Univerzita Karlova v Praze 1. lékařská fakulta

Studijní program: Psychologie

Studijní obor: Lékařská psychologie a psychopatologie



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Použití omezovacích opatření v psychiatrii

The use of coercive measures in psychiatry

Doktorská disertační práce

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Identifikační záznam:

NAWKA, Alexander. *Užití omezovacích opatření v psychiatrii. [The use of coercive measures in psychiatry].* Praha, 2013. 95 s., 1 příl. Disertační práce. Univerzita Karlova v Praze, 1. lékařská fakulta, Psychiatrická klinika. Vedoucí práce Raboch, Jiří.

Abstrakt

Psychiatrie má jedinečné postavení mezi ostatními lékařskými disciplínami vzhledem k tomu, že omezení autonomie pacientů používá v jejich nejlepším zájmu jak k jejich léčbě tak k jejich kontrole. Omezovací opatření, jako jsou umístění pacienta do izolace, omezení pacienta v pohybu, nebo užití neklidové medikace jsou široce užívané v klinické praxi jako metody zvládání akutních psychiatrických stavů či neklidných pacientů. Tato dizertační práce byla provedena v rámci mezinárodního projektu EUNOMIA (European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice), který probíhal ve dvanácti Evropských státech. Byly stanoveny tyto výzkumné otázky: jaké jsou sociodemografické a klinické charakteristiky nedobrovolně hospitalizovaných pacientů u kterých jsou použita omezovací opatření; jaké typy omezovacích opatření jsou užívaná nejčastěji; jaké jsou interní a externí rizikové faktory související s jejích užitím; a konečně jaké jsou genderové rozdíly u pacientů se schizofrenií, u kterých bylo užito omezovacích opatření. Do studie bylo zařazeno 2,030 nedobrovolně hospitalizovaných pacientů, z nichž celkem u 770 (38%) bylo použito 1,462 omezovacích opatření. Procento pacientů, u kterých bylo použito omezovacích opatření, se ve sledovaných zemích nachází v rozmezí 21% až 59%, a do velké míry kolíše i v typu použitých omezovacích opatření. V osmi státech je nejčastěji použitým omezovacím opatřením neklidová medikace, ve dvou státech je to omezení pacienta v pohybu. Umístění pacienta do izolace bylo použito zřídka, a to pouze v šesti sledovaných státech. Nejčastějším důvodem, který vedl k užití omezovacího opatření bylo heteroagresivní chování pacienta. Diagnóza schizofrenie a závažnější psychiatrická symptomatika jsou asociovány s větší pravděpodobností užití omezovacích opatření. Nicméně technické charakteristiky zařížení, jako jsou počet nemocničních lůžek na 100.000 obyvatel, průměrný počet zdravotního personálu na jedno lůžko, a průměrný počet lůžek na jeden nemocnční pokoj, se v tomto ohledu neukázali jako signifikantní. Genderové rozdíly mezi pacienty se schizofrenií poukazují u žen na zvýšený práh vedoucí k zahájení léčení za použití omezovacích opatření. Na základě výsledků této práce lze konstatovat, že omezovací opatření jsou použita v evropských státech u významné skupiny nedobrovolně přijatých pacientů. Míra jejich užití závisí na diagnóze a tíži psychiatrické symptomatiky, a je dále ovlivněna i státem, ve kterém byl pacient léčen. Národní a mezinárodní doporučení ohledně omezovacích opatření by měla obsahovat a dále rozvíjet cílené léčebné postupy, se zvážením všech dostupných evidencebased informací ohledně užití omezovacích opatření které by vedli k jejich racionalizaci.

Klíčová slova: nedobrovolná hospitalizace, omezovací opatření, izolace, omezení v pohybu, neklidová medikace, gendrové rozdíly, schizofrenie

Abstract

Psychiatry has unique status among other medical disciplines where patients' autonomy might be restricted in the best interest of the patient in order to both cure and control the patient. Coercive measures such as seclusion, physical restraint or forced medication are widely used in clinical practice as methods for managing acute, disturbed or violent psychiatric patients. This thesis was carried out as a part of the EUNOMIA project (European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice) in which centers from twelve European countries recruited involuntary admitted patients. The research questions of this thesis were the following: what are the socio-demographic and clinical characteristics of the patients who receive coercive measures; what types of coercive measures are used with involuntarily treated patients; what are the internal and external risk factors for their use; and finally what are the gender differences among involuntary admitted coerced patients with schizophrenia. All together we evaluated a group of 2,030 involuntarily admitted patients, in which 1,462 coercive measures were used with 770 patients (38%). The percentage of patients receiving coercive measures in each country varied between 21% and 59%. These twelve countries varied greatly in the frequency and type of coercive measure used. In eight of the countries, the most frequent measure used was forced medication, and in two of the countries mechanical restraint was the most frequent measure used. Seclusion was rarely administered and was reported in only six countries. The most frequent reason for prescribing coercive measures was patient aggression against others. A diagnosis of schizophrenia and more severe symptoms were associated with a higher probability of receiving coercive measures. Moreover we did not find any statistically significant influences of the technical characteristics of countries such as, number of psychiatric hospital beds per 100.000, number of staff per bed, and average number of beds per room. In regards to the gender differences among shizophrenia patients results point towards a higher threshold for women to be treated with the use of coercive measures. Based on the results we conclude that coercive measures are used in a substantial group of involuntarily admitted patients across Europe. Their use depends on diagnosis and the severity of illness, but was also heavily influenced by the individual country. National and international recommendation on coercive treatment practices should include and further develop targeted treatments with appropriate consideration of the current evidence in inpatient populations that would rationalize the use of coercive measures in psychiatric facilities.

Key words: involuntary treatment, coercive measures, seclusion, restraint, forced medication, gender differences, schizophrenia

Acknowledgement

First of all I would like to express deepest appreciation to my supervisor, Prof. Jiří Raboch for leading me through my research career for more than ten years. Whithout his guidence and persistent help this dissertation would not have been possible.

As this thesis has been prepared within the large European study EUNOMIA (European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice), I would also place on record, my sense of gratitude to one and all who, directly or inderectly, have lent their helping hand in this venture, especially to Prof. Thomas Kallert, Prof. Stefan Priebe, Dr. Andrea Fiorillo and Dr. Domenico Giacco. I would also like to gratefully acknowledge the valuable contribution of all the research workers involved in the data collection, the patients who participated and the staff of the participating hospitals.

Many more persons have been extremely helpful during my work on this thesis and have provided my with constructive comments when writing the articles. In this respect I would like to thank Dr. Lucie Kališová, Dr. Martin Černý and Dr. Eva Kitzlerová for their important support throughout this work. I would also like to thank our statistician Dr. Libor Číhal who has spent an enormous amount of time on the numbers with which we have kept him busy for many weeks.

Furthermore I should not forget to thank Prof. Howard Goldman, for his unweavering support and his wise guidence he has provided me throughout my short research career.

Last but not least, I wish to thank my entire family for providing a loving environment for me, especially to my wife Lucie and my sweet daughter Margareta. A special thought is devoted to my parents for all the support I have been receiving from them since my very first steps. Without all of yours encouragement and understanding it would have been impossible for me to successfully finish this thesis.

The EUNOMIA study was funded by a grant from the European Commission (Quality of life and Management of Living Resources Programme, contract number QLG4-CT-2002-01036).

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1. INTRODUCTION

Psychiatry has unique status among other medical disciplines where patients` autonomy might be restricted in the best interest of the patient in order to both cure and control the patients (Salize & Dressing, 2004; Keski-Valkama, 2010). Coercive measures such as seclusion, physical restraint or forced medication are widely used in clinical practice across the world as methods for managing acute, disturbed or violent psychiatric patients (Salize & Dressing, 2004; Priebe et al., 2008; Kallert et al., 2008). They are regarded as indispensable in preventing physical and psychological damage to the patient and/or others (Lay et al., 2011). Yet, in many countries these measures are regarded as controversial (Steinert et al., 2010; Janssen et al., 2011) and are sharply criticized by various organizations and institutions (Press Release, 2005).

The main reason why controversies continue to arise is that appropriately designed controlled studies for assessing the beneficial or harmful effects of coercive measures do not exist, or they results might not be usually generalized for other populations (Sailas & Fenton, 2000; Sailas & Wahlbeck, 2005; Keski-Valkama, 2010). Some believe that these procedures signal failures in care (Bernstein, 2008) and others have the opinion that the total elimination of coercive measures may be difficult to achieve when treating individuals who have acute psychosis and a history of violence, and whose recent violent behavior led to hospitalization (Sharfstein, 2008). In Europe the pattern of coercive psychiatric treatment varies widely between countries with regard to its frequency, type, and legal regulations (Steinert et al., 2010; Fiorillo et al., 2011).

Because freedom and dignity are fundamental values in the Western world (Keski-Valkama, 2010) the use of coercive measures should be avoided as much as possible (Georgieva, 2012). The importance of following the individual human rights has been reflected in health care, which can be observed in the last decades by a trend moving away from paternalistic approach towards the one which is putting more importance on patient's autonomy (Sjostrand & Helgesson, 2008; Keski-Valkama, 2010).

1.1. THE INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES – HISTORICAL PERSPECTIVE

1.1.1. THE USE OF COERCIVE MEASURES IN ANCIENT TIMES

The coercive measures have been used in psychiatry since its beginning (Brown & Tooke, 1992). More than 2000 years ago Roman encyclopaedist Celsus who considered insanity to be due to perversion of the secretions, attached great importance to individual differences in patients and the treatment. Among exercise in the open air, bathing, music, reading, the removal of fear by kindness or by deceit, other measures which he deemed remedial were decidedly harsh, and consisted in restraints and even severe punishments of various kinds, to subdue violent cases of mental disease (Kellogg, 1897).

With the advance of Greek civilization at this period some of the biggest superstitions with regard to mentally ill were dispelled, and they were recognized as human with certain rights to be respected. Caelius Aurelianus in the second century had most humane and enlightened views as to the treatment of the mentally ill, and might be held for the first historical defender of the system of non-restraint, and of the control of patients by nurses instead of by mechanical means (Kellogg, 1897). He denounced the iron chains and other crude instruments which were used at that time.

The description of the humane use of the coercive measures might be traced in the script of the Greek physician Soranus of Ephesus, who wrote in the second century AD (cited by Alty & Mason, 1994, 17–18 in Keski-Vakama, 2010): "Have the patient lie in a moderate and slightly warm room. The room should be perfectly quiet, unadorned by paintings... and the bed should be firmly fastened down. It should face away from the entrance to the room so that the patient will not see those who enter. In this way the danger of exciting and aggravating his madness by letting him see many different faces will be avoided." After the decline of the Greek school much of that which was known, also from the ways on how to deal with dignity with mentally ill, was forgotten.

1.1.2. THE USE OF COERCIVE MEASURES IN THE MIDDLE AGES

The Middle Ages are usually referred to as the "dark ages" of psychiatry. The "insane" were regarded everywhere as afflicted by the gods or possessed by the Devil. Their symptoms were mistaken for willful demonstrations of wickedness they were treated accordingly in prison cells and cages, or in cells attached to the cloisters under the care of the priests (Kellogg, 1897). Their purpose was less to provide treatment than to protect society by locking up the mentally ill. This belief prevailed even till the 17th century (Brown & Tooke, 1992).

In Europe, the first institutions for mentally ill people were opened in the 13th century (Shorter, 1997). In 1403 mentally ill patients were first received at Bethlehem Hospital in London and in 1472 there was a special place for mentally ill in Ghent, in Belgium. Although these places were custodial rather than curative, and they were not conducted with a true understanding of the mental illness as a brain disease, to be treated like other somatic diseases, they represented the very beginnings of the institutions that shall be established some 400 years later. Even after the shift towards the institutional model, the treatment of mentally ill persons in the 18th century did not dramatically change (Keski-Valkama, 2010). Coercive measures were used frequently for the management of the most disturbed and violent patients in the asylums, where they were isolated from the society (Dix et al., 2008; Keski-Valkama, 2010).

1.1.3. THE USE OF COERCIVE MEASURES IN THE MODERN HISTORY

The darkest hour in the history for the mentally ill had passed when Phillipe Pinel (1745 -1826) realized his reform on behalf of mentally ill at the Bicetre in 1793 and introduced the first basic principles of coercive measures as non-punitive measures in "Memoir of Madness" (Weiner, 1992; Keski-Valkama, 2010). "Moral treatment" as he called it, presented a new approach in the treatment of mentally ill. Not that the coercive measures were totally banned, the straightjacket continued to be used in practice (Paterson, 2010) in most severe cases, but more humane and sensitive approach was put in practice. In Germany Fricke reduced the amount of restraint in

mentally ill patients and improved the condition of patients in the asylums in 1793 (Kellogg, 1897).

Conolly and Hill almost fully abolished restraint in the Lincoln Asylum in England in 1837, followed by Ellis and Hanwell during a strong anti-restraint movement (Shorter 1997; Haw & Yorston, 2004). This aim was not well received everywhere, and led to controversy and ongoing discussions in several European countries (Colaizzi, 2005). Coercive measures such as padded seclusion rooms, wet packs and tight wrapping sheets were used as a last resort by Conolly at that time (Colaizzi, 2005; Keski-Valkama, 2010). Around the same time in America Benjamin Paish made similar attempts to better the condition of the mentally ill by reducing the use of cruel interventions when calming down disturbed patients (Kellogg, 1897).

1.1.4. THE USE OF COERCIVE MEASURES IN THE 20th CENTURY

Even at the beginning of the 20th century coercive measures still presented one of the main therapeutic and controlling mechanisms in the management of violent and disturbed psychiatric patients (Keski-Valkama, 2010). In this period, clinicians used various ways to restrain patients. Thermal therapy was used to calm aggressive patients, who spent the whole day in a warm bath with a sailcloth cover that prevented them from getting away (Georgieva, 2012). Many controversial therapies were used, such as an electric bath for healing depression, or, psychosurgical interventions such as frontal lobotomy, which treated psychosis by cutting the connections to and from the prefrontal cortex (Georgieva, 2012).

Situation changed gradually in the second half of the 20th century due to introduction of modern therapeutic tools, mainly because of psycho-pharmacotherapy (Brown & Tooke, 1992). However, till today, the total removal of the coercive measures from the clinical practice seems as an unfeasible goal, as the complete abolition of such freedom-restricting coercive interventions has never been convincingly reported in any country or period (Steinert et al., 2010), and coercive measures are still being used throughout the world (Dix et al., 2008).

1.2. INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES - LEGISLATIVE AND ETHICAL PERSPECTIVE

1.2.1. LEGISLATION FOR INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

Although European countries do share a similar background in terms of societal systems and history of psychiatry, their legislation for and practice of involuntary hospital admission differs significantly (Kallert & Torres-Gonzalez, 2006; Felthouse & Sass, 2008; Priebe et al., 2008). A comprehensive study carried out in 2001 across European Union member states regarding the legislation of involuntary placement and treatment of mentally ill patients (Salize et al., 2002) indicated that almost all member states had reformed their legislation in the last decades, but only minority of countries had detailed regulations of the use of coercive measures (Keski-Valkama, 2010). Controversy remains how involuntary hospital admissions should best be legislated for and regulated (Zinkler & Priebe, 2002; Welsh & Deahl, 2002).

Even though several attempts have been made to standardize rules and instruments (Priebe et al., 2005; Abas et al., 2006), such as the publication of the volume "Mental health legislation and human rights" by the World Health Organization in 2003 (WHO, 2003), in which the issue of involuntary hospital admissions was specifically addressed from a legal and technical perspective, the differences on the legislative and clinical procedures of involuntary treatment and the use of coercive measures still remain, both within and among European countries (Fiorillo et al., 2011; Steinert & Lepping, 2009).

There are basically two complementary aspects that can lead to the involuntary hospitalization and the use of coercive measures; the first aspect is the one of treating and curing the patient; and the second one is more focused on controlling patient's disturbed or dangerous behavior (Kaltiala-Heino et al., 2000; Keski-Valkama, 2010). As for the latter one, involuntary treatment as well as coercive measures might be useful tools in preventing one's auto-aggressive behavior or preventing hetero-aggressive deeds in agitated patients, to ensure one's safety. These

measures are used as a method of control only in situation where a patient's violent, or potentially violent behavior threatens the safety of oneself or others (Kaltiala-Heino et al., 2003; Keski-Valkama, 2010). If coercive measures have to be used, the decision on, and supervision of these procedures by a physician is mandatory in most Western countries (Muraliharan & Fenton, 2006, Kontio et al., 2012).

The criterion of dangerousness of mentally ill persons represents one out of two settling criteria for involuntary hospital admission according to the WHO definition (,,there is likelihood of self-harm or harm to others and/or of a deterioration in the patient's condition if treatment is not given", the other being ,,the evidence of a given mental disorder of specified severity as defined by internationally accepted standards" (WHO, 2003) and to the recommendations of the Council of Europe (CoE, 1983).

1.2.2. ETHICAL ASPECTS AND HUMAN RIGHTS PERSPECTIVE IN INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

Freedom and dignity are fundamental values in the Western world and as it has been already postulated in the first article of the United Nations (UN) Universal Declaration of Human Rights in 1948, "all human beings are born free and equal in dignity and rights and that they are endowed with reason and conscience and should act towards one another in a spirit of brotherhood" (Keski-Valkama, 2010).

Use of coercive measures therefore opens up a variety of ethical questions in relation to human rights and in particular to the patient's autonomy (Bloch & Green, 2006; Katsakou & Priebe, 2007; Prinsen & Van Delden, 2009). In the mental health field traditional justification for using coercive measures in psychiatry is derived from paternalism and from the nature of mental illness (O'Brien & Golding, 2003, Keski-Valkama, 2010). Person is on the grounds of mental illness considered incompetent because of lack of autonomy and/or lack of decision-making competence, therefore others need to intervene in the interest of the patient (medical paternalism)

or in the interest of others who might be affected (social paternalism) (Kjellin & Nilstun, 1993; Keski-Valkama, 2010).

Even though the expressed purpose for using coercive measures is legitimate, the risk of their application for punitive and repressive purposes as a result of the misuse of power cannot be fully excluded (O'Brien & Golding, 2003; Keski-Valkama, 2010). What is of great risk, that patients with mental illness are automatically considered being total incompetent in every aspect of their life (Appelbaum, 2006; Keski-Valkama, 2010).

To prevent misuse of involuntary treatment and the use of coercive measures in psychiatry, the World Psychiatric Association adopted in 1977 the Declaration of Hawaii, which was the first effort to elucidate the ethical principles of respect for person's autonomy (Kingdon et al., 2004; Keski-Valkama, 2010). In 1993 by the Declaration was updated in Madrid and the principle of "least restrictive interventions" in the use of coercive measures was upheld and involuntary acts "unless withholding treatment would endanger the life of the patient and/or those surrounding him or her" were forbidden. In agreement with the existing laws in the different countries and in accordance with the Helsinki Declaration (WHO, 2005) and with the European Convention on Human Rights (LECHR, 1994), the recommendations for good clinical practice (Fiorillo et al., 2011) have been developed with the direct and active involvement of national leaders and key professionals.

1.2.3. EUROPEAN RECOMMENDATIONS FOR GOOD CLINICAL PRACTICE IN INVOLUNTARY HOSPITAL ADMISSIONS

An involuntary hospital admission should be performed only if the following clinical prerequisites are simultaneously present:

- the patient is suffering from a serious mental disturbance;
- the patient needs urgent therapeutic hospital-based interventions;

- the patient does not agree to such care, so that the care cannot be given with his or her consent

Furthermore these recommendations (Fiorillo et al., 2011) stress the need to:

- provide information to patients about the reasons for hospitalization and its presumable duration;
- protecting patients' rights during hospitalization;
- encouraging the involvement of family members;
- improving the communication between community and hospital teams; and organizing meetings, seminars and focus-groups with users;
- developing training courses for involved professionals on the management of aggressive behaviors, clinical aspects of major mental disorders, the legal and administrative aspects of involuntary hospital admissions, on communication skills

Beside this it is necessary to find a quick and clear decision about the hospitalization in the patient's interest. The patient can ask to be taken to the hospital with his/her relatives, and he/she should be ideally admitted to the closest hospital. The whole procedure should have a limited time-frame and overly long waits should always be avoided. Nobody can be involuntarily hospitalized without being assessed by a psychiatrist and this assessment should be carried out in the most comfortable conditions while ensuring the necessary level of safety for both the examining physician and for the patient (Fiorillo et al., 2011).

Coercive measures should always be considered as last resort, and only when all other possible specific strategies for aggression management failed. They are allowed only in the framework of existing legislation, national standards, and relevant ethical norms and policies. Applied coercive measures (e.g., mechanical restraint, forced medication, seclusion) must be recorded in the patient's clinical file by the physician; in this file, information about persons ordering coercive

measures and those executing them, duration of coercive measures, patient's physical and mental conditions should be reported (Fiorillo et al., 2011).

1.2.4. IMPORTANT ORGANIZATIONS AND DOCUMENTS PROTECTING HUMAN RIGHTS OF MENTALLY ILL PATIENTS

Health care provided to patients should respect the principle of the "least restrictive alternative" and the relationship between patients and physicians should be based on reciprocal respect, in agreement with points 1 and 3 of the ethical standards approved by the Madrid declaration of the World Psychiatric Association (WPA, 1997), and subsequently listed by the WHO among the "key areas" to be included in mental health legislations (WHO, 2003). The protection of users' civil rights and personal freedom, which represents a fundamental achievement of psychiatry; the protection from physical and psychological violence and abuses, as reported in the 1994 Recommendation No. 1235 on psychiatry and human rights of the European Union, and as ratified in the basic principles of the Oviedo Convention, as well as in the most recent statements of the Convention on disabled persons' rights adopted by the UN General Assembly should be guaranteed.

In the last several decades also other documents were passed by international organizations, such as UN and the Council of Europe (CoE): "UN Resolution for the Protection of Persons with Mental Illness and for the Improvement of Mental Health; and CoE recommendations dealing with legal protection of people with a mental illness, rights of a detained patients and psychiatry and human rights. The documents should enhance the protection of the dignity, human rights and fundamental freedom of persons with mental illness, especially to coercive measures applied during involuntary hospitalizations (Jones & Kingdon, 2005; Keski-Valkama, 2010). Although all these international recommendations are not legally binding, they have at least moral obligation towards all the providers of psychiatric services (Keski-Valkama, 2010).

In order to prevent violations against human rights in the mental health care settings, CoE organized so called "European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT)". The CPT found that, in clinical practice, the application of legal recommendations and regulations were subject to discrepancies: "no country is free of dysfunction or erroneous practices in any closed psychiatric institution" (Niveau, 2004). The problem in the clinical practice is that the use of coercive measures is not routinely examined by local or national authorities (Keski-Valkama, 2010).

1.3. INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES – CLINICAL PERSPECTIVE

1.3.1. EPIDEMIOLOGY OF THE INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

The remarkable variety of the numbers of involuntary hospitalization and the use coercive measures across Europe is striking in an era of evidence-based medicine (Steinert & Lepping, 2009; Steinert et al., 2010). Involuntary admission rates vary by a factor of more than 10 (Zinkler & Priebe, 2002; Salize & Dressing, 2004; Kallert et al., 2007). In most European countries they range between 3 and 30% (Zinkler & Priebe, 2002; Salize & Dressing, 2004), but even higher numbers have been reported in Switzerland (more than 50%) (Riecher-Rossler & Rossler, 1993) and Norway (47%) (Hatling et al., 2002). Seeing it from another perspective, the prevalence of involuntary admitted patients in psychiatry ranges from 12.4/100.000 inhabitants in Italy to 232.5/100.000 in Finland (Salize & Dressing, 2004; Zinkler & Priebe, 2002) and the average duration of the coercive measures varies between 1.5 hours to 50.6 hours (Brown & Tooke, 1992).

Numbers of patients who have been exposed to seclusion, restraint or forced medication in acute psychiatric wards fluctuates in European and United States (US) studies from 6 to 30% of all admitted patients (Steinert et al., 2010, Lay et al., 2011). At least one coercive measure was used in 9.5% of patients in German hospitals (Steinert et al., 2007), but in an Finland study, restraint

or seclusion was used in 32.3% of patients and in 8.4% of all inpatients forced medication was applied (Kaltiala-Heino et al., 2000). In Switzerland 6.4% of the patients were either secluded or restraint, and 4.2% of them received forced medication (Lay et al., 2011). Some institutions are however reporting figures on those secluded or restrained as high as 66% of all inpatients (Way & Banks, 1990; Brown & Tooke, 1992). But the epidemiological data of the use of coercive measures varies widely not only on European level, but also on national, regional and even hospital level (Brown & Tooke, 1992; Busch & Shore, 2000). Although professionals within and between countries have not found consensus on the least harmful and the most effective coercive measure, the preferred method of dealing with emergencies in most European countries is forced medication (Raboch et al., 2010).

Even when the psychiatric hospitals were subjects to the same legal regulations, considerable differences in the quantity of applied coercive measures have been reported, as robust as two- or threefold higher numbers between hospitals (Lay et al., 2011). Similar results were reported also in a Scandinavian study (Hansson et al., 1999), suggesting, that the risk factor being involuntary admitted and treated with the use of coercive measures is strongly related to the specific psychiatric service, rather than to the individual patient (Lay et al., 2011). This however only further demonstrates the extent to which such measures are still based mainly on local and national traditions rather than scientific evidence (Georgieva et al., 2012c).

1.3.1.1. LIMITATIONS OF THE EPIDEMIOLOGICAL DATA OF THE INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

The comparison between countries simply based on the percentages of patients being coerced or involuntary admitted raises major methodological questions (Janssen et al., 2011). Countries with lower rates of coercive interventions might be carried out in places other than psychiatric hospitals to which problematic patients are diverted, e.g. prisons, residential homes, forensic psychiatry units and medical wards (Steinert et al., 2010). One should therefore interpret these data with caution, as it is complicated to compare the prevalence of the use of coercive measures as different studies are applying different methodologies (Busch & Shore, 2000; Whittington et

al., 2006; Bowers, 2000; Janssen et al., 2011; Steinert & Lepping, 2009) and they are including services that are treating only specific populations, e.g. not including old age psychiatry (Steinert et al., 2010).

Better in some ways, although still posing significant caution, is to compare the rates of coercive measures used per 100.000 inhabitants, or reporting outcomes separately for the major diagnostic groups (Steinert et al., 2010; Janssen et al., 2011). Some claim that observational comparisons between sites with different legislation and practice, present the only method to explore the link between procedures and outcomes (Priebe et al., 2010).

1.3.2. RISK FACTORS FOR INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

1.3.2.1. INTERNAL RISK FACTORS FOR INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

1.3.2.1.1. AGE AS A RISK FACTOR

There are many studies which report that younger patients have been coerced more frequently (Salib et al., 1998; Keski-Valkama et al., 2010b; Goldbloom et al., 2010; Lay et al., 2011). However, findings regarding a potential age effect are inconclusive, as other researchers have identified higher age to be risk factor for the use of coercive treatment (Riecher-Rossler & Rossler, 1993), and finally others have failed to find an association between age and being coerced (Brown & Tooke, 1992; Kaltiala-Heino et al., 2000). Some research suggests that while younger patients are more likely to be restrained and secluded, older patients are restrained and secluded for a longer period of time (Smith et al., 2005), and that restraint is more frequently applied to younger patients and seclusion to older ones (Wynn, 2002; Keski-Valkama, 2010a).

1.3.2.1.2. PSYCHOPATHOLOGY AS A RISK FACTOR

Increased rates of involuntary treatment and the use of coercive measures were found in specific psychiatric populations. Psychotic disorders (in particular schizophrenia) (Kelly et al., 2004; Cougnard et al., 2004; Xiao et al., 2004; Steinert et al., 2007), organic mental disorders (in particular dementia) (Spengler, 1986; Steinert et al., 2007), substance abuse disorders (Kaltiala-Heino et al., 2000; Steinert et al., 2007), personality disorders (Mason, 1998; Salib et al., 1998), and mental retardation (Tardiff, 1981; Way & Banks, 1990) have been related to involuntary treatment and also been associated with restraint and seclusion. Finnish authors have reported that psychotic behavior is the most frequent reason for using coercive measures, even without any signs of potential violence, meaning that clinical practice deviates from the theoretical and legal ground established for coercive measures (Keski-Valkama et al., 2010b). The results of studies that have included all major diagnostic groups are showing that the highest proportion of coercive measures used is among people with organic brain disorders, which were being used mainly as a prevention of falls (Steinert et al., 2007, Martin et al., 2007).

The common denominators which are being identified as the most frequent reason for the use of coercive measures, regardless of the psychiatric diagnosis, is acute (Thompson, 1986; Morrison & Lehane, 1996; Salib et al., 1998) or threatening violence (El-Badri & Mellsop, 2002; Way, 1986). Aside from acute or threatening violence, disorientation and agitation have been reported to be a frequent motivation in the use of coercive measures (Oldham et al., 1983; Kaltiala-Heino et al., 2003). Not surprisingly, the coercive measures are mostly applied short after being admitted (Binder, 1979; El-Badri & Mellsop, 2002). Only few studies reported that also chronic patients were subjects of coercive treatment in a substantial proportion (Way & Banks, 1990; Forquer et al., 1996). Psychopathological factors seems to play the most important part in the sum of all risk factors for involuntary hospitalization and the use of coercive measures during the inpatient care (Lay et al., 2011).

1.3.2.1.3. OTHER INTERNAL RISK FACTORS

The risk of being coerced during psychiatric treatment depends besides the diagnosis of the patient and actual psychopathology also on other socio-demographic characteristics in addition to age and gender, e.g. higher risk for ethnic minorities patients (Bhui et al., 2003), those socially marginalized, socially deprived or unemployed (Riecher et al., 1991; Bindman et al., 2002; Cougnard et al., 2004). However these findings are inconclusive, as other have not find any association between such characteristics and the use of coercive measures (Kelly et al., 2004; Bonsack & Borgeat, 2007).

1.3.2.2. EXTERNAL RISK FACTORS FOR INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

The variations in the use of seclusion or mechanical restraint point to powerful local effects often more related to external factors (e.g. environmental factors such as staffing resources, staff education level or organizational structure and the facilities, type of shift when admission occurred, lack of single-bed rooms, overcrowding, lack of privacy, presence of noisy patients) (Way et al., 1990; Morrison & Lehane, 1995; Nitschke-Janssen & Branik, 2006; Stolker et al., 2006; Bowers et al., 2010; Keski-Valkama, 2010a) than to internal factors (age, gender, psychopathology) (Fisher, 1994; Crenshaw & Cane, 1997; Martin et al., 2007; Georgieva, 2012). Authors moreover conclude that involuntary treatment is more likely to occur in services with smaller number of beds and shorter mean length of inpatient stay (Lay et al., 2011).

To make the situation even more complicated, other factors have been linked to the increased use of coercive practices in psychiatry, such and the functioning of local mental health service and shortages of crisis resolution teams (Bindman et al., 2002; Kmietowitcz, 2003; Lay et al., 2011). The actual frequency of the use of coercive measures between different hospitals is therefore dependent not only on the characteristics of patients (internal factors), but as well as on characteristics of wards (Mason & Alty, 1994; Bowers et al., 2004) and/or staff members

(Janssen et al., 2007) (external factors), and what is very important on their interplay (Janssen et al., 2007).

1.4. INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES – PATIENTS, CAREGIVERS AND STAFFS PERSPECTIVE

In the challenging context of involuntary treatment and the use of coercive measures, which can lead to high levels of distress among all parties involved including patients, caregivers and staff members, requires good mutual collaboration to optimize treatment and further care planning (Jankovic et al., 2011).

1.4.1. PATIENTS PERSPECTIVE

Most patients experience the use of coercive measures mainly in a negative way, with adjective such as harmful or traumatic (Frueh et al., 2005). Their complaints focus mainly on lack of information (Kontio et al., 2012). Many patients do not know the reason why they are placed in seclusion/restraint, or why forced medication is being used (Meehan et al., 2004). Experiences close to a punishment-like procedures (Holmes et al., 2004; Keski-Valkama et al., 2010a) and feelings of violation of their autonomy are not rare (Hoekstra et al., 2004). Very common negative patients' emotions related to the use of coercive measures are anger, helplessness, confusion, loneliness and humiliation (Hoekstra et al., 2004).

In a recent qualitative study the perspectives of people who experienced involuntary hospital admission and treatment were systematically explored (Sibitz et al., 2011), with the results indicating, that people viewed the experience of involuntary hospital admission as a 'necessary emergency brake', an 'unnecessary overreaction' or a 'practice in need of improvement'. The involuntary admission was viewed by the patients as 'over and not to be recalled' or a 'life-changing experience'.

Patients' retrospective view of the appropriateness of the admission and the use of coercive measures has been studied in many studies worldwide and 33 to 81% of involuntary patients found the admission "right" in retrospect (Srinivasan et al., 1980; Spence et al., 1988; Rusius, 1992; Kjellin & Nilstun, 1993; Kjellin et al., 2004; Priebe et al., 2010). It is necessary to acknowledge right from the beginning, that from a patient perspective coercive measures do not primarily represent a problem of safety, but a problem of human rights and the subjective experience of strain and lack of freedom (CoE, 1998; CoESCB, 2000).

In one of the studies which were carried out under the EUNOMIA (European Evaluation of Coercion in Psychiatry and Harmonisation of Best Clinical Practise) project, one month after involuntary hospital admission, between 39 and 71% patients believed that the admission was right (Priebe et al., 2010). The approval rates were even higher after 3 months, when on average 63% of patients found the admission right, symptom levels showed on average a significant but limited improvement (Kallert et al., 2011) and a reduction of positive symptoms was associated with less perceived coercion of patients (Fiorillo et al., 2012) which may be a reassuring finding for many clinicians, patients and their families (Priebe et al., 2010). One must however not oversee the substantial proportion of patients who did not agree retrospectively with the appropriateness of the admission.

1.4.1.1. PATIENT PREFERENCES IN REGARDS TO DIFFERENT COERCIVE MEASURES

Studies on the preferences of involuntary treated patients in regards to the use of coercive measures have produced mostly contradictory findings (Sheline & Nelson, 1993; Welles & Widderschoven, 2007; Veltkamp et al., 2008; Mayers et al., 2010). In a recent study (Georgieva et al., 2012c) authors conclude that patients' preferences were mainly defined by earlier experiences, where patients without coercive experiences or who had had experienced seclusion and forced medication, favored forced medication, but those who had been secluded preferred seclusion in future emergencies, but only if they approved its duration (Georgieva et al., 2012c).

In another study patients who had been secluded or received forced medication or had undergone both measures judged these measures to be equally effective and repulsive (Veltkamp et al., 2008). Others reported that secluded patients viewed seclusion and physical restraint as negative measures (Wynn, 2002; Hoekstra et al., 2004; Holmes et al., 2004; Meehan et al., 2004) and even as a form of punishment (Holmes et al., 2004; Meehan et al., 2004) or torture (Veltkamp et al., 2008). The opinions of physically restrained patients tended to be even more negative (Wynn, 2002). However, some positive aspects of seclusion and physical restraint were recognized by substantial part of patients (Meehan et al., 2000), who reported positive experiences such as a feeling of safety or security and that seclusion had a calming effect on them (Keski-Valkama, 2010). Some patients did see the use of coercive measures as a part of the treatment of their aggressive and violent behavior (Kjellin et al., 2004; Kuosmanen et al., 2007). Nonetheless, seclusion tends to remain a significant and negative experience in the minds of patients even after their discharge from hospital (Keski-Valkama, 2010).

Forced medication was experienced as the least distressing overall and least humiliating, caused less physical adverse effects and less sense of isolation (Georgieva et al., 2012a). Other authors came to the same conclusion, meaning that the patients preferred forced medication over other types of coercive measures (Sheline & Nelson, 1993; Mayers et al., 2010). It is necessary to comment also on the combined use of coercive measures (Bilanakis & Peritogiannis, 2008; Moran et al., 2009, Raboch et al., 2010), which are regardless of the type (restraint and forced medication or seclusion and forced medication) causing significantly more physical adverse effects and feelings of isolation than individual measures (Georgieva et al., 2012a).

1.4.1.2. MEASUREMENT OF PATIENT SATISFACTION WITH THE INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES

Patient satisfaction with the treatment presents one of the ways how the measure the mental health care is patients who have experienced involuntary treatment or the use of coercive measures (Ruggeri et al., 2007, Hackman et al., 2007). In general, psychiatric inpatients tend to be satisfied with their care (Hansson et al., 1989; Muller et al., 2002; Howard et al., 2003).

However the use of coercive measures may undermine this satisfaction levels (Kuosmanen et al., 2006) as well as treatment adherence (Jenkins et al., 2002; Kontio et al., 2012). The data in involuntary treated patient are in this regard however scarce (Svensson & Hansson, 1994; Greenwood et al., 1999). A recent study in United Kingdom (UK) showed, that satisfaction with treatment among involuntary patients was associated with perceptions of coercion during admission and treatment, rather than with the documented extent of coercive measures, which might indicate, that the main focus should be beside the quantity of coercive measures used during hospitalization oriented also towards patients' perceived coercion (Katsakou et al., 2010).

Just recently a first instrument to measure the psychological impact during psychiatric coercive interventions has been developed, the "Coercion Experience Scale" (Bergk et al., 2010). This instrument can be used to compare different coercive interventions, not only in clinical practice, where it can be used as a screening instrument for patients who need support after coercive interventions to prevent consequences from traumatic experiences, but also in research settings, where it can be used to compare different coercive interventions (Bergk et al., 2010). Ideally, a patient's individual preference of a particular type of coercive measure should be taken into account and registered in a crisis-management plan (Georgieva, 2012).

Some practical suggestions from patients who have experienced involuntary treatment on how to improve the practice of the use of coercive measures are well known and include a possibility to use toilet facilities and take care of their hygiene, more comfortable bed and bedclothes, smoking provisions, more therapeutic furnishing, alarm bell, and ordinary clothing (Keski-Valkama et al., 2010b). Patients' autonomy should be continuously supported by staff members, by letting them make their own decisions in minor matters such as deciding which clothes to wear, what to eat and drink or when to go to the toilet or shower (Hoekstra et al., 2004; Kuosmanen et al., 2007, Keski-Valkama et al., 2010b, Kontio et al., 2012). To ensure high-quality patient-centered psychiatric services, patients' experiences and practical suggestions on the improvement of the use of coercive measures and alternatives are essential (Kontio et al., 2012).

1.4.2. CAREGIVERS PERSPECTIVE

Recent mental health policies emphasize the need for psychiatric services to involve family caregivers in treatment planning, to help them cope with practical and psychological difficulties related to their role as caregivers and also to consider their views in the evaluation of treatment (WHO, 2008; DoH 1999), especially when involuntary treatment takes place.

Only a small number of studies have been conducted on caregivers' views of involuntary hospital treatment and almost all of them used qualitative methods with rather small samples (Wilkinson & McAndrew, 2008; Jankovic et al., 2011). In these studies caregivers expressed high levels of dissatisfaction and complained they received too little information and poor guidance from staff and were insufficiently involved in treatment decisions, particularly discharge planning (Wilkinson & McAndrew, 2008; Jankovic et al., 2011). These studies did use quantitative methods for assessing relatives views on in-patient care focused on burden, perceived coercion and need for support and information rather than on appraisals of the psychiatric treatment received by the patients (Hoge et al., 1998; Greenwood et al., 1999; Ostman & Hansson, 2004).

Just recently for the first time a quantitative study on the caregivers' appraisals of involuntary treated patients was carried out as a part of the EUNOMIA project (Giacco et al., 2012). Overall, caregivers seemed to view the involuntary hospital treatment of patients rather positively, with an average mean score of 8.5 on a scale of seven items, each of which had a maximum score 10. Their appraisal was more positive than that of the patients and moderately associated with it. When patients showed a more favorable symptom change after 4 weeks, caregivers tended to have a more positive view of treatment (Giacco et al., 2012). Patients can base their appraisal of treatment on the everyday lived experience of treatment on the ward. Caregivers do not have that direct experience. They can assess treatment only through observations during visits and reports by patients and clinicians (Giacco et al., 2012).

Caregivers' appraisals were also positive in comparison to those found in studies on caregivers' satisfaction with treatment in out-patient and non-coercive in-patient settings (Stengard et al., 2000; Perreault et al., 2012). The explanation for this might be that patients who are involuntarily admitted to hospital treatment commonly have high symptom levels and challenging behavior with risks to themselves or others before admission. In such a context, caregivers may experience high levels of burden and, therefore, appreciate more the treatment provided in a hospital and perceive the aspects of that treatment as rather positive (Magliano et al., 2005; Awad & Voruganti, 2008; Magliano et al., 2009).

1.4.3. STAFFS PERSPECTIVE

Not only patients and caregivers but also staff members who are directly involved in the involuntary admission and the use of coercive measures are exposed to certain degree of emotional stress (Keski-Valkama, 2010b). Fear from a violent patient may affect the quality of care the mental health-care workers provide (Clarke et al., 2010). It has been shown that the use of seclusion elicits predominantly negative emotions and a high level of distress in staff members (El-Badri & Mellsop, 2008). Application of any coercive measures of an aggressive patient can be a distressing and anxiety provoking experience for staff members (Bonner et al., 2002; Fish & Culshaw, 2005).

Shame, anxiety and distress as well as concern over abusing patients' rights were associated with the use of coercive measures in reports by the staff members (Bonner et al., 2002). Concerns that some staff members may abuse coercive measures or that some staff members will use such measures too quickly, to 'deck them first' are being reported (Lee et al., 2003; Stubbs et al., 2009). Also concerns have been raised about the impact on other patients of witnessing the use of coercive measures (Lee et al., 2003). The same authors reported that some staff members found the experience of coercing a patient demeaning (Lee et al., 2003) and others found out that for staff members who have been involved in adverse incidents in the past so called retraumatization may occur (Bonner et al., 2002).

Anger can occur during the use of coercive measures, particularly if staff or colleagues are hurt (Sequeira & Halstead, 2004). Anxiety expressed by staff members and worrying that they or colleagues were going to get hurt present the most prevalent themes when exploring the experiences with the use of coercive measures (Sequeira & Halstead, 2004). In a UK study in several psychiatric facilities over one third of staff members reported some concerns about their last experience in using mechanical restraint and stated that in 23% there was a negative outcome for the patient (Lee et al., 2003). A qualitative study revealed, that the doctors and nurses most often believed patients felt scared, angry and helpless, and less than 40% of staff members felt that seclusion was used too much and only one-fifth felt that hospital would be better without seclusion (El-Badri & Mellsop, 2008). Negative emotional responses such as anxiety, anger, boredom, distress and crying were also reported by the nursing staff to the use of physical restraint (Sequeira & Halstead, 2004).

As already said, the use of coercive measures can have physically and emotionally damaging effects on the staff members who are directly involved in the use of such measures, however, staff may view the use of restraint as a routine and acceptable means of maintaining safety (McCue et al., 2004). The majority of psychiatric professionals tended to believe that coercive measures are used correctly (Wynn, 2003), which may reflect attitudinal adjustment to prevailing practices (Bowers et al., 2004; Bowers et al., 2007; Whittington et al., 2009; Keski-Valkama, 2010).

The decision-making process in staff members on the use of physical restraint is hindered by context- and nurse-related factors from making an ethical decision on such use (Goethals et al., 2012). Authors recognize an urgent need to stimulate and educate mental health staff to arrive at an appropriate decision about the use of physical restraints (Goethals et al., 2012).

Different coping mechanisms of staff members following on application of restraint were described. Some staff members used laughter as a way how to reduce stress following an incident and reported how distressing emotions had to be taken home. Others had become 'hardened' to the experience of restraint, or they referred that they haven't had any emotional reactions and acted in an "automatic" way (Sequeira & Halstead, 2004).

1.5. INVOLUNTARY TREATMENT AND THE USE OF COERCIVE MEASURES – GENDER PERSPECTIVE IN PATIENTS WITH SCHIZOPHRENIA

1.5.1. HYPOTHESES ON GENDER DIFFERENCES IN SCHIZOPHRENIA

Although there has been lately an increase of interest in involuntary treatment and the use of coercive measures (Raboch et al., 2010; Priebe et al., 2010; Fiorillo et al., 2011; Fiorillo et al., 2012; Giacco et al., 2012), gender differences among coerced patients still remain understudied (Dressing & Salize, 2004; Kallert et al., 2005). Gender differences have in general an impact on mental health and in particular on the course of schizophrenia (Judd et al., 2009). Neurodevelopmental (Woods, 1998; McDonald & Murray, 2000), neuro-pathological (Shenton et al., 2001; James et al., 2002); and the estrogen protection hypothesis (Cohen et al., 1999; Hoff et al., 2001) have been postulated to explain how gender differences develop in schizophrenia. Taken together, the three theoretical frameworks can integrate a wide variety of findings of gender differences in schizophrenia, with compelling evidence existing for all approaches (Leung & Chue, 2000; Taylor & Langdon, 2006).

1.5.2. GENDER DIFFERENCES IN SCHIZOPHRENIA – SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS

Gender modifies the phenotypic expression of the disease and such effects have been reported quite consistently (Goldstein, 1997). Schizophrenia onset occurs at a significantly earlier age in male patients compared to female patients (Leung & Chue, 2000; Moriarty et al., 2001; Tang et al., 2007). Male patients are more severely impaired in ratings of negative symptoms (Shtasel et al., 1992; Moriarty et al., 2001; Morgan et al., 2008), cognitive impairment (Leung & Chue, 2000), less severe positive symptoms (Moriarty et al., 2001) and are more likely to show severe deterioration over time (Tang et al., 2007). Female patients are likely to have more severe

positive symptoms (Tang et al., 2007), with more hallucinations (Thorup et al., 2007), persecutory delusions (Leung & Chue, 2000), affective symptoms (Leung & Chue, 2000; Tng et al., 2007) and greater number of suicide attempts (Thorup et al., 2007). Women also show lower pre-morbid cognitive performance (Weiser et al., 2000) and have a considerably less severe course of illness (Tamminga, 1997). In opposition to what has been said, several studies have shown no gender difference in symptom severity (Andia et al., 1995), neurocognitive functioning (Andia et al., 1995; Bozikas et al., 2010), delusional symptoms (Thorup et al., 2007, positive symptoms (Shtasel et al., 1992), minor physical anomalies or neurological soft signs (Lueng & Chue, 2000).

Course of illness is more favorable in females in the short- (Usall et al., 2003) and middle-term (Lueng & Chue, 2000), with females manifesting better social functioning (Shtasel et al., 1992; Tamminga, 1997; Ochoa et al., 2006) and having fewer hospitalizations with shorter inpatient stays (Angermayer et al., 1990; Tamminga, 1997). Women with schizophrenia were also more often married (Gureje, 1991; Andia et al., 1995), employed and lived independently (Andia et al., 1995). Males had poorer premorbid functioning (Lueng & Chue, 2000; Thorup et al., 2007; Cotton et al., 2009), were unemployed, lived alone (Tang et al., 2007; Thorup et al., 2007) had poorer social network (Thorup et al., 2007) and had poorer functional outcome (Moriarty et al., 2001). No gender difference in social functioning has been found only in Australia (Cotton et al., 2009). The duration of untreated psychosis was found to be similar for both genders (Thorup et al., 2007).

1.5.3. GENDER DIFFERENCES IN THE USE OF COERCIVE MEASURES IN PATIENTS WITH SCHIZOPHRENIA

Psychotic disorders, including schizophrenia, are the most common diagnosis among patients who are involuntarily admitted to psychiatric hospitals and treated against their will (Sanguineti et al., 1996). It is the aggressive behavior and poor insight which are playing a major role in these involuntary (re)hospitalizations (Steinert et al., 1999). Ries et al. found 65% males in a population of acutely admitted patients with schizophrenia (2000). Males with schizophrenia

commit severe acts of violence more frequently than females (Wessely et al., 1994; Elbogen & Johnson, 2009), on the other hand, less severe aggression, like verbal threats, is more frequent among women (Kiejna et al., 1993; Sebit et al., 1998). Others have found no gender differences in aggressive behavior among patients with schizophrenia (Hodgkinson et al., 1985; Miller et al., 1993).

Gender differences in biological correlates and clinical presentations of severe mental illness might result in a different use of coercive measures during the acute phases of psychiatric disorders and hospitalizations (Wynn, 2002; Beck et al., 2008). Physical restraint was preferred more often with male patients, while forced medication and seclusion was preferred more often with female patients (Forquer et al., 1996; Wynn, 2002; Knutzen et al., 2011). Male gender was associated also with higher rates of seclusion (Forquer et al., 1996; Carpenter et al., 1988; Lay et al., 2011), restraint (Knutzen et al., 2011) and psychiatric intensive care (Whittington et al., 2009). Other studies have found that physical restraint was more often used with females (Beck et al., 2008) and female patients were more frequently secluded than their male counterparts (Way & Banks, 1990; Mason, 1998; Salib et al., 1998). No gender differences in the use of physical restraint have been found in an USA study (Smith et al., 2005), and in Finland, where all the forms of coercive measures studied were equally commonly applied to male and female patients (Kaltiala-Heino et al., 2000; Keski-Valkama et al., 2010). Approval rates of coercive methods however, are greater by male than by female patients (Bowers et al., 2007; Whittington et al., 2009). This finding was also replicated in EUNOMIA project, where female patients expressed more negative views on whether involuntary admission was right or wrong (Priebe et al., 2010).

2. RESEARCH STUDY OBJECTIVES

The research questions postulated for this thesis were the following:

- 1) What are the socio-demographic and clinical characteristics of the patients who receive coercive measures?
- 2) What types of coercive measures are used with involuntarily treated patients?
- 3) What are the patient's (internal) and environmental (external) risk factors for the use of coercive measures?
- 4) What are the gender differences among involuntary admitted coerced patients with schizophrenia?

3. METHODOLOGY OF THE RESEARCH PROJECT

3.1. PARTICIPATING CENTERS

The EUNOMIA project was conducted as a multicenter prospective cohort study in 11 European countries and Israel: Dresden, Germany; Sofia, Bulgaria; Prague, Czech Republic; Thessaloniki, Greece; Tel Aviv, Israel; Naples, Italy; Vilnius, Lithuania; Wroclaw, Poland; Michalovce, Slovak Republic; Granada and Malaga, Spain; Orebro, Sweden; and East London, UK (Fig.1).



Fig.1 Centers participating in the EUNOMIA study

The characteristics of the participating centers were assessed by the following instruments: a) the European Socio-Demographic Schedule (ESDS) (Beecham & Johnson, 2000), to evaluate the

socio-demographic characteristics of the catchment area; b) the European Service Mapping Schedule (ESMS Version 3) (Johnson et al., 2000) for the standardized description and classification of established mental health services; and the c) an instrument for the standardized assessment of structural/organizational characteristics of hospitals (Salize et al., 2000) (Table 1).

3.1.1. CATCHMENT AREAS

More than half of the EUNOMIA catchment areas had a population size of approximately 500,000 inhabitants (Table 2). Three areas had a substantially smaller population, and two areas had a significantly larger one. Since seven of the catchment areas included rural components, the density of the population varied enormously even between areas of similar population size, ranging from 32 (Orebro) to 8845 inhabitants (East London) per square kilometer. As showed by the unemployment rates, huge economic differences existed across these regions. While the population in the Prague, Orebro and Dresden catchment areas included rather high percentages of old people, this was not the case in the Tel Aviv, Naples and East London areas. An almost 20-fold difference for males and a more than 10-fold difference for females was observed in suicide rates across the regions, due to the low risk in the Naples, Thessaloniki, Michalovce and East London areas and the high risk in the Vilnius one (Kallert et al., 2005).

The ratio of psychiatric beds per 1.000 inhabitants ranged from 0.05 to 0.64. The highest ratios were observed in the Dresden (0.64) and Prague (0.56) areas, and the lowest in the Naples, Granada/Malaga (both below 0.07), Sofia (0.14), Thessaloniki (0.15), and Tel Aviv (0.25) areas. Staffing of hospital facilities showed an East-West difference across Europe, with 0.4-0.7 staff per bed in the Eastern areas, and 0.9 or more staff per bed in the Western areas; the highest ratios are those of Orebro and Naples (both 2.0).

Table 1. Characteristics of the EUNOMIA centers

						Tel							East	
		Dresden	Sofia	Prague*	Thessaloniki	Aviv	Naples	Vilnius	Wroclaw	Michalovce	Granada	Malaga	London	Orebro
Number of hospitals involved in EUNOMIA		4	2	2	1	1	5	1	1	1	1	1	2	3
	no. of beds	305	125	268	68	136	106	86	196	100	30	30	161	89
ESMS-R2-facilities ^a	staff per bed	1.0	0.7	0.7	0.7	0.5	2.0	0.8	0.7	0.4	1.3	1.2	0.9	2.0
	no. of beds	0	70	180	53	0	0	0	184 <u>°</u>	60	15	20	45	0
ESMS-R6-facilities ^b	staff per bed	-	0.8	0.4	0.6	-	-	-	0.2	0.3	2.2	1.4	1.1	-
Number of acute wards involved in EUNOMIA		5	5	6	1	2	6	2	4	4	1	1	10	7
Number of acute wards always locked		4	5	6	0	2	6	2	4	2	1	1	1	6
General psychiatric beds on these wards		89	139	220	50	68	80	80	110	100	30	30	163	$100^{\underline{d}}$
Average number of beds per room		1.9	5.6	4.2	1.8	3.1	3.0	8.0	3.3	2.7	1.7	3.0	1.3	1.2
Working hours: physicians (per bed per week)		5.3	2.6	5.5	11.2	5.9	20.5	4.1	3.4	2.2	14.0	6.7	5.6	2.8
Working hours: nurses (per bed per week)		26.9	9.4	18.0	32.0	23.5	52.1	7.7	15.5	8.4	15.2	12.0	22.3	18.1
Working hours: all clini	cal staff (per bed per week)	38.1	19.9	26.5	46.4	32.9	77.2	22.0	31.7	11.4	51.3	44.7	38.5	59.8

^{*}Prague areas 2,3,4,8 and 10, ESMS – European Service Mapping Schedule; ICMHC – International Classification of Mental Health Care

^a hospital wards (in psychiatric and general hospitals) to which acute admissions from a catchment area are routinely made

^b long-stay psychiatric inpatient wards to which patients are admitted for indefinite periods and which have 24-hour staffing

^c not standardized to the catchment area, applies to a greater region

d includes 8 beds for the treatment of addiction

Table 2. Demographic information on the catchment areas of the EUNOMIA centers

												East	
	Dresden	Sofia	Prague ^a	Thessaloniki	Tel Aviv	Naples	Vilnius	Wroclaw	Michalovce	Granada	Malaga	London	Orebro
Inhabitants in the catchment area	478,631	900,000	477,626	450,000	538,200	2,265,547	217,800	640,367	326,534	445,497	600,000	451,119	273,412
Size of catchment area (km²)	328	1,311	99	ca. 7,000	284	13,595	163	293	4,312	ca. 6,300	ca. 3,600	58	8,546
		urban +		urban +		urban +			urban +	urban +	urban +		urban +
Character of catchment area	urban	rural	urban	rural	urban	rural	urban	urban	rural	rural	rural	urban	rural
Unemployment (%)	14.7	14.4	5.6	8.1	15.8	24.9	7.1	16.4	34.3	21.9	17.3	11.2	<u>_a</u>
Population aged 65 years or older (%)	17.4	15.4	19.7	11.3	9.4	8.1	11.5	14.9	10.7	15.5	14.0	8.0	18.2
Suicide rate per 100,000 inhabitants:													
males/females	22.9/10.9	17.8/7.5	21.3/5.9	$5.7/1.6^{\underline{b}}$	$10.5/2.6^{b}$	2.3/0.7	43.3/9.0	12.6/3.5	7.9/0.6	11.4/4.1	12.6/2.8	8.3/1.7	22.9/13.7

^a no valid regional data available, but low unemployment rate

^b national data, no data available for catchment area

^{*}Prague areas 2,3,4,8 and 10

The data describing some core features of the acute wards in the hospitals (Table 1) demonstrate that wards were operated differently across the sites. One indicator of comfort during hospital stay, the average number of beds per room, showed some West-East gradient, which may have affected the use of coercive treatment measures such as mechanical restraint or seclusion. Similarly, it was assumed that the practice of coercive treatment was influenced if the doors of the acute ward were not always locked (notably at the Thessaloniki and London centers). Additionally, clinical practice was likely to be influenced by the substantial differences in staffing levels: some Central European centers (Sofia, Vilnius, Michalovce) displayed the most prominent shortages (11.4-22.0 working hours of all relevant professional groups per bed per week), whereas the Granada/Malaga, Thessaloniki, Orebro and Naples centers seemed to be very well staffed (Kallert et al., 2005).

Despite these differences in staffing, the levels of specialization of the most important modalities of care for people with acute mental illness seemed to be similar across the participating EUNOMIA wards. This included problem and functional assessment (i.e., all activities necessary to formulate, monitor and consequently adjust an individual plan for treatment or rehabilitation), general health care (provided by professionals to patients suffering from somatic as well as psychiatric problems), and psychopharmacological and other somatic interventions. None of these modalities of care were provided below an intermediate level of specialization (with the exception of general health care in the Sofia center). The level of specialization in other modalities of care was also similar across all wards: these included establishing and maintaining relationships (i.e., all activities aimed at involving individuals in need of professional help in the mental health care process); care coordination (which includes all activities necessary for individuals to have access to all required health and social services in the catchment area); reeducating basic, interpersonal and social skills (i.e., providing activities based on well-defined theoretical models designed to help individuals cope with their impairments and personal disabilities), and psychological interventions based on well-defined theoretical models provided by specifically trained professionals.

The characteristics of the catchment areas show that the EUNOMIA project was conducted in European regions with significant socio-demographic and economic differences. Data on unemployment rates and health status of the population, in particular, show that living conditions are vastly different. The structure of the hospital-based services clearly reflects different stages of the psychiatric reform processes and the underlying intentions of health policies.

The staffing of the participating acute wards cannot be discussed according to established international standards. If we consider the German guidelines for staff levels in these services (Kunze & Kaltenbach, 2000), it appears that several EUNOMIA centers have staffed their acute wards at a similar level. The two centers of Naples and Orebro are well above this standard, possibly due to their specific situation of having a few small acute psychiatric wards integrated in a strictly community oriented system of general hospitals. In contrast, several Central European centers (in particular the centers in Sofia, Michalovce and Vilnius) show a low staff level at these wards, due to poor economic resources for health care.

3.1.2. RECRUITMENT OF PATIENTS

Each participating center recruited all patients who were legally involuntarily admitted between July 2003 and December 2005 and who fulfilled the following criteria: aged between 18 and 65 years; able to sign an informed (written) consent form; not admitted to a special unit for only forensic or intoxicated patients; not admitted to a special treatment program for eating disorders, because that type of treatment would automatically include coercive treatment; no diagnosis of dementia; not included in the study before (repeated admissions during the study period); not transferred to a participating clinic from another hospital; and having a permanent living address in the catchment area of the participating hospitals.

Eligible patients were identified through administrators or staff in the wards upon admission. Once identified, they were approached by researchers (independent from the patients' care) and invited to take part in the study. Informed consent was obtained from all patients in this study

after they were provided a complete description of the study. The national or regional review boards of the participating centers approved the study (Research Ethics Committee, Medical University Sofia, Sofia, Bulgaria; The Ethics Committee of the General Teaching Hospital, Prague, Czech Republic; Ethics committee at the Faculty of Medicine at Dresden University of Technology, Dresden, Germany; Scientific Board of the Psychiatric Hospital of Thessaloniki, Thessaloniki, Greece; The Tel Aviv University IRB-Helsinki Committee, Tel Aviv, Israel; Ethical Committee of the Second University of Naples, Naples, Italy; Lithuanian Bioethics Committee, Vilnius, Lithuania; Commission of Bioethics at Wroclaw Medical University, Wroclaw, Poland; Ethical Committee of the Michalovce Psychiatric Hospital, Michalovce, Slovak Republic; Ethical Committee (Comité Ético) of University Hospital of San Cecilio. Granada, Spain; Research Ethics Committee of Orebro University Hospital, Orebro, Sweden; East London and The City Research Ethics Committee, London, UK). Once written informed consent was received (Kjellin, 2011), patients were asked to take part in interviews within a week after admission (baseline) and at one and three month follow-ups. All baseline interviews were conducted in the hospital. The follow-up interviews were completed most commonly in the interviewees' homes, and sometimes in the hospital or on the telephone.

All consecutive involuntary admitted patients were aimed to be included in the study, following national legislation of involuntary admission (Kallert & Torres-Gonzalez, 2006) and routine practice in each country. Each patient who fulfilled the criteria was assessed at three different time points: within the first seven days of admission (T1), at four weeks (T2), and at three months after admission (T3), independent of the patient's current living situation.

3.1.2.1. RECRUITMENT PROCESS FOR THE STUDY ON GENDER DIFFERENCES

For the hypothesis on gender differences in coerced patients with schizophrenia, patients needed to fulfill the following criteria: diagnosis of schizophrenia (i.e., F20.0-F20.9 diagnosis according to ICD-10 as established by psychiatric reports within the first seven days of admission); patient has received any form of coercive measure (seclusion and/or forced medication and/or physical restraint) during their hospital stay, age between 18 and 65 years; ability to sign an informed

(written) consent form; not admitted to a special unit for only forensic or intoxicated patients; not included in the study before (repeated admissions during the study period); not transferred to a participating clinic from another hospital; and having a permanent living address in the catchment area of the participating hospitals

3.2. INSTRUMENTS USED TO ASSESS PATIENT-RELATED DATA

As an indicator of clinical functioning, symptom levels were assessed on the 24-item version of the Brief Psychiatric Rating Scale (BPRS) (Overall et al., 1967), which ranges from 24 to 168, with higher scores indicating greater symptom severity. Each single item on the BPRS ranges from 1, not present, to 7, extremely severe. Items of the BPRS scale were divided into the following 5 subscales: 1) Depression/anxiety (5 items - depression, anxiety, guilt, suicidality, somatic concerns); 2) Positive psychotic (5 items - unusual thought content, hallucination, conceptual disorganization, bizarre behavior, grandiosity); 3) Activation/manic (6 items - excitement, tension, mannerism and posturing, motor hyperactivity, distractibility, elevated mood); 4) Negative psychotic (5 items - blunted affect, psychomotor retardation, emotional withdrawal, disorientation, self-neglect); and 5) Hostility/suspiciousness (3 items - suspiciousness, hostility, uncooperativeness).

Global Assessment of Functioning scale (GAF) (Goldman et al., 1992) was used as an indicator of global social functioning. This scale constitutes axis V of the Diagnostic and Statistical Manual for Mental Disorders 4th edition (DSM-IV) (APA, 1994) and assesses patient's social occupational and psychological functioning in a hypothetical continuum of 1 to 100 points, which is divided in 10 ranges of 10 points, although a single score that represents patient's level of functioning is obtained.

All researchers were trained to use both scales. Inter-rater reliability for BPRS scale was assessed throughout the project (videotaped interview on the international level and with personal interviews on the national level) and an inter-rater reliability with interclass correlation

coefficient of 0.78 was achieved. As for the training on GAF scale, 72 GAF vignettes were jointly rated by researchers that had received first a local training session and then a common international video training session (in English). The GAF inter-rater reliability for the whole training process was good with an interclass correlation coefficient of 0.74.

The Modified Overt Aggression Scale (MOAS), a widely used aggression scale with documented reliability and validity, was used to evaluate violent behavior for the duration of hospitalization. The scale has four categories of aggressive behavior (verbal aggression, aggression against property, auto-aggression, and physical aggression) (Sorgi et al., 1991). Perceived coercion at admission reflects the amount of pressure perceived by patients at admission and the level was assessed on the Cantril Ladder scale, from 1 (minimum) to 10 (maximum) (Hoyer et al., 2002).

Data concerning details of each application of coercive measures during the first 4 weeks of hospitalization or up to his/her discharge were gathered using a special 16-item questionnaire designed by the EUNOMIA group for the purpose of this project (Kallert et al., 2005). The assessment included documentation of coercive measures, which were defined as follows:

- 1. Seclusion was defined as the involuntary placement of an individual alone in a locked room, which may be set up especially for this purpose.
- 2. Restraint was defined as the fixation of at least one of the patient's limbs by a mechanical appliance or at least one limb being held by staff for greater than 15 minutes.
- 3. Forced medication referred to activities which use restraint or high psychological pressure (involving at least three staff members) to administer medication against the patient's will.

Involuntary detention was defined by any of the following criteria: a) the patient was initially admitted on a legally voluntary basis and withdraws his consent to hospitalization at a later

stage; b) the legally defined time period (different between countries) in which the hospital is allowed to initially detain a patient without applying for a decision of the responsible legal authorities has passed; c) the detention is based on the authorization of legal authorities. The whole list of instruments that were used to collect data from all the recruited patients is shown in the Table 3.

3.3. STATISTICAL METHODS

Different types of statistical analyses were performed. For the whole sample analysis all statistical analyses were performed with SPSS, version 17.0. One-way analysis of variance (ANOVA), chi square analysis, and Fisher's exact tests were performed to determine group differences in age, gender, and some clinical characteristics. The prevalence of diagnoses in countries was compared with Kruskal-Wallis test and the differences in the types and frequency of coercive measures used among countries were compared with the Kolmogoroff test.

Descriptive analyses, correlation analyses and binary logistic regressions were used for assessing the influence of patient- and ward-related factors on the use of coercive measures. Since we used a dichotomous variable (having received coercive measures vs. not having received coercive measures) as an outcome, logistic regression was used to estimate bivariate and adjusted odds ratios of tested explanatory variables. The candidate explanatory variables for a multiple regression were screened with univariate ordinal logistic regression. A main effect multivariable model followed by a model that included interactions were applied. Chi-square test, Mann Whitney test, T-test were used to assess bivariate associations. In some cases continuous variables were dichotomized at median in order to get illustrative presentation of bivariate associations for both outcomes (e.g. BPRS). To assess facility-related characteristics, cluster analysis methods were used.

 $\label{thm:continuous} \textbf{Table 3. Instruments used to assess patient-related data}$

Construct	Instrument (source of information)	T	ime poir	nts
		T1	T2	T3
Perceived coercion concerning hospital admission	Perceived coercion items from MacArthur Admission Experience Survey (patient interview)	X		
Perceived coercion and pressures concerning hospital admission	Cantril Ladder of Perceived Coercion, items from Nordic Study on Coercion (patient interview)	X		
Perceived coercion and pressures concerning stay in hospital (only if index episode continues)	Cantril Ladder of Perceived Coercion, items from Nordic Study on Coercion (patient interview)		X	X
Outcome assessment, e.g. use of psychiatric services and contact with the police and criminal justice services after discharge (only if the patient has been discharged after the index episode)	Self-defined items (patient interview, records)			X
Characteristics of treatment	Self-defined items (records)	co	ntinuou	sly
Details of each coercive measure applied in the first 4 weeks after the index admission	Self-defined items (records)	co	ntinuou	sly
Fixed socio-demographic and clinical characteristics	Self-defined items (records, patient interview)	X		
Variable socio-demographic characteristics	Self-defined items (records, patient interview)	X	X	X
Patient's compliance with treatment	Self-defined items (staff rating if patient is in hospital, otherwise patient interview)	X	X	X
Coercion perceived by staff (only if index episode continues)	Cantril Ladder of Perceived Coercion, rephrased (staff rating)	X	X	X
Patient's aggression (only if patient is currently in hospital)	Modified Overt Aggression Scale (staff rating)	X	X	X
Symptom severity	Brief Psychiatric Rating Scale, 24 item version (researcher's rating)	X	X	X
Symptom severity and level of functioning	Global Assessment of Functioning scale (researcher's rating)	X	X	X
Patient's satisfaction with treatment (retrospective evaluation, if the patient has been discharged after the index episode)	Client's Assessment of Treatment, 7 main items (patient interview)	X	X	X
Quality of life, self-rating (optional to each center)	Manchester Short Assessment of Quality of Life (patient interview)	X	X	X

3.3.1. STATISTICAL METHODS USED FOR THE STUDY ON GENDER DIFFERENCES

For the hypothesis on gender differences in coerced treated schizophrenia patients T-test was performed to identify differences in socio-demographic factors between male and female patients. Differences between the groups in categorized background variables were assessed by chi-square analysis or, where appropriate, Fisher's exact tests. Correlation analysis and binary logistic regression were used for evaluation of influences on the outcome in order to assess associations with the use clinical characteristics, social characteristics and aggressive behavior. Logistic regression was used to estimate bivariate and adjusted association ratios for the dichotomous sex outcome categories. The candidate explanatory variables for a multiple regression were screened with uni-variate ordinal logistic regression. A main effect multivariable model was applied. Chi square test, Mann Whitney test, T-test were used to assess bivariate associations.

4. RESULTS

4.1. BASIC CHARACTERISTICS OF THE SAMPLE

For the first part of this study data for 2.030 involuntary admitted patients from 10 European countries were analyzed. Table 4 summarizes the recruitment of patients for the study in the centers. For the evaluation reported here the centers in Tel Aviv and Michalovce were excluded because of shortcomings in their databases, which left ten countries in the sample. Two centers were sampled in Spain (Granada and Malaga), and one center was sampled in each of the other nine countries. 462 incidents of coercive measures were recorded and were applied to 770 patients (38% of the whole sample) during the first four weeks of the index hospitalization. There was great variability between countries (21% of detainees in Granada/Malaga centers and 59% in Wroclaw).

The baseline characteristics of the study sample are summarized in Table 5. Baseline characteristics of the two groups of patients were compared: those who experienced coercive measures (N=770) and those who did not (N=1.260). No significant differences regarding gender, age, employment, and living situation was found. However, in the group with coercive measures, there was a greater proportion of patients with a diagnosis of schizophrenia (68% versus 60%) (p=.004) and the BPRS (T1) score was significantly higher (58 versus 52) (p<.001).

Some international variation was evident with the average BPRS scores ranging from 48.4 to 77.0 (the highest scores in Naples and the lowest in Wroclaw). Coerced patients had higher levels of hostility/suspiciousness and positive psychotic symptoms. Depressive and anxiety symptoms were more often found in non-coerced group. Patients who have received coercive measures have showed significantly worse global functioning according to GAF scores $(30.5\pm13.8 \text{ vs. } 33.6\pm14.9)$. A significant variation was also found among centers $(20.6-30.9, \text{with the highest average score in Naples and the lowest score in Sofia).$

 $\ \, \textbf{Table 4. Recruitment of patients in the EUNOMIA centers} \\$

	Sofia	ı	Prag	ue	East Lond		Dres	den	Thess	aloniki	Napl	les	Vilniı	ıs	Wroc	law	Gran /Mal		Oreb	ro	Total sampl	le
Variable	N	%	N	%	N	— %	N	%	N	 %	N	%	N	%	N	 %	N	— %	N	 %	N	— %
Recruitment																						
Eligible patients	475		581		451		466		349		280		120		334		850		306		4,212	
Absconded or																						
discharged	27		80		30		186		58		7		1		30		219		49		687	
Clinically too unwell	76		160		89		59		43		60		17		52		84		44		684	
Asked to take part	372		341		332		221		248		213		102		252		547		213		2,841	
Refused to take part	63		139		64		76		26		84		17		100		126		116		811	
Participation																						
Assessed at baseline	309	100	202	100	268	100	145	100	222	100	129	100	85	100	152	100	421	100	97	100	2,030	100
Patients with coercive																						
measures	98	32	92	46	95	35	62	43	116	52	75	58	25	29	90	59	88	21	29	30	770	38

Table 5. Baseline characteristics of patients and comparison of their risk factors between coerced and non-coerced patients

		erced	Not co		
	,	=770)		,260)	p
Variable	N	%	N	%	
Gender					
Female	345	45	540	43	ns
Male	425	55	719	57	
Age (M±SD)	38.1±11		38.8±11		ns
Employment ^a					
No	579	78	1,006	81	ns
Yes	160	22	239	19	
Living situation ^a					
With others	272	36	449	36	ns
Alone	479	64	790	64	
Past hospitalization ^a					
At least one	528	75	867	70	p<0.01
None	173	25	368	30	
Diagnosis					
Schizophrenia	522	68	762	60	p<0.01
Affective disorders	130	17	214	17	
Other	118	15	283	22	
BPRS score (M±SD)	58.0	0±17	52.3	±15	p<0.01
GAF score (M±SD)	30.5	5±13.8	33.6±	14.9	p<0.01
Perceived coercion (M±SD)	7.5	5±3.1	6.4	<u></u> ±3.4	p<0.01

^a Data were missing for some patients.

Age, gender, BPRS, GAF: T-test, Status, diagnosis, previous hospitalization: Chi-square

In results gathered in counting bivariate and adjusted odds for the main effect model and also a model including interactions in Table 6 patients with higher levels of symptoms had increased odds of receiving coercive measures. The odds ratio for the anxiety-depression subscale is .96, which means that a one point increase in the anxiety-depression subscale corresponds to a 4% decrease in the odds of receiving coercive measures (since 1- (0.96)*100%=4%). In contrast, higher scores of the other four subscales are associated with increased odds of the use of coercive measures. A one point increase in the positive psychotic subscale corresponds to a 7% increased odds, a one point increase in the suspiciousness/hostility subscale corresponds to an 8% increased odds, and a one point increase in the negative psychotic subscale is associated with a 4% increased odds, and a one point increase in the active/manic subscale is correlated with a 3% increased odds of the use of coercive measures. A one point decrease in the GAF score implies a 2% increased odds of the use of coercive measures.

4.2. COERCIVE MEASURES USED IN THE SAMPLE

As shown in Table 7, there was great variation in the frequency of various coercive measures used in the countries. The application of a single coercive measure per patient was the typical pattern in Dresden, Sofia, Prague, Thessaloniki, Naples, Vilnius and Orebro; whereas in Wroclaw, East London and Granada/Malaga, two or more measures per patient were frequently applied. These differences between the two groups of centers in the number of coercive measures used per patient were statistically significant. The pattern of the frequency of individual coercive measures used also differed significantly when each center was compared with all other centers investigated. Forced medication was the most frequently used intervention (56%), followed by restraint (36%) and seclusion (8%). This "average" pattern was found in centers in Prague, Vilnius and Granada/Malaga. In centers in Sofia and Orebro, forced medication was applied more frequently than the average. Use of physical restraint exceeded the average in Dresden and Thessaloniki centers. Use of seclusion exceeded the average only in East London and Naples.

The most commonly used forced medication among patients with coercive measures was first-generation antipsychotics, especially haloperidol (in 229 cases) and zuclopenthixol (in 120

Table 6. Logistic regression analysis of effects in selected patient-related variables on risk of the use of coercive measures

Independent	Bivariate	associations	Main eff	fects model	Interac	ction model
Variables	95% CI	OR	95% CI	OR	95% CI	OR
Age	0.99	(0.93-1.29)				
Gender - male	1.08	(0.98-1.01)				
GAF	0.98 **	(0.97-0.99)	0.99	(0.88-1.09)	1.00	(0.99-1.01)
Perceived coercion	1.10 **	(1.07-1.13)	1.09 **	(1.05-1.13)	1.05 *	(1.01-1.10)
BPRS clusters						
Depression/anxiety	0.95 **	(0.93-0.97)	0.96 **	(0.94-0.99)	0.96 **	(0.94-0.97)
Positive psychotic	1.07 **	(1.05-1.09)	1.05 **	(1.02-1.07)	1.05 **	(1.02-1.07)
Activation/manic	1.03 **	(1.02-1.04)	1.01	(0.98-1.03)	1.01	(0.99-1.04)
Negative psychotic	1.04 **	(1.01-1.06)	1.02	(0.98-1.05)	1.01	(0.98-1.05)
Hostility/suspiciousness	1.08 **	(1.05-1.11)	1.07 **	(1.03-1.11)	1.07 **	(1.02-1.11)
Diagnosis						
Schizophrenia	1.36 **	(1.13-1.65)	1.05	(0.83-1.33)	1.21	(0.87-1.69)
Mania	0.99	(0.78-1.26)				
Schizophrenia in males					1.54 *	(1.03-2.32)
Perceived coercion in males					1.06 *	(1.01-1.11)

Hosmer and Lemesh.: χ2(8)=9.65; p=0.21; Nagelkerke Rsquare=0.2; *p<0.05; **p<0.01

Table 7. Coercive measures used among 770 involuntary admitted patients in ten European countries

	Seclus	sion	Restra	Forced Restraint medication				Number of coercive measures	Number of coercive measures applied per
Center	N	%	N	%	N	%	p ^a	applied	patient
Dresden	0	_	51	55	42	45	<.001	93	1.50
Sofia	4	4	17	15	90	81	<.001	111	1.13
Prague	9	6	50	33	94	61	ns	153	1.66
Thessaloniki	0		131	69	59	31	<.001	190	1.64
Naples	19	19	24	24	59	58	<.001	102	1.36
Vilnius	0		9	27	24	73	ns	33	1.32
Wroclaw	0		83	32	174	68	<.001	257	2.86
Granada/Malaga	10	5	82	37	129	58	ns	221	2.51
East London	79	30	68	26	113	43	<.001	260	2.74
Orebro	1	2	7	17	34	81	.004	42	1.45
Total	122	8	522	36	818	56		1,462	1.90

^a For the difference (Pearson chi square) in the pattern of applied coercive measures compared with other countries investigated.

cases). Also, benzodiazepines were often used separately or in combination with antipsychotics (diazepam in 111 cases, clorazepate in 92 cases, and clonazepam in 82 cases). The most frequent reasons for use of a coercive treatment (it was possible to name more than one reason) were aggression against others (N=866, 59%), threat to his or her health (N=398, 27%), autoaggression (N=326, 22%), aggression against property (N=352, 24%), prevention of escape (N=193, 13%), and inability to care for oneself (N=165, 11%).

Only in the center in East London were nurses more likely than physicians to order coercive measures (N=154, 59%, versus N=103, 40%). In addition, the order was expressed in writing in most centers, although in the East London and Naples an orally expressed order was also sufficient: orders were given orally in 74 of 260 orders (28%) in East London, and 49 of 102 orders (48%) in Naples (N=49, 48%). Almost all patients were informed about the reason (N=1.256, 98%) and the type of the coercive measure being used (N=1.225, 96%).

4.3. PATIENT RELATED FACTORS FOR THE USE OF COERCIVE MEASURES

Characteristics of patients whom the different types of coercive measures were used are summarized in Table 8. The statistical analysis found that age, gender, and BPRS score at time 1 were significantly different according to the type of coercive measure used. Seclusion was used more often among younger men. Forced medication was applied with older male patients who had more severe psychopathological symptoms. Restraint was used with equal frequency for both men and women.

No significant difference between the two groups was found with regard to age and gender. The proportion of men was however higher in both groups (57% in coerced group vs. 55% in non-coerced group) and men were younger than women in both groups (41.0±11.0 vs. 35.8±11.0 in coerced group; 41.1±11.0 vs. 37.1±11.0 in non-coerced group). Separation of the group samples to age deciles however revealed significant differences in first and last decile between coerced and non-coerced groups. Patients aged 22-29 had a higher risk of receiving

Table 8. Characteristics of 770 involuntarily admitted patients who experienced coercive measures, by type of coercive measure

	Seclusion (N=122)		Forced medication (N=818)		tion		
Variable	N	%	N	%	N	%	p
Age (M±SD)	30.9±9.7	30.9±9.7		0.9	38.5±1	1.4<.01	
Women	18	15	256	49	303	37	<.01
Persons with a diagnosis							
of schizophrenia	72	59	329	63	540	66	.21
BPRS score (M±SD) ^a							
Within 7 days of admission	55.9±12.	854.2	±15.1	57.1±	16.1	.012	
4 weeks after admission	42.1±12.	741.3	±12.8	42.9±	12.6	.208	

^a Brief Psychiatric Rating Scale. Possible scores range from 24 to 168, with higher scores indicating greater symptom severity.

coercive measures (OR 2.07; 1.15 - 3.7), while those who were older (57 - 64 years) had a significantly reduced risk of receiving coercive measures (OR 0.56; 0.32 - 0.97).

A statistically significant difference was found regarding diagnosis, with patients affected by psychosis being more represented in coerced group (68% in coerced vs. 60% in non-coerced group). Patients from coerced group had also a higher number of previous hospitalizations (75% vs. 70%). We did not found any difference concerning living situation between groups, with 64% of patients from both groups living alone. Patients from coerced group were more often unemployed in comparison with those non-coerced, but the difference was not statistically significant (Table 5).

Table 6 shows bivariate and adjusted odds for the main effect model and also a model including interactions. Diagnosis of schizophrenia is positively associated with higher odds of the use of coercive measures in a model including interactions. The interaction with gender (last two columns in the Table 6) strengthens the effect of diagnosis of psychosis on the use of coercive measures. The interaction adjusted odds ratio 1.54 describes a positive correlation of male gender together with a diagnosis of psychosis with the use of coercive measures. Levels of perceived coercion at admission were significantly higher in patients who have experienced coercion. Level of perceived coercion at admission had a significant effect related to the use of coercive measures; a one point increase on the scale is associated with a 10% increase of odds of receiving coercive measures.

4.4. WARD RELATED FACTORS FOR THE USE OF COERCIVE MEASURES

Significant differences in ward related characteristics were found. The number of psychiatric hospital beds per 100.000 (4.6 in Naples and 63.7 in Dresden), the number of staff per bed (.4 in Michalovce and 2.0 in Orebro and Naples), and the average size of ward varied from 13 beds in Naples to 50 beds in Thessaloniki. The number of beds per room showed an increase from West to East (1.2 beds in Orebro and Naples and up to 8 beds per room in Vilnius). The clinical

staff/patient ratio is only approximate and also varies greatly among centers, with the highest numbers in Naples and Orebro and the lowest in Sofia. Facility-related characteristics followed in the study did not have a significant influence on the application of coercive measures using cluster analysis (Table 9).

4.5. GENDER DIFFERENCES IN COERCED PATIENTS WITH SCHIZOPHRENIA

4.5.1. BASIC CHARACTERISTICS

1284 involuntary patients with schizophrenia were identified and the final sample of coerced patients recruited in this study consisted finally of 291 male and 231 female patients (55.8% vs. 44.2%). 74.6% males and 64.0% females were patients with paranoid type of schizophrenia (F20.0), residual type of schizophrenia (F20.5) was the second most represented group with 21.2% being women and 12.0% men. Undifferentiated type of schizophrenia (F20.3) did account for 12.1% female and 8.6% male patients. Other types of schizophrenia; disorganized (F20.1); catatonic (F20.2); and other or unspecified schizophrenia types (F20.8 and F20.9) did represent all together only 4.8% of male, and 2.7% of female patients.

Female patients were significantly older (41.1±10.8) than their male counterparts (35.7±10.8) (p<.05). Men were significantly more likely single (77.0% vs. 41.2%) while women were more likely married (30.3% vs. 14.4%), divorced (22.2% vs. 8.6%) or widowed (6.3% vs. 0%) (p<.001). Female patients did live on their own significantly more often than male patients (70.5% vs. 46.1%), on the other hand almost half of male patients (48.4%) did live by their family/partner/friend, compared to only 26.7% of women (p<.001). Only 1.4% male and female patients did live in social institutions and the proportion of homeless was also very low (2.4% males and .9% females). Male patients were significantly more likely to be unemployed (41.0% vs. 29.2%), but the numbers on those partially or fully employed (20.0% vs. 19.6%) did not

Table 9. Description of facility-related characteristics

Country	% of coerced patients	Number of beds per	Number of beds	HCS/W/B
		ward	per room	
Dresden	43	18	1,9	38.1
Sofia	32	28	5,6	19.9
Prague	46	37	4,2	26.5
Thessaloniki	52	50	1,8	46.4
Naples	58	13	3,1	77.2
Vilnius	29	40	8,0	22.0
Wroclaw	59	28	3,3	31.7
Granada/Malaga	21	30	2,3	48.0
East London	35	16	1,3	38.5
Orebro	43 - 30	14	1,2	59.8

HCS/W/B: working hours of clinical staff per week per bed reflects staff/patient ratio

differ among genders. The biggest proportion of both genders, however, was on social welfare (33.1% males and 43.0% females).

There was no significant difference in respect to the past hospitalizations, about one-quarter of male patients and one-fifth of female patients have been admitted for the first time, and over three-quarters from both genders have been re-hospitalized. No significant difference among genders was found in respect to the past involuntary hospitalizations (χ^2 =.12 df=1,p=.73), but due to partial data availability no reliable proportions could be calculated.

4.5.2. CLINICAL CHARACTERISTICS

The BPRS total score, as an indicator of overall severity of symptoms, was significantly higher for female patients (58.9±14.5 vs. 54.6±14.0) (p=.004) at T1. When performing an in depth analysis of individual items of BPRS several gender differences have been traced. Female patients did score significantly higher on several items, from "positive cluster"; hallucinations (3.15±2.0 vs. 2.80±1.8) (p<.001); bizarre behavior (3.28±1.7 vs. 2.80±1.7) (p<.001); conceptual disorganization (2.57±1.6 vs. 2.27±1.5) (p<.001); from "negative cluster"; emotional withdrawal (2.37±1.4 vs. 2.10±1.3) (p<.001); and from "activation/manic cluster"; uncooperativness (2.29±1.6 vs. 2.03±1.5) (p<.001); and motor hyperactivity (2.51±1.7 vs. 1.94±1.3) (p<.001). Male patients did not scored significantly higher on any of the individual items.

Very similar results as for BPRS total scores comparison were observed when comparing GAF scores as measures of global social functioning. Male patients scores were significantly higher $(30.5\pm12.7 \text{ vs. } 26.2\pm12.8)$ (p<.001) indicating better social performance (Table 10).

Table 11 shows bivariate and adjusted association for the main effect model. Clinical characteristics among coerced patients, according to BPRS subscales discriminate to certain level between genders. More severe psychopathology in "positive psychotic" subscale was associated

Table 10. Sociodemographic, clinical and social functioning characteristics

	Female	Male	p
	N=231 (%)	N=291 (%)	
Age (mean±SD)	41.1±10.8	35.7±10.8	t-test, p<.001
Type of schizophrenia			
Paranoid schizophrenia	148 (64.0)	217 (74.6)	$X^2 = 14.441$, $df = 6$, $p = .025$
Psychiatric hospitalization in the past	178 (79.5)	211 (74.0)	$X^2=2.052$, $df=1$, $p=.152$
Marital status			
Single	95 (41.2)	224 (77.0)	$X^2 = 75.514$, $df = 3$, $p < .001$
Employment status			
Unemployed	67 (29.2)	119 (41.0)	$X^2 = 24.969$, $df = 6$, $p < .001$
Housing situation			
Live on their own	205 (70.5)	106 (46.1)	X^2 =46.516, df=5, p<.001
BPRS total score (mean±SD)	58.9±14.5	54.6±14.0	t-test, p=.004
GAF score (mean±SD)	26.2±12.8	30.5±12.7	t-test, p<.001

Table 11. Logistic regression analysis of effects on gender categories in involuntary treated psychotic patients

Bivariate	associations	Main	effects model
OR	95% CI	OR	95% CI
0.96*	0.93-0.99	1.06*	1.01-1.12
0.95*	0.91-0.99	NS	
0.92*	0.89-0.96	0.95*	0.9-0.99
NS		NS	
0.94*	0.91-0.97	0.95*	0.9-0.99
1.02*	1.01-1.04	1.03*	1.01-1.05
	OR 0.96* 0.95* 0.92* NS 0.94*	0.96* 0.93-0.99 0.95* 0.91-0.99 0.92* 0.89-0.96 NS 0.94* 0.91-0.97	OR 95% CI OR 0.96* 0.93-0.99 1.06* 0.95* 0.91-0.99 NS 0.92* 0.89-0.96 0.95* NS NS 0.94* 0.91-0.97 0.95*

^{*}p<.005

with men category, and "active/manic" and "negative psychotic" subscales with women category. Overall global functioning also discriminated between sex categories, showing higher scores for men category.

More than two-thirds of both groups, men and women, have developed aggressive behavior during the first four weeks after admission (79.6% females and 71.7% males). When assessing aggressive behavior simply by counting average MOAS scores for both groups, no significant difference was found (females 5.20±5.61 vs. males 5.62±6.80) (p=.462). Women were more likely to show aggressive behaviors but with a lesser intensity (total MOAS score 1 to 7) (50.2% vs. 40.2%) and men were found to be more severely aggressive when counting only those who scored 8 or higher in MOAS (14.47±5.61 vs. 12.34±4.97) (p=.01) (Table 12).

4.5.3. USE OF COERCIVE MEASURES

373 incidents of coercive measures were applied to 231 women and 573 to 291 men during the first four weeks of the hospitalization. Most frequently used coercive measure was forced medication (80.7%), followed by physical restraint (57.1%) and seclusion (10.7%). Women were more likely to receive forced medication (87.9% vs. 74.9%) (OR=2.4, 95% confidence interval 1.51-3.90), whereas men were more likely to end physically restraint (66.2% vs. 45.5%) (OR=2.4, CI 1.66-3.67) or secluded (17.2% vs. 2.6%) (OR=7.8, CI 3.27-18.50) (p<.001). No significant difference has been observed in the reasons that led to the use of coercive measures. From those provided in this study the most common reasons in both genders were "to prevent acts of violence against others" (56.0% females and 59.0% males), followed by "worsening of condition" (31.4% females and 27.8% males), and by "aggression against objects" (23.6% vs. 18.5%) (Table 13).

Table 12. Aggressive behavior observed during the hospital stay of involuntary treated psychotic patients

		Female	Male	p
		N=231 (%)	N=291 (%)	
Verbal aggression	Total	169 (73.2)	192 (67.1)*	$X^2=2.203$, $df=1$, $p=.138$
	Severe¥	18 (7.8)	60 (21.0)*	$X^2 = 17.346$, $df = 1$, $p < .001$
	Avarage score	1.57±0.69	1.88 ± 1.00	<i>p</i> =.015#
Aggression against	Total	79 (34.2)	72 (25.5)*	$X^2 = 4.593$, $df = 1$, $p = .032$
property	Severe¥	7 (3.0)	26 (9.2)*	$X^2 = 8.082$, $df = 1$, $p = .004$
	Avarage score	1.5±0.77	2.0±0.96	<i>p</i> <.001#
Autoaggression	Total	25 (10.8)	34 (11.8)*	X^2 =.123, df=1, p=.726
	Severe¥	5 (2.2)	12 (4.2)*	$X^2=1.622$, $df=1$, $p=.203$
	Avarage score	1.76±0.97	2.32±1.01	p=.023#
Physical aggression	Total	95 (41.3)	115 (39.8)*	$X^2 = .122$, $df = 1$, $p = .727$
	Severe¥	10 (4.4)	21 (7.3)*	$X^2=1.943$, $df=1$, $p=.163$
	Avarage score	1.47±0.74	1.66 ± 0.84	p=.09#
MOAS total score 1-7	(mean±SD)	116 (50.2) 3.18±1.92	117 (40.2) 3.13±2.17	p=.58#
MOAS total score 8 o	r higher (mean±SD)	67 (29.0) 12.34±4.97	83 (28.5) 14.47±5.61	<i>p</i> =.01#
MOAS total score (me	ean±SD)	5.20±5.61	5.62±6.80	<i>p</i> =.462#

^{*}scores 3 or 4 on respective MOAS items, *Mann-Whitney test

Table 13. Coercive measures used in involuntary treated psychotic patients and the reasons for their use

		Female	Male	p
		N=231 (%)	N=291 (%)	
	Forced medication	203 (87.9)	218 (74.9)	$X^2=13.871$, $df=1$, $p<.001$
Type of	Physical restraint	105 (45.5)	193 (66.3)	$X^2 = 22.892$, $df = 1$, $p < .001$
coercive measure used	Seclusion	6 (2.6)	50 (17.2)	X^2 =28.602, df =1, p <.001
Total number of	f coercive measures applied	N=373	N=573	$X^2=0.07$, $df=1$, $p=.78$
	Prevent acts of violence against her/himself	74 (19.8)	95 (16.6)	$X^2=1.636$, $df=1$, $p=.224$
	Severe danger or threat for his or her health	117 (31.4)	159 (27.8)	$X^2=1.432$, $df=1$, $p=.242$
Reasons for the use of coercive	Inability to care for him- /herself	34 (9.1)	62 (10.8)	$X^2 = .720$, $df = 1$, $p = .441$
measures (chosen)	Prevent acts of violence against others	209 (56.0)	338 (59.0)	$X^2 = .809$, $df = 1$, $p = .382$
(chosen)	Prevent acts of violence against property	88 (23.6)	106 (18.5)	$X^2 = 3.595$, $df = 1$, $p = .059$
	Prevent escape	49 (13.1)	88 (15.4)	X^2 =.900, df =1, p =.347

5. DISCUSSION

5.1. DISCUSSION ON THE GENERAL SAMPLE RESULTS

The study that was performed was the largest prospective study of the use of coercive measures among involuntarily admitted patients in Europe, and it is the first one to use the same methods across centers in several countries. It included centers in ten European countries with different legislation and practice concerning involuntary admissions (Kallert et al., 2007). It is known that involuntary legal status on admission is a predictor of "heavy use" of restrictive interventions (Korkeila et al., 2002) and higher levels of restraint and seclusion (Bilanakis et al., 2010). Therefore, the frequency of coercive measure use in the sample of hospitalized patients was 38%, which was higher than the rates found in other studies of different groups of patients in various European countries, for example, 11% in Greece (Bilanakis et al., 2010) and 10% in Germany (Steinert et al., 2007).

According to EUNOMIA project results almost 40% of involuntarily admitted patients received some form of coercion during their treatment. Similar results were reported from other studies on involuntarily admitted patients (Georgieva et al., 2012b; Husum et al., 2010). The variance in clinical practice of the use of coercive measures is extensive. Differences are found internationally and also among hospitals, or even individual wards within one country. Even when psychiatric hospitals are subject to the same regulations, significant differences in the number of applied coercive measures have been found, as robust as two- or threefold higher numbers between hospitals (Steinert et al., 2007; Lay et al., 2011).

5.1.1. PATIENT RELATED FACTORS FOR THE USE OF COERCIVE MEASURES

It is quite important to find specific patient factors and health care factors that predict use of coercive measures, so that treatment programs can be adjusted to better help these groups of patients and thus reduce the number of involuntary admissions and compulsory treatments (Van der Post et al., 2008).

5.1.1.1. BASIC CHARACTERISTICS OF THE GENERAL SAMPLE

We report only a slight association between patients' socio-demographic characteristics (age, gender, occupational and social status) and the use of coercive measures. However, it should be emphasized that this study comprises a specific group of involuntarily admitted patients, the majority of which were male and young. Several studies have examined the frequency of various types of restrictive measures and the preferences of staff and patients. In a Norwegian university psychiatric hospital (Wynn, 2002), a retrospective examination of hospital records showed that physical restraint was preferred with younger, male, and nonpsychotic patients.

Pharmacological restraint was preferred with female patients and older patients with a nonorganic psychotic disorder. Seclusion was preferred with older male patients with an organic psychotic disorder. However, other analyses regarding a potential age effect yielded inconclusive findings, some researchers have identified a higher age to be a risk factor for the use of coercive treatment (Riecher-Rossler & Rossler, 2013), and others have failed to find any association between age and being coerced (Binder, 1979; Fischer, 1994; Kaltiala-Heino et al., 2000; Brown & Tooke, 2002). Some studies suggest that while younger patients are more likely to be restrained and secluded, older patients are restrained and secluded for longer periods of time (Smith et al., 2005).

In a Netherlands hospital, 166 patients underwent one or more restrictive measures during hospitalization (Veltkamp et al., 2008). An equal number of patients preferred seclusion and forced medication, and the two measures were equal in perceived aversiveness and perceived efficacy. Women preferred medication over seclusion, while men preferred seclusion over forced medication. Older patients considered both seclusion and forced medication less effective than younger patients did (Veltkamp et al., 2008). In England, service users and staff strongly disapproved of net beds and mechanical restraint (Whittington et al., 2009). The three methods that received the most approval by the service user group were intermittent observation, timeout, and as-needed medication.

5.1.1.2. CLINICAL CHARACTERISTICS OF THE GENERAL SAMPLE

We found a positive association between a diagnosis of psychosis, the severity of symptoms according to the BPRS scale, and the use of coercive measures. Previous studies suggest that the diagnosis of psychosis (in particular schizophrenia) or of mania is consistently associated with the risk of receiving coercive measures (Betemps et al., 1993; Way & Banks, 2000; Cougnard et al., 2004; Husum et al., 2010; Keski-Valkama et al., 2010). Organic mental disorders (in particular dementia) (Spengler, 1986; Steinert et al., 2007), substance abuse disorders (Kaltiala-Heino et al., 2000; Steinert et al., 2007), personality disorders (Mason, 1998; Salib et al., 1998), and mental retardation (Tardiff, 1981; Way & Banks, 1990) are also related to the use of restraint and seclusion. Studies including all major diagnostic groups showed the highest proportion of coercive measures in people with organic brain disorders, mainly to prevent falls (Martin et al., 2007; Steinert et al., 2007). One of the main limitations of the EUNOMIA study was the exclusion of patients over 65 years, including those with dementia therefore it is not possible to make any comparison with the literature on this data.

For more than one-third of patients in our sample, at least one coercive measure was used during the period up to four weeks after involuntary hospitalization. A diagnosis of schizophrenia and higher scores on the BPRS were significantly correlated with receipt of coercive measures. Severity of illness also appeared in previous studies as a factor influencing the use of coercive measures (Husum et al., 2010; Keski-Valkama et al., 2010; Lay et al., 2011). The common denominator, which has been identified as a frequent reason for the use of coercive measures regardless of the diagnosis in the past, was acute (Thompson, 1986; Morrison & Lehane, 1995; Salib et al., 1998; Smith et al., 2005) or threatening violence (Way & Banks, 1990; Swett, 1994; El-Badri & Mellsop, 2002). In addition to acute or threatening violence, disorientation and agitation have been reported to be a frequent reason for the use of coercive measures (Kaltiala-Heino et al., 2000; Raja & Azzoni, 2005; Georgieva et al., 2012b). These findings correspond with our results, where the BPRS sub-categories most significantly associated with the use of coercive measures included hostility, uncooperativeness and positive psychotic symptoms.

According to our data, a decreased level of global functioning is also associated with a higher likelihood that a patient will be coerced. The level of global functioning seems to be correlated with the severity of psychosis, as reported in other studies (Petkari et al., 2011; Fiorillo et al., 2012; Georgieva et al., 2012b). An Italian study on hostility and violence of acute psychiatric inpatients reported that lower GAF scores at admission are connected with hostile and violent behaviors (Raja & Azzoni, 2005).

5.1.1.3. PERCEIVED COERCION IN INVOLUNTARY TREATED PATIENTS

The change from a paternalistic medical approach to a more balanced attitude model of treatment has resulted in an increased interest to the patients' subjective feelings (Greenberg et al., 1996; Bindman et al., 2006; Kontio et al., 2012). The perception of being coerced is presumed to be associated with the severity of psychopathology and lack of insight (Kjellin et al., 2004; Kjellin & Wallsten, 2010). According to our results, a relationship between the levels of perceived coercion and the probability of receiving a coercive measure was found. Previously published study showed a mutual relation between the severity of positive symptoms, the level of global functioning and perceived coercion at admission (Fiorillo et al., 2012).

5.1.1.4. USE OF COERCIVE MEASURES IN THE GENERAL SAMPLE

We found significant variations in relative frequency and type of measure used in the participating centers. This is in line with other authors who are reporting from 6 to 30% of all admitted patients to have experienced seclusion, restraint or forced medication in acute psychiatric settings (Steinert et al., 2010, Lay et al., 2011). The most frequent coercive measure that was found in the general sample was forced medication.

Pharmacological treatment has in the algorithm of the management of an acutely agitated patient its indisputable place and should be initiated only if previous de-escalation techniques and other non-pharmacological methods had fail (Vevera et al., 2007). The most commonly used forced

medication among patients with coercive measures was first-generation antipsychotics, especially haloperidol and zuclopenthixol. Second-generation antipsychotics, although preferred by several recommendations, were not that frequently applied (Allen et al., 2005; NICE 2006). Benzodiazepines were often used separately or in combination with antipsychotics. Ideal drug for such purpose should be non-invasive; easy to apply; with rapid onset of action; effectively decreasing agitation without excessive sedation; well-tolerated and should positively affect the underlying psychiatric condition (Allen et al., 2005; NICE 2006). Despite the wide variety of currently available drugs nor one meets all the criteria.

Physical restraint and seclusion were used less frequently than forced medication. Some studies are however reporting figures on those secluded or restrained as high as 66% of all inpatients (Way & Banks, 1990; Brown & Tooke, 1992). Our results are showing numbers twice or even three-times lower. Only in two centers included in the study (Dresden and Thessaloniki) were mechanical restraints used more often than the average. Seclusion was used more than the average only in Naples and East London. In many hospitals these special rooms for seclusion were not available at all. The application between one and two coercive measures per patient was predominant pattern in majority of the centers, but there have been centers (Wroclaw, East London) where the number of coercive measures per patient was close to three.

5.1.2. WARD RELATED FACTORS FOR THE USE OF COERCIVE MEASURES

Recently, many studies have analyzed ward-related characteristics and their impact on the use of coercive measures (Palmstierna et al., 1991; Morrison & Lehane, 1995; Sandhu et al., 2010; Lay et al., 2011; Bowers et al., 2012). In contrast to other studies, our results did not show any significant association between the size of the ward, the number of patients per room and the use of coercive measures (Palmstierna et al., 1991; Lay et al., 2011; Van der Schaaf et al., 2013). Palmstierna et al. showed that an increased number of patients in the ward significantly increased the risk of aggressive behaviors in patients with psychosis (1991). Results on the association of staffing levels have depicted contradictory findings in the past. It would be expected that a higher clinical staff/patient ratio would ensure a decrease in the use of coercive measures.

It is presumable that a low number of ward personnel is connected with a higher probability of staff exhaustion. From a different viewpoint, more staff during the day could mean more activities for patients, which could lead to their over-stimulation (Terpstra et al., 2006). During the night shift, a lower number of staff may lead to a higher need of the staff to control (and unfortunately in some patients to prevent) violent behaviors (Lendemeijer, 1997). Some studies, including ours, have not found a significant relationship between the number of staff and the use of coercive measures (Way & Banks, 1990; Husum et al., 2010). The female/male ratio of staff has been found to be important in previous studies. Staff with a higher proportion of women tended to use coercive measures more frequently (Morrison & Lehane, 1995; Janssen et al., 2007). Also, a significant association was previously found between the use of coercive measures with the education and experience of nurses (Klinge, 1994; Morrison & Lehane, 1995; Janssen et al., 2007).

5.1.3. OUTCOMES BASED ON THE RESULTS OF THE GENERAL SAMPLE

In conclusion, the data presented for the general sample revealed that despite the fact that the studied countries have markedly different practices concerning the use of coercive measures, which are influenced by socio-cultural and legal norms it appears that coercive measures are used in a very similar group of patients. These patients have high levels of positive symptoms and hostility, have poor global functioning before admission, and have high levels of coercion at admission. The research and clinical focus should be oriented on these traits and predictors when considering the preparation of specific programs to reduce the use of coercive measures in psychiatry. It can be assumed that programs, which support minimal coercion at admission, could reduce the use of coercive measures. Results from a comprehensive study in Germany confirmed that lower levels of compulsory measures were associated with the use of guidelines for compulsory measures and proper de-escalation techniques (Steinert et al., 2007).

The EUNOMIA group has published general recommendations on appropriate procedures for involuntary hospital admission based on multi-level gathering of information from representatives participating in the process of involuntary admission in each center. These

guidelines, which include exact detailed recommendations, took into account the experiences of professionals, ex-users of psychiatric care, relatives of patients, representatives of emergency services and the police (Cougnard et al., 2004). It would probably improve the current situation if this material were incorporated into routine clinical practice across Europe. Standardization of the legal framework for the use of coercive measures would be a first step. The need for standardization should be addressed on a policy level, based on the recommendations from the EUNOMIA project. But it seems that legislative steps are not enough to influence the level of the use of coercive measures. Data from Finland show that cultural factors, including ward organization, are more important for changing clinical practice (Keski-Valkama et al., 2007).

On the basis of our results, programs could focus on techniques leading to effective and fast management of hostility and of positive symptoms. Experiences from the Netherlands also suggest that uniform guidelines or uniform methods are still not enough to manage violent behaviors and patients' individual choices should be considered (Georgieva et al., 2012c). In spite of many international guidelines on the management of agitated patients, clinical practice still relies mostly on local and national traditions rather than on scientific evidence (Georgieva et al., 2012b). Some efforts should be made to include efficient guidelines in daily practice. Some studies also reported on programs aimed at reducing the use of coercive measures in acute psychiatric settings (Donat, 2005). These programs try to change the routine practice of using coercive measures by making changes to the ward structure and climate (training of staff, changes in unit rules) and also by including a higher involvement of patients in treatment planning (Jonikas et al., 2004; Donat, 2005; Scanlan, 2010; Borckardt et al., 2011). Future research should focus on programs, ideally at the international level, which could support staff training and would reduce the use of coercive measures.

5.2. DISCUSSION ON THE RESULTS OF THE GENDER DIFFERENCES IN COERCED PATIENTS WITH SCHIZOPHRENIA

This is the first international multicenter study focused on gender differences which assessed a large sample of coerced, involuntary treated patients with schizophrenia using standardized

instruments. There are several interesting findings we would like to point out; 1) both genders do not differ in socio-demographic or clinical characteristics from the non-coerced inpatient populations; 2) coerced female patients do show a worse social functioning than their male counterparts which is contrary to the non-coerced inpatient populations; 3) patterns of aggressive behavior are different between men and women; women are exhibiting more frequently aggressive behavior, but men are more frequently accounted for severe aggressive acts; this may lead, along with "cultural factors" to 4) different patterns of use of coercive measures among genders; where forced medication is preferred by the staff in women and physical restraint and seclusion in men.

Males accounted for 55.8% of the patients and females for 44.2%, which is literally replicating the numbers from the study on 1755 involuntary admitted patients in USA (57.8 vs. 42.2) (Sanguineti et al., 1996) and study on 2222 patients in Denmark (63.6% vs. 36.4%) (Ohlenschlaeger & Nordentoft, 2008). In Salize's report the percentage of compulsory admitted male patients varied between (50% in Sweden and 69% in France) (Salize et al., 2000).

5.2.1. MAIN DIAGNOSIS

Study sample comprised mainly patients with paranoid schizophrenia (with slight prevalence of men) and residual schizophrenia (with slight prevalence of women). The preponderance of women within the residual subtype of schizophrenia is in contrast with the studies showing men evolve more often in residual schizophrenia mostly because of greater frequency of negative symptoms and multiple admissions (Beratis et al., 1997). One of the explanations might be the age difference between genders in the sample of involuntary admitted patients, women being older than men. All the other types of schizophrenia accounted only for less than fifteen percent in both genders.

5.2.2. SOCIO-DEMOGRAPHIC CHARACTERISTICS

In conformity with what is known about socio-demographic characteristics for the "voluntary" treated patients with schizophrenia (Andia et al., 1995; Thorup et al., 2007), the study shows no major differences with the involuntary ones. Coerced women were significantly older than men; they were more likely married, divorced or widowed; more often did live on their own; and were less often unemployed. Coerced men were significantly more likely single; did more often live by their families, partners or friends; and were more often unemployed. Half of all patients of both genders were on social welfare. The proportion of the homeless psychotic patients who have been treated involuntarily is very low in both genders, which is a huge difference to the data from US, where the numbers are ten times higher (Craw & Compton, 2006). The chronicity of the psychotic illness has proven to be an important factor in receiving coercive measures. More than three-quarters of all patients were re-hospitalized and the vast majority of women and men have already experienced involuntary hospitalization.

5.2.3. CLINICAL CHARACTERISTICS

Overall female patients did show more severely impaired clinical functioning in comparison to men. Women have scored higher than men on several individual positive symptoms such as hallucinations and bizarre behavior, which is in line with other studies on schizophrenia populations (Leung & Chue, 2000; Tang et al., 2007; Thorup et al., 2007), however overall higher scores on "positive psychotic" subscale was associated with men category. Furthermore coerced women were not more severely delusional than men and did also not score higher on affective symptoms, facts that have been described in other gender studies with non-coerced schizophrenia patients (Leung & Chue, 2000; Thorup et al., 2007). They have though scored higher than coerced men also on "negative symptom" emotional withdrawal, which is different to what has been described elsewhere in non-coerced populations (Shtasel et al., 1992; Moriarty et al., 2001; Morgan et al., 2008). Women did also score higher on two symptoms from the "excitement/hostile cluster"; uncooperativeness and motor hyperactivity, fact that is mirrored in their higher involvement in aggressive behavior.

Although there are clinical manifestations that are showing differences between this study sample and other non-coerced schizophrenia populations, of greater interest is the finding that coerced females showed a significantly worse social functioning than men. This is a noteworthy fact, as almost all studies dealing with schizophrenia populations have reported opposite findings, women showing higher social functioning than men (Shtasel et al., 1992; Tamminga, 1997).

Aggressive behavior is very common among involuntary admitted patients with schizophrenia. In this study female patients were involved in almost 80% in some kind of aggressive behavior, while men in slightly more than 70%. Although this difference wasn't significant this finding might look discrepant with the data on violence in out-patient psychiatric populations, where men are more violent than women. There are however at least two reasons explaining this discrepancy; assaults in men are associated with substance abuse, property crime and school truancy (Krakowski & Czobor, 2004), factors that are almost of no influence in the inpatients setting; and secondly, the presence of major mental disorders, including schizophrenia, increases the risk for violent offending relatively more in women than in men (Hodgins, 1992). Therefore these results are in line with studies showing that male overrepresentation vanishes in inpatient psychiatric populations (Lam et al., 2000). In one study hospitalized women patients were actually more assaultive than their male counterparts, although men engaged in more fearinducing behavior (Binder & McNiel, 1990). These results are similar with our findings, where female patients were more frequently aggressive with lesser intensity on the other hand males were responsible for the most severe aggressive deeds. These results have been observed for overall aggression as well as for verbal aggression and aggression against property items in MOAS. Interestingly, when only average scores for the aggression as measured by the MOAS instrument would be used, no significant difference among genders would have been detected.

5.2.4. USE OF COERCIVE MEASURES

Although some studies found no association between the risk of being coerced and the gender (Kaltiala-Heino et al., 2000; Keski-Valkama et al., 2010a) in psychiatric populations, this study

revealed several differences in the use of coercive measures. In European institutions men with schizophrenia are more than twice likely to end up being physically restrained than women, while the opposite is true for forced medication. One can only speculate on the reasons for such difference. One of the explanations of higher use of forced medication among women might be the fact that they do express more positive psychotic symptoms, plus positive psychotic symptoms are more likely to result in assaults in women than in men (Krakowski & Czobor, 2004). As for the more frequent use of physical restraint by men, we assume that the most likely explanation is that more serious aggressive behavior in men puts the staff on guard more easily than the same aggressive type of behavior by women. Physical restraint may be seen as a more immediate way to control hetero-aggression and a "safer" option to avoid aggressive acts against the hospital staff and other patients. However, as Lam et al. (2000) conclude, injuries to staff members are as likely to be caused by violence by female patients as by male patients and thus signs of an elevated risk of violence should not be discounted on the basis of gender.

When it comes to seclusion the likelihood of men being secluded is almost eight times higher than the one by women. The reasons for the large disproportion of the use of seclusion might be again explained by more severe aggressive behavior that was observed in males (although seclusion was not used in all centers). Obviously cultural and local traditions, as well as legislative practices play a crucial role in the process of applying specific coercive measure (Raboch et al., 2010; Fiorillo et al., 2011). For example in Netherlands involuntary medicating is being highly restricted and mechanical restraint is being forbidden in the UK (Steinert & Lepping, 2009).

In a Norwegian study younger male patients reported that if they would undergo coercive measure, they would have preferred physical restraint and older male patients seclusion over forced medication, whereas forced medication was preferred by female patients (Wynn, 2002). These findings were confirmed by a Netherlands study where female patients preferred forced medication over seclusion, while male preferred seclusion over forced medication (Veltkamp et al., 2008). In England physical restraint was strongly disapproved by both genders (Whittington

et al., 2009) and female patients accounted for more seclusions than their male counterparts and they were secluded more often but for shorter periods (Mason, 1998). Georgieva et al. concludes that women reported that they had experienced coercive interventions as more burdensome than men (2012a), which may reflect their greater emotional responsiveness and lower average tolerance thresholds for painful stimuli (Fillingim et al., 2009). In the future instruments which measure the psychological impact during psychiatric coercive interventions, such as the "Coercion Experience Scale" (Bergk et al., 2010) might be used to compare different coercive interventions.

No significant difference has been observed in the reasons that led to the use of coercive measures. The most common reasons in both genders were "to prevent acts of violence against others", followed by "worsening of condition", and by "aggression against objects". Autoaggressive behavior accounted "only" for less than one-fifth of reasons that led to the use of coercive measures and surprisingly also here no gender differences have been traced, although women with schizophrenia do usually have greater number of suicide attempts (Thorup et al., 2007).

5.3. LIMITATIONS OF THE STUDY

The major strength of this study is the large sample size, which allowed for interpretation of both positive and negative findings and the number of assessed factors and, in particular, the thorough documentation of the coercive measures received by patients. The sample was large but not epidemiologically representative of all psychiatric in-patient wards in participating countries; yet, due to the large sample size we had enough statistical power to interpret findings. There were however also several limitations regarding our findings. Overall, only about 50% of the eligible patients were interviewed. This rate may be seen as low in many other fields of health research, but it has been described as good for this type of study in acute settings with difficult-to-recruit patients (Katsakou & Priebe, 2006). For the comparison of recruited and non-recruited patients, only minimal data were available for the UK, which did not suggest a selection bias on the assessed characteristics (Priebe et al., 2010).

Furthermore patients with dementia were excluded by the exclusion criteria. Patient ethnicity was not followed and could have an important influence (Gudjonsson et al., 2004). The severity of symptoms of admitted patients may also vary between countries according to their criteria for involuntary admission; this might have influenced the rate of coercive measures used in different countries. The EUNOMIA project did not take into account dual diagnoses, mainly the abuse of psychoactive drugs, which may have an important impact according to previously published studies (Carra et al., 2012).

Because only few centers in each country were assessed (Kallert et al., 2005), and as we know that the variance in use of coercive measures even between hospitals in the same country is high (Martin et al., 2007), these our results cannot be generalized. However, they seem to be valid for the catchment areas that we were able to describe in detail (Kallert et al., 2005). Data on use of coercive measures were based on available documentation and additional sources. The routines for documentation of coercive measures may differ between participating centers, and the number of unrecorded or unreported measures may also differ. However, all centers used a uniform and standardized protocol for data collection and thoroughly gathered all available information.

Only a restricted number of characteristics related to psychiatric facilities in each of the 10 centers could be analyzed, thus further limiting the generalizability of the findings. We cannot exclude that other characteristics (for example staff experience, training, organizational aspects etc.) of the psychiatric wards may be associated with the use of coercive measures and should be the focus of future research.

5.4. FUTURE PERSPECTIVES IN THE FIELD

Over the past decade, especially in the US, several programs minimizing the use of coercive measures during psychiatric treatment were launched, and these have been discussed in several publications (Smith et al., 2005; Hellerstein et al., 2007; Prescott et al., 2007; Martin et al., 2008;

Ashcraft & Anthony, 2008; Lewis et al., 2009). It was even found that reducing compulsory treatment decreased financial expenditures (Le Bel & Goldstein, 2005). Scanlan's analysis (2010) of recent literature described seven key strategies for coercive measure reduction programs: change in policy or leadership, external review or debriefing, data use, training, consumer and family involvement, increase in staff-to-patient ratio or use of crisis response teams, and changes in program elements.

Similar trends are also evident in some European countries (Steinert et al., 2010). It is imperative that during procedures for involuntary hospital admission and the admission itself, patients' rights should be recognized and interventions should adhere to the principle of the "least restrictive alternative" (Fiorillo et al., 2011). Avoidance of all coercive measures in clinical practice is an unrealistic goal for the time being. Coercive measures are used in many hospitals for acute patients (Raboch, 2006) and regulated through legislation. Therefore, acceptance of official national guidelines and even of European guidelines on regulating and using and use coercive measures (Kallert et al., 2007; Fiorillo et al., 2011) could be an appropriate step in maximizing the individual freedom of psychiatric patients during hospital treatment.

6. CONCLUSION

Coercive measures such as seclusion, restraint, or forced medication are considered as interventions of last resort when managing violent, disturbed or suicidal patients, and when other methods of calming a patient have failed (Nelstrop et al., 2006; Bergk et al., 2010; Lay et al., 2011). Even though severe and even fatal side effects have repeatedly been described by the use of coercive measures (Hem et al., 2001; Mohr et al., 2003; Laursen et al., 2005), the authors of recent publications from several countries agree that it would not be currently possible to abolish such measures completely (Fisher, 1994; Salib et al., 1998; Needham et al., 2002; Fiorillo et al., 2012).

In the thesis we evaluated a group of more than 2.000 detained patients in psychiatric facilities in twelve countries. For more than one-third of patients, coercive measures were applied during the first four weeks of involuntary treatment. These twelve countries varied greatly in the frequency and type of coercive measure used. Age, gender, diagnosis, and severity of psychopathology played an important role in this regard. Overall, we did not find any statistically significant influences of the technical characteristics of countries (that is, number of psychiatric hospital beds per 100.000, number of staff per bed, and average number of beds per room).

Nonetheless, the influence of an individual center was obvious. Therefore, we share the opinion of other authors (Larue et al., 2009) that is a country's sociocultural traditions, as well as its treatment customs in individual psychiatric facilities play a decisive role in this very sensitive issue. However, this very important area of psychiatric care needs further study. Future research projects could identify the factors in legislation and clinical practice, including important staff-patient interactions (Beck et al., 2008) that could lead to a more constructive cooperation of all parties involved. Currently, programs and practice guidelines that would rationalize and minimize the use of coercive measures in psychiatric facilities are needed.

Further results of this study point towards a higher threshold for women to be treated with the use of coercive measures. The reasons for it might be that even less serious aggression actions can lead to application of coercive measures in men as the aggression of men puts the staff on guard more easily then in women. Moreover coerced women are in comparison with their non-coerced counterparts in contrast to men showing lesser social functioning, and more importantly more severe symptoms from the "excitement/hostile" cluster.

Delineating gender differences in the use of coercive measures in patients with schizophrenia is important for developing targeted treatments (Thorup et al., 2007; Koster et al., 2008). Therefore national and international recommendation on coercive treatment practices should include appropriate consideration of the evidence of gender differences in clinical presentation and aggressive behaviors found in inpatient populations.

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8. LIST OF ABBREVIATIONS

Abbreviation Meaning

AD Anno Domini

ANOVA Analysis of variance

BPRS Brief Psychiatric Rating Scale

CI Confidence Interval

CoE Council of Europe

CoESCB Council of Europe Steering Committee on Bioethics Working Party

CPT European Committee for the Prevention of Torture and Inhuman or

Degrading Treatment or Punishment

DoH Department of Health

DSM-IV Diagnostic and Statistical Manual for Mental Disorders, 4th edition

ESDS European Socio-Demographic Schedule

ESMS European Service Mapping Schedule

EUNOMIA European Evaluation of Coercion in Psychiatry and Harmonization of Best

Clinical Practice

Fig. Figure

GAF Global Assessment of Functioning scale

ICD-10 International Classification of Diseases, 10th revision

IRB Institutional Review Board

LECHR Law of the European Convention on Human Rights

MOAS Modified Overt Aggression Scale

OR Odds Ratio

SPSS Statistical Product and Service Solutions

Tab. Table

UK United Kingdom

UN United Nations

US United States

WHO World Health Organization

WPA World Psychiatric Association

9. ATTACHMENTS

9.1. PUBLICATIONS AND ABSTRACTS RELATED TO THE DISSERTATION THESIS

9.1.1. PUBLICATIONS

Nawka A, Kalisova L, Raboch J, Giacco D, Cihal L, Onchev G, Karastergiou A, Solomon Z, Fiorillo A, Del Vecchio V, Dembinskas A, Kiejna A, Nawka P, Torres-Gonzales F, Priebe S, Kjellin L, Kallert TW: Gender differences in coerced patients with schizophrenia. *BMC Psychiatry* 2013, 13:257. doi:10.1186/1471-244X-13-257. **IF=2.55**

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9.1.2. ABSTRACTS

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