Royal Cornwall Hospitals
NHS Trust

Cryotherapy Treatment in the RCH Dermatology Unit Standard Operating Procedure

V2.0

March 2025

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. Cryotherapy is a minimally invasive procedure that uses an extremely cold liquid or instrument to freeze and destroy abnormal tissue that requires elimination. It is also referred to as cryosurgery or cryoablation (CRUK, 2018).

1.2. Cryotherapy is an outpatient department procedure that can be performed in a clinic or procedure room.

1.3. Tissue destruction is achieved by rapid cooling, resulting in the formation of intracellular ice crystals causing subsequent necrosis (Lawrence 1996). The extent of injury is determined by the rate of freezing, the coldest temperature reached, the freeze time and the rate of thawing. Repeating the freeze/thaw cycle produces much greater tissue damage than a single freeze because the greater conductivity of the previously frozen skin and the already impaired circulation both allow a greater and faster depth of cold penetration (Bell, Gardiner 1995).

1.4. This procedure should be read in conjunction with the following Trust documentation:

- Policy for Consent to Examination or Treatment Link.
- Policy to Manage Information and Link .
- Infection prevention and control - roles and responsibilities policy Link.
- Aseptic non touch technique (ANTT) policy Link.
- Medical Devices Training Policy Link .
- Policy (Cryotherapy storage policy).

2. Purpose of this Standard Operating Procedure

The aim of this standard operating procedure (SOP) is to:

2.1. Ensure safe, efficient and effective practice for dermatology cryotherapy services.

2.2. Ensure all staff in the dermatology unit are carrying out cryotherapy treatment are adhering to the same practice standards.

It is important to note that no set of guidelines can cover all variations required for specific patient circumstances. There may be times when, after careful consideration of the risks and benefits, it is appropriate to offer cryotherapy outside the parameters of this guideline. Cryotherapy in these instances should be performed by the patient's responsible clinician or discussed with them prior to proceeding.

2.3. Clarify definitions of cryotherapy.

2.4. Clarify indications, contraindications, and precautions for the use of cryotherapy

2.5. Clarify roles and responsibilities of those delivering care.

2.6. Clarify the consent process when care is delivered.

2.7. To ensure compliance with local and national recommendations.

3. Ownership and Responsibilities

The Standard Operating Procedure should be used by staff involved with and responsible for the management of patients receiving cryotherapy in the Outpatient Department, Dermatology Unit, Royal Cornwall Hospital.

3.1. Role of the Dermatology Responsible Clinician

- To be familiar with this SOP.
- To ensure the patient is suitable for cryotherapy treatment.
- To understand and follow this SOP. They must ensure all patients being considered for or receiving cryotherapy are managed according to this SOP.

3.2. Role of the Department Sister

- Ensuring that all staff responsible for cryotherapy treatment adhere to this procedure.
- Ensuring all staff members receive appropriate training to assure competency in cryotherapy treatment.
- Ensuring staff have access to update training as required.

3.3. Role of Individual Staff

- They should be competent and confident to carry out cryotherapy, having completed the appropriate training pathway for carrying out cryotherapy.
- Registered competent nurses carrying out cryotherapy will be accountable for their own practice in line with the NMC code of conduct.
- Registered competent nurses to ensure that they carry out the procedure in line with the standards required and refer to the medical clinician on site if they have any concerns.
- To always adhere to Trust policies and procedures.
- To ensure knowledge and competence is maintained.
- To confirm patient consent and area to have cryotherapy, in line with RCHT consent policy.
- To ensure patient is fully informed of appropriate post-cryotherapy care and advice.

4. Standards and Practice

4.1. Indications for cryotherapy:

- Viral warts in older children and adults.
- Seborrheic keratoses.
- Actinic keratoses.
- Molluscum contagiosum in adults.
- Skin tags (Diathermy may be more effective for acrochordons / fibroepithelial polyps).

The following skin cancers may be suitable for cryotherapy if performed by a medical practitioner with appropriate training and, where clinically necessary, the lesion has been identified by biopsy:

- Small, thin, typical, superficial basal cell carcinoma on trunk and limbs.
- Small, typical intraepithelial squamous cell carcinoma on trunk and limbs.

4.2. Contraindications to cryotherapy:

- Undiagnosed skin lesions.
- Lesion for which tissue pathology is required.
- Lesion within a circulation compromised area.
- Melanoma.
- Previous sensitivity or adverse reaction to cryosurgery.
- Patient unable to accept side effects.
- Patients with poor circulation.
- Unconscious patients.
- Young children.
- Dark skinned patients.

4.3. Precautions when using cryotherapy:

- Areas **not recommended** for liquid nitrogen application: corners of eyes, fold of skin between nose and lip, skin surrounding nostrils and skin overlying nerves, e.g., sides of digits, below the knee in certain groups (e.g., diabetics, elderly).

- Re-appearance of a lesion previously treated with cryotherapy should be referred for review by medical practitioner.
- Recurrent skin cancers after cryotherapy may be more difficult to treat.
- Exercise care in patients with history of slow healing or skin infection.
- Prolonged freezing may result in scarring – better to freeze lightly and for the patient to return for re-freeze if response is inadequate.
- Cryotherapy leaves permanent white marks which may be very unsightly, especially in dark skinned patients.
- Cryotherapy may sometimes cause nerve damage and on-going pain in some danger areas where the nerves lie superficially (eg sides of the fingers).

4.4. Checklist for cryotherapy:

4.4.1. Pre-procedure

- Medical clinician should review any lesion where the treating clinician has any uncertainty about the diagnosis, indication or suitability for cryotherapy.
- Obtain informed consent.
- Patient should be fully counselled on the procedure, alternative treatments, achievable results, recurrence rates and possible complications and side-effects (including potential blistering and pigment change).
- **Complications and side-effects:**

  Acute:

  - Oedema.
  - Pain.
  - Headache after treatment of facial lesions.

  Delayed:

  - Bleeding at the frozen site.
  - Infection at the site.
  - Skin discomfort.
  - Hyperpigmentation (slowly resolves).

Permanent (uncommon):

- Alteration of sensation.
- Hypopigmentation.
- Hypertrophic scarring.
- Hair loss.

Agreed RCHT Cryotherapy Patient Information Leaflet should be provided for the patient. http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/PatientInformation/Pain/RCHT0564Cryotherapy.pdf

4.4.2. **Application of Liquid Nitrogen:**

- Complete effective hand hygiene prior to commencing treatment application.
- Ensure the correct spray tip is secured on the liquid nitrogen flask.
- Apply the liquid nitrogen to the lesion for a few seconds, depending on the required diameter and depth of the freeze.
- A margin of 1–2 mm is recommended for benign lesions.
- Freeze times vary from around five seconds (after the freeze ball appears) for actinic keratoses to 10 or 20 seconds for thicker lesions.
- Two freeze/thaw cycles (with a shorter freeze time) are more effective for thicker lesions.

4.4.3. **Post–procedure:**

- Cleaning and sterilisation of cryospray nozzles should be performed according to manufacturer's recommendations.
- If the nozzle comes into contact with patient skin, then sterilisation by autoclave is required (refer to the practice Infection Control policy).
- Wipe down the flask with Clinell cleaning wipes.
- Document the lesion and treatment provided in the patient management system. This includes (but not limited to):
  - Informed consent obtained.
  - Specific instructions from the general practitioner.
  - Lesion site.

- Duration of liquid nitrogen application.
- Follow-up advice.

4.4.4. **Post treatment patient information:**

- May blister within a few hours (clear, red or purple).
- Bleeding may occur (though this is not common).
- The blister shrinks to be replaced by a scab within a few days.
- Swelling should settle in a few days.
- Healing depends on the site the scab peels off within a week after cryotherapy to facial actinic keratoses, after about three weeks to a similar lesion on the hand and may cause ulceration on the lower leg and take three months or longer to heal.
- A white mark (hypopigmentation) or scar may result.

4.4.5. **Safety considerations:**

- Always ensure the working area has adequate ventilation when handling liquid nitrogen.
- Additional PPE required when decanting the liquid nitrogen from the storage Dewar flask (storage container) to the cryospray or non-permeable container: leather gloves, safety glasses and covered footwear.
- Caution is to be taken when transporting liquid nitrogen.
- Liquid nitrogen Dewar flask and cryospray are to be stored in an upright position, in a cool, well-ventilated area away from heavily trafficked areas. These are to be secured to prevent accidental knocking.
- To eliminate the potential build of condensation liquid nitrogen Dewar flask and cryospray should be stored closed as per manufacturers instruction.
- Dewar flasks used for liquid nitrogen storage must have a loose lid or ventilation in the lid to prevent build-up of pressure and consequent risk of explosion.

5. Dissemination and Implementation

5.1. This policy will be available on the RCHT Dermatology shared folder. There will also be a hard copy available to view within the Dermatology Department.

5.2. The Departmental Sister will be responsible for ensuring nursing staff undertaking cryotherapy treatment has been suitably trained before delegating

this task.

5.3. The theoretical knowledge for registered nursing staff carrying out cryotherapy will be achieved through an appropriate competency pathway, reading and experientially working under supervision by a competent, skilled person and then being signed off as competent.

5.4. Records of nursing staff competency will be available within the Dermatology unit.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with consent process for cryotherapy treatment.
Lead	Specialty service lead/audit lead/governance lead.
Tool	Adherence to guidelines will be monitored as part of the ongoing audit process within the department on a Word or Excel template specific to the topic.
Frequency	Annual audit initially then reviewed interval required.
Reporting arrangements	Specialty annual audit meeting.
Acting on recommendations and Lead(s)	Specialty service lead/audit lead/governance lead.
Change in practice and lessons to be shared	Specialty governance meetings.

7. Updating and Review

This document will be reviewed every 3 years and/or in the event of any significant change with the Organisational structure/management arrangements.

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Cryotherapy Treatment in RCH Dermatology Unit Standard Operating Procedure V2.0.
This document replaces (exact title of previous version):	Cryotherapy Treatment in RCH Dermatology Unit Standard Operating Procedure V1.0.
Date Issued / Approved:	February 2025.
Date Valid From:	February 2025.
Date Valid To:	February 2028.
Author / Owner:	Sarah Carswell, Skin Cancer Clinical Nurse Specialist.
Contact details:	01872 253253.
Brief summary of contents:	RCHT SOP for Cryotherapy within Dermatology.
Suggested Keywords:	Cryotherapy, Dermatology, Consent.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Dermatology Governance Meeting. Specialist Services and Surgery Governance Meeting. Care Board Meeting.
Manager confirming approval processes:	Ian Moyle-Browning, Head of Nursing (HoN), Specialist Services and Surgery.
Name of Governance Lead confirming consultation and ratification:	Michele Reed.
Links to key external standards:	https://cks.nice.org.uk/topics/warts-verrucae/prescribing-information/cryotherapy/

Information Category	Detailed Information
Related Documents:	RCHT Health and Safety Policy - Link. RCHT Liquid Nitrogen Policy - Link. RCHT Standard Infection Control Precautions - Link. Cancer Research UK (2018) Cryotherapy. Available from: https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/other/cryotherapy (Accessed: 11 October 2021). Bell. M. Gardiner P (1995) Surgical Procedures in Primary Care Oxford University Press. Lawrence C. (1996) An introduction to Dermatological Surgery Blackwell Science, Edinburgh.
Training Need Identified:	No.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Clinical / Dermatology.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
March 2022	V1.0	Initial issue.	Sarah Carswell Skin Cancer Clinical Nurse Specialist.
February 2025	V2.0	Full review of document.	Sarah Carswell Skin Cancer Clinical Nurse Specialist.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The

Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Cryotherapy treatment in RCH Dermatology Unit Standard Operating Procedure V2.0.
Department and Service Area:	Specialist Services and Surgery.
Is this a new or existing document?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Sarah Carswell Skin Cancer, Clinical Nurse Specialist.
Contact details:	

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Staff performing cryotherapy treatment on behalf of the RCH Dermatology Unit Service.
2. Policy Objectives	To standardise cryotherapy procedural practice.
3. Policy Intended Outcomes	A safe, standardised cryotherapy treatment delivery within the service.
4. How will you measure each outcome?	Annual audit.
5. Who is intended to benefit from the policy?	Staff involved with cryotherapy treatment delivery and patients.
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No

Information Category	Detailed Information
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Dermatology Business and Governance members. Specialist Services and Surgery Governance team. Skin Cancer MDT members. British Dermatology Nursing Group. British Association of Skin Cancer Nurses.
6c. What was the outcome of the consultation?	Agreed and passed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	Yes	
Sex (male or female)	Yes	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	Yes	
Race	Yes	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	Yes	
Religion or belief	Yes	
Marriage and civil partnership	Yes	
Pregnancy and maternity	Yes	

Protected Characteristic	(Yes or No)	Rationale
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	Yes	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Sarah Carswell Skin Cancer, Clinical Nurse Specialist.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis