Presidenza del Consiglio dei Ministri

MEDICAL RESTRAINTS: BIOETHICAL ISSUES

23 April 2015

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Presentation

The opinion “Medical restraints: bioethical issues” addresses the issue of the use of medical restraints for psychiatric patients and the elderly, highlighting the forms of mechanical restraint, which raise major concern from an ethical and juridical point of view.

Numerous standpoints of international bodies and the NBC itself in previous opinions – see, *Psychiatry and mental health: bioethical guidelines* (2000), *Bioethics and the rights of the elderly* (2006), *Dementia and Alzheimer disease: ethical issues* (2014) – have clearly set out the objective of the reduction to the actual overcoming of medical restraint, which has to be considered a remnant of the asylum culture. Nevertheless, the practice of strapping down patients against their will is still carried out, and in no way as an exceptional measure, with insufficient attention being paid to the gravity of the problem both by public opinion and the institutions.

Despite the lack of studies on this question, a certain amount of data appear from the research available regarding the variables mostly having a bearing on the recourse to the use of medical restraint: culture, the organisation of services and approach of the mental health professionals have a decisive role in this, more than the seriousness of the patients and their psychopathological profile. This demonstrates that it is possible to avoid restraining patients: the existence of services that have chosen not to apply medical restraints and the success of programmes aimed at monitoring and reducing this practice are the confirmation of this information.

For these reasons the NBC stresses the bioethical standpoint of the overcoming of the practice of restraint, within the context of a new paradigm of care based on the recognition of the person as such, in their full rights (even before being a patient). The respect for the autonomy and dignity of the person is also the prerequisite for an effective therapeutic intervention. Conversely, the use of force and medical restraint represent in themselves a violation of the fundamental rights of the person.

The fact that in absolutely exceptional circumstances the mental health professionals can resort to justifications for applying medical restraint does not take away from the force of the rule of non-restraint, nor does it modify the foundations of the ethical discourse.

At the juridical level, since the fundamental rights of the person are at stake, it is important to stress the strict limits of the justification for medical restraint. Recourse to mechanical restraint techniques must represent the last resort and it must be considered that – even in the context of the Compulsory Medical Treatment – it can take place only in situations of real necessity and urgency, proportionally to the actual needs, with the least invasive modalities and only for the amount of time needed to overcome the conditions leading to their application. In other words, the fact that the patient is in a mere state of agitation cannot be considered a sufficient condition for medical restraint to be justified, but a *serious and real* danger must exist that the patient carries out self-harming acts or commits an offence against third parties. When such danger no longer exists, the use of restraints must cease, as it would not be justified by necessity and would amount to potential criminal conduct.

This opinion sets out to highlight that the overcoming of restraint is a fundamental element in the advance of a care culture - in psychiatric services

and in the care for the elderly – in line with the ethical criteria which are generally recognised and applied in all healthcare sectors.

In its conclusions the NBC furthermore recommends an increase in research and the setting up of specific monitoring, at regional as well as national level, starting from the daily practice in the wards where the cases of restraint should be precisely recorded, with the specific reasons for choosing to restrain the patient and the duration of the measure; *the introduction of programmes aimed at the overcoming of restraint; to introduce quality standards in the evaluation of services* that encourage *non-restraint* services and facilities; to *maintain and possibly increase the diffusion and quality of the services for the more vulnerable subjects*, such as the elderly, who are more exposed to being subjected to inhuman and degrading practices.

The opinion was drafted by Dr. Grazia Zuffa, Prof. Stefano Canestrari, coordinators of the work group which was established on 28 February 2014.

A number of experts were invited to give their professional advice on the subject during the plenary session, and a special thank you goes to: Dr. Piero Cipriano, consultant at the Servizio Psichiatrico di Diagnosi e Cura dell'Ospedale San Filippo in Rome and author of the volume *La fabbrica della cura mentale* (2013); Dr. Pietro Sangiorgio, Vice Secretary of the Coordinamento Nazionale di Servizi di Diagnosi e Cura, and once director of the Mental Health Department ASL RMH1; Prof. Maria Grazia Giannichedda, lecturer in the Sociology of political phenomena at the University of Sassari, President of the Fondazione Franco e Franca Basaglia and WHO expert in mental health and human rights.

The following also gave their contribution to the workgroup: Prof. Salvatore Amato, Prof. Luisella Battaglia, Prof. Carlo Caltagirone, Prof. Carlo Casonato, Prof. Antonio Da Re, Prof. Lorenzo d'Avack, Prof. Assuntina Morresi, Prof. Andrea Nicolussi, Prof. Laura Palazzani, Dr. Carlo Petrini, Prof. Monica Toraldo Di Francia.

Those taking part at the hearings and plenary discussion were also: Dr. Rosaria Conte, Prof. Andrea Nicolussi, Prof. Carlo Flamigni, Prof. Massimo Sargiacomo, Prof. Mario De Curtis, Prof. Giancarlo Umani Ronchi.

The opinion was voted unanimously by those present in the plenary session of 24 April 2015: Prof. Salvatore Amato, Prof. Stefano Canestrari, Prof. Bruno Dallapiccola, Prof. Antonio Da Re, Prof. Lorenzo d'Avack, Prof. Mario De Curtis, Prof. Riccardo Di Segni, Prof. Carlo Flamigni, Prof. Assunta Morresi, Prof. Demetrio Neri, Prof. Andrea Nicolussi, Prof. Laura Palazzani, Prof. Massimo Sargiacomo, Prof. Monica Toraldo Di Francia, Prof. Giancarlo Umani Ronchi, Dr. Grazia Zuffa.

The members without the right to vote expressed their approval: Dr. Carla Bernasconi, Dr. Rosaria Conte, Dr. Carlo Petrini.

Prof. Luisella Battaglia, Prof. Carlo Caltagirone, Prof. Cinzia Caporale, Prof. Carlo Casonato, Prof. Paola Frati were absent in the plenary session but endorsed the opinion at a later date.

1. Premise

In this document the National Bioethics Committee sets out to draw the attention of the institutions and public opinion to medical restraint, practised on patients in different typologies of socio-healthcare facilities in Italy. Restraint can be of a physical or pharmacological nature. In this opinion the NBC deals with the problem in particular of the form of restraint most giving rise to concern from both ethical and juridical points of view: mechanical restraint or the practice of forcefully restraining patients against their will. Hereinafter the term 'restraint' will be used to refer to this practice, without any other specification.

The practice of restraint is used for psychiatric patients in the Mental Healthcare and Diagnosis Services (SPDC in Italy/MHDS in the English version of the opinion) of hospitals and private clinics; it is also used on minors with problems of mental or physical disability who are hospitalised or on the elderly in hospitals or nursing homes[1]. Particular attention is paid to the latter, owing to their vulnerability and because the rise in the average life expectancy has entailed a rise in invalidating illnesses and senile dementia, with massive recourse to institutionalisation. Since the context in which restraint is used and the motivations adopted to justify it are partly different for psychiatric patients and the elderly, the two questions will be examined separately. It must not be forgotten nevertheless that restraint, whether it be for the elderly or for psychiatric patients and the disabled, is deeply rooted in a common culture and healthcare tradition that pays little attention to the therapeutic relationship and the subjectivity of the patient.

2. The bioethical scenario

The NBC has already expressed its opinion on restraint use on many an occasion, urging it to be overcome. This new opinion arises from the affirmation that, despite the intervening years, restraint is still widely used without any evidence of decisive efforts to reach its resolution and not even sufficient awareness with regard to the gravity of the problem.

Going in order, we can refer to the 2006 document, "*Bioethics and the rights of the elderly*": in calling for the respect of the integrity of the elderly person and for nonmaleficence, the NBC stresses how "maleficence towards the elderly patient can amount to restraint, understood as the mechanical or pharmacological limitation of the possibility of an individual to move autonomously"[2]. With regard to restraint in a psychiatric context, the opinion "*Psychiatry and mental health: bioethical guidelines*", of 2000, clearly states that "mechanical restraint must be avoided insofar as harmful to the dignity of the person". Such practice is considered a remnant of the asylum culture, which produces "a chronic condition rather than the recovery of the illness"[3].

The year before this in the document of September 1999, "*The treatment of psychiatric patients: bioethical issues*", the NBC denounced "the frequent use of even prolonged restraint in most of the MHDS, the JPHs (Judicial Psychiatric Hospitals), and above all in private facilities (but often ones under the NHS)",

[1] For the subjects at developmental age, see the report of the family associations quoted in the State-Regions document of 2010.
[2] CNB, *Bioetica e diritti degli anziani*, 2006, pp. 7-8.
[3] CNB, *Psichiatria e salute mentale: orientamenti bioetici*, 2000, p. 18.

pointing out that "such practices are in the first place against good medical-psychiatric practice". It was thus recommended that restraint and isolation be "drastically reduced and practised only in exceptional cases should alternatives be lacking or in an emergency" and that anyway they should be limited in time, underlining at the same time "the convergence of the ethical norm of the respect for personal dignity and the clinical-therapeutic criterion"[4].

Also the recent document "*Dementia and Alzheimer disease: ethical issues*" of 2014, analyses the questions of placement and involuntary treatment for these highly vulnerable people, stressing the connection between the rights of patients and an appropriate assuming of responsibility "since the lack and inadequacy of assistance for people with mental disorder leads to situations that are inhuman and degrading"[5].

In the bioethical debate on mental health, the passage to a new paradigm is therefore crucial to the substitution of the asylum approach: from a consideration of the mentally ill person as the victim of coercion and segregation (insofar as the being socially dangerous), to one of a suffering person to be taken care of, according to the principles and modalities of caring for patients which are the same as those used for other pathologies and affliction.

The overcoming of the "remnant of asylum culture" denounced by this Committee in 2000, means setting up psychiatric services that fully satisfy the ethical criteria that are generally recognised and applied in any other healthcare sector: from the commitment to offer treatment that might improve the quality of life (according to the principle of beneficence), to the obligation not to cause harm (principle of nonmaleficence), to the respect for the autonomy and dignity of the person (even when it is a question of deciding whether to medically intervene or not), to the respect of the criteria of justice in the allocation of resources.

At international level there are many standpoints against coercion being used in psychiatry (in the context of which the issue of restraint is dealt with).

See the Recommendation by the Committee of Ministers of the Council of Europe on the protection of human rights and the dignity of persons with mental disorder, adopted in 2004, following the European White Paper (commented upon by the Italian NBC in the above mentioned opinion of 1999). In the recommendation the questions of hospitalisation and involuntary treatment in psychiatric hospitals are dealt with (as quite separate moments, Ch. III)[6] along

[4] CNB, *Il trattamento dei pazienti psichiatrici: problemi bioetici,* in "Council of Europe White Paper on the treatment of psychiatric patients", 1999.

[5] CNB, *Le demenze e la malattia di Alzheimer: considerazioni etiche*, 2014, pp. 18 and ff.

[6] Council of Europe, *Recommendation Rec (2004) 10 of the Committee of Ministers to Member States concerning the protection of human rights and the dignity of persons with mental disorder and its explanatory memorandum. Adopted by the Committee of Ministers on 22 September 2004 at the 896th meeting of the Ministers' Deputies*, 22 September 2004. The distinction between involuntary placement is based on the assumption that the presumption must avail in favour of the capacity to decide, even if the patient was admitted involuntarily, the presumption of competence to decide about his/her own treatment prevails, unless inability to decide on his/her own treatment was one of the legal criteria behind placement (cfr. The White Paper and the NBC's opinion of 1999). With regard to the cases of involuntary treatment of the Recommendation: a serious danger to the person concerned and/or a serious danger to other persons; the treatment must have a therapeutic aim; other less restrictive treatment alternatives must not be available; the opinion of the person suffering from mental disorder must be taken into consideration. Criteria for the execution are also set out (e.g. the treatment must be proportional to the conditions of health; it must be part of a written programme; record

with *seclusion* (the isolation room) and restraint (Ch.V, art.27), recommending the limitation of the measures to "cases of imminent danger for the person or for others and in proportion with the risks entailed", which must be written down in the person's medical record and in a special register. Note that restraint is dealt with in a separate article as a completely separate measure from treatment.

Furthermore, the conclusive declaration of the conference of Helsinki 2005 signed by the health ministers of 52 countries of the European area of the WHO (*Facing the challenges, building solutions*) and the resolution of the European Parliament of 2006[7], known as the *Bowis Resolution*, calls for the respect of the human rights of persons with mental disorder (among which the right to autonomy is fundamental): to explicitly ask governments to "offer people with severe mental health problems effective and comprehensive care and treatment in a range of settings and in a manner which respects their personal preferences", and "to introduce or enforce mental health policy and legislation that sets standards that end inhumane and degrading care"[8]. On the specific subject of restraint, the *Bowis Resolution* takes the view that "any restriction of personal freedoms should be avoided, with particular reference to physical containment, which requires monitoring, verification and vigilance by democratic institutions responsible for upholding individual rights, in order to guard against abuses"[9]. And moreover it believes "that the use of force is counterproductive, as is compulsory medication", recommending that all forms of compulsory medication should be with the authorisation of the appropriate authorities and used only as a last resort[10]. It is clear that these documents stress the close connection between therapeutic efficacy and the respect of the rights and dignity of the person[11]. The practice and culture of institutionalisation are condemned, since the lack of respect of rights is not only a violation of the person, but also one of the factors leading to the worsening of the mental pathology.

A clear connection can be seen between the right to the autonomy of the person and the right to receive appropriate treatment, that is to say, the right to autonomy becomes the driving force of a valid and efficient therapeutic intervention. This has an important consequence with regard to the bioethical framework of restraint: in the case of the patient subject to mechanical restraint, there are no excuses for the violation of the person's autonomy in the name of their "wellbeing" and it is therefore not appropriate to assume two principles in conflict, the freedom of the person on the one hand, and the (supposed) therapeutic aim of the coercive practice (principle of beneficence) on the other. It is not so much a question of finding a balance between these principles, thus

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of the treatment must be kept; it must be directed at the use of an acceptable treatment for the person as soon as possible; etc.) and their rights be upheld (e.g. the giving of information to the person or to their legal representative, communication and visits etc.).

[7] J. Bowis, *On improving the mental health of the population. Towards a strategy on mental health for the European Union* (Bowis Resolution), 2006/2058 INI.

[8] Cfr. The documents: *Mental Health Declaration for Europe, Facing the challenges, Building solutions*, (EUR/04/5047810/6) e *Mental Health Plan for Europe,* (EUR/04/5047810/7), WHO European Ministerial Conference on Mental Health, Helsinki, 12-15 January 2015.

[9] Bowis Resolution, point 34.

[10] Bowis Resolution, point 33.

[11] Cfr. M.G. Giannichedda, *La salute mentale e i diritti della persona*, in Laura Canovacci (edited by), 1978-2008: *Trent'anni di sanità fra bioetica e prassi quotidiane*, Commissione Regionale di Bioetica della Toscana, 2010.

attempting to identify the situations in which the principle of beneficence may prevail over the right to autonomy of the patient (a position that runs the risk of institutionalising/regulating the violations of liberty)[12] as a question of confirming the principle that the use of force is always a violation of the person, with counterproductive effects. The fact that in quite exceptional situations the healthcare professionals can resort to justifications to apply restraint does not only disempower the rule of non-restraint but above all it does not modify the bases of the ethical discourse.

As also confirmed by the Danish Ethics Committee, in the significantly entitled document of 2012, *Power and powerlessness in psychiatry,* the principle stands firm that coercion invariably represents a violation, independently of the reasons for which it is applied. It must be remembered above all that restraint constitutes a hindrance to the relationship between physician and patient, which remains the main therapeutic instrument.

The use of force must nevertheless be avoided. This is a pressing invitation to the healthcare professionals involved at various levels in the giving of treatment, and is at the same time an appeal to the institutions for suitable policies to be drawn up.

This point of order is even more appropriate considering that, many decades following the psychiatric reform, and despite the numerous appeals to overcome restraint, it is still used in a non "exceptional" modality, as shall be seen below.

The above mentioned international documents point to a way to overcoming the use of restraints, by means of the creation of area community services "that offer people with mental health problems choice and involvement in their own care, sensitive to their needs and culture"[13]. The above mentioned Danish Ethics Committee is also confident of a change in culture, structured on two pillars: the recognition of the person as such, even before as a subject with an illness; and consequently, the consideration of the person "on an equal standing" with the medical staff (equal rights, equal dignity and the bearer of an irreplaceable "knowledge of himself/herself"). Such "equality" should foster a therapeutic relationship full of empathy and respect, so that the asymmetry of technical-scientific knowledge between patient and physician is not translated into a relationship of prevarication[14]. These are important recommendations in line with the community guidelines on mental health, aimed at defining and valorising the role of environmental and relational factors in treatment, in agreement moreover with the principles behind the Italian psychiatric reform.

The overcoming of restraint is thus interwoven with a new culture and organisation of services. This does not mean leaving the resolution of the problem to the change in culture, actually accepting a division between

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[12] Cfr. C. Petrini, *Ethical considerations for evaluating the issue of physical restraint in psychiatry*, Ann. Ist. Super Sanità, 2013, vol. 49, n. 3, pp. 281-285; Cfr. also F. Maisto, *Imputabilità e vulnerabilità*, Quaderni di SOUQ - Centro Studi Sofferenza Urbana, 2011, No. 4. Scrive il giudice Francesco Maisto: "Si diffondono pratiche e protocolli ospedalieri e professionali sulla contenzione, nell'errato convincimento del valore giustificativo e tutorio per gli operatori in caso di lesioni, decessi e danni di qualsiasi genere ai pazienti. Tutti gli argomenti giuridici giustificativi di dette pratiche non tengono conto che nella legislazione vigente la contenzione in senso stretto, meccanica (distinta dall'occasionale ed eccezionale contenzione fisica e dalla contenzione farmacologia) non è prevista e che non trattasi di lacuna per distrazione del Legislatore, bensì di consapevole scelta dello stesso".

[13] Dichiarazione di Helsinki, cit. V, p. 4.

[14] *The Danish Council of Ethics Statement on coercion in psychiatry*, p. 8.

principles and practices and downgrading the former to moralistic proclamations as much as, on the contrary, departing from the refusal of restraint as the basis of "good practice", that is, an assumption to actually build a different healthcare culture, starting with an appropriate physician and patient relationship. This is the sense and value of initiatives such as the Mental Healthcare and Diagnosis Services which simply do not use restraint (*non-restraint*); or "restraint free" cities like Trieste, that are committed to avoiding restraining persons in all the socio-healthcare facilities of the city and the nursing homes for the elderly[15]. There are also examples of Judicial Psychiatric Hospitals in which restraint has been eliminated, like the one in Montelupo Fiorentino in 2012[16]. Moreover, the guideline for the prohibition of restraint can be found in the healthcare programmes of a number of regions, as will be seen below.

The very existence of facilities that do not make use of restraint shows how the respect of the ethical principle, within an approach to care that places the physician and patient relationship between "equals" at the centre, might lead to good practices. One must, therefore one can.

3. The normative scenario

As well as representing the expression of a wide phenomenon, rich in facets in various fields of experience and human knowledge, under the legal profile the practices of restraint put the law scholars and lawyers before issues of great reach and considerable complexity.

In the light of this, a detailed study of the subject has been embarked upon in recent years – by virtue also of the importance of recent legal cases[17], which came to the attention of the newspapers in all their distressing aspects – by legal doctrines, particularly regarding constitutional and criminal law.

A brief outline of the various problem areas that have been pinpointed within the legal debate should therefore be given.

First of all, it must be specified that there are doubts concerning the very lawfulness of the use of restraints, particularly when they are used in the recourse to mechanical restraint: basically the question must be asked whether one is before legal acts, insofar as foreseen by the law, or whether they are prohibited acts (therefore illegal) and however in conformity with the legal system by the existence of a cause of justification determined each time.

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[15] The initiative was begun by the Local Health Authority 1 of Trieste, in collaboration with the Medical Association. On 21 December 2013 the mayor of Trieste, Roberto Cosolini, launched an appeal to the mayors and healthcare representatives of Italy for the rejection of all forms of mechanical, pharmacological and environmental restraint which still today are used on weak citizens in violation of article 13 of the Constitution.

[16] The director, Antonella Tuoni, thus stated her reasons for prohibiting restraint: "Tenere legata ad un letto una persona per giorni e giorni come pratica usuale richiamando l'articolo dell'Ordinamento Penitenziario che prevede l'impiego della forza fisica e l'uso dei mezzi di coercizione, ovvero la normativa in materia di trattamento sanitario obbligatorio, oltre che inumano è illecito" (Ristretti Orizzonti, 17 settembre 2013).

[17] In particular reference is made to the cases of the deaths of Giuseppe Casu and Francesco Mastrogiovanni, for which see summarily and respectively, G. Dodaro, *Morire di contenzione nel reparto psichiatrico di un ospedale pubblico: la sentenza di primo grado sul caso Mastrogiovanni*, www.penalecontemporaneo.it, 12 June 2013, and, by the same author, *Il nodo della contenzione in psichiatria tra gestione della sicurezza, diritti del paziente e "inconscio istituzionale*", www.penalecontemporaneo.it, 25 February 2014.

As highlighted in literature[18], the question appears to be closely linked to the one concerning the exact limitation of the obligations coming into the healthcare providers' position as the upholders of human rights as set down in art. 40, 2nd para, p.c.: in particular the question must be asked whether among these obligations can be included the impediment of acts that are harmful to the patient and to others by means of restraint.

A first opinion, partly held by the doctrine and jurisprudence, states that the obligations regarding this also include the recourse to restraints, stating that they must be used whenever it is a question of avoiding direct self-harming or harm to others. Furthermore, similar conclusions would be valid after Law No. 180 of 13 May 1978, despite the abandoning – promoted by this very law – of the "custodialistic" model, strictly linked to the obsolete asylum approach of mental suffering on the basis of the presumption of the dangerousness of the patients.

Nonetheless, a different orientation of the doctrine and jurisprudence, valorising the absence of a specific set of regulations in the Italian legal system, has excluded the possibility of establishing a similar position for the mental healthcare professionals as the upholders of human rights, stressing how for these very reasons, also the general guidelines inferable from Law 180/1978 would provide in this sense[19].

According to this different reconstruction, mechanical restraint would in principle be open to embodying a criminal offence in accordance with arts. 605 p.c. ("Kidnapping") and 610 p.c. ("Private violence"), but allowed should a cause of justification arise.

The justifying hypotheses identified in the doctrine are those in particular foreseen by art. 51 ("Exercise of a right or fulfilment of a duty"), art. 52 ("Legitimate defence") or by art. 54 ("State of need") of the penal code.

From this point of view, it is worth stressing that, setting aside the necessity to closely evaluate the assumptions and limits of applicability of all the causes of justification in question, the prevailing doctrine has privileged the application of the state of need and – should there be the grounds for this - legitimate defence. This is above all on the basis of the argument whereby while the justification of the fulfilment of duty would lead to an asymmetrical concept of the care relationship, confining the role of the patient in a certain sense, the call for the causes of justification as laid down in arts. 52 and 54 p.c. on the contrary seems to draw from an equal interpretation of the same relationship, in this case more respectful of the patient's dignity[20].

It must be remembered nevertheless that in the case of mechanical restraint it is the fundamental rights of the person that are at issue. For this reason the subject has also raised the problem, mostly dealt with in constitutional literature, of verifying the legitimacy in relation to the principles of the Charter of Fundamental Rights.

With regard to this it has been highlighted how the problem must be seen in the light of arts. 13 and 32 of the Constitution[21]. Under this profile, the very

[18] Cfr. the summary by C. Sale, *Analisi penalistica della contenzione del paziente psichiatrico*, www.penalecontemporaneo.it, 27 April 2014, pp. 8 and ff.

[19] There could be a doubt only with regard to the specific condition of the patient undergoing Compulsory Healthcare Treatment during hospitalisation.

[20] See for example, G. Dodaro, *Morire di contenzione*, cit.

[21] M. Massa, *Diritti fondamentali e contenzione nelle emergenze psichiatriche*, "Rivista italiana di medicina legale", 2013, pp. 179 and ff.

nature of the restraint practices are in fact dealt with: the question is far from being irrelevant and this can be deduced just by considering that while art. 13 concerns *coercive* practices, establishing the principle of the inviolability of personal liberty and foreseeing, in the fourth paragraph, punishment for any physical and moral violence "against a person subjected to restriction of personal liberty", art. 32 regards *compulsory* practices. At discipline level, art 13 foresees stricter limits than art. 32 of the Constitution: the latter establishes a so-called relative reserve, whereby "No one may be obliged to undergo any health treatment except under the provisions of the law", which "may not under any circumstances violate the limits imposed by respect for the human person" (2nd paragraph); on the other hand, at the same time art. 13 establishes a so-called absolute reserve and a so-called jurisdictional reserve, foreseeing in the 3rd paragraph that "No one may be obliged to undergo any health treatment except under the provisions of the law", which "may not under any circumstances violate the limits imposed by respect for the human person" (2nd paragraph); instead, at the same time art. 13 establishes a so-called absolute reserve and a so-called jurisdictional reserve, foreseeing in the 3rd paragraph that "In exceptional circumstances and under such conditions of necessity and urgency as shall conclusively be defined by the law, the police may take provisional measures that shall be referred within 48 hours to the Judiciary for validation and which, in default of such validation in the following 48 hours, shall be revoked and considered null and void".

Lastly, an intermediate solution is also assumed, which proposes a merging of restraint practices with compulsory healthcare treatment, suggesting their joint regulation by arts. 13 and 32 of the Constitution.

Independently of the case being examined, it has furthermore been underlined how it is nonetheless necessary – again from the point of view of constitutional legitimacy – that the possibility to use restraint on a mental patient must be foreseen by a law decreed by Parliament, ruling the premises for application[22].

In the Italian legal system no specific set of regulations is to be found: leaving aside arts. 41, 3rd para. of Law No 354 of 26 July 1975, (*Norms on prison rules on the enforcement of measures involving the deprivation and limitation of liberty*) and 77 of the regulation to which this refers[23], which regard the specific situation of the psychiatric patient in prison, the main normative reference still has to be identified – at least according to the majority of jurisprudential orientations – in art. 60, royal decree, 16 August 1909, No. 615 (*Rules on asylums and the alienated*, implementation of Law No. 36 of 14 February 1904). With regard to this latter measure, "[in] the mental asylums means of coercion of the mentally infirm shall be abolished or reduced to absolutely exceptional circumstances and cannot be used without the written authorisation of the director or a doctor of the institute. Such authorisation shall

[22] On this point see also G. Dodaro, *Il problema della legittimità giuridica dell'uso della forza fisica o della contenzione meccanica nei confronti del paziente psichiatrico aggressivo o a rischio suicidario*, "Rivista italiana di medicina legale", 2011, pp. 1499 and ff.

[23] Art. 41, 3rd para. states: 'No means of physical coercion shall be used that is not expressly foreseen by the regulations in force and, nevertheless, there can be no recourse to this for disciplinary aims but only to avoid causing harm to persons or things or to guarantee the safety of the subject himself/herself. Therefore its use must be limited to the time strictly necessary and must be constantly monitored by the physician'. Art. 77 of the abovementioned legislation foresees the possible use of wrist and ankle cuffs, even though setting down a number of specific criteria.

define the nature and duration of the means of coercion". Nevertheless, the present enforcement of art. 60 not only appears to be the subject of debate (since while the jurisprudence mostly tends to recognise its survival from the reform brought about by Law 180/1978, which says nothing on the subject, according to others it must be considered that it has been swept away by a tacit repeal), but even its very suitability to satisfy the relative reserve requested by the constitutional norms has been questioned, also when the one relative to art. 32 of the Constitution had to be dealt with: in fact, under this profile the norm does not appear sufficiently structured and precise.

As can be seen therefore, (also) from the juridical point of view the use of mechanical restraints raises questions, even though limiting the view to a perspective anchored to the present normative situation, that are not easy to resolve and which need further reflection for its interpreters to reach full agreement. Nevertheless, it seems that some core issues can already be identified.

It must above all be stressed once again how – all the more so following Law 180/1978, but as can clearly be seen for reasons that are not limited to and prescind from this – a vision of the mentally ill patient as an allegedly dangerous subject and for whom care must be given in "custodialistic" forms can no longer be accepted. Hence arises the need to understand the therapeutic relationship with the patients with mental disorders in terms which can superimpose those in any care relationship and, therefore, according to the fundamental criteria that are identical to those adopted for other pathologies and forms of suffering. In this sense, the National Bioethics Committee expresses its hope that the physician-patient relationship can be conducted on an equal footing, fully respecting the canons of a human relationship inspired by the equal dignity and liberty of the subjects involved.

Consequently, any recourse to mechanical restraining techniques must represent the *extrema ratio* and it has to be considered that even in Compulsory Healthcare Treatment they can be used only in situations of real need and urgency, proportionately to the actual demands, using the least invasive modalities and only for the time necessary to overcome the conditions making them necessary. In other words, it is not sufficient for the patient to be simply in a state of agitation for restraints to be "justified" but there must be a *serious and immediate* danger that the patient commits self-harm or harm to others. When the patient ceases to pose this risk, the restraining treatment must stop as it would no longer be justified by need and would add to the offences mentioned above.

Lastly, these guidelines seem to represent useful and in some respects inalienable points of reference for a more appropriate application also of forms of restraint different from the mechanical one, as long as opportunely restricted in the respective situations and specific circumstances.

4. Restraints in the Mental Healthcare and Diagnosis Services: research guidelines

As mentioned above, the different forms of physical and pharmacological restraint must be distinguished. Mechanical restraint is a type of physical restraint but there are other forms of physical restraint which are quite different from the mechanical one. *Holding* is one of these, a technique used by the healthcare professional to restrain the patient's crisis, talking and listening to

the patient and using their own body in an attempt to establish a dialogue. In this case, the use of force and physical limitation of the person are contingent, of short duration, useful for creating the relationship, keeping the negotiation open in the search for solutions and shared choices. *Holding* can thus represent one of the *de-escalation* procedures during the crisis management of aggressive patients, which are alternative to mechanical restraints (with the objective of restraining – in the sense of understanding and "keeping inside oneself" the patient's experiences – alleviating their anger and suffering).

Mechanical restraint is different and is carried out by using a straight jacket, restraining beds, wrist and ankle straps. *Seclusion* is another method used, or the closing of the patients in isolation cells. It is moreover used in Anglo-Saxon countries, unlike in Italy where mechanical restraint is usually preferred.

As far as pharmacological restraint is concerned, this consists in the giving of drugs in higher doses than those prescribed in the current therapeutic guidelines, aimed at the dulling of the patient's will and reactions. Pharmacological sedation undoubtedly represents an instrument to deal with the crisis management of aggressive patients, but that does not mean that it is opportune to substitute mechanical restraint with a pharmacological one. In fact it is evident that the high drug dosages for restraining purposes can have risky side effects, as well as delaying the start of the therapeutic relationship which is an indispensable resource towards recovery. For this reason in the healthcare programmes and guidelines of a number of regions it is recommended to keep to the correct dosages of sedatives and to carefully monitor any recourse to improper posology, which should anyway be limited in time.

Lastly, in the Mental Healthcare and Diagnosis Services that choose not to restrain patients or which attempt to limit such practice to a minimum, more intensive use of psychotropic medications with respect to the services resorting more heavily to restraint is not evident from the data available [24].

The underlying issue is that it is the orientation of the service that makes the difference. Therefore the solution lies not so much in the substitution of pharmacological restraint with mechanical restraint, as in the overcoming of the very culture of restraint, making proper use of all the therapeutic instruments, drugs included.

Mechanical constraint can be called the "remnant" of psychiatric healthcare. In 1978 the law for psychiatric reform decreed the end of new admissions to asylums and the course towards their closure begins; the new system of area responsibility is set up, delegating acute cases to the Mental Healthcare and Diagnosis Services in the general hospitals. There is no reference to restraint in the psychiatric law, nor is the problem dealt with at a later date as urgently and seriously as it should have been in the healthcare programmes and other mental health guidelines, as shall be seen below.

Even more surprising is the lack of research and the absence of systematic monitoring of such a physically invasive and harmful practice, despite the

[24] Data from the SPT study, a longitudinal survey by the Istituto Mario Negri of Milan on 61 area services and 39 MHDS of 12 regions on the results of serious mental disorders over five years from its being set up; cfr. Giuseppe Cardamone, Angelo Guarnieri, Luisa Mari, *Una elaborazione critica dei dati sui SPDC. Riflessioni sul senso della crisi e del ricovero in psichiatria,* "Rivista sperimentale di Freniatria", Vol. CXXVII, supplement No. 2/2003, pp. 23-24. The authors also point out that services that make less use of restraint do not have a larger personnel than the others. Cfr. also P. Cipriano, *La fabbrica della cura mentale*, Eleuthera, Milano 2013, p. 51.

appeals for the above mentioned methods to be overcome. Restraint generally becomes the subject of public debate when a person being restrained dies in tragic circumstances, with the consequent investigation by the judiciary. This happened in 2006 when the death of Giuseppe Casu, who had been tied to a psychiatric ward bed for seven days in Cagliari hospital, fuelled the protest of the associations of patients' families and the indignation of public opinion; in 2010, Francesco Mastrogiovanni died in Vallo di Lucania after ten days of continuous restraint. In this case too the role of his family, the promoters of the Committee "Verità e Giustizia per Francesco Mastrogiovanni", was fundamental in informing and raising public opinion awareness**.**

Despite the poor level of research on the subject, there are some Italian and foreign studies that give an overall picture of the working of services in which the use of restraint is included[25].

Progres Acuti, some research carried out between 2002 and 2003, made it possible to gather national data on the characteristics and operational models of the 262 Mental Healthcare and Diagnosis Services running in Italy and the 16 area Mental Health Centres open 24 hours a day (able to treat patients with acute mental health crises): during this period, there was a 12.9% Compulsory Healthcare Treatment rate. 80% of the MHDS are not open, while 15 MHCs out of 16 are open 24 hours a day. The "closed door" model is more widespread in Italy with respect to abroad.[26] However, at national level, the number of patients who have undergone mechanical restraint is not known, nor is the number of restraints or the total number of hours of restraint over a yearly period.

A more exhaustive picture is given at regional level by the research on MHDS of metropolitan Rome, edited by the coordination of the Lazio Mental Healthcare and Diagnosis Services, and which began in 2005 with a successive *follow up*[27]. This study made it possible to monitor the use of mechanical restraints in that period, understand the reason for their use, identify their evolution and put forward solutions; this is all the more important insofar that it concerns a large metropolitan area, with a variety of old and new mental health issues. They are reflected on the activities of the MHDS which have to deal with all sorts of urgent cases (psychopathic behaviour, co-diagnosis of addiction and mental disorder, emergencies linked to the new social poverty and crises).

23 (out of 24) MHDS took part in the first step of the Lazio research, in the four months from January to April 2005: of these only one of the MHDS at the San Giacomo hospital in Rome did not use restraint[28].

Out of 3,130 patients admitted to the centres in that period, 297 were restrained, corresponding to about one out of ten, with some being restrained more than once. The restrained patients were subjected to two restraining interventions on average, with a maximum number of 12 restraints per single patient (the total number of restraints was in fact 581). The average number of restraints was 26 per service, with a large variability: apart from the San

[25] The studies mentioned below have been outlined and debated during the NBC hearings.

[26] Dell'Acqua et al., *Caratteristiche e attività delle strutture di ricovero per pazienti psichiatrici acuti: i risultati dell'indagine nazionale Progres-Acuti*, "Giornale Italiano di Psicopatologia", 13, 2007, pp. 26-39.

[27] P. Sangiorgio, *La prevenzione, la gestione e, in prospettiva, l'eliminazione della contenzione nelle emergenze psichiatriche dell'area metropolitana di Roma*, in P. Sangiorgio and G.M. Polselli (edited by), *Matti da (non) legare*, Alpes, Roma 2010, pp. 1-40.

[28] Moreover this service no longer exists as some time later the hospital centre was closed under this Region's rationalisation programme.

Giacomo hospital which used none at all, the figures range from a minimum of 5 restraints in 4 months to a maximum of 71.

The average duration for restraint was about 14 hours, ranging from 20 minutes to 216 hours: this means that a person was restrained for 9 consecutive days.

The average duration of the restraint per patient was 23 hours, varying from a minimum of 8 hours to a maximum of 62 hours.

The number of restrained patients is surprising despite being under Compulsory Healthcare Treatment, and subject to procedures for the upholding of individual rights foreseen by the law: in 34% of the cases the patient was strapped down simply in accordance with art. 54 of the penal code (owing to "state of need").

With regard to the motivations: most of the patients (48%) were restrained due to *psychomotor agitation*, 37% due to *other-directed aggressiveness*, 9% to *self-harm*, 7% to *risk of escape*, 3% to *refusal of treatment* and 13% due *to states of confusion of organic, toxic or pharmacological origin.*

In a comparison with other countries in areas with metropolitan features that can be considered on a par with those of Rome, the following emerges: from the study carried out in 2000 on 50 emergency psychiatric units in New York, it appears that the rate of restrained patients out of those discharged from care is 3.1%, for an average duration of 3.3 hours. The comparison therefore puts Italy in a bad light, since in the survey on the Lazio Region there is a rate of 9.48 restrained patients out of 100 discharged, with a rather higher average duration of restraint (14 hours).

This rather poor data does however offer some interesting considerations. Firstly, one cannot say that mechanical restraint is an exceptional practice and a last resort, if it is true that on average 10% of patients admitted for acute mental health crises is restrained, all the more so if the services over the average are considered, which reach peaks of 23, or 25%. Also the data on the commonly adopted reason to justify the use of restraint, "psychomotor agitation" (a somewhat general term), suggests that it is not an "extreme" intervention at all. Lastly, the very fact that the healthcare providers are not requested to give more precise motivations and more convincing justifications reneges the routine nature of the practice.

Furthermore, the data on the duration of restraint is cause for concern, since the strapping down of a person for such prolonged periods does not seem to be in keeping with the "immediacy" of "danger of serious harm", as per art. 54 of the p.c., often used by the professionals to justify their decision to restrain (see the paragraph on the juridical standpoint).

Moreover, the significant variability in the use of restraint in services, which also insist on areas having similar features and types of usage, suggests that the culture and organisation of the services play a decisive role in the use of restraints rather than the typology of usage.

The primary role of the approach of mental health services is confirmed by other surveys conducted abroad: in the Commission's report on the quality of treatment in the State of New York for the evaluation of psychiatric care in hospital environments of 1994, it is stated that the differences in the rates of

restraint use are not so much correlated to the characteristics of the patients, as to the "philosophy" of the services[29].

5. *Restraint* and *non-restraint* culture

The above mentioned Italian SPT study (Area Psychiatric Service) makes it possible to understand the different approaches of the services. From the examination of a sample of 39 MHDS and two university clinics from all over the country, it can be seen that in only 12% of the services is mechanical restraint banned by choice. Among the remaining ones, restraint is a somewhat rare event in just short of one third of the cases, while in one third it is quite a frequent practice, with peaks of up to thirty restraints in the last month. Patients admitted to a psychiatric unit voluntarily are also subject to restraint and 42% of the MHDS examined does not transform voluntary admission into CHT when it is decided to restrain the patient, letting it pass as "normal" practice, which does not interrupt the voluntary nature of the admission. Moreover, in 64% of the MHDS using restraints no record of the cases is kept[30].

The MHDS that use restraint have "weak" regional services and socio-healthcare networks behind them; that is, area services open for a limited number of hours without a sufficient variety of staff, with poor links with other centres and services of the local socio-healthcare network. Furthermore, restraint is accompanied by a series of other practices limiting the patient's freedom of choice, like the taking away of personal belongings, the obligation to wear pyjamas, the limitation of visits by family members and telephone calls, the rationing of cigarettes etc.

Instead, the *non-restraint* MHDS have community services that are open all day or 24 hours a day, hence with a good emergency filter capacity made even more efficient by the fact that the local healthcare providers already know the person who arrives during a crisis, and in turn the patient is less afraid when received by staff already familiar to him or her.

In commenting on these data the researchers focus the attention on the correlation between restraint and aggressive practices, such as body search and others already mentioned. In units that opted for non-restraint, no restrictive practices are used. Hence the conclusion: "Since it is not credible that the seriousness, behavioural expressiveness and the psychopathological profile of the patients admitted by these services are different", it is the approach to work of the healthcare providers and the services system operating in the regional hospital service that makes the difference[31]. Lastly, as already shown, it does not appear that the *non-restraint* MHDS make recourse to a greater use of drugs with respect to the *restraint* ones.

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[29] NYS Commission on quality of care, *Restraint and seclusion practices in New York State psychiatric facilities and voices from the Frontline: Patients Perspectives of restraint and seclusion use,* 1994.

[30] G. Cardamone et al., cit., p. 23.

[31] E. Terzian, G. Tognoni, *Indagine sui servizi psichiatrici di diagnosi e cura*, "Rivista sperimentale di Freniatria", 2003, vol. 127, suppl. n. 2, pp. 3 e ss.; M.G. Giannichedda, *La democrazia vista dal manicomio. Un percorso di riflessione a partire dal caso italiano*, "Animazione sociale", No. 4 April 2005, pp. 19-31.

6. Reasons for not restraining

Despite the fact that the research carried out in Lazio shows that only a part of the restraints is decided by the healthcare providers in order to deal with the patient's aggressiveness, the reasons more commonly given regard the safety and management of the conflict with the patient.

It is important to stress that international research also confirms this contradiction. Data from the United Kingdom offer a similar picture to the Lazio one: only in 44% of the cases are patients strapped down owing to their confrontational actions. Furthermore, in many cases the choice to use restraints decreases safety instead of furthering it: preventive or reactive restraint can generate or exacerbate conflicts with patients, as often happens when a person is tied down to be given medication or when it is decided to preventively restrain patients who have committed acts of aggression. On the contrary, treating the patient with respect and a "normalised" management of the service, starting from the "open doors" practice as in other units, contributes to creating a more serene atmosphere, conducive to reducing aggressive and self-harming behaviour[32].

In the United Kingdom an attempt has been made to draw up a new conflict management model in psychiatric wards, analysing different operational models. A key factor of the new model lies in the attention to rights, starting from the giving of information to the patient and the possibility for them to express their point of view and file complaints. "The attention to the procedure for the upholding of the rights, information and the requests of the patients could increase the legitimacy of the psychiatric ward, strengthen the patients' self-esteem, suppress or decrease anger, contribute to lowering the conflict and reducing the restraint rates". The model is based on a normative framework that is concerned with rights and which fosters a care approach where there is room for "the listening, negotiation, flexibility, compromise": these are all useful elements in reducing conflict. Conflict management is thus part of a general direction towards the respect for the autonomy of the person, which is reconfirmed in all the stages of recovery: giving space to the choices of the patients for food, schedules and the taking care of personal belongings. Lastly, the staff is asked to intervene to try and "reply to the loss of faith and hope and self-stigmatisation of the persons following admission to a psychiatric facility"[33].

To summarise, there are various reasons not to restrain of an ethical nature, along with those of safety, prevention and good services management: non-violent and non-coercive management in MHDS eliminates the atmosphere of fear (for patients and healthcare professionals) and reduces stigma. And there are also therapeutic reasons, first of all so as to avoid compromising the therapeutic relationship by means of a vicious circle that physical restraint triggers off: the agitation of the restrained person is aggravated and higher doses of sedatives are needed, with the result that their state of confusion worsens, in turn reducing the communication between them and staff.

These therapeutic principles are at the basis of the model of community psychology and psychiatry, but they have even more ancient origins. It suffices to mention the concepts of the psychiatrist John Conolly, expressed in 1856: if

[32] L. Bowers, *On conflict, containment and relationship between them*, Nursing Inquiry, 2006, 13, 3, pp. 172-180; P. Sangiorgio, M. Polselli, *Matti da non legare,* 2010, cit*.*, p. 8.

[33] L. Bowers, *Safewards: a new model of conflict and containment in psychiatric wards*, "Journal of Psychiatry and Mental Health", 2014, 21, p. 507.

it is allowed to restrain hands and feet, in a short time there will a total process of regression in the patient and there will be the start of all sorts of neglect and tyranny, "until the repression becomes the usual substitute of attention, patience, tolerance and correct management"[34]. In other words, the respect of the person qualifies the assistance and is the measure of the professional skills of the healthcare providers.

7. Strategies of change

The idea that by means of a change in the culture and organisation of services one can significantly influence restraint is confirmed by the outcome of the initiatives aimed specifically at this. This was the case in the Danish project, *National Breakthrough Project on Coercion in Psychiatry*, adopted in 27 psychiatric wards in all, from August 2004 to June 2005. In the final report of the project, it says that a change has begun and there was greater attention by staff to dialogue and the involvement of the patients. With respect to the number of coercive episodes, these had decreased by 20% in 33% of the wards taking part in the project, while 8% of the services had achieved over 50% fewer coercive practices[35].

Positive signs also come from the monitoring carried out through the follow-up of the research on MHDS in Lazio from 2005 to 2011. In the space of six years, the number of restrained patients decreased by one quarter. The average number of restraints for MHDS also went down, just as the average number of hours of containment per service did. Instead, there was no reduction for the average duration of restraints, which in fact increased[36].

This shows that the setting up of specific programmes along with the simple attention to cases of restraint through monitoring can achieve positive results, increasing the level of awareness of healthcare providers with regard to the extreme meaning of containment as the violation of a right. This is all the more so in Italy where it appears that not always is the use of restraint noted down by the physicians in medical records.

Healthcare providers are therefore asked to use more thoroughness, in the respect of the ethics of care and in the upholding of the law. It must be remembered that a recent first instance judgement defined the narrow limits of the lawfulness of the practice, clearly stressing that – even though having to recall the ongoing debate on the subject in legal doctrine – mechanical restraint is an unlawful act of healthcare in itself (since, it follows that, it can be allowed, insofar as being "exceptional, episodic and contingent", should a cause for its justification arise); furthermore, it highlighted the fact that "*the gravity, plurality and temporal extension of mechanical restraints in an* MHDS *mark a consolidated contrast between usual practice and norms of the state in force*"[37].

It is the duty therefore of the healthcare professionals to always note down the decision to strap down the patient in their medical record. Not only: the

[34] J. Conolly, *The Treatment of the Insane without Mechanical Restraints,* 1856; P. Cipriano, *La fabbrica della cura mentale*, Eleuthera, Milano 2013, p. 50.

[35] *The Danish Council of Ethics statement on coercion in psychiatry,* cit., p. 7.

[36] The average number of cases of restraint has gone from 92 in 2005 to 57 in 2011, while the average number of hours of restraint per MHDS has gone from 1,500 hours to 999 (from the consultation by Pietro Sangiorgio).

[37] Grounds for the first instance judgement in the trial for the death of Francesco Mastrogiovanni, filed 27 April 2013/T. Vallo della Lucania, 30 October 2012 (filed 27 April 2013), in www.penalecontemporaneo.it, 12 June 2013.

reasons and the context of the cause for justification advocated each time must be specified in full detail.

The institutions are also called upon to play their part, particularly the Regions in charge of local healthcare services. It is also necessary to give clearer guidelines. At national level the document "*Physical restraint in psychiatry: a possible prevention strategy*", approved by the Conference of Regions on 29 July 2010, contains a series of recommendations, the first of which regards the monitoring and systematic collection of information on the phenomenon of restraint (duration of restraint, night time restraints, the frequency of restraint episodes, the number of patients restrained, the diagnoses associated with the use of restraints). The data flow from the Departments of Mental Health should merge together at central regional level, so as "to represent an instrument for the observation of restraint as a sentinel event". Other recommendations of the document concern the monitoring of violent behaviour, the training of staff to deal with critical situations, the definition of facility and operating standards for the management of violent acts, the monitoring of the organisation model in its impact on the number of restraint episodes, the ascertainment of crisis management, the fostering of the "transparency of care facilities so as to improve accessibility, liveability, the acceptance of service and to facilitate communication with the outside".

Even though many of these recommendations make very good sense, they are nonetheless too generic on some points and on the whole do not appear sufficient to give a clear sign towards the overcoming of restraints.

This is confirmed by the fact that the guidelines of the various regional programmes differ quite significantly: from Tuscany, which in its 2012-2015 healthcare and social programme, reconfirms "the absolute prohibition of any form of physical restraint whatsoever" within the MHDS whose doors "must stay open" and recommends "constant attention to the appropriateness of the recourse to pharmacological therapy"[38], to the Lombardy regional mental health programme 2004-2012, which interprets the document of the Regions as an invitation to "regulate" the practice of restraint, referring to protocols at hospital level, both for the use of restraint in a psychiatric and non-psychiatric context, "even though recognising the extraordinariness of the recourse to restraint, but at the same time aware of the incidence of the phenomenon in general"[39]. An examination of the guidelines on restraint of the Niguarda hospital, one of the biggest in Lombardy, highlights the ambiguity of the regulations. From the very premise the document acknowledges that restraint is a practice that is "more frequent that could be thought": nevertheless, it chooses to stress in the first instance "that mechanical restraint can be made necessary in various stages of different mental pathologies", rather than underlining the reasons (of an ethical and therapeutic order) for *not applying* restraint[40].

Other passages of the guidelines are even more interesting, as they implicitly bear witness to the widespread and indiscriminate use of restraint. In

[38] Social healthcare programme 2012-2015 of the Region of Tuscany, p. 181.

[39] Regional Mental Health programme 2004-2012 of Lombardy, pp. 156 and 158.

[40] The above mentioned ambiguity is also to be found in other crucial passages of the document. On the one hand, it seems that restraint is considered possible only for violent patients, so much so that great emphasis is placed on the identification of the "patients at risk" of aggressive behaviour; on the other hand, a series of different disorders are listed "which are unusually dealt with physical restraint" and which have nothing to do with violent behaviour (see below).

the paragraph entitled “Research and the use of alternative solutions”, a long and varied list of “*situations and high-risk behaviour which is usually dealt with by using physical restraint*”: these range from anxiety disorders, to psychomotor agitation, to delirium and hallucinations, to changes in the sleep-wake cycle, the prevention of falls and even (pharmacological) therapeutic treatment. It is evident that many of these situations – for example anxiety disorder and changes in the sleep cycle – do not seem to satisfy the requirement of a state of need and urgency. To simply consider that “the search for other solutions is to be hoped for” in the “risk behaviour” listed, as stated in the Niguarda guidelines, is a message that does not do any justice to the gravity of the problem[41].

The appeal made to the Regions to monitor the phenomenon, as already stated in the 2014 Regions document, becomes even more urgent in the presence of the habitual recourse to restraint. A national monitoring institution should be set up, with the pooling of regional data so as to be able to compare regional policies and overcome the disparities.

Programmes should also be promoted and financed to evaluate the progress in mental-healthcare, clearly establishing the non-recourse to restraint as a quality factor in services evaluation.

The American approach to this is worth mentioning here, where stricter limits in the use of restraint and isolation constitute quality factors in the evaluation of the service and represent an obligatory requirement for the establishments wanting accreditation[42].

8. Restraints and the elderly

It has been said that the subjects most exposed to the use of restraints are mental patients and the elderly. The latter are an even greater cause for concern, not only owing to the high number of elderly patients and therefore the possible recipients of restraint but also because the practice is passed over and forgotten to an even greater extent than with psychiatric patients. In a psychiatric context restraint was debated at the time of the outdating of asylums, even if not sufficiently so, since due attention was not (and is not) paid to the survival of the asylum culture. The debate on the elderly on the other hand is much more lacking.

There are many forms of mechanical restraint for the elderly, aimed at limiting the freedom of movement of the whole body or parts of it: from bracelets to immobilise wrists and ankles, to chest straps to block the patient to the bed or wheel chair, to pelvic straps, corsets with braces or pelvic belt; wheelchair trays, various types of straitjackets, like the “safety vests”, that are worn like a vest garment leaving arms and hands free but at the same time stopping the person from getting out of bed, and finally the “four-side rails” (uprights on the bed).

[41] Azienda Ospedaliera Ospedale Niguarda, *La contenzione fisica in ospedale*, Evidence based Guideline, 2006 (reviewed in 2008), pp. 4-10.

[42] In particular, in 2000, la *Joint Commission on Accreditation of Healthcare Organizations* (JCAHO) decided to apply the “one hour rule”, according to which the facility applying for accreditation must see that patients subjected to restraint or seclusion are examined within one hour by an independent physician for an assessment of the suitability of the measure adopted (*Psychiatric News*, October 6, 2000).

The list of restraint techniques has been given since their mere description gives an idea of the amount of suffering they can cause and how harmful to the dignity of the elderly person they can be. It must be stressed that many of these instruments have been devised to enhance the possibility of movement and action and not to limit it: this is the case of the "serving tray", designed to enable the person confined to a wheelchair to eat their meals but which instead is often used to stop them from getting up autonomously and walk around.

Pharmacological restraint is also used, which amounts to a restraint when the drugs acting on the central nervous system are aimed at limiting or suppressing the movement capacity and interaction of the person. These are often sedatives, antidepressants and antipsychotic drugs which, in excessive doses, have many side affects, such as drowsiness, confusion and agitation. Pharmacological restraint is often used together with a mechanical one[43].

The use of restraints is worsened by the fragility of the elderly. The increase in life expectancy does not yet correspond to an improvement in the quality of life, and most elderly people have invalidating illnesses and senile dementia in the last 3/5 years of life: these are the patients most hit by the use of restraints.

9. The spread of the use of restraints in residential care facilities and hospitals

As stated above, the phenomenon is deeply rooted and the data quite poor. In a survey carried out in Italy, big differences are to be seen from region to region. The spread of restraint is confirmed by the fact that in many areas guidelines and operational procedures have been drawn up[44]. In 2006 research was carried out in the province of Trieste on 44 facilities for the elderly out of 100 present in the area. At the time of the research, 63% of the patients were fully or partially self-sufficient. 18 facilities out of 44 claimed that they used restraint, while 19 did not, even if in a more in-depth survey a number of restraint measures were found to be used such as tray tables and drug overdose.

Foreign data also shows that the recourse to restraint is frequent and for prolonged periods, especially in hospitals[45].

As far as concerns the variables correlated to the non-restraint facilities with respect to those using restraint, not only does the seriousness of the state of health have a bearing on this but also the approach of the nursing staff to restraining patients[46]. The training and professional skills of the staff are

[43] L. Bicego, *Luci ed ombre sulla contenzione alle persone fragili*, in M. Mislej, L. Bicego, *Contro la contenzione*, Maggioli Editore, Santarcangelo di Romagna 2011; M. Mislej, L. Bicego, *Assistenza e diritti. Critica alla contenzione e alle cattive prati*che, Carocci Faber, Roma 2007.

[44] See for example: E. Zanetti, S. Costantini, *Uso dei mezzi di contenzione fisica,* Gruppo di Ricerca Geriatria di Brescia, 2001.

[45] Cfr. O.J. De Vries, G.J. Ligthart, T. Nikolaus, on behalf of the participants of the European Academy of Medicine of Ageing-Course III, *Differences in period prevalence of the use of physical restraints in elderly inpatients of European hospitals and nursing homes [Letter]*, "Journal of Gerontoly Medical Sciences", 2004, 59A, pp. 922–923.

[46] See for example the study of 33 nursing homes and 12 residential units in Sweden for elderly dementia sufferers: the 540 residents, of an average age of 82 and the 529 carers were evaluated in order to identify the environmental features affecting restraint (S. Karlsson, G. Bucht, S. Eriksson, P.O. Sandman, *Factors relating to the use of physical restraints in geriatric care settings*, "Journal American Geriatric Society", 2001, 49 (12), pp. 1722-28).

stressed as being key factors and more important than the actual number of personnel: in a study on 15,000 nursing homes, differences in the number of personnel between *restraint* and *non-restraint* facilities did not come out[47] .

On this basis, a number of countries went ahead with regulatory action to protect the more vulnerable patients from abuse, especially the elderly. America has the *Nursing Home Reform Act* of 1987 which contains a charter of rights of persons in nursing homes: among the rights listed stands out the right to "be free from physical restraint"[48].

Furthermore, there is evidence of the harmfulness of restraining practices not only due to the immediate effects, but also the long term ones: restrained subjects suffer from loss of autonomy, a reduction in activity, an increase in morbidity and mortality[49]. The negative effects not only affect the individuals that are restrained but also the general atmosphere of the homes or wards, owing to the fear and bewilderment of the other patients who anticipate similar treatment.

10. Conclusions and recommendations

The NBC takes the opportunity to stress the general lack of attention with regard to the use of restraint, and in particular to mechanical restraint, which is still used in a non "extraordinary" way. This is even more serious as the aim to overcome the use of restraint is not new and has for some time now been expressed at different institutional, national and international levels, not least in the above mentioned NBC document of 2000. This is even more worrying in as much as the available research, even though insufficient, highlights the fact that the orientation and culture of the services influence the choice of whether to use restraints or not rather than the behaviour and characteristics of the patients. This shows that the use of restraints can be avoided and the presence of wards where restraint instruments do not even exist bear witness to this.

In this framework the NBC:

- *Stresses the need to overcome the use of restraints*, in the context of the fostering of a care culture that respects the rights and dignity of persons, especially those who are more vulnerable.

- *Condemns the present widespread use of restraints*. It is true that the possibility to use mechanical restraint has never been completely excluded. Nevertheless this should be interpreted as a caution, with respect to any extreme situations of jeopardy that the healthcare professionals are unable to deal with in any other way. Instead, this absolutely exceptional "emergency exit" – as it could be defined – which allows staff to depart from the regulation not to restrain patients against their will, has all too often been converted into

[47] N.G. Castle, B. Fogel, *Characteristics of nursing homes that are restraint free*, "Gerontologist", 1998, 38, pp. 181-188.

[48] N.G. Castle, V. Mor, *Physical restraint in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987*, "Medical Care Research and Review", 1998, 55, 2, pp. 139-170.

[49] See the retrospective study on 122 deaths during restraint: 78% were women, of an average age of 81. The victims died while they were strapped to a chair (42%) or to the bed (58%). 83% of deaths took place in nursing homes.

routine practice. Tolerance, granted in extreme cases for an intervention that is so harmful to the freedom and the dignity of the person, has been wrongly interpreted as a licence for its standard use.

- *Reminds the carers of sick persons, but also the competent healthcare bodies that the use of force and mechanical restraints represent a violation of the fundamental rights of the person.* The awareness of this violation, with the responsibility deriving from it, should guide the daily actions of the healthcare providers and be a stimulus to the institutions to urgently adopt all possible measures to reach the objective of overcoming the use of restraints.

The NBC thus urges the regions and government to:

- *Increase research on restraints* in relation to the organisation and culture of the services, particularly as far as concerns the elderly who are the most defenceless subjects in the face of coercive practices.

- *Start a careful monitoring of the phenomenon*, at regional and national level. This requires constant attention being paid to the daily practice in the wards: in particular, the healthcare professionals are asked to use extreme accuracy in recording the cases of restraint, the specific reasons for choosing to strap down the patient, the duration of the measure. A role of surveillance, prevention and cultural promotion shall be reserved for associations and family associations in particular.

- *Set up programmes aimed at the overcoming of the use of restraints* in the context of the fostering of a general treatment culture that respects rights, taking action on the organisation models of the services and the training of personnel.

- *Use the evaluation instrument to foster innovation, introducing quality standards promoting non-restraint services and facilities.*

- *Pay the greatest attention, during cuts in healthcare and the social services, to maintaining and possibly increasing the diffusion and quality of the services aimed at more vulnerable subjects, insofar as being more exposed to being subjected to inhuman and degrading practices*.