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Clinical Research and Studies

Clara Aurora Zamorano Jimenez *

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Review Article

# Challenges of Mexican Pediatrics from its Origins to Teaching, Clinical Practice, and Research

**Zamorano Jimenez CA [1]* and Chirino-Barceló YA [2]**

[1] Neonatologist Pediatrician High Specialty in Neonatal Intensive Care Master in Medical Sciences

[2] Neonatologist Pediatrician Medicine Coordinator at ABC Medical Center.

***Corresponding Author:** Clara Aurora Zamorano Jimenez, Centro Médico ABC Observatorio. Consultorio 7 segundo piso Torre central. Sur 136 No. 116, colonia Las Américas, Alvaro Obregón. CP 01120. Ciudad de México.

**Received date: November 30, 2023; Accepted date: December 27, 2023; Published date: January 08, 2024**

**Citation:** Zamorano Jimenez CA, Chirino Barcelo YA, (2024), Challenges of Mexican Pediatrics from its Origins to Teaching, Clinical Practice, and Research, *Clinical Research and Studies*,3(1); **DOI:10.31579/2835-2882/032**



## Abstract

The first hospital functions in colonial times were overseen by friars, with children then regarded as "small adults". Post-Independence saw a lapse in attention to this demographic, but the 20th century heralded the National Pediatric movement, leading to dedicated children's hospitals and institutes. Diagnostic and therapeutic clinical trials have advanced scientific practice, yet they're infrequent in pediatrics due to the unique challenges like high biological variability and ethical concerns. As professors, it is important to create a mind that involves the complexity between pediatric practice, teaching and research, considering these three elements as the axis in medical education.

This article reviews the Mexican Regulation for Research on Children, part of the General Health Law on Research for Health (RIMS), and emphasizes the confluence of pediatric practice, teaching, and research in medical education.

The first medical care provided in colonial times was directed by friars. At this time the child was considered a "small adult". During Independence and immediately posterior to it, a lag in care in the attention to this age group, but finally, in the 20th century, the National Pediatric movement began; Hospitals exclusively for children arose during this period, followed by the creation of modern Institutes dedicated to the care of Mexican children.

The development of diagnostic and therapeutic clinical trials and systematic reviews constitute an important needed advance in the practice of science in the Mexican pediatric population, although in the pediatric age they are less frequent; and faces many structural and ethical challenges.

We will analyze the Mexican Regulation for Research on Children, through the Regulation of the General Health Law on Research for Health (RIMS), which regulates how research should be carried out in public or private institutions in the country.

**Keywords:** origins; teaching; clinical practice; research

## Introduction

Pediatric records in Mexico trace back to the "*Mexicas"*, especially to *"Ixtlicotehuas",* priests of the child god "*Ixtliton"* or "*Tlaltecuin*". They practiced magical-religious therapy and monitored Aztec children's nutrition. Their teachings included neonatal prophylaxis, newborn bathing techniques, and ritual circumcision for health promotion. Throughout the colonial era, friars managed hospitals, with scant pediatric literature available. The post-Independence period witnessed a gap in care for children. The 20th century, however, saw the rise of the National Pediatric movement through doctors like *Aquilino Villanueva and Isidro Espinoza de los Reyes*. Numerous child health institutions emerged during this era. Followed by the creation of modern Institutes dedicated to the care of Mexican children and the current groups serving children such as the Mexican Academy of Pediatrics, the Mexican Association of Pediatrics preceded by the National Confederation of Mexican Pediatrics must view pediatrics as an "opportunity stage" to address and prevent future adult health issues.

The first thousand days of life, which span from the moment of gestation to the second year of life, constitute a crucial stage for immunological maturation, metabolic programming, physical growth, psychomotor development, and the generation of emotional bonds. Thus, the importance of this period has been a watershed in the need for intervention in current pediatrics. [3]

We know that in Mexico since 2000, metabolic syndrome with its two main complications (ischemic heart disease and type 2 diabetes mellitus) is the most frequent cause of death in adulthood. Likewise, there are childhood diseases that have an impact on.

While the rise of diagnostic and therapeutic clinical trials has revolutionized science, they remain rare in pediatrics. Informed consent and informed assent are pivotal for ethical pediatric research, requiring clear, accessible information. Pediatric research necessitates both sick and healthy children, making transparent information crucial. [4,5]

Informed consent: constitutes an essential legal document, which is signed by parents or guardians or in patients above 18 years of age who are intellectually capable of voluntarily participating in the study. It is important to provide clear and objective information, what will be carried out for the investigation, the implications and possible risks. [6,7]

Informed assent: It is the explanation to patients under 18 years of age in a simple way, linked to the culture to which the child belongs, with the aim of treating the child with maximum respect. [6,7]

**Challenges of the pediatric population**

The pediatric population is characterized by high biological variability; From birth, children present rapid and complex growth and maturation processes, which begin in intrauterine life.

Childhood is a period of life NOT comparable to adulthood. Metabolic processes, pharmacodynamics and pharmacokinetics change at different ages in pediatric patients. Even with basic current knowledge, data are scarce. The parameters that determine the processes of absorption, distribution, metabolism, and excretion are different in children due to the growth and maturation process of the systems and devices involved.8

The effects of medications can be different in both the magnitude and nature of the response. For example, some adverse effects only occur in children associated with the maturation and growth processes, such as the discoloration of teeth due to tetracyclines. Another example is the different response to opioids in the newborn, due to incomplete differentiation of opioid receptors. [9]

The population pharmacokinetics and pharmacodynamics approach obviates the practical and ethical difficulties involved in extracting the numerous serial samples that a conventional pharmacokinetic study requires, which is why population pharmacokinetics is of particular interest in Pediatrics and has made it possible to identify the more appropriate dosage regimens for numerous medications for pediatric use: aminoglycosides, antiretrovirals, anticonvulsants or anesthetics, among others. [8,10,11]

With the above, we conclude that pharmacological data from adults cannot be extrapolated to pediatric patients with a simple proportionality rule based on body size, whether by weight or surface area. [10,11]

In addition to the high biological variability, there are ethical limitations. The pediatric population belongs to a group considered vulnerable, which is why both current legal regulations and ethical guidelines establish the need for them to be subject to special protection. We know that there is a need to carry out clinical studies on diseases that are specific to them or that have special characteristics, in addition to appropriate therapeutic management to address them. [8]

This has generated a situation of certain helplessness and lack of medications in pediatrics, which has been defined as “therapeutic orphanhood.” Unfortunately, there are few projects and phase I and phase II clinical trials in children, and the use of many drugs is based on extrapolations of the findings obtained in adults and are administered with special permission, with the added risk of not having parameters of protection. efficacy and biosafety adjusted to the different stages of pediatric age. [8,12]

It is understandable that we try to avoid the risks of research in children; however, up to 70% of the medications available on the market have been reported to not include sufficient pediatric information, especially regarding dosage. Many medications also do not have specific formulations, which poses practical difficulties, as well as the lack of adequate information on the absorption, metabolism and excretion process. Therefore, children are subject to special risk situations and adverse drug reactions (ADR). Efficacy and safety data are frequently extrapolated from other populations and children are at greater risk when treatments that are not sufficiently studied in that population are applied; Sometimes there are no special formulations.8

Within research that involves healthy volunteer children, we must ensure that the risk is minimal, and that we can respond if something happens. A level of risk is sought with a view to greater benefit. [13] A great example of the importance of research with children is the Acute Lymphoblastic Leukemia study, in which in the late sixties and early seventies survival was only 10%, after the research work, survival has increased and today 80-85% achieve a cure. [14]

**Mexican Regulation for Research in Children**

The right to health protection became a constitutional right in 1983-1984. The General Health Law encompasses this right, with the Regulation of the L.G.S. in Health Research (RMIS) detailing research norms for public and private entities. The RMIS necessitates three specific commissions in research-focused health institutions, [arts. 99, 104 and 109] with the characteristics and functions inherent to its competence: 1) A Research Commission (internal Institutional regulations), 2) a Biosafety Commission (evaluation of the use of elements that may present a risk to health), and 3) an Ethics Commission in the event that research is carried out in Humans. The latter must issue the technical opinion on the ethical aspects of the proposed research, by reviewing the risks, benefits and the letter of consent in the protocols and its competent authorities, to guarantee the well-being and rights of the research subjects. [6,7,12]

The Ethics Commission, analogous to the U.S.'s Institutional Review Board (IRB), safeguards research subjects' well-being and rights, it must have medical professionals, and it will be recommended that at least one of its members does not belong to the health institution in question, so that it has the capacity to represent the moral, cultural and social values of the groups research. Children’s rights”. [6]

The National Bioethics Commission (of the Ministry of Health) issued the National Guide for the Integration and Functioning of Research Ethics Committees, (guidelines to guide institutional Research Ethics Commissions or Committees) (REC) in the exercise of their functions. The precondition for carrying out research in children is to ensure that similar studies have already been done in older people and in mature animals, except when it comes to studying conditions that are typical of the neonatal stage or specific conditions of certain ages. [6,7]

Initiating pediatric research requires prior similar studies on adults and mature animals unless studying neonatal or age-specific conditions. The rapid development of COVID-19 vaccines underscores the ethical and equity challenges of pediatric research. To optimize child healthcare globally, a multidisciplinary group of professionals is indispensable. In the words of the Unicef 2020 report, the value of every developmental phase is distinct yet interconnected. Embracing the trifecta of pediatric practice, teaching, and research can significantly enhance education, and promote collaboration and global knowledge sharing. Teaching should instill in students an appreciation of the distinctiveness of childhood and broader societal needs to elevate pediatric care. [6,7,12,13]

“The right of boys and girls to satisfy their needs for food, health, education and healthy recreation for their integral development” (Article 4, Constitutional) is enshrined; For this purpose, it establishes the correlative duty of ascendants, guardians and custodians to preserve these rights and of the State to provide what is necessary to promote respect for the dignity of children and the full exercise of their rights.

It is of extraordinary importance to create a multidisciplinary group of specialists, composed of pediatricians, pediatric subspecialists, clinical pharmacologists, pharmacists, bioethicists and jurists who work in different areas (hospitals, universities, regulatory agencies, pharmaceutical industry, etc.), willing to highlight the importance and need for specific research to address the health problems of children both in Mexico and in the world.

With everything described here we see how valuable it is to take into account the “beginning of life”. Create a mind that involves the complexity between pediatric practice, teaching and research, considering these three elements as

the axis in education. Stimulate the carrying out of important research studies in our area, during their preparation period, as well as create agreements that allow sharing the work carried out in our environment and enriching ourselves with researchers who are working on a similar aspect even with another vision. in another Institution, whether national or international, which will allow us to expand and grow knowledge, in a "globalized" way. We consider that it is important as teachers to awaken sensitivity in students to know and recognize not only the biological characteristics of childhood but also national and global needs, which allows us to modify our pediatric care towards excellence.

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