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**Understanding the Implementation Gap in Colombia's Neonatal Screening Policy for Rare
Diseases through the Lens of Street-Level Bureaucracy**

Dissertation submitted by

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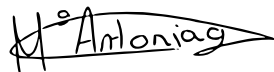
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ABSTRACT

Policy implementation has been recognized as pivotal to bridge the gap between policy goals and desirable outcomes. However, literature has recognized policy implementation as a complex phase in the policy cycle, particularly in low- and middle-income countries (LMICs). Yet, the barriers to implementing policies, especially health policies, remain under-investigated. For this reason, this thesis aims to contribute to the ongoing debate on the implementation of healthcare policies in LMIC by using Colombia's lack of implementation of Law 1980 of 2019, which was intended to expand neonatal screening for rare diseases. This dissertation is based on a bottom-up approach, particularly Michael Lipsky's Street-Level Bureaucracy theory; hence, semi-structured interviews were conducted, which helped identify fourteen key barriers to implementation. Among the most prominent are insufficient funding, ambiguous political will, lack of coordination, infrastructure deficiencies, and the absence of specific regulatory guidance. This research concludes that having a policy in the national legislation doesn't imply the success of a policy. The successful implementation of Law 1980 of 2019 was hampered primarily by a lack of funding, which constrained street-level bureaucrats or implementers to achieve the intended policy outcomes.

INTRODUCTION

The policy implementation phase aims to translate the policy's intended outcomes into practice. This is a complex process that has diverse challenges, some authors argue that the relationship among stakeholders might have a direct effect on the failure or success of a policy (FitzGerald, O'Malley & Ó Broin, 2019) and other authors mention that when institutions are weak, meaning, when they have a lack of commitment, coordination and cooperation, the implementation of a policy becomes even harder (Osmani et al., 2022). Especially in LMICs, the gap between policy design and implementation is vast, and there is often miscommunication among policymakers and policy implementers. To exemplify this gap, this thesis will use the neonatal screening program, which has been an important strategy and a milestone achievement for the rare disease community, as it aims to identify and treat rare diseases in newborns, thereby improving their health outcomes. This dissertation will show that policies themselves do not address any societal problem, as they must be effectively implemented to achieve their intended outcomes.

More than five years have passed since Law 1980 of 2019 was enacted. Gaikwad, S., Ganvir, S., & Uke, P. (2024) argue that neonatal screening is not only a widespread practice in developed countries, but it has also been recognized as a cost-effective health policy aimed at preventing morbidities and mortalities. This practice has a significant impact on newborns; if not diagnosed, some of them might die, contributing to neonatal mortality, or others can have long-term consequences on their health. This law promised to reduce disability and improve life outcomes of the people living with rare conditions and their families, meaning, significant improvements in public health and the lives of those affected by rare diseases. However, the intended goals of the policy remain unmet.

The mismatch between the legislation and the practical outcomes raises a pressing question: Why has the policy on neonatal screening for rare diseases in Colombia not been effectively implemented, despite its inclusion in national health legislation? This is not just a theoretical concern, but a pressing issue that demands immediate attention and action.

With the growing reliance on street-level bureaucrats, this research question hypothesizes that despite its formal inclusion in national health legislation, neonatal screening for rare diseases in Colombia is poorly implemented since according to Lipsky's street-level bureaucracy theory, this is primarily due to insufficient resources, which forces frontline health workers to exercise discretion in ways that limit the program's reach. To confirm or reject this hypothesis, this thesis is structured as follows. The first part provides an overview of the Colombian healthcare system, with a focus on rare diseases, which is the topic of the law that will be analyzed. The second part will expose the relevant literature on policy implementation, focusing on health policy implementation in LMICs.

The third part outlines the theoretical framework, drawing on Michael Lipsky's Street-Level Bureaucracy (SLB) theory, which underscores the pivotal role of the implementers in shaping how policies are delivered. These actors not only interpret the policies but, most importantly, they often change the policy's initial goal since they act with limited resources, high workloads, and ambiguous rules, which leads them to take discretionary decisions that, in the end, alter the policy's goal. This theoretical framework offers a critical perspective for understanding why the 2019 law, which is already included as part of national legislation, fails to materialize. The fourth part of the thesis will delve into the relevant literature on policy implementation, focusing on health policy implementation in LMICs, to provide a comprehensive understanding of the theoretical framework.

Finally, the analysis of the results not only confirms the findings but also supports the hypothesis, which states that despite its formal inclusion in national health legislation, neonatal screening for rare diseases in Colombia is poorly implemented primarily due to insufficient resources, which according to Lipsky's street-level bureaucracy theory forces frontline health workers to exercise discretion in ways that limit the program's reach.

CHAPTER I. BACKGROUND

1.1 COLOMBIA'S HEALTH CARE SYSTEM

Colombia is divided into 32 departments and 1,102 municipalities (Mesa Remolina, Pérez, Igua, 2011). According to Urrea (2025), the most recent DANE projections, as of December 31, 2024, Colombia's population is approximately 52,695,952 people. Historically, Colombia had operated a centralized state; however, that changed with the constitution of 1991, where the national government introduced decentralization, aiming to improve the efficiency and effectiveness of the state, which promoted the expansion of coverage, access, and the quality of public services (Molina, Spurgeon, 2007). Since this model was established, Law 100 of 1993 was enacted, Colombia's health system began to be based on Universal Health Coverage (UHC), and the Social Security System (SSS) was created. This new model is based on two regimes: the first for individuals who can afford to pay (contributory) and the second for those who cannot pay (subsidiary), which is publicly funded. This means that Colombia has a mixed public and private health care system (Guerrero, Gallego, Becerril-Montekio, Vásquez, 2011).

There are multiple actors in the healthcare system. The regulation of health policies is in charge of the Ministry of Health and the National Institute for Food and Drug Surveillance (INVIMA) and the Health Superintendency (SNS) are responsible for the surveillance, regulation, inspection and control of food, medicines and health supplies, medical devices, and more (Guerrero, Gallego, Becerril-Montekio, Vásquez, 2011). The insurance is administered by the Entities that Promote Services (EPS), both public and private, and the delivery by the Institute of Service Delivering (IPS), both public and private (which can be hospitals, clinics, and so on) (Guerrero, Gallego, Becerril-Montekio, Vásquez, 2011). These actors aim to prevent sickness and promote health, covering the basic health services (PBS) to the entire population living in the territory, which translates into achieving UHC (Guerrero, Gallego, Becerril-Montekio, Vásquez, 2011)

Health services are financed differently depending on the regime. In the contributory system, salaried and self-employed workers affiliated with EPSs pay their contribution to the social security fund called ADRES, this entity distributes the UPC (per capita payment unit—a

fixed amount of money that the government allocates per person affiliated to the EPS) for guaranteeing health services and after this, the EPS pays to the IPS to deliver the services (Guerrero, Gallego, Becerril-Montekio, Vásquez, 2011). On the other hand, in the subsidized system, funding comes primarily from fiscal transfers from national and local governments, which are also administered by ADRES to the EPSs to fulfill the necessities of the population that cannot pay. After the money allocation, the EPS pays the IPS to deliver the services (Guerrero, Gallego, Becerril-Montekio, Vásquez, 2011).

Although Colombia aims to achieve UHC using the SGSSS model, it is essential to highlight the main challenges that the system's users and the country have faced over the past few years. Regarding the challenges faced by users, notable researchers include Giron, Gustavo, & Tena-Monferrer, Sandra, & Roig, Juan (2023) mentions that it is essential: the lack of solvency among users despite being insured is leaving the system unfunded, and at the same time, it delays access to the treatment, which makes the users use protective actions to protect their right to health and get their most essential medical services. Geographical barriers are a significant problem that hinders the promptly delivery of the public services. The entire healthcare system in Colombia is mainly developed in only five main cities: Bogotá, Medellín, Cali, Barranquilla, and Cartagena. The rest of the municipalities have poor infrastructure, which highlights the gap between the people who live in these five cities and the rest, showing how the geographical barrier affects a considerable percentage of the population, highlighting the inequity (Giron, Gustavo, & Tena-Monferrer, Sandra, & Roig, Juan, 2023).

On the other hand, there are administrative barriers, including the "insufficient hiring of personnel, suppliers, providers, the procedures to access the services, and the cancellation of contracts" (Giron, Gustavo, Tena-Monferrer, Sandra, & Roig, Juan, 2023, p. 155). These factors directly affect the patients who do not access their treatments due to administrative constraints. Within the administrative barriers, the job insecurity of health workers also affects the delivery of services, as there is a shortage of professionals in charge, which makes the delivery of services almost impossible. Finally, the EPS have been a controversial part of the system because, although they were created within the SGSSS, It has been revolutionary to achieve the UHC, "there are multiple complaints of denial-of-service provision, authorization of third and fourth level procedures, and

delivery of high-cost medications" (Giron, Gustavo & Tena-Monferrer, Sandra & Roig, Juan, 2023, p. 156). This has led to a discussion about the alternatives to EPS, which is currently under revision by the government.

Furthermore, there are some challenges that the system itself has encountered and that should be considered when passing the current health reform. Considering that the right to health has been a fundamental right in Colombia since 2008, Giron, Gustavo, & Tena-Monferrer, Sandra, & Roig, Juan (2023) recommend that health authorities should develop accurate health indicators and develop public health policies to strengthen the health sector in general. Additionally, it is crucial to develop a primary healthcare strategy that incorporates more community engagement to inform legislation and focuses on marginalized communities. On the other hand, reducing fragmentation by creating integrated networks might also help in achieving UHC and ultimately build a comprehensive, unique online health information system, which currently doesn't exist. This can help connect all health actors more effectively and aim for a better way of interconnecting the healthcare sector.

1.2 NATIONAL AND INTERNATIONAL LEGISLATIVE BACKGROUND ABOUT RARE DISEASES

It is essential to consider the broader context to comprehend how the system operates. However, since this thesis focuses on neonatal screening for rare diseases, I would like to highlight some critical aspects of the healthcare system that were not previously mentioned.

In 2000 Colombia established its national NBS program to detect, confirm and treat Congenital Hypothyroidism in newborns. This program was seen as successful since by 2015, it covered approximately 80% of all newborns in the country". (Giugliani, R., Castillo Taucher, S., Hafez, S., Oliveira, J. B., Rico-Restrepo, M., Rozenfeld, P., Zarante, I., & Gonzaga-Jauregui, C. 2022, p.05). These results gave the government high credibility and hope for the rare disease community.

Afterwards, Law 1392 of 2010 was enacted to expand the basic neonatal screening to six additional diseases, aiming to recognize and protect patients with rare diseases and their caregivers, who make up part of a vulnerable and marginalized community. By creating these rules, the government

pretended to guarantee the social protection of these people as a special population. This law has 16 articles in which they mentioned what are rare diseases, why do the patients and caregivers are subject to a special constitutional protection, the principles, the financing of their medicines and treatments, the obligations and responsibilities of the state and the accurate capabilities that must be built to guarantee the special protection, such as the infrastructure, capabilities, the registry and the social inclusion and finally, the tasks of inspection, oversight and control that the health Superintendency has over the other health care actors of the system (Law 1392 of 2010).

After this law was passed and the government acknowledged the importance of neonatal screening for rare diseases, a second law, Law 1980 of 2019, was passed. This law aimed to regulate and expand the practice of neonatal screening in Colombia through the early detection of congenital blindness and deafness, as well as other congenital disorders subject to screening that cause diseases whose early diagnosis prevents their progression, sequelae, and disability, or alters the quality or life expectancy (Law 1980 of 2019). Regardless the effort of making a precise mandate, the allocation of the budget remains unclear, and this hasn't improved to date.

In 2024, the health ministry launched the National Plan of Rare Diseases, which aimed to establish a concrete path to guarantee the protection that the rare diseases community acquired with the previous laws enacted. Considering the massive concern about financing, the government also passed Resolution 217 of 2024, which stated that the UPC would finance the neonatal screening. This approach could be effective in addressing the problem; however, it raises concerns about the funding of the UPC itself, as it has been running short of budget lately.

In the international sphere, there are two main milestone achievements, the first one is the UN declaration of People Living with Rare Diseases, which recognizes this population with special protection and encourages the member states to take all the actions to guarantee their rights, and the WHO Resolution adopted in the WHA of 2025. This Resolution demonstrates that rare diseases are a global health priority and highlights the challenges that the rare disease community has faced for a long time. This historical Resolution is part of a long process of advocating for rare diseases. Still, at the same time, it marks the beginning of creating a global action plan to strengthen health systems worldwide and make a difference for the rare disease community.

1.3 CURRENT STATISTICS ABOUT COLOMBIA

The OECD (2023) Health at a Glance report provided data and trends on population health and healthcare system performance. This report includes a section that analyzes each country in LATAM and compares it with the key indicators of the OECD average. There are five key indicators: health status, risk factors, quality of care, access to care, and health system resources. Regarding Colombia, when assessing its health status, factors such as life expectancy, preventive mortality, diabetes prevalence, and others were taken into account. This analysis concluded that Colombia performed better than the OECD average on 38% of the indicators.

Regarding the quality of care, which included preventive care, primary care, and acute care, Colombia performed better than the OECD average on 33% of indicators. In terms of access to care, Colombia performed better than the OECD average on only 50% of indicators. Furthermore, regarding health system resources, Colombia is not above the OECD average on any indicators. This is especially concerning since it highlights the nature of the financial situation and the importance of these types of reports in revealing the reality of the situation and taking accurate actions to improve it. (OECD, 2023).

On the other hand, PAHO (2024) updated Colombia's country profile in 2024, analyzing the determinants, digital coverage, health situation, mortality, and prospects. PAHO (2024) exposes that Colombia has the right to health, establish since 2008 and has been taking all the possible actions to achieve UHC, such as having almost all the population (97.7%) covered by the SGSSS and enacting different plans, such as the Ten-Year Health Plan 2022-2031, which shows the commitment of the government in improving and achieving UHC. However, there are still multiple challenges that the country is facing such as the leadership in health, the adequate financing of the health sector and the lack of integration, coordination and high-quality care in the isolated areas, such as the rural areas and regardless of the measures taken by the government to enact the diverse plans to tackle this major issues, such as the PDSP 2022–2031, it is essential to acknowledge that enacting the law is just the first step and it is necessary collaboration and planning to carry out them to improve the current situation.

1.4 WHAT IS CURRENTLY HAPPENING IN COLOMBIA?

The government has enacted multiple laws since 2010 to protect this community. These laws have been incredible milestones in LATAM, as they have recognized patients and their families with special constitutional protection. However, most of these achievements have been just on paper. In reality, the provisions established in the laws are hard to implement. For instance, the Law 1980 of 2019, regarding neonatal screening, has not yet been implemented; therefore, the progress made is more theoretical than practical.

Delgadillo, in the article “*Tamizaje Neonatal, el examen para identificar 30 enfermedades, que en Colombia solo identifica una*” (Neonatal Screening, the test to identify 30 diseases, which in Colombia only identifies one), argues that the norms and resolutions enacted by the government tried to regulate the neonatal screening for rare diseases across the country. However, even though the neonatal screening program for congenital hypothyroidism, established in 2000, was successful, the 2019 law that included two levels of screening for other rare diseases hasn’t been implemented yet (Delgadillo, M. M., 2024).

According to Cardona, J. (2025), Colombia is facing a financial crisis, particularly within its healthcare system, which has raised concerns about the sustainability and equity of the system. Recently, the Ministry of Health increased the Capitation Payment Unit (UPC) to 5.36%, despite a recommended increase of 16.4% to cover all provisions of healthcare services for each system user. The UPC, which is calculated based on an actuarial model that incorporates variables such as the epidemiological profile of the population, healthcare costs, and healthcare inflation, is a system that prioritizes the financial balance and competition over the real needs or even the rights of the population. It is pivotal to consider the current crisis of the UPC since according to the Resolution 2717 of 2024 the neonatal screening program for rare diseases must be covered by this system.

According to Cardona, J. (2025), the UPC crisis escalated to the Constitutional Court, through Auto 007 of 2025, that ordered the Ministry of Health to establish technical roundtables to review the adequacy of the UPC by 2024. However, the same Court, through Order 504 of March 22,

2025, ordered the suspension of the sessions of this technical roundtable for 30 days, as a precautionary measure adopted by the Special Chamber for Monitoring Judgment T-760 of 2008, due to substantial risks to the effective participation of system stakeholders and the financial sustainability of health insurance. The suspension of the sessions was mainly because of the failures in effective participation of the different stakeholders and the economic risks, since the sessions were not adequately addressing the accumulated backlogs of the UPC or the adequacy of the current value to guarantee PBS coverage, which could affect the financial sustainability of the system (Moreno, N., 2025) The Constitutional Court's decision highlights the importance of ensuring legitimate, participatory, and technically sound processes in defining key health system policies; however, it creates a very uncertain outlook, especially for patients with rare diseases (Moreno, N., 2025).

On the other hand, the Comptroller's Office issued the “Report on the status of health insurance provision by the eps and the health programs of the family compensation funds”, which revealed the critical situation in the Colombian healthcare system as of December 31, 2024. It highlighted that 29,536,614 (56.65%) of the Colombian population are affiliated with a Health Promotion Entity, which is currently operating under Compulsory Administrative Intervention or Special Measures by the National Health Superintendency. Additionally, the total UPC increased by 12%, indicating that the health system allocated more resources to serve its beneficiaries. However, the amount increase doesn't match the income reported by these companies; therefore, this will be the subject of investigation by the CGR. Overall, this report highlighted the lack of resources, problems accessing healthcare services, inefficient interventions for EPSs, flaws in primary care, and an increase in requests, complaints, and claims (Comptroller's Office, 2025).

CHAPTER II. LITERATURE REVIEW

2.1 DEFINITION OF POLICY

"A policy is a decision made by an authority about an action—either one to be taken or one to be prohibited—to promote or limit the occurrence of a particular circumstance in a population" (Shi, L, 2023, p. 16) It is essential to differentiate between public and private sector since when talking about the public sector the authority in charge of creating the policy is one of the branches of the

government, meaning legislative, executive or judicial. Therefore, public policy is a decision that intends to impact the general population.

A public policy "is a series of actions and decisions taken by the government to address the problems faced" (Listiana, Yunika & Yumame, Jackson & Pugu, Melyana, 2025, p. 1) and to transform the ideas to precise plans it is necessary to build a framework to guide implementers in achieving specific goals that benefit society. Therefore, if a public policy is well-formulated, it is crucial that the government effectively implements it to benefit society as a whole.

2.2 DEFINITION OF POLICY IMPLEMENTATION

Multiple actors contribute to defining the concept of policy implementation. For instance, Stewart et al., 2008, as cited in Rahman, 2016 considers policy implementation as the means of executing a law; therefore, to reach policy goals, stakeholders must be involved. On the other hand, Pressman & Wildavsky (1973), as quoted by Professor Rahman (2016), argue that implementation can be "viewed as a process, an output, and an outcome, involving a number of actors, organizations, and control techniques. It is the process of the interactions between setting goals and the actions directed towards achieving them" (Pressman & Wildavsky, 1973, as cited in Rahman, 2016, p. 4).

On the other hand, policy implementation refers to the mechanisms, resources, and relationships that link policies to program action. More specifically, it means carrying out, accomplishing, fulfilling, producing, or completing a given task. Hence, understanding the nature of policy implementation is essential because it indicates that policies, once adopted, are not consistently implemented as envisioned and do not necessarily achieve the intended results (Pressman & Wildavsky 1973:32; Calista 1994:120; Love 2004:72; Bhuyan et al. 2010:1, cited by Seraw & Lu (2020), p.113). Finally, Sager & Gofen (2022), as quoted by Matsieli & Sooryamoorthy (2023), refer to implementation as an interactive political process involving multiple stakeholders in transforming these ideas from paper to actual reality or implementation.

2.3 CHALLENGES OF POLICY IMPLEMENTATION

Policy implementation is a complex process, that has diverse challenges, some authors argue that the relationship among stakeholders might have a direct effect on the failure or success of a policy

(FitzGerald, O'Malley & Ó Broin, 2019) and other authors mention that when institutions are weak, meaning, when they have a lack of commitment, coordination and cooperation, the implementation of a policy becomes even harder (Osmani et al., 2022).

Rahmat (2015) identifies six main issues that affect policy implementation: the lack of administrative capability, corruption, lack of motivation, misutilization of funds, inadequate enforcement against defaulters, and poor working conditions. Whereas Seraw & Lu (2020) divided the obstacles of the implementation in 3, political, analytical competence and operational capacity, in the first category they mainly mentioned the weak political support and poor implemented incentives, in the second one, the lack of clear priorities, that make achieving the goal almost impossible and the third one the management capacity. The authors argue that the presence or absence of these factors can make policies more or less successful.

Listiana, Yunika & Yumame, Jackson & Pugu, Melyana, (2025) insist that often, policies fail due to various factors, first when there is a mismatch between the planning stage, typically conducted by the central government, and the implementation of the policy, which is usually done at the regional level. Second, coordination between stakeholders is essential, especially when it comes to public policies involving public institutions, as it is crucial to acknowledge the complex bureaucracy that can impact policy implementation. Additionally, it is crucial to consider the interest groups that may facilitate or hinder the implementation process. Third, the lack of capacity among implementers makes this role essential. If there are no capable people to perform it, likely, the policies will not be adequately implemented. (Listiana, Yunika & Yumame, Jackson & Pugu, Melyana, 2025)

Whether a policy is successful or not is a question that Giacchino, S., & Kakabadse, A. (2003) try to address through their article "Successful policy implementation: the route to building self-confident government". They started by saying that a policy is successful when implementers follow the plan that was established in the policy formulation, which leads to the expected policy outcomes. However, this can be criticized since it assumes that only policies with the intended outcomes are successful. Even though some factors might influence the policy outcomes, this

definition might be outdated or inaccurate. Nevertheless, it is important since it highlights that policies represent the government's intentions.

2.4 CHALLENGES OF THE POLICY IMPLEMENTATION IN LMICs

According to the policy cycle, once a policy is formulated, it should be automatically implemented; however, this is not the case, especially in LMICs. According to Smith (1973), cited by Matsieli, Molefi & Sooryamoorthy, Radhamany. (2023) the reason why this is not the case in countries like Colombia is that policymakers, meaning the central government, design policies that governmental bureaucracies are not capable of implementing, due to many reasons, such as a lack of resources or a lack of qualified personnel.

It is essential to recognize that LMICs face additional challenges when implementing policies in comparison to HICs, because of the gap between the policy's intentions and its direct outcomes (Egonmwan, 2009, as cited in Ahmed & Dantata, 2016). More specifically, according to Bhakta (2023), the lack of commitment of the governors, the weak state, the political disputes, the pressure of interest groups, the economic crisis, the unethical behavior, the bureaucratic culture and lack of research are factors that can have a significant impact to the implementation of policies in LMIC such as Colombia.

2.5 HEALTH POLICY IMPLEMENTATION

Paola Abril Campos & Michael R. Reich (2019) wrote a compelling article about the politics of policy implementation in the health sector, especially in LMICs. They argue that implementing a health policy is very complex; it is not only about enacting a law and providing instructions about it, but it is so much more. It requires consistent planning and distribution of tasks. The authors argue that one critical aspect that must be considered is the allocation of responsibility. Usually, the responsibility for implementing the policy lies with the implementers; however, the ones who created the policy are the policymakers, who are not typically part of the implementation of the law. It seems that both stages of the policy cycle are entirely separate; therefore, the actors

contributing to each stage are not connected. However, the policy cycle is not linear; it does not have a specific order. Collaboration and coordination are essential factors that must be considered, that is why it is essential to translate a policy into action; the implementers must acknowledge their context to analyze whether it is feasible to implement that policy (Paola Abril Campos & Michael R. Reich, 2019).

Kakade, S. V., Suke, S. P., Patil, D., Ali, G. S., Garud, S. K., & Pandit, P. V. (2023) highlighted five obstacles that enable the implementation in healthcare policies in LMIC. The first one, financial constraints, is a common issue, as most LMICs often lack sufficient funds to implement policies. This can directly impact the health policy's aim, as it may lead to a shortage of facilities and healthcare professionals, which in turn can affect the overall healthcare system. The second is the infrastructure. When analyzing infrastructure deficiencies, it is crucial to consider the remote locations, such as rural areas, which often lack equitable access to healthcare, affecting primarily the most vulnerable populations. Third, the shortage of skilled healthcare professionals affects the implementation of healthcare policies, as it is essential to have skilled professionals who can effectively implement the policies enacted by the government. Fifth, the political landscape. This is a factor that significantly impacts the implementation of a policy. If a government is unstable, it may lack the necessary planning or even delay the implementation of a policy; therefore, an unsuccessful policy is not unexpected Kakade, S. V., Suke, S. P., Patil, D., Ali, G. S., Garud, S. K., & Pandit, P. V. 2023).

2.6 WHAT ARE THE CONDITIONS FOR SUCCESSFUL HEALTH POLICY IMPLEMENTATION?

According to Rechel, B., Williams, G., Wismar, M., (2019) health policies often take several years to be fully implemented. The authors identified several factors that can determine the success of implementing a health policy. First, to ensure contexts are appropriate and receptive. Every country has a unique context, which is why its economic, social, and political conditions can significantly impact policy implementation. The receptivity of countries can depend on external factors that impact policy implementation, as well as the quality and coherence of the policy, which

refers to the alignment between policy design and implementation within the organization, particularly in terms of leadership.

Second, get the right timing, which means understanding that economic, social, or political circumstances can vary the possibilities for a policy to be implemented. For this factor, the authors drew on Kingdon's model of policy windows and streams to understand what can lead to a policy change. The model suggests that there is a "policy window," meaning policies are in the scope of the government only when the problem stream, the policy stream, and the politics stream merge, which means when they are fully connected. Since they are disconnected, they do not set a clear path or even understanding of the situation. Third, ensuring good governance will contribute to effective coordination therefore, the success of policy implementation. It is also essential to consider the five key attributes of strong governance: transparency, accountability, participation, integrity, and capacity (Rechel, B., Williams, G., Wismar, M., 2019).

Fourth, working with other sectors. There is a need for a multisectoral approach, where all sectors work together, even beyond the health sector, as cross-sectoral collaboration may facilitate an understanding of the context and the implementation of policy. Finally, fifth, moving from exploration to implementation. Rechel, B., Williams, G., Wismar, M., (2019) argue that within the implementation stage of the policy cycle, there are sub-stages of the implementation phase. There are four stages: exploration, where it is analyzed whether the policy is feasible or not, and stakeholders start to be involved; installation, where financial and human resources are distributed, as well as activities are carried out. The initial implementation, when the practical phase starts, and the full implementation, when all the things that were being implemented they transformed into daily life (Rechel, B., Williams, G., Wismar, M., 2019).

These six conditions set a path for health policy-makers to increase the probability of achieving a successful policy, but it is important to acknowledge first the reality of every context because not all the conditions are relevant for a specific context. Second, the complexity of the policies themselves, third, the "wicked problems," and fourth, the number of stakeholders involved. (Rechel, B., Williams, G., Wismar, M., 2019).

On the other hand, whereas Sabatier and Mazmanian (1979) cited by Rechel, B., Williams, G., Wismar, M., (2019) argue that six essential conditions to determine an effective successful implementation are clear objectives, causal theories of actions and outcomes, organization, skilled implementers, supportive interest groups and the respect of social economic conditions. Hogwood and Gunn (1984) presented ten preconditions for the "perfect implementation", which are the following: Circumstances external to the agency do not impose a paralyzing situation, accurate time and resources available, a policy based on a valid theory, a direct relation between cause and effect, the dependency relationships are minimal, understanding of the objectives, allocating tasks, the importance of communication and coordination and the power of compliance that the authority has.

2.7 IMPORTANCE NEONATAL SCREENING

Gaikwad, S., Ganvir, S., & Uke, P. (2024) argue that neonatal screening is not only a popular practice in developed countries, but it has been recognized as a cost-effective health policy aimed to prevent morbidities and mortalities. Even though, more than the half of the total births globally are in developing countries, this practice hasn't been implemented in most developing countries. This practice has a huge impact in the newborns, if not diagnosed and treated in a timely manner some of them might die, that way contributing to neonatal mortality or others can have long-term consequences in their health.

Some of the factors that might enable the implementation of the neonatal screening programs, especially in a LMIC are the following: "lack of government support, poor economy, inadequate public health education, lack of awareness among health care workers, early discharge from hospital, and many births out of hospital" (Gaikwad, S., Ganvir, S., & Uke, P, 2024, parr. Abstract) By introducing neonatal screening in the governments agendas there will be an evident drop in the mortality but also in the disabilities caused by the lack of neonatal screening.

Wilson and Jungner establish 10-point criteria for neonatal screening, that is the following:

“The illness needs to be a serious medical problem, patients with recognized diseases have to receive an accepted course of therapy, there should be facilities for patient diagnosis and therapy, a distinct latent or early symptomatic stage must present, an appropriate test or examination should be available, the test should be acceptable, it is important to have an adequate knowledge of the natural history, progress, and latent disease, the diagnosis and treatment should be cost-effective, a common policy regarding who should be treated as a patient is required and finding cases should not be a "once and for all" endeavor but rather an ongoing one”. (Gaikwad, S., Ganvir, S., & Uke, P, 2024, parr.5)

This means, that the diseases that fulfil these criteria can be screened. Some of the diseases that can be so far screened according to these criteria are the following: PKU, Hyperphenylalaninemia, Congenital Hypothyroidism, Galactosemia, Cystic Fibrosis. At the end of the article, Gaikwad, S., Ganvir, S., & Uke, P. (2024) recommend encouraging to develop policies and create national plans for neonatal screening. It will be necessary, political commitment, funding and advice from developed nations.

2.8 NEONATAL SCREENING IN DEVELOPING COUNTRIES

According to Carmencita D. Padilla, Danuta Krotoski, and Bradford L. Therrell (2010), neonatal screening is an essential public health strategy with the primary goal of identifying and managing diseases in newborns, thereby reducing infant morbidity and mortality. However, this is not only a test, but also a comprehensive system that includes education, screening, follow-up, diagnosis, treatment, and evaluation. Considering this is a complex strategy, many developing countries struggle when implementing it. Some of the most common challenges these countries face are as follows: First, planning a comprehensive strategy that allows for the full implementation of all the objectives set by policymakers. Second, identify the key leaders to implement the plan. Third, provide medical, technical, and logistical support to establish a highly specialized team for implementing the policy. Fourth, educate healthcare providers, consumers, and even policymakers. Fifth, create protocols to implement NBS. Sixth, create a management and evaluation system, and finally, consider sustainability, with a focus on financial sustainability, to effectively integrate the NBS into the public health system.

Besides exposing the difficulties of implementing NBS programs in developing countries, the article proposes some strategies to overcome these challenges. First, encourage coordination and leadership of the NBS program with the government. Second, establish information systems that allow the NBS to be implemented using the information already recorded. Third, create and enact laws that assign responsibilities. Policies need to be carefully explained and provide a plan that allows for implementation at all stages of the operation. Fourth, activating advocacy programs is essential for people to understand the relevance of the NBS. Fifth, connect with experts in the field; their collaboration can be essential to improving the credibility of the program that will be implemented. Sixth, it is essential to have the intervention and support of the health ministry to achieve political awareness and perseverance. Seventh, engage with healthcare professionals to inspire them to be passionate about this pivotal program. Apart from health professionals, healthcare institutions, and the government, non-governmental organizations and parents should also be involved, as they can be essential to the success of the NBS program (Carmencita D. Padilla, Danuta Krotoski, Bradford L. Therrell, 2010).

Regarding the lack of sustainability in developing countries, it is essential to consider program institutionalization, which involves the formal recognition and institutionalization of the program as a public health initiative. It is also pivotal to financial sustainability; without the accurate allocation of money, it is impossible for implementers to implement any policy, regardless of their enthusiasm and/or political will. Finally, it is essential to ensure the quality of the program, as "Where quality does not exist, programs cannot maintain the confidence of the public or the medical community and they soon fail" (Carmencita D. Padilla, Danuta Krotoski, Bradford L. Therrell, 2010, p. 153).

In conclusion, the authors noted that due to recent technological advancements, NBS has been incorporated into the conversation to enhance the quality of life, even in developing countries. Therefore, it is very common to see "initial screening for congenital hypothyroidism, which is known to be cost-effective in most screening settings" (Carmencita D. Padilla, Danuta Krotoski, Bradford L. Therrell, 2010, p.154). However, this is not enough, other diseases that are also be pivotal to screen are being left behind, mainly due to the costs. Developing countries continue to struggle with implementing these programs. However, acknowledging the power of technology,

strategic planning, and multinational collaboration will help support the actual implementation of these policies and improve the quality of life for millions of people.

2.9 OPPORTUNITIES AND CHALLENGES FOR NEONATAL SCREENING PROGRAMS IN LATAM

"NBS is a public health strategy conducted on newborns to identify potentially serious disorders before symptom onset or early enough to warrant a therapeutic intervention, reducing morbidity and mortality, and improving QoL" (Giugliani R, Castillo Taucher S, Hafez S, Oliveira JB, Rico-Restrepo M, Rozenfeld P, Zarante I, and Gonzaga-Jauregui C, 2022, p. 03). The authors argue that rare diseases (RDs) in LATAM have many challenges, starting from the lack of consensus on the definition across the region. Patients often face a diagnostic odyssey, which means a lack of timely diagnosis, given the limited knowledge and research about RDs. This delay can lead to unmanageable situations and create a burden for patients and their families, as well as financially for the healthcare system due to the unmet needs of this population. To mitigate the consequences of late diagnosis, the establishment of newborn screening (NBS) programs may be a solution to improving the lives of individuals affected by these diseases. However, this should be a joint effort among patient organizations, the government, industry, and all relevant health actors (Giugliani R, Castillo Taucher S, Hafez S, Oliveira JB, Rico-Restrepo M, Rozenfeld P, Zarante I, and Gonzaga-Jauregui C, 2022).

Most of the RDs appear in a very early stage of life, meaning childhood, and one of the common aspects of them is the diagnostic delays they experience between 5 and 10 years. The average time for them to wait is significant, which may cause patient deterioration. However, they can also miss the opportunity for an accurate treatment. Having a diagnosis translates into having proper medical care and the possibility on making life-planning decisions and access social benefits. Therefore, it is crucial to recognize that an early diagnosis can significantly impact patients' lives (Giugliani R, Castillo Taucher S, Hafez S, Oliveira JB, Rico-Restrepo M, Rozenfeld P, Zarante I, and Gonzaga-Jauregui C, 2022).

LATAM is facing numerous challenges regarding NBS, one of which is the fragmentation of the healthcare system, which hinders patients from navigating it easily. Most of the time, there is a lack of integration among healthcare actors. There are "few or even no comprehensive care centers for RDs" (Giugliani R, Castillo Taucher S, Hafez S, Oliveira JB, Rico-Restrepo M, Rozenfeld P, Zarante I, and Gonzaga-Jauregui C, 2022, p.10). Very often, patients who are born outside the healthcare institutions or moms who are discharged very soon get lost, and they lose the opportunity to do the first or the confirmatory test.

The authors conclude that RDs are a global challenge, and early diagnosis can reduce or even prevent severe consequences and even death. Therefore, by introducing NBS programs, the lives of patients and their families can be substantially improved, and their quality of life can be improved. However, to do this it is necessary a join effort of different stakeholders to adopt this strategy to every different context, because since LATAM is a very heterogenic region it is important to take into account the diverse characteristics of each country and even within each country their different regions (Giugliani R, Castillo Taucher S, Hafez S, Oliveira JB, Rico-Restrepo M, Rozenfeld P, Zarante I and Gonzaga-Jauregui C, 2022).

2.10 BOTTOM-UP APPROACH: ANALYSIS OF HEALTH POLICY IMPLEMENTATION

- Tobacco policy: The street-level bureaucrats (SLBs) created by Michael Lipsky

Menon S. (2018), in the article "Street-Level Bureaucracy in Tobacco Control: A Qualitative Study of Health Department in District Jalandhar, Punjab," shows how the implementers of the tobacco control policy were neglected by policymakers even though they had firsthand experiences in the field. Worldwide, the implementation of tobacco policies had been a continuous concern, usually the implementers face challenges, such as lack of clarity of the problems or even lack or contradictory goals that do not allow them to implement a policy properly, therefore, the paper aimed to examine the concept of SLB given by Michael Lipsky and understand if it can be used to explain the current situation in the District hospital in Jalandhar.

First, the paper highlighted what the SLB framework says and why it is pivotal to analyze it in this case. They began by stating that, according to Lipsky, SLB are the front-line workers or implementers who interact directly with citizens, serving as "mediators of the legitimate relationship of the citizens to the state" (Menon S, 2018, p. 1). They face multiple problems when implementing the policies, such as a lack of resources, not only financial but also personal and organizational, which means that some of them are not even well-trained. This poses a threat to the correct implementation of the policies due to the lack of knowledge. In this case, the tobacco control policy is a regulatory policy with specific goals and targets; for this reason, it is the ideal one to apply Lipsky's theory, as it acknowledges the nature and challenges of implementing the policy (Menon, S., 2018).

In this study, semi-structured interviews were conducted with medical officers and sanitary inspectors from the community centers of the district hospital in Jalandhar. The findings were analyzed through inductive analysis, developed within the framework of Lipsky.

After applying the framework, the authors conclude the following:

"The street-level bureaucrats (SLBs) were not given adequate training, and various organizational resources for tobacco control are missing in the district. There are threats and challenges that they face in the field, and they do not exercise decision-making power to handle these barriers for effective implementation of the tobacco control program" (Menon S, 2018, p. 1).

Considering the results, Menon S (2018) recommended that the government be more inclusive in all policymaking stages, which means listening to the suggestions provided by the SLBs and granting them discretionary powers to exercise their role more effectively.

2.11 GAPS IN THE LITERATURE

While Lipsky's theory has been widely recognized and used as a theoretical framework for multiple cases to explain the behaviors of implementers and why the expected outcomes of a policy might not be the actual result of the implementation of the policy the fact that implementation has been a problematic stage of the policy cycle, especially in LMIC like many authors have been showing,

yet, the reason why Law 180 of 2019 in Colombia has not been implemented remains under-investigated mainly. For this reason, this thesis aims to contribute a possible answer to this question and thereby continue the ongoing debate about the barriers to implementing health policies in LMIC.

CHAPTER III. THEORETICAL FRAMEWORK

Policy implementation within the health sector, and especially in LMICs, presents numerous challenges. Hence, to understand the complexity of this issue, this thesis will adopt a bottom-up analytical perspective, emphasizing Michael Lipsky's Street-Level Bureaucracy (SLB) theory, to analyze the lack of implementation of Law 180 of 2019, which established extended neonatal screening for rare diseases. This approach will be pivotal in understanding how public policies develop, particularly during the implementation stage, and how frontline actors influence outcomes.

3.1 BOTTOM-UP APPROACH

Signé (2017) argues that bottom-up approaches focus on the local-level actors' perspective who implement and oversee policies directly. This approach emphasizes on the external factors that might influence street-level bureaucrats when implementing the guidelines. The exponents of this approach believe that "centralized decision-making is poorly adapted to local conditions and flexibility is important to reach goals" (Signé, 2017, p. 14).

Also, Nakamura and Smallwood (1980:7-19), cited by Marume, S. B. M., Mutongi, C., & Madziyire. (2016) sees the policy cycle as a whole process in which all stages and stakeholders are equally important and acknowledges the importance of the involvement of the members of the government from the formulation of the policies, until their evaluation. Therefore, conclude that, the bottom-up approach is close to reality, considering that this approach encourages scholars to recognize that policymaking and policy implementation must be viewed as a whole. Implementers can indeed influence the public policy process, as they are the ones who are familiar with the context of their territories.

Furthermore, Birkland (2015), as cited by Seraw, W., & Lu, X. (2020), assert that the bottom-up approach analyzes the success of a policy by examining the lowest levels first. The authors consider the policy cycle as a whole; therefore, they take into account the intentions and actions of the implementers and consider a possible policy design from that point and upwards. Regardless of the real-world application of this theory, one of its leading critics is the discretion of street-level bureaucrats' decisions, which might alter the success of the policies (Birkland, 2015, cited by Seraw, W., & Lu, X., 2020).

3.2 STREET-LEVEL BUREAUCRACY BY MICHAEL LIPSKY

Sabatier and Mazmanian (1979), as cited by Rechel, B., Williams, G., and Wismar, M. (2019), argue that one of the most influential studies in the field was conducted by Lipsky (1980). Gilson L, Orgill M, Shroff ZC (2018) argue that Lipsky's work underscores that "street-level bureaucrats" or implementers shape the "clients" or beneficiaries' experiences of the policy based on their actions, and his work also explains what influences implementers' behavior. Overall, as Sabatier and Mazmanian (1979) cited by Rechel, B., Williams, G., Wismar, M., (2019) said, Lipsky's work was eye-opening, he shaped the vision of the implementation as more interactive and as a political process in which not only the policy makers were involved but also other actors that were never considered when making the policies.

According to Erasmus (n.d), multiple factors integrate Lipsky's theoretical framework that must be developed more deeply:

First, street-level bureaucrats possess a certain level of autonomy and discretionary power to implement policies. This has been acknowledged and accepted, as it is assumed that they are experts in that field, which makes them competent enough to make the necessary decisions for the policies to be implemented. Therefore, this means that they act as representatives of the policy, as they supposedly seek to implement the policies, considering the goals and route established by the policymakers. However, the combination between discretion and having certain freedom "can lead to street-level bureaucrats 'making policy' in unwanted or unexpected ways" (Erasmus, n.d., p. 1) Therefore, their decisions may not always turn out to the policy that was intended or the goals that wanted to be achieved by the ones that created the policy.

Second, they need to cope with the current workplace, which can be challenging since they might experience a lack of resources, and high demand can affect their performance. Additionally, a lack of clear goals is another issue that implementers need to address. If they don't have clear objectives, it is impossible to perform as expected, which leads to a significant problem, measuring their performance and complexity of the power dynamics, implementers may have to deal with clients that have no other alternative than taking that service and this may affect their commitment to the job or even the service quality (Erasmus, n.d).

Third, they develop patterns and routines to cope with current realities; however, these coping mechanisms may affect or even transform the policy itself and ultimately contradict the original goals. Hence, even though it seems that implementers mission is to follow what is written in the law, at the end they need to understand the reality of the situation for implementing a policy, which might be translated into another policy. (Erasmus, n.d)

To summarize, Erasmus (n.d) mentioned that a street-level bureaucrat refers to policy implementers, who are often committed to delivering policies as established by policymakers. However, considering the stressful environment they live in, they usually offer an adjustment policy in which they develop patterns, routines, and simplify their job to ease the complex dynamics they must deal with, given the high demand of work they have. However, some of these strategies may conflict with the policy's intended goals, failing to deliver on the policy as initially envisioned.

3.3 ANALYTICAL RELEVANCE TO THE COLOMBIAN CASE STUDY

The selection of Lipsky's SLB theory as the main analytical approach for this study is based on the particular challenges of the health system in Colombia, highlighted by the lack of implementation of the Law 1980 of 2019, which introduced the expanded neonatal screening for rare diseases, strategy that can save the life of millions and the importance of looking at the reality, instead of what is written in the law.

The Colombian health system is decentralized and involves multiple actors, which means that the actual provision of neonatal screening depends largely on local actors, not just on national-level decisions. In this context, professionals closer to citizens, such as health professionals, hospital administrators, and public health officials at the regional or municipal levels, become the primary policy implementers —precisely the street-level bureaucrats introduced by Lipsky.

Despite what was established in Law 1980 of 2019, mainly the lack of concrete budget allocation has contributed to ambiguity among implementers. Therefore, Lipsky's framework allows for an analysis of the policy-practice gap in Colombia. By examining how frontline implementers act, considering institutional gaps, policy neglect, and systemic fragmentation, this study contributes to a deeper understanding of why a legally sound policy, such as Law 1980 of 2019, remains poorly implemented.

3.4 CRITICS AND LIMITATIONS OF THE MODEL

Evans, T. (2020) examines Lipsky's model and provides a critique of it. First, he argues that the street-level bureaucracy generalize the implementers by saying that all public services are more or less the same and all the street-level bureaucrats use the same level of discretion to implement the policies, which is not true since all services and policies have a different nature as well as all implementers need to use their discretionary power in various ways. Lipsky assumes that policies are always vague; however, this is not always the case, because policies can be more concrete and explicit, which restricts an interpretative approach and narrows discretionary power.

Considering this, Evans (2020) underlines the broad point of view that Lipsky has with his SLB framework, which might enable capturing the big picture of compliance in public services. By equating policy with instruction, judgment with organizational thinking, and non-compliance as a consequence of discretion, it fails to capture the reality of the relationships between policy and public services, the different ways discretion can manifest, and the ethical concerns and commitments in various services.

As mentioned before, Lipsky's theory tends to homogenize street-level bureaucrats, assuming they all act similarly. However, in practice, there is great diversity among these actors, for this reason,

this paper acknowledges this heterogeneity and examines the differences in perspective among various types of implementers or experts on the topic, particularly regarding the lack of implementation of Law 1980 of 2019.

When discussing discretion, it is essential to recognize not only that all discretionary powers are exercised to varying extents but also that there are institutional settings that extend beyond the discretionary power of the actors. In the Colombian context, this implies recognizing that local actors do not act in isolation, but are subject to budgetary rules, technical standards, and limited institutional coordination, factors that must be incorporated into the analysis.

This theory will provide insights from experts on the limitations of implementing Law 1980 of 2019. Meanwhile, this study will broaden the analytical scope by incorporating essential factors that influence the implementation process. It will provide a more complete and nuanced view of the reasons for noncompliance with Law 1980 of 2019. Therefore, this research extends beyond a legal analysis of the policy itself, as it prioritizes the interactive, political, and adaptive nature of implementation. The aim will be to underline where the gap between policy design and implementation is often pronounced, to have a better understanding of how local-level discretion, contextual constraints, and structural limitations jointly influence the outcomes of newborn screening policy implementation in Colombia.

CHAPTER IV. METHODOLOGY

This dissertation project uses a qualitative approach that enables a comprehensive understanding of the lack of implementation of Law 1980 of 2019, as it gives voice to the experts who have witnessed the problems faced by the implementers and, in general, the healthcare system that has hindered the desired outcomes of the implementation of this policy. Semi-structured interviews were chosen as the primary data collection technique, as this methodology enabled the exploration of participants' perceptions, experiences, and knowledge while maintaining a consistent structure aligned with the research objectives. The interviews were designed to identify any barrier that, in the opinion of the interviewees, has hindered the effective implementation of the Law.

Five key actors were selected for their expertise and specific knowledge of the current barriers to implementing newborn screening for rare diseases in Colombia. They were invited to participate in interviews and contribute to this research. The interview group included healthcare professionals, geneticists, patient foundation leaders, and public policy experts. They were chosen to promote a diverse representation of the policy implementation ecosystem, which aligns with a bottom-up approach since it values the perspectives of different stakeholders that operate at the levels closest to the day-to-day implementation of public policies. All the interviews were conducted individually and virtually.

Regarding data analysis, an inductive coding approach was used to allow the creation of categories and patterns directly from the participants' narratives. The process began with *in vivo* coding, identifying essential words and terms used by the interviewees. These codes were subsequently grouped into thematic categories that show the main obstacles identified. From an ethical perspective, the confidentiality and anonymity of the participants were always guaranteed. All participants participated individually and virtually in the interviews. They also signed an informed consent form, in which they were informed of the study's purpose, the use of their contributions, and their right to withdraw from the study at any time without repercussions. Likewise, sensitivity and respect were maintained during the interviews, especially given the sensitive topic of complex health conditions and vulnerable populations.

The decision to use semi-structured interviews as the primary data collection method was grounded by the bottom-up approach, especially Lipsky's classic Street-Level Bureaucracy theory that recognizes actors operating close to the implementation process—including health professionals, foundation leaders, and policy experts—as key stakeholders with valuable knowledge about the fundamental obstacles facing the execution of Law 1980. From this perspective, their experiences enable the research to more precisely identify the structural, institutional, and political factors that explain the gap between what is written in the law and what occurs in practice. It is essential to clarify that the five chosen interviewees do not directly take the samples that are part of the screening process; however, they have been following the process and proposing to the central government adjustments to make it feasible to implement it in all of the Colombian territory.

Therefore, they understand how the system operates in real life since they work closely with those directly responsible for carrying out the law.

CHAPTER V. FINDINGS

Based on the information collected through the interviews conducted to the five experts in the field, a qualitative analysis of the lack of implementation of Law 1980 of 2019 was explored. To this end, thematic categories were organized according to their frequency of mention and level of emphasis expressed by the various stakeholders consulted.

The objective of this analysis is to identify the factors perceived as most critical about the lack of implementation of Law 1980 of 2019, which introduces the expanded neonatal screening program for rare diseases. The responses were categorized thematically and evaluated based on both frequency and level of emphasis (high, medium, low). Three visualizations were created to support the analysis: two tables and one pie chart.

Figure 1

Categories/ interviewees	Expert in public policy, especially on neonatal screening of rare diseases	Expert in public policy, especially on neonatal screening of rare diseases	Member of a patient association, serving as advocate for neonatal screening of rare diseases	Member of a patient association, serving as advocate for neonatal screening of rare diseases	Healthcare professional, specialist and advocate for neonatal screening of rare diseases
Funding	4/high	4/high	10/high	6/ high	3-/high
Inequality	1/high	1/high	0	1/high	0
Political will	3/high	2/high	2/medium	4/medium	1/medium
Lack of infrastructure	2/medium	1/medium	1/medium	4/high	1/ medium
Lack of qualified personnel	1/medium	1/medium	0	1/medium	1/ medium

Coordination	4/high	5/high	0	2/high	1/medium
Lack of specific regulation	3/medium	1/medium	3/ high	0	1/medium
Lack of information systems	1/low	2/medium	1/medium	0	0
Leadership	0	3/high	1/medium	0	0
Fragmentation of the system	0	2/ high	1/ medium	0	0
Lack of local cost-effectiveness studies	1/medium	0	0	0	0
Limited operational research	7/medium	0	0	0	0
Inter-administrative continuity	0	1/medium	1/medium	0	0
Lack of feasibility study to pass the law	0	1/high	0	0	0

Table 1 is a matrix that show all the evidence collected through the in vivo coding. It summarizes the main barriers to the implementation of Law 1980 of 2019, which aimed to expand the neonatal screening for rare diseases in Colombia. Five key experts were selected for semi-structured interviews. These informants include health professionals, geneticists, and advocates from patient associations, who even though were not directly implementing the law themselves they have been actively involved in studying, promoting and advising all related with the neonatal screening program.

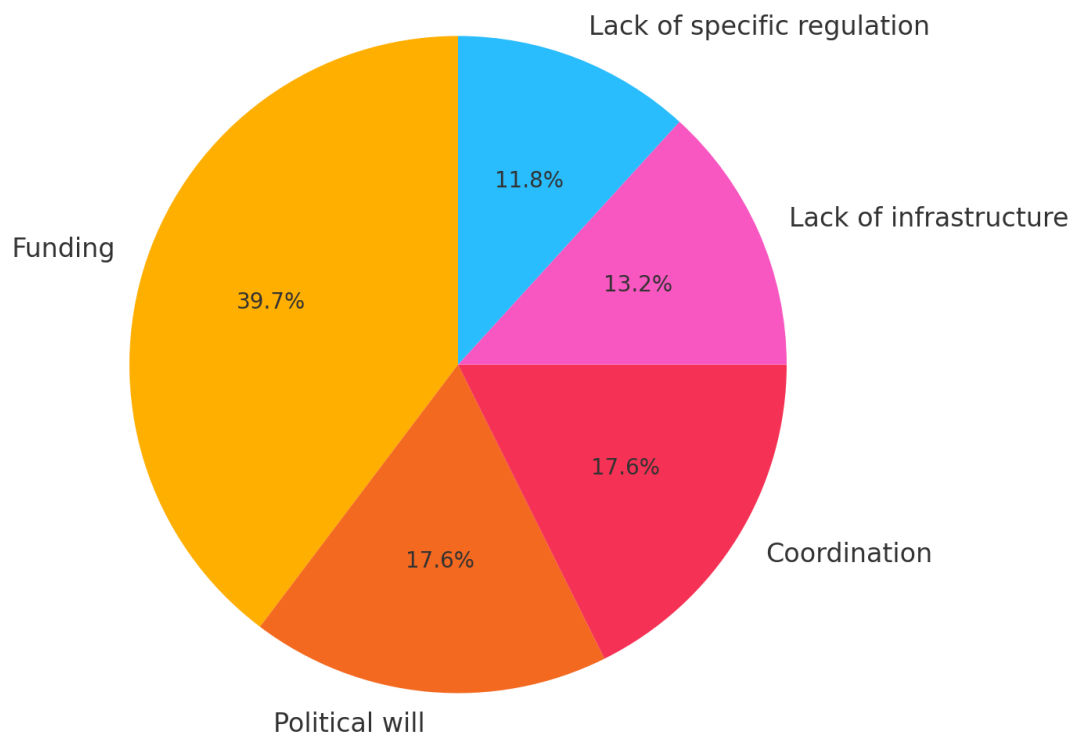
Each row corresponds to a category identified through the methodology used. In total, 14 categories represented in the table. Each column represents one of the interviewees. The numbers indicate the intensity or frequency of the mention (e.g., how many times the issue was raised). At the same time, the weight labels (e.g., high, medium, low) reflect the perceived level of importance or impact as interpreted from the respondent's language and emphasis.

It is particularly interesting to see how each person's narrative changes due to their background and specific knowledge of the 1980 Law's implementation. For instance, multiple factors, including funding, political will, and lack of infrastructure, were mentioned by all interviewees. However, the remaining 11 categories were introduced by some but not all experts. This diversity of responses enriches the research because every person has a different perspective that allows a more comprehensive understanding of the current scenario of the neonatal screening process in Colombia.

As it was mentioned before, this table is the matrix that comprises all the results of the in vivo coding, however, to make it simple and easier to understand, from this table two more figures were created, one chart and another table.

Figure 2

Top 5 Most Mentioned Categories (Weighted Scores)



The pie chart titled "Top 5 Most Mentioned Categories (Weighted Scores)" displays the distribution of the top five key challenges based on how frequently they were mentioned. Each category represents a specific type of barrier or issue commonly identified when implementing the Law 1980 of 2019. Overall, according to the pie chart, funding is one of the most critical issues that must be considered. The political will, coordination, lack of specific regulation, and infrastructure are also reasons why the policy hasn't been implemented yet.

Figure 3

Category	Frequency (number of mentions)	Overall Level of Emphasis
Funding	5/5	High
Lack of coordination	4/5	High
Political will	5/5	Medium - High
Lack of infrastructure	5/5	Medium
Lack of qualified personnel	4/5	Medium
Absence of specific regulation	4/5	Medium
Weak information systems	3/5	Low - Medium
Inequality in access and coverage	3/5	High
Lack of institutional leadership	2/5	Medium
Fragmentation of the health system	3/5	Medium
Lack of local cost-effectiveness studies	1/5	Medium
Lack of feasibility studies to pass the law	1/5	High (but isolated mention)
Inter-institutional administrative continuity	2/5	Medium

Lack of operational research	1/5	Medium
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This table displays the 14 categories selected from the in vivo coding; however, it differs from the first table since it provides a summary or overview of all the participants. For instance, the frequency column, instead of considering how many times each participant mentioned each category, takes into account the number of participants who mentioned that category. Based on the in vivo coding, it was found that the interviewees mentioned funding, political will, and lack of infrastructure as essential barriers that have obstructed the implementation of the law. Therefore, those categories had the highest frequency, which highlights their importance.

It is pivotal to underscore other challenges, such as lack of Coordination and Inequality in Access and Coverage, since they also receive high emphasis, despite being mentioned less frequent. Meanwhile, problems such as Weak Information Systems and a Lack of Operational Research are mentioned occasionally and tend to have a lower overall emphasis, suggesting they are less prioritized or possibly considered more technical or background issues. The dataset also includes unique cases, such as the lack of Feasibility Studies to pass the Law, which, despite only one mention, is rated as highly emphasized, indicating critical but under-discussed barriers.

CHAPTER VI. ANALYSIS OF RESULTS

According to the first table, the interviews show common and differentiated barriers affecting the implementation of the neonatal screening law for rare diseases in Colombia. The differences are evidently based on the knowledge and expertise of each person that contributed to the interviews and given their background, they were able to explain more in detail some factors, different than others. For instance, the most frequently mentioned barrier is the lack of funding. The five interviewees agreed that this factor is a high-impact obstacle, directly affecting the entire policy implementation process.

All of them acknowledge the fact that the UPC, which is the fund that must cover all the neonatal screening for rare diseases, is currently in crisis since it is underfunded and if this fund hasn't been

able to cover the current expenses of the system, it is highly likely that won't cover the neonatal screening program either. Therefore, what most of the experts mentioned is that it is not possible to talk about political will if there is no money being allocated to that program, meaning the budget constraints can be translatable into lack of political will. Something that was mentioned by some of the experts was that if the financial situation improves, the scenario could change completely, and the full implementation of this policy could be possible.

Additionally, political will was also mentioned by all the interviewees, therefore it emerges as a significant factor. Some of the experts consider it is a high-impact barrier, whereas others consider it to be at a medium level. This might have happened since each of them has a different perception of the government's commitment with the rare disease community. What was a constant in the interviews was the emphasis on the necessity of prioritizing this issue in the government and therefore take key steps to implement the law.

Another key barrier mentioned by most of the interviewees is the lack of coordination which it has been evident not only with this law but also with the previous one that included hypothyroidism screening in the national legislation since 25 years have passed since the law was enacted and yet it has only reached 80% coverage. This lack of coordination increases the gap between what is written in the paper and what is the reality. Without a joint effort the system will always seem fragmented.

On the other hand, barriers such as a lack of infrastructure were also mentioned by all the experts. This is important since adequate infrastructure can help deliver timely neonatal screening in all territories, reducing inequities. However, to have an infrastructure that addresses the challenges faced by the rare disease community in Colombia, it is pivotal to take into account the resources. If no money is allocated to these programs, it is impossible to invest in better infrastructure, and consequently, there will be no progress.

Beyond these barriers, it is noticeable that the public policy experts had a comprehensive understanding of the situation, since they cover multiple aspects. Some of the topics that they mentioned that were not by others were lack of cost-effectiveness studies, limited operational

research and lack of feasibility study to pass the law. In contrast, the other interviewees cover specific topics to a certain extent. This difference suggests that each actor's experience and institutional role influence their understanding of the problem. Furthermore, although specific categories were mentioned only a few times, such as the absence of information systems, the lack of local cost-effectiveness studies, limited operational research, and administrative discontinuity, these might represent invisible structural barriers that affect the program's long-term sustainability and quality. Their low prevalence may be related to a lack of awareness or technical knowledge on the part of some actors, rather than to their actual irrelevance.

Overall, the analysis in the table reveals a multidimensional gap in newborn screening implementation, influenced by both material constraints and institutional, regulatory, and policy weaknesses. This diversity of barriers suggests that any effort to improve program coverage and effectiveness must comprehensively address the different levels of the problem, ranging from operational to structural. Regardless, it is important to underscore the main obstacle mentioned by the experts that was the financial constraints.

On the other hand, the pie chart specifically offers a visual summary of the most cited challenges. The most recurrent issue among stakeholders was funding, which dominates the chart and overshadows the other categories. This suggests that the lack of financial resources is perceived as the most fundamental barrier, which in turn implies that unless this financial gap is addressed, other improvements may not be sustainable or even possible.

Political will and Coordination, each equally important according to the pie chart, were the following most essential categories, meaning that the presence of willingness and cooperation is seen as equally necessary. Additionally, the lack of infrastructure indicates concerns related to the absence or inadequacy of basic facilities and equipment that constraint the effective implementation and finally the lack of specific regulation. The experts highlighted that the lack of complete regulation for the law that defines the how, when, and with what resources it should be implemented is one of the most critical points and it must be addressed by the Health Ministry.

In summary, the chart establishes a hierarchy of concerns. Funding being the most critical issue, followed by systemic and operational governance factors, and finally, infrastructure and regulatory clarity.

To strengthen the analysis, Table 2 presents a multifaceted view of the challenges facing the healthcare system, which doesn't allow Law 1980 of 2019 to be implemented accurately. One of the most evident observations is the emphasis on Funding, which was mentioned by all the experts as a high-priority issue. This highlights the crucial role of the budget allocation in the neonatal screening program since without the adequate funding all the other needs remain unmet. Therefore, the law remains just in the paper. Also, Political Will, also featured prominently, reflecting the need for committed leadership and policy prioritization to secure funding, hence the adequate implementation of the policy.

On the other hand, Lack of Infrastructure and Lack of Qualified Personnel were rated with a medium emphasis, suggesting that the physical and human resources necessary to implement this policy are lacking. Furthermore, the lack of coordination indicates that experts recognize that the inefficiencies and fragmentation of the healthcare system hinder the effectiveness of newborn screening. Additionally, the absence of specific regulations and the lack of institutional leadership indicate that, even though resources are essential, they must also be complemented by robust regulatory frameworks.

Regarding equity, the results show first ongoing concerns about how babies are screened in the entire Colombian territory and second the importance of the neonatal screening since this is not just a diagnostic tool but a pivotal factor of health equity. Interestingly, the data also highlights gaps in information and evidence-based decision-making. Categories such as Weak Information Systems, Lack of Local Cost-Effectiveness Studies, and Lack of Operational Research appear less frequently and are assigned lower emphasis. This suggests these issues might be perceived not as important compared to other governance problems. An outlier in the data is the Lack of Feasibility Studies to pass the Law, which, despite being mentioned only once, is given high emphasis.

It is essential to analyze the data collected through the theoretical approach of Lipsky, who states that the implementation of public policies is profoundly influenced by frontline actors who have a direct relationship with the beneficiaries of the policy. These actors, who are most known as street-level bureaucrats, make decisions in complex situations, where they ultimately redefine the content and scope of public policies, as they are the only ones who understand the real problems faced by the population.

These actors, known as street-level bureaucrats, operate in contexts of high demand and scarce resources, requiring them to make practical decisions that, in practice, often redefine the content and scope of public policies.

The obstacles identified in the interviews, such as a lack of funding, a shortage of trained personnel, the absence of information systems, the fragmentation of the healthcare system, and weak inter-institutional coordination, demonstrate the challenges faced by the Colombian healthcare system. The daily decisions of each hospital, on whether to implement the policy, are often conditioned by budgetary constraints, structural limitations, or regulatory ambiguities, and ultimately shape how Law 1980 of 2019 is (or is not) implemented. For example, the lack of budget is the most common answer among the interviewees, which prevents its uniform application and forces implementers to prioritize other tasks or implement the law partially.

Furthermore, the experts in the sector note that, although the government has demonstrated political will, the necessary conditions, such as a budget, to enable frontline actors to implement the policy effectively have not been established. Hence, the results confirm that implementation fails not only due to omissions at the macro level, when designing the policy, but also due to the conditions that are causing a crisis in the healthcare system, specifically the financial crisis.

It is essential to note that the budget allocated to this policy is nonexistent; therefore, discussing implementation will be impossible. Second, although some actors acknowledge progress with the law, there is a lack of government oversight, changes in administration, and shifts in government priorities to other programs. Third, the absence of a governing authority that articulates actors and levels within the health system appears to be a significant barrier, which hinders sufficient

coordination to implement this policy. Fourth, some deficiencies have been identified regarding the infrastructure, which do not allow for the collection of samples in some territories, nor for calling positive tests after discharge. Fifth, despite the existence of Law 1980, specific regulations detailing protocols, obligations, and operational guidelines are still lacking.

CHAPTER VII. DISCUSSIONS AND CONCLUSIONS

This thesis examines the lack of implementation of healthcare policies in LMICs, exemplified by the impossibility to carry out the Law 1980 of 2019, which expanded neonatal screening for rare diseases. Despite Colombia's formal commitment to this policy, its implementation remains a matter of concern. Through the lens of Street-Level Bureaucracy, this study has identified, based on semi-structured interviews with stakeholders, 14 key barriers to implementation.

The most frequently and mentioned issues include lack of funding, ambiguous political will, poor coordination, deficient infrastructure, and the absence of clear regulatory guidelines. These factors create a scenario where frontline implementers cannot effectively implement the policy. When they are left without the resources, direction, or support, the written policy and desirable outcomes will never transform into practice. Therefore, there is a mismatch between national policy ambitions and local-level feasibility, which makes a significant contribution to the understanding of the lack of implementation of the law 1980 of 2019 of the Colombian healthcare system.

Importantly, the findings confirm Lipsky's central argument: SLB or frontline implementers not only implement the policy, but they also need to interpret and adapt it under certain constraints that often redefine its outcomes. Therefore, the lack of implementation of neonatal screening represents not per se the failure of the central government nor the implementers but also shows that laws do not implement themselves. It is only through adequate budget allocation, sustained political will, operational capacity, and inclusive governance that neonatal screening can be more than an aspiration in Colombia and other LMICs. The implications of this study's findings are clear: urgent and immediate action is needed to bridge the gap between policy design and implementation in Colombia's healthcare system.

Given the above, it is possible to confirm the hypothesis that the poor implementation of neonatal screening for rare diseases in Colombia, despite its legal inclusion in Law 1980 of 2019, is primarily due to a lack of resources, resulting in inefficient budget allocation across different areas in Colombia. Although the interviews were conducted with experts, rather than direct implementers, their insights revealed that the absence of mainly budget allocation constrains implementation capacity in the regions. These gaps, as described by the interviewees, help explain why frontline health workers often struggle to implement the policy as intended. This aligns with Lipsky's theory of street-level bureaucracy, which suggests that when public policies reach the implementation phase, frontline actors—facing limited resources and unclear guidance—must make discretionary decisions that effectively redefine the policy on the ground, which in this case might be not carry out the actions of the neonatal screening program. Therefore, the results validate the hypothesis by showing that implementation failure is not only a legislative or political issue, but also a consequence of the conditions faced at the operational level, such as financial constraints, which Lipsky's framework can explain.

In conclusion, this thesis makes empirical and theoretical contributions to the field of health policy implementation in LMICs, and it confirms the value of bottom-up approaches to uncover the realities of implementation beyond the written policies. It also highlights the decisions that implementers must take to adapt to the realities of limited resources. It is important to acknowledge that neonatal screening is not just a diagnostic tool, but a cornerstone of health equity and its accurate implementation saves lives. Its success does not only depend on the central government or the implementers, but it will also depend on the financial capacities, a systemic vision, a sustained political commitment, and the empowerment of communities. Colombia's experience with this policy underscores that closing the gap between the formulation of a policy and its implementation requires more than legislative action. Therefore, by addressing the multiple barriers identified, Colombia and LMICs facing similar challenges can move from policy enactment to tangible advances in public health and equity.

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Appendix 1



MA Thesis Proposal Ethical Review Form

Student Information

Full name: María Antonia Gonzalez

Email Address: mgonzalez@student.ibe.org

Program of Study: Erasmus Mundus Global Public Policy

Research Overview

Tentative Thesis Title: From Policy Design to Implementation: Bridging the Gap in Neonatal Screening for Rare Diseases

Research Question(s): Why do problems arise in the implementation of public health policy in middle-income countries, such as Colombia?

Research Objectives:

- Policy Analysis: Examine the existing legal and regulatory framework governing neonatal screening for rare diseases in Colombia.
- Implementation Assessment: Evaluate the effectiveness of policy implementation, identifying gaps between legislation and real-world execution.
- Institutional & Stakeholder Roles: Analyze the roles and interactions of key stakeholders, including government agencies, healthcare institutions, and advocacy groups, in the implementation process.
- Barriers & Enablers: Identify structural, economic, and logistical challenges hindering the successful execution of neonatal screening programs and explore key enablers for improving coverage and efficiency.

Methodology (including research design, data collection methods, and data analysis techniques):

- This thesis project will adopt a qualitative research approach to explore and understand the implementation obstacles of the neonatal screening program for orphan

diseases in Colombia. This type of methodology will be the most accurate since it will analyze and explain the complexity of these issues, the aim is to explore the experiences, perceptions or various stakeholders involved in the implementation of the neonatal screening in Colombia. By doing semi-structured interviews, I will get valuable insights and furthermore create or arise new dilemmas and questions within this topic.

I am planning to do a “stakeholder mapping” to identify the key players of the rare disease field in Colombia. Since I have been involved in this field since 2021, I already know some of the people that I will interview, mainly within the advocacy and research field and after talking to them (via whatsapp or email) I will ask for other contacts so I can reach out to them and conducted interviews to them too. I will start by asking them about the Colombian healthcare system, more specifically regarding the rare disease field, how does the policy process works when talking about this narrow topic, the key stakeholders that are involve. Then I will proceed to ask about the Law 1980 of 2016, which is the one I will be analyzing in this study. I will ask them questions about the implementation of it and the possible challenges faced by the people in charge of the implementation process.

Ethical Considerations:

1. Does your research involve human participants? (Yes/No)

Yes, interviews

2. Does your research involve collecting, using, or disclosing sensitive data or information? (Yes/No)

No

3. Does your research involve vulnerable populations? (Yes/No)

No

4. Is there a potential for physical, psychological, or emotional harm to the research participants? (Yes/No)

No

5. Are there any additional ethical considerations specific to your field (e.g., International Security or International Development)? (Yes/No)

No

Informed Consent and Data Protection:

1. Explain how you will obtain informed consent from the research participants (if applicable):

I will obtain informed consent by providing participants with a clear explanation of the study, ensuring voluntary participation, securing written or verbal consent, and guaranteeing confidentiality.

2. Describe the measures you will take to ensure the anonymity and confidentiality of the research participants and their data:

To ensure participant anonymity and confidentiality, I will obtain informed consent, anonymize data by removing personal identifiers, and encrypt all electronic data. Access will be restricted to authorized staff, and data will be stored securely with regular backups. Data will be retained only as necessary and securely destroyed when no longer needed. Any published results will be de-identified, and the study will be reviewed by an ethical committee to comply with privacy laws.

Declaration:

I declare that the information provided in this form is accurate and complete to the best of my knowledge. I understand that providing false or misleading information may result in the rejection of my thesis proposal or other disciplinary actions. If any ethical considerations arise during the course of my research, I commit to informing my supervisor and the IBEI ethics coordinator immediately.

Student Signature: _____

Date: _____

Please submit this completed form to **Tutku Ayhan (tayhan@ibei.org)** for further review by the IBEI ethics coordinator.

This section is to be completed after review only
Thank you for your application. We have completed the review process and can offer a favorable opinion, contingent upon the supervisor's continued guidance in the research and development of interview questions, as well as the student's use of the provided informed consent form during participant recruitment. Name of reviewer: Tutku Ayhan Date: 9 April 2025

Appendix 2



Information Sheet

Objectives and duration of the project: The goal of this study is to analyze why do problems arise in the implementation of public health policy in middle-income countries, such as Colombia?

Methodology and participation: This thesis project will adopt a qualitative research approach to explore and understand the implementation obstacles of the neonatal screening program for orphan diseases in Colombia. This type of methodology will be the most accurate since it will analyze and explain the complexity of these issues, the aim is to explore the experiences, perceptions or various stakeholders involved in the implementation of the neonatal screening in Colombia. By doing semi-structured interviews, I will get valuable insights and furthermore create or arise new dilemmas and questions within this topic.

The interviews will be conducted online, and they will last approximately 1 hour per person. The interviews will be schedule depending on the availability of the interviewer and interviewees.

Inclusion criteria for participation:

- Experts in the rare disease field.
- Experts with specific knowledge of the law of 1980 of 2016 which will be analyze in this study.
- People that understand how the policy making process is, or that are involve in it, to gain insights from their participation.

Privacy: To ensure participant anonymity and confidentiality, I will obtain informed consent, anonymize data by removing personal identifiers, and encrypt all electronic data. Access will be restricted to authorized staff, and data will be stored securely with regular backups. Data will be retained only as necessary and securely destroyed when no longer needed. Any published results will be de-identified, and the study will be reviewed by an ethical committee to comply with privacy laws.

Compensation: Your participation will not be compensated.

Risks and benefits: Participating in this study does not entail risks greater than those ordinarily encountered in daily life. We cannot and do not guarantee that you will receive any benefits from this study.

Voluntary nature of participation: Your participation in this study is on a voluntary basis and you may withdraw from the study at any time without having to justify why.

Informed Consent Form

Title of the thesis: From Policy Design to Implementation: Bridging the Gap in Neonatal Screening for Rare Diseases

Principal investigator: Frank Borge Wietzke, fbwietzke@ibei.org

Institution: Institut Barcelona d'Estudis Internacionals (IBEI)

I HEREBY CONFIRM that:

- I have received enough information on the project,
- I am above 18 years of age.

I UNDERSTAND that my participation is voluntary and that I can withdraw from or opt out of the study anytime without any need to justify my decision. I UNDERSTAND that the research is being conducted for an individual master's thesis project, and my personal data will not be kept, stored, or processed in any way. I UNDERSTAND that my participation is completely anonymous and confidential.

- I GIVE MY CONSENT to participate in this study.

First and last name(s):

Signature:

Place and date: