1	Title: Validation of the Comprehensive ICF Core Set for obstructive pulmonary diseases		
2	from the patient's perspective		
3	Running head: Comprehensive ICF Core Set for OPD		
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1 Abstract

Objective: This study aimed to validate the Comprehensive International Classification of
 Functioning, Disability and Health (ICF) Core Set for Obstructive Pulmonary Diseases (OPD)
 from the perspective of patients with COPD.

Methods: A cross-sectional qualitative study was conducted with outpatients with Chronic
 Obstructive Pulmonary Disease using focus groups with an ICF-based approach. Qualitative
 data were analysed through the meaning condensation procedure by two researchers with
 expertise in the ICF.

9 Results: Thirty-two participants (female 37.5%; 63.8±11.3 years old) were included in 6 focus 10 groups. A total of 61 (86%) ICF categories of the Comprehensive ICF Core Set for OPD were 11 confirmed. Thirty-nine additional second level categories not included in the Core Set were 12 identified: 15 from the Body Functions component, 4 from the Body Structures, 9 from the 13 Activities and Participation and 11 from the Environmental Factors.

Conclusions: The majority of the categories included in the Comprehensive ICF Core Set for OPD were confirmed from the patients' perspective. However, additional categories, not included in the Core Set, were also reported. The categories included in the Core Set that were not confirmed and the additional categories need to be further investigated to develop an instrument tailored to patients' needs. This will promote patient-centred assessments and rehabilitation interventions.

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*Key words:* Chronic Obstructive Pulmonary Disease; International Classification of Functioning,
 Disability and Health; Patient's perspective.

### 1 Introduction

Chronic Obstructive Pulmonary Disease (COPD) currently affects 210 million people worldwide (World Health Organization, 2007). This condition is primarily characterised by a progressive airflow limitation however, as the disease progresses, exacerbations and comorbidities, such as cardiovascular diseases, skeletal muscle dysfunction and osteoporosis, contribute to a decreased physical and emotional participation in everyday activities (Vestbo *et al.*, 2013). Thus, it is imperative to systematically assess functioning of patients with COPD to optimise the management of their health condition and, ultimately, improve their quality of life.

9 The World Health Organization (WHO) recommends the use of the International Classification 10 of Functioning, Disability and Health (ICF) to comprehensively assess the health experience of 11 patients living with specific health conditions (World Health Organization, 2001). This 12 classification uses a globally agreed-on language and reflects the biopsychosocial model in an 13 unified view of various dimensions of health (World Health Organization, 2001). However, it is 14 composed of 1424 categories and, therefore, it is not feasible to use in clinical practice (Stucki 15 et al., 2008). To facilitate the implementation of the ICF, Core Sets have been developed (Cieza 16 et al., 2004). Core sets represent a selection of ICF categories describing the prototypical 17 spectrum of problems in functioning of patients with specific health conditions (Cieza et al., 18 2004). For Obstructive Pulmonary Diseases (OPD), under which COPD is the most 19 representative worldwide, two ICF Core Sets are available: the Brief and the Comprehensive 20 (Cieza et al., 2004, Stucki et al., 2004). The Brief ICF Core Set is composed of minimum data to 21 be used at any clinical context (Cieza et al., 2004, Stucki et al., 2004). The Comprehensive ICF 22 Core Set has the ability to collect more information and it is indicated for multidisciplinary 23 assessments in the rehabilitation process (Cieza et al., 2004, Stucki et al., 2004).

The current version of the Comprehensive ICF Core Set for OPD has been validated from the perspective of physicians (Jobst *et al.*, 2013) and physiotherapists (Rauch *et al.*, 2009). However, the WHO advocates a patient-centred care model, where patient's expectations, needs and preferences are considered in health and social care planning (World Health Organization, 2005). A key aspect in the validation process is therefore to integrate the patient's perspective (Coenen *et al.*, 2006). A recent study validated the Activities and Participation 1 component of this ICF Core Set according to the patient's perspective using individual 2 interviews (Marques *et al.*, 2013). Nevertheless, Body Functions, Body Structures and 3 Environmental Factors components were not validated. Therefore, this study aimed to examine 4 to what extent the health experience of patients with COPD is reflected in all components of the 5 current version of the Comprehensive ICF Core Set for OPD.

6 Methods

7 Study design

8 A cross-sectional qualitative study, using focus groups with an ICF-based approach, was
9 conducted with outpatients with COPD. The study received full approval from the Institutional
10 Ethics Committee.

11 Participants

The sample was recruited from December 2011 to October 2012 in three primary care centres of the central region of Portugal. Patients were eligible if they were: i) diagnosed with COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria (Vestbo *et al.*, 2013); ii) 18 years old or older; and iii) able to understand the purpose and procedures of the study. Patients were excluded if they presented severe psychiatric conditions and/or inability to understand and co-operate.

18 Data Collection

Potential eligible patients were identified by General Practitioners. The clinic secretaries contacted via telephone all potential participants, explained the purpose of the study and asked about their willingness to participate. If patients agreed to participate, they were invited to attend a meeting with the researchers in their primary care centre where they were informed, both verbally and in a written form, about the study procedures. All patients were included after signing the informed consent form.

Socio-demographic (gender, age, education level, marital status and current occupation) and clinical (lung function) data were first collected. Then, one moderator conducted all focus groups in a non-directive manner. At least one group assistant was present in each focus group to take observational notes of the group interaction and topics of discussion. Both moderator and group assistants were researchers with expertise in the ICF and in conducting focus groups. At the

beginning of each focus group, a brief explanation about the procedures of the session as well 1 2 as the concept of the ICF was provided. As the ICF-based approach was used, the titles of the 3 ICF chapters included in the Comprehensive ICF Core Set for OPD were presented to the 4 participants using a Microsoft PowerPoint presentation (Coenen et al., 2006, Kirchberger et al., 5 2009). For each chapter, open-ended questions on possible experienced problems related to 6 COPD were used ("If you think about your body and mind: what does not work the way it is 7 supposed to? In which parts are your problems?", "If you think about your daily life, what are 8 your problems?" and "If you think about your environment and your living conditions: what do 9 you find helpful or supportive? What barriers do you experience?"). To obtain more information, at the end of each ICF component the participants were asked whether they thought that 10 11 important information was missing in Body Functions, Body Structures, Activities and 12 Participation or Environmental Factors, respectively ("What is missing?"). The presentation 13 order of the ICF chapters in each focus group was randomised. The focus group sessions were 14 digitally recorded and transcribed.

15 Data analysis

16 A qualitative analysis was performed independently by two researchers with expertise in ICF 17 following the meaning condensation procedure (Kvale, 1996). Firstly, the full transcriptions were 18 read to obtain an overview of the collected data. Secondly, data were divided into meaning 19 units. A meaning unit was defined as a part of the transcription (few consecutive words or 20 sentences) about the same theme. Therefore, a meaning unit division was rather based on 21 meaning shifts than on grammatical linguistic rules. Thirdly, the concepts contained in each 22 meaning unit were identified. As proposed by the meaning condensation procedure, a meaning 23 unit could contain more than one concept. Then, the identified concepts were linked to ICF 24 categories based on established linking rules (Cieza et al., 2005). One concept could be linked 25 to one or more ICF categories (Cieza et al., 2005). The code nd (not defined) was used to 26 describe a concept that was not specific enough to be assigned to an existing ICF category, 27 whereas the code nc (not covered) represented concepts not yet included in the ICF (Cieza et 28 al., 2005).

The number of focus groups conducted was determined by data saturation, defined as the point
 during data analysis when the linking of the concepts of two consecutive focus groups revealed
 less than 5% additional second level categories (Coenen *et al.*, 2006).

The final decision of the identified ICF categories was based on consensus and then compared with the categories of the current version of Comprehensive ICF Core Set for OPD. Categories included in the Comprehensive ICF Core Set for OPD were confirmed if the same category emerged in the focus groups. Since the ICF categories are arranged in a hierarchical system, the second level categories of the Comprehensive ICF Core Set for OPD were also confirmed when the corresponding third or fourth level category was identified.

10 Descriptive statistics were used to characterise the sample. To determine the consistency of the 11 qualitative analysis performed by the two researchers, an inter-observer agreement analysis 12 using the Cohen's kappa was performed for each level of the ICF classification (Elliott and 13 Woodward, 2007). Fifteen percent of the qualitative analysis was randomly selected to perform 14 this test (Coenen et al., 2006, Margues et al., 2013). The value of Cohen's kappa ranges from 0 15 to 1 and can be categorised as slight (0.0-0.20), fair (0.21-0.40), moderate (0.41-0.60), 16 substantial (0.61-0.80) or almost perfect (≥0.81) agreement (Landis and Koch, 1977). All 17 statistical analyses were performed using PASW Statistics (Version 18.0, SPSS Inc., Chicago,

18 IL).

28

### 19 Results

20 Participants

A total of 45 patients were contacted for inclusion in the study, however, 7 refused to participate as they did not perceive the study as relevant and 6 failed to attend the meeting. Thirty-two participants (female 37.5%) were included in 6 focus groups. Participants' mean age was 63.8±11.3, ranging from 44 to 81 years old. According to the GOLD criteria, 12 (37.5%) participants had mild COPD, 13 (40.6%) moderate and 7 (21.9%) severe to very severe. The characteristics of the participants are summarised in Table 1.

27 (Insert table 1 about here)

Inter-observer agreement

The agreement between the two researchers was almost perfect for the ICF component
 (Kappa=0.94; 95% CI 0.78-1), first (Kappa=0.92; 95% CI 0.79-1), second (Kappa=0.96; 95% CI 0.78-1), third (Kappa=0.86; 95% CI 0.71-1) and fourth (Kappa=1) levels.

4

ICF categories according to the participants' perspectives

A total of 1184 concepts were identified. Of these, 1127 were linked to 167 ICF categories, 76 from the second, 86 from the third and 5 from the fourth levels. For the categories from the third and fourth levels, the correspondent second level category was considered. Thus, the concepts were linked to 98 second level categories. However, 57 concepts could not be linked to the ICF: 10 were coded as *not defined*, 8 as *not covered* (e.g. sputum characteristics; coordinating breathing with talking and walking) and 36 as Personal Factors (e.g. being calm and tolerant; being active; fearing the future).

12 (Insert figure 1 about here)

13 A total of 61 (86%) ICF categories included in the Comprehensive ICF Core Set for OPD were 14 confirmed. However, 10 (14%) categories could not be confirmed: 3 from the Body Structures 15 component (s710 structure of head and neck region, s720 structure of shoulder region, s760 16 structure of trunk); 4 from the Activities and Participation component (d230 caring out daily 17 routine, d465 moving around using equipment, d470 using transportation, d660 assisting 18 others); and 3 from the Environmental Factors component (e340 personal care providers and 19 personal assistants, e575 general social support services, systems and policies and e585 20 education and training services, systems and policies).

Thirty-nine additional second level categories that are not included in the Comprehensive ICF Core Set for OPD were identified by the participants' perspective. Fifteen belonged to the Body Functions component, 4 to the Body Structures, 9 to the Activities and Participation and 11 to the Environmental Factors.

25 (Insert tables 2, 3 and 4 about here)

26 Discussion

27

In this study, the majority of the categories included in the Comprehensive ICF Core Set for 1 2 OPD were confirmed from the perspective of patients with COPD. Nevertheless, ten categories 3 from the Body Structures, Activities and Participation and Environmental Factors components 4 were not confirmed. Impairments in the structures of the head, neck (s710), shoulder (s720) and 5 trunk (s760) were not significant categories according to the participants' view. In studies using 6 the ICF, problems in these structures were also not relevant for patients with COPD, with 7 prevalences below 30% (Jácome et al., 2013, Ewert et al., 2004). Regarding the Activities and 8 Participation component, carrying out daily routine (d230) was not an issue to the participants. 9 However, in a recent study, this activity was one of the most restricted for patients with COPD (Jácome et al., 2013) and in the study of Marques et al. (2013) it was confirmed by patients' 10 11 interviews (Marques et al., 2013). This category is defined as "carrying out simple or complex 12 and coordinated actions in order to plan, manage and complete the requirements of day-to-day 13 duties" (World Health Organization, 2001). In the present study, instead of reporting difficulties 14 in carrying out daily routine, patients focused their reports on exemplifying difficulties in 15 activities of daily routine, which require complex and coordinated actions; e.g., d630 preparing 16 meals, d640 doing housework and d650 caring for household objects. This has also been 17 observed in patients with Rheumatoid Arthritis (Stamm et al., 2005). The activities moving 18 around using equipment (d465), using transportation (d470) and assisting others (d660) were 19 also not reported by the participants in the current study. One possible explanation is that these activities may not be part of participants' routines and characteristics and, therefore, they are 20 21 not meaningful for patients. A recent study supports these findings (Marques et al., 2013). This 22 needs careful attention as in the physicians' perspective these categories were also not 23 relevant, with one exception, the category d470 (Jobst et al., 2013). However, even this 24 exception had only 39% of agreement using the Delphi technique (Jobst et al., 2013). In the 25 Environmental Factors, the category e340 personal care providers and personal assistants was 26 not confirmed. This category was also not validated in the physicians' perspective (Jobst et al., 27 2013). Personal care providers may not be part of participants' lives, since family carers are 28 typically the primary source of support to patients (Spence et al., 2008). The other two not 29 confirmed categories, e575 general social support services, systems and policies and e585

education and training services, systems and policies, have been described as not relevant for patients with COPD in previous studies (Ewert *et al.*, 2004, Jácome *et al.*, 2013). As these ten categories were not confirmed by the participants' perspective, its role in the Comprehensive ICF Core Set for OPD is unclear. These findings, together with the evidence from other studies pointing out to the need of making minor revisions in this Core Set (Rauch *et al.*, 2009, Marques *et al.*, 2013, Jobst *et al.*, 2013), might contribute for the decision on the final version of the OPD Core Set.

8 Additional categories, currently not included in the Comprehensive ICF Core Set for OPD, were 9 identified. Six of these categories were derived from the chapters b3 voice and speech functions 10 (b330 and b340), s3 structures involved in voice and speech (s310, s330 and s340) and d3 11 communication (d350), emphasising the relevance of communication problems for patients. The 12 category d330 speaking is already included in the ICF Core Set (Stucki et al., 2004), however, 13 this ICF category alone might not be able to provide sufficient detail to allow a comprehensive 14 assessment of patients' communication problems. Four other categories from the chapter b1 15 mental functions were also identified, associated to consciousness (b110), temperament and 16 personality (b126), attention (b140), memory (b144) and thought (b160) functions. These 17 functions emerged in participants' report frequently associated with the worsening of respiratory 18 symptoms, "when I'm with a cold, I have difficulty in concentrating and I feel hopeless". 19 Therefore, it may be more important to assess these categories in patients with COPD during exacerbations than in stable periods. Other four categories from the chapter b5 functions of the 20 21 digestive, metabolic and endocrine systems (b510, b515, b535 and b545) were identified. This 22 is supported by previous literature on the topic which suggests that patients with COPD have 23 concomitant impairments in these systems (Shoikhet Ia and Klester, 2010). Similarly to Margues 24 et al. (2013), additional categories from the chapter d7 interpersonal interactions and 25 relationships were identified. This finding reinforces the well-described difficulties that patients 26 with COPD have to face when they are interacting with other people and managing their 27 relationships, including with their family members. Therefore, the inclusion of these categories 28 in the Comprehensive ICF Core Set for OPD should be discussed. Further identified topics were 29 derived from the chapter e5 services, systems and policies, related to architecture (e515), open

space planning (e520), utilities (e530) and social security (e570). These Environmental Factors emerged as barriers in participants' daily life and probably translate the inefficiency of those services, systems and policies to meet patients' specific needs. This topic should be further explored to design appropriate policies to improve the daily life of these patients.

5 In this study, almost all concepts identified by the participants could be linked to the unified and 6 standard language of the ICF, demonstrating that the ICF broadly represents the most 7 significant impairments in the functioning of patients with COPD. However, eight concepts 8 identified in this study are currently not covered in this classification. For example, the sputum 9 characteristics are not present in the ICF, despite of chronic sputum production being a typical 10 symptom among patients with OPD (Trappenburg et al., 2011, Vestbo et al., 2013). Difficulties 11 in coordinating breathing with walking were also not covered (Bourbeau, 2009). These findings 12 reveal two major limitations of the ICF: some individual experiences are not included in the ICF 13 classification and even when the individual experience is included it may not be with the level of 14 specification required. These limitations have been previously reported (Kirchberger et al., 15 2009, Marques et al., 2013).

### 16 Strengths and limitations

17 Different approaches for the development of the Comprehensive ICF Core Set for OPD have 18 been applied previously to characterise the functioning of patients with COPD (Jácome et al., 19 2013), to validate the Core Set in the perspective of health professionals (Rauch et al., 2009, 20 Jobst et al., 2013) and to validate the Activities and Participation component from patients' 21 perspective (Marques et al., 2013). However, the present study is the first to validate the 22 integral Comprehensive ICF Core Set for OPD from patients' perspective and, therefore, it 23 provides an important contribution for the decision on the final version of the OPD Core Set. 24 Nevertheless, there are some limitations that need to be acknowledged. Firstly, most 25 participants had mild and moderate COPD. A sample including a higher proportion of patients 26 with advanced COPD would be more representative of the general population with COPD. 27 Secondly, the sample was composed by Portuguese citizens. As patients in other countries may 28 experience different functioning problems in their daily life due to cultural reasons, future studies 29 using a similar methodology in other countries should be conducted to establish a cross-cultural perspective. Moreover, COPD is one subtype of OPD and may not be representative of the all spectrum of problems of patients with different OPD. Using this study as a starting point, future studies could be conducted in other countries including patients with others OPD, such as asthma. Lastly, the linking process was performed by two researchers and, in cases of disagreement, consensus was reached. It is believed that this potential bias was reduced, since the inter-observer agreement was almost perfect for the component and also for the second, third and fourth levels of the ICF classification.

### 8 Conclusion

9 The majority of the categories included in the Comprehensive ICF Core Set for OPD were 10 confirmed from the patients' perspective. However, additional categories, not included in the 11 Core Set, were also reported. Further studies are needed to ascertain categories included the 12 Comprehensive ICF Core Set that were not confirmed and to authenticate additional categories. 13 This will contribute to the development of an instrument that integrates the full perspective of 14 patients with COPD and that will enable a patient-centred assessment and planning of tailored 15 health and social interventions. Some limitations of the ICF were also identified and should be 16 considered in future revisions of this classification. The present study contributes for the 17 decision of the final version of the Comprehensive ICF Core Set for OPD and the potential 18 future revision of the ICF.

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1 Table 1 - Characteristics of the participants (n=32).

Characteristics			
Female n(%)	12 (37.5%)		
Age (years) M±SD	63.8±11.3		
Educational level n(%)			
Primary school	15(46.9%)		
Secondary school	11(34.3%)		
High school/ University	6(18.8%)		
Marital status n(%)			
Married	21(65.6%)		
Divorced	3(9.4%)		
Widowed	6(18.8%)		
Single	2(6.2%)		
Current occupation n(%)			
Retired	23(71.9%)		
Employed	7(21.9%)		
Unemployed	2(6.2%)		
Living alone n(%)	5(15.6%)		
Current smoker n(%)	13(40.6%)		
FEV <sub>1</sub> (% predicted) M±SD	66.1±23.6		
GOLD Classification n(%)			
Mild	12(37.5%)		
Moderate	13(40.6%)		
Severe/Very severe	7(21.9%)		

# 2 M:Mean; SD:Standard Deviation; FEV<sub>1</sub>:Forced expiratory volume in one second.

## 3 Table 2 – Participants' reporting of ICF categories: Body Functions and Structures.

ICF Code	ICF Category Title	Number of linked concepts
ICF Catego	ries of the Comprehensive ICF Core Set for OPD	
b130	Energy and drive functions	19
b134	Sleep functions	5
b152	Emotional functions	6
b1522	Range of emotion	1
b280	Sensation of pain	34
b2801	Pain in body part	25
b310	Voice functions	17
b410	Heart functions	16

b430	Haematological system functions	3
b435	Immunological system functions	11
b440	Respiration functions	88
b445	Respiratory muscle functions	2
b450	Additional respiratory functions	23
b455	Exercise tolerance functions	89
b460	Sensations associated with cardiovascular and respiratory functions	85
b530	Weight maintenance functions	4
b730	Muscle power functions	14
b740	Muscle endurance functions	1
b780	Sensations related to muscles and movement functions	2
s410	Structure of cardiovascular system	12
s430	Structure of respiratory system	28
s710	Structure of head and neck region	-
s720	Structure of shoulder region	-
s760	Structure of trunk	-
Additional IC	F categories	
b110	Consciousness functions	2
b126	Temperament and personality functions	11
b140	Attention functions	2
b144	Memory functions	1
b160	Thought functions	1
b240	Sensations associated with hearing and vestibular function	2
b330	Fluency and rhythm of speech functions	9
b340	Alternative vocalization functions	5
b415	Blood vessel functions	1
b420	Blood pressure functions	1
b510	Ingestion functions	7
b515	Digestive functions	4
b535	Sensations associated with the digestive system	4
b545	Water, mineral and electrolyte balance functions	1
b830	Other functions of the skin	1
s310	Structure of nose	7
s330	Structure of pharynx	6
s340	Structure of larynx	1
s610	Structure of urinary system	1

1 Confirmed ICF categories of the Comprehensive ICF Core Set for OPD are shown in bold typeface.

ICF Code	ICF Category Title	Number of linked concepts
ICF Catego	ries of the Comprehensive ICF Core Set for OPD	
d230	Carrying out daily routine	-
d240	Handling stress and other psychological demands	12
d330	Speaking	23
d410	Changing basic body position	22
d430	Lifting and carrying objects	22
d450	Walking	48
d455	Moving around	49
d460	Moving around in different locations	1
d465	Moving around using equipment	-
d470	Using transportation	-
d475	Driving	1
d4750	Driving human-powered transportation	1
d510	Washing oneself	1
d540	Dressing	1
d570	Looking after one's health	5
d620	Acquisition of goods and services	1
d640	Doing housework	16
d650	Caring for household objects	6
d660	Assisting others	-
d770	Intimate relationships	-
d845	Acquiring, keeping and terminating a job	3
d850	Remunerative employment	2
d910	Community life	1
d920	Recreation and leisure	31
Additional I	CF categories	
d210	Undertaking a single task	2
d350	Conversation	7
d415	Maintaining a body position	3
d520	Caring for body parts	2
d630	Preparing meals	2
d710	Basic interpersonal interactions	1
d720	Complex interpersonal interactions	1
d760	Family relationships	1

1 Table 3 –Participants' reporting of ICF categories: Activities and Participation.

1 Confirmed ICF categories of the Comprehensive ICF Core Set for OPD are shown in bold typeface.

1 Table 4 –Participants' reporting of ICF categories: Environmental Factors.

ICF Code	ICF Category Title	Number	of linked concepts
ICF Catego	ries of the Comprehensive ICF Core Set for OPD	F	В
e110	Products or substances for personal consumption	38	14
e115	Products and technology for personal use in daily living	21	-
e120	Products and technology for personal indoor and outdoor mobility	-	1
	and transportation		
e150	Design, construction and building products and technology of	-	4
	buildings for public use		
e155	Design, construction and building products and technology of	-	1
	buildings for private use		
e225	Climate	-	44
e245	Time-related changes	-	9
e2450	Day/night cycles	-	8
e260	Air quality	-	81
e310	Immediate family	24	6
e320	Friends	7	-
e340	Personal care providers and personal assistants	-	-
e355	Health professionals	14	-
e410	Individual attitudes of immediate family members	11	10
e420	Individual attitudes of friends	1	-
e450	Individual attitudes of health professionals	7	5
e460	Societal attitudes	-	2
e540	Transportation services, systems and policies	2	1
e555	Associations and organizational services, systems and policies	-	1
e575	General social support services, systems and policies	-	-
e580	Health services, systems and policies	28	22
e585	Education and training services, systems and policies	-	-
e590	Labour and employment services, systems and policies	1	4
Additional I	CF categories		
e210	Physical geography	2	1
e220	Flora and fauna	-	11
e235	Human-caused events	-	2
e325	Acquaintances, peers colleagues, neighbours and community members	3	-
e350	Domesticated animals	-	1
e425	Individual attitudes of acquaintances, peers colleagues, neighbours and	1	2

	community members			
e445	Individual attitudes of strangers	-	1	
e515	Architecture and construction services, systems and policies	-	1	
e520	Open space planning services, systems and policies	-	1	
e530	Utilities services, systems and policies	-	1	
e570	Social security services, systems and policies	1	-	

- Confirmed ICF categories of the Comprehensive ICF Core Set for OPD are shown in bold typeface. F-facilitators; B-barriers.



3 Figure 1 – Saturation of the qualitative analysis in the six focus groups.