ACTION, REACTION AND INACTION: 
GOVERNING BY EVIDENCE THE DIFFUSION OF TECHNOLOGICAL 
INNOVATION IN HEALTHCARE

Valentina Mele  
Department of Institutional Analysis and Public Management  
Università Bocconi  
Via Roentgen 1  
20136 Milan

Amelia Compagni  
Department of Institutional Analysis and Public Management  
Università Bocconi  
Via Roentgen 1  
20136 Milan

Marianna Cavazza  
Center for Research in Health and Social Care Management  
Università Bocconi  
Via Roentgen 1  
20136 Milan

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ABSTRACT

In healthcare, the evidence-base paradigm has permeated the spheres of policy making and of management. This article investigates the concept of evidence as a policy instrument in governing technological innovation in healthcare. It does so by analyzing, through a multiple case design, the process of diffusion of the Da Vinci robot in the Italian healthcare system. The work has two main theoretical implications. Firstly, it combines the literatures on evidence-based policy and tools of government in order to conceptualize evidence as an instrument in the hands of policy-makers to engage in a new relational arrangement whomever they would like to govern. Secondly, the study proposes a theoretical framework of evidence-based policy more encompassing than the prevailing rationalist model of decision-making. It accounts, on the one hand, for a plurality of evidentiary bases to be employed and, on the other hand, it structures the process of governing by evidence around three focal steps: the organization of a new relationship between governing and governed, the identification of the “best available evidence” and the crafting of standardized and portable decisional criteria and procedures.

INTRODUCTION

This article explores the concept of evidence as a policy instrument to govern the diffusion of technological innovations in healthcare, which is an instance of a complex social phenomenon. The pace of technological change in medicine is “higher than elsewhere” (Zweifel and Manning 2000) and this poses a thorny dilemma for governments. Medical technologies have the tremendous potential to change our understanding of disease, transform the delivery of health-care services and improve health outcomes. At the same time, an unusual consensus has emerged among economists and international organizations regarding technological progress as the main driver of the healthcare expenditure increase, not only in the United States (Bodenheimer 2005; Newhouse 1992; Peden and Freeland 1995) but across all OECD countries (Organization for Economic Cooperation and Development Data 2010).

Scholars have indicated to public policy makers several directions to tackle the unprecedented level of technology diffusion (Weisbrod 1991). Some recommend “taming the beloved beast” (Callahan 2009). The imperative of cost control, in fact, requires some limits on the spread of technology (Chernew et al. 2004), prone to overuse (Wennberg 2004) and likely to
expand the demand for insurance coverage (Weisbrod 1991). Others urge decision makers to settle with the uncontainable rate of technological developments in healthcare, since the resulting medical advantages are bound to outweigh the costs (Cutler and McClellan 2001). Notwithstanding the considerable differences in the remedy that is being proposed, these works unanimously assume that the ideal criteria for taking decisions on health technology ought to be based on evidence (Bodenheimer 2005).

In healthcare, the evidence-base paradigm has spilled so pervasively from the sphere of clinical decision making over to the spheres of policy making (Black 2001; Davis and Howden-Chapman 1996) and of management (Learmonth and Harding 2006) to be characterized as the “zeitgeist in healthcare” (Raine 1998, 251). The role of evidence, thus, is to provide a systematic indication of “what works” (Martin and Sanderson 1999), beyond prejudices, fads and ideology (Frey 2010). Such theorization resonates with rational accounts of decision making in the public sector (Nutley and Webb 2000; Sanderson 2002).

Despite the burgeoning literature on evidence and evidence-based policy, we did not find a convincing answer to the question of “How to govern with evidence?” In this study, we attempt to fill this gap by analyzing how decision makers govern the diffusion of a highly innovative technology in healthcare. To do so, we have tracked the spread since its introduction in 1999 of the DaVinci surgical robot in Italy, which has the world’s highest concentration of robots in public healthcare organizations, second only to the US in absolute value. Our study encompassed the whole sample of 43 robots distributed in 16 Regions, the decentralized jurisdictional level responsible for healthcare in the country.

By analyzing the patterns of action in all these cases, we have distinguished those instances in which policy makers have purposively exercised their governing role, by controlling ex ante the robots’ adoption (action) or bending in itinere the diffusion curve (reaction), from those cases in which policy makers have opted out from a direct policy intervention (inaction). Drawing from the former group, we have identified four archetypes for “governing technological diffusion” and, for each, the different roles regional policymakers have carved out for themselves. Across all these approaches, regional policy makers have used evidence to occupy a policy domain traditionally populated by multiple professional communities.

Finally, we have elaborated a theoretical framework of an evidence-based policy alternative to the prevailing rationalist model of decision-making. This framework accounts for
the plurality of evidentiary bases normally produced in policy domains and by a variety of actors, and proposes a more relational (versus mechanistic) conception of the processes of government.

The paper is divided into six sections. The first is devoted to a discussion of the evidence-base as a dominant decisional paradigm in healthcare and to some pregnant critiques to this model. The following section presents our research design and methodology. The third describes the findings, as in the archetypes we have elaborated. The fourth section introduces our proposed theoretical model and provides a discussion of its analytical contribution. Finally, the last section wraps-up, accounts for the limitations of the current study, offers some indications for future research as well as implications for policy.

THE EVIDENCE-BASE PARADIGM: FROM MEDICINE TO POLICY

Evidence-based practices, now considered mainstream in all aspects of healthcare (Learmonth and Harding 2006), do not represent a strictly novel phenomenon. The 1940s marked a growing recognition that traditional approaches to medicine were flawed (Davies and Nutley 1999) by an inexplicably high variance in patterns of clinical practice, by the poor uptake of therapies considered effective and by an excessive use of technologies known to be ineffective (Walshe and Rundall, 2001). In other words, a wide gap existed between research findings and their translation into practice.

Over the following decades, with an acceleration from the 1970s (Cochrane 1972), Evidence-Based Medicine (EBM) has emerged as the paradigm filling that gap. It has done so by shifting clinical decision-making from an old-fashioned approach based on the “vagaries of individual experience” (Armstrong 2002, 1772), to a model of therapy based on the “conscientious, explicit and judicious” (Sackett et al. 1996, 71) selection of the best available treatment. Such a model, defined as the most important project to recompose contemporary biomedical culture and applications (Mykhalowskii and Weir 2004), is based on the use of experimental methods, quantitative data and empiricism. Its epistemological trademark is the hierarchy of evidence (Goldemberg 2006; Woolf et al. 1990), starting at the top from randomized controlled studies and their systematic reviews, through observational studies, to the lowest quality of evidence represented by expert opinion and consensus. The sources of evidence are ordered on the basis of the research design that is being used. This, in turn, signals the extent to which a method is reliable for estimating the incremental consequences of an intervention in a
particular clinical setting (i.e. provides evidence of efficacy and, in case of wide implementation, of effectiveness; Oliver and McDaid 2002).

The alignment between evidence-based medicine and a highly rationalist conceptual model rests on two assumptions. First, science is based on laws that can be revealed through research (Wood and Ferlie 2003) and are independent from the social circumstances of their production (Learmonth and Harding 2006). Second, the adoption of new scientific knowledge is the final passage of a linear algorithm according to which research generates evidence which, once published, affects doctors’ behavior (Greenhalg et al. 2005).

From the sphere of clinical practice, the evidence-based approach has percolated into virtually all domains of healthcare policy and management. Academic research has provided two complementary accounts of this phenomenon. One stream identifies this stance with the need in the healthcare sector to make policymakers and managers accountable for their decisions. There, evidence is saturated with positive cultural valences (Learmonth and Harding 2006) for it allows others to critically examine the steps employed by decision-makers, thus evoking rigor and transparency in the process (Lambert et Al. 2006). The ascendancy of evidence as a value has been reinforced by the expenditure pressures faced by most welfare states, which have consequently shifted their government rhetoric from “what’s right” to “what works” (Oliver and McDaid 2002). Another stream looks more closely at the micro-level effects of such a cultural climate, concluding that clinicians and stakeholders at large have been increasingly expecting an evidence-based modus operandi from managers and policy makers. Hence, these professionals have swiftly rearticulated their areas of practice around the new approach, also as a strategy to legitimize their expertise (Walshe and Rundall 2001).

In the domain of governing technological innovation in healthcare, one of the most striking illustrations of the geographical and thematic breadth of the evidence-based policy and management approach is Health Technology Assessment (HTA), defined as a “scientific and policy movement […] seeking to foster the institutionalization of knowledge-based changes in health systems” (Lehoux 2006, 1). Such institutionalization has typically proceeded through the establishment of central or local programmatic agencies, in support of policymakers, and through the issuing of guidelines advising, and sometimes ruling, on the introduction of new medical technologies and interventions in healthcare organizations (Perry et al. 1997). HTA has been granted from its inception, a broad mandate, for its units of analysis include not only medical
devices but also drugs, medical and surgical procedures and healthcare services (US Office for Technology Assessment 1978). Moreover, the mandate is broad, concerning policy orientation. Purportedly, HTA is meant to bring the contribution of cutting-edge scientific inquiry to policymaking (Battista and Hodge 1999). Last, the mandate of HTA has expanded from assessing medical technologies in relation to safety (Leape and Berwick 2005) to evaluating clinical effectiveness, cost-effectiveness (Royle and Waugh 2003) and, when appropriate legal, social (Jacob and McGregor 1997) and ethical (Hofmann 2005) impacts.

HTA agencies conduct technology appraisals according to a rational and planned model (Walshe and Rundall 2001) aimed at systematically assessing direct and indirect consequences of a particular technology. The evidence employed in such appraisals, like in other applications of evidence-based policy, is seen as a function of its quality: the higher the quality of the evidence gathered, the higher the quality of the final decision (Dobrow et al. 2004), be it clinical or allocative in nature. Needless to say, what constitutes valid evidence in a health technology assessment is normally a set of experimental and quantitative data, meeting the criteria of the hierarchy of evidence proposed by the EBM movement.

In summary, evidence-based medicine, policy, management and the HTA movement, all propose a paradigm for decision-making that implies a certain evidentiary base, neutral and objective, a process in which it is plugged in, prior to an authoritative step, and the final output: the decision, held tight in a logical framework of action with clear causal relationships.

Both health technology assessment and, more in general, the evidence-base movement, however, have not escaped criticisms from different quarters. Some have focused on the actual risks posed by this new paradigm to healthcare systems. Illustrative of these risks is the repertoire of experimental and quantitative evidence (e.g. population studies, randomized control trials or meta-analyses) that might completely displace the individual judgment rooted in clinical experience (May et al. 2006), resulting in a limited professional autonomy (Armstrong 2002). In a similar vein, despite its alleged neutrality, evidence-based decisions may penalize some diseases or clinical interventions for which randomized controlled trials are harder or unlikely to be conducted. As a consequence, such interventions may be ignored by health policy makers irrespectively of how significant their social impact is (Lambert 2006). Finally, purchasing authorities and healthcare managers may employ the evidence gathered to control resource allocation, in particular when the question of “what works?” starts to be framed as “is it worth
it?” (Davies and Nutley 1999). Clearly, these critiques acknowledge that the evidence-based approach in healthcare is likely to generate adverse, though mostly unintended consequences. Yet, they do not question the paradigm itself. Some scholars, on the other hand, have challenged the concept of evidence, as found in evidence-based decision making, also from an epistemological and ontological perspective. For example Goldemberg (2006) warns us that values, culture and, above all, context do influence what constitutes evidence, that, as such, cannot be conceived as neutral (Dobrow et al 2004).

In parallel, a strand of literature has acknowledged the co-existence of three evidentiary bases\footnote{Several studies provide a dichotomous definition of evidentiary bases, differentiating between a scientific knowledge (episteme) and a practical knowledge (techne). We adopt the theorization of Scott in “Seeing like a State” (1998) who further distinguishes non-scientific, practical knowledge in techne and mētis. An alternative taxonomy of knowledge-types (see Flyvbjerg 2001) has adapted the Aristotelian intellectual virtues of episteme, techne and phronesis. The latter has a practical connotation like techne, but addresses also ethical issues, (i.e. by asking which are the important values).}. Episteme is knowledge produced through scientific research. At the apex of the cognitive pyramid, it provides causal and theoretical knowledge of what works through rigorously designed and executed empirical studies. Episteme, corresponds, therefore, to the scientific ideal (Scott 1998; Tenbensel 2006) proposed by the evidence-base movement; in other words, the “hard facts that support the grand edifice of modernized policy making” (Parsons 2002, 3). The second evidentiary base, techne, refers to knowledge that is concrete. It can be defined as the application of technical knowledge and skills to solve a problem following a pragmatic, instrumental rationality (Flyvbjerg 2001). Both episteme and techne are capable of being made explicit and codified. The last, mētis is the realm of pure practical and experiential knowledge, which is learnt only by doing. Its findings are “opportunistic and contextual rather than integrated into the general conventions of scientific knowledge” (Scott 1998, 323).

Besides critiques of the nature of evidence, incrementalist and pragmatist approaches have built upon similar premises (i.e. recognizing the coexistence of different forms of evidence) to deconstruct the rational paradigm of the policy making process. For example Lindblom and Cohen’s “Usable Evidence” (1979) compares scientifically-generated knowledge and ordinary knowledge to conclude that urgent problems, exactly the ones that require a prompt political intervention, can rarely wait for research evidence to pile-up and provide an unambiguous input into the policy process. The picture is complicated by scientific controversy, which, far from being an alien phenomenon (Clarence 2002) should be considered an intrinsic feature of the
scientific process (Tenbensel 2004). Therefore, policy makers should settle for ordinary knowledge, such as the one embedded in standard procedures of organization, in professional evaluation and in tacit knowledge (Albæk 1995), to inform most of their decisions. Majone (1989) pushes the argument forward contending that even research-based evidence does not speak for itself. Evidence, whatever its nature, is a specific set of information selected from the available stock and plugged into the political discourse to persuade the targeted audience that an argument is veridical. Hence, politicians may employ or ignore particular evidence to stimulate debates that change an issue status on the agenda, to reinforce decisions already made or to clarify positions over contentious subjects (Sanderson 2002; Lehoux 2006; Weiss 1979).

Evidence might, in the end, become “an instrument of, rather than a substitute for, politics” (Goldemberg 2006, 2629).

In synthesis, problematizing voices have raised issues close to our concerns. According to these perspectives, political matters and decision-making are unlikely to be resolved by the recourse to a formalized epistemic device and process. Yet, these critics have remained abstract and none of the authors has proceeded, through an empirically-based research, to an alternative theorization. If the dominant paradigm of evidence-based policy falls short from reality, what then? What other theoretical frameworks can be devised to better account for the role of evidence in governing?

Here we posit that, to overcome this conceptual impasse, it is necessary to link the evidence-based policy literature to the research on the instruments of government, and conceive evidence as one. Identifying archetypal government tools among the gamut of public interventions has been the central enterprise of a stream of studies that has developed slowly but steadily since the 1950s (Dahl and Lindblom 1953). Over time these studies have developed to become a corpus of literature interested mainly in the classification of policy tools. The resulting taxonomies differ in some significant respects, such as labels and level of sophistication. Yet, the analytical categories they employ grossomodo converge (Elmore 1987; Hood 1983, 2007; Salamon 2002; Schneider and Ingram 1990; Vedung 1998), in that all include a set of government tools meant to guide either through authority and coercion, the provision of financial resources, institutional capacity or shared learning. Recently, there have been several calls for an empirical exploration of policy instruments (Lascoumes and Le Gales 2007). In particular, these calls invite to extend the knowledge on the features of the tools, on the political (Peters 2002)
and management skills that many of these tools demand (Salamon 2002), on developing a better understanding of the tools’ selection (Hood 2007) as well as their effects on the level of participation by stakeholders in the government process (Schneider and Ingram 1990).

Our theoretical point of view does not involve providing a further taxonomy of the tools of government or arbitrating among the existing ones. Instead, we embrace the definition of policy instrument proposed by Lascoumes and Le Gales (2007, 3-4) as “a condensed form of knowledge about social control and ways of exercising it….a device that is both technical and social that organizes specific social relations between the state and those it is addressed to”. Given that evidence, it is argued, represents a “knowledge relation in its local dimensions” (Mykhalovskiy and Weir 2004, 1067) we propose that an alternative theoretical framework of evidence-based policy will necessarily need to attend to the specificity of evidence as a means to establish a relational and mediated approach to problem solving (Head 2008). “Governing by evidence”, we conclude, therefore, entails structuring new relational arrangements among the actors involved in the decision-making process, using evidence as the language of this exchange.

We address this proposition empirically by exploring how evidence is employed by policymakers in the specific instance of governing technological innovation in healthcare. We purposively chose a domain in which policymakers are crafting their way ex-novo and where their role is not yet consolidated. We hoped in this way to capture a more realistic picture of policymaking that could expand our understanding and theorization of governing by evidence.

METHOD
The study is based on a multiple case design. Examining multiple cases, comparing and contrasting, recognizing patterns of relationships among constructs are appropriate and solid methodological tools to extend extant theory as well as to build new theory (Eisenhardt 1989, Eisenhardt and Graebner, 2007). In addition, we deemed appropriate the use of a qualitative and inductive research approach since a rich qualitative account permits to contrast observed events with the current understandings and extend existing theory (Lee et Al. 1999). This study is born, in fact, from the recognition that theories of evidence-based policymaking often fall short from the complexity of real-world decision-making and provide little account of the variety of potential mechanisms for governing that policymakers might have devised.
In conducting the study, we began by analyzing the policy domain and the constraints and contextual pressures to which regional policymakers are exposed and in which they carry out their actions in governing technological innovation. We drew from different data sources: (1) national and regional policy documents (e.g. health plans) in the period from the mid-nineties until 2010; (2) interviews with leading experts in medical technologies and related policy issues; (3) interviews with healthcare managers and clinicians (from the cases).

We identified not only how prominent the issue of technological innovation in healthcare has been over time, but also what tools for governing it have been proposed, the role regional policymakers should assume as well as the tensions and trade-offs that decision makers had to face in dealing with this issue.

Second, we proceeded with the selection of a technological innovation for which to reconstruct the diffusion process and the potential contribution of policymakers to shaping it. In choosing the innovation, we started from three assumptions: first, that the technology to be analyzed had to have diffused through the Italian healthcare system during the last decade. This is the time span in which the topic of governing technological innovation in healthcare has emerged as a relevant one in the policy agenda. Second, the evidence of the clinical benefits of such technology could not be completely defined or validated ex-ante, for instance for regulatory purposes as it occurs for pharmaceuticals. We assumed that a technology for which evidence was still unclear was more amenable to the construction and use of evidence by policymakers when intervening to govern it. As indicated by Denis et al. (2002) and Ferlie et al (2005), evidence of medical value might influence the spread of an innovation and the dynamics among actors. Finally, it had to be a technology with significant economic and organizational impact so that policymakers felt the urge to be involved in acquisition decisions, if not only for reasons of funding.

The technology has been identified through a participatory process (i.e. focus group) involving ten healthcare experts (i.e. representatives of national and regional health agencies, clinicians, hospital general and medical directors and health technology experts). The Da Vinci surgical robot has emerged as a technology meeting the assumptions we had set.

The Da Vinci robot was first introduced on the market in 1999, in the US and in Europe. With forty-three machines\textsuperscript{2}, Italy has, after the United States, the highest number of robots in

\textsuperscript{2} At time of writing this paper the number of robots has further increased to forty-six
public healthcare organizations in the world. Since 1999 when the first prototype of the Da Vinci robot was acquired in Italy, the number has rapidly increased, to the extent that almost a quarter of all Da Vinci robots in Europe are located in the country.

The technology is applied to laparoscopic or minimally invasive surgery and, as such, does not introduce a totally new surgical procedure (‘robot-assisted’, in fact; Mack, 2001). The help of computer and mechanics is supposed to overcome some of the limitations of traditional laparoscopic surgery, providing a three-dimensional vision of the operated area and instruments that rotate and bend beyond what a human wrist can do and follow the surgeon’s movement unlike what happens in laparoscopy. Evidence of the clinical benefits for patients and of the superiority of this technology in comparison to more traditional surgical procedures has taken a long time to emerge and it still debated in most areas of application, with the only exception of urology (e.g. radical prostatectomy).

Acquiring a Da Vinci surgical system represents a relevant investment for any hospital, both in economic and organizational terms. The price of the machine ranges between 1.5 and 2 million US$ to which the costs of regular maintenance and of the surgical instruments need to be added (Gerhardus, 2003). The overall operation theatre team needs ad hoc training to set up the machine and assist the chief surgeon during the operation, the learning curve for surgeons to master the use of this technology might be long and delay the routine activity in the hospital’s operation theatre. In addition, the robot is heavy, of rather bulky dimensions, and requires an appropriate room with specific logistics and structural features. Given its costs, the complexity of the implementation and the ambiguity of its impacts, policymakers are more likely to be involved in adoption decisions.

After choosing the technological innovation to be studied, we proceeded with identifying all hospitals in which the robot had been acquired and the actors that might have been involved in the decision-making process at the different jurisdictional levels. To achieve this we have proceeded in multiple ways through: (i) an analysis of national and local newspapers in the period 1999-2010; (ii) an analysis of the conference programs and proceedings for the main Italian surgery professional associations (1999-2010); (iii) an analysis of the websites and of national and regional governments; (iii) a comparison with the list of all hospitals that have acquired a Da Vinci robot provided by the Italian distributor of this technology. We then grouped the hospitals with a robot by Region.
Through the process described above, we identified a number of actors: not only representatives of regional governmental agencies and health directorates, but also surgeons, hospital managers and the technology producer/distributor. Additional players - e.g. representatives of bank foundations that have financed the acquisition of the robot, mayors, university rectors as well as experts- were identified through snowballing during the interviews.

We started interviewing in late 2009 and terminated almost one year later having completed over 140 interviews (Table 1). In-depth interviews lasted from 40 minutes to 2-3 hours and were audio-recorded. They covered information about the nature of the evidence used or produced in support to the decision-making process, the role of national and regional policymakers and administrators, and the dynamics of the relationship between managers/clinicians and policymakers. Rather than a thematic interview, though, we preferred reconstructing step by step, with the informants, the chronology of events related to the adoption and further implementation of the robot/s and the mesh of actors involved (Eisenhardt, 1989; Eisenhardt and Graebner, 2007). We did not want to induce the interviewees, and in particular policymakers, to report actions that were not actually undertaken but seemed appropriate. For this purpose, we also guaranteed anonymity to informants and reiterated in all correspondence and conversations that the study had a scientific purpose and was not journalism (Huber and Power, 1985). In addition, we were aware that some of these processes could be rather unstructured and informal. Our intention was exactly that of understanding if and how, over time, policymakers had influenced and governed these instances and, from this, build theory inductively. We did not neglect to ask some final, more abstract questions about how interviewees conceived “governing technologies”, what it actually entailed, and what contribution each actor, with specific reference to policymakers, could or should give to guiding the diffusion of technological innovation in healthcare.

Interviews were transcribed and for each of the cases (16 Regions with 43 hospitals) we reconstructed a tick narrative. Each narrative was further completed by the analysis of all internal documents, produced within the technocratic apparatus of regional governments and at hospital level or, that were mentioned during the interviews and made available to us. Overall we have examined over 1,500 pages of text. Considering the narratives, the first distinction we drew was between those Regions in which policymakers had intentionally exercised a governing role from those in which policymakers have opted out from a direct policy intervention. A variety of
reasons might explain these latter choices (e.g. lack of competences in this domain, reliance on the decisional autonomy of healthcare organizations, limited relevance of this issue in the policy agenda). Since it was not our endeavor to elaborate on “what policy makers do not do”, rather theorizing about “what they do” we have concentrated on the cases of active Regions (8 out of 16).

By repeatedly comparing across narratives, identifying similarities and differences, we built the three meta-categories of “evidentiary bases” or policy instruments, “devices for governing” – i.e. the concrete operationalization of policy instruments according to Lascoumes and Le Gales (2009)-, and “processes for governing” in which we included all those mechanisms that allowed to structure a relationship between the governing and the governed (i.e. policy-makers and managers/clinicians). Meta-categories were derived from merging a series of grounded codes (Strauss and Corbin 1988) used to analyze interview transcripts. For coding we employed the software program Atlas.ti. For each meta-category we tabulated quotes and we began clustering regional cases on the basis of general accordance within categories. We then put the meta-categories described above in relation, addressing their combinations and potential interdependences until we were confident we had identified archetypes or templates for the roles assumed by policymakers in governing technological innovation. McKinney defines an archetype a "constructed type, a purposive, planned selection, abstraction, combination, and (sometimes) accentuation of a set of criteria with empirical referents that serves as a basis for comparison of empirical cases" (1966: pp 3).

Our understanding is that archetypes are not merely descriptive abstractions but embody coherent patterns of intentions, purposes and preferences for certain courses of action (Greenwood and Hinings 1993). In this case archetypes, we argue, are based on a common conception of what “governing technologies” means as construed by policy-makers as well as by the other actors involved in the process. In other words, it is unrealistic to think that the act of policy-making and governing in a field such as this, traditionally occupied by healthcare professionals and managers, is the result of the isolated elaboration of policy-makers but is likely to be devised and adjusted through the repeated interaction with the other players.

Finally, all cases were further reviewed on the basis of these archetypes and classified or attributed accordingly.
GOVERNING TECHNOLOGICAL INNOVATION BY EVIDENCE

CONTEXTUAL FRAME AND PRESSURES

In Italy the healthcare system assures, free of charge to all its citizens, healthcare services and universal health coverage (Ferrera, 1995). Since the nineties, devolution has progressively shifted decision power and responsibility for healthcare policies from central to twenty-one regional governments (France and Taroni, 2005). Within each Region, local health authorities are the public entities responsible for providing healthcare services, partly through their own facilities or through contractual agreement with independent professionals and private accredited providers (e.g. hospitals). The process of region-building (i.e. the strengthening of the institutional role of Regions; Pierson, 1995) has been long. Although since 2001 Regions have been granted complete jurisdiction over healthcare issues, spending decisions and the overall organization and coordination of services, they have proceeded at different paces and with different modalities in appropriating this domain for themselves.

When examining the period 1990-2010, it is apparent that the issue of technological innovation in healthcare has been rather marginal on the national policy agenda and has gained salience only in recent years (Table 2). Governing technologies is increasingly framed as a necessary step to be undertaken in order to face the inexorable progress of medicine and manage the delicate balance of assuring the best quality of services to all citizens, for whom health is a constitutionally-sanctioned right, of supporting innovation and, at the same, of guaranteeing the sustainability of the system and an efficient allocation of scarce economic resources. This culminates in the most recent National Health Plan, in the equation between governing technologies and the elaboration of an explicit policy framework able to identify priorities and suitable actions in this domain.

From regional health plans and interviews it emerged that governing, meant for policymakers also balancing two often concurring pressures. One pressure is represented by societal expectations for the newest medical technologies matched by the professional aspiration of physicians to master the latest clinical practices. Depending on the level of perceived competition in the system (e.g. the tension to attract patients and/or to recruit and retain reputed professionals), healthcare managers might vehicle the requests of their most prominent physicians to the Region, hoping for financial backing. In other cases they will proceed autonomously and involve actors from the private sector (e.g. bank foundations) and local
politicians in order to create consensus and support around their decisions. The producers/distributors of technology often act as information brokers among these actors, providing the ‘evidence’ they have collected on different aspects of the technology, ranging from clinical effectiveness to potential economic returns, and in this way help clinicians and managers build a case in favor of the new technology. Policy-makers, therefore, find themselves facing a mesh of relationships, often informal, whose actions lead to important decisions concerning the introduction of new technologies in the healthcare system and from which they might be excluded or only marginally involved.

The second pressure, or reason for urgency perceived by policy-makers, is the need to counteract some of the most burning issues in this domain, such as an uneven distribution of technologies in the different Regions, inappropriate or limited use of expensive machines, duplications and inefficiencies. The ability to guide the diffusion and use of technological innovation is, therefore, not only construed as relevant to deal with what is yet to come but also as the capacity to rationalize the existing technological endowment of the healthcare system. (Table 2).

Regions are the level of government entrusted with this task and are supposed to engage healthcare managers and professionals in order to fulfill their new mandate. In policy documents of the mid-nineties the type of evidence necessary to carry out this action appears mainly experiential (metis), in other words, policy-makers are supposed to inform their actions and decisions based on the experience with the introduction of technologies in healthcare and learn from the mistakes already made (e.g. wastes, inadequate use). With time, more structured forms of evidence are proposed. They span from inventories of existing technologies and the determination of the patient pool able to support the adequate use of a technology (techne) to codified instruments typical of evidence-based medicine such as systematic reviews and multicenter research studies (episteme). To this latter category belong also the instruments of health technology assessment that progressively dominate policy documents, with explicit and pre-defined dimensions for evaluation (clinical, economic and organizational) and established procedures such as the calculation of cost-effectiveness ratios (Table 2).

In conclusion, the analysis of policy guidelines in this domain, triangulated with the interviews to our informants, shows that “governing medical technologies” has been progressively ‘defined as a new mandate for regional policymakers. Although still open to
interpretations in its implementation, it is proposed that this activity is based on a specific kind of evidence, *episteme*, according to the prevailing paradigm of health technology assessment and evidence-based policy.

We now turn to describe the four archetypes of “governing by evidence” that have emerged from the empirical analysis of the cases. They have been named on the basis of the role that regional policy-makers have carved out for themselves in each one. Table 3 provides evidence in support of the four archetypes through exemplifying quotes drawn from the case narratives. The quotes are organized on the basis of the three meta-categories on which typologies have been built.

**FOUR ARCHETYPES**

*Enabler*

Evidence here is associated to *episteme* and is the result of scientific research. The final purpose is to establish a ‘golden standard’: “Technological innovations get to the market largely incomplete in terms of usage indicators, effectiveness, safety and costs. Governing their adoption requires the capacity to issue new scientific information needed to orient decision-making at the different levels of the regional health system”.

There is a clear hierarchy of evidence with randomized controlled trials scoring the highest. Since the critical mass of interventions and patients for such kind of trials is not easily achievable and randomization is highly controversial for surgical procedures, the second best is sought in one case through an observational prospective study, in another by trying to enlarge the base for a randomized study through the participation in national or even international studies. Decision-makers are aware they are moving down the hierarchy, though the prevailing attitude is that their main responsibility resides in the participation in the production of evidence.

With this conception of evidence, the role that the Regions carve out for themselves is clearly of network managers. A network of clinicians and experts is assembled around a codified and step-wise process in which professionals first evaluate the existing evidence through a systematic review of the scientific literature and its critical appraisal. The timing of network assembly is not fortuitous. It follows communication by the Region to hospital healthcare managers of its intentions, communication that opens a window of opportunity for the Region to pursue its strategy for governing this technological innovation: “Given that the concrete role of robotic surgery is still unclear, the routine use of the robot is not justified. As such it should be
used only within research studies designed to evaluate its effectiveness, safety and cost-effectiveness. It will be the care of the Region together with the regional HTA Unit to provide indications and support hospitals in setting up such a study with a regional scope.”

Once the systematic review has been carried out, clinicians are called to produce robust evidence of safety, clinical effectiveness and the superiority of robot-assisted versus pre-existing surgical techniques (i.e. laparoscopic and even open surgery) through the design of a research protocol and the production of new scientific knowledge. The uncertainty of the evidence produced so far, therefore the problems healthcare managers and clinicians are facing in terms of justification and usage, represent the main contextual driver for them in participating in the network. In this way, at the same, they sanctioned the legitimacy of the process initiated by the Region. Any hospital-based initiative, preexisting to the start of this process, such as a small study or evaluation of robot applications is made to converge into the regional master plan and is discussed in a venue at regional level.

A stable institutional setting, in the form of a regional observatory or of a regional HTA Unit, is considered the natural venue to carry out ad hoc initiatives such as a Region-University project or a pilot HTA project. The institutional capacity needed to support these initiatives at the regional level includes not only logistics but more importantly the in-house expertise, guaranteed by the presence of legitimate regional specialists that activate and manage the professional network.

The portability and objectivity of evidence are intrinsic to the process used to build and assess it. In both cases there is emphasis on the need to standardize a method that can be then replicated for other technologies. Following a scientifically rigorous protocol is the assurance for impartiality and for the creation of a consensus. Ultimately, if the scientific outcome resulting from these projects will show that the robot does not offer advantages for the patients compared to the extant technique, the Region contemplates in one case a dismantling scenario, in another the fact that healthcare organizations will not be authorized to buy any further machines. In both cases the situation envisioned in such a scenario does not include recourse to coercive measures. Instead, it relies on a voluntary compliance with results that have been produced with a joined-up approach.
In this case the Region participates in the assessment of a technology only when prompted to do so by healthcare organizations. Organizations bring evidence to urge a regional intervention regarding the robot. This evidence has been of two types. The first is an organizational report of the problems generated by the current reimbursement system, namely a level of usage which is far from optimal and access criteria that privilege paying patients. In the words of one of our informants: “One hospital came and told us that due to the reimbursement fees for robot-assisted surgeries they could not make 300 interventions but only 30. Another hospital came and told us that considering the existing reimbursement fees they were offering the robot only to paying patients”. The second evidentiary base is an observational study of robot-assisted surgery for one specific indication in urology. The healthcare organizations use this study to engage the Region in this issue, by showing the advantages of the robot-assisted surgery.

As a reaction, the Region does not plan to create in-house scientific research (*episteme*) to support its decisions. Instead, despite recognizing the substantial lack of solid evidence on most robot applications, it limits the search for evidence to reviewing briefly the studies at the international level and to identifying, together with the requesting organizations, the only indication where there is wide, though not unanimous, consensus on clinical effectiveness.

Declaredly, the Region has adopted a strategy of ex post government of technological innovation. The underlying assumption is that orchestrating a sophisticated HTA procedure at the regional level is useless when single organizations have already taken their decisions and have bought the machine. Instead, the role that the Region has carved for itself is to react to the calls of healthcare organizations by providing a financial incentive which helps organizations to reach the appropriate volumes of interventions, while also producing the evidence needed to evaluate the potential benefits of this new technology. The element of standardization and portability here is the reimbursement mechanism, in this case attributed to the toolkit for the interventions of prostatectomy. Such procedure signals an endorsement of the robot by the regional government, as a strategy to avoid an unfair access to the new technology. Scientific research is employed only as a reference, which is to make sure the Region is not providing incentives to a technology that is unsafe or of very controversial clinical effectiveness.
Health organizations pre-negotiate with the Region an expenditure cap for reimbursing the kit, so that if a single organization exceeds the predefined volume of operations it will not be reimbursed.

**Planner**

In these Regions policy makers explicitly disregard evidence as *episteme*, the associated rational paradigm of decision-making and the related applications such as HTA. In the words of one of our informants “HTA and the like are absolutely inadequate instruments because they work on things that are already there. We need to anticipate them. We need an HTA of the future”. Since evidence based on scientific research is not considered timely enough to support decisions, policy makers have to rely on different evidentiary bases. One is experiential evidence, grounded in specialist training as well as in personal intuition. Such “art of deciding” is considered crucial when the evidence about an emerging technology is contradictory or not available yet. When policy makers envision the potential of a technology, they somehow formulate the hypothesis and remain open to the possibilities to test it in the field. This approach enables the introduction in the healthcare system of innovative devices and knowledge. Yet, this might result in an unfair concentration of resources across the territory. Therefore, *metis* is balanced by another source of evidence, namely the set of explicit criteria guiding the inclusion of healthcare organizations in this hypothesis testing (*techne*). The criteria respond to the need to ensure equity throughout the regional healthcare system and, at the same time, to envision a system-wide plan of technological development and investments. Only organizations where training and specialization are delivered (i.e. university hospitals) or organizations where there is an epidemiological rationale (i.e. hospitals with large patient pools) are candidates to receive the robot. HTA and highly structured decisional approaches are employed ex-post as validation. The Regions have carved out for themselves the role of planner. Healthcare organizations willing to engage in an exchange and dialogue with the Region have to “bring the evidence” that they respect certain criteria, meaning they have to align their requests with the larger framework of the regional perspective and show they fit into the overall vision of governing technological innovation proposed by the Region. The process of creating evidence is thus standardized and made objective exactly through the criteria set to ensure the regional mantra of central planning and system-wide integration.
The Regions contemplate a scenario where research and practice might show that the robot is not the best solution available (e.g. because, compared to the extant technique, interventions take longer or because it is more expensive or even because in this phase of the technological development it is not completely clear that there are advantages for the patients). But even in such scenarios, the regional support to the organizations that have acquired the robot should not be withdrawn since it represents an act of capacity building for the future: “The robot is not an expensive device but it is a philosophy to approach surgery. Discarding such an approach on the basis of a cost-benefit analysis means preventing the system from internalizing the philosophy of the future”.

**Authorizer**

In this case, the Regions propose an evidentiary basis for governing technologies comprised of a mix of *episteme* and *techne*. Clinical effectiveness is assessed through the systematic review and appraisal of the existing scientific literature and is then completed with the evaluation of the feasibility of the overall investment from a financial, economic and organizational perspective. Evidence is construed as an integral part of a structured decision-making process that terminates in an authoritative decision and charges the Regions with the responsibility of the final authorization of a new technology.

The Region has created an institutional venue, in the form of a committee composed of regional experts and technocrats, to which healthcare organizations submit full documentation and a proposal. All deliberations of the committee are published in the official regional bulletin assuring transparency of decisions, disseminating the results of this process and strengthening the legitimacy of the committee’s activities. The work of the committee, in addition, is fully integrated with the overall flow of regional administrative procedures and its decisions are, therefore, sanctioned by the Regional Council, composed of elected political representatives. The process of submitting evidence to the committee remains participatory and there is space for organizations to argue their case, providing additional evidence and bringing additional experts in support to their request. Still, the final decision of the committee is binding and there have been cases in which the committee has negated a technology to the proponents.

The Regions with the support of internal experts have prepared a master file with the list of criteria for the evaluation of proposals. The criteria represent the dimensions deemed relevant
by the Region in assessing technologies and making authoritative decisions, and healthcare organizations are forced to collect and submit evidence to the committee according to these dimensions. These criteria are not only standardized but also portable as they are considered valid for the evaluation of a variety of other technologies of the caliber and complexity of the robot. Criteria are given explicit weight and even combined in a precise algorithm mimicking as much as possible a rational and logic method.

The process of providing evidence is framed as a “health technology assessment” based on the necessary consideration of a variety of aspects: technical characteristics of the technology, clinical effectiveness, economic and organizational impacts. The Regions are aware that for many technologies, such as the robot, evidence of effectiveness might be uncertain and not always will it be available. Yet, combining pre-defined criteria and a standardized decision-making process will guarantee that the best available evidence has been collected, the most complete prediction of the impact of that technology has been formulated and, as such, that the decision by the Region is likely to be the right one.

In this case, the Regions, therefore, attempt to build their role in governing technologies by putting themselves in a hierarchically higher position with respect to healthcare organizations. Not only are they the only members of the examining committee but also the entity that decides what constitutes valid evidence. In addition, to counteract the information asymmetry surrounding technologies, that they might suffer from in comparison with hospitals, the Regions have conducted a systematic inventory of all the machines present on their territory and, in this manner, assumed the role of who best understands the overall situation: “In the end when the committee operates it doesn’t see just one organization or one technology but the whole system and it can decide for the whole system”.

ANALYSYS

The analysis of the four archetypes enables us to define a formal proposition, namely that governing technological innovation by evidence entails structuring a relationship between the governing and the governed through such evidence. Doing this in a way that leads to an actual governing action (i.e. through guidance, constraint or motivation) requires the identification of an evidentiary base that is the most suitable or coherent with the relationship proposed by policy-
makers. Figure 1 depicts the components of the framework that connects the elements for the emergent theory of governing through evidence that we propose.

In this study, regional policymakers carve a role for themselves in the light of the new mandate they have received. The mandate to govern technologies is complicated by the contextual tension between stimulating technological developments and ensuring that system-wide coherence is maintained at the level of service access, resource allocation and appropriateness. Furthermore, the lack of clear and univocal indication of the clinical effectiveness of the technology poses an additional challenge to the decisional process. In other words, it barely resembles the ideal and logical process proposed by health technology assessment and the evidence-based movement. Finally, in order to appropriate for themselves this domain, policy-makers ought to recompose the web of relationships at play during the steps leading to the acquisition of a new technology and become the principal interlocutors of managers and clinicians.

With this backdrop, the approaches that policy-makers embrace to structure a new relationship with the other actors involved in the process can be divided in two groups. In the first group we find Regions that govern technology in a non-hierarchical fashion. A way to do so is through the activation and orchestration (Salamon 2002) of a professional network of clinicians and experts belonging to healthcare organizations to carry out research on technology. This approach is frequently employed (Weiss 2002) when government officials ought to confide in decision heuristics for lack of the knowledge needed to produce the input. Hence they require or, as in our case, enable other actors to generate and to share it. As a result Regions affirm not only their jurisdictional advantage but, perhaps more importantly, their nodality (Hood and Margetts 2007), that is the propriety of being in the middle of a network. Structuring a network around scientific collaboration has the expected advantage of creating consensus among healthcare organizations on whichever evidence will emerge, thus leading to a government based on voluntary compliance.

The other non-hierarchical approach we have identified is based on leveraging a reimbursement system through which the Region provides incentives to healthcare organizations to use the technology for specific clinical indications, purportedly those that are evidence-based. Providing incentives is considered the main ‘indirect’ way of governing (Beam and Conlan 2002), and is particularly relevant when public entities delegate functions to other parties and
then need to steer their behavior towards the achievement of certain goals. Here evidence is used to set the terms for the attribution of tangible payoffs aimed at inducing compliance (Schneider and Ingram 1990) or, as in our case, at encouraging a level of technology utilization coherent with the overall objectives of the Region.

In the second group we find Regions that exert their governing function by structuring a hierarchical relationship with healthcare organizations. In line with previous studies we have found the Regions might enact the prescription (Bardach 1977) with different levels of automaticity (Salamon 2002), that is the extent to which the act of governing relies on existing administrative venues or procedures for its operations rather than requiring an ad hoc apparatus. Schneider and Ingram (1990) associate high or low degrees of automaticity to the use of formula decisions versus judgmental decisions. In this perspective, setting selection criteria for healthcare organizations through centralized regional planning is to be considered an automatic approach, differently from a formal authorization process that requires the establishment at the regional level of a special approving commission.

Hood and Margetts highlight the fact that, without compliance, government indications, as authoritative as they may be, are “no more than self-proclaimed statements” (2007, 77). The Regions that have structured hierarchical relationships with healthcare organizations have used evidence to strengthen the expected level of compliance. One way has been appealing to system-wide coherence in setting the selection criteria and in investing managers and physicians with the role of providers of feasibility data. Another way has been ensuring accountability and legitimacy to the authorization procedure by incorporating a negotiation phase with managers and physicians in the role of applicants, as well as by including elected administrators and by officially disclosing all details of the process.

We now turn to the second component of our framework. Finding the ‘best available evidence’ has been the normative assumption underlying evidence-based policy movement. True, also the rational paradigm concedes a second-best scenario (Weiss 2002). In the absence of a sound scientific indication of what works, policy makers should move down the notches of the epistemological pyramid while waiting for experimental, quantitative research to coalesce into unambiguous evidence.

Our empirical analysis, however, has provided a more assorted account of how the concept of ‘best available evidence’ is interpreted and sought by policy makers in a situation
where the clinical effectiveness of the technology is uncertain. For policy makers specifying the nature of the evidence to be exchanged with their counterparts becomes one of the stepping stones in crafting their governing action. In doing so they draw freely from a variety of evidentiary bases (Flyvbjerg 2001; Lindblom and Cohen 1979; Tenbensel 2004; 2006; Scott 1998).

This use of evidence as a policy instrument, able to organize a relationship between the governing and the governed, resonates with the qualities that have been attributed to ‘technologies of government’ in sociological studies (Foucault 1991; Neylan 2008). Scholars have argued, for instance, that “statistics in action” (Neylan 2008, 13), through a blend of technical and non-technical factors (Neylan 2005; Porter 1994), can work as a premium instrument of social steering (Giddens 1990) and government by becoming the science of the State (Foucault 1991)

For Regions where evidence is by definition associated to episteme, recognizing the uncertainty of the clinical benefits of the technology prompts policy makers to craft it in-house together with a network of professionals from healthcare organizations that, in this way, assume the prime role of researchers. Others achieve the last mile by pairing the feeble clinical evidence with criteria such as organizational capacity or economic impact (techne) to strengthen the corpus of evidence on whose basis decisions are taken. Yet other Regions are reluctant to engage in HTA-like efforts that at best are there to provide a rigorous basis to assess the decisions already taken (i.e. the technology ought to be already there before running an HTA). These regional policy makers base their decisions mainly on the evidence that the recipient healthcare organization has the adequate capacity to use the technology or else that such capacity might be unexploited without the regional intervention (techne). Assessing the quality of technology is overtly left to the intuition of skilled and experienced policy makers (metis), or else is based on the selection of the exclusive indications where a certain consensus of the clinical effectiveness has emerged.

The last component of our framework is the definition of what we have labeled ‘standardized and portable devices’. Devices are operationalizations of the policy instrument adopted in governing that is evidence. They can be organizational forms, mechanisms or procedures (Hood and Margetts 2007; Salamon 2002). In this study, they represent all the concrete means through which evidence, in its different variants, is made understandable,
replicable and objective. Two features emerge from the cases as characterizing devices: standardization and, consequently, portability - the faculty to travel easily across domains, agencies and Regions by virtue of standardized meaning and universal language (Norton Wise 1995; Porter 1994). The standardization process, be it the elaboration of a research protocol, the attribution of incentives, the identification and monitoring of criteria or an authorization procedure, is the leverage available to policy makers to strengthen the relationship they have established with managers and clinicians and, as such, reinforce the roles that they have carved for themselves and attributed to the others.

DISCUSSION

In this paper we have investigated how to govern by evidence technological innovation in healthcare. Empirically, we have studied the entire sample of the Italian Regions where the Da Vinci surgical robots are concentrated and the level of analysis has been the interaction between regional policy makers, healthcare managers and clinicians in the process of governing this technology, which entails deciding on its acquisition and use.

Our work has two main theoretical implications. First, by combining the literatures on evidence-based policy and on the tools of government (Elmore 1987; Hood 1983; Hood and Margetts 2007; Salamon 2002; Schneider and Ingram 1990) we have conceptualized evidence not as a set of information introduced at a specific point in the decisional process but as a policy instrument able to structure a relationship between the governing and the governed. This affords us to revise the extant, monolithic notion of evidence as a more or less sophisticated input to be plugged in the policy cycle. Second, we have elaborated a tentative theoretical framework that grants an equal standing as policy instruments, to experiential and more practical forms of evidence in comparison to episteme. Moreover, it uncovers a process that begins with policymakers proposing to their counterparts a new way of relating through an exchange of evidence and continues with the consolidation of their roles by standardizing decisional criteria and procedures.

The present study is not spared from limitations. Archetypes have been built on a comprehensive and solid empirical basis but they would need to be further tested and validated through the consideration of additional and diverse cases. It would be meaningful, for example, to address the instance of a technology for which the evidence of its clinical effectiveness is
more certain. In addition, testing archetypes for governing by evidence in a policy terrain in which policymakers have a consolidated role would allow to further validate not only the plurality of employable evidentiary bases but also verify how evidence is construed in these cases as a policy instrument.

Last, we deem the paper has a few policy implications worthy of discussion. Policymakers working in the field we have analyzed know all too well that governing the diffusion of technological innovations requires rapid, critical decisions. More often than not, the evidentiary basis available does not provide a sound indication of the marginal or even absolute effectiveness of the innovation being analyzed. We hope we have contributed to clarifying that in these circumstances the path to governing is not univocal but there is a repertoire of alternative routes to finding the ‘best available evidence’. Moreover, selecting the route should be a decision informed also by the assessment of the in-house capacity to produce the evidence needed, as well as of the existing relationships with the other actors involved. Thus, whichever the route, policymakers might make a conscious attempt to turn the decision process into an understandable and replicable device. These considerations may be of interest to policymakers called to govern complex phenomena without a well established evidentiary basis, particularly in the myriad of policy domains characterized by a tension between nurturing innovation and maintaining an equal, fair and appropriate level of service.
REFERENCES


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http://www.oecd.org/topic/0,3699,en_2649_37407_1_1_1_1_37407,00.html


### Tables

**Table 1: Summary of interviews**

<table>
<thead>
<tr>
<th>Regional policy-makers &amp; top-bureaucrats</th>
<th>Experts, national policy-makers &amp; others¹</th>
<th>Managers and hospital professionals</th>
<th>Surgeons</th>
<th>Technology producers</th>
<th>Total N. of interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>11</td>
<td>42</td>
<td>57</td>
<td>2</td>
<td>142</td>
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</table>

¹ Bank foundations, mayors, focus group members (some also interviewed for specific case studies), pharmacists, device purchasing unit, operations managers, health technology assessment units
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<tbody>
<tr>
<td>Promoting technological progress with a direct impact on healthcare services</td>
<td>Identifying priorities for investment in new technologies</td>
<td>Promoting the advancement of new knowledge and technologies</td>
<td>Guaranteeing access to technologies but with an efficient allocation of resources</td>
<td>Identifying priorities for investment in new technologies</td>
<td>Developed a policy framework of technological innovation for governing its impact on services</td>
<td>Guaranteeing the balance between higher quality of services through new technologies and sustainability</td>
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<tr>
<td>Limiting the intensive use of technology in healthcare and the consequent rise in costs</td>
<td>Replacing obsolete technologies</td>
<td>Being directly involved in the creation of new technologies in order to achieve cultural and economic development</td>
<td>Promoting the understanding of the clinical, technical and economic impact of the use of technologies</td>
<td>Promoting the advancement of research on new technologies and supporting innovation</td>
<td>Demonstrating the efficacy of new technologies through health technology assessment</td>
<td>Joining the evaluation of clinical effectiveness with the assessment of economic impacts</td>
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<tr>
<td></td>
<td>Developing procedures for the evaluation of technologies (efficacy, organizational and economic impacts)</td>
<td>Maintaining high standards and replacing obsolete technologies</td>
<td>Evaluating the economic impact of new technologies together with their influence on organizations and regional planning</td>
<td></td>
<td></td>
<td>Rationalizing the current system</td>
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<tr>
<td>Rising costs due to technology</td>
<td>Systematic reviews of the existing information</td>
<td>Knowledge of the great clinical and health benefit brought by new technologies</td>
<td>Knowledge of the clinical, organizational and economic impacts of technologies</td>
<td>Inappropriate distribution of technologies and inadequacy of use</td>
<td>Cost-effectiveness</td>
<td>Health technology assessment</td>
</tr>
<tr>
<td>Waste, inappropriate and inefficient acquisition of technologies; no economies of scale</td>
<td>Multi-centre research projects</td>
<td>Inventory of technologies and their distribution</td>
<td>Appreciation that only a certain level of need is apt to support the use of a new technology</td>
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<tr>
<td>Awareness that technology is not the only element determining the quality of healthcare services</td>
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</table>
### Table 3: Exemplifying quotes of the four archetypes

<table>
<thead>
<tr>
<th>Processes for governing:</th>
<th>Enabler</th>
<th>Incentivizer</th>
<th>Planner</th>
<th>Authorizer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structuring a relationship between the Region and the other actors through evidence</strong></td>
<td>“The region is at the service of any healthcare organization that needs to assess an emerging technology”</td>
<td>“Based on the dossiers produced by two of our hospitals, we have decided to grant an addendum of reimbursement (…), thus covering disposable kits of the robot”</td>
<td>“The Region is able to align a healthcare system well governed, of high quality and with many areas of excellence with the capacity to create a network. The system tries to look at research and innovation but as a counterbalance maintains a strong public function of planning”</td>
<td>“The creation of the committee proofs the intention of the Region to occupy and govern the domain of medical technologies and their evaluation”</td>
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<td></td>
<td>“This group is an opportunity to share practices, to think aloud about problems and doubts”</td>
<td>“We have a very pragmatic approach in our Region: we have frequent relations with the professionals and as a consequence we move when we feel that the times are ripe. I mean, we do not have a theoretical approach to assess technologies”</td>
<td>“In the Region we take the luxury to look farther, since the single healthcare organizations must always focused on their emergencies stolidly”</td>
<td>“The committee has been created to express a technical judgment over requests by healthcare organizations of investment in new technologies”</td>
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<td></td>
<td>“Acknowledged the lack of robust scientific evidence about the added value and the clinical effectiveness of the robot, one would expect to carry studies able to bring such robust evidence. By mapping the available evidence we had the objective of providing usage guidelines”</td>
<td>“The government of technologies through HTA is impossible, because the Regions are like the valley floor when the landslide is already in motion”</td>
<td>“The natural collocation of the robot had to be a university hospital, which, in our regional system, is the place where we deliver training and specialization”</td>
<td>“The overall procedure is formalized: a preliminary investigation based on an HTA is conducted by the Regional Health Agency who looks at the evidence provided by the healthcare organization. Then the examining committee rules and finally the Regional Council formally approves by deliberation the decision”</td>
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<td></td>
<td>“Our Observatory is to enable a shared reasoning, certainly under our leadership - also because it is useful if someone writes down everything and then send it along. We are the logbook of the network”</td>
<td>“We can not only look back and try to contain the costs. We also have to try hard, while we keep costs under control, not to mortify the innovation, that would mean to close the future”</td>
<td>“I always ask the organizations that have the robot in mind: do you have the epidemiological figures to support it? Don’t you go in structural disequilibrium? Then I ask them why they want to buy the robot. And I”</td>
<td>“Given the intrinsic uncertainty and incompleteness of...”</td>
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<td></td>
<td>“The function of Research”</td>
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and Development must be carried out as the core institutional mandate of a Regional Healthcare System, jointly with the traditional task of healthcare assistance. This implies the ability to assess and promptly adopt technological innovation.”

*Policy Document*

“We favor the development of competency networks able to carry out the much needed research”

*Policy Document*

“When our hospital promoted an observational study on the robot applications in urology we didn’t have in mind a scientific publication, but rather a way to involve the Region on this theme and show the advantages for the patients”

“Expect that they answer they have a great doctor, a great urologist for example who shows the willingness and the abilities to move in that direction. It is only then that I recommend the assessment of feasibility, resources available, impact on the budget, etc”.

“As a public healthcare organization we wanted to be reassured in our decision, particularly when it is so expensive... thereby the final decision is always resulting from an important confrontation between the Region and the organization.”

“Information for most technologies the idea is that healthcare organizations elaborate the best and most explicit prediction of the impacts and evolution of a certain technology”

**Table 3: Exemplifying quotes of the four archetypes (continued)**

<table>
<thead>
<tr>
<th>Enabler</th>
<th>Incentivizer</th>
<th>Planner</th>
<th>Authorizer</th>
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<tbody>
<tr>
<td><strong>Policy instruments: Evidentiary bases</strong></td>
<td><strong>“We need to find a theoretical rationale for the machine”</strong></td>
<td><strong>“The problem is not to validate this technology. How could I possibly validate a technology already sold in 1,000 pieces? At least I try to assess whether it is used appropriately”</strong></td>
<td><strong>“We got convinced that this new technology in minimally invasive surgery represented the best possible technology, in addition to the human and surgical knowledge. We did not have an HTA, we didn’t do anything. We only had our intuition, our previous knowledge and our professional knowledge”</strong></td>
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<td></td>
<td><strong>“We still miss an evidence of best outcome with the robot for any pathology. Unfortunately we are still far from the definition of golden-standard for robot-”</strong></td>
<td><strong>“I cannot forbid”</strong></td>
<td><strong>“We first needed to have an overall view of the technologies in our system so we proceeded with a comprehensive census. This was a way to understand if we had enough of certain technologies, how they were distributed and if”</strong></td>
</tr>
</tbody>
</table>
“In some applications for urology and gynecology we do have scientific evidence of the robot as gold standard.”

“We hope we will get evidence that an intervention done with the robot is better than one done in laparoscopy, for example.”

“Even if we cannot run a randomized control trial, we can at least rely on observational studies, limiting the idiosyncrasies of individual physicians.”

“To carry out a study might mean a randomized control trial, which is perfect, but might also mean an intense monitoring or a cohort study but prospective”

“Our cut-off has been clinical safety”

“We recognize top priority to clinical effectiveness”

“We carried out a brief review of evidences at the international level. We can not claim there are definite data on any pathology. There are more solid data on the prostatectomy, fine, but an absolute evidence…no, we didn’t find it”

“Yes, we conducted an economic evaluation of how much it would have costed to use the robot in an occasional vs a systematic manner, considering the costs of the operating room, the amortization, etc…”

“HTA and the alike are instruments absolutely inadequate because they work on things that are already there. We need to anticipate them, we need an HTA of the future”

“Yes, we conducted an economic evaluation of how much it would have costed to use the robot in an occasional vs a systematic manner, considering the costs of the operating room, the amortization, etc…”

“If then we need an instrument to validate our decisions, I do not have any doubts HTA is the right instrument to validate what we think”

“We did not have HTA yet: I was the HTA”

“There are threads of reasoning that stem from intuition and that are hypotheses (…). An
A hypothesis is already a great condition for a researcher that works on the health side, no? The robot was an hypothesis to be experimented”

Table 3: Exemplifying quotes of the four archetypes (continued)

<table>
<thead>
<tr>
<th>Devices for governing:</th>
<th>Enabler</th>
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<th>Planner</th>
<th>Authorizer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardization and portability</td>
<td>“This assessment methodology is a structured exercise that can be replicated”</td>
<td>“We have decided to pay the disposable kit by adding to the reimbursement tariff 80% of the cost. This is done on the basis of a precise data collection and for this purpose we have set up an ad-hoc system tracking the number of kits”</td>
<td>“The fairness and justice of the regional system must be ensured in the situations of high risk of inequity such as the access to technological innovation” We should use at their best the human, technological and financial resources”</td>
<td>“To guarantee homogeneity, reproducibility of decisions and transparency the decision-making process of the committee has been standardized on the basis of a set of criteria that the Region considers relevant for an evaluation”</td>
</tr>
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<td></td>
<td>“We are standardizing a rational model for assessing and evaluating complex interventions in healthcare”</td>
<td></td>
<td>“According to the criteria of planning and service integration”</td>
<td>“Given that clear criteria have been set in advance the result is super partes so if we say no is not that we say it to that particular healthcare organization but because its request does not meet the pre-defined criteria”</td>
</tr>
</tbody>
</table>
Table 3: Exemplifying quotes of the four archetypes (continued)

<table>
<thead>
<tr>
<th>Enabler</th>
<th>Planner</th>
<th>Incentivizer</th>
<th>Authorizer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governing Output</td>
<td>“Our report ends with possible scenarios of adoption as well as of dismantling”</td>
<td>“If you compare the robot and laparoscopy for banal interventions I suppose it is very hard to establish the superiority of the robot. But if the conclusion is that the robot is more expensive and should be dumped…this is absolutely a wrong thing to be done because the robot contains a revolutionary germ that laparoscopy does not”</td>
<td>“The Region has in fact introduced the reimbursement of the toolkit for the interventions of prostatectomy, but has set as constraint that the expenditure cap negotiated with the single organizations”</td>
</tr>
<tr>
<td>Non-hierarchical and hierarchical output</td>
<td>“Since the Regional Agency will provide the resources and since in the while the people will be trained on the issues at stake, the horizon should be sufficient to ensure that any request to acquire the technology will be reasonable and that the Commission won’t have to say no”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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FIGURES

Figure 1: Schematic representation of the elements of the theoretical framework on governing by evidence