European Cooperation in Science and Technology
- COST -

Secretariat

Brussels, 16 December 2010

COST 4212/10

MEMORANDUM OF UNDERSTANDING

Subject :	Memorandum of Understanding for the implementation of a European Concerted Research Action designated as COST Action TD1005: Pain Assessment in Patients with Impaired Cognition, especially Dementia

Delegations will find attached the Memorandum of Understanding for COST Action TD1005 as approved by the COST Committee of Senior Officials (CSO) at its 180th meeting on 1 December 2010.

MEMORANDUM OF UNDERSTANDING
For the implementation of a European Concerted Research Action designated as

COST Action TD1005
PAIN ASSESSMENT IN PATIENTS WITH IMPAIRED COGNITION, ESPECIALLY DEMENTIA

The Parties to this Memorandum of Understanding, declaring their common intention to participate in the concerted Action referred to above and described in the technical Annex to the Memorandum, have reached the following understanding:

1. The Action will be carried out in accordance with the provisions of document COST 4159/10 "Rules and Procedures for Implementing COST Actions", or in any new document amending or replacing it, the contents of which the Parties are fully aware of.

2. The main objective of the Action is the development of a comprehensive and internationally agreed-on toolkit for assessing pain in adults with cognitive impairment, especially with dementia.

3. The economic dimension of the activities carried out under the Action has been estimated, on the basis of information available during the planning of the Action, at EUR 36 million in 2010 prices.

4. The Memorandum of Understanding will take effect on being accepted by at least five Parties.

5. The Memorandum of Understanding will remain in force for a period of 4 years, calculated from the date of the first meeting of the Management Committee, unless the duration of the Action is modified according to the provisions of Chapter V of the document referred to in Point 1 above.

A. ABSTRACT AND KEYWORDS

The number of older adults will increase considerably in the next decades. Since age is the main risk factor for dementia and pain, the number of patients with both dementia and pain will also grow. When dementia and pain concur, their impact on the European society multiplies and asks for transnational solutions. It seems already now evident that pain is grossly undertreated in dementia. Other unanswered questions regard the underlying brain pathology, optimal pain treatment and care. The lack of validated pain assessment tools has yet prevented major progress. A few centres in Europe have started relevant research but these are not yet linked in a systematic fashion. This COST Action will bring together leading researchers from a wide range of scientific disciplines. The major aim is the development of a comprehensive and internationally agreed-on assessment toolkit for older adults targeting the various subtypes of dementia and various aspects of pain, including pain diagnostics, cognitive examination and guidelines for proper assessment. Validation of this toolkit requires joint action of both basic and clinical sciences. Only hereby, the urgently needed improvement of pain management in dementia can start.

Keywords: Impaired cognition, dementia, pain, diagnosis, treatment

B. BACKGROUND

B.1 General background

The burden of pain in dementia

"Alzheimer Europe" estimates that 7.3 million Europeans suffer from dementia. This figure will inevitably rise as the population ages. As stated in the Council Conclusions on "public health strategies to combat neurodegenerative diseases associated with ageing and in particular Alzheimer's disease" in December 2008, these issues have been recognized to be among the "grand challenges", the European society will face over the coming years.

Due to their advanced age, individuals with dementia often suffer from multiple morbidities associated with pain. However, the exact pain prevalence in dementia is unknown because adequate reliable and validated pain assessment tools are still missing. Most tools rely on intact cognitive and communication skills and, thus, often fail to detect pain in the cognitively impaired. Therefore, pain is frequently underdetected and often undertreated in people with dementia. Similar diagnostic and therapeutic challenges are produced by other forms of cognitive impairment such as mental retardation or cognitive dysfunctions after acquired brain injuries.

Need for better pain assessment

It is vital that more adequate tools for pain assessment in adults with cognitive impairment will be developed. A variety of tools have recently become available; however, neither their empirical convergence nor their external validity have yet been tested systematically. Some potentially pain signalling behaviours (e.g. mimic, vocalisation, agitation) are not sufficiently attended to, and specific forms of pain (e.g. acute vs. chronic or nociceptive vs. neuropathic; e.g. headache) are not addressed at all. Only when appropriate tools are made available, brain pathology with impact on pain will be identified. Good pain management is reliant on effective pain assessment. Well-validated tools will allow for the adjustment of pharmacological and other pain treatments to the needs of cognitively impaired individuals. Specialised care models for pain in demented patients can then be developed. As a result, unnecessary suffering in this population will be prevented.

Problems and solutions

Research centres with appropriate research facilities as well as access to patients with cognitive impairment are scattered all over Europe. So far, no international centre or network for collaboration has been established. This leaves the dissemination of expertise on a small scale, rarely passing national organizational barriers and, thus, inhibiting international research.

COST is best suitable scheme to overcome these problems because

(i) it promotes collaborative activities within and across disciplines (from bench to bedside),

(ii) it integrates regionally scattered research activities by facilitating European networks and

(iii) it supports contacts also to non-scientific partners such as patient organizations, carers, partners from industry, etc.

Thus, this COST Action will focus on international integration and coordination of research on the development, testing and distribution of a toolkit for pain assessment in patients with cognitive impairment, especially dementia.

B.2 Current state of knowledge

Pain and analgesic treatment in elderly people

The risk of suffering from pain increases significantly over the lifespan, reaching highest levels in the later years. The prevalence of pain in nursing homes (NH) is estimated to range from 40% to 80% of the residents. These figures suggest a serious impact on the quality of life and the psychosocial as well as physical functioning. Although pain is such a frequent complaint in NH residents, 25% of them do not receive analgesics on a regular basis. The administration and prescription of analgesics occurs below levels of expert recommendations.

Pain and analgesic treatment in patients with dementia

The NH residents in the developed countries represent also - with reported frequencies of around 50% to 60% - those, who are mainly affected by dementia. Pain in patients with dementia is assumed to be at least as frequent as in cognitively healthy individuals of the same age. In vascular dementia the pain prevalence might even be higher due to a pain-promoting neuropathology. However, patients with dementia receive even fewer analgesics drugs than cognitively unimpaired individuals as has been observed in a series of studies. The exact reasons for this undertreatment of patients with dementia are still not determined. However, pain is in any case a threat of human dignity. Preventable pain in those, who cannot speak up for themselves, is therefore an imperative of joining forces to improve the situation.

Shortcomings of pain assessment in patients with dementia

One of the most likely reasons for the underdetection and undertreatment of pain in patients with dementia is the fact that nowadays standards of both classificatory pain diagnosis and dimensional pain assessment rely strongly on intact cognitive functioning and communication skills, which are no longer given in patients with dementia. As reaction to these insights – starting in the early 1990s – a variety of pain assessment tools specialized for NH residents and, in particular, patients with dementia have been developed. Pros and cons of these scales have been acknowledged in recent reviews on this topic. However, due to the lack of internationally coordinated research, aiming at validating these scales and selecting the best available solutions, almost each clinical and each research centre favours its own scale. Consistent practice has at best developed at national levels and is only described in national guidelines.

None of the scales available distinguish between acute and chronic pain, which are both relevant for older people and which require different approaches for pain management. Similarly, the distinction of nociceptive, neuropathic and central pain is still difficult. A further shortcoming is the lack of scales for specific forms of pain like headache, toothache or musculoskeletal pain with a few promising exceptions. Since most of the scales are based on observer ratings, scales for specific types of pain do not only require general knowledge about pain but also specific expertise, which has to be provided along with the assessment instrument. Older people with dementia often require palliative care and one in three people in Europe over the age of 65 years will die whilst suffering from dementia. A vital component of good palliative care is pain assessment. Patients with advanced dementia suffer a range of symptoms, similar to those found in the terminal stages of cancer for example, dyspnoea, pressures sores, agitation and eating problems. Accordingly, the development of new assessment tools is necessary to improve end of life care. Additionally, pain in dementia can lead to agitation and aggression but other causes of these symptoms exist. Until now, there is no standard method for differentiating these symptoms caused by pain from those due to other forms of distress. Consequently, patients with pain are sometimes (mis)treated with psychotropic drugs and restraint, which could be prevented by use of behaviourally orientated scales with validated pain specificity.

Next necessary steps in the development of new tools for pain assessment

The apparent urgent need for pain assessment in dementia was the starting point for the described "uncontrolled" growth of scale developments, which now requires systematic reviews and testing as well as reduction to best possible solutions along with further developments in neglected domains such as special forms of pain (headache, toothache and the like), differentiation of acute and chronic pain or nociceptive and neuropathic pain, differentiation of pain from other forms of distress and pain assessment in palliative care. This COST Action will be an innovative approach to fulfil these requirements in an internationally coordinated form to avoid further national solo attempts.

Furthermore, better usage of experimental and neuroscientific methodology is mandatory for clarifying the empirical content of the clinical scales. Experiments allow for a strict control over the level of pain induced, which is not possible in clinical settings. Physiological and behavioural markers of pain can be used to validate these observational scales, since using self-report for validation is no longer possible in the non-communicative patients suffering from dementia. This COST Action will collaborate with the leading laboratories in that field.

Given the high prevalence of dementia, it is understandable that most scientific developments and clinical applications in the field of pain in cognitively impaired individuals have focused on pain in dementia. The vicinity of the problems and their potential solutions to challenges of pain assessment in other cognitively and verbally impaired individuals such as patients with mental retardation and acquired brain injuries (stroke, brain trauma, etc.) suggests wider application to many disorders. The common denominator might be a tool-kit with strong emphasis on observer-based and non-verbal pain assessment. The integration of these lines of research will be a further scientific and clinical impact of this COST Action.

B.3 Reasons for the Action

To overcome the current state of rather unorganized diversity and indecision with regard to pain assessment in patients with cognitive impairment, especially with dementia, this COST Action will allow for establishing internationally coordinated research in Europe. It will enable the exchange of expertise and will help to educate and train a new generation of early-stage professionals. International research projects can be prepared or run, incorporating large-scale multi-centre, longitudinal or epidemiological studies.

This COST Action will facilitate grant applications for related collaborative research projects, both on European (e.g. Joint Programming-Neurodegenerative Disease (JPND)) and on national levels. Due to the recent establishment of the JPND, which is currently only in the process of developing a common Strategic Research Agenda (SRA), the landscape of funding instruments in this area of research is reshaping, leaving a degree of uncertainty on how national funding, JPND, FP7 and the ERA-Net Neuron are going to attune their processes in the future. A European network will be advantageous because it provides flexibility in adjusting strategies for application.

Cross-cultural perspectives informed by the pros and cons of the European health care systems will result from this COST Action and internationally relevant solutions for best-practice in pain assessment can be derived. Such activities will also help to identify ineffective pain assessment and management, contributing to cost reductions in the overstressed budgets of health care. Finally, this COST Action will enhance the profile for the participating members**,** which helps to find new scientific and financial partners, as well as contacts with other European projects on pain or dementia.

B.4 Complementarity with other research programmes

The great relevance of the topic can be shown by the pilot “Joint Programming Neurodegenerative Disease” (JPND) initiated by the European Commission, with the aim to coordinate national funding on a European level. The issue of pain in dementia has so far been underrepresented in the calls of Framework Programme 7 of the EU and the ERA-Net Neuron.

An interesting partner project might be the FP7 Project PRISMA (Reflecting the Positive diveRsities of European prIorities for reSearch and Measurement in end of life cAre) which devotes its activities to “end of life” cancer care. A European organization active in the same field and worth being contacted is the European Association for Palliative Care (EACP), which promotes palliative care in Europe, also by inspiring research.

C. OBJECTIVES AND BENEFITS

C.1 Main/primary objectives

The main objective of the Action is the development of a comprehensive and internationally agreed-on toolkit for assessing pain in adults with cognitive impairment, especially with dementia.

Specification of achievements

The toolkit will target pain intensity, pain unpleasantness, pain sites, pain-concurrent behavioural and emotional problems - like agitation, aggression, sleep and eating disorders, anxiety and depression. Cognitive examination by neuropsychological methods will be included. It will be based mainly on observer ratings (carer, family, nurses) and will rely on self-report only in mild cases of cognitive impairment. The assembled tools will cover pain in general as well as the most prevalent specific forms of pain (toothache, headache, joint and back pain, etc.). The various stages of the disorders will be considered; particularly, specific tools for palliative care will be integrated into the toolkit. The development of the toolkit will require as final step a systematic testing of its validity and its sensitivity to analgesic treatment. Accordingly, multi-centre clinical studies and controlled drug trials will be run. The necessary convergence of the toolkit with physiological and behavioural markers of pain such as motor and autonomic reflexes, brain electrical activity and magnetic resonance imaging will be investigated.

Deliverables

The COST Action will provide the following deliverables as final outcome:

(i) comprehensive survey of the literature on existing assessment tools for pain in patients with cognitive impairment, especially dementia,
(ii) expert evaluation of these tools,
(iii) modification of existing and development of new tools,
(iv) planning basic and clinical studies for testing the validity of the tools,
(v) application for research grants for further validation,
(vi) approval of the composition of the toolkit,

(vii) identifying feasible physiological and behavioural markers of pain in patients with cognitive impairment, especially dementia,
(viii) establishing international databases for managing data assessed with the toolkit,
(ix) publication of guidelines for assessment by use of the toolkit
(x) publication of clinical and experimental validation studies,
(xi) development of training programs for nursing and medical staff,
(xii) liaison with clinical, research and self-help organizations.

C.2 Secondary objectives

Furthermore, this COST Action aims at:

- preparing appropriate dissemination strategies for both toolkit and guidelines,
- analysing and, if possible, correcting scientific, social and political barriers against dissemination,
- encouraging cross-national learning and consideration of cross-national differences in this process,
- increasing the overall awareness for the deleterious situation of pain sufferers with cognitive impairment in the public and in bodies of experts.

C.3 How will the objectives be achieved?

Panels of experts and consensus conferences
In order to achieve the objectives, it will be necessary to form a group of international scientific experts, who monitor and coordinate scientific activities, which have been run so far mainly on national levels. The resulting panel will be required to transform uncontrolled growth into flexible unity for further developments of the toolkit for pain assessment in patients with cognitive impairment, especially dementia. Since valuable first moves have already been made in some of the national scientific communities, this COST Action will not start from square zero. Since small-scale funding already exists on national levels, which favours certain assessment approaches and tools, a call for a complete re-start would not be an ideal strategy. Thus, as a first step consensus conferences will be organized, on which the panel of experts will have to determine:

(i) the scientific status quo

(ii) the commonalities and differences of national solutions

(iii) those differences, which are necessary as reflection of national differences in health care, management of nursing homes, geriatrics, andragogy, etc.

(iv) those differences, which are unnecessary and indicative of earlier arbitrary decisions such as purely formal differences of the tools not based on any data.

Development of a master plan and progress monitoring

On the basis of these considerations, a scientific master plan will be designed to overcome unnecessary differences. One way might be better theoretical modelling of the process and function of pain assessment in patients with cognitive impairment, another one might be head-to-head comparisons between available tools to find the best ones. Altogether, the consensus conferences will provide a description of the status quo and a master plan for future developments.
Later on, further meetings will become necessary to monitor the progress. Finally, consensus conferences will become necessary in order to approve the toolkit and the associated guidelines for proper pain assessment in patients with cognitive impairment. The purposes of the meetings will change from purely scientific at the onset of the COST Action to a mixture of science, clinical application and health care politics at later stages. Accordingly, participants at a later stage will be international scientific, clinical and political experts and opinion leaders.

Parallel activities

Concurrently, international training (Training Schools and Short-Term Scientific Missions (STSM)) of early-stage researchers in the use of the toolkit and the guidelines will take place and will guarantee sustainability.

C.4 Benefits of the Action

Interdisciplinary knowledge transfer

A European network of scientists based on this COST Action will allow for the exchange of expertise on pain assessment in patients with cognitive impairment, especially dementia and will help to educate a new generation of early-stage researchers. Professionals involved in research on cognitive impairment do usually not interact with experts in pain research. The overdue knowledge transfer between these professionals will provide the basis for not yet reached comprehensiveness that is urgently needed when trying to validly assess pain in patients with cognitive impairment, with input from all necessary sub-specialities. The neglect of crucial aspects can thus be avoided.

International research management

International research projects can be developed or managed, incorporating multi-centre, longitudinal or epidemiological studies. Further grant applications for such research projects become possible, both on European (e.g. Joint Programming Neurodegenerative Disease) and on national levels.

Cross-national learning

Cross-cultural perspectives informed about the pros and cons of the European health care systems will result and consequently, internationally relevant solutions for best-practice in pain assessment can be derived. Such activities will also help to identify ineffective pain assessment and management, contributing to cost reductions in the overstressed budgets of health care in Europe.

Profiling of participants

This COST Action will enhance the profile for the participating members**,** which helps to find new scientific and financial partners, as well as contacts with other European projects on pain or dementia.

Benefit for the people

Finally, the COST Action will help to identify a major problem which crucially affects the well-being and quality of life for the millions of older people in Europe, who suffer from dementia and other forms of cognitive impairment as well as from pain, and will prepare solutions.

C.5 Target groups/end users

(i) Basic and clinical scientists in the research fields of pain, anaesthesia, aging, dementia, mental retardation, nursing and palliative care,

(ii) (Nursing home) physicians, psychologists (i.e. neuropsychologists), geriatricians, nurses and carers involved with pain management and care in patients with cognitive impairment,

(iii) Patients with cognitive impairment, especially dementia as well as mental retardation and their relatives as well as friends,

(iv) Health services, senior residences and children's homes involved with management and care of elderly, patients with dementia and patients with mental retardation,

(v) European health policy planners and advisors.

D. SCIENTIFIC PROGRAMME

D.1 Scientific focus

Basic and translational impact

The development of an internationally agreed-on toolkit for pain assessment and diagnosis in patients with cognitive impairment, including cognitive examination, is an essential prerequisite for many scientific endeavours in this field, which are only briefly summarized in the following.

Only if pain can be validly identified, it is possible to better characterize pain epidemiology in dementia, to isolate specific brain pathology related to pain, and to optimize pain management (pharmacological, psychological, physical, etc.). Such activities in basic and applied sciences will provide data to be used in new models of nursing care and, by that, practical insights into best ways of housing, elderly and palliative care, family and patient support, etc. for patients with cognitive impairment. Psychosocial and clinical implementations of these insights are intended. This COST Action will try to scientifically identify barriers which might hinder implementation, and to change them to the better, which is translational research in its best sense.

Research questions

Research tasks arise directly out of the attempt to answer research questions. The research questions which will guide the development of the toolkit (this is the major objective of this COST Action) are as follows:

(i) What is the exact scope of the toolkit?

(ii) What are neighbouring scientific fields of the toolkit, which may provide useful insight and tools?

(iii) What types (scientific, clinical, etc.) and levels (screening, grading, etc.) of application have to be considered?

(iv) What type of information should be preferred (observer, self-report, etc.)?

(v) What psychometric parameters of reliability and sensitivity to treatment are appropriate?

(vi) What psychometric parameters of validity (see below) have to be considered?

(vii) What types of norm data are necessary (for each diagnosis or groups of diagnosis, population or institution based, etc.)?

(viii) Is the toolkit useful for any stage and intensity of the disorders under investigation?

(ix) Are the diagnostic results gained by use of the toolkit and the toolkit itself transdisciplinarily and internationally communicable?

(x) How is the convergence of the toolkit with validated physiological markers and behavioral of pain? Have such markers to be considered for the toolkit?

Critical relevance of validation studies

Answers to the question of validity cannot be found at bedside alone but additionally require research at the bench. This means that laboratory research, using up-to-date methods of neurophysiology, neuroimaging, algesiometry and neuropsychology, is required to determine the construct validity of the scales. In experimental settings, pain can be induced and assessed under controlled conditions, which is not possible in clinical settings. Hereby, it will be possible to correlate outcomes of the toolkit with autonomic (e.g. heart rate), cerebral (e.g. Electroencephalography and functional Magnetic resonance imaging (fMRI)) and motor (e.g. spinal reflexes) pain responses as well as with neuropsychological measures (e.g. attentional processes),

and only hereby it will be possible to test the pain-specificity of the modules of the toolkit. This position does not deny that the ecological validity of the toolkit (usefulness, usability, etc.), which is to be determined in the nursing residence and the hospital, is the ultimate goal of all scientific endeavours.

D.2 Scientific work plan - methods and means

The description of the work plan refers to integrated actions, which will belong both to the international part of activities coordinated in the network of this COST Action and to the national parts, which are funded and organized in single member countries of the Action.

Necessary work steps and applied methods

The necessary work steps including the applied methods of the COST Action for the development of the described toolkit will be:

(i) to theoretically analyze the existing tools for their scale qualities, usability and dissemination,
(ii) to constructively integrate existing tools, considering their theoretical and statistical commonalities and differences,
(iii) where integration fails or is not wanted on the available base of empirical evidence, to plan and run trials for head-to-head comparisons of existing tools,
(iv) to psychometrically develop new tools for neglected aspects of pain in dementia such as regional-specific pains and pain-related behavioural disturbances,
(v) to extract long and short test versions for different purposes (e.g. bedside vs. science) and different settings (e.g. nursing home, the acute hospital ward, etc.),
(vi) to adapt tests for specific types of pain (e.g. acute vs. chronic; e.g. headache),
(vii) to determine the reliability and sensitivity to change in pain (including controlled drug trials with analgesics) of the instruments,
(viii) to test the validity of the instruments by assessing their statistical convergence with other objective criteria for pain (e.g. physiological markers) in patients with limited skills of communication, which requires both the application of clinical and experimental methods,

(ix) to assess the robustness of the tools for applications in advanced disease (e.g. palliative care) and the flexibility for application in various stages of disorders,

(x) to develop guidelines for use of the toolkit and proper assessment of pain in patients with cognitive impairment.

Stages of the COST Action

The necessary methods and means will change with the stages of the COST Action. At the beginning, panels of experts, representing all necessary scientific sub-specialties, will be formed and, where necessary, further experts will be recruited. This process will end with the establishment of the Working Groups. Existing assessment tools for pain in dementia will be surveyed. Decisions on the need for modification and development of tools will be reached. Items and tests of the battery will be designed or modified.

Concurrently, pilot studies will test the usability of each module of the new toolkit. Finally, multi-centre studies will be prepared to test the toolkit's validity and reliability. This includes establishing research collaborations and applying for supplementary funding. Decisions will be reached which of the planned studies are large scale and require extra-funding and which ones are small scale, complementary and sufficiently supported by STSM. In this phase, education and training of graduates in international schools will become a task of relevance because the trainees will be thought to run the studies and to disseminate the new tools.

Evaluation studies of the toolkit will be run. First user experiences will be shared with patient organizations, clinicians, carers and industry partners. Recent findings will be discussed and modifications of the projects will be considered. A further panel will be appointed, which will edit guidelines on the proper assessment of pain in dementia.

Evaluation studies will be completed and available data will be analyzed. The final toolkit will be composed. The guidelines for proper assessment will be prepared for publication. This includes recommendations for scientific (basic research, clinical trials) and clinical use (care at home, in palliative centres, residential care). Dissemination of the new toolkit within the scientific and clinical community, and amongst interested laymen, e.g. through national Alzheimer's disease associations will be continued.

Activities of the Working Groups

The necessary work steps require a variety of expertise and methods. In order to guarantee such variety, the following specialized Working Groups will be set up:

Psychometrics and Algesimetry (WG1): Members of WG1 will be those, who evaluate the formal qualities of the existing scales and propose alternatives where necessary.

Nursing and Care (WG2): Members of WG2 will be those, who assess the usability and usefulness of the tools for preparing and monitoring pain management.

Clinical Evaluation and Epidemiology (WG3): Colleagues experienced in large-scale research and knowledgeable in the epidemiology of pain, dementia and similar conditions will be those, who initiate and run the necessary clinical multi-centre and international population-based studies.

Experimental Evaluation (WG4): Neuroscientists, physiologists, pharmacologists and neuropsychologists will contribute by providing experimental tests for the validity of the tools and physiological markers of pain, which do not solely rely on self-report.

Palliative Care (WG5): The implementation of such a Working Group is almost a moral obligation of the COST Action.

E. ORGANISATION

E.1 Coordination and organisation

The overall management structure of this COST Action will be set up as specified in the “Rules and Procedures for Implementing COST Actions” (COST 4159/10). During the kick-off meeting of the Action, a Chair and Vice-Chair will be elected.

After the start of the COST Action, new members will be recruited to broaden the expertise, where gaps exist, and more importantly, to create a network, which is representative for a large number of COST countries. The latter is relevant because healthcare and elderly care differ in Europe, resulting into different conditions for assessing pain in patients with cognitive impairment and requiring mutual international learning.

Besides the Management Committee and the Working Groups, a Steering Group for the management of the multi-centre studies and an Editorial Board for preparing and supervising the publication of the toolkit, the guidelines and related study reports will be set up (see Figure below).

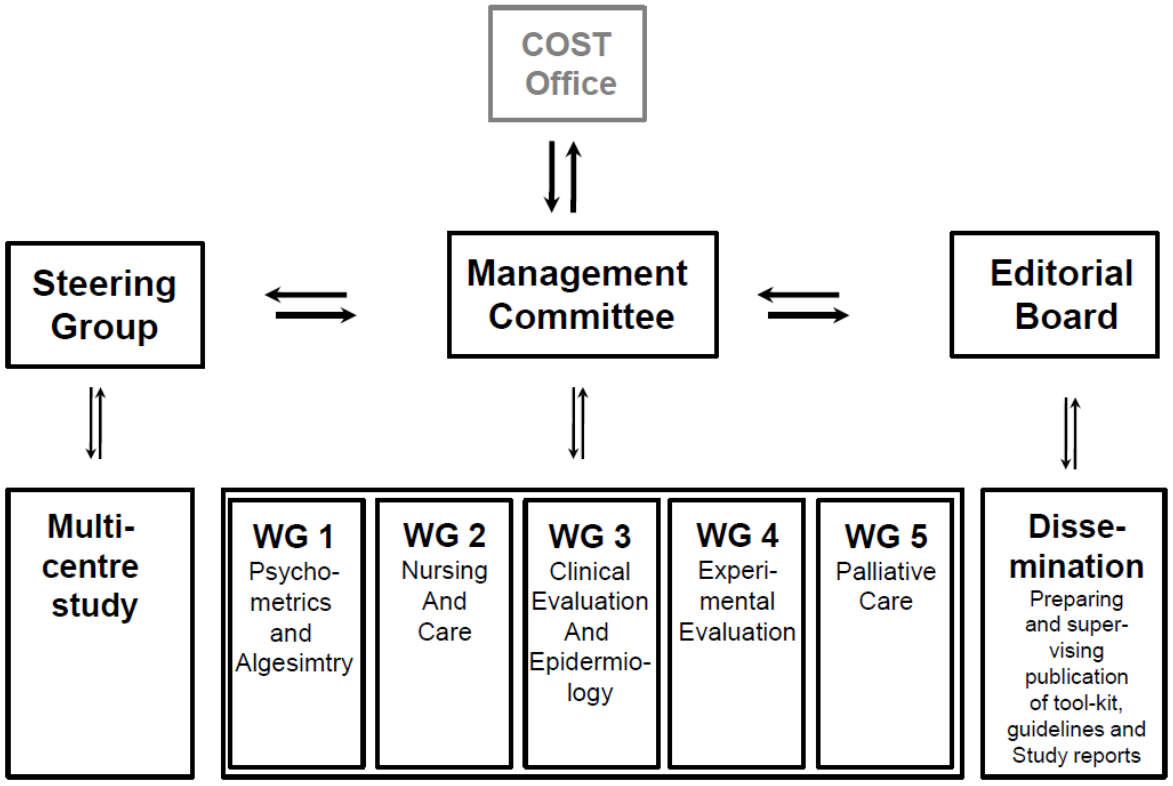

Figure: Organisational structure

The major platform of communication within the network of the COST Action will be regular meetings, which will take place in the form of plenary meetings or meetings of sub-groups (Steering Group, Working Groups, and Editorial Board).

Furthermore, a website informing about the COST Action, contacts with professionals and self-help organizations, guidelines and events will be provided. The website will also be used to run surveys about the interests and professional background of the users. Distribution and exchange of information between the participants of the COST Action will be supported by use of project management software (e.g. “Project Place”). This ease of information exchange will enable the webmaster that will be appointed and supervised by the Management Committee, to keep the website updated.

Exchange visits (STSM) mainly for PhD students and early-stage researchers as well as common education in international Training Schools will be established.

Milestones:

Milestones with critical relevance for the future development of the COST Action will be in their temporal order:

(i) build-up of panels of experts (including Management Committee, Working Groups, etc.),
(ii) development and approval of a master plan for the COST Action,
(iii) preparation and execution of clinical multi-centre studies,
(iv) preparation and execution of collaborative experimental studies,
(v) composition and approval of the toolkit,
(vi) publication of the guidelines for use of the toolkit and proper assessment of pain in patients with cognitive impairment.

E.2 Working Groups

Working Groups selected according to the expertise of members (neuroscience, medicine, dentistry, psychology, nursing, education and translation) will be implemented (see Figure above). Working Groups will provide unique insight in the problem of assessing pain in cognitively impaired patients, which can be considered from various angles just by using this form of organization. Some Working Groups will focus on the somatic aspects of pain assessment, some on the psychological ones. Others will provide experimental tests whereas still others help to prepare or preserve the usability at bedside. Applications for extra-funding will be fuelled by this multiple expertise and can be planned on this background for various research programs with emphases in basic and clinical research.

The following Working Groups will be set up (see D.2 for the description of their activities):

- Psychometrics and Algesimetry (WG1),
- Nursing and Care (WG2),
- Clinical Evaluation and Epidemiology (WG3),
- Experimental Evaluation (WG4),
- Palliative Care (WG5).

Regular plenary meetings will prevent developments in single groups from becoming too separate. Plans for the future as regards, for example, dissemination strategies and application for extra funding will be made based on informed interaction between Working Groups.

E.3 Liaison and interaction with other research programmes

Research on neurodegenerative diseases is currently being funded under the 7th Framework Programme of the EU in the specific programme “Cooperation” (Theme 1: “Health”), the ERA-NET Neuron as well as the recently established Joint Programming Initiative on Neurodegenerative Diseases (JPND). This high degree of transnationally coordinated research funded by European or national sources stresses the importance of this research. However, the research on pain in patients with cognitive impairment has yet been poorly coordinated on a European level.

Representatives of this COST Action will contact national and European associations for research and management on pain and dementia. The contacts with the EU (FP7) and related organisations (JPND) for research funding will be improved and appropriate calls will be monitored.

E.4 Gender balance and involvement of early-stage researchers

This COST Action will respect an appropriate gender balance in all its activities and the Management Committee will place this as a standard item on all its MC agendas. The Action will also be committed to considerably involve early-stage researchers. This item will also be placed as a standard item on all MC agendas.

The early running of international Training Schools during the COST Action will promote early-stage researchers in terms of workforce development and capacity-building. In the same line, early-stage researchers will be the main target group for STSMs.

F. TIMETABLE

time	Activities
Year 1	• Nomination of Management Committee members • Kickoff-meeting • Recruitment of experts where expertise might be improved or missing • Survey of existing assessment tools for pain in patients with cognitive impairment • Selection of appropriate tools • Decisions on the need for modification or translation and development of new tools • Planning head-to-head comparisons of seemingly equivalent tools when no consensus can be reached by available information • Preparation of the international multi-centre studies on the toolkit's validity and reliability (new research collaborations and supplementary funding will be necessary) • Preparation of the experimental validation studies in specialised pain laboratories

Year 2	• Design or modification of items or tests for the toolkit • Pilot studies on the usefulness and usability of new modules of the toolkit • Short-Term Scientific Missions (STSM) as exchange programs in the preparation phase of the multi-centre studies • Start of the international multi-centre studies on the toolkit's validity and reliability • Start of the experimental validation studies in specialised pain laboratories • Set-up of a European database • First international Training School
Year 3:	• Running of the international multi-centre studies on the toolkit's validity and reliability • Running of the experimental validation studies in specialised pain laboratories • First user meetings including patient organizations, clinicians, carers and industry partners. • First draft of international guidelines on the proper assessment of pain in cognitive impairment • Continuation of international Training School
Year 4:	• Completion of the international multi-centre studies on the toolkit's validity and reliability • Completion of the experimental validation studies in specialised pain laboratories • Composition of the final toolkit • Preparation of publication of the international guidelines on proper assessment of pain in cognitive impairment including recommendations for scientific (basic research, clinical trials) and clinical use (care at home, in palliative centres, residential care) • Dissemination of the new toolkit within the scientific and clinical community, and amongst interested laymen • Continuation of international Training School

G. ECONOMIC DIMENSION

The following COST countries have actively participated in the preparation of the Action or otherwise indicated their interest: BE, DE, DK, FR, IL, IT, NL, NO, UK. On the basis of national estimates, the economic dimension of the activities to be carried out under the Action has been estimated at 36 Million € for the total duration of the Action. This estimate is valid under the assumption that all the countries mentioned above but no other countries will participate in the Action. Any departure from this will change the total cost accordingly.

Australia has expressed its interest to participate to the Action.

H. DISSEMINATION PLAN

H.1 Who?

Three target groups will be considered for dissemination:

Researchers and clinicians

This group will consist of basic and clinical scientists in the research fields of pain, anaesthesia, aging, dementia, mental retardation, nursing and palliative care as well as nursing home physicians, neuropsychologists, geriatricians, nurses and carers engaged in pain management and care in patients with cognitive impairment.

Patients and relatives

This group will consist of patients with cognitive impairment, especially dementia, their relatives as well as friends and related self-help groups.

Managers and policy makers

Managing representatives of health services, senior residences and children's homes engaged in the management and care of elderly, patients with dementia, patients with mental retardation, etc. will be members of this third group. This group will be completed by European health policy planners and advisors.

H.2 What?

Publication of guidelines

The major instrument of dissemination will be the international guidelines for the use of the toolkit and the proper assessment of pain in patients with cognitive impairment. The publication is scheduled as a supplement of a first-class journal active in any of the following fields of research: pain, dementia, nursing, care, neuropsychology or the like. Although planned as scientific publication, comprehensibility for all disciplines engaged in pain management of patients with cognitive impairment is prerequisite. Translations into different European languages will be early on the agenda. The guidelines have to cover the following topics:

- Scope of the problem of assessing pain in “non-verbal” individuals (individuals, who lack verbal communication skills due to any kind of cognitive decline)
- Alternatives in pain assessment to self-report (behaviour, physiology)
- Suitable tools for pain assessment in patients with cognitive impairment
- Indications for use of additional or more specific tools
- Specific problems of assessment due to non-compliant patients and biasing conditions of diagnosis
- Evidence base
- Implementation in nursing homes and related settings
- Country-specific problems and solutions
- Contact to interested parties

Further methods of scientific dissemination

This core publication will be accompanied by other journal publications on the results derived from the usage of the toolkit in the participating clinical centres or experimental laboratories.
This central information will be augmented by the content of the website of the COST Action, which provides contacts with professionals and self-help organizations as well as information about guidelines and events.

Translational dissemination

Translation of the scientific results to publications with the character of popular science will be given high priority. These attempts may take the form of news letters, journal articles, brochures and videos. Equipped with this material, dissemination will cross the scientific borders and will be able to inform and educate non-scientific interested parties. These parties may be patients, heath service managers, policy makers, partners in the industry and the like. The Website of the COST Action will support the dissemination of this material by providing a down-load area.

H.3 How?

Scientific formats of dissemination

The usual dissemination of publications in internationally visible journals will be accompanied by editorials and letters by the participants of the COST Action to enhance interest. Scientific symposia and lectures as well as workshops for practitioners and interested laymen organized by the same individuals will attract further attention.

Training Schools

The Training Schools for early-stage researchers will be used to train the participants in the assessment and management of pain in cognitively impaired individuals, with a special focus on the application of the toolkit under consideration of the newly developed guidelines. A new generation of experts will emerge, who will be personal multipliers of this knowledge.

Interface to national organizations

Where national guidelines on the management of patients with dementia or patients with chronic pain exist, national representatives of the COST Action will become active to suggest incorporation of the new international guidelines into the national ones. Where no guidelines exist, the national societies engaged in that clinical and scientific field will be prompted to adopt the new international ones.

Mailing lists

To reach all relevant parties a system of mailing lists will be developed, which covers all target audiences.