ANNEX I IX/2007
DESCRIPTION OF THE ACTION

1. OVERVIEW

1.1. Title

Geriatric study in Europe on health effects of air quality in nursing homes. - GERIE & No 2006343

1.2. Priority area and action

3. HEALTH DETERMINANTS (HD 2006)

3.3.2. PUBLIC HEALTH ACTIONS TO ADDRESS WIDER DETERMINANTS OF HEALTH: ENVIRONMENTAL DETERMINANTS

3.4 DISEASE PREVENTION

1.3. Summary (objectives, methods, expected results)

Background: Indoor air pollution (IAP) is a major global public health problem requiring increasing efforts in research and policymaking. IAP may have special significance for elderly that are likely to spend most of their day indoors and appear to be particularly susceptible to the adverse respiratory and cardiovascular effects (i.e. symptoms, exacerbations, mortality) of air pollutants. Yet, evidence existing on the effects of IAP in elderly is scanty.
Objectives: The GERIE study aims to: 1) assess health effects of major indoor air pollutants and thermal conditions in elderly (> 70 years) living stably in nursing homes, and 2) measure air quality and thermal conditions in these homes; in 8 European countries with contrasting lifestyle; to 3) explain health and environmental disparities in elderly in the EU and seek to identify best practices.
Methods: 8 nursing homes will be randomly selected in 8 European countries. In each nursing home, 20 individuals will be randomly selected. A follow-up study design will be used in order to allow investigating the evolution of air quality and health indicators. Major indoor air pollutants will be assessed twice with standardised procedures. Major health status indicators will be assessed twice and will include symptoms, diseases, neuropsychological status and medical records. Furthermore, the prognostic value in terms of severe morbidity and mortality of non invasive clinical tests and blood and urine biomarkers assessed at the inclusion of the individuals in the study will be determined. Standardised protocols and devices will be used to assess both clinical indicators and biomarkers. Exposures to occupational hazards and outdoor pollution will be modelled retrospectively. In the long term, gene-environment interactions will be searched for.
Expected results: The GERIE study will provide the inventory of air quality and thermal conditions in nursing homes across Europe and the knowledge of potential air related hazards to which elderly people are exposed in nursing homes.
To sum up, the main long-term purpose of the GERIE study is to improve the health of elderly who permanently reside in nursing homes or of those who are exposed to indoor air pollution because of reduced mobility. The study will bring up also information on mechanisms underlying the response of the organisms to air pollutants in elderly.

2. OBJECTIVES

Background

The main challenge for the future in industrialised countries is the aging of the population, particularly the growing number of very old people, and how they live in our cities (in terms of housing and social integration) or in nursing homes (quality of healthcare and management). In industrialised countries, approximately 5% of persons aged ≥ 65 years and 20% of those ≥ 85 years are nursing home residents (http://www.uscare.com). Medical care is an essential part of nursing home care and this is associated with an excessive use of disinfectants and cleaning products. Disinfectants, cleaning products and bio-contaminants are the major pollutants found in nursing homes[1]. Inadequate ventilation can increase indoor pollutant levels by not bringing in enough outdoor air to dilute emissions from indoor sources and by not carrying indoor air pollutants out of the home. High temperature and humidity levels can also increase concentrations of some pollutants. This is a crucial issue as elderly are at greater risk of the effects of air pollution because of increased exposure and vulnerability[2] [3]. There is scientific evidence that due to existing co-morbidity (including cardiovascular, chronic bronchitis, emphysema, and asthma), elderly suffer from reduced ability to breathe, and thereafter are greatly affected by the increased impairment that can result from exposure to air pollutants. Due to reduced activities, elderly result also to be more exposed to indoor air pollutants. Health effects of indoor air pollutants have been largely documented[4] except in elderly.

2.1. General objectives

The general objective of the GERIE study is to fill the gap that exists in the field of the knowledge of the effects of indoor air quality in permanent residents of nursing homes and similar places hosting stably elderly people in Europe. More explicitly, the GERIE study is intended to contribute to the knowledge on the current levels of air pollution and thermal conditions in nursing homes and similar places hosting stably elderly people and the associated health risks. The main long-term purpose of the GERIE study is to improve the health of elderly who permanently reside in nursing homes or of those who are exposed to indoor air pollution because of reduced mobility. Another general aim is to explain health and environmental disparities in elderly in the EU and seek to identify best practices. The study will bring up also information on mechanisms underlying the response of the organisms to air pollutants in elderly.

2.2. Specific objectives

More specifically, the GERIE study is intended to inventory on a community wide basis the current levels of air pollution and thermal conditions in nursing homes across Europe and to contribute an effort in the understanding of health risks in elderly permanent residents of nursing homes associated with thermal conditions and indoor air pollutants found there, among which cleaning products and biocontaminants related to infections. Furthermore, the GERIE study is intended to provide the best practicable protection to human influenza and other infections in elderly by setting an appropriate

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1 Makris AT, Morgan L, Gaber DJ, Richter A, Rubino JR. Effect of a comprehensive infection control program on the incidence of infections in long-term care facilities. Am J Infect Control. 2000 Feb;28(1):3-7.

2 Sandstrom T, Viegi G. Air pollution effects in the elderly. Eur Respir J 2003; 21: Suppl. 40. pp 1 -96.

3 Viegi G, Sandstrom T. Air pollution effects in the elderly. Abstract book of the workshop held in Pisa (Italy), March 12–14, 2001. Pisa, CNR.

4 Viegi G; Simoni M; Scognamiglio A, Baldacci S; Pistelli F, Carrozzi L, Annesi-Maesano I . Indoor air pollution and airway disease. Int J Tub Lung Dis. 2004; 8: 1-15

strategy. The ultimate objective is to provide a framework to help to improve air quality and thermal conditions in nursing homes and human health of elderly by setting health-based objectives for main air pollutants present in nursing homes.

Specific objectives of the GERIE study (and related WPs) are directed to:

(1) identify all routine and population-based data providing useful information on indoor air pollution, thermal conditions, health status and the relationships of indoor air pollution and thermal conditions to health status in institutionalized elderly (WP4). Particular attention will be put to take into account societal differences of the collected data;

(2) record at a population level and using standardised protocols new data on indoor air quality and thermal conditions in nursing homes where there live resident elderly people in various European countries (WP4);

(3) register at a population level and using standardised protocols new data on health status of elderly (aged > 70 years) that are resident in nursing home in various European countries, with a particular attention for cardiorespiratory health (WP5 and WP6). This will implicate the implementation of a database of standardised data on health status of institutionalised elderly persons;

(4) assess health effects of indoor air pollution and thermal conditions in elderly (aged > 70 years) (WP7 and WP8). This will implicate assessing the predictive values in terms of severe morbidity and mortality of various biomarkers;

(5) develop indoor air quality guidelines in nursing homes and public education and outreach and provide the Healthy Nursing Home Environment Assessment Tool (HNHEAT), a free software tool, to help nursing home systems to more effectively manage all of their environmental issues (WP2);

(6) an additional outcome that is expected from the GERIE study is constituted by recommendations on control policies for airborne infections, such as influenza, flu... These will concern both the environment and the individuals (WP9);

(7) in the long term, the collected data should allow the search for gene-environment interactions in the response to pollutants' aggression as well as in the expression of health effects in elderly as a biobank will be created (WP6).

2.3. Indicators chosen

Verifiable and quantifiable indicators allowing determining whether the specific objectives of the GERIE study will be reached are of 2 types: 1) scientific quality indicators and 2) project management indicators. Both are needed to measure that the planned activities have been achieved. They will be directly linked to the WPs. Inside each WP a step-by-step procedure will be followed in order to complete the objectives.

1) Scientific quality indicators:

They will consist of survey process indicators (PI) and/or outcome and long-term impact indicators (OLTI) (Table presented in WP3).

Process indicators

PI will include quantitative indicators classically employed in epidemiologic and clinical research in order to evaluate the pertinence of a study such as:

- sample size of the setting (nursing homes)

- sample size of the sample (elderly population)

- response rate to the questionnaires

- response rate to the medical visits

- failure rate in performing medical tests, including specimen samples

- failure rate in performing particular tests (i.e. spirometry (the OFT according to ERS/ATS guidelines))

- number of lost view

- pilot survey

In the case of WP9: the implementation of airborne infectious control policies will be assessed using a questionnaire for hospital nurses and admistrators, local audits and review of clinical records. The main outcome measure for assessment will be the verification of the adoption and publicisation of a written policy for health personnel and visitors. Secondary outcomes will be the rate of immunization and the number of flu-like disease assessed by reviewing clinical records.

A PI indicators checklist will be filled at the end of the conduction of the WPs in order to allow seeing whether the chosen indicators were adequate and whether they have been attained (see WP3). Similarly, a checklist to be filled at the end of the survey will be developed for the OLTIs (Table presented in WP3).

Furthermore, at the end of the survey, the global summary indicator checklist will be filled (Table presented in WP3).

2) Project management indicators:

They will include:

- respect of the timetable

- respect of the workplan

- quality control of the data

- number of people who visit the website

- adoption rate of the recommendations issued from the project

- adoption of the Healthy Nursing Home Environment Assessment Tool (HNHEAT) software

2.4. Rationale and relative merits of the project

Although an important goal is that each generation have better health among its older adults than preceding generations, age-related increases in the prevalence of chronic diseases and injuries or their *sequelae* are not expected to disappear. Older adults will continue to experience more chronic conditions than younger persons, experience more activity limitations and disability related to chronic disease, use more health-care resources because of chronic diseases, and have multiple chronic conditions (co-morbidities) among the oldest of the elderly. It has been suggested that air pollution could precipitate health status in elderly people because of their frailty.

Thereafter the justification for conducting GERIE is both societal and scientific.

- Europe's population is getting older (the greying for Europe).

By 2030, the EU will have 34.7 million citizens aged over 80 (compared to 18.8 million today) and the baby-boomer generation will become senior citizens (http://ec.europa.eu/employment_social/news/2005/mar/demog_gp_en.html). The impact on the whole of society of such demographic changes in terms of health and economic costs could be reduced by improving health status and quality of life of the elderly. One way to obtain it is through the prevention of the exposure to the contaminants that in elderly people are responsible for severe morbidity as well as for mortality. This passes through the assessment of exposure and of the burden associated to prolonged exposure to contaminants in elderly populations.

- The knowledge on adverse effects of air pollution in elderly is scanty.

Sparse population data indicate an ongoing threat to the health of the elderly population as the elderly appear to be particularly susceptible to air pollution[5]. However, the extent of the impact of air pollution in elderly is not exhaustively assessed. Similarly, the basis of the increased sensitivity in elderly is not known but it is likely that it is linked to age-related impaired function of the lung and deteriorated health status. These phenomena are influenced by a number of factors, both individual and environmental. Furthermore, elderly people spend most of their time indoors where the concentrations of several pollutants can be many times higher than outdoors and are therefore at increased risk of being exposed to indoor air pollutants compared to the rest of the population (sources). Although at low concentrations, indoor air pollutants present in nursing homes may have important biological impact on the health of elderly living there stably because of the long exposure periods. Also, nursing homes present extremely high concentrations of disinfectants, cleaning products and bio-contaminants, such viruses and bacteria, due to the conditions of confinement found there[5]. As a consequence, elderly living stably in nursing home constitutes a valid model for the study of the effects of air pollutants. Furthermore, there are still few studies having related biomarkers to indoor air pollution[6] [7]. A variety of mediators are involved in the host response to air particles, and several cytokines and inflammatory mediators have been proposed as markers of mucosal damage and inflammation, including TNF, GM-CSF interleukin 1, 4 , 6, 8, cationic protein, nitric oxide and other substances. Informative samples will be obtained non-invasively using nasal lavage or breath condensate or exhaled NO. New techniques for the multiplex analysis of several cytokines on the same sample have been recently developed and have been used for analysis of breath condensate in patients with respiratory diseases, but they have not yet used to characterize the nasal response to pollutants. Among clinical measurements, tear film stability and acoustic rhinometry are simple non invasive methods which may be used in children to evaluate respectively ocular and nasal irritation. To our knowledge, the GERIE study will be the first to investigate these relationships in elderly persons.

GERIE will be the first study to use different sources of information in relation to adverse health reactions of environmental hazards in older adults. It will contribute to a better knowledge of the role of biomarkers in the assessment of the role of atmospheric pollution.

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5 The AFORDEE (in Anticipation of Focus On Respiratory Disease in the European Elderly) initiative funded in the frame of F5 Eur allow to hold a workshop on "Air Pollution Effects in the Elderly" in Pisa, March 12–14 2001, which proceedings were published in an issue of the Eur Respir J (2003; 21: Suppl. 40),

6 Nel A. Atmosphere. Air pollution-related illness: effects of particles. Science. 2005; 308:804-6.

7 Norback D, Wieslander G. Biomarkers and chemosensory irritations. Int Arch Occup Environ Health. 2002;75:298-304

Lastly, the GERIE study will deal with the multi-pollution issue. At present, at the EU level there is not a general recommended approach to conduct the risk assessment for chemical mixtures or for combined effects due to concomitant exposure to different chemicals through different routes. Due to the complexity of indoor air pollution and its variability with time, estimation of risk associated with exposure to the complex mixture as such and the generalization of the obtained results is rarely feasible. The GERIE study has two WPs (WP7 and WP9) focusing this need. The chemical mixtures or combined effects will be characterised using statistical methods and modelling that will be developed in this respect.

3. EXPECTED RESULTS

3.1. Outcomes

The GERIE study is expected to provide:

• a state of art of existing data on the effects of air pollution on health in elderly living in nursing homes (specific objective 1);

• the inventory of air quality and thermal conditions in nursing homes across Europe (specific objective 2);

• standardised data on health status of institutionalized elderly people (specific objective 3);

• the knowledge of potential air related hazards to which elderly people are exposed in nursing homes, due to thermal conditions and to the presence of air pollutants (specific objective 4). This will include the estimation of the predictive values in terms of severe morbidity and mortality of biomarkers reflecting the integrity of the pulmonary barriers or renal function (specific objective 4);

• the implementation of indoor air quality guidelines in nursing homes and of the Healthy Nursing Home Environment Assessment Tool (HNHEAT) (specific objective 5);

• whenever possible, the implementation of recommendations on control policies at the administrative level (countries and local authorities) in order to ensure the application of the guidelines in the nursing homes;

• an additional outcome that is expected from the GERIE study is constituted by recommendations on control policies for airborne infections (specific objective 6).

3.2. Deliverables

Deliverable No	*Deliverable title*	*Delivery date*	*Nature*	*Confidentiality level*	*Dissemination*
D1.1 to D1.3	<u>WP1: Coordination of the project</u> D1.1: Action plan D1.2: Intermediate report of the activities of the project D1.3: Intermediate report of the activities of the project D1.4: Final report of the activities of the project	 M1 (+2) M12 (+2) M24 (+2) M38	 Report Report Report Report	 H H H L	 EC, PHEA, partners EC, PHEA, partners, Steering committee EC, PHEA, partners, public
D2.1 to D2.5	<u>WP2: Dissemination of the results</u> D2.1: Implementation of the GERIE Website D2.2: Publications of scientific results in peer-reviewed journals D2.3: Dissemination of guidelines to health authorities and stakeholders D2.4: Dissemination of recommendations in lay press and to stakeholders D2.5: Providing the Healthy Nursing Home Environment Assessment Tool (HNHEAT) in nursing home	 M3 to M36 M24 to M36 M36 (+2) M24 to M36 (+2) M24 to M36 (+2)	 Website Papers Fac-sheet Fac-sheet Fac-sheet, website	None	All the deliverables will be largely disseminated in order to reach countries and local authorities, scientists, physicians, caregivers as well as patients, relatives and public. However, scientific papers are not expected to be of interest to patients and public.

D3.1 to D3.3	<u>WP 3: Evaluation of the project</u> D3.1: 1st interim report covering D3.2: 2nd interim report covering D3.3: Final and evaluation report	 M1 to M12, due in M14 M13 to M24, due in M26 M1 to M36, due in M38.	All reports	High for the public	Only the final report will be disseminated
D4.1	<u>Environmental assessments</u> D4.1: Air contaminants and related sources in NH[ϰ] across Europe. Baseline and evolution data.	 M1 to M30	Report and databases Scientific paper(s) as final result	None after validation by experts	Reports and papers will be disseminated. The former to authorities. The latter to the scientific communities.
D5.1	<u>Clinical investigation</u> D5.1: Health status of elderly in NH. Outcomes assessments and observed results.	 M1 to M30	Report and databases Scientific paper(s) at the end	None after validation by experts	Reports and papers will be disseminated. The former to authorities. The latter to the scientific communities.

ϰ nursing homes

D6.1 to D6.3	<u>Biomarkers</u> D6.1: A European database providing the concentrations of cardiopulmonary and renal biomarkers in the elderly according to gender, age and disease. D6.2: Data about the influence of lifestyle and environmental factors, in particularly indoor pollutants, on the levels of these biomarkers. D6.3: Assessment of the predictive value of the studied biomarkers.	M6 to M30	Report, , databank and databases. Paper(s) at the end	None after validation by experts	Reports and papers will be disseminated. The former to authorities. The latter to the scientific communities.
D7.1 to D7.2	<u>Cross-sectional studies</u> D7.1: Information on the relationship between health status and environmental factors in NH in 8 European countries. D7.2: Evolution data on the relationship between health status and environmental factors typical of nursing homes in 8 European countries.	M1 to M27	Report and databases Scientific paper(s) at the end	None after validation by experts	Reports and papers will be disseminated

D8.1 to D8.3	Longitudinal study D8.1: Information on the role of health and environmental parameters in the prediction of severe morbidity and mortality in institutionalized elderly living in 8 European countries D8.2: Information on the influence of the severity of diseases and functional impairment in the development of severe morbidity and mortality in institutionalized elderly living in 8 European countries. D8.3: Information on how to take into account the effects of multiple exposures to pollutants.	M18 to M36	Report and database but in the case of D8.3 for which a statistical package is expected. Paper(s) at the end.	None after validation by experts	Reports, papers and statistical packages will be disseminated
D9.1 to D9.3	Airborne infection control policy D9.1: Questionnaire for COPD-friendly nursing homes. D9.2. Questionnaires for infection and indoor air quality control. D9.3: A report on airborne infection control in elderly across Europe.	M3 (+2) M3 (+2) M36 (+2)	Questionnaires, reports, fac-sheets and database. Paper(s) as final result	None after validation by experts	Reports and papers will be disseminated

4. METHODOLOGY

4.1. Methods used, references, significances

The GERY study would consist of a multicenter, European, cohort study, designed to collect and to integrate information belonging to several different aspects of the interaction between health status and the nursing home environment.

GERIE is a cohort study of elderly which will be followed-up almost 18 months, in order to investigate the evolution of key health and environmental indicators. The first phase of the study will be started at T1 (month 4) of the project and the second at T2 (month 22). The first phase will last 6 months (from m 4 to m 9) and will provide baseline health and environmental indicators. The second phase will last only 3 months (from m 22 to m 24) as the protocol will be simpler and the individuals would have already been contacted and known the procedures. This phase will provide data on the evolution of health and environmental indicators. A smaller sample size is expected because of morbidity and mortality and lost-of-view. At both phases of the survey, individuals will fill the same questionnaires and undergo the same physical examinations. Same indoor air contaminants and thermal conditions will be assessed during both phases. It must be underlined that the proposed non invasive methods do not need the contribution of the individual. Thereafter, they can be performed even in individuals suffering from depression or dementia. The written consent of the individuals or of the parents responsible for them will be asked for. The individuals will be duly informed.

Population

Eight nursing homes will be randomly selected in a geographical area representative of the city in each of the 8 countries participating in the GERIE study. In each nursing home, at least 20 individuals aged ≥70 years will be randomly selected to fill in standardised questionnaires on health and risk factors and undergo physical examination including noninvasive clinical tests such as breath analysis and blood and urine sampling for a total of almost 1200 individuals (almost 150 in each country). The size of the sample reaches the statistical power necessary to investigate the relationship between frequent exposures to indoor air pollutants and common diseases or symptoms. In each, the lack of representativeness of the sample of nursing homes will be checked using the information obtained in the state of art on “Nursing Homes across Europe”. This report will provide an idea of the estimated elderly population resident in homes in the eight countries. In each country, the list of residents will be obtained by the managers of the nursing homes after having filled the terms and the conditions of the respect of the privacy.

All the individuals randomly chosen will be included in the study in order to be interviewed and undergo the physical examination including the tests and specimen collection. Those with neurological or psychiatric problems (conditions which preclude the filling of the questionnaire) will only be visited by the doctor and undergo clinical investigation that does not implicate their reasoning. They will be enrolled after having obtained the contentment of their relatives. When the patient is not cooperative, a simplified version of the questionnaire will be filled by close relatives if they consent. Excluding the subjects with neurological and psychiatric problems will engender a major selection bias that is why they will be included in spite of the fact that for them less clinical data will be available.

In case of refusal at the recruitment, other individuals will be randomly chosen in the same nursing homes in order to attain the fixed sample. To this extent, in each NH, 50 names of elderly will be randomly selected before starting the field survey. The obtained ranking will be respected to recruit the individual.

An information plan to explain the study method to the individuals or to their relatives and receive their informed consent to be enrolled in the study will be prepared. It will contain an information letter and a consent form.

The study protocol will undergo the approval of the Ethical committee of each country as requested by the country law.

Methods

Environmental assessments will be performed in the living room, i.e. the room where the elderly persons pass the majority of their time, at the first cross-sectional survey.

In each nursing home, detailed inspection of the buildings will be performed. The buildings will be visited and measurements performed in the same time period as the medical investigations. Details on constructions, materials, type of ventilation system, and signs of building dampness will be recorded. Information on physical space e.g. m^2/person, m^2 of the living room / shared rooms will be collected.

Indoor climate parameters will be performed in each living room, in the same period while the clinical investigation is performed. Selected chemical and biological pollutants will be measured including room temperature, relative air humidity, PM_{10}, $PM_{2.5}$, $PM_{0.1}$, formaldehyde, nitrogen dioxide (NO_2); ozone (O_3), specific volatile organic compounds (VOC) and carbon dioxide (CO_2) concentrations.

Dust samples will be collected from floors and chairs by using vacuum cleaning in a standardised fashion and used for analysis of allergens (cat, dog, horse, house dust mites) and microbial markers (see below). Moreover, a simplified method to collect fungal and bacterial DNA will be evaluated, by means of a sterile top, from the upper part of the door frame, which contains dust accumulated during many months. The Petri-dish method (Karlsson et al., 2002) will be used to collect airborne particles, and analysed for allergens, bacterial DNA and fungal DNA. In addition, acoustics (reverberation time), noise level (dBA) and illumination (lux) will be measured in the living rooms. Information about daily (24h) mean outdoor temperature, relative outdoor air humidity, and wind velocity during the measurement days will be collected from local meteorological authorities, and during the colder part of the year (heating season).

All measurements will be made during normal activities and under representative conditions. Outdoor exposure measurements of chemical and microbial pollutants will also be performed during the same time period and by the same methods as the indoor measurements. To ensure the quality and reproducibility of data collection, a specialized Environmental Team will be established. Before the beginning of the field survey, members of the Environmental Team will organize a technical meeting to which at least one member of each centre should participate. The aim of the meeting is to describe the methods to be used and to provide some hands-on training to local operators who will be involved in the field survey. At least one member of the Environmental Team shall then participate in the field survey in each centre, with the help of the local operator trained in the preliminary technical meeting. After participating to the survey with the supervision of a member of the Environmental Team, local operators may become members of the team and participate as team member in surveys in other centres.

Assessments will be repeated at the second cross-sectional survey for the environmental parameters that have been shown to be meaningful (i.e. related to health or clinical indicators) at the first cross-sectional study.

Methodological details are as follows:

• Temperature, relative humidity, and carbon dioxide concentrations will be measured during two days by an instrument with data loggers (Q-track)

• Illumination will be measured at 20-30 points in each living room by a conventional lux-

meter, at two different days.

• Acoustics in the living room (reverberation time) will also be measured

• Noise level will be measured in the living room at three different conditions. Empty living room with windows closed and empty living room, windows opened. These measurements will both be performed during lunch time. In addition, noise measurements (dBA) during the day will be performed by an integrating sound meter. Microbial exposures will include

• Particles PM_{10}, $PM_{2.5}$ and ultra fine particles ($PM_{0.1}$) will be measured during two days by portable instruments with data loggers (Dust-track and P-track)

• In addition, high flow pumps (18 L/min) will be used to collect $PM_{2.5}$, PM_{10} particles on filter, for gravimetric analysis.

• Measurements of NO_2, and ozone is performed with two samples per living, each sampled during one week, with diffusion samples from IVL (Gothenborg, Sweden).

• Benzene and other specific volatile organic compounds (VOC) will be measured by passive samplers (either the ORSA diffusion sampler or the RADIELLO diffusion sampler) during the heating season with two samples per living room (one week sampling time), and by pumped sampling on charcoal tubes (0.25 L/min; 4 hours sampling time). Analysis will be performed by gas chromatography-mass spectrometry (GC-MS, Norbäck et al., 1995).

• Formaldehyde will be measured during one week by another diffusion sampler (RADIELLO or other) (Levin et al., 1988).

• ELISA/monoclonal antibodies will be used for allergen analysis (house dust mite, cockroach, mould allergens)(Kim et al., 2005) in settled dust and airborne dust.

• Viable and total airborne moulds and bacteria will be sampled on nucleopore filter, analysed by the CAMNEA Method (Palmgren et al., 1986)

• Bacterial DNA and fungal DNA in settled dust (and if possible in air samples collected), will be determined by quantitative PCR, in co-operation with Sangtec, Stockholm, and Ancona, Uppsala. General bacterial and fungal DNA, as well as species specific DNA for some more relevant species will be analysed. Measurement of species specific and general fungal DNA-sequences, by quantitative PCR (Vesper et al., 2005) will be performed in settled dust and airborne dust, collected by the Petri dish method. Recent studies indicate that bacterial DNA as such can be a potent stimulator for the immune system, and that endotoxin is a marker of bacterial DNA (Roy et al., 2003). DNA analysis of fungal sequences have been recently developed (Vesper et al., 2005).

• Chemical markers (ergosterol for fungal biomass, muramic acid for bacterial peptidoglycan, and 3-hydroxy fatty acids for endotoxin) will be analysed in settled dust sampled by vacuuming floor and chairs according to a standardised protocol and analysed by gas chromatography/ tandem mass spectrometry (GC-MSMS) (Saraf et al, 1999; Sebastian and Larsson, 2003).

• Microbial particles by an electrostatic samples (5 L/min flow) and used for viral analysis

• Irritants from disinfectants (e.g. chlorine) by classical analysis

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Health assessments

Questionnaires and neuropsychological test during the 2 cross-sectional surveys

An epidemiological questionnaire including a depression scale and 2 test interviews to identify the presence of depression and cognitive problems will be administrated by trained personnels to all the selected elderly individuals. Some facultative tests to evaluate cognitive performance and quality of life will be proposed to individuals that agree. They will be performed by trained personnels. In the case of non response or refusal from the elderly, close relatives will be interviewed with a simplified questionnaire.

Elderly

Assessment of symptoms and diseases will be done using a questionnaire, which will be derived from published experiences and will be validated by site inspection and by analysis of clinical records in a randomized sample. We will use the questionnaires of the European Respiratory Health Survey (ECRHS) (Burney et al., 1994) and of the Three-City Study which has been conducted in older French adults on cognitive decline

and vascular aging (Zureik et al, 2005). The latter questionnaire contains questions on cardiovascular diseases, depression and dementia. Questions on depressive symptoms in it are derived from the Center for Epidemiological Study Depression Scale and the Mini-International Neuropsychiatric Interview to assess history of major depressive episodes (MDE). The questionnaire also contains questions on personal factors and medical background data, such as smoking habits, alcohol consumption, medical consumption, socio-economic conditions, familial status, occupational history, exposures in the home environment in the past as well as brief information about other morbidities. Risk factors for illness and disability will be recorded.

The AB Clinician Depression Screen (ABCDS), comprising five questions, will rapidly allow identifying patients with depression or eliminate that diagnosis (Molloy et al). The 5-word cognitive test (Robert et al. 2003) will be performed in order to measure the cognitive function of the elderly and evaluate its evolution in time. For those who will agree, cognitive function will be evaluated by several neuropsychological tests including the Mini-Mental State Examination (MMSE), Trail Making Test, Isaacs Set Test and Benton Visual Retention Test[8]. Urinary incontinence (UI) severity will be measured by SANDVIK's index[9]. General quality of life will be also assessed with well-known standardised instruments (SF-36, Nottingham Health Profile, Contilife QoL specific for UI)[9.] Information upon chronic diseases of which the elderly is suffering will be collected using the clinical records of the nursing homes. The feasibility of the administration of the questionnaires will be tested during the pilot study.

Relatives

Questionnaire for relatives will contain questions relative to the individual´s and family medical history, home environment, socioeconomic background, food and lifestyle. The assessment of symptoms and diseases and functional impairment at the period of the survey will be performed during the medical visit that accompanies clinical tests. A working group will be set up to define the questionnaire and to translate and back-translate it in all the languages of the partners.

Clinical investigation

All clinical investigations are performed in the nursing home, in the same period as the first environmental survey, by an experienced nurse or specialist physician, under the supervision of at least one member of a specialized Clinical Team formed according to the same rules as described for the Environmental Team above. A technical meeting to prepare and train local operators involved in the field survey will be held at the same time as the Environmental technical meeting.

The clinical investigation includes measurement of electrocardiogram, spirometry (by the forced oscillation technique (FOT), tear film stability (BUT) to assess the functionality of the eye, nasal patency measured by acoustic rhinometry, CO in exhaled air or according to the capacity of the individual. Furthermore, NO in exhaled air, and rinsing of the nasal mucosa and breath condensate will be performed in order to assess markers of nose and airways inflammation. All the assessments will be performed using

8 Godin O, Dufouil C, Ritchie K, Dartigues JF, Tzourio C, Peres K, Artero S, Alperovitch A. Depressive symptoms, major depressive episode and cognition in the elderly: the three-city study. Neuroepidemiology. 2007;28(2):101-8. Epub 2007 Apr 4.

9 Saadoun K, Ringa V, Fritel X, Varnoux N, Zins M, BrÃ©art G. Negative impact of urinary incontinence on quality of life, a cross-sectional study among women aged 49-61 years enrolled in the GAZEL cohort. Neurourol Urodyn. 2006;25(7):696-702.

the same portable devices in all the centres and according a standardized protocol (Dr Isabella Annesi-Maesano, Paris (FOT and electrocardiogram), Prof. Dan Norback, Upsala (BUT), and Prof Torben SIsgaard, Aarrhus (acustic rhinometry, NO, CO, breath condensate) will provide the device). Field personnel will be trained for the purpose of GERIE.

Electrocardiogram (including blood pressure assessment) will be performed according to the guidelines of the European Society of Cardiology. FOT (Guo et al, 2005) has been chosen as it does not demand the participation of the subjects. It will be performed according to the guidelines of the European Respiratory Society. Tear film stability will be estimated in each subject by two standardized methods: by measuring the time the subject could keep the eyes open when watching a fixed point at the wall (Wieslander et al., 1999; Wieslander et al., 2000) and directly, using a small eye microscope (Keeler Tearscope Plus. Keeler UK). Acoustic rhinometry℘ (Rhin 2000; wideband noise; continuously transmitted) is performed under standardised forms (sitting), after 5 min of rest, and prior to the lavage (Wieslander et al., 2000). NO is measured in exhaled breath by a portable equipment (NIOX MINO). Carbon monoxide (CO) will be measured in exhaled air using a portable device (Smokerlyzer, www.bedfont.com).

For the nasal lavage, the subjects are sitting, with their head flexed ca 30 degrees forward. It will be operated with a 20 ml plastic syringe attached to a nose olive The room-tempered (20-22 C) sterile 0.9% sterile saline solution is introduced into the nasal cavity (Norbäck et al., 2000). Each nostril is lavaged with 5 ml solution, which is flushed back and forth five times via the syringe at an interval of a few seconds. The fluid is transferred into a 10 ml polypropylene centrifuge tube. Samples are kept on ice and within 300 minutes the solution is centrifuged at 800 g for five minutes. The supernatant is recentrifuged at 1,400 g for five minutes and immediately frozen to -20 C. Exhaled breath condensate will be collected by breathing for 10 minutes through a tefloncoated metallic tube previously cooled at -20° C and kept in a vertical position. The frozen liquid coating the inner surface will be pushed in a tube with the use of a plastic plunger and immediately frozen at -20°C. Both nasal and exhalate samples will be shipped to the centralized laboratory (Partner 3) in dry ice.

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℘ By means of acoustic reflection the minimum cross-sectional areas (MCA) on each side of the nose is measured from 0 and 22 mm (MCA1) and from 23 and 54 mm (MCA2) from the nasal opening. Also, the volumes of the nasal cavity on the right and the left sides is measured from 0 and 22 mm (VOL1) and from 23 to 54 mm (VOL2). The mean values are calculated from three subsequent measurements on each side of the nose.

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Biomarkers

Biomarkers will be assessed during the first cross-sectional survey and will include:

- Biomarkers of nasal inflammation and breath condensate.

Nasal lavage (NAL) will be assayed for an array of cytokines (IL-1, TNF, IL-6, IL-8) by means of a multiplex cytofluorimetric assay (Luminex). The Luminex technique enables the measurement of many different analytes in the same test with a minimum of test material. (100µl)1. In each individual we will include markers for acute inflammatory responses (TNF-alpha and IL1, IL-6, IL-8) for inflammatory responses to a 10-plex assay of NAL on the Luminex platform. Lysozyme will be analyzed by radioimmunoassay. Albumin is measured by rate nephelometry on an Array protein system (Beckman Instruments Inc). Exhaled breath condensate will be analyzed for IL-1 by high sensitivity kits from R&D, for pH and for conductivity. All these analyses will be performed at a centralized laboratory in Arrhus (Prof. Torben Sisgaard, Aarrhus).

- Serum or urinary markers reflecting the integrity of the pulmonary barriers (SP-D, CC16 in serum) or renal function (serum Cystatin C, urinary RBP and albumin) (Hermans and Bernard, 1999).

After approval by the institutional ethics committee, one blood sample (10 ml) and one spot urine sample will be collected for each patient both in the first cross-sectional survey and in the follow-up study. A section of the main questionnaire (see above) filled by the patient or his/her family will collect information about the medical history of the patient, his occupation and the various environmental (indoor pollutants) and lifestyle factors (smoking, sport, alcohol..) likely to be linked to affect the respiratory tract and the renal function. In serum, we will measure Clara cell protein (CC16) and surfactant-

associated protein D. These two proteins have been validated as markers of the integrity (permeability or integrity of cells secreting them) of the lung epithelium. Not only markers have been found to be altered in a variety of lung disorders (COPD, fibrosis...) and of lung toxicants, but recent studies suggest they might be precitice of an increased risk of mortality. We will also measure serum Cystatin C, a sensitive and reliable marker of the glomerular filtration rate that has been found to predict mortality in elderly. In urine, we will determine albumin and retinol-binding protein (RBP) to assess the integrity of the glomerular filter and of the proximal tubule respectively. These renal markers are frequently altered in elderly as a result of degenerative (diabetes) or cardiovascular diseases. Concentrations of urinary proteins will be adjusted for creatinine. All these markers will be determined using sensitive immunoassays in a unique laboratory in Brussels (Prof. Alfred Bernard).

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Airborne infection control policies

This workpackage will include: 1) a global questionnaire survey to be conducted in all the nursing homes and 2) a satellite study to be conducted only in one centre.

1) All nursing homes

At T1 questionnaire survey will be conducted in people living or working in all the European nursing homes recruited for the environmental studies (nursing home residents, caregivers, and administration staff). The questionnaire will contain information on a variety of aspects including the presence and characteristics of Infection Control and/or Indoor Air Quality policy, incontinence management practices; immunization policy about residents and heath caregivers; occurrence and type of infection outbreaks (particularly respiratory, urinary, cutaneous and gastrointestinal infections); presence of infection control guidelines for indwelling devices, antimicrobial resistant pathogens, diarrhoea, and pressure ulcers; employee education regarding infection control, smoking, asthma and COPD tobacco smoking policy, availability of tobacco smoking programs for nursing home residents and caregivers.

The questionnaire will be derived from published experiences and will be validated by site inspection and by analysis of clinical records in a randomized sample (Roup BJ et al, 2006). An additional questionnaire for “COPD friendliness” will be derived from the “asthma-friendly school checklist” (http://www.lungusa.org)

Serum samples will be specifically obtained from each nursing home resident to evaluate seroepidemiology of influenza virus A and B using enzyme-linked immunosorbent assay.

2) Satellite study

To provide a more thorough assessment of the possible impact of airborne infection control measures, a satellite study will be conducted in one of the centers (Prof. Piersante Sestini, Siena) between T1 and T2. In addition to the studies described above and in other workpackages, outdoor and indoor environmental conditions (particularly

temperature, humidity, PM_{10}, CO_2 and ultrafine particles) will be repeated at monthly intervals for one year, to provide a more careful estimate than allowed by a single measurement. Colonization by *pneumococci* will be evaluated in residents and caregivers using throat swab cultures and PCR analysis using standardised methods. Infection outbreaks by influenza, respiratory syncitial virous (RSV) and metapneumovirus will be actively monitored by PCR analysis of throat swabs of suspected cases. The measurements will be repeated at T2 after modifying the infection control policy to address all the critical factors detected during the previous local assessment. Depending on the findings of the preliminary survey, these could include changes in air quality control (i.e. Improved ventilation), vaccination (i.e. Pneumococcal vaccine), caregiver vaccination and control (including antiviral prophylaxis when a case occurs) during influenza season, more accurate monitoring, and other *ad hoc* measures, according to the "Infection Control Measures for Preventing and Controlling Influenza Transmission in Long-Term Care Facilities" of the Center of Disease Control

(http://www.cdc.gov/flu/professionals/infectioncontrol/longtermcare.htm).

Both study protocols will undergo the approval of the Ethical committee of each country as requested by the country law. The elderly will be informed. A written consent will be signed.

References

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Variables for the analyses

They will be defined according to the literature (see previous references) as follows:

- environmental data include indoor air pollutants, luminosity, noise and weather conditions according to the existing literature. Continuous and categorical quartile variables will be used in the analyses, the latter to define classes of exposure of the individuals. The definition of extreme climate conditions will be site specific in order to reflect local conditions. Heat waves will be defined as days with maximal temperature > 90^{th} annual percentile and for the first day an increase of 2°C compared with the previous days. This definition was elaborated on the basis of the literature **(**Extreme Weather Events And Public Health Responses Par R. (EDT) Bertollini, Bettina Menne, Wilhelm Kirch). In analogy, cold waves will be defined as days with minimal temperature < 90^{th} annual percentile;

- urine and blood markers of the integrity of the pulmonary barriers or renal function. Continuous and categorical quartile variables will be used, the latter to define classes of exposure of the individuals;

- noninvasive tests of airways inflammation. Data on nasal dimensions in the present study are presented as the sum of the values recorded for the right side and the left side. Elsewhere continuous and categorical variables will be considered;

- electrocardiogram and spirometry will be defined according to the existing literature;

- data on health status drawn from clinical investigation, clinical records, epidemiological questionnaires and scales for cognitive impairment (the 5-word scale), depression (the AB Clinician Depression Screen (ABCDS) and quality of life ((Contilife QoL, SF-36, Nottingham Profile) will be defined according to the existing literature. Facultative neuropsychological tests will be scored according to the literature.

A compilation of selected indicators measuring health status, non-medical determinants of health, health system performance, and community and health system characteristics in elderly will be provided:

- morbidity data according to the physician's diagnosis and the clinical record

- results of the clinical tests performed in the survey as described in WP5 and WP6

- disability

- service-use rates in terms of specialised consultations, visits...

- mortality data

Links to the ECHI database will be set as much as possible and the variables defined accordingly. The ECHI (European Community Health Indicators) project was carried out in the framework of the Health Monitoring Programme and the Community Public Health Programme 2003-2008. The result is a list of 'indicators' for the public health field arranged according to a conceptual view on health and health determinants (http://ec.europa.eu/health/ph_information/dissemination/echi/echi_en.htm).

With concern to WP9, tools will contain a questionnaire survey of health operators, patients and family caregivers about current policies of infection control and vaccination and frequency of infectious episodes in the previous year (validated by influenza seroepidemiologic study and by inspection of clinical records in a random sample).

Epidemiological and statistical analysis

Classical methods of epidemiology and statistics will be used. Health outcomes will be defined according to the existing literature. The prevalence of each outcome will be estimated according to age (in class), sex and centre. For each indoor air pollutants, the distribution will be provided by centre. Exposure to indoor air pollutants of the individuals participating in each survey will be defined according to the median of the distribution. However, it is not excluded to correlate continuous values of the pollutants with health outcomes measured in continuous (HTA, Forced Expiratory Volume in 1sec…). Uni- and multi-polluant models will be developed. Data from the two cross-sectional studies (phase 1 and 2 of the cohort study) will be analysed separately to determine ecological evolutions of air quality and health in nursing homes of Europe. The analysis will be stratified according to whether the individuals have replied to the questionnaires or not.

Potential confounders of the relationships between exposure and health indicators will be defined as usually and taken into account in the analyses. Expected confounders include, sex, social class, education center, active and passive smoking, previous exposure to air pollutants, co-morbidities… Past exposures to occupational and environmental hazards, will be assessed also retrospectively. In particular, exposure to outdoor pollution will be modelled using appropriate approaches.

The sex/gender issue as well as the societal dimension which depend among others on the country will be taken into account. Thereafter, data will be presented also after stratification.

Furthermore, analysis of missing data will be performed.

The methodology of case-control and cross-over studies will be used in WP9.

Lastly, the GERIE study will collect data to be used in the search for gene*environmental interactions in the response to indoor pollutants and in the expression of the disease to be conducted later.

References

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4.2. Analysis of the risks and contingency planning

The risks which can engender the implementation of the GERIE study can be classified in terms of the following three criteria and corresponding categorical scores.

- Probability of event: high/medium/low
- Magnitude of impact: high/medium/no action
- Action (when magnitude is medium or high): action to be taken
- explanation (when magnitude is 'no action'): explanation of low impact

Project risks

1. Nursing home sample size is inadequate[ϒ].
a. Probability of event: medium.
b. Magnitude of impact: high.
c. Action: It is possible to find other nursing homes.

2. Population sample size is inadequate.
a. Probability of event: medium.
b. Magnitude of impact: high.
c. Action: It is possible to find other individuals.

3. Response rate to questionnaires is insufficient
a. Probability of event: low.
b. Magnitude of impact: medium.

ϒ In each centre, nursing homes are randomly selected. However, the general objective is to be representative. This will be allowed by information obtained with "Nursing homes across Europe : the state of art describing ».

c. Action: Providing help to fill questionnaires.

4. Response rate to medical visit is insufficient.
a. Probability of event: low.
b. Magnitude of impact: medium.
c. Action: Providing help to see the doctor.

5. Excessive failure rate in performing medical tests.
a. Probability of event: medium.
b. Magnitude of impact: no action for some individuals.
c. Explanation: Overabundance of "invalid" medical test outcomes as not correctly performed.

6. Excessive failure rate in performing spirometry.
a. Probability of event: high.
b. Magnitude of impact: no action.
c. Explanation: In general, the FOT we will use in the survey is easy to perform.

7. Excessive lost of view by death.
a. Probability of event: medium[ℑ].
b. Magnitude of impact: no action.
c. Explanation: Death will be informative in longitudinal analysis.

8. Excessive lost of view (not for death).
a. Probability of event: medium[ℜ].
b. Magnitude of impact: medium.
c. Explanation: Lost of view will be contacted by mail, phone, home visits in order to obtain information on their health status and to control whether they have died in the meanwhile.

Another major risk which may endanger the implementation of the GERIE project is represented by the delay in obtaining the authorisation from ethic committee in the various countries. In order to avoid this, the authorizations will be requested as soon as the project starts.

It must be underlined that many partners have already worked together and with success in the frame of the HESE project.

ℑ Estimation of death number should be available after having contacted the nursing homes.

ℜ This will be established by looking the records of each NH in the past 5 years.

4.3. Work package overview

Work-package (WP) No	*Work package title*	*Lead partner*	*Number of person days*	*Global cost (€)*	*Starting date*	*Ending date*	*Deliverable No need to be defined*
WP 1	Coordination of the project	UPMC-Paris	260	158016	M1	M36 (+2)	D1.1, D1.2, D1.3, D1.4
WP 2	Dissemination of the results	CNR-PISA and UPMC-Paris	198	67798	M3	M36	D2.1, D2.2, D2.3, D2.4, D2.5
WP 3	Evaluation of the project	UPMC-Paris and others	73	28459	M1	M36 (+2)	D3.1, D3.2, D3.3
WP 4	Environmental assessments	UU-Uppsala	139	109117	M1	M30	D4.1
WP 5	Health assessments	UAAR-Aarrhus	138	74589	M1	M30	D5.1
WP 6	Biomarkers	ULB-Brussels	138	65513	M6	M30	D6.1, D6.2, D6.3, D6.4
WP 7	Cross-sectional studies	UPMC-Paris and others	1520	318900	M1	M27	D7.1, D7.2
WP 8	Longitudinal study	UPMC-Paris and KCL-London	368	98658	M18	M36	D8.1, D8.2, D8.3

WP 9	Airborne infectious control policies	Siena	127	77226	M5	M36 (+2)	D9.1, D9.2, D9.3
Tot			**2961**	**998276**			

4.4. Time schedule

Work package	M 1	M 2	M 3	M 4	M 5	M 6	M 7	M 8	M 9	M 10	M 11	M 12	M 13	M 14	M 15	M 16	M 17	M 18	M 19	M 20	M 21	M 22	M 23	M 24	M 25	M 26	M 27	M 28	M 29	M 30	M 31	M 32	M 33	M 34	M 35	M 36	M37	M38
WP 1	M1								S				M2							R				Mint.			S			D						M3+R		
WP 2			W																																	W+ R		P
WP 3														R												R										R		
WP 4				E	E	E	E	E	E	A	A											E	E	E	A					R+ D								P
WP 5				C	C	C	C	C	C		A	A																		R+ D								P
WP 6						A	A	A	A																					R+D								P
WP 7			F	F	F	F	F	F	F															F	F	F	F						D+R					P
WP 8																																				R+SP		
WP 9						I																I					R											
WP 10																																						

A = assessments
C = clinical investigation
D = databank, database
E = environmental survey
F = field survey
I = infection survey (beginning and end respectively)
M = meeting (1, 2, intermediate, 3) will be reported in minutes
P = publications
Q = questionnaire
R = report
S = survey (end of the survey)
SP = statistical package
W = operational website

5. WORK PACKAGES DECRIPTION

The work plan of the GERIE study is composed of the following scientific WPs:

WP4: Environmental assessments. In order to define a standardised protocol and to assess major indoor contaminants in the randomly selected nursing homes at the beginning and the end of the cohort study.

WP5: Clinical investigation. In order to define a standardised protocol to assess health status of elderly individuals at the beginning of the cohort study, with a particular attention for cardiorespiratory symptoms and diseases.

WP6: Biomarkers. In order to define a standardised protocol to assess biomarkers of health and environmental effects at the beginning of the cohort study.

WP7: Cross-sectional studies. The two cross-sectional studies conducted at T1 (month 4) and T2 (month 22) respectively in the same individuals that compose the 2 phases of the cohort study. The first phase of the study will last 6 months (from m 4 to m 9) and will provide baseline health, clinical and environmental indicators using methods identified by WP4 , WP5, WP6. The second phase of the study will last only 3 months (from m 22 to m 24) as the protocol will be simpler and the individuals would have already been contacted and known the procedures. This phase will allow collecting health and environmental indicators. In order to ensure comparability of data, at both cross-sectional studies, the individuals will fill the same questionnaire and undergo the same physical examinations and neuropsychological tests. Indoor air contaminants and thermal conditions will be assessed during both cross-sectional studies using the same methods.

WP8. Longitudinal study. In order to assess the predictive value in terms of severe morbidity and mortality as assessed at the end of the follow-up (at T2) of baseline (at T1) health and environment indicators and of the interrelationships among them. Information on health and environment from the two phases of the study will be used for a longitudinal analysis in which the predictive value in term of severe morbidity and mortality of baseline indicators will be established.

WP9. Airborne infection control policies in European nursing homes. This consists of an intervention in a group of nursing homes to promote adoption of validated infection and vaccination policies for influenza and *S. pneumoniae* (http://www.cdc.gov/flu/professionals/infectioncontrol/longtermcare.htm). This workpackage is linked to WP7 but has also a proper investigation which consists of the follow-up of some individuals in some nursing homes in order to verify the implementation, acceptance, sustainability and effectiveness of infection control policies, particularly on influenza and *pneumococcus* infections.

Ethical committees and local authorities will be consulted in order to obtain the authorizations necessary to conduct the surveys. Individuals will give their consent.

5.1. Work package n° 1: Coordination of the project

5.1.1. List of partners involved

UPMC - Paris

5.1.2. Description of the work

This work package is linked to all the specific objectives.

The coordination will be ensued by UPMC.

UPMC, as a leading national university in France, has considerable experience of national and international activities, some at the European level. UPMC has participated in several collaborative European projects, and co-ordinated some of which. Dr Isabella Annesi-Maesano will be responsible for overall project management in cooperation with UPMC. She leads the Allergic and respiratory diseases Dept at UMR-S 700 INSERM - UPMC and has responsibility for a research programme. The French NIH (INSERM) to which IAM belongs has also considerable experience in national and international activities.

As Project Co-ordinator, Dr Annesi-Maesano will be responsible for:

• The overall progress of the project

• Meeting of milestones and deliverables

• Ensuring high quality of experimental and written outputs and reports

• Meeting the contractual obligations of the project in relation to reporting and financial matters and other issues that may arise

• Overall planning of the project

• Organisation, chairmanship and reporting of progress meetings and technical meetings

• Maximising the dissemination activities of the project required to optimise its impact

• Resolving any conflict that arises in the project, through discussions with the relevant parties and reference to the PHEA/EC where necessary.

Four consortium meetings are planned (M1, M13, M24, M36), eventually during the ERS annual meetings. The GERIE "plan of action" will be delivered as outcome of the first project consortium meeting

5.1.3. Milestones

Date	*Milestone*
M1-M3	Completion of the unique protocol as an integration of protocols of WP4 (environment), WP5 (health), WP6 (biomarkers), WP7 (field)
M3	Selection of the nursing homes and of the individuals
M3	Completion of the pilot survey

M4-M9	Completion of phase I. Field survey, data collection
M12+2	First interim assessment and report
M225-M24	Completion of phase I. Field survey, data collection
M24+2	Second interim assessment and report
M30	Completion of the databases
M30-M36	Completion of the statistical and epidemiological analyses (cross-sectional and longitudinal)
M36+2	Delivery of the final report
M36+2	Completion of procedures and guidelines for clean air in nursing homes.

5.1.4. Deliverables

Four are the deliverables of this WP:

D1.1: Action plan
D1.2: Intermediate report of the activities of the project
D1.3: Intermediate report of the activities of the project

D1.4: Final report of the activities of the project

All the partners will be concerned by this WP.

5.2. Work package n° 2: Dissemination of the results

5.2.1. List of partners involved

IFC-Pisa and UPMC-Paris

5.2.2. Overall strategy and methods

Dissemination activities

A carefully targeted dissemination strategy will be followed to maximise the impact of the project, both within the project period and following its completion. The principal dissemination activities and routes are summarised below:

Recommendations: The principal dissemination route for the outcomes of this project will be through appropriate medical and scientific societies and committees for the development of new and improved recommendations. Those implicated in the care of elderly will be considered more particularly (see below). This dissemination will occur throughout the project period and also beyond the project completion date as the project's final recommendations are implemented. The participation of all the partners on relevant EU committees will be critical in achieving this plan and will help to speed up change.

Best practice: Specific Best practice guidance will be produced on the different workpackages in the project to ensure a consistency of approach and lead to common practice across Europe. The Healthy Nursing Home Environments Assessment Tool (HNHEAT), a free software tool, to help nursing home systems to more effectively manage all of their environmental issues will be available in a modular format that and also will be offered as a combined package that deals with the entire chain. In addition to making this package available in paper format, it will also be included on the project Web site for open access. Awareness of the best practice guidance will be promoted through article in relevant journals.

Scientific Journals: Publication of papers in scientific journals and at relevant conferences will be carried out to reach the European research community. At least one scientific paper per year is anticipated

Web site Project: A web site for the project will be established at its inception which will be used to raise awareness of the project objectives and will include relevant outputs as they are produced during the project. The web site will contain the e-mail address of the Co-ordinator to facilitate electronic communication with interested parties outside the project. The web site will be linked to the web sites of other organisms and bodies implicated in the health and care of elderly. The web site project will be conducted by a subcontractor.

Together the activities described above will help to maximise impact both within and outside the project. Any other opportunities that rise that help to promote take-up of the projects findings will be considered and appropriate actions taken.

5.2.3. Objectives

- Make available to involved nursing homes, professionals, and to the general public information, protocols and results of the study as well as general information on the importance of indoor air and infection control in nursing homes.

5.2.4. Description of the dissemination work

Promoting awareness is seen as a major tool to obtain significant changes by eliciting action by local communities. As a result, dissemination of the results will be a key component of the project, addressing nursing homes communities, health professionals, health authorities, families, and the general public. Specific actions will be conducted toward each of these groups, to ensure maximal awareness of our study. The exact role of the authorities will be defined after the review of the literature describing NH in Europe. An individualized report will be provided to each stakeholder, each participating institution and to local authorities with a summary of the results and suggestion for improvements. Health professionals will be addressed by communications at scientific meetings and by publications on large access, peer reviewed journals. Guidelines and recommendations will be disseminated during medical conferences and similar events

All the partners will be concerned by this WP. The participation in the project of many officers of the leading European scientific society in the field of respiratory health (ERS) will greatly assist in the dissemination of the results among the public and the health professions. Contacts will be sought with European associations such as AGE (European Older People's Platform, www.age-platform.org), EURAG (European Federation of Older People, http://www.eurag-europe.org/), ECHO (European Confederation of Care Home Owners, www.echo-eu.com) and with their national affiliates, to ensure maximal diffusion of the results to all the parties interested in their optimal exploitation.

The general public will be reached by making all the results and development of the study available through our web site, with public initiatives to be covered by media at the local level, and by attracting media attention to national and international conferences where the results will be communicated.

5.2.5. Milestones and deliverables

Five are the major deliverables:

Dissemination of the results

D2.1: Implementation of the GERIE Website

D2.2: Publications in peer-reviewed journals

D2.3: Guidelines (to health authorities and stakeholders)

D2.4: Dissemination of recommendations in lay press and to stakeholders

D2.5: Providing the Healthy Nursing Home Environment Assessment Tool (HNHEAT) in nursing home.

All the partners will be concerned by this WP.

5.2.6. List of stakeholders

A wide range of stakeholders are expected for GERIE, including patients and the public; local and regional NHS organisations; local authorities and social care providers; charities, the voluntary and community sector; and many others. Contacts will be sought with European associations such as AGE (European Older People's Platform, www.age-platform.org), EURAG (European Federation of Older People, http://www.eurag-

europe.org/), ECHO (European Confederation of Care Home Owners, www.echo-eu.com) and with their national affiliates, to ensure maximal diffusion of the results to all the parties interested in their optimal exploitation. This list is not exhaustive.

5.3. Work package n° 3: Evaluation of the project

5.3.1. List of parties involved

UPMC-Paris

5.3.2. Description of the work and methodologies

The objectives consist of a:

- formal evaluation of the project reports by the project co-ordinator by: a) listing concrete achievements based on clear definitions of indicators and on the elaboration of an evaluation plan, b) outputs, c) meeting the formal requirements of the contract.
- continuous in-depth examination of the project implementation (monitoring).

The following elements will be considered for the in depth evaluation.

1. Ability to carry out the action successfully: a. Follow-up and synthesis of the project indicators' values. b. Attention to partnerships within the consortium - synergy - added value of cooperation - assessment of the efficient use of the partners' complementary competencies. c. Survey and analysis of (formal or informal) feedbacks experienced during the project implementation from partners in the field. d. Survey about the development of the policy and social environment, their influence on the project's aims. e. SWOT (Strengths Weaknesses Opportunities Threats) analysis of the project – collecting and comparing all partners' opinion.

2. Scientific excellence: a. Evaluation by strengthened peer review system (European Respiratory Society) - individual reviews - panel sessions - hearings of experts.

3. European added value: Synergy with other similar EU initiatives. b. Proposals for future actions, continuation, deployment of the project.

4. Knowledge management: a. Approach systematically and efficiently the accumulated information and experience. b. Inventory of the new aspects, approaches, tasks, ideas emerged during the realization – in comparison with the initially used ones. c. Continuous cooperation with the Commission to present achievements and highlight emerging potential of the project. d. "Communication interface" (web site) towards partners and users of project outcomes.

The tools will be:

Mid-term peer review:

- 2 individual reviews by experts

- one panel session within ERS members (Health and Environment Committee)

- building the midterm evaluation report

Final peer review:

- 2 individual reviews by experts

- one panel session within ERS members (Health and Environment Committee)

- building the final evaluation report

N.B. The ERS offers highly qualified competence in both health and environment and will be willing of participating in this process (I. Annesi-Maesano is head of the ERS Assembly Occupation and Epidemiology, and member of the Health and Environment Committee of the ERS).

Three are the deliverables of this WP.

D3.1: First interim report
D3.2: Second interim report

D3.3: Final and evaluation report

There will be links with:

- WP1 “Project Management”

- “Indicators”

- “Analysis of risk”

that have been already presented previously.

All the partners will be concerned by this WP.

Indeed, indicators and analysis of risk will be used to evaluate whether the specific objectives of the GERIE study are reached. As indicated in chapter 2.3 of this annex, both scientific quality indicators (Process Indicators (PI) and Outcomes and Long-Term Impact (OLTI) Indicators respectively) and project management indicators will be used Scientific quality indicators are presented in the following table.

Scientific quality indicators summary sheet

	Process Indicators (PI)	**Outcomes and Long-Term impact (OLTI) Indicators**
Specific objective (WP)		
(1) Identify data on the relationships of indoor air pollution (IAQ) and thermal conditions to health status in institutionalized elderly **(WP4)**	PI 1: Use data sets to prepare basic descriptive analyses related to elderly health issues associated with exposure to IAQ to address country- and local-specific knowledge base gaps	OLTI1: A state of art on the topic will be produced and submitted in a peer-reviewed journal
(2) Inventory and record new data on indoor air quality and thermal conditions in nursing homes (**WP4)**	PI 2: Sample size of nursing homes (NH). At least 80% of the selected nursing homes *(in order to avoid selection bias)*	OLTI2: A dataset of environmental data will be constituted. OLTI3: A paper of presentation of results will be produced and submitted to a peer-review journal.
(3) Register new standardised data on clinical status of elderly NH residents **(WP5 and WP6)**	PI 3: Sample size of elderly. At least 50% of the selected individuals should participate to the entire protocol.[1]	OLTI4: A dataset of health data will be constituted. OLTI5: A paper of presentation of results will be produced and submitted to a peer-review journal.

(4) Assess health effects of indoor air pollution and thermal conditions in elderly **(WP7 and WP8)**	PI 4: Generate and analyze primary data to quantify the relationship between IAQ and health in elderly PI 5: Interpret and report on primary and secondary data analysis for use in policy and programme development.	OLTI6: At least 2 papers reporting on the observed relationships will be submitted in peer-reviewed journals
(5) Develop guidelines on IAQ in NH and provide the Healthy Nursing Home Environment Assessment Tool (HNHEAT), **(WP2)**	PI6: Implementation and validation of guidelines on IAQ and of the HNHEAT tool	OLTI7: Provide training/expertise about the collection and use of data on IAQ to local health agencies or other constituents. OLTI8: An intervention survey: Percentage of NH adopting of written policies on IAQ. OLTI9: Provide a free software tool, to help nursing home systems to more effectively manage all of their environmental issues
(6) Assess and estimate the effect of different vaccination strategies on preventing morbidity due to influenza, flu… **(WP9)**	PI7: Questionnaire survey: availability of data from at least 80% of the sample	OLTI10: An intervention survey: Percentage of NH adopting of written policies of infection control and coverage of anti-pneumococcal and anti-influenza vaccination in NH residents, health operators and family caregivers (influenza only) in nursing homes with intervention as compared to baseline survey and to control nursing homes. OLTI11: Changes in influenza seroepidemiology and in frequency of influenza outbreaks.
(7) In the long-term, investigating susceptibility of elderly to air pollution **(WP6)**	PI8: Use biological specimens to constitute a databank to study susceptibility. Availability of 50-80% of the specimens according to the type of specimen.	OLTI12: A databank and the corresponding dataset will be constituted

[1]A sample of at least 20 elderly will be targeted in each NH

The following PI indicators checklist will be filled at the end of the conduction of the WPs in order to allow seeing whether the chosen indicators were adequate and whether they have been attained (see WP3). Similarly, a checklist to be filled at the end of the survey will be developed for the OLTIs (Table presented in WP3).

Process indicator (PI) checklist

(Please thick the case)

PI	Minimally or partially adequate	Substantially adequate	Fully adequate	Achievement of the PI

PI 1: Use data sets to prepare basic descriptive analyses related to elderly health issues and IAQ. Major data sources considered. **(WP4)**	☐	☐	☐	☐
PI 2: Sample size of nursing homes (at least 80% of the selected nursing homes). **(WP4)**	☐	☐	☐	☐
PI 3: Sample size of elderly (at least 50% of the selected individuals should participate to the entire protocol). **(WP5-WP6)**	☐	☐	☐	☐
PI 4: Generate and analyze primary data for the relationship IAQ and health. **(WP7-WP8)** PI 5: Interpret and report on primary and secondary data analysis. **(WP7-WP8)**	☐	☐	☐	☐
PI6: Implementation of guidelines and of the HNHEAT too**l. (WP2)**	☐	☐	☐	☐
PI7: Questionnaire survey on infection control policies (availability of data from at least 80% of the sample). **(WP9)**	☐	☐	☐	☐
PI8: Sample size of biological specimens for seroepidemiology (between 50 and 80% of the specimens). **(WP6)**	☐	☐	☐	☐

Similarly, a checklist will be filled for the OLTIs.

Outcomes and long-term impact (OLTI) Indicators checklist

(Please thick the case)

PI	Minimally or partially adequate	Substantially adequate	Fully adequate	Achievement of the OLTIs
OLTI1: A state of art on the topic submitted in a peer-reviewed journal. **(WP4)**	☐	☐	☐	☐
OLTI2: A dataset of environmental data. **(WP4)** OLTI3: A paper of presentation of results submitted to a peer-review journal. **(WP4)**	☐	☐	☐	☐

OLTI4: A dataset of health data. **(WP5-WP6)** OLTI5: A paper of presentation of results submitted to a peer-review journal. **(WP5-WP6)**	☐	☐	☐	☐
OLTI6: At least 2 papers reporting on the observed relationships submitted to peer-reviewed journals. **(WP7 and WP8)**	☐	☐	☐	☐
OLTI7: Training/expertise about the collection and use of data on IAQ to local health agencies or other constituents. **(WP2)** OLTI8: An intervention survey in NH adopting of written policies on IAQ. **(WP2)** OLTI9: A free software tool to help nursing home systems to more effectively manage all of their environmental issues. **(WP2)**	☐	☐	☐	☐
OLTI10: An intervention survey in NH adopting written policies of infection control and coverage. **(WP9)** OLTI11: Changes in infection (influenza…) seroepidemiology and in frequency of influenza outbreaks. **(WP9)**	☐	☐	☐	☐
OLTI12: A databank and corresponding dataset. **(WP6)**	☐	☐	☐	☐

[1]To be filled at the end of survey

At the end of the survey, the global indicator checklist will be filled.

Summary scientific quality indicators checklist[1]

(Please thick the case)

WP	Achievement of the related PIs	Achievement of the related OLTIs
WP1: Coordination	☐	☐
WP2: Management	☐	☐
WP3: Dissemination	☐	☐
WP4: : Environmental assessment	☐	☐
WP5: Clinical investigation	☐	☐
WP6: Biomarkers	☐	☐
WP7: Cross-sectional	☐	☐

WP8: Longitudinal study	☐	☐
WP9: Airborne infection control policies	☐	☐

[1]To be filled at the end of survey

Project management indicators will include the respect of the timetable of the workplan, the quality control of the data, the number of visit to the web-site, the success of the recommendations and of the Healthy Nursing Home Environment Assessment Tool (HNHEAT) software issued from the project. They will be assessed by the various experts.

5.4. Work package n° *4*: Environmental assessments

5.4.1. List of partners involved

Uppsala U

5.4.2. Objectives

- To assess air quality, thermal conditions, luminosity and noise in nursing homes
- To identify sources of air pollution in nursing homes.
- To investigate how thermal conditions interact with air pollutants in nursing homes.

5.4.3. Description of the work

Major pollutants that will be assessed include: PM_{10}, $PM_{2.5}$, ultrafine particles, NO_2, O_3, CO_2, CO, COV (formaldehyde, benzene), allergens, moulds, and irritants from disinfectants. Additional assessments will include thermal conditions, luminosity and noise. They will be assessed in the living rooms of the nursing homes after a visit of the building. All measurements will be made during normal activities and under representative conditions. Outdoor exposure measurements will also be performed during the same time period and by the same methods. Furthermore, monitoring stations for air quality will be contacted for obtaining background concentrations of major pollutants in the cities through the past decades and at the period of the surveys.

The assessments will concern about 64 nursing homes. They will be performed for all the above mentioned environmental parameters at the first cross-sectional study and only for those that have been shown to be of interest at the second cross-sectional study. Methodology for the assessments is standardised. Assessments will be performed in the frame of WP4 by the partner involved.

5.4.4. Deliverables and links with other work packages

There is only one deliverable in this WP:

D4.1: Air contaminants and related sources in NH[א] across Europe. Baseline and evolution data. This is based on the implementation of a database with environmental data for the 8 countries participating in the study.

This WP is linked to WP7.

א nursing homes

5.5. Work package n° *5*: Clinical investigation

5.5.1. List of partners involved

UAAR-Aarhus

5.5.2. Objectives

- To assess objective health status of elderly in nursing homes
- To study health status evolution of health status in institutionalized elderly
- To relate subjective and objective (physician and clinical records) health status and clinical tests.

5.5.3. Description of the work

Clinical non invasive tests of the elderly will be performed using standardised methodology (see methods).

Almost 1200 subjects will be targeted in about 64 nursing homes in 8 countries of Europe. We will devise a series of clinical tests selected, after approval by the institutional ethics committee, to be both non-invasive and informative on possible irritative phenomena of the nose, the eyes and the airways. They include measurement of electrocardiogram, dynamic spirometry (by the forced oscillation technique (FOT), measurement of tear film stability (BUT), nasal patency measured by acoustic rhinometry, biomarkers of inflammation in nasal lavage fluid (NAL) and airways (exhaled NO), and biomarkers of inflammation in exhaled breath condensate as well as CO in exhaled air.. Field personnel will be trained for the purpose of GERIE. All the assessments will be performed using the same portable devices in all the centres and according a standardized protocol (Dr Isabella Annesi-Maesano, Paris (FOT and electrocardiogram), Prof. Dan Norback, Upsala (BUT), and Prof Torben Sisgaard, Aarrhus (acustic rhinometry, NO, CO, breath condensate) will provide the device). There exist standardised protocols for these tests and for the biological assessment of interleukines (IL1, 6, 8…).

Additional data upon chronic diseases of which the elderly is suffering and medical treatment will be collected using the clinical records of the nursing homes. This procedure will provide health data based on medical diagnoses.

Assessment of symptoms and diseases and functional impairment at the period of the survey will be done during the medical visit that accompanies clinical tests.

The consent of the individuals or of their relatives, when needed, will be sought for.

Laboratory assessments will be performed by the involved partner and in relation with the partner involved in WP6 in order to use when possible the same resources and methods and thus ensure quality control.

5.5.4. Deliverables and links with other work packages

There is only one deliverable:

D5.1: Health status of elderly in NH. Outcomes assessments and observed results.

This includes the implementation of a database containing health data for the 8 countries.

This WP is linked to WP7.

5.6. Work package n° *6*: Biomarkers

5.6.1. List of partners involved

ULB-Brussels

5.6.2. Objectives

- To evaluate the predictive value of serum or urinary markers reflecting the integrity of the pulmonary barriers (SP-D, CC16 in serum) or renal function (serum Cystatin C, urinary RBP and albumin)
- To identify environmental or lifestyle factors affecting the levels of these biomarkers either after prolonged exposure (e.g. occupation, smoking...) or as a result of short-term indoor exposure,

5.6.3. Description of the work

After approval by the institutional ethics committee, one blood sample (10 ml) and one spot urine sample will be collected for each patient in the first phase of the survey. The questionnaire as described in WP7 (filled by the patient or his family) will collect information about the medical history of the patient, his occupation and the various environmental (indoor pollutants) and lifestyle factors (smoking, sport, alcohol…) likely to be affect the renal function and the respiratory tract. In serum, we will measure Clara cell protein (CC16) and surfactant-associated protein D, markers of the integrity (permeability or integrity of cells secreting them) of the lung epithelium. We will also measure serum Cystatin C, a sensitive and reliable marker of the glomerular filtration rate that has been found to predict mortality in elderly. In urine, we will determine albumin and retinol-binding protein (RBP) to assess the integrity of the glomerular filter and of the proximal tubule respectively. These renal markers are frequently altered in elderly as a result of degenerative (diabetes) or cardiovascular diseases. Concentrations of urinary proteins will be adjusted for creatinine. All these markers will be determined using sensitive immunoassays in one centre (Prof. Alfred Bernard, Brussels).

5.6.4. Deliverables and links with other work packages

D6.1: An European database providing the concentrations of renal and pulmonary biomarkers in the elderly according to gender, age and disease.

D6.2: Data about the influence of lifestyle and environmental factors, in particularly indoor pollutants, on the levels of these biomarkers.

D6.3: Assessment of the predictive value of the studied biomarkers.

The conduction of these deliverables includes the implementation of a database containing health data for the 8 countries.

This WP is linked to WP7, WP5 and WP6 will be linked to perform biological assessments in order to use the same resources and thus ensure quality control.

5.7. Work package n° 7: Cross-sectional studies

5.7.1. List of partners involved

UPMC-Paris

5.7.2. Objectives

- To assess in T1 and in T2 (18 months later) levels of major indoor air pollutants in the nursing homes.
- To ascertain for the same individuals in T1 and in T2 respectively exposure to major indoor air pollutants and health outcomes.
- To relate, in T1 and T2 respectively, major indoor air pollution to health outcomes.
- To produce ecological data on the evolution of air quality and health in nursing homes in Europe.

5.7.3. Description of the work

A questionnaire survey including an epidemiological questionnaire, neuropsychological tests and QOL questionnaires will be conducted in older adults ≥70 years being resident stably in 8 nursing homes randomly selected in the 8 cities. In each nursing home, 20 individuals will be randomly selected.

The questionnaires, neuropsychological tests and QOL questionnaires have been previously described (see chapter 4 on “Methodology”). Relatives will fill a reduced version of the questionnaire.

At T1 (months 4 to 9), the individuals will fill the questionnaires and undergo the clinical visits including the clinical tests and assessments described in WP 5 and WP6 respectively. Simultaneously, environmental assessments will be performed as described in WP4.

At T2 (months 22 to 25), the same individuals will fill the same questionnaires and undergo the same clinical visits and assessments as at T1. Simultaneously, environmental assessments will be performed as described in WP4.

Data from the two cross-sectional studies will be analysed separately to determine ecological evolutions of air quality and health in nursing homes of Europe.

5.7.4. Deliverables and links with other work packages

There are 2 deliverables in this WP:

D7.1: Information on the relationship between health status and environmental factors in NH in 8 European countries.
D7.2: Evolution data on the relationship between health status and environmental factors typical of nursing homes in 8 European countries.

The conduction of these deliverables includes the implementation of a database containing health data for the 8 countries.

This WP is linked to WP4 for environmental assessment, WP5 for health assessment, WP6 for biomarker of individual integrity of pulmonary mucosa and renal fonction, WP 9 for infection control and WP7 for longitudinal analysis

5.8. Work package n° 8: Longitudinal study

5.8.1. List of partners involved

KCL-London

5.8.2. Objectives

- To study the predictive values of baseline assessments of both environmental and health with regards to severe morbidity and mortality.
- To develop methods for longitudinal data taking into account multi-exposure to air pollutants.

5.8.3. Description of the work

Baseline data on health and environment obtained at T1 in WP7 will be used as independent variables in proportional hazards model predicting morbidity and mortality (Cox's model) 18 months later. Morbidity and mortality data will be obtained by questionnaires, clinical records and national and regional morbidity and vital statistics. The analysis will be stratified according to sex.

Evaluation of multiple exposures effects will be performed using mixed models but also new models (partition distribution models). Evaluation of multiple exposures effects is a challenging problem in epidemiology (Greenland, 1993)[10]. The several variables of exposure are very often strongly correlated (e.g. the different air contaminants), and we can not assume the absence of any other effects of other variables not included in the model. Then a “classical” regression model is not correct as we have correlation between the explicative variables, and it does not suit as it eliminates the potential effect of other variables linked to the context (Greenland, 2000)[10]. The model needs to be complex to capture correlation problems and uncertainty about the relations: mixed models are adapted to this kind of framework (Greenland, 1994)[10]. Variables of contaminants measures would be introduced as fixed effects and habitation type as a random effect for example. However, more appropriate models exist although they have been applied in other context. These are the partition distribution models that take into account the non-independence of the models (Gianola et al, 2004; Rusinko et al, 1999) [10]. These will apply to disentangle the proper relationships of contaminants to health outcomes.

Furthermore, longitudinal analysis will be performed to identify predictors of morbidity and mortality.

5.8.4. Deliverables and links with other work packages

D8.1: Information on the role of health and environmental parameters in the prediction of severe morbidity and mortality in institutionalized elderly living in 8 European countries

10 See references in the methods.

D8.2: Information on the influence of the severity of diseases and functional impairment in the development of severe morbidity and mortality in institutionalized elderly living in 8 European countries.

D8.3: Information on how to take into account the effects of multiple exposure to pollutants.

5.9. Work package n° *9*: Infection control policies

5.9.1. List of partners involved

UNISI-Siena

5.9.2. Objectives

To provide data on:

- the current situation of indoor air quality and infection control policies
- the distribution of addressable risk factors for infection
- the current level of protection against viral infections (seroepidemiology) in nursing homes

5.9.3. Description of the work

This WP include: 1) a global questionnaire survey to be conducted in all the nursing homes at T1 and 2) a satellite study to be conducted only in one centre between T1 and T2.

The main questionnaire will contain information on a variety of aspects related to infection control. An additional questionnaire for "COPD friendliness" will be derived from the "asthma-friendly school checklist" (http://www.lungusa.org). Serum samples will be obtained from each nursing home resident to evaluate seroepidemiology of influenza virus A and B using enzyme-linked immunosorbent assay.

The satellite study will be conducted in one of the centers (Siena) at T1 and T2. Outdoor and indoor environmental conditions (particularly temperature, humidity, PM10, CO2 and ultrafine particles) will be repeated at monthly intervals for one year, to provide a more careful estimate than allowed by a single measurement. Colonization by *pneumococci* will be evaluated in residents and caregivers using throat swab cultures and PCR analysis. Infection outbreaks by influenza, RSV and metapneumovirus will be actively monitored by PCR analysis of throat swabs of suspected cases. The measurements will be repeated at T2 after modifying the infection control policy to address all the critical factors detected during the previous local assessment.

5.9.4. Deliverables and links with other work packages

Three are the deliverables of this WP:

D9.1: Questionnaire for COPD-friendly nursing homes.
D9.2. Questionnaires for infection and indoor air quality control.

D9.3: A report on airborne infection control in elderly across Europe.

This report will include different chapters dealing with the following issues: adoption of indoor air quality and infection control policies in European nursing homes; data on the preparedness of nursing homes personnel to prevent and treat infections; data on the preparedness of nursing homes personnel to cope with the needs of elders with asthma or COPD; data on the level of antibody titers (sieroepidemiology) against Influenza virus subtypes, Hepatitis B in European elders; data on the current level of vaccination against influenza and *pneumococcus* in European nursing homes; prevalence of risk factors for infections in European nursing homes; incidence of infections in European nursing homes.

6. MEASURES TO ENSURE VISIBILITY OF COMMUNITY CO-FUNDING

Community co-funding has the added benefits of:

• promoting the standardisation of methods in order to have the possibility to compare data drawn from different countries across Europe;

• homogenizing standards and recommendations on indoor air quality in nursing homes as well as on vaccination strategies against influenza and *pneumococcus* in elderly across Europe;

• creating synergies between research teams and potential users of the results;

• overcoming limited equipment budgets within anyone by pooling the resources of many;

• raising the level of awareness among partners, which will broaden the responsibility for and commitment to providing support to the European public;

• most important, co-funding will contribute to reduce inequalities in health care of elderly across Europe by providing information on care access and management.

It is clear that the GERIE study could not be accomplished without Community co-funding. Accordingly, this contribution will be acknowledged in all the stages of the project. It will be immediately announced on the website of the European Respiratory Society through the web coordinator of the Assembly of Epidemiology and Occupation, and recognized with links to the programme website (http://ec.europa.eu/comm/health/) both on the announcement on the ERS website and on the homepage of the project website when established. The role of the Community in the project will be clearly stated in all the communications with local health structures, community representatives, ethical committees, associations, university administrations that will be contacted during the planning, execution and exploitation of the study, as well as in all the stages of dissemination and exploitation of the results (reports, press releases, congress events, communications, published papers). We logo itself of the project will have explicit graphical elements to recall the European participation in the project. As members of the European Respiratory Society, we will promote initiatives to publicize the participation of ERS member to this and others projects funded by the PHEA/EC, such as *ad hoc* symposia or other congressional events. The Community co-funding will be explicitly reported in all the scientific papers derived from the study both by mention of the GERIE acronym in the author list and by acknowledging the received funding in the article's notes, according to the publication policy of the publisher.

7. LIST OF PROPOSED COLLABORATING PARTNERS (TO BE FINALISED)

Collaborating organisation			*Contact person*			
Organisation	*Town / City*	*Country*	*Title / Function*	*Family name & First name*	*Telephone No*	*E-mail*
European Respiratory Society	Lausanne	Switzerland	Executive Manager	Turnbull Archibald	**+41 21 213 0101**	archie.turnbull@ersnet.org
AGE (European Older People's Platform, www.age-platform.org)		Belgium	Director	Anne-Sophie Parent -	+32.2.280.14.70	annesophie.parent@age-platform.org
European Federation of Older People, http://www.eurag-europe.org	Luxembourg	Luxembourg			+43 316 814 608	office@eurag-europe.org
EURAG						
ECHO (European Confederation of Care Home Owners, www.echo-eu.com)						
APHEA/EC						
These partners have to be contacted						