

## **MASTER PROTOCOL**

### **Depression, Anxiety and Somatic Symptoms in Global Primary Care Settings: A Field Study for the ICD-11-PHC**

**Version 2 for WHO Research Ethics Review Committee  
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## MASTER PROTOCOL

### Depression, Anxiety and Somatic Symptoms in Global Primary Care Settings: A Field Study for the ICD-11-PHC

#### PART 1

#### PROJECT SUMMARY

This is a master protocol for field trials to be conducted in five countries regarding the utility and reliability of key changes being recommended for the *International Classification of Diseases, Version 11, Mental and Behavioural Disorders in Primary Health Care* (ICD-11 PHC), specifically focusing on the most common mental disorders seen in PHC settings (e.g., depression, anxiety and somatic symptoms). The public health significance of the proposed research is that the ICD-11 PHC is intended as key tool for identifying people in need of mental health services at the point at which they are most likely to come into contact with the health care delivery system. This will provide a better opportunity to deliver effective interventions in order to reduce the burden of mental and behavioural disorders at the individual and population level.

The World Health Organization (WHO) is currently revising the International Classification of Diseases and Related Health Problems, and ICD-11 is scheduled for approval by the World Health Assembly in 2018. In conjunction with ICD-10, the previous version of the classification (WHO, 1992), the Department of Mental Health and Substance Abuse (MSD) also developed a Primary Health Care version of the ICD-10 Mental and Behavioural Disorders chapter (ICD-10 PHC) (WHO, 1996), which provided a much briefer diagnostic classification and recommendations on management of each included condition. MSD intends to develop an equivalent product for ICD-11—the ICD-11 PHC—and appointed a Primary Care Consultation Group to make recommendations regarding its structure and content.

The Primary Care Consultation Group has developed a preliminary draft of a primary care classification of mental and behavioural disorders for ICD-11, designed for use by physicians and other health care providers in global primary care settings. For the most part, the proposed ICD-11 classification is similar to the primary care classification for ICD-10. The innovations in the proposed ICD-11 primary care classification relate to the assessment of anxiety, depressive, and somatic symptoms.

First, depression in general medical settings most commonly presents together with anxious symptoms. Depression without current anxiety is less common. However, both of these presentations are formally diagnosed as depression, whether or not anxious symptoms are simultaneously, even though the treatment implications of depression with and without anxiety are different. The proposed ICD-11-PHC approach allows for a diagnoses of ‘anxious depression’, as well as depression without significant anxiety symptoms and anxiety without significant depressive symptoms. The proposed assessment for all three categories consists of two 5-item scales. The Primary Care Consultation Group believes that both the construct of anxious depression and this approach to its assessment will be better suited to use in primary care settings, and this study seeks to validate these approaches.

The second main issue concerns the proposed category of Bodily Distress Disorder, another common presentation in primary care settings. The Primary Care Consultation Group proposes to assign a diagnosis of Bodily Distress Disorder based on the presence of at least three specific types of symptoms that are not related to known medical conditions, and to differentiate Bodily Stress Disorders from Health Anxiety, in which the focus is on worry about health but not specific symptoms complaints. Both of these approaches are different from traditional approaches to diagnosis of ‘somatoform disorders’ and from what is being recommended for the main ICD-11. This study seeks to validate the symptom profile descriptions proposed by the Primary Care Consultation Group, and to examine the relationships among Bodily Distress Disorder, Health Anxiety, and other common mental disorders in primary care settings.

The proposed study will test the application of these new constructs in a variety of primary care settings in a five countries with different levels of income, different languages, and different cultural contexts to examine whether primary care clinicians can accurately identify the intended groups of patients using the proposed categories, and how these assessments relate to the results of a computerised psychiatric research interview designed for general medical settings in primary care. The interview covers anxiety, depressive, and somatic disorders, and will serve as a ‘gold standard’ for diagnostic conclusions in the present study.

This is not an epidemiological study intended to establish the prevalence of these disorders in the general population. The rates of these disorders in global primary care settings are already known. It is also not feasible within available resources to construct a random or representative sample of clinicians who may possibly be users of the primary care classification, and this study makes no attempt to do that. This is an implementation or effectiveness study to examine the application of these aspects of the proposed primary care classification in a broad spectrum of specific primary care settings across countries, languages, cultures, and resource levels. This is intended to assist MSD in determining whether the proposed ICD-11-PHC is suitable for use at a global level by examining whether it can be used in different and specific settings in widely divergent countries that include Brazil, China, Mexico, Pakistan and Spain.

The point of this study is to provide support for the global application of the proposed ICD-11-PHC, rather than to make generalizations about the primary care clinicians who assist us in the Field Trials. That is, the study focuses on the behaviour of the proposed classification, not the behaviour of clinicians. If there are problems in implementation in certain types of settings, or if the findings regarding the implementation of the proposed assessments by primary care clinicians suggest poor convergence with the results of structured interviews, this will provide MSD with an opportunity to make changes in the proposed ICD-11 PHC in order to improve its clinical utility in global primary care settings.

The study specifically focuses on “common mental disorders” seen in PHC settings (e.g., depression, anxiety and somatic symptoms), and does not attempt to cover the whole range of disorders that may be seen in primary care. It is observational and cross-sectional, consists of an initial evaluation by the primary care clinician followed by administration of a detailed structured interview by a trained Research Assistant. The WHO’s Department of Mental Health and Substance Abuse (MSD) will use the results of this study, along with the data gathered through other investigations, as a basis for making changes in the proposed ICD-11 PHC in order to improve its clinical utility in global primary care settings.

## GENERAL INFORMATION

**Title:** Depression, Anxiety and Somatic Symptoms in Global Primary Care Settings: A Field Study for the ICD-11-PHC

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## RATIONALE AND BACKGROUND INFORMATION

The World Health Organization's (WHO) International Classification of Diseases and Related Health Problems, 11<sup>th</sup> Edition (ICD-11) is currently under revision. WHO's Department of Mental Health and Substance Abuse (MSD) has the responsibility for the technical content of the ICD-11 chapter on Mental and Behavioural Disorders.

Substantial concerns have been expressed about the clinical utility of the current version of the ICD classification system (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders, 2011; Reed, 2010), particularly in primary care settings (Gask, Klinkman, Fortes, & Dowrick, 2008). MSD plans to conduct a series of systematic

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<sup>1</sup> DOIs for Local Investigators are not being provided with the current Master protocol, but will be provided with the country-specific protocols.

field studies focusing on clinical utility and global applicability of proposed changes to the classification.

Despite the enormous contribution of mental disorders to global disease burden (World Health Organization, 2008), only a minority of people with even serious mental disorders worldwide receive any treatment at all (WHO World Mental Health Survey Group, 2004). Of those who do receive mental health treatment, they are far more likely to get it in primary health care (PHC) settings rather than in specialty mental health settings (Wang et al., 2007). By definition, PHC settings are those in which people are most likely to come into contact with the health care system, and therefore represent the best opportunity to improve the identification and effective treatment of people with mental disorders.

To assist primary care physician and other primary health care workers in identifying patients with mental disorders, WHO developed a Primary Health Care version of the ICD-10 Mental and Behavioural Disorders chapter (ICD10-PHC) for the previous version of the classification (WHO, 1996). This version provided both a brief diagnostic classification for use in PHC setting and recommendations on management. This system was subjected to international field studies (Goldberg et al, 1995), in which it was evaluated for acceptability and ease of application. However, the usefulness and adoption of this system in the field has been limited by the fact that it was *adapted for*, rather than *developed in*, primary care settings; thus, missing the complexity of psychological disorder as it manifests in primary care settings (Gask et al., 2008).

The current ICD-11 revision process represents an important opportunity to improve the PHC version's clinical utility because it is being created simultaneously with the main version, based on the diversity and particularities of primary care settings and the characteristics of the health care personnel who work in them. Leading the ICD11-PHC classification of Mental and Behavioural Disorders is the Primary Care Consultation Group (PCCG), which includes a balance of primary care professionals and mental health specialists. The PCCG is working with the MSD and reports to the International Advisory Group for the Revision of ICD-11 Mental and Behavioural Disorders. Its main task is to develop and test the newly revised ICD11-PHC for Mental and Behavioural Disorders. The PCCG has met on four occasions between October 2010 and November 2011 and developed proposals that have been reviewed by focus groups for primary care professionals (PCPs) in eight countries (Austria, Brazil, People's Republic of China (Hong Kong), India, New Zealand, Pakistan, Tanzania, and the United Kingdom (see Lam, Goldberg, Dowell, Fortes, Mbatia, Minhas, & Klinkman, 2012). The PCCG's proposals have been modified based on the focus group feedback, and the proposals are now ready to be tested in field studies.

This protocol describes two proposed field studies, each designed to evaluate the ICD-11 PHC proposed diagnostic categories in primary care settings in several countries. The specific diagnostic categories to be field tested are the most "common mental disorders" seen in PHC settings and also represent areas of important substantive change from ICD-10 PHC. These disorders are described in the next section.

### **Common Mental Disorders in Global Primary Care Settings**

The most common mental disorders encountered in PHC settings are various mixtures of depressive disorders, anxiety disorders and somatization disorders. In these settings, the prevalence of depressive disorders ranges from 5% to 20% (Pingitore & Sansome, 1998;

Brody, 1996; deGruy & Pincus, 1996; Patel et al., 2003, 2007; Tyler et al., 2005; WHO, 2001, 2006, 2008; WONCA, 1998), anxiety disorders range from 4% to 15% (Brody, 1996; Craighead et al., 1998; deGruy & Pincus, 1996; Pingitore & Sansome, 1998; WHO 2000, 2001), and somatization disorders from 0.5% to 11% (Brody, 1996; deGruy & Pincus, 1996; WHO, 2000, 2001). Furthermore, there are high correlations (0.70 to 0.95) among all three of these groups of disorders (Üstün & Sartorius, 1995; VonKorff, Scott & Gureje, 2009).

**Anxious Depression.** It is extremely common in PHC settings to see patients with both anxiety and depression at case level. The proposed ICD-11 PHC definition treats this as a single diagnosis rather than as two quite different disorders. The previous classification for primary care (ICD-10-PHC) introduced the concept of “Mixed Anxiety and Depression” (Üstün et al., 1995), to denote individuals with symptoms of both disorders, but each just not sufficient to reach the “case” threshold. These patients are extremely common in primary care, and in one national epidemiological survey were found to account for 20% of all sickness absences in the UK (Das-Munshi et al 2008). The proposed ICD-11-PHC category of Anxious Depression, includes four severity levels: Sub-threshold, Mild, Moderate, and Severe. The Sub-threshold level corresponds to Mixed Anxiety and Depression in the ICD11-PHC, so this separate category is no longer necessary. The Mild, Moderate, and Severe levels correspond to the severity levels for Depressive episode in the main classification, though the proposed ICD-11 PHC version is distinct in incorporating anxiety symptoms into the overall severity determination.

Field testing of the proposed ICD-11 PHC diagnostic categories is necessary, particularly the ability of primary care providers (PCPs) to accurately detect patients with this subclinical degree of anxious depression, as well as other depressive and anxiety disorders. Accurate diagnosis is particularly important in PHC settings because sub-threshold depressive and anxiety symptoms can also be caused by systemic disease, and appropriate treatment for both physical and mental health problems requires accurate diagnosis. In research, accurate diagnoses are made typically through the use of structured interviews or other standardized assessment methods. This is not practical in busy PHC settings across the world, in which there is little time to administer pencil-and-paper tests, tests are simply not available, or PCPs have difficulty remembering all the symptoms required for particular mental disorders. To address this problem, researchers have developed very brief scales that enable a clinician in any general medical setting to assess and detect anxiety and depressive disorders (Goldberg, Prisciandaro, & Williams, 2012; Zimmerman et al., 2008).

To evaluate the proposed ICD-11 diagnoses for Anxiety Disorder, Major Depression and Anxious Depression in PHC settings, this study will utilize two brief 5-item scales: the Dep5 and the Anx5 (further described in the Measures section). There are two screening questions in each scale, and the other 3 questions in each scale need not be asked if both screening questions are answered negatively. These scales were developed and evaluated in primary care clinics and were found to have high positive predictive power for ICD-10 and DSM-IV anxiety and depressive disorders (Goldberg, Prisciandaro, & Williams, 2012). They were also found to be particularly helpful in PHC settings because they were brief, no forms were necessary, and PCPs could easily remember the items.

In this study, these scales will be further validated against ICD-11 proposed diagnoses for anxiety and depression in order to determine precise symptom thresholds that best correspond with ICD-11 diagnoses. Furthermore, we will evaluate PCPs’ ability to assess and detect depression and anxiety using the two scales, as well as PCPs’ ability to reliably administer

these two scales. Finally, these scales will be used to determine if there are differences between sites and countries in the appropriate thresholds.

**Bodily Stress Syndrome (BSS).** Another important change recommended for ICD-11-PHC involves a diagnosis commonly given to primary care patients who have multiple and persistent somatic symptoms but no evidence of a threshold mental health disorder. These patients have been previously labeled as having ‘medically unexplained symptoms’. However, there is general agreement that this label is unhelpful in describing these symptoms to the patient, since it carries the suggestion that perhaps the patient exaggerates or even imagines his symptoms, and provides no explanatory link to enhance understanding of what may be causing the symptoms (Fink & Schroder, 2010).

A new disorder called Bodily Stress Syndrome (BSS) (Fink P, Rosendal M, Olesen, 2005; Fink & Schroder, 2010; Fink et al., 2007) is proposed for ICD-11-PHC to replace the previous edition’s “somatoform” disorders. The proposed BSS diagnosis requires that a patient to have (a) multiple persistent bodily symptoms or (b) unreasonable fear/anxiety, or conviction, of having an undetected physical illness. Symptoms are distressing and/or result in significant disruption in daily life, as well as persistent concerns about the medical seriousness of the symptoms. Patients with multiple symptoms typically present with symptom clustering and a distinct pattern of cardiopulmonary, gastrointestinal, musculoskeletal and/or general (e.g., headache, dizziness, memory impairment, concentration difficulties, and fatigue) symptoms. Those with anxiety about their health may have an intense awareness on bodily functions, physical sensations, physiological reactions or minor bodily problems that are misinterpreted as serious disease.

The proposed BSS diagnosis for ICD-11, with its emphasis on symptoms patterns and health anxiety, is based on research that was conducted primarily in one country (see Fink P, Rosendal M, Olesen, 2005; Fink & Schroder, 2010; Fink et al., 2007). Because the ICD-11 is used globally, it is important to evaluate the proposed BSS in patients across countries. Furthermore, a description of this disorder that is clear and easy for PCPs to utilize must be tested in the field study against findings from a more elaborate, structured research interview. Finally, because presentations of anxiety or depression (“anxious depression”) have been found in patients with medically unexplained physical symptoms (i.e., BSS) across countries (VonKorff, Scott & Gureje, 2009), it is important to examine how BSS patients differ from those with depressive and anxiety symptoms.

## **STUDY GOALS AND OBJECTIVES**

This is a master protocol for two proposed field studies aimed at improving the assessment and diagnosis of the most common mental disorders (e.g., depression, anxiety and somatic symptoms) in PhC settings in multiple countries. This is not an epidemiological study intended to establish the prevalence of these disorders in the general population. The rates of these disorders in global primary care settings are already known. It is also not feasible within available resources to construct a random or representative sample of clinicians who may possibly be users of the primary care classification, and this study makes no attempt to do that. This is an implementation or effectiveness study to examine the application of these aspects of the proposed primary care classification in a broad spectrum of specific primary care settings across countries, languages, cultures, and resource levels. This is intended to assist WHO's Department of Mental Health and Substance Abuse (MSD) in determining whether the proposed ICD11-PhC is suitable for use at a global level by examining whether it can be used in different and specific settings in widely divergent countries that include Brazil, China, Mexico, Pakistan, and Spain.

The field studies will be carried out as two separate studies: (a) The anxious/depression study will focus on patients with anxious and/or depressive symptoms, and (b) the bodily stress syndrome (BSS) study will focus on patients with multiple somatic symptoms. The study objectives are presented in the following two sections:

### **Anxious/Depression Study Objectives:**

1. To establish the precise symptom thresholds on a brief depression screening instrument (i.e., the Dep5) and a brief anxiety screening instrument (i.e., the Anx5) that produces the best correspondence with corresponding ICD-11 diagnoses made by a standardized research interview (i.e., the Clinical Interview Schedule-Revised [CIS-R]), and to measure the positive predictive values of these thresholds.
2. To evaluate primary care providers' (PCPs) ability to detect and assess depression and anxiety using the two screening items for anxiety and the two screening items for depression contained within the Anx5 and the Dep5, to be followed by the additional items if a positive reply is obtained.
3. To evaluate PCPs' ability to reliably administer the Dep5 and Anx5.
4. To establish whether there are differences between sites and countries in the appropriate thresholds.
5. To analyze the relationship between PCPs' ratings of patient disability with an external measure of disability (i.e., the 12-item WHO-DAS 2.0), which will be incorporated into the version of the PROQSY used in the study.

The anxious/depression study is designed to include individuals who are at sub-threshold levels of anxiety and/or depressive disorders as indicated by scores just below those found in the earlier WHO study (Ustun & Sartorius 1995, Goldberg et al 2012) on the screening instruments. As such, this is intentionally an enriched sample of patients, which will result in substantial numbers of non-cases on the CIS-R. This is intentional in order to assess the extent to which cases may be missed, as well as to establish the best threshold on each scale for caseness.

### **Bodily Stress Syndrome (BSS) Study Objectives:**

1. To determine whether the presentation of BSS is similar across the various countries and primary care settings participating in the field study.
2. To compare the rates of somatic symptoms among BSS patients with the rates of somatic symptoms in patients identified as anxious, depressed or anxious in the first study.
3. To determine if an association between symptoms of anxious depression and persistent somatic symptoms equally strong in all countries.
4. To analyze the relationship between PCPs' rating of patient disability with an external measure of disability (i.e., the 12-item WHO-DAS 2.0)

Although some research studies have found that BSS encompasses distinct symptom patterns (e.g., cardiopulmonary, gastrointestinal, musculoskeletal and/or general), it is important to evaluate whether these symptom patterns occur in BSS patients across countries. Furthermore, a description of this disorder that is clear and easy for Primary Care Providers (PCPs) to apply must be tested in the field study against findings from a more elaborate, structured research interview.

Finally, presentations of anxiety or depression (“anxious depression”) have been found in patients in all self-reported chronic physical diseases consistently across countries, as well as among persons with medically unexplained physical symptoms (i.e., BSS) (VonKorff, Scott & Gureje, 2009). Thus, it is important to examine how BSS patients differ from those with depressive and anxiety symptoms.

## **STUDY DESIGN AND METHODS**

### **Study Design**

This is an observational, cross-sectional study, drawing on a sample of adult patients seeking routine health care in primary health care (PHC) settings that are designated field study sites in several countries. Because the ICD11-PhC is designed for use by physicians and other health care providers with primary care patients, the study will be conducted in generalist, primary care practices rather than in specialized care settings.

There is no attempt being made to construct a random or representative sample of global primary care settings or of primary care clinicians who may possibly be users of the primary care classification. This is an implementation or effectiveness study to examine the application of these aspects of the proposed primary care classification in a broad spectrum of specific primary care settings across countries, languages, cultures, and resource levels. This is intended to assist MSD in determining whether the proposed ICD11-PhC is suitable for use at a global level by examining whether it can be used in different and specific settings in widely divergent countries that include Brazil, China, Mexico, Pakistan and Spain.

The point of this study is to provide support for the global application of the proposed ICD-11-PhC, rather than to make generalizations to all primary care clinicians. We are concerned about the behaviour of the proposed classification, not the behaviour of clinicians. If there are problems in implementation in certain types of settings, or if the findings regarding the implementation of the proposed assessment by primary care clinicians suggest poor convergence with the results of structured interviews, this will provide MSD with an

opportunity to make changes in the proposed ICD11-PHC in order to improve its clinical utility in global primary care settings.

The five countries involved in this study are countries where MSD has been able to identify a competent local investigator with connections to specific primary care settings in that country that would be willing to implement the study. Individual primary care clinicians within the selected primary care settings will participate voluntarily, based on their own interest and ability to do so. In this sense, the participating clinicians in the study will represent a purposive ‘sample of convenience’, but this does not detract from the value of examining the implementation of the ICD11-PHC across primary care settings in different countries, languages, cultures, and with widely varying levels of resources.

The study is observational and cross-sectional, consisting of an initial evaluation by the primary care clinician followed by administration of a detailed structured interview by a trained research assistant. The study procedures include an initial screening among patients being seen for routine care in primary health care settings in multiple countries. The use of a screening procedure by participating primary care clinicians is intended to result in a pool of study participants that are likely to exhibit the conditions that are the focus of the study.

### Field study Sites

The countries chosen for this study represent different geographic regions and different country income levels and include Brazil, China, Mexico, Pakistan, and Spain. Other countries may be added.

The proposed field study sites are listed below by country:

#### Brazil

- **Local Investigator:** Dr. Sandra Fortes
- **Sponsoring Institution:** Psychiatry Department of Paulista, Medical School of the Federal University of São Paulo, Medical Sciences Schools, University of Rio de Janeiro State and the State University of Campinas
- **Site Description:** The study will be implemented in the “Family Health Strategy units” (ESF) in the National Health System (SUS) in three different cities (Rio de Janeiro, São Paulo, Campinas) in Brazil. Each ESF unit has Family Health teams (the number of teams vary depending on the area’s population) that are responsible for caring for a population of around 4000 peoples in a delimited community. The majority of the population attended by the Family Health teams are individuals seeking preventive and health promotion interventions in addition to treatment of the most prevalent health problems, such as hypertension, diabetes, and obesity.

#### China

- **Local Investigator:** Dr. Tai-Pong Lam
- **Sponsoring Institution:** Department of Family Medicine and Primary Care, University of Hong Kong, Hong Kong, People’s Republic of China
- **Site Description:** The study will be implemented through the Department of Family Medicine and Primary Care (FMPC) at the University of Hong Kong. This research-intensive department provides primary health care services, medical education and mental health services. The patient population is primarily adults who live in urban

settings, seeking health care services. The patient population represents a wide range of demographics among Chinese individuals living in Hong Kong, and only a small proportion of patients are considered vulnerable.

### **Mexico**

- **Local Investigator:** Dr. Maria Elena Medina-Mora
- **Sponsoring Institution:** National Institute of Psychiatry Ramon de la Fuente Muñiz, Department of Epidemiology & Psychosocial Research, Calzada Mexico-Xochimilco No. 101, Colonia San Lorenzo Huipulco, Delegacion Tlalpan, Mexico
- **Site Description:** The field studies will be conducted at the Health Center “Dr. Cardenas Manuel De La Vega” and the Health Centre “San Francisco Culhuacan,” both located in Mexico City, Mexico. These community health centers are situated in low-income urban areas and provide a variety of health care services, including general medicine, mental health services, nutrition and pharmacy. The population of the centers’ catchment area exceeds 150,000 people.

### **Pakistan**

- **Local Investigator:** Dr. Fareed Minhas
- **Sponsoring Institution:** Institute of Psychiatry, Rawalpindi Medical College, Benazir Bhutto Road, Rawalpindi, Pakistan
- **Site Description:** The field studies will be conducted at the rural health facilities (Basic Health Units and Rural Health Centres) in the 5 pilot districts of Pakistan (1 district from each province). Most families in the districts depend on subsistence farming, supplemented by one or more of the men serving in the armed forces or working as government employees, or as semi-skilled or unskilled labourers in the cities. The Basic Health Units and Rural Health Centres provide primary health care to the population through outpatient and indoor facilities.

### **Spain**

- **Local Investigator:** Dr. Julio Bobes
- **Sponsoring Institution:** Psychiatry Department. University of Oviedo – CIBERSAM, c/ Julian Claveria, 6, 33006 Oviedo, Spain
- **Site Description:** The field studies will take place in several Community Health Centers in Barcelona, Madrid, Sevilla and Oviedo. The patient population all individuals (Spain has universal health care) who live in urban settings, seeking health care services. The patient population represents a wide range of demographics among individuals living in urban settings in Spain.

### **Participants**

Within each country, specific participating primary care setting will do so by specific agreement between the appropriate authorities within that setting and the local (country-level) investigator. That is, there will be institutional permission on a setting-wide basis to participate in the study before any primary care clinicians are approached about participating.

Within each setting, primary care providers (PCPs) will be informed about the study in a manner jointly determined by the local (country-level) investigator and the setting, and will be offered the opportunity to participate in the study. The requirements of the study will be explained to PCPs, and participation will be entirely voluntarily. The PCPs will be free to

withdraw from the study at any time. A study Consent Form for participating PCPs, which includes a PCP confidentiality statement, is included in **Appendix A**. At least 24 PCPs in each country will be involved in the study.

Patient participants will be recruited from adults seeking routine care from a PCP who has agreed to participate in the study. Participating PCPs will screen patients for study eligibility based on one or both of the following **inclusion criteria**:

- 1) The PCP suspects that the adult patient is experiencing some degree of emotional distress based on the patient's routine clinical presentation, and administers a brief 10-item assessment of anxiety and depressive symptoms (called here the Anx5 and Dep5; see page 16). Patients who respond positively to one or more items on the Anx5 or Dep5 are eligible to participate in the study. Each PCP will recruit 20 patients who meet this symptom profile.
- 2)

**OR:**

- 2) The PCP identifies at least three persistent somatic, medically unexplained symptoms in the adult patient, **or** views the patient as highly preoccupied with persistent but unfounded worry about potential health problems. Either condition must cause distress to the patient, and must negatively affect the patient's functioning (e.g., social functioning, abilities of daily living, work performance). Each PCP will recruit at least 10 patients who meet this symptom profile.

Because we are attempting to examine implementation of ICD11-PHC as it is likely to be used by clinicians, we are not providing specific instructions regarding the methodology the clinician should use for assessing emotional distress, and in any case this is a routine and central aspect of primary care. The screening using the Anx5 and the Dep5 will not result in the identification of all patients who may be experiencing some degree of emotional distress. Different PCPs will have different levels of sensitivity and skill in regard to the assessment of emotional distress among their patients, but this replicates the conditions under which the classification will be used in 'real world' settings. The sample of patients is likely to include both 'cases' and 'non-cases' of depression and anxiety. This is important because it is precisely this boundary that is one of the key questions for the research. The study is attempting to assess the behaviour of the proposed classification and not the behaviour of the participating clinicians, so replicating real-life conditions as closely as possible is important. While an experimentally valid alternative would be to assess all consecutive patients, for example, this is not feasible because of the far greater number of patients that would need to be assessed in order to identify a sufficient number with the index conditions if no PCP-level screening were being used.

Similarly, the procedure related to unexplained symptoms and persistent worry about health will not result in the identification of all patients with medically unexplained symptoms that are distressing and affect functioning or all people with high levels of health concern, but is rather intended to approximate the conditions under which the ICD1-PHC will be used. Patients with conditions such as fibromyalgia, irritable bowel syndrome and effort syndrome ARE eligible for this part of the study, as are patients without any such label for their symptoms.

Patients who agree to participate will receive a full explanation of the study by reading the information on the Informed Consent Form (see **Appendix B: Patient Informed Consent Form**), as well as provide written consent by signing the Informed Consent Form. Patients will be excluded if they are severely physically ill or in severe pain, or have difficulty understanding what the PCP or research assistant (RA) says, or primarily speak a language in which the RA is not fluent.

As indicated, patients will be purposively rather than randomly identified. They may be new or existing patients, depending on whether the PCP feels that he or she has the necessary information to determine study eligibility. The PCP screening procedure is intended to yield a pool of patient participants likely to exhibit the conditions that are the focus of the study. Again, we are not attempting to determine the prevalence of these conditions among the total primary care population. Rather, we wish to examine the implementation of the proposed diagnostic categories, and the concordance of PCPs' judgments with the results of a detailed diagnostic interview.

**Participant vulnerability:** As primary care settings, the participating field study sites serve individuals who are seeking routine medical care for a variety of medical problems. The primary vulnerability factors for recruited patients in some of the sites will be low income and poverty. Because these factors are generally characteristic of the population served by those settings, the Local Investigators and PCPs are already knowledgeable about and responsive to the health needs of the clinic population. Participation in this study does not in any way capitalize on this vulnerability, or confer any additional risk.

## Measures

**Clinical Interview Schedule-Revised (CIS-R).** The CIS-R was developed from the Clinical Interview Schedule (CIS) (Goldberg et al., 1970) and was designed specifically to be administered using a computer-assisted version (Lewis et al., 1992) (see **Appendix C**). The CIS-R is a fully structured interview designed to be used by lay interviewers. It is a gold standard instrument for detection of common mental disorders in community settings and has been used widely in both rich and poor countries (Patel & Mann, 1997). It has recently been used in Kenya (Jenkins et al., 2012) and Tanzania (Jenkins, Mbatia, Singleton & White, 2010), and was used in the Office of Population Censuses and Surveys study of general psychological morbidity in the UK population (Office for National Statistics, 2000).

The CIS-R elicits responses to 14 areas of symptoms: *somatic symptoms, health worries, panic, compulsions, obsessions, phobias, irritability, worry, anxiety, concentration, fatigue, sleep, depression, and depressive thoughts*. Each symptom area is scored on a 4-point severity scale, except depression, which uses a 5-point scale. After inputting CIS-R data it provides diagnostic categories according to ICD-10 criteria of depressive episode (mild, moderate or severe), obsessive-compulsive disorder, panic disorder, phobic disorder, generalised anxiety disorder and mixed anxiety/depressive disorder. Furthermore, if any of the 14 symptom areas have a score of 2 or above, a new variable is created called "IMPAIR," which is a measure of the overall effects of the symptom(s) on daily activity. IMPAIR is scored as follows: 1 (no effect), 2 (made things more difficult), 3 (stopped one activity), and 4 (stopped more than one activity).

The CIS-R has been revised to incorporate ICD-11 diagnoses, to the extent that they are known in 2013, under the supervision of the PROQSY developer, Dr. Glyn Lewis.

**Clinician Encounter Form – Anxiety/Depression.** This is a screening instrument for use solely by the PCP. The form consists of three sections: (1) items from the Anx5, (2) items from Dep5, and (3) items about disability, distress level, and provisional ICD-11-PHC diagnosis (see **Appendix D**). Each of these sections is described in the subsequent paragraphs.

The Anx5 is a set of five questions developed to detect anxiety in patients in primary care settings. The items were derived from IRT analysis using a dataset of 5,500 interviews from primary care settings in 14 countries from the WHO's primary care study (Goldberg, Prisciandaro & Williams, 2012). The Anx5 was found to have high positive predictive value (PPV = 0.78) when used when a PCP suspected that a psychological disorder was present in the patient. Furthermore, the anxiety items have been incorporated into the current draft of the ICD-11-PHC by the Primary Care Consultation Group.

The Dep5 is a set of five questions developed to detect depression in patients in primary care settings. The items were derived from item response theory (IRT) analysis using a dataset of 5,500 interviews from primary care settings in 14 countries from the WHO's primary care study (Goldberg, Prisciandaro & Williams, 2012). The Dep5 was found to have high positive predictive value (PPV = 0.90) when used when a PCP suspected that a psychological disorder was present in the patient. Furthermore, the depressive items have been incorporated into the current ICD-11-PHC draft by the Primary Care Consultation Group.

To administer the Anx5 and Dep5 parts of the Clinician Encounter Form – Anxiety/Depression, the PCP asks the patient (who the PCP suspects that a psychological disorder may be present) the ten questions for depression and anxiety :

Depression Questions (Dep5):

- D1 Have you been feeling depressed every day for the past 2 weeks?
- D2 During the past 2 weeks, have you experienced less interest or pleasure from activities?
- D3 During the past 2 weeks, have you had difficulty concentrating?
- D4 During the past 2 weeks, have you had feelings of worthlessness?
- D5 During the past 2 weeks, have you felt you wanted to die, or had thoughts of death?

Anxiety Questions (Anx5):

- A1 Have you felt nervous or anxious nearly every day in the past 2 weeks?
- A2 During the past 2 weeks, have you found that you are not able to control worrying?
- A3 During the past 2 weeks, have you been having trouble relaxing?
- A4 During the past 2 weeks, have you felt so restless it was hard to keep still?
- A5 During the past 2 weeks, have you felt afraid that something awful might happen?

Any patient with one or more positive replies to the ten questions will be asked whether they would agree to take part in a study the clinician is doing in the clinic, and invites the patient

to talk to the RA for further information. Clinicians are of course free to ask additional questions they feel that they need to ask in order to make their diagnostic assessments.

If a patient indicates to the PCP that he or she has suicidal thoughts in response to question D5, it is the PCP's responsibility to make an assessment of the seriousness of these thoughts, asking whether the patient has made a specific plan; if so, what has prevented him or her from carrying it out, and whether the patient lives alone, and to take appropriate protective measures. A local protocol for the provision of additional support and services for suicidal patients will be developed by the Local Investigator (LI) for each country. This will be included in the training session for PCPs (see Appendix G, page 72). It should be noted that patients describing suicidal thoughts is not uncommon in primary care settings, and assisting patients with appropriate preventive responses is a part of the normal scope of practice of PCPs.

The Clinician Encounter Form – Anxiety/Depression also provides the PCP's assessment of (a) the patient's disability using a 4-point scale from 0 (no disability whatever) to 3 (impaired in all activities), (b) the patient's distress level using a 5-point scale from 0 (completely normal) to 4 (severely disordered or distressed), and (c) the patient's provisional ICD-11-PHC diagnosis by endorsing one or more of a brief list of relevant diagnostic categories that are included on the form.

The data from the Clinician Encounter Form – Anxiety/Depression will be completed by the PCP and inputted into the CIS-R system by the RA.

**Clinician Encounter Form – Bodily Stress Syndrome / Health Anxiety.** This instrument specifies which somatic symptoms the patient presents with during the PCP visit, for which no known physical basis is suspected (see Appendix E). It is based on the proposed Bodily Stress Syndrome (BSS) classification (Fink, Rosendal & Olesen, 2005; Fink & Schroder, 2010; Fink et al., 2007) and includes cardiopulmonary arousal symptoms, gastrointestinal arousal symptoms, musculoskeletal tension, and general unspecific symptoms (e.g., concentration problems, memory impairment, fatigue, headache, dizziness). The PI and LI may add any culture-specific somatic symptoms (e.g., semen loss, insects crawling under the skin) to the form's list of somatic symptoms.

This form also provides the PCP's assessment of (a) the patient's disability using a 4-point scale from 0 (no disability whatever) to 3 (impaired in all activities), (b) the patient's distress level using a 5-point scale from 0 (completely normal) to 4 (severely disordered or distressed), (c) the patient's provisional ICD-11-PHC diagnosis by endorsing one or more of a brief list of relevant diagnostic categories that are included on the form and whether the patient is highly preoccupied with persistent worry about health problems.

The data from the Clinician Encounter Form – Bodily Stress Syndrome / Health Anxiety will be completed by the PCP and entered into the CIS-R system by the RA.

**12-Item World Health Organization Disability Assessment Schedule 2.0 (12-item WHO-DAS 2.0).** The 12-item WHO-DAS 2.0 is a 12-item, self-administered scale (see Appendix F). Items are grouped by pairs in 6 domains: 1- Understanding and communicating with the world, 2- Moving and getting around, 3-Self care, 4-Getting along with people, 5-Daily life activities (domestic responsibilities, leisure, and work), and 6- Participation in society. The scale contains another 5 items: one about overall health and four about the number of days with activity limitations in daily life. Scoring is standardized on a

0 to 100 metric, where 0 means no disability and 100 the highest disability. This brief version is useful in health settings where time constraints do not allow for application of the longer 36-item version, and the 12-item version explains 81% of the variance of the 36-item version (Üstün, Kostanjsek, Chatterji, & Rehm, 2010).

The items from the 12-Item WHO-DAS 2.0 will be added to the CIS-R system; thus, the RA will ask patients each of the 12 items and input their answers into the CIS=R.

## **Procedures**

This is an observational, cross-sectional study, drawing on a sample of adult patients seeking routine health care in primary health care settings that are designated field study sites in several countries. Because the ICD11-PHC is designed for use by physicians and other health care providers with primary care patients, the study will be conducted in generalist, primary care practices rather than in specialized care settings. There is no attempt being made to construct a random or representative sample of global primary care settings or of primary care clinicians who may possibly be users of the primary care classification. This is an implementation or effectiveness study to examine the application of these aspects of the proposed primary care classification in a broad spectrum of specific primary care settings across countries, languages, cultures, and resource levels.

The five countries involved in this study are countries where MSD has been able to identify a competent local investigator with connections to specific primary care settings in that country that would be willing to implement the study. Individual primary care clinicians within the selected primary care settings will participate voluntarily, based on their own interest and ability to do so. In this sense, the participating clinicians in the study will represent a purposive ‘sample of convenience’, but this does not detract from the value of examining the implementation of the ICD11-PHC across primary care settings in different countries, languages, cultures, and with widely varying levels of resources.

The study specifically focuses on “common mental disorders” seen in PHC settings (e.g., depression, anxiety and somatic symptoms). The study is observational and cross-sectional, consisting of an initial evaluation by the primary care clinician followed by administration of a detailed structured interview by a trained research assistant. The study procedures include an initial screening among patients being seen for routine care in primary health care settings in multiple countries. The use of a screening procedure by participating primary care clinicians is intended to result in a pool of study participants that are likely to exhibit the conditions that are the focus of the study.

The study procedure involves the following steps:

1. Recruit Primary Care Providers

Local Investigators (LIs) in each country will recruit at least 24 Primary Care Providers (PCPs) from primary care settings for which an agreement has been made between the setting the LI. The PCPs who are recruited will be informed about the study in a manner jointly determined by the local (country-level) investigator and the setting, and will be offered the opportunity to participate in the study. The requirements of the study will be explained to PCPs, and participation will be entirely voluntarily. The PCPs will be free to

withdraw from the study at any time. A study Consent Form for participating PCPs is included in **Appendix A**. A least 24 PCPs in each country will be involved in the study.

## 2. Primary Care Provider and Research Assistant Training:

LIs will organize a mandatory training about the study to be completed by (a) PCPs (**see Appendix G: PCP Training**) and (b) Research Assistants (RAs), who are already working in the PCPs' settings (**see Appendix H: RA Training**). The RAs are responsible for conducting the study sessions. It should be noted that the CIS-R computerized system to be used in this study was designed to be administered by lay persons and does not require expert knowledge on the part of interviewers. However, due the possibility of encountering patients in psychological distress or who report suicidal thoughts, RAs will be university graduates in health-related fields. The RA training will include information about the informed consent procedure, the administration of the study measures, and procedures for dealing with suicidal or emotionally distressed patients. Furthermore, all RAs will sign a "Research Assistant Confidentiality Agreement" (**see Appendix I: RA Confidentiality Agreement**).

## 3. Recruit Patients

After completing the mandatory training, PCPs will begin recruiting (a) 20 patients experiencing some degree of emotional distress based on the patients routine clinical presentation, and who have at least one symptom of either anxiety or depression (as indicated on the Clinician Encounter Form – Anxiety/Depression); and (b) 10 patients who have at least three somatic symptoms **or** have persistent worry about potential health problems and have associated distress and disability (as indicated on the Clinician Encounter Form – Bodily Stress Syndrome).

Because we are attempting to examine implementation of ICD-11-PHC as it is likely to be used by clinicians, we are not providing specific instructions regarding the methodology the clinician should use for assessing emotional distress, and in any case this is a routine and central aspect of primary care. Each PCP will recruit 30 patients, which is likely to include both 'cases' and 'non-cases' of depression and anxiety and bodily distress disorder/health anxiety. This is important because it is precisely this boundary that is one of the key questions for the research.

This procedure will not result in the identification of all patients who may be experiencing some degree of emotional distress. Different PCPs will have different levels of sensitivity and skill in regard to the assessment of emotional distress among their patients, but this replicates the conditions under which the classification will be used in 'real world' settings. While an experimentally valid alternative would be to assess all consecutive patients, this is not feasible because of the far greater number of patients that would need to be assessed in order to identify a sufficient number with the index conditions if no PCP-level screening were being used. The patients will be purposively rather than randomly identified, so that the study will be conducted only on patients that cause a question to arise in the PCP's mind that the patient is psychologically distressed. They may be new or existing patients.

The PCP will carry out the patient visit as clinically indicated for an eligible patient. At the end of the clinic visit, the PCP will describe the study to the eligible patient, ask if the patient would like to participate, and inform the patient that his or her assessment and treatment will not be affected if he or she does not agree to participate. If the patient agrees to participate,

the PCP will (a) complete either the Clinician Encounter Form – Anxiety/Depression or the Clinician Encounter Form – Bodily Stress Syndrome depending on the patient’s presentation (b) refer the patient to the RA (who will conduct the study session) along with the completed Clinician Encounter Form.

The Encounter Form items are similar to questions routinely asked in primary care settings; thus, they are unlikely to have any adverse effects on patients. Please note that a patient consent form is *not* necessary for PCPs using either the Clinician Encounter Form – Anxiety/Depression or the Clinician Encounter Form – Bodily Stress Syndrome. The anxiety and depression questions are questions that PCPs routinely ask during patient visits, particularly if the PCP suspects that the patient has a psychological disorder. The Bodily Stress Syndrome Encounter Form contains items that are routinely asked to patients presenting with somatic symptoms; thus, no patient consent is required for this form as well. If patients choose not to participate in the study, the PCPs will store the encounter forms in their patient’s medical file.

#### 4. Study Session

After the PCP refers the patient to the RA and gives the RA the completed Clinician Encounter Form, the RA will conduct the study session with the patient as soon as possible. This will typically be done if possible on the same day as the PCP visit. However, in the event that the patient is unable to wait or prefers to arrange a separate time, this may be arranged by the RA and the patient, provided that it is within 7 days of the time of the initial contact. The patient may return to the clinic, if it is convenient, or the interview may be conducted over the telephone. In the event that a follow-up appointment is arranged by telephone or in person, the RA should still review and complete the Informed Consent Form with the patient on the day of the initial visit. Local Investigators will be asked to establish appropriate local policies for reimbursement for transportation expenses in the event of a second visit, which will be specified in the local protocols.

The session will take place in a private area of the clinic, or the RA will phone the patient at home. At the beginning of the study session, the RA will provide the patient with a full explanation of the study by reading the information on the Informed Consent Form (**see Appendix B: Informed Consent Form**). If the patient agrees to participate, the RA will obtain the patient’s written consent. If the study session occurs via telephone, the study explanation and signed consent form will be obtained on the same day as the PCP consultation, at the time the appointment is made. Illiterate patients can make a thumbprint or a distinctive mark.

After the consent procedure, the RA will administer the CIS-R and the WHO-DAS 2.0 to the patient using the PROQSY computerized system. The CIS-R includes questions about suicidal thoughts and self-harm (see items Appendix C).

If the patient endorses any of these items, at the end of the interview the RA will respond to the patient in a way that has been customized by the Local Investigator to be appropriate for that country and setting. If the Local Investigator is not a psychiatrist, this language will be developed in consultation with mental health experts in that country. Possible wording might be: ‘Earlier in the interview you mentioned suicidal ideas. I am rather concerned about this. As you may remember, when you signed the Consent Form I told you that if you described any thoughts or feelings about hurting yourself, I would inform your doctor and the local

research investigator so that they can determine whether you need additional clinical services. I will therefore do this right away. If you have already talked to your doctor about this, he or she may already have talked with you about a plan, but I just need to make sure.’ The specific response plan and provision of follow-up care in this situation will vary according to the setting and the country. This will therefore be further specified in each local protocol.

#### 5. Post Study Session

After the study session is complete, the RA will input the data from the Encounter Form(s) into the CIS-R computer system, and return the form to the PCP. All patient data will be coded using pre-assigned sequential code numbers. Thus, the data will be anonymous with no patient identifying information on any collected patient data (except the Informed Consent Form). The RA will be blind to the CIS-R results, so there is no danger of the RA attempting to discuss the results with the patient (which is important since the RA is not trained to do so). However, if the patient endorses individual assessment items that assess suicidal thoughts or self-harm, RAs will be instructed to notify the PCP and LI immediately, who will then be responsible for assuring appropriate follow-up care for the patient. The Encounter Forms will be retained in the patient’s medical at the PCP clinic so that the PCP, the PCP can follow-up with the patient on any depression, anxious or somatic symptoms indicated on those forms.

#### 6. Follow-Up Session with Participating Clinicians

At the end of the study in each centre, the LI will arrange a meeting with as many of the PCPs as are able to attend. Having thanked the PCPs for their help, the LI will ask them their views about the revised classification, and an RA will record their comments. For each of the proposed diagnostic categories in ICD-11-PHC, the PCPs will be asked to endorse a single response on the following 5-point scale:

0	1	2	3	4
This disorder should be removed from ICD11-PHC	This disorder is not important in PHC	I am not sure about this disorder	This sounds important but I never see it myself	This disorder is important and must be in the ICD11-PHC

This information will be extremely valuable when final recommendations are made to the Advisory Committee about which disorders should be included in the final ICD11-PHC system.

### **SAFETY CONSIDERATIONS**

The Encounter Form items are similar to questions routinely asked in primary care settings; thus, they are unlikely to have any adverse effects on patients.

The CIS-R includes questions about suicidal thoughts and self-harm (see items #95 - # 98 in Appendix C). As discussed in preceding section, if the patient endorses any of these items, the RA will inform the patient that the PCP and the LI will be informed so that an appropriate decision can be made about follow-up care.

## **FOLLOW-UP**

If a patient endorses instruments items on suicidal thoughts or severe emotional distress, PCPs and LIs will be immediately notified to assure appropriate follow-up care for the patient. The information from the Encounter Forms will be retained in the patient's medical file at their PCP clinic; thus, the PCP can follow-up with the patient on any depression, anxious or somatic symptoms indicated on those forms.

Follow-up clinical care for patients that respond positively to these items will be according to the standard procedures and resources available in the specific local setting. It is important to note that the study has in no way created or contributed to the patient's experience of suicidal thoughts or impulses, but has simply identified that these are occurring, therefore creating an opportunity to provide additional care according to standard practice in that setting.

## **DATA MANAGEMENT AND STATISTICAL ANALYSIS**

### **Date Management**

Data for this study will consist of information collected from the (a) Encounter Forms, and (b) the CIS-R and (c) WHO-DAS 2.0. All data will be collected electronically using the CIS-R computerized software on laptops, which will be provided for each RA. The LI is responsible or ensuring that the RA correctly enters and combines all patient data into the CIS-R.

For each patient participant, the CIS-R generates two separate files: a Word file and a Text file with all the variables. The files are labeled with pre-assigned sequential code numbers; thus, the files are anonymous with no patient identifying information. The files consist only of a series of numbered variables. The CIS-R files will *not* provide the ICD-11 diagnosis until it is analysed by staff at the Institute of Psychiatry; thus, RAs and PCPs will *not* have access to patient diagnoses.

The CIS-R data collected on laptops will be backed up on USB flash drives. The USB drives will be password protected, and only the PI, LI, PCP and RA will know the password. Furthermore, laptops will remain at the PCP site and locked in a file cabinet.

CIS-R data collected from the various sites will be transmitted to staff at the Institute of Psychiatry. The data will be transmitted via email in batches at least once per month in password-protected zip files. The data will then be stored at the server in the Institute of Psychiatry. Although the electronic data is anonymous, thus minimizing data security issues, we are also employing the use of password protection on laptops and backup pin drives, as well as on the batch document zip files that will be emailed to the Institute of Psychiatry. Once data is transmitted and the Institute of Psychiatry acknowledges safe receipt to the PI, it is the LI's responsibility to assure that all data located on the laptop and USB drives are erased.

The data will be retained at the Institute of Psychiatry indefinitely for potential future data re-analysis. The Institute of Psychiatry has state-of-the art storage and server options that ensure research data is safely stored and accessible. The data will be stored on a folder on a secure server to which only project staff and the HSPR IT manager will have access.

## Statistical Analysis

**Recruitment and Representativeness.** A summary will be constructed to include the number of eligible patients, the number of patients agreeing to participate, and the number of interviews the RA is able to complete. PCPs will be asked to record the reason that patient who meet the study inclusion criteria but who do not agree to meet with the RA give for refusing the study as well as basic demographic and symptom characteristics (see Appendix J, Patient Refusal Form.) The RA will complete the same form for patients who decide not to participate in the study after it is explain by the RA.

**Sample Characteristics.** A number of site level and individual level data will be collected. These will be shown graphically and tabulated to identify outliers. Proportions and percentages will be given where appropriate. Site level characteristics will be stated in an appropriate manner. Individual level characteristics will be summarized by site in the appropriate manner. Proportions will be given for categorical data whereas continuous data will be expressed as a mean with standard deviation (normally distributed data) or as a median with inter-quartile range (skewed data). No significance testing will be done.

**Loss to Follow Up and Other Missing Data.** The numbers, proportions, and characteristics of patients refusing the study will be summarized by site, as will the characteristics of those who agreed to participate in an interview with the RA by telephone or at a later appointment, but failed to do so. Missing data for other reported measures will be summarized accordingly along with the descriptions of those measure. Missing individual level data will be reported per site as percentages per variable. Mean imputation (the mean score of a variable for the specific institution will be used to replace missing values) will be used in the case of missing individual data for normally distributed variables otherwise median imputation or imputation based on prevalence will be used.

Investigations will be carried out to investigate whether or not missing data appear to be random. Regression of a binary indicator variable of missingness on demographic and site level predictors whilst accounting for clustering by clinician will be performed. Any indication of predictors of missingness (classified by a statistical significance level of  $<0.2$ ) will be included in analysis models as part of a sensitivity analysis.

**Data Analysis Plan.** All analyses will be performed using STATA v11 (StataCorp, 2011). All outcome measures will first be visually inspected as described above to check for normality and for outliers. Where normality is not achieved, an appropriate transformation will be considered and data analysed parametrically as the preferred alternative. Failing this, an appropriate alternative to parametric analysis will be used.

The main aim of the analyses will be to identify appropriate cut-off scores on the new case-detection questionnaire for predicting CIS-R (ICD-11) diagnoses of depression and anxiety disorders. Area Under the Curve (AUC) analyses will be performed, and Receiver Operating Characteristic (ROC) Curves constructed.

Performance of the new case-detection questionnaire will be assessed in terms of the sensitivity, specificity and predictive values. Logistic regression will be used to explore the use of alternative cut-off scores on the new case-detection questionnaire using the total score on the new case detection questionnaire as the predictor and the CIS-R diagnosis dependent variable. Clustering by clinician will be specifically addressed by including clinician as a

random effect in the mixed logistic regression model. Differences between countries will be assessed by including Country as a fixed effect in regression models.

Sensitivity-specificity plots will be constructed to further assess the cut-off scores. Effects of differing population prevalence of common mental disorders on the positive predictive values (PPV) of the new case detection questionnaire will be explored by constructing scatter plots of the PPV against prevalence of anxiety and depressive disorders found in primary care.

**Power Calculation.** Each participating country site will need to recruit 24 participating PCPs to the study, who need not all be working in the same clinic. The study will attempt to recruit (a) 20 patients for each of the 24 PCPs for a total of 480 patients for the anxious/depression study, and (b) 10 patients for each of the 24 PCPs for a total of 240 patients for the BSS study. This will total 720 patients with a wide range of scores. It must be emphasized that each phase of the study will collect patients who are eligible for the other part of the study – since cases of anxiety/depression often have multiple somatic symptoms, and *vice versa*.

In order to increase generalisability, patients will be assessed by PCPs in five countries. It is assumed that patients in each practice setting within each country are likely to differ. To make adjustments for this effect, the sample size must be adjusted for clustering. Clustering inflates the sample size by an amount known as the design effect. This is calculated from the number of eligible patients per PCP (patient eligibility depends on whether the PCP thinks the patient to be psychologically distressed, and whether the patient has answered ‘yes’ to at least two of the ten questions and by the ICC (the proportion of true total variation in the outcome that can be attributed to differences between the clusters). A recent review of a large number of primary care variables<sup>24</sup> found the inter-quartile range of ICCs to be between 0 to 0.032. It seems reasonable to use a value of 0.05 as a conservative estimate. Estimating the sensitivity of the 10 item symptom scale to differentiate between categories to be 0.85, an unadjusted sample size (unadjusted to the effects of clustered data) of 250 participants would be needed in order to be 95% certain that the true sensitivity was higher than 0.8 (calculated using Stata 11.2).

A total of 30 patients per PCP was chosen for practicality considering the prevalence of mental illnesses and the time limitations in general practice. After adjusting for the design effect due to clustering (a), this resulted in a total sample size of 613 participants required to maintain the power as previously mentioned.

$$(a) \text{ Design effect} = 1 + (k - 1) \text{ ICC}$$

Where k is the average number of patients per cluster

With 30 patients per PCP, this implies the need for 20.4 PCPs in order to maintain the required power. The number of PCPs was rounded up to 24 to account for *a possible 15% dropout of PCPs from the study*. This implies a total of 30 patients x 24 PCPs = 720 patients. This will be a practical and conservative number that will retain the required power assuming that the estimated sensitivity of the scale and value for the ICC are reasonable.

## QUALITY ASSURANCE

Data collection will be monitored throughout the study by the Local Investigators (LIs) and coordinated by the Principal Investigator (PI). A detailed process for data coding, collection and entry has been developed to ensure accurate and standardized records. The PI and LIs will be responsible for training the research assistants (RAs) and data management.

## EXPECTED OUTCOMES OF THE STUDY

The study is necessary in order to allow WHO to make modifications to the classification system proposed for ICD-11-PHC. It will provide data on the performance of the scales that, if satisfactory, is likely to lead to wide adoption of the scales. There are two important potential consequences of the Anxious Depression field study – a reduction in *unnecessary prescribing of antidepressants* in primary care, and an increase in the rate at which those with *moderate and severe depressive illnesses are offered treatment*. In the case of Bodily Stress Syndrome field study, the concept of autonomic arousal is likely to lead to a more *productive therapeutic dialogue* between PCPs and their patients.

## DISSEMINATION OF RESULTS AND PUBLICATION POLICY

Results of the field study will be extensively discussed by the PCCG of WHO before being referred to the International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders and the Department of Mental Health and Substance Abuse. They will also be published in the medical literature, over the names of the Principal Investigators in each country, Mr. Paul Williams, and lead members of the WHO Secretariat. Dr. Goldberg will take the lead in publication.

## DURATION OF THE PROJECT

The entire project is intended to occur within a period of 12 months, as presented in the Gantt diagram provided below:

Tasks	Month											
	1	2	3	4	5	6	7	8	9	10	11	12
Ethics	X	X										
Recruit PCPs	X	X										
Appoint RAs	X	X										
Train PCPs		X	X									
Train RAs		X	X									
Produce paper work		X	X									
Recruit 200 patients			X	X	X							
Recruit 200 patients				X	X	X						
Recruit 200 patients					X	X	X					
Recruit 120 patients						X	X	X				
Data collection			X	X	X	X	X	X				
Data Analysis						X	X	X	X			
Report writing								X	X	X		
Paper writing										X	X	X

## PROBLEMS ANTICIPATED

The following problems might arise in the process of study implementation:

- Although we anticipate the availability of the necessary numbers of PCPS to participate, we are unclear about the number of PCPs who will participate in each country until the study begins. However, previous studies have been successful in recruiting numerous PCPS for similar types of research.
- Issues of privacy and confidentiality may be raised by the participants, and if the appropriate safeguards are not in place and used effectively, refusals to participate may result. Safeguards will be in place at the organizational level (i.e., RA confidentiality agreements, patient informed consents, etc.) and the technological level (e.g., anonymous data, password protected data transit and storage, locks, secure server storage, etc.) to ensure the highest levels of data protection.
- Issues of stigma are always of concern; however, by ensuring privacy and confidentiality of all participants, we will reduce the likelihood of stigmatization to occur.
- Concerns about potentially suicidal or otherwise emotionally distressed patients exist; however, a specific protocol is in place to deal with any patient whose behaviours or responses suggest that the patient poses a risk to self (e.g., suicidality, self-harm) or to others, or that the patient is in severe emotional distress. If an RA is confronted with this situation, he or she will immediately contact the patient's PCP as well as the LI. The LI will consult with the PCP in order to make a determination about the appropriate referral or treatment for these patients.

## PROJECT MANAGEMENT

The project implementation and management will involve collaboration of a team of experts from different institutions worldwide. Overall project coordination is with the WHO Evidence, Research and Action on Mental and Brain Disorders (MER) unit in the WHO Department of Mental Health and Substance Abuse.

Technical support for the project implementation will be provided jointly by the Institute of Psychiatry, London, United Kingdom, and the WHO Department of Mental Health and Substance Abuse.

The members of the project management team include the Principal Investigator (PI), Co-Investigator, Local Investigators (LI), and statistician. The following table lists the team members and provides a description of their role and responsibilities:

Team Members	Role and Responsibilities
<b>Dr. David Goldberg</b> Institute of Psychiatry, King's College 16 De Crespigny Park, London SE5 8AF United Kingdom 7 Woodhall Drive, London SE21 7HJ	<b>Principal Investigator:</b> Oversees all aspects of the study in all study sites, including study design, evaluation and quality control of the study methodology, recruitment of participants, data collection and management, statistical data analysis,

<p>United Kingdom Email: davidpgoldberg@yahoo.com</p>	<p>interpretation, writing and dissemination of results.</p>
<p><b>Dr. Geoffrey Reed</b> Department of Mental Health and Substance Abuse World Health Organization 20, avenue Appia CH-1211 Geneva Switzerland Email: reedg@who.int</p>	<p><b>Co-Investigator:</b> Collaborates with the Principal Investigator in overseeing the study, including study design, evaluation and quality control of the study methodology, recruitment of participants, data collection and management, statistical data analysis, interpretation, writing and dissemination of results.</p>
<p><b>Dr. Julio Bobes</b> Department of Psychiatry CIBERSAM University of Oviedo Julian Claveria 6 33006 Oviedo Spain Email: bobes@uniovi.es</p>	<p><b>Local Investigator:</b> Directs and coordinates the implementation of the study at their specific study site, including quality control of the study methodology, recruitment of primary care providers, and data collection and management.</p>
<p><b>Dr. Sandra Fortes</b> Associate Professor of Mental Health and Medical Psychology Department of Mental Health and Psychological Medicine Pedro Ernesto University Hospital, State University of Rio de Janeiro Rio de Janeiro Brazil Email: sandrafortes@gmail.com</p>	<p><b>Local Investigator:</b> Directs and coordinates the implementation of the study at their specific study site, including quality control of the study methodology, recruitment of primary care providers, and data collection and management.</p>
<p><b>Dr. Tai-Pong Lam</b> Assistant Dean, Faculty of Medicine Professor, Department of Family Medicine and Primary Care University of Hong Kong Hong Kong People's Republic of China Email: tplam@hku.hk</p>	<p><b>Local Investigator:</b> Directs and coordinates the implementation of the study at their specific study site, including quality control of the study methodology, recruitment of primary care providers, and data collection and management.</p>
<p><b>Dr. Maria Elena Medina-Mora</b> Chief Director Instituto Nacional de Psiquiatria Ramon de la Fuente Muñiz Department of Epidemiology &amp; Psychosocial Research Calzada Mexico-Xochimilco No. 101 Colonia San Lorenzo Huipulco Delegacion Tlalpan Mexico D.F., 14370 Mexico Email: medinam@imp.edu.mx</p>	<p><b>Local Investigator:</b> Directs and coordinates the implementation of the study at their specific study site, including quality control of the study methodology, recruitment of primary care providers, and data collection and management.</p>
<p><b>Dr. Farid Aslam Minhas</b> Professor &amp; Head, Institute of Psychiatry Rawalpindi Medical College University of Health Sciences Consultant Psychiatrist, Rawalpindi General</p>	<p><b>Local Investigator:</b> Directs and coordinates the implementation of the study at their specific study site, including quality control of the study methodology, recruitment of primary care providers, and data collection and management.</p>

Hospital Rawalpindi Pakistan Email: minhas.fa@gmail.com	
<b>Mr. Paul Williams, BSc MPH</b> Statistician Institute of Psychiatry, Kings College Box P029, De Crespigny Park London, SE5 8AF United Kingdom	<b>Statistician:</b> Analyzes the data collected during the project.

## **ETHICS**

In each participating country, ethical approval will be sought from the local ethics committee. All materials for country sites and documentation of local Ethics approval will be presented to the WHO ERC for approval prior to beginning the study in that country.

## **INFORMED CONSENT FORMS**

The informed consent form (ICF) for patients is attached to this protocol in **Appendix B**. Please note that a patient consent form is not necessary during patients' visits if the PCP uses either the (a) Clinician Encounter Form – Anxiety/Depression or (b) the Clinician Encounter Form – Bodily Stress Syndrome. The Anxiety/Depression form contains questions about anxiety and depression that PCPs routinely ask during patient visits, particularly if the PCP suspects that the patient has a psychological disorder. The Bodily Stress Syndrome Encounter Form contains items that are routinely asked to patients presenting with somatic symptoms. If patients choose not to participate in the study, the PCPs will either destroy the Clinician Encounter Forms or put them in the patient's medical file.

## **PART 2**

### **COLLABORATION WITH OTHER SCIENTISTS OR RESEARCH INSTITUTIONS**

The collaboration with the Institute of Psychiatry, King's College, London has been described above.

**LINKS TO OTHER PROJECTS:** None

### **CURRICULUM VITAE OF INVESTIGATORS**

Please find attached a one-page CV of the principal investigator and of the Local Investigators (see Appendix K).

**OTHER RESEARCH ACTIVITIES OF THE PRINCIPAL INVESTIGATOR:** None

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## **LIST OF APPENDICES**

- Appendix A: Primary Care Provider (PCP) Study Information, Consent Form & Confidentiality Statement
- Appendix B: Patient Informed Consent Form
- Appendix C: PROQSY Clinical Interview Schedule-Revised (CIS-R)
- Appendix D: Clinician Encounter Form – Anxiety/Depression
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- Appendix G: Primary Care Provider (PCP) Training
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## APPENDIX A

### *Field Study for the ICD-11 for Primary Care*

#### **Primary Care Provider Study Information, Consent Form & Confidentiality Statement**

This Informed Consent Form is for primary care providers (PCPs) who we have invited to participate in a research project entitled, "Field Study for the ICD-11 for Primary Care."

**Name of Principal Investigator:** Dr. David Goldberg, Institute of Psychiatry, King's College, 16 De Crespigny Park, London SE5 8AF, United Kingdom, 7 Woodhall Drive, London SE21 7HJ, United Kingdom. Email: davidpgoldberg@yahoo.com

**Local Investigator:** \_\_\_\_\_

This Informed Consent Form has two parts:

1. Information Sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

#### **PART I: Information Sheet**

*N.B.: This is a template to be adapted for each county site, including the provision of the locally relevant information, and translated into the local language(s)*

##### **Introduction:**

Your principal and local investigators listed above are conducting a research project to assist the World Health Organization (WHO) revise its classification of common mental disorders that occur in primary care settings. I am going to give you information and invite you to be part of this research.

##### **Purpose of the research:**

The WHO is currently updating its classification of health disorders: the International Classification of Diseases and Related Health Problems, 11th Revision (ICD-11). Because most people receive health care from primary care practices, it is important to test the revised classification in these settings. The results of this study will help the WHO find out if the revised classification is useful in primary health care settings and applicable in different countries.

##### **Type of research intervention:**

You will be asked to (a) identify new and/or existing adult patients, during routine medical appointments, who meet the criteria to participate in the study, (b) explain the study to prospective participants, (c) complete a brief checklist about the patient, (d) refer the patient to a research assistant who will conduct the study, and (e) be available for any follow-up care or referral if required by the patient.

##### **Participant selection:**

The local investigator for this study suggested that you might be able to help us because you are a primary care provider who works with adult patients seeking primary care.

**Voluntary participation:**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. There are no consequences to any decision to participate or not to participate. Do you have any questions about participating?

**Procedures and protocol:**

If you agree to take part in this research, you will be asked to do the following:

1. Participate in a mandatory one-day training about the study.
2. Recruit new and/or existing adult patients based on certain criteria during a routine medical appointment to participate in the study.
3. Complete a brief symptom checklist on the patient and refer the patient (and give the checklist) to the research assistant (RA) who will be conducting the study session.
4. Be available to answer questions that the patient may have before, during and after the study session.
5. Be available to provide services to patients who endorse items on any of the study assessment instruments that assess thoughts of suicide and/or severe emotional distress, consult with the local investigator about such patients, and make patient referral to appropriate follow-up care.

**Risks:**

There are no risks if you participate in the study.

**Benefits:**

There are also no direct benefits to you from taking part, except that you will have helped to improve the ICD-11 classification system for mental and behavioural disorders and obtained assessment data on your patient's mental health that may aid patient services.

**Confidentiality:**

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name.

**Sharing the results:**

Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research.

**Right to refuse or withdraw:**

You do not have to take part in the research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will be respected.

**Who to contact:**

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions? If you wish to ask questions later, you may contact me or the principal investigator listed on the first page.

**PART II: Certificate of Consent**

**Name of Study:** Field Study for the ICD-11 for Primary Care

**Study Sponsor:** World Health Organization (WHO) Department of Mental Health and Substance Abuse (MSD)

**Principal Investigator:** Dr. David Goldberg, Institute of Psychiatry, London, United Kingdom

**Local Investigator:** \_\_\_\_\_

**Consent to Participate:**

I, \_\_\_\_\_, have read the Information Sheet for the study named, "Field Study for the ICD-11 for Primary Care." My role as a primary care provider is to help investigators collect information that will be used to improve the utility of the ICD-11 diagnostic concepts related to anxiety, depression and somatic symptoms. My questions, if any, have been answered to my satisfaction. By signing this form I do not waive any of my rights.

**Confidentiality Statement:**

I also agree to keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format (e.g. electronic, paper) with anyone other than the Principal Investigator, Local Investigator, and the patient.

I have been offered a signed copy of this form.

**Primary Care Provider Volunteer:**

**Print Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

## Appendix B

### *Field Study for the ICD-11 for Primary Care*

#### Patient Informed Consent Form

[YOUR INSTITUTIONAL LETTERHEAD]

This Informed Consent Form is for adult patients who we have invited to participate in a research project entitled, "*Field Study for the ICD-11 for Primary Care.*"

**Name of Principal Investigator:**

**Dr. David Goldberg**, Institute of Psychiatry, King's College, 16 De Crespigny Park, London SE5 8AF, United Kingdom, 7 Woodhall Drive, London SE21 7HJ, United Kingdom. Email: [davidpgoldberg@yahoo.com](mailto:davidpgoldberg@yahoo.com)

**Local Investigators:** \_\_\_\_\_

**This Informed Consent Form has two parts:**

1. Information Sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)

**You will be given a copy of the full Informed Consent Form.**

#### **PART I: Information Sheet**

*N.B.: This is a template to be adapted for each county site, including the provision of the locally relevant information, and translated into the local language(s)*

**Introduction:**

Your doctor and the investigators listed above are conducting a research project to assist the World Health Organization (WHO) change its classification of common disorders that occur in medical clinics in the community. I am going to give you information and invite you to be part of this research. Before you decide whether to participate, you can talk to anyone you feel comfortable with about the research. As we go through the information about the study, please ask me to stop and explain any words that you do not understand. If you have questions later, you can ask them of me or your doctor.

**Purpose of the research:**

The WHO is currently updating its classification of health disorders: the International Classification of Diseases and Related Health Disorders, 11th Revision (ICD-11). Because most people receive health care from medical clinics in the community, it is important to test the revised classification in these settings. For this study, we are also interested in how a person's physical health is also influenced by things like stress and

how they are feeling emotionally and psychologically. The study your (doctor) is participating in will help the WHO find out if the revised classification is useful in medical clinics in the community and applicable in different countries.

**Type of research intervention:**

If you agree to take part in this research, you will be asked to answer some detailed questions about your recent health by a research assistant (myself) helping in this study. Questions you will be asked include questions about your general health and functioning, how you have been feeling recently, symptoms you have been experiencing, and things like sleep, appetite, and weight. You will also be asked questions about your mood and how you have been feeling emotionally.

These questions will take up to an hour. You do not have to take part if you'd prefer not to do so. If possible, I would like to interview you today, as soon as I have finished telling you about the study. If that is not possible, we can make an appointment for another time as soon as it is convenient for you, or we can do the interview on the telephone. It would just have to be within the next 7 days.

**Participant selection:**

Your doctor has suggested that you might be able to help us because some of the problems you have mentioned to him/her are directly relevant to the study that we are doing.

**Voluntary participation:**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you decide not to participate, this will not affect the services that you receive or are entitled to receive, or your relationship with your doctor. The services you receive at this clinic will continue as before and nothing will change. Do you have any questions about participating?

**Procedures and protocol:**

You will only be asked to talk to the research assistant on one occasion, and you can stop the interview at any time if you wish to do so, or you can decide not to answer a particular question. You will be asked about your recent health, and your experience of a range of possible symptoms that may have troubled you recently.

**Risks:**

There are no risks if you participate in the study.

**Benefits:**

There are also no direct benefits to you from taking part, except that you will have helped to improve services in this clinic, and helped people in other countries as well, to improve the services in their clinics.

**Confidentiality:**

The information that we collect from this research project will be kept confidential. Any information connecting your name with your responses to this interview will be kept by the researchers in a locked file. Your name will not be shared with anyone but who is not part of the research team that is directly involved with this project. The forms and computer files that contain your responses to this interview and other information about you that we will use for research purposes will not mention your name, but only a number. No report will ever be made about your individual responses in a way that could identify you.

However, I do need to tell you that if you tell me know about thoughts related to hurting yourself, I will need to talk to your doctor and the local research investigator about that, so that they can determine whether you might need some additional services or support.

**Sharing the results:**

Your name will not be shared with anyone not directly involved in this research, and will not be linked to your response to the interview questions. The information that comes from this study may be published so that

others can learn from our research, but no names or individually identifying information will be included in any such publications.

**Right to refuse or withdraw:**

You do not have to take part in the research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice. As I said before, if you decide not to participate, this will not affect the services that you receive or are entitled to receive, or your relationship with your doctor.

**Who to contact:**

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions? If you wish to ask questions later, you may contact me, your physician, or the local investigator or principal investigator listed on the first page.

## PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant: \_\_\_\_\_

Signature of Participant: \_\_\_\_\_

Date: \_\_\_\_\_  
Day/month/year

*If illiterate, a literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.*

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness: \_\_\_\_\_ AND Thumb print of participant

Signature of witness: \_\_\_\_\_

Date: \_\_\_\_\_  
Day/month/year



### Statement by the Researcher/Person Taking Consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the procedures involved in this study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent: \_\_\_\_\_

Signature of Researcher /person taking the consent: \_\_\_\_\_

Date: \_\_\_\_\_  
Day/month/year

**APPENDIX C**

***Field Study for the ICD-11 for Primary Care***

**Clinical Interview Schedule-Revised**

**INTRODUCTION:** "This computerised questionnaire will ask you a range of questions about yourself, your symptoms, and your health and well-being. Your answers will be kept confidentially, like any medical notes. The information you give will be treated in strict confidence and will only be used for research purposes.

*"To begin with, I would like to ask you about yourself and your background"*

1. "Are you male or female?"
  - 1 "Male"
  - 2 "Female"

"How old are you?" \_\_\_\_\_
2. "What is your marital status?"
  - 1 "Married/Living as married"
  - 2 "Single"
  - 3 "Separated"
  - 4 "Divorced"
  - 5 "Widowed"
3. "What is your current employment status?"
  - 1 "Working full-time"
  - 2 "Working part-time"
  - 3 "Student"
  - 4 "Retired"
  - 5 "Housewife/Househusband"
  - 6 "Unemployed job seeker"
  - 7 "Unemployed due to ill-health"
4. "In your current or last PAID employment, are/were you?"
  - 1 "Self-employed with paid employees"
  - 2 "Self-employed with no paid employees"
  - 3 "Employee"
  - 4 "Foreman/Supervisor"
  - 5 "Manager"
5. "What is your housing situation?"
  - 1 "Home owner"
  - 2 "Tenant"
  - 3 "Living with relative/friend"
  - 4 "Hostel/Care home"
  - 5 "Homeless"
  - 6 "Other"

*"I would now like to ask you about your health and well-being"*

**APPETITE/WEIGHT**

6. "Have you noticed a marked LOSS in your appetite in the PAST MONTH?"
  - 1 "No"
  - 2 "Yes"
7. "Have you lost any weight in the PAST MONTH?"

- 1 "No"
- 2 "Yes"
  
- 8. "Were you trying to lose weight or on a diet?"
  - 1 "No, I was not trying to lose weight"
  - 2 "Yes, I have been trying to lose weight"
  
- 9. "Did you lose half a stone or more, or did you lose less than this (in the PAST MONTH)? (NOTE:  
Half a stone = 7 pounds or 3 kg)"
  - 1 "I lost half a stone or more"
  - 2 "I lost less than half a stone"
  
- 10. "Have you noticed a marked INCREASE in your appetite in the PAST MONTH?"
  - 1 "No"
  - 2 "Yes"
  
- 11. "Have you lost any weight in the PAST MONTH?"
  - 1 "No"
  - 2 "Yes"
  
- 12. "Have you gained any weight in the PAST MONTH?"
  - 1 "No"
  - 2 "Yes"
  - 3 "Yes, but I am pregnant"
  
- 13. "Did you gain half a stone or more, or did you gain less than this (in the PAST MONTH)? (NOTE:  
Half a stone = 7 pounds or 3 kg)"
  - 1 "I gained half a stone or more"
  - 2 "I gained less than half a stone"

*ILLNESS/DISABILITY/PAIN*

- 14. "In the PAST YEAR, approximately how many times have you talked to or visited a GP or family  
doctor about your OWN health? Do NOT include any visits to hospital."
  - 0 "None"
  - 1 "1 or 2 times"
  - 2 "3 to 5 times"
  - 3 "6 to 10 times"
  - 4 "More than 10 times"
  
- 15. "Do you have any long-standing illness, disability or infirmity? Long-standing means anything that  
has troubled you over a period of time or that is likely to affect you over a period of time."
  - 1 "Yes"
  - 2 "No"
  
- 16. "Do you have any of the following conditions?"
  - 1 "Diabetes"
  - 2 "Asthma"
  - 3 "Arthritis"
  - 4 "Heart disease"
  - 5 "High blood pressure"
  - 6 "Lung disease"
  - 7 "More than one of the above"
  - 8 "None of the above"
  
- 17. "Have you had ANY sort of aches or pains in the PAST MONTH, including headaches or  
indigestion?"
  - 1 "No"
  - 2 "Yes"

18. "Was this pain or ache BROUGHT ON or MADE WORSE because you were feeling low, anxious or stressed?"
  - 1 "Never"
  - 2 "Sometimes"
  - 3 "Always"
  
19. "On how many days have you noticed this pain during the PAST SEVEN DAYS?"
  - 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
  
20. "In total, did the pain or ache last for more than 3 hours on ANY day during the PAST WEEK?"
  - 1 "No, less than 3 hours"
  - 2 "Yes, it has lasted for more than 3 hours on at least one day"
  
21. "Has the pain been unpleasant in the PAST WEEK?"
  - 1 "Not at all"
  - 2 "A little unpleasant"
  - 3 "Unpleasant"
  - 4 "Very unpleasant"
  
22. "Has the pain bothered you when you were doing something interesting in the PAST WEEK?"
  - 1 "No, pain has not bothered me"
  - 2 "Yes, pain bothered me while doing something interesting"
  - 3 "I haven't done anything interesting in the past week"
  
23. "Have you been troubled by any sort of bodily discomfort in THE PAST MONTH?"
  - 1 "No"
  - 2 "Yes"
  
24. "Was this discomfort BROUGHT ON or MADE WORSE because you were feeling low, anxious or stressed?"
  - 1 "Never"
  - 2 "Sometimes"
  - 3 "Always"
  
25. "On how many days have you noticed this discomfort during the PAST SEVEN DAYS?"
  - 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
  
26. "Did the discomfort last for more than 3 hours on any day during the PAST WEEK?"
  - 1 "No, less than 3 hours"
  - 2 "Yes, it has lasted more than 3 hours on at least one occasion"
  
27. "Has the discomfort been unpleasant in the PAST WEEK?"
  - 1 "Not at all"
  - 2 "A little unpleasant"
  - 3 "Unpleasant"
  - 4 "Very unpleasant"
  
28. "Has the discomfort bothered you when you were doing something interesting in the PAST SEVEN DAYS?"
  - 1 "No, discomfort has not bothered me"
  - 2 "Yes, discomfort bothered me while doing something interesting"
  - 3 "I haven't done anything interesting in the past week"
  
29. "How long have you been feeling this ache, pain or discomfort as you have just described?"
  - 1 "Less than 2 weeks"

- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

*FATIGUE*

- 30. "Have you noticed that you've been getting tired in the PAST MONTH?"
  - 1 "No"
  - 2 "Yes"
  
- 31. "What do you think is the main reason for feeling tired?"
  - 1 "Problems with sleep"
  - 2 "Tablets or medication"
  - 3 "Physical illness"
  - 4 "Working too hard, including looking after children"
  - 5 "Stress, worry or other psychological reason"
  - 6 "Physical exercise"
  - 7 "Other cause"
  - 8 "Don't know"
  
- 32. "On how many days have you felt tired during the PAST SEVEN DAYS?"
  - 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
  
- 33. "Have you felt tired for more than 3 hours in total on ANY day in the PAST WEEK?"
  - 1 "No, less than 3 hours"
  - 2 "Yes, I felt tired for more than 3 hours on at least one day"
  
- 34. "Have you felt so tired that you've had to push yourself to get things done during the PAST SEVEN DAYS?"
  - 1 "No"
  - 2 "Yes, on one or more occasion"
  
- 35. "Have you felt tired when doing things that you enjoy during the PAST WEEK?"
  - 1 "No, not tired during enjoyable activities"
  - 2 "Yes, tired during an enjoyable activity"
  - 3 "I haven't done anything enjoyable in the past week"
  
- 36. "During the PAST MONTH, have you felt you've been lacking in energy?"
  - 1 "No"
  - 2 "Yes"
  
- 37. "What do you think is the main reason for lacking in energy?"
  - 1 "Problems with sleep"
  - 2 "Tablets or medication"
  - 3 "Physical illness"
  - 4 "Working too hard, including looking after children"
  - 5 "Stress, worry or other psychological reason"
  - 6 "Physical exercise"
  - 7 "Other cause"
  - 8 "Don't know"
  
- 38. "On how many days have you felt lacking in energy during the PAST SEVEN DAYS?"

- 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
39. "Have you felt lacking in energy for more than 3 hours in total on ANY day in the PAST WEEK?"
- 1 "No, less than 3 hours"
  - 2 "Yes, I felt lacking in energy for more than 3 hours on at least one day"
40. "Have you felt so lacking in energy that you've had to push yourself to get things done during the PAST SEVEN DAYS?"
- 1 "No"
  - 2 "Yes, on one or more occasion"
41. "Have you felt lacking in energy when doing things that you enjoy during the PAST WEEK?"
- 1 "No, not lacking in energy during enjoyable activities"
  - 2 "Yes, lacking in energy during an enjoyable activity"
  - 3 "I haven't done anything enjoyable in the past week"
42. "How long have you been feeling tired or lacking in energy in the way you have just described?"
- 1 "Less than 2 weeks"
  - 2 "Between 2 weeks and 6 months"
  - 3 "Between 6 months and 1 year"
  - 4 "Between 1 and 2 years"
  - 5 "Two years or more"

*CONCENTRATION*

43. "In the PAST MONTH, have you had any problems in concentrating on what you are doing?"
- 1 "No"
  - 2 "Yes, problems concentrating on what I am doing"
44. "Have you noticed any problems with forgetting things in the PAST MONTH?"
- 1 "No"
  - 2 "Yes"
45. "On how many days have you noticed problems with your concentration OR your memory during the PAST SEVEN DAYS?"
- 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
46. "In the PAST WEEK could you concentrate on all of the following without your mind wandering?:
- a whole TV programme
  - a newspaper article
  - talking to someone?"
- 1 "Yes, I could concentrate on all of them"
  - 2 "No, I couldn't concentrate on at least one of these things"
47. "In the PAST WEEK, have these problems with your concentration actually STOPPED you from getting on with things you used to do or would like to do?"

- 1 "No"
- 2 "Yes"

48. "How long have you been having problems with your CONCENTRATION as you have described?"

- 1 "Less than 2 weeks"
- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

#### MEMORY

49. "Have you forgotten anything important in the PAST SEVEN DAYS?"

- 1 "No"
- 2 "Yes, I have forgotten something important"

50. "How long have you been having the problems with your MEMORY as you have described?"

- 1 "Less than 2 weeks"
- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

#### SLEEP

51. "In the PAST MONTH, have you been having problems with trying to get to sleep or with getting back to sleep if you woke up or were woken up?"

- 1 "No"
- 2 "Yes"

52. "On how many nights in the SEVEN NIGHTS did you have problems with your sleep?"

- 1 "None"
- 2 "Between one and three nights"
- 3 "Four nights or more"

53. "Thinking about the night you had the LEAST sleep in the PAST WEEK, how long did you spend trying to get to sleep? Only include time spent lying awake in bed TRYING to return to sleep."

- 1 "Less than 15 minutes"
- 2 "Between 15 minutes and 1 hour"
- 3 "Between 1 and 3 hours"
- 4 "Three hours or more"

54. "In the PAST WEEK, how many nights did you spend 3 or more hours trying to get to sleep?"

- 1 "None"
- 2 "Between one and three nights"
- 3 "Four nights or more"

55. "In the PAST WEEK, have you woken more than two hours earlier than you needed to and found that you couldn't get back to sleep?"

- 1 "No"
- 2 "Yes, and I couldn't get back to sleep"

56. "What are your sleep difficulties caused by?"
- 1 "Noises (babies crying,busy roads etc.)"
  - 2 "Shift work or late nights"
  - 3 "Pain or illness"
  - 4 "Worries"
  - 5 "Reason not known"
  - 6 "Other"
57. "Has sleeping more than usual been a problem for you in the PAST MONTH?"
- 1 "No"
  - 2 "I have slept more than usual but this is not a problem"
  - 3 "Yes"
58. "On how many nights in the PAST SEVEN NIGHTS did you have problems with your sleep?"
- 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
59. "Thinking about the night you slept the longest in the PAST WEEK, how much longer did you sleep compared with how long you normally sleep for?"
- 1 "Less than 15 minutes"
  - 2 "Between 15 minutes and 1 hour"
  - 3 "Between 1 and 3 hours"
  - 4 "Three hours or more"
60. "In the PAST WEEK, on how many nights did you sleep for more than 3 hours longer usual?"
- 1 "None"
  - 2 "Between one and three nights"
  - 3 "Four nights or more"
61. "How long have you had these problems with your sleep as you have described?"
- 1 "Less than 2 weeks"
  - 2 "Between 2 weeks and 6 months"
  - 3 "Between 6 months and 1 year"
  - 4 "Between 1 and 2 years"
  - 5 "Two years or more"

*IRRITABLE*

62. "Many people become irritable or short tempered at times, though they may not show it. Have you felt irritable or short tempered with those around you in the PAST MONTH?"
- 1 "No"
  - 2 "Yes, I have felt irritable or short tempered recently"
63. "During the PAST MONTH, did you get short tempered or angry over things which now seem trivial when you look back on them?"
- 1 "No"
  - 2 "Sometimes"
  - 3 "Yes"

64. "On how many days have you felt irritable, short tempered or angry in the PAST WEEK?"
- 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
65. "In total, have you felt irritable, short tempered or angry for more than one hour on any day in the PAST WEEK?"
- 1 "No"
  - 2 "Yes, I felt this way for more than one hour on at least one day"
66. "During the PAST WEEK, have you felt so irritable, short tempered or angry that you have wanted to shout at someone, even if you haven't actually shouted?"
- 1 "No"
  - 2 "Yes, but I didn't actually shout at someone"
  - 3 "Yes, and I actually shouted"
67. "In the past SEVEN DAYS, have you had arguments, rows or quarrels or lost your temper with anyone?"
- 1 "No"
  - 2 "Yes, but this was justified"
  - 3 "Yes"
68. "How long have you been feeling irritable, short-tempered or angry as you have described?"
- 1 "Less than 2 weeks"
  - 2 "Between 2 weeks and 6 months"
  - 3 "Between 6 months and 1 year"
  - 4 "Between 1 and 2 years"
  - 5 "Two years or more"

*ILLNESS WORRY*

69. "Many people get concerned about their physical health. In the PAST MONTH have you been at all worried about your physical health?"
- 1 "No"
  - 2 "Yes"
70. "Do you find yourself worrying that you might have a serious illness like cancer, heart disease or AIDS?"
- 1 "No"
  - 2 "Yes"
71. "Thinking about the PAST SEVEN DAYS, on how many days have you found yourself worrying about your physical health, or worrying that you might have a serious physical illness?"
- 1 "None"
  - 2 "Between one and three"
  - 3 "Four days or more"
72. "In your opinion, have you been worrying too much in view of your actual physical health?"
- 1 "No"
  - 2 "Yes, I worry too much"

73. "How unpleasant has this worrying been in the PAST WEEK?"
- 1 "Not at all"
  - 2 "A little unpleasant"
  - 3 "Unpleasant"
  - 4 "Very unpleasant"
74. "In the PAST WEEK, have you been able to take your mind off your health worries at least once, by doing something else?"
- 1 "Yes"
  - 2 "No, I could not take my mind off these worries even once"
75. "How long have you been worrying about your physical health in the way you have described?"
- 1 "Less than 2 weeks"
  - 2 "Between 2 weeks and 6 months"
  - 3 "Between 6 months and 1 year"
  - 4 "Between 1 and 2 years"
  - 5 "Two years or more"

*DEPRESSION*

- "Almost everyone becomes low in mood or depressed at times.
76. Have you had a spell of feeling sad, miserable or depressed in the PAST MONTH?"
- 1 "No"
  - 2 "Yes"
77. "In the PAST WEEK, have you had a spell of feeling sad, miserable or depressed?"
- 1 "No, not in the past week"
  - 2 "Yes"
78. "During the PAST MONTH, have you been able to enjoy or take an interest in things as much as you usually do?"
- 1 "Yes"
  - 2 "No, less enjoyment than usual"
  - 3 "No, I don't enjoy anything"
79. "In the PAST WEEK, have you been able to enjoy or take an interest in things as much as usual?"
- 1 "Yes"
  - 2 "No, less enjoyment than usual"
  - 3 "No, I don't enjoy anything"
80. "In the PAST WEEK, on how many days have you felt sad, miserable or depressed OR unable to enjoy or take an interest in things?"
- 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
81. "Have you felt sad, miserable or depressed OR unable to enjoy or take an interest in things for more than 3 hours in total on any day in the PAST WEEK?"
- 1 "No, less than 3 hours"

- 2 "Yes, for 3 hours or more on at least one day"
82. "What is the MAIN thing that made you feel sad, miserable or depressed OR unable to enjoy or take an interest in things in the PAST WEEK?"
- 1 "Family members, including spouse or partner"
  - 2 "Relationships with friends or people at work"
  - 3 "Housing"
  - 4 "Money or bills"
  - 5 "Your own physical health, including pregnancy"
  - 6 "Your own mental health"
  - 7 "Work or lack of work (including studying)"
  - 8 "Legal difficulties"
  - 9 "Political issues or the news"
83. "In the PAST WEEK when you felt sad, miserable or depressed OR unable to enjoy or take an interest in things, did you ever become happier when something nice happened, or when you were in company?"
- 1 "Yes, always"
  - 2 "Sometimes I cheered up"
  - 3 "No, nothing cheered me up"
84. "How long have you been feeling sad, miserable or depressed OR unable to enjoy or take an interest in things as you have described?"
- 1 "Less than 2 weeks"
  - 2 "Between 2 weeks and 6 months"
  - 3 "Between 6 months and 1 year"
  - 4 "Between 1 and 2 years"
  - 5 "Two years or more"
85. "I would now like to ask you about when you have been feeling sad, miserable or depressed OR unable to enjoy or take an interest in things. In the PAST WEEK, was this worse in the morning, in the evening, or did this make no difference?"
- 1 "Worse in the morning"
  - 2 "Worse in the evening"
  - 3 "Sometimes worse in the morning sometimes in the evening"
  - 4 "No difference between morning and evening"
86. "Many people find that feeling sad, miserable or depressed, OR unable to enjoy or take an interest in things can affect their interest in sex. Over the PAST MONTH, do you think your interest in sex has increased, decreased or stayed the same?"
- 1 "Not applicable"
  - 2 "No change"
  - 3 "Increased"
  - 4 "Decreased"
87. "In the PAST SEVEN DAYS, when you have felt sad, miserable or depressed OR unable to enjoy or take an interest in things have you been so restless that you couldn't sit still?"
- 1 "No"
  - 2 "Yes"
88. "In the PAST SEVEN DAYS, when you have felt sad, miserable or depressed OR unable to enjoy or take an interest in things have you been doing things more slowly than usual, for example walking more slowly?"

- 1 "No"
- 2 "Yes"

89. "In the PAST SEVEN DAYS have you on at least one occasion felt guilty or blamed yourself when things went wrong, even when it hasn't been your fault?"

- 1 "Never"
- 2 "Only when it was my fault"
- 3 "Sometimes"
- 4 "Often"

90. "In the PAST SEVEN DAYS have you been feeling you are not as good as other people?"

- 1 "No, I've been feeling as good as anyone else"
- 2 "Yes, I've NOT been feeling as good as others"

91. "Have you felt hopeless at all during the PAST SEVEN DAYS, for instance about your future?"

- 1 "No"
- 2 "Yes, I have felt hopeless sometimes"

#### SUICIDE

92. "In the PAST SEVEN DAYS, have you felt that life isn't worth living?"

- 1 "No"
- 2 "Sometimes"
- 3 "Always"

93. "In the PAST WEEK, have you thought of killing yourself?"

- 1 "No"
- 2 "Yes, but I would never commit suicide"
- 3 "Yes, I have had thoughts about it in the past week"

94. "In the PAST WEEK, have you thought about a way in which you might kill yourself?"

- 1 "No"
- 2 "Yes"

95. "Have you talked to your doctor about these thoughts of killing yourself?"

- 1 "Yes"
- 2 "No, but I have talked to other people"
- 3 "No"

*"Thank you for answering those questions on feeling unhappy or depressed. The next section is about worrying and anxiety."*

#### WORRY

96. "In the PAST MONTH, did you find yourself worrying more than you needed to about things?"

- 1 "No"
- 2 "Sometimes"
- 3 "Often"

97. "Have you had any worries at all in the PAST MONTH?"
- 1 "No"
  - 2 "Yes"
98. "What is the MAIN thing you have been worried about in the PAST WEEK?"
- 1 "Family members, including spouse or partner"
  - 2 "Relationships with friends or with people at work"
  - 3 "Housing"
  - 4 "Money or bills"
  - 5 "Your own physical health, including pregnancy"
  - 6 "Your own mental health"
  - 7 "Work or lack of work (including studying)"
  - 8 "Legal difficulties"
  - 9 "Political issues or the news"
99. "On how many of the PAST SEVEN DAYS have you been worrying about things OTHER than your physical health?"
- 1 "None"
  - 2 "Between one and three days"
  - 3 "Four days or more"
100. "In your opinion, have you been worrying too much in view of your circumstances?"
- 1 "No"
  - 2 "Yes, worrying too much"
101. "How unpleasant has your worrying been about things OTHER than your physical health in the PAST WEEK?"
- 1 "Not at all"
  - 2 "A little unpleasant"
  - 3 "Unpleasant"
  - 4 "Very unpleasant"
102. "Have you worried about something OTHER than your physical health for more than three hours in total on any day in the PAST WEEK?"
- 1 "No, Less than 3 hours"
  - 2 "Yes, 3 hours or more on at least one day this week"
103. "How long have you been worrying about things OTHER than your physical health in the way that you have described?"
- 1 "Less than 2 weeks"
  - 2 "Between 2 weeks and 6 months"
  - 3 "Between 6 months and 1 year"
  - 4 "Between 1 and 2 years"
  - 5 "Two years or more"
104. "Have you been feeling anxious or nervous in the PAST MONTH?"
- 1 "No"
  - 2 "Yes"
105. "In the PAST MONTH, did you ever find your muscles felt tense or that you couldn't relax?"
- 1 "No"

- 2 "Sometimes"
- 3 "Often"

#### PHOBIAS

*"Some people have phobias; they get nervous or uncomfortable about specific things or situations when there is no real danger. For example they may get nervous when speaking or eating in front of strangers, when they are far from home or in crowded rooms, or they may have a fear of heights. Others get nervous at the sight of things like blood or spiders.*

106. In the PAST MONTH, have you felt anxious, nervous or tense about any specific things or situations when there was no real danger?"

- 1 "No"
- 2 "Yes"

107. "In the PAST MONTH, when you have felt anxious, nervous or tense was this ALWAYS brought on by the phobia about some SPECIFIC thing or did you sometimes feel GENERALLY anxious, nervous or tense?"

- 1 "These feelings were ALWAYS brought on by specific phobia"
- 2 "I sometimes felt generally anxious, nervous or tense"

#### ANXIETY

*"The next questions are concerned with GENERAL anxiety, nervousness or tension ONLY. Questions about the anxiety which is brought on by the phobia(s) about specific things or situations will be asked later."*

108. "On how many of the PAST SEVEN DAYS have you felt GENERALLY anxious, nervous or tense?"

- 1 "None"
- 2 "Between one and three days"
- 3 "Four days or more"

109. "How unpleasant has your anxiety, nervousness or tension been in the PAST WEEK?"

- 1 "Not at all"
- 2 "A little unpleasant"
- 3 "Unpleasant"
- 4 "Very unpleasant"

110. "In the PAST WEEK, when you've been anxious, nervous or tense, have you had ANY of the following symptoms?"

heart racing or pounding	hands sweating or shaking
feeling dizzy	difficulty getting breath
butterflies in your stomach	dry mouth "

- 1 "No"
- 2 "Yes, one or more of the symptoms"

111. "Have you felt anxious, nervous or tense for more than 3 hours in total on any day in the PAST WEEK?"

- 1 "No"
- 2 "Yes, more than 3 hours on at least one day"

112. "How long have you had these feelings of general anxiety, nervousness or tension, as you have described?"

- 1 "Less than 2 weeks"
- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

#### PHOBIAS

*"Sometimes people AVOID a specific situation or thing because they have a phobia about it. For instance, some people avoid eating in public or avoid going to busy places because it would make them feel nervous or anxious."*

113. In the PAST MONTH, have you AVOIDED any situation or thing because it would have made you feel nervous or anxious, even though there was no real danger?"

- 1 "No"
- 2 "Yes"

114. "Here is a list of things that some people feel nervous about. Which one of these are you MOST afraid of?"

- 1 "Travelling alone by bus or train"
- 2 "Being far from home"
- 3 "Eating or speaking in front of strangers"
- 4 "The sight of blood"
- 5 "Going into crowded shops"
- 6 "Insects, spiders or animals"
- 7 "Being watched or stared at"
- 8 "Enclosed spaces or heights"
- 9 "I am not frightened of anything on this list but I am frightened of something else"

115. "On how many days in the PAST SEVEN DAYS have you felt nervous or anxious about the situation or thing you are most frightened of?"

- 1 "None"
- 2 "Between one and three days"
- 3 "Four or more days"

116. "In the PAST WEEK, on those occasions when you felt anxious, nervous or tense about this, did you have ANY of the following symptoms?"

heart racing or pounding	hands sweating or shaking
feeling dizzy	difficulty in getting breath
butterflies in the stomach	dry mouth"

- 1 "No"
- 2 "Yes, at least one symptom"

117. "In the PAST WEEK, have you AVOIDED any situations or things because it would have made you feel anxious, nervous or tense, even though there was no real danger?"

- 1 "No"
- 2 "Yes, on one or more occasion"

118. "How many times have you avoided such situations or things in the PAST SEVEN DAYS?"

- 1 "None"
- 2 "Between one and three times"
- 3 "Four times or more"

119. "How long have you been having these feelings about the situations or things as you have just described?"

- 1 "Less than 2 weeks"
- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

120. "Thinking about the PAST MONTH, did your anxiety or tension ever get so bad that you got in a panic, for instance make you feel that you might collapse or lose control unless you did something about it?"

- 1 "No, my anxiety never got that bad"
- 2 "Yes, sometimes"
- 3 "Yes, often"

121. "How often has this panic happened in the PAST SEVEN DAYS?"

- 1 "Not in the past seven days"
- 2 "Once"
- 3 "More than once"

122. "In the PAST SEVEN DAYS, how unpleasant have these feelings of panic been?"

- 1 "A little uncomfortable"
- 2 "Unpleasant"
- 3 "Unbearable, or very unpleasant"

123. "In the PAST WEEK, did the worst of these panics last for longer than 10 minutes?"

- 1 "Less than 10 minutes"
- 2 "10 minutes or more"

124. "Do these panics start suddenly so you are at maximum anxiety within a few minutes?"

- 1 "No"
- 2 "Yes"

125. "In the PAST SEVEN DAYS when you had these panics: Did your heart beat harder or speed up?"

- 1 "No"
- 2 "Yes"

126. "In the PAST SEVEN DAYS when you had these panics: Did you have sweaty or clammy hands?"

- 1 "No"
- 2 "Yes"

127. "In the PAST SEVEN DAYS when you had these panics: Were you trembling or shaking?"

- 1 "No"
- 2 "Yes"

128. "In the PAST SEVEN DAYS when you had these panics: Did you have shortness of breath or difficulty breathing?"

- 1 "No"
- 2 "Yes"

129. "In the PAST SEVEN DAYS when you had these panics: Did you have a choking sensation?"

- 1 "No"
- 2 "Yes"

130. "In the PAST SEVEN DAYS when you had these panics: Did you have pain, pressure or discomfort in your chest?"

- 1 "No"
- 2 "Yes"

131. "In the PAST SEVEN DAYS when you had these panics: Did you have nausea (feeling as though you were going to vomit) or stomach ache?"

- 1 "No"
- 2 "Yes"

132. "In the PAST SEVEN DAYS when you had these panics: Did you feel dizzy, unsteady, lightheaded or faint?"

- 1 "No"
- 2 "Yes"

133. "In the PAST SEVEN DAYS when you had these panics: Did things around you feel strange, unreal or detached OR did you feel outside or detached from yourself?"

- 1 "No"
- 2 "Yes"

134. "In the PAST SEVEN DAYS when you had these panics: Did you fear that you were losing control or going crazy?"

- 1 "No"
- 2 "Yes"

135. "In the PAST SEVEN DAYS when you had these panics: Did you fear that you were dying?"

- 1 "No"
- 2 "Yes"

136. "In the PAST SEVEN DAYS when you had these panics: Did you have tingling or numbness in parts of your body?"

- 1 "No"
- 2 "Yes"

137. "In the PAST SEVEN DAYS when you had these panics: Did you have hot flushes or chills?"

- 1 "No"
- 2 "Yes"

138. "Is this panic ALWAYS brought on by specific situations or things?"

- 1 "No"
- 2 "Yes"

139. "How long have you been having these feelings of panic as you have described?"

- 1 "Less than 2 weeks"
- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

140. "Thank you for answering those questions on anxiety and worry."

#### *COMPULSIVENESS*

141. "In the PAST MONTH, did you find that you kept on doing things over and over again when you knew you had already done them, for instance checking things like taps, or washing yourself when you had already done so?"

- 1 "No"
- 2 "Sometimes"
- 3 "Often"

142. "On how many days in the PAST WEEK did you find yourself doing things over again that you had already done?"

- 1 "None"
- 2 "Between one and three days"
- 3 "Four days or more "

143. "During the PAST WEEK, have you tried to stop yourself repeating things over again?"

- 1 "No, not in the past week"
- 2 "Yes, on at least one occasion"

144. "Has repeating things over again made you upset or annoyed with yourself in the PAST WEEK?"

- 1 "Not at all"
- 2 "Yes, it has upset or annoyed me"

145. "In the PAST WEEK, what is the GREATEST NUMBER of times you repeated something you had already done?"

- 1 "Once (ie 2 times altogether)"
- 2 "Two repeats"
- 3 "Three or more repeats"

146. "How long have you been repeating things that you have already done in the way you have described?"

- 1 "Less than 2 weeks"
- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

#### *OBSESSIONS*

147. "In the PAST MONTH, did you have any thoughts or ideas over and over again that you found unpleasant and would prefer not to think about, that still kept coming into your mind?"

- 1 "No"
- 2 "Sometimes"
- 3 "Often"

148. "Are these the SAME thoughts or ideas over and over again, or are you worrying about something in GENERAL?"

- 1 "The same thoughts or ideas over and over again"
- 2 "Worrying about something in general"

149. "On how many days in the PAST WEEK have you had these unpleasant thoughts?"

- 1 "None"
- 2 "Between one and three days"
- 3 "Four days or more"

150. "During the PAST WEEK, have you tried to stop yourself thinking any of these thoughts?"

- 1 "No, not in the past week"
- 2 "Yes, I have tried to stop these thoughts at least once"

151. "Have you become upset or annoyed with yourself when you have had these thoughts in the past week?"

- 1 "Not at all"
- 2 "Yes, they have upset or annoyed me in the past week"

152. "What is the longest time you have spent thinking these thoughts, in the PAST WEEK?"

- 1 "Less than fifteen minutes"
- 2 "Fifteen minutes or more"

153. "How long have you been having these thoughts in the way which you have described?"

- 1 "Less than 2 weeks"
- 2 "Between 2 weeks and 6 months"
- 3 "Between 6 months and 1 year"
- 4 "Between 1 and 2 years"
- 5 "Two years or more"

*"Thank you for answering those questions."*

#### OVERALL

154. "How have ALL of these things that you have told me about affected you overall? In the PAST WEEK, has the way you have been feeling actually STOPPED you from getting on with the tasks and activities you used to do or would like to do?"

- 1 "Not at all"
- 2 "They have made things more difficult but I get everything done"
- 3 "They have stopped one activity"
- 4 "They have stopped more than one activity"

**IF the patient has admitted to thoughts of suicide, the RA should say:**

"Earlier in the interview you mentioned suicidal ideas. I am rather concerned about this. As you may remember, when you signed the Consent Form I told you that if you described any thoughts or feelings about hurting yourself, I would inform your doctor and the local research investigator so that they can determine whether you need additional clinical services. I will therefore do this right away. If you have already talked to your doctor about this, he or she may already have talked with you about a plan, but I just need to make sure."

RA should then follow care plan described in the local protocol.

## APPENDIX D

### *Field Study for the ICD-11 for Primary Care*

Numbered Form

#### **Clinician Encounter Form: Anxiety/Depression**

Patient's age: \_\_\_\_\_

Patient's gender: \_\_\_\_\_ Male \_\_\_\_\_ Female

**Please make a mark in the box before only those questions in the two 5-item scales that the patient answered positively. If there is a single positive reply in all of 10 questions, all the other questions should be asked. 5 questions in that set should be asked. Please refer cases with at least one positive reply to the RA. You do NOT need to refer cases with NO positive replies to the RA.**

- D1 Have you been feeling depressed every day for the past 2 weeks?
- D2 Have you experienced less interest or pleasure from activities?
- D3 Poor concentration
- D4 feelings of worthlessness
- D5 felt you wanted to die, thoughts of death
  
- A1 Have you felt nervous or anxious in the past 2 weeks?
- A2 Have you found that you are not able to control worrying
- A3 having trouble relaxing
- A4 so restless, hard to keep still
- A5 afraid that something awful might happen

In the questions that follow, make only a single mark in one box for each question:

1. *The disability associated with this symptom profile is*

- 0 = no disability whatever
- 1 = able to carry out all activities, but with increased difficulty
- 2 = impaired in at least one activity
- 3 = impaired in all activities (household duties / outside work / social activities)

2. *My own clinical assessment is that this patient is*

- 0 = completely normal
- 1 = sub-clinically distressed
- 2 = mildly disordered or distressed
- 3 = moderately disordered or distressed
- 4 = severely disordered or distressed

3. *My provisional ICD-11-PHC diagnosis would be:*

- Anxious depression
- Depression only
- Anxiety only
- Bodily Stress syndrome
- Health Anxiety
- (*Other Dx, specify:*)
- NO DIAGNOSIS



Please complete **ALL** questions for **ALL** patients you are referring to the RA, whether you judge them to have **Bodily Stress Syndrome** or **Health Anxiety**.

I. Please mark the symptoms the patient complains about (check all that apply):

**Gastro-intestinal arousal:**

- abdominal pains
- frequent loose bowel movements
- feeling bloated
- regurgitations
- constipation
- diarrhoea
- nausea
- vomiting
- burning sensation in epigastrium

**Musculoskeletal tension:**

- pains in arms or legs
- muscular aches or pains
- pains in the joints
- feelings of paresis or localized weakness
- back ache
- pain moving from one place to another
- unpleasant numbness
- unpleasant tingling sensations

**Cardio-respiratory arousal:**

- palpitations
- precordial discomfort
- breathlessness without exertion
- hyperventilation,
- hot or cold sweats
- trembling or shaking
- dry mouth

**General unspecific symptoms:**

- concentration difficulties
- impairment of memory
- excessive fatigue
- headache
- dizziness

**Other symptoms (specify):**

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

II. Is there a **known** physical pathology to explain any of the above symptoms?

- No
- Yes (please specify:) \_\_\_\_\_

III. Please indicate whether the patient has the following symptoms (check all that apply):

- Persistent, intrusive ideas or fears of having illness that cannot be stopped or can only be stopped with great difficulty
- Intense preoccupation with minor bodily sensations or problems that are misinterpreted as signs of serious disease
- Neither of the above is present

IV. For each of the questions that follow, make only a single mark in one box for each question:

1. **The disability associated with this symptom profile is:**

- 0 = No disability
- 1 = Able to carry out all activities, but with increased difficulty
- 2 = Impaired in at least one activity
- 3 = Impaired in most or all activities (household duties/outside work/social activities)

2. **The level of distress exhibited by the patient is:**

- 0 = Not significant distress
- 1 = Mild distress
- 2 = Moderate distress
- 3 = Severe distress

3. **My provisional ICD11-PHC diagnosis would be (check all that apply):**

- Bodily Stress Syndrome
- Health Anxiety
- Anxious Depression
- Depression without Anxiety
- Anxiety without Depression
- (Other Dx, specify:) \_\_\_\_\_
- No Diagnosis

4. **Based on my own clinical assessment, I would describe the severity of this patient's disorder as:**

- 0 = No disorder present
- 1 = Symptomatic but subthreshold (subclinical)
- 2 = Mild disorder
- 3 = Moderate disorder
- 4 = Severe disorder

**APPENDIX F**

*Field Study for the ICD-11 for Primary Care*

**12-Item WHO-DAS 2.0**

In the past <u>30 days</u> , how much <u>difficulty</u> did you have in:					
	None	Mild	Moderate	Severe	Extreme/ Cannot Do
1. <u>Standing for long periods</u> such as 30 minutes?	0	1	2	3	4
2. Taking care of your <u>household responsibilities</u> ?	0	1	2	3	4
3. <u>Learning a new task</u> , for example, learning how to get to a new place?	0	1	2	3	4
4. How much of a problem did you have <u>joining in community activities</u> (for example, festivities, religious or other activities) in the same way as anyone else can?	0	1	2	3	4
5. How much have you been <u>emotionally affected</u> by your health problems?	0	1	2	3	4
6. <u>Concentrating</u> on doing something for ten minutes?	0	1	2	3	4
7. <u>Walking a long distance</u> such as a kilometre [or equivalent]?	0	1	2	3	4
8. <u>Washing your whole body</u> ?	0	1	2	3	4
9. Getting <u>dressed</u> ?	0	1	2	3	4
10. <u>Dealing with people you do not know</u> ?	0	1	2	3	4
11. <u>Maintaining a friendship</u> ?	0	1	2	3	4
12. Your day-to-day <u>work</u> ?	0	1	2	3	4
WHO-DAS 2.0 Score = Sum of the above					

## Appendix G

### *Field Study for the ICD-11 for Primary Care*

#### **Primary Care Provider (PCP) Training**

All PCPs who agree to participate in field studies will be required to complete a day-long training session about the study. The PCP training will be conducted by the PI and/or LI. WHO will provide a set of power point slides to ensure uniformity of presentation in each centre.

#### **Training Objectives.**

By the end of the training, PCPs will:

- Be familiar with the new disorders they are to investigate.
- Demonstrate, through discussion and role-plays, the ability to identify eligible patients through accurate application of the eligibility criteria and screening measures and to recruit them for the study.

#### **Session Topics/Activities**

1. *Study Description*: Overview of hypotheses, methods, and analysis plan for the study, as well as the forms and measures.
2. *Recruiting Patients*: PCPs will be trained in recruiting patients for (a) the anxious depression study and (b) the Bodily Stress Syndrome study.
  - a. Anxious depression study: PCPs will be trained in the “non-verbal” and “verbal” cues that suggest that a patient has an emotional disorder. In those patients who may be emotionally distressed, PCPs will utilize the Clinician Encounter Form – Anxiety/Depression and ask the patient the first two depression questions and the first two anxiety questions. If the patient answers one or more of these questions positively, the PCP asks the remaining questions in the corresponding set (depression, questions, anxiety questions, or both). Any patient with two or more positive replies to the total 10 questions are asked whether they would agree to take part in a study the PCP is doing in the clinic, and invites the patient to talk to the RA for further information.

If a patient agrees that he or she has suicidal thoughts in replying to question D5, or if the PCP has discovered this in another part of the interview, it is the PCPs responsibility to make an assessment of the seriousness of these thoughts and possible preventive resources (e.g., asking the patient whether he or she has made specific plans; if so, what prevents him or her from them carrying out; whether he or she lives alone; whether he or she has talked with family or friends about these thoughts). Specific strategies for assessing and managing suicidal patient will be provided as a part the training. The LI will develop a specific protocol to be used in the local setting; in countries where the LI is not a psychiatrist, he/she will consult with local mental health experts to develop such a protocol.

Only after an appropriate follow-up plan has been made per the specified protocol and the PCP is confident of the patient’s safety should the patient be referred to the study. The study interview that will be administered by the RA also contains some items on suicidal thoughts. If the patient indicates that he has suicidal thoughts, the RA will respond in a way that has been customized by the LI to be appropriate for your country and setting. Possible wording might be:

‘Earlier in the interview you mentioned suicidal ideas. I am rather concerned about this. As you may remember, when you signed the Consent Form I told you that if you described any thoughts or feelings about hurting yourself, I would inform your doctor and the local research investigator so that they can determine whether you need additional clinical services. I will therefore do this right away. If you have already talked to your doctor about this, he or she may already have talked with you about a plan, but I just need to make sure.’

The PCP and the LI will then be notified by the RA, and will follow the protocol developed by the LI for your setting. If the PCP has already discussed this with his or her patient and made a plan consistent with the country-level protocol, then no further action may be necessary. The LI will contact the PCP to discuss and make any additional necessary follow-up plans, per the country-level protocol.

- b. Bodily stress syndrome study: PCPs will be trained in recruiting patients who present with at least three persistent somatic, medically unexplained symptoms, or the patient is highly preoccupied with persistent worry about potential health problems. The symptoms must cause distress to the patient, and there must be associated disability.
3. PCP Script for Referring Patients to the Research Assistant: PCPs will be given a script that provides wording to refer eligible patients to the research assistant. The script states the following:

*I would like to invite you to participate in a research study that is sponsored by the World Health Organization (WHO) and (local sponsoring institution). The WHO is currently updating its classification of health disorders: the International Classification of Diseases and Related Health Problems, 11th Revision (ICD-11). Because most people receive health care from primary care practices, it is important to test the revised classification in these settings. This study will help the WHO find out if the revised classification is useful in primary health care settings and applicable in different countries. If you would like to participate, I will refer you to a research assistant in this office who will provide you with more information about the study. Whether or not you choose to participate in the study will not affect your treatment here in this clinic, or my services to you as your doctor. Would you like to participate in the study? Do you have any questions?*

4. *Role-Plays*: PCPs will form into triads as “doctor,” “patient,” and “observer,” and carry out three role-plays – rotating the roles each time – so that each PCP will have been the “doctor” once, and watched 2 other role-plays. The “patient” will be given a sheet telling him/her what their main complaint is and what symptoms they should say they have. The “observer” provides feedback to the other two about how the assessment seemed to go, and to ensure that the “doctor” completed the assessment form correctly. The role-plays will conclude with the “doctor” asking the “patient” to agree to participate in the study, and then referring the “patient” to the research assistant “RA.” At the end of the role-play, the doctor will complete the Clinician Encounter Form, and this will be given to the “observer,” who will check the correspondence between the “patient’s” reported symptoms and the data on the form.

## Appendix H

### *Field Study for the ICD-11 for Primary Care*

#### **Research Assistant (RA) Training**

All RAs who agree to participate in field studies will be required to complete a day-long training session about the study. The RA training will be conducted by the PI and/or LI. WHO will provide a set of power point slides to ensure uniformity of presentation in each centre.

#### **Training Objectives**

By the end of the training, RAs will:

- Demonstrate the informed consent procedure.
- Demonstrate the accurate administration of the study measures.
- Demonstrate the ability to implement procedures for dealing with suicidal or emotionally distressed patients.

#### **Session Topics/Activities**

1. *Study Description*: Overview of the study, as well as the consent forms and measures to be used in the study.
2. *Consent Procedure*: The LI will present and demonstrate the informed consent procedure.
3. *Role-Play of Consent Procedure*: RAs will be divided into groups of three to represent the “RA,” the “patient,” and an “observer.” The “RA” will practice explaining the study and administering the consent procedure to the “patient,” and the “observer” will give critical comments about how it went. The group changes roles, and the procedure is repeated three times with each “RA” having a turn playing each role. When the role-plays are complete, the PI will evaluate whether the RAs have learned the procedure or whether additional information and/or practice needs repeating.
4. *Administration of the Measures*: The LI will present and demonstrate the process for administering the PROQSY and WHO-DAS 2.0.
5. *Role-Play of Administering Measures*: The RAs return to their triads, and this time the “patient” should complain of the symptoms allocated at the outset. The RA will proceed with administering the PROQSY and WHO-DAS 2.0 to the “patient,” and the “observer” will give critical comments about how it went. The group changes roles, and the procedure is repeated three times with each RA having a turn playing each role. When the role-plays are complete, the LI will evaluate whether the RAs have learned the procedure or whether additional information and/or practice needs repeating.
6. *Protocol for Suicidal/Emotionally Distressed Patients*: The LI will present and demonstrate the protocol for responding to and dealing with suicidal or emotionally distressed patients.

If a patient agrees that he or she has suicidal thoughts in replying to questions 94 – 97 on the PROQSY, at the end of the interview the RA will respond in a way that has been customized by the LI to be appropriate for each country and setting. Possible wording might be:

‘Earlier in the interview you mentioned suicidal ideas. I am rather concerned about this. As you may remember, when you signed the Consent Form I told you that if you described any thoughts or feelings about hurting yourself, I would inform your doctor and the local research investigator so that they can determine whether you need additional clinical services. I will therefore do this right away. If you have already talked to your doctor about this, he or she may already have talked with you about a plan, but I just need to make sure.’

7. *Role-Play of Protocol:* In their triads, RAs will role-play the protocol for dealing with patients who express suicidal thoughts.

## Appendix I

### *Field Study for the ICD-11 for Primary Care*

#### **Research Assistant Confidentiality Agreement**

This study, Depression, Anxiety & Somatic Symptoms in Global Primary Care Settings: A Field Study for the ICD-11-PHC, is being undertaken by Sir David Goldberg at the Institute of Psychiatry, (name of Local Investigator and Site), and the World Health Organization (WHO) Department of Mental Health and Substance Abuse.

The purpose of this study is to improve the assessment and detection of the most common mental disorders in primary care settings in multiple countries. Data from this study will be used to improve the utility of the ICD-11 diagnostic concepts related to anxiety, depression and somatic symptoms.

I, (name of Research Assistant), agree to:

1. Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format (e.g. electronic, paper) with anyone other than the Principal Investigator, Local Investigator, and Primary Care Physician.
2. Keep all research information in any form or format secure while it is in my possession;
3. Return all research information in any form or format to the Principal Investigator/Local Investigator when I have completed the research tasks.

Research Assistant:

\_\_\_\_\_

(print name)

(signature)

(date)

Local Investigator:

\_\_\_\_\_

(print name)

(signature)

(date)

If you have any questions or concerns about this study, please contact:

Local Investigator Name:

Address:

Phone Number:

## APPENDIX J

### *Field Study for the ICD-11 for Primary Care*

#### **Patient Refusal Form**

This PCP should complete this form each time that a patient who meets the eligibility criteria for the study but who declines to talk with the RA.

*Do it from memory, do not ask questions of the patient*

Which study did the patient qualify for?

- Anxious depression
- Bodily distress / health anxiety

Patient's age:

- Young (18 - 29)
- Middle age (30 – 59)
- Older (60+)

Patient's gender:

- Male
- Female

Reason for refusing:

- Too ill
- Did not have time
- Could not speak/understand language
- Would prefer not to take part
- No reason given
- Other reason (specify):

## APPENDIX K

### *Field Study for the ICD-11 for Primary Care*

#### **Curriculum Vitae of external investigators**

**SIR DAVID GOLDBERG, KB, DM, FRCP, MA, MSc.**

Professor Emeritus  
Institute of Psychiatry, King's College  
London, United Kingdom

#### **Employment**

01/09/1970	Senior Lecturer	University of Manchester
01/08/1978	Professor of Psychiatry	University of Manchester
01/04/1993	Professor of Psychiatry, Director of R&D	Institute of Psychiatry
01/01/2000	Professor Emeritus	

#### **Education**

01/12/1959	MBBCh, Medicine & Surgery	University of Oxford
01/08/1964	Doctorate in Medicine	University of Oxford
01/08/1978	MSc (Hons), Psychiatry	University of Manchester

#### **Selected Publications** (from over 370 publications)

Goldberg DP, Krueger RF, Andrews G, Hobbs M.J. (2009) Emotional disorders: Cluster 4 of the proposed meta-structure for DSM-V and ICD-11 *Psychological Medicine* Vol.39(12),. 2043-2059.

Goldberg D 2010 The classification of mental disorder: A simpler system for DSM-V and ICD-11. *Advances in Psychiatric Treatment*. 16 (1) (pp 14-19)

Goldberg D. (2010) Should our major classifications of mental disorders be revised? *British Journal of Psychiatry*. 196 (4) (pp 255-256),

Goldberg D. (2010) The detection and treatment of depression in the physically ill. *World Psychiatry*. 9 (1) (pp 16-20),

Goldberg D, Simms LJ, Gater R, Krueger, RF. (2011) Integration of dimensional spectra for depression and anxiety into categorical diagnoses for general medical practice. In Ed. Regier, D et al. *The conceptual evolution of DSM-5*. American Psychiatric Publishing, Arlington, VA, US. (pp. 19-35).

Goldberg DP (2011) A revised mental health classification for use in general medical settings, the ICD11-PHC. *International Psychiatry* 8 (1) 1-3.

#### **Honors, Award, Research Grants**

1972 Factors that determine the ability of GP's to detect emotional illness; Orlando Oldham Charitable Trust; Principal Investigator

1978 Training Family Practice Residents to Recognise Psychiatric Disturbances; National Institute of Mental Health, Washington; Principal Investigator

1982 Clarification and Assessment of a way of teaching psychotherapy; Medical Research Council; Principal Investigator

1985 Determinants of somatised presentations of emotional distress in general practice settings; Jules Thorn Charitable Trust; Principal Investigator

1985 Costs & Benefits of screening for psychological disorder on a medical ward; Medical Research Council; Principal Investigator

1985 Development of teaching methods for primary care physicians in mental health skills; Gatsby Charitable Trust; Principal Investigator

1990 Psychological Problems in General Health Settings; World Health Organisation; Principal Investigator

1993 Depressive illnesses seen in primary care settings, including biological concomitants, social and personality factors; Wellcome Project Grant Support; Co-principal investigator

**JULIO BOBES, MD, PH.D.**  
Professor of Psychiatry  
Department of Psychiatry, CIBERSAM  
University of Oviedo, Oviedo, Spain

### **Present Appointment**

Since 26 April 2000: Professor of Psychiatry - University of Oviedo and Head of Service of Psychiatry - University Central Hospital of Asturias. Activities: teaching, research and assistance in psychiatry

### **Education**

July 1977: Degree in Medicine and Surgery, Faculty of Medicine, University of Oviedo (which comes under the Spanish Ministry of Education and Science)

June 1980: Diploma in Occupational Medicine, National School of Occupational Medicine (which comes under the Spanish Ministry of Health and Social Security)

December 1980: Specialist in Psychiatry, Faculty of Medicine, University of Oviedo

September 1982: Doctor (PhD) in Medicine and Surgery, Faculty of Medicine, University of Oviedo

March 1992: Specialist in Family and Community Medicine, Faculty of Medicine, University of Oviedo

### **Current Research Activities**

Title: Eficacia de un programa de cesación tabáquica multicomponente en pacientes con trastorno mental grave (esquizofrenia y trastorno bipolar) Funding Entity: Instituto de Salud Carlos III (FIS)

Multicenter project PI: Julio Bobes García Financing: 81.917€ Duration: 2012-14

Title: SEYLE - Saving and Empowering Young Lives in Europe

Funding Entity: European Commission-7 Framework Programme (FP7-HEALTH-2007-B)

coordinates: Danuta Wasserman (Suecia). PI Spain: Julio Bobes

Reference: UE-09-223091 Duration: 01/01/2009-31/12/2012

Title: Working in Europe to Stop Truancy Among Youth - WE-STAY

Funding Entity: European Commission-7 Framework Programme (FP7)

Coordinates: Danuta Wasserman. PI Spain: Julio Bobes Reference: UE-10-WE-STAY-241542

Duration: 01/05/2010-30/04/2013

### **Relevant Publications**

Pregabalin for the discontinuation of longterm benzodiazepines use: an assessment of its effectiveness in daily clinical practice

Bobes J, Rubio G, Terán A, Cervera G, López-Gómez V, Vilardaga, Pérez M

European Psychiatry. 2011. (aceptado 17-12-10). (doi:10.1016/j.eurpsy.2010.12.004). FI 2010=3.365.

Cardiovascular and metabolic risk in outpatients with schizoaffective disorder treated with antipsychotics: results from the CLAMORS study

Bobes J, Arango C, Aranda P, Carmena R, García-García M, Rejas J, on behalf of the CLAMORS Study Collaborative Group

European Psychiatry. 2011. (aceptado 4-9-10). (doi:10.1016/j.eurpsy.2010.09.001). FI 2010=3.365.

Physical illness in patients with severe mental disorders. II. Barriers to care, monitoring and treatment guidelines, plus recommendations at the system and individual level

De Hert M, Bobes J, Cetkovich-Bakmas M, Cohen D, Leucht S, Maj M, Ndeti DM, Newcomer JW, Uwakwe R, Asai I, Möller HJ,

Gautam S, Detraux J, Correll CU, World Psychiatry 10 (2): 138-151. 2011. FI 2010=5.562.

**DR. SANDRA FORTES, MD, PhD, MSc**

Associate Professor of Mental Health and Medical Psychology  
Department of Mental Health and Psychological Medicine  
Pedro Ernesto University Hospital, State University of Rio de Janeiro  
Rio de Janeiro, Brazil

**Present Appointment**

1. Associate Professor of Mental Health and Medical Psychology - Medical Specialists' Department - School of Medical Sciences, University of Rio de Janeiro State (UERJ)
2. Psychiatrist - Health Ministry – Brazil - Mental Health Supervisor for Family Health Strategy in Rio de Janeiro and Head of the Mental Health Service in the Policlínica Piquet Carneiro/UERJ.

**Education**

Medical Degree by Universidade do Estado do Rio de Janeiro (UERJ -1982)  
Residence in Psychiatry by Universidade Federal do Rio de Janeiro (1984)  
MSc in Psychiatry by Universidade Federal do Rio de Janeiro (1995)  
PhD in Public Health- Epidemiology by Universidade do Estado do Rio de Janeiro (2004).

**Current Research Activities**

- 1) Supervisor in the MSc and PhD Pos-Graduation Program in Medical Sciences of the UERJ.
- 2) Leader of the Research Groups - UERJ-National Counsel of Technology and Scientific Development – CNPq: Mental Health in Primary Care/Interdisciplinary Research in Primary Care Group.
- 3) Coordination of the following research projects ( 2010-2012):
  - a) PET-SM CRACKProgram-National Health Ministry(MS/Brasil): Treatment for Alcohol and Drug Problems in Primary Care in Rio de Janeiro – financing MS/Brasil
  - b) Evaluation of Depression Treatment in Primary care in the National Health System Units from Programmatic Area 2.2 of Rio de Janeiro City” – financing – CNPq
  - c) Evaluation of the Integration of Mental Health Care in Primary Care in the Programmatic Area 2.2 of Rio de Janeiro City – financing FAPERJ – Foundation for Research Support in Rio de Janeiro State

**Recent Past Research Activities**

- 1) Project: Evaluation of the Impact of a Mental Health Training Program for Primary Care – 2008-2010: Coordinator – financing CNPQ –
- 2) Project: Therapeutic Intervention for Anxiety and Depression in Primary Care – 2006-2008 - Field Coordinator – General Coordinator: Claudia Souza Lopes - financing CNPQ

**Selected Papers**

- 1) Linda Gask, Michael Klinkman, Sandra Fortes and Christopher Dowrick. Capturing complexity: The case for a new classification system for mental disorders in primary care. *European Psychiatry (Paris)*, v.23, p.469 - 476, 2008.
- 2) Daniel A. Gonçalves ; Fortes, S ; Tófoli, Luis Fernando; Campos MR; Mari JJ . Determinants of Common Mental Disorders Detection by General Practitioners in the Family Health Program in Brazil. *International Journal of Psychiatry in Medicine*, v. 41, p. 3-13, 2011
- 3) Tófoli Luis Fernando; Andrade, Laura Helena and Fortes, Sandra. Somatization in Latin America: a review of the classification of somatoform disorders, functional syndromes and medically unexplained symptoms. *Rev. Bras. Psiquiatr.* 2011, vol.33, suppl.1, pp. S59-s69.
- 4) Fortes, S ; Lopes, CS ; Villano, LA.; Campos MR ; Gonçalves DA; Mari, J. J. . Common Mental Disorders in Petrópolis-RJ: a challenge to integrate mental health into primary care strategies. *Revista Brasileira de Psiquiatria (São Paulo. 1999. Impresso)*, v. 33, p. 50-156, 2011.

**Tai-Pong Lam**

Department of Family Medicine and Primary Care, University of Hong Kong  
Hong Kong, People's Republic of China

**Professional Appointments**

Assistant Dean, Faculty of Medicine; Professor, Department of Family Medicine and Primary Care, University of Hong Kong, Hong Kong, People's Republic of China, Email: [tplam@hku.hk](mailto:tplam@hku.hk)

Education

Recent Research Activities

**Selected Publications**

- Lam TP, Mak KY, Goldberg D, Lam KF, Sun KS. Western mental health training for Traditional Chinese Medicine practitioners. *Acta Psychiatrica Scandinavica*. 2012 Apr 26. doi: 10.1111/j.1600-0447.2012.01867.x. [Epub ahead of print]
- Lam TP, Wun YT, Lam KF. Hong Kong physicians' views on who should treat mild depression. *Psychiatric Services*. 2011; 62: 565-566.
- Wun YT, Lam TP\*, Lam KF, Goldberg D, Li DKT, Yip KC. Introducing family medicine in a pluralistic health care system: how patients and doctors see it. *Family Practice*. 2011;43(5):344-50. \*Corresponding Author
- Lam TP, Chow RWM, Lam KF, Lennox IM, Chan FHW, Tsoi SLT. Evaluation of the learning outcomes of a year-long postgraduate training course in community geriatrics for primary care doctors. *Archives of Gerontology and Geriatrics*. 2011;52(3):350-6
- Lam TP, Goldberg D, Tse EYY, Lam KF, Mak KY, Lam EWW. What do primary care doctors get out of a year-long postgraduate course in community psychological medicine? *International Journal of Psychiatry in Medicine*. 2011;42(2): 133-149.
- Lam TP, Wong JGWS, Ip MSM, Lam KF, Pang SL. Psychological wellbeing of interns in Hong Kong: what causes them stress and what helps them. *Medical Teacher*. 2010;32(3):e120-6.
- Lam TP, Lam YY. Medical education reform: the Asian experience. *Academic Medicine*. 2009 Sep;84(9):1313-7.
- Lam TP, Wan X, Ip MS. Current perspectives of medical education in China. *Medical Education*. 2006;40:940-949.
- Lam TP, Lam KF, Tse EYY. Why do primary care doctors undertake postgraduate diploma studies in a mixed private/public Asian setting? *Postgraduate Medical Journal*. 2006;82:400-403
- Lam TP, Khoo US, Chan YS, Cheng YH, Lam KF. The first batch of graduates of a new medical curriculum in Asia: how do the teachers see them? *Medical Education*. 2004;38:980-986.
- Lam TP, Lam KF. Why do family doctors prescribe antibiotics for upper respiratory tract infection? *International Journal of Clinical Practice*. 2003;57(3):167-169
- Lam TP, Irwin M, Chow LWC, Chan P. Early introduction of clinical skills teaching in a medical curriculum - factors affecting students' learning. *Medical Education*. 2002;36:233-240.
- Lam TP. The strengths and weaknesses of Traditional Chinese Medicine and Western Medicine in the eyes of some Hong Kong Chinese. *Journal of Epidemiology and Community Health*. 2001;55:762-765.
- Lam TP, Irwin M, Chow LWC, Chan P. The use of focus group interviews in Asian medical education evaluative research. *Medical Education*. 2001;35(5):510-513.
- Lam TP, Lam KF. Management of upper respiratory tract infection by family doctors. *International Journal of Clinical Practice*. 2001;55(6):358-360.
- Lam TP, Chan TYK. Management of NIDDM by family doctors in Hong Kong: A questionnaire survey. *International Journal of Clinical Practice*. 1999;53(2):89-92.
- Lam TP. Is There a Better Chinese Term for Our College? *The Hong Kong Practitioner*. 1993;15(3):2524-2525.

**Maria Elena Medina-Mora, Ph.D.**

General Director, Instituto Nacional de Psiquiatria Ramon de la Fuente Muñiz  
Calzada Mexico-Xochimilco No. 101, Colonia San Lorenzo Huipulco, Delegacion Tlalpan,  
Mexico D.F., 14370, Mexico

**Present Appointment**

2008-Present General Director of the National Institute of Psychiatry Ramón de la Fuente Muñiz

**Education**

1979 M.A. Psychology Iberoamerican University  
1993 Ph.D. Social Psychology Universidad Nacional Autónoma de México (UNAM), National Autonomous University

**Current Research Activities**

- UNICEF, UNDCP, DIF National Census of working children in 101 cities (Responsible for the addiction's component) 1999.
- Principal Investigator: 1) 2000 WHO initiative in mental health. Mental disorders in México: Addictions, Health Needs and Health Care Utilization. INP/CONACYT. Epidemiology: The National Survey on Psychiatric Epidemiology. The major goal of this project is to study trends in the prevalence and correlates of mental disorders in the Urban population of México 18-65 year olds. 2000-2005.
- Alcohol in Mexican-Origin Groups: US and Mexican Surveys .ARG 2003
- UC/MEXUS. Intervention programs among workers and their families, 2004.
- OPS/CONACYT: Cost Effectiveness of interventions to reduce burden of alcohol abuse, depression and schizophrenia. 2009-2009.
- Ministry of Health, Mexico. National and local surveys on addictions 1998, 2002, 2005, 2008

**Selected Publications**

1. Scott KM, Von Korff M, Alonso J, Angermeyer M, Bromet E, Fayyad J, De Girolamo G, Demyttenaere K, Gasquet I, Gureje O, Haro JM, He Y, Kessler R, Levinson D, **Medina-Mora ME**, Oakley Browne MA, Ormel J, Posada-Villa J, Watanabe M, and Williams D.(2008). Mental-physical co-morbidity and its relationship with disability: results from the World Mental Health Surveys. *Psychological Medicine* 39(1), 33-43.
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3. Lara C, Fayyad J, De Graaf R, Kessler R, Aguilar-Gaxiola S, Angermeyer M, Demyttenaere K, De Girolamo G, Haro JM, Jin R, Karam EG, Lépine JP, **Medina-Mora ME**, Ormel J, Posada-Villa J, and Sampson N.(2009). Childhood predictors of adult attention-deficit/hyperactivity disorder: Results from the World Health Organization World Mental Health Survey Initiative. *Biological Psychiatry* 65(1), 46-54.
4. **Medina-Mora ME** and Real T.(2008). Epidemiology of inhalant use. *Current Opinion in Psychiatry* 21(3), 247- 251.
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9. Orozco R, Borges G, Benjet C, **Medina-Mora ME**, and López-Carrillo L.(2008). Traumatic life events and posttraumatic stress disorder among Mexican adolescents: results from a survey. *Salud Pública de México* 50(Supl. 1), S29-S37.
10. Rodríguez AC, Martínez NA, Juárez F, López EK, Carreño S, and **Medina-Mora ME**.(2008). Relación entre el consumo de tabaco, salud mental y malestares físicos en hombres trabajadores de una empresa textil mexicana. *Salud Mental* 31(4), 291-297.

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Consultant Psychiatrist, Rawalpindi General Hospital  
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**University Appointments**

Professor and Head of Institute of Psychiatry, Rawalpindi Medical College, University of Health Sciences, Pakistan

**Hospital Appointments**

1991 – Present Visiting Consultant Psychiatrist, Institute of Psychiatry & Rawalpindi General Hospital

**Selected Publications**

1. B. Rahman A, Nizami A, Minhas A, Niazi R, Slatch M, Minhas F. (2006) e-Mental Health in Pakistan - a pilot study of training and supervision in child psychiatry using the internet. *Psychiatric Bulletin*. 30: 149-152
2. Iqbal K, Minhas FA, Niazi RS, Mujshid A. (2004) Demographic Characteristics of Narcotic Addicts. *Journal of Rawalpindi Medical College*, 8(1). 21-25.
3. Yusuf A, Sheikh W I, Minhas F, Khokar R A. (2002) Trichobezoar: Surgical and Psychiatric Management. . *Journal of College of Physicians and Surgeons of Pakistan*, 12 (2). 133-136.
4. Minhas F.A., Farooq S., Rahman A., Husain N. (2001) In-patient psychiatric morbidity in a tertiary care mental health facility: A study on a psychiatric case register. *Journal of College of Physicians and Surgeons of Pakistan*, 11, 224-228.
5. Minhas FA. (2001) Community Psychiatry in Developing Countries – a misnomer? *Psychiatric Bulletin*, 2,226-227.
6. Minhas FA. (2000) Attitudes of Medical Students towards psychiatry in Pakistan. *Journal of College of Physicians and Surgeons of Pakistan*, 10, 69-72.
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8. Mumford, D.B., Minhas, F.A. et al. (2000) Stress and psychiatric disorder in urban Rawalpindi: Community Survey. *British Journal of Psychiatry*, 177, 557-562.
9. Minhas, FA. et al (1999) Prevalence and recognition of depressive disorder at primary health care centre in Pakistan. *Journal of the Institute of Medicine*, 21, 19-27.
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11. Minhas, FA. et al (1995) Detection of depression in medical inpatients using depression scale. *Journal of College of Physicians and Surgeons of Pakistan*, 5 (2).
12. Minhas FA, Iqbal K, Mubbashar MH. (1995) Validation of Self-Reporting Questionnaire in primary care setting of Pakistan. *Journal of Pakistan Medical Association*, 2, 60-64.
13. Minhas FA. (1993) Detection of anxiety in medical inpatients using Brief Anxiety Scale. *Pakistan Journal of Clinical Psychiatry*, 3.
14. Minhas FA, Mubbashar MH. (1985) Schizophrenia. *Medical News*, 46, 22-23.

**Since 2006 I have been involved as PI or co-investigator on 15 different research projects, including:**

- 2006 – PI, Maternal depression and duration of breastfeeding – a prospective study. Institute of Psychiatry, Rawalpindi & University of Manchester, Higher Education Commission funded and led by Prof Minhas.
- 2006 – Collaborator, Community management of mental retardation in Pakistan: An exploratory study. R21. Funded by National Institute of Health (USA) and led by Dr Ilyas Mirza, HEC foreign-faculty at IOP.
- 2005 - Co-investigator, Prevalence of Depressive Illness in Women attending the Postnatal Clinic of a Tertiary Care Hospital, with the department of Obstetrics and Gynaecology, Rawalpindi General Hospital.
- 2005 - Co-investigator, Exploring the Aspirations of Female Doctors for Future Professional Careers, a study in collaboration with the National Institute of Psychology, Islamabad.
- 2005 - Co-investigator, The Epidemiology and Natural History of Functional neuro-muscular disorders (Conversion Disorder), a multi-centre study with University of Leeds and University of Cardiff, UK.
- 2005 - Co-investigator, The First Symptoms of Alzheimer’s Disease: A Cross Cultural Study with University of Manchester, UK.
- 2004 – Collaborator, Development and Evaluation by Randomized Trial of a Community-Based Early Multimodal Intervention (EMI) for Depressed Mothers and their Infants in Rural Rawalpindi, Pakistan with School of Psychiatry and Behavioural Sciences, Manchester, UK. Wellcome Trust funded