The European Study of the Epidemiology of Mental Disorders (ESEMeD/MHEDEA 2000) Project: rationale and methods

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ABSTRACT The European Study of the Epidemiology of Mental Disorders (ESEMeD/MHEDEA 2000) is a new cross-sectional study investigating the prevalence and the associated factors of mental disorders, as well as their effect on health-related quality of life and the use of services in six European countries. This paper describes the rationale, methods and the plan for the analysis of the project.

A total of 22,000 individuals representative of the non-institutionalized population aged 18 and over from Belgium, France, Germany, Italy, the Netherlands and Spain are being interviewed in their homes. Trained interviewers use a computer-assisted personal interview (CAPI) including the most recent version of the Composite International Diagnostic Interview (CIDI, 2000), a well-established epidemiological survey for assessing mental disorders.

This is the first international study using the standardized up-to-date methodology for epidemiological assessment. Sizeable differences in prevalence, impact and level of need that is met by the health services are expected.

The analysis of these differences should facilitate the monitoring of ongoing mental health reform initiatives in Europe and provide new research hypotheses.

Key words: cross-sectional survey, disability, mental disorders, mental health services, prevalence

Mental disorders are a major source of disability in industrialized countries. According to the World Health Organization (WHO), major depression is forecast to be the condition causing the second highest loss in disability-adjusted life years by the year 2020 (Murray, Lopez and Jamison, 1994). Costs of mental health services are high

and yet there is evidence that the coverage of mental health care is insufficient to address current need (Rice and Miller, 1995). The ESEMeD/MHEDEA 2000 project has been designed to examine the prevalence, the impact and the patterns of treatment of mental disorders in European countries. The study is a joint effort of a number of institutions with the financial support of the European Commission and GlaxoSmithKline and the endorsement of the WHO. The project is included in the WHO World Mental Health 2000 (WMH200). This paper presents an overview of project objectives and methods.

Prevalence and burden of mental disorders

Prevalence data obtained both in general population surveys (Canino, Bird, Shrout, Rubio-Stipec, Bravo, Martinez, Sesman and Guevara, 1987; Faravelli, Guerrini Degl'Innocenti and Giardinelli, 1989; Faravelli, Guerrini, Aiazzi, Incerpi and Pallanti, 1990: Hwu, Yeh and Chang, 1989; Orn, Newman and Bland, 1988; Robins, Helzer, Weissman, Orvaschel, Gruenberg, Burke and Regier, 1984; Wells, Golding and Burnam, 1989) and primary care surveys (Olfson, Fireman, Weissman, Leon, Sheehan, Kathol, Hoven and Farber, 1997; Ormel, VonKorff, Ustun, Pini, Korten and Oldehinkel, 1994; Spitzer, Kroenke, Linzer, Hahn, Williams, deGruy, Brody and Davies, 1995) have documented that up to a quarter of the population of Western countries meets criteria for an anxiety or mood disorder in a given year (Kessler, McGonagle, Zhao, Nelson, Hughes, Eshleman, Wittchen and Kendler, 1994). Recent studies have provided information concerning the magnitude of these problems in some European countries. However, data are incomplete and comparability of the studies is limited. The DEPRES survey (Depression Research in European Society, 1995), conducted in four European countries and based on interviews with approximately 78,000 subjects, showed an estimated six-month prevalence of 6.9% for major depression and demonstrated that these disorders place a significant burden on the community (Lepine, Gastpar, Mendlewicz and Tylee, 1997). However, this study was limited by very a low response rate and high variability in the sampling frame across countries. Bijl et al. conducted the Netherlands Mental Health Survey and Incidence study (NEMESIS), a national population-based prospective survey in 1996 using an in-home structured diagnostic interview (Bijl, Ravelli and van Zessen, 1998). The results demonstrated a significant prevalence of mental disorders in the Netherlands (lifetime: 41%: 12-months: 23%).

It has been noted that the high-prevalence estimates of mental disorders may not be very informative because many of the community cases may have self-limiting conditions (Orn, Newman and Bland, 1988). However, few studies have addressed this issue (Bijl and Ravelli, 2000a; Jenkins, Lewis, Bebbington, Brugha, Farrell, Gill and Meltzer, 1997) because they have not included detailed questions about the level of severity or impairment.

Factors associated with mental disorders

There is general interest in understanding social and biological risk factors associated with disease. A number of social factors appear to play a critical role in the development and response to symptoms of mental illness, including family and community dynamics and stress and cultural factors (Alderete, Vega, Kolody and Aguilar-Gaxiola, 2000). There is great interest in documenting secular changes in society that could help account for these changes. Probable contributing factors include increases in geographic mobility, the decline in the nuclear family, and the decline in religiosity. Recent research in several countries has documented that interpersonal problems are among the most important adverse consequences of earlyonset psychiatric disorders. People with early onset disorders in other countries have been shown to have higher rates of premature sexual activity, early marriage, marital instability, and relationship violence.

Burden of mental disorders

A number of recent studies suggested that the effects of mental disorders on quality of life (especially social role functioning) are enormous. Bijl and Ravelli (2000a) reported that mood disorders were associated with poor levels of vitality and social functioning. The study suggested that comorbidity strongly aggravated disability. The disability associated with the high prevalence of mental disorders appear to contribute about the 15% of the disability adjusted years of life (DALYs) lost in the developed world (US Department of Health and Human Services, 1999). Detailed data about the impact of mental disorders in the general population are still scarce, however.

Use of services for mental disorders

One of the most pressing health-policy issues in all industrialized countries is how to provide access to high-quality mental healthcare to people with emotional problems (US Department of Health and Human Services Agency for Health Care Policy and Research, 1993; World Health Organization (WHO), 2000). Several population-based regional and national studies in the US during the mid 1980s and early 1990s showed that most people with psychiatric problems do not receive professional help (Katz, Kessler, Frank, Leaf, Lin and Edlund, 1997b; Kessler, Frank, Edlund, Katz, Lin and Leaf, 1997; Regier, Narrow, Rae, Manderscheid. Locke and Goodwin. Furthermore, among those who did access the formal care system, there were low rates of evidence-based active treatment, defined by a combination of number of visits and self-reported use of appropriate medications (Katz, Kessler, Lin and Wells, 1998).

Valid and comparable population-based information in other developed countries about use of mental healthcare services for different need groups is limited. Most developed countries have not conducted national or regional surveys that have addressed services use, access to care, and unmet need. However, there have been several exceptions. The DEPRES survey showed that only a quarter of the subjects with a severe major depressive episode received antidepressants. Another important exception was the Ontario Mental Health Supplement (OMHS) to the 1990 Ontario Health Survey and the National Comorbidity Survey (NCS). This showed that, although there were marked differences in patterns and correlates of services use in Ontario compared to the US, underuse of services for those with mental disorders, disability, and distress was apparent in both regions (Bland, Newman and Orn, 1997; Katz, Kessler et al., 1997b; Katz, Kessler, Frank, Leaf and Lin, 1997a; Katz, Kessler et al., 1998; Kessler, Frank et al., 1997; Olfson, Kessler, Berglund and Lin, 1998; Parikh, Lin and Lesage, 1997). Although differences in provider categories and field dates between the North American surveys and NEMESIS limit direct comparison of services use, two publications that addressed comparative services use suggested that the Netherlands has a pattern of use more similar to Ontario, Canada than the US (Alegria, Bijl, Lin, Walters, Kessler, 2000; Bijl and Ravelli, 2000b).

Against this background, the ESEMeD/MHEDEA-2000 project was launched to investigate the issues mentioned above at the European level. Data are being collected as this manuscript is being prepared. In what follows, the project objectives and methods are briefly described. Details on the specific methods of the project protocol are available at the project public Web page (www.esemed.org).

Objectives

The ESEMeD/MHEDEA 2000 project has four main objectives:

- To estimate and compare across selected European countries the one-month, 12-month and lifetime prevalence of the most common mental disorders in the general population. The disorders included are: anxiety disorders (generalized anxiety disorder, panic disorder, simple phobia, social phobia, agoraphobia, obsessive compulsive disorder, post-traumatic stress disorder and separation anxiety disorder), mood disorders (major depression, dysthymia, premenstrual dysphoric syndrome) and other disorders (attention deficit, conduct disorder, hyperactivity disorder, oppositional-defiant disorder, substance use disorders, eating disorders, and personality disorders).
- To assess and compare, across selected European countries, the independent association of mood and anxiety disorders with sociodemographic factors (gender, age, education, and urban/rural location) and selected risk factors (including family history, ethnicity, childhood experiences, religion, partnership status, and sexual problems, among others).
- To assess and compare, across selected European countries, the quality of life (disabilities and general health perceptions) of persons with different mood and anxiety disorders and to analyse how other variables (such as physical medical conditions and sociodemographic factors) may influence these outcomes.
- To assess, and compare, across selected European countries, the treatment for psychiatric disorders and to evaluate the unmet need and the quality of care received. The study will investigate in detail the use of services across formal and informal care settings and the variations in care seeking and

patterns of treatment by levels of need, the quality of treatment and care received based on standards to be developed for common mood and anxiety disorders, the need for treatment and other care, the use of psychoactive drugs, the duration of treatment (current and in the past 12 months), and the use of mental healthcare services.

Sampling and recruitment

The ESEMeD/MHEDEA 2000 study is a cross-sectional 'in person' household interview survey based on probability samples that are representative of the adult, non-institutionalized population of six European countries: Belgium, France, Germany, Italy, the Netherlands, and Spain. In each country, a nationally representative household sample of individuals aged over 18 years of age, non-institutionalized (excluding individuals living in prisons, hospitals, nursing home, hotels, and other institutions), male or female, with a known household addresses, and able to understand the language in which he or she is being assessed (the official language of the country). Persons who are temporarily away from home are eligible for the study – they are either interviewed when they return home (for example, if they are temporarily hospitalized) or are followed to their temporary addresses (for example, students).

A stratified, multi-stage, clustered area probability sample design without replacement was followed in each country. Replacement is not allowed to ensure that every individual has a known probability of selection. Differences in access to specific population data dictate slightly different approaches in each country.

The *first stage sampling units* consists of municipalities. The largest cities in each country are automatically included in the sample. Municipalities are stratified by geography and population size. Selection of municipalities is proportional to size within strata.

The second stage sampling units are persons selected from these municipalities. In countries where a personal registry was available, such as Belgium, Germany and Italy, it is used as the sampling frame for the selection of subjects. In the Netherlands and Spain, the addresses are selected first and the subjects are selected in a subsequent step. In France, a telephone directory is used as the sampling frame. Second stage units are also proportional to population size and selected using a random start.

About 22,000 individuals are expected to provide a complete and valid interview. This will assure sufficient

precision for most cross-country comparisons. The study has been specifically designed to be sufficiently powerful to estimate confidently the proportion of individuals with selected diagnoses who do not receive necessary treatment. For instance, in major depression we expect this to happen in approximately a quarter of those with 12-month prevalence.

Survey instrument

The Composite International Diagnostic Interview (CIDI)

The CIDI (Composite International Diagnostic Interview) (WHO, 1990) is a comprehensive, fully structured diagnostic interview for the assessment of mental disorders. It provides, by means of computerized algorithms, lifetime and current (12 months and one month previous to the interview) diagnoses according to accepted criteria such as the International Classification of Diseases (ICD-10) and the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV) (American Society of Psychiatry, 1994; World Health Organization, 1993). During the CIDI interview, respondents are asked questions about symptoms related to mental disorders. If enough symptoms are endorsed, and these symptoms occur in a pattern that suggests a diagnosis might be present, respondents are asked about the onset and the recency of the particular cluster of symptoms that they have endorsed. The paper-and-pencil version of the CIDI has been shown to be reliable and valid (Wittchen, Robins, Cottler, Sartorius, Burke and Regier, 1991; Wittchen, 1994).

For the ESEMeD/MHEDEA 2000 study, a new version of the instrument, the CIDI 2000, was developed and adapted by the Coordinating Committee of the WHO-WMH2000 Initiative. This version is longer and it is computerized to facilitate its administration (for instance, it allows using different itineraries or different proportions of respondents answering each questionnaire section in order to maximize the information collected per time unit). The CIDI 2000 includes fully structured questions on presence, persistence and intensity of clusters of psychiatric symptoms followed by probes for age of onset and lifetime course. The screening section (the Life-Time Psychiatric Screening Instrument) is located at the beginning of the questionnaire and is administered to all the respondents. All subjects responding positively to a screening question are

eligible to complete the corresponding CIDI section, although some exceptions apply.

The CIDI 2000 also gathers information on risk factors, symptoms, disability and quality of life, use of services, and use of medication (see Table 1). Information on risk factors includes: family history, stressful emotional experiences, life events, childhood disorders, personality, spouse relationship, sexual life, religion, age, gender, ethnicity and social class.

The CIDI 2000 also incorporates measures of the severity of depression and anxiety disorders. These measures are based on modifications of standardized instruments (for example, the short version of the Hamilton Scale for depression (Hamilton, 1960) or the short version of the Hamilton Scale for anxiety disorders (Hamilton, 1959)). Also embedded in the CIDI 2000 computerized questionnaire are sections that assess dimensions of health-related quality of life as measured by the WHO Disablement Assessment Schedule II (WHO-DAS-II), the Short Form SF-12 Health Survey (SF-12) (Ware, Kosinski and Keller, 1995) and the EuroQol 5D (EQ-5D) (The EuroQol Group, 1990). A set of questions about the burden imposed by illness on the family is included. The complete list of standard severity scales used in the study is shown in Table 2.

A battery of questions regarding use of services has also been included. Items address whether respondents sought help from a professional (psychiatrist, psychologist, general practitioner and other medical doctors) for specific emotional problems, co-morbid conditions and general health. The questions also assess the reasons for use or non-use of health services, whether the respondents received treatment, the type of treatment (name of medication and dose), the duration and intensity of care by type of provider and clinical setting, and barriers to care. While these detailed questions focus mainly on the prior 12 months, we have also included more basic questions about timing and receipt of services over the continuum of lifetime symptoms. Also included is a set of questions about whether respondents have been under the care of a doctor or have received treatment for a standard list of chronic physical health conditions (such as asthma, diabetes or hypertension, among others).

The CIDI 2000 was first produced in English and it underwent a rigorous process of adaptation in order to obtain conceptually and cross-culturally comparable versions in each of the target countries/languages. This

process included forward and backward translations, review by expert panels, pre-testing using cognitive interview and debriefing techniques and the intervention of focus groups.

Survery procedures

Eligible individuals are asked for their informed consent to perform a face-to-face interview. The interview takes place in the respondent's home and requires an average of less than 90 minutes to complete. Questions are administered by a trained lay interviewer using computer-assisted personal interviewing (CAPI) that has been programmed centrally using the Blaise software system. The Blaise program is an interviewing application developed by Statistics Netherlands (1999), which guides the interviewer through the respondent selection process, delivers the questions, and directs the interviewer through the questioning sequence.

A survey firm in each country has been contracted to undertake the survey fieldwork. A detailed description of work was negotiated with each survey firm to ensure standardization between countries and specifically to document all scientific and administration elements that could affect comparability of data. All interviewers have received the same training and adhere to the same protocol regarding contacts and interview administration. The trainers of the interviewers attended a one-week training course, carried out by WHO-certified trainers. A pre-test phase was carried out in each country participating in the project. This used a convenience sample of 50 respondents age 18 or older and provided the opportunity to evaluate the survey procedures on a small scale and to make further adjustments of the computerized version of the CIDI 2000.

Clinical reappraisal

After the main (CIDI) interview, a clinical reappraisal study is being carried out with 600 respondents. The study aims at comparing the CIDI diagnoses obtained by the lay interviewer with those obtained by the reappraisal clinician administering the Axis I Structured Clinical Interview for DSM-IV (SCID), a semistructured interview that has been found reliable in community surveys (First, Spitzer and Williams, 1995). The clinical reappraisal interviewers were trained centrally to assure uniform calibration in the evaluation. It included an initial training of more than 40

Table 1. List of sections of the Composite International Diagnostic Interview (CIDI) 2000

Section	Number of items	Administration time (minutes) †
Screening	51	12.21
Depression	232	2.51
Dysthymia screen	86	2.48
* Mania		•
* Irritable depression		•
Panic disorder	165	2.41
Specific phobia	163	4.58
Social phobia	114	7.3
Agoraphobia	105	5.64
Generalized anxiety disorder	180	2.4
Post-traumatic stress disorder	813	9.89
* Tobacco		•
Substance use	386	4.96
Personality, part 1	55	•
Obsessive-compulsive disorder	155	2.58
Eating disorder	86	0.33
Premenstrual dyndrome	72	2.38
Psychosis screen	21	2.21
Suicidality	40	0.42
Personality, part 2	20	•
Pharmacoepidemiology		1.98
Services	245	1
Chronic conditions	184	8.3
30-Day functioning	59	7.51
30-Day symptoms	26	•
Family burden	87	2.68
Personality disorders screen	34	•
Employment + spouse employment section	60 + 23	2.61
Finances	14	3.58
Marriage	86	1.13
Children	44	0.4
* Social networks		•
* Life events		•
Demographics	108	2.08
Childhood	211	1.75
Attention-deficit/hyperactivity	147	2.3
Conduct disorder	61	2.73
Oppositional-defiant disorder	68	1.51
Separation anxiety disorder	111	2.25
‡ Dementia		•
Health state	6	1.48

Administered to:

☐ All respondents ☐ Only respondents with positive screening ☐

Respondents with screen positive + a random subgroup of screen negatives

 $[\]ast$ Sections not included in the ESEMeD questionnaire.

[†] Median values, based on 823 initial interviews.

[‡] For documenting Dementia, a paper version adaptation of the MMSE is used instead.

Table 2. Standard scales included in the Composite International Diagnostic Interview (CIDI) 2000

MOOD DISORDERS:

Depression:

Hospital Anxiety and Depression Scale (HADS)

*Irritable Depression:

• Hospital Anxiety and Depression Scale (HADS)

ANXIETY DISORDERS

Panic Disorder:

- Panic Disorder Severity Scale (PDSS) (Shear)
- Sheehan Disability Scale

Generalized Anxiety Disorder:

• Hospital Anxiety and Depression Scale (HADS)

Obsessive-Compulsive Disorder:

 Yale-Brown Obsessive Compulsive Scale (Y-BOCS) – separate scales for Obsessions and Compulsions.

OTHER HEALTH-RELATED SCALES

Chronic Conditions:

- Migraine
- Daytime Sleepiness Scale
- Insomnia Scale
- IBS Irritable Bowel Syndrome
- Perceived Treatment Efficacy

30-day Symptoms:

- Non-Specific Distress Scale
- Dissociative Experience Scale Short Form (DES)

Health Status:

- WHO Disablement Assessment Schedule II (WHODAS-II)
- EuroQol (EQ-5D)
- Short Form 12 (SF-12)

OTHER DISORDERS

*Tobacco:

• Fagerstrom Test for Nicotine Dependence (FTND)

Personality, part 1:

Zuckerman Personality Scales

Personality, part 2:

- Internal Locus of Control scale
- Luck scale
- Power scale
- Self-steem scale
- Fatalism scale
- Iustice scale

Personality Disorders Screen:

International Personality Disorder Examination(IPDE) screen

OTHER SCALES

Marriage /Steady Partnership:

• Dyadic Adjustment Scale (DAS)

Childhood:

- Family History Research Diagnostic Criteria (RDC) interview
- Parental Bonding Instrument

hours, plus group videotaped interviews with a WHO-certified trainer and up to five tape-recorded supervised interviews.

The SCID was adapted to the specific purpose of the clinical reappraisal study. Only the sections covered in the main CIDI interview have been maintained (specifically, anxiety, depressive and substance-use disorders) and only 12-month prevalence is assessed. The purpose of the clinical reappraisal interview is to allow clinicians to probe and clinically evaluate responses already obtained by lay interviewers using the CIDI, so the

results of positively answered screening questions in the CIDI interview are incorporated into the SCID questionnaire provided to the clinician (CIDI screening questions refer to lifetime symptoms, whereas SCID ratings will refer only to the previous 12 months). In order to increase the test's ability to evaluate subthreshold cases, most of the skip rules embedded in the original SCID have been deleted. Clinical severity scales have been incorporated to the SCID and are interleaved within the modules to ease administration (for example, the MADRS (Montgomery and Asberg,

^{*}Sections not included in the ESEMeD questionnaire.

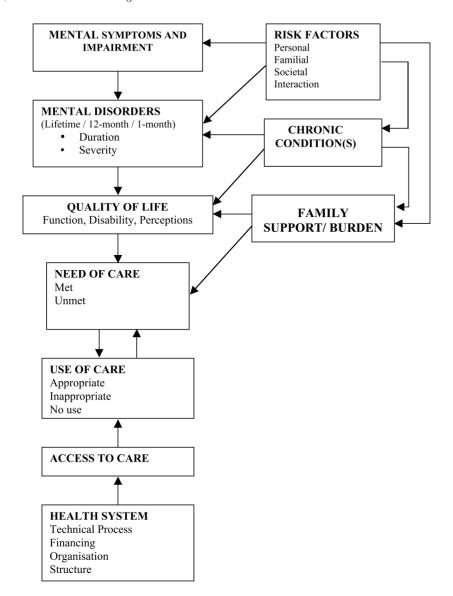


Figure 1. Conceptual framework of the ESEMeD/MHEDEA 2000 project: relationship between main study variables.

1979) for depression or the HAD for generalized anxiety disorder). At the end of the interview, the clinician will also rate the Global Assessment of Functioning (GAF) scale, a standard measure of overall clinical severity used to assess need for treatment (National Institute of Mental Health, 1976).

Data management and control

Data are being received, checked and stored at the project data centre, the Institut Municipal

d'Investigació Mèdica (IMIM), in Barcelona, Spain. The survey firm in each country is securely transferring the raw data files to an IMIM server via a secure Web site and IMIM is transferring information back using the same site. This site uses the transmission protocol SSL (Secure Socket Layer) to encrypt data that flow through the server.

A data quality-control plan has been implemented with the goal of ensuring that data collection activities yield the highest quality data possible and are

Table 3. Selected indicators of the mental health care system in each of the ESEMeD project countries

Social Social Social Social National Health Social Insurance I		Belgium	France	Germany	Italy	Netherlands	Spain
2,125 (WHO, 2000) (WHO, 2000) (WHO, 2000) Essential drugs free Co-payments of 15% Others: 30% or 60% co-payment (Lassey et al., 1997) (Lassey et al., 1997) Mental Health Care System 1.5 (Temes Montes and Gil Redrado, 1997) Gil Redrado, 1997) Gil Redrado, 1997) Gil Redrado, 1997) O.1 O.2 (Kovess et al., 1995) Cazsey et al., 1997) (Hease Montes and Caze, 2000) O.3 (Kovess et al., 1995) Limited Wedium Higher Lower		Social Insurance		Social Denomination System Social Insurance	National Health System	Social Insurance	National Health System
Essential drugs free Co-payments of 15% (Lassey et al., 1997) (Lassey et al., 1997) (Lassey et al., 1997) (Lassey et al., 1997) Mental Health Care System 1.5 (Temes Montes and Gil Redrado, 1997) (Rovess et al., 1995) (Redrado, 1997) (Rovess et al., 1995) (Redrado, 1997) (Redrado, 1997) (Ge Girolamo and Office, 1998) (Ae Girolamo and Office, 1998)		1,738 XHO, 2000)	2,125 (WHO, 2000)	2,365 (WHO, 2000)	1,824 (WHO, 2000)	1,911 (WHO, 2000)	1,211 (WHO, 2000)
1.5	Esse Oth or 8 (Las	ers: 25%, 50, 60 0% co-payment sey et al., 1997)	Essential drugs free Others: 30% or 60% co-payment (Lassey et al., 1997)	Co-payments of 15% with generic prices (Lassey et al., 1997)	Co-payment of 40% (Lassey et al., 1997)	Fully covered with tight price control. (Lassey et al., 1997)	Free for pensioners, 40% co-payment for the rest
1.5			Me	ntal Health Care System			
6* (Kovess et al., 1995) (Lassey et al., 1997) (de Girolamo and Cozza, 2000) n.a. (Rederal Statistical (de Girolamo and Office, 1998) Cozza, 2000) Limited Yes Very limited Medium Higher Lower	Gil Gil	1.8 mes Montes and Redrado, 1997)	1.5 (Temes Montes and Gil Redrado, 1997)	1.6 (Temes Montes and Gil Redrado, 1997)	0.6 (Temes Montes and Gil Redrado, 1997)	1.83 (Andrews and Henderson, 2000) 1.6 (Temes Montes & Gil Redrado, 1997)	0.7 (Temes Montes and Gil Redrado, 1997)
n.a. 0.09 0.03 (Federal Statistical (de Girolamo and Office, 1998) Cozza, 2000) Limited Yes Very limited Medium Higher Lower		0.14	6* (Kovess et al., 1995)	O.1 (Lassey et al., 1997)	0.08 (de Girolamo and Cozza, 2000)	0.11 (Andrews and Henderson, 2000)	0.05 (Temes Montes and Gil Redrado, 1997)
Limited Yes Very limited Medium Higher Lower	<u> </u>	0.32 RIZIV, 2000)	n.a.	0.09 (Federal Statistical Office, 1998)	0.03 (de Girolamo and Cozza, 2000)	0.03 (Brunenberg et al., 1995) (Temes Montes and Gil Redrado, 1997)	0.03) (Temes Montes and Gil Redrado, 1997)
Medium Higher Lower		Limited	Limited	Yes	Very limited	Yes	Very limited
		Medium	Medium	Higher	Lower	Higher	Lower

*per 1,000 patients per year

completed on time. The control procedures are organized at the local and central levels and are coordinated by staff at the data centre and by members of the scientific committee. The data centre is in charge of monitoring a number of procedures that are developed with the purpose of ensuring that survey firms implement data collection procedures according to survey specifications, that they complete the reporting requirements, and that interviewers perform according to the training specifications. A number of reports are evaluated centrally: weekly production, sample releases, verification, and monitor contacts. The duration of the interviews and several survey variables (for example, the proportion of positive responses to selected screening questions) is routinely monitored.

At the local level, the national investigator team is responsible for

- reviewing the responses to open-ended questions (to check informal information does not rule out a clinical diagnose of mental disorders, for instance because symptoms are due to a physical illness);
- verifying at the survey firm headquarters the contact and the verifications records, the mailing of the study brochure and letter, and the informed consent and the contact information files.

Conceptual model and analysis plan

Figure 1 depicts the conceptual framework of the ESEMeD/MHEDEA 2000 project, which will govern the analysis. The central part of the figure illustrates the relationships between mental disorders (and the role of duration and severity), the individual's quality of life, need for care, and the extent to which this need is met. Additionally, risk factors, medical conditions and family support/burden may have a modifying role in this relationship. Beyond this central part, there are a number of characteristics that may influence the previous set of relations in a causal way.

The analyses will obviously focus on the main project objectives. Specifically, the prevalence of 15 psychiatric disorders and their co-morbid combinations; the association of disorders with selected risk factors; the overall health perceptions of persons with different disorders; and the care-seeking, and the intensity of service used by persons with different mental morbidity and disability levels. All the analyses

will be carried out for each country and then between countries using a pooled sample. Analyses will be performed between groups of patients, for the conditions of interest to the study, as well as between individuals with and without these conditions. Analyses will use design-based estimation methods that take into consideration the clustering and weighting of the data to compute accurate significant tests. In addition, adjustment for non-response bias will be attempted (Kessler, Little and Groves, 1995).

Prevalence of mental disorders and associated risk factors Estimates of the prevalence and correlates of psychiatric disorders will focus on the 12 months prior to the interview. Focus will be on common disorders (generalized anxiety disorder, panic disorder, simple and social phobia and agoraphobia, and post-traumatic stress disorder; major depression, dysthymia, and bipolar disorder; as well as alcohol abuse and dependence, and drug abuse and dependence). The primary comorbid combinations of interest will be affective anxiety disorders and substance dependence/abuse. Major risk factors that will be analysed include personality, as well as characteristics related to family and sexual behaviour, and religion. Appropriate emphasis will be given to the directionality and the plausibility of a causal relationship, as well as to the validity limitations of the measurement of those factors.

Consequences of mental disorders on quality of life

The goal of this part of the analysis is to examine components of the quality of life of persons with different mental disorders. Those components will be the standardized global score and dimension-specific scores of the instruments used (WHO-DAS II, SF-12 and EQ-5D). First, we are interested in the measurement of the unique association of mental disorders (that is, adjusted for the presence of other medical and psychiatric conditions) with indicators of disability and overall health status and perceptions of wellbeing. Secondly, we will compare the impact of different mental disorders and groups of disorders with that of medical conditions and with the absence of any disorders. Finally, the proportion of disability attributable to mental disorders will be estimated by considering both the above-mentioned associations and the prevalence of each particular disorder and group of disorders examined. We will consider the interaction between mental and physical disorders.

Patterns of health services use for mental disorders and disability

In this part of the analysis, care seeking, intensity of service use and appropriateness of care will be examined. We will take several approaches in order to construct the need variables, based on the prevalence, persistence and severity of mental disorders (the impact of different approaches to the estimation of need will be taken into account through sensitivity analysis).

First, we will examine aspects of services use by number and recency of disorders, with care seeking (any contact made for a mental health symptom) as the dependent variable. Another set of analyses will assess factors associated with the type of provider and the setting of care. A wide range of mental health providers and institutions will be considered in addition to psychologists and psychiatrists. Intensity of care will also be examined.

A final set of analyses will probe more deeply into the quality of treatment for selected disorders, including depression and selected anxiety disorders, considering both pharmaco-therapy and psychotherapy treatment. Our approach to these analyses will decompose services utilization into its two components:

- any visit to a professional for a cluster of symptoms;
- service used (medications and visits) among people who made any contact with services.

All services analyses will emphasize the comparison across countries with the specific hypothesis that access to mental healthcare will modify the use of services. The indicators used to evaluate the level of access to mental health services in each country participating in the study are shown in Table 3.

The ESEMeD/MHEDEA 2000 project will emphasize the extent to which mental healthcare needs are met in each of the participating countries. The project will provide new knowledge that should be useful for future research, including testing hypotheses about the differences found across countries in the prevalence of mental disorders and associated risk factors, the burden of mental disorders and the use of treatment and care services for mental health problems.

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