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Informed consent in forensic treatment. Lights, shadows, assumptions, perspectives

Il consenso informato al trattamento psichiatrico-forense. Luci, ombre, presupposti, prospettive

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Abstract

The progressive process leading to deinstitutionalization of socially dangerous insanity acquittees in Italy seems to have come to its conclusion. Forty years after the closure of psychiatric hospitals, the latest custodial models regarding forensic psychiatric patients also gave way to approaches to care and rehabilitation. In our opinion, however, the treatment of the forensic psychiatric deserves specific profiles in relation to treatments, methods, motivations, objectives, setting.

In this paper, the authors will address the topic informed consent to forensic psychiatric treatment, its relationship with the security measure and implications for treatment in the judicial context.

Key words: informed consent • sex offenders • juvenile offenders • psychiatric social dangerousness • psychiatric security measure

Riassunto

Il progressivo processo di deistituzionalizzazione dei malati di mente autori di reato socialmente pericolosi, sembra essere giunto infine alla sua conclusione. A quaranta anni circa dalla chiusura degli ospedali psichiatrici anche il modello custodialistico per i pazienti forensi lascia il passo a favore di un modello orientato alla cura ed alla riabilitazione. A nostro parere tuttavia il contesto forense possiede un suo profilo di specificità che riguarda metodi, trattamento, motivazioni, obiettivi, setting di cura.

Nell'articolo gli autori affrontano la tematica del consenso al trattamento psichiatrico-forense in corso di misure di sicurezza ed in differenti contesti giudiziari.

Parole chiave: consenso informato • sex offenders • minori autori di reato • sociale pericolosità • misure di sicurezza

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Introduction

The progressive process leading to deinstitutionalization of socially dangerous insanity acquittees in Italy seems to have come to its conclusion. In 1980, psychiatric hospitals were closed in Italy, but forensic psychiatric hospitals (Ospedali Psichiatrici Giudiziari, OPGs) remained open and continued to admit patients. In 2008 the Italian Government issued a decree establishing the progressive closure of the 6 forensic psychiatric hospitals. In 2012 Law 9/2012 established that new small-scale residential facilities (Residenze per l'Esecuzione della Misura di Sicurezza, REMS) should be developed to admit insanity acquittees showing danger to public safety, consequently needing a custodial security measure. Finally, in 2014 Law 81 set deadlines, operational procedures and requested individualized discharge programs for such patients (Carabellese & Felthous, 2016).

The REMS are part of the Departments of Mental Health (DSM) of the Italian National Health Service (INHS), are under the responsibility of the Local Health and Social Associations (ASSL)¹. This nature implies that the function of REMS is purely healthcare². On the other hand, the Italian penal code still determines that the security measure involves detention of the patients. We therefore believe that this provision implies the existence of a custodial profile also within the REMS³.

The same intentions of change seem to be seen, however, regarding the treatment of specific types of forensic patients. Among them, particularly sex offenders, a clinically heterogeneous group of subjects (Carabellese et al, 2012), for whom specific treatment projects are entrusted also to the IHNS.

There is also the varied world of the underage patients who commit crimes, which was already founded and addressed on rehabilitation and treatment approaches rather than punishment. (Aebi & Linde, 2012; Caldwell, 2011). This population often present with mental disorders (Green, 2014) whose treatment has been increasingly involving public psychiatric services.

This is not the place to face the difficulties associated with the transition period that coincides with the closure of

- 1 II DL n. 211 del 22.12.2011, convertito in seguito con alcune modifiche nella Legge n. 9 del 2012, all'art 3-ter, co. 3 sancisce l'esclusiva gestione sanitaria delle REMS.
- 2 Il DM del 1 ottobre 2012, all'Allegato A stabilisce che le REMS hanno "funzioni terapeutico/riabilitative e socio/riabilitative", che la "gestione interna è di esclusiva competenza sanitaria" e che "la responsabilità della gestione all'interno della struttura è assunta da un medico dirigente psichiatra".
- 3 L. 26.07.1975 n. 354 (Norme sull'ordinamento penitenziario e sulla esecuzione delle misure privative e limitative della libertà).

the OPGs (Carabellese, 2017), nor the heterogeneity of the approaches and treatment models pertaining to minor offenders and/or sex offenders. The focus of this work is rather on the question of the right of the individuals to voluntarily consent or dissent to treatment in the context of forensic care, given the coercive nature of the placement in the REMS. In this respect, the Italian legislator appears, at least in part, to move in the direction of what is foreseen by the United Nations Convention on the Rights of Persons with Disabilities (CRPD⁴), ratified by Italy in February 2009.

We must point out that the Constitutional underpinnings of informed consent, which implies a competent, free, and informed choice preceded by a complete disclosure of clinically relevant information, also apply within a coercive measure. This includes the inviolable right to refuse treatment and care.

There are, however, obvious management and medicolegal issues that may arise if a REMS internist refused to adhere to the treatments provided by the Individual Rehabilitative Therapeutic Rehabilitation Project (PTRI). Considering the natural course of severe mental illness, refusal of treatment of adherence problems can emerge at different times and with different intensity over time. Different types of approaches may be required in response to such refusal (Carabellese, et al 2015): acute refusal in the face of a psychotic disruption with agitation presents intrinsically different profiles and implications than a chronic refusal to adhere to a cure provided by a safety measure.

The purposes of control and social defense are a specific mandate in forensic treatment, that inevitably affects the medical / patient relationship, making it different from others, forcing public health care providers to consider specific aspects of the forensic contexts (Felthous, 2010), which they would not otherwise consider, also having a privileged and to some extent challenging interlocutor to the Judicial Authority (AG).

1. Informed consent to treatment in the REMS

Why informed consent to treatment in the REMS has great ethical, clinical, and deontological implications? A possible answer underlines two questions: on the one hand we should consider the coercive nature of the psychiatric security measure, which entails the concept of medical care as necessary for the patients' rehabilitation and recovery, as well as for containment of the risk of recurrence and criminal behavior. In other respects, there we should consider the right to self-determination of the patient under the psy-

4 United Nations General Assembly (2007). Convention on the Rights of Persons with Disabilities and Optional Protocol.

chiatric security measure, a right that could conflict with the purposes of the security measure itself, as well as with the principle of benefit.

The problem therefore lies in how much the right to self-determination, and possibly refusing to adhere to the therapeutic measure, may extend and with what limits in subjects subjected to psychiatric security measures. In trying to deal with this problem it is useful to recall the address of the Constitutional Court⁵, which has determined that informed consent to care is a "fundamental principle of health protection", "the true right of the person, founding in the principles expressed by articles 2, 13, and 32 of the Constitutional Chart". Following this view, informed consent could be considered an expression and synthesis of two fundamental rights of the person, "that of self-determination and that of health"6. It is "an expression of conscious adherence to medical treatment proposed by the physician", a source of "legitimacy and foundation" of the medical act. Consequently, in those situations where there is lack of consent, the medical act "is certainly illicit, even when it is in the patient's interest". This approach explains why, in Italy, the validity of consent lies on the assumption of natural capacity and not of legal capacity. The natural capacity of the patient should be assessed on a case-by-case basis, and in Italy, differently from other European countries, the physician completely covers it.

Patients affected by severe mental illness, including those under a coercive psychiatric security measure, are not an exception to the rule that informed consent is necessary for any treatment and that treatment can be refused in case of patients' dissent. Considering that a valid consent requires patients' mental capacity to decide, we need to look at the real levels of forensic patients' capacity to accept or refuse treatment. Nonetheless, an assessment of decision-making capacity of forensic patients does not appear to be required by the law (Carabellese, et al, 2017; Mandarelli, et al, 2017a; Mandarelli, et al, 2017b).

In fact, even in the case of patients coercively admitted to the REMS informed consent to treatment is a prerequisite or legitimizing treatment his/her therapeutic-rehabilitative process which should be calibrated on the specific needs of care (Catanesi, Carabellese, La Tegola & Alfarano, 2013), and inevitably custody that the Health Department provides through the security measure issued by the judge.

The Italian Law includes only a few exceptions: a) involuntary commitment (TSO) b) involuntary assessment (AS) c) state of necessity. Nonetheless, Law 81 of 2014 did

- 5 Corte Costituzionale, Sent. N. 438 del 15.12.2008
- 6 Corte Costi., Sent. N. 438 del 15.12.2008: "...quello all'auto-determinazione e quello alla salute, in quanto, se è vero che ogni individuo ha il diritto di essere curato, egli ha, altresì, il diritto di ricevere le opportune informazioni in ordine alla natura e ai possibili sviluppi del percorso terapeutico cui può essere sottoposto, nonché delle eventuali terapie alternative; informazioni che devono essere le più esaurienti possibili, proprio per garantire la libera e consapevole scelta da parte del paziente e, quindi, la sua stessa libertà personale, conformemente all'art. 32, secondo comma, della Costituzione. Discende da ciò che il consenso informato deve essere considerato un principio fondamentale in materia di tutela della salute, la cui conformazione è rimessa alla legislazione statale".

not foresee anything specific for psychiatric patients under a security measure⁷. The judge must moreover preliminarily try to consider and adopt any alternative measure to detention in REMS, making the latter the extreme choice after finding the inadequacy of any other alternative solution.

No change from the outlined scenario is derived from Law n. 103 of 23 June 2017, aimed at reforming the dual Italian criminal "dual track system". Law 103/2017 redefines the "second track" constituted by security measures, which are greatly diminished in favor of rehabilitative and therapeutic measures with the slightest possible limitation of personal freedom, to be implemented within the care and control (collective protection) framework.

A verdict of the Tutelary Judge of Reggio Emilia underlines the complexity of the problem⁹, it established that involuntary civil commitment should not be invoked in case of a patient detained in the REMS due to the nature of the security measure. We are not aware of other similar judgments that have reiterated the same decision. We deem, however, that the clinical conditions that motivated such judgment are particularly frequent in forensic psychiatric

- 7 L.81/2014 co. 1, let. B: "Il giudice dispone nei confronti dell'infermo di mente e del seminfermo di mente l'applicazione di una misura di sicurezza, anche in via provvisoria, diversa dal ricovero in un ospedale psichiatrico giudiziario o in una casa di cura e custodia, salvo quando sono acquisiti elementi dai quali risulta che ogni misura diversa non è idonea ad assicurare cure adeguate e a fare fronte alla sua pericolosità sociale..."; "Allo stesso modo provvede il magistrato di sorveglianza...". Ed ancora:"...il programma documenta in modo puntuale le ragioni che sostengono l'eccezionalità e la transitorietà del prosieguo del ricovero" (L.81/2014 co. 8, 1-ter).
- La Legge differenzia l'applicazione delle misure di sicurezza a seconda che i soggetti siano imputabili, semi-imputabili e non imputabili (art. 1, comma 16, lett. c.): Per i soggetti imputabili il regime del doppio binario è limitato ai soli gravi delitti ex art. 407, comma 2, lett. a) c.p.p.; Per i soggetti semi-imputabili il doppio binario cede il passo all'introduzione di un trattamento sanzionatorio finalizzato al superamento delle condizioni che hanno diminuito la capacità dell'agente, anche mediante il ricorso a trattamenti terapeutici o riabilitativi e l'accesso a misure alternative, fatte salve le esigenze di prevenzione a tutela della collettività; Per i soggetti non imputabili rimangono applicabili esclusivamente misure terapeutiche e di controllo, determinate nel massimo e da applicare tenendo conto della necessità della cura, e prevedendo l'accertamento periodico della persistenza della pericolosità sociale e della necessità della cura e la revoca delle misure quando la necessità della cura o la pericolosità sociale siano venute meno. Le REMS sono destinate inoltre ad accogliere (art.1, comma 16, lett. d) anche tutti coloro per i quali occorra accertare le relative condizioni psichiche, qualora le sezioni degli istituti penitenziari alle quali sono destinati non siano idonee, di fatto, a garantire i trattamenti terapeutico-riabilitativi, con riferimento alle peculiari esigenze di trattamento dei soggetti e nel pieno rispetto dell'art. 32 della Costituzione. (non so se questa parte forse si potrebbe mettere nel corpo del testo)
- 9 Sent. N. 602/2012 N.C.:"...non sussiste intrinsecamente alcuna esigenza di disporre un trattamento sanitario mediante ricovero in condizioni di degenza ospedaliere forzose di un soggetto che è già ristretto in struttura con duplice natura detentiva e curativa in forza di provvedimento dell'Autorità Giudiziaria...".

patients who are detained in the REMS (Carabellese, Rocca, Candelli, Catanesi, 2014).

The legislator's attitude is based on the indication of the "favor libertatis", i.e. giving subjectivity and dignity also to the mentally ill and socially dangerous, subjected to a security measure, and to provide fullness of intent to exercise the right to self-determination.

There are those who see potential difficulties in equally respecting fundamental rights that may become conflicting (Carabellese &Mandarelli, 2017), particularly the patients' right to self-determination, including refusal of treatment, and protection of the community, if such denial poses the consequent risk of aggressive and violent behavior (Simon & Gold, 2010). In other countries, treatment is compulsory as well as the security measure in its purely custodial aspect.

In other Countries¹⁰ specific rules on forensic care have been provided, to protect the rights and dignity of offenders subjected to coercive treatment, as well as to guide and legitimate the healthcare professionals.

Informed consent to treatment in other forensic settings

2.1 Informed consent to treatment of sex offenders

We are now considering informed consent to the treatment of sex offenders, believing that this population is particularly explanatory of consent issues in forensic patients. Treating sex offenders in a forensic setting could imply responding to opposing needs, which must necessarily be met, and might therefore require caution by the health care staff involved.

The informed consent to forensic treatment of sex offenders, independently of its nature (psychotherapeutic, pharmacological, hormonal, socio-rehabilitative) follows a process that is certainly related to the traditional medical/patient relationship, but includes expectations, objectives, information obligations, individual factors, family, social, cultural-related factors affecting that relationship, connotating it precipitously. It is understood that, in our view, health care professionals should know these additional levels of complexity in the relationship with the sex offender, and take them into account to achieve effectiveness of forensic treatments. It is well known that sexual offenders tend to recur in their conduct more frequently than other offenders (Prentky, Barbaree, & Janus, 2015), although these are data on which there is no unambiguous convergence (Harris et al. al, 2011). In Italy, in the decade following year 2000 (Istat, 2011), the percentage of formerly criminal convicted individuals for a new sexual offense was 3.3%. Those pedophiles with preference for male pre-teen victims, seem to have the highest recurrence rates, (up to 35% in 15-year follow-up period, Harris & Hanson, 2004), compared to other sex offenders, whose criminal career tends to be more heterogeneous (Harris, 2009; Lussier & Cale, 2013; Blockland & Lussier, 2015).

10 For example the UK "Mental Health Act" of 1983, part II e part III.

A treatment-specific aspect to consider is therefore the need to achieve adequate knowledge of the type of sex offender to be treated. This implies preliminary acquisition of accurate information, prior to rehabilitation or other treatments. Factors which be assessed include some editable ones (Henning & Holdford, 2006), which can be a specific target for the treatment project (Hanson & Yates, 2013), psychosocial and family-related factors, (Bond & Ahmad, 2014; Andrews & Bonta, 2010; Saleh et al., 2009;), the offender's personality structure, with specific interest for psychopathic personality traits (Hanson, Morton-Bourgon, 2009; Bonta & Wormith, 2007), sexual interests and sexual fantasies (Carabellese, Maniglio, Greco, Catanesi, 2011; Maniglio, Carabellese, Catanesi, Greco, 2011).

A distinct psychopathic component of personality, with the manipulative attitude that characterizes it (Hare, 1993), can be an impediment to accept a therapeutic relationship which could be perceived as a "down" position (Kilgus et al, 2016), as well as to make a real change. These psychological features might imply reduced treatability of the offender; thus, they must be specifically assessed and disclosure of possible treatment risks, possible benefits and limits should be disclosed when acquiring informed consent.

Many Authors (Parens, 1998; Bloch et al, 1999; Scott & Holmberg, 2003; Smith, 2005; Sjostrand & Helgesson, 2008; Grubin & Beech; 2010; Gooren, 2011; McMillan, 2012) have questioned the validity of consent to the treatment of sex offenders, believing that they might not be completely free in their choice. Adhesion to the treatments could be in fact motivated on the thrust of possible juridical benefits, a common problem when considering forensic patients.

In some European Countries and in several US States specific rules provide for the possibility of voluntary hormonal and / or surgical antiandrogenic treatments, which are not necessarily alternative to restrictive measures, based on specific evidence indicating efficacy in reducing paraphilic thoughts and behavior (Gijs & Gooren, 1996; Losel & Schmucker, 2005; Schmucker, 2008 Krueger et al, 2009; Jordan et al, 2011).

In Italy, sex offenders are generally treated with psychological and socio-rehabilitative approaches. Realizing that this type of approach can be an alternative to restrictive measures, the actual motivation of the patient should be carefully considered.

It is therefore necessary to consider how the process of acquiring consent to the treatment of sex offenders should also be based on the availability of information not strictly related to the treatment, but which may determine both the validity / invalidity of the consent and an element on which to focus the treatment itself.

2.2 Informed consent to treatment in forensic child and adolescent mental health

The context for the care and treatment of underage offenders, subject to security measures, is particularly complex and articulated. There are several factors that explain this complexity: age-related cerebral maturation, possible neurodevelopmental disorders, or other psychiatric disorders, possible physical and / or emotional distance or lack of attachment and support figures.

In Italy the parents, or others juridically exerting the parental authority, are the appointed decision-makers provided by the Law, as concerning informed consent to treatment of people under 18 years of age. In case of lack of consent or dissent, TSO and ASO (Articles 33, 34 and 35 L. 833 of 1978) are the only ways to medically intervene for diagnostic and/or therapeutic purposes, in which it is possible to overcome the patients' will. The normative framework, however, does not make explicit mention of the minors, but does not exclude them either.

At a regulatory level, consent to care is considered valid where expressed by a person aged more than 18 years, thus the ability of minors to give a valid consent is considered "imperfect and incomplete". However, if medical intervention significantly affects the child's personal integrity and quality of life, and if there is a conflict between parent / guardian and a "mature" child/adolescent, the parents' opinion may not prevail over the will of the minor.

The latest national and international standards¹¹ have tended to overcome the premise that parents, or those exercising the parental authority, are the only ones to be able to exercise the right to express consent to medical acts involving children. Recent regulatory changes lead to consent being a "unilateral legal act" and not a contractual act; therefore, to express a valid consent, the ability to act, which is subject to age, but the natural capacity which can be present even in the "mature" minor.

The physician must therefore verify with the means at his/her disposal the actual consent / dissent of the child and whether the young patient is able to assume his responsibilities as well as appreciating the consequences of his will with respect to the specific treatment offered to him/her.

In this case, the doctor must consider as much as possible the will of the child evaluating also the context and the conditions in which it is located. The coercive sanitary procedures for patients aged under 18 years, must be the *extrema ratio*, regardless of whether there is parents' consent. In the event of a conflict between the will of those exercising parental responsibility and the minor, and if this can result in serious injury, the physician is obliged to report it to the competent authority only after having completed all attempts to acquire consent. The Juvenile Court is specifically responsible for the protection of the child even when the injury is only hypothetical.

The physician has the duty to transmit without delay the information concerning potential injury to health of an underage patient to the Public Prosecutor's Office at the Juvenile Court. The Public Prosecutor Office, upon receiving the information, verifies the validity of any prejudices that may arise in relation to the minor and the actual need to activate specific protection. The presence of these two conditions implies the timely intervention of the Juvenile

11 Onu, New York 1989, Convenzione sui diritti del fanciullo, artt. 3 e 12. Convenzione per la protezione dei diritti dell'uomo e della dignità dell'essere umano, Oviedo 1997, artt. 5, 6 e 10. Carta dei diritti fondamentali della UE, Nizza 2000, artt. 1, 3 e 24. Carta Costituzionale, artt. 13 e 32. Codice Civile, artt. 2, 147, 333 e 348. Codice di deontologia medica, artt. 29, 33 e 34.

Court, which in turn works with a series of interventions aimed at protecting the child and sometimes, if necessary, also with measures aimed at the decay of parental responsibility or at the estrangement of the minor. In cases of urgency, it is also possible to send the report directly to the Juvenile Court.

In the case of a child considered "mature" by doctors, therefore capable of appropriate decision-making, the following five situations may arise:

- 1) The minor and both parents give their consent to diagnostic procedures and treatment; in this case you can proceed according to your agreement with your doctor without the need to involve the competent court;
- 2) The child expresses his / her assent, but one or two parents deny consent to diagnostic procedures / treatment; in this case, the health care provider directs the report to the Public Prosecutor's Office at the Juvenile Court before conducting any further clinical approach;
- 3) The underage patient, one or two parents refuse and urgently needed psychiatric treatment; in this case, the health care provider activates the TSO by reporting the case to the Public Prosecutor's Office at the Juvenile Court afterwards;
- 4) The underage patient dissent with the proposed care, but both parents give their valid consent; it may be useful, if there are any requirements, to proceed to a TSO to better guarantee the child; the case is reported to the Public Prosecutor's Office at the Juvenile Court;
- 5) The underage patient dissent to accept care, the parents give consent to treatment, but there may be likely prejudices to the child's health; there are no conditions of urgency; in this case, the health care professional reports to the Public Prosecutor's Office at the Juvenile Court, including clarifications on the situation, specifying the efforts made to obtain the consent of the child, what are the feared prejudices as well as any suggestions for both the resolution of the situation and the elimination / reduction of prejudices deemed imminent to the minor;
- 6) About the place of execution of the TSO against a minor, it should be done considering the age of the subject and the necessary safeguards, but the law does not provide any specifics. For these reasons, we think that it is inappropriate to use adult psychiatric wards for involuntarily committed underage psychiatric patients. Following the acute hospitalization phase, an outpatient project should be set up to ensure the continuation of care and protection in suitable spaces even of a residential type.

We also believe that the required certifications of proposals and confirmation of a TSO toward a minor should be performed by specialists in child and adolescent psychiatry. The Child and Adolescent Neuropsychiatry Service must always be involved in the diagnosis and treatment process during the child's stay in TSO. The natural reception center, if present, is just the infantile neuropsychiatry department as it is adequately equipped to meet the needs of the child as well as the presence of clinically specific staff.

Summarizing, children and adolescents should be involved in the decision-making process on care and in parallel with the verification of the actual mental and cognitive abilities. A cerebral structural immaturity has been associ-

ated with an incorrect assessment of the long-term consequences of their choices (Partridge, 2013). It is conceivable, however, that there is a degree of different and age-related capacity and that some underage patients, even those suffering with psychiatric disorders, have good decision-making capacity (Mandarelli et al., 2016), although there are no data in forensic populations of minors.

Community based involuntary psychiatric treatment

In the case of a patient interned in REMS who refuses to adhere to treatment, how to behave? We might hypothesize at least two different situations: a) there are no conditions for compulsory treatment (TSO); (b) there are the conditions to apply a compulsory treatment i.e. involuntary civil commitment (TSO).

In the first case, when the patient's dissent to treatment is valid, and there are no conditions for urgent intervention, his/her will should be respected according to the right to self-determination. At the same time, it will be necessary to activate, within the medical-patient therapeutic alliance, which will be built in the meantime with the internship to recover the voluntary adherence to the treatment. If this approach fails, and if the legal requirements are met, a TSO should be implemented to protect the patient. However, we believe it is appropriate to relate this refusal to the criminal justice authority, considering the possible medium and long-term impact of a denial of treatment in terms of social dangerousness.

An obvious problem arises from the fact that the TSO in Italy does not distinguish forensic from non-forensic patients, and it was developed and structured for non-forensic patients. This limitation is found in the fact that the law provides for the possibility of performing the TSO for psychiatric reasons only at public or contract hospital (civil) facilities (Art. 33, Law 833 of 1978). Therefore, in TSOs for psychiatric reasons in a hospital stay, there can be no provision for REMS, which are considered as community and non-hospital structures.

However, the law provides for the possibility of an extra-hospital TSO, which could potentially fall within the healthcare facilities of REMS, in the event of urgent care and refusal by the interned patient. To our knowledge, extra-hospital TSO is an infrequently used procedure in Italy, although it is subject to specific indications and norms. The extra-hospital TSO needs a motivated proposal from a physician-although the plausible grounds for doing so are not clarified by the law- and the subsequent ordinance of the city mayor¹² (Articles 33 and 34, Law 833 of 1978). Extra-hospital TSOs should be considered in the case of clinically more manageable situations (Carabellese & Man-

12 Conferenza delle Regioni e delle Province autonome del 2009: Raccomandazioni in merito all'applicazione di accertamenti e trattamenti sanitari obbligatori per malattia mentale. Conferenza delle Regioni e delle Province Autonome, Roma 29 Aprile 2009. BURP 04/9/2009 darelli, 2017), where there is no need for hospitalization. It is undoubtedly a coercive treatment approach that can be implemented, however, even within REMS, as well as in other contexts other than the hospital, with some benefits in terms of clinical management.

The duration of the extra-hospital TSO, like the hospital TSO, could be 7 days, however, Law 833 of 1978 provides clear procedural information only for hospital TSO (Article 35). The implementation of the extra-hospital TSO, as well as the hospital TSO, must be associated with initiatives aimed at ensuring the consent and participation of those who are subject to such compulsory measures (Article 33 of Law 833).

A second possibility concerns a patient interned in the REMS that poses refusal to treatment that is considered valid in terms of his decision-making ability, but which, at the same time, is associated with a concrete and imminent risk of violent behavior directed against others or against oneself. What to do in this case? Hospital or extra-hospital TSO in theory should not be practicable, as Law 833/1978 does not provide a criterion of danger for self or other, as a possibility underlying the coercive measure. An extensive interpretation of care and protection requirements, so that in this case a TSO should be carried out, for reasons that appear to be defensive medicine rather than legitimate grounds for care, does not appear to be sustainable.

Other assumptions that can be considered, as provided by the penitentiary system¹³ – which is believed to be valid at REMS –, concern the possibility of physical isolation and restraint (Catanesi et al, 2010). These are hypotheses that have controversial aspects in psychiatry and are generally used as an extreme ratio, but if implemented in appropriate modes, they are useful in the treatment of aggressive and violent behavior. In the case of application of such physical coercive measures, an indication of the psychiatrist who directs REMS in a clinical record must be provided. it is necessary to proceed to such extreme interventions, according to the methods widely described in the literature, with a monitoring that must safeguard the psycho-physical integrity of the international, prevent any complications and respect for its personal dignity and to safeguard its rights.

13 Art 14-bis: "Possono essere sottoposti a regime di sorveglianza particolare... i condannati, gli internati e gli imputati: ...b) che con le violenze o minacce impediscono le attività degli altri detenuti o internati...". Ed ancora (art. 14-quater): "... 4) in ogni caso le restrizioni possono riguardare: ... le esigenze di salute...".

Per quanto attiene la contenzione fisica, l'Art. 41 (Impiego della forza e uso dei mezzi di coercizione) prevede che "Non è consentito l'impiego della forza fisica nei confronti dei detenuti e internati se non sia indispensabile per prevenire o impedire atti di violenza. Non può essere usato alcun mezzo di coercizione fisica che non sia espressamente previsto dal regolamento e, comunque, non vi si può fare ricorso ai fini disciplinari ma solo al fine di evitare danni a persone o cose o di garantire l'incolumità dello stesso soggetto. L'uso deve essere limitato nel tempo strettamente necessario e deve essere costantemente controllato dal sanitario".

4. The physicians' duty of care in non-consensual psychiatric treatment

Given the specific characteristics of patients undergoing a psychiatric safety measure, one must wonder whether doctors have a specific obligation to intervene, focusing on the polarity of "control" according to the doctrine of the duty of care. This is, of course, outside of those clinic situations that shape the assumptions for a TSO. The question arises mainly because of the specificity of the type of patient interned in REMS or, in any case, subjected to a psychiatric security measure.

The perpetrator of a crime with highly reduced or abolished responsibility and deemed socially dangerous, interned in the REMS, is not obliged by the judicial authority to comply with certain prescriptions or a specific personalized therapeutic rehabilitative project because of the risk of new offenses, a risk which is expression of the mental illness. He may oppose his dissent, if it is valid, to the treatment. This is the exercise of a fundamental right which, however, can in some sense confuse or frustrate the effectiveness of the "protection" requirement, another polarity inherent in the duty of care, which always falls on the health care professionals.

We deem that there are risks in terms of treatment and accountability associated with choices made in the interests of defensive medicine (Felthous, et al, in press), rather than being the result of weighted decisions and discussed within the care unit. In these situations, the comparison within the curating, multidisciplinary team and involving the magistrate should be the solution for decisions that are never simple nor risk-free.

In 2014, the "Working Group on the Guarantee Position" of the Italian Society of Psychiatry, referred to both the polarities inherent in the guarantee position, indicating that the more serious the state of the patients' incapacity and therefore their vulnerability, more so the patients should be "protected" by healthcare providers by fully assuming their duty to the protection of health and psycho-physical integrity.

More complexity is inherent in all those frequent cases in which the state of total or partial inability to protect one's own interests is well-known and has been appointed support administrator or another substitute decision-maker in relation to the consent to care. We refer to those cases in which the patient declares a dissent (legally ineffective) against a treatment decision which has been given by the substitute decision-maker. Such discrepancies can create significant difficulties, as well as ethical issues and, moreover, it could be difficult to allow a treatment that, while having a legally valid consent, would end up being coercive.

Conclusion

The closure of the OPGs in Italy and the legislative changes that led to the opening of REMS, have shown critical points that require further and appropriate regulatory action or practices that have yet to consolidate. Among the most obvious points of criticism, there is certainly the problem associated with the consent / denial of the individual therapeutic project prepared for the patient subjected to psychiatric security measures.

Such safety measures (detention: REMS; non-detention: supervised freedom). are compulsory and apply to different types of offenders, they include an individualized therapeutic-rehabilitative program, outlined in conjunction with the competent psychiatric services, with the dual purpose of care and control of the risk of criminal recurrence. The therapeutic program, however, is likely to face a violation of the irrevocable fundamental right to self-determination and freedom (Articles 2, 13 and 32 of the Constitutional Charter), creating a possible conflict between constitutionally guaranteed rights.

The right of every person to be cared for or not also corresponds to the right of individuals who make up the community to be protected by possible aggressive or violent behaviors associated with a mental disorder. Essentially, the coercivity of the security measure does not include a compulsory treatment counterpart. As previously discussed, the hypothesis of the TSO is not specific to forensic patients and concerns only urgent and acute situations. Temporary transfer of a socially dangerous patient to a civil hospital, as expected by the hospital TSO, however, presents intrinsic issues both for REMS and for the Hospital. The extra-hospital TSO could solve some situations that are not overly complicated, but there is also a regulatory hole about the implementation modalities.

Further complexity concerns the consent to the rehabilitation specific clinical populations such as sex offenders, burdened by very particular ethical implications, for which reason we believe that the involved healthcare should be specifically trained.

The correct application of the new post-OPG legislation seems to depend entirely on the will of the psychiatric forensic patient to adhere, or not, to the therapeutic program. This approach has the logical consequence that the psychiatrist may have to retain in the REMS acutely ill patients, at imminent risk of violent behaviors, with which it is not possible to provide a containment when there are no conditions for intra and / or extra-hospital TSO. Unless you resort to physical restraint or isolation, extreme solutions that always create severe discomfort in both psychiatrists and patients.

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