WORLD HEART FEDERATION®

Secondary cardiovascular disease prevention and control: Focus on Italy

A World Heart Federation report

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Secondary cardiovascular disease prevention and control

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Worldwide, there are about 17 million deaths due to cardiovascular disease (CVD) each year and at least two or three times as many non-fatal events. In Italy, CVD accounted for about 29.5% of premature death in 2010 (measured in terms of 'years of life lost'), with ischaemic heart disease and stroke the first and second most common causes of premature death in the country.[1]

The World Heart Federation has identified secondary prevention of CVD as a public health priority, and as a significant part of a comprehensive strategy to reduce premature mortality, as individuals with established atherosclerotic vascular disease are at very high risk of suffering a new cardiovascular event, which could prove fatal.

The successful implementation of secondary prevention of CVD is key to achieving the World Health Organization's target of a 25 percent reduction in premature mortality from non-communicable diseases (NCDs) by 2025. Successfully addressing secondary CVD prevention will have a major impact on health outcomes and reduce the associated economic burden. Although effective secondary prevention treatments have been available for over two decades and are recommended by the WHO and other professional organisations, there is still a significant gap between evidence and practice.

The World Heart Federation reviewed the global policy framework around NCD and CVD prevention, and specifically around the prevention of secondary CVD. It mapped policy efforts from eight countries (Australia, Brazil, China, France, Germany, Italy, Spain, and the USA), and it identified gaps between publication of guidelines and their adoption and implementation at both the national policy and healthcare provider levels.

This report provides insights from the global World Heart Federation research, and focuses specifically on Italy. It provides a comprehensive picture of the country's CVD burden, as well as of Italy's policy landscape with regard to addressing secondary prevention of CVD, focusing on relevant issues such as governance, financing, access and quality coverage. In doing so, it identifies bottlenecks at the policy level, which are preventing the successful implementation of guidelines for secondary prevention. The report provides useful tools and lessons for policymakers and healthcare professionals that can support the implementation of cost effective cardiovascular secondary prevention.

A better understanding of the reasons for the existing evidence-practice gap is crucial for the design of effective implementation strategies to address those most at risk and to reduce the disproportionate economic burden. The WHO target of 25 percent reduction in premature mortality from non-communicable diseases by 2025 (the '25 by 25' target) cannot be reached unless effective measures are put in place to address those most at risk of premature CVD death.

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1 Global Burden of Disease (GBD) 2010 Profile Italy.

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Champion Advocates Programme journalists' briefing in Italy 2014

The cardiovascular disease (CVD) burden

The number of people dying from Non-communicable diseases (NCDs) – cardiovascular disease, cancer, diabetes, and chronic respiratory diseases – worldwide has grown 30% from 1990 to 2010, due to several factors, including ageing populations and changing patterns of risk factor exposure. About two thirds of global deaths are due to NCDs, with one third of global deaths attributed to cardiovascular disease.[1]

Cardiovascular disease (CVD), including heart disease and stroke, is the world's largest killer and the main driver of NCD deaths. In 2008 there were 17 million CVD deaths, and by 2030 it is estimated that more than 23 million people will die from CVD each year.[2] CVD places a significant burden not only on the individual, but also on healthcare systems and economies. In 2010, CVD cost $863 billion globally and by 2030, CVD costs are projected to rise by 22%, to $1,044 billion.[3]

Italy's CVD burden

Data from the Global Burden of Disease Study 2010 reveal a heavy CVD burden for Italy.

Mortality and morbidity

Heart disease ranks among the most significant causes of premature mortality. CVD accounted for about 29.5% of premature death in 2010 (measured in terms of years of life lost, YLLs).[4]

Ischemic heart disease and stroke were, respectively, the first and second most common causes of premature death in the country. Ischemic heart disease accounted for 14.8% of premature mortality, while stroke accounted for 9% of premature mortality. Hypertensive heart disease was ranked the tenth leading cause of premature mortality, accounting for 2.7% of total premature mortality.[4]

Between 1990 and 2010 the role of CVD in premature deaths diminished, from 32.1% to 19.5%. For ischemic heart disease and stroke, there was a drop in their role in premature death from 1990 to 2010, in terms of absolute numbers of premature deaths and their relative contribution to overall premature death.[4]

During this period, premature death attributed to ischemic heart disease dropped by 26% while that attributed to stroke dropped by 32%. In 2010, ischemic heart disease accounted for the largest burden of disease among all diseases in Italy, as measured by death and disability.[4]

From 1990 to 2010 the burden of disease attributed to ischemic heart disease declined by about 20%. Stroke was the third largest contributor to the disease burden in 2010. The disease burden attributed to stroke experienced a decline of over 20% from 1990 to 2010. Hypertensive heart disease ranked 19th in contribution to overall disease burden in 2010, reflecting an over 20% increase in the diseases burden attributable to hypertensive heart disease from 1990 to 2010.[4]

Risk factors

The leading risk factor in Italy in 2010 was dietary risks, accounting for over 13% of the total disease burden. In addition, a variety of other risk factors linked to CVD were ranked in the top nine leading risk factors for the overall disease burden: high blood pressure, smoking, high body-mass index, physical inactivity, high fasting plasma glucose, high total cholesterol, and harmful use of alcohol. Of these risk factors, high blood pressure and smoking are of particular significance because they each accounted for over 10% of the total disease burden and have strong links to CVD. Other important disease risk factors linked to CVD include high body-mass index and physical inactivity, which were found to contribute to over 8% and 5% of the total disease burden in the country. High total cholesterol, which is strongly linked to CVD, accounted for over 3% of the disease burden.[4]

1 Institute for Health Metrics and Evaluation (IHME) The Global Burden of Diseases, Injuries and Risk Factors Study 2010 (GBD 2010). Generating Evidence, Guiding Policy Report.

2 WHO (World Health Organization). Cardiovascular Diseases, Fact Sheet Number 317, September 2009, WHO, Geneva.

3 World Economic Forum, The Global Economic Burden of Non-communicable diseases, Harvard School of Public Health, 2011.

4 GBD 2010 Profile Italy.

The Emerging Leaders programme convened global talent to discuss CVD issues at a local level

Addressing CVD: The global policy landscape

In September 2011, the United Nations (UN) held a High-Level Meeting of the General Assembly on the Prevention and Control of Non-communicable diseases (NCDs). The meeting, attended by heads of state from across the world, led to the adoption of the Political Declaration on NCDs, which outlines commitments and priorities to strengthen the prevention and control of these collective diseases. As a result of this declaration, the World Health Organization developed an NCD Global Monitoring Framework in consultation with governmental and non-governmental stakeholders to enable global tracking of progress in preventing and controlling NCDs and their key risk factors. The framework aims to provide a foundation for action on the global commitments and drive progress in the prevention and control of NCDs.

Cardiovascular disease (CVD), the biggest driver of NCD deaths, has been afforded unprecedented global political momentum, as part of the worldwide effort to fight NCDs. Secondary prevention, in particular, is seen as a public health priority and a significant part of a comprehensive strategy to reduce premature mortality. Unless prevention strategies targeting individuals with the highest risk of dying in the next ten years, i.e. those with underlying cardiovascular disease, are successfully implemented, the World Health Organization's target of 25 percent reduction in premature mortality from NCDs by 2025 is unlikely to be achieved. This could have an unprecedented impact in terms of number of lives lost and economic implications.

Although effective secondary prevention treatments have been available for over two decades and are recommended by the WHO and other professional organisations, there is still a significant gap between evidence and practice. Systematic approaches are needed to improve the implementation of cost effective interventions and their long-term use. Tailored implementation strategies are also needed, addressing constraints and barriers at the local level. Actions to improve secondary cardiovascular disease prevention must focus on healthcare systems, the community in which a health system is embedded, and the policy environment that surrounds it.

Figure 1 Global NCDs Targets

Source: Adapted from WHO Global NCDs Monitoring Framework

The NCD Global Monitoring Framework includes targets with clear implications for the secondary prevention of CVD, specifically:

- **An overall target on the 25% relative reduction in risk of premature mortality caused by the main NCDs, including cardiovascular disease**
- **A target to ensure at least 50% of eligible people receive drug therapy and counselling to prevent heart attacks and strokes**
- **A target on 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major NCDs in both public and private facilities.**

The NCD Global Monitoring Framework allows for global monitoring on progress against NCDs – and CVD by consequence – with WHO Member States expected to report back at regular intervals. Member States are also encouraged to develop national targets and indicators building on the global framework. Actions on secondary CVD prevention will be key in achieving the targets outlined to the left.

Addressing CVD: The global policy landscape

The WHO also established an Action Plan on NCDs, providing crucial global policy for CVD, including policy options relevant to secondary CVD prevention. These are captured in Table 1 below:

Table 1 The WHO 2013-2020 Global Action Plan and policy options relevant to secondary CVD prevention.

Objectives	Policy options
WHO 2013-2020 Global NCDs Action Plan	**WHO 2013-2020 Global NCDs Action Plan**
Objective 2: To strengthen national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of NCDs.	Selected policy options relevant to secondary CVD prevention **Leadership** ● **Strengthen programmes for the prevention and control of NCDs** ● **Develop National NCDs Plan and allocate budget.**
Objective 4: To strengthen and orient health systems to address the prevention and control of NCDs and the underlying social determinants through people-centred primary healthcare and universal health coverage.	**Financing** ● **Progress towards universal health coverage through financing of cost effective interventions at different levels of care** ● **Shift from reliance on user fees levied on ill people.** **Expanded Quality Services Coverage** ● **Improve the efficiency of service delivery and set national targets consistent with voluntary global targets for increasing the coverage of cost-effective, high-impact interventions to address CVD and other NCDs, including drug therapy and counselling to individuals who have had a heart attack or stroke.** **Access** ● **Access to comprehensive and cost-effective prevention, treatment and care for the integrated management of NCDs, including increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies** ● **Relevant medicines included in country's essential medicines list.**

Addressing CVD: Policies and practice in Italy

To assess governments' national progress in secondary prevention of CVD, the World Heart Federation mapped government policies and action in the key areas relevant to secondary CVD prevention recommended by the WHO 2013-2020 Global Action Plan on NCDs. The areas examined cover:

- **National capacity: acceleration of country response for the prevention and control of NCDs, as evidenced by national CVD plans, national NCD plans, legislation**
- **Financing: progress towards universal health coverage through financing of cost effective interventions at different levels of care; decrease reliance on user fees**
- **Expanded quality services coverage: improved efficiency of service delivery and coverage of cost effective high-impact interventions - such as drug therapy and counselling for those who have had a heart attack or stroke; set national targets consistent with global targets**
- **Access: to affordable, safe and effective and quality medicines, relevant medicines included in country's essential medicines list.**

The policy options set out by the WHO in consultation with Member States and agreed at the World Health Assembly 2013 provide a roadmap for government policy and action on secondary CVD prevention. This section provides a snapshot of how Italy is addressing the WHO recommendations, outlining national policies and actions adopted in the country.

Addressing CVD: Policies and practice in Italy

National Capacity (National CVD Plans, National NCDs Plans, Legislation)

According to data from the European Heart Network, Italy's mortality rate from coronary heart disease (CHD) and stroke are among the lowest in Europe for both men and women.[1] The OECD reports that in 2011, life expectancy at birth in Italy was 82.7 years, more than two years greater than the OECD average (80.1 years), with only Switzerland registering a higher life expectancy.[2] Nonetheless, CVD is the main cause of death and hospitalisation in Italy and, as such, has been identified as a priority health concern by the government. Among the adult population (35-74 years) 12% of all deaths are due to ischaemic heart disease, and 8% to acute myocardial infarction, although since the mid-1970s, the mortality rate due to CVD has been declining.[3]

The most recent National Health and Prevention Plan includes multiple interventions for tackling the most important risk factors for NCDs, in accordance with the integrated approach proposed by the World Health Organization. Together with other European countries, Italy follows a common strategy for NCDs control and in 2007 adopted a programme called Guadagnare Salute (Gaining Health).[4] The National Prevention Plan (2005-2007)[5] identifies four main areas of action: prevention of CVD (including prevention of complications of diabetes and obesity); cancer screening; immunisation; and prevention of accidents. For CVD, the Plan specifies prevention activities related to reducing CVD risk and events. In the first phase of implementation, each region committed to organising a 'CVD Commission' to guide prevention programming and was given autonomy to develop its own prevention plans. As a result, the activities endorsed by the Commission varied significantly and lacked central coordination and oversight. The second phase of implementation called for the further involvement of the healthcare sector beyond the regional level.[2]

The Centre for Disease Prevention and Control

In 2004, the Ministry of Health (MoH) established the Centro nazionale per la prevenzione e il controllo delle malattie (CCM) (Centre for Disease Prevention and Control),[6] with the objective of active prevention through the promotion of healthy lifestyles and screening.[7]

The CCM acts as a coordinating centre to build collaborative networks, to conduct special projects and to develop public health monitoring and surveillance systems. The goal of the CCM is to create synergies through the identification and dissemination of best practices, and to promote cross-regional sharing of objectives and tools.[8]

Both the MoH and the CCM play critical roles in facilitating and monitoring the roll out of the National Prevention Plan at the regional level (e.g. through hosting training courses, maintaining a website for project management). A special Agreement between the National and the Regional Government ('Intesa Stato-Regioni 23 Marzo 2005') designated the CCM directly accountable for monitoring and evaluating the results of the Plan. According to the Italian Ministry of Labour, Health and Social Policy, the cooperation between the CCM and Regions in the implementation of the Plan was 'a milestone in National planning that has involved for the first time Regions and Autonomous Provinces, through the exact definition and monitoring of their programmes, in the evaluation of the subsequent activity carried out in the field of prevention.'[9] The year 2008 was designated a transition period to review both the objectives and management procedures of the Plan.[2] As a part of this process, the CCM developed a tool, the 'Project Advancement Index' (IAP), to measure the progress of each project in the Plan. An IAP defined as 'CVD relapse' was developed under the area of 'CVD risk prevention' to measure the progress of secondary prevention.[8]

A European Heart Network survey of 16 countries in Europe indicated that Italy was one of 7 countries reporting 5 or more national policies in relation to cardiovascular health promotion and/or cardiovascular disease prevention, coronary heart disease, hypertension, stroke and hyperlipidaemia.[9] According to the 2008 Euro Consumer Heart Index, which measures the performance of European countries on differing aspects of delivery of cardiovascular care,[10] the Italian healthcare system was deemed 'competent' in terms of its CVD-related policies and programmes, along with Austria (769 points), Netherlands (761), and Sweden, Slovenia, U.K., Finland, Denmark (all above 700 points).[10]

There are currently no national plans for secondary prevention of CVD in Italy. Secondary prevention is often integrated into routine care at the discretion of the GP, with only a minority of post-myocardial infarction and post-revascularisation patients receiving cardiac rehabilitation services.[11] While there are no significant reimbursement problems for rehabilitation after an acute or chronic cardiac event, there is a disparity between the potential number of participating patients and the availability of cardiac rehabilitation units. A 2008 survey[12] by the Italian Association for Cardiovascular Prevention, Rehabilitation and Epidemiology (IACPR-GICR) described compromised access to cardiac rehabilitation units.

The National Plan for Clinical Guidelines

The National Plan for Clinical Guidelines (2008) has been implemented in recent years and has produced guidelines on topics such as cardiology and cancer prevention,[7] including a specific Guideline for Secondary Prevention and Cardiac Rehabilitation (Linee guida nazionali su cardiologia riabilitativa e prevenzione secondaria delle malattie cardiovascolari).[13] While these national guidelines on secondary prevention were strongly endorsed by the Italian Servizio Sanitario Nazionale (SSN) within the context of the National Plan for Clinical Guidelines, they have not been fully adopted by the medical community. The European Society of Cardiology (ESC) Guidelines on cardiovascular disease prevention in clinical practice (version 2012)[14] are used as the basis for reimbursement policies and have been widely adopted by physicians who utilise electronic or web-based tools in clinical practice. Italian cardiologists, however, have not officially endorsed the ESC guidelines, perhaps due to the fact that there are several competing cardiology societies (e.g. Italian Association of Hospital Cardiologists (ANMCO), Italian Society of Cardiologists (SIC), Regional Association for Ambulatory Cardiologists (ARCA), and Italian Society of Cardiologists of Accredited Hospitals (SICOA)), potentially limiting their uniform adoption.[15]

In October 2013, a consensus conference on clinical management after acute coronary syndrome (ACS)[11] was held in Naples, under the auspices of two Italian scientific societies, the Italian Association for Cardiac Prevention and Rehabilitation (GICR-IACPR) and the Italian Association of Hospital Cardiologists (ANMCO), to propose a network dedicated to the management of secondary prevention. This ambitious programme for pharmacological implementation and long-term maintenance of recommended therapies is still under construction. The network will feature drug therapy targets and strategies to improve adherence and promote lifestyle changes.[11]

1 http://www.ehnheart.org/projects/euroheart/wp-5-country-summary-reports.html, European Heart Network, accessed on March 20, 2014.

2 OECD Health Data 2013: How Does Italy Compare http://www.oecd.org/els/health-systems/Briefing-Note-ITALY-2013.pdf, accessed on March 23, 2014.

3 http://www.cuore.iss.it/eng/other/cuore.asp, accessed on March 25, 2014.

4 http://www.cdc.gov/pcd/issues/2011/jan/10_0030.htm, accessed on March 25, 2014. Features and Initial Assessment of the Italian Behavioral Risk Factor Surveillance System (PASSI), 2007-2008.

5 http://www.epicentro.iss.it/focus/piano_prevenzione/indice_prevenzione.asp, accessed on March 21, 2014.

6 http://www.ccm-network.it, accessed on March 21, 2014.

7 The Commonwealth Fund, International Profiles of Health Care Systems, 2013 (November 2013) http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2013/Nov/1717_Thomson_intl_profiles_hlt_care_sys_2013_v2.pdf, accessed on March 23, 2014.

8 Greco D and the CCM Project Management Group, Palumbo F, Arcangeli L, Di Martino MP, La Falce M, Carinci F, Romagnoli C and the DVSS Collaborators, 'Stewardship and governance in decentralized health systems: an Italian Case Study,' Italian Ministry of Labour, Health and Social Policy, Rome, 2008.

9 EuroHeart work package 5: National plans, policies and measures impacting on cardiovascular health promotion and cardiovascular disease prevention. Cardiovascular disease prevention in Europe – the unfinished agenda. September 2009.

10 http://www.healthpowerhouse.com/files/euro-heart-index-2008.pdf, accessed on March 29, 2014. Health Consumer Powerhouse Euro Consumer Heart Index 2008 Report.

11 G Ital Cardiol 2014;15(1 Suppl 1):3S-27S, Documento ANMCO/GICR-IACPR/GISE L'organizzazione dell'assistenza nella fase post-acuta delle sindromi coronariche.

12 Tramarin R, Ambrosetti M, De Feo S, Piepoli M, Riccio C, Griffo R; ISYDE-208 Investigators of the Italian Association for Cardiovascular Prevention, Rehabilitation and Prevention. The Italian Survey on Cardiac Rehabilitation-2008 (ISYDE-2008). Part 3. National availability and organization of cardiac rehabilitation facilities. Official report of the Italian Association for Cardiovascular Prevention, Rehabilitation and Epidemiology (IACPR-GICR). Monaldi Arch Chest Dis. 2008 Dec;70(4):175-205. Erratum in: Monaldi Arch Chest Dis. 2009 Mar;72(1):43. PubMed PMID: 19263795. http://www.ncbi.nlm.nih.gov/pubmed/19263795, accessed on March 25, 2014.

13 http://www.snlg-iss.it/, accessed on March 24, 2014.

14 http://www.escardio.org/communities/EACPR/prevention-in-your-country/Documents/germany-country-report.pdf, accessed on March 28, 2014.

15 Personal communication with Dr. Pompilio Faggiano, Cattedra di Cardiologia, Università di Brescia e Divisione di Cardiologia, Ospedali Civili di Brescia, Divisione di Cardiologia, Azienda Ospedaliera Santa Maria degli Angeli di Pordenone, Divisione di Cardiochirurgia, Ospedali Civili di Brescia.

Addressing CVD: Policies and practice in Italy

Launched in 1998, the Progetto Cuore (epidemiology and prevention of ischaemic heart diseases), is financed by 1% of the national health fund and is coordinated by the Istituto Superiore di Sanità (National Institute of Health). Its mandate is to estimate the impact of CVD through indicators (prevalence, incidence and mortality rates) and evaluate the distribution of CVD risk factors and CVD risk in representative samples of the population by collecting data on the distribution of risk factors and the frequency of CVD in middle-aged men and women. Progretto Cuore has developed and implemented a National Registry of CVD events,[3] which is a surveillance system designed to monitor both fatal and non-fatal CVD events in the general population aged 35-74 years, in eight geographically strategic and representative areas of the country: Brianza, Caltanissetta, Florence, Friuli-Venezia Giulia, Modena, Naples, Rome and Veneto. The project is built on the WHO-MONICA Project (Friuli, Brianza, Latina), the Osservatorio Epidemiologico Cardiovascolare and the Brisighella Heart Study (started in 1972 as a longitudinal study on atherosclerosis risk factors).[16] The Registry provides reliable estimates of the incidence, attack and fatality rates of coronary and cerebrovascular events; moreover, it shows how often diagnostic and therapeutic procedures are used in the acute and postacute phases in the North, Centre, South and Islands. Methodologically, data collection is achieved using two sources of information: death certificates (ISTAT) and hospital discharge records (HDR).[3]

Financing

According to OECD estimates (2011), total health spending accounted for 9.2% of GDP, slightly below the OECD average (9.3%). In terms of health spending per capita, Italy ranks below the OECD average, with spending of $3,012 USD in 2011, compared to the OECD average of $3,339 USD. Between 2000 and 2009, in real terms, health spending grew by an average of 2.2% per year; in 2010, this growth rate slowed down slightly to 1.8% and dropped by -1.6% in 2011. In 2011, 77.8% of national health spending was funded by public sources (above the average of 72.2% in OECD countries).[2] In 2011, approximately 18% of total health spending was paid out of pocket, mainly for drugs not covered by the public system (over-the-counter drugs) and for dental care.[7]

Created in 1978, the Italian Servizio Sanitario Nazionale (SSN), the publicly financed healthcare service modelled after the British National Health Service, provides all citizens and legal foreign residents with automatic and universal coverage. Voluntary private health insurance (PHI) complements and supplements the public scheme, but plays a limited role in the health system, accounting for roughly 1% of total health spending in 2009. The central government controls the distribution of tax revenue to support the SSN and defines the 'essential levels of care' (LEAs), which is the national legal minimum benefits package offered to all residents in every region. The SSN offers free primary and in-patient care at the point of use. The government determines a 'positive' list of services to be offered through the SSN (e.g. pharmaceuticals, in-patient care, preventive medicine, ambulatory care, home care, primary care) and a 'negative' list of services that are not offered to patients (e.g. cosmetic surgery) or services that are covered only on a case-by-case basis (e.g. laser eye surgery).[7]

The 19 regions and two autonomous provinces have responsibility for delivering health services through local health units (LHUs). The regions have considerable autonomy, and are responsible for achieving health targets established by national and regional planning. Each region determines its own schedule of payment rates for hospital and outpatient care, with national rates (determined by the MoH) as a reference. Regions may offer non-LEA services, but must finance them themselves. The National Drug Agency (Agenzia Italiana del Farmaco), founded in 2003 and accountable to the MoH and the Ministry of Economy and Finance, sets the reference price for drugs.[7]

The coverage of CVD-related costs falls under the jurisdiction of each Regional Administration. Hospital admissions (including device implantation and surgery), drugs, follow-up visits and follow-up examinations are free of charge for all patients under the SSN. There are no specific mechanisms for the financing of secondary CVD prevention within Italy and there is no available data on the actual costs of secondary prevention. However, it is estimated over a ten year horizon, a total cost related to diagnosed and treated hypertensive patients would be €6.4 billion (CI 95 %: €5.5–7.2 billion).[17]

In August 2012, the national parliament passed a law aimed at cost containment. The law promoted the prescription of generic drugs, cuts to the hospital bed ratio and reduced the public financing of the SSN by €900 million in 2012, €1.8 billion in 2013, €2 billion in 2014, and €2.1 billion in 2015.[7] Under the new health contract cost containment reforms for 2014-2018, the availability of in-hospital beds will be reduced to 0.5 per 1,000 population for rehabilitation. This reduction is slightly offset by the fact that nearly 180 cardiac rehabilitation centers already exist within the country and are covered by the SSN.[11] The 2012 reforms also reorganised healthcare at the regional level by: introducing primary health teams; updating healthcare tariffs; restructuring governance of hospitals and LHUs; revising the list of reimbursable pharmaceuticals; and renegotiating the price of less effective medicines.[7]

The government has long been concerned about inter-regional inequity in public healthcare provision and variations in fiscal capacity. The National Health Plan for 2006–2008[18] named overcoming large regional discrepancies in access and quality as a key objective. In terms of capacity for secondary prevention of CVD, the less affluent southern regions lag behind the northern regions in the number of beds and availability of advanced medical equipment, and have less-developed community care services. There are also considerable interregional variables in the prospective payment system for hospitals, such as how the fees are set, which services are excluded, and coding and classification systems. The Ministry of Health and the Ministry of Economics and Finance signed an agreement in April 2007 to direct EU resources toward health services in eight regions in the south, as a first step in addressing the variation. Regions receive a proportion of funding from an equalisation fund (the National Solidarity Fund), which seeks to reduce inequalities between regions.[7]

2 OECD Health Data 2013: How Does Italy Compare http://www.oecd.org/els/health-systems/Briefing-Note-ITALY-2013.pdf, accessed on March 23, 2014.

3 http://www.cuore.iss.it/eng/other/cuore.asp, accessed on March 25, 2014.

7 The Commonwealth Fund, International Profiles of Health Care Systems, 2013 (November 2013) http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2013/Nov/1717_Thomson_intl_profiles_hlt_care_sys_2013_v2.pdf, accessed on March 23, 2014.

11 G Ital Cardiol 2014;15(1 Suppl 1):3S-27S, Documento ANMCO/GICR-IACPR/GISE L'organizzazione dell'assistenza nella fase post-acuta delle sindromi coronariche.

16 EuroHeart work package No 5: National plans, policies and measures impacting on cardiovascular health promotion and cardiovascular disease prevention: Country Summary: Italy.

17 Mennini FS et al. Cost of poor adherence to anti-hypertensive therapy in five European countries. Eur J Health Econ DOI 10.1007/s10198-013-0554-4.

18 http://www.salute.gov.it/imgs/C_17_pubblicazioni_655_allegato.pdf, accessed on March 23, 2014.

Addressing CVD: Policies and practice in Italy

Expanded Quality Services Coverage

As the result of modifications to the National Constitution in the late 1990s, the regions maintain responsibility for developing their own local health policies, including those related to secondary prevention of CVD. At the same time, nearly all preventive, diagnostic and rehabilitative interventions are covered by the SSN and out-of-pocket costs for patients are generally limited to cost contributions for middle and high-income individuals. However, not all aspects of secondary prevention of CVD are covered as LEAs under the SSN (e.g. preventive physical activity). Researchers highlight the benefits of a comprehensive approach to reducing total cardiovascular risk through smoking cessation, diet, and physical activity, and supplemented with control of blood pressure, lipids and glucose, and the use of cardioprotective drug therapies. Despite strong evidence that secondary prevention reduces hospital re-admission rates and death rates,[19] researchers have underscored the poor utilisation of effective preventive drug treatments, cardiac rehabilitation and adherence to lifestyle recommendations as a major challenge to the provision of secondary prevention within the country.

A five-country study found Italy, along with France and Spain, to have low levels of adherence to anti-hypertensive treatment.[17] Secondary prevention drugs are generally prescribed by physicians at hospital discharge or by general practitioners (GPs) at follow-up visits, but long-term adherence to therapy and follow-up tends to be poor and can include a variety of factors (such as socio-economic status, patient beliefs and lifestyle, health-literacy) and their interaction with the healthcare system.[17]

Data from the EUROASPIRE surveys[20] demonstrates a substantial gap between the standards set in the CVD prevention guidelines and clinical practice. These surveys show that lifestyle trends in patients with CVD in Europe are a growing cause for concern.[19] In Italy, the GOSPEL Study, a randomised trial performed in 78 Italian cardiac rehabilitation centers testing the efficacy of educational and behavioral intervention verses. usual care after MI, demonstrated that a multifactorial, continued reinforced intervention up to 3 years after rehabilitation following MI is effective in decreasing the risk of several important CVD outcomes.[21]

Within the context of secondary prevention of CVD, the Guideline for Secondary Prevention and Cardiac Rehabilitation *(Linee guida nazionali su cardiologia riabilitativa e prevenzione secondaria delle malattie cardiovascolari)*[13] recommends the implementation of cardiac rehabilitation units to address the high rates of CVD-related disability. At the same time, the European Society of Cardiology Guidelines[22] recommend that CVD prevention be considered as a continuum, with less of a differentiation between 'primary' and 'secondary' prevention.[23]

Clinical guidelines for Italy

The Italian Society of Cardiology has endorsed the European Guidelines on cardiovascular disease prevention.[24]

19 Dialogues in Cardiovascular Medicine - Vol 14 . No. 2 . 2009. http://www.dialogues-cvm.com/document/DCVM52.pdf, accessed on March 25, 2014.

20 Kotseva K, Wood D, De Backer G, De Bacquer D, Pyorala K, Keil U. Cardiovas- cular prevention guidelines in daily practice: a comparison of EUROASPIRE I, II, and III surveys in eight European countries. Lancet 2009;373:929–940.

21 http://archinte.jamanetwork.com/article.aspx?articleid=414622, accessed on March 23, 2014. Arch Intern Med. 2008;168(20):2194-2204. doi:10.1001/archinte.168.20.2194. Global Secondary Prevention Strategies to Limit Event Recurrence After Myocardial Infarction. Results of the GOSPEL Study, a Multicenter, Randomized Controlled Trial From the Italian Cardiac Rehabilitation Network.

22 http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-CVD-prevention.pdf, accessed on March 25, 2014.

Access

According to 2009 EU data, Italy spent an estimated 10% of total healthcare expenditure on CVD, with an estimated €5,148,000 spent on CVD medications.[25] Over time, the use of secondary CVD prevention medications, including lipid-lowering drugs and statins, have increased significantly. In terms of reported use of medication upon discharge of hospital patients with established CHD, data from the EUROASPIRE surveys shows an increase over three time periods (1995-96, 1999-2000 and 2006-07) as follows in Italy: anti-platelet therapy (from 86-98%); beta-blockers (from 49-88%); ACE-inhibitors and AT2-antagonists (from 32-71%); lipid-lowering drugs (from 25-91%); and statins (from 7-90%).[25] In terms of national targets and monitoring for secondary prevention, the prescription of drugs affecting lipid metabolism is linked to the individual risk, measured by a national score *(Progetto Cuore)*.[9]

For some classes of drugs, therapeutic plans are mandated, and prescriptions must follow clinical guidelines.[7] Differing reimbursement policies (those applying to both GPs and cardiologists and those applying to cardiologists only) may affect the availability of certain secondary CVD prevention drugs, limiting their prescription to specific conditions (e.g. an Italian Drug Agency Therapeutic Plan, which applies to cardiologists only, sets the reimbursement policy for statins for patients with hypercholesterolemia after ACS). According to the National Drug Agency classifications, which are derived largely from European Society of Cardiology (ESC) Guidelines, cardio-protective drugs in primary prevention are reimbursable, with no significant barriers to access of secondary prevention drugs.[26]

Drugs used for secondary CVD prevention are identified on the basis of scientific evidence and based on international and national guidelines recommendations. Most drugs approved are available both as generic and as branded. Health authorities at regional and local level recommend the use of less costly drugs when similar efficacy and safety have been demonstrated. To date, there are several drugs of potential interest for secondary prevention (e.g., ranolazine, eplerenone, and ticagrelor) that have been approved by the Italian Drug Agency and covered by the SSN, but they are subject to stricter controls via a web-based monitoring system to monitor indications, efficacy and safety (i.e. they generally can only be prescribed by a cardiologist). A similar approach is used for certain drugs approved for pulmonary hypertension (e.g. Bosentan, Sildenafil, Epoprosentol).[26]

23 http://eurheartj.oxfordjournals.org/content/28/19/2375.full.pdf, accessed on March 28, 2014. European Heart Journal (2007) 28, 2375–2414 doi:10.1093/eurheartj/ehm316, page 2378.

24 European Guidelines on cardiovascular disease prevention in clinical practice. European Heart Journal (2012) 33, 1635–1701.

25 Nichols M, Townsend N, Luengo-Fernandez R, Leal J, Gray A, Scarborough P, Rayner M (2012). European Cardiovascular Disease Statistics 2012. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis.

26 Personal communication with Dr. Pompilio Faggiano, Cattedra di Cardiologia, Università di Brescia e Divisione di Cardiologia, Ospedali Civili di Brescia, Divisione di Cardiologia, Azienda Ospedaliera Santa Maria degli Angeli di Pordenone, Divisione di Cardiochirurgia, Ospedali Civili di Brescia.

Making the facts available to healthcare professionals and media

National barriers in the secondary prevention of cardiovascular disease

The World Heart Federation has identified barriers in the secondary prevention of cardiovascular disease (CVD) in Italy, as a result of mapping government action and policy against policy options set by the WHO NCD 2013-2020 Global Action Plan. These barriers help provide a starting point for national advocacy efforts aimed at improving the secondary prevention of CVD, reducing the country's burden.

Lack of a comprehensive national CVD action plan with targets for secondary prevention of CVD

Italy lacks specific time bound targets for CVD mortality reduction and for drug therapy related to secondary prevention of CVD, as recommended by the WHO in the NCDs Global Monitoring Framework. Other disease groups, such as cancer, have received governmental attention and dedicated resources through the institution of national rather than regional commissions. For example, the National Health Plan for 1994–1996 led to the establishment of the National Oncology Commission; it was tasked with developing an intervention programme to monitor and prevent cancer. Screening guidelines were then produced with the aim of reducing the heterogeneity of interventions and enhancing evidence-based programme planning.[1] For CVD, on the other hand, only regional level Commissions have been established (e.g. the Lombardy Regional CVD Commission, charged with developing programmes for the post-acute and chronic periods). Government targets in the area of CVD prevention and control, including secondary prevention, would help drive action, improve service delivery, monitor country progress and address north-south regional disparities in service delivery and access to secondary prevention throughout the country.

Evidence-practice gap: Under-utilisation of secondary CVD services

Over the past decade, a series of scientific meetings, conferences and campaigns have been dedicated to increasing adherence to CVD treatment in Italy (e.g. the 2013 consensus conference on clinical management after acute coronary syndrome (ACS)),[2] with the aims of increasing awareness, improving the attainment of targets (pharmacological and non-pharmacological) and improving outcomes. Despite this, recent data on drug adherence, smoking cessation, weight control and physical inactivity suggest that uptake remains inadequate. As a consequence, despite a relative reduction of acute phase MI mortality, researchers report little improvement in hospital readmission and mortality rates from 30 days to one year after ACS.[2] This disconnect points to the clinical and economic importance of improving adherence at the national level. Advocates recommend actions to increase patient adherence to anti-hypertensive therapies, such as psychological support to enhance patients' motivation, patient reminders, and the use of fixed dose combination therapies to decrease pill burden.[3] Some advocates recommend the development of a post-ACS network. This would allow the coordination of health professionals (e.g. cardiologists, general practitioners, nurses, other health personnel devoted to risk factor control) working in cardiac rehabilitation units, acute phase hospitals, and out of hospital services to promote drug adherence and lifestyle interventions.

1 The Commonwealth Fund, International Profiles of Health Care Systems, 2013 (November 2013) http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2013/Nov/1717_Thomson_intl_profiles_hlt_care_sys_2013_v2.pdf, accessed on March 23, 2014.

2 G Ital Cardiol 2014;15(1 Suppl 1):3S-27S, Documento ANMCO/GICR-IACPR/GISE L'organizzazione dell'assistenza nella fase post-acuta delle sindromi coronariche.

3 Mennini FS et al. Cost of poor adherence to anti-hypertensive therapy in five European countries. Eur J Health Econ DOI 10.1007/s10198-013-0554-4.

National barriers in the secondary prevention of cardiovascular disease

Inconsistency in service delivery/secondary prevention services by region/lack of national coherence

Many researchers and policymakers note that addressing the inequities in health access and status by region, particularly as it relates to the provision of secondary prevention of CVD, is a key priority. Some regions are more advanced than others in the development, implementation and financing of secondary CVD prevention strategies. For example, in the Lombardy Region during the period 2005-2010, the CVD Commission organised the ST-elevation myocardial infarction (STEMI) network[4] (based on the hub and spoke concept) with the active involvement of general cardiologists, cardiac rehabilitation cardiologists and general practitioners. The federal government could promote and facilitate the adoption by the other regions of the Lombardy model of an integrated network to deliver secondary prevention of CVD services.

Italy is not the only country facing these types of barriers. The World Heart Federation's research revealed there are many commonalities in the challenges countries face in terms of the secondary prevention of CVD. Barriers include a lack of a long-term comprehensive national CVD strategy; lack of national secondary CVD prevention targets; financial constraints; lack of stated national policy; lack of consistency and adherence to national policy; and lack of monitoring systems with data linkages to track patients. It is essential for countries to overcome these barriers, in order to effectively address those most at risk of premature CVD death, and to achieve the '25 by 25' target.

4 Marzegalli M et al. G Ital Cardiol (Rome). 2008 Oct;9(10 Suppl 1):56S-62S.[Cardiological emergency network in Lombardy].

Barriers to healthcare provider uptake of guidelines

In addition to examining national policies for the secondary prevention of cardiovascular disease (CVD), the World Heart Federation conducted research among healthcare professionals to understand physicians' knowledge, attitudes and practices in relation to secondary prevention guidelines.

Results from an on-line survey and in-depth interviews revealed a number of barriers at the healthcare professional level, which prevent the optimum uptake of guidelines – even when relevant national policies are in place. Doctors reported feeling overwhelmed by the number of guidelines available. They perceive guidelines as lengthy, complex, too prescriptive, and too frequently updated, making it difficult for them to keep up-to-date with the latest recommendations.

Although physicians in general recognise the importance of clinical guidelines, they feel their usefulness is limited, as they can't always be applied to all patients or be easily adapted to specific settings. Some doctors also expressed concerns about the involvement of the pharmaceutical industry in the development of guidelines, perceiving the industry as having undue influence. Younger healthcare providers were reported as more likely to implement guidelines, potentially as a result of being more comfortable with a culture of evidence-based practice.

Improving the uptake of clinical guidelines

With regard to possible strategies to improve the uptake of clinical guidelines, physicians participating in this research suggested simplifying and unifying existing guidelines, and using technology to make them more easily available.

The World Heart Federation also reviewed existing literature on strategies to increase the uptake of guidelines. Strategies identified include influence by local opinion leaders; auditing and providing feedback on individual healthcare professionals' practice or performance; the use of computerised clinical decision support systems for the management of chronic conditions; financial incentives; continuing medical education and educational outreach.

Champion Advocates Programme journalists' briefing in Italy 2014

Section 6

Conclusion and recommendations

There is a clear need for a comprehensive approach to improve the prevention of secondary cardiovascular disease (CVD) in order to achieve the '25 by 25' mortality reduction target. The time for the cardiovascular community to act globally in a coordinated way is now. The World Heart Federation is leading the development of a practical and comprehensive roadmap, addressing policy and health system barriers and proposing implementation strategies that could be adapted accordingly to the setting.

The World Heart Federation's research into Italy's policy landscape provides a starting point for national advocacy efforts aimed at improving the secondary prevention of CVD, reducing the country's burden. The research highlighted that while Italy has identified CVD as a priority health concern, there are still steps for the country to take to improve the secondary prevention of CVD.

Italy currently lacks time bound targets for CVD mortality reduction and for drug therapy related to secondary prevention of CVD. In addition, while a number of secondary CVD services are in place, their uptake remains inadequate. There are also inequities in health access and status by region – however, the federal government could promote and facilitate the adoption of effective models pioneered by some regions, e.g. the Lombardy model of an integrated network to deliver secondary prevention of CVD services, by other regions.

The World Heart Federation has developed a checklist of actions for all relevant stakeholders in the secondary prevention of cardiovascular disease, and is calling on individuals, organisations, and governments to review these and adopt the calls to action that are relevant to their country.

The World Heart Federation calls on national policymakers to:

- **Ensure their countries have a formal comprehensive national CVD plan, appropriately prioritising secondary prevention, and that the plan includes concrete time-bound targets, accompanied by adequate funding**
- **Monitor the uptake of guidelines to ensure effective preventive drug treatments and cardiac rehabilitation are being offered**
- **Identify, highlight, and address any financial constraints preventing the implementation of guidelines that impact on patient health outcomes**
- **Ensure equitable access to healthcare and to CVD-specific services across a country's entire population.**

The World Heart Federation calls on professional organisations and societies responsible for the development of guidelines in secondary prevention to:

- **Prepare guidelines that are concise, clear, and tailored to the context of the country they are addressing. Where a number of relevant guidelines already exist, unify them to ensure clarity.**
- **Provide healthcare professionals at the primary and secondary care levels with effective training packages on how to implement guidelines, and with support on how to best coordinate communication between them for the care of patients with cardiovascular disease, and/or with other co-existing conditions**
- **Consider the potentially helpful role of technology in training or in supporting clinical decision-making (e.g. via computerised, shareable patient records)**
- **Identify, highlight, and address any financial constraints preventing the implementation of guidelines at both primary and secondary care levels**
- **Explore and promote the most suitable evidence-based strategies to promote healthcare professional uptake of guidelines.**

Conclusion and recommendations

The World Heart Federation calls on individual healthcare professionals to:

- **Improve coordination between primary and secondary care, to ensure healthcare professionals at both levels can have a holistic view of a patient, and to ensure secondary care prevention is appropriately coordinated throughout the healthcare system**
- **Institute individual case management for patients, to ensure the appropriate utilisation of secondary CVD services.**

The World Heart Federation calls on patient advocacy groups to:

- **Elevate the issue of secondary prevention of cardiovascular disease, equitable access to treatments and service, and implementation of guideline adherence on relevant public health agendas**
- **Identify, highlight, and address any financial constraints preventing the implementation of guidelines that impact on patient health outcomes**
- **Provide patient-friendly materials on relevant aspects of national guidelines.**

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Links to resources

OECD Health Data 2013

www.oecd.org/health/healthdata and www.oecd.org/italy

The Commonwealth Fund, International Profiles of Health Care Systems, 2013 (November 2013)

http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2013/Nov/1717_Thomson_intl_profiles_hlt_care_sys_2013_v2.pdf

Linee guida nazionali su cardiologia riabilitativa e prevenzione secondaria delle malattie cardiovascolari

http://www.snlg-iss.it/cms/files/LG_cardiologia_riabilitativa.pdf

2007 Gaining Health

http://www.ministerosalute.it/stiliVita/stiliVita.jsp

29/03/2006 National Health Plan

http://www.ministerosalute.it/resources/static/primopiano/316/PSN_2006_08_28_marzo.pdf

2005 National Prevention Plan

http://www.epicentro.iss.it/focus/piano_prevenzione/indice_prevenzione.asp

2004 Heart Project

http://www.cuore.iss.it/

English Version **http://www.cuore.iss.it/eng/other/cuore.asp**
Mennini FS et al. Cost of poor adherence to anti-hypertensive therapy in five European countries. Eur J Health Econ DOI 10.1007/s10198-013-0554-4.

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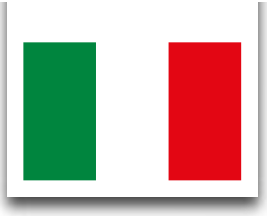

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