Clinical care protocol for patients with psychomotor agitation

Hospital Clínic de Barcelona

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Authors and contributors

Manager/Coordinator:

Dr Eduard Vieta
Psychiatrist
Chief of Department of Psychiatry and Psychology
Hospital Clínic de Barcelona
Full-time lecturer in Psychiatry
University of Barcelona
IDIBAPS and CIBERSAM researcher

Authors:

Dr Marina Garriga
Psychiatrist
Psychiatrist in the Department of Psychiatry and Psychology
Hospital Clínic de Barcelona
CIBERSAM researcher

Ms Laura Cardete
Nurse
Nursing Care Coordinator in the Child and Adolescent Psychiatry Unit
of the Hospital Clínic de Barcelona

Contributors:

Dr Miquel Bernardo
Psychiatrist
Head of the Barcelona Clinic Schizophrenia Unit
and President of the Spanish Society of Biological Psychiatry
Full-time lecturer in Psychiatry
University of Barcelona
IDIBAPS and CIBERSAM researcher

Dr María Lombraña
Nurse
Director of Nursing at the Clinic Institute of Neurosciences
of the Hospital Clínic de Barcelona

Dr Jordi Blanch
Psychiatrist
Head of the Intrahospital Psychiatry Department at the Hospital Clínic de Barcelona and President of the Catalan Society of Psychiatry and Mental Health
Associate lecturer in Psychiatry
University of Barcelona
CIBERSAM researcher

Dr Rosa Catalán
Psychiatrist
Psychiatrist in the Department of Psychiatry and Psychology
Associate lecturer in Psychiatry
University of Barcelona
IDIBAPS and CIBERSAM researcher

Dr Mireia Vázquez
Psychiatrist
Psychiatrist in the Department of Psychiatry and Psychology

Dr Victòria Soler
Psychiatrist
Psychiatrist in the Department of Psychiatry and Psychology

Dr Noélia Ortuño
Psychiatrist
Psychiatrist in the Department of Psychiatry and Psychology

Dr Anabel Martínez-Arán
Clinical psychologist
Psychologist in the Department of Psychiatry and Psychology
Associate lecturer in Psychology
University of Barcelona
IDIBAPS and CIBERSAM researcher

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Table of contents

List of figures

List of tables

01

Protocol framework

1.1. Introduction

Within the scope of medical care for patients with behavioural disorders, **psychomotor agitation** is the most common condition observed in the health care services[1], not only in emergency cases but also during patients' inpatient or outpatient care[2].

Despite the current lack of consensus with regard to its definition, **psychomotor agitation** can be described as an increase in motor activity associated with a feeling of internal tension[3], during which there is an **uncontrollable increase in motor activity combined with significant emotional arousal**[1]. Moreover, it is a clinical entity that can also be accompanied by vegetative activation and a decreased level of consciousness, attention, and impaired cognitive functions. Typically, the patient is restless, alert, uses exaggerated gestures and can appear angry, upset or show significant emotional lability[1].

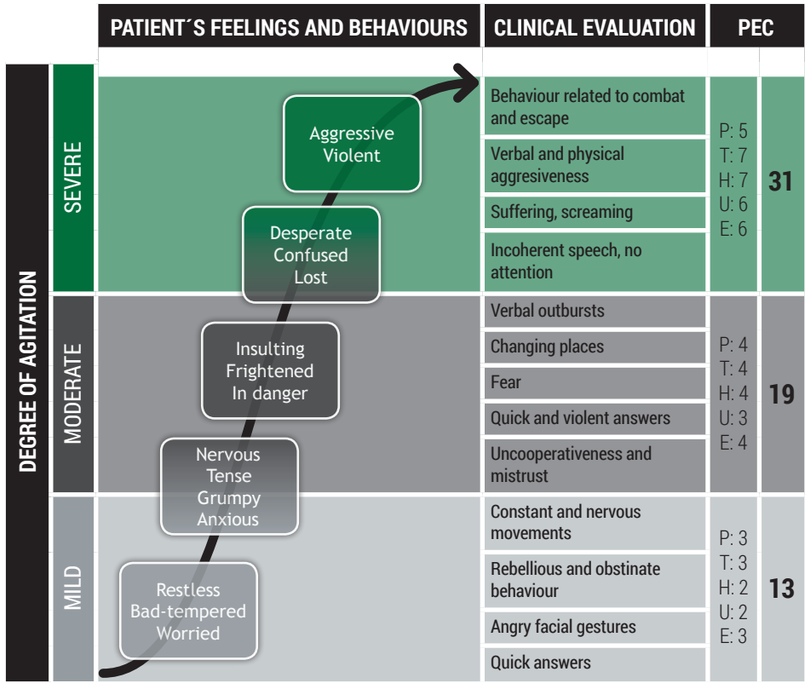
This syndrome can occur in some **medical conditions**, during periods of **substance withdrawal** or **intoxication**, although it is often associated with **psychiatric disorders** (Table 1)[1,2].

With regard to psychiatric conditions, **psychomotor agitation is an especially common syndrome in schizophrenia and bipolar disorder**[2]. According to the Spanish experts consulted, approximately 25% of patients with schizophrenia and 15% of patients with bipolar disorder experience at least one agitation episode per year, with a median of 2 episodes per year[4].

Recent studies have reported that up to 10% of patients treated in general emergency departments might present an episode of psychomotor agitation[5]. At the same time, in psychiatric emergency departments, this percentage would range between 20 and 50% of patients treated[6,7].

For these reasons, the identification of psychomotor agitation remains an important therapeutic goal, especially in those with psychiatric conditions[8].

Identifying **psychomotor agitation** is not an easy task. This is usually presented as a ***continuum*** of different levels of clinical severity (Figure 1), and can range from mild, with intense anxiety levels, to severe clinical situations, which may even involve aggressive and violent behaviour. Severe agitation forms might also imply aggressive behaviour directed against the patient himself/herself (auto-aggression) or against others (hetero-aggression), although sometimes its onset can be unpredictable[1]. Although aggression and violence are not necessarily essential characteristics of agitation[9,10], it may involve a high risk to the patient, family, medical personnel and/or other people[1].



See Annex II for a complete description of the scale

Figure 1. PEC scale

Effective management of psychomotor agitation requires early identification (preferably in the initial stages of its presentation), an evaluation of the patient's clinical condition and the situational factors that may increase the risk of aggression/violence, as well as the proactive use of environmental modifications and verbal strategies to avoid escalation of agitation.

Inefficient management of agitation might result in the unnecessary use of coercive measures (involuntary medication, physical restraint, seclusion), escalation to aggression/violence, adverse outcomes for both staff and patient, and a substantial financial burden on the health system[11].

It should be noted that aggressiveness alone does not define agitation, although sometimes there may be an overlap between the two[12,13]. To facilitate the work of health care professionals, we must **differentiate between**[14]:

- **Psychomotor agitation:** state of restlessness, anxiety or intense emotional reaction accompanied by an increase in nonpurposeful motor activity. It can range from mild motor restlessness to extreme cases of involuntary movements[1,3].
- **Aggressiveness:** hostility, manifested through verbal or physical behaviour directed against people or objects. It is usually caused by some trigger (external or internal), it is associated with negative emotions such as anger or fear and represents a response to a perceived stress[15].
- **Antisocial behaviour:** behaviour involving direct or indirect violation of the boundaries and rules of coexistence. This may involve varying degrees of aggressiveness[14].

Table 1. Possible causes of psychomotor agitation[2]

Medical cause		• Cerebral trauma • Encephalitis, meningitis or other infections • Encephalopathy • Exposure to environmental toxins • Metabolic derangement • Hypoxia • Thyroid disease • Seizure • Toxic levels of medication
Psychiatric cause	**Psychotic disorders:**	• Schizophrenia • Mania and mixed states • Psychotic depression • Unspecified delusional and psychotic disorders
	Non-psychotic disorders:	• Personality disorders (borderline, antisocial, etc.) • Anxiety disorders • Affective disorders (agitated depression) • Autism spectrum disorder. • Mental retardation • Reactive or situational (adjustment disorders, etc.)
Substance intoxication/ withdrawal		• Alcohol • Other substances (cocaine, hypnotics, sedatives, ecstasy, ketamine, methamphetamine, etc.)
Undifferentiated agitation		• Always suspect a medical condition until proven otherwise

- **Violence:** according to the WHO, violence is the intentional use of physical force or threats against oneself, another person, a group or community, which may occur as a result of trauma, psychological damage, developmental problems or grief[16].*

The existence of a protocol facilitates proper evaluation and treatment by healthcare professionals and increases patient safety, as well as the safety of third parties and staff. Moreover, **the implementation of appropriate and standardised protocols** promotes good clinical practice and fosters respect for the rights of the patient, as well as increasing patient safety.

1.2. Objectives

Overall objective:

- Establish a suitable and high-quality pattern for the assessment and approach of the agitated patient, through a series of regulated and standardised actions.

Specific objectives:

- Promote the safety of the patient, of others and of healthcare professional.
- Reduce patient anxiety.
- Anticipate and prevent the escalation of agitation symptoms, especially in cases where they are combined with aggression and violence.

1.3. Professionals to whom this protocol is addressed

All professionals who may at some point deal with agitated patients. That is, doctors, nurses, nurse staff and security staff.

* Note 1: Do not forget that violence by mental health patients outside clinical settings is limited, comparable to that of the general population, except when suffering a decompensation of their disease. This is the most common situation in emergency departments and psychiatric units, where patients are treated at their own request or, more often, at the request of third parties. We should note that a small group of mental health patients are responsible for a high percentage of aggressive episodes[17].

1.4. Target population

Patients who experience an episode of psychomotor agitation at any stage, regardless of the cause of agitation.

1.5. Clinical application scenarios

This protocol is applicable in the emergency departments, any inpatient unit, outpatient clinics and day hospitals.

In each case we will try to adapt the environmental conditions in order to provide the patient with the best possible care.

02

Identifying an episode of agitation

In order to achieve **effective management** of agitation, we must be able to **detect and recognise** episodes of agitation **early on**. This section describes the two possible detection scenarios:

- **Identification of agitation risk (see section 2.1):** recognise the factors that may favour the onset of an episode of agitation.
- **Identification of a patient in a state of agitation (see section 2.3):** recognise the signs and symptoms that may be present in an episode of agitation with the aim of preventing a potential escalation.

2.1. Origin of agitated patient

There are **several scenarios** in which various healthcare professionals may come into contact with an agitated patient. In all of them the **first approach** occurs ***in situ*** but, depending on the degree of agitation, patient **transfer** to the corresponding **hospital emergency department** may be necessary.

Table 2. Origin of agitated patient

Scenario	Characteristics	Possible pre-hospital treatments administered	Protocol section
Patients who come to the emergency department on their own	The patient comes to the emergency department of the hospital by his/her own will or at the encouragement of family or friends.	N/A	2.3.
Emergency Department	The episode of agitation has started at a private home, on the street or in another public space. Normally it is necessary to transfer the patient to the emergency department.	Verbal De-escalation	2.3.
		Physical restraints	3.2.
		Pharmacological intervention	3.3.
Outpatient clinics	The patient has visited a health or care centre because of an episode of agitation, or the episode has started in one of them. Transfer to the emergency room is not always necessary.	Verbal de-escalation	2.3.
Continuous Care Units		Physical restraints	3.2.
Community mental health services		Pharmacological intervention	3.3.
Hospital inpatient unit (ward)	The patient was hospitalised at the time of the episode of agitation. These cases are resolved *in situ* and are not usually referred to the emergency room.	N/A	2.1.

When patients are admitted to the emergency department, they will receive the appropriate care based on their clinical status, taking into account any potential pre-hospital care they may have already received.

Table 2 shows these scenarios, their characteristics, the pre-hospital treatment that can be applied to each of them and the section of the protocol that should be consulted in each case[18]:

2.2 Identifying the risk of agitation in psychiatric patients

Although agitation may occur without any prior symptoms, today we know that **early identification** of patients at risk of an episode of agitation facilitates early intervention. This intervention will help in the reduction of the potential clinical escalation of an episode of agitation. This requires a good knowledge of both **predisposing factors**, as well as **protective factors** of agitation episodes.

These factors should be known by all staff that comes into contact with patients at risk of agitation. The assessment of these factors will be made by the physician and/or nurse, by observing the patient's behaviour and assessing the information provided by the patient's caregivers as well as the patient's prior medical history. The measures to take will be different depending on the outcome of this assessment.

Both, the result of the assessment and the measures taken on the basis of the risk identified, will be recorded in the patient's medical history.

2.2.1. Predisposing factors

Factors that may favour the onset of an episode of agitation are shown in Table 3. It is important to consider these factors, as they may indicate an increased risk of agitation in patients[17].

2.2.2. Protective factors

Factors that may prevent the onset of an episode of agitation are shown in Table 4. It is important to understand and apply these factors, as this will help in **preventing episodes of agitation**[17].

Table 3. Factors increasing the risk of agitation

Demographic factors	Interpersonal, environmental and/or psychosocial factors	Clinical factors
• Males • Less than 40 years • Low educational level • Financial difficulties • Unstructured socio-familiar environment	• Past history of being admitted in uncomfortable and overcrowded units with an unstructured environment. Involuntary or long-term admission. • History of conflict with staff or other patients • Experience of recent disasters or stressful life event • Patient´s perception of treatment received (waiting time, etc.) • Existence of potential victims and immediate availability of potential weapons	• Personal and/or family history of previous agitation episodes • Anxiety, fear • Traits of impulsivity, hostility, low level of frustration tolerance, low self-esteem • History of mental health disorders (especially schizophrenia and bipolar disorder) with an exacerbation of psychotic and/or manic symptoms • Substance use • Low treatment adherence

Table 4. Factors decreasing the risk of agitation

Personal factors	Interpersonal or environmental factors
• Social skills • Good premorbid adjustment	• Appropriate level of therapeutic alliance with the healthcare team • Involvement of the patient in his care plan, on both an informative and decision-making level • Availability of alternative activities during the patient's stay in the healthcare center • Well trained staff, who can dedicate enough time to the patient and who have defined roles • Level of comfort of the physical space

2.2.3. Assessment of the risk of agitation

Assessment of the risk of agitation must be as **objective** as possible, and must provide the clinic or nurse **information** regarding any **factors favouring it** that are present in the patient at the time of assessment.

The primary objective of this assessment is to **detect** the **possible causes** of the disruptive behaviour and to **assess** the potential **risk** of harm to the patient or those around him/her.

Subsequently, appropriate strategies will be determined in order to[17]:

- Prevent the appearance of agitation and/or violent behaviour.
- Avoid the escalation of symptoms.
- Minimize the risk of complications.

There are several **assessment scales of the factors that imply the risk of agitation**, aggression, and even violence*, although their clinical practice is not standardised.

Some examples are:

- ***Broset Violence Checklist (BVC):*** this was developed as a predictive tool of a violent episode in the next 24 hours in psychiatric inpatients. The BVC measures 6 items: confusion, irritability, distress, physical threats, verbal threats, and attacks on objects[2].

- ***Historical Clinical Risk Management – 20 (HCR-20):*** this tool allows assessment of 20 items related to the potential for aggression/violence[2]. These items are organised into 10 factors regarding the past ("historical"), 5 present variables ("clinical"), and 5 aspects regarding the future ("risk management")[17]. Its efficacy has been verified in the prediction of violent behaviour in psychiatric, forensic, and prison clinics, as well as among patients who suffer from acute episodes of severe mental health disorder[2].

- ***McNiel-Binder Violence Screening Checklist (VSC):*** this was initially designed to assess the short-term risk of aggression/violence among patients with acute mental illness admitted to hospitalisation units. It entails a scale of five items that include clinical, historical, and demographic factors[2].

Although the use of these scales may not be standardised in daily clinical practice, their use is advisable. Sufficient compilation of this information could contribute to the qualitative improvement of the assessment and the subsequent management of agitation. If they are used, the results should be recorded in the patient's clinical history.

2.3 Identification of the patient in a state of agitation

Agitation is understood as a ***continuum*** (Figure 1) on which the patient may present from initial symptoms of less severity to symptoms of greater severity, and even aggressive or violent behaviour*. Therefore, in order to attain **effective management of agitation**, it is essential to detect episodes of agitation in their **earliest form**, thus **avoiding** a possible **escalation of symptoms**[2].

* See definitions in Section 1.1.

Table 5 presents a list of **signs and symptoms** that may or may not be present in episodes of agitation, but awareness of them will be helpful **at the moment of recognising these early stages**. In general, the condition of agitation tends to present three different clinical topics to assess: behavioural, cognitive, and that of physical parameters.

It is recommended to all healthcare professionals that may be in contact with an agitated patient that they familiarise themselves with this list. Identification of the agitated patient will be performed by nursing and/or medical staff.

Table 5. Signs and symptoms present in an episode of agitation

Type of alteration	Signs and symptoms
Behavioural	• Combative attitude • Inappropriate behaviour without clear purpose (motor as well as verbal) • Hyperreactivity to stimuli (internal as well as external) • Inability to remain quiet, seated, or calm • Exaggerated gesticulations • Tense, angry facial expression • Defiant and/or prolonged visual contact • Elevated, mute, or negative tone of voice in communication • Altered emotional state with possible appearance of anxiety, irritability, hostility, etc. • Verbal and/or physical aggression against the patient himself/herself, other users, healthcare staff, or against objects
Cognitive	• Fluctuations in level of consciousness and state of alertness • Temporal-spatial disorientation • Tendency to frustration • Difficulties in anticipating consequences of his/her current state, in remembering how to be calm or reason normally • Presence of delusional ideas, hallucinations
Physical parameters	• Fever • Tachycardia • Tachypnoea • Sweating • Trembling • Any neurological sign such as difficulties walking...

2.3.1 Initial evaluation of the agitated patient

With an agitated patient, there is a series of **objectives** that are **critical** to manage:

1. Provide a **safe environment** for the patient and health care professionals.
2. Assess the potential **risk of escalation** to aggression/violence, and conduct an appropriate evaluation of the patient.
3. Establish a correct **differential diagnosis**.
4. Implement the most appropriate **care plan approach** (see Chapter 3. Interventions in an episode of agitation).

The first consideration is to transfer the patient to a safe environment. This will help us evaluate the patient's status, and assess the potential risk of escalation of symptoms. When we reach this point, we will be able to establish a correct differential diagnosis and implement the type of approach (environmental, verbal, pharmacological, or physical restraint) that is most appropriate for the patient.

1. Provide a safe environment for the patient and healthcare professionals

With an agitated patient, a series of preliminary measures with the goal of **providing a safe environment for the patient and healthcare professional** should be considered:

- Avoid delays in the care of the agitated patient[2].
- Inform the rest of the team of the patient's condition so they can provide support if necessary.
- It is recommended that two healthcare professionals conduct the initial patient interview. The presence of sufficient staff is persuasive and calming.
- Use of trained healthcare professionals familiar with the current site protocols in these cases.

Doctors as well as relevant nursing staff and security staff should be familiar with and apply these safety measures.

2. Assess the potential risk of escalation to aggression/violence, and conduct an appropriate evaluation of the patient.

The assessment of potential risk of the agitated patient escalating to aggression or violence will be performed by the responsible doctor or nursing staff and will attempt to determine:

- Degree of severity of the patient's episode of agitation
- Verbal or non-verbal indicators of aggressiveness: verbalisation of a desire to attack, attack position, closed fists, etc.
- Degree of impulsiveness
- Means available to the patient for harm
- History of previous aggression/violence

The results of the assessment will be recorded in the patient's clinical history.

There are several **scales to assess the risk of escalation of symptoms** that can set off aggression or even violence, though their clinical practice is not standardised. Some of them are shown below.

- ***Clinical Global Impression Scale for Aggression (CGI-A):*** this is an adaptation of the CGI-Severity (CGI-S) scale but for agitated patients with mental disorders. The CGI-A is especially promising, given that its administration is fast and it is based solely on the clinical observation. It entails a 5 point Likert scale; where 1 is "aggressive behaviour not present" and 5 is "aggressive behaviour present"[19] (see Annex I).

- ***Positive and Negative Syndrome Scale – Excited Component (PANSS-EC or PEC):*** this scale has commonly been used to measure the severity of aggressiveness in agitated patients. It evaluates 5 items, which are scored from 1 to 7. It has been referenced as one of the simplest and most intuitive scales to use in agitated psychiatric patients[2] (see Annex II).

- ***Behavioural Activity Rating Scale (BARS):*** in contrast to the other two scales, this one measures the severity of agitated behaviour using a single item that describes seven levels of severity (from a state of sedation to a state of agitation). This scale is quick and easy to administer and has been useful even for doctors not trained in psychiatry or emergencies[2] (see Annex III).

Moreover, an **appropriate evaluation** of the agitated patient also includes a recorded anamnesis from the patient, family, and previous clinical reports. Medical, toxicological, psychiatric, and pharmacological history has to be also checked.

It is important to be able to **reconstruct the episode** with the patient as well as with relatives or caregivers. It will be useful to perform a **chronological description** of the episode, from the preceding days to the current care of the patient, in order to be able to find possible **precipitating factors** for the episode of agitation.

The most extensive possible **physical** and **neurological examination** should be performed, as well as a mental status examination and any other complementary explorations that may be performed.

The minimum **complementary explorations** to be performed should include:

- Vital signs
- Capillary glycaemia
- Oxygen saturation
- Drug test

Other **complementary explorations**, depending on the patient's potential risks, should include the possibility of performing:

- Plasma glycaemia
- Renal function
- Liver function
- Electrolyte panel
- Acid-base balance
- CBC test
- Electrocardiogram
- Chest X-ray
- Brain CT
- Lumbar puncture
- Pregnancy test

The results of all the clinical examination, as well as the results of the complementary explorations, will be recorded in the patient's clinical history.

3. Establish an appropriate differential diagnosis

A **correct differential diagnosis** will help **identify the possible underlying cause** of the episode of agitation. Defining this cause is important for an adequate management of agitation. Despite

Table 6. Evaluation of possible cause of an episode of agitation

Cause	Evaluation
Medical	Acute or subacute onset, frequently in patients of advanced age, without prior psychiatric history and of a rather fluctuating course. They tend to show altered level of consciousness, temporal-spatial disorientation, and altered vital signs (sweating, tachycardia, tachypnoea, fever, etc). There may be visual hallucinations and delusional ideas, as well as impaired cognitive functioning.
Substance intoxication/ withdrawal	Different patterns relating to the type of substance consumed. See Annex IV.
Psychiatric	Acute or subacute onset and without altered level of consciousness. If the patient presents with prior psychiatric history, it tends to appear in the context of an acute relapse. It may be: • Psychotic: schizophrenia, bipolar disorder. • Not psychotic: panic disorder, affective disorders, personality disorder, mental retardation, autism spectrum disorders, adjustment disorders.

that, if the patient's clinical status does not allow for adequate particulars for the initial clinical profile, agitation will be assumed to be medically caused until otherwise demonstrated[17].

Initially, the presence of a confusional state, cognitive deterioration, and substance intoxication/ withdrawal will be considered before considering a mental disorder, especially in cases without past psychiatric history. Table 6 details different possible causes of an episode of agitation.

If agitation due to substance intoxication/withdrawal is suspected, complementary explorations should be requested and the case should be handled in a Medicine Emergency Department. If the agitation is due to a psychiatric cause, the patient will be treated in Psychiatric Emergency Department, if it exists at the centre. If the hospital does not have a Psychiatric Emergency Department, the patient will be treated in the Medicine Emergency Department.

The diagnosis results should be recorded in the patient's clinical history.

03

Interventions in an episode of agitation

The basic objectives that the **care of an agitated patient** must satisfy in the Emergency Department are[2,10]:

Table 7. The six objectives of care in the Emergency Department

Objectives of care in the Emergency Department	
1	Rule out medical conditions
2	Stabilize the patient quickly
3	Avoid coercive measures
4	Treat in the least restrictive manner
5	Form a therapeutic alliance
6	Ensure an adequate plan for subsequent care

Adaptado de Zeller (2010)[10]

To satisfy these objectives, there are **several interventions to address an episode of agitation**. These measures range from the least restrictive (environmental modification) to the most restrictive (physical restraint), and are applied depending on the stage of the agitation episode (Figure 2). Figure 1 (page 13) shows the continuum of agitation with its various phases.

Each of these interventions are described below, indicating the healthcare professional in charge to conduct them, recommendations, and guidance.

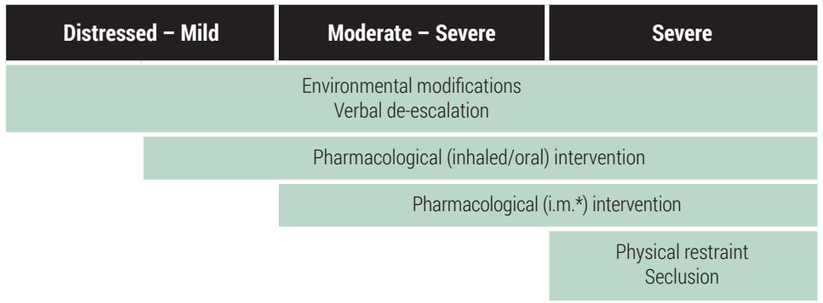


Figure 2. Interventions based on the stage of the agitation episode

3.1 Environmental modification

The use of **environmental modification** measures may be useful to prevent an episode of agitation, to treat it in its initial stages, as well as to prevent its escalation. This measure, which can be executed by any staff member, also represents a series of strategies to ensure the safety of the patient, other users, and healthcare professionals[17].

Environmental modifications to consider are listed below:

- Ensure the patient is **physically comfortable**, reducing external stimuli (such as light, noise, air currents, etc.), favouring a personal, calm space for the patient (e.g., a quiet individual room)[2,20].
- All items or objects that may be potentially dangerous must be removed from the room[2,20].
- It is appropriate to maintain an optimal **safe distance** when evaluating the agitated patient, respecting his/her personal space[2].
- **Avoid interruptions** during the intervention, such as telephone calls, doorbells, etc.[17].
- Ensure the clinical intervention to be performed in a quiet place (with the minimum possible stimuli), that is spacious, free of dangerous objects and with furniture that allows for exit. Take away any dangerous objects that may be near the patient.
- If the patient is accompanied, assess if his/her companions are destabilising and increasing aggressiveness, in which case they should be asked to leave. Otherwise, if they are supportive and help control the patient, they will remain present[2].

3.2 Verbal de-escalation

Verbal de-escalation is defined as a complex and **interactive process** in which it is attempted to orient the patient toward a state of calm, reducing, and even ameliorating, the agitation. These verbal de-escalation techniques have shown that they can **reduce agitation** and **reduce the risk** of associated violence[2], as well as **prevent** the use of **coercive measures**[11]. In addition to environmental modification, it will be used for the prevention of the episode of agitation, to treat it in its initial stages, or to prevent its escalation.

Verbal de-escalation techniques are considered the intervention of choice in the management of agitation, with the goal of calming the patient and gaining his/her cooperation[21].

Table 8 Compiles the primary **objectives** of verbal de-escalation[17,20].

Some authors[2,20,22] have identified **10 key principles** to consider when verbal de-escalation techniques are used. These principles, together with key recommendations, are listed in Table 9.

Table 8. Objectives of verbal de-escalation

Objectives of verbal de-escalation
• Re-establish patient's self-control and introduce some clear behavioural limits. • Ensure the safety of the patient, staff, and other users of the health care system. • Achieve a therapeutic alliance with the patient that permits performance of an appropriate diagnostic evaluation. • Involve the patient in his/her own therapeutic decision-making process. • Reduce hostility and aggressiveness, preventing possible episodes of violence. • Inform the patient of the temporary nature of the crisis he/she is suffering, thus strengthening his/her self-control.

Table 9. The 10 principles of the verbal de-escalation technique

Principle	Key recommendations
1. Respect personal space	Respect the patient's personal space as well as that of the healthcare staff.
2. Do not be provocative	Avoid iatrogenic escalation.
3. Establish verbal contact	Only one person verbally interacts with the patient. Introduce yourself and provide orientation and calmness.
4. Be concise	Be concise and maintain simple language. Repetition is essential for a successful verbal de-escalation.
5. Identify desires and feelings	Use free information to identify desires and feelings.
6. Listen to the patient attentively	Use active listening. Use Miller's Law: "In order to understand what another person is saying, you must assume that it is true and try to find out what it could be true of".
7. Agree or agree to disagree	Reach agreements with the patient: regarding specific and clear truths; in relation to general issues; with respect to minor situations; even if there is no way to honestly agree with the patient, agree to disagree.
8. Set clear rules and limits	Establish basic working conditions. The setting of limits must be reasonable and done in a respectful manner. Coach the patient on how to maintain control, among other possibilities.
9. Offer alternative choices and optimism	Offer real alternatives. Address the topic of medications. Be optimistic and provide hope.
10. Debrief the patient and staff	Inform the patient. Review of the case with staff.

It is recommended that all doctors and relevant nursing staff who work frequently with agitated patients be familiar with verbal de-escalation techniques and capable of executing them.

3.2.1. Verbal de-escalation procedure

An **effective verbal de-escalation** requires that healthcare professionals pay special attention to a series of **non-verbal behaviour** (Table 10) and **environmental guidelines** (Table 11), and communication directives (Table 12)[17].

Table 10. Non-verbal behaviour guidelines

Non-verbal behaviour guidelines
• Active listening without interrupting the patient's discourse. • Be careful with non-verbal language: do not look directly and continuously at the patient (that can increase hostility). However, completely avoiding looks can be interpreted as a sign of fear. Gestures must be neither threatening nor defensive. Avoid the use of brusque and spontaneous gestures. Use a neutral facial expression and body language. • Always maintain empathy and a positive attitude with respect to resolution of the episode. • Open, calm attitude that invites dialogue and privacy. • Approach the patient cautiously (without fear) and avoid startling him/her. • Offer real alternatives such as food, drink, contacting a relative, etc.

Table 11. Environmental guidelines

Environmental guidelines
• Same guidelines as for environmental modification (Part 3.1). • Verbal de-escalation should be done in an area that is spacious, calm, free of blunt or sharp objects, with appropriate placement of furniture to allow for exit, and with a call system to the outside for emergencies (17). • If the situation permits, the interview will be done only with the patient and the two people responsible for the intervention. • In each case, assess the calming effect that the company of relatives/caregivers may have during treatment of the patient. • Monitor the patient frequently to assess signs that may indicate the agitation is escalating. • Approach the patient from the front or the side (never from the back).

Table 12. Communication directives

Communication directives
• Talk with the patient in a gentle, relaxed, confident tone. • Answer calmly, maintaining a firm attitude. • Be flexible in the dialogue. • Reserve your own judgement regarding what the patient "should" and "should not" do. • Do not seek confrontation of ideas or reasons, only simple partnerships that calm and reinforce the patient. • Use simple language and short sentences. Repeat as many times as necessary. • Be honest and accurate. • Clearly communicate that the patient is expected to maintain self-control, and that the staff can help him/her achieve this. • Redirect the conversation when disruptive questions are asked. • Paraphrase what the patient tells you. • Ensure the patient that you have understood him/her well. • Use open-ended questions. • Establish limits, while at the same time offering the patient acceptable and realistic options to improve the symptoms. Avoid unrealistic promises. • When faced with imminent violence: – Warn the patient that violence is not acceptable. – Propose a resolution to any problem through dialogue. – Offer pharmacological treatment. – Inform the patient that you will use physical restraint if necessary. – Evaluate showing force in the form of an increased number of medical and nursing staff, and even security guards ready to act if necessary

On the other hand, you must remember certain **precautions during verbal de-escalation**, in other words, all of the things that are not recommended when dealing with an agitated patient (Table 13) due to their possible iatrogenic effect on worsening the symptoms.

It should be noted that, on numerous occasions when there has been a type of **coercive/involuntary intervention**, the use of **verbal de-escalation** may have **reconverted** the patient's admission into a **voluntary** situation, without the need for coercive measures, making the **therapeutic partnership** between the patient and physician much easier, and allowing **early evaluation** and the most appropriate **pharmacological treatment**.

Tabla 13. Precautions during verbal de-escalation

Precautions during verbal de-escalation
• Negarse a escuchar al paciente. • Avergonzar al paciente. • Elevar el tono de voz. • Continuar negociando habiendo comprobado que el paciente lo rechaza en ese momento. • Mostrar miedo y/o actitudes defensivas delante del paciente. • Volver la espalda al paciente. • Discutir con el paciente.

3.3 Pharmacological intervention

If verbal de-escalation is insufficient, you will need **pharmacological intervention as a coadjuvant measure**, with the goal of **avoiding symptom escalation**, as well as the use of more coercive measures, and even physical restraints. Throughout the process, you will attempt to continue using both verbal de-escalation and environmental de-escalation techniques (Section 3.1).

Various clinical guidelines concur that the **primary goal** of pharmacological treatment should be to **rapidly calm the patient** without over-sedating him/her, in such a way that he/she can be clinically evaluated by on-duty healthcare professionals[2,11].

The person responsible for pharmacological intervention will be the physician, who will instruct the nursing staff on what medication to use, as well as the dosage and route of administration. It will also be their responsibility to decide whether to repeat or increase the dose of the medication administered.

All pharmacological interventions must be recorded in the patient's medical record, as well as the degree of clinical response, the appearance of adverse events, and all interventions performed in relation to these.

3.3.1. The ideal medication

The description of the **ideal medication** in the management of agitated patients has been collected from various published works[2,11,23,24]. The requirements that should be fulfilled are shown in Table 14.

Tabla 14. Ideal medication requirements

Requirements that the ideal medication should cover
• Rapid onset of action. • Calms the patient without sedating. • Non-invasive and easy to administer. • Non-traumatic. • Allows the patient to be involved in decision-making process to promote long-term adherence to treatment. • Good tolerability. • Good safety profile: low risk of severe adverse effects and interactions with other medications.

3.3.2. Choosing a pharmacological treatment

Table 15 shows the **most frequently used medications to treat agitation** according to their diagnostic orientation, as well as the **guidelines** to use these treatments and the route of administration. This route may vary depending on **patient cooperation** and the degree of severity.

A cooperative patient is understood as one who does not resist receiving the best treatment possible.

Table 15. Pharmacological treatment options

Pharmacological Group	Cooperative Patient	Route of administration:	Drug substance	Dose	Cause of Agitation
Antipsychotics (AP)	Yes	Inhaled	Loxapine	9,1 mg	• **Psychiatric disease:** Psychotic syndrome (schizophrenia / bipolar disorder)
		Oral	Olanzapine Risperidone Asenapine* Aripiprazole Quetiapine Ziprasidone Haloperidol	5-10 mg 1-3 mg 5-10 mg 15-30 mg 50-100 mg 20-40 mg 5 mg	• **Undifferentiated agitation** • **Medical conditions:** cognitive deterioration and confusion syndrome • **Substance intoxication/ withdrawal:** cocaine or other synthetic substances and alcohol and/or BZD intoxication • **Psychiatric disease:** schizophrenia, bipolar disorder, mental retardation, autism spectrum disorder
	Yes/No	Intramuscular	Haloperidol Olanzapine Ziprasidone Aripiprazole Levomepromazine	5-15 mg 5-10 mg 10 mg 9,75 mg 25 mg	
Benzodiazepines (BZD)	Yes	Oral	Diazepam* Clonazepam Lorazepam*	5-10 mg 1-2 mg 1 mg	• **Alcohol and/or BZD** withdrawal • **Psychiatric:** anxiety disorder, affective disorder, personality and adjustment disorder
	Yes/No	Intramuscular	Midazolam Diazepam	5 mg 5-10 mg	

* Also sublingual

Table 16. General recommendations in pharmacological intervention

General recommendations in pharmacological intervention
• Attempt monotherapy. Avoid combinations, especially intramuscular (i.m.) olanzapine with benzodiazepines (due to increased risk of respiratory depression). • In general, all of the above-mentioned treatment regimens can be repeated every 45-60 minutes until the agitation resolves, keeping in mind the maximum daily dose for each medication, and monitoring vital sings closely. • Exceptions to remember are: inhaled loxapine (maximum of two administrations/24 h), i.m. olanzapine (recommended maximum of two administrations/24 h) and i.m. levomepromazine (repeat at half the dose). • For ages <14 years and >65 years, administer one quarter to one half of the treatment dose (as a guideline). • Review the technical data sheet for each medication's necessary dosage adjustments for renal and/or hepatic impairment. • **Dosis máximas** a tener en cuenta: — Haloperidol 30 mg/24 h — Levomepromazine 150 mg/24 h (monitor for cardiovascular risk, check BP every 15-30 min) — Olanzapine 30 mg/24 h — Risperidone 6 mg/24 h — Ziprasidone 40 mg/24 h (160 mg if oral) — Aripiprazole 30 mg/24 h — Loxapine 18.2 mg/24 h • In cases where a rapid effect of the antipsychotic medication is needed, consider the use of the inhaled route[11]. • Remember that in the case of i.m. BZD, absorption may be erratic. • Rule out this route in the use of intravenous haloperidol, except in cases where the benefit will be greater, and always under strict supervision and ECG monitoring (e.g. anti-coagulated patients and those at risk for haemorrhage).

Table 17. Special situations in approaching agitation

Special situations in approaching agitation
• Diagnostic aetiology unclear along with altered level of consciousness: consider medical condition until demonstrated to be the contrary. Avoid treatments with a BZD-type sedative profile, evaluate the use of physical restraint while you obtain more information. • Alcohol and/or BZD intoxication: caution with sedative medications and the risk of respiratory depression. Use APs to avoid the risk of hypertension and respiratory depression. • Alcohol and BZD withdrawal: use BDZ to reduce the risk of seizures and delirium tremens. • Combined intoxication (e.g. cocaine + alcohol): decide based on the most acceptable risk. • Cocaine and synthetic drug intoxication: initial sedation with BZD. Limit the use of APs if there is comorbid psychotic symptomatology, due to the risk of rigidity and hyperthermia. • Agitation in patients with Parkinson's or Parkinson's-like disease: avoid using first generation APs (haloperidol, levomepromazine). Ziprasidone is advised as an alternative. • Postictal agitation: may be advisable to use BZD so as not to lower the seizure threshold.

When choosing the best pharmacological option to treat an episode of agitation, it is important to follow a series of **general recommendations**, which are shown in table 16.

You must also consider certain **special situations** (Table 17) where the approach to an episode of agitation may vary.

However, there are also side effects or **possible complications** that arise from pharmacological treatment (Table 18). It is important to know and remember these possible complications when approaching an episode of agitation with drugs.

Tabla 18. Possible complications of pharmacological intervention

Possible complications of pharmacological intervention
• Sedation • Decreased level of consciousness • Respiratory depression • Cardiorespiratory collapse • Complications from interactions with substances of abuse • Complications from medical conditions and underlying treatments

Table 19 shows **other treatments** that may also be effective in managing agitation[17,25,26], although it is possible that they are not widely used.

Tabla 19. Other treatments available to manage agitation

Pharmacological Group	Cooperative Patient	Route of administration:	Drug substance	Dose	Cause of agitation
AP	Yes	Oral Sublingual	Clometiazole Chlorpromazine Clotiapine Promethazine	192-768 mg 25-150 mg 20-40 mg 25-100 mg	• **Undifferentiated agitation** • **Medical condition:** confusional illness, cognitive impairment, etc. • **Substance intoxication/ withdrawal:** cocaine or other synthetic substances and alcohol and/or BZD intoxication • **Psychiatric disorder:** schizophrenia, bipolar disorder, mental retardation and autism spectrum disorder
	Yes/No	Intramuscular	Zuclopenthixol Chlorpromazine Promethazine	50-150 mg (cada 48/72h) 25-150 mg 25-100 mg	
BZD	Yes	Oral	Clorazepate dipotassium Alprazolam*	50 mg 0,5-2mg	• **Alcohol and/or BZD** withdrawal • **Psychiatric disorder:** anxiety disorder, affective disorder, personality and adjustment disorder
	Yes/No	Intramuscular	Flunitrazepam	2 mg	

* Also sublingual

3.4 Seclusion

According to the *American Psychiatric Association*[3], the use of seclusion is a measure consisting of "involuntary confinement of a person in a room alone to physically prevent his/her exit". Therefore, in these cases, the patient will be taken to a quieter place away from stimulus that is upsetting them[17,27].

Some psychiatric units have rooms equipped for seclusion (with protective walls and equipped doors). These rooms guarantee the reduction of stimuli and the safety of the patient.

Any staff member can implement this measure, yet the responsible doctor or nurse should always be informed[17].

3.5 Physical restraint

Approaching an agitated patient in hospital emergencies is a complicated, stressful and often unpredictable situation. About 30% of these patients require treatment or coercive and/or restrictive interventions, such as physical restraint[28].

The objectives of physical restraint are:
» To promote patient safety, avoiding risks and preventing physical injury to the patient and others.
» To ensure pharmacological treatment for the episode of agitation.

Physical restraint is a procedure in which approved mechanical holding devices are used to limit the patient's physical mobility[4]. This type of restraint is indicated in **patients with risky behaviour** for themselves or for those around them, with agitation that cannot be controlled pharmacologically and/or who require temporary restraint to receive the appropriate treatment.

This **measure** must be considered as **exceptional** and a **last resource**, only when other prior strategies have failed. Several authors have questioned the use of coercive measures due to their **doubtful therapeutic effectiveness**, their frequent **inappropriate use**, and the potential **negative outcomes** on patients, staff, and the therapeutic relationship between the two[2,11].

It must be taken into account that applying physical restraint **increases the person's fragility**. According to a study, the rate of complications, both physical and mental, in patients to whom physical restraint was applied in the urgent care service is 7%[29]. The trauma of coercive measures, especially among patients with a history of trauma, can induce psychological complications such as **feelings of terror, humiliation** and **impotence**. The physical complications are described in Table 20.

Also, the use of coercive measures generates an **important use** of medical and non-medical **resources**, required during restraint and later to monitor the agitated patient. So reducing their use may result in economic savings, with more resources being earmarked for other types of measures[4].

If physical restraint is finally necessary as a last resource, **before starting** this technique the following must be done:

» **Inform the patient** about the reason for the restraint, about what the **allow his/her cooperation** are and **allow his/her cooperation**[17].

» Explain to the patient that **it is not a punishment**, but it is a measure with a therapeutic purpose[17] which aims to keep the patient in a position of safety.

Legal and ethical considerations:

Physical restraint is a measure limiting the individual's freedom and, therefore, has to be authorised by the patient or the appropriate judicial authority.

Following the Spanish law, physical restraint may be done in these three different cases:

- Voluntary admission and patient consent for immobilisation: restraint is voluntary or requested by the patient in the event of failure of other restraint measures. Despite this, since they are deprived of liberty, this must be communicated to the corresponding judicial authority.
- Voluntary admission without patient consent for immobilisation: physical restraint is applied against their will and, although under voluntary admission, it would then be considered involuntary and the corresponding judicial authority must be informed.
- Involuntary admission: when the doctor or nurse responsible for the episode of agitation requests the physical restraint against the patient's will. Prior to the application of physical restraint, the corresponding judicial authority must be communicated about the involuntary admission.

The patient's attending physician will have a period of 24 hours to inform the judicial authority, from the moment when the measures are taken against the will of the patient. In Spain, the application of these procedures is governed in the Civil Procedure Act (Art. 173), the Law on patient autonomy and rights and obligations regarding clinical information and documentation, the General Health Law and the Spanish Constitution[4]. All teams involve in the care of agitated patients should review and follow local legislation and guidelines.

As stated earlier, physical restraint must be considered as an **exceptional** measure and a **last resource**, only when previous strategies have failed. If necessary, the specific physical restraint protocol will be followed (see Section 3.5.1).

The person responsible of making the decision to apply physical restraint shall be the patient's attending doctor or nursing staff, while the head nurse staff shall be responsible for the restraint techniques. All team members involved must know the protocol and be trained, understanding in detail the role they need to perform at each moment[17].

Upon violent agitation, always keep in mind the standard alert and emergency procedures and devices (panic buttons, phone numbers for specialized teams in agitation episodes, etc.) at each centre, in case activation of a special protocol is needed, including support from more personnel or even security staff*.

* Security personnel: They will provide support to the medical staff in the event of severe behaviour alteration with risk of aggression/violence of the patient, always at the request of the medical staff. They will collaborate on restraining the patient to enable medical care [18]. Their action will be indicated at the request of attending doctors or nurse staff.

3.5.1 Physical restraint protocol

The most relevant aspects included in this physical restraint protocol are:

- Prior preparation of the environment and the patient.
- Sequence of interventions of the physical restraint:
  - Establishment.
  - Maintenance.
  - Removal.
- Observations in physical restraint.
- Possible adverse effects
- Details to highlight.

In Section 4.3 the specific **algorithm** is attached, where the steps to be followed if a patient requires **physical restraint** are outlined.

Prior preparation of the environment and the patient.

Before establishing physical restraint to an agitated patient, there are a number of items to take into account:

- The triggers of risk factors will be identified, if possible:
  - The physical condition will be assessed with regard to pain, infections, constipation
  - The use of medications that may trigger risky behaviours will be assessed.
  - The mental, psychological and emotional status will be assessed for disoriented or confused patients or those with dementia.
- Situations in which the use of physical restraint is contraindicated, such as eye surgery or neurosurgery, which may result in increased intraocular or intracranial pressure (level of evidence B), will be considered.
- The need to change/remove invasive therapeutic treatment administrations (venous/urinary catheters) to others less or non-invasive will be considered.
- Distraction techniques will be used to divert the patient's attention.
- Healthcare professionals intervening during the procedure will take care of removing dangerous objects such as glasses, watches, earrings, necklaces and anything they are carrying in their pockets.
- All potentially harmful objects that the patient is carrying will be removed.
- The bed must have the approved restraint equipment.
- Sensory stimuli will be reduced and we will confirm that the patient feels comfortable, ensuring that their basic needs are met. The presence or absence of pain will also be assessed.
- The safety of the environment will be increased: place the bed at the lowest possible height, move the furniture so that it does not impede the patient's mobility, check that the floor is not wet and place the bell so that the patient can reach it easily.
- The patient will be helped to feel oriented: introducing themselves every time they enter the room, reporting the current day and time, the place where they are located, turning off the lights at night, among other things.

» Close contact will be maintained with the patient throughout the duration of physical restraint.

Equipment:

The material to be used in the physical restraint must be approved. Figure 3 shows all possible restraints that may be used for physical restraint.

Figure 3. Material for physical restraint

Sequence of interventions:

I. Establishment of physical restraint

» Once the decision is made to apply physical restraint, verbal de-escalation should not be attempted.
» The reason for which the patient requires restraint measures will be assessed and at the discretion of the nurse, the doctor will be advised in order to treat the cause of the need to apply physical restraint.
» Once the patient is assessed and the need to apply restraint is identified, the patient and/or relatives will be informed and we will ask for their consent.
» We will determine the type of restraint with the whole team participating in the procedure.
» The coordinator in charge of the action taken will be the nurse or doctor. The person who addresses the patient will be the coordinator. The rest of the team should not have any conversations with the patient.
» Before proceeding with the restraint, we will inform the patient and attempt to get him/her to cooperate. If it is not possible, we will apply the procedure without discussion.
  — If the patient cooperates, we will accompany them to the room by having two people take him/her by their armpits and wrists.
  — If the patient does not cooperate, we will take the patient down to the floor, grabbing him/her by the shoulders and forearms, and by the legs under the knees and ankles. Another person will hold their head. Five people are needed to apply this technique.
» The restraint equipment will be placed as follows:
  — **Abdominal**: put the device on the bed and tie them to it with strips that are very taut (the belt should be strapped to the mattress of the bed). Place the patient on the belt, so that it is at the height of their waist. Pass the ends of the belt so that they cross in front of the patient and close it with the clamps. If the belt is placed correctly, you should be able to pass your hand between the belt and the person's body (Figure 4).
  — **Upper and lower limbs**: pass the strip device through by the handle of the belt, for the upper limbs, and through the handles of the extension strip fixed on the bed, for the

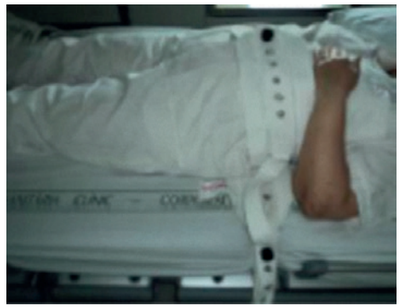


Figure 4. Abdominal restraint

lower limbs. Put the widest part of the device around the wrist or ankle, with the soft surface in contact with the skin. Pass it through the metal ring and spin it backwards. Pass it again through the handle of the device and affix it with the clamp of the handle of the belt for the upper limbs and with the handle of the strip affixed to the bed for the lower limbs (Figure 5).

Figure 5. Restraint of upper and lower limbs

- The order for placing the restraint devices must be followed. First abdomen, then lower limbs and finally upper limbs. Each person has an assigned limb and the fifth person handles the head.
- Never place a restraint device on a movable part of furniture, such as banisters.
- Leave the patient with a shirt from the unit, making sure that they have nothing in their pockets. The patient must not wear socks or stockings. An exception is if they wear therapeutic stockings to promote circulation in the lower limbs.
- Respect patient privacy by keeping the restraint device covered so that it is out of sight. Never cover the patient's face.
- Remove any objects from the upper limbs: rings, bracelets, etc., which may hinder blood flow.
- If the patient has free upper limbs, check that they have access to the call device.
- Ensure that the holding points are properly placed.
- Administer the prescribed medication.
- Open the restraint log sheet (see Annex V).
- Once the process has finished, inform the family of everything that has happened.
- At the same time, inform the room-mate or other patients who witnessed the process. Above all, we must preserve the patient's privacy, and explain that it is a therapeutic measure, that it is for the benefit of the patient and those around him/her and that he/she will be cared for at all time by medical personnel.

II. Maintenance of physical restraint

- Monitor the **clinical variables**: if i.m. medication is administered for the patient to feel calmer, the clinical variables will be measured every 30 minutes during the first two hours, and then they will be measured at four hours and at six hours. This time range will be maintained for as long as the patient is restrained, and as long as the administration of the i.m. medication lasts. The frequency will be determined by the patient's condition and the nurse's criteria.
- Assess the **level of consciousness**.
- **Directly observe the patient every 15 minutes** for the first two hours, then every hour. **Monitoring** over closed-circuit TV (if possible).
- Arrange the incorporated head of the bed to 30 degrees.
- Make changes to the patient's posture every hour.
- Rotate the holding devices to reduce the risk of skin lesions and promote circulation.
- The patient's basic needs will be met: food, hydration, hygiene, elimination, active-passive mobilisation, posture, body alignment, well-being and communication.
- Care for the patient's surroundings: restrict stimuli and maintain the comfort regarding temperature and lighting.
- Identify and store the patient's personal objects.
- **Protect the privacy** and maintain the dignity and self-esteem of the patient.
- Control and assess the adverse effects of the restraint.
- Maintain verbal contact at intervals while the patient is awake.
- Provide emotional support, if possible, and also to the family.
- Assess the need to continue with the restraint with the goal of removing it as soon as possible.

III. Removal of the physical restraint

- Proceed to remove the restraint gradually.
- Explain to the patient the limits to be respected in order to deactivate the restraint.
- At least two people must be present for the definitive removal.

Observations of the restraint:

- Restraint must be individual and limited in time (as soon as it is established, a plan to gradually remove it should be put in place).
- Never ask for cooperation to other patients or family members.
- Restraint must allow the placement and maintenance of catheters.
- **Belt restraint**: this will be used on cooperative patients who, as a result of immobilisation, calm down. It will be performed in the patient's bed, with or without pharmacological support. It must be accompanied by measures that provide a safe and calm environment.
- **Physical restraint of waist and/or upper limbs**: this will be applied when the patient is restless even when immobilised, and attempts to sit up in bed, get out of it, hit himself/herself or remove an IV line. It may or may not be accompanied by pharmacological support. It can be performed on the patient's own bed but it is recommended to do so in isolation if the concern is growing or the patient's behaviour is threatening to other patients.
- **Physical restraint of waist, upper limbs and lower limbs**: this will be applied in uncooperative and very restless patients who are unable to calm down, who can turn over the bed if they

are only restrained by their waist and hands, and for whom there is a risk of injury because of their condition. This type of restraint will be accompanied by isolation of the patient (whenever possible and/or as close to the nursing station as possible) and medication intended for cases of agitation.

Possible adverse events of physical restraint

The physical restraint may lead to associated risks for the patient:

Tabla 20. Possible adverse events of physical restraint

Possible adverse events of physical restraint
• Breathing difficulties (asphyxia, difficulty in removing secretions) derived from restraints that are too tight, due to an improper position of the restraint and/or of the patient or due to the use of restraints that have not been approved. • Cardiovascular problems (thromboembolism, oedemas) due to restraints that are too tight and/or extended, immobility of the patient and/or use of restraints that have not been approved. • Risk of impaired skin integrity due to the patient's immobility, from restraints that are too tight and their failure to rotate. • Anxiety arising from the patient's situation of helplessness and their dependence to meet their basic needs. • Risk of falls due to improper placement of the restraints or the use of holding devices that have not been approved. • Excretion problems (incontinence, constipation) due to the immobility and/or dependence of the basic needs. • Death due to the accumulation of the adverse effects described.

Aspects to consider::

- Make sure that the **alternative measures** have been reviewed and/or have failed prior to restraint.
- The application of a **restraint** is the **last resource**; it must be an **exceptional measure**.
- The **purpose** must always be **therapeutic**, not a punitive measure.
- It must be **individual** and **limited in time**, always using the least restrictive systems or techniques possible..
  - It usually occurs in emergency situations, against the patient's will, which is a condition that violates the patient's right of autonomy and freedom and requires the **informed consent** of the patient or of the family (verbal consent is sufficient).
  - It must be emphasised in the information to the family while the patient remains restrained.
  - **Physical restraint can have harmful physical and psychological effects on the patient relatives and on the medical personnel**.
  - Physical restraint of the patient contains the agitation episode but does not guarantee their safety, and a **strict follow-up** by the healthcare professional is necessary.

When the decision to place restraints on a patient is taken, the reason for which the restraints are placed must be documented, as well as measures performed earlier, on the evaluation sheet of the application of the physical restraint procedure (see Annex V). On the other hand, the entire restraint process must be recorded, as well as the follow-up until removal, on the restraint log sheet (Annex V).

The application of physical restraint on an agitated patient may lead to risk of injury and/or trauma, not only to the patient, but also to the medical personnel. If this occurs, the process will have to continue as a workplace accident.

3.6 Evaluation after the agitation episode

After acting in an agitation episode, it is **advisable to debrief what happened** with the therapeutic team and with the patient and other patients, as applicable.

An adequate review of how the initial care, assessment and treatment process in each case developed can help to improve quality in future care.

Reflexive process with the therapeutic team:

It is necessary to discuss the episode with the therapeutic team to **better understand what happened**, to share comments on relevant variables, to review the action taken and **to analyse possible improvements for future episodes**[17,30].

For this reason, the results of the action performed should be reviewed at several levels:

- Appropriate assessment of possible risk factors or presence or absence or not of predisposing factors for scaling of the agitation.
- Assessment of the differential diagnosis process (complementary exams, professionals who have been consulted, information obtained from relatives).
- Accurate therapeutic decision making (use of verbal de-escalation, environmental and pharmacological intervention as applicable to the case).
- In the case of use of coercive measures, assessment of their indication.
- Review of the adequate time, personnel and space necessary for the action.
- Proper documentation of the process with pertinent registry pages.
- Use of protocols in force in the centre.

Reflexive process with the patient:

It is advisable to emphasise the **subjective experience of the patient**, what they experienced, and what their ideas and **feelings** were **during their care**. The objective of this reflection is to help them to be conscious of how they process reality and their emotional state during the agitation episode. It is important to look for options with the patient to **prevent new episodes** and establish an agreed treatment plan in which the patient can participate voluntarily[17,30].

It is also important to show the patient how to **recognise the signs of alert**, which predict agitation episodes (see continuum of agitation in Figure 1). This way, the patient can safely ask for help from medical personnel in states of early agitation. On the other hand, it is also advisable to explain to the patient the **role of medication in the prevention of scaling of symptoms**[22].

Benefits of these assessments include **the restoration of the therapeutic relationship**, decreasing the traumatic nature of some events such as emergency intramuscular injections, and the risk of new episodes of agitation[22]. It should be taken into account that a **strong therapeutic alliance** between the patient and the doctor leads to improved **long-term control of episodes of agitation**.

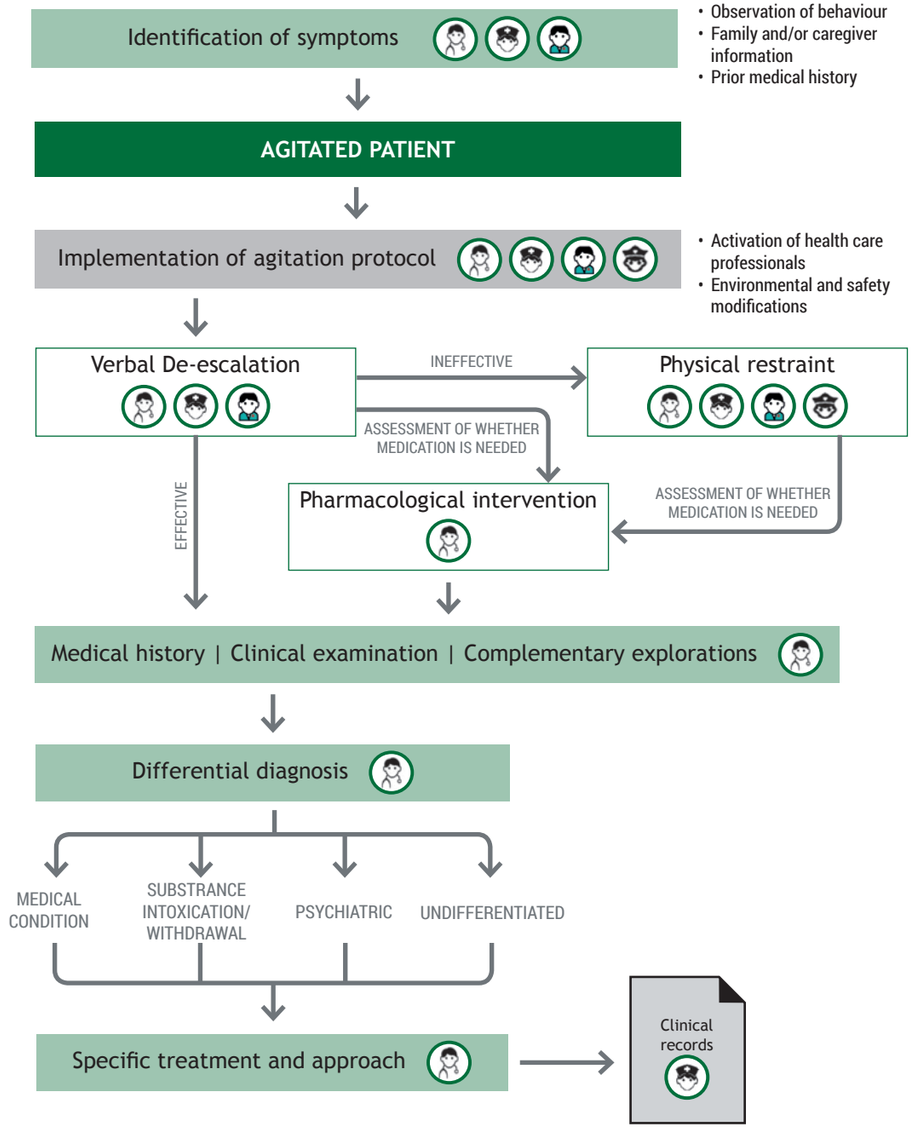
Reflexive process with other patients:

Depending on the presence in which the episode of agitation occurs, it is appropriate to reflect with other patients on what happened, both in individual and group visits for patients to express their experience with any aggressions that have occurred, or the control measures established by the therapeutic team[17,30].

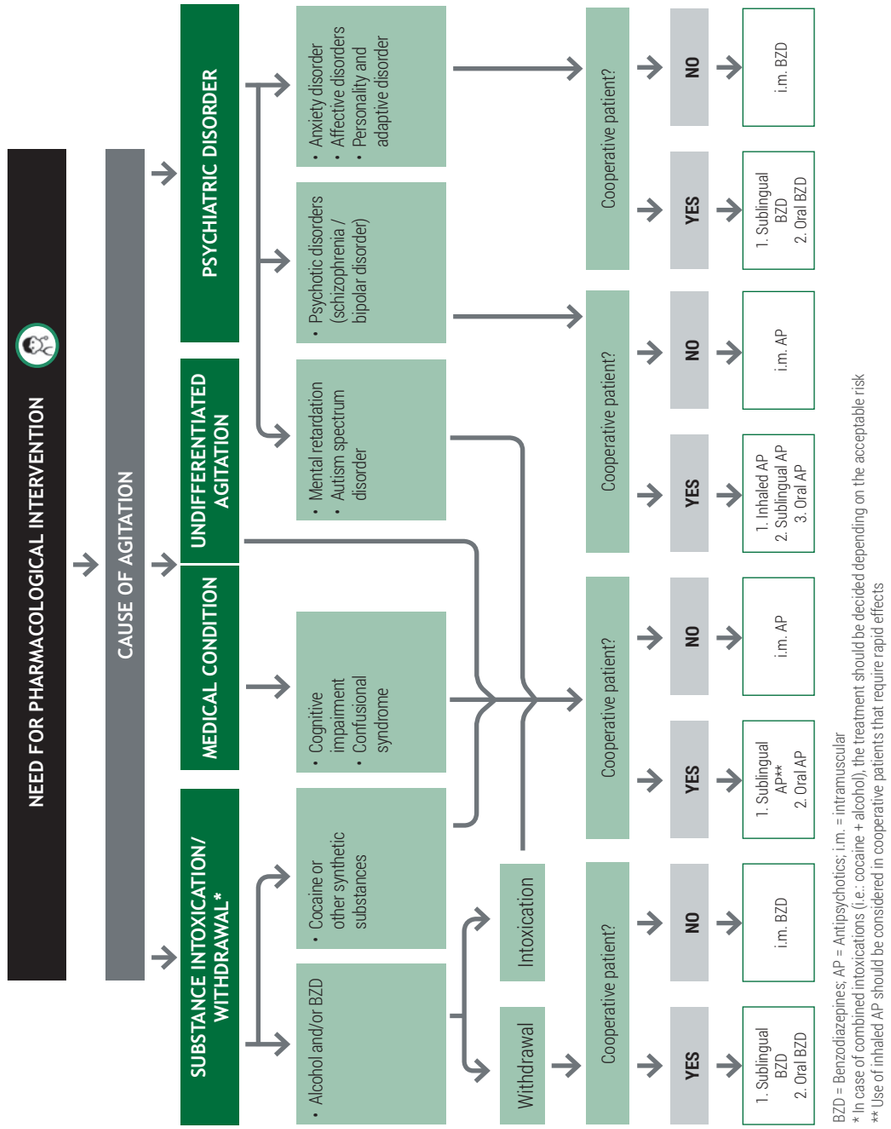
04

Algorithms

4.1. Algorithm for action in agitation



4.2. Algorithm for choice of medication



4.3. Algorithm for physical restraint

4.4. Summary table

Table 21. Protocol of action for an agitated patient

Action	When	Health care professional	Content	Outcome	Tools
Identification of agitation risk factors	Admission and first contact with the patient	Doctor or nursing staff	Prior history Behaviour observation Information of relatives	Record in clinical history Safety precautions	Table 3. Factors increasing the risk of agitation (page 22) Table 4. Factors decreasing the risk of agitation (page 22)
Initial care plan	Following risk assessment	Doctor, psychologist, nursing staff	Reduce risk factors. Maximise protective factors. Assign tasks. Start treatment.	Record of measures adopted in the clinical history. Record of the treatment started in the clinical history.	Care plan approach. Management of environmental factors. HCR-20 Scale, BVC Scale or VSC Scale (page 23)
Medical assessment and differential diagnosis	Interview with doctor.	Doctor or nursing staff	Differential diagnosis Assessment of mental status (where applicable). Establishment of the therapeutic relationship. Creation of an action plan.	Record in clinical history. Diagnosis of the underlying condition. Assessment of the degree of risk to the patient and others. Request of complementary exams. Adoption in writing of preventive measures: environment, contextual stimuli, etc.	Clinical interview (personal and/or family). CGI-A Scale (Annex I), PEC Scale (Annex II) or BARS Scale (Annex III).
Identification of signs and symptoms of alarm	At any moment of the care process	Any staff member in the hospital	Observation of attitudes and behaviours of restlessness, agitation and/or antisocial behaviour	Notice to nurse and/or doctor. Record documented in Medical History record. Adoption of preventive measures. Creation of a protective environment.	Relationship of prodromal signs. Table 5. Signs and symptoms present in an episode of agitation (page 24) Observation

4.4. Summary table (cont.)

Table 21. Protocol of action for an agitated patient

Action	When	Health care professional	Content	Tools	Outcome
Performance of complementary exams prescribed by a psychiatrist	As soon as possible	Nursing staff	Identify or rule out physical abnormalities or substance use	Biochemistry, cell blood count, serology, urine tests, neuroimaging, etc. (page 27)	Differential Diagnosis. Record in clinical history. Results report
Application of techniques of verbal de-escalation	From the identification of prodromal signs and throughout the intervention	Doctor and/or nursing staff	Reduce the patient's tension by promoting a safe and secure environment	Professional relationship. Table 9. The 10 principles of the verbal de-escalation technique (page 32) Table 10. Non-verbal behaviour guidelines (page 33) Table 11. Environmental guidelines (page 33) Table 12. Communication directives (page 34)	Calming the patient. Record in clinical history.
Pharmacological intervention	Whenever the doctor deems it convenient or when verbal de-escalation fails	Doctor prescribes. Nursing staff administers.	Rapid decrease of uneasiness to lessen the risks of agitation	Table 15. Pharmacological treatment options (page 37) Prescription registry pages. Observation of side effects	Calm the patient down. Prevention of the risks associated with the use of tranquillizers. Record in clinical history.
Physical restraint	When the clinical situation so advises	Decision making process: Attending doctor or nursing staff. Healthcare team	Protect the patient from self-harm or harm to others	Approved material. Physical restraint protocol (page 43). Continued training.	Application of physical restraint protocol. Record in clinical history. Restraint log sheet.

4.4. Summary table (cont.)

Table 21. Protocol of action for an agitated patient

Action	When	Health care professional	Content	Tools	Outcome
Aggression record	When a member of the staff is attacked	Staff member attacked. Attending doctor.	Electronic communication of the aggression. Record of the patient's clinical and psychopathological condition and report of what happened	Incident notification.	Record in clinical history Incident report form.
Evaluation after the agitation episode	After the end of the behaviour and in a phase of clinical stability	Attending doctor	Analysis in the therapeutic report of the episode. Analysis by the team of precipitating factors and the action taken	Team meetings. Ordinary meetings between patients and professionals (page 50)	Learning from experience for the patient and the team. Incorporation of actions for improvement. Creation of specific goals in the treatment of the patient relating to agitation.

05

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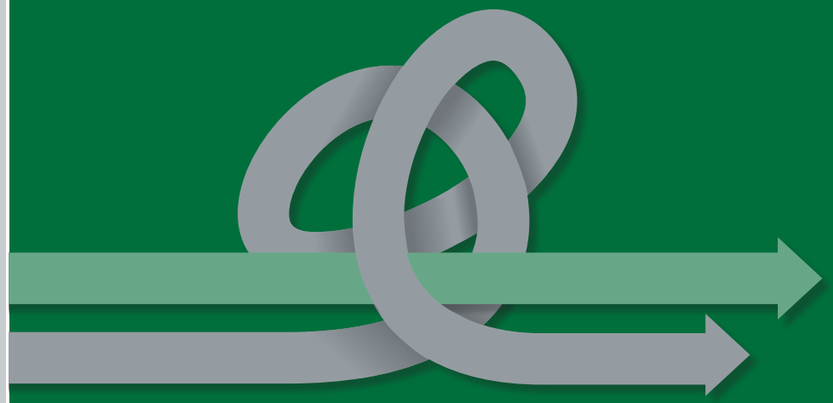

06

Annexes

Annex I. CGI-A Scale

The CGI-A Scale can be quickly applied to assess the severity level of the aggression in patients. It is a 5-point Likert scale with the following scoring [19]:

1. Non-aggressive patient

2. Mildly aggressive patient

3. Moderately aggressive patient

4. Severely aggressive patient

5. Aggressive behaviour present

Annex II. PEC Scale

The excitation component of the Positive and Negative Syndrome Scale (PANSS-EC or PEC) assesses five items (poor impulse control, tension, hostility, lack of cooperation and excitement) from 1 (no presence) to 7 (extremely severe). Scores range from 5 to 35 points, with a score of ≥20 points corresponding to severe agitation. The items that are assessed, along with their description and what each point refers to, are specified below:

Table 22. Elements PEC Scale

POOR IMPULSE CONTROL		
Definition		Disorder in the regulation and control of internal impulses, resulting in a sudden, unmodulated, arbitrary or misdirected release of stress and emotions without concern for the consequences.
Bases for assessment		Behaviour during the interview and information from the medical personnel and family.
Score:	**1. Absent**	Does not meet the definition.
	2. Minimum	Doubtful pathology may be the upper limit of normality.
	3. Mild	The patient tends to react angrily to stress or frustration easily, but rarely engages in impulsive acts.
	4. Moderate	The patient shows anger and verbal aggression for minimal frustrations. They can be occasionally threatening, have destructive behaviours, or have one or two episodes of physical confrontation or a minor altercation.
	5. Moderately severe	The patient has repeated impulsive episodes with verbal abuse, destruction of property or physical threats. There may be one or two episodes of serious violent attacks that require seclusion, physical restraint or sedation.
	6. Severe	The patient often presents aggression, threats, demands and impulsive violence, without any regard for the consequences. The patient has attacks of violence, including sexual, and can respond violently to hallucinatory voices.
	7. Extreme	The patient carries out homicidal attacks, sexual assaults, repeated brutality or self-destructive behaviour. They require direct and constant supervision or external restraint because of their inability to control violent impulses.

Annex II. PEC Scale (cont.)

Table 22. Elements PEC Scale (cont.)

MOTOR TENSION		
Definition		Clear physical manifestations of fear, anxiety and agitation, such as muscle tension, trembling, profuse sweating and restlessness.
Bases for assessment		Verbal manifestations of anxiety and severity of the physical manifestations of tension observed during the interview.
Score:	**1. Absent**	Does not meet the definition.
	2. Minimum	Doubtful pathology, may be the upper limit of normality.
	3. Mild	The posture and movements indicate a slight fear, as well as some motor tension, occasional restlessness, changes in posture, or a mild hand tremor.
	4. Moderate	Clear nervous appearance, as deduced by restless behaviour, manifest hand tremors, excessive sweating or nervous tics.
	5. Moderately severe	Marked tension as evidenced by nervous shaking, profuse sweating and restlessness, but behaviour in the interview is not significantly altered.
	6. Severe	Marked tension that interferes with interpersonal relationships. The patient, for example, may be constantly restless, is unable to remain seated or hyperventilates.
	7. Extreme	The marked tension is manifested through symptoms of panic or due to significant motor hyperactivity, such as accelerated gait or the inability to remain seated for more than one minute, which makes it impossible to hold a conversation.

Annex II. PEC Scale (cont.)

Table 22. Elements PEC Scale (cont.)

HOSTILITY		
Definition		Verbal and non-verbal expression of anger and resentment, including sarcasm, passive-aggressive behaviour, insults and physical violence.
Bases for assessment		The interpersonal behaviour observed during the interview and the information provided by medical personnel or family.
Score:	**1. Absent**	Not applicable.
	2. Minimum	Doubtful pathology: may be on the upper extreme of the normal limits.
	3. Mild	Indirect or repressed manifestations of anger, such as sarcasm, disrespect, hostile expressions, and occasional irritability.
	4. Moderate	They have an openly hostile attitude and have frequent irritability and direct manifestations of anger and resentment.
	5. Moderately severe	The patient is highly irritable and, occasionally, may express insults or threats.
	6. Severe	The lack of cooperation and insults or threats notorious during the interview and have a serious impact on social relationships. The patient may act violently and in a destructive way, but they do not manifest physical violence toward others.
	7. Extreme	Anger is very pronounced and causes a total lack of cooperation and the rejection of interacting with others, or episode(s) of physical violence towards others.

Annex II. PEC Scale (cont.)

Table 22. Elements PEC Scale (cont.)

LACK OF COOPERATION		
Definition		Active rejection of granting the desires of others, including the interviewer, medical personnel or family. This rejection may be associated with wariness, defensiveness, stubbornness, negativity, rejection of authority, hostility or belligerence.
Bases for assessment		Behaviour observed throughout the interview and the information provided by the medical personnel and family.
Score:	**1. Absent**	Does not meet the definition.
	2. Minimum	Doubtful pathology, may be the upper limit of normality.
	3. Mild	Attitude of resentment, impatience or sarcasm. They refuse to cooperate throughout the interview.
	4. Moderate	Occasional refusal to cooperate with normal social demands. The patient may manifest a hostile, defensive or negative attitude, but it generally may be manageable.
	5. Moderately severe	The patient frequently does not cooperate with the demands of their environment and may be considered by others as "undesirable" or having "difficulties dealing with them". The lack of cooperation is manifested by a marked defensive attitude or irritability with the interviewer and scant willingness to answer many of the questions.
	6. Severe	The patient cooperates very little, is negative and possibly also belligerent. The patient refuses to cooperate with most social demands and may refuse to start or complete the whole interview.
	7. Extreme	Active resistance seriously disrupts almost all areas of functioning. The patient may refuse to be involved in any social activity, personal care, talking with family or medical personnel, and refuse to participate, if only briefly, in the interview.

Annex II. PEC Scale (cont.)

Table 22. Elements PEC Scale (cont.)

EXCITEMENT		
Definition		Hyperactivity, manifested through the acceleration of motor behaviour, intensification of responsiveness to stimuli, exaggerated alert attitude or excessive volatility of mood.
Bases for assessment		The behaviour manifested during the interview, as well as information on the patient's behaviour provided by the medical personnel or family.
Score:	**1. Absent**	Not applicable.
	2. Minimum	Doubtful pathology: may be on the upper extreme of the normal limits.
	3. Mild	They tend to feel slightly restless, in an excessive state of alertness, or moderately over-stimulated throughout the interview, but without clear episodes of excitement or great instability of mind. Speech may be slightly nervous.
	4. Moderate	Nervousness or overstimulation is clearly evident throughout the interview, affecting speech and general mobility, or episodic accesses occur sporadically.
	5. Moderately severe	A significant degree of hyperactivity or frequent accesses of motor activity is seen. At any time, the patient has a hard time staying seated and without moving for more than a few minutes.
	6. Severe	A notable nervousness dominates the interview, limits attention and, to a certain extent, affects personal functions, such as food and sleep.
	7. Extreme	A notable nervousness seriously interferes with food and sleep and makes interpersonal contact virtually impossible. The acceleration of speech and motor activity may produce incoherence and physical exhaustion.

Annex III. BARS Scale

The BARS Scale assesses the level of sedation and divides patients into seven levels of agitation:

1. Difficulty or inability to wake

2. Asleep, but responds normally to verbal or physical contact

3. Drowsiness, appears sedated

4. Calm and awake (normal level of activity)

5. Shows signs of activity (physical or verbal), calms down with instructions

6. Extremely or continuously active, does not require restraint

7. Violent, requires restraint

Annex IV. Assessment in cases of substance intoxication/withdrawal

The criteria for the diagnosis of intoxication and withdrawal of different substances are listed below[3]:

Tabla 23. Criteria for the diagnosis of substance intoxication and withdrawal

Substance	Intoxication	Withdrawal
Alcohol	One (or more) of the following symptoms: 1. Slurred speech 2. Lack of coordination 3. Unstable gait 4. Nystagmus 5. Impaired attention or memory 6. stupor or coma	Two (or more) of the following symptoms: 1. Autonomic hyperactivity (e.g., sweating, or more than 100 bpm) 2. Distal hand tremor 3. Insomnia 4. Nausea or vomiting 5. Transient visual, tactile and auditory hallucinations or delusions 6. Psychomotor agitation 7. Anxiety 8. Seizures
Hallucinogens	Two (or more) of the following signs: 1. Dilated pupils 2. Tachycardia 3. Sweating 4. Palpitations 5. Blurred vision 6. Tremors 7. Lack of coordination	N/A
Amphetamines and related substances	Two (or more) of the following signs and symptoms: 1. Tachycardia or bradycardia 2. Dilated pupils 3. Increased or decreased blood pressure 4. Sweating or shivering 5. Nausea or vomiting 6. Psychomotor agitation or retardation 7. Muscle weakness, respiratory depression, chest pain or cardiac arrhythmias 8. Confusion, seizures	Dysphoric mood and two (or more) of the following physiological changes: 1. Fatigue 2. Vivid, unpleasant dreams 3. Insomnia or hypersomnia 4. Increased appetite 5. psychomotor agitation or retardation
Cannabis	Two (or more) of the following symptoms: 1. Conjunctival injection 2. Increased appetite 3. Dry mouth 4. tachycardia	N/A
Cocaine	Two (or more) of the following signs: 1. Tachycardia or bradycardia 2. Dilated pupils 3. Increased or decreased blood pressure 4. Sweating or shivering 5. Nausea or vomiting 6. Psychomotor agitation or retardation 7. Muscle weakness, respiratory depression, chest pain or cardiac arrhythmias 8. Confusion, seizures	Dysphoric mood and two (or more) of the following physiological changes: 1. Fatigue 2. Vivid and unpleasant dreams 3. Insomnia or hypersomnia 4. Increased appetite 5. Psychomotor agitation or retardation

Annex IV. Assessment in cases of substance intoxication/withdrawa (cont.)

Tabla 23. Criterios para el diagnóstico por intoxicación/abstinencia a sustancias (cont.)

Phencyclidine or similarly acting substances	Two (or more) of the following signs: 1. Horizontal or vertical nystagmus 2. Hypertension or tachycardia 3. Drowsiness or decreased pain arousal 4. Ataxia 5. Dysarthria 6. Muscle stiffness 7. Seizures or coma 8. Hyperacusis	N/A
Inhalants	Two (or more) of the following signs: 1. Dizziness 2. Nystagmus 3. Lack of coordination 4. Slurred speech 5. Unstable gait 6. Lethargy 7. Decreased reflexes 8. Psychomotor retardation 9. Tremors 10. Generalised muscle weakness 11. Blurred or double vision 12. Stupor or coma 13. Euphoria	N/A
Opiates	Myosis (or mydriasis by anoxia in severe poisoning) and one (or more) of the following signs: 1. Sleepiness or coma 2. Slurred speech 3. Impaired attention or memory	Three (or more) of the following signs and symptoms: 1. Dysphoric mood 2. Nausea or vomiting 3. Muscle pain 4. Lacrimation or rhinorrhea 5. Dilated pupils, piloerection, or sweating 6. Diarrhoea 7. Yawning 8. Fever 9. Insomnia
Sedatives, hypnotics and anxiolytics	One (or more) of the following signs: 1. Slurred speech 2. Lack of coordination 3. Unstable gait 4. Nystagmus 5. Impaired attention or memory 6. Stupor or coma	Two (or more) of the following signs: 1. Autonomic hyperactivity (e.g., sweating, or more than 100 bpm) 2. Increased tremor of hands 3. Insomnia 4. Nausea or vomiting 5. Transient visual, tactile and auditory hallucinations or delusions 6. Psychomotor agitation 7. Anxiety 8. Seizures
Other substances (e.g., cimetidine, digital, benztropine)		

Annex V. Physical restraint log sheet

Date and time of restraint start:

Date and time of restraint end:

Total hours in restraint:

Name and signature of the employees responsible for indicating the restraint:

Nursing sheet:

Isolation room: Yes ☐ No ☐

Description of the reason:

- Risk of self-harm
- Risk of harm to others
- Placement and/or maintenance of catheters
- Other: _____

Action to prevent physical restraint:

- Verbal de-escalation ☐
- Pharmacological intervention: oral ☐ parenteral ☐
- Reduction of sensory stimuli. Isolation of patient, if possible: ☐
- Other: _____

Type of restraint:

Sedation: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Date:

Control time: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Status at control: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1. Worsening **2.** Partial improvement **3.** No changes **4.** Removal of restraint with supervision
5. Restraint without supervision **6.** Complete improvement and removal of restraint

1

Annex V. Physical restraint log sheet (cont.)

Type of restraint:

Sedation: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Date:
Control time: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Status at control: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
1. Worsening **2.** Partial improvement **3.** No changes **4.** Removal of restraint with supervision
5. Restraint without supervision **6.** Complete improvement and removal of restraint

Type of restraint:

Sedation: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Date:
Control time: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Status at control: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
1. Worsening **2.** Partial improvement **3.** No changes **4.** Removal of restraint with supervision
5. Restraint without supervision **6.** Complete improvement and removal of restraint

Type of restraint:

Sedation: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Date:
Control time: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Status at control: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
1. Worsening **2.** Partial improvement **3.** No changes **4.** Removal of restraint with supervision
5. Restraint without supervision **6.** Complete improvement and removal of restraint

Type of restraint:

Sedation: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Date:
Control time: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Status at control: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
1. Worsening **2.** Partial improvement **3.** No changes **4.** Removal of restraint with supervision
5. Restraint without supervision **6.** Complete improvement and removal of restraint

2

Annex VI. Evaluation sheet of physical restraint procedure application

Place of implementation: ____________________ Date of restraint: ____________

Clinical Record Number: ____________________ Age: ___ Male ☐ Female ☐

Other conditions: ____________________

Procedure compliance (tick with an X)

Duration of the restraint:	5'	10'	20'	30'	40'	50'	1h	2h	3h	4h	5h	6h	7h	8h	9h	10h	11h	12h	24h	36h	+

PRIOR PHASE

Application of verbal de-escalation prior to physical restraint	Yes, but it is not effective	
	Impossible to perform due to patient's condition	
Preparation of the room with approved physical restraint materials	Without incident	
	Lack of material or material in poor conditions	
	Limited time to prepare the material	
Preparation of the environment (room and staff taking part in the restraint without dangerous objects)	Without incident	
	With difficulties but with a positive result	
	With difficulties that impede the procedure	
Information to the patient on the application of physical restraint	Yes	
	No	
Notice to the support staff on the application of physical restraint: - Medical assistant adults room - Medical assistant central pool - Safety	Impossible to perform due to patient's condition	
	Without incident	
	With difficulties but with a positive result, they arrive on time	
	With difficulties that impede the procedure, they do not answer the phone	
Number of people who took part in the restraint and professional category:	Nursing	
	Nursing Assistant	
	Medical Assistant	
	Medical Assistant *"door"*	
	Security	

1

Annex VI. Evaluation sheet of physical restraint procedure application (cont.)

IMPLEMENTATION PHASE

The nursing staff or head physician leads the restraint process	Yes	No
Each person who takes part in the physical restraint has an assigned extremity	Yes	No
The patient is wearing the hospital gown	Yes	No
Dangerous objects for the patient have been removed (rings, socks, etc.)	Yes	No
The fastening points have been checked and the correct positioning has been ensured	Yes	No
The log sheet has been opened	Yes	No
The family has been informed of the application of restraint	Yes	No

MAINTENANCE PHASE

The clinical variables have been checked every 30 minutes for the first two hours, later every 4 hours and then every 6 hours	The vital signs have not been taken	Yes
	The vital signs have been taken, but not in the stipulated frequency	Yes / No
The patient's condition has been checked every hour		Yes / No

REMOVAL PHASE

Two people took part in the removal of the physical restraint	Yes	No
Effective control of agitation (control every 2 hours) remarks	Yes	No

COMMENTS:

2