

Rare diseases in Colombia. Overview

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- In 2016, Colombia's population was estimated at 48,747,708, with 50.8% women.
 - The population is predominantly urban (79%), with a population density of 42.7 inhabitants per km².
- Population concentrated in half part of the country. Most of the rest difficult to reach to provide health services.
- Life expectancy at birth in 2010-2015 was estimated at 73.74 years (77.39 for women and 70.19 for men).
- The birth rate, 18.8 births per 1,000 population; and the total fertility rate, 1.93 children per woman,
- The natural growth rate fell from 22.03 per 1,000 population in 1985-1990 to 13.07 in 2010-2015. 50% are subsidized by government and 50% affiliated (contributors) pay proportionally to the salary. Any person in Colombia should be covered by the health system. Close to 98% according to the official statistics.



Law 1392 of the National Congress of Colombia July 02, 2010, recognizes orphan diseases of special interest for the health system and dictates norms in favor of the patients afflicted by these diseases, and their caregivers.

Recognize the orphan diseases- rare of special interest in health and dictate norms to guarantee social protection to this population and their caregivers. Perhaps the first law RD in Latin America.

The law contemplates almost all the important aspects. Diagnoses. Treatment, Research, social inclusion, education

Significant progress have been made but 12 years after many aspects still await to be implemented or improved to fulfill the needs.

Principles that inspire the law 1392.

Universality under conditions of quality, access and timely.

Solidarity

Co-responsibility Family, society and state

Equity

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Definition of Orphan/rare diseases, less than 1 in 5000 persons. It does not include the most common of rare diseases.

A list will be established and will be updated every two years. This list comprises 2197 diseases actually. The most common are not covered by the law.

Law 1392

A special fund will be created to finance diagnosis, treatment, medicines and procedures for the patients . The government is empowered to allocate resources from different sources. So far the patients have received health services some from the regular health programs.

- Any patient may receive the benefits of the obligatory health program. Some exams and drugs are included under the generic names. Plastic surgeries and other cosmetics procedures are excluded.
- Not many beneficiaries are aware of those benefits. However the ombudsman office, help them and also the patient`s associations .

Through private insurance patients may get faster and complementary services for diagnosis hospitalization services.

If a person feels that is not being attended, he or she may appeal trough the legal system (tutelage) . It is usually decided within one to two weeks in Favor of the patient. The services have to be available within the country. Obviously it needs education of the patient and rationality to make adequate use of the limited resources of the health system

A large number of patients are receiving enzyme replacement therapy compared with other of wealthier countries..

Law 1392 Government responsibilities

To promote, organize and implement research activities aimed to study and promote early diagnosis, treatment and to improve quality of life. Some advances have been made mainly thanks to academic institutions initiative and funding from Science and technology ministry.

To establish guidelines for the diagnosis and treatment. Close to 12 have been written. Many have been made by the commercial companies and wait validation by the government.

Jointly the government, patient's organizations, academy and scientific societies must implement educational and promotional actions in order to create awareness and broad public knowledge of orphan/rare diseases. Much to be done in the different levels of formal education and specially in primary health sector. Although the coverage in the media has increased immensely, It is also necessary to have more public there is much room for work.

To promote social and educational inclusion of patients. There are several laws and initiatives for handicapped population in Colombia. The associations have been very active in this respect, and slow advancements have been made.

Education and awareness

There are more than a 100 associations of which about forty are very active. Two specially ACOPEL and FECOER. They were organized initially for those diseases that have commercial products. Thanks to their work the Rare diseases have a good coverage in the media and the associations specially ACOPEL has been a permanent pressure (advocacy) group for the different governments. But most diseases so far have no associations. Mainly thanks to them an Observatory for rare diseases with participation of public sector and patients organizations.

We have good resources for diagnoses but most of the molecular tests are being sent out of the country. Those test should be performed in Colombia by Colombians to build capacities and diminish costs.

Law 1392. National registry of patients

To establish a national registry in order to know the current situation, to have a better knowledge and draw or reorient the national policies for those diseases.

Some work has been done and some is in progress.

Law 1392. Orphan Drugs

A centralized system of negotiation and purchasing will be established in order to diminish costs and to have more knowledgeable negotiators on behalf of the patients and the health system.

(It has not been implemented).

Summary. Pending tasks

Currently the specialized diagnosis is concentrated in four cities.

It is urgent to overcome somehow the geographical barriers to reach the patients all over the country. It is necessary to establish a network of Reference centers throughout the country.

It is necessary to expand the newborn screening. Presently only for congenital hypothyroidism, close to 90% coverage. A recent law includes seven more pathologies, PKU, CAH, galactosemia, biotinidase deficiency, CF. No resources have been allocated.

It is needed a permanent well-funded coherent plan for RD. It should be adopted as a long-term state program and non-based on short-term individual government initiatives.

Better help and genetic counseling for relatives in the psychosocial aspects.



Summary. Pending tasks

- Improve education in the general population in general and particularly for all health professionals but especially in the primary care sector. Much more research and education needed.
- To establish centers for production of vectors and facilities for in vitro cell therapies and new therapies To study human genome of our populations looking for mutations that prevent or predispose more to disease.
- To negotiate more affordable prizes for drugs.
- To try to do more translational medicine in order to apply the knowledge being generated in the academic sector.
- The government should undertake the initiative to promote research, education, prevention, and search for patients for those diseases that have not been diagnosed and for those that being diagnosed do not provoke commercial interest.