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STATE-OF-THE-ART REVIEW

State-of-the-Art Review on Diabetes Care in Italy

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Abstract

BACKGROUND Diabetes is a significant health problem in Italy as in other western countries.

OBJECTIVE To review available epidemiological data and the legislative framework for diabetes care in Italy.

METHODS Review of Italian Health Ministry's official documents and analysis of epidemiological data published by Italian Scientific Societies.

FINDINGS Diabetes affects more than 5% of the Italian population. The expenditures for the care of people with diabetes are about €10 billion ($US 11 billion) a year and are increasing over time. Italian law regulates the clinical care of people with diabetes and creates a clinical framework involving medical organizations, prevention programs, personnel training, and legal protection. The National Health Program is structured in essential levels of assistance that can be defined differently in the various regions. In 2013, the "National Diabetes Plan," defining priority areas for intervention, was approved and represents the main regulatory tool for the management of diabetes within the Italian National Health Service. In Italy, the status of diabetes care is being monitored using the data from 2 permanent observatories: the ARNO Observatory Diabetes and the Associazione Medici Diabetologi Annals.

CONCLUSIONS A comprehensive approach to diabetes is offered to all citizens, consonant with the constitutionally guaranteed right to health. However, this important effort translates into a relevant financial burden for the National Health Service.

KEY WORDS costs, diabetes, diabetes care, diabetic complications, Italy, legislative framework, prevalence

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THE SCOPE OF THE PROBLEM

In Italy, diabetes affects more than 3.5 million people, about 5.5% of the general population.[1] In the last 20 years, the number of Italians with diabetes has increased by about 60%, from only 3.4% in 1993.[1-3] As a result of these epidemic proportions, the Italian Health Service estimates spending about €10 billion ($US 11 billion) yearly for direct and indirect costs related to diabetes care.[4] This relative increase in expenditure is, at least in part, due to the increase of the mean lifetime expectancy observed in Italy over the last decades. Current epidemiological data show that 1 person out of 3 affected by diabetes is older than 65, and of these, 1 out of 4 is older than 75 years of age.[2]

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ITALIAN NATIONAL HEALTH SERVICE AND DIABETES

The Italian National Health System (INHS) is strongly focused on pediatric care, the aging population, and the chronically ill, all contributing to a favorable effect on life expectancy in Italy. This is exemplified by a high quality of diabetes care, offered without cost to patients, and provided by dedicated specialists. The Italian Constitution ensures the "right to health" to every citizen. No one can be excluded from health care in Italy because of age, gender, creed, conduct, or income level. The Italian health care system may still be regarded as "fee for service" because the patient is a virtual payer as fees collected by the national and regional governments through the tax system represent the actual reimbursement.[5] However, the growing economic burden of universal coverage by the Italian government is a formidable problem.

The National Health Program is structured in LEAs (essential levels of assistance).[6] LEAs define all of the medical assistance modalities offered by the INHS offers to citizens, with or without partial contributions based on a patient's income. Each Italian region has the right to define these levels in different ways, but they must still adhere to a nominal set of medical assistance guidelines that remain free of charge. Foreign residents have full access to the medical assistance as well. For example, the financial responsibility for European citizens is the same as for the Italian people, whereas for the non-European citizens, the costs of assistance are regulated by specific agreements between the governments.

ORGANIZATION OF THE MEDICAL ASSISTANCE FOR DIABETES

The INHS promotes a comprehensive approach to diabetes[7] organized by assistance levels—type 1 diabetes (T1D) (pediatric and adult) and type 2 diabetes (T2D)—and offers 2 different options for outpatients: primary care and secondary/specialist care (limited to those patients requiring a higher level of care). Primary care is managed by general practitioners with the collaboration of diabetes specialists depending on the presence of complications, comorbidities, and therapeutic modalities. Specialist care is provided by structured diabetes units, usually in hospital centers, in which a team composed of different specialists (endocrinologists, nurses trained in the prevention and management of diabetic complications, nutritionists, podiatrists, and psychologists) provides integrated disease management.

The principal focus of these units is patients' education, prevention, and treatment of diabetic complications and associated conditions: diabetic foot complications, pregnancy and gestational diabetes, bariatric surgery for patients with diabetes and obesity, cardiovascular disease and metabolic syndrome, retinopathy, neuropathy, and nephropathy. In addition, lifestyle interventions incorporate psychological support and educational approaches to obesity and weight management, healthy eating patterns, medical nutrition therapy and carbohydrate counting, physical activity, and sensor augmented pump (SAP) therapy.

THE LAW 115/1987

Diabetes care in Italy follows dedicated rules,[7] which are outlined by the March 1987 law 115/87 titled "Measures for the Prevention and Treatment of Diabetes Mellitus"; this represented a relevant civil and medical achievement for people with diabetes in Italy. This law regulated the clinical care of people with diabetes and also created a framework for medical organizations, prevention programs, personnel training, and legal protection. In short, this law resulted from unwavering actions of volunteer associations that pressured the political system to recognize the need for a comprehensive management of this important chronic disease.

Today, the legislative framework for diabetes care in Italy is different. First of all, the INHS changed in 1996 when welfare was delegated by law 662/96 to various geographic regions. In addition, rules were modified for institutional accreditation of the facilities for diabetes (DL January 14, 1997), of staff training (National Health Plan for the Continuous Medical Education, the State-Regions Agreement of March 23, 2005) and, finally, the lobbying of the patients themselves (agreement of the LEA State-Regional Conference, November 8, 2001).

Thus, 26 years after the enactment of law 115/87, in 2013 the National Diabetes Plan (*Piano Nazionale Diabete;* PND) was approved and currently represents the basic regulatory tool that the scientific societies and patients' associations use for the management of diabetes within the INHS.[5] The PND was based on the analysis of the best scientific evidence and practices but was also influenced by the worldwide developments in these fields, including patient associations and scientific societies. Consequently, diabetes care was included in the priorities

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