Setting priorities for public health in the EU

Italian national experience

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Long-term prediction of major coronary or ischaemic stroke event in a low-incidence Southern European population: model development and evaluation of clinical utility

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ABSTRACT

Objective: To develop a long-term prediction model of first major cardiovascular event and to assess its clinical utility in a low-incidence European population.

Setting: Four independent population-based cohorts enrolled between 1986 and 1993 in Northern Italy.

Participants and methods: N=5247 35-year-old to 69-year-old men and women free of cardiovascular disease at baseline. Absolute 20-year risk of first fatal or non-fatal coronary or ischaemic stroke event (monitoring trends and determinants in cardiovascular disease (MONICA) validated) was estimated from gender-specific Cox models.

Main outcome measures: Model discrimination (area under the receiver operating characteristic (ROC)-curve, AUC). ‘High-risk’ subjects were identified based on several threshold values for the 20-year predicted risk. Clinical utility was defined in terms of fraction of missed events (events among those considered at low-risk) and unnecessary treatment (false-true positive).

and stroke events recommend the use of a multivariable risk prediction model to identify high-risk subjects.1 2 Several risk scores are available in different US3 4 and European5 populations of middle-aged adults, including the Italian one,6 to estimate the risk of first fatal and non-fatal cardiovascular event over a 10-year time interval. Primary prevention, however, has been recently moved towards the concepts of ‘lifetime’7 and ‘long-term’ risks,8 motivated also by the increasing life expectancy in western countries. To this extent, 10-year risk prediction models are inadequate to distinguish between those at both low short-term and long-term risks, and those at low short-term but at elevated long-term risk due to the presence of non-optimal risk factors levels.9–11 In the Framingham
How do I use the SCORE charts to assess CVD risk in asymptomatic persons?

1. Use the low risk charts in Andorra, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, The Netherlands, Norway, Portugal, San Marino, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

2. Use the high risk charts in other European countries. Of these, some are at very high risk and the charts may underestimate risk in these. These include Armenia, Azerbaijan, Belarus, Bulgaria, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Macedonia FYR, Moldova, Russia, Ukraine and Uzbekistan.

3. Each cell in the chart is color-coded to show the 10-year risk of fatal CVD in people at low risk.

4. To use the charts, find the cell nearest to the person's age, cholesterol, and BP values. If the cell is red, the risk of CVD is high. If the cell is green, the risk is low. If the cell is yellow, the risk is in between.

5. Calculate the total 10-year risk for fatal CVD by adding the percentage from the top row to the percentage from the left column.

Example:

- Age: 50
- Cholesterol: 200
- BP: 120/80

Total 10-year risk for fatal CVD: 20% + 5% = 25%
NCDs: Italian situation

Cardiovascular diseases:
• 38% of deaths

Cancers:
• second leading cause of death (30% of all deaths)
• incidence increasing (approximately 250,000 new cases each year)

Chronic respiratory diseases:
• third leading cause of death
• prevalence expected to increase (also due to the aging of the population)

Diabetes:
• 3,000,000 people with diabetes (5% of the population)
• about a million people not aware of having the disease
The Italian strategy

- National Health Plan
- National Prevention Plan

Program “Gaining health: making healthy choices easier”

- Poor nutrition
- Physical inactivity
- Alcohol abuse
- Smoking

- strengthen NCDs prevention and health promotion
- improve cooperation with European Union and WHO
The National Prevention Plan

**Governance**

- National Health goals
- Regional planning
- Central Actions of support

- Sharing of principles, aims and tools
- Coordinated actions with participation at different levels
- Technical-scientific and methodological support
- *Stewardship* at the central level

Programmatic document, shared between State and Regions, that engages all the Italian Regions to implement prevention programs addressed to the population, on the basis of:

- **Priority** (epidemiological surveillance)
- Evidence of effectiveness
- Attention to the citizen (healthy or sick)

(since 2007)
Population: 4,925 Ml.
400,000 (8%) 50-54 yrs old
9 «new» Local Health Units/Authorities
22 «old» Local Health Units/Authorities
11 involved in the project
Objectives:
- To estimate cardiovascular risk among the 50 years old population (both males and females)
- Identify persons with unhealthy life styles
- Identify new cases of hypertension, hyperglicemia and hyper cholesterolemia
CCM Pilot Project

11 LHA of Veneto
Belluno, Feltre, Alto Vicentino, Pieve di Soligo, Asolo, Veneziana, Alta Padovana, Este, Rovigo, Adria, Verona

12 LHA not Veneto
Friuli Centrale, Trento, Bergamo, Torino, Bologna, Genovese, Lucca, Prato, Roma 1, Latina, Taranto
Cardio 50 Process

• Active invitation by letter
• **Screening** visit and evaluation by a health professional:
  – Blood sugar/cholesterol level tests (Sticks)
  – Weight, height and blood pressure measurement
• Life style **Assessment** (smoking, eating and exercise habits) with a standardised questionnaire
• **Classification** in 4 groups (through software)
• Life style **Counselling** with healthier habits proposals
• Assignement of medical report
• Referral to GP (if required)
• Follow-up for specific class (B)
FLOW CHART “Cardio 50”

**POPULATION TARGET** (50 Year olds)

- **ELIGIBLE POPULATION**
  - Accepts invitation
    - Yes: CLASSIFICATION Nurse/Health Ass
      - **NO** STOP
      - **SI**
        - REMINDER letter One time only
          - **NO** STOP
          - **SI**

  - **NOT ELIGIBLE** STOP

- Invitation letter with appointment

**CLASS A** Healthy life style, no risk factors

**CLASS B** Unhealthy lifestyle, no risk factors

**CLASS C** Unhealthy lifestyle with risk factor(s)

**CLASS C1** Healthy lifestyle with risk factor(s)

**CLASS D** In therapy, exits screening

**GROUP B**
- COUNSELLING
  - **PARTICIPATES** NO STOP
  - **YES**
    - COUNSELLING PROPOSED:
      - 1. HEALTHY NUTRITION PACKAGE
      - 2. QUIT SMOKING PACKAGE
      - 3. PHYSICAL ACTIVITIES PACKAGE
    - RE-EVALUATION at 6-12 months
      - RESULT
        - **POSITIVE** Positive reinforcement STOP
        - **NEGATIVE**

- C/C1 COUNSELLING
  - SEND TO GPs

- D COUNSELLING STOP
Class A
Healthy lifestyle, no risk factors

Class B
Unhealthy lifestyle, no risk factors

Class C
Unhealthy lifestyle with risk factor(s)

Class C1
Healthy lifestyle with risk factor(s)

Class D
In therapy, exits screening

27%
6%
20%
10%
37%
Some results - First visit (1)

<table>
<thead>
<tr>
<th>Total invited (2015-2017)</th>
<th>~44,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation rate</td>
<td>~61%</td>
</tr>
<tr>
<td>Follow-up compliance</td>
<td>~53%</td>
</tr>
</tbody>
</table>

### Physical activity

- **16.1%** insufficient *
- **56.6%** moderate
- **27.2%** high

* less than 30’ a day 5 times a week

### Smoking Habits

- **21%** Smokers *
- **22.8%** males
- **19.5%** females

* 11.6 average n. cigarettes smoked daily
Some results - First visit (2)
Nutrition and Weight

- **72,5%** Fruit and vegetables consumption*
  - 71% males,
  - 74,4% females

- **36,6%** Fish intake at least twice a week

*less than 5 portions a day

**Waist circumference**
- **27,7 %** males (≥ 102 cm),
- **42,8%** females (≥ 88cm)

- **48,8% Overweight**
  (BMI ≥25)
  - 60,3% males
  - 39% females

- **15% Obese** (BMI ≥30)
New subjects with:

- **23%** Hypertension  
  (16% females, 31% males)
- **9%** Hyperglycemia
- **21%** Hypercholesterolemia  
  (22% females, 19% males)
### First visit vs. follow up

*Class B subjects*

<table>
<thead>
<tr>
<th>First Visit</th>
<th>Follow up after 6-12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 30,4% Smokers</td>
<td>• 21,9 %</td>
</tr>
<tr>
<td>• 35,4% Fish consumption less than twice a week</td>
<td>• 39,3%</td>
</tr>
<tr>
<td>• 60% Overweight</td>
<td>• 56,7%</td>
</tr>
<tr>
<td>– 51% Females</td>
<td>– 47,5% Females</td>
</tr>
<tr>
<td>– 71,6% Males</td>
<td>– 67,3% Males</td>
</tr>
</tbody>
</table>
First visit vs. follow up: Physical activity

(Class B subjects)

- **1 visit**
  - Low: 22.5%
  - Moderate: 52.5%
  - Intensive: 25%

- **Follow-up**
  - Low: 14%
  - Moderate: 53%
  - Intensive: 33%
Cardio 50 «European» Path

- Submitted and accepted in JA «CHRODIS» Platform as Best Practice (BP) (2016)
- Selected by the EU Commission in the first round of potential BPs to be endorsed by newly instituted SGPP and to be implemented on the basis of MS choices (Mar 2017)
- Selected as Practice to be implemented after survey among SGPP members/MS health authorities (1 half 2017)
- Included as background in EU HP 2018 WP (Dec 2017)
- Call for Implementation project launched (June 2018)
- «YOUNG50» Application submitted (September 2018)
Partners (Countries) involved in EU project application:

2 LHA in Veneto (Italy)
VIESTOJI ISTAIGA CENTRO POLIKLINIKA (Lithuania)
MINISTERE DE LA SANTE’ (Luxembourg)
ASOCIATA AER PUR ROMANIA (Romania)
Scientific Partners:

ASOCIACION CENTRO DE EXCELENCIA INTERNACIONAL EN INVESTIGACION SOBRE CRONICIDAD (Kronikgune)

EUROPEAN SOCIETY OF CARDIOLOGY (ESC)
Specific Objectives

1. Adaptation and export of the CARDIO50 screening model to the EU member countries participating in the project (Lithuania, Romania, Luxembourg)
2. Reduce risk factors of cardio-vascular diseases through the change of lifestyles
3. Perfecting the model to achieve maximum performance, maximum sustainability and dissemination
Phase Development

1. Provide a needs assessment and situation analysis; adapting the Cardio 50 example to local context and defining implementation action plans
2. Rolling out and piloting of the screening and prevention intervention in selected MSs
3. Impact evaluation of the pilot and follow up study in order to institutionalize the project
WP 4 - Situation analysis and feasibility/needs assessment (KRONIKGUNE)

WP 4 will describe the current situation in terms of epidemiological context and existing cardiovascular health promotion and prevention activities in the three pilot sites countries. Partners will identify core features in CARDIO 50 which are essential to achieve desired results in YOUNG50. They will identify and categorize significant factors faced in their region/country in deploying YOUNG50, their adapted YOUNG50 local prevention plan and produce an Action Plan and process indicators to define local prevention programs deployment and monitoring.

WP 5 - Adaptation of cardio 50 procedures and materials (CENTRO POLIKLINIKA)

The main goal of WP5 is successful adaptation of Cardio 50 procedures and material to local contexts. This will ensure the sustainable and reliable process of implementing the best practice, reaching objectives and accurate quantitative and qualitative analysis of the data. A study visit of to Italy will ensure an alignment of intent and procedures of software during design, development and adaptation. The interventions defined in CARDIO50 will be reviewed and customized/adapted to local sites. A survey one month after the beginning of implementation will provide information for any necessary changes. WP5 will also provide training of IT and health professionals. The issues of data protection and consent to use the data received for the statistics in accordance with the laws in force in each country is also addressed.

WP 6 - Implementation of Screening and prevention intervention (MINISTERE DE LA SANTE)

WP6 will extend the CARDIO 50 model to other countries (Romania, Lithuania and Luxemburg). The CARDIO 50 good practice transfer and implementation will be prepared. It will be necessary to set up local governance structures for the implementation of the project, with the help of local key stakeholders. Local sites will launch the adapted YOUNG50 Prevention Programs. The different implementations experiences will be assessed by analysing some process indicators. In this way it will be possible to find out improvement solutions, since programs will continue operating. The development and the pilot launch of an APP for the collection of follow-up data is provided, and more in general it will be studied the program’s ability to be sustainable in future.

WP 7 - Follow up and recommendations (AZ. ULSS6 EUGANEA)

WP 7 will focus on the future, making the implementation of YOUNG50 sustainable. A set of output health-related indicators will be defined, in order to follow-up data collection and analysis. The final goal is a better understanding of ways to integrate screening and prevention intervention into regional and national policy and planning. Outcomes expected are the development of recommendations and Policy Guidelines to foster the inclusion of CVD prevention though the YOUNG50 model in Regional or National
GUARDavo sparire l’isola,
ella quale avevo raggiunto
il fondo della solitudine
mentre trascinato nelle amicizie
decisive della mia vita,
avevo fatto la fame,
avevo contemplato
come da un lontano loggiamento
la tragedia della seconda guerra
mondiale, avevo tirato le somme,
finché di quel che ero andato
meditando durante sedici anni,
avevo scoperto l’abisso
della dissociazione.
La virtù del distacco,
il facere del pensare pulito,
l’eretica della creazione politica,
il frenetico dell’apparire
delle cose impossibili,
nessuna formazione politica
esistente mi attraeva.
Ne si preparava a partire festa
ad accogliermi nelle sue elle,
con me non avevo per ora
òltre me stesso,
che un manifesto, alcune tesi
è tre o quattro amici

Alfredo Siniscalchi
10 agosto 1948

A sessanta anni dallo scoppio della
manifesto di ventotene
per una Europa libera e unita
il 20 settembre 1940 a Bari
i rappresentanti dei 25 paesi
dell’unione europea firmavano
il trattato
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Thanks for your attention!