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## **Prospective Case Study Design**

# **Qualitative Method for Deductive Theory Testing**

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The article advances a *prospective case study design* in social sciences as an alternative to traditional post hoc case study research in deductive theory testing. It is argued that some limitations of post hoc qualitative methods in deductive theory testing can be alleviated by using a prospective case study design, where researchers formulate a set of theory-based hypotheses in respect to the evolution of an ongoing social process and then test these hypotheses at a predetermined follow-up time in the future by comparing them with the observed outcomes using *pattern matching* or a similar technique. Some challenges of conducting prospective research in social sciences are discussed. An illustration of the application of this method in deductive testing of two competing theories is provided.

**Keywords:** qualitative methods; case study; quasi-experimental research design; deductive theory testing; philosophy of science

The deductive theory testing is usually associated with a positivist paradigm of scientific research and with quantitative research methods in social sciences (Guba & Lincoln, 1994; Lee, 1989; Yin, 1981, 2003). The tight coupling of deductive research with quantitative methods in our field has created a situation where theories are tested only on those elements of the social environment that are amenable to quantification, whereas the generalizability of these theories beyond the scarce quantifiable aspects of the social processes remains unaddressed. It is argued here that this methodological deficiency in deductive research can be addressed by further development of qualitative theory testing methods. In research contexts where unique phenomena, lack of adequate quantitative measures, or reductionist operationalizations requiring an unacceptable "leap of faith" make the application of quantitative methods unfeasible, insufficient, or not meaningful, theory testing using qualitative case studies can provide a critical test for a theory, similar to a test performed with a single experiment (Yin, 2003).

A substantial body of empirical research using case study methodology (Allison, 1971; Keil, 1995; Markus, 1983; Ross & Staw, 1993; Shane, 2000) has demonstrated that case

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studies can serve as an important form of quasi-experimental theory test providing us with a better understanding of the explanatory power of competing social theories (Langley, 1999; A.S. Lee, 1989). Nevertheless, the rigor of theory tests performed using case studies is often suspect to positivist researchers who are more comfortable with traditional quantitative theory-testing methods. Specifically, the validity of hypotheses inferred from the theories subjected to testing using qualitative methods is often vulnerable to positivist critiques related to the ambiguity of the inferred hypotheses (more than one plausible hypothesis can be inferred from a given theory) and the selective bias introduced by researchers' awareness of the qualitative case outcomes at the time of hypothesis formulation. The purpose of this article is to introduce a novel case study design that can address these concerns and improve the rigor of theory tests conducted using qualitative case studies.

I argue that the limitations of qualitative methods in deductive theory testing described above can be alleviated by using a *prospective* case study (PCS) design, where the researcher formulates a set of theory-based hypotheses in respect to the evolution of an ongoing social process and then tests these hypotheses at a predetermined follow-up time by comparing these hypotheses with the observed process outcomes. Such a test can be performed by using the pattern-matching technique (Campbell, 1966; Trochim, 1989). The use of PCS design advanced here can contribute substantially to the rigor of qualitative studies by eliminating some of the biases and shortcomings associated with post hoc research. In this respect, the PCS study design, although remaining *qualitative*, suggests an analogy with prospective *quantitative* research designs used in medicine, where study designs, such as *prospective case control study* and *prospective case series study*, are used to statistically validate the hypothesized effect of a clinical intervention on a sample of patients (i.e., "cases" in a clinical sense). Such prospective study designs are deemed to produce more rigorous results than the retrospective clinical studies.

The proposed PCS design is based on the application of the principles of prospective study design adapted from medicine to the qualitative case study methodology developed in organizational studies for deductive theory testing (Langley, 1999; Lee, 1989; Markus, 1983). This article describes the qualitative PCS methodology for deductive theory testing in social sciences and presents an illustration of its application on the material of an ongoing study of electronic health record (EHR) system implementation in Canada.

#### **Research Designs for Deductive Theory Testing**

#### Quantitative and Qualitative Methodology in Deductive Theory Testing

The social science methodology is currently clustered around two major research paradigms formed by a tight coupling of deductive approach with quantitative research methods, on one hand, and of inductive approach with qualitative research methods, on the other. Nevertheless, these combinations do not exhaust the full spectrum of possible methodological approaches: Many important contributions in our field were made when the findings obtained using quantitative methods laid the ground for inductive theory building (e.g., Hannan & Freeman, 1987)<sup>1</sup> or when qualitative methods were used in deductive theory testing (e.g., Markus, 1983; Shane, 2000). As unexplained empirical observations (quantitative or

qualitative) create the need for inductive theory building, the presence of multiple competing theories creates the need for deductive theory testing using the methods dictated by the phenomenon being researched (Leonard-Barton, 1990). The view taken here is that a comprehensive test of a social theory should explore not only the scarce quantifiable aspect(s) of the social process explained by the theory but also those multiple aspects of this process that cannot be adequately quantified. The latter task can be accomplished using qualitative case study methods for deductive theory testing.

#### **Case Study Methods for Deductive Theory Testing**

Because "the study of a single case commonly yields more variables than data points" (Lee, 1989, p. 35), theory testing using qualitative study usually does not rely on comparison between groups of observations on a single measure (Trochim, 1989). Instead, it uses a comparison of a pattern of observed outcomes (on several variables) with some pattern of expected values derived from a given theory. This pattern-matching technique (Campbell, 1966; Yin, 2003) allows for outcome evaluation on multiple dimensions, where as little as one actual observation for a given dimension is available. All that the pattern matching requires is "a theoretical pattern of expected outcomes, an observed pattern of effects, and an attempt to match the two" (Trochim, 1989, p. 360). Although the mentions of the pattern-matching technique are frequent in qualitative studies, researchers seldom proceed to explicit and formal application of the method, with the sets of variables, hypothesised values of these variables, and observed outcomes explicitly stated, and the actual matching operation performed (among notable exceptions, one can mention Keil, 1995; Lee, Mitchell, Wise, & Fireman, 1996; Ross & Staw, 1993).

Another qualitative approach that yielded interesting results in deductive theory testing is the approach termed alternate theoretical templates strategy (Langley, 1999), where different theoretical templates are applied to a single case to contrast the assumptions, explanations, and recommendations that form each of the alternate theories. The alternate theoretical templates strategy gives an opportunity to use a "real-life" case to subject different theoretical approaches to a *falsification* test (Popper, 1968). One of the strengths of the postpositivist falsification approach to theory testing with case studies is that the growth of our knowledge is achieved not through the "proof" of a single theory, which, in effect, cannot be accomplished with a single case study, but through the "falsification" and rejection of other theories that are inferior in their ability to explain the natural case phenomena. Such study design has proven to generate interesting "arena theorizing" insights into the explanatory and predictive power of the contrasted competing theories. The two classical examples of application of this approach are the Cuban missile crisis case analysis by Allison (1971) and the analysis of management information system implementation in a multidivisional organization by Markus (1983). In the analysis of the Cuban missile crisis, Allison (1971) provided the interpretations of actual events in light of three different theoretical approaches: rational choice, organizational routines, or political processes. Lynne Markus (1983) has contrasted three theories: people-determined theory, where resistance to management information systems (MIS) implementation was explained by the factors internal to a person; system-determined theory, where resistance to MIS implementation

was explained by the system factors or "bugs"; and *interaction theory*, which had two variants—sociotechnical (focusing on distribution of responsibility) or political (focusing on distribution of power). Her conclusion was that resistance to MIS is a product of settings, users and designers, interactions of different political interests, and power distribution within the organization. In another interesting study, Shane (2000) used eight case studies to test the explanations of entrepreneurial opportunity discovery provided by neoclassical economics, psychological theory, and Austrian economics.

A combination of pattern matching and alternate template strategy has substantial promise. An interesting application of this combined approach can be found in Keil (1995), where three theories of information technology (IT) project escalation were retrospectively applied to a single case study involving a "runaway" project in a large computer company. In this article, the combination of pattern matching and alternate template strategy is used in deductive theory testing using a PCS design described below.

#### Retrospective Versus Prospective Research Design

The deductive theory testing in a qualitative case study poses certain methodological challenges. The validity of these tests can be questioned on the grounds that the case study outcomes are known to the researcher at the time when the hypotheses are being formulated. In effect, the researcher formulates the hypotheses inferred in a certain way from a given theory, already knowing which hypotheses are supported by the outcomes of the case study and which ones are not. Because the theories in social sciences are not fully formalized and the inference of testable hypotheses from a given theory rarely can be accomplished by relying solely on formal logic, the process of hypotheses selection and formulation is not free from a researcher's retrospective rationalization and selective biases. This awareness of the outcome gives researchers a temptation to cherry-pick the cases that support a given theory or to select (or generate) a theory that a particular case supports, leaving out theoretical propositions and factual data that do not fit with the author's plan. Both practices are vulnerable to positivist criticisms in respect to rigor, construct validity, and generalizability of the results of such studies.

Another issue with the post hoc, or retrospective, study design is that it may conceal serious methodological flaws in sampling and data collection. Several methodological problems, such as left-censoring or survivor bias in sampling or "attributional" biases (Staw, 1975) and "post hoc rationalization" (Campbell, 1975) in data collection from the interviewees have been shown to be a common problem in post hoc studies.

For these reasons, in other disciplines where the application of formal logical inference in hypothesis formulation is also problematic; but, the need for rigor and reliability of research is high (e.g., in medicine), such retrospective, or post hoc study designs are not considered to be a preferred option, and the preference is given to *prospective longitudinal study designs* with hypotheses, follow-up times, and evaluation criteria established in advance. The view taken here is that *PCS design*, where the formulated testable propositions indeed function as documented "predictions" of future outcomes, may provide additional rigor and legitimacy to the case study methodology in deductive theory testing. With

such designs, even a failure of a prediction derived from a given theory may generate important insights into the confounding factors, variable interactions, and other complex mechanisms that made the prediction fail.<sup>2</sup>

The proposed study design entails two major steps. Step 1, accomplished in the first, baseline case study, involves formulation and development of the following study elements:

- 1. Formulation of the research question and the selection of the theories to be tested.
- Identification of the case study, where the competing theories can be tested, and selection of the data collection and analysis methods. This would also include justification of case study selection for the stated research purpose (cf. study inclusion and exclusion criteria in clinical research).
- Analysis of the case and formulation of the patterns of testable hypotheses/predictions of the future case development based on the foundations provided by the theory.
- Formulation of criteria for outcome evaluation at Step 2 (e.g., What will be considered a success or a failure? What outcome(s) will be deemed to support a given theory? etc.).

The second step would involve a follow-up research that will be conducted in a set period of time to evaluate the case outcomes versus the propositions/hypotheses formulated in Step 1. The evaluation will be conducted using the criteria and methodology formulated for the Step 2 study at the outset of this research project (see Item 4 on the list of Step 1 study elements above). The sections that follow will provide an item-by-item description of the components of the Step 1 study, including formulation of evaluation criteria and methodology considerations for the Step 2 of this research project. The illustrations from an ongoing PCS study will be drawn.

The proposed method departs from the case study research designs described in the literature in two respects. First, in PCS design, the procedure where hypotheses in respect to the ongoing process are deduced from the theories is completed and documented before the outcomes of the process are known to the researchers, and hence, these outcomes cannot taint case selection, choice of theories, and the hypotheses formulation. Such rigor controls are not built into the traditional, post hoc case study design for deductive theory testing (e.g., Keil, 1995; Markus, 1983). Second, Step 1 in the proposed PCS goes beyond the role of a traditional pilot case study that sometimes precedes the formal data collection. Although an optional pilot study can "help you to refine your data collection plans with respect to content of the data and the procedures to be followed" (Yin, 2003, p. 79), Step 1 of the PCS is a critical part of the formal data collection procedure itself: It is focused on establishing connections between theories and the live social process that will be used as a test bed in this quasi-experimental design. Thus, the critical objective of Step 1 is to define how a given theory would interpret this process, what predictions it would make in respect to the outcome and why.

The formulation and development of the four elements of the Step 1 study is illustrated here with an example of an ongoing PCS of EHR system implementation in Canada. Although the observable outcomes of the EHR implementation that would constitute the focus of the follow-up and the Step 2 study is several years away, the case study described below establishes a baseline for this research project and provides the empirical data for formulation of testable propositions.

#### The Elements of the Baseline PCS Study

### Formulation of the Research Question and the Selection of the Theories to Be Tested

Methodology considerations. A potential limitation of prospective research design is that not every social theory allows for formulation of deterministic predictions that can be tested over time. The ideal theory subjected to a test using the prospective study design should be deterministic in nature: The outcomes should follow from the initial conditions according to the hypothesized causality relations. Very few sociological theories fall into this category. Nevertheless, the scope of application of the proposed study design can be broadened substantially through the use of alternate template strategy (Langley, 1999) where two competing theories are tested at the same time. By selecting two theories that are based on mutually exclusive assumptions and where only one theory is deterministic, we can obtain important insights into the explanatory power of a nondeterministic theory as well, if we show that the alternative explanation drawn from the deterministic theory holds or fails in the context of a given case study. Table 1 illustrates such study design using initial condition A and the range of possible outcomes - B (predicted by the deterministic theory, given A) and not B (i.e., Outcomes C, D, . . . or Z).

Outcome B would suggest that the observed social process can be explained by the factors and relations advanced in the deterministic theory. Although this outcome does not allow us to falsify (Popper, 1968) the nondeterministic theory, it makes the explanation advanced by the nondeterministic theory redundant, because much stronger (deterministic) assertions about the observed social processes are possible. The outcome "not B" would clearly falsify the deterministic theory and make a stronger case for adoption of the nondeterministic theory in explaining the outcomes of a given process. Thus, "not B" would provide indirect evidence in favor of the nondeterministic theory by eliminating the competing explanation. The case below illustrates an application of such research design in a prospective study of EHR system implementation in Canada.

EHR study motivation. Researchers have traditionally provided two fairly divergent accounts of organizational action: The actions can be explained on the basis of rational interests of actors (rational choice and political theories) or, alternatively, the actions can be explained without the assumptions of rational objectives and intentionality (e.g., organization process theory [Allison, 1971] and early institutional theory [DiMaggio & Powell, 1983; Meyer & Rowan, 1977]). The recent trend towards reintegration of intentionality and interest into institutional accounts of organizational actions (DiMaggio, 1988; Oliver, 1991; Rao, 1998) stimulates interest to the explanatory potential of these contrasting theoretical approaches. DiMaggio (1988) has called for research efforts to overcome the theoretical opposition between interest-based political and interest-free institutional models and "to recognize the explanatory tasks to which each kind of model is better suited" (p. 16). The implementation of this research agenda requires an exploration of the explanatory and predictive power of the following two approaches:

Table 1			
Study	Design		

	Logical Structure	Outcome	
Theory Type	of the Proposition	В	Not B
Deterministic Nondeterministic	"If A then B" "If A then B or not B"	(True) <sup>a</sup> (True)	(False) <sup>b</sup> (True)

a. The support for the hypothesis about the relation between A and B is usually tested in the alternative hypothesis.

- 1. The *interest-based approach* emphasizes the agent's self-interests in determining organizational actions and outcomes of social processes. The interest-based approach, which has a long tradition in sociology, political science, and economics, is built on a rational, utilitarian account for human interests and actions. The behavior of actors is determined by their interests, and the conflict of different interests forms the core of most political and economic theories (Alford, 1975; Marshall, 1997; Marx, 1993; Wright, 1978). In this study, a political version of the interest-based approach will be used (thereafter, *political theory*). According to this approach, "different groups pulling in different directions produce a result, or better a resultant a mixture of conflicting preferences and unequal power of various individuals distinct from what any person or group intended" (Allison, 1971, p. 145). The political, interest-based approach is, thus, nondeterministic and does not lend itself to a direct testing in a prospective case study research.
- 2. The *interest-free approach* explains the patterns of organizational actions based on factors other than agents' utility and interests. In this study, this approach will be represented by early neo-institutional theory, which emphasizes the taken-for-granted social norms that determine individual and organizational actions, conformance, and isomorphism in organizational forms, strategies, and actions (thereafter, *institutional theory*). The emphasis of early neo-institutionalists on actor conformance with established social norms makes the behavior of social actors predictable (as long as the prevailing norms stay constant) and hence allows the formulation of predictions that can be tested directly in PCS design settings.

Recognizing the possibility of mixed results in the study outcomes, we have allowed for the third option that would call for integration of the two approaches described above:

3. A *combined approach* where elements of both political (interest-based) and institutional (interest-free) logic have to be introduced to provide a more complete account for organizational actions and the social dynamics.

The combined, political/institutional approach stems from the view that these theories are not mutually exclusive. Political models often incorporate elements of institutional accounts to complement actor interests and power with legitimacy considerations and other sociocultural factors (Allison, 1971; Pfeffer & Salancik, 1978). On the institutional theory side, it has

b. The support for the hypothesis asserting lack relation between A and B is usually tested in the null hypothesis.

been observed that organizations conform to the norms not only because they "constitute a reality" or are taken for granted but also because conformance is often in organizations' best interests (Meyer & Rowan, 1977). Thus, under the integrative approach, the predictions of the institutional theory need to be adjusted for an actor's self-interested agency wherever we can expect (a) the possibility of intentional self-interested, illegitimate behavior of actors who choose to break the institutional norms or (b) the availability of conflicting institutional norms that offer actors a choice of different legitimating accounts depending on which course of action has been chosen based on their self-interest.

#### Identification of the Case Study and Methodology Selection

Given the deductive nature of this research, the case sampling for this study is *theory based* (Patton, 2001, p. 238): The most interesting test case for testing the three theories would be a case where (a) ambivalent structural change affects power distribution between the actors (and, therefore, political contest dynamics described by the political theories can be expected [Markus, 1983]), and (b) this political contest among the actors occurs in a highly institutionalized environment, where institutional theory would predict a high degree of actor conformance to the established institutional norms, practices, and roles.

Thus, the selection of the EHR implementation in Canada as a test case was motivated by several factors. First, health care is a highly institutionalized organizational field where multiple organizations, professions, and interest groups have well-established and institutionalized roles and power bases. The second factor is the nature of social changes, including changes to the distribution of power that EHR implementation may introduce into health care. The third factor is the presence of extensive literature on the sociology and the politics of health care in both utilitarian/conflict-oriented tradition (Alford, 1975; Freidson, 1970; Kingdon, 1984; Pfeffer, 1973) and in institutional theory (Jespersen, Nielsen, & Sognstrup, 2002; Ruef & Scott, 1998). This literature will facilitate formulation of testable hypotheses on EHR outcomes.

The main unit of analysis in this study is the EHR system implementation in the context of the Canadian health care sector. Given the complexity of the domain and involvement of multiple actors engaged in a complex network of relations, the embedded case study design, where different units of analysis were explored within a single case study (Yin, 2003), is believed to be most appropriate. The key subunits of analysis (Yin, 2003) in this embedded study design are health care stakeholder/interest groups characterized by their interests in respect to the EHR, their power in health care, and their ability to affect the EHR implementation process.

The exploratory baseline study is based on multiple sources of evidence: secondary data (records, press, public political statements/reports/electoral platforms and legislative acts, Medline search, etc.); in-depth interviews with eight domain experts; and the academic literature on social, economic, and political dynamics in health care. The interviews were conducted face-to-face or by telephone in 2003 and 2004 in Montreal, Toronto, Ottawa, and Vancouver. The sampling of the interviewees was done using a snowball sampling technique, where every interviewed person was asked to provide the names of other people that could add a new perspective to the research. Because snowball sampling is based on informants' personal networks, which also comprise their political context, this technique is

likely to introduce a bias in favor of the political theory if used for study results evaluation at Step 2 of this research. Nevertheless, the EHR case study has benefited from the use of this technique at Step 1 (baseline) research, where it helped the researcher to understand the case study settings and to identify important connections, preferences, and affiliations of the potential informants. Although the use of this technique at Step 1 could have had an effect on what case study measures/variables received greater attention of the research team, the expected values assigned to these variables at Step 1 were derived from the theories and hence were unlikely to be affected by the possible sampling bias. Overall, snowball sampling is believed to be appropriate and beneficial for the baseline (Step 1) research, but not for the evaluation of the outcomes at the Step 2 follow-up study.

The informants not participating in EHR pilots were first presented with a description of the project and then asked to comment on their willingness to participate in such an initiative and then probed on specific issues that could have affected their decision. The interviewed project managers were asked to share their experiences of interaction with different stakeholder groups, their impressions of stakeholder sentiment in respect to the project, as well as relationships between stakeholder groups. The leaders of other interest groups in health care were asked about their attitudes to e-prescribing and EHR, the issues that pose a challenge to such projects, issues related to project support from their constituents, and about the impact that e-prescribing initiatives may have on their constituents.

At the first stage of the PCS study, the *construct validity*, or "establishing the correct operational measures for the concepts being studied" (Yin, 2003, p. 34), is the primary concern. Failure to adequately operationalize the tested theories at this stage may invalidate the whole study, regardless of the observed outcomes. The construct validity was ascertained through the triangulation (Patton, 2001, p. 247) of multiple data sources (interviews vs. publicly available information in mass media vs. domain studies/reports). The hypotheses were validated with observations presented in the extant literature on health care. Where possible, the key findings and formulated hypotheses were reviewed with some of the interviewed domain experts and fellow researchers with interests in institutional and political theories to ensure construct validity.

### **Analysis of the Case and Formulation of the Patterns of Testable Hypotheses**

The EHR system. EHR systems are composed of all lifelong electronic patient records incorporating data fed from various sources: health care providers (e.g., hospitals, physicians, community and home care), as well as support and feeder systems (e.g., pharmacies and laboratories). An integrated EHR system would make the data available to health care providers anywhere on a need-to-know basis by connecting them through electronic networks and databases. One of the key parts of EHR is electronic prescribing (e-prescribing), which has the potential to produce substantial changes in power distribution among the actors. In a narrow sense, e-prescribing can be defined as entering a prescription for a medication into an automated data entry system (handheld, PC, or other), thereby generating a prescription electronically, instead of writing it on paper (Kilbridge & Dladysheva, 2001).

The general hypotheses. The political and institutional theories would see different aspects of the EHR development as relevant for the outcome of the project implementation. For political theories to be truly successful, initiatives like EHR have to secure a broad support from major constituents that control one or several important resources (Pfeffer & Salancik, 1978) vital to the project. Each constituent group would also have its own interests and concerns related to the potential impact of EHR on their role within the health care system, and based on calculations of self-interest, the constituent will support, resist, or be neutral to the changes introduced by the EHR system.

For the interest-free version of the neo-institutional theory, the focus is on the social norms and practices established in health care (Meyer & Rowan, 1977) and the legitimacy of the EHR innovation (Suchman, 1995) with its key audiences. According to the institutional theory, institutionalization and legitimation of an organization, practice or organizational form confers a survival advantage (DiMaggio & Powell, 1983; Meyer & Rowan, 1977; Scott, 1987). Constituents are more willing to make their resources available to a more legitimate organization (Parsons, 1960). Thus, the EHR's success is predicated on its legitimacy with its stakeholders (Meyer & Rowan, 1977).

Because of the three theories discussed above, only the interest-free approach advanced in early institutional theory (DiMaggio & Powell, 1983; Meyer & Rowan, 1977) allows derivation of deterministic predictions, the general hypotheses for the study were formulated as follows:

- $H_O$ : The outcomes of the EHR implementation process in the Canadian health care sector is independent of the prevailing institutional norms and rules currently established in the health care field (and, therefore, even in a highly institutionalized environment, such as health care, the explanations advanced by the interest-free version of the institutional theory are not sufficient to account for the unfolding social processes.
- Strong  $H_A$ : The outcomes of the EHR implementation process in the Canadian health care sector can be predicted on the basis of the prevailing institutional norms and rules currently established in the health care field (and, therefore, the explanations advanced by the interest-free version of the institutional theory provide a better account of actor behavior and the unfolding social processes in a highly institutionalized environment).
- Weak  $H_A$ : Only some of the outcomes of the EHR implementation process in the Canadian health care sector can be predicted on the basis of the prevailing institutional norms and rules currently established in the health care organizational field (and, therefore, a combination of political and institutional explanations suggested by the combined approach is required to account for the outcomes of the EHR implementation process).

Because political interests are specific to each actor group (Allison, 1971) and different audiences use different norms and criteria to judge the social acceptability of an organization (DiMaggio & Powell, 1983; Meyer & Rowan, 1977; Suchman, 1995), the evaluation of these hypotheses and the differentiation between the weak and strong forms of H<sub>A</sub> requires formulation of specific, lower level propositions that will form theoretical patterns for each approach. Thus, the critical steps in deductive testing of the formulated above macro hypotheses are (a) identification of the social norms of the organizational field in which the project is embedded (Granovetter, 1985) and (b) inference of actor-specific, testable hypotheses in respect to the way these norms would control the actor behavior and determine the final outcome of the innovation adoption process. These hypotheses would allow

us to differentiate the outcomes consistent with the strong and weak forms of  $H_A$  when they will be tested against the outcomes of the EHR implementation process at Step 2 of this prospective case study.

The social norms in health care and the EHR legitimacy. In a study of survival of hospitals in the United States, Ruef and Scott (1998) have identified two types of legitimacy that are critical in health care: "technical legitimacy," which is focused on quality of patient care, medical technology, staff qualifications and training, and "managerial legitimacy," which is focused on efficiency and cost containment. Because norms and values are reflected in communications of a society (Dowling & Pfeffer, 1975), the public legitimacy of the EHR was assessed from content analysis of the full corpus of 366 articles discussing EHR in the Canadian press from 1996 to 2004. The analysis showed a significant uptake in public interest to EHR starting in 2001: from practically no mentions of EHR in 1996 to 110 mentions in 2003. The EHR-promoting discourse usually addressed both technical and managerial legitimacy of the EHR, but overall, EHR's technical legitimacy received the greatest attention in press. The patient benefit forms the normative core of the medical profession (cf. The Oath of Hippocrates<sup>3</sup>). Most of the actions, changes, and resource allocations within health care are usually legitimated through the reference to patient benefit as the principal sociocultural norm in this organizational field. Although this fundamental claim never gets contested, heated debates continue around what is in best patient interests. The definitions of patient benefit often come in conflict. For example, the goal of enhancing compliance, overcoming patient care fragmentation, and avoiding dangerous drug interactions by tracking patients' drug claims and feeding this information back to physicians represents a clear benefit to a patient, but this practice also encroaches on patient privacy, which is a major patient right as well. To a great extent, the outcome of the EHR implementation and adoption process will depend on which definition of patient benefit will become dominant. Historically, the dominance of privacy benefit has led to discontinuation of major data integration projects in Canada. Recently, this happened with the Federal Longitudinal Labour Force File and Quebec's Smart Card projects.

Finally, among the critical factors that contribute to the high legitimacy of the EHR one should mention a strong endorsement by the federal government, which commits substantial resources toward the implementation of this initiative, and substantial international isomorphic pressures that mount as more countries adopt e-prescribing and EHR systems. In the United Kingdom, more than 50% prescriptions written by physicians are expected to be transmitted electronically in 2005 (Pye, 2002), and other G7 countries have some major components of the EHR system already in place or in a pilot stage. Although this isomorphic pressure is felt most strongly by the federal government, other actors, connected with their counterparts in other countries, are not immune from this pressure either. The legitimacy of EHR, thus, is grounded in the social norms of both managerial and technical value systems and is reinforced by government support and international isomorphic pressures toward system adoption.

Actor-specific (low-level) hypotheses. The complexity of the health care industry makes it necessary to take into account a broad range of collective actors<sup>4</sup>—from patients and physicians to public and private payers and regulatory bodies. Based on the interviews and

secondary data search, cooperation or lack of resistance from the following interest groups is critical for the implementation of the project: physicians, pharmacists, patients/general public, federal and provincial government institutions, for-profit organizations (insurance and pharmaceutical companies), and project implementation teams. The actor-specific hypotheses in respect to the outcomes of the EHR project were formulated for each of the three theories subjected to a test here. These hypotheses are summarized in Table 2.

The hypotheses in Table 2 document patterns of expected outcomes for each of the three theories. The resulting three patterns will then be used in pattern matching (Campbell, 1966; Yin, 2003) at Step 2 to compare the observed outcomes with the pattern of expected outcomes derived from a given theory. In the research fields that are particularly concerned with the rigor of theory testing, such as medicine, the hypotheses, as well as the methodology of the baseline and the follow-up studies, are documented using an institutionalized practice of publishing small, 3- to 4-page study design articles in peer-reviewed journals. This exposes the motivation, the formulated hypotheses, and methods to the review by the research community well before the outcomes of the study are known to anyone. In addition, this practice prevents researchers from engaging in "data dredging," where, following the evaluation of final results, a quantitative or qualitative researcher can write up the hypotheses as if these hypotheses were deductively formulated before the study was conducted. In social sciences, major methodology journals, such as Organizational Research Methods, can take the lead in adopting the practice of publishing study design articles, which can increase the credibility and broaden the application of qualitative research methods in our domain. For the EHR study, such a study design article detailing the methodology, as well as the justification for the formulated low-level hypotheses, is available from the author upon request.

#### Formulation of Criteria and Procedures for Outcome Evaluation at Step 2

Follow-up time. The follow-up time at which the Step 2 study should be conducted is determined by the nature of the social process and by the theories under investigation. In estimating when the outcomes of the social process can be expected, researchers should rely on both theoretical predictions and on expert informants, whose opinion reflects the expectations of well-informed social actors in respect to the timing of the process completion. Following the recommendation of the interviewed EHR experts, the proposed follow-up time for this study has been set at 5 years. This is consistent with the timelines set by the Romanow Comission Report (Romanow, 2002) for the EHR implementation in Canada: first fully functional EHR by 2006, full interoperability of provincial EHRs by 2010.

Methodology of the Step 2 follow-up study. In addition to the pattern of expected outcomes documented in the Step 1 study (see Table 2), the application of the pattern-matching technique (Campbell, 1966; Yin, 2003) requires also a set of observed outcomes, which will be documented and interpreted at Step 2. Whereas the primary concern at Step 1 of the PCS is establishing construct validity, ensuring that the formulated predictions indeed follow from the theories under investigation, the primary concern at Step 2 is the reliability of two components in outcome evaluation: the reliability of data collection and the reliability of data interpretation.

#### Table 2 **Actor Specific Hypotheses**

(Institutional Approach)

# Strong H<sub>A</sub>

Physicians' attitudes to EHR and e-prescribing will be driven by their political interests (the defense of their professional autonomy and status from behavioral controls introduced by EHR expert systems).

H<sub>O</sub> (Political Approach)

- Physicians will resist EHR as a potential threat to their autonomy and status (e.g., EHR as a micro-policy tool to control physicians' prescribing behavior) (Markus, 1983).
- Pharmacists will support EHR if it gives more access to patient information, such as lab tests (and thereby gives them ability to diagnose, which will help them in their turf battle for prescribing rights).
- Pharmacists will resist EHR if it interferes with pharmacy work flow, facilitates patient "channeling" by physicians (i.e., directing patients to a specific pharmacy in return for some favors), or requires substantial expenditures.
- Because the system has very low visibility with patients, the attitude of patients/general public to EHR will be highly dependent on mass media coverage of the initiative.
- Patient advocacy groups seeking publicity and "the cause" to mobilize its audience will attempt to resist EHR implementation as infringing on patient privacy.
- The federal government's support to EHR projects will be directly related to its degree of control over these initiatives and inversely

- Physicians' attitudes to EHR and e-prescribing will be positive, driven by the technical (i.e., patient benefit) legitimacy of the project as reflected in media and professional press
- Given the high legitimacy of EHR, the physicians will support the implementation of the system, conforming to the institutionalized norms (Meyer & Rowan, 1977; DiMaggio & Powell, 1983).

accounts.

- Pharmacists' attitudes to EHR and e-prescribing will be positive, driven by the technical (i.e., patient benefit) legitimacy of the project as reflected in media and professional press accounts.
- Given the high legitimacy of EHR, the pharmacists will support the implementation of the system for its potential to reduce errors because of unreadable prescriptions and improve monitoring for drug interactions.
- Major controversy around patient information privacy may undermine the "technical" (or "patientbenefit") legitimacy of EHR and lead to EHR legitimacy challenges.
- Patients will be neutral (or indifferent) in respect to EHR as long as the issue of patient privacy is not brought onto the public and political agenda.
- Unless EHR in Canada is delegitimized through a patient privacy controversy, the federal government will continue to support EHR as a

- Weak H<sub>4</sub> (Combined Approach)
- Physicians' understanding of their political "self-interest" and their ability to act based on their self-interested calculations will be constrained by the institutional norms of "technical" and "managerial" legitimacy.
- Given the high legitimacy of EHR, the resistance by physicians, if any, will not be open and will take a form of system nonuse or nonadoption (Markus, 2004).
- Pharmacists' understanding of their political self-interest and their ability to act based on their self-interested calculations will be constrained by the institutional norms of technical and managerial legitimacy.
- Given the high legitimacy of EHR, the resistance by pharmacists, if any, will not be open and will take a form of system nonuse or nonadoption (Markus, 2004).
- The understanding of "technical" legitimacy of EHR can be redefined with greater focus on "confidentiality" as a paramount "patient benefit."
- A controversy around patient privacy may be socially constructed by the purposeful self-interested actions of some interest groups.
- Both government self-interest in EHR implementation and strong legitimacy of EHR would stimulate both federal and provincial governments to

#### **Table 2 (continued)**

#### H<sub>O</sub> (Political Approach)

- related to the degree of control that the provinces have (Pfeffer & Salancik, 1978).
- The federal government will seek implementation of a nationwide EHR system that would ensure portability of the patient record (Canada Health Act) and give it more control over provinces in health care (Markus, 1983)
- The provincial governments will get much more involved in implementation of the EHR and will attempt to take over the control of provincial EHR systems to implement their cost-saving agendas and signal another health care renewal (Alford, 1975).
- The provincial health ministries will increase their financial and other resource support to the project as they acquire greater control over project management.
- Private insurance companies, which may benefit from access to patient health information and from prescribing controls in the EHR, will support the EHR implementation and will seek control and access to it.
- Brand name pharmaceutical companies, who will lose sales because of prescribing controls built into the EHR system, will resist the implementation of EHR in Canada.

### Strong H<sub>A</sub> (Institutional Approach)

- legitimacy-enhancing initiative.
- The public support of the EHR by the federal government will have a "legitimacy contagion" (Zucker, 1988) effect on the initiative, improving its acceptance by other actors.
- The provincial governments will continue to support EHR to display their commitment to the social norms of "managerial" and "technical" legitimacy in health care (Meyer & Rowan, 1977; Ruef & Scott, 1998).
- Given low legitimacy of the provincial governments with patients and physicians, greater involvement of provincial ministries in management of the EHR will be met with resistance by professions and patient groups.
- The involvement of private insurers and other profit-seeking organizations with the EHR projects will be perceived as illegitimate and will be actively resisted by other health industry constituents.
- Brand name pharmaceutical companies will provide at least some symbolic support to EHR implementation to signal their conformance with society values (DiMaggio & Powell, 1983) on both technical and managerial legitimacy dimensions (Ruef & Scott, 1998).

### Weak H<sub>A</sub> (Combined Approach)

- actively support the project.
- The attempts to use coercive power to legislate out the patient consent requirement (to speed up EHR adoption) will be perceived as highly illegitimate and will lead to a patient privacy controversy.
- The provincial governments will use EHR symbolically to signal their commitment to the social norms of managerial and technical legitimacy (Meyer & Rowan, 1977) and to signal another health care renewal (Alford, 1975).
- Unless EHR in Canada is delegitimized through a patient privacy controversy, the provincial governments will continue to support EHR as a cost-saving and legitimacy-enhancing initiative.
- Because profit-seeking organizations have low legitimacy in health care, insurers will abstain from active involvement with EHR in order to not compromise the project and avoid further legitimacy challenges.
- Because of high legitimacy of EHR and legitimacy challenges experienced by the pharmaceutical industry, brand name companies will not openly resist the implementation of EHR, despite its potential negative impact on their revenue.

(continued)

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Table 2 (	(continued)	1

H <sub>o</sub> (Political Approach)	Strong H <sub>A</sub> (Institutional Approach)	Weak $H_A$ (Combined Approach)
Technology implementers will pursue strategies that maximize (a) their individual utility in project implementation (e.g., prestige, power, potential future revenue) and (b) the utility of a professional group or organization to which they belong. The issue of control over EHR project management and design will be the subject of active political struggle among the actors (federal vs. provincial government, physicians vs. pharmacists).	The projects managed by physicians will attempt to implement the best possible standard of care for patients, in accordance with the logic of technical legitimacy. The projects managed by the government agencies will attempt to implement the most efficient systems, in accordance with the logic of managerial legitimacy.	The project design and implementation decisions that are consistent with the interests of the implementer group (physicians, government, etc.) and for which the legitimating accounts are readily available, will be the most likely choices for implementers/ administrators. Physicians will be more satisfied with the systems designed and managed by the members of their own professional group (Markus, 2004).

Note: EHR = electronic health record.

Data collection. The need for greater reliability in data collection at Step 2 of the PCS dictates that a more extensive study be conducted at Step 2. For this reason, the Step 2 follow-up study of EHR implementation will differ from that of the Step 1 study in three respects:

- 1. More in-depth interviews will be conducted to ensure the reliability of the results.
- The sampling frame will be built from public records, media mentions, and other secondary sources, so that the perspectives of multiple interest groups on the EHR implementation are captured in the study results.
- 3. Where necessary, quantitative survey methods will be used to explore opinions of highly fragmented stakeholders (e.g., physicians, general public, etc.). For hierarchically structured actors (such as Health Canada), on the other hand, a few in-depth interviews with key decision makers may yield a more thorough understanding of the social processes than a quantitative survey of many officials.

The process of identification of the potential informants for such interviews started during the baseline, Step 1 study and will continue until the Step 2 study fieldwork is completed. The sample of the informants will be stratified to ensure that representatives of each stakeholder/interest group are captured in the sample. Informants' role, knowledge, and potential influence on the EHR project implementation will also be used as criteria guiding informant selection for the interviews. Although no interviews or systematic secondary data collection will be performed until the follow-up time, the pertinent EHR case materials that the author can come across while pursuing other research projects will be filed and documented for future use in the Step 2 study.

The development of questionnaires and discussion guides for this follow-up research was deferred to the follow-up time, because the nature of specific questions to be asked and

probes to be made during Step 2 research is largely predicated on the overall outcomes of the EHR implementation in Canada (i.e., whether the system is built and successfully used, built but not widely adopted, not built, delayed, etc.).

Data interpretation. There are two methodological issues associated with data interpretation that have to be addressed at Step 2: (a) How can we establish boundary conditions for determining a sufficient match that would support or falsify a given hypothesis, and (b) how can we ensure that a researcher's analysis is not biased toward his or her favorite theory?

Boundary conditions for determining a sufficient match. Qualitative research, by definition, deals with fuzzy and ambiguous, rather than discrete and quantifiable, data, and an ideal situation where there is overwhelming evidence that favors one hypothesis over another is not so common. Although currently there is no precise way of setting strict criteria for interpreting findings in pattern matching (Yin, 2003, p. 27), some guidance on this can be derived from the principle of theoretical saturation (Glaser & Strauss, 1967). Theoretical saturation, which is commonly used in the context of theory building, rather than theory testing, represents the point at which additional data collection yields no further conceptual elaborations of a given theoretical element (Eisenhardt, 1989; Glaser & Strauss 1967). The theoretical saturation principle can also be used in the deductive theory testing to determine whether additional data collection and further search for evidence for a given theoretical element is warranted. The view taken here is that the point of theoretical saturation in deductive theory testing is achieved when the amount of available evidence becomes sufficient to develop the propositions of a given theory from scratch based on the available case study data. It has to be noted, however, that theoretical saturation does not "prove" the theory but rather shows that a given theoretical element is applicable to the case and is not "falsified" (Popper, 1968) by the case study data collected so far. Further researcher efforts then should be directed at the search of evidence that can falsify, rather than support, this theoretical proposition. The principle of theoretical saturation, thus, can be useful not only in inductive theory building but also in deductive research by helping researchers establish when sufficient case study evidence for a given hypothesis is collected and by suggesting directions for further data collection.

In the Step 2 study of the EHR implementation in Canada, the ambiguity of data will be addressed through further data collection, until sufficiently persuasive evidence exists in favor or against a given lower level hypothesis. Such further investigation will continue until either (a) some newly uncovered evidence provides an overwhelming support for decision to accept/reject the hypothesis, (b) no more empirical data are available, or (c) further investigation becomes impractical as additional data collection yields the same mixed support for the hypothesis in question. The latter two situations would suggest that the case study findings for such hypotheses should be deemed inconclusive (similarly, statistically insignificant differences in quantitative studies are deemed inconclusive as well).

Although the principle of theoretical saturation provides a useful criterion for deciding when a given theory can be deemed to be supported by the case study and further data collection on a given theoretical element can be stopped, this principle is not sufficient to prevent researchers from jumping to a premature conclusion about the lack of supporting evidence for a given theory. This problem is a part of a broader issue of a researcher's selective bias in data collection and evaluation, which becomes particularly problematic in

deductive theory testing using qualitative case studies. The section that follows addresses some of the Step 2 study design considerations that can alleviate this problem.

Managing a researcher's selective bias. The researcher's selective bias in outcomes data collection and interpretation may affect which data elements the researcher sees in a given case and which ones remain unnoticed or get filtered out as irrelevant. Several techniques can be used at Step 2 to address this potential bias: (a) hypothesis blinding, (b) competitive case analysis, and (c) hypothesis "outsourcing."

The hypothesis-blinding technique draws on a common practice in medical research where physicians evaluating patient outcomes and the patients themselves are kept unaware of which intervention (e.g., a drug or placebo) was administered to a given patient (Jadad, 1998). In quasi-experimental settings of prospective case study where no experimental intervention takes place, similar blinded evaluation of the outcome can be achieved by presenting researchers conducting evaluation with a specific low-level hypothesis without disclosing which theory this hypothesis is intended to support. The researchers are then asked to find the support to this hypothesis in the collected data and/or to do additional data collection if required. The necessary conditions for the use of this technique are (a) the availability of an extended team of evaluators that did not participate in the formulation of the hypotheses at Step 1 and (b) limited ability of these evaluators to attribute a given low-level hypothesis to a particular theory.

Another technique, which can be termed *competitive case analysis*, can help balance the "find what you look for" bias by assigning the alternative theories to different researchers, whose role on the team is to look for the data supporting the theory assigned to them and to defend it in competition against the theories assigned to others. This way, the competition between different scientific theories (Popper, 1968) can be replicated by the competition within the research team. A Delphi technique or an "arbitration" procedure can then be used by the team to determine which theory is better supported by the empirical material of the Step 2 study. The potential limitations of this approach are (a) the need for a team of at least three researchers (one for each of the alternative theories) and (b) the potential bias introduced by the effects of differences in personality, assertiveness, and status among the researchers assigned to the competing theories.

Finally, the *hypothesis-outsourcing* technique can mitigate the possible selective bias by leaving the formulation of low-level hypotheses to the external experts in a given theory. Although such outsourcing would make the team conducting the evaluation more detached from the theories and hence less biased, the main advantage of this approach is the external validation of the initial sets of hypotheses by theory experts. The low-level hypotheses formulated this way are less likely to be questioned later by the proponents of any particular theory if that theory is not supported by the final outcomes of the study.

To benefit from the techniques described in this section, the team conducting the prospective case study of the EHR implementation in Canada will be expanded at Step 2 follow-up. This would provide additional resources for extensive data collection and, at the same time, would help reduce the exposure to the selective bias by enabling the use of hypothesis blinding or competitive case analysis technique. The Step 2 study will conclude with the evaluation of the three general hypotheses by combining the assessment of the overall EHR implementation outcome and the analysis of the pattern of matches (Campbell,

1966; Trochim, 1989; Yin, 2003) produced by empirically supported lower level hypotheses for  $H_0$ , Strong  $H_A$ , and Weak  $H_A$ .

#### **Discussion and Conclusion**

In this article, I have proposed a qualitative method of deductive theory testing using *prospective case study design*. The proposed design is based on the application of the principles of prospective study design adapted from medicine to the qualitative case study methodology developed in organizational studies for deductive theory testing (Langley, 1999; Lee, 1989; Markus, 1983).

The deductive theory testing using qualitative methods is believed to have a major potential: Social theory testing in vivo, or using the rich data of a live social process, may generate important insights into the applicability and explanatory power of our theories and provide an important complement to theory tests performed using traditional quantitative methods. By establishing theory generalizability to those aspects of the social phenomena that are not amenable to quantification, theory testing using qualitative methods can reduce the need for "leaps of faith" when conclusions based on measurable, quantitative evidence are extended to other, nonmeasurable aspects of the social processes. Given that only few aspects of our social environment can be reliably measured and quantified, the possibility of using nonquantifiable, qualitative data in deductive theory testing holds a great potential, especially if the rigor and validity of such tests is augmented through the application of the techniques described here.

The view taken here is that the need for deductive theory testing using PCS design and other qualitative methods is the greatest in the areas where few or no quantitative measurements exist or where substantial leap of faith is required to connect the existing quantitative operational measures with the postulated theoretical constructs. In such research contexts where unique phenomena (Yin, 2003) and lack of adequate quantitative measures hinder the application of quantitative methods, theory testing using case studies can be a preferred option. Particularly promising for future research using this method are the domains where seemingly idiosyncratic social processes unfold in complex organizational settings. Among the notable examples of such domains one can mention research on technology adoption, social movements, institutional entrepreneurship, and fads and fashions and other studies on diffusion and adoption of innovations, social norms, and values in various institutional environments.

The use of prospective study design may contribute substantially to the rigor of such studies by eliminating some of the biases and shortcomings associated with post hoc qualitative research. It is important to note that the gain in rigor associated with the choice of *prospective* case methodology over the *post hoc* case study design does *not* come at the expense of richness of the collected qualitative data. Prospective case study design, thus, may be viewed as an attractive solution to the rigor/richness trade-off that researchers face when choosing an appropriate method for their study.

Although prospective case study design allows improvement in rigor of deductive theory test without the sacrifice in richness of qualitative data, this net gain in rigor still comes at some cost: a cost to the researcher(s). Prospective research in various disciplines (cf.

clinical trials) is associated with substantial time spans: Sometimes years separate the baseline Step 1 study from the final evaluation at Step 2. Not all researchers can afford waiting for the results that long. The need to ensure continuity of the research project over an extended time period suggests that a team-based approach to conducting such a study may be a preferred option. The requirements of the selective bias management techniques proposed here (hypothesis blinding and competitive case analysis) would also favor the teambased approach in PCS research.

The researchers engaging in PCS study should also be aware of the possibility of the study yielding negative results (i.e., when predictions derived from a given theory fail). A great advantage of qualitative research, however, is the ability to adjust to surprises (positive or negative) and to dig deep into the causes of the outcomes observed at Step 2 follow-up. Negative results can shed light on important confounding factors, variable interactions, and other complex mechanisms that made the prediction fail. PCS study can only benefit from keeping the option of digging deeper into the causes open, especially if none of the three hypotheses are found to be supported at Step 2. It has to be noted, however, that although negative outcomes can be very insightful, they tend to produce an effect captured in the notion of "negative result bias" (Jadad, 1998): A study of medical articles showed that negative results are less likely to be published in peer review journals than positive ones. This negative-result risk can be alleviated with the use of alternate template strategy (Langley, 1999) in PCS design: When multiple competing theories are tested simultaneously as alternatives, failure of one theory may actually give some indirect support to another theory, thereby "hedging" the researchers from the "negative result bias."

The elements of the Step 1 of the prospective case study were illustrated in this article with the materials of the baseline study of the EHR system implementation in Canada conducted in 2003 and 2004 as a part of an ongoing PCS project. This baseline EHR study will form the Step 1 of the prospective case study project seeking to test the explanatory and predictive power of three different theoretical approaches: the political approach, which emphasizes an agent's self-interests; the interest-free institutional approach, which attempts to explain organizational actions through isomorphic and coercive pressures from the environment; and the combined approach, where elements of both political (interestbased) and institutional (interest-free) logic have to be introduced to provide a more complete account for organizational actions and social dynamics. Because of the three theories only the interest-free early neo-institutional approach allows derivation of deterministic predictions, the hypotheses for the study were formulated with the null hypothesis (H<sub>0</sub>), suggesting the unpredictability of the EHR implementation outcome; a strong form of alternative hypothesis (Strong H<sub>A</sub>), stating that the outcome is determined by the institutional norms; and the weak form of H<sub>A</sub> (Weak H<sub>A</sub>), proposing that only some elements of the EHR implementation process can be predicted, and, therefore, both political and institutional accounts are required to explain the outcomes. The differentiation between the weak and strong forms of H<sub>A</sub> required formulation of specific, lower level propositions for each major actor group. These propositions will be tested in Step 2 of this prospective study, which would involve a follow-up research at the established time of 5 years using the methodology documented in the *study design paper* at Step 1 of this research.

#### **Notes**

- 1. For example, the observed inverted U-shaped form of the population density function has stimulated organizational ecologists to develop a theory of density-dependent legitimation (see Hannan & Freeman, 1987).
- 2. The approach adopted in this article follows Yin's (2003) view of case study as an experiment. Similar to the experiment, then, a case study can also yield negative results, and these negative results can be very insightful.
- 3. It is interesting to note how the understanding of patient benefit has evolved since Hippocrates' times to include a physician commitment to preserve patient privacy but at the same time to exclude a promise not to perform abortion or assisted suicide (see American Medical Association, 2002).
  - 4. Other terms frequently used to describe such institutional actors are *interest groups* and *stakeholders*.

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