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Rosario Declaration

MERCOSUR Health Summit

2019

ROSARIO DECLARATION

Mercosur Health Summit

On May 29th and 30th, 2019 the First MERCOSUR Health Summit took place in the city of Rosario, Argentina, organized by the World Heart Federation (WHF), the Inter-American Society of Cardiology (SIAC) and the Parliamentarians Union of South America and MERCOSUR (UPM), with the goal of achieving a dialogue for "Access to Public Health".

Scientific, parliamentary, parliamentary institutions and health sector officials were part of the event, who addressed the problem of access to health services, medicines and policies to promote healthy lifestyles in relation to chronic non-communicable diseases.

As an outcome of this meeting, the written Declaration seeks to disseminate towards the community and to do the analysis for parliamentary production in relation to a problem that involves millions of deaths every year in the continent, many of which can be prevented from comprehensive prevention strategies.

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A) FUNDAMENTALS

Chronic non-communicable diseases (NCDs) constitute one of the main health threats to the Americas. Each year they cause 4 out of 5 deaths in the region, mainly represented by cardiovascular, cancer, respiratory diseases and diabetes.

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Cardiovascular disease is the leading cause of death and disability in the world, with an estimated 17 million lost lives a year. It is also the cause of premature deaths, which implies high costs for the health system and for the countries' productivity.

Since the "High Level Meeting" developed by the United Nations around the NCDs in 2011, the favorable environment for the development of prevention and control strategies for cardiovascular diseases worldwide has been generated, as never previously happened in the history of public health. Among the variables that have determined this new scenario, we find the explicit recognition of the threat that the impact of these pathologies mean for the economies of the countries and the awareness of the responsibility that governments have in finding appropriate and effective answers, along with all sectors of society. From this new instance, each Member State must strengthen and integrate policies and programs aimed at the control of NCDs.

The "Sustainable Development Goals" of the 2030 Agenda (SDG) are part of a document issued by the United Nations that establishes 17 global objectives, 169 goals, and more than 230 indicators by 2030 in all countries of the world, including countries of the MERCOSUR. This new document, which does include NCDs in the SDG, linked to Health and Welfare, is a matter of intense debate as to whether it can guide the direction of national policies and the allocation of economic resources effectively. Objective 3.4 is to reduce one third of deaths from NCD in the world by the year 2030, and although there is still no information available regarding the results of the first year, the scope of the goals will depend on the adequate investment of resources accompanying the monitoring of the data arising from the different indicators. In this context, the WHO, supported by organizations such as WHF and SIAC, launched a call to reduce 25% of premature deaths caused by NCDs by the year 2025 with strong international support.

As important actors in the construction of health policies, either in their foundation or in the armed regulatory support of their design, scientific societies, legislative bodies and health officials convened to hold the "Mercosur Health Summit".

B) SUSTAINABLE DEVELOPMENT GOALS OF THE 2030 AGENDA (SDG)

The 2030 Agenda for "Sustainable Development" is a global commitment that aims to eliminate poverty and guide the world on a sustainable path towards inclusive development.

This ambitious agenda was approved by government leaders at the "United Nations Summit" in September 2015, and its core is made up of a series of 17 SDGs and 169 action goals, which can be developed at various territorial scales, with a diverse inclusion of actors and sectors.

The SDGs have been designed to focus and coordinate public policies towards a vision of the future of humanity; they include the three pillars - economic, social and environmental - of sustainable development and add efforts to strengthen institutions in order to promote the new global development agenda. These objectives drive change in the way we approach the complexity of social, economic and environmental problems, helping to transcend the barriers between the work of different actors and geographies, and creating the space of opportunities for the emergence of new forms of collaboration around specific agendas or problems.

In this way, the 2030 Agenda and the SDGs reaffirm the commitment to end poverty without exclusions, and invite us to create a more sustainable, safe and prosperous planet for present and future generations.

In this context, the development of policies, programs and projects that coordinate international, national and local efforts in an effective and associative way, is essential for the articulation of global efforts. Thus, through greater and more efficient coordination between and with the various sectors and actors we can influence the way in which the SDGs are implemented.

To achieve the "Sustainable Development Goals" it is essential to ensure a healthy life and promote universal well-being. However, in many regions, including the MERCOSUR, they face serious health risks, such as high rates of maternal and neonatal mortality, the spread of infectious and NCDs and poor reproductive health. In recent decades, great progress has been made in relation to increasing life expectancy and reducing some of the most common causes of death related to infant and maternal mortality. Likewise, to achieve the objective of reducing premature deaths due to NCDs by a third by 2030, for example, more efficient technologies for clean fuels for cooking, and tobacco risk education will be required.

Many more initiatives are needed to completely eradicate a wide range of diseases and to address numerous and varied persistent and emerging health issues. If we focus on providing more efficient financing to health systems, improving sanitation and hygiene, increasing access to medical services and providing more advice on how to reduce

environmental pollution, we will make significant progress in helping to save millions of people's lives.

C) OBJECTIVE 25 X 25. ROLE OF THE SCIENTIFIC INSTITUTIONS. ROADMAPS OF THE WORLD HEART FEDERATION

In September 2011, the "Heads of State" of all the nations of the world met at the United Nations to discuss the problem of NCDs (cardiovascular diseases, cancer, diabetes and chronic respiratory diseases). As a result of that meeting, the "Political Declaration of the High Level Meeting of the General Assembly on the Prevention and Control of NCDs" was advanced. In this document, the "Heads of State" say: "Recognize that the global burden and the threat of NCDs is one of the main challenges for development in the 21st century, which undermines social and economic development worldwide and threatens the achievement of internationally agreed development goals."

Given this serious public health situation, the World Health Organization (WHO) established that the overall priority objective at NCDs is to reduce preventable deaths by 25% by 2025. This objective has been called "25x25".

- **Epidemiological perspective in South America**

The countries of South America have an epidemiological situation similar to the rest of the world regarding the causes of mortality with a high prevalence of death from NCDs. However, unlike those in North America, they must cope with both NCDs, increasing in the region, and communicable diseases, still of high prevalence. North America has made great progress in the prevention and control of NCDs. On the contrary, there is an increase in mortality from these causes in South America. This is a pending and priority issue for government agendas. In addition, it is expected that the greatest increase in the prevalence of NCDs will occur in the coming years in low or middle income countries. Moreover, it is verified that these countries receive the least immediate and long-term treatment for NCDs.

- **Risk Factors**

In epidemiology, any circumstance or situation that increases a person's chance of contracting a disease or any other health problem is considered a risk factor. This concept, of utmost importance in prevention, considers biological factors such as age, sex and constitutional and lifestyle factors, up to considering the social and community environment as the general socio-economic, cultural and environmental conditions. Thus the concept of "social determinants of health" represented by the circumstances in which people are born,

grow, live, work and get old, including the health system, has emerged. As WHO points out, "these circumstances are the result of the distribution of money, power and resources at the global, national and local levels, which in turn depends on the policies adopted."

- **Prevention and Control of Cardiovascular Disease**

The modern concept of health necessarily includes from episodic treatment (acute event) to population management, through the treatment of the disease. As stated in the "Political Declaration of the High Level Meeting of the General Assembly on Prevention and Control of NCDs", there is consensus that: 1) NCDs are a priority in development and in the economic agenda, 2) a global approach of governments and society is required to implement recommendations on surveillance, prevention and care of WHO's health and 3) the role of WHO in coordinating global action to fight NCDs is essential.

South America faces a huge challenge to NCDs not only from a health perspective, but also for its sustainability. In these circumstances it is essential to achieve the goal of prevention of CVD, to reduce its burden. Risk factors such as hyperlipidemia, hypertension, obesity and diabetes can be avoided and treated at a very low cost.

The objectives set by WHO for the prevention and control of NCDs are:

• Premature mortality from NCDs

Objective: 25% relative reduction in the mortality due to NCDs.

• Arterial hypertension

Objective: 25% relative reduction in the prevalence of hypertension.

• Tobacco use

Objective: relative reduction of 30% on the current prevalence of smoking.

• Salt / sodium intake

Objective: relative reduction of 30% in the average salt consumption of the population, in order to reach a goal of less than 5 g of salt/day.

• Physical inactivity

Objective: relative 10% reduction in the prevalence of insufficient physical activity.

• Obesity

Objective: to avoid the increase in the prevalence of obesity

• Fat intake

Objective: relative reduction of 15% in the average proportion of total energy consumption of saturated fatty acids with the goal of achieving the recommended level of less than 10% of total energy consumption.

• Alcohol

Objective: relative reduction of 10% in total alcohol consumption (including dangerous and harmful alcohol consumption).

• High total cholesterol

Objective: relative reduction of 20% in the prevalence of high total cholesterol.

• Availability of generic essential medicines for NCDs and basic technologies to treat the main NCDs

Objective: 80% availability in public and private facilities of basic technologies and essential generic medicines necessary to treat the main NCDs.

• Pharmacological treatment to prevent heart attacks and stroke

Objective: 50% of eligible people should receive drug treatment to prevent heart attacks and stroke as well as counseling.

❖ **Historic perspective of WHF roadmaps**

Evidence-based Medicine (EBM) is defined by "the precise, explicit, judicious and reasonable use of the best current evidence to make decisions about the care of individual patients". In relation to EBM, the "Clinical Practice Guidelines" (CPG) appeared, which are "statements that include recommendations aimed at optimizing patient care based on a systematic examination of the evidence and an evaluation of the benefits and damages of the care alternatives " However, CPG does not ensure the universal implementation of a certain recommendation. This is attributable to different factors such as price of medicines, availability, affordability, non-compliance with the prescription, etc. In response to this need, arises the idea of a roadmap. These constitute a tool for public health and clinical implementation that integrates the best available evidence, explained in the CPG, for patient's care. WHF defines "roadmap" as a framework designed to help identifying obstacles and suggest potential solutions on the road to 25x25. WHF roadmaps are

intended to serve as models for regions and countries to develop their own roadmaps and create or update their national action plans in NCDs. They offer a framework to bring together stakeholders with the objective of determining, prioritizing and implementing solutions to reduce premature CVD deaths in a specific context, in a collaborative and consultative approach.

❖ The roadmaps of the WHF

Roadmaps offer a framework for governments, NGOs, health activists, health professionals and many others to reduce premature cardiovascular mortality in their countries. With a collaborative approach in mind, they can involve health advocates, corporations, academic and research institutions, policy makers, health professionals, patients, etc. As described above, the WHF roadmaps focus on issues aligned with the objectives of the WHO Global Plan of Action for NCDs. These issues have been identified on the basis that they can potentially have the greatest impact on premature mortality for 2025.

Roadmaps are not a rigid prescriptive tool but, on the contrary, they are an instrument to identify obstacles and to design efficient, effective and feasible solutions. Indeed, at the national and regional level, roadmaps should serve as models for countries to develop their own roadmaps and create or update their national plans of action of the NCDs.

❖ Conclusions

South America's health situation shares the global challenge that CVDs represent in the context of NCDs. To understand this phenomenon, it is necessary to consider the social determinants of health and adhere to the objectives set by the WHO for the prevention and control of NCDs. In this scenario, scientific, national, regional, continental and global organizations must play a fundamental role not only oriented to professional development, research and dissemination of knowledge; but also to the formation of alliances and advocacy for the health of South American inhabitants.

D) ACCESS TO ESSENTIAL MEDICINES. ADHERENCE TO TREATMENTS

❖ List of WHO essential medicines

Essential medicines are drugs that must meet the priority health needs of the population. Ideally they should be relevant to public health, effective, safe, and cost-effective.

The first "List of Essential Medicines" (LEM) was developed by the WHO in 1977, and the 22nd list was finished in 2019.

Currently, more than 160 countries have LEMs. It serves as a reference but each country must adapt it to local epidemiology (health priorities are different in each country and region). In low- and middle-income countries, it serves as a tool to point out what are essential medicines to politicians, while in high-resource countries the LEM offers health coverage companies a neutral point for reimbursements ("it is or it is not in the list"). It is also useful for donations of medicines and international help.

It has been reclassified into two listings, essential or core list, and complementary list of useful drugs that require additional technology (second or third level medical care, infrastructure for administration). With respect to patents, most drugs have expired patents, but if a drug still holds a patent, it is not excluded from being considered an essential medicine.

Those who determine whether a drug belongs to the LEM are members of the WHO, which every 2 years gathers independent evaluators, contacted specialists and committee of experts, also offering an opinion space to NGOs.

The review is published on the WHO website, the reviewers being unidentified in order to avoid any possible attempt to influence, leaving it open to comments. Subsequently, the Committee meets in full for five days to compile the Model List and finally the final approval depends on the WHO General Director.

The required characteristics of a drug to be incorporated into the LEM could be defined as following: To be useful in prevalent diseases (although not always, for example drugs that causes total remission of a rare cancer), to be effective, safe, cost-effective (especially in drugs of the same therapeutic category, the cost of the complete treatment must be

considered at this point), appropriate pharmacokinetics, non-complex storage conditions, available in formulations that guarantee good quality, and in general, only an active ingredient, although combined fixed dose treatments have been incorporated under certain conditions (for example in HIV or tuberculosis).

Implementation of the LEM: The essential drugs incorporated by each country, must be available in the health systems at all times, in sufficient quantities, with guarantee of the quality of their production (just do not fall into the production of generic of poor quality), at a price that patients and the community can afford.

Costs: the cost of new drugs is a major concern. Drugs with a higher success rate or better pharmacokinetics or less adverse effects profile that still retain their patent, many times they cannot be financially supported by the health systems of the countries of low or intermediate resources. As an example, in the last list in 2019, more than 10 drugs with a current patent were presented, including some antineoplastic drugs with very high prices.

A program from the University of Toronto (https://essentialmeds.org/) offers an updated analysis of the application of the LEM in each country in the world. All South American countries and members of the Mercosur currently have LEM, although highly different from each other. An attractive idea would be to unify criteria for the selection of common cardiovascular drugs to the regional needs of the Mercosur member countries. In the European Union, as an example, it has been useful to unify criteria in the purchase of high-cost medicines for rare diseases.

- **Adherence to treatments. Role of the Polypill**

The burden of cardiovascular disease is the leading cause of disability and premature mortality. In this sense, a very remarkable point is that practically the 80% of patients who have suffered a major cardiovascular event have prior cardiovascular disease, high blood pressure or are smokers. This must be taken into account when planning intervention strategies in this population group.

The most frequent pharmacological interventions in terms of secondary prevention after acute myocardial infarction mainly include aspirin, statins, angiotensin conversion enzyme inhibitors (ACEI) and beta blockers. If you consider the impact of the sum of the risk reductions contributed by each one of the drugs, it turns out that among all, a reduction of about 70% is achieved in the probability of having further events.

These pharmacological interventions (aspirin, statins and ACEI) have been included in all clinical guidelines for cardiovascular prevention, both in patients with coronary heart disease and in patients after having suffered a stroke or in patients with peripheral vascular disease.

However, there is a huge gap between knowledge and action, that is, between the patterns of action on which there is consensus and what happens in the real world. According to data from the World Heart Federation, the percentage of patients who, after having suffered a myocardial infarction, receive adequate medication does not exceed 14% overall. In the context of stroke, the figure is even lower, since less than 8% of patients receive all three essential medications.

In Latin America, these figures are very similar: data from the PURE study (Prospective Urban Rural Epidemiology) show that only 14-15% of patients after a myocardial infarction receive all three essential medications and about 30% do not receive any treatment. The situation is even worse among those who have suffered a stroke.

The concept of polypill is very simple. Since it is well known that the amount of medications taken is one of the reasons that most influences the patient to abandon treatment, if all medications are included in a single tablet taken once a day, obviously it should improve adherence. This concept was theoretically introduced in 2001 by the WHO. A year later, in its annual report, WHO insisted on the same concept, since at that time there were no polymers in the field of cardiology. In 2003, Wald and Law published an article in which they proposed a polypill composed of fixed combinations of medications that individually have been shown to effectively reduce cardiovascular disease risk factors.

From a conceptual point of view, if each one of these drugs obtains benefits by itself and if they enhanced each other when co-administered, a strategy that guarantees the take of all of them in a single tablet, should be clearly effective.

A meta-analysis with more than 3,000 patients from six countries assessed the effectiveness of the polypill compared to the usual therapy. In terms of control of arterial hypertension and cholesterol, the polypill was more effective than the usual therapy separately.
A systematic review of the Cochrane published in 2017 showed that the polypill achieved a significant reduction in blood pressure and also a significant reduction in cholesterol.

Therefore, from the point of view of efficacy, this strategy is particularly valid for controlling risk factors (arterial hypertension and cholesterol), probably through increased adherence. On the other hand, cost-effectiveness studies have been done, which have shown that this strategy is cost-effective in different countries, such as Mexico, Spain and Chile.

It has not been possible to demonstrate so far that this intervention reduces mortality, but mainly because studies to date have been carried out only to demonstrate efficacy in the control of risk factors. The reality is that it seems logical to think that if there is a better control of risk factors, especially blood pressure and low-density lipoprotein (c-LDL) cholesterol, there will also be a reduction in cardiovascular events. The studies that are currently underway will provide information on this.

All these data have had a great impact on the medical community, so that in recent years numerous clinical guidelines have spoken about the polypill and have included it in their recommendations, including the European Society of Cardiology, the European Society of Hypertension, the Spanish Society of Cardiology and cardiology societies from various Latin American countries, such as Mexico, Chile and Argentina.

The Inter-American Society of Cardiology has assumed a strong commitment to the polypill strategy and taken the initiative to develop a consensus and a positioning document. To this end, it convened a group of more than 40 experts from Latin America, representatives of thirteen scientific societies, with the objective to position the polypill to increase prevention and to reduce the burden of atherosclerotic disease in our region.

The most important conclusions were the following:

- The polypill significantly reduces systolic blood pressure, total cholesterol and LDL-C.
- There is no significant increase in adverse effects with the use of the polypill.
- It is likely that there will be a reduction in cardiovascular and cerebral vascular events, although ongoing studies will provide this information.
- The polypill is a very cost-effective recommendation.

Therefore, the expert committee, based on these conclusions, recommends the introduction of the polypill into the public health programs for cardiovascular prevention, especially secondary prevention.

❖ **Conclusions**

- Treatment with the polypill has proven to be an effective and safe strategy to control risk

factors (reduction of systolic blood pressure, total cholesterol and LDL-C), to reduce costs and possibly to reduce the occurrence of cardiovascular events during the follow up.

• The implementation of this simple strategy is particularly useful in terms of improving global cardiovascular health, especially in the countries of our region.

E) POPULATION APPROACH. HEALTHY POLICIES.

The implementation of effective actions in the field of NCDs depends on strategies that include:

- Epidemiological surveillance, i.e. the survey of health data that feed a control board
- Individualized approach for people at high risk of developing disease or with active disease, to facilitate their access to health services and the necessary drugs for their treatments
- Population approach, with actions that affect the entire population transversely, regardless of the risk of each individual, thus ensuring a better state of community health.

For decades, in order to raise awareness, to know, to treat and to control risk factors; programs and actions called "population interventions" have been implemented. There is clear scientific evidence regarding the effectiveness of these interventions in community behavior changes. In a systematic evaluation of 36 community programs developed between 1970 and 2008 (Pennant M. et al 2010) it was seen that despite the diversity of implementation profiles, in general, all show positive results, with different magnitude of impact in terms of reduction of cardiovascular risk and even global mortality rates.

Some components of these “population interventions” have to do with field work on the detection of risk factors, the assessment of global cardiovascular risk, the development of campaigns focused on raising awareness and mobilizing the community in pursuing of a healthy lifestyle, use of the media, with informative, educational and health promotion activities open to the community. However, the greatest impact is achieved when the support of norms and laws regulates aspects that may be harmful or beneficial to health. A clear example of the impact that comprehensive initiatives can achieve has been the response to tobacco consumption policies that have led to a significant reduction. Higher taxes on tobacco, advertising bans, limits on tobacco promotion and sponsorship, regulations that ensure smoke-free environments in all public and workplaces, large and graphic health warnings on tobacco packages have been powerful tools.

Today, obesity as a result of poor diet and sedentary lifestyle, is perhaps the biggest health challenge to overcome. Among the multiple actions to be implemented in this field, without a doubt, the frontal food labeling is of utmost importance, an action already implemented in countries such as Chile and Uruguay. Prior experiences show that this type of actions that affect the interests of the food industry, find numerous pitfalls when it comes to implementation. However, they are an unavoidable step to stop the escalation of disease, which does not find a brake until today, with a strong impact on costs for the health care system and indirectly on the economy of the countries, by engaging many individuals of working age. This risk factor is more prevalent in the most vulnerable populations, which are that of lower educational level and lower income. This data is relevant since according to CEPAL, 184 million Latin Americans, more than 30% of the total population, live below the poverty line. 46% of children up to 14 years old are poor while 17.3% suffer from extreme poverty. This perspective shows a greater dimension of the problem, since in an adverse scenario insufficient resources or poor management tend to deepen the threat. For the best cost-effectiveness of the interventions, the articulation between the health and education sectors is crucial, with a clear role of the scientific institutions.

A preliminary step in this type of strategies is to obtain adequate information from the community, which is often the victim of content in the media and social networks that lead to a profound distortion regarding real damages and benefits (fake news). This reality gives an important role to scientific institutions as reliable opinion generators. In this way, the "Clinical Practice Guidelines" and the "Consensus" should contemplate material to inform the community. These contents must be access material for the legislative bodies, which in this way, may be in a better position to develop standards with real health impact.

In this way, health promotion campaigns developed by institutions such as WHF and SIAC throughout the world and particularly in the American continent through their member societies are very useful. These interventions are aimed at the participation of society and its empowerment to achieve effective inclusion in the public agenda of issues such as access to healthy eating, appropriate public spaces for physical activity, environments not contaminated by tobacco smoke or other agents, access to essential medicines, access to health services for prevention purposes and not only for disease care.

Undoubtedly, this awareness of the society must be accompanied by a legislative framework

that helps generating profound changes and thus reverse the current health status. A child born today in any of the Mercosur countries has a life expectancy about 7 years shorter than those born in countries of the developed world.

This harsh reality leads scientific institutions also to perform advocacy tasks interpreted as a mechanism to articulate with various state agencies in pursuit of health objectives. Spaces for the discussion of health actions, technical advice, elaboration of consensus documents, policy monitoring health, discussion of the incorporation of new technologies, training of health teams are among others the contributions that they must do permanently.

F) CONCLUSIONS

A commitment assumed by member countries to work towards a 2030 “Agenda for Sustainable Development” that includes specific health objectives around the reduction of the burden of morbidity and mortality due to chronic NCDs in the world has emerged from the United Nations.

In this context, the WHO has launched the challenge of reducing 25% of premature deaths by 2025.

The Mercosur Summit has been a meeting of scientific institutions and legislators to analyze the problem of “Access to Health” in the region. This document, called "Rosario Declaration", condenses information regarding the main initiatives to be taken into account when developing standards in national, provincial and municipal spheres to prevent and control cardiovascular diseases. However, its greatest utility lies in being a source of debate for the analysis of the situation in each corner of the continent, allowing the generated legislative material to adapt to the needs of each community.

The joint venture between Scientific Institutions, Legislators and Public Officials is a matrix that must be replicated in all the countries of the continent so that in all communities the principles of equity in access to health are respected and thus contribute to reach of the proposed goals.

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