

CHAPTER 4

Forced immobilization ('Restraint') during medical procedures in young children

An ethical and legal investigation of a common practice

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Submitted

Abstract

It is frequently the case that children need to be physically restrained in order to allow medical procedures to be carried out. It is safe to assume that restraint is part of daily practice in the provision of medical care to children. However, the use of restraint in sick children raises important objections.

This paper lists the objections and summarizes the relevant scientific literature and available guidelines on this topic. The use of restraint is tested against ethical and legal considerations in the field of health care. The decision on whether to apply restraint must be approached from the perspective of the quality of care. All patients, including children, are entitled to good medical care. In non-lifesaving conditions, healthcare professionals facing the need for procedural restraint of an individual child must firstly consider all possible alternatives and next, choose the best option. The use of restraint is only acceptable if it is unquestionably the best alternative.

Introduction

For medical procedures that require the patient to sit or lie still, young children often need help. By using a certain level of force, health professionals can achieve or support the necessary level of immobility. In literature, this action is called ‘therapeutic holding’.¹ It is nevertheless not uncommon for children to resist this, because they experience the procedure as frightening and/or painful. If a necessary procedure threatens to go wrong as a result, the decision may be taken to restrain the child, thereby physically forcing it to undergo the procedure. This method is known in literature as ‘restrictive physical intervention’ or simply ‘restraint’.¹

The application of *restraint* probably forms part of day-to-day paediatric care (table 1). The practice of applying restraint nevertheless faces a number of objections. By applying restraint, the professional consciously acts counter to the child’s wishes. Since the procedure (for which restraint is applied) is after all in the child’s interest, a difficult dilemma ensues: does the child’s medical interest warrant ignoring or overpowering the child’s resistance? In acute life-threatening situations, it seems only natural to protect a non-cooperative child against itself and to force it to undergo necessary procedures. But what about procedures that are less urgent? Is it acceptable under such circumstances to restrain a child if better alternatives are available (table 2) and moreover if it is unlikely that a temporary delay of the treatment (in anticipation of applying the alternative) would adversely affect the child?

Table 1: Possible grounds for restraint during medical procedures in children

The procedure threatens to go wrong because the child is not cooperating and/or resisting a procedure which is experienced as very painful and/or frightening by the child.
The child's capacity for understanding is insufficient, as a result of which: <ul style="list-style-type: none">it is impossible to give an explanation of the required medical procedure;the child is not susceptible to distraction techniques.
The child risks hurting itself by resisting the procedure.
The procedure lasts longer or is much more painful than the child had understood.
The professionals concerned have insufficient time or patience to look for alternatives.
The procedure is considered as so urgent or crucial to the child's treatment that it is impossible to consider comfort-enhancing measures.
Insufficient information for and preparation of the child and its parent(s) or guardian(s)
Insufficient use of distraction techniques and local sedation.
Inability to use or absence of an effective technique for procedural sedation and/or analgesia (PSA).

A young child that cannot yet understand the significance and objective of a specific treatment is unable to refuse or accept such treatment. It can nevertheless be aware of (the threat of) an impending treatment and understand the situation *to that extent*. Does the child have any right to stand up for its own will and - more importantly - how should a health worker deal with that right, if it exists?

Lastly, it is important to note that restraint is not a standard part of a medical treatment, but in fact a separate, additional treatment. Should a professional applying restraint therefore have a demonstrable competency for it, and should restraint be specified in protocols, partly for the same reason? Should the application of restraint be recorded in the patient’s notes and, also important, should it be preceded by a fully *informed consent*, including an offer of alternative options?

Table 2: Measures and provisions to optimize procedural comfort

Strategy	Examples
Preventive measures	Avoid superfluous procedures. Only allow an experienced professional to carry out procedures. Agree a maximum number of attempts at the procedure in advance. Early insertion of a central venous line under general anaesthesia (for example, during long-term treatment with intravenous antibiotics).
Optimal local and topical anaesthesia	Allow sufficient time for topical anaesthesia to become effective (for example, at least 60 minutes for EMLA®). Apply topical anaesthesia to the correct location. Implementation of new topical anaesthetic techniques. ¹⁸ For infiltration with lidocaine: buffer lidocaine with bicarbonate and use the smallest possible needle to significantly reduce the pain upon infiltration. ¹⁹
Non-pharmacological techniques	Optimal positioning of the child. ²⁰ Presence of the parent(s) or guardian(s). Preparation, game therapy. Distraction techniques and hypnosis.
Ready availability of effective Procedural Sedation and/or Analgesia (PSA)	Light sedation for 'small' procedures (e.g. blends of nitrous oxide and oxygen). Deep, titratable sedation for very painful procedures (e.g. propofol). Professionals trained in PSA.
Rescue Anaesthesia	Availability of anaesthesia if other techniques appear or turn out to be ineffective or unsafe.

Restraint in medical literature

In 2007, Brenner summarized the literature on this subject. She pointed out a lack of research and concluded that this demonstrates that medical professionals tend to ignore the existence and relevance of restraint or consider it a taboo subject.² Various authors argue for more research, to shed light on medical grounds, age-related techniques, alternatives, required training for professionals, and the ethical and legal framework.³⁻⁸

In a few publications, restraint (in terms of the effects it has) has been associated with speech and language problems, a negative self-image, fear of and distrust of medical care, and with post-traumatic stress disorder.² According to paediatric nurses, restraint is more traumatic for a child than the treatment itself.⁹ Longitudinal research with leukemia patients has shown that any participation by parents in restraint has a negative effect on the relationship with their child.¹⁰

Existing guidelines on restraint

The guideline 'Safe sedation of children undergoing diagnostic and therapeutic procedures' from the Scottish Intercollegiate Guidelines Network calls restraint during a procedure that is not life-saving unacceptable.¹¹ A recent British guideline for paediatric nurses states that restraint must only be used to prevent serious injury to the child or to bystanders. According to this guideline,

restraint must meet a number of basic principles, including the prevention of unnecessary procedures, setting a low threshold for using PSA, determining in advance the maximum number of attempts to perform the procedure, access to a training course and protocols, full informed consent from parents/carers, rigorous documentation of the procedure, and a subsequent evaluation of how the child, parents, and staff experienced it.¹ As far as we could ascertain, the *British Society of Paediatric Dentistry* is the only one of all the medical occupational groups to have drawn up and published a policy document on the use of restraint. Based on ethical and legal considerations, the document recommends extreme reticence in applying restraint.¹²

Ethical considerations

Three important ethical basic principles in health care are: first and foremost, non-maleficence (*primum non nocere*) and beneficence, respect for life, and respect for autonomy. When a painful procedure needs to be performed on a child that resists, it is crucial to weigh off whether applying restraint is in the child's interest. Creating psychological trauma is not in the child's interest; it could actually harm the child. Moreover, knowledge and technology are available for most procedures to make them (more) comfortable for the child. In this perspective, it is unethical to deny the child these techniques and using restraint on a fearful child cannot actually be fair.¹³ If the methods concerned are not immediately available, the question arises as to whether postponing the treatment would harm the patient's condition. In most non life-threatening situations, this will not be the case and sufficient time is available to look for an alternative without using restraint.

Legal considerations

In the Netherlands, there are no specific legal regulations concerning resistance put up by young children. The section in the Dutch Civil Code (BW) relating to the Medical Treatment Contracts Act (WGBO) contains only one provision on resistance put up by patients aged twelve and older incapable of giving legal consent (article 7:465 clause 6 BW). However, a special regime is nevertheless in place for the provision of information and obtaining of consent. For children up to the age of twelve, only the parent(s) or guardian(s) are required to give their consent for medical procedures to take place (article 7:450 and 7:465 clause 1 BW). In addition to the parent(s) or guardian(s), the child itself is nevertheless entitled to information, to be provided in a manner appropriate for its ability to understand (article 7:448 clause 1 BW). This means that a procedure for which consent has been given is allowed to take place even if the child resists. But is this really the case?

The International Convention on the Rights of the Child (ICRC), which became effective in the Netherlands on 8 March 1995, starts out from a number of fundamental principles regarding the interests and (legal) position of children in relation to available facilities, protection, and participation (including: freedom of opinion), also in relation to health care (articles 3 and 24) (table 3). Although not all provisions of the ICRC have a direct effect on health care, they serve to educate our State and our citizens (including health care workers) regarding an important body of ideas: for any measures relating to children, the interest of the child itself is paramount. As far as health care is concerned, this means that children are entitled to the best possible care.

In the Netherlands, health care workers are bound by the general standard of 'good care provision' (article 7:453 BW). Applying restraint is therefore only permitted if it is absolutely certain to constitute the most adequate form of care in the absence of a better or practical alternative. Since restraint is no longer a standard component of a medical procedure, it also requires separate informed consent from the parent(s) or guardian(s). In respect of the child itself, good care provision means that in the event of resistance, the care provider must first use dialogue to try and convince the child of the importance of the treatment in order to gain as much trust and cooperation as still possible. Useful guidelines, hints, and tips for dealing and communicating with children can also be found in the model guideline for care providers in relation to information and consent for under-age patients¹⁴ and in the Code of Behavior in the event of resistance from under-age patients taking part in medical research, which is also very useful with regard to general clinical situations.¹⁵

Table 3: Articles from the Convention on the Rights of the Child*, that may apply to restraint during medical procedures.

Article 3, clause 1: "In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities, or legislative bodies, the best interests of the child shall be a primary consideration".

Article 12, clause 1: "The child who is capable of forming his or her own views shall have the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child".

Article 19, clause 1: "*Children will have the right to be protected against all forms of physical or mental violence, both within the family and outside it*".

Article 24, clause 3: "*All effective and appropriate measures will be taken with a view to abolishing traditional practices prejudicial to the health of children*".

* The ICRC was unanimously accepted on 20 November 1989 by the General Meeting of the United Nations and became effective in September 1990. For the Netherlands, the Convention took effect on March 8, 1995

Recent jurisprudence shows that a care provider who does not allow sufficient time and effort to adopt a suitable approach to a resisting child may have to face the - negative - consequences: courts may rule that a defensive (panic) response from children resulting in injuries to the care provider is not unlawful. In that case, any claim for damages against the parent(s) would fail.¹⁶ Seen from the child's perspective, it could furthermore be argued that the child has a right to oppose a medical treatment, at least within certain specific boundaries (to what extent could the defensive behavior have been expected? How serious was the injury caused?).

The norm of good care provision returns to the denominator of the right of the patient or client to 'good care' which is set to largely replace section 7.7.5 of the Dutch Civil Code (WGBO): the Clients' Rights (Care Sector) Act (WCZ).¹⁷ Not explicit, but implied in the draft legislation for the WCZ, is nevertheless the provision set out in article 7:448 clause 1 of the Civil Code, namely that a child under twelve years of age must be informed in accordance with his or her level of comprehension. According to the legislator, the right to be provided with information about the treatment, associated with the patient's or client's right to express his or her own opinion on the treatment, already follows from the right to receive good care. This view is susceptible to criticism. Particularly when young children are concerned, whose fear and tendency to protest call for a particularly careful approach, it must not be a mere formality to imprint on care providers'

minds that they must proceed with the necessary care and prudence. This requires more than a broadly formulated, open standard ('good care'). Adopting a confidence-building approach and providing information come top of the list.

New draft guidelines on Procedural Sedation and Analgesia (PSA) outside the operating theatre

Under instructions from the Dutch Healthcare Inspectorate, the Netherlands Society of Anaesthesiologists (NVA) and the Dutch Society of Paediatrics (NVK), a working group with representatives of 21 professional associations with support from the Dutch Institute for Healthcare Improvement (CBO), have drawn up evidence-based guidelines for PSA. These guidelines are a follow-up to guidelines issued in 1998 and set out the conditions for safe and effective PSA in adults, children, and intensive-care patients. In the meantime, all professional associations have expressed their agreement with the content of the final draft version, which is now only waiting for ratification by the NVA and NVK. The guidelines state that applying restraint to children during non life-saving procedures is in principle unacceptable, unless it is certain that it amounts to providing the best possible care.

Conclusions and recommendations

Everyone is entitled to good care, including children. The application of physical restraint must be approached from the viewpoint of quality of care. Unless the child's life is at stake, health care providers encountering resistance from children against a procedure must first consider all possible alternatives and then opt for the most appropriate care for the case. If restraint is applied nonetheless, it must be carried out within a strict, transparent framework. This includes determining in advance the duration of the treatment and the number of attempts. Health care providers must be given good-quality training, including in adequate protocols. Furthermore, the parent(s) or guardian(s) must be asked for their full, informed consent, the treatment must be rigorously documented and motivated in the patient notes and the experiences of the child, parents, and attending care staff must be evaluated.

The above can only be achieved if functional alternatives are widely available and safe, including effective PSA techniques (table 2). It is therefore hoped that anaesthesiologists and paediatricians (NVA and NVK) will assume responsibility by making it a priority to ensure that the new guidelines can be applied in practice.

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Appendix bij hoofdstuk 4

Een kind in het nauw maakt rare sprongen

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De rechtbank in 's Hertogenbosch wees recentelijk een vordering af van een tandarts die gewond raakte bij een poging een vierjarig kind te behandelen.²¹ Het letsel ontstond door een afweerreactie van het kind. De vader was niet aansprakelijk omdat de paniecreactie niet onrechtmatig was. De uitspraak is bijzonder omdat zij de facto aan het kind een recht op verzet toekent. Het schaderisico ligt bij de hulpverlener als deze op de reactie bedacht kan zijn en veiligheidsmaatregelen kan treffen.

Maar hoe moet een arts met verzet van een kind omgaan? Voor een volwassene is het niet moeilijk om het verzet met kracht te doorbreken. Deze praktijk, 'restraint' genaamd, behoort tot de dagelijkse kindergeneeskundige zorg. Beschikbare comfortbevorderende methoden worden vaak niet toegepast. Ethisch is dit moeilijk te verdedigen. Voor verzet door kinderen (wilsonbekwame minderjarigen van 12 jaar en ouder daargelaten) bestaat geen wettelijke regeling. Daardoor kan een verrichting waarvoor de ouders toestemming hebben gegeven ondanks verzet gewoon doorgaan. Echter, een hulpverlener is gebonden aan de norm van goed hulpverlenerschap (artikel 7:453 BW) en dient het recht van het kind op de best mogelijke zorg te waarborgen. Restraint toepassen kan dan alleen als vaststaat dat er geen alternatief is en na instemming van de ouders.

De nieuwe conceptrichtlijn Procedurele Sedatie en/of Analgesie buiten de operatiekamer stelt dat restraint bij niet-levensreddende handelingen ontoelaatbaar is. Dit is alleen te realiseren als effectieve technieken voor lichte en diepe sedatie veilig inzetbaar zijn. Het is daarom te hopen dat anesthesiologen en kinderartsen hun verantwoordelijkheid nemen door er met voorrang voor te zorgen dat de richtlijn ook in de praktijk toepasbaar wordt.

Een kind in het nauw maakt rare sprongen

In het leven van een kind zijn de bezoeken aan de dokter doorgaans niet de meest vreugdevolle episodes. Een kind is niet geneigd tot het maken van een vreugdesprong bij een injectie in de arm, een neusendoscopie of druppels in de ogen of oren. Zeker na een – in de ogen van een kind – traumatische ingreep is de spontane bereidheid tot medewerking aan een vervolgbehandeling meestal niet erg groot. Zo ook bij de 4-jarige jongen in onderstaande casus. De week daarvoor was bij hem, nota bene zonder verdoving, een kies getrokken. En alweer mocht hij zitting nemen op de stoel van de tandarts, ditmaal voor het vullen van een kies.

Dat de jongen de kaken stijf op elkaar hield en de handen voor de mond, zal een gemiddelde arts niet verbazen. Ook nadat de tandarts tien minuten op de jongen had ingesproken en de hulp van een tweede assistente had ingeroepen, bleef de jongen zich verzetten. De tandarts vond het daarop welletjes geweest. Nog voor de komst van de tweede assistente hield hij beide handen van de jongen vast om zo alsnog de ingreep te kunnen verrichten. De tandarts had er evenwel geen rekening mee gehouden dat de angstige jongen in staat was een hand los te rukken. Daarbij verdraaide de tandarts zijn duim.

De tandarts stelde daarop de vader van de jongen aansprakelijk voor het letsel. De rechter gaat hierin niet mee. De paniecreactie van de jongen was niet geheel onverwacht. Het is bovendien onduidelijk waarom de tandarts niet heeft gewacht totdat de tweede assistente was gearriveerd. De rechter vindt het voorts veelbetekenend dat de jongen zich na de komst van deze assistente zonder problemen heeft laten behandelen.

Les uit onderstaande zaak is dat u ook rekening moet houden met de gevoelens van kleine kinderen. Het geven van informatie over de behandeling, waartoe u ook bij kinderen verplicht bent, waarborgt nog geen medewerking. Daarvoor zijn andere vaardigheden vereist.

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