National Cancer Information System Within the Framework of Health Insurance in Colombia: A Real-World Data Approach to Evaluate Access to Cancer Care

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PURPOSE The National Cancer Information System (NCIS) has been operating since 2014, including information reported by health care insurers and providers on people with cancer diagnosed and treated within the Colombian health system. Its main purpose is to identify barriers to an effective access to cancer diagnosis and treatment across the country. We aimed to describe the methodology, scope and results in terms of access to health services with real-world data provided by the NCIS.

METHODS Reporting of all cases of cancer by insurers and providers is mandatory by law. Data gathered include demographic and clinical information about new and old cases of cancer who receive health services. Over the years, the reporting process has been automated and it is currently performed in real time. Data quality is ensured through a standardized data-monitoring process. Access to health services is monitored by quality measures defined by consensus.

RESULTS Since 2015, prevalent cases of invasive cancer have increased from 163,776 to 331,021 in 2020 (increment of 102.12%). Regarding quality measures, the proportion of people staged at diagnosis has increased over the years, especially in breast cancer. Meanwhile, early diagnosis is still concerning for breast and prostate cancer. Time to diagnosis and treatment have not consistently reached the expected goals in breast, cervical, and prostate cancer, whereas they have shown a better level of compliance for stomach and colon and rectum tumors, still not reaching the highest performance.

CONCLUSION The real-world information approach provided by the NCIS may be complementary for cancer control planning in Colombia, emphasizing better management processes of health insurers and providers by identifying barriers for timely access to health care.

INTRODUCTION Cancer is a leading cause of morbidity and mortality worldwide. The estimated 18.1 million new cases and 9.6 million cancer deaths in 2018 by the Global Cancer Observatory could rise to more than 22 million new cases and 14 million deaths by 2030, with a major impact in countries with low or medium human development index.

The growing burden of cancer requires national control plans on the basis of high-quality data provided by nationwide information systems. In this context, data from population registries and country-level surveillance systems can be useful to monitor its frequency, find patterns of access to screening and treatment services, and improve cancer survival.

On the other hand, the Colombian health system is public-private with universal and mandatory coverage. There are two main regimes of insurance (third payer and state) based on individual financial status. The first one groups the country's workforce, whereas people unable to pay for health care are enrolled under the state program. Despite universal health coverage and a government-sponsored 10-year cancer control plan, barriers in accessing cancer care persist. They are mainly administrative, social, and economic, which means that the objectives set by the government are not always achieved, with patients being diagnosed at advanced stages, which affects quality of life, survival, and costs of care. Some of them can also be explained by the fragmentation of cancer care because of the lack of comprehensive care medical centers and trained medical personnel, and geographic barriers that finally harm the diagnostic and therapeutic process.

Taking into account the need for real-world information with a national scope, the National Cancer Information System (NCIS) has been operating since 2014, including information reported by health care insurers and providers on people with cancer diagnosed and treated within the Colombian health system. Its main purpose is to identify barriers to an effective access to cancer diagnosis and treatment across the country. We aimed to describe the methodology, scope and results in terms of access to health services with real-world data provided by the NCIS.
Information System (NCIS), managed by the High Cost Diseases Fund (Cuenta de Alto Costo [CAC] in Spanish), was created by the Colombian Health Ministry\textsuperscript{11,12} for improving the decision-making process through the evaluation of access to cancer diagnosis and follow-up within the framework of the national health system. Data from the NCIS are translated into information that allows the stakeholders to take action through policies and processes aimed to reduce the burden of disease and improve financial sustainability.

Therefore, we aimed to describe the methodology and scope of the NCIS, focusing on its results in terms of access to health care through quality measures.

**METHODS**

**NCIS Overview**

Cancer has been defined by the national government as a high-cost disease and a central public health issue.\textsuperscript{13} The Ministry of Health has established a regulatory framework to improve survival and quality of life of people living with cancer, which includes the creation of national surveillance systems.\textsuperscript{11} The model of cancer care was defined in the 10-year Plan for Cancer Control in Colombia, 2012-2021,\textsuperscript{14} including three strategic aspects: surveillance, situational analysis, and research. In 2014, the reporting of people with cancer was stated as mandatory for health insurers by Resolution 247 and the NCIS was created.\textsuperscript{12}

Since then, the NCIS has collected and analyzed demographic, clinical, and health-related quality measures in people with cancer across the country\textsuperscript{11,12} (Appendix Fig A1).

Taking into account that the national health system covers about 96% of the total population in Colombia\textsuperscript{15} and they must be reported by their health care insurers, the NCIS estimations reflect a real-life pattern of cancer distribution and risk management.

The Ministry of Health\textsuperscript{13} defined 11 priority cancers according to their epidemiologic burden, the possibility of prevention, and the associated cost: seven solid tumors (breast, prostate, cervical, stomach, colon and rectum, lung, and melanoma) and four hematologic neoplasms (acute lymphoblastic and myeloid leukemia, and non-Hodgkin and Hodgkin lymphomas). Nonetheless, the NCIS includes information on other types of cancer.

**Variables**

The NCIS yearly collects 132 variables stated by the Ministry of Health through a resolution,\textsuperscript{12} defined following a 10-step consensus conference methodology,\textsuperscript{16} developed with a panel of clinical experts and the stakeholders from the health system, scientific and patient associations, the academy, and state regulatory authorities.

Variables are classified into three groups. There are 16 sociodemographic variables: sex, occupation, health insurance, ethnic background, municipality of residence, and identification of the health insurer that provided care during the period. Clinical section has 108 variables: diagnosis, staging, and first treatment (25 variables); history of a previous cancer diagnosis (three variables); and specific information about systemic therapy (29 variables), surgery (12 variables), radiation therapy (20 variables), cell transplant (five variables), or complementary treatment (14 variables). The final section has 10 variables to determinate vital status.

Each year, the operational definition of the variables is reviewed and updated with an expert panel.
Clinical Classification and Staging
The anatomic site is coded using the International Classification of Diseases 10th revision (ICD-10). Invasive cancer is defined following the International Agency for Research on Cancer criteria on the basis of ICD-10. Staging is determined with the eighth edition of the American Joint Committee on Cancer tumor-node-metastasis (TNM) classification in solid tumors, except for some types such as cervical cancer, for which the revised 2018 International Federation of Gynecology and Obstetrics system is used.
Non-Hodgkin lymphoma staging in pediatrics is defined with the Murphy’s classification, whereas for non-Hodgkin lymphoma in adults and Hodgkin lymphoma in adults and pediatrics, it is based on the Ann Arbor or Lugano systems. In leukemia, risk stratification is used.

Reporting Process
Annually, health care providers must report information on the clinical management of people with cancer to their health insurers. For cases reported in previous periods, clinical data are updated, whereas for new cases, a complete registration is performed. Each patient is identified with a unique ID for linking data sets. Health insurers upload the information into an interconnection system called SISCAC (Sistema de Interconexión e Intercambio de Información en Salud [by the Spanish acronym for System of interconnection and exchange of health information]) that allows the registration process in real time (Fig 1).

Data-Monitoring Process
Once the report is completed, a data-monitoring process is performed to guarantee data quality. It is achieved in two steps. An initial cross-check is done through a systematized validation mesh that identifies loading mistakes according to specified filters and rules, by evaluating variable’s structure, coherence, and consistency.
Then, information is compared with clinical records to verify its authenticity in an auditing process performed by a trained health professional staff. All new cases of a prioritized type of cancer and people previously diagnosed with a prioritized cancer who were treated during the period are audited. From nonprioritized cases, a random sample is audited.
During the auditing process, the first step is the verification of vital and affiliation status with external sources provided by the Ministry of Health. Inconsistent data are adjusted according to the information on clinical records. Finally, all observations (audited or not) are reviewed in three essential aspects: people who died before the measurement period, records with administrative inconsistencies or lack of clinical supports for diagnosis confirmation, and duplicates (Fig 1).

Exhaustiveness of Death
It is confirmed with the official source of the Ministry of Health. The annual matching allows determining the vital status and the date of death (Fig 1).

Cases Included in Epidemiologic Analyses
Although the main purpose of the NCIS is not to establish epidemiologic burden of cancer, it estimates an approach of morbidity and mortality measures among insured people. In that sense, cases who died before the measurement period are excluded, as well as some records without confirmed cancer diagnosis or valid supports to prove it. Duplicates are excluded under certain conditions. In multiple primary tumors of different locations or organs, all records are analyzed, but metastases are excluded. When a tumor appears in subsites of the same organ or on opposite sides of the body (for paired organs), it is determined if they are two different primary tumors or a reporting error; thus, cases are included or excluded, respectively (Fig 1).

Cancer Frequency
Counts of new and prevalent cases and deaths are based on the reporting process by health care insurers and providers. Frequency measures are calculated including only invasive cancers, except for cervical cancer, which may include carcinomas in situ (ICD-10: D060, D061, D067, or D069) following the International Agency for Research on Cancer criteria. New cases are those diagnosed by either clinical or pathologic methods during the reporting period. Point prevalence is estimated for each period including all cancer cases, regardless of vital status at the cutoff date. The all-cause mortality rate is also calculated. The estimated population at the national, department, and municipality level by the Department of National Statistics are used as denominators.

Risk Management Indicators (quality measures)
Conforming to the main goal of the NCIS, a set of indicators to evaluate access and quality of care were established, among other aspects. They were defined using the consensus methodology, and the detailed process has been previously described. Currently, risk management indicators are measured for breast and cervical cancer, stomach and colon and rectum cancer, prostate cancer, lung cancer, and melanoma, as well as hematologic neoplasms in adults, Hodgkin and non-Hodgkin lymphomas and myeloid and lymphoblastic acute leukemia, and leukemia (myeloid and lymphoblastic) in childhood. They are measured annually and their compliance is evaluated through a three-category scale: low, medium, and high performance. The cutoff points for each category vary according to the indicator and were also defined by consensus after a systematic review.
Most quality measures are focused on the process of attention and a few on results of the health care continuum, covering aspects related with diagnosis, staging, treatment,
Reporting of people with cancer

Real-time data

Health clinical records

Health care providers
Health insurers

Reporting process

Uploading information

Process-monitoring process
Statistical analyses
Resource allocation mechanism

High Cost Diseases Fund (CAC, by its Spanish acronym)

2

3a

3b

Creation and validation of data upload rules

Data-loading process

Web validation tool

Verification of consistency, structure, and completeness

Health insurers

Resource allocation mechanism

Final database

Statistical analyses

4

5

Database to audit

Data audit process

All new and prevalent cases (prioritized cancers) and a random sample of nonprioritized cases

Consistent with clinical records

Data available

Findings report

Final database

Statistical analyses

Measure of risk management indicators (defined by consensus methodology)

Annual report of cancer situation

Books (adults and pediatrics)

High Cost Diseases Fund (CAC, by its Spanish acronym)

3a

3b

Crossing with external sources: BDUA

Evaluation of the death exhaustiveness and vital status

Duplicates (multiple tumors)

Records without inconsistencies

Cases included in epidemiologic analyses

Morbidity and mortality estimations

Cases included in epidemiologic analyses

Measure of risk management indicators (defined by consensus methodology)

Annual report of cancer situation

Final database

Prevalence of prioritized cancer types

Risk management indicators by Resolution 3339

Resource allocation mechanisms

Reimburse a percentage of the most expensive patients for insurers

Handbook for a proper reporting process

Verification of consistency, structure, and completeness

Consistent with clinical records

Data not available

Findings report

Validated database

Ministry of Health

Statistical analyses

Resource allocation mechanism

Final database

Statistical analyses

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Annual report of cancer situation

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FIG 1. General structure and information flow through the NCIS. First, health insurers and providers must report people with cancer who received care within the national health system. Once data are loaded, their consistency, structure, and completeness are validated according to some reporting rules previously defined. Then, the resulting data set goes to a standardized data-monitoring process where a random sample is taken and information reported is validated with clinical records. Finally, after some additional validation with external sources, a depurated data set is ready to be analyzed. BDUA, Base de Datos Única de Afiliados (National Database of Affiliated People); HIGIA, Hechos, Información, Gestión, Innovación, Acción (Epidemiologic and Quality Measures Dashboard); NCIS, National Cancer Information System; NCSR, Registro Nacional del Estado Civil (National Civil Status Registry); SISCAC, Sistema de Interconexión e Intercambio de Información en Salud (System of interconnection and exchange of health information).

Other  
$n = 8,102$ (46.85%)

Lung  
$n = 763$ (4.41%)

Hematologic  
$n = 1,511$ (9.29%)

Melanoma  
$n = 223$ (1.29%)

Colon and rectum  
$n = 1,609$ (9.30%)

Prostate  
$n = 3,692$ (21.35%)

Stomach  
$n = 1,394$ (8.06%)

Breast  
$n = 6,550$ (28.00%)

Cervical  
$n = 1,960$ (8.38%)

Stomach  
$n = 882$ (3.77%)

Breast  
$n = 6,550$ (28.00%)

Cervical  
$n = 1,960$ (8.38%)

Stomach  
$n = 882$ (3.77%)

FIG 2. New cases distribution by type of cancer and sex in Colombia, 2020: (A) females of all ages and (B) males of all ages. Includes invasive cases only. Lymphomas (Hodgkin and non-Hodgkin) and leukemia (myeloid and lymphoid) were included in hematologic neoplasms.
waiting times to be diagnosed and treated, access to interdisciplin ary attention, palliative care, and end-point outcomes such as 5-year observed survival.

Evaluation and monitoring of risk management indicators is highly valuable to identify gaps in cancer diagnosis and treatment, considering the sources of heterogeneity related to health care services that include type of insurance, availability of trained personnel and facilities, and social and economic disparities between regions.

**Ethical Considerations**

The NCIS follows international standards by the Council for International Organizations of Medical Sciences and national regulations (Resolution 8430 of 1993, stated by The Colombian Health Ministry) for conducting human research. Confidentiality is guaranteed in compliance with Law 1581 of 2012, which stated conditions for protecting personal data in Colombia. All NCIS members follow a security policy for maintaining confidentiality and privacy of personal information. Access to data is also according to predefined user profiles by security passwords. Furthermore, each case is identified with an internal ID assigned by the NCIS, all data sets are anonymized for statistical analysis, and the results only can be used for approved purposes.

**RESULTS**

**Registry Evolution: Frequency of Cancer Within the Colombian Health System**

Since 2015, prevalent cases of invasive cancer reported to the CAC have increased by 102.12%, going from 163,776 to 331,021 in 2020. Furthermore, 40,689 new cases of invasive cancer and 26,305 deaths were reported by 2020 among people who receive health care within the national health system.

By 2020, among new cases of invasive cancer, the most frequent type was breast cancer (16.36%; n = 6,656), followed by prostate (9.07%; n = 3,692) and colon and rectum cancer (8.27%; n = 3,363). Breast cancer was the leading cause of death (11.35%; n = 2,986), followed by colon and rectum (8.83%; n = 2,324) and prostate cancer (8.10%; n = 2,131). Figure 2 shows the distribution of new cases by sex and type of cancer.

**Trend of Quality Measures in the NCIS**

TNM staging in newly diagnosed cancer cases is described in Figure 3. When comparing the current reporting period with the baseline, the biggest improvement in TNM coverage was observed in breast and prostate cancer, although the high level of compliance (≥ 90%) has not been reached for any type of cancer.

**FIG 3.** Trend of TNM staging at diagnosis by type of cancer in Colombia, 2015-2020. High level of compliance for TNM staging at diagnosis has been established up to 90%. TNM, tumor-node-metastasis.
Figure 4 shows the proportion of new cases diagnosed in early stages by type of cancer. A heterogeneous pattern has been identified over the years, especially for stomach and colon and rectum cancer. By 2020, early diagnosis was higher than the baseline for all types, except prostate and stomach cancer. Despite well-established screening programs for breast and prostate cancer, early diagnosis remains a challenge for insurers and providers.

Access to health care can be assessed with waiting times for diagnosis and treatment initiation. According to the NCIS quality measures, goals have not been consistently achieved during the follow-up (Fig 5). Regarding diagnosis, the longest waiting time was observed in prostate cancer. When comparing with 2019, there was a generalized increase in delays to be diagnosed. Time to treatment initiation (TTI) showed a more stable trend, with the lowest waiting time for breast and cervical cancer. Gaps between time to diagnosis and treatment were broader for stomach and colon and rectum cancer than prostate.

**Diffusion of the Results**

The results of the current situation of cancer in Colombia are published in different formats. Annually, the epidemiologic trends, clinical characteristics, and risk management of the prioritized types of cancer are described in two electronic books in adult and pediatric population. Data are also available on interactive platforms such as SISCAC (accessed by health insurers and providers) and HIGIA (public access).

**DISCUSSION**

The NCIS provides real-time data to improve risk management and decrease the burden of cancer in Colombia. It adds value through the identification of gaps in access to cancer care contributing to the generation of interventions for their mitigation. It is also a source of information to evaluate compliance with cancer policies and improve the comprehensive health care routes. On the other hand, it contributes to the financial stability of the health system through the redistributive allocation mechanisms on the basis of results that were stated by law from data analyzed by the NCIS with the objective of improving clinical outcomes, health quality, and timeliness of cancer care.

From the analysis of quality measures trend, a heterogeneous pattern in access to cancer care was identified. It is important to mention that delays in diagnosis and treatment initiation have been associated with worse health outcomes, with negative impact on survival.

A cohort in the United States that evaluated the association between delays in treatment initiation and survival found a median TTI increased from 20 days (interquartile range
(IQR: 0-27) in colorectal cancer to 57 days (IQR: 31-87) in prostate cancer. All waiting times in this study were higher than that estimated in the NCIS and longer delays in prostate cancer are consistent with our results. In this study, delays in TTI were associated with an increased risk of mortality ranging from 1.20% to 3.20% per week in early-stage breast, lung, renal, and pancreatic cancers. These results are consistent with a prospective cohort that estimated a median TTI of 26 days (IQR: 16-40) for colorectal, 32 days (IQR: 21-48) for breast, and 79 days (IQR: 55-117) for prostate cancer, similar to our population. In addition, shorter TTI was directly associated with a lower mortality. The broader difference was identified in colorectal cancer with an increase of 47.80% in the 5-year predicted mortality when delays for TTI were more than 180 days.

Finally, a systematic review and meta-analysis found that each 4 weeks of surgical delay increased the chance of death by 6%-8% for all types of cancer. In breast cancer particularly, an 8-week delay in surgery would increase the risk of death by 17% and a 12-week delay by 26%. In the NCIS, TTI in Colombian women was higher than 4 weeks, meaning that barriers to an effective access to treatment could be directly increasing the risk of death.
Diagnosis and treatment delays are multifactorial, including among others, system barriers. National quality measures in terms of access to cancer health care are a good strategy to quantify and minimize system delays.38 Most health systems have implemented this metric, setting that TTI should be < 30 days, being able to increase even to a maximum of 45 days in middle-income contexts.39 Level of compliance for the NCIS indicators was established following international targets, although they have not been achieved. In this sense, the role of the NCIS is crucial to identify the barriers and patterns of access to cancer care and promote a more integrated, centralized, and multidisciplinary approach from the health system perspective.

Several factors have contributed to the continuity of the NCIS. The most important is the mandatory report by health insurers. Besides, the CAC has established standardized policies to collect, validate, analyze, and disseminate its information. Furthermore, the innovation has been a vital aspect in the NCIS, finishing with the launch of SISCAC, the most ambitious platform in the country to interconnect the health system stakeholders.

Moreover, the CAC has settled continuous training strategies with the health insurers to guarantee an adequate reporting process. Another important strength is the data-monitoring process from which the data quality and reliability are verified.

On the other hand, estimations obtained from the NCIS offer an opportunity to design policies to improve access to high-quality cancer care from a precise real-world source of data.

The NCIS has some limitations. Since the NCIS depends on the reporting process performed by health insurers and although it is mandatory, there is a risk of underreporting, especially in undiagnosed cancers with high mortality, affecting the completeness of the NCIS. In addition, as each health care provider has autonomous and independent procedures to handle the data, information bias cannot be ruled out.

In conclusion, the NCIS is helpful to identify barriers in accessing care from the health system perspective. It also describes the real-life situation of cancer care in the insured population being complementary to other sources of information for cancer planning. Targets in time to diagnosis and treatment have not been achieved and delays could be associated with worsened survival.

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AUTHORS’ DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST
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APPENDIX

FIG A1. Legal framework of cancer as a high cost disease in Colombia. Since 2009, health policies to improve cancer control have been established in Colombia, including the 10-year national plan in 2012 which stated the basis of national surveillance systems. Then, in 2014 the NCIS was created to collect and analyze access to cancer care among insured population. Finally, in 2019 a resource allocation mechanism based on cancer results in terms of access to health care was stated by the Ministry of Health. It aims to control the economic burden of cancer among insurers.