ADMINISTRATIVE WELFARE AS POLITICS BY NUMBERS: EXPLORING THE LINKS OF QUALITY IN GOVERNMENT AND NPM IN SWEDISH PHARMACEUTICAL BENEFITS

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1. Introduction

The issue of how to improve government is an ever-present concern, for practitioners and researchers alike. In the area of welfare policies, the need for "good government" is arguably of particular relevance (Rothstein, Stolle, 2003). These policy areas are dependant on perceived high legitimacy in order to secure continued state involvement in terms of financial, regulatory and operational service provision. In recent decades, New Public Management (NPM) has been a dominant model for reforming the public sector in order to achieve a more efficient organization and management (Hood, 1995; Pollitt, Bouckaert, 2004). Welfare organizations are among those who have been subjected to such restructuring. NPM-reforms have in particular focused on adopting corporate models for control and performance assessment that emphasize value-for-money and economic efficiency. The wide-scale deployment of NPM-inspired initiatives across the world has spawned considerable scholarly interest in analyzing the spread and effects of such reform strategies (Hood, 1991, 1998; Kickert, 1997; Pollitt, Bouckaert, 2004 [2000]; Christiansen, Lægreid, 2001). The findings from such studies often point towards reoccurring problems of goal displacement and an excess of faith in uniform steering instruments for setting targets and measuring performance.

More recently, in a hitherto largely parallel development to the continued interest in improving policy-making within central government and national administrations, other scholars have turned to judging the quality of public organizations' activities, from the perspective of quality of government ("QoG") (See for example La Porta et al., 1999; Evans, 2005; Rothstein, Teo-

rell, 2008)[1]. This latter interest has in part centered on a consideration of the determinants of corruption in political organizations. In general, however, the focus of QoG studies has been on the realization of impartial, competent and efficient public organizations broadly defined (cf. Rothstein, Teorell, 2008). This has involved inquiry into the activities of the organizations undertaking implementation of public policy. The quality of these activities is seen as important factors for economic development and social sustainability. Our approach in the present paper is aligned with the notion that an assessment of quality of public policy necessitates a careful consideration of the exercise of power on the part of those implementing reform programs (cf. Rothstein, Teorell, 2008). In other words, it is not sufficient to judge the quality of the political system in terms of citizens' representation and public access to decision-making. The output side, in terms of the completion of policies, also needs to be investigated. Since citizens' commonly have direct contact with these parts of the political system, the implementation-level play a critical role in building and maintaining the legitimacy of the political system as a whole (Lipsky, 1980).

NPM and QoG have somewhat different views as regards what constitutes "good government". Generically, they can be characterized as focusing on different parts of the policy process, and deploying different tools for quality assessment. NPM-initiatives typically concern the exercise of control ex ante, as realized by practitioners through technical management tools such as management by objectives, TQM (total quality management) and bench-marking (Pollitt, Bouckeart, 2004 [2000]). QoG-evaluations have recently expanded beyond a limited consideration of economic development (La Porta et al., 1999) to non-economic outcomes as judged by researchers and third party auditors ex post. Third party evaluations are based on quality indicators produced by various organizations such as: the World Bank, OECD and the EU; research institutes, and private NGOs such as Transparency International. Democracy has also been a greater concern for this stream of thought as the fundamental question concerns the definition of the functional role of the state. In exploring conceptual and empirical links between NPM and QoG, we

[1] The term 'public institutions' is commonly used as a synonym to 'public organizations'. So as to avoid confusion with theoretical assumptions regarding the regulatory power of institutions as conceptualized in terms of informal norms and formal rules (Meyer, Rowan, 1977; Jepperson, 1991), we will refrain from using the term 'public institutions' to denote such organizations as governmental agencies, policy-making organizations and representative electoral bodies.

will argue that despite their differences, NPM and QoG have a common, sustained belief in the deployment of systematic – preferably scientific – knowledge as a tool for realizing "good government". In other words, the assumption is that knowledge-based decision-making (and knowledge-based evaluation of the same) can serve to resolve potential value conflicts within the political system and make needed prioritizations of resources in a fair and efficient manner. Using an example from the healthcare sector, this paper inquires into the practical consequences for democratic priority-setting which follow the implementation of a form of knowledge-based decision-making. The Swedish Pharmaceutical Benefits Board (henceforth "the PBB") is a Swedish governmental agency tasked with deciding prescription pharmaceuticals' subsidization status based on a combined consideration of knowledge about medical and economic effects of use. In this paper we will address the question of whether the deployment of knowledge-based decision-making in an organization governed by NPM-tools has relevance for the possibilities to realize QoG values such as transparency, reliability, impartiality, rule of law and efficiency/effectiveness.

We will develop our argument in the following way: In the first section of the paper we start out by giving a short account of the development of NPM-reforms in the Swedish public administration. This is done in order to situate the PBB and its creation in a wider organizational context. We then proceed to develop a theoretical framework, which builds on behavioral decision theory and science and technology studies. These two strands of thought provide us with a perspective to inquire into the way in which knowledge is used in complex decision-making within the empirical field of pharmaceuticals benefits. Accounting for the case of the PBB constitutes the second part of the paper. Finally, we conclude with a discussion on the empirical links between NPM and QoG that can be derived from the case at hand. By linking issues of good governance to the use of knowledge in governance processes, we hope to enrich the debate on measuring policy outcomes and their quality.

2. Politics by Numbers NPM and the Swedish Public Administration

The Swedish Public Administration could be characterized as one of the "trail blazing" countries undertaking administrative reforms inspired by the movement known as NPM (Pollitt, Bouckaert, 2000; Christiansen, Laegreid, 2001; Sundström, 2003). From the late 1980's, so-called "management by objectives and results" (MBOR, swe. mål- och resultatstyrning) has been implemented and reformulated in several phases. Initially, there was a strong emphasize on restricting budget expenditures. There has also been a move towards more decentralization in allowing executive agencies[2] to allocate their budgets within frames set by the government (Pollitt, Bockaert, 2004:288). MBOR leans heavily on the belief that politicians are capable of setting precise and quantifiable goals for the agencies, which can be expressed in government approval documents (Sundström, 2003). Agencies then report back in annual accounts of their goal attainment. MBOR has mainly been implemented as a strategy for steering subordinate agencies, however it is also intended to be applicable to the ministries themselves.

Following a strong path dependency, MBOR has been situated and integrated in the archaeology of management reforms, and now constitutes an important framework for new administrative reform initiatives (Jacobsson, 1989; Persson, 2001; Sundström, 2003). Scholars analyzing the development of Swedish NPM reforms have, like in many other country studies, found that goal displacement has been a highly present feature. That is to say, the instrumental activities have become values in themselves in a way that defeats the basic objective. In other words, the reporting requirements become goals rather than means to an end (Sieber, 1981; Hood, 1995:114). To date the political leadership has shown little interest in the reforms of public management and the major initiatives have been undertaken by dominant administrative organizations. These have been the Swedish National Audit Office, (swe. Riksrevisionsverket), The Swedish Agency for Public Management, (swe: Statskontoret) led by the budget department within the Ministry of Finance

[2] The Swedish administrative system is characterized as dualistic, with an organizational separation of ministries and agencies where the latter represent the administrative level while the ministries provide politically decided guide lines and assigns budget allocations to the respective agencies.

(Lindström, 1997; Premfors, 1999). The low politics character of the policy area as such has been one determinant of its organization, as well of its strong focus on technical features (Sundström, 2003).

The creation of the PBB, the Agency studied in this paper, can be seen as an example of a reform undertaken in an administrative system heavily relying on NPM-tools. Furthermore, the creation of the PBB could in Christiansen and Lægreid's vocabulary be described as a post NPM-reform whose main element consists of a change in form of affiliation to subordinate institutions (Christiansen, Lægreid, 2008:12). Pharmaceuticals constitute a sizeable often growing cost for many healthcare service financiers, including the Swedish state[3]. Various solutions have been proposed to manage access to pharmaceutical treatment, and increase control of pharmaceutical spending. One initiative, which has been adopted in several countries with publicly financed healthcare services, has been the creation of healthcare technology assessment organizations (see examples in Jost, 2005). The Pharmaceutical Benefits Board is one example of such an organization. The Agency is tasked with deciding which prescription drugs should be included in the public pharmaceutical benefits scheme, based on a combined consideration of medical and economic effects of use. According to the government approval documents for 2008, one of the main goals that the Agency is to fulfill includes making sure that the benefits scheme works in an appropriate and cost effective way. The Agency has a legal mandate to establish practice, through knowledge-based decisions. This follows the logic of NPM-strategies, where the use of scientific and systematic data is seen as a means for achieving cost effectiveness.

The NPM-strategies' quest to achieve an ever more efficient bureaucracy has not specifically focused on issues of democratic legitimacy although some of its critics have raised such concerns. The broader issue of good governance is however addressed by the QoG perspective in a more methodical way.

[3] Sweden provides its residents with a comprehensive, publicly financed system of health insurance. Since 1955, this health insurance coverage has included a pharmaceutical benefits scheme. In the current scheme, a patient pays the full cost of prescription pharmaceuticals up to the amount of 900 SEK (~94 Euro). A graduated subsidy then reduces the patient's direct cost for prescription medication so that she never pays more than 1800 SEK (~188 Euro) in a twelve-month period. All additional costs are billed to the patient's resident county council by the state-owned monopoly distributor of pharmaceuticals: the National Corporation of Swedish Pharmacies.

3. Quality of government in policy implementation

The overarching question of the research field with which we seek to engage with and hope to contribute to is: what is an acceptable standard and quality for public policies and organizations? The research and practices focused around QoG take on the ambitious task of exploring and developing tools for such measurement (for a practitioner example see Kaufmann, Kraayt, Mastruzzi, 2007). In developing indexes for measuring quality of public activities, QoG scholars hope to provide answers to questions concerning under which circumstances we can expect to find successful and robust public organizations providing services in a just and predictable way (Rothstein, Teorell, 2008). So can we then measure the result of the NPM-influenced reform of the pharmaceutical benefits scheme? Perhaps. However, we will propose a somewhat different approach in order to attend more closely to the issue of how to understand policy implementation.

In theories of public administration it is well understood that the separation of politics and administration is not an easy task in practice. The appointment of officials within the two realms secure a certain separation of tasks, but the expertise and continuity contained within the administration provides a basis for impact on the policies both in the initiating phase and in the implementation of decisions taken (Beetham, 1996:43). Thus, if we recognize implementation as policy development, we need theoretical concepts that explain complex decision making, rather than merely focus on evaluating implementation. For this purpose, we will use literature on decision making to attempt to move the discussion on links between the literatures on NPM and QoG forward. In the following section, we will provide a perspective on decision making that will be used to analyze the consequences of a particular management reform.

In addition, NPM strategies within the public sector and the underlying theoretical assumptions of such practices as well as the QoG perspective deemphasize the "politics" of constructing measurements and indicators (Power, 1997; Thedvall, 2006; Moreira, 2008) and the performative, rather than solely descriptive, capacity of indicators in judging the quality of public organizations (Djelic, Sahlin-Andersson, 2006; Dahl, 2007). In order to better capture that knowledge is constructed and negotiated in the process of making a particular decision, we will turn to another field of research which explicitly addresses these matters. Empirically this relates to the PBB's mission to make knowledge-based decisions.

4. A framework for understanding complex decision-making in practice

Our consideration of policy formulation and implementation processes as examples of complex decision-making draws on behavioral decision theory. This extensive stream of research broadly posits that the means of organizing "decision-making in practice" has significance for the outcome of decision-making processes. Behavioral decision theory is, from the outset, formulated as a critique of the well-known and widely used rational choice model of organizational decision-making (von Neumann, Morgenstern, 2004 [1944]; Arrow, 1963 [1951]). The rational choice model, on which both the NPM and QoG-perspectives are based, is premised on the basic assumption that decision-making determines organizational behavior through the choice of an optimal course of action. It posits a normative model for making optimal choices. This model hinges on a dual assumption that decision-makers have perfect knowledge about future consequences of choice alternatives, and future preferences as regards these future consequences. The rational choice model also assumes the linear implementation of decision outcomes[4].

The starting point for researchers within the field of behavioral decision theory is that organizational decision-making in practice systematically fails to live up to the prescriptive tenets of the rational choice model (March, Simon, 1958; Cyert, March, 1963; March, 1978). It is against this backdrop that scholars have sought to develop more descriptive theories, based on studies of how organizations make decisions in practice. One particular focus has been on how organizations deal with ambiguity of preferences when making and implementing decisions[5]. The role of knowledge in decision-making has also generated scholarly attention. The analytical treatment of knowledge in behavioral decision theory must be understood in relation to this research stream's overarching critique of assumptions in the rational choice model. The rational choice model is deterministic as regards the role of knowledge.

[4] The normative value of linear implementation is foundational to the formulation of "principle-agent" problems, which arise due to non-linear implementation of choices.

[5] Implementation problems are understood as a consequence of organizations having to manage ambiguity of preferences regarding desirable courses of action. Organizations maintain a loose coupling between decision formulation and implementation, for example through the formulation of vague outcomes, in order to avoid conflict between multiple principles (Sahlin-Andersson, 1989; Baier, James, Saetren, 1986).

In studying how organizations use knowledge in practice – as compared to this rational ideal, two overarching strands of research findings have emerged within behavioral studies of organizational decision-making.

The first attributes the paradoxical situation that information is collected and then disregarded by decision-makers to the symbolic role of information collection activities (Feldman, March, 1981). Contrary to the rational choice assumption that knowledge from various sources is collected and then used by decision-makers to determine the outcome of decision-making processes, knowledge is characterized as a means of signaling procedural rationality and a commitment to substantive rationality (cf. March, 1994).

The conclusion that knowledge is used to legitimate the output of decision-making processes ex post complements findings in the second stream of studies that take issue with rationalistic assumptions about knowledge as a neutral input to decision-making processes. Various studies argue that the interpretation of knowledge is influenced by who collects and presents it and how it is collected and presented (March, 1988). This conceptualization has been used to examine the relationship between civil servants and politicians, and explain how and why civil servants can exercise influence over political decisions (Brunsson, Jönsson, 1979; Jacobsson, 1984; Lipsky, 1980). The idea that those in control of how knowledge is used to frame relevant problems and solutions can exercise influence mirrors Kingdon's research on power in the policy process (1995 [1986]). Other studies have similarly illustrated how ostensibly "technical" artifacts, such as accounting reports (Cohen, March, 1974) or investment calculations (Jansson, 1992), can be strategically used to influence the choice of a particular course of action.

In summary, the rational choice model assumes that knowledge determines the optimal choice outcome, and that this knowledge is exogenous to the decision-making process. In contrast, behavioral studies of organizational decision-making illustrate how knowledge is used to legitimate outcomes after they have been made; how knowledge is used strategically by actors in decision-making processes; how knowledge can be interpreted in different ways. However, these overarching conclusions raises several questions. More generally, it is questionable whether knowledge is a readily available resource to legitimate any decision outcome. While it may be possible to justify a particular decision based on a certain interpretation of knowledge, it is possible that this interpretation might be challenged. This could be particularly problematic if the expectation is that decision-making outcomes can be justified on the ba-

sis of scientific knowledge as an objective representation of a coherent reality (Drori et al., 2003). To generically attribute scientific knowledge a legitimating function in organizational decision-making fails to address the issue of how to justify decisions when there are many legitimate but together incoherent knowledge claims. If scientists propose different solutions to one and the same problem, say in climate politics, which option is appropriate to choose? Scientists proclaiming the superiority of emission trading for lowering carbon emissions were opposed by other scholars recommending traditional regulatory measures to lower the human impact on climate. Earlier on in the debate there were also scientist claiming that we were not experiencing a global warming, but rather moving towards a period of global cooling. In the course of a policy process, who decides which knowledge is relevant? And how are decisions based on this relevant knowledge legitimated?

The aforementioned ambiguity of scientific knowledge, suggests the relevance of posing further questions about how decision-able knowledge is constructed to make justifiable decisions. To address these questions, however, requires different – if complementary – analytical tools to those provided by behavioral decision theory. To take the question of ambiguous knowledge seriously requires a theoretical approach that has the construction of knowledge as a topic of inquiry. To this end, we will now introduce ideas from science and technology studies (STS). This area of research, broadly speaking, centers around questions of how knowledge is shaped by the settings in which it is produced and deployed.

5. Production of knowledge in social settings

A more comprehensive "history of STS" is outside the scope of the present paper (see Yearley, 2005 for a serious attempt), but briefly, a foundational point of departure for this stream of research is the view of knowledge as situated in and mediated by social circumstances (Bloor, 1991 [1976]). Thus, knowledge can be studied as a practice, in a manner that emphasizes the production of knowledge rather than its use.

Several streams of research have followed from this approach, many of which can be characterized as taking the matter of "displaced politics" of technology and science as topic (Nahuis, van Lente, 2008). One way of inquiring into where politics takes place, has centered on the role of expertise

and expert advisors. This topic has a long tradition in many disciplines, and encompasses a variety of approaches. Nonetheless, a point of differentiation of relevance in the present study is between researchers who emphasize the importance of experts "speaking truth to power" (i.e. policy-makers), and those that are more critical to the capacity of experts to speak truth and the possibility and desirability that policy-makers listen to it. Whereas the former approach is typically focused on developing techniques for improving the means by which experts engage in policy-making, the latter is characteristic of 'STS-informed studies' which take an interest in what expert advisors actually do (for an overview see Haas, 2004; Jasanoff, Wynne, 1998).

Numerous STS-inspired studies of policy-making processes in different countries and time periods have resulted in a characterization of scientific or other expert knowledge as a situated outcome, rather than something separate from and external to decision-making processes. Studies highlight the difficulty for scientific advisors to provide decision-makers with coherent facts, since there are no simple criteria for resolving incoherence between knowledge claims through generic appeals to objectivity and impartiality (Jasanoff 1990). When different scientific arguments are evoked by different parties, they do not automatically lead to the resolution of conflicts since a burden of proof for a given policy is not available separate from the setting in which the knowledge claims are evoked (Hilgartner 2000). Agreement on what is evidence is needed before 'the evidence' is determined. Thus, scientists will engage in adaptation and negotiation about what is true knowledge, such that the activities of experts are not fundamentally different from those of other participants in policy-making processes (cf. Jasanoff, 1990).

An overarching conclusion is that multiple knowledge claims remain separate and incoherent from one another without shared procedures or methods. Scholars have therefore pointed to the importance of inquiring into how multiple sources of knowledge are coordinated in practice. This aligns with the circumstances in the specific case of the PBB. The formal requirement is that the Agency reach a conclusion about a pharmaceutical's subsidization status based on a combined consideration of knowledge about a drug's medical, humanitarian and socio-economics characteristics (Act on Pharmaceutical Benefits, 2001:160). Going forward, we will focus on how ambiguities between multiple sources of knowledge are handled by the PBB.

6. Reorganizing the Pharmaceuticals Benefits Scheme: creating a new agency

The PBB was created in 2002, following long-standing debates about problems attributed to increases in pharmaceutical spending (SOU 2000:13). A few months before the Act on Pharmaceutical Benefits (2002:160) was passed into law, the Government had taken the widely publicized – and subsequently also heavily criticized – decision to exclude two pharmaceuticals from the public pharmaceutical benefits system. The two drugs were Viagra, a pharmaceutical approved for treatment of male impotence, and Xenical, a drug approved for treatment of obesity (see Junker, 2003 for a more detailed account). This unprecedented decision was justified on the grounds that the two drugs were being prescribed inappropriately in large volumes by medical practitioners. Patients who wished to continue to have their use of these pharmaceuticals subsidized were required to submit applications for exemption to the Government. The exclusion of the two drugs from subsidy was subsequently reversed, in part due to practical and administrative difficulties with managing the many applications for exemption. Concurrently, legislation was passed that created the PBB, and gave the new agency the task of deciding which prescription drugs should be included in the public pharmaceutical benefits scheme.

6.1. Regulatory framework

According to the New Pharmaceutical Benefits Bill (2001), the primary purpose in creating the PBB was to change the existing practice of "automatically" subsidizing all prescription pharmaceuticals with marketing authorization. A systematic oversight of drugs' subsidization status, undertaken by experts, was intended to improve the efficiency of resource use. In particular, the introduction of economic efficiency criteria for evaluating pharmaceuticals' subsidization status was a step to realize the goal of «ensur[ing] a rational and cost effective public use of medicinal products» (Ordinance 2002:719, section 1).

Since the inception of the PBB, a pharmaceutical is not included unless the Agency has approved subsidy[6]. Through its work, the Agency classifies prescription drugs into one of three categories: pharmaceuticals with approved subsidy (either with or without explicit restrictions on subsidized use) and those denied subsidy. How a pharmaceutical is classified has significant effects as the denial of subsidy for a pharmaceutical requires all out-patient use[7] of the drug to be paid for by patients.

According to the Agency's governing legislation, it is certain characteristics of a pharmaceutical's use that determines which category of subsidy the drug is placed in. By law, the PBB is instructed to grant subsidy to those drugs where:

> [T]he cost of using the pharmaceutical [...] is reasonable from medical, humanitarian and socio-economic perspectives
>
> [and] there are no other available drugs or treatment methods which [...] can be judged as significantly more suitable for the purpose

Regardless of which conclusion the Agency reaches about whether or not to include a drug fulfills the criteria for subsidy, it must publicly justify this outcome in a so-called decision justification document.

However, the legislation does not specify in detail what it means for a pharmaceutical to have a reasonable cost of use. Although some clarification is provided in the legislative bill, it is also stated that the precise interpretation of the law is left to the PBB as it develops practice (The New Pharmaceutical Benefits Bill, 2001:47). The responsibility is on the PBB to make decisions that can be publicly justified as being in accordance with the Agency's governing legislation.

When building practice, the PBB is instructed to adopt "a broad approach" (Ibid.:46), and take into consideration the three principles of priority-setting that were approved by Parliament in 1997, namely: equal human value, need solidarity and cost-effectiveness. Again, there are no detailed instructions about what it means in practice to take these principles into consideration.

[6] Prior to the creation of the PBB, a drug was included in the public pharmaceutical benefits scheme once it had been approved for use by the Swedish Medical Products Agency (or its European equivalent, the European Medicines Agency).

[7] Out-patient treatment refers to medical services that are provided to patients who are not hospitalized.

However, the Agency is explicitly encouraged to use health economic techniques for evaluating drugs (Ibid.). Furthermore, the law grants the pharmaceutical company marketing the drug in question the right to appeal the Agency's decisions to the administrative courts (Ordinance 2002:687, section 20).

6.2. The PBB: organizational structure and activities

The PBB is made up of two parts: the Board and the Bureau. These two entities have different structures, members and formal roles. The Board formally makes the decisions about pharmaceuticals' subsidization status. It has eleven members appointed by the government on personal mandates. Hence, the Board members do not formally represent any organization, professional group or political party. The selection of Board members is to be done in such a manner that their combined expertise reflects different interest groups within the healthcare sector. Present members include practicing general physicians, health economists, medical specialists, a medical ethicist, individuals with experience from patient organizations and county council health administrators.

The Bureau, meanwhile, undertakes evaluations of pharmaceuticals to support the Board in its decision-making. These evaluations are made in accordance with the Board's instructions, and the results are presented to the Board for consideration. The Bureau also authors the decision justification documents which justify the Board's decision outcomes. The Bureau employs approximately thirty individuals, many of whom hold doctorates in pharmacy or health economics.

The PBB's evaluations takes place in a broader context of regulation concerning various aspects of the use of drugs in Sweden. Notably, there is a separation between the PBB's evaluation of a pharmaceutical's subsidization status and the prescription of a drug in medical practice. The Agency is not responsible for providing patients with healthcare services. Nor does the PBB have budgetary responsibility for pharmaceutical spending, or any specific targets to fulfill as regards changing the level of pharmaceutical spending. Both the provision and funding of healthcare services are the responsibility of the regional county councils[8]. The choice of pharmaceutical treatment for an

[8] The twenty-one county councils finance the majority of healthcare services directly through an income tax levied on all county residents who are in paid employment.

individual patient is, in turn, made by her treating medical practitioner. Legislation grants licensed medical practitioners, in particular physicians, significant autonomy regarding treatment choice.

The following section will focus on the PBB's work practices when making decisions based on multiple sources of knowledge about pharmaceuticals' characteristics.

6.3. Using or producing knowledge when evaluating pharmaceuticals

The focus in the this account will be the activities of the stomach-acid group[9]. Three interrelated issues will be accounted for. The first section will outline how the stomach-acid group worked to determine which pharmaceutical usage to evaluate. The second section concerns debates within the PBB over how to evaluate the cost of pharmaceuticals, in particular their price. The third and final section discusses the PBB's use of "lack of urgency" as a justification for the denial of subsidy for a group of pharmaceuticals.

6.4. Which pharmaceutical usage to consider?

In the stomach-acid group, the question of which pharmaceutical usage to evaluate was raised in relation to the Board's instruction to take into account drugs' actual use, in order to evaluate the real costs and effects of usage. But to consider actual use was challenging in practice:

A first, generic problem that emerged in the stomach-acid group's evaluation work stemmed from the agreement among various sources that there was significant off-label prescription[10] taking place for certain products. The term

[9] The Agency evaluates the subsidization of two kinds of pharmaceuticals: those granted marketing authorization after the inception of the PBB, and those drugs that were included in the public pharmaceutical benefits scheme prior to the PBB's creation. The former are evaluated when applications for subsidy are submitted. The latter are initiated on the PBB's own initiative. The first reviews of drugs in the existing assortment – pharmaceuticals for treatment of migraine and stomach-acid related disorders – in October 2003. By mid-September 2008, the Agency had completed four of its planned forty-nine reviews.

[10] The term "off-label use" refers to prescriptions of registered medicines for a use that is not included in the prescribing information or that is disclaimed in the approved information. This includes use outside approved indication [medical condition], dosage, age and route.

"off-label use" refers to prescriptions of registered medicines for a use that is has not been formally approved. Hence, the usage in medical practice was not consistent with the formal definition of usage for which the drugs had received marketing approval. This posed a practical problem for the PBB when deciding which product usage to compare. The Agency had at an early stage interpreted its formal instruction to only allow for an evaluation of the formally approved treatment areas for a drug[11]. Yet, clearly off-label use generated costs in the same manner as approved uses. How was this incoherence between real use and formally approved use to be addressed?

A second problem was the specific suspicion that medical practitioners were prescribing a class of drugs called proton pump inhibitors (PPI) to patients that had "stomach-ache" rather than gastro-oesophageal reflux disease (GERD). These two conditions could have similar symptoms, but numerous sources[12] agreed that whereas GERD could be successfully treated with PPI, stomach-ache could not. The problem, as highlighted by the stomach-acid group's seconded medical experts, was the ambiguity which commonly arose in determining which patients had GERD and stomach-ache, respectively. The question, then, was whether – and how – the PBB should take the ambiguity of "treatable" patients into consideration?

The matter of off-label prescription was raised by the stomach-acid group and discussed within the PBB Board on several occasions. Eventually it was concluded that while off-label use was a real usage in medical practice, it was not coherent with the Agency's formal mandate to evaluate or even explicitly deny subsidy for such use. It was uncontested that off-label use was a source of real costs, since this type of prescription was also covered by the pharmaceutical benefits scheme. But the PBB chose to disregard off-label use, and instead define usage according to the drugs' formally approved treatment areas. The example of off-label use therefore illustrates how relevant knowledge about pharmaceutical use in medical practice was set aside when it interfered with the definition of use interpreted from the PBB's formal instructions. To privilege the PBB's formal instruction was necessary because of the need to justify decisions.

[11] In its first two decisions, the PBB denied subsidy for off-label prescription of two drugs.
[12] These sources included multiple clinical studies of pharmaceuticals' treatment effect, the drugs' SPCs and a recent knowledge overview issued by the Swedish Council on Technology Assessment in Health Care.

The aforementioned issue of off-label prescription took approximately a year to resolve. The second matter, concerning how the PBB should handle the ambiguity of treatable patients, remained an on-going concern until the stomach-acid group completed its work. One reason why the matter was subject to frequent and recurring discussion was the possible consequences of an evaluation reflecting differences in pharmaceutical treatment regimes for different medical conditions. Such a diagnosis-based evaluation could support decisions that would run counter to the legislators' explicit intentions of a product-based system[13]. A further concern was that a decision to place diagnosis-based restrictions on the subsidy of pharmaceuticals could require intervention in the behavior of medical practitioners. Members of the PBB Board were quick to point out that it was essential that any diagnosis-based restrictions avoided being "fussy", since the PBB had no means of forcing compliance with restrictions[14].

As a suggested means of addressing the suspected problem of inappropriate prescription, the project group proposed to the Board that subsidy be restricted to patients with a "confirmed diagnosis". One of the proposed means of diagnosing patients was to make subsidy of treatment of GERD contingent on a gastroscopic examination[15]. This suggestion was discussed several times by the Board. Ultimately, however, it was rejected. Informants noted that a key argument for this was that the PBB could not hope to standardize diagnostic practice[16]. For example, the PBB could not ensure access to the necessary diagnostic equipment. So while the difficulty of diagnosing "treatable patients" remained, it was delegated to medical practitioners to resolve. This was done by approving subsidy for the pharmaceuticals without any restrictions on which patients could receive subsidy for treatment.

There was broad agreement among informants that this was an appropriate course of action, since the PBB should not risk making decisions that became "a hard strike in the air"[17]. Thus, the example of GERD once again illustrates how the need to comply with the regulatory framework for the Agency meant

[13] The New Pharmaceutical Benefits Bill, 2001:37-38.
[14] Interview PBB Chairman of the Board, March 24 and June 28 2004.
[15] Gastroscopy is an examination of the inside of the esophagus (gullet) and stomach. It is performed using a thin, flexible fibre-optic instrument that is passed through the mouth.
[16] Interview project manager stomach-acid group, November 23 2005.
[17] Interview project manager stomach-acid group, February 6 2006; Interview PBB Chairman of the Board, April 5 2004.

that relevant knowledge about the matter was disregarded. Furthermore, the example illustrates how important ambiguity regarding the appropriate circumstances for prescribing a drug with subsidy was delegated to individual medical practitioners. This delegation also indirectly left the matter in the hands of the county councils employing the medical practitioners.

6.5. How to value price?

Another preoccupation in the stomach-acid group, aside from the characterization of pharmaceuticals' medical effects, was the financial consequences of use. In this section, we will focus on efforts to determine and evaluate pharmaceuticals' price. Informants agreed at an early stage that price was a critical matter, because of differences in the price within the same group of drugs[18]. But determining the price of a pharmaceutical was not straightforward as one might think. There was no single price for a drug. Rather, there were multiple prices for the same tablet, depending on factors such as package size, the timing of the PBB's evaluation relative patent expirations and whether prices changed due to the Agency's on-going review. Determining one price for a drug was therefore not a trivial matter. On the contrary, it required significant effort (see Sjögren, 2006). In addition to these problems with determining one price for each drug, the stomach-acid group was also faced with the matter of how to value differences in pharmaceutical price. This question became an issue because the stomach-acid group included both generic and brand-name pharmaceuticals within the class of drugs called PPI[19]. All the PPIs (with the exception of one product) had been deemed to have the same effect, as measured by a specific metric related to the change of stomach-acid level. Yet the cost per tablet for the PPIs varied by up to 300%. How should the PBB deal with these differences in price for pharmaceuticals with "the same" effect?

[18] Interview project manager migraine group, February 27 2004; Interview health economist stomach-acid group, March 23 2004.
[19] A brand-name or patented pharmaceutical is 'the first' drug of its kind. The patent(s) on the drug's active substance gives the patent owner the exclusive right to produce and sell or license production for the active substance. When a patent has expired, this exclusive right is lost and so-called 'generic' pharmaceuticals that contain the active substances can be introduced.

In the process of addressing this matter within the PBB Bureau and Board, the argument was put forth by some of the pharmaceutical companies that a direct comparison of generic and brand-name pharmaceuticals' price was not coherent with the intentions of existing patent legislation. Specifically, the argument was that a direct comparison would limit pharmaceutical companies' ability to recoup research costs through higher prices[20]. Members of the PBB Board also noted other possible negative effects of a direct price comparison. One undesirable outcome was a decreased level of competition. Since the branded drugs typically had higher prices, a direct comparison would result in them being denied subsidy. Such an outcome could lead to higher prices, if only products with the same active substance where included in the pharmaceutical benefits scheme. To remove all but one kind of treatment would also limit the therapeutic choice for patients. Future medical research could also be threatened if only the cheapest product(s) in the stomach-acid group were subsidized[21]. These possible negative consequences of a direct comparison needed to be weighted against the PBB's mandate to evaluate "value-for-money".

Several attempts were therefore made by the stomach-acid group and the PBB Board to formulate an appropriate "decision rule" that addressed the principally important issue of how to take patents into consideration. Following a few unsuccessful proposals by the stomach-acid group, where the PBB Board was unable to reach an agreement, it was finally agreed that products with the same effect were to be removed on the basis of a maximum price differential. Specifically, the suggestion was that pharmaceuticals within the stomach-acid group with "the same" treatment effect could not be priced at more than 25% of the cheapest pharmaceutical.

Allowing for variation in the price of different products with the same effect would secure a diversity of products used to treat stomach-acid disorders[(I)]. The price tolerance also gave pharmaceutical companies some compensation for differences in treatment effect that were not captured by the chosen comparison metric. The choice of this particular metric – which measured changes in the level of stomach-acid concentration – did not reflect other differences that the PBB recognized to be relevant in medical practice. For example, the speed of treatment effect was not considered. The principle of price tolerance therefore sought to compensate the producers for the fact that

[20] Recounted in interview with project manager stomach-acid group, April 22 2005.
[21] Interview health economist stomach-acid group, December 17 2004.

the PBB's choice of a single metric inherently meant not measuring all relevant pharmaceutical characteristics. At the same time, the tolerated price differential between similar products was limited.

However, it is notable that a particular price at which a pharmaceutical would be approved subsidy was not set by the PBB. The cost of the cheapest drug could fluctuate; this was delegated "for the market to decide"[(II)]. In other words, the PBB judged that it was reasonable to subsidize all pharmaceuticals that cost up to 25% of the cheapest product. But the Agency did not take into consideration what the possible financial consequences of this decision. Thus, the aforementioned example points to a principle gap between the PBB's evaluation of a reasonable cost of use and the feasibility of paying for potential increases in price, on the part of the county councils.

6.6. Whether to judge urgency?

The final example concerns the PBB's evaluation and decisions concerning a class of drugs in the stomach-acid group called the H2-blockers. During most of the study, these products were not a central topic of debate. One possible explanation for this is their relatively smaller cost, as compared to the aforementioned PPIs[(III)]. The H2-blockers were an earlier generation of treatment that had been largely replaced by the PPIs. Various sources suggested that most patients with stomach-acid related disorders were now treated with PPIs, since the H2-blockers tended to provide a lower level of medical effect. Nevertheless, it was acknowledged within the stomach-acid group that certain categories of patients could receive adequate treatment with H2-blockers. If these patients were prescribed H2-blockers rather than PPIs, then their cost of treatment was significantly lower. At the same time, the evidence suggested that the patients who received adequate treatment with H2-blockers had less severe forms of diseases caused by stomach-acid. The question that the stomach-acid group and the PBB Board had to resolve was: how should the "sufficient effectiveness" and lower price of the H2-blockers be valued against the higher price but also greater treatment effect of the PPIs?

When the PBB released its final report and attendant decision justification documents for the stomach-acid group, the H2-blockers were all denied subsidy. These decisions were justified on the grounds that conditions for which the H2-blockers were cost-effective treatment alternatives gave rise to a small

loss in quality of life. Thus, the treatment was not urgent enough to be publicly funded:

> For diseases caused by excess stomach acid it is crucial that more serious diseases are treated with medicines with more powerful suppression of stomach acid production so that the treatment outcome can become satisfactory. The opposite is also true that a satisfactory treatment outcome for milder conditions can be achieved with a less powerful drug [...] H2 antagonists can therefore be a cost-effective treatment alternative [...] in the treatment of milder conditions of heartburn. We however believe that for illnesses where treatment with H2 antagonists could be an option, the disease gives so small losses in quality of life that the treatment should not be reimbursed (PBB, 2006:15-16).

In other words, the denial of subsidy for the H2-blockers hinged on the definition of certain medical conditions as outside the scope of public responsibility. It was not solely premised on the characteristics of the drugs' medical and economic effects relative other treatment alternatives within the stomach-acid group of drugs.

The PBB's decisions concerning the H2-blockers were appealed to the Stockholm County Administrative Court by the marketing pharmaceutical companies. In its subsequent rulings, the Court upheld the Agency's argumentation on the grounds that less severe forms of heartburn and acid reflux give rise to small losses of quality of life. Thus, it is reasonable that the treatment not be subsidized by the state.

The Court's ruling confirmed the PBB's right and capacity to judge that a medical condition is outside the scope of public responsibility on the grounds of lack of urgency. Furthermore, the Court's ruling also explicitly supported that the Agency followed necessary procedural requirements, notably the requirement for «a statement of reasons based upon objective and verifiable criteria» when excluding a pharmaceutical from the pharmaceutical benefits scheme (Article 7, Council Directive 89/105/EEC).

Thus, the issue of the H2-blockers gives an example of the broader scope of priority-setting considerations which the PBB can make in the course of its work. Clearly, the Agency is in practice not limited to mechanically calculating whether or not pharmaceuticals fulfill the legal criteria of a reasonable cost of use. The PBB's decision to deny subsidy for the H2-blockers rested in part on a judgment regarding the urgency of a few medical conditions. Yet determining where to set the boundary for public fiscal responsibility for treat-

ing a medical condition is arguably a matter which might be a relevant issue for political consideration.

7. Discussion

The previous illustrations, drawn from the PBB's work to evaluate the subsidization status of a group of drugs, highlights instances where knowledge claims about important pharmaceutical characteristics such as use and price were contested or ambiguous. These instances of contestation and ambiguity were a result of different circumstances, such as incoherence between the assumed characteristics of drugs in different formal rules within the healthcare sector. It was necessary for the PBB to resolve each instance of incoherence, in order to have a coherent knowledge base with which to justify its decisions. Thus, the examples show how decision-able knowledge was something that the Agency needed to produced, rather than mechanically compile and then use.

In the process of producing both decision-able and justifiable knowledge, the PBB can be seen to privilege certain knowledge claims while excluding others, and to delegate certain ambiguities of knowledge to be resolved elsewhere (often in medical practice but also, in at least one case, to the market). In producing knowledge and making its decisions, the PBB can be seen to more or less directly intervene in matters that have a larger political importance. For example, whether a medical condition is urgent enough to merit public fiscal responsibility is arguably a political matter. How to value patents when comparing the cost and effects of pharmaceutical-based treatment alternatives can also have implications for areas outside the pharmaceutical benefits scheme, such as research policy. Similarly, the budgetary impact of the PBB's decision to subsidize pharmaceuticals without any formal restrictions is of direct concern for the county councils, and their elected politicians.

The broad potential implications of the PBB should not be taken as evidence that the PBB made inappropriate decisions in the aforementioned case of the stomach-acid, or could have gone about its evaluation in a different way. Knowledge is not an inherently coherent, uncontested and neutral resource. Furthermore, the PBB is situated in a wider regulatory environment. Thus, the crucial point is that the institutional arrangement of the Agency's

decision-making activities has consequences, which go far beyond the technical implementation of a policy initiative in line with legislators' intentions.

In other words, our argument is that the organizational structure, task and control of the PBB limit the Agency's means for fulfilling the rationalistic demands for both knowledgeable and justifiable decision outcomes, which are presumed. The Agency is supposed to be governed through MBOR, using objectives and various formal steering documents. However, as has been shown in the study, the formal organizational structure, task and control shape the mandate of the Agency with various unintended consequences. One important conclusion is thus that the government also steers through organization. However, this does not take place in a coherent and conscious way. For example, the Agency is not equipped with the organizational tools to ensure that all relevant knowledge may be taken on board and considered. That is to say, many relevant matters are placed outside the control and consideration of the PBB. Concurrently, many matters within the PBB have been organized outside of external parties' control, since the Agency develops practice continuously when it interprets principles into practice. Notably, the PBB's decisions have considerable potential consequences for the county councils, since they bear the costs for the pharmaceutical benefits scheme. Yet the county councils have no formal avenues of influence on the activities of the Agency. Since the PBB is organized within the traditional governmental structure of an agency, it is not controlled or linked to one of its most important stakeholders, which represent the regional political majorities.

Is, then, the example of the PBB relevant for efforts to realize quality in policy implementation?

8. Conclusions

The example of the PBB suggests that attempts to transform Swedish welfare politics into uncontroversial calculations is failing. The intention behind the creation of the PBB was to scientifically underpin decisions about pharmaceutical subsidy, on the assumption that this involved the compilation of knowledge. The failure to realize this ambition has to do with the aforementioned institutional arrangements but also with the characteristics of knowledge, which together limit the possibility of achieving coherent and objective evidence on which to make and justify decisions. Knowledge about pharma-

ceuticals medical and economic effects is routinely ambiguous and uncertain. This makes it necessary to negotiate a coherent and decision-able knowledge – rather than merely compile it, as posited by rational choice-based models. Yet the governing of the Agency is done according to a model, which is built on precisely this idea. Hence, the transparency and predictability of what the Agency is actually doing is limited, since much of the activities are not described in the control documents. So, while seeking to fulfill values of transparency and accountability that are characterized as important QoG values, the deployment of NPM-strategies limits their fulfillment as politically charged decisions about societal priority-setting are masked as neutral administrative choices.

A further, perhaps more surprising conclusion, is that procedural and substantive rules contribute to making it more difficult for politicians to actually govern and control priority-setting. In the case of the PBB, this is because many of the choices regarding pharmaceuticals' subsidization status are de facto delegated to local medical practitioners or the market. Taken together, this risks depriving politicians at different levels of government of tools for making priorities about how and where collective resources should be spent. This can in turn limit the democratic anchorage of welfare policies, and decrease the capacity of the political system as a whole to realize the many politically decided goals for the healthcare sector, including quality, equality and value-for-money. Of course, the precise consequences of particular arrangements will vary depending on the political system in question. A UK-based study which accounts for the visible and protracted public conflicts over decisions by NICE (now National Institute for Health and Clinical Excellence) to deny subsidy for dementia drugs, clearly illustrates that attempts at depolitization of resource allocation decisions do not always succeed (Moreira 2008). In this case, alternative avenues were used for addressing the political concerns raised by NICEs work. This experience contrasts markedly with the Swedish example set out in the present paper. To date, the work of the PBB has garnered very limited public and political attention. This could be taken as an indication for the particular relevance of making explicit the circumstances and functioning of this organizational arrangement.

Is, then, the example of the PBB relevant for efforts to evaluate quality in policy implementation?

Audit as politics-in-practice. As mentioned above the two strands of thought labeled NPM and QoG both rely heavily on the notion of using

knowledge-based tools for measurement in the evaluation of activities. However, the evaluation of policies may in itself contain regulatory powers and could thus be considered as a type of policy making (Power, 1997). The so-called audit explosion with a growth of both public and private auditing organizations such as OECD, the European Commission, Transparency International and Amnesty International has provided an immense field of study for those interested in the production of indicators for measuring the performance of states (Brunsson, Jacobsson, 2000; Barnett, Finnemore, 2004).

Many scholars pursing that path have been inspired by Power and his view on how auditing may become a regulatory activity, providing tools of power for those lacking formal authority in the political processes at hand (Djelic, Sahlin-Andersson, 2006; Dahl, 2007). The measurement and audit of public organizations in numerous areas orient action and create social reality, it is party to construction what a well functioning and high quality public organizations should look like (Finnemore, Barnett, 2000). In light of such results, it thus becomes problematic to treat the expert reports, rankings and indicators produced by evaluators as objectively describing the performance of public organizations. The evaluation of public policy carried out by various organizations and researchers can hence be seen as a practice through which states are regulated.

The stream of research on good governance more broadly measuring the quality of public organizations from a number of normative ideals defined in terms of democracy, rule of law, efficiency or effectiveness also encompasses a certain degree of regulatory measures. Those who evaluate the quality of government are therefore party to constructing what an appropriate administration should look like, through their choice of evaluation metrics. As has been illustrated by the case of the PBB, knowledge-based assessment not only involves compiling knowledge – it also encompasses the production of knowledge. In other words, what characterizes quality of government is constructed in the production of evaluations about good governance. Presenting and describing the quality of activities in a particular way does not merely account for the results of the reforms, it is also party to constructing what can be perceived as a good government reform (Dahl, 2007). This is an important matter for consideration, given the formative consequences of evaluations, where best practices become models to imitate for states in transition.

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(II) Interview health economist stomach-acid group, November 23 2005.
(III) The PBB final report on the stomach-acid group review noted that the most recent sales statistics, covering the period October 1 2004 to September 30 2005, gave a total sales value of 900 mSEK (~94 mEuro) for the whole group. Proton pump inhibitors accounted for 93 percent of the sales value (approx. 825 mSEK), while the sales value of H2-blockers amounted to 45 mSEK (PBB 2006:33).