

THE EUNOMIA-STUDY: EUROPEAN EVALUATION OF COERCION IN PSYCHIATRY AND HARMONISATION OF BEST CLINICAL PRACTICE

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Coercive psychiatric treatment (involuntary hospitalisation, seclusion, restraint and forced medication) varies widely between European countries with regard to legal background, prevalence and type of involuntary treatment measures and other variables. However, little research and no trans-national comparisons on these variations exist so far. Furthermore, there are no European guidelines for best clinical practice of coercion in psychiatry. EUNOMIA is a three-year research project funded by the European Union, which aims at the analysis of the existing variation in coercive psychiatric treatment. This naturalistic study is conducted in 12 psychiatric inpatient units, in 12 European countries (Bulgaria, Czech Republic, Germany, Greece, Israel, Italy, Lithuania, Poland, Slovakia, Spain, Sweden, and United Kingdom). Two groups of patients are being assessed, at three time points: patients admitted involuntarily and patients who, although admitted voluntarily, feel coerced to admission. Data is gathered on all coercion, their influencing factors and outcomes. Interviews and structured assessment instruments are used to assess perceived coercion during hospitalisation, current symptoms and treatment- and life-satisfaction. All data is being entered into a web-based computerised documentation system. The findings of the study will be integrated with knowledge from legal and ethical experts as well as from users' organisations into national and European guidelines for best clinical practice of coercive psychiatric treatment. Dissemination of the results will be directed towards all professional groups involved in the process of involuntary treatment and users' organisations in order to advocate the harmonisation of best practice across Europe, to strengthen users' involvement and to influence political and legal decisions.

Key words: coercive psychiatric treatment, coercive measures, perceived coercion, mental health act, patients' rights

INTRODUCTION

The satisfaction of users from mental health services alongside with the question of whether psychiatric treatment can be considered successful if patients themselves are dissatisfied, have often been the focus of psychiatric research during the past decade¹. A frequent source of dissatisfaction and of negative feelings is involuntary psychiatric treatment, which today is acknowledged by researchers as an extremely sensitive and hotly debated ethical issue²⁻⁷.

The term "involuntary psychiatric treatment" refers to both involuntary admission to a Mental Health Unit and also the use during hospitalisation of coercive measures, such as seclusion, mechanical restraint and forced medication. The procedure of involuntary admission is defined by country-specific legislation and its theoretical basis is either the dangerousness of psychiatric patients to others or to themselves, or the need for treatment. Seclusion is defined as the involuntary placement of an individual alone in a locked room specially set up for this purpose, whereas restraint is the fixation of at least one of the patient's limbs by mechanical devices⁸⁻¹¹. Finally, forced medication aims at the 'inner' chemical restriction of the patient⁸.

Both clinical practice and research¹² have shown that it is impossible to avoid the use of some form of coercive measures in Mental Health Units that admit patients with

severe psychiatric disorders. Moreover, it seems that coercive measures work; not only do they prevent injury and reduce agitation, but they are often necessary for patients in order to regain control upon themselves and eventually become engaged in therapy¹¹.

On the other hand, the use of seclusion and restraint can have substantial deleterious physical and (more often) psychological effects on both patients and staff¹³⁻²⁰. Moreover, according to research findings, the use of coercive measures can be substantially influenced by non-clinical factors such as cultural biases, staff role perceptions, the attitude of the hospital administration etc^{19,21-27}.

Public awareness of coercive psychiatric treatment is growing. Although patients often seem to accept their own involuntary treatment²⁸⁻³¹, users' organisations emphasise its negative effects. Patients experience coercive treatment as an extra burden on their already vulnerable mental condition and as a violation of their freedom and human dignity. The use of coercion can also obstruct the formation of a trusting therapeutic relationship, it is related to poorer outcome and it can result in pushing the patient away from mental health services³². Psychiatrists have raised concerns that coercive measures may represent a failure of the ongoing psychiatric therapeutic intervention⁵.

Another equally sensitive issue in psychiatry is that of perceived coercion. Patients' subjective perception of

coercion does not always correspond to the actual coercive measures imposed upon them or to the legal status of hospitalisation³³. Therefore, the reduction of coercive measures alone does not necessarily result in greater treatment satisfaction. Equally important for the subjective perception of coercion is the patient's notion of being respectfully included in a fair decision making process as well as the use of negative pressures, such as force and threats^{34,35}.

Despite the existing debate on the issue of involuntary psychiatric treatment, there is still much unexplained variation in the use of coercive measures among countries³⁶⁻⁴¹. Although in 2000 the European Working Party on Psychiatry and Human Rights published the "White Paper on the protection of the human rights and dignity of people suffering from mental disorder, especially those placed as involuntary patients in a psychiatric establishment", up to now there are no European guidelines that would regulate the use of coercive treatment. On the other hand, although several studies on predictors and effects of coercive treatment have been published, research in this field remains sporadic and for the practical application of the results trans-national comparisons and integration are necessary. Little research has been carried out in issues such as legislation, clinical practice and cross-national comparisons (e.g. on patients' socio-demographic and clinical characteristics, patients', clinicians', and relatives' views, legislation) regarding the application of coercive measures in member states of the European Union. Although different procedures and legislation make comparisons between countries difficult, this kind of research is necessary for the development of common guidelines for best clinical practice and for legal regulations. However, as long as inconsistent findings and controversies persist, there will be a growing concern that coercive measures in psychiatry may entail unnecessary infringements of patients' rights.

Within this scope, a research study focusing on coercive psychiatric treatment as it is implemented in different European countries is more useful and better timed than ever. A European multi-centre research project was introduced on December 1st 2002. This was funded by the Fifth European Commission Frame Program (no. of contract QLG4-CT-2002-01036), under the title EUNOMIA (European Evaluation of Coercion in Psychiatry and Harmonisation of Best Clinical Practice).

AIMS OF THE STUDY

EUNOMIA is an initiative of the Department of Psychiatry and Psychotherapy of Dresden University. This specific Department is also the co-ordinating centre of the study.

The aim of this naturalistic study, which is unique regarding its methodology and cross-national comparisons, is the analysis of the existing variations in the use of coercive measures in psychiatry. Following this general research framework, the study is conducted in 12 psychiatric inpatient settings with catchment areas of similar size, in 12 different

European countries (Bulgaria, Czech Republic, Germany, Greece, Israel, Italy, Lithuania, Poland, Slovakia, Spain, Sweden, United Kingdom). Between these countries great variations exist regarding legislation, prevalence and documentation of involuntary treatment measures, social and cultural background, users' involvement and other variables.

The specific scientific aims of the study are:

- to include regions of comparable size from all over Europe in order to study as much of the existing variation as possible
- to systematically describe and compare demographic characteristics and mental health services of these regions
- to systematically describe and compare patients hospitalised both voluntarily and involuntarily with regard to variables that might be connected with the use of coercive treatment measures or with patients' perceived coercion
- to explore the connection between coercion during treatment, treatment outcome and future treatment seeking
- to document views of staff, users and family members on coercive measures
- to identify factors that may influence staff to select coercive treatment measures in favour of non-coercive alternatives
- to provide information on the legal basis for the use of coercive measures in psychiatry in the participating countries
- to establish a critical mass for influencing future research in this area as well as legal and political decisions in order to harmonise the clinical practice of coercive measures in psychiatry on both national and European level.

The research questions of the study protocol are:

1. What are the socio-demographic and clinical characteristics of legally involuntarily admitted patients and of voluntarily admitted patients who feel coerced to admission?
2. How frequent and intense is perceived coercion in legally voluntarily and legally involuntarily patients admitted to the participating centres?
3. What coercive treatment measures are applied to these two groups of patients?
4. What is the medium-term outcome for legally involuntarily admitted patients and for voluntarily admitted patients who feel coerced to admission?
5. What are the baseline predictors of a more or less favourable medium-term outcome in the two groups of patients?
6. What is the international variation in questions 1 - 5?

Data regarding coercive measures, their influencing factors and their effects is gathered through structured interviews with patients and from clinical documentation. A central database for the documentation and evaluation of all information has been established. The findings of the study will be integrated with knowledge from legal and ethical

Table 1. The centres participating in the Eunomia study

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* Department of Psychiatry, Wroclaw Medical University, Wroslaw, Poland
* Psychiatric Hospital of Michalovce, Michalovce, Slovakia
* Department of Legal Medicine and Psychiatry, University of Granada, Granada, Spain
* Unit for Social and Community Psychiatry, Newham Centre for Mental Health, London, Great Britain
* Psychiatric Research Centre, Orebro, Sweden

experts as well as from users' organisations into national and European guidelines for best clinical practice of coercive psychiatric treatment.

PARTICIPATING CENTRES

The twelve participating centres of the study are being presented on *Table 1*. Overall 17 inpatient wards are included, of which 9 are Psychiatric Wards in General Hospitals (Bulgaria, Czech Republic, Italy, Spain, Sweden, Germany) and 8 belong to independent Psychiatric Hospitals. Greece is represented by the D' Acute Ward of the Psychiatric Hospital of Thessaloniki. This is one of the five Acute Wards of the hospital, admitting new patients every five days. According to data from a previous research project⁴³, in 1999 272 patients were hospitalised in the ward (a total of 387 admissions). Of these, 34 patients (13.5%) were admitted involuntarily for hospitalisation and 40 (15.9%) were admitted involuntarily for evaluation. The percentages are similar for the total of admissions to the Psychiatric Hospital of Thessaloniki in the same year (76% voluntary admissions, 24% involuntary admissions) and they do not change significantly through time. According to a retrospective study for the years 1988-1993, 23% of the admissions to D' Acute Ward were involuntary⁴⁴.

Regarding the special characteristics of the participating centres, 11 wards (among them D' Acute Ward) admit both male and female patients, 4 wards (Bulgaria, Czech Republic, Italy, Poland) admit male patients only and 2 wards (Bulgaria, Czech Republic) female only. Thirteen wards (76%) are 'closed', and 3 (Italy, Great Britain) are 'partly closed'. Interestingly enough, the only 'open' ward is the Greek one. All the Wards at the Psychiatric Hospital of Thessaloniki are open and this reflects its general attitude for the psychiatric

Table 2. Description of the wards participating in Eunomia

	Number of beds	Beds / Physician	Beds / nurse
DRESDEN	35	6	1
SOFIA	45	6	3
PRAGUE	77	10	2
THESSALONIKI	25	3	2
TEL AVIV	36	7	2
NAPLES	18	3	1
VILNIUS	40	8	4
WROSLAW	29	5	2
MICHALOVCE	10	10	1
GRANADA	30	6	2
LONDON	33	4	1
OREBRO	11	11	2

Table 3. Instruments used for the description of catchment areas

CONSTRUCT	INSTRUMENT
Socio-demographic profile of the catchment area	European Socio-Demographic Schedule (ESDS) ⁴⁵
Socio-demographic profile of the catchment area	Parts of the Area Socio-demographic Sheet ⁴⁶
Inventory of the mental health services in the catchment area	European Service Mapping Schedule (ESMS) ⁴⁷
Description of the participating wards	International Classification of Mental Health Care (ICMHC); instrument by H.J. Salize ⁴⁸

inpatient care. However, this attitude is often being criticised by both the staff and the public due to the problems that are raised, e.g. patients often abscond and the only way to prevent this is the use of mechanical restraint.

Finally, the ratios bed per physician and bed per nurse (*Table 2*) reveal that D' Acute Ward is one of the most adequately staffed centres of the study, with three beds per physician (trainees are included) and two beds per nurse.

STUDY DESIGN

The study consists of three phases: a 9-month preparatory, a 21-month data collection and a 6-month phase for data analysis, preparation of guidelines for best clinical practice and dissemination of result.

A. PREPARATORY AND PILOT PHASE (12/2002 – 8/2003)

The preparatory phase of the study began with the setting up of reliable communication links between the 12 participating centres. Approval on ethical and data protection issues was provided to each centre by the local Ethics

Committees. A special working group of legal experts was formed and reports were drawn up on the legal background for involuntary hospitalisation and treatment in the 12 countries. A computerised documentation system with a central database was designed and implemented. Each centre formed a focus group, with the participation of both professionals and representatives of users and their families. The twelve partners agreed on the assessment instruments, which were then translated in the national languages and validated. All researchers and staff were trained in using these instruments, in order to reach high inter-rater and intra-rater reliability. Finally, certain assessment instruments were used for the description of the catchment area of each participating centre, regarding socio-demographic characteristics and mental health services (Table 3). The preparation and piloting phase was concluded with a 3-month piloting of all assessment instruments in clinical routine.

B. DATA GATHERING PHASE (09/2003 – 05/2005)

The project at present is in the process of this phase. All participating centres are collecting data according to the study design, using the selected assessment instruments.

During this phase, two groups of patients are being assessed: a. patients admitted to the hospital on an involuntary legal basis (140 patients per centre) and b. legally voluntarily admitted patients who feel coerced to admission (40 patients per centre). For building up the second group, voluntarily admitted patients are approached and screened whether they feel coerced to admission. As an assessment instrument, the so called “Perceived Coercion Scale” from the MacArthur Admission Experience Survey⁴⁹ is used. Patients are asked to participate in the study if they report perceived coercion in three or more out of the five questions in this instrument. The definition of the two study groups (voluntarily and involuntarily admitted patients) in each centre is according to the national legislation for mental health. On Table 4 the

Table 4. Criteria for patients to be included in the Eunomia study

* Age between 18 and 65 years old
* Patients after being informed about the project, give their written consent to participate to the study (before T1)
* Patient is not hospitalized in a special unit for only forensic or only intoxicated patients
* Patient is not hospitalized in a special unit for only eating disorders, which automatically means coercive treatment
* Patient has not been diagnosed with dementia (note: diagnoses such as brain trauma, epilepsy, drug-induced psychosis, alcohol intoxication associated with a mental disorder are acceptable for study inclusion)
* Patient has not yet been included in the study
* Patient lives in the catchment area of the participating hospital

inclusion criteria for the study are reported.

Each patient included in the study is assessed at three time-points: T1 (within the first ten days of admission), T2 (four weeks after admission) and T3 (three months after admission independently of their current living situation). Patients' perception of coercion during admission and hospitalisation, current symptom severity, satisfaction with treatment and quality of life are being assessed. The instruments (Table 5) have been selected so that they provide a valid and reliable assessment, while accommodating the sometimes-limited mental capacity of the participating patients.

Included in the assessment is the documentation of all individual incidents of the following coercive measures during the first four weeks of hospitalisation:

- o Involuntary admission to a Psychiatric Hospital
- o Involuntary detention after being admitted voluntarily

Table 5. Instruments for the assessment of patients participating in the Eunomia study

CONSTRUCT	INSTRUMENT
Perceived coercion in voluntarily admitted patients	Screening with perceived coercion items from MacArthur Admission Experience Survey ⁴⁹
Characteristics of treatment episode	Records
Socio-demographic and clinical characteristics	Records, interview
Perceived coercion and pressures concerning hospital admission	Parts of the MacArthur Admission Experience Survey + Cantril Ladder of perceived coercion ^{50,51}
Details of each coercive measure applied in the first 4 weeks after index admission	Routine documentation, additional records
Perceived coercion and pressures during hospitalisation and outcome assessment	Structured interview + Cantril Ladder of perceived coercion (rephrased)
Outcome assessment ²	Structured interview
Quality of life	Manchester Short Assessment of Quality of Life (MANSA) ⁵²
Satisfaction with treatment	Client's Assessment of Treatment (CAT), 7 main items ⁵³
Compliance with treatment	Structured interview
Perceived coercion (staff rating)	Cantril Ladder of perceived coercion (rephrased)
Patient's aggression (staff rating)	Modified Overt Aggression Scale (MOAS) ⁵⁴
Symptom severity and level of functioning	Global Assessment of Functioning scale (GAF)
Symptom severity	Brief Psychiatric Rating Scale (BPRS), 24 item version ⁵⁵

- o Seclusion / Placement in a locked room
- o Restraint / Fixation by holding or/and by mechanical appliance
- o Forced medication

Finally, interviews are conducted for the assessment of family members' attitudes towards coercive treatment.

On a continuous basis, all twelve centres enter the gathered data into the computerised documentation system and all entries are being checked regularly.

C. ANALYSIS AND DISSEMINATION PHASE (06/2005 – 11/2005)

During this phase the statistical analysis of all data will be completed and the research questions will be answered. The findings of the study will be integrated with material deriving from the legal experts' reports and with users' views into specific guidelines for the best clinical practice of coercive measures in psychiatry. The results of the study will be presented at national and international scientific conferences and will be published in leading scientific journals. All national and European bodies involved in the elaboration of the legal frame for mental health as well as the World Health Organisation will also be informed.

Dissemination of the findings will be directed towards all professional groups involved in the process of involuntary treatment and at users' organisations in order to advocate the harmonisation of best clinical practice across Europe, to strengthen users' involvement and to influence political and legal decisions.

CONCLUSION

Psychiatric reform is still an ongoing process in all European countries. Common aims are the deinstitutionalisation of chronic patients with mental health problems, the reduction of beds in psychiatric hospitals and the development of mental health services in the community. Fundamental principles in this process are the strengthening of patients' autonomy, the recognition of their needs, the improvement of their quality of life and the flexibility of all therapeutic interventions.

So far there has been little research at a European level on the quality of care and on the effects of therapeutic interventions in one of the most vulnerable groups of psychiatric patients, namely those who are admitted involuntarily or feel coerced to admission and who are subjected to coercive measures during their hospitalisation. Moreover, although these people form a very vulnerable population group in terms of possible infringements of autonomy, dignity, freedom and human rights, they are not protected adequately by national or European guidelines for best psychiatric treatment.

The EUNOMIA study aims at the establishment of a vast empirical database for the detailed analysis at a European level of the existing variation in the use of coercion in psychiatry. The recording of patients' subjective experiences and the involvement of users' organisations aim at strengthening their autonomy and human rights. Finally, it is expected that

through the development of European Guidelines and dissemination to governmental, legal and professional bodies EUNOMIA will contribute to the establishment of a common clinical practice regarding coercive measures in psychiatry for all present and future member states of the European Union. More information about EUNOMIA can be found at the project's site: **www.eunomia-study.net**

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