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Essays on External Context and Operating Models

A dissertation presented

by

Budhaditya Gupta

to

The Technology and Operations Management Unit

in partial fulfillment of the requirements

for the degree of

Doctor of Business Administration

in the subject of

Technology and Operations Management

Harvard Business School

Boston, Massachusetts

April, 2016

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Essays on External Context and Operating Models

ABSTRACT

Effective operating models based on carefully selected resources, processes and logic allow organizations to develop the right products and services and deliver them to customers. However, there has been little investigation of how organizations design and manage their operating models when they enter new contexts due to changes in regulation, competition, markets, technology, location and/or a combination of these factors. This dissertation examines the relationship between an organization's external context and its operating model by carefully examining the choice of operating resources, processes and logic as organizations enter new contexts. The dissertation specifically focuses on one developing country, India, and adopts an inductive approach to study the design of operating models in response to significant changes in location and/or market in three different empirical settings within the healthcare industry.

The first study, conducted jointly with Stefan Thomke, explores the influence of the institutional context on the R&D processes. Inductive field work, focused on medical device development at a newly established R&D center of a US MNC in India, suggests that institutional flexibility in emerging markets (such as India) might allow for high fidelity experimentation and testing during early stages of product development. This, in turn, has implications for R&D search performance and the locus of innovation and entrepreneurship.

The second study, a joint project with Rob Huckman and Tarun Khanna, identifies the development of an operating model based on the practice of shifting less complex surgical tasks from senior surgeons to skilled junior surgeons as fundamental in enabling Narayana Health (NH) to provide high-quality, low-cost cardiac surgery care to the indigent population in India. Our analysis of surgical outcome data suggests that the task shifting based model – while costing significantly less – does not negatively affect clinical outcomes. Further, we highlight the location-specific contextual factors that allow for such a model in India.

The third study, conducted with Tarun Khanna, focuses on NH's design of a low-cost, high-quality tertiary care hospital in the Cayman Islands. The prior experience of developing different hospital models in response to the heterogeneous market in India allowed NH to develop a deep understanding of the environmental context and a diverse set of knowledge and

practices. This understanding of and experience at diverse contexts informed the Cayman project, and NH was able to selectively borrow and recombine elements from their different models in India while setting up the Cayman hospital. Building on these findings, we develop a process model that highlights how recombination of elements developed to address heterogeneity of context in the home country can allow an organization to develop an effective operating model in the host country.

Collectively, the studies illustrate how the external context shapes an organization's ability to design, implement and transfer operating models. At the same time, they emphasize that organizations can successfully develop an operating model to accommodate any significant context change by approaching the design effort as a fundamentally new design problem. This latter approach is in contrast to the often discussed replication-adaptation balancing approach that emphasizes marginal adaptation of prior established model(s). Further, by uncovering the importance of the local context in selecting and adopting specific operational resources and processes in healthcare settings in an emerging market, the studies contribute rich insights to the new yet growing streams of literature related to healthcare management in resource-constrained settings, innovation and entrepreneurship in emerging markets, and the transfer of innovations from developing to developed markets. In conclusion, by focusing on the relation among (1) the external context of an organization, (2) the design of operating logic, resources and processes and (3) organizational performance, this dissertation contributes to research in operations strategy, organization theory and the management of innovation and entrepreneurship.

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ACKNOWLEDGEMENTS

This dissertation would not have been possible without the support I received from my professors, family and friends. First of all, I wish to thank my dissertation committee, comprised of Tarun Khanna, Stefan Thomke, and Rory McDonald, as they have invested heavily in my development as a conscientious researcher.

Tarun has not only forced me to think rigorously about my research projects but also provided constant encouragement to explore important and interesting topics. He has invested his valuable time in guiding me, accompanied me on research trips, and provided multiple rounds of input on my paper drafts. I am both amazed and motivated by Tarun's insatiable desire to learn and understand new topics. The rich learning experiences of talking, writing and thinking with him have deeply shaped me as a researcher. Stefan has been my academic advisor from the day I joined the doctoral program at HBS. All along he has provided detailed feedback on my research, pushing it to be both rigorous and relevant. His belief in my potential and capabilities, from the initial discussions of my research ideas through the culmination of the dissertation, has been unwavering and accelerated my development as a researcher. I am particularly grateful for the emotional support Stefan provided as I went through this challenging journey. Rory has guided me on innumerable decisions related to my research and has always been extremely generous with his time and feedback. Discussions with him have shaped the way I think of field-based, inductive, qualitative research today. Most importantly, Rory's steady support and kind demeanor helped in making this challenging journey more manageable both from a professional and personal standpoint. Overall, I consider myself extremely privileged to have been guided by such supportive and dedicated scholars and I cannot thank them enough for their intellectual generosity, patience and kindness. Perhaps the only way I can show my gratitude to Tarun, Stefan and Rory is by continuing to work on important and interesting research projects and by being a supportive mentor to my future students.

I have been fortunate to receive academic mentorship from numerous other professors during my time at HBS and wish to thank Juan Alcacer, Ryan Buell, Michel Anteby, Ethan Bernstein, Amy Edmondson, Vijay Govindarajan, Eric von Hippel, Rob Huckman, Karim Lakhani, Ian Larkin, Gary Pisano, Ananth Raman, Ravi Ramamurti, Mike Toffel, Mike Tushman, and Dennis Yao. The HBS Doctoral Office, especially John Korn, LuAnn Langan, Jen

Muccarione, and Marais Young, supported me throughout my time at HBS and I would like to express my profound gratitude to them. Jen and Marais are indeed special and I cannot count the number of times they helped me with both academic and personal matters. Further, this dissertation would not have been possible without generous financial support from the Division of Research at Harvard Business School.

I would also take this opportunity to thank Dr. Devi Shetty and the staff at Narayana Health, India and the several other healthcare practitioners across different organizations in the US and India for sharing their time and insights with me. My fellow doctoral students Liz Altman, Akash Chattopadhyay, Carolyn Deller, Anil Doshi, Ray Fung, Cheng Gao, Ohchan Kwon, Hila Lifshitz-Assaf, Sam Lipoff, Juan Ma, Frank Nagle, Pam Park, Hummy Song, Everett Spain, Haris Tabakovic and Rajesh Vijayaraghavan made my time at HBS memorable by being exceptional colleagues and friends and I am grateful to have met and known them.

Finally I would like to acknowledge the never-ending support I have received from my family. This dissertation would not have been possible without their unconditional love, sacrifice and encouragement. My parents, Pinaki Gupta and Chaitali Gupta, have always provided me with love and support and had encouraged me to join the doctoral program at HBS. My brother Bodhisattwa has always been kind and thoughtful and he and my sister-in-law Payel gave me the support I needed to pursue my dissertation research. Last but certainly not the least, I am immensely grateful to my wife Shalini and my children Tanisha and Rohan for their kindness, love and patience. Shalini believed in me and my dreams when at times I did not and without her understanding, support and love this dissertation would not have been possible. I dedicate this dissertation to my parents and Shalini.

CHAPTER ONE

Operating Model Design in Response to New Contexts: An Introduction to the Research Agenda

1.1. Introduction

Effective operating models based on carefully selected resources, processes and logic allow organizations to develop the right products and services and deliver them to customers, and thereby drive organizational performance (Anderson, Cleveland, and Schroeder 1989; Clark and Fujimoto, 1991; Hayes and Wheelwright, 1984; Skinner 1969; Swamidass 1986). However, designing these operating models is not a one-time effort for today's organizations. These organizations exist in a world of constant flux and are required to design appropriate operating models in alignment with ongoing changes in regulation, competition, markets, technology, location and/or a combination of these factors. This dissertation focuses on the design of operating models by organizations as they enter new contexts and thereby explores the more fundamental relationship between an organization's external context and its operating model.

Understanding the impact of an organization's external context is vital to management research from practically every major perspective, including contingency theory, resource dependence theory, institutional theory, and population ecology theory. And while there has been much research on the impact of context on organizations' strategy, structure and performance (Burns and Stalker, 1961; Lawrence and Lorsch, 1967), there has been little investigation of how organizations design their operating models when they enter new contexts. This is surprising given not only that today's organizations must often design operating models to accommodate

changes in the external context, but also that these organizations find it challenging to respond to such changes, especially when the new context differs significantly from past contexts (Haveman, 1992; Henderson and Clark, 1990; Smith and Grimm, 1987).

This dissertation examines the relationship between an organization's external context and its operating model by carefully examining the choice of operating resources, processes and logic as organizations enter new contexts. The main themes explored in this dissertation include (1) the design of operating models by organizations to manage changes in the external context, (2) the transferability of operating models across contexts and (3) the influence of the context on operation model design considerations and feasibility.

1.2. Overview of Dissertation Essays

The dissertation focuses on one developing country, India, and adopts an inductive approach to study the design of operating models in response to significant changes in location and/or market in three different empirical settings within the healthcare industry. The first essay (Chapter Two) focuses on a US medical device MNC starting a R&D center in India and re-designing its internal R&D processes to manage development projects. The second essay (Chapter Three) studies the development of an operating model by a private hospital in India to offer cardiac surgery to the local indigent population; this was a significant development given that such services were only available to the urban affluent in India before that time. The third and final essay (Chapter Four) looks at the development of a tertiary care hospital in the Cayman Islands by a low-cost, high-quality hospital from India with the aim of serving patients from the US, the Caribbean islands and other proximate geographies.

All three studies show that the design of the new operating model was essential for the organizations' success in the new context. This is because the significant context change resulting from the new location/market invalidated the established prior model. For instance, the first essay highlights that when the US MNC established an R&D center for the first time in India, the center was unable to adopt practices that were well-established in the US, given the critical absence of external partners in India. Similarly, the second essay suggests that the arrangement of resources and processes in delivering cardiac surgery to the urban affluent would not have been able to support the scale and cost-structure desired while offering the same procedure to the indigent population in India. The third essay, following the same pattern, illustrates that the design of the operating model of the tertiary hospital in Cayman was different from operating models designed in India given the unique requirements of patients from the US, who were expected at the Cayman hospital. Below is a detailed overview of these three essays.

The first essay, co-authored with Stefan Thomke, explores how multinationals design their resources and processes as they engage in product development activities at locations that vary widely in institutional context. While there is a significant body of work that explores the factors influencing choice of R&D location, the mechanisms by which the institutional context of the R&D center location influences the design of the R&D activities are still somewhat unclear. Based on a detailed field study of a medical device development project at the R&D center of a US MNC located in India, the essay discusses how the local context motivated and allowed the project team to engage in higher fidelity experimentation and testing during the early stages of the project and how this approach might dramatically expedite the R&D search process. Specifically, the R&D center in our study decided to collaborate with physicians to evaluate early-stage prototypes directly in clinical settings. Such practices are not feasible in the US

context but allowed for rich, expedited learning and early, valuable design changes in India. Thus the essay highlights how the emerging market institutional context might benefit innovation and entrepreneurship efforts and concludes with a discussion of the implications of the study for research, policy and practice related to innovation and entrepreneurship.

The second essay, co-authored with Rob Huckman and Tarun Khanna, studies how the healthcare provider Narayana Health (NH) organized its resources and process to offer cardiac surgery to the indigent population in India—the first time this service had been provided to this hugely underserved population segment in India. Specifically, the essay discusses how NH adopted task shifting, the transfer of activities from senior to junior colleagues, in its efforts to deliver quality cardiac surgery care to a large number of indigent patients. It identifies the contextual factors driving the adoption of task shifting at NH and the implications of task shifting for surgeon training, surgical capacity, and procedure costs. A comparison of the outcomes of two senior surgeons with similar experience, workload, and patient profiles—but varying in their level of task shifting—suggests that shifting of lower complexity tasks from senior surgeons to trained junior colleagues does not negatively impact in-hospital mortality or post-procedure length of stay. The essay highlights task shifting's tremendous potential to improve access to affordable tertiary care in resource-constrained settings, especially in poor countries, and concludes with the challenges of adopting a task-shifting-based operating model in developed countries like the US.

The third and final essay, co-authored with Tarun Khanna, presents a longitudinal study of the expansion of NH within India and its subsequent development of a tertiary care hospital in the Cayman Islands. Contrary to past research suggesting that the alignment of a firm's knowledge, practices, and managerial mindset to its home-country context can make pursuit of

international opportunities difficult, this essay explains how the Cayman project benefited from NH's experience in India. First, NH sensed how the external context affected its operations while responding to, and shaping, the institutional voids[1] (Khanna and Palepu, 1997, 2010) in India and developed context-driven design capabilities in order to design models for different market segments. These capabilities, in turn, informed and enabled the Cayman project. Second, NH recombined select practices and knowledge elements from different models in India while setting up the Cayman hospital. Building on these findings, the essay proposes a recombination-based process model for international entrepreneurship in which firms (1) develop a deep understanding of context, design capabilities and a diverse set of knowledge and practices while adapting to the home country's specificities and heterogeneity and (2) subsequently draw on these competencies to recombine select elements from different home country models based on the host country's context requirements. The proposed model is significant as it suggests that variation in home-country operating logics and models due to local contextual heterogeneity can make a firm more effective in managing the much-discussed yet challenging act of developing the host country operating model.

1.3. Discussion

Collectively the essays illustrate how the external context shapes the organization's ability to design, implement and transfer operating models, while at the same time they highlight

[1] Khanna and Palepu (1997, 2010) developed the idea of institutional voids as the defining characteristic of emerging markets. It refers to institutional inadequacies due to the absence or underdevelopment of specialized intermediaries—such as accreditation agencies, rating agencies, financial analysts, media rankings auditing firms, talent-development and placement agencies, credit-card providers, clearing institutions, brokers, and employment exchanges—that allow buyers and sellers to transact efficiently.

that organizations can successfully develop an operating model to accommodate any significant changes in context by approaching the design effort as a fundamentally new design problem.

Influence of context on operating model design and transferability: The first essay suggests that the adoption of iterative, high-fidelity experimentation and testing practices by medical device development project teams in India was enabled by the nature of the local context: the cognitive orientation of the development teams, the normative orientation of the physicians, regulatory ease and flexibility, and further highlights the fact that such practices would not be feasible in more developed countries like the US. Similarly, the second essay highlights that the adoption of a task-shifting-based operating model by NH was enabled by local contextual factors like (1) a permissive regulatory structure that allows less-skilled staff to play a larger role in the performance of surgical procedures, (2) a large and steady volume of patients at the NH hospital due to absence of other care options, (3) the willingness of outpatients, often from socioeconomically disadvantaged backgrounds, to be flexible and wait for the senior surgeon as he balanced his outpatient duties with inpatient surgeries, and (4) the surgical patient's trust in and acceptance of the *entire* surgical team based on the reputation and track record of both NH and the individual senior surgeon leading the team. In the absence of such supportive factors, a task-shifting-based model is likely to be infeasible, and the essay in fact points to the absence of such task-shifting-based cardiac surgery operating models in both teaching and non-teaching hospitals in the US.

The basic idea here is that the design effort and emergent form related to the operating model might be significantly influenced by the specific nature of the new context. In cases where the new context is significantly different from those the organization has experienced in the past, the organization might be able to consider design options that were

infeasible in prior contexts. This consideration of new options may result in either the adoption of entirely new resources or processes or a fundamental reorganization of the existing resources and processes, and either outcome would, in turn, result in operating models that differ distinctly from those used in the past.

A problem-solving based approach to operating model design: Research in strategy and organization theory suggests that the operating model development efforts by organizations entering new contexts would perhaps be best managed by the principle of replication-adaptation (Kostova and Roth, 2002; Rosenzweig and Singh, 1991; Westney, 1993; Winter et al., 2012). This approach emphasizes copying select elements that are critical to the already-established operating model and at the same time calls for adaptation of other elements to fit the new context.

In contrast, the essays in this dissertation collectively suggest that organizations that are successful in developing effective operating models in new contextual settings engage in a problem-solving effort that is typically more involved than adapting at the margins as suggested by the replication-adaptation perspective; this is likely to be especially true when the new context is significantly different from past contexts, as in such cases the replication-adaptation approach provides little guidance for deciding what needs to be replicated, what needs to be adapted and what extent of adaptation is required.

Further, the essays suggest three distinct principles critical to this problem-solving-based effort to design operating models when the external context changes. First, the design effort is likely to benefit from providing the autonomy necessary for senior management to develop models that are distinct from the ones established in the past. This was evident in all three cases,

as the management of the organizations studied had significant freedom in developing models and was not required to replicate established prior models. However, one must note that given the natural tendency of organizations to consider past experiences and learning as reference points (Jeannet, 1999; Vermeulen and Barkema, 2001) and the bounded rationality of managers (Simon, 1955; Kiesler and Sproull, 1982), this is easier said than done. Second, contextual intelligence (Khanna, 2014) is critical in such problem-solving efforts, as designing the operating model is not just about adjusting to or compromising with the new context. Designing the new operating model might in fact be about taking advantage of specific characteristics of the new context that were not considered or exploited earlier. The adoption of high-fidelity testing practices and the development of the task-shifting-based cardiac surgery model are both cases where the operating models were established by taking advantage of the flexibility offered by the new context. Third, the problem-solving effort can benefit by drawing from and building on diverse organizational experiences and learning; a broad exposure to diverse contexts in the past and success in integrating experiences in these contexts will improve the organization's ability to assemble an appropriate operating model for the new context. The benefit of such diverse experiences in varying contexts is evident in the third study illustrating the development of the tertiary care hospital in the Cayman Islands.

Beyond the central goal of the dissertation, the essays also provide rich insights into the mechanisms underlying the design and management of new products and processes in healthcare settings in an emerging economy market, specifically India, and the transferability of these mechanisms, products and processes to developed countries like the US. The essays jointly highlight that the resource-constrained nature of emerging markets and their prevalent institutional voids (Khanna and Palepu, 1997, 2010) often facilitate the development and

adoption of products and processes that enable low-cost healthcare; these efforts would not be feasible in developed countries. Further, the essays point to two distinct types of solutions related to healthcare delivery designed in emerging markets: (1) in the first type, the emerging economy context enables and accelerates the developmental search process, but the eventual solution developed is not dependent on the local context (illustrated by the discussion of medical device development in the first essay); thus these solutions are not sticky to the emerging market location; and (2) in the second type, the developed design is dependent on the local emerging economy context and as such, these designs are harder to transfer to developed countries (e.g., the task-shifting model discussed in the second essay). This emerging market design typology, in turn, allows us to build on recent discussions of reverse innovation (Govindarajan, Ramamurti, 2011) that suggest that emerging market innovations will increasingly be relevant in developed country markets (USA, Western EU, Japan). Specifically, the essays highlight that the innovative products and processes developed and adopted in developing countries might not be equally transferable to developed economy markets.

1.4. Conclusion

The essays in this dissertation use a problem-solving lens to explain how organizations can successfully develop operating models to respond to context change. In addition, they highlight how the new context can itself influence the emergent design form. This work extends prior research that has typically focused on organizations' inability to deal with significant context change by highlighting the importance of developing effective operating models to successfully manage such change. Further, by uncovering the importance of the local context in

designing specific operational resources and processes in healthcare settings in an emerging market, the essays contribute rich insights to the novel yet growing streams of literature related to the management of healthcare in resource-constrained settings, innovation and entrepreneurship in emerging markets, and the transfer of innovations from developing to developed markets. In conclusion, by focusing deeply on the relation among (1) the external context of an organization, (2) the design of operating logic, resources and processes and (3) organizational performance, this dissertation contributes to research in operations strategy, organization theory and the management of innovation and entrepreneurship.

CHAPTER TWO

How Does Institutional Context Matter for R&D Search? An Exploratory Study of Medical Device Development in India

2.1. Introduction

To gain access to new markets, resources and knowledge, multinational corporations (MNCs) from developed countries routinely engage in research and development (R&D) activities at different locations (Eppinger, Chitkara, 2006; Kuemmerle, 1997; Ronstadt, 1978), which vary widely in institutional context[2]. And while there has been much research on the impact of context on a firm's strategy, structure and performance (Burns, Stalker, 1961; Lawrence, Lorsch, 1967), there has been surprisingly little investigation of *how* the local institutional context influences R&D activities and their effectiveness. This lack of explicit consideration of institutional context was perhaps a non-issue in the early stages of R&D globalization as the MNCs established R&D centers in other developed countries with similar environments. However, over the last two decades MNCs have established R&D centers in emerging economies, such as China and India (Motohashi, 2012, 2014), and an understanding of context's influence on R&D activities has become especially relevant.

In this paper, we specifically explore how the local institutional context influences experimentation and testing activities critical to the search for solutions of R&D problems (Allen, 1966; Clark, Fujimoto, 1991; Simon, 1969; Thomke, 1998; Thomke, von Hippel, Franke, 1998; Wheelwright, Clark, 1992). Research has highlighted that a significant amount of R&D

[2] We define institutional context at a location based on earlier work on institutions (Scott, 1995) and consider such context to be shaped by the regulative, normative, and cognitive elements prevalent at the location.

resources and time are dedicated to experimentation and testing (Cusumano, Selby, 1995; Shooman, 1983) and has studied related design, capabilities and enablers (Cusumano, Selby, 1995; Edmondson, 1999; Edmondson, Nembhard, 2009; Loch, Terwiesch, Thomke, 2001; Nembhard, Edmondson, 2006; Thomke, 1998; Thomke, Bell, 2001). However, the mechanisms by which the institutional context influences such R&D practices are still somewhat unclear.

In this paper, we present our observations based on an inductive field study of a medical device development project at the India R&D center of a US medical device MNC. The study illustrates that the differences in regulative, normative and cognitive elements across locations allow for significant variation in how experimentation and testing activities are managed. Interestingly, these variations, often considered by MNC headquarters as undesirable deviations from the standardized process model prescribed for all global R&D centers, might improve product development performance. For instance, the R&D center in our study decided to collaborate with physicians to evaluate early-stage prototypes directly in clinical settings. Such practices are not feasible in the US context but allowed for rich, expedited learning and valuable design changes early in the project.

To ensure that our observations are not overly influenced by a single case study, we validated the above idea in two additional projects in India and with medical device practitioners and physicians in both India and the US. Overall, this paper suggests that institutional context can sometimes enable more effective R&D search by enabling higher fidelity[3] experimentation and testing early in the project. This, in turn, has implications for the locus of innovation and entrepreneurship.

[3] Fidelity refers to the extent to which the experimentation and testing design represents the true operating environment in which the developed product will be used. Higher fidelity typically leads to more reliable experimentation and testing results and thus better design (Pisano, 1994; Pisano, 1996).

The paper proceeds as follows. We begin (Section 2) with a discussion of experimentation- and testing-based search processes in R&D projects and explore how the search process may be affected by institutional context. Next we describe our empirical research setting and the field study methods (Section 3), present our observations (Section 4) and discuss our findings (Section 5). Finally, we generalize our findings and conclude with a discussion of implications for research and managerial practice (Section 6).

2.2. Experimentation, Testing and Search in R&D

Studies (Allen, 1966; Alexander, 1964; Clark and Fujimoto, 1991; Iansiti, 1997; Marples, 1961; Smith and Eppinger, 1997; Thomke, 1997; Wheelwright and Clark, 1992) have shown that product and process development efforts consist of extensive experimentation and testing to support an underlying iterative trial and error problem-solving process (Baron, 2000). At the outset of such a process, one (or many) potential solution alternative(s) is (are) identified. The alternative(s) is (are) then tested against a set of predefined acceptance criteria. Given that the preferred solution is seldom a candidate in the initial set of alternatives, the learning from these tests is used to inform and refine the next set of solutions considered. The incremental learning at each step of the search process drives the progress towards identifying the preferred solution.

Past studies of such R&D search has not has not adequately explored the role of the institutional context[4] on the experimentation and testing processes. Below we highlight three

[4] By institutional context, we refer to the regulative, normative and cognitive elements prevalent at a location; specifically regulative elements are the "explicit regulative processes: rule-setting, monitoring, and sanctioning activities" (Scott, 1995). The normative elements are the "rules that introduce a prescriptive, evaluative, and obligatory dimension" (Scott, 1995), while cognitive elements are “shared conceptions that constitute the nature of social reality and the frames through which meaning is made” (Scott, 1995).

critical aspects of the process – modes, timing and fidelity – that might be affected by the nature of the institutional context.

Experimentation and Testing Modes - According to Thomke (1998), experiments and tests to resolve uncertainty can be performed using different modes (e.g., computer simulation, prototyping). Each mode is characterized by the cost of conducting experiments/tests and the amount of uncertainty resolved. Further, the efficiency of each mode, measured as the magnitude of uncertainty removed per unit cost, typically varies depending on the stage of the project (e.g., early versus late). This suggests that the ability to identify multiple modes and operationalize the most efficient one at each project stage will improve project performance.

Experimentation and Testing Timing - Research has also noted that the sooner new information becomes available, the higher its value in any product or process development effort (Krishnan, Eppinger, Whitney, 1997; Terwiesch, Loch, Meyer, 1998; Thomke, Fujimoto, 2000), because the cost and time required to make changes to an evolving design increase rapidly as the project progresses.[5] Naturally developers prefer experiments and tests that generate critical information early in the process (Boehm, Gray, Seewaldt, 1984; Gino, Pisano, 2005). However, experimentation and testing is often expensive and time-consuming, and it is not unusual for organizations to evaluate prototypes closer to project completion (Reinertsen, 1997).

Fidelity of Models - Experimentation and testing models are often simplified representations of reality and have varying degrees of fidelity (Bohn, 1987; Thomke,

[5] For example, Boehm (1981) found that a change in the maintenance phase of a software development project is typically 100 times more costly compared to the change occurring during the specification phase, given the significant incremental work involved in updating specifications, revising code, updating user and maintenance manuals, revising training materials and re-training users, and retesting and revalidation.

1998; Wall, Ulrich, Flowers, 1992). However, past research has shown that poor learning resulting from incompleteness (or low fidelity) of models can lead to unexpected errors when the design is eventually tried out in the real environment (Pisano, 1994; Pisano, 1996); this is especially true when developers have an incomplete understanding of the underlying knowledge of the form and/or the operating context. In contrast, easy and inexpensive access to high-fidelity settings, such as the real operating context, could result in improved problem-solving as such efforts often benefit from being located in actual operating environments where the problem solver can interact iteratively with relevant resources and information to product developers (Tyre, von Hippel, 1997; von Hippel, 1994).

Prior research on feasible modes, uncertainty resolution rates, sequence and frequency, and model fidelity has not adequately explored whether and how the location-specific institutional context influences micro-level R&D experimentation and testing practices and overall project performance. Perhaps the implicit dominant assumption is that the standard processes of a MNC R&D center designed in the home country are optimal and can be replicated at R&D centers in other countries. Evidence from research in international business provides an alternative perspective.

Past research on the internationalization of MNCs has questioned the replicability of practices across national boundaries and suggested the need for adaptation to fit into the institutional context at the new location (Rosenzweig and Singh, 1991; Westney, 1993). The need to adapt R&D practices is especially true for developed-country MNCs entering emerging economies given the significant institutional differences (Ghemawat, 2001; Kogut and Singh, 1988, Kostova and Zaheer, 1999) between developed and developing countries (say, between

Bangalore and Boston). Thus an institutional context-contingent view appears plausible for experimentation and testing activities in R&D efforts. For instance:

- Differences in cognitive models across locations can result in different modes and models of R&D experimentation and testing. An R&D center location with a vastly different cognitive framework would likely be less susceptible to the inertia, rigidity and biases resulting from the dominant logic at the MNC HQ location (Bazerman, Watkins, 2004; Katz, Allen, 1982; Levitt, March, 1988; Prahlad, Bettis, 1986) and thus may be less constrained by past experiences and more likely to conceive of novel yet effective experimentation and testing approaches.
- Differences in regulations and laws impacting the R&D search process might also influence R&D performance. In general we expect locations with fewer regulatory requirements to have an advantage in learning from experimentation and testing processes in terms of speed, cost and learning. Reduced time and cost of experimentation and testing at a location will in turn allow for a greater extent and variety of such experimentation and testing, and this will lead to discovery of additional design insights.
- Differences in cognitive models, normative orientations and regulatory requirements might lead to differences in the ability to conceive and access high-fidelity models. In general we expect R&D practitioners at locations with higher levels of institutional flexibility to engage in the search process in high-fidelity settings earlier in the design and development process.

In summary, we expect that after controlling for differences in resources and experiences, the R&D centers at locations with a more favorable context, i.e., those with a more permissible regulatory context and less rigid cognitive and normative orientations, will be able to

resolve uncertainties more efficiently and effectively through an experimentation and testing approach that is rapid, iterative, novel and perhaps less expensive. Such influence of institutional context on R&D search performance, if at all true, will not only add to the existing body of knowledge on R&D management but will also be particularly relevant for MNCs as they consider alternative R&D locations.

2.3. Research Setting and Methods

2.3.1. Research Setting

The economic growth of developing countries like China and India motivated medical device MNCs to consider new business opportunities in these emerging economy markets (Prahalad and Hart, 2002). Medical device MNCs like Covidien, General Electric Healthcare, Johnson & Johnson, Medtronic, Philips, Stryker, St. Jude, and Smith & Nephew have established R&D centers in emerging economies with the intent to develop products for local markets. At the same time, a number of local startups have emerged in the med-technology space (for example, entrepreneurial startups like Perfint and Forus in India, and LifeTech Scientific and Kinetic Medical in China). The move to develop solutions for local markets was further supported by the realization that healthcare providers in countries like China and India have often found MNC products, typically developed for the more affluent Western markets, expensive and unsuitable for the local environment (because of electricity requirements, exposure to heat/dust, etc., limited availability of maintenance technicians and spare parts, etc.).

Given the central question of interest in this paper, the significant institutional distances between the developed and developing countries (e.g., the US and India) provide an

ideal high-contrast setting for explorative studies on how the context of a location might influence experimentation and testing activities during R&D efforts. Accordingly, we studied medical device development efforts in the US and India.

2.3.2. Research Method

We used an inductive, in-depth, field-based approach that is appropriate for developing new theory and elaborating previously under-explored theory (Eisenhardt 1989, Glaser and Strauss, 1967). We started by studying the nature of experimentation and testing practices in the US during device development projects, based on discussions with medical device companies and startups. We specifically focused on the early-stage search process for product design using experimentation and testing; this focus on the early-stage process critical to product design is a distinctive feature of our study, as past studies have often focused on activities related to clinical trials and the approval phase. Given the regulated nature of the US medical device industry, our observations on early-stage search process experimentation and testing were consistent across different sources. Once we were satisfied with our understanding of the medical device R&D process in the US, we initiated fieldwork in India. The high level of standardization of activities in the US allowed us to compare the US approach with the observed practices in India as we explored the influence of institutional context on such practices.

Over several months from 2012 to 2014, we studied medical device development efforts in India. Specifically, we collected data on different projects and interacted with R&D practitioners and physicians. In this paper, we present in detail one specific project; coincidentally this project is the first we studied in-depth. Our choice to focus in detail on a single case is motivated by our intent to present the rich details of design decisions and practices in the real world, develop new insights on a relatively unexplored topic and explore the meaning

of institutional context and its relevance for experimentation and testing (Siggelkow, 2007). In particular, we focus on the testing of early-stage prototypes during knee implant surgeries by the Indian R&D center of a leading US medical device manufacturer. We suggest that this testing approach, enabled by the institutional context in India, represented a significant deviation from standard practices in the US medical device industry and accelerated the design uncertainty resolution process.

In order to ensure the generalizability of our observations from the initial study, we studied two additional device development efforts in India at two other organizations. These projects are distinctly different from our initial case in terms of the nature of the device being developed and the specifics of the developing organization. The first project focused on the development of a software solution for enhancing critical patient care by a tertiary care hospital; the second project involved the development of an affordable, rugged ophthalmology diagnostic device by a local Indian startup. We present a summarized overview of these two device development projects in the Appendix to highlight the context-enabled iterative, early-stage, high-fidelity nature of testing during the development process.

2.3.3. Data Collection and Analysis

For data collection on the device development projects in India, we relied on a combination of project-specific archives and semi-structured interviews. For instance at the US MNC R&D center, details like project scope, team, timeline, budget and activities were collected based on our access to project-specific documents like the project mandate, project plans, design files, etc. The set of documents included detailed information on testing done at different dates, the hospitals and surgeons involved, resulting learning, follow-up activities and other project-relevant data. In addition to the archival data, we conducted 15 semi-structured interviews with

the R&D center managing director, project manager and other team members. Respondents were specifically asked about the device design and its testing, both in groups and individually. Numerous informal conversations and interactions with R&D center employees allowed us to obtain a strong understanding of the project decisions and activities. Given that most of the interviews were conducted around the time the device was launched, study participants were eager to share facts and experiences. Moreover, we do not expect any issues related to forgetfulness or retrospective bias given that the events discussed were recent at the time of data collection. To reduce the risk of information bias, we questioned multiple individuals on overlapping topics and ensured a high level of consensus on all factual matters. Our data collection efforts at the US MNC R&D center also benefited from extensive formal and informal discussions with the managing director of the R&D center. Prior to his current role, the managing director had multiple years of experience in various roles at the MNC's US R&D center and was able to provide comparative insights across the locations (US versus India). Post-data collection, we discussed our observations with the R&D center managing director and project manager and used their feedback to validate and refine the study facts.

Data collection at the two subsequent sites (the tertiary care hospital and the startup) was based on a similar approach that used semi-structured interviews and review of project documents. Interviews at these sites typically lasted 45 minutes to 3 hours and some individuals were interviewed multiple times as we worked through the iterative process of data collection, comparison and theory development. We stopped interviewing and collecting new information at each site when a level of theoretical saturation was reached (Glaser and Strauss, 1967). A particular strength of our in-depth field-based approach is the reconstruction of technical details related to early-stage product conception and testing; as our analysis and understanding evolved,

it became clear that most of the impact of context on the experimentation- and testing-based search process could be observed during the early phases of a project.

Consistent with a field-based inductive research process, the process of collecting data, analyzing data, developing and validating inferences and scanning extant research was iterative in nature (Glaser and Strauss, 1967). Further, as we analyzed the data, we also developed a detailed narrative for each site to capture the sequence of events and activities in each project. Over time, the narrative offered a systematic way to explore similarities and differences across the three projects and explore the interrelations between the different themes and inferences emerging from the data. In the next section, we present the detailed narrative of the medical device development project at the India R&D center of a US MNC, in order to display the data and logic that underpin the core arguments of this paper (Miles and Huberman, 1994). A summarized overview of the projects at the other two sites is presented in the Appendix.

2.4. US MNC R&D Center Project

MedTech[6], headquartered in the US, is a multi-billion-dollar Fortune 500 firm that specializes in the development, manufacturing and marketing of devices for a variety of medical specialties. MedTech established the Indian Research and Development Center (IRDC) in Bangalore, India in 2004. Around late 2010, IRDC identified an opportunity to develop an orthopedic surgical jig for the Indian market.

2.4.1. Project Background

[6] Names and other identifiable details of organizations studied have been anonymized based on prior confidentiality agreements with research sites

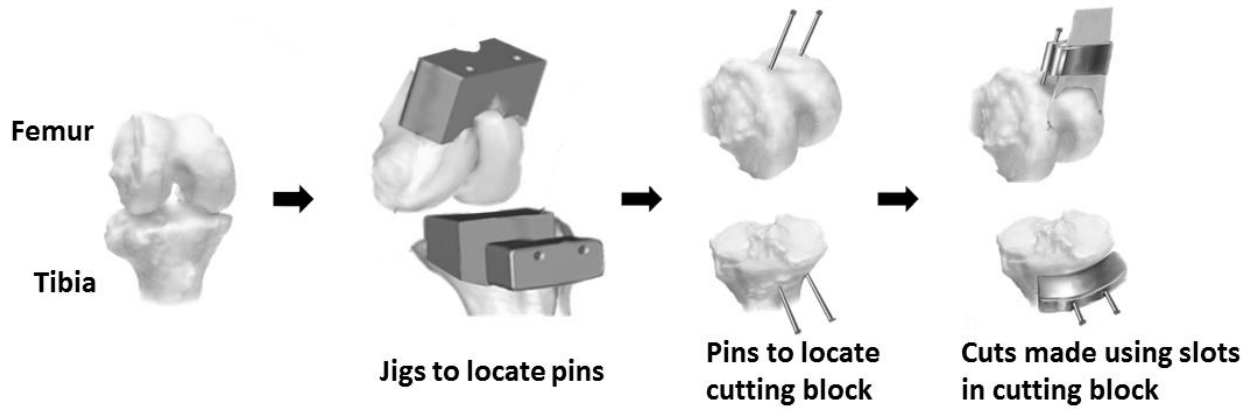
India has one of the largest aging populations in the world, and increased longevity, along with changes in lifestyle, family structure and affluence, has led to a large increase in demand for knee implant surgeries. These surgeries involve cutting off the damaged ends of the bones surrounding the knee joint (femur and tibia) and placing an artificial knee implant. The precision of these cuts on the femur and tibia is critical for a successful surgery; however, the traditional technique for deciding the location of these cuts requires considerable surgical skill and experience as it involves drilling an inter-medullary canal in the femur and tibia and then placing an external guide in the drilled canal to determine the positioning of a cutting block.

IRDC realized that an affordable tool, designed and manufactured in India, which allowed orthopedic surgeons to accurately and rapidly determine the cutting planes would not only increase surgical capacity by allowing less experienced surgeons to undertake complex knee implant surgeries, but would also (1) decrease the operating time and (2) reduce post-surgery recovery time, given the trauma and bleeding during the drilling of the inter-medullary canal. Thus IRDC planned to launch a customized jig based on a pre-surgery scan of the patient's knee. It launched the project in March, 2011.

2.4.2. Search for an Optimal Design

The basic idea of the device planned by IRDC was to scan the patient's femur and tibia bone prior to the surgery. A 3-D model capturing the patient's bone anatomy and deformities would then be developed based on the scan. Using the model, a jig would be designed and manufactured for the individual patient's bone anatomy.

Figure 2.1: Conceptual Design of Jig



During the surgery, the surgeon would place the jig on the patient's femur and tibia. Pin holes on the jig surface would then allow placement of the cutting blocks (see Figure 2.1) in order to permit easy identification of the cutting plane. IRDC was aware that the optimal design of the jig could not be determined from saw-bone models of the femur and tibia, as those were poor representations of actual human bone anatomy and lacked the bone deformities (osteophytes) typically present in knee implant patients. At the same time, MedTech's standard R&D policy stated that without validating that such a customized jig could be fabricated accurately for different patients with varying degrees of knee bone damage, the project could not proceed to clinical testing for establishing product feasibility, safety and efficacy.

2.4.3. US Context: Testing and Experimentation

The IRDC team was aware that MedTech's standardized product development processes in the US required that early-stage concept validation and any design refinements be performed in a cadaver lab. Cadaver knee bones would be scanned to design and develop jigs

and then the jig would be tested on cadavers. Typically multiple cadaver sessions would be conducted iteratively as the team refined the process and product design. Only when the process and product designs were stable would MedTech R&D perform early-stage clinical feasibility testing in hospitals.

MedTech's early-stage testing policy was consistent with device development practices in the US. Specifically, the early-stage experimentation and testing practices are characterized by an absolute avoidance of human patients and the clinical setting. All early-stage concept validation and refinements are based on animal or bench testing (3D models, saw-bone models, artificial eyes for ophthalmology devices, cadaver testing, etc.), presumably to avoid any risk to human subjects. This approach is focused on validating the overall product concept but does not generate insights on product feasibility in clinical settings.

Early-stage feasibility testing is conducted according to established regulatory guidelines and industry norms once the concept is validated and refined through animal or bench testing. On receipt of an Investigational Device Exemption (IDE) clearance from the FDA (the US regulatory body overseeing medical device development and launch), the product development team must find a clinical partner. A clinical trial agreement that covers IP ownership, liability issues, insurance details, etc. is then signed by legal representatives of the development team and partnering physician/hospital. In some cases, especially for startups, it can be challenging to find a physician/hospital to partner with for feasibility clinical studies. It is mandatory to obtain approval from an Institutional Review Board (IRB), and typically the IRB review asks for details like the study hypothesis, background of study, aims, outcomes being measured, methodology, safety, etc. based on the established product concept. Upon approval by the IRB, informed consent from each individual patient is required prior to any testing. It is not

uncommon for patients to refuse to participate in the study, especially for high-risk devices like the planned jig by IRDC, and development teams in the US are allowed to pay patients only a nominal amount for participation in such an early-stage feasibility testing process. If any design change is made based on learning from the IRB-approved study, the IRB protocol typically needs to be updated and approval re-sought before any further tests. If the learning from the feasibility study calls for significant changes to the original concept, the development team has to loop back to rework the concept refinement and validation and then redo the feasibility studies.

Overall, our fieldwork suggested that early-stage experimentation and testing for designing the product was linear and sequential in nature, with a clear demarcation of concept development and feasibility testing in the US. A product prototype could only be tested in the clinical setting once the concept was finalized and other requirements, such as an IDE, IRB approval, clinical trial agreement and informed consent were met. Some of these policies are the result of focus on patient safety and related regulations; others stem from a desire to minimize legal risk and liability. Collectively, they drive up cost and development time significantly, as they fit poorly with the mostly iterative nature of product development, particularly during the earlier stages. Moreover, they drive some of the important high-yield testing activities toward later development phases, when design changes are significantly more costly and time-consuming.

2.4.4. India Context: Testing and Experimentation

IRDC was unable to partner with a cadaver lab in India to refine and validate the design of the proposed jig and the jig development process concept. In India, unlike in the US, few medical device companies have access to an established network of cadaver labs, as the

majority of such companies focus primarily on low-complexity devices that do not require cadavers. When repeated attempts by the team to partner with a local cadaver lab were unsuccessful, another option emerged. “Lots of the surgeons who were aware of our concept were encouraging us to try the idea in a surgical setting,” recollected the project manager. These surgeons had seen the simple prototypes IRDC had developed based on saw-bone models but felt the need to test the concept more rigorously. The team worked with three senior surgeons at different hospitals to iteratively test the product prototype on patients undergoing knee implant surgery so that IRDC could simultaneously refine design and establish feasibility.

The design of the testing approach was as follows: (1) IRDC engineers would design the jig prototype based on scans of patients performed prior to the surgery; (2) the team would work with rapid-prototyping suppliers to develop physical prototypes of the jig using bio-compatible material; (3) during the surgery, surgeon would place the prototype jig on the bone of the patient and use an external computer-assisted system to test whether the jig design, form and fit and the suggested cutting plane were accurate; (4) the surgeon would then proceed with the actual surgical activities by using the traditional method of drilling an inter-medullary canal in the femur and tibia and then placing an external guide in the drilled canal; (5) post-surgery, the surgeon would share his observations and inputs about the prototype jig with the IRDC team.

Given that the device was still in the development stage, the team took steps to ensure that there was minimal or no risk to the patient. The surgeons did not use the jig for any surgical decisions or activities, instead using the traditional techniques for determining the cutting plane. More importantly, the team decided not to place any pin-holes on the surface of the prototype; in the absence of pin-holes, the surgeon could not place the cutting block using locator pins on the bone. In addition, the team used bio-compatible material for manufacturing the testing jig

prototypes to prevent post-surgical infection. Given that the testing approach was considered low-risk and had no impact on treatment protocols or outcomes, IRDC and the surgeons decided not to seek IRB approval or patient consent.

2.4.5. Learning Outcomes

A total of 15 knee implant testing sessions were conducted by the three surgeons over an 8-month period (August, 2011 – March, 2012). During these iterative studies, the team was able to test alternate shapes for fit quality, stability, etc. Once the surgeons placed the prototype on the patient bone in the operating room, they could immediately identify design-related issues and suggest necessary design revisions. At the end of each session, the team made refinements based on what they had learned. Review of the project documents and our interviews showed that these sessions generated a broad and rich set of insights related to three important aspects: product design, process design, and surgical protocol & workflows. For example, during the first iteration, the blocks on the femur and tibia did not fit well because osteophytes (bone deformities) were impinging. Moreover, the team identified a need to redesign the jig for the tibia by adding a chamfer (rocket cut). These observations were shared with the IRDC analysis team involved in developing the 3D bone model and designing the jig so they could make adjustments.

The different testing iterations allowed IRDC access to multiple patients with varying knee bone problems and osteophyte structures; thus the testing approach offered a high-fidelity environment early in product development. Further, the team emphasized that the design process benefitted from testing on patients, as the positioning of the jig on the bone during surgery was based on the jig's accounting for the osteophyte structures present on the bone surface. Testing on cadavers would have presented only limited opportunities to refine and validate the process

design, as cadavers typically do not have knee bone deformities or osteophytes. Development of the surgical jig based on cadavers would have thus likely required numerous expensive design corrections during later clinical testing, when changes are frowned upon.

The testing iterations also revealed additional insights. The third study pointed to the need for further modification of the jig profile to avoid impingement on soft tissues on the bone. No one realized the need for these design changes during the saw-bone sessions, as the saw-bone models lacked soft tissue, or in other words were of lower fidelity. The fifth study highlighted the need to increase the surface area of the jigs in order to allow the surgeons to get an easy grip.

Moreover, based on continuous interactions with the surgeons, the team was able to better understand the end-to-end process at the hospital and decide on the device delivery and operating room surgical protocol. For example, after discussions with the surgeons, the team decided to engrave the patient identifier (patient name, date of surgery, right or left leg, etc.) on the jig to avoid any quality issues. Furthermore, they agreed to deliver the jig to the hospital the day before the surgery to allow for sufficient sterilization time. A key takeaway for the surgical protocol was the need to clean the bone surface where the jig was to be placed of soft tissue to ensure proper fit and stability. The team emphasized that similar insights into surgeon preferences, process flow and surgical protocols were unlikely to emerge from testing in cadaver labs.[7]

Another salient aspect of this case was the speed at which testing was done in the initial months. Often two to three such test iterations were conducted in a month, including the

[7] The IRDC eventually managed to locate a cadaver lab that allowed them to complete the final bone cutting step using the jig prototype; they had avoided testing this last step during surgeries for safety purposes. The two cadaver lab sessions conducted in December 2011 and January 2012 resulted in strong positive ratings of the design developed based on testing during surgeries. The team froze the design in March, 2012. Four more cadaver lab tests were conducted between March and June, 2012 as the team verified and validated the process and product design using planned commercial manufacturing processes.

associated design changes. This rapid testing was enabled by the large volume of patients in India, easy access to the surgeons, the ability to rapidly incorporate design changes, and, most of all, less paperwork and fewer approvals compared to the US context. More importantly, the testing approach adopted by IRDC allowed for simultaneous validation of concept, refinement of design, and assessment of feasibility based on feedback from surgeons and other hospital staff. Reflecting on the process, the managing director of the IRDC commented, "If you go through a linear standardized process that the US follows, say by going to cadaver labs, it takes very long to get to a suboptimal design and then you have to wait very long to get feedback from surgeons on what needs to change. It can take multiple generations in the US to get the design right and that leads to delayed product launch and increased costs."

In June 2012, the team commenced a limited clinical trial in India. Results from the clinical trial were positive and the product was successfully launched in India in December, 2012. The fact that it took a little more than a year to develop the device and less than two years to launch the product was attributed to the learning from high-fidelity testing early in product development and was considered a huge achievement for the team, given its resource constraints and limited experience with similar projects. The equivalent time to reach a clinically validated product and post-trial launch by MedTech in the US would be significantly longer (typically 2x-3x) and the increased timeline would be associated with higher costs related to R&D staff, legal issues, clinical trials, etc. Moreover, the experience helped IRDC realize that the testing regime in India would likely be beneficial for resolving design problems in other complex projects in the US. Specifically, high-fidelity experimentation- and testing-based product and process designs developed in India by MedTech were likely to be successful in the US both during the FDA-managed pre-launch clinical trial process and after the launch of the device.

2.5. Study Finding: Influence of Institutional Context on R&D

Reflecting on the project experience, the managing director of IRDC commented, "The product development capabilities and processes in the US medical device industry were developed for quality and safety. In India we need to focus on speed and cost given the constraints and needs of the market. The early-stage testing we did with the surgeons allowed us to achieve that." He added, "We could not have taken such an approach in the US given FDA requirements, our own design controls, expectations from and concern of the medical community, patient consent, worries about litigation, etc."

Indeed the testing approach adopted by IRDC during product conceptualization and initial design was drastically different from that practiced by MedTech in the US. Our earlier fieldwork in the US had suggested that it is only after the product concept has been fully validated in low-risk simulated settings, and IRB approval has been received, that it is possible to test in a clinical setting to establish product feasibility, efficacy and safety. However, such a linear sequence of activities leads to longer timelines and increased costs due to late identification and resolution of critical design considerations. In contrast, IRDC successfully conducted early-stage iterative testing during knee implant surgeries and managed to accelerate the search process.

Based on our interviews with IRDC team members, interviews with other medical device development teams in India (see Appendix for a summarized overview of two additional projects), and extensive discussions with physicians in India and the US, we suggest that the testing approach in India was enabled by the institutional context: the cognitive orientation of the

development teams, normative orientation of the physicians and regulatory ease and flexibility in India.

2.5.1. Cognitive Orientation of the R&D Team

Past research (Bazerman and Watkins, 2004; Katz and Allen, 1982; Levitt and March, 1988) has suggested that the inertia, rigidity and biases resulting from a firm's dominant logic (Prahlad and Bettis, 1986) and experiences can be disadvantageous in novel and uncertain environments, as they lead to restricted search and the selection of inappropriate solutions for novel problems. The idea of dominant logic applies not just to the firm but also to groups/functions within the firm, and it is likely that the R&D centers of MNCs in developed countries will have strong preferences and biases towards certain logic, methodologies and processes based on various factors like experiences, available technologies and skills, applicable regulatory frameworks (e.g., FDA guidelines in the US) and approved suppliers and partners. These experiences, preferences and biases lead to a "dominant logic of experimentation and testing." Specifically, in the US, the experimentation and testing models are "developed for quality and safety" and are thus extremely linear and sequential. However, in the case of India, the lack of experience working on end-to-end medical device development projects in a regulated environment freed the product development teams from strong preferences and biases about processes. Instead, the team members at these projects adopted an approach similar to software development methodologies like "Agile" and "Scrum," which emphasized fast iterations and feedback. Specifically, in these projects we saw the development teams introduce early-stage prototypes in clinical settings with the aim of learning from the high-fidelity setting and iteratively improving the design. One development team member at the tertiary care hospital developing the software solution (discussed in the Appendix) commented, "There was no way

for us to figure out and design a complex solution like this without testing early versions of the product on real patients along the way and getting timely feedback from the doctors and nurses."

This approach was also enabled by the teams' assessment, perhaps naively, that the risks to patients from the early-stage prototypes were minimal and manageable, and thus a formal IRB process and patient consent were not essential. This assessment highlights a different perception of risk and individual patient rights across the broader medical device development community in India—a perception that has likely stemmed from the overall harsh and resource-constrained realities of the emerging market environment, limited awareness of unethical cases of human subject experimentation like the Tuskegee syphilis experiment[8] and the absence of clear guidelines driving medical device development. Further, the approach was enabled by the simultaneous trust and ignorance of the patient pool. Our interviews across the projects suggested that the patients did not question the presence of prototype versions in clinical settings.

In contrast, we repeatedly heard from the managers and engineers at medical device companies in the US that non-compliance with standardized processes is unacceptable, given the significant costs for failing to present risks to the IRB and during patient consent, penalties for not complying with FDA guidelines, and other factors like litigation risks and the firm's internal guidelines. These costs created an environment that led the development team to rule out any possibility of adopting high-fidelity testing during early stages.

2.5.2. Normative Orientation of the Physicians

The support and involvement of the surgeons were critical in ensuring the feasibility of the testing approach adopted by the IRDC project team. From the beginning, the surgeons

[8] The Tuskegee syphilis experiment was performed from 1932 to 1972 by the Tuskegee Institute contracted by the United States Public Health Service. The study followed more than 600 African-American men who were not told they had syphilis and were denied access to the known treatment of penicillin.

were not only excited to participate in an effort to deliver a complex device for the Indian market but also optimistic about the ability of the planned device to improve access to care for a large number of patients. In our discussions with physicians, we observed a growing recognition that for affordable healthcare to be accessible to large numbers in India, products like the surgical jig had to be designed and manufactured locally. Thus, when the absence of cadaver labs had stalled the project, surgeons working with IRDC were open to iteratively testing early-stage prototypes during knee implant surgeries in the operating room.

In our discussions with doctors across specialties, we consistently heard that such early-stage low-risk experimentation and testing of devices is supported by most medical practitioners in India, given their desire to gain access to devices that are affordable and appropriate for the Indian market and the belief that devices developed by MNCs in affluent countries will not address the requirements for India market. One surgeon commented, "As long as someone brings a reasonable new product idea to me, I am ready to work with him to try it out in the operating room." In the case of the IRDC surgical jig development project, there was a general consensus among the physicians that the testing approach posed no/low risk to patients and that the surgeons were justified in testing given the significant potential gain to the larger patient pool.

In comparison, our interviews in the US suggested that US physicians would not consider undertaking any testing of an early-stage prototype developed by a medical device company, given their concern about risk to patient outcomes and possible liability. This is especially true in cases where the device development team has not obtained IRB approval and/or not designed appropriate mechanisms to seek patient consent before commencing testing activities, as these suggest a lack of concern for patient safety.

2.5.3. Regulatory Flexibility

Though our interviews and discussions consistently pointed to the cognitive orientation of the project teams and patients and the normative orientation of the participating physicians as factors explaining the testing approach, the discussion would be incomplete without recognizing the role of the regulatory environment in India. In case of IRDC, testing in the operating room was possible because the surgical jig was unregulated, like most other medical devices in India, and because there were no clearly defined regulatory requirements for developing or launching the device. The IRDC project manager observed, "There was no legal violation in India from IRDC's standpoint. We followed all the rules in India while doing the testing in the operating rooms."

It should be noted that the regulatory aspect is not just limited to the lack of regulations related to medical device development in India; compliance with laws related to testing on human subjects in general is poor in India. Moreover, an over-burdened judiciary system and lack of awareness due to poverty and low education levels create an environment that reduces litigation risk for physicians. In comparison, the regulatory environment in the US clearly stipulates the need for concept validation, Investigational Device Exemption, IRB approval, patient consent, clinical trial agreement, etc. before a device is introduced to a clinical setting for testing. Non-adherence to these requirements presents serious professional risk to both the physicians and hospitals involved.

Overall, the cognitive, normative and regulative dimensions jointly allow for high-fidelity experimentation and testing, which in turn leads to an accelerated search process. We acknowledge, however, that a limitation of our work is that we cannot disentangle the effects of each of these three dimensions—cognitive, normative and regulative—on the experimentation

and testing process, given that they are typically interrelated; for example, cognitive frameworks drive normative values; normative values influence regulative guidelines, and regulative guidelines in turn influence both cognitive frameworks and normative values.

2.6. Discussion and Conclusion

Our field study explored the impact of context on experimentation and testing practices. Based on the study described, a distinct theme emerged: the local institutional context in India enabled high-fidelity experimentation and testing early in product development by allowing the development team easy and repeated access to clinical settings. More importantly, such practices can accelerate the R&D search process and improve project performance.

We realize that the details of the single case study presented may lead to concerns regarding the generalizability of our observations and findings; however, observations from other medical device development projects and numerous conversations with physicians and hospital administrators in India allowed us to validate our findings. A review across projects led us to uncover strong similarities with the IRDC project: iterative testing of prototypes in a clinical setting without IRB approval or patient consent early in product development, iteratively tweaking product design and incorporating learning from each iteration before subsequent testing, willingness of medical staff to collaborate on these projects, and lack of regulatory barriers.

We do, of course, acknowledge that there may be a cost to this location-specific institution-based R&D advantage. Given the flexibility of institutions (such as weak regulatory laws for medical devices in India), there is a significant risk that innovators will engage in

practices that can potentially hurt human subjects. In the case study presented, IRDC took steps to ensure that patient safety was not compromised due to the testing, yet one cannot guarantee that innovators will always behave responsibly. At the same time, such an institutional context provides opportunities to respond to the inadequate supply of appropriate medical devices in these markets.

Early-stage high-fidelity experimentation- and testing-based device development processes may also hold promise for developed economies like the US. Numerous high-risk medical devices are approved for launch by FDA in the US today based on data from a small number of clinical studies. Often these studies to check for efficacy are not randomized, controlled or blinded given the inherent issues and complexity of testing high-risk devices such as stent, orthopedic implantable etc. Given the low-fidelity testing approach during initial development and the subsequent shortcomings of the approval process, launched medical devices often prove ineffective (or even harmful). Perhaps allowing for high-fidelity experimentation and testing early in the development process would offset some of the drawbacks inherent in the development and approval process. Ultimately it is beyond the scope of this paper to decide on clear policy guidelines for such a complex dilemma; however, we recognize the need for further studies to allow policy makers and government administrators to appropriately balance the need for processes that allow for development of effective and reliable healthcare devices against the risks to human subjects involved in the development process.

We also realize that given the unique institutional context in India related to the development of medical devices, the theoretical implications discussed earlier might be based on an “extreme case” (Eisenhardt, 1989). However, such a facilitative institutional context is not exclusive to the medical device industry in emerging countries today. Our observations are

therefore applicable to innovation efforts in other industries, geographies and time periods: for example, the development of microfinance products in Bangladesh and mobile money in Kenya was guided by institutional context-enabled search processes. Furthermore, we were interested to see whether our observation that institutional flexibility can accelerate innovation projects holds true outside of developing economies like India, Kenya and Bangladesh, especially in a developed country setting like the US. A study of the development of valued medical devices like the heart-lung machine (Cohn, 2003; Fou, 1997) and the implantable pacemaker (Jeffrey, 2001) and surgical procedures like open-heart surgery (Miller, 2000) in the US suggests that these developments benefitted from the prevalent institutional context; the experimentation and testing for these development efforts was led by individual physicians and often ignored today's requirements regarding informed patient consent, IRB approvals, legal agreements, litigation concern, preponderance of efficacy and safety evidence. Similar to what we see in India today, the US context at that time (1940s-1960s) allowed doctors, engineers, and patients to participate in a process of trial and error experimentation.

The institutional context in the US has evolved over last few decades. Today the complexity of FDA policies and guidelines, significant litigation concerns, difficulty in acquiring patient consent, concerns about protecting IP ownership, coordinating with independent third-party IRB companies, clinical trial agreements with hospitals, significant involvement of lawyers, and so on not only make innovation efforts in healthcare longer, more complex and more costly, but also inhibit doctors, patients and scientists from coming together early in product development to conduct well-designed, low-cost, low-risk experiments and tests that resolve project uncertainties. In our review of past healthcare innovations and discussions with senior medical practitioners and administrators in the US, it is broadly agreed that these advances

would likely not have been possible today, given the institutional context in the US. Many highlighted the fact that it is extremely difficult, if not impossible, to develop innovations without the ability to participate in a flexible trial-and-error-based learning process. This is especially true for novel products for which prior experience and existing assets are of little use, meaning that firms must instead depend on a search process based on experimentation and testing (West and Iansiti, 2003).

Today, it is becoming increasingly common for US device manufacturers to develop and launch devices first outside the US. Our discussions with medical device industry practitioners in both the US and India suggest that though resource availability and lower costs were the initial motivators for the shift of med-tech innovation efforts to emerging markets like India, more recently the MNCs have realized the power of local context in searching for solutions to complex R&D problems and this, in turn, has implications for decisions related to R&D center location and assignment of project activities to different centers in a global R&D set-up. This idea of institutional context driven R&D center location is a major implication of our study and complements extensive prior work on determinants of global R&D center locations (for detailed references please see Alcacer and Delgado, 2012)[9].

We conclude this paper with the observation that context matters for experimentation and testing in R&D, sometimes in subtle and unexpected ways that managers need to recognize. This paper contributes to past and current research related to innovation and entrepreneurship;

[9] Prior work has highlighted four broad factors determining R&D location: *1. location endowments* (for example, IP regimes, labor regulation, quality of higher educational systems and the unique technological knowledge present in universities), *2. external agglomeration* (the central premise being that collocated R&D centers would enjoy higher productivity because geographic concentrations of R&D centers would attract larger pools of specialized labor and suppliers, and would also facilitate the flow of knowledge from one firm to another), *3. interdependence between activities* (say, interdependence between manufacturing and R&D or among different R&D activities), and *4. market proximity* (the need to be close to final markets in order to respond to local market requirements).

specifically, it complements research on a host of topics like allocation of product development project activities to specific product development centers, entrepreneurship enablers, innovation by lead users and reverse innovation. For example, should MNCs locate problem-solving efforts for some of their high-novelty innovation projects in locations more conducive to early-stage high-fidelity experimentation and testing instead of being exclusively driven by a resource availability and/or market proximity perspective? Do certain locations see more entrepreneurial activity as the context allows for the experimentation and testing necessary to develop new products, processes and business models? How does the influence of context on experimentation and testing encourage/impede lead users from innovating, and does this help us to better explain and identify the boundary conditions of the lead user theory (von Hippel, 1987)? Lastly, recent discussions on reverse innovation (Govindarajan, Ramamurti, 2011) suggest that developed country MNCs should engage in innovation in emerging economy markets like China and India to develop winning products for developed country markets (USA, Western EU, Japan). This paper suggests that the access to the emerging economy context that allows for accelerated search processes in R&D projects may be one of the underlying reasons for reverse innovation.

2.7. Appendix

Case 1: A large tertiary care hospital located in Mumbai partnered with a software services company to develop a patient-specific software solution for enhancing critical patient care in the intensive care unit (ICU) through improved patient condition tracking and better care planning. The initial prototype, a base version, was designed based on physician and nurse inputs and the solution was installed for two ICU patients in January, 2010 for early-stage testing. A team from the software service company was given access to observe the clinical staff operating the installed solution for these two patients and get feedback. Based on these observations and interactions, decisions were made on what modifications were necessary, what new features to be added and in what sequence. Software features were released periodically and feedback was obtained from the clinical staff all along the process. Over time as the solution improved, it was deployed on additional patients and this led to further feedback/learning. By December 2010, the solution was stable, feature-rich and ready to be launched across all critical patients at the hospital and also in partnering hospitals.

All through the development process, the standard ICU practices/procedures were adopted in parallel to the software prototypes to ensure patient safety was not compromised. As a safety measure, additional nurses were assigned to the ICU patients who received the prototype solution. Given that the risk to the patient was deemed negligible because of these measures and there was no direct physical intervention, formal IRB approval and patient consent were not considered necessary. During our discussions, the team acknowledged that being able to test different product versions and features in the operating context (multiple patients with different profiles and clinical staff) all through the development cycle led to rich learning and accelerated development. The general consensus is that the development timeline of just one year could not

have been realized in the absence of such an approach as (1) the IT development team would find it difficult to independently access the domain knowledge necessary and identify and validate the requirements early in the process and (2) doctors/nurses would have been less effective in stating the requirements if they had not been using the software prototype with ICU patients.

Our study of the US processes suggests that such an accelerated approach would have been difficult to achieve in the US. This is due to a number of reasons that include but are not limited to the development team's lack of easy and continuous access to critical care patients; the impossibility of installing or testing prototypes without the approval of the FDA; IRB approval and re-approvals after each round of software enhancement; patient consent; concerns around protection of patient data; concerns around litigation risks; contractual agreement between parties involved in development, etc.

Case 2: A medical device startup located in Delhi sought to develop an affordable, non-invasive, and rugged ophthalmology device that could develop an image of the anterior (cornea) and posterior (retina) surface of the eye and thus check for common eye problems related to cataracts, glaucoma, diabetes, etc. The affordable and rugged nature of the planned device would allow it to be used in rural areas by a minimally trained technician.

The team had the opportunity to partner with a leading ophthalmology hospital in India; the hospital was supportive of the device development effort as the device would address the need of the large population in rural India who did not have access to quality eye care. The primary design issues to be addressed during the project involved ensuring high image quality for diagnostic purposes and determining the external physical form to ensure ease of use, ruggedness and acceptability by both physicians and patients. The startup team, consisting

primarily of business and engineering talent, had limited experience and expertise in ophthalmology and approached the development effort as a series of iterative trials on the patients at the hospital. During each trial, the ophthalmologists at the hospital took the eye images of 20 or more eye patients using the latest prototype and provided feedback to the startup team on the quality of the images for clinical diagnostics and how the images compared with those from devices by high-end manufacturers. To ensure the start-up team had rich feedback to develop a robust device, the ophthalmologists provided image feedback for a variety of eye diseases. Further, the ophthalmologists used the prototype in a rural eye camp to test the operability of the device in the field. As the startup team observed the imaging process at the hospital and at times got directly involved in the effort, they developed rich insights about the product form.

Given the low risk to the patients, IRB and patient consent were not deemed necessary. In all, six trials were conducted with the hospital and the startup team used the learning from these iterations to improve the prototype for subsequent testing. The team was able to launch the device at the end of the first year of the development effort. Subsequently, the team did a small-scale clinical trial to establish that the device efficacy was comparable to the available high-end products in the market. During our discussions, the team acknowledged that given their limited clinical background, it would have been extremely hard for them, if not impossible, to develop the device without the repeated iterations with patients and ongoing ophthalmologist feedback.

CHAPTER THREE

Task Shifting in Surgery: Lessons from an Indian Heart Hospital

3.1. Introduction

An open question in many healthcare settings is the extent to which specific tasks can be shifted from senior to junior colleagues so as to reduce cost without compromising quality. This study examines the feasibility of such task shifting in tertiary surgical care through a two-month field study of the Narayana Health City Cardiac Hospital (NH), a leading heart hospital in Bangalore, India. Task shifting is one of the critical enablers allowing NH to perform approximately 5,000 adult cardiac surgeries each year—including roughly 2,400 coronary artery bypass graft (CABG) procedures at a price[10] of between $2,000 and $3,000 per case. In contrast[11], a typical large hospital in the United States might perform between 600 and 1,800 cardiac surgical cases per year with CABG charges exceeding $100,000 per case (New York State Department of Health Cardiac Surgery Report 2008-2010; Richman et al, 2008; Govindarajan and Ramamurti, 2013).

This case illustrates the practice of task shifting during cardiac surgeries at NH and uncovers a set of insights related to the rationale for and impact of task shifting. The case specifically explores several questions: Why and how did NH adopt task shifting? What are the implications of task shifting at NH? To what extent can task shifting be adopted in other resource-constrained, tertiary care settings?

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[10] Refers to price paid by patient. Internal costs for a CABG at NH are approximately $1,500-$1,600

[11] The difference in volume can be explained in terms of both the number of surgeons (10 at NH versus three to six at a typical large US hospital) and the average number of cases per surgeon per week (10 at NH versus four to six in US hospital).

3.2. Context

Heart disease is one of the leading causes of death worldwide and one of its most-common forms is atherosclerotic coronary artery disease (CAD) (Mendis, Puska and Norrving, 2011). CAD patients who are deemed unlikely to benefit from lifestyle changes, medication, or non-invasive procedures often undergo a coronary artery bypass graft (CABG) surgery, where a vein or artery from another part of the body is used to create an alternate path (or bypass graft) for blood to flow around an arterial blockage.

The main phases of a CABG procedure are as follows: induction, chest opening, vein/artery harvesting, main procedure, and chest closure. Induction involves preparing the patient for surgery. Chest opening consists primarily of activities such as skin incision, opening both the sternum, or chest bone, and pericardium (a sac that covers the heart) to access the heart. Vein/artery harvesting focuses on obtaining the saphenous vein from the leg, the radial artery from the arm, or the left internal mammary artery (LIMA) from the chest for creating the grafts. The main procedure is the phase where the two ends of the graft are constructed, referred to as anastomosis, and requires considerable surgical skill and judgment. Finally, chest closure involves closing the sternum, subcutaneous layer, and skin prior to transporting the patient from the operating theater (OT) to the intensive treatment unit (ITU).

The primary tasks performed by surgeons during a CABG are chest opening, LIMA harvesting, main procedure, and chest closure. The anesthesiologists induce anesthesia and monitor the condition of the patient (e.g., heart rate and blood pressure) during the procedure, a junior surgeon or physician assistant or operating room nurse typically harvests the saphenous vein and radial artery, and the scrub nurse or junior surgeon assists the surgeon. In the event a

heart-lung machine is used to maintain blood circulation and oxygenation during the main procedure, a perfusionist is present to operate the machine.

It is estimated that one half of the approximately 120,000 cardiothoracic surgeries performed each year by 1,400 cardiothoracic surgeons across roughly 250 hospitals in India are CABGs. These figures are particularly small relative to the estimated need of between two and three million cardiothoracic surgeries for the 30-35 million CAD patients in India (Kaul and Bhatia, 2010; Vaithianathan and Panneerselvam, 2013). More importantly, most of the available healthcare delivery infrastructure and capacity in India are targeted toward the urban affluent, making access a particular problem for indigent and rural populations. In comparison, there are approximately 3,000 to 4,000 cardiothoracic surgeons spread across the roughly 1,000 hospitals in the US that perform cardiac surgery (Grover et al, 2009; Society of Thoracic Surgeons website). The Centers for Disease Control and Prevention website indicates that, in 2010 alone, approximately 400,000 CABGs were performed in the US (CDC/NCHS National Hospital Discharge Survey, 2010). This number does not include other cardiac surgeries such as valves, aneurysms repairs, and transplants. The resource constrained nature of cardiac surgery is obvious if one compares the number of cardiac surgeons and surgery centers in India to the corresponding numbers in the US, especially considering that the US population of 320 million is about one-fourth that of India's 1.2 billion.

The gap between the demand and supply of cardiac surgery in India was much greater in the mid-1990s, when approximately 3,000 to 4,000 CABG surgeries were being performed per year in a limited number of cities in India, and the total population of India was 850 million people. Moreover, these surgeries, typically priced at $3,000 to $4,000, were unaffordable for most Indians, especially those in the large indigent population. Within this context, NH opened

its doors in 2001 with the goal of providing affordable healthcare to the masses in India and quickly faced a heavy load of incoming cardiac patients (Khanna, Rangan and Manocaran, 2005).

3.3. Problem

At the time NH was founded, the hospital's leadership realized that delivering high-quality outcomes would require offering the NH senior surgeons salaries that were consistent with market rates in India. At the same time, it was important to ensure that these salaries did not prevent NH from offering affordable care to the indigent populations it aimed to serve. This resulted in an acute form of the common tension between care quality and cost. This problem was further exacerbated by the heavy inpatient and outpatient workload placed on the limited number of NH surgeons. The organization of resources and processes at the few urban hospitals offering cardiac surgery to the affluent segment of the population at that time was not appropriate for NH as it failed to deliver surgical care (1) to the high volume of incoming patients and (2) at the desired lower operating costs; both these criteria were critical to achieving NH's mission.

3.4. Solution: A Task-Shifting Based Operating Model

Different surgical tasks during a CABG require varying skill levels and decision making ability. Some tasks, such as chest opening, chest closing, and saphenous vein harvesting, fall towards the lower end of the complexity spectrum. More-complex tasks, such as anastomosis during the main procedure, require that the cardiac surgeon be assisted by a clinical staff member

standing on the other side of the operating table. Since the development of modern open-heart surgery in the 1950s, it has been common for junior surgeons, keen on developing their surgical skills, to assist the senior surgeon on complex tasks and take the lead on the least-complex tasks, such as skin incision and chest closure.

The senior surgeons at NH argued that if they performed only on the main procedure during a CABG surgery, they would then have ample time to attend to other patients in the outpatient department, inpatient ward, or intensive care unit. This approach would allow NH to take on a larger number of patients and thereby reduce the average cost of a surgery, as NH surgeons were salaried and not reimbursed based on number of surgeries performed. As a result, senior surgeons began to assign greater responsibility to the junior surgeons who were assisting them in the operating room. As various senior surgeons adopted this approach, each would explore issues such as what tasks could be done by the junior surgeon, how could the junior surgeon's activity scope be increased over time, and how long the senior surgeon could be outside the operating-room. Co-location in adjacent operating rooms allowed both senior and junior surgeons to observe and learn from each other. As the junior surgeons developed into independent senior surgeons at NH, they adopted a similar approach and thereby institutionalized the practice of task shifting at NH.

Over time, an effective and stable approach to task shifting has emerged at the hospital. The standard approach at NH today is to have one senior and one junior surgeon involved with each procedure. Prior to the surgery, the senior surgeon explains to the patient and his or her family exactly which tasks he will perform and which ones will be performed by other members of the surgical team. One senior surgeon remarked, "We have a wonderful gift to be able do what we do – save lives. If we can see more patients and do more surgeries in a day with help from

others, we have just managed to get more out of our skill and knowledge and make a bigger impact. Which surgeon would not want to do that?"

Our fieldwork suggested that the success of NH's task shifting approach has been to a large extent determined by the preparation, or rather the lack thereof, of junior cardiothoracic surgeons for independent practice at the completion of their residency programs. Cardiothoracic training in India follows a six-year format in which surgical residents complete a three-year general surgery residency (MS/DNB) followed by a three-year thoracic surgery residency (MCh/DNB) (Kaul and Bhatia, 2010; Vaithianathan and Panneerselvam, 2013). In our discussion with NH surgeons, we repeatedly heard that cardiothoracic residents often do not get sufficient opportunities to perform, even under supervision, critical CABG surgical tasks such as LIMA harvesting and grafting. Thus, it is common for young cardiothoracic surgeons in India to work for a few more years after residency under the supervision of a senior surgeon to develop necessary skills. We note that junior surgeons at NH tended to view task shifting primarily as an opportunity to learn by participating in a high volume of complex cases with experienced senior surgeons. As a result, task shifting at NH did not appear to create any significant challenges related to the professional motivation of junior surgeons.

The time for a junior surgeon at NH to develop the set of skills required to be an independent senior surgeon typically varies from four to six years beyond the end of residency. The first four to six months of this period are marked by training under supervision resulting in a rapid, sequential handover of the more-routine surgical tasks (i.e., everything except the main procedure) to the junior surgeon. Subsequently, the junior surgeon continues to perform these transferred activities independently, while also assisting the senior surgeon during the main procedure. This intermediate, multi-year "steady" phase typically involves no additional task

shifting but rather leverages the senior surgeon's time by allowing him to meet new patients or participate in other concurrent surgeries. Finally, during the last three-to-six months of the skill development period, the junior surgeon performs the main procedure under supervision of the senior surgeon. This staffing approach based on task shifting is not restricted to CABG procedures but has also been adopted extensively by the majority—though not all—of the NH surgeons for other cardiac surgeries, such as valve repair/replacement, aortic surgery, heart transplant, and pediatric procedures.

Our discussions with NH surgeons revealed that no internal or external (e.g., regulatory) approval was required to implement task shifting at the hospital. In particular, the origin of task shifting at NH was not the outcome of an administrative mandate. Rather, it resulted from a few surgeons developing an approach that allowed them to be effective in delivering affordable care. Over time, this approach evolved into a standardized routine adopted across the cardiac surgery team. Even today, individual surgeons at NH have the authority to decide if and to what extent they want to adopt task shifting; there are no strict guidelines in place to manage or monitor the practice. For example, depending on the initial skill-level of the junior surgeon and his ability to pick up new skills, the senior surgeon may vary the pace at which tasks are shifted. Similarly, the senior surgeon may decide to spend more time in the OR if he considers a particular case to be more complex.

3.5. Results

Task shifting allows the typical NH surgeon to perform two to four surgeries per *day* compared to a typical US surgeon performing four to six such surgeries per *week*. This difference is particularly significant given the shortage of cardiac surgery facilities and capacity in India.

Our discussions revealed that cardiac surgery patients typically are not turned away at NH. In fact, other hospitals in India, Bangladesh, Pakistan, and the Middle East often refer patients to NH given its expertise in cardiac care and lower costs. Due to the high level of patient demand, less critical patients are sometimes asked to wait for a few days while more-urgent cases are expedited. Typically, once the decision to perform surgery has been made based on an angiogram and other clinical tests, the average wait time for the ensuing operation is two to three days.

In addition to the large number of surgeries performed, task shifting allows senior surgeons at NH to meet with an average of 20 outpatients per day, many of whom are candidates for surgery. It is, therefore, likely that, in the absence of task shifting, the number of surgeries at the hospital would have fallen significantly. During our field study, we noticed a senior surgeon shift to a one-surgery-per-day routine over multiple consecutive days (versus his standard of two per day) as his assisting surgeon was on leave. He remarked, "It gets difficult to do multiple surgeries a day if one has to be in the OR from skin incision to skin closure, given that there are outpatients and other work." Multiple surgeons also referred to the fact that in case they have to be in the operating room from skin incision to skin closure, they will either have to do fewer surgeries per day or perform surgeries on fewer days of the week to create more time to see outpatients. Based on the extensive use of task shifting by the majority of senior surgeons, we estimate that, in the absence of task shifting, the typical surgeon would have performed three to four (or 25-30%) fewer cases per week. This drop in surgical volume would have led not only to a reduction in surgical revenue but also to an increase in costs due to the erosion of scale economies in areas such as procurement of consumable supplies, administration, and other

overhead. The salaries of senior surgeons were typically three to five times higher than those of junior surgeons at NH, suggesting significant savings in labor cost per case due to task shifting.

Moreover, junior surgeons consistently noted that being on their own in the OT for certain phases of the procedure led to a richer learning experience. They felt more responsible and motivated, and tended to think ahead about possible issues but, at the same time, were comforted by the fact that multiple senior surgeons were available in adjacent operating rooms for immediate guidance if necessary. That said, the senior surgeons were conservative in managing this task shifting due to their ultimate accountability for all activities performed by the assisting surgeon. One senior surgeon commented, "Task shifting should never affect clinical outcomes. We will not shift tasks unless the assisting surgeon is ready to take on those activities, and we will not let them perform independently unless we see them perform the shifted tasks properly. We do realize that during the initial stages of task shifting, the surgical durations will increase as the junior surgeons are in the early stages of skill development, but they tend to catch up in six months after they have done the first 100-150 cases." Interestingly, several surgeons at NH maintained that task shifting should, in fact, *improve* surgical performance as it allows a senior surgeon to focus on and be fresh for the most critical anastomosis tasks during a four to six hour procedure that can be mentally and physically tiring for a surgeon. Related to this point, both senior and junior surgeons repeatedly emphasized the importance of working together as a team over long periods of time to build the familiarity and trust that they viewed as critical in ensuring successful outcomes (Reagans, Argote, and Brooks, 2005; Huckman and Pisano, 2006).

3.6. Effect of Task Shifting on Clinical Performance

Shifting tasks during a complex procedure, however, naturally raises important questions about potential negative effects on clinical performance. To examine the potential impact of task shifting on surgical performance, we compared the outcomes of two surgeons (hereafter referred to as Surgeon A and Surgeon B), who were similar in experience, workload, and patient profile but varied in their levels of task shifting.

The two surgeons had extensive experience in cardiothoracic surgery. Surgeon A had 18 years of experience and had performed more than 8,000 surgeries during his career. Surgeon B had 15 years of experience and had performed more than 5,000 surgeries. The majority of cases for both surgeons were CABG or valve repair/replacement surgeries, with CABG representing approximately 60% of the total cases performed by each of them in 2013. Typically, Surgeons A and B each performed two surgeries a day from Monday to Friday and one case on Saturdays.

During our study we performed detailed observation of 35 CABG cases (17 by Surgeon A and 18 by Surgeon B) and collected data on the time of each entry and exit by the surgeons during a given procedure. These cases all occurred during October and November of 2013. Our observations highlighted the different approaches each surgeon consistently took with respect to task shifting. Surgeon A entered the OT during or after the induction stage and would perform skin incision, LIMA Harvesting, grafting during the main procedure, and closing the sternum. Surgeon A's junior surgeon had been working with Surgeon A over multiple years; he would assist Surgeon A with all the steps and would typically perform only the closure of the subcutaneous layer and skin independently. In contrast, Surgeon B would come to the OT specifically to perform the main procedure but would visit the OT an additional three to four times before and after the main procedure for short intervals of roughly two to three minutes each, to make sure the surgery was proceeding smoothly. The junior surgeon had been working

with Surgeon B over multiple years and would conduct all other primary surgical activities (e.g., chest opening, LIMA harvesting, and chest closing) without Surgeon B in the room. Both junior surgeons had started working with their respective senior surgeon years earlier, and there was no obvious difference in their ability to perform the less-complex surgical tasks such as skin incision or skin closure.

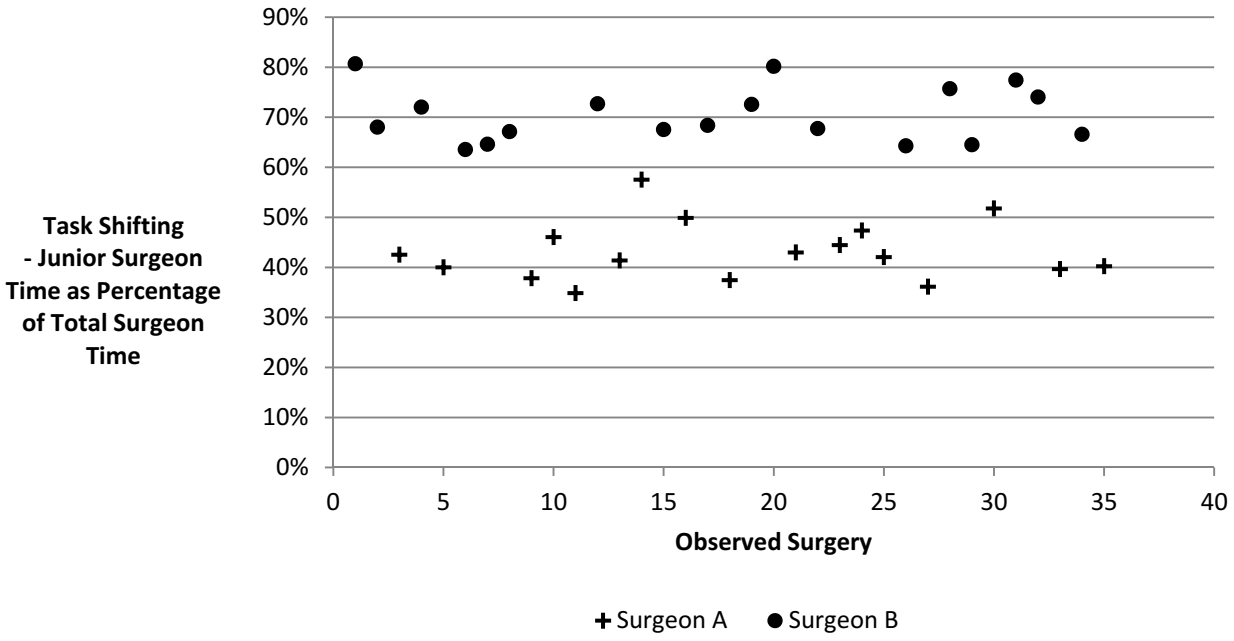
We used data collected from the 35 procedures to create a measure of task shifting: *Junior Surgeon Time as a Percentage of Total Surgeon Time*. This measure was calculated as the OT time for the junior surgeon as a percentage of the sum of OT times for the senior and junior surgeons. Higher values of this measure thus suggested higher levels of task shifting. As seen in Table 3.1, Surgeon B exhibited a substantially greater level of task shifting than Surgeon A.

Table 3.1: Mean and Standard Deviation of Procedure and Surgeon Time (in Hours and Minutes)

	All	**Surgeon A**	**Surgeon B**	**p-value**
Number of Cases	35	17	18	
OT Time (Patient In to Patient Out)	4:21	3:58 (0:38)	4:43 (0:43)	0.003
Senior Surgeon Time in OT	2:14	2:53 (0:42)	1:38 (0:31)	0.000
Task Shifting Measure - Percentage of Junior Surgeon Time to Total Surgeon Time	57%	43%(6%)	70%(5%)	0.000
Time Interval of Activities				
Induction	0:43	0:41 (0:09)	0:45 (0:10)	0.249
Chest Incision and LIMA Harvesting	0:53	0:56 (0:15)	0:51 (0:16)	0.337
Main Procedure	1:27	1:10 (0:25)	1:43 (0:35)	0.003
Chest Closure	0:56	0:51 (0:13)	1:01 (0:14)	0.033
Average Time Per Graft	0:41	0:41 (0:09)	0:41 (:06)	0.889

In Figure 3.1, we plot the procedure-level values of *Junior Surgeon Time as a Percentage of Total Surgeon Time* separately for each surgeon. This plot reveals that Surgeon B exhibited a *consistently* higher level of task shifting that Surgeon A. In fact, there is no overlap in the range of values for the two surgeons.

Figure 3.1: Task Shifting Extent Observed in 35 CABG Procedures



Discussions with surgeons and other OT staff confirmed the regularity of the differences between the two surgeons. Moreover, our discussions with anesthesiologists and perfusionists who worked with both senior surgeons suggested that their patient pools had been similar in terms of risk for several years prior to our observations. Our detailed observations of the 35 procedures supported this view, with the two surgeons displaying similar average values for patient covariates including age, sex, ejection fraction, number of diseased vessels, disease

history, and other comorbidities. Nonetheless, our comparison of outcomes for these surgeons includes categorical controls for differences in patient severity.

Having established the difference in task shifting between these two otherwise-similar surgeons, we compared their performance using archival data for the isolated CABG procedures performed by each over the 10-month period from January 2013 to October 2013. Surgeons A and B each worked with only one junior surgeon—though the particular junior surgeon was different for the two senior surgeons—for all of the CABGs we observed. Moreover, both of the junior surgeons had well defined and stable roles in the operating room during the period covered by the archival data from January to October 2013. The archival data reveals that clinical outcomes for Surgeon B are no worse than those for Surgeon A over this 10-month period, as illustrated by the second and third columns in Table 3.2.

Table 3.2: Outcomes for Isolated CABG Cases over 10-month period for Surgeon A and B

	Past 10 month – All Patients			**Past 10 month – Risk Rating A**		
	Surgeon A	**Surgeon B**	**p-value**	**Surgeon A**	**Surgeon B**	**p-value**
Number of CABG Patients	271	256		242	247	
In-Hospital Mortality Count	2	4		2	3	
In-Hospital Mortality Rate (%)	0.74%	1.56%	0.356	0.83%	1.21%	0.667
ITU Stay in days	3.23 (0.736)	3.01 (0.464)	0.000	3.06 (0.512)	2.98 (0.392)	0.047
Post-Op Stay in days	7.41 (2.734)	7.81 (8.154)	0.457	7.36 (2.727)	7.83 (8.289)	0.398

Given the comparability in patient characteristics for Surgeons A and B, the shifting of tasks to appropriately trained junior surgeon during CABG procedures does not appear to negatively impact the key outcomes of mortality and postoperative length of stay.

Even with our observed controls, there may still be concern that the patient profiles for Surgeons A and B were not comparable. To address this issue, we limited the comparison of outcomes only to those patients assigned a risk rating of A by NH's internal risk rating system. The internal risk rating system at NH collapsed clinical factors to place each CABG patient into one of three risk categories at the time of admission: Risk A (elective cases standard risk without any major complications), Risk B (high risk), and Risk C (extreme risk). Risk C patients, though small in absolute number, included critically ill patients who were referred to NH by other tertiary hospitals in India. Risk ratings were determined based on a weighted model that considered key patient comorbidities including, but not limited to age, ejection fraction, COPD, diabetes, renal dysfunction, active endocarditis, physiological disorders, recent stroke/MI, and the occurrence of prior surgeries and procedures. For the 10-month sample, 82% of CABG patients received a risk rating of A, 16% patients received B, and 2% patients received C. As expected, Surgeons A and B had similar distributions in terms of risk rating; Surgeon A had 89% patients with risk rating A and 11% patients with risk rating B, while the corresponding figures for Surgeon B were 96% and 4%. Neither surgeon operated on any Risk C patient during this period.

Table 3.3 captures the volume and outcomes of CABGs of different risk ratings performed by all surgeons at NH, a majority of whom have adopted the task shifting practice. The magnitude and variability of clinical outcomes for CABG patients with different risk ratings provide a rough validation of NH's approach to risk rating. Specifically, patients with a higher

risk rating tended to have a higher likelihood of mortality, longer ITU stays, and longer postoperative hospital stays. Moreover, as expected, the variability (measured by coefficient of variation) in ITU stays and postoperative hospital stays tended to be higher for the extreme risk patients (i.e., risk rating C) than for the two lower-risk categories.

Table 3.3: Outcomes for All Isolated CABG Cases over 10-month period by Risk Rating

Risk Rating	Number of CABG Patients	In-Hospital Mortality (%)	ITU Stay (Days)		Post-Op Hospital Stay (Days)	
			Mean	Coefficient of Variation (=SD/Mean)	Mean	Coefficient of Variation (=SD/Mean)
A	1,688 (82%)	1.1%	3	0.22	7.9	0.72
B	338 (16%)	3.5%	4.7	0.24	9.1	0.63
C	33 (2%)	9.0%	5.6	0.4	11.8	1.04

The results of our comparison of outcomes for standard risk patients (Risk Rating A) appear in the right panel of Table 3.2. Consistent with results for the full sample, there was no evidence of negative impact of task shifting on outcomes considered. Thus, to the extent that costs were reduced without jeopardizing quality, these results suggest that shifting selected tasks of low complexity from senior physicians to appropriately skilled junior colleagues may have improved medical productivity in this tertiary care setting.

3.7. Caveats and Limitations

Though our analysis offers suggestive evidence that task shifting does not negatively impact the performance of tertiary surgical procedures, several caveats must be acknowledged.

First, we deliberately focused only on two surgeons at NH. This approach allows us to isolate the concept of interest, as the two surgeons are comparable in experience, patient mix, and other characteristics, but vary significantly in terms of task shifting. We note, however, that the majority of cardiac surgeons at NH use task shifting extensively and successfully during CABG procedures, as suggested by the clinical outcome data in Exhibit 4. Second, our comparison cannot fully explain the reasons for different levels of task shifting across surgeons and does not account for unobservable residual factors such as underlying surgeon skill. Third, our comparison draws upon a limited set of outcomes for a specific procedure at a single institution. Like many hospitals in developing countries such as India, NH tracks a limited set of clinical outcomes focused on the in-hospital stay period; long-term outcomes are not systematically tracked at NH given the difficulties of follow up with a large number of patients from different parts of India, Bangladesh, the Middle East, and Africa. This problem is compounded by the absence of electronic medical records and reliable, unique identifiers (such as social security numbers) for individual patients. Fourth, the archival analysis of outcomes relies on a relatively small sample of patients (n=527) treated by only two surgeons and for whom we had only categorical information about preoperative risk. It is, therefore, challenging to compare the NH patient pool to that of other hospitals in India and that of other countries.[12] Further, the detailed observations used to capture each surgeon's degree of task shifting are drawn from an even smaller sample of procedures (n=35). Finally, the tendency at NH of junior surgeons to work with a single senior surgeon over an extended period of time did not allow us to observe task shifting from one senior surgeon to *multiple* junior surgeons.

[12] Related to the comparability of NH CABG patients to those at other hospitals in other countries, we note that cardiac patients at NH are first seen by a cardiologist and are referred to a surgeon for CABG based on angiogram results and globally accepted clinical criteria, such as the presence of triple-vessel disease or diffused stenosis. NH has five catheterization labs and performs about 15,000 catheterization procedures per year.

3.8. Discussion and Conclusion

Several recent studies have suggested that the shifting of routine tasks and interventions (e.g. standard blood work, follow-ups, data-recording) from physicians to less expensive, lower-skilled staff (e.g., nurses) is an effective response to the shortage of qualified medical staff in resource constrained settings (Govindarajan and Ramamurti, 2013; Krupp and Madhivanan, 2009; Zachariah et al, 2009; Morris et al, 2009; Macdonnell and Darzi, 2013; Fulton et al, 2011). These studies note the potential for task shifting to reduce labor costs with no adverse effect on patient outcomes. However, complex procedures (e.g., cardiac surgery, neurosurgery) at tertiary care centers are often assumed not to be appropriate for task shifting, as they require nuanced skills, deep knowledge, rapid decision making, and specialized multi-year training (Chu et al, 2009). Thus most of the discussion about task shifting to date has focused on administrative and lower-end clinical processes. Moreover, concerns about quality and safety, as well as professional and institutional resistance, pose significant challenges to the adoption of task shifting in tertiary care.

This case study on CABG at NH illustrates task shifting in the context of tertiary care. It is worth noting that at NH, select portions of a larger complex procedure are shifted to less-experienced individuals *within a given level of professional qualification* (in this case, among licensed surgeons). This situation stands in contrast to the established notion of task shifting in which an entire activity or procedure is delegated to a less-qualified category of professionals. As a result, the task shifting at NH was not subject to professional resistance; instead it was enabled by a spirit of mentoring on the part of senior surgeons and a desire to learn and improve among junior surgeons.

It is important to note that NH did not start with a fully developed model based on task shifting. Rather, the task shifting model in place at NH today is a consequence of efforts to deliver quality cardiac surgery to a large number of patients in the face of significant resource constraints. Such scarcity of qualified clinical resources is found across multiple specialties in India and, as highlighted earlier, is particularly prevalent among indigent and rural populations. Data from the World Bank notes that, in 2012, the number of physicians in India per 1,000 people is roughly 0.7 versus 2.5 in the US (World Bank website accessed on 2015). Further, the delivery of healthcare, especially complex tertiary care, is a challenge given that the medical education system routinely produces graduates who are not immediately prepared to take on these complex procedures independently. These recent graduates thus often need to work with more-experienced physicians to further develop their skills before they can practice independently. Coupled with the resource constraints in India, this need to develop the skills of junior physicians creates a context where the adoption of task shifting is both relevant and critical.

Outside of cardiac surgery, NH leverages task shifting to varying degrees in other specialties including cardiology, neurology, and orthopedics. Task shifting is also currently prevalent at other Indian hospitals performing high volumes of other complex surgical procedures in specialties such as orthopedics. Senior surgeons at NH indicated that if task shifting were either eliminated or significantly curtailed, both capacity and access would decline and costs would increase potentially to a point where overall health outcomes would be negatively affected. There is general acknowledgement among NH leadership that task shifting at the hospital was not initiated by, but rather facilitated by, a permissive regulatory structure that allows less-skilled staff to play a larger role in the performance of surgical procedures. Further

the extensive adoption of this practice at NH is enabled by (1) a large and steady volume of patients at the NH hospital, (2) the willingness of outpatients, often from socioeconomically disadvantaged backgrounds, to be flexible and wait for the senior surgeon as he balances his outpatient duties with inpatient surgeries and (3) the surgical patient's trust and acceptance of the *entire* surgical team based on the reputation and track record of both NH and the individual senior surgeon leading the team. In fact, the evolution of task shifting in cardiac surgery has had important strategic implications for NH, which has leveraged the learning from this experience to add both new specialties and new hospitals to its system. In short, NH's experience with task shifting in cardiac surgery has helped it develop a broader capability in planning for and managing the human resources required to expand in an environment characterized by high patient demand and constraints on the availability of skilled clinicians.

The evolutionary nature of task shifting at NH offers a cautionary note for organizations in other parts of the world that intend to adopt task shifting. Specifically, these organizations should not attempt to blindly copy NH's task shifting model but rather carefully consider how the key enablers illustrated by the NH experience apply to their own contexts. These enablers include, but are not limited to, regulatory flexibility, sufficient patient volume, the availability of motivated staff to perform shifted tasks, a deep understanding of the impact of task shifting on quality, and a receptive population of patients. Assuming that these contextual factors are acknowledged, the breadth with which task shifting is used in tertiary healthcare delivery in India suggests that other developing countries with similar regulatory environments, demand for health care, and constraints related to the supply of trained medical practitioners might also benefit from task shifting as they build their delivery infrastructure.

Finally, it is important to consider whether and how task shifting can be applied to tertiary care delivery in a developed country, such as the United States. Basic forms of task shifting have expanded in the US healthcare system in recent years, as an aging population and efforts to reduce healthcare costs have driven the growth of a broader healthcare workforce including nurse practitioners, medical assistants, and home health aides. The involvement of senior physicians during tertiary complex procedures at US hospitals, however, has typically been higher than that observed at NH due to both norms of practice and regulations concerning both provider liability and reimbursement (see Appendix for a more detailed discussion). That said, the preliminary evidence from India presented in this case study suggests that task shifting, when applied in a contextually appropriate manner, might hold promise for reducing the costs of high-quality tertiary care in developed countries.

3.9. Appendix

Observations of CABG at both teaching and non-teaching hospitals in the US suggest the absence of the task-shifting-based staffing approach as practiced at NH and further point to factors that make adoption of task shifting difficult in the US.

Teaching Hospital: Six CABGs by three surgeons were observed at a leading teaching hospital located in Boston, MA, USA. Given that it is a teaching hospital, residents in training were assisting the experienced surgeons (the closest equivalent to the junior surgeons observed at NH). In all six cases, the experienced senior surgeon was present in the operating room for the entire duration of the surgery, either leading the different activities or supervising/assisting the resident in order to facilitate his/her skill development. This resulted in a mean Junior Surgeon Time as a Percentage of Total Surgeon Time measured across the six cases of 52%. Follow-up discussions with the surgeons, residents and other surgical staff confirmed that task-shifting as observed at NH was absent and that the three surgeons performed approx. 150-250 cases annually. Also given the absence of a task-shifting-based model and the norms of outpatient practice, these and other surgeons at the teaching hospital had clearly distinct surgery and outpatient days every week (typically two outpatient days and three surgery days each week). Further discussions with surgeons and hospital administrators confirmed that various factors like (1) the responsibility of training residents, (2) regulations regarding reimbursement, (3) concerns over litigation risk, (4) patient concern about resident roles during surgery, (5) internal work protocols, and (6) required presence of surgeons in close proximity to the operating room in order to be available during the surgery collectively discouraged the adoption of a task-shifting-based model as practiced at NH.

Non-Teaching Hospital: Five CABG cases were observed at a leading non-teaching hospital in the US. In all five cases, the surgeon was assisted by a first assist (a registered nurse with certification in surgery) in all the surgical activities. Further, the surgeon was in the operating room for almost the entire duration of the case and typically performed all the surgical activities related to LIMA harvesting and the main procedure and often performed (at least some of) the less complex activities related to skin incision and closure. Across the five cases the mean Junior Surgeon Time as a Percentage of Total Surgeon Time was 54%. Discussions with surgeons indicated that the surgeons did 200-300 cases per year and they typically operated on three days of the week (the other two days were usually for outpatient appointments). Further, the discussions suggested the absence of a task-shifting-based model as observed at NH. Similar to the observations at the teaching hospital, adoption of task shifting was not possible due to a number of factors such as (1) regulations regarding reimbursement, (2) concerns about litigation risk, (3) practice norms and internal work protocols, and (4) lack of other adequately qualified professionals to undertake surgical activities.

CHAPTER FOUR

A Recombination-Based Internationalization Model: Perspectives from Narayana Health's Journey from India to the Cayman Islands

4.1. Introduction

How does a firm design an operating model[13] in the host country when pursing opportunities abroad? Conceptually, researchers have sought to understand this process as a trade-off between copying the model that worked well in the home country and modifying it to fit the new context in the host country—the so-called "replication versus adaptation" dilemma (Kostova and Roth, 2002; Rosenzweig and Singh, 1991; Westney, 1993; Winter et al., 2012). But research has also suggested that even when internationalizing firms are aware of this trade-off, they have a hard time developing operating models in the host country—especially during the early stages—because their home-country operating model and managerial mindset often fail to fit the different context of the host country (Khanna, 2014, 2015; Kostova, 1999; Kostova and Roth, 2002; Nadkarni et al., 2011; Sapienza et al., 2006; Szulanski and Jensen, 2006). The search for the optimal operating model in the home country can narrow management's mindset and organizational knowledge and practices in a way that constrains its ability to respond to a new context at the host country; possibly the more so the more successful the firm was in the home country.

[13] Operating model refers to organization of individual elements (e.g. knowledge, infrastructure, processes, resources) to support overall firm strategy. The notion of operating model is fundamental concept in Operations Strategy literature (Anderson, Cleveland, and Schroeder 1989; Skinner 1969; Swamidass 1986)

In this paper, we present evidence from our two-year field study of an international entrepreneurship initiative by a healthcare provider in India that prompted us to rethink the prevailing view that the home-country experience act as a deterrent to successful internationalization. Our observations and analyses suggest, rather, that the home-country experience can give a firm (a) deep understanding of different contextual dimensions and their implications, (b) context-based design skills, and (c) multiple operating models made up of diverse knowledge and practices. These capabilities, in turn, can then allow the firm to recombine elements from these home country operating models to develop a successful operating model for the host country. We therefore propose a recombination-based process model that complements the much-discussed replication-adaptation process and sheds light on how home-country experience might improve an organization's ability to pursue international opportunities.

The remainder of the paper is organized as follows: In the next section, we review prior work on the development of operating models in host countries and elaborate on the idea of a recombination-based internationalization mechanism. Then we describe our research setting and the field research used to develop the ideas in this paper. Next, we present the details of our empirical case to illustrate the focal firm's process for developing an operating model in the host country. Subsequently, we present the proposed internationalization process model, discuss the implications of this study, and conclude with a summary of our findings.

4.2. How do internationalizing firms develop operating models in host countries?

International entrepreneurship has been defined as the discovery, enactment, evaluation, and exploitation of opportunities by firms—across national borders— to create future goods and services (Oviatt and McDougall, 2005). Especially in the early phases of such pursuit, firms are

likely to try to transfer and leverage their home-country knowledge and practices by replicating their operating model in the host country (Jonsson and Foss, 2011; Nelson and Winter, 1982; Rosenzweig and Singh, 1991; Winter and Szulanski, 2001). Past research on internationalization has, however, questioned the replicability of knowledge and practices across national boundaries and suggested the need for adaptation rather than replication (Kostova and Roth, 2002; Rosenzweig and Singh, 1991; Westney, 1993; Williamson, 2007).

This need to adapt is especially true for firms expanding from developed countries into emerging economies or vice-versa to pursue entrepreneurial opportunities, given the significant economic, cultural, and institutional differences (Ghemawat, 2001; Kogut and Singh, 1988; Kostova and Zaheer, 1999) between such locations as Bangalore and Boston. However, ambiguity with respect to the interrelated factors driving the firm's performance in its home country (we refer to the idea of causal ambiguity, as discussed by Lippman and Rumelt, 1982) makes such adaptation challenging. Moreover, Szulanski and Jensen (2006) find that adaptation based on presumptions held prior to entering the host country is typically unsuccessful, as senior management often does not know the new context well enough and is ill-equipped to decide what needs to be adapted, why, how, and to what extent.

Research also finds that significant differences between home and host country increase the likelihood of failure due to the ''liability of foreignness'' (Zaheer and Mosakowski, 1997) and that firms with prior experience in a context similar to the host country are more likely to be successful there (Barkema, Bell, and Pennings, 1996; Delios and Henisz, 2003; Perkins, 2014). Multiple researchers (Chang, 1995; Davidson, 1980; Erramalli, 1991, Perkins 2014) have referred to the fact that firms, especially in the early stages of internationalization, are more likely to select foreign locations that are similar to their home country or in which they are

already operating. As firms gain more experience with investing abroad, they will be more likely to choose less similar markets. Further, Perkins (2014) suggests that such an approach allows the firm to recombine lessons from its experiences in different countries, while investing and developing its operating model in a subsequent host country.

A related stream of literature (Caproni, Lenway, and Murtha, 1992; Kobrin, 1994; Levy, Beechler, Taylor, and Boyacigiller, 2007; Sapienza, Autio, George, and Zahra, 2006; Vermeulen and Barkema, 2001) emphasizes the role of managerial mindset in internationalization efforts: lacking firsthand in-depth understanding and experience of the international market, senior management uses the mental models developed through its home-country experience as reference points for developing its international operating models (Jeannet, 1999; Vermeulen and Barkema, 2001). However, bounded rationality (Simon, 1955; Kiesler and Sproull, 1982) often makes it hard for senior management to notice, interpret, and respond to the differences in the new context (Bartlett and Ghoshal, 1989; Black, Mendenhall, and Oddou, 1991; Nadkarni, Herrmann, and Perez, 2011; Nadkarni and Perez, 2007). In effect, firms lack the contextual intelligence essential to transfer an operating model from the home country to the host country (Khanna, 2014). These observations on the difficulty of internationalization are consistent with a larger body of work on the difficulty of adapting to changes to the environment—such as technical innovations (Henderson and Clark, 1990), regulatory changes (Smith and Grimm, 1987), and market crises (Haveman, 1992)—due to senior management's cognitive inability to identify, assess, and respond to such changes (Kiesler and Sproull, 1982; Knight 1921/1965; Tripsas and Gavetti, 2000).

Observations from our field study make us wonder whether research on early-stage internationalization, in playing up the constraining nature of home-country experience and the

tension between replication and adaptation, has implicitly assumed that home-country experience results in a narrow set of mental models, knowledge, and practices tied to a monolithic operating model, necessarily limiting the ability to succeed in a different context. In this paper, we explore how a firm's diversity of home-country experience and related learning can influence its ability to develop appropriate operating models in the host country. Specifically, we highlight that researchers may have inadvertently overlooked the possibility that, prior to venturing abroad, home-country experience might allow a firm to develop a varied set of knowledge and practices, deep context-based design capabilities, and an overall understanding of the external context. These, in turn, are likely to improve the firm's ability to identify and respond to contextual differences in the host country and design an appropriate operating model early in the internationalization effort. This possibility raises important strategic considerations for a firm's ability to deal with contextual changes in general.

To explore the relationship between internationalization and home-country-based knowledge, practices, and mindset, we present an in-depth longitudinal study of the expansion of Narayana Health (NH), a healthcare provider, within India (2001-2014) and its subsequent opening of a tertiary care hospital in the Cayman Islands (2014). The Cayman hospital project was an ideal setting in which to study the development of an operating model in a host country; while NH had been very successful for over a decade delivering low-cost high-quality care in India, it had never designed or operated a hospital abroad.

NH managed not only to establish an effective operating model in the Cayman Islands, but to do so quickly, and delivered promising performance during the first year. The key insight that allowed us to explain this success emerged from our fieldwork. Contrary to past research suggesting that the alignment of a firm's managerial cognition, knowledge, and practices to the

home country impedes the development of an appropriate operating model in the host country, we found that the Cayman project benefitted from NH's previous experience. In India, NH developed (a) an understanding of how context affects operations, (b) context-based design capabilities, and (c) a broad managerial mindset while responding to institutional voids[14] (Khanna and Palepu, 1997, 2010) and adapting its core model to various market segments in India. These strengths, in turn, informed and enabled the Cayman project. We also found that NH could recombine practices and knowledge from its varied Indian models while setting up the Cayman hospital. In essence, experience dealing with institutional voids and adapting to varied market segments in India increased NH's ability to interpret and address the context in the Caymans.

One way to explain NH's experience is in terms of LEGO blocks. NH's diverse experiences in India allowed it to identify, understand, and develop discrete yet interrelated practices and capabilities, akin to the blocks in different LEGO block models. While designing its operating model in the Caymans, NH combined blocks from different models in an intelligent manner. This is in contrast to the much-discussed replication-adaptation balancing act which suggests that internationalizing firms, especially in the early stages, are starting with a limited set of elements from a single model, developed in the home country, and then attempting to modify them to fit to the host country. Building on our field study observations, we develop a recombination-based process model that builds on the acquisition of varied experience and

[14] Khanna and Palepu (1997, 2010) developed the idea of institutional voids as the defining characteristic of emerging markets. It refers to institutional inadequacies due to the absence or underdevelopment of specialized intermediaries—such as accreditation agencies, rating agencies, financial analysts, media rankings auditing firms, talent-development and placement agencies, credit-card providers, clearing institutions, brokers, and employment exchanges—that allow buyers and sellers to transact efficiently.

capabilities while adapting to heterogeneity in the home-country and then intelligent retrieval and recombination in the host country of elements from different home-country adaptations.

Our paper makes a number of contributions. First, it (a) illustrates that the external context in the home country might have unique institutional characteristics and market heterogeneity and (b) points out how a firm's simultaneous engagement with and experimentation in such a context could affect managerial cognition, organizational learning and capabilities, and—subsequently—the firm's international entrepreneurship efforts. However, countries differ in the extent of context heterogeneity and firms differ in their exploration of the home-country context; firms may therefore have unequal opportunities to prepare for venturing abroad. This creates the need for a home-country-contingent theory of internationalization processes and international entrepreneurship capabilities. Further, our study suggest the need for a more granular understanding of the on-the-ground context experienced by firms instead of the usual emphasis on higher-level aggregate constructs associated with context, such as the regulatory, normative, and cognitive dimensions (Scott, 1995).

Second, we illustrate adaptation to the home-country context followed by recombination of home-country knowledge and capabilities—deriving from these adaptations—as an effective mechanism of developing the host-country operating model. This mechanism complements the much-discussed replication-adaptation balancing act in the host country. More importantly, it suggests that home-country experience is not necessarily constraining; rather, variation in home-country experience can enhance the firm's ability to manage the replication-adaptation process while pursuing new opportunities abroad.

Third, the paper elaborates on the notion of contextual intelligence in international business. Recent research has highlighted a firm's contextual intelligence—the ability to transfer

capabilities to an environment different from the one in which they were developed—as a critical enabler for internationalization (Khanna, 2014). In this paper, we show that engaging with diverse markets and experiences in the home country can help a firm to transfer its capabilities (in our particular case, an affordable, high-quality healthcare delivery model) to an unfamiliar host country; we thus identify a possible mechanism of developing contextual intelligence.

Fourth, though not the goal of the study, the paper illustrates how recombination happens. Although researchers have already noted that an innovation or new knowledge is often a novel recombination of existing ideas from different sources (Fleming, 2001; Hargadon and Sutton, 1997; Henderson and Clark, 1990; Nelson and Winter, 1982; Schumpeter, 1934), the mechanisms by which such recombination takes place remain relatively unexplored. We illustrate the recombination process in the international entrepreneurship context and suggest that the decomposition of a large problem into a set of sub-problems and the development and integration of solutions to these sub-problems based on retrieval of past analogous problem-solving experiences in different settings is one possible path by which recombination happens.

Finally, and perhaps most importantly, we provide suggestive evidence on how constant engagement, experimentation, and learning in challenging yet familiar settings can lead to a flexible management mindset and diverse firm capabilities; these, in turn, will likely allow the firm to better identify, assess, and respond to significant external context variation such as technological or regulatory changes.

4.3. Research Setting and Methods

4.3.1. Research Setting

This study is based on the origin and expansion of Narayana Health (NH) within India (2001-2014) and its establishment of a hospital on the Cayman Islands (2014). In 2001, Dr. Devi Shetty founded the NH hospital in Bangalore, India with the intent of delivering high-quality, affordable cardiac care to the poor. Over the years, NH earned a strong reputation for doing just that.[15]

Dr. Shetty, a strong advocate of affordable tertiary care across the world, was keen on demonstrating NH's low-cost, high-quality model to the US, as he believed that recognition by the US healthcare system would speed up adoption of his model worldwide. When, in 2008-2009, the Cayman Islands[16] government considered developing the island as a medical tourism hub, NH agreed to develop Health City Cayman Islands (HCCI), a 2,000-bed conglomeration of super-specialty hospitals within a single campus (for a detailed description of NH's entry into the Cayman Islands, see Khanna and Gupta, 2014). The idea behind the HCCI project was to provide affordable tertiary healthcare to patients from the US, Canada, and the Caribbean Islands, including the Caymans.

For NH, the Cayman Islands seemed to be an attractive location for the project. Their reputation as a popular, high-end tourism destination only one hour by air from Miami suggested that US patients might be comfortable going there. At the same time, HCCI planned to serve the local population; given the absence of a well-developed tertiary healthcare facility there prior to HCCI, patients had to go to the US for tertiary healthcare.

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[15] For example, the average price for coronary artery bypass graft surgery, a common tertiary procedure across the world, was $3,000 at the main NH hospital in Bangalore—compared to $60,000-$100,000 in the US—while clinical outcomes were comparable to those at leading US hospitals (Khanna et al., 2005).

[16] The Cayman Islands, known for their natural beauty, are a British Overseas Territory in the western Caribbean Sea consisting of three islands—Grand Cayman, Cayman Brac, and Little Cayman—with a total population of approximately 50,000. The Cayman Islands' GDP per capita (US$ 58,000) was the 14th highest in the world and the highest in the Caribbean. Tourism and financial services together made up 75% of the country's GDP.

4.3.2. Research Approach

The HCCI project was interesting to us as we believed it would allow us to develop insights on the development of operating models in host countries with contexts significantly different from that of the home country. NH's success in India was primarily based on the knowledge and practices it had developed there for over a decade; however, there were questions about their relevance and transferability to the developed world, especially since healthcare solutions typically originate in developed countries and diffuse to developing countries.

This research setting was also attractive to us because NH had neither developed nor operated a hospital outside India before. Given the unprecedented nature of the phenomenon—the transfer of an affordable hospital model from a developing to a developed world setting—we theoretically sampled the HCCI project as a single longitudinal case research site (Yin, 1994). This approach is consistent with earlier discussions (Eisenhardt and Graebner, 2007; Siggelkow, 2007) pointing out that case studies offer researchers the opportunity to embed themselves in unique empirical settings in order to understand processes and mechanisms that evolve over time and to develop novel theoretical insights or elaborate underexplored theory.

In mid-2013, we formally launched a project to study NH's Cayman hospital, then just getting off the ground. We started off with a simple question: How would NH design and develop the hospital in the Cayman Islands? The assumption and expectation behind this broad and simple question was that it would allow us to (a) understand how firms manage the replication-adaptation balancing act while pursuing opportunities in host countries with significantly different contexts and (b) develop insights into a broader set of questions related to the internationalization of emerging-economy firms and the transfer of innovative models and solutions from developing to developed countries. We adopted an inductive field-based approach

and designed our data collection and analysis based on the key principles of grounded theory development (Glaser and Strauss, 1967). First, we focused on exploring our empirical setting and identifying our emerging insights. Second, throughout the project we iterated between data collection and analysis, the ongoing data collection being itself informed by emerging insights. Third, as we iterated between data collection and analysis, we compared new data to previously analyzed data to see if the new data supported the emerging patterns and/or offered new insights. This paper is based on our study of the Cayman project till mid-2015.

Given our interest in how the home-country experience influenced the development of an operating model in the host country and given our initial field observations, we focused our data collection on NH's origin and expansion in India and the resulting knowledge and practices. In parallel, we tracked—in real time—the design and progress of the Cayman hospital. Thus, in contrast to longitudinal case studies developed entirely retrospectively (Siggelkow, 2002; Tripsas and Gavetti, 2000), our study is based on data collected both retrospectively and in real time.

4.3.3. Data Collection

We adopted a broad approach to data collection, as our primary aim was to develop a deep understanding of how the operating model was designed in the Caymans, what knowledge and practices were being transferred there from India, and the extent to which the transferred elements were relevant in the Cayman context. We collected both primary and secondary data. In addition to conducting semi-structured interviews with the NH senior management team, we collected data on the NH hospitals in India, reviewed archival information related to NH, discussed the project with external members familiar with NH operations in India and the Caymans, and visited NH hospitals in both countries, where we engaged in informal conversation and observed processes and staff. Such a diverse set of sources extended our

understanding beyond how the transfer process was described by NH senior management. Table 4.1 in Appendix summarizes the primary data-collection sources and mechanisms.

Below we provide details on our data collection:

1. Semi-structured interviews and conversations with NH senior management and HCCI staff. We conducted 57 semi-structured interviews with members of NH senior management—including the chairman, CEO, CFO, and representatives from key functions like New Projects, Finance, Human Resources, and Procurement—on NH's expansion in India, the opportunity in the Caymans, and the design and development of the Cayman hospital. These interviews typically lasted between 30 minutes and an hour. Subsequent interviews with senior management during the latter part of the project focused on themes we wanted to explore, such as recombination.

Since the Cayman hospital staff was selected from the NH hospitals in India, we could converse with many of them before they moved to Cayman. Finally, the first author got to interact with NH management and HCCI staff members as he attended key events preceding the Cayman project launch, including soft-skill training workshops at NH Bangalore organized for the Cayman hospital non-physician clinical staff and the NH senior management's address to Cayman hospital staff at the Bangalore hospital prior to departure for the Caymans.

2. Observations, interviews, and informal conversations during visits to the Cayman Islands hospital. Both authors attended the inauguration of the Cayman facility in February 2014 and interviewed NH senior management and Cayman hospital staff. The first author made two further visits to the Caymans that year, in June and November, to conduct additional interviews and observe the hospital operations. His observation focused on, but was not limited to, hospital layout, staffing, patient flow, and clinical processes and protocols. Further

conversations with Cayman staff (including administrative staff, physicians, nurses, and technicians) helped us understand other operational aspects, such as training, patient interaction and feedback, and supply chain design. We continued to collect information by conducting phone interviews every other month between and after our trips to the Caymans.

3. Data on NH hospitals in India. To better understand the NH hospitals in India, we used questionnaires to collect data from the corporate team on those facilities' location, scale, scope, focus, patient demographics, employee base, financial performance, and competition. This hospital-level data and subsequent discussions with the corporate team allowed us to identify five operating models addressing different market segments and to understand the relevance of these models to the development of the Cayman hospital. We then conducted phone interviews with the various facility directors to refine our data collection, clarify pending questions, and further explore hospital design and operations.

Perhaps the activity that allowed us to make the most sense of our interviews and data collection and to develop the emergent notion of recombination was our visits to 14 NH facilities. These hospitals were selected to expose us to the different NH operating models; we also took into account management's input, given our project focus. These visits, typically one or two days, allowed us to conduct a detailed tour of the facility; observe the staff, patient flow, and interactions; and conduct informal conversations with the facility director, physicians, nurses, and other staff. Detailed field notes taken during the visits were analyzed to identify which elements from different hospital models were recombined in the Caymans.

4. Conversations with external entities in India, the US, and the Cayman Islands. We sought inputs from external informants throughout our study. Specifically we interacted extensively with representatives from Ascension, the largest nonprofit hospital group in the US

and a joint venture partner in the Cayman hospital project, to get inputs on NH's design and planning of the Cayman hospital and on its post-launch progress. We also interacted with non-NH medical practitioners in India, officials from the Cayman government health insurance company, medical professionals on the Cayman Islands, and senior administrative and clinical staff at a large US hospital.

5. Archival information. To complement the data collected from interviews, questionnaires, and observations, we examined publicly available information on NH and internal NH documents such as corporate presentations, annual reports, and organization charts. The public information included but was not limited to extensive documentation on the healthcare infrastructure and policies in India, articles in the business press focusing on NH's hospitals in India, NH press releases, the agreement between the Cayman Islands government and HCCI, the NH and HCCI websites, information on HCCI on social networking websites such as Facebook, and interviews with Dr. Shetty, the founder and chairman of the NH Group. The publicly available information on NH was supplemented by detailed case studies on NH developed by the second author (Khanna et al., 2005; Khanna et al., 2011).

As we collected our data, we took steps to ensure its validity. First, we had complete access to all NH employees and hospitals. This allowed us to check for consistency across different informants. The confidentiality of the interviews allowed the informants to speak openly. Second, in order to reduce any retrospective bias emerging from interview responses, we triangulated our data based on information from public sources, observations during site visits, external informant perspectives, management interviews, and data from hospital operations. The data from such a variety of sources also improved the integrity of the analysis (Miles and Huberman, 1994; Silverman, 2006). Third, the opportunity to talk informally with NH and HCCI

employees and to join internal discussions during social events (such as New Year's parties and the inauguration event dinner) helped us validate our data and interpretations. When details from one source were missing or vague, we obtained additional information from different sources. Fourth, towards the latter part of the project, we shared our observations and insights with several key NH personnel to get their views. Finally, the publicly available interviews, business articles, case studies, press releases, and so on throughout NH's history (2001-2014) allowed us to follow its expansion and the evolution of its knowledge and practices real-time sources. By May 2015—the end of the Cayman hospital's first year of operations—we had reached a level of saturation (Glaser and Strauss, 1967) and stopped collecting more data.

4.3.4. Data Analysis

Consistent with a field-based inductive research process, our process of collecting the data, analyzing the data, developing and validating inferences, and scanning extant research was iterative (Glaser and Strauss, 1967; Strauss and Corbin, 1997). Following Glaser and Strauss (1967) and Miles and Huberman (1994), the data analysis usually began with the identification of a topic or the generation of a hunch based on a review of the data collected. Then we tried to see if the topic or hunch could be validated with evidence already collected or with subsequent data collection. Accordingly, we decided whether or not to retain the initial topic or hunch. For example, our initial identification of the different NH hospital models in India was based on interviews with senior management focused on NH's expansion in India. Subsequent iterative activities—collection and constant comparison of data collected from hospitals using questionnaires, interviews of hospital staff, and observations during visits—allowed us to validate the idea. As we went through the iterative collection and analysis, the diversity of

practices and knowledge related to these models and the associated managerial thinking and design capabilities emerged as a fundamental element of NH's expansion in India.

Similarly, ongoing review of our field notes from our visits to hospitals in India and the Caymans allowed us to sense an emergent insight into the recombination of elements from different hospital models. To explore this idea, we used subsequent observations and interviews to compare aspects of the Cayman hospital design to the practices and knowledge that NH had developed in its various Indian hospitals. To understand the mechanisms underlying our hunch, we collected and reviewed additional data based on interviews, field observations, and archival documents to study the external context, organizational and managerial processes, and senior management's decision-making logic at NH. Once we reached a saturation point, we shared our overall findings and the observed individual instances of recombination with members of the NH leadership team. The ensuing discussions allowed us to validate and refine our understanding of the rationale for and specific instances of the recombination process. Finally, we tracked and analyzed the hospital's first-year performance along critical dimensions such as clinical outcomes, patient experience and feedback, and patient volume to ascertain the effectiveness of the design choices involved in the recombination process.

As we collected and analyzed the data, we developed a detailed narrative to capture NH's journey to the Cayman Islands, then explored the connections amongst the validated topics and hunches and the supporting evidence. The first author developed this narrative; the second author, who was familiar with NH's India operations and expansion over the last decade, reviewed the narrative periodically to ensure its accuracy, consistency, and comprehensiveness. At first, the narrative offered a systematic way to capture the sequence of events. As we gathered and analyzed more data, the narrative allowed us to explore the interrelations between the themes

and insights emerging from the raw data. As we validated the themes and explored their interrelationships, we continuously compared our emerging insights with existing research on context, cognition, and internationalization. We concluded the iterative analysis and narrative development process once we had achieved a strong correspondence between the empirical data, past literature, and the emergent model of recombination.

Research has shown that detailed narratives can be very effective in both identifying and illustrating key underlying mechanisms and tracing intraorganizational processes that unfold over a long time (Hoopes and Postrel, 1999; Montealegre, 2002; Siggelkow, 2002; Tripsas and Gavetti, 2000). Such storyline-based narratives are effective sense-making tools. In the next section, we present the developed narrative to show the underlying data and logic on which the core arguments and inferences of our proposed internationalization process model have been developed (Miles and Huberman, 1994).

4.4. NH'S Journey from India to the Cayman Islands

4.4.1. NH in India

The first NH hospital, started by Dr. Shetty in 2001, was on the outskirts of Bangalore and focused on cardiac care for the indigent population. At first, it adopted the principles of a focused factory model (Skinner, 1974) and concentrated on doing a few things (cardiac surgeries) extremely well (low cost, high quality); the low prices led to a high volume of patients and that, in turn, led to improved learning and clinical outcomes and also to lower costs and prices (Khanna et al., 2005). By 2004, the Bangalore hospital had the highest volume of any cardiac surgery center in India, performing more than 4000 cardiac surgeries and 5000

catheterization procedures a year, with clinical outcomes comparable to those of leading hospitals across the world. To keep costs low while providing care to as many patients as possible, NH focused on a number of mechanisms related to procurement, multi-tasking by clinical staff, and task-shifting from senior physicians to junior and less-expensive clinical staff. (For a detailed description of NH's low-cost, high-quality operating model, see Gupta et al., 2015; Khanna et al., 2005).

Addressing institutional voids. NH's early success was largely based on Dr. Shetty's recognition that the barriers resulting from the numerous institutional voids typical in a developing country, such as India, had to be circumvented to allow poor patients access to cardiac care. On the supply side, these voids included an incredible scarcity of cardiac surgeons, cardiologists, trained nurses and technicians and the unavailability of affordable medical devices and technology. On the demand side, the absence of public insurance programs made cardiac care unaffordable to the indigent population

One of the senior management members commented, "From the beginning, we realized it is not enough that we build a good hospital. It is not enough that we put good equipment, that we get the best doctors, make surgeries affordable. That is the bare minimum we have to do." Accordingly, during NH's initial years, Dr. Shetty focused on a host of activities that included but were not limited to working with the local state government (state of Karnataka) to set up a health insurance scheme for the indigent population, development of clinical talent by setting up nursing and technician colleges and establishing physician development programs related to cardiac care, leveraging the satellite network of the Indian Space Research Organization to provide telemedicine support to remote areas, and incubating the development of affordable suppliers and technology solutions (for details on NH's efforts to address institutional voids, see

Khanna and Gupta, 2015). Overall, these efforts made NH acutely cognizant of its dependence on specific environmental dimensions such as the availability of clinical talent and technology and the ability of patients to access and afford care. Moreover, the experience of addressing India's multiple institutional voids over an extended period allowed NH to recognize similar contextual constraints in the Cayman Islands and to design responses early.

Developing clinical expertise. From the beginning, high patient volume allowed NH to develop deep clinical expertise. Over time, the NH Bangalore hospital took on complex, less-common procedures and established itself as a leading cardiac center in India. For example, in 2008, the hospital performed an artificial heart transplant in which an external device takes over the functioning of the patient's heart; it was one of the first hospitals in Asia to do so. In 2009, NH performed the first heart transplant surgery in the state of Karnataka. In January 2011, to dispel any doubts that the low-cost approach did not compromise the quality of care, the NH cardiac hospital in Bangalore earned accreditation from the US-based Joint Commission International (JCI), the not-for-profit global division of the Joint Commission Resources.

Delivering care to international patients. The Bangalore cardiac hospital's JCI accreditation and its growing reputation as a center of clinical excellence attracted more and more patients from South Asia, the Middle East, and Africa. This, in turn, required NH to develop a set of hospitality-oriented services that were distinctly different from the practices initially established to treat the indigent. A help desk was set up to help international patients with treatment information, travel plans, airport pick-up and drop-off, visa support, local accommodations, and language interpreters. A dedicated relationship manager was assigned to each international patient to ensure a comfortable experience.

The health city. By 2013, the volume of cardiac inpatients at the NH Bangalore hospital (5,000 adult and 2,800 pediatric cases and 17,600 catheterization lab procedures) exceeded that of most, if not all, hospitals in the world. The Bangalore hospital was now much more than just a cardiac hospital. Since 2004, it had been adding other non-cardiac specialties, with the plan of housing each specialty in one of the buildings being constructed nearby. By 2011, the multispecialty 3,100-bed "health city" consisted of a 25-acre campus with a 900-bed cardiac hospital, a 1,400-bed cancer hospital, a 500-bed orthopedic and trauma hospital, a 300-bed eye hospital, an organ transplant institute, and departments of neurosurgery, neurology, pediatrics, nephrology, urology, gynecology, and gastroenterology. Each of these hospitals had a huge patient volume that allowed it to operate as a focused factory and to benefit from economies of scale in managing costs and improving quality. Collectively, too, they enjoyed economies of scope, as they could share specialized clinical knowledge, expertise (such as infection management), support centers (such as a blood bank and a clinical laboratory), clinical resources (such as graduates from nursing and technician schools located in the health city), high-end equipment (such as CT scanners and MRI machines), and a single management and finance team. The success of the volume-driven focused factory hospitals within the health city in Bangalore motivated NH to replicate this model in other cities, including Kolkata, Ahmedabad, and Jaipur.

Expansion within India. From the beginning, NH was keen to acquire scale (in terms of number of beds), convinced that this would allow it to further reduce costs without compromising quality. However, as NH considered further expansion, it realized the need to consider alternatives to the high-volume model. This realization was motivated by factors including the significant investment and resources (such as land, capital, and staff) required to

develop additional health cities, the increasing number of patients in small towns and cities who wanted to have local healthcare options instead of traveling to the centrally located health cities, and the difficulty of providing the personalized care expected by the urban affluent, given the health city's standardized processes and factory-like environment.

To address the different needs and markets within India, NH developed different models during 2008-2012. Aside from the high-volume model discussed earlier, our analysis suggests four broad yet distinct models: (1) the Tier 1-2 Model[17]—100-200 bed hospitals in smaller cities and towns, (2) the High-End Model—100-bed higher-end hospitals for the more affluent urban population, (3) the Implant Model—30-50 bed setups at non-NH hospitals to manage their cardiac care units, and (4) Stand-Alone Clinics—outpatient multispecialty clinics with 2,000 to 20,000 outpatients annually. Table 4.2 in Appendix provides additional details on these models.

As Dr. Shetty recollected, *"*The whole thrust was to reach out… The idea is to grow and become big and touch as many people as possible." The varying models allowed NH to offer services to sub-segments of the Indian healthcare market, but certain practices had to be adapted to ensure that the emerging models fit the target market segment. At the same time, in order to leverage past learning, NH standardized and retained critical aspects such as clinical protocols, IT systems, procurement practices, medical supplies, supplier base, financial processes, and the work culture and ethics. As the multi-model NH network emerged over time, NH started referring complex clinical cases from the newly developed hospitals to the high-volume facilities that were better able to handle them.

[17] In India, the smaller towns and cities are referred to as Tier 1 and Tier 2 cities while the large cities like Bangalore, Delhi, and Mumbai are referred to as metros. The term "Tier 1-2 Model" in this paper refers to NH hospitals based in Tier 1 and Tier 2 cities and towns.

By 2008-2009, NH had developed a reputation in India both for delivering quality care to the less affluent and for clinical expertise. Dr. Shetty and his mission were increasingly respected by politicians, government administrators, private businesses, and healthcare practitioners. During the expansion process, all this goodwill helped NH in its interactions with key stakeholders such as state governments, administrative bodies, investors, and suppliers. In addition, most of the new hospitals were near NH's big hospitals in Bangalore and Kolkata, which allowed senior management and operating staff to be significantly involved in these projects.

Below, we highlight select practices and knowledge associated with the Tier 1-2 and the High-End models to illustrate how NH managed cost-effective operations at smaller hospitals and delivered a good patient experience to the urban affluent. These two capabilities were subsequently key in the development of the Cayman hospital. Our analysis of the other models (Implant, Stand-Alone Clinics) and NH's ongoing expansion, though supportive of the critical idea of deliberate experimentation and learning from the contextual variation in India, did not lead to any significant additional insights related to the recombination-based internationalization approach adopted by NH in the Caymans.

Tier 1-2 hospitals. For the Tier 1-2 hospitals in the smaller towns and cities, NH realized that patient volumes would be significantly lower than they were in Bangalore. NH would have to find other ways to keep costs low, particularly since the patients in these smaller towns typically had lower spending capacity. One area that NH focused on was to reduce the capital investment. For example, in the Mysore project, NH partnered with India's largest construction company to develop the 200-bed super-specialty Mysore hospital at a cost of $6 million in eight months; construction of similar hospitals in India cost $25 million and took two years. The

hospital used prefabricated materials and, to minimize construction costs such as expensive fire-safety systems and elevators, was a single-storied structure. Large windows allowed for natural lighting and ventilation and minimized electricity and air-conditioning costs; only the operating theaters and intensive care units, which had to be sterile, were air-conditioned. Also to keep construction, operations, and staffing costs low, there were no private rooms. With open wards, the nursing station had an easy view of all patients and therefore required fewer nurses. Learning related to the Mysore hospital design and construction was leveraged in subsequent projects and, over time, NH's ability to plan, design, and develop these smaller hospitals improved.

Given the small number of physician consultants in each specialty at many of these smaller-town Tier 1-2 hospitals, NH realized that the physicians' ability to perform a broad range of procedures was critical in order to deliver value to the patients while keeping physician staffing costs low. Whereas physicians in the high-volume big-city hospitals could afford to specialize in a narrow set of procedures, an orthopedic surgeon in a Tier 1-2 hospital ideally had to be proficient in procedures related to shoulders, knees, and hips. And because there were typically only a handful of nurses and technicians to support surgeries in the Tier 1-2 hospitals, NH decided to staff those operating rooms on an on-call basis—based on the timing of scheduled procedures—rather than in shifts, which made more sense in the high-volume hospitals. Similarly, whereas nurses in the high-volume hospitals were assigned either to the intensive care unit (ICU) or the wards, based on their experience and skills, nurses in the small-town hospitals moved between the ICU and the general wards. Overall, these flexible Tier 1-2 staffing models were in contrast to the approach used in the High-Volume model and allowed NH to lower its operating costs at the lower-volume hospitals. Given the remote and underdeveloped location of

some of these hospitals, NH also had to deal with a new range of problems in sourcing supplies and managing inventory and in supporting and retaining clinical staff.

High-End hospitals. At the High-End hospitals, NH offered—for the first time—a service targeted exclusively to the well off. The adaptations in this case were geared towards delivering a patient experience consistent with the expectations of the urban affluent and in developing the High-End hospitals in Bangalore, NH leveraged its experience with affluent patients at Health City Bangalore.

The typical patient profile at the High-End hospitals in Bangalore was a professional, often from India's booming service industry. Unlike the poor patients at a health city campus, the High-End facility patients were well informed and expected more hospitality services. These patients often had researched their treatment options online and asked the nurses a lot more questions. The indigent patients in a high-volume main hospital rarely asked questions.

The facility director at one of these High-End hospitals commented:

> The top priority for us is service excellence. . . . Communication skills are very important and we consider that very seriously when we bring any physician or staff onboard. Patients coming here have a lot of information, right or wrong, and that makes communication very important for us. . . . Patients have lot of expectations outside of clinical care in areas like reception, housekeeping, security, how we are communicating. Whether the physician is competent or not seems secondary.

To ensure that the nurses and other staff interacting with the patients were comfortable and successful in their roles, NH designed training programs, often based on principles of the hospitality industry. In fact, the hospitality industry became a source for recruiting supervisor-level staff in order to develop a service culture that would make the target patient pool more comfortable.

The adaptations at the High-End hospitals went beyond patient interaction and staff training. The hospitals were given the look and feel of other hospitals serving the affluent in Bangalore. For example, while the Tier 1-2 hospital in Mysore had no private or semi-private rooms, the High-End hospitals had *only* private and semi-private rooms. This, in turn, had staffing implications: fewer patients could be assigned to each nurse.

The affluent patients' expectations of physician availability and timeliness required the physicians at the High-End hospitals to handle fewer cases. In the main cardiac hospital in the high-volume health city in Bangalore, surgeons routinely performed two or three surgeries and met with outpatients six day a week. Outpatients usually met the surgeon on a first-come-first-served basis when he or she came out of the operating room after the critical part of the surgery; the remaining surgical tasks were taken over by the assisting junior surgeon. However, this often required the outpatients to wait, as there was no guarantee the surgeon would come out of the operating room at a pre-specified time. This approach seemed to be acceptable to the patients at the high-volume health city cardiac hospital, but the affluent patients at the High-End hospitals expected appointments with their surgeons, which made the surgeons less productive in terms of number of surgeries per week. This decrease in productivity was balanced, however, by higher per-patient revenue.

Table 4.3 in the Appendix shows knowledge and practice elements associated with the various NH models that subsequently became relevant to the design of the Cayman hospital.

4.4.2. Learning and Retention

Learning. Our interviews suggest that in the initial phase of NH's journey, there was agreement that the high-volume health city campus was the ideal model for India. However, as NH tried to attain scale and considered the requirements of differing market segments, the various adaptations emerged.

As NH established different models to address the different market segments, it became clear that there was no one optimal model for India after all. During our discussions, the leadership repeatedly emphasized that the context matters for hospital design and that the appropriate design is determined by a constant process of experimentation and learning. As CEO Dr. Ashutosh Raghuvanshi put it, "There is no one model that works for all of India." Elaborating on the same idea and the need for constant experimentation to develop context-specific models within India, Dr. Shetty commented:

> The whole issue is none of us really know what is the [ideal] model for delivering healthcare in this world. We are all really grappling in darkness. So if you look at [our] different models, it is predominantly because we want to see which is the ideal model. One thing is it has to be affordable, a low-cost model, but within the low-cost model we do not know whether we should build health cities or 100-bed hospitals. Because there is no model available anywhere in the world today that is known to be the ideal model which will fit in with this country [India]. So what we realized is that we need multiple models. For different locations, we need different models. . . . If somebody wants to develop

a cookie-cutter model and roll it like McDonalds, healthcare is not going to happen.

Each of these models required NH to explore the associated context and develop appropriate designs and capabilities. "We do not go into a new project with a definite template and believe that everything needs to be done according to that," remarked Dr. Raghuvanshi. "We go in, look at what is going on and do what needs to be done." As NH repeatedly developed new hospitals, one of its core strengths became its ability to sense market needs and design context-appropriate solutions. During our field visits, we observed numerous such contextualization efforts, such as customization of the menu or of the languages supported by the hospital staff. NH's expansion, unlike that of many businesses, was not based on a single dominant logic or replication approach.

None of this is to say that some of the new hospitals projects didn't run into problems. For example, it was hard to retain physicians in some of the smaller hospitals on the outskirts of big cities; physicians preferred to pursue opportunities in the city. In locations where physician-led practice was the norm (rather than physicians being employed by a hospital), NH found it hard to recruit experienced physicians and have them comply with its standardized work practices.

Retention. It is often difficult for a business to manage different operating models, given the differences in their logic and practices. In particular it can be difficult to organize and retain the learning from these distinct models for future use. How, then, did NH manage to retain the different operating models and subsequently leverage the associated learning in the Cayman Islands? Our field work suggested that NH's expansion was guided by its vision of delivering affordable care to the masses in India and by a strong pragmatic intent to build scale in order to

reduce costs and improve quality. This mission orientation allowed NH to experiment and to build and retain different models even though this was sometimes at the expense of financial returns. Referring to the differing financial performance of the different NH hospitals, the CFO noted that, although management had high EBITDA expectations for each of the hospital models, they also saw clearly that the differences in patient volume and mix, staffing requirements, and ability to reduce costs would lead to different profitability levels. Elaborating on the mission orientation and the relevance of retaining the multiple models, Dr. Shetty commented: "For any business, there is no single model. You have to experiment with multiple models. Those which work, you stick with them. Those which do not work, tweak them. But in the end, everything has to work, as we are in the business of touching people's lives. All these models will eventually work, but there is a lot of painful process we will need to go through."

In addition to NH's mission focus and willingness to experiment, the overall institutional flexibility in India made it easier for the firm to generate and retain variation and its associated learning. The lack of rigid regulative, normative, and cognitive frameworks in India allowed NH to establish alternate building designs, staffing norms, and clinical practices and to develop a larger and more varied stock of knowledge. Such experimentation and variation would probably not be feasible in an industry and/or location with more restrictive regulatory guidelines and normative orientations. For example, at the Tier 1-2 hospital in Mysore, a patient's family members were trained and involved in less-critical postoperative care in order to improve the patient's care after discharge; such practices would not be feasible in regulated and litigious environments.

We also observed several organization-specific characteristics and mechanisms that may have allowed NH to retain the learning from its different models. First, the senior management

team—the chairman, CEO, functional heads, and regional heads—had only 16 to 18 members, most of whom were in the Bangalore corporate office. This small team and NH's flat organizational structure (see Figure 4.1 in Appendix) allowed for constant information exchange and deliberations between members of senior management on plans, actions, and performance at each of the hospital units and new projects.

Knowledge retention was helped by the fact that the core leadership team had been with NH for a long time and, because the firm's expansion had taken place over only five years and many of its hospitals were therefore developed in parallel, team members had been involved in many development projects. Senior management's operations-focused managerial style also aided the retention process. For example, both the chairman and the CEO had significant hands-on operational and entrepreneurial experience and placed significant emphasis on the operational details at each hospital. Zonal directors, facility directors, and project managers were regularly asked to explain the numbers in the monthly and quarterly review meetings, which were attended by the entire senior management team; this allowed for widespread dissemination of knowledge and learning based on experiences at each facility. Senior management team members were also asked to take on roles in functions outside their own areas. For example, the head of marketing would regularly participate in reviews of new projects or in audits of other functions, such as human resources. The fact that the members of the Corporate New Projects team had dual operational roles and were already responsible for the performance of one or more hospitals ensured that new projects benefitted from past experience. Finally, the continuous involvement of the functional heads and zonal directors in identifying and evaluating new initiatives based on past experience allowed NH to constantly revisit its diverse set of knowledge, practices, and experience.

Research on organizational memory (Huber, 1991; March and Simon, 1958; Walsh and Ungson, 1991) has emphasized that firms respond to new situations based on past responses to similar situations, but it is difficult to observe the retention of past responses directly. Our study suggests that the retention of diverse learning from the expansion in India was enabled by (a) the relatively short time during which these different hospital projects were developed, (b) their nearness to each other, (c) NH's core mission orientation, (d) the variety of top managers' experience due to NH's flat hierarchy and multi-functional focus, and (e) the external context's overall institutional flexibility—regulatory and normative.

4.4.3. Retrieval and Recombination in the Cayman Islands

Early in the Cayman project, the NH senior management recognized that, because there was no tertiary care hospital in the Caymans, it would be hard to recruit the people to staff one and to access the necessary supplies. From its founding, NH had dealt with similar but even more extreme institutional voids. So before committing to establishing the Cayman hospital, it asked the Cayman government for support with factors critical to the project's success, such as the recognition of Indian medical degrees and diplomas, exemption of import duties on medical equipment and supplies, the expansion of the Cayman airport, and better flight connectivity with neighboring countries. The Cayman government agreed to these requests and, in April 2010, NH and the government signed an agreement that NH would establish Health City Cayman Islands. The first phase would be a small hospital offering a limited number of specialties, but subsequent phases would expand the hospital's scope and size, set up a medical college, and develop assisted-living homes for seniors.

In 2012, NH entered into a joint venture with Ascension, the largest nonprofit hospital group in the US and the world's largest Catholic health system, agreeing that Ascension would

fund 70% of the HCCI project. Because Ascension began as a membership of hospitals managed by different religious orders, it could appreciate NH's vision of delivering care to the indigent masses in India and across the world. At the same time, Ascension's leadership was aware of the unsustainable economics of US healthcare and saw the HCCI project as an opportunity to learn about affordable quality healthcare. Throughout our study, our discussions with people at NH and Ascension confirmed that the design of the HCCI operating model was carried out by NH. Ascension's role, especially in the project's initial phase, was largely that of an investor; given Ascension's goal of learning the NH way, it was careful not to influence the early stage HCCI design.

Upon signing the agreement with Ascension, NH focused on designing the hospital. This effort was primarily led by Dr. Shetty and Dr. Raghuvanshi and included four to five other senior management members who had been extensively involved in the development and operation of other NH hospitals in India. The goal was to develop a 100-bed hospital that met the design requirements: a JCI-accredited facility with clinical quality and patient experience as good or better than those of US hospitals and at significantly lower cost. The team expected that, in the initial months, most of the patients would be Cayman Islanders, as international patients, especially those from the US, would be unlikely to come until the new hospital's clinical performance had been proven.

The team focused on four fundamental questions: (1) How to achieve excellent clinical outcomes? (2) How to deliver a great experience in terms of comfort and satisfaction? (3) How to be cost-effective in the short term, given the limited number of patients on the island? (4) How to attain JCI accreditation rapidly in order to gain credibility? These questions generated a set of interrelated design requirements related to clinical protocols and performance, clinical staffing,

soft-skill training, international patient management, supply chain management, building construction and layout, and so on. NH realized that its task would not be to replicate any one of the models it had developed in India; each of them would require significant adaptation. Rather, NH recognized that it had already addressed similar design considerations—clinical expertise, cost containment at small facilities, patient experience, JCI accreditation—with its various models. The team therefore recombined practices and knowledge from these different models while designing the Cayman hospital (see Table 4.4 in Appendixfor a list of recombined items). Broadly, NH borrowed and recombined:

1. Clinical processes and protocols and supply sources from the High-Volume hospitals, given the knowledge and expertise at these hospitals.
2. JCI accreditation and international patient management processes from the High-Volume hospitals, given their past experience with similar initiatives.
3. Hospital layout, construction practices, physician staffing, nurse scheduling, and material management practices from the low-volume Tier 1-2 hospitals located in smaller towns and cities, given their remote locations and cost focus.
4. Patient experience, physician scheduling, soft-skills, and hospital interior design from the High-End hospitals in Bangalore, given their experience with affluent patients.

For example, in order to ensure clinical excellence and accelerate the accreditation process, NH copied the JCI-accredited clinical protocols and processes from its high-volume health city hospitals in Bangalore. At the same time, the anticipated low patient volumes during the initial stages at HCCI and the need to keep costs low prompted NH to adopt the staffing principles used at some of the smaller Tier 1-2 hospitals. For example, NH staffed physicians

who were able to support a range of procedures within each specialty and rotated nurses between private rooms and the ICU. NH also planned to develop a team to support the international patients at Cayman—such as those from the US—based on its experience with international patients in Bangalore. Finally, the processes driving patient interactions and experiences were based on what had been learned from serving international patients at the High-End hospitals.

The approach of recombining elements from different NH models was also evident in the design and construction of the HCCI hospital. In order to keep costs low, the NH team decided to base the layout on that of the Mysore hospital, discussed earlier. Other ideas borrowed from the Mysore hospital included insulated walls and large windows to reduce electricity bills and two floors to ensure easy compliance with Caymanian safety regulations and to minimize construction costs. However, keeping the Cayman hospital's more affluent patients in mind, the team decided not to have an open general ward like that in Mysore, but instead copied the interiors at the High-End hospitals in Bangalore, especially the outpatient areas and the private and semi-private inpatient rooms.

Each choice was based on NH's understanding of what was required in that context and its effort to match the requirement to past solutions based on analogical reasoning. For example, while discussing the design choices with us, one NH leadership member commented, "[The] Cayman hospital is very similar in terms of size and patient volume to our Jamshedpur [Tier 1-2] facility and there the nurses go across ward and ICU. This allows us to staff leanly." A senior person at the Cayman hospital observed that "the architects and designers were asked to see the rooms at the Whitefield [High-End] facility before designing the Cayman private rooms," given the affluent patient pools at both hospitals.

The recombination process was not, however, a simplistic mechanical effort of stitching together elements from different models. NH would often adapt these elements and in some cases rejected potential solutions. For example, although reuse of some medical devices was common in many Asian, European, and African hospitals to keep operational costs down and NH itself had learned to manage the risks related to such reuse through its years of experience in India, it decided not to do this in the Cayman hospital, for fear of the reputational risk amongst an affluent and demanding patient pool. Nurses in the Cayman hospital were not only given soft skill-training to support the more affluent patient base, but were also assigned lower-end tasks to avoid the cost of the nurse assistants who would have performed such tasks in the Indian hospitals. Similarly though most supplies were sourced from NH's Indian suppliers, certain drugs (such as narcotics) were locally sourced as Indian law prohibited their export.

NH designed an open-bay 17-bed intensive care unit for its Cayman facility, rather than the individual private ICU rooms which were the norm in US hospitals. This lowered capital and operating costs, reduced the footprint, and allowed the nursing station to be staffed with fewer nurses since they could easily keep an eye on all the patients. Responding to a query on why HCCI decided to have private ward rooms but an open shared ICU, Dr. Shetty commented, "See, we know that patients in the ICU do not care much about where they are as they are not fully conscious. It is only when they move to the ward [after recovering at the ICU], they like to have their privacy."

Thus, while recombination-based replication of practices and knowledge from the different models and experiences in India allowed NH to make design decisions that addressed the specific situation in the Caymans, these elements were adapted to ensure that they fit with each other and that the model as a whole fit the requirements in the Caymans.

As Dr. Raghuvanshi commented:

> Whether it [the Cayman hospital] should be based on the design of Hospital A or Hospital B [NH hospitals in India] was not what we thought initially. We just thought of what would be the ideal thing to do in such an environment and that was of course based on our experiences in the past. We thought that these are the problems and unique challenges of the location and, based on that, some of the design and other considerations were made. . . . Many of the things [in the Caymans] were designed based on ground realities and some of the things were based on our earlier experiences and some of it was based on our assumptions of what patients may or may not like. . . . We never did things [in India] only in one way. If we had a cookie-cutter approach [in India], we would never be able to manage a challenging project like Cayman.

4.4.4. Early-Stage HCCI Performance

By end of the first year, the fees at HCCI were amongst the lowest in the region and 30%-40% lower than Medicare rates in the US.[18] Moreover, during its first year, HCCI had more than 2,200 outpatients and performed around 250 surgeries and inpatient procedures. These volumes were even lower than the conservative numbers initially anticipated and were a result of HCCI's inability to attract a steady flow of patients from outside the Cayman Islands even by the end of the initial year. On the positive side, the Cayman hospital was able to sign contracts with a number of insurance companies operating in the Caribbean region.

[18] Medicare rates refer to pre-negotiated reimbursements paid to providers by Medicare, the US program that provides health insurance for Americans aged 65 and older. These reimbursement rates are the lowest in the US for tertiary care procedures.

HCCI had significant clinical achievements, performing two very complex artificial heart transplant cases (LVAD procedures) in its first year. This was the first time artificial heart transplant surgeries had been done in the Caribbean region and resulted in the entire region noticing HCCI's clinical expertise. HCCI also performed life-saving heart surgeries for 16 Haitian youth free of charge (in collaboration with Digicel, a local telecom company, and the charitable organization Have a Heart). Overall, the hospital achieved excellent clinical outcomes across all inpatient procedures during its first year (May 2014 through April 2015). The emphasis on patient experience led to patients consistently reporting high satisfaction; one US patient remarked, "This place is just unbelievable—the quality of care, the quality of facilities, equipment, the nurses, the technicians, the food … everything's just been top-notch."

The first year also saw the addition of new specialties such as pulmonology and medical oncology, based on perceived demand. Significant wins that year included a contract with a large employer in the Caribbean region and accreditation by JCI, the latter a significant milestone as a number of insurance companies, large employers, and medical-tourism facilitators in the US had shown interest in working with HCCI once it received JCI accreditation.

Reflecting on HCCI's progress, senior management noted that it typically takes from three to five years for a new hospital to be financially viable. However, early indicators of success at HCCI—such as procedure complexity, clinical outcomes, patient satisfaction, contracts signed, and quality accreditation—indicated that NH had been able to address many of the design requirements in the Caymans early in its internationalization process and suggested that the hospital was heading towards stronger performance. Overall, there was a consensus amongst the senior management team that NH's rich set of experiences in India had helped them design the Cayman hospital and get off to a good start. According to Dr. Raghuvanshi, "If we

had stuck to one particular segment, then we would not have known some of the problems which we would face when we would go to new areas or when we try to take the model outside the country."

4.5. Discussion

The sequence of events related to NH's growth, as described above, is captured in Figure 4.2 in Appendix. NH grew from a single cardiac care hospital to a network of hospitals in India in a little over a decade (2001 to 2013). This expansion was not based on the principle of replication; rather, NH engaged in a variety of activities to address numerous institutional voids and adapt its core model to different market segments. Factors such as NH's reputation and mission orientation in India and the regulative, normative, and cognitive flexibility associated with healthcare delivery there supported its expansion activities, including its context-shaping pre-launch negotiations with the Cayman government. Over time, NH managed to develop (a) an understanding of how the external context affects its operations, (b) context-based design capabilities, (c) a diverse set of knowledge and practices, and (d) a broad and open managerial mindset that appreciated the necessity of different approaches to delivering care in different contexts.

The final but perhaps most novel part of NH's expansion was the recombination of knowledge and practices from different hospital models in India to develop an operating model in the Cayman Islands. The fundamental question of interest here is: how did NH manage the recombination process? First, senior management, based on its ability to identify the key design considerations for the Cayman facility, decomposed the larger design problem into sub-problems. The subsequent recombination process was based on the retrieval of knowledge and

practices that had been designed earlier in India for different markets to address analogous requirements; the leadership's deep familiarity with these different models and their associated knowledge and practices facilitated that retrieval process. This retrieval process is consistent with earlier work on how analogies allow individuals to link past actions and/or decisions to current problems (Barron, 2000; Dunbar, 1998; Gavetti, Levinthal, and Rivkin, 2005; Gick and Holyoak, 1980; Neustadt and May, 1986; Schon, 1993; Simon, 1973) without adopting a rational exhaustive deductive search process. Once individual solutions to similar problems in different home-country hospital models were identified, NH recombined them into a context-appropriate solution. We want to emphasize that NH's recombination process is not a substitute for or alternative to the internationalization process based on replication-adaptation; in fact, the recombination happened in parallel with replication and adaptation. NH both replicated and adapted elements of different models in India at Cayman. Thus, in this case, the replication-adaptation process does not take place at the operating-model level, but rather at the practice level as practices are drawn from the different models.

NH's adaptations to new market segments in India gave it the ability to operate with new elements (akin to LEGO blocks) and subsequently to put them to use in developing the Cayman hospital. This is consistent with past research that suggests that unless there are enough elements available for recombination, the ability to innovate and address new problems will decline (Fleming, 2001; Hargadon and Sutton, 1997), akin to being constrained by limited number of LEGO blocks while developing a model. It is important to highlight that had NH not developed and operated its multiple models, existing research on internationalization suggests that the elements selected for the Cayman facility would likely not have been considered ex-ante, NH would have been less able to incorporate and integrate them there, and its adaptation of its India-

based models to serve the patient pool in the Caymans would have likely taken longer. Delay in establishing an appropriate operating model can hobble or sink an entrepreneurial initiative in a new market; in HCCI's case, for example, poor patient experience, bad clinical outcomes, failure to earn accreditation, inability to handle complex procedures, or lack of cost differentiation could have derailed the project in its early stages and a turnaround would have been difficult.

That said, we acknowledge that random recombination of elements could lead to inferior designs and poor performance. Given our methods, we cannot compare the developed model to other models that might have been developed from the elements that NH had developed in India. However, it is obvious that the choice of certain elements—such as open wards, lack of emphasis on patient service, or noncompliance with JCI requirements—would have resulted in a suboptimal model. NH avoided such missteps by carefully selecting optimal elements for different design dimensions and intelligently managing the replication-adaptation-integration process. Its significant experience in designing different models in India allowed it to carefully manage the conflict of logics while trying to balance cost, experience, and quality. For example, neither the quality of the staff nor the quality of the hospital furniture were ever compromised in order to reduce cost, as such steps would have degraded clinical quality and patient experience. HCCI's initial positive performance and its ability to deliver on most of the requirements suggest that the recombination-based model is effective; however, we cannot assess its optimality.

At its core, NH's approach of developing its hospital in the Cayman Islands suggest a more effective model for internationalization. Our extensive fieldwork suggests that this model has two stages (see Figure 4.3 in Apendix):

1. *Learning from adaptation to contextual specificities and heterogeneity in the home country*: Past research in strategy and organizational theory has emphasized the internal fit

between a firm's strategy and its structure (e.g., Chandler, 1962; Learned, Christensen, Andrews, and Guth, 1965) and the external fit between a firm's structure and its environment (e.g., Lawrence and Lorsch, 1967; Pennings, 1987). Further studies of organizational adaptation and performance (Levinthal, 1997; Rivkin, 2000), based on the idea of performance landscape (NK simulation models), have encouraged firms to develop an optimal structure that is internally consistent, given the home-country context. Successful firms have often focused on developing one model based on their interpretation of their home-country context, avoiding contextual variability as it is difficult to manage. This approach, however, reduces their cognitive flexibility and narrows the leadership's range of interpretation and response with respect to opportunities. Though this focus helps the firm succeed in its home country, the resulting narrow mindset and limited set of practices constrains it abroad.

Our study of NH suggests that firms can benefit by experimenting with contextual specificities and heterogeneity in the home country. These benefits will likely include—but not be limited to—a more flexible senior management mindset, better design capabilities, better understanding of contextual factors critical to success, and a greater stock of knowledge and practices. Firms adopting such an approach will have to deal with issues such as managerial bandwidth, financial returns, mission integrity, and practice standardization; these typically play a part in any exploratory effort and often result in underperformance or abandonment.

2. *Recombination of select home-country knowledge and practice elements in the host country*: Firms that acquire a rich set of experiences in the home country will be better prepared to develop a model in a host country. They will be less constrained by a single dominant logic and narrow managerial cognition and thus able to identify the contextual requirements in the host country sooner and more accurately. Their ability to develop and use a variety of models,

practices, and knowledge elements in the home country will allow them to analogously retrieve and intelligently recombine those solutions to develop a successful operating model for the host country. Given that the recombined elements had already been adopted in the home country, the operating model in the host country will likely be effective in addressing critical design considerations. Overall, we propose that the intelligent recombination of diverse home-country knowledge and practices, guided by deep understanding of context and by context-based design capabilities, may be an effective mechanism to develop an operating model in the host country. This, in turn, implies that a firm does not necessarily have to experience the replication-adaptation dilemma while localizing to a new context.

Our proposed internationalization process model for developing an operating model while pursuing opportunities in a host country suggests that firms that originate in home countries with complex, rich, and heterogeneous contexts might be more successful in international entrepreneurship than comparable firms from countries with a more uniform or restrictive context, especially if the former have engaged with the heterogeneity of their home-country context. In such cases, the greater likelihood of success is explained jointly by the firm's ability to decipher contextual complexities in the host country and its ability to draw from a broad set of home-country knowledge and practices. However, not all home countries are the same and not all firms in a given country accumulate the same set of experience; firms originating in home countries with limited contextual heterogeneity (say, hospitals starting out in the Cayman Islands), firms in countries where the institutional context does not allow for easy experimentation and variation (say, hospitals in the US), or firm's adhering primarily to a replication-based strategy in the home market (like many US retail chains) might face greater uncertainty and hardship in adapting to a host country. Research (Perkins, 2014) suggests that

such a recombination based approach might also be possible based on experiences accrued by a firm in multiple countries. Though perhaps the underlying logic of such an approach is similar to our study, the effort, time, cost, and challenges of pulling together experiences from multiple countries designed and managed by different executives and teams over different time periods is going to be exponentially higher than experienced by NH, if such an approach is at all feasible.

We acknowledge that the recombination-based approach does not guarantee a perfect operating model in the host country. Rather, it improves the firm's ability to design an initial model that is consistent with the design requirements of the host country. For firms in the early stages of internationalization, this is an advantage compared to the alternative of replicating the dominant home-country model in the host country and then having to adapt it in real time. Of course, the greater the firm's ability to recognize the key design considerations in the host country ex-ante and address them by designing context-appropriate features and borrowing from solutions that have already worked well in the home country, the greater the firm's chances of establishing a viable host-country operating model from the start. In situations where the home country experience does not allow the firm to recognize a host-country-specific requirement or provide any idea how to respond to it, then our proposed internationalization approach would not be helpful. For example, HCCI's inability to attract patients from outside the Caymans and its challenges in ramping up patient volume may be attributed to its initial underestimation of the extensive international marketing efforts necessary in North America and the Caribbean. This, in turn, was due to the lower emphasis on marketing in India (relative to the focus on operations and supply chain), given the high demand for affordable, high-quality tertiary healthcare across all market segments in India and NH's strong reputation from the outset.

We also recognize that the recombination-based approach is not a substitute for real-time onsite learning in the host country. The possibility of onsite learning, along with other confounding factors such as the presence of local Caymanian staff at HCCI, the inputs from Ascension (the joint venture partner), and the prior international experience of Dr. Shetty and other NH physicians, restrict us from making any strong claim for the causal effect of the recombination-based internationalization approach on HCCI's long-term performance. Rather, our observations and interviews suggest that the recombination-based approach allowed NH to make a number of appropriate design decisions related to the layout, staffing, supply chain, and other factors early in the project and that these decisions helped HCCI to deliver strong performance in the short term.

Finally, we realize that one cannot safely generalize from a single case. We argue, however, that the focused, in-depth, single-case-study approach allows us to better motivate our research topic by demonstrating a real-world phenomenon, developing new insights on a relatively unexplored topic, and illustrating the specific dimensions of home-country context and why and how it matters for internationalization (Siggelkow, 2007). The extent to which our proposed recombination-based internationalization model develops into a more general theory depends on how well the model, or subsequent related work, can illuminate the process and outcomes of international entrepreneurship in other settings. Of course, the first-order question to explore in any subsequent related work is whether the recombination approach has been adopted by other firms from home countries with heterogeneous contexts or is idiosyncratic to Narayana Health. Assuming the former, the generalizability of our model can then be tested in studies of samples of firms pursuing international opportunities.

4.6. Conclusion

Our goal was to explore the relationship between a firm's experience in its home-country context and its ability to transfer its operating model to a host country during internationalization. While prior research has shown that a firm's capabilities and home-country-based managerial mindset often constrain its ability to develop operating models in a host country, especially during the early stages of internationalization, there has been little emphasis on understanding how contextual heterogeneity and the specificities of the home-country environment might in fact improve a firm's international entrepreneurship ability.

Given that NH's experience prior to its Cayman venture was limited to India, one would expect it to have a hard time designing a tertiary care hospital in the Western Hemisphere, a much more affluent region, and delivering care to patients from multiple countries, including a highly developed country such as the US. However, NH was able to develop a successful operating model in the Cayman Islands right at the outset and to make significant progress during its first year of operation. To understand this counterintuitive outcome, we studied NH's growth in India and the influence that store of experience had on the Cayman project. Our primary motivation was the rationale that only by considering the local context and the evolution of home-country knowledge, practices, and mindset can one gain deeper insight into a firm's ability to develop an operating model to pursue opportunities in a host country. As reported in this paper, we observed that, in India, NH developed a deep understanding of contextual interdependencies, the ability to design context-specific solutions, and a broad set of knowledge and practices. These, in turn, helped in setting up the Cayman hospital. Thus, we observe that an entrepreneur's adaptations to address the institutional inadequacies and sub-segments of the home-country market can yield improved design capabilities and operating model variations.

Subsequent pursuit of international entrepreneurship might then involve recombining elements of the home-country experience to develop an operating model for the host country. Contrary to the established notion of firms adapting the replicated operating model in the host country, the conceptual novelty of our proposed model lies in its explanation of how operating models are developed in a host country during internationalization.

We believe that our study makes a number of contributions. It illustrates the recombination process in the internationalization context and suggests that the decomposition of a large problem into sub-problems and the subsequent solution of these sub--problems, based on past analogous experiences, is one possible path by which recombination takes place. While recent research has highlighted a firm's contextual intelligence—that is, its ability to transfer an operating model to an environment different from the one in which it was developed—as a critical enabler for internationalization (Khanna, 2014), we show how being embedded in and engaged with certain home-country environments can help develop such contextual intelligence.

In addition to illustrating an interesting case of reverse innovation (Govindarajan and Ramamurti, 2011)—the transfer of a low-cost, high-quality healthcare model from an emerging economy to a developed economy—our study has implications for existing research on the internationalization of emerging market multinationals (Ramamurti, 2012). To pursue international opportunities, firms must be able to engage with and respond to the specificities of their host-country context and, for that to happen, they need to develop related competencies. In particular, this is critical for emerging market firms in the early stages of internationalization and thus lacking the multi-country experience of MNCs in the developed world. Our recombination-based internationalization model thus holds promise for emerging economy firms, especially those from countries with heterogeneous environmental contexts such as China and India.

4.7. Appendix

Table 4.1: Data Collection

Mode	Activity details	Timeline
Interviews	57 interviews with NH/HCCI senior management	September 2013 to May 2015
	40 interviews with HCCI staff	January 2014 to May 2015
	34 interviews with staff at NH hospitals in India	December 2013, January 2014, March 2015
	20 interviews with external members	January 2014 to May 2015
Observation at hospitals	5 weeks at Cayman hospital	February, June, November 2014
	6 weeks at 14 NH hospitals in India	December 2013, January 2014, March 2015
Informal conversations	Hundreds of informal conversations with members of NH senior management, staff at NH hospitals in India, HCCI staff, external non-NH members	September 2013 to May 2015
Questionnaire	HCCI operations data (patient volume, patient feedback, financials, clinical outcomes) for first year of operations	April 2014 to April 2015 (collected on an ongoing basis)
	Operations data for 24 hospitals in India related to revenue, profitability, scale, staffing, patient volume, specialties, pricing, etc.	November to December, 2014
Archival information	Internal NH documents such as corporate presentations, annual reports, organization charts	October 2014 to March 2015
	Publicly available information on NH origin and expansion in India and on the Cayman hospital, such as press articles and contract between Cayman government and NH	September 2013 to May 2015

Table 4.2: NH Hospital Models in India

	High-Volume	**Tier 1-2**	**High-End**	**Implant**	**Stand-Alone Clinics**
Fundamental design objective	Provide high-quality, low-cost tertiary care for large patient volumes.	Provide tertiary care in smaller towns and cities. Refer more complex cases to high-volume NH hospitals.	Develop high-end brand for the affluent that draws on NH's clinical expertise. Refer more complex cases to high-volume NH hospitals.	Develop and manage cardiac care specialty at non-NH hospitals. Refer more complex cases to high-volume NH hospitals.	Provide outpatient services to locals in different areas within big cities. No inpatient services. Complex cases referred to nearby NH hospitals.
Year started	2001	2008	2013	2008	2013
Location	Outskirts of big cities like Bangalore, Kolkata, Jaipur	Smaller towns and cities (referred to as Tier 1 and 2 cities)	Affluent neighborhoods within Bangalore	Usually within hospitals associated with medical colleges	Prime areas within large cities like Bangalore, Kolkata
Specialties	Single or multispecialty	Multispecialty	Multispecialty	Cardiac care	Multispecialty
Level of care	Complex tertiary	Standard tertiary	Secondary	Standard tertiary	Primary
Number of facilities	4	8	2	10	7
Number of beds	400-800	100-300	50-100	40-80	0
Annual number of outpatients	100K- 400K	40K-80K	30K-50K	10K-20K	10K
Annual number of inpatients	20K-30K	5K-10K	3K-5K	2K-5K	0
Number of employees	2000 (approx. 150-250 physicians)	400-700 (approx. 50-90 physicians)	250-350 (approx. 50-70 physicians)	75-150 (approx. 15-20 physicians)	15-25 (staffed primarily with physicians employed in other NH hospitals)

Table 4.3: Select Knowledge and Practices from NH Models

Model	Core operating logic	Associated knowledge and/or practice	Description of associated knowledge and/or practice	Common design elements
High-Volume	Affordable healthcare based on economies of scale. Essentially, a focused factory model.	Health city concept	Establishment of multiple high-volume hospitals on same campus	1. Clinical protocols and processes 2. IT systems 3. Procurement practices and sourced items 4. Supplier base 5. Financial processes 6. Human resources policies 7. Clinical training 8. Culture, values, and ethics
		Access to clinical talent	Established nursing and technician schools	
		Establishing cost-effective supply sources	Identified appropriate supplier and, in many cases, developed cost-effective suppliers (e.g., incubate new supplier)	
		International patient services	Practices and dedicated resources to support international patients	
		Clinical protocols and practices	Established clinical processes and practices to manage complex cases and ensure high-quality outcomes.	
		JCI accreditation	Implemented JCI-compliant practices and developed expertise to manage JCI accreditation process	
Tier 1-2	Cost reduction focused on practices related to hospital construction and layout, ward design, staff selection and scheduling	Lean hospital construction	Adopted innovative construction practices (e.g., Mysore project)	
		Lean hospital layout	Designed cost-efficient layout (e.g., Mysore project) to reduce costs	
		Leverage supply base of large-volume hospitals	To keep procurement costs low, supplier base and supplies kept identical to high-volume hospitals	
		Material management practices at remote hospitals	Lack of suppliers at remote locations can lead to supply disruption. Material management practices geared to avoid stockouts.	
		Physician staffing	Physician recruitment and retention requires focused effort from NH in small towns. Physicians able to perform multiple procedures preferred, to keep staffing costs low.	
		Design of hospital interiors	Fewer private or semi-private rooms in smaller towns. In extreme case, like Mysore, no private rooms. Interiors minimalist to keep costs low.	
		Flexible nurse scheduling and staffing	Operating room support team staffed on as-required basis. Nurses are allowed to move between intensive care unit and ward based on demand.	
		Consult state government on regulations and policies	In some less-developed states, NH provides inputs to local government to establish appropriate healthcare regulations and policies	
High-End	Focus on delivering personalized service and care to the affluent and ensuring excellent patient experience	Design of hospital interiors	Interiors comparable to other high-end hospitals in India to please affluent patient base. Rooms are private and semi-private; no general ward.	
		Patient experience	Staff trained to ensure high satisfaction of affluent patient pool	
		Physician staffing	Dedicated outpatient and inpatient time to ensure patient satisfaction, which leads to reduced physician productivity in terms of number of patients	
		Leverage supply base of large-volume hospitals	To keep procurement costs low, supplier base identical to and sourcing consolidated with high-volume hospitals	

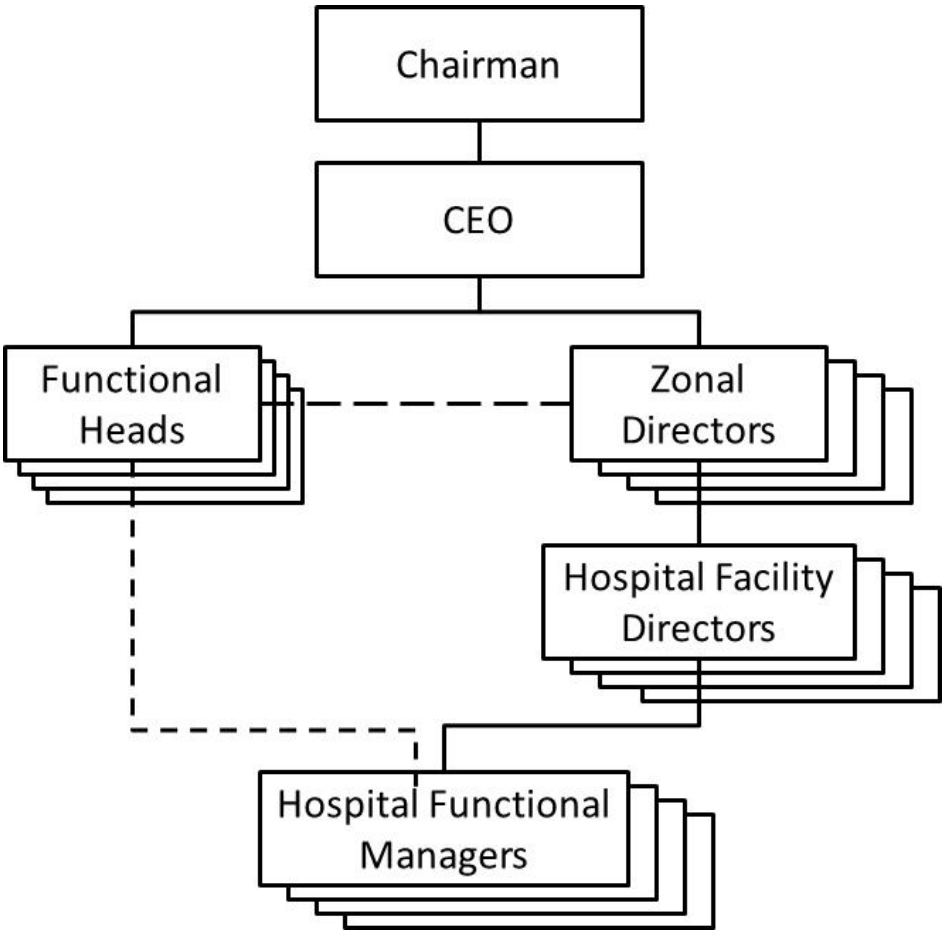
Table 4.4: Health City Cayman Island (HCCI) Hospital Design Based on Recombination

HCCI design			Recombination source			
Design focus	**Specific solution**	**Solution rationale**	**High-Volume**	**High-End**	**Tier 1-2**	**Post-launch implication**
Access to clinical talent	NH ensured that Indian medical degrees and diplomas are recognized in the Caymans and staffed the HCCI hospital with physicians, nurses, and technicians from India.	Challenges of clinical talent availability in India early on at health city and subsequently in smaller towns made NH recognize this challenge in the Caymans early.	√			Critical for high-quality clinical outcomes and to avoid learning-curve issues typical in a new hospital. Reduced manpower costs compared to US hospitals. Retained the frugal and hard-working culture of NH in India.
Facility Design	HCCI layout based on Mysore layout.	To allow for reduced capex, operational efficiencies, and easy future expansion.			√	Efficient layout helped lower construction and operating costs.
	Interior (outpatient area and inpatient rooms) design based on Whitefield Hospital, Bangalore for affluent patients.	Cayman patients were expected to resemble affluent patients in India in their expectations for facilities, aesthetics, etc.		√		Aesthetics of interiors helped create favorable impression on local Caymanians and others (insurance companies, patients, US healthcare practitioners, etc.).
Supply chain and procurement	Establishing oxygen-generation plant within HCCI hospital to meet demand for clinical-grade oxygen.	Reduced cost of procuring oxygen on island. Though NH had not used oxygen-generation plants in India, the decision to generate oxygen was motivated by and consistent with its extensive experience there of internalizing supply sources (e.g., operating room gowns, ICU software) to address supply challenges, reduce procurement costs, and improve operations.	√			As anticipated, the oxygen-generation plant significantly reduced procurement costs. Also reduced risk of supply disruption of an input critical to all tertiary care procedures.
	Sourcing of medical supplies and equipment from Indian suppliers.	Experience in India of supporting smaller and newer NH hospitals by letting them source from contracted high-volume hospital suppliers at pre-negotiated attractive rates.		√	√	Reduced procurement costs at the beginning and gave the HCCI team the necessary flexibility to identify and negotiate with suppliers in the Cayman region for critical items.
	Material management practices at HCCI influenced by practices at remote smaller hospitals.	HCCI had to build its material management practices based on existing processes, experience, and learning at remote low-volume hospitals in India with similar, though			√	Material management at HCCI during initial months was a challenge due to variability in patient volume and difficulties getting supplies to the island.

		less severe, supply challenges: unavailability of local suppliers, demand volatility, and limited shelf-life of certain consumables and drugs.				However within months, HCCI was able to improve supply chain performance.
Patient experience	International patient management process at HCCI included but was not limited to assured medical visa from Cayman govt. within 3 days of application, airport pick-up/drop-off, other support during stay.	Experience of managing international patients at the health city campus in Bangalore.	√			These processes not only increased patient satisfaction, but proved to be important in discussions with insurance companies, large employers, and medical tourism facilitators in US.
	Implemented processes, recruited personnel from hospitality industry, and trained staff to ensure quality patient experience.	Based on experience of managing affluent patients at High-End hospitals in Bangalore. Cayman patients and other international patients, familiar with healthcare in the US, were expected to have similar service and hospitality expectations.		√		Patients at HCCI consistently reported an excellent or very good experience during the first year of operations. This feedback was captured in the hospital anonymous feedback forms and personal testimonials of US patients.
Clinical excellence	Clinical protocols and processes at HCCI were based on documented processes and protocols at health city, Bangalore.	Processes and protocols developed and documented in health city Bangalore were based on over a decade of experience and were JCI-accredited.	√			The tested processes and protocols from health city Bangalore allowed HCCI to take on complex tertiary cases in the initial year, deliver excellent clinical outcomes, and accelerate the JCI accreditation process.
	Develop clinical expertise and knowledge at HCCI by transferring senior physicians from India and ensuring remote clinical support, as required, from health city, Bangalore.	Experience of opening smaller hospitals in India by staffing experienced physicians from health city, Bangalore and supporting these, especially during initial period, from the health city.		√	√	The presence of highly experienced doctors at HCCI and the ability to consult with NH senior staff in health city, Bangalore on complex cases allowed HCCI to realize excellent clinical outcomes.
JCI accreditation	JCI accreditation team and processes based on prior experience of JCI accreditation at health city cardiac hospital in Bangalore and multi-specialty hospital in Jaipur.	NH knew JCI accreditation would be important in marketing HCCI to large employers and insurance companies in the US. As JCI standards are global, NH decided to staff the team and develop processes based on JCI accreditation experiences in India.	√			By end of first year of operations, HCCI was JCI-accredited. Discussions with members of healthcare industry suggest that this is likely the minimum possible time for any new hospital.
Staffing and scheduling	Physicians staffed at HCCI, other than being highly experienced, were able to perform different tertiary	Experience at smaller NH hospitals with heterogeneous cases but overall low volumes suggested that this			√	Decision helped lower operating costs at HCCI but still allowed it to treat broad range of cases related to

	procedures related to their specialties.	reduces operating costs in initial stages of smaller, low-volume hospitals.				interventional cardiology, cardiac surgery, and orthopedic surgery.
	Physician scheduling at HCCI based on dedicated outpatient and inpatient times, as at High-End hospitals, allowing outpatients pre-specified appointments.	Adopted this scheduling practice as Cayman patients would likely resemble affluent patients in High-End hospitals in India in their unwillingness to wait for physician without pre-scheduled time. This approach differs from the approach in high-volume hospitals primarily serving indigent population.		√		Patients at HCCI consistently reported an excellent or very good experience. At a more operational level, this allowed for no/little waiting time for outpatients with appointments.
	Nurse and technician staffing at HCCI adopted the nurse staffing practice from smaller, lower-volume hospitals, especially those in smaller towns and cities with less clinical talent availability.	This approach allows the hospital to keep operating costs low by optimizing the number of staff. For example, highly skilled nurses are cross-staffed across intensive care units and wards based on demand (no fixed assignment based on skill or experience level). Support nurses and technicians for operating room available on call; no dedicated shift-based staffing as in high-volume hospitals.			√	Lowered operating costs at HCCI while maintaining operational flexibility.
Managing regulatory environment	From the beginning, NH worked with Cayman govt. to develop regulations, laws, and policies to allow for successful hospital development and operations. Post-launch, NH continued to work with Cayman govt. to ensure appropriate interpretation of laws and regulations and determine plan of action when laws/regulations were absent.	This approach was based on NH's long involvement in India on regulatory matters related to the larger healthcare ecosystem, especially while establishing the Bangalore hospital. NH also helped some underdeveloped states in India develop appropriate healthcare regulations and policies to discourage poor practices at private hospitals.	√		√	HCCI was able to work with Cayman govt. to ensure a regulatory regime that allowed it to manage cost-effective, high-quality operations. This approach also allowed the Caymans to develop the foundations of a healthcare regulatory system and make progress in establishing itself as a medical tourism hub.

Figure 4.1: NH Senior Management Organization Chart in India



Note: Organization chart not exact and not exhaustive. The above figure is for illustrating the linkages between members of the senior management team only.

Figure 4.2: NH Journey from India to Cayman Islands

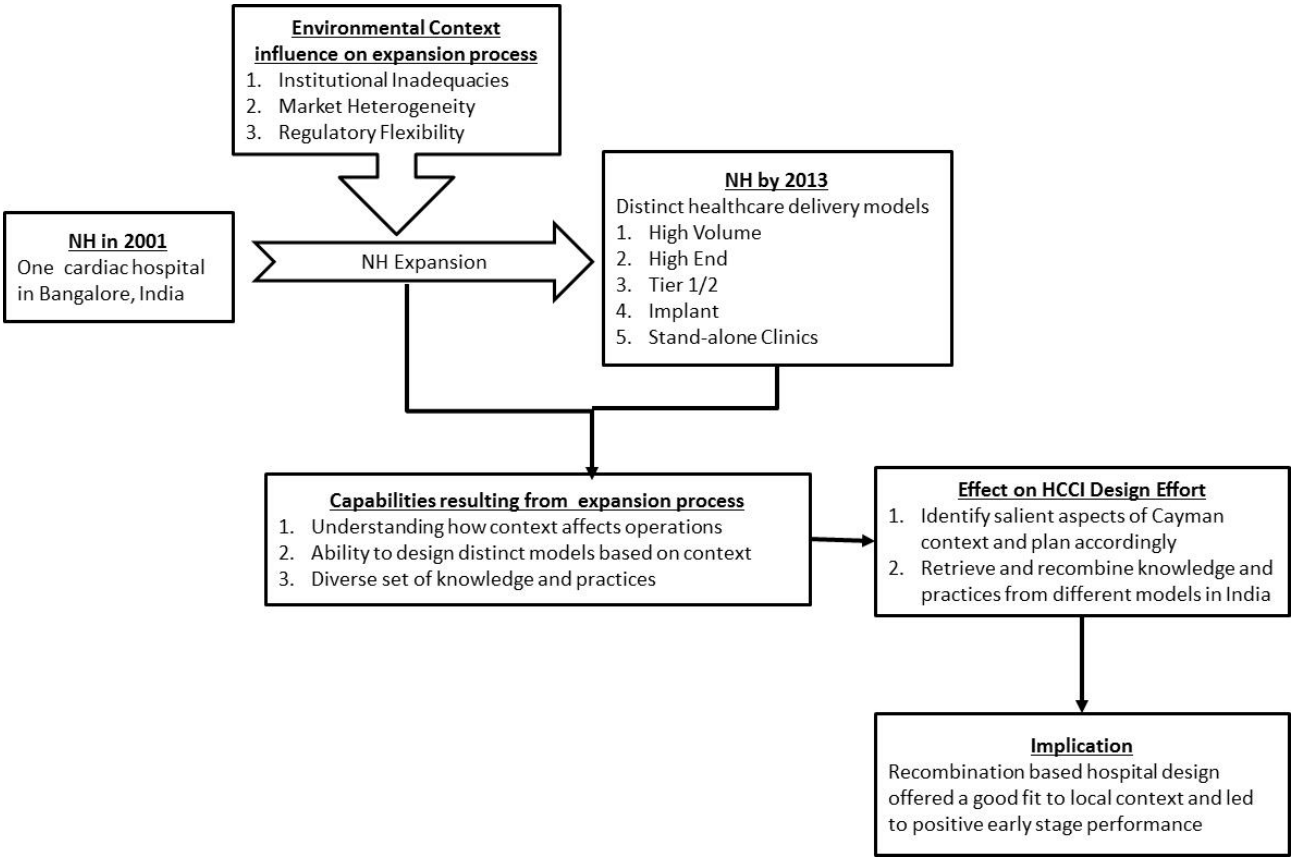
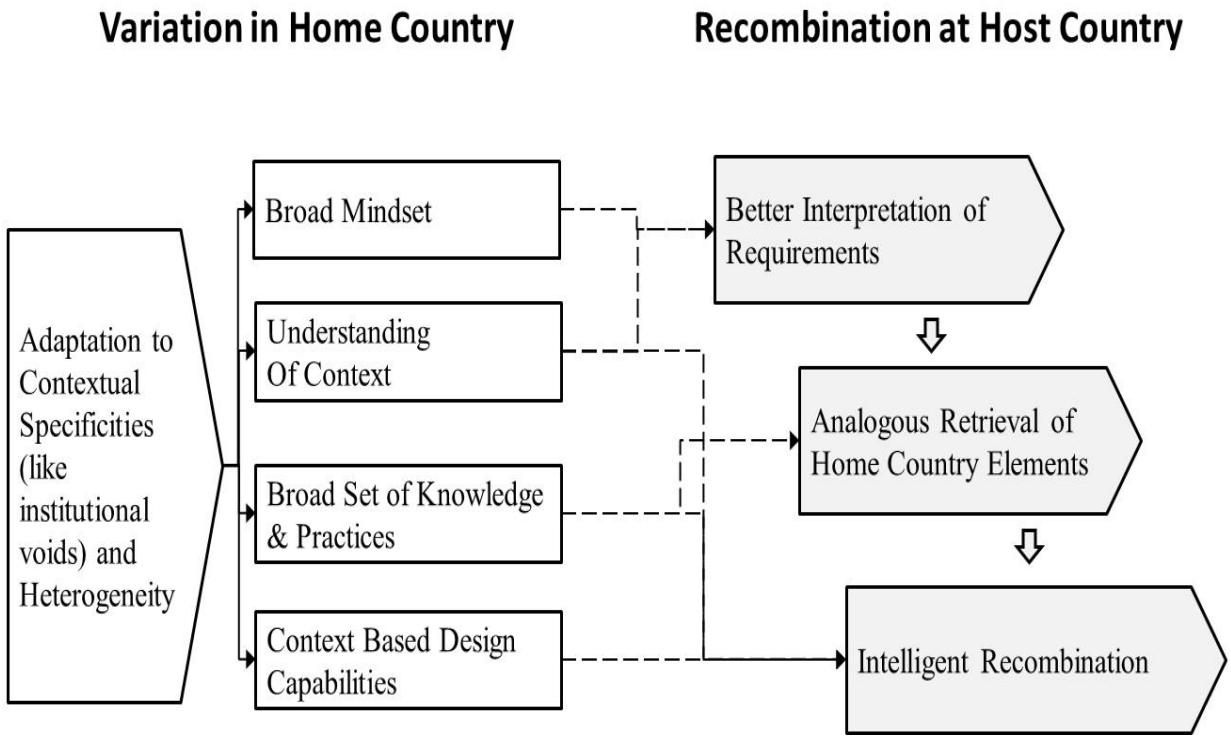


Figure 4.3: Recombination Based Internationalization Process Model



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