Deliverable 7: Final report on risk assessment case study
This report is a final product of work package 6 on of risk assessment case study completed by project partner institutions during 2011 within project Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012 EU (DG-SANCO) Grant agreement N° 20081105. The report provides first the work package identifiers, describes and discusses the suggested methodology after applied for selected EC policy and in annex provides full texts of each individual national reports contributed by partners involved in work package 6.

Work package identifiers
Work package No. 6: Case study on an EU policy
Work package leader: SDU
Work package partners: UD MHSC, LIGA.NRW, MUS, RUVZ, TU, IVZ RS, UBB

Content
DELIVERABLE 5: FINAL REPORT ON RISK ASSESSMENT CASE STUDY ................................................................. 1
WORK PACKAGE IDENTIFIERS ......................................................................................................................... 1
1. AIM AND CONDUCT OF THE WORK PACKAGE 6 ............................................................................................ 4
2. METHOD OF ASSESSMENT ........................................................................................................................... 4
3. EXECUTIVE SUMMARY ................................................................................................................................. 5
3.1. APPLICATION OF THE RAPID GUIDANCE TO EC STRATEGY ............................................................... 7
   Policy (strategy, program, regulation) .............................................................................................................. 7
   • Determinants of health ............................................................................................................................... 7
   • Risk factors .............................................................................................................................................. 8
   • Health outcomes ...................................................................................................................................... 9
   • Cross-level issues ................................................................................................................................... 9
3.2. REFERENCES ............................................................................................................................................ 10
4. IVZ RS LJUBLJANA, SLOVENIA REPORT .................................................................................................... 11
   4.1. Introduction .......................................................................................................................................... 12
   4.2. Hazard Identification (Policy description) .............................................................................................. 13
   4.3. Hazard characterization (Determinants of health) ................................................................................ 18
   4.4. Exposure assessment (Risk factors) ........................................................................................................ 30
   4.5. Risk Characterization (Health outcome) .............................................................................................. 35
   4.6. Conclusion .......................................................................................................................................... 42
6.3. Risk factors ........................................................................................................... 86
6.4. Health outcomes .................................................................................................... 87
6.4.1. Population affected ............................................................................................ 88
6.4.2. Costs related to health outcomes ....................................................................... 89
6.5. Cross-level issues .................................................................................................. 89
6.5. Full chain discussion ............................................................................................. 91
6.6. References ............................................................................................................. 94

7. UD MHSC DEBRECEN, HUNGARY NATIONAL REPORT ........................................ 97
7.1. Introduction ............................................................................................................ 98
7.2. Assessment ............................................................................................................ 99
7.2.1. Policy .................................................................................................................. 99
7.2.2. Determinants of health ....................................................................................... 103
7.2.3. Risk factors ....................................................................................................... 106
7.2.4. Health outcomes ............................................................................................... 112
7.3. Discussion ............................................................................................................. 120
7. 4. References ........................................................................................................... 121

8. LIGA.NRW DUSSELDORF, GERMANY NATIONAL REPORT ..................................... 124
8.1. METHODOLOGY .................................................................................................. 125
8.2. DISTRIBUTION OF DISEASES WITHIN EUROPE ........................................... 126
8.2.1. Healthy Life Years (HLY) in EU-27 ................................................................. 126
8.2.2. Disability-Adjusted Life Years (DALY) in EU-27 ............................................. 127
8.2.3. Preliminary conclusions .................................................................................... 131
8.3. MAJOR RISK FACTORS FOR HEALTH IN THE EU-27 COUNTRIES ................ 132
8.4. TO WHAT EXTENT CAN THE EC HEALTH STRATEGY CONTRIBUTE TO TAP THE FULL POTENTIAL HEALTH GAINS? ......................................................................................................................... 132
8.5. CONCLUSIONS .................................................................................................... 133
8.6. REFERENCES ....................................................................................................... 134
ANNEX I. MINUTES OF THE INTERVIEW AT DG SANCO ............................................. 135
1. Aim and conduct of the work package 6

Work package 6 aimed to test the developed policy risk assessment methodology by conduct of policy risk assessment of a European Union policy. Previous work packages of RAPID project developed a top-down and bottom-up methodology for policy risk assessment and the project coordinator opened a negotiation with EAHC and DG SANCO to identify an EU policy which will be used to test the developed top-down methodology. At the end of negotiation all parties agreed on testing the methodology on “the EU Health Strategy 2008-2013”.

The process started by interviewing two employees of DG SANCO Christoph Hofbeck and Laurent Bontoux at DG SANCO in Brussels; Paloma Martin focal person of the RAPID project from EAHC also attended the interview. After interview work package partners were informed about the outcomes of the interview and all partners started to assess the Health Strategy using the top-down methodology developed in previous work packages. The project group met first at 11th. HIA International conference in Granada, Spain; that meeting was followed by two virtual meetings of the project group using Adobe Pro Connect system, numerous e-mail exchanges and a project group meeting in Copenhagen, Denmark at beginning of November 2011. This report summarizes the whole process, includes the updated top-down methodology guidance and in annexes the national reports.

2. Method of assessment

The main objective of this work package was to tests the developed policy risk assessment tool on a real case, the case of EC Health strategy. First an interview with DG SANCO colleagues was conducted and after that the work package group underwent an intensive discussion process to conduct the assessment. As final agreement, LIGA.NRW, UD MHSC, MUS, IVZ RS and UBB decided to apply the RAPID tool to EC Strategy on specific topics as a kind of continuation of their work within previous work package of the project. IVZ RS presents a slightly different approach as the other impact assessment oriented national reports; they fit the risk assessment terminology to four levels of full chain. Hazard identification is the policy level, hazard description is the determinants of health level, exposure assessment is done on risk factor level and health effects are the risk characterization part. SDU, TU and RUVZ agreed to focus on an attempt to apply the standard risk assessment terminology for policy and approach the task as an assessment of what kind of hazard can put success of EC health strategy into risk and whether or not such a risks could be quantified. The following description attempts to summarize findings of all partners. Annex I. contains the minutes of the interview at DG SANCO. In summary, the meeting and interview provided more insight into Strategy and helped to identify some issues relevant to be included in top-down methodology especially on policy level. Looking at inclusion of performance indicators and divisions of aims and objectives of a policy into short, medium and long term ones could further improve content of policy risk assessment on policy level of the full chain. The discussion opened the issue of difference between evaluation, risk assessment and impact assessment which needs to be addressed in final RAPID product and report. DG SANCO colleagues also informed
about mid-term evaluation of the Strategy expected to be completed by fall 2011 (has been published in meantime).

3. Executive summary

Does policy risk assessment differ from policy evaluation? Yes, it does! Policy evaluation can be defined as a process by which general judgments about quality, goal attainment, program effectiveness, impact, and costs can be determined. In essence, policy evaluation is the process used to determine what the consequences of public policy are and what has and has not been achieved. (Theodoulou and Kofinis, 2004). Policy evaluation consists of process, outcome, impact and cost-benefit evaluation and it is mostly done retrospective, e.g. after a policy is implemented.

Risk assessment in broader sense could be defined as the identification, evaluation, and estimation of the levels of risks involved in a situation, their comparison against benchmarks or standards, and determination of an acceptable level of risk (http://www.businessdictionary.com/definition/risk-assessment.html). According to FAO/WHO hazard identification, hazard characterization, exposure assessment and risk characterization are the main steps of risk assessment process (IPCS 2004). Using this approach for a policy means that in a policy risk assessment we are looking at factors (hazard identification) which might hinder achieving the full potential of a policy and if possible attempting to quantify the risk related to those factors. Accordingly, in every step of the tool, at every question the aim should be on identification of hazard (as first), discussion on possibility to measure it (characterize), express dose-response relationship (second) and express qualitatively or quantitatively the risk (third). Policy risk assessment is expected to be done prospectively, before a policy is implemented or parallel with policy implementation; this is a major difference in comparison to policy evaluation.

The RAPID guidance (methodology, tool) is predominantly targeted for use within health impact assessment (HIA) of policies. Impact assessment can be part of policy evaluation. It needs to be stressed that the time direction is again the main difference in case of HIA and policy evaluation (not to mention at this point participation and other value based principles of HIA as another set of differences). HIA aims to assess future (health) impacts of recent or planned policies whereas policy evaluation does the work retrospective way. Expected users of RAPID guidance (methodology, tool) are therefore HIA practitioners, planner on different levels of administration, public policy developers and civil servants on different levels of administration.

A glossary of risk assessment terminology would support easy and practical use of the guidance. There is several risk assessment glossaries mostly related to the traditional use of risk assessment (toxicological, technological, economic) which could be applied to policy risk assessment as well. The glossary of US Environmental Protection Agency available at http://www.epa.gov/risk_assessment/glossary.htm and the glossary of the International Program on Chemical Safety by WHO available at http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf seem to be the two most
comprehensive and relevant glossaries. Yet, application of the standard risk assessment terminology for policy risk assessment is not easy.

Policy risk assessment at policy level of the full chain approach aims to identify hazards which might put success of the policy (impact of the policy) at certain risk. It could be hypothesized that if a policy due to those hazards will not lead to change in status of the determinants of health the chain will stop and there will be no changes in prevalence of risk factors and at the end in prevalence of health effects (due to policy assessed. The RAPID guidance therefore suggests combination of risk assessment methodology on policy-determinant level with impact assessment method across determinants of health – risk factors – health effect levels. Quantification, if possible and relevant, always happens between two closest levels.

Applying the full chain concept the hardest issue is to distinguish between the determinants of health and risk factors. This is a general issue within public health and there are several explanations including terminology. The Commission on social determinants of health of WHO introduced the term “causes of the causes” (Marmot, 2005), Keleher is using the term proximal and distal determinants of health (Keleher 2007), Turrel (Turrel 1999) introduced classification as downstream, midstream and upstream determinants and the term “wider determinants of health” is also used in public health literature (Wanless 2004). For RAPID purposes and for the RAPID guidance we understand determinants of health those structural determinants which are directly linked to policies. Typically the term risk factor is used in epidemiology to describe the (positive or negative) association between a factor and health outcomes. In the RAPID guidance risk factors are understood to be directly linked to concrete population at risk and are direct outcome of changes in determinants of health.

The RAPID guidance developed in previous work packages proved to be a useful tool to assess potential risks related to EC Health strategy. The work package group applied it on three different ways focusing on application of risk assessment methodology to policy level only (SDU, TU, RUVZ), on full chain by dividing the risk assessment steps by levels of full chain (IVZ RS) and as a guidance to conduct the risk appraisal part of a HIA addressing a policy (LIGA.NRW, MS, UD MHASC and UBB). In all three directions the guidance allowed to identify major hazards and outline possible impacts (in selected cases lead to quantification of impact). The identified hazards were:

- Coherence among objectives, principles and implementation methods
- Lack of monitoring and evaluation processes as well as performance indicators
- Unclear policy actors
- Unclear target groups

It seems to be obvious, that a full chain policy risk assessment using the RAPID guidance needs to combine risk assessment and impact assessment approaches; the policy level could be described by risk assessment approach, yet quantification of risks need more work. For practice even identification of hazards which might question success of policy in terms of its impact is a useful thing. The remaining three levels, determinants of health, risk factors and health effect could be assessed by more impact assessment methodology as presented in enclosed national reports. The RAPID guidance has been modified by adding more information in “how to do part” and most importantly by adding the
horizontal prioritization tool developed by IVZ RS. However, users need to be aware that the tool similarly as the whole RAPID guidance would need more testing after the project is over. Further changes of the tool are expected after closure of recently ongoing national workshops where the tool is discussed with potential users.

3.1. Application of the RAPID guidance to EC Strategy

Policy (strategy, program, regulation)

- **Must do:**
  - Place the policy into international and/or national context
  - Describe policy content (main goals, scope, implementation plan, methods of monitoring and evaluation)
  - Identify the problem, demand for action, policy actors and ideas
  - Identify target population of the policy
  - Identify performance and outcome indicators in policy
  - Assess whether goals and actions are divided to short, medium and long term
  - Consider if cross-analysis across actions, principles and goals could be conducted
  - Determine the time course, feasibility and costs of implementation
  - List information sources for the description

- **Determinants of health**
  - **Must do:**
    - Define the model of health determinants applied, preferably presenting the holistic model of health
    - Identify influenced health determinants
    - Decide upon using a full-scale or limited selection of health determinants for assessment; if limited selection is used, describe horizontal prioritization of health determinants.
    - Consider strength of evidence of causality/association/plausibility of the change in determinants caused by policy and importance of the related effect (size of population affected, severity of health effects, costs involved), feasibility of assessment favourably in a quantitative way, demand of policy-makers and extent of resources available
    - Assess interactions between health determinants
    - List information sources used to do the assessment and description

- **How to do:**
  - Identify the most applicable and scientifically approved/accepted models for the policy (Lalonde, Dahlgren & Whitehead, others...)
  - Make extensive literature review
- Use systematic reviews on determinants of health and policies to choose the model and the determinants; if not available consult planner, policy makers, experts form public health research
- Use expert opinion, even with the involvement of stakeholder participation
- Use the horizontal prioritization tool developed by Slovenian partner:
  - Score each of following criteria were selected: number of people affected, quality of life affected, national expenses affected and literature evidence from 1 (minimum effect) to 5 (maximum effect) for each relevant determinant of health.
  - Place results into a table, summarize them by determinants and make a ranking
- Consider loops and horizontal interactions of individual determinants

- **Risk factors**
  - **Must do:**
    - Enlist all attendant risk factors by wider determinants of health
    - Prioritize risk factors in a transparent way; make internal loops of consideration between risk factors and health outcomes (include also health determinants if necessary) in the prioritization process
    - Consider strength of evidence (reliability of literature source, biological plausibility etc.) between determinants of health and risk factors and significance of induced changes in prevalence and distribution of risk factor (size of change influenced by the policy, size of population affected and severity of the change)
    - Consider feasibility of quantitative exposure assessment (availability of applicable exposure measures, numerical information on the baseline level/prevalence of exposure and on the expected change of exposure related to policy implementation)
    - Describe routes of exposure and population exposed
    - Assess exposure, dose response functions
    - If direct exposure measures are not available, use proxy measures
    - Assess interaction between risk factors
    - List information sources where did you get your information

- **How to do:**
  - Literature search with focus on epidemiological literature
  - Database search /specify (Eurostat, national statistics offices, environmental exposure databases, etc...)
  - Qualitative assessment (indicating the direction of change or by categorically describing its size) of the determinants-risk factor relation
  - Quantitative assessment of determinant-risk factor relation(calculating frequency (prevalence) or level (dose, concentration) of exposure), distribution f risk factor in population by available and relevant population groups
  - Use the horizontal prioritization tool developed by Slovenian partner:
• Score each of following criteria were selected: number of people affected, quality of life affected, national expenses affected and literature evidence from 1 (minimum effect) to 5 (maximum effect) for each relevant determinant of health.
• Place results into a table, summarize them by determinants and make a ranking

• **Health outcomes**
  - **Must do:**
    - Define health outcomes (apply ICD codes)
    - Prioritize health outcomes in a transparent way
    - Consider strength of evidence for causality, severity (morbidity, disability and mortality), reversibility and frequency of occurrence in the population (in short the public health importance) of relation between risk factor and health effect
    - Identify populations affected with special attention to susceptible subgroups
    - Consider availability and validity of baseline frequency data of the health condition and of dose/exposure-response functions applying dose-response coefficients or relative risk estimates
    - Assess change in health outcomes
    - Calculate cost related to health outcome if possible
  - **How to do:**
    - Literature search including medical, epidemiological and health economic literature
    - International, national, regional, local statistics
    - Qualitative assessment (by indicating the direction of change or by categorically describing the size of effect)
    - Quantitative assessment (by calculating simple frequency measures such as morbidity, hospitalization, mortality etc.) or measures of disease burden (attributable death, potential years of life lost and disability adjusted life years); give preference to complex disease burden measures (disability adjusted life years) if available and feasible

• **Cross-level issues**
  - Consider disadvantages of quantification (a single estimate may cover the complexity of the issue as well as the uncertainty of estimation, double counting)
  - There are likely to be many different full chain pathways within one case; if possible assess interrelations between various causal pathways
  - Indicate baseline scenario (what if current trends continue without policy change) at the various levels of the chain
  - Acknowledge limitations in the use of methodology
Describe uncertainty in a qualitative or quantitative way (provide ranges for estimates) at relevant points of the causal pathways as well as the overall uncertainty related to the full chain assessment.

Consider latency period of the realization of health effects, differentiate short and long term effects.

3.2. References


Keleher H, Murphy B: Understanding Health; a determinants approach, OUP 2007, Oxford, UK

Marmot M: Social determinants of health inequalities, the Lancet 2005, 365 (9464), p. 1099-1104


Turrel G, Oldenburg B, McGuffog I, Dent R: Socioeconomic determinants of health: Towards a National Research Program and a Policy and Intervention Agenda, 1999, School of Public Health, Queensland University of Technology Ausinfo, Canberra

4. IVZ RS Ljubljana, Slovenia report

Prepared for the project Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012

EU (DG-SANCO) Grant agreement No 20081105

**Top – down case study – Managing possible threats in the public health (testing the algorithm for meningococcal invasive outbreak)**

Peter Otočec, Katarina Bitenc

National Institute of Public Health, Slovenia
4.1. Introduction

The new Community health strategy set out in the White Paper relates to health in all sectors. It must also, in a single strategic framework, confront the growing challenges for the health of the population, such as demographic changes, pandemics, bioterrorism and illnesses related to unhealthy lifestyles (Commission Of The European Communities, 2007).

The main goal of objective 2 is to strengthen mechanisms for surveillance and response to health threats, because protection of human health is an obligation under Article 152 EC. Improving safety and security and protecting citizens against health threats have therefore always been at the heart of Community health policy, while at the same time the EU has a responsibility regarding the health of citizens in third countries.

The Strategy encompasses whole Public health issues and one of them is also protecting citizens from health threats.

Community-level work also includes scientific risk assessment, preparedness and response to epidemics.

The Strategy has impact on Community lead actions, which are implemented on National level.

In this document, the implementation of Community health strategy is presented on a case of reduction of Meningococcal disease on National level.

Meningococcal disease is caused by Neisseria meningitidis, a bacterium with human carriers as the only reservoir. It is carried in the nose, where it can remain for long periods without producing symptoms. Following exposure (inhalation of infective droplets) the carrier state may develop and last for some time. Due to a series of factors, a very low proportion of carriers (less than 1 %) will eventually become ill. This most frequently occurs in young children, but a second disease peak is observed among adolescents and young adults. (European Centre for Disease Prevention and Control. Meningococcal Disease, n.d.).

The incidence of meningococcal disease varies throughout Europe, and although there are many reasons for this, it is important to quantify the degree of under-ascertainment in order to validate international comparisons. The notification rate of meningococcal disease remains low across Europe (0.9 per 100 000) and appears to have stabilised over recent years after having, decreased by half since 1999 (1.9 per100 000) (European Centre for Disease Prevention and Control, 2010).

Serogroup B is the most common cause of invasive meningococcal disease in Europe, followed by serogroup C. The proportion of cases attributable to serogroup C disease is highly variable. The case-fatality rate is 6-7 % on average, although this varies by age and serogroup.

European Union gives special attention to vaccine-preventable diseases and immunisation programmes in EU countries. Vaccination has been an increasingly effective weapon in the fight against infectious diseases since their first development in the 19th century. Indeed, vaccination has been so effective that
in most European countries the incidence of formerly common childhood diseases is low and their detrimental effects are extremely rare. This has been achieved through continuous high levels of vaccination coverage, and the resulting high immunity in the population needs to be maintained (European Union Invasive Bacterial Infections Surveillance, 2001).

Based on the EU strategy, European Centre for Disease Prevention and Control has decided to prepare a guidance called Public health management of sporadic cases of invasive meningococcal disease and their contacts. The purpose of this guidance is to provide evidence-based guidance for good practice in public health management of sporadic cases of meningococcal disease and their contacts. It has the additional aim of assisting countries across Europe in making decisions about appropriate measures to control and prevent meningococcal disease at national and sub-national levels (European Centre for Disease Prevention and Control, 2010).

This guidance document should assist European countries in reviewing their own policies on public health management and microbiological diagnosis of meningococcal disease. That is why a special additional document has also been created in Slovenia which presents the theoretical support for different emergency situations regarding meningococcal disease and general guidelines, how to manage the possible threats in the public health (National Institute of public health, 2011).

4.2. Hazard Identification (Policy description)

Health is the main concern in people's lives and needs to be supported by effective policies and actions in Member States, at EC level and at global level.

Member States have the main responsibility for health policy and provision of healthcare to European citizens. But there are areas where Member States cannot act alone effectively and where cooperative action at Community level is indispensable. These include major health threats and issues with a cross-border or international impact, such as pandemics, as well as those relating to free movement of goods, services and people.

The White Paper which has been adopted on 23rd October 2007 sets out a new Community health strategy until 2013, which is designed to confront the growing challenges to the health of Europe's citizens, such as population ageing, cross-border health threats or illnesses linked to unhealthy lifestyles. This strategy is also intended to strengthen, in a single strategic framework, Community cooperation in the areas in which the Member States cannot act alone, ensure that health is better understood at European level and worldwide, and secure a bigger role for health in all policies. To this end, the White Paper proposes four principles and three strategic objectives for the coming years (Commission Of The European Communities, 2007).

Fundamental principles for EC action on health:

Principle 1: a strategy based on shared health values
Principle 2: "health is the greatest wealth"

Principle 3: health in all policies

Principle 4: strengthening the EU's voice in global health

Health policy at Community level should foster good health, protect citizens from threats, and support sustainability. In order to meet the major challenges facing health in the EU, this strategy identifies three objectives as key areas for the coming years:

Objective 1: fostering good health in an ageing Europe

Objective 2: protecting citizens from health threats

Objective 3: supporting dynamic health systems and new technologies

The main goal of objective 2 is to strengthen mechanisms for surveillance and response to health threats, because protection of human health is an obligation under Article 152 EC. Improving safety and security and protecting citizens against health threats have therefore always been at the heart of Community health policy, while at the same time the EU has a responsibility regarding the health of citizens in third countries.

Community-level work includes scientific risk assessment, preparedness and response to epidemics and bioterrorism, strategies to tackle risks from specific diseases and conditions, action on accidents and injuries, improving workers' safety, and actions on food safety and consumer protection.

The Commission will continue this work, but will also focus on challenges that have not yet been fully addressed. Globally, increased trade and travel have brought new risks by facilitating the spread of communicable diseases. Combating pandemics or biological incidents and addressing the threat of bioterrorism requires Community-level cooperation and coordination between Member States and international actors.

Action is also needed on emerging health threats such as those linked to climate change, to address its potential impact on public health and healthcare systems. Patient safety is a further key area of concern. 10% of patients admitted to hospital in the UK experience adverse effects from their healthcare27, and this problem may well be of a similar scale in other EU countries. A new focus is needed to tackle health threats within and outside the EU (Commission Of The European Communities, 2007).

**Actions**

Strengthen mechanisms for surveillance and response to health threats, including review of the remit of the European Centre for Disease prevention and Control (Commission).

**Implementation mechanisms**
This strategy aims to deliver concrete results in improving health. As set out in the Treaty, the EC has a unique role to improve and protect health and in addition to facilitate cooperation on health.

Given Member States’ responsibilities in health at national, regional and local levels, and the need to respect subsidiarity, they must be closely involved in the implementation of the Strategy. To that end, the Commission will put forward a new EC-level structured cooperation mechanism to advise the Commission and to promote coordination between the Member States. This will include a new structure with Member States replacing some existing committees. This cooperation mechanism will assist the Commission in identifying priorities, defining indicators, producing guidelines and recommendations, fostering exchange of good practice, and measuring progress. It will also provide opportunities for local and regional involvement. The Commission will work across sectors and ensure consistency with other bodies that deal with health-related issues such as the Administrative Commission and the Social Protection Committee.

Value can be added to Member States’ action through fostering cooperation with stakeholders at Community level. The Commission will continue to develop partnerships with them, building on the experience of bodies such as the Health Forum, the European Alcohol and Health Forum, and the Platform on diet, physical activity and health.

**Description of the health threat, which EU policy can affect**

**Case of Meningococcal disease**

Meningococcal disease is a contagious bacterial disease caused by Neisseria meningitis (N. meningitis). The bacteria causing meningococcal invasive disease can invade the blood or spinal fluid of an individual, causing sepsis (blood infection) or meningitis. Even when appropriate treatment is administered, 5-15% of people diagnosed with this disease will die. Survivors may have permanent hearing loss, neurological damage, or loss of a limb.

In 2007, 5 586 cases, of which 5 180 cases were confirmed, were reported by all countries in EU, except Liechtenstein (Figure 1). Ireland and the United Kingdom reported the highest notification rates with 3.8 per 100 000 and 2.5 per 100 000, respectively. The lowest notification rate was reported by Italy (0.3 per 100 000), but the country rates were very similar at just under 1 per 100 000. The overall notification rate was one per 100 000, similar to that for 2006 (0.98 per 100 000). Considering the numbers of reported cases over recent years, there appears to have been an overall decline in incidence since 2000, though this does not seem to have continued in 2007 (European Centre for Disease Prevention and Control, 2010).

There are between 6 and 18 cases of meningococcal meningitis reported yearly in Slovenia and the patients are all hospitalized. Infants (0-2 year old) have the highest occurrence of new cases of
meningococcal meningitis. However all age groups are at risk, particularly young adults and the elderly (National Institute of Public Health, 2011).

Figure 1. Number of confirmed cases of invasive meningococcal disease in Slovenia, 2005-2010

Table 1. Number and notification rate of reported cases of invasive meningococcal disease in the EU and EEA/EFTA, 2007

<table>
<thead>
<tr>
<th>Country</th>
<th>Report type</th>
<th>Total cases</th>
<th>Confirmed cases</th>
<th>Notification rate per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>C</td>
<td>69</td>
<td>61</td>
<td>0.74</td>
</tr>
<tr>
<td>Belgium</td>
<td>C</td>
<td>160</td>
<td>160</td>
<td>1.5</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>A</td>
<td>38</td>
<td>24</td>
<td>0.31</td>
</tr>
<tr>
<td>Cyprus</td>
<td>C</td>
<td>4</td>
<td>4</td>
<td>0.53</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>C</td>
<td>76</td>
<td>76</td>
<td>0.74</td>
</tr>
<tr>
<td>Denmark</td>
<td>C</td>
<td>78</td>
<td>78</td>
<td>1.4</td>
</tr>
<tr>
<td>Estonia</td>
<td>C</td>
<td>11</td>
<td>11</td>
<td>0.82</td>
</tr>
<tr>
<td>Finland</td>
<td>C</td>
<td>43</td>
<td>43</td>
<td>0.81</td>
</tr>
<tr>
<td>France</td>
<td>C</td>
<td>723</td>
<td>680</td>
<td>1.3</td>
</tr>
<tr>
<td>Germany</td>
<td>C</td>
<td>436</td>
<td>436</td>
<td>0.53</td>
</tr>
<tr>
<td>Greece</td>
<td>C</td>
<td>129</td>
<td>129</td>
<td>0.95</td>
</tr>
<tr>
<td>Hungary</td>
<td>C</td>
<td>16</td>
<td>16</td>
<td>0.43</td>
</tr>
<tr>
<td>Ireland</td>
<td>C</td>
<td>179</td>
<td>162</td>
<td>3.8</td>
</tr>
<tr>
<td>Italy</td>
<td>C</td>
<td>183</td>
<td>178</td>
<td>0.30</td>
</tr>
<tr>
<td>Latvia</td>
<td>C</td>
<td>21</td>
<td>21</td>
<td>0.66</td>
</tr>
<tr>
<td>Lithuania</td>
<td>C</td>
<td>66</td>
<td>50</td>
<td>1.5</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>C</td>
<td>2</td>
<td>2</td>
<td>0.42</td>
</tr>
<tr>
<td>Malta</td>
<td>C</td>
<td>6</td>
<td>6</td>
<td>1.5</td>
</tr>
<tr>
<td>Netherlands</td>
<td>C</td>
<td>195</td>
<td>189</td>
<td>1.2</td>
</tr>
<tr>
<td>Poland</td>
<td>C</td>
<td>392</td>
<td>336</td>
<td>0.88</td>
</tr>
<tr>
<td>Portugal</td>
<td>C</td>
<td>117</td>
<td>98</td>
<td>0.92</td>
</tr>
<tr>
<td>Romania</td>
<td>C</td>
<td>155</td>
<td>145</td>
<td>0.67</td>
</tr>
<tr>
<td>Slovakia</td>
<td>C</td>
<td>37</td>
<td>35</td>
<td>0.65</td>
</tr>
<tr>
<td>Slovenia</td>
<td>C</td>
<td>18</td>
<td>18</td>
<td>0.90</td>
</tr>
<tr>
<td>Spain</td>
<td>C</td>
<td>816</td>
<td>619</td>
<td>–</td>
</tr>
<tr>
<td>Sweden</td>
<td>C</td>
<td>49</td>
<td>49</td>
<td>0.56</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>C</td>
<td>1522</td>
<td>1522</td>
<td>–</td>
</tr>
<tr>
<td>EU total</td>
<td></td>
<td>5586</td>
<td>5180</td>
<td>1.00 (0)</td>
</tr>
</tbody>
</table>

Source: European Centre for Disease Prevention and Control, 2010b, p. 162
4.3. Hazard characterization (Determinants of health)

EU LEVEL

Hazard characterization could be considered as a description of determinants of health addressed by policy. Based on actions enlisted above we can consider as only determinant of health targeted by Strategy of health systems / health care. This actions address health care or health system issues.

Based on this strategy a special document has been created by European Centre for Disease Prevention and Control (ECDC). Guidance was prepared and is called Public health management of sporadic cases of invasive meningococcal disease and their contacts. This guidance document assists European countries in reviewing their own policies on public health management and microbiological diagnosis of meningococcal disease. This documents covers the following relevant areas:

- Laboratory tests to confirm the diagnosis of IMD.
- Use of antibiotics at discharge from hospital.
- Chemoprophylaxis for close contacts considering different settings.
- Choice of antibiotic for chemoprophylaxis for different groups (adults, children, pregnant women).
- Use of meningococcal vaccine in addition to chemoprophylaxis.

In addition to the quality of scientific evidence, the conclusions take into account potential benefit and harm, values, burdens and costs (European Centre for Disease Prevention and Control, 2010).

Three main population groups that this policy could affect:

- Public health services (epidemiologists, policy makers...),
- whole population,
- patients.

NATIONAL LEVEL

The guidance document from ECDC should assist countries across Europe in making decisions about appropriate measures to control and prevent meningococcal disease at national and sub-national levels. This work was prepared to ensure the countries’ strong and proper surveillance of meningococcal disease so that is why in Slovenia we also created a Document for Management of Meningococcal
Disease focused specifically on the procedure and relationships between national and local public health institutions and was prepared by epidemiologists from both levels (National Institute of public health, 2011).

The objective of public health management of outbreaks is to interrupt the transmission of disease and prevent further cases occurring. This can be achieved by establishing a response team, making a site visit if appropriate, undertaking intensified surveillance, providing adequate information and initiating appropriate use of clearance antibiotics and/or vaccination. It is important to prepare in advance a flowchart regarding the communications between the outbreaks.

National policy description

Once an outbreak is either suspected or recognised there is an immediate need to initiate a coordinated response. Elements of this response include:

- a situation review to determine if there is an outbreak and its extent;
- the establishment of a response team(s) and, if possible, a site visit;
- ensuring the institution of clearance antibiotics and/or immunisation as required for the setting, and the provision of information to all contacts and other persons involved;
- establishment of heightened surveillance;
- determination of the population at risk and calculation of age-specific and region-specific attack rates;
- decisions on what action is to be taken;
- provision of adequate information to health care providers, affected communities, the media and the general public; and
- review of all actions taken and the preparation and dissemination of final documentation and a report. (National Institute of public health, 2011).

Involved sectors:

- Ministry of health,
- National Institute of Public Health,
and other representatives from the field of policy and medicine.

The document was discussed with representatives of all involved sectors and groups.
Figure 2: Flow chart for meningococcal invasive outbreak

- Clinician suspecting a meningococcal meningitis
- Early notification to regional institute of public health (IPH)
- Microbiological laboratory of national IPH: diagnostics (PCR) and typing
- Noticing laboratories; transport of samples
- Feedback about the partial and final results and serogroups
- Microbiological laboratory of regional IPH: sends isolates for typing
- Epidemiologist located at regional IPH: treatment of all possible cases and
- Department for providing supplies for appropriate chemoprophylaxis (NIPH)
- Reporting and receiving notices (EWRS, IHR, ...)
- Epidemiologist located at NIPH: coordination, informing epidemiologists and public, risk assessment
- Reporting NIPH

The National Document for Management of Meningococcal Disease is expected to have impact on following health determinants:

SOCIOECONOMIC DETERMINANTS

Financial burden of disease;

**Lower cost of treatment and lost workdays**

Vaccination with serogroup C conjugate vaccines has contributed to a decrease in incidence of the disease in European countries over the last ten years (Trotter, C.L. et al., 2007).

The standard cost of illness approach is used for acute hospitalisations, and consists in applying unit economic values approach to each case, including direct medical and indirect costs.

In Slovenia, the average direct cost\(^1\) of a meningococcal meningitis hospital admission is 2400 € (10 days of hospitalization x 240 € average cost per day for hospitalization) and the corresponding indirect cost\(^2\) related to work loss is 680€ (2 x 10 days of hospitalization x 34 € is average cost per day for work loss).

The total medical costs for meningococcal meningitis hospital admissions are obtained by adding together the direct and indirect components. Overall, the unit economic value related to a meningococcal meningitis hospital admission is 3080 €.

There are approximately 12 cases of meningococcal meningitis per year and that is overall cost 36.960 € for 12 cases of meningococcal meningitis in Slovenia (National Institute of Public Health, 2011).

Activities stated in national document regarding fast response and giving appropriate prophylaxis can prevent from new cases of the disease.

Although occupational injuries and illnesses have declined in recent years, lost work time remains an important and costly problem for employers.

---

\(^1\) The direct medical costs related to meningococcal meningitis hospital admission are computed as the cost per inpatient day times the average length of stay in hospital. These cost data are taken from CEC (2008). The average lengths of stay in days are obtained from National Institute of Public Health databases for hospital admissions (National Institute of Public Health, 2011).

\(^2\) The indirect costs are computed as the average gross loss of production per day times twice the average length of stay in hospital. Since we cannot control whether these days were actual working days, we then compute the daily loss of production as the average gross earnings in industry and services (full employment) obtained from Eurostat (2003), expressed in 2005 and divided by 365 days.
Quantification of the impact of Determinant of health – Socio–economic determinant – financial burden

There are approximately 12 cases of meningococcal meningitis per year and that is overall cost 62,280 € for 12 cases of meningococcal meningitis in Slovenia (National Institute of Public Health, 2011).

Such estimate is hard to do as the number of cases may change during the years, but in any case there is still a significant number of people whom develop disease and represent not needed expense.

Living in lower socioeconomic communities and in crowded housing

Although the policy does not tackle directly socio–economic determinants leading to overcrowding, the aim of the policy is still raising awareness of the determinants and therefore the policy has very vague impact on the improvement of socio–economic conditions.

Poor and less affluent population groups tend to be more often affected by inadequate housing conditions and higher environmental burden in their residential environments.

An epidemic caused by group C sulfonamide-resistant Neisseria meningitidis occurred during an eight-month period in two lower socioeconomic communities in Dade County, Florida. Five of 85 close contacts of patients (5.9%) contracted meningococcal disease. Nasopharyngeal carriage and serologic evidence of meningococcal infection were significantly more frequent among close contacts than among controls in the neighborhood. The risk of meningococcal infection was found to be significantly greater for persons who shared five-person bedrooms than for those who slept in less crowded bedrooms (Kaiser, A.B. et al., 1974).

The relationship between overcrowding and health is complex. Overcrowding is associated with other health determinants such as income as well as exposure to other risk factors such as tobacco smoke. Some studies found that people who live in more crowded housing have poorer physical and mental health (Ministry of Health, 1999; Howden-Chapman, P. Wilson, N., 2000).

In national Document for Management of Meningococcal Disease is explicitly stated that it is important to provide adequate information to health care providers, affected communities, the media and the general public and to determine the population at risk and calculation of age-specific and region-specific attack rates.

In a document there is a strong need to inform people and raise awareness of other health determinants and risks that follow for development of Meningococcal disease.
Personal determinants of health (smoking, drinking, poor hygiene) have important impact on development of disease.

For that reason the strategy has also impact on other determinants of health (smoking, alcohol abuse...).

**Environmental determinants – indoor environment**

For many years, the indoor environment has been acknowledged as one of the main settings that affect human health. Living and housing conditions are the basis of many factors influencing residential health. Epidemiological findings suggest strong associations between housing conditions and health effects. Indoor air quality, humidity and mold growth, indoor temperatures, lack of hygiene and sanitation equipment, and crowding are some of the most relevant possible health threats to be found in dwellings in can help transmitting microorganisms that cause diseases including meningococci (Bonnefoy, X., 2007).

Meningococcal Disease and College Students: Multiple studies have been conducted in the United States and the United Kingdom concerning the risk for meningococcal disease among college students. The risk for meningococcal disease among U.S. college students was higher for those who resided in dormitories than for those residing in other types of accommodations. (Cases of meningococcal disease occurred 9 to 23 times more frequently among students living in dormitories than among those living in other types of accommodations.). A recent study conducted in the United Kingdom demonstrated a rapid increase in carriage rates of meningococci among university students in the first week of the fall semester, although rates of disease peaked later in the academic year (Infectious Disease Epidemiology Section, Office of Public Health, 2008).

**Behavioral and personal determinants**

**Smoking**

Smoking is the main cause of exposure to cigarette smoke. Smoking rate depends on a number of reasons, which can be divided in sub determinants. Smokers are more likely to be male than female, under 54 years of age (European Commission, 2010). Active smoking and passive exposure to tobacco smoke increase the risk of illness.

Smoking rate depends on number of reasons (very personal, psychological, lifestyle) within the behavioral and personal factors. There is also dependency between sub factors of the group (smoking rate has impact on alcohol abuse and close contacts).

Meningococcal carriage has been associated with cigarette smoking and/or passive smoke exposure in several studies (Blackwell, C. C., et al., 1992; Blackwell, C. C. et al., 1990; Caugant, D. A. e tal., 1994).
Active smoking and the presence of other smokers in the household were independently associated with meningococcal carriage; the risk of carriage increased significantly with heavier smoking (Stuart, J. M. Cartwright, K. A. V. Robinson, P. M. Noah, N. D.. 1989).

Smoking prevalence in Slovenia

Figure 3: The proportion of smokers among men and women

In 2007 in Slovenia, there were around a quarter of smokers 15 years and over – 28 % of men and little less than 22 % of women. On average there are 25 % of people over age of 15 years smoking regularly. The proportion of smokers among men have been declining for some years now, while the proportion of smokers among women in the past few years do not record significant changes (National Institute of Public Health of the Republic of Slovenia, 2008).

There are 25 % of people in Slovenia who smoke regularly and are regularly exposed to cigarette smoke, but there are no data on number of people being permanently exposed indoors to SHS, because living with people who smoke (National Institute of Public Health of the Republic of Slovenia, 2008).

Consumption of alcohol

Data from the Canadian study suggest that both alcohol consumption and additional factors common to campus bar environments enhances transmission of N. meningitidis. Evidence from both the stratified and multiple logistic analyses is strongly consistent with a dose-response effect of alcohol consumption on carriage prevalence (Imrey P.B. et al., 1995).

Slovenia is among the European countries with the higher overall (registered and unregistered) consumption of alcohol per capita, and among EU countries with the highest alcohol related disease ratio (Figure 4). Apparent per capita consumption of ethanol from all beverages combined decreased from 11.5 L in 1981 to 9.8 L in 2002.
The decline was substantial in the period from 1981 to 1991. From 1991 to 2000 per capita alcohol consumption decreased by 8.5%, and increased again in 2001 and 2002 (Harkin, A.M. Anderson, P. Goos, C., 1997).

**Figure 4: Preferences for alcoholic drinks in Europe**

![Graph showing preferences for alcoholic drinks in Europe.](image)


Alcohol consumption is a sub determinant of personal determinant that leads to higher likeliness for development of Meningococcal disease.

**Close contacts - Personal hygiene**

Sometimes the bacteria that cause meningitis have spread to other people who have had close or prolonged contact with a patient with meningitis. People in the same household or daycare center, or anyone with direct contact with a patient's oral secretions (such as a boyfriend or girlfriend) would be considered at increased risk of getting the infection. People who qualify as close contacts of a person with meningitis caused by N. meningitidis should receive antibiotics to prevent them from getting the disease (Centers for Disease Control and Prevention, 2011).

There is a high rate of carriage of the pathogenic strain of N meningitidis in patients’ household...
members and kissing contacts, and this supports the practice of giving chemoprophylaxis to these contacts (Bjørn-Erik Kristiansen, Yngvar Tveten, Andrew Jenkins, 1998.).

**Interactions between health determinants**

Low socioeconomic status has influence on crowded housing and this can influence on a large variety of social and personal determinants such as alcohol consumption and smoking, both risk factors for meningococcal disease.

Household density has long been viewed as both an indicator of low socioeconomic status and as a stressful situation associated with high morbidity and mortality risks. Several decades of research have correlated a high household crowding index, denoted by the number of coresidents per room, with socioeconomically deprived urban communities and a wide range of pathological health outcomes (Melki, I. et al., 2004.)

Personal determinants of health act on each other. Going to crowd places means also smoking, consumption of alcohol and unhygienic behaviour and that all determining likeness to develop disease.

Crowded places can affect on smoking which is a social activity as well. Many people who smoke do so as a way to start conversations and interact at parties or in crowded places. This is known as "social smoking," and it usually involves alcohol as a complement. These people smoke mainly or only in social settings, and in the presence of others (particularly other smokers). Social smokers tend to drink more alcohol than non-smokers and they tend to smoke more when they are in social situations than when they are alone. Also different studies of college students reveal that their smoking is strongly associated with alcohol use and attending social events (Rigotti, N. Lee, J.E. Wechsler, H., 2000; Schorling, J.et al., 1994; Emmons, K. Wechsler, H. Dowdall, G. Abraham, M., 1998; Hines, D. Fretz, A. Nollen, N., 1998).

Surprisingly, only few studies have addressed the association between smoking and drinking despite the fact that 80 to 95 % of alcoholics smoke cigarettes. National Institute on Alcohol Abuse and Alcoholism estimates that alcoholism is 10 to 14 times more prevalent among smokers than non-smokers. Other studies estimate that roughly 70 % of alcoholics are classified as "heavy smokers", smoking more than one pack a day (AlcohodMD, 2011.) There is a strong connection between subdeterminants smoking and drinking in the group of Behaviour and Personal determinant of health.

**Risk perception about health determinants**

There were a number of discussions and meeting about the impact of National Meningococcal policy on determinants of health.
Determinants of Health – Setting the hierarchy

How we set hierarchy among determinants of health?

A small easily used table was developed with scoring system (scoring from 1 (minimum effect) to 5 (maximum effect)) (Table 2).

Following criteria were selected: number of people affected, quality of life affected, national expenses affected and literature evidence.

We looked mostly what would unfulfilment of the policy mean for selected criteria.

Table 2: Hierarchy between the determinants

<table>
<thead>
<tr>
<th>Determinant of Health</th>
<th>Number of people affected</th>
<th>Quality of life affected</th>
<th>National expenses affected</th>
<th>Literature evidence</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-economic determinants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of treatment and Lost work days</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>Low socioeconomic status</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>Crowded housing</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>Environmental determinants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indoor environment</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Behavioural and personal determinants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Consumption of alcohol</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Close contacts</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>7</td>
</tr>
</tbody>
</table>

The most important health determinant is low socioeconomic status. The criteria were assessed on very broad way and must be considered with big uncertainty.
The standard cost of illness approach is used for acute hospitalizations, and consists in applying unit economic values approach to each case, including direct medical and indirect costs (Table 3).

We are assuming that hospitalization for meningococcal meningitis last approximately 10 days.

Table 3: Daily hospitalisation average costs and work loss, direct and indirect hospitalisations cost per patient and unit economy values for meningococcal meningitis

<table>
<thead>
<tr>
<th>Country</th>
<th>Average cost per day (€ 2005)</th>
<th>Direct costs related to hosp.</th>
<th>Indirect costs related to hosp.</th>
<th>Unit econ. values</th>
<th>Confirmed Cases (d)</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hosp. all causes (a)</td>
<td>Work loss (b)</td>
<td>Meningococcal meningitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Austria</td>
<td>319</td>
<td>83</td>
<td>3190</td>
<td>1660</td>
<td>4850</td>
<td>61</td>
</tr>
<tr>
<td>Belgium</td>
<td>351</td>
<td>98</td>
<td>3510</td>
<td>1960</td>
<td>5470</td>
<td>160</td>
</tr>
<tr>
<td>France</td>
<td>366</td>
<td>83</td>
<td>3660</td>
<td>1660</td>
<td>5320</td>
<td>680</td>
</tr>
<tr>
<td>Greece</td>
<td>389</td>
<td>48</td>
<td>3890</td>
<td>960</td>
<td>4850</td>
<td>106</td>
</tr>
<tr>
<td>Hungary</td>
<td>59</td>
<td>18</td>
<td>590</td>
<td>360</td>
<td>950</td>
<td>43</td>
</tr>
<tr>
<td>Ireland</td>
<td>349</td>
<td>81</td>
<td>3490</td>
<td>1620</td>
<td>5110</td>
<td>162</td>
</tr>
<tr>
<td>Italy</td>
<td>379</td>
<td>62</td>
<td>3790</td>
<td>1240</td>
<td>5030</td>
<td>178</td>
</tr>
<tr>
<td>Romania</td>
<td>57</td>
<td>6</td>
<td>570</td>
<td>120</td>
<td>690</td>
<td>145</td>
</tr>
<tr>
<td>Slovenia</td>
<td>240</td>
<td>34</td>
<td>2400</td>
<td>680</td>
<td>3080</td>
<td>18</td>
</tr>
<tr>
<td>Spain</td>
<td>321</td>
<td>55</td>
<td>3210</td>
<td>1100</td>
<td>4310</td>
<td>619</td>
</tr>
<tr>
<td>Sweden</td>
<td>427</td>
<td>92</td>
<td>4270</td>
<td>1840</td>
<td>6110</td>
<td>49</td>
</tr>
<tr>
<td>UK</td>
<td>581</td>
<td>116</td>
<td>5810</td>
<td>2320</td>
<td>8130</td>
<td>1522</td>
</tr>
<tr>
<td>Mean (c)</td>
<td>373</td>
<td>73</td>
<td>3730</td>
<td>1460</td>
<td>5190</td>
<td>5146</td>
</tr>
</tbody>
</table>

Sources: (a) CEC (2008), annex 7, cost/bed/day corr; (b) Eurostat (2003); (c) population-weighted average, 2005 population data from OECD Health Data (2010); (d) European Centre for Disease Prevention and Control, 2010b, p. 162.

In EU, the average direct cost of a meningococcal meningitis hospital admission is 3730 € (10 days of hospitalization x 373 € average cost per day for hospitalization) and the corresponding indirect cost related to work loss is 1460 € (2 x 10 days of hospitalization x 73 € is average cost per day for work loss).

3 The direct medical costs related to meningococcal meningitis hospital admission are computed as the cost per inpatient day times the average length of stay in hospital. These cost data are taken from CEC (2008). The average lengths of stay in days are obtained from National Institute of Public Health databases for hospital admissions (National Institute of Public Health, 2011).
The total medical costs for meningococcal meningitis hospital admissions are obtained by adding together the direct and indirect components. Overall in EU, the unit economic value related to a meningococcal meningitis hospital admission is 5190 €.

There are approximately 5146 cases of meningococcal meningitis per year and that is overall cost 26,707,740 € for all cases of meningococcal meningitis in EU (European Centre for Disease Prevention and Control, 2010b, p. 162.).

---

4 The indirect costs are computed as the average gross loss of production per day times twice the average length of stay in hospital. Since we cannot control whether these days were actual working days, we then compute the daily loss of production as the average gross earnings in industry and services (full employment) obtained from Eurostat (2003), expressed in 2005 and divided by 365 days.
4.4. Exposure assessment (Risk factors)

The Policy has strong intention to raise awareness, to educate people about how to prevent themselves from illness. Therefore risk factors on which Policy may have impact are listed and described below.

Persons who have deficiencies in the terminal common complement pathway and those with anatomic or functional asplenia are at increased risk for acquiring meningococcal disease. Antecedent viral infection, household crowding, chronic underlying illness and both active and passive smoking also are associated with increased risk for meningococcal disease. During outbreaks - bar or nightclub patronage and alcohol use also have been associated with higher risk for meningococcal disease (Infectious Disease Epidemiology Section, Office of Public Health, 2008).

Risk factors that derive from Socio – Economical Health Determinant

Protection of risk with vaccination –

Vaccination rates

The risk of low vaccination rates comes from different socioeconomic determinants - low socioeconomic status and high cost treatment.

Higher socio-economic status was associated with a higher rate of full vaccination and private vaccination for children under 5 years of age in Turkey (Topuzoglu, A. et al., 2005).

Socio-economic status can strongly influence on vaccination rates. That was also demonstrated with the survey in Poland where the project of the study was to find out if the childhood immunization rate depends on the social economical status of the families. Non-immunization rate was associated with self-reported poor socio-economic status. The multivariate logistic analysis confirms the effect of socio-economic status variables on the childhood immunization rate (Hubicki, L. Czech, E. Kowalska, M. Zejda, J.E., 2004).

Widespread use of meningococcal vaccination can protect against disease, benefiting adolescents, their close contacts and the public. For these reasons, the Centers for Disease Control and Prevention (CDC) and numerous professional organizations recommend routine meningococcal vaccination for all persons 11-18 years of age at the earliest opportunity, and for college freshmen living in dormitories who have not been vaccinated previously (Centers for Disease Control and Prevention, 2005).

A recent survey of healthcare providers indicates that meningococcal vaccine coverage for teens is disappointingly low (32.4 percent), leaving far too many adolescents vulnerable to serious and deadly
illness. This immunization rate is also well below the 90 percent goal established for most routine immunizations by Healthy People 2010, the Department of Health and Human Services’ national preventive healthcare initiative (U.S. Department of Health and Human Services, 2008).

In countries with MenC conjugate vaccination (MCC), incidence rates were very low in age groups targeted for the vaccination (<0.0036), compared with figures in countries without MCC vaccination (Figure 5) (Czumbel, I. Jansson, A. Pastore-Celentano, L. Gauci, A.A., 2009).

Figure 5: Age group-specific incidence (per 100 000) of IMD serogroup C cases, in countries with MCC and without MCC vaccination, 2007


**Household crowding**

Household overcrowding increases transmission of infectious diseases, particularly those spread by respiratory means and direct person-to-person contact. Given that overcrowding increases contact between people, it is highly plausible that overcrowding is also associated with higher rates of skin and enteric (intestinal) diseases (Patel, P. Mendall, Khulusi, S. et al., 1994).

A large case-control study of meningococcal disease in Auckland children showed that household crowding was the most important risk factor for this disease (Baker, M. McNicholas, A. et al., 2000).
Risk factors that derive from Environmental determinants – indoor environment

Meningococcal Disease and College Students: Multiple studies have been conducted in the United States and the United Kingdom concerning the risk for meningococcal disease among college students. The risk for meningococcal disease among U.S. college students was higher for those who resided in dormitories than for those residing in other types of accommodations. Cases of meningococcal disease occurred 9 to 23 times more frequently among students living in dormitories than among those living in other types of accommodations (Infectious Disease Epidemiology Section, Office of Public Health, 2008.).

Historically, military recruits have been also at high risk of acquiring meningococcal disease. Beginning in the 1940s, the US military relied on mass treatment with sulfadiazine to control outbreaks in training camps. In the 1960s, a vaccine was developed in response to the emergence of sulfadiazine-resistant strains. Since 1971, all new recruits in the US military have been immunized against Neisseria meningitidis during their first days of service (Brundage, J.F. Ryan, M.A.K. Feighner, B.H. Erdtmann, F.J., 2002).

Risk factors that derive from Behavioural and personal determinants

Close contacts – Personal hygiene

In risk assessments, it is important to distinguish between salivary contact and respiratory droplet contact. Neisseria meningitidis colonises the posterior pharyngeal wall and is transmitted through respiratory droplets. In practice, some contact activities may involve both. For example, activities such as intimate (mouth-to-mouth) kissing are likely to involve both an important exchange of saliva and also an important exchange of respiratory droplets, and have been linked to increased risk of carriage (MacLennan, J. et al., 2006) and disease (Tully, J. et al., 2006).

Sharing food and drinks

Auckland study found a slightly higher risk of disease linked to sharing food and drink (Baker, M. et al. 2000), but the association was of marginal statistical significance. It is difficult to separate the risk of this behaviour from the risk of close respiratory contact, which may confound the relationship. If sharing drinks is a risk factor, then the likely route of transmission would be through saliva residue on a cup or glass. (Holdsworth, G. Jackson, H. Kaczmarski, E., 1996).

Smoking rate

One study investigated environmental factors in 74 confirmed cases of meningococcal disease. In children aged under 5, passive smoking in the home (30 or more cigarettes daily) was associated with an odds ratio of 7.5 (95% confidence interval 1.46-38.66). Odd ratios increased both with the numbers of cigarettes smoked and with the number of smokers in the household, suggesting a dose-response
relationship. Public health measures to lower the prevalence of cigarette smoking by parents of young children may reduce the incidence of meningococcal disease (Stanwell-Smith, R.E. e al., 1994).

Queensland study has found that one of the main risk factors among children under six is having a carer who smokes. Smokers are more likely to carry the bacteria that cause the disease. The risk of IMD in young children could be further reduced if primary caregivers did not smoke. (McCall, B.J. Neill, A.S. Young, M.M., 2004).

Alcohol abuse

Data from the Canadian study suggest that both alcohol consumption and additional factors common to campus bar environments enhances transmission of N. meningitidis. Evidence from both the stratified and multiple logistic analyses is strongly consistent with a dose-response effect of alcohol consumption on carriage prevalence. The data also suggest a dose-response effect of exposure to the campus bar environment. However, it is difficult to isolate specific environmental conditions promoting transmission in campus bars by epidemiologic means. Crowding, cigarette smoke, and alcohol would seem the most prominent candidates (Imrey P.B. et al., 1995).

Interactions between risk factors

Socio – economic risk factor - household crowding can have impact on different Behaviour and personal risk factors like alcohol abuse and smoking rate.

Household crowding is also having impact on Environmental risk factors – indoor environment, because a lot of studies have confirmed connection between crowding, risk of spreading diseases and living in dormitories where students have a lot of close contacts (Infectious Disease Epidemiology Section, Office of Public Health, 2008). Strong connection exists between dormitory crowding, smoking and alcohol abuse (Schorling, J. et al., 1994).

Close contacts – Personal hygiene seems to be pretty independent risk factor although there is interaction between Socio – economic risk factor household crowding. There seems to be a connection between poor socio – economic status and same behaviour like sharing food in those groups of people.

Vaccination can protect against disease, benefiting adolescents, their close contacts and the whole public (Centers for Disease Control and Prevention, 2005).

Risk factors – Setting the hierarchy
A small easily used table was developed with scoring system (scoring from 1 (minimum effect) to 5 (maximum effect)) (Table 4).

Following criteria were selected: number of people affected, quality of life affected, national expenses affected and literature evidence.

We looked mostly what would unfulfilment of policy mean for selected criteria.

Table 4: Hierarchy between the risk factors

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Number of people affected</th>
<th>Quality of life affected</th>
<th>National expenses affected</th>
<th>Literature evidence</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-economical risk factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccination rates</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>5</td>
<td>16</td>
</tr>
<tr>
<td>Household crowding</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>Behavioral and personal risk factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol abuse</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Smoking rate</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>Close contacts</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Sharing food &amp; drinks</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

The most important risk factor is household crowding. The criteria were assessed on very broad way and must be considered with big uncertainty.
4.5. Risk Characterization (Health outcome)

Meningococcal Invasive Disease (Meningococcal Meningitis, ICD-10 = A39.0) is a disease caused by the systemic invasion by the bacteria Neisseria meningitidis, also known as meningococcus. Neisseria meningitidis, which in most instances asymptptomatically colonises the human nasopharynx, may also cause rapid-onset septicaemia or meningitis – conditions that are referred to as invasive meningococcal disease (IMD). Although cases of IMD usually appear only sporadically, they may also emerge in clusters, outbreaks and large epidemics (Stephens, D.S. Greenwood, B. Brandtzaeg, P., 2007).

Meningococci are common colonizers of the upper respiratory tract (about 1% to 5% of healthy people are carriers at any time). Meningococci are transmitted when a person coughs, sneezes, or speaks and sends droplets containing meningococci into the air, with other people inhaling the bacteria. The bacteria enter the nose or throat and multiplies locally. If the immune system of the recipient is temporarily weakened, the bacteria may invade the blood, meninges or lung. The host factors that protect carriers from developing invasive disease are: specific functional antibodies, intact complement system and normal reticuloendothelial function. The incubation period is 1 to 10 days, usually less than 4 days. The disease usually develops within a few days of initial colonization (Infectious Disease Epidemiology Section, Office of Public Health, 2008).

Clinical Description

The onset often is abrupt with fever, chills, malaise, prostration and a rash that initially may be macular, maculopapular, or petechial. The signs and symptoms of meningococcal meningitis are indistinguishable from signs and symptoms of acute meningitis caused other meningeal bacterial pathogens. Common symptoms of meningitis include headache, nausea and often vomiting, stiff neck and photophobia. Less common manifestations include pneumonia, febrile bacteremia and conjunctivitis. Complications are arthritis, myocarditis, pericarditis and endophthalmitis. The fulminant cases (Waterhouse-Friderichsen syndrome) are characterized by purpura, disseminated intravascular coagulation, shock and coma. Death may follow within several hours despite appropriate therapy. Meningococcal invasive disease also causes substantial morbidity: approximately 10% to 20% of survivors have sequelae (e.g., neurologic disability, limb loss and hearing loss). Mortality: Despite the continued sensitivity of meningococcus to multiple widely available antibiotics, including penicillin, the case-fatality ratio for meningococcal disease is 10%–15% (Infectious Disease Epidemiology Section, Office of Public Health, 2008).

The European Union case definition of confirmed meningococcal case, encompassing patients meeting the following inclusion criteria (Commission Decision of 28/IV/2008):

- having symptoms of invasive bacterial disease (at least one of the following: fever, meningeal signs, petechial rash, septic shock or septic arthritis); and N. meningitidis isolated from a normally sterile site; or meningococcal DNA identified by polymerase chain reaction (PCR) in material from a normally sterile site; or Gram-negative diplococci detected in cerebrospinal fluid.
The case fatality rate remains around 5–15%, clusters and outbreaks generate significant amounts of anxiety, and even a single case can sometimes have important public health implications (Zuschneid, I. et al. 2008; Caugant D.A. et al., 1994).

Peaks of incidence are seen in children younger than five years of age and, to a lesser extent, teenagers. Infants aged below 1 were the most affected age group (16.98/100 000), followed by those aged 1-4 years (7.07/100000) and teenagers 15-19 years old (2.29/100 000) (Figure 6) (Czumbel, I. Jansson, A. Pastore-Celentano, L. Gauci, A.A., 2009).

Figure 6: Notification rate (per 100 000) of IMD cases by age group in EU/EEA, 2007


Invasive meningococcal disease remains rare in Europe and overall incidence decreased over the last 10 years from around 2 per 100 000 population in 1999 to around 1 per 100 000 in 2007 (Figure 7) (Czumbel, I. Jansson, A. Pastore-Celentano, L. Gauci, A.A., 2009).

Figure 7: Notification rate (per 100 000) of IMD confirmed cases in EU/EEA, 1999-2007

Most IMD cases in Europe are caused by serogroups B and C. Vaccination with serogroup C conjugate vaccines (MenC) has contributed to a decrease in incidence of the disease in European countries over the last ten years (Trotter, C.L. et al., 2007. A surveillance network for meningococcal disease in Europe. FEMS Microbiol Rev., 31(1):27–36.). In countries using MenC, the incidence of serogroup C-caused IMD was lower in the age groups targeted by the vaccination in comparison with countries without vaccine (Czumbel, I. Jansson, A. Pastore-Celentano, L. Gauci, A.A., 2009).

A total of 5 583 cases of IMD were reported (overall population incidence of 1.12 per 100 000). Notification rates varied from 0.31 to 4.15 per 100 000 population (Figure 8) (Czumbel, I. Jansson, A. Pastore-Celentano, L. Gauci, A.A., 2009).

Figure 8: Notification rate (per 100 000) of IMD reported cases in EU/EEA, 2007


If the national policy regarding meningococcal meningitis will came into force, a decrease in incidence of meningococcal disease will lower cost of treatment and cost of lost work days for more than 50.000 € per year. In Slovenia, the average direct cost of a meningococcal meningitis hospital admission is 3730 € and the corresponding indirect cost related to work loss is 1460 €. Overall, the unit economic value related to a meningococcal meningitis hospital admission is 5190 € (National Institute of Public Health, 2011).

The same proportion of financial burden could be anticipated elsewhere in EU.
Full chain discussion

Figure 9: Top down approach scheme

PROTECTING CITIZENS FROM HEALTH THREATS:

Determinants:
- low socioeconomic status
- cost of treatment and lost work days
- indoor environment
- consumption of alcohol
- smoking

Risk factors:
- alcohol abuse
- vaccination rates
- close contacts
- smoking rate
- household crowding
- sharing food and drinks

Health outcomes:
- higher prevalence of other diseases
- meningococcal meningitis

The whole process was based on literature review and communication with stakeholders.
Selected National Policy is a response to EU – Public Health Policy. It was prepared by National Institute of Public Health (Slovenia) with aim to strengthen mechanisms for surveillance and response to health threats, particularly emergency situations regarding communicable diseases as meningococcal disease and general guidelines, how to manage the possible threats in the public health as it was stated in EU policy.

The assessment was made in direction what would be if proposed policy program would not be implemented.

Figure 10: Scheme with selected pathway across levels
From policy to determinants of health is crucial.

The determinants were selected upon literature review and discussion process. The important determinant proved to be socio-economic what seems to be in general important one, having a broad influence. The socio-economic determinant has some sub determinants, like, low socioeconomic status, high cost of treatment, lost work days, but most important is low socioeconomic status. Looking each sub determinant it gets clear that there is a hierarchy between the group of socio-economic determinants, one having impact on the other.

For example lot of lost workdays are having negative impact on lower socioeconomic status and other way around. To be a bit provocative, it seems like sub determinant influence each other, not that much as top down model but more as a circle model. Therefore one policy with just one positive impact on one sub determinant can have a chain reaction on few determinants and the other way around. The main aim of this program is to strengthen mechanisms for surveillance and response to health threats what would have also positive impact on socioeconomic status, which is one of the most important socio-economic determinant also for public health.

Socio-economic determinant of health - housing conditions has strong impact on the environmental determinant of health – indoor environment. The context of settlement is very diverse and can be influenced by a large variety of social and environmental determinants. Poor and less affluent population groups tend to be more often affected by inadequate housing conditions and higher environmental burden in their residential environments. Social status and low income is strongly associated with increased exposure to environmental risks in the private home or related to residential location (World Health Organization, 2010).

Living and housing conditions are the basis of many factors influencing easier transmission of meningococcal. Epidemiological findings suggest strong associations between housing conditions and health effects.

Socio-economic determinant of health social status has impact on the behavioural and personal determinants of health. It is known that smoking and excessive drinking is more common among less affluent people.

We can claim that determinants of health do have impact also on each other, the impact can be again as a top down model or circle model, co-dependancy.

Part from Determinants of Health to Risk factors

From first step (from policy to determinant of health) it is clear that in case the program is not implemented, the most affected determinant of health is socioeconomic determinant of health.
The main risk factor for disease is household crowding and poor vaccination rates. Household crowding can affect other health risks related to Personal and Behaviour risks such as alcohol abuse, smoking rates and close contacts. The risk of household crowding comes from socioeconomic sub determinants (lower socioeconomic). It has impact also on environmental risk - poor indoor environment.

We can claim that not only determinants of health do have impact on each other, what can be top down or circle model impact, but also risk factors deriving from certain determinant of health, do have impact on risk factors of other determinant of health. The determinants of health and risk factors are well connected.

**Part from Risk Factors to Diseases**

This part is pretty easy to assess in terms what could happen if someone is exposed to certain risks. There is a disease with well-known and established ethiology. There is a massive body of literature on different risk factors described above and health outcome, which is known in our case – meningococcal disease.

What it is still not known it is a lack of good quantification of diseases and risk factors, for exposures and time of exposure needed for development of diseases. That makes quantification a bit difficult. The other problem is also poor exposure data. Also data of people who are affected by policy/health determinant and that they are affected by risk factors in such way that health can deteriorate, leading to development of disease is pretty poor.

There is a strong connection between the determinants of health, and also between different risk factors, what can multiply the impact of one or act protective at some points. On top of that genetic predisposition plays an important role in any disease.

There are still a lot of uncertainties, they could get overcome in future with more complex methods and the picture of impact of any policy on disease development will get clearer.
4.6. Conclusion

The objective of the document which helps to manage the possible threats in the public health is presenting the recommendations for the control of meningococcal disease in Slovenia in Ograda1 one comprehensive document.

This document was developed as a result of EU Community Health Strategy, which confronts different health challenges and intends to strengthen Community cooperation in the areas in which the Member States cannot act alone. One of three strategic objectives from this Strategy is protecting citizens from health threats and the main goal of this objective is to strengthen mechanisms for surveillance and response to health threads.

Based on this strategy a special document has been created by European Centre for Disease Prevention and Control and is called Public health management of sporadic cases of invasive meningococcal disease and their contacts. This guidance was prepared to ensure the countries' strong and proper surveillance of meningococcal disease. Slovenia has also participated in that aim with her own Document for Management of Meningococcal Diseas.

Guidance is offered on pre-admission management to reduce mortality rate, investigation of suspected cases, case definitions, public health action after a single case and management of clusters. These recommendations now form the definitive guidance on public health management of meningococcal disease in Slovenia. The important part of the document is also awareness rising and education of the public.

The main group that might be affected is a group of epidemiologists and also the whole population in case of failure of this program. Low surveillance and response to health threats like meningococcal disease could result in higher carriage rates of meningococcal cause of disease and faster spreading of the disease. Lack of education and rising awareness can further increase exposure to meningococcol and make burden of disease heavier.

Our final conclusion is that the implementation of EU Public Health Policy has important impact on health,
4.7. References


Ministry of Health.
38. Centers for Disease Control and Prevention, 2011. Meningitis Questions & Answers. [online]
Available at: [http://www.cdc.gov/meningitis/about/faq.html][Accessed 1 September 2011].
39. American Psychiatric Association, 2000. Diagnostic and Statistical Manual of Mental Disorders (DSM-
40. European Commission, 2010. Eurobarometer 2010, Tobacco. [online]. Available at:
Available at: <eurovaccine-ID7-Czumbe-inv-meningococcal-disease-Europe-2007.pdf> [Accessed 1 September 2011].
43. Zuschneid, I. et al. 2008. Invasive meningococcal disease with fatal outcome in a Swiss student
44. Melki, I. et al., 2004. Household crowding index: a correlate of socioeconomic status and inter-
for reporting communicable diseases to the Community network under Decision No 2119/98/EC of
47. World Health Organization, 2010. Social inequalities in environmental risks associated with housing
and residential location in World Health Organization. Environment and health risks: a review of the
Available at: [http://www.euro.who.int/__data/assets/pdf_file/0003/78069/E93670.pdf][Accessed 1
September 2011].
49. Topuzoglu, A. et al., 2005. Assessment of sociodemographic factors and socio-economic status
affecting the coverage of compulsory and private immunization services in Istanbul, Turkey. Public
various socioeconomic status in the town of Bytom. Przeglad Epidemiologiczny 58.4: 713-723.
699– 705.


5. MUS Katowice, Poland national report

RAPID WP6 EC CASE STUDY

Silesian Medical University in Katowice

Public Health Department

Joanna Kobza, Mariusz Geremek

Title: EC Health Strategy top down risk assessment: supporting dynamic health systems and new technologies

5.1. Introduction

One of the main objective of EC strategy is to support dynamic health systems and new technologies. As the trends in health status and patterns in life expectancy and morbidity highlighted health systems can play a major role in improving the health status of populations across the European Region (WHO, 2009). Health systems can play an important role in improving overall population health through the four functions of health systems:
- service provision,
- financing,
- resource generation,
- stewardship.

Ideally, stronger health systems will improve health equitably, achieve a fairer distribution of financial contributions, respect the rights of patients and sustainably and efficiently use human, financial and other resources (WHO, 2005).

Recent research has demonstrated that effective health services can considerably influence health outcomes. In particular, Nolte & McKee have sought to apply the concept of avoidable mortality to assess the performance of health systems, providing evidence that improved access to effective and timely health care, combined with other factors, clearly reduced mortality in many countries in the European Region during the 1980s and 1990s (Nolte, McKee, 2004).
Poland is a very good example where we could observe strong association between innovative health care changes and tremendous success in better health indicators. Cardiovascular deaths in Poland increased steadily through the 1970s and 1980s. This unfavorable trend started to change in the beginning of democratic transformation. There were sudden sharp falls in mortality rate from 1991, one of the fastest declines in the world. This reflects a dynamic development in clinical cardiology in Poland in the late 20th century. Several new centers of invasive cardiology were created during this period, with medical standards comparable with those in Western countries. Moreover, physicians could more easily participate in training focused on modern evidence based pharmacotherapy. Pharmacological treatments and invasive procedures together explained barely a third of the decrease in mortality (37%). The modern management of heart failure therefore made the single biggest treatment contribution to the reduction in mortality from coronary heart disease (12%). Despite huge financial support, the impact of invasive cardiology on mortality was modest (Bandosz 2012).

According to estimations of WHO ischaemic heart disease and cerebrovascular disease are main causes of mortality worldwide and account for more than 20% of all deaths. Those two diseases provoke also long-term morbidity. Cardiovascular diseases are also main reason of deaths within European Union (227,2/100000 inhabitants for circulatory diseases and 84,1/100000 inhabitants for heart diseases in EU-27 in 2008). There are significant differences concerning death from CVD diseases among European Union countries (Tab.1). While in France death rate is on level of 124,7 and 33,8, Spain (151,4 and 47,4), the death rate in Germany 223,2 and 86,4, Denmark 193,7 and 71,6, the biggest level occur in new member states: Latvia 505,9 263,5, Lithuania 520,1 and 321,4, Poland 356,4 and 102,2, Hungary 428,6 and 216,9 (Eurostat, 2010).

The mortality rate per 100000 inhabitants differs from 61 (11,4% of all deaths) in Portugal, 222 (27,4% of all deaths) in Estonia, 205 (28,9% of all deaths) in Slovakia, 251 (31,6% of all deaths) in Lithuania. Ischaemic Heart Disease DALY per 100 000 inhabitants differs from 507 (4,4% of all DALYs) in Portugal, 1332 (9,6% of all DALYs) in Slovakia, 1682 (10,2% of all DALYs) in Lithuania. Ischaemic heart disease was responsible for 17% of DALYs in Estonia. Ischaemic heart disease mortality rates are higher in Eastern Europe countries and former Soviet Union members (Kim, 2011).

Cardiovascular diseases are responsible for 49% of all deaths and 30% of all premature deaths before the age 65 in Europe, although age-specific mortality rates have been reduced significantly during last 2 decades, the prevalence of CVD is increasing due to an ageing population (Lloyd-Williams,
2008). The cost of CVD diseases for whole EU population was estimated on level of 169 billion of euro annually (Lloyd-Williams, 2008).

WHO estimated, that cardiovascular diseases are responsible for 30,5% of all deaths which occurred in year 2008 (17327000, out of 56888000). As main cardiovascular diseases most important are: ischaemic heart disease, 12,8% of all deaths (7254000), cerebrovascular disease, 10,8% of all deaths (6152000). Among all deaths, which occurred in 2008 in European Region of WHO (9222832) cardiovascular diseases were responsible for 4583972 deaths, ischaemic heart disease 2195095 cases, cerebrovascular diseases 1277623 cases, other heart diseases for 745605. Most cases occur at age groups of: 70-79 (643843 for male), 80+ (636984 for male), 60-69 (371816 for male), 45-59 (335163 for male), 80+ (1457665 for female), 70-79 (681135 for female), 60-69 (216811 for female), 45-59 (123760 for female) (WHO, 2009).
Tab.1. Circulatory disease and heart disease in EU countries, 2008

<table>
<thead>
<tr>
<th></th>
<th>Cancer</th>
<th>Lung cancer</th>
<th>Colorectal cancer</th>
<th>Circulatory disease</th>
<th>Heart disease</th>
<th>Respiratory diseases</th>
<th>Transport accidents</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
<td>(5)</td>
<td>(6)</td>
<td>(7)</td>
<td>(8)</td>
<td>(9)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EU-27</td>
<td>1730</td>
<td>19.3</td>
<td>1272</td>
<td>84.1</td>
<td>47.7</td>
<td>8.3</td>
<td>7.4</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>174.5</td>
<td>18.4</td>
<td>1452</td>
<td>67.5</td>
<td>58.6</td>
<td>10.6</td>
<td>6.2</td>
<td>294</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>171.6</td>
<td>22.7</td>
<td>411.3</td>
<td>126.0</td>
<td>41.7</td>
<td>13.3</td>
<td>9.3</td>
<td>233</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>201.0</td>
<td>27.9</td>
<td>355.8</td>
<td>176.2</td>
<td>40.3</td>
<td>10.3</td>
<td>9.7</td>
<td>21.2</td>
</tr>
<tr>
<td>Denmark</td>
<td>230.0</td>
<td>26.2</td>
<td>192.7</td>
<td>71.6</td>
<td>60.6</td>
<td>5.8</td>
<td>7.0</td>
<td>31.1</td>
</tr>
<tr>
<td>Germany</td>
<td>162.5</td>
<td>18.8</td>
<td>225.2</td>
<td>86.4</td>
<td>37.7</td>
<td>5.4</td>
<td>5.6</td>
<td>246</td>
</tr>
<tr>
<td>Estonia</td>
<td>101.3</td>
<td>19.7</td>
<td>451.4</td>
<td>224.4</td>
<td>35.5</td>
<td>11.4</td>
<td>13.4</td>
<td>254</td>
</tr>
<tr>
<td>Ireland</td>
<td>176.7</td>
<td>20.6</td>
<td>190.7</td>
<td>102.3</td>
<td>64.8</td>
<td>6.2</td>
<td>7.8</td>
<td>31.1</td>
</tr>
<tr>
<td>Greece</td>
<td>172.8</td>
<td>12.4</td>
<td>250.9</td>
<td>67.3</td>
<td>53.5</td>
<td>14.1</td>
<td>4.9</td>
<td>21.7</td>
</tr>
<tr>
<td>Spain</td>
<td>146.6</td>
<td>19.8</td>
<td>151.4</td>
<td>47.4</td>
<td>52.8</td>
<td>7.2</td>
<td>5.7</td>
<td>182</td>
</tr>
<tr>
<td>France</td>
<td>160.0</td>
<td>16.7</td>
<td>124.7</td>
<td>33.8</td>
<td>27.3</td>
<td>6.9</td>
<td>6.4</td>
<td>241</td>
</tr>
<tr>
<td>Italy</td>
<td>183.7</td>
<td>17.6</td>
<td>170.1</td>
<td>52.0</td>
<td>29.6</td>
<td>9.2</td>
<td>5.4</td>
<td>236</td>
</tr>
<tr>
<td>Cyprus</td>
<td>121.6</td>
<td>22.0</td>
<td>206.6</td>
<td>73.9</td>
<td>36.7</td>
<td>11.6</td>
<td>7.1</td>
<td>119</td>
</tr>
<tr>
<td>Latvia</td>
<td>193.9</td>
<td>20.0</td>
<td>505.9</td>
<td>25.5</td>
<td>25.0</td>
<td>15.9</td>
<td>13.7</td>
<td>247</td>
</tr>
<tr>
<td>Lithuania</td>
<td>195.0</td>
<td>21.2</td>
<td>520.1</td>
<td>21.3</td>
<td>30.5</td>
<td>16.8</td>
<td>15.4</td>
<td>251</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>167.7</td>
<td>20.5</td>
<td>210.8</td>
<td>63.8</td>
<td>43.4</td>
<td>8.7</td>
<td>7.3</td>
<td>205</td>
</tr>
<tr>
<td>Hungary</td>
<td>241.7</td>
<td>33.7</td>
<td>428.6</td>
<td>216.9</td>
<td>43.4</td>
<td>11.7</td>
<td>10.5</td>
<td>266</td>
</tr>
<tr>
<td>Malta</td>
<td>155.0</td>
<td>21.4</td>
<td>231.5</td>
<td>119.9</td>
<td>52.2</td>
<td>3.6</td>
<td>10.2</td>
<td>279</td>
</tr>
<tr>
<td>Netherlands</td>
<td>184.4</td>
<td>27.2</td>
<td>150.3</td>
<td>46.8</td>
<td>53.4</td>
<td>4.1</td>
<td>5.5</td>
<td>290</td>
</tr>
<tr>
<td>Austria</td>
<td>151.6</td>
<td>17.2</td>
<td>21.2</td>
<td>97.4</td>
<td>28.6</td>
<td>7.4</td>
<td>6.2</td>
<td>218</td>
</tr>
<tr>
<td>Poland</td>
<td>284.6</td>
<td>22.1</td>
<td>366.4</td>
<td>133.2</td>
<td>40.9</td>
<td>14.6</td>
<td>13.1</td>
<td>212</td>
</tr>
<tr>
<td>Portugal</td>
<td>135.6</td>
<td>22.4</td>
<td>184.9</td>
<td>44.4</td>
<td>62.0</td>
<td>9.1</td>
<td>7.7</td>
<td>198</td>
</tr>
<tr>
<td>Romania</td>
<td>17.5</td>
<td>18.8</td>
<td>557.9</td>
<td>194.1</td>
<td>49.5</td>
<td>16.6</td>
<td>17.8</td>
<td>216</td>
</tr>
<tr>
<td>Slovakia</td>
<td>219.3</td>
<td>26.2</td>
<td>234.9</td>
<td>57.4</td>
<td>36.4</td>
<td>11.5</td>
<td>8.8</td>
<td>274</td>
</tr>
<tr>
<td>Slovenia</td>
<td>201.7</td>
<td>30.3</td>
<td>4650</td>
<td>200.5</td>
<td>49.0</td>
<td>13.3</td>
<td>13.3</td>
<td>221</td>
</tr>
<tr>
<td>Finland</td>
<td>137.0</td>
<td>13.3</td>
<td>224.0</td>
<td>128.8</td>
<td>22.3</td>
<td>6.9</td>
<td>5.0</td>
<td>198</td>
</tr>
<tr>
<td>Sweden</td>
<td>149.1</td>
<td>17.5</td>
<td>200.9</td>
<td>93.0</td>
<td>30.8</td>
<td>5.0</td>
<td>6.3</td>
<td>200</td>
</tr>
<tr>
<td>United Kingdom (1)</td>
<td>178.1</td>
<td>21.7</td>
<td>188.7</td>
<td>93.0</td>
<td>73.2</td>
<td>5.3</td>
<td>5.9</td>
<td>268</td>
</tr>
<tr>
<td>Iceland</td>
<td>197.2</td>
<td>11.4</td>
<td>1737</td>
<td>93.7</td>
<td>43.4</td>
<td>4.0</td>
<td>5.2</td>
<td>273</td>
</tr>
<tr>
<td>Norway</td>
<td>150.5</td>
<td>22.5</td>
<td>167.2</td>
<td>50.6</td>
<td>49.0</td>
<td>6.0</td>
<td>6.7</td>
<td>187</td>
</tr>
<tr>
<td>Switzerland</td>
<td>146.1</td>
<td>15.1</td>
<td>161.2</td>
<td>66.1</td>
<td>27.2</td>
<td>5.0</td>
<td>5.1</td>
<td>221</td>
</tr>
<tr>
<td>Croatia</td>
<td>213.6</td>
<td>28.6</td>
<td>402.7</td>
<td>157.1</td>
<td>33.5</td>
<td>15.0</td>
<td>9.8</td>
<td>258</td>
</tr>
<tr>
<td>FYR of Macedonia</td>
<td>170.0</td>
<td>18.1</td>
<td>573.9</td>
<td>92.2</td>
<td>37.8</td>
<td>7.0</td>
<td>13.4</td>
<td>239</td>
</tr>
</tbody>
</table>

(1) Italy, Luxembourg, Malta, Sweden, the United Kingdom and Switzerland, 2007; Denmark, 2006; Belgium, 2005.
(2) Malignant neoplasms.
(3) Malignant neoplasms of brain, trachea, bronchus and lung.
(4) Ischaemic heart diseases.
Source: Eurostat

It is confirmed the strong relation between particular mortality due to CVD diseases and value of life expectancy. Studies which were undertaken in the UK and US described, that about half of the reduction in coronary deaths between 1980 and 2000 could be attributable to reductions in major risk factors and about half to improvements in medical treatment of people with established vascular disease (Capewell, 1999) (Ford, 2000). Modern hospital treatment affect quality of life and health status of patients, who survived stroke or myocardial infarction (Keun-Sik Hong, 2011).
Health systems have to evolve to respond to different requirements of the nearest future of the European population. Basic tool is development and applying of new technologies. Newer and more effective medical technology and treatment limit acute effects and mortality for cardiovascular diseases (WHO, 2009). The problem is that technological change plays a complex role in increasing health care cost.

New technologies can reduce costs by improving efficiency or health, thereby reducing the need for further care that may be more costly. Nevertheless, new technologies can lead to increased use of health care, and therefore costs, because they extend the scope and range of the treatments available and can extend treatment to a wider set of indications that may or may not contribute to overall health gain in society (WHO, 2009). The uptake and use of new technology, and thus their potential to increase costs, depend on the incentives given to providers in the system (Evans, 2007). Estimates of the effects of technological change on expenditure in Europe suggest that the impact of adopting technical and medical developments serves to increase use and thus costs (EC, 2006). For example based on expenditure data for Switzerland for 1970–1995, one study has estimated an expenditure growth factor of 1% per year due to technological change (Breyer, Felder, 2006). Applying this estimate to projections of health expenditure suggests such changes in technology and its use will account for 77% of the growth in health care costs by 2050. Ensuring the use of health technology assessment to support the introduction of new technologies that offer real benefits and to discourage those that are less cost effective is an important challenge for policy-makers, given rising health care costs (Sorenson, 2006).

Screening of the policy

The function of health systems in improving health by delivering effective and high quality services based on implementing innovative technologies has been assessed and debated in most important documents and reports of key European institution, especially WHO and European Commission. According to text of the CONSOLIDATED VERSION OF THE TREATY ON EUROPEAN UNION the European Union will have competence to carry out actions to support, coordinate and supplement the actions of the Member States. The protection and improvement of human health is mentioned as one of such action. Treaty of Lisbon confirms that the Union will take into account requirements linked to the protection of human health. Point 3, article 114 (ex Article 95 TEC) underlines, that the Commission, will take as a base a high level of protection, taking account in particular of any new
development based on scientific facts. Article 153 Point 1 support idea, that the Union will support the activities of the Member States in field of the working environment to protect workers’ health and safety. Point 2, article 168 (ex Article 152 TEC) states, that the Union shall encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas (Council of The European Union, 2008).

The competences in actions for health has been confirmed in ‘White paper, Together for Health: A strategic Approach for the EU 2008-2013’ Document states, that health of the Member States citizens must be strengthened by effective policies and actions and that there is necessity of cooperation between Member States and European Community, to achieve high level of health status within European Union. Among strategic objectives of EC Health Strategy, supporting dynamic health systems and new technologies (objective 3) is mentioned.

It has been underlined, that new technologies have the potential to strongly influence health care and health systems, especially in aspect of prevention of illness, delivery of treatment, prevention and primary care. There is a strong need of proper evaluation of new technologies in aspects of cost-effectiveness, equity and ethical concerns (Commission of the European Communities, 2007).

One of the European documents, which confirmed competences of Member States in aspect of introducing new technologies, was Corrigendum to Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems. It stated, that task of the administrative commission (The Administrative Commission for the Coordination of Social Security Systems) should focus on encouraging “the use of new technologies in order to facilitate the free movement of persons, in particular by modernizing procedures for exchanging information and adapting the information flow between institutions for the purposes of exchange by electronic means, taking account of the development of data processing in each Member State”. The document confirmed, that all activities aimed at improving exchanges of information between the social security authorities and institutions of the Member States, particularly the electronic exchange of data should be supported (The European Parliament and the Council, 2004).

The official European Union regulations has influenced Member States policy. E-health strategy is one of the most recent term for health care practice influenced by the new technologies. Polish E-health Strategy 2009-2015 is an answer for the evolution and development of the electronic devices and applying it in health care. Among the main points of
the E-health Strategy the following were mentioned: making the system of health care and health service protection more efficient for citizens, improving the health data collecting system and their statistic compilation, to develop possibilities of ‘on-line’ registering for medical treatment, to make the health care system more economically efficient (MZ, 2009).

Also most of WHO documents suggests that policy makers can improve population health by enhancing the performance of the health system by delivering innovative technologies being aware it’s complex role in increasing health care costs (WHO 2009).

Thanks to innovation and research, new technologies in aspect of medical treatment are continuously being introduced and health care should benefit from the technological innovations in the health sciences in general, and in medical science in particular. Health technology assessment (HTA) should be focused on informing health policy-makers and decision making processes precisely (WHO, 2008).

The Polish Agency for Health Technology Assessment was established in 2005. It is the advisory unit of the Ministry of Health. Since 2009, according to the Act of 25 June 2009 is defined as a legal entity. Among the main tasks of the Agency for Health Technology Assessment, recommendations of non-drug technologies (medical devices and medical procedures funded by public payer) were mentioned (Agencja Oceny Technologii Medycznych, 2012).

As regards other political action there are also several long-lasting programs oriented on main health threats and problems of the Polish society in aspect of new technologies and their influence on the health promotion, health prophylaxis and early diagnosis.

The second National Health Program 2007 – 2015 program states, that there is a need of engaging health service units and local government in aspect of securing more efficient prophylaxis, early diagnosis in aspect of CVD diseases, diabetes and it’s consequences (Ministerstwo Zdrowia, 2007).

The National Programme for Cardiovascular Diseases Treatment and Prophylaxis Polkard –2010-2012 focused not only on reducing main risk factors of the cardiovascular diseases, but also on the developing and introducing into health service units modern diagnostic and therapeutic procedures together with actions focused on reducing geographical inequalities in access to modern health care units (especially modern cardiologic and neurologic units).
The experiences of POLKARD program editions underlines, that there is a constant need of introducing new technologies in aspect of early diagnosis and treatment of CVD diseases. It was also concluded, that reducing territorial inequalities in aspect of health care accessibility is one of the main goal. The access to modern invasive cardiology units, with high quality equipment combined with proper health education and rehabilitation was mentioned as a priority (Ministerstwo Zdrowia, 2008).

5.2. Health determinants - access to health care

Many agents affect life of individuals and communities. People’s health is influenced and determined by the surrounding environment both, in place of living and working area. Health determinants are grouped in those connected with social, economic and physical environment, person’s individual characteristics and behaviours. Dahlgren and Whitehead model includes the following factors: general socioeconomic, cultural and environmental, living and working conditions, social and community factors and individual lifestyle factors (Dahlgren, 1991). Lalonde describes human life and health as related with lifestyle in 50%, genetics in 20%, environmental factors in 20% and health care activity in 10% (Lalonde, 1974). The differences between the western and eastern parts of the European Region have been suggested to result from interaction between key lifestyle factors (diet, smoking and physical activity) and psychosocial factors (stress), but other aspects, such as access to and the quality of health care, are thought to play a role (WHO, 2009).

Health systems are a vital determinant of health, and unequal distribution of care is a social determinant of health (Nolte, Mc Kee, 2004) (WHO, 2008). Recent studies have shown great variation in the prevalence of cerebrovascular diseases worldwide and higher rates in low-income countries, perhaps because of limited access to and quality of health care (Buchan, 2009). Although the reductions in the prevalence of major risk factors are contributed to about two-thirds of the decline of the cardiovascular diseases, the reminded third part is attributable to medical treatments (Capewell, 2009).

First balloon angioplasty in Poland was done in 1981. As a common practice in Poland balloon angioplasty was introduced 2 years later. In 1985 first hemodynamic procedures were realized in hemodynamic units in two other Polish cities. The number of 1000 angioplasties per year was achieved in 1989 and in 1997 it reached 5000. The second half of ’90s was groundbreaking in the aspect of invasive cardiology. In the period of 1996-1998 number of angioplasties and stents was doubled. Number of angioplasties increased from 4986 to 10846, with 24% increase of coronarography
procedures at the same period. The vital moment for invasive cardiology in Poland was 1999 (after introducing Universal Health Insurance Act), when the above mentioned procedures were decided to be more adequately financed by the public payer of health care in Poland. It effected in better equipment and intensification of formations of Polish cardiology centers. In 1999 there were 31 invasive cardiology centers in Poland and total number of coronary procedures grew up for 31.8% (up to 44964 procedures) and angioplastics procedures for 32.8% (up to 14422 procedures) comparing to 1998. In 2000 there were about 43 cardio angiographic units in Poland and year later this number reached 52. In 2001 about 60000 coronary procedures and 23000 of angioplastics procedures were done. In 2006 the number of hemodynamic and invasive cardiology units was estimated on level of 86 and in 2011 reached 120. The number of deaths as a result of cardiac infarcts has been reduced to 4% of hospitalized patients during last decade (Rynek Zdrowia, 2010). NHF policy in Poland during last decade has confirmed the WHO statement that providers have an important role in determining the uptake and use of health technologies (WHO 2009), especially in the context that in the same period Poland had the lowest public expenditures per capita on health among the EU countries (MZ,2008).

![Number of invasive cardiology procedures in Poland (1999-2007)](image)

Fig.1. Based on data of Główny Urząd Statystyczny
5.3. Risk Factors

Health inequity in access to new technologies treatment

Health systems are responsible for ensuring that their policies and interventions do not unintentionally increase socioeconomic and health inequity. A recent study found that successfully implementing current best practice interventions on four classical risk factors to reduce coronary heart disease in groups with both high and low socioeconomic status could reduce most of the inequity in mortality from this cause (Kivimaki, 2008).

1. Financial aspects

Economic factors have their influence on CVD mortality and burden of cardiovascular diseases (WHO, 2010). The burden of disease from noncommunicable diseases, such as stroke and ischemic heart disease, is supposed to outnumber the burden of disease from infectious disease in low-income and middle-income countries over the next few decades. Lower national income was strongly connected with higher stroke mortality (Kim, 2011). In the sensitivity analysis, which excluded 80 countries with incomplete mortality data for which modeling was required, the rates of age-adjusted mortality and DALYs lost were higher in low-income countries than in middle-income or high-income countries (Johnston, 2009).

The latest research shows that during last decade (2000-2011) it is observed the increase of rate of households in Poland who profit both, public medical sector (86,4 in 2000-91,5 in 2011) and the private one (38,6 in 2000–49,1 in 2011) (Czapiński 2011).

The availability of adequate resources may impact case fatality and long-term morbidity due to epidemiological monitoring and prevention, access to modern treatment, and follow up health care. There was observed constant increase in financing of cardiovascular procedures in Poland. In 2009 about 900 million of Polish zloty (PLN) out of about 55,28 billion of whole budget of National Health Fund (public payer of medical procedures) was spent on procedures connected with myocardial infarction. Health care expenditures on myocardial infarction procedures in 2009 increased in some voivodships from a few percent up to 40% comparing to year 2008 (PTK-T, 2011) (NFZ, 2010). Although as regards invasive cardiology Poland reached West European countries level, the problem is still the limitation of financial sources, and the refundment of public payer of some procedures, especially these
concerning more complex cases, when NHF pay only for one, there are still limitation in access to ambulatory care and non-invasive diagnostic treatment (Rynek Zdrowia, 2011).

Administration reform of 1999 divided Poland into 16 voivodship (regions). National Health Fund (NFZ) (public payer of medical procedures in Poland) has its regional branch offices in every voivodship. There is a stable increase of number of invasive cardiology procedures on territory of Poland during last years (GUS, 2011) (Fig.1). The significant change of coronarography procedures number has been observed on the whole territory of Poland and in aspect of single voivodships. This aim was reached due to the stable increase of number of invasive cardiology units and increase of expenditures on invasive cardiology procedures.

The latest research showed that the expenditures on the invasive cardiology procedures and their number have been increasing significantly since 2007 until 2011 in most of the National Health Fund Regional Branch Offices. A special questionnaire was sent to all NHF Regional Branch Offices, the response rate was to 100%, but not all offices sent standardized data. Most of them confirmed the stable trends in increase of finance sources and number of procedures as regards coronarography procedures (Tab.2 - Tab.11). (There are some differences between the collected data till 30.06.2008 and after, from 01.07.2008 coronarography procedures have been included to DRG system, so from this time NHF has applied new statistic and refund system).

Tab.2. Coronarography procedures in the Pomorski Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
<th>Average price of single procedure (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>6654</td>
<td>5482,49</td>
</tr>
<tr>
<td>2008</td>
<td>7609</td>
<td>6142,52</td>
</tr>
<tr>
<td>2009</td>
<td>8796</td>
<td>7179,05</td>
</tr>
<tr>
<td>2010</td>
<td>9156</td>
<td>7308,89</td>
</tr>
<tr>
<td>2011</td>
<td>12260</td>
<td>8011,30</td>
</tr>
</tbody>
</table>
Tab.3. Coronarography procedures in the Zachodniopomorski Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography and other invasive procedures</th>
<th>Total expenditures (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>3109</td>
<td>2480800</td>
</tr>
<tr>
<td>2008</td>
<td>3042</td>
<td>3659328</td>
</tr>
<tr>
<td>2009</td>
<td>2448</td>
<td>3993504</td>
</tr>
<tr>
<td>2010</td>
<td>3028</td>
<td>4941696</td>
</tr>
<tr>
<td>2011</td>
<td>3082</td>
<td>5029824</td>
</tr>
</tbody>
</table>

Tab.4. Coronarography procedures in the Warmińsko-Mazurski Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
<th>Total expenditures (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>2762</td>
<td>15771252,80</td>
</tr>
<tr>
<td>2008</td>
<td>4275</td>
<td>27042782,12</td>
</tr>
<tr>
<td>2009</td>
<td>4479</td>
<td>30093060,03</td>
</tr>
<tr>
<td>2010</td>
<td>4398</td>
<td>30493039,32</td>
</tr>
<tr>
<td>2011</td>
<td>4916</td>
<td>32139407,74</td>
</tr>
</tbody>
</table>

Tab.5. Coronarography procedures in the Lubelski Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
<th>Total expenditures (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>4207</td>
<td>3366400</td>
</tr>
<tr>
<td>2008</td>
<td>4576</td>
<td>5489648</td>
</tr>
<tr>
<td>2009</td>
<td>2913</td>
<td>4754016</td>
</tr>
<tr>
<td>2010</td>
<td>2634</td>
<td>4298688</td>
</tr>
<tr>
<td>2011</td>
<td>3457</td>
<td>5641824</td>
</tr>
</tbody>
</table>

Tab.6. Coronarography procedures in the Podkarpacki Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>5615</td>
</tr>
<tr>
<td>2008</td>
<td>6929</td>
</tr>
<tr>
<td>2009</td>
<td>7965</td>
</tr>
<tr>
<td>2010</td>
<td>8068</td>
</tr>
<tr>
<td>2011</td>
<td>8146</td>
</tr>
</tbody>
</table>
Tab. 7. Coronarography procedures in the Podlaski Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
<th>Total expenditures (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-06.2008</td>
<td>5510</td>
<td>4529455</td>
</tr>
<tr>
<td>07.2008-12.2011</td>
<td>4607</td>
<td>7402444</td>
</tr>
</tbody>
</table>

Tab. 8. Coronarography procedures in the Dolnośląski Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
<th>Total expenditures (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>5506</td>
<td>4838680</td>
</tr>
<tr>
<td>2008</td>
<td>4592</td>
<td>5344938</td>
</tr>
<tr>
<td>2009</td>
<td>2561</td>
<td>3682223</td>
</tr>
<tr>
<td>2010</td>
<td>2339</td>
<td>3817248</td>
</tr>
<tr>
<td>2011</td>
<td>2671</td>
<td>4359072</td>
</tr>
</tbody>
</table>

Tab. 9. Coronarography procedures in the Łódzki Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
<th>Total expenditures (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>3165</td>
<td>2531200</td>
</tr>
<tr>
<td>2008</td>
<td>2672</td>
<td>3172065</td>
</tr>
<tr>
<td>2009</td>
<td>1702</td>
<td>2722797</td>
</tr>
<tr>
<td>2010</td>
<td>1943</td>
<td>3163306</td>
</tr>
<tr>
<td>2011</td>
<td>1952</td>
<td>3185664</td>
</tr>
</tbody>
</table>

Tab. 10. Coronarography procedures in the Świętokrzyski Regional Branch Office of the National Health Fund (NFZ). (RAPID research, 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronarography procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.2007-12.2011</td>
<td>27021</td>
</tr>
</tbody>
</table>
2. Territorial inequity in access to new technologies treatment

Although the number of invasive cardiology units is considered to be on the advised level (one per 300 000 inhabitants), there are still concerns targeting their geographical localization. (Pracodawcy Medycyny Prywatnej, 2011). At the beginning there were territorial disproportions concerning access to invasive cardiology procedures, but it became less important when cardioangiographic units were established in last two voivodships in 2011 (out of 16). Since this moment there was access to invasive procedures on the territory of whole country. According to European Society of Cardiology there should be about 2 invasive cardiology units per 1000 000 of inhabitants. According to this guidelines Poland would need about 80 such units. In 2006 the number of hemodynamic and invasive cardiology units was estimated on level of 86.

In the beginning of 2000s there was a group of about 300 specialists who realized invasive cardiology procedures in Poland (Gil, 2003). Than the number of diagnostic specialists doubled and reached the level of 602. The number of operating specialists reached the level of 441 (Polish Cardiac Society, 2007).

Actually the number of invasive cardiology units is to 127 and number of invasive cardiology procedures during myocardial infarction (proportionally for number of inhabitants) is on higher level than in Luxembourg, Belgium or France (PTK-T, 2011). Today each patient has an access to such medical institution in the distance no longer than 50 km, they are situated in whole regions and there is no territorial inequity in access to cardiology units.

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of coronaryography procedures</th>
<th>Total expenditures (PLN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-06.2008</td>
<td>3732</td>
<td>3202880</td>
</tr>
<tr>
<td>07.2008-12.2008</td>
<td>1101</td>
<td>1684131,84</td>
</tr>
<tr>
<td>2009</td>
<td>1749</td>
<td>1602950,40</td>
</tr>
<tr>
<td>2010</td>
<td>1995</td>
<td>3128599,68</td>
</tr>
<tr>
<td>2011</td>
<td>1773</td>
<td>2828256</td>
</tr>
</tbody>
</table>
There are 2887 angioplasty and 5153 coronarography procedures done for 1 million of inhabitants, it is few times more than a few years ago so high number of interventions is a prove that there is rather easy access to such procedures what situated Poland in the middle on the European statistics. Generally a patient must wait 4 weeks for coronarography, 2 weeks for angioplasty.

3. Gender and age inequity

Health inequity may disadvantage men and women for mortality from cardiovascular diseases (WHO, 2007). Studies underlines remarkable reductions in hospital mortality due to the myocardial infarction for both men and women during the last decade, however, women experienced larger improvements in mortality than men of similar age (Vaccarino, 2009).

The distribution of diseases of the circulatory system, mainly ischaemic heart and cerebrovascular diseases, varies considerably by age and sex. Currently older people have a 30-65% higher risk of almost all chronic diseases than affluent and younger people (Wait, Harding, 2006). For example the risk of dying from ischaemic disease increases with age and is almost 25 times higher among people 65 years or more than younger people, further this risk is 90% higher among males than females (WHO 2009).

The latest research results as regards the effectiveness of modern treatment are rather contradictory; Canadian studies showed that the decrease during last decades in observed CHD deaths was concentrated in older patients aged 75 to 84 years. Between 1994 and 2005, the age adjusted CHD mortality rate in Ontario decreased by 35% from 191 to 125 deaths per 100 000 inhabitants, (Wijeysundera, 2010). Other research found no substantial improvement in mortality rate and hospital readmission during the 1990s among elderly patients hospitalized with heart failure. These findings suggest that recent innovations in heart failure management have not yet translated into better outcomes in this population. (Kosiborod, 2006)

There are significant territorial and gender specific differences concerning cardiovascular mortality indicators among Polish population. According to ICD-10 classification cases of acute coronary syndromes (I21-I22) for whole population it was estimated on level of 62,4 deaths per 100 000 inhabitants in 2005 and 60,5 deaths per 100 000 inhabitants in 2006. The gender specific mortality was estimated on level of 80,3 deaths per 100 000 men in 2005, 78,0 deaths per 100 000 men in 2006, 45,6 deaths per 100 000 women in 2005 and 44,2 deaths per 100 000 of women in 2006. Territorial
differences were estimated on level: 61.2 deaths per 100,000 inhabitants of town and cities, 59.5 per 100,000 inhabitants of rural area.

The total number of CVD deaths as an effect of acute coronary syndromes in year 2005-2006 was lower than in 1999, in 15 out of 16 Polish voivodships. The hospitalization indicator (per 100,000 inhabitants) analysis showed, 208.0 patients were hospitalized due to the acute coronary syndrome in 2006 (I21-I22). Among them 269.1 men and 150.8 women. 220.8 inhabitants of town and cities (294.1 men and 154.5 women) and 186.6 inhabitants of rural area (230.0 men and 143.8 women) (Wojtyniak 2008).

5.4. Health outcome

Avoidable mortality has been proposed to indicate the potential premature mortality that may be reduced by timely and effective intervention by the health system. This may include health promotion, primary prevention (to reduce exposure) or secondary prevention (to diagnose and treat disease). Accordingly, avoidable mortality can be further separated into amenable (treatable) and preventable. Amenable mortality is considered a better indicator of health care services and helps to indicate how much they contribute to health, either positively or negatively (WHO, 2009).

Identifying the underlying factors associated with this decline is critical for planning future health policy, and prioritizing strategies for primary and secondary prevention (Ford, 2007). Treatment strategies also have played a pivotal role, with 25% to 55% of the decreases in CHD mortality worldwide being attributed to the improved up take of evidence-based pharmacological and interventional therapies (Capewell, 2008).

Recent Canadian study shows that between 1994 and 2005, there was a decrease in CHD mortality rates in Ontario that was associated primarily with trends in risk factors and improvements in medical treatments, each explaining about half of the decrease (Wijeysundera, 2010). The Ontario population, aged 25 to 84 years between 1994 and 2005, was evaluated using an updated version of the IMPACT model. This was a cell based model, constructed using Microsoft Excel which integrated available country-specific epidemiological data to explain an observed decrease in CHD mortality. Specifically, the IMPACT model incorporated temporal trends in major CHD risk factors in addition to the
uptake of evidence-based medical and surgical treatments for CHD at 2 cross-sectional time points, and estimated the relative reduction in CHD mortality associated with each. The IMPACT model has been validated in the United States, New Zealand, China, and Europe. Of the 8.4 million Ontario residents between the ages of 25 and 84 years in 2005, there were 10,060 CHD deaths. In contrast, there were 13,010 CHD deaths in 1994 despite an overall population of only 7 million residents between the ages 25 to 84 years. With indirect age standardization, the IMPACT model estimated that there were 7,585 deaths prevented or delayed in 2005; given the observed mortality rates compared with the deaths expected, the 1994 CHD mortality rates remained constant. Risk factor changes were associated with 48% (range, 28%-64%) of the total mortality decrease, whereas new medical and surgical treatments were associated with 43% (range, 11%-124%) of the decrease. An estimated 3,280 of the total deaths prevented or delayed were associated with improvements in medical and surgical treatments between 1994 and 2005.

In the Netherlands, for instance, 46% of the decline in mortality from heart disease between 1978 and 1985 has been attributed to treatment in coronary care units, post infarction treatment and coronary bypass grafting. A further 44% of the decline in mortality over the same period is credited to primary prevention efforts: smoking-cessation campaigns, change in serum cholesterol and treatment of hypertension (Bots, Grobbee, 1996).

Many investigations proved the role of some therapies which contributed to decrease the CVD mortality rate. A 25-Year Experience From the Mayo Clinic showed that procedural success rates for CTO (coronary intervention for Chronic Total Occlusions) have not improved over time in the stent era, highlighting the need to develop new techniques and devices. Compared with the prestent era, in-hospital major adverse cardiac events and 1-year target vessel revascularization rates have declined by approximately 50% (Prasad, 2006). Another research showed that during 1992 to 2000, mortality and morbidity improved among elderly patients with heart failure, with increased utilization of beta-blockers contributed most to the beneficial trends in outcomes (Lee, 2004). For patients admitted with heart failure over the past 16 years, it was observed reductions in length of stay and in-hospital mortality, less marked reductions in 30-day mortality, and increases in 30-day readmission rates and use of skilled nursing facilities after discharge (Bueno, 2010). Both in-hospital and 6-month mortality in patients with a first AMI decreased during the last decade, probably due to more frequent reperfusion and revascularization therapy and better medical treatment. (Garcia-Garcia, 2010). Decreasing mortality from ST elevation myocardial infarction has been explored due to the role of primary percutaneous
coronary intervention. Primary percutaneous coronary intervention consistently reduces short- and long-term mortality by 15% to 25%, reinfarction by 50% to 60% and stroke by 50% (Charbonneau, 2009).

According to worldwide importance of Cardiovascular Diseases (CVD) DALY factor’s application in measuring CVD years of life lost (YLL) and years of healthy life lost due to disability (YLD) is one of the key usage, especially important because DALY takes into consideration disability due to neurological disorders (Keun-Sik Hong, 2011). Ischemic heart disease and cerebrovascular disease are the leading causes of DALYs lost (Kim, 2011).

Modern and efficient health care and emergency system result in gain of life years free of disability. For example DALY analysis confirms that _3-hour thrombolytic therapy is a treatment of substantial benefit for individual patients and for society. For the nearly one-third of patients who benefit from treatment, thrombolytic therapy adds the equivalent of 4.4 years of healthy life, free of disability (Keun-Sik-Hong, 2010).

Understanding the underlying mechanisms for past trends in CHD mortality is critical for strategic planning and prioritization of health policy (Wijeysundera, 2010). Rates of CHD mortality have decreased substantially over the last three decades.

In Poland it was observed about 37% decreases in CVD mortality rate during last two decades (Fig. 2.). Also the improvements in life expectancy were mainly attributable to decreases in cardiovascular mortality (Fig.3). The latest study confirms that the decline in CVD mortality in Poland was also connected with implementation of innovative treatment (Bandosz 2012). From 1991 to 2005, the death rate from coronary heart disease in Poland halved, resulting in 26 200 fewer coronary deaths in 2005 in people aged 25-74. About 37% (minimum estimate 13%, maximum estimate 77%) of this decrease was attributable to treatments (pharmacological treatments and invasive procedures together), including treatments for heart failure (12%), initial treatments for acute coronary syndrome (9%), secondary prevention treatments after myocardialinfarction or revascularisation (7%), chronic angina treatments (3%), and other treatments (6%). About 54% of the fall was attributed to changes in risk factors (minimum estimate 41%, maximum estimate 65%). Data on the clinical effectiveness of each intervention and treatment were based on the most recent meta-analyses and large randomised clinical trials (Bandosz 2012).
Summarizing over half of the recent fall in mortality from coronary heart disease in Poland can be attributed to reductions in major risk factors and about one third to evidence based medical treatments using innovative technologies.

Fig. 2. Based on data of Główny Urząd Statystyczny
There is a fundamental contradiction at the core of health policy in the EU that makes it difficult to draw a line between EU and Member State responsibilities. This raises a number of difficult questions for policy makers and practitioners as they struggle to interpret both 'hard' and 'soft' laws at EU and Member State level and to reconcile tensions between economic and social imperatives in health care (Mossialos, 2010). New technologies with the potential to improve the health of populations are continuously being introduced. But not every technological development results in clear health gains. Health technology assessment provides evidence-based information on the coverage and usage of health technologies, enabling them to be evaluated properly and applied to health care efficaciously, promoting the most effective ones while also taking into account organizational, societal and ethical issues (Garrido 2008). Polish phenomenon suggests that it is necessary to prioritize policies to manage effective, innovative medical interventions and reduce major risk factors.
5.4. References


Buchan J., (2008), How can the migration of health service professionals be managed so as to reduce any negative effects on supply? Copenhagen, WHO Regional Office for Europe (http://www.euro.who.int/document/hsm/7_hsc08_ePB_10.pdf, accessed 27 May 2009).


GUS data, <www.gus.stat.gov.pl>


Sorenson C et al. (2008), *How can the impact of health technology assessments be enhanced?* Copenhagen, WHO Regional Office for Europe (http://www.euro.who.int/document/hsm/2_hsc08_ePB_5.pdf, accessed 28 June 2009).


Risk assessment on policy level

European Case Study - November 2010

The Center for Health Policy and Public Health
Institute for Social Research
Faculty of Political, Administrative and Communication Sciences
Babes-Bolyai University Cluj Napoca

Developed for the Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012
EU (DG-SANCO) Grant agreement N° 20081105
6.1. **International/national context**

The EU Health Strategy represents an elaborated plan of cooperative action among European countries, in order to prevent and treat, if needed, issues with a large scale impact, such as pandemics. Discussing this issue in the European context by taking into account all the aspects reflected when analyzing the possibilities of a disease emergence and widespread, we can define the problem in terms of assessing the impact it may have and applying measures to prevent and cease it with the purpose of protecting citizens’ health status. In the attempt to place the policy into international context, we extend the characteristics of a model intended for a national case, by exploring how we could implement the measures at the European level by making allowance for the objectives enlisted in European Commission’s Health Strategy.

The policy model we propose is targeting, on the one hand, all European citizens’ health assurance and, on the other hand, to broaden European Commission’s assignments regarding pandemic influenza. Also, the goal is to produce a feasible structure so as to be enforced in all member states and become able to handle with health related activities focusing on influenza pandemic. Aiming to test the top-down-assessment tool, the second objective of the EU Health Strategy, “Protecting citizens from health threats” was analyzed using Romania’s national case study (Romanian National Plan for Interventions in Influenza Pandemics).

6.1.1. **Policy content**

EC Strategy includes pandemics in the category of potential major threats to health, establishing a general frame for action. The term of pandemics is used in a broadly way, having the same acceptance in terms of how we need to deal with the problem, as other major threats. In the “Together for Health: A Strategic Approach for the EU 2008-2013” document there are three general references to pandemics. In the introductive section of the document “Why a New Health Strategy” the “pandemics” term appears in the following context: “...there are areas where Member States cannot act alone effectively and where cooperative action at Community level is indispensable. These include major health threats and issues with a cross-border or international impact, such as pandemics and bioterrorism, as well as those relating to..."
free movement of goods, services and people”. In the same section of the EC Health Strategy “pandemics” are seen as major threats to health: “…pandemics, major physical and biological incidents and bioterrorism pose potential major threats to health”. “Pandemics” are also mentioned in the third section of the document, namely “Strategic Objectives”, under the second objective “Protecting citizens from health threats”: “Combating pandemics or biological incidents and addressing the threat of bioterrorism requires Community-level cooperation and coordination between Member States and international actors”.

Being the fact that we are using the term of “pandemics” in a specific context, we conducted an extensive literature review that revealed the main official documents which are referring to the pandemic as having the same acceptance as the one we used in our case study: pandemic influenza. In order to find the relevant papers to be included in the extensive literature review, a search was pursued on the official European Commission website, European Centre for Disease Prevention and Control (ECDC) and World Health

<table>
<thead>
<tr>
<th>Author Year</th>
<th>Policy Working Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO Europe 2011</td>
<td>WHO Regional Office for Europe guidance for sentinel influenza surveillance in humans</td>
</tr>
<tr>
<td>WHO Europe 2009</td>
<td>The European health report 2009. Health and health systems</td>
</tr>
<tr>
<td>WHO 2009</td>
<td>Regional Pandemic Influenza Preparedness and Response Plan, 2009-2010</td>
</tr>
<tr>
<td>WHO 2011</td>
<td>Pandemic (H1N1) 2009</td>
</tr>
<tr>
<td>European Commission 2010</td>
<td>Pandemic2009-EU commission</td>
</tr>
<tr>
<td>ECDC 2009</td>
<td>ECDC health information-pandemic</td>
</tr>
<tr>
<td>ECDC 2009</td>
<td>ECDC Risk Assessment-2009 influenza A(H1N1) pandemic</td>
</tr>
<tr>
<td>WHO 2010</td>
<td>Use of Influenza Rapid Diagnostic Tests</td>
</tr>
<tr>
<td>WHO 2011</td>
<td>Comparative analysis of national pandemic influenza preparedness plans</td>
</tr>
<tr>
<td>WHO 2009</td>
<td>Comparative analysis of national pandemic influenza preparedness plans</td>
</tr>
<tr>
<td>European Commission 2009</td>
<td>Commission Staff Working Document. Vaccination strategies against pandemic (H1N1) 2009</td>
</tr>
<tr>
<td>WHO 2011</td>
<td>Reducing transmission of pandemic (H1N1) 2009 in school settings</td>
</tr>
<tr>
<td>ECDC 2009</td>
<td>Guide to public health measures to reduce the impact of influenza pandemics in Europe: ‘The ECDC Menu’</td>
</tr>
<tr>
<td>European Commission 2005</td>
<td>Pandemic Influenza Preparedness and Response Planning</td>
</tr>
</tbody>
</table>

Author Year | Policy Working Documents |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO Europe 2011</td>
<td>WHO Regional Office for Europe guidance for sentinel influenza surveillance in humans</td>
</tr>
<tr>
<td>WHO Europe 2009</td>
<td>The European health report 2009. Health and health systems</td>
</tr>
<tr>
<td>WHO 2009</td>
<td>Regional Pandemic Influenza Preparedness and Response Plan, 2009-2010</td>
</tr>
<tr>
<td>WHO 2011</td>
<td>Pandemic (H1N1) 2009</td>
</tr>
<tr>
<td>European Commission 2010</td>
<td>Pandemic2009-EU commission</td>
</tr>
<tr>
<td>ECDC 2009</td>
<td>ECDC health information-pandemic</td>
</tr>
<tr>
<td>ECDC 2009</td>
<td>ECDC Risk Assessment-2009 influenza A(H1N1) pandemic</td>
</tr>
<tr>
<td>WHO 2010</td>
<td>Use of Influenza Rapid Diagnostic Tests</td>
</tr>
<tr>
<td>WHO 2011</td>
<td>Comparative analysis of national pandemic influenza preparedness plans</td>
</tr>
<tr>
<td>WHO 2009</td>
<td>Comparative analysis of national pandemic influenza preparedness plans</td>
</tr>
<tr>
<td>European Commission 2009</td>
<td>Commission Staff Working Document. Vaccination strategies against pandemic (H1N1) 2009</td>
</tr>
<tr>
<td>WHO 2011</td>
<td>Reducing transmission of pandemic (H1N1) 2009 in school settings</td>
</tr>
<tr>
<td>ECDC 2009</td>
<td>Guide to public health measures to reduce the impact of influenza pandemics in Europe: ‘The ECDC Menu’</td>
</tr>
<tr>
<td>European Commission 2005</td>
<td>Pandemic Influenza Preparedness and Response Planning</td>
</tr>
</tbody>
</table>
Organization (WHO) websites as well as on Google Academic. The terms we searched for were: “pandemics”, “pandemic influenza”, “influenza preparedness”, “pandemic influenza surveillance and response”, and “influenza pandemics policies”. The terms were searched for in the publication title, abstract, keywords, as well as in all the component parts of the publications. The reason for using Google Academic for the search was our intention to find also any other technical reports on the issue of pandemic influenza.

These official papers were used as working documents in order to reveal the main health determinants, risk factors and health outcomes associated with influenza pandemics.

6.1.2. Main goals
The main goals of the second objective of the strategy “Protecting citizens from health threats” are based on the article 152 of the Amsterdam EC treaty and follow to improve safety and security of citizens against health threats, in this particular case, maintaining and assuring healthcare services in case pandemic influenza emerges.

The strategy advanced by this paper is aiming to support the strengthening of health action at national, regional and local level. Preventing the occurrence of disease and reducing the prevalence of pandemic influenza by proposing a series of cost-effective actions taken on cross-border level and implemented equally by all member states is another goal. Aiming to deliver concrete health improvements in Europe, the strategy calls for hard work in order to improve surveillance, rapid detection and rapid response to health threats. In order to be covered, these needs require a close cooperation and coordination between European Commission and Member states as well as cooperation between healthcare systems.

6.1.3. Scope
Taking into consideration the macro level involved by European Union and the given fact that crossing borders could cause heavy issues (Technical Report: Pandemic Influenza Preparedness in the EU/EEA, 2007), it is vital to stress the improvement of prevention, surveillance and response mechanisms to health threats. It has become increasingly important to focus on these objectives, especially because there are cross-border issues and Member States cannot tackle the problem individually. Therefore, influenza pandemic threat requires close cooperation and
coordination between European Commission and Member in order to cover the need of improving surveillance, rapid detection and rapid response. Collaboration not only that will be helpful in order to reduce the gaps between the strategies develop at each level but will be also helpful in order to increase the visibility and accessibility of health information in general by exploiting the benefits of sharing best practices across the borders. In order to develop an operational strategy that meets the aim of reducing the spread of pandemic influenza among humans and through communities, the target group should cover the entire population of Europe.

6.1.4. Implementation plan
As implementation mechanisms, the strategy promotes involvement and a close cooperation between national, regional and local levels, but with the respect of the subsidiarity principle. The action group should move from one level to another: from member states to EC and vice versa, from EC to member states when it is about those authorities such as Ministries of Health which must ensure that in every country an efficient and sustainable health system is developed or other stakeholders.

Since the EC has not yet developed a Structured Cooperation implementation mechanism, the cooperation with Member States will be the starting point in reducing the gaps between the strategies develop at each of these two levels by identifying priorities and defining indicators. This will be also helpful in order to increase the visibility and accessibility of health information in general by exploiting the benefits of sharing best practices across the borders so as to ease the process of developing a set of guidelines and recommendation.

6.1.5. Methods of monitoring and evaluation
Even if EC Strategy does not state clear methods of monitoring and evaluation of the policies and there is no frame proposed in order to guide the Member States in their attempt of reducing pandemic influenza transmission, the strategy has been designed so as to be able to support the strengthening of health action at national, regional and local level.

In order to be able to monitor and evaluate the results, clear and measurable performance indicators should cross the local, regional and national borders and be assumes and developed
at EU level by European Commission, but only after the issues at member state level was taken into consideration and analyzed. Developing and implementing an effective strategy aimed to reduce communicable diseases transmission requires collaboration between Member States and EC so as, in case of pandemic everyone be prepared and know who acts first and how. The importance of taking preventive measures, prepare the member states in order to know how to deal in case of a pandemic disease, and increase the role of European Commission in managing this issue is vital for the health of population, the maintenance of socio demographic parameters and economical equilibrium. In addition, expanding the role of the European Commission is vital for the management of such situation, because a higher institution, above the member states is the only one able to orchestrate such a dynamic and proportionate phenomenon and stop it.

6.1.6. Problem identification - Policy actors
Considering all the EC Strategy aspects, there are three main challenges to the population health:

- Demographic changes and population ageing
- Pandemics and other incidents (biological, physical, climate change) with major potential to threatening health
- Development of new health technologies that require support

6.1.7. Specific actions
The strategic objectives of the EC Strategy are listed along with specific actions supporting them. For the second objective “Protecting citizens from health threats”, in order to cover the specific European needs regarding pandemic influenza, in the strategy was suggested the following action:

“Strengthen mechanisms for surveillance and response to health threats, including review of the remit of the European Centre for Disease prevention and Control (Commission)”
6.1.8. Policy actors
As it was mentioned above, although it is hard to clearly identify who are the policy actors involved, European Commission can be identified as being the main promoter of health policy being the author of Health Strategy. We propose in this manner advancing the attributes of the European Commission so as to assure the best possible pandemic influenza management. More than that, it is increasingly important to stress the fact promoting a top-down control in such situations can assure a in a brief period of time the implementation of the plan. Besides, member states actions are coordinated, follow the same procedure, being permanently monitored by a superior institution.

<table>
<thead>
<tr>
<th>EC official recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ General personal hygiene measures (regular hand washing, general mask wearing, respiratory hygiene, self-isolation)</td>
</tr>
<tr>
<td>✓ Travel and trade restrictions (travel advice, entry screening, border closure, international travel restrictions)</td>
</tr>
<tr>
<td>✓ Social distancing and quarantine (isolation and quarantine, workplace closure, avoiding personal contact, canceling public events, school closure)</td>
</tr>
<tr>
<td>✓ Community infection control (prophylaxis, animal and bird surveillance, prison and elderly homes surveillance, vaccination).</td>
</tr>
</tbody>
</table>

Although it is hard to clearly identify who are the policy actors at each level because they could be the European Commission as well as the governments and Ministries of health of member states, it is necessary for the European countries to cooperate so as to be prepared to action in case if such a problem emerges, and also to be able to minimize the damages caused by pandemics, as well as stop it’s spread and generate a solution to cease the disease.

6.1.9. Target population
The objectives enlisted in the strategy developed by EC are resuming the holistic vision regarding the whole European population’s health.

In order to protect the European citizen’s health from the emergence of a disease, it is extremely important to discuss the risks involved by influenza and the fact that it could transform in a pandemic spread across the Europe, threatening population’s health condition and causing several damages in many domains. Therefore,
influenza is an unpredictable and constant public health threat to European citizens and has an important impact both on individual and society level. Taking into consideration the possible damages it could create on a large scale by assuming a hypothetical case, there is a demand for the identification of risks and the generation of solutions to face such issue. Expanding the discussion and broadening the vision across the borders of Europe, there are involved requirements lying in solutions elaborated taking into account larger measurements, leading to the conclusion that on global scale are required such measures in order to lower the impact of this disease on the population health. Protection of citizens from health threats represents a key issue that requires a comprehensive approach that not only can prevent illness and disease but also can remove the hazards of human health.

The health determinants and risk factors stressed in official European documents may have a major impact, injuring a large number of people in case of emerging pandemic influenza. Taking into account these health determinants and risk elements, we identified specific actions that tackle with influenza pandemic.

First of all, the European Commission must focus on surveillance of health threats, in order to develop good mechanisms of preparedness and response for pandemic influenza that can lead to a lower prevalence of pandemic influenza. The countermeasures are addressing policy makers on European Community level and are aiming: general personal hygiene, travel and trade restriction, social distancing and quarantine and community infection control. These public health measures are directly tackling with pandemic influenza risk factors and can low the prevalence of influenza infection if are used according to the official recommendations.
Estimated policy results

Based on the earlier Top-down assessment case study on Romania, we assume that proactive school closure will have a direct effect on the transmission of pandemic influenza virus in school age population (a drop of 20% in the number of pandemic influenza cases) and an indirect effect on the inter-age group transmission – from children to family members – (a drop of 10% in the number of pandemic influenza cases). In the case of vaccination, an individual
protection is achieved but also a herd immunity effect would lower the transmission of the influenza virus in a given population. This means that the more people will get vaccinated, the lower transmission rate will be. As these two countermeasures can be adopted by all Member States, they will have a significant effect on lowering the pandemic influenza transmission. In order to estimate the impact of premature deaths due to pandemic influenza, we choose YPLL (Years of Potential Life Lost before age 65) as policy performance indicator (see Fig. 1).

6.1.11. Time course – Feasibility – Costs

Time course

The policy model we propose in this report is addressed to all Member States of European Union, therefore its implementation requires a longer period of time. The time course to affect the goals recommended is given in title 2008-2013 because of the complex process of assessing and applying the mechanism of surveillance and intervention both on national and European level.

Feasibility

Project feasibility is discussed under the need of implementing such policy model in order to prevent and solve the emergence of pandemic influenza. Taking into account the large impact it could have on European citizens health, our policy model meets a real need demanded by the EC Health Strategy. Concerning the increased role played by the European Commission in preventing influenza pandemics to occur, we consider it is mandatory in the co-operational process between Member States. The responsibilities enlisted in the content of the project may be assumed by both EC and national states because they are a matter of public health which objective is to reduce the prevalence of pandemics. Also, the measures we proposed are feasible and can be applied in all healthcare systems, because of the support given by previous studies related to the subject, such as European Union influenza pandemic process map (2006), European legislation on communicable diseases, EMEA Pandemic Influenza Crisis Management Plan for the Evaluation and Maintenance of Pandemic Influenza Vaccines and Antivirals (2006) or Innovations in EU Pandemic Preparedness - ECDC special report (2007).

Costs of implementation
We estimated the costs of implementation by expanding the calculus made for Romanian case of pandemics at the population of European Union assuming there is a similar distribution in European schools as well as in the Romanian schools. Giving the fact that for the Romanian population of 22 million people the costs involved were approximated at 14 million €, we evaluated the necessary amount of money for the 500 million population of EU at approximately 320 million €.

6.1.12. **Policy risk assessment**

In order to be preventive, it is crucial to develop a proper and effective strategy which requires an appropriate identification of all potential hazards which could increase the prevalence of pandemic influenza. As a result of applying the tool developed by RAPID and interviews conducted with Directorate General for Health & Consumers DG SANCO, unclear target groups and lack of performance indicators were identified as hazards. The possible explanation lies in the fact that, on the one hand EC Strategy had not been established a well-defined target, so it targets everyone, and moreover, there had not been empowered an authority clearly specified as being responsible with strategy implementation. On the other hand the strategy impact on health outcomes is hard to assess due to the lack of clear and measurable performance indicators.

6.2. **Determinants of health**

Defining them in large terms, pandemics are carriers of new infectious diseases that seriously affect the people’s health, in some cases leading to the death of the person infected (City of Redmond Hazard Mitigation Plan, 2004). Moreover, it is critical to state that pandemics are spreading immediately among human beings, then through communities, nations and even globally (ECDC Risk Assessment. 2009 Influenza A(H1N1) pandemic). Even though pandemics may follow the same pattern, taking as example the past experiences, they differ from each other (Technical Report. Pandemic Influenza Preparedness in the EU/EEA, 2007). In general, the most vulnerable groups exposed to such diseases are young children, the elderly, and people with pre-existing illnesses (WHO Regional Office for Europe guidance for sentinel influenza surveillance in humans, Updated—May 2011). Moreover, the problem is of much more
complexity, and the consequences may have a devastating effect on socio demographic and economic dimensions of the states, by causing economic losses due to staff absenteeism, schools and business closure and travel restrictions (Technical Report. Pandemic Influenza Preparedness in the EU/EEA, 2007; Regional Pandemic Influenza Preparedness and Response Plan, 2009-2010; Guide to public health measures to reduce the impact of influenza pandemics in Europe, 2009).

6.2.1. Model of health determinants applied
The health determinants model used for the policy assessment is the Dahlgren & Whitehead Social Model of Health that describes the levels and the interconnectedness of the various health determinants making a relationship between individuals, environment, and disease (Dahlgren and Whitehead 1991, cited in Leeds NHS Primary Care Trust).

6.2.2. Health determinants
Based on the Dahlgren& Whitehead health determinants model, after an extensive literature review on official documents regarding influenza pandemics, the following health determinants and risk factors were identified.

Based on the literature review and our case study “Romanian National Plan for interventions in Influenza Pandemics” we considered the strength of evidence and effect size of the selected health determinants. The strength of evidence was considered according to the frequency of occurrence in working documents. The effect size of the policy on the health determinants was assessed based on our assumptions (Table 1).
Performing an analysis on health determinants, a series of factors can be recognized as vital in respect of health status impact assessment. Providing a description of these elements is extremely important for placing the policy at a cross-national level, universally available for all member states.

Health status has been identified in several reports as being one of the major health determinants which may lead to contacting the virus of influenza pandemic (Comparative analysis of national pandemic influenza preparedness plans, 2011). The researchers underlie the fact that elderly population and chronic diseases sufferers are much exposed to the risk of getting ill than the rest of the population (Technical Report Pandemic Influenza Preparedness in the Eu/EEA, 2007; Use of Influenza Rapid Diagnostic Tests, 2010). One important aspect lies in identification of pregnant women as being inclined to be affected by influenza. Other risk factors are the transmission from animals to humans and an interesting aspect is the emergence of influenza near the borders (Technical Report. Pandemic Influenza Preparedness in the EU/EEA, 2007). The studies identified as health outcomes of the previous risk elements high mortality rates and high incidence of pandemic influenza (The European health report. Health and health systems, 2009).

Other studies focusing on pandemic influenza also reveal health status as being a major health determinant, adding the social factors as source. They bring evidence that young child (Evolution of a pandemic. A(H1N1), 2009) are as vulnerable as immunocompromised individuals...
and those exposed to some type of professions (Comparative analysis of national pandemic influenza preparedness plans, 2011).

As reports consulted show (The European health report. Health and health systems, 2009; Guide to public health measures to reduce the impact of influenza pandemics in Europe, 2009), social factors bring a large contribution to the spread of pandemic influenza, mostly if related with poverty. Furthermore, these agents are constant for ethnic communities, where lack of health care and limited access to health services causes increased mortality rates, high risk of pandemic influenza and decreased life expectancy (The European Health Report. Health and health systems, 2009).

### 6.3. Risk factors

Using the same scheme as in the case of health determinants, based on the literature review and our case study “Romanian National Plan for interventions in Influenza Pandemics” we considered the strength of evidence and effect size of the selected risk factors. The strength of evidence was considered according to the frequency of occurrence in working documents. The effect size of the policy on the risk factors was assessed based on our assumptions (Table 2).

All the studies regarding health care are insisting on the same risk factors as being vital for protection against pandemic influenza. Besides, it is disclosed that personal protection may be considered a crucial feature for preventing contacting influenza pandemic. Dirty hands, cough and sneeze are the cause of rapid spread of influenza virus (Frequently asked questions on pandemic (H1N1) 2009, 2009), poor health hygiene being underlined as extremely significant for fast extent of influenza virus (Guidance for Sentinel Influenza Surveillance in Humans, 2011). Besides, reports place vaccination as the most important action in controlling infection and suggest that a reduced number of people vaccinated may lead to a high mortality rate (Pandemic (H1N1) 2009, 2010).

Firstly, there had been identified the socio-economic factors to influence health status because they imply poverty, financial hardship, social disruption. In this case, some risk factors such as
lack of supplies and medical care, wage losses, unemployment, self-isolation lifestyle, loneliness may increase their potential (The European health report. Health and health systems, 2009)

Secondly, elderly and young children have been labeled as high risk individuals. Also, priorities are focused on elderly as well as other population-disabled and minorities. Thirdly, access to services such as education, health services or transport is categorized as important health determinants, bringing risk factors such as no access to health care services (Vaccination strategies against pandemic (H1N1), 2009).

### 6.4. Health outcomes

The model we provide regarding health policy with a specific approach on pandemic influenza is an extent of a pre-existing case study, but on a wider scale, implying an increased number of actors involved in the process. It is also crucial to already have developed a strategy and aware member states how to deal with the disease in order to action immediately and in the same way.

Firstly, we promote a **vaccination campaign** deployed in all countries part of the European Union because of its effectiveness for preventing to contact influenza virus. Immunization
against influenza is considered to be an essential public-health intervention to control both seasonal epidemics and pandemic influenza. Influenza vaccine development and deployment are critical elements of pandemic influenza preparedness. This is identified as being the most efficacious way to decrease the chances of getting infected as well as spreading easily further. (WHO, Global pandemic influenza action plan to increase vaccine supply, 2006; ECDC 2009).

Secondly, we propose school closure in case of pandemic influenza, by considering it a vital step to thwart influenza expanding process. Limiting one of the most important socialization factors, therefore stopping people to come in contact with each other will constantly reduce the probabilities to communicate the disease (Cauchemez, et al., 2009; Flahault, 2008; Vynnycky, 2008).

The impact on health outcomes at a national level can be assessed by using the YPLL estimates, and stakeholders can decide upon the most beneficial alternative policy that will improve the population health. In a similar manner, YPLL estimates can be calculated at European level, provided enough data about the pandemic is provided by each member state.

**6.4.1. Population affected**

Although all categories of population are exposed to influenza pandemic, several categories deserve special attention, given that they constitute specific risk groups. The individuals in these groups are those displaying a severe form of disease or die directly or indirectly from infection (European Center for Disease Prevention and Control, Pandemic (H1N1) 2009 planning assumptions to end of May 2010 for EU/EEA countries). In UK, for instance, 70-80% of deaths during the 2009 influenza pandemic were among people in risk groups.
6.4.2. Costs related to health outcomes

The two major dimensions need to be closely analyzed: the school closure (which is the most used social distancing measure in case of influenza) and the vaccination rate (part of the community infection control measure). We consider that some changes have to be made on these two dimensions in order to decrease the spread of the virus, but at the same time we have to be aware of the costs of applying these changes: which determinants of health are influenced by implementing one of the alternative policy and what would be the most relevant health outcomes if we would assume some case scenarios in each particular alternative policy.

Most analyses of data from Europe and the USA suggest that $R_0$ is most likely to be $1.2–1.7$, with higher estimates in specific contexts (for example, in Japan $R_0=2.3$; 95% confidence interval [CI], 2.0–2.6; in New Zealand $R_0=1.96$; 95% CI, 1.80–2.15; in Victoria, Australia, $R_0$ was initially $>2$ but dropped during the containment phase; in Argentina and Chile $R_0>1.7$). Differences in $R_0$, even in this range, may have a profound impact on the extent to which interventions can control an epidemic (World Health Organization, 2009).

6.5. Cross-level issues

Complexity of the issue

The complexity of the policy we proposed brings a series of limits, such as an overwhelming process to be assessed both at institutional and practical level, involving legislative as well as medical practice changes.

Causal pathways interrelations

Another barrier could be the differences regarding the economic development. The differences between E.U. member states are involving different pathways of applying the policy. These differences could contribute at improving interrelations between European countries so as to maintain permanent communication and regulate the implementation process in order to equally put the policy in practice. The process of applying the policy could encounter difficulties because of the dissimilarities regarding the Member States healthcare systems and also, the national economical contribution due to the variance of state budget income.
**Status-quo**

The main risk implied by the policy model we proposed consists in being unable to produce the changes enlisted in this document regarding pandemic influenza. Moreover, the dimensions of pandemic could exceed the numbers and figures we provided but, with a high grade of confidence we can stance that our assumptions are correct since the estimated costs are associated with real prices and number of population.

**Methodology limitations**

The pandemic influenza European policy must intervene in the healthcare systems of all member states. The methodology of implementing the policy requires a well-defined plan which could be limited by high costs and, as we previously highlighted by the diverse phases of systems development.

**Quantitative/ qualitative approach of uncertainty**

A quantitative approach of uncertainty could consist in the economic development and healthcare system differences and, from a qualitative perspective it could be related to the attention paid to this problem - some states could insist to implement the policy and subscribe to all its levels and others could implement only some of the objectives.

**Health effects time realization**

We state the length of the periods of time using assumptions and, analyzing the rapidness of the process in the past. Short term effects could be seen in the immediate period of time (1-2 weeks) from applying the policy because the urgent character demanded by its content and, long term effects could be observed at institutional level after a longer period of time (1 year).

Assessing the factors which may influence the policy process and giving a holistic vision upon them, we can identify the economic factors and healthcare systems specific for each Member States as being the independent variables and, policy implementation process as dependent of them.
6.5. Full chain discussion

To integrate all the characteristics of the discussion developed previously, to be more specific and facilitate the understanding of our purpose, we provided a scheme with all the policy levels, target groups (European Commission and Member States), actions for the two target groups and specific influenza pandemic countermeasures.

Starting from the EC Health Strategy as first policy level we analyzed the second objective of the Health Strategy, “Protecting citizens from health threats” from the two target groups perspective (second policy level). For each of these two, using official documents, we stated the actions related to the Health Strategy Objective and specific pandemic influenza countermeasures and health outcomes (third and fourth policy level). We described each policy level, also we exposed the manner in which these four levels are connected and influence each other, building a correlation between them and the protection of European citizens from health treats, after the objective inscribed in European Commission Strategy.

The first policy level is being identified in the Health Strategy act developed by the European Commission in order to display the goals to be achieved by member states in respect of health care. As already have been discussed, this document contains the purposes to follow in providing and assuring health services by each member state, more than that implementing a plan so as to be able to deal with the spread of an illness or pandemics.

The second level of policy drifts from the European Commission and Member States. An important aspect characterizing this level consists in the fact that is bipolar, catching simultaneously the European institutional level as well as member states health institutions.

The third policy level is identified as the specific actions for each of the two actors of the second level.

The fourth policy level is the ultimate level of implementing health services and is drifting from the ones above it. It also represents the translation into practice of all the rules and principles regarding the health protection system and related to both member states and European Commission apparatuses. European Commission’s actions of applying a mechanism of
surveillance in order to prevent health threats imply in the fourth level of health policy a decreased prevalence of influenza pandemics. It is natural that the measures taken in order to diminish the prevalence of health threats at macro level to be universally available for all member states so as to action equally and apply the same steps in reducing the widespread of influenza pandemics. Analyzing the facts from this perspective, we can identify two objectives to focus on to European level: travel and trade restrictions and general personal hygiene.

Travel and trade restrictions are welcomed in case of influenza pandemics because they represent the heart of social and business activities nowadays, and the main measures which should be taken in case of consists in travel advice so as to offer information about the risks people are exposed to, entry screening to identify and control the infected people, borders closure to stop the widespread of the virus and ultimately international travel restrictions so as to block it to become an global issue.

Promoting general personal hygiene is also a feasible action which can be put in practice by the all citizens of Europe. Some of the measures identified in the scheme we provided are part of the natural course of personal daily hygiene, consisting in hand washing so as to protect the human body from ingesting bacteria and respiratory hygiene. Other measures are focusing on protecting the citizens in case of pandemics, advising them to wear masks in order to prevent the contact with the virus and self-isolation so as to protect other people from getting the virus.

These are the measures proposed by Health Strategy document which may be applied in case of pandemic influenza break out, insisting on the one hand on prevention and providing protection for European citizens, and on the other hand on establishing the measures should be taken in such situation to action immediately and cease the illness.

The other aspect of the fourth policy regarding member states is focusing on the implementation of the measure but at a national level. The main goal identified is to change the incidence of pandemic influenza. We followed the same pattern as in Romania case study, inscribing in the scheme the two measures proposed at the national level, namely school closure and vaccination. Adopting these two steps may have a great impact on the ordinary
course of the society, but they are mandatory to prevent, control and cease a case of pandemic influenza at national level.

School closure may constitute a limitation for continuing the usual social life, firstly causing social distancing and quarantine. Even though the magnitude of such action could paralyze the entire social order, it is increasingly important to appeal to isolation and quarantine so as to separate from the healthy people and avoid infesting them. Workplace closure is also a manner for preventing the extent of diseases, moreover avoiding personal contact could decrease the percentage of infected people. Another measure taken on national level which may have a great contribution in stopping pandemics may reside in canceling the public events.

Starting a vaccination campaign could be the most preventive achievement in order to assure and shelter population’s health. We highlight this way of intervention because it can be the main supplier for controlling community infection. Furthermore, is involves surveillance for prisons and elderly homes, prophylaxis and animal and bird surveillance for thwarting the transmission of the virus from animals to human beings.

The four health policy levels are functioning after top-down mechanism; policy content is translated into practice on the one hand, at member states level by vaccination campaign and school closure and on the other hand at European level by promoting general personal hygiene notions and by asserting travel and trade restrictions.

The main objective of the detailed explanation of the scheme delivered above lies in the attempt to offer a justification for strengthening the role and the implication of the European Commission in managing situations involving pandemics. We underlined previously the main implications of this discussion may have on Europe’s health status and we are maintaining this view bringing as sustainable argument the fact that all these measures are scheduled in Objective 2 from European Commission’s Health Strategy. We underline that the major objectives enlisted in this act are designed for improving safety and security and protecting citizens against health threats, scientific risk assessment, preparedness and response to epidemics and bioterrorism, actions on food safety and consumer protection, communication and coordination between member states, action on health threats produced by climate
change, to address its potential impact on public health and healthcare systems (Together for Health: A Strategic Approach for the EU 2008-2013, 2007).

6.6. References


EC Health Strategy

1st Policy Level

European Commission
- European Commission, Council of the EU, ECDC, WHO, WHO Europe official documents

Member States
- Romanian National Plan for interventions in Influenza Pandemics

2nd Policy Level

Surveillance of health threats

Mechanisms of surveillance / response

Lower prevalence of influenza pandemics

3rd Policy Level

Development and delivery of actions on surveillance / response

Change in incidence of pandemic influenza

4th Policy Level

School closure

Vaccination

General personal hygiene
- Hand washing
- Mask wearing
- Respiratory hygiene
- Self-isolation

Travel and trade restrictions
- Travel advice
- Entry screening
- Borders closure
- International travel restrictions

Social distancing and quarantine
- Isolation and quarantine
- Workplace closure
- Avoid personal contact
- Cancel public events

Community infection control
- Prison and elderly homes surveillance
- Prophylaxis
- Animals and birds surveillance
Policy risk assessment of the EU Health Strategy (2008-2013)

Fostering good health in an aging Europe – tackling tobacco consumption

Pilot testing of the Top-down Risk Assessment Tool

Prepared for the project
Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012
EU (DG-SANCO) Grant agreement N° 20081105

Via

Project coordinating partner:
University of Southern Denmark
Unit for health promotion research
Niels Bohrs Vej 9 - 10 6700 Esbjerg, Denmark
www.healthpromotion.sdu.dk

By
Balazs Adam, Agnes Molnar and Roza Adany
University of Debrecen
Faculty of Public Health
Department of Preventive Medicine
H-4028 Debrecen Kassai 26, Hungary
November 10th 2011
7.1. Introduction

Noncommunicable diseases account for the largest share of the disease burden in the European population, representing over three quarter of the total burden measured in disability adjusted life years (DALY). Among noncommunicable diseases, cardiovascular diseases, neuropsychiatric disorders and malignant neoplasms have the largest contribution (WHO Europe, 2009). Tobacco smoking is the number one preventable cause of death and the leading contributing factor to the burden of disease in most of the European countries (WHO, 2008). According to projections, its role in mortality and morbidity is going to rise globally. Tobacco use killed 100 million people in the 20th century and is going to kill an estimated one billion in this century (WHO, 2008). Smoking accounted for 10.7% of all DALYs in high income countries in 2004 (WHO, 2009a).

It’s large and increasing public health importance necessitates effective actions to be taken to tackle tobacco epidemic and minimize its health consequences. The white paper of the Commission of the European Communities (EC) entitled “Together for Health: A Strategic Approach for the EU 2008-2013” acknowledged the significance of tobacco smoking by incorporating the fight against tobacco consumption into its 1st objective “Fostering good health in an aging Europe” as one of the key issues to be tackled (European Commission, 2007).

The European Union’s (EU) population is aging due to the low birth rate and increasing lifespan. By 2050, the number of elderly people over 65 years of age will grow by 70% (European Commission, 2007). Longer life expectancy is a favourable phenomenon; however, aging poses several challenges, too. With increasing age of the population, the work activity rate is lower and the prevalence of morbidity is higher, resulting in an increased disease burden on individuals and, through direct and indirect costs, also on the whole society. According to estimations, the healthcare expenditure in the Member States of the EU will increase by 1-2% of GDP by 2050, but this rise could be lessened to the half if people were prevented from getting diseased as they live longer (Economic Policy Committee, 2006). Therefore, effective prevention of chronic noncommunicable diseases as a prerequisite of healthy aging is indispensable for the feasible management of the economic and social challenges that increasing share of elderly age groups poses on the EU population.

According to the International Agency for Research on Cancer (IARC), tobacco smoke is a proven human carcinogen (IARC, 2004). Tobacco smoke exposure induces atherosclerosis in the circulatory system, irritates mucus membranes resulting in the development of chronic inflammation in the respiratory tract and inhibits immune activities. It has teratogenic and several other effects, too (U.S. Department of Health and Human Services, 2004). Thus, tobacco consumption is a good target for preventive measures designed to support healthy aging, since it is proven to cause a wide range of health effects, most of them resulting in the development of chronic diseases that can shorten life and impair quality of life during the years one must live with them.

Prepared for the project Risk Assessment from Policy to Impact Dimension (RAPID), the report provides experimental results about the pilot use of the guidance previously developed for top-down policy risk assessment. The observations may prove the usefulness of the methodological tool, as well as contribute to the overall assessment of the EU Health Strategy on the European level.
7.2. Assessment

The assessment is based on the mapping of the whole impact scheme of a chosen tobacco control policy. One priority causal pathway was selected from the scheme for detailed evaluation. The selection process and the assessment were carried out on each level of the impact chain with the use of the previously developed top-down risk assessment tool with special attention on testing the applicability of the guidance. The impact assessment applies on EU level and includes quantification of measures of a selected health outcome.

7.2.1. Policy

7.2.1.1. Context of the EU Health Strategy

The European Union has a pivotal role in the improvement of the health status of its citizens. European Treaties have placed obligations on the EC in the field of health since the 1990s, after the integration of public health provisions into the EC Treaty. Article 129 of the Maastricht Treaty gives the European Commission a degree of legal competence in the area of public health protection for the first time, reinforced by Article 152 of the Amsterdam Treaty that stipulates a high level of health protection in the definition and implementation of Community policies. These provisions gave the European Community legal responsibility, developing health mandate in various ways intended to strengthen public health and disease prevention actions and encourage cooperation between countries.

Besides complementing public health policies at national level, Community actions ensure European added value in the fight against global health challenges. In 2000, a coherent and co-ordinated approach to health policy was adopted by the European Commission in the form of the first EU Health Strategy, accompanied by the Public Health Programme for 2003-2007, which set out a comprehensive framework for action on health information, rapid reactions to health threats related to various health determinants at EU level.

However, in response to new global health challenges the Commission soon acknowledged that new approaches are required to tackle the ageing of the population, globalisation, infectious disease threats and lifestyle-related chronic diseases, and the need for health information and novel technologies at EU level. The Commission launched a consultation process in 2004 involving stakeholders to express their vision on the direction of a future EU health strategy who called for better co-ordination between public health and other policy areas, need for more comparable data on the impact of public health interventions and further debate on healthcare (EurActive.com, 2007).

In 2005, the Commission adopted a strategy and a proposal for the Community Programme for Health and Consumer Protection 2007-2013. As public health and consumer protection policies share many objectives (e.g. promoting health protection, safety, information and education) the Commission aimed, by combining the two programmes, to exploit synergies between health and consumer policies. It also wished that bringing the two policies together would generate greater policy coherence, economies of scale, increased visibility and streamlining of procedures. Due to its cautious welcome from both health and consumer stakeholders and the Parliament, the Conference of Presidents of the EP decided to split the programme (EurActive.com, 2007). In May 2006 two separate amended proposals were presented by the Commission, which were
followed by an impact assessment in 2007 and by a broad consultation, asking the people what future health action the EU should take and what the priorities for a future strategy should be. As a result, in October 2007 a new Health Strategy 'Together for Health: A Strategic Approach for the EU 2008-2013' was adopted. The strategy came at a crucial time – just after the EU had completed an increase in membership from 15 to 27 countries.

The new Health Strategy puts in place an overarching, strategic framework for work on health at the EU level, and sets the direction of public health actions till 2013. It replaces the diverse range of health related policies, legislation and fragmented actions at EU level. The Strategy encompasses work not only in the health sector but across all policy areas. The Strategy focuses on four principles and three strategic themes for improving health in the EU. The principles include developing a value-driven approach to EU health care systems, recognising the links between health and wealth, integrating health in all policies, and strengthening the EU's voice in global health. The strategic objectives include fostering good health in an ageing Europe, protecting citizens from health threats, and supporting dynamic health systems and new technologies.

The Second Programme of Community Action in the Field of Health (2008-2013) – repealing the first programme for the period 2003-2008 – is a key instrument to support the Strategy's objectives. The programme has a budget of 321 500 000 euro. The Commission is responsible for implementing the programme in close cooperation with the Member States, based on an annual work schedule, which sets the priorities to be respected and the actions to be taken. In order to support the integration of health into other Community policies, joint strategies and actions in coherence with other Community programmes can be established.

The Strategy is supported by financial tools both in the Directorate-General for Health and Consumers (DG SANCO) and in other sectors, such as the 7th Framework Programme for Research, and Regional Policy funding; ICT Policy Support Programme to stimulate innovation through the wider use of ICT in health; PROGRESS programme on employment, social affairs and equal opportunities; Sixth Environment Action Programme; and funding opportunities on health security preparedness. Implementation of the Strategy is supported by cooperation mechanisms at EU level based on the EU Council senior working party and selected Commission-led health committees and expert groups. Healthy life years (HLY) is established as a main indicator of monitoring results of the strategy.

The Strategy aims at the setting clear objectives to guide future work on health at the EU level. The Strategy intended to act as a means for developing policies and actions not only at EU level, but also at national level. The Strategy is in coherence with the provisions of the EU Treaty, other EU policies and programmes. The document contains several proposed actions for Member States that can use it as a reference framework for formulating their own policies, e.g. tobacco control policies.

Although the Strategy contains principles and general objectives, it does not define concrete, measurable targets, timeframes or specific target populations of actions. In this sense, the success and overall impact of the Strategy depend on the means of implementation that is concrete actions supported by available financial tools and effective coordination mechanisms. Desk approach of the analysis of the Strategy can rely on the results of different consultation processes, also findings of the mid-term evaluation, which can serve as information on the implementation of the Strategy. Among others the need for clear annual objectives with clear outcomes and measurable targets, explicit responsibilities for all the European institutions and increased work on Health in All Policies was highlighted by the European Public Health Alliance (EPHA, 2009).
Consultation on the role of local and regional authorities in the implementation of the Health Strategy identified several challenges to be overcome, including the impact of the economic crisis and more optimal use of the Structural Funds, hindered by ineffective implementation, lack of administrative capacity in the regions, insufficient expertise and the lack of a strategic and long-term approach (Committee of the Regions, 2010).

The mid-term evaluation of the strategy pointed to questionable influence of the EU Health Strategy on national health strategies and EU policies, restricted potential of the coordination mechanisms, as well as to generality and limited usefulness, the latter claimed by international organizations. The evaluation also stated that added value of the Strategy can be considered as to act as a guiding framework or catalyst for action in the EU (Public Health Evaluation and Impact Assessment Consortium, 2011).

7.2.1.2. Context of tobacco control policies in the EU

The main theme of our study is related to tobacco control. Principle 3 of the strategy, „Health in all policies” (HiAP) have special importance in the analysis of this policy context. Smoking policies provide great examples for the HiAP approach, which prove that population’s health is not an issue for health policy alone but developing synergies with these and other sectors is crucial for a strong Community health policy. Principle 4 “Strengthening the EU’s voice in global health” underpin the importance of encouraging implementation of international health agreements such as Framework Convention on Tobacco Control (FCTC), which provides a framework for countries to enact comprehensive tobacco control policies (WHO, 2003). Objective 1 of the Strategy “Fostering good health in an ageing Europe” outlines the crucial issue of supporting healthy ageing in the European population by the development and delivery of actions to promote health and prevent disease throughout the lifespan, among them tackling key issues like tobacco consumption.

The EU is actively developing a comprehensive tobacco control policy, which is characterised by a four-stage approach, such as legislative measures, support for Europe-wide smoking prevention and cessation activities, mainstreaming tobacco control into a range of other Community policies (e.g., agricultural policy, taxation policy, development policy) and establish the Community as major actor in tobacco control at a global level. The EU tobacco control is based on two main directives. The Tobacco Products Directive 2001/37 sets out two main objectives: facilitating the functioning of internal market in tobacco products sector and ensuring a high level of public health. The Tobacco Advertising Directive 2003/33 bans cross border tobacco advertising and sponsorship (European Commission, 2011).

Tobacco is a heavily taxed product in most Member States, underpinned on public health grounds as it discourages consumption, especially among young people due to their limited disposable income. Besides preventing particularly young people from taking up tobacco, higher prices supports smoking cessation, reduce the number of ex-smokers who resume the habit, and reduce the average cigarette consumption among continuing smokers. Tax policies may reduce tobacco consumption either by increasing the overall level of taxation and consequently the retail selling prices, or by imposing minimum taxes or specific duties on cheaper categories of cigarettes (European Commission, 2007b).

At national level, in recent years many Member States has increased taxation of tobacco as part of a comprehensive strategy for tobacco control. The EU harmonises, to some extent, taxation on tobacco products, the most recent legislation dates from 2011 (Directive 2011/64/EU). Previous directives adopted in
1992 and 1995 defined the structure of taxation for tobacco products and provided for a limited degree of harmonisation of these taxes. In 2004, the Council approved the WHO Framework Convention on Tobacco Control. Article 6 of the FCTC stipulates that “The Parties recognize that price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons.” “...each Party should adopt or maintain, as appropriate, measures which may include: implementing tax policies and, where appropriate, price policies, on tobacco products so as to contribute to the health objectives aimed at reducing tobacco consumption;...” (WHO, 2003).

In November 2009, a political agreement was reached on the new tax structure of manufactured tobacco, followed by the adoption of Council Directive 2010/12/EU. The new regulation aimed at a gradual increase in the EU minimum taxation levels on cigarettes and fine cut tobacco up to 2014 and 2018 respectively and a reduction in tobacco consumption by 10% within the next 5 years.

In June 2011, Council Directive 2011/64/EU was adopted on the structure and rates of excise duty applied to manufactured tobacco which repealed Directives 92/79/EEC, 92/80/EEC and 95/59/EC assembling them into a single act.

The new Directive

- defines the various categories of manufactured tobacco (cigarettes, fine cut tobacco intended for the rolling of cigarettes, cigars and cigarillos, other smoking tobacco);
- lays down the general principles governing taxation of manufactured tobacco;
- provides for an overall minimum excise duty of 57% of the weighted average retail selling price of cigarettes;
- provides for a minimum amount of excise duty of 64 Euro per 1000 cigarettes irrespective of the weighted average retail selling price;
- determines the minimum rates for fine-cut smoking tobacco, cigars and cigarillos and for other smoking tobaccos.

According to this Directive, Member States have to apply to cigarettes a specific excise duty per unit of the product and a proportional excise duty calculated on the basis of the weighted average retail selling price. Furthermore, the new Directive allows more flexibility for Member States to choose between either an ad valorem duty, or a specific duty or a mixture of both on manufactured tobacco other than cigarettes. The Directive pay particular attention to the relationship between public health and the final price of the products, bringing the structure and the rates of excise duties for fine-cut smoking tobacco (hand rolled), into line with excise duties for cigarettes. A broad consultation process involving associations and other stakeholders from the field of health preceded impact assessment of the Directive (European Commission, 2008).

The most effective strategy of tobacco control is taxation of tobacco products that can result in substantial reduction of smoking related morbidity and mortality as identified by the CHOICE project of the World Health Organisation (Shibuya, 2003). Based on its central role among the various tobacco control measures and on the availability of information on the expected change in exposure level related to policy implementation that enables quantitative exposure assessment, taxation of tobacco products has been chosen for detailed assessment.
7.2.2. Determinants of health

7.2.2.1. Impact scheme and prioritization

In the policy impact assessment, the holistic model of health was used following the concept first addressed in the Lalonde Report (Lalonde, 1974). According to this fundamental piece of work, health is determined by not only the provision of health care, but also by biologic determination (genetics), environmental factors and lifestyle. The used set of health determinants was made in line with the Lalonde concept.

Identification of the health determinants influenced by the policy was carried out based on an extensive literature review. The evidence for causal link was judged upon the proof provided by studies published in high value scientific literature.

Tobacco taxation policy affects two determinants of health in a direct and several others in an indirect way (Table 1). It essentially influences substance use, as its primary goal is to affect smoking behaviour, and state income due to the changing prices of tobacco products. All other health determinants are affected indirectly through the changing consumption of tobacco products.

During smoking environmental tobacco smoke exposure (ETS) develops that substantially impairs air quality. By now, we know that in the vicinity of smoking people, especially in indoor environments, absolute elimination of ETS with engineering control measures is not feasible (U.S. Department of Health and Human Services, 2006).

Air quality influences housing conditions and work environment; in general, the value of built environments. Tobacco smoke-free environment can have a higher aesthetic and an increasing financial value (WHO, 2008).

Besides its direct effect on state income, tobacco taxation policy, as a consequence of changing consumption of tobacco products, may also influence the income of the tobacco industry and due to the restructuring family expenses, the income and savings of families, too (World Bank, 1999).

The changing income of the tobacco industry may result in a revised employment policy of the sector that can influence employment. However, there has been negligible impact of tobacco taxation reported on the overall employment of the European tobacco industry (ASPECT, 2004).
Table 1 Health determinants predicted to be influenced by the policy

<table>
<thead>
<tr>
<th>Health determinant</th>
<th>Description of the impact on the determinant</th>
<th>Evidence</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lifestyle</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substance use</td>
<td>Direct effect on smoking behaviour</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td><strong>Physical environment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air</td>
<td>Air quality influenced by smoking habits</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Built environment and land use</td>
<td>Built environment influenced by ETS exposure</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Work environment and housing conditions</td>
<td>Work and housing environment influenced by ETS exposure</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td><strong>Socio-economic environment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income and social status</td>
<td>Direct effect on state income from excise duty</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Indirect effect on tobacco industry’s income from sale of tobacco products</td>
<td>+++</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Indirect effect on family income (expenses)</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Employment and working conditions (job safety)</td>
<td>Indirect effect on the employment in the tobacco industry including retailers</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Uncertain effect on overall employment</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

ETS: environmental tobacco smoke

The study aimed at limiting the analysis for one causal pathway. Substance use has been chosen for detailed assessment due to its crucial status in the impact scheme since it is directly affected by the policy while other determinants are typically influenced through changing smoking habits (Figure 1). The choice is supported by the strong evidence for causality as well as by the importance of the projected effect in terms of the size of population affected and severity of related health effects. Assessment of an influenced risk factor and health outcome, even in a quantitative way, was also deemed to be feasible.
Figure 1 The impact scheme of the policy. Selection of health determinant for assessment

Red background: selected element of the impact scheme

Light-green background: health determinants with indirect impact

7.2.2.2. Description of the selected health determinant

Individual-level determinants of health as tobacco – along with alcohol, diet and physical activity – continue to play an important role in Europe (WHO Europe, 2009). Seven lifestyle and behavioural risk factors are responsible for about 60% of the burden of disease in the European Region: high blood pressure, tobacco use, alcohol consumption, high serum cholesterol, overweight, unhealthy diet and insufficient physical activity (WHO Europe, 2005). In most countries of the Region, the leading risk factor for death is high blood pressure, while tobacco is the leading risk factor for burden of disease and the most important preventable single cause of death (WHO Europe, 2005; WHO Europe, 2006; WHO, 2008). It is a very straightforward public health problem accounting for about 25% of mortality and 17% of DALYs lost (Coleman, 2005).

The impact of tobacco on public health has been and remains to be a strong concern for the European Union since, according to projections, its role in mortality and morbidity remains high because a significant proportion of the Europeans continue to smoke (European Commission, 2010). Consequently, about 650,000 people die each year from smoking related illnesses, of which around half are between 35-69 years of age, who could have lived longer according to the average life expectancy (Health-EU, 2011).

Rising excise duty of tobacco products is an important policy measure that has been found the most effective measure for decreasing smoking in the population (Shibuya, 2003). It makes tobacco less accessible to the public due to increased prices. Several studies have pointed out the relationship between raised taxes and reduced tobacco consumption (World Bank, 1999; Jha P and Chaloupka F, 2000; ASPECT, 2004).
7.2.3. Risk factors

7.2.3.1. Impact scheme and prioritization

The risk factors influenced by the identified health determinants in the impact scheme are shown in Table 2. Tobacco smoking evidently exposes the users with the components of mainstream tobacco smoke that has been related to a wide range of health effects (U.S. Department of Health and Human Services, 2004).

Table 2 Risk factors predicted to be influenced by the selected health determinant

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Description of the impact on the risk factor</th>
<th>Evidence</th>
<th>Effect size</th>
<th>Quantification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active smoking</td>
<td>Active smoke exposure influenced by changing smoking behaviour</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Environmental tobacco smoke</td>
<td>ETS level influenced by changing smoking behaviour</td>
<td>+++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Aesthetic values</td>
<td>Perceived aesthetic value of the environment influenced by changing tobacco smoke exposure</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Income (tobacco industry, state)</td>
<td>Direct effect on state income from excise duty and from decreasing smoking related health care cost</td>
<td>+++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Direct effect on tobacco industry’s income from sale due to altered purchase of tobacco products related to changing smoking habits</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Income (family)</td>
<td>Indirect effect on the structure of family expenses due to the altered purchase of tobacco products</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Indirect effect through changing employment in the tobacco industry</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

Environmental tobacco smoke exposure consists of sidestream smoke and the exhaled mainstream smoke. ETS poses risk to any people nearby the smoking person, although the establishment of causal relationship between ETS exposure and health effects is difficult due to the diluted low concentrations of constituents (U.S. Department of Health and Human Services, 2006).

People feel better in a clean environment that is not stained by tobacco smoke. However, it is rather difficult to evaluate such an impact, especially to relate it to health outcomes. The aesthetic value may also affect the financial value of properties, influencing income and social status in this indirect way. 55% of the US and 90% of the Canadian population live in smoke-free houses that have a higher price on the real estate market than houses where someone smokes inside (Bergman and Arbor, 2007; WHO, 2008).
Decreased tobacco consumption of the population means reduction in the sale of tobacco products that causes income loss to the tobacco industry. The reduced income of sector may result in cutback and layoff that can increase unemployment. However, that impact has not been supported by previous observations (ASPECT, 2004). Due to the decreased sale, the government may also lose income from excise duty on tobacco products, however, that loss can be compensated by the increased tax content of tobacco items as well as from other sources, therefore the loss is usually rather virtual (World Bank, 1999).

The money spent on tobacco products by a family could be saved when consumption drops that may positively influence family budget. The extra money can be used to buy other products. Depending on the purchase habit of present smokers and quitters, the fall-back of expenses spent on tobacco may result in improved commercial balance, increased investments and employment in other areas, therefore negligible impact of the contingent employment reduction in the tobacco industry is expected on the overall employment rate (ASPECT, 2004).

The strongest impact of the policy is expected to be on the prevalence rate of active tobacco smoke exposure through changing substance use. The highest priority health effects and the most supporting scientific evidence for causality is also related to active tobacco smoke exposure. It affects a sizable proportion of the population and there is unequivocal proof with well-known pathomechanism in most of the cases for the causation of various diseases, many of them severe, life-threatening conditions. Considering the above arguments, active tobacco smoking has been chosen for detailed assessment (Figure 2). The choice is also supported by the possibility to carry out quantitative exposure assessment related to the taxation policy that makes the quantification of some of the health outcomes influenced by the selected risk factor possible.

7.2.3.2. Description of the selected risk factor

There are several thousand chemicals identified in tobacco and in tobacco smoke produced during smoking. Over 3000 constituents have been detected in tobacco and over 4700 in mainstream smoke, but the number of unidentified components is most probably even higher (Roberts, 1988; Smith and Fischer, 2001). Tobacco smoke is a complex exposure factor. The mainstream cigarette smoke inhaled by the smoker through the tip directly into the airways can be differentiated from the sidestream smoke that is released from the burning cigarette to the environment. ETS is therefore a mixture of sidestream smoke and residual mainstream smoke exhaled by the smoker and diluted in the atmosphere (IARC, 2004).
Cigarette smoke is an aerosol containing vapour and particulate phases (Table 3). The latter is made up by several billion semi-liquid particles per cm$^3$ within the mixture of combustion gases. Physical and chemical properties of the substances as well as the characteristics of the environment determine how chemicals are distributed between the particulate and vapour phase. There are close to 500 chemicals in the vapour phase which contributes with 95% to the mass of smoke. Although the number of components identified in smoke is high, the majority of them is present in very low concentrations (Hoffmann and Hoffmann, 1997; Smith and Fischer, 2001; IARC, 2004).

The four main components of tobacco smoke:

Vapour phase

- carbon dioxide
- other vapour phase constituents (e.g. acetaldehyde, formaldehyde, acrolein, nitrogen oxides and carbon monoxide)

Particulate phase

- particulate matter (tar)
- nicotine

### Table 3 Components present in at least 0.5 μg quantity in mainstream smoke of non-filtered cigarettes (Smith and Fischer, 2001)

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity/cigarette</th>
<th>Component</th>
<th>Quantity/cigarette</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vapour phase</strong></td>
<td></td>
<td><strong>Particulate phase</strong></td>
<td></td>
</tr>
<tr>
<td>Carbon monoxide</td>
<td>10-23 mg</td>
<td>Particulate matter</td>
<td>15-40 mg</td>
</tr>
<tr>
<td>Carbon dioxide</td>
<td>20-40 mg</td>
<td>Nicotine</td>
<td>1-2.5 mg</td>
</tr>
<tr>
<td>Carbonil sulphide</td>
<td>18-42 μg</td>
<td>Anabasine</td>
<td>2-20 μg</td>
</tr>
<tr>
<td>Benzene</td>
<td>12-48 μg</td>
<td>Phenol</td>
<td>60-140 μg</td>
</tr>
<tr>
<td>Toluene</td>
<td>100-200 μg</td>
<td>Catecol</td>
<td>100-360 μg</td>
</tr>
<tr>
<td><strong>Table 1 (contd)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>70-100 μg</td>
<td>Hydroquinone</td>
<td>110-300 μg</td>
</tr>
<tr>
<td>Acrolein</td>
<td>60-100 μg</td>
<td>Cholesterin</td>
<td>22 μg</td>
</tr>
<tr>
<td>Acetone</td>
<td>100-250 μg</td>
<td>γ-Butyrolacetone</td>
<td>10-22 μg</td>
</tr>
<tr>
<td>Pyridine</td>
<td>16-40 μg</td>
<td>Quinoline</td>
<td>0.5-2 μg</td>
</tr>
<tr>
<td>3-Methylpyridine</td>
<td>12-36 μg</td>
<td>Harman</td>
<td>1.7-3.1 μg</td>
</tr>
<tr>
<td>3-Vinylpyridine</td>
<td>11-30 μg</td>
<td>Benzoic acide</td>
<td>14-28 μg</td>
</tr>
</tbody>
</table>
Tobacco smoke contains several carcinogenic agents. Most of them are observed to induce cancer only in animals (probable and possible human carcinogens, 2A and 2B, respectively) but several chemicals can also be identified as proven human carcinogens (group 1) (IARC, 2004).

There are persistent organic pollutants, like polychlorinated dibenzodioxins, dibenzofurans and polychlorinated biphenyls, present in tobacco smoke in low quantity (Wilson, 2008). Stabile polychlorinated agents bound to particles are present in detectable amount and have low toxicity, meanwhile the most toxic 2,3,7,8-tetrachlorodibenzodioxin, which is considered to be the prototype of the chemical group, is not detectable. The amount of persistent organic pollutants shows a positive correlation with the particulate and tar content of the smoke. The total daily dioxin exposure from tobacco smoke is lower even in heavy smokers than the tolerable daily intake (TDI = 1-5 pg/ kg bw per day) (Wilson, 2008).

In the combustion of organic matters, like during cigarette smoking, free radicals are formed. These highly reactive molecules can enter into contact with the macromolecules of the body and damage them. The radicals can be inorganic (·OH, ·OOH), organic carbon-centred (·R) and oxygen-centred (·OR, ·OOR). The free radicals produced during burning react with O₂, NO and NO₂ molecules and with partially oxidised organic chemicals resulting in the production of further free radicals (Flicker and Green, 2001; Smith, 2002).

Almost one-third (29%) of EU citizens currently smoke either cigarettes, cigars or a pipe being actively exposed to tobacco smoke in this way. Over one fifth claim that they have given up smoking (22%) (Figure 3). Only the remaining half considers themselves as never smokers. According to their socio-demographical characteristics, smokers are more likely to be male than female, under 54 years of age and from lower social groups. In terms of occupation, smokers are more likely to be unemployed, manual workers or self-employed (European Commission, 2010).

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration (µg)</th>
<th>Substance</th>
<th>Concentration (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogene cyanide</td>
<td>400-500</td>
<td>Lactic acide</td>
<td>62-174</td>
</tr>
<tr>
<td>Ammonia</td>
<td>50-130</td>
<td>Glycolic acid</td>
<td>37-126</td>
</tr>
<tr>
<td>Methylamine</td>
<td>11.5-28.7</td>
<td>Succinic acide</td>
<td>110-140</td>
</tr>
<tr>
<td>Dimethylamine</td>
<td>7.8-10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitrogen oxides</td>
<td>100-600</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formic acide</td>
<td>210-490</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetic acide</td>
<td>330-810</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methyl chloride</td>
<td>150-600</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 3 Tobacco smoking in the European Union, 2009

Source: EC. Tobacco. Eurobarometer 72.3., 2010

Although one-third of the EU population is active smoker, the rate considerably varies between countries and genders (Figure 4).

Figure 4 Prevalence of smoking in EU member states, 2005

7.2.3.3. Exposure assessment

The change in the prevalence of active smoking due to the taxation policy of tobacco products can be predicted quantitatively using coefficients reported by observational epidemiological studies. Smoking prevalence data are available from EU countries, thus the future situation can be assessed.

The coefficient is typically provided as price elasticity of demand for taxation policies that refers to the extent to which use of a product falls or rises after increases or decreases in its price.

Depending on the size of the price increase, the reduction in the consumption of tobacco products can be significant. A World Bank review in 1999 found that if everything remains the same but price rises of about 10% would on average reduce tobacco consumption by about 4% in developed countries and 8% in developing countries (Jha P and Chaloupka F, 2000). More recently a large-scale meta-analysis that reviewed 86 studies published -0.48 mean price elasticity of demand for tobacco products (Gallet and List, 2003). The same authors also analysed the gender sensitivity for price increase and found average price elasticity of -0.50 for men and -0.34 for women.

In this study, gender-specific price elasticities were applied for the quantitative exposure assessment. In the model, the scenario of 10% increase in the price on tobacco products due to taxation was used that results in 5% reduction in tobacco consumption among males and 3.4% reduction among females. The decrease was assumed to be applicable not only for the consumption volume, but also for smoking prevalence.
7.2.4. Health outcomes

7.2.4.1. Impact scheme and prioritization

Tobacco smoke exposure is the selected risk factor for detailed assessment. It can be related to a wide range of health effects. Tobacco smoke is a proven human carcinogen classified by IARC (2004). It irritates mucus membranes resulting in the development of chronic inflammation in the respiratory tract, induces atherosclerosis in the circulatory system, inhibits immune activities, induces reproductive, gastrointestinal and other diseases (U.S. Department of Health and Human Services, 2004).

Several studies have been published about the relationship between active tobacco smoke exposure and various diseases (Table 4). The overall impact of smoking on health is significant: the relative risk for morbidity and mortality due to smoking related diseases among moderate smokers (1-20/day) is 1.77 (95% CI 1.40-2.24) for females and 1.42 (95% CI 1.23-1.64) for males, while among heavy smokers (over 20/day) 2.75 (95% CI 2.14-3.52) for females and 1.95 (95% CI 1.70-2.24) for males (Mucha, 2006).

Table 4 Health outcomes predicted to be influenced by the selected risk factor

<table>
<thead>
<tr>
<th>Health outcome</th>
<th>Description of the impact on the outcome</th>
<th>Evidence</th>
<th>Effect size</th>
<th>Quantification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>Proven carcinogenic effect</td>
<td>++++</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Oral cavity</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Nasal and paranasal</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Pharyngeal</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Laryngeal</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Stomach</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Liver</td>
<td>Carcinogenic effect</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Renal</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Urinary system</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Cervix</td>
<td>Proven carcinogenic effect</td>
<td>+++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Myeloid leukaemia</td>
<td>Carcinogenic effect</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
### Respiratory

<table>
<thead>
<tr>
<th>Chronic obstructive respiratory diseases</th>
<th>Airway injury (irritation, oxidati-ve stress, antiprotease imbalance)</th>
<th>+++</th>
<th>+++</th>
<th>+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>Exacerbation of asthmatic symptoms</td>
<td>+-</td>
<td>++</td>
<td>+-</td>
</tr>
<tr>
<td>Acute respiratory infections</td>
<td>Airway injury (irritation, oxidati-ve stress), suppressed immunity</td>
<td>+++</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

### Circulatory

<table>
<thead>
<tr>
<th>Coronary heart diseases</th>
<th>Atherosclerosis, thrombosis, impaired oxygen transport</th>
<th>+++</th>
<th>+++</th>
<th>+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>Atherosclerosis, thrombosis, impaired oxygen transport</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
</tr>
</tbody>
</table>

### Cont.

<table>
<thead>
<tr>
<th>Arterial diseases</th>
<th>Atherosclerosis, degradation of elastin, inflammation</th>
<th>+++</th>
<th>+</th>
<th>+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sudden cardiac death</td>
<td>Acute thrombosis, arrhythmias</td>
<td>++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Heart failure</td>
<td>Atherosclerosis, thrombosis, impaired oxygen transport</td>
<td>++</td>
<td>++</td>
<td>-</td>
</tr>
</tbody>
</table>

### Gastrointestinal

<table>
<thead>
<tr>
<th>Ulcer</th>
<th>Increased acidity and duodenogastric reflux, decreased mucus and alkaline pancreatic secretion</th>
<th>++</th>
<th>+</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crohn disease</td>
<td>Unknown (thrombosis, immune alterations, impaired defences?)</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Bile stone</td>
<td>Unknown (metabolic changes?)</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

### Reproductive

<table>
<thead>
<tr>
<th>Sudden infant death</th>
<th>Unknown, hypoxia, impaired CNS development</th>
<th>+++</th>
<th>+</th>
<th>+-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm birth</td>
<td>Induced PROM, infections, pla-centa previa, placental abruption</td>
<td>+++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td>Low birth weight</td>
<td>Nicotine effect on the respiratory, nervous and circulatory system</td>
<td>+++</td>
<td>++</td>
<td>+-</td>
</tr>
<tr>
<td>Female infertility</td>
<td>Impaired ovary function and</td>
<td>+++</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>
When considering the selection of a health outcome for detailed assessment, strong scientific evidence, large effect size that expresses public health importance and possibility of quantification assigned four priority diseases: lung cancer, chronic obstructive respiratory diseases, coronary heart diseases and stroke. The final choice for detailed evaluation fell on lung cancer; in the selection, severity of the disease and its especially strong association with the risk factor were taken into account (Figure 5). Quantitative outcome assessment was, however, carried out not only for lung cancer but also for the other three prioritized diseases.

Figure 5 The impact scheme of the policy. Selection of health outcome for assessment
7.2.4.2. Description of the selected health outcome

The 2004 Monograph of the IARC (2004) classified tobacco smoke as a proven human carcinogen (group 1) that contains over 60 compounds with proven or suspected carcinogenic and teratogenic properties. Tobacco smoke exposure can be related to the induction of lung cancer, various malignancies of the respiratory and gastrointestinal tract, pancreas, liver, urinary, renal and cervical cancer and myeloid leukaemia. The level of risk is mainly determined by the length of smoking history and by the number of cigarettes smoked daily. There are insufficient data that smoking can cause colon cancer and there is no established relationship between smoking and breast, endometrial and prostate cancer (IARC, 2004; U.S. Department of Health and Human Services, 2004).

Lung cancer (ICD C33-34, D0210, -20) is the most frequent malignant cause of death related to smoking. The relationship between smoking and lung cancer has been proven by many studies after the milestone articles published by Doll and Hill (1950) as well as Wynder and Graham (1950). Smoking can induce any histological types of lung cancer, like squamous, small, large cell and adenocarcinomas. Lung cancer risk is associated with the number of cigarettes smoked daily but even more with the number of years spent with smoking; at the same time quitting stops the further increase of risk (IARC, 2004). A meta-analysis summarising the results of 216 studies published between 1961 and 2003 on the correlation of smoking and cancer (Gandini, 2008) found that smoking increases the risk for developing lung cancer 8.96-fold (95% CI 6.73-12.11). The strength of association (value of relative risk, RR) increases with daily cigarette consumption (Table 5). In populations where the custom of smoking has a long history the population attributable risk of smoking is 90% (IARC, 2004); in the United States it contributes to 90% of lung cancer deaths among males and to 80% among females (U.S. Department of Health and Human Services, 2004).

Table 5 Dose-response relative risk estimates for smoking and lung cancer

<table>
<thead>
<tr>
<th>Cigarette consumption</th>
<th>Men RR (95% CI)</th>
<th>Women RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-9 cigarette/day</td>
<td>1.39 (1.28-1.50)</td>
<td>1.49 (1.37-1.61)</td>
</tr>
<tr>
<td>10-19 cigarette/day</td>
<td>2.67 (2.11-3.37)</td>
<td>3.30 (2.59-4.20)</td>
</tr>
<tr>
<td>≥20 cigarette/day</td>
<td>13.70 (7.40-25.50)</td>
<td>24.10 (12.70-45.90)</td>
</tr>
<tr>
<td>Overall</td>
<td>9.87 (6.85-14.24)</td>
<td>7.58 (5.36-10.73)</td>
</tr>
</tbody>
</table>

RR: relative risk, CI: confidence interval

7.2.4.3. Outcome assessment

In outcome assessment, disease burden was measured for a baseline and a predicted future scenario where policy action applies. The health outcome of the policy impact was perceived as the difference between the burdens in the two scenarios. Due to the limited availability of data on country level, only the calculation of attributable death as a disease burden measure was found feasible.

Applied input data were the age- and sex-specific absolute numbers of death (D) due to health outcome of lung cancer and the prevalence of exposure, i.e. active smoking (P_e). From the latter, sex-specific population attributable risk fractions (PARF) could be calculated for each country using association measures for males and females available from the literature. The product of D and PARF gave the number of death attributable for smoking (AD).

Data source for the absolute number of death was the Eurostat database (Eurostat, 2011). Mortality data were available for 2009, except for Italy, France (2008) and Belgium (2005). Exposure data, that is prevalence of active smoking, were derived from the World Health Statistics, 2009 database (WHO, 2009b). It provided data for 2005, except for Cyprus for which 2004 data were available from the Eurostat database. Association measures were acquired from the literature. Sex-specific relative risk (RR) of lung cancer was used from Gandini (2008) and RRs of chronic obstructive respiratory diseases, coronary heart diseases and stroke from Thun (2000).

The disease burden of tobacco smoking expressed as the absolute number of attributable death due to lung cancer, chronic obstructive respiratory diseases, coronary heart diseases and stroke in the EU shows a clear correlation with age and gender as calculated for the baseline scenario (Figure 6). Older age groups have a much higher burden for all diseases investigated. It is also demonstrated that the male predominance before the age of 65 lessens, even equalises or turns to female dominance in case of circulatory diseases over 65 years. These observations indicate that the disease burden related to smoking becomes an increasing problem in the aging EU countries in case no intervention is carried out to lower the exposure level in the populations.
Figure 6 Attributable death of active smoking due to lung cancer, chronic obstructive respiratory diseases, coronary heart diseases and stroke by sex and age groups in the EU countries.

The calculation of disease burden for a future scenario when 10% increase in the price of tobacco products is presumed can be seen in Figure 7. Price increase reduces tobacco consumption and as a result, decreases burden related to smoking.
Figure 7 Attributable death of active smoking due to lung cancer, chronic obstructive respiratory diseases, coronary heart diseases and stroke before and after 10% increase in tobacco prices by sex in the EU countries

The price increase results in a considerable decrease of attributable death that is the health gain of the policy measure (Figure 8).

According to the results, a considerable amount of 7668 lives among males and 4658 among females could be saved annually by the tax increase in the 27 member states of the European Union. The health gain is higher in males compared to females, especially in younger age groups (Figure 9). It is also definitely higher among elderly people. The considerable amount of annually saved lives among people over the age of 65 underpins the importance of tackling tobacco smoking in the aging population of the European Union.
Figure 9 Reduction in attributable death of active smoking due to lung cancer, chronic obstructive respiratory diseases, coronary heart diseases and stroke in result of 10% increase in tobacco prices by sex and age groups in the EU countries.
7.3. Discussion

In the study, the health impact of the tobacco tax policy was evaluated applying integrated quantitative impact assessment. The full impact structure of the hypothesized policy action of increasing price of tobacco products by 10% was mapped. Influenced health determinants, risk factors and health outcomes were identified and prioritized so as to select one causal chain of high importance for detailed quantitative assessment. In this process, the guidance provided by the methodological tool developed in a previous phase of the RAPID project was used and found to be applicable for the task.

The selected impact chain included substance use as determinant, active smoking as risk factor and lung cancer as health outcome. Quantitative exposure and outcome assessment was found feasible for the selected causal pathway. The study used -0.5 and -0.34 price elasticity that is 5% and 3.4% reduction in tobacco use induced by 10% price increase among males and females, respectively. The calculated measure was attributable death determined for the baseline and the projected scenario after the price increase. The difference, perceived as the health gain of the policy measure, was calculated to be 12326 lives (7668 among males and 4658 among females) that can be saved annually as a result of increasing tobacco prices by 10% in all member states of the European Union.

The health consequences of tobacco smoking pose a high burden on the European population, especially in older age groups, since smoking-related diseases of public health importance are typically chronic conditions that need long lag phase for development. Therefore, the importance of tackling the issue of smoking becomes more and more evident in an aging population. The inclusion of smoking into the 1st objective “Fostering good health in an aging Europe” of the EU Health Strategy as a factor to be dealt with is supported by the finding of this study. The selected tobacco policy proved to be effective measure providing example for how to manage the public health problem caused by smoking in the European population in the future.

In the study, quantitative assessment was integrated in the policy health impact assessment process in a structured way and proved to be feasible for four health outcomes that are diseases of high public health priority. Full chain approach and prioritization on each level of the impact chain proved to be essential for systematic quantification and the followed guidance provided valuable help in this process. Some difficulties were noted in the consistent rigid separation of health determinants and risk factors that can be hardly discussed in an isolated way in some cases. It has also been pointed out that those who intend to use the guidance with limited previous practice in health impact assessment may find the methodological instructions (How to do) insufficient. In spite of the noted shortcomings of the applied tool, the demonstrated methodology offers a practicable example for using quantitative assessment integrated in the health impact assessment of policies carried out on EU level.
7.4. References


EPHA. Comments on the implementation of the EU Health Strategy. 2009 http://www.epha.org/a/3737 accessed 18 November, 2011


Lalonde M. A new perspective on the health of Canadians. Minister of Supply and Services, Canada, 1974


Roberts DL. Natural tobacco flavor, Recent Adv Tob Sci 14: 49-81, 1988


Smith CJ and Fischer TH. Particulate and vapor phase constituents of cigarette mainstream smoke and risk of myocardial infarction, Atherosclerosis 158: 257-267, 2001


Thun MJ, Apicella LF, Henley S. Smoking vs other risk factors as the cause of smoking-attributable deaths: confounding in the courtroom, JAMA 284: 706-712, 2000

U.S. Department of Health and Human Services. The health consequences of involuntary exposure to tobacco smoke: A report of the Surgeons General, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health: Atlanta, Georgia, 2006

U.S. Department of Health and Human Services. The health consequences of smoking: A report of the Surgeons General, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health: Atlanta, Georgia, 2004


World Health Organisation Regional Office for Europe. The European health report 2009: health and health systems, WHO Regional Office for Europe: Copenhagen, 2009

World Health Organisation Regional Office for Europe. Gaining health: the European strategy for the prevention and control of noncommunicable diseases. WHO Regional Office for Europe: Copenhagen, 2006

World Health Organisation Regional Office for Europe. The European health report 2005: public health action for healthier children and populations, WHO Regional Office for Europe: Copenhagen, 2005


Wynder EL, Graham E. Tobacco smoking as a possible etiologic factor in bronchiogenic carcinoma: a study of 684 proven cases, JAMA 143: 329-336, 1950
8. LIGA.NRW Dusseldorf, Germany national report

WP 6 Draft Report prepared for project:
Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012
EU (DG-SANCO) Grant agreement No 20081105

Assessment of the EC Health Strategy: Test of the RAPID methodology

Sarah Sierig, Odile Mekel, Rainer Fehr

NRW Institute of Health and Work
WHO CC Regional Health Policy and Public Health
Düsseldorf/Bielefeld, Germany

Contact: odile.mekel@liga.nrw.de

Bielefeld, 30 November 2011
8.1. Methodology
The RAPID project developed a top-down and bottom-up methodology for policy risk assessment. The main objective of this assessment is to test the developed policy risk assessment tool (RAPID tool or methodology) on the case of EC Health strategy.

RAPID methodology consists of four parts: analysis of the policy, of health determinants, of risk factors and of health outcomes. Beside these parts some cross-level issues have to be considered. As RAPID methodology is a full-chain methodology, all connections between the four parts should be analysed. Other case studies of this working package have worked out these parts, issues and connections in detail on specific topics within the EC case study (Hungarian, Slovenian and Romanian case studies).

The present assessment shows how to analyse the EC Health Strategy as a whole – by means of the RAPID tool. A main part of the RAPID methodology is the definition, including and prioritizing of health outcomes, risk factors and health determinants. The EC Health Strategy includes nearly all health outcomes even if only a few of them are specifically defined (see Table 1).

Table 1: Health outcomes mentioned in the EC Health Strategy

<table>
<thead>
<tr>
<th>Health outcome</th>
<th>Where to find in EC Health Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific diseases including genetic disorders</td>
<td>objective 1</td>
</tr>
<tr>
<td>Alzheimer’s</td>
<td>objective 1</td>
</tr>
<tr>
<td>Injuries</td>
<td>objective 2</td>
</tr>
<tr>
<td>Communicable diseases</td>
<td>objective 2</td>
</tr>
<tr>
<td>Specific diseases</td>
<td>objective 2</td>
</tr>
</tbody>
</table>

The risk factors and resources mentioned in the strategy are nearly covering all determinants of health. Especially in objective 1 ‘key issues’ to tackle are listed which include most health relevant risk factors or determinants: “Healthy ageing must be supported by actions to promote health and prevent disease throughout the lifespan by tackling key issues including poor nutrition, physical activity, alcohol, drugs and tobacco consumption, environmental risks, traffic accidents, and accidents in the home” (EC 2007, page 7).

This makes it difficult to include or exclude risk factors and health outcomes only on the basis of the Strategy. Therefore we decided to identify the most relevant health outcomes for Europe in general (share of Burden of Disease – BoD) and the current attributable fraction of BoD for risk factors mentioned in the EC strategy. This overview has been worked out in chapter two of this report using the indicators healthy life years (HLY) and disability-adjusted life year (DALY). Additionally, the Burden of Disease studies of WHO were used to identify the most important risk within EU-27 (chapter three of this report). Based on this overview it is possible to examine to what extent the EC Health Strategy can contribute to reduce the differences between EU-27 countries for two main health indicators (HLY and DALY) and to tap the full potential health gains (chapter four).
8.2. Distribution of diseases within Europe

To assess the potential health gains of the EU Health Strategy it is important to have an overview of the distribution of diseases within Europe.

8.2.1. Healthy Life Years (HLY) in EU-27

The indicator Healthy Life Years (HLY) was used to compare EU-27 countries. HLY are the “expected remaining years lived from a particular age without long-term activity limitation”. HLY “takes into account both mortality and ill-health, providing more information on burden of diseases in the population than life expectancy alone” (EC, Heidi Data Tool).

Here the HLY at birth is used. For 2008 we see large differences in healthy life expectancy between the EU-27 countries (see Figure 1).

![Healthy Life Years at birth (HLY) in the EU-27 countries 2008 (own illustration, data adapted from the HEIDI Data Tool)](image)

Figure 1: Healthy life years at birth (HLY) in the EU-27 countries 2008 (own illustration, data adapted from the HEIDI Data Tool)

Regarding potential maximum health gains, we compare the ‘best’ and the ‘worst’ countries (see Table 2).

---

5 http://ec.europa.eu/health/indicators/indicators/index_en.htm
Table 2: Highest and lowest Healthy Life Years (HLY) of EC-27 countries

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>69.2</td>
<td>-</td>
</tr>
<tr>
<td>Latvia</td>
<td>51.5</td>
<td>-</td>
</tr>
<tr>
<td>Malta</td>
<td>-</td>
<td>71.9</td>
</tr>
<tr>
<td>Slovakia</td>
<td>-</td>
<td>52.3</td>
</tr>
</tbody>
</table>

Difference = Potential health gain 17.7 19.6

8.2.2. Disability-Adjusted Life Years (DALY) in EU-27

One of the most extensive studies is the WHO Global Burden of Disease Study (WHO GBD). It measures burden of disease using the disability-adjusted life year (DALY). DALY is a time-based measure and combines years of life lost due to premature mortality (YLL) and years of life lost due to time lived in states of less than full health (YLD) (WHO 2008).

Box 1: The disability-adjusted life year

The disability-adjusted life year (DALY) extends the concept of potential years of life lost due to premature death to include equivalent years of “healthy” life lost by virtue of being in states of poor health or disability (3). One DALY can be thought of as one lost year of “healthy” life, and the burden of disease can be thought of as a measurement of the gap between current health status and an ideal situation where everyone lives into old age, free of disease and disability.

DALYs for a disease or injury cause are calculated as the sum of the years of life lost due to premature mortality (YLL) in the population and the years lost due to disability (YLD) for incident cases of the disease or injury. YLL are calculated from the number of deaths at each age multiplied by a global standard life expectancy for each age. YLD for a particular cause in a particular time period are estimated as follows:

YLD = number of incident cases in that period x average duration of the disease x weight factor

The weight factor reflects the severity of the disease on a scale from 0 (perfect health) to 1 (death). The weights used for the GBD 2004 are listed in Annex Table A6 of Mathers et al. (11).

In the standard DALYs reported here and in recent World Health Reports, calculations of YLL and YLD used an additional 3% time discounting and non-uniform age weights that give less weight to years lived at young and older ages (6). Using discounting and age weights, a death in infancy corresponds to 33 DALYs, and deaths at ages 5-20 years to around 36 DALYs.

Figure 2: Definition of the DALY indicator (WHO 2008)

WHO GBD covers more than 100 diseases (defined by ICD code). These diseases are divided into three main categories: 1) communicable, maternal, perinatal and nutritional conditions (includes 39 defined diseases); 2) noncommunicable diseases (includes 57 diseases) and 3) injuries (includes 9 causes of injuries).

An initial comparison of DALY rates (DALY per 100 000 population) shows that the noncommunicable diseases play the most important role regarding the burden of disease in Europe. In all countries of EU-27 they account for 80 % - 90 % of the whole burden of disease in this country (Table 3).
Table 3: DALY rates (DALY per 100,000 population by cause, WHO 2009a)

<table>
<thead>
<tr>
<th>EU27</th>
<th>DALY rate all causes</th>
<th>Communicable, maternal, perinatal and nutritional conditions</th>
<th>Noncommunicable diseases</th>
<th>Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>12 069</td>
<td>495</td>
<td>10583</td>
<td>990</td>
</tr>
<tr>
<td>Belgium</td>
<td>12 948</td>
<td>543</td>
<td>11239</td>
<td>1166</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>18 296</td>
<td>943</td>
<td>16044</td>
<td>1308</td>
</tr>
<tr>
<td>Cyprus</td>
<td>12 010</td>
<td>833</td>
<td>10275</td>
<td>902</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>14 326</td>
<td>526</td>
<td>12378</td>
<td>1422</td>
</tr>
<tr>
<td>Denmark</td>
<td>13 447</td>
<td>486</td>
<td>11971</td>
<td>990</td>
</tr>
<tr>
<td>Estonia</td>
<td>18 900</td>
<td>1183</td>
<td>14649</td>
<td>3068</td>
</tr>
<tr>
<td>Finland</td>
<td>13 205</td>
<td>504</td>
<td>10981</td>
<td>1720</td>
</tr>
<tr>
<td>France</td>
<td>12 262</td>
<td>579</td>
<td>10517</td>
<td>1167</td>
</tr>
<tr>
<td>Germany</td>
<td>12 536</td>
<td>488</td>
<td>11312</td>
<td>736</td>
</tr>
<tr>
<td>Greece</td>
<td>11 826</td>
<td>495</td>
<td>10404</td>
<td>928</td>
</tr>
<tr>
<td>Hungary</td>
<td>17 941</td>
<td>693</td>
<td>15688</td>
<td>1560</td>
</tr>
<tr>
<td>Ireland</td>
<td>11 692</td>
<td>653</td>
<td>10155</td>
<td>884</td>
</tr>
<tr>
<td>Italy</td>
<td>11 245</td>
<td>495</td>
<td>9984</td>
<td>766</td>
</tr>
<tr>
<td>Latvia</td>
<td>19 615</td>
<td>1150</td>
<td>15341</td>
<td>3125</td>
</tr>
<tr>
<td>Lithuania</td>
<td>18 401</td>
<td>1090</td>
<td>13861</td>
<td>3450</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>12 341</td>
<td>670</td>
<td>10452</td>
<td>1219</td>
</tr>
<tr>
<td>Malta</td>
<td>11 141</td>
<td>600</td>
<td>9875</td>
<td>666</td>
</tr>
<tr>
<td>Netherlands</td>
<td>11 486</td>
<td>578</td>
<td>10294</td>
<td>614</td>
</tr>
<tr>
<td>Poland</td>
<td>14 911</td>
<td>699</td>
<td>12454</td>
<td>1759</td>
</tr>
<tr>
<td>Portugal</td>
<td>13 615</td>
<td>923</td>
<td>11582</td>
<td>1110</td>
</tr>
<tr>
<td>Romania</td>
<td>17 685</td>
<td>1447</td>
<td>14450</td>
<td>1788</td>
</tr>
<tr>
<td>Slovakia</td>
<td>15 340</td>
<td>767</td>
<td>12978</td>
<td>1595</td>
</tr>
<tr>
<td>Slovenia</td>
<td>14 002</td>
<td>552</td>
<td>11929</td>
<td>1521</td>
</tr>
<tr>
<td>Spain</td>
<td>11 352</td>
<td>609</td>
<td>9883</td>
<td>860</td>
</tr>
<tr>
<td>Sweden</td>
<td>11 478</td>
<td>481</td>
<td>10164</td>
<td>833</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>12 871</td>
<td>674</td>
<td>11489</td>
<td>708</td>
</tr>
<tr>
<td><strong>ALL average</strong></td>
<td><strong>13 961</strong></td>
<td><strong>709</strong></td>
<td><strong>11 886</strong></td>
<td><strong>1 365</strong></td>
</tr>
</tbody>
</table>

Regarding possible health gains, we compare again the ‘best’ and the ‘worst’ countries. The “best” country, Malta has 11 141 DALY per 100 000 population for all causes. The country with the “worst” DALY rate, Latvia, has 19 615 DALY per 100 000 population for all causes. The difference between these two values is 8474 DALY per 100 000 population (all causes) and can be interpreted as potential health gain (see Table 4).
Table 4: EU-27 countries with highest and lowest DALY rate

<table>
<thead>
<tr>
<th></th>
<th>EU-27 countries with highest and lowest DALY</th>
<th>DALY rate all causes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>high</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia</td>
<td></td>
<td>19 615</td>
</tr>
<tr>
<td>Estonia</td>
<td></td>
<td>18 900</td>
</tr>
<tr>
<td>Lithuania</td>
<td></td>
<td>18 401</td>
</tr>
<tr>
<td>Bulgaria</td>
<td></td>
<td>18 296</td>
</tr>
<tr>
<td>Hungary</td>
<td></td>
<td>17 941</td>
</tr>
<tr>
<td>Romania</td>
<td></td>
<td>17 685</td>
</tr>
<tr>
<td><strong>low</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greece</td>
<td></td>
<td>11 826</td>
</tr>
<tr>
<td>Ireland</td>
<td></td>
<td>11 692</td>
</tr>
<tr>
<td>Netherlands</td>
<td></td>
<td>11 486</td>
</tr>
<tr>
<td>Sweden</td>
<td></td>
<td>11 478</td>
</tr>
<tr>
<td>Spain</td>
<td></td>
<td>11 352</td>
</tr>
<tr>
<td>Italy</td>
<td></td>
<td>11 245</td>
</tr>
<tr>
<td>Malta</td>
<td></td>
<td>11 141</td>
</tr>
</tbody>
</table>

To explore where the health gains can be reached concretely we need to have a closer look on specific diseases or disease categories. The three main categories of BoD-studies (communicable, maternal, perinatal and nutritional conditions; noncommunicable diseases and injuries are further divided into 2-14 subcategories. Finally, per subcategory, there are 1 – 16 ICD-coded diseases (or causes of injuries) listed.

Within the noncommunicable diseases three subcategories are crucial for the burden of disease in Europe: a) Neuropsychiatric conditions, b) Cardio-vascular diseases, and c) Malignant neoplasms.

In 25 countries of EU-27 these subcategories are the first, second or third important contribution to the total DALY. Exceptional cases are Cyprus with Sense organ diseases and Lithuania with Unintentional injuries, each on the third rank (see Table 5).

Table 5: Main noncommunicable diseases subcategories which contribute as first, second or third importance to total DALY in a country

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuropsychiatric conditions</td>
<td>18</td>
<td>9</td>
<td>0</td>
<td>27</td>
</tr>
<tr>
<td>Cardiovascular diseases</td>
<td>9</td>
<td>11</td>
<td>7</td>
<td>27</td>
</tr>
<tr>
<td>Malignant neoplasms</td>
<td>0</td>
<td>7</td>
<td>18</td>
<td>25</td>
</tr>
<tr>
<td>Sense organ diseases</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Unintentional injuries</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
On average (EU-27), *malignant neoplasms* account for 2072 DALY per 100 000 population, *neuropsychiatric conditions* for 3179 and *cardio-vascular diseases* for 2888 DALY per 100 000 population. Regarding potential health gains, we compare the ‘best’ and the ‘worst’ countries again: Cyprus has the lowest DALY rate for *malignant neoplasms* (971) while Hungary has the highest rate (3044). The difference between these two values (“potential health gain”) is 2073 DALY per 100 000 population. For *neuropsychiatric conditions* the ‘best’ country is Italy (2546), the ‘worst’ Finland (3709), the difference amounts to 1163 DALY per 100 000 population. For *cardio-vascular diseases* the DALY rate of 6924 in Bulgaria is the highest and the rate of 1415 in France is the lowest, with a difference of 5509 DALY (see Table 6).

Table 6: DALY rates, three major noncommunicable diseases (DALY per 100,000 population by cause, WHO 2009a)

<table>
<thead>
<tr>
<th>EU27</th>
<th>Malignant neoplasms</th>
<th>Neuropsychiatric conditions</th>
<th>Cardiovascular diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>1882</td>
<td>3211</td>
<td>1828</td>
</tr>
<tr>
<td>Belgium</td>
<td>2193</td>
<td>3183</td>
<td>2129</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>2162</td>
<td>3166</td>
<td>6924</td>
</tr>
<tr>
<td>Cyprus</td>
<td>971</td>
<td>2591</td>
<td>2258</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>2571</td>
<td>2970</td>
<td>3358</td>
</tr>
<tr>
<td>Denmark</td>
<td>2350</td>
<td>3199</td>
<td>2093</td>
</tr>
<tr>
<td>Estonia</td>
<td>2329</td>
<td>3493</td>
<td>4676</td>
</tr>
<tr>
<td>Finland</td>
<td>1612</td>
<td>3709</td>
<td>2305</td>
</tr>
<tr>
<td>France</td>
<td>2234</td>
<td>3439</td>
<td>1415</td>
</tr>
<tr>
<td>Germany</td>
<td>2114</td>
<td>3088</td>
<td>2392</td>
</tr>
<tr>
<td>Greece</td>
<td>1897</td>
<td>2607</td>
<td>2764</td>
</tr>
<tr>
<td>Hungary</td>
<td>3044</td>
<td>3645</td>
<td>4193</td>
</tr>
<tr>
<td>Ireland</td>
<td>1725</td>
<td>3286</td>
<td>1735</td>
</tr>
<tr>
<td>Italy</td>
<td>2056</td>
<td>2546</td>
<td>1941</td>
</tr>
<tr>
<td>Latvia</td>
<td>2340</td>
<td>3418</td>
<td>5705</td>
</tr>
<tr>
<td>Lithuania</td>
<td>2175</td>
<td>3455</td>
<td>4319</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>1798</td>
<td>3260</td>
<td>2002</td>
</tr>
<tr>
<td>Malta</td>
<td>1688</td>
<td>2661</td>
<td>2022</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2112</td>
<td>3013</td>
<td>1707</td>
</tr>
<tr>
<td>Poland</td>
<td>2368</td>
<td>3229</td>
<td>3245</td>
</tr>
<tr>
<td>Portugal</td>
<td>2032</td>
<td>2982</td>
<td>2416</td>
</tr>
<tr>
<td>Romania</td>
<td>2115</td>
<td>3156</td>
<td>5009</td>
</tr>
<tr>
<td>Slovakia</td>
<td>2144</td>
<td>3667</td>
<td>3422</td>
</tr>
<tr>
<td>Slovenia</td>
<td>2452</td>
<td>3283</td>
<td>2464</td>
</tr>
<tr>
<td>Spain</td>
<td>1890</td>
<td>2760</td>
<td>1556</td>
</tr>
<tr>
<td>Sweden</td>
<td>1680</td>
<td>3387</td>
<td>2004</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>2007</td>
<td>3432</td>
<td>2083</td>
</tr>
<tr>
<td>ALL average</td>
<td>2072</td>
<td>3179</td>
<td>2888</td>
</tr>
</tbody>
</table>

In the 18 countries where *neuropsychiatric conditions* are the main causes of total DALY a closer look shows that *unipolar depressive disorders* lead to the most DALY within this group (see Table 7).
Table 7: Main neuropsychiatric conditions which are the first, second or third important cause of DALY in a country

<table>
<thead>
<tr>
<th>Neuropsychiatric conditions</th>
<th>Number of countries with rank</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Unipolar depressive disorders</td>
<td>18</td>
</tr>
<tr>
<td>Alzheimer and other dementias</td>
<td>0</td>
</tr>
<tr>
<td>Alcohol use disorders</td>
<td>0</td>
</tr>
<tr>
<td>Drug use disorders</td>
<td>0</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>0</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>0</td>
</tr>
<tr>
<td>Migraine</td>
<td>0</td>
</tr>
</tbody>
</table>

8.2.3. Preliminary conclusions

With the indicator HLY it is possible to get an overview of differences in health status between countries. The difference in HLY between the ‘best’ (highest HLY) and the ‘worst’ (lowest HLY) country can be interpreted as health gain potential: the highest HLY should be possible to reach for all countries; of course adequate measures are needed.

The health gain potential seems to be enormous: nearly 20 healthy life years seem to be possible.

A possible next step to assess the causes of these differences would lie in a comparison between policies and measures in “best” and “worst” countries. But it is not possible to break this indicator down into single disease or disease groups and link causal-effect-relationships for single risk factors to the healthy life expectancy. For further assessment the indicator disability-adjusted life year (DALY) offers more detailed information.

With the DALY indicator it is possible to compare the contribution of different diseases to the total burden of disease in one country and between countries. So the DALY indicator offers more detailed information about the concrete diseases which lead to differences in healthy life expectancy.

The difference in DALY rate between the ‘best’ (lowest DALY rate) and the ‘worst’ (highest DALY rate) country could also interpreted as health gain potential: the lowest DALY rate should be possible to reach for all countries of course with adequate measures (see Table 8).

Table 8: Potential health gains based on the comparison of HLY and DALY rates between EU-27 countries

<table>
<thead>
<tr>
<th>Health outcome</th>
<th>Potential health gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLY at birth for men</td>
<td>17.7 HLY</td>
</tr>
<tr>
<td>HLY at birth for women</td>
<td>19.6 HLY</td>
</tr>
<tr>
<td>All causes</td>
<td>8474 DALY</td>
</tr>
<tr>
<td>Malignant neoplasms</td>
<td>2073 DALY</td>
</tr>
<tr>
<td>Neuropsychiatric conditions</td>
<td>1163 DALY</td>
</tr>
<tr>
<td>Cardio-vascular diseases</td>
<td>5509 DALY</td>
</tr>
</tbody>
</table>
8.3. Major risk factors for health in the EU-27 countries

The leading risk factor in the EU-27 is tobacco (WHO 2005); it is the leading cause of the total burden of disease expressed in DALY in 16 out of 27 countries. In the remaining countries tobacco is the second or third cause of the total burden of disease (see Table 9).

Table 9: Major risk factors in EU-27 countries

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Rank 1</th>
<th>Rank 2</th>
<th>Rank 3</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco</td>
<td>16</td>
<td>6</td>
<td>5</td>
<td>27</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>4</td>
<td>10</td>
<td>7</td>
<td>21</td>
</tr>
<tr>
<td>Alcohol</td>
<td>7</td>
<td>9</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>High BMI</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

In average tobacco accounts for 12.7% of all DALY of a country in EU-27 (range 5.6% - Cyprus to 20.9% - Hungary). The prevention potential is vast, as demonstrated in the Hungarian EU assessment.

Other leading risk factors are related to lifestyle, too. The top 5 in each country are accounting for ~ 50% of all DALY.

8.4. To what extent can the EC Health Strategy contribute to tap the full potential health gains?

Based on this overview, we were able to examine to what extent the EC Health Strategy can contribute to reduce the differences between EU-27 countries for two main health indicators (HLY and DALY) and to tap the full potential health gains. In the first three parts of this report the most relevant diseases for EU-27 and the most important risk factor were identified.

In this fourth part of the report, the actions of the strategy to tackle diseases and risk factors are identified (see Table 10).
Table 10: Strategies mentioned in the EC Health Strategy

<table>
<thead>
<tr>
<th>No.</th>
<th>Actions</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Measures to promote the health of older people and the workforce and actions on children’s and young people’s health (Commission)</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Development and delivery of actions on tobacco, nutrition, alcohol, mental health and other broader environmental and socioeconomic factors affecting health (Commission, Member States)</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>New Guidelines on Cancer screening and a Communication on European Action in the Field of Rare Diseases (Commission)</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Follow up of the Communication on organ donation and transplantation (Commission)</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Strengthen mechanisms for surveillance and response to health threats, including review of the remit of the European Centre for Disease prevention and Control (Commission)</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>Health aspects on adaptation to climate change (Commission)</td>
<td>2</td>
</tr>
<tr>
<td>7</td>
<td>Community framework for safe, high quality and efficient health services (Commission)</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Support Member States and Regions in managing innovation in health systems (Commission)</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>Support implementation and interoperability of e-health solutions in health systems (Commission)</td>
<td>3</td>
</tr>
</tbody>
</table>

To assess the impact of these actions on health outcome we have to define how they influence health determinants, risk factors and health outcomes. A problem is, that most of the actions are too less concrete to show these connections.

As an example to demonstrate how the impacts of these actions could be estimated, the second action “Development and delivery of actions on tobacco, nutrition, alcohol, mental health and other broader environmental and socioeconomic factors affecting health” was chosen.
Tobacco is the major health risk factor within the EU-27. Tackling these factors promises the largest health gain: 6-20% of all DALY per country. It is not very probably to achieve 100 % tobacco-free environments in the EU and to tap the full prevention potential.

8.5. Conclusions
Main objective of this assessment was to test the developed policy risk assessment tool (RAPID tool or methodology) on the case of EC Health Strategy. The EC Health Strategy is a very special case for using the RAPID tool. An important aspect of the RAPID tool is to assess affected health determinants, risk factors and health outcomes, define the connections between them, and to prioritize. The EC Health Strategy includes nearly all health outcomes and health determinants, so it was very difficult to exclude and prioritize. Another difficulty was that the Strategy included very broad objectives, clear aims are missing, and only a few health outcomes were mentioned concretely (“specific diseases”).

The approach to define important diseases and risk factors using comprehensive indicators like DALY and HLY was a very suitable extension of the RAPID tool.

We were able to show a large health gain potential for major diseases and related to major risk factors. Actions defined in the EC Health Strategy can contribute to achieve health gains but it has to be defined in what extent. In general the potential health gains regarding actions on lifestyle risk factors can be assumed as very large. A possible next step in assessment could be a comparison between policies and measures in “best” and “worst” countries to identify reasons for differences.

We have shown the enormous health gain potential by tackling specific major diseases and tackling main risk factors. But it is the wrong conclusion to neglect other diseases and risk factors. For example, the communicable diseases could lead to a huge amount of DALY if there are outbreaks. The number of DALY might be very low because of existing well implemented surveillance mechanisms. On the other hand is a low DALY rate or a small amount of DALY not necessarily a product of a good prevention or treatment policy. For some diseases underreporting might be a cause of a low DALY rate.

8.6. References
Annex I. Minutes of the interview at DG SANCO

Minutes of the interview at DG SANCO on risk assessment of EC health strategy

Luxembourg/Brussels, April 5, 2011

Attendees:

- Gabriel Gulis – RAPID project coordinator
- Paloma Martin – EAHC Luxembourg
- Christoph Hofbeck – DG SANCO (christoph.hofbeck@ec.europa.eu)
- Laurent Bontoux – DG SANCO (laurent.bontoux@ec.europa.eu)

After Gabriel explained briefly the RAPID project, Paloma introduced the aim of the interview. Christoph provided some basic information about the recent happening around the EC strategy:

- A mid-term evaluation of Strategy is ongoing, final report expected at the end of July 2011 – RAPID will get access to it
- Clearly one major issue is how to monitor success of the Strategy
- Need of performance indicators and indicators on impact on health outcomes
- How to define “intervention logic” toward a health outcome? Full chain approach seems to be relevant; a major issue is how to link a change to the Strategy
- The Strategy is a framework for policy actions, initiatives on area of health, not a real blueprint for action. Sub-strategies might be needed to provide direct actions
- Impact on national policies – case study model on rare diseases could show it; at the moment no official case study completed. Member states are analyzed in depth recently
- As one implementation mechanism the “working parties” are used; groups of experts of member states on special themes like cancer for example; they meet 2x a year and evaluate what works, have indicators.

- Member states asked via survey whether they use the Strategy; all replied positively. From among them those who claimed using the strategy as a model for their own national health policy/strategy development 6 member states were selected and are analyzed in depth at present.

- However, the Strategy did not aim to be a guidance to national policies.

- Action areas were identified via series of consultancies; cross analysis of action areas, objectives and principles is needed.

- Pharmaceutical/medical devices are missing from action areas.

- All major determinants of health are included and aim to be tackled; the Strategy is not limited to health care.

- Inter-service consultation is ongoing within EC and via that all policies are entering the discussion on health impacts; there is an inter-service group on health! Such a group does exist but what is important is how do they work.

- However, the traditional “silo” based approach is still a major communication barrier even within EC.

- Governance procedures are very important.

- Short term – long term results, goals issue is very political. Prevention/promotion requires long term investments but the reality is the opposite; there is larger interest on short term goals, products. Risk assessment should include short term – long term division.

- Target group of Strategy – all kind of stakeholders within and outside of health sector; different government levels (regions, cities).

- Information sources for Strategy – see “EU Health Policy Forum”, presidency related documents.

- Could RAPID be compared to a SWOT analysis?