Abstract

Study objective—URALIM (EUrope ALIMentation), a European collaborative study, aimed to determine and describe the extent to which European data on risk factor distributions from different populations could be pooled and harmonised in a common database for international comparisons.

Setting—Seven independent population-based surveys from six European countries (France, Italy, Northern Ireland/United Kingdom, Spain, Switzerland, the Netherlands).

Methods—Data for 18,381 women and 12,908 men aged 40–59 were pooled in a common database. Central statistical analyses on major cardiovascular risk factors were conducted with careful consideration of methodological issues, including differences in study designs, data assessment tools, and analytic techniques used.

Main results—Because of the detected variability among methods used, direct comparisons of risk factor distributions and prevalences between studies were problematic. None the less, comparisons of within population contrasts by sex, age group, and other health determinants were considered to be meaningful and apt, as illustrated here for obesity. Results were targeted and disseminated to both the general public and public health professionals and framed in the context of a European information campaign.

Conclusions—International and national comparisons between existing locally run studies are feasible and useful, but harmonisation methods need improvement. Development of an international risk factor surveillance programme based on decentralised data collection is warranted. In the meantime, risk factor contrasts across populations can be used as a basis for targeting needed public health intervention programmes.

Worldwide, considerable research is focused on the frequency of cardiovascular disease and cancer, as well as on the risk and protective factors related to these diseases. Interest is growing in continuously monitoring and comparing distributions of risk factors in diverse populations to inform public health professionals and guide needed actions. Many independent locally-based studies of good quality produce results that cannot be directly compared because of methodological variability. To date, three main approaches have been used to compare data across national and international studies, namely: (1) comparative standardised studies based on a uniform core protocol, (2) meta-analyses, and (3) the harmonisation of data from independent studies.

The third approach of harmonising data from independent studies has been less extensively investigated to date. It is known that variables measured using different methodologies are not easily compared. Because distributions of risk factors in the population are usually narrow, slight errors in measurement can lead to dramatic variations in the estimation of the prevalence of high risk groups and therefore severely bias the intended comparisons.

Although the use of different protocols limits comparability, the prospect of pooling locally-based surveys should not be rejected out of hand. In the long run and for international comparisons, it is unlikely that concerted, centralised projects will become the main source of population data. Many locally run programmes of good quality generate information on the distributions of risk factors in specific populations. It is comparatively cheap to pool and analyse these data rather than obtain new data through large concerted actions. Additional work is therefore needed to practically determine the extent to which these data can be harmonised and integrated into an international system of risk factor surveillance. Public health professionals need efficient and valid ways to compare data across national and international studies that lack uniform data collection procedures.

In 1995, the Directors of the Division of Clinical Epidemiology in Geneva and the Institut Scientifique et Technique de la Nutrition et de l’Alimentation in Paris launched a European project to determine and describe the extent to which non-uniform data could be harmonised and pooled in a common database for international comparisons. This health promotion project was jointly supported by the
European Community and the Swiss Federal Office for Education and Science. Here we describe the main objectives, design, and conduct of EURALIM, as well as its main methodological findings. Obesity was used as the risk factor of interest for illustrative purposes.

EURALIM pursued three main objectives that were achieved in a series of steps between March 1997 and September 1998, namely, to: (1) improve methods for comparing European data on risk factors that were collected in non-uniform manners; (2) provide the general public as well as public health professionals and politicians involved in public health issues with important contrasts found within and across included European populations; and (3) develop a technical document to assist public health professionals in the critical interpretation of risk factor data originating from various populations. This paper focuses on the methodology and first objective of EURALIM.

**Methods**

**STUDY DESIGN**

EURALIM is a collaborative European project comprised of seven local studies of high quality that provided population data on risk factors representative of the following countries, regions or cities, that is: SU.VI.MAX, France; Progetto ATENA, City of Naples (Italy); Progetto MATISS, Province of Latina (Italy); Belfast MONICA Project, Greater Belfast area (Northern Ireland/UK); Catalonia Nutrition Survey, Province of Catalonia (Spain); Bus Santos 2000, Canton of Geneva (Switzerland); Monitoring Project on Cardiovascular Disease Risk Factors, the Netherlands.

EURALIM used a harmonisation approach to compare the data from these seven locally run studies with different methods of data collection across sites. Database management and analyses were performed centrally at the data coordinating centre. Figure 1 gives an overview of the study plan.

**DATABASE MANAGEMENT**

Based upon a review of the assembled study protocols, questionnaires, and variable lists from the participating sites, the EURALIM group defined new, common variables covering demographic, diet, health, and lifestyle factors. A “EURALIM Coding Manual” was prepared that defined the exact content of each variable, as well as their prescribed length and order of assembly (unpublished data). All seven research partners locally prepared their own “EURALIM data sets” accordingly.

Study partners followed a common convention for data transfer developed by the advisory group (unpublished data). Manageable ASCII text files were transferred to the data coordinating centre in Geneva, Switzerland. Before file transfer, each partner ran a quality check on a defined selection of variables for verification at the data coordinating centre.

The construction of the EURALIM Database was performed using SAS software (Statistical Analyses System SAS 6.12. SAS Institute Inc, Cary NC, USA: 1996). The resulting seven SAS files underwent the same quality checks as were performed locally to help identify any remaining inconsistencies. The common EURALIM database was finalised by merging together the seven individual files and labelling all 227 variables.

The EURALIM database thus comprised data from seven population-based studies with somewhat different designs, as shown in table 1. For instance, the Italian sample from Naples consisted almost only of female volunteers. Other differences related to specific variables, for example, dietary data were assessed in only a small sub-sample of women in the Italian Province of Latina. All final analyses were performed with a database restricted to the common age group represented in all participating studies, that is, ages 40–59 years, for a total of 18 381 women and 12 908 men. Table 2 provides the population sizes by site.

**DATA ANALYSES**

While a multitude of preliminary analyses were conducted and examined, final analyses focused on the following major cardiovascular risk factors: increased blood cholesterol, high blood pressure, smoking, excessive body

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**Table 1  Characteristics and sampling methods of the participating EURALIM study populations**

<table>
<thead>
<tr>
<th>Population that study sample is representative of</th>
<th>Year(s) of survey</th>
<th>Urban and/or rural</th>
<th>Sexes and age (y) sampled</th>
<th>Sampling method</th>
<th>Response rate by sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>1995–1996</td>
<td>urban and rural</td>
<td>F, M: 35–65</td>
<td>random selection of a representative sample out of a large volunteer population (intervention study)</td>
<td>F: 86%; M: 81%</td>
</tr>
<tr>
<td>Naples (Italy)</td>
<td>1993–1996</td>
<td>urban</td>
<td>F: 30–69</td>
<td>volunteer sample (95%) &amp; random selection (5%)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Province of Latina (Italy)</td>
<td>1993–1996</td>
<td>rural</td>
<td>F, M: 20–84</td>
<td>random selection, stratified by sex, age</td>
<td>F: 72%; M: 67%</td>
</tr>
<tr>
<td>Catalonia (Spain)</td>
<td>1992</td>
<td>mainly urban</td>
<td>F, M: 25–75</td>
<td></td>
<td>F: 72%; M: 66%</td>
</tr>
</tbody>
</table>

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**Figure 1** EURALIM study plan—harmonisation approach.
Table 2  Number and percentage of 40–59 year old participants by EURALIM population

<table>
<thead>
<tr>
<th>Population that study sample is representative of</th>
<th>Women</th>
<th>Men</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>6 424</td>
<td>4 791</td>
<td>11 215</td>
</tr>
<tr>
<td>the Netherlands</td>
<td>5 664</td>
<td>5 144</td>
<td>10 808</td>
</tr>
<tr>
<td>Naples (Italy)</td>
<td>3 013</td>
<td>0</td>
<td>3 013</td>
</tr>
<tr>
<td>Province of Latina (Italy)</td>
<td>1 254</td>
<td>1 084</td>
<td>2 338</td>
</tr>
<tr>
<td>Geneva (Switzerland)</td>
<td>1 083</td>
<td>1 040</td>
<td>2 123</td>
</tr>
<tr>
<td>Province of Latina (Italy)</td>
<td>1 254</td>
<td>1 084</td>
<td>2 338</td>
</tr>
<tr>
<td>Italy</td>
<td>3 013</td>
<td>0</td>
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<td>5 144</td>
<td>10 808</td>
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<td>Province of Latina (Italy)</td>
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<tr>
<td>Geneva (Switzerland)</td>
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<td>2 123</td>
</tr>
<tr>
<td>Province of Latina (Italy)</td>
<td>1 254</td>
<td>1 084</td>
<td>2 338</td>
</tr>
<tr>
<td>Italy</td>
<td>3 013</td>
<td>0</td>
<td>3 013</td>
</tr>
</tbody>
</table>

Weighted percentiles

For each observation \(i\), the weights \(w_i/n_i\) were used to compute weighted percentiles. Let \(V_i\) represent a percentile of rank of \(q\) of a variable \(V\). \(V_i\) was selected so that the sum of weights of the observations smaller than \(V_i\) was equal to \((N - 1)q + 1\), where \(N\) denotes the total sample size. If no observation corresponded exactly to this sum of weights, a linear interpolation between the closest values obtained was performed.

Individual weights \(w_i/n_i\) allowed for computing large sample 95% CIs for percentiles.\(^{21}\) Ranks \(q_L\) (lower bound) and \(q_U\) (upper bound) of a percentile \(V_i\) were computed as

\[
q_L = (N - 1)q + 1 - \frac{1}{2} - 1.96\sqrt{Nq(1-q)}
\]

and

\[
q_U = (N - 1)q + 1 + \frac{1}{2} - 1.96\sqrt{Nq(1-q)}
\]

The procedure used for determining the upper and lower limits of the ranks was the same as that used for determining the percentile \(V_i\).

INFORMATION CAMPAIGN

Results were targeted and disseminated to both the general public and public health professionals and framed in the context of a European information campaign. Figure 2 provides an example of how the data were presented in the general public brochure entitled *Nutrition and the heart. Healthy living in Europe*,\(^{22}\) to allow for comparisons of gender contrasts across populations.

The supplement for public health professionals presented and discussed the most important methodological sources of variability, additional analyses, and the rationale for interpretation of each considered risk factor.\(^{23}\) Figure 3 gives an example of how age standardised gender differences were presented as the prevalence of risk factors with their associated 95% CIs. Additional analyses stratified by age group (40–49 versus 50 to 59 years),

weight, and unhealthy diets (notably low fruit and vegetable intakes). The S-Plus statistical package (S-Plus 3.3-1 for Sun SPARC, SunOS 5.3, MathSoft Inc Seattle, USA; 1995) was used for all analyses.

The main statistical methods used by the project were descriptive, specifically, proportions and 25th, 50th and 75th percentiles (P25, P50, P75). Gender contrasts within each population were expressed as the difference (and ratio) of the prevalence of a given risk factor for men and women. All values were presented together with their corresponding 95% confidence intervals (95% CI).

To control for a possible age effect, the data were stratified by four, five-year age groups (40–44, 45–49, 50–54 and 55–59 years). Of note, the age distributions for men and women from Catalonia and France, as well as women from Naples, were not uniform across these five-year strata and differed from those in the other studies. Ordinary proportions and percentiles were computed for each stratum. When analysing data for the entire age group of 40–59 years, differences in age distributions between the studies were removed by computing weighted proportions and percentiles (see below).

Calculation of weights

Weighted analyses were used to adjust the age distribution of each study to the standard European age distribution.\(^{19}\)–\(^{20}\) For each participating study, the observations in age group \(i\) were weighted by \(w_i/n_i\), where \(n_i\) is the sample size of the given age group \(i\). Age groups of all studies have respective relative weights \(w_i\). The sum of the weights over all observations is equal to 1.

Weighted means and variances

Weighted means of continuous variables were calculated as the sums of means weighted by \(w_i\) for each age group. Weighted proportions were calculated as the sums of proportions weighted by \(w_i\) for each age group. Similarly, weighted variances were calculated as the sums of variances weighted by \(w_i\). Finally, the variances of differences between two proportions were calculated as the sums of the variances of the single proportions. As the sample size was sufficiently large, a normal distribution of means and proportions was assumed and the corresponding 95% CIs were calculated as

\[
\text{mean(proportion)} \pm 1.96\sqrt{\text{variance}}.
\]
educational level, and smoking status provided additional insights into the issues associated with intra-national and international data comparisons.

The information campaign was evaluated by public health professionals in all seven collaborative centres by administering a common evaluation questionnaire (data not presented).

Results

The investigation of differences among study designs and the methodological sources of variability identified for all of the factors considered in the common EURALIM database led to the conclusion that direct comparisons of risk factor distributions and prevalences between studies was overly problematic. None

Excessive body weight increases the risk of hypertension, unhealthy lipid profile, heart disease, diabetes, and some cancers. Overweight and obesity can be assessed using Quetelet’s Body Mass Index (BMI) calculated as weight in kg divided by height in meters² (e.g., a woman weighing 70 kg and measuring 1.6 m, BMI = 70/(1.6 × 1.6) = 27 kg/m²). Overweight is defined as a BMI in the range of 25 to 30 kg/m², and obesity as a BMI of equal to or greater than 30 kg/m². BMI values between 20 to 25 kg/m² indicate desirable body weight.

In general men have higher Body Mass Indices than women. In the Province of Latina and in Catalonia however women have higher Body Mass Indices than men.

More men compared with women are overweight, but in almost all populations more women than men are obese.

Weight reduction in overweight and obese individuals can reduce the risk of heart disease. A diet with less calories and fat, as well as regular physical activity, will help a person to lose weight and to maintain the weight loss.

Figure 2  Brochure for the general public—Overweight and Obesity.
Table 3 Impact of a 3% measurement error for body weight on gender differences in the prevalence of obesity (BMI ≥ 30 kg/m²) with their associated 95% CIs, 40–59 years.

<table>
<thead>
<tr>
<th>Population that study sample is representative of</th>
<th>Error</th>
<th>% in men</th>
<th>% in women</th>
<th>Difference in %</th>
<th>Ratio Men to women</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>0%</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td>1.14</td>
</tr>
<tr>
<td>the Netherlands</td>
<td>3%</td>
<td>5</td>
<td>6</td>
<td>–1</td>
<td>0.83</td>
</tr>
<tr>
<td>Province of Latina (Italy)</td>
<td>3%</td>
<td>14</td>
<td>11</td>
<td>–3</td>
<td>0.73</td>
</tr>
<tr>
<td>Geneva</td>
<td>0%</td>
<td>11</td>
<td>9</td>
<td>2</td>
<td>1.22</td>
</tr>
<tr>
<td>(Switzerland)</td>
<td>3%</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td>1.14</td>
</tr>
<tr>
<td>Belfast</td>
<td>0%</td>
<td>15</td>
<td>16</td>
<td>–1</td>
<td>0.94</td>
</tr>
<tr>
<td>(United Kingdom)</td>
<td>3%</td>
<td>11</td>
<td>13</td>
<td>–2</td>
<td>0.85</td>
</tr>
<tr>
<td>Catalonia</td>
<td>0%</td>
<td>11</td>
<td>22</td>
<td>–11</td>
<td>0.50</td>
</tr>
<tr>
<td>(Spain)</td>
<td>3%</td>
<td>7</td>
<td>18</td>
<td>–11</td>
<td>0.39</td>
</tr>
</tbody>
</table>

Figure 3  Supplement for public health professionals. Age standardised gender differences in the prevalence of obesity (BMI ≥ 30 kg/m²) with their associated 95% CIs, 40–59 years.

Table 3 presents the gender differences and ratios of obesity in the six populations reporting data on both genders. The data presented by EURALIM (figs 2 and 3) are provided along with the corresponding data assuming a 3% underestimation error on the measurement of body weight. For illustrative purposes, it was assumed that the measurement error was similar in men and women. Results show that the nominal prevalence of obesity changes with measurement error present and that this affects the direct comparisons across groups, for instance, between women from Latina and the Netherlands. Still, the impact of measurement error on the comparisons of gender differences was minimal. Although the gender differences and ratios changed, the qualitative interpretation remains the same—that is, there is more obesity in southern European women than in southern European men, but similar levels of obesity in northern European men and northern European women.

EURALIM Day was held on 19 May 1998 in all participating centres to kick off the information campaign that ultimately reached about 1500 public health professionals across Europe. The general public brochure was in turn distributed to about 60 000 people through these 1500 contacts.

**Discussion**

Overall, results showed that gender differences for the considered risk factors varied substantially across populations, implying that examined factors may be amenable to modification through public health interventions.

Surveillance of risk factors requires timely data collection. The WHO recently called for the continuous monitoring of BMI to assess the trends in obesity in populations across time.23 EURALIM used a harmonisation approach to compare the distributions of cardiovascular risk factors assessed in disparate ways among seven European research centres. Defining new uniform variables permitted joint, comparative analyses to be conducted. The constitution of a common database was a key factor in this project. None the less, only a fraction of the examined variables were essentially similar across all seven participating studies. Methods for assessing important factors such as physical activity, socioeconomic status (education, occupation), and smoking...
hhabits varied considerably across studies. For certain factors (for example, physical activity) it was not possible to define a satisfactory common variable as the methods used were so dissimilar. As educational systems differ substantially across Europe, the best possible common cut point was to set “high education” equal to “university or equivalent degree”. Thus, the category “medium/low education” comprised a large, diverse spectrum of degrees. For smoking habits, the most uniform definition was able to distinguish “never”, “former” and “current” smokers, but not to provide any common information on duration or intensity. Analyses by educational level and smoking status thus require careful interpretation.

Because age is associated with most chronic disease risk factors, age standardisation is a crucial step in international surveillance projects. The problems tackled by EURALIM are probably typical of those that future harmonisation projects will encounter. For example, the overrepresentation of the youngest age group in the Catalan population was because of reliance on what turned out to be incorrect census information. The inclusion of volunteers was responsible for the unequal age distributions in the samples from France and Naples. Age standardisation helped to correct the age inconsistencies between studies. As expected, the presented population estimates were less precise for smaller samples, as reflected in the larger width of the corresponding 95% CIs for percentiles and frequency bar charts.

A key methodological finding of EURALIM is that international comparisons of within population contrasts by sex, age group, and other health determinants (for example, educational level and smoking status) are meaningful and apt. The rationale is that for any single study, the biases are similar among the groups compared and therefore tend to cancel each other out. For example, if weight is overestimated in one survey in both men and women, the gender ratio of median BMIs will be unbiased (the gender difference of median BMIs will be slightly biased, however, if the gender difference is not null). The situation is more complicated when you compare the gender prevalences of a given condition (for example, gender specific prevalences of obesity). As shown in table 3, both the ratios of prevalences and the differences of prevalences may be biased, but it is reasonable to expect that the qualitative relation (that is, whether men are more obese than women or vice versa) will not be affected if the two distributions have comparable variances.

This central finding can be of great use in future international comparisons of risk factor distributions, that is, comparing the nominal levels of prevalences may be less valid than comparing prevalence contrasts. For example, it is worth noting that obesity is more prevalent among Latina women than among Latina men, but that the reverse situation is found in France, the Netherlands and Belfast. This may indicate that environmental and therefore potentially modifiable risk factors play important parts in these differences. Similar contrasts can be computed and compared for smokers versus non-smokers, upper versus lower socio-economic groups, etc. The disadvantage of ratios over differences is that they give no idea of the magnitude of the affected populations. Therefore, differences may be more important to public health professionals and preferred (or presented along with ratio estimates). The development of an international risk factor surveillance system based upon the continuous monitoring of locally-based standardised studies will provide repeated measurements of key risk factors. Ongoing health promotion actions that are based upon continuously collected data using within population contrasts across sites will help to better elucidate the influence of environmental and behavioural factors on health.

Standardised methods are needed to present meaningful statistics on risk factor distributions and to compare population groups. The biological variables and physiological measurements investigated in EURALIM often had asymmetric distributions, which generally hampers the interpretation of the mean as a measure of central tendency. Atypical people with outlying characteristics may also influence the usual estimates of means and variances. Therefore, three percentiles were used to summarise the distributions, namely the median or 50th percentile as a measure of central tendency, and the 25th and the 75th percentiles as measures of variability. The latter percentiles are preferred to the 5th and 95th percentiles because they can be more precisely estimated given the usual sample sizes of local surveys.

To illustrate the proposed methodology for international risk factor comparisons, we presented important gender contrasts for excessive body weight across populations. Overweight is common in Europe. Up to 43% of women and 57% of men had BMIs between 25 and 30 kg/m\(^2\). Obesity (BMI \(\geq 30\) kg/m\(^2\)) is also frequent in both genders, although any gender differences found were generally smaller. Overall, a north-south European gradient was perceptible in the results. Higher BMI values were observed for women from Catalonia, Spain and the two Italian study centres. On the other hand, women from France and Geneva showed the lowest BMIs and therefore had the lowest prevalences of overweight and obesity. These may be true international differences, attributable in part to varying social and cultural environments, including different kinds of occupational and leisure time activities and dietary habits. Methods of direct measurement for body weight and height varied slightly between studies. Differences in study designs may explain part of the international differences found. However, these methodological variations are probably too small to meaningfully influence the overall results. Although some of the gender differences in the body weights of men and women are biological, men and women could potentially reach the same prevalences of overweight and obesity as their female or male counterparts by adopting
healthier lifestyles. Health promotion programmes to lower body weight can use as targets the optimum conditions found not only within but also across populations. The general public needs to be provided with effective ways of maintaining healthy weights, or of losing excess weight, which are culturally acceptable and contextually supportable. Eating and exercise habits of female and male populations with the most desirable body weights, such as those in France and Geneva, need to be investigated for possible clues to effective interventions to mount in other populations.

The development of an international risk factor surveillance system is warranted. Further work in harmonisation procedures is needed to increase comparability among locally run studies. Gender, age group, and other health determinant contrasts may be useful in describing how chronic disease risk factors vary locally, nationally, and worldwide. One suggestion for improving harmonisation methods is to perform calibration studies to assess the amount of measurement variability in each centre from commonly defined standard measures. In addition, locally run surveys may do well to incorporate a standardised “surveillance core” comprised of a short set of simple measures to allow for improved national and international comparisons over time.

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References