

Sustainable Health Systems

*the role of change agents in health system
innovation*

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system innovation

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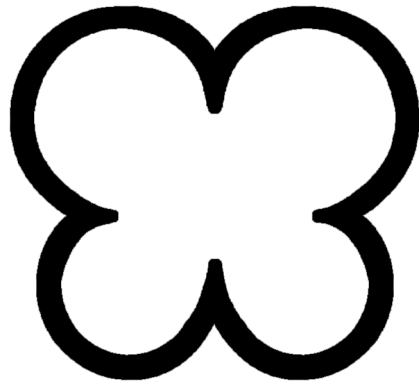
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Account

Chapters 4 to 9, and parts of chapter 2 and 10, are based on co-authored book-chapters and articles, accepted, in review or submitted to peer-reviewed journals or books. I have chosen to maintain the 'we-form' in which the articles were originally written.

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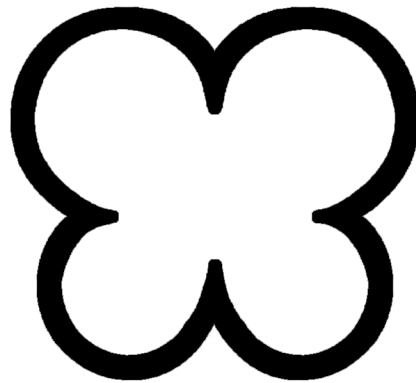
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Part 1 - Setting the Stage

The backdrop of this book can be found in the global need for more sustainable health systems and a series of failed attempts to render our health systems more responsive. The increased recognition of the complex (adaptive) nature of the health system and the difficulty in addressing its complex problems have led to a widely shared concern that we need a new approach to health system change.



1. Introduction

1.1. Aim of the study

Good health is a blessing and poor health is a problem, and in the pursuit of happiness the on-going pursuit for good health is substantial. This is not merely an individual quest; families, communities, health professionals, governments and international organizations all, for various reasons, join in this pursuit. Together they (re)produce the health system: *“All the activities whose primary purpose is to promote, restore, improve or maintain health, protect people against the impoverishing effects of illness, and ensure that those who need care are treated with dignity and respect”* (WHO, 2000, p24). In this pursuit of good health, health systems are instrumental.

Although the various health systems found around the world are quite diverse, little controversy exists about their underlying values: they should be acceptable, accessible, equitable, affordable and deliver high-quality care (based on Toebes, 1999; see chapter 4 of this book). However, there is growing concern about whether we can sustain or even attain a desirable balance between these values. In both high- and low-income countries, there are numerous dynamics that seem to jeopardize the short- and long-term sustainability of our health systems (see section 1.2).

Conventional solutions to the problems facing health systems have generally not led to the desired effects. Top-down reforms have been largely unable to curb costs simultaneously with maintaining or improving the quality of care in health systems, and have had unforeseen effects (often adverse). Bottom-up interventions have often failed to scale up and have therefore had limited system-wide effects (see also section 1.3). Scholars, policymakers and health professionals have suggested that we have been looking at the wrong problems and finding the wrong solutions: *“Without a correct diagnosis there is no cure”* (Flier, 2009, p2850). Many scholars argue that conventional approaches to health system change do not offer adequate governance and management heuristics (e.g. Flier, 2009; Plsek and Greenlagh, 2001; de Savigny and Adam, 2009; Atun et al., 2010; Broerse and Bunders, 2010).

In this search for new approaches, we move beyond the health domain and turn to a scientific field that could perhaps provide more insight into how we may go about changing our health systems. In the novel field of *system innovation* and *transition theory*, interesting governance approaches exist that deal with system change towards more sustainable systems. ‘System innovation’ (or ‘transitions’) can be described as long-term processes of fundamental change of societal (sub)systems (Rotmans, 2005; Grin et al., 2010). These processes are often initiated and ‘steered’ by *change agents*, individuals or organizations (e.g. from civil society, the market

and the government¹) that have a strong sense of the necessity to approach societal needs from a different perspective. At the start of this PhD study in 2008, system innovation management had not explicitly been used in the governance of health systems change. In this thesis this is the specific focus.

From the perspective of the need for system change towards sustainable health systems and in the recognition of failing attempts, I explore the significance of the field of system innovation, to acquire insights into the role of change agents in system innovation. Specifically, the aim of this study *is to gain insight into the way change agents may facilitate health system innovation towards more sustainable health systems, in order to contribute to the improvement of approaches for progressing towards such systems*. My theoretical explorations (chapter 2) and the case studies (chapters 4 to 9) provide insights that may guide innovative actors in the health system in their endeavours towards more sustainable health systems. In the next section I will highlight the background to the aim of this study.

1.2. The problems facing our health system

Although, after decades of health system reform many may have grown rather tired of the next 'call for change', there still is a broadly acknowledged societal feeling of discontent with the current health systems, and change is considered urgent (see e.g. Roberts, 2004; WHO, 2007; Broerse and Bunders, 2010a). Below we briefly indicate why change is deemed necessary.

Our complex society is facing problems for which there are no ready-made solutions (Dirven et al., 2002; Rotmans et al., 2005). This is also true for our health system. In high- and low-income countries alike, the sustainability of health systems is at risk. In both the short and long-term, there are numerous dynamics relating to accessibility, acceptability, affordability and quality threatening our health systems (see e.g. Broerse and Bunders, 2010a). In high-income countries, these problems mainly concern the ever-rising costs of health care which have long outpaced economic growth (OECD, 2011). The increasing costs are mainly driven by (i) the rising cost of technology, (ii) the ageing population, (iii) the increasing numbers of chronically ill patients, and (iv) the growing demand for care by the population (RIVM, 2006 and 2007; OECD, 2009; Schuitmaker, 2010). The increasing costs for care were acceptable when the return on investment – *more health* – was substantial. However, there appears to be a diminishing return on investment, e.g. new, high-cost technologies do not always lead to significant improvements in health outcomes (Morgan et al., 2005; Fisher et al., 2003a and 2003b). In addition, the use of evidence-based medicine (EBM) seems to turn into a counterproductive

¹ In this thesis we have an explicit focus on non-governmental organizations and governments in processes of system innovation (see section 2.3).

dogma;² it overemphasizes effects on populations, is often used as a tool for *cost-cutters*, while neglecting patient-specific needs and strengths of care providers in their own context (Schuitmaker, 2010).

Health systems in low- and middle-income countries face different problems as they generally fall short of providing universal, equitable, appropriate and high-quality services. These countries increasingly face a so-called double burden of disease where both communicable (infectious) and non-communicable (chronic) diseases are affecting the health of many who do not have access to adequate care services. Also, people living with mental or physical disabilities, particularly in low- and middle-income countries do not generally have sufficient access to healthcare. Approximately 20% of the global burden of disease is attributed to (physical) disabilities, leading to poor educational attainment and social exclusion (WHO, 2011). These problems have gained increasing attention as 'weak' health systems have been labelled one of the main causes for not achieving the health-specific Millennium Development Goals³ (WHO, 2007). The characteristics of these weak health systems are lack of skilled personnel, poor facilities, inability to mobilize resources, and weak governance structures.

Problems are also manifested in sub-systems of the health system. For example, irrational drug use is a long-standing problem in many countries, leading to suboptimal therapeutic value, adverse effects and even death, and a waste of scarce resources. WHO (2003) indicates that approximately 50% of drugs are prescribed irrationally. Similarly, there are avoidable mistakes in healthcare. In the USA, approximately 98,000 people die each year due to avoidable fatal mistakes in hospitals (Kohn et al., 2000), making it a common cause of death. In the Netherlands, there were an estimated 3,000 avoidable fatal mistakes in 2005 (VWS, 2005), almost four times as high as deaths in traffic (817 in 2005). Despite various interventions, these figures are not improving.

1.3. Failed change

Individuals, local actors, national and international governments alike have not been idle in responding to health system problems. Above we highlighted the inability of most of our attempts to address the many complex problems facing health systems; in this section we will discuss in greater depth the disappointing outcomes of both top-down reforms and bottom-up interventions in health systems.

² There are many benefits in the use of EBM, but we stress it is only one method to deal with diagnosis and treatment and should not be seen as a panacea.

³ MDG 4 concerns reducing child mortality, MDG 5 concerns improving maternal health, and MDG 6 concerns combating HIV/AIDS, malaria and other diseases.

Perhaps the most significant report that endorsed health system reform was that of the World Bank (1993), entitled 'Investment in Health'. This report marked the start of a wave of 'privatization' reforms of health systems. In this report, the major problems of health systems globally were diagnosed as misallocation of resources, inequitable access to health care, inefficiency of service delivery, and exploding costs. The World Bank advocated financial mechanisms focusing on optimization of practices to deal with these problems, involving more emphasis on private providers, cost efficiency, increased competition and decentralization. As an example, the past 3 decades EU countries mainly adopted the following strategies to deal with these problems (van Kemenade, 2007; Hacker, 2004): containing costs, improving quality of care and administrative efficiency, shifting costs to patients, and introducing market-related concepts taken from the private sector.

Evidence of the effects of such reforms is scarce due to poor monitoring and evaluation, and the high number of variables makes causality difficult to determine. However, evidence is growing that neo-liberal health system reforms have not had the intended effects. Generally, costs have not been curbed, quality has not improved, the poor are not benefiting, and reforms have had unintended effects, such as reduced equity (see Gwatkin, 2001; Whitehead, 2001; Stambolic, 2003; Pollock, 2005; WHO, 2007; de Savingy and Adam, 2009; Mills, 2012). An influential study by Homedes and Ugalde (2005, p92) reviewed the reforms in Latin American countries, demonstrating very few positive effects and attributing this to the neo-liberal character of reforms:

"Our research confirms that Latin American countries, 10 and 20 years after the implementation of neoliberal reforms, are spending more resources in health care without corresponding improvements in efficiency; high and in some countries higher percentages of the population continue without access to care; in some regions there are higher inequities; and often there is administrative uncertainty. The financial sustainability of the sector has been placed into question because of increased health expenditures: today there are more administrators, higher salaries, higher expenditures for medicines, and more foreign debt as a result of the WB and IDB reform loans."

Worldwide, similar studies have revealed that such reforms have increased inequities in access to care and reduced quality (Fins, 2007; Janes et al., 2006; Navarro, 2007; Danis et al., 2008; Unger et al., 2008; Muntaner et al., 2006) with the wealthy having been able to visit doctors more frequently than lower-income groups (Dahlgren, 2008). Also, it cannot be claimed that the neo-liberal policies have resulted in increased efficiency of health systems (Janes et al., 2006; Unger et al., 2008). Various studies indicate that these reforms have undermined values of solidarity, fairness and equity in health systems (Gwatkin, 2001; Janes et al., 2006; Martinez and Garcis, 2001). Furthermore, the reforms in eastern European countries demonstrate that reform processes have not been evidence-based and have often overlooked the needs of the population (Rechel and McKee, 2009).

Partly as a reaction to the disappointing results of top-down reforms (WHO, 2007; de Savingy and Adam, 2009), countless experimental projects have been implemented to address problems in health systems using more bottom-up approaches. According to Travis et al. (2004), efforts to reduce the burden of specific diseases – most notably those targeted by the Millennium Development Goals – have led many stakeholders to focus on priority-disease interventions, with the underlying assumption that these interventions will automatically diffuse or scale up when they are proven to be beneficial and will strengthen the system as a whole. It is, however, increasingly acknowledged that weak health systems may be compromised by the introduction of disease-specific interventions because they draw resources away from other parts of the health system (Travis et al., 2004; Simmons et al., 2007; WHO, 2007; Atun et al., 2010). According to several scholars, spontaneous and complete diffusion, or scale up, of health interventions is rare; many remain marginal or fold back after financial support ceases (e.g. Simmons, 2007; de Savingy and Adam, 2009). In both high-income and low-income countries, these bottom-up solutions often fail to scale up to the system level (Atun et al., 2010; Simmons et al., 2007).

1.4. Persistent problems and the need for a different approach

Why is it not possible to solve the problems in our health systems or to meet the commitments of *Health for All* (e.g. Alma Atta Declaration, 1978; MDG, 2000)? The paradigm of complex adaptive systems in health systems research, and other fields, might offer an explanation (see section 2.1). Plsek and Greenlagh (2001) argue, in a series of articles, that we tend to try to solve large problems in complex systems by breaking them down into smaller parts and then try to solve these by processes of rational deduction. *'But the machine metaphor lets us down badly when no part of the equation is constant, independent, or predictable'* (Plsek and Greenlagh, 2001: p625). They claim that health systems are, in fact, complex adaptive systems. This implies that the problems in our health systems are complex and need to be conceptualized differently. In particular, long-standing, complicated problems require frame reflection, a new way of thinking about practices and system structures.

The problems that we described earlier are indeed complex. These problems affect many different stakeholders, who are often also part of the problems themselves. For example, patients are affected by high costs but also demand expensive drugs. The multitude of stakeholders leads to almost as many different problem conceptualizations. At the same time, stakeholders often only feel to a certain degree responsible for a particular problem, partly because they are not affected by all its aspects and partly because the overview is difficult to conceive. In the policy science literature, these problems are defined as 'wicked problems' (Rittel and Webber, 1973) or 'unstructured problems' (Hisschemöller and Hoppe, 1996), problems for which there is no agreement on facts and values. In addition, the failed attempts

to solve these problems also makes them 'enduring' (Rotmans, 2000; Loorbach, 2007; Schuitmaker, 2010). This may be due to the fact that the system itself is the *cause of* the problem (Loorbach, 2007; Schuitmaker, 2010).

With such complex problems in complex societies, we can only expect that the governance will be complex as well (Loorbach, 2007). For these so-called 'persistent' problems, command-and-control management is considered counterproductive. Instead, transdisciplinary and deliberative governance approaches are required. These approaches are grouped under the heading of 'system innovation'. In this thesis, we explore this novel field with a specific focus on the contribution of the role of change agents in system innovation.

In the following chapter we further describe the theoretical background of this research.

2. Theoretical Background: health systems and system innovation

In this chapter, insights from health systems research, and system innovation and transition theory (hereafter more briefly referred to as system innovation theory) will be used to build a conceptual framework to analyze health system change and the way change agents can contribute to this. I will discuss developments in health system research and argue that there are few approaches to investigate and manage radical system change in this field. To remedy this, we will consider approaches from the fields of system innovation theory which have generally been applied in other sectors (e.g. the energy, mobility and agricultural sector). This chapter ends with a conceptual framework for the research design.

2.1. Complex adaptive health systems

The aim of this section is to define health systems in order to aid our understanding of the systemic features that need to change. We initially draw on health systems research and then move on to system innovation research.

Health systems: towards complex adaptive systems thinking

Like other socio-economic systems, the health system has evolved in a unique historical process, influenced by many societal dynamics, according to many, as a construct to fulfil a societal need, *health* (see e.g. Hsiao, 2003, p1). The myriad of actors in health systems (e.g. the ministry of health, public and private, western and traditional providers, financiers, the population, patients, pharmaceutical industries), operating in a diversity of contexts (e.g. urban or rural), has led to a seemingly endless number of national and regional, organizational configurations of health systems, making them difficult to describe. Or, as Hsiao (2003, p1) puts it, '*comparing health systems is like comparing apples and oranges*'. Many scholars have however, attempted to conceptualize and define health systems (box 2.1). Most of these conceptualizations originate from the perspective of describing or improving health system performance (Atun et al., 2008 and 2010) and thus have the, normative, perspective of improving health systems. These are of explicit interest in this study and we briefly highlight some of them below.

Early definitions of health systems were often descriptive, emphasizing economic and financial aspects and largely neglecting how health systems produce outcomes and why they do so (see e.g. Evans, 1981; Hurst, 1991; Roemer, 1991 and 1993; Cassels, 1995). As an example, a popular definition has been that of Roemer (1991, p2) who conceptualizes health systems as: *'A combination of resources, organization, financing and management that culminate in the delivery of health services to the population'*. In his conceptualization, Roemer primarily looked at the capacity of systems (e.g. hospital beds) and activities of its actors. National health systems are categorized according to their foundations, for example, the dominant payment model, dominant underlying philosophy (socialist/capitalist) or the level of Gross Domestic Product. However, these conceptualizations overlook the health system's performance as a result of the interactions between elements, such as how do finance mechanisms relate to accessibility and mortality (Mills and Ranson, 2012, p617)? These categorizations are even less applicable to the fragmented health systems of many low- and middle-income countries where there may be different arrangements for groups and regions (McPake and MacRay, 1997, Mills and Ranson, 2012).

Box 2.1: Health systems frameworks and system innovation frameworks

Health systems frameworks

- Actors framework (Evans, 1981)
- Fund flows and payment framework (Hurst, 1991)
- National health system of the world (Roemer, 1993)
- Demand-supply framework (Cassels, 1995)
- Performance framework (WHO, 2000) (see also Murray and Frenk, 2008)
- Control knobs framework (Hsiao, 2003)
- Reforms framework (Roberts et al., 2004)
- Public management framework (Khaleghian, 2004)
- Capacity framework (Mills et al., 2006)
- Building blocks framework (WHO, 2007)
- Essential public health functions framework (PAHO and WHO, 2008)
- Systems framework (Atun, 2008)
- Systems thinking framework (de Savingy and Adam, 2009)

System innovation frameworks for health systems research

- Multi-level perspective (Rip and Kemp, 1998; Geels, 2002)
- Multi-phase concept (Rotmans, 2000)
- Constellation perspective (de Haan, 2010)

Mills (2000, p1-24) uses a more functional approach to describe health systems. For example, Mills identified four functions and associated actor groups: regulation, financing, resource allocation and service provision. Although such approaches to health systems are useful to understand the health systems functions, one criticism is that they do not link these functions

to particular goals in the health system such as financial risk protection, responsiveness and good health (see e.g. Hsiao, 2003). To address this criticism the WHO (2000) and Murray and Frenk (2008) link the functions of health systems (stewardship, financing, resource generation and delivery) explicitly to their intrinsic goals: health and the (equitable) distribution of health, responsiveness and its distribution, and the fair financial contribution to the system. From WHO (2000, p24), we take the following definition of health systems:

“All the activities whose primary purpose is to promote, restore, improve or maintain health, protect people against the impoverishing effects of illness, and ensure that those who need care are treated with dignity and respect.”

From 2000 onwards, however, an increasing number of health systems researchers are breaking with such functionalistic and deterministic approaches to get a better grip on performance and problems in health systems. Researchers (e.g. Plsek and Greenlagh, 2001; de Savigny and Adam, 2009; Atun et al., 2010) increasingly argue that health systems have many interconnected, interdependent elements that are constantly creating feedback loops which affect the functioning of the system. The system has and creates feedback loops of information flows that constantly moderate the behaviour of actors in the system. As a result, the outcomes of actions in the system, and the (negative) side effects, cannot always be predicted. Atun et al. (2010) use these insights to explain the failure to implement interventions system-wide which have previously been proven successful in local settings.

As a result of these observations, health system researchers increasingly turn to complex adaptive systems theory (see section below on complex adaptive systems) to explain the functioning of health systems (e.g. Plsek and Greenlagh, 2001; Travis et al., 2004; Simmons et al., 2007; WHO, 2007; de Savigny & Adam, 2009; WHO, 2010). The WHO and the Alliance for Health Systems and Policy Research have produced two influential reports in response to this trend (WHO, 2007; de Savigny and Adam, 2009). The first one (Everybody’s Business, Strengthening Health Systems to Improve Health Outcomes, 2007) presents WHO’s new framework for action (see figure 2.1). This framework can be seen as another in a series of health systems frameworks, albeit this time with an explicit focus on how the building blocks contribute through unpredictable and interrelated pathways to the goals of the health system. The building blocks cannot be seen separately from each other; service delivery, health workforce, information, medical products, vaccines & technologies, financing and leadership/governance in health systems are all interconnected and interdependent. The health system goals are similar to those previously listed by WHO (2000, p23-24) but now with the explicit emphasis of improving efficiency through constant feedback loops.

This framework has been further positioned as a systems framework in a report on systems thinking for health systems research (de Savigny and Adam, 2009). This report emphasizes that systems are always ‘nested’. A system cannot be viewed as consisting of isolated parts; it

involves the interaction and relationships of these parts that make up the system. For example, the pharmaceutical care system is nested in the health system and the health system is nested in the national welfare system. De Savigny and Adam (2009, p19) reflect on the WHO's framework for action by stating that health systems:

"...are non-linear, unpredictable and resistant to change, with seemingly obvious solutions sometimes worsening a problem. Systems are dynamic architectures of interactions and synergies. WHO's framework of health system building blocks effectively describes six sub-systems of an overall health system architecture. Anticipating how an intervention might flow through, react with, and impinge on these sub-systems is crucial and forms the opportunity to apply systems thinking in a constructive way."

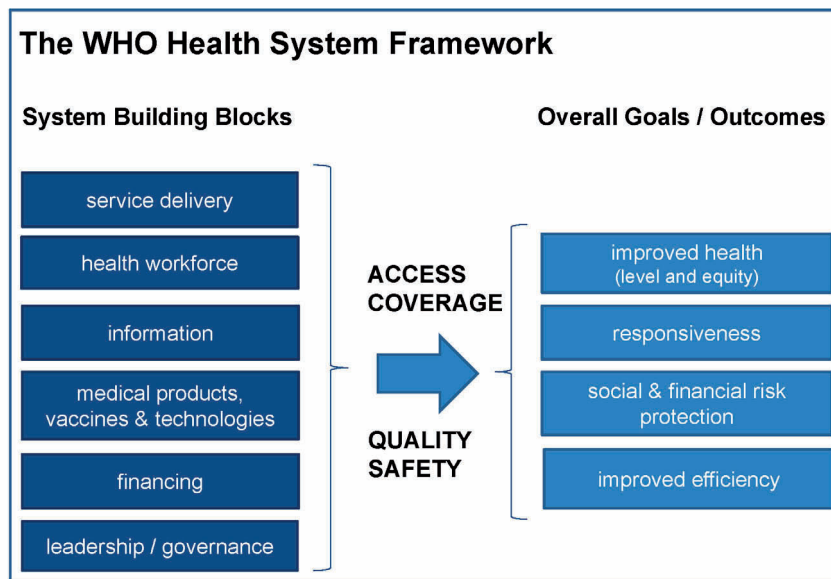


Figure 2.1: The building blocks for health systems: aims and attributes (WHO, 2007)

Complex systems and complex adaptive systems

We acknowledge the interesting work done by health systems researchers to incorporate insights from complex adaptive systems theory into health systems research (see e.g. de Savigny and Adam, 2009; Plesk and Greenlough, 2001). But it is still rather limited and not well elaborated. Below we use insights of health systems research on complex adaptive systems and complement this with advanced insights from system innovation theory, to progress in our understanding of health systems as complex adaptive systems.

Complex adaptive systems theory has its roots in the general systems theory of von Bertalanffy (1968) who first linked the complexity of biological systems to social systems, and stated that social systems consist of multiple, interrelated components (actors and structures) that constantly influence each other, without having clear boundaries. Many researchers have elaborated on this concept and, gradually, it has evolved into what is now called the complex adaptive systems theory (e.g. Holland, 1995; Kaufmann, 1995). Complex adaptive systems theory has been used in a variety of scientific disciplines such as biology (Kauffman, 1995), economics (Arthur et al., 1997), ecology (Gunderson, 2002) and public administration (Kickert, 1991). Under the heading of transition theory, it has been used to address problems in the field of energy, agriculture and water management (Kemp et al., 2005; Loorbach, 2007). Below we highlight some important features of complex adaptive systems in relation to health systems.

Complex adaptive systems theory considers societal systems metaphorically as biological organisms, extrapolating evolution theory to systems behaviour (Plsek and Greenlagh, 2001). A biological organism is the prime example of a complex adaptive systems in that it constantly changes its properties in response to, sometimes even in anticipation of, changes in its environment. At the same time, the system is resistant to substantial changes and is bounded by its own structure and rationality.

Complex adaptive systems are a collection of agents (semi-autonomous) who constantly act and react upon one another. In this way, they constantly modify the environment and influence the actions of other agents. Agents are not limited to human actors, but can be bacteria, organizations, or even nations (Plsek and Greenlagh, 2001). Health system agents can be pathogens, organs, doctors, patients, pharmaceutical companies, or international organizations. Complex adaptive systems are nested and open systems. They have fuzzy boundaries; the agents in the system are constantly in interaction with their environments, and they can be part of multiple systems at the same time (Plsek and Greenlagh, 2001). As a result, there is a constant exchange of information between systems (and nested systems), increasing their complexity and creating feedback loops (e.g. de Savigny, 2009).

The decisions of all actors contribute to the behaviour of the system. However, agents in the system do not necessarily act autonomously. Generally, they respond to their environment by using a set of (collective) rules (interpretive frames, mental models, behaviour) that are embedded in the system. According to Plsek and Greenlagh (2001, p625), *'agents respond to their environment by using internalised rule sets that drive action'*. The shared rules provide meaning to the functioning of the system. But, at the same time, the rules restrict the behaviour of the agents, as agents in general are unlikely to act in conflict with them; this makes a complex adaptive systems rather resistant to substantial changes. The rules are largely the product of past interactions and partly determine future actions of agents which means that history cannot be ignored when studying complex adaptive systems (e.g. Geels and Schot, 2007, p402-403). For example, dominant interpretive frames in our health systems (e.g.

solidarity) and associated structures (e.g. social insurances) have been established over time and give meaning to the functioning of actors in the system (paying premiums).

Not only agents are adaptive, but also the system itself. This is a clear link with biological evolution theory in the sense that systems and agents adapt to their environments. However, the adaptation of systems is not necessarily for 'the better'; this largely depends on whose viewpoint is being considered. Generally, the system is not amenable to substantial change, as most agents are geared towards a common 'attractor' and are resilient to changes that are not in tune with the attractor (Loorbach, 2007, p57-58). An attractor can be defined as the set of underlying values and assumptions that gives direction and sets limits to the adaptability of the system. In health systems, the attractor can be the values we want to uphold in our system.

Change in complex adaptive systems towards an attractor occurs through three broad mechanisms: *co-evolution*, *emergence* and *self-organization* (see e.g. Loorbach, 2007, p55). Co-evolution implies that the agents, (sub)systems and the larger context always co-evolve together and constantly adapt to one another. Thus, as a researcher, we can only understand the agents and structures in the system with reference to other agents and systems. Emergence is the result of the multitude of interactions in the system from which novel patterns 'emerge', both novel behaviours and novel structures. The outcome of a complex adaptive system is thus more than the sum of its parts. Self-organization refers to the self-ordering capacity of complex adaptive systems. This implies that, without the control of any agent, order can spontaneously occur. Emergence and self-organization are closely related and are both strengthened by positive feedback loops in the system. Rotmans and Loorbach (2010, p120) state that:

'In complex, adaptive systems, emergence and self organization occur together . . . emergent properties are the result of a self-organising process . . . and emergence results in self organization.'

From the perspective of system change, this implies that new ways of dealing with problems in systems can emerge and form a new complex 'order' without 'steering'. These processes can co-evolve with, and be strengthened by other processes.

Culture, Structure, Practice; the reproduction of systems and the constellation perspective

From the perspective of complex adaptive systems theory, the WHO's building block framework (see fig 2.1) appears somewhat deterministic. This framework puts the functions in the spotlight, while the behaviour of complex adaptive systems revolves around actors and their collective rules, and how these shape the functions and goals. Below, building on the constellation perspective of the Haan (2010) and van Raak (2010), we further conceptualize societal systems.

In system innovation theory, it is argued that the system can best be described by its dominant structures (organizing), cultures (thinking) and practices (doing) (e.g. de Haan, 2010, p25). De Haan (2010, p25) and van Raak (2010, p53) argue that these structures, cultures and practices are both the medium and outcome of actions of actors. Here they follow Giddens (1984, p25) who states that *'structural properties in systems are both the medium and outcome of the practices they recursively organize'* and *'structure is not to be equated with constraint, it is always constraining and enabling'*⁴. This implies that agents 'produce' structure, draw on structure to act and reproduce it (enabling), albeit always in a slightly different way. At the same time, agents may find it difficult to perform behaviour that is not in tune with the structure of the system (constraining). This renders the system resistant to change.

According to de Haan (2010, p25) and van Raak (2010, p53), culture and structure (structuring elements) are shaped by a historical sequence of practices of actors (agency) but also give structure to the practices of actors. The embedded cultures and structures enable the practices of actors to fulfil a specific societal need and give meaning to this; the fulfilling of which is called its 'societal functioning' (de Haan and Rotmans, 2010) (see figure 2.2). To define these properties, we use van Raak (2010, p54-55):

- *'Practice is defined as the actual actions (operations) undertaken within the system, which are relevant for the functioning of the constellation'* (van Raak, 2010, p54). These can be for example the interactions between patients and doctors, or between health insurance companies and policy makers. There are countless of such interactions in a (sub)system, so, what is sought are those actions that characterise the (sub)system. *'Practices are the result of the behaviour of actors, but this behaviour is also influenced or even constrained by the structure and culture. The structure and culture in turn are influenced by practices'* (van Raak, 2010, p54).
- *Culture* is defined as the set of shared values, perceptions, and interpretative frames –of the involved actors. *'These elements can contain notions about structure and practice or about the actors and functioning of the system, for example an opinion about a law is not the same as a law'* (van Raak, 2010, p55).
- *'Structure is defined as the physical, economic, legal, financial, organizational, and power structures that facilitate and/or constrain the behaviour of involved actors with regard to the system'* (van Raak, 2010, p55). Although, actors may have to organize matters differently, and can aim to change the structure, in mostly structures are coercive for actors. *'For instance, if an actor performs a novel treatment that does not*

⁴ The reasoning that structure is both medium and outcome of agency, and enabling and constraining, is what Giddens (1984, p25-26) calls the duality of structure, which underlies the cycle of structuration (reproductive nature) of systems.

qualify under most insurance schemes, he/she either has to take a loss, or change the structure' (van Raak, 2010, p55).

- Actor is defined as individuals or organized groups that act as a unity in practices relevant to the system and make decisions regarding actions in these practices. These 'choices are constrained – or at least influenced – by the structure and culture within a system, but actors do at least have some freedom of choice (agency)' (van Raak, 2010, p55). Actors, drawing on the structuring elements in the system, produce the system's functioning through actions and give meaning to this.

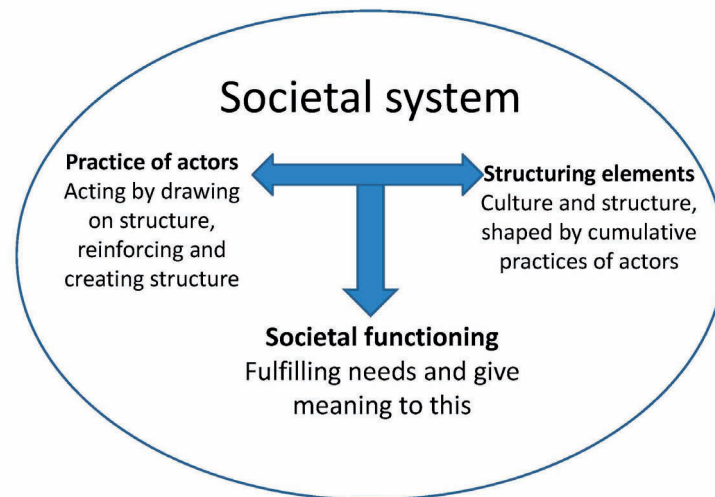


Figure 2.2: The enabling and constraining nature of culture, structure and practice contribute to the societal functioning in systems (adapted from van Raak, 2010, p54)

The dominant cultures, structures and practices in the system together make up the *regime* (see section on the multi-level perspective, page 20 of this book). However, on its own, the regime does not make up the entire societal system. Regimes are nested in larger regimes, and the system also encompasses other cultures and structures that deal differently with the same societal need. De Haan (2010) and van Raak (2010)⁵ developed a theorem that is explicitly used to describe nested health systems: the constellation perspective. They argue that a multitude of complementing and competing regimes are nested in the health regime: so-called constellations. The needs in society, and in the health system, are diverse and require that the system be organized into diverse complementary constellations and sub-constellations,

⁵ Building on Giddens (1984), Geels (2002), Geels and Schot (2007) and Rotmans (2001 and 2005).

forming a composite system. All (sub)constellations have their own culture, structure and practice. Here we use the definition of van Raak (2010, p52):

“Constellation: a set of interrelated practices and relevant, interrelated, structuring elements that together both define and fulfil a function in a larger societal system in a specific way. Note that this definition is functional in the sense that it considers practices and their underlying elements to be centred around a function, but this function definition is contained within the constellation itself.”

Thus, each societal (sub)constellation contributes to a different degree to the total functioning of the whole societal system, while giving meaning to its functioning. For example, the health system is a component of the welfare system, but has several components of its own: the care component, the cure component, the preventive component. There can also be competing (sub)constellations in which actors fulfil societal needs in a different way. As an example, the homeopathy constellation conceptualizes disease differently from the biomedical constellation and deals with it accordingly. Also, as we will explain in section 2.2, there are usually small nuclei of alternative practices, so-called niches, present in the system that constantly emerge and may gain power through processes of self-organization and co-evolution. In these emerging niches, actors can develop cultures, structures and practices that deviate from the dominant regime to fulfil a societal function.

Conceptualizing health systems as complex adaptive systems

To summarise, health systems can be seen as functional systems, and there appears to be common understanding of the goals they should meet: improving health (equitable), being responsive to the needs of the population, and based on a *fair* financial contribution⁶. Furthermore, health systems are diverse and consist of a multitude of actors and nested subsystems. Health systems are complex adaptive systems, and they cannot be separated into isolated parts; the interactions and relationships of these parts make up the system. As a complex adaptive system, the health system constantly changes but, at the same time, it is constricted to pathways of change that are embedded in the system. From the perspective of system innovation, the health system is best described by the (dominant) cultures, structures and practices (CSP) on which actors draw.

On the basis of the above, we conceptualize a health system *as an open complex adaptive system with the socially embedded goal to fulfil a societal need. It comprises a patchwork of dominant regimes that are characterized by their specific cultures, structures and practices.* The

⁶ *Fairness* is a normative concept, thus fair financial contribution and even equitable distribution of *health* are very dependent on whose viewpoint is being considered. As an example, a *fair* financial contribution to health in the UK via direct (progressive) income tax – guaranteeing access - differs a lot from *fairness* in the USA where it has long been considered *fair* that you pay for what you consume.

health system is open and, at any time, competing regimes and niches can be present in which actors deal with the system's functioning differently (fig 2.3).

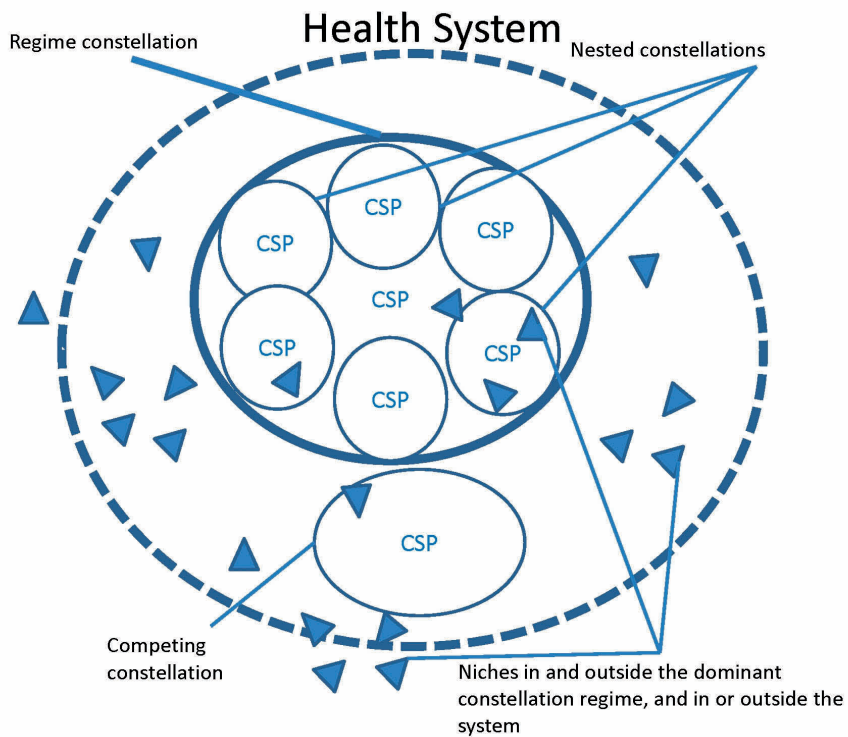


Figure 2.3: A health system as an open complex adaptive system at a point in time (CSP stands for Culture, Structure and Practice).

2.2. System Innovation Processes

In this section, we reflect on frameworks in system innovation theory. These frameworks generally aim to describe, analyse and/or explain processes of system innovation and the driving forces for change. We first conceptualize persistent problems as a driving force for transitional change. Then we describe the processes of change. These frameworks are the multi-level perspective (Rip and Kemp, 1998; Schot, 1998; Geels, 2002), the multi-phase perspective (Rotmans et al., 2001), and the constellation perspective and transition pathways (de Haan and Rotmans, 2007; de Haan, 2010). These frameworks have been used to describe and explain socio-technical transitions in the field of energy (Verbong and Loorbach, 2012),

agriculture (Grin, 2006; Klerkx and Leeuwis, 2009) and mobility (Geels et al., 2012), and form the basis of our framework to analyse transitional change in health systems.

Persistent problems

The legitimacy of system innovation is the perceived urgency of agents to solve persistent problems. As mentioned before, persistent problems involve many actors that do not agree on facts and values in the system; in this sense, persistent problems share similarities with Rittel and Webber's (1973) 'wicked problems' and Hisschemöller and Hoppe's (1996) 'ill-structured problems' or 'unstructured' problems. What sets persistent problems apart is that they are reproduced by the dominant cultures, structures and practices embedded in the regime. Schuitmaker (2012, p1022) states that '*a persistent problem then is an enduring problem, in combination with the features and mechanisms effecting (re)production.*' Actors may find it difficult to solve the problem as they (un)consciously use the same properties in the system that created the problem in the first place⁷. Schuitmaker (2012) reasons that problems are enduring as they can be negative side-effects of 'successful' actions in the system. In box 2.2 we provide an example of how a success factor can contribute to the persistency of a problem. To define a persistent problem, I refer to Schuitmaker (2010, p35):

"Therefore, I propose designating a persistent problem as a systemically (re)produced enduring problem. In other words, a persistent problem comprises the features underlying an enduring problem as well as the pathways and mechanisms through which production/reproduction is effectuated. These pathways and mechanisms exist because agents act out rules, regulations, financial structures, etc."

To summarise, the cultures, structures and practices in (health) systems are enabling and constraining. As a consequence, systems tend to have a specific way of solving problems; certain solution pathways are preferred over others. So if new problems arise, either as side-effects of the success factors of the system or as a result of new emerging patterns in the landscape (such as, for example, demographic changes and new diseases), the system may not be able to deal with these problems effectively. Actors may hamper the realization of an effective solution, consciously or unconsciously, because their thinking and acting work against

⁷ On the reproduction of persistent problems: It can be said that actors rationalize their actions. But these actions do not have to be rational, as they evolve from an existing structure that is not necessarily rational, nor are these actions always conscious (Schuitmaker, 2010, p37; Massey, 2002). Actors often search for solutions to problems as they are observed, largely neglecting how they are manufactured in the system as side-effects of other actions (Voss and Kemp, 2006; Bos and Grin, 2008). This would require actors to reflect on the underlying assumptions of their actions (e.g. Voss and Kemp, 2005; Regeer, 2009; Cuppen, 2012).

it (Schuitmaker, 2012). Hence, persistent problems come into existence, are reproduced and remain largely unresolved. To deal with this, actors need to be able to reflect on the underlying structure in the system and change structures through their actions and vice versa. However, although problems only exist when actors perceive them, we argue that the cultures and structures from which persistent problems will later appear, are always present in systems. But actors will only act when they feel an urgency to solve the problem. In that case a persistent problem becomes a trigger for system innovation.

Box 2.2: Example of a how a persistent problem manifests itself (based on Schuitmaker, 2010)

The enduring inability of the health system to provide 'proper' care to over 500,000 patients in the Netherlands suffering from medically unexplained physical symptoms (MUPS) is partly the result of the success of standardization in the health system. Standardization has led to the creation of evidence-based medical protocols that prescribe uniform treatment for similar health problems. But it is rather a poor philosophy in the case of MUPS, as a standardized diagnosis and treatment are not known. Nevertheless, doctors generally aim to solve the problem via familiar pathways already proven to be successful. Every specialist aims to solve the problem through successful pathways in their professional field, leading to misdiagnosis, persistent failing diagnosis, or neglecting the problem altogether (if we cannot diagnose the problem, it is not there).

Multi-level perspective

The multi-level perspective (MLP) has its origins in the work of Rip and Kemp (1998), Schot (1998) and Geels (2002). The MLP essentially describes how dominant cultures, structures and practices are replaced by new ones. To do so, it distinguishes three levels: the niche, the regime and the landscape. In figure 2.4 we have visualized the MLP (taken from Geels and Schot, 2007, p401). Geels and Schot (2007) emphasize that these levels are not ontological descriptions of reality, but serve as analytical concepts to understand the dynamics of change.

The regime comprises networks of actors (e.g. health providers, patients, governments, researchers, industries) with shared assumptions that interact via the dominant culture, structure and practice (CSP) in the system to fulfil a societal need: 'the incumbent regime'. The incumbent regime is resistant to change. In the words of Geels (2002, p1258). '*radically new technologies have a hard time to break through, because regulations, infrastructure, user practices, maintenance networks are aligned to the existing practice. New technologies often face a mismatch with the established social-institutional framework*'. The regime gives the societal system stability and guides the decision-making (thinking) and practice of individual actors. As such, the regime is path-dependent and is geared towards incremental change and optimization of practices. The regime also shows resilience through its ability to absorb shocks

and external changes while basically remaining unchanged (Geels and Schot, 2007). The stability of the regime is relative to the extent to which it gives meaning and structure to everyday practice (see e.g. Loorbach, 2007, p63).

The niches are spaces outside the regime where actors can develop alternative practices, on the basis of different cultures and structures. In that sense, niches do not concern the pathways of reproduction, as explained earlier, which lead to incremental changes in the regime but are, in fact, 'reserved' for those areas of the production of 'radical' novelties which can evolve through emergent design and self-organization. These novelties can be technological, social or policy innovations. In system innovation processes, these changes are mostly initiated at this level, with societal actors acting as frontrunners (Loorbach, 2007, p118; van den Bosch, 2010, p45). Change agents undertake actions, create small networks in the niche and are willing to invest time and resources. Setting up niche experiments is a crucial feature in system innovation management to test and experiment with novelties involving new sets of cultures, structures and practices. At the intermediate level, the niche regime is also described by some system innovation researchers (e.g. van den Bosch, 2010, p41). This level describes how niches with a relative stability can compete with dominant regimes in the system.

The landscape is the overall societal setting in which transitions occur. It consists of the material infrastructure (e.g. roads), the macro economy, demography and the natural environment, as well as shared cultures, world views and social values. Dynamics at the landscape level can cause instability (or stability) in the regime, or stimulate (or hamper) novelties in niches; e.g. the economic crisis puts pressure on the affordability of health systems, globalization increases the threats of pandemics, while world views on human rights may reinforce efforts for universal access. The landscape largely develops independently but is never neutral to influences of all kinds of regimes. Changes at the landscape level are often long term, although shocks can occur overnight (e.g. revolution or natural disaster).

Increasing structuration
of activities in local practices

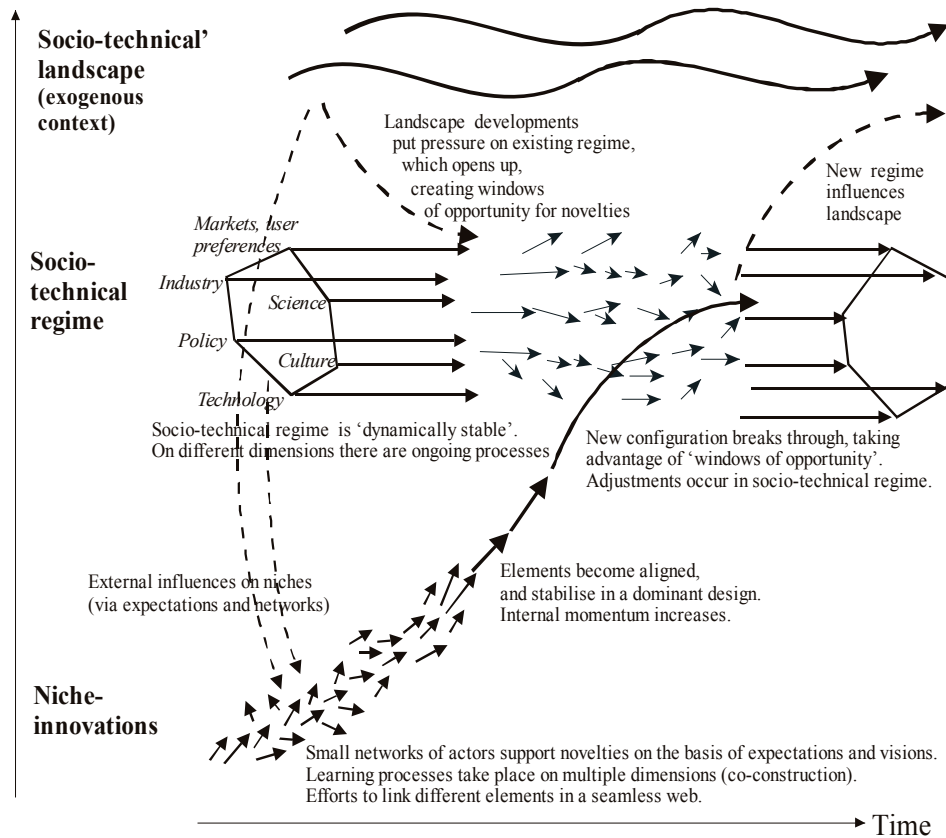


Figure 2.4: Multi-level perspective on transitions (taken from Geels and Schot, 2007)

In the discussion about whether systems are shaped through the agency of their actors or by their structuring elements, the MLP has been criticized in that it places too much emphasis on the structuring forces of the system (e.g. Smith et al., 2005). However, in this thesis we are largely interested in the agency of change agents in system innovation. We concur with Grin (2010, p265) when he argues that the active and creative agency of actors may lead to restructuring of the regime. Also, Geels and Schot (2010, p43) indicate that actors are not passive rule followers in systems:

“Actors are not passive rule-followers (cultural-dopes), but knowledgeable agents who actively use rules to interpret the world, make decisions and act. Actors draw upon rules in (inter)actions, interpreting and tailoring them to the demands of specific local practices. This means that instantiation of rules in local practices always creates (some) variety, even when

actors in a community share rule-sets (regimes) that provide coordination. Because structures do not determine, there is space for local creativity and different interpretation. Constantly, local variations exist within the coordinating structures, an interpretation that fits well with evolution theories."

Multi-phase perspective

The multi-phase concept describes the process in which the incumbent regime is replaced, how it moves from one equilibrium via unstable developments to a new equilibrium (Rotmans et al., 2001). Generally, these are very slow processes which may take 20-30 years, although some breakthroughs might be relatively fast. Rotmans (2001) states that these transformational processes are not gradual, but rather represent sudden drastic changes, or 'punctuated equilibria' (Gersick, 1991). This model (figure 2.5) is descriptive and, as such, it is not a process in which the direction and the end goal of the system innovation are fixed. In this process of change, four phases can be distinguished as described by the multi-phase concept which is visualized as an S-curve (Rotmans et al., 2001; Rotmans, 2003; Bunders and Broerse, 2010, p11):

1. In the *predevelopment phase*, the status quo does not evidently change. At the niche level there are novel practices being developed, but these lack a clear direction, are hardly noticed and have marginal impact on the regime. The successful changes mainly concern optimizing existing structures and practices.
2. In the *take-off phase*, societal change starts. Change at the niche level begins to diffuse to the regime level as feedback is stronger than negative feedback. Nonetheless, most practices in the system are unaffected, while the direction of the change process is still uncertain.
3. In the *acceleration phase*, structural change takes place. Various changes that influence each other accumulate: e.g. socio-cultural, economic, technological, environmental, and institutional changes. In this phase the direction of change becomes visible and parts of the regime are changing fundamentally.
4. In the *stabilization phase*, change slows down, resulting in a new equilibrium. The new ways of thinking and acting have replaced the old ways, which now become the exception. It may take time before the old regime is completely replaced.

Little literature exists that discusses when a transition is actually completed. Rotmans and Loorbach (2010) indicate that there is no status quo in any phase of stabilization. This implies a new dynamic equilibrium, with relative stability, but constant adaptation. Processes of system innovation do not necessarily stabilize at an optimal level, or stabilize at all. This is called *backlash* or *lock-in*. A backlash implies that developments that seem promising go at high speed but results do not materialize and there is a return to the 'normal' state. Lock-in occurs

when system innovations stabilize at a suboptimal level, with solutions being developed that are not necessarily the best in the long run (Loorbach, 2007, p.94). Lock-in may occur when standardization of rules in the system occurs (Verbong and Geels, 2006). However, in any system that stabilizes, formal and informal rules and norms will be standardized, leading to resistance.

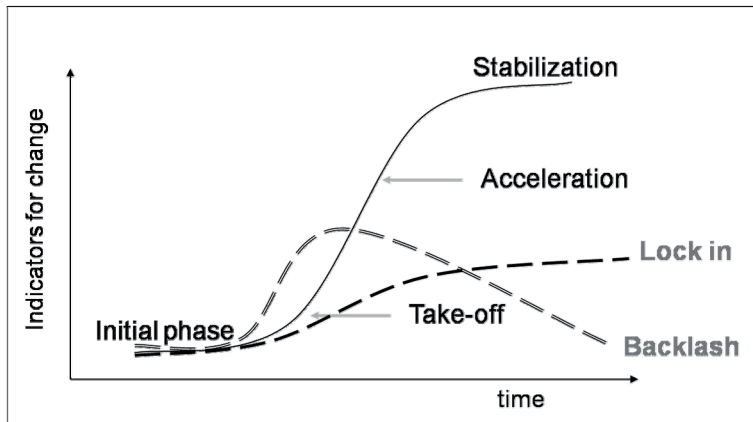


Figure 2.5: Four phases of a transition process (adapted from Rotmans, 2003, p17)

The constellation perspective and patterns of change

Building on the constellation perspective presented earlier, de Haan (2010, p49) argues that landscape developments, or developments from 'higher' regimes, or nested constellations, or constellations that appear as niches, can cause strain (misalignment) among communities of actors in the dominant constellation. Constellations prefer to solve these strains via pathways of optimization (incrementalism⁸). However, embedded cultures, structures and practices may inhibit the incumbent constellation regime from dealing with the strain. In such cases, the constellation has to change its embedded cultures, structures and practices, and system (or constellation) innovation may be required. De Haan (2010, p47-52) further specifies the concept of strain as condition for change: (1) *stress*, strain within (sub)constellations; (2) *pressure*, strain between (sub)constellations; and (3) *tension*, strain between the (sub)constellation and the landscape, its wider environment, or hierarchal constellations.

The nature of the transitional change can be described in terms of patterns. Although there are a large number of patterns that can be considered when analyzing the diversity of societal change processes, three ideal-typical processes are identified: *reconstellation*, *bottom-up*

⁸ It can be expected that constellations naturally strive constantly to remove inconsistencies in the (sub)constellations, not unlike Lindblom's (1979) incrementalism.

empowerment and *adaptation* (de Haan and Rotmans, 2010). Below, based on de Haan (2010, p57), we further explain these processes.

Reconstellation is considered a top-down constellation change, where a new or existing constellation gains power from a higher level constellation: e.g. from governmental policies or international health organizations. In this way, transitional change is imposed on the societal system. For instance, as discussed in the introduction, national governments have imposed neo-liberal reforms on the health system; they decided that actors in the health system should work on the basis of different practices. A common failure of top-down reform is that systems break down; actors are unable to do what they are supposed to do.

On the other hand, *empowerment*, or *bottom-up constellation change* sees a new or already existing constellation gaining power on its own or by interacting or merging with other constellations within the same societal system. This is what happens, for instance, when niches are developed and slowly gain power. These systems often seem promising, forming *niche-regimes*, but are highly vulnerable to backlash.

Adaptation (self-change) concerns a constellation regime adapting its functioning to mitigate conditions that would otherwise result in a radical change (replacing the system altogether). The constellation incorporates functioning from other constellations, through interacting or merging with them. This may lead to lock-in as the regime may lose interest in change when urgency has passed. As a result, it will not continue with system innovation but will stabilize at a sub-optimal level.

Table2.1: Ideal-type paths in transitions (van Raak 2010, p62).

	Dominant transition pattern	Ideal-type transition path	Ideal-type failure path
Top-down change	Reconstellation	Macro-to-meso	Breakdown
Self-change	Adaptation	Meso-to-meso	Lock-in
Bottom-up change	Empowerment	Micro-to-meso	Backlash

The system and process of change

Different concepts – persistent problems, constellation perspective, multi-level perspective and multi-phase perspective – have significant value to describe, analyse and explain the process of system innovation and its driving forces. These approaches describe what needs to be changed in social systems in order to overcome persistent problems: the incumbent regime and associated cultures, structures and practices (CSP). Thus, system innovation implies a radical change from the old dominant sets of CSPs in the nested regime to a new set: CSP₀ to CSP₁.

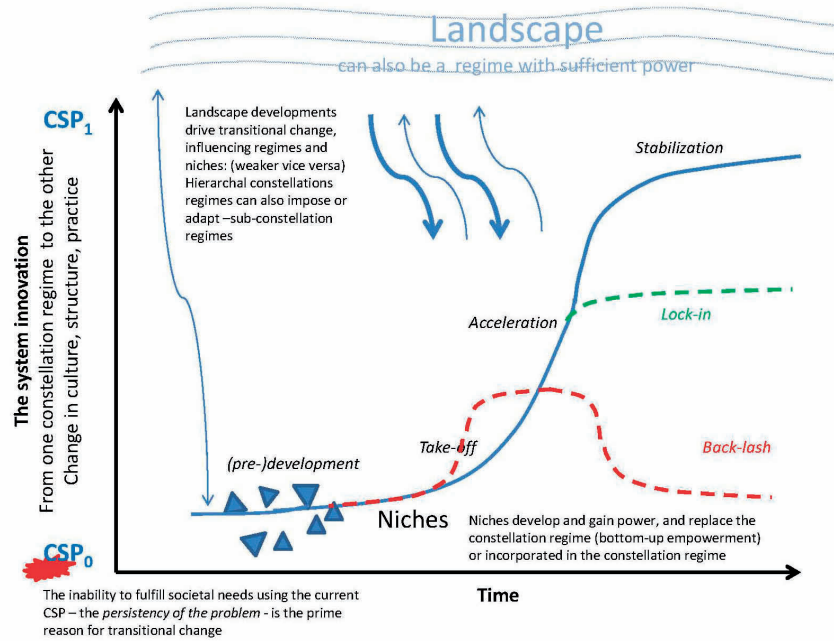


Figure 2.6: Visualization of the transition process from one regime with a specific culture, structure and practice to another.

The need for transitional change in a constellation is driven by the inability of the dominant regime to solve problems or fulfil needs of actors; the failure of old pathways of problem-solving. Furthermore, these processes are long-term and uncertain. In the predevelopment phase, regimes inhibit system innovations, while experiments at the niche level and trends at the landscape level may disturb the status quo and exert pressure on the regime (Geels and Kemp, 2000; Rotmans et al., 2001). However, developments at the landscape level may also slow down rather than accelerate a transition. Only when new ways of doing at the niche level and wider political and societal trends coincide change can occur (Berkhout et al., 2003; Rotmans, 2003). Thus, there are multiple dynamics within and outside regimes that create a climate for change but the change is actually initiated by a small group of actors, who are able and willing to erode and ultimately dismantle the regime. In figure 2.6⁹ we have visualized this

⁹ The part of the S-curve at the far bottom left indicates the regime as it was prior to the transition (CSP₀) at the same point the niches are drawn. Note that at this point the niches and regime are not one, but that they are both present in the social system; this visualization means to indicate pressure on the regime from niches. Also, we do not imply that niche activity can only be observed at these points. Niches

process based on the theory discussed above. On the x-axis we have depicted the change in regimes, and on the y-axis, the time it takes. The S-curve depicts how the system progresses from one CSP equilibrium to another, influenced by niche activity and landscape dynamics. At CSP_0 we have indicated that persistent problems are present.

2.3. The governance of health system innovation

In the previous sections we have defined health systems and have provided insights into how processes of system innovation and driving forces for change can be described, analyzed and explained. It has been acknowledged that processes of system innovation can probably neither be fully controlled nor steered (Rotmans, 2006). But to what extent can these long-term, uncertain processes be managed and governed, and what is the role of change agents in these processes? In this section, we provide a governance perspective to better understand what change agents do in the management of system innovation. First, we highlight insights on the governance of system innovation (Grin, 2010) and transition management theory (TM) (Rotmans, 2005; Loorbach, 2007; van den Bosch, 2010); both address agency in system innovation. Then, we turn to more specific 'management generics' that change agents can apply and, lastly, we will briefly discuss 'the change agents'. These approaches form the basis of our conceptual framework to analyse how change agents can contribute to sustainable health system innovation.

Insights on governance of system innovation

The long-term governance of system innovation of complex adaptive systems is an intricate matter, with no shared understanding of the nature of the problem, or of the problem-solving process. As a result, any governance (or policy) trajectory should be one of learning and cannot take a reductionist view on problem-solving:

"To cope with escalating complexity in health care we must abandon linear models, accept unpredictability, respect (and utilize) autonomy and creativity, and respond flexibly to emerging patterns and opportunities" (Plsek and Greenlagh, 2001, p323).

This implies that the traditional policy-making, management-oriented paradigm, which assumes that a well-functioning system is akin to a well-oiled machine, has to be replaced. We need approaches that focus on learning, deliberation, constant reflexivity, experimentation, integration and 'seizing opportunities' (Bunders et al., 2010; Loorbach, 2007; Greenlagh et al., 2001; Grin, 2010). Thus, each governance approach dealing with system innovation should be

here indicate pressure that contributes to transitional change. In complex adaptive systems we can expect that there is always niche activity present.

the product of constant iterative cycles of deliberation between a wide variety of actors. According to Grin (2010, p223):

“This view holds that the quintessence of a governance perspective is the recognition that the process of steering society and the market can no longer be located exclusively in the political-administrative institutions, taking the shape of central control (government). In this view, governance implies the attribution of a much more prominent role to the interactions between state, market and society.”

Thus, in these processes of system innovation, all parties (non-governmental organizations, business and science) become part of the learning policy/change process rather than an external force or passive subject of government.

Grin (2010, p265-284) draws on studies of system innovation processes to better understand how transitions can be governed by active, creative agency. He distinguishes three types of planning to bring about transitional change:

“The first type of planning seeks to shape local practices by adapting their institutional conditions [...] The second type of planning seeks to promote innovative practices and from there may critically scrutinize and even attempt to adapt their structural context and the self evident assumptions embedded therein [...] and a third type of planning] is located in between the two and seeking to connect them.” (Grin, 2010, p274)

The first type of planning has a focus on structural change of the regime, in which structural adaptations are brought about through trial and error learning. This requires reflexivity that is promoted through visioning: *‘elaborating a long-term perspective (vision, “Leitbild”) to guide long-term action’* (Grin, 2010, p269). This type of planning assumes that changing institutional arrangements will lead to changes in practices. The second type of planning focuses on realizing novel practices beyond the pathway of the regime. It takes a different approach than the first type; rather than assuming that institutional change will lead to novel practices, this type focuses on the change that may come from novel practices beyond the incumbent regime. In these novel practices actors modulate and link niches that can culminate in pressure on the regime, and ultimately change the regime. The third type of planning –intermediary planning– tries to stimulate reinforcing dynamics between the two other types of planning and seeks to connect them. Intermediary planning focuses on prolonged interaction between the changes in structure and changes in novel practices. It is more than simple brokering. *‘Beyond mere brokering, intermediary planning helps actors from a variety of practices to join insights and resources, so as to voice their wishes concerning the regime, benefiting from opportunities and pressures associated with the proximity of the regime’* (Grin, 2010, p274). These three planning approaches have in common that they require reflexive monitoring (Grin, 2010, p275).

To summarise: governance strategies for system innovation need a long-term perspective (approximately 25 years), should have a long-term, flexible goal, and acknowledge that change

can come from the interaction of many actors. These actors are not restricted to the usual suspects (e.g. governments) and they can be active in the regime as well as in the niche. System innovation is a non-linear, uncertain process, which requires governance/management that involve constant learning, reflection and deliberation. It is a multi-level process, which demands understanding of landscape, regime and niche interactions.

Transition management (TM)

Transition management (Rotmans, 2005; Loorbach, 2007) is in many ways similar to the above governance perspective but provides more specific management tools for change agents in system innovation. TM is primarily a prescriptive framework, although it can also be used descriptively. From the perspective of the complexity of society, its problems and its solutions, Loorbach (2007, p25) argues:

“In such a context, the best possible way forward is that of goal-oriented incrementalism: a directed search-and-learning process. Transition management uses the concept of sustainable development as a normative frame to develop the future orientation (vision) and to structure and organize the search-and-learning process. In doing so, it tries to deal with the inherent complexity of the modern society and its associated problems”.

This vision can serve as a new attractor to a new equilibrium.

In TM, prescriptive guidelines are formulated in three spheres (figure 2.7). These spheres are labelled as strategic, tactical, and operational (Loorbach, 2007; van Raak, 2010, p75-76):

- Strategic sphere: this concerns activities that intend to change the culture of a sector. This requires engaging in visioning processes to promote new perceptions, values, and paradigms in a sector.
- Tactical sphere: this concerns activities that intend to change the structure of a sector. This involves negotiation and policy entrepreneurial skills, as well as insights into the relevant institutional networks, amongst others to adjust rules and to create room and resources for experimentation.
- Operational sphere: this concerns activities that intend to create novel practices in a sector and locally experiment with new cultures and structures for a sector. This requires good project management skills, willingness to learn continuously, but also commercial skills to attract investments.

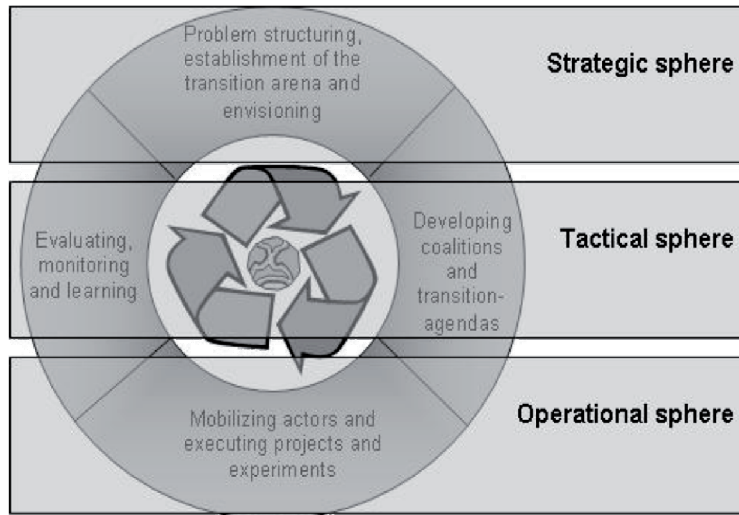


Fig 2.7: Transition management cycle and spheres (taken from van Raak, 2010, p77)

Figure 2.7 shows how these spheres are spread over a series of cyclical management phases that start with problem structuring and vision assessment with frontrunners (the transition arena). Next, coalitions are built and transition agendas are formed. From these, short-term activities are developed to experiment with new approaches. Constant monitoring and evaluation of experiments contributes to informing and adapting the vision, problem, agenda, etc. in an iterative way, making the whole process one of adaptation and anticipation.

Generics for system innovation management

In this section we formulate broad generic tools, concepts and approaches for system innovation, based on insights from governance approaches for system innovation, TM and health systems research. We expect them to be helpful in the realization of system innovation and in the analyses of the role of change agents. The generic tools can be divided into (a) formulating a vision, (b) problem structuring, and (c) from niche experimentation to scale up. Furthermore, we discuss (d) overarching principles in the management of system innovation: transdisciplinary approaches and alignment between actors and activities. Finally, we focus on (e) the role of change agents, although we refer to agency in all other parts as well. Below we highlight these components and indicate how change agents can be involved.

a. *Formulating a vision: 'to a new attractor'*

An explicit focus on a *long-term vision* in health system innovation can be a way to address problems resulting from partial tinkering (top-down) in health systems. Since transitions typically cover periods of 20-30 years or longer, a long-term vision of the change process is crucial. Within TM a vision for transitions is normative (sustainable development) and mainly rooted in the values of those who aim for change. To develop a strong vision, it preferably needs to be broadly shared by the relevant stakeholders. However, it can be expected that the increase in one value may hamper others, e.g. increasing accessibility may hamper affordability. The vision on *sustainability* offers an intriguing possibility to focus on balancing values in health systems. Developing a long-term, shared vision may help actors in change processes to redefine assumptions and can provide guidance for actions in the short and middle term. Therefore, the vision primarily serves as a tool to motivate actors and to give direction to the change process by back-casting activities (Robinson, 1982; 2003; Vergragt and Jansen, 1993; Grin and van Staveren, 2007; Grin, 2010). In backcasting it is recognized that tools and solutions to problems are never pre-determined. A (shared) vision can be used to invent and/or adapt interventions or policies that in the long term may aid to progress towards this vision. The product of backcasting is an action plan, consisting of multiple scenarios that deal with multiple pathways for change (e.g. Elzen, et al., 1996; Loorbach, 2007, p144).

Loorbach (2007, p132-133) extensively describes the strategic instrument of establishing a *transition arena* – a group of frontrunners strongly committed to realizing system change. From our perspective, change agents *are* such frontrunners, projecting future desires to develop a vision. In several approaches, interesting methods have been proposed to identify/develop visions, e.g. vision assessment (Grin and Grunwald, 2000) and constructive technology assessment (Rip and Schot, 1997). All share the idea that visions need to be developed and constantly adapted in a participatory manner to ensure that they are shared by actors and incorporate a variety of viewpoints. Vision development for constellation change (sub-systems) can take place before niche experiments are started or during the execution of niche experiments.

b. *Problem structuring: 'rationalizing the process'*

Problem structuring serves to elucidate problems that need to be addressed and to forecast change activities. The way to analyze persistent problems remains largely unclear in system innovation literature, although recent insights of Schuitmaker (2010 and 2012) suggest that they can be analyzed from the perspective of the situated agent (Stones, 2005). Analyzing persistent problems can be done in two ways: (1) by experimenting with novel cultures, structures and practices, and (2) through deliberative processes. In both methods, actors need to reflect upon the problems they encounter from practice, and anticipate problems (as side

effects) in the future. The problems that are associated with the regime we call 'regime barriers' (see e.g. Loorbach, p111).

The field of knowledge on deliberative governance approaches offers methods to structure problems through either consensual or conflict design (see, e.g., Chilvers, 2008; Rowe & Frewer, 2005; van Asselt and Rijkens-Klomp, 2002; Cuppen, 2012). All these forms are rooted in the active engagement of relevant stakeholders on an equal footing, warranting diversity, inclusion of expert and experiential knowledge, knowledge co-creation through mutual learning (via dialogue), and coalition building (see e.g. Broerse et al., 2008; Cuppen, 2012). But how to apply deliberative governance to analyzing persistent problems has, to our knowledge, hardly been undertaken.¹⁰

c. From niche experimentation to scale up

System innovation deals with the process of how niches may alter or replace the regime (through adaptation, re-constellation, or empowerment). Management tools to develop and scale-up niches can thus be powerful aids in the management of system innovation. Of course, niches always emerge. Based on a perceived need, a variety of niche experiments are started by various change agents. This resembles the bottom-up change, which often comes naturally to non-governmental organizations (NGOs) (e.g. Buse et al, 2008, p102-103). Also, niche experiments can be purposefully set up and 'aligned' to a shared vision on system innovation. This can be seen as a sort of top-down organized, bottom-up initiated, change.

In TM specific attention is paid to the characteristic of so-called 'transition experiments' and how to manage them. Transition experiments are small-scale, practical experiments with a high potential to contribute to transitions (Rotmans, 2005; van den Bosch, 2010). They can be used as an instrument to stimulate a system innovation (Kemp and van den Bosch, 2006; Loorbach, 2007). The focus of a transition experiment is a societal challenge (van den Bosch and Rotmans, 2008; van den Bosch, 2010). Under the heading of TM, three steering mechanisms have been developed to guide system innovations in their contribution to sustainable system change: deepening, broadening and scaling up (Loorbach, 2007; van den Bosch and Rotmans, 2008; van den Bosch, 2010). The sequence of steering mechanisms is iterative, and involves learning and adaptation, and is context dependent.

Deepening refers to innovating in a real-life context, relatively protected from the regime: learning in a local context how to fulfil a societal need in a deviant way (van den Bosch and Taanman, 2006). This involves social learning processes, where actors interact to learn about the cost-effectiveness and practicality of the innovation and to develop different perspectives on reality (Röling 2002; van den Bosch and Rotmans, 2008). In essence, this learning can be

¹⁰ Loorbach (2007) suggests that this can be done in the above-mentioned transition arena, but we believe that the nature of the actors of the transition arena, frontrunners, is perhaps too limited for problem structuring.

considered an interactive process to develop or obtain knowledge, skills, norms and values, and required system changes. Furthermore, generating 'proof-of-principle' or 'best practices' is essential to convince new actors to become involved. This could lead to the enhancement of a shift in thinking and doing (Schot and Geels, 2007). Deepening is often started by change agents, who have a perspective on the problem and a vision on change. It is important that change agents explore the perspective of other actors involved and create a shared vision. This is done by experimenting with new CSP in protected niches distinct from the incumbent regime.

The notion of *broadening* (van den Bosch et al., 2010, p66-67) involves repetition of an experiment in various contexts and translating practices between contexts, meaning that the outcomes of the innovations and learning processes in the deepening phase are repeated and/or linked up with other innovations. As a result, ever more actors are drawn into the innovation and join in the learning process.

Scaling up of an innovation involves embedding it in the dominant culture, practice, and structure (van den Bosch and Rotmans, 2008), and is largely associated with phases of acceleration and stabilization. This process is a challenging one as the regime controls the incorporation of these innovations (Smith, 2007). Only when a window of opportunity opens up, because of ongoing processes in the regime and landscape, can the innovations break free from their niche (Kivisaari et al., 2009). Scaling up requires analyzing regime barriers that hinder the scale-up of innovations, and adaptation thereof (e.g. legal frameworks, educational programs), as well as continuous experimentation. Scaling-up calls for networking with power holders in the regime. How to scale up interventions is perhaps the least explored and most challenging field in managing transition experiments. In this thesis we have a specific focus on scaling-up processes.

Niche experimentation beyond the transition literature: There is also know-how on the experimentation, adaptation and scale up of health interventions outside system innovation theory. However, the approaches in scaling-up health interventions seldom take a systemic perspective, but generally assume that when proof-of-principle is obtained, and the intervention is adapted to its context it will diffuse naturally. Recently, an interesting comprehensive framework for the strategic planning and management of the process of scaling up health interventions was presented by Simmons et al. (2007, p12). In this framework scaling up is viewed as a long-term, systemic approach comprising five interacting elements: the innovation, the user organization, the environment, the resource team or organization, and the scaling up strategy. The scaling-up process cannot be separated from the innovation process; it is context dependent. Therefore, all stakeholders should participate in the process, and monitoring and evaluation should be conducted throughout to ensure that opportunities are taken and challenges can be met. The methods applied in this process cannot be strictly defined and planned beforehand.

This framework on scaling up shares a number of similarities with system innovation and transition theory; to name a few, they all emphasize the importance of:

- experimentation in real-life settings (i.e. deepening)
- replication and expansion of the innovation in different geographical sites or to serve larger or new categories of populations (i.e. broadening)
- context-dependent nature of scaling up in a complex system
- ongoing learning during the development and scaling up of the intervention
- inclusion of a broad network (policy makers, managers, end users, health professionals, etc.)
- health system and environment analysis (i.e. regime and landscape analysis)
- the inclusion of both top-down and bottom-up activities.

There are other frameworks, or keynotes (Atun et al., 2010; de Savigny and Adam, 2009), that share similar aspects with system innovation. Nonetheless, it should be noted that research on scaling up health services has a somewhat less ambitious goal; it concerns the strengthening of health systems by integrating priority health interventions in mainstream healthcare rather than specifically aiming for a profound system innovation: scaling up new sets of cultures, structures and practices.

Furthermore, a more explicit focus on capacity training to contribute to sustainable system change has been evident for a long time (e.g. Korten, 1987). It is believed that scale-up, and sometimes even experimentation, can only be successful when many people understand from which resources they have to draw.

“The central development task should not be viewed as one of transferring financial resources, but rather as one of developing human and institutional will and capacity to put whatever resources are available to sustainable, productive and equitable use to the service of people.” (Korten, 1987, p147)

Thus, education or capacity building can have a central role in system innovation. Obviously, it can help to institutionalize new cultures, structures and practices. But it can also be seen as an instrument for individuals to change their world (Freire, 1970). Remarkably, education or capacity building to promote niche activity has not often been mentioned in the theory on system innovation (with the exception of Broerse et al., 2010b).

d. Overarching principles: the need for a transdisciplinary approach and alignment

It is generally acknowledged that managing transition experiments needs a transdisciplinary approach (Rotmans et al., 2004; van den Bosch, 2010; Broerse et al., 2010). Transdisciplinary research is defined by Thomson Klein (2001, p7) as:

“A new form of learning and problem solving involving co-operation between different parts of society and science in order to meet complex challenges of society. Transdisciplinary research starts from tangible, real world problems. Solutions are devised in collaboration with multiple stakeholders.”

Most system innovation researchers consider transdisciplinary knowledge production to be important in system innovation processes. This refers to knowledge production that transcends scientific institutions and disciplines in contexts with a variety of actors and a variety of disciplines and is action oriented (Klein, 2001; Bunders et al., 2010; Regeer, 2009). A transdisciplinary approach is characterized by the following key concepts (Bunders et al., 2010, p223):

- multi-stakeholder: including actors from both science and society and bringing in their perspectives on problems and possible solutions,
- participatory: in the sense of shared decision-making among a multitude of stakeholders,
- real-world problems as points of departure for analysis and action,
- emergent process design: each phase building on the results of the previous one as a conversation between theory and practice, and
- reflexive learning cycles: implementation of change processes through reflexive learning cycles of planning, action, observation, reflection and re-planning.

Although not all transition researchers and practitioners refer explicitly to a *transdisciplinary* approach, there is often an implicit reference to some of these key concepts. All refer to the need for multi-stakeholder involvement and active participation of stakeholders in the learning that takes place in the context of experimenting, vision development and problem structuring. In addition, most scholars mention that it is important to focus activities on an actual perceived problem. These researchers also indicate that similar activities should be adopted during vision assessment and problem structuring. Health systems researchers who take the perspective of complex adaptive systems also argue that any problem-solving strategy needs *creativity*, should *anticipate emergent design* and also advocate participatory and action research approaches to some extent (e.g. Simmons et al., 2007; Atun et al., 2010; de Savigny and Adam, 2009). Grin (2010, p275-276) implicitly refers to transdisciplinary approaches by putting reflexive monitoring and reflexive design central in processes of system innovation, taking into account serial learning, with a specific focus on frame reflection and the use of experiential knowledge.

Another overarching principle is the need for constant alignment in system innovation. This is similar to the need for participation and coalition building in transdisciplinary approaches but also includes alignment between actors and activities, and actors and structures. Scholars in

system innovation research argue that alignment is important but may refer to different forms of alignment. De Haan (2010, p49) states that misalignment of (sub)constellations and actors drives (transitional) change, as actors tend to seek for alignment in and of (sub)constellations. Loorbach (2007, p128) considers that:

“The aim of transition management is to align all governance activities that are directed towards sustainable development and enhance the chances for a breakthrough, and up scaling of these activities.”

In general, scholars in system innovation share that there is a need for alignment between the niche and regime so that the niche activities can contribute to adjustments of the regime (see e.g. Grin, 2010, p274). They also argue that change agents should search for alignment with landscape trends, alignment between several niches, and alignment between agents, to increase the robustness and power of the change process.

e. About the change agents

Most researchers in the governance and management of system innovations discuss the role of change agents, albeit not all use the term as such. Loorbach (2007, p118) refers to ‘frontrunners’, who are selected on the basis of their ambition for change to develop “coherent, inspiring and meaningful new discourse and visions”. Loorbach further refers to ‘pioneers’ and ‘innovators’ to indicate that change agents can also be active in developing new practices. Grin (2010, p265), for example, refers to active and creative agency to induce bottom-up experimentation and institutional change. This agency is performed by actors who are able to critically reflect on their own actions and those of others, and possess the creativity and ambition to pursue change. Schuitmaker (2010, p37) refers to change agents who encounter persistent problems. These change agents can then contribute to problem structuring and change. Furthermore, scholars refer to agents of change in the niche (Geels, 2005; Hoogma et al., 2002; Kemp et al., 1998; Loorbach, 2007; Elberse, 2012; van den Bosch, 2012). The plural composition of actors in a multi-level network society produces a diverse spectrum of possible change agents in system innovation: organizations, governments or people.

In this thesis, we consider human agency, involving persons, organizations, governments or clusters of them. Implicitly, we have already referred to some characteristics of change agents: they should (1) be frontrunners, aiming for change, (2) have a value-driven vision, as system innovation towards sustainable health systems is a normative perspective on societal change, and (3) be active in a change process and be willing to spend resources (money, time, etc.).

In this research we have an explicit focus on governments and civil society actors as change agents. Governments, as the steward of health systems, have a vital role and interest in sustainable system building. Civil society actors have also been identified as interesting actors in system innovation (e.g. Loorbach, 2007, p174; Elberse, 2012, p4). We define civil society

actors as non-governmental, not-for-profit organizations, and refer to either civil society organizations (CSOs) or non-governmental organizations (NGOs) in this research, using these terms interchangeably. Elberse (2012, p4), for instance, refers to patient organizations (NGOs) as change agents for more needs-oriented health research systems. NGOs are also identified as change agents in a variety of health system development studies (e.g. Korten, 1987; Lewis, 2006, Buse et al., 2008; de Savingy and Adam, 2009). They often try to tackle societal problems by operating from a grassroots, niche perspective but also often have mandates to induce societal change (e.g. Buse et al., 2008; Loorbach, 2007; Korten, 1987). Korten (1987) developed a typology of NGOs in the field of international development, arguing that a number of them are sustainable system builders. Nevertheless, even though NGOs are relevant players in the field of social development (Korten, 1987; Corell, 2001; Buse, et al., 2008), their role in processes of system change and niche innovation remains underexposed (Donk and Hendriks, 2001). In this thesis we do not focus on for-profit actors, although we acknowledge their potential, particularly given the new trend of 'corporate responsibility for sustainable development' (e.g. Kingo, 2010).

2.4. Conceptual framework

Based on our theoretical explorations, we have developed a conceptual framework (fig 2.9) to support our aim *to gain insight into the way change agents may facilitate health system innovation towards more sustainable health systems*. We take the perspective that health systems are a patchwork of constellation regimes that all contribute to the socially embedded functioning of the health systems. The constellation perspective makes it possible to look at change in subsystems of health systems, for example the long-term care system or the tuberculosis control system. The composition of these constellations relates to their embedded culture, structure and practice. System innovation implies a radical change of these elements towards a new equilibrium: CSP_0 to CSP_1 . These constellations and systems are never static; their complex adaptive nature implies that large and small changes occur as punctuated equilibria. The framework incorporates the processes and phases of system innovation which are influenced by landscape – niche – regime interactions (see also figure 2.6). These processes can take the pathway of empowerment, adaptation or reconstellation.

This framework explicitly has a focus on the role of change agents in all phases of transitional change. The framework, mainly in the table part of the figure, incorporates a number of generics on what change agents can do, or should do, to contribute to a societal transition.

1: Visioning: system innovation towards sustainable health systems is geared towards the normative goal of sustainability. This implies the use of sustainable development as a guiding vision for health system innovation. Therefore change agents contributing to the process of

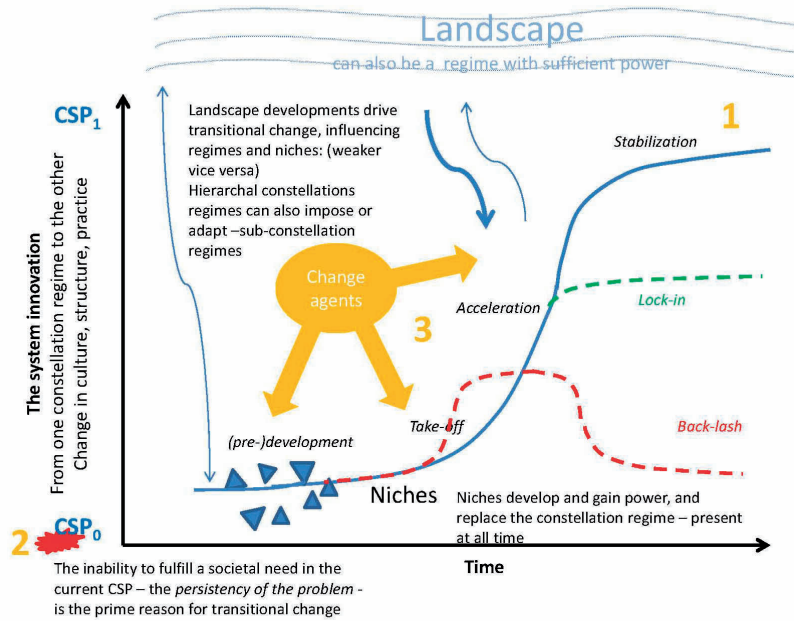
system innovation towards sustainable health systems are expected to formulate value-driven visions on a new equilibrium – they want change in terms of different practice, cultures and structures. A vision serves as a beacon for iteration, although the vision is not necessarily fixed. The vision thus deals with the direction for change.

2: Problem structuring: system innovation is needed to solve persistent problems that cannot be solved on the basis of the current incumbent constellation regime. Problem structuring can help in rationalizing the system innovation process within infinite complexity and forecasting activities.

3: The management from niche experimentation to scale up: ultimately, there are many activities but developing actual alternative practices is key. It encompasses visioning and problem structuring as well as the three steering mechanisms: deepening, broadening, and scaling up.

Among all the activities visioning, problem structuring and the management from niche experimentation to scale up, it can be expected that the change agents use transdisciplinary approaches throughout, to learn and to act. Another crucial activity for change agents is realizing alignment.

The aspects of the framework are largely unexplored in relation to health systems. For example the following questions need further investigation; what entails a vision on sustainable development in health systems; how do processes of health systems innovation come about; and how can we structure persistent problems in health systems? But in system innovation theory there are also aspects that need resolving, such as: the role of change agents in processes of system innovation and whether change agents in system innovation can be trained. Also, in both research fields processes of scaling up complex non-compatible interventions and (transdisciplinary) tools to guide these processes need further investigation. These issues represent, in many ways, elaborations on a question posed by Grin (2010, p.265), *'How may active, creative agency help to realize transitions, understood as bringing about re-structuration?'*, and the application of this question to the health domain.



Principal methods		Explanation of the methods	Overarching transdisciplinary methods and alignment
<i>Visioning: to progress towards sustainable health system (1 in figure)</i>		Guiding other activities, value-based, long-term, shared, leads to backcasting, concrete steps and mobilizing actors	<i>Multi-stakeholder: bringing in different views, perspectives and knowledge</i>
<i>(persistent) Problem structuring (2 in figure)</i>		Analyzing the problems. Leads to forecasting, rationalizing activities on the short/middle term	<i>Participatory: shared 'development and decision making'</i>
<i>Niche experimentation (3 in figure)</i>	<i>Deepening</i>	Learning about the problem and solutions in a protected space, learning about a new set of culture, structure and practice	<i>Real-world problems</i>
	<i>Broadening</i>	Broadening the experiment to other contexts, linking it up with other experiments or functions in the domain and partners	<i>Emergent process design</i>
	<i>Scaling up</i>	Embedding the innovation in the regime (as a new constellation) or replacing the regime.	<i>Reflexive learning cycles: constant iteration, evaluation, monitoring, learning and adaption</i>
			<i>Realizing alignment</i>

Figure 2.9: Conceptual framework, the process of change and the generic strategies for change.

3. Research design

In this chapter we will elaborate on the research design. First, the research objectives, the main research question and the study questions are presented. Then we describe the study approach and methods used and give a description of the various cases, followed by issues of validity and the outline of the thesis.

3.1. Objectives and main research question

In chapter two the importance of change agents in system innovation has become evident. At the same time their role in system innovation towards sustainable health systems is underresearched. These insights lead to the objective of this thesis: *to gain insight into the way change agents may facilitate health system innovation towards more sustainable health systems, in order to contribute to the improvement of approaches for progressing towards such systems*. There can be as many change agents as there is diversity of actors. For reasons described earlier (see chapter 1 and section 2.3), we place an explicit focus on the role of not-for-profit NGOs/CSOs and governmental actors as change agents. Based on the objective of this thesis the following main research question is formulated:

What can we learn from change agents' contributions in realizing system innovation in order to progress towards sustainable health systems?

Against the backdrop of the formulated objective and the conceptual framework (see pages 37-39 of this book and figure 2.9), the main research question is divided in four study questions.

1. *How may we operationalize the concept of sustainable development in the context of health system innovation towards more sustainable health systems?*
 - a. *To what extent can we extrapolate the concept of sustainable development, as used in other societal systems, to the health system?*
 - b. *How can it serve as a guiding vision in health system innovation?*

One of the recurring themes in the governance of system innovation is the aim to progress towards sustainable systems. Within Transition Management explicit use is made of the normative notion 'sustainable development' as a vision to guide the direction for change. In systemic processes in other sectors such as energy, water management, mobility, agriculture and construction, this concept has already been applied to guide change processes. In health system innovation the concept of sustainable development is however ill-defined as a guiding

vision. A literature review on the application of sustainable development as a guiding vision in other societal systems and the role of values in health systems is needed to understand the concept in relation to health systems (question 1a). To understand how such a guiding vision can function in practice an analysis is made of a real-world example in which sustainable development has been applied as a guiding vision for change towards more sustainable health systems (question 1b). To investigate such a real-world phenomenon a case study approach is applied.

2. *How can we structure persistent problems in the health system?*

The focus on sustainable health systems is driven by the perceived 'unsustainability' of health systems. This 'unsustainability' is manifested in persistent problems in health systems. Therefore question 2 focuses on structuring persistent problems. Persistent problems can be structured through the eyes of the problem owners, possibly using deliberative approaches. Such problem structuring approaches are hardly operationalized in the context of health systems. To investigate how to use a deliberative approach to structure persistent problems we conduct a case study in which such an approach is applied in a real-world setting.

3. *How does health system change come about? With a specific focus on:*

- a. *Regime shifts ($CSP_0 \rightarrow CSP_1$) and the scale up of non-compatible health interventions*
- b. *Pathways of change Phases of change*

Besides insights in visioning and problem structuring the issue of the process of change needs to be addressed. Question 3 therefore has a focus on the process of system innovation. All three components of the question, a, b and c, can be addressed by analyzing long-term, context-dependent processes of change that involve experimentation and scale-up of health interventions. To this end we conduct retrospective case studies, covering periods of change ranging from several years to more than 30 years.

4. *How do change agents, with a specific focus on NGOs and governments, contribute to processes of system innovation with respect to*

- a. *Vision development?*
- b. *Problem structuring?*
- c. *Deepening, broadening and scaling up?*
- d. *The use of transdisciplinary research methods?*
- e. *Alignment of niche and regime activities?*

Having studied the process of system innovation, we then analyze the roles and activities of change agents in these processes. Question 4 has an explicit focus on improving our understanding on the role and activities of change agents in health systems change. This question is best answered by investigating the efforts of change agents in real-life settings. We therefore conducted case studies on the activities of a diversity of change agents to investigate how they contribute to niche innovation and/or regime shifts.

3.2. Multiple Case Study Approach

As described above most of our questions can be addressed using a case study approach. System innovations are by their nature complex phenomena and heavily context-dependent, and there are no boundaries between the context and the phenomena. In addition, agents that aim to change these systems are as much constrained as enabled by them. Case studies in the social sciences are typically used to intensively analyze such intricate processes of individual units, persons, events, policies, etc. in relation to their context (Yin, 2009, p4). These analyses aim to explore, validate or illustrate theoretical concepts and to understand, describe or explain the phenomena (Yin, 2009; Flyvbjerg, 2006). For the above reasons and in analogy with other researchers in system innovation studies, we have chosen a case study approach (see also e.g. van den Bosch, 2010; Geels, 2002; Loorbach, 2007; Hoes, 2010; Elberse, 2012).

This research is based on a multiple case study design (Yin, 2009, p53-54). Our principal units of analysis are (1) the system innovation we aim to describe, and (2) the contributions of change agents we aim to identify and analyse. In our research we sought out illustrative cases to provide insights into a broad *pallet* of processes of system innovation. Each of the separate cases can be seen as a single case studie covering different elements of this PhD study. These cases can best be described as *unique, critical and adequate* (Yin, 2009, p47). Unique in the sense that the cases were selected for their specific contribution to system innovation; critical as the cases also investigate whether the theory of system innovation is applicable to the health domain; and adequate as processes of system innovation are uncertain and complex, and events that may look unimportant when they occur were perhaps critical when looking back. To overcome this, we studied cases of system innovation retrospectively (see also e.g. Geels, 2002, 2004; de Haan, 2010).

3.3. Research Methods

For specific methodological approaches we refer to the separate case studies we report on in chapters 4 to 9. Case studies can be classified among the range of qualitative research options (but it is not restricted to qualitative research as it may very well make use of quantitative

inquiry) (Creswell, 2007; Yin, 2009, p132-133). A variety of data collection methods have been applied in this dissertation. They mainly utilize qualitative data from focus group discussions, open and semi-structured interviews and desk studies of scientific, archival and project documentation. In each of the chapters discussing the cases, reference is made to the methods used for data collection and analysis. Also in the next section (3.4) we highlight which principal methods are used in each case study. Data collection in all except one case followed the subsequent trajectory:

- Exploratory desk study and informal interviews to assess the relevance of the case for our research (see section below on case selection).
- A desk study of the scientific literature, followed by a desk study of available project documentation. Especially the latter was crucial in understanding what the system innovation was about and what the change agents did.
- Based on this knowledge, we collected data from respondents through interviews, group interviews and focus group discussions, and/or personal observation, to reflect on findings from the literature and documents. They were all semi-structured in nature to an extent, although in practice, interviews often took the form of talks on how change agents perceived the processes of change in which they were active, how they contributed to this, and how they were constrained or enabled. A number of cases were discarded after this phase (see below).
- Then we analyzed the data and formulated initial conclusions and generalization through deduction.
- Thereafter, another set of data was collected to verify our initial findings. This was done through a second series of interviews with key stakeholders (who were first made aware of the initial findings), reflective focus groups (workshops) with key stakeholders, having key stakeholders review and add to our analysis, and a specific analysis of the project documentation.
- Then we drew our conclusions and lessons from this in relation to the literature.

Selection Criteria

To select the cases we used information-oriented selection (Flyvbjerg, 2006; Yin, 2009). Information-oriented selection implies searching for cases to maximize the utility of the single case. For the selection of appropriate case studies, the following criteria were used:

- The case should be about a contribution to health system innovation, or at least the intention to contribute to health system innovation.
- The case should concern one or more aspects of the management of system innovation, e.g. formulation of a vision, problem structuring, niche experimentation, scaling up.
- The case should involve one or more evident change agents.

- They belong to the category of NGOs/CSOs or government.
 - They have a value-driven perspective on a different system state, and
 - Link this perspective to an act of change.
- The selected cases should – together – be sufficiently diverse in context and approaches, as we aim to identify a *pallet* of heuristics in system innovation management.
 - The cases should be accessible for in-depth investigation.
 - The cases should –together– contribute to answering all study questions posed in this thesis.

Three cases were excluded from our research as they did not convincingly address processes of system innovation, or were not accessible for in-depth investigation. Cases that were excluded were two cases concerning mental health reform, one in Georgia and one in South Africa, and a niche experiment in the long-term care sector in the Netherlands.

In the section below we describe the selected cases and indicate how the specific cases contribute to answering specific sub-questions.

3.4. Selected cases

The journey through this book will take us past six cases studies, initiated by a number of change agents in a variety of contexts. All inform us on how change agents contribute to processes of system innovation towards more sustainable health systems, albeit with a different emphasis. The first two case studies focus on a specific approach in system innovation, the use of ‘sustainable development’ as a guiding vision in system innovation towards more sustainable health systems (the direction of change) and structuring of a persistent problem using a deliberative approach (the rational for change). These two cases also provide insights into the concepts ‘sustainable development in the context of health systems’ and ‘persistent problems in health systems’. The cases 3, 4, 5 and 6 have a broader scope and time frame regarding the process in which change agents aim to contribute to system innovation. For instance, cases 4 and 5 have a focus on the role of change agents from niche development to stabilization of novel constellation regimes. Cases 3 and 6 have a more narrow timeframe, focussing on the role of change agents in niche development (only limitedly addressing other phases in transitions).

Together these cases provide insights into the main research question and the four study questions; study questions are generally addressed by more than one case. Question 4 for example is addressed by all cases. Below we describe the six cases and indicate which system was the subject of investigation, what was the problem addressed, who was the change agent, what was the focus with respect to generics for system innovation, what research methods

were applied, and which study questions were central. All these aspects as well as the method of data analysis are described in more detail in the chapters 4 to 9.

Case 1: Sustainable development: a guiding vision in health system innovation

- The system: the Canadian health system
- The problem: imbalance of values in the system
- The principal change agent: the Romanow Commission
- The focus with respect to generics for system innovation: developing a vision
- Research method: desk study and analytical deduction
- This case mainly addresses study questions 1a, 1b and 4a, with a specific focus on the role of a governmental actor
- See chapter 4 for more insights into this case

This case was chosen to operationalize the concept of sustainable development in health system change. In this case the concept of sustainable development as used in the ecological system is translated to the health system: the need for balancing core values. Few examples exist that explicitly use sustainable development as a vision for health system innovation, and when doing so, most refer to sustainability as used in the ecological domain. A notable exception is Canada's explicit notion of sustainable development as a guiding vision in health system innovation. In Canada the Romanow Commission consulted over 30,000 citizens, experts and health professionals to formulate a vision explicitly using the notion of sustainable development as a new direction for health system innovation. Based on this vision an action plan for the short and middle term was developed.

This case contributes to answering study question 1a and 1b, through the exploration of sustainable development as a guiding vision in health system innovation. In addition it provides insight into how change agents can contribute to vision formulation through a broad deliberative process (4a).

Case 2: Contributing to the management of system innovation: Analyzing persistent problems in the Dutch pharmaceutical care system

- The system: the pharmaceutical care system –
- The problem: irrational use of drugs
- The principal change agent: the Dutch Ministry of Health, Welfare and Sports
- The focus with respect to generics for system innovation: problem structuring
- The research method: interactive learning and action, including desk research, over 20 focus group discussions and 30 interviews. (see chapter 5 for more details)
- This case mainly addresses study questions 2 and 4b
- See chapter 5 for more insights into this case

In the second case persistent problems are structured using a deliberative governance approach. The problem is irrational drug use in the Dutch pharmaceutical care system. The Dutch government expressed the urgent ambition to encourage 'rational' drug use among both users and producers. After numerous failed attempts to mitigate irrational use, it realized that the problem was systemic in nature. The symptoms of the problem are rather obvious: suboptimal therapeutic values are obtained, drugs are wasted, and costs are rising. This is further aggravated by landscape dynamics, such as demographic changes, that put more pressure on this system. In response, the Dutch Ministry of Health, Welfare and Sports commissioned the Athena Institute (VU University Amsterdam) to investigate the systemic nature of the problem of irrational drug use. To this end a deliberative governance approach called *policy-interactive learning and action* (P-ILA), was applied to structure the problem of irrational drug use within the context of the Dutch pharmaceutical care system from a system perspective. P-ILA consists of 5 phases, the first ones being: (1) initiation and preparation, (2) in-depth consultation and (3) integration and analysis. Phases 4 (policy formulation) and 5 (implementation) were left out of our analysis as they do not concern the problem-structuring process and were the responsibility of the Ministry.

This case provides an answer to study question 2. In addition, this case contributes to answering question 4b as it is a clear example of how a change agent can contribute to system innovation through problem structuring.

Case 3: Civil Society Organizations and Innovation of the Dutch Long-Term Care System

- The system: the Dutch long-term care system
- The problem: the long-term care system faces pressure from increasing costs, human resource shortages and increased demand, at the same time it is a supply-driven system, and not needs-oriented
- The principal change agent: Civil Society Organizations active in long-term care innovation
- The focus with respect to generics for system innovation: deepening, broadening and scaling up
- The research method: interviews, workshops, desk study (see chapter 6 for more details)
- This case mainly addresses study questions 4, 2 and 3c with a specific focus on NGOs (CSOs)
- See chapter 6 for more insights into this case

Taking into account the greying of society and the depletion of the workforce in healthcare, this case addresses attempts by CSOs to induce change through niche experimentation in the Dutch long-term care system. In this case study we look at how niche experiments are developed relatively independent from the regime. We specifically investigated change agents

that operate from a value-based perspective transcending economic values, as we anticipate that these are most interesting for contributing to system innovation towards sustainable health systems. For this reason we conducted an inventory study into 14 CSOs and their innovation projects in long-term care, and analyzed how they applied tools in the management of transition – formulation of visions, deepening, broadening, and scaling up – and the barriers they encountered.

This case provides insights into all facets of question 4, how change agents contribute to processes of system innovation. This case study has an explicit focus on how change agents conduct processes of deepening, broadening and scaling-up, by learning in the niche and by understanding the alignment of the vision on system change and the alignment of actors in niche experimentation. This case study also has an explicit focus on understanding phases of niche development (3c), and how change agents can be aided in scaling up. Furthermore, this case shows how (persistent) problems are structured by analyzing novel practices (2).

Case 4: NGO management of system innovation: the analysis of scaling up DOTS in Vietnam 1975-2010.

- The system: the change of the tuberculosis control system in Vietnam – towards a population health approach
- The problem: high infectivity and mortality of tuberculosis (medical paradigm)
- The principal change agent: a NGO, the Medical Committee Netherlands Vietnam
- The focus with respect to generics for system innovation: experimentation and scale-up
- Research methods: semi-structured interviews and desk study (see chapter 7 for more details)
- This question mainly addresses question 3 (a, b and c) and question 4 (a to e), with a specific focus on NGOs and NGO-government partnerships
- See chapter 7 for more insights into this case

This case is a retrospective study into a successful change process of a value-driven change agent (NGO). It describes the innovation of the Vietnamese TB system (1975-2010), and how a change agent (the Medical Committee Netherlands Vietnam, MCNV) contributed to this change process from experimentation to stabilization, with a specific focus on the scaling up process. It gives insights into how these processes can be managed, taking into account the context specificity. It allows for the investigation of long-term processes of system change, as the efforts of the MCNV stretched over more than 30 years of TB control in Vietnam. In addition, Vietnam was a pioneer in DOTS experimentation and scale up. Initial experiences in the late 1970s and 1980s with DOTS in countries such as Vietnam¹¹ allowed for the strategy to become a global one (Ravigione, 2003). The program in Vietnam was considered an illustration

¹¹ DOTS was first tried out in Tanzania and Malawi, but Vietnam stands out as a long-term success.

of success by leading TB agencies like the WHO and the International Union Against Tuberculosis and Lung Disease (IUATLD). The MCNV was instrumental in the scale up of DOTS.

This case provides insights into all aspects of question 3, processes of change and how change agents contribute to this change process. We investigate how a constellation-regime is replaced by scaling up health interventions (3a) and how this relates to phases of change (3c), with a specific focus on the phase of stabilization. This case also addresses the role of a change agent in bringing about this change. We focus on how they apply a vision on change, how they experiment with novel practices and scale these up. In this case study we have an explicit focus on the application of transdisciplinary approaches (4d).

Case 5: NGO management of experimentation and scale-up of community-based rehabilitation in Vietnam.

- The system: the change of the disability support system in Vietnam – towards a community-based system
- The problem: high number of disabled, poor coverage of services, and a general neglect of the needs of disabled
- The principal change agent: a NGO, the Medical Committee Netherlands Vietnam
- The focus with respect to generics for system innovation: deepening, broadening and scaling up
- Research methods: semi-structured interviews, group interviews, personal observation and desk study (see chapter 8 for more details)
- This question mainly addresses question 3 (a, b and c) and question 4 (a to e), with a specific focus on NGOs and NGO-government partnerships
- See chapter 8 for more insights into this case

This case was selected because it provides retrospective and prospective insights in an ongoing transition process of the disability support system in Vietnam. This case describes 25 years of top-down change and bottom-up experimentation. The change agent, MCNV, has a specific focus on building sustainable health systems and has been a major contributor to developing and scaling up community-based rehabilitation structures in specific regions. Furthermore, the system is a highly complex one, rooted in many societal domains: medical, educational, economic and social. This case is of particular interest as it involves experimentation in, and alignment between, multiple domains. This case discusses phases of (pre)development up to take-off. It thus serves to clarify the process of system innovation from deepening in niches, broadening and scaling up.

This case provides insights into all aspects of question 3, processes of change, and question 4, how change agents contribute to the change process. We investigate how a constellation-regime is replaced by scaling up health interventions (3a), how this relates to phases of change (3c) and pathways of change (3b). This case also addresses the role of a change agent in

bringing about this change. We focus on how they apply a vision on change and how they deepen, broaden and scale-up niche experiments. In this case study we have an explicit focus on the application of transdisciplinary approaches (4d) and realizing alignment (4e) to broaden and scale-up experiments.

Case 6: The EXTRA Program; contextualizing evidence in Canadian healthcare

- The system: the Canadian health system, towards evidence-informed decision-making
- The problem: the poor use of evidence, and the lack of the contextualization and production of local evidence
- The principal change agent: the EXTRA Program of the Canadian Health Services Research Foundation and the fellows
- The focus with respect to generics for system innovation: training change agents and inducing and linking niche experimentation
- The research method: author observation, desk study, analytical deduction
- This case mainly addresses study questions 4 (c, d and e) and 3c, with a specific focus on the role of a governmental actor
- See chapter 8 for more insights into this case

In the governance of system change, governments initiate programs to induce change. This case describes such a program, Canada's Executive Training for Research Application (EXTRA) program. This case is of interest for its innovative design and explicit focus on system-wide improvements and because its explicit aim to train change agents that conduct niche experiments (intervention projects). The system innovation that is envisaged involves a shift to increase the use and production of contextualized evidence throughout the Canadian health system; or in the EXTRA parlance, diffusing a culture (and practice) of evidence-informed decision making. This program is essentially a fellowship program designed to train leaders in the Canadian health system to promote the use of evidence (scientific, experiential and contextualized) and conduct applied research within their own settings. The fellowship consists of residency trainings in which fellows build competences for change, and are required to conduct an intervention project to induce change.

This case provides insights into how a government can contribute to bringing about structural change. This case study has an explicit focus on study questions 4c, 4d and 4e. Investigating how change agents can be trained to set-up experiments using transdisciplinary approaches and aligning experiments within their organization structures and among peers. This question also addresses how phases of development can be initiated by change agents (3c).

3.5. Validation of data

A variety of strategies has been applied to ensure, internal and external validity in the study.

Internal validity

Internal validity deals with ensuring the right inference of data by researcher(s). This is crucial as I aim to explain how system innovations come about through the actions of change agents in complex real-life settings; we have to infer why action x leads to result y. Stake (1995) suggests that in case study research, common sense and intuition work to reveal whether we are finding the 'right' thing. But although useful in the iterative process of research, common sense does not validate the outcomes of research. In qualitative studies triangulation of data does provide a way to test internal validity. Triangulation implies cross-checking data from multiple data sources or multiple researchers (Stake, 1995; Denzin, 1989). To increase the internal validity of our data, we used both ways of triangulation.

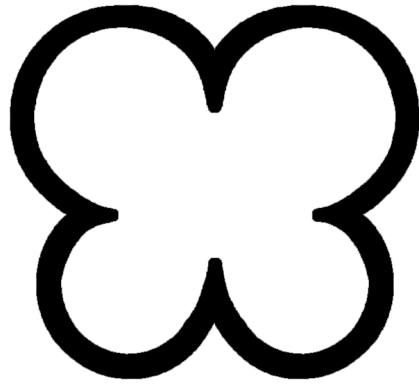
Multiple data sources: In the cases we used data from multiple data sources, e.g. interviews and focus groups, or at least by interviewing multiple 'different' respondents with different stakes in the process. Primary data was extensively documented through verbatim transcripts of interviews, focus group discussions, and meetings. In the research process, saturation of the data was sought as much as possible. Interviews and focus group discussions were preferably conducted until no new issues came up. This resulted in rich data. After focus group discussions and interviews, a draft transcript was sent to the participants in order to check if the researchers had correctly interpreted their input and to confirm accuracy (except for the interviews done in Vietnam). In Vietnam, during and after the interviews and focus group discussions, we summarized the statements and asked for immediate confirmation. In this way, mistakes and misunderstanding by the researchers were minimized. Also, in cases 2, 3, 4 and 5, we made a draft analysis that was discussed in focus groups and interviews with stakeholders, or the stakeholders reviewed the written analysis.

Multiple researchers: In all cases multiple researchers were involved in the design of the study and the collection and analysis of data. Researchers focussed on comparing contesting findings. During the research continuous reflection with colleagues and stakeholders was done to reduce researcher bias.

External validity

We employed two ways to ensure external validity, by using theory-driven case study explorations to compare multiple cases, and contrasting them to other findings and theories. The diversity of cases analyzed by a similar theory offers opportunities for generalization of the

Part 3 - Reflections



10. Conclusions and discussion

The aim of this study was to gain insight into the way change agents may facilitate health system innovation towards more sustainable health systems. We have described and analyzed six cases that provided insights into the role of change agents in health system innovation by using a conceptual framework based on insights from system innovation theory. In Part 2, we presented six cases. Two of these cases provided insights into specific activities of change agents, e.g. visioning and problem structuring. In these cases we further explored ‘sustainable development in the context of health systems’ and ‘persistent problems in health systems’. The cases 3, 4, 5 and 6 have a broader scope and time frame regarding the process in which change agents aim to contribute to system innovation. Most of our conclusions are analytical insights, which can be starting points for prescriptives for the management of system innovation. In some instances, we explicitly hypothesise the prescriptive use of the findings. In this chapter, we accumulate our insight regarding our main research question: *What can we learn from change agents’ contributions in realizing system innovation in order to progress towards sustainable health systems?* Below we discuss our conclusions according to the four study questions posed in chapter 3.

10.1. Sustainable development in the context of health systems

1. *How may we operationalize the concept of sustainable development in the context of health system innovation towards more sustainable health systems?*
 - a. *To what extent can we extrapolate the concept of sustainable development, as used in other societal systems, to the health system?*
 - b. *How can it serve as a guiding vision in health system innovation?*

Conceptually, sustainability in health systems can best be understood as a dynamic equilibrium in which the system easily rests on its constituent values (e.g. affordability, accessibility, acceptability and quality). Thus, sustainability implies that actors in the system judge that these values are sufficiently maintained and provide a framework for meaning and action. Unsustainability is the opposite: a system in which actors cannot maintain, or do not agree on, a proper balance in the health system. The observation that health systems are unsustainable was already made in the introduction, but it is further underlined in the various cases, in which change agents refer to values that cannot be maintained or are insufficiently addressed:

- In chapter 4, Canadian citizens, health professionals and experts refer to ‘imbalance’ between affordability and quality which jeopardizes other values in the system, e.g. equity and solidarity.
- In chapter 5, the Dutch government stated that the current pharmaceutical care system is not affordable (now and in the future), and fails to improve quality.
- In chapter 6, we have seen how several CSOs start niche innovations when they perceive a tension between the current cultures and structures and the needs of clients. According to them, the client is not the focus of the system.
- In chapter 7, the TB control system in Vietnam was incapable of offering access to quality care to patients.
- In chapter 8, the Vietnamese health system was unbalanced as it failed to provide access to acceptable quality care for a large group in society, those living with disabilities.
- In chapter 9, the Canadian care system experienced multiple threats to affordability and quality care (see above chapter 4). The CHSRF and the EXTRA program managers aimed to uphold values of publicly funded, solidarity health care in Canada, emphasising the value of contextualized evidence.

Sustainable development as a guiding vision: From the perspective of complex adaptive systems, a sustainable health system is never in a steady state. Subsequently, sustainability can best be operationalized as a vision, or the attractor, in a dynamic equilibrium. Therefore, we link the diagnosis of unsustainability (‘unbalanced’ values) in health systems to the concept of *sustainable development*, as used in the environmental domain. In chapter 4, we further operationalized the concept of sustainable health systems in the context of the management of health system innovation. We argued that by lifting the formal structure and dynamics of the triple P bottom line concept from the original practice where it was formulated and developed, it might be possible to generalize the intrinsic function of sustainable development beyond the environmental context. We identified four central elements of a guiding vision for sustainable health systems: (1) identification and analysis of the persistent problems within the health system that lead to urgency for change; (2) formulation of a limited set of shared core values through a broad participatory process; (3) an explicit focus on balancing these values; and (4) anticipation beyond generations by addressing the need for healthcare in the present and the future. Such a holistic, long-term vision, on the basis of a limited set of core values, may seem abstract but can lead to more concrete steps when activities are back-casted from this vision (see e.g. Loorbach, 2007; Vergragt and Jansen, 1993; Robinson, 2003).

We hypothesize that constructing a vision on sustainable health system change, through participatory processes with stakeholders in the system, can be constructive for change

processes; it re-affirms values in society (and opens up the discussion on what is important), allows for back-casting change (see table 4.4), and mobilizes and aligns actors for change. Such processes can be meaningful to address the health system as a whole, or elements thereof (e.g. drug use). There are multiple examples in the literature that describe how to establish such visions (and develop agendas for change), of which three are especially useful as they have been developed in the context of system innovation or long-term change: the transition arena (Loorbach, 2007), vision assessment (Grin and Grunwald, 2000), and constructive technology assessment (Rip et al., 1995). However, in health system change, processes that explicitly adopt sustainable development as guiding a vision remain rather scarce (with Canada being a notable exception – see chapter 4). Nevertheless, in various cases, we observed that actors developed visions on systemic change that clearly aimed at strengthening and balancing values in the system, for example making human values key in home care (client-oriented) and aiming towards a society in which people with disabilities are included and actively participate in their communities (equity and equality in care). (see also section 10.4)

10.2. Structuring persistent problems

2. *How can we structure persistent problems in the health system?*

Change agents in practice experienced persistent problems as complex problems that were enduring and difficult to solve because many barriers were encountered that frustrated change. However, as we will demonstrate later, change agents generally did not develop very systematic ways to structure persistent problems.

In chapter 5, we described a framework and approach to unravel and structure persistent problems. Reducing a system to constellation regimes, characterized by three embedded features (cultures, structures and practices), and looking at how actors use these features to contribute to a certain functioning, makes it possible to get a grip on the quintessence of problems, where they originate and how. The persistency can then be framed in terms of *stress* within constellations, *pressure* between constellations, and *tension* between constellations and the landscape. The constellation theorem of de Haan (2010) proved to be very useful here.

In line with Stones (2005) and Schuitmaker (2012), we argue that these problems can be unravelled through the eyes of ‘the beholders’ of the problems. We contribute to theory and practice on persistent problem structuring by applying a deliberative approach (P-ILA), described in chapter 5 (see section 5.3). Having various actor groups holding different power positions in systems reflect in homogenous focus groups, and later integrating them in several heterogeneous meetings, produced a clear description of problems. In addition, it gave the opportunity to rationalize further policy-making (forecasting).

Other transition researchers (e.g. Hoes, 2010; van den Bosch, 2010) generally approach problem structuring by analyzing regime barriers encountered in niche experimentation. In our other cases, this indeed appeared to be the common way of problem structuring by change agents, without adopting clear methodologies to do so. In chapters 6, 7 and 8 CSOs clearly adopted a learning-by-doing manner to better understand the problems they experienced; end-user feedback was crucial in this.

10.3. The process of health system change

3. *How does health system change come about? With a specific focus on:*
- a. *Regime shifts ($CSP_0 \rightarrow CSP_1$) and the scale up of non-compatible health interventions*
 - b. *Pathways of change*
 - c. *Phases of change*

Throughout our research we have found much supporting evidence that the dynamics in health systems resemble those described in the multi-level perspective. For instance, we found niche activity in the various fields that we studied, which often coincided with landscape trends, e.g. the CSOs anticipated demographic changes and related to the discourse of healthy ageing in their niche activities. Also, the regime was very resistant to change at times. The Dutch example especially displayed this embedded resistance.

$CSP_0 \rightarrow CSP_1$: We have demonstrated how culture can be useful to determine the value-based direction for change, and how persistent problems can be clearly framed by a better understanding of strain in constellation regimes, which can be characterized by their cultures, structures and practices. Furthermore, in chapters 7 and 8, we used the features culture, structure and practice to actually describe change (and later better understand agency in change). In these cases, the analysis of the dimensions of this change helped to elucidate the activities of change agents in these processes. Both these cases demonstrated that scaling up a cluster of niche innovations requires a prominent change in thinking and organizing at multiple levels and domains in the health system.

The constellation (or system innovation) perspective was useful in understanding processes of scaling up (health) interventions. Whereas most of the literature in this field focuses mainly on making interventions compatible with its systemic environment so that it can be integrated in the system (as in Simmons et al., 2007; Rodgers, 1995), the constellation perspective takes the viewpoint that, for transitional change, the systemic environment itself must change or co-evolve with the intervention. This requires more than the integration of an intervention into a system. This system innovation perspective is thus useful in better understanding processes of

change and adopting effective heuristics to do so: e.g. anticipate a long time frame (see e.g. van den Bosch, 2010).

The pathways of change: In the cases we described, pathways of adaptation appear to be the dominant way for system innovation to occur. In the two Canadian cases (chapters 4 and 9) and the case of irrational drug use in the Netherlands (chapter 5), the governments deliberately chose to stimulate regime actors to induce self-change in niche experimentation (thus not top-down). Also, in both Vietnamese cases (chapters 7 and 8), the MCNV specifically chose for pathways of adaptation by working closely together with regime actors, and by using already existing structures. In the case of CBR, the regime (government) first tried to reorganize the system through re-constellation. This was not successful, and the system change was subject to backlash. However, this did open a window of opportunity which was ultimately important for system change. In chapter 5, the Dutch government aimed to induce change after problem structuring by subsidizing the experimentation of regime actors. In chapter 6, the CSOs that experimented in niches were often organizations that were already part of the long-term care regime, or expected that regime organizations would adopt their methods. One of the experiments, when scaled up, created an organization that expanded in size (scale-up through expansion); this example closely resembles bottom-up empowerment. Nevertheless, niche actors are the ones that work in this organization, and it appears that these actors organize self-change.

We hypothesize that adaptation is the most likely route for sustainable system innovation in health systems.⁴⁷ Many of the current actors are searching for new configurations to contribute to solving societal needs. Reconstellation, or bottom-up empowerment, on its own may be insufficient for sustainable system innovation. This was also considered in the introduction, where system change through top-down and bottom-up innovations were separately insufficient to lead to a satisfying result for very complex problems. As many scholars have argued, combined strategies are necessary, and it is essential that these strategies are aligned (see e.g. Loorbach et al., 2007, p128).

On the phases of change: Pathways of adaptation are prone to lock in at a suboptimal level (de Haan, 2010, p61-62). We found that in health systems innovation there seems to be a thin line between lock-in and stabilization of change processes. Conceptually, lock-in and stabilization are difficult to distinguish. Stabilization implies a state where a new equilibrium is reached, but pathways of incrementalism have to contribute to further optimization (Rotmans, 2001). Lock-in is defined as a situation in which a sub-optimal, or unsustainable, solution stabilizes.⁴⁸ Both

⁴⁷ However, perhaps the fact that health systems strive for adaptation for incorporating preventive health in many aspects of our health system.

⁴⁸ In addition, that which is labelled unsustainable, and needing to be replaced, can later be seen again (partly) as a sustainable alternative to current practices. As an example, in long-term care we are now

deal with a certain sub-optimality. How system change is labelled, stabilized or locked in, largely depends on which viewpoint is taken. As observed in the TB case, from the perspective of the NGO, lock-in occurred when the urgency for change faded among most of the actors. Other actors, among which the National Tuberculosis Program (NTP), argued that the system actually stabilized at the right moment. Stabilization was required to standardise and ensure access to services and stimulate further optimization.

As a way forward, Loorbach (2007) states that we need to be reflexive to prevent lock-in. In this research, we do not deny the need for reflexivity, we will later even state that it is essential, but we do stress that in health systems there is also a recurrent need for standardization; there is an inherent pressure to standardize (stabilize) a certain level of quality and access to health care for citizens. Thus, from the perspective of maintaining values, innovation without closure may not always be an option. We hypothesize that we rather strive for cycles of standardization and reflexive learning.

In the CBR case, the system change went through phases from take-off to backlash and acceleration. Health system change is indeed not linear, not even from a helicopter view neglecting the constant niche dynamics. This means that cycles of backlash, lock-in stabilization, development, take-off can occur in unsystematic order.

10.4. The role of change agents in health system innovation

In this section, we synthesize our findings on the role of change agents in health system innovation. In chapter 3 we posed the following sub question: *How do change agents contribute to processes of system innovation?* Underneath we will address this question according to its specific elements.

4. *How do change agents, with a specific focus on NGOs and governments, contribute to processes of system innovation with respect to*
 - a. *Vision development?*
 - b. *Problem structuring?*

In the section above on sustainable health systems, it was already indicated that change agents have value-based visions on change. We also showed how a vision can be developed (chapter 4) and a persistent problem structured (chapter 5). Here we discuss how visions were developed and used by change agents in the cases to bring about system innovation.

returning to old community-based solutions, which had lost their functions as they could not guarantee equal access (chapter 6).

Visions were deemed important in every single case that we investigated for three reasons: alignment of actors in experimentation and alignment of experiments, giving direction to change processes, and further mobilizing for change. Remarkably, however, despite the weight actors gave to visions, they hardly mentioned ways to develop *shared* visions. The urge to address observed or felt imbalances in values formed the stimulus for most of the visions. Also, the urgency to act upon a shared vision mostly came from shared understanding of landscape pressures (aging of society) or landscape opportunities (opening up of Vietnam). Shared visions were largely established by searching for, and engaging with, like-minded actors. For example, in the CBR case, the vision regarding the rights of the disabled had already been developed by the WHO and communicated by a Dutch physiotherapist to the MCNV, which adopted it; this subsequently formed a basis for action. In chapter 6, we described how CSOs use visions to indicate the direction for change. It was even argued that visions are the only thing that cannot be changed. Some CSOs constructed their vision with end-users. Although visions were not developed in coalitions, visions did strongly align actors and mobilized them for change.

Likewise, we did not come across any detailed problem-structuring processes apart from the deliberative governance approach sketched in chapter 5. Change agents saw the problem as a given. Nevertheless, they invariably aimed to increase their understanding of the problem by trying to solve it in practice. This was mainly done by 'trial and error' or 'learning by doing'. However, change agents (apart from MCNV) did not structure the problems in a way to better understand barriers of the incumbent regime. Problem structuring was mainly conducted to understand how to realize results in the niche. When change agents did come across regime barriers, they were often considered contextual factors that constrained the process, not as *problems* in themselves that could become focal points for change. In box 10.1 we describe one particular regime barrier, related to the nature of evidence in the health system which is described in more detail in chapters 6, 8 and 9. This is of interest because changing how we think about evidence in health systems may facilitate change.

Box 10.1: The nature of evidence, a regime barriers

Here we describe one regime barriers that is of particular interest and was encountered in chapters 6, 8 and 9, of evidence in health systems. We propose that changing how we think about evidence in health systems may facilitate change in many of our health systems. We found that lack of contextualization of evidence and lack of appreciation of contextualized evidence were common in the described change processes. As we will discuss later, contextualization of evidence and appreciation of transdisciplinary knowledge production form facilitators of change. For example, in chapter 6, regime players were unresponsive to transdisciplinary knowledge that was generated in practice, despite overwhelming qualitative evidence. Regime actors favoured evidence that rested on the rigorous results of cost and effectiveness analysis or randomized controlled trials. Innovators indicated that these are hard to establish for many interventions. It even

reached the point, described in chapter 6, that CSOs could only get subsidies to start an innovative project after they had already obtained evidence. Similar findings were noted in chapter 9, where people were specifically trained to improve the understanding and use of contextualized evidence. The major problem in the current system is a rather singular perspective on knowledge; knowledge is produced in research settings and straightforwardly adopted in health settings (or wrongly adopted). This was problematic in the Canadian health system; the EXTRA program was even set up to deal with this. EXTRA staff members indicated that it remained extremely difficult to communicate on contextualized and other evidence in their organizations.

Based on this we are facing *double trouble*; health systems need to innovate but so does the research system. This change process needs to co-evolve.

We hypothesize that change agents could benefit from better (deliberative) problem structuring. Similarly, *shared* broad visions and change agendas can be formulated in a deliberative and consultative manner, as was done in Canada (chapter 4) and by the WHO on CBR. Subsequently, these visions can mobilize for change and give direction to the change process. Developing shared guiding visions, as proposed in transition arenas (Loorbach, 2007, 129), can be instrumental in mobilizing for sustainable change. However, change agents themselves also have a role in developing and communicating visions, and keeping track of the problems they encounter.

4. *How do change agents, with a specific focus on NGOs and governments, contribute to processes of system innovation with respect to*
 - c. *Deepening, broadening and scaling up?*
 - d. *The use of transdisciplinary research methods?*
 - e. *Alignment of niche and regime activities?*

The core idea in the management of sustainable system innovation is that a variety of niche experiments contribute to bringing a vision to life. A (cluster of) niche(s) can ultimately scale up and adjust or replace cultures and structures in regimes. In this section, we address how change agents go about these processes from niche experimentation to scale up. In all six cases, including the more conceptual cases, we discussed niche innovations and how they came to being:

- Niche innovations were initiated relatively independently⁴⁹ by change agents who did not necessarily aim for system change (see chapter 6 on the CSOs active in long-term care)⁵⁰
- Niche innovations were purposefully induced by change agents (in our case governments, e.g. chapter 9, the EXTRA program, and chapter 5, irrational drug use).⁵¹
- Niche innovations were started and supported by intermediary organizations (chapters 7 and 8, MCNV).⁵²

Here we discuss how these change agents go about deepening, broadening and scaling up these niche innovations. In chapter 2, we argued that transdisciplinary approaches are needed throughout the phases of broadening, deepening and scaling up. This also became apparent in the cases that we studied. The change agents in our cases focused on a *real-world problem* in a *real-life context*, both crucial in niche experiments and transdisciplinary approaches. In this section, we will investigate the processes of deepening, broadening and scaling up and how these processes contribute to shifts in cultures, structures and practices by analyzing how they focus on multi-stakeholder participatory networks; conduct learning and frame reflection (first- and second-order learning); and include reflexivity (cycles of planning: action–evaluation–planning–action, etc). We also position alignment among transdisciplinary activities as it involves aligning vision goals and stimulates/activates actors through coalition building and participatory methods (see also table 10.1).

Preparing for learning – deepening

In a niche (transition) experiment, an open search and learning process (‘deepening’) can take place in a relatively protected space at the niche level, which is distinct from the regime. Deepening aims to develop new practices in localities that require new cultures and structures to fulfil desired societal needs. The role of experiments⁵³ is clearly supported in all of the cases in this book. We saw that actors organize their creativity to bring visions to life⁵⁴. Our research

⁴⁹ One can argue that these are clear examples of emerging niches through self-organization in the niche

⁵⁰ This resembles type 2 planning of system innovation (Grin 2010; chapter 2 of this book)

⁵¹ This resembles type 1 planning of system innovation (Grin 2010; chapter 2 of this book)

⁵² This resembles parts of type 3 planning of system innovation (Grin 2010; chapter 2 of this book)

⁵³ However, when we consider constellation change, the diversity of experiments does not necessarily have to be wide. As an example, in the TB case (chapter 7) the basics of the experiments were developed in an elementary manner outside the context of Vietnam. Deepening in this case concerned how to adapt the process to the context of Vietnam. This was to an extent also the case in the CBR case. These cases can be seen as system innovation through knowledge translation. But this does not principally alter the required activities.

⁵⁴ The need for visions to start innovations studies has been well described in innovation the literature (see e.g. Bunders et al. 1991).

largely found that change agents use inherently similar methods as described in prescriptive theories on deepening.

Most change agents were part of *multi-actor networks* which were almost all created by engaging others with their vision on change,⁵⁵ apart from the EXTRA program, where networks were mostly based on organizational structures. Change agents generally cooperated with end-users (clients and health providers), public or private not-for-profit care institutes and scientific institutes. These multi-actor networks can generally be described as a network of change agents, strongly *aligned* around a *shared* vision on change, *shared* consensus on the urgency for change, and *shared* norms and values. Most networks of change agents consisted partly of regime players (niche-regime alignment), e.g. many of the CSOs in chapter 6 were part of conventional homecare organizations, while the EXTRA fellows and EXTRA program were embedded in the conventional health system. Alignment with regime players facilitated making space for learning⁵⁶. Creating space for learning was also partly about 'assertiveness'. MCNV, for example, made use of emerging opportunities, joining in the global development of DOTS and CBR strategies. Based on our research, we argue that learning space is either actively created by regime players, structural space (e.g. EXTRA, NTP), or is part of the inherent capacity of change agents that sprouts from their vision, cultural space, drawing on the self-organising capacity of complex adaptive systems⁵⁷. The iron triangle of KNCV/NTP/MCNV, described in chapter 7, is a prime example of a strong multi-actor network, comprising scientific, civil society and regime actors, which facilitated space for experimentation and learning by doing.

These networks were primarily brought into existence to organize learning and acquire proof-of-principle to fulfil a societal need in a deviant way. Collecting proof-of-principle was part of the TB interventions, organized by the MCNV/KNCV/NTP (see chapter 7). During experimentation (and standardization), health professionals were obliged to carefully record epidemiological data and to participate in bottom-up planning activities. The latter mainly facilitated reflexive learning to constantly address new needs. For instance, when it was learned that TB infected fishermen were unable to collect medicines on time, they were given larger quantities of medicines. However, for various reasons, this led to misuse of the regimen. Subsequently, a capsule pill was developed in cooperation with the consortium that contained all the medicines in the right dose. This proved to be a successful way forward. The same

⁵⁵ The networks of the CSOs in long-term care and MCNV emerged through processes of self-organization, in which small acts may almost logically turn into big events. For example, when MCNV was approached by a Dutch physiotherapist to help structure medical CBR, they got involved in the CBR field, and in collaboration organized a whole network. However, this does not happen without taking initiative and showing persistence.

⁵⁶ CSOs (chapter 6) that did not have affiliation with the regime found it difficult to acquire funds for experimentation, and were restricted in space.

⁵⁷ The literature on the need for space is abundant (e.g. Kemp et al., 1998; Weber et al., 1999; Hoogma et al., 2002), but how to create space remains largely unexplained.

capsule was also of benefit to other aspects of the program because it inhibited selling single drugs on the black market. Thus, reflexive learning cycles in one program aspect were able to benefit other program areas. The consortium acquired proof-of-principle, through the collection of epidemiological data, and through learning by learning-by-doing and monitoring.

The latter, learning-by-doing and monitoring (preceded by a desk study), formed the principle method used to obtain proof-of-principle by nearly all change agents (chapters 6, 7, 8 and 9)^{58,59}. In chapter 6, the CSOs indicated that deepening was a *communicative* learning process which primarily focused on increasing understanding of the problem and 'possible' solutions by aiming to acquire proof-of-principle. Proof-of-principle was strengthened by iterative learning cycles, often in cooperation with clients of the home-care organizations. In chapter 8, the MCNV collected proof-of-principle and adapted the CBR interventions using *reflexive* cycles of monitoring and evaluation, in cooperation with health professionals and people with disabilities.

Frame reflection is crucial in transdisciplinary knowledge production to escape the reproduction of CSP in niches and formulate different perspectives on reality (Rolling, 2002; van den Bosch, 2010; Broerse et al., 2010b). In many of our cases this appeared to come naturally to actors in the niche. Frame reflection mostly preceded experimentation and network building; e.g. CSOs that aimed to establish community-based services sought out likeminded individuals and started working on their ideas. We can distinguish three examples of how frame reflection was addressed in niches. In the lifestyle monitoring case (chapter 6), proof-of-principle was important to convince nurses that the technology would not lead to less interaction with the clients. In the Vietnam TB cases, showing-by-doing by Dutch consultants of the consortium was an eye-opener for grassroots health providers. This allowed health workers to shift their thinking towards TB (stigmatization), the need for planning and reporting (public health attitude), and the use of low-cost technologies (choosing microscopy diagnostics over X-ray). Direct training in niches (CBR and TB) also proved beneficial for frame reflection. New knowledge and new insights facilitated the change process and frame reflection in particular.

⁵⁸ Perhaps with the exception of some niches in the EXTRA program, where change agents applied business processes and traditional change management plans in making organizational change, and attempted to get everyone "rowing in the same direction". This is currently addressed in the program (chapter 9).

⁵⁹ In chapter 6 it is also indicated that scientific evidence was important. The larger, often public-contract, CSOs were able to engage in processes of formal evidence-based studies in cooperation with universities or knowledge institutes, often based on action research principles (similar in the EXTRA program, but the smaller once found this difficult).

Prepare for take-off - Broadening and scaling up

To induce system innovations, experiments have to grow beyond the niches, broaden and ultimately scale up. Broadening involves multiplication of an experiment in various contexts and translating practices between contexts. In other words, the outcomes of the innovation and learning processes in the deepening phase are repeated and linked to other innovations. Broadening increases the influence and stability of the innovation (van den Bosch and Rotmans, 2008; van den Bosch, 2010) and facilitates diffusion to various contexts. This process of broadening needs to be complemented by a process of scaling up. Scaling up implies the embedding of the new model or service in the dominant way of thinking (culture), doing (practice) and organizing (structure) at the regime level of a societal system, eventually contributing to regime shifts (van den Bosch and Rotmans, 2008). All change agents that aimed for scaling up indicated that both strategies are part of cycles of iteration going back and forth between the experimentation and scaling up. Thus, scaling up is inherently a reflexive process.

Change agents mentioned a range of activities for broadening and scaling up, e.g. participatory agenda setting, networking, marketing, advocacy, in all sorts of ways. Broadening mainly involved identifying and working with similar actors in other contexts, or linking niche experiments to other niche experiments or regime processes. Scaling up is mainly about linking to regime players. However, apart from the MCNV cases in chapters 7 and 8 and a notable exception of one of the CSOs (the neighbourhood nurse teams) in chapter 6, most of the change agents were not very active in broadening and scaling up. For example, experiments that started after the formulation of a vision in chapter 4 led to a 'patchwork of pilot projects', which did not scale up. Likewise, the change agents in the EXTRA program and the Dutch CSOs also generally remained stuck in their own settings. In the EXTRA program, it was assumed that diffusion would occur autonomously. Most CSOs even indicated that scaling up is not part of their role in system innovation, others should *pull* the innovation. In relation to this, niche change agents largely neglected learning about which structures needed to change. This was only done actively in the cases in which MCNV spearheaded the change process. In the Dutch cases, although many barriers were experienced, they were not addressed but rather taken for granted as contextual barriers. Even in the EXTRA case, a regime program, lessons learned about regime flaws were not systematically collected. This was partly because the time frame of niche experimentation was short (less than two years), and follow-up was barely organized.

The EXTRA program in chapter 9 does have the potential to induce change (culture of EIDM). The change agents that were trained indicated that they are part of a 'group of change agents' which wants to change their organizations. In addition, there are clear indications that the EXTRA program will run for some years, thus broadening is possible. As a growing group of like-minded change agents, they can form a powerful tool for scaling up. MCNV (chapters 7 and 8) aimed at scaling up and was successful in both the TB and CBR case. Broadening and scaling up

were framed as an extension of learning in the niche and linking niches, with similar actors, in different localities. As an example, the CBR program linked health interventions to educational interventions, and repeated experiments in multiple districts. Furthermore, the MCNV kept addressing old and new possibilities and threats. For instance, in phases of stabilization of the TB system, when other actors were more concerned with stabilization, they pressed for addressing long-standing threats in the system (e.g. HIV-TB, MDR-TB and hard to reach groups). The MCNV kept track of what we call a dynamic learning agenda (Regeer, 2009).

As part of their scaling up strategy, MCNV did not aim to radically change structures or set up many new structures, but rather to shift the thinking and use of already existing structures: purposefully choosing a pathway of adaptation through participation with public health providers and end-users at all levels. Part of the scaling up strategy was massive capacity development, of both health providers and leaders in the programs (PhDs, MScs). In order to manage the change process, the MCNV chose a slow and stepwise approach to allow for cycles of learning and adaptation. This requires long-term commitment to the programs: the MCNV has participated in both programs for over 15 years. The long-term participation facilitated coalition building at all levels, both horizontally⁶⁰ and vertically. At the grassroots level, health professionals and end-users were part of a horizontal network (e.g. PWDs in commune CBR steering committees), and built coalitions (alignment) with various regime players (network of technical support groups to support the CBR system). Participatory learning and planning was helpful to induce action, but also formed a platform for frame reflection in which actors mutually made plans and formulated new ambitions (e.g. as described above with the 'fishermen pill'). Together, they learned about the changes needed and adapted regime structures. For example, formulating legal frameworks, institutionalized bottom-up planning to allow for needs-oriented planning (TB case), and shifted tasks from village health workers to the families in CBR to make the programs work.

The MCNV and the EXTRA program never used the rhetoric of the regime vs. the niche, neither did they propagate *radical* change. This was purposefully done to get and keep everyone on board.⁶¹ In table 10.1, we present a summary of how change agents organize deepening, broadening and scaling up in the cases we described with respect to multi-stakeholder networks, learning (first-order) and frame reflection (second-order learning) and building in reflexive cycles of learning.

⁶⁰ The personal relationships, based on friendship, shared norms and values, and reciprocity, were constantly referred to as a facilitator of change in the TB and CBR cases.

⁶¹ In informal conversations with many NGOs and CSOs, the term regime was offensive. They recognized resistance to change, but felt that when one needed to align for change, such revolutionary language as *radical* and *regime* may be counterproductive.

Table 10.1: Deepening, broadening, scaling up and transdisciplinary approaches.

As found in our cases	Deepening	Broadening	Scaling up
Multi-actor networks <i>This is necessary to start innovation processes in which mutual, participatory knowledge production can take place. It forms a dynamic skeleton of the change process and a robust network of implementation later</i>	<ul style="list-style-type: none"> - Consists of small core of innovators that share an idea, vision and urgency for change; and a larger contextual network - Mostly a combination of regime actors and change agents, and end-users - Allow for participatory knowledge production - Create an initial space for experimentation 	<ul style="list-style-type: none"> - Consists of similar actors as in deepening, but in a variety of contexts / experiments - Change agents increasingly link up with other regime actors - Expanding the network is mainly done by communicating proof-of-principle - Facilitated through already existing networks 	<ul style="list-style-type: none"> - Increasingly more regime players are drawn in (associated regimes e.g. financial / educational) - Facilitated through standardizing procedures, already existing networks, proof-of-principle and shared sense of urgency
	Expanding network with increasingly more regime players, and actors who can practise in deviant system structures - from horizontal to more vertical networks		
Learning (first-order learning) <i>Learning to establish proof-of-principle (on innovations and new cultures, structures and practices)</i>	<ul style="list-style-type: none"> - Learning from desk studies, acquire (global) knowledge and insights - Participatory learning by doing about problems and solutions and societal challenges - Conduct scientific research - Monitor learning and change - Learn about needed competences and structures (CSP) 	<ul style="list-style-type: none"> - Participatory learning by doing and - Repeat learning in new contexts - Learning about linking experiments to existing structures - Learn about linking (regime) contexts and experiment 	<ul style="list-style-type: none"> - Participatory learning by doing - Learn about: a model for scale up; institutionalizing change (policy formulation); needed supporting structures (financial / educational); how to balance system-wide capacities and structures
	Continue with small incremental steps for improvement along the way, gradually shift weight of learning from the niche to standardization/institutionalization		
Frame reflection (second-order)	<ul style="list-style-type: none"> - Often change agents already had 	<ul style="list-style-type: none"> - New actors that may not share the 	<ul style="list-style-type: none"> - Learn how to induce system-

<p>learning) <i>This deals with the needed shifts in thinking of actors; different paradigms or cultures in systems.</i></p>	<p>different perspectives on reality</p> <ul style="list-style-type: none"> - Communicate visions, train actors, or show by doing, to bring about frame reflection - Communicate urgency 	<p>initial vision and enthusiasm have to be drawn in</p> <ul style="list-style-type: none"> - Participatory planning (and visioning), capacity building with focus on attitude change - Demonstrate proof-of-principle 	<p>wide paradigm shifts</p> <ul style="list-style-type: none"> - Massive capacity training - Generate overwhelming proof-of-principle - Slow cycles, not imposing, helps
<p>In niches, relatively easy (deliberation with like-minded actors), increasingly frame reflection needs to be organized through communicating proof-of-principle, and competence building</p>			
<p>Reflexive cycles <i>Implementation of change processes through reflexive learning cycles of planning, action, observation, reflection and re-planning.</i></p>	<ul style="list-style-type: none"> - Reflexive learning cycles to optimize interventions, and to alter interventions; <i>reflexive monitoring. Dynamic learning agenda</i> - To adapt interventions to target groups 	<ul style="list-style-type: none"> - Go back and forth between learning in niches - Back and forth to connect multiple niches. (Go back and forth to learn from regime barriers) 	<ul style="list-style-type: none"> - Go back and forth between understanding regime barriers and adapting them - Go back and forth between standardization and flexibility in the niche
<p>Going back and forth between standardization of CSP and flexibility in the niche</p>			
<p>Alignment <i>This serves to connect actors, activities and levels. Alignment is about engaging and understanding dynamics</i></p>	<ul style="list-style-type: none"> - Alignment between visions, actors and change process - Alignment between niches and the landscape 	<ul style="list-style-type: none"> - Alignment between niches in various context (repeating) - Alignment of niches of various purpose (linking) 	<ul style="list-style-type: none"> - Alignment between niche solutions and regime standardization - Vertical alignment between actors.
<p>Horizontal and vertical alignment of agency, of structure, and alignment of agency and structure (within niches, between niches and between niches and regime)</p>			

A note on balancing the dimensions of change

From the cases described in this thesis and from our experience in transition research (Broerse et al., 2010), learning in niche experiments predominately focuses on learning about which changes in *structures* are required and what new *competences* professionals and others need in order to implement the new model or health service. This conceptualization of the change process has many similarities with the description of system change as put forward in transition theory, as a fundamental change of dominant structure (organizing), culture (thinking) and practice (doing) (Rotmans et al., 2001). But a primary focus on changing

competences (the knowledge, skills and attitudes of the professionals' active in the structures) – rather than on changing cultures and practices – may be of added value in the management of broadening and scaling up. Changing competences can be actively moulded by lifelong training and may subsequently lead to the ability to perform different practices as well as to changing perspectives on the system itself and the functions performed by it. The cases presented in the thesis show that – in the process of deepening – learning about required changes in structure and competences is important. At the same time, this is often done naturally in these niches. For example, the neighbourhood care project (the neighbourhood nurse teams, chapter 6) showed that nurses need to have particular competences to work autonomously in small teams. And in the Vietnam cases, most learning was done to understand which structures needed to change and who needed which capacities. Sometimes these capacities were trained as part of the deepening in the niche, namely capacity training for deepening.

Furthermore, changes in structure and competences probably need to be developed simultaneously in order to prevent lock-in or backlash. This was clearly apparent from the CBR case where structures were changed after an initial reconstitution by the government, but hardly any effort was put into training the competences of actors who had to work with these new structures. This resulted in a (temporary) backlash of the system. Similarly, we see that the EXTRA program actors have gained competences to think differently about knowledge production but the surrounding structures have hardly changed. Actors are expected to work on changing these structures, but lock-in, or maybe even backlash, is likely to occur unless due attention is paid to adjusting structures so that professionals can fully use their new competences.

It was noted in cases that we analyzed elsewhere (Broerse et al., 2010) that lack of competences is particularly constraining for broadening and scaling up of the experiments. These findings seem to indicate that broadening and scaling up require the right balance between the change processes affecting structures and competences, in addition to the identification of a new set of culture, structure and practice, in order to prevent lock-in and backlash. In chapters 7 and 8, in both Vietnam cases, we found that balancing changes in competences and structures proved instrumental in scaling up DOTS and CBR structures. However, this issue of balancing competences and structure needs to be investigated further in transition research.

In figure 10.1 we depict how this balancing of competences relates to the governance of sustainable system innovations; balancing transdisciplinarity and non-structures; and balancing system-wide competences and structures. Furthermore, there is a need for balancing experimentation and standardization. The change process in the figure below is not linear.

Ideally, there is constant agency in quadrant 1 and 2, and this requires constant cycles of reflexive learning (plan, act, revise, plan, etc.). This figure distinguishes four quadrants:

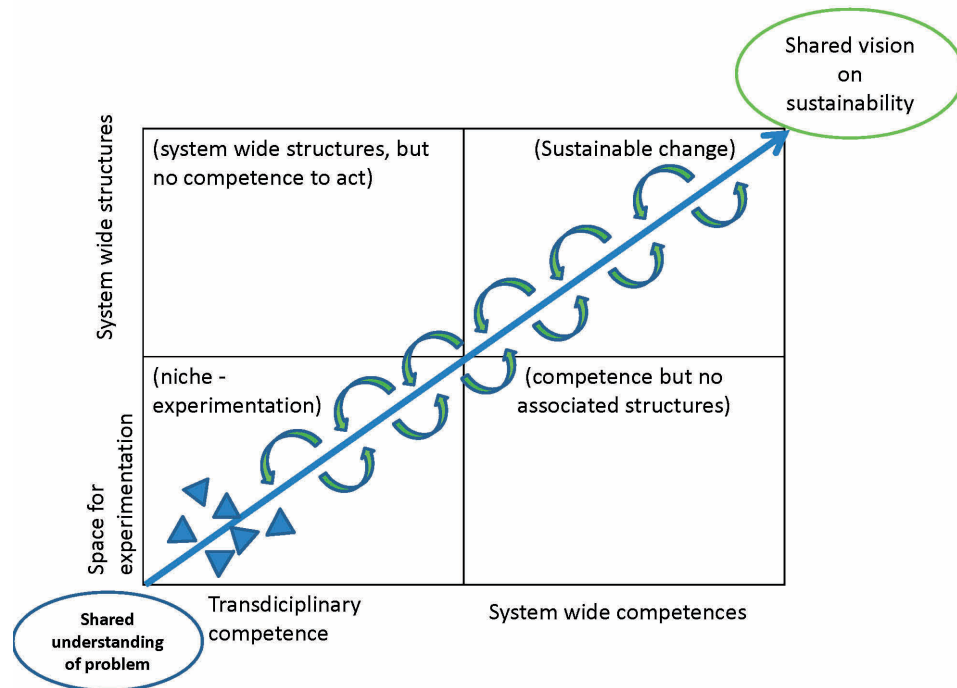


Figure 10.1: Balancing the dimensions of change: Transdisciplinarity and non-structure for reflexive learning and experimentation, system-wide standardized competences and structures for stabilizing change.

- 1 **Niche experimentation:** In this quadrant, the change process focuses on learning in niches directed towards a vision on sustainability. This requires transdisciplinary competences and space to acquire proof-of-principle on novel sets of cultures, structures and practices (*or competences and structures*). This quadrant has a primary focus on deepening and broadening, but also learning about scaling up and involvement of regime players.
- 2 **Sustainable change:** The change process in this quadrant focuses on scaling up and standardization. Here system-wide structures (building new, adapt existing, and link to existing structures) and associated competences need to be developed. Proper translation of niche developments is required.
- 3 **System-wide structures and no competence:** This represents a misalignment between the structures that are in place, and no competences to practise within these structures,

as described above. This may lead to lock-in or backlash. Top-down reforms are prone to this. However, it is not unlikely that the change processes will get back on track, moving from this quadrant to quadrant 1 or 2.

- 4 **System-wide competence and no structures:** In contrast to quadrant 3, there are no appropriate structures in which to practise competences in. This may lead to lock-in or backlash, and change process that fail to adjust structures in regimes are prone to this. However, it is not unlikely that the change processes will get back on track, moving from this quadrant to quadrant 1 or 2.

Typology of change agents in system innovation

We came across a wide variety of change agents in this research; change agents that were generally only active at the niche level (e.g. CSOs, or EXTRA fellow), change agents that worked on the intersection of the niche and regime (e.g. the MCNV and the EXTRA program), and change agents that were part of the regime and largely remained restricted to the regime (e.g. the government of Vietnam, that aimed to induce change in the CBR constellation - 1987). Furthermore, change activities either emerged relatively independent from regime interference, or were purposefully induced (top-down) by the power holders in the regime. Based on these observations, and in the awareness that we need 'radical' niche activity and regime change, we suggest a typology of change agents for system innovation. This typology is based on two features: (1) the extent to which the activities of change agents are induced by regime actors (high/low) and (2) the degree of focus on the change agent, towards the niche or the regime.

When we refer to regime induced change, this means that change activities are induced by power holders in the regime. This power holder can be the government or other organizations, such as insurance companies or a hospital. Regime-induced change agents have formal legitimacy and formal support from the regime in system innovation processes. At the same time, this makes them less likely to escape the reproductive nature of the regime. In contrast, low regime-induced (vision induced) change activities probably face more resistance and less support from regimes but are more likely to evade the reproductive nature of the regime and be able to propagate novel cultures, structures and practices. Their legitimacy is largely determined by the recognition of the social values they pursue. The focus of change can be geared towards (changing) the regime (directly), or on (experimenting in) the niche, while change can focus on both sides of the spectrum: going back and forth between niche and regime (alignment). The focus and the extent to which the change process is regime induced are two continuous features because it is, for instance, unlikely that a niche change agent has no focus whatsoever on the regime; or a change agent may acquire regime support (subsidy), but induces change also from the perspective of a vision. We hypothesise that the combination

of these two features lead to 6 types of sustainable system innovation change agents, namely the *authentic niche agent*, the *induced niche agent*, the *independent facilitator*, the *formal facilitator*, the *top-down agent* and the *advocacy agent* (see figure 10.2) which we will describe in more detail below.

The authentic niche agent: This change agent focuses on experimenting (deepening) in the niche for the purpose of realizing a vision. These change agents do not focus on regime change (scaling up). Activities of authentic agents are self-induced, emerging from a vision. It is likely that such change agents are able to evade the reproductive nature of the regime, but may have limited institutional support for deepening. From a governance perspective, authentic niche agents are of interest as they are likely to develop truly novel cultures, structures and practices in the niche. However, niche regime alignment may be difficult to establish. Many of the CSOs described in chapter 6 fit in this category; most had little regime interference and primarily initiated change from the perspective of perceived need, and expected others to *pull* their innovations to system level. We hypothesize that grassroots NGOs and (for-profit) social entrepreneurs generally fit this category.

The induced niche agent: This type of change agent is geared towards experimenting (deepening) in the niche and is induced by the regime⁶², with the purpose of developing best practices and inducing system-wide change. Induced niche agents do not focus on scaling up. The regime connection offers the institutional space to change but, at the same time, this connection may keep them locked in to the reproductive cycle of the regime⁶³. From a governance perspective, these change agents are a tool for regime actors to induce change and learn from these attempts. The regime can provide induced niche agents with space and resources to develop new cultures and structures. The fellows in the EXTRA program are a good example of such change agents; they have been induced by the regime but work only marginally on regime alignment themselves.

The independent facilitator: These change agents focus on the niche *and* regime to bring a vision to life, system-wide. Their role is mainly to go back and forth between facilitating the development of new cultures, structures and practices, and link them to the regime, actively searching for alignment between the two. These organizations are (legally and financially) independent from the regime, and can therefore pursue system change from their own perspective. From a governance perspective, independent facilitators are interesting as they may have strong grassroots connections and are likely to pursue novel cultures, structures and

⁶² The extent to which change is induced by the regime may vary. Niche agents can be actively engaged by the regime to change, whether they want to or not (e.g. home-care organizations that have to develop 'cheaper' interventions), but change agents can also be induced by the regime that offers subsidies for change in a particular area. This gives authentic change agents the ability to join regime induced change.

⁶³ This was also put forward by Grin (2010) who explains that regime induced niche activities makes it difficult to develop truly new perspectives.

practices. But their effectiveness is highly dependent on whether they have access to the actors in (higher) constellation regime: e.g. policy making. The MCNV is an excellent example of such an organization that pursues its *vision*, constantly going back and forth between deepening, broadening and scaling up. The potential of NGOs to fulfil such a role in the context of social development has been put forward by Uvin et al. (1995 and 2000) and Korten (1990). In the Dutch healthcare system, patient organizations are increasingly taking up a role of facilitator change agent (see e.g. Elberse, 2012)

The formal facilitator: This type of change agent shares similarities with the independent facilitator and has a similar focus on alignment between niche and regime. Such agents are induced by the regime and have formal (legal, financial) connections to the regime. They are primarily a tool of regime actors to induce niche activity and align this with the regime, and they can therefore be excellent in informing the regime about what structures need to change. Their potential drawback is that they are too confined by their regime affiliations to develop *truly* novel cultures, structures and practices. For instance, the CHSRF and its EXTRA program are examples of formal facilitators. They were capable of initiating change but the niche activities that they promoted had a focus on incremental change. The Dutch Transition Platform Long-term Care (TPLZ) is also an example of such a change agent. This program was set up by the Dutch Ministry of Health, Welfare and Sports in association with a research institute and an accountancy business to induce niche innovation and facilitate niche-regime interactions (see e.g. van den Bosch, 2010).

The top-down agent: Power holders in the regime itself can work on change without interacting with niches. This type of change agent is typically governmental (or large international organizations, such as the WHO) and has the (democratic) mandate to induce change. It primarily functions to standardize change and provide sufficient room for change. These agents have strong formal power to induce system-wide change through reconstellation but can also induce change more tentatively by, for example, developing a vision on change (chapter 4). The top-down reconstellation of the disability support system in Vietnam in 1987 (ten years before MCNV involvement) is a clear example of the government as a top-down change agent, with little to no niche interaction.

The advocacy agent: In our research we did not come across a change agent that was independent of the regime and which focussed their change activities on the regime. However, we hypothesize that causal pressure groups (Buse et al., 2008) can be such advocacy groups that advocate for change independent of the regime, without conducting niche experimentation. For instance, Health Action International is such an organization that advocates for radical change of the global pharmaceutical sector, aiming to change policies to increase access to medicines, without conducting niche experimentation.

Regime induced change	High	<i>The induced niche agent</i> (e.g. EXTRA fellows chapter 9)	<i>The formal facilitator</i> (e.g. EXTRA program, chapter 9)	<i>The top-down agent</i> (e.g. Government, chapter 8)
	Low	<i>The authentic niche agent</i> (e.g. CSOs, chapter 6)	<i>The independent facilitator</i> (e.g. MCNV, chapter, 7 and 8)	<i>The advocacy agent</i> (not in this research)
		← Niche	Niche/Regime	Regime →
Focus of change activity				

Figure 10.2: Typology of change agents in the context of system innovation, based on whether they are induced by the regime or self induced, and the focus of their change activity.

Assuming that system innovation is largely a bottom-up/top-down phenomenon, the facilitators are the most interesting from the perspective of system innovation. They have one foot in the niche, and another in the regime, and can go back and forth between niches and regimes. The MCNV was very successful at this, and the EXTRA program showed potential in this regard. Moreover, the CSOs in chapter 6 generally argued that they need facilitators to scale up experiments. Grin (2010, p274) also noted that facilitators conducting activities at the intersection of the niche and regime are needed: ‘Processes of system innovation may obviously be facilitated by a third type of activities [besides niche and regime] located in between the two and seeking to connect the two’.⁶⁴ It is unlikely that change agents can induce system innovation on their own. The state, society and the market (although not discussed in this paper), all have a role in participatory change efforts. This was apparent in the TB case where an iron triangle between MCNV, KNCV and NTP facilitated the change process.

A note on training of change agents

In one of our cases, the EXTRA program (chapter 9), change agents were specifically trained to induce change. This is of specific interest as we have already demonstrated that competences are an important dimension for change. This was the rationale to train fellows in the EXTRA program in competences for experimentation *and* systems thinking. A number of the EXTRA fellows brought about change, albeit minor, in their organizations. Moreover, they also felt part of a larger group of change agents. In the Vietnam cases, a success factor for facilitating change was training leaders in the program (MScs and PhDs) who further pushed for change. Based on the above, we argue that it can be worthwhile to train change agents to induce

⁶⁴ Boon (2008) also refers to intermediary change agents to bring about change.

system innovation. In system innovation, most programs focus on identifying change agents and guiding their experiments. We argue that similar programs can also be set up with a specific emphasis on training these agents.

We hypothesise that training competences should focus on knowledge, attitudes and skills required for transdisciplinary approaches. And the change agents requiring these competences can be found at the niche level – to create knowledge – as well as the regime level – to assess and facilitate this kind of knowledge production. Transdisciplinarity is needed for niche innovation, broadening and scaling up. Besides training change agents, we also found a need for training for standardisation. Both these types of learning have been put forward by Freire (1970, p16). He explains that we need two types of learning: education as an instrument for standardization (integrating in systems) and education for transformation (transdisciplinarity).

"Education either functions as an instrument which is used to facilitate the integration of generations into the logic of the present system and bring about conformity to it, or it becomes the 'practice of freedom', the means by which men and women deal critically with reality and discover how to participate in the transformation of their world."

10.5. Lessons learned and main conclusions

In this thesis we have gained insights into the role of change agents in processes of system innovation towards sustainable health systems, using system innovation theory. In this section, we summarize the main conclusions and lessons learned from this research (see box 10.2). System innovation is useful in studying health systems change because of the combination of bottom-up and top-down activities and the explicit focus on sustainable (value-driven change) and radical change (new cultures, structures and practices) to break the reproductive cycle of systems. We demonstrated how sustainable development can be used as a guiding vision in health system reform, how we can structure persistent problems and how system innovation theory is useful to describe change processes. In particular, the constellation perspective provides insights into how and where persistent problems originate and how we can understand their reproductive nature. Moreover, it is helpful to elucidate how interventions, as newly formed constellations, scale up to 'integrate' in health systems.

We therefore emphasize that system innovation theory is useful in analyzing and understanding processes of health system innovation towards sustainable health systems and conclude that the conceptualization of health systems (chapter 2) is meaningful: *Health systems can be conceptualized as an open, complex, adaptive system with the socially embedded goal to fulfil a societal need. It comprises a patchwork of dominant regimes that are characterized by their specific cultures, structures and practices. The social system is open, and competing regimes and niches can be present at any time in which actors deal with the*

system's functioning differently. Based on this health system, innovation is conceptualized as the fundamental change of cultures, structures and practices in health systems, contributing to sustainability.

Our research has provided valuable insights into the role of change agents in these processes of system innovation. However, we can give no simple, unequivocal answer concerning how change agents can contribute to sustainable system innovation. We demonstrated the success, potential and pitfalls of value-driven, assertive change agents in processes that deal with system innovation; meaning changing the thinking and organising in systems. Although our findings are mainly analytical⁶⁵, we hypothesize that these can be translated to prescriptive for the management of system innovation. It is crucial that change agents adopt transdisciplinary approaches throughout phases of deepening to scaling up and go back and forth between (shared) visioning and problem solving, experimentation and deliberation, learning and doing, innovation and standardization, competences and structures, to contribute to system innovation. In addition building competences for change can be a useful addition to the system innovation toolbox.

However, not all change agents have the ambition to go back-and-forth between niche experimentation and structural change. This role is increasingly taken on by what we call facilitator change agents. These change agents have the specific ambition to contribute to sustainable health system innovation, and they have been successful in the cases that we described⁶⁶.

In box 10.2 we have summarized the main lessons and conclusions from this research.

Box 10.2 Main conclusions and lessons learned

- The insights from system innovation studies are useful to describe health systems and their change process: The conceptualization of health systems and health system innovation that we formulated in chapter 2 is constructive: *Health systems can be conceptualized as an open, complex, adaptive systems with the socially embedded goal to fulfil a societal need. This system comprises a patchwork of dominant regimes that are characterized by their specific cultures, structures and practices. The social system is open, and competing regimes and niches can be present at any time in which actors deal with the system's functioning. Health system innovation is conceptualized as the fundamental change of cultures, structures and practices in health systems, contributing to sustainability.*
- The constellation perspective was particularly helpful to elucidate processes of system innovation and the agency of actors within them. A constellation can settle within the regime, between other constellations, and alter the systems configuration. This perspective gave new

⁶⁵ Our insights on P-ILA (chapter 5) do give clear prescriptive insights on a problem structuring process in the context of system innovation.

⁶⁶ This is similar to Grin (2010, p274). *“going back and forth between adapting structure and deliberative processes of reflexive design [that] may lead to experimentation without closure.”*

insights in the scale up or 'integration' of non-compatible interventions, which require new cultures, structures and practices, in the health system.

- Sustainability in health systems can be conceptualized as a system that rests on its constituent values. Sustainability as a guiding vision in health system change can be conceptualized as follows: (1) identification and analysis of the persistent problems within the health system that lead to urgency for change; (2) formulation of a limited set of shared core values through a broad participatory process; (3) an explicit focus on balancing these values; and (4) anticipation beyond generations by addressing the need for healthcare in the present and the future. Shared visions on sustainability can be developed through deliberative and consultative methods. The outcome of such a process can be used to back-cast a change agenda, and mobilize actors for shared, value driven change.
- Persistent problems can be framed in terms of *stress* within constellations, *pressure* between constellations and *tension* between constellations and the landscape, and can be unravelled through deliberative governance strategies (e.g. P-ILA). The outcome of such a process can be used for forecasting change; policymaking in the wake of infinite complexity.
- In this study, it appeared that health system change often comes about through pathways of adaptation: *self change of regimes*.
- Like any social system, health systems have an inherent pressure to standardize (stabilize) a certain level of quality and access for citizens. Therefore, health system innovation probably always needs to deal with the inherent contradiction between standardization and reflexivity.
- Change agents in health system innovation conduct change activities from a value-based perspective, they dare to take initiatives and are committed.
- Successful strategies from deepening to scaling up involve: long-term commitment, transdisciplinary approaches, building multi-actor *participatory* networks, a focus on learning by doing, alignment of activities and levels, and developing proof-of-principle. Alignment is important within niches, between niches, between niches and regimes, and between regimes and niches, to facilitate the ongoing change process.
- There is a clear need for balancing competences and structures when developing niche innovations and when scaling up.
- Competence/capacity building is an interesting addition to the system innovation toolbox: for niche experimentation, capacity building should focus on transdisciplinary approaches, both for niche change agents as well as for regime change agents that have to make decisions on which structures to change. Capacity building for standardization (life-long learning) is important to stabilize systems.
- There is a need for a diversity of change agents that all have a different relevance from the perspective of the governance of system innovation. These can be divided on the basis of their focus (niche, niche/regime, or regime) and the origin of their activity (regime induced, or independent)
- We hypothesize that the facilitating change agents are the most interesting ones for system innovation as they have the flexibility to go back and forth between innovation and adjusting structures in the regime. In addition, active engagement of niche change agents may make it possible to capitalize on the numerous promising niche innovations.

10.6. Research validity

In this section, issues regarding the internal and external validity of the research findings are discussed.

Internal validity

Researcher bias is a pertinent issue in any case study research, and even more so when some of the authors were part of the implementation team of the projects we investigated. For instance, in the case of the Dutch pharmaceutical care system, the researchers had also been commissioned to conduct the problem structuring. This provided an excellent opportunity for research but means that the researchers are judging their own work. In other cases, we conducted inquiries into best practices which may have created a bias towards finding the results we wanted.

Nonetheless, we consider that researcher bias was minimized in this research, as the strategies to ensure validity (see chapter 3) worked out well. In most case studies, we presented rich data from various respondents and various methods (interviews, desk study, and focus group discussions). Through triangulation we validated data; the cycles of desk study, interviews, desk study and interviews created a certain intrinsic validation method in data collection. Moreover, the interviewees were involved in checking their own validated data. Also, the involvement of key stakeholders who reflected on our analysis (either written feedback or in focus groups) further increased the rigour of our findings. For example, the CSO respondents interviewed (in chapter 6) were sent a verbatim transcript of interviews for checking. Afterwards, we invited respondents for a reflexive workshop on the integrated findings, the results of which were again validated by those involved.

This study also ran the risk of respondent bias in the interviews and focus groups. As our primary data sources were the change agents, they may have been overly positive about their own roles, and perhaps critical of the role of those opposing change. Respondent bias was most likely to occur in the Vietnam cases, where we specifically aimed to describe best practices. We minimized respondent bias by thorough archival analysis of the projects (spanning 30 years for the TB project and 15 years for the CBR project) and the international literature. This allowed the researchers to address these documents in interviews when inconsistencies were observed. Also, colleagues who were not involved in the project were invited to reflect on our analyses. In all cases data saturation was reached.

Furthermore, we aimed to avoid selection bias by including a diverse range of case studies. In retrospect it became apparent that we did not include a case study involving an advocacy change agent, which, according to our hypothesis can be a relevant change agent (see section 10.4). This would be an interesting topic for further research.

External validity

Taking into account the usual limitations of cases studies with respect to generalization (see e.g. Yin, 2009, p43), generalization based on cross-case comparison was feasible in this research. We argue that similar findings on the role of change agents can be observed across cases, e.g. the need for value-driven guiding visions, the use of transdisciplinary approaches, and the need for competence building. Similarly, we found that system innovation theory was applicable to different cases. Interestingly, cross-cutting findings were made despite the large variety between cases, addressing different problems with different change agents in different contexts.

Furthermore, our findings are well supported by findings in the literature. In both the system innovation and health systems research field we found findings that complemented our conclusions. For example, there is a marked need for competence building to facilitate health system change. This is hardly discussed in the system innovation discourse.⁶⁷ However, capacity building is seen in the health systems research field as a long-standing key strategy for change (WHO, 2007; Eade, 1997; Korten, 1987). We also provide insights into similarities between our findings and theories on the governance of system innovation. For instance, the types of change agents that we described relate well to the type 1, 2 and 3 planning approaches described by Grin (2010; chapter 2 of this book). Nevertheless, more research has to be conducted to allow for (grand-theoretical) generalizations.

10.7. Future research

The research described in this thesis opens up a range of questions for future research on how change comes about in health systems and how we can govern this change. Here we will highlight a few. We stress that there is a need for retrospective studies to be able to analyze the change process over long time-frames (>20 years), as well as contemporary action studies into the management of long-term change to develop and test tools for system innovation management.

Understanding the process of (health) system change: Any system has a need for standardizing practices to increase certainty and improve efficiency. However, the phase of stabilization is hardly addressed in most system innovation literature which was predominantly developed to escape the reproductive nature of standardized systems. Retrospective case studies into (health) systems innovation, with a focus on phases of stabilization and radical change, could

⁶⁷ In the system innovation discourse they do stress that change agents should have a certain set of competences: transdisciplinary skills, daring, creativity, etc. (Loorbach, 2007; van den Bosch, 2010). This is very similar to what we found was needed for change agents: value-driven, commitment, dare to act and transdisciplinary skills.

increase our insights into how we can manage reflexive cycles of standardization and flexibility. From this, we learn how to keep systems dynamic and escape lock-in and backlash. These studies need long (>20 years) to very long time frames to cover multiple cycles of transitions. Related to the above, other retrospective cases could focus on the hypothesis that the health system tends to choose pathways of adaptation for change, since such pathways may inhibit 'radical' change and lead to 'lock-in'.

Understanding the governance of change: The empirical research in this thesis has mainly focussed on retrospective cases and thus did not actively deal with the management of long-term transitions. It is vital that we try to conduct research into the long-term management of these processes, and investigate whether the insights acquired during this thesis research represent significant prescriptive tools. Most of the research in managing contemporary system innovation processes is undertaken with a focus on niche experiments (e.g. van den Bosch, 2010; Hoes, 2010; Regeer, 2009), while there has been relatively little prescriptive research on the management of scaling up these experiments. Based on our findings, we hypothesize (similar to e.g. Grin, 2010) that the success of scaling up relevant experiments depends mainly on the alignment strategies between niches and regimes, and vice versa. In addition, research is needed on how change agents can benefit from monitoring and evaluation techniques developed to guide niche experiments towards scaling up and aligning with regime players. Furthermore, the role of intermediary organizations as change agents is pertinent in this field; research can focus on prescriptives for facilitator organizations as change agents in health system innovation. The central theme would then be how to manage constant cycles of reflexivity and standardization, and to capitalize on already existing niche activity and capacity. In this way, we build further on what van den Bosch (2010) calls the transformation of niche experiments: how to support these experiments and how to align with regimes.

Understanding the role of capacity-building for system innovation: One important insight of this thesis was the role of capacity-building for system innovations. We argue that this is a relevant governance tool and therefore is an important subject of research, including research questions such as how we can train various actors to acquire transdisciplinary skills for deepening, broadening and scaling up, and how we can balance competences and structures while innovating. One experiment could involve setting up a similar program as the EXTRA program (chapter 9) with a more explicit emphasis on training transdisciplinary approaches, and long-term monitoring of the experiments conducted by trained agents. From this, we can increase our learning about how to manage the experiments of trained change agents.

The role of change agents in system innovation: The conduct of more historical case studies could further increase our insight into how change agents can contribute to change and further elaborate on types of change agents. This research could also provide insights into how the lessons learned from such studies can be utilized as management tools for change agents. Interesting work has been done in the field of development research (e.g. Korten, 1990; Buse,

2006), but little research has been conducted to develop heuristics for change agents in health system innovation.

Final remarks

Policymakers, politicians, scientists, managers, health professionals, patients, civil society organizations and other actors can learn from this research that in order to realize health system innovation towards more sustainable health systems, we need to balance reflexivity of change agents and *standardization* within the scope of core values that we wish to maintain through experimentation and deliberation. *Change agents* are flexible and assertive, and have the capacity for realizing new cultures, structures and practices through constant cycles of deliberation and experimentation. The quintessence is that we - learn how to – go back and forth between, (shared) visioning and problem solving, learning and doing, innovation and standardization, competences and structures. In doing so, we may direct the evolutionary process in social systems, and health systems in particular and progress towards sustainable societal goals. We say 'progress', and not 'reach', as inherent to this thinking, we cannot fully control or steer these processes, and there will always be new challenges on our way to *health for all*.

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Summary

Worldwide, there is growing concern about whether we can sustain or even attain a desirable balance between the values in our health systems. In both high- and low-income countries, there are numerous dynamics that seem to jeopardize the short- and long-term sustainability of our health systems relating to accessibility, acceptability, affordability and quality. In high-income countries, these problems mainly concern the ever-rising costs of health care which have long outpaced economic growth. The increasing costs for care were acceptable when the return on investment – *more health* – was substantial. However, there appears to be a diminishing return on investment. Health systems in low- and middle-income countries face different problems as they generally fall short of providing universal, equitable, appropriate and high-quality services. These countries increasingly face a so-called double burden of disease where both communicable (infectious) and non-communicable (chronic) diseases are affecting the health of many who do not have access to adequate care services. This has gained increasing attention as ‘weak’ health systems have been labelled one of the main causes for not achieving the health-specific Millennium Development Goals. The characteristics of these weak health systems are lack of skilled personnel, poor facilities, inability to mobilize resources, and weak governance structures.

Conventional solutions to the problems facing health systems have not always led to the desired effects. Top-down reforms have been largely unable to curb costs while simultaneously maintaining or improving the quality of care in health systems, and have had unforeseen effects (often adverse). Bottom-up interventions have often failed to scale up and have therefore had limited system-wide effects. Several scholars, policymakers and health professionals have suggested that we have been looking at the wrong problems and finding the wrong solutions. These scholars argue that conventional approaches to health system change do not offer adequate governance and management heuristics. Or, as stated by Flier in 2009, “*without a correct diagnosis there is no cure*”.

In this PhD-research we turn to the field of *system innovation* and *transition theory*, with the intention to provide novel insights in how we may go about changing our health systems. This novel field offers interesting governance approaches that deal with system change towards more sustainable systems. ‘System innovation’ (or ‘transitions’) can be defined as long-term processes of fundamental change of societal (sub)systems. These processes are often initiated and ‘steered’ by *change agents*, individuals or organizations that have a strong sense of the necessity to approach societal needs from a different perspective. In this thesis we have an explicit focus on non-governmental organizations and governments, as change agents, in processes of system innovation.

Specifically, the aim of this study is to *gain insight into the way change agents may facilitate health system innovation towards more sustainable health systems, in order to contribute to the improvement of approaches for progressing towards such systems.*

Theoretical background

A health system is conceptualized as an open complex adaptive system, encompassing many different actors and organisations, with the goal to fulfil a societal need. It comprises a patchwork of dominant regimes that are characterized by their specific cultures, structures and practices. The composition of these constellations relates to their embedded Culture (thinking), Structure (organising) and Practice (doing): CSP. In contrast to optimization of dominant culture, structure and practice, (sub)system innovation implies a radical change of these features towards a new equilibrium: CSP_0 to CSP_1 . These processes tend to take a generation or longer. The dominant CSP in (sub)systems is termed the regime, and is geared towards optimization and is rather resistant to radical change. In niches, relatively detached from regime practices, new deviant practices can be developed that can contribute to regime shifts. The exogenous environment of the regime, termed the landscape, may also pressure the regime and/or reinforce niches, to induce regime shifts.

Change agents can be active at regime level or at niche level, inducing change. Most strategies to induce system innovation are as yet ill explored, but from literature we abstracted three generic strategies for system innovation.

(1) Vision development (and scenario building): change agents aiming at change towards sustainable health systems, or scaling up non-compatible innovations, are expected to have a value-driven vision on a new equilibrium. A vision serves as a beacon for action and iteration, and thus deals with the direction for change.

(2) Problem structuring: system innovation is needed when a system cannot solve needs on the basis of its current CSP. Problem structuring can help in rationalizing the policy process within infinite complexity, helping in forecasting activities.

3: The management from niche experimentation to scale up: ultimately, there are many activities but developing actual alternative practices is key. It encompasses visioning and problem structuring as well as the three steering mechanisms: deepening, broadening, and scaling up.

The strategies for system innovations all appear to share that change agents use transdisciplinary approaches throughout the process, to learn and to act. Another crucial element for change agents is alignment of activities. These aspects, in relation to system innovation theory, are largely unexplored in the health system. For example, it raises the

questions of what is a vision on sustainable development in health systems. But, in system innovation theory, there are also aspects that need resolving, such as: the role of change agents in processes of system innovation.

Research design

Against the backdrop of the formulated objectives and the conceptual framework, the following main research question is formulated: *What can we learn from change agents' contributions in realizing system innovation in order to progress towards sustainable health systems?* In order to answer the central research question, four study questions were formulated. Which are further specified in the separate chapters.

1. *How may we operationalize the concept of sustainable development in the context of health system innovation towards more sustainable health systems?*
2. *How can we structure persistent problems in the health system?*
3. *How does health system change come about? With a specific focus on; regime shifts ($CSP_0 \rightarrow CSP_1$) and the scale up of non-compatible health interventions; pathways of change; phases of change*
4. *How do change agents contribute to processes of system innovation with respect to vision development, problem structuring, deepening, broadening and scaling up, the use of transdisciplinary research methods, alignment of niche and regime activities?*

In order to provide answers to the main question and sub questions we conducted a multiple case study analysis. Our principal units of analysis are (1) the system innovation we describe, and (2) the contributions of change agents who's activities we research. In total we selected six cases. Each case describes a study of the management of system innovation. One case focuses on sustainable development as a vision for system innovation, one case on the problem-structuring process, and four cases focus on niche experimentation with, and scale up of, novel cultures, structures and practices. It is expected that together these cases provide insights in our main research question. Data collection in all except one case followed the subsequent trajectory:

- Exploratory desk study and informal interviews to assess the relevance of the case for our research.
- A desk study of the scientific literature, followed by a desk study of available project documentation. Especially the latter was crucial in understanding what the system innovation was about and what the change agents did.
- Based on this knowledge, we collected data from respondents through interviews, group interviews and focus group discussions, or personal observation, to reflect on

findings from the literature and documents. A number of cases were excluded after this phase.

- Then we analyzed the data and formulated initial conclusions and generalization through deduction.
- Thereafter, another set of data was collected to verify our initial findings. This was done through a second series of interviews with key stakeholders (who were first made aware of the initial findings), reflective focus groups (workshops) with key stakeholders, having key stakeholders review and add to our analysis, and a specific analysis of the project documentation.
- Then we drew our conclusions and lessons from this in relation to the literature.

CASE STUDIES

In *section 2* of the book – which comprises chapters 4 to 9 – we elaborate on 6 cases studies in processes of system innovation.

In **chapter 4**, we further operationalized the concept of sustainable development in the context of the management of health system innovation. We did this through an analytical deduction of the concept and an empirical study into how sustainability was used as a vision to structure the health care reform in Canada. We argued that by lifting the formal structure and dynamics of the triple P bottom line concept from the original practice where it was formulated and developed, it might be possible to generalize the intrinsic function of sustainable development beyond the environmental context. We identified four central elements of a guiding vision for sustainable health systems: (1) identification and analysis of the persistent problems within the health system that lead to urgency for change; (2) formulation of a limited set of shared core values through a broad participatory process; (3) an explicit focus on balancing these values; and (4) anticipation beyond generations by addressing the need for healthcare in the present and the future. The Canadian example shows that such a vision can lead to concrete steps in the present.

In **chapter 5** we describe a problem structuring approach, that we call Policy Interactive Learning and Action (P-ILA), to unravel persistent (long-standing unstructured) problems in the Dutch pharmaceutical care system. P-ILA is a form of deliberative governance, using focus group discussions and interviews, which explicitly takes a system perspective. We conducted a case study into irrational drug use in the Dutch pharmaceutical care system. We distinguished six different sub-constellations and found that irrational drug use originates from strain within and between sub-constellations: e.g. diversity in cultures, driving values, structural power and authority conflicts. This results in the (re)production of irrational drug use; e.g. poor compliance, poor cooperation, and a general lack of shared responsibility to tackle the problem. We conclude that, as a tool in the management of system innovation, P-ILA and the

constellation perspective stand out as a method that allows for problem structuring, communication and policy implementation in the context of infinite complexity.

Chapter 6 addresses the role of Civil Society Organizations (CSOs) in bottom-up innovations in the Dutch home-care sector. We studied 14 innovations initiated by CSOs in the long-term care sector. Data shows CSOs are active in a variety of technological and social innovations. They envision a system that is more needs-oriented, and some CSOs also aim to strengthen social cohesion and envision a community-based health system. The innovative process was one of learning on the societal problem they aimed to tackle and on acquiring proof-of-principle. However, although CSOs conduct bottom-up innovations, they remain rather passive in scaling up their innovations and largely expect that successful innovations will simply diffuse. There is a need for other organizations to contribute in the processes of scaling up to induce system innovation, as it does not correspond to CSOs' role-perception.

In **chapter 7 and 8** we have a focus on the role of an NGO contributing to health system innovation in Vietnam. These two case studies provide insight into the role of NGOs in scaling up complex, non-compatible, interventions. In chapter 7 we describe a retrospective qualitative case study into the scale-up of the Directly Observed Treatment Short-Course strategy in Vietnam (1975-2010), to reduce the impact of tuberculosis. In chapter 8, in a similar case study, we focus on community-based rehabilitation (CBR) to innovate the disability support system in Vietnam (1987-2012). Our analysis shows how the NGO scaled up a cluster of CBR interventions (structure) and the associated mind-set (culture) in regions of Vietnam and currently contributes to scaling up CBR country-wide. We conclude that, to contribute successfully to scaling up non-compatible innovations, NGOs need to establish long-term (>15 years) partnerships, have a strong (value-driven) vision on change, focus on constant cycles of learning, and frame reflection, as well as balance changing capacities and structures to induce paradigm shifts. These cases show that transdisciplinary approaches and a system innovation framework may be constructive for the governance of experimentation and scale-up.

In **chapter 9** we discuss Canada's Executive Training for Research Application (EXTRA) program, which can in some ways be seen as a transition program *avant la lettre*. This program is a fellowship course to build capacity among leaders (physicians, nurse executives, managers) in the Canadian health system. The program contributes to the creation, application and contextualization of evidence that can be used by practitioners in their settings; in the EXTRA parlance, "a culture of Evidence-Informed Decision Making" (EIDM). The fellows have to attend training sessions for a period of 2 years and conduct their own intervention project (niche experiment). The program is fairly successful in training change agents to apply and generate evidence in their own settings and a committed group of change agents has been formed. We conclude that training competences for system innovation is an interesting addition to the toolbox of system innovation managers.

Conclusions

The thesis demonstrates the usefulness of applying system innovation and transition theory to the study of health systems change because of their combination of bottom-up and top-down activities and the explicit focus on long-term, sustainable (value-driven) and radical change (new cultures, structures and practices) to break the reproductive cycle of systems. In particular, the constellation perspective provides insights into the reproductive nature of systems. Moreover, it is helpful to elucidate how interventions, as newly formed constellations, scale up to 'integrate' in health systems.

Our research has provided insights into the role of change agents in these processes of system innovation. However, we can give no simple, unequivocal answer concerning how change agents can contribute to sustainable system innovation. We demonstrated the success, potential and pitfalls of value-driven, assertive change agents in processes that deal with re-structuration of systems; meaning changing the thinking and organising in systems. It is crucial that change agents adopt transdisciplinary approaches throughout phases of deepening to scaling up, and go back and forth between (shared) visioning and problem solving, experimentation and deliberation, learning and doing, innovation and standardization, competence and structures, to contribute to system innovation. However, not all change agents have the ambition to go back-and-forth between niche experimentation and regime re-structuration. This role is increasingly taken on by what we call facilitator change agents. These change agents have the specific ambition to contribute to sustainable health system innovation, and they have been successful in the cases that we described.

Samenvatting

Een gezondheidssysteem is het geheel aan organisaties, betrokkenen, bedrijven, regels, etc. die bijdragen aan de gezondheid van individuen en gemeenschappen. In toenemende mate staat de duurzaamheid van gezondheidssystemen ter discussie; de waarden die centraal staan in gezondheidssystemen, zoals toegankelijkheid, betaalbaarheid, wenselijkheid en kwaliteit, lijken niet langer houdbaar of zelfs niet haalbaar. In zowel hoge- als lage-inkomens-landen zijn tal van maatschappelijke trends die de korte en lange termijn duurzaamheid van gezondheidssystemen in gevaar brengen. In hoge inkomens-landen vormen de steeds toenemende kosten het grootste probleem; deze stijgen al decennia sneller dan de economische groei. Deze toenemende kosten waren acceptabel zolang deze een duidelijk profijt inhielden. Echter, het blijkt dat de grote extra investeringen niet leiden tot 'veel meer gezondheid'. Gezondheidssystemen in lage- en midden inkomens-landen hebben een geheel andere problematiek, aangezien deze er over het algemeen niet in slagen om adequate zorg universeel toegankelijk te maken. Deze problematiek heeft momentum onder de noemer 'zwakke gezondheidssystemen'. Karakteristieken van zulke 'zwakke gezondheidssystemen' zijn onder andere gebrek aan geschoold personeel, slechte medische faciliteiten, gebrek aan (financiële) middelen en zwak bestuur.

Conventionele oplossingen voor de beschreven problematiek hebben niet altijd het gewenste resultaat opgeleverd. *Top-down* veranderingen om de kosten te beperken hebben vaak niet geleid tot kostenvermindering en tegelijkertijd verbetering van de kwaliteit. *Bottom-up* interventies slagen er vaak niet in om op te schalen en hebben daardoor weinig impact, zelfs al zijn deze bewezen effectief op lokaal niveau. Wetenschappers, beleidsmakers en professionals in de gezondheidszorg opperen steeds vaker dat we verkeerd naar problemen kijken en dat daardoor het huidige veranderingsbeleid en bijbehorende heuristiek geen soelaas biedt. Zoals in de woorden van Flier, "zonder de juiste diagnose is er geen goede behandeling".

In dit promotie-onderzoek maken we gebruik van systeeminnovatie- en transitietheorie, met de assumptie dat deze theorieën nieuwe inzichten bieden in het managen van lange-termijn veranderingen in onze zorgsystemen. Dit nieuw wetenschapsveld houdt zich expliciet bezig met het beschrijven en 'sturen' van duurzame verandering. Systeeminnovaties kunnen worden gedefinieerd als processen van fundamentele veranderingen in maatschappelijke (sub) systemen. Deze processen worden geïnitieerd en bestuurd door 'change agents', individuen of organisaties die sterk het idee hebben dat maatschappelijke problemen een ander systeem vereisen om oplossingen mogelijk te maken. In deze dissertatie staan niet-gouvernementele organisaties (NGOs) en overheden centraal als change agents in systeeminnovatie.

Het doel van deze studie is het vergaren van inzicht in de rol van *change agents* in het faciliteren van innovatie in gezondheidssystemen met als doel bijdragen aan maatschappelijke verandering richting duurzame gezondheidssystemen.

Theoretische basis

Een gezondheidssysteem wordt in deze dissertatie geconceptualiseerd als een complex adaptief systeem waarin vele actoren bijdragen aan het 'produceren' van gezondheid. Het is als het ware een lappendeken van verschillende dominante (sub)systemen (*regimes*), die gekenmerkt worden door elk hun eigen Cultuur (gedachtegoed), Structuur (organisatie) en Praktijk (het doen): CSP. Normaliter is een systeem altijd veranderlijk en streeft het naar optimalisatie in overeenstemming met haar onderliggende structuur en cultuur; wat men noemt *padgebondenheid*. Systeeminnovatie betekent echter een radicale breuk met de dominante CSP in systemen: $CSP_0 \rightarrow CSP_1$. Dergelijke veranderingen zijn nodig als de huidige opbouw van het CSP niet in staat is (nieuwe) maatschappelijke doelen te behalen, en het CSP onderdeel is van het probleem. Zo tonen we in hoofdstuk 5 aan dat de huidige opbouw van het farmaceutische systeem in Nederland een zeer gefragmenteerde structuur heeft, en geen eenduidig gedachtegoed (cultuur). Dit draagt sterk bij aan het falen van interventies gericht op het doelmatiger gebruik van geneesmiddelen.

De dominante CSP in het systeem wordt in systeeminnovatietheorie geduid met *regime*. Het ontwikkelen van alternatieve CSP, ofwel het proces van systeeminnovatie, start vaak in loci van veranderingen buiten het dominante systeem, bijvoorbeeld in pilot-projecten. Deze loci worden aangeduid als niches. Het opschalen van niches draagt bij aan systeeminnovatie. Zowel niches als regimes worden beïnvloed door grote maatschappelijke trends - het landschap -, zoals demografische ontwikkelingen.

Systeeminnovaties zijn onzeker en moeilijk te controleren, maar we kunnen ze wel richting geven. Het centrale idee van het managen van systeeminnovatie is dat nieuwe alternatieven in niches kunnen worden ontwikkeld. Deze kunnen worden opgezet aan de hand van gemeenschappelijk gedragen visies op een duurzaam toekomstbeeld, maar worden vaak ook autonoom gestart door *change agents*. Het iteratief leren over en opschalen van deze experimenten en het aanpassen van het systeem zijn vervolgens essentieel in het managen van systeeminnovatie.

Change agents kunnen verandering nastreven door bij te dragen aan dergelijke activiteiten. Specifieke strategieën hiervoor zijn momenteel slechts beperkt beschreven en gevalideerd, zeker binnen het gezondheidsdomein. Uit de literatuur zijn drie generieke strategieën te herleiden:

(1) visie-ontwikkeling: systeeminnovaties zijn grotendeels onvoorspelbare processen, een lange termijn visie kan richting geven aan deze processen. In deze dissertatie kiezen we specifiek voor een normatief kader voor visievorming; duurzame ontwikkeling.

(2) Probleemstructurering: systeeminnovatie is nodig wanneer een systeem behoeften op basis van zijn huidige CSP niet kan oplossen. Het structureren van de systemische problematiek kan bijdragen aan het rationaliseren van het beleidsproces in het kader van grote onzekerheid.

(3) Experimenteren in niches en opschalen: dit behelst het experimenteren met en opzetten van nieuwe producten, diensten, overkoepelende structuren, etc. Hiervoor zijn drie stuurmechanismen ontwikkeld: verdiepen, verbreden en opschalen. Verdiepen is het ontwikkelen van en leren van experimenten met alternatieve CSP in de niche. Het verbreden behelst het herhalen en verbinden van verschillende niche experimenten. Het opschalen refereert naar het systeembreed verankeren van nieuwe CSP. Dit houdt onder meer het aanpassen en vervangen van systeemstructuren in (bijv. financieringsstructuren).

De strategieën voor systeeminnovaties zijn allen gebaseerd op transdisciplinaire benaderingen; dat wil zeggen multi-actor, multidisciplinaire, participatieve processen, waar geen van de betrokkenen het monopolie heeft op kennis. Een ander essentieel element voor change agents is het verbinden van activiteiten; tussen experimenten, actoren, niches en regime. Al deze strategieën zijn nog relatief nieuw in gezondheidssystemonderzoek, zeker buiten de Nederlandse grenzen. Bijvoorbeeld, wat betekent een duurzaam gezondheidssysteem, hoe structureren we problemen en hoe schalen we complexe gezondheidssysteminnovaties op? En hoe dragen innovatieve, creatieve change agents bij aan het realiseren van systeemveranderingen?

De onderzoeksopzet

De volgende onderzoeksvraag is geformuleerd: *wat kunnen we leren van de bijdrage van change agents aan systeeminnovaties richting duurzame gezondheidssystemen?* Om deze vraag te beantwoorden hebben we vier studievragen geformuleerd:

1. *Hoe kunnen we een duurzaam gezondheidssysteem operationaliseren?*
2. *Hoe kunnen we persistente problemen analyseren in het gezondheidssysteem?*
3. *Hoe verlopen processen van gezondheidssysteem innovatie? Met een specifieke focus op regime verandering; trajecten van verandering; fasen van verandering.*
4. *Hoe kunnen change agents van systeeminnovatie bijdragen aan systeemverandering met betrekking tot visie-ontwikkeling, probleemstructurering, verbreden, verdiepen en opschalen.*

Om antwoorden op de hoofd- en studievragen te geven hebben wij een multiple-case-study opgezet. In totaal hebben we zes casussen geselecteerd. In al deze casussen kijken we naar (1) de systeeminnovatie, en (2) de bijdrage van change agents die wij onderzoeken. In de eerste

casusstudie onderzoeken we hoe het concept duurzame ontwikkeling kan worden gebruikt als visie voor systeeminnovatie. In de tweede casus beschrijven we een probleem-structurerings proces. De laatste vier casussen concentreren zich op activiteiten van change agents met betrekking tot het experimenteren met en opschalen van nieuwe culturen, structuren en praktijken en de processen van systeeminnovatie. Samen geven deze casussen inzicht in onze hoofdvraag. Met uitzondering van één casus verliep dataverzameling volgens het onderstaande traject:

- Oriënterende desk-studie van wetenschappelijke literatuur en projectdocumentatie en informele gesprekken om de relevantie van de casus voor het onderzoek te beoordelen.
- Gebaseerd op deze kennis, verzamelden wij data door middel van kwalitatieve onderzoeksmethoden zoals interviews, focus groep discussies, informele gesprekken, persoonlijke observatie en verder documentatie onderzoek. Deze onderzoeksmethoden waren gericht op de processen van verandering en de rol van change agents. Na deze fase werden een aantal casussen niet verder behandeld.
- Vervolgens analyseerden wij de gegevens en formuleerden tussentijdse conclusies.
- Daarna werd getracht aanvankelijke bevindingen te verifiëren. Dit werd gedaan door een tweede reeks gesprekken en/of groepsgesprekken met sleutel betrokkenen, en een specifieke analyse van de projectdocumentatie.
- Tot slot hebben wij conclusies gespiegeld aan de wetenschappelijke literatuur.

De casus studies

In deel 2 van dit boek beschrijven we in de hoofdstukken 4 tot en met 9 zes casus studies waarin we de rol van change agents in systeem innovatie onderzoeken.

In hoofdstuk 4 hebben we het concept duurzame ontwikkeling, zoals eerder gebruikt in veranderingsprocessen in het ecologisch domein, verder toegespitst op gezondheidssystemen. Dit is gedaan door middel van analytische deductie van het concept en een casus studie van hervormingen in Canada waar dit concept expliciet in het hervormingsproces van het gezondheidssysteem is toegepast. Onze analyse wijst uit dat visies op duurzame ontwikkeling kunnen worden vertaald naar het gezondheidsdomein. Hiervoor hebben wij vier centrale elementen geïdentificeerd die bijdragen aan het (participatief) vormen van een dergelijke visie: (1) identificeer en analyseer kernproblemen die leiden tot de *noodzaak* tot verandering; (2) selecteer een beperkt aantal breed-gedragen kernwaarden in het systeem; (3) streef naar balans tussen deze waarden; en (4) anticipeer lange-termijn behoeften. Het Canadese voorbeeld wees uit dat een dergelijke visie kan leiden tot concrete interventies op de korte- en middellange termijn.

In hoofdstuk 5 beschrijven we een probleemstructureringsaanpak om persistente problemen te ontrafelen die we *Policy - Interactive Learning and Action (P-ILA)* noemen. P-ILA is een deliberatief beleidsinstrument dat expliciet een systeembenadering heeft en is verankerd in participatieve methoden. Samen met het ministerie van VWS hebben wij deze aanpak toegepast op ondoelmatig geneesmiddelen gebruik in het farmaceutische systeem (bijv. therapieontrouw, te duur voorschrijven). We onderscheiden in totaal zes subsystemen in het farmaceutische gezondheidssysteem. De wrijving tussen de soms zeer contrasterende culturen en structuren van de subsystemen dragen in grote mate bij aan het persistente karakter van ondoelmatig geneesmiddelen gebruik. Het deliberatief proces dat wij hebben ingezet heeft geleid tot een start met het veranderen van systemische structuren door middel van een beleid van leren en experimenteren.

In hoofdstuk 6 bestuderen we de rol van NGOs in *bottom-up* innovaties in de Nederlandse thuiszorgsector. Hier hebben we specifiek interesse in de intrinsieke potentie van deze organisaties in het faciliteren van systeeminnovatieprocessen. Wij bestudeerden 14 innovaties die door NGOs geïnitieerd zijn om fundamentele verandering te bewerkstelligen; de innovaties waren een scala aan technologische en sociale innovaties. De NGOs waren redelijk succesvol in het ontwikkelen van innovaties in niches (verdiepen), hoewel het verkrijgen van bewijs voor alternatieve praktijken vaak lastig was. Echter, de NGOs waren in de regel passief met betrekking tot het opschalen van hun innovaties. In het algemeen werd verwacht dat wanneer de meerwaarde duidelijk was de innovaties zonder veel moeite zouden verspreiden. Dit blijkt in de praktijk echter weinig te gebeuren. Temeer omdat de innovaties veelal contrasteerden met huidige culturen, structuren en praktijken in het systeem. NGOs gaven herhaaldelijk aan dat zij opschalen niet tot hun taak rekenen. Wij constateren dat er behoefte is aan faciliterende organisaties die bijdragen aan het identificeren en opschalen van de niche-innovaties. Zodoende kan geprofiteerd worden van de innovatieve capaciteit van deze NGOs.

In hoofdstuk 7 en 8 analyseren we in twee studies de rol van een NGO (het MCNV) in (sub)systeeminnovaties in Vietnam van respectievelijk het tuberculose bestrijdingssysteem en het systeem ter bevordering van de gezondheid en participatie van mensen met een beperking. Deze twee studies geven inzicht in de rol van waarden-gedreven change agents gedurende het lange proces van (sub)systeem innovatie. In hoofdstuk 7 beschrijven wij een retrospectieve casus (1975-2010) van het experimenteren met en landelijk opschalen van de DOTS strategie om tuberculose incidentie en mortaliteit te reduceren. Deze strategie was niet compatibel met heersende opvattingen, structuren en praktijken in het Vietnamese zorgsysteem; het vereiste bijvoorbeeld een verschuiving in denken van actoren over (medische) behandeling van individueel niveau naar protocollaire behandeling en preventie op populatie niveau. In hoofdstuk 8 staat het ontwikkelen en opschalen van medische, educatieve en sociale interventies voor mensen met een beperking op gemeenschapsniveau (1987-2012) centraal. Ook dit betreft een radicale breuk met heersende culturen, structuren en praktijken.

Onze analyse van beide casussen toont de rol aan van NGOs in het opschalen van nieuwe culturen, structuren en praktijken: dit vereist een lange-termijn betrokkenheid (>15 jaar), waarin wordt gestreefd naar het verbinden van experimenteren en opschalen, het vormen van een sterk netwerk, een sterke (waarden-gedreven) visie op systeemverandering, initiëren van constante cycli van reflexief leren en competentie-opbouw. Deze twee hoofdstukken tonen aan dat de transdisciplinaire benaderingen en het conceptuele kader van de systeeminnovatie voor het managen van systeeminnovatie constructief zijn. Tevens leren we van deze casussen dat het balanceren van competentie-opbouw en structuur-opbouw een kernaspect is van het managen van systeeminnovatie.

In hoofdstuk 9 bespreken wij het EXTRA programma in Canada dat gezien kan worden als een systeeminnovatieprogramma *avant la lettre*, dat tot doel heeft bij te dragen aan een duurzamer gezondheidssysteem. Eén van de kernproblemen in het Canadese zorgsysteem (zoals gedefinieerd door de Canadese overheid, burgers en zorgprofessionals) is dat het systeem slecht gebruik maakt van beschikbare kennis, en dat er geen cultuur heerst om in de eigen praktijk kennis te genereren en toe te passen (door middel van experimenten). In essentie richt EXTRA zich op het creëren, contextualiseren en toepassen van kennis in zorgorganisaties: een cultuur van *'evidence-informed decision making'*. In de praktijk behelst het programma een twee-jarige competentie-opbouw cursus voor leiders (artsen, verpleegkundigen, managers) in het Canadese gezondheidssysteem, met daaraan gekoppeld een praktijkexperiment. Het programma toont tot op zekere hoogte aan dat het mogelijk is om change agents te trainen in de juiste competenties, die zodoende kunnen bijdragen aan het versterken van de innovatieve capaciteit in zorgsystemen.

Conclusies

Deze dissertatie geeft inzichten in het nut van systeeminnovatie theorie in het bestuderen van fundamentele veranderingen in gezondheidssystemen. Vooral de conceptualisatie van systemen in cultuur, structuur en praktijk bleek nuttig. Dit geeft inzicht in het ontstaan van problemen, waarom deze moeilijk zijn op te lossen, en waarom het lastig is om niet compatiebele-experimenten op te schalen. Deze inzichten dragen op hun beurt weer bij aan het begrijpen hoe change agents kunnen bijdragen aan deze veranderingsprocessen. Nochtans, kunnen wij geen eenduidig antwoord geven hoe de change agents tot duurzame systeeminnovatie kunnen bijdragen. Wij hebben het succes, het potentieel en de valkuilen van waarden-gedreven, assertieve change agents in processen van systeeminnovatie aangetoond. Het is essentieel dat de change agents een transdisciplinaire aanpak hanteren tijdens het verdiepen, verbreden en opschalen van interventies. Ook is het van belang dat change agents heen en weer blijven gaan tussen visievorming en actie, innovatie en standaardisatie en het aanpassen van structuren en competenties. Een belangrijke conclusie is tevens dat niet alle

Samenvatting

change agents de ambitie hebben om zich naast experimentatie, ook bezig te houden met het opschalen van deze experimenten en het aanpassen van het regime. Deze rol wordt ingevuld door wat wij *facilitator change agents* noemen. Deze change agents hebben de specifieke ambitie om bij te dragen aan syteeminnovatie richting meer duurzame gezondheidssystemen.

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Dirk Essink, oktober 2012, Amsterdam

