Use of a Smartphone for Self-Management of Pulmonary Diseases

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Mestrado Integrado em Bioengenharia

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Abstract

Chronic obstructive pulmonary disease is a serious health problem which places a significant economic burden on health systems worldwide, due mostly to a significant number of acute exacerbation events. The prevention of these events is a common goal of COPD treatments, being imperative that patient education and self-management programs are developed in order to arouse patient’s awareness of their activity behavior and health condition.

Home telemonitoring has gained interest as a potential solution to the global challenge of providing home care and encouraging patients to become more involved in the management of their own health condition, and also as a way to bridge the gap between professional care and patient self-management.

Making use of smartphone technology, the COPDHelper was developed, an application aimed to improve the patient’s self-management of the pulmonary disease, assisting and guiding in the diverse fields of pulmonary rehabilitation and treatment. Developed only for Android OS, in order to be integrated in the Fraunhofer’s SmartCompanion, this telemonitoring system is composed by two major modules: (1) Monitoring and (2) Counseling and Education. However, and since self-awareness of the actual state of the disease is as much important as monitoring of the COPD symptoms and patient’s vital signs, the focus of COPDHelper rests more precisely in detecting and solving the small mistakes on the part of the patient when managing this pulmonary disease, marking its main difference when compared with available methods.

By successfully adopting already implemented features of the SmartCompanion and making use of external biomedical sensors, COPDHelper became an in-depth application, capable of covering the most relevant aspects of pulmonary disease self-management.

The evaluation of the developed system was performed via usability tests, to assess its efficiency and coherence, and also user satisfaction when interacting with the system. The results indicated that COPDHelper would be a successfully management tool for COPD patients, but with some reservations regarding its use by senior patients. As commonly encountered in other systems in its early stages of development, some COPDHelper features and components need further improvements before this application is fit for routine use.

Keywords: Chronic Obstructive Pulmonary Disease. Self-management. Telemedicine and telemonitoring. Android application. SmartCompanion
Resumo

A doença pulmonar obstrutiva crónica representa, globalmente, um fardo econômico significati-
vo para os sistemas de saúde, devido em grande parte ao número significativo de ocorrências
de exacerbações. A prevenção destas exacerbações é um dos principais objetivos do tratamento
da DPOC, sendo imperativa a criação e o desenvolvimento de programas capazes de educar e
consciencializar o paciente do seu atual estado da doença.

O conceito de telemonitorização tem ganho interesse como uma solução potencial para o de-
safio de prestação de cuidados domiciliários e de incentivo aos pacientes para estes se envolverem
mais ativamente na gestão da sua doença, e também como uma forma de colmatar a lacuna entre
os profissionais de saúde e a gestão que está a ser praticada pelo paciente.

Recorrendo a um smartphone, foi desenvolvido o COPDHelper, uma aplicação com o objec-
tivo de melhorar a gestão desta doença pulmonar, assistindo e aconselhando os pacientes nos mais
diversos campos dos programas de reabilitação pulmonar e tratamento da doença. Desenvolvido
apenas para sistema operativo Android, de modo a ser integrado num projeto desenvolvido pela
Fraunhofer, SmartCompanion, este sistema de telemonitorização é composto por dois módulos
principais: (1) monitorização e (2) aconselhamento e educação.

Contudo, e tendo em conta que a auto-consciencia do estado da doença por parte do paciente
é tão importante como a monitorização da progressão dos sintomas e dos sinais biomédicos do
paciente, o foco do COPDHelper incide de forma mais vincada na deteção e resolução de erros
praticados pelos pacientes aquando da gestão desta doença, destacando-se, desta forma, dos já
existentes sistemas de telemonitorização. Com a utilização de sensores biomédicos externos e da
integração de funcionalidades do SmartCompanion já implementadas, o COPDHelper torna-se
numa abrangente aplicação, capaz de cobrir os aspectos mais revelantes na gestão da DPOC.

A avaliação do sistema desenvolvido foi realizada via testes de usabilidade, de maneira a
avaliar não só a eficiência e coerência do sistema, mas também a satisfação do utilizador após uma
interação ativa com o sistema. Os resultados obtidos indicaram que o COPDHelper poderá vir a
ser uma ferramenta de gestão benéfica para os pacientes com DPOC, mas com algumas reservas
quanto à sua utilização por utilizadores séniores.

Como é comum em sistemas nas fases iniciais do desenvolvimento, algumas funcionalidade e
componentes do COPDHelper necessitariam ainda de melhoramentos futuros antes da sua incorpo-
ração em aplicações reais.

Keywords: Doença pulmonar obstructiva crónica. Auto-gestão. Telemedicina e telemon-
itorização. Aplicação Android. SmartCompanion
Agradecimentos

No fim desta fantástica viagem, acontece todo um flashback de grandes momentos que não seriam possíveis sem o apoio e palavras sábias de certas pessoas. A elas, o meu sincero obrigada.

Aos meus orientadores, Liliana Ferreira e Luís Teixeira, pelo apoio e orientação que tornaram a realização deste projecto possível. À Franhofer AICOS por me ter autorizado a entrar nas fantásticas instalações e proporcionar-me momentos de aprendizagem com os experientes investigadores do departamento R&D.

À Barbara Moreira e Pedro Pereira, por todas as intermináveis horas passadas a trabalhar, praguejar e desesperar para ter o trabalho feito, pelos coffee breaks a cantar músicas parolas para toda a empresa ouvir, e pela oportunidade de fazer figuras tristes a testar os vossos algoritmos.

À minha família, que esteve sempre disposta a ajudar mesmo nas minhas fases de "pessoa irritante devido ao stress".

Às BFF’s, um grupo criado e vivido na faculdade, mas cuja existência nunca cessará. À Ana Gerós, uma mente brilhante difícil de lidar, que me aturou por longos 5 anos sem nunca me deixar para trás. À Maria Almeida e à Lia Costa, pelo vosso exagerado OCD em design de apresentações, posters, folhetos e associados.

À Diana e às suas caminhadas espirituais, e à Pico e às suas teorias de imaginar a mão como sendo feita de pequenos átomos visíveis.

Ao mestre do inglês, que conseguiu pegar em frases que envergonhavam Shakespeare e torná-las faustas demais para os antepassados britânicos.

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Joana Inês Marques Costa
“To $\lim_{x\to\infty}(\sqrt{x})^{\sqrt{x}}$ and beyond!”

Anonymous
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<th>Description</th>
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<tbody>
<tr>
<td>CAT</td>
<td>COPD Assessment Test</td>
</tr>
<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FEV₁</td>
<td>Forced Expiratory Volume in 1 second</td>
</tr>
<tr>
<td>FVC</td>
<td>Forced Vital Capacity</td>
</tr>
<tr>
<td>GOLD</td>
<td>Global Initiative for Chronic Obstructive Lung Disease</td>
</tr>
<tr>
<td>HDP</td>
<td>Health Data Platform</td>
</tr>
<tr>
<td>mMRC</td>
<td>Modified British Medical Research Council</td>
</tr>
<tr>
<td>PₐCO₂</td>
<td>Arterial Carbon Dioxide Partial Pressure</td>
</tr>
<tr>
<td>PₐO₂</td>
<td>Arterial Oxygen Partial Pressure</td>
</tr>
<tr>
<td>SUS</td>
<td>System Usability Scale</td>
</tr>
<tr>
<td>UX</td>
<td>User Experience</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Chapter 1

Introduction

"The lives of far too many people in the world are being blighted and cut short by chronic diseases such as heart disease, stroke, cancer, chronic respiratory diseases and diabetes" - Lee Jong-wook, former Director-General of World Health Organization (WHO).

Over the XXI century, the epidemiological burden of chronic diseases and their risk factors have been increasing worldwide, especially in low and middle income countries [1]. Most countries, in special the ones where the increase of chronic disease has been remarkably noted, do not have clear national policies for prevention and treatment of such diseases, having also to deal with the practical realities of low resources [1].

In 2004, the projection of the number of deaths related to chronic disease was 35 million. Figure 1.1 depicts such projections worldwide.

![Figure 1.1: Estimated age standardized death rate caused by chronic diseases. Adapted from [2].](image)

In 2012, the top ten was led mostly by chronic diseases, double the estimations for all infectious diseases combined, (Figure 1.2). With this daunting death’s estimates, it is vitally important that the impending chronic diseases pandemic is recognized, understood and acted on urgently. [1]

The causes of the main chronic disease are well established and well known. Between the most relevant risk factors are: unhealthy diet and excessive energy intake; physical inactivity; and tobacco use. The high death rate in the low and middle income countries is mostly due to the excessive tobacco consume.
Introduction

From all listed death causes in Figure 1.2, chronic diseases present the most interesting challenge for telemonitoring, given that the long and continuous treatment needed for such diseases becomes an advantage for such applications. Among the vast array of chronic diseases, there are five which are gaining some relevance in the research field of telemonitoring: asthma, chronic obstructive pulmonary disease (COPD), diabetes, coronary disease and congenital heart disease. The scope of this master’s thesis will be directed towards the development of a monitoring system to COPD, as will be further motivated in the next section.

1.1 Motivation

Chronic obstructive pulmonary disease is a serious health problem and a major cause of chronic morbidity and mortality worldwide. According to World Health Organization estimates, COPD was the fourth leading cause of death worldwide in 2004, accounting for 5.1% of all disease-related deaths. The same study predicts an absolute increase of 3.5% in such numbers by 2030 [4]. In 2012 this disease was already the third leading cause of death worldwide, killing over 3 million people [5]. In the particular case of Portugal, according to the Fundação Portuguesa do Pulmão, COPD was the fifth leading cause of death in 2006 [6]. Its prevalence was 5.3% in 2004, increasing to 14.2% in 2009 [7, 8].

COPD places a significant economic burden on health systems worldwide, due mostly to a significant number of hospital admissions and high frequency of urgency services [8, 9]. The larger fraction of this total cost (58%) [10] is associated to COPD exacerbations, which are acute events characterized by a significant worsening of lung function and symptoms, that lead to hos-
1.2 Objective

The main goal of this master’s thesis is the development of a monitoring system for COPD, capable of advising the user in several topics regarding the management of the disease, warning both user and healthcare specialist whenever some worrisome activity is detected, as well as monitoring the vital signs and progression of the patient’s symptoms.

The rest of this master’s thesis is organized as follows: Chapter 2 presents an overview on COPD and its clinical features, diagnosis and treatment as well as the current strategies to successfully manage this pulmonary disease and prevent COPD exacerbations; Theoretical concepts of telemonitoring and self-management and a literature review are presented in Chapter 3. Chapter 4 details the tools and resources used to developed this monitoring system, as well as detailing the functioning modules of the monitoring system itself. Chapter 5 details the system evaluation results and a general discussion of the system’s limitations. Finally, in Chapter 6 is presented the overall analysis of all the work done and of the possible future improvements.
Chapter 2

Chronic Obstructive Pulmonary Disease

2.1 Overview

Chronic obstructive pulmonary disease is a chronic disorder characterized by irreversible and progressive airflow limitation that causes severe physiologic and functional impairment in patients with advanced disease [13]. Of all the major diseases, COPD is the only with continued increases in prevalence and mortality rates, and it is estimated that the global burden of COPD will increase substantially in the coming decades [14]. However, this disease is markedly underdiagnosed and frequently undermanaged, as patients often attribute COPD symptoms to aging or cigarette smoking. Is is also difficult to differentiate between this disease and asthma, do to the overlap in pathophysiology, clinical presentation, pulmonary function test results, and treatment [13].

As the increasing global burden is associated with a great number of COPD exacerbations, which are acute events characterized by a significant worsening of lung function and symptoms [11], understanding their pathogenesis and determining their optimal treatment is an important part of the overall management of this pulmonary disease [14].

2.1.1 Pathology

The pathologic changes in COPD are complex and occur in different locations: central conducting airways, peripheral airways, lung parenchyma, and pulmonary vasculature [15]. The most pathologic lesion associated with COPD is inflammation, initiated by exposure to particles or gases. Changes in the central airways can lead to chronic hypersecretion of mucus, produced by the mucus glands in the larger airways.

The smaller bronchi and bronchioles (Figure 2.1), less than 2mm in diameter, are the major site of airflow obstruction in COPD. An inflammation on these small airways is one of the earliest changes to occur in the development of this pulmonary condition [15].

Pulmonary emphysema (Figure 2.2) is a pathologic change in the lung parenchyma characterized by an abnormal permanent enlargement of airspaces distal to the terminal bronchioles, as a result of destruction of alveolar walls [15].
Pulmonary vascular changes are characterized by a thickening of the vessel walls. Thickening of the intima, followed by an increase in smooth muscle and infiltration of the vessel wall with inflammatory cells, are changes that occur early in the course of COPD. Greater amounts of smooth muscle, collagen, and proteoglycans present in the arterial wall will lead to its thickening as COPD progresses [15].

2.1.2 Risk factors

A series of host factors and environmental exposures are considered to be risk factors of COPD, as the disease arises from the interaction between these factors [17].

Smoking habit is considered to be the most important risk factor in COPD, as cigarette smokers have more respiratory symptoms, lung function abnormalities, and a greater death rate from COPD.
2.2 Clinical features

than non-smokers [18]. However, not all smokers show deterioration in lung function and develop clinically significant COPD, which may suggest that other risk factors, such as genetic factors, must modify each individual’s risk [17]. Passive smoking may also contribute to chronic airflow limitations, but its effect is not yet powerful enough to demonstrate clinical significance [15]. Still concerning cigarette smoking, maternal smoking poses as a risk factor by affecting lung growth and increasing the frequency of respiratory illness in the first years of life [17].

High levels of air pollution have been also recognized as a risk factor in COPD, as a result of various air pollution episodes, such as the London smog of 1952 in which 4000 excess deaths due to cardiorespiratory disease occurred. However, the role of air pollution in the development of COPD seems to be small when compared with cigarette smoking [15].

Occupational exposure to dust or chemicals is associated with an increased risk of developing COPD by an increase in airway hyperresponsiveness [17]. Airway hyperresponsiveness is also identified as a risk factor to the development of COPD but its way of influence is unknown. This disorder is related to a number of genetic and environmental factors and may be a result of smoking-related airway disease [17].

Concerning genetic factors, a variety of genes have been associated with the development of this pulmonary condition, but the only proven association is with a rare hereditary deficiency of alpha\(_1\)-antitrypsin [17]. Studies have shown that premature and accelerated development of panlobular emphysema and decline of lung function occur in patients with the severe deficiency [19, 20].

The prevalence of COPD is, also, often associated with both low socioeconomic status, as well as clinical history of respiratory infections in childhood [17].

2.2 Clinical features

Most patients with COPD seek for clinical attention late in the course of their disease. They typically present a combination of signs and symptoms of chronic bronchitis, emphysema, and reactive airway disease [15].

Breathlessness is a characteristically persistent and progressive symptom that often drives patients to seek for medical help and is usually a sign for the existence of moderate impairment of expiratory flow. Changes in environmental temperature and exposure to dust or gases can trigger severe breathlessness, with a sense of increased effort to breathe, heaviness, air hunger or gasping [15].

Persistent or intermittent chronic cough is the most frequent symptom reported by COPD patients. However, most patients frequently neglect it as a clinical sign. It may initially be intermittent, but later extends throughout the day and throughout the year with sputum production. In 75% of the patients, cough either precedes the onset of breathlessness or appears simultaneously with it [21].
Sputum production often appears after coughing bouts, but its evaluation is rather difficult because patients may swallow sputum instead of expectorate it. The presence of purulent sputum reflects an increase in inflammatory mediators [21].

Regarding severe chest pain, it is not a feature of COPD, and its manifestation suggests complication or other conditions that frequently coexist with COPD [21]. The sense of chest tightness is usually complaint during worsening of breathlessness, particularly during exercise, and its cause may be due to an overinflation of the lung [15].

In a severe stage of the disease, fatigue, weight loss, and anorexia are common symptoms, thought to result from both decreased calorie intake and hypermetabolism. Depression is also manifested in the severe stage of COPD [22].

2.3 Diagnosis and Assessment

2.3.1 Diagnosis

A clinical diagnosis of COPD should be considered to patients with symptoms of cough, sputum production, or dyspnea, and/or history of exposure to risk factors for the disease.

In the early stages of the disease, physical examination may be inconclusive, as physical signs are not usually present until significant impairment of lung function has occurred. Such signs are also non-specific and depend on the degree of airflow limitation and pulmonary overinflation [15]. As a diagnosis method for COPD, physical examination has relatively low sensibility and specificity [17].

Pulmonary function tests play a key role in COPD, as not only help in the diagnosis, but also assess the severity of the disease and evaluate the response to therapy. Spirometry is the most robust and objective measurement of airflow limitation available [23], and although it measures only a small aspect of COPD effects in patient’s health, it remains the gold standard for diagnosis due to its availability and high reproducibility [17]. This method assesses the degree of airflow limitation by measuring the force expiratory volume in 1 second (FEV$_1$)$^1$ and the ratio of FEV$_1$ to forced vital capacity (FEV$_1$/FVC) [10]. Forced vital capacity corresponds to the total exhaled breath and, like FEV$_1$, is measured in liters. In people with normal lung function, FEV$_1$ is at least 70% of FVC whereas for patients with COPD presents low FEV$_1$ with an FEV$_1$/FVC ratio below the normal range (normal range determined based on age, height, sex and race) [15].

To patients with FEV$_1$ value below than 40% of the predicted or clinical signs of respiratory failure or right heart failure, a complementary diagnosis method to assess arterial blood gases is generally performed. This measurement will assist in the decision of whether or not the patient needs ventilatory support [17].

The assessment of the reversibility of airflow limitations to bronchodilators has also been an important test to differentiate between COPD and asthma, as higher postbronchodilator FEV$_1$ value ( > 1.2%) is usually evidence of the presence of asthma. As for COPD patients, the spirom-

---

$^1$FEV$_1$ measures how much air a person can exhale during a forced breath at the first second
metric test is characterized by a decreased $\text{FEV}_1$ and $\text{FEV}_1/\text{FVC}$ ratio after the inhalation of a bronchodilator, as illustrated in Figure 2.3. However, bronchodilator reversibility can vary between patients, change over time and differ according to the used bronchodilator [15].

![Figure 2.3: Spirogram contrasting postbronchodilator FVC in patient with COPD and normal FVC.](image)

The diagnosis of COPD disease by imaging techniques is not performed, as this pulmonary disease does not produce any specific features on plain chest radiograph [15]. Nevertheless, imaging techniques can support the diagnosis and help exclude other conditions that produce similar signs and symptoms. Most of the information collected in chest radiography on COPD relates to pulmonary emphysema. Also, computer tomography scanning has been used to assist in the COPD diagnosis, by detecting and quantifying emphysema [21]. Measurement of diffusing capacity can provide information on the functional impact of emphysema in COPD and may be helpful in patients with breathlessness that may seen out of proportion with the degree of airflow limitation [23].

### 2.3.2 Assessment of the Disease

The assessment of COPD is intended to determine (1) the severity of airflow limitation, (2) the impact of the disease on the patient’s health status, and (3) the risk of future events, such as exacerbations and hospital admissions. These three goals are accomplished by taking into consideration some aspects of the disease separately: severity of airflow limitation, current level of patient’s symptoms, exacerbation risk and the presence of comorbidities [24].
Chronic Obstructive Pulmonary Disease

According to the GOLD classification system, there are four categories for airflow limitation severity, based on the degree of airflow limitation after the administration of an adequate dose of short-acting inhaled bronchodilator (Table 2.1) [22].

Table 2.1: GOLD classification of airflow limitation severity. Adapted from [15].

<table>
<thead>
<tr>
<th>Stage</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>I: mild</td>
<td>FEV₁ &gt; 80% predicted</td>
</tr>
<tr>
<td>II: moderate</td>
<td>50% &lt; FEV₁ &lt; 80% predicted</td>
</tr>
<tr>
<td>III: severe</td>
<td>30% &lt; FEV₁ &lt; 50% predicted</td>
</tr>
<tr>
<td>IV: very severe</td>
<td>FEV₁ &lt; 30% predicted or 30% &lt; FEV₁ &lt; 50% predicted*</td>
</tr>
<tr>
<td></td>
<td>*with respiratory failure or clinical signs of right heart failure</td>
</tr>
</tbody>
</table>

The worsening of airflow limitation is associated with an increasing prevalence of exacerbations and risk of death. For that being, this classification should be used as an indication to manage COPD and guide therapy, in order to reduce and prevent the development of this chronic disease [17, 24].

Measurements of the current level of patient’s symptoms and the impact of the disease in their quality of life have proved to be of important value in addition to the assessment of airflow limitation severity, as the latter has limitations with respect to symptoms and some aspects of lung function. One of the most reported symptoms, dyspnea, can be measured during exercise tests, where a modified Borg scale (Table 2.2) or a visual analogue scale are used to rate it [23]. There are also several validated questionnaires to assess patient’s symptoms, being the GOLD primary recommendations the Modified British Medical Research Council (mMRC), more focused on breathlessness, and the COPD Assessment Test (CAT), which assesses not only the severity of patient’s symptoms but also the impact that COPD has on the patient’s daily activities and well being [23, 24]. Other questionnaires, such as Chronic Respiratory Disease Index Questionnaire and the St. George’s Respiratory Questionnaire, are too complex to use in routine practice and time-consuming, discouraging patients to complete them [15, 21].

Table 2.2: Modified Borg scale for the assessment of dyspnea. Adapted from [15].

<table>
<thead>
<tr>
<th>Scale</th>
<th>Severity experiment by Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Nothing at all</td>
</tr>
<tr>
<td>0.5</td>
<td>Very, very slight (just noticeable)</td>
</tr>
<tr>
<td>1</td>
<td>Very slight</td>
</tr>
<tr>
<td>2</td>
<td>Slight (light)</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>4</td>
<td>Somewhat severe</td>
</tr>
<tr>
<td>5</td>
<td>Severe (heavy)</td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Very severe</td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Very, very severe (almost maximal)</td>
</tr>
<tr>
<td>10</td>
<td>Maximal</td>
</tr>
</tbody>
</table>
2.3 Diagnosis and Assessment

The history of hospitalizations and treated events is the best predictor of the occurrence of frequent exacerbations (two or more per year) and risk detector of possible future exacerbations and hospital admissions. The severity of exacerbations can be classified in three stages: mild if a change on the inhaled treatment is required; moderate when medical intervention including short course of antibiotic/oral steroids is needed; and severe when the patient has to be hospitalized [24].

As a way of combining the aforementioned analysis of the different aspects of this pulmonary disease and improve its management, GOLD developed the Combined COPD Assessment, where patients are clustered into four different groups (A to D), depending on the triangulation of the different assessments results.

Figure 2.4: Combined COPD Assessment. Adapted from [23].

<table>
<thead>
<tr>
<th>Patient category</th>
<th>Characteristics</th>
<th>Spirometric classification</th>
<th>Exacerbations per year</th>
<th>mMRC</th>
<th>CAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Low risk: less symptoms</td>
<td>GOLD 1-2</td>
<td>&lt;1</td>
<td>0-1</td>
<td>&lt;10</td>
</tr>
<tr>
<td>B</td>
<td>Low risk: more symptoms</td>
<td>GOLD 1-2</td>
<td>&lt;1</td>
<td>&gt;2</td>
<td>&gt;10</td>
</tr>
<tr>
<td>C</td>
<td>High risk: less symptoms</td>
<td>GOLD 3-4</td>
<td>&gt;2</td>
<td>0-1</td>
<td>&lt;10</td>
</tr>
<tr>
<td>D</td>
<td>High risk: more symptoms</td>
<td>GOLD 3-4</td>
<td>&gt;2</td>
<td>&gt;2</td>
<td>&gt;10</td>
</tr>
</tbody>
</table>

Figure 2.4 depicts the combined COPD assessment’s table. By using the aforementioned questionnaires (CAT or mMRC), it is determined if the patient belongs to the left or right side of the table, depending on the final score of the questionnaires. To assess if the patient belongs to the lower part (low risk) or the upper part of the table (high risk), the healthcare specialist can resort to either spirometry, and assess the risk by the patient’s airflow severity, or, alternatively, assess such risk by the number of exacerbation events that occurred within the previous 12 months [24]. In some patients, these two methods can lead to two different levels of risk. In this case, the risk should be determined by the method indicating a higher level, preventing possible complications in the patient’s treatment [24]. Hereupon, the healthcare specialist can properly direct the most effective treatment and care to the patient. This combined assessment presents marked advantages over the unidirectional analysis of airflow limitation, allowing a more in depth representation of
the COPD complexity. Such capability makes this combined assessment a viable starting point to achieve an individualized management of this pulmonary disease [24].

2.4 Management of COPD

An effective management of COPD consists, initially, on the early and accurate diagnosis, and secondarily on the prevention and pharmacological treatment to reduce the impact of the disease on patients [15]. As COPD is usually a progressive disease, where patient’s lung function can be expected to worsen over time, it is necessary to perform an ongoing monitoring of the disease to assess its severity and determine when to adjust therapy. This monitoring extends from oxygen saturation, FEV\(_1\) value, and arterial blood gases measures to the evaluation of the health-related quality of life, by means of questionnaires. Also, educational advice on health living should be transmitted to COPD patients [17].

2.4.1 Reduction of risk factors

Smoking cessation is the most effective way to reduce the risk of developing COPD and stop its progression [17]. The first Lung Health Study showed that stopping smoking was associated with a reduced decline in FEV\(_1\) [25]. Specific resources to support COPD patients to quit smoking should be an integral part of their care. Practical counseling and social support are part of an effective smoking cessation intervention process but may not always be successful [17]. Numerous effective pharmacotherapies have been developed to help patients quit smoking when counseling is not sufficient. Nicotine replacement therapy in any form (nicotine gum, inhaler, nasal spray, transdermal patch or sublingual tablet) reliably increases long-term smoking abstinence rates [17]. Reducing the risk of indoor and outdoor air pollution is feasible and requires a combination of public policy, local and national resources, cultural changes, and protective changes taken by individual patients. Also, reduction of exposure to dust or gases is crucial to reduce the prevalence of COPD [17].

2.4.2 Reduction of symptoms and complications

Inhaled bronchodilators are currently considered the most effective pharmacologic therapy, as they provide symptomatic relief and improve exercise capacity [15]. They are prescribed either on an as-needed basic for relief of persistent or worsening of symptoms, or on a regular basis to prevent and reduce symptoms. There are different classes of bronchodilators and the choice of which to use depends on the patient’s response, and its availability and effectiveness in achieving the desired outcome [15]. All categories of bronchodilators have been shown to increase exercise capacity without necessarily producing significant changes in FEV\(_1\). This therapy has, however, the disadvantage of having significant cost implications. Corticosteroid drugs are the most commonly prescribed anti-inflammatory agents, in order to reduce pulmonary inflammation. To patients in a more severe stage of the disease, inhaled corticosteroids are prescribed with the view to prevent ex-
acerbations. Nonetheless, patient education is required in furtherance of successfully conducting this therapy, which is not always provided to the patients [26]. The intake of oral corticosteroids increases FEV$_1$ in approximately 10% on patients with symptomatic COPD [21]. However, in patients in an advanced stage of the disease, the regular oral corticosteroids produce significant side effects, like steroid myopathy, that contributes to muscle weakness, decreased functionality, and respiratory failure. Also, there is no evidence of long-term benefits from this therapy [17]. Vaccines containing killed or live, inactivated viruses are a recommended treatment that should be administered once or twice a year (autumn and winter) [17].

As a non-pharmacological treatment, pulmonary rehabilitation is an effective therapeutic program that provides benefits over and above those that can be achieved with medications alone [15]. This therapeutic program aims towards the reduction of symptoms, improvement of the quality of life, and to optimize physical and social performance. To achieve these goals, pulmonary rehabilitation covers a wide range of nonpulmonary problems, including exercise deconditioning, relative social isolation, depression, muscle wasting, and weight loss. The two key principles that guide the application of this program are that it should be tailored to meet the needs of each patient, and several therapeutic components should be included [21]. One of them is the initial assessment and goal setting to determine the actual health status, and enhance patient motivation and participation in the program. Education is another program component, that should be undertaken with the goal of improving patient adherence with the most effective health-enhancing behaviors. Correct use of the medication and breathing exercises are some of the teaching given in the pulmonary rehabilitation program [15]. Exercise training is the most important component. Training programs include both extremity aerobic training and upper extremity strengthening exercises, and should follow the principles of exercise duration, session frequency, and exercise intensity. The benefits of this training are an increase of the maximal oxygen uptake and exercise tolerance. After the formal program, patients are encouraged to keep a balanced diet and to exercise three or four times a week, in order to maintain the gains in performance and reduce the risk of hospital readmissions [15].

Oxygen therapy is also provided to COPD patients in order to improve survival and reduce breathlessness, and allow more exercise by eliminating exercise-induced hypoxemia [15]. It can be administered in three forms with different purposes, depending on the arterial oxygen partial pressure (P$_{a}$O$_2$) levels. Long-term continuous domiciliary oxygen therapy is provided in order to raise the P$_{a}$O$_2$ to prevent mortality; ambulatory domiciliary oxygen therapy is provided to increase exercise endurance and reduce dyspnea; and short-burst oxygen therapy is provided in healthcare facilities for relief of breathlessness and improve the degree of pulmonary hypertension[15]. Usually patients do not fully understand the role of oxygen therapy. One of the most common misunderstandings arises from the misconception that oxygen is only usable for dyspnea treatments, and that, consequently, high doses of oxygen eliminate dyspnea. Therefore, patient education is a prerequisite for proper use and adherence to oxygen therapy [15].

Another available treatment is lung volume reduction surgery that involves the removal of areas of relatively poorly perfused but well-ventilated lungs. The resulting changes of this proce-
Chronic Obstructive Pulmonary Disease

dure should translate into less dyspnea during daily activities, and improved exercise capacity and health status [15]. Notwithstanding these benefits, this surgery presents a high associated mortality rate and should only be suggested to patients who have significant dyspnea despite maximal medical therapy [15].

2.4.3 Management of exacerbations

COPD is often associated with acute exacerbations of symptoms that occur more frequently with increasing severity of the disease. Exacerbations of this pulmonary disease are a major cause of morbidity and mortality, and lead to frequent hospital admissions and readmissions. They highly contribute to the cost of managing patients who have COPD. Several factors can precipitate exacerbations, such as respiratory tract infections, air pollution, and the interruption of the maintenance therapy. Influenza and pneumococcal vaccinations are recommended for all patients with COPD in order to prevent the respiratory tract infections and, consequently, diminish the occurrence of acute exacerbations. The pneumococcal vaccine is indicated to patients older than 65 years or below 65 years with FEV<sub>1</sub> < 40% [15]. Exacerbations most frequently present with increasing sputum production, an increase in the purulence and viscosity of the sputum, increasing cough, and worsening of dyspnea. Their diagnosis relies on the clinical presentation of the patient complaining of an acute change of symptoms that is beyond the normal daily variations. The measurement of arterial blood gases is essential to assess the severity of an exacerbation. When the P<sub>a</sub>O<sub>2</sub> is below 8.0 kPa, it is an indication of respiratory failure. In addition, P<sub>a</sub>O<sub>2</sub> < 6.7 kPa, P<sub>a</sub>CO<sub>2</sub> > 9.3 kPa, and pH > 7.3 indicate a life-threatening episode that needs close monitoring or intensive care unit management [17].

When respiratory impairment is observed in the absence of a history of COPD, and if the patient does not have clinical evidence of pneumonia, chest radiographs are useful in identifying alternative conditions that mimic the symptoms of an exacerbation [15].

Treatment of COPD exacerbations depends on the severeness of the symptoms and ranges from pharmacological therapy to ventilatory support. In the presence of mild symptoms, suitable for community management, the patient’s bronchodilator administration technique should be checked and the dosage increased as appropriate. If the symptoms encompass increased dyspnea and increased sputum volume, antibiotic therapy and ventilatory support should be provided. Also, oral or intravenous corticosteroids should be administered in short courses. In the presence of severe symptoms that require hospital management, low flow oxygen therapy, bronchodilator therapy every 4–6 hours, ventilatory therapy (in case of pH < 7.3 and rising P<sub>a</sub>CO<sub>2</sub>) should be provided to the patient in order to manage the exacerbations [15].

Most exacerbations of COPD are treated in a short period of time and have no long-term sequelae. Increased patient education is necessary about detecting and tracking exacerbations, and how to proper take the prescribed medication and maintain an active lifestyle [15]. Therefore, in daily care facilities, healthcare professionals advice their patients to plan their days and weeks carefully, in order to use their energy efficiently, spreading tasks and alternating between light and heavy activities over the day [27].
Chapter 3

Telemonitoring and Self-Management

3.1 Overview

Acute exacerbations of COPD have a profound effect on the patient’s quality of life and prognosis. The economic burden of exacerbations is extremely high, being imperative a patient education and self-management programs to reduce the economic burden of the disease and improve the quality of life. The ability to understand the activity behavior, the relationship with daily symptoms, and the willingness of the patients to change is important for the success of any treatment. [28].

Self-management programs were developed to help patients acquire and practice skills they need to carry out specific medical regimens. As patients’ awareness of their activity behavior is the prerequisite for an effective treatment and management of the disease, the self-management programs also have the goal to guide changes in health behavior and to provide emotional support [28]. These programs are part of a pulmonary rehabilitation program that should be provided not only to COPD patients but also to all patients with chronic illness. Schulman-Green et al. [29], presented self-management as ongoing and dynamic, having overlapping processes (tasks and skills), which consist in three categories: focusing on illness needs, activating resources and living with a chronic illness.

Typically, outcome measures of self-management are encompassed in the following types: Clinical/physiological (lung function and disease severity), functional (pain, exacerbations), cognitive (physiological health, self-efficacy), healthcare resource use (hospitalizations, emergency appointments), healthcare cost, and behavior outcomes (exercise, diet) [12]. Barlow et al., Warsi et al. and Rijken et al. [30, 31, 32], when assessing the effectiveness of self-management programs, reported that, generally, programs reveal positive results on some of the aforementioned outcome measures, but rarely on all of them.

A Cochrane Collaboration review on 27 studies comparing self-management versus usual care showed that self-management interventions are associated with improved quality of life, and reduced hospital admissions and readmissions [28]. It also concluded that self management without exercise and self-management with exercise are equally effective in improving the health-related quality of life of the COPD patients.
Alongside pulmonary rehabilitation programs provided by healthcare facilities, the number of patients with COPD being managed at home is increasing to reduce health-related costs while increasing the patient’s comfort and health status [33]. Home telemonitoring is a relatively new approach in the field of telemedicine, defined as the use of telecommunication technologies to transmit data on patient’s health status from home to a healthcare center, and it is increasingly seen as a way to bridge the gap between professional care and patient self-management [33]. A first feasibility analysis of home-based services to prevent hospitalizations of COPD exacerbations was reported in 1998 by Gravil et al. [34]. Over 3 – 5 years, COPD patients were daily visited by a respiratory nurse who monitored the progress of the disease with spirometry and oxygen saturation. She also monitored adherence to the recommended treatment and offered reassurance, support, and education [34]. The nurses collaborated with the respiratory medical staff to arrange hospital admission if the patient deteriorated or failed to improve after completion of treatment [34]. Gravil et al. [34] concluded that from the total of patients treated at home, only 12% required admission during follow-up because of deteriorating of the disease and development of other complications. Three subsequent controlled trials [35, 36, 37], performed in 2000, have demonstrated both safety and cost reduction to the healthcare facilities when these types of services are applied to COPD patients. In all of these trials, patients were followed by respiratory nurses every two days at home, who monitored their health condition and the progression of the disease. Notwithstanding the benefits that home telemonitoring has over the reduction of hospital admissions costs, this service is highly dependent on nursing support, being necessary a countermeasure when this support is scarce [34].

By systematically monitoring the health status of COPD patients, home telemonitoring can be used for a timely assessment of an acute exacerbation or as a mechanism to generate alarms when clinical changes that may constitute a risk to the patient occur [33]. This proactive monitoring has a valuable advantage over its reactive counterpart, as the delayed seeking for treatment increases recovery time and, consequently, lowers health-related quality of life [38]. In recent years, many authors have tried to assess the importance and effectiveness of telemonitoring services for COPD patients, without routine home visits by respiratory nurses. Technological devices, such as mobile phones and personal computers, have been playing a leading role in the telemonitoring field, as they store and transmit clinical data and, in the case of irregular values, they alert the clinicians [39]. The landscape of these technological devices and wireless telemonitoring for disease management is extremely complex and rapidly evolving. However, some limitations are pointed out by some authors as limiting factors of the aforementioned approaches. Despite of reducing the hospital admissions and exacerbation treatment cost, the technology itself is expensive [40] and elder patients have shown difficulties in the management of these new technologies, and in viewing the information provided on screen [41]. Table 3.1 summarizes some of the most relevant studies for COPD telemonitoring methodologies discussed in the Bartoli et al. and Cruz et al. reviews [33, 39]. In all of these studies, patients were monitored and relevant clinical data was recorded, such as oxygen saturation, pulse rate, FEV₁, and level of dyspnea, through portable sensors and medical devices (spirometer, oximeter). The recorded data was transmitted wirelessly to a central
server, and subsequently monitored by a nurse or another healthcare professional [33, 39].

Table 3.1: Summary of the main characteristics of the studies.

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Participants</th>
<th>Duration</th>
<th>Main Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>De Toledo [42]</td>
<td>2006</td>
<td>157</td>
<td>1 year</td>
<td>Improved health status</td>
</tr>
<tr>
<td>Casas [43]</td>
<td>2006</td>
<td>158</td>
<td>2 years</td>
<td>Reduced exacerbations hospitalizations</td>
</tr>
<tr>
<td>Paré [40]</td>
<td>2006</td>
<td>29</td>
<td>6 months</td>
<td>Reduced exacerbations hospitalizations</td>
</tr>
<tr>
<td>Antoniades [44]</td>
<td>2012</td>
<td>44</td>
<td>1 year</td>
<td>No significant difference in health status</td>
</tr>
<tr>
<td>Chau [41]</td>
<td>2012</td>
<td>53</td>
<td>2 months</td>
<td>No significant difference in health status</td>
</tr>
<tr>
<td>Dale [45]</td>
<td>2003</td>
<td>55</td>
<td>3 months</td>
<td>Decreased in rates of hospital readmissions</td>
</tr>
<tr>
<td>Kim [46, 47]</td>
<td>2012</td>
<td>144</td>
<td>6 months</td>
<td>Positive results in patient satisfaction</td>
</tr>
<tr>
<td>Koff [48]</td>
<td>2009</td>
<td>40</td>
<td>3 months</td>
<td>Improved quality of life</td>
</tr>
<tr>
<td>Lewis [49, 50]</td>
<td>2011</td>
<td>40</td>
<td>6 months</td>
<td>No significant difference in health status</td>
</tr>
<tr>
<td>Sicotte [51]</td>
<td>2011</td>
<td>46</td>
<td>5 months</td>
<td>Positive results in patient empowerment</td>
</tr>
<tr>
<td>Sund [52]</td>
<td>2009</td>
<td>20</td>
<td>6 months</td>
<td>Decreased hospitalizations</td>
</tr>
<tr>
<td>Trappenburg [5]</td>
<td>2008</td>
<td>165</td>
<td>6 months</td>
<td>Decreased hospitalizations</td>
</tr>
</tbody>
</table>

It is easily observable from Table 3.1 that all studies present a highly heterogeneous distribution with regard to both number of participants, as well as results regarding the effectiveness of telemonitoring applications/services. Such variability limits the possibility of an objective direct comparison between studies. However, some interesting observations can still be performed regarding individual conclusions from each singular study. Most patients reported that the telemonitoring system improved self-management of their health condition, as they had a better understanding of their disease, symptoms and ways to control them, were more involved in their health care, and recognized earlier the signs of exacerbations [33]. However, high dropouts were found in some studies [5, 41, 44, 46, 47, 52], as patients were not comfortable about using this technology to monitor their health condition or had difficulties on using the technology in a correct way. The authors concluded that patients should receive training over a period of several days to help them learn how to use the technology and, therefore, optimize its use and reduce the number of dropouts. Notwithstanding the disparities of experimental conditions regarding the technological device used, the quality and reliability of data acquired during the survey were similar to those obtained by clinical staff. It can, thus, be concluded that telemonitoring presents a great potential to improve the outcomes in COPD patients and the feedback made possible by the numerous studies and reviews on the different existing methodologies can be a valuable input when developing a new methodology. This technology should be: easy to use, operate without interruptions, and provide security and confidentiality of data collected [33].

### 3.2 Related Work

In recent years, telemonitoring and self-management have been thoroughly explored to help in the provision of feedback of symptoms and educational content, so that the health-related quality of
life may be increased and the chronic condition controlled. From the available literature on the topic a few works can be highlighted.

In order to allow a proper contextualization for the work developed in this master’s thesis, the product *SmartCompanion*, where such project will be integrated, will be outlined in the following section.

### 3.2.1 SmartCompanion

*Fraunhofer Portugal Research Center for Assistive Information and Communication Solutions* (Fraunhofer AICOS), is the first research center operated by *Fraunhofer Portugal*, focused on enhancing the people’s living standards, by offering them intuitive and useful technological solutions [53]. One of these solutions is the *SmartCompanion*, a customized android platform-based foundation for other applications, appropriate to help and support the users in their daily activities [53]. Also referred as a *Swiss Army Knife*, the SmartCompanion includes features designed to promote the autonomy and quality of life, by giving access to relevant information, to improve health management, by enabling monitoring or cognitive stimulation, and to prevent isolation, by providing better communication tools, adapted for a senior user [53]. This product also enables the user’s caretaker to receive alerts upon detected irregularities in the monitoring of the user [53]. The application developed in this Master’s Thesis will reinforce the sector of health management, helping the user to keep its chronic disease under control (described in further detail on Chapter 4).

### 3.2.2 eCAALYX

Another project involving Fraunhofer AICOS is the *eCAALYX* project - Enhanced Complete Ambient Assisted Living Experiment -, aimed to monitor user’s health status and improve the quality of life [54, 55]. This is achieved by recording their vital signs over a longitudinal period of time, to detect changes in their condition and, subsequently, in COPD progression. In addition, and to improve the patient’s quality of life, this project proposes focused education on their lifestyle and self-management [54]. The *eCAALYX* system uses two individual methods of monitoring: a wearable body sensor system alongside a home-based system comprising multiple sensors integrated into the user’s environmental [54]. The first method includes a smart garment with embedded health and mobility sensors for respiratory rate, skin temperature, and heart rate, controlled by an electronic control unit and connected via *Bluetooth* to a mobile phone, in order to display the monitored data. The latter method encompasses a set top-box connected to a TV that allows the visualization of the recorded vital signs and their historical recorded data. Furthermore, an intelligent sensor system, which integrates the most relevant sensors for monitoring chronic conditions, and a router are also incorporated (Figure 3.1). Such system is responsible for receiving and processing all the measurements, as well as generating alarms on detection of a health problem, and sending all monitored data to a caretaker site. [54].
3.2 Related Work

Figure 3.1: Global schematics of eCAALYX project. Adapted from [55].

3.2.3 Chronic Care Management Center

A chronic care telemedicine system, located at CCMC - Chronic Care Management Center -, was designed to integrate a one year experience to determine the impact of telemedicine systems on home care of chronic patients suffering from COPD. This system consists of a telemedicine server and several user terminals that provide access to the services available, as well as a network interconnecting all the elements [42]. The telemedicine center is composed by a call center, an application server and an education material server. The call center uses computer-telephony integration technology to, based on the service’s needs, delegate the phone calls to a member of the care team or to direct the call to an automated voice response unit [42]. The patient’s records are allocated in the application server, which can be accessed by all the members of the care team from any location. Among the recorded data, the care team can consult the home-monitoring reports, the schedule of medical appointments, the patient’s work plan and log of phone calls to the call center. At last, the educational material server provides education on the disease to both patients and professionals, either through web pages or using video-on-demand technology [42]. A disadvantage of this system is the required education sessions to patients and professionals, in order for them to benefit more effectively from it.

3.2.4 AMICA

Based on innovative information and communication technologies and current chronic guidelines, AMICA - Autonomy, Motivation & Individual Self Management for COPD Patients -, is a recent telemedical solution that supports early detection of COPD exacerbations [56]. AMICA combines a technical solution with a holistic service approach for disease management, encouraging risk prevention and self-management through immediate, comprehensive feedback and efficient
case management services [56]. This system provides two coexisting services. To healthcare professionals it provides an ubiquitous access to an electronic patient record, which includes demographic information, respiratory disorder history, therapy, exams, medical scale, and remote monitoring data. To COPD patients it provides a remote monitoring of biomedical parameters, such as ECG, pulse oximetry, lung sound, and symptoms; access to educational material and social-motivation tools through dedicated mobile device; and report of problems to patients by use of different media (Figure 3.2). The monitored data is transmitted via wireless to the patient record for further analysis by a clinician and respective feedback [56].

Figure 3.2: Global schematics of AMICA telemedical platform. Adapted from [56].

3.2.5 ASTRI

The ASTRI telecare system [41] was developed to provide healthcare to COPD patients through a combination of a modern broadband communications infrastructure and database, and software for critical decision analysis and support (Figure 3.3a). It comprises a device kit, which includes a designed mobile phone, a respiratory rate sensor and a pulse oximeter, a network platform, a call center, and a networking system [41]. All the monitoring data acquired by the set of devices is displayed on the mobile phone and sent to the platform and network server in which the data is monitored and recorded. The device kit was also designed to send medication and purse-lip breathing reminders. In the same way as AMICA [56], ASTRI does not provide autonomous feedback. All the monitored data is analyzed *a posteriori* by a nurse, who can take the necessary actions to address the patients’ needs [56].
3.2 Related Work

Figure 3.3: Schematic representation of the ASTRI and M-COPD projects. (a) ASTRI telecare system, adapted from [41]; (b) M-COPD home care model, adapted from [57].

3.2.6 M-COPD

M-COPD [57], a mobile technology assisted home care model, was developed to enhance the link between patients and clinicians (Figure 3.3b). It enables clinicians to remotely monitor COPD patients conditions, diagnose exacerbations in the early stages, and treat mild or moderate exacerbations with prescribed medications at home [57]. The core functionality of the system is related to the use of a mobile phone by the patient to update self-assessment and observation data relating to COPD symptoms and vital signs, such as sputum, cough, wheezing, among others. The updated data is stored in a remote server, being subsequently available to clinicians on a web portal [57]. With the transmitted information, clinicians are able to assess the patient health condition and disease progression, and take the necessary actions to prevent or treat the exacerbations. Also, patient education regarding the correct form to administrate the medication is given through mobile video calls [57].
3.2.7 CHRONIOUS

The CHRONIOUS platform [58] is a partially automated system based on multi-parametric sensor data processing and fusion to monitor people affected with chronic diseases (Figure 3.4). The system consists of multiple unobstructive wearable sensors (Figure 3.4a), which monitor the electrocardiographic and respiratory activity, arterial oxygen saturation, and skin temperature. The aforementioned data is acquired and processed by different microprocessors integrated within a data collector device. This device has the ability to analyze in real-time the collected data and, according to decision tree-based algorithms, trigger special events. All the monitored data is transmitted via Bluetooth to a PDA (Figure 3.4b), capable of directly issuing an alert to a clinician when a problem is detected [58]. In addition to the wearable sensors, the CHRONIOUS system also utilizes numerous wireless sensors placed within the home environment, recording data on carbon monoxide levels, volatile organic compounds, and air particles. All of the monitored data is also transmitted to a Central System (Figure 3.4b), capable of supplying clinical suggestions, by integrating the interpretation of collected patient’s data and the clinical knowledge suitably formalized [58].

3.2.8 VitalmobileTM Health

The VitalmobileTM Health company developed a wireless monitoring system capable of monitoring the condition of the patient’s airways [59]. Using a series of biomedical sensors, continuously monitoring the patient’s vital signs and transmitting the acquired data via Bluetooth to a smartphone and then to a secure database center, this system allows the processing and storage of the raw data collected for future analysis (Figure 3.5). The analysis of this data by a specialist can provide meaningful determinations of disease severity and predict future respiratory events [59].

3.2.9 EDGE

The EDGE - Self management and Support Programme - was developed in order to evaluate the efficacy of a telemonitoring application and, subsequently, improve the user’s quality of life [60]. This program consists of a symptom diary and monitoring of pulse oximetry in regular periods of time. Multimedia and self-management materials, such as videos, text and images were also incorporated in this program. A tablet computer encompassed all the aforementioned components, as patients were asked to complete the symptom diary, and the pulse oximetry values measured by an external sensor [60].

3.2.10 Projects under development

The It’s Life! [62] is an innovative monitoring and feedback tool, still under development, aiming to support the self-management of people with chronic diseases to obtain an active lifestyle. This can be accomplished by measuring their activity behavior, and, subsequently, giving automatically generated tailored feedback to the patient and to the clinician [62]. It consists in a 3D accelerom-
3.2 Related Work

Figure 3.4: CHRONIOUS platform components: (a) wearable sensors; (b) monitoring data analysis services. Adapted from [58].

Another autonomous system [61] is currently under development (AERIAL), aiming to provide computer aided self-management assistance and education, while also enabling the detection of an ongoing exacerbation (Figure 3.6). The system consists of a mobile phone as the main component, taking care of communication and computation [61]. Pulse oximeter and spirometer are used to obtain valuable information about the patient’s health status, transmitted wirelessly to the mobile phone. Another component of this system is a web-center, which receives the data from
the mobile phone and provides data access for health-care workers [61]. The monitored data is analyzed by means of a disease-specific probabilistic model that incorporates clinical variables considered relevant by a clinical specialist. Subsequently to this analysis, feedback is given to the patients regarding their current health status. This system also provides a questionnaire to assess the development and stage of the patient’s symptoms [61].

3.2.11 Complements to COPD monitoring systems

3.2.11.1 TELEMOND

A Portuguese project, named TELEMOLD [63], was conducted with the objective of improving long-term oxygen therapy, by monitoring oximetry and physical activity of chronic pulmonary failure patients. These two parameters were monitored and recorded through the use of a portable oximeter sensor and accelerometer, connected via Bluetooth to a mobile phone. This data is then transmitted via 3G or radio service to a server, where healthcare professionals can analyze the monitored data and adjust the oxygen prescription to a more adequate therapy [63]. This project was not directly related to telemonitoring of COPD patients. However, as oxygen therapy is a prescribed treatment to COPD patients, the monitoring of oximetry and physical activity of each patient is an asset to a better and more adequate management of COPD and exacerbation prevention.

3.2.11.2 Propeller sensor

The Propeller sensor [64], which is placed in an inhaler, works by collecting, recording, and analyzing patient data in real time. It can track how often the patient takes the medication and register the hour and location of their use. It was also developed to keep track of patients’ symptoms. This device, which has been approved by the Food and Drug Administration (FDA), is linked via...
3.2 Related Work

Figure 3.6: Autonomous system schematic setup. Adapted from [61].

Bluetooth to a mobile phone. All the recorded data can be shared with the clinicians, allowing them to remotely monitor the patient’s health and disease progression.

3.2.12 Comparative analysis

To promote an easy comparative analysis between the existing COPD monitoring systems, Table 3.2 summarizes their principal components and characteristics.

Table 3.2: Comparative analysis between the different existing projects on COPD telemonitoring*.  

<table>
<thead>
<tr>
<th>BWS1</th>
<th>Education</th>
<th>Questionnaires</th>
<th>Web-Portal</th>
<th>Home Monitoring</th>
<th>RT Data Analysis2</th>
</tr>
</thead>
<tbody>
<tr>
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*• illustrates the presence of the characteristic and o illustrates the absence of the characteristic.

The market of COPD monitoring systems presents a wide variety of alternatives, as well as different priorities regarding the implemented features. The presence of a web-portal is the most common of such features among these systems. The possibility of remote monitoring of the patient data has been shown to be the most valuable characteristic for most of the systems. Patient education and biomedical wireless sensors are other features present in a quite significant number of systems. Since the biggest failures of COPD monitoring lie in education, it is expected that systems in this area would invest in this feature, as an attempt to surpass these problems. Few sys-

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1Biomedical wireless sensors
2Real-Time data Analysis
3VitalmobileTM Health
tems keep in track the symptoms’ progression, by means of questionnaires, and fewer systems are capable of giving real-time feedback to the patient. Monitoring the patient’s symptoms is indispensable to achieve a tight control over the disease’s progression and, thus, prevent the occurrence of severe exacerbations. The monitoring system that will be developed under the scope of this master’s thesis will take into consideration these valuable characteristics as well as the necessity of a mobile monitoring system well adapted to the different user’s skills of interaction with this type of technology. In order to achieve the most complete coverage regarding the prevention of this pulmonary disease, the focus of the presented system will be more biased towards educational and symptoms monitoring rather than clinical data monitoring.

Therefore, the next chapter will outline the main functionalities of the proposed system, as well as detailed analysis of both its architecture and stakeholders.
Chapter 4

COPDHelper

Gathered all the important information about COPD and how viable the usage of telemonitoring can be to chronic disease patients, the general concept of the monitoring application proposed in this master’s thesis can be developed, having in mind all the desired characteristics for this kind of systems. Hereupon, this chapter aims to present the system requirements and its architecture, by identifying the stakeholders and their interaction with the system, and, also, by systematizing the technologies and devices needed for this project’s implementation and development.

4.1 General overview

Based on User-Centered Design, the COPDHelper was developed taking into consideration the needs, wants and limitations of the target user. Thereby, and with this philosophy of product design, the system will be more adapted to the user, rather than obligating the user to changes in natural behavior to accommodate the system. Within the context of helping pulmonary diseases’ patients to better self-manage their disease, the COPDHelper encompasses two modules with different purposes:

- The first, named Counseling and Education module, is capable of educating and advising the user on inhalation and breathing techniques, nutrition and diet tips, and routine exercises. This module has the purpose of empowering the user to be active in the management of its chronic disease, so the impact of COPD in the daily activities can be diminished.

- The second, the Monitoring module, allows a periodic monitoring of the user’s oxygen saturation and the evolution of its symptoms, by means of simple questions and predefined questionnaires.

In order for this system to be directed to the patient’s needs and disease’s stage, the monitoring module is adjusted depending on the combined COPD assessment associated to each patient. To patients with A or C combined COPD assessment, where the level of dyspnea and symptoms is in the same range (low), the monitoring of oxygen saturation is not needed to keep the disease under control. It is important to keep an active and healthy lifestyle, exercising everyday and
keeping healthy nutrition habits. For patients with B or D combined COPD assessments, with high dyspnea and symptoms levels, it is important not only to keep in track the symptoms progression and appearance, but also to monitor the oxygen saturation and be sure that its level keeps higher than 90%.

With this in mind, the monitoring module of COPDHelper is subdivided into two sub-modules: simple monitoring and complete monitoring. The simple monitoring is intended to monitor only the evolution of symptoms, by means of a questionnaire. Complete monitoring is intended to not only monitor the evolution of symptoms, but also to monitor the patient’s vital signs, by means of biomedical sensors.

As this system will be integrated within the SmartCompanion (Section 3.2.1), some of its functionalities will also be employed in the development of COPDHelper.

4.2 Requirements analysis

A general overview of the system stakeholders and their role and interaction with the system is a necessary procedure in order to achieve a global understanding about its main functionalities. In this section the main features of each tool and resource composing the system will be also outlined.

4.2.1 Tools and Resources

In this section the development platforms used to construct this project are identified, among with the tools and resources that were necessary to achieve the proposed goals. The SmartCompanion resources that will be implemented in this system will also be detailed further ahead in this section, pointing out its main characteristics.

4.2.1.1 Questionnaires

As detailed in Section 2.3, to assess the impact of COPD in the patient’s health status and daily activities, different kinds of questionnaires were developed. Excluding the ones referred as too complex and time-consuming in Section 2.3, two valid options could be chosen for the purpose in the scope of the developed system: CAT (composed by eight questions related to the impact of COPD and evolution of symptoms) or mMRC (composed by a single question, scaling the feeling of breathlessness). As the principle of this monitoring system’s questionnaire is to globally assess the impact of not only dyspnea but every other symptom related to COPD, the CAT questionnaire was considered to be more adequate and complete than mMRC. For that reason, the CAT was adapted, in order to be more easily answered on an Android application environment. Instead of classifying from zero to five (quantitative classification), the answers were converted to a qualitative scale, specific to each question of the questionnaire. In Appendix A, the CAT and mMRC can be visualized in detail.
4.2 Requirements analysis

4.2.1.2 Educational Videos

As described in Chapter 2, one of the patient’s main sources of failure in the management of the disease occurs during the usage the medication inhalers. There are many types of inhalers, each with different techniques to properly administer the medication. Patient education to properly intake this medication is, most of the times, miscarried or overlooked. So, for the purpose of improving the patient’s technique and ensuring that medication is properly inhaled, this system will integrate educational videos related to each different inhaler in existence. The videos were made available by the Harvard Vanguard Medical associates, Harvard Medical School - Portugal, and Deutsche Atemwegsliga.

4.2.1.3 Medication Reminder

One of the SmartCompanion functionalities is the Medication Reminder, an application that, as its name suggests, creates alarms reminding the user to take the necessary medication. This application also informs about the correct dosage of the referred medication, in order to diminish possible oversights on the part of the user. Hereupon, this functionality will be integrated in COPDHelper. The frequency of the alarm (daily, weekly, every other day), depends on the registration carried out by the healthcare specialist, since it is his responsibility to define such parameters.

4.2.2 Stakeholders Identification

Healthcare specialist

The first contact of the COPD patient with the COPDHelper is introduced by the healthcare specialist. By initializing the patient’s registration on the system and thoroughly explaining what is the major focus of the system and how the user must and can interact with it, the healthcare specialist has a preponderant role in the COPDHelper’s functioning. In order for the monitoring system to be individually adequate for each patient, during patient’s registration, the specialist introduces the combined assessment COPD, which will determine the type of monitoring performed, as well as the corresponding monitoring schedule. It is also his/her responsibility to input information regarding the prescribed medication, if applicable, as well as the dosage and frequency at which it should be consumed. By doing so, the system will generate medication reminders at the specified frequency.

COPD Patient

The final COPDHelper’s users are the COPD patients. Even though the target population is becoming generally younger (early 40’s), there is still a considerable incidence of the disease in aged population, generating, thus, a very heterogeneous array of patients to whom the system shall serve its purpose. Following this rationale, the system must be designed so it is easy to use even for individuals with no experience interacting with information technologies, as is the case with the vast majority of elderly patients. Having identified the main user of the system, it is necessary to also
define both the tasks and functions which fall under the scope of patient’s direct interaction with the system.

The COPD patient has an active role in the system by monitoring its vital signs and symptoms for a better control of its disease. By the means of a biomedical sensor and depending on the specifications indicated by the doctor upon the patient’s registration, the patient can monitor the vital signs at home (if (s)he possesses an oximeter) or in the local pharmacy, as well as get counseling on how to take the prescribed medication, breathing techniques to empower the lung’s function, and nutrition advice, and exercises to keep an active lifestyle.

Figures 4.1a and 4.1b illustrate the two aforementioned stakeholders and their role in this monitoring system. Figure 4.1a depicts the complete monitoring sub-module for patients with B or D combined COPD assessment, whereas Figure 4.1b details the simple monitoring, for patients with A or C combined COPD assessment. Their role and interaction with the system will be more detailed in the next sections.
4.2 Requirements analysis

Figure 4.1: Monitoring system use cases: (a) illustrates the use case of the system with the complete monitoring sub-module; and (b) illustrates the monitoring system with the simple monitoring sub-module implemented.
4.3 Architecture

After a detailed research on the major oversights practiced in the management of COPD, and the developed alternatives to counteract such practices, the structuring of the developed system’s architecture was made possible. Envisioning a mobile monitoring system capable of not only periodically monitor the patient’s vital signs, but also educating and providing counseling on the different topics that pulmonary rehabilitation programmes cover, the COPDHelper was designed to be composed by two essential and distinct modules: (1) Counseling and Education and (2) Monitoring. With the implementation of Medication Reminder, the final system will have three modules. Since self-awareness of the actual state of the disease is as much important as monitoring of the symptoms and vital signs, the focus of the developed system rests, more precisely, in detecting and solving the small mistakes on the part of the patient when managing this pulmonary disease, marking its main difference when compared with available methods (section 3.2).

The overall functioning of the COPDHelper is depicted in Figure 4.2. Starting with patient registration, upon the first pneumologic consult, where the chronic disease is assessed, the pulmonologist inserts the patient data on the system. This information will determine the specifications of the COPDHelper, in order for the system to be individually adequated to each patient’s specific case.

![System architecture diagram.](image)

The following parameters represent a significant part of the determinant information: Combined COPD assessment, prescribed medication (with or without corticosteroids), and frequency of medication intake. The first parameter will act as an activator of the type of monitoring: if it expresses A or C evaluation, the simple monitoring sub-module will be activated; on the other hand, if it expresses B or D, the complete monitoring sub-module will be activated. Regarding the type of medication and its frequency of usage, these parameters will serve as entries to enable the Medication Reminders. The medication alert will then work autonomously, without any dependency.
on the COPDHelper. Coupled to this alarm is an extra feature, with the goal of reminding the user to rinse the mouth after the intake of medication, in the case of presence of corticosteroids. By doing so, the user will prevent a sore throat. After registration is completed, the system is ready to serve its purpose.

Notwithstanding the fact that the monitoring module is sub-divided, its standard functionalities allow the patient to:

- check if the oxygen saturation level fits the normal range of acceptability, through oximeter’s measurements;
- evaluate the impact of the disease in their daily activities, by means of the CAT questionnaire;
- control the progression of the disease, by graphically displaying the evolution of previously registered results in both questionnaire and oximeter.

The local pharmacy can have an active role in the oxygen saturation monitoring, in case the user either does not possess an oximeter, or does not have the self-confidence to perform such measurement without any technical supervision.

Whenever the monitored oxygen saturation value is worrisome, or the impact of COPD in the user’s daily activities and health status is elevated, the COPDHelper instantly alerts the user, conceding advices on how (s)he should proceed. These advices go from small physical exercise or daily living habit tips, if the level of concern is low, to advising medical appointments if the level of concern is high.

Regardless of how critical the measured parameter values are, COPDHelper is designed so as to never override medical indications, either by altering medical dosage, counseling the intake of new medications or suggesting any medical examinations.

The other composing module of this system is, as aforementioned, the counseling and education. Unlike the previous module, no feedback is provided to the user. Instead, this module assists in a more direct way the patient, by clarifying some common doubts and serving as an aid in multiple daily activities that positively affect the management of the disease. The main functionalities of this module allow the patients to:

- visualize educational videos on how to properly take the medication with the different existent inhalers and, so, lessen the mistakes made in taking the prescribed medication;
- do breathing exercises, to learn how to control breathing, diminish the breathlessness sensation, and strength the respiratory muscles;
- perform routine exercises, to keep their life active and provide them an healthier lifestyle;
- consult diet and nutrition tips, to prevent a possible malnutrition, lack of vitamin supplements or mass loss.
4.4 Stages of Development

The different modules of COPDHelper suffered modulations and adjustments during their development, promoted by different factors. In this section the original design of each module will be presented, as well as the difficulties encountered and their final layout.

- Monitoring module

This module was originally thought to encompass two biomedical sensors, spirometer and oximeter, with wireless transmission of the collected data to the smartphone. This monitoring would be autonomous, without requiring the patient to insert any type of data in the system, and would control not only the vital signs of the patient but also the pulmonary function, one of the aspects that decays the most with disease progression. These schematics had to be promptly altered due to the impossibility of acquiring such wireless sensors. However, and despite the fact that the digital sensor was not acquired, the system is prepared to both easily integrate this sensor as well as wirelessly register not only patient’s oxygen saturation, but also the blood pressure value. This feature ceased to be autonomous and started to require the user’s manual introduction of the oxygen saturation. This data can be obtained with personal oximeters or in the local pharmacies. The final design of this module can be observed in Figure 4.3.

As previous detailed, after the insertion of the oxygen saturation level, the system will generate a feedback and present it to the user. If the saturation is below 90%, the system will display a red light and advise the patient to contact the healthcare specialist (Figure 4.3c). Otherwise (saturation above 90%), the system will display a green light (Figure 4.3b). In the case of unreasonable levels of oxygen saturation, COPDHelper alerts the patient to re-introduce values within the acceptable range (Figure 4.3d).

After the input of this monitored parameter, the patient can save it in the system, for future consult or analysis on the part of the physician, reintroduce another value in case the previous was wrongly measured, or simply go back and do not save any record.

Still concerning the monitoring module, on par with the biomedical sensor, was carried out the implementation of the questionnaire to track the symptoms’ progression. This system’s activity allows the patient to answer eight question (adapted from the CAT questionnaire) and in the end of those questions the total impact of COPD disease is determined. Based on the level of impact (determined using the CAT guidelines detailed on Appendix A.1), the system advises the patient according to the qualitative classification of impact, ranging from low to very high. The questionnaire result is saved on a system’s database for further consult and analysis on the part of the physician, in line with the oxygen saturation. The storage of data allows, in future appointments, for the doctor to evaluate the physical state of the patient during a specific time period, without having to rely solely on the information orally transmitted by the patient (possibly altered by memory limitations or lack of assertivity and objectivity). Figure 4.4 illustrates a demonstration of this monitoring feature.

- Counseling and Education module
4.4 Stages of Development

Figure 4.3: Illustrative example of the monitoring module: (a) before the introduction of the patient’s oxygen saturation (in percentage); (b) and (c) illustrate the generated feedback whenever the values are within the normal range or below the acceptable, respectively; (d) depicts the generated alert when the level of oxygen saturation introduced is unreasonable.

As the main goal of this monitoring system is to help improving patient’s self-management of the disease, the counseling and education module represents a critical part of the system. With this in mind, this module is composed by four different features (Figure 4.5a). The first, Medication, encompasses the different educational videos that will help the patient on how to take the medication correctly, by means of inhalers (Figures 4.5b and 4.5c). All videos are available to every patient, covering the possible changes of inhalers during the treatment and management of this disease.
Figure 4.4: Illustrative example of questionnaire: (a) shows a simple introduction to the patient about the purpose of this questionnaire; (b) illustrates a question example; (c) and (d) depicts the result of the questionnaire and the impact’s classification in two of the four possible classifications.

The *Respiration* feature is destined to guide the patient on respiratory exercises, to help learn how to control the respiration and strengthen the respiratory muscles. As the green circle expands and contracts (illustrated in Figure 4.6b), the patient must inhale or exhale respectively, fulfilling the whole duration of each instance. This exercise duration must be close to 5 minutes and repeated 3 times a day. The *Exercises* feature, on the other hand, will encompass the most diverse exercises to keep the patient active, in order to contrary the sedentary lifestyle characteristic of patients suffering from lung diseases. Unfortunately, at this process’s stage, this feature is still under development, as requires the integration of the *ExerGames*, another Franhofer’s application. The *Nutrition* functionality advises the patient on how to keep an healthy diet, giving key information about the different food portions composing the food balance wheel, and how the ingestion of such portions positively or negatively affects the pulmonary functions and disease (Figures 4.6c and 4.6d). By clicking on the different available images, the user can learn relevant nutrition’s guidelines in order to prevent a possible mass loss, lack of vitamin supplements or malnutrition, common on COPD patients that do not take special attention in their food habits.
4.4 Stages of Development

Figure 4.5: Illustrative example of (a) this module layout and (b, c) medication’s education videos. (b) shows the list of the different inhalers and (c) an example of an educational video layout.

Figure 4.6: Illustrative examples of the features Respiration and Nutrition. (a) and (b) show the input of the respiratory exercise and the exercise itself; (c) and (d) show advices for diet and nutrition respectively.
4.5 Final Monitoring System

Gathered all the different modules’ attributes, the final aspect of the designed monitoring system is as illustrated in the set of subfigures displayed in Figure 4.7. For demonstration purposes, the COPDHelper is set to a patient with combined COPD assessment of B, in order to activate all the system’s functionalities.

![Figure 4.7: The COPDHelper: (a) shows the representative icon adapted to the SmartCompanion layout; (b) illustrates the main menu of the system, with all of its attributes active.](image)

The chosen icon for COPDHelper followed the directives of SmartCompanion applications, which determine that icons for applications in the Care group should present red color. This facilitates the senior user in the identification of the application’s scope (Figure 4.7a).

As mentioned in Section 4.3, the information entered in the system by the healthcare professional will serve as entries to the Medication Reminder application. For demonstration purposes, one situation where the patient was taking Symbicort with the presence of corticosteroids was simulated. The corresponding result is depicted in Figure 4.8.

In summary, a mobile monitoring system capable of not only monitoring but also advising and educating the patients in the more diverse aspects of the disease was successfully developed. However, future improvements and features can be equated and will be mentioned in further detail in the next chapter. Furthermore, an evaluation regarding the COPDHelper usability was performed and will also be further detailed in the following chapter.
Figure 4.8: Illustrative example of the medication reminder: (a) shows the alarm to remind the patient to take the medication and (b) alerts the patient to rinse the mouth with water in case of medication intake with corticosteroids.
Chapter 5

Evaluation Results and Discussion

When developing a product, or, more precisely in this case, an application based on a user-centered design, the user experience is one of the most important aspects to have in mind when managing and developing the proposed system. User Experience (UX) focuses on having a deep understanding of users, what they need, what they value, their abilities and limitations. Within the various factors that influence the UX are system usability, directed to how well users can learn and use a product to achieve their goals, and also how satisfied they are with that process [65]. With this in mind, the following chapter will present the methodology and the results obtained regarding the system usability evaluation, as well as a detailed discussion focused on the developed system, its values and limitations.

5.1 System Evaluation

Jakob Nielsen [66] reports that the most basic and useful method for studying usability is user testing, which has three components: (1) gather some representative users, (2) ask the users to perform representative tasks with the application/product and (3) observe that interaction and collect where they succeed, and where they had difficulties and doubts. It is important that during user testing, no interactions happen between the developer and user. By considering the user’s profile, the context, the needs, and the interaction with the system, and using those parameters in favor of the system’s development, the final user’s interaction will be more fit to the purpose as well as more intuitive, reducing the need for training and support, error rates, increasing satisfaction and productivity, and diminishing a possible loss of interest on using such system. All of these aspects are important for telemonitoring systems, intended as a solution to be adopted at scale for the management of patient suffering from long-term conditions in an ageing population [67]. However, as usability does not exist in any absolute sense, there is no objective way of measuring it. If the usability of a system is defined by the context in which that system is used, the specific measurements should also be defined by that same context. A possible way to make more generalised assessments of usability is through the use of questionnaires [68]. Hereupon, the usability
Evaluation Results and Discussion

Evaluation of the COPDHelper will be based on a standardized questionnaire and will be detailed in the next section.

5.1.1 Methodology

To evaluate COPDHelper in terms of usability, it was proposed to 13 volunteers, with ages between 29 and 70 years, in different stages of COPD, to interact with the system by performing different tasks. Afterwards, the filling of a questionnaire allowed the users to evaluate their interaction with COPDHelper. This questionnaire is available in Appendix B.1. It is worth mentioning that the constitution of this group was made to encompass patients from different age ranges, in order to not only evaluate the system usability in daily users of smartphones, but also on patients without a daily contact with these type of technologies.

With the purpose of better simulating the real environment where this application will be inserted, the usability tests were conducted by a healthcare specialist, previously acquainted with the context and system’s functionalities. Therefore, such tests were performed in a hospital environment, at the endpoint of each pneumologic consult, under supervision of the system’s developer.

Hereupon, and before starting the test and evaluation, a simple presentation was made to each user, explaining the major objective and functionalities of the developed application. Completed the contextualization, it was asked each user to execute some tasks, related to the daily activities of a COPD patient in the management of the disease:

- Assess the level of oxygen saturation and introduce the respective value on the system;
- Assess the impact of the pulmonary disease in the previous week, by filling the questionnaire component;
- Visualize the educational video referred to the inhaler in use.

Completed the tasks, the user was able to freely explore the application, in order to acquire a more global view of the system. Afterwards, the user was asked to fill the usability questionnaire, having in consideration the experience acquired during the interaction and task’s execution. The referred questionnaire was composed by twelve questions, being that the ten first were related to the already existing System Usability Scale (SUS). SUS is a likert scale, developed in 1986, that has become an industry standard with references over 600 publications, by evaluating a variety of aspects of system usability, such as the need for support, training, and complexity of a hardware, software, system or product [68]. As SUS globally assesses such usability, the incorporation of two more questions, more directed to the senior sector and their ability to interact with such system, was seen as necessary. As a complement to this questionnaire, the user also had the opportunity to suggest possible changes in the system’s design or new features they found to play a relevant part in future versions of to the project.
5.1 System Evaluation

5.1.2 Results

The questionnaire results were processed in order to express them in the standardized way. With this usability scale, an overall score above 68 is considered above average and an overall score under 68 is considered below average. As SUS is a 10 item questionnaire with 5 response options, the contribution of each item is summed to achieve the overall score. However, this summation is constrained by the following parameters [68]:

- For odd items: subtract one from the user response;
- For even-numbered items: subtract the user responses from 5;
- Add up the converted responses for each user and multiply that total by 2.5.

The average score of SUS observed for the developed system was $81.3 \pm 12.6$ out of 100. It is important to mention that this result is not a percentage, as the middle point of this scale is 68 (from 0 to 100) [68]. Nevertheless, and with this in mind, COPDHelper proved to have a good learnability and usability dimension in a very heterogeneous group of volunteers, both in terms of age and smartphone usage experience. With this in mind, Figure 5.1 shows the average result for each of the ten items, in order to allow an independent and clear analysis in the different aspects assessed by the questionnaire. The items 4 and 10 evaluate the learnability dimension and the other 8 items the usability dimension. As referred above, the last 2 questions of the questionnaire, which were designed outside the scope of the SUS items, were introduced so that users could rate the usability of the system by senior users, and are also displayed in Figure 5.1, making a total of 12 items evaluated from 0 to 4 (being 4 the most positive classification).

Figure 5.1: Usability test results. Each dot represents the average score of each questionnaire’s item.

Analysing, primarily from a global point of view, the results depicted in Figure 5.1, there are two items that stand out from the rest. Item 4, related to learnability, stands out negatively and item 6, related to a possible existence of inconsistencies in the system, stands out positively. Overall, the usability of this system was classified as good (equals to a 3 in the scale). All the volunteers had the opinion that the system did not have any inconsistencies, was easy to use and its diverse
functions were well integrated. Notwithstanding this general assessment, as the group’s age and experience range were highly heterogeneous, some of the items did not gather a consensual assessment, especially when questioned about the capability of users to interact with the system without any technical help and about the capability of most people to rapidly learn how to interact with and use the system. The mobile nature of the application, using a touch-screen cellphone, aroused doubts to all of the participants about the ability of COPD patients to use this monitoring system, in particular elder patients. However, when questioned about if the system could help senior patients to learn and control their disease, the result was, in general, positive (Item 12).

Globally, this results support the pre-defined idea of being a challenge to adapt this system so that users with little or no contact with with type of technology can make the most out of all its features. On Appendix B are available the questionnaire and information on test data.

As a way of also gathering healthcare specialists’ feedback about the utility of such systems, and collecting possible relevant suggestions, three healthcare specialist were interviewed (pneumologist, immunoallergologist and general practitioner). Their general opinion regarding the applicability of COPDHelper in the pretended context was consensually good. As concluded from the questionnaire’s results, the specialists alerted for a possible incapacity on the part of certain patients to use this system and making the most out of it, suggesting as a possible improvement the introduction of a brief tutorial, as a way to inform and teach the user how to interact with each section. Concerning the questionnaire’s feature, it was also suggested the introduction of a "observations and comments" block, in order to allow the input of relevant extra aspects about the expectoration (consistency and color, for example).

Although this results show some promise, the COPDHelper is still far away from perfection and in the next sections some of its main limitations will be pointed out.

5.2 General Discussion

COPDHelper, like most systems in the first stages of their development, possesses a number of flaws and limitations that must also be highlighted in order to provide a solid base for future improvements. Starting with the monitoring module, where the value of oxygen saturation is assessed, one of the main limitations regards the need for a manual input of such data. As was previously referred, initially the main goal of the monitoring module was to automatically acquire the oxygen saturation signal, making use of a wireless digital oximeter. Unfortunately, the acquisition of such sensor was rendered impossible by the lack of local distribution of the desired sensor or identical models in Portugal and other European countries. With an estimated deadline for this project’s development, the most viable solution found to bypass this obstacle was enabling the manual insertion of the oxygen saturation level, making use of a simple oximeter, both easily accessible (at local pharmacies, for example) and affordable to the average user.

Still regarding the monitoring features, it was originally thought to also integrate a wireless digital spirometer, to serve as a complement to the oxygen saturation assessment. But, similarly to what happened with the digital oximeter, the acquisition of such spirometer was made impossible,
not only due to problems with local distributors, but also because its high acquisition price, which far exceeded what was supported by this project’s budget.

Now concerning the counseling and education module, the main present limitations befall in the medication and respiration components. Not all of the educational videos available at this stage of development are presented in European Portuguese. The scarcity of Portuguese-spoken educational videos led to the integration of spoken videos in both English and Brazilian Portuguese. As for the respiration component, the absence of an audio support to the circle animation (which guides the user in the respiratory exercise) is a limitation. The integration of such aspect would make this feature more easy to comprehend and more intuitive. One of the problems encountered when trying to implement such parameter was the lack of RAM memory available to run at the same time the animation and voice support.
Chapter 6

Conclusions and Future Work

Chronic obstructive pulmonary disease is a serious health problem which places a significant economic burden on health systems worldwide, due mostly to a significant number of acute exacerbation events. It is estimated that its global burden will increase substantially in the coming decades, in a directly proportional relation with the noticeable rise in smoking habits. The prevention of the acute exacerbations is a common goal of COPD treatment, being imperative a patient education and self-management programs to arouse patient’s awareness of their activity behavior and health condition, and also to educate them how to properly take the prescribed medication.

Home telemonitoring is defined as the use of telecommunication technologies to transmit data on patient’s health status from home to a healthcare center. Based on literature review, home telemonitoring of COPD seems to be a promising patient management approach that produces accurate and reliable data, empowers patients, as well as their activity behavior and potentially improves their health-related quality of life. It is also increasingly seen as a way to bridge the gap between professional care and patient self-management.

As the main objective of the proposed master’s thesis was the development of a mobile application that, with the principles of telemedicine and telemonitoring, could diminish this gap and had the capability of assisting and guiding COPD patients towards an improved self-management of the disease, the overall balance is positive, with the main goals of the proposed project successfully fulfilled.

The result of such work is incorporated in the COPDHelper, an application capable of guiding the user in the diverse fields of pulmonary rehabilitation and management of diseases such as COPD. Making use of external biomedical sensor and questionnaires, the vital signs and symptoms’ progression are periodically assessed, to diminish the number of acute exacerbations provoked by oversights and lack of self-awareness of the symptom’s progression.

In comparison with the already available systems or studies described in the Chapter 3, COPDHelper is a strong competitor in the sector of symptom’s progression assessment and real-time feedback, as only 4 of the 10 referred systems are capable of analysing the collected data and instantly generate a feedback, and only 1 of those systems tracks the symptom’s manifestation. Also, the capacity of the COPDHelper to remind the patient about the need to take the medication, while also guid-
ing them in how to properly take it, is another strong argument when comparing with the state of the art in telemonitoring systems. Although most of the referred systems have a mobile component that allows a continuous monitoring of the patient’s activities, the fact that COPDHelper is integrated within the SmartCompanion, which supports other valuable monitoring features and applications, enhances the monitoring potential and versatility of this system.

The COPDhelper usability among COPD patients was tested and confirmed by the use of a questionnaire. A positive usability evaluation renders the system’s acceptability easier, as it improves and facilitates the interaction between the user and the system, thus reducing the natural lack of interest that is associated to highly complex and non-intuitive software.

Nevertheless, there are still some features that need further improvements before the application is fit for routine use.

6.1 Future Work

With the aforementioned COPDHelper limitations in mind, a set of future improvements can be outlined. As mentioned during the writing of this thesis, some features of COPDHelper were not implemented, but both the system and, ultimately, the final user would benefit with their integration. Starting with one of the counseling and education module’s components, exercises, the implementation of ExerGames, another SmartCompanion application, composed by different exercises and games, would complete this module, by making the user more active and, thus, improving his quality of life and and control over the disease. Also in this module, an uniformization of the educational videos and its spoken-language would be necessary, especially considering that not all the potential users will dominate more than their native language. Also, and as previously referred, the addition of an audio support to the respiratory exercises will further increase the user experience and make it more intuitive.

Regarding future prospectives to the monitoring module, the utilization of wireless sensors could be seen as an advantage, especially to elderly patients, since the manual introduction of the assessed values would be rendered obsolete, representing one less level of dependency of the system on the user.

Another feature that was initially thought of to be part of the COPDHelper was Mover, another application of the Fraunhofer’s Swiss Army Knife, that by making use of the smartphone’s accelerometers and gyroscope, can determine if the user is being active or not. The implementation of the Mover’s library would be beneficial to, upon a long inactivity detection (excluding the hours for nightly rest), alert the user and recommend specific exercises to fight the sedentary lifestyle common in COPD patients at advanced stages, mostly due to progressive deterioration of the respiratory capacities.

Also as future work is the implementation of a functionality capable of adapting the main features of the software to fit each specific patient’s diagnosis and observations, performed a priori by the healthcare specialist. By accessing previous diagnosis, stored in an Internet server instead of being input into the mobile application by the healthcare specialist, such information would
be used to make the application unique and adapted to each patient’s needs. In this way, upon patient’s registration in the mobile application, this system would connect to the Internet server and acquire the respective medical information.

It is also noteworthy, and having in consideration the results of the usability tests, that a design improvement destined to make the application more adapted and easy understandable to elderly people would be a valuable asset to improve both the acceptance and system’s functionality.
Bibliography


Appendix A

Questionnaires

A.1 COPD Assessment Test

Como está a sua DPOC (Doença Pulmonar Obstrutiva Crônica)? Faça o Teste de Avaliação da DPOC (COPD Assessment Test™—CAT)

Esse questionário irá ajudá-lo e ao seu profissional de saúde a medir o impacto que a DPOC (Doença Pulmonar Obstrutiva Crônica) causa no seu bem estar e o no seu dia a dia. As suas respostas e a pontuação do teste podem ser utilizadas por você e pelo seu profissional de saúde para ajudar a melhorar o controlo da sua DPOC e a obter o máximo benefício do tratamento.

Para cada um dos itens a seguir assinale com um (X) o quadrado que melhor o descrever presentemente. Certifique-se de selecionar apenas uma resposta para cada pergunta.

Por exemplo: Estou muito feliz

<table>
<thead>
<tr>
<th>PONTUAÇÃO</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
</tr>
</tbody>
</table>

O seu nome: ________________________________ Data de hoje: ________________________________
### A.2 COPD Assessment Test impact scale

In addition, for each scenario, the CAT Development Steering Group has proposed some potential management considerations:

#### CAT score

<table>
<thead>
<tr>
<th>CAT score</th>
<th>Impact level</th>
<th>Broad clinical picture of the impact of COPD by CAT score</th>
<th>Possible management considerations</th>
</tr>
</thead>
</table>
| 30+       | Very high    | Their condition stops them doing everything they want to do and they never have any good days. If they can manage to take a bath or shower, it takes them a long time. They cannot go out of the house for shopping or recreation, or do their housework. Often, they cannot go far from their bed or chair. They feel as if they have become an invalid. COPD stops them doing most things that they want to do. They are breathless walking around the home and when getting washed or dressed. They may be breathless when they talk. Their cough makes them tired and their chest symptoms disturbs their sleep on most nights. They feel that exercise is not safe for them and everything they do seems too much effort. They are afraid and panic and do not feel in control of their chest problem. | Patient has significant room for improvement. In addition to the guidance for patients with low and medium impact CAT scores consider:  
- Referral to specialist care (if you are a primary care physician)  
- Additional pharmacological treatments  
- Referral for pulmonary rehabilitation  
- Ensuring best approaches to minimising and managing exacerbations |
| 20+       | High         | COPD is one of the most important problems that they have. They have a few good days a week, but cough up sputum on most days and have one or two exacerbations a year. They are breathless on most days and usually wake up with chest tightness or wheeze. They get breathless on bending over and can only walk up a flight of stairs slowly. They either do their housework slowly or have to stop for rests. | Patient has room for improvement – optimise management. In addition to the guidance provided for patients with low impact CAT scores consider:  
- Reviewing maintenance therapy – is it optimal?  
- Referral for pulmonary rehabilitation  
- Ensuring best approaches to minimising and managing exacerbations  
- Reviewing aggravating factors – is the patient still smoking? |
| 10-20     | Medium       | COPD is one of the most important problems that they have. They have a few good days a week, but cough up sputum on most days and have one or two exacerbations a year. They are breathless on most days and usually wake up with chest tightness or wheeze. They get breathless on bending over and can only walk up a flight of stairs slowly. They either do their housework slowly or have to stop for rests. | Pati |
A.3 Modified Medical Research Council

MODIFIED MEDICAL RESEARCH COUNCIL
DYSPNEA SCALE

ID NUMBER:   FORM CODE: MRC
VERSION: 1.0 10/26/10
Visit Number
SEQ #

0a) Form Date ............
0b) Initials ............

Instructions: This form should be completed during the participant’s visit. Choose the one best response.

Please choose the one best response to describe your shortness of breath.

Grade

0  “I only get breathless with strenuous exercise”

1  “I get short of breath when hurrying on the level or walking up a slight hill”

2  “I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level”

3  “I stop for breath after walking about 100 yards or after a few minutes on the level”

4  “I am too breathless to leave the house” or “I am breathless when dressing”

1. Grade ......................................................
Appendix B

Usability Evaluation

B.1 Usability Questionnaire
Profissão: 
idade:  M □  F □

Usando a escala abaixo, por favor coloque um círculo no número mais próximo da palavra que mais se aproxima aos seus sentimentos acerca do COPDHelper.

1. Penso que gostaria de usar este sistema frequentemente
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

2. Achei o sistema desnecessariamente complexo
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

3. Achei o sistema fácil de usar
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

4. Penso que precisaria do apoio técnico para conseguir usar o sistema
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

5. Achei que as várias funções do sistema estavam bem integradas
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

6. Achei que havia demasiadas inconsistências neste sistema
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

7. Imagino que a maioria das pessoas consegue aprender a usar este sistema muito rapidamente
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

8. Achei o sistema muito incômodo de usar
   Discordo fortemente 1  2  3  4  5 Concordo fortemente

9. Senti-me muito confiante ao usar o sistema
   Discordo fortemente 1  2  3  4  5 Concordo fortemente
10. Precisei de aprender muitas coisas antes de conseguir começar a usar o sistema

Discordo fortemente

1 2 3 4 5

Concordo fortemente

Responda às duas últimas questões considerando uma mudança de perspectiva mais focada na população envelhecida

11. Utilizadores séniores seriam capazes de utilizar o sistema

Discordo fortemente

1 2 3 4 5

Concordo fortemente

12. Este sistema ajudaria os pacientes séniores a entender e controlar a sua doença

Discordo fortemente

1 2 3 4 5

Concordo fortemente

Sugestões:

1. Mudaria algum aspecto do COPDHelper?

2. Adicionaria alguma funcionalidade extra ao presente sistema?

3. Outras observações:
## B.2 Questionnaire Results

Table B.1: Average scores and standard deviations of each usability questionnaire’s item

<table>
<thead>
<tr>
<th>Item</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>6</th>
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<tbody>
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<td>3</td>
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<td>0.6</td>
<td>0.8</td>
<td>1</td>
<td>0.5</td>
<td>0.5</td>
<td>1</td>
<td>0.8</td>
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