

Restraints and seclusion in psychiatry: striking a balance between protection and coercion. Critical overview of international regulations and rulings

Contenzione e isolamento in psichiatria: stabilire un equilibrio tra protezione e coercizione. Panoramica critica di regolamentazioni e sentenze internazionali

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SUMMARY. Restraint and seclusion (R&S) measures in psychiatric settings are applied worldwide, despite poor scientific evidence to back up their effectiveness. The medical, ethical and medico-legal implications of coercive interventions are broad-ranging and multifaceted. The review aims to shed a light on the most relevant and meaningful standards that have been laid out by international treaties, supranational institutions (United Nations, Council of Europe, World Health Organization), scientific institutions (American Medical Association, Australian Department of Health), legislative bodies and courts of law. Several court cases are herein expounded upon, with a close focus on meaningful analysis, decisions and conclusions that have laid the groundwork for a different, more restrictive and more clearly defined approach towards R&S imposed upon psychiatric patients. It is reasonable to assume that changing norms, civil rights enforcement, court rulings and new therapeutic options have influenced the use of R&S to such an extent that such measures are among the most strictly regulated in psychiatric practice; health care providers should abide by a strict set of cautionary rules when making the decision to resort to R&S, which must never be put in place as a substitute for patient-centered therapeutic planning. Case law shows that R&S should only be weighed in terms of their effectiveness towards therapeutic goals. Being able to prove that R&S was employed as part of a therapeutic path rather than used to maintain order or to exact punishment may go a long way towards shielding operators against negligence lawsuits and litigation.

KEY WORDS: restraint and seclusion, psychiatric patients, guidelines, medical liability.

RIASSUNTO. Le misure di contenzione e isolamento in contesti di cura psichiatrica vengono applicate a livello mondiale, nonostante l'insufficienza di evidenza scientifica che ne suffraghi la validità. Le possibili implicazioni cliniche, etiche e medico-legali derivanti da tali misure coercitive non sono trascurabili e presentano molteplici complessità. La presente rassegna è stata concepita con il proposito di fare luce sui criteri e i parametri più significativi elaborati e sottoscritti da trattati internazionali, istituzioni sovranazionali (come l'Organizzazione delle Nazioni Unite, il Consiglio d'Europa, l'Organizzazione Mondiale della Sanità, ecc.), società scientifiche (American Medical Association, Australian Department of Health), enti legislativi e Corti di Giustizia. Gli autori illustrano diversi casi giudiziari, discutendo gli aspetti più significativi, le decisioni e le conclusioni che hanno aperto la strada a un approccio diverso, più restrittivo e più chiaramente delineato nei confronti delle misure di contenzione e isolamento che colpiscono pazienti psichiatrici. È ragionevole dedurre che i mutamenti legislativi, una maggiore attenzione nella salvaguardia dei diritti umani, le sentenze giudiziarie e le nuove opzioni terapeutiche siano tutti fattori che abbiano contribuito a influenzare l'incidenza e l'applicabilità delle misure di contenzione psichiatrica a un livello tale che, oggi, tali interventi risultano essere fra i più rigorosamente regolamentati nella pratica psichiatrica; gli operatori sanitari devono attenersi a precise regole cautelative quando decidono di ricorrere a tali interventi, i quali non devono mai essere impiegati al fine di sostituire una adeguata pianificazione terapeutica individuale. La casistica giudiziaria mostra come contenzione e isolamento debbano essere ponderati sempre nell'ottica del perseguimento degli obiettivi terapeutici; la capacità di comprovare e documentare che le misure contenitive siano state adottate nella dimensione di un percorso terapeutico, e non a fini punitivi o di "mantenimento dell'ordine", nel rispetto delle linee guida e delle buone pratiche assistenziali, può giocare un ruolo fondamentale nel mettere al riparo gli operatori e le strutture sanitarie da accuse di malpractice e conseguenti contenziosi.

PAROLE CHIAVE: contenzione e isolamento, pazienti psichiatrici, linee guida, responsabilità medica.

INTRODUCTION

Restraint and seclusion (R&S), whether physical or pharmacological, are a common, and at times valuable, tool in psychiatric settings. Yet whether, when and how to use them is a complex and multifaceted issue. Principles of ethics may often come in mutual conflict in those instances where patients have to be physically restrained¹. Particularly, the core principles of justice, autonomy, beneficence and non-maleficence all come into play. Non-maleficence, for instance, which means “do no harm”, requires health-care providers to reconcile therapeutic goals with possible side effects. Still, bodily restraint may give rise to physical injuries (skin injury, nerve system damage, pulmonary disease, deep vein thrombosis, or even death) and psychological trauma (demoralization, fear, anger, and the loss of dignity, apathy and depression)². Applying restrictions to a given patient is bound to affect an individual’s right to self-determination (thus the principles of justice and autonomy), human rights, as well as the ethical responsibilities of mental health care providers and staff³. Broadly speaking, everyone is entitled to life, personal liberty, security and physical integrity and psychiatric patients are no exception, as stated in the UN Convention on the Rights of Persons with Disabilities (UN-CRPD), which was adopted by the Nations General Assembly in 2006 and has been ratified by 159 states. That being said, there are certain situations in psychiatric care in which patients have to be hospitalized, committed and treated against, or irrespective of, their will. Violent and aggressive tendencies, possibly harmful to the patients themselves or others, are the most widespread and acceptable reason warranting restrictive measures such as involuntary admission, forced medication, use of R&S⁴, which are arguably the harshest among such measures. It is worth noting, however, that the clinical effectiveness of R&S in reducing or alleviating patients’ aggressive behaviour or serious mental disorders is not yet fully supported by available scientific evidence. Verbal de-escalation strategies should always be attempted before deciding to use of any form of restraint. When it comes to resorting to restraint, there is widespread agreement on a few core criteria; they must be used:

- as a last resort only, when it is absolutely necessary to protect the patient’s or others’ safety, after attempts at de-escalation have failed;
- as safely as possible;
- with respect for the patient’s human dignity;
- under constant medical supervision.

Furthermore, it is essential that any restrictions be applied, whenever possible, within a context of mutual understanding between the patient and the staff. Medical and nursing ethics both greatly value respect for patient autonomy and dignity by prioritizing choice over paternalistic approaches: Thus, staff members strive to build a solid, trust-based therapeutic relationship with their patients, to be perceived as a fundamentally ethical, well-balanced relationship between nurses and physicians and patients⁵. This relationship can be undermined by the choice to use of R&S, and it is often hard to weigh the best interest of patients against that of other people. A dearth of evidence-based, broad-ranging practices and guidelines adds to the pressure, conflict

and ethical dilemmas among health care operators⁶. Striking a balance is of utmost importance, since it is obvious that the use of restraint and the common ground between security and ethics pose still unsolved dilemmas in clinical psychiatry. All the legal, ethical and clinical issues related to professional identity, and the role of the therapeutic relationship, call for exploration, development and implementation of alternative ways to treat aggressive behaviour⁷⁻¹⁰. Obviously, therefore, limitations need to be put in place, based on solid and well-grounded guidelines to provide standards. As shown in several studies, restraints may frequently turn out to be counterproductive or traumatic to patients. R&S are therefore limited by law in most countries, and a wide array of recommendations and professional guidelines have been devised to regulate their use¹¹.

MEDICAL SOCIETIES AS WELL AS INTERNATIONAL INSTITUTIONS WEIGH IN AND LAY OUT VALUABLE CRITERIA

An opinion from the American Medical Association appears to be particularly significant in that respect; according to AMA, in fact, restraining patients is sometimes warranted, but never “punitively”, “for convenience” or to offset staff shortages; it is paramount that individuals be free from unreasonable bodily restraint, except when patients are at risk of harming themselves or others. In such situations, the use of chemical or physical restraint to protect the patient may be ethically justifiable. Patients should be restrained only on a physician’s explicit order, except for emergencies, and never punitively, for convenience, or as a way to offset understaffing¹². Furthermore, physicians should use best professional judgment to determine whether restraint is clinically indicated for the individual patient; moreover, the patient’s informed consent to the use of restraint is necessary, or, should the patient lacks decision-making capacity, the consent of the patient’s surrogate¹³.

A truly informed consent necessarily requires the thorough provision of key information, among which:

- the reason why restraint is recommended;
- what type of restraint will be used;
- length of time for which restraint is intended to be used, which is meant to prevent an arbitrary and unaccounted for use of such restrictive measures.

Documentation plays a key role as well: the need for R&S should be regularly reviewed and documented in the patient’s medical record, along with the resulting decision.

Even though restraint is ultimately deemed necessary, the least restrictive restraint reasonable should be implemented and it should be removed promptly when no longer needed.

In that regard, recommendations from supranational bodies while not legally binding, have moral value and constitute a well-defined frame of reference.

Both the United Nations and the Council of Europe have issued their specific recommendations as to the use of medical restraint and seclusion in psychiatry. According to Principle 11 of the UN General Assembly patient dignity is paramount, and that is fully reflected in its wording: «Physical restraint or involuntary seclusion of a patient shall not be em-

ployed except in accordance with the officially approved procedures of the mental health facility and only when it is the only means available to prevent immediate or imminent harm to the patient or others [...]. Hence, every instance of restraint or seclusion, the needs for them and their length must be thoroughly documented in the patient's medical record; patients must be kept under humane conditions, and constantly supervised»¹⁴. Similarly, The Council of Europe issued a recommendation in 1977 that stressed the need for legal protection of mental patients, followed by one dealing with the rights of a patient detained for involuntary treatment in 1983, one more recommendation on psychiatry and human rights in 1994, and the most recent one in 2004^{15,16}. In accordance with the UN General Assembly, the Council of Europe introduced special Article 27, regulating the use of seclusion and restraint: «Seclusion and restraint should only be used in appropriate facilities, and in compliance with the principle of least restriction, to prevent imminent harm to the person concerned or others, and in proportion to the risk entailed [...]». Those fundamental principles have been reaffirmed by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), in a set of revised standards¹⁷. In order to further develop the UN General Assembly Resolution, the World Health Organisation (WHO) issued The Resource Book on Mental Health, Human Rights and Legislation in 2005, aimed at providing guidance for mental health legislation worldwide.

With regards to medical restraint and seclusion, such guidelines outline several foundational precepts¹⁸. Specifically, the WHO points out that national pieces of legislation are needed to make sure that such measures are used as a last resort, meant to avert harm and hazard to patients or third parties, for as short a time as possible; moreover, they should never be implemented for punitive purposes nor for the comfort of the health care staff; hence, the use of restraints and seclusion in mental health facilities ought to be discouraged by targeted sets of norms. In order to facilitate this, countries will have to develop their mental health infrastructure, restraints and seclusion overuse or abuse is in fact often ascribable to a lack of resources, which encourages staff to unduly use these interventions.

Plus, one period of seclusion and restraint should not be followed immediately by another, and an ongoing active and personal contact with the person subject to R&S is to be fostered, which goes beyond passive monitoring and towards effective deescalation¹³. Besides, staff training is of utmost importance for the ultimate purpose of reducing the need for restraint to a minimum. A comprehensive and full understanding of mental illnesses and their manifestations relative to behavioral dynamics is essential for staff who work with difficult patients. In fact it can foster the tailoring and honing of therapeutic paths to best meet the needs of every single patient¹⁹.

Article 11 of the already mentioned 2005 Resource Book on Mental Health, Human Rights and Legislation, in fact, deals with professional standards and stresses the importance of appropriate training of staff on «measures to avoid the use of restraint and seclusion» and «the limited circumstances in which different methods of restraint or seclusion may be justified, taking into account the benefits and risks entailed, and the correct application of such measures». An-

other important perspective is provided by the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), which was meant to ensure enforcement of Article 3 of the European Convention on Human Rights, according to which «no one shall be subjected to torture or to inhuman or degrading treatment or punishment»²⁰. The Conventions also address the use of seclusion and restraint in the clinical practice of psychiatric in-patient treatment. Most Council of Europe member states have ratified the CPT, by which overseeing authorities have the power to conduct inspections in member states for the purpose of verifying compliance. Several violations have thus been reported in clinical psychiatric practice. Recently, following one of its three meetings (held in March 2017), the CPT released a new set of standards on use of restraints in psychiatric institutions. The CPT sets out the basic principles regarding the use of restraint measures, and recommends that they be the subject of comprehensive protocols in all psychiatric establishments²¹. Several key points have been laid out by the CPT, among which:

- every psychiatric establishment should have a comprehensive, carefully developed policy on restraint;
- the involvement and support of both staff and management in elaborating the policy is essential. Such a policy should ultimately be aimed at:
 - preventing as far as possible the resort to means of restraint;
 - clarifying which means of restraint may be used;
 - specifying under what circumstances they may be applied;
 - outlining the practical means of their application, the supervision required and the action to be taken once the measure is terminated.

All sets of policies should also include sections on other important issues such as staff training, recording, internal and external reporting mechanisms, debriefing, complaints procedures.

As far as the Italian state of affairs is concerned, in terms of restraint and seclusion policies in psychiatric facilities, the CPT report has examined the situation of forensic psychiatric patients, pointing out that after the closure of judicial psychiatric hospitals (OPGs), improvements have been made in terms of treatment and care in the new Residenze per l'Esecuzione delle Misure di Sicurezza (REMS); still, several deficiencies were also noted at some facilities undergoing conversion into REMSs. The issue which is somewhat complicated by the fact that psychiatric institutions come under the responsibility of the respective region in which they are located²².

A relevant opinion and recommendations were issued by the in 2010²³ by the Conference of Italian Regions and Autonomous Provinces, which stressed that preventing violent conduct is vital in psychiatric settings, and R&S needs to be assessed not from a merely medical perspective, but from a legal-constitutional one too; such practices, in fact, may entail a disregard for the Constitutional principles that enshrine respect for personal freedom, human dignity and health as fundamental rights²⁴. An official report from the Assembly is meaningful in terms of gauging progress made in Italian psychiatric institutions by each region: the regions and provinces that have put in place regional directives along the lines of

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the 2010 conference indications are Trento, Friuli-Venezia Giulia, Lombardy, Emilia-Romagna, Puglia, whereas Tuscany and Umbria have codified the indications, yet do not pursue regular oversight. Val d'Aosta, the Autonomous Province of Bolzano, Piedmont, Veneto, Liguria, Marche, Latium, Molise, Campania have not yet issued formal directive at the regional level, although they did adopt procedures freely inspired by the 2010 recommendations. Finally, four regions have not yet taken into account the directives, nor have they autonomously enacted new ones along those lines: Abruzzo, Basilicata, Sicily (with the exception of the Ragusa province), Sardinia²⁵.

NOT ONLY MORAL AND ETHICAL IMPLICATIONS: R&S IS CONTROVERSIAL FROM A MEDICO-LEGAL STANDPOINT TOO. INNOVATIVE LEGAL ELEMENTS SURFACE

A recent ruling from Germany's Constitutional Court in Karlsruhe has brought the controversial nature of restraint and seclusion of psychiatric patients to the forefront. It has also proved how inpatient psychiatrists face ever more intense scrutiny and pressure from regulatory agencies to reduce the use of R&S. On July 24th 2018, in fact, the Court ruled that psychiatric patients may not be restrained for more than 30 minutes without a court order²⁶.

Judges have ordered Germany's 16 Länder to amend their laws so that they comply with federal guidelines. Only the states of North Rhine-Westphalia and Lower Saxony currently require a court order before patients can be restrained. Moreover the ruling reinforces some key principles espoused by international health care institutions and regulatory bodies, recommending that restraining patients can only be used as a "last resort" and only in instances in which a patient poses a threat to themselves or others, patients must also be supervised during the entirety of their restraint and not simply left alone; patients may not be restrained due to lack of personnel. In addition, mental health care facilities will be required to attain a court order before restraining a patient, or to do so retroactively, should they be unable to do so ahead of time. Previously, some states allowed doctors to order the restraint of patients on their own. Interestingly, only in cases in which a patient is restrained for less than 30 minutes can such a decision be made without the need for a court order. The legal prerogatives of patients cannot be overlooked, and they must be informed of their right to challenge the validity of the order. In the view of the Court, the key distinction between restriction of liberty and deprivation of liberty cannot be disregarded: German Basic Law, in fact, protects against both. However, German case-law draws a difference between the two, taking into account the intensity of the interference. Any act may constitute a "restriction" of liberty if it keeps somebody from going anywhere (which would otherwise be accessible to them) or forces them to stay confined against their will within a given place by public authority. The "deprivation" of liberty, on the other hand, constitutes the harshest form restriction, in that it takes away from the patient the freedom of movement altogether, which would generally be enjoyed under normal factual and legal circumstances. The restraining measure, in such cases, goes

beyond short-term, and has a high degree of invasiveness and intensity.

The Court's remarks are particularly telling in that regard. It goes on to enunciate that the use of five-point or seven-point restraints, which entails that all limbs of the person concerned are strapped to a bed, constitutes a deprivation of liberty within the meaning of German Basic Law, unless it is only applied for a short period of time. Short-term application is to be presumed when the restraining measures will predictably be kept on for no longer than approximately half an hour. If the patient involved is strapped to the bed by way of five-point or seven-point restraints, their freedom of movement has been completely taken away from him or her, and so has the freedom to move within the closed psychiatric ward, or at least within the respective patient room; such a form of restricted freedom had still been available while they were confined in a psychiatric hospital, and it is totally taken away by the restraining measures: such a kind of physical restraint is in fact put in place in order to keep the patients in their hospital beds, as they are rendered completely unable to move. Moreover, as the Court stated, additional authority is to be required for total physical restraint, especially for an extended period of time, which indisputably constitutes an additional deprivation of liberty, even in cases where the individual is lawfully detained²⁷. Overall, in Germany, the Court's ruling was well-received overall. Arno Deister, President of the German Society for Psychiatry and Psychotherapy, Psychosomatic and Neurology (DGPPN), called the decision heartening, stating that «it creates clear, long overdue rules that apply to all». Critics, however, contend that the decision somehow falls short. Martina Heland-Graef, a representative from the Federal Association of Psychiatry Experienced (Persons), criticized the Karlsruhe ruling, pointing to the need for more far-reaching, broader-ranging decisions, going so far as denouncing the verdict as a legalization of R&S, characterized as torture by the United Nation Human Rights Convention²⁸.

A case brought before the European Court of Human Rights (ECHR) in 2012 by British national Colonel Munjaz further sheds a light on the criteria and standard procedures that should be complied with when imposing restrictions on mental patients' liberty²⁹. Munjaz, who was born in 1947, was a long-term patient at Ashworth Special Hospital, a maximum security hospital, where he had been admitted for the first time in 1984. Even when he was not in seclusion, the patient was already imposed greater restrictions on his liberty than an average a mental health patient would have been. Munjaz made the case that his seclusion amounted to a further, harsher deprivation of liberty that was not prescribed by law; also, the right of review or appeal to an independent body had allegedly been taken away from him. Significantly, the Court held that whether there was a further deprivation in respect of someone who was already detained would depend on the circumstances (paragraph 65). The standards for the determination of their concrete situation (such as the type of measures, their duration, effects, and way of execution) "must apply with greater force" when the person was already detained (paragraph 67). As for Article 8 of the European Convention on Human Rights³⁰, the Court established that the seclusion was tantamount to an interference within the scope of Article 8. The applicant's mandatory seclusion did in fact interfere with his physical and psycho-

logical integrity under the precepts codified in Article 8. However, the seclusion was upheld on the basis that it was “in accordance with the law” under Article 8, which allows interferences as long as they are warranted and proportionate («except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety...»). The Court held that the Policy on seclusion met the requirements of the “quality of law” test as set out in the Court’s case law on Article 8. The policy implemented by the hospital, in fact, was reasonably accessible and predictable, since it was formulated with an adequate degree of precision so as to enable patients to adjust their behavior. The administration of public health, the ECHR pointed out, requires a degree of flexibility: the policy was ultimately aligned with the law, not being unforeseeable or arbitrary³¹. In addition, since the applicant was as a patient already subject to lawful restrictions on his liberty, Article 5 of the ECHR (right to liberty and security) could not apply either, as the seclusion did not entail a further deprivation of liberty. The basis for that decision was the way in which the applicant was secluded: he was in fact able to enjoy long periods of association; only one day was found when he was not allowed any association whatsoever³².

In the United States, regulatory activity and scrutiny of R&S have been significantly stepped up, on the heels of a damning exposé of R&S-related deaths in the 1990s from the Hartford Courant; the inquiry confirmed 142 deaths during or shortly after restraint or seclusion in mental health or mental retardation facilities all across the United States over the past 10 years. Yet, the paper suggested, on account of many cases going unreported, the real number of casualties could be as high as 1,500 over the course of the past decade, as shown by statistical estimates^{33,34}.

THE EVER-GROWING NEED FOR HARMONIZED, MORE EFFECTIVE GUIDELINES

As more patients with mental disabilities are moved from public institutions into smaller, often private facilities, the need for uniform standards and stronger oversight is ever more pressing. As a result of that, reports and policies calling for the reduction and regulation of R&S have been released by various agencies, including the Joint Commission (TJC), the American Psychiatric Association (APA)³⁵, the American Hospital Association (AHA)³⁶, the National Mental Health Association (NMHA)³⁷, the American Psychiatric Nurses Association (APNA)³⁸, the Substance Abuse and Mental Health Services Administration (SAMHSA)³⁹, and the US General Accounting Office (GAO)⁴⁰. Furthermore, new rules were released by the Centers for Medicare and Medicaid Services (CMS) in 2007 prohibiting the use of R&S as a means to restore order in a ward, encouraging less restrictive standards⁴¹. New guidelines were also outlined for the purpose of training hospital employees who order restraint or seclusion and define requirements for reporting R&S-related fatalities. In an attempt to deal with concerns about improper R&S use, the final set of regulations emphasizes and strengthens the staff training standards, clarifying all various aspects relative to training⁴². Plus, it broadens the category of health care operators who are authorized to car-

ry out patient assessment prior to and following the implementation of R&S measures. CMS rules currently call for a “face-to-face” patient evaluation within an hour of a patient being restrained or secluded for the prevention of risks arising from violent or self-harming conducts. Before the new rule was adopted, such initiatives needed to be reviewed within that hour by a doctor or “other licensed independent practitioner (LIP)”. The regulatory update thus broadens that list, which now comprises trained registered nurses or doctor assistants. Still, in cases of nurses or doctor assistants performing an evaluation, the physicians or other LIP treating that patient must be notified and consulted as soon as possible. The basic rights specified in the regulation include a patient’s right to notification of his or her rights concerning their care, privacy and safety, confidentiality of their records, and freedom from the inappropriate use of all restraints and seclusion, in all hospital settings.

In 2008, CMS published a revised set of interpretive guidelines for R&S, which require face-to-face examination by a physician, nurse, or physician’s assistant within one hour of placement in restraints or seclusion. The revision also offers valuable guidance about staff training requirements⁴³.

Along the same lines, a 2005 assessment from the Australian Department of Health has highlighted critical areas need to be addressed, among which a lack of identified good practice/agreed clinical standards for the use of restraint and seclusion; no national standards on appropriate use of seclusion currently exist; the inappropriate use of interventions and variation in practice, e.g. threatening to use restraint or seclusion in order to coerce particular behaviour; known adverse events associated with use of restraint and seclusion need to be further investigated⁴⁴.

RECENT DEVELOPMENTS: THE DANISH SUPREME COURT RULING AND THE FIRST CLASS ACTION LAWSUIT AGAINST R&S

More recently, the Danish Supreme Court has contributed to clarifying the standards that must be met when applying R&S to potentially dangerous patients. In a ruling issued on 31st January 2017 (case “A”, the patient, vs. Capital Region of Denmark) the Court asserted that the physical restraint imposed upon the patient amounted to violation of Article 3 of the European Human Rights Convention and awarded him compensation of DKK 75,000 (10,049.48 €).

A had been sentenced and involuntarily committed for acts of serious violence and abuse, rape and deprivation of liberty and transferred to the psychiatric hospital Psykiatrisk Center Sct. Hans to serve that sentence. During his stay there, A, who suffered from paranoid schizophrenia, acted threateningly and was often violently aggressive to other patients. His behaviour was regarded as “unpredictable”, according to the medical information provided. Eventually, in the summer of 2013, A was physically restrained to his bed. The illegality of his restraint, which lasted 18 days, was undisputed in the trial. In the autumn of 2013, A was committed to the maximum-security forensic psychiatric facility in Nykøbing Sjælland after it was found that he still posed a serious and imminent danger to others. In the determination of compensation, the Supreme Court asserted that unlawful

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physical restraint for 18 days was a serious infringement of A's rights. However, it needed to be taken into account that the doctors at Psykiatrisk Center Sct. Hans had assessed on a regular basis whether the conditions for continuing physical restraint of A were met, and that such evaluations had proved extremely difficult to make, in light of A's mental issues and unpredictable behaviour. Hence, even though the Danish Justices ultimately conceded that R&S may amount to a violation of human rights, but also pointed out that a medico-legal assessment may prove quite challenging and controversial⁴⁵.

A very recent case from California, United States, has further highlighted the daunting complexities inherent to R&S use, especially when minors are involved. In May 2019, four special education students and their parents or guardians sued the state of California, claiming to have been illegally put in restraint holds and secluded during behavioral interventions at their Concord school, a public school that offers special education services and integrated counseling to 85 children with emotional and behavioral disabilities. The class-action suit, which alleges battery, negligence and civil rights violations, named the California Department of Education, the Contra Costa County Office of Education and staff members at the school as defendants⁴⁶. The plaintiffs blame state officials for their alleged failure to monitor and supervise the use of restraint and seclusion as behavioral interventions. It also claims school and state officials violated the rights of students forced to sit in seclusion, thus preventing them from accessing basic educational services. The lawsuit also cites the death of Max Benson, a 13-year-old boy with autism who died in November 2018 while in a prone restraint at Guiding Hands School, a school in El Dorado Hills certified by the state to provide special education services. A prone restraint involves one or more adults holding a child face down on the floor. California regulators found that the school had violated restraint rules and revoked its certification in January, according to the Sacramento Bee newspaper. The California Department of Education has found "sufficient evidence" that staffers at Guiding Hands School in El Dorado Hills had violated multiple state rules governing how and when physical restraints can be used on students.

The Department of Education's own preliminary investigation (still ongoing) found that:

- the staff used an emergency intervention to counter non-emergency, predictable behavior;
- an emergency intervention was used as an improper substitute for the minor's behavioral intervention plan (BIP), which is designed to change, replace, modify or eliminate a targeted behavior;
- the intervention was drawn out for longer than necessary and applied with a degree of strength that was «not reasonable and necessary under the circumstances»;
- the school staff's actions also failed to take into account Max's individualized education program, or IEP, which called for specific intervention strategies that were not used, the letter says⁴⁷.

A recently enacted California assembly bill seems to have been modeled along the lines of the recommendations and guidelines that we have extensively discussed, except that it focuses on R&S on special needs students. The law basically

covers all critical aspects of R&S, stressing that "There is no evidence that restraint or seclusion is effective in reducing the problem behaviors that frequently precipitate the use of those techniques"⁴⁸.

KNOWLEDGE AND AWARENESS ARE KEY IN AVOIDING EXPOSURE TO MEDICO-LEGAL REPERCUSSIONS AND LIABILITY

Physicians and other health care operators who take it upon themselves to deprive someone of his/her freedom, take on a "fiduciary responsibility." A fiduciary is similar to a parent, guardian, or prison. It is a relationship based on accountability for the patient's health and well-being.

Liability and responsibility for monitoring a patient after he or she has been restrained are of paramount importance and should be at the forefront of health care providers at all times⁴⁹.

As a matter of fact, improperly imposed R&S are legally hazardous, possibly exposing operators to charges of battery (not necessarily causing physical harm, but damaging the patient's dignity is enough to have to answer for it in court), false imprisonment (intentional infliction of a confinement, which is warranted only when the patient is deemed incompetent and a danger to himself or someone else).

Besides, multiple areas of medico-legal risk come to the fore when providing care for an agitated patient in emergency medicine; medical and nursing staff ought to weigh special measures for the patients who are at a higher risk for being restrained⁵⁰. More frequent visits and better training for both patients and staff could help reduce the need for physical restraints in such individuals⁵¹. Two obligations need to be borne in mind: a thorough, solid assessment of competence/consent (physicians have a duty to evaluate the patient's ability to consent) and the duty to protect (if restraints are placed, doctors have a constant duty to protect the patient and should fill out all necessary forms, reflecting why they have decided to take away the patient's liberty). Therapeutic planning and quality improvement in mental health facilities must be prioritized over mere regulations. As it is apparent to anyone familiar with the issues at play, attempts to reduce or eliminate R&S by means of regulation alone are likely doomed to fail in producing long-term, lasting benefits and changes in the psychiatric therapeutic setting. We believe that sensible strategies and blueprints aimed at improving and fine-tuning how treatment is delivered (through individualized treatment plans, for instance) are ultimately far more effective than mere attempts to devise and to impose compliance with a given set of strict regulations. Multiple court cases back up the conclusion that practicing emergency physicians must be familiar with provisions as to R&S for psychiatric patients, and should be able to prove that the treatments carried out were in adherence with recommendations and guidelines issued and updated by national scientific societies or facilities, (or, in absence of those, by international institutions), and accreditation standards⁵². Such compliance needs to be provable in a court of law. Any failure to abide by guidelines, recommendations and best practices can likely lead to operators being held liable and charged with malpractice, resulting in litigation.

The considerations above are clearly extensible even to the psychiatric populations once committed in judicial psychiatric hospitals and now assisted at REMS (residenze per l'esecuzione delle misure di sicurezza)⁵³ and charged with malpractice, resulting in litigation.

Ultimately, patient restraint must be viewed a means to a therapeutic end, never an end in itself: in order to be legally sound, R&S should only be considered and resorted to within the context of therapeutic goals. Thoroughly documenting that the health care team has weighed R&S as part of a therapeutic intervention (rather than used them to maintain "law and order" or to exact punishment) can shield operators from claims that R&S were used in an unorthodox, possibly unlawful fashion⁵⁴.

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