Ethical considerations for evaluating the issue of physical restraint in psychiatry

Carlo Petrini

Address for correspondence: Carlo Petrini, Unità di Bioetica, Presidenza, Istituto Superiore di Sanità, Rome, Italy

Abstract
This article examines some of the ethical issues associated with the use of physical restraint in psychiatry and neurology. It offers no specific answers to individual operational problems, but a methodological matrix is proposed as an aid to experts in the various settings in which decisions are taken. The subject is addressed mainly by considering two sources: reference documents published by eminent organisations, and the theoretical framework of ethical values (or principles). A number of analytical criteria arising from these sources are then identified and proposed. The proposed criteria can be applied in cases for which the legitimate use of restraint may be an option, bearing in mind that restraint is an extremely serious affront to human dignity and is widely held to be of no therapeutic value. Its abuse is illegitimate in both ethical and legal terms.

Key words
• bioethics
• human rights
• mental health
• psychiatry
• physical restraint

INTRODUCTION
The practice of physical restraint in psychiatry and neurology is a matter of controversy. The present article attempts to propose a methodological framework and to stimulate reflection, in the hope of facilitating decision-making for experts in the different settings involved (clinical, legal, etc.). No answers are proposed for specific operational problems.

A glance at the literature shows that the Italian word “contenzione” (restraint), in common with the terms “constriction” in English and “contention” in French, has numerous meanings.

Physical restraint is a specific form of coercive measure. A broad definition of “coercive measure” proposed by the Swiss Association of Medical Sciences (ASSM) distinguishes between “limiting freedom” (“when restraint is limited to freedom of movement”) and “coercive treatment” (“when as well as limiting freedom a person’s physical integrity is also affected”) [1].

The literature on the bioethical and bioregal aspects of restraint in psychiatry addresses two main elements:
• the problem of abuse (which is both ethically and legally illegitimate);
• the requisites for legitimate use (in clinical, ethical and legal terms).

The present article focuses on the second element: specifically on the ethical requisites for permitting the use of restraint, bearing in mind that restraint is seriously detrimental to the dignity of the person and is widely held not to be of any therapeutic value [2, 3].

Before going any further it may be helpful to look briefly at the first of the two elements.

ABUSE: SOME INDICATIONS OF THE PROBLEM
On 16 October 2006 the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) released its annual “General Report on the CPT’s activities” [4]. Although not particularly recent, this document is interesting on account both of the respect due to the organisation that issued it and of the fact that it deals in particular with measures of restraint in psychiatric institutions for adults in various countries, including Italy. Subsequent Italian documents refer to the CPT’s report, including one published by the Conference of the Autonomous Regions and Provinces [5], which states, among other things: “the CPT’s opinion regarding practices of restraint is that they should not ordinarily be used in the care of psychiatric patients; they should be considered only in emergency situations – which should be prevented by every means possible, including by adapting conditions of care so as to deal with acute situations – and should be of minimum duration. Such measures should always be properly recorded, partly in order to demonstrate that the level of force applied does not exceed the violence it was intended to control”.

THE REQUISITES FOR LEGITIMATE USE
There are essentially two ways to approach this issue: by referring either to documents released by eminent organisations or to the theoretical framework of ethical values, or principles. The two are closely intersected, since the former necessarily refer to the latter.
Reference documents
Documents published by scientific associations, commissions and various national and international organisations are a highly useful source of inspiration when addressing questions of bioethics and biolaw.

The Council of Europe, under whose umbrella the CPT has published a number of documents, is one example. One such document is the Recommendation (Rec (2004)10) on “the protection of human rights and the dignity of persons with mental disorder”, adopted on 22 February 2004 [6], which was preceded by a consultation process based on a “White paper” [7]. This Recommendation (and particularly Chapter III concerning “Involuntary placement in psychiatric facilities, and involuntary treatment, for mental disorder”) identifies criteria for using involuntary treatment (e.g. the person’s behaviour must represent a significant risk of harm to him/herself or to others; the treatment should include a therapeutic purpose; no less restrictive therapeutic alternatives are available; the person’s opinion has been taken into consideration, etc.), for administering such treatment (e.g. the treatment should be proportionate to the person’s state of health; it should form part of a written protocol; it should be documented; it should aim to enable the earliest possible use of treatment acceptable to the person; etc.) and the rights that must be guaranteed (e.g. provision of information to the person and to his/her legal representative, right to communication and visits, etc.). Other more generic documents published by the Council of Europe also include principles that can be applied to restraint. Article 7 of the “Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine” states that “Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health” [8].

Another example is the “Report of the International Bioethics Committee of UNESCO (IBC) on consent”; a paragraph headed “Constrained individuals”, includes binding requisites for the conduct of clinical trials with persons with a mental disorder [9].

A further important document is the “Convention on the Rights of Persons with Disabilities”, adopted on December 6th, 2006. Article 14 reads as follows: 1) States Parties shall ensure that persons with disabilities, on an equal basis with others: a) Enjoy the right to liberty and security of person; b) Are not deprived of their liberty unlawfully or arbitrarily, and that any deprivation of liberty is in conformity with the law, and that the existence of a disability shall in no case justify a deprivation of liberty. 2) States Parties shall ensure that if persons with disabilities are deprived of their liberty through any process, they are, on an equal basis with others, entitled to guarantees in accordance with international human rights law and shall be treated in compliance with the objectives and principles of this Convention, including by provision of reasonable accommodation” [10].

The general consensus among such documents essentially amounts to a clear rejection of physical restraint. While leaving the specialists to deliberate on the clinical conditions in which it might possibly be admissible, the following paragraphs offer some reference criteria to help decide whether or not it is acceptable in ethical terms.

Ethical values
The conflict between values. The dilemmas posed by the use of restraint in psychiatry are an eloquent example of the conflict between divergent values (or principles) that are equally deserving of respect [11, 12]. It is obvious, for instance, that the well-known principles of North American bioethics proposed by TL Beauchamp and JF Childress (respect for autonomy, non-maleficence, beneficence, and justice) [13] are in conflict, and the difficulties posed by reconciling these contrasts are evident even in the reference texts, including regulations. Article 1 (d, e) of Italian Law no. 180 of 13 May 1978 on “Voluntary and compulsory health tests and treatments”, for example, states that: “In the course of compulsory health treatment the persons being treated have the right to communicate with anyone they think fit. Compulsory health tests and treatments pursuant to the above must be accompanied by measures aimed at ensuring the consent and participation of those being compulsorily treated” [14]. Clearly, it is “difficult to reconcile compulsion and consent” [15].

The North American principles of bioethics are widely accepted as a model, but are certainly not the only one. Numerous others have been proposed and each can be variously interpreted [16]. This is not the place to examine them all. Seen in a personalist light, the North American principles can be restated as: the principle of freedom-responsibility, the therapeutic principle, the principle of sociality-subsidiarity [17].

These principles can be considered as “prima facie” duties, in agreement with WD Ross [18] who, in seeking to reformulate the typical Kantian [19] deontological principle of ethics, drew a distinction between prima facie or conditional duties and actual duties. Prima facie duties are the primary principles of the moral life: self-evident, intuitive, instantly recognisable and imperative. Actual duties, on the other hand, are currently present or effective obligations. Prima facie duties should always be respected, though this may occasionally be impossible, mostly on account of conflicts between equally prima facie values. When this happens criteria must be found to decide whether or not a violation is justified. In the case of physical restraint it is obvious, for instance, that freedom (autonomy and informed consent) may conflict with therapeutic aims (beneficence) as well as with the duty to protect the patient from risk to him/herself or to others (justice). The same authors who defined the North American principles of bioethics also proposed a reference grid to help decide – where there is a conflict between principles – when a violation of
one or more of those principles is justified. According to TL Beauchamp and JF Childress, a violation may be justified provided that [13]:

- the moral goal that justifies the violation has a realistic chance of being achieved;
- the violation of an obligation is necessary in the specific circumstances, meaning that no other morally preferable alternatives are available;
- the violation is of as little significance as is compatible with achieving the goal;
- the agent attempt to minimise the effects of violation.

The principle of double effect. Another principle we can apply – albeit not too strictly – to the issue of restraint is the so-called “principle of double effect”, which comes into play when an act performed towards a good end (e.g. treatment, risk prevention, etc.) also has one or more undesired adverse effects (violation of the principle of autonomy, absence of consent, etc.).

The principle of double effect had already entered the philosophical and ethical stage at the time of the Scholastic philosophers [20]; it has been revisited and widely debated in recent decades [21].

Briefly, according to the “principle of double effect” an act that is performed with good intentions (such as therapy, risk prevention) but which also has harmful consequences (such as curbing freedom) is morally acceptable only if four conditions are met:

- the principal aim of the act, and the act itself, are good;
- the harmful effects are not intentionally pursued;
- the harmful effects are not the aim of the act and the good effect is not a direct cause-and-effect result of the harmful effect;
- the intended good effect is as great as or greater than the harmful effects and proportionate to them [22].

PRACTICAL SUGGESTIONS FOR DECISION-MAKING

In seeking to identify operating criteria, it may be useful to combine the two approaches mentioned above: the so-called “principles of bioethics” and institutional documents.

Autonomy (freedom)

Priority for less traumatic alternatives. In operational terms one of the ethical criteria that all the major institutional documents recognise as underlying any decision is the fact that restraint should be considered only as a last resort, when no less traumatic alternatives are feasible. This concept is reiterated:

- in documents dealing mainly with human rights. For instance the Council of Europe states this principle in Article 8 of “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” in the following terms: “Persons with mental disorder should have the right to be cared for in the least restrictive environment available and with the least restrictive or intrusive treatment available, taking into account their health needs and the need to protect the safety of others” [6].

The Council’s CPT allows the acceptability of restraint only “as a measure of last resort; an extreme action applied in order to prevent imminent injury or to reduce acute agitation and/or violence” [4]:

- in documents dealing chiefly with clinical aspects. The Swiss Academy of Medical Sciences, for example, suggests that “ordinarily (…) all possible measures to avoid coercive measures” should be examined. “Before adopting coercive measures, all other less radical therapeutic options that have some chance of success should be taken” [1].

Information. Physicians have an ethical duty to give information. This obligation is also valid for restraint, as well as for coercive measures in general. Clearly, this may not always be possible, particularly if a patient is not able to comprehend. In these cases information should be given later, if the patient recovers his or her mental capacity. The physician is also obliged to inform the patient’s family or legal representative, according to circumstances.

Beneficence (treatment)

Assessment of individual cases. In order to establish the proportionality (between the need for and the application of restraint), each case should be assessed individually and all relevant circumstances (e.g. age, mental capacity, etc.) should be considered.

Justice (solidarity and sociality)

Proportionality. The sole fact that the coercive measure is strictly necessary and cannot be substituted by less traumatic measures does not make it legitimate: it must also be proportionate to the level of danger.

Serious risk assessment. A distinction should be made as to whether the patient is a danger to himself or herself or to others, or poses a serious threat to the community. According to the Swiss Academy of Medical Sciences “coercive measures in response to a risk to the patient are acceptable only if the patient is incompetent [1].

Time limit. “When the emergency situation resulting in the application of restraint ceases to exist, the patient should be released immediately” [4].

FROM GENERAL PRINCIPLES TO THE NATIONAL CONTEXT

As already noted, an analysis of contingencies in facilities in which restraint is practised is beyond the scope of this article. Some mention has been made of the situation in Italy, but the above considerations are prevalently of a general nature.

The principal reason for this approach is the need not to stray into the territory of the other professional fields involved: it is not the bioethicist’s job to provide procedural regulations, but to put forward suggestions to help the experts and decision-makers in their task of identifying the most appropriate practical applications. To this must be added the complexity of the subject: it would be totally inappropriate for a bioethicist, in the short space of an oral contribution and a few pages of written summary to address the numerous operational aspects involved. In Italy these include, to name but a few: the imminent closure of forensic psychiatric
hospitals, originally scheduled for 31 March 2013 [23] but now re-scheduled for 1 April 2014 [24, 25]: the still unresolved and animated debate concerning Law 180/78 [14].

For all these problems legislation is the most important and binding reference, although particular situations may arise in which the regulations conflict with the duty to act in a patient’s best interest. The latter is, of course, an imperative in medical ethics. The International Code of Medical Ethics published by the World Medical Association is explicit: “A physician shall act in the patient’s best interest when providing medical care” [26]. Aside from the obvious problems of conscientious objection to specific medical practices, which are beyond the scope of this article, conflicts between regulations and professional obligations can arise, for example, when limits to the allocation of resources mean that some measures must take precedence over others. Psychiatry is a medical field in which possible tensions of this kind can become particularly acute. The American Psychiatric Association recognises that “a physician shall respect the law and also recognise a responsibility to seek changes in those requirements which are contrary to the best interests of the patient” [27].

There are numerous other respected documents, apart from legislation, that are essential (and in some cases binding) points of reference in different nations. Because these documents address both ethical and legal aspects they are an excellent aid to the correct contextualisation of such complex issues as restraint in psychiatry.

These documents can be grouped into three major categories. The following examples and quotations for each category refer to Italy.

**Ethical codes of the various professions involved.** Article 18 of the Code of Medical Ethics (headed “Treatments that affect psycho-physical integrity”) establishes that “Treatments that affect a patient’s integrity and psycho-physical resistance may be administered, once their therapeutic necessity has been ascertained, only for the purpose of procuring a tangible clinical benefit or of alleviating the suffering of the patient” [28].

**Declarations, treaties, conventions and similar documents signed by governments or approved by parliaments.** Through the Minister for Health, Italy is a signatory to the “Mental Health Declaration” adopted by the World Health Organisation on the occasion of the European Ministerial Conference on Mental Health held in Helsinki on 12-15 January 2005. Paragraph 8(vii) of this document obliges Health Ministers 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 protects them from neglect and abuse” [29] (the implications of this undertaking are described in the Report accompanying the Declaration [30]).

**Appeals, manifestos, open letters.** These are manifestations of public opinion and therefore occupy a very different level in comparison with the above two categories. They may nonetheless express highly useful recommendations by respected experts. As an example, Article 4 (“The veto on restraint and the control of pharmacological abuse”) of the “Manifesto-appeal for mental health” states that: “in the majority of Psychiatric Facilities for Diagnosis and Treatment patients are bound, doors are kept locked, massive doses of psychoactive drugs are administered as the only response to the complex nature of the suffering and needs of patients. Restraint is an explicit violation of human rights, as it impairs the freedom and dignity of the person. The prohibition of restraint and the opening of doors in healthcare facilities should be among the quality goals of health services” [31].

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