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REVIEW

Global alliance against chronic respiratory diseases in Italy (GARD-Italy): Strategy and activities

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Summary
The steady increase in incidence of chronic respiratory disease (CRD) now constitutes a serious public health problem. CRDs are often underdiagnosed and many patients are not diagnosed until the CRD is too severe to prevent normal daily activities. The prevention of CRDs and reducing their social and individual impacts means modifying environmental and social factors and improving diagnosis and treatment. Prevention of risk factors (tobacco smoke, allergens, occupational agents, indoor/outdoor air pollution) will significantly impact on morbidity and mortality.

The Italian Ministry of Health (MoH) has made respiratory disease prevention a top priority and is implementing a comprehensive strategy with policies against tobacco smoking, indoor/outdoor pollution, obesity, and communicable diseases. Presently these actions are not well

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coordinated. The Global Alliance against Chronic Respiratory Diseases (GARD), set up by the World Health Organization, envisages national bodies; the GARD initiative in Italy, launched 11/6/2009, represents a great opportunity for the MoH.

Its main objective is to promote the development of a coordinated CRD program in Italy. Effective prevention implies setting up a health policy with the support of healthcare professionals and citizen associations at national, regional, and district levels. What is required is a true inter-institutional synergy: respiratory diseases prevention cannot and should not be the responsibility of doctors alone, but must involve politicians/policymakers, as well as the media, local institutions, and schools, etc. GARD could be a significant experience and a great opportunity for Italy to share the GARD vision of a world where all people can breathe freely.

Contents

Introduction

Today the National Health System is responding to new needs for assistance characterized by the high prevalence of chronic conditions that require long term continuous care and the use of strategies to stabilize acute pathological situations and improve patients' quality of life. A new and different equilibrium must be sought in which the patient, not the disease, is at the heart of the system. We need to create new partnerships with the various stakeholders - not only those directly involved in the medical world - for an extensive interchange amongst all partners, highlighting the role of the different associations as a reference point. The person and not the disease must be at the center of the care pathway. This signifies the need for integration between hospitals and the local community, preserving the role of the network specialist and reinforcing the role of general practitioners (GPs) and pediatricians.

In the last decade several European countries have undertaken national initiatives to achieve these goals. In Finland, for instance, programs on COPD and asthma have been developed. The National Asthma Program was undertaken from 1994 to 2004 to improve asthma care and prevent increasing costs. The main goal was to lessen the burden of asthma on individuals and society. Data show that the incidence of asthma is still increasing but that its burden has decreased considerably and that it is possible to reduce asthma morbidity and its impact on both individuals and society, e.g. the number of hospital days has fallen by 54% from 110,000 in 1993 to 51,000 in 2003 (69% in relation to the number of asthmatics), with the trend still downwards. In 1993, 7212 patients of working age received a disability pension from the Social Insurance Institution compared with 1741 in 2003. The absolute decrease was 76% and 83% in relation to the number of asthmatics. The increasing cost of asthma (compensation for disability, drugs, hospital care, and outpatient doctor visits) ended: in 1993 the costs were € 218 million; they fell to € 213.5 million in 2003 (cost per patient per year decreased by 36%).[1] The Finnish National Program for Chronic Bronchitis and COPD (1998—2007) was set up with similar aims. Its major strengths were: multidisciplinary strategies and web-based guidelines in nearly all primary healthcare centers around the country. The prevalence of COPD remained unchanged. Smoking decreased in males from 30% to 26% and in females from 20% to 17%. Significant improvements in the quality of spirometry were obtained. Hospitalization decreased by 39.7% and COPD costs were 88% lower than had been anticipated for earlier investigations.[2]

In England, the Department of Health (DH) recently introduced a number of service frameworks for major health problems, such as heart disease and diabetes, to reduce

inequalities and improve patient outcomes, with dramatic results. The same methodology of reviewing evidence, setting standards and markers of good practice in conjunction with professionals, managers and service users was used to introduce a national strategy for COPD. A recorded prevalence of COPD was estimated from primary care disease registers of 1.5% of the total registered population (all ages) against a calculated underlying prevalence of 9.7% (DH, 2008). Deprived urban populations had the highest prevalence and highest underdiagnosis of COPD, and accounted for a considerable part of the life expectancy gap compared to England as a whole (DH, 2007), representing a major challenge for DH in terms of diagnosing and optimally treating the missing millions. The COPD strategy has, at the core of its standards for the NHS, the aspiration to promote good lung health, helping individuals and others to reduce risks, early identification and accurate diagnosis including severity, regular review and promotion of self care, access to pulmonary rehabilitation, proactive management of exacerbations, early assessment for surgical intervention and supported palliative and end of life care. Implementation is being supported through the development of a competent workforce and the evaluation of patient reported outcome measures and quality indicators.[3]

In Italy respiratory diseases, after cardiovascular and malignant diseases, are the 3rd leading cause of death and, given the aging population, their prevalence is expected to rise in the next decades.[4] The fight against respiratory diseases is primarily on two fronts: primary prevention (e.g. through interventions against smoking and pollutants in the home and workplace) and secondary prevention (e.g. early diagnosis). Equally important is information to patients and family members, who must be trained to recognize the disease characteristics, follow the prescribed treatment correctly, react promptly in the case of exacerbation and utilize the home care services provided.

The 55th World Health Assembly, recognizing the enormous suffering caused by chronic diseases, called for a global effort to combat them through international alliances and partnerships to coordinate the mobilization of resources, formulate a defense strategy, and strengthen research capacity and collaboration.[5] The Global Alliance Against Chronic Respiratory Diseases (GARD) was set up in 2004 to effectively address the problems caused by chronic respiratory disease (CRD). GARD is a voluntary alliance at national and international level made up of organizations, institutions and agencies working for the common goal of improving global lung health.[6,7] GARD has the following working goals:

1. to develop national programs of prevention and control of CRDs, starting with health education campaigns and a better knowledge of epidemiology, impact, and relative risk factors;
2. to provide training and continuing education on prevention and treatment of CRDs, disseminating the existing guidelines;
3. to facilitate access to essential treatments and favor adherence to long term treatment, including drug treatment and pulmonary rehabilitation, particularly amongst disadvantaged sectors of the population.

The Alliance is part of the World Health Organization's (WHO) activities for prevention and control of non communicable diseases and is based on: estimating the population's needs and interventions, defining and adopting policies, and identifying the stages of implementation of policies. GARD is working to make CRDs a public health priority in all countries and to ensure that governments, the media, citizens, patients, health professionals and all stakeholders are aware of the scope of this problem.

A national planning policy in all countries is essential in order to assign the right priorities and ensure that resources are allocated efficiently. Therefore, the added value of GARD is to provide a collaborative network through which the parties can join forces to achieve results that could not be obtained alone and to improve the coordination between governmental and non-governmental programs to avoid duplicating efforts and wasting resources. The GARD action plan 2008—2013 is an instrument of WHO's global strategy for prevention and control of chronic diseases.[8] GARD implements actions at local level through the establishment of national alliances.

Within this context, the Italian GARD (GARD-I) was set up to develop a strategy for prevention and care of respiratory diseases in Italy. GARD-I is a voluntary national alliance — made up of institutions, scientific societies, patients' associations and other potential partners working in the respiratory field. The overall objective of each national GARD body, based on the rules established by the international GARD, is to reduce the incidence, morbidity and mortality of respiratory diseases in the long term through an integrated approach.[8] With regard to Italy, GARD-I will discuss and identify actions, strategies and tools according to those defined by the National Health planning.

The fields of activity fixed for the first two years are:

1) Prevention of respiratory disease in schools
2) Smoke and home environment
3) Early diagnosis
4) Continuity of care
5) Education/Training

Epidemiology of respiratory diseases in Italy

Assessments of mortality/morbidity for COPD often include chronic bronchitis, emphysema and asthma. Chronic bronchitis and asthma affect more than 20% of the elderly population (>64 years). Mortality from chronic bronchitis, emphysema and asthma is particularly high in Liguria, Piedmont and Valle d'Aosta (about 36/100,000), while the regions with the lowest rates are Trentino Alto Adige, Veneto and Lazio (23—24/100,000).[9] From 1990 to 2002 there was an almost continuous decline in mortality for chronic bronchitis, emphysema and asthma in males. In females, the decline was arrested in 2000; however 2002 saw an increase. From 2002 to 2003, the mortality rate further increased in females (8—12/100,000), and also increased in males (26—36/100,000) (European mortality database of 'Health for All'-MDB-HFA 2008). In contrast, deaths from asthma alone decreased continuously from 1995 (1500 deaths) to 2006 (513, 41% males). In 2006, there were 20,257 deaths from chronic lower respiratory

diseases.[10] But as mortality data refer only to the *primary* cause of death as reported on death certificates, there is a possible underestimation of mortality due to COPD. An Italian study found that COPD, as a contributing cause of death, accounts for 62% of total mortality. This doubles the mortality estimate from COPD as the main cause.[11]

With regard to morbidity, in 2004 COPD was the 4th leading cause of chronic disease in Italy, affecting 4 million people. After arthrosis/arthritis, hypertension and osteoporosis, COPD together with diabetes has the highest increase of incidence (about 6%) in the elderly.[12] More than 4 in 100 people claim to have chronic bronchitis/emphysema (Figure 1) and more than 3 in 100 have asthma (Figure 2) (ISTAT 2008).

Overall, underdiagnosis of COPD in Italy ranges from 25 to 50% and epidemiological investigations conducted in the Po river delta and in Pisa-Cascina confirm and extend international observations.[13] The lack or delay of diagnosis affects the timing of therapeutic intervention, contributing to the evolution toward more severe disease. The last annual report by the Ministry of Health[14] on hospitalization, based on hospital discharge records (HDR), shows that in 2005 COPD was the 2nd leading cause of hospitalization for acute respiratory disease (after pneumonia/pleurisy), followed in 3rd place by respiratory failure/pulmonary edema and in 4th place by asthma/bronchitis. From 2000 to 2005, the number of hospitalizations for COPD and asthma/bronchitis decreased, while there was a very obvious increase in hospitalizations for respiratory failure/pulmonary edema (Figure 3). The decline of admissions for COPD may be a consequence of compilation of the SDO (hospital discharge form), in that COPD patients hospitalized for respiratory failure (i.e. the prevalent cause for hospital admission, simple COPD normally being managed in an outpatient regime) may have been encoded into the DRG (diagnosis-related group) of the latter and not COPD, so permitting a higher reimbursement by the NHS. Moreover, in many hospitalized COPD patients respiratory failure is the first diagnosis with COPD associated, hence the DRG is 87 and not 88.[15–17]

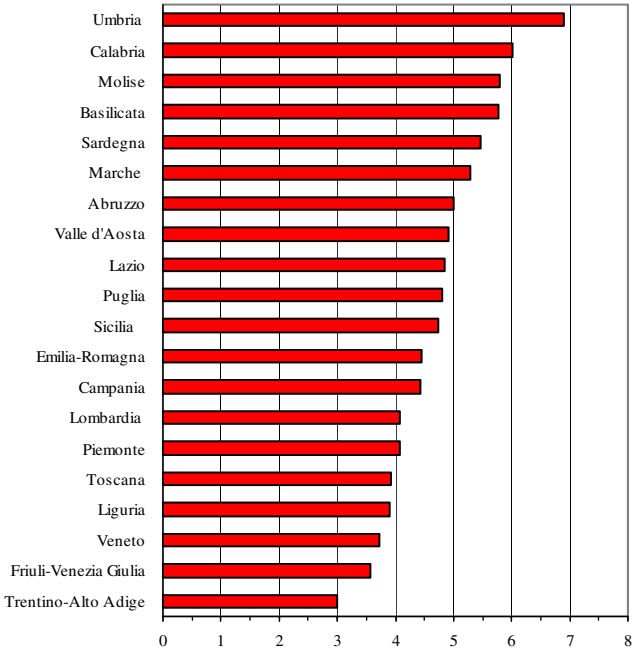

Figure 1 People reporting chronic bronchitis/emphysema in Italy, by region — Standardised rates per 100 people — Years 2004—2005 (Source: State of health and use of health services, ISTAT 2008).

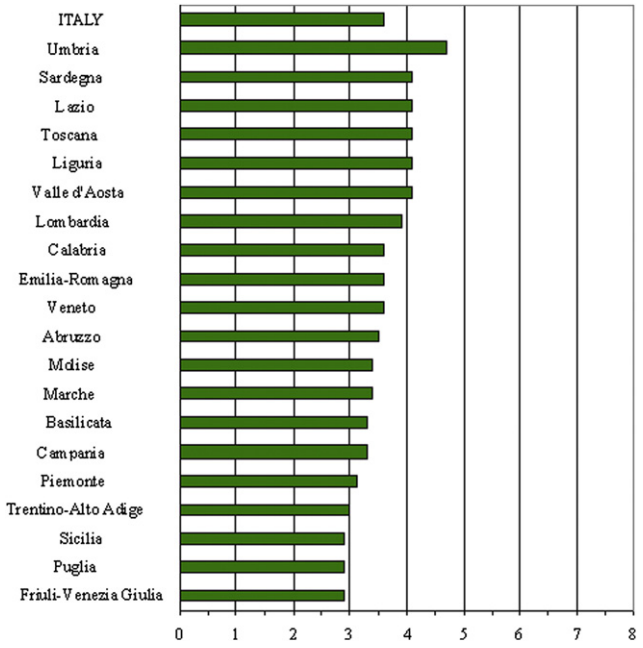

Figure 2 People reporting asthma in Italy, by region - Standardised rates per 100 people — Years 2004—2005 (Source: State of health and use of health services, ISTAT 2008).

Important data on the prevalence of asthma in Italy emerge from the ECRHS study (The European Community Respiratory Health Survey),[18] epidemiologic studies of the Po Delta and Pisa[16] for adults, and the study SIDRIA (Italian studies on respiratory disorders in childhood and the environment, under the international protocol ISAAC) for children.[19–22] The prevalence of asthma in Italy, lower than in many other European countries, ranges from 3.3 to 5.3% in adults and 10% in children. These data place Italy in a low position in the European ranking. The only data on general population samples are derived from surveys conducted by the Institute of Clinical Physiology CNR (Pisa) in the Po Delta and Pisa. These surveys indicate a prevalence of asthma ranging from 5.3 to 6.5%, of chronic bronchitis from 1.5 to 2.5% (chronic sputum from 11.7 to 14.4%), and of emphysema from 1.2 to 3.6%.[13]

A recent population-based cross-sectional epidemiologic survey of asthma and COPD was carried out in an adult representative national sample of 55,500 subjects affected by asthma and 25,762 subjects aged $\geq$14 years with COPD, selected to be representative of the whole Italian population. The asthma/COPD ratio in the general population was 2.16. The odds ratio (OR) of developing asthma decreased with age in both men and women, but in the first age group (15—34 years) it was higher in men (1.69 vs. 1.00) although it became $<$1 from 35 years old and up in men and from 75 years old and up in women. On the contrary, the OR

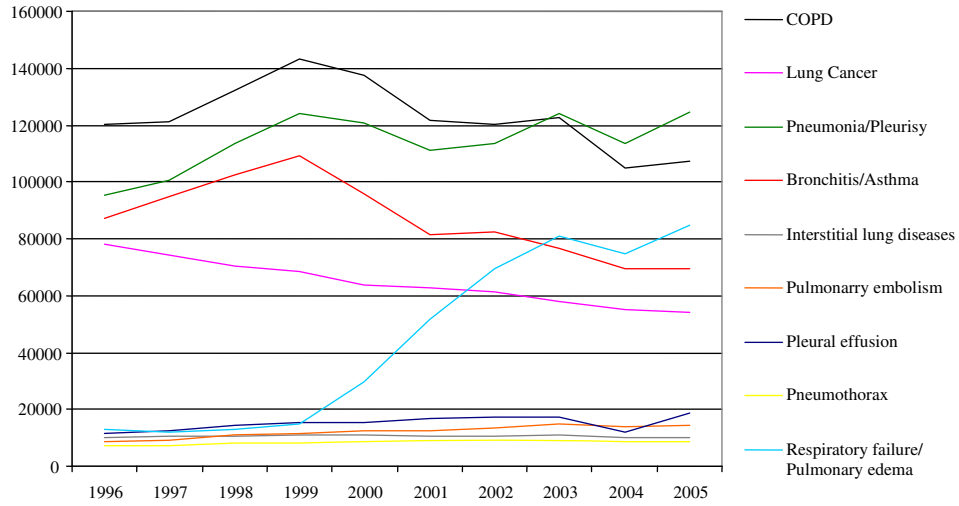

Figure 3 Time trend of hospitalizations (number) for respiratory diseases (Source: Annual report on the activities of hospital-2005, Ministry of Health 2007).

of developing COPD became >1 from 55 years old and up in both men and women and progressively increased with age (in the group 75—84 years it was 6.16 in men and 4.07 in women).[23]

GARD-I

GARD-Italy (GARD-I) was set up in June 2009, under the umbrella of GARD International,[24] with 38 scientific societies and associations as foundation members. This high number represents a peculiarity of the Italian situation, with 3 major scientific respiratory societies (one hospital-based, one academic and one interdisciplinary) which cooperate in preparing statements, guidelines, and carrying out scientific projects. The other entities consist, on one hand, of small societies with a very narrow target (alpha1 antitrypsin deficiency, pediatric pulmonology, respiratory allergic diseases etc.) and, on the other, of many patient associations for specific diseases (only in the case of asthma are they grouped into a large federation). The mission and intent of GARD-I are indicated in the strategy paper prepared by the Ministry of Health in collaboration with the scientific societies and patient associations in the area of respiratory disease. Each member of GARD-I in Italy accepts unreservedly the strategy document and goals of the Alliance expressed in it. The specific objectives are:

- building alliances
- creation of a database for respiratory diseases
- advocacy
- implementation of policies for health promotion and prevention of respiratory disease (intervention on the population)
- implementation of strategies for management of chronic respiratory diseases (intervention on the individual)
- implementation of policies across sectors.

With regards to the Italian context, GARD-I identifies and discusses its actions, strategies and instruments in reference to the issues defined by the National Health Plan, the National Prevention Plan or any other measure of health planning. GARD-I has set up its own rules of procedure, and is divided into a General Assembly and an Executive Committee and also operates through working groups. The Alliance is not financed by the Ministry of Health. Members and experts participate voluntarily in meetings of the Assembly, the Executive Committee and Working Groups. Publications (any form, whether printed, video or electronic) on the activities of GARD-I, including those written by experts or members, must receive authorization from the Ministry of Health before their release. The Ministry of Health is assigned the role of technical leadership and secretariat of GARD-I.

GARD-I represents a real opportunity for developing a comprehensive strategy of prevention and care of respiratory disease adapted to the Italian context. The objectives can be achieved only if fragmentation and lack of coordination can be avoided. Even though the Alliance has just recently been created, it accepts the challenge for a global strategy and a shared vision in the prevention and care of respiratory diseases worldwide.

GARD-I: working groups so far implemented

Prevention of respiratory diseases at school

The prevention, management and control of diseases related to indoor living spaces frequented by children (schools, kindergartens) are priority objectives of the strategy for the environment and health of the European Union. The strategy, also known as "SCALE" (Science, Children, Awareness, Legal instrument, Evaluation), supports the importance of protecting first and foremost children's health from environmental threats. Such an investment is essential to ensure an adequate social and economic development. The strategy's goals are also laid down in the European Plan of Action for the Environment and Health 2004—2010, which was an important contribution to the 4th Intergovernmental Conference on

Environment and Health, organized in Budapest by the WHO European Region.

In 2004—2005 the European study HESE (Health Effects of School Environment) collected comparable information on indoor air quality (IAQ) and on respiratory health of more than 600 pupils from a sample of 21 schools in Europe (Italy, France, Sweden, Denmark and Norway). Samples were obtained using common standardized procedures. The final report (HESE Final Report, 2006) showed that, in general, air quality in schools (46 classrooms tested) is poor, with regard to the measurement of PM_{10} (particulate matter consisting of particles smaller than 10 μm), CO_2, mold and allergens. The analysis showed that effects on respiratory health of children may be attributable to exposure to high levels of PM_{10} and CO_2 in schools. In Italy, children spend from 4 to 8 h a day in school buildings for at least 10 years. The studies conducted so far show that Italian school buildings often have serious sanitation problems due to poor quality of buildings, lack of maintenance and problems related to poor air conditioning (Circular No. 85/2001 of the MIUR - monitoring of safety at school - data 2001). There are not yet official guidelines on air quality in schools. An important initiative in this area is the project "Indoor Air Pollution in Schools" developed by EFA (European Federation of Allergy and Airways Diseases Patients Associations) which receives financial assistance from the European Commission.

Smoke and home environment

Italian households spend nearly all their time (90%) indoors (home, public buildings, shopping centers). Hence the importance of attention to indoor pollution. One of the main sources of indoor pollutants is cigarette smoke.[25] Tobacco smoke is generally divided into: active smoke and passive smoke, with a small difference in the physical-chemical composition and degree of disease risk entailed. It is estimated that non-smokers exposed to passive smoke are actually forced to "smoke" the equivalent of 1—3 cigarettes daily. This implies the risk of disease that, although less than active smoking in terms of individual cumulative exposure, concerns a large portion of the population (65% of non-smokers, i.e. about 20 million people are at risk).[26] Risk, in this case unwanted and preventable, often falls upon people with pre-existing conditions and who are subject to immediate consequences, as in the case of asthmatics, children and pregnant women. Although generally divided into two separate categories in terms of physical-chemical composition, there are other major differences between active and passive smoking. Many are found in the smoke carcinogens (polycyclic hydrocarbons, benzene, nitrosamines), irritants and allergens such as formaldehyde, harmful gases such as carbon monoxide or irritants such as sulfur oxides and nitrogen, in addition to nicotine which is responsible for drug dependence. Like active smoking, passive smoking has also been recently classified as carcinogenic to humans. For both types of risk there is the concept of a dose—response relationship: the greater the amount of exposure, the greater the risk of disease. Indoor cigarette smoke can cause very high concentrations of fine particles, up to 100 times above the legal limits allowed for the external environment. ETS is a true agent of pollution. According to ISTAT (National Institute of Statistics), smoking of parents and other family members strongly influences the behavior of the young.

Training in early diagnosis

The fight against respiratory diseases is carried out primarily through interventions aimed at both primary prevention (e.g. combating smoke and pollutants in the living and work environment) and secondary. Equally important is the information provided to patients and family members, who must be trained to know the characteristics of the disease, to follow the prescribed treatment correctly and to react promptly in the case of exacerbation.

The GP and family pediatrician play a major role in prevention: the context of primary care is the local community and its role is of fundamental importance in the NHS. GPs and pediatricians need to be sensitized, educated and updated on the importance of prevention and early diagnosis in respiratory diseases.

Predictive medicine

CRDs represent a wide range of serious medical conditions in chronic diseases and constitute a serious public health problem, with important effects on patients' quality of life and serious but underestimated economic effects on families, communities, and populations in general. We are all exposed to risk factors for respiratory disease: environmental risk factors (smoking, occupational exposure, indoor and outdoor air pollution, social conditions, diet, infections) and individual risk factors (genetic and family-related) which, interacting with each other, determine the onset of the disease. Prevention of these factors can have a significant impact on morbidity and mortality.

This project aims to introduce predictive medicine into the respiratory area. There are several definitions in the literature of predictive medicine, each emphasizing one or other aspect of the field of investigation. Here, predictive medicine is intended as an individual approach, before and/or after birth, that attempts to discover and evaluate risk factors in probabilistic terms in order to prevent the disease. Predictive medicine is probabilistic, individual and as such allows to determine the risk profile of each person, to monitor progress and implement appropriate preventive measures. Predictive medicine is an approach that requires knowledge and innovation in current patterns of medical thinking.

Continuity of care

In epidemiological terms, the CRDs with the greatest weight include asthma, COPD, occupational respiratory diseases, allergic rhinitis and allergies, sinusitis, sleep apnea syndrome, and pulmonary hypertension. CRDs represent a major part of global disability-adjusted life years (DALYs). Hospital discharge records (HDR) show that in 2004 there were 70,343 hospitalizations for bronchitis and asthma (11.3% of total admissions for respiratory causes), which led to an average stay of 6.5 days. There are no significant differences between males and females in the number of hospitalizations (36,514 males and 38,290 females) or in average number of hospital days (6.2 and 6.8 in males and females).

To improve the continuity of care, models of integrated management need to be developed. Secondly, efforts must

be made to ensure the appropriateness of diagnosis and of the treatment provided. Profiles of nursing care based on a multidisciplinary approach must be developed to ensure a continuity between the actions of prevention, care and rehabilitation, with cross-sectoral interventions embracing both the health and social sectors, in which the family has a key role in the care pathway.

Integration with national programs of the Ministry of Health

The Ministry of Health works in the context of devolution in accordance with the reform of the Constitution (Article V of the 2001 Amendment). The state's role in health today is essentially to guarantee equity and health rights, as enshrined in Article 32 of the Constitution, by:

1. ensuring for all fairness, quality, efficiency and transparency of the system, with proper and adequate communication;
2. highlighting inequalities and inequities and promoting corrective actions and improvements;
3. collaborating with the Regions to assess the reality and improve health;
4. planning innovation and change and confronting the issues that threaten public health.

The National Health Plan (NDP) 2006—2008[27] identified four major diseases: cancer, cardiovascular diseases, diabetes and respiratory diseases. These latter are in our country the 3rd leading cause of death and of these, COPD is responsible for about 50% of deaths, males being most affected. To these epidemiological data it is important to add the significant social costs linked to respiratory disease (e.g. lost productivity for sick leave, absence from school and consequent parental absence from work for child care, etc.). Following the recognition of the impact of respiratory diseases, the NDP has identified the following priority actions:

- cross-sector programs to reduce environmental and occupational risk;
- measures to inform and educate individuals and families on positive behaviors to combat the main causative agents and reduce risk;
- information, communication and promotion of early diagnosis, involving in particular GPs and pediatricians;
- prevention and treatment of disability.

Although there are effective preventive measures, CRDs are underdiagnosed, undertreated and inadequately prevented. The National Plan of Prevention,[28] approved by the State-Regions Agreement, lists the prevention of respiratory diseases as a priority for the years 2010—2012. Among actions already under development, the Ministry recently participated in an advisory role with the National Agency for Regional Health Services (AGENAS) in drafting a Statement on Integrated Clinical Management of COPD prepared by a working group composed of the 3 major respiratory scientific societies (AIMAR, AIPO and SIMeR) and the Italian Society of GPs (SIMG). This document, which aims to offer a practical care model for all healthcare professionals involved in COPD management, was presented at the 2011 ERS Congress in Amsterdam, while the Ministry will coordinate its implementation in Italy.

Conclusions

The WHO has long promoted an integrated approach to prevention and treatment of all chronic diseases. An integrated approach combining the prevention and treatment of CRDs (similar to what has been done for a long time for heart disease, cerebral vascular and other chronic diseases) is necessary as these diseases share many risk factors and call for a similar response from the National health services. This approach is summarized in the recent report of WHO "Preventing chronic diseases: a vital investment"[29] and represents not only the best form of prevention and diagnosis but also the most cost-effective one. GARD-I is an essential step for creating a path to provide Italy with a comprehensive strategy of prevention and assistance, sharing that journey with scientific societies and patient organizations.

Conflict of interest statement

None declared.

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