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# Original article

# How to improve clinical practice on forced medication in psychiatric practice: Suggestions from the EUNOMIA European multicentre study



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#### ABSTRACT

Background: The decision to adopt forced medication in psychiatric care is particularly relevant from a clinical and ethical viewpoint. The European Commission has funded the EUNOMIA study in order to develop European recommendations for good clinical practice on coercive measures, including forced medication.

Methods: The recommendations on forced medication have been developed in 11 countries with the involvement of national clinical leaders, key-professionals and stakeholders' representatives. The national recommendations have been subsequently summarized into a European shared document. Results: Several cross-national differences exist in the use of forced medication. These differences are mainly due to legal and policy making aspects, rather than to clinical situations. In fact, countries agreed that forced medication can be allowed only if the following criteria are present: 1) a therapeutic intervention is urgently needed; 2) the voluntary intake of medications is consistently rejected; 3) the patient is not aware of his/her condition. Patients' dignity, privacy and safety shall be preserved at all times.

Conclusion: The results of our study show the need of developing guidelines on the use of forced medication in psychiatric practice, that should be considered as the last resort and only when other therapeutic option have failed.

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## 1. Introduction

All involuntary treatments should be used as last resort when other treatments failed, and with the aim to improve patients' safety and health [1,2]. Forced medication is defined as the

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application of intramuscular medication by force or by definite psychological pressure, i.e. announcing intramuscular treatment if medication is not taken orally at once [3]. The National Institute for Health and Care Excellence (NICE) defined forced medication as "the use of medication by the parenteral route (usually intramuscular or, exceptionally, intravenous) if oral medication is not possible or appropriate and urgent sedation with medication is needed" [4], with the aim to calm or sedate patient reducing the risk of self-harm or to others [5].

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In mental health care, from 2 to 8% of hospitalized patients receive forced medication [6,7]. The most frequently adopted coercive intervention in mental health practice is forced medication (56%), followed by restraint (36%) and seclusion (8%) [8]. The use of forced medication can be predicted by some patients' clinical characteristics, such as, male gender, younger age, having a psychotic or a mood disorder, being homeless, and substance abuse [9]. Other predictive factors are related to staff attitudes and ward characteristics, and include professionals' educational level and background, staff composition [10], hospitals located in urban, deprived and overcrowded areas [11,12].

The use of forced medication in clinical settings arises clinical, ethical and prognostic concerns. In particular, there isn't a consensus on mental disorders requiring more frequently forced medication [13], but usually guidelines refer to "agitation" as a transdiagnostic term. Moreover, an "ideal medication" to be used in acute settings is not yet available, considering that such a medication should be easy to administer, not traumatic, providing rapid tranquilisation without excessive sedation, have a fast onset and a sufficient duration of action, and have a low risk for significant adverse events [14]. Another significant issue is related to ethical and legal factors; in fact, the balance between the use of coercion and the loss of patients' autonomy is still one of the major controversial issues in mental health practice [13,15]. Finally, from a prognostic viewpoint, the effects of forced medication on patients' social and clinical outcome as well as on patients' satisfaction are still debated [16]. In fact, while some positive aspects, such as rest and security, have been identified when using forced medication [17], several studies found that patients' experience of forced medication is mainly negative [18-22]. Patients report different feelings, such as loss of control and lack of information about their situation and about the reasons for the use of forced medication. According to the patient's perspective, if coercion is unavoidable, this should be managed more appropriately, while too often forced medication is used arbitrarily [19], without adhering to clinical guidelines.

Despite forced medication is frequently adopted, only a few guidelines or clinical recommendations on the use of forced medication in mental health practice are available. The few available clinical guidelines focus on the management of violence and aggression [4,5,14,23,24], and none of them deals specifically with procedures to be adopted in case forced medication is needed. In particular, all procedural aspects needed in forced medication are not reported or are reported only marginally.

The study "European evaluation of coercion in psychiatry and harmonization of best clinical practice - EUNOMIA" [25-27], funded by the European Commission, coordinated by the University of Dresden and carried out in 12 European countries (Germany, Bulgaria, Czech Republic, Greece, Italy, Lithuania, Poland, Slovakia, Spain, Sweden, United Kingdom and Israel) aimed to: a) assess all involuntarily admitted patients living in the catchment areas of the participating centers and a sub-group of voluntarily admitted patients who felt coerced at admission; b) produce standardized reports on the national legal situations on coercive treatment measures in psychiatry, on the basis of the original national legal texts; c) develop suggestions of good clinical practice on involuntary treatments in psychiatry (namely coercive measures, forced medication, hospital admission). In this paper we report the development of suggestions for good clinical practice on forced medication.

## 2. Materials and methods

Eleven EUNOMIA centres – with the exception of the London site, acting on the already established Code of Clinical Practice [28] – worked out local suggestions. Because of different centre-specific

resources, a range of methods was used. Seven centers (Dresden, Prague, Naples, Wroclaw, Michalovce, Granada, Orebro) established regional expert groups, composed by 10–15 persons representing the different stakeholders involved in the administration of coercive treatments (e.g., psychiatrists, nurses, police officers, members of relatives' and service users' organizations). These expert groups run semi-structured discussions or focus groups to develop national suggestions. In the remaining three centres (Sofia, Thessaloniki, Tel Aviv) a written survey among the national representatives of stakeholders involved in the administration of coercive measures was carried out.

Within a second phase of the study, all centres in which local expert groups were established asked for comments on their suggestions to different national professional organizations (e.g., psychiatrists, nurses, lawyers or judges, patients and relatives, ministries). These comments were collected by means of structured or non-structured questionnaires, or by discussions in specific thematic workshops; modifications of the text of the local suggestions according to the comments received were inserted by the expert groups. All national suggestions were translated into English, and collected by the coordinating centre, where national suggestions were analyzed using the method of qualitative content analysis independently by two researchers.

According to the EUNOMIA study protocol, the following five categories for forced medication were identified: 1) clinical conditions and legal requisites; 2) professionals involved in the application of the coercive measure; 3) ethical aspects; 4) practical aspects concerning the procedure of forced medication; 5) proposals for improving patients' healthcare.

All relevant information from national drafts have been extracted by three independent researchers from the coordinating centre and placed into "summary tables", specific for each country. In case of missing data, each centre was contacted to provide the relevant information. The summary tables were sent to the relevant participating centre for validity, comprehensiveness and completeness review.

In the final step of the study, the recommendations were reviewed by researchers from the coordinating centre according to comments received from all EUNOMIA centres. All information that significantly differed among centres where removed from the final recommendations. The final version of the document on good clinical practice in the use of forced medication in psychiatric care is presented herein.

#### 3. Results

3.1. Clinical conditions and legal requisites for forced medication

3.1.1. Clinical situation for the adoption of forced medication

General criteria for the adoption of forced medication are: 1) the therapeutic intervention is urgently needed in order to improve patients' mental health state; 2) voluntary intake of medication is consistently rejected; 3) the patient is not aware of his/her condition. Furthermore, forced medication can be applied only if other measures have shown their ineffectiveness, and a clinical emergency is present, including: 1) sexual and physical attacks against other patients and/or staff; 2) violent and/or threatening behaviors; 3) intermediate loss of control with evidence of aggressive behaviors; 4) immediate intentions for suicide attempt. The participating centres agreed about the difficulties to identify specific clinical diagnoses that would benefit from the use of forced medication.

### 3.1.2. Lawfulness

The use of forced medication requires legitimization according to the national civil commitment laws. In general, only measures

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