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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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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

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

¹ These two authors contributed equally to this manuscript.

http://dx.doi.org/10.1016/j.eurpsy.2018.07.002 0924-9338/© 2018 Elsevier Masson SAS. All rights reserved. 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 and interventions listed in the national, local, hospital legislation's norms, regulations, policies, ethical norms, procedures and standards regulating the use of forced medication should be adopted. The adoption of forced medication should be carefully documented in a special register form at the unit, where all relevant information (including date, time, reason of measure, medical staff and nurses involved, as well as patients' symptoms and behaviours), circumstances and reasons for the adoption of forced medication should be safely stored.

3.2. Professionals involved in the procedure of forced medication

3.2.1. Psychiatrists/physicians and clinical decisions

Before forced medication is applied, the psychiatrist must personally assess patient's conditions and consider all possible therapeutic alternatives. He/she should evaluate the need for urgent pharmacological treatment, including the consideration of risks, such as excessive psychomotor excitement or drug and alcohol abuse, dehydration or presence of physical illnesses

Forced medication should be considered only in the case that all other interventions failed and could be ordered only by a psychiatrist who has to: 1) provide the paramedical staff with unambiguous and clear instructions, avoiding the "in the case of need"; 2) be sure that the paramedical staff understood the instructions properly; 3) inform, preferably in collaboration with nurses, the patient and his/her carers (if possible) about the procedures to be adopted (i.e., type of medication, rationale for its use, doses, effects and side-effects); 4) detail the procedures in advance and define who is responsible for the activities to be implemented during the forced medication (the presence of the physician is mandatory in case of intramuscular or intravenous forced medication); 5) decide the frequency of supervision and the intervals in which vital parameters should be monitored; 6) document everything into the clinical records and sign every activity by his own hand signature. In the clinical records, the physician should report: 1) reasons for the use of forced medication; 2) the name of the psychiatrist who ordered the procedure and the names of all involved professionals; 3) the adopted alternative strategies before using forced medication; 4) starting time, type, dose and way of application of the medication; 5) use of physical or mechanical restraint and patients' behaviours during forced medication.

The ward physician should discuss with the clinical team every time when a forced medication is adopted, including the evaluation of whether forced medication could have been avoided.

3.2.2. Nurses and other involved professionals

If forced medication cannot be avoided, ideally it should be done by experienced staff members in order to make the procedure as safe as possible for the patient and the staff. The following decisions should be made before initiating a procedure of forced medication: 1) who will take the lead of the team performing the intervention; 2) who will inform and keep contact with the patient; 3) where the forced medication will be given (preferably, this should happen in the treatment room or in the patient's room); 4) who will take care of other patients.

The leader should approach the patient, repeat the information concerning the reasons for forced medication and provide the following information: 1) why the medication is necessary; 2) why the doctor has ordinated it; 3) where medication will be given. Nurses should document the procedure and the level of coercion used in administering the medication; a member of the staff will be responsible to discuss the episode with the physician and with the patient afterwards.

3.2.3. Others

The presence of police officers or security personnel has to be avoided in the application of forced treatment. In case of severe danger, security personnel can be involved only after clinician's disposition in order to protect the personnel and other patients.

3.3. Ethical aspects

Patients' dignity, privacy and safety should be preserved to the greatest possible extent at all times during the use of forced medication. If the administration of forced medication cannot be avoided, it must be as safe as possible for the patient; the least restrictive method that is safe and effective should always be used. The measure should be applied only when other interventions are not effective or inappropriate, and all de-escalation strategies (including verbal de-escalation, offering oral medication clarifying that intramuscular medication will be used if the patient refuses it, inviting the patient to stay in a quiet place, involving the patient into relaxing or distracting activities, offering a walk or something to eat, granting wishes, proposing other options to solve the situation, involving other persons whom the patient trusts, having a talk with a professional, etc.) have been adopted. Never forced medication should be considered a form of punishment, humiliation, or with the aim to inflict pain or establish dominance.

If there are cameras or monitors in the room where the forced medication is applied, only the caring nurse is authorized to see the screen. The physician should strive to involve the patient and the family in decisions regarding treatment choices in order to guarantee effective treatment.

3.4. Practical aspects concerning the procedure of forced medication

3.4.1. Information

The patient, preferably within 24 h and before discharge, should be informed about the reasons for the adoption of forced medication and about possible alternatives to be adopted in the future. A written agreement with the patient on how to behave in case of similar symptoms will occur again in the future can be useful.

In the case of an escalating conflicting situation, the procedure of forced medication has to be reasonably explained to the patient. If this is not possible, the patient has to be informed after he/she has calmed down. In particular, patients should be informed about:

1) intent, reasons and planned measures; 2) the way forced medication will be applied; 3) the duration of the treatment and its possible effects; 4) possible alternatives (e.g. voluntary medication) with the aim of avoiding long term "forced" pharmacological treatment. The patient should also be informed where the injection will be made.

3.4.2. Behaviors

Mental health professionals should make all efforts to avoid forced medication, by checking in advance all possible alternatives. This implies that voluntary intake of medication, which should be always preferred because it might improve compliance to future treatments, is consistently rejected by the patient.

If forced medication cannot be avoided, it must be applied only upon a physician/psychiatrist order. The following steps should be considered: 1) offer an oral medication; 2) adopt an adequate level of persuasion; 3) offer again an oral medication; 4) communicate to the patient the possibility to administer a forced medication joined by offering again oral medication; 5) adopt forced intramuscular or intravenous medication.

Also forced medication should be individualized. In other terms, if a patient has had previously a good clinical response to a given medication, that medication should be given again to that patient.

patient's vital parameters (blood pressure, pulse, temperature and frequency of respiration), safety, human care and quality standards must be constantly monitored after forced medication is administered at regular intervals (approximately every 15 min). Special attention should be paid to possible psychiatric and physical complications.

3.4.3. Ward characteristics

Psychiatric units should provide relaxing and spacious settings, in order to reduce the risk of patient's agitation and aggressive behaviours. Ideally, forced medication should be performed in a different room from other patients and visiting relatives. In emergency situations, forced medication may be adopted in the corridor, but as soon as possible it should be continued in a different space. A separate room is not always necessary.

3.4.4. Other patients

Because the situation can be very upset both for the patient and other patients, it is useful that one or more staff member takes care of other patients.

3.5. Proposals to improve patient's health care

In order to prevent traumas to patients during the administration of forced medication, medical staff should be adequately trained and should be skilled enough in performing the measures and in using de-escalation techniques, which include: 1) establishing a good relationship with the patient; 2) demonstrating active participation; 3) active listening; 4) obtaining a more detailed case history; 5) adopting good communications skills (establishing verbal and visual contact, using short sentences with very clear content, speaking with a warm and reassuring tone of voice, declaring agreement with the patient's statements without arguing nor disagreeing). This technique should be combined with particular behavioral strategies, like having positive and friendly attitudes, keeping at a useful distance and giving alternatives to the patient.

4. Discussion

This is the first study carried out with the aim to produce European recommendations on the use of forced medication in psychiatric clinical practice. Several guidelines on the use of pharmacological treatments in case of agitation exist [14], but none of them specifically addresses the theme of forced medication in routine clinical setting.

Forced medication represents one of the most frequently adopted coercive measures, which is considered as a "chemical cosh" by several authors [10] and perceived as one of the most stressful for the patient, followed by seclusion (isolation in a locked room), physical and mechanical restraint (using leather straps and belts) [29].

The development of this consensus document allowed a synthesis of the most significant national aspects regarding forced medication, identifying the main differences and common aspects on the procedures of forced medication. In particular, crossnational differences are mostly related to legal and policy-making aspects, rather than to clinical situations. Although these differences represent an obstacle for the development of common guidelines [30], participating countries easily found consensus on clinical and legal requisites needing forced medication. In fact, aggressive and violent behaviours have been considered as necessary phenomena requiring a forced medication [31]. According to the scientific literature, it is not a specific diagnosis itself that needs to be treated with forced medication, but rather transdiagnostic symptom dimensions, such as thought disturbances,

disorganized behaviours, agitation, would benefit most from forced medication [32]. The low level of clinical definition, as well as the tendency to use broad and generic diagnostic categories, reflect the difficulties of physicians in identifying predictive factors for forced medication of patients with mental disorders. However, this situation may also represent a practical advantage for mental health professionals, in particular as regards the difficulties in formulating valid and reliable psychiatric diagnoses in emergency situations [25].

A consensus has been reached on the importance of multidisciplinary teams in emergency situations, with a clear distinction of rules and responsibilities, and on the establishment of well-defined and clear tasks for each involved professional, in particular for nurses, whose role should include drug administration, emotional support, observation and daily contact with patients.

The importance of conducting meetings with psychiatrists, nurses and patients after the forced medication has been highlighted in all participating centres. These groups could be useful to improve skills of mental health professionals to understand patients' needs, to increase patients' engagement in their treatment plan, and to improve their understanding of the situation which determined the use of forced medication [33–35].

Several needs emerged from the discussions held in each centre. In particular, professionals suggested the need to develop training courses for all professionals involved in the procedure of forced medication with the aim to: 1) improve staff knowledge on clinical characteristics of mental disorders and on the legal and administrative aspects of forced medication; 2) improve mental health professionals' communication skills and their ability to adequately manage aggressive behaviours using deescalating techniques [4,36].

As far as the relationship with users and relatives is concerned, one of the most important issues that emerged during the process of recommendations' development was the need to develop initiatives aimed at obtaining patient's consent to treatment as much as possible. In fact, recent studies found that shared decision making in psychiatric practice is associated with a better long-term outcome and satisfaction with received treatments [37]. In particular, it may be useful that patients are informed about reasons for the use of forced medication and its possible adverse effects [38]. A possible strategy to increase satisfaction with received treatments and to reduce consequences of forced medication is the implementation of patients' advanced directives (PADs), which have been proved to be effective in promoting a patient-centered treatment approach, respecting patients' will and therapeutic choices [39]. PADs allow individuals to state their preferences for future treatment at times when they may be unable to make informed decisions. They can be considered a way to help people to retain control over their treatment when incapacitated [40]. Despite their potential usefulness, PADs in mental health care have been implemented only in a few countries [41].

In agreement with the existing laws in the different countries and in accordance with the Helsinki Declaration and with the European Convention on Human Rights, the EUNOMIA team agreed that patients should be treated as any other person [25]. In particular, one of the most frequent issues that emerged during the process of developing the EUNOMIA recommendations is the protection of patients' civil rights and personal freedom, which represents a fundamental achievement of modern psychiatry [42]. All centres unanimously affirmed that psychiatric care should always follow the principle of the "least restrictive choice" also in emergency settings, and the relationship between patients and physicians should be based on reciprocal respect, in agreement with the Madrid Declaration of the World Psychiatric Association [43], endorsed by the World Health Organization [44] and the report of the Convention of the United Nations on the rights of persons with disabilities [45].

From a methodological viewpoint, this work contains several strengths, such as the involvement of different professionals and of users' and relatives' associations in the drawing up of the final consensus document, and the participation of 11 European countries from different geographic, political and health care organizations. However, the following limitations must be reported, such as the lack of a rigorous and standardized methodology in the development of national suggestions, the exclusion of patients with more than 65 years of age, and the fact that the recommendations have been developed a few years ago. It may be that the development of recommendations herein reported could be affected by changes in the legal framework occurred in the last years in some countries (i.e., those occurred in Germany in 2013) and by the approval of new pharmacological agents for the treatment of mild and moderate psychomotor agitations. However, we believe that this limitation does not reduce the strengths of the EUNOMIA recommendations on forced medication because these refer to good clinical practice procedures to be adopted in case of forced medication, and have nothing to do with the pharmacological agents. Lastly, one possible limitation is that EUNOMIA clinical recommendations did not provide information on which coercive intervention (i.e. forced medication vs. physical restraint or seclusion) would be the best treatment option in psychiatric settings. However, the aim of the EUNOMIA study was not to discriminate among different coercive measures, but to provide clinically useful and practical indications on how to apply coercive measures in routine care.

Conflict of interest

The authors report no competing interests.

Ethical standard

This manuscript does not contain patients' data.

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