WELCOME – Innovative Integrated Care platform using Wearable Sensing and Smart Cloud Computing for COPD patients with Comorbidities

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Abstract— **We propose WELCOME, an innovative integrated care platform using wearable sensors and smart cloud computing for Chronic Obstructive Pulmonary Disease (COPD) patients with co-morbidities. WELCOME aims to bring about a change in the reactive nature of the management of chronic diseases and its comorbidities, in particular through the development of a patient centred and proactive approach to COPD management. The aim of WELCOME is to support healthcare services to give early detection of complications (potentially reducing hospitalisations) and the prevention and mitigation of comorbidities (Heart Failure, Diabetes, Anxiety and Depression). The system incorporates patient hub, where it interacts with the patient via a light vest including a large number of non-invasive chest sensors for monitoring various relevant parameters. In addition, interactive applications to monitor and manage diabetes, anxiety and lifestyle issues will be provided to the patient. Informal carers will also be supported in dealing with their patients. On the other hand, welcome smart cloud platform is the heart of the proposed system where all the medical records and the monitoring data are managed and processed via the decision support system. Healthcare professionals will be able to securely access the WELCOME applications to monitor and manage the patient's conditions and respond to alerts on personalized level.**

I. Introduction

COPD (Chronic Obstructive Pulmonary Disease) is a common preventable and treatable disease, characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients.

COPD poses a significant public health burden with a morbidity and mortality rate that is increasing. One WHO report anticipates that by 2030, COPD will become the fourth cause of mortality and seventh cause of morbidity worldwide [1]. The prevalence of COPD in Europe ranges from 3.5% to 14%. However, in its report the WHO maintains that this an underestimation as estimates via spirometry were higher than those estimated using methods based on symptoms.

The successful management of COPD patients requires a multidisciplinary approach. Pharmacological treatment of patients with mild COPD should be initiated using a short-acting bronchodilator (β2 agonist or anticholinergic). A long-acting bronchodilator is added in patients with moderate COPD. Treatment with inhaled corticosteroids is needed in patients with severe COPD. Other aspects of treatment include vaccinations, antibiotics, mucolytics etc. In the late-stage of severity long-term oxygen therapy, non-invasive ventilation and surgical treatment become necessary. An important aspect of COPD management is maintaining adherence and proper inhaler technique.

Non-pharmacological treatment is also important and it includes; pulmonary rehabilitation and exercise (physiotherapy), nutritional assessments and smoking cessation. The latter has been shown to reduce disease progression, exacerbations, hospital admissions and mortality rate. This is supported by several studies. Despite its proven positive impact, smoking cessation is hard to achieve in clinical practice. This has been linked to co-existing addiction (ex-alcohol) and psychiatric diseases which reduce success rates and consequently increase mortality. In addition, exposure to pollution and chemicals may have an adverse effect on COPD management. A recent EU funded study [2], examined the distribution of various ambient particle metrics in four European cities and the results revealed a correlation between course particle concentration and COPD symptoms.

COPD is often associated with several co-morbidities such as cardiovascular disease (such as congestive heart failure-CHF), metabolic syndrome (including diabetes), osteoporosis, mental health diseases (depression and anxiety) and lung cancer. The most frequent chronic diseases often develop together. Comorbidities markedly affect health

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outcomes in COPD; in fact, patients with COPD mainly die of non-respiratory diseases [3], such as cardiovascular diseases (25%), cancer (mainly lung cancer, 20–33%) and other causes (30%).

WELCOME is an innovative system that goes beyond the state of the art though: a) Integrated care encompassing socio-medical aspects and technology of monitoring and treatment of COPD patients with comorbidities of CHF, diabetes, anxiety and depression, b) Technological elements, like sensing components and microelectronics that will compose system's motoring devices, c) Cloud services and advanced content delivery that will lead to an integrated healthcare approach than can be adopted to different countries, and d) Unified content delivery to a variety of devices (mobile and stationary) implemented in software applications with intuitive user interfaces provided to all actors involved in the therapy line.

II. Integrated Care Approach and Countries Scenarios

A. Integrated Care Approach

The concept of integrated care has been introduced into the management of various disease states. It supports the implementation and incorporation of multiple types of interventions in the patient care pathway. These might include patient related (patient education, self-management), professional directed (Provider education, re-distribution of roles: e.g. expanding the role of the pharmacist) and/or organizational (continuity of care, case management, follow up, use of information and communication technology) interventions. In COPD, current evidence from a systematic review of integrated disease management programs shows improvements in quality of life and reductions in hospitalisations in triple interventions [4].

Moreover, the use of ICT in such successful integrated care models has been evident in several studies. One study evaluated the effect of integrated care (IC) on COPD patients as compared to usual care (UC). The IC model included a comprehensive assessment of the patient (adherence, comorbidities, severity etc.), patient education, individualized care with follow up and a 24 hour access to care via an information and ICT platform. One hundred and thirteen patients were recruited and randomised to 2 groups IC and UC. After 12 months, the IC group had improved nutritional status and self-management scores which included (knowledge, exacerbation identification, inhaler adherence and correctness). These factors translated into a reduced hospital re-admission rate [5].

B. Countries Scenarios

The WELCOME system will be tested in five countries with different health-care systems (Germany, Greece, UK, Netherlands and Ireland), in order to be evaluated in terms of feasibility, acceptance and impact as a treating tool, with the appropriate contextualisation required for each pilot country.

A major concern for the development such system is the unified handling of the treatment processes followed in the different countries participating in the project. A mapping of the patient care pathways followed in the countries participating in the project has started in order to identify differences or possible contradictions. The WELCOME system will implement different user scenarios for each country, adapted to its own patient care pathways. The definition of these scenarios is part of the ongoing system requirements process.

As a use case scenario of the WELCOME system, figure 1.b shows the WELCOME system as part of the current healthcare pathway for COPD patient in UK. The care pathway for COPD patients start at the GP in UK, the follow up is provided by GP visits, community services, hospital chest clinics and special clinical teams [6]. The follow-up care services involve GP, consultants, physiotherapist and nurses. The special clinical team includes the respiratory teams and community matrons providing specialist input and basic support including respiratory teams' clinics, pulmonary rehabilitation and smoking cessation.

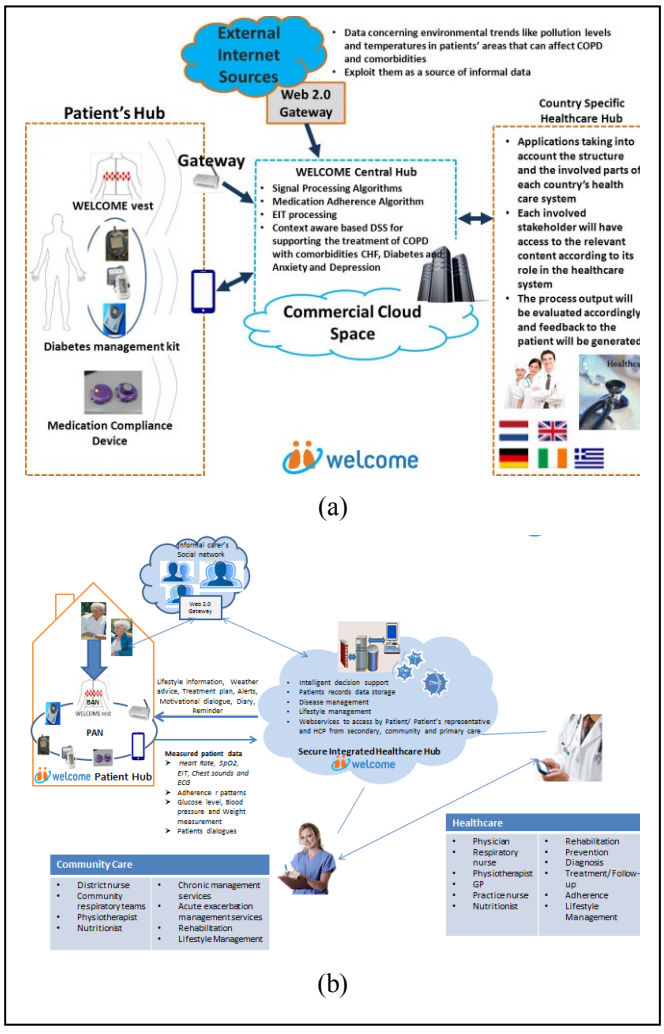

Figure 1. a) Integrated care concepts in WELCOME, b) WELCOME System – UK use case scenario

III. System Architecture

Figure 2 shows the architecture of the welcome system demonstrating the functional modules of the system and partly their interaction. We designed the system architecture

in a highly modular fashion in order to ease its development and task distribution between the partners.

The cloud part of the system consists of several modules (storage server, feature extraction module, decision support system and external applications connector). Patient hub handles the interaction with the patient and the transfer of the patient's biosignals. WELCOME applications interact with the medical staff and facilitate the comorbidities treatment. The functionality described in this section is currently refined during the ongoing process of the system requirements.

A. WELCOME patient Hub

Welcome patient hub includes all the software and hardware components interacting with the patient, including: a) a unified data acquisition application to collect the medical data from the medical sensors and submit those data to the WELCOME cloud, and b) interactive applications to collect information and present the results including alarms, motivation messages, and guidelines for the patient in intuitive ways with a capability of providing feedback, etc.

The patient sensor system is built around a light vest including a large number of standalone non-invasive chest sensors for measuring and monitoring various parameters of COPD and co-morbidities. It incorporates 26 sensors connected together via a two-wire bus Body Area network, working in concert for measuring and monitoring various parameters of COPD and co-morbidities. More specifically, the vital signs and parameters to be measured include: a) SpO2: lowering below a predefined threshold (usually 90%) is a concern, b) EIT: Electrical Impedance Tomography findings consistent with increased degree of ventilation heterogeneity associated with exacerbation of COPD, inadequate therapy or natural progression of the disease, pulmonary oedema and/or pleural effusion (especially in the COPD and CHF subgroups), c) Chest sounds: crackles, rhonchi or wheezing, d) Multichannel electrocardiogram (ECG): onset of a not previously reported tachycardia or arrhythmia like atrial fibrillation, e) activity. For patients with comorbidity like diabetes and inhaler adherence problems, the patient hub incorporates the diabetes kit (including the Glucose meter, Blood pressure meter and Weight scale) in addition to the Dry powder inhaler (figure 1b).

Transferring medical data of such volume to the cloud is not a trivial task. Many considerations regarding bandwidth efficiency and security rise through the current ongoing design process. Following standardized security/privacy procedures (anonymizing data, securing network, etc.) adds valued overhead and therefore compression techniques are engaged before transmitting data to the cloud. The wireless communications of all Patient Hub components with the rest of the system will be reflected to the communication APIs.

According to the WELCOME system design, the patient hub platform is a software application that can be implemented on portable devices (e.g. android or windows mobile), and collects the vest data via the Wifi short range communication, the Diabetes sensors via the Bluetooth communications and the inhaler adherence data via the USB connectivity. In this Personal Area Network based structure of the patient hub, data gets aggregated and processed in the patient hub platform and once ready gets transmitted to the cloud via the mobile communication network or the Broadband home communications network.

B. WELCOME Cloud

The welcome cloud system consists of three main parts, the *storage server*, the *feature extraction module* and the *decision support system* (DSS). These modules handle the medical data provided by the end users, after anonymization in order to ensure data privacy. The workflow of data and the system's activities is coordinated by an *orchestrator* software agent who will handle the communication between the various system's sub-modules and trigger the DSS.

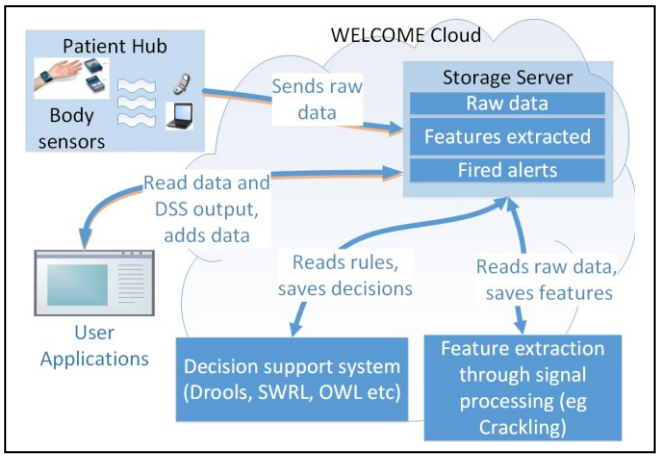

Figure 2. WELCOME high level system architecture

The storage server saves the patient data, biosignals and bioparameters coming from the patient hub and medically relevant data coming from the patient's evaluation by medical staff. It should be noted that the storage server does not save data regarding the applications' realm (user data, etc.) but only data having to do with the patient's medical condition. Monitoring of such multiparameter signals leads to a large and complex data set to be stored. Therefore, the storage server will face the big data challenge, in terms of maintenance and performance [7].

The feature extraction module retrieves from the storage the raw signals originating from the patient hub (ECG, EIT, lung sounds, etc.). The module extracts several higher level features, for example the occurrence of crackles, to be used in the decision process [8].

WELCOME decision support system (DSS) will engage semantic web technologies and dynamic rules to enhance the inference process [9]. The outcome of the decision support procedure will be alarms, warnings and estimations regarding the patient's status based on patients' clinical data, biosignal data and extracted features. The definition of the rule set is one of the main parts of the currently ongoing system's requirements definition process. The definition of the specific rule set is far from trivial as it will engage multidisciplinary medical rules, potentially contradicting, for treatment of COPD multimorbid patients.

The WELCOME cloud system will communicate with the rest of the system's parts using standardized and secure procedures based on web services. We are oriented in using

REST services inside a VPN accessed through certified router devices from user side.

C. WELCOME Healthcare Applications

The healthcare applications handle the interaction of the users with the system. The system's user roles are the patients, the medical personnel, the patient's informal carers (e.g. family) and the system's administrators. During the ongoing design phase, we organize the applications mainly in two groups: the applications running on the patient hub and the applications provided as services through a unified platform. The content of the applications will be accessible from both stationary (PCs, desktops) and mobile devices (tablets, smartphones). Patient hub applications will be available on the patient's home infrastructure and mainly interact with the patient. One such application is the lifestyle application which will monitor the patient's lifestyle and provide related advice and support [6], e.g. on smoking cessation and physical activity. The informal carer application will be used to access the patient's medical information, history and schedule in order to help the informal carers in their everyday care of the patient.

The platform services will be accessed through a secure network infrastructure and standardized control access mechanisms. The provided functionality will depend on the specific user's permissions and will include administration tasks, clinical evaluation applications, visualizing of patient's biosignals and patient's behavioural/lifestyle assessment. They will be adjustable to local Healthcare needs, for providing integrated care services. On these applications' design, we emphasize on the need of coordinated care of the COPD and the respective comorbidities.

IV. Standardization and Legal Issues

WELCOME system includes non-intrusive electronic equipment, a clinical decision support system and management of sensitive personal data. Issues of legal regulation and standardization rise for such systems. Despite the fact that WELCOME is research oriented and not a production system, we design its development taking into account the most commonly accepted standards, guidelines and relevant best practices in the domains of network communications infrastructure, data model, user interaction and security, including HL7, ISO, HIPAA and CEN. More specifically, we plan to integrate the EPSOS Patient Summary and ePrescription data model concepts [10] in our system (keeping in mind that concepts of patient information may be compatible but the information flow may differ in EPSOS) and also implement HL7 specifications for interoperable resources [11], as well as apply pseudonymization techniques (ISO/TS 25237) for the protection of personal sensitive data. Moreover, we investigate the Continua Alliance guidelines for sensor communication and decided to implement https RESTful services for our network communications [12, 13]. Regarding our overall development lifecycle, we decided to follow the ANSI IEC 62304:2006 standard which relates to the medical software lifecycle processes and ISO 14971 for the risk management of our system [14].

V. Conclusion and Discussion

Many integrated care approaches were reported in literature [15]. These approaches can be classified based on the implementation degree on the healthcare hierarchy levels, including System, Organisational, Functional, Professional, Service and Personal level. The WELCOME system will target the Functional level (as an ICT platform), the personal level (as a patient's and informal carer centric platform), Service level (bringing healthcare and social care together), Professional level (requires the cooperation and the communication of the different Healthcare professionals responsible for the COPD patients and other co-morbidities).

Currently the project is on the requirements gathering and design phase. We have already identified some major issues of implementing this big and complex system. Integrating such a multi-parametric monitoring system with enhanced data management and decision support concepts is far from trivial. However, the difficulties are not only technical, but most importantly conceptual as the project intends to unify the treatment of COPD with its comorbidities in order to present a new approach in the medical practice, taking into account contextualisation for each healthcare system.

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