AMICA

Autonomy Motivation & Individual Self-Management for COPD patients (AMICA)

DELIVERABLE 7

Field Trial Concept and Preparation (Germany)

Workpackage WP7 – User Inclusion, Evaluation & Field Trials

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Abstract

The Autonomy Motivation & Individual Self-Management for COPD patients (AMICA) is aimed at the disease management and medical care of chronic obstructive pulmonary disease (COPD) patients. AMICA is a Research and Development project funded by the states associated to the AAL Joint Programme and by the EC financial contribution (http://www.aal-europe.eu).

AMICA project started April 2009 and lasts for 3 years until April 2012 with a total budget of 2.783.139,48€. Seven partners spread across Europe are involved including medical companies and foundations (Vitaphone - Germany, I.S.S- Spain. and the Foundation for Biomedical Research Management- Spain), Academics (Institute of Communication and Computer Systems from the National Technical University of Athens- Greece, the Engineering School from Cádiz– Spain and the Research Centre for Information Technology from Karlsruhe – Germany) and an electronic design company (M.S.C.- Spain/Germany).

This report is part of the deliverable 7 belonging to the Workpackage 7. This report describes the methodology that will be followed during the field trial for the evaluation of the acceptance, the technical stability and, to a lesser degree, of medical impacts. of the AMICA system. The start of the field trial in Germany is planned for january/february 2011.

This document has been developed by Vitaphone GmbH.

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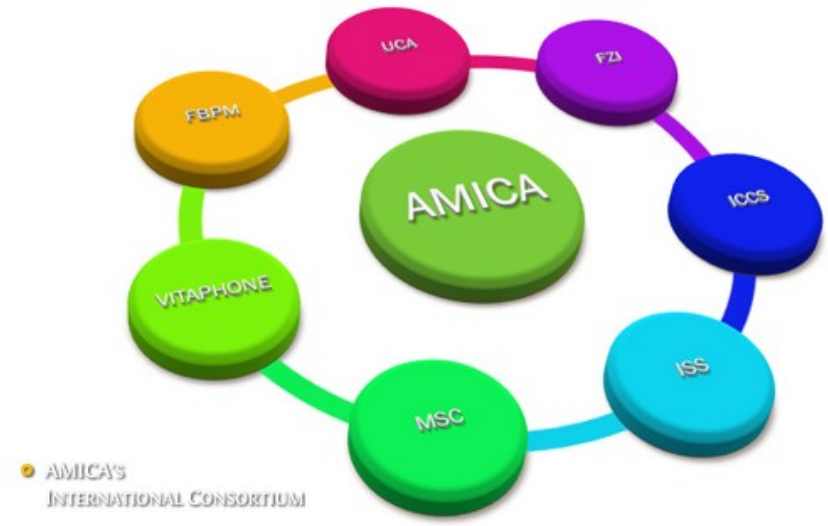
AMICA PARTNERS



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0 BACKGROUND

The purpose of this section is to introduce the:

- ✓ AMICA Project
- ✓ Purpose, scope and context of this deliverable
- ✓ Intended audience for the deliverable

AMICA Project

The Autonomy Motivation & Individual Self-Management for COPD patients (AMICA) is aimed at the **disease management** and **medical care of chronic obstructive pulmonary disease (COPD) patients**. AMICA is a Research and Development project co-funded under the Ambient Assisted Living Joint programme as well as its projects members. Its official website is http://www.amica-aal.com.

It is aimed at providing medical management and medical care to patients suffering from Chronic Obstructive Pulmonary Disease (COPD). COPD is a progressive pulmonary disease characterized by reduction in airflow and is not fully reversible. COPD is the major cause of mortality and increased levels of disability, particularly in the elderly. Symptoms vary among individuals and include breathlessness, dyspnea, abnormal sputum and chronic cough. Exposure to tobacco smoke is by far the most important risk factor in the development of COPD and is associated with high levels of morbidity and mortality.

AMICA'S main objective is to develope and assess long-term COPD management solutions based on innovative Information and Communication Technologies (ICT) that:

- ✓ Allows early detection of COPD exacerbations through the use of a multifunction biomedical system able to yield continuous and sporadic data on heart, breathing and physical activity. This helps to avoid hospitalization and enhances quality of life of elderly COPD patients.
- ✓ Offers a user-friendly design for the elderly.
- ✓ Provides remote monitoring and home-based care
- ✓ Integrates a technical solution with a holistic service approach.
- ✓ Fosters prevention and self-management through immediate comprehensive feedback and efficient personalized assistance.
- ✓ Increases levels of therapy compliance providing effective incentives schemes such as health treatments abroad as an added bonus while it reduces public

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health care costs and provides business opportunities on the health tourism market.

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Deliverable purpose, scope and context

The present report is the deliverable no. 7 "Field Trial Concept of the AMICA disease management solution in test regions in Germany" belonging to workpackage no. 7 "User inclusion, Evaluation and Field Trials of the AMICA Project".

The AMICA project, "Autonomy, Motivation & Individual Self-Management for COPD patients", is being funded by the Ambient Assisted Living Joint Programme and is aimed at the disease management and medical care of chronic obstructive pulmonary disease patients. This management will be achieved by the means of the development of a healthcare and telemedical solution and service platform: the AMICA system.

Concretely, workpackage number 7 is aimed at ensuring the inclusion of end users needs and requirements in the AMICA research and development tasks. To comply with this aim, within this workpackage, an evaluation of the AMICA system will be made with end users. To achieve this objective, the present deliverable is aimed at the development of the methodology that is going to be followed during the trial period in order to assure the acceptance, the technical stability and – to a lesser degree – the medical impact of the final product.

Audience

This report is included within a RESTRICTED deliverable. This document has been developed as a guide for the management and implementation of the field trial of the AMICA system. For this reason, this document is addressed to the people who will perform this activity within the AMICA project.

The intended audience includes:

- ✓ All the AMICA partners
- ✓ especially the Vitaphone staff which deals with project- und product-management, the software development department and the staff from the Telemedical Service Center

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1 SERVICE CONCEPT AS BASIS FOR FIELD TRIAL

The AMICA service concept is modularly designed and has been confectioned for two main groups of patients briefly summarized in Table 1 (for details see WP 6 Health Economics, Service & Business Models; 6.2 Development of the AMICA service concepts). These patient groups differentiate in severity of the disease, as a key criterion for the assignment of Group 1 or Group 2 an anamnestically determined exacerbation with hospital stay was chosen. This division is primarily arbitrarily, but helps to define two very important medical situations:

- ✓ **Group 1, planned with 10 patients,** (inclusion criteria: **no exacerbation, spirometric monitoring not recommended**) can primarily be conducted in terms of a prevention system. This includes, e.g. measures such as training units to improve the understanding of diseases, conscious lifestyle, physical training to prevent an acute deterioration, in terms of threatening exacerbation. Patients in this group, which is located at an early stage of disease receive only a **motion sensor** that is worn daily. The patient continuously records his activity (walking, running) in daily or professional situations, and automatically transmits the data via a PC with Internet access to the TSC in the electronic patient file. In TSC, experts of science of sport, nutrition and medicine evaluate the movement profile of the patient and give an individual feedback within the scope of personal advice, motivation conversations as well as via e-mail and SMS contacts.

- ✓ **Group 2, planned with 10 patients,** (inclusion criterion: **acute exacerbation with hospitalization, spirometric monitoring recommended**) represents a clinically manifest disease after exacerbation, which cannot be stabilized by preventive measures and thus has to undergo intensified care using acute or long–term medication. Patients in this group receive in addition to a **motion sensor** a **spirometer**, so that pulmonary function values can be measured and transferred into the electronic patient file. Timing and frequency of the automated transmission takes place after a medical protocol or acute symptoms. The transfer unit should be chosen so that it offers data transmission or the functionality of a questionnaire, so that the patient can also answer questions on the subject of dyspnoea, cough and sputum. These answers along with the lung function values will allow for a more complete picture of the patient´s current health status.

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The AMICA service concept is constructed in a modular manner and is subdivided into the following elements:

- ✓ **Monitoring:** Measurement of vital parameters for continuous surveillance
- ✓ **Compliance Management:** Telephony as means of supporting active communication and as shelter for patients in case of queries and emergencies
- ✓ **Self Management:** Information to convey knowledge about diseases

In the making, it is of paramount importance that the AMICA service concept sets in action at an early stage of the disease. In this stadium, the patient is suffering only little, and thus needs little support costs according to insurance companies. Along with an increasing disease progression, both perspectives seem to vary and the service concept must therefore dynamically adapt to the particular patient status.

Module	Group 1 Inclusion criteria: - No exacerbation - Spirometric monitoring not recommended	Group 2 Inclusion criteria: - Acute exacerbation with in-hospital treatment - Spirometric monitoring recommended
Monitoring*	**Hardware:** • Activity Sensor • Gateway **Electronic Patient File (EPF)** **Monitoring von:** • Activity monitoring **Availability of TSC:** • 10-hours on-call-duty/24h • Limited emergency service	**Hardware** • Activity Sensor • Spirometer incl. Peak Flow-Measurement • Gateway **Electronic Patient File (EPF)** **Monitoring of:** • Activity monitoring • Automatic transfer of spirometric data with medical report • Event-triggered transfer of data in case of acute pulmonological symptoms • Reminder function according to medical report for special examinations **Availability of TSC:** • 24-hours emergency service
Compliance Management	1 x per quarter Outbound Calls from TSC to patient with standardised questionnaire on • Quality of Life (QoL) • Current symptoms • Current medication & Health economics	2 x per quarter Outbound Calls from TSC to patient with standardised questionnaire on • Quality of Life (QoL) • Current symptoms • Current medication & Health economics
Self-Management	**Bristol COPD Knowledge Questionnaire (BCKQ) (at start of program and 1/year in the follow-up period):** **Group "badly informed": Less than 70% correct answers (Motto: Patient passive / TSC active):** 1 x per quarter Training material incl. a questionnaire on illness-specific contents; field of topics: • Symptoms • Medication • Approaches based on behavioural therapy (sports & movement, diet, travelling) **Group "well informed": More than 70% correct answers (Motto: Patient active / TSC passive):** • Self-information in Content-Portals and Chatrooms • Set-up of a COPD-consultation-hour/-hotline 1 x per week • Patient-Information Portal (PIP)	

Table 1: Modular AMICA Service Concept

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2 FIELD TRIAL CONCEPT FOR GERMANY

These previously mentioned modules assigned to the different groups build the basis for the development of the field trial concept in Germany. This concept has been mainly designed to collect information and valid data on the **acceptance of the system** by patients and their corresponding doctors, on the **stability of the technical equipment** in general and to a lesser degree on **medical impacts**. Greatest importance is attributed to the question whether the system can deliver so convincing results that the associated insurance companies will transfer the concept to a fully reimbursed treatment modality for COPD patients in integrated care contracts after completion of the field test. Taking this into account some major steps have to be fulfilled before the implementation of the system.

1. Select a renown and experienced doctor for the inclusion of patients and provide him with all necessary documents
2. Educate the medical and non-medical staff in the Telemedical Service Center and set up a precise protocol of the necessary tasks
3. Organize a training course for the patients in the state of the inclusion process
4. Specify clearly which data have to be collected at given times in the course of the field trial

2.1 Selection of a medical partner for user inclusion

The selection of a renown physician specialized in the field of pulmonology sounds unproblematic but is hard to achieve in Germany. This is mainly due to the fact that there are only very few specialized physicians working in this area, as pulmonological diseases are normally treated by physicians of internal medicine or – even more often – by cardiologists. However, for the study, we preferred a pulmonologist with a high volume practice who could guarantee – by his given expertise in this field – a clear assessment of the chosen concept. On the one hand, this would open up some options to adjust the program during the study period according to the physicians advice. On the other hand it seemed attractive to convince the doctor during the study period to become a partner for the continuation of the program at the end of the field trial in an integrated care contract. It was also important that the selected doctor had good relations to a specialized clinic necessary for hospital admissions in case of acute exacerbations or other emergency cases. After selection and the consent of the physician to participate all necessary documents must be prepared according to his ideas, including:

2.1.1 information material (flyer) for the physicians and patients

2.1.2 informed consent of the patients including declaration of data protection

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2.1.3 document for patient anamnesis (for medical data)

2.1.4 document for patient intake (core data)

All these documents are part of this deliverable. Taking into account that the trial will be held in Germany, all the documents made to be used by or with the patients (questionnaires, and forms) have been developed in German. If needed, all of them can be translated into English later.

2.2 Education and tasks of staff

Core of the concept is a central Telemedical Service Center (TSC), which is run under medical supervision and is equipped with appropriately qualified and trained specialist nurses and personnel enabling a 24-hour service throughout the whole year. Relevant clinical data are recorded in an electronic case file, which is centrally managed in the TSC. The patient automatically transfers his vital parameters (e.g. peak flow and other respiratory parameters) via special devices (e.g. spirometer) to the TSC. If individually set limit values are undershot or exceeded, an alarm is immediately triggered so that therapeutic measures can be initiated immediately. Regardless of alarm reactions, the patient will also be proactively contacted and interviewed based on a standardized questionnaire on quality of life, medication, clinical symptoms and the frequency of doctor visits and hospital stays. The objective is to promote medical compliance, and to detect changes in health status of the patient as early as possible. In case of an emergency, appropriate therapeutic measures in terms of an escalation procedure are initiated. As part of the intensive monitoring with spirometry – based on the received vital parameters – escalation algorithms and warning systems are possible, which might indicate a need for action to the TSC on a traffic light system, when signs of a deterioration of the health status are shown. The patient is then informed by the TSC and is sent to a doctor if applicable. This early warning system aims at the earliest possible detection or prediction of an impending exacerbation thus allowing a faster treatment and preventing a hospital stay.

To fulfill all the necessary tasks of the TSC, the training of the staff is an absolut necessary requirement for the success of the program. The use of selective COPD patients requires a sound medical knowledge of the medical and non-medical staff about the disease per se, but also a deeper understanding of the specific problems and difficulties in dealing with these patients. These patients are often hard to convince that a strict adherence to the given medication in combination with a change in their daily behaviour, i.e. cessation of smoking or exercise, can dramatically improve their health status and can also prevent the progression of the disease or long-term damage. For that reasons a medical training program must be set up focusing not only on pulmonary functions including typical patterns of spirometric parameters but also reflecting the socioeconomic and psychological background of the affected persons. In

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addition, a clear protocol must be given with all necessary details on the tasks of the TSC, as outlined exemplarily for a two quarter period in Table 2.

quarter	month	week	date	Call or Action
Q1	JAN	1	03.01. – 07.01.11	
		2	10.01. – 14.01.11	
		3	17.01. – 21.01.11	
		4	24.01. – 28.01.11	**Welcome Calls for Group 1 und 2** • Infos on the program • Explaining details on hardware • Explaining data synchronisation • Explaining limits for sportif activity • Open questions
	FEB	5	**monday 31.01.11**	**Start Monitoring for all patients**
			31.01. – 04.02.11	**Modul Compliance Management:** **1 x per Quarter Calls for group 1 und 2** with standardized questionnaire • Life quality • Actual symptoms • Actual medication and health economics • Sportif activities
		6	07.02. – 11.02.11	
		7	14.02. – 18.02.11	
		8	21.02. – 25.02.11	
		9	28.02. – 04.03.11	
	MAR			Monitoring during the whole test period; alerting system ready by lacking data transmission and out of range values
		10	07.03. – 11.03.11	**Modul Compliance Management:** • **Second Quarter Call for group 2*** with standardized questionnaire Life quality • Actual symptoms • Actual medication and health economics
		11	14.03. – 18.03.11	**6 week-Reporting to treating physician for group 2** Summarizing report with medically relevant data in statistical form
		12	21.03. – 25.03.11	
		13	28.03. – 01.04.11	**Modul Self-Management:** **1 x per quarter delivery of educational material incl. questionnaires** Theme: „COPD disease"
Q2	APR	14	04.04. – 08.04.11	**Quarter-Report to treating physician on Q1 for group 1** Summarizing report with medically relevant data in statistical form
				Modul Compliance Management: **1 x per Quarter Calls for group 1 und 2** with standardized questionnaire • Life quality • Actual symptoms • Actual medication and health economics
		15	11.04. – 15.04.11	**Modul Self-Management** **Reminder Questionnaire**
		16	18.04. – 22.04.11	
		17	25.04. – 29.04.11	**6 week-Reporting to treating physician for group 2** Summarizing report with medically relevant data in statistical form
	MAI	18	02.05. – 06.05.11	
		19	09.05. – 13.05.11	
		20	16.05. – 20.05.11	**Modul Compliance Management:** • **Second Quarter Call for group 2*** with standardized questionnaire Life quality • Actual symptoms • Actual medication and health economics
		21	23.05. – 27.05.11	
	JUN	22	30.05. – 03.06.11	
		23	06.06. – 10.06.11	**6 week-Reporting to treating physician for group 2** Summarizing report with medically relevant data in statistical form
		24	13.06. – 17.06.11	
		25	20.06. – 24.06.11	**6 month Reminder Call pulmonologist** "Make an appointment with your specialist in the next quarter "
		26	27.06. – 01.07.11	**Modul Self-Management:** **1 x per quarter delivery of educational material incl. questionnaires** Theme „COPD Medication"

Table 2: Tasks of the Telemedical Service Center during the first two quarters in the field trial

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2.3 Training course for the patients

For logistical reasons, it seems reasonable to summon the selected patients for group 1 and 2 to a training course in the physicians practice. During this course

- ✓ all details of the study can be explained to the patients and they will get acquainted with the responsible persons of the telemedical provider,
- ✓ all devices can be handed out including an extense description of the functionality and of the handling of the devices by a technician,
- ✓ lacking documents can be filled out and signed by the patients if necessary,
- ✓ lacking medical data can be collected,
- ✓ the BCKQ-test can be performed with all patients to provide the subgrouping according to the level of knowledge of COPD, and, at least,
- ✓ all open questions can be discussed and clarified.

At this event, a first questionnaire is handed over to the patients focusing mainly on the acceptance of technological (telemedical) support in this new and complex medical treatment concept.

2.4 Collection of data

In the course of the field trial period, that will last for appr. 12, months data will be collected focusing mainly on

- ✓ the acceptance of the system by patients and their corresponding doctors,
- ✓ the stability of the technical equipment,
- ✓ to a lesser degree: on medical impacts.

For that reason the protocol in Table 3 has been set up.

In this context, it should be pointed out that this field trial is definitely not a clinical but exclusively a feasibility study. Thus, the study in the German field can never aim at classical clinical endpoints like death, deterioration or improvement of status etc. To achieve such goals the number of patients included is far to low for any statistical significance. However, there is very good chance to get an impression whether the service concept can modulate the patients behavior thereby leading to an improvement of the health status at least leading to a slowing down or even to a stagnation in the progression of the disease.

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Timing	Item of Questionnaire	Target or Data Input	Documents
Acceptance of the system			
	Intra- and interindividual comparison on the acceptance of the system by COPD patients in different stages of their disease before and after the field trial; subgroup analysis		
t = 0 mo	Questionnaire on the knowledge about and on the acceptance of technical telemedical system before the inclusion in the field trial	unexperienced patients **not** familiar with the service concept	• Questionnaire • Evaluation Report
t = 12 mo	Questionnaire on the acceptance of technical telemedical system after completion of the field trial	experienced patients familiar with the service concept	• Questionnaire • Evaluation Report
t = 12 mo	**Structured interview with the medical partners involved in the field trial on the acceptance of the system and their willingness to participate in a putative roll-out of the service concept in an integrated care contract**	medical partners	• Structured Interview Form • Evaluation Report
t = 12 mo	**Structured interview with associated insurance companies on the acceptance of the system and their willingness to reimburse and promote a putative roll-out of the service concept in an integrated care contract**	insurance companies	• Structured Interview Form • Evaluation Report
Technical stability			
t = 0 – 12 mo	Ongoing throughout the field test documenting in a **summarizing report** at the end of the field trial the functionality of the system including a detailed analysis of systems defaults or of any other technical problems	Technicians & TSC-staff	• Evaluation Report
Medical aspects			
t = 0 – 12 mo	**Ongoing throughout the field test documenting in a summarizing report at the end of the field trial medical data as well as health economic related aspects including** • Intra- and interindividual comparison with respect to adherence and/or improvement of proposed measures/parameters (training activity; spirometry and spirometric data) • Intra- and interindividual comparison with respect to changes and/or improvement in the "daily AHA" score during the observation period • Intra- and interindividual comparison with respect to an improvement of the current health status, i.e. decreasing numbers of acute exacerbations • Intra- and interindividual comparison with respect to healtheconomic data, i.e. hospital admissions, days of work loss due to an acute deterioration of health status, number of doctor visits to the family physician or to the pulmonologist • Intra- and interindividual comparison of any other medicinally documentable situation	Eletronic patient file	• Evaluation Report

Table 3: Protocol of data collection

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