Trust Standard Operating Procedure

University Hospitals Plymouth NHS Trust

Intensive Care Unit (ICU) Safe Holding System to Manage Serious Self-Harm & Prevent Prolonged Restraint

Issue Date	Review Date	Version
June 2021	April 2024	V.2

Purpose

To provide guidance and context for the use of a Safe Holding System (SHS) for managing serious self-harm and reducing violence to prevent prolonged restraint in ICU. The SHS will be applied to those patients who engage in significant and life threatening incidents of self -harm or who pose significant risk of serious harm to others.

Who should read this document?

All staff working in UHPNT ICU, involved in caring for patients.

Key Messages

Up to 80% of seriously ill patients who require intensive care become agitated or confused during their stay. A small number of patients become combative and may injure themselves, staff, their family or their carers. “Chemical Restraint” is employed in the majority of cases, but is not without risk and in the long term sedative agents may be relatively ineffective at controlling agitation and may actually provoke or prolong confusion.

Restraint is lawful so long as you have the capability to do so and it is in the patient’s best interest.

This document forms a framework for the use of higher level mechanical restraint devices, for this specific challenging patient group in ICU.

Core accountabilities	
Owner	Sophie King Physical Interventions Lead
Review	Safeguarding Steering Group
Ratification	Chief Nurse and Director of Integrated Clinical Professions – Lenny Byrne
Dissemination (Raising Awareness)	Safeguarding Steering Group
Compliance	All staff working in UHPNT ICU, involved in caring for patients.

Links to other policies and procedures

UHPNT Plymouth Hospitals NHS Trust (UHPNT) Paediatric Physical Intervention Policy
UHPNT Management of Physical Intervention (Restraint) for Adults in an Acute Hospital Setting Policy
UHPNT Mental Capacity Act Policy 2005
UHPNT Policy and Procedure for individuals who are violent or aggressive
UHPNT Prevention of violence policy to staff at work
UHPNT Incident Management Policy
UHPNT Decontamination Guidelines and Procedures
UHPNT Medical Equipment Users Guide
UHPNT Moving and Handling People and Objects Policy

Version History		
V.1	**February 2020**	First publication
V.2	**June 2021**	Review Minor amendments:

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

University Hospitals Plymouth NHS Trust

Standard Operating Procedure (SOP)

Title: Intensive Care Unit (ICU) Safe Holding System to Manage Serious Self-Harm & Prevent Prolonged Restraint

1 Introduction

This Standard Operating Procedure (SOP) details where the use of the Safe Holding System is necessary to manage incidents of serious and life-threatening self-harm or significant risk of harm to others. There is a requirement that these measures form part of a Medical Consultant led prescribed care plan with the intention of minimising the risk associated with serious self-harm and prolonged restraint within ICU to patient, staff and visitors.

This SOP applies **only** within the context of ICU. Staff within this identified area may use the Safe Holding System in strict accordance with this SOP, in order to reduce the risk of serious harm to a patient's health and possible harm to others whilst they are an inpatient on ICU.

This policy must be read in conjunction with:

UHPNT Plymouth Hospitals NHS Trust (UHPNT) Paediatric Physical Intervention Policy
UHPNT Management of Physical Intervention (Restraint) for Adults in an Acute Hospital Setting Policy
UHPNT Mental Capacity Act Policy 2005
UHPNT Policy and Procedure for individuals who are violent or aggressive
UHPNT Prevention of violence policy to staff at work
UHPNT Incident Management Policy
UHPNT Moving and Handling People and Objects Policy
Intensive Care Society (2021) The Use of Physical Restraints in UK Adult Intensive Care Units.

The following principles should be applied when using the Safe Holding System to manage serious and sustained self-harm (for example the attempted removal of safety critical indwelling devices), or significant attempts to harm others.

- Paragraph 15.31 of the Mental Health Act (1983) Code of Practice (DH, 2015, p. 296) states:

"Mechanical restraint is a form of restrictive intervention that refers to the use of a device to prevent, restrict or subdue movement of a person's body, or part of the body, for the primary purpose of behavioural control".

- Mechanical restraint should only be used exceptionally (as a last resort) where other forms of restriction cannot be safely employed, or are contra-indicated. For those patient`s whom lack capacity to consent it should be used in line with the principle of least restrictive option and proportionality, in the patient`s best

interests and should not be an unplanned response to an emergency situation. Mechanical restraint must never be used instead of adequate staffing.

- The Safe Holding System must **never** be used as a threat or a form of punishment.

- Consideration must be given to the placement of the SHS and pre-existing patient injuries, co-morbidities and the position of any indwelling devices.

- **The Safe Holding System must not be used on a pregnant woman under any circumstances.**

- When considering using the SHS to manage children (patients under 18 years) other means of safely managing behaviour must be fully explored. When assessing risk if there is no other safe alternative appropriate restraint must be used for the minimum time only under the direct management and instruction of a specialist consultant. A referral made to the internal safeguarding team via SALUS to enable support to be provided as needed.

The patient's care plan should clearly document the following:

- What legal framework is in place to ensure compliance with the law e.g. Mental Capacity Act, Mental Health Act.

Medical Consultant's prescription must detail:

- At what point the SHS would be used in cases of potential serious self-harm/harm to others, non-capacity to consent and non-compliance to life saving treatment which would lead to prolonged high level physical restraint to keep the patient and others safe.

- The care plan should give specific rationale and targeted reasons for the use of the SHS.

The need to ensure the safety of the person to which the SHS is applied remains paramount.

Only the SHS approved for use with ICU is to be applied.

The use of the SHS must be reported via UHPNT reporting (datix), and recorded on the UHPNT restraint register as soon as is practically possible and no later than end of shift.

The SHS will be stored in a designated area in ICU that is secure but is easy to access should the SHS be required, and this area communicated to staff.

In all instances where the SHS is used for prolonged periods, risk assessment and reviews must be on-going with a view to end prolonged usage as soon as practicably possible. The use of soft cuffs in relation to applying SHS is for the sole purpose of minimising risk of the patient's arms /legs struggling free and compromising the safety of the patient and those members of staff caring for the patient.

Use of the SHS for short periods of time is within the spectrum of usual care for patients with emergence delirium, but safer and more secure than posey mitts and low level wrist restraints. However the use of the SHS will require on-going risk assessment and review in the decision to continue or discontinue its use.

Staff must have had training in the application, use and management of the SHS which must be updated on an annual basis.

This equipment must only be used for patients in adult intensive care and must not be used in any other part of the Trust.

The escalation process and procedure for using the SHS for managing serious self-harm can be found in section 5 of this SOP.

The Chief Nursing Officer must be informed of the decision to use the SHS via the UHPNT Restraint Register; however the decision to use, implement and remove the SHS rests with the clinical team. Discontinuation of the SHS must be noted on the Restraint Register as soon as is practically possible, but no later than the end of shift.

There may be extenuating circumstances where the SHS is used to manage patients with a pre-existing history that indicates there is the potential for high risk of assault to others, or high risk of self-harm, and who lack capacity to consent to a necessary medical treatment. The decision to use the SHS must be Consultant (Medical) prescribed.

It may be necessary to use the SHS to ensure that the patient receives such treatment. **This circumstance is covered by Sections 5 & 6 of the Mental Capacity Act 2005. (Refer to Multi-Agency Joint Policy and Procedure on the Mental Capacity Act 2005).**

The SHS utilised by the organisation has been risk assessed to be used in conjunction with soft cuffs by an independent assessor. This restraining device has also been risk assessed by UHPNT Physical Interventions Lead and the Clinical Director ICU.

2 Definitions

Best Interest

Before a best interest decision is made under the Mental Capacity Act 2005 a person must be assessed as lacking capacity in relation to that specific decision (as per the process outlined in the MCAct) and the decision must be undertaken in that persons best interests. The decision must be the least restrictive option and proportionate to the identified risk. Consultation with all the people involved in that person’s care must take place where reasonable and practical to do so, including the family and those who know the patient best (where possible).The decision maker must take into consideration the views expressed. The consideration of best interests is set out in more detail in section 4 of the Mental Capacity Act 2005.

Challenging Behaviour

Reducing Distress NHS Protect (2014) indicates that its definition of clinically related challenging behaviour is "any non-verbal, verbal or physical behaviour by a person which makes it difficult to deliver good care safely", to perform clinical tasks and/or poses a safety risk. It can describe actions, but can also include non-compliance,

particularly if staff needs to intervene to deliver treatment or care. Behaviour can also be described as challenging when it is of such an intensity, frequency or duration as to threaten the quality of life and / or the physical safety of the individual or others" (Royal College of Psychiatrists and others – A Unified Approach, 2007).

Consent

Consent is the legal means by which a person gives a valid, informed and voluntary authorisation, including a care plan or treatment. For consent to be legally valid: (i) the consent must be given by someone at a time when they were deemed to have capacity, (ii) sufficient information must be given to the person so that an informed decision can be made, including the options, benefits and associated risks. There is also a legal duty to ensure the patient is aware of the material risk involved in the recommended treatment or action and of any reasonable alternative or variant. (iii) The consent must be freely given without duress, undue influence, inappropriate pressure, coercion or bullying.

Deprivation of Liberty & Deprivation of Liberty Safeguards (DoLS)

Deprivation of liberty is a term used in the European Convention on Human Rights about circumstances when a person's freedom is taken away and is not lawful unless authorised by a procedure prescribed in law.

Deprivation of Liberty Safeguards (DoLs) is the procedure prescribed in law to authorise a deprivation of liberty under the Mental Capacity Act 2005 for people who need to be deprived of their liberty in a hospital or care home in their best interests for care or treatment and who lack capacity to consent for themselves.

Safe Holding System

The SHS is a soft restraint belt and is used in conjunction with Soft –cuffs fixed in place. This is the Safe Holding System. The Safe Holding System provides a practical alternative to more intrusive methods of prolonged manual restraint for the most challenging patients within ICU. Its use in conjunction with the Soft-cuffs include assistance in the prevention of self-injurious behavior, behavior that poses a significant risk to others, and managing the transition from manual holds to mechanical restraint and reintegration of patients without restraint. The SHS provides comfort for the patient, can be cleaned in between patient use, and provides optimum strength.

Safe Holding System has been tested to EN ISO 10535 standards, reviewed by the Home office’s preferred leading medical expert and are proved to reduce injuries and subsequent litigation and provide the least intrusive option to manual restraint.

Independent Mental Capacity Advocate (IMCA)

This is a statutory role under the Mental Capacity Act whose role includes support and representation for a patient who lacks capacity to make a specific decision, where that person has no one else (other than a paid professional) who can support them. They make sure that major decisions for a patient who lacks capacity are made in accordance with the Mental Capacity Act 2005.

Mechanical Restraint

Mechanical restraint is a form of restrictive intervention which involves the use of a device or equipment (for example 'Posey Control Mitts') to prevent, restrict or subdue movement of a person's body or part of the body.

Restraint

The use or threat of force to help undertake an act which the person resists, or the restriction of the person's freedom of movement, whether or not they resist. Restraint may only be used where it is reasonably believed that it is **necessary** to protect the person from **harm** and is **proportionate** to the likelihood of that person suffering harm and the seriousness of that harm, or where it is believed to be necessary to prevent harm from happening to others.

Restraint Intervention

Defined in the Positive & Proactive Care (DoH 2014) guidance as: 'deliberate acts on the part of other person(s) that restrict an individual's movement, liberty and/or freedom to act independently in order to: take immediate control of a dangerous situation where there is a real possibility of harm to the person or others if no action is undertaken; and end or reduce significantly the danger to the person or others; and contain or limit the person's freedom for no longer than is necessary'.
The use of force to limit the movement and freedom of an individual can involve bodily contact, mechanical devices, chemical restraint (e.g. the use of medication to alter or change a persons' behaviour), or changes to a person's environment. Such interventions can be:

- Highly Restrictive – i.e. severely limit the movement and freedom of an individual
- Low Level Restrictive –i.e. limit or contain the movement and freedom of an individual who is less resistant with low levels of force

Pharmacological or Chemical Restraint

Pharmacological or chemical restraint is defined as: "A drug used as a restraint to control behaviour or to restrict the patient's freedom of movement and is not standard treatment for the patients' medical or psychological condition." Any pharmacological or chemical drug used for restraint must be prescribed by a registered doctor who has started specialist training and administered by those who are trained and competent to do so.

Psychological Restraint

Can include the telling of someone not to do something, or a positive message to direct their actions, or depriving an individual of equipment or possessions which enable them to do what they want to do, or making a threat or indication that physical, chemical, or mechanical restraint will occur in the absence of compliance.

This may involve simple verbal directions to the patient in order to direct their behaviour and may be a positive message to direct their actions or a negative message to alert them to behaviour or action which is prohibited. Psychological restraint may also include the removal of equipment or possessions that would be required by a patient to undertake autonomous activity. For example the removal of walking aids, or glasses with the intention of reducing their freedom of movement.

Prone Position (patient lying on their stomach)

There must be no planned proning of patients for the purposes of restraint in UHPNT, due to the risk of positional asphyxia. Positional asphyxia is defined as occurring when 'the position of the body interferes with respiration, resulting in asphyxia (suffocation). Positional/restraint asphyxia can occur extremely rapidly when a patient is in a position that interferes with inspiration and / or expiration and the individual cannot alter that position.

Soft Cuffs

Soft –cuffs are used in conjunction with the Safe Holding System.

3 Key Guidance

All episodes of planned and unplanned restraint must comply with Human Rights Framework for Restraint (2019) and Equality Act (2010).

All restraint interventions must be carried out in accordance with UHPNT Management of the following:

- Physical Intervention (Restraint) for Adults in an Acute Hospital Setting Policy, UHPNT
- Paediatric Physical Interventions Policy, and UHPNT Mental Capacity Act (MCA, 2005), including Deprivations of Liberty (DoLS, 2007).

Key Guidance:

NICE Guidance 10 (2015) Violence and aggression: short-term management in mental health, health and community settings.
DOH (2014) Positive and Proactive Care: reducing the need for restrictive interventions.
DOH (2019) Reducing the Need for Restraint and Restrictive Intervention.
Children and young people with learning disabilities, autistic spectrum conditions and mental health difficulties in health and social care services and special education settings.
CQC (2016) Brief Guide: Restraint (Mechanical and Physical).
Equality and Human Rights Commission (2019) Human Rights framework for restraint. www.equalityhumanrights.com/sites/default/files/human-rights-framework-restrai…
Intensive Care Society (2021) The Use of Physical Restraints in UK Adult Intensive Care Units. Physical Restraints Guidance - ics.ac.uk
NPSA (2015) the importance of checking vital signs during and after restrictive interventions/manual restraint.

4 Key Duties

Responsibilities

Clinical teams are responsible for making sure that risk assessments, physical health assessments and a care plan are completed and that the Chief Nursing Officer is **informed** when SHS is part of an individual's risk management strategy, by means of the Restraint Register. The application of the SHS is decided by the clinical team based on the presenting or historical risks

Chief Executive

The Chief Executive and wider Trust Board have key roles and responsibilities to ensure the Trust meets requirements set out in law, and of statutory and regulatory authorities such as the Department of Health, Commissioners and the Care Quality Commission. The Trust's Chief Executive has overall responsibility to have processes in place to:

- Ensure that ICU clinical staff are aware of this SOP and adhere to its requirements
- Ensure that appropriate resources exist to meet the requirements of this SOP

Executive and Non-Executive Directors

The Executive Directors are responsible for ensuring that all operational managers for ICU are aware of this SOP, understand its requirements and support its implementation.

Role of Non- executive and elected leads

The Non-Executive and elected leads are responsible for:

- Championing & maintaining focus on Mental Capacity
- Providing independent scrutiny
- Holding Executive Directors and the Board to account

Medical Directorate /Medical Consultants

The Medical Director and Lead Medical Consultant (Clinical Service Lead or equivalents) for ICU are responsible for ensuring legal frameworks and procedures detailed in this SOP are understood and adhered to by medical staff.

ICU Matron, Line Managers, Team Leaders

- Ensuring that all staff working in ICU have access to and comply with this SOP in relation to the appropriate and agreed use of the Safe Holding System, in order to prevent self-harm, harm to others, compliance to life saving treatment whereby the patient does not have capacity.

- Ensuring that staff know what to do if they expect inappropriate or abusive use of physical interventions (mechanical, physical, chemical).

- Ensuring that the nursing team (registered and non-registered) have been trained and annually updated in the use of the Safe Holding System and deemed competent.

- Ensuring that their staff understand the legal and ethical frameworks relevant to physical interventions, and the use of mechanical restraint (Safe Holding System).

- Ensuring that staff understand the circumstances in which restrictive interventions may be legally or ethically required (mechanical, physical, chemical).

- Ensuring that staff know what to do if they suspect inappropriate or abusive use of physical interventions (mechanical, physical, chemical).

- Ensuring that person centred care is provided, that minimises the need for physical intervention.

- Ensuring staffing levels are appropriate to the potential risk of patient led violence and aggression whether clinically or non-clinically driven.

- Ensuring that all incidents involving the use of the Safe Holding System are reported in line with UHPNT Reporting of Incidents procedures, and on the Restraint Register.

- Providing appropriate and timely feedback for UHPNT staff involved in any incident involving use of the Safe Holding System. De-brief should take place as soon as is practically possible following any incident involving the Safe Holding System both with the staff and the patients (and families/carers) involved. De-brief of staff should take place in the first instance by the staff member's line manager.

- Reviewing and auditing each incident of SHS use in order to learn lessons and improve practice.

- Ensuring that staff are supported to attend training (including refresher training) as appropriate to the assessed needs of the work area and the role that the staff have within that area.

- Ensuing that wherever appropriate learning incidents are fed back to UHPNT Physical Interventions Service.

ICU Clinical Educators

Ensuring that clinical area training needs analysis accurately reflects training requirements for staff in relation to physical intervention training, and Safe Holding System training.

Identifying training needs from learning outcomes from Incidents, with regards to the use of the Safe Holding System.

Working with the Line Managers to ensure all appropriately identified staff attend physical intervention and SHS training, to include refresher training.

Raising any concerns regarding the use of the SHS to The Physical Interventions Lead.

Ensuring that local records are kept to evidence that the training has taken place.
Working with UHPNT Physical Interventions Training Lead to ensure that the any physical intervention training (including SHS) accurately reflects the needs of both staff and patients with in clinical area.

Medics

Medics have responsibility to comply with the requirements of this and associated policies and have a legal duty to adhere to the Mental Capacity Act (MCA, 2005) when working with, or caring for, adults who may lack capacity to make decisions for themselves.

Role of Safeguarding Adults and Medical/Nursing Leads with Safeguarding and Mental Capacity Act (MCA, 2005) responsibilities

The Safeguarding Adults and Medical/Nursing Leads are responsible for:

- Ensuring the process and procedures are consistent for recording mental capacity and applying restraints lawfully.
- Providing systems and structures to support MCA implementation e.g. procedures, training.

The Safeguarding Team are responsible for:

- Ensuring the Trust fulfills its responsibilities in protecting vulnerable adults within UHPNT.
- Ensuring that the Mental Capacity Act 2005, Deprivation of Liberty Safeguards 2007 and the use of restraint intervention are fully implemented within the Trust, to ensure that the rights of persons lacking capacity are respected.

The UHPNT Physical Interventions Lead

- Ensuring this policy is updated, and in line with current guidelines and legal frameworks.
- Working with ICU Matron, Line Managers and Clinical Educators to ensure that staff identified as requiring physical interventions and SHS training can access it.
- Identifying training needs through review of UHPNT ICU incidents.
- Ensuring all training records are kept in line with Information Governance recommendations.

All Staff

All staff that carries out physical interventions techniques including the application, management and removal of the Safe Holding System are responsible to:

- Identify their own training needs in respect of this SOP document and informing their line manager.
- Attend the identified level of training, and engage in regular supervision when required.
- Ensure that the use of physical intervention and the Safe Holding System is clearly documented and reported via UHPNT incident reporting procedure.
- Take appropriate and proportionate actions only.
- Raise concerns with regard to the inappropriate use of restrictive interventions including the use of the Safe Holding System via Trust Incident Management Policy, Physical Interventions Lead, or Safeguarding.

5 Procedure to Follow

1. Formal documented assessment of patient's mental capacity must be by a Medical Consultant/s responsible for the patient.

2. Is SHS the least restrictive option and in the patient's best interests?

    a. It must be clear that physical restraint is required to protect the patient from harming themselves (e.g. by removal of safety critical indwelling devices or striking themselves against solid objects striking/kicking/punching/staff members/falling from bed).
    b. The restraint must be a proportionate response to the likelihood of the patient harming themselves (or others) and the seriousness of that harm (MCA 2005 Section 6).
    c. Decision to use the Safe Holding System must be discussed by the multi-disciplinary team caring for the patient, and must always include a Medical Consultant, who must prescribe the use of the Safe Holding System for that patient.
    d. Ideally the decision should be discussed with Next of Kin (NOK) or advocate before the Safe Holding System is applied, however it is recognised that this will not always be possible in emergency situations. The NOK or Advocate must be

informed when the restraints have been applied as soon as practicable and absolutely before they arrive to see the patient.

3. The restraint must be prescribed on patient's notes/SHS tab in one time nursing assessments by the Medical Consultant.

4. In instances whereby the decision to use the SHS is made the patient must be nursed 1:1 (level 3).

5. Patient continuously assessed, documented hourly on nursing care flow sheet.

6. Formal Medical Consultant review documented every 12 hours. Nurse to record shift review in notes.

    a. This confirmation should include a clear decision why the Safe Holding System remains the most suitable restraint, rather than re-sedating (and why).
    b. If the Safe Holding System is used for more than 48hours at least 2 Medical Consultants and a senior (B7) nurse should agree that on-going use of Safe Holding System is still required and remains more appropriate than re-sedation.

7. The Safe Holding System must be removed regularly (every 2-3 hours) and the patient checked for friction or pressure damage, to include inspection of fingers/toes as applicable. Removal of the Safe Holding System must be risk assessed if the patient is still aggressive as it may be unsafe for both the patient and staff to fully remove the system. It may be safer for several members of the team to slacken particular parts of the system in isolation (one part at a time) to check for pressure damage, whilst additional members of the team apply physical restraint to maintain safety whilst these checks are undertaken.

    - The nurse in charge and Medical Consultant must be informed immediately of any concerns regarding pressure damage in order that the risk-benefit assessment to continue with the Safe Holding System can be re-assessed.

    - The use of the Safe Holding System must be added to the Restraint Register as soon as is practically possible and no later by end of shift.

    - The discontinuation of the Safe Holding System must be recorded on the Restraint Register as is practically possible and no later by end of shift.

    - All incidents of Safe Holding System use must be recorded on via UHPNT Datix Incident as is practically possible and no later by end of shift.

    - A member of nursing staff must be responsible for communicating with the patient throughout any period of restraint (DoH 2014).

- After 6 hours continuous use or over 24 hours intermittent and on-going use a discussion with Safeguarding and Trust DoLS Team should take place. If the SHS is used intermittently or permanently for over 24 hours and it is anticipated that this will continue then advice should be sought from the legal team with a view to consideration of making an urgent application to the Court of Protection to authorise a deprivation of liberty (see section on article 5 on page 21 of this document for rationale).

- The use of the SHS should be imposed for no longer than is absolutely necessary (DoH 2014).

- Patients ***must not*** be transferred from ICU to another clinical area if they require SHS restraining therapies.

Using the Safe Holding System:

Staff should make sure that the patient's fingers and hands are regularly checked for discolouration that may indicate the soft cuffs are applied too tightly. If soft cuffs are used on the ankles then toes should also be regularly checked for discolouration.

The Medical Consultant's prescription for application of the Safe Holding System must give clear instructions on the arrangements for regular medical review and what form these should take and documented in the patient notes. Nursing staff are required to review the patient continuously and must document this on the nursing care flow sheet.

Using the Safe Holding System to Aid Prolonged Physical Restraint:

The SHS will only be used in a situation where a prolonged restraint can be made safer for both the patient and the staff applying the restraint by its use, and its use represents the most appropriate, last resort and pragmatic method of managing an extremely challenging patient who is a significant risk to self and others, and for whom chemical sedation/restraint would be contra indicated.

The SHS will only be used where the balance of risk suggests that the deployment of the SHS is considered a safer alternative to prolonged active physical restraint (manual) for both the patient and the staff.

The assessment and decision to employ the SHS in such circumstances will be made by the Medical Consultant.

Previous history of employment of the SHS or the requirement for prolonged high level physical interventions should be considered an indicator that its use may need to be considered (particularly where chemical sedation/chemical restraint is contra indicated). If it is used for the first time then this should inform subsequent care planning procedures, in the event the patient returns to ICU.

6 Staff Training in Management and use of the Safe Holding System

Training

Staff training in the Safe Holding System will be updated annually.

Training records will be updated on ESR/OLM by the Conflict Resolution Administration Team.

All nominated registered and unregistered staff must have attended the annual ICU physical interventions training programme. Additionally they must maintain their update refresher training for BLS, ILS, ALS, (as appropriate) and Manual Handling.

The SHS and soft cuffs will only be applied and removed by staff who have attended the necessary and appropriate training provided by UHPNT.

Monitoring and Reviewing SHS Use

Use of the SHS must be reported using Datix. Use of the SHS must also be entered onto the Restraint Register.

Analysis of the numbers of incidents with regard to the use of the SHS and the rationale for its use will be audited and reviewed on a quarterly basis and reported through the Safeguarding Steering Committee.

7 Legal Framework for the use of Mechanical Restraint Safe Holding System

Mechanical Restraint

It must be reiterated that the Mental Health Act Code of Practice 2015 (page 296) cites that the use of mechanical restraint is not a standard means of managing disturbed or violent behaviour. Mechanical restraint should only be used exceptionally, where other forms of restriction cannot be safely employed. It should be used in line with the principle of least restrictive option and should not be an unplanned response to an emergency situation.

Mechanical restraint should never be used instead of adequate staffing when caring for a patient.

The Mental Capacity Act 2005

Section 6(4) of the Mental Capacity Act 2005 defines restraint as:
"…the use or threat of force to enforce the doing of anything to which that person resists, or restriction of liberty or movement, whether or not he or she resists…"
A clinician who is considering the use of restraint must firstly reasonably believe on the balance of probability that the patient does lack capacity.
Section 2(1) states that: a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.
Section 3(1) states that a person is unable to make a decision for himself if he is unable:-

- To understand the information relevant to the decision;
- To retain that information;
- To use or weigh that information as part of the process of making the decision; or

• To communicate his decision (whether by talking, using sign language or any other means)

Restraint of a person who has capacity is not permissible under the Mental Capacity Act.

Section 6 of the Mental Capacity Act states that restraint of a person who lacks capacity is only allowed under certain conditions:
1. The first condition is that the person doing the restraint reasonably believes that it is necessary to do the act of restraint in order to prevent harm to the person who lacks capacity.
2. The second condition is that is that the act of restraint is a proportionate response to—
(a) The likelihood of the person suffering harm, and
(b) The seriousness of that harm.
Restraint is therefore only permissible if it is reasonable and proportionate response to keep the person (patient) from harm. It is not possible to restrain the person under this Act in order to prevent them from harming others. The Mental Capacity Act Code of Practice (MCA Code Paragraph 6.43) reminds staff that they have a duty of care to all people to whom they provide services. Therefore there may be occasions when reasonable and proportionate restraint of the person who lacks capacity is necessary to prevent harm to others in the immediate vicinity.

Common Law (1988 Beckford Case) makes provision for a person to use such force as is reasonable in the circumstances to prevent harm (patient without capacity/ patients who may be at risk of harming others for example staff/visitors/relatives).

Criminal Law 1967 Section 3 makes provision for a person to use such force as is reasonable in the circumstances to prevent a crime (for patients or others who have capacity at the time of carrying out an act of violence against another.)

Best Interests
The Mental Capacity Act 2005 requires that:
".. An act done or decision made, under the Act for or on behalf of a person who lacks
capacity must be done, or made, in his best interests…"
It must be clearly evident in the risk assessment and in care plan documentation that the use of restraint is considered to be in the patient's best interests.

Doctrine of Necessity

6.1 Where a patient is in immediate danger, the ability to undertake a full and thorough assessment of their mental capacity is not always possible. In such circumstances decisions must be made based on the evidence available at that time and based on the principle that on the balance of probabilities (i.e. being more likely than not), it would suggest that in the circumstances the patient lacks capacity.

6.2 Any actions then undertaken on this basis must be considered immediately necessary to save life and / or prevent very serious deterioration in the patient's

physical or mental wellbeing. The doctrine is a positive duty in law, which means that failure to act could be deemed to be negligent.

6.3 However the doctrine of necessity must not be used where there is sufficient time to assess the patient's capacity and implement the above restraint framework. This is important because if the doctrine of necessity is used inappropriately there is again a risk of civil trespass to the person which may amount to a crime depending on the severity and impact of the restraining measure.

6.4 Any decision made to undertake restraint on this basis must be supported with a clear and reasoned rationale in relation to the basis upon which staff believed that they needed to take action out of necessity as opposed to the wider legal framework. This must be documented. Essentially the doctrine of necessity enables immediate action in extreme emergency to immediately save life or prevent very serious harm or deterioration.

Least Restrictive Intervention

The **Mental Capacity Act 2005** also requires that:

"…Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action…"

It must be clearly evident in a risk assessment and in care plan documentation that the use of restraint is considered to be the least restrictive intervention. **All other less restrictive interventions must have been ruled out before the use of mechanical restraint is considered**.

When caring for the person who lacks capacity, Section 5 of the Mental Capacity Act protects the person providing the care or treatment from liability from what otherwise might be liability for trespass to the person or assault. Note however that this section does not provide protection from liability for negligent acts or omissions, and it does not protect staff from liability for the inappropriate use of restraint.

Section 44 of the Mental Capacity Act provides for an offence of ill treatment or wilful neglect of a person who lacks capacity. The deliberate and unnecessary use of mechanical restraint where other methods such as de–escalation and appropriate physical restraint have not been attempted may incur liability under this section.

The MCA and Deprivation of Liberty

Acts of restraint of a person who lacks capacity which are frequent cumulative and on-going and taken together with other aspects of the patient's care may indicate that the person is being deprived of their liberty. Deprivation of liberty is not permissible without further legal authorisation. That authorisation may be from the Court of Protection, or an authorisation under the Mental Capacity Act Deprivation of Liberty Safeguards procedure. Note that a deprivation of liberty authorisation under the Deprivation of Liberty Safeguards procedure - if granted - does not authorise the actual use of restraint. The authorisation renders lawful the state of deprivation of liberty. The use of restraint itself must still be lawful under the principles of the Mental Capacity Act as set out above. If a patient who lacks capacity is regularly being restrained, there must be consideration of whether detention under the Mental Health Act is a more appropriate course of action.

Human Rights

The disproportionate and unnecessary use of restraint may breach Article 3, Rights to Prohibition of Torture, Article 5, Right to Liberty and Security or Article 8, Right to Respect Family and Private Life of the European Convention on Human Rights.
Section 6(1) of The Human Rights Act 1998 states that: it is unlawful for a public authority to act in a way which is incompatible with a Convention right.

Article 3 provides that no one is to be subjected to inhuman or degrading treatment or punishment. Degrading treatment may occur if it arouses feelings of fear, anguish and inferiority which is capable of humiliating and debasing the patient. In order to avoid a breach of Article 3, an interference with that right must be convincingly shown to be a medical and therapeutic necessity (Nevmerzhitsky v Ukraine (2006) 43 EHRR 32).

Article 5 provides that no one should be deprived of liberty except in accordance with a procedure prescribed by law and in specified situations (detention of what the convention calls 'persons of unsound mind' is the situation relevant to this Trust). The frequent cumulative and on-going use of any type of restraint may amount to deprivation of liberty. Any deprivation of liberty must be rendered lawful by either an order of the Court of Protection, detention under the Mental Health Act 1983 or an authorisation under the Deprivation of Liberty Safeguards procedure.

In 2015 in the case of R (Ferreira) V HM Coroner for inner south London EWHS 2990 the UK Courts ruled that there is in general no need in non-mental health wards where critical care of physical illness for a person of unsound mind to have the benefits of safeguards against a deprivation of liberty where the treatment is given in good faith and is materially the same treatment as would be given to a person of sound mind with the same physical illness. Therefore, as long as the person is not objecting to that treatment there is no need to seek authorisation. The law has also since clarified that DoLS does not apply to patients in Intensive Care Units; however, these patients still have rights under Article 5.

Therefore, in cases where restraint being used may be seen as exceptional and /or excessive, either physically or chemically, there is a risk that this would amount to a deprivation of liberty, therefore would require a procedure set out by law to authorise this. As DoLS would not apply then authorisation from the Court of Protection may need to be considered if such restraint was beyond a negligible period of time.

Article 8 provides that everyone has the right to respect of his private life. This includes the right to physical integrity. It is a qualified right which means that a public authority must not interfere with the right unless it is in accordance with the law and necessary for the prevention of disorder or crime, protection of health or protection of the rights of others. In order to avoid a breach of Article 8 any interference with that right must be convincingly shown to be a medical and therapeutic necessity (Herczegfalfy v Austria (1992) 15 EHRR 211).

Key Legislation:

Care Act (2015)
Children's Act (1989 & 2004)
Health and Safety at Work Act (1974)

Health and Social Care Act (2008)
Equality Act (2010)
Human Rights Act (1998) (Article 3 (prohibition on torture, inhuman and degrading treatment, Article 8 (respective for autonomy, physical and psychological integrity) and Article 14 (non-discrimination) of the European Convention on Human Rights).
Mental Capacity Act (2005)
Mental Health Act (2007)

8 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as one year from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Safeguarding Steering Committee and ratified by the Chief Nursing Officer.

Non-significant amendments to this document may be made, under delegated authority from the Chief Nursing Officer, by the nominated author. These must be ratified by the Chief Nursing Officer and should be reported, retrospectively, to the Safeguarding Steering Committee.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades that are directly affected by the proposed changes.

9 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Chief Nursing Officer and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

10 Monitoring and Assurance

The monitoring and compliance of this SOP will be undertaken by the Lead Nurse Critical care Education and the Physical Interventions Lead, reporting to the Safeguarding Steering Committee. Any risks and associated action plans will be discussed in these forums.

The use of the Safe Holding System will be monitored and audited via the Restraint Register.

- Compliance will be measured by CQC Regulation 13.

- Compliance with NICE Guideline 10 (2015): Violence and aggression: short-term management in mental health, health and community settings
- Working to National Occupational Standards (2013) the Prevention and Management of Violence in the Workplace.
- Working to Department of Health Guidelines (2014) Positive and Proactive Care: reducing the need for restrictive interventions.
- Compliance with UK Core Skills Framework Statutory/Mandatory Subject Guide Version 1.6 Subject 4.

11 Reference Material

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CQC (2016) Brief Guide: Restraint (Mechanical and Physical) https://www.cqc.org.uk/sites/default/files/20180322_900803_briefguide... (accessed 10.09.2019)

DOH (2014) Positive and Proactive Care: reducing the need for restrictive interventions. https://www.gov.uk/government/publications/positive-and-proactive-care-reducing-restrictive-interventons (accessed 10.09.2019)

DOH (2019) Reducing the Need for Restraint and Restrictive Intervention Children and young people with learning disabilities, autistic spectrum conditions and mental health difficulties in health and social care services and special education settings. https://www.gov.uk/.../reducing-the-need-for-restraint-and-restrictive-intervention (accessed 10.09.2019)

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NHS Protect (2013) Meeting Needs and Reducing Distress-Guidance on the prevention and management of clinically related challenging behavior in NHS Settings London: DH

NICE Guidance 10 (2015) Violence and aggression: short-term management in mental health, health and community settings. https://www.nice.org.uk/guidance/ng10 (accessed 10.09.2019)

NPSA (2015) the importance of checking vital signs during and after restrictive interventions/manual restraint. https://www.england.nhs.uk/2015/12/psa-vital-signs-restrictive-interventions (accessed 10.09.2019)

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Children's Act (2004) www.legislation.gov.uk (accessed 05.10.2019)

Health and Safety at Work Act (1974) https://www.legislation.gov.uk/ukpga/1974/37 (accessed 10.09.2019)

Health and Social Care Act (2008) www.legislation.gov.uk/ukpga/2008/14/pdfs/ukpga_20080014_en.pdf (accessed 10.09.2019)

Equality Act (2010) https://www.equalityhumanrights.com/en/equality-act-2010/what-equality-act (accessed 10.09.2019)

Human Rights Act (1998) Article 3 (prohibition on torture, inhuman and degrading treatment), Article 8 (respective for autonomy, physical and psychological integrity) and Article 14 (non-discrimination of the European Convention on Human Rights). https://www.legislation.gov.uk/ukpga/1998/42/section/6 (accessed 10.09.2019)

Mental Capacity Act (2005) www.legislation.gov.uk (accessed 05.10.2019)

Mental Health Act (1983) www.legislation.gov.uk (accessed 05.10.2019)

United Nations (1989) Convention on the Rights of the Child. https://www.unicef.org.uk (accessed 05.10.2019)

National Health Service England (2015): Patient Safety Alert: The importance of vital signs during and after restrictive interventions and manual restraint. NHS England.

Patient Safety Alert (2015) Stage One Warning: The importance of monitoring vital signs during and after restrictive interventions/manual restraint.

Royal College of Nursing (2008): *"Restraint Revisited – Rights, Risk and Responsibility: Guidance for Nursing Staff."* RCN. London

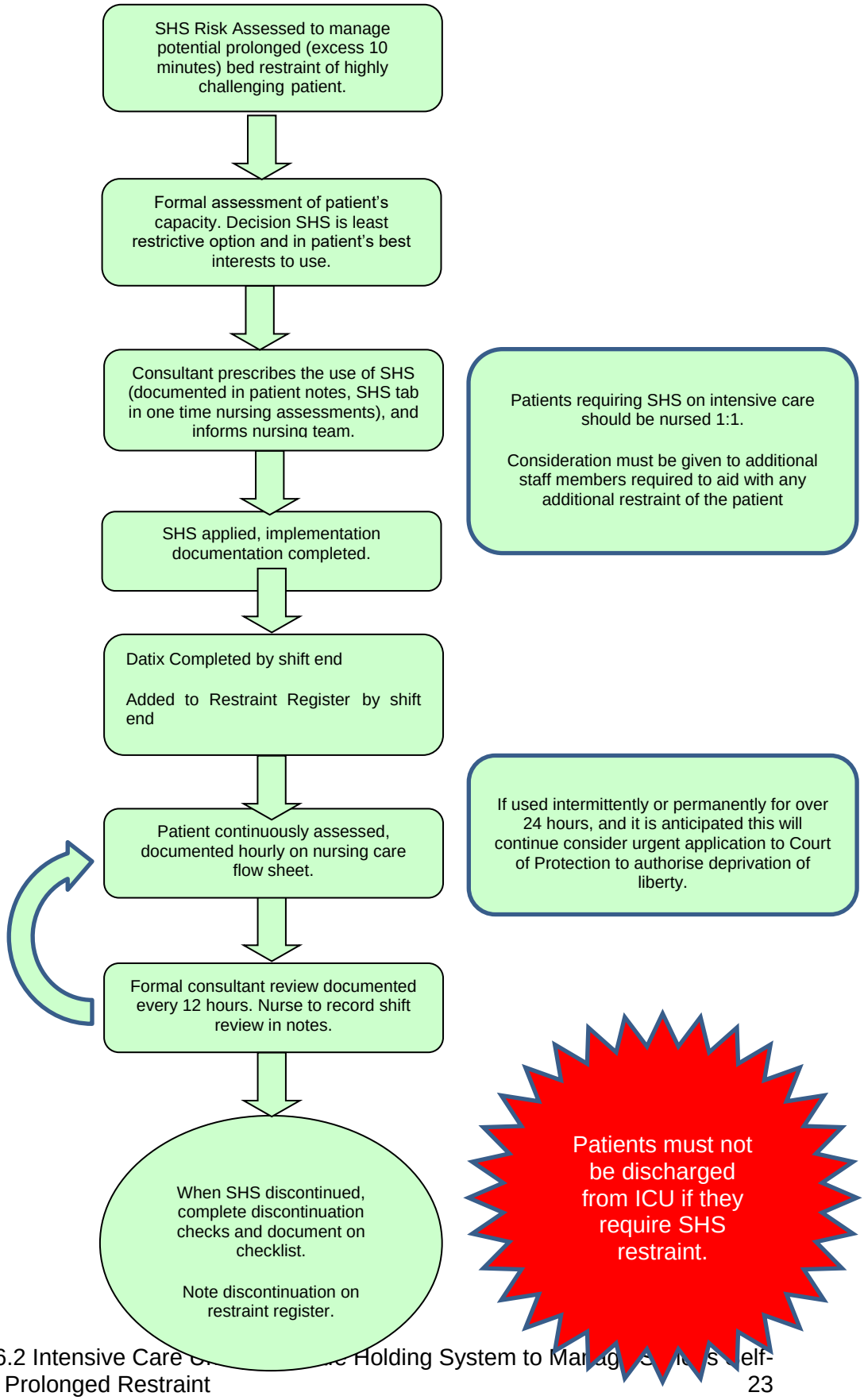
UHPNT Incident Reporting Procedure http://staffnet.plymouth.nhs.uk

UHPNT Incident Management policy http://staffnet.plymouth.nhs.uk

UHPNT Medicines Management Policy http://staffnet.plymouth.nhs.uk

UHPNT Prevention of Violence Policy to Staff at Work http://staffnet.plymouth.nhs.uk

Use of SHS to Manage Prolonged (excess of 10 minutes continuously) Bed Restraint in ICU: Escalation Process Flow Chart



SHS Soft- Cuffs Equipment Care and Maintenance Guidance	Appendix B

The Safe Holding System is single use; once the patient has been discharged from ICU the SHS must be discarded.

As soon as the SHS is prescribed for the patient a replacement SHS must be order following ICU procurement protocols.

Three Safe Holding System kits should be in stock at all times, within an identified designated and secure area of ICU.

Bespoke Safe Holding System Application (ICU)	Appendix C

This bespoke protocol has been established to assist in managing the challenges staff face when bringing patients round, who have exhibited combative behaviour previously, and must be read in conjunction with the SHS SOP ICU.

The Safe Holding System puts "handles on the body" and acts as an aid to ensure the manual holds staff are already trained in, actually work for a long enough period to either ensure the person is calm and can regain control or, staff can get their medication balance right to keep them under control chemically.

The two absolutes for using any form of Soft restraints are;

1. The patient must be under control or compliant BEFORE they are applied

(The SHS will be applied to the patient before withdrawal of sedation)

2. Once the kit has been safely applied, the patient must NEVER be left unattended

The recommended maximum time to keep someone in the SHS is 30 minutes; however there may be instances whereby this recommended time is exceeded, ICU staff must refer to Nursing Care Plans and ICU Safe Holding System SOP, for guidance on how to appropriately manage such situations.

This document should be read in conjunction with Trust Polices and ICU SOP'S and procedures with regard to restraint and chemical sedation.

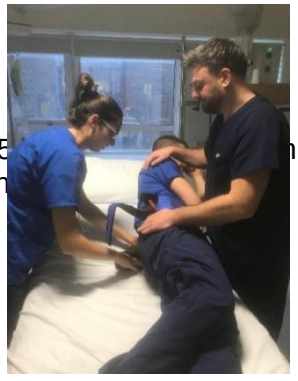
The Safe Holding System is modular and its application will depend on the level of force offered and any other medical contra-indications that exist which may prohibit aspects of the system being used on certain areas of the body. ICU's Clinical education team are able to answer any questions or queries you may have with regard this Safe Holding System, as is the Physical Interventions Lead.

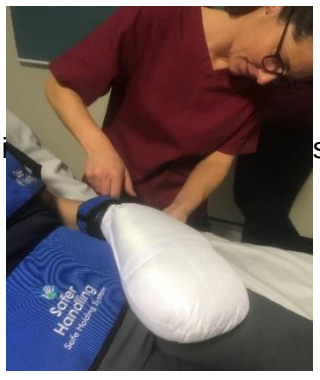
<u>Step by step application of the Safe Holding System</u>

1. Application of the Safe Holding System

a) Safe Holding system is applied either across the abdomen (reclined) or slightly lower (when in supine) to keep the arms in a natural resting position.

This is achieved by turning the sedated patient using staff's manual handling procedures and sliding the Velcro strap underneath and through the D-ring.





b) SHS is tightened (taking into consideration the need for extension straps) and a comfort pad/dressing is applied to protect the skin from the D-ring.

c) The secure and lock straps are closed to keep the cuffs in place (orange strips on each cuff) extension straps are also an option for each aspect of the kit (POSEY mitts are an option if risk assessed as appropriate).

When applying the cuff over arterial lines, a dressing must be used to cover and protect this with a diamond cut out to accommodate it in a well. A comfort pad or dressing may also allow extra protection (see image to right).

2. Application of the Soft Restraint Belt to the knees

a) A comfort pad is slid between the knees, a Soft Restraint Belt is unfolded, the compression strap deployed.

b) The SRB is laid flat and slid under the patient's knees. The compression strap is fed over the front of the knees and fed through the handles, under the belt, back through the handles, through the D-ring and back through the handles.

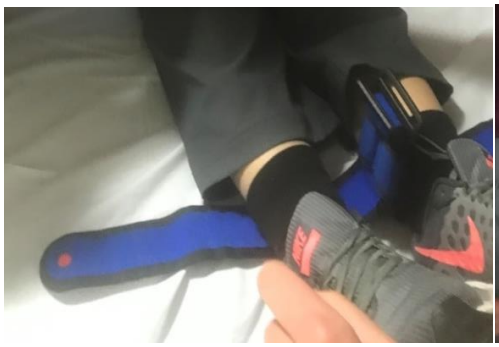
c) It is then slid round so the panel covers the front of the knees and tightened accordingly fixing the Velcro in place.

d) Secure and lock straps keep the Velcro strap in place.

3. Soft-cuff application to the ankles

a) Soft-cuffs are opened up and applied around the ankles (two fastened together may be required) with the buckle on top

b) Fix the secure and lock strap in place across the Velcro join underneath (orange strip).



4. SRB application to the upper torso


a) An additional SRB is made ready and the Velcro compression strap deployed.

b) The SRB is passed across the patient's chest, deployed and then slid underneath the patient's back by the normal manual handling procedure for turning a patient.

c) A comfort pad/dressing is applied as per the SHS. The Velcro compression strap is fed straight through the D-ring which is placed low on the triceps with the top of the belt at the bottom of the deltoid

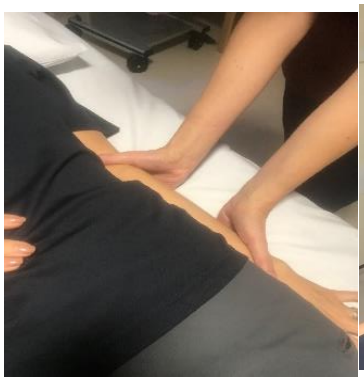
d) Two fingers must be able to fit between the belt and the patient, the patient is instructed to take a deep breath in once it is applied.

5. Managing combative behaviour as the patient is brought round

The regular manual handling stances and holds taught as per the ICU's bed restraints are to be used, the SRB has now put handles on the body and when a patient is brought round, staff are able to manage with a combination of:

- Staff on the legs (1 as a minimum) with a pillow across the thighs (as per ICU bed restraint)

- staff member on each arm holding the SRB handle and gripping the cuff of the SHS/using normal holds
- a fourth person to administer a head block technique where necessary



6. Removing the SHS safely

a) Gradually de-escalate by loosening and releasing belts as the risk subsides (in whichever order is required – usually

b) In a medical emergency the belts are pulled free by holding the D-ring and sliding them out, secure and lock straps and Velcro undone first.

Contents of ICU Safe Handling System Kit:

Each SHS kit bag should contain:

1. 1 x Safe Holding System with integral wrist restraints (apply first)
2. 2 x Soft Restraint Belts (apply 1 x Soft Restraint Belt to the legs second) N.B. Only apply the second Soft restraint Belt to the chest if required)
3. 3 x Comfort Pads (1 for in-between knees, 1 x to protect patient from D Ring on Safe Holding System, 1 x to protect against buckle of Soft Restraining belt) If second restraint belt used, please use other padding to protect patient from buckle.
4. 3 x Soft Restraint Cuffs (1 x pair for ankles. Secure ankles after Safe Holding System applied and Soft Restraint Belt for Legs applied. Other 2 pairs are spares.)
5. 6 x secure and lock straps (to secure Velcro fastenings)
6. 3 x Extension Straps (Side Pocket) – only use if required i.e. for large patients.