when applicable.
4. Define a performance measure for the PSs (abbreviated PSm) when applicable.
5. Check for interactions/coupling among the PSs and FRs at the current level. Coupling is found by asking the question, **"does the choice of PSj affect the achievement of FRi within a branch at a specific level?"** (See "Possible Design Cases" below for a better understanding of coupling.) Arrows are drawn from physical solutions to functional requirements within a branch at a single level in order to indicate coupling. **NOTE:** Level I is considered a one FR design which means coupling is not possible.
6. Decompose the design to the next level. **NOTE:** A design must be checked for interactions/coupling before the design can be decomposed to the next level. The decomposition can only proceed if the design is uncoupled or partially coupled at that level (See Possible Design Cases). In addition, a design can only be decomposed to the next level if at least **two** or more FRs expand on the preceding higher level PS. Stop decomposing when the PS expresses the design

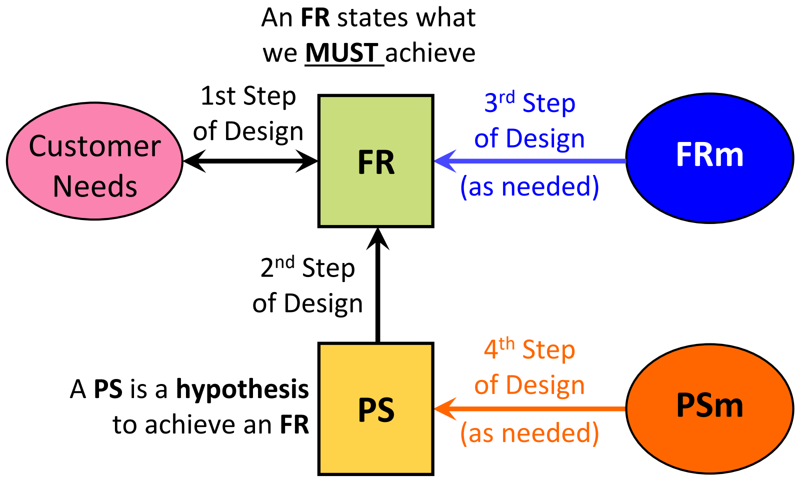

Fig. 1.4. Collective System Design Language

well enough that it can be implemented. To determine interactions, the designer must ask the question, **"does the choice of PSj affect the achievement of FRi within a branch at a specific level?"**

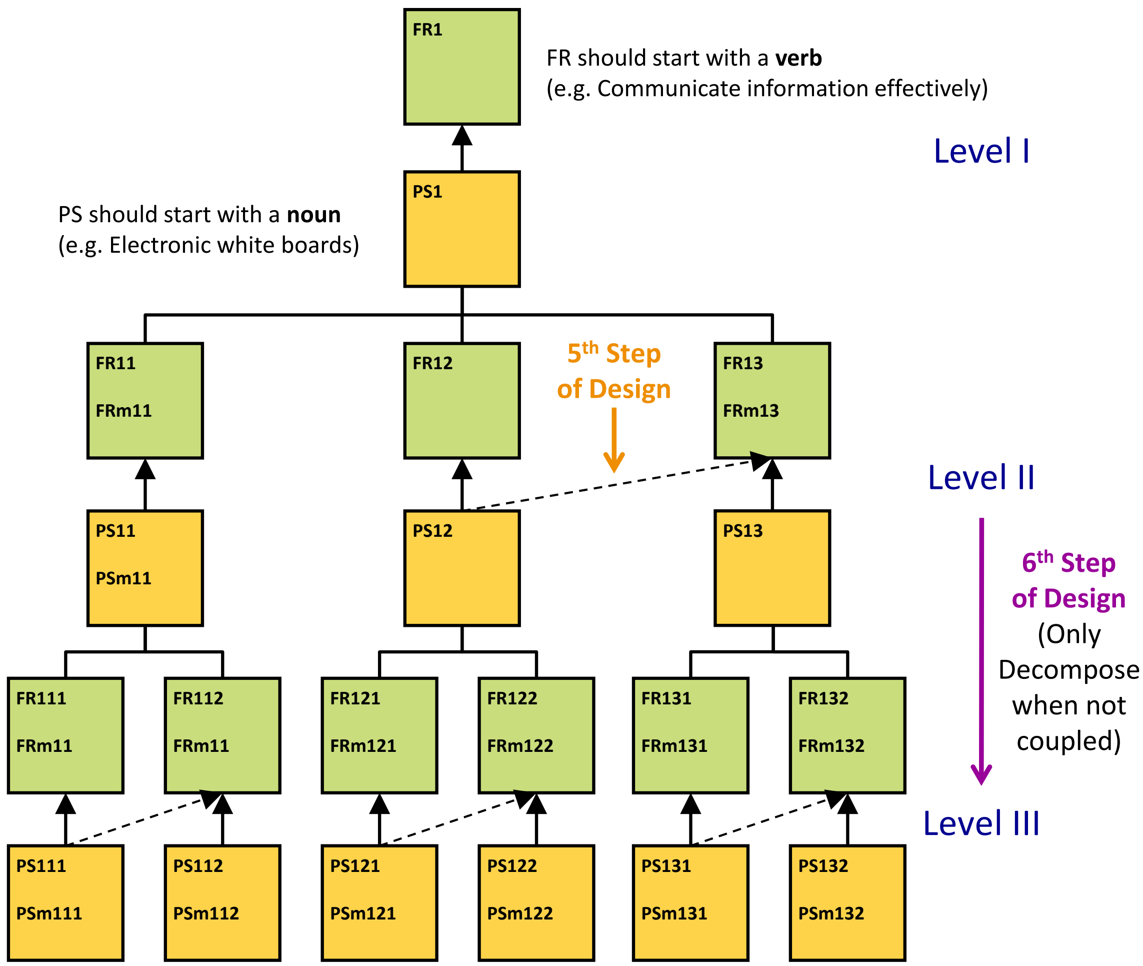

Fig. 1.5. CSD Decomposition Process [15]

Possible Design Cases

During the decomposition process, different types of design cases will emerge. The possible design cases are listed below. These include both acceptable and unacceptable designs. A design is acceptable when it is either uncoupled or path dependent. As stated before, interactions (X's in the below matrices) are determined by asking the question, **"does the choice of PSj affect the achievement of FRi within a branch at a specific level?"** Equation 1.1 represents the design equation for the relationship between FRs and PS within a branch at a specific level.

$$FRi = \begin{bmatrix} Aij \end{bmatrix} PSj \tag{1.1}$$

Where Aij is the design's relationship matrix for a branch at a specific level of the design decomposition.

Acceptable Cases

The acceptable cases include uncoupled (Eq. 1.2) and path dependent (Eq. 1.3).

- Uncoupled

$$\begin{bmatrix} FR1 \\ FR2 \end{bmatrix} = \begin{bmatrix} X & O \\ O & X \end{bmatrix} \begin{bmatrix} PS1 \\ PS2 \end{bmatrix} \tag{1.2}$$

- Path Dependent (Partially Coupled)

$$\begin{bmatrix} FR1 \\ FR2 \end{bmatrix} = \begin{bmatrix} X & O \\ X & X \end{bmatrix} \begin{bmatrix} PS1 \\ PS2 \end{bmatrix} \tag{1.3}$$

Unacceptable Cases

The unacceptable cases related to Axiom 1 (Maintain the independence of the functional requirements (FRs)) are coupled(Eq.1.4), incomplete(Eq.1.5), and redundant(Eq.1.6). These cases are presented below with the corresponding design matrices.

1. Coupled

$$\begin{bmatrix} FR1 \\ FR2 \end{bmatrix} = \begin{bmatrix} X & X \\ X & X \end{bmatrix} \begin{bmatrix} PS1 \\ PS2 \end{bmatrix} \tag{1.4}$$

2. Incomplete

$$\begin{bmatrix} FR1 \\ FR2 \end{bmatrix} = \begin{bmatrix} X & O \\ O & O \end{bmatrix} \begin{bmatrix} PS1 \\ PS2 \end{bmatrix} \tag{1.5}$$

3. Redundant

$$\begin{bmatrix} FR1 \end{bmatrix} = \begin{bmatrix} X & O \\ X & O \end{bmatrix} \begin{bmatrix} PS1 \\ PS2 \end{bmatrix} \tag{1.6}$$

1.9 Research Hypotheses

The hypothesis of this thesis (H_A) is that systems that meet customer needs will improve the health of people. The null hypothesis H_0 is that systems that meet customer needs do not improve the health of people. The main objective of this thesis is to provide the logical argument for why the null hypothesis can be rejected in favor of the alternative. Due to breadth of the topic, no experimental data was taken, rather this thesis uses empirical evidence through observation to attempt to provide the burden of proof to argue why the null hypothesis can be rejected in favor of the alternative.

H_0: Systems that meet customer needs do not improve the health of people.

H_A: Systems that meet customer needs will improve the health of people.

CHAPTER 2. LITERATURE REVIEW

The literature review presented below includes information applicable to the key areas of research of this thesis. The literature review begins with a discussion about the research regarding the use of Collective System Design and proceeds on to a more general discussion of the current health care crisis. This discussion covers the applicable research related to the current food and farming systems, the development of obesity and type-2 diabetes, a method for reversal of type-2 diabetes, and the possibility of detecting diabetes earlier than currently practiced.

2.1 Use Cases of Collective System Design

As noted in the introduction, Collective System Design has been applied to many different fields of study. Collective System Design was born out of research related to manufacturing system design as it relates to the Toyota Production System. The Toyota Production System, or TPS for short, is what many people refer to as "Lean" today [24]. As the true meaning of Lean has become a bit convoluted, companies embarking on their "Lean Journeys" have failed to replicate what Toyota had accomplished [25]. Collective System Design was born out of the discovery that a team must collectively agree on the system design to become "Lean", which stands in contrast to the idea of "implementing Lean as a toolkit." As Collective System Design (CSD) continually evolved based on further applications and research, Dr. David Cochran began expanding the scope to which the CSD Methodology could be applied. In the following pages, CSD will be discussed it terms of its application to manufacturing system design as well as its application to the design of a hospital's emergency room, to illustrate its applicability to various enterprise designs. The goal of CSD is the development of systems that are sustainable for the long term.

2.1.1 Manufacturing

Part of the application of CSD to manufacturing system design involves the development of a physical simulation model [25]. Using the simulation model in conjunction with the CSD language facilitates an environment in which a cross-functional team of the organization can agree on the why (Customer Need (CN)), what (Functional Requirement(FR)), and the how (Physical Solution(PS)) of their manufacturing system. The physical simulation model provides the means for trying out different PSs and to see how they affect achieving the teams' stated FRs. Agreeing on these aspects of the system design allows the team to determine how they want to run their manufacturing system.

To further aid in the system design process, the design team is introduced to the 7 FRs of Manufacturing [15]. The 7 FRs provide 7 fundamental Functional Requirements of all manufacturing systems. Fig.2.1 depicts how these 7 FRs are derived from the Manufacturing System Design Decomposition (MSDD) which is a comprehensive CSD map that expresses the fundamental design relationships of any manufacturing system whose goal is to achieve sustainability [10]. The 7 FRs as they relate to the MSDD are presented in Fig. 2.1. It can be observed that 5 of the 7 FRs correspond to 5 of the branches in the MSDD. For example, identifying and resolving abnormal conditions is derived from the predictable output branch of the MSDD.

2.1.2 Hospital Emergency Room Redesign

This discussion covers the application of Collective System Design to the redesign process of a hospital's emergency room [13]. The application of the CSD Methodology provided significant increase in the Emergency Room's capacity. The process started by determining the needs of both the internal customers (nurses) and external customers (patients) who were involved in or used the emergency room. These needs were translated into Functional Requirements. Physical Solutions were chosen to

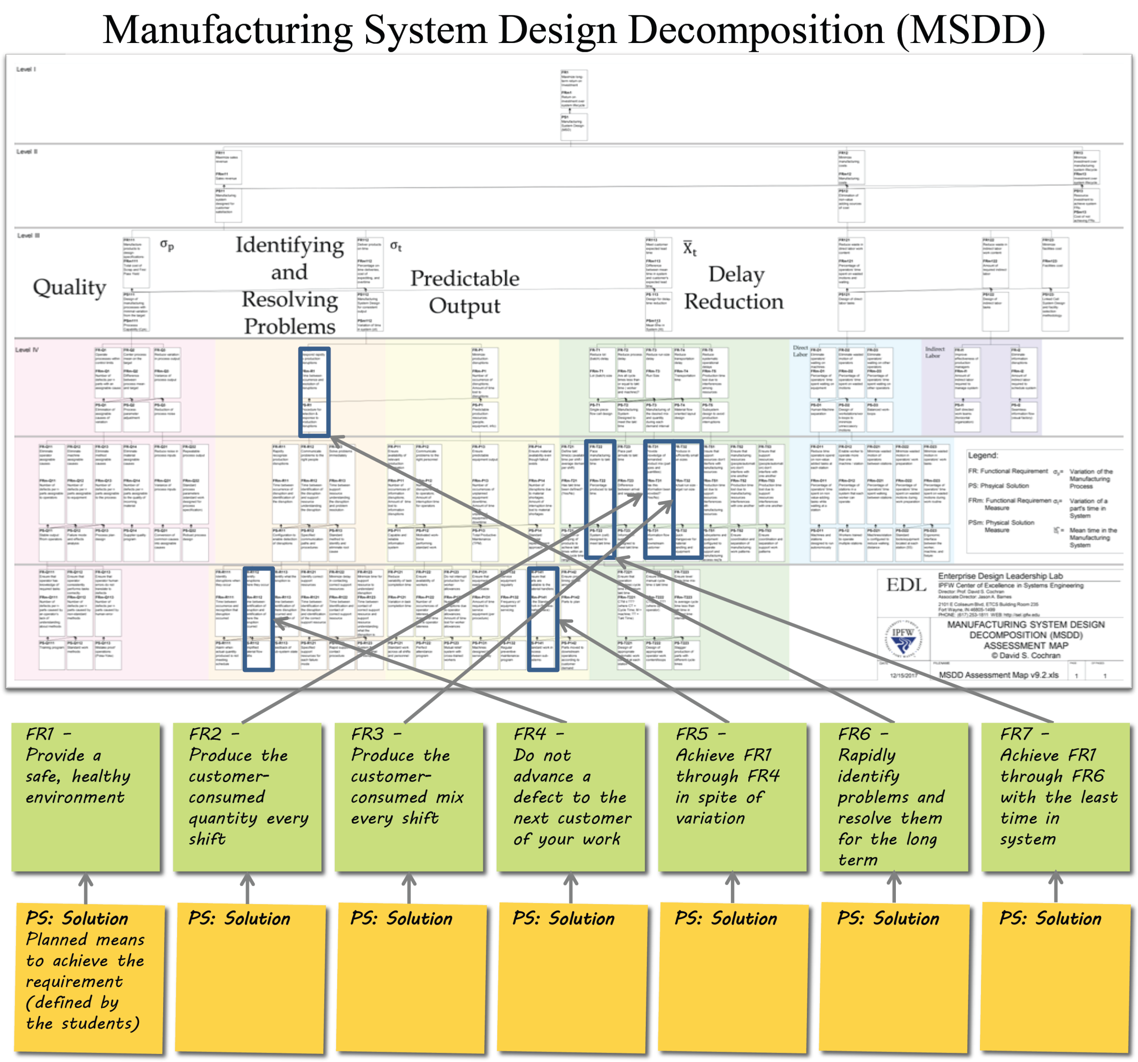

Fig. 2.1. 7 Functional Requirements Derived from the MSDD, presented at [15]

achieve the defined Functional Requirements. An example of one design relationship from the emergency room redesign is presented below:

- Customer Need: Receive quality care
- Functional Requirement: Improve Emergency Room patient satisfaction
- Physical Solutions: 2-step triage process

The customer need was clear that the patients want to receive quality care. The redesign team translated this customer need into a Functional Requirement(FR) to define what the redesigned system must achieve. The FR was to "improve emergency room patient satisfaction." The team proposed a 2-step triage evaluation process as the PS to achieve to this FR.

For a second example, please refer to Figure 2.2. The addressed customer need was that the nurses wanted to reduce their walking distance. This customer need is decomposed to state "what" the system must achieve to reduce the walking distance for the nurses. This "what" represents the FR and was stated to be, "save nursing time (FR1)." The design team hypothesized a PS to achieve this FR. The PS that the team chose was the, "tube system location." Essentially, the idea was to centralize the tube system that transferred lab results to a more centralized location for the nurses. This improvement saved an average of 21.7 seconds per trip. In total, by achieving FR1, the nurses saved 78.2 minutes each day [13]. This savings roles up into a substantial reduction in wasted time and therefore wasted money as well.

2.2 Current Food and Farming System

This thesis is centered around improving the health of people, and it recognizes that the current way food is produced results in poor health [26]. Much of the literature on the current food and farming systems points to the resulting decline in both public health as well as environmental degradation [26–28]. The motives behind why the food and farming systems of the 20th and 21st century have evolved

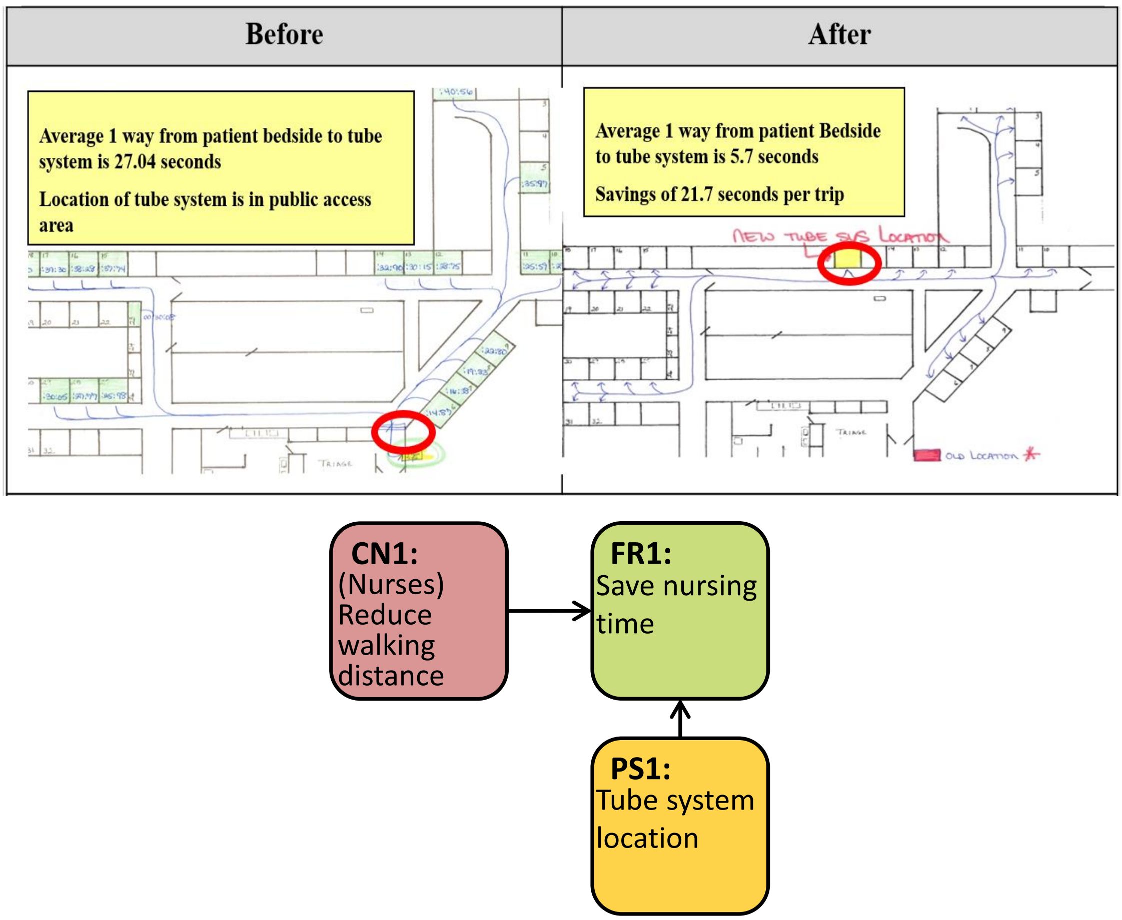

Fig. 2.2. Example Application of CSD. Modified from [13].

in such a way so as to become destructive to humans is outside of the scope of this thesis. Investigative journalists, such as Gary Taubes and Nina Teicholz, have thoroughly documented the political and financial motives that are the root cause of the destructive food and farming systems of today [1, 29]. The focus here is on the current food and farming practices that are resulting in the decline of the health of people.

Food is no longer sourced directly from family farms but from supermarkets and grocery stores. Instead of getting single ingredient food items such as meat and vegetables from family farms, anyone can now get an enormous variety of ingredient dense "food like substances" at the grocery store [26]. The grocery store is now full of engineered food products that arguably taste better and provide more pleasure than any whole foods known to man [26].

Although meat and vegetables are still staples at the grocery store, the quality of these items may not be what they were like when they were sourced from small-scale family farms. On small-scale farms, animals would be raised outdoors on a natural feed source such as grass for ruminants and insects for poultry. Now animals are raised in Concentrated Animal Feeding Operations (CAFOs) where they are fed unnatural diets of corn for ruminants and soy for poultry that are part of a blanket antibiotic feed program [27].

Vegetables originating from small-scale farms would have come from nutrient-dense soils that were carefully taken care of by the farmer to ensure abundant vegetable production. Manure from the livestock and compost would be added to the vegetable plots to ensure the soil had all of the vital nutrients needed. Today, fossil-fuel based fertilizers are used in an attempt to subsidize the soil with nutrients that are no longer provided by compost and manure. Nitrogen, phosphorous, and potassium (NPK) are all that are deemed important for vegetable growth because with the right ratio of these elements, vegetables and other crops will grow. This reductionist view of soil health and composition fails to recognize that if other nutrients are not present in the soil, then they will not be present in the vegetable [30,31]; calcium and magnesium being the most notable nutrients.

In summary, the current food and farming systems provide a convenient way to get food, but the majority of the food is either highly processed, nutrient deficient, or both. This realization is important to begin to understand the health crisis in terms of the rising numbers of obese and diabetic individuals. Highly-processed food is addictive because it is designed to be highly palatable. The resulting food addiction leads to an over-consumption of food. Excessive sugar and calories leads the human body to become obese and diabetic [1]. The fact that non-nutritive foodstuffs represents the most readily available food for many places in the world begins to highlight the systemic issues that are causing these health problems.

2.3 Development of Abdominal Obesity and Type-2 Diabetes

The title of this section references the development of a specific type of obesity and diabetes: abdominal obesity and type-2 diabetes. The body of research around the disease progression of both obesity and diabetes points to the need to clearly specify the type of obesity because the pathophysiology of each greatly differs [32].

Obesity can be classified by the type of fat that is present. Fat is either stored under the skin (subcutaneous fat) or in the abdominal cavity (visceral fat). There is an elevated risk for developing type-2 diabetes or metabolic syndrome associated with an increase in visceral fat, which is referred to as abdominal obesity [33].

On the other hand, there is a subset of obese individuals that are known as the obese, metabolically normal (OBMN) subgroup [34]. In short, this subgroup represents obese individuals who are not at an increased risk for developing diabetes or metabolic syndrome. What is important is that a key sign for diagnosing someone as OBMN is the universal distribution of excess fat without visceral abdominal accumulation [34].

Therefore, abdominal obesity is the real concern and visual cue when it comes to the development of type-2 diabetes. Type-2 diabetes is characterized by a resistance to using one's own insulin to maintain safe blood glucose levels. This resistance is most commonly referred to as insulin resistance and develops in response to chronic hyperglycemia and hyperinsulinemia [32, 35, 36].

Insulin, the fat storage hormone is responsible for shuttling glucose out of the blood stream into various cells [32,36,37]. To understand how insulin works and why it is necessary, it is important to understand how glucose gets into the blood stream to begin with. This realization represents the potential to understand how diabetes develops and possibly how it can be reversed and prevented.

There are 3 types of macro-nutrients that are consumed in food. These are proteins, carbohydrates, and fat. Of these 3 macro-nutrients, carbohydrates almost entirely break down into sugar (blood glucose) when consumed [38]. Therefore, when carbohydrates are consumed, a person's blood sugar will rise. As the blood glucose levels increase, insulin will be secreted by the pancreas to shuttle this sugar into the muscle cells to fuel activity or into glycogen stores for later use. In the event that the cells do not need the sugar (i.e., person is sedentary) or the glycogen stores are full, the liver will store the sugar in fat cells or adipocytes [38].

During this phase of excess sugar in the blood stream, which comes from excess carbohydrate consumption, more and more insulin must be secreted to attempt to shuttle the sugar into cells and glycogen stores to maintain safe levels. Over time, the cells become resistant to allowing sugar to enter, namely because the cells are already completely packed with glucose. The cells become resistant to insulin and the pancreas continues to create more insulin in an attempt to overcome this resistance [32]. After a good fight, there will come a time in which the pancreas wears out, or simply cannot produce enough insulin to overcome the resistance, and at this point the individual will suddenly have extremely high blood sugar levels. The person may end up in the hospital and be diagnosed with type-2 diabetes.

2.4 Reversal of Type-2 Diabetes

The idea of being able to reverse type-2 diabetes is relatively new and alarming to many health-care professionals [32]. Although there is debate over whether diabetes can be reversed, or only placed into remission, there is great importance in simply believing that diabetes can be reversed. This thesis argues that systems that meet customer needs will improve the health of people, and a person believing that diabetes can be reversed is a fundamental customer need. A person's physiological state of disease progression ultimately determines whether their diabetes can be reversed or placed into remission [36].

The argument that diabetes can only be placed into remission stems from two key points. First, if the diabetes is reversed, but the person reverts to their original diet and lifestyle that originally caused the diabetes, they will then get diabetes again. The argument is that the diabetes was only placed in remission since it came back [32,36]. The second point is that the increased risk for all of the complications that come with type-2 diabetes may not be able to be reversed [36]. Said another way, the disease itself may be able to be reversed, but the risk of complications may not be reversed. The logic of the argument is that the diabetes was only placed into remission because the person is still at an increased risk for complications.

There is much more to the argument though, especially from a physiological standpoint. Consider two separate states that an individual with type-2 diabetes can be in. First, the person's beta cells (pancreatic cells that produce insulin) may be working very hard in an attempt to overcome the insulin resistance. This person would not require injected insulin to maintain blood sugar levels, and if the underlying insulin resistance was reversed, they would be able to return to a metabolically normal state. Once in the metabolically normal state, this individual could eat cake and ice cream without spiking their blood sugar to unsafe levels.

For the second state, consider a person whose beta cells (pancreatic cells that produce insulin) are burned out, meaning they can no longer produce their own insulin. More than likely this individual is injecting insulin to maintain safe blood sugar levels. Again, this person is suffering from insulin resistance, but if this resistance is reversed, the person will not return to a metabolically normal state (i.e., regain sensitivity to insulin). This person may be able to live on a low carbohydrate diet without medication (including injected insulin), but this person would require injected insulin if he/she had cake and ice cream.

As with other forms of resistance, the stimulus must be removed to regain sensitivity. For example, consider alcohol resistance. As an individual partakes in drinking alcoholic beverages he/she will begin to develop a resistance to becoming intoxicated. Therefore it will take more and more alcohol for this person to become intoxicated. If this person wants to return to a state where it takes only a little alcohol to become intoxicated, he/she must refrain from drinking for an extended period of time in order to regain sensitivity. Dr. Sheron, a liver specialist from Southampton University, says that, “For most people, you can ‘reset’ your whole system by having an alcohol-free period [39].”

As explained above, carbohydrates stimulate the secretion of insulin. Therefore, the process of reversing insulin resistance may be as simple as not consuming carbohydrates. By not consuming carbohydrates, the amount of insulin circulating in the blood stream will continue to decline. As the level of insulin decreases, the cells’ insulin receptors become more sensitive to the insulin.

Restricting carbohydrates stimulates a physiological shift in the body from a fuel source of sugar (glucose) to a fuel source of fat (ketones). In the literature, this shift in fuel sources is referred to as nutritional ketosis and represents a range in blood ketone levels from 0.5 to 5 mM [38].

A common misconception surrounding carbohydrate restriction is that the human body cannot survive without sugar (i.e., carbohydrates). When an individual restricts carbohydrate consumption to a level of less than 50 grams per day, he/she will enter nutritional ketosis after his/her glycogen stores have been depleted [38]. The bodies’ ability to shift fuel sources represents the physiological capability of sustaining normal bodily functions even when carbohydrates are not part of the diet. One other point to note is that the human body does requires sugar in the blood stream to feed certain parts of the body (mainly the brain) that cannot survive on ketones. The fact that certain parts of the body cannot survive without sugar is the main argument for why the human body needs sugar, and the argument is sound. The misconception is that the sugar has to be consumed as part of an individual's diet. What is not commonly discussed is the fact that the human body can produce its own glucose through a process known as gluconeogenesis [38]. Gluconeogenesis is the process in which blood glucose is produced from glycerol: the backbone of triglycerides (or fat molecules).

The system design approach to reversing diabetes presented in this thesis has its foundation on the use of the Very Low Carbohydrate Ketogenic Diet (VLCKD). The current literature regarding the use of the VLCKD to reverse diabetes shows great promise [40–44]. As noted by its name, the VLCKD requires restricting carbohydrate consumption to less than 20 grams of carbs per day.

One study from 2017 highlights the VLCKD's ability to reverse and provide meaningful improvements in the lives of type-2 diabetics [41]. The study which consisted of 262 participants focused on the relationship between type-2 diabetes and the use of the VLCKD. The program participants were enrolled in an outpatient protocol that provided intensive nutritional and behavioral counseling, digital coaching and an education platform, and physician-guided medication management [41]. At the start, only 19.8% of the participants had a glycated hemoglobin percentage (HbA1c, a 3-month average of blood glucose levels) of less than 6.5% [32], but after 10 weeks, 56.1% of participants had an A1c below 6.5%.

2.5 Early Detection of Type-2 Diabetes

As with obesity, the sooner a person takes control of their life and loses the weight, the better and easier the journey will be for the person. It may go without saying, but the reason it is easier is the sooner a person starts their weight-loss journey, the less weight they will have to lose. As for reversing diabetes, the sooner a person begins eating a VLCKD, the easier and faster the reversal process [32]. The way in which diabetes is currently defined and diagnosed leaves a potential gap in the ability to detect diabetes.

With the main problem associated with type-2 diabetes being a resistance to insulin, the ability to detect the future development of diabetes may be centered around insulin levels, instead of blood glucose, as argued in the Diabetes Reversal System in Chapter 5. Currently blood glucose levels, both fasting and a 3 month average (A1c), are used to detect and diagnose someone as being prediabetic or diabetic. The problem with this method is that a person's blood glucose levels only become abnormal when insulin is no longer able to cover up the problem (i.e., keep the blood glucose levels in a safe range) [32]. A person may have severe insulin resistance for many years prior to having abnormal blood sugar levels.

Fig. 2.3 shows a theoretical representation of when the onset of diabetes occurs in relation to when the actual diagnosis takes place. Note that the onset of diabetes is depicted as early as 5 years prior to the actual diagnosis of the disease. The findings of the Whitehall II study supports this assertion [45]. In this study, 6,538 non-diabetic individuals were tested for insulin sensitivity using the HOmeostasis Model Assessment (HOMA). After seven to nine years, 505 of these individuals were diagnosed diabetic. Retrospective trajectories of the insulin sensitivity values showed that a steep decrease in HOMA insulin sensitivity began five years prior to diagnosis [45].

The red line on the figure depicts how a person may be feeling (i.e., energy levels, fatigue). When a person begins to notice the symptoms of unsafe blood sugar levels (i.e., headaches, blurred vision), he/she may end up in the hospital, and at this point, the individual is diagnosed diabetic. Clearly the onset of diabetes occurred years prior to the diagnosis and waiting for a person to develop symptoms is not the logical way to identify a chronic disease.

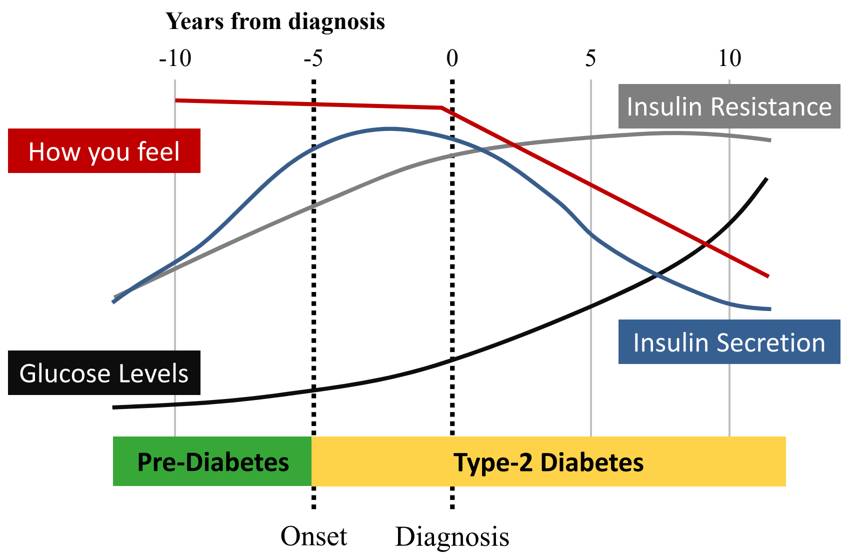

Fig. 2.3. Time line depicting physiological changes 5 years before and after diagnosis [14]

This figure explains how the diagnosis process may be enhanced if the blood marker of concern was insulin instead of blood glucose. Notice that both insulin secretion and insulin resistance begin to climb before blood glucose becomes a problem. An increase in blood glucose levels is a response as the body can no longer cover up the problem with insulin [32].

CHAPTER 3. SYSTEM-LEVEL VIEWPOINT

Chapter 3 describes the first research objective which is to use a systems-level viewpoint to explain why the current diabetes and obesity epidemic is due to systemic problems. This research objective provides the argument for applying system design methodologies to mitigate the epidemic.

The key focus of this thesis is to understand the application of a system design methodology (Collective System Design) in an attempt to improve the health of people. To “improve the health of people” here means to prevent and reverse disease by eliminating the root causes of illness. At the heart of this argument lies the assumption that poor health is the result of a systemic issue. Therefore, the first assumption to consider is that if someone is suffering from poor health, a systemic issue is at the root of the cause. This assumption is broad and relates to many different systems that all interact with each other in some form or fashion. A few of these systems and the evidence indicating that they cause poor health will be discussed in this chapter. The main goal of discussing these different systems is to understand the current-state drivers that dictate why and how these systems perform their current functions to understand how a systems engineering approach can mitigate the problems.

3.1 Medical and Health Care System

As with any large system or enterprise, it must produce what the customer wants in terms of quality, quantity, lead time, and variety. Although this idea is most commonly discussed in reference to manufacturing, it has great synergy with many different type of systems. For a health care system to be sustainable, it must be financially viable. Therefore, health care system design must focus much of its effort on meeting the needs of its customers. Although the "customer" in this scenario may not be the actual patient receiving the care, but instead the customer may be the person, or business entity, that is paying for the services. In many cases, the business entity that is paying for the services is the health insurance companies.

The way in which the health insurance companies structure their reimbursement policies will drive the behavior of hospitals and other healthcare facilities. If a hospital is not rewarded financially for preventing and reversing diseases, then this outcome will not be the key focus for the hospital.

A proposed way to improve the current health care system is to provide incentives to primary-care physicians to prevent chronic disease and the consequences associated with these patients. For example, the approach with Medicare and Medicaid to pay a certain dollar amount, called a Capitation payment care model, incentivizes a medical system to promote wellness among patients so that overall costs are lowered. In turn, a healthcare system makes money when the cost of care is less than the dollar amount received on average for patients treated within the system.

The way the current reimbursement model is setup is to reward specialist care-centered operations. For example, a primary-care physician may see a patient for many years and his/her health may continue to decline as they become over weight. There is no incentive for the primary-care physicians to help improve this patients physical well being. After many years, this individual may have a heart attack. A cardiologist and interventional radiologist will be required to put a stent in and hopefully save the individual's life. This procedure will cost a little over $100,000 and the patient will walk away saying, "they saved my life [46]."

3.2 Food Supply System

The discussion here is to simply recognize that consumers have come to expect low-cost and convenience in relation to their food choices. Without much surprise, this expectation has led food producers to flood the market with cheap, unhealthy, "food like substances [26]." The rates of chronic disease currently seen around the world reveals that these food-like substances are having an effect on our health. According to the Centers for Disease Control and Prevention (CDC),"Six in ten adults in the US have a chronic disease and four in ten adults have two or more [47]." These numbers express the leading drivers for the nations $3.3 trillion in annual health care costs [47].

3.3 Unmet Customer Needs

Within the context of Systems Engineering, a customer represents any one who interacts with the system of interest. In terms of the Health Care System as well as the Food Supply System, the customer discussed in this section refers to the consumer. The consumer has many needs that he/she recognizes but also needs that are subconscious, or simply not stated.

This thesis argues that by using a systems engineering methodology, namely Collective System Design, to design systems that meet customer needs, systems that improve the health of people can be created. This argument is based on the premise that the systems currently in place that should improve the health of people are not meeting customer needs. This discussion on unmet customer needs will be analyzed in terms of both the current health care systems and the current food supply system.

3.3.1 Unmet Health Care Customer Needs

This thesis recognizes two key customer needs of the health care system that are arguably not being met based on the current trends with the prevalence of chronic disease. First, physicians need and want to improve the health of their patients. It is a safe assumption that people become doctors because they want to save lives and improve the health of their patients. They care about people and want to help them. Unfortunately, some doctors do not feel that the current system allows them to get to the root cause of poor health but rather prescribe medication to mask the symptoms for the time being. Jason Fung M.D. expressed this case in his books about obesity, diabetes, and fasting by explaining that he could not deal with patients getting worse and dying under his care and knew that there had to be another way [32, 48, 49]. Dr. Fung refuted conventional treatment plans and began, "The Fasting Method," which focuses on the use of diet and fasting to reverse obesity and diabetes [50].

Although there is much work being done in terms of process improvement, or what some refer to as Lean Healthcare, these improvements are aimed at streamlining medical and healthcare services. For example, improving the capability, in terms of throughput (i.e., number of patients per hour or day), is applicable to the focus of lean healthcare. Joe Swartz, Administrative Director of Business Transformation at the Franciscan Alliance Hospitals in Indiana, has done incredible work in the field of healthcare improvement [51]. Much of his work has focused on engaging the front-line staff to practice continuous improvement by practicing the tone required to facilitate lasting change.

This thesis argues that the healthcare improvement efforts can and should be applied to reducing the throughput of patients by improving the health of people. This approach provides an example on solving the capacity problem that many hospitals are experiencing such as Parkview in Northern Indiana [52]. By applying the systems-level improvement approach to the physicians need to improve the health of their patients, then the health care systems can focus their effort on evolving their system to better meet this need.

The second customer need stems from the patients themselves. Patients want to live long, high-quality lives. This need mirrors the physicians need to want to improve their patients' health. Medication arguably improves the quantity of life but maybe not the quality of life due to only suppressing symptoms or because of the resulting side effects. Diet could potentially improve both the quantity and quality of life better than medication in some cases. For example, Ross Robinson, a Pharmacist at Parkview Lagrange Hospital noted that major pharmaceutical products for diabetes are approved based on an A1C lowering of 0.8 to 1.2. The Parkview Lagrange Food Pharmacy Program, which aims to improve the health of people with diabetes by lowering their A1c through a dietary intervention, has accomplished an average drop in A1c of 1.7 after only a six month program [53]. This example provides one case for how dietary intervention outperformed the use of medication.

3.3.2 Unmet Food Supply Customer Needs

The major unmet need of the customers of the food supply is simply for easily-accessible, healthy, high-quality food. The current food supply does offer healthy, high-quality food if one is willing to literally drive the extra mile in some cases. Anyone who has gone on a diet, or tried to follow a more health eating pattern, has discovered that fast-food and prepackaged meals may no longer be an option. Now this individual will have to deal with the inconvenience of locating healthy food (health food store or farmers' market) and the inconvenience of preparing the meal. These are just two barriers that the current system has to people eating healthy food.

The other problem with the current food system is the overabundance and easy access to high-calorie, low-nutrient, processed food stuffs [26]. One point here is to remember that people should have the choice to eat whatever they want, whether it is healthy or not. Similarly, as people have the right to smoke cigarettes, they should have the right to eat junk food. Both products will kill them, and just as with cigarettes, it should be clear to consumers (maybe through warning labels) that this food is not healthy. This thesis does not attempt to argue how junk food should be regulated, it only seeks to point out the junk food is the most readily available food item. Junk food is highly processed and "designed" to provide maximum pleasure; it results in food addictions, and it skews the playing field when a person has to choose between healthy and unhealthy food. The current system actively promotes junk food over health food. This systemic problem results in an unmet need of the customers of the food supply system which is easily-accessible, healthy, high-quality food.

3.4 Summary

This Chapter described the first research objective which is to use a systems-level viewpoint to explain why the current diabetes and obesity epidemic is due to systemic problems. This research objective provides the argument for applying system design methodologies to mitigate the epidemic. The first research objective was achieved in this chapter by describing the systemic issues of the current food supply and health care systems.

CHAPTER 4. CASE STUDY: PARKVIEW LAGRANGE HOSPITAL FOOD PHARMACY PROGRAM

4.1 Introduction

Chapter 4 covers the second research objective which is to describe the logical structure of the Parkview Lagrange Food Pharmacy Program using Collective System Design (CSD). This research objective is used to show that CSD can describe the design of systems that improve the health of people.

This Chapter presents the evidence for arguing why Collective System Design can effectively be used to represent the design of systems that improve the health of people. The approach of this Chapter is to take a real model (i.e., Parkview Lagrange Food Pharmacy Program) and show it can be modeled and reproduced with the CSD language which argues the assertion that CSD is capable of expressing the actual logical design of the Parkview Lagrange Food Pharmacy Program.

If CSD can be shown to thoroughly describe an existing health care system, this evidence provides the argument for using CSD to design future health care systems. The Parkview Lagrange Hospital (PLH) Food Pharmacy program is used as the existing health care system to be described with CSD.

Parkview identified obesity and diabetes as two significant health concerns from a 2016 Community Health Needs Assessment [54]. The Parkview Lagrange Hospital, located in Lagrange, Indiana, created a multidisciplinary task force in an attempt to address these issues. This multidisciplinary team is comprised of family physicians, clinical dietitians, nurses, pharmacists, and lab technicians. In early February 2018, the Parkview Lagrange Hospital (PLH) launched the Food Pharmacy pilot program. According to Business Weekly, the Food Pharmacy program was created by Jared Beasley, Vice President of Patient Services at Parkview LaGrange Hospital; Adam

Gehring, Registered Dietitian at Parkview LaGrange and Noble hospitals; Ross Robison, Pharmacist at Parkview LaGrange Hospital; Brenda Armentrout, Director of Pharmacy at Parkview LaGrange; and Shannon Reinbold, RN, Nurse Leader of medical and surgical units [55].

The main focus of the Food Pharmacy program is to treat food as medicine [54]. By using food as medicine, the program's purpose is to ensure that each participant will experience measurable success. This success is achieved by, "reducing the negative health effects of obesity and diabetes, learning and practicing the skills needed to change their lifestyle, and by practicing careful and collaborative medication management [54]."

The program is comprised of 18 sessions (classes) over a 6 month time period. The classes are divided between educational courses, physical activity training, grocery store tours, and cooking classes [54]. From the educational courses, a participant should learn about food insecurity, medication management, lifestyle change, disease state, potential complications, and healthy eating. The physical activity training arms the participants with the skills to not only feel comfortable exercising, but it also ensures they are safe while exercising. The grocery store tour and cooking classes gives the participants the knowledge and skills to find and prepare healthy food.

Labs are taken before, midway, and at the end of the program for each participant to give the participants and the program an idea of the progress that is taking place. The midway lab also serves as an indicator for any changes that may need to take place in regards to dietary, lifestyle, and medicinal changes. The labs themselves are focused on the complete lipid panel (Low-Density Lipoproteins (LDL) Cholesterol, High-Density Lipoproteins (HDL) Cholesterol, total cholesterol, and triglycerides), A1c (HbA1c, glycated hemoglobin), and weight. In essence the program works to remove barriers that participants have to leading healthier lives. These barriers are different among the participants but in summary they include food insecurity, lack of cooking skills, lack of knowledge regarding healthy eating, lack of medication management skills, and the lack of confidence to perform physical exercises [56].

4.2 Hypothesis

The barriers to healthy living as described above may represent systemic issues that have plagued these individual's lives. Whether these individuals are financially unable to afford food and medicine, or live in a location where convenience stores are the only source of food, these individuals need assistance from outside help to improve their health. There are many reasons regarding why people are in these situations. Why someone has developed poor health conditions is not the question though. What is important is to recognize that the system these individuals are living in is killing them and a new system has to be developed for them to be able to change their lives.

4.3 Methodology

In collaboration with the Parkview Food Pharmacy Team, the Collective System Design Methodology was applied to the Food Pharmacy Program. The proposed outcome of this application of CSD was to codify the logical structure of the Food Pharmacy Program in an attempt to understand the underlying system design of the program. A system design map of the Food Pharmacy program was developed and reviewed with the team to determine accuracy. The process for developing this map is discussed below.

The CSD mapping process was facilitated with the PLH Team for two key reasons. First, the mapping process unveils the logical design of the food pharmacy program. This program came about through hard and meaningful work by the PLH Team, and the system has been adapted overtime to ensure the patients improve their health. Therefore, there is an underlying system that meets certain fundamental needs and therefore improves the health of people. Documenting this logical design in the form of a system design map simply makes the thinking behind the system more conscious and replicable. Replicability is the second reason for facilitating the mapping process. By making the thinking (logical design) conscious, the design intent of the system can be communicated across cross-functional teams.

4.3.1 Step 1: Introduce Food Pharmacy Team to Collective System Design Language

The first step in the process for this application of Collective System Design was to familiarize the Food Pharmacy Team with the CSD Language. This language is discussed in detail in section 1.7. Understanding the language and getting the team to talk about their program in terms of customer needs, functional requirements, and physical solutions was imperative for being able to develop a system design map of their program (system). A system design map represents the thinking (logical design) of a system. The CSD methodology provides a language for communicating design thinking or design intentions. By teaching everyone on the team the CSD Language, confusion behind why a system exists (customer needs), what a system must accomplish (functional requirement), and how a system will achieve those functional requirements (physical solutions) can be eliminated.

To introduce the CSD Language, the team used Sticky Notes to begin to write down customer needs and functional requirements. Figure 4.1 represents the summary of this initial discussion with the team. Note that customer needs are depicted in magenta, but these are not directly tied to any Functional Requirements(FRs) yet. Also note that there are incomplete design relationships at first meaning there are FRs without Physical Solutions(PSs) and PSs without FRs.

After the collection of the initial Customer Needs(CNs), FRs, and PSs, small hierarchical relationships were brought to life to help explain the mapping process to the team. Figures 4.2 and 4.3 provide two examples of the beginnings of these hierarchical relationships. Fig. 4.2 illustrates a case in which the team knew a PS (YMCA Personal Trainer) but were unsure of the FR that the solution was intended to achieve. In comparison, Fig. 4.3 identifies an FR (Provide info regarding acceptable foods), but the PS is unknown. In addition, there are lower level PSs (grocery store walk through and cookbook containing safe foods) but the FRs were not identified.

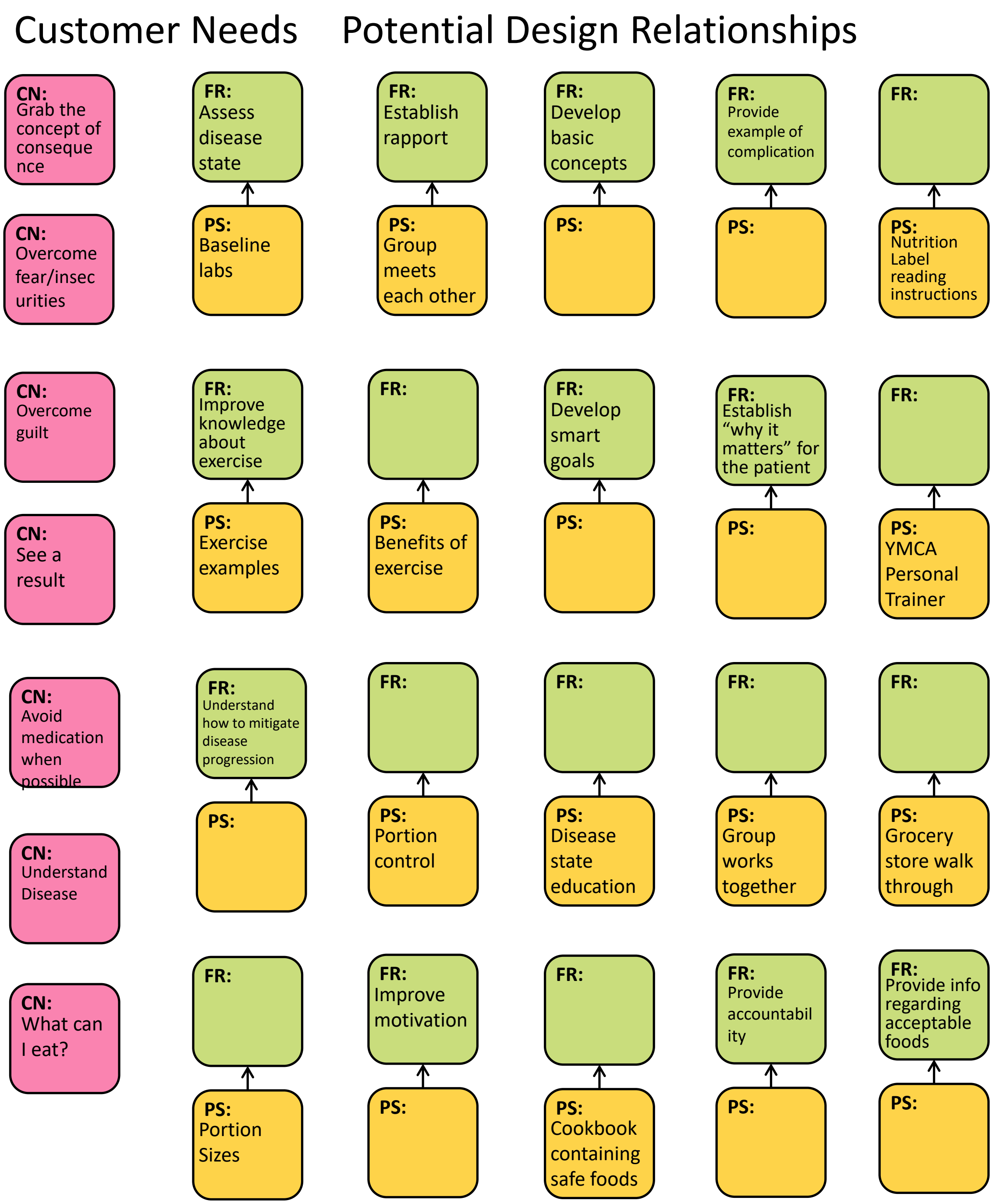

Fig. 4.1. First Collection of CNs and FRs

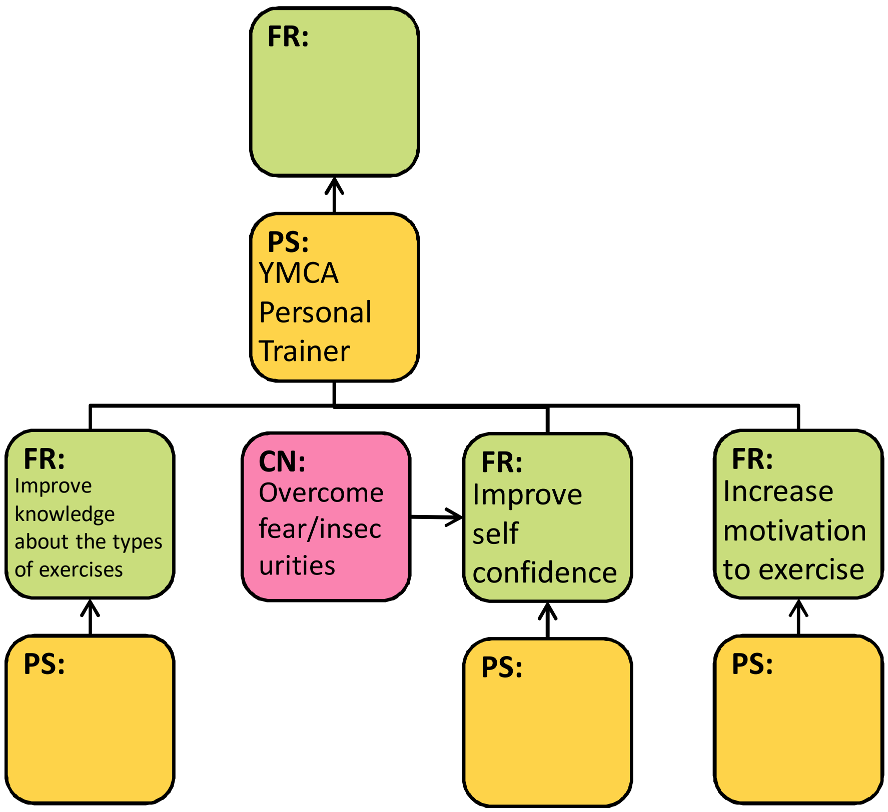

Fig. 4.2. First Collection of CNs and FRs

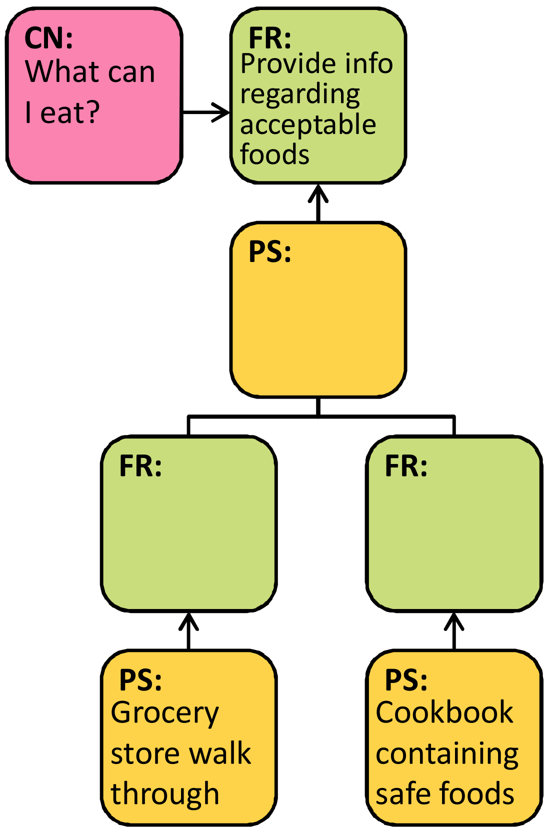

Fig. 4.3. Sample Hierarchy of Design Relationships Taking Form

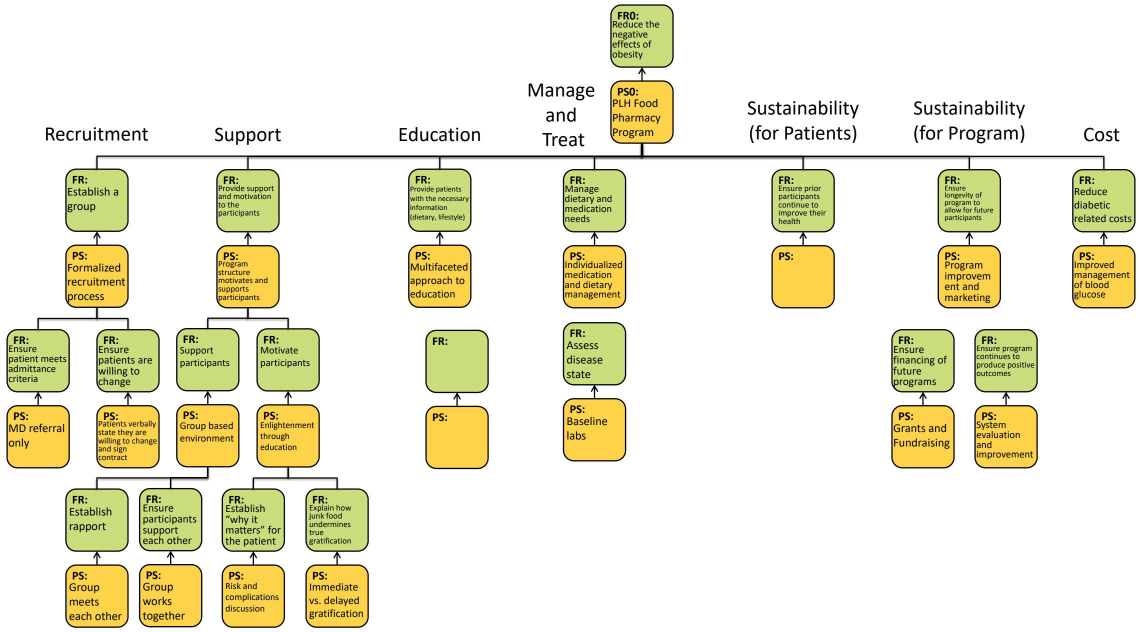

Fig. 4.4. Draft of Version 1 Map for the PLH Food Pharmacy Program

4.3.2 Step 2: Draft of Version 1 Map for the Parkview Lagrange Food Pharmacy Program

The information gathered and learned through working with the PLH team was organized into the first draft of a system design map of the PLH Food Pharmacy Program (please see Fig. 4.4). This map was shared with the team for feedback and validation of the design relationships. The team helped fill in some gaps and provided insight for further revisions of the map.

4.3.3 Step 3: Determine Path-Dependency of PLH Food Pharmacy Map Version 2(V2)

With the feedback from the V1 map, the V2 map was developed. During this process the V2 map was modified to incorporate the feedback and new learning that took place during the review of the V1 map. An overview of the v2 map is presented

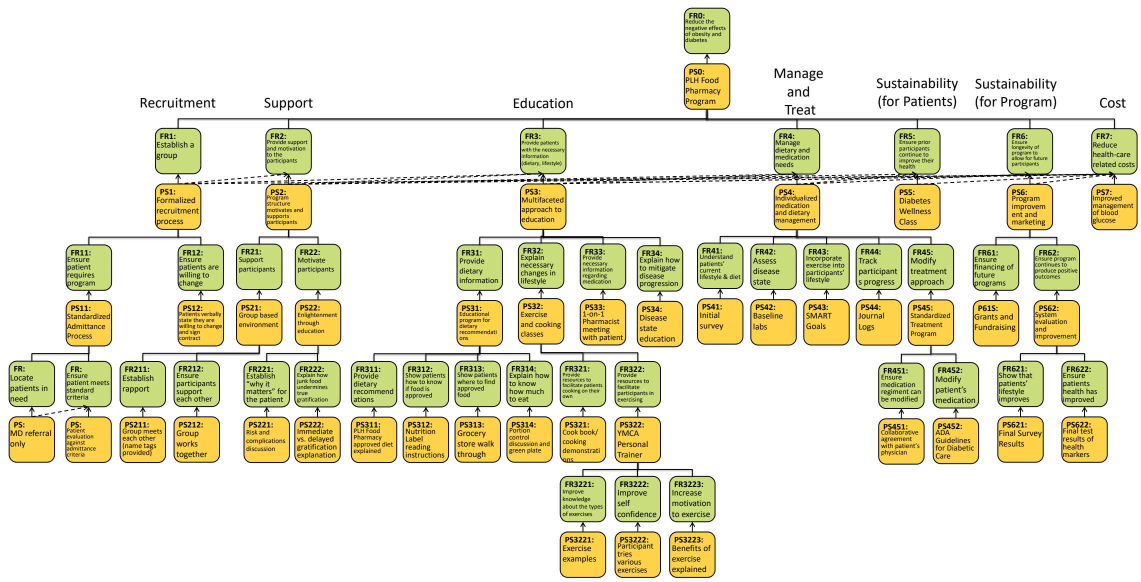

Fig. 4.5. Draft of the V2 Map for the PLH Food Pharmacy Program

in Figure 4.5. The V2 map is shown only to help explain how the overall structure of the map changed over time.

The path-dependency of the V2 map in Fig. 4.5 was assumed without involvement of the PLH Team for the initial development of the map. These assumptions were made only to illustrate how path-dependency is expressed in a system design map. For the map to be a better representation of the Food Pharmacy Program, the path-dependency of the map needed to be assessed from the view point of the PLH Team. Path dependency is important in system design because it describes which Physical Solution (PS) to implement first. The V2 map and a questionnaire were given to the PLH Team to help assess the correct representation of the path-dependency that is present within the Food Pharmacy Program. Figures 4.6 and 4.7 are scans of the V2 map with feedback from the PLH Team. Figure 4.8 is a scan of one of the pages of the questionnaire that was answered by the PLH Team to assess the path-dependency of the program.

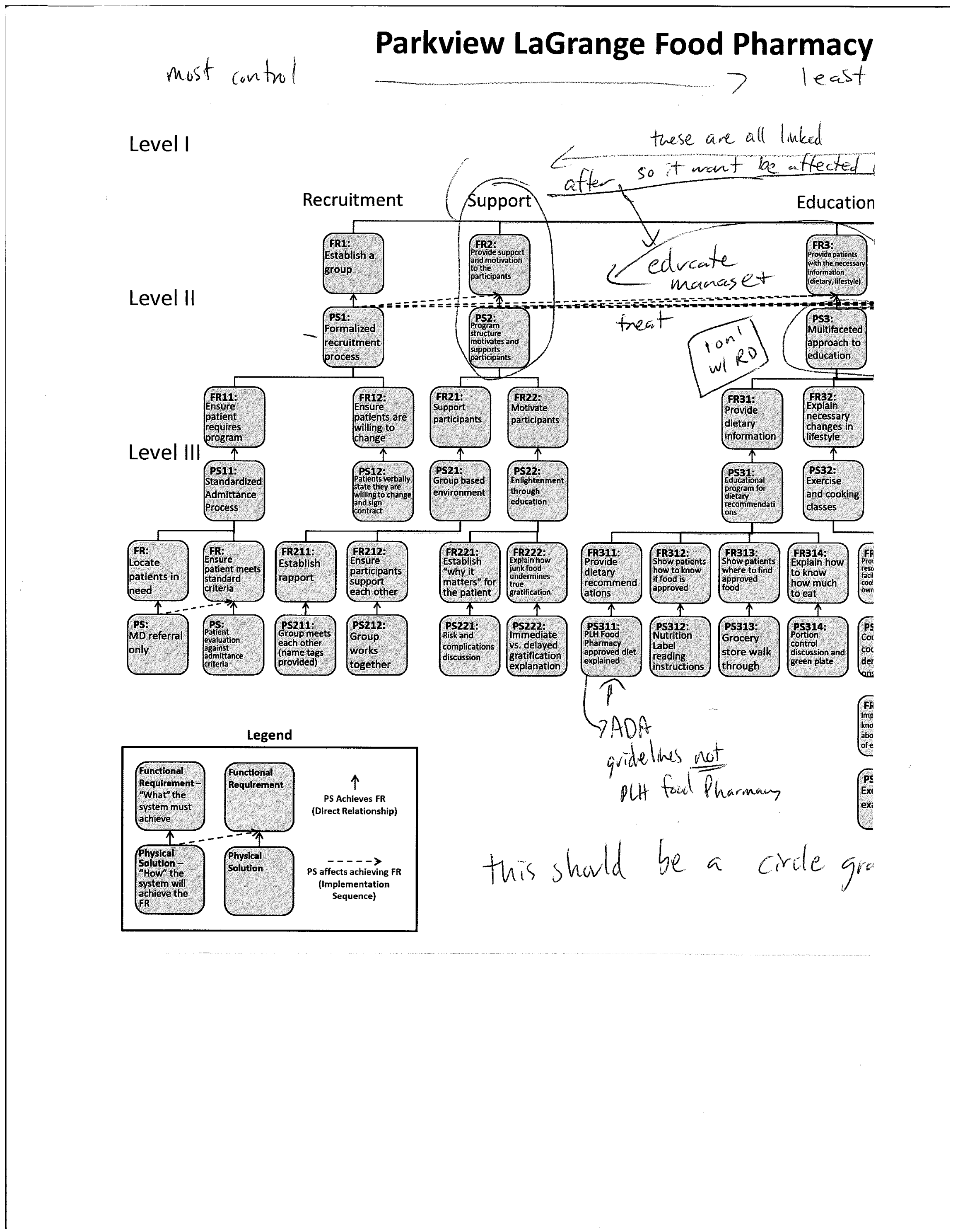

Fig. 4.6. Parkview Lagrange Food Pharmacy Map V2 Team Feedback (left half of map)

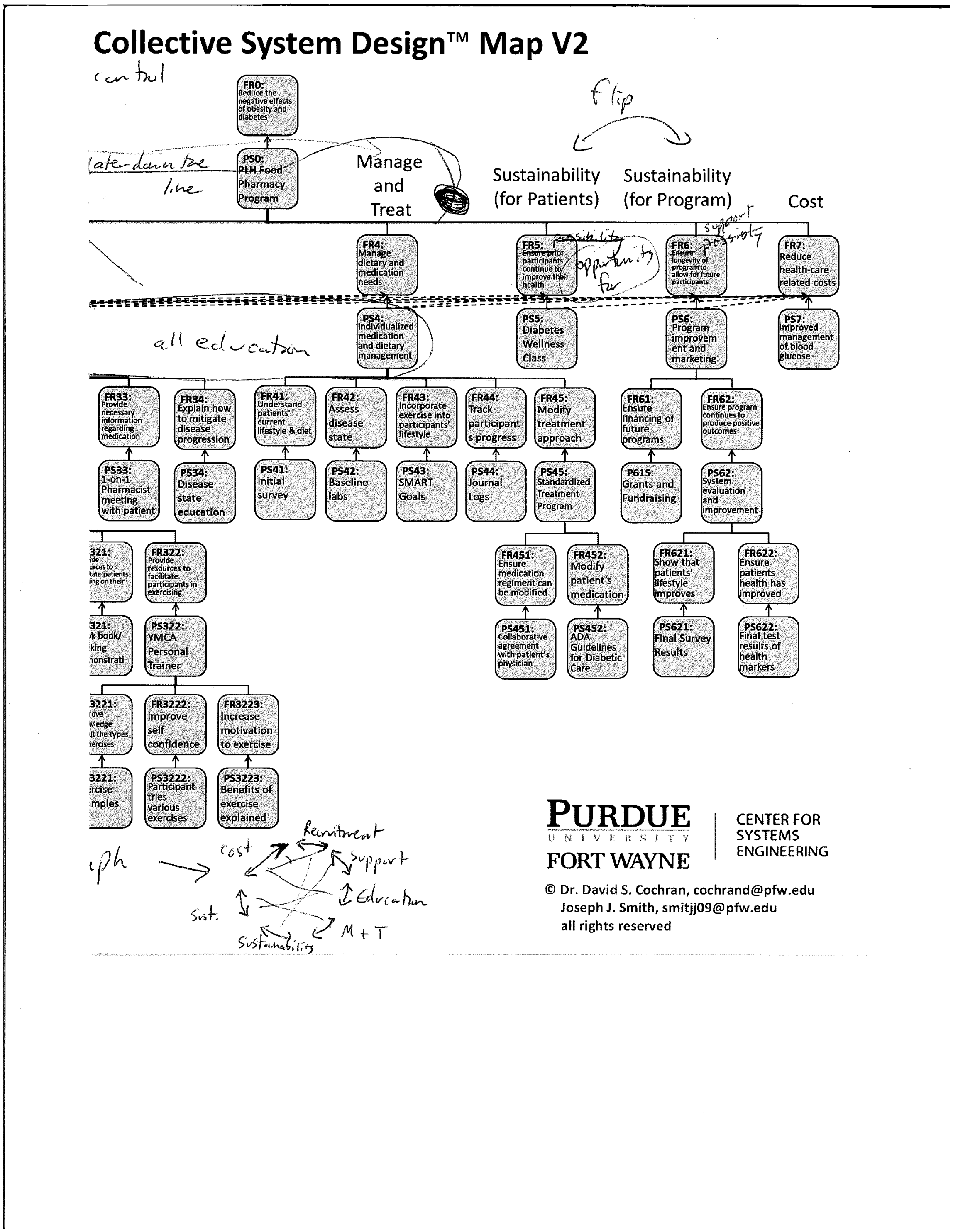

Fig. 4.7. Parkview Lagrange Food Pharmacy Map V2 Team Feedback (right half of map)

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4. Does the physical solution you choose to **manage dietary and medication needs** affect the achievement of: yes

   FR: Establishing a group? NO

   FR: Providing support and motivation to the participants? yes

   FR: Providing patients with the necessary information (dietary, lifestyle)? yes

   FR: Ensuring prior participants continue to improve their health? yes

   FR: Ensuring longevity of program to allow for future participants? yes
   ↳ all about potential results of program + another green light

   FR: Reducing health-care related costs?
   ↳ yes, potential to!

5. Does the physical solution you choose to **ensure prior participants continue to improve their health** affect the achievement of: yes

   FR: Establishing a group? no

   FR: Providing support and motivation to the participants? no, not to the "Food Pharmacy" class at that time

   FR: Providing patients with the necessary information (dietary, lifestyle)? no (") same as above, "all after the fact"

   FR: Managing dietary and medication needs? no, same reason,

   FR: Ensuring longevity of program to allow for future participants? no, not for food Pharmacy

   FR: Reducing health-care related costs? yes, ongoing support for participants in the diabetes wellness class

6. Does the physical solution you choose to **ensure the longevity of the program to allow for future participants** affect the achievement of: yes

   FR: Establishing a group? ~~no~~ yes

   FR: Providing support and motivation to the participants? yes, if we improve the program, it could affect the support
   ↳ or guideline

   FR: Providing patients with the necessary information (dietary, lifestyle)? yes

   FR: Managing dietary and medication needs? yes

   FR: Ensuring prior participants continue to improve their health? yes

   FR: Reducing health-care related costs? yes

program improvement can affect all of these by changing the process of how its done

2

Fig. 4.8. Sample of Questionnaire to Assess Path-Dependency

To assess the path-dependency of a system design, the designer (or team of designers) must answer the question, **"does the choice of PSj affect the achievement of FRi within a branch at a specific level?"**. Since this question can be rather cumbersome to fully develop and understand by looking at a system design map, a questionnaire was developed by the Purdue Fort Wayne SE Center Team researchers with the full range of questions that were needed to be answered by the PLH Team. The questionnaire allowed for a simple yes/no response to the presence of path-dependency between all of the design relationships at level 2 of the map. A simple yes/no response ensured that the PLH Team would discuss and come to a consensus regarding the presence path-dependency between two design relationships.

With the questionnaire fully completed, the V2 map was updated to include all of the path-dependencies (see Fig. 4.9) identified by the PLH Team. The resulting path-dependency is identified in Figure 4.9. The branches within level II (i.e., Support, Recruitment, etc...) were reordered to minimize the coupling (red arrows) on the map.

According to the Collective System Design methodology, the red arrows in Figure 4.9 would represent an unacceptable design. At this point in the development of the map, there was considerable confusion on how the map could indicate such an unacceptable design, but the program itself was producing positive outcomes; meaning that the health of the participants was improving. The V2 expresses a highly coupled design evident by the numerous red arrows that are present. These red arrows were determined to either be misrepresented or not entirely understood in the context of the real-life system. The map was reassessed with the goal of removing as much of the coupling as possible by rewording, and reorganizing the map. The product of this work is now the V3 map which is presented in the next section.

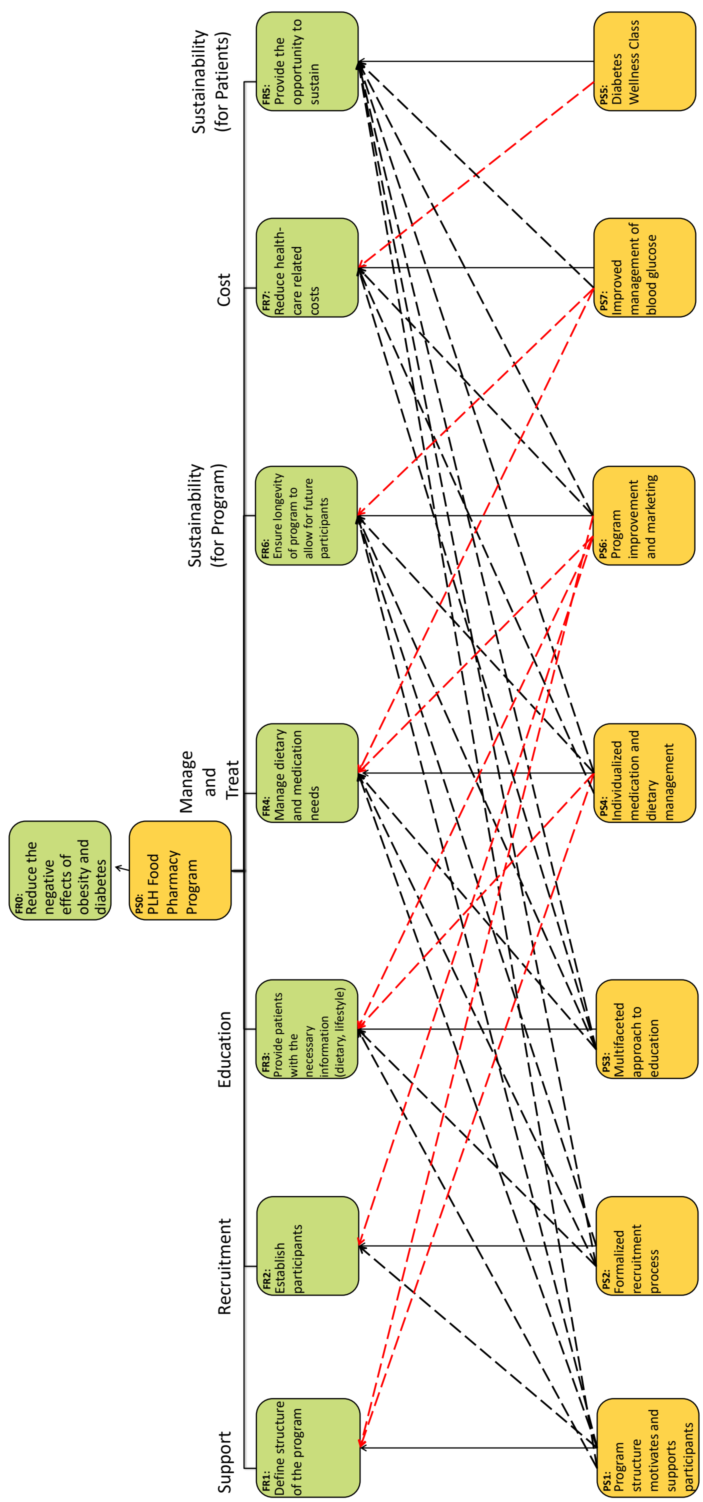

Fig. 4.9. Parkview Lagrange Food Pharmacy Map V2 Level II Path Dependency

4.3.4 Step 4: Understand and Resolve Coupling of System Design Functional Requirements (Version 3 Map)

After much discussion and trial and error, the SE Team made the conclusion that the coupling expressed in the system design map did not accurately represent the Food Pharmacy program in terms of being a coupled design. The coupling expressed in the V2 map (Fig.4.9 reveals that when certain PSs are implemented, they may affect the achievement of FRs that were previously thought to be achieved. For example, when PS1 (program structure motivates and supports participants) is implemented it acts to achieve FR1 (define structure of program), but it also affects the achievement of FR2, FR3, FR4, FR5, FR6. The concern here is that for example, when PS4 (individualized medication and dietary management) is implemented, it also affects the achievement of FR1. The fact that this interaction between FR1-PS1 and FR4-PS4 cannot be avoided by implemented PS4 first shows that the design is coupled and will require rework to achieve both FRs.

In the example of coupling between FR1-PS1 and FR4-PS4, it becomes clear that these FRs are coupled because they both work to define the structure of the program. This realization led to the conclusion to reorganize the map and to attempt to remove coupling if possible.

The level II requirements resulted in branches that were too detailed. Therefore, there was much overlap between many of the branches and there was coupling taking place (please see Fig. 4.9. By using a method of taking design relationships that were coupled and moving them to different levels, the result was a system design that still expressed the identified path-dependencies but in a more logical form. For example, lower level design relationships should, together, result in the achievement of the higher level FR in which they were derived. By changing the level in which many of the design relationships resided, the coupling expressed in Figure 4.9 was eliminated. By the method of moving design relationships to lower levels, it is understood that these requirements are now sub-requirements of achieving a higher level requirement.

Having to reorganize the map is not uncommon since the map was developed based on an existing system. The benefit of this reorganization is that it adds clarity behind the logical design and further details which FRs are the most important (bottom left) and why the PSs are being implemented.

Therefore, level II of the Food Pharmacy Map became much more broad. The two main branches of the map became (1) to *recruit participants* (FR1: Recruit participants) and (2) to *provide positive outcome for: [the various customers of the system]* (FR2: Ensure program provides positive outcomes). Keeping level II this broad allowed for better organization of the map. The coupling expressed in the V2 map was eliminated by reorganizing the map.

The V3 map expressed in Figure 4.10 was developed as a result of these methods to reorganize the map. The map is detailed and therefore is not legible in a single figure. Therefore, the map is broken down into more legible figures. These figures are explained in more detail now.

Figure 4.11 provides an overview of the two main branches of the map. This figure provides a high level view of the top-level FR for why the program even exists. The top-level FR (FR0) is to, "Reduce the negative effects of obesity and diabetes," and it may go without saying, but the top PS (PS0) is the, "PLH Food Pharmacy Program." PS0 is decomposed into FR1: Recruit Participants and FR2: Ensure the program provides positive outcomes.

Figure 4.12 provides the details of the Recruitment Branch. The Recruitment Branch is the leftmost branch meaning that it must be implemented first. This notion holds true in the actual facilitation of the program for two reasons. First, there must be participants for the program to exist. Second, the types of patients that are recruited greatly affects all other aspects of the program. For example, having a patient who is unwilling to change his/her lifestyle will probably not find much benefit in the program. This example refers to FR12: Ensure patients are willing to change and PS12: Patients verbally state they are willing to change and sign contract.

Fig. 4.10. Parkview Lagrange Food Pharmacy Map Version 3

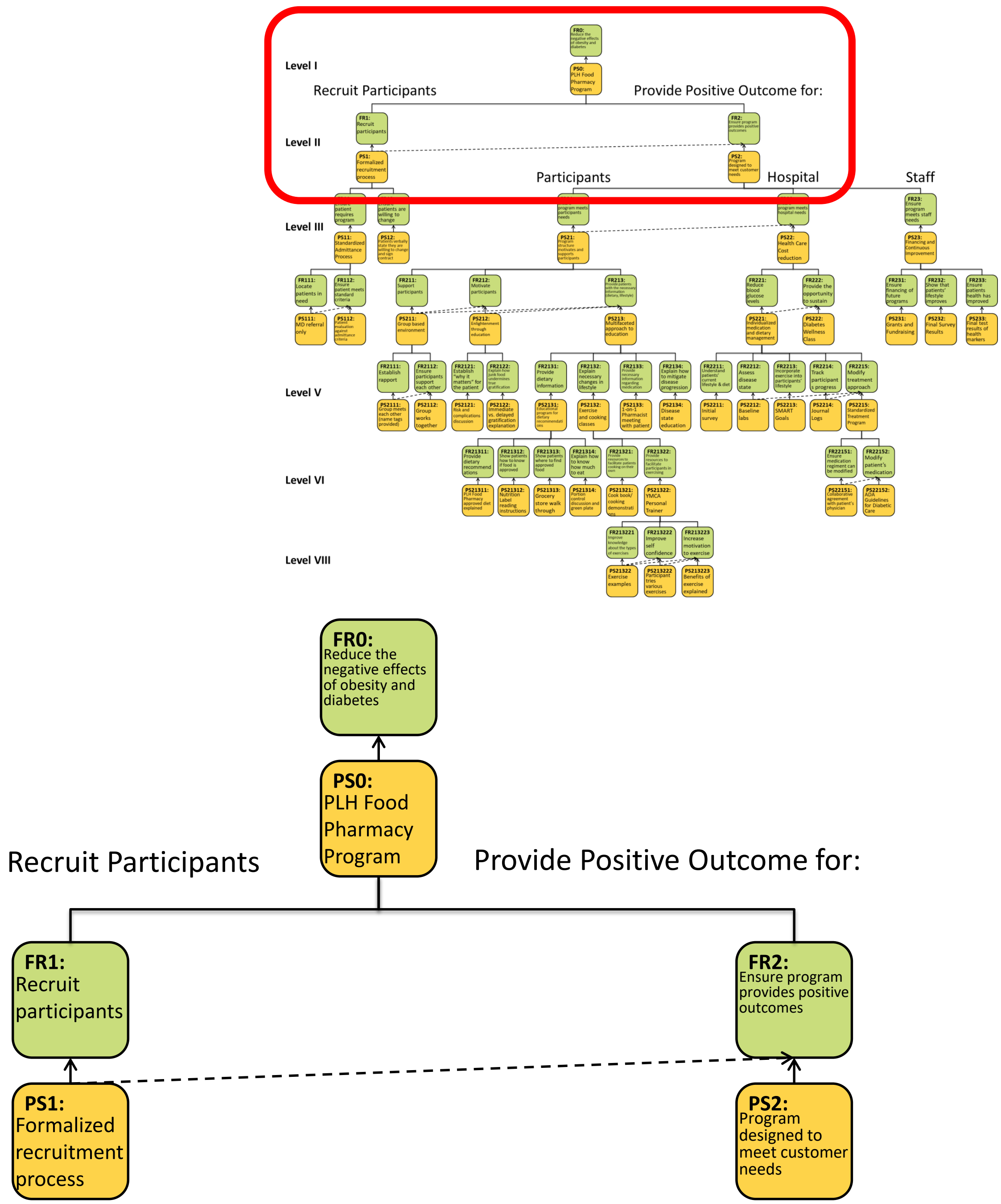

Fig. 4.11. Parkview Lagrange Food Pharmacy Map Version 3 - Top Level

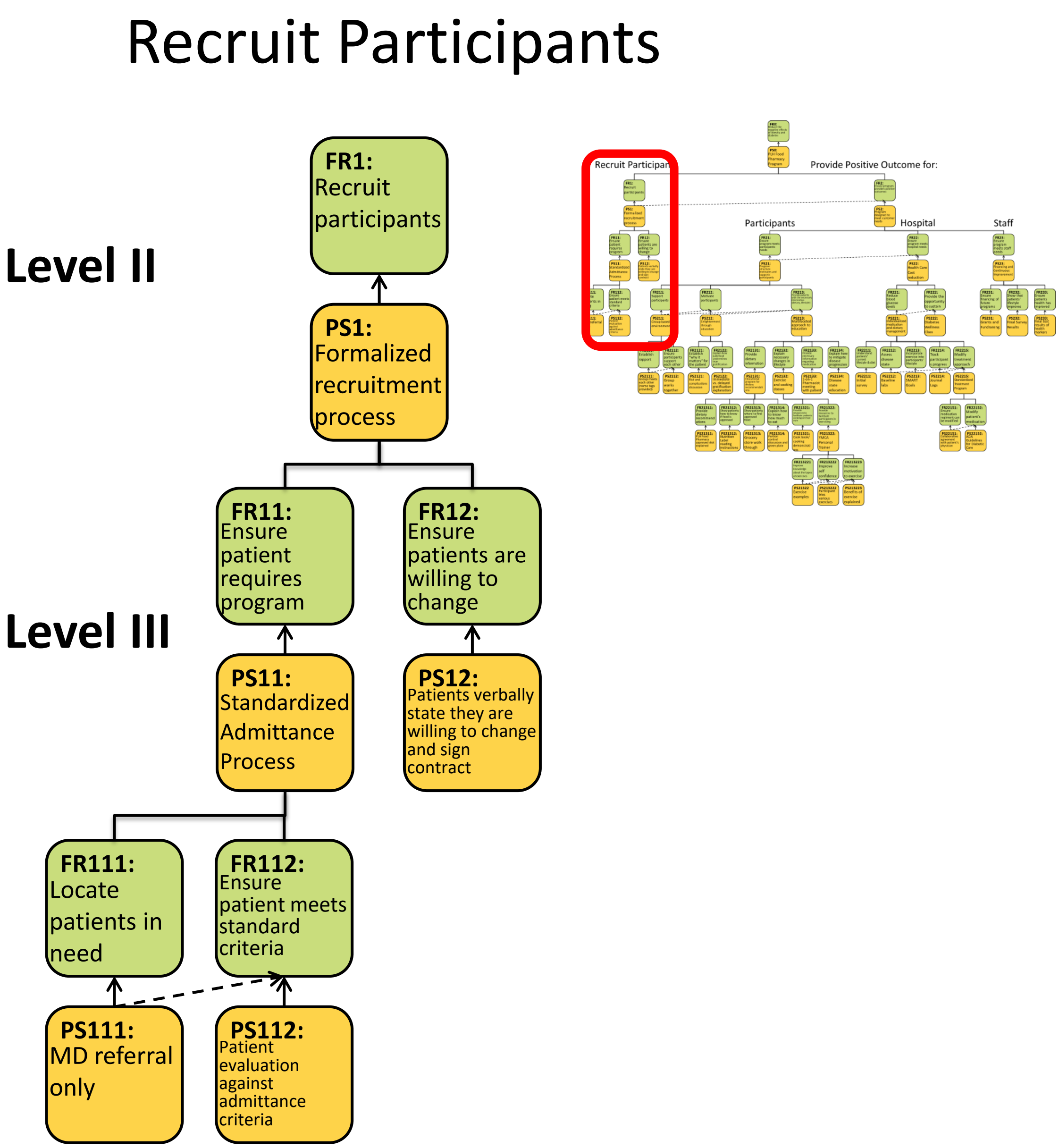

Fig. 4.12. Parkview Lagrange Food Pharmacy Map - Recruitment Branch

The next 3 Figures (4.13, 4.14, and 4.15) explain in more detail how the program is designed to meet customer needs. Figure 4.13 details how the, "program structure motivates and supports participants”(PS21). Figure 4.14 details how the program implements, “Health Care cost reduction” (PS22). Figure 4.15 details how the program implements, “Financing and Continuous Improvement” (PS23).

The V3 Map now actively expresses a system design that is not coupled. Based on the success of the Food Pharmacy Program, the V3 map aligns much more closely with the actual implementation. The V2 map expressed a system in which many design relationships were coupled. After the above methods were used to reorganize the map, the coupling was remove and the map results in a more logical representing of the actual Food Pharmacy Program. The design is still partially-coupled, but partially-coupled is acceptable since there is a implementation sequence that does not affect the achievement of already achieved FRs.

4.3.5 Summary

The focus of this thesis is to understand the relationship between systems that meet customer needs and whether or not they improve the health of people. This thesis argues that designing systems to meet customer needs will in fact improve the health of people. The Parkview Lagrange Food Pharmacy Program is improving the health of people and represents and applicable case study for this thesis.

The two key outcomes from this chapter are (1) Collective System Design provided a way to express the logical design of the Food Pharmacy program to the point that it identified how the program meets customer needs, and (2) the program is designed to meet customer needs to improve the health of people. The Food Pharmacy program has been shown to lower an individual’s A1c on average by 1.7 points over 6 months [53] which provides evidence for the notion that the program improves the health of people. The V3 Map expresses three key FRs of the program that ensure that customer needs are met (see Fig. 4.16). These three FRs are (1) FR21:

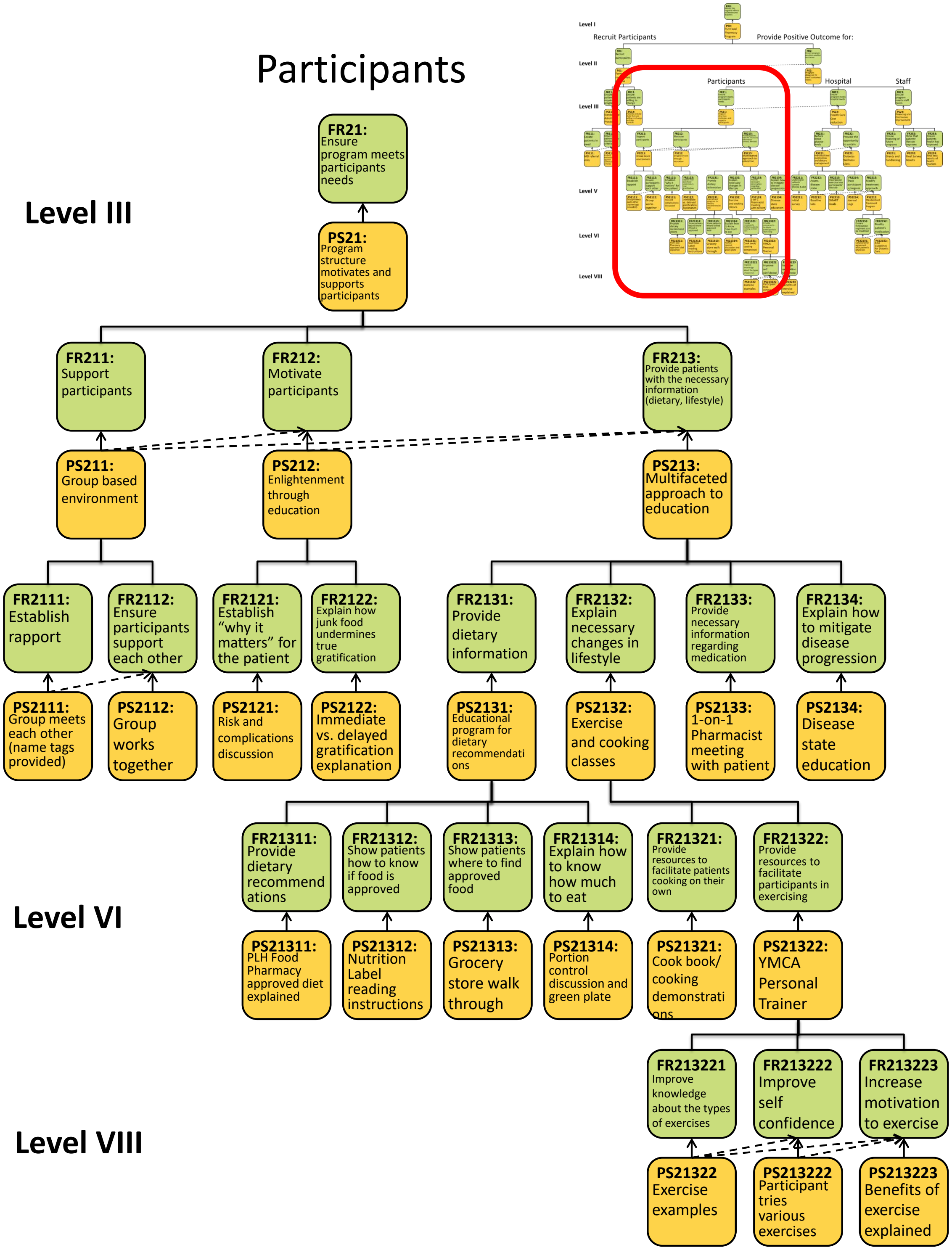

Fig. 4.13. Parkview Lagrange Food Pharmacy Map - Participant's Branch

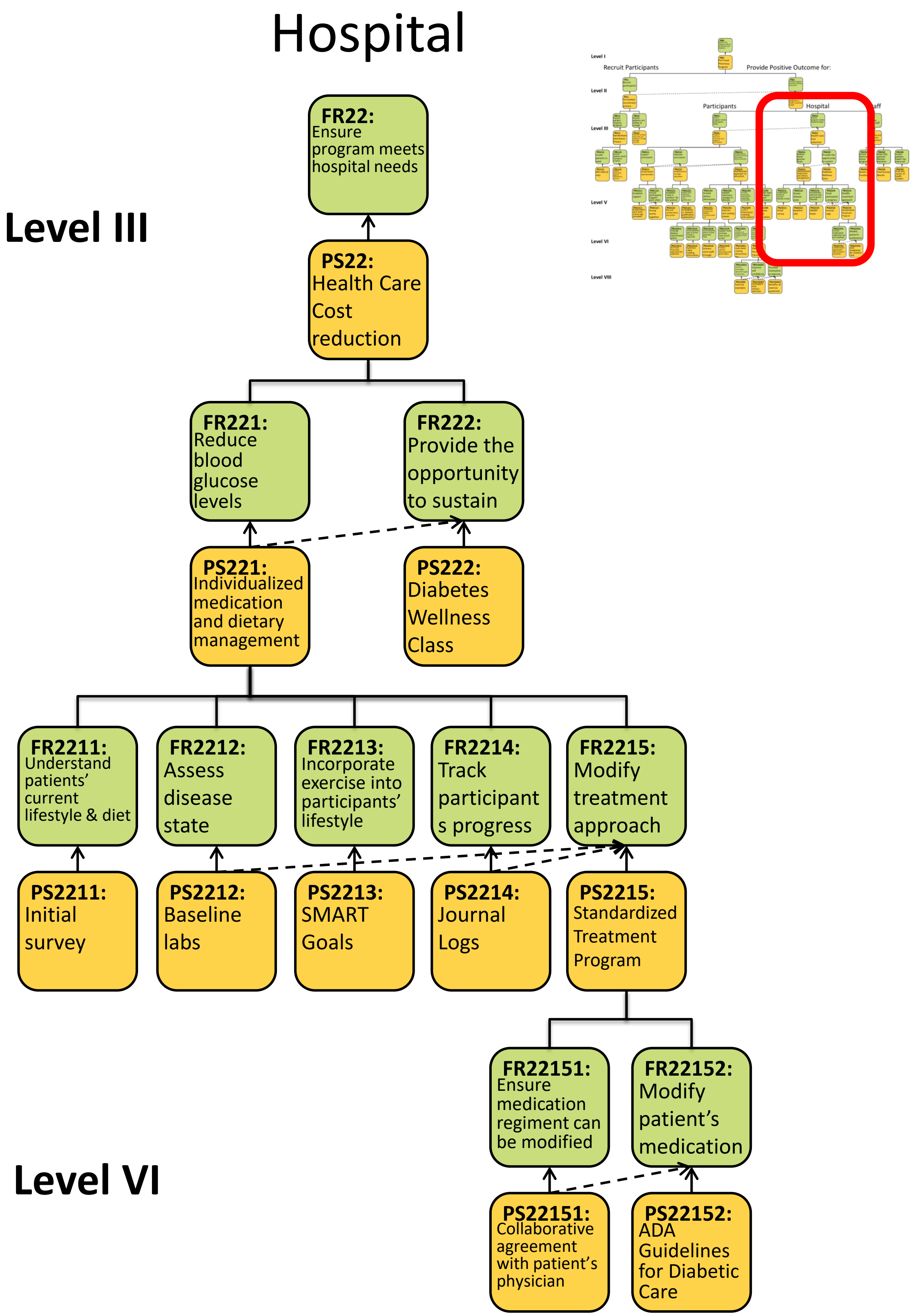

Fig. 4.14. Parkview Lagrange Food Pharmacy Map - Hospital's Branch

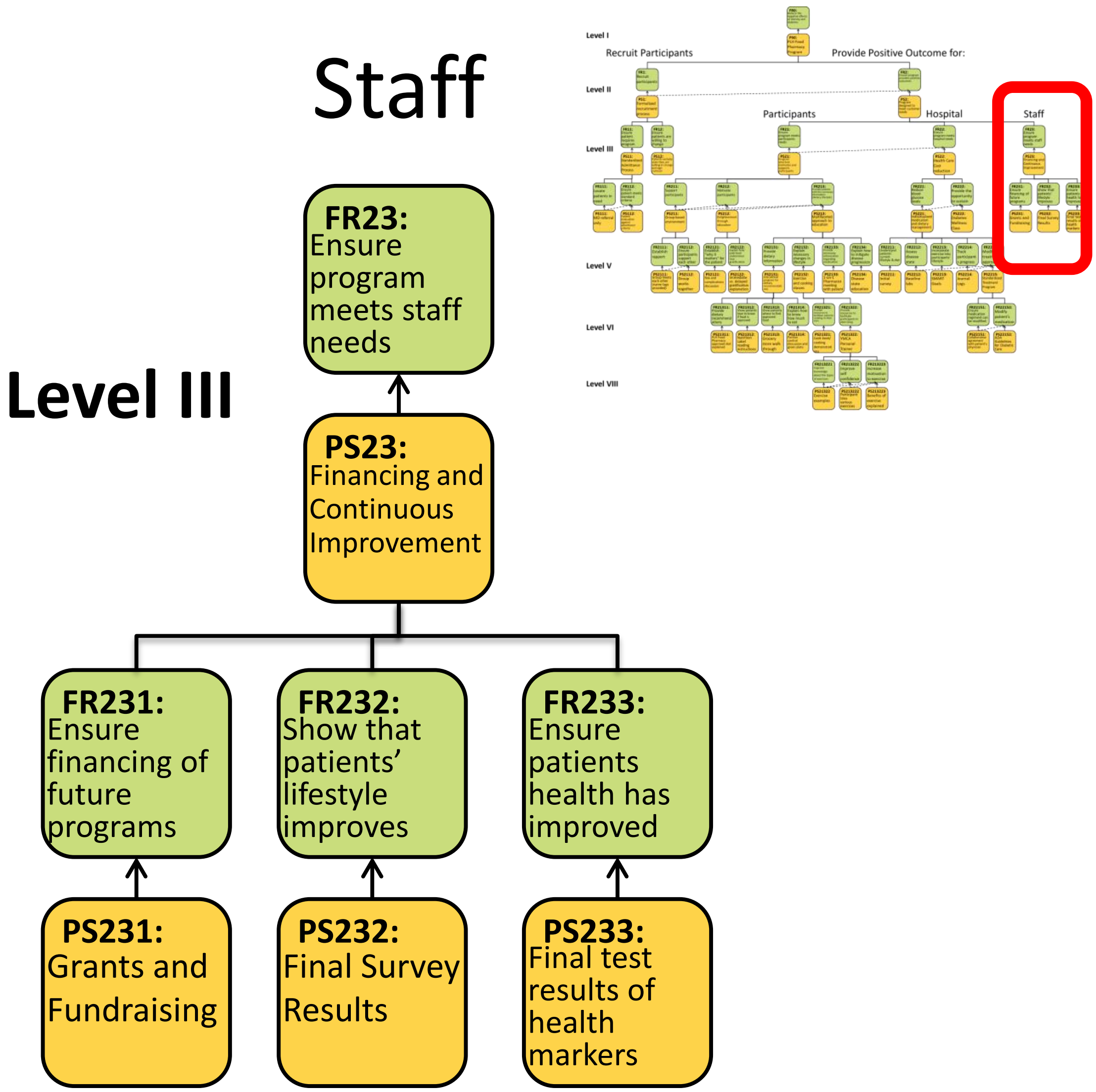

Fig. 4.15. Parkview Lagrange Food Pharmacy Map - Staff's Branch

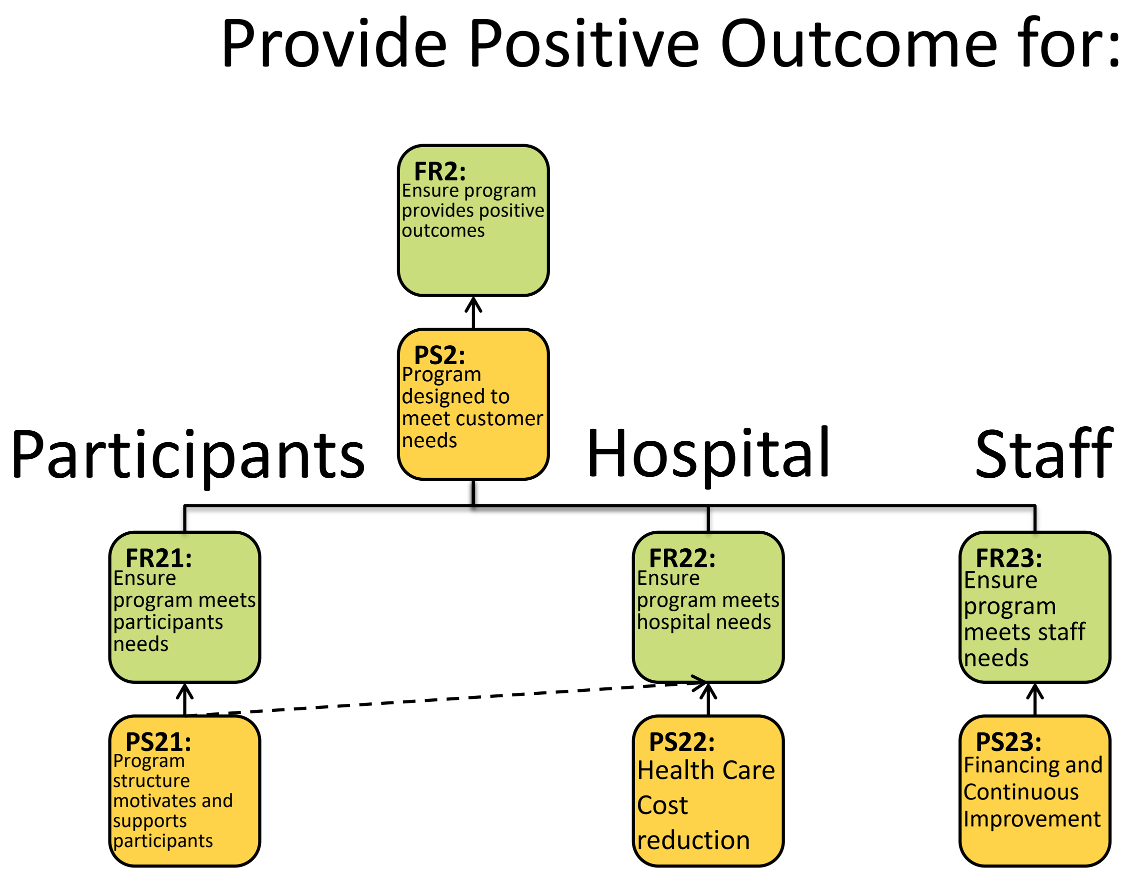

Fig. 4.16. Parkview Lagrange Food Pharmacy Map - Meeting Customer Needs

To ensure program meets participants needs, (2) FR22: To ensure program meets hospital needs, and (3) FR23: To ensure program meets staff needs. These three functions and the fact that the program has PSs in place to achieve these FRs shows that the system is designed to meet customer needs. By achieving these FRs, and the other FRs expressed in the V3 map, the Parkview Lagrange Food Pharmacy achieves its top level FR (FR0) which is to, "Reduce the negative effects of obesity and diabetes." By achieving FR0, this program is improving the health of people.

The benefit of having developed the map is that it provided clarity to the PLH team regarding the "what" (FR) and "how" (PS) behind the PSs that the PLH team have implemented. In addition, the map details the path-dependency of the program which provides insight into what the most important FRs are for the PLH Food Pharmacy Program to achieve.

CHAPTER 5. PREVENTION, EARLY DETECTION, AND REVERSAL OF TYPE-2 DIABETES USING COLLECTIVE SYSTEM DESIGN

5.1 Introduction

Chapter 5 addresses the third research objective which is to apply Collective System Design (CSD) to create the design of a system that would prevent, early detect, and reverse type-2 diabetes. This research objective provides the argument that CSD can describe new and innovative system designs that improve the health of people. Chapter 5 builds on Chapter 4. Chapter 4 describes the design of an existing health care system. Chapter 5 provides the design of a new health care system that is focused on diabetes reversal. This new system design has a foundation that is based on the extension of proven efficacy in Chapter 4.

Type-2 Diabetes is recognized as a progressive chronic disease and remains the 7th leading cause of death [57]. On a positive note, studies are showing that diet and lifestyle play a major role in the development, progression, and possible reversal/remission of the disease. The extent to what we put in our mouth and the effect it has on our body was greatly documented by Weston A. Price in his book entitled, "Nutrition and Physical Degeneration" [30]. Price documented numerous cases of isolated primitives eating their native diets of whole unprocessed food who were not experiencing any of the diseases of modern society.

These studies provide the foundation for considering that we can eat our way to good health. Will everyone be able to overcome disease with what they eat? To what extent can diet and lifestyle prevent disease at a population level? These are tough research questions that are beyond the scope of this thesis.

However, to be able to get a country, community, or even just kids to eat healthier, will require a system that meets key Functional Requirements(FRs) derived from customer needs. There is already a food supply and healthcare system that has a huge impact on our lifestyle and diet choices. How these systems came about, and how they have shaped our world is up for debate and is a popular topic among investigative journalists such as Gary Taubes [1] and Nina Teicholz [29].

5.2 Hypothesis

The hypothesis of this thesis (H_A) is that systems that meet customer needs will improve the health of people. Chapter 3 provided a system-level viewpoint of the current food supply and health care systems to make the argument that these systems do not meet customer needs and have no affect on improving the health of people. Chapter 4 provided a case study of an existing system that improves the health of people and the argument was made that this improvement was due to the system meeting its customers' needs. This Chapter builds on Chapters 3 and 4 to propose a method for designing a system to improve the health of people in relation to type-2 diabetes by meeting customer needs.

5.3 Methodology

Collective System Design(CSD) is used to codify the logical structure of a system designed to meet the needs of individuals who have or are at risk for type-2 diabetes. The logical structure is expressed as a Collective System Design Map in order to codify the thinking behind the design of a system that would prevent, early detect, and reverse of Type-2 Diabetes (see Fig. 5.1). This map will be referred to as the Diabetes Reversal System (DRS). Figure 5.1 is included to show the breath and depth of the DRS map and to provide context for where the detailed figures later on in this chapter were derived.

A key idea of CSD is that systems should be designed to not let people fail. If a system is truly designed to improve the health of people, then blame should never be placed on the person but on the system's inability to truly meet the needs of that person. This idea is crucial for the design of a wellness system because it helps leaders to design and build systems that will continually learn and improve in response to failure. Therefore, the designers of a system can consciously and quickly recognize when the system is not meeting customer needs and understand that the system must adapt accordingly.

5.4 Collective System Design Map for the Prevention, Early Detection, and Reversal of Type-2 Diabetes

The Collective System Design Map for the Prevention, Early Detection, and Reversal of Type-2 Diabetes is expressed in Fig. 5.1. A high-level view of the logical design is expressed in Fig. 5.2. As depicted in that figure, the five branches of the map include Tone Improvement, Prevention, Early Detection, Reversal, and Cost.

Most importantly, the high level Customer Need (CN0) of this system is to, "Improve the health of people." From this need, the high level Functional Requirement (FR0) is derived to be to, "Prevent, detect, and reverse type-2 diabetes." To achieve FR0, the Physical Solution (PS0) is chosen to be a, "System design for diabetes elimination." This PS is considered to be a hypothesis for how to prevent, detect, and reverse type-2 diabetes.

To further develop this system design, the system designers expand on the chosen PS, PS0, by defining the FRs that this PS must be able to achieve. These FRs are determined by understanding the needs of a patient (customer) that would use such a system. These needs, the derived FRs, and the corresponding PSs are expressed in table 5.1.

Although the specifics of each branch will be discussed in the corresponding sections, take note of the order in which the branches occur. The order is not by accident but is realized by carefully understanding the affect that each PS has on achieving all of the FRs within level II. Recall that this “order” is determined by understanding the path-dependency of the design. An acceptable design can be partially-coupled,

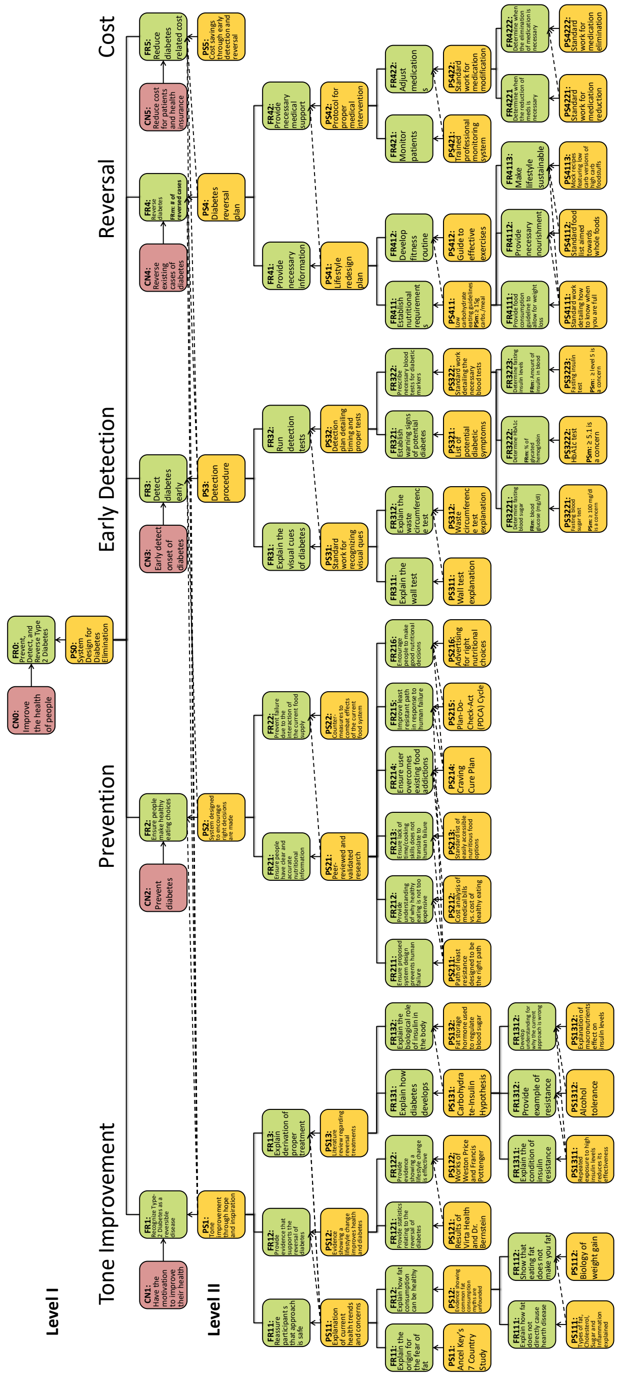

Fig. 5.1. Overview of the System Design Map for Diabetes Reversal

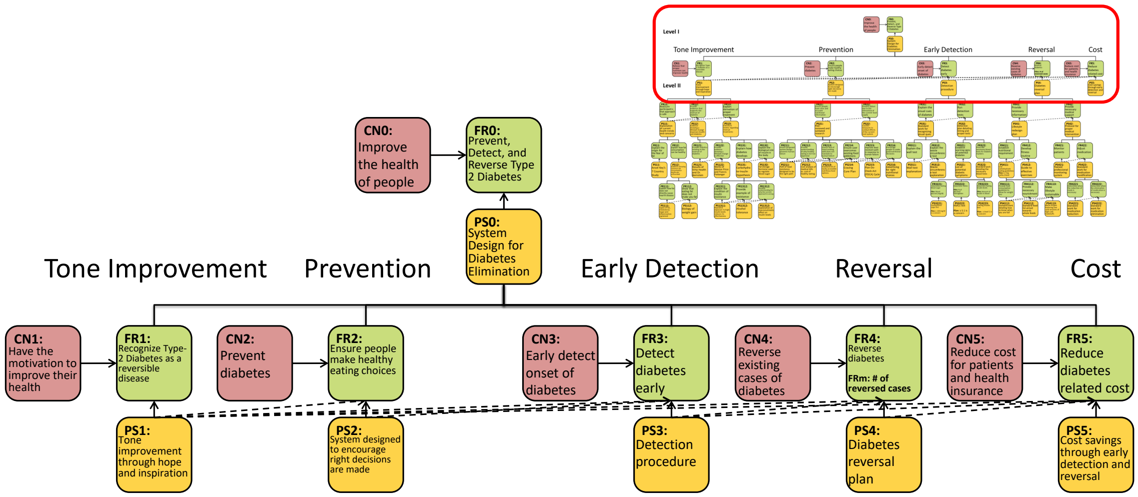

Fig. 5.2. Top Level of the Diabetes Reversal System

Table 5.1.
High-Level Design relationships for the Diabetes Reversal System

Customer Need	**Functional Requirement**	**Physical Solution**
CN1: Have the motivation to improve their health	Recognize type-2 diabetes as a reversible disease	Tone improvement through hope and inspiration
CN2: Prevent diabetes	Ensure people make healthy eating choices	System designed to encourage right decisions are made
CN3: Early detect onset of diabetes	Detect Diabetes early	Detection procedure
CN4: Reverse existing cases of diabetes	Reverse diabetes	Diabetes reversal plan
CN5: Reduce cost for patients and health insurance	Reduce diabetes related cost	Cost savings through early detection and reversal

therefore the design expressed in Figure 5.2 is acceptable because there is a single path of implementation that does not require revisiting previously implemented PSs.

The two key discoveries from understanding the path dependency of this system is that the ability to improve tone affects the achievement of all of the other design relationships. In simple terms, the DRS map expresses the key idea that if a patient does not feel inspired or does not see hope in overcoming his/her condition, the ability to prevent, early detect, reverse, and reduce cost will be negatively impacted. Secondly, cost is expressed as more of an outcome of the system. Although this result may seem intuitive, the map explains that by improving tone, preventing, detecting, and reversing diabetes, total cost will be reduced.

In the following sections each branch of the DRS will be discussed in detail. Relevant literature is cited to illustrate the importance of the FR-PS relationships expressed in the DRS map.

5.4.1 Tone Branch

The Tone Improvement branch in Figure 5.3 seeks to meet Customer Need 1 (CN1) which is to, "Believe that proper nutrition can improve health." Lifestyle and diet improvement, which is a foundation to the DRS, relies heavily on the patients' willpower or desire to change. Usually willpower, or the lack of it, is cited for why an individual cannot stick to a diet or exercise regime [58]. The idea of someone lacking will power is actually the key motivation for the tone improvement branch.

If the lack of will power is a common reason that people fail to achieve good health, then a system that improves the health of people must be able to mitigate this cause of failure. Although will power will remain central to the success a person experiences when changing their diet and lifestyle, the system can be designed to overcome the lack of will power by inspiring people to take charge of their health.

The DRS builds on the idea that if a patient does not believe in the approach being taken, he/she will lack the motivation to continue. For example, if one does

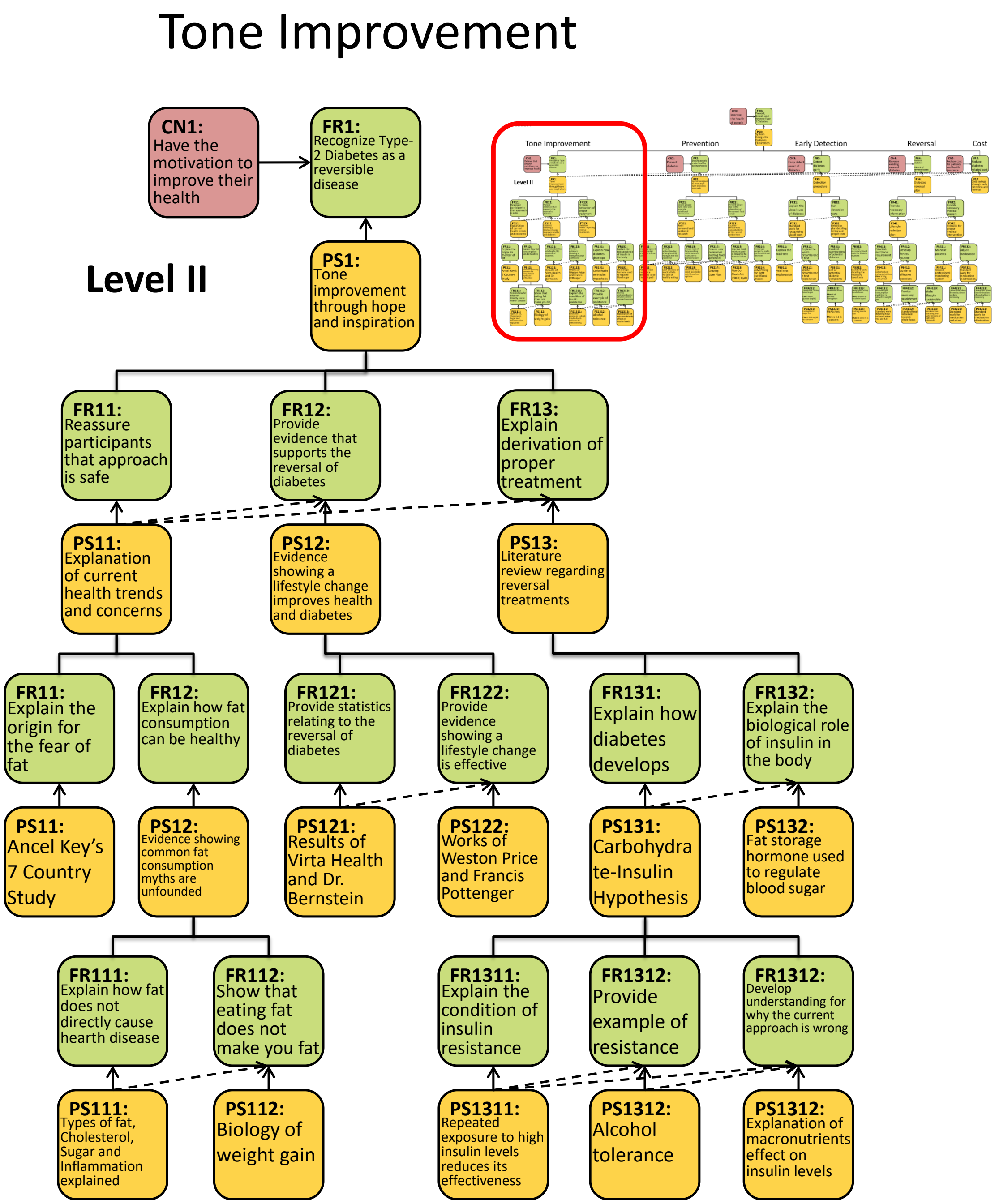

Fig. 5.3. Tone Branch of the Diabetes Reversal System

not believe an apple a day will keep the doctor away, then one will probably not consume an apple everyday. This lack of motivation comes from a psychological idea in which people do not really believe that proper nutrition can improve their health.

The DRS hypothesizes many reasons for why a person may not believe that proper nutrition can improve their health. These reasons include a lack of education, poor nutritional advice, overabundant/confusing nutritional advice, and the time delay between a good diet and positive health outcomes. These reasons were recognized through both the literature and personal experiences and functional requirements to mitigate these problems were built into the tone branch.

Therefore, the top-level functional requirement (FR1) to meet CN1 is to,"Recognize Type-2 Diabetes as a reversible disease." The proposed physical solution to achieve FR1 is, "tone improvement through hope and inspiration." This hope comes about through education that is structured to reinforce the point that proper nutrition can improve ones health. The lower levels of this branch (Fig. 5.3) depict the key understandings that the patient needs to have to ensure that they have the hope and inspiration they need to take charge of their health.

5.4.2 Prevention Branch

The Prevention branch (see Fig. 5.4) seeks to meet Customer Need 2 (CN2) which is to, "Prevent diabetes." Therefore the top-level FR (FR2) is to, "Ensure people make health eating choices." The chosen PS to achieve this FR is a, "System design to encourage the right decisions are made."

As with the Tone Improvement branch, the focus was mitigating the psychological reasons that a patient might not improve their health. One of the most notable reasons for not improving one's health is because of overindulging in processed food as a result of food cravings. Food is no longer only grown or raised and turned into a meal, but it is now highly processed to ensure maximum palatability [1, 26, 29, 37].

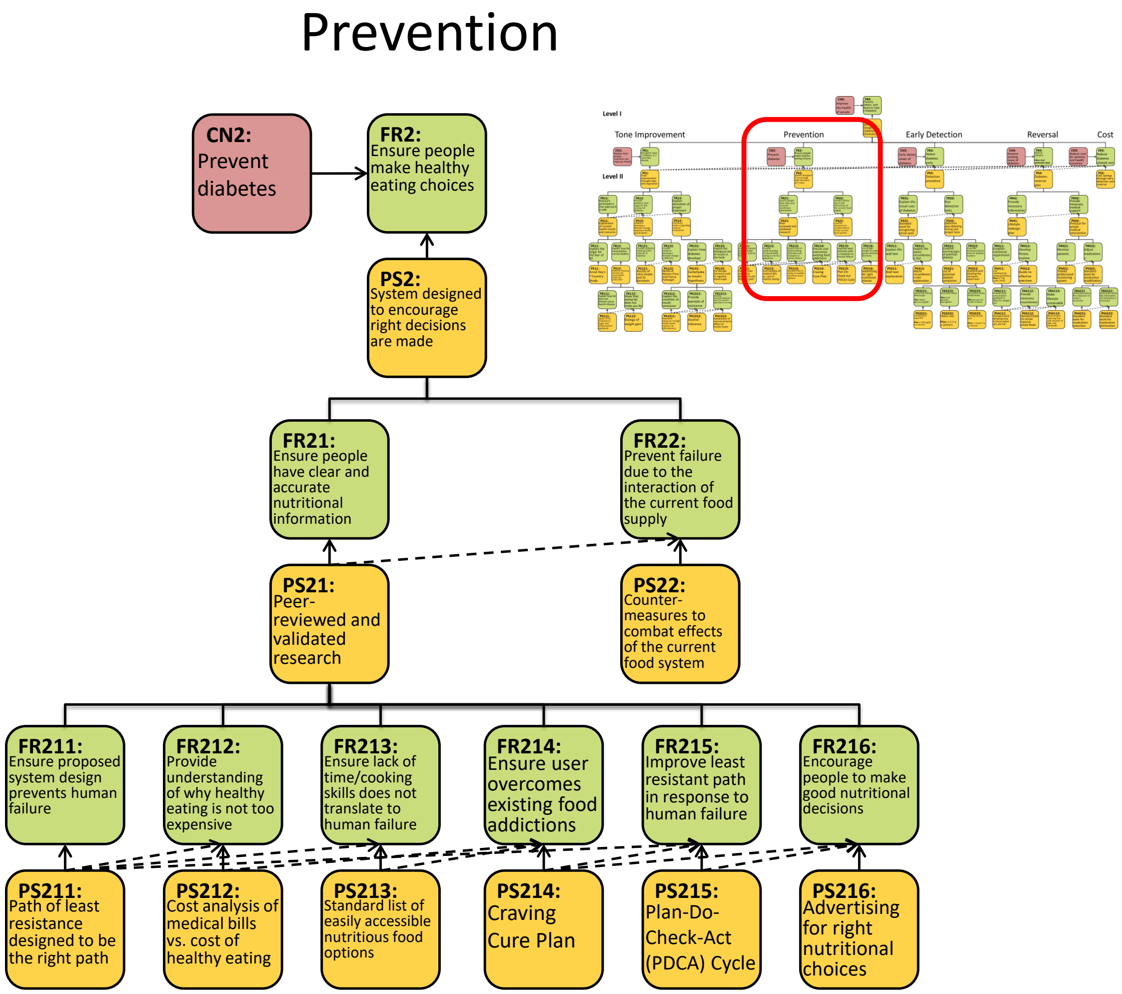

Fig. 5.4. Prevention Branch of the Diabetes Reversal System

Because food is so highly processed, it results in an overfed but undernourished society [26]. This understanding becomes crucial to designing a system that improves the health of people. An unstated customer need could simply be to, "help me overcome my existing food cravings." This need is described as unstated because sometimes people do not understand that they are addicted to food [32]. This need develops as a person tries to improve their diet and discovers the overbearing and random cravings for their favorite processed foods. These processed foods provide high calories, low long-term satisfaction and set up a vicious cycle from the highs and lows of binge eating.

By recognizing this unstated need (i.e., the ability to resist food cravings), the DRS was enhanced by adding FRs to the system design to mitigate failure due to existing food cravings. Most notably, FR211 through FR216 detail these FRS, and PS211 through PS216 are the proposed PSs to achieve those FRs. The overall idea of these FRs is to ensure that making the right (healthy) decisions is the easiest, and making the wrong (unhealthy) decisions become the hardest to do.

5.4.3 Early Detection Branch

The Early Detection branch (see Fig. 5.5) seeks to meet Customer Need 3 (CN3) which is to, "early detect onset of diabetes." Therefore the top-level FR is to, "detect diabetes early." The chosen PS to achieve this FR is a, "detection procedure." This PS may seem broad, but the FRs below it describe it in more detail.

The detection procedure is logically divided into two categories; visual tests (cues) (FR31) and blood tests (FR32). Both of these PSs are decomposed to further specify the FRs that the DRS needs to achieve to meet CN3. The visual ques of the development of type-2 diabetes are extremely important and potentially go unnoticed in the current health care system. As noted in Chapter 3, the current health care establishment system relies heavily on specific blood tests and predetermined values for making medical decisions. To contrast this form of disease recognition, the DRS

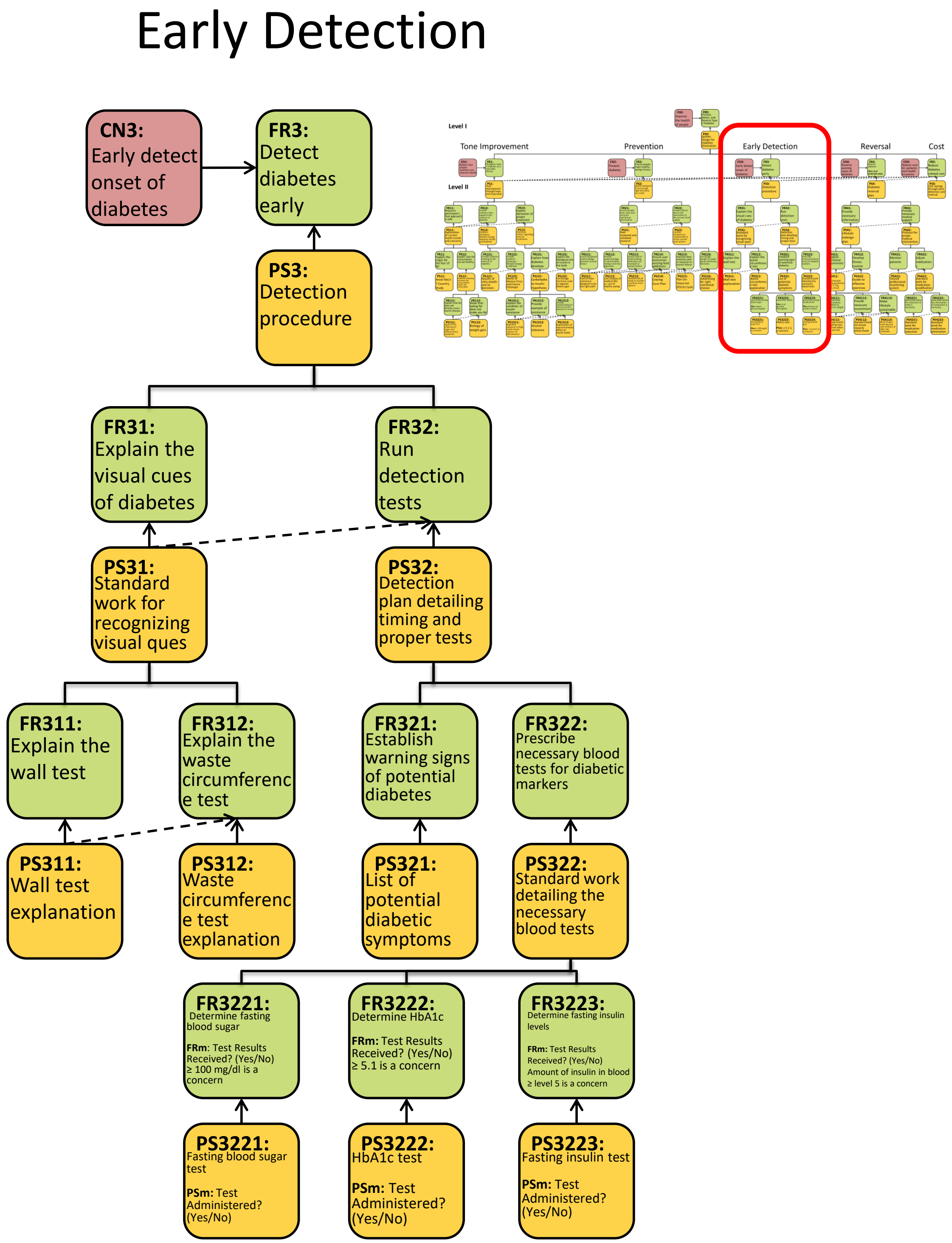

Fig. 5.5. Early Detection Branch of the Diabetes Reversal System

describes how it will rely heavily on visual cues to detect diabetes much earlier than what is experienced in the current health care system.

Also note the path-dependency of FR31-PS31 and FR32-PS32(i.e., design relationships) in Figure 5.5; the ability to notice visual cues affects the achievement of running the detection tests. In simple terms, if health care professionals are unable to pick up on the visual cues that a patient may exhibit, then the health care professionals might not run the detection tests because they do not realize they are needed.

Identifying a visual cue is the trigger for knowing when to run the detection test. It is important to understand that fat located around the abdomen should be the visual cue that the patient is at an elevated risk for type-2 diabetes or metabolic syndrome [33, 34].

Once a visual cue is noticed, then the necessary blood tests are conducted. FR3221 through FR3223 in Fig. 5.5 details these blood tests. Although there is no path-dependency expressed between these design relationships, the order is not haphazardly defined. These tests are conducted in an easiest, but least thorough to hardest, but more thorough order. Therefore, a simple fasting blood sugar test is conducted first. This test is easy for a patient as it requires the patient to fast for 12 hours, and then they will receive instant feedback regarding the test results. If the fasting blood sugar is elevated, then the patient must take immediate action to improve his or her lifestyle to prevent further progression and to begin the reversal process [36].

If the patient expresses the visual signs of diabetes or metabolic syndrome (abdominal fat) but does not have an elevated fasting blood sugar level, then the testing process should continue on to PS3221 (Fig 5.5) which is the HbA1c test. These initial outcomes could mean that the patient is still in the infancy of developing diabetes. The next test to run is a glycated hemoglobin test (HbA1c, more commonly known as A1c) which represents the average blood sugar level of the patient over the last 3 months. According to the American Diabetes Association, a normal A1c is anything below 5.7%, a prediabetic A1c is anything between 5.7% and 6.5%, and a diabetic A1c is anything over 6.5% [59].

These values can mask the idea that the development of diabetes happens over a long period of time and that when an a1c level is 5.5% then the patient is well on their way to being prediabetic. Only when the A1c value hits a threshold (either 5.7% or 6.5%) or above, will the patient then be alerted to a problem. Sudden measures will be taken based on how high of A1c levels are found. This form of diagnosis lends to the idea that diabetes is just a sudden onset; almost to the point of saying that, "you weren't diabetic at your last visit, and now you are." Obviously, this example is could be an exaggeration regarding the view patients have on the diagnosis process, but for those patients who have zero knowledge regarding the development of diabetes, this diagnosis process can be confusing. The main concern with the diagnosis process is centered around how confusing A1c levels can be for patients. The argument of the DRS is that a patient should be concerned and motivated to change in response to increasing A1c levels and not only when an individual's A1c hits a threshold.

The DRS explicitly seeks to mitigate the confusion of the diagnosis process by making it a gradual process. For example, the DRS relies first on visual cues to determine if a person is at risk or becoming at risk for diabetes. If a person exhibits the visual cues (i.e., excess accumulation of abdominal fat) then he/she will be notified. Contrary to the current health care system that waits for a blood marker threshold to be met, the DRS will continually indicate to the patient over time that his/her risk for diabetes is increasing. If a person still becomes diabetic, the actual diagnosis will not come as a surprise. In addition, the person will be able to correlate his/her weight gain and poor lifestyle habits with the gradual onset of diabetes. This understanding will help remove the time delay between poor lifestyle/eating habits and poor health outcomes.

If the A1c test does not exhibit a threshold value, then the final test to run is a fasting insulin test as indicated by PS3223 (see Fig. 5.5. This test is the most rigorous as it gets to the root cause of the problem. The concern with only relying on tests that measure blood glucose is that blood glucose levels fluctuate in response to insulin levels. Therefore, excess circulating insulin could be keeping blood glucose levels low which render the fasting blood glucose and A1c test useless. Only when an individual's own insulin is no longer able to cover up the high blood sugar levels, or when the individual's beta cells in the pancreas are no longer able to produce enough insulin, will the blood sugar levels rise.

There has been much progression to the disease by the time an individual's own insulin is no longer able to cover up the problem of excess blood glucose. This window of progression represents an opportunity to diagnose the disease much earlier. Therefore with the use a fasting insulin test, diabetes may be able to be diagnosed during this time window.

Note that measures (FRm and PSm, explained in Section 1.7 and Fig. 1.4) on the PS and FR are provided in design relationships FR3221-PS3221, FR3222-PS3222, and FR3223-PS3223 in Fig. 5.5. The FRm measures the outcome result of achieving the FR. Therefore the measure is whether or not the results of each test were received. This measure is binary as it only requires a yes/no response. In FR3221, blood glucose is what is being measured. The PSm measures whether or not the PS was actually implemented. Again, the measure here requires only a simple yes/no response.

5.4.4 Reversal Branch

The Reversal branch (see Fig. 5.6) seeks to meet Customer Need (CN4) which is to, "Reverse existing cases of diabetes." Therefore the top-level FR (FR4) is to, "Reverse diabetes." The chosen PS (PS4) to achieve FR4 is a, "Diabetes reversal plan." The functions of the diabetes reversal plan are expressed as the design is decomposed into FR41 and FR42.

The Diabetes Reversal Plan (PS4) is further decomposed into two main functions: FR41: Provide necessary information, and FR42: Provide necessary medical support. The Diabetes Reversal Plan itself is built around the literature discussed in Chapter 2

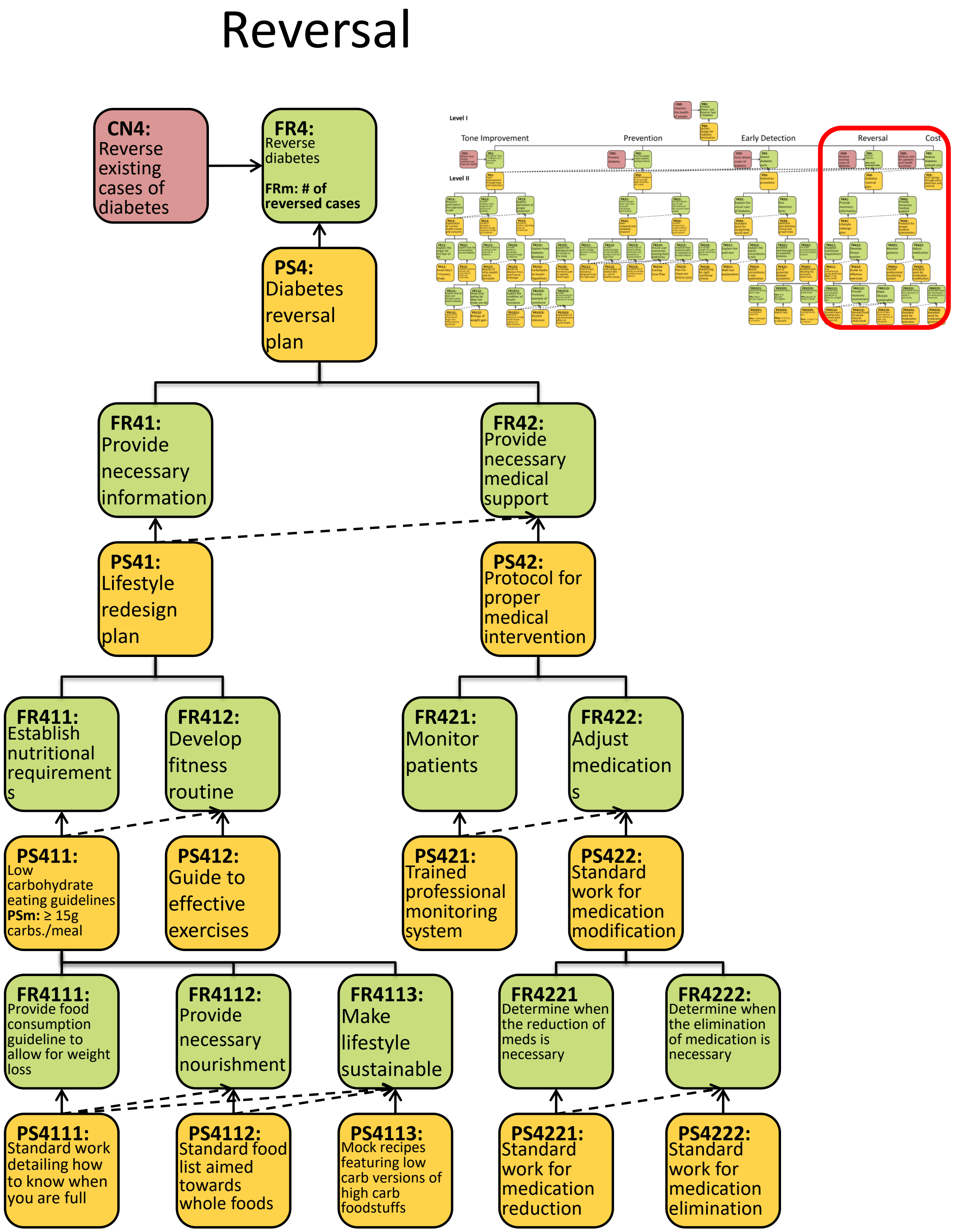

Fig. 5.6. Reversal Branch of the Diabetes Reversal System

in regards to the reversal of type-2 diabetes through the use of carbohydrate restriction to control insulin secretion [32, 35, 36].

To achieve FR41, the proposed PS is PS41: Lifestyle Redesign Plan. The FRs of this PS are decomposed further to include nutritional requirements (FR411: Establish nutritional requirements) and fitness requirements (FR412: Develop fitness routine). This part of the DRS will provide the necessary education for the patient to know what he/she can eat, and the type of exercises that should be routinely practiced. It is expected that these design relationships will need modification after this system is implemented. Some PSs may require radical change while others only small modifications/changes as the system is improved, but the map provide the "normal" (initial) state of the system. "Normal" can be updated and improved in response to abnormal conditions.

To achieve FR42: Provide necessary medical support, the proposed PS (PS42) is a protocol for proper medical intervention. This sub-branch details a process for monitoring and adjusting patients' medication. When switching to a low carbohydrate diet, blood sugar control will be improved and blood pressure will drop relatively fast [38]. If a patient is on blood sugar lowering medicines, like insulin, or on blood thinners to lower blood pressure, he/she will need to be carefully monitored as many times these drugs will cause blood sugar and blood pressure to drop too low, respectively [38]. These health concerns with the use of medication while on a low carbohydrate diet explain the need for the protocol for proper medical intervention (PS42). PS42 is further decomposed into FR421: Monitor Patients and FR422: Adjust medications.

5.4.5 Cost Branch

The Cost branch (see Fig. 5.7) seeks to meet Customer Need (CN5) which is to, "Reduce cost for patients and health insurance." Therefore the top-level FR (FR5) is to, "Reduce diabetes related cost." The chosen PS to achieve this FR is, "cost savings

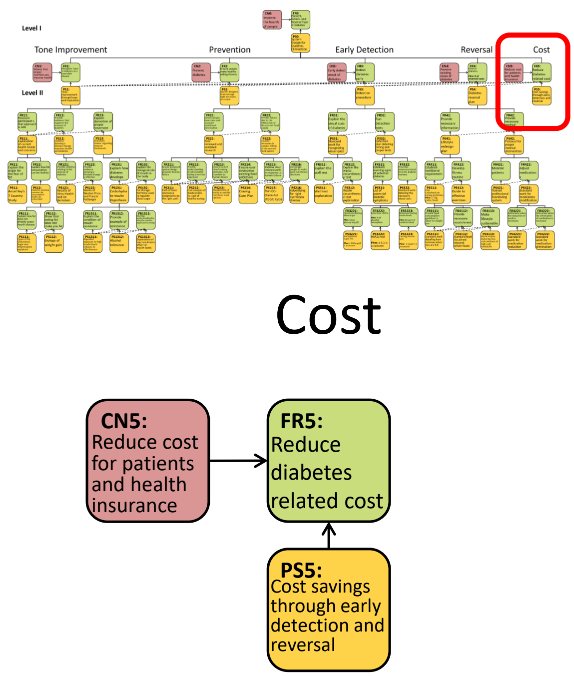

Fig. 5.7. Cost Branch of the Diabetes Reversal System

through early detection." This PS is not decomposed any further as the emphasis of this design relationship is that cost will be reduced by improving the health of people. The premise is that if people were healthier then their care would be cheaper for them and their health insurance. For example, cost can be reduced through meeting FR2: Ensure people make healthy eating choices, FR3: Detect diabetes early, and FR4: Reverse Diabetes. Therefore, reducing cost is a result of meeting customer customer needs.

5.5 Improvement of the Diabetes Reversal System

The Diabetes Reversal System presented above represents the logical design of a system that will improve the health of people with diabetes or who are at risk for developing diabetes. These functions are derived from customer needs. These needs have various origins and without a doubt many needs are not understood or recognized.

What good would a system design be if it could not adapt in response to unmet customer needs? The argument here is that such a system would not be sustainable. The system needs to have a built-in process to continually check and make modifications to the design of the system in response to unmet needs. The application of the Plan Do Check Act(PDCA) continuous improvement cycle to the DRS will accomplish this continuous improvement process.

In addition, the conscious recognition that the system will never be perfect, but can always be improved as everyone learns about new or unmet needs, is vital to ensuring the system always provides the best outcome. Patients with diabetes truly want to improve their health, and that has to be the assumption during the system design and improvement process. Therefore, when patients' health is not improved, then the system design has to be improved in response to mot meeting that customer need.

To make these improvements to the system design to meet customer needs, the PDCA continuous improvement cycle is applied to the Diabetes Reversal System. Please see Fig. 5.8 to see how the PDCA interacts with the DRS Map. This approach is adapted from Dr. Cochran's work with respect to manufacturing system design [13]. The Plan represents a physical solution, and a physical solution represents a hypothesized solution for meeting the stated requirement. The key is to remember the word "hypothesized," because this notion implies that it is ok to change the PS. It is also ok if the solution does not work the way the designer intended. Through each iteration of implementing a PS through standard work, much is learned about the appropriate PS and way to do the work, and that is ok and should be captured as an improvement in the system design map.

The *do* represents the physical implementation of the PS. Therefore, the PS will be implemented and then *check*ed to see whether the desired outcome specified by the FR is being achieved. The *act* represents the conscious recognition that change

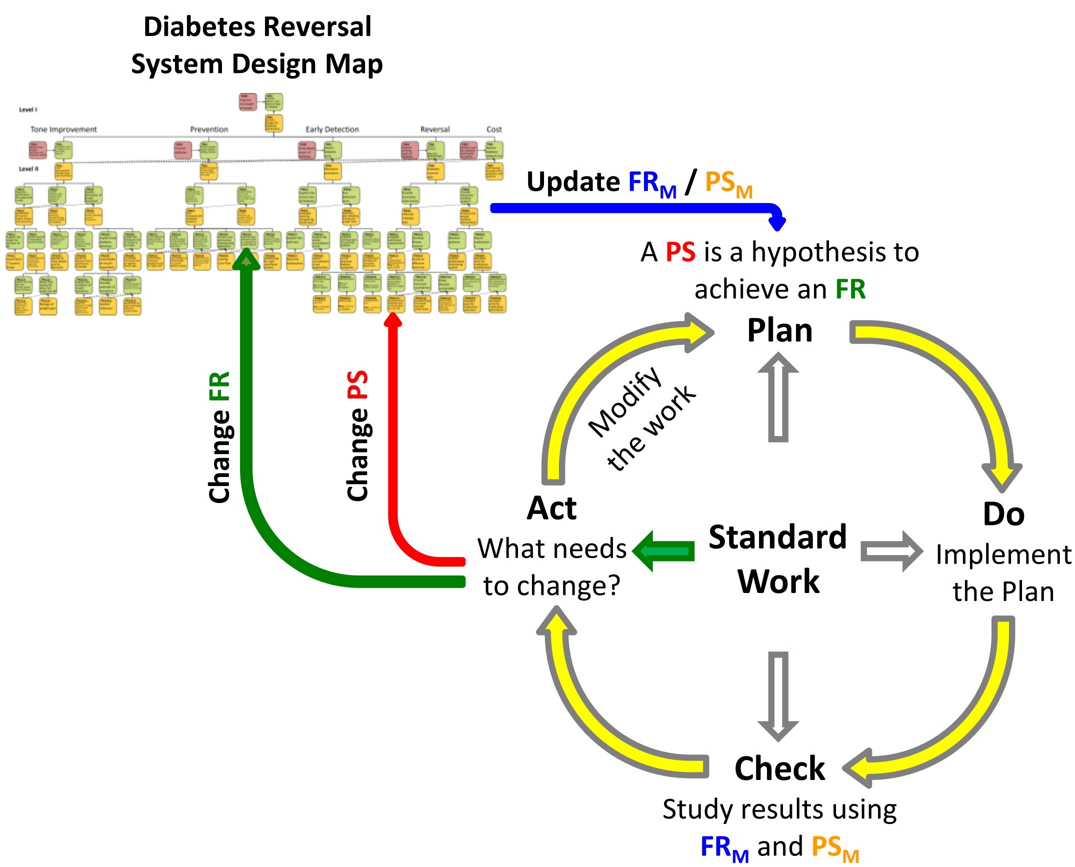

Fig. 5.8. Plan Do Check Act(PDCA) Cycle with the Diabetes Reversal System Map

is required to improve the DRS. As expressed in Fig. 5.8, there are four actions that can take place; (1) modify the work, (2) change the FR, (3) change the PS, and (4) update the measure on the FR, PS, or both.

5.6 Summary

The prevalence of type-2 diabetes around the world demands novel ways to prevent and reverse this chronic disease. The current health care system has evolved in such a way that does not meet the needs of its customer. The current system does not meet many of the requirements expressed in the DRS, such as PS14. If reversing diabetes

(FR14) was a functional requirement of the current health care system, then ongoing pharmaceutical treatments may not be required as they are now. By codifying a system for Prevention, Early Detection, and Reversal of Type-2 Diabetes, the best known methods right now can be documented and communicated. As better practices are developed and as improvements and changes are made in response to failure, the map can be improved. In addition, this product of Collective System Design provides a road map to implement a Diabetes Reversal System. Within the development of the DRS map, the path-dependency of the design is recognized. Therefore, rework is minimized since the design can be clearly communicated to everyone involved in the system design and implementation.

The development and implementation of a Diabetes Reversal System represents a benefit to all of society. The DRS expressed in this chapter does not only benefit individuals with diabetes, but it addresses the prevention and early detection aspect for those individuals who are on the path to developing the disease. The DRS has the potential to reduce health care costs related to diabetes and its complications. Most importantly, the DRS has the potential to improve the quality and quantity of life for all people.

CHAPTER 6. CONCLUSIONS AND FUTURE RESEARCH

6.1 Research Objectives

This thesis provided a systems-level viewpoint to explain why the current diabetes and obesity epidemic is due to systemic problems (Research Objective 1). This viewpoint provided the argument for applying system design methodologies to mitigate this epidemic. Next, this thesis described the logical structure of the Parkview Lagrange Food Pharmacy Program using Collective System Design (CSD)(Research Objective 2). By describing an existing health care system with CSD, the argument was made that CSD can effectively describe the design of systems that improve the health of people. Finally, the design of a new health care system was proposed (Research Objective 3). This new health care system design focused on the prevention and reversal of type-2 diabetes to show that CSD can describe new and innovative health care system designs.

6.2 Conclusion Regarding Research Hypothesis

The hypothesis of this thesis (H_A) was that systems that meet customer needs will improve the health of people. The null hypothesis (H_0) was that systems that meet customer needs do not improve the health of people. This thesis provided the logical argument for why the null hypothesis can be rejected in favor of the alternative. Due to breadth of the topic, no experimental data was taken. Rather, this thesis used both direct and participant based evidence through observation to attempt to provide the burden of proof as outlined by [60]. This burden of proof provides the argument for why the null hypothesis can be rejected in favor of the alternative.

H_0: Systems that meet customer needs do not improve the health of people.

H_A: Systems that meet customer needs will improve the health of people.

6.3 Contribution to the Existing Body of Knowledge

This thesis brings together the bodies of knowledge in systems engineering and health care. By applying a systems engineering methodology to the prevention and reversal of type-2 diabetes, this thesis provides a novel approach for chronic disease care. In addition, the application of systems engineering within health care provides a interface for collaboration to ensure the best of both fields can have a positive influence on each other. This thesis argues for the application of systems engineering to help with designing systems, organizations, and programs that will improve the health of people. Systems engineering represents a potentially valuable viewpoint for the design of health care systems due to the assertion that systemic issues that occur within a system are due to the system design and not the people involved [14, 61]

6.4 Future Research

The future research related to this thesis involves the refinement and implementation of the ideas expressed in the Diabetes Reversal System (DRS) Design Map. To complete this research, there are numerous steps that must completed.

First, the life-cycle of the Diabetes Reversal System needs to be assessed. More specifically, who will be the core customers of the system? Children would represent a core focus group for the prevention branch, but diagnosed type-2 diabetics would be the key beneficiaries of the ideas within the reversal branch.

Second, the DRS needs to be examined both from a internal (topic area experts) and external (patients) viewpoints and refined accordingly. From this knowledge, the standardized processes required to implement the DRS can be defined test whether the system meets customer needs.

Third, a pilot program needs to be developed. This pilot program could be an entirely new program offered by a hospital or other health care system. The core concepts of the DRS could be examined in existing programs that seek to improve the health people with type-2 diabetes through clinical trials.

Finally, after actual patient outcomes are assessed, the DRS Map can be validated if the health of the patients improved. The DRS map FR outcomes could then be used to understand and quantify the benefit of achieving the Functional Requirements expressed in the map. At this point, both the financial benefit and improvement in health care outcomes can be tied to meeting Functional Requirements. The consequence of this quantification is enormous, since there would be a detailed road map to allocating resources that are necessary to achieve health care system Functional Requirements.

6.5 Vision for this Research

The long-term hope and vision for this research is that the underlying ideas of system design are adopted in health care systems to mitigate the root causes of systemic problems. The main idea is that widespread unmet customer needs is a symptom of systemic problems. Therefore, the vision is that future and existing health care systems will consciously recognize when customer needs are not being met and where improvement is needed to mitigate the problem. As a result, systemic problems will not be blamed on the customer of the system, but instead the system design itself. To achieve this vision, the Tone of everyone in the health care system must be that people want to improve their health. With this new assumption, health care systems must work to remove barriers that patients have to improving their health.

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