Structuring the National Policy for Laboratory Diagnosis in the Context of Healthcare – PNDL

Estruturação da Política Nacional de Diagnóstico no Contexto da Atenção à Saúde - PNDL

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CONTEXTUALIZATION

The Brazilian Society of Clinical Analysis (SBAC), concerned with the evolution of Clinical Analysis activities in Brazil, motivated by debates surrounding the update of RDC 302/2005, which culminated in the publication of RDC 786/2023 by ANVISA, and the impact on the sector that may bring consequences for users of the Unified Health System (SUS), positions itself in favor of the development of a National Policy for Laboratory Diagnosis (PNDL – Política Nacional de Diagnóstico Laboratorial).

The SBAC, supported by strategic entities, has been consolidating political forces to ensure that laboratory diagnostic actions emerge as key players in the healthcare landscape in Brazil. Alliances are essential for achieving this important nationwide objective. Therefore, this document also serves as a call to unite efforts toward the establishment of a PNDL that encompasses clinical, toxicological, and environmental analyses. The current state of Clinical Analysis in Brazil stems from the absence of a National Healthcare Policy that incorporates Diagnostic Actions into the Healthcare Process. Clinical, toxicological, and environmental analyses stand out for their contribution of essential elements to public health promotion, emphasizing the importance of analytical quality, user and worker safety, and the provision of timely responses regarding individuals' health status.

Public policies aimed at Healthcare depend on political participation and engagement, requiring scientific and technical advancements, as well as appropriate tools for management, technology integration, and the application of strategies to overcome service fragmentation. These efforts must align with the concrete perspective of achieving the effective universality and comprehensiveness of healthcare actions, with equity.

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Clinical and toxicological analyses are essential for the diagnosis, prevention, and treatment of various diseases, a fact that became particularly evident during and after the COVID-19 pandemic, which demanded an unprecedented volume of laboratory testing. However, these services are often inadequately recognized within the context of Healthcare services, which frequently overlooks the significance and complexity of clinical analyses within the Health System.

It is widely acknowledged that laboratory diagnostics play a crucial role in early detection, treatment, and disease prevention, contributing to approximately 70% of medical decisions. However, it is important to recognize that access to these services is not always equitable across the population. Numerous challenges must be addressed to ensure effective and equal access to laboratory diagnostic services.

Integrating laboratory diagnostic actions into the Healthcare process, within the Care Pathways and considering the network-based organization within the Health Care Network (HCN), requires not only the critical and sustainable incorporation of technologies but also a reevaluation of the logistics currently employed in delivering these services and a redefinition of the professionals involved in clinical and toxicological analyses.

The importance of professionals working in a multidisciplinary manner is underscored here, ensuring reception, comprehensive care, and ongoing support to SUS users in their processes of health promotion, protection, and recovery, taking into account the various determinants of health.

The reorganization and expansion of the diagnostic assistance network, both public and complementary, play a strategic role in guiding the criteria for technology incorporation, defining costs, and ensuring the quality of diagnostic services. This latter perspective is intrinsically linked to government policies aimed at ensuring patient safety and funding, highlighting their inseparable interconnections.

NATIONAL POLICY FOR LABORATORY DIAGNOSIS IN THE CONTEXT OF HEALTHCARE

The inclusion of Laboratory Diagnosis within the framework of Healthcare Policy under the Unified Health System is supported by a range of documents and references, including:

a) Documents from the Ministry of Health:
   - Clinical Protocols and Therapeutic Guidelines (PCDT).
   - National List of Essential Medicines (RENAME).
   - Manuals and specific guidelines for the Pharmaceutical Assistance sector.

b) Technical and Scientific Guidelines:
   - Technical guides related to pharmaceutical practice and clinical analyses.
   - Technical and scientific manuals produced by pharmaceutical scientific societies.

c) Academic and Scientific Publications:
   - Scientific articles highlighting the relevance of clinical laboratory diagnosis.
   - Theses and dissertations exploring the integration of laboratory diagnosis into Pharmaceutical Assistance practices.

d) International Experiences:
   - Documents from international health organizations (WHO, PAHO) describing successful cases of integrating clinical laboratory diagnosis with care and/or pharmaceutical assistance.

e) Public Consultations and Social Participation:
   - General and thematic health conferences.

f) Resolutions and Norms from the Federal Pharmacy Council (CFF):
   - Specific resolutions and norms from the Federal Pharmacy Council addressing the role of pharmacists in clinical laboratory diagnosis.

g) Reports and Evaluations:
   - Evaluation reports on Pharmaceutical Assistance in SUS.
   - Assessments of pilot programs or regional initiatives related to pharmaceutical clinical laboratory diagnosis.

Brazil has several policies and programs aimed at laboratory diagnosis, particularly in the healthcare sector. Some of the main ones include:

a) National Quality Control Program (PNCQ): This program aims to ensure the quality of laboratory tests through the participation of laboratories in external quality control evaluation programs.

b) Provision of Tests by the Unified Health System (SUS): SUS offers a range of laboratory tests free of charge to the population, particularly those considered essential for disease diagnosis and monitoring.

c) Public Health Laboratory Program (LACEN): The Central Public Health Laboratories (LACENs) are responsible for

performing medium- and high-complexity laboratory tests, especially those related to the monitoring and control of communicable diseases.

d) National Policy for Public Health Laboratories (PNLSP): This policy seeks to strengthen the SUS laboratory network by ensuring the quality of tests and fostering integration among the country's various laboratories.
e) Program for the Expansion and Improvement of Specialized Assistance (AMA/AME): This program aims to expand and improve access to high-complexity laboratory tests, especially for the diagnosis and management of chronic diseases.
f) National Neonatal Screening Program (PNTN): Also known as the "Heel Prick Test," this program offers laboratory tests for the early detection of metabolic, genetic, and infectious diseases in newborns.
g) Women's Health Program: This program ensures women's rights by reducing morbidity and mortality from preventable and avoidable causes, including the performance of cervical-vaginal cytopathological examination.

The rapid availability of new technologies applied to diagnostics, given the dynamic nature of this sector, enables the provision of products and services that incorporate concepts such as miniaturization, parallelism, and connectivity. The growing demand for solutions that increasingly meet the goals of expanding access, enabling early diagnosis, and guiding clinical decision-making highlights the need for innovations aimed at delivering diagnostics to the most remote areas, serving populations neglected by current public policies.

Emerging health technologies have the potential to transform patient care, improve diagnostic and prognostic procedures, and enhance the processes of health service management and delivery. They enable continuous patient monitoring for various health conditions, as well as the provision of personalized and targeted healthcare services.

Considering that over 70% of all clinical diagnoses are based on laboratory test results—an indispensable resource for accurately determining patients' clinical conditions and aiding in the selection of appropriate therapeutic approaches for each disease—and given that more than 98% of the diagnostic services within the SUS are performed by the complementary network, it is essential to review the procedures conducted. This review should aim to eliminate obsolete tests, ensure proper remuneration for the services performed to maintain public health, and adjust the compensation of professionals operating laboratory services, while upholding the ongoing quality advancements that are inherent to laboratory diagnostics.

The National Policy on Laboratory Diagnostics must include a broad and accessible educational program for citizens to foster an understanding of the critical role of clinical laboratories as tools for assessing health status, physical recovery, and the restoration of human health. This policy should emphasize the safety and reliability of laboratory results. Furthermore, the National Policy on Laboratory Diagnostics should contribute to laboratory quality management without rigidly constraining its practice with fixed concepts and activities. Instead, it should allow flexibility to accommodate regional and cultural specificities inherent to Brazil's vast territorial expanse, ensuring the quality and safety of diagnostic services while respecting the diversity of the country's territories.

FINAL CONSIDERATIONS

Given the aforementioned, it is imperative to have a technical, scientific, and strategic document that can be adopted as a reference for the development, implementation, and governance of a national policy that includes laboratory diagnostic actions (clinical, toxicological, and environmental analyses) within the healthcare process in Brazil. This policy aims to address existing gaps, ensuring the quality of diagnoses and promoting effectiveness in public health interventions.

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