



Transformations in the management of diabetes: an analysis of the scientific evidence published by two scientific societies (1980-2010)

Transformaciones en el abordaje de la diabetes: análisis de las evidencias científicas publicadas por dos sociedades científicas (1980-2010)

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ABSTRACT The aim of this study was to describe and analyze changes in the definition of diabetes as a disease and the relationship between these changes and subsequent modifications in the therapeutic management of the disease. A content analysis was performed using articles, guidelines, and consensus published by the Argentina Diabetes Society and the Latin American Diabetes Association between 1980 and 2010. The different classifications, values used to define a person as diabetic, and treatments were assessed and the changes and modifications discovered were critically analyzed using categories such as medicalization, risk and lifestyles. As a result of the analysis we can observe how the growing process of medicalization, the dependence on the scientific knowledge of central countries, the interests of the pharmaceutical industry, and the crucial role played by pharmacological treatments are all inscribed within the management of diabetes, which can be made visible through the changes that have taken place over the last 30 years.

KEY WORDS Diabetes Mellitus; Medicalization; Risk; Life Style; Chronic Disease; Practice Guideline.

RESUMEN El objetivo de este trabajo es describir y analizar los cambios en la definición de la diabetes como enfermedad y la relación con las transformaciones en su abordaje terapéutico. Se realizó un análisis de contenido sobre los artículos, guías y consensos publicados por la Sociedad Argentina de Diabetes (SAD) y la Asociación Latinoamericana de Diabetes (ALAD) entre los años 1980 y 2010. Se desagregaron las diferentes clasificaciones, los valores considerados normales para definir a una persona como diabética y el tratamiento, analizando críticamente los cambios y modificaciones encontrados con el auxilio de categorías como medicalización, riesgo y estilos de vida. Como resultado del análisis hemos podido observar cómo el creciente proceso de medicalización, la dependencia con respecto al conocimiento científico de países centrales, los intereses de la industria farmacéutica y el lugar central del tratamiento farmacológico se inscriben en el abordaje de la diabetes y se hacen visibles a través de los cambios sucedidos en los últimos 30 años.

PALABRAS CLAVES Diabetes Mellitus; Medicalización; Riesgo; Estilo de Vida; Enfermedad Crónica; Guía de Práctica Clínica.

INTRODUCTION

In central countries, the current prevalence of diabetes is thought to exceed 7% in the adult population (1). Moreover, between 30% and 50% of people who suffer from this health problem are not aware of it (2). In Argentina, a national diabetes prevalence of 8.4% was registered in the National Survey of Risk Factors carried out in 2005. In 2009, a second survey showed the prevalence climbing to 9.6%, with only 55.2% of those affected receiving some type of treatment (3).

Diabetes is the fifth leading cause of death in women aged between 45 and 64 years, and the fourth and sixth cause of death among women and men over 65, respectively (3).

This problem has therefore become of crucial importance to the health care system, due to its high prevalence, its increasing trend, the high direct and indirect costs that the disease produces and the serious consequences of the disease, which may endanger the lifespan and quality of life of the population (3).

In that sense, many changes have taken place during the last 30 years in the management and treatment of diabetes: on the one hand, the values considered normal have decreased (which has led to an increase in diabetes diagnoses) and, on the other hand, diabetes has been increasingly medicalized.

Therefore, the aim of this work (a) is to describe and analyze the changes in the definition of diabetes as a disease and in its treatment according to the guidelines and consensus published by the Argentine Diabetes Society (SAD) [*Sociedad Argentina de Diabetes*] and the Latin American Diabetes Association (ALAD) [*Asociación Latinoamericana de Diabetes*] between 1980 – when the first international classification was released – and 2010, in order to reflect upon the different ways of managing this health problem in Argentina.

Particularly, a question is raised concerning the relationship existing between the changes proposed by these two scientific societies and the medicalization of diabetes as a health care problem in the last 30 years.

On epidemiology and medical consensus

Starting in the second half of the 20th century, *chronic disease epidemiology* or *risk epidemiology* gained importance as a new epidemiological paradigm. It aims to establish measures of risk at the individual level in the population, thereby relating exposure to risk factors with the production of disease. The interventions to be implemented seek to control these risk factors through changes in people's lifestyles (4). Although risk epidemiology is at present the predominant epidemiological theory, it has been questioned since the 1980s mainly for its difficulty in explaining and promoting successful interventions regarding serious health concerns, such as cardiovascular diseases, alcoholism or violence (4).

Within the framework of risk epidemiology, the concept of *evidence-based medicine* (EBM) emerged in the 1980s from the Anglo-Saxon clinical epidemiology movement, in McMaster University, Canada. EBM is specially related to scientific rationalism. According to Castiel, "it is based on the idea of objectivity, reducing the universe of the observable to the quantifiable [...] discounting the non-quantifiable features that give meaning to practice" (5 p.120).

The information resulting from scientific research studies that use EBM methodology is communicated to healthcare professionals through "clinical practice guidelines" published by different scientific societies. These guidelines are developed in a systematic manner in order to help doctors decide about the most appropriate care to provide in concrete clinical situations. Three methods are used for the development of these guidelines: experts' opinions, consensus and evidence-based methods (6). Included in this line of work are the consensus and articles found in the journals of the Latin American Diabetes Association, in which it is specifically stated that they were carried out in accordance with EBM methodology. A level of evidence is assigned to each recommendation depending on the type of epidemiological study carried out, based on its design, methodology and results analysis. As a consequence, studies are given a level of evidence from 1 to 4 or "others," where level 1 represents the recommendations arising from meta-analyses and controlled clinical trials and level 4 represents

the results of cohort or case-control studies, while “others” includes case series and experts’ opinions. These levels are then assigned *categories of recommendation*, ranging from AA to D, where the first category signifies “optimum evidence for recommendation,” with at least one level 1 evidence, and D indicates that “evidence is insufficient or non-existent” (2 p.74).

In this way, clinical experience is no longer enough; scientific evidence is mandatory in order to make accurate clinical decisions. With this approach the value of experience and experts becomes hazy, as randomized experimental studies and meta-analyses are prioritized.

The aim of this discussion is not to adopt an anti-scientific stance, as some developments were and are able to offer better health conditions to people who have access to these benefits. Moreover, science has been able to provide technical and technological answers to many health problems. As Marcia Angell states (7), it was thanks to academic and industrial research and development that many good, effective drugs are now available:

There is no doubt that many people live better and longer thanks to them. However, they should be prescribed carefully and only when necessary; and doctors’ opinions – about when they should be prescribed – should be based on true indications and real research studies rather than on commercial promotion which pretends to be both of them. (7 p.192)
[Own translation]

It is necessary to recognize that clinical trials made possible the commercialization of medicines that have benefited humanity, but it cannot be denied that the number of clinical trials (which so far have not been quantified) responds not to scientific aims but economic purposes (8).

METHODOLOGICAL CONSIDERATIONS

To carry out this study, all publications of the Argentine Diabetes Society’s *Revista SAD* and of the Latin American Diabetes Association’s *Revista de la ALAD* were collected. Both are scientific

societies and, as such, are specialist associations (of diabetes in this case) that aim at presenting and disseminating the results of research studies through publications and conferences.

Both collections were reviewed starting with their first publications: in 1967 for *Revista SAD* and 1993 for *Revista de la ALAD*. The search was carried out in different libraries of the City of Buenos Aires: the Juan José Montes de Oca Central Library of the Faculty of Medicine of Universidad de Buenos Aires and the libraries of the Argentine Medical Association and Argentine Diabetes Society. The latter was the most complete, and it was possible to access there the print versions of the entire collections of both journals. Research was also carried out online, as virtual access to the publications of *Revista de la ALAD* since 2006 was possible. However, *Revista SAD* was not accessed virtually given that subscription was required.

The archive material was searched for consensuses or guidelines involving classification, diagnosis and/or treatment of diabetes, with general management guidelines. As a result of this search, three articles were found in *Revista de la ALAD* and five in *Revista SAD*.

The study was carried out according to content analysis methodology (9) in two diachronic lines: one permitted the chronological reconstruction of changes in the therapeutic management of diabetes; the other was focused on understanding the meanings and relationships surrounding the changes produced, by grouping the material into two central themes (classifications and terminology). The way the terminology and the categories used to define diabetes – as well as the different classifications of this health problem – have changed throughout the years was analyzed. The successive laboratory values considered normal were analyzed in each category. Both so-called *therapeutic changes in lifestyle* as well as drug therapy were also analyzed.

In order to examine the new classifications and new values used for establishing a diagnosis, articles published by *Revista SAD* were used, the contents of which are centered on the emerging changes in these categories. In order to analyze diabetes treatment, *Revista de la ALAD* was primarily used, as the topic was more thoroughly covered in this journal.

RESULTS

Articles from *Revista SAD*

The five articles analyzed from *Revista SAD* were published after the changes proposed by the World Health Organization (WHO), the National Diabetes Data Group and the American Diabetes Association (the latter two organizations are from the United States). What is published in such articles are the proposals and debates regarding certain recommendations, outlined as discussions and not as strict recommendations or instructions.

The first article found in *Revista SAD* is entitled "*Clasificación de la diabetes*" [Diabetes classification] and was published in 1982 based on the proposals of two meetings of diabetes experts: one by the National Diabetes Data Group, including diabetes specialists from the USA and Europe, held in April, 1978; and the other by the WHO, held in 1979. Categories, diagnostic criteria and diabetes terminology were reviewed in both meetings (10).

Later, in 1997, when the American Diabetes Association published a new report, *Revista SAD* published two articles outlining the new diagnosis criteria proposed. The first was entitled "*Diagnóstico de diabetes mellitus: ¿Necesitamos nuevos criterios?*" [Diagnosis of diabetes mellitus: do we need new criteria?] (11) and the second was entitled "*Informe del comité de expertos para el diagnóstico y clasificación de diabetes mellitus*" [Expert committee report on the diagnosis and classification of diabetes mellitus] (12).

In 1998 another article was published, entitled "*Definición, diagnóstico y clasificación de la diabetes mellitus y sus complicaciones. Parte 1: Diagnóstico y clasificación de la diabetes mellitus. Informe preliminar de un comité de consulta de la OMS*" [Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: Diagnosis and classification of diabetes mellitus. Preliminary report from a WHO advisory committee], where conclusions of a new consultancy commissioned by the WHO were outlined (13).

Finally, the last article found in this journal was published in 2007, entitled "*Consenso sobre criterio diagnóstico de la glucemia alterada en ayunas*" [Consensus on the diagnosis criterion

for impaired fasting glucose]. It focused on the reasons why the American Diabetes Association had decreased the cut-off values for impaired fasting glucose and listed the recommendations proposed by SAD (14).

Articles from *Revista de la ALAD*

From 1992 to 2010, three guidelines or consensuses were published in *Revista de la ALAD*. The first was published in 1998 and was entitled "*Consenso sobre la prevención, control y tratamiento de la diabetes mellitus no insulino-dependiente*" [Consensus on the prevention, control and treatment of non-insulin dependent diabetes] (15). A group of subject-matter experts was selected, with the purpose of standardizing the prevention, diagnosis, control and treatment measures of non-insulin dependent diabetes mellitus in Latin America.

The next ALAD consensus was published in 2000 as "*Guías ALAD para el diagnóstico y manejo de la diabetes mellitus tipo 2 con medicina basada en evidencia*" [ALAD guidelines for the diagnosis and management of type 2 diabetes mellitus using evidence-based medicine]. The text explains that such an update was necessary due to the results of some key studies, such as the United Kingdom Prospective Diabetes Study – which followed 4,075 patients recently diagnosed with type 2 diabetes for an average of 10 years – and the development of new drugs for the treatment of diabetes. In this framework, ALAD once again convened a group of specialists in order to create the new guidelines (16).

The third and last set of guidelines found was published in 2006 under the title "*Guías ALAD de diagnóstico, control y tratamiento de diabetes mellitus tipo 2*" [ALAD guidelines for diagnosis, control and treatment of type 2 diabetes mellitus] (2). The main reason for updating the recommendations published in 2000 was related to the pharmacological management of diabetes, and justified by the fact that the goals aimed at controlling some clinical parameters had become

increasingly strict as the studies show the benefit obtained [...] Therefore, other alternatives are being proposed to achieve these

goals more quickly and effectively using more aggressive strategies such as the early administration of oral antibiotics and basal insulin therapy. (2 p.5) [Own translation]

In these guidelines it is explained that the ALAD has remained in alignment with changes that other international diabetes organizations have made, with the objective of offering updated clinical practice recommendations to diabetes care teams (2).

On diabetes classifications and values considered normal: reconstructing the history

As concepts are used over time, they are inevitably modified by those who use them and according to certain objectives. Thus, diabetes – like so many other health issues – faces changes in its classifications, in the ways it is named, or in the ways it is diagnosed (Figure 1).

Therefore, taking into account the international recommendations, the analyzed scientific societies proposed several changes. In order to look at these changes, three main dimensions will be analyzed: first, the successive classifications proposed to categorize patients as diabetic; second, how categories prior to diabetes have been modified over the years; and finally, what have been considered the “normal” blood glucose levels at which to diagnose a patient as diabetic at different moments in time.

Classifications

The first classification in 1982 was related to successive stages of this health problem: “prediabetes, chemical diabetes and clinical diabetes” (10 p.4). Several years later, in 1988, the Argentine Diabetes Society stated that the widely accepted first classification was first introduced by the WHO in 1980, “putting into order a chaotic situation in which the nomenclature and diagnostic criteria showed great variation” (13 p.212).

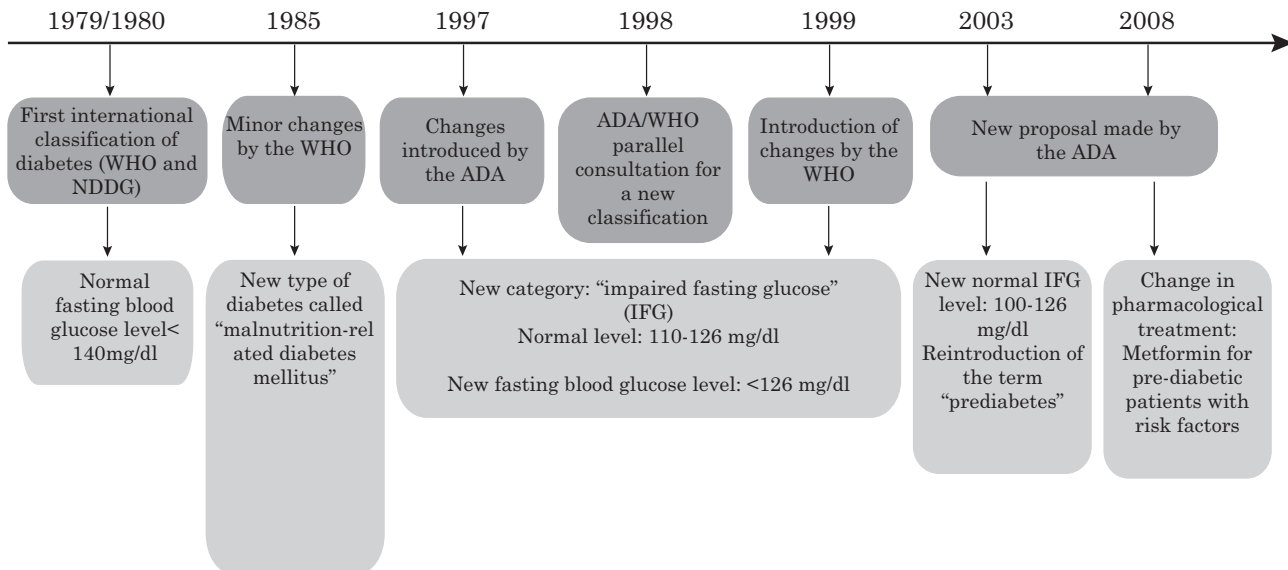


Figure 1. Changes made over the years in diabetes classification and normal laboratory levels according to the changes proposed by scientific societies. 1979-2008.

Source: Own elaboration based on the analyzed consensuses of the Argentine Diabetes Society and the Latin American Diabetes Association (12,13,14).

WHO = World Health Organization. NDDG = National Diabetes Data Group. ADA = American Diabetes Association. IDD = insulin-dependent diabetes. NIDD = non-insulin-dependent diabetes.

The classification introduced in 1979 and 1980 by the NDDG and the WHO divides patients into two large groups. The first group is called "clinical classes," in which the classification depends on the pharmacological treatment being undertaken, that is to say, if the patient does or does not "depend" on insulin: insulin-dependent diabetes mellitus (IDD) or type 1 and non-insulin-dependent diabetes mellitus (NIDD) or type 2. The second group, called "statistical risk classes," comprises

...a category which has potential risk as it includes individuals who may at some point alter their glucose metabolism on account of ethnic, genetic, obstetric or immunity reasons (10 p.6). [Own translation]

The following classification was published in 1985, in which

...the terms type 1 and type 2 were omitted, keeping the terms IDD and NIDD, and a new type of malnutrition-related diabetes mellitus (MRDM) was introduced (13 p.216). [Own translation]

Later, in 1997, both the WHO and the American Diabetes Association made a new proposal in which the classifications were based on etiology. The Argentine Diabetes Society explains:

...of particular importance is the fact of replacing the system that classified diabetes according to the type of pharmacological treatment used for its control, for another system based – whenever possible – on the etiology of the disease (12 p.96). [Own translation]

This classification "eliminates the concepts of insulin-dependent diabetes mellitus and non-insulin-dependent diabetes mellitus and its acronyms" (12 p.99) because "these names caused confusions, and patients were frequently classified according to the disease treatment instead of its etiology" (12 p.99). The 1997 classification is still in force (Table 1).

Prior to diabetes: other categories?

The first analyzed consensus published by the Argentine Diabetes Society, in 1982, mentions the creation of a "new entity, different from diabetes mellitus" (10 p.7), known as *impaired glucose tolerance* (IGT), established by the National Diabetes Data Group. This category includes patients that show "plasma glucose levels between normal test levels and those corresponding to diabetes mellitus" (10 p.7). It is explained that, within this group:

...although in some cases it may be a stage in the progression towards diabetes mellitus, in others the glucose curve may become stabilized and, often, remain unchanged for an indefinite period of time. (10 p.7) [Own translation]

The classification carried out prior to that of the international consensus (prediabetes, chemical diabetes, clinical diabetes) included a category calling this type of situation prediabetes (8,10).

In 1997, the American Diabetes Association and, later in 1999, the WHO introduced a new category to identify individuals at greater risk of suffering from diabetes: *impaired fasting glucose* (IFG), involving fasting glucose levels between 110 and 126 mg/dl (14). This category, rather than a class, as in the previous classification, is categorized as a stage in the natural development of carbohydrate metabolism disorders.

According to the Argentine Diabetes Society, people with impaired fasting glucose "have a higher risk of progressing towards diabetes and macrovascular disease" (13 p.219). This society states that both impaired fasting glucose and impaired glucose tolerance are not clinical conditions in themselves but risk categories for diabetes and/or future cardiovascular diseases, serving as indicators or markers of increased risk (13). They add that

...impaired glucose tolerance was reclassified as a stage of impaired glucose regulation, because it can be observed in any hyperglycemic disorder and it is not in itself diabetes. (13 p.218) [Own translation]

Table 1. Classification of diabetes according to the scientific societies, 1980, 1985 and 1997.

Classification, 1980.			Classification, 1985.			Classification, 1997.	
1. Clinical classes	<i>a. Diabetes mellitus</i>	Type 1 Insulin-dependent diabetes mellitus	1. Clinical classes	<i>a. Diabetes mellitus</i>	Insulin-dependent diabetes mellitus	1. Type 1 diabetes	<ul style="list-style-type: none"> ▪ Immune mediated ▪ Idiopathic
		Type 2 non-insulin-dependent diabetes mellitus			Non-insulin-dependent diabetes mellitus		2. Type 2 diabetes
	i. Non-obese ii. Obese iii. Other types including diabetes mellitus associated with certain conditions and syndromes	i. Non-obese ii. Obese iii. Other types including diabetes mellitus associated with certain conditions and syndromes			3. Other specific types of diabetes	<ul style="list-style-type: none"> ▪ Genetic defects ▪ Diseases of the exocrine pancreas ▪ Endocrinopathies ▪ Drug- or chemical-induced ▪ Infections ▪ Other genetic syndromes sometimes associated 	
		iv. Malnutrition-related diabetes mellitus					
	<i>b. Impaired glucose tolerance</i>	i. Non-obese ii. Obese iii. Other types including diabetes mellitus associated with certain conditions and syndromes		<i>b. Impaired glucose tolerance</i>	i. Non-obese ii. Obese iii. Diabetes mellitus associated with certain conditions and syndromes		
	<i>c. Gestational diabetes</i>			<i>c. Gestational diabetes mellitus</i>		4. Gestational diabetes mellitus	
2. Statistical risk classes	<i>a. Previous abnormality of glucose tolerance</i>		2. Statistical risk classes	<i>a. Previous abnormality of glucose tolerance</i>			
	<i>b. Potential abnormality of glucose tolerance</i>			<i>b. Potential abnormality of glucose tolerance</i>			

Source: Own elaboration based on publications of the Argentine Diabetes Society (10 p.5, 12 p.100) and the World Health Organization (36 p.19).

When in 2003 the American Diabetes Association recommended lowering the threshold level for the diagnosis of impaired fasting glucose to 100 mg/dl (14), this criterion was not universally accepted, and many diabetes-related associations expressed their disagreement. Given the consequences of this recommendation, the Argentine Diabetes Society “called in a group of experts order to

analyze the available evidence, and based on such evidence, to give their opinion on the issue” (14 p.102).

In relation to the diagnostic values for this category, the Argentine Diabetes Society stated that “the diagnostic level threshold regarding fasting glycemia should not be lowered” (14 p.103) and recommended:

...keeping the original cut-off level for IFG (110 mg/dl) in individuals without diabetes risk factors and using a level of 100 mg/dl for patients with risk factors. (14 p.103) [Own translation]

Additionally, members of the Argentine Diabetes Association stated that the recommendation would be upheld until such a time as more evidence for modifying it and promoting studies aimed at establishing its relevance using well-defined clinical parameters was available, including the application of prevention strategies for diabetes and cardiovascular diseases "based primarily on lifestyle changes and not on the use of drugs" (14 p.103).

Regarding one of the categories prior to diabetes, the consensus concludes that:

...the term "prediabetes" must not be used; it is better to replace it with "impaired fasting glucose" because, although progression towards diabetes occurs in certain cases, in others the condition remains stable for a long time and it has even been described that a group may present normal levels in subsequent tests. (14 p.102) [Own translation]

In 2006, the Latin American Diabetes Association also offered its view regarding the changes in terminology:

...the term prediabetes has once again come to be used to categorize those individuals who do not meet the criteria to be diagnosed as diabetic but have abnormal results in their diagnostic tests. These people are at high risk of developing diabetes and also have a higher risk of cardiovascular problems. [...] Some experts in this subject prefer the term "dysglycemia" or even the more descriptive term "impaired glucose regulation." (2 p.13) [Own translation]

With regard to the levels considered normal for impaired fasting glucose, the Latin American Diabetes Association outlines the proposal of other associations such as the American Diabetes Association, according to which the new

diagnostic levels are between 100-125 mg/dl (2). In the analyzed text it is explained that such criteria are recommended by the American Diabetes Association, however, the proposal of the ALAD itself, regarding whether or not these new diagnostic criteria should be adopted or whether the previous levels should be maintained, is not described.

Consequently, the creation of new concepts to refer to the "risk factors for developing diabetes and cardiovascular disease in the future" can be observed (12 p.107). Throughout the years, different names have been chosen depending on the historical moment or the scientific society involved: *prediabetes*, *impaired or decreased glucose tolerance*, *impaired fasting glucose*, *glucose intolerance*, *dysglycemia*, *impaired glucose regulation*. All of them refer to two types of situations: one is the fasting glycemia level and the other is the tolerance test that shows levels that are neither "abnormal" nor "normal."

Therefore, it is possible to notice that the successive classifications go hand in hand with the debates and proposals regarding health-disease management, the proposal of an early diagnosis and the detection of risk factors, and they are all within the framework of the currently prevailing epidemiological paradigm: "risk epidemiology."

"Normal" and "abnormal" diagnostic levels

In 1982, the Argentine Diabetes Society listed certain procedures by which it is possible to diagnose diabetes mellitus (10 p.6):

- a. By the clinical symptomatology of diabetes with evidence of fasting hyperglycemia.
- b. By a fasting plasma glucose level higher than 140 mg/dl, tested no less than two times consecutively.
- c. When an oral glucose tolerance test (OGTT) shows, after 2 hours, a plasma glucose level higher than 200 mg/dl and an equal or higher level between 0 and 120 minutes.

In 1997, the Argentine Diabetes Society proposed new diagnostic criteria (12 p.108) which were modified according to the previous criteria recommended by the National Diabetes Data Group:

- a. Diabetes symptoms along with random plasma glucose levels ≥ 200 mg/dl.
- b. Fasting glucose level > 126 mg/dl.
- c. Two-hour post-load glucose level of 200 mg/dl during the oral glucose tolerance test (OGTT).

In a subsequent document, the Argentine Diabetes Society mentions:

...the most important change, regarding the previous recommendations made by the WHO, is the decrease in the fasting glucose diagnostic level to 126 mg/dl, the previously considered level being ≥ 140 mg/dl. (13 p.215) [Own translation]

According to the statements analyzed, there was a decrease in the normal levels of two parameters: fasting glucose level (from 140 mg/dl to 126 mg/dl) and impaired fasting glucose level (from 110 mg/dl to 100 mg/dl).

As we can see, agreement regarding the categories prior to diabetes is not established. This can be observed in how such categories are named and managed: the American Diabetes Association suggests starting with drugs in high risk patients at these clinical levels, while the Argentine Diabetes Society does not agree. Therefore, there is great divergence both at a global and local level depending on which scientific society is used as a reference.

In Argentina, where there are no uniform guidelines used by health professionals, if local guidelines are taken into account, the normal fasting glucose level would be less than 110 mg/dl. However, if the American Diabetes Association guidelines are followed, the level would be 100 mg/dl. Therefore, a person is or is not diabetic or "prediabetic" within the same country, even in the same city, depending on the professional who treats the patient.

In this sense, the consequences for patients diagnosed as diabetic must be taken into account, highlighting the "possible adverse effects, including psychological and economic damages caused by a diagnosis and treatment providing no medical benefits" (11 p.90).

It is true that the concept of normality "is not static and pacific, but rather dynamic and controversial" (17 p.187). Moreover, since these levels

are continuous variables, an artificial dichotomy is established such that an individual may have a "normal" glucose level one day and an "abnormal" value a day after. We overlook the fact that there is a person involved who was diagnosed with a disease that still has no cure. This implies the ("imperfect") labelling of someone as having an "abnormality."

All of this is related to the medicalization of diabetes, as in the background lies the potential profits of the pharmaceutical industry: starting a pharmacological treatment before the definitive diagnosis of diabetes implies an increase in the amount of drug consumers.

Individualized treatment and "therapeutic lifestyle changes" as an individual responsibility

Non-pharmacological treatment: "therapeutic lifestyle changes"

The analyzed consensuses first highlight "non-pharmacological measures" or "therapeutic lifestyle changes," with proposals related to health education, physical activity and healthy habits. The Latin American Diabetes Association stresses that educational strategies are extremely important and must be used with the person with diabetes as well as his/her family members. In this way, an "educational plan" is justified because

...diabetes mellitus is a chronic disease that compromises all the aspects of a person's daily life. Therefore, the educational process is essential for the treatment of a diabetic patient. (16 p.128) [Own translation]

The Latin American Diabetes Association suggests that the mass media plays a very important role in the educational process of the community. It also mentions that both the basic knowledge of diabetes and the aspects related to the disease – referring to diabetes prevention and education – should be included in medicine and health sciences curricula (16). It proposes that a budget should be established for the education of diabetic patients within the official programs for control and treatment of chronic diseases. At the same time, "the contributions of

the pharmaceutical industry to this end must be sought" (2 p.128).

Diet is outlined by the Latin American Diabetes Association as "the key pillar of the diabetes treatment" (2 p.21). Some features of the recommended diet are explained and certain goals for physical activity and recommendations regarding so-called healthy habits, referring exclusively to smoking, are proposed (2).

Pharmacological treatment

In the consensus published by the Latin American Diabetes Association in 1998, it is recommended that

...as a primary therapeutic measure, it is important to try to reach a healthy weight. Within this group a three-month diet plan with periodic controls will be established before adding any possible drug treatment. If despite losing weight a suitable metabolic control is not reached, a treatment with biguanide, thiazolidinedione or an alpha-glucosidase inhibitor will be initiated. (15 p.17) [Own translation]

The subsequent consensus, published in 2000, offers the same proposal as the previous consensus. However, it is explained that

...some patients require pharmacological treatment from the start, because they are clinically unstable or have a high level of decompensation that makes it possible to anticipate a poor response to an exclusively non-pharmacological treatment [...] pharmacological treatment can be initiated from the start as per the doctor's judgement. (16 p.136) [Own translation]

In 2006, the Latin American Diabetes Association proposed:

...pharmacological treatment using antidiabetic drugs should be initiated in any person with type 2 diabetes in whom the goals of a good glycemic control have not been achieved with therapeutic lifestyle changes (TLC) [...] In cases where the clinical conditions of a

patient allow doctors to anticipate that this will happen, pharmacological treatment must be considered from the moment of diabetes diagnosis along with therapeutic lifestyle changes. (2 p.25) [Own translation]

In order to justify such a recommendation, the Latin American Diabetes Association mentioned the changes that had been recently proposed by the American Diabetes Association and the European Association for the Study of Diabetes (EASD), stating that those scientific societies:

...have published an algorithm for the management of type 2 diabetes, where they propose that a metformin treatment must be initiated along with TLC in all patients with type 2 diabetes, considering that non-pharmacological management ends up being insufficient in the first year of treatment. (2 p.25) [Own translation]

"Therapeutic lifestyle changes" in diabetic patients are mentioned without considering that the lifestyle of each patient is in fact his or her life and not just a "style," including the conditions of reproduction, working conditions, and the material conditions of existence of each human being. The concept of *lifestyle* has its origins in the concept of *living conditions*, which was developed outside of the realm of biomedicine: by Marxist thought, in relation to the mode of production and the general conditions of production (19); and in Weberian comprehensive sociology (18), articulating the social structure and individuals with a certain style in their daily life, personally and socially.

This concept was first posited as holistic and was subsequently reduced to personal risk behavior in the health sector. In this way, its explanatory capacity was eliminated, casting aside both material and ideological conditions (20). Menéndez states that although it is true that a part of the population may be able to lower its specific risk, the ability to choose is reduced to individual behavior (20).

It must be borne in mind that risk as a construct placed solely at the individual level presupposes – explicitly and implicitly – that the subject is a totally free being, with the capacity and ability to choose whether or not to smoke or eat healthy

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Abbott - Astra Zeneca - Bayer - Bristol Myers Squibb - Eli Lilly - Euroeteca Servier - GlaxoSmithKline - Johnson & Johnson - Merck - Merck Sharp & Dohme - Novo Nordisk - Productos Roche - Sanofi Aventis

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Abbot - Astra Zeneca - Bayer - Bristol Myers Squibb - Eli Lilly - Euroeteca Servier - GlaxoSmithKline - Johnson & Johnson - Merck - Merck Sharp & Dohme - Novo Nordisk - Productos Roche - Sanofi Aventis

Figure 2. Acknowledgement to pharmaceutical laboratories published in one of the journals of the Latin American Diabetes Association.

Source: Latin American Diabetes Association (2 p.3).

food (20). However, there are certain social groups in which the ability to make certain choices is practically nonexistent. As Castiel and Álvarez Dardet state: "many people do not choose the lifestyles they lead. In reality there aren't any options available, only possible survival strategies" (21).

It does not appear to be evident that eating appropriately, although a personal decision, is strongly conditioned by economic, advertising and social circumstances which do not always reflect personal choice (22). Therefore, these contexts are not taken into account when considering the disease management approach proposed by the analyzed scientific societies. As was previously mentioned, the articles from *Revista de la ALAD* were elaborated using the evidence-based medicine methodology, and make general recommendations for all of Latin America. Such methodology does not allow for the consideration of the particularities of each place: it is based on "scientific evidence" from studies carried out in

other populations in other countries and translated directly to Latin American contexts. On the other hand, the articles from *Revista SAD* include general proposals related to classifications and names proposed by international organizations.

In the analyzed articles as well as in the journals and on the websites of these scientific societies, advertisements for pharmaceutical laboratories concerning drugs or products aimed at "controlling" diabetes can be found. Moreover, at the end of the analyzed article published in 1998 by *Revista SAD*, an acknowledgement of the financial contribution received by some laboratories (Bayer and Novo Nordisk) appears. Similarly, the fragment shown in Figure 2 was found at the beginning of one of the articles published by *Revista de la ALAD*.

Based on the abovementioned articles, the Latin American Diabetes Association states that laboratories limited themselves to "providing medical literature during the evidence research stage" (2 p.3). Such provision is analyzed by

Doval, who discusses that the development of these guidelines is “normally constrained to the available published information” (23 p. 499), in which there are different factors that can lead to biased conclusions. Examples of these factors include the selection of studies to be submitted, which of these studies are then accepted for publication, the presence of duplicate publications that are difficult to detect, and the way in which the results are communicated (23).

Moreover, one of the articles from *Revista de la ALAD*, after suggesting the role the State plays in the education of individuals with diabetes, adds that “at the same time it is necessary to seek out the contributions of the pharmaceutical industry to this end” (16 p.128).

Consideration must be given to the interests of the pharmacological industry, which are not different from those of any other private company: that is, generating the greatest possible profit. Therefore, if investment is made in scientific research, it is not off base to think that the aim of such research is to profit from the results. The problem is that the profit motive affects scientific research and subverts its essence (24). When profits are involved, revenue-based financing and conflicts of interest arise, which – in the end – affect those who should be benefitted by such scientific progress: the population and, especially, those with greater difficulties accessing dignified healthcare services. Thus, Doval states that

The clinical research studies that are published are increasingly designed, supported and financed by drug manufacturing companies. Therefore, the question may arise as to whether, in addition to the power of such companies to decide that only that which might be profitable will be researched, there also exists the possibility of biases regarding the communication, publication and interpretation of clinical findings. (23 p.498) [Ówn translation]

Efficacy focused on drugs is one of the features that sustains diabetes treatment as well as many other health problems. The medicalization of these issues does not only involve drug prescription as an essential part of healthcare workers’ actions, but also implies

the demand for practices characteristic of this model by different sectors of society. Therefore, medicalization is directly related to the growing pharmacodependence of social groups (25).

FINAL COMMENTS

Medicalization of risk

On the one hand, the lack of agreement among the different scientific societies regarding certain changes, such as the names of certain categories or the levels considered normal proposed over the last five years, is surprising. This disagreement was clearly reflected in the last changes, when the American Diabetes Association proposed a return to the term “prediabetes” in the case of impaired fasting glucose and a decrease in the normal glucose level. On the other hand, this scientific society proposes that for certain “high-risk” groups it is necessary to start pharmacological treatment when prediabetes is diagnosed (26).

If we recall the definition of the stages prior to diabetes according to the analyzed articles from the Argentine Diabetes Association, patients with impaired fasting glucose “have a higher risk of progressing towards diabetes and macrovascular disease” (13 p.219). Furthermore, this scientific society states that although “although in some cases it may be a stage in the progression towards diabetes mellitus, in others the glucose curve may become stabilized and, often, remain unchanged for an indefinite period of time” (10 p.7). Moreover, the concept of risk refers to “the probability of the occurrence of an event” (27 p.89). Thus, we can see that these stages are considered risks and, as such, they do not always occur.

Consequently, these changes lead to an increase in the medicalization of this health problem, since medicating individuals pertaining to “high risk” groups is proposed, although they have not yet fallen into the category of diabetes and their glucose levels could stabilize. Thus, we face another situation in which we must include within the adverse effects of each treatment those related to the diagnosis and treatment of problems which many never actually occur (28).

Castiel and Álvarez Dardet state that there are some sectors of health sciences that:

...started to collaborate strongly with corporate strategies of the pharmaceutical industry to make the occurrence of disease a space that could be broadened, both in the present by creating new diseases and, through the notion of risk, also medicalizing the future. (28 p.462) [Own translation]

These authors comment that the idea of risk is related to “that sense of great insecurity of our age that seems to generate a search for predictability in relation to the possible scenarios and events that may happen to us” (28 p.462). This is the reason why we, as healthcare professionals as well as users, need clearer answers for each of the problems with which we are presented. We are influenced by the idea that “truth can only be obtained through an almost paroxysmal search for evidence” (28 p.462).

Medicalization and creation of new diseases

In this study we analyzed how normal glucose levels to categorize a person as diabetic were modified and how new categories prior to diabetes were created. Marcia Angell (7), when analyzing changes in normal blood pressure parameters, states that the drug markets aimed at blood pressure grew when the experts’ committee changed the definition of high blood pressure (hypertension), introducing a term called *prehypertension*: blood pressure between 120/80 and 140/90 mmHg. Previously, a level lower than 140/90 mmHg was considered to be normal. Thus, “overnight, people with blood pressures in this range found that they had a medical condition.” Angell adds that:

Although the panel recommended that prehypertension generally be treated first with diet and exercise, human nature being what it is, many people will almost certainly prefer to be treated with drugs. That expansion in the definition will add millions of customers for blood pressure drugs – despite the absence of convincing evidence of their benefit in this group. (7 p.107)

Thus, changes in laboratory levels for diagnosis have significantly increased the number of

patients now classified as having prehypertension or prediabetes (29). Homedes and Ugalde explain that “once there is an official modification of the parameters or thresholds of certain diseases and new diseases are created, the powerful marketing machine of the great innovative drug industry comes into motion to promote the sales of drugs for these health conditions” (29 p.317).

Drugs are not ordinary commodities; as a result, it can be suggested that their development and production should be guided by different criteria than those followed by other industries (29). Lorenzo and Garrafa state that “at present, the multinational pharmaceutical industry is one of the most powerful economic conglomerates on the planet” (30 p.167). The main drug patents belong to 15 companies and most clinical trials are related to chronic diseases (such as diabetes, asthma, dyslipidemia and hypertension). They conclude by affirming that this “generates a generally captive market, with business stability and continuous profitable growth” (30 p.167).

Medicalization and scientific research

Based on the analyzed articles, it is surprising to observe that a health concern such as diabetes – a disease known for centuries – has in the last thirty years undergone so many changes and raised so many debates regarding normal glucose levels, different denominations or the proper time to start treatment. This is not a feature exclusive to diabetes, but, as Silvia Ayçaguer (31) states, all scientific research is experiencing increasingly rapid changes. Both the speed at which technological advances occur as well as the amount of available information grow unstoppably. Similarly, healthcare professionals have many more opportunities to be informed, although this may become overwhelming (31).

Menéndez analyzes these changes in relation to how guidelines and published works become outdated increasingly quickly. Similarly, the time and number of tests that a new chemical product has to undergo are reduced in order to activate its launch into the market. These reductions help to sustain a systematic obliviousness regarding the negative consequences these products cause in the population (18). According to Menéndez:

Research results gain autonomy from medical knowledge, and “are bought down” to doctors as instruments that only they can apply [...] Personal processes – both those of patients and of doctors (the clinical eye) – which were relevant in the doctor-patient relationship are increasingly disappearing in practice, due not only to the development of a medicine of the masses that is ruled by the criteria of productivity but also to the replacement of clinical conduct by pharmacological conduct, which makes drug prescription its main objective and its primary technical/professional identification. (32 p.26) [Own translation]

Pharmaceutical companies try to find new uses for their drugs, because in this way they can extend the sales monopoly granted by the relevant patent (29). Angell affirms that “the pharmaceutical industry is not especially innovative [...] The great majority of ‘new’ drugs are not new at all but merely variations of older drugs already on the market. These are called ‘me-too’ drugs” (7 p.19).

Me-too drugs “generally target very common, lifelong conditions – like arthritis or depression or high blood pressure or elevated cholesterol. The conditions are not so serious that they are imminently lethal, but they don’t go away, either” (7 p.106). Therefore, many people will consume these drugs for many years, generating a constant sales volume. However, people who suffer from uncommon diseases, with a small market, or people suffering from short-lived diseases, such as many acute infections, are not the target of pharmaceutical companies. Deadly diseases kill the consumer; therefore, drugs aimed at these diseases do not generally obtain great sales success (7).

Medicalization and technical/professional dependence

Ugalde and Homedes (8) analyze how clinical trials have been exported to low- and middle-income countries over the last years with the aim of increasing business and transferring risks to very poor people. When describing the situation in Latin American, the authors discuss how doctors’ recruitment of patients is facilitated by the fact that it is conducted in public health

care services which tend to serve people with low incomes and low levels of education, along with the lack of free access to medication (8 p.143-4). As most are multicenter and multinational studies, local researchers do not analyze the information that arises from these studies; rather, it is the industry that gathers the results and “sends them to their headquarters [...] usually located in a high income country, to be analyzed” (8 p. 143-4). Often, what is being tested are drugs for a chronic disease, where “there is no guarantee that those participants who enjoyed the benefits while the trial was conducted will have access to the drug in the future, as once the drug is released on the market it will be unaffordable to them” (8 p.144). This inequity, in which the most vulnerable sectors are those exposed to the risks caused by clinical trials, comes into contrast with the benefits that the trials generate for transnational companies, the professionals that work for them, and the consumers of high-income countries (8 p.145).

The study designs most commonly used for determining the efficacy of a treatment or preventive measure are controlled clinical trials and meta-analyses (33): both designs have the *highest level of recommendation* according to evidence-based medicine methodology (2). The final goal of these types of studies is to be able to generalize the results beyond the study population (33). However, these studies may present problems related to their internal and external validity, connected to the way in which subjects are chosen to participate in the study. To be useful clinically, results must have both internal and external validity; a justifiable concern has been raised regarding the fact that this validity tends to be poor in controlled clinical trials (34 p.90). There are certain limitations that may affect the external validity of these studies. Different types of diagnostic methods might be used, and there may be differences in access to the healthcare system among the different countries taking part in a clinical trial. Therefore, results may be different if presented separately or unified in a single clinical trial (36). The same may happen if there are differences in the way that participants are recruited: in health care centers with different levels of complexity or by physicians with different medical specialties (34). Differences in socioeconomic, geographic, ethnic or temporary conditions may exist between the

studied population and the target population (35), or between the onset and the outcome of the disease among the different populations. It is worth asking whether those conditions may have influence on the results, and, consequently, limit their generalizability (35). The aim of these studies is to determine the effect of the treatment, not to measure the benefits of treatment in clinical practice, therefore, it cannot be expected that the results of these types of studies are relevant for all patients and all settings (34).

It is true that many of the changes in the management of diabetes have been proposed by countries in the Northern Hemisphere, because most of the recommendations on the management of diabetes come from studies in that area. Thus, in a country like Argentina where local health care research is scarce, we base treatment for many of the most prevalent health concerns on the "evidence" arising from studies carried out with the clear mark

of the pharmaceutical industry, in which the generalization of results represents a problem, due to the differences existing in health care access and in socioeconomic and cultural conditions, which could have influenced the development and outcome of diabetes and other health problems.

We should therefore keep these debates in mind when defining changes in the management of a medical concern as increasingly prevalent as diabetes. The generalization of the results of clinical trials designed in central countries, generally sponsored by the pharmaceutical industry, have their limitations, especially when the focus is placed on commercial interests to the detriment of the health of the most vulnerable sectors.

ENDNOTES

a. This article is based on the final work presented at the Universidad Nacional de Lanús (UNLa) for the degree of Specialist in Epidemiology, entitled "Abordaje de la Diabetes entre los años 1980 y

2010. *Transformaciones y medicalización del cotidiano*" [Diabetes management between 1980 and 2010. Transformations and medicalization of the everyday]. The study was directed by Dr. Laura Recorder.

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