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# Complexity around the Colombian Childhood Cancer Law: Requirements for its Evaluation

## Complejidad de la Ley de Cáncer Infantil colombiana: requisitos para su evaluación

### ABSTRACT

**Introduction:** The complexity of health problems such as childhood cancer poses challenges in health care and in the evaluation of interventions. This situation is aggravated if policy makers and decision makers assume that a healthcare system works in a delimited environment with defined rules. The approach to childhood cancer in Colombia required the promulgation of a law to contribute to the reduction of mortality from this cause with implications for nursing. This study characterized its complex nature, evidenced the potential implications in its evaluation and proposed an evaluation scheme. **Methods:** Documentary research with related information available between the years 2010 and 2020. Bowen's guidelines for the analysis of the information were followed, the categories included were relevant actors, context, components, organizational levels involved and results. **Results:** The analysis of the problem made visible the influence of the social determinants of health, the interaction of multiple actors in various scenarios and a high degree of uncertainty in a complex health system. The response is a complex intervention with multiple components and actors involved at different levels to achieve the proposed results. **Conclusion:** Evaluating this intervention implies context-sensitive approaches, a clear definition of the problem and identification of the underlying theory necessary to achieve the expected results; Establishing its evaluability provides important inputs to reorient its scope and its transferability.

**Keywords:** Evaluation of Health Programs and Projects, neoplasms, public policy



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## RESUMEN

**Introducción:** La complejidad de problemas de salud como el cáncer infantil plantea desafíos en la asistencia sanitaria y la evaluación de las intervenciones. Esta situación se agrava si los responsables políticos y los tomadores de decisiones asumen que un sistema sanitario funciona en un entorno delimitado con reglas definidas. El abordaje de cáncer infantil en Colombia exigió la promulgación de una ley para contribuir a la disminución de la mortalidad por esta causa, con implicaciones para la enfermería. Este estudio caracteriza su naturaleza compleja, evidencia las potenciales implicaciones en su evaluación y propone un esquema evaluativo. **Métodos:** Investigación documental con información relacionada disponible entre los años 2010 y 2020. Se siguieron las orientaciones de Bowen para el análisis de la información y las categorías incluidas fueron las siguientes: actores relevantes, contexto, componentes, niveles de organización involucrados y resultados. **Resultados:** El análisis de la problemática visibilizó la influencia de los determinantes sociales de la salud, la interacción de múltiples actores en diversos escenarios y un elevado grado de incertidumbre en un sistema de salud complejo. La respuesta es una intervención compleja con múltiples componentes y actores involucrados a diferentes niveles para lograr los resultados propuestos. **Conclusión:** Evaluar esta intervención implica abordajes sensibles al contexto, una clara delimitación del problema y la identificación de la teoría subyacente que se requiere para lograr los resultados esperados; establecer su evaluabilidad aporta insumos importantes para reorientar su alcance y transferibilidad.

**Palabras clave:** Evaluación de Programas y Proyectos de Salud, neoplasias, política pública

## INTRODUCTION

Childhood cancer poses an economic burden on individuals, families, and society. Leukemia, the most common cancer in children worldwide, had the greatest impact on overall cancer incidence in the first decade of this century, and in 2017, it accounted for the highest proportion of Disability-Adjusted Life Years (DALYs) with 34.1%, followed by brain and nervous system cancers with 18.1% (1).

In Colombia, in 2019, the prevalence of pediatric cancer for all cancer types was 397.3 cases, and the mortality rate was 20.2 per million inhabitants under the age of 18, with an average age of 10.4 years. The most frequent types were Acute Lymphoblastic Leukemia (ALL), followed by Central Nervous System (CNS)

tumors, Non-Hodgkin Lymphoma (NHL), tumors of the urinary tract, and Hodgkin Lymphoma (HL). The median time between clinical suspicion and confirmed diagnosis was 14 days, and between diagnosis and first treatment was seven days (2).

This group of diseases often leads to fatal outcomes due to inadequate and untimely diagnosis and treatment, as well as limited susceptibility to prevention strategies (3). There is also a lack of evidence regarding the effectiveness of population-based screening programs to improve outcomes (4). Addressing these conditions requires a systemic approach that includes early and accurate detection, as well as completion of treatment to increase survival rates. Hence, appropriate planning by decision-makers is necessary in order to ensure sufficient resources and proper functioning of

the healthcare system; in addition, the development and strengthening of capacities of those responsible for implementing policies are also important, aspects that are often overlooked due to missed opportunities for diagnosis and treatment. From the perspective of complexity, considering those aspects allows the recognition of instability and uncertainty faced by patients and their families <sup>(5)</sup> and it involves the identification of the needs for human-centered, compassionate care <sup>(6)</sup> to enable timely and adequate management.

Success in the treatment of diagnosed children can be achieved in 80% of cases, but access to modern treatments and solid supportive care is required <sup>(7)</sup>. In high-income countries, the five-year survival rate after diagnosis is 80%. However, over 90% of children at risk of developing childhood cancer live in low-income and middle-income countries (LMICs). This situation has been associated with resource scarcity, fragility of the healthcare system, limited awareness among providers, and absence of policies <sup>(3)</sup>.

Addressing complex issues like this group of diseases, where social determinants of health (SDH) play a significant role in achieving outcomes, generates diverse opinions among stakeholders regarding appropriate actions. Imperfect or paradoxical knowledge for the best course of action has contributed to difficulties in providing adequate healthcare, particularly when policymakers and decision-makers adopt a reductionist and linear approach regarding the healthcare system <sup>(8)</sup>.

The suggested strategies for addressing these issues are based on systematic reviews and controlled clinical trials, given the rigor of evidence-based approaches. However, the results of these tools often become procedures that fail to consider the context of implementation <sup>(9)</sup>, assuming that the healthcare system operates within a well-defined and delimited environment, which is not the case in reality. Therefore, it is necessary to expand the approaches used to identify, implement, and evaluate effective responses to the challenges posed by this morbidity, including a focus on complex systems.

Health systems are built upon numerous interacting subunits, resulting in collective behaviors that provide feedback, adapt to change, evolve over time,

and exhibit nonlinearity—a characteristic of complex systems <sup>(10)</sup>. Complex interventions combine individual components with collective action to achieve a purpose, with well-defined objectives and complex collective behaviors. They process sophisticated information and adapt to ensure contextual adequacy and success <sup>(11)</sup>. Such interventions involve interactions among their components, the targeted groups or organizational levels, and are influenced by the degree of flexibility allowed, the behavior required from those delivering or receiving the intervention, and the number and variability of outcomes <sup>(12)</sup>.

In this analytically approached study, grounded in critical realism, it is acknowledged that phenomena exist and operate within open systems, and as a result, a wide range of contexts and different mechanisms can affect the outcomes. We seek to approach the complexity of the childhood cancer law enacted in 2010 <sup>(13)</sup> to identify its background, the constituent parts (components, interacting organizational levels, and proposed outcomes), and propose key elements to consider in its evaluation and an evaluative framework.

## MATERIALS AND METHODS

The conducted research was documentary from the perspective of complex systems, which is particularly useful for the case of public policies as it provides significant information on what, why, and how they operate <sup>(14)</sup>. This study takes into account the distinctive characteristics of such interventions, such as interactivity, disorder, and emergence.

The analysis of the documents was carried out based on Bowen's guidelines, using an iterative process that combines content analysis (organizing information into categories related to the central research questions) <sup>(15)</sup> and thematic analysis (identifying patterns within the data, with emerging themes becoming the categories of analysis).

The data sources included debates in the Congress of the Republic prior to the enactment of the law (2008-2010) and the related regulations available on the website of the Ministry of Health and Social Protection between 2010 and 2020. These documents

were categorized by type (legislative: proposals, judgments, bills, laws; executive: resolutions, decrees, agreements).

The data extraction and analysis process involved developing a manual of data codes with categories such as relevant actors, context, components, organizational levels involved, and identified results related to the law (immediate, intermediate, and long-term). The documents were carefully read and reread to identify patterns within the data, and from these patterns, emerging themes were developed as complementary categories for the analysis.

The coding process was performed using the MAXQDA 11<sup>®</sup> software (16), which facilitated organizing the data to identify and develop themes. During the coding of the documents, inductive codes were assigned to segments of data that described a new theme observed in the text. The themes were connected by grouping them under headings related to the predefined categories.

Quality control criteria included authenticity, credibility, representativeness, and meaning (17). The recommendations of the Standards for Reporting Qualitative Research (SRQR) (18) were followed in preparing the article.

## RESULTS

### REGARDING THE PROBLEM

After analyzing 57 documents, including laws (4), discussions in the Congress of the Republic (7), judgments of the Constitutional Court (24), decrees (2), resolutions (19), and agreements related to the childhood cancer law, it was found that national studies on childhood cancer in the first decade of this century reported survival rates for acute lymphoblastic leukemia (ALL) between 61.3% and 40-50%, in contrast to 92% in high-income countries (19). In high-income countries, the reported treatment toxicity for ALL was 2%, with almost no treatment abandonment and a relapse rate of 12% between 1990 and 1999, while in the country, documented treatment abandonment rates were 17.35% and 22% between 1999 and 2003, respectively.

The observed increase in cases of children under 15 years old, with leukemia being the most frequent cancer, represented the second leading cause of infant mortality, placing the country with the highest levels in all Latin America. Structural economic, social, and cultural aspects related to the timeliness, quality, and follow-up of children treated were identified as causes related to the problem. The absence of a public policy led by the Ministry of Health to achieve substantial improvements in the care and outcomes of children diagnosed with the disease was reported, along with insufficient regulations to guarantee relevant, comprehensive, and effective services aimed at impacting mortality, survival, and patient abandonment.

It was argued that the existing regulations in 2009 had weaknesses in aspects related to establishing requirements for procedures, human resources, psychosocial support, palliative care, hospitalization, and care standards, as well as information issues that led to the failure to guarantee the right to health. Evaluations indicated scarce or no results even after more than 10 years of implementing the reform to the social security system in terms of reducing morbidity and mortality rates.

The care provided to this population fell short of the requirements for comprehensiveness, quality, and relevance that would improve mortality rates, leading to inadequate management from a clinical and emotional point of view. Therefore, significant improvements were considered feasible since the treatments were guaranteed, requiring the adaptation of care models and adjustments in the organization of services related to timely authorizations, the supply of quality medications, and the provision of appropriate care units according to the requirements presented in the proposed law (20).

### REGARDING THE INTERVENTION

a) **Components:** The law is aimed at ensuring the care of children diagnosed with pediatric acute leukemia or any of the diseases related to hematopoietic cancer, covering all required diagnostic or therapeutic procedures without administrative authorizations procedures.

Key elements defined in the law included the creation of a unique database for streamlined care, a National Childhood Cancer Registry to allow real-time monitoring of the patient's treatment progress, which included a Network Monitoring System for active and real-time surveillance of early alerts identified as potential threats to the patient's life and safety: accessibility, timeliness, safety, relevance, and continuity.

Additionally, the law proposed the definition of a care model for children with this disease to guarantee the integration of health service networks and full coverage of the required treatments in specialized units called Units for Comprehensive Care of Childhood Cancer (UCCCC). These units were responsible for assessing the patients' health status, defining their management, and providing treatment, ensuring acceptability and quality in healthcare with accessibility, timeliness, relevance, continuity, and comprehensiveness.

Moreover, the development of Comprehensive Care Guidelines for early detection, timely diagnosis, and comprehensive treatment of childhood leukemia was also included, aiming to standardize criteria and provide quality care based on the highest level of scientific evidence. This initiative also implies training actions for general practitioners and other clinical specialties in early case detection, as well as the provision of social support services such as a type of halfway houses, psychosocial support, transportation costs, and educational support for children and their caregivers <sup>(21)</sup>.

**b) Interacting organizational levels:** Multiple stakeholders were identified at different levels. At the national level, these include the Ministry of Social Protection (MSP), the National Cancer Institute (NCI), the Colombian Association of Hematology and Pediatric Oncology (CAHPO), the Solidarity and Guarantee Fund (SGF), the Advisory Council for Childhood Cancer, the National Institute of Health (NIH), Health Plan Management Companies (HPMC), and the entities responsible for inspection, surveillance, and control (SC) of the system's actors.

At the departmental level, the stakeholders include the Departmental Health Directorates, the Advisory

Council on Childhood Cancer, and the entities responsible for inspection, surveillance and control (SC) at that level. Finally, at the local level, the stakeholders include the Comprehensive Units for Comprehensive Care (UCCCC), high-complexity Health Service Providers (HSP), Local/District Health Directorates, educational institutions, cancer population registries, the physician establishing the diagnostic presumption in minors, the educational institution, and the affected families and children <sup>(21)</sup>.

**c) Expected outcomes:** The law aimed to reduce mortality in children under 18 years old, with results related to continuity in the educational system, patient traceability, information for decision-making, service delivery, guarantee of acceptability of care, and availability and sufficiency of care, administrative, and logistical components. It also aimed to support management for service provision, as well as evaluation and monitoring of management and results. These results, in turn, should contribute to diagnostic timeliness, treatment adherence, and quality of care, the latter defined by access, timeliness, relevance, continuity, and comprehensiveness of care <sup>(21)</sup>.

## CONTRIBUTIONS OF THE EVALUATION

Evaluating complex interventions involves making decisions related to the evaluation question, objective, and intention, which depend on multiple factors such as the feasibility, viability, and utility of the evaluation. The abundance of available inputs to understand the intervention complicates a clear understanding of it, which can significantly impact the planning of a high-quality evaluation. Therefore, it is necessary to develop a theoretical understanding of the probable process of change to demonstrate the justification of the intervention, the expected changes, and how they will be achieved. This implies reviewing the related information to identify any ambiguities and clarifying them with the developers before finalizing the evaluation design <sup>(12)</sup>. This exercise should be complemented by constructing a logical model of the intervention to identify the

central components, how they relate to generate change, the expected short, medium, and long-term results, and the necessary resources and structures to ensure the implementation (22).

It is also important to conduct an evaluability assessment to determine if the evaluation is premature given its development stage or disproportionately costly considering data availability, expected effects size, and the difficulty of designing a high-quality evaluation study (23).

The process evaluation explores how the intervention is implemented and provides valuable information on why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimized (12). It allows the evaluation of fidelity and implementation quality, clarifying causal mechanisms, and the identification of contextual factors associated with variation in outcomes.

Finally, it is possible to develop an evaluation aimed at identifying and evaluating the effects that contexts have on the underlying mechanisms or processes that describe how the intervention produces its effects. The interaction between context (C), mechanisms (M), and outcomes (O) allows us to understand what works, for whom, under what circumstances, and why (24).

Based on the above, the following evaluation framework is proposed for the intervention outlined (Figure 1), starting with (1) reconstructing the intervention theory, followed by (2) conducting an evaluability assessment that allows (3) adjustment of the initial design. With these inputs, the theory is (4) validated by evaluating the relevance and sufficiency of the intervention according to the problem, followed by a process evaluation to (5) assess performance during implementation and subsequently (6) evaluate the outcomes and (7) refine the intervention theory.

## DISCUSSION

The analysis of the problem has highlighted the influence of social determinants of health (SDH) on children suffering from these conditions, with the interaction of multiple actors in diverse settings and a high degree of uncertainty in a complex healthcare system. While the relationship between SDH and childhood cancer is widely recognized, the response has mainly focused on the provision of healthcare services, neglecting actions in other essential fronts and levels required for comprehensive care. Therefore, it is

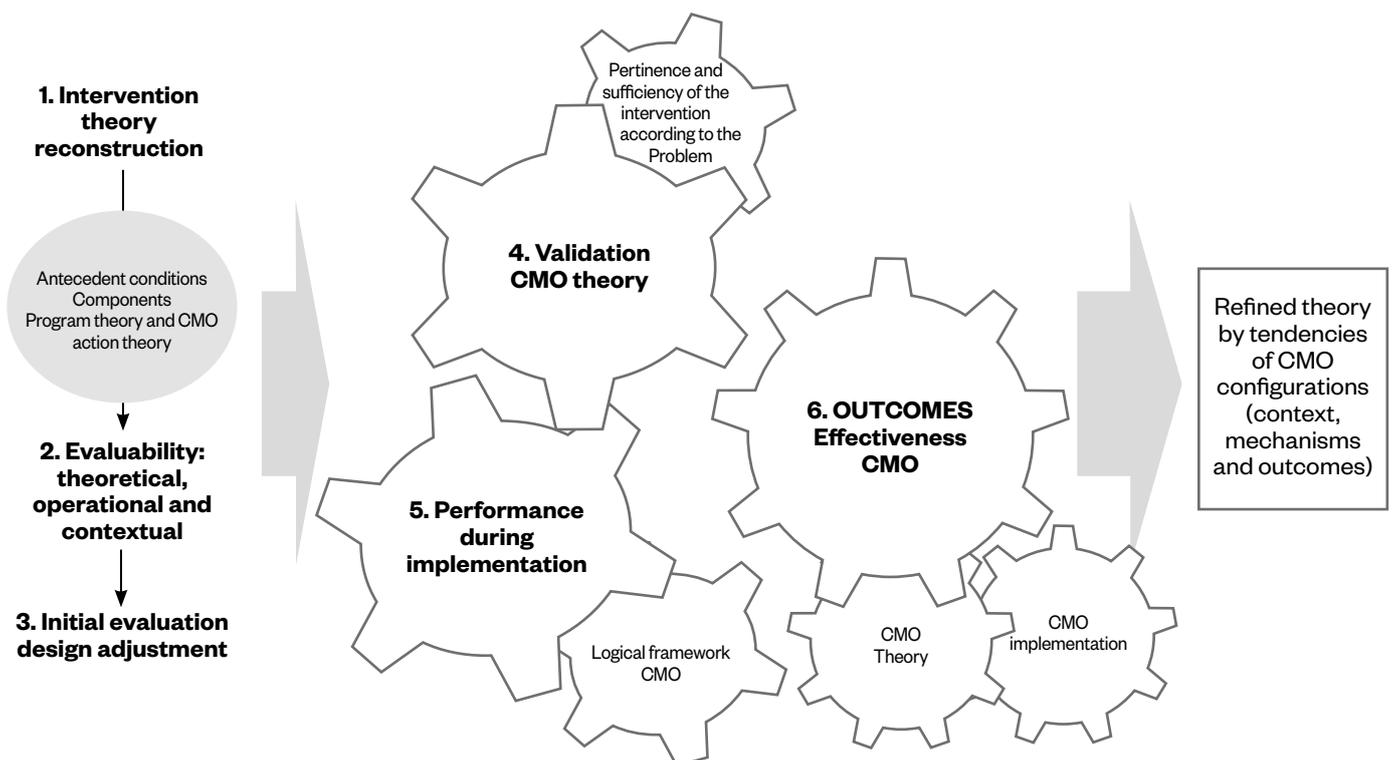


Figure 1. Evaluation Framework

considered that focusing efforts solely on the service component is limited and insufficient, and a broader perspective is needed in the response, including the active participation of intervention beneficiaries. Petrie and Peters (8) argue that this type of problem significantly hampers the ability to provide healthcare assistance to citizens, hence, it is crucial not only to acknowledge it but also to accept complexity as fundamental in addressing the challenges it represents.

Internationally, interventions for these conditions assume that survival is influenced by the quality of care, which depends on a functioning healthcare system with supportive services and activities at the health care centers (4). Therefore, for LMICs, key components have been proposed, such as financial coverage of treatment to alleviate caregivers' financial burdens, accreditation of health care centers, mandatory registries to inform resource allocation, evaluation of policy implementation related to these conditions, and the development of national care standards that consider local capacities and realities with financial incentives, among others (25). Thus, the guidelines for the care of children with these conditions involve their care, their caregivers', and guidance to the working team, creating connections that enable addressing SDH, humanizing care, and alleviating suffering related to the disease and its management (26).

From the review of the regulation, support services, information system, care model, national cancer observatory, and childhood cancer care units were identified as components. These components characterize the intervention as complex since they interact, target different organizational levels, and aim to achieve a

series of results. However, it should be considered that complex interventions exhibit properties similar to the complexity of the broader systems in which they are introduced (11), such as the healthcare system in this case.

The limitations of this study include issues related to the accessibility and quality of policy documents (27) and the organizational context of the entities involved in policy formulation. The available documents adhere to the norms and procedures of the organization and may have limitations in the required information they incorporate.

## CONCLUSIONS

The problem regarding childhood cancer requires evaluation approaches that are sensitive to the context and its complex nature, with a clear delineation of the problem and identification of the underlying intervention theory necessary to achieve the expected outcomes, information that is often not available at the time of evaluation. Therefore, the evaluation perspective needs to be expanded to account for these factors, going beyond measuring final outcomes. Additionally, the evaluation process should serve as a political tool that encourages informed decision-making and ongoing reflection on practice by using innovative, open, and diverse approaches for evaluation. The evaluability study of the intervention provides important inputs for reorienting the scope of evaluation and the transfer of interventions.

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