

# Aims, outcome measures, study sites and patient sample

## EPSILON Study I

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**Background** Cross-national research into the care of people with severe mental illnesses is hampered by a lack of standardised measures. The European Psychiatric Services: Inputs Linked to Outcome Domains and Needs (EPSILON) Study is a European Union funded project within the BIOMED-2 programme. The project aims to develop standardised instruments to facilitate future cross-national research.

**Aims** To describe the aims, outcome measures, study sites and patient samples of the EPSILON Study.

**Method, results, conclusions** See companion papers in this supplement.

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Cross-national research requires adequate methodology and instrumentation. The EPSILON Study, the acronym for which was derived from European Psychiatric Services: Inputs Linked to Outcome Domains and Needs, is an EU BIOMED-2 funded research project intended to make a substantial contribution in this direction (Becker *et al*, 1999).

### AIMS

The project of instrument translation, adaptation and reliability assessment presented in this supplement was part of a wider research project. This is a comparative cross-sectional study of care for people with schizophrenia in five European countries. Six research teams in five centres were involved, and the teams are located in Amsterdam, Copenhagen, London (Centre for the Economics of Mental Health and Section of Community Psychiatry, Institute of Psychiatry), Santander and Verona. The centres had experience in health services research and instrument development, and all had access to mental health services providing care for local catchment areas.

The instruments used assess a variety of dimensions of the care process, such as needs for care, service utilisation and costs, informal carer involvement, quality of life and service satisfaction. This research instrumentation was used to study care for people with schizophrenia in five centres cross-sectionally in a sample of patients in contact with secondary mental health services. The EPSILON Study aims: (a) to produce standardised versions of five key research instruments in five languages; (b) to compare data about social and clinical variables, mental health care and costs; and (c) to test instrument-specific and cross-instrument hypotheses. Facilitating future cross-national research into care for the severely mentally ill is a central objective of the EPSILON Study. This paper gives a

brief outline of the aims and design of the study and the patient sample.

### STUDY INSTRUMENTS

Five key study instruments were adapted for use in the five languages and different service settings (EU denotes European Version):

- (a) Camberwell Assessment of Need (CAN; adapted CAN-EU);
- (b) Client Service Receipt Inventory (CSRI; adapted CSSRI-EU);
- (c) Involvement Evaluation Questionnaire (IEQ; adapted IEQ-EU);
- (d) Lancashire Quality of Life Profile (LQoLP; adapted LQoLP-EU);
- (e) Verona Service Satisfaction Scale (VSSS; adapted VSSS-EU).

Some characteristics of these instruments are outlined in Table 1.

### Patients' needs

The CAN (which became CAN-EU), an interviewer-administered instrument, was used to assess patients' needs (Phelan *et al*, 1995). It comprises 22 individual domains of need (accommodation, food, household skills, self-care, occupation, physical health, psychotic symptoms, information about condition and treatment, psychological distress, safety to self, safety to others, alcohol, drugs, company of others, intimate relationships, sexual expression, child care, transport, money, welfare benefits, basic education and telephone).

### Service use and cost

The CSSRI-EU (Client Socio-Demographic and Service Receipt Inventory – European Version) is an adaptation of the CSRI (Becham & Knapp, 1992) which, on the basis of an interview, records socio-demographic data, accommodation, employment, income, and all health, social, education and criminal justice services received by a patient during the preceding 6 months. It allows costing of services received on the basis of unit cost data.

### Caregiving consequences

The IEQ (adapted IEQ-EU) is an 81-item questionnaire measuring the consequences of psychiatric disorders for relatives of patients (Schene & van Wijngaarden, 1992). It contains six sections: general

**Table 1** Core study instruments

Instrument	No. of domains	No. of facets/ sub-scales explored	No. of items administration	Average completion time (min)	Time frame	Sub-scale score	Summary score	Type of response scale	Presence of manual training required	Degree of training required
CAN-EU	22	–	22 × 6	20–30	Past month	Yes (met needs, unmet needs, total needs)	Yes	Categorical ratings for presence of need and level of help	Yes	Moderate
CSSRI-EU	5	–	110	20–30	Past 3 months	Yes, 5 service use domains	Various	Categorical and structured responses	Yes	Modest
IEQ-EU	7	4 sub-scales and one total score	31 IEQ; 81 all modules	10 min IEQ; 20–30 min for whole set	Past 4 weeks	Yes, 4+GHQ	Yes	Likert, 5-point (never to always)	No manual needed as IEQ contains instruction sheet	None
LQoLP-EU	9	Positive and negative affect, affect balance	105	30	Past week, month or year (varies)	Yes	Yes	Yes/no, Likert, 7-point	Yes	Little
VSSS-EU	7	7	63	20–30	Past year	Yes, one for each domain	Yes	Likert, 5-point	Yes	None/little

I. Assisted in some places.

EU, European Version; CAN, Camberwell Assessment of Need; CSSRI, Client Service Receipt Inventory; IEQ, Involvement Evaluation Questionnaire; LQoLP, Lancashire Quality of Life Profile; VSSS, Verona Service Satisfaction Scale; GHQ, General Health Questionnaire; INT, interview-administered; SA, self-administered; QU, questionnaire.

information on the patient, caregiver and household (15 items); caregiving consequences of psychiatric disorders (31 items); extra financial expenses (eight items); the General Health Questionnaire (GHQ-12); professional help for patients' relatives (three items); and the consequences for patients' children (11 items). The time frame is the past 4 weeks. Caregiving consequences are summarised using four scales (tension, worrying, urging, supervision) and a summary score.

### Quality of life

The LQoLP (adapted LQoLP-EU) elicits objective quality of life indicators and subjective quality of life appraisal through patients' answers to interviewer-administered questions relating to nine fields: work/education, leisure/participation, religion, finances, living situation, legal and safety, family relations, social relations and health (Oliver *et al*, 1996).

### Service satisfaction

Satisfaction with services was assessed using the VSSS (adapted VSSS-EU), a self-administered instrument comprising seven domains (global satisfaction, skill and behaviour, information, access, efficacy, intervention and relatives' support) (Ruggeri & Dall'Agnola, 1993).

Other instruments used included the Brief Psychiatric Rating Scale (BPRS 24-item version; Ventura *et al*, 1993) and Global Assessment of Functioning (GAF; American Psychiatric Association, 1987). These were used in English. Instruments documenting the sampling process (Prevalence Cohort Data Sheet), area socio-demographic descriptors (Area Socio-Demographic Data Sheet) and patients' psychiatric history (Psychiatric History Data Sheet) were developed for the EPSILON Study (available from study co-ordinating centre upon request). Descriptions of site level characteristics included socio-demographic area descriptors, availability of in-patient beds and other service components, and staff availability. The European Service Mapping Schedule was also used (Johnson *et al*, 1998). Data collection in this study was from September 1997 to August 1998.

## STUDY SITES

### Amsterdam

#### General area characteristics

Data were collected in Amsterdam South-East, which is a 30-year-old borough in

the south of the city. It is mainly a residential area, with a mixed lower- and middle-class population of 110 000. Unemployment is high. Fifty per cent of the inhabitants are from one of the 60 minority ethnic groups. Data were collected for 1 January 1998.

#### Mental health services in the local area

The mental health services in the Amsterdam South-East catchment area are in a process of change and integration, and this paragraph describes the services in January 1998 (while the study was ongoing). The large Santpoort mental hospital, located 25 kilometres to the west of Amsterdam, has during the past 5–10 years started to provide services (out-patient, in-patient and residential) across the city. Having moved to Amsterdam, these services, formerly hospital-based, are now in the process of integrating with mental health services which have been available in the city for many years, such as the Regional Institute for Ambulatory Mental Health Care (RIAGG) and the Department of Psychiatry at the Academic Medical Centre (AMC).

Since 1998 these three organisations (Santpoort, RIAGG and AMC) have been merged into one organisation called De Meren, with three separate services, for people aged over 65, 18–64, and below 18 years. For the adult population this new organisation offers out-patient services in three locations: the former RIAGG, the out-patient department formerly at Santpoort and the AMC out-patient department. These three services have been merged into the Social Psychiatric Service Centre (SPSC). This SPSC has its in-patient units (eight beds on a closed ward, six beds on an open intermediate care ward, 20 beds on an open ward) in the AMC, where a 24-hour emergency room is also available. For long-term patients, non-acute 24-hour staffed residential services and sheltered accommodation are available within the SPSC. Services for the catchment area population also include intensive home care, two shelters for homeless people with mental illness, a day care centre and a vocational rehabilitation centre. The wider context of mental health services in Amsterdam is described in more detail elsewhere (Schene *et al*, 1998; Becker *et al*, 1999).

### Copenhagen

#### General area characteristics

Copenhagen is the capital of Denmark, with a total population of about 480 000.

Copenhagen is divided into 14 social districts (boroughs). The two social districts Vesterbro and Kongens Enghave are neighbouring and were the catchment areas for the project, with a population of about 50 000.

#### Mental health services in the local area

The mental health services in Vesterbro and Kongens Enghave are provided by Hvidovre Hospital. The psychiatric department of this hospital has an emergency unit with four beds and 130 in-patient beds distributed across three locked wards, three open wards, one ward for young people with first-episode psychosis, one ward open Monday to Friday (each with 15 beds) and an old age psychiatry ward with 10 beds. They provide an extensive liaison psychiatric service to the general hospital. Further, Hvidovre Hospital has three Community Mental Health Centres (CMHC): Vesterbro, Valby and Vanløse. Vesterbro Community Mental Health Centre provides services for inhabitants in the catchment areas Vesterbro and Kongens Enghave (pop. about 50 000) with chronic mental illness, mostly schizophrenia. Hvidovre Hospital's total catchment area is 130 000. The CMHC has a multi-disciplinary team: psychiatrist, psychologist, social workers, nurses, occupational therapist and physiotherapist. The total number of staff is 22. Every patient has a case manager and a psychiatrist in the CMHC. At any one time, approximately 300 patients are on the CMHC case-load. The CMHC provides out-patient care, structured day activities (mostly workshops as social training: arts, cooking, gymnastics and psycho-education) and home visits to patients. The CMHC and the psychiatric department at the general hospital collaborate in setting up different types of conferences, educational programmes etc. There is close collaboration between the CMHC and other services in the catchment area, such as general practitioners, social services, sheltered accommodation, voluntary organisations, etc. (Kastrup, 1998; Becker *et al*, 1999).

### London (Croydon)

#### General area characteristics

Croydon is predominantly a suburban borough (local government area in England) in south London, with a total population of 330 000. The population

ranges from the somewhat deprived inhabitants of the north of the borough to a more affluent, middle-class and semi-rural southern area. Patients in this study were recruited from a population of about 80 000 in the borough.

#### *Mental health services in the local area*

Specialist mental health services in Croydon are purchased by Croydon Health Authority and provided by the Bethlem & Maudsley NHS Trust. These specialist mental health services for the general adult population include 70 acute adult psychiatric beds for the 330 000 population; 10 low-security in-patient places in a locked ward; and four medium-security forensic beds. Residential provision includes 25 places staffed around the clock by nurses, 166 places not nurse staffed around the clock and 22 less well supported places. For the provision of community mental health services, the borough is divided into three localities, each serving a population of about 100 000. Sampling in this study was from the Central, East and West localities, with a population of about 67 000. Each of these three localities contains two or three general adult community mental health teams, which typically include community psychiatric nurses, an attached social worker, attached occupational therapist, consultant psychiatrist and junior psychiatrist. There are four CMHC for the whole borough of Croydon. These function as community multi-disciplinary team bases, settings for out-patient and depot medication clinics, and as day centres, providing occupational therapy and psychotherapeutic groups. The Social Services and the private and voluntary sectors also provide day care places, work opportunities and 'drop-in' services (Johnson *et al*, 1997; Thornicroft & Goldberg, 1998; Becker *et al*, 1999).

#### **Santander**

##### *General area characteristics*

The study was conducted in Cantabria, an Autonomous Community with a population of about 560 000 in northern Spain. Patients were recruited from Cantabria as a whole. The city of Santander, a university town with a total population of about 194 000 inhabitants, is predominantly middle-class, with the majority of those employed working in services and light industry.

#### *Mental health services in the local area*

The Spanish Psychiatric Reform, which was formally initiated in 1985, had as its main objective the replacement of the old mental hospitals with alternative services in the community and in-patient psychiatric units in general hospitals (Vázquez-Barquero & García, 1999). These services are integrated in the Spanish National Institute of Health (INSALUD), providing free health care for the whole of the Spanish population. In this context, psychiatric services in Santander are mainly provided as follows:

- (a) There is an acute psychiatric in-patient unit of 42 beds (there are also 12 beds in a long-term psychiatric hospital, used mainly by patients from the private sector, insurance companies and health consortia). This unit, which also meets the needs of the whole region of Cantabria, is located within the Marqués de Valdecilla University Hospital, which is both a teaching general hospital with 1199 beds, providing in-patient services for the region of Cantabria, and a referral hospital for the rest of Spain for tertiary, specialised forms of medical care.
- (b) A 24-hour acute emergency unit is located in the university hospital.
- (c) For the provision of community mental health services, Cantabria is divided into four areas, each with a community mental health service. Santander is one of these mental health service areas: the Santander mental health centre is divided into two multi-disciplinary adult mental health teams, each including two psychiatrists, a community nurse, a psychologist and a social worker.
- (d) For long-term psychiatric care, patients can be referred to a long-stay psychiatric hospital belonging to the Cantabria local authorities (114 beds) or to a long-stay psychiatric hospital belonging to a non-profit-making religious organisation (89 beds). Further information is given in Becker *et al* (1999).

#### **Verona**

##### *General area characteristics*

Data were collected in the South Verona community-based mental health service (CMHS). South Verona is a predominantly urban area with a population of about 70 000, on the southern outskirts of Verona,

a city in Northern Italy. Verona is predominantly middle-class, with services and industry comprising more than 90% of the economic sector.

#### *Mental health services in the local area*

The South Verona CMHS has developed gradually over the past 20 years, and it is the main psychiatric service providing care to South Verona residents (Tansella *et al*, 1998). It includes a comprehensive and well-integrated number of programmes, and provides in-patient care, day care, rehabilitation, out-patient care and home visits, as well as a 24-hour emergency service and residential facilities (three apartments and one hostel) for long-term patients. CMHS staff members are divided into three multi-disciplinary teams, each referring to a subsector of the catchment area. With the exception of hospital nurses, all staff (psychiatrists, psychologists, social workers, community nurses) work both inside and outside hospital. The 'single staff' module ensures continuity of care through the different phases of treatment and the different components of the service. A Psychiatric Case Register (PCR), which covers the same geographical area, has been operating since 31 December 1978. Private hospitals and other agencies in the larger province of Verona also provide information to the PCR. However, 1989–1998 data indicate that 88.8% of patients living in the area are receiving care from the South Verona CMHS, either solely (83.2%) or together with other services, including the specialist service for drug addicts (5.6%). On the other hand, only 11.2% of patients receive care from other services only (including the specialist service for drug addicts). The vast majority of patients with a diagnosis of schizophrenia are on the case-loads of public mental health services. It can be assumed that the sample assessed in this study is representative of all patients with a diagnosis of schizophrenia under 'active treatment' in the South Verona catchment area (Tansella *et al*, 1998; Becker *et al*, 1999).

#### **Case ascertainment**

In this study, adults aged 18–65 inclusive with any ICD-10 diagnosis from F20 to F25 were included at the screening stage. These administrative prevalence samples of patients with psychotic disorders were identified either from psychiatric case registers (in Copenhagen and Verona) or from the case-loads of local specialist mental

health services (in-patient, out-patient and community). Patients needed to have been in contact with mental health services during the 3-month period preceding the start of the study. Thus, an administrative prevalence sample of people with schizophrenia in contact with mental health services was used in each site as the sampling frame. Cases identified were diagnosed using the item group checklist (IGC) of the Schedule for Clinical Assessment in Neuropsychiatry (SCAN) (World Health Organization, 1992). On this basis, only patients with an ICD-10 F20 research diagnosis were included in the study.

Exclusion criteria included current residence in prison, secure residential services or hostels for long-term patients; co-existing learning disability (mental retardation), primary dementia or other severe organic disorder; and extended in-patient treatment episodes longer than one year. This was done in order to avoid any bias between sites due to variation in the population of patients in long-term institutional care, and to concentrate on those in current 'active' care by specialist mental health

teams. The numbers of patients finally included in the study varied from 52 to 107 between the five sites, with a total of 404.

### Patient sample

The distribution of diagnoses on the basis of the item group checklist (Table 2) shows that between 45% (in Verona) and 86% (in London) of the patients screened had an item group checklist diagnosis of schizophrenia. Schizotypal disorders were most likely to be diagnosed in Copenhagen (13%), persistent delusional disorders and acute transient psychotic disorders were more likely to be diagnosed in Santander and Verona.

Table 3 shows the attrition of the samples and reasons why interviews could not be completed. Some differences require comment. The order of events was: (a) collection of administrative data, including all prevalent cases in contact with catchment area services; (b) random selection of patients who were diagnosed and/or interviewed (not in London and Verona, where all were eligible, in order to achieve a big enough sample); (c) diagnostic assessment

on the basis of the IGC SCAN (World Health Organization, 1992); and (d) the study interview. In the Santander site, the patients were from the whole of Cantabria, which led to a larger sample ( $n=423$ ) than in the other sites, with a smaller proportion ( $n=125$ ) selected for IGC rating/interview. In Copenhagen, the matching of prevalent cases and those interviewed was not possible, due to patient confidentiality regulations in the Danish legal and data protection systems. In Amsterdam, London and Verona all (or most) patients were contacted for interview, because large numbers of refusers and patients who could not be found, as well as substantial diagnostic heterogeneity, were expected. The proportion of patients excluded on the basis of the IGC diagnosis varied from none (Santander) to high rates of 18% and 22% (Amsterdam, Verona). This may reflect differences either in clinical diagnostic routine or in the case-load composition of the secondary mental health services in the various sites. Patients not located varied from 1% (Santander, Verona) to 16% (London), which may reflect more social integration in the

**Table 2** Diagnostic distribution in initial sample at screening stage

ICD-10 diagnostic group	Amsterdam		Copenhagen		London		Santander		Verona	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
F20 schizophrenia	123	79	100	69	149	86	300	71	84	45
F21 schizotypal disorders	–	–	18	13	9	5	4	1	8	4
F22 persistent delusional disorder	9	6	6	4	–	–	44	10	29	15
F23 acute and transient psychotic disorder	–	–	9	6	5	3	52	12	20	11
F24 induced delusional disorder	–	–	–	–	–	–	1	–	1	1
F25 schizoaffective disorder	2	1	5	4	6	4	22	5	17	9
Others	15	10	3	2	4	2	–	–	15	8
No diagnosis	5	4	3	2	–	–	–	–	14	7
Total	154	100	144	100	173	100	423	100	188	100

**Table 3** Sample attrition

	Amsterdam	Copenhagen	London	Santander	Verona	Total
All prevalent cases	170	144 <sup>1</sup>	173	423	188	1174
Selected for IGC rating/interview	154		173	125	184	–
Excluded (SCAN or IGC)	31		4	0	42	–
Lost/died/ill/refused/age-excluded	62		85	25	35	–
Final dataset	61	52	84	100	107	404

1. Match between prevalent cases and subsequent screened individuals not possible due to Danish patient confidentiality regulations (72 excluded altogether). IGC, item group checklist; SCAN, Schedule for Clinical Assessment in Neuropsychiatry.

former, and more deprivation and loss of social networks in the latter. The rate of interview refusals varied from 3% (Santander) to 32% (London). Again, Santander and Verona had low rates and contrasted with London, and this might reflect social context and degree of deprivation/integration. Between 21% (Amsterdam) and 57% (Verona) completed the interview at time 1, and this may reflect differences between recently established (Amsterdam) and long-standing (Verona) community mental health services. Table 4 shows comparisons between patients interviewed and those not interviewed; there were no significant differences.

## CONTENTS AND OUTLOOK

This supplement summarises the EPSILON Study methodology in terms of instrument adaptation (Knudsen *et al*, 2000, this supplement) and in terms of psychometric methodology applied in testing instrument reliability (Schene *et al*, 2000, this supplement). The individual instruments used and adapted in this study will be described in detail, and reliability results will be outlined in papers focusing on each individual instrument: the Camberwell Assessment of Need (CAN-EU; McCrone *et al*, 2000, this supplement), Involvement Evaluation Questionnaire (IEQ-EU; van Wijngaarden *et al*, 2000, this supplement), Lancashire Quality of Life Profile (LQoLP-EU; Gaite *et al*, 2000, this supplement), and Verona Service Satisfaction Scale (VSSS-EU; Ruggeri *et al*, 2000, this supplement). For the Client Socio-Demographic and Service Receipt Inventory (CSSRI-EU), face validity and cross-cultural adaptation were achieved as described in Chisholm *et al* (2000, this supplement). The output of this process is a set of 'EU' instrument versions available in five languages (Danish, Dutch, English, Italian and Spanish). Data obtained using these instruments provided a multi-dimensional picture of the needs of people with schizophrenia, their service use and their subjective appraisal of quality of life and services available. In a further series of papers, the results obtained in studying patterns of mental health care in the five sites will be presented.

The set of instruments presented in this supplement will be made available to the wider audience of researchers and service managers involved in mental health services research and planning in the five countries.

**Table 4** Comparisons between those interviewed, and those selected at random and meeting inclusion criteria but not interviewed (excluding Copenhagen)

	Interviewed	Not interviewed <sup>2</sup>	P <sup>1</sup>
Number (maximum <sup>1</sup> )	352	203	–
Age (years)	41.2	40.1	0.27
Years since first contact	11.7	11.7	0.95
Total number of contacts	1.96	1.98	0.37
Lifetime psychiatric admissions	4.0	6.3	0.14
Male	57%	59%	0.59
Married	18%	13%	0.21
White	93%	89%	0.26

1. Data missing for some individual variables.

2. Because lost, ill, died, refused.

For the EU instrument versions produced in this study to have an impact on research and practice in mental health care it is necessary to disseminate them properly. Ultimately, the applicability and easy use of the instruments in settings across Europe will decide whether they can make a lasting contribution to the field of mental health services research.

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