Institutional Dynamics and Bureaucratic Agencies: Adoption of Health Technology Assessment (HTA) in the Western Balkans

By

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Declaration of Authorship

I hereby certify that this thesis has been composed by me and is based on my own work, unless stated otherwise. No other person's work has been used without due acknowledgement in this thesis. All references and verbatim extracts have been quoted, and all sources of information, including graphs, have been specifically acknowledged.

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Abstract

The proliferation of health technology assessment (HTA), policy of evidence-based evaluation of health care technologies, has not bypassed Western Balkans, with Croatia pioneering institutionalized HTA in 2009 by establishing a national HTA agency. However, other countries did not follow, most of them still lacking institutionalized HTA. Assuming that implementation of HTA is a type of gradual institutional reform, where existing bodies within the healthcare sector represent main opponents, a comparison was made between Croatia and Serbia (which has not successfully institutionalized HTA despite some initial momentum). Timeline of the most important events was reconstructed using the method of episode analysis, in order to identify key mechanisms of (non-)adoption. Analysis confirms initial assumption that Serbia failed to establish formalized HTA because of the structural and actor-based opposition coming from the bodies within the healthcare system. It also demonstrates that Croatia managed to overcome this opposition most probably due to the external pressure related to EU integration. However, it also shows that Croatian HTA agency is, in fact, very weak and ineffective, and that pre-existing bodies within Croatian healthcare system have managed to retain all their prerogatives.

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Contents

List of figures

List of abbreviations

AAZ – Agency for Quality and Accreditation in Healthcare (*and Social Welfare*) (Croatia)

ALIMS - Medicines and Medical Devices Agency of Serbia

CDC – Central Drug Committee (Serbia)

CEE – Central and Eastern Europe

EUnetHTA – European Network for Health Technology Assessment

HALMED - The Croatian Agency for Medicinal Products and Devices

HAS – National Health Authority (France)

HTA – Health technology assessment

HZZO - Croatian Health Insurance Fund

NICE – National Institute for Health and Care Excellence (UK)

OTA – Office of Technology Assessment (USA)

QHA - Quality of Healthcare Act (Croatia)

QUANGO – Quasi-autonomous non-governmental organization

RFZO – State Fund for Health Insurance (Serbia)

SBU - Swedish Agency for Health Technology Assessment and Assessment of Social Services

WB – The World Bank

WHO – World Health Organization

1. Introduction

The challenge of welfare state reform is recognized as one of the main issues in the functioning of welfare states today, and this is an especially important issue for healthcare systems and their services, which are "the biggest single consumer of resources in modern welfare states", if cash transfer programs such as public old-age pension funds are excluded (Pierson 2001, Moran 2000:138). The need for increasing healthcare efficiency (or "performance") in order to manage the rising costs and resource constraint has been recognized as a major task for countries throughout the world by the World Health Organization (WHO) (Murray and Evans 2003, WHO 2011). This has led to the emergence of new and innovative policy solutions whose main focus is the economic optimization of the functioning of national health systems, which are gaining ground mostly in the developed countries of the world. An example of these policies is a widely relied on way of dealing with the price-quality tradeoff in healthcare - the introduction of the health-technology assessment (HTA), the "systematic evaluation of properties, effects and/or influences of health care technology" (Hailey et al. 2014:1).

The term HTA can have several different meanings depending on the context of use, and one of them is HTA as a specific type of bureaucratic agency within the health system. These agencies employ different types of experts and use their (presumably) evidence-based opinions to produce credible and standardized information which can be used to make better decisions on the allocation of scarce resources in healthcare, especially when it comes to large-scale investments in new technologies and pharmaceuticals reimbursement decisions (Löblová 2016a, Huić et al. 2017). HTA as agencies, i.e. bureaucratic organizations within the healthcare systems (usually in the form of QUANGOs – quasi-autonomous non-governmental organizations; see Cavazza and Jommi 2012) are the main subject of this thesis, since their organizational nature (in the sense of

North 1990) makes them suitable for analysis from the perspective of positivist-oriented political science.

The proliferation of HTA agencies is a clear example of policy transfer, the mechanism when policies "travel" across borders, i.e. one country's policy choices affect other country's policy choices (Obinger et al. 2013, Löblová 2016b:27-29). The area of welfare state reform is a typical example of this phenomenon, since countries which are in need for such actions often implement the policies which have proven to be effective (or avoid the ones which are considered ineffective) from other countries, usually the ones with whom they share borders, region or sociopolitical characteristics. The particular case of HTA agencies dissemination is a clear subtype of the policy transfer mechanism that Obinger et al. (2013:14) have termed "*transnational learning process*". Since the confrontation of European healthcare systems with increasing healthcare costs is pressuring them to become more efficient, they try more and more to draw lessons from other countries and implement their solutions, which are considered effective (typical examples are the policies dealing with containing the cost of pharmaceuticals; see Novaković 2016). HTA is a great example of a policy so popular that its proliferation has been even faster than the proper and systematic evaluation of its results, so some authors are even talking about HTA "success bias" (Löblová 2016b:38). Nevertheless, policy diffusion often faces impediments, both institutional and actor-based, and in the case of HTA agencies there are examples of "non-adopters" – the countries which have not instituted formal HTA agencies – all over Europe, from Luxembourg and Czech Republic to Serbia and Bulgaria. The opinion of the so-called "laggard hypothesis", that the countries have merely not adopted the policy *yet* but they eventually will, is becoming increasingly problematic (Löblová 2016b:18-19). The diffusion of policies is not something that happens spontaneously – it is almost always mediated by politics and it should be looked upon as a political

process. Since the focus of this thesis is on the Western Balkans, the main question it addresses is: why have some countries in this region established HTA agencies, while others have not? Through what political process does the establishment of a national HTA agency take shape or fail to do so, and why?

To answer these questions, this thesis presents an empirical investigation in the form of a case study of the two largest (both in terms of area and population) Western Balkans countries – Serbia and Croatia. As the largest and the second-largest market for healthcare in the region, both states share many characteristics which makes them suitable for comparative health policy analysis. First of all, they share the legacy of the Semashko model of healthcare dating back to the Yugoslav Federation, which both Serbia and Croatia were the part of. Second, both countries have Bismarckian welfare systems, i.e. mandatory public insurance-based healthcare systems with similar organization (Bambra 2007, Jakovljević 2013). Furthermore, countries are relatively comparable in population, health behavior habits and the structure of the healthcare system, which is in both cases heavily centralized. Croatia is richer than Serbia, with 1,656 US$ PPP healthcare expenditure per capita in 2015, compared with the Serbian 1,323 US$ PPP (World Bank 2018). On the other hand, Serbia has been consistently spending approximately 2% more on healthcare since 2002 measured as percentage of GDP, which points to the big inefficiencies in Serbian healthcare (as of 2015, Serbia has spent 9.4% of GDP on healthcare, while Croatia has spent 7.4%) (World Bank 2018). It is also worth noting that mean life expectancy in Croatian is 3 years longer than in Serbia, averaging 78 years in 2016 compared to Serbian 75.2 years. A report from The Economist Intelligence Unit (2016), titled "Modernizing Health Systems in the Balkans: Uneven Progress" has identified the lack of HTA agency as a major source of inefficiency in Serbian healthcare, mainly because access to treatment for patients that need innovative drugs is limited –

Serbia is significantly slower in approving new medication than most of the countries in the region. For example, from 2010 to 2012 Serbia has approved only one out of the 139 drugs which were given permission for sale, while at the same time Bulgaria has added 44 drugs on its list, and Croatia 27 (Brkić 2016). This is important if one bears in mind two facts – that Croatia established its HTA agency in the summer of 2009 and has been developing HTA ever since, with mixed results (Huić et al. 2017, Respondent 2 2018, personal communication, May 25), and that Serbia has been in the process of institutionalizing HTA at least since 2005, with the small community of experts advocating for it, but with no formally established agency yet (Jakovljević et al. 2011, Löblová 2016b). Within the existing institutions with HTA competencies, Serbia lacks technical support and cooperation with the European agencies and suffers from chronic corruption problems (The Economist 2016:21). These two countries, therefore, present themselves as excellent cases for comparison exploring the reasons for which HTA is or is not adopted in post-Yugoslav contexts as a part of the healthcare system reforms.

The most important findings of this thesis are: (1) the pre-existing (i.e. the ones that exist prior to the establishment of HTA agency) bureaucratic bodies are key actors in the political process of establishing HTA, which is a type of gradual institutional reform; (2) these bureaucratic bodies are extremely path-dependent and generally hostile to any reform (as demonstrated in the case of Serbia), unless their incentive structure changes exogenously (like in the Croatian case); and (3) even if institutional reform takes place, it does not guarantee that the new arrangement will produce efficient results, but more likely the opposite. Functioning of the Croatian HTA agency provides a good illustration for this claim.

The thesis provides a number of contributions to the existing literature on HTA implementation and healthcare system reform in transition countries in general. First, it provides

insight into the mechanism of institutional change and the impediments that pre-existing conditions, both structural (the type of healthcare financing, the coherence of different bodies within the system) and actor-based (reform opportunism) pose for the prospects of institutional change. The conclusions may be relevant for exploring bureaucratic reform as well as policy reform (and their entanglement) in the healthcare sector. Second, it provides novel and detailed insight into the process of the adoption of HTA in two Western Balkans countries. Third, it further explores the role of international organizations in ongoing healthcare reforms in CEE. Fourth, its practical and policy insights are very important for all policymakers and future reformers who want to familiarize with what they can expect to face in Bismarckian, centralized post-socialist welfare state contexts.

2. Literature review

As a relatively new phenomenon, the health-technology assessment (HTA) literature is growing rapidly, with the topic being explored by a wide spectrum of experts, from medical doctors and pharmacologists to political scientists and policy scholars (e.g. Banta 2003, Philips et al. 2006). HTA agencies serve multiple functions within the healthcare system, among which are the provision of scientific advice to different bureaucratic and political bodies, evaluation of the therapeutic and economic value of new therapies and medicines, determination of the reimbursement rate for new medicines and treatments and all kinds of public consultations and dissemination of new health, healthcare and health administration data (Allen et al. 2013). It is also important to emphasize that these agencies are intertwined with other relevant actors within the healthcare system, such as other regulatory agencies, academic institutions and public healthcare funds, which might shape the dynamics of their establishment and evolution.

2.1 History of HTA implementation

The first body dealing with HTA in the world was the US Congressional Office of Technology Assessment (OTA), established in 1972 (Banta 2003:123). It performed assessment of health technologies based on cost-effectiveness, among which were some groundbreaking developments in health technology, such as the computer tomography (CT) scanner. However, Reagan-administration Republicans were never fond of the agency, deeming it unnecessary since the 1980s, and it was defunded and shut down by the Republican-dominated Congress in 1995. Nevertheless, the concept of HTA gained ground in Europe, and the first national-level HTA agency was established in Sweden (Council on Technology Assessment in Healthcare in 1987). Other countries followed, and in two waves in the 1990s and mid-2000s most of the Western European countries adopted some form of HTA (Löblová 2016b:16). Outside of Europe, however,

HTA bodies are still rare, but there are examples: faced with financial constraints and market pressures, Colombia transitioned from health sector reform to the establishment of an HTA agency in the process which involved all three branches of government (presidential decree laying out framework, Parliament passing the laws and Constitutional Court ordering judicial action) (Vargas-Zea et al. 2012). Another example is Thailand, which has not only established its own HTA body (Health Intervention and Technology Assessment Program, founded in 2007), but it also assists other, less developed countries (such as Myanmar and Vietnam) in their HTA programs (Tantivess et al. 2017).

A considerable group of scholars have devoted their attention to the implementation of HTA in Central and Eastern Europe (CEE), where the implementation of the policy has had more heterogeneous outcomes, with a few countries which have introduced it and the majority which have not (Moran and Fidler 2010, Gulacsi et al. 2014, Löblová 2016a, Kaló et al. 2016). For instance, a typical example of the HTA success story among the CEE countries is Poland, which established its HTA agency in 2004, after a long period of advocacy by a few idealistic individuals, and it has since played an important role in solving many issues within the Polish health system, especially when it comes to reimbursement decisions (Nizankowski and Wilk 2009). Alongside with Poland, only Hungary, Latvia and Croatia have formally established HTA agencies in the CEE group (Löblová 2016a:257). An interesting question to be raised here is the paradox of HTA implementation in CEE countries. Namely, the CEE countries, which are poorer and thus under bigger pressure to make their health systems more efficient, would benefit comparatively much more from establishing HTA agencies than their Western European counterparts, but CEE countries (or low and middle-income countries in general) are still less keen on putting such

agencies in place. This paradox might have multiple explanations, which are closely connected to the dynamics of HTA adoption, discussed later in this chapter.

2.2 Typology of HTA agencies

It should be noted that HTA agencies, as independent bodies within the healthcare systems which perform unbiased, evidence-based, scientific assessment of health technology, are just "ideal types". In reality, there are many subtypes, with a large degree of heterogeneity, among the organizations that are labeled as such (Allen et al. 2013). These agencies across Europe (and a handful of countries in the rest of the world) have different amounts of institutional power and independence, with some independently making decisions themselves (UK's National Institute for Health and Care Excellence, - NICE and the Swedish SBU) and others having a merely consultative role (German Institute for Quality and Efficiency in Healthcare) (Löblová 2016a:255). This division is sometimes referred to as "light" vs. "heavy" HTA – while "light" agencies only control the analysis submitted to them by a third party (for example, a pharmaceutical company which already had assessment performed in another country for a particular product), "heavy" agencies assess the technology using their own capacities, for their own national context (Atanasijević and Rikanović 2009). This implies that "heavy" HTA agencies are much closer to the ideal type, but also much costlier to set up and operate (at least in the short run). Furthermore, different HTA bodies have different reimbursement procedures, and there are big differences in market and patient access for new drugs which can partially be explained by the differences in HTA processes (Akehurst et al. 2017).

Another source of variety is whether they are standalone bodies or a part of a larger organization (e.g. HTA Scientific Advisory Group within the Irish Health Information and Quality Authority), and also the difference in productivity and engagement with other bodies (Löblová

2016a:255). The place of the HTA agency within the network of akin organizations makes a huge difference in its output, functioning and overall significance, which are criteria highly relevant for the posed research questions. Whatever the differences are, what they all share is that all of them are at least somewhat *independent public bodies* which provide expertise on healthcare spending, health economics and procurement decisions. This type of operationalization, with it's broad inclusion criteria, allows for comparison of bodies which at first seem unalike – even if HTA is not the primary object of some agency, it can be considered an HTA agency if at least one of its subcommittees fit the aforementioned description.

2.3 Why do countries adopt HTA?

There are many factors which can influence the process of HTA agency adoption, such as the necessary resources, the external influences, changes in bureaucracies and many others (INAHTA 2014:15), but the main question of interest for this thesis deals with the decision-making process which leads (or not) to the establishment of the formalized HTA in the first place. While the policy diffusion argument can explain the proliferation of HTA agencies in Western Europe, there is still a puzzle of the non-adoption of the HTA among the CEE and the majority of non-European countries. The literature identifies several possible reasons for non-adoption of the HTA agencies, but the precise mechanisms are rarely properly developed. The impediments to diffusion of HTA coming from structural theories, such as the degree of centralization of the healthcare system or the Bismarck vs. Beveridge cleavage, have been discredited (Löblová 2016a). One possible explanation for non-adoption in the CEE and low- and medium-income countries might be that such countries face more serious issues, which makes HTA adoption lower priority. Another one could be found in the resistance coming from the key domestic actors, or the diffuse nature of benefits that come with the HTA to the most policymakers (they cannot see the immediate

benefits of HTA, while the costs are always evident). Some authors suggest that the crucial argument might be the lack of funds or experts needed for implementation, but this argument, both in terms of financial and human resources, has also been demonstrated to be weak (Löblová 2016a:260). Others point to the vested interests of powerful actors, which have the incentives to preserve the status quo, making such actors the key factor for non-adoption (Kaló et al. 2016). This argument can be further developed using the concept of "statist bureaucrats" prevalent in post-communist countries, who make political actors compromise when reforms take place (Adascalitei 2012). They prevent reform and play an important role in the development of social policies in CEE, and often demand to be compensated if the particular change within the system hurts them (so-called *compensation hypothesis*) (Adascalitei 2012:65). This type of behavior can at least partially explain the variation in timing and scope of reforms across CEE. Furthermore, there are authors who point to the remnants of the former centrally planned socialist states, claiming that their legacy makes the system poorly responsive to the real population needs, leading to the lack of evidence-based resource allocation even with potentially greater budget impact of the cutting-edge technologies (Jakovljević 2015). The role of international organizations should also not be overlooked, since many international and supranational (such as the EU) initiatives are linked to development agendas – promoting access to products that would otherwise be unaffordable, such as new medicines, and prioritizing products which have major public health impact (Novaković 2016). The absence of those initiatives can be a part of the explanation of why non-adoption occurs.

Finally, in the most systematic study of the non-adoption of the HTA agency, the main mechanism which explains non-adoption is the influence of epistemic communities on decision-makers (Löblová 2016b, Löblová 2018a). In this study, epistemic communities are defined as

"networks of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy relevant knowledge within that domain or issue-area. Although an epistemic community may consist of professionals from a variety of disciplines and backgrounds, they have (1) a shared set of normative and principled beliefs […] (2) shared causal beliefs, […] (3) shared notions of validity […] in the domain of their expertise (4) a common policy enterprise" (Haas, 1992:3).

Using the examples of the Czech Republic and Poland, the author constructs a mechanism of policy influence in which epistemic communities go from beliefs and policy promotion to consolidation of bureaucratic power and policy adoption by the decision-makers. According to this approach, the HTA agency in the Czech Republic was not established because of the major interruption of the mechanism of influence when the Czech government fell in 2013 (Löblová 2018a:174). This breaking of the causal mechanism made the epistemic community lose their influence and power to change existing policies afterwards. The conclusion was corroborated by the lack of decision-makers' "policy demand" in the following period, where path-dependency won over epistemic community influence (Löblová 2018a:181).

2.4 Bureaucratic approach to the (non-)adoption of HTA

While the epistemic communities approach certainly has many merits, this paper will put emphasis on the role of already existing agencies, actors within them and their interests, which could be much more suitable for explaining different outcomes in Serbia and Croatia. While noticeable HTA epistemic communities existed (and still exist) in both countries (Löblová 2016b:51), their influence might be marginal compared to the existing agencies within the healthcare systems, so predominantly focusing on their activity instead of epistemic communities might be a more fruitful research effort in this particular case. It is not always easy to draw the line between the agents within agencies and the epistemic community, since we can expect that some of the members of the epistemic community (as defined by Haas) have their place within the existing agencies. Still, there is a fundamental difference between the two groups – the difference

in interests. According to the typology presented in Banta (2003), actors within agencies in the healthcare system can be classified either as *policy-makers* or *payers*. While epistemic community members are necessarily for HTA implementation, both policy-makers and payers may have positions both in favor and against HTA agencies. On the one hand, an HTA agency provides budget control, real expertise and opportunity for blame-avoidance in case of unpopular decisions, but on the other hand it might make existing agencies lose their competences and privileges, in accordance with bureau-maximization and power-maximization principles (Banta 2003, Mueller 2003).

Furthermore, this focus on the actors within existing bureaucratic agencies in the central healthcare administration instead of epistemic communities has an additional benefit. Having in mind that these *bureaucrats* are the main catalysts for the adoption of a new agency, the establishment (or non-establishment) of the agency can be considered as a type of institutional change and thus examined through the frame of institutional theory, which is the approach taken in this thesis. In order to explain why Croatia has managed to establish an HTA agency, while Serbia has not, we need to examine the dynamics within the existing agencies which make the fragmented patchwork of bodies with HTA competences. The lack of focus on the existing bodies is a major flaw of the approach based on epistemic communities[1], and inclusion of this view will probably offer new, valuable insights. It has been demonstrated that HTA is not something that appears out of thin air – there are procedures and practices which are performed by various agencies in the domain of HTA even without the formal HTA agency, practices like regulation of new interventions and pharmaceutical reimbursements (Löblová 2018b).

[1] This opinion was also supported by Löblová in our personal correspondence on 14 May 2018.

2.5 Status of HTA in Serbia and Croatia

In the particular cases which are the focus of this thesis, Serbia does not have a formal HTA agency, but it has multiple agencies in this domain with relatively similar competences like *The Medicines and Medical Devices Agency of Serbia*, the *Serbian Pharmaceutical Chamber* or the *Agency for Accreditation and Continuous Quality Improvement of Health Care*. Their role and position within the healthcare system will be further explored in Chapter 5. However, when it comes to the implementation of HTA in the country, the literature is very scarce: so far, there are a few published scientific papers on the prospects of the implementation of HTA in Serbia, one in a relatively obscure Serbian journal (Atanasijević and Rikanović 2009) and another, more recent one (Atanasijević and Zah 2017), which offers a comprehensive review and outlines the current trends in HTA development and conducting in Serbia. A short overview of HTA in Serbia, with emphasis on medical devices, was also offered by Djukić (2010). There are also papers analyzing Serbian healthcare system which deal with HTA indirectly (e.g. Jakovljević et al. 2011), and also one in a Hungarian periodical (Zah 2011). Other materials on Serbian HTA available in English are mostly lectures from pharmacoeconomic-related conferences (Brian 2015, Atanasijević 2012). All these publications mostly describe different HTA procedures and state the need for further development, but there is no much discussion on the *reasons* for the lack of formalized HTA.

In contrast, Croatia has an established HTA agency since 2009, but it also has a multitude of bodies which perform HTA-related functions, which predate the establishment of the agency. For example, *The Croatian Agency for Medicinal Products and Devices* (HALMED) was established in 2003, and it still performs some HTA-related functions (see section 5.1.1). Scholarly literature on Croatian HTA, it's establishment and functioning is somewhat larger than Serbian, but not drastically. Due to the existence of a national HTA agency, Croatia has a somewhat more

vibrant community of HTA experts, who regularly publish on the topic. Mittermayer et al. (2010) provide a timeline of crucial events in the development of Croatian HTA, while Huić et al. (2017) reflect on the HTA activities in a more recent periods. Both papers are very similar in structure, but comparing them provides important insights into the development of Croatian HTA over time, which will be further explored in Chapter 5. What is also important to add is that many international scholars also write on the topic of Croatian HTA, since the Croatian agency is a member of important international HTA bodies, which allows for comparison (e.g. Hulstaert et al. 2012, Guegan et al. 2014, Pavlović et al. 2014).

To sum up, the main goal of this chapter was to illustrate the development of HTA and to present different explanations for HTA adoption, with a short overview of the literature on Serbia and Croatia. My choice to focus on the role of existing bureaucracies was validated by arguments which demonstrate that HTA *sectors* within the health system transform from heterogeneous decision-mechanisms into a formal agency, and understanding this process is the main prerequisite for answering the posed research questions.

The theoretical framework for explaining the institutional change (based on "new institutionalist" theories) such as the establishment (or the lack of one) of a new agency will be presented in the following chapter.

3. Theoretical framework

The dominant paradigm in explaining the establishment, existence and change of institutions in political science is the "new institutionalism", with its three “traditional” schools of thought (historical institutionalism, rational-choice institutionalism and sociological institutionalism) (Hall and Taylor, 1996) and, a relatively new addition in the form of “discursive” institutionalism (Schmidt 2010). When it comes to analytical tools, one key concept in historical institutionalism are events called "critical junctures", brief phases when institutional change is possible after a long period of stability due to the relaxation or disappearance of usual constraints on actor’s’ agency (Capoccia and Kelemen 2007). This concept, alongside with path-dependency, is the main building block of any institutional explanation for institutional change (and non-change or stasis) (Pierson 2000, Schmidt 2010). However, the division between the schools is not and should not be considered very strict, since each of the approaches is better than the other in pointing out the certain elements of institutional change – historical institutionalism explains better suboptimal outcomes and unintended consequences, while the rational-choice approach better captures the role of self-interested or strategic actors’ agency. The study of institutional change especially benefits from this multi-perspective approach, since the disputes do not prohibit this particular research agenda (Mahoney and Thelen 2010:32). Peter Hall, who is an advocate of combining different schools of thought, suggests that the study of institutional change should begin with an assumption of the existence of a coalition which is in favor of the changes, and that it should also be recognized that existing organizations condition the power of various groups, as well as the pace and direction of the change (Hall 2010:214-215). These insights allow for the combination of rational-choice and historical institutionalism in the way that manages to solve most of the issues.

The particular case of HTA agencies implementation falls within the sphere of health policy, which is usually characterized by incremental change (Oliver 2006:203-214). Having this in mind, concepts from both historical and rational-choice institutionalism have their place in constructing the theoretical framework. One could argue that the critical junctures might be the moments when crucial decisions were made or when certain important bills were passed, like the key HTA implementation points listed in Mittermayer et al. (2010) for the Croatian case – there are at least three points in time when decisions with far-reaching consequences were made, in the form of the passing of a bill (e.g. Healthcare Quality Law of 2007) or another type of document (Strategy of the development of the Croatian Health Care System of 2006 or Act on Quality of Healthcare from 2011). However, these points are not radical, exogenous shocks, but more of a "business-as-usual" type of process, part of a wider trend of modernizing Croatian healthcare in accordance with the EU regulations. Thus, the shifts that are interest of this thesis are much more endogenous developments, coming from the processes within the existing system, so it is very hard to identify "critical junctures" which might have lead to a certain outcome. In fact, this concept is of little value for the type of research this thesis is concerned with, mostly due to the incremental nature of the observed changes (or the lack of them).

On the other hand, rational-choice institutionalism emphasizes the strategic interaction that takes place within the institution itself and determines outcomes (Hall and Taylor 1996:945). The "game" played by actors with different interests provides several possible outcomes, out of which one is the equilibrium, the relatively persistent "solution" of the interaction. Analyzing interactions among the key individuals within the organizations (and among different organizations) which existed within the healthcare system before the establishment of the HTA agencies might give us an answer why in the Croatian case the equilibrium meant the establishment of the new agency

(the prevalence of the arguments "in favor" from the Banta typology), while in Serbia that was not the case. However, only by putting actors into concrete historical points in time with a unique context can we make a complete picture which is needed for the explanation.

The framework that successfully captures both aspects of institutional change is the theory of gradual institutional change presented by Mahoney and Thelen (2010). The basic sketch of their model is illustrated in Figure 1:

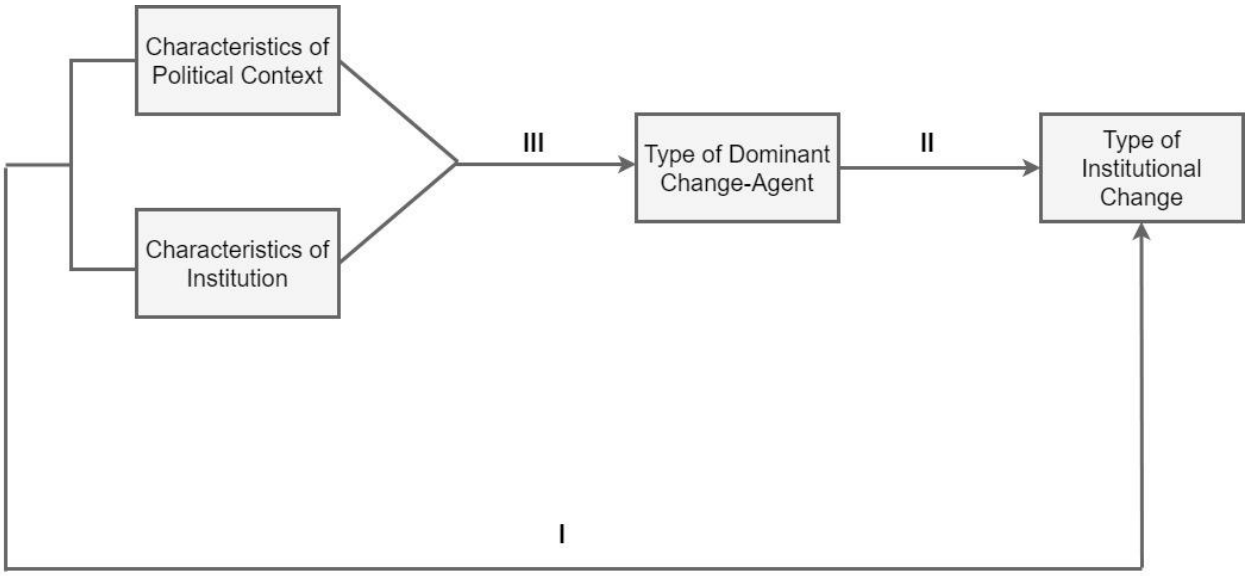

Figure 1. Framework for Explaining Modes of Institutional Change
Source: Mahoney and Thelen 2010:15

First, the characteristics of the political context and the characteristic of institutions together drive the type of institutional change. This process can have four outcomes – layering, displacement, conversion and drift, with each outcome representing a unique mode of institutional change. *Layering* implies that the new rules have been attached to the existing ones, *displacement* means that the old rules were replaced by the new ones, while in the cases of *conversion* and *drift* rules formally stay the same, while being reinterpreted or, the case of drift, having drastically different consequences due to external factors, respectively (Mahoney and Thelen 2010:16-17).

Key dimensions for determining the outcome are the veto powers of the status quo defenders within the given political context (i.e. the access to institutional or extrainstitutional means of blocking change) and the opportunities for discretionary interpretation or enforcement for the actors (the sources of such opportunities are irrelevant). After determining the type of institutional change, the relationship between it and the agents is established, once again on two criteria – depending on whether the actors want to preserve the institution and whether the actors follow the rules of the institution (Mahoney and Thelen 2010:23). This helps us to identify the type of agents, i.e. whether they are insurrectionaries, symbionts, subversives or opportunists. Insurrectionaries seek to eliminate existing institutions, symbionts depend on them and therefore will actively and openly contribute to maintaining them, subversives seek to quietly displace it, while opportunists use them to achieve their personal ends, whether this means supporting them or changing them. Finally, the third link pulls together the actors with the political context and institutional rules, together with emphasizing coalitional dynamics (Mahoney and Thelen 2010:28-30) to explain the outcomes of incremental (policy) change. This is important because actors can rarely put into motion any significant change by themselves – depending on their type and political context, they form coalitions and support one another. The greatest value of this model is that it successfully captures both the role of actors in strategic interaction, as well as structural conditions and already existing institutions, which generate opportunities for and constraints on specific courses of action in relation to the institution in question.

The framework that was presented is broad enough for various research agendas, but when it comes to our question of interest, this framework needs some further development and clarifications. In the particular case of HTA implementation in Serbia and Croatia, the decision-making process is similar – in order to create the new body within the healthcare system, an

existing law should be amended (or a new one, stipulating the creation and competences of an HTA agency, passed). The legislative procedure usually starts in the Health Ministry, where the law is drafted[2]. Due to the centralization of the system, healthcare-related legislation rarely comes from external actors, such as public petitions or NGO initiatives (Jakovljevic 2015). The only exception are healthcare provisions for veterans and incarcerated citizens, which fall under the domain of Defense Ministry, Ministry of Justice or the Ministry in charge of veteran affairs in both countries. After drafting, Government submits the law to the Parliament, which deliberates and votes on the law. In the Croatian case of instituting an HTA agency, the main focus of this thesis are the decision-making episodes within the Parliament, but for the Serbian case (which might be considered, at least on the first sight, a "near miss") we need to go several steps back, to the decision-making processes within the Health Ministry. For this reason, the structure of the system must be examined in order to identify potential veto points and the type of actors that operate within it. When the actors playing the decision-making game within a certain political context are discussed, we need to take into account not only the actors within the country, but also the role of international and supranational bodies and organizations. International bodies are heavily involved with reforms in different policy sectors – for example, World Bank assists countries in environmental reforms (Nielson and Tierney 2003), trade policy reforms (Edwards 1997) and, of course, healthcare reforms (Armada et al. 2001, Prah Ruger 2011). This assistance comes with strings attached, and this is the reason why the role of such organizations must be included in the framework. In the case of HTA, most of the domestic bureaucratic agencies, experts and policy advocates have some connection with the international organizations such as the European HTA

[2] Over 97% of all bills passed in Parliament are submitted by the government in Serbia, but the MPs and the general public can also submit them. Notable example from Serbian healthcare is the passing of the so-called "Zoja Law" in 2015, which was submitted by an MP after long public pressure. The law allows for additional funding for children suffering from rare diseases that need treatment abroad (Blic 2015).

platform EUnetHTA, whose goal is "creating, facilitating and promoting sustainable Health Technology Assessment (HTA) cooperation in Europe" (EUnetHTA.eu 2018). Other organizations, like the World Bank (which funds projects of introducing HTA and has financed several consecutive cycles of health projects which included HTA implementation in Serbia) and the European Commission (which directly recommends the use of HTA) also have potentially significant influence on institutional dynamics (Kolasa 2012, Adascalitei 2012:66-67). Besides international influence, "political context" must also capture the other conditions relevant for HTA agencies which are not strictly political, like the healthcare development indicators and the interests and presence of actors which are not within the public healthcare agencies (industry, scientists, some physicians[3]). International projects are usually conditional and comprised of several components, which might serve as both "carrot" and "stick" for the implementers of reforms. Structural factors should also not be overlooked - there are some indices that the medical devices market might have affected the structure of HTA decision-making in Serbia (Djukic 2010). Only by taking into account these important influences on the dynamics of change we can get a complete mechanism and thus strengthen our case and minimize the possible objections to the explanatory model.

In short, the goal of the analysis in accordance with the presented framework is to (1) outline the characteristics of context and institution, which serves as the "playing field" for the observed process; (2) identify the type of the dominant change-agent (in this case agents – bureaucrats within the healthcare system); (3) identify the type of observed institutional change and (4) examine whether observations are congruent with the theoretical assumptions and draw

[3] According to Banta (2003) typology, clinical physicians are either against HTA (due to the loss of their professional autonomy) or indifferent, since they are not concerned with the healthcare expenses. However, many physicians are employed within the healthcare system organizations, so they cannot be seen as a homogenous group – these "insiders" are not insulated from the system like scientists or industry.

conclusions from the findings. The exact methodology of analysis and its peculiarities are the subject of the following chapter, together with a short discussion on data collection.

4. Research design and data collection

As already stated, the goal of this study is to explain the dynamics of institutional establishment (Croatian adoption and Serbian non-adoption of the HTA agency). The theoretical framework which was presented in the previous chapter provides guidelines for the choice of the research design, since the latter has to reflect the conceptual building blocks specified by the former. Because of the process-oriented puzzle examined, a comparative most-similar case study design seems most appropriate. The research question is Y-centered (main interest is in the causes of outcome – the establishment or absence of HTA agency – and not in the effect mechanism of a specific cause X), so the goal is to identify potential cause among the many (Blatter and Haverland 2014:80). In order to successfully establish the causal links, the degree of "control" must be high (cases that are compared must be similar in as many other variables as possible), and the small-n study which compares only two cases is the simplest design imaginable.

4.1 Case selection

The similarities between Serbia and Croatia, in terms of size, population and other characteristics, including healthcare system, were mostly outlined in the Introduction. As already noted, Serbia and Croatia tend to have rather similar healthcare systems in terms of funding and rules of access to primary, secondary and tertiary healthcare, while the provision, especially of primary and tertiary medical care, is public-dominated (Djukić 2010, Voncina et al. 2006). Both systems are based on principles of social health insurance, with mandatory health insurance implemented by the health insurance funds (State Fund for Health Insurance – RFZO in Serbia and Croatian Health Insurance Fund – HZZO). These health insurance funds are, together with Ministries of Health, the most important organizations within the healthcare system. They are also highly relevant for this thesis since both funds have prerogatives in HTA, along with several other

organizations. The Croatian Health Insurance Fund was set up in 1993, and it has authority over the provision of both mandatory (social) and voluntary health insurance, as well as reimbursement decisions (based on "budgetary impact and demonstrated efficacy over comparator treatments and price setting") (The Economist 2016:19). The Croatian Agency for Medicinal Products and Devices (HALMED), subordinated to the Ministry of Health, was established as an independent agency in 2003, with responsibilities marketing authorization, medicines quality and pharmacovigilance, while Serbian Medicines and Medical Devices Agency of Serbia (ALIMS), a government body responsible for market authorization of medical devices, was set up in 2004 with the same role. The uncanny similarities between the healthcare systems become evident after outlining all the HTA-related bodies in sections 5.1.1 and 5.1.2. It should also be noted that both countries have the same political system with parliamentary predominance, similar political decision-making structure and legal framework, which is almost ideal for the comparison of the process of establishing new public agencies, since it is virtually identical. The choice of cases also guarantees external validity for other Western Balkans countries, since all ex-Yugoslav and Albanian healthcare systems share many features (Jakovljević et al. 2017), while it allows for precise identification of causes (other countries have much more "third variables" - Slovenia is much more developed, Bosnia and Herzegovina has a complicated political system which is also reflected in healthcare, and several Western Balkans countries are still in the earlier stages of healthcare systems development).

4.2 Methodology of episode analysis

The main challenges in this particular case study are not to ignore the causal heterogeneity and not to overlook the strategic interaction between the actors. Thus, the method of analysis that is used is a specific type of causal process-tracing called episode analysis (Capoccia and Ziblatt

2010), focusing on moments of decision-making pertaining to the adoption and non-adoption, respectively, of legal provisions related to the establishment and functioning of a national HTA agency. Episode analysis systematically reconstructs the potential variables which might have been the causal force in leading to institutional reform (or non-reform), encompassing both structural and conjunctural determinants (Capoccia and Ziblatt 2010:942). The goal is to identify critical episodes of decision-making or near-misses, their structural antecedents, and the conditions of the decision-making process (terms of debate, actor's interests, the range of options actually considered, political and social support and political interaction that leads to outcome) (Capoccia and Ziblatt 2010:943). Establishing the chain of events that led to a certain outcome is the main goal of every such study, but while studies based on "normal" process-tracing usually uncover the configuration of structural, political or institutional conditions which are necessary and sufficient for the occurrence of the phenomenon (Blatter and Haverland 2014), this method goes one step further and allows for identifying the key actors involved in institutional change, their ranked options and their strategic choices, and thus fits the explanatory model that was presented. The advantage of this method is that it can uncover the "near-misses" (or negative cases) which are particularly interesting, such as in the Serbian case, and identify processes which lead to them (Capoccia and Ziblatt 2010:943). Using counterfactuals, it is possible to identify whether the causal link for the near-miss comes from the actors' strategic interaction, the contextual environment or even some exogenous event. Also, it allows for comparison of the "criticalness" of different episodes, with the goal of identifying the crucial one. Careful process-tracing in this manner combines the best insights from various approaches and allows for an elaborate causal mechanism which includes every component presented in the theoretical framework and their

combined influence (not only on the process which is being examined, but also on the possible future institutional change).

4.3 Data collection

While the explanatory model and the research design are straightforward, the most important and most difficult issue is data collection. Data is represented by relevant policy documents, and the sources are extremely heterogeneous. For the Croatian case, the situation is easier, since the Croatian HTA agency *Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi* (AAZ) publishes reports on the development of HTA in Croatia, alongside various other publications, mostly surveys and scientific papers (aaz.hr 2018.). These reports are a good starting point for obtaining additional data, by referring to particular pieces of legislation or important actors (former and current) within the system. Besides that, some scholarly literature on Croatian HTA was already mentioned in Section 2.5, so these publications can be used for identifying important episodes (and actors) in the development of HTA in Croatia in the relevant period of time. When it comes to Serbia, however, data collection is more challenging, due to it's unavailability and the lack of scholarly publications. Thus, relying on other sources of data, such as news articles, information from governmental websites, presentations and materials - from conferences, but also budget reports and legal documents is of paramount importance. Furthermore, interviews or correspondence with the representatives of the healthcare policy community and officials in agencies will be used as an auxiliary method for data triangulation. To summarize, the types of data that this thesis is using are:

- Legal documents which establish national healthcare strategies and relevant agencies within the system;

- Transcripts of parliamentary debate in the moment of passing such documents (with "HTA" or "healthcare quality" as keywords);
- Scholarly literature on HTA in both countries;
- News reports that contain information relevant for the implementation of HTA;
- Relevant presentations from HTA-related conferences;
- Websites of relevant agencies;
- Reports that evaluate the performance of international programs in healthcare.

Data collection was performed in two stages: in the first stage, all potentially relevant documents were gathered with the purpose of establishing the general timeline of HTA institutionalization in both countries and identifying the main actors, both individual and organizational. Documents gathered in this stage are legal documents, reports and news articles that are publicly available online. The number of this documents is manageable, since the topic is specialized and only a small number of professionals in both countries produce data sources which can be used, so almost all the available documents were included in the analysis. One criterion that was implemented is that all the data had to have a verifiable source and author, so some news articles from sensationalist tabloid newspapers had to be excluded, in order to make the analysis as rigorous as possible.

The second stage of data collection was characterized by contacting a number of relevant people (policy experts and employees within the healthcare system, identified in the body of documents collected during the first stage of data collection) via e-mail and asking standardized questions about the establishment of HTA in their respective countries (for a list of these, see Annex A). The goal of the second stage of data collection was to obtain details which are not included in the documents available online. Personal opinions, informal interest and power

structures and difficulties are not something necessarily contained in formal reports and scholarly papers, so this stage of the analysis was necessary for providing a clearer picture of what was really going on during the crucial decision-making moments.

Five healthcare professionals from Serbia and three from Croatia were contacted via e-mail in order to gather data on their hands-on experience in the relevant episodes which are analyzed in this thesis in their respective countries. One out of the three contacted Croatian experts responded, while three out of five contacted Serbian prominent experts were willing to answer the questions. However, one Serbian expert responded that they know nothing about HTA, which reduces the effective number of Serbian respondents to two. It should also be noted that there were two attempts in contacting the persons of interest. Despite the lower number of answers from the Croatian experts, this outcome is still satisfying, since the Serbian episodes of decision-making are much less documented in available sources, as already noted in Chapter 4 – Croatian establishment of the Agency was preceded by the deliberation in Parliament, while the data on HTA implementation in Serbia is scarce. All three respondents were contacted again and asked for an interview on the topic. One respondent answered and agreed, and a semi-structured interview was conducted via Viber on 25th of May 2018. It lasted for 90 minutes, it was conducted in Serbian and was not recorded. The respondents and their short biography witnessing their involvement in HTA is contained in Annex B, available only to thesis committee members[4].

The contribution of the second stage of data collection has proved crucial. Not only did the experts provide some key insights in the functioning of the system and the decision-making episodes related to HTA implementation, but they also shared their personal opinions on the

[4] Majority of the responders requested anonymity, hence the procedure.

implementation and prospects of development of HTA, which mostly correspond to the theoretical assumptions of the thesis. Their main insights could be summed up as following:

- Many of the formal competences of different bodies within the healthcare systems of both countries are, in fact, very poorly defined, and there is no clear distinction in who does what, which allows for a high level of discretion in the interpretation of rules. This leads to informal (usually political) divisions regarding bureaucratic competences, with some agencies performing functions which are out of their legally defined scope. The implication of this is that, in theory, there is very large space for maneuver to enact policy conversion, potentially rendering formal (new) rules ineffective.
- There is strong path-dependency in both systems, with multiple causes going back to the communist Semashko model of state-dominated healthcare. One of the main sources of path-dependence is the budgeting structure in the form of line item budgeting, where the budget is organized according to the types of expenses and cost categories (WHO 2016), giving strong incentives to actors for maintaining the status quo. Any reform which tries to introduce innovative budgeting (e.g. introduction of Diagnosis-Related Groups) is perceived as a threat and informally obstructed.
- All the experts that responded are very dissatisfied with the conditions within the healthcare system and with HTA implementation. Also, they mostly agree that the majority of decision-makers within the system have no idea what HTA is, while those who do see it as a threat to the status quo (since it disrupts existing funding patterns or render many existing positions unnecessary), label it as an "unnecessary novelty".

4.4 Limitations of data collection

There are several limitations of the data collection which should be acknowledged, since they might affect the analysis and the conclusions of the thesis. First, the topic is heavily specialized even within the field of health economics (and also insufficiently developed in the observed countries), which naturally limits the amount of data that can be used, especially for a politically focused analysis. Second, the data obtained in the first stage was subsequently insufficiently triangulated, since only one respondent provided in-depth data via interview for the Serbian case, while none of the Croatian experts was interviewed. This is an objective limitation to this type of study, since there is no other way of obtaining data available only to insiders, but it nevertheless leaves some room for skepticism towards the conclusions of the thesis. Third, the bigger part of the second stage of the analysis for Serbia (episode analysis) was based on the data from the second stage of data collection, which means that it is essentially based on the information provided by only two respondents. Indeed, the respondents are experts on the topic and were at some point (or currently) insiders within the healthcare systems and analyzed episodes, but this does not eliminate the potential for bias - they might have wanted to present themselves in a more positive light, or they might have simply forgot some crucial facts (key episodes happened almost 10 years ago). A final potential concern is the fact that all respondents were healthcare experts, not politicians (in the narrow sense), so their perception of the process that is examined might be biased in favor of reviewing the whole process more negatively – since they were heavily involved with the reforms, they might not be aware of all the political intricacies, which could have caused personal grievances and resentment towards the other actors.

5. Analysis and discussion

In order to reflect the theoretical framework of incremental institutional change presented in Chapter 3, the analysis is divided into two stages. The first stage maps all HTA-related bodies within the healthcare systems of both countries. This provides us with the institutional setting in which the process of HTA establishment is happening. Knowing the layout of elements of the system, i.e. the institutional actors their prerogatives and relations with other bodies makes the characteristics of institution and political context (opportunities for discretion and veto points and actors, see Mahoney and Thelen 2010) clear enough for classification. The second stage puts together episodes of decision-making, by looking at the discourse used by relevant actors, piecing together data from all the previously mentioned sources and looking for additional information in order to provide as much detail as possible. The episodes are put together as segments of wider periods relevant for HTA implementation in both countries, and the ones that are deemed most important were used for analysis of the type of institutional change. Finally, the two cases (Croatian adoption and Serbian non-adoption) were compared using the insights from the institutional mapping as well as episode analysis.

5.1 First stage of the analysis: mapping HTA bodies within the healthcare system

Subsection 5.1.1 describes the structure of the Croatian healthcare system and all the agencies with HTA prerogatives within, their legal basis and competences, as well as position vis-à-vis other bodies, while subsection 5.1.2 does the same for Serbia. This stage is mostly based on data from the first stage of data collection, predominantly legal documents.

5.1.1 Croatian HTA within the health system structure

Before establishing the HTA agency, Croatia passed the 2006 National Healthcare Development Strategy, which for the first time explicitly formulated the importance of HTA within

the Croatian healthcare system (Narodne novine 72/2006). In the section 6.8 titled "The fundamentals of the new healthcare financing policy", the importance of HTA is clearly stated, with UK's NICE given as an example of good practice (Narodne novine 72/2006). This coincides with the change in the Ministry of Health a year earlier, where dr. Neven Ljubičić replaced dr. Andrija Hebrang, who was involved with the ministry, with short breaks, since the 1990 and Croatian independence (Hebrang was Health Minister from 1990-1998 and 2003-2005). The Croatian agency was established on the basis provided by the Quality of Healthcare Act (QHA) from 2007 as the Agency for Quality and Accreditation in Healthcare (*Agencija za kvalitetu i akreditaciju u zdravtsvu,* AAZ). It was defined by the law as an independent legal entity with competences in ensuring and improving the quality of healthcare (Narodne novine 107/2007). Also, the law gives the Agency the authority to "perform health technology assessment" and keep a database of HTA reports (article 24) without any further details. In fact, the law predominantly focuses on the accreditation element, with HTA being mentioned just in two articles. It also provided a one-year deadline for the establishment of the agency. Dr Mirjana Nasić, who was previously chief of the quality improvement commission in the University Hospital Center Zagreb, was at the time appointed by the Government as director *pro tempore* (Crnjak 2007), a position which she held until the Agency became operational. It should be noted that there were indications of her political involvement with the ruling HDZ party when she was nominated for the position of the National Eye Bank director (Nacional redakcija 2006).

The Agency became operational in October 2009, and its first order of business was to become a part of international HTA bodies – it joined the Health Technology Assessment International and became an associate partner of the European Network for Health Technology Assessment (EUnetHTA) (Mittermayer et al. 2011:430). After that, a multidisciplinary HTA

committee was formed by the members of different organizations and started working on the first Croatian Guideline for HTA Process and Reporting, which was finished in July 2010 and published in 2011 (Mittermayer et al. 2011:430). Another accomplishment of the Agency was approval of an EU technical assistance project in 2010 (Mittermayer et al. 2011:431), but that was soon followed by the abolishment of the agency by the Croatian parliament in 2011. At the same time, a new agency was set up, Agency for Quality and Accreditation in Healthcare and Social Welfare (with the same acronym, AAZ), in accordance with the 2011 Quality of Healthcare and Social Welfare Act (Narodne novine 124/2011), and it was deemed a "legal successor" of the first agency. This new agency, which integrated quality assessment and accreditation of both healthcare and social welfare providers together with HTA (within the AAZ Department for Development, Research and Health Technology Assessment) has continued to exist in this form until today.

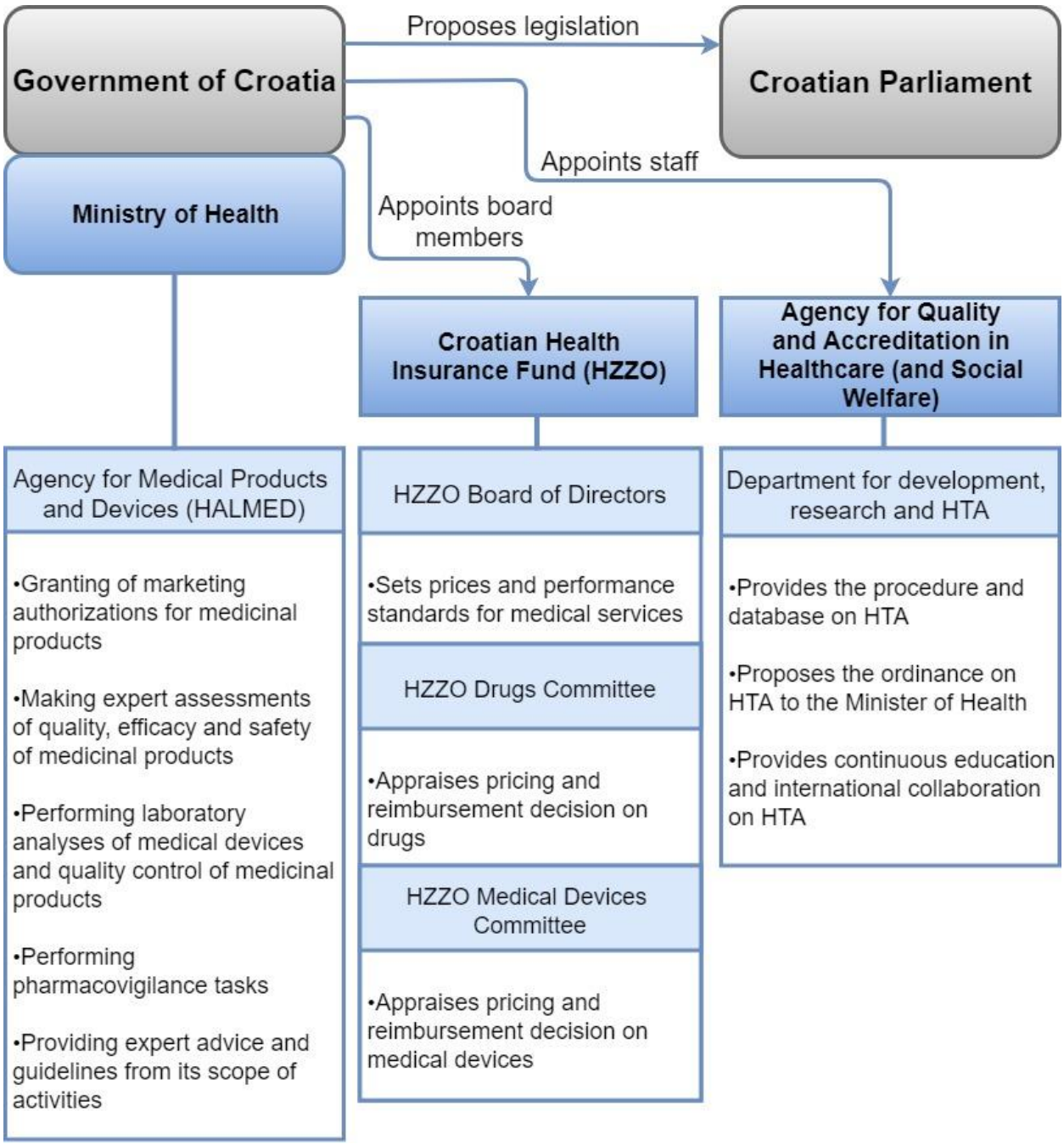

Figure 2: Bodies relevant for HTA decision-making within the Croatian healthcare system

Sources: Huić et al 2017, HALMED website

There are three important conclusions of this examination of HTA structure. First, it is obvious that the main decision-maker (and veto player) in the process is the Government, i.e. the Ministry of Health. Without its approval, no decisions or appointments can be passed. Since the Ministry has the capacity for blocking change, it implies that the political context (as an element of the

conceptual framework discussed in Chapter 3) is the one with strong veto possibilities. Second, it is evident that actors within the HTA-related bodies fall under two categories of Banta's typology: policy-makers (Ministry and agencies) and payers (HZZO). This will have further implications in the analysis of establishment of the agency in the following chapter. Thirdly, it can already be observed that the most competence-needy and cash-relevant HTA prerogatives have been retained by existing bodies (Ministry of Health and HZZO), while HTA agency has only consultative role. HTA remains bureaucratically fragmentary and, therefore, with potentially many veto actors.

5.1.2 Serbian HTA within the health system structure

Serbia does not have a formal HTA agency, neither is it a part of international networks such as the EUnetHTA, but different bodies within the healthcare system nevertheless fragmentarily deal with HTA-related tasks. One of the existing bodies with responsibilities in HTA is the Commission for Health Technology Assessment within the Ministry of Health (Head of the commission is Dr Danica Grujičić, who holds several other important positions within the healthcare system). It was founded by article 67 of the 2005 Healthcare Act (Službeni glasnik RS 107/2005), which also defines its competencies: coordinating health technology development, evidence-based assessment of existing and new health technologies and participating in the development of national healthcare guides and planning. Its competences are more focused on the monitoring and coordination of the development and use of health technologies and the recognition of capital investment needs, rather than affordability, and the evidence of effectiveness of a particular health technology provided by the applicant is not often re-assessed (Atanasijević and Zah 2017). The Commission is predominantly adhering to the French standards (France's National Health Authority - *Haute Autorité de Santé*, or HAS) that 25 patients are the necessary minimum for applying a new treatment (RTS 2015). When the Commission is not sure whether a particular

healthcare facility has adequate staff for implementing new technology or sufficient number of patients, they consult with other state expert commissions. There are "no clear procedures with objective and verifiable criteria related to the effectiveness, cost-effectiveness, or budget impact, in the process of listing medical devices or healthcare services at NHIF[5] or MoH" (Atanasijević and Zah 2017:388). It is also worth mentioning that the National Institute for Public Health has a Section for health technology under the Center for analysis, planning and organization of healthcare, but it's tasks are not connected to HTA as defined in this thesis.

Another important body is the already mentioned National Health Insurance Fund (RFZO) and, within the fund, the Central Experts Committee on Medicines (sometimes abbreviated as Central Drug Committee – CDC) and Pharmacoeconomics Committee (Jakovljević et al. 2011). They make decisions on the inclusion of particular drugs in the positive reimbursement list, and their decisions are based on foreign pharmacoeconomic assessments, including NICE reports, which is especially important having in mind that drugs account for 18% of expenditure by the Fund (Brkić 2016). This process is much closer to the concept of HTA, which is understandable since the Serbian drug market is constantly increasing: it tripled in the last decade (Atanasijević and Zah 2017). The CDC is closest to the HTA ideal, although it operates with limited resources in both financial and human terms. Due to these constraints, it sometimes makes decisions which are more expert-based than evidence-based, often preferring clinical to cost-effectiveness assessments (this is sometimes deemed "rapid assessment") (Atanasijević and Zah 2017:388). However, in the process of decision making, there is "no scope for inclusion of or input from civil society or patient group representatives", and there are "no criteria that specify the process of prioritization of either priority area or drugs inside them" (Atanasijević and Zah 2017:388). In other words, the CDC

[5] RFZO

operates as a closed bureaucratic organization, with monopoly over agenda and decisions, with the latter having notable financial and other consequences for the effectiveness and budget of the national healthcare system, but without clear decision-making criteria or protocols that can be publicly scrutinized and challenged.

Finally, there is the Medicines and Medical Devices Agency of Serbia (ALIMS), which is a government body responsible for market authorization of medical devices, subordinated to the Serbian Health Ministry. It rates the quality, safety and efficiency of pharmaceuticals and medical devices based on technical reports. In recent years, the medical devices market in Serbia has grown considerably (e.g. heart valve implantations grew from 973 in 2005 to 1350 in 2009, the number of pacemakers from 350 to 4200 and number of stents from 1900 to 13500) – all medical devices are financed by the RFZO (Djukić 2010).

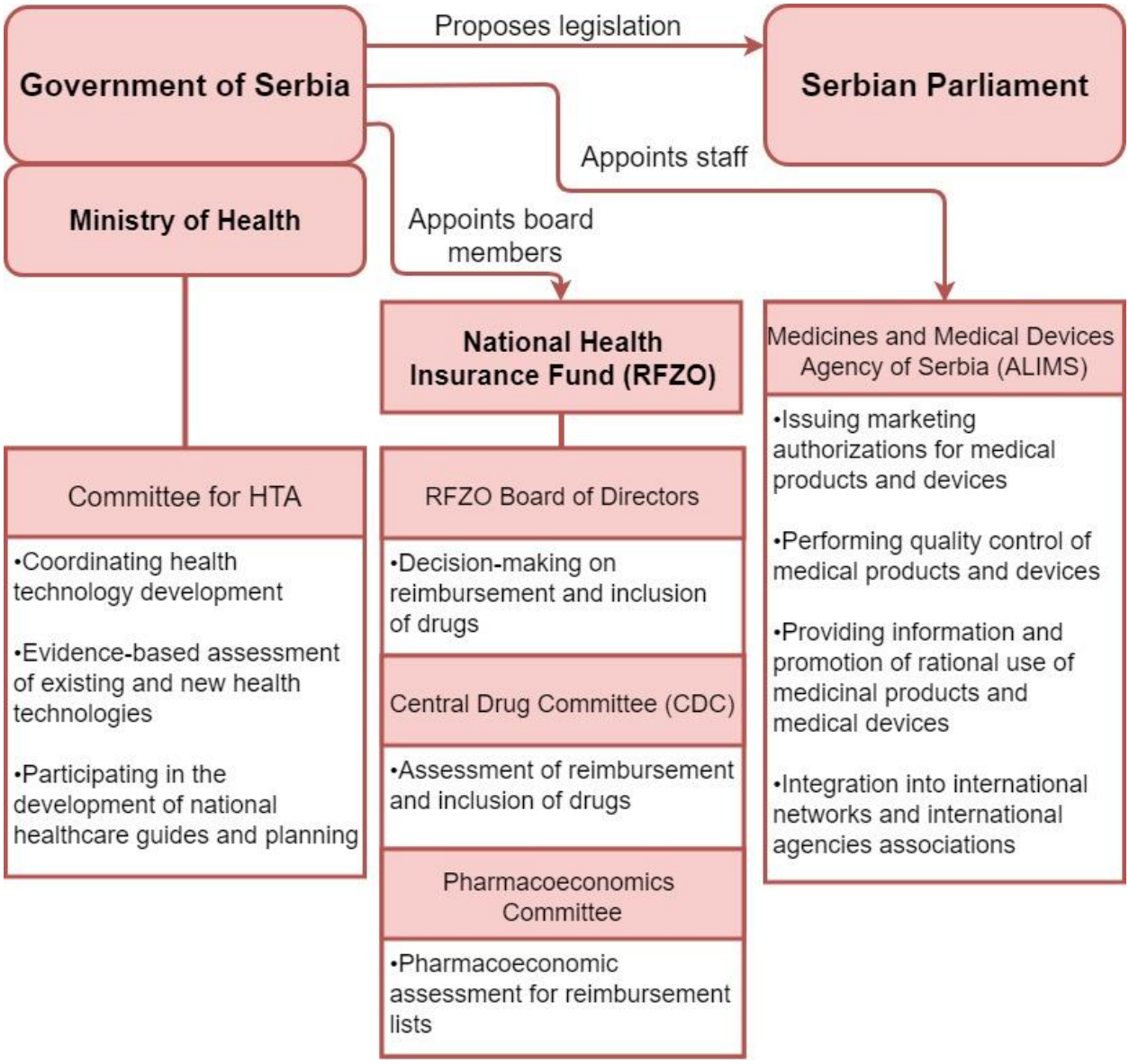

Figure 3: Bodies relevant for HTA decision-making within the Serbian healthcare system

Sources: ALIMS website, Atanasijević and Zah 2017, Jakovljević 2015

It is evident that almost the only difference of Serbian HTA bodies from Croatia is that there is no separate HTA agency, with the organization and decision-making structure being almost identical in the two countries.

5.2 Second stage of the analysis: mapping episodes of HTA adoption

Three distinct periods relevant for HTA adoption in the Croatian healthcare system can be identified: the period of the establishment of HTA agency (2006-2009), period of its functioning (2009-2011) and its repeal and replacement (2011). These are the subject of sections 5.2.1, 5.2.2 and 5.2.3, respectively, below. The key episodes for the establishment of HTA agency in Croatia are the (1) the deliberation and passing of the 2007 Quality of Healthcare Act in the Croatian parliament (period one) (2) the replacement of old provisions in the new law, with much greater focus on HTA (period 2) and (3) the passing of the 2011 Quality of Healthcare and Social Welfare Act (period 3). Analysis is predominantly based on parliamentary transcripts (Transcript 2006, Transcript 2007a, Transcript 2007b, Transcript 2011). In the Serbian case, the relevant period for HTA adoption begins with the World Bank Serbian Health Project (2005) and comes to its conclusion (2009). These are the subjects of sections 5.2.4 and 5.2.5 of this subchapter. Again, the most important episodes for HTA adoption are (1) the negotiations with the WB on the content of the program; (2) the implementation of the second component of the WB project; and (3) the change in Ministry happening in 2011, which led to the partial reversal of reforms.

5.2.1 The establishment of the Croatian HTA agency (2006-2009)

As already stated, the Croatian implementation of HTA can be traced back to June 2006 and the National Healthcare Development Strategy. Before the strategy was passed in the Parliament, many actors participated in the process of creation – healthcare unions, chambers and patient associations, all coming to an agreement on the content of the Strategy. During the parliamentary debate, the main opposition to it's passing was the Social Democratic Party, whose representative expressed fear that the focus on the "taming rising healthcare costs" and "financial stability" would in fact mean less money for the less fortunate patients. The strategy was passed with 79 votes in

favor and 23 against. On the basis of the strategy, Government submitted the bill for urgent procedure to the Parliament in July 2007 for deliberation. The bill provided that the Agency for Quality and Accreditation was to be formed in the next two years, and that it would deal with quality of healthcare, accreditation of the healthcare-providing institutions and health-technology assessment. However, HTA was merely defined as "analysis and research procedure which gathers the information on costs, effectiveness and effects […] in application of health technologies" (Narodne novine 107/2007). The specificities of HTA were not addressed, which gave the prerogatives for closer definition of it's prerogatives to the Agency board (with necessary government approval). The deliberation and the adoption of the law clearly reveal that the main reason for the adoption of such a weak agency, with a focus on HTA only in name, are EU directives. As a prospective member of the EU, Croatia was in the process of legal harmonization with the acquis, in accordance with chapter 28 of the National Program for Joining the EU. The passing of the law was characterized as "inevitable" by the government representative, state secretary in the Health and Social Welfare Ministry Ante Zvonimir Golem, who explained that the law was deemed "urgent" because of the EU accession demands.

The opposition MP's criticized the law because it dealt with issues which were not as urgent as some other within the system (long waiting lists, lack of beds, lack of prevention programs), and also pointed out that the definitions and legal provisions of the law were not precise and vastly open to interpretation. In the second reading, Health Minister Ljubičić again stressed the urgency of harmonization of the law with the EU standards, and former minister Hebrang (now chief of Parliamentary Committee for Health) pointed out the involvement of multiple stakeholders in the process of discussing the draft bill, hinting at its broad legitimacy. Again, the biggest objection of the opposition was the ambivalence and lack of clarity in many propositions, which could allow

for different interpretation and potentially huge influence of HZZO and the Ministry on the work of the Agency. Nevertheless, the bill was passed with clear majority (75 for, 14 against).

This episode reveals important insights in the decision-making process. We have already seen that the structure of the Croatian healthcare system indicates that the key actor is the Ministry – it is practically the sole agenda-setter, which was also the case here, with a limited input from professional organizations during the drafting and discussion. The establishment of the Agency is a „layering" type of institutional change: dominant change agents (high-ranking people from the Ministry of Health, who also elaborate the establishment of the Agency in the Parliament) are either symbionts or opportunists: they cannot prevent the change of old elements (part of larger agenda coming from external factors – implementing European standards, which are characterized as "inevitable"), but they add new elements which are created as initially ineffective (reason for lack of clarity of provisions and ambivalence in competences). For this reason, Croatia has managed to institute the agency without major opposition from existing bodies – the agency itself is designed as small and powerless (not even qualifying as a "light" type of agency, its role at best consultative). It can still be classified as an HTA agency, as Löblová (2016b:26) does, but it is far from the ideal type. Pre-existing bodies keep all their prerogatives, including genuine HTA-related competences.

5.2.2 Croatian HTA agency functions on its own (2009-2011)

As already stated, the Agency started working in October 2009. The focus of the Agency was predominantly accreditation and quality, while HTA was lagging behind. Soon after its establishment, the Department for development, research and health technologies (which was the HTA section within the agency) defined it's six major aims, among which were publishing the Croatian Guideline for Health Technology Assessment Process and Report, establishment of

international cooperation and national collaboration, provision of HTA reports and scientific publication, education programs for workers in healthcare and setting up of a transparent website (Mittermayer et al. 2011, Huić et al. 2017). These goals in hindsight appear very modest, but they closely follow from the unclear HTA competences given to the Agency in the legislation. Furthermore, with the focus on quality and accreditation (which were the EU requirements), the lack of appearance of HTA in the law indicates that the lawmakers did not devote much attention to it. This transposed to the Agency leadership, which did not really have a clear idea what HTA is supposed to be or accomplish.

The lack of political leadership and policy vision led to an even more ineffective Agency over time, which was constantly on low budget and with limited capacity. While this might be understandable for HTA, which was nobody's priority at the time, the quality and the accreditation did not achieve significant results either. During this brief time, none of the healthcare providers were given accreditation, while quality improvement has come down to developing quality standards which were never to be finished. The only relevant mechanism the Agency possesses is the voluntary accreditation by healthcare providers (which has nothing to do with HTA)[6]. The HTA-related work of the Agency has been described as "tragic", with "poor leadership" and "lack of understanding for HTA from both bureaucrats and politicians" (Respondent 2 2018, personal communication, May 25). Everything points to the conclusion that the Agency was just a mirage for satisfying formal healthcare requirements under Chapter 28.

[6] The Agency was subject to widespread criticism since in 2014, 5 years after it's establishment it still did not perform a single accreditation of the hospital, despite two failed calls for application and huge interest from the facilities (Jureško 2014).

5.2.3 Croatian HTA agency is merged with social welfare (2011)

In October 2011, in the last days of the Kosor government, a new bill came into Croatian parliament for urgent procedure. This bill was abolishing the Agency for Quality and Accreditation in Healthcare and establishing a new one, which would be its legal successor – Agency for Quality and Accreditation in Healthcare and Social Welfare. Before elaboration on the new agency, state secretary Golem summarized the achievements of the previous Agency: it performed all the "necessary preparations" for the commencing of the accreditation of healthcare providers; it categorized hospitals ("for the first time in history") and defined "minimal standards" in healthcare quality for licensing. In the elaboration of the new bill, the need for harmonization with the EU was once more invoked as the major reason for passing the new law. Healthcare committee chief, Dr Hebrang, also stated that the new law "strengthens the influence of professional associations" by giving them representatives on the board. However, the opposition MPs pointed out to the vague formulations on quality improvement indicators and the lack of indications that the previous agency's existence and functioning have significantly contributed to the rise of quality of healthcare. The government responded with examples of success of the agency, such as the initial work on the Hospital Accreditation Handbook, the Healthcare Quality Standard Handbook and multiple education programs on accreditation in many healthcare facilities in the country. The government also assured the MPs that the new Agency will not demand more funds than the previous one. In the end, the bill was unanimously passed (with 77 votes for).

Is it possible to make sense of this process within the proposed framework? Essentially, Government wanted to implement quality control for social welfare bodies (this is probably copied from the Swedish case), in accordance with EU directives, but did not want to commit additional funding to it, so it decided to merge it with the healthcare quality agency, since they were already

under the same Ministry (Ministry of Health and Social Welfare existed from 2003 to December 2011). Still, while HTA was not discussed in the parliamentary procedure, the new law did include much more advanced provisions than the previous one. First, the definition of HTA was much more in line with the European standard, now being:

> "multidisciplinary, expert, unbiased, objective, evidence-based and transparent process of assessing clinical effectiveness and safety, including economic analysis, of new or existing healthcare technologies […] having in mind ethical, social, legal and organizational principles". (Narodne novine 124/2011).

The law also clearly defines the competencies of the Agency regarding HTA: performing assessment, managing database of assessed technologies, educating the participants in HTA process, proposing the Ordinance on HTA to the Ministry of Health and cooperating with relevant domestic and international bodies (article 36). This is a major step forward from the previous law where HTA was just vaguely mentioned among the duties of the Agency, most accreditation-centered. This might be an indicator that HTA was recognized as an important policy tool, which would go against the hypothesis of symbiotic or opportunistic actors and fragmented veto actors within the system. The alternative is that it was just an ambitious provision of an idealistic policymaker which will not be implemented or adhered to, in accordance with the assumptions.

The latter is true. New provisions and clearer duties have hardly improved the state of HTA in Croatia. The Agency has remained a mere consultative body, with HTA process staying a voluntary procedure which relevant bodies (HZZO, Ministry of Health, healthcare facilities) can request for consultative purposes, but they were still the main decision-makers when it comes to reimbursement or investment decisions (Huić et al. 2017). The Agency remained small and underfunded (in 2017 there were only two permanent full-time employees), and the relevant stakeholders still simply ignore the existence of the Agency (Respondent 2 2018, personal communication, May 25). Mirjana Huić, the head of the AAZ, observed that the establishment of

HTA was "not an easy and quick process", and that much more is needed in order to make HTA sustainable in the long term – support and commitment of government institutions; educated, permanent staff; appropriate stakeholder involvement; cooperation with other domestic and international bodies and appropriate funding (The Economist 2016:19). Other experts are much more skeptical – they believe that proper HTA will never be implemented in Croatia, since it would pose a major threat to the way in which the system currently functions, the clear formulation of the bureaucratic vested interests hypothesis outlined in Chapter 2. While this might be too pessimistic, there is evidence that any further development of the Agency will be stalled. For example, as provided by the 2011 Law, the Agency has completed the Croatian Ordinance on HTA, which passed public consultation process in 2016. However, it is not in place for "unknown reasons" (Huić et al. 2017). This is an obvious example of how the Ministry of Health prevents the Agency from fulfilling its tasks provided by the law – it simply does not make relevant documents operational, which is its prerogative, although they are made and ready for implementation. To sum up, while technically AAZ is an HTA agency, at least in terms defined in Section 2.2, it is far from a success story.

5.2.4 Serbia prepares for implementing HTA (2005-2008)

The process of implementation of HTA in Serbia is inseparable from the World Bank's Serbian Health Project, which was approved in May 2003. Prior to the project, the WB provided a consultancy grant to the HTA expert Henry David Banta to make a report on the prospects of HTA implementation in Serbia. The report entitled "Consultancy on Health Technology Assessment and Strategy Development in Serbia Report" provided three recommendations: (1) incorporating HTA into Serbian law; (2), resolving the unclear competency division between the Ministry of Health and RFZO; and (3) strengthening and expanding the work of the Commission for HTA,

which should be renewed with new membership[7]. After the Serbian Government submitted its Health Care statement with the directions of healthcare reform in 2002, the World Bank has approved US $20 million for the whole endeavor. The project had three components: Health Services Restructuring, comprised of civil works and equipment purchase for five medical centers (around US $11.6 million); Health Finance, Policy and Management Quality Improvement (which contained multiple subdivisions including HTA – US $6.2 million) and Project Management and Monitoring and Evaluation (US $2.2 million) (World Bank 2012:27). It is important to stress that components were conditional on each other and were evaluated simultaneously. The implication of this is that opportunistic actors within the system, in order to get the funding for the projects which were in their personal interest (such as the first component of this project) also needed to (at least pretend to) implement the other components. This conditionality was, in fact, the main driver of reforms in the system with such high degree of path-dependency, but the results show that it was far from perfect.

The second component of the project was the most contested one, since it initially consisted of five subcomponents which aimed to alter the structure of the bureaucratic system and make it more efficient. After restructuring, there were four subcomponents in total: (1) improving health financing; (2) establishment of accreditation bodies, development of HTA and continued medical education; (3) development of ICT services for digitalization and data-sharing; and (4) building capacities for policy development and public relations and communication (World Bank 2012:6). This structure of subcomponents was the consequence of long informal negotiations between the Ministry and the World Bank, since actors within the Ministry knew which reforms were

[7] The document is not publicly available, it was made for the Health Ministry during the WB project. Contents of the document were revealed in conversation with one of the respondents.

unfeasible from the beginning (Respondent 1 2018, interview, May 25). The only subcomponent that was undoubtably successful was the digitalization – all the others stumbled upon internal difficulties during implementation.

Introducing formal HTA faced opposition from the beginning, with policymakers involved with the World Bank project calling it "too fancy" or "unnecessary" (Respondent 1 2018, interview, May 25, Respondent 3 2018, personal correspondence, May 29). However, some progress was made – several types of training in HTA were completed by 19 policy- and decision-makers (Atanasijević 2012), and capacity building for Clinical Practice Guidelines and HTA practitioners was also carried out (World Bank 2012). Later on, two studies were published: "Feasibility Study on HTA Agency in Serbia" and the "Basic Benefit Package on the Way towards Evidence-Based Health Care in Serbia" (unfortunately, the second one is unavailable to the public). The feasibility study describes two scenarios - how would the process of HTA assessment look if Serbia had "light" or "heavy" (regular) HTA agency, and strongly recommends the institutionalization of some form of HTA within the Serbian healthcare system. Additionally, Serbian experts engaged in the preparation of the Handbook on HTA Capacity Building within the EUnetHTA Project (with Serbia as collaborating partner, but not a member).

In hindsight, is was clear from the beginning that the HTA implementation, alongside other structural reforms, would not go as far as some policymakers hoped. Improving health financing failed miserably: the only tangible result was a mere audit of 15 healthcare institutions, with no systemic changes (World Bank 2012:29). The Agency for Accreditation in Healthcare was established only because it was a solid stream of revenue for the persons involved (without much transparency) (Respondent 1 2018, interview, May 25), and no reliable guarantees were given that the accreditation process would take place. The same goes for professional chambers, which were

instituted at the time – the membership was made compulsory so that every licensed physician or pharmacist had to pay a mandatory fee for membership, while money was being managed by top-level members in a rather intransparent way – some instances of its notoriously lavish spending reached the public (Todorović 2016a, Todorović 2016b). The chambers still continue to exist and function it this manner.

All the difficulties and opportunistic behavior of decision-makers are missing from the official reports which assessed the performance of WB healthcare programs in Serbia, one by the World Bank itself, and the other by ECORIS research and consulting, funded by the EU (The World Bank 2012, Venekamp et al. 2010). According to the World Bank, the project as a whole was rated "Satisfactory". On the other hand, the ECORIS report acknowledges that "the system has not changed much" and that new expenditure-type reforms are much easier to implement than systemic changes (Venekamp et al. 2010:11). In the following part, the mechanisms of halting will be addressed, followed by the discussion on the Croatian "overcoming" of the obstacles.

5.2.5 Serbia falls short of establishing an HTA agency (2008)

The HTA implementation, despite all the work, awareness raising and capacity building did not catch on within the system. Serbia never reached the decision-making momentum on HTA establishment in the first place, neither during the WB program when implementation started, nor later – it never became a policy issue. However, from the previous episode analysis two groups of causes for this outcome can be identified: the obstacles conditioned by the structural factors, and the opposition coming from health policy actors involved within bureaucratic structures.

Due to the structure of healthcare financing, there are strong incentives for keeping the status quo in both countries. The centralized Health Insurance Fund operating via line item

budgeting each year[8] makes every change in budgeting seem like a threat to certain actors (Respondent 1 2018, interview, May 25). Another issue is the relationship between the RFZO and Ministry of Health. While nominally the Ministry of Health is hierarchically above RFZO, with Health Minister choosing the majority of Board members of RFZO, informally RFZO is much more powerful, since it controls a larger part of the healthcare cash flow. Furthermore, both bodies are the subject of partisan spoils division, with heads of RFZO and Ministry often from different parties, and since there are no clear boundaries between the competencies of the two, this leads to the policy of "non-interference" – the fund deals with funding and disbursements, while the Ministry creates policy (Respondent 1 2018, interview, May 25) This makes substantive reform (such as the implementation of HTA) much more difficult, since even if the Ministry wants to implement policy, RFZO can always have informal veto in the process, which is usually the case when financing schemes are on the agenda. When the Ministry initiates some reform, RFZO has the final say, since it controls the largest part of the healthcare funding (in fact, the Ministry has power over only a small portion of healthcare budget, mostly related to natural disasters and measures targeting the general population, such as vaccination). Due to the unclear competences division, RFZO can simply refuse to provide funding for any decision made by the Ministry. This is very hard to avoid because of the already mentioned partisan division (and even if heads of Ministry and RFZO are from the same party, it still does not have to imply cooperation). Since actors within the Ministry know this, success of any change that would go against the interest of RFZO is close to zero.

[8] The division of the budgetary "pie" is relatively stable for decades: 43-43% on salaries, 17% on drugs, 14-15% on supplies etc. This percentages are only an estimation (by Respondent 1) – exact data is impossible to obtain (Simić 2018)

Another potential opponent for the establishment of HTA in Serbia is in the Ministry itself – more precisely, the Commission for HTA. Despite the name, it has almost nothing to do with HTA as defined in this paper, but represents a mere inspection body for new medical devices, which rarely gives negative opinions (Respondent 1 2018, interview, May 25). Also, people which were heads of the committee were not HTA experts, but the ones close to the Ministry (often for a very long time) who also hold multiple other positions within the system, like already mentioned Dr Grujičić. The committee nominally has a variety of responsibilities, but it does not perform them in reality - it is not the only "mirage" agency which can serve as the proof for the existence of HTA. The Pharmacoeconomics committee, which makes pharmacoeconomic assessment for reimbursement lists and gives advice to the director of the RFZO is effectively useless, since the drug prices are decided by the Ministry of Trade anyway (Atanasijević 2012). Despite the multiple prerogatives in this area, drug price negotiations and their inclusion on the positive reimbursement list does not utilize any official HTA, and there is limited data on patients (Brkić 2016). Despite all of this information, current officials still try to paint a rosy picture about HTA reforms (RTS 2015), but it seems that there is a fundamental misunderstanding of what HTA actually is (another similarity with the Croatian case).

The veto power of the RFZO offers a clear mechanism for blocking any change coming from the main decision maker (Ministry), while internal opposition does not make things any easier. However, the question remains – why would reforms be blocked in the first place? What do existing actors have to lose? In other words, why is incremental change, which has been observed in Croatia, not taking place in the Serbian case?[9]

[9] Obviously, "heavy" HTA agency always goes against the interests of the fund, but the opposition coming from the fund might be the reason for the "weakness" of the Croatian agency.

The reasons for this are more actor-based that institutional in nature. First, decisions on the inclusion of drugs and reimbursements provide great opportunities for personal gain - backdoor deals with big pharma among members of bureaucracies are a widespread phenomenon (Kaljević 2007). This is also in accordance with Banta's typology, where *payers* are against HTA because they are reluctant to let go their pricing and reimbursement competences (Banta 2003). The actors within the RFZO have no incentive to make decisions on reimbursement and introduction to an independent agency which would use evidence-based arguments (this is also not the case in Croatia). Second, agencies have big discretionary spending – because the area is too technical, no one in Parliament wants to hear the justification for costs and, consequently, nobody bothers to justify them. When the Committee for HTA started operating, there was the trend of buying radiology equipment in many healthcare provision centers – nobody got rejected even though they might have not needed the equipment at all (the whole process of getting this equipment was controversial; see Vuković 2013). During the WB project implementation, only those reforms which provided tangible benefits for certain actors, mostly introduction of new bodies with discretionary spending, gained support. Intransparent bureaucratic decision-making, discussed earlier, perpetuates and reinforces this as the key modus operandi. However, these arguments might not apply for the introduction of a "weak" HTA agency, since it would not have such competences which would threaten powerful bodies.

Nevertheless, it is still possible to explain even the lack of establishment of "weak" HTA agency: constellation of several factors makes it impossible for actors who favor change to push for reforms. First, the outside pressure for health modernization, which was characteristic for the Croatian case is absent, so the impulse has to come from internal actors. However, the actors within the existing bodies (especially RFZO) do not have any potential gain from the agency – they are

cozy with the existing arrangements, over which they have control, so there is no reason to disrupt it with the agency that deals with topics that majority of actors simply does not understand. Even if HTA comes to the agenda, they can always point to the "mirage" HTA which is already in place in the form of Ministerial and Pharmacoeconomics committee. The actors are fully aware that further institutionalization would, from their perspective, only bring additional costs (which might even become higher *for them* if the agency potentially develops in the future – more efficient healthcare and transparent decisions based of cost-effectiveness mean farewell to shady deals and arbitrary spending).

After the end of the two WB projects, the reforms stalled, but not completely. One major success was the implementation of the Clinical Practice Guide in 2010, which was a major step in improving service quality (Transcript 2010). However, the change in the leadership of the Ministry in 2012 would soon worsen the situation, with regression in implemented reforms. Between 2008 and 2011 there was somewhat of a stagnation in the reforms, but after Minister Tomica Milosavljević resigned and Dr Slavica Đukić-Dejanović took his place, the reversal of reforms started. New government has since 2012 abolished some legal provisions implemented during the WB project, while the remaining ones are simply ignored in some areas (Respondent 1 2018, interview, May 25). Quality reform, which began thanks to the WB project, was abandoned; Commission for HTA was scaled down in 2013, and international cooperation is constantly shrinking due to the lack of adequate staff (Respondent 1 2018, interview, May 25). This reversal can be put in the wider context of rising "state capture" across all central public bodies in Serbia in the previous years (European Commission, 2018). The Ministry itself was shaken by numerous scandals, from implementation of a defunct information system to the minister's alleged connections with the mafia (Dojčinović and Petrović 2016). With more pressing issues burdening

the Serbian healthcare system, the fate of institutionalized HTA might not be far from the pessimistic outlook of one of the responders, who said: "I do not expect the institutionalization of HTA nor any other substantive reform in Serbia in my lifetime".

5.3 Difference in outcomes and institutional change

How does previous analysis fit into the theoretical framework presented in Chapter 3? It seems that the main difference between the two countries is in the characteristics of institutions. Croatian institutions are slightly less prone to discretionary interpretation of the rules than Serbian (reasons for this are beyond the scope of this thesis), so the actors within the Croatian system tend to clearly define all formal relations. This can be illustrated by comparing AAZ to Serbian Committee for HTA – AAZ was *formally* not given many competences in the first place, while Serbian Committee has a lot of competences, but does virtually nothing. However, when it comes to the characteristics of political context, both countries are characterized by strong veto possibilities, especially by the Ministry and the fund. This juxtaposition in the Croatian case fits the expectations from theoretical model really well – strong veto possibilities with low level of discretion leads to layering when institutions change, which is exactly the type of change that characterized the establishment of Croatian HTA agency.

On the other hand, actors in both countries are symbionts, which "feed" off the system and try to keep the status quo at all costs. While the Serbian lack of change fits this picture, how come that Croatian institutions managed to change despite it's symbiotic actors? As we already stated, the main reason is the exogenous pressure, which is not accounted for in the Mahoney and Thelen (2010) framework. For them, institutional change (more specifically, layering) comes from subversive actors – but we cannot claim that Croatian actors were in any sense subversive (however, they might have turned more opportunistic under outside pressure). We can conclude

that in institutional framework with strong veto points, layering does not necesarily come from subversives, but also from opportunists or symbionts. More importanly, layering does not always produce functioning new bodies, Croatian AAZ being the perfect example – it is not even a proper "light" agency, but a mere consultative, powerless body. Sometimes, it is indeed true that „the more things change, the more they stay the same" – especially if powerfull bureaucratic agents want them that way. While these actors might not always understand the new policy completely, they very much understand whether it goes against their interests or not, as the case with HTA implementation clearly demonstrates.

6. Conclusion

This thesis was built on an argument that bureaucratic actors within the healthcare system play a crucial role in the process of establishment of an HTA agency. This approach has proven capable of answering posed research questions. Countries which have successfully established institutionalized HTA have managed to do so because the interests of existing actors were not threatened by the institutionalization, since the newly established agency is not given all the prerogatives that existing actors want to keep. The countries which have not established institutionalized HTA were not able to come up even with this sort of arrangement – the influence of existing bodies is too strong. This was illustrated by the Croatian and Serbian case: both systems are similar in their structure and actors, with status quo bias and path-dependency as dominant forces due to historical legacy and budgeting structure. However, due to external pressures, Croatia wanted to at least nominally establish an agency, and it managed to do so by creating an agency so weak that it does not threaten competences of existing bodies. It is evident that, in the end, Croatia is not that different from Serbia – much of the institutional reform is just a façade.

The thesis also challenges the concepts used in explaining gradual institutional change. While some observation fit into the predictions made by theoretical framework, others go against the predicted outcomes. This is understandable if we take into account that Mahoney and Thelen (2010) framework was developed in the context of Western political institutions. Post-transitional contexts are, as we were able to see, somewhat specific. Path-dependent legacy of the previous regime is still alive and well, and thus we can observe "layering" without any substantial change in the functioning of institutions, or symbiotic actors who turn opportunist under exogenous pressure. The main takeout is that researches should be careful in applying such broad frameworks to heavily idiosyncratic environments such as the Western Balkans.

Of course, the conclusions of this thesis should be taken with the grain of salt. Difficulties coming from data collection were already adressed, so it is possible that the thesis has overlooked some important episodes or mechanisms, formal and informal, which might have played a role in the process of HTA adoption in both countries. Another source of justified scepticism towards the conclusions might come from the approach that was initally taken. Predominant focus on the role of bureaucratic agencies might have led to confirming the preconceived hypothesis that *they* are the most important factors. Potential prospects for future research might be in other approaches, such as focusing on epistemic communities, but this would require a much more intensive engagement with data sources, which is simply out of scope for a master thesis. Also, including other countries from the region into the explanatory model might potentially disprove some of the claims that were made here (but my hunch is that this inclusion would only further strengthen claims presented here).

There is a very important final point to be made. Beyond HTA implementation, thesis reveals a lot about prospects of other institutional reforms in the healthcare sector. The analysis has demonstrated the structural and actor-based impediments HTA implementation was faced with. However, this policy, in terms of involved stakeholders and required expertise, is still a mere niche compared to some other potential reforms which would aim to increase healthcare system efficiency and combat rising costs, such as large-scale restructuring of healthcare facilities network or implementing new budgeting scheme. While it may sound pessimistic, it is reasonable to expect that actors within existing bodies would fight tooth and nail against such radical reforms, which in the context of rising healthcare costs might be inevitable. It seems that the introduction of more efficient payment models, such as value-based purchasing (pay for performance), primary or secondary capitation or the introduction of diagnosis-related groups in the region will be a mere

science-fiction for a long time. This point should be taken seriously by all scholars of reforms in transitional countries, but especially by potential future policymakers. Since it was demonstrated that in the examined institutional layout (post-transitional Western Balkans systems) outside pressure plays the key role in changing incentives, policymakers should, instead of trying to push for impossible, focus on recognizing opportunities which might affect the incentives structure and use them at least for laying ground for some future reforms. However, they should be aware that much more people have failed in this herculean task than succeeded - which is why most of them seek success and acomplishments far away from the public sector.

Appendix A: Sample questions (original in Serbian / Croatian)

Introduction: *I focus on institutionalist theories and health economics, and I am currently writing a master thesis which deals with HTA bodies in the Balkans.*

It would be very helpful if You could answer a few questions. Answering will not take long, and You can choose the length of the answer. Also, if You wish, Your answers can stay anonymous, if You say so in the response.

(Serbian version)

- *When did, in Your opinion, health technology assesment become a relevant topic in Serbia?*
- *Do You think that establishing an independent HTA agency in Serbia would be a good thing? Are You farmiliar with the previous attempts of such establishment?*
- *Who do You think would suffer the most damage if an independent HTA agency was established in Serbia?*

(Croatian version)

- *When did, in Your opinion, health technology assesment become a relevant topic in Croatia?*
- *What were, in Your opinion, the biggest obstacles in establishing an independent HTA agency in Croatia?*
- *Do You think that Agency for Quality and Accreditation in Health Care and Social Welfare should play a more important role in Croatian healthcare system? If Your answer is yes, what are, in Your opinion, the biggest obstacles to this?*

Appendix B. List of interviewees (Confidential)

(For Thesis Committee members only)

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