IMCA

Indicators for Monitoring COPD and Asthma in the EU

Final report

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A report for the Directorate for Public Health and Safety Work
(DG-SANCO) of the European Commission

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Executive Summary

This report presents the results of the project "*Indicators for Monitoring COPD and asthma in the EU* (IMCA)". The overall aim of the project was to get a consensus among clinicians and researchers in the field of respiratory diseases, representatives from international organizations (i.e. WHO Europe) and scientific societies (i.e. ERS and EACCI) on a proposal for a set of indicators to monitor these two conditions among all EU Member States.

In all project development stages, we have taken into account all previous projects carried out under the Health Monitoring Program and we have considered in detail the framework and proposals of the European Community Health Indicators (ECHI) project and the proposals set up by DG-SANCO under the New Public Health Program (2003-2008) to build a "*European System of Information and knowledge on Major and Chronic Diseases"*.

The project work was carried out according to the agreed work plan and it was divided into five major steps. First, the co-ordinating centre, based on the initial selection of indicators carried out by the COPD and asthma panels, created the "Initial matrix list of indicators" for COPD and asthma and based on the framework suggested by the ECHI group. Second, based on a scientific literature review, a summary report of the relevant information for each group of indicators was produced and included into the "Initial matrix of indicators" creating the "Annotated list of indicators". Third, the consistency of the indicators proposed in relation to international research studies, routine data sources and clinical guidelines was assessed. Fourth, the same process was carried out at national level by each IMCA participant. Finally, a process to decide indicators final selection and priorities was established.

Overall, including demographic and socio-economic indicators (mainly used as denominators or for stratification) a total of **117** and **145** indicators are proposed and defined for COPD and asthma respectively. Indicators are grouped into four main groups: 1) Demography and socio-economic, 2) Health status, 3) Determinants of Health and 4) Health systems. The number of indicators may seem too large for many readers having a general interest in Public Health. However, the IMCA group, strongly suggest a careful reading of detailed information attached to each group of indicators to appreciate their value and appropriateness. For each group of indicators you will find the following information: a) rationale, b) aims, c) data sources, d) data quality, e) methods to be used for new data collection, f) data presentation, g) potential use, h) consistency at international level, i) comments, j) availability and consistency at national level and k) priority.

In order to facilitate the indicators implementation process according to the DG-SANCO plans for operating a European Union Public Health Information and Knowledge System we established a prioritization process but without excluding any indicator. The process is explained in detail on the methodology section. In this summary, we will mention only the indicators selected as the top 20 for COPD and asthma and among these, those selected as the top 4 recommended for short time implementation and to be included in the "ECHI-2 short list".

The top 20 indicators selected for COPD were: **current smokers**, past smokers, **hospital admissions**, age, **age-specific death rate**, standardized death rate (SDR), interventions to prevent tobacco exposure, emergency room visits, prevalence of chronic

symptoms, **prevalence of physician diagnosed COPD**, gender, COPD patients invited to stop smoking, COP patients who followed a stop smoking program, prevalence of chronic bronchitis, prevalence of airway obstruction, crude death rates, current smokers (<15 pack years), COPD patients that have managed stop smoking, hospitalization costs and total number of death. The top four indicators are marked in bold.

The top 20 indicators selected for asthma were: **prevalence of physician diagnosed asthma, prevalence of wheeze, prevalence of asthma attacks,** inhaled corticosteroids, **hospital admission rates,** current smokers, prevalence of asthma treatment, age-specific death rates, past smokers, current ETS exposure at present, standardized death rates (SDR), short acting β_2 agonists, total number of death, crude death rates, ETS exposure at home, ETS exposure at work, smoking exposure during mother pregnancy, hospitalization cost, total cost of medicines prescribed for asthma treatment and cost of total asthma care. The top four indicators are marked in bold.

Either the top twenty and four are marked in the *"Annotated list of indicators for COPD and asthma"* and also summarized in Annex V. As we said before, all indicators are important and each indicator or group of indicators is relevant to monitor specific issues of these two conditions. However, a clear strategy for short, middle and long term implementation may be needed. In order to facilitate implementation priorities without excluding any indicator, independently of the previously mentioned selection, all indicators were classified into three levels of priority by each subcategory. This classification is also described in the *"Annotated list of indicators for COPD and asthma"*

In conclusion, a large number of indicators useful to monitor COPD and asthma have been identified and defined. Only a small proportion of them are routinely available but with small methodological changes a great improvement on the quality and quantity of indicators could be achieved. A very large number of indicators are not available from routine health examination surveys but they could be obtained from large international research studies. Although these studies have been carried out several years ago, a systematic analysis of these databases could provide a good picture on the variability of these indicators within and between countries across Europe. In the near future, specific modules including the appropriate questionnaires and measurements required to monitor COPD and asthma have to be developed. The inclusion of these modules into future Health Examination Surveys have to be explored in feasibility studies.

We truly wish that the indicators selected and presented in this report will contribute and stimulate the development of information systems to monitor COPD and asthma in all member estates of the European Union.

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Part II

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1. Background

In 1977 the European Commission established the Health Monitoring Programme (hereafter called HMP) seeking to produce comparable information on the health and health related behaviour of the population, on health promotion and health systems. The activities under the HMP were set out under three headings or "Pillars": A: Establishment of Community Health Indicators; B: Development of a Community-wide network for sharing health data; and C: analysis and reporting reporting[1,2]. The three Pillars served different functions. ***Pillar A*** asks the question ***which*** data and indicators should be included in a Community health data exchange system. ***Pillar B*** addresses the question ***how*** this system should, technically, be made to operate. ***Pillar C*** refers to the ***use*** of the data for policy decision makers.

Under Pillar A, over the past years, around 47 projects have been funded to develop indicators in many areas of public health and produce recommendations on how to collect these indicators to be incorporated to the future European Union Public Health Information Network (EUPHIN)[3] developed under Pillar B. Most projects covered a wide spectrum of health issues (i.e. child-health indicators, perinatal health indicators, work related health, etc.). However, since it is not possible to monitor all relevant areas of chronic diseases using just one indicator (i.e. prevalence, treatment, mortality, etc.) some projects had a focus on acute or chronic diseases and with the objective of recommending a set of indicators for monitoring these conditions: cancer[4,5] musculoskeletal[6], cardiovascular[7] and diabetes mellitus[8]. Although the ECHI project had already recommended some indicators for monitoring respiratory diseases no previous project had a specific focus on indicators for COPD and asthma.

These two conditions are affecting a large proportion of the population, and have an important impact on the quality of life of those suffering them and on costs of health services. The asthma prevalence among children is about 13% and in adults 8.4%[10,11]. The prevalence of chronic obstructive pulmonary disease (COPD) ranges from 4 to 8%[12,13]. Although asthma may cause death, the impact of COPD on mortality is higher. The World Health Organisation (WHO) estimates that COPD is currently the twelfth most common cause of morbidity and sixth leading cause of death in the world [14].

The routine data currently available to monitor these two conditions, their risk factors, and their impact of health services and clinical care on outcomes is extremely limited.

Mortality and hospital discharge data are routinely collected in most countries and they may allow to monitor trends and geographical variations between and within countries. However, these data sources have important limitations in terms of the accuracy of data[15] and also with regard to the level of information they provide about the epidemiology or clinical management of the disease.

Health interview/examination surveys are other important sources of information, which could provide better information on both, the epidemiology and the process of clinical care of these two conditions. However, the reality is extremely disappointing, during the period 1998-2002, 60 health interview surveys were carried out at national/international level and 49 collected information about chronic conditions. However, only 12 carried out clinical examinations and only 5 of them collected information on respiratory function (spirometry)[16].

The limited information available (in terms of quality and quantity) contrasts with the large number of aspects identified by the international clinical guidelines such as GINA[17] or GOLD[18] that could be monitored in order to have a full picture of the epidemiology (prevalence and risk factors), the process of care (diagnosis, treatment, exacerbations), interventions for prevention (avoidance of specific risk factors) and the main outcomes (quality of life, use of health services, mortality etc.) for these two conditions.

Using the guidelines standards, an important number of research studies have been able to investigate specific issues of these two conditions but in most cases, results may not be considered representative at national or even regional level. Some examples are the identification of under-diagnosis and under-treatment in both conditions and its determinants[13,19,20] or the impact of different forms of health care organisation on clinical outcomes[20]. In contrast with this view at national level, there are specific projects (I would say exceptional) focused on small geographical areas that have developed a comprehensive surveillance systems based on several surveys carried out in different setting and target populations. We can use the Chicago Asthma Surveillance Initiative (CASI)[21] as an example. Although they are extremely interesting, they may not be cost-effective for national or international surveillance systems.

The implementation of a community-wide surveillance system that describes the epidemiology, characterize health care for asthma and COPD and its impact on outcomes its a complex task, and probably even more difficult at international level. It requires careful thinking in terms of either the issues to be covered, the potential users of the information at different geographical levels, the relevance of the information for either

prevention or strategies to improve clinical management and the feasibility and costs associated to the methods to be used.

Over the past decades, large international research studies such as ECRHS[22] or ISAAC[23] have developed methods and tools that could be incorporated in the routine information systems for monitoring COPD and asthma across the EU. This project, will identify the most relevant areas of these two conditions for monitoring, and by ***consensus among project participants will recommend a set of indicators appropriate for monitoring asthma and COPD in the EU, and the methods and tools that should be used for data collection.***

References:

1. McKee M, Ryan J. Monitoring health in Europe: opportunities and challenges and progress. Eur J Publ Health 2003; 13(3 Suppl):1-4.

2. Byrne D. Foreword. Eur J Publ Health 2003; 13(3 Suppl):5.

3. The Euphin, the telematics support for public health in the EU. Eur J Publ Health 2003; 13(3 Suppl):114-115.

4. Micheli A, Cpocaccia R, Martinez C, Mugno E, Coebergh JW, Baili P, Verdecchia A, Berrino F, Coleman M. Caqncer control in europe: a proposed set of european Cancer Health Indicators. Eur J Publ Health 2003; 13(3 Suppl):116-118.

5. Bray F, Guerra M, Parkin DM. The Comprehennsive Cancer Monitoring Programme in Europe. Eur J Publ Health 2003; 13(3 Suppl):61-66.

6. Bruusgaard D. International monitoring of musculoskeletal complaints: a need for consensus. Eur J Publ Health 2003; 13(3 Suppl):20-23.

7. The EUROCISS Working Group. Coronary and cerebrovascular population-based registers in Europe: are morbidity indicators comparable? Ressults from the EUROCISS Project. Eur J Publ Health 2003; 13(3 Suppl):55-60.

8. De Beaufort CE, Reunanen A, Raleigh V, Storms F, Kleinebreil L, Gallego R, Giorda C, Midthjell K, Jecth M, De Leeuw I, Schoeber E, Boran G, Tolis G. European Union diabetes indicators: fact or fiction? Eur J Publ Health 2003; 13(3 Suppl):51-54.

9. Kramers PG. The ECHI project. Eur J Publ Health 2003; 13(3 Suppl):101-106.

10. The International Study of –asthma and allergies in Childhood (ISAAC Steering Committee). Worldwide variations in the prevalence of asthma symptoms: the International study of Asthma and Allergies in Childhood (ISAAC). Eur Respir J; 12:315-335.

11. European Community Respiratory Health survey. Variations in the prevalence of respiratory symptoms, self-reported asthma attacks, and use of asthma medication in the European Community Respiratory Health Survey (ERHS). Eur Respir J 1996; 9:687-695.

12. Antó JM, Vermeire P, Vestbo J, Sunyer J. Epidemiology of chronic obstructive pulmonary disease. Eur Respir J 2001; 17:982-994.

13. Rennard S, Decramer M, Calverley PMA, Pride NB, Soriano JB, Vermeire PA, Vestbo J. Impact of COPD in North America and Europe in 2000: subjects' perspective of Confronting COPD International Survey. Eur Respir J 2002; 20:799-805.

14. Murray CJ, Lopez AD. Alternative projection of mortality by cause 1990-2020: global burden of disease study. Lancet 1997; 349:1498-1504.

15. William VM, Molly OL, Buist S. Uses and limitations of mortality and health care utilization satatistics in asthma research. Am J Respir Crit Care Med 1994; 149:579-587.

16. Aromaa A, Koponen P, Tafforeau J, Vermeire C and the HIS/HES Core Group. Evaluation of health Interview Surveys and Health examination Surveys in the European Union. Eur J Publ Health 2003; 13(3 Suppl):67-72.

17. Global Initiative for A (GINA). Global Strategy for Asthma Management and Prevention. NHLB/WHO workshop report.National Institutes of Health, National Heart, and Blood Institut. February 2002, NIH Publication No. 02-3659.

18. Pauwells RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary

disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Worshop summary. Am J Resp Crit Care Med 2001; 163:1256-1276.

19. Janson C, Chinn S, Jarvis D, Burney P, on behalf of the European Community Respiratory Health Survey. Physician-diagnosed asthma and drug utilizationin the European Community Respiratory Health Survey. Eur Respir J 1997; 10:1795-1802.

20. Maziak W, von Mutius E, Beimfohr C, Hirsch T, Leupold W, Keil U, Weiland S. The management of childhood asthma in the community. Eur respir J 2002; 20:1476-1482.

21. Weiss KB, Grant E and the Chicago Asthma Surveillance Initiative Project Team. The chicago asthma surveillance Initiative. Chest 1999; 116:141S-145S.

22. Janson C, Anto J, Burney P et al. The European Respiratory Health survey: what are the main results so far? Eur Respir J 2001; 18:598-611.

23. The International Study of Asthma and Allergies in Childhood (ISAAC) Steering Committee. Worldwide variation in prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and atopic eczema: ISAAC. Lancet. 1998 Apr 25;351(9111):1225-32.

2. Aims

2.1 General:

- To get a consensus among participants of all EU countries about a set of indicators relevant for monitoring asthma and COPD across the EU.

2.2 Specific:

- To identify all routinely and research (large studies) sources of data providing useful information for monitoring COPD and asthma in the EU and assess their comparability (within and between countries), and their strengths and limitations.

- Explore to what extent international databases such as OCDE, WHO, EUROSTAT could be improved based on the information available for these two conditions.

- To identify the best scientific evidence on risk factors (exposures), prevalence, clinical management and policy interventions and explore to what extent the evidence is (or could be incorporated to the information systems).

- To identify the most important protocol or clinical guidelines recommend by national or international scientific societies implemented in each EU country and assess their comparability.

- To identify a set of indicators useful for monitoring and covering several aspects of these two conditions such as risk factors, prevalence, clinical management, and outcomes.

3. Organization and management

3.1 Steering Committee

The Steering Committee (SC) was integrated by the "core group" as it was established in the initial proposal submitted to DG-SANCO. The role of the SC was to advice on specific methodological issues of the project, to establish on links with other international organizations or scientific societies and to monitor the overall project development. The SC was integrated by the project co-ordinator, Enric Duran (Spain), Josep Mª Antó (Spain), Christer Janson (Sweden), Debborah Jarvis (UK), Stephen Weiland (Germany) and Francesco Forastiere (Italy) and Giovanni Viegi in representation of the European Respiratory Society (ERS).

3.2 Study co-ordinating Centre

The study co-ordinating centre was established at the Fundació IMIM in Barcelona and co-ordinated by Enric Duran. The centre was responsible for the ongoing administrative and financial management tasks, meetings organization and overall project development according to decisions taken by the Steering Committee and suggestions from other partners.

The centre was also responsible for guaranteeing good communication between partners, DG-SANCO representatives, other DG-SANCO project co-ordinators and representatives of international organisations and scientific societies.

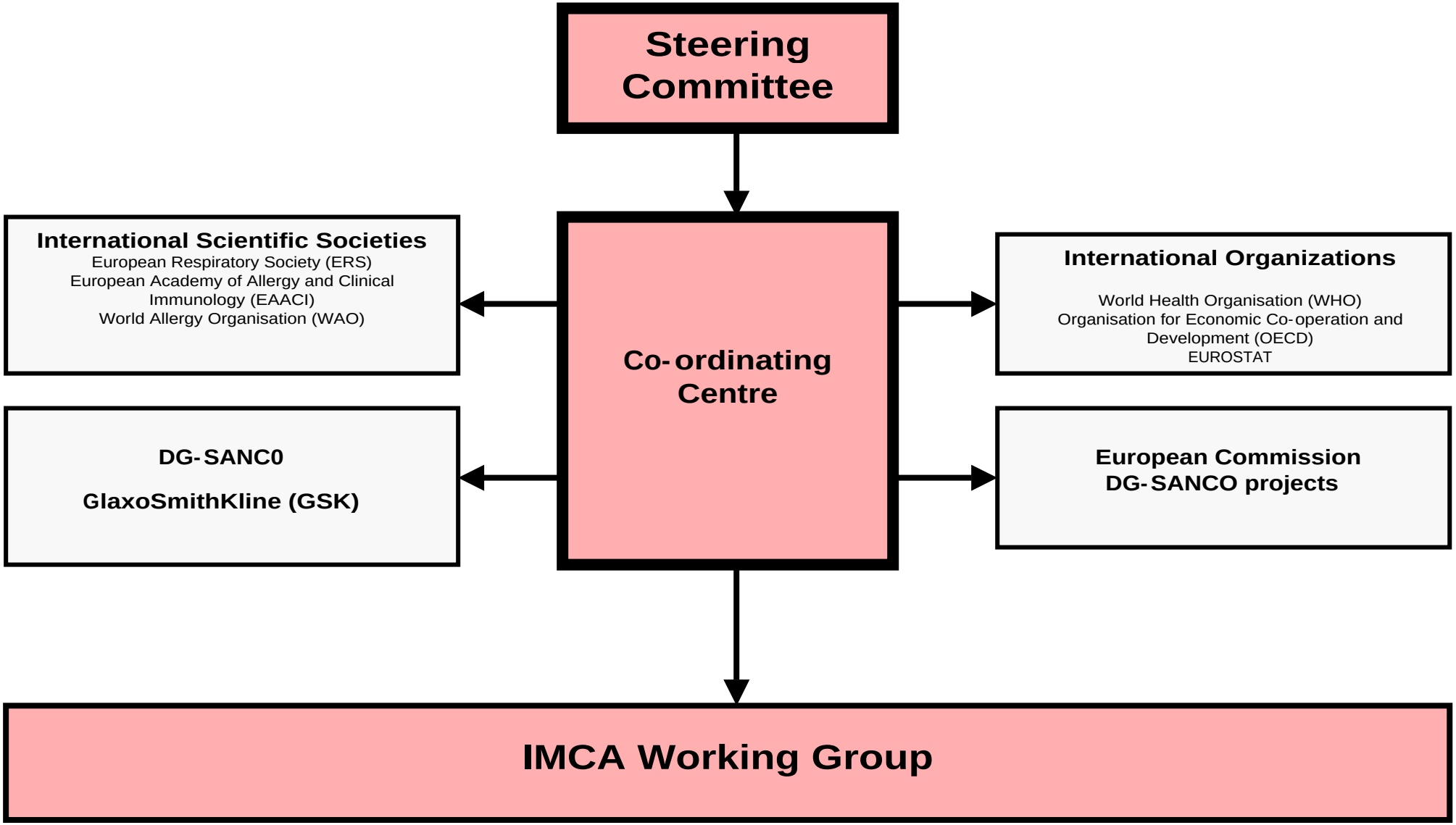
Over the past years, the Health Monitoring Programme (DG-SANCO) funded several projects aiming to contribute to the development of a new EU health information system. Although each project studied specific areas of information or diseases, there were several issues common to our project. In order to get good interaction between projects, the co-ordinating centre and according to the SC advice, identified projects with common links and established appropriate ways of communication and collaboration. Some of these projects were: The European Community Health Indicators (ECHI), Environment and Health Indicators, European Health Risk Monitoring, Hospital Data Project and Health Surveys in the EU.

The IMCA group, through the co-ordinating centre established appropriate links and identify areas of collaboration with international organisations such as Eurostat, OECD, and WHO that have been collecting data from MS for a long period of time with large experience in data collection and reporting.

3.3 IMCA Working Group

All IMCA participants representing most EU Member States (MS) were members of the group. The group had two general meetings of two and one days. During the first meeting, it was decided which DG-SANCO project co-ordinators, experts, or representatives of international organizations or scientific societies had to be contacted to discuss specific issues related to the project.

3.4 Organization framework



4. Work plan and methodology

In the original project proposal there was a brief description of the tasks and timetable to carry out the project and reach the objectives previously set up. In order to reach a consensus among the IMCA participants on the work plan and methods to follow, the co-ordinating centre prepared a "New Work Plan Proposal" (Annex I) to be discussed during the 1st IMCA general meeting (Annex VII) and to decide a definitive strategy for the project development.

After and overall discussion and considering in detail all objectives of the project and the methods previously suggested, the IMCA group considered very important to start the project with the identification of the main issues or indicators more relevant for monitoring COPD and asthma. Participants considered that issues related to the assessment of routine sources of information, research databases and consistency with clinical guidelines should be carried out in a second step.

Consequently, during the 1st IMCA meeting and as a starting point, two different panels were set up to select the first list of indicators. The composition of the two panels was established as follows:

The Asthma panel included : Deborah Jarvis (Chair), Enric Duran (Rapporteur), Roman Nati, Henriette Smit, Mario Morais, Denis Charpin, Hans Moshammer.

The COPD panel included : Giovanni Viegi (Chair), Josep Mª Antó (Rapporteur), Mina Gaga, Per Bakke, Pekka Jousilahti, Paul Vermeire, Nikolai Khaltaev.

The two panels were asked to provide the first list of indicators related to the main areas described in the "New Work Plan Proposal" (Annex I) including indicators on risk factors, measures of disease frequency, clinical management and outcomes for the two conditions under study. For both conditions, in addition to the indicators, the sources of information available, or desirable to be developed in the future were also identified. The two lists provided by the COPD and asthma panels (Annex VII, minutes of the 1st IMCA general meeting) were used as the starting point for the project development and a definitive timetable was established (Annex II, "Revised Work Plan Timetable"). In addition to the timetable, the group decided the steps to follow in order to reach the project objectives according to the new timetable. It was decided to structure the project development in five steps that

will be described in detail in the following section under the heading "Revised Work Plan".

4.1 Revised Work Plan

One of the outcomes of the 1st IMCA general meeting was the establishment of a Revised Work Plan and timetable for the project development that included five important steps.

4.1.1 Step 1: The initial matrix list of indicators.

Although the group clearly identified several models and ways for indicators classification, it was decided to use the model/matrix suggested by "The European Community Health Indicators (ECHI)". There were two main reasons for this selection. First, it was clear that the ECHI proposal was widely accepted by other projects focused on indicators development. Second, DG-SANCO had high interest in integrating all indicators into the ECHI list as a methods for avoiding duplications, generate common methodologies and prepare future information strategies. As the first step, the co-ordinating centre, based on the initial list of issues selected by the COPD and asthma panels, prepared a matrix list of indicators using the same axis of classification as proposed by the ECHI project. In carrying out this work, the co-ordinating centre, produced a much more detailed description of the indicators previously selected by the IMCA group, including the operational definition, information on availability and data sources. This initial matrix list of indicators have not been included as an annex because it was very similar to the annotated list of indicators that will be described in the following section (step 2). After the review by all participants, the gaps identified and new suggestions were incorporated into the matrix.

4.1.2 Step 2: An annotated list of indicators.

The co-ordinating centre carried out a scientific literature review and produced a summary report of the relevant scientific information for each group of indicators selected and included in three major areas of classification established by the IMCA group: measures of disease frequency, risk factors and clinical management.

The literature review and summary of the information was extremely useful for: a) better specification of the areas to include, b) justification of each indicator, c) to

know the scientific validity and d) to provide information on data sources. Based on the literature review, an annotated list of indicators was produced. The annotated list was reviewed by all participants and a final document was produced.

4.1.3 Step 3: Assessment of the consistency of the list of indicators at the international level.

This step was introduced to assess the consistency of the indicators proposed in relation to international research studies, routine data sources and international guidelines. This work contributed to the better specification of indicators and to discard some indicators previously selected including a wider perspective of the information on clinical and public health needs and also considering the ECHI perspective (user-window notion). This work was carried out by the co-ordinating centre with the contribution of all participants.

4.1.4 Step 4: Assessment of the consistency of the list of indicators at the national level.

All participants checked the consistency at national level for all indicators included on the annotated list of indicators. The consistency was assessed like at international level in routine data sources, international guidelines and research studies at national level. This process was carried out in two steps. First, the co-ordinating centre prepared a questionnaire (Annex III) to be completed by all participants in order to assess the data availability and the priority for each indicator in their own country. The first column of the questionnaire was designed to collect the information on data availability in each country. The co-ordinating centre produced a brief guideline (details in Annex III) to complete the first column of the questionnaire. Each participant completed the column indicating the availability of each indicator taking into account the specifications of the indicators provided by the *"Annotated list of indicators for COPD and asthma"* and the availability of the information in their own country.

Before filling up the first column, each participant considered the information published in specific national or regional reports, in scientific publications with a clear Medline reference or reports produced without making it available to the public (internal reports). The concept of availability was understood as data available independently if its publication. The data available should be representative at national level.

In cases for which data were available and perhaps representative but only for sub-national geographical areas, the details were reported for each indicator in the report on the national consistency or communicated to the co-ordinating centre.

In order to classify the indicators according their availability at national level we took into account the sources of data available at present (mainly routine data, general HIS/HES surveys and specific research surveys) and the ones that may be needed to develop in the future at national level.

Based on these criteria, we suggest to classify the availability of each indicator at national level by using six groups of classification. However, once the co-ordinating centre had the data analyzed, in order to have a better picture of the reality and in order to simplify the view on the availability in each country for the summary of the information, the IMCA group decided to reduce the classification into three main groups: 1) data available either form routine or HIS/HES surveys (yellow), 2) data available but from specific research surveys more or less than ten years old (orange), 3) not available and in the future data have to be developed in the most appropriate way (red).

A. Available from routine data and no modifications are required.
B. Available from routine data but methodological changes are required.
C. Available from national HIS/HES surveys (less than 10 years).
D. Available from national HIS/HES surveys (more than 10 years).

E. Available from specific research surveys (less than 10 years).
F. Available from specific research surveys (more than 10 years).

G. Not available and in the future data should be developed from routine data.
H. Not available and in the future data should be developed from HIS/HES surveys.
I. Not available and in the future data should be developed from specific national/international surveys.

The results of this information are summarized and incorporated in the "Annotated list of indicators for COPD and asthma" under the section on "Availability and national consistency". For a more detailed information by country, the information is described in the Annex IV.

4.1.5 Step 5: Final selection and prioritisation of the list of indicators.

The general objective of the IMCA project was to get a consensus among the project participants on a set of indicators for monitoring the prevalence, risk factors, clinical management and outcomes of asthma in the EU.

Although the IMCA group considered all indicators very important, in order to facilitate the implementation process according to DG-SANCO needs on information strategies, the group designed and organized a prioritization process to select the most relevant indicators. The methods to follow were agreed during the 1st and 2nd Steering Committee meetings and carried out once steps 1, 2, 3, and 4 were completed. During the project development, taking into account the number of indicators developed, DG-SANCO invited the IMCA group to make a core list selection.

Why it was necessary to select a core list of indicators?

The first question the group had to deal with was why it was important to decide indicators priorities. The European Community Health Indicators (ECHI-2) project, already mentioned, developed a long list of indicators that included about 400 items/indicators. By March 2003, DG-SANCO expressed a strong wish to extract a shortlist from the main indicators list in order to prioritize the work for harmonization of the EU member State's data collection. The ECHI project selected a shortlist of core indicators by using the following methods: 1) nineteen public health generalists individually selected 50 first and 50 second choice priorities from the total of approximately 400 items in the long ECHI list; 2) explicit criteria were: size of the public health problem and possibilities to improve on these; 3) ranking the items according to the number of votes, taking an arbitrary cut-off point, produced a list of approximately 50 indicators. This list was further developed after amendments from specific projects and other general discussions.

When the results of this first selection were available to participants of other HMP projects defining indicators, most felt that the recommendations made by their own project were not considered with enough detail and required further discussions in order to be included in the first shortlist of indicators. This situation led to the revision of the methods used by other projects in selecting indicators. From this review it was possible to see that some projects already carried out a prioritisation process, selecting only top ten indicators and others did not.

Based on the discussions of this situation, DG-SANCO recommended all projects not already finished to provide recommendations that include clear priorities for implementation and development. The specification of indicators priority should not mean that only a small number of indicators should be implemented. This should be understood as a priority for short-term implementation.

Based on this background, the co-ordinating centre suggested a methodology for deciding priorities on indicators which will not exclude any indicator selected but will clearly establish the priorities for immediate, short and long term implementation. The methodology was approved by the IMCA Steering Committee and the rest of the group.

Which methods did we use?

As it has been explained before, the co-ordinating centre developed two questionnaires that included a complete list of the indicators selected for COPD and asthma. The questionnaire included one column to collect information on data availability and three columns to collect information on indicators priority **(Annex III)**. The questionnaires were designed using the software Teleform. Each participant had to sent the questionnaires to the co-ordinating centre by fax and automatically a database was created. The columns, second, third, and fourth were designed to collect data on indicators priority. The data collected in each column, reflected an independent way of classifying indicators priority.

The second column of the questionnaire (which was the first of the questionnaire for collecting data on priorities), was completed by each participant putting a score for each indicator based on their own experience and view and considering the scientific information provided in the *"Annotated list of indicators for asthma"*.

It was difficult to establish a common set of criteria for all indicators of each disease since usually different criteria reflect different aspects of the disease. However, since this should be a score helping to produce a ranking of all indicators we decided to use the following criteria:

1) Importance of the indicator to describe the burden of the disease at population level or within the group of patients suffering from the disease.
2) Evidence on the strength of the association (in case of risk factors) or evidence on its relationship with health outcomes (in the case of health system indicators).
3) Susceptibility to interventions, either to reduce the burden of the disease or health outcomes inequalities.

Taking into account these criteria, each participant gave a score ranking from 0 to 4 (4 = essential; 3 = very important; 2 = important; 1 = less important; and 0 = not useful) to each indicator.

For each indicator, the scores given by each participant were added and the mean estimated. Based on the mean score, all indicators were ordered within each sub-category and the rank and order number was attached to each indicator. The indicator with the highest mean value had the order number 1.

In order to be able to decide the priority of the indicators within each sub-category (in case some indicators had the same score in the column two), participants were asked to complete the third column ordering the indicators in a decreasing order of priority. For instance, the sub-category, "*2.2.8 Mortality Respiratory System*" that have six indicators, participants had to order the six indicators in a decreasing order of relevance from 1 to 6, attaching the number "01" to the most relevant and the "06" to the less relevant. this process was done for all indicator sub-categories.

The priority order given by each participant to each indicator within sub-category did not help in deciding priorities within the main groups of indicators. As explained before, all COPD and asthma indicators were grouped in four main groups (Class 1 to 4) each representing relevant information of both conditions. To solve this problem, each participant was asked to complete the fourth column ordering the indicators in decreasing order of relevance for each main category. For instance, if we considerer the main category "Class 2- Health status" for asthma, since there are 21 indicators included, participants had to order them from "01" to "21" in decreasing order.

In addition to scoring individual indicators, ordering them within sub-categories and main categories, each participant was also asked to considerer the relevance of each section for monitoring COPD and asthma and order the main categories attaching to each category the order priority number (from 1 to 4). To collect this information the questionnaire had a special box on the right hand side of each main section title.

The results of the priority exercise were presented and discussed in the final IMCA meeting in a plenary session and decisions taken according to debate results. The most strong point that was made evident early in the final meeting was the difficulty in classifying indicators within sub-categories and main categories. As we already said before, most participants considered all indicators relevant although each group reflected different aspects or even stages of disease development making the classifications of the second and third column extremely difficult. Although the results of the methods previously established are described in detail (Annex V) the group decided not to take into account the results of the third and fourth columns due to the lack of validity of the information given. The group decided to use mainly the results of the scores given in the second column and to recommend different levels of priority. First, based on the score of the second

column a score was attached to each indicator. These scores were used to order all indicators according to the level of priority. From this list, the top 20 indicators for COPD and asthma were selected. In order to recommend at least four indicators for each condition to be included in the "ECHI short list" for immediate implementation, a final exercise to select the top 4 indicators for each condition was carried out.

Taking into account that the group considered all indicators important and because considering just the top 4 or 20 can be an underestimation of the value of many indicators it was decided to classify the indicators within each sub-category into three levels of priority. This process was carried out taking into account the scores of the second column and the group consensus. This three levels classification is included in the corresponding section on indicators priority of the "Annotated list of indicators for COPD and asthma".

4.2 How we did the main results summary?: "Annotated list of indicators for COPD and asthma".

The "Annotated list of indicators for COPD and asthma" was established as the "Step 2" in the project development. Basically, as it has been explained before, in this step we only included the information collected from the scientific literature review for each group of indicators. As the project was progressing, we decided to include all new information produced into the annotated list in order to summarize the information specifically for each group of indicators and to facilitate its readership. In general the information for each group of indicators takes two pages. At the top of the first page there is always the title describing the indicators group according to the ECHI taxonomy but including the relevant indicators selected by the IMCA group. The top box on the left, contains the indicators list. The top box on the right, contains the indicators definition. Under these two boxes, there are several paragraphs containing the following sections: rationale, aims, data sources, data quality, methods to be used for new data collection, data presentation, potential use, consistency at national level, comments, availability and consistency at national level, and finally priority including a table describing the scores and the IMCA group recommendation. This will facilitate to get the relevant information for each group without having to read all text.

ANNOTATED LIST OF INDICATORS

Indicators for monitoring COPD in the EU

ECHI-2/IMCA framework

Class 1

Demography and socioeconomic situation

INDICATOR	DEFINITION
1.1.1 Population status.	
• **Population composition by age.**	• **Age groups:** 0-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, >89.
• **Population composition by gender.**	• **Gender:** Male, female.
• **Population composition by geographical area.**	• **Geographical area:** National and sub-national level.

RATIONALE: The population structure stratified by age and sex is essential to be able to estimate age and sex specific death rates, prevalence, hospital admissions or any other possible indicators to be estimated for a specific community populations. Epidemiological studies show that the prevalence of COPD increases with age,[1] males have higher prevalence rates compared to females[1,2,3] and there are large variations according to geographical areas.[3] Based on this characteristics, it is important to stratify the population in small age groups (5 years each).This data should also be available by sex and at national and sub-national geographical levels within countries.

Although the age group to be included in cross sectional studies on the prevalence of COPD is still not well established, data presentation should be based on standardized five years age groups. This will allow comparisons between studies. The differences in the age groups included in prevalence studies have been shown by Hallbert et al.[4] that have reviewed the characteristics of COPD prevalence studies. The age range of individuals included in the studies reviewed is very wide (from 16 to 90) and some studies included all ages. Other studies focusing on diagnosed COPD patients have been limited to >45 age groups.[5] Age may also influence the prevalence estimates depending on the COPD definiton used in the study. Celli et al.[1] have shown that the impact of different definitions on prevalence estimates depends on age. Recently, Hardie et al.[6] have also shown that using the GOLD criteria (as a definiton and staging) there is a risk of over-diagnosis of COPD in those aged >70 years and clearly suggested that the criteria to define COPD stages should be age-specific.

AIMS: To describe the population structure taking into account age groups and gender and to monitor changes over time. This information should be available at different geographical levels: national, sub-national or local if it is possible. These data should be used for the estimation of population based indicators described and proposed in the following sections.

DATA SOURCES: In each European country there is a national center for health statistics or a specific agency responsible for national statistics. This centers or agencies provide national population estimates to Eurostat[7] database. In this database, most indicators provides the population structure by five years age groups we suggested and most indicators can be estimated for each of these groups. However, in contrast to Eurostat, OECD[8] or WHO[9] provide many indicators only for a wide range of age groups (0 to 65 or >65) which are clearly inadequate for COPD. Only Eurostat database provide population estimates by sub-national geographical area level. This estimates are based on the Eurostat NUTS classification.

DATA QUALITY: The population estimates are usually provided by national centers or statistical agencies and are based on national censuses and other national vital registries. The accuracy of population estimates depends on the quality of reporting in national censuses, the level of control of immigrants or emigrants and the quality of mortality and birth registries. In many cases there is not an agreement between the estimates provided by different international databases.
METHODS TO BE USED FOR NEW DATA COLLECTION: Population data by age, gender and geographical level is already available at international level from EUROSTAT database. However, it has to be considered if the NUTS geographical aggregation is still useful or the ISARE project classification has to be used in the future.

DATA PRESENTATION: The population structure should be presented in a table using the age groups defined at the top of this section and stratified by gender. This table should be available at different geographical levels: national, sub-national or local if data is available and is of interest for policy decision makers.

POTENTIAL USE: To monitor changes in the structure of the population which may have an impact on health of the population. This information could be useful for health care planning and needs assessment evaluations.

CONSISTENCY AT INTERNATIONAL LEVEL: At present, either in research studies or routine information systems there is not a consistent level of age stratification to present epidemiological estimates for COPD. The age range of individuals included in epidemiological studies of COPD is very wide and this shows another inconsistency. Some investigators have suggested that prevalence estimates of severity according to GOLD criteria should also be presented by age group. However, there is not a general accepted agreement on this. With regard to populations estimates at sub-national level the ISARE[10] project recommended to substitute the Eurostat NUTS classification by another health policy and management related geographical areas.

COMMENTS: In the "1.1.1 Population status" section of the ECHI-2,[11] the demographic data only four indicators are described and proposed to be collected. Specifically, with regard to population composition by age (without stratification by gender) only three indicators are defined: median age of the population, proportion of population under 15 and proportion of population aged 65 or over. The IMCA specifications should be taken into account when a final ECHI list is agreed. With regard to the population, the IMCA group suggested that for some specific type of analysis could be useful to present epidemiological estimates by groups such as: young, adults and elderly.

According to the ECHI matrix prepared by Pieter Kramers several projects have suggested specific requirements on the population structure. These projects are: Phnut, ISARE, EUROSTAT EUROCHIP and ECHI-2. An agreement should be reached to find a solution for all possible project needs.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Data on the population structure by age, gender and structure is available in all countries included in the study. All countries can provide this data in different age groups according to the user needs.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 1.1.1 Population status	Indicator Score	Rank	Order	IMCA Group recommendation
? Population composition by age.	**3.7**	(2-4) 2	**1**	**1**
? Population composition by gender.	3.5	(2-4) 2	2	**1**
? Population composition by geographical area.	2.7	(1-4) 3	3	**2**

INDICATOR	DEFINITION
1.2 Socio-economic factors.	
• **Level of education.**	• Proportion of population by level of education in 4 classes: elementary, lower secondary, upper secondary, tertiary (ISCED, 1997).
• **Social class.**	• Proportion of population by social class in 6 ISCO groups: upper non-manual, lower non-manual, skilled manual, unskilled manual, self-employed, farmer. (Based on occupation).
• **Ethnicity.**	• Proportion of population in each ethnic group (to de agreed among DG-SANCO projects.
• **GDP.**	• The GDP at national level. (As defined in the OECD).
• **Poverty.**	• Proportion of population within income below 60% of the national median.

RATIONALE: Socioeconomic factors are considered determinants of population health status. However, the effects of socioeconomic status are not equal for all conditions and have to be considered specifically for each disease or health status problem. In the case of COPD, there is evidence showing that the risk of developing COPD is inversely related to socioeconomic status.[12] This is consistent across different type of studies and in different populations.[13] It is not clear, however, whether this pattern reflects exposures to indoor and outdoor air pollutants, crowding, poor nutrition, or other factors that are related to low socioeconomic status. In Europe, de Marco et al.[3] using data from the European Community Respiratory Survey have shown that individuals from low socioeconomic groups have a higher risk of COPD either in stage 0 or stages I or more. In US mortality rates for COPD are higher in whites than in non whites, but the difference is decreasing in males.[14] Morbidity and mortality rates are inversely related to socioeconomic status and are higher in blue collar than white collar workers.[15]

The socioeconomic indicators to monitor inequalities in health in the European Union have been reviewed recently by Kunst et al.[16] The socioeconomic indicators can be classified into five main groups according to the characteristics they are based on: education, occupation, income, wealth and composite indicators. Some indicators may be preferred over other for theoretical reasons. However, there is no consensus on these issues, and the measures are complementary rather than exclusive. The theoretical preferences depend on many factors. Some data sources or research studies have collected information in one or more indicators. Most of these indicators are collected at individual level but they can also be used at ecological level. With regard to ethnicity and COPD the information available is limited but differences may exist either in prevalence or in many other indicators of health care management and outcomes. An agreement should be reached on the classification of ethnic groups across European countries. There is not information on the association between GDP and level of poverty but it could be very useful to incorporate these indicators for future ecological analysis.

AIMS: 1) To describe the distribution of the population at community level according to the socioeconomic indicators proposed (level of education, social class and ethnicity) and to monitor changes over time. **2)** To compare countries according to the GDP and the level of poverty (if it is possible at sub-national level. **3)** to describe the distribution of COPD patients according to the socioeconomic indicators proposed and to monitor changes over time. This information should be available at different geographical levels: national, sub-national or local if it is possible. These data should useful in monitoring policy interventions to reduce society inequalities.

DATA SOURCES: In general most general health interview or examination surveys include questions on socioeconomic status. However, there are important differences in the questions used in surveys carried out either in the same or different country. For specific question comparisons between health surveys the HIS/HES database can be used.[17] Information on socioeconomic status can be obtained also from routine data bases such as mortality or specific registries. However, the number of countries including socioeconomic information in this databases is much more limited. Many research studies also collect this information but in many occasions the information produced is not representative of the general population. The indicator which describes the proportion of population living in poverty is collected by EUROSTAT.[7,18]

DATA QUALITY: Three major problems have been identified in socioeconomic indicators: a) high non response rates in some countries (these problems are greater when income indicators are used, b) some populations may be excluded (institutionalized populations), c) problems with comparability (both over time and across countries) of some health indicators specially in those based on occupation.[16] Data on ethnicity has to be developed in order to have a homogeneous classification.

METHODS TO BE USED FOR NEW DATA COLLECTION: Specific questions should be incorporated in HIS/HES surveys or research studies in order to collect information on the level of education and social class according to the IMCA recommendations. The GDP is usually provided by the OECD and no further development is required. The level of poverty, is provided by the EUROSTAT database, but it has to be explored if it is possible to have this indicator at sub-national level or for specific geographical areas. This information is well developed in countries like UK but nearly impossible in most EU countries.

DATA PRESENTATION: For each of the three indicators, a table showing the distribution of the population according to the categories established should be presented. In addition cross tabulations with the age groups proposed and stratified by gender should be presented or available. These tables should be available at different geographical levels: national, sub-national or local if data is available and is of interest for policy decision makers.

POTENTIAL USE: To monitor changes in the structure of the population according to socioeconomic status indicators. To monitor changes in the distribution of COPD patients according to socioeconomic status indicators. This information could be useful for health care planning and needs assessment evaluations for COPD patients and also to monitor policy interventions to reduce health and health care inequalities among COPD patients.

CONSISTENCY AT INTERNATIONAL LEVEL: Although the association between socioeconomic status and COPD seems to be consistent in most studies, the major problem is to identify a reliable and useful measure to compare socioeconomic status across different EU countries.

COMMENTS: The ECHI project, the section "1.2 Socioeconomic factors" have been structured in six parts: "1.2.1 Population by household situation"; "1.2.2 Population by ethnicity"; "1.2.3 Education"; "1.2.4 Employment"; "1.2.5 Income distribution"; and "1.2.6 General economics". From these sections, the IMCA group selected only four indicators which have been used in epidemiological research studies and are clear determinants of health.

The ones selected, are the most consistently used although potential bias have to be considered when cross country comparisons are made. The level of education and social class indicators should be used in three different ways: 1) to describe the distribution of the population according to socioeconomic status by the age groups suggested, gender and national and sub-national geographical levels; 2) to adjust prevalence estimates and 3) to describe the proportion of individuals with COPD according to socioeconomic status. In this group, ethnicity should also be included with a consistent classification of ethnic origin for all the EU countries (to be developed). This information should also be available by the age groups suggested, gender and national and sub-national geographical levels. The level of poverty may be useful as an ecological indicator but difficult to incorporate in cross-sectional studies of COPD. We believe it is more important to have socioeconomic indicators at individual level, however in some ecological analysis, GDP and the level of poverty could be very useful.

According to the ECHI matrix prepared by Pieter Kramers several projects have suggested specific requirements on socioeconomic indicators. The level of education and social class based on occupation are proposed by the SES and PHNUT projects. Ethnicity and GDP are proposed only by the ECHI-2 project only despite its interest for many conditions. Poverty is only recommended by the PHNUT project. Due to the limitations of each indicator individually, in many occasions several indicators of socioeconomic status are used. It would be good to have all five indicators proposed by the IMCA group, although some of them require further development.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Data for most socioeconomic indicators is available in all countries included in the study with the exception of ethnicity. However, it is not clear to what extend the comparability of these indicators between countries is good enough at present. In some countries methodological modifications are required to improve comparability.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 1.2 Socio-economic factors	Indicator Score	Rank	Order	IMCA Group recommendation
? Level of education	**2.9**	(1-4) 3	**1**	**1**
? Social class	**2.9**	(2-4) 2	**1**	**1**
? Ethnicity	2.3	(0-4) 4	3	**2**
? GDP	1.7	(0-3) 3	4	**3**
? Poverty	2.4	(1-4) 3	2	**2**

Class 2

Health Status

INDICATOR	DEFINITION
2.2 Mortality by cause specific.	
• **2.2.8 Respiratory system.**	
• **Total number of death.**	• Death defined by ICD-9: 490-492, 494 and 496, (493 should be excluded); ICD-10: J40-J44, J47 (J45 and J46 should be excluded).
• **Crude death rates.**	• Total number of COPD death by 100.000 population.
• **Standardized death rates (SDR).**	• Standardization method and standard population should be the same as WHO/EUROSTAT databases).
• **Age-specific death rate.**	• Total number of COPD death by 100.000 population by the age groups specified.
• **Age-specific death rate having COPD as a contributing cause of death.**	• Total number of death by 100.000 population having COPD as underlying cause of death or with a contributing cause of death by the age groups specified.
• **Potential years of life lost (PYLL).**	• Number of death in each age group multiplied by the number of remaining years to live until selected age limit. The same methods used in WHO / EUROSTAT databases should be used).

RATIONALE: The World health Organization (WHO) estimates that COPD is the fifth leading cause of death in the world and it is estimated to be the third most frequent cause of death by 2020.[19] The social burden, in terms of days lost to disability, is also expected to increase from twelfth to fifth among all chronic disease. [20,21]

In a review of international patterns of respiratory mortality with ICD-9 490-496 codes which also include asthma (ICD-9, 493), the highest rates were found in UK, Easter Europe, Scandinavian countries, Israel and Japan.[22] In the ERS consensus Statement, after considering together the ICD codes 490-493, the mortality rates in males for the period 1988-1991 ranged from >30 deaths per 100,000 person-years in Hungary, Denmark and former East Germany to <10 in Spain, France and Greece.[23] In the UK, from 1970 to 2000, there has been a steady and continuing decline in COPD mortality in men but an increase in mortality in women. During the 1990s, there was a 25% fall in male mortality but a 33% rise in female mortality so that in 1999 women accounted for 44% of the total deaths attributed to COPD.[24] In the recent European Lung Book,[25] using data from the WHO database, standardized mortality rate for COPD have been published. In 1990, the standardized mortality rate of COPD was 50 / 100,000 population in males and 20 / 100,000 population in females in 45 European countries. This means that in Europe, mortality rates are 2-3 times higher in men compare to women. From this data it was estimated that between 200,000 to 300,000 people die from COPD each year in Europe. There were large variations between countries. This estimates were based on ICD-8/9 codes 490-493 which omits codes 519.3 in ICD-8 and 496 in ICD-9.

In Canada, from 1980 to 1995, the total number of death from COPD increased from 4,438 to 8,583. although the age-standardized mortality rate remained stable throughout this period in men (around 45/100,000 population), it doubled in women 8.3/100,000 in 1980 to 17.3/100,000 in 1995.[26] This rates were estimated using ICD-9 490-492 and 496). In the United States mortality data can be obtained form the National Vital Statistics System. The age-adjusted death rates for COPD have been rising steadily from 1960 to 1996 for men and women. COPD death rates are very low among people under the age 45 in the US, but then increase with age, and COPD becomes the fourth or fifth leading cause of death among those over 45 and there are clear differences among socioeconomic groups.[27] While the death rate among men has reached a plateau, the rate among women has continued to increase. In 1998, 54,615 men and 51,377 women died from COPD. From 1995 to 1998, the death rate attributable to COPD among men remained stable at 53.1 death per 100,000 population (age-adjusted to the 2000 US population), whereas the death rate attributable to COPD among women increased 9.5% from 29.3 to 32.1 death per 100,000 population.[28] All these estimates were based on the ICD-9-CM (codes 490, 491, 492 and 496).

AIMS: 1) To describe and compare COPD mortality using the indicators proposed; **2)** To assess

changes in the total number of death, crude and age-specific death rates by the age groups suggested and gender. **3)** Changes should be monitored at different geographical levels: national, sub-national or local if it is possible.

DATA SOURCES: At present, the World Health Organization (WHO) international database[9] presents mortality data based on two lists of diseases categories (A and B) to limit the number of individual codes to be published. Under the list A, standardized rates for bronchitis, emphysema and asthma (ICD-10, J40 – J46) by 100,000 population and for ages 0-64 and all ages are estimated. At present, it is not possible to distinguish between COPD and asthma. The same estimates are published in the OECD database[8] in addition to another category for COPD which include ICD-9 code 490-496**.** From EUROSTAT database[7] you can obtain estimates for asthma alone but not COPD without asthma. For respiratory diseases you can select two codes: (40) Chronic lower respiratory disease (ICD-10, J40-J47; ICD-9, 490-494, 496) and (41) Asthma (IVD-10, J45-J46; ICD-9, 493). In this database you can obtain these estimates by five years age groups and also by geographical level according to NUTS classification. This classifications recently have been challenged by the ISARE project.[10] In all these databases DALYs or PYLL specific for COPD are not available.

DATA QUALITY: Although among the descriptive epidemiological data for COPD mortality data are the most readable available, there are several problems that should be taken into consideration when analyzing mortality data and specially trends over time. In addition to the limitations of the validity of medical death certificates, the analysis of mortality data is further complicated by the lack of using the same standardized codes in all analysis (either in research or routine databases). This is further complicated when time trends are analyzed due to changes over time in the International classification of Diseases (ICD-8, ICD-9, ICD-10, ICD-9-CM). This changes have not been introduced at the same time in many EU countries and this brings serious problems when the analysis is focused on geographical variations. Several studies have shown that many death with COPD have their death attributed to another cause.[29] In 1998, only 45.4% of the 233,610 deaths with COPD mentioned on their death certificates had this ultimately listed as the underlying cause of death, despite the presence of prospective studies showing that people with COPD listed on their death certificates have severe disease.[12,30] In a study carried out in UK and using mortality data for England and Wales (1993-1999), estimated that obstructive lung disease comprised underlying cause of death in 59.8% of deaths with mention of COPD. In this analysis ICD-9 490-493, 496 were used. These studies show that using only underlying cause of death underestimates mortality rates.[31]

METHODS TO BE USED FOR NEW DATA COLLECTION: The same used at present by international organizations (EUROSTAT, WHO, OECD) but introducing the changes specified in the indicators.

DATA PRESENTATION: The total number of death and crude death rates should be presented as a total and also by age group. Tables by age group should also be stratified by gender. Age-specific and also when using COPD as a contributing cause of death, should also be presented by gender. These tables should be available at different geographical levels: national, sub-national or local if data is available. Person years of life lost should also be presented by gender.

POTENTIAL USE: To monitor changes in COPD mortality across age, gender and geographical areas. These data should useful for monitoring policy interventions aiming to reduce COPD mortality. Unfortunately, occupation is not available in all countries to make comparisons according to socioeconomic status.

CONSISTENCY AT INTERNATIONAL LEVEL: For all European countries mortality data is available and international databases (OECD, WHO and EUROSTAT) provide information at international level. However, there is not a consistent presentation of COPD mortality indicators for all these databases. Changes should be recommended on the indicators provided, the precise codes to be used (differentiating asthma and COPD), the age group stratification. The relevance of using multiple cause mortality to avoid underestimation of COPD mortality should also be pointed out. The changes in ICD classifications over time may have introduced important bias on mortality estimates. This possible bias have not been evaluated consistently at national or international level. The impact of recent changes (from ICD-9 to ICD-10) on mortality estimates have not been evaluated.

COMMENTS: Most indicators suggested by the IMCA project on COPD mortality are already included in the ECHI-2 list. <u>However, age-specific death rates and the age-specific death rate having COPD as a contributing cause of death are not included.</u> The ICD-10 codes used at present by EUROSTAT in the 65 European shortlist of causes of mortality <u>should be corrected</u> in order to clearly separate asthma and COPD as it is indicated in the indicator definition.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Mortality data is available from routine data sources in all EU countries. However, most participants have indicated that methodological changes will be required in order to improve the comparability of these indicators between countries and to improve the way in which these indicators are published according to IMCA group recommendations. Although the indicator: "Age-specific death rate having COPD as contributing

cause of death" is strongly recommended by the group, in several countries may not be available until multiple-cause of death are recorded.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 2.2.8 respiratory system	Indicator Score	Rank	Order	IMCA Group recommendation
? **Total number of death**	3.1	(1-4) 3	4	3
? **Crude death rates**	3.2	(2-4) 2	3	3
? **Standardized death rates (SDR)**	3.4	(2-4) 2	2	2
? **Age-specific death rate**	**3.5**	(2-4) 2	**1**	1
? Age-specific death rate having asthma as contributing cause of death	3.1	(1-4) 3	4	1
? Potential years of life lost	2.8	(1-4) 3	5	3
Top 4 **Top 20**				

INDICATOR	DEFINITION
2.3.8 Respiratory system.	
• **Prevalence of chronic symptoms (cough, phleghm or sputum production).**	• Proportion of individuals having cough and/or phleghm from the chest, usually in winter, and as long as 3 months each year and for at least two successive years.
• **Prevalence of chronic bronchitis.**	• Proportion of individuals with FEV1/FVC < 70% with or without chronic symptoms (post bronchodilator).
• **Prevalence of airway obstruction.**	• Proportion of individuals reporting to have suffered chronic bronchitis.
• **Prevalence of physician diagnosed COPD.**	• Proportion of individuals reporting to have been diagnosed of COPD by a physician.

RATIONALE: Chronic obstructive pulmonary disease is a leading cause of chronic morbidity. However, reliable COPD prevalence estimates are lacking for many parts of the world. The conflicts among published COPD prevalence rates may be due to many factors, including true differences in disease occurrence, differences in defining COPD, cultural biases, and methodological issues such as the use of lung function test in contrast to self reported symptoms or estimates based on physician diagnosis. The number of epidemiological studies which have assessed the prevalence of COPD is still limited. In a recent review which included population based studies from 1962 to 2001, Hallbert et al. only found 32 prevalence studies.[4] Most studies were carried out in a single country although some countries had more than one study. Only three studies provided data for more than one country. These studies could be broadly grouped into four categories according to the methods used to assess prevalence: 1) spirometry, with or without clinical examination; 2) the presence of respiratory symptoms; 3) patient-reported disease; and 4) expert opinion. A similar classification of studies have been used in the GOLD conensus report.[32]

In these studies, COPD prevalence estimates ranged from < 1 to > 18%, and tended to vary by the method used to estimate the prevalence. Only eleven of these studies used spirometry, either in conjuntion with clinical examination or used alone but most of them carried out in recent years and there was considerable variation in the spirometric criteria for defining COPD. The use of different criteria may be due to the lack of consensus and continuing changes over time adopted by the consensus statements provided by the scientific societies. In 1997, in the UK the prevalence of COPD was 1.7% among men and 1.4% among women. These estimates are low because the database used includes all ages and thus underestimates the true impact of COPD on older adults. Between 1990 and 1997, the prevalence increased by 25% in men and 69% in women. These prevalence estimates were based on data from the UK General Practice Research Database,[33] which is based on 525 practices serving 3.4 million patients (6.4% of the total population of England and Wales) and provides data on physician-diagnosed COPD.

AIMS: 1) To describe the prevalence of chronic respiratory symptoms, chronic bronchitis, airways obstruction and physician diagnosed COPD by age group, gender, socioeconomic status and geographical area. **2)** The availability of this data at fixed intervals will allow monitor changes over time in the indicators proposed.

DATA SOURCES: Information on the prevalence of COPD can be obtained from two main sources of data: 1) general health interview or examination surveys and 2) research studies. However, the quality of the information is very poor and limited in general health interview surveys and the information provided from research studies is difficult to compare as it will be described in the following section. In UK, the General Practice Research Database is another source of data. However, this kind of database is not widely available across European countries.

DATA QUALITY: The data quality mainly depends on the methods used in each specific study. However, the most relevant problems seems to be the difficulties in comparing results between studies due to the lack of consensus on the methods and definitions. Over the past decade, several definitions for COPD have been proposed, and these different definitions can have a large impact on the population estimates of the burden of disease. The differences in COPD definitions have been recently examined by several authors. [1,2,28] The American Thoracic Society (ATS) has defined COPD as "a limitation due to chronic bronchitis or emphysema: the airflow obstruction is generally reversible".[34] The European Respiratory Society (ERS) defined COPD as " reduced maximum expiratory flow and slow forced emptying of the lungs which is slow progressive and mostly irreversible to present medical treatment".[23] More recently, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) defined COPD as "a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with and abnormal inflammatory response of the lungs to noxious particles or gases.[32] However, the precise classification of the airflow, reversibility, and severity of disease varies.

The 1995 ATS definition did not list specific level of the FEV1/FVC ratio for airflow limitation.[34] The 1995 ERS definition for airflow limitation is an FEV1/FVC capacity ratio of < 80% of the predicted value.[23] The recent GOLD definition for airflow limitation is an FEV1/FVC ratio < 70% post-bronchodilator.

The 1995 ATS definition did not list specific level of the FEV1/FVC ratio for airflow limitation.[34] The 1995 ERS definition for airflow limitation is an FEV1/FVC capacity ratio of < 80% of the predicted value.[23] The recent GOLD definition for airflow limitation is an FEV1/FVC ratio < 70% post-bronchodilator. The recent GOLD definition for airflow limitation is an FEV1/FVC ratio < 70% post-bronchodilator. However, the fact that the ratio should be estimated after bronchodilator administration, was not clearly specified and adopted in recent studies.[32] Some studies have investigated the effects of using different definitions on the prevalence estimates. They concluded that the prevalence of COPD in a general population depends very much on the criterion used for definition of airways obstruction. Differences in the definition may produce variations on the estimates more than 200%.[1]

Alternatively to studies which have used lung function measurements, as mentioned previously, other studies have used only self-reported symptoms or diagnosis or a combination of both with smoking status. This method is used in general health interview surveys. The question most frequently used is: "Do you have chronic bronchitis or emphysema?" . However, in many cases this is mixed with asthma. An example of the combination of self-reported disease combined with symptoms and smoking status is the recent multinational study "The Confronting COPD International Survey". The definition used in this study was: "Proportion of individuals aged ≥45 years who had cumulative cigarette consumption of ≥10 pack-years and who had been diagnosed with COPD, emphysema or chronic bronchitis, or whose symptoms fulfilled a definition of chronic bronchitis, i.e. "persistent coughing with phleghm or sputum from the chest for the last 2 years or more".[5]

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend to incorporate in future questionnaires several questions in order to assesses the prevalence of COPD. It is desirable, to be able to estimate the prevalence of individuals with specific symptoms, chronic bronchitis, airway obstruction or physician diagnosed COPD independently. Using different questions, there is always the possibility of combining them according to any consensus or newly established criteria for a specific definition of COPD (including risk factors such as smoking). The use of lung function measurements is costly and introduces complexities in the study fieldwork. However, the group highly recommend to introduce its use in future studies either research or routine HIS/HES surveys.

DATA PRESENTATION: Prevalence estimates should be obtained using different questions and presented independently for the following indicators: a) chronic symptoms, b) chronic bronchitis, c) airways obstruction and d) diagnosed COPD. From these questions, specific estimates taking into account different aspects of the questions previously mentioned could be obtained. Tables by age group and also stratified by gender should be presented. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: To evaluate the impact on COPD prevalence of possible health policy interventions focused on the reduction specific COPD risk factors susceptible to intervention.

CONSISTENCY AT INTERNATIONAL LEVEL: Over the past decades several methods to estimate prevalence of COPD have been used. Several consensus statements have improved definitions and criteria for lung function measurements. However, the recommendations have been changing over time and led to more complex methodologies. At present, there is not any study in which the most recent GOLD criteria have been used and the number of studies including several countries is very limited. The questions used in general health interview surveys in European countries are very different and difficult to compare estimates. The results are not presented in a standardized age groups by sex and severity at national and sub-national geographical levels.

COMMENTS: Based on this review, we recommend to use several questions in order to be able to assesses the prevalence of symptoms, chronic bronchitis, airway obstruction and physician diagnosed COPD and avoid problems of comparability. Using different questions, there is always the possibility of combining them according to any consensus or newly established criteria for a specific definition of COPD. The use of lung function measurements is costly and introduces complexities in the study fieldwork. However, the group highly recommend to introduce its use in future studies. The ECHI-2 project have only included one indicator on the prevalence of COPD. We strongly recommend to introduce four indicators to describe the prevalence of COPD. These indicators should also be presented by age, gender, socioeconomic status and geographical level.

The ECHI-2 project included the section "2.4 Perceived and functional health" which include "2.4.1 Perceived health"; 2.4.2 Chronic disease general"; "2.4.3 Functional limitations"; 2.4.4 Activity limitations"; "2.4.5 Short-term activity restrictions"; "2.4.6 General mental health"; "2.4.7 General quality of life" and "2.4.8 Absenteeism from work". Most of the indicators that could be included in this section have been distributed in other sections of health systems section and included as outcome measures. The next section "2.5 Composite measures of health status" includes disease specific measures and the IMCA project recommends DALYs as a composite indicator for COPD.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: The availability of prevalence data is much more limited compared to mortality. Only two participants have indicated that prevalence data is available for all prevalence indicators and three more for just one or two prevalence indicators. An important group indicated that prevalence data are available from national or international HIS/HES surveys. Four participants indicated that these data have to be developed and collected by national surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 2.3.8 Respiratory system	Indicator Score	Rank	Order	IMCA Group recommendation
? Prevalence of chronic symptoms	**3.3**	(1-4) 3	**1**	**1**
? Prevalence of chronic bronchitis	3.2	(1-4) 3	2	**1**
? Prevalence of airway obstruction	3.2	(1-4) 3	2	**1**
? Prevalence of physician diagnosed COPD	**3.3**	(1-4) 3	**1**	**1**
Top 4 Top 20				

INDICATOR	DEFINITION
2.3.8 Respiratory system	
• **COPD Severity :**	
• **Stage 0.**	• Proportion of individuals with normal spirometry and chronic symptoms (cough, sputum production) (FEV1/FVC >70) .
• **Stage I (Mild).**	• Proportion of individuals with FEV1/FVC < 70%, FEV1 ≥80% predicted with or without chronic symptoms (cough, sputum production).
• **Stage II (Moderate).**	• Proportion of individuals with FEV1/FVC < 70%, FEV1 50-80% predicted with or without chronic symptoms (cough, sputum production).
• **Stage III (Severe).**	• Proportion of individuals with FEV1/FVC < 70%, FEV1 30-50% predicted with or without chronic symptoms (cough, sputum production).
• **Stage IV (Very Severe).**	• Proportion of individuals with FEV1/FVC < 70% FEV1 ≤30% predicted plus chronic respiratory failure.
• **Modified Medical Research Council (MRC) dyspnea scale (Rang 0-5).**	• **5)** Too breathless to leave the house; **4)** Have to stop for breath every year few minutes when walking even on level ground; **3)** Have to stop even when walking at my own pace or walk slower than most people at my age; **2)** Get breathless when hurrying on level ground or walking on slight incline; **1)** only get breathless after strenuous exercise; **0)** None of these.
• **Self-assessed COPD severity.**	• Proportion of individuals with **self assessed** COPD severity: (Mild, Moderate, Severe)

RATIONALE: Like the definitions of COPD, the classification of severity based on lung function measurements have also changed over time in accordance with new consensus statements produced by scientific societies. In 1995, the ATS defined three stages and criteria to classify COPD: stage 1 (FEV1 ≥50% of predicted); stage 2 (FEV1 35-49% of predicted); and stage 3 (FEV1 < 35% of predicted).[34] The European Respiratory Society criteria classified COPD into the following three stages: mild (FEV1 ≥70% of predicted); moderate (FEV1 50-80% of predicted); and severe (FEV1 < 50% of predicted).[23] The GOLD criteria classified COPD according to the stages described at the top of this page and proposed as indicators of severity.[32] In this classification the values of FEV1 are based on post-bronchodilator values.[35]

Data form the European Community Respiratory health Survey show that the prevalence of different stages of severity was 11.8% for stage 0, 2.5% for stage I, and 1.1 % for stages II and III. The study showed wide variations across countries for all stages. For stage 0 the prevalence ranged from 7.2% in Australia to 23.7% in Spain; for stage I ranged from 0.8 in Iceland to 7.4% in Switzerland; and for stages II and III ranged from 0.5% in France to 3.4% in Denmark.[3]

The classification of severity based on lung function measurements do not take into account disability that is weakly related to lung function measurements. The Medical Research Council (MRC) dyspnea scale[36] is a simple an valid method of categorizing patients with COPD in terms of their disability that can be used to complement FEV1 in the classification of severity. The scores in this scale goes from 5 to 0 and based on the following statements: 5) too breathless to leave the house; 4) have to stop for breath every year few minutes when walking even on level ground; 3) have to stop even when walking at my own pace or walk slower than most people at my age; 2) get breathless when hurrying on level ground or walking on slight incline; 1) only get breathless after strenuous exercise; 0) none of these. More recently other studies have collected information on the individual perception of severity. Comparing the different methods of assessing severity it is possible to know to what extent patients are aware of the severity of their health problem.

These comparisons have been made using data from the Confronting COPD International Survey were the self assessed severity and the MRC disability score were compared. In this study, 31.8% of patients classified themselves as mild, 44.1% as moderate and 21% as severe. Important disparities between subjects' perception of disease severity and the severity measured by the MRC scale. Of those with the most severe breathlessness, 35.8% described their condition as mild or moderate.[5]

AIMS: 1) To describe the prevalence of chronic respiratory symptoms, chronic bronchitis, airways obstruction and physician diagnosed COPD according to three different indicators of severity. **2)** To provide estimates of the prevalence severity by age group, gender, socioeconomic status and geographical area. **3)** To describe the distribution of COPD patients according to three different indicators of severity. **4)** The availability of this data at fixed intervals will allow monitor changes over time in the indicators proposed.

DATA SOURCES: General health interview surveys do not collect information on severity. Only health examination surveys which have measured lung function can provide data on severity. However, to date there are not studies which have reported information on severity based on the new criteria established by GOLD. As far as we know only the European Community Respiratory Health Survey[3] have estimated variations on the prevalence of COPD across European countries using the recently established GOLD criteria, although they were not based on post-bronchodilator measurements. Data based on the self assessed severity and the MRC scale have been collected by the Confronting COPD International Survey.[5]

DATA QUALITY: The data quality of severity measurements based on lung function tests depends on the standards of quality of each individual study. However, the major problem that may arise in epidemiological studies is the non acceptance of the tests by participating individuals. In some circumstances, the non acceptance rates can be high and creating serious problems of representativeness. In spite of these problems, lung function measurements in epidemiological studies should be encouraged. The MMRC scale and the self-assessed severity can be influenced by cultural factors and individual perceptions of severity.

METHODS TO BE USED FOR NEW DATA COLLECTION: We strongly recommend to introduce lung function measurements to assess severity in future research or routine studies. In addition appropriate questions based on the MMRC and the self-assessed scale should be incorporated.

DATA PRESENTATION: In this section different indicators of severity are presented and recommended. However, each one independently may reflect clearly differentiated aspects of severity. We suggest to present cross-tabulations between the four groups of prevalence estimates suggested with the three different methods of severity assessment. These estimates would be population based estimates of the prevalence and severity. In addition to population based estimates it would be good to know within the COPD patients group the proportion of individuals in each severity group. This should be available for each of the three methods of severity measurement proposed and presented as total and stratified by age and sex. In order to know the level of agreement between the different methods of severity classification and its possible clinical management implications for COPD patients, cross-tabulations of the self-perceived severity with the severity (according to GOLD criteria) and severity (according to MMRC dyspnea scale) should be presented. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: To evaluate the impact on COPD severity of possible health policy interventions focused on the reduction specific COPD risk factors susceptible to intervention.

CONSISTENCY AT INTERNATIONAL LEVEL: The criteria for severity classification have changed over time during the last years and between different consensus statements. The GOLD consensus have provided standards useful to be applied in epidemiological or clinical studies. However, to date only one study have attempted to use them. The post-bronchodilator estimation of FEV1 may be incompatible with the performance of a bronchial responsiveness (BHR) test. The latest is important in all asthma studies or in COPD studies in which BHR is included as a risk factor. If the performance of both measurements is incompatible, it may imply that COPD and asthma studies should be carried out separately. The self-perceived severity and the MRC classification of disbility have been used in a limited number of studies.

COMMENTS: Based on this review, we recommend to monitor COPD severity based on the three measures indicated. This measures of severity should be presented in two different ways: 1) as the prevalence of different COPD stages in the community and 2) as the proportion of individuals at each severity stage in COPD patients. The ECHI-2 project have only included and indicator on the prevalence of COPD and severity is not considered. We strongly recommend to introduce COPD severity indicators as suggested. These indicators should also be presented by age, gender, socioeconomic status and geographical level.

AVAILABILITY CONSISTENCY AT NATIONAL LEVEL: Similarly to data on prevalence, severity is not collected and routinely available in all EU countries. At present, severity indicators can only be estimated from the specific surveys such as ECRHS. Although six participants said that severity data are available the rest of participants said that they have to be developed and collected in the future. Self-assessed severity can be obtained form The Confronting COPD survey.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 2.3.8 Respiratory system	Indicator Score	Rank	Order	IMCA Group recommendation
? COPD severity	2.9	(1-4) 3	4	**2**
? Stage 0	2.6	(1-4) 3	6	**2**
? Stage I (Mild)	2.6	(1-4) 3	6	**2**
? Stage II (Mderate)	2.6	(1-4) 3	6	**2**
? Stage III (Severe)	2.8	(1-4) 3	5	**2**
? Stage IV (Very severe)	3.0	(1-4) 3	3	**2**
? Modified Medical Research Council dyspnea scale	2.6	(1-4) 3	6	**2**
? Self-assessed COPD severity	2.3	(0-4) 4	7	**3**

Class 3

Determinants of health

INDICATOR	DEFINITION
3.1.1 Biological risk factors.	
• **Age.**	• Age
• **Gender.**	• Gender
• **Body Mass Index (BMI).**	• Proportion of individuals in each category of the BMI defined as weight (in Kg) / height^2. The categories according to the values are: underweight(<18.4); normal weight 18.5-24.9); overweight (25.0-29.9); obese (>30.0).
• **BODE Index.**	• The proportion of individuals in each category of the BODE Index: 1) scores of 0 to 2; 2) scores 3 to 4; 3) scores 5 to 6; 4) scores 7 to 10. The BODE Index is a multidimensional 10 point scale in which higher scores indicates higher risk of death and based on four factors: BMI, degree of airflow obstruction (based on FEV1), dyspnea (based on the MMRC scale) and exercise capacity (based on a six minute walk test).
• **Family history.**	• Proportion of individuals with either the father or mother history of having COPD.
• **Childhood infections.**	• Proportion of individuals with history of having had serious childhood infections before 5 year of age.
• **Birth weight.**	• Proportion of individuals in the lowest birth weight quartile.
• **Sensitization to indoor/outdoor allergens.**	• Proportion individuals **sensitized** to at least one of the tested common indoor/outdoor allergens.
• **Bronchial hyperresponsiveness (BHR).**	• Proportion of individuals with a positive **bronchial responsiveness** test.

RATIONALE: Epidemiological studies show that the prevalence of COPD increases with age,[1,37] males have higher prevalence rates compared to females[1,2,3,37] In addition to considerer age as a risk factor for COPD, it is very important to take into consideration age in any research study when the selection of the study population is made. Hallbert et al.[4] that have reviewed the characteristics of COPD prevalence studies have shown large variations in the age range of individuals included in the studies reviewed (from 16 to 90) and some studies included all ages.

Other studies focusing on diagnosed COPD patients have been limited to >45 age groups.[5] Although it is rare to identify individuals with a diagnosis of COPD before 40 years old, recent studies have shown that a considerable proportion of young people already suffered from COPD. The results from a ECRHS analysis, which included a population between 20-44 years, 11.8% were already in stage 0, 2.5% in stage I and 1.1% in stages II-**III**.[3] So studies focusing only in populations more than 45 years, like the Confronting COPD international Survey may miss a substantial proportion of individuals.[5] Another important issue is the age group stratification used in research or routine studies. Although the age range of individuals included may be different, it would be important to use a standard age group stratification in all studies like it have been suggested before in the population indicators section. If these issues are not standardized, in the future, there will be serious difficulties in comparing prevalence estimates or exposure effects between studies.

Differences in mortality and prevalence between men and women suggest a gender effect on the development of COPD but the role of gender remains unclear. Studies carried out in the past, showed that COPD prevalence and mortality were greater among men than women.[22,38,39] However more recent studies [27,39] show that the prevalence of the disease tend to be equal and probably this reflects changing patterns of tobacco smoking.

Recent studies have suggested a relationship between COPD and obesity.[40,41] Patients with emphysema are more likely to be underweight, and patients with chronic bronchitis are more likely to be obese. However, the temporal relationship between abnormal BMI and the onset of COPD is still uncertain.[40] COPD patients with overweight or obesity have a higher risk of death compared to those with normal BMI.[41] The risk of death in COPD patients can be predicted by the BODE index.[42] This index is a multidimensional 10-point scale in which higher scores indicate a higher risk of death. The index is composed by four factors: the body mass index, the degree of airflow obstruction, dyspnea and exercise capacity.

It is believed that genetic factors may have an influence on the development of COPD (increase or decrease a person's risk). Studies have demonstrated and increased risk of COPD within families with COPD probands. Some of these risks may be due to shared environmental factors, but several studies in diverse populations also suggest a shared genetic risk.[43,44] However, the only well identified gene associated to COPD is the x-1-antitripsine.[45] A European study, using pooled data from England, Netherlands and Italy found an association between family history of chronic bronchitis and a reduced lung function but only in ever smoker subjects.[46]

A relationship between birth weight and adult lung function have been found in a study carried out by Edwards et al. in which a positive linear trend in mean FEV1 and FVC was observed between birth weight quintiles of both men and women. However, after adjusting for maternal factors, the results for women appears to be explained mainly by an effect of the lowest quintile versus the other quintiles , in contrast to a clearer trend in men.[47] A history of severe childhood infection has been associated with reduced lung function and increased respiratory symptoms in adulthood.[45,48,49,50]The recent ECRHS analysis have shown that infection before 5 years old increased the risk of COPD at all stages.[3]

Several markers of allergy such as a positive skin prick test, elevated serum IgE , and eosinophilia a clearly related to asthma phenotypes. However, age-sex standardized serum IgE levels have not been found associated to chronic bronchitis or emphysema.[51] However, some studies have found atopy associated to airways obstruction in non-smokers[52] and in no asthmatics[53] The role of atopy in the development of COPD de Asthma and airway hyperresoponsiveness, have been identified as a possible risk factors for the development of COPD. However these are complex disorders related to a number of genetic and environmental factors. The raltionship between asthma/airway hyperresponsiveness and increased risk of developing COPD was originally described by Orie and colleagues[54] and termed the "Dutch hypothesis". Asthmatics experience a slightly accelerated loss of lung function [55,56] compared to non asthmatics, as do smokers with airway hyperresponsiveness compared to normal smokers.[57] However, how these is related to the development of COPD is still unknown.

AIMS: 1) To describe the prevalence of biological risk factors for COPD development or death in the community by age group, gender, socioeconomic status and geographical area. **2)** To describe the distribution of COPD patients according to the categories established for each risk factor **3)** The availability of this data at fixed intervals will allow to monitor changes over time in the risk factors indicators proposed.

DATA SOURCES: The population structure by age and gender is available in most countries from National Census Statistics. Also most routine or research studies contain information on age and gender but not always the age groups available are comparable between data sources. BMI is available from several routine (general health interview/examination surveys) and research data sources. The BODE Index requires specific information on different issues usually not collected at the same time even in research studies. In future routine or research studies the information required to construct this indicator should be included. Family history and childhood infections are collected in some specialized studies (i.e. ECRHS) but not in routinely collected data. Birth weight is available from birth registries but it is not always possible to have appropriate links with these registries. In general, this information is collected by self-reported questionnaires or interviews in general or specialized surveys. Sensitization to specific allergens and bronchial hyperresponsivenes is only available in a limited number of research studies. At international level only the ISAAC II (in some centers) and the ECRHS I and II have collected this data.

DATA QUALITY: In general the quality of data on the population structure based on National Census Statistics is good. In routine or research surveys the proportion of missing data for these variables is extremely low. The quality of the data on the BMI depends on the methods used to collect information on weight and height. When this data is collected by direct measurements rather by questions the reliability of the data is much better. However, possible bias introduced by measurement errors either from the instruments or from the variability between and within fieldworkers. The information required to construct the BODE Index is usually collected by questionnaire and possible information bias can be introduced in the process of data collection. There are several methods for the measurement of sensitization to specific allergens and bronchial responsiveness and the quality of data depends on the method used, having a good standardized protocol and have a good training and quality control of data collection. Information on these methods can be obtained form the ISAAC II (for children) and the ECRHS I and II (for adults).

METHODS TO BE USED FOR NEW DATA COLLECTION: In future COPD studies we recommend to introduce measurements of weight and height, sensitization to indoor/outdoor allergens, bronchial hyperresponsiveness and the necessary measurements already recommended to estimate the BODE Index. Questions on family history, childhood infections and birth weight should also be included.

DATA PRESENTATION: We suggest to present tables showing the prevalence of the risk factors for COPD recommended by age group, gender, social class and severity. Tables showing the distribution of COPD patients according to the categories established for each risk factor should also be presented. Cross-tabulations showing these distributions by age group, gender, social class and severity are also recommended. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: 1) To monitor changes over time on COPD biological risk factors, **2)** to evaluate the impact of possible health policy interventions focused on the reduction specific COPD risk factors susceptible to intervention.

CONSISTENCY AT INTERNATIONAL LEVEL: Although the independent effect of age and gender it is still not very well clarified these factor have to be included in order to adjust or stratify prevalence estimates or other indicators by age and gender. BMI and infant infections are not always included in surveys. Atopy and BHR have to be carefully considered before to incorporate them into COPD surveys unless asthma is also assessed.

COMMENTS: In the ECHI-2 project unde the section "3.1.1 Biological risk factors" only BMI is included as a risk factor and recommended by several projects. However, there is not a clear agreement on how to present this indicators and on which categories should be used. An agreement should be reached by EHHRM, EUDIP AND CHILD projects to finally define this indicators. In the ECHI-2 the prevalence of this estimate is included but the IMCA group feels that it is important to have it stratified by age group, gender, social class and severity. In addition the distribution of COPD patients according to the categories established for each risk factor should also be presented. As we said before these tables should be available at different geographical levels.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Age, gender and BMI are available for most countries However, there are high variations between countries on the availability of the rest of indicators. The Bode Index have to be developed for all countries. Questions in order to collect information on these indicators have to be included in future national and international surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 3.1.1 Biological risk factors	Indicator Score	Rank	Order	IMCA Group recommendation
? **Age**	**3.6**	(2-4) 2	**1**	**1**
? **Gender**	3.3	(1-4) 3	2	**1**
? Body Mass Index (BMI)	2.8	(1-4) 3	3	**2**
? BODE Index	2.3	(0-4) 4	4	**2**
? Family history	2.2	(1-4) 3	5	**2**
? Childhood infections	2.2	(1-4) 3	5	**2**
? Birth weight	1.7	(0-4) 4	8	**3**
? Sensitization to indoor / outdoor allergens	1.8	(1-3) 2	7	**3**
? Bronchial responsiveness (BHR)	1.9	(1-3) 2	6	**3**
Top 4 **Top 20**				

INDICATOR	DEFINITION
3.2 Health behaviors.	
3.2.1 Substance use. • **Smoking exposure in general population:** **1) Current smokers.** **2) Past smokers.** **3) ETS exposure at home.** **4) ETS exposure at work.** **5) Smoking exposure during his/ her mother pregnancy.** • **Smoking exposure in COPD patients**: **1) Non smokers with ETS.** **2) Non smokers without ETS.** **3) Past smokers with ETS.** **4) Past smokers without ETS.** **5) Current smokers (<15 pack years).** **6) Past smokers (≥ 15 pack years).** **7) Smoking exposure during his/ her mother pregnancy.**	• Proportion of individuals in the general population in each of the five categories described (1 to 5). • Proportion of COPD patients in each category of tobacco exposure according to the seven categories described.
3.2.2 Nutrition. • **Anti-oxidants :** **(Vitamin C, E, β-corotene, flavonoid, selenium, vegetables, cereals, etc.).** • **Alcohol.**	• Proportion of individuals which consume fruits daily. • Proportion of individuals which consume vegetables daily. • Proportion of individuals drinking an excess of alcohol daily.
3.2.3 Other relayed health behaviors. • **Physical activity in general population.** • **Physical activity in COPD patients.**	• Proportion of individuals carrying out some exercise during the week. • Proportion of individuals able to carry out a six minutes walk without problems.

RATIONALE: Tobacco smoking is an important risk factor for several diseases and the most important risk factor for COPD. The available evidence consistently shows that smoker are at higher risk of decreased FEV_1 both in cross sectional and longitudinal studies. There is also consistent evidence about a dose-response relationship between the amount of smoking and the decline in FEV_1. [58,59] Passive smoking or environmental tobacco smoke (ETS) may also contribute to respiratory symptoms and COPD. Maternal smoking have been found associated with small but statistically significant deficits in FEV_1 and other spirometric indices in school-aged children. The results of the recent ECRHS show that a substantial proportion of the population is exposed to some form of tobacco exposure. According to GOLD criteria, in stage 0, only 21.4% of individuals were not exposed to any form of tobacco exposure, 5.4% were non smokers but were exposed to ETS, 10.2% were past smokers and not exposed to ETS, 28.5% were smokers (< 15 pack years) and 30.1% were also smokers (> 15 pack years).[3] Despite the benefits of smoking cessation,[60] in GOLD severity stages I or more, the level of tobacco exposure was still very high.

In a recent review, the role of dietary factors implicated in the cause and prevention of COPD have been summarized by Romieu at al.[61] It is suggested that the impact of nutrition on COPD is most evident for antioxidant vitamins, particularly vitamin C and, to a lesser extent, vitamin E. Although epidemiologic data suggest that consumption of fresh fruit may reduce the risk of airway limitation, there are no clear data on which nutrients may be most relevant. In several studies fruit consumption is used as a surrogate for antioxidant intake. Studies on the lung function decrement and COPD in adults suggest that daily intake of vitamin C at levels slightly exceeding the current Recommended Dietary Allowance (60mg/day among nonsmokers and 100 mg/day among smokers) may have a protective effect.[62] Some studies have shown that an increase of 40mg/day in vitamin C intake led to an approximate 20 ml increase in FEV1. [63,64] In contrast, results from the MORGEN study have shown beneficial effects of fruits, whole grains and alcohol on COPD that are largely

additive and could not be explained by smoking habits.[66] In another analysis, using data from the same study protective effects of vitamin E were found but not from vitamin C, beta carotene and vegetables.[67]

Exercise training have been indicated as a component of the pulmonary rehabilitation programs to reduce symptoms, improve quality of life, and increase physical and emotional participation in everyday activities. However, there are important variations in the methods of assessing physical activity. They can be very complex such as using cycle ergometer measurements or very simple such as simples questions introduced in a self-answered questionnaire. The minimum lengths of an effective rehabilitation program is two months; the longer the program continues, the more effective results.[68,69] However, no effective program has been developed to maintain the effect over time. [70] Due to these problems doctors tend to recommend to patients to do exercise on their own (i.e. walking 20 minutes daily).

AIMS: 1) To describe the prevalence of behavioral risk factors for COPD development or death in the community by age group, gender, socioeconomic status and geographical area. **2)** To describe the distribution of COPD patients according to the categories established for each risk factor **3)** The availability of this data at fixed intervals will allow to monitor changes over time in the risk factors indicators proposed.

DATA SOURCES: All routine general health interview or examination surveys and research studies provide information on tobacco smoking. However, the precise definition and questions used in all these studies are highly variable. The information on alcohol is perhaps more limited but have the same problems of comparability mentioned for tobacco. Physical activity is also collected in general surveys but there is a wide range of methods that goes from simple questions to a complex methods of measurement. The information on anti-oxidants or other nutrition aspects usually are collected by specific nutrition surveys and in some research studies interested in identifying associations between some aspects of nutrition and specific diseases.

DATA QUALITY: The quality of data on tobacco exposure even when collected by questionnaire (in comparison with cotinine measurements or other methods) can be good. The major problem is the comparability of questions used in different studies and the categories of interest to assess exposures. The data on nutrition is difficult to collect and standardized questionnaires should be used to provide comparable information. The quality of data collection on physical activity also depends on the methods used for its measurement. Standardized methods should be agreed.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend the used of standardized questions already used in previous studies. For smoking status ECRHS questions could be used. For nutrition and physical activity questions suggested by an European Respiratory Review could be used.

DATA PRESENTATION: We suggest to present tables showing the prevalence of the risk factors for COPD recommended by age group, gender, social class and severity. Tables showing the distribution of COPD patients according to the categories established for each risk factor should also be presented. Cross-tabulations showing these distributions by age group, gender, social class and severity are also recommended. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: 1) To monitor changes over time on COPD behavioral risk factors, **2)** to evaluate the impact of possible health policy interventions focused on the reduction specific COPD risk factors susceptible to intervention.

INTERNATIONAL CONSISTENCY: It seems clear that most of the indicators proposed are relevant to the prevention or reduction of progression of COPD. Tobacco smoke is the most important risk factor for COPD and in general is included in most surveys. However, the data presentation in order to show different levels of exposure in COPD patients is not consistent. The ECRHS analysis have used the following categories for tobacco exposure: 1) Non-smokers and ETS - ; 2) Past smokers and ETS -; 3) Non-smokers and ETS +; 4) Past-smokers and ETS +; 5) Smokers <15 pack years; 6) Smokers >15 pack years; 7) Smokers of other tobaccos. BMI or changes in BMI probably are not always included. The BMI and how to assess changes in BMI in cross sectional surveys should be discussed. Physical exercise can be measured by different methods and with high degree of complexity and costs. The methods to use in HIS/HES surveys or specific COPD surveys have to be discussed.

COMMENTS: In the ECHI-2 several indicators on tobacco exposures are proposed and several projects have suggested specific proposals. It is necessary to review the current proposal and reach a rational number of indicators relevant to health. The project that should be contacted are: CHILD, EUROCHIP, EHRM, PERISTAT, EUDIP, PHNUT and ECHI-2. The same agreement should be reached among PHNUT, ECAS, CHILD, ECAS and ECHI-2 on alcohol exposure; with DAFNE, EFCOSUM, PHNUT on nutrition indicators; with EUPASS, PHNUT, CHILD and ECHI-2 for physical activity.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: There are high variations between countries on the availability of these indicators. Only current and past smoking seems to be available for most

countries. Specific indicators on ETS exposures and smoking exposures in COPD patients. Questions in order to collect information on these indicators have to be included in future national and international surveys. The situation is very similar for nutrition and health behaviors.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 3.2.1 Substance use 3.2.2 Nutrition 3.2.3 Other health related behaviours	Indicator Score	Rank	Order	IMCA Group recommendation
Smoking exposure in general populations:				
? **Current smokers**	**3.9**	(3-4) 1	**1**	**1**
? **Past smokers**	3.8	(2-4) 2	2	**1**
? ETS exposure at home	3.1	(2-4) 2	4	**1**
? ETS exposure at work	3.1	(2-4) 2	4	**1**
? Smoking exposure during mother pregnancy	2.4	(1-4) 3	8	**3**
Smoking exposure in COPD patients:				
? Non smokers with ETS exposure	2.8	(1-4) 3	6	**2**
? Non smokers without ETS exposure	2.8	(1-4) 3	6	**3**
? Past smokers with ETS exposure	2.7	(1-4) 3	7	**2**
? Past smokers without ETS exposure	2.4	(1-4) 3	8	**3**
? **Current smokers (<15 pack years)**	3.2	(1-4) 3	3	**1**
? Past smokers (=15 pack years)	3.0	(1-4) 3	5	**1**
? Smoking exposure during mother pregnancy	2.3	(1-4) 3	9	**3**
Nutrition				
? Anti-oxidants exposure	2.2	(1-4) 3	10	**3**
? Alcohol	2.1	(1-4) 3	11	**3**
Other related health behaviours				
• Physical activity	2.2	(1-3) 2	10	**3**
? Physical activity in COPD patients	2.3	(1-3) 2	9	**3**
Top 4 **Top 20**				

INDICATOR	DEFINITION
3.3 Living and Working conditions.	
3.3.1 Physical environment. • **Air pollution exposure to:** **NO_2, SO_2, O_3, PM_{10}, $PM_{2.5}$**	• Annual average of concentrations in micrograms/m3 for a specific geographical area. • Population-weighted exposure to selected air pollutants (as defined by the ECOEHIS project).
3.3.2 Working conditions. • **Occupational COPD risk.** • **Change of occupation to avoid risk factors for COPD.**	• Proportion of individuals exposed to high risk occupations for COPD. • Proportion of individuals having had to change occupation to avoid risk factors for COPD.

RATIONALE: The evidence about a relationship between outdoor air pollution and the development of COPD is still incomplete since most of the studies have focused on lung function, chronic bronchitis and mortality rather than on clinical definitions of COPD. It is difficult to conclude from the actual evidence that a certain pollutant is related with the slowing of the lung function development, due to the poor characterization of the atmosphere components and the problem of comparing between few levels of exposure. [71] Evidence that adults living in areas with high levels of air pollution have lower levels of lung function have been obtained in studies on British postmen in the 1960s,[72] general population in Holland [73] and young adults in Southern California.[74] More recently the SAPALDIA study in Switzerland also found that levels of particulate matter < 10μm (PM10) and home outdoor measurements of NO2[75] as well as personal measurements of NO2[76] were related to lower FVC. The AHSMOG study[77] and SAPALDIA study[78] consistently found a higher prevalence of symptoms of hypersecretion, breathlessness, or diagnoses of chronic bronchitis, emphysema or COPD in areas with higher particulate air pollution. However, despite the limitations of the present studies, it seems that urban air pollution may be involved in lung function development and consequently be a risk factors for COPD.[71]

The WHO – European Centre for Environment and Health is implementing the project "development of Environment and health Indicators for the EU (ECOEHIS) to establish an environmental health indicator system. At present, the following air pollutants are proposed for routinely data collection and monitoring: NO_2, SO_2, O_3, PM_{10}, $PM_{2.5}$.[79] In order to obtain better estimates of the effects of air pollution on respiratory symptoms the ECRHS II have collected some of these indicators including PM2.5 in the 29 European centers included in the study.[80]

Some occupational environments are likely to involve a risk of COPD. In industry based studies, several exposures in particular occupations have been considered a risk for COPD including: grain, isocyanates, cadmium, coal and other mineral dust and welding fumes.[81,82] Results from the ECRHS have shown that high levels of biological dust, measured with a job exposure matrix, was associated to high levels of FEV1 in Spain . However this association was of significant magnitude in some of the participating countries.[83]. However, the possible occupational effects may be much lower than the smoking effect on COPD.[81]

AIMS: 1) To describe the prevalence of behavioural risk factors for COPD development or death in the community by age group, gender, socioeconomic status and geographical area. **2)** To describe the distribution of COPD patients according to the categories established for each risk factor **3)** The availability of this data at fixed intervals will allow to monitor changes over time in the risk factors indicators proposed.

DATA SOURCES: The information on environmental health indicators is limited and mainly concentrated in urban areas. In general it is difficult to have information for large geographical areas. More details information will be obtained from the APHEIS and SCALE projects that have reviewed this information. Some specific research studies have collected data at ecological and individual level.

DATA QUALITY: The data quality depends on the instruments used for the measurements, its comparability, the geographical area covered and the ability to link environmental indicators to health issues.

METHODS TO BE USED FOR NEW DATA COLLECTION: In many countries information on the air pollution indicators is already collected in some specific areas but in many cases difficult or impossible to link data on exposure and health. The challenge for the future is to collect air pollution data routinely in selected geographical areas over time and for this specific areas to evaluate the health effects over time. On the other hand and alternative to the routine data collection would be to incorporate ecological or individual measurements on the exposure to air pollution in the research or routine surveys.

DATA PRESENTATION: Details should be specified according to ECOEHIS project recommendations.

POTENTIAL USE: 1) To monitor changes over time on COPD risk factors related ot living and working conditions, **2)** to evaluate the impact of possible health policy interventions focused on the reduction specific COPD risk factors susceptible to intervention.

INTERNATIONAL CONSISTENCY: It seems difficult to distinguish which air pollutants have a specific risk for COPD. However, the data collection of most of the pollutants indicated for monitoring are going to be collected across Europe. Perhaps it would be important to discuss how to link cross sectional-surveys with this ecological data. Air pollutants are not going to be collected in all geographical areas and this may be a problem for designing surveys with a national representation. In the ECRHS indoor and outdoor exposures are collected and in some areas of the ISAAC Phase II. However, these are not nationally representative studies. How to links indoor and outdoor exposures in HIS/HES or specific surveys on COPD is probably and issue for discussion.

COMMENTS: Several projects have proposed indicators on environmental exposures but there is not a specific definition and method of data presentation. These issues should be mainly discussed with the ECOHIS project and also with projects that have suggested some indicators such as EUROCHIP, CHILD AND ECHI-2 projects.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Nearly all countries have information available collected routinely on the annual average of NO_2, SO_2, O_3 and PM_{10}. The information on $PM_{2.5}$ is available only in nine countries and is available form research studies or have to be produced in the future in seven countries. Participants from three countries said that population weighted indicators have to be produced in the future from specific surveys and three said that they are only available from research surveys. Most indicators on working conditions are available only from research surveys or have to be produced in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 3.3.1 Physical environment 3.3.2 Working conditions	Indicator Score	Rank	Order	IMCA Group recommendation
Annual average				
? NO2	2.4	(1-3) 2	5	**2**
? SO2	2.3	(1-4) 3	6	**3**
? O3	2.2	(1-3) 2	7	**3**
? PM10	2.8	(1-4) 3	2	**2**
? PM2.5	2.7	(1-4) 3	3	**2**
Population weighted				
? NO2	2.3	(1-3) 2	6	**3**
? SO2	2.3	(0-4) 4	6	**3**
? O3	2.2	(1-3) 2	7	**3**
? PM10	2.7	(2-4) 2	3	**2**
? PM2.5	2.5	(2-4) 2	4	**2**
Working conditions				
? Occupational COPD risk in general population	**2.9**	(2-4) 2	**1**	**1**
? Occupational exposures in COPD patients	**2.9**	(1-4) 3	**1**	**1**

Class 4

Health Systems

INDICATOR	DEFINITION
4.1 Prevention health protection and health promotion.	
4.1.2 Health promotion. • Invitation to stop smoking. • COPD patients invited to stop smoking. • COPD patients invited to follow a stop smoking program. • COPD patients that have managed stop smoking.	• Proportion of smokers in the general population which have been offered a stop smoking program during the last year. • Proportion of smoking individuals with COPD which have been offered a stop smoking program during the last year. • Proportion of smoking individuals with COPD which have been offered and followed a stop smoking program during the last year. • Proportion of smoking individuals with COPD which have been offered and followed a stop smoking program during the last year and managed to stop smoking.

RATIONALE: The advice to stop smoking is important for the general population since smoking is a risk factor for several diseases. This is the reason why the fist indicators "invitation to stop smoking have been introduced". However, to stop smoking is very important for COPD patients in order to avoid disease progression.

Smoking cessation is the single most effective and cost-effective way to reduce exposure to COPD risk factors. Quitting smoking can prevent or delay the development of airflow limitation or reduce it progression although without returning to its basal level.[84]

All clinical guidelines have indicated that COPD patients should be offered stop smoking programs in order to prevent further developments of the disease**.** The indicators suggested will facilitate the monitoring of the accessibility to this programs and their effectiveness. Although many clinicians can easily give advice to patients on the benefits to stop smoking in many occasions the accessibility to specific programs may be limited and unknown.

AIMS: 1) To describe actions carried out from the health care services to prevent smoking exposure, **2)** To describe the efficacy of these interventions, **3)** To monitor changes over time in the indicators proposed.

DATA SOURCES: As we have mentioned before, most routine data provide information on smoking, but there is not information collected on interventions to prevent tobacco exposure. Some studies aiming to evaluate the efficacy of prevention programs provide some data but not at community level or informing about the activities carries out in health services.

METHODS TO BE USED FOR NEW DATA COLLECTION: In most epidemiological studies on COPD there are no questions to assess the indicators proposed in this section. In future studies, in addition to risk factors and prevalence, appropriate questions to assess the prevalence of individuals that follow a stop smoking program and manage to succeed should be included in questionnaires of future studies.

DATA QUALITY: Since this information it is not collected in routine surveys, we cannot provide information on the data quality. Some bias may be introduced since there is not a clear definition of a stop smoking program.

DATA PRESENTATION: Data on this indicators should be presented stratified by age group, sex, social class, severity and geographical area.

INTERNATIONAL CONSISTENCY: Although some cross-sectional provide information on current and past status in relation to smoking the accessibility, follow-up and effectiveness of stop smoking programs is not well monitored. This indicators have not been consistently collected in population based surveys and international studies. Its inclusion in future studies could facilitate the monitoring of prevention strategies.

COMMENTS: In the ECHI project, no indicators have been proposed to monitor stop smoking interventions. They should be included in the final list since they are important for several diseases.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: These indicators are not available and the data required for its estimations is not included in COPD studies. In the future, the appropriate questions to collect the information required have to be introduced in HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.1.2 Health promotion	Indicator Score	Rank	Order	IMCA Group recommendation
? **Invitation to follow a stop smoking program**	3.1	(1-4) 3	3	**1**
? **COPD patients invited to stop smoking**	**3.3**	(1-4) 3	**1**	**1**
? COPD patients which followed a stop smoking program	**3.3**	(1-4) 3	**1**	**2**
? **COPD patients that have managed stop smoking**	3.2	(1-4) 3	2	**1**
Top 20				

INDICATOR	DEFINITION
4.1 Prevention health protection and health promotion.	
4.1.3 Health protection.	
• **Interventions to prevent tobacco exposure**	• Presence of smoking restriction in specific types of buildings. • Existence and enforcement of laws/regulations to protect children from tobacco exposure in public places.
• **Occupational risk**	• Proportion of individuals with COPD which are exposed to vapors, gasses or fumes at work.
• **Air pollution**	• Proportion of individuals with COPD which are living near highways or high traffic density.
• **COPD patient vaccinated against influenza**	• Proportion of individuals with COPD that have had influenza vaccinations during the last year.
• **COPD patients vaccinated against pneumococcus**	• Proportion of individuals with COPD that have had pneumoccocus vaccinations during the last year.

RATIONALE: Indicators on interventions to reduce environmental exposure to tobacco in public places have been proposed by the ECHI, the Child Health and the ECOHIS project. Since, tobacco smoke, as have already been mentioned before is the strongest risk factor for COPD these indicators perhaps should also be recommended by the IMCA project. However, although they can provide information on the policies being implemented in different countries, they may be a poor indicator of exposure.

In the previous section on risk factors, it was already mentioned that some occupational exposures may be a risk for COPD (although smaller than tobacco). Although the proportion of individuals exposed to vapors, gases or fumes at work is not a very detailed measure of exposure, it could be used as a proxy of occupational risk. This question have been used in the ECRHS. In the same way, the proportion of individuals with COPD which are living near highways or high traffic density could be a crude measure of persistent exposure to air pollution (in absence of other measures more specific). This indicator could be important to assess prevention policies.

Influenza vaccines can reduce serious illness and death in COPD patients by about 50%.[85] Vaccines containing killed or live , inactivated viruses are recommended[86] as they are more effective in elderly patients with COPD. Influenza vaccination is recommended in the GOLD guidelines at all COPD severity stages. So the indicator on the proportion of individuals with COPD vaccinated during the last year could be an indicator of good management.

AIMS: 1) To describe actions carried out from the health care services to prevent smoking exposure, at community level **2)** To describe the proportion of patients expose to air pollution or occupational risk despite knowig they have COPD, **3)** To describe the number of COPD patients that are taking preventive actions (vaccinations), **4)** To monitor changes over time in the indicators proposed.

DATA SOURCES: As we have mentioned before, most routine data provide information on smoking, but there is not information collected on interventions to prevent tobacco exposure. The information on legislation may be very unreliable and specific measurements may be required. Information on occupational risks and air pollution can be obtained form simple questions already used in studies such as ECRHS.

DATA QUALITY: The data quality may depend on the quality of individuals reporting. However some of these questions have already been validated for other studies and have been found very useful and simple.

METHODS TO BE USED FOR NEW DATA COLLECTION: Information on these indicators is not available form routine statistics. Standardized definitions for the health care resources indicated should be developed and compared with the existing ones in different countries.

DATA PRESENTATION: : Data on this indicators should be presented stratified by age group, sex, social class, severity and geographical area.

INTERNATIONAL CONSISTENCY: In the international studies on respiratory diseases there are not questions on interventions to prevent smoking in public places and on the number of COPD patients vaccinated. In contrast questions on air pollution and occupational risk as it is described on these indicators have been used in the ECRHS and possibly in other studies.

COMMENTS: In ECHI project some indicators have been proposed to monitor interventions on tobacco exposure and several projects have suggested different indicators. This have to be discussed with the ECOEHIS, CHILD and ECHI-2 projects.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: These indicators are not available and the data required for its estimations are not included in routine or research studies. In the future, the appropriate questions to collect the information required have to be introduced in HES or specific surveys. Only one participant said that this information is available from routine data.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.1.3 Health protection	Indicator Score	Rank	Order	IMCA Group recommendation
? **Invitation to follow a stop smoking program**	3.1	(1-4) 3	3	**2**
? COPD patients invited to stop smoking	**3.3**	(1-4) 3	**1**	**2**
? COPD patients which followed a stop smoking program	**3.3**	(1-4) 3	**1**	**1**
? COPD patients that have managed stop smoking	3.2	(1-4) 3	2	**1**
Top 20				

INDICATOR	DEFINITION
4.2 Health care resources.	
4.2.1 Facilities	
• **PHCC with capability of performing an spirometry.**	• Proportion of PHCC having a general practitioner or nurse trained to perform a spirometry.
• **PHCC with a nurse specialized in COPD education.**	• Proportion of PHCC having a nurse specialized in COPD education.
• **PHCC offering rehabilitation programs.**	• Proportion of PHCC offering rehabilitation programs for COPD patients.
• **Use of oxigen-therapy at home.**	• Proportion of individuals with COPD at stage III which have been using oxigen-therapy during the last year.
• **Pneumology (Respiratory Medicine) units.**	• Number of Pneumology (Respiratory Medicine) units per 100.000 population (for adults).

RATIONALE: A section on the availability of health care resources was introduced by the ECHI project. However, the indicators included in this section were mainly based on indicators already available form international databases such as OECD, EUROSTAT or WHO. Since in this databases there are not indicators that could be useful for the provision of health care to respiratory diseases we suggest to include indicators that could help to monitor accessibility to health care resources relevant to COPD patients.

It is generally accepted that many patients with COPD are undetected or detected at a very late stage of the disease. In general primary health care is the first step to access health care and in most countries and centers, general practitioners are not able to perform and spirometry. Similarly, there is not information on the nurses specialized in COPD education and programs of rehabilitation offered in PHCC. The use of oxigen-therapy can be considered as a treatment and required at advanced stages of the disease but the availability at home could be an indicator of quality of care.

Pneumology units provide specialized care for COPD patients and the detection of the disease and follow-up may depend on the accessibility to these units.

AIMS: 1) To monitor health care resources available for the care of patients with COPD**. 2**) To monitor changes over time in these resources.

DATA SOURCES: There is not any published data on these indicators although the information may exist from Health Departments.

METHODS TO BE USED FOR NEW DATA COLLECTION: Information on these indicators is not available form routine statistics. Standardized definitions for the health care resources indicated should be developed and compared with the existing ones in different countries.

DATA QUALITY: The quality of possible data available have to be explored.

DATA OPRESENTATION: Data should be presented as it is described in the indicator definition.

POTENTIAL USE: To describe and monitor changes over time in the resources available for the care of COPD patients.

INTERNATIONAL CONSISTENCY: At present there is not any information on this indicators in the international databases. The definition and comparability between countries may be difficult since the structure, organization and funding of health care have important differences across EU countries. We have to considerer to what extent it is feasible to have a simple definition and comparable between countries for primary care centers and pneumology units. The Health Systems in transition (HiTs) elaborated by the Health Care Observatory of the WHO provide a good picture of the macro structure, organization and financing of health services across Europe. However, detailed information on this indicators it is not available. Perhaps, we have to considerer how important would be to have this information.

COMMENTS: In the ECHI-2 the indicators on health care resources included are very general and not related to disease specific. The indicators included in this section were mainly based on indicators already available form international databases such as OECD, EUROSTAT or WHO. Since in this databases there are not indicators that could be useful for the provision of health care to respiratory diseases we suggest to include indicators that could help to monitor accessibility to health care resources. These indicators proposed should be included for further development.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Most of the information required to construct these indicators is available from routine data in all countries. Methodological changes are required in some countries to produce the indicators according to the definition established. In France and Luxembourg do not exist primary health care centers. This is way the information for some indicators is missing for these two countries.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.2.1 Facilities	**Indicator Score**	**Rank**	**Order**	**IMCA Group recommendation**
? PHCC with capability to perform a spirometry	**2.9**	(0-4) 4	**1**	**1**
? PHCC with a nurse specialized in COPD	2.3	(0-4) 4	2	**2**
? PHCC offering rehabilitation programs	2.3	(0-4) 4	2	**2**
? Use of oxygen therapy at home	**2.9**	(1-4) 3	**1**	**1**
? Pneumology units	**2.9**	(1-4) 3	**1**	**1**

INDICATOR	DEFINITION
4.2 Health care resources.	
4.2.2 Manpower.	
• **General practitioners in PHCC.**	• Number of primary care general practitioners per 100.000 population working in PHCC.
• **General practitioners in single practices.**	• Number of primary care general practitioners per 100.000 population working in a single practice.
• **Pneumologists.**	• Number of Pneumologists per 100.000 population.
• **Nurses or other health workers specialized in pulmonary rehabilitation.**	• Number of nurses **or other health workers** specialized in pulmonary rehabilitation per 100.000 population.
• **Nurses or other health workers specialized in education programs for COPD.**	• Number of nurses **or other health workers** specialized in education programs for COPD per 100.000 population.

RATIONALE: In the previous section relevant indicators on the availability of services relevant to COPD patients. In this section, indicators on the human resources available are proposed. There is not scientific evidence showing a relationship between the type of professional taking care of COPD patients and health outcomes. However, it is clear that important variations in the distribution of human resources exist. The effect of these variations on outcomes should be further investigated and the distribution of human resources monitored.

AIMS: 1) To monitor human resources available for the care of patients with COPD**. 2**) To monitor changes over time in these resources.

DATA SOURCES: There is not any published data on these indicators although the information may exist from Health Departments.

DATA QUALITY: The quality of possible data available have to be explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: Information on these indicators is not available form routine statistics. Standardized definitions for the health care resources indicated should be developed and compared with the existing ones in national statistics in different countries. In health care systems with a public/private mix in the provision of health services the data collection of this information may be more difficult.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition.

POTENTIAL USE: To describe and monitor changes over time in the resources available for the care of COPD patients.

INTERNATIONAL CONSISTENCY: At present there is no any information on these indicators in the international databases. However this information should be available in most countries certainly for general practitioners and pneumologists. It may be more difficult to collect information on nurses or other health workers specialized in pulmonary rehabilitation and specific education programs. We have to considerer to what extent it is feasible to have a simple definition and comparable between countries for all these indicators.

COMMENTS: In the ECHI-2 the indicators on health care resources included are very general and not related to disease specific. The indicators proposed should be included.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Most of the information required to construct these indicators is available from routine data in all countries. Methodological changes are required in some countries to produce the indicators according to the definition established. In France and Luxembourg do not exist primary health care centers. This is way the information for some indicators is missing for these two countries. The only indicator that the information is not available is “nurses specialized in pulmonary rehabilitation and for education programs for COPD”. They have to be developed in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.2.2 Manpower	Indicator Score	Rank	Order	IMCA Group recommendation
? General practitioners in PHCC	1.9	(0-4) 4	4	**3**
? General practitioners in single practices	2.2	(1-4) 3	3	**3**
? Pneumologists	**2.7**	(1-4) 3	**1**	**1**
? Nurses specialized in pulmonary rehabilitation	2.3	(1-4) 3	2	**2**
? Nurses specialized in education programs for COPD	2.2	(1-4) 3	3	**2**

INDICATOR	DEFINITION
4.2 Health care resources.	
4.2.3 Education. • **COPD education program.**	• Proportion of individuals with COPD which ever have participated in an education program during the last year.
4.2.4 Technology. • **Accessibility to lung function tests.**	• Proportion of individuals with COPD which have ever had a lung function lung function. • Proportion of individuals with COPD which have ever had a lung function lung function .measurement during the last year.

RATIONALE: Studies that have been done indicate that patient education alone does not improve exercise performance or lung function but it can play a role in improving skills, ability to cope with illness, and health status.[87] Howver, patient education regarding smoking cessation has the greatest capacity to influence the natural history of COPD. An international Study has shown that only 67% of COPD patients were shown how to use an inhaler in the past year.[5]

The Global Inititative for Obstructive Lung disease (GOLD) has been the establishment of a working relationship with primary care, with the involvement of the World Organiztion of Family Doctors (WONCA) and the International Primary Care Respiratory Group (IPCRG) have developed the International Primary care Airways Guideline (IPAG) to improve the process of diagnosis and treatment in primary care of patients with lung diseases.[88] However, the key issues that guidelines do not solve by themselves is the access to quality spirometry in primary care. This is still an important limitation in many health services across Europe. So, indicators to monitor accesibility to spirometry would be very useful.

In most surveys there is not information on the accessibility to spirometry in the past. However, results from the Confronting COPD International survey have shown that only 45.5% of COPD patients had an spirometry in the past year and only 25% had a peak flow meter at home.[5]

AIMS: 1) To monitor health care resources available for the care of patients with COPD**. 2**) To monitor changes over time in these resources.

DATA SOURCES: There is not routinely collected data on these indicators although some studies have shown it is easy to collect in specific surveys.

DATA QUALITY: There is not data available on the quality of data for these indicators. However, the only problem in data collection may be the recall bias.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend to include appropriate questions to collect this information in future studies or routine surveys. Some studies have already shown that it is easy to collect this information. It is important to have this information by public and private care and for different models of health care in those countries that a complex organization of health services exist.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition.

POTENTIAL USE: To describe and monitor changes over time in the resources available for the care of COPD patients.

INTERNATIONAL CONSISTENCY: We have not been able to evaluate to what extent all relevant COPD studies have collected information on this indicators. It would be good to agree on standardized questions to collect this information in all surveys.

COMMENTS: In the ECHI-2 the indicators on health care resources included are very general and not related to disease specific. The indicators proposed should be included.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Only few participants have indicated that the information required for a small number of indicators is available from routine data. The real picture is that most of the indicators can be obtained from the ECRHS or the ISAAC but in the future have to be incorporated into new HES or specific international surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.2.3 Education 4.2.4 Technology	Indicator Score	Rank	Order	IMCA Group recommendation
? COPD education program	2.4	(1-4) 3	2	**2**
? Access to lung function measurements	**3.0**	(1-4) 3	**1**	**1**

INDICATOR	DEFINITION
4.3 Health care utilization.	
4.3.1 In-patient care utilization.	
• **Emergency room visits.**	• Proportion of individuals with COPD that have been admitted to an emergency unit during the last year (exacerbations).
• **Hospital admissions.**	• Proportion of individuals with COPD that have been admitted to hospital during the last year (exacerbations).
• **Intensive care units admissions.**	• Proportion of individuals with COPD that have been admitted to hospital in an ICU during the last year (exacerbations).
• **Length of stay.**	• Average length of stay of all hospital admissions for COPD (including all of any of the previous groups of individuals described).
• **Primary care visit.**	• Proportion of individuals with COPD that have had a follow-up visit in primary care during the last year.
• **Specialist visit.**	• Proportion of individuals with COPD that have had a follow-up visit in a specialist pneumology unit during the last year.
• **Rehabilitation session.**	• Proportion of individuals with COPD that have had a rehabilitation session during last year.

RATIONALE: Exacerbations on respiratory symptoms requiring medical intervention are important clinical events in COPD. The most common cause of exacerbations are infections of the tracheobronchial tree and air pollution. Depending on the severity of the exacerbation the patient may require a visit to an emergency unit, may need a hospital admission or even to be admitted to an intensive car unit. The first group of indicators is proposed to monitor the use of health services by COPD patients. This information can be collected using routine data or questionnaires.

In 1994, according to statistics from the UK Office of national statistics, there were 203,193 hospital admissions for COPD.[89] The average length of hospital stay among those admitted for a COPD diagnosis was 9.9 days. US data indicate that in 1997 there were 16.365 million (60.6/1000) ambulatory care visits for COPD AND 1.66/1000 hospitalizations for which COPD was the first liste discharge diagnosis.[90]

Data from the confronting COPD survey shows that patients more 45 year old and with COPD, 23% had a hospitalization in the past year and 14% a visit to an emergency room.[5] Information on specialist visits and rehabilitations sessions was not available in these report.

AIMS: 1) To describe and monitor health services utilization by patients with COPD. **2**) To monitor changes over time in these indicators.

DATA SOURCES: Information can be obtained from routine data collected in each country and also from specific surveys.

DATA QUALITY: The quality of possible data available is limited from routine data and surveys. The quality of these data have to be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: There are two different methods for data collection. In-patient care utilization could be collected form routine data statistics or by health surveys. Primary care or specialist visits and rehabilitations sessions would be better collected by surveys.

DATA OPRESENTATION: Data should be presented as it is described in the indicator definition.

POTENTIAL USE: To describe and monitor changes over time in the utilization of services available for the care of COPD patients.

INTERNATIONAL CONSISTENCY: To monitor these indicators there is information available from routine data and from surveys. However, the information on the validity of routine data is very limited. In surveys questions are not standardized. Certainly the information available could be useful to monitor use for health services but it's difficult to say how valid the information is when monitoring exacerbations. Indicators on follow-up visits to primary care or specialist probably would be better when collected from surveys.

COMMENTS: In the ECHI-2 the indicators on health care resources included are very general and not related to disease specific. The indicators proposed should be included.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Three indicators: hospital admission rates, average length of stay and intensive care admissions are available from routine data in most countries although in some countries methodological changes are required. For the other indicators, primary care visits, specialist visits and rehabilitation sessions the availability is less consistent across countries. The information on these indicators have to be collected from HES or specific surveys in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.3.1 In-patient care utilization 4.3.2 Out-patient care utilization	Indicator Score	Rank	Order	IMCA Group recommendation
? **Emergency room visits**	3.4	(2-4) 2	2	**1**
? **Hospital admissions**	**3.7**	(2-4) 2	**1**	**1**
? Intensive care units admissions	3.1	(1-4) 3	3	**1**
? Length of stay	2.6	(1-4) 3	6	**3**
? Primary care visit	**2.7**	(1-4) 3	5	**2**
? Specialist visit	2.7	(1-4) 3	5	**2**
? Rehabilitation session	3.0	(2-4) 2	4	**2**
Top 4 | Top 20				

INDICATOR	DEFINITION
4.3 Health care utilization.	
4.3.4 Medicine use/medical aids.	
• **Influenza vaccination.**	• Proportion of individuals with COPD (stage 0) that have had a influenza vaccine during the last year.
• **ß$_2$-agonists prescribed.**	• % of individuals with COPD (stage I) that have had bronchodilators prescribed and taken during the last year.
	• % of individuals with COPD (stage IIA) that have had bronchodilators and inhaled steroids prescribed and taken during the last year.
• **ß$_2$-agonists and steroids prescribed.**	• % of individuals with COPD (stage IIB) that have had bronchodilators, inhaled steroids prescribed taken and rehabilitation during the last year.
• **ß$_2$-agonists, steroids and rehabilitation prescribed**	• % of individuals with COPD (stage IIB) that have had bronchodilators, inhaled steroids prescribed and taken and rehabilitation during the last year.
• **ß$_2$-agonists, steroids, rehabilitation and oxigenotherpy prescribed.**	• % of individuals with COPD (stage III) that have had bronchodilators, inhaled steroids prescribed taken, rehabilitation and oxigenotherapy during the last year.
• **DDD on ß$_2$-agonists sales**	• DDD on ß$_2$-agonists sales.
• **DDD on steroids sales**	• DDD on steroids sales.

RATIONALE: The GOLD initiative have established the criteria for treatment according to the severity of patients. The indicators included are proposed to monitor the appropriate treatment of COPD patients according to severity. More recently the ATS/ERS consensus statement provided recommendations on pharmacological treatment but related to symptoms rather than severity.[87]

In addition to these indicators other drugs could be used in the treatment of COPD such as vaccines (already mentioned), antibiotics, mucolytic, antioxidant agents, immunoregulators, antitussives, respiratory stimulants, vasodilators or narcotics. In some countries, alternative medicine have to be considered as part of the treatment. In some stages of the disease development a combination of drugs may be prescribed. Since the disease usually is detected at very late stages, a substantial proportion of patients may be under-treated.

AIMS: 1) To describe and monitor the utilization of drugs prescribed by patients with COPD. **2**) To monitor changes over time in these indicators.

DATA SOURCES: Information can be obtained from specific surveys. Information on defined daily doses (DDD) can be obtained form public databases established in each EU country. However the level of coverage of these data sources varies across countries.

DATA QUALITY: he quality of possible data from surveys is relatively good. However, possibilities of recall bias may exist and although the drugs are prescribed may not be taken. The quality of routine data have to be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend to include the appropriate questions in future research or routine COPD studies on pharmacological treatment to detect the level of under-treatment and changes in prescription. Routine data on sales (DDD/1000 population) can also be useful at ecological level but are less informative.

DATA OPRESENTATION: The data collected from surveys can be presented in two different ways. One way can be to present the indicators as prevalence estimates of drugs prescribed. The other way is to present them as the proportion of individuals with COPD having any of the drugs prescribed. These indicators should also be presented by level of severity, gender and social class at each national and sub-national level. To detect the level of under-treatment the proportion of individuals with symptoms and airways obstruction without having appropriate drugs prescribed. Data from sales should be presented as DDD per 1000 population.

POTENTIAL USE: To describe and monitor changes over time in the utilization of drugs prescribed for COPD patients and assess possible intervention policies.

INTERNATIONAL CONSISTENCY: The information available on drugs taken by patients is very limited. It is believed that COPD may be under-diagnosed and probably under-treated. This information should be included in future surveys and a standardized method of data collection and data presentations should be agreed. The EURO-MED-STATS project coordinated by Pietro Folino have explored the use of public databases on drug sales but data on indicated drugs for COPD have not been properly explored yet.

COMMENTS: In the ECHI-2 the indicators there is a section on the use of drugs but not related to specific diseases and certainly not to indicate possible under-treatment or appropriateness. The ECHI-2 list should be expanded with the indicators proposed by the IMCA group.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Some participants have indicated that the information required for these indicators is available form routine data although methodological changes may be required. However, if we considerer the definition of the indicators that specifically says that these indicators have to be estimated for COPD patients, the information is only available form specific studies. In the future, the information have to be collected by HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.3.4 Medicine use / medical aids	Indicator Score	Rank	Order	IMCA Group recommendation
? Short acting with $ß_2$-agonists prescribed	**3.0**	(2-4) 2	**1**	**1**
? Long acting with $ß_2$-agonists prescribed	**3.0**	(2-4) 2	**1**	**1**
? Anticholinergic prescribed	2.8	(1-4) 3	3	**2**
? Methilxantines prescribed	2.3	(0-4) 4	4	**2**
? Glucocorticoidsl prescribed	2.9	(2-4) 2	2	**1**
? Other drugs	2.0	(0-3) 3	5	**2**
? Alternative medicines	1.5	(0-3) 3	6	**3**
? DDD on bronchodilators sales.	2.3	(0-4) 4	4	**3**
? DDD on glucocorticoids sales	2.3	(0-4) 4	4	**3**

INDICATOR	DEFINITION
4.4 Health expenditures/financing.	
4.4.1 Health care system. • **Hospitalization cost.** • **Out-patient cost.** • **Emergency room cost.** • **Specialist visits cost.**	• cost of COPD hospitalizations (including public and private care). • Mean cost of out-patient COPD care (including public and private care). • Mean cost of unexpected emergency room visits for COPD (including public and private). • Mean cost of follow-up visits to specialist for COPD (including public and private).

RATIONALE: The cost of illness studies provide an insight into the economic impact of a disease but this information is limited to a number of specific studies and in general this type of data is not collected in epidemiological COPD studies. In general, economic studies provide information on direct and indirect costs. The direct cost is the value of health care resources devoted to diagnosis and medical management of the disease. Indirect costs reflect the monetary consequences of disability, missed work and school, premature mortality, and caregiver or family costs resulting from illness. Indirect costs are more difficult to estimate and to compare between countries. In 1996 in United Kingdom the direct cost of COPD was approximately 846 million pounds equivalent to 1.154 pounds per person and per year according to data from the National Health Service Executive (NHSE).[93] The total direct costs varies across countries depending on the prevalence of the disease, risk factors, utilization of health care and other factors. After adjusting for several factors the direct costs of COPD were evaluated for different countries. In UK, in 1996 the direct costs were 778 million dollars, in Netherlands 256, in Sweden 179 and in USA 14,700. showing high variations across countries.[87] In a USA study of COPD – related illness costs based on the 1987 National Medical Expenditure Survey, per capita expenditures for inpatient hospitalizations of COPD patients were 2.7 times the expenditure for patients without COPD.[94,87]

AIMS: 1) To describe and monitor health care costs related to utilization of health services by patients with COPD. **2**) To monitor changes over time in these indicators.

DATA SOURCES: Information on utilization should be estimated from specific surveys and data on costs could be obtained from Health Departments of each country. Using both sources of information total direct costs of COPD can be estimated.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend to collect data on utilization by specific surveys and data on costs should be obtained from databases in the Health Department of each country. The information necessary to be able to link economic and utilization data should be further explored.

DATA QUALITY: The quality of possible data available is limited from routine data and surveys. The quality of these data have to be further explored.

DATA PRESENTATION: Data can be presented as it is described in the indicator description however it would be interesting to present it also stratified by severity, social class and this tables produced by national and sub-national levels.

POTENTIAL USE: To describe and monitor changes over time in costs of health care utilization. Information on direct costs would be also useful to incorporate into surveys and probably the most appropriate way of incorporating health care costs in relation to severity.

INTERNATIONAL CONSISTENCY: The organization and methods of financing health care is very different in each European country. However, if we considerer only direct costs, perhaps is feasible to collect this information. Information on direct costs would be also useful to incorporate into surveys and probably the most appropriate way of incorporating health care costs in relation to severity.

COMMENTS: In the ECHI-2 the indicators on health care costs of health services utilization are not included. The indicators proposed should be expanded for disease specific indicators in order to be able to assess the impact of different diseases.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Most participants have indicated that data for this group of indicators is available but methodological changes are required. Some participants indicated that the data required is not available and have to be developed and incorporated into routine data in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.4.1 Health care system	Indicator Score	Rank	Order	IMCA Group recommendation
? **Hospitalization cost**	**3.2**	(1-4) 3	**1**	**1**
? Out-patient cost	2.7	(1-4) 3	2	**2**
? Emergency room cost	2.7	(1-4) 3	2	**1**
? Specialist visits cost	2.6	(1-4) 3	3	**2**
Top 20				

INDICATOR	DEFINITION
4.4 Health expenditures/financing.	
4.4.3 Expenditure on medical services. • **Total cost of medicines prescribed for COPD treatment.**	• Total cost of medicines prescribed for COPD treatment. • Mean cost of medicines prescribed for COPD treatment. • Total cost paid by the patient (out of pocket) for medicines prescribed for COPD. • Mean cost paid by the patient (out of pocket) for medicines prescribed for COPD.
4.4.5 Total expenditure by age group and severity. • **Cost of COPD health care.**	• Total cost of asthma health care (including public and private health care utilization, medication and insurance costs).
4.4.6 Health expenditure by fund source. • **Additional insurance cost.**	• Proportion of individuals paying and additional private insurance to cover health care services. • Mean cost paid for additional private insurance.

RATIONALE: In the previous section it was mentioned that data on COPD economic impact is limited and comes from specific studies. However, it is very important to collect this information in order to know the impact of the disease on social and health care costs. This section include more economic indicators that include aspects of private and public health care costs. In Europe the effects of different methods of organization and financing of health care are poorly evaluated although there many differences across countries.

AIMS: 1) To describe and monitor direct costs related to drugs prescribed to patients with COPD. **2)** To describe and monitor total costs related to COPD care by age group and severity. **3)** To monitor changes over time in these indicators.

DATA SOURCES: Information can be obtained by a combination of specific surveys and some routine data provided by Health Department of each country.

DATA QUALITY: The quality of possible data available is limited from routine data and surveys. The quality of these data have to be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend that data is collected on utilization of drugs and insurance coverage by specific surveys while data on costs should be obtained from databases in the Health Department of each country. The information necessary to be able to link economic and utilization data should be further explored.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition.

POTENTIAL USE: To describe and monitor changes over time in total/mean direct costs of COPD care according to different factors and assess possible interventions.

INTERNATIONAL CONSISTENCY: The organization and methods of financing health care is very different in each European country. However, if we considerer only direct costs, perhaps is feasble to collect this information. Information on direct costs would be also useful to incorporate into surveys and this is probably the most appropriate way of incorporating health care costs in relation to severity. In this section could be useful to discuss to what extent is relevant in Europe to monitor and evaluate the effects of public and private health care.

COMMENTS: In the ECHI-2 the indicators on health care costs of specific drugs utilization for specific diseases, costs according to age and severity and additional insurance costs are not included. The indicators proposed should be expanded for disease specific indicators in order to be able to assess the impact of different diseases.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Information on costs can be available form most countries although important methodological changes may be required. However, several participants indicated that data on costs of private care and out of pocket payment may be difficult to obtain and special efforts have to be made in order to collect this information in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.4.3 Expenditure on medical services 4.4.5 Total expenditure 4.4.6 Total expenditure by fund source	**Indicator Score**	**Rank**	**Order**	**IMCA Group recommendation**
? Total cost pf medicines prescribed for COPD treatment	**3.1**	(1-4) 3	**1**	**1**
? Total cost of medicines paid by the patient (out of pocket) prescribed for COPD	2.3	(1-4) 3	3	**2**
? Cost of total COPD health care	3.0	(1-4) 3	2	**1**
? Total cost of COPD private care	2.2	(1-4) 3	4	**2**
? Individuals paying a private insurance	1.7	(0-3) 3	5	**3**

INDICATOR	DEFINITION
4.5 Health care quality/performance.	
4.5.3 Health outcomes.	• Quality of life to be defined. • Number of exacerbations in the last 12 month. • Unscheduled urgent care visits during last year. • Emergency visits last year. • Limitation of activities. • Limitation of sports. • Normal physical activity. • Choice job / career. • Work absence days.

RATIONALE: In this section on outcomes was included in the ECHI project in order to comply with the requirements of some projects that wanted to have a group of indicators on the effectiveness of health care. From the IMCA point of view we also supported this. In this section, several indicators that have been suggested to be used as outcome measures are described. The first indicator on quality of life is an important outcome measure but there are several ways and instruments for measuring it. A review on key outcome measures was published in 2002 and three approaches were suggested to measuring HRQL: generic, disease/condition specific, and utility. In order to be able to compare results between COPD patients and also with the general population, both a generic measure such as the SF-36 and a disease specific instrument such as St George Respiratory Questionnaire could be used. The number of exacerbations may be difficult to have a reliable measure by questionnaire but despite this difficulty questions should be introduced in surveys inn order to have information on exacerbations. Unscheduled and emergency care visits can be considered as failures of treatment or increasing severity and they have been considered outcomes in many studies. The limitation of activities such as sports, normal physical activity choice of job and work absence days can be collected by simple questions and reflect the outcome of different problems on the management of the disease.

AIMS: 1) To describe and monitor COPD outcomes based on indicators recommended by the scientific literature. **2)** To monitor changes over time in these indicators.

DATA SOURCES: Information can be obtained by a combination of specific surveys and some routine data provided by Health Department of each country.

DATA QUALITY: The quality of possible data available is limited from routine data and surveys. The quality of these data have to be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend that data on COPD outcomes indicators is collected by specific surveys.

DATA PRESENTATION: Data should be presented as the proportion of COPD patients having the characteristics described in each indicator. It would be very important to be able to stratify this data by severity, social class and to produce this information at national and sub-national level.

POTENTIAL USE: To describe and monitor changes over time in COPD outcomes and evaluate the effectiveness of health care.

INTERNATIONAL CONSISTENCY: In general the outcomes suggested here are collected in specialized surveys but not in general HIS/HES surveys. Perhaps in this section the issues to discuss would be for which groups of COPD patients this outcomes have to be estimated.

COMMENTS: In the ECHI-2 some indicators on outcomes of health care are included but they are very limited. The COPD outcome indicators should be include in the ECHI-2 list in order to monitor the effectiveness of health care for COPD patients.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: The information required to construct these indicators is only partially available form research studies like the ECRHS or The Confronting CCOPD survey. In future, the information have to be collected by HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.5.3 Health outcomes	Indicator Score	Rank	Order	IMCA Group recommendation
? Quality of life measured by SF-36	2.6	(1-4) 3	3	**2**
? Number of exacerbations in the last 12 months	**2.8**	(1-4) 3	**1**	**1**
? Unscheduled urgent care visits during last year	2.3	(1-4) 3	5	**1**
? Emergency visits last year	2.7	(1-4) 3	2	**1**
? Limitation of activities	2.5	(1-4) 3	4	**2**
? Limitation of sports	2.0	(0-4) 4	7	**3**
? Normal physical activity	2.5	(1-4) 3	4	**2**
? Choice of job / career	2.1	(1-4) 3	6	**3**
? Work absence days	2.6	(1-4) 3	3	**2**

1. Celli BR, Halbert RJ, Isonaka S, Schau B. Population impact of different definitions of airway obstruction. *Eur Respir J* 2003;22:268-73.

2. Viegi G, Pedreschi M, Pistelli F, Di Pede F, Baldacci S, Carrozzi L *et al*. Prevalence of airways obstruction in a general population: European Respiratory Society vs American Thoracic Society definition. *Chest* 2000;**117**:339S-45S.

3. de Marco R, Accordini S, Cerveri I, Corsico A, Sunyer J, Neukirch F *et al*. An international survey of chronic obstructive pulmonary disease in young adults according to GOLD stages. *Thorax* 2004;**59**:120-5.

4. Halbert RJ, Isonaka S, George D, Iqbal A. Interpreting COPD prevalence estimates: what is the true burden of disease? *Chest* 2003;**123**:1684-92.

5. Rennard S, Decramer M, Calverley PM, Pride NB, Soriano JB, Vermeire PA *et al*. Impact of COPD in North America and Europe in 2000: subjects' perspective of Confronting COPD International Survey. *Eur.Respir.J.* 2002;**20**:799-805.

6. Hardie JA, Buist AS, Vollmer WM, Ellingsen I, Bakke PS, Morkve O. Risk of over-diagnosis of COPD in asymptomatic elderly never-smokers. *Eur Respir J* 2002;**20**:1117-22.

7. EUROSTAT. Demographic Statistics 2000. Luxembourg. European Commission 2000. Available from http://www.europe.eu.int/newcronos.

8. Organization for the Economic Cooperation and Development (OECD). Health data 2000. Available form http://www.oecd.org.

9. World Health Organization(WHO). Regional Office for Europe. International mortality database. 2000. Available from http://www.who.dk.

10. Ochoa A. ISARE project. European Commission.

11. Kramers PGN. The ECHI project: health indicators for the European Community. Eur J Public Health 2003; 13:101-6.

12. Hendrick DJ. Occupation and chronic obstructive pulmonary disease. Thorax 1996; 51:947-55.

13. Ries AL, Kaplan RM, Myers R, Prewitt LM. Maintenance after pulmonary rehabilitation in chronic lung disease: a randomized trial. Am J Respir Crit Care Med 2003; 167:880-8.

14. Prescott E, Lange P, Vestbo J. Socioeconomic status, lung function and admission to hospital for COPD: results from the Copenhaguen City Heart Study. Eur Respir J 1999; 133:1109-14.

15. Higgins MW, Thorn T. Incidence, prevalence, and mortality: intra-and inter-country differences. In Hensley MJ and Saunders NA editors. Clinicla Epidemiology of Chronic Obstructive Pulmonary Disease. Marcel Dekker, New York. 23-43.

16. Kunst AE, Bos V, Mackenbach JP and the EU Working Group. Monitoring socioeconomic inequalities in health in the European Union: guidelines and illustrations. A report for the Health Monitoring Program of the European Commission. Available from: http://www.europe.

17. Aromaa A, Koponen P, Tafforeau J. Vermeire C and the HIS/HES Core Group. Evaluation of Health Interview Surveys and Health Examination Surveys in the European Union. Eur J Public Health. 2003;13(3 Suppl):67-72. (Database available from: https://www.iph.fgov.be/hishes/).

18. Menke R, Streich W, Rösler G. Report on socio-economic differences in health indicators in Europe. Health inequalities in Europe and the situation of disadvantaged groups. European Commission. Available from: http://www.europe.

19. World Health Organization. World Health Report: Making a difference. Geneve, World Health Organization, 1999.

20. Murray CJ,.Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. *Lancet* 1997;**349**:1498-504. Ref ID: 29.

21. Murray CJ,.Lopez AD. Evidence-based health policy--lessons from the Global Burden of Disease Study. *Science* 1996;**274**:740-3. Ref ID: 288.

22. Thom TJ. International comparisons in COPD mortality. Am Rev Respir Dis 1989; 140: S27-S34.

23. Siafakas, N.M. ; Vermeire, P. ; Pride, N.B. ; Paoletti, P. , Gibson, J. ; Howard P. et al. ERS consensus statement. Optimal assessment and management of chronic obstructive pulmonary disease (COPD). A consensus statement of the European Respiratory Society (ERS). Eur. Respir. J. 1995;8: 1398-1420.

24. Pride NB,.Soriano JB. Chronic obstructive pulmonary disease in the United Kingdom: trends in mortality, morbidity, and smoking. *Curr.Opin.Pulm.Med.* 2002;8:95-101.

25. European Respiratory Society. European Lung White Book. The first comprehensive survey on respiratory health in Europe. Chapter 03, 34-43. Chronic Obstructive pulmonary disease. Lausane, switserland 2003.

26. Lacasse Y, Brooks D, Goldstein RS. Trends in the epidemiology of COPD in Canada, 1980 to 1995. COPD and Rehabilitation Committee of the Canadian Thoracic Society. *Chest* 1999;**116**:306-13.

27. National Heart, lung and Blood Institute. Morbidity & mortality: chartbook on cardiovascular, lung, and blood diseases. Bethesda, MD: US department of health and Human services. Public health Service. National Institutes of health; 1998. available from: URL: www.nhlbi.nih.gov/nhlbi/seiin/other/cht-book/htm.

28. Mannino DM. COPD: epidemiology, prevalence, morbidity and mortality, and disease heterogeneity. *Chest* 2002;**121**:121S-6S.

29. Mannino DM, Brown C, Giovino GA. Obstructive lung disease deaths in the United States from 1979 through 1993. An analysis using multiple-cause mortality data. *Am.J.Respir.Crit Care Med.* 1997;**156**:814-8.

30. Camilli AE, Robbins DR, Lebowitz MD. Death certificate reporting of confirmed airways obstructive disease. *Am.J.Epidemiol.* 1991;**133**:795-800.

31. Hansell AL, Walk JA, Soriano JB. What do chronic obstructive pulmonary disease patients die from? A multiple cause coding analysis. *Eur.Respir.J.* 2003;**22**:809-14.

32. National Heart, Lung, and Blood Institute. World Health Organization. Global initiative for chronic obstructive lung disease. Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease. Updated 2003. (http://www.goldcopd.com).

33. Soriano JB, Maier WC, Egger P, Visick G, Thakrar B, Sykes J *et al*. Recent trends in physician diagnosed COPD in women and men in the UK. *Thorax* 2000;**55**:789-94.

34. American Thoracic Society. Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1995; 152: S77-S121.

35. Sterk PJ. Let's not forget: the GOLD criteria for COPD are based on post-bronchodilator FEV1. *Eur.Respir.J.* 2004;**23**:497-8. factors. Eur Respir Rev 2001; 11(80):55-64.

36. Siafakas, N.M. ; Vermeire, P. ; Pride, N.B. ; Paoletti, P. , Gibson, J. ; Howard P. et al. ERS consensus statement. Optimal assessment and management of chronic obstructive pulmonary disease (COPD). A consensus statement of the European Respiratory Society (ERS). Eur. Respir. J. 1995;8: 1398-1420.

37. Pride NB,.Soriano JB. Chronic obstructive pulmonary disease in the United Kingdom: trends in mortality, morbidity, and smoking. *Curr.Opin.Pulm.Med.* 2002;**8**:95-101.

38. European Respiratory Society. European Lung White Book. The first comprehensive survey on respiratory health in Europe. Chapter 03, 34-43. Chronic Obstructive pulmonary disease. Lausane, switserland 2003.

39. Lacasse Y, Brooks D, Goldstein RS. Trends in the epidemiology of COPD in Canada, 1980 to 1995. COPD and Rehabilitation Committee of the Canadian Thoracic Society. *Chest* 1999;**116**:306-13.

40. National Heart, lung and Blood Institute. Morbidity & mortality: chartbook on cardiovascular, lung, and blood diseases. Bethesda, MD: US department of health and Human services. Public health Service. National Institutes of health; 1998. available from: URL: www.nhlbi.nih.gov/nhlbi/seiin/other/cht-book/htm.

41. Mannino DM. COPD: epidemiology, prevalence, morbidity and mortality, and disease heterogeneity. *Chest* 2002;**121**:121S-6S.

42. Mannino DM, Brown C, Giovino GA. Obstructive lung disease deaths in the United States from 1979 through 1993. An analysis using multiple-cause mortality data. *Am.J.Respir.Crit Care Med.* 1997;156:814-8.

43. Camilli AE, Robbins DR, Lebowitz MD. Death certificate reporting of confirmed airways obstructive disease. *Am.J.Epidemiol.* 1991;**133**:795-800.

44. Hansell AL, Walk JA, Soriano JB. What do chronic obstructive pulmonary disease patients die from? A multiple cause coding analysis. *Eur.Respir.J.* 2003;**22**:809-14.

45. National Heart, Lung, and Blood Institute. World Health Organization. Global initiative for chronic obstructive lung disease. Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease. Updated 2003. (http://www.goldcopd.com).

46. Soriano JB, Maier WC, Egger P, Visick G, Thakrar B, Sykes J *et al*. Recent trends in physician diagnosed COPD in women and men in the UK. *Thorax* 2000;**55**:789-94.

47. American Thoracic Society. Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1995; 152: S77-S121.

48. Sterk PJ. Let's not forget: the GOLD criteria for COPD are based on post-bronchodilator FEV1. *Eur.Respir.J.* 2004;23:497-8.

49. Shaheen SO, Barker DJ, Holgate ST. Do lower respiratory tract infections in early childhood cause chronic obstructive pulmonary disease? *Am.J.Respir.Crit Care Med.* 1995;151:1649-51.

50. Shaheen SO, Barker DJ, Shiell AW, Crocker FJ, Wield GA, Holgate ST. The relationship between pneumonia in early childhood and impaired lung function in late adult life. *Am.J.Respir.Crit Care Med.* 1994;**149**:616-9.

51. Burrows B, Bloom JW, Traver A, Cline MG. The course and prognosis of different forms of chronic airway obstruction in a sample from the general population. N Engl J Med 1987; 317:1309-14.

52. Kauffman F, Neukirch F, Korobaeff M, Marne MJ, Claude JR, Lellouch J. Eosinopphils, smoking, and lung function. An epidemiologic survey among 912 working men. Am Rev Respir Dis 1986; 134 :1172-5.

53. Burrows B, Knudson Rj, Cline MG, Lebowitz MD. A reexamination of risk factors for ventilatory impairment. Am Rev Respir Dis 1988 ; 138:829-36.

54. Auerbach O, Hammond Ec, Garfinkel L, Benante C. Relation of smoking and age to emphysema. Whole lung section study. N Engl J Med 1972; 286:853-7.

55. Peat JK, Woolcock AJ, Cullen K. Rate of decline of lung function in subjects with asthma. Eur J Respir Dis 1987 ; 70 :171-9.

56. Lange P, Parner J, Vestbo J, Schnohr P, Jensen G. A 15-year follow-up study of ventilatory function in adults with asthma. N Engl J Med 1998; 339:1194-200.

57. Tashin DP, Altose MD, Connett JE, Kanner RE, Lee WW, Wisw RA. Methacoline reactivity predicts changes in lung function over time in smokers with early chronic obstructive pulmonary disease. The Lung Health Study Research Group. Am J Respir Crit Care Med 1996; 153 :1802-11.

58. Tashkni PD, Detels R, Simmons M. The UCLA population studies of chronic obstructive respiratory disease : XI. Impact of air pollution and smoking on annual change in forced expiratory volume in one second. Am j Respir Crit Care Med 1994 ; 149 :1209-1217.

59. United States Department of Health and Human Services, Public health Service. The health benefits of snoking cessation. A report fo the Surgeon General. US Government Printing Office, Washington DC, 1990.

60. Anthonisen NR, Connet JE, Kiley JP, Altose MD, Bailey WC, Buist AS. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV1. The Lung Health Study. JAMA 1994; 272:1497-505.

61. Romieu I,.Trenga C. Diet and obstructive lung diseases. *Epidemiol.Rev.* 2001;**23**:268-87.

62. National Research Council. Recommended dietary allowances. 10th ed. Washington, DC: National Academy Press, 1989.

63. Schwartz J,.Weiss ST. Relationship between dietary vitamin C intake and pulmonary function in the First National Health and Nutrition Examination Survey (NHANES I). *Am.J.Clin.Nutr.* 1994;**59**:110-4.

64. Britton JR, Pavord ID, Richards KA, Knox AJ, Wisniewski AF, Lewis SA *et al*. Dietary antioxidant vitamin intake and lung function in the general population. *Am.J.Respir.Crit Care Med.* 1995;**151**:1383-7.

65. Sherrill DL, Lebowitz MD, Burrows B. Epidemiology of chronic obstructive pulmonary disease. *Clin.Chest Med.* 1990;**11**:375-87.

66. Tabak C, Smit HA, Heederik D, Ocke MC, Kromhout D. Diet and chronic obstructive pulmonary disease: independent beneficial effects of fruits, whole grains, and alcohol (the MORGEN study). *Clin.Exp.Allergy* 2001;**31**:747-55.

67. Walda IC, Tabak C, Smit HA, Rasanen L, Fidanza F, Menotti A *et al*. Diet and 20-year chronic obstructive pulmonary disease mortality in middle-aged men from three European countries. *Eur.J.Clin.Nutr.* 2002;**56**:638-43.

68. Gray-Donald K, Gibbons L, Shapiro SH, Macklem PT, Martin JG. Nutritional status and mortality in chronic obstructive pulmonary disease. Am J Repir Crit Care Med 1996; 153:961-6.

69. Behnke M, Taube C, Kirsten D, Lehnigk B, Jorres RA, Magnussen H. Home-based exercise is capable of preserving hospital-based improvements in severe chronic obstructive pulmonary disease. Respir Med 2000; 94:1184-91.

70. Finnerty JP, Keeping I, Bullough I, Jones J. The effectiveness of outpatient pulmonary rehabilitation in chronic lung disease: a randomized controlled trial. Chest 2001; 119:1705-10.

71. Anto JM, Vermeire P, Vestbo J, Sunyer J. Epidemiology of chronic obstructive pulmonary disease. Eur Respir J 2001; 17:982-984.

72. Holland WW, Reid DD. The urban factor in chronic bronchitis. Lancet 1965; I:445-46.

73. Van der Lende R, Kok TJ, Peset Reig R, Quanjer PhT, Schouten JO, Orie NGM. Decreases in FVC and FEV1 with time: indicators fro effects of smoking and air pollution. Bull Eur Physiopathol Respir 1981; 17:775-792.

74. Detels R, Tashkin DP, Sayre JW, et al. The UCLA population studies of CORD: X. A cohort study of changes in respiratory function associated with chronic exposure to Sox, Nox, and hydrocarbons. Am J Public Health 1991; 81:350-359.

75. Ackermann-Liebrich U, Leuenberger P, Schwartz J, et al. SAPALDIA TEAM. Lung function and long term exposure to air pollutants in Switzerland. Am J respir crit Care Med 1997; 155:122-129.

76. Schindler C, Ackermann-Liebrich U, Leuenberger P, et al. SAPALDIA team. Associations between lung function and estimated average exposure to NO2 in eight areas of Switzerland. Epidemiology 1998; 9:405-411.

77. Euler G, Abbey DE, Magie AR, Hodgkin J. chronic obstructive pulmonary disease symptom effects of long-term cumulative exposure to ambient levels of total suspended particulates and sulfur dioxide in California Seventh-day Adventist residents. Arch Environ Health 1987; 42:213-222.

78. Zemp E, Elasser S, Schindler C, et al. SAPALDIA team. Long-term ambient air pollution and respiratory symptoms in adults (SAPLADIA study). Am J Respir Crit care Med 1999; 159: 1257-1266.

79. Development of Environmental and health indicators for EU countries (ECOHIS). Air quality and health indicators. (Proposal for revision, March 2004) World Health Organization project.

80. Hazenkamp-von Arx ME, Gotschi FT, Oglesby L, Ackermann-Liebrich U, Gislason T, Heinrich J *et al*. PM2.5 assessment in 21 European study centers of ECRHS II: Method and first winter results. *J.Air Waste Manag.Assoc.* 2003;53:617-28.

81. Hendrick DJ. Occupation and chronic obstructive pulmonary disease. Thorax 1996; 51:947-55.

82. Niewoehner DE. Anatomic and Pathophysiological correlations in COPD. In: Baum GL, Crapo JD, Celli BR, Karlinsky JB eds. Textbook of pulmonary diseases. Philadelphia: Lippincott.Raven; 1998. p. 823-42.

83. Sunyer J, Kogevinas M, Kromhout H, Anto JM, Roca J, Tobias A *et al*. Pulmonary ventilatory defects and occupational exposures in a population-based study in Spain. Spanish Group of the European Community Respiratory Health Survey. *Am.J.Respir.Crit Care Med.* 1998;**157**:512-7.

84. Anthonisen NR, Connet JE, Kiley JP, Altose MD, Bailey WC, Buist AS. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV1. The Lung Health Study. JAMA 1994; 272:1497-505.

85. Nichol KL, Margolis KL, Wuorenma J, Von Stembergs T. The efficacy and cost effectiveness of vaccination against influenza among elderly persond living in the community. N engl J Med 1994; 331:778-84.

86. Edwards KM, Dupont WD, Westrich MK, Plummer WD, Palmer PS, Wright PF. A randomized controlled trial of cold-adapted and inactivated vaccines fro the prevention of influenza A disease. J Infect Dis 1994; 169:68-76.

87. Celli BR, MacNee W and committee members. ATS/ERS Task Force. Standards for the diagnosis and treatment of patients with COPD : A summary of the ATS/ERS position paper. Eur Respir J 2004 ; 23 :932-946.

88. Pulmonary rehabilitation : official statement of the American Thoracic Society. Am J respir Crit Care Med 1999 ; 159 :1666-1682

89. Ashikaga T, Vacek PM, Lewis SO. Evaluation of a community-based education program for individuals with chronic obstructive pulmonary disease. J Rehabil 1980; 46:23-7.

90. Schemer T, Eaton T, Pauwels R, van Weel C. Spirometry in primary care: is it good to face demands like World COPD Day?.

91. Office of National Statistics. Mortality statistics (revised) 1994. Engalnd and Wales. London. Her Majesty's Stationary Office; 1996.

92. National Center for health statistics. National hospital interview survey. Vital and health statistics, series 10.

93. National Health Service Executive. Burdens of disease: a discussion document. London: Department of Health; 1996.

94. Sullivan SD, Strassels S, Smith DH. Characterization of the incidence and cost of COPD in the US. Eur Respir J 1996; 9:S421.

ANNOTATED LIST OF INDICATORS

Indicators for monitoring asthma in the EU

ECHI-2/IMCA framework

Class 1

Demography and socioeconomic situation

INDICATOR	DEFINITION
1.1.1 Population status.	
• **Population composition by age.**	• **Age groups:** 0-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, >89.
• **Population composition by gender.**	• **Gender:** Male, female.
• **Population composition by geographical area.**	• **Geographical area:** National and sub-national level.

RATIONALE: The population structure stratified by age and sex is essential to be able to estimate age and sex specific death rates, prevalence, hospital admissions or any other possible indicators to be estimated for specific community populations.

Asthma may develop during the first year of life, persist during childhood and in some cases disappear (up to two thirds) in adulthood. Asthma can also begin in adult life.[1] Taking into account the natural history of asthma it would be desirable to have information on the prevalence of asthma across a wide range of age groups. There is a large number of epidemiological studies on the prevalence of asthma but difficult to compare because they have not used standardized methods and also because most studies have focused in specific age groups and in general not covering a wide range of ages. Three major international studies (using standardized methodologies) have provided comparable data across countries. The ISAAC have provided data on children aged 6-7 and 12-13 in Phase I[2] and 9-11 in Phase II,[3] the ECRHS on young adults 20-44 years.[4,5,6] These studies, although provide prevalence estimates for specific small geographical areas, do not proved estimates being representative at national or regional level. More recently the AIRE study[7] that have provided information for a wider age range group, representative at national level but not at sub-regional. It is important that future surveys (routine or research) cover a wider age range since the prevalence of asthma varies with age. Hospital admissions for asthma are higher in children aged 0 to 4 and 5 to 14 in contrast with older groups and is decreasing with age.[8] In contrast to hospital admissions, asthma mortality increases progressively with age.[9]

Taking into account the natural history of the disease, it seems important to stratify the population in small age groups (5 years each) in order to correctly describe the epidemiology of asthma. This data should also be available by sex at national and sub-national geographical levels within countries.

AIMS: To describe the population structure taking into account age groups and gender and to monitor changes over time. This information should be available at different geographical levels: national, sub-national or local if it is possible. These data should be used for the estimation of population based indicators described and proposed in the following sections.

DATA SOURCES: In each European country there is a national center for health statistics or a specific agency responsible for national statistics. This centers or agencies provide national population estimates to EUROSTAT[10] database. In this database, most indicators provides the population structure by five years age groups we suggested and most indicators can be estimated for each of these groups. However, in contrast to EUROSTAT, OECD[11] or WHO[12] provide many indicators only for a wide range of age groups (0 to 65 or >65) which are clearly inadequate for COPD. Only EUROSTAT database provide population estimates by sub-national geographical area level. This estimates are based on the EUROSTAT NUTS classification.

DATA QUALITY: The population estimates are usually provided by national centers or statistical agencies and are based on national censuses and other national vital registries. The accuracy of population estimates depends on the quality of reporting in national censuses, the level of control of immigrants or emigrants and the quality of mortality and birth registries. In many cases there is not an agreement between the estimates provided by different international databases.

METHODS TO BE USED FOR NEW DATA COLLECTION: Population data by age, gender and geographical level is already available at international level from EUROSTAT database. However, it has to be considered if the NUTS geographical aggregation is still useful or the ISARE project[13] classification has to be used in the future.

DATA PRESENTATION: The population structure should be presented in a table using the age groups defined at the top of this section and stratified by gender. This table should be available

at different geographical levels: national, sub-national or local if data is available and is of interest for policy decision makers. For some specific analysis, it may be useful to present epidemiological estimates by groups such as: young, adult and elderly.

POTENTIAL USE: To monitor changes in the structure of the population which may have an impact on health of the population. This information could be useful for health care planning and needs assessment evaluations.

CONSISTENCY AT INTERNATIONAL LEVEL: At present, either in research studies or routine information systems there is not a consistent level of age stratification to present epidemiological estimates for asthma. As already mentioned, the age group in childhood asthma epidemiological studies is focused in a very narrow age groups and there is very limited data for adolescents. For young adults data is mostly limited at ages 20 to 44 and a very limited number of studies have provided data for older groups. Elderly is an important group to be considered but due to the difficulties in differentiating asthma and COPD most studies do not include individuals from this age group.. With regard to population's estimates at sub-national level the ISARE project[13] recommended to substitute the EUROSTAT NUTS classification by another health policy and management related geographical areas.

COMMENTS: In the "1.1.1 Population status" section of the ECHI-2,[14] the demographic data only four indicators are described and proposed to be collected. Specifically, with regard to population composition by age (without stratification by gender) only three indicators are defined: median age of the population, proportion of population under 15 and proportion of population aged 65 or over. The IMCA specifications should be taken into account when a final ECHI list is agreed. With regard to the population, the IMCA group suggested that for some specific type of analysis could be useful to present epidemiological estimates by groups such as: young, adults and elderly.

According to the ECHI matrix prepared by Pieter Kramers several projects have suggested specific requirements on the population structure. These projects are: Phnut, ISARE, EUROSTAT EUROCHIP and ECHI-2. An agreement should be reached to find a solution for all possible project needs.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Data on the population structure by age, gender and structure is available in all countries included in the study. All countries can provide this data in different age groups according to the user needs.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 1.1.1 Population status	Indicator Score	Rank	Order	IMCA Group recommendation
? Population composition by age.	**3.5**	(2-4) 2	**1**	**1**
? Population composition by gender.	**3.5**	(2-4) 2	**1**	**2**
? Population composition by geographical area.	2.9	(1-4) 3	2	**3**

INDICATOR	DEFINITION
1.2 Socio-economic factors.	
• **Level of education.**	• Proportion of population by level of education in 4 classes: elementary, lower secondary, upper secondary, tertiary (ISCED, 1997).
• **Social class.**	• Proportion of population by social class in 6 ISCO groups: upper non-manual, lower non-manual, skilled manual, unskilled manual, self-employed, farmer. (Based on occupation).
• **Ethnicity.**	• Proportion of population in each ethnic group (to de agreed among DG-SANCO projects.
• **GDP.**	• The GDP at national level. (As defined in the OECD).
• **Poverty.**	• Proportion of population within income below 60 % of the national median.

RATIONALE: Socioeconomic factors are considered determinants of population health status. The association between asthma (either childhood or adult) in the population and socioeconomic status, although assessed in many studies have provided contradictory information for childhood asthma.[15] Studies have shown that the prevalence of asthma is not consistently related to socioeconomic status, but a few studies have shown that severe asthma may be more frequent in the poorer groups of society.[15,16,17] In adults this relationship is also not well understood. Hospital admission rates are higher for those who are materially deprived[18,19] and increased asthma severity in low social class groups.[20] However, the association between socioeconomic factors and asthma prevalence is less clear. Studies using socioeconomic measured based on occupation, income, or education have found a negative association, but in others was positive. More recently, a study which have used data from 32 centers in 15 European countries, have found that community influences of living in a low-educational area are associated with asthma independently of subjects' own educational level and social class.[21] This indicates that ecological indicators of socioeconomic status may be as important as individual indicators. Other studies (in children) have found that individual indicators of socioeconomic status correlated better with asthma indicators than area-based indicators. However, living in an underprivileged area was a strong independent risk factor for asthma hospital admission.[22]

Despite the information provided by some specific studies there is not a consistent measure of socioeconomic status comparable and to be applied to all EU countries. However, the socioeconomic indicators useful to monitor inequalities in health in the European Union have been reviewed recently by Kunst et al.[23] and the group have provided some recommendations. Socioeconomic indicators can be classified into five main groups according to the characteristics they are based on: education, occupation, income, wealth and composite indicators. Some indicators may be preferred over other for theoretical reasons. However, there is no consensus on these issues, and the measures are complementary rather than exclusive. The theoretical preferences depend on many factors. Some data sources or research studies have collected information in one or more indicators. Most of these indicators are collected at individual level but they can also be used at ecological level. Ethnicity is another factor that should be taken into account in order to assess social inequalities. There are variations in the prevalence of symptoms between ethnic groups and clear differences in the management of asthma.[24] There are more studies on asthma ethnic differences in USA than Europe. Most of them show higher prevalence and hospital admission rates. However, one study conclude that black children are at increased risk of hospitalization for asthma, but that some or all of this increase could be related to poverty rather than to race.[25] Using the ISAAC data, a study have explored the association between GNP per capita and has found an association between wheeze in the last 12 months and GNP per capita in the 13-14 years old group, but not in the 6-7 year age group.[26] However, the associations were of moderate strengths suggesting that environmental factors are not just related to wealth of the country.

AIMS: 1) To describe the distribution of the population at community level according to the socioeconomic indicators proposed (level of education, social class and ethnicity) and to monitor changes over time. **2)** To compare countries according to the GDP and the level of poverty (if it is possible at sub-national level. **3)** to describe the distribution of asthma patients according to the socioeconomic indicators proposed and to monitor changes over time. This information

should be available at different geographical levels: national, sub-national or local if it is possible. These data should useful in monitoring policy interventions to reduce inequalities in health.

DATA SOURCES: In general most general health interview or examination surveys include questions on socioeconomic status. However, there are important differences in the questions used in surveys carried out either in the same or different country. For specific question comparisons between health surveys the HIS/HES database can be used.[27] Information on socioeconomic status can be obtained also from routine data bases such as mortality or specific registries. However, the number of countries including socioeconomic information in this databases is much more limited. Many research studies also collect this information but in many occasions the information produced is not representative of the general population. The indicator which describes the proportion of population living in poverty is collected by EUROSTAT.[10,28]

DATA QUALITY: Three major problems have been identified in socioeconomic indicators: a) high non response rates in some countries (these problems are greater when income indicators are used, b) some populations may be excluded (institutionalized populations), c) problems with comparability (both over time and across countries) of some health indicators specially in those based on occupation.[23] Data on ethnicity has to be developed in order to have a homogeneous classification.

METHODS TO BE USED FOR NEW DATA COLLECTION: Specific questions should be incorporated in HIS/HES surveys or research studies in order to collect information on the level of education and social class according to the IMCA recommendations. The GDP is usually provided by the OECD and no further development is required. The level of poverty, is provided by the EUROSTAT database, but it has to be explored if it is possible to have this indicator at sub-national level or for specific geographical areas. This information is well developed in countries like UK but nearly impossible in most EU countries.

DATA PRESENTATION: For each of the three indicators, a table showing the distribution of the population according to the categories established should be presented. In addition cross tabulations with the age groups proposed and stratified by gender should be presented or available. These tables should be available at different geographical levels: national, sub-national or local if data is available and is of interest for policy decision makers.

POTENTIAL USE: To monitor changes in the structure of the population according to socioeconomic status indicators. To monitor changes in the distribution of asthma patients according to socioeconomic status indicators. This information could be useful for health care planning and needs assessment evaluations for asthma patients and also to monitor policy interventions to reduce health and health care inequalities among asthma patients.

CONSISTENCY AT INTERNATIONAL LEVEL: Although the association between socioeconomic status and asthma seems not to be consistent in most prevalence studies, more consistent associations exist in relation to health care management indicators. The major problem for the future is to identify a reliable and useful measure to compare socioeconomic status across different EU countries.

COMMENTS: The ECHI project, the section "1.2 Socioeconomic factors" have been structured in six parts: "1.2.1 Population by household situation"; "1.2.2 Population by ethnicity"; "1.2.3 Education"; "1.2.4 Employment"; "1.2.5 Income distribution"; and "1.2.6 General economics". From these sections, the IMCA group selected only four indicators which have been used in epidemiological research studies and are clear determinants of health.

The ones selected, are the most consistently used although potential bias have to be considered when cross country comparisons are made. The level of education and social class indicators should be used in three different ways: 1) to describe the distribution of the population according to socioeconomic status by the age groups suggested, gender and national and sub-national geographical levels; 2) to adjust prevalence estimates and 3) to describe the proportion of individuals with asthma according to socioeconomic status. In this group, ethnicity should also be included with a consistent classification of ethnic origin for all the EU countries (to be developed). This information should also be available by the age groups suggested, gender and national and sub-national geographical levels. The level of poverty may be useful as an ecological indicator but difficult to incorporate in cross-sectional studies of asthma. We believe it is more important to have socioeconomic indicators at individual level, however in some ecological analysis, GDP and the level of poverty could be very useful. According to the ECHI matrix prepared by Pieter Kramers several projects have suggested specific requirements on socioeconomic indicators. The level of education and social class based on occupation are proposed by the SES and PHNUT projects. Ethnicity and GDP are proposed only by the ECHI-2 project only despite its interest for many conditions. Poverty is only recommended by the PHNUT project. Due to the limitations of each indicator individually, in many occasions several indicators of socioeconomic status are used. It would be good to have all five indicators proposed by the IMCA group, although some of them require further development.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Data for most socioeconomic indicators is available in all countries included in the study with the exception of ethnicity. However, it is not clear to what extend the comparability of these indicators within and between countries is good enough at present. In some countries methodological modifications are required to improve comparability.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 1.2 Socio-economic factors	Indicator Score	Rank	Order	IMCA Group recommendation
? Level of education	**2.8**	(1-4) 3	**1**	**1**
? Social class	2.7	(2-4) 2	2	**1**
? Ethnicity	2.4	(1-4) 3	3	**2**
? GDP	1.7	(0-3) 3	4	**3**
? Poverty	2.4	(1-4) 3	3	**2**

Class 2

Health Status

INDICATOR	DEFINITION
2.2 Mortality cause specific.	
• **2.2.8 Respiratory system.**	
• **Total number of death.**	• Death defined by ICD-9: 493; or ICD-10: J45 and J46.
• **Crude death rates.**	• Total number of asthma death by 100.000 population.
• **Standardized death rates (SDR).**	• Standardization method and standard population should be the same as WHO/EUROSTAT databases).
• **Age-specific death rate.**	• Total number of asthma death by 100.000 population by the age groups specified.
• **Age-specific death rate having asthma as a contributing cause of death.**	• Total number of death by 100.000 population having asthma as underlying cause of death or with a contributing cause of death by the age groups specified.
• **Potential years of life lost (PYLL).**	• Number of death in each age group multiplied by the number of remaining years to live until selected age limit. The same methods used in WHO / EUROSTAT databases should be used).

RATIONALE: Asthma mortality is low and there is a tendency to decrease in most European countries.[29] In Denmark an upward trend was described from 1973-1987 but this was due an increase in mortality one specific age group.[30] In Norway, a continuously low mortality rate was found in children over five years of age from 1960 onwards.[31] In Netherlands, asthma mortality declined among 5-14 years old during 1984-1994 and remained stable among other age groups.[32] One analysis of mortality in several countries showed that mortality rates ranged from 0.12 per 100.000 population in Sweden to 0.86 in Australia in the age group 5 to 34 in 1993.[33] The low mortality rates probably reflects improvements in the management of asthma.

Although mortality is low, most asthma deaths result from acute exacerbations and are generally thought to be avoidable. Increases in asthma deaths, especially those persisting over a long period, thus raise concerns about the potential effects of changes in the medical management of asthma in addition to concerns about changes in asthma's underlying prevalence or severity. Death from asthma may thus be viewed as a sentinel health event.[34] Asthma is also an important cause of potential years of life lost. In the US, during 1980 to 1986, an average of 17,366 deaths and 286,813 years of potential life (YPLL) before age 65 were lost each year due to all 12 sentinel causes combined. Of these causes, hypertensive heart disease, pneumonia and bronchitis, cervical cancer and asthma accounted for the greatest number of deaths.[35]

AIMS: To describe asthma mortality using the indicators proposed and to monitor changes over time. To assess changes in the total number of death, crude and age-specific death rates by the age groups suggested and gender. Changes should be monitored at different geographical levels: national, sub-national or local if it is possible.

DATA SOURCES: At present, the World Health Organization (WHO) international database[12] presents mortality data based on two lists of diseases categories (A and B) to limit the number of individual codes to be published. Under the list A, standardized rates for bronchitis, emphysema and asthma (ICD-10, J40 – J46) by 100,000 population and for ages 0-64 and all ages are estimated.

Although mortality data is low, it is not possible to distinguish between asthma and COPD. The same estimates are published in the OECD database[11] in addition to another category for COPD which include ICD-9 code 490-496**.** From EUROSTAT database[10] you can obtain estimates for asthma alone. For respiratory diseases you can select two codes: (40) Chronic lower respiratory disease (ICD-10, J40-J47; ICD-9, 490-494, 496) and (41) Asthma (ICD-10, J45-J46; ICD-9, 493). In this database you can obtain these estimates by five years age groups and also by geographical level according to NUTS classification. This classifications recently have been challenged by the ISARE project.[10] In all these databases DALYs or PYLL specific for asthma are not available.

DATA QUALITY: The most readable available epidemiological data for asthma at international level is mortality data. However, several problems should be taken into consideration when analyzing mortality data and specially trends over time. In addition to the limitations of the validity of medical death certificates, the analysis of mortality data is further complicated by the lack of using the same standardized codes in all analysis (either in research or routine databases). ICD classifications and codes have changed over time and this may create important problems when trends over time or geographical variations are analyzed since changes are not introduced at the same time in all countries. Misclassification of asthma at the time of death has led to inaccuracies in mortality figures for asthma in the elderly.[36] In spite of the general unreliability of asthma mortality data, it is thought that for patients under 35 years of age the accuracy of diagnosis on death certificates is over 85%.[37,38]

DATA PRESENTATION: The total number of death and crude death rates should be presented as a total and also by age group. Tables by age group should also be stratified by gender. Age-specific and also when using asthma as a contributing cause of death, should also be presented by gender. These tables should be available at different geographical levels: national, sub-national or local if data is available. Person years of life lost should also be presented by gender.

POTENTIAL USE: To monitor changes in asthma mortality across age, gender and geographical areas. These data should useful for monitoring policy interventions aiming to reduce asthma mortality. Unfortunately, occupation is not available in all countries to make comparisons according to socioeconomic status.

CONSISTENCY AT INTERNATIONAL LEVEL: For all European countries mortality data is available and international databases (OECD, WHO and EUROSTAT) provide information at international level. However, there is not a consistent presentation of asthma mortality indicators for all these databases. Although asthma mortality can be differentiated in the EUROSTAT database, this is not possible in the WHO or OECD databases. Changes should be recommended on the indicators provided, the codes used to clearly distinguish asthma and COPD. The age group for mortality data presentation should be discussed in relation to validity data.

COMMENTS: Most indicators suggested by the IMCA project on COPD mortality are already included in the ECHI-2 list. However, age-specific death rates and the age-specific death rate having COPD as a contributing cause of death are not included. The ICD-10 codes used at present by EUROSTAT in the 65 European shortlist of causes of mortality should be corrected in order to clearly separate asthma and COPD as it is indicated in the indicator definition.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Mortality data is available from routine data sources in all EU countries. However, most participants have indicated that methodological changes will be required in order to improve the comparability of these indicators between countries and to improve the way in which these indicators are published according to IMCA group recommendations. Although the indicator: "Age-specific death rate having asthma as contributing cause of death" is strongly recommended by the group, in several countries may not be available until multiple-cause of death are recorded.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 2.2.8 Respiratory system	Indicator Score	Rank	Order	IMCA Group recommendation
? **Total number of death**	3.2	(1-4) 3	3	**3**
? **Crude death rates**	3.2	(2-4) 2	3	**3**
? **Standardized death rates (SDR)**	3.3	(2-4) 2	2	**2**
? **Age-specific death rate**	**3.4**	(2-4) 2	**1**	**1**
? Age-specific death rate having asthma as contributing cause of death	3.1	(1-4) 3	4	**1**
? Potential years of life lost	2.8	(1-4) 3	5	**3**
Top 20				

INDICATOR	DEFINITION
2.3.8 Respiratory system	
? **Prevalence of asthma symptoms.**	• Proportion of individuals having had wheeze at any time during the last 12 month. • Proportion of individuals woken up by and attack of shortness of breath at any time in the last 12 months. • Proportion of individuals woken up by and attack of coughing at any time in the last 12 months. • Proportion of individuals having had any nasal allergies including hay fever.
? **Prevalence of asthma attacks.**	• Proportion of individuals having had an asthma attack at any time in the last 12 months.
? **Prevalence of asthma diagnosis.**	• Proportion of individuals with ever diagnosed of asthma by a doctor.
• **Prevalence of bronchial hyperresponsiveness (BHR).**	• Proportion of individuals with a positive bronchial hyperresponsiveness test.
? **Prevalence of treatment for asthma.**	• Proportion of individuals taking any medicine for asthma at any time in the last 12 months.

RATIONALE: Before the 1990s a large number of epidemiological studies on the prevalence of asthma were carried out. However, no standardized methods were used and its comparability was very difficult. In early 1990s two large studies were set up and standardized the methods for data collection on asthma. The European Community Respiratory Health Survey[4,5] was the first study to assess geographical variations in the prevalence of asthma and allergy in young adults using the same instruments and definitions. The study was set up in 1993 and was carried out in two stages and included individuals from 20 to 44 years of age. In stage I, subjects were sent the ECRHS screening questionnaire asking about symptoms suggestive of asthma, the use of medication for asthma and the presence of hay fever and nasal allergies. In stage II, a smaller random sample of subjects who had completed the screening questionnaire were invited to attend for a more detailed interview-led questionnaire, skin prick test (SPT), blood tests for the measurement of total and specific immunoglobulin-E (IgE), spirometry and methacoline challenge. This study found that prevalence of all asthma symptoms varied widely. Although variations were lower in northern, central and southern Europe and higher in British Isles, New Zealand, Australia and the United States, there were wide variations even within some countries. The prevalence of wheeze ranged from 13% in Erfurt (Germany) to 30% in Caerphilly (United Kingdom). The prevalence of diagnosed asthma ranged from 2% in Tartu (Estonia) to 8.4% in Cambridge (United Kingdom).[40]

From 1999-2001, study participants were re-contacted to determine symptoms status and exposure to a variety of factors, including tobacco smoke, animals occupational agents and air pollutants.[6]

Another large international study initiated to gain new insights into the etiology of asthma and allergic disorders in children through standardized comparisons of diverse child populations worldwide was the International Study of Asthma and Allergies in Childhood (ISAAC).[2] In this study participated 463.801 children aged 13-14 years in 155 collaborating centers in 56 countries. In the Phase I of ISAAC the prevalence of symptoms of asthma, allergic rhino-conjunctivitis and atopic eczema in 6-7 and 13-15 years old were assessed and >20 fold differences in prevalences between centers were found.[39] The information was collected by a self administered questionnaire. Phase II of ISAAC (in a large number of countries) assessed the prevalence of objective markers of atopic diseases and investigates atopic determinants.[3] In this phase children from 9 to 11 were included. In this study bronchial responsiveness was assessed using inhaled hyperosmolar (4.5%) saline.

In contrast with these two studies, more recently, the AIRE study has been carried out using different methodologies for data collection (telephone interviews) and being nationally representative and including patients with current asthma and from all age groups.[7] In this study no objective measurements were carried out.

AIMS: 1) To describe the prevalence of asthma related symptoms, asthma attacks, physician diagnosed asthma by age group, gender, socioeconomic status and geographical area. **2)** To monitor changes over time on the indicators proposed.

DATA SOURCES: Information on the prevalence of asthma can be obtained from several sources of data: 1) general health interview or examination surveys. However, important limitations of the questions used have to be carefully checked (in general it is difficult to distinguish asthma and COPD and 2) the research studies previously, the ECRHS, ISAAC, and AIRE but again advantages and limitations have to be considered. In UK, the General Practice Research Database is another source of data. However, this kind of databases is not widely available across European countries.

DATA QUALITY: Most epidemiological studies have used symptom questionnaires to obtain prevalence estimates because of their advantages in terms of cost, convenience, and the resulting optimization of sample sizes and response rates. Symptom questionnaires have however, potential problems arising from subjective symptom recognition and recall. However, this issues have been well investigated and perhaps the most important is to use standardized questions and questionnaires in order to be able to compare data internationally. In order to have more objective measures of asthma it has been suggested that, in epidemiological studies, asthma should be defined based on the presence of asthma symptoms together with bronchial hyperresponsiveness (BHR). However, more recently, it has been suggested that it would be better to report symptoms and BHR separately rather than combined due to poor agreement between BHR and clinical asthma.[41] This is way we suggest to report each symptom or diagnosis individually without other objective measurements.

METHODS TO BE USED FOR NEW DATA COLLECTION: In the future, we recommend to incorporate appropriate questions to distinguish asthma and COPD in the general health interview/examination surveys. However this surveys only can provide a very limited picture the epidemiology of asthma and specially in those areas which interventions are possible. It is important that specific surveys on asthma are implemented and carried out periodically. This surveys should be based on the methods and standards already developed (either questionnaires or objective measurements) by the ECRHS for adults and the ISAAC for children. However, new methods to implement surveys which could provide estimates being representative of the general population at national or sub-national level have to be studied in feasibility studies.

DATA PRESENTATION: Prevalence estimates should be presented independently for teach symptom as it is described in this section: a) asthma symptoms in the last 12 months: wheeze, shortness of breath, woken up by an attack of coughing and nasal allergies b) asthma attacks, c) diagnosed asthma d) bronchial hyperresponsiveness (BHR) and e) treatment for asthma. Tables describing this estimates by age group and also stratified by gender, social class and severity should be presented. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: To evaluate the impact on asthma prevalence of possible health policy interventions focused on the reduction specific asthma risk factors susceptible to intervention.

CONSISTENCY AT INTERNATIONAL LEVEL: The studies previously described have used standardized questionnaires and many questions are similar. However, the are several issues that are different in each study that have to be considered for future surveys: age groups, sampling frames, different questions, time frame of questions and methods of data collection.

COMMENTS: The ECHI-2 project have only included an indicator on the prevalence of asthma. We strongly recommend to introduce several indicators to describe the prevalence of asthma. These indicators should also be presented by age, gender, socioeconomic status and geographical level. The ECHI-2 project included the section "2.4 Perceived and functional health" which include "2.4.1 Perceived health"; 2.4.2 Chronic disease general"; "2.4.3 Functional limitations"; 2.4.4 Activity limitations"; "2.4.5 Short-term activity restrictions"; "2.4.6 General mental health"; "2.4.7 General quality of life" and "2.4.8 Absenteeism from work". Most of the indicators that could be included in this section have been distributed in other sections of health systems section and included as outcome measures. The next section "2.5 Composite measures of health status" includes disease specific measures and the IMCA project recommends DALYs as a composite indicator for COPD.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: The availability of prevalence data is much more limited compared to mortality. Only four participants have indicated that prevalence data is available from national HIS/HES surveys. However, most participants have indicated that prevalence data is available from specific research surveys less than 10 years and two of them indicated these data is not available and indicating that in the future should be collected by HIS/HES surveys. Probably, those participants saying that data on prevalence is available have considered the ECRHS I and II and the ISAAC as a national representative samples and those saying these data should be collected by HIS/HES surveys have considered these international surveys as not representative at national level. In summary, data on prevalence at national level is not routinely available and comparable indicators can only be estimated from the ECRHS, ISAAC or AIRE in some countries.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 2.3.8 Respiratory system	Indicator Score	Rank	Order	IMCA Group recommendation
? **Prevalence of wheeze**	**3.5**	(1-4) 3	2	**1**
? Prevalence of shortness of breath	3.1	(1-4) 3	4	**1**
? Prevalence of cough	2.3	(0-4) 4	9	**2**
? Prevalence of nasal allergies	2.6	(1-4) 3	7	**2**
? **Prevalence of asthma attacks**	3.5	(2-4) 2	2	**1**
? **Prevalence of asthma diagnosis**	**3.6**	(2-4) 2	**1**	**1**
? Prevalence of BHR	2.4	(1-4) 3	8	**2**
? **Prevalence of asthma treatment**	3.4	(3-4) 1	3	**1**
Top 4 **Top 20**				

INDICATOR	DEFINITION
2.3.8 Respiratory system	

• **Asthma severity:**
  • **Mild intermittent**.
  • **Mild persistent.**
  • **Moderate persistent**.
  • **Severe persistent**.
• **Self assessed asthma severity.**
	• Proportion of individuals with mild intermittent asthma.
	• Proportion of individuals with mild persistent asthma.
	• Proportion of individuals with moderate persistent asthma.
	• Proportion of individuals with severe persistent asthma.
	• Proportion of individuals with self assessed asthma severity.
	(Mild, Moderate, Severe)

RATIONALE: In the past studies, no consistent assessment of the asthma severity have been used. In general, the number of asthma attacks (in adults) and the number of wheezy attacks (in children) have been used as a proxy of severity. In some occasions, positive answers to questions such as shortness of breath have also been used. In the latest update of the GINA[42] guidelines, a methods to classify asthma severity have been recommended. The guidelines distinguish the classification before and on treatment and suggest four main groups of classification: 1) intermittent, 2) mild persistent, 3) moderate persistent and 4) severe persistent. For each of these groups the frequency of symptoms and the FEV_1 measurements are used.

The clinical characteristics for each group of classification are as follows:

1) **Intermittent:** symptoms less than once a week, brief exacerbations, nocturnal symptoms not more than twice a month, FEV_1=80% predicted and FEV_1 variability <20%.
2) **Mild persistent:** symptoms more than once a week but less than once a day, exacerbations may affect activity and sleep, nocturnal symptoms more than twice a month, FEV_1=80% predicted and FEV_1 variability 20-30%.
3) **Moderate persistent:** symptoms daily, exacerbations may affect activity and sleep, nocturnal symptoms more than once a week, daily use of inhaled short acting $ß_2$-agonist and FEV_1 60-80% predicted and FEV_1 variability >30%.
4) **Moderate persistent:** symptoms daily, frequent exacerbations, frequent nocturnal asthma symptoms, limitation of physical activity and FEV_1 =60% predicted and FEV_1 variability >30%.

When patients are already on treatment, the classification of severity should be based on the clinical features present and the step of the daily medication regime that the patient is currently on. A table combining the four groups of severity and the three steps of treatment is described in the GINA guidelines. The categories of this table are reduced to the four categories already described but taking into account treatment and they should be used in epidemiological studies.

The AIRE study have used a very similar classification but with a specific classification of symptoms based on their frequency in short periods of time. In this study which included 753 children and 2050 adults with current diagnosed asthma. The distribution of asthma severity in children was as follows: mild intermittent 54.1%, mild persistent 17.9%, moderate persistent 12.9% and severe persistent 15.1%. The distribution of asthma severity in children was as follows: mild intermittent 37.0%, mild persistent 19.3%, moderate persistent 23.2% and severe persistent 20.5%. The same study included a measure of self assessed asthma severity and individuals classified themselves or by parents (in case of children) and clearly the perception of asthma control did not match their symptoms severity.[7]

Aims: 1) To describe the prevalence of asthma severity, **2)** To describe the prevalence of asthma symptoms, asthma attacks, asthma diagnosis and bronchial hyperresponsiveness by two indicators of severity. **3)** To provide estimates of the prevalence severity by age group, gender, socioeconomic status and geographical area. **4)** To describe the distribution of asthma patients according the two indicators of severity. **5)** The availability of this data at fixed intervals will allow monitor changes over time in the indicators proposed.

DATA SOURCES: General health interview or examination surveys do not collect information on asthma severity. The ECRHS and the ISAAC have used the number of asthma attacks or wheezy as a measure of severity and measures of severity as recommended by GINA are impossible to obtain based on the questions included on their questionnaires. The ECRHS-I and the ISAAC I questions usually refer to symptoms in the last 12 months and this do not allow the classification according to

GINA. In the ECRHS-II some questions refer to symptoms to shorter time frame (i.e. three months) but still do not much GINA criteria.

In the ISAAC II no changes on the time frame of questions have been introduced. Measurements of FEV_1 are also required and only in the ECRHS I and ECRHS II are available but not for the ISAAC I. The AIRE study have used short time frame questions but FEV_1 measurements are not available. Self assessed asthma severity is only available in the AIRE study.

DATA QUALITY: The data quality of severity measurements based on questionnaires and lung function tests depends on the standards of quality of each individual study. However, the major problem that may arise in epidemiological studies is the non acceptance of the tests by participating individuals (low response/acceptance rates) and the used standardized methods allowing comparisons between studies. At present neither the ECRHS or the ISAAC have the appropriate questions to classify patients according to GINA recommendations in order to be able to compare severity in children and adults. The validity of self assessed severity and its use on clinical management have to be further validated.

METHODS TO BE USED FOR NEW DATA COLLECTION: In future surveys, questions used in the ECRHS and in the ISAAC have to be used adapted to GINA recommendations and self assessed severity questions should be included. We strongly recommend to introduce lung function measurements to be able to combine questions and objective measurements.

DATA PRESENTATION: In this section two different indicators of severity are presented and recommended. However, each one independently may reflect clearly different aspects of severity. We suggest to present cross-tabulations between the five groups of prevalence estimates suggested with the two different methods of severity assessment. These estimates would be population based estimates of the prevalence and severity. In addition to population based estimates it would be good to know within the asthma patients group the proportion of individuals in each severity group. This should be available for each of the two methods of severity measurement proposed and presented as total and stratified by age and gender and socioeconomic group. In order to know the level of agreement between the different methods of severity classification and its possible clinical management implications for asthma patients, cross-tabulations of the self-perceived severity with the severity (according to GINA criteria) should be presented. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: To evaluate the impact on asthma severity of possible health policy interventions focused on the reduction specific asthma risk factors susceptible to intervention.

CONSISTENCY AT INTERNATIONAL LEVEL: The criteria for severity classification have changed over time during the last years and between different consensus statements. The GINA consensus have provided standards useful to be applied in epidemiological or clinical studies. However, this criteria can not be applied in most epidemiological studies with data already collected. The ECRHS and the ISAAC questions have to be complemented with more short time frame questions on symptoms and lung function measurements have to be introduced in all studies. Only one study have used self assessed severity.

COMMENTS: The ECHI-2 project have only included an indicator on the prevalence of asthma and severity is not considered. We strongly recommend to introduce asthma severity indicators as suggested. These indicators should also be presented by age, gender, socioeconomic status and geographical level.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Similarly to data on prevalence, severity is not collected and routinely available in all EU countries. Indicators can only be estimated from the ECRHS, ISAAC or AIRE but there are methodological issues still not solved in comparing severity among studies according to the latest GINA guidelines. Self-assessed severity is only collected by the AIRE study at present.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 2.3.8 Respiratory system	Indicator Score	Rank	Order	IMCA Group recommendation
? Asthma severity	2.8	(2-4) 2	6	**2**
? Mild intermittent	2.8	(2-4) 2	6	**2**
? Mild persistent	2.8	(2-4) 2	6	**2**
? Moderate persistent	2.9	(2-4) 2	5	**2**
? Severe persistent	3.1	(2-4) 2	4	**2**
? Self assessed asthma severity	2.6	(1-4) 3	7	**3**

Class 3

Determinants of health

INDICATOR	DEFINITION
3.1.1 Biological risk factors.	
• **Bronchial hyperresponsiveness (BHR).**	• Proportion of individuals with a positive bronchial hyperresponsiveness test.
• **Sensitization to indoor/outdoor allergens.**	• Proportion individuals **sensitized** to at least one of the tested common indoor/outdoor allergens and having allergy symptoms.
• **Sensitization to specific allergens.**	• Proportion of individuals **sensitized** to: • *Dermatophagoides pteronyssinus (dust).* • *Timothy grass* • *Cat* • *Dog* • *Cladosporium herbarum (mold)* • *Alternaria alternata (mold)* • *Cockroach* • *Local allergen*
• **Total IgE.**	**?** Geometric mean total serum IgE (kU/L).
• **Birth weight.**	• Proportion of individuals in each birth weight quartile.
• **Body Mass Index (BMI).**	• Proportion of individuals in each category of the BMI defined as weight (in Kg) / height^2. The categories according to the values are: underweight(<18.4); normal weight 18.5-24.9); overweight (25.0-29.9); obese (>30.0).
• **Family history.**	• Proportion of individuals with either the father or mother having a history of asthma.

RATIONALE: Airway responsiveness, a state in which the airways narrow too easily and too much in response to provoking stimuli, and is a risk factor for asthma. The condition has a heritable component and is closely related to serum IgE levels and airway inflammation. Asymptomatic airway hyperresponsiveness is considered a risk factor for asthma. The European Community Respiratory Health Survey (ECRHS) have assessed variations in bronchial responsiveness using the methacoline test across Europe and the results show considerable variation across countries.[43] The proportion of individuals with a provocative dose of methacoline causing a 20% fall in forced expiratory volume in one second ranged from 3.4% in Galdakao (Spain) to 28.8% in Hwkes-Bay (New Zeland). The study concluded that BHR varies considerably in Europe but high levels were not confined to English-speaking countries.

Atopy, defined as the production of abnormal amounts of IgE antibodies in response to contact with environmental allergens, is demonstrated by increased total or specific serum IgE and by a positive response to skin-prick test. The distribution of serum specific IgE[44] and sensitization to individual allergens in Europe have also been studied using data from the ECRHS.[45] The prevalences of IgE to specific allergens for the 35 centers included in the ECRHS were 20.3% for house dust mites, 18% for grass, 8.5% for cat and 2.4% for cladosporium. The estimated prevalence of sensitization to any allergen included in the study ranged from 16% in Albacete (Sapin) to 45% in Christchurch (New Zealand). The geometric mean total serum IgE varied from 13 kU/L in Reykjavik (Iceland) to 62 kU/L in Bordeaux (France).

The relationship of birth weight and asthma have been investigated in several studies. One of these studies found that high birth weight neonates had a significantly increased risk of emergency visits for asthma during childhood compared with neonates born with normal birth weight.[46] Another study found that birth weight is positively associated with atopic sensitization but not consistent relationship with wheezing or diagnosed asthma was found.[47] Another study found that low birth weight increased the risk of asthma at age 7.[48]

Despite the inherent difficulty in associating two common disorders, there is some evidence to the higher body mass index BMI and greater risk of developing asthma[49] In addition there is some evidence that weight loss improves lung function[50] symptoms, morbidity and health status.[51]

There is good evidence to indicate that asthma is a heritable disease. A number of studies have shown an increased prevalence of asthma and phenotype associated with asthma among the offspring subjects without asthma. [52,53] Family studies have convincingly shown that atopy (as measured by allergen skin tests , total IgE, and/ or specific IgE, airway hyperresponsiveness, and asthma as diagnosed by questionnaire are at least partly under genetic control.[53,54]

AIMS: 1) To describe the prevalence of biological risk factors for asthma development. **2)** To describe the prevalence of risk factors by age group, gender, socioeconomic status and geographical area. **3)** To describe the distribution of asthma risk factors among asthma patients. **4)** To monitor changes over time in the risk factors indicators proposed.

DATA SOURCES: Bronchial hyperresponsivenes, sensitization to specific allergens and total IgE measurements at international level are only available in a limited number of research studies, basically the ECRHS I and II and in the ISAAC II in some centers. Birth weight is available from birth registries but it is not always possible to have appropriate links with these registries. In general, this information is collected by self-reported questionnaires or interviews in general or specialized surveys. Information on birth weight is also collected in the ISAAC II. BMI is available from several routine (general health interview/examination surveys) and research data sources. Family history is in general collected by questionnaire in specialized studies.

DATA QUALITY: There are several methods for the measurement of bronchial responsiveness and sensitization to specific allergens and the quality of data depends on the method used, having a good standardized protocol and have a good training and quality control of data collection. We recommend the methods used by the ECRHS for adults and the ISAAC for children. Information on these methods can be obtained form the ISAAC II (for children) and the ECRHS I and II (for adults) web sites. Alternative methods of measuring sensitization to specific allergens exist and they are provided by several companies. As we said before, birth weight is available from birth registries but it is not always possible to have appropriate links with these registries. When this is not possible, birth weight have to be obtained by questionnaire and it is subject to recall bias. The quality of the data on the BMI depends on the methods used to collect information on weight and height. When this data is collected by direct measurements rather by questions the reliability of the data is much better. However, possible bias introduced by measurement errors either from the instruments or from the variability between and within fieldworkers. Data collection on family history is also subject to recall bias.

METHODS TO BE USED FOR NEW DATA COLLECTION: In future asthma studies we recommend to introduce measurements bronchial hyperresponsiveness, sensitization to indoor/outdoor allergens, weight and height, and questions on birth weight and family history of asthma.

DATA PRESENTATION: We suggest to present tables showing the prevalence of the risk factors recommended for asthma by age group, gender, social class and severity. Tables showing the distribution of asthma risk factors among asthma patients should also be presented. Cross-tabulations showing these distributions by age group, gender, social class and severity are also recommended. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: 1) To monitor changes over time on asthma biological risk factors, **2)** To evaluate the impact of possible health policy interventions focused on the reduction specific asthma risk factors susceptible to intervention.

CONSISTENCY AT INTERNATIONAL LEVEL: There are clear methodological differences between the two largest international studies on asthma. The bronchial hyperresponsiveness test used are different and the sampling framework is also different. The methods used to measure sensitization are the same but alternative cost-effective measurements could be considered. The questions to classify severity should be improved to meet the GINA criteria of classification. The AIRE study included all population and was representative at national level but no measurements were used.

COMMENTS: In the ECHI-2 project under the section "3.1.1 Biological risk factors" only BMI is included as a risk factor and recommended by several projects. However, there is not a clear agreement on how to present this indicators and on which categories should be used. An agreement should be reached by EHHRM, EUDIP AND CHILD projects to finally define this indicators. In the ECHI-2 the prevalence of this estimate is included but the IMCA group feels that it is important to have it stratified by age group, gender, social class and severity. In addition the distribution of asthma risk factors among asthma patients should also be presented. As we said before these tables should be available at different geographical levels.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: With the exception of birth weight and BMI that are available form national HIS/HES surveys the rest of indicators of this group are only available from the ECRHS and some ISAAC II centers. In the future these indicators should be collected from nationally representative HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 3.1.1 Biological risk factors	Indicator Score	Rank	Order	IMCA Group recommendation
? Bronchial hyperresponsiveness (BHR)	2.7	(1-4) 3	2	**2**
? Sensitization to outdoor allergens	**3.1**	(2-4) 2	**1**	**1**
? Sensitization to Dermatophagoides pteronyssimus	**3.1**	(2-4) 2	**1**	**1**
? Sensitization to timothy grass	2.4	(1-4) 3	4	**2**
? Sensitization to cat	2.5	(1-4) 3	3	**2**
? Sensitization to dog	2.1	(1-4) 3	6	**3**
? Sensitization to mold	2.3	(1-4) 3	5	**2**
? Total IgE	2.7	(1-4) 3	2	**1**
? Birth weight	2.1	(1-4) 2	6	**3**
? Body Mass Index (BMI)	2.7	(1-4) 3	2	**3**
? Family history	**3.1**	(2-4) 2	**1**	**1**

INDICATOR	DEFINITION
3.2 Health behaviors.	
3.2.1 Substance use. ? **ADULTS** • **Smoking exposure in general population:** **6) Current smokers.** **7) Past smokers.** **8) ETS exposure at home.** **9) ETS exposure at work.** **10) Smoking exposure during his/ her mother pregnancy.** • **Smoking exposure in ASTHMA patients**: **8) Non smokers with ETS.** **9) Non smokers without ETS.** **10) Past smokers with ETS.** **11) Past smokers without ETS.** **12) Current smokers (<15 pack years).** **13) Past smokers (≥ 15 pack years).** **14) Smoking exposure during his/ her mother pregnancy.** ? **CHILDREN ETS** **1) Smoking exposure during his/ her mother pregnancy.** **2) ETS exposure during his/her first year of life.** **3) Current ETS exposure at present.**	• Proportion of individuals in the general population in each of the five categories described (1 to 5). • Proportion of ASTHMA patients in each category of tobacco exposure according to the seven categories described. • Proportion of children in each of the three categories.
3.2.2 Nutrition. • **Anti-oxidants exposure.** **(Vitamin C, E, β-corotene, flavonoid, selenium, vegetables, cereals, etc.).**	• Proportion of individuals which consume fruits daily. • Proportion of individuals which consume vegetables daily.

RATIONALE: Active smoking may increase the risk of developing occupational asthma in workers exposed to some occupational sensitizers.[55] There is still limited evidence that active smoking is a risk factor for the development of asthma. However, active smoking is associated with accelerated decline of lung function in people with asthma, greater asthma severity and poor response to asthma treatment, supporting the concept that active smoking may contribute to asthma severity[56] and poor response to asthma treatment[57] even without contributing to the development of asthma.[56] There is evidence that exposure to environmental tobacco smoke increases the risk of lower respiratory track illness in utero,[58] in infancy[59] and in childhood.[60]

In a recent review, the role of dietary factors implicated in the cause and prevention of asthma have been summarized by Romieu at al.[61] Some studies in adults and in children have investigated the association between antioxidant intake and airway hypperreactivity or asthma like symptoms. In these studies, diet was assessed through administration of dietary questionnaires (24 hours recall) or food frequency questionnaires including different numbers of foods or by measuring serum levels of antioxidant vitamins. Based on this review, the authors conclude that vitamin C supplementation suggest a short term protective effect on airway responsiveness and pulmonary function. Longitudinal data support the hypothesis that fresh fruit consumption has a beneficial impact on the lung. Among children, consumption of fresh fruit high in vitamin C, has been related to a lower prevalence of asthma symptoms and higher lung function.[62] However, it has to be proved whether consistent use of vitamin C would have a protective effect on the evolution chronic asthma. and it is difficult to determine the amounts of antioxidant vitamins that people should consume.

AIMS: 1) To describe the prevalence of behavioral risk factors for asthma development. **2)** To describe the prevalence of behavioral risk factors for asthma development by age group, gender, socioeconomic status and geographical area. **3)** To describe the distribution of smoking and nutrition risk factors among individuals with asthma symptoms. **3)** To monitor changes over time in the risk factors indicators proposed.

DATA SOURCES: All routine general health interview or examination surveys and research studies provide information on tobacco smoking. However, the precise definition and questions used in all these studies are highly variable. The information on anti-oxidants or other nutrition aspects usually are collected by specific nutrition surveys and in some research studies interested in identifying associations between some aspects of nutrition and specific diseases. However, the methods for data collection are still not well standardized.

DATA QUALITY: The quality of data on tobacco exposure even when collected by questionnaire (in comparison with cotinine measurements or other methods) can be good. The major problem is the comparability of questions used in different studies and the categories of interest to assess exposures. The data on nutrition is difficult to collect and standardized questionnaires should be used to provide comparable information.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend the used of standardized questions already used in previous studies. For smoking status ECRHS questions could be used. For nutrition (antioxidants) a standardized method of data collection have to be agreed.

DATA PRESENTATION: We suggest to present tables showing the prevalence of the risk factors for asthma recommended by age group, gender and social class. Tables showing the distribution of these risk factors among asthma patients according to the categories established for each risk factor should also be presented. Cross-tabulations showing these distributions by age group, gender, social class and severity are also recommended. These tables should be available at different geographical levels: national, sub-national or local if data is available.

POTENTIAL USE: 1) To monitor changes over time on COPD behavioral risk factors, **2)** To evaluate the impact of possible health policy interventions focused on the reduction specific asthma risk factors susceptible to intervention.

INTERNATIONAL CONSISTENCY: It seems clear that most of the indicators proposed are relevant to the prevention of asthma development or progression. Tobacco smoke is an important risk factor for asthma and in general is included in most surveys. However, the data presentation in order to show different levels of exposure in asthma patients is not consistent. The ECRHS analysis have used the following categories for tobacco exposure: 1) Non-smokers and ETS - ; 2) Past smokers and ETS -; 3) Non-smokers and ETS +; 4) Past-smokers and ETS +; 5) Smokers <15 pack years; 6) Smokers >15 pack years; 7) Smokers of other tobaccos. As it was mentioned there are several methods to assess antioxidant consumption and standardized methods have to be agreed.

COMMENTS: In the ECHI-2 several indicators on tobacco exposures are proposed and several projects have suggested specific proposals. It is necessary to review the current proposal and reach a rational number of indicators relevant to health. The project that should be contacted are: CHILD, EUROCHIP, EHRM, PERISTAT, EUDIP, PHNUT and ECHI-2. The same agreement should be reached among with DAFNE, EFCOSUM, PHNUT on nutrition indicators.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Information on current and past smoking (in general population) is available in most countries from national HIS/HES surveys. This information is also available in a limited number of countries for "ETS exposure at home", "ETS exposure at work" and "Smoking exposure during mother pregnancy". Information on smoking in asthmatics (adults and children) and nutrition indicators is only available form specific research surveys. In the future data collection on these indicators should be carried out by routine HIS/HES surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 3.2.1 Substance use 3.2.2 Nutrition	Indicator Score	Rank	Order	IMCA Group recommendation
Adults				
? **Current smokers**	**3.5**	(1-4) 3	**1**	**1**
? **Past smokers**	3.4	(1-4) 3	2	**1**
? **ETS exposure at home**	3.2	(2-4) 2	3	**1**
? **ETS exposure at work**	3.2	(1-4) 2	3	**1**
? **Smoking exposure during mother pregnancy**	3.1	(2-4) 2	4	**1**
Top 20				

Asthma patients					
?	**Non smokers with ETS exposure**	2.7	(1-4) 3	5	**2**
?	**Non smokers without ETS exposure**	2.5	(1-4) 3	7	**3**
?	Past smokers with ETS exposure	2.6	(1-4) 3	6	**3**
?	Past smokers without ETS exposure	2.3	(1-4) 3	8	**3**
?	Current smokers (<15 pack years)	3.1	(1-4) 3	4	**1**
?	Past smokers (=15 pack years)	2.6	(1-4) 3	6	**3**
?	Smoking exposure during mother pregnancy	2.7	(1-4) 3	5	**3**
Children ETS exposure					
?	Smoking exposure during mother pregnancy	3.2	(2-4) 2	3	**1**
?	ETS exposure during his/her first year of life	3.1	(2-4) 2	4	**1**
?	**Current ETS exposure at present**	3.4	(2-4) 2	2	**1**
Nutrition					
?	Anti-oxidants exposure	2.2	(1-4) 3	9	**2**
	Top 20				

INDICATOR	DEFINITION
3.3 Living and Working conditions.	
3.3.1 Physical environment. • **Air pollution exposure to:** **NO_2, SO_2, O_3, PM_{10}, $PM_{2.5}$**	• Annual average of concentrations in micrograms/m3 for a specific geographical area. • Population-weighted exposure to selected air pollutants (as defined by the ECOEHIS project).
3.3.2 Working conditions. • **Occupational asthma risk.** • **Occupational exposure in asthmatics**	• Proportion of individuals (general population) which are exposed to vapors, gasses or fumes at work. • Proportion of individuals with asthma which are exposed to vapors, gasses or fumes at work.

RATIONALE: The role of air pollution on asthma have been reviewed in the latest version of GINA guidelines. Two main types of outdoor pollution have to be considered: industrial smog (sulfur dioxide particulate complex) and photochemical smog (ozone and nitrogen oxides), and they can coexists in a given area. Levels of air pollutants are affected by weather conditions and local geographic features. Several studies have implicated various pollutants as aggravating asthma,[63] mainly in experiments with chamber exposure. However, because of the great number of variable, epidemiological studies trying to link the rising trend of asthma with ambient pollution have been inconclusive. Exposure to traffic, particularly to diesel exhaust, may exacerbate preexisting allergic conditions but does not necessarily induce the development of new cases of asthma and atopy.[64] Similar conclusions reached the Committee on the Medical Effects of Air Pollutants (COMEAP) established by the Department of Health in UK which concluded that most of the available evidence does not support a causative role of air pollution in the development of asthma. Also concluded that most asthmatic patients should be unaffected by exposure to air pollution. Only a small proportion of patients may experience clinically significant effects which may require an increase in medication or attention by a doctor.[65] However, since environmental air pollution have to be monitored in order to control changes in the environment and this data may be useful to provide new information on the relationship between air pollution and asthma symptoms, we recommend to include these indicators also suggested by the ECOEHIS project.

With regard to occupational exposures, an extensive list of occupational sensitizing agents has been described. Occupational sensitizers are usually classified according to molecular weight. The mechanism of action of low molecular weight sensitizers remains largely unkown.[66] High molecular weight sensitizers probably sensitize subjects and cause asthma exacerbations by the same mechanisms as allergens. Acute exposure to irritant gases in the workplace or during accidents may induce a long lasting airway hyperresponsiveness.

AIMS: **1)** To describe the prevalence of air pollution risk factors. **2)** To describe the proportion of asthmatics exposed to occupational exposures. **3)** To monitor changes over time in the risk factors indicators proposed.

DATA SOURCES: The information on environmental health indicators is limited and mainly concentrated in urban areas. In general it is difficult to have information for large geographical areas. More detailed information will be obtained from the APHEIS and SCALE projects that have reviewed this information. Some specific research studies have collected data at ecological and individual level.

DATA QUALITY: The data quality depends on the instruments used for the measurements, its comparability, the geographical area covered and the ability to link environmental indicators to health issues.

METHODS TO BE USED FOR NEW DATA COLLECTION: In many countries information on the air pollution indicators is already collected in some specific areas but in many cases difficult or impossible to link data on exposure and health. The challenge for the future is to collect air pollution data routinely in selected geographical areas over time and for this specific areas to evaluate the health effects over time.

On the other hand and alternative to the routine data collection would be to incorporate ecological or individual measurements on the exposure to air pollution in the research or routine surveys.

DATA PRESENTATION: Details will be specified after consultation with ECOEHIS project.

POTENTIAL USE: 1) To monitor changes over time on air pollution and occupational risk factors. **2)** To evaluate the impact of possible health policy interventions focused on the reduction specific air pollutants susceptible to intervention.

INTERNATIONAL CONSISTENCY: It seems difficult to distinguish which air pollutants have a specific risk for asthma. However, the data collection of most of the pollutants indicated for monitoring are going to be collected across Europe. Perhaps it would be important to discuss how to link cross sectional-surveys with this ecological data. Air pollutants are not going to be collected in all geographical areas and this may be a problem for designing surveys with a national representation. In the ECRHS indoor and outdoor exposures are collected and in some areas of the ISAAC Phase II. However, these are not nationally representative studies. How to link indoor and outdoor exposures in HIS/HES or specific surveys on asthma is probably and issue for discussion.

COMMENTS: Several projects have proposed indicators on environmental exposures but there is not a specific definition and method of data presentation. These issues should be mainly discussed with the ECOHIS project and also with projects that have suggested some indicators such as EUROCHIP, CHILD AND ECHI-2 projects.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Nearly all countries have information available collected routinely on the annual average of NO_2, SO_2, O_3 and PM_{10}. The information on $PM_{2.5}$ is available only in nine countries and is available form research studies or have to be produced in the future in seven countries. Participants from three countries said that population weighted indicators have to be produced in the future from specific surveys and three said that they are only available from research surveys. Most indicators on working conditions are available only from research surveys or have to be produced in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 3.3.1 Physical environment	Indicator Score	Rank	Order	IMCA Group recommendation
Annual average				
? NO_2	2.5	(1-4) 3	4	**1**
? SO_2	2.3	(1-4) 3	6	**2**
? O_3	2.5	(1-4) 3	4	**1**
? PM_{10}	2.6	(1-4) 3	3	**1**
? $PM_{2.5}$	2.6	(1-4) 3	3	**1**
Population weighted				
? NO_2	2.3	(1-3) 2	6	**2**
? SO_2	2.2	(0-3) 3	7	**3**
? O_3	2.3	(1-3) 3	6	**2**
? PM_{10}	2.5	(2-3) 1	4	**1**
? $PM_{2.5}$	2.4	(2-3) 1	5	**1**
Working conditions				
? Occupational asthma risk in general population	2.7	(2-4) 2	2	**1**
? Occupational exposures in asthmatics	**3.0**	(1-4) 3	**1**	**1**

Class 4

Health Systems

INDICATOR	DEFINITION
4.1 Prevention health protection and health promotion.	
4.1.2 Health promotion.	

• **Persistent exposure to allergens of sensitized but non symptomatic individuals.**	• Proportion of individuals **sensitized and still exposed to**:
	  • *House dust mites.*
	  • *Grass*
	  • *Cat*
	  • *Dog*

• **Persistent exposure to allergens of sensitized and symptomatic individuals.**	• Proportion of individuals **sensitized and still exposed to**:
	  • *House dust mites.*
	  • *Grass*
	  • *Cat*
	  • *Dog*

RATIONALE: One of the key points of the in the management of asthma indicated in the GINA guidelines is the avoidance of exposure to risk factors. Interventions to avoid exposures to risk factors can be classified in three main groups: primary, secondary and tertiary prevention.

Since allergic sensitization is the most common precursor to the development of asthma and sensitization can occur antenatally, primary prevention will focus on perinatal interventions. Secondary prevention will focus on individuals sensitized to one or more allergens but not having any asthma related symptoms. The aim is to prevent the establishment of chronic , persistent disease in people who are susceptible and who have early signs of the disease. Tertiary prevention involves avoidance of allergens and non specific triggers when asthma is established. The aim is to prevent exacerbations or illness that would otherwise occur with exposure to identified allergens or irritants. The occurrence and severity of asthma symptoms are related to environmental allergens[67] Indoor environmental control measures to reduce exposure to allergens might be important, although it is difficult to achieve complete control, and there is conflicting evidence about whether such control measures are effective at reducing asthma symptoms[68,69] The majority of single interventions have failed to achieve a sufficient reduction in allergen load to lead to a clinical improvement. Is is likely that no single intervention will achieve sufficient benefits to be cost effective. Despite these difficulties, indicators showing the level of avoidable exposure would help to monitor exposure to risk factors and to know the scope for intervention.

AIMS: 1) To describe the proportion of individuals sensitized but without symptoms and still exposed to specific allergens. **2)** To describe the proportion of individuals sensitized with symptoms and still exposed to specific allergens. **3)** To monitor changes over time in the exposure to specific allergens in symptomatic and non symptomatic patients.

DATA SOURCES: Sensitization to specific allergens at international level is only available in a limited number of research studies, basically the ECRHS I and II and in the ISAAC II in some centers. Form the data available in these studies these indicators can be estimated. Some general health examination surveys like the one carried out in the United Kingdom have also data which would allow to estimate the proposed indicators.

DATA QUALITY: We recommend the methods used by the ECRHS for adults (specific IgE in serum) and the ISAAC for children (skin prick test). Information on these methods can be obtained form the ISAAC II (for children) and the ECRHS I and II (for adults) web sites. Alternative methods of measuring sensitization to specific allergens exist and they are provided by several companies.

METHODS TO BE USED FOR NEW DATA COLLECTION: : In future asthma studies we recommend to include skin prick test or other commercial test for allergic sensitization testing to indoor/outdoor allergens.

DATA PRESENTATION: We suggest that a table is presented with the prevalences of sensitized individuals specific allergens and still exposed to the allergen sensitized. This table should be presented for individuals with symptoms and individuals without symptoms.

POTENTIAL USE: 1) To describe the pattern of sensitization and exposure to specific allergens in symptomatic and non symptomatic individuals. **2)** To monitor changes over time in the exposure to specific allergens in these two groups of individuals.

INTERNATIONAL CONSISTENCY: The ECRHS and the ISAAC as it has been explained before have collected data on symptoms and also have carries out blood sampling for measurement of specific IgE or skin prick test which allows us to know which individuals are sensitized to any of the specific allergens tested. Despite that the information is available and the indicators described could be estimated, no data have been published showing the level of persistent exposure in sensitized individuals in symptomatic or non symptomatic individuals.

COMMENTS: This indicators are not common indicators relevant to other diseases and they have not been included in the ECHI-2 list. However, if future health examinations surveys are going to be conducted (including data on sensitization) these indicators should be included in the list.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: This indicators are not available from routine HES. Some participants have indicated that these indicators are available from research surveys, probably thinking about ECRHS and ISACC. The other participants indicated that they have to be collected by national or international specific or HES surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.1.2 Health promotion	Indicator Score	Rank	Order	IMCA Group recommendation
Persistent exposure to allergens of sensitized but non symptomatic individuals				
? House dust mites	2.3	(1-4) 3	3	**2**
? Grass	1.8	(1-3) 2	6	**3**
? Cat	2.1	(1-4) 3	5	**2**
? Dog	1.7	(1-3) 2	7	**3**
Persistent exposure to allergens of sensitized and symptomatic individuals				
? House dust mites	**2.7**	(1-4) 3	1	**1**
? Grass	2.2	(1-3) 2	4	**2**
? Cat	2.4	(1-4) 3	2	**2**
? Dog	2.1	(1-3) 2	5	**2**

INDICATOR	DEFINITION
4.1 Prevention health protection and health promotion.	
4.1.2 Health promotion.	
• **Invitation to stop smoking.**	• Proportion of smoking individuals of the general population which have been offered a stop smoking program during the last year.
• **Asthma patients invited to stop smoking.**	• Proportion of smoking individuals with asthma which have been offered a stop smoking program during the last year.
• **Asthma patients invited to follow a stop smoking program.**	• Proportion of smoking individuals with asthma which have been offered and followed a stop smoking program during the last year.
• **Asthma patients that have managed stop smoking**.	• Proportion of smoking individuals with asthma which have been offered and followed a stop smoking program during the last year and managed to stop smoking.

RATIONALE: The advice to stop smoking is important for the general population since smoking is a risk factor for several diseases. This is way the fist indicator "invitation to stop smoking have been introduced". The GINA guidelines has included avoidance of tobacco exposure as part of the management plan.[1] However, the British guideline on the management of asthma is much more explicit and suggest that parents who smoke should be advised about the dangers for themselves and their children and offered appropriate support to stop smoking.[70] The association between passive smoking and respiratory health has been extensively reviewed.[71] There is a direct causal relationship between parental smoking and lower respiratory illness in children up to three years of age, infants mothers smoke are four times more likely to develop wheezing illness in the first year of life.[72] The information on to what extent stop smoking could influence asthma severity is very limited. However one observational study have shown that giving up smoking in adults was associated with improved severity of asthma scores.[73] The effects are clear and based on this evidence, clinicians can easily give advice to patients on the benefits of stop smoking. However, in many occasions, the accessibility to specific programs is limited and unknown by patients.

AIMS: 1) To describe actions carried out from the health care services to prevent smoking exposure, **2)** To describe the efficacy of these interventions, **3)** To monitor changes over time in the indicators proposed.

DATA SOURCES: As we have mentioned before, most routine data provide information on smoking, but there is no information collected on interventions to prevent tobacco exposure. Some studies aiming to evaluate the efficacy of prevention programs provide some data but not at community level or informing about the activities carried out in health services.

DATA QUALITY: Since this information it is not collected in routine surveys, we cannot provide information on the data quality. Some bias may be introduced since there is not a clear definition of a stop smoking programs.

METHODS TO BE USED FOR NEW DATA COLLECTION: In most epidemiological studies on asthma there are no questions to assess the indicators proposed in this section. In future studies, in addition to risk factors and prevalence, appropriate questions to assess the prevalence of individuals that follow a stop smoking program and manage to succeed should be included in questionnaires of future studies.

DATA PRESENTATION: Data on these indicators should be presented stratified by age group, sex, social class, severity and geographical area.

INTERNATIONAL CONSISTENCY: Although some cross-sectional studies provide information on current and past smoking status in relation to smoking, the accessibility to stops smoking program, level of follow-up and effectiveness is not well monitored. This indicators have not been consistently collected in population based surveys and international studies. Its inclusion in future studies could facilitate the monitoring of prevention strategies.

COMMENTS: In the ECHI project, no indicators have been proposed to monitor stop smoking interventions. They should be included in the final list since they are important for several diseases.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: These indicators are not available and the data required for its estimations was not included even in the ECRHS or ISAAC studies. In the future, the appropriate questions to collect the information required have to be introduced in HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.1.3 Health protection	Indicator Score	Rank	Order	IMCA Group recommendation
? Invitation to stop smoking	2.8	(1-4) 3	**1**	**2**
? Asthma patients invited to stop smoking	2.7	(1-4) 3	2	**2**
? Asthma patients invited to follow a stops smoking program	2.7	(1-4) 3	2	**1**
? Asthma patients that have managed stop smoking	2.6	(1-4) 3	3	**1**

INDICATOR	DEFINITION
4.1 Prevention health protection and health promotion.	
4.1.3 Health protection.	
• **Interventions to prevent tobacco exposure.**	• Presence of smoking restriction in specific types of buildings. • Existence and enforcement of laws/regulations to protect children from tobacco exposure in public places.
• **Avoidance of occupational risk.**	• Proportion of individuals with asthma which have changed job to avoid exposure to vapors, gasses or fumes at work.
• **Avoidance of air pollution.**	• Proportion of individuals with asthma that have moved to another house to avoid living near highways or high traffic density.

RATIONALE: Indicators on interventions to reduce environmental exposure to tobacco in public places have been proposed by the ECHI, the Child Health and the ECOHIS project. Since, tobacco smoke is a risk factor for respiratory health, indicators on public interventions to prevent exposure should be implemented. However, although they can provide information on the policies being implemented in different countries, they may be a poor indicator of exposure and further research is needed to implement these indicators. In a previous section on risk factors, it was already mentioned that some occupational exposures may be a risk factor for asthma. Although the proportion of individuals exposed to vapors, gases or fumes at work is not a very detailed measure of exposure, it could be used as a proxy of occupational risk. This question have been used in the ECRHS. In the same way, the proportion of individuals with COPD which are living near highways or high traffic density could be a crude measure of persistent exposure to air pollution (in absence of other measures more specific). This indicator could be important to assess prevention policies.

AIMS: 1) To describe actions carried out by health policy makers to prevent smoking exposure, at community level **2)** To describe actions carried out by asthmatic patients or health care services to avoid expose to air pollution or occupational risks. **3)** To monitor changes over time in the indicators proposed.

DATA SOURCES: As we have mentioned before, most routine data provide information on smoking, but there is not information collected on interventions to prevent tobacco exposure. The information on legislation may be very unreliable and specific measurements may be required. Information on occupational risks and air pollution can be obtained form simple questions already used in studies such as ECRHS.

DATA QUALITY: The data quality may depend on the quality of individuals in reporting. Another problem may be to what extent these questions are capable of reflecting real exposures. However, these questions have already been validated for other studies and have been found very useful and simple.
METHODS TO BE USED FOR NEW DATA COLLECTION: In most epidemiological studies on COPD there are no questions to assess the indicators proposed in this section. In future studies, appropriate questions should be incorporated to assess interventions to avoid exposure to known risk factors.

DATA PRESENTATION: : Data on this indicators should be presented stratified by age group, sex, social class, severity and geographical area.

INTERNATIONAL CONSISTENCY: In the international studies on respiratory diseases there are not questions on interventions carried out by health policy makers or patients to avoid exposure to asthma risk factors. Although information on smoking, air pollution and occupational exposures have been collected by several studies (i.e. ECRHS), its avoidance is not usually collected.

COMMENTS: In the ECHI project some indicators have been proposed to monitor interventions on tobacco exposure and several projects have suggested different indicators. This have to be discussed with the ECOEHIS, CHILD and ECHI-2 projects.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: These indicators are not available and the data required for its estimations was not included even in the ECRHS or ISAAC studies. In the future, the appropriate questions to collect the information required have to be introduced in HES or specific surveys. Only two participants said that this information is available from routine data.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.1.3 Health protection	Indicator Score	Rank	Order	IMCA Group recommendation
? Interventions to prevent tobacco exposure	**2.9**	(1-4) 3	1	**1**
? Avoidance of occupational risk	**2.9**	(2-4) 2	1	**2**
? Avoidance of air pollution	2.6	(1-4) 3	2	**2**

INDICATOR	DEFINITION
4.2 Health care resources.	
4.2.1 Facilities	
• **Primary health care centers (PHCC).**	• Number of PHCC by 100.000 population.
• **Pediatrician in primary health care centers.**	• Proportion of PHCC having a pediatrician to provide care to asthmatic children.
• **Pneumology (Respiratory Medicine) Units.**	• Number of Pneumology units per 100.000 population (for adults). • Number of Pneumoloogy units per 100.0000 population (for children).
• **Allergy Units.**	• Number of Allergy units per 100.000 population (for adults). • Number of Allergy units per 100.0000 population (for children).
• **Pneumology and Allergy Units.**	• Number of Pneumology and Allergy units per 100.000 population (for adults). • Number of Pneumology and Allergy units per 100.0000 population (for children).

RATIONALE: The organization of health care is very important for the prevention, diagnosis and treatment of asthma. In general three levels of care are considered. The first, is primary health care level in which general practitioners, pediatricians and nurses carry out the first assessment of patients. The second level is the specialized care in which some patients are referred to for a final diagnosis or treatment monitoring in severe cases. At this level, there are Pneumology (Respiratory Medicine) or Allergy units run by specialists (Pneumology or Allergy and some by both). At present there is not enough scientific evidence on the effectiveness of any of these models of health care organization and no recommendations from clinical guidelines exist. Despite the limitations on the scientific evidence, it would be good to compare the resources available for asthma and evaluate to what extent there is equity in the resource allocation within or between countries. It is well known that many patients are under-diagnosed and under-treated but it is not well known to what extent these problems could be improved by intervention to the organization of health care.

Some clinical guidelines makes strong recommendations on some aspects o health care delivery such as the BTS guideline.[70] In this guideline, it is recommended that people with asthma should be reviewed regularly by a nurse with training in asthma management and says that general practices should maintain a list of people with asthma. However, no recommendations are made with regard to specialized care.

AIMS: 1) To monitor availability of specific health care resources for the care of patients with asthma**. 2**) To monitor changes over time in the resources available.

DATA SOURCES: There is not any published data on these indicators although the information may exist from Health Departments. Further work is required to assess the feasibility of collecting these indicators.

DATA QUALITY: The quality of possible data available have to be explored in possible future feasibility studies. At present it may be difficult to obtain comparable data without previously agreed definitions of pulmonary rehabilitation, pneumology units, etc.

METHODS TO BE USED FOR NEW DATA COLLECTION: Information on these indicators is not available form routine statistics. Standardized definitions for the health care resources indicated should be developed and compared with the existing ones in different countries.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition.

POTENTIAL USE: To describe and monitor changes over time in the resources available for the care of asthma patients.

INTERNATIONAL CONSISTENCY: At present there is not any information on these indicators in international databases. The definition and comparability between countries may be difficult since the structure, organization and funding of health care have important differences across EU countries. We have to considerer to what extent it is feasible to have a simple definition and comparable between countries for primary care centers and Pneumology or Allergy units. The Health Systems in transition (HiTs) elaborated by the Health Care Observatory of the WHO provide a good picture of the macro structure, organization and financing of health services across Europe. However, detailed information on this indicators it is not available.

COMMENTS: In the ECHI-2 the indicators on health care resources included are very general and not related to disease specific. The indicators included in this section were mainly based on indicators already available form international databases such as OECD, EUROSTAT or WHO. Since in these databases there are no indicators that could be useful for the provision of health care to respiratory diseases we suggest to include indicators that could help to monitor accessibility to health care resources. These indicators proposed should be included for further development.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Most of the information required to construct these indicators is available from routine data in all countries. Methodological changes are required in some countries to produce the indicators according to the definition established. In France and Luxembourg do not exist primary health care centers. This is way the information for some indicators is missing for these two countries.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.2.1 Facilities	Indicator Score	Rank	Order	IMCA Group recommendation
? Primary health care centers	2.5	(0-4) 4	2	**2**
? Pediatrician in primary health care centers	2.1	(0-4) 4	4	**2**
? Pneumology units - adults	2.7	(1-4) 3	1	**1**
? Pneumology units – children	**2.7**	(1-4) 3	**1**	**1**
? Allergy units – adults	2.3	(1-4) 3	3	**1**
? Allergy units – children	2.3	(1-4) 3	3	**1**
? Pneumology and allergy units – adults	2.5	(1-4) 3	2	**1**
? Pneumology and allergy units - children	2.5	(1-4) 3	2	**1**

INDICATOR	DEFINITION
4.2 Health care resources.	
4.2.2 Manpower.	
• **General Practitioners.**	• Number of primary care general practitioners per 100.000 population working in PHCC. • Number of primary care general practitioners per 100.000 population working in a single practice.
• **Specialized asthma education nurses.**	• Proportion of PHCC having a nurse specialized in asthma education.
• **Pediatrician.**	• Number of primary care pediatricians per 100.000 population working in PHCC. • Number of primary care pediatricians per 100.000 population working in a single practice.
• **Pneumology specialists.**	• Number of Pneumology specialists per 100.000 population.
• **Allergy specialists.**	• Number of Allergy specialists per 100.000 population.

RATIONALE: In the previous section relevant indicators on the availability of services relevant to asthma patients. In this section, indicators on the human resources available are proposed. There is no scientific evidence showing a relationship between the type of professional taking care of asthma patients and health outcomes. However, it is clear that important variations in the distribution of human resources exist. The effect of these variations on outcomes should be further investigated and the distribution of human resources monitored.

AIMS: 1) To monitor human resources available for the care of asthma patients. **2**) To monitor changes over time in these resources.

DATA SOURCES: There is not any published data on these indicators at international level although the information may exist from national statistics or Health Departments.

DATA QUALITY: The quality of possible data available have to be explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: Information on these indicators is not available form routine statistics. Standardized definitions for the health care resources indicated should be developed and compared with the existing ones in national statistics in different countries. In health care systems with a public/private mix in the provision of health services the data collection of this information may be more difficult.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition and should be available at national and sub-national geographical level.

POTENTIAL USE: To describe and monitor changes over time in the resources available for the care of asthma patients.

INTERNATIONAL CONSISTENCY: At present there is not any information on these indicators in the international databases. However this information should be available in most countries certainly for general practitioners and pneumology specialists. It may be more difficult to collect information on nurses specialized in pulmonary rehabilitation and specific education programs. We have to considerer to what extent it is feasible to have a simple definition and comparable between countries for all these indicators.

COMMENTS: In the ECHI-2 the indicators on health care resources included are very general and not related to disease specific. The indicators proposed should be included in order to improve the information related to specific diseases, in this case asthma.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Most of the information required to construct these indicators is available from routine data in all countries. Methodological changes are required in some countries to produce the indicators according to the definition established. In France and Luxembourg do not exist primary health care centers. This is way the information for some indicators is missing for these two countries. The only indicator that the information is not available is "specialized asthma education nurse" and have to be developed in the future. The lack of this information may be due to the inexistence of specialized nurses incorporated into the health care system.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.2.2 Manpower	Indicator Score	Rank	Order	IMCA Group recommendation
? General practitioners in PHCC	2.4	(0-4) 4	3	**2**
? General practitioners in single practices	2.2	(1-4) 3	5	**3**
? Specialized asthma education nurses	2.5	(1-4) 3	2	**1**
? Pediatricians in PHCC	2.3	(0-4) 4	4	**2**
? Pediatricians in single practices	2.2	(1-3) 2	5	**3**
? Pneumologists	**2.7**	(1-4) 3	**1**	**1**
? Allergy specialists	2.3	(1-4) 3	4	**1**

INDICATOR	DEFINITION
4.2 Health care resources.	
4.2.3 Education. • **Management plan.**	• Proportion of individuals with wheeze in the last 12 months but not a diagnosis of asthma and having an asthma management plan. • Proportion of individuals with a diagnosis of asthma that have an asthma management plan.
• **Peak flow meter at home.**	• Proportion of individuals with wheeze in the last 12 months but not a diagnosis of asthma and having a "*peak flow meter*" at home. • Proportion of individuals with a diagnosis of asthma that have a "*peak flow meter*" at home for monitoring.
4.2.4 Technology. • **Access to an allergy test.**	• Proportion of individuals with wheeze in the last 12 months or a diagnosis of asthma which have had an allergy test.
• **Access to lung function measurements.**	• Proportion of individuals with wheeze in the last 12 months or a diagnosis of asthma which have had a lung function measurement during the last year.

RATIONALE: As it has been described in the BTS guidelines[70] the use of personalized written asthma action plans, also called self-management plans, results in fewer days lost from work and school, fewer emergency department visits, hospital admissions, emergency episodes, less use of rescue medication and improved lung function. According to a meta-analysis, asthma management action plans are the most effective interventions available to improve clinical management.[74] In a study carried out in Germany it was shown that asthma management plans and peak flow meters were strong determinants of inhaled steroid use among children with current wheeze.[75] Measurement of lung function are essential to monitor the course of asthma and the patient's response to therapy. Poor perception of the severity of asthma symptoms on the part of the patient and health care professional may be a major factor causing delay in treatment and thus may contribute to increased morbidity and mortality from asthma axacerbations.[76] Patients who have access to peak expiratory flow information may use their medication lees frequently and more appropriately. In addition peak expiratory flow meters, patients should have access to spirometry for a proper assessment of FEV_1 and FVC. Skin tests with allergen represent the primary diagnostic tool in determining atopic status. The main limitation of methods to asses allergic status is that a positive test does not necessarily mean that the disease is allergic as some individual have specific IgE anibodies without any symptoms. However, recommendations to avoid allergens may be recommended.

AIMS: 1) To monitor utilization of health care resources available for the care of patients with asthma**. 2**) To monitor changes over time in the use of health care resources for asthma patients.

DATA SOURCES: There is not routinely collected data on these indicators although some studies have shown it is easy to collect in specific surveys.

DATA QUALITY: There is not data available on the quality of data for these indicators. However, the only problem in data collection may be the recall bias.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend that appropriate questions to collect this information are included in future studies or routine surveys. Some studies have already shown that it is easy to collect this information. It is important to have this information by public and private care and for different models of health care in those countries that a complex organization of health services exist.

DATA OPRESENTATION: Data should be presented as it is described in the indicator definition. It would be good to have this information stratified by social class and severity.

POTENTIAL USE: To describe and monitor changes over time in the use resources available for the care of COPD patients.

INTERNATIONAL CONSISTENCY: We have not been able to evaluate to what extent all relevant asthma studies have collected information on this indicators. It would be good to agree on standardized questions to collect this information in all surveys.

COMMENTS: In the ECHI-2 the indicators on health care resources included are very general and not related to disease specific. The indicators proposed should be included.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Only few participants have indicated that the information required for a small number of indicators is available from routine data. The real picture is that most of the indicators can be obtained from the ECRHS or the ISAAC but in the future have to be incorporated into new HES or specific international surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.2.3 Education	**Indicator Score**	**Rank**	**Order**	**IMCA Group recommendation**
? Management plan in wheezers without asthma diagnosis	2.5	(2-4) 2	4	**2**
? Management plan in wheezers with asthma diagnosis	2.9	(2-4) 2	2	**1**
? PFM at home in wheezers without asthma diagnosis	2.1	(0-4) 4	5	**2**
? PFM at home in wheezers with asthma diagnosis	2.6	(1-4) 3	3	**1**
? Acces to an allergy test	2.5	(1-4) 3	4	**1**
? Acces to lung function measurements	**3.1**	(1-4) 3	**1**	**1**

INDICATOR	DEFINITION
4.3 Health care utilization.	
4.3.1 In-patient care utilization.	
• **Hospital admission rates.**	• Number of hospital admissions for asthma / 1000 population.
• **Hospital admissions for individuals appropriately treated.**	• Proportion of individuals having had wheeze in the last 12 months, having a diagnosis and taking treatment for asthma being admitted to hospital at least one time during the last year.
• **Hospital admissions for individuals not appropriately treated.**	• Proportion of individuals having had wheeze in the last twelve months, having a diagnosis but not taking treatment for asthma being admitted to hospital at least one time during the last year.
• **Hospital admissions for individuals possibly under-diagnosed but treated.**	• Proportion of individuals having had wheeze in the last 12 months, not having a diagnosis of asthma but taking treatment for asthma being admitted to hospital at least one time during the last year.
• **Hospital admissions for individuals possibly under-diagnosed but not treated.**	o Proportion of individuals having had wheeze in the last twelve months, not having a diagnosis of asthma but not taking treatment for asthma being admitted to hospital at least one time during the last year.
• **Emergency room visits.**	• Proportion of individuals having had wheeze in the last 12 months without a diagnosis of asthma, taking treatment for asthma having had an emergency room visit during the last year.
	• Proportion of individuals having had wheeze in the last twelve months, a diagnosis of asthma, treatment and having had an emergency room visit during the last year.
• **Length of stay.**	• Average length of stay of all hospital admissions having a primary diagnosis of asthma.
	• Proportion of individuals admitted to hospitals for more than 2 days and having a primary diagnosis of asthma.
RATIONALE: Hospital admission rates are routinely collected in most European countries an usually available at international level and used as a surrogate for prevalence or severity. However the relationship between hospitalization rates and mortality remains unclear.[77,78] In several countries, hospital admission rates increased during the 1980s[79,80] and in some cases this have been explained by the increasing prevalence of asthma. In contrast in other countries like Finland were asthma in more commonly treated at outpatient clinics hospital hospitalization rates declined. In Sweden, the prevalence of asthma increased between 1985 and 1993 but hospital admission decreased 45% in children aged 2 to 18 and a decreasing trend in the total number of hospital days was observed. These decreasing trends can also be explained by the increasing use of inhaled steroids for the asthma treatment.[81] However, hospital admission rates have to be interpreted cautiously. A recent study carried out in UK which compared different sources of data including mortality, emergency, hospital admission, general practitioner contacts and prevalence have found very inconsistent disease patterns between these different data sources and weak correlations at regional level.[82] Despite the difficulties in using hospital admission rates as a surrogate of morbidity, they are still very important for understanding the use of health services, estimating health care costs and planning future needs. Hospital admission rates and also emergency room visits are considered clinical management outcome indicators.	

Individuals under-diagnosed and under-treated have a higher risk of having an acute exacerbation of asthma compared to those appropriately treated and may require more hospital admissions.

AIMS: 1) To describe the pattern of hospitalization and emergency room use by asthmatic patients. **2**) To describe the pattern of hospitalization and emergency room use by asthmatic patients by different groups of symptoms/diagnosis and treatment. **3)**To monitor changes over time in these indicators.

DATA SOURCES: Hospital admission rates are collected routinely in most European countries and can also be available at international level. The number of hospital admissions or emergency room visits in relation to different groups of symptoms/diagnosis and treatment should be collected by specific surveys. This information is available in the ECRHS and also in the ISAAC studies. Information can be obtained from routine data collected in each country and also from specific surveys.

DATA QUALITY: The information on the quality of possible data available is very limited. However, general issues usually found in routine utilization data and survey data should be expected. The quality of these data have to be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: There are two different methods for data collection. In-patient care utilization could be collected form routine data statistics or by health surveys. Emergency room visits would be better collected by surveys.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition. First, hospital admission rates should be presented by age-specific group and gender. Data on hospitalization and emergency room visits obtained from surveys could be presented like it is described at the top of this section. This information is collected by surveys should be presented at national and sub-national geographical levels.

POTENTIAL USE: To describe and monitor changes over time in the utilization of services available for the care of asthma patients and also describe the possible effects of treatment on the utilization of health services.

INTERNATIONAL CONSISTENCY: To monitor these indicators there is information available from routine data and from surveys. However, the information on the validity of routine data is very limited. In surveys questions are not standardized. Certainly the information available could be useful to monitor use of health services but it is difficult to say how valid the information is when monitoring exacerbations. Indicators on follow-up visits to primary care or specialist probably would be better collected from surveys.

COMMENTS: In the ECHI-2 the indicators on health care utilization (hospitalization rates and length of stay) are included for specific disease group. The ICD codes have to distinguish asthma and COPD like it has been described for mortality. Specific utilization indicators for asthma patients collected from surveys should also be included.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Three indicators: hospital admission rates, average length of stay and % > 2 days of stay are available from routine data although in some countries methodological changes are required. For the other indicators of the group the information have to be collected from HES or specific surveys in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.3.1 In-patient care utilization	Indicator Score	Rank	Order	IMCA Group recommendation
? **Hospital admission rates**	**3.5**	(2-4) 2	**1**	**1**
? Hospital admissions for individuals appropriately treated	2.5	(1-4) 3	5	**1**
? Hospital admissions for individuals not appropriately treated	2.5	(1-4) 3	5	**2**
? Hospital admissions for individuals possibly under-diagnosed but treated	2.3	(1-4) 3	7	**1**
? Hospital admissions for individuals possibly under-diagnosed but not treated	2.3	(1-4) 3	7	**2**
? Emergency room visits (wheeze no asthma diagnosis)	2.4	(1-4) 3	6	**2**
? Emergency room visits (wheeze and asthma diagnosis)	2.9	(1-4) 3	2	**1**
? Average length of stay	2.7	(2-4) 2	3	**3**
? % > 2 days of stay	2.6	(0-4) 4	4	**3**
Top 4				

INDICATOR	DEFINITION
4.3 Health care utilization	
4.3.2 Out-patient care utilization.	
• **Primary care visits of possible under-diagnosed individuals in PHCC or private care.**	• Proportion of individuals having had wheeze in the last 12 months without a diagnosis of asthma and having regular follow-up visits at the PHCC with the general practitioner or pediatrician. • Proportion of individuals having had wheeze in the last 12 months, without a diagnosis of asthma and having regular follow-up visits in a private care center (insurance or fully private).
• **Primary care visits of individuals with a diagnosis of asthma in PHCC or private care.**	• Proportion of individuals having had wheeze in the last twelve months with a diagnosis of asthma having a regular follow-up visit at the PHCC with the general practitioner or pediatrician. • Proportion of individuals having had wheeze in the last twelve months with a diagnosis of asthma having a regular follow-up visit in a private care center (insurance or fully private).
• **Out-patient visits of individuals with a diagnosis of asthma in a Respiratory Unit.**	• Proportion of individuals having had wheeze in the last twelve months and a diagnosis of asthma having a regular follow-up visits in a special unit with a specialist in Respiratory Medicine.
• **Out-patient visits of individuals with a diagnosis of asthma in a Allergy Unit.**	• Proportion of individuals having had wheeze in the last twelve months and a diagnosis of asthma having a regular follow-up visits in a special unit with a specialist in Allergy.

RATIONALE: Individuals having asthma related symptoms for first time, usually seek medical consultation at primary care or in medical specialist units (depending on the organization and regulations established in each country). In many occasions, patients despite having symptoms do not present to GP's or specialists and this may led to the problem of under-diagnosis of asthma and the consequent under-treatment.[83] Once symptoms are clearly identified or the diagnosis of asthma is made regular follow-up visits are needed. In the light of the scientific evidence, clinical guidelines have reinforced self-management plans and inhaler skills as part of the clinical management of asthma but this skills need to be reinforced in regular follow-up visits.[1,70] Indicators showing the pattern of out-patient utilization (either primary or specialist care) would help to monitor clinical management of asthma and allow the identification of gaps and consequences of possible under-utilization or using different specialist units. The difference between public and private health care are not well investigated in Europe and the indicators proposed should help to understand better the relationship between public and private services.

AIMS: 1) To describe the pattern of out-patient primary and specialist care utilization by asthmatic patients. **2**) To describe the pattern of out-patient primary and specialist care utilization by asthmatic patients by different groups of symptoms/diagnosis, treatment and organization of care. **3)**To monitor changes over time in these indicators.

DATA SOURCES: Routinely collected primary care data on utilization is collected in a limited number of European countries. The indicators suggested in relation to different groups of symptoms/diagnosis, treatment and health care organization should be collected by specific surveys. This information is available in the ECRHS and also in the ISAAC studies although the issues of public and private health care may not be available.

DATA QUALITY: The information on the quality of possible data available is very limited. However, general issues usually found in routine utilization data and survey data should be expected. The quality of these data have to be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: The indicators suggested in this section can be easily collected by specific health surveys. Most of the information required to construct these indicators is already available in the ECRHS and the ISAAC but new questions should be introduced in order to be able to differentiate public and private care.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition. This information should be presented by social class and at national and sub-national geographical levels if the survey design allows it.

POTENTIAL USE: To describe and monitor changes over time in the primary or specialist utilization of services available for the care of asthma patients and also describe the possible effects of under-diagnosis and under-treatment on the utilization of health services.

INTERNATIONAL CONSISTENCY: To monitor these indicators there is information available from specific surveys only. However, in surveys all questions are not standardized and variables which would allow to identify and compare different models of health care are not available. These variable should be incorporated in future surveys.

COMMENTS: In the ECHI-2, only indicators on hospital utilization are included. The inclusion of specific indicators on out-patient utilization have to be discussed.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: The information required for these indicators can be obtained form the ECRHS or ISAAC. However, in the future the appropriate questions to collect this information have to be included in HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.3.4 Out-patient care utilization	Indicator Score	Rank	Order	IMCA Group recommendation
? Primary care visits of possible under-diagnosed individuals in PHCC	2.2	(0-4) 4	3	**1**
? Primary care visits of possible under-diagnosed individuals in private care	2.1	(0-4) 4	4	**2**
? Primary care visits of individuals with asthma diagnosis in PHCC	**2.5**	(0-4) 4	**1**	**1**
? Primary care visits of individuals with asthma diagnosis in private care	2.3	(1-4) 3	2	**2**
? Out-patient visits of individuals with a diagnosis of asthma in a Respiratory Unit	2.3	(1-4) 3	2	**1**
? Out-patient visits of individuals with a diagnosis of asthma in a Allergy Unit	2.1	(1-4) 3	4	**2**

INDICATOR	DEFINITION
4.3 Health care utilization	
4.3.4 Medicine use/medical aids.	
• **Short acting ß$_2$-agonists prescribed.**	• Proportion of individuals with asthma that have had short acting inhaled ß$_2$ agonists prescribed in the last 12 months.
• **Long acting ß$_2$-agonists prescribed.**	• Proportion of individuals with asthma that have had short acting inhaled ß$_2$ agonists prescribed in the last 12 months.
• **Inhaled glucocorticosteroids prescribed.**	• Proportion of individuals with asthma that have had glucocorticosteroids prescribed in the last 12 months.
• **Theophyline prescribed.**	• Proportion of individuals with asthma that have had theophyline prescribed in the last 12 months.
• **Leukotriene modifier prescribed.**	• Proportion of individuals with asthma that have had leukotriene prescribed in the last 12 months.
• **DDD on all listed drugs.**	• DDD for each of the listed drugs per 1000 population.
• **Ratio steroids/ ß$_2$-agonists.**	• Ratio individuals having steroids prescribed / individuals having ß$_2$-agonists prescribed in the last 12 months.

RATIONALE: The GINA[1] and other national (BTS)[70] or international guidelines specify that effective long-term control of asthma may be achieved by selecting appropriate medications. The type of drugs to be prescribed to patients is specified for each level of severity. Despite the availability of good treatment, many individuals with symptoms are not diagnosed as asthmatics and a substantial proportion of them are not treated. This has been demonstrated in several studies. The results of the DIMCA project have shown that of all patients with objective airflow obstruction only 34% consulted their GP which indicates under-presentation by 66% of patients. Of all subjects identified with objective airflow limitation only 79% were recorded in the medical files as having asthma indicating under-diagnosis by the GP in 21% of cases.[83] A population based study on childhood asthma management carried out in Germany have shown that only 36% of children with wheeze in the lat year had used bronchodilators and only 19% were on regular anti-inflammatory treatment. Only 47% of children with wheeze had been diagnosed as asthmatics and less than 10% received appropriate treatment for asthma.[84] There is wide variation in the utilization of anti-inflammatory drugs in young adults with physician-diagnosed asthma in Europe. The level of utilization ranged form 49% in the UK and 17% in Italy.[85] Smokers,[86] ethnic minority and low socioeconomic groups are less likely to use anti-inflammatory drugs.[87] The AIRE study (in Europe), have also shown that only 63% of individual with asthma diagnosis were taking quick relief medications and only 23% inhaled corticosteroids.[7]

AIMS: 1) To describe he utilization of drugs prescribed by patients with asthma. **2)** To detect the proportion of individuals with asthma not treated. **3**) To monitor changes over time in the utilization of drugs prescribed for asthma.

DATA SOURCES: Information can be obtained from specific surveys. Information on defined daily doses (DDD) can be obtained form public databases established in each EU country. However the level of coverage of these data sources varies across countries.

DATA QUALITY: The quality of possible data from surveys is relatively good. However, possibilities of recall bias may exist and although the drugs are prescribed may not be taken. The quality of routine data have to be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend to include the appropriate questions in future research or routine asthma studies on pharmacological treatment to detect the level of under-treatment and changes in prescription. Routine data on sales (DDD/1000 population) can also be useful at ecological level but less informative.

DATA OPRESENTATION: We recommend that the several indicators on treatment are presented in the following order. The first indicators could be the prevalence of each drug as it is described at the top of this section by gender, severity, social class and smoking status. Second, the proportion of individuals having each drug prescribed in two groups of symptoms: a) individuals with wheeze but not asthma diagnosis and b) individuals with wheeze and asthma diagnosis. This would help to know the level of prescription of each drug in those with diagnosis and those with possible under-diagnosis. These indicators should also be presented by gender, severity and social class. Data from sales should be presented as DDD per 1000 population.

POTENTIAL USE: To describe and monitor changes over time in the utilization of drugs by asthmatic patients and assess possible intervention policies.

INTERNATIONAL CONSISTENCY: The information available on drugs utilization is limited to the one provided by the large research studies and difficult to compare due to the different approaches used to describe utilization of drugs. The methods to present data reflecting the level of prescription in individuals with asthma diagnosis and also in those possibly under-diagnosed should be standardized. The EURO-MED-STATS project coordinated by Pietro Folino have explored the use of public databases on drug sales but data on indicated drugs for asthma have not been properly explored yet.

COMMENTS: In the ECHI-2 the indicators there is a section on the use of drugs but not related to specific diseases and certainly not to indicate possible under-treatment or appropriateness. The ECHI-2 list should be expanded with the indicators proposed by the IMCA group.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Most participants have indicated that the information required for these indicators is available form routine data although methodological changes may be required. However, if we considerer the definition of the indicators that specifically says that these indicators have to be estimated for asthma patients, the information is only available form ECRHS or ISAAC. In the future, the information have to be collected by HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.3.4 Medicine use / medical aids	Indicator Score	Rank	Order	IMCA Group recommendation
? **Short acting with ß$_2$-agonists prescribed**	3.3	(2-4) 2	2	**1**
? Long acting with ß$_2$-agonists prescribed	3.2	(2-4) 2	3	**1**
? **Inhaled glucocorticosteroids prescribed**	**3.5**	(2-4) 2	**1**	**1**
? Theophyline prescribed	2.4	(1-4) 3	7	**2**
? Leukotriene modifier prescribed	2.5	(1-4) 3	6	**2**
? DDD on all listed drugs	2.6	(0-4) 4	5	**3**
? Ratio steroids/ ß$_2$-agonists	2.9	(1-4) 3	4	**3**
Top 20				

INDICATOR	DEFINITION
4.4 Health expenditures/financing.	
4.4.1 Health care system. • **Hospitalization cost.** • **Out-patient cost.** • **Emergency room cost.** • **Specialist visits cost.**	• Total/mean cost of asthma hospitalizations (including public and private care). • Total/mean cost of out-patient asthma care (including public and private care). • Total/mean cost of unexpected emergency room visits for asthma (including public and private). • Total/mean cost of follow-up visits to specialist for asthma (including public and private).

RATIONALE: The cost of illness studies provide an insight into the economic impact of a disease but this information is limited to a number of specific studies and in general this type of data is not collected in epidemiological asthma studies. In general, economic studies provide information on direct and indirect costs. The direct cost is the value of health care resources devoted to diagnosis and medical management of the disease. Indirect costs reflect the monetary consequences of disability, missed work and school, premature mortality, and caregiver or family costs resulting from illness. Indirect costs are more difficult to estimate and to compare between countries. In a review of nine studies carried out in different countries, Barnes et al. have provides and estimation of the proportion of direct cost of asthma care.[88] The average physician costs in these studies was 22%, of which 75% relates to general practitioner consultations and 25% o specialist consultations. Drug costs make up approximately 37% of the total direct cost of asthma. Hospital costs were approximately 20-25% although high variations between countries were observed. In-patient costs were the most important component 70-85%, whilst emergency room treatment was 14-18%. It is considered that asthma costs are largely due to uncontrolled disease and are largely expected to rise as its prevalence and severity increase. Better asthma should lead to reduction of hospital and emergency room costs.

AIMS: 1) To describe direct health care costs related to utilization of health services by patients with asthma. **2**) To monitor changes over time in these indicators.

DATA SOURCES: Information on utilization should be estimated from specific surveys and data on costs could be obtained from Health Departments of each country. Using both sources of information total direct costs of asthma can be estimated.

DATA QUALITY: The quality of possible data available is not well known and should be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend that data on utilization is collected by specific surveys while and data on costs should be obtained from databases in the Health Department of each country. The information necessary to be able to link economic and utilization data should be further explored.

DATA OPRESENTATION: Data can be presented as it is described in the indicator description however it would be interesting to present it also stratified by severity, social class and this tables produced by national and sub-national levels.

POTENTIAL USE: To describe and monitor changes over time in costs of health care utilization and its distribution within different levels of health care. These indicators should help to evaluate possible health intervention policies to improve asthma care.

COMMENTS: In the ECHI-2 the indicators on health care costs of health services utilization are not included. The indicators proposed should be expanded for disease specific indicators in order to be able to assess the impact of different diseases.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Most participants have indicated that data for this group of indicators is available but methodological changes are required. Only four participants indicated that the data required is not available and have to be incorporated into routine data in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.4.1 Health care system	Indicator Score	Rank	Order	IMCA Group recommendation
? **Hospitalization cost**	**3.2**	(1-4) 3	**1**	**1**
? Out-patient cost	2.7	(1-4) 3	2	**2**
? Emergency room cost	2.7	(1-4) 3	2	**1**
? Specialist visits cost	2.7	(1-4) 3	2	**2**
Top 20				

INDICATOR	DEFINITION
4.4 Health expenditures/financing.	
4.4.3 Expenditure on medical services. • **Total cost of medicines prescribed for asthma treatment.**	• Total/mean cost of medicines prescribed for asthma treatment. • Total/mean cost paid by the patient (out of pocket) for medicines prescribed for asthma.
4.4.5 Total direct costs. • **Cost of total asthma health care.**	• Total/mean cost of asthma health care (including public and private health care utilization, medication and insurance costs).
4.4.6 Private Health expenditure. • **Total cost of private care.**	• Proportion of individuals paying an additional private insurance to cover health care services or having paid some private health care services. • Total/mean cost paid for additional private insurance or private health care.

RATIONALE: The rationale for collecting economic indicators have already been descried in the previous section. This section include more economic indicators related to direct costs of pharmacological treatment, total cost of asthma care and the costs of private and public health care, age and severity of the disease and additional insurance costs. In Europe the effects of different methods of organization and financing of health care are poorly evaluated although there many differences across countries.

AIMS: 1) To describe direct costs related to drugs prescribed to patients with asthma. **2**) To describe total/mean costs of asthma care and specifying the cost of private care. **3)** To monitor changes over time in these indicators.

DATA SOURCES: Information can be obtained by a combination of specific surveys and some routine data provided by Health Department of each country.

DATA QUALITY: The quality of possible data available is not well known and should be further explored.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend to collect data on utilization of drugs and insurance coverage by specific surveys and data on costs should be obtained from databases in the Health Department of each country. The information necessary to be able to link economic and utilization data should be further explored.

DATA PRESENTATION: Data should be presented as it is described in the indicator definition. The cost of total asthma health care would be good to estimate it by age group and severity.

POTENTIAL USE: To describe and monitor changes over time in total/mean direct costs of asthma treatment, total costs and private care by age and severity. This indicators should help to evaluate possible health policy interventions.

INTERNATIONAL CONSISTENCY: The organization and methods of financing health care is very different in each European country. However, if we considerer only direct costs, perhaps is feasible to collect this information. Information on direct costs would be also useful to incorporate into surveys and probably the most appropriate way of incorporating health care costs in relation to severity. In this section it could be useful to discuss to what extent the information is relevant in Europe in order to monitor and evaluate the effects of public and private health care.

COMMENTS: In the ECHI-2 the indicators on health care costs of specific drugs utilization for specific diseases, costs according to age and severity and additional insurance costs are not included. The indicators proposed should be expanded for disease specific indicators in order to be able to assess the impact of different diseases.

AVAILABILITY AND CONSISTENCY AT NATIONAL LEVEL: Information on costs can be available form most countries although important methodological changes may be required. However, several participants indicated that data on costs of private care and out of pocket payment may be difficult to obtain and special efforts have to be made in order to collect this information in the future.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.4.3 Expenditure on medical services 4.4.5 Total direct costs 4.4.6 Private health expenditure	Indicator Score	Rank	Order	IMCA Group recommendation
? **Total cost pf medicines prescribed for asthma treatment**	**3.2**	(1-4) 3	**1**	**1**
? Total cost of medicines paid by the patient (out of pocket) prescribed for asthma	2.3	(1-4) 3	2	**2**
? **Cost of total asthma health care**	3.2	(1-4) 3	1	**1**
? Total cost of asthma private care	2.1	(1-4) 3	3	**2**
? Individuals paying a private insurance	1.8	(0-4) 4	4	**3**
Top 20				

INDICATOR	DEFINITION
4.5 Health care quality/performance.	
4.5.3 Health outcomes.	
• **Minimal chronic symptoms.**	• Proportion of individuals with daytime symptoms at least once a week. • Proportion of individuals with sleep disturbances at least one a week.
• **Minimal episodes.**	• Proportion of individuals with reported episodes of coughing, wheezing, chest tightness or shortness of breath in the last month.
• **No emergency visits.**	• Proportion of individuals without unscheduled emergency care visits during the last year.

• **No limitation of activities.**	• Proportion of individuals with limitations in each of the following activities:
	  • Sports.
	  • Normal Physical activity.
	  • Choice job / career.
	  • Work absence days.

• **Normal or near normal lung function.**	5) Proportion of individuals with FEV_1=80% predicted and FEV_1 variability <20%.

RATIONALE: The GINA guidelines[89,1] specify eight goals for long-term management of asthma: minimal chronic symptoms; no emergency visits; minimal need for as-required $ß_2$-agonsists; no limitations to daily activities; near normal PEF; PEF circadian variation < 20%; and minimal adverse effects from asthma medication. Over the past years several studies have shown that asthma was under-diagnosed and under-treated but a limited number have provided comparable information on the GINA goals across EU countries. The AIRE study was the first study to provide a summary with empirical data on the GINA goals in Europe.[7] In current asthmatic patients , 46% reported daytime symptoms and 30% reported asthma-related sleep disturbances, at least once a week. In the past 12 months, 25% of patients reported an unscheduled urgent care visit, 10% reported one or more emergency room visits and 7% reported overnight hospitalization due to asthma. In the past 4 weeks, more patients had used prescription quick relief medication (63%) than inhaled corticosteroids (23%). Patient perception of asthma control did not much their symptoms severity. Approximately 50% of patients reporting severe persistent symptoms also considered their asthma to be completely or well controlled.

AIMS: 1) To describe asthma outcomes based on indicators recommended by GINA guidelines and the scientific literature. **2)** To monitor changes over time in these indicators.

DATA SOURCES: Information can be obtained from specific surveys such as the ECRHS or ISAAC however the information on all indicators refers to the past year rather than last week or month. The AIRE study provided comparable data for these indicators in some EU countries.

DATA QUALITY: The quality of possible data obtained by surveys is relatively good. Problems due to recall bias may exist but in general are well standardized questions with a previous validation.

METHODS TO BE USED FOR NEW DATA COLLECTION: We recommend that to data on asthma outcomes indicators is collected by specific surveys and based on the questions already available from ECRHS (for adults) and ISAAC (children) although these questions should be adapted to provide a short time frame information.

DATA PRESENTATION: We recommend that these outcomes indicators are presented in two groups of symptoms/diagnosis: a) individuals with wheeze but not asthma diagnosis (possible under-diagnosis) and b) individuals with wheeze and asthma diagnosis (individuals with current asthma). These indicators should be stratified by gender, severity, social class and smoking status and to produce this information at national and sub-national level.

POTENTIAL USE: To describe and monitor changes over time in asthma outcomes and evaluate the effectiveness of health care.

INTERNATIONAL CONSISTENCY: In general the outcomes suggested here are collected in specialized surveys but not in general HIS/HES surveys. The information available from international studies is useful but the time frame of the questions should be standardized for future studies.

COMMENTS: In the ECHI-2 some indicators on outcomes of health care are included but they are very limited. The asthma outcome indicators should be included in the ECHI-2 list in order to monitor the effectiveness of health care for asthma patients.

CONSISTENCY AT NATIONAL LEVEL: The information required to construct these indicators is only available form the ECRHS and ISAAC or AIRE some of them. In the future, the information have to be collected by HES or specific surveys.

PRIORITY: The following table describes the final individual score for each indicator and the priority level recommended by the IMCA group in case data for all indicators can not be collected. The indicators have been classified according to three levels of priority.

Indicators 4.5.3 Health outcomes	Indicator Score	Rank	Order	IMCA Group recommendation
? Day time once a week	2.4	(1-4) 3	5	**2**
? Sleep disturbances once a week	2.6	(1-4) 3	3	**2**
? Shortness of breath once a month	2.2	(1-4) 3	6	**2**
? Minimal epidoses	2.2	(1-4) 3	6	**2**
? No emergency visits	2.7	(0-4) 3	2	**1**
? No limitation of sport activities	2.1	(0-3) 3	7	**1**
? No limitation of physical activity	2.6	(0-4) 4	3	**1**
? No limitations in the choice of job	2.5	(1-4) 3	4	**2**
? Work absence days	2.7	(1-4) 3	2	**1**
? Normal or near normal lung function	**2.9**	(1-4) 3	**1**	**1**

1. Global Inititative for Asthma. Global strategy for asthma management and prevention. National Heart, Lung, and blood Institute. NIH Publication No 02-3659.

2. Asher MI, Keil U, Anderson HR, Beasley R, Crane J, Martinez F *et al*. International Study of Asthma and Allergies in Childhood (ISAAC): rationale and methods. *Eur Respir J* 1995; 8:483-91.

3. ISAAC Steering Committe. Phase II Modules of the International Study of asthma and Allergies in childhood (ISAAC). Münster, 1998.

4. Burney PG, Luczynska C, Chinn S, Jarvis D. The European Community Respiratory Health Survey. *Eur Respir J* 1994; 7:954-60.

5. Janson C, Anto J, Burney P, Chinn S, de Marco R, Heinrich, Jarvis D, Kuenzli N, Leynaert B, Luczynska C, Neukirch F, Scvanes C, Sunyer J, Wjst. The european Community Respiratory Health survey: what are the main results so far? Eur Respir J 2001; 18:598-611.

6. The European Community Respiratory Health Survey II Steering Committee. The European Community Respiratory Health Survey II. Eur Respir J 2002; 20: 1071-1079.

7. Rabe KF, Vermeire PA, Soriano JB, Maier WC. Clinical management of asthma in 1999: the Asthma Insights and Reality in Europe (AIRE) study. *Eur.Respir.J.* 2000; 16:802-7.

8. Hyndman SJ, Williams DR, Merrill SL, Lipscombe JM, Palmer CR. Rates of admission to hospital for asthma. *BMJ* 1994; 308:1596-600.

9. Woolcock AJ. Worldwide differences in asthma prevalence and mortality. Why is asthma mortality so low in the USA? *Chest* 1986; 90:40S-5S.

10. EUROSTAT. Demographic Statistics 2000. Luxembourg. European Commission 2000.

11. Organization for the Economic Cooperation and Development (OECD). Health data 2000.

12. World Health Organization(WHO). Regional Office for Europe. International mortality database. 2000.

13. Ochoa A. ISARE project. European Commission.

14. Kramers PGN. The ECHI project: health indicators for the European Community. Eur J Public Health 2003; 13:101-6.

15. Mielck A, Reitmeir P, Wjst M. Severity of childhood asthma by socioeconomic status. *Int.J.Epidemiol.* 1996; 25:388-93.

16. Strachan DP, Golding J, Anderson HR. Regional variations in wheezing illness in British children: effect of migration during early childhood. *J.Epidemiol.Community Health* 1990; 44:231-6.

17. Duran-Tauleria E,.Rona RJ. Geographical and socioeconomic variation in the prevalence of asthma symptoms in English and Scottish children. *Thorax* 1999; 54:476-81.

18. Watson JP, Cowen P, Lewis RA. The relationship between asthma admission rates, routes of admission, and socioeconomic deprivation. Eur Respir J 1996; 9:2087-93.

19. Walters S, Phupinyokul M, Ayres J. Hospital admission rates fro asthma and respiratory disease in the west Middlands: their relationship to air pollution levels. Thorax 1995; 50:948-54.

20. LittleJohns P, Macdonald LD. The relationship between severe asthma and social class. Respir Med 1993; 87:139-43.

21. Basagana X, Sunyer J, Kogevinas M, Zock JP, Duran-Tauleria E, Jarvis D *et al*. Socioeconomic Status and Asthma Prevalence in Young Adults: The European Community Respiratory Health Survey. *Am.J.Epidemiol.* 2004; 160:178-88.

22. Cesaroni G, Farchi S, Davoli M, Forastiere F, Perucci CA. Individual and area-based indicators of socioeconomic status and childhood asthma. *Eur Respir J* 2003; 22:619-24.

23. Kunst AE, Bos V, Mackenbach JP and the EU Working Group. Monitoring socioeconomic inequalities in health in the European Union: guidelines and illustrations. A report for the Health Monitoring Program of the European Commission. Available from: http://www.europe.

24. Duran-Tauleria E, Rona RJ, Chinn S, Burney P. Influence of ethnic group on asthma treatment in children in 1990-1: national cross sectional study. *BMJ* 1996; 313:148-52.

25. Wissow LS, Gittelsohn AM, Szklo M, Starfield B, Mussman M. Poverty, race, and hospitalization for childhood asthma. *Am.J.Public Health* 1988; 78:777-82.

26. Stewart AW, Mitchell EA, Pearce N, Strachan DP, Weilandon SK. The relationship of per capita gross national product to the prevalence of symptoms of asthma and other atopic diseases in children (ISAAC). *Int.J.Epidemiol.* 2001; 30:173-9.

27. Aromaa A, Koponen P, Tafforeau J. Vermeire C and the HIS/HES Core Group. Evaluation of Health Interview Surveys and Health Examination Surveys in the European Union. Eur J Public Health. 2003;13(3 Suppl):67-72. (Database available from: https://www.iph.fgov.be/hishes/).

28. Menke R, Streich W, Rösler G. Report on socio-economic differences in health indicators in Europe. Health inequalities in Europe and the situation of disadvantaged groups. European Commission. Available from: http://www.europe.

29. European Respiratory Society. European Lung White Book. The first comprehensive survey on respiratory health in Europe. Chapter 02, 28-29. Chronic Obstructive pulmonary disease. Lausane, switserland 2003.

30. Jorgensen IM, Bülow S, Jensen VB, Dah m TL, Prahl P, Juel K. Asthma mortality in Danish children and young adults, 1973-1994: epidemiology and validity of death certificates. Eur Respir J 2000; 15:844-848.

31. Jonasson G, Lodrup Carlsen KC, Leegard J, Carlsen KH, Mowinckel P, Halvorsen KS. Trends in hospital admissions for childhood asthma in Oslo, Norway, 1980-95. Allergy 2000; 55: 232-239.

32. Lenney W, Wells NEJ, O N'eill BA. The burden of pediatric asthma. Eur Respir Rev 1994; 4:49-62.

33. Beasley CRW, Pearce Ne, Crane J. Worldwide trends in asthma mortality during the tentieth century. In: Sheffer AL, ed. Fatal asthma. New York: Marcel Dekker; 1998. p 13-29.

34. Rutstein DD, Berenberg W, Chalmers TC, et al. Measuring the quality of medical care utilization : a clinicla method. NEJM 1976; 294:582-8.

35. Schwartz E, Kofie VY, Rivo M, Tuckson RV. Black/white comparisons of deaths preventable by medical intervention: United States and the District of Columbia 1980-1986. *Int.J.Epidemiol.* 1990;19:591-8.

36. Campbell DA, McLennan G, Coates JR, Frith PA, Gluyas PA, Latimer KM. Accuracy of asthma statistics from detah certificates in South Australia. Med J Aust 1992; 156:860-3.

37. A subcommittee of the BTS Research committee. Accuracy of death certificates in bronchial asthma . Accuracy of certification procedures during the confidential inquiry by the British Thoracic Association. Thorax 1984; 39:505-9.

38. Sears MR, Rea HH, de Boer G, Beaglehole R, Gilies AJ, Holst PE. Accuracy of death certification of deaths due to asthma. A national study. Am J Epidemiol 1986; 124: 1004-11.

39. International Study of Asthma and Allergies in Childhood (ISAAC) Steering Committee. Worldwide variation in prevalence of symptoms of asthma, allergic rhino-conjuntivitis and atopic eczema: The international Study of Asthma and Allergies in Childhood (ISAAC). Lancet 1988; 351: 1225-1232.

40. Variations in the prevalence of respiratory symptoms, self-reported asthma attacks, and use of asthma medication in the European Community Respiratory Health Survey (ECRHS). *Eur.Respir.J.* 1996; 9:687-95.

41. Pekkanen J,.Pearce N. Defining asthma in epidemiological studies. *Eur Respir J* 1999; 14:951-7.

42. Global Initiative for Asthma. Global strategy for asthma management and prevention. National Heart, Lung, and blood Institute. NIH Publication No 02-3659.

43. Chinn S, Burney P, Jarvis D, Luczynska C. Variation in bronchial responsiveness in the European Community Resppiratory Health Survey (ECRHS). Eur Respir J 1997; 10: 2495-2501.

44. Burney P, Malmberg, Chinn S, Jarvis D, Luczynska, Lai E. The distribution of total and specific serum IgE in the european Community Respiratory Health Survey. J Allergy Clin Immunol 1997; 316-322.

45. Chinn S, Burney P, Sunyer J, Jarvis D, Luczynska. Sensitization to individual allergens and bronchial responsiveness in the ECRHS. Eur Respir J 1999; 14:876-884.

46. Sin DD, Spier S, Svenson LWW, Schopflocher DP, Senthilselvan A, Cowie RL, Man SF. The relationship between birth weight and childhood asthma: a population-based cohort study. Arch Pediatr Adolesc Med 2004; 158(1):60-4.

47. Bolte G, Schmidt M, Maziak W, Keil U, Nasca P, von Mutius E, Weiland S. The relation of markers of fetal growth with asthma, allergies and serum immunoglobulin E levels in children at age 5-7 years. Clin Exp Allergy 2004; 34(3):381-8.

48. Jaakola JJ, Gissler M. Maternal smoking in pregnancy, fetal development, and childhood asthma. Am J Public Health 2004; 94(1):136-40.

49. Camargo CA, Weiss ST, Zhang S, Willet WC, Speizer FE. Prospective study of body mass index, weight change, and risk of adult onset asthma in women. Arch Intern Med 1999; 159: 2582-8.

50. Hakala K, Stenius-Aamiala B, Sovijarvi A. effects of weight loss on peak flow variability, airways obstruction, and lung volums in obese patients with asthma. Chest 2000; 118:1315-21.

51. Stenius-Aamiala B, Poussa T, Kvamstrom J, Gonlund EL. Inmediate and long term effects of weigtht reduction in obese people with asthma: randomized controlled trial. BMJ 200; 320:827-32.

52. Sibbald B, Hom ME, Gregg I. A family study of the genetic basis of asthma and wheezy bronchitis. Arch Dis Child 1980; 55:354-7.

53. Holgate ST. Genetic and environment interaction in allergy and asthma. J Allergy Clin Immunol 1999; 104:1139-46.

54. Holgate ST. The epidemic of allergy and asthma. Nature 1999; 402:B2-4.

55. Barker RD,. van Tongeren MJ, Harris JM, Gardiner K, Venables KM, Newman Taylor AJ. Risk factors for bronchial hyperresponsiveness in workers exposed to acid anhydrides. Eur Respir J 2000; 15:710-5.

56. Siroux V, Pin I, Oryszczyn MP, Le Moual N, Kauffmann F. Relationships of active smoking to asthma and asthma severity in the EGEa STUDY. Epidemiological Study on the Genetics and Environment of Asthma. Eur Respir J 2000; 15:470-7.

57. Pedersen B, Çdahl R, Karlstrom R, Peterson CG, Venge P. Eosinophil and neutrophil activity in asthma in a one-year trial with inhaled budesonide. The impact of smoking. Am J Respir Crit Care Med 1996; 153:1519-29.

58. Gilliland FD, Berhane K, McConnell R, Gauderman WJ, Vora H, Rappaport EB *et al*. Maternal smoking during pregnancy, environmental tobacco smoke exposure and childhood lung function. *Thorax* 2000; 55:271-6.

59. Nafstad P, Kongerud J, Botten G, Hagen JA, Jaakkola JJ. The role of passive smoking in the development of bronchial obstruction during the first 2 years of life. *Epidemiology* 1997; 8:293-7.

60. Ferrence R,.Ashley MJ. Protecting children from passive smoking. *BMJ* 2000;321:310-1.

61. Romieu I,.Trenga C. Diet and obstructive lung diseases. *Epidemiol.Rev.* 2001;23:268-87.

62. Forastiere F, Pistelli R, Sestini P, Fortes C, Renzoni E, Rusconi F *et al*. Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children. SIDRIA Collaborative Group, Italy (Italian Studies on Respiratory Disorders in Children and the Environment). *Thorax* 2000; 55:283-8.

63. Koenig JQ. Air pollution and asthma. J Allergy clin Immunol 1999; 104:717-22.

64. Oosterlee A, Drijver M, Lebret E, Brunekreef B. Chronic respiratory symptoms in children and adults living along streets with high traffic density. Occup Environ Med 1996; 53:241-7.

65. Holgate ST. Anderson HR. Committee on Medical effects of Air Pollutants. Asthma and outdoor air pollution. Department of Health. HMSO. London, 1995.

66. Mapp C, Boschetto P, Miotto D, De Rosa E, Fabbri LM. Mechanisms of occupational asthma. Ann Allergy asthma Immunol 1999; 83:645-64.

67. Custovic A, Simpson A, Woodcock A. Importance of indoor allergens in the induction of allergy and elicitation of allergic disease. *Allergy* 1998; 53:115-20.

68. Gotzsche PC, Hammarquist C, Burr M. House dust mite control measures in the management of asthma: meta-analysis. *BMJ* 1998; 317:1105-10.

69. Gotzsche PC, Johansen HK, Burr ML, Hammarquist C. House dust mite control measures for asthma. *Cochrane.Database.Syst.Rev.* 2001; CD001187.

70. Scottish Intercollegiate Guidelines Network. The British Thoracic Society. British Guideline on the Management of Asthma.

71. Strachann DP, Cook DG. Health effects of passive smoking I. Parental smoking and low respiratory illness in infancy and early childhood. Thorax 1997; 52:905-14.

72. Dezateau C, Stocks J, Dundas L, et al. Impaired airway function and wheezing in infancy: the influence of maternal smoking and genetic predisposition to asthma. Am J Respir Crit Care Med 1999;1 59:403-10.

73. Eisner MD, Yelin EH, Henke J, et al. Environmental tobacco smoke and adult asthma. The impact of changing exposure status on health outcomes. Am j Respir Crit Care Med 1998; 158:170-5.

74. Bernard-Bonnin AC, Stachenko S, Bonin D, et al. Self-management teaching programs and morbidity of pediatric asthma: a meta-analysis. J Allergy Clin Immunol 1995; 95:34-41.

75. Maziak W, von Mutius E, Beimfohr C, Hirsch T, Leupold W, Keil U, Weiland SK. The management of childhood asthma in the community. Eur Respir J 2002; 20:1476-1482.

76. Sears MR. Increasing ashtma mortality-fact or artifac ? Pediatr Pulmonol 1991; 11:166-74.

77. Haahtela T, Lindholm H, Bjorksten F, Koskenvuo K, Laitinen LA. Prevalence of asthma in Finnish young men. *BMJ* 1990; 301:266-8.

78. Weiss KB, Gergen PJ, Wagener DK. Breathing better or wheezing worse? The changing epidemiology of asthma morbidity and mortality. *Annu.Rev.Public Health* 1993; 14:491-513.

79. Anderson HR. Increase in hospital admissions for childhood asthma: trends in referral, severity, and readmissions from 1970 to 1985 in a health region of the United Kingdom. *Thorax* 1989; 44:614-9.

80. Storr J, Barrell E, Lenney W. Rising asthma admissions and self referral. *Arch.Dis.Child* 1988; 63:774-9.

81. Wennergren G, Kristjansson S, Strannegard IL. Decrease in hospitalization for treatment of childhood asthma with increased use of antiinflammatory treatment, despite an increase in prevalence of asthma. *J.Allergy Clin.Immunol.* 1996; 97:742-8.

82. Hansell A, Hollowell J, McNiece R, Nichols T, Strachan D. Validity and interpretation of mortality, health service and survey data on COPD and asthma in England. *Eur.Respir.J.* 2003; 21:279-86.

83. van Schayck CP, Der Heijden FM, van Den BG, Tirimanna PR, van Herwaarden CL. Underdiagnosis of asthma: is the doctor or the patient to blame? The DIMCA project. *Thorax* 2000; 55:562-5.

84. Maziak W, von Mutius E, Beimfohr C, Hirsch T, Leupold W, Keil U *et al*. The management of childhood asthma in the community. *Eur.Respir.J.* 2002; 20:1476-82.

85. Janson C, Chinn S, Jarvis D, Burney P. Physician-diagnosed asthma and drug utilization in the European Community Respiratory Health Survey. *Eur.Respir.J.* 1997; 10:1795-80.

86. Janson C, Chinn S, Jarvis D, Burney P. Individual use of antiasthmatic drugs in the European Community Respiratory Health Survey. *Eur.Respir.J.* 1998; 12:557-63.

87. Adams RJ, Fuhlbrigge A, Guilbert T, Lozano P, Martinez F. Inadequate use of asthma medication in the United States: results of the asthma in America national population survey. *J.Allergy Clin.Immunol.* . *J.Allergy Clin.Immunol.* 2002; 110:58-64.

88. Barnes PJ, Jonsson B, Klim JB. The costs of asthma. *Eur.Respir.J.* 1996; 9:636-42.

89. Global Initiative fro Asthma (GINA). Global Strategy for asthma management and prevention. NHLBI/WHO workshop report. National Institutes of Health. National Heart, Lung and Blood Institute. January 1995. INH publication number 95-3569.