

São Paulo Megacity Mental Health Survey – A population-based epidemiological study of psychiatric morbidity in the São Paulo Metropolitan Area: aims, design and field implementation

São Paulo Megacity – Um estudo epidemiológico de base populacional avaliando a morbidade psiquiátrica na Região Metropolitana de São Paulo: objetivos, desenho e implementação do trabalho de campo

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Abstract

The São Paulo Megacity Mental Health Survey is a population-based cross-sectional survey of psychiatric morbidity, assessing a probabilistic sample of household residents in the São Paulo Metropolitan Area, aged 18 years and over. Respondents were selected from a stratified multistage clustered area probability sample of households, covering all 39 municipalities, without replacement. Respondents were assessed using the World Mental Health Survey version of the World Health Organization Composite International Diagnostic Interview (WMH-CIDI), which was translated and adapted into the Brazilian-Portuguese language. Data was collected between May 2005 and April 2007 by trained lay interviewers. The World Mental Health Survey version of the Composite International Diagnostic Interview comprises clinical and non-clinical sections, arranged as Part I and Part II, producing diagnoses according to the Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition, and the International Classification of Diseases – 10th Revision. Mood, anxiety, impulse-control and substance use disorders, and suicide-related behavior, considered core disorders, as well as socio-demographic information, were assessed in all respondents. Non-clinical modules and non-core clinical sections (obsessive-compulsive disorder, post-traumatic stress disorder, gambling, eating disorders, neurasthenia, pre-menstrual disorders, psychotic symptoms and personality traits) were assessed in a sub-sample (2,942 respondents), composed by all respondents with at least one core disorder and a 25% random sample of those who were non-cases. A total of 5,037 individuals were interviewed, with a global response rate of 81.3%. Saliva samples were collected from 1,801 respondents, with DNA extracted stored pending further investigations.

Descriptors: Mental health; Cross-sectional studies; Mental disorders; Developing countries; Psychiatric epidemiology

Resumo

O Estudo Epidemiológico dos Transtornos Mentais São Paulo Megacity é um estudo de corte transversal de base populacional avaliando a morbidade psiquiátrica em uma amostra probabilística da população geral residente na Região Metropolitana de São Paulo, com 18 anos ou mais. Respondentes foram selecionados através de um processo probabilístico multiestratificado de domicílios, cobrindo os 39 municípios, sem substituição. Respondentes foram avaliados usando a versão desenvolvida para o Estudo Mundial de Saúde Mental (World Mental Health Survey) do Composite International Diagnostic Interview da Organização Mundial da Saúde, que foi traduzido e adaptado para o Português vigente no Brasil. A coleta de dados ocorreu entre maio/2005 e abril/2007, por entrevistadores treinados. O WMH-CIDI é composto por seções clínicas e não-clínicas, dispostas em duas partes, gerando diagnósticos de acordo com o Manual Diagnóstico e Estatístico de Doenças Mentais – Quarta Edição e a Classificação Internacional de Doenças – 10^a Revisão. Todos os respondentes receberam os módulos de avaliação de transtornos do humor, de ansiedade, do controle de impulsos, decorrentes do uso de substâncias psicoativas e comportamento suicida, considerados transtornos nucleares, assim como foram coletados dados sociodemográficos. Módulos não-clínicos e clínicos complementares (transtornos obsessivo-compulsivos, estresse pós-traumático, jogo patológico, alimentares, pré-menstruais, neurastenia, sintomas psicóticos e rastreamento de personalidade) foram aplicados àqueles que tiveram pelo menos um dos transtornos nucleares e a uma amostra aleatória de 25% dos negativos (2.942 respondentes). Um total de 5.037 indivíduos foi entrevistado, com uma taxa global de resposta de 81,3%. Amostras de saliva foram coletadas de 1.801 respondentes, com extração de DNA e armazenamento para investigação futura.

Descritores: Saúde mental; Estudos de corte transversal; Transtornos mentais; Países em desenvolvimento; Epidemiologia psiquiátrica

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Introduction

The field of psychiatric epidemiology has made considerable progress in the last few decades, with the expansion and refinement of the definitions and criteria for mental disorders in the main diagnostic systems: the World Health Organization's (WHO's) International Classification of Diseases (ICD),¹ and the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM),² allowing the use of operationalized diagnostic criteria within fully structured research questionnaires that can be administered by trained non-clinical interviewers. Using such procedures, community epidemiological surveys have started to be carried out in many countries, leading over time to the refinement of survey methods design and questionnaire development.

During the 1990s, the WHO published *The Global Burden of Disease* (GBD), a comprehensive assessment of the burden of mortality and disability from diseases, injuries and risk factors, taking into account the number of years of life lost (YLL) due to premature mortality and years of healthy life lost as a result of disability (YLD), as well as the combined measure DALY, or disability-adjusted life years.^{3,4} Unveiling the disability associated with several health conditions, the GBD has thrown light on the huge impact of mental disorders in the public health scenario, as psychiatric morbidity is a major source of disability, both in developed and developing regions. Depression is a major public health problem, owing to its high lifetime prevalence and its associated significant disability, accounting, in 2002, for 4.5% of the worldwide total burden of disease (DALYs) and 12% of the total years lived with disability (YLD), the greatest proportion of burden associated with non-fatal conditions.⁵ Depression was considered the leading cause of disease burden affecting women aged 15 to 44, in both developed countries (where it represented almost 20% of the burden) and developing countries (around 13%).³ Furthermore, it is estimated that Unipolar Major Depressive Disorder (MDD) will be the condition causing the second highest loss in DALYs in the world by the year 2020, exceeded only by ischemic heart disease.³ According to the WHO's Statistical Information System (WHOSIS),⁶ unipolar depression was the leading cause of DALYs in Brazil in 2002, accounting for 7.8% of the total DALYs. Other psychiatric conditions fall within the top 25 causes of

disability and premature death, including alcohol use disorders, in 5th place with 4% of the total DALYs, schizophrenia in 16th with 1.4%, bipolar disorder in 21st place with 1.2%, and illicit drug use disorders, which come 24th with 0.9%. Moreover, other mental health-related conditions also fall within the most important causes of disability and mortality, including violence, road traffic accidents, cirrhosis of the liver, and self-inflicted injuries.⁶ Neuropsychiatric disorders, added together, were the major cause of YLDs (34%) and DALYs (8.6%) and accounted for 2% of YLLs, ranking 12th.⁷

In an attempt to obtain more refined information on the epidemiology of psychiatric morbidity and its contribution to the global burden of disease in different cultures, the WHO, in collaboration with researchers from Harvard and Michigan Universities, launched the World Mental Health (WMH) Survey Initiative in the year 2000 (<http://www.hcp.med.harvard.edu/wmh/index.php>), a series of population-based epidemiological studies of the adult resident population, which is being carried out in over 30 participating countries around the world, conducted within the same methodological framework, as far as sampling procedures and instruments used are concerned.⁸⁻¹⁶ The *São Paulo Megacity Mental Health Survey* is the Brazilian component of the WHO-World Mental Health Survey, a population-based cross-sectional survey of psychiatric morbidity in the São Paulo Metropolitan Area (SPMA).

This paper covers the aims, design, field implementation and data management of the *São Paulo Megacity Mental Health Survey*, which assessed a probabilistic sample of the adult population living in the SPMA.

The São Paulo Metropolitan Area

The SPMA is formed by the state capital city of São Paulo and its 38 surrounding municipalities (Figure 1), covering a geographical area of 8,051 km², which is comparable to the area of small countries such as Puerto Rico (9,104 km²) and Lebanon (10,452 km²). It is amongst the most populous metropolitan areas in the world and occupies the top place in South America, with 20.7 million inhabitants,¹⁷ corresponding to almost 10% of the total population of the country and with a demographic density of 2,500 inhabitants/km². The SPMA is the major financial and

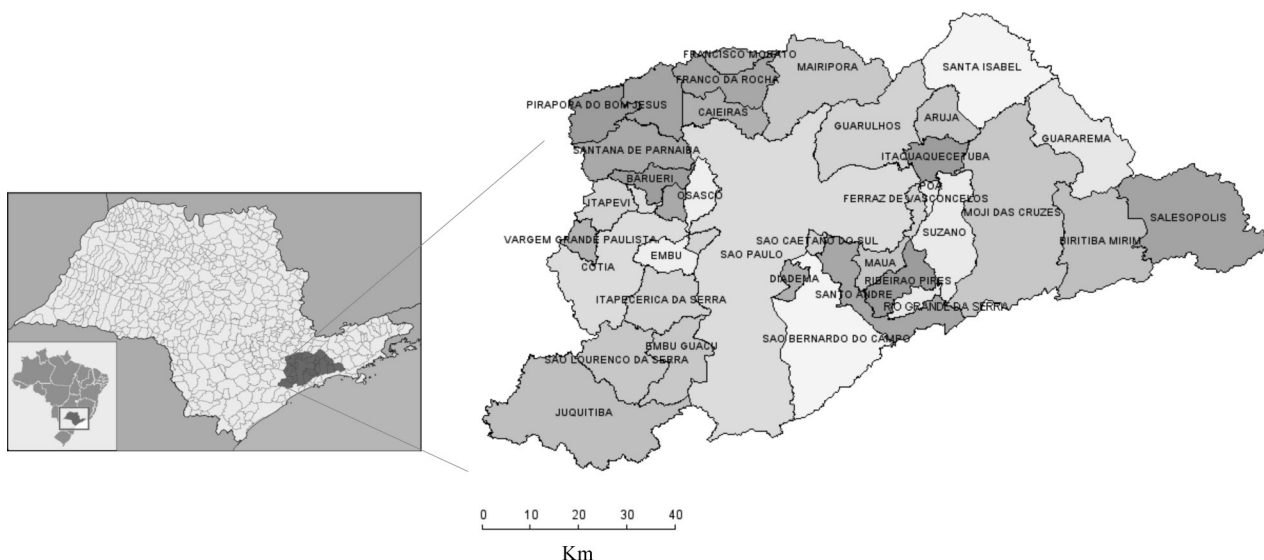


Figure 1 - The São Paulo Metropolitan Area

economic center of Brazil, with a Gross Domestic Product (GDP) reaching US\$ 99.1 billion in 2000, corresponding to 16.7% of total Brazilian GDP. The concentration of economic activities has attracted over the years a large number of migrants from all Brazilian regions, leading to a worsening of the overall quality of life, and increasing social and economic inequity in the region. According to the map of social exclusion/inclusion in the city of São Paulo,¹⁸ 8.6 million (83.5%) inhabitants have living conditions below a desirable standard, with low incomes and poor access to education, sanitation and housing, among other services. Such extremes of poverty exist side by side with wealth, resulting in social tension and high rates of urban violence. In a study describing the Human Development Index (HDI – which takes into account life expectancy, education and income) in the city of São Paulo, Pedroso¹⁹ showed that, although the city had an estimated global index of 0.841, there is significant socio-economic heterogeneity. The most developed neighborhood, Pinheiros, contrasts strongly with Jardim Angela (ranked 31st) with HDIs of 0.91 and 0.65 respectively, and with very distinct figures regarding life expectancy (78.2 vs 63.5 years), illiteracy rate (1.8% vs 10.3%), years of education (12.7 vs 5.8), and per capita income (R\$ 1,604.16 vs R\$ 155.19 per month).

The importance of the *São Paulo Megacity Mental Health Survey* within the context of the SPMA is emphasized and corroborated by the detection of worsening living conditions in large urban conglomerates and the identified positive association between social exclusion and psychiatric disorders.^{20,21}

Comprehensive epidemiological data on the levels of psychiatric disorders in the general population living in the São Paulo Metropolitan Area may contribute to the production of more precise indicators of quality of life and human development.

Aims of the *São Paulo Megacity Mental Health Survey*

The *São Paulo Megacity Mental Health Survey* is the first population-based study assessing a probabilistic sample of the general adult resident population of the whole São Paulo Metropolitan Area, with rigorous application of explicit diagnostic criteria and standardized fully-structured psychiatric interviews. The most relevant contribution of this study may be the ability to guide the allocation of the scarce mental health budget towards the development of health policies which match the needs of the local population.

The global aims of the *São Paulo Megacity Mental Health Survey* are to provide lifetime and 12-month prevalence estimates for a wide range of mental disorders in the general population; to identify correlates of psychiatric morbidity as well as its severity and associated impairment; to determine the patterns of use of health services; and to estimate the global burden of mental disorders.

The specific aims are to obtain more comprehensive and thorough information on each disorder assessed (operational diagnostic criteria, age of onset, clinical profile, duration and number of episodes, severity of symptoms, disability, treatment, family history); to assess a wide array of risk factors, enabling prevalence rates to be adjusted for socio-economic status, internal migration and other confounding variables; and to produce population-adjusted rates.

In addition, this study will also provide novel and relevant information in several important areas, such as mental and physical comorbidity, adverse outcomes following mental illness, use of services and identification of barriers to accessing them, costs of treatment, family burden, exposure to violence and traumatic events, and geographical referencing to assess the impact of

socio-economic status and societal infrastructure in mental health, providing information on which to base an adequate response to local problems. Finally, it will enable the establishment of a DNA Bank for future testing of candidate genes for a wide range of psychiatric conditions.

Method

1. Study design and target population

The *São Paulo Megacity Mental Health Survey* is a population-based cross-sectional survey of psychiatric morbidity, designed to be representative of the general population of Portuguese-speaking adults aged 18 or older who are permanent residents of non-institutionalized civilian households in the SPMA, State of São Paulo, Brazil. It can be argued that this population is comparable to that of other Brazilian large urban centers. The year 2000 Population Census,²² conducted and updated by the Brazilian Institute of Geography and Statistics Census Count (*Instituto Brasileiro de Geografia e Estatística* – IBGE), served as the basis for the sampling design. The estimated population of the São Paulo Metropolitan Area was 17,517,230, of whom 8,464,796 were men and 9,052,434 women, and a total of 12,021,837 individuals were 18 or older.

2. Survey mode

The data collection for the *São Paulo Megacity Mental Health Survey* was carried out in the households of a representative sample of the metropolitan adult population between May 2005 and April 2007. The questionnaire was administered in face-to-face interviews conducted by professional interviewers, who were employed by the survey firm (*Sampling Pesquisas, Comércio e Participações Ltda*) contracted to carry out the field procedures under the strict guidance and close supervision of the research team. It was essential to have a professional survey firm involved in the sampling enrollment and data collection, due to the complexity of the survey methods and the length of the fieldwork. The paper-and-pencil version (PAPI) of the instrument was used. When the interviews were too long, leading to fatigue on the part of respondents, perhaps because of the complexity of the questionnaire, an extensive history of psychopathology, a respondent's disability or a busy agenda within the household, either short breaks could be offered, or interviews could be divided into two or more sessions over a period of days or even weeks, in order to avoid respondents' dropping out without completing the interview and to improve the quality of information collected. Whenever this was the case, the same interviewer would administer the remainder of the interview, returning to the respondent's home at a previously arranged time.

3. Data collection: instrument used and biological material obtained

The instrument used in all participant countries of the WHO-WMH Survey Initiative was the WHM version of the Composite International Diagnostic Interview, referred to as the WMH-CIDI,²³ which was translated into Brazilian Portuguese and adapted for use in this survey.²⁴ As it is a complex instrument that can take a long time to administer, depending on several issues, this had to be taken into consideration in the design and field procedures. The instrument is divided into two parts. Part I, which was administered to all respondents, covers the screening section for the WMH-CIDI core psychiatric disorders (mood, anxiety, impulse-control and substance use disorders, as well as suicidal behavior), and sections assessing chronic physical conditions, 30-day functioning and

impairment and 30-day non-specific symptoms, and the specific modules for each core disorder. Part I also included sections about socio-demographical information, childhood and family burden. Part II included assessment of risk factors, use of services, use of psychiatric medications, social and occupational consequences of psychiatric disorders, socio-demographic information, family and social support, history of affective relationships and children, as well as additional diagnostic modules for less common disorders (such as eating disorders, pre-menstrual disorder, obsessive-compulsive disorder and post-traumatic stress disorder, as well as pathological gambling, neurasthenia, and tobacco dependence) and screening sessions for personality traits and psychotic experiences. At the end of Part I, respondents would be directed, according to their answers to the instrument questions, to go on to take Part II or to resume the interview.

There were, therefore, three possible interview schemes, if we consider their length and the time necessary for their completion: 1) the long interview (Parts I and II), administered to all respondents who had met lifetime diagnostic criteria for at least one of the core disorders assessed in Part I or who had ever made a plan or attempt to commit suicide; this was the longest interview scheme, with an average administration time of 3 hours (median 3 hours and 14 minutes), although it could be as long as 9 hours for respondents displaying a very complex history of psychopathology; 2) the intermediate interview (Parts I and II) administered to a random sub-sample of 25% of all respondents who had not fulfilled the diagnostic criteria for any of the core disorders (i.e. non-cases), and who therefore skipped most of the clinical modules, with an average administration time of 2 hours and 26 minutes (median 2 hours and 15 minutes); and 3) the short interview (Part I only) for those who were not in the first two samples (not a core case and not part of the randomly selected sub-sample of non-cases), with an average administration time of 1 hour and 31 minutes (median 1 hour and 20 minutes). It should be emphasized that all respondents were interviewed using the same instrument, but the clinical modules to be applied and their length depended upon the psychopathology presented.

Part I only was administered to 41.6% ($N = 2,095$) of the total sample ($N = 5,037$ respondents), who were negative for the WMH-CIDI core disorders. Part I and II were administered to a total of 2,942 respondents, divided into two strata, based on their Part I responses. The first stratum was formed of the 2,236 (44.4%) who met lifetime criteria for at least one of the mental disorders assessed in Part I. The second stratum consisted of a random 25% sub-sample of non-cases for WMH-CIDI Part I disorders, and comprised 706 (14.0%) respondents; the inclusion of this stratum enabled the comparison of cases and non-cases and study correlates of psychiatric morbidity, and also allowed the assessment of other diagnoses among respondents who were negative for core disorders.

A special arrangement was designed for respondents aged 60 years or older. After the screening module for mental disorders, chronic conditions, 30-day-impairment and 30-day non-specific symptoms, a section assessing cognitive functioning was administered (WMH-CIDI Dementia Section). An impairment cut-off point was determined which interrupted the interview for those respondents who were unable to continue. Apart from the research interest in assessing the cognitive functioning of the elderly, this procedure was undertaken to objectively identify respondents who were otherwise ineligible to participate adequately in such a complex interview because of a cognitive impairment condition. This occurred with 200 respondents.

At the end of each interview, the respondent was invited to provide a sample of saliva, a second written consent was requested, and an individual disposable mouthwash kit was offered to collect the sample. The interviewers took the kits to the survey firm, and, within 72 hours, the samples were collected and subjected to DNA extraction followed by storage at -70°C , in the Laboratory of Genetics and Molecular Cardiology, Heart Institute (InCor), Universidade de São Paulo School of Medicine.

4. Fieldwork organization and implementation

1) Interviewer training

The firm's staff, including nine field supervisors, the project manager and the general director, were given full-time training lasting five days overall, from 03 to 07 December 2004. This was conducted by the research team, including the two principal investigators (MCV and LHA) and four research assistants. During this period, all the project methods were presented and the research instrument was explained. A detailed plan of the fieldwork procedures was then drawn up and all the preparations needed to start the fieldwork began. The data collection itself was conducted from May 2005 to April 2007.

The interviewers were preselected on the basis of their previous professional experience and were trained by the principal investigators (who were certified by the University of Michigan's CIDI Training and Reference Center <http://www.hcp.med.harvard.edu/wmhcidit/training.php>) in a five-day standard WHO-CIDI training program, and received certification to work in the *São Paulo Megacity Mental Health Survey* only after satisfactorily completing a series of interviewing practices, which consisted of the administration of scripted interviews and interviewing two real subjects. In addition, during data collection, each interview conducted was discussed with the field supervisor and constant feedback and guidance were provided. Several training sections were necessary during the fieldwork period, whenever it became necessary to hire new interviewers.

2) Fieldwork procedures

The fieldwork was carried out by the professional survey firm, closely assisted and supervised by the academic research team. The survey firm team involved varied in the course of the 24-month period of data collection, according to research needs and personal availability. A total of 149 professional interviewers participated in the data collection, with 20 to 40 interviewers working simultaneously, grouped into five teams managed by five field supervisors, who were responsible for the distribution and follow-up of the interviews allocated to their interviewing team, up to the finalization and handing over of the questionnaires to the next phase. The questionnaires were then fully read, edited and coded (for open-ended questions) by the interview editing team, which comprised four people. If information was missing, the questionnaire was returned to the field supervisor and then to the interviewer if it proved necessary to return physically to the household concerned. If the information could be obtained by telephone, the questionnaire was handed over to the telephone contact team, which consisted of two to six workers, who, apart from completing information, were also responsible for checking the accuracy of the sampling and data collected (quality control, described below), and for booking interviews with already selected respondents. Once the questionnaire was complete, it was double-entered by two different professionals into the data entry program based on a Blaise® framework, prepared by the WHO-Harvard WMH Survey Initiative Coordinating Team, according to the Brazilian questionnaire. Data entry was conducted

during the whole process of fieldwork, and required three people and one coordinator. The whole survey firm team was overseen by a project manager and a general director and assisted by a statistician. Two research assistants who were part of the research team were located inside the firm facilities, controlling the fieldwork progress through a computer spreadsheet. They were also responsible for the direct supervision of all the fieldwork procedures, ensuring the strict application of the study methods over time, in all phases of the fieldwork, including sampling, household enrolment, release of replicates, editing of interviews, quality control, refusal conversion and data entry. Regular meetings involving the principal investigators, the research team and the survey firm supervisors and project managers were held throughout the fieldwork. Once the households were selected (see sampling selection below), an advance letter was sent to each of the households explaining the study aims and procedures and the importance of participating in the survey, and informing them that an interviewer would visit the house, in order to interview one of the residents, in the following two weeks, but with a clear statement that participation was voluntary. A toll-free telephone number was made available for working-hours contact if additional information regarding the study was needed. The interviewers received an assigned non-switchable coversheet for each of the households they were designated to approach, with a unique identification number and address. At the first in-person contact attempt with the household, the interviewer explained the study purposes, clarified any pending doubts, and obtained a list of all residents in the household from any informant. This listing was necessary to select a random respondent within the household (see sampling procedures below). Once the random respondent was approached, the interviewing process was explained, confidentiality procedures were described and written informed consent was obtained. In the households where the interviewer had difficulty in making contact to obtain the household listing or to approach the selected respondent, or the respondent was reluctant to participate, extra efforts at persuasion were made, such as sending letters to explain the importance of their role in such a survey, attempting to make telephone contact, visiting the house during weekends or in evening hours, all these being planned attempts to convert a potential refusal into agreement. In any case, up to 10 in-person attempts were made before a refusal was accepted, unless the respondent firmly stated that he/she would definitively not participate. At the end of the fieldwork period, the best interviewers were designated to make special efforts to re-contact refusals or to complete interrupted interviews in municipalities or areas where the response rate was under 35%, for which they received extra financial incentives.

The interviewers were paid by the type of interview bearing in mind its length (Part I only, Parts I and II non-core-CIDI cases, or Parts I and II core-CIDI cases), as an attempt to avoid the differential selection of easy-to-approach respondents and easy-to-conduct interviews, and to encourage the interviewer to take time to obtain appropriate information in long interviews with individuals with a complex history of psychopathology, which were of particular interest to the survey. In cases where the interviews were too long, interviewers were encouraged to set up as many appointments as necessary to complete the interview and were financially backed.

3) Fieldwork quality control

There were several sources of error that could occur during the process of sampling and data collection, and every effort was made to minimize them. In order to avoid interviewers' bias in selecting households, all addresses were selected centrally, by one

of the field supervisors and the firm's statistician. Even though the coversheet procedures used to select randomly one subject within the household were very strict, the residents listing and the use of the Kish table were checked for every interview and, in case of error, the material was discarded and another interview was appointed with the appropriate respondent. Although the questionnaire was very complex and fully structured, unintentional errors and cheating in its completion could occur. Attempting to minimize these sorts of error, the field supervisors made telephone contact with a random 20% of all interviewed households to check the address, the resident listing and the approximate length of the interview, and also repeated a random sample of questions confirming that the full interview was administered and properly recorded. All completed interviews were verified and edited and the completeness of open-ended responses was checked. If any problem was detected, the interviewers were contacted and instructed to re-contact the respondent to obtain missing data, either in person or by telephone, depending on the amount of data required to be completed.

The research assistants in the survey firm controlled all phases of the fieldwork through a computer spreadsheet designed to facilitate quality control over the field and allow follow-up of the fieldwork process. It kept a record of the status of every single interview, the response rate per area and the productivity of the interviewers, and also recorded, among other information, attempted contacts, length of the interviews, gender and age of respondents and the type of interview administered. At any time, this program would produce point statistics that could aid monitoring of the fieldwork progress and identify interviewers with consistent potential problems, such as low response rates, incomplete work, non-expected distributions of cases/non-cases, etc. Where this was the case, these interviewers were provided with new training and guidance, but if low performance was maintained, they were excluded from further participation in the study. This was also the case when deliberate errors were found, in which event all the material produced by them was rejected. Whenever fraud was suspected, 100% of the interviewer's material was checked and, if fraud was confirmed, the interviewer was dismissed and all his/her production was discarded (14 interviews were found to be made-up by two interviewers at the beginning of the fieldwork). Systematic patterns of negative screening questions and under-reporting of diagnostic stem questions, leading to shorter interviews, were not found in this survey, possibly prevented by the use of differential payment according to length of interview.

4) Ethical issues

Respondents were interviewed only after informed written consent was obtained, and total confidentiality was assured. Interviewers were prepared to hand over leaflets containing information on the mental health facilities available within the area, upon respondents' or household members' request. The *São Paulo Megacity Mental Health Survey* was approved by the Ethical and Research Committee of the School of Medicine, Universidade de São Paulo (Process 792/03 and 696/05 for genetic investigation), and was supported by the *Fundação de Apoio à Pesquisa do Estado de São Paulo* (FAPESP - State of São Paulo Research Foundation).

5) Sampling design and procedures

Respondents were selected from a stratified multistage clustered area probability sample of the non-institutionalized civilian population living in private households in the SPMA.

Six stages of selection were employed to target 5,000 households from the two geographic strata which compose the SPMA: the City of São Paulo and the remaining 38 municipalities (Figure 1).

In all strata, the primary sampling units (PSUs) were the year 2,000 census count areas, cartographically defined and updated by the IBGE.²² The estimated non-response rate was 35%. Each of the 38 municipalities was self-representative, contributing altogether to the total sample size according to their demographic density, making up 60% of the total sample. The city of São Paulo, formed of five regions with a total of 96 PSUs, made up 40% of the total sample. The sampling design of the survey according to the stratification procedures is illustrated in Table 1.

The first stage of selection consisted in defining the Primary Sampling Units (PSUs). Each PSU is either a borough of the city of São Paulo, or an individual city. A total of 134 PSUs with defined geographic boundaries was distributed as follows: 96 boroughs within São Paulo City, and 38 municipalities, each one considered a PSU, thus covering all the geographic São Paulo Metropolitan Area (Table 1).

For the second stage of selection, the IBGE Census Units (CUs) were considered, which represent small-area segments of 200–500 households, the smallest unit for which census data are available. At the time of the sampling design, the whole Metropolitan Area was covered by a total of 21,158 CUs, geographically defined and updated by IBGE.

In the third stage of selection, CUs were clustered according to geographic proximity within each PSU. The number of clusters varied according to the population size in each PSU. A total of 1,540 clusters was necessary to select 5,000 households, allowing for a 35% non-response rate (7,700 households). The number of clusters in each PSU was obtained by dividing by five (assuming five houses per cluster) the total number of households to be selected in that specific PSU, which was previously calculated according to its demographic density.

In the fourth stage, one CU was randomly selected within each cluster, from an ordered list produced from the previous stage.

In the fifth stage, one block within each selected CU was randomly selected from a large-scale road map of the area, where all blocks were numbered. The selected block was visited by a survey firm enroller, who identified all existing households, up to the 40th, starting from the block's north-west corner, and working in a clockwise direction. All existing households in each selected block were recorded, with street names and numbers. If the selected block did not have 40 occupied households, a second block facing north from the starting point was used to complete the sampling framework. With this information in hand, the next sampling stage took place centrally, at the survey firm: one every fifth house was systematically selected, starting at the first house, obtaining five households selected by block. If a second cluster was selected within the same PSU, the systematic counting would be started at the second house of the selected block; in the third cluster, it would start at the third house and so on, up to the sixth cluster, where the selection would start again at the first house. A different approach to selecting the households was applied to slums (*favelas*), where there are no defined streets or blocks, and housing units are not

regularly disposed. Where a slum area was selected, the interviewer went into the field without any previous selection of households, and followed the survey firm's instructions for such situations: in high hill slums, the area was mentally divided into five regions, vertically, from top to bottom, and one interview was collected in the middle of each region; the same procedure was applied to more spread-out slums, but horizontally. If the slum was dominated, as was usually the case, by drug-related gangs, previous consent to enter the area was necessary. In the event that it was denied, the closest slum in the same area was selected. This was the only case where replacing a selected area was allowed, without considering issues of non-response, as it was of great importance to have slum residents represented in the sample. The sample distribution throughout the area is shown in Figure 2.

In the last stage of sampling, in the first in-person contact with the household, the interviewer obtained a household listing of all residents from any household informant, with information on age, gender and family relationship to the informant, and their ability to speak Portuguese. This listing was then sorted by gender and inverse order of age, and the eligible respondents were identified, i.e. those who were 18 or older, Portuguese-speaking, and without any disability or handicap that would otherwise impair their ability to participate in the interview. One, out of 12 different Kish tables, was assigned to each coversheet and was used to select a random respondent within the household from the household list of eligible participants. Only one respondent per dwelling was selected and, once selected, there was no substitution.

In addition, in a random 20% sample of households where the selected respondent was married or living as married, the spouse was identified to be further selected to make up a sample of couples, in order to study within-household and within-marriage aggregation of mental disorders. No attempts to select or interview a second

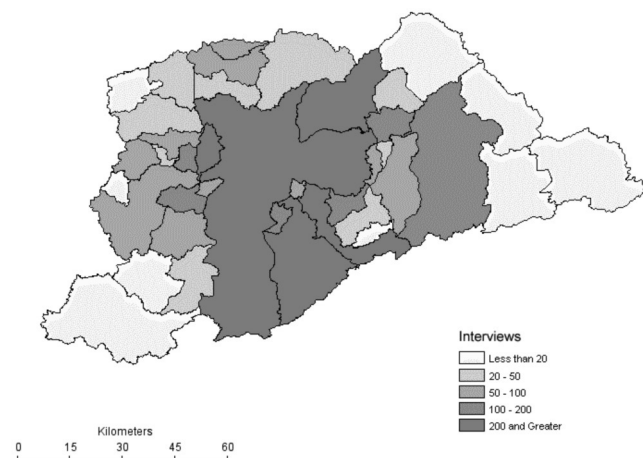


Figure 2 - Distribution of respondents interviewed in the SPMA municipalities

Table 1 - The São Paulo Megacity Mental Health Survey sampling design

STRATA	% Population census	% Sample	Sample size	PSUs	Selected households*
São Paulo City	60%	40%	2,000	96	3,080
Remainder 38 municipalities	40%	60%	3,000	38	4,620
Total SPMA	100%	100%	5,000	134	7,700

* Allowing for a 35% non-response rate

person in a household were made before the main respondent had completed the interview. The sampling fraction for those households with two respondents was later corrected with a within-household probability of selection weight.

The listings of all 7,700 selected housing units were displayed on a spreadsheet in order of selection with a unique respective identification in crescent numbering, disposed in consecutive groups of 500 households, named replicates. The replicates were made when the household selection took place, each representing a random sub-sample of the whole sampling frame. After advance letters had been sent to the households, each replicate was released to the interviewers in order of the household identification numbering, and only after a response rate higher than 65% had been achieved could the next replicate be released to the fieldworkers. This was a planned precautionary measure to ensure that at any point of the fieldwork, the sample already assessed was representative of the target population and that the hard-to-recruit respondents were not left out of the study. In addition, once the sample size was achieved, the fieldwork could be interrupted without undesirable consequences for the representativeness of the sample. It was not necessary to release all the replicates, since the response rate was higher than initially estimated: the total sample size was completed and the fieldwork was therefore interrupted with the release of the first 6,199 housing units selected. A total of 200 elderly respondents (187 main respondents and 13 spouses) with assessed cognitive impairment who were not able to complete the interview were excluded, although all assessments conducted with those subjects were entered in the dataset and will be analyzed in further papers related to cognitive function of the elderly. The final disposition of the sample and the response rates are shown in Table 2. A total of 5,037 respondents was assessed, with a global response rate of 81.3%. The sub-sample of spouses comprised 491 respondents; this will provide a sub-sample of couples consisting of 982 subjects. The global response rate was high compared to that in other countries participating in the WMH Survey Initiative, and higher among spouses (87.2%) than among main respondents (80.7%).

5. Data management

1) Data entry

While the fieldwork was progressing, all questionnaires that were completed and subject to the quality control procedures were considered ready for data entry. All written and coded information contained in the questionnaire (paper and pencil version – PAPI) were then transferred to a specific database, which was produced for this purpose and made available by the WHO – Harvard WMH Survey Initiative Coordinating Center (<http://www.hcp.med.harvard.edu/wmhcdi>). The data entry program was created with Blaise 4.7 Enterprise®, a software system developed by Statistics Netherlands for computer-assisted survey processing, which works in the Microsoft Windows® operating system and supports the export

of data to external statistical packages or databases, such as SAS or SPSS (<http://www.cbs.nl/en-GB/menu/informatie/onderzoekers/blaise-software/blaise-voor-windows/productinformatie/default.htm>). The original data entry program was adapted to the changes introduced in the Brazilian Portuguese questionnaire, changes necessary in order to adapt to the local language and culture.²⁴

All questionnaires were double-entered by two different professionals. The two versions were systematically compared, and all inconsistencies between them were checked and corrected. Whenever necessary, the questionnaire would go back to the editors and/or interviewers to complete or correct information, but this was very infrequent at this stage, as it was subsequent to the quality control. For ethical reasons, a separate database containing information on respondents and household residents, which could permit personal identification, was also produced.

2) Data cleaning

Once the data-entering process was completed, it was exported to an SPSS datafile, and an overall inspection was performed, looking at the basic features of the data. The unique respondent identification number (ID) was checked for the correct number of digits and digit scheme, and the main respondent's ID number was matched with the corresponding spouse's ID. Basic checks, looking for variables with blank or missing data for all or most respondents, and with out-of-range codes, were also performed, and identified errors were corrected in the Blaise data entry. The resulting SPSS datafile was then sent to the WHO—Harvard WMH Survey Initiative Data Coordinating Center (<http://www.hcp.med.harvard.edu/wmh/>) for a systematic, standard process of data checking and cleaning, which is performed on all incoming datasets from all countries participating in the WMH Survey Initiative, to ensure good standards of data quality in the international dataset, formed by joint data from individual countries.

A series of analyses was performed which looked at internal consistency of the data collected at individual respondent level. The first set of checks looked for skipping errors that might have occurred during data collection or resulting from errors in the data entry programming. Inconsistencies related to the reported/recorded ages were also checked: respondent's age at interview should be \geq any other reported age of onset of events or symptoms; and the age at the most recent episode should always be \geq age of onset; service use age should also be \geq onset of problem. Inconsistencies related to dates of onset and end, as well as duration of episodes or symptoms, were also assessed, as was gender-related information throughout the interview. The verification and correction of all identified errors occurred in a dynamic interactive process between the Brazilian research team and the WHO – Harvard WMH Data Coordinating Center until data were considered clean and added to the international WMH Survey Initiative databank. The whole process of data cleaning and final preparation took place between September 2007 and March 2008.

Table 2 - The São Paulo Megacity Mental Health Survey final sample disposition and response rates

Respondent	Complete interviews	Refused	Total selected	Non-response	Response rate
	N	N	N	%	%
Main	4546	1090	5636	19.3%	80.7%
Spouse	491	72	563	12.8%	87.2%
Total	5037	1162	6199	18.7%	81.3%

3) Organic exclusions

In each WMH-CIDI clinical module, after the occurrence of symptoms had been investigated through questions that operationalized criteria for DSM-IV diagnoses, and if the respondent fulfilled the criteria for diagnosis there was one question asking if the respondent believed that the occurrence of symptoms/episodes could be explained by any organic reason, including physical illness, injury, the use of alcohol, drugs or medication. If the answer was in the affirmative, there was an open-ended question in which respondents' answers were entered, in their own words, for all clinical modules with the exception of Obsessive Compulsive Disorder, where the response was coded from a list of plausible organic causes, already compiled in the questionnaire (including "don't know" and "refused").

For the purpose of diagnostic assignment, all open-ended questions were reviewed by a trained psychiatrist with extensive clinical experience (MCV) in order to determine if each respondent's explanation consisted of a plausible organic cause for the psychiatric disorder under investigation and met the criteria for organic exclusion. All cases with a valid organic exclusion are coded as negative for that psychiatric diagnosis, while all others will be coded as meeting full diagnostic criteria.

A systematic process of assessment was undertaken for all cases where organic causes were stated (Table 3). First, all causes offered were examined, and all those with no etiological relation were excluded (e.g. mother's cancer, surgery to the left knee, or severe back pain, offered as organic justifications for depressive illness).

All remainder respondents' cases were then examined through the following procedures: 1) For each diagnostic group, a spreadsheet was constructed with all remainder respondents who stated organic reasons for symptoms and/or episodes in that diagnostic module. The spreadsheet contained data on demographics (gender and age) and clinical information (respondent's responses to screening questions, all CIDI diagnosis for which the respondent fulfilled criteria, information on use of alcohol, illicit drugs and psychotropic medication, and diagnosis of alcohol and drug abuse and dependence). 2) A list of all possible organic causes for each psychiatric disorder was constructed based on the Structured Clinical Interview for Axis-I DSM-IV Diagnoses - Patient Version (SCID) guidelines. 3) A thorough examination of each respondent's answer was conducted, comparing the organic reason given with the list of plausible organic causes (in 2), in the light of the complete clinical available information (in 1), in an attempt to understand the clinical case, as in a psychiatric anamnesis. 4) Following this assessment, a code was given to each answer (1 = valid organic cause; 2 = organic cause not plausible; 8 = don't know; 9 = refused, i.e., said yes, but refused to answer the open-ended question). The specified psychiatric diagnosis was discarded in 34 respondents in whom it was considered to be due to one (or more) plausible and valid organic cause(s) (Table 3).

Once the final dataset was complete, it was added to the international WMH Survey Initiative dataset, with data from 21 other countries. The final dataset comprises 4,551 variables, distributed along 43 modules or sections.

4) Weighting

Weights were applied to adjust for differences in the probability of selection (W1), to non-response (W2), to post-stratify the final sample to approximate the general population 2,000 Census regarding gender and age distribution (W3), and to adjust for Part II selection (W4). The joint product of W1, W2 and W3 is the consolidated weight used to analyze data from the Part I sample ($n = 5,037$), while the joint product of all four weights is the consolidated weight used to analyze data from the Part II sample ($n = 2,942$). When the data to be analyzed include variables assessed in Part I and other variables assessed in Part II, the Part II sample and Part II consolidated weight are used.

The probability of selection weight (W1) was calculated considering the probability of selection in each of the sampling multistage procedures, including within-household selection, as the inverse of the following probability equation:

$$f_{hijk} = \frac{1}{a_{hi}} \times \frac{5}{n_j} \times \frac{1}{e_k}$$

Where a = number of census units in a specific cluster of a specific PSU; n = number of households in a selected census unit; e = number of eligible respondents in a selected household; and h indicates PSU; i indicates cluster; j indicates census unit; and k indicates respondent.

There were 134 PSUs and the probability of selecting one PSU equals 1 as all (100%) PSUs were auto-representative. There were 21,158 Census Units (CUs) grouped into 1,540 clusters and the probability of selecting one cluster was also 1, as all clusters were constructed to be representative of their respective PSU. However, each cluster had a different number of CUs and each CU had a different number of households, which were used to calculate the individual weight for each respondent, considering also the number of eligible respondents per household (i.e. the within-household probability of selection), as the individual probability of selection varies inversely with the number of residents living in the household. In the households where two respondents were selected the same procedures were used, but the equation was adjusted accordingly. In the areas where slums were selected, the mean number of household units of the CU was used to estimate the probability of selection of those respondents at this level.

A second weight (W2) was created to adjust for non-response (NR), and was done separately for main respondents and for the sample of spouses (Table 2), according to the following equation:

Table 3 - Organic explanations for psychiatric disorders offered by respondents per diagnostic module, in Part I and II

Diagnostic module	Number of respondents	Number of organic reasons given	Number of respondents with valid organic reasons
Major depressive disorder	112	335	12
Mania	37	78	8
Panic disorder	6	11	0
Agoraphobia	16	16	0
GAD	44	72	2
Intermittent explosive disorder	27	258	11
OCD	11	21	1

$$W2 \text{ (Non-Response Weight)} = \frac{\text{Number of Eligible Persons (complete and incomplete)}}{\text{Number of Eligible Persons (complete only)}}$$

The joint product of W1 and W2 was consolidated for each respondent and applied to the 5,037 respondents. A third weight (W3) was created to adjust for variation between the weighted sample (after the joint product of W1 and W2 was applied) and the general population according to the IBGE 2,000 Census data.²² This post-stratification (PS) weight was based on the general population distribution by gender and age, involving persons aged 18 years and older in the São Paulo Metropolitan Area, ensuring that the joint distribution of gender and age in the sample matches the known population joint distribution. The weight obtained by the joint product of W1, W2 and W3 was then normalized, to ensure that the sum of the weights was equal to the total sample size of the Part I data, and the upper and lower 5% were trimmed to the mean of each tail, and applied to the 5,037 cases. This defines the consolidated Final Part I Weight to be used in all statistical analyses involving Part I variables and diagnoses.

An additional weight (W4) is needed to analyze data in the Part II sample, in view of the differential probability of selection into Part II. As mentioned earlier, only a proportion of the sample would complete the long form interview (or Part II of the survey): all respondents with Part I disorders and 25% of Part I non-cases. The probability of inclusion into Part II is based, therefore, on the presence or absence of disorder symptoms, as defined in the interview schedule. All respondents (100%) meeting criteria for at least one diagnosis assessed in Part I or who had ever planned or attempted to commit suicide were selected into the Part II sample with certainty, or a probability of 1.0. The proportion of Part I non-cases were selected into Part II with a constant probability of 26.1%. For weighting purposes, the empirical probabilities of selection into the Part II sample were calculated for each group and the inverse probability of participation in Part II was assigned to each respondent, using the Part I weighted counts of persons. Again, a PS weight was created based on the general population distribution of gender and age, considering persons aged 18 years and older on the IBGE 2,000 Census.²² The Part II weight was then consolidated as follows:

$$W4 \text{ (Part II Weight)} = \text{Final Part I Weight} * \text{Part II Selection Weight} * \text{PS Weight}$$

These weight values were then normed to ensure that the sum of the weights was equal to the total sample size of the Part II data (2,942).

Table 4 shows the Part I and Part II sample distributions by gender and age, weighted and unweighted, as well as the 2,000 IBGE Census population distributions. Comparison of these distributions provides information on the effects of weighting. As shown in Table 4, the unweighted Part I and Part II samples slightly overrepresented females and young adults (ages 18-29), in a similar fashion. These biases were corrected with the consolidated Part I weight for the Part I sample, and with Part II weight for the Part II sample.

6. DNA extraction

The saliva sample collection was implemented in January 2006, in collaboration with the Harvard School of Medicine, Harvard University, which provided the mouthwash supplies and the DNA extraction kits. A total of 1,801 samples were collected and DNA was extracted and stored for further investigations in the Laboratory of Genetics and Molecular Cardiology, Heart Institute (InCor), Universidade de São Paulo School of Medicine.

7. Clinical reassessment

In addition to the household survey which made up the World Mental Health Survey research protocol, the *São Paulo Megacity Mental Health Survey* comprises a series of clinical and specific investigations, in an attempt to integrate epidemiological findings, clinical investigation and neurobiological assessments. A sub-sample of respondents (N = 780) interviewed in the community was invited to attend a one-day series of assessments at the Institute of Psychiatry (School of Medicine, Universidade de São Paulo) and participate in several sub-projects, using the community study as the sampling frame. One of these consisted of a clinical reappraisal, where respondents were reassessed through the Structured Clinical Interview for DSM Disorders (SCID)²⁵ applied by trained psychiatrists, with the objective of assessing clinical validity and calibrating the CIDI-based prevalence rates found in the community. Another sub-project was set up to identify risk behaviors for sexually transmitted diseases and HIV/AIDS and their association with psychiatric morbidity and use of alcohol and drugs.

Standardized assessments of physical health regarding common physical symptoms (dyspepsia, headache, dizziness, fatigue and chest pain), anthropometric measures and blood tests (glucose, total and HDL-cholesterol, triglycerides and thyroid function hormones) were also conducted, aimed at studying in detail and using more objective methods the mental-physical comorbidity, as well as the physical manifestations of mental disorders and psychiatric treatments, and also at guiding the implementation of better assistance with health and social needs. At the same time as the blood was collected for the lab tests, a sample intended to extract

Table 4 - Demographic distribution of the sample compared to the Census population on post-stratification variables

	Part I sample Unweighted	Part I sample Weighted	Part II sample Unweighted	Part II sample Weighted	Census
	%	%	%	%	%
Age					
18-29	25.6	33.5	26.5	34.0	33.9
30-39	23.7	24.1	23.7	24.1	24.1
40-49	21.6	18.9	21.8	18.8	18.8
50-59	16.1	11.5	15.9	11.4	11.4
60-69	8.2	6.9	7.5	6.8	6.8
70+	4.8	5.1	4.6	4.9	5.0
Gender					
Male	43.4	47.0	42.1	47.2	47.2
Female	56.6	53.0	57.9	52.8	52.8

DNA was also collected, after written consent had been obtained from the respondent. The DNA extraction was conducted and stored with the saliva-derived DNA, for further genetic investigations. A total of 758 blood samples was collected and DNA extracted from them.

In view of the mega-urban characteristics of the target population and the high rates of criminality in the São Paulo Metropolitan Area, an important sub-project was also implemented, looking at the profile of violence and traumatic experiences to which respondents were either exposed or which they had themselves perpetrated, and evaluating their association with psychiatric morbidity by trying to identify causal and consequential relationships. Respondents were assessed through an in-depth questionnaire looking at exposure to adversity and violence in childhood and adolescence, including neglect, physical and sexual abuse, dysfunctional family environment, and death of parents and close relatives, and also through a questionnaire assessing adult exposure to violence and involvement with criminal and/or violent behavior. The Revised Conflict Tactics Scale,^{26,27} looking at domestic violence between intimate partners, was also applied, with added questions related to the correspondent behavior between parents during respondents' childhood.

Finally, the personality profile was assessed through the self-reported Cloninger's Temperament and Character Inventory (TCI);²⁸ a questionnaire about use of health services was also applied, as well as a brief questionnaire about religious beliefs and practices.

Overview

This paper has presented a detailed overview of the *São Paulo Megacity Mental Health Survey* aims, design, sampling procedures and field implementation. It was the greatest achievement that our research team could hope to attain, in terms of rigor of methodological procedures and quality of information collected, and with a very high response rate. The *São Paulo Megacity Mental Health Survey* contains a great deal of data, and it is likely to take several years of hard work to reveal all this information and extract all the knowledge it has the potential to contain. Hopefully, it will serve to better understand the population's mental health needs and guide public expenditure towards implementing preventive measures and appropriate care.

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Disclosures

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* Modest

** Significant

*** Significant. Amounts given to the author's institution or to a colleague for research in which the author has participation, not directly to the author.

Note: IPq-HCFMUSP = Instituto de Psiquiatria do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo; FACITEC = Fundo de Apoio à Ciência e Tecnologia do Município de Vitória; FAPESP = Fundação de Amparo à Pesquisa do Estado de São Paulo; OMS = Organização Mundial de Saúde; PAHO = Pan American Health Organization; NIMH = National Institute of Mental Health; CISA = Centro de Informações sobre Saúde e Álcool.

For more information, see Instructions for authors

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