FSS an Iarthair agus an Iarthuaiscirt
HSE West and North West

SLIGO UNIVERSITY HOSPITAL
The Mall, Sligo. F91 H684 Tel:071 917 1111 Fax:071 912 4648

CLINICAL RESEARCH PROTOCOL

Study Title **TREATS**: Telemedicine Rash Evaluation and Assessment of Toxicity in Skin in Acute Oncology and Haematology Care: A Pilot Study

Protocol Number: Version 3a

Date: 17th Oct 2025

Protocol Authors

Margaret Burke and Moira Maxwell

Principle Investigator

Margaret Burke, Cancer Research Nurse, Sligo university Hospital, Ireland

INVESTIGATOR PROTOCOL AGREEMENT PAGE

I, the undersigned, am responsible for the conduct of the trial at this site and agree to the following:

- I understand and will conduct the trial according to the protocol, any approved protocol amendments, ICH GCP and all applicable regulatory authority requirements and national laws.
- I will not deviate from the protocol without prior written approval from the Institutional Review Board or Independent Ethics Committee, except where necessary to prevent any immediate danger to the subject.
- I have sufficient time to properly conduct and complete the trial within the agreed trial period, and I have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
- I will ensure that any staff at my site(s) who are involved in the trial conduct are adequately trained regarding the protocol and their responsibilities.

Signed Date

_____ _____

Margaret Burke, Principal Investigator, Sligo University Hospital

CO-INVESTIGATORS

Christina Callaghan, Acute Haematology Oncology Nurse, Sligo University Hospital.

Moira Maxwell, CNM2, Cancer Research Department, Sligo University Hospital.

Dr Lore Komanyane, Consultant Medical Oncologist, Sligo University Hospital.

Contents

1. Introduction

1.1. Background and Rationale

Dermatological adverse events (AEs) or toxicities are a common and significant side effect of systemic anticancer therapies (SACT), including chemotherapy, targeted therapies and immunotherapy. These AEs affect the skin, hair, nails, and mucosa, manifesting as rashes, dryness, itching, and other changes that can severely impact patients' quality of life (QoL) and adherence to treatment protocols.

Prevalence and Impact: Dermatological adverse events (AEs) occur frequently across various cancer treatments. For example, papulopustular eruptions are seen in up to 91% of patients treated with epidermal growth factor receptor inhibitors (EGFRis). These AEs can result in physical discomfort, altered body image, reduced self-esteem, social inhibition, and an increased risk of infection. In severe cases, dermatological AEs may necessitate dose reductions, treatment deferrals, or even discontinuation, which can compromise therapeutic outcomes. In 2024, skin toxicities accounted for 4.7% of referrals for AHOS assessments at Sligo University Hospital (SUH), leading to significant and repeatable face-to-face consultations. These consultations required chair time in the hospital and also contributed to travel time and a potential financial burden for patients.

Psychosocial Implications: Dermatological AEs also contribute significantly to emotional distress, including anxiety and depression. This form of "psychosocial toxicity" has been referred to as the "sixth vital sign" in cancer care. Quality of life (QoL) scales, such as the Dermatologic Life Quality Index and Skindex, highlight the profound impact these conditions can have on patients' daily lives and emotional well-being.

Management Challenges: Early identification and effective management of dermatological AEs are essential for preserving patients' quality of life and ensuring uninterrupted cancer treatment. However, traditional in-person dermatological assessments are not always feasible due to logistical or geographical barriers, which presents a significant challenge in delivering timely and appropriate care

Role of Telemedicine:Attend Anywhere is a secure, web-based platform utilised by the HSE that enables remote video consultations for clinical assessments, including skin toxicities. It improves patient access, reduces travel, and streamlines clinic flow. The platform supports individual, urgent, and group consultations, making it suitable for both solo and multidisciplinary team use.

Key features include shared virtual waiting areas, automatic patient arrival alerts, and the ability to transfer patients between virtual rooms. The system offers customisable patient-facing content, such as branded leaflets and messages in multiple languages. Post-consultation follow-up materials can be sent automatically. Training for healthcare professionals is mandatory before clinical use. Overall, Attend Anywhere supports timely, accessible, and high-quality virtual care

2. STUDY RATIONALE:

Given the high prevalence of dermatological AEs and their impact on treatment adherence and patient well-being, developing effective telemedicine protocols for skin toxicities is crucial. This approach could improve access to dermatological care, enable early intervention, and ultimately enhance patient outcomes in oncology settings.

3. STUDY AIM:

Evaluate the effectiveness of telemedicine as alternative to traditional in person clinical review, in diagnosing and managing skin toxicities in acute oncology/haematology patients using existing UKONS guidelines.

4. STUDY OBJECTIVES

4.1 Primary Objective

To evaluate the clinical effectiveness of telemedicine consultations, compared with traditional in-person review, in diagnosing and managing dermatological toxicities in acute oncology and haematology patients in accordance with United Kingdom Oncology Nursing Society (UKONS) guidelines.

4.2 Secondary Objectives

To assess patient satisfaction with the telemedicine intervention.

To evaluate healthcare provider satisfaction with telemedicine consultations.

To assess the feasibility of implementing telemedicine within acute oncology and haematology services.

To identify potential barriers to implementation of telemedicine in this clinical context.

5. STUDY ENDPOINT

5.1 Primary Endpoint

Clinical Resolution of Skin Toxicity (Non-Inferiority Endpoint)

Definition:
Proportion of patients achieving complete resolution or downgrade to Grade 0–1 skin toxicity within 6 weeks of initial assessment.

Comparison:

- Prospective telemedicine cohort (Attend Anywhere) vs
- Retrospective 2024 in-person AHOS cohort (n=56)

Non-Inferiority Margin:
Pre-specified absolute margin (e.g., −10%) to demonstrate telemedicine is not clinically inferior to face-to-face care.

Measurement Standard:
Grading performed using United Kingdom Oncology Nursing Society (UKONS) standardised toxicity assessment.

Analysis:
Difference in proportions with 95% CI; non-inferiority concluded if lower bound does not cross margin.

5.2 Secondary Endpoints

Time-to-Clinical Resolution

Definition:
Number of days from first AHOS contact to documented resolution (Grade 0–1).

Comparison:
Telemedicine vs retrospective in-person cohort.

Analysis:
Kaplan–Meier time-to-event analysis or median time comparison.

Escalation to In-Person Review

Prospective Cohort Only

Definition:
Proportion of telemedicine patients requiring:

- Conversion to face-to-face review
- Emergency department attendance
- Hospital admission

This is a safety endpoint, ensuring remote triage is clinically appropriate.

Treatment Modification Rate

Definition:
Proportion of patients requiring:

- SACT dose reduction
- Treatment delay
- Treatment interruption

Comparison between cohorts to assess impact of telemedicine on oncologic management.

Unscheduled Acute Oncology Contacts

Definition:
Number of unplanned re-contacts with AHOS within 6 weeks.

Comparison between telemedicine and retrospective face-to-face care.

Patient-Reported Endpoints (Prospective Only)

Quality of Life (QoL)

Instrument:
QLQ administered:

- Post initial assessment
- At resolution or week 6

Endpoint Measures:

- Change in QoL score from baseline to resolution/week 6
- Mean QoL score at 6 weeks

Patient Satisfaction

Definition:
Mean satisfaction score following telemedicine consultation.

Secondary **Measure:**
Proportion rating telemedicine as acceptable/preferable to in-person review.

Feasibility Endpoints (Prospective Only)

Uptake Rate

Proportion of eligible patients who:

- Accept telemedicine
- Decline telemedicine

Safety Endpoints

1. Incidence of toxicity progression from Grade ≤2 to Grade ≥3
2. Adverse clinical outcomes attributable to delayed assessment
3. Hospital admission related to dermatologic toxicity

6. STUDY DESIGN

This study will use an interventional prospective pilot study using quasi-experimental design.

Duration: 6 months.

7. STUDY POPULATION

7.1 Participant Selection and Recruitment

Participant will be used from 2 cohorts

- A prospective telemedicine cohort
- A retrospective comparator cohort (2024 in-person AHOS patients, n=56)

Prospective Cohort (Telemedicine Arm)

Participants will be recruited using convenience sampling from patients accessing the Acute Haematology/Oncology Service (AHOS) with suspected skin toxicity secondary to systemic anti-cancer therapy (SACT).

At first point of contact (patient-initiated telephone call to AHOS), patients requiring visual dermatologic assessment will be offered review via the Attend Anywhere telemedicine platform.

If patients express interest:

- Written study information will be sent via SMS.
- An individualised Attend Anywhere link will be issued.
- Study-related data will be collected following consultation.

Patients declining telemedicine will receive standard face-to-face review but will not be included in the prospective study cohort.

Participants will undergo assessment and management according to United Kingdom Oncology Nursing Society (UKONS) standard of care guidelines.

Remote follow-up will occur weekly for up to 6 weeks or until toxicity resolution.

Retrospective Comparator Cohort

A retrospective review of medical records from 2024 (n=56 patients) will be undertaken. These patients accessed AHOS via traditional in-person consultation for SACT-related skin toxicities.

Data collected will include:

- Toxicity grade
- Management interventions
- Time to resolution
- Escalation rates
- Treatment modifications

This cohort will serve as the comparator group for non-inferiority analysis.

Setting: Acute oncology/haematology nursing service within Saolta University Health Care Group.

7.2 Study Inclusion Criteria

Participants must meet all of the following criteria:

- Oncology or haematology patients receiving systemic anti-cancer therapy (SACT).
- Presentation with new skin toxicity recognised as a known adverse effect of the administered SACT.
- Skin toxicity graded ≤ Grade 2 according to UKONS assessment criteria.
- Clinical stability not requiring immediate in-person review.
- Access to a smartphone or computer with internet capability sufficient to support telemedicine consultation.

7.3 Study Exclusion Criteria

Participants will be excluded if any of the following apply:

- Skin toxicity graded ≥ Grade 3.
- Requirement for urgent or immediate in-person clinical assessment.
- Presentation of unexpected or atypical dermatologic toxicity not consistent with known SACT-related adverse effects.
- Inability to access or use required telemedicine technology.

8. WITHDRAWL FROM STUDY

Participants will be informed of their right to refuse to participate and their right to withdraw from this research study

9. INFORMED CONSENT

Informed consent to take part in the research will be obtained. Patients will be consented by a member of the study team. Participants will be given the opportunity to take their time between receiving the PIL and agreeing to participate in the study.

Informed consent Pathway-

1 Patient contact made for assessment to AHOS

2 Study explained, offered participation to study, verbal consent obtained.

3 Written information sent electronically ie SMS with explicit I consent to participate in study discussion upon clicking the link for assessment

4 Link sent for Attend Anywhere

10 METHODOLOGY

10.1 Schedule of assessments

Data Collection Instrument	Baseline	End of treatment
Consent And Demographics		
DLQI		
Telemedicine Effectiveness		
Patient Satisfaction		
Quality Of Care		

10.2. Data Collection Instrument Development

Patient experience and service utility were evaluated using a hybrid assessment framework comprising the validated Telemedicine Satisfaction Questionnaire (TSQ) and a study-specific Tele-Toxicity Service Evaluation Tool. The 14-item TSQ (Yip et al., 2003) was utilized to measure three core domains: Quality of Care, Similarity to Face-to-Face Encounters, and Perception of Interaction, using a 5-point Likert scale ranging from 'Strongly Disagree' to 'Strongly Agree.' To supplement these validated metrics, a secondary service evaluation tool was developed to capture domain-specific operational data, including technical performance (e.g., image upload success), perceived benefits (e.g., avoided travel and faster access to specialist care), and specific barriers to remote skin toxicity assessment. This dual-instrument approach ensures a comprehensive evaluation of both the psychological acceptability of the telemedicine platform and its practical efficacy in the management of Systemic Anti-Cancer Therapy (SACT) toxicities. All quantitative survey data will be cross-referenced with clinical outcomes, including time-to-resolution and SACT dose modifications, to identify correlations between patient-reported satisfaction and objective clinical recovery.

Impact on patient well-being was evaluated using the **Dermatology Life Quality Index (DLQI)**, a validated 10-item questionnaire designed to measure the health-related quality of life in patients suffering from skin diseases (Finlay & Khan, 1994). The DLQI assesses six primary domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment burden. Each item is scored on a 4-point Likert scale (0 = 'not at all' to 3 = 'very much'), with a total score ranging from **0 to 30**; higher scores indicate a greater impairment in quality of life. For the purposes of this study, DLQI scores were collected at the point of toxicity onset and again at the 6-week follow-up (or upon resolution). This longitudinal data allows for the calculation of the **'Minimal Clinically Important Difference' (MCID)**, enabling the research team to correlate improvements in the Kaplan-

Meier resolution curve with a quantifiable reduction in the psychosocial burden of SACT-induced skin toxicities.

11. INTERVENTION

Implementation of the telemedicine platform Attend Anywhere to assess and manage skin toxicity, following the UK Oncology Nursing Society (UKONS) standard of care guidelines. Currently, these guidelines are applied in face-to-face consultations for this patient group.

12. ASSESSMENT AND PROCEEDURES

Point of contact- the patient in the community rings the AHOS in the usual manner to discuss symptoms of dermatology toxicity secondary to SACT.

1st contact assessment indicates visual assessment required.

AHOS offers telemedicine assessment via Attend Anywhere.

If interested provide written information to patient via text.

If the patient is willing to proceed the Attend Anywhere individualised link will be sent to the patient.

If not interested, patient will be reviewed in traditional face to face manner as appropriate.

Patient is assessed using SOC UKONS assessment. SEE APPENDIX

QLQ sent via SMS post assessment 1.

Weekly remote monitoring for 6 weeks or until resolution. Treated per standard of care (SOC) and repeat assessment using Access Anywhere.

QLQ via SMS at resolution or week 6 of follow-up.

Data Collection

Clinical Outcomes:

Diagnostic concordance

Time to resolution or escalation of care.

Patient Satisfaction:

Standardized patient satisfaction and QLQ survey at 6 weeks using Redcap data collection tool.

13. STATISTICAL METHODS

Sample Size: 25 prspective patients

13.1. Statistical Analysis Plan

Primary Outcome: Time-to-Resolution (TTR)

The primary clinical endpoint is the Time-to-Resolution (TTR), defined as the interval (in days) from the onset of SACT-induced skin toxicity to the documented return to Grade 0 or the patient's baseline skin health.

- Method: TTR will be analyzed using Kaplan-Meier (KM) survival estimates.
- Censoring: Patients who do not achieve resolution within the 6-week (42-day) observation window, those who withdraw from the study, or those who experience a competing event (e.g., death or treatment cessation for non-toxicity reasons) will be right-censored at the date of their last assessment.
- Comparative Analysis: The Log-Rank (Mantel-Cox) test will be used to compare TTR curves stratified by key covariates: Initial Toxicity Grade (UKONS 1 vs. 2 vs. 3), SACT Type (Chemotherapy vs. Immunotherapy/Targeted), and Management Strategy (Topical vs. Systemic).

Secondary Outcome: Patient Satisfaction and Usability (TSQ & Service Evaluation)

Patient-reported satisfaction and service utility will be assessed descriptively and analytically.

- Descriptive Statistics: For the Telemedicine Satisfaction Questionnaire (TSQ), mean scores and standard deviations will be calculated for each of the three domains (Quality of Care, Similarity to Face-to-Face, and Perception of Interaction).
- Benchmarking: A global TSQ mean score of > 4.0 (on the 5-point scale) will be predefined as "High Satisfaction."
- Service Evaluation: Categorical data from the custom survey (e.g., "Would you use again?", "Technical difficulties experienced") will be presented as frequencies and percentages.

Tertiary Outcome: Quality of Life (DLQI)

The impact of skin toxicity on patient well-being will be evaluated using the Dermatology Life Quality Index (DLQI).

- Scoring: DLQI scores (0–30) will be categorized into clinical bands (e.g., 0–1 = No effect; 11–20 = Very large effect).

- Longitudinal Analysis: A Paired t-test (or Wilcoxon Signed-Rank test for non-normal distributions) will be used to compare DLQI scores at onset versus 6-week follow-up to determine the magnitude of improvement following telemedicine intervention.

Correlation and Multivariate Analysis

To bridge the clinical and patient-reported data, the following inferential tests will be applied:

- Correlation: Spearman's Rho (ρ) will be used to assess the correlation between the maximum DLQI score and the total Time-to-Resolution (TTR).

- Predictive Modeling: Multiple Logistic Regression will be employed to identify predictors of "Unscheduled AHOS Contacts." Independent variables will include Initial Toxicity Grade, DLQI score at onset, and the presence of technical difficulties (Service Evaluation).

- Significance Level: All statistical tests will be two-tailed, and a p-value of < 0.05 will be considered statistically significant. Analysis will be performed using SPSS

14. STUDY RISKS

Risks are minimal. There is a small risk that telemedicine assessment may miss a severe skin problem, but clear protocols are in place for escalation to in-person review if needed.

15. STUDY BENEFITS

Participants may benefit from more convenient and timely care, and the study may help improve future services for patients with skin toxicities.

16. ADVERSE EVENT REPORTING

An Adverse Event (AE) is any untoward medical occurrence in a participant that arises during the course of the study, regardless of whether it is considered related to the study intervention.

A Serious Adverse Event (SAE) is defined as any AE that:

- Results in death

- Is life-threatening
- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly/birth defect
- Is deemed medically significant by the investigator Adverse Events (AE) refers to any untoward event or medical occurrence that may not have a causal relationship with the treatment.

16.1 Monitoring and Detection

Participants will be provided with contact information for the study team and instructed to report any symptoms or concerns. Study staff will proactively inquire about potential adverse effects during scheduled check-ins. Participants will be monitored through routine clinical care and follow-up appointments.

16.2 Documentation of Adverse Events

All adverse events must be documented in the patient's medical records and recorded in the study Adverse Events Log, Appendix VIII, to include:

- Date and time of event onset
- Description of the event
- Severity (mild, moderate, severe)
- Assessment of relatedness to the study intervention (definitely, probably, possibly, unlikely, or unrelated)
- Action taken (e.g., medical treatment)
- Outcome and resolution date

16.3 Reporting of Adverse Events

Non-serious AEs:

- Logged in patient medical records and AE logs

- Reviewed during regular team meetings
- Reported in study summary at conclusion

Serious Adverse Events

- Must be reported to the Principal Investigator and patients medical consultant within 24 hours of awareness.
- Principal Investigator reports to the Research Ethics Committee (REC) within 7 calendar days of awareness (for unexpected and related SAEs)
- Documentation medical records and AE log.

16.4 AE/SAE Follow-up and Management

All AEs will be followed until:

- The event resolves
- The participant returns to baseline health status
- A final outcome is established

17. ETHICS AND REGULATORY CONSIDERATIONS

Ethics approval has been obtained for this study from the ethics committee governing Sligo University Hospital. All study procedures will be conducted in line with Good Clinical Practice Guidelines.

18. DATA PROTECTION

Explicit consent will be sought from participants for the processing of their data.

Sligo University Hospital, HSE is both the data controller and data processor for this study.

19. DATA HANDLING

19.1 Data Storage

Data will be retained for a period up to 5 years post completion of study and destroyed as per HSE policy.

19.2 Data Processing

All data collected is for the purpose of achieving the objective of this research study. The data will not be processed in any way that will cause damage or distress to the participant.

Once explicit consent has been obtained from participants their data will be pseudonymised by assigning a unique identifier to their data. Only members of the research team will have access to the identifier key which will be locked in restricted office within Sligo University Hospital.

All study documents and participant data will be stored in a locked and restricted office within Sligo University Hospital. Only study team members will have access to the data. Data analysis will be completed on a HSE computer that is password protected, encrypted and cyber secure per the HSE IT security policy.

19.3 Data Confidentiality

All information regarding the study data or results supplied to the investigator is privileged and confidential information. All research team members who have access to the data are bound to maintain confidentiality in line with their employment contract and professional conduct per their regulatory body.

20. PUBLICATION OF STUDY FINDINGS AND USE OF INFORMATION

Data associated with this study may be used in the context of scientific research and publications or educational material. No participant will be identifiable from the data presented.

21. INDEMNITY

This study is registered with the Clinical Research Development Office and CIS cover obtained where applicable.

Appendix 1 Patient information leaflet and consent

Study title: **TREATS**: Telemedicine Rash Evaluation and Assessment of Toxicity in Skin in Acute Oncology and Haematology Care: A Pilot Study

Principal investigator's name:	**Margaret Burke**
Principal investigator's title:	**Cancer Research Nurse**
Telephone number of principal investigator:	**086 0479985**
Consultant co-investigator's name:	**Lore Komanyane**
Consultant co-investigator's title:	**Consultant Oncologist**
Data Controller's/joint Controller's Identity:	Health Service Executive
Data Controller's/joint Controller's Contact Details:	0719171111
Data Protection Officer's Identity:	Mr Liam Quirke
Data Protection Officer's Contact Details:	DPO @HSE west **0**91 524222

You are being invited to take part in a research study to be carried out at Sligo University Hospital by the Cancer Services department.
Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

You are being invited to take part in a research study at Sligo University Hospital because you are receiving cancer treatment and have developed a skin problem.
This study is being done to find out if video consultations (telemedicine) can be used to safely and effectively assess and manage skin problems caused by cancer treatments. Instead of always coming to the hospital for a face-to-face appointment, you may be able to use your smartphone or computer to show your skin to a nurse or doctor over a secure video call. We want to see if this is as good as a regular clinic visit, and whether patients and staff are happy with this new way of working.

Who is organising and funding this study?

This study is organised by Cancer Services and the Acute Oncology/Haematology Service at Sligo University Hospital. There is no external funding for this study; it is being carried out using existing hospital resources

Why am I being asked to take part?

You have been invited because you are a cancer patient under our care who has developed a skin problem during treatment. We aim to include about 25 patients in this study.

How will the study be carried out?

When you contact the Acute Oncology/Haematology Service with a skin problem, you may be offered a video consultation instead of an in-person visit. If you agree, you will receive a secure video link for your appointment. The nurse or doctor will assess your skin and recommend treatment. You may be asked to send a photo of your skin problem. As part of the study you will be asked to fill in a short questionnaire about your experience and quality of life. Your care will continue as usual, and you can still attend the hospital in person if needed.

What will happen to me if I agree to take part?

- You will have a video call with a nurse or doctor to assess your skin problem.
- You may be asked to send a photo of your skin problem using your phone or computer.
- You will be asked to complete a satisfaction and quality of life questionnaire.
- Your care will not be affected by your decision to take part or not.
- You can withdraw at any time without giving a reason

How long will the study take?

You will be followed up weekly via video call until your skin problem has resolved as would be usual in a face to face setting. At 6 weeks (or before that if your problem has resolved) you will be asked again to complete a questionnaire about your experience of telemedicine assessments.

Will I need to attend the hospital for extra visits?

No extra hospital visits are planned as part of this study. If your skin problem needs to be seen in person, we will arrange a clinic appointment for you.

Will researchers look at my medical records?

Yes, the research team will review your medical records to confirm your diagnosis, treatment, and outcome of your skin problem in addition to your questionnaire responses. All information will be kept confidential. The AHOS nurse will have full access to your clinical information in order to best assess your needs.

Video/and or Audio recordings?

You may be asked to send a photo of your skin problem. These images will be stored securely and only used as part of your standard care. They will form part of your medical record as they would if provided in the event of a routine face to face consultation and will not be evaluated as part of the research project.

What other treatments are available to me?

If you do not wish to proceed with a video assessment, the AHOS nurse will schedule an appointment for assessment in the usual manner.

What are the benefits?

You may benefit from faster and more convenient care. The study may help improve services for other patients with similar problems in the future.

What are the risks?

Risks are minimal. There is a small chance that a skin problem may not be fully assessed by video, but you will be offered an in-person appointment if needed. All information you provide will be kept confidential.

What if something goes wrong when I'm taking part in this study?

If you become upset or unwell during the study, please let the research team or the Acute Haematology Oncology Nurse know. If you have any concerns or complaints, you can contact the Principal Investigator or your usual care team.

Will it cost me anything to take part?

No. There are no costs for taking part, and you will not be paid for participation.

Is the study confidential?

You will join your consultation via a unique link, and it will be hosted in secure "virtual waiting rooms" accessible only to authorized persons.

The video consultation will take place in a secure clinical area where there will be no other persons present for the duration of your consultation to ensure no inadvertent disclosures during the call.

The consultation is not recorded by default however it should be noted that the consultation would not be recorded without your express consent to same.

Any identifiable health information will not be stored on the video platform.

All notes/photos taken as part of the consultation will be stored with the current hospital patient record. Questionnaires completed will be stored on a password protected database

with a unique number to identify it and stored separate from your patient record in a secure office.

Data Protection

How will my information be used?

We will use your personal information to help us study whether telemedicine is a good way to assess and manage skin problems in cancer patients.

What is the legal basis for processing my data?

We are processing your data for scientific research in the public interest, under Article 6(1)(e) and Article 9(2)(j) of the General Data Protection Regulation.

Who will have access to my information?

Only the research team at Sligo University Hospital will have access to your identifiable information. Any data used in reports or publications will be anonymised so you cannot be identified.

How long will my information be kept?

Your data will be kept securely for 5 years after the end of the study, after which it will be deleted or destroyed.

What are the risks to my data?

All reasonable steps will be taken to protect your information from loss or unauthorised access. In the unlikely event of a data breach, you will be informed and the breach will be reported to the Data Protection Commissioner.

What are my rights?

- You have the right to withdraw your consent at any time.
- You have the right to ask for a copy of your data.
- You have the right to have your data corrected or deleted.
- You have the right to restrict or object to processing of your data.
- You have the right to make a complaint to the Data Protection Commissioner.

How can I withdraw my consent?

You can withdraw your consent at any time by contacting the Principal Investigator at the contact details above. This will not affect your care.

Will my data be used for future research?

Your data will only be used for this study unless you give separate permission for future use. If future use is planned, you will be asked for your consent.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.
If you need any further information now or at any time in the future, please contact:
Name : Chrissie Callaghan, AHOS Nurse Specialist.
Address: Day Services Oncology Unit
087 9932448

PATIENT CONSENT FORM

What do I do next?

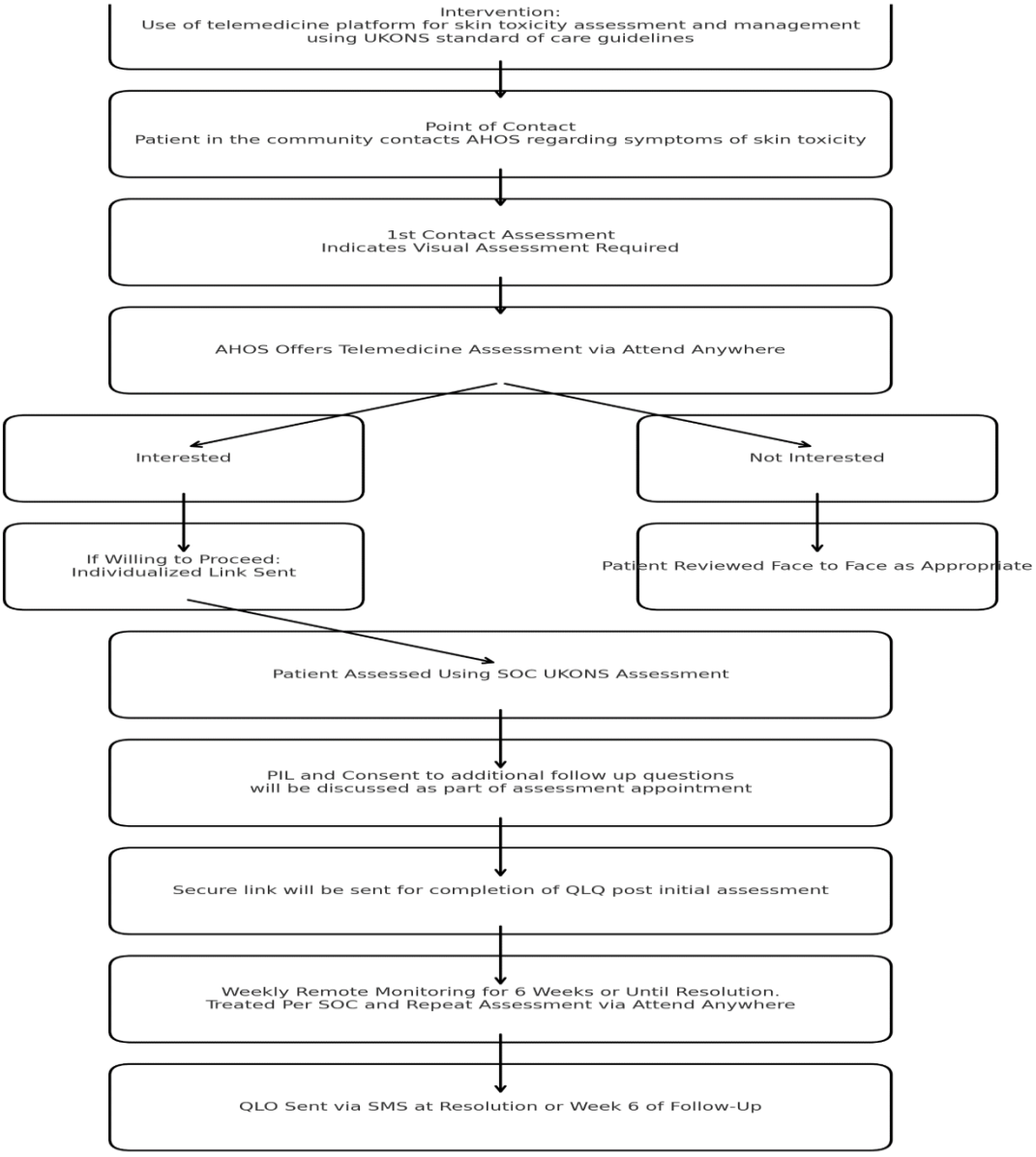
If you are not interested in participating in the study, please respond to this to indicate you would like an in person appointment which will be arranged for you in the usual manner.

If you wish to proceed with the research using video call assessment and follow up please read the table below.

1	I have read and understood the **Information Leaflet** about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.
2	I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.
3	I am aware of the potential risks, benefits and alternatives of this research study.
4	I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential.
5	I have been given a copy of the Information Leaflet and this consent form will be held in my records. My consent will be recorded in the medical notes
6	I consent to take part in this research study having been fully informed of the risks, benefits and alternatives.
7	I give informed explicit consent to have my data processed as part of this research study.
8	I consent to be contacted by researchers as part of this research study.

If you are satisfied and agree with all of the above statements and wish to participate in the study, please respond using the words 'I consent' and an appointment using video call will be arranged for you.

Appendix 2 Work Flow



Appendix 3 Escalation Protocol

Escalation Protocol: SACT Skin Assessments via Telemedicine

1. Urgent Clinical Indicators (Immediate Escalation)

Escalate to urgent in-person review if the telemedicine assessment identifies:
- Suspected UKONS grade > amber(Grade >2 skin toxicity per CTCAE v5.0), including:
  - Painful or widespread rash
  - Blistering, ulceration, desquamation
  - Suspected Stevens-Johnson Syndrome or toxic epidermal necrolysis
  - Infected lesions with systemic signs (e.g. fever, chills)
- Rapid worsening of dermatologic symptoms since last assessment
- Skin toxicity impacting performance status or treatment continuation

Action: Immediate referral to acute oncology service for urgent face-to-face review.

2. Moderate or Persistent Skin Toxicity (Planned Escalation)

Escalate to non-urgent in-person review if:
- Lesion or rash is not resolving with prescribed treatment
- Diagnostic uncertainty (e.g. unclear whether rash is drug-related or infective)
- Rash recurs despite previous intervention
- Multiple concurrent toxicities affecting skin, mucosa, or nails

Action: Book an acute oncology service for urgent face-to-face review.

3. Patient Factors or Preference

Escalate if:
- Patient requests in-person review or expresses anxiety about appearance/progression
- Patient has communication barriers (hearing, language, cognition) making remote assessment unreliable
- Concerns arise about adherence, self-care, or need for hands-on support

Action: Schedule face-to-face review.

Workflow Summary for SACT Teledermatology Escalation

Trigger	Action	Timeline
UKONS grade >amber	Urgent face-to-face via oncology team	Same-day
Persistent rash or unclear diagnosis	Routine in-person review (OPD/clinic)	Within 6 week
Patient preference or communication need	Face-to-face booked with appropriate clinician	As appropriate

Documentation & Patient Safety

- All escalation decisions will be recorded in the oncology patient record

Full UKONS assessment should be documented at each teleconsultation.

- Patients will be given clear safety netting advice and contact details for the acute oncology line.

Appendix 4 UKONS Skin Toxicity Assessments

GUIDELINE 13.
Skin Rash
Urgent Initial Triage Assessment

Skin rash can be a side effect of:

- **Systemic Anti-Cancer Therapy**: Rash can be frequent and sometimes severe with:
  - Immunotherapies – see guideline 26 P.33
  - IV antibodies e.g. panitumumab/cetuximab
  - 5-FU/capecitabine/sunitinib
  - Targeted- agents: EGFR antagonists, BRAF and MEK inhibitors (see guideline 14 P.21)
- **Radiotherapy**- radiation toxicity see guideline 15 P.22
- **Graft versus host disease** in a patient who has undergone allogeneic stem cell transplant (**Contact haematology team**).

Questions:

- Is there a cancer diagnosis/primary disease?
- Is the patient taking anticancer treatment at the moment or recently? If so what treatment and when did it stop? Is skin rash a commonly associated and sometimes serious toxicity of their treatment, please see specific DRUG INFORMATION SHEET
- Have they received immunotherapy proceed to guideline 26 P.33
- Have they received oral targeted agents: EGFR antagonists, BRAF and MEK inhibitors; see guideline 14 P.21
- Have they received radiotherapy recently: see guideline 15 on P.22
- Have they had a stem cell/ bone marrow transplant? If yes contact the haematology team
- If the patient has received 5FU, Capcitabine: see guideline 16 on P.23
- Are they otherwise well? Does the patient have any signs of infection e.g. pain, swelling, pustules, fever, discharge?
- Has the patient recently started any other medication including antibiotics?
- Does the patient have a history of skin complaints?
- Where is the skin rash, what % BSA does it cover and what does it look like?
- Does the rash itch? Itch only, consider liver/kidney problems/ dry skin/ allergy.
- Has the patient been in recent contact with infectious disease e.g. shingles/chicken pox?
- Does the patient have any other SACT toxicity related symptoms, if so, please see symptom specific guideline.

Examination: Clinical evaluation, history, physical examination, and review of observations.
Observations: Calculate and monitor NEWS score.
Investigations: Urgent FBC, U&Es, LFT, CRP, blood cultures if signs of systemic sepsis.

Differential diagnosis:

Side effect of medication	Allergic reaction
Infection e.g. shingles/ impetigo	Thrombocytopenia

Illness e.g. cellulitis

Identify: Patients who have received/receiving systemic anti-cancer treatment or receiving radiotherapy or are at risk of disease related immunosuppression or a history of allogeneic stem cell transplant. These patients may be myelosuppressed / neutropenic and are at risk of neutropenic sepsis and/or thrombocytopenia due to reduced marrow production or marrow infiltration and/or graft versus host disease: If present, this should be managed as per guideline 12 on P.19, immediate antibiotics if sepsis suspected.

Grade 1 (Green)
Rash covering <10% BSA, Macular/Papular eruption

- Provide appropriate skin care advice and emphasise the importance of skin care regimen -See P 22
- Treat with emollient creams and antihistamines if required
- Advice to keep nails short
- Ask patient to contact 24-hour advice line if symptoms worsen or persist.

Grade 2 (Amber)
If any of the following are present:

- Pruritus, or Purpura or burning tightness.
- Rash covering 10 -30% BSA.
- Affecting ADL or sleep.

- Check all blood results and act on abnormalities
- Treat symptomatically as grade 1 and consider additional topical or oral steroids
- Telephone/review patient within 24 hours ask patient to contact the 24-hour advice line if symptoms worsen/ persist.

Grade 3 (Red)
If any of the following are present:

- Pruritic symptoms >30% skin surface
- Generalised
- Exfoliative
- Ulcerative
- Bullous dermatitis
- Spontaneous bleeding or signs of associated infection.

Grade 4 (Red)
Life threatening

- Check all blood results and act on abnormalities
- For unusual, severe, or persistent rash, particularly if the patient is unwell –urgent referral to dermatology
- Assess for SDEC or admission if clinically indicated
- Urgent admission if symptoms suggestive of Steven Johnson Syndrome or Toxic Epidermal Necrolysis
- Analgesia, fluid balance monitoring and skin care support and advice
- Determine cause and treat appropriately, this may include I.V. / oral or topical steroids.

Always make sure that the Acute Oncology Team are informed of the patient's assessment and/or admission as soon as possible.

Immediate advice is available from the Acute Oncology Service or the 24-Hour Oncology on call rota.

WITHHOLD SACT, including oral therapy, until you have discussed with the Acute Oncology or Site Specific Team.

GUIDELINE 14.
Skin Toxicities: Targeted therapy related (Papulopustular rash)

Newer targeted anticancer therapies, particularly EGFR antagonists, BRAF, MEK and MTOR inhibitors, are frequently associated with skin toxicities, which are often seen in particular patterns and at different stages of treatment.

- **Papulopustular ("acneiform") rash**: predominately affects the scalp, face and upper trunk. Pruritus, irritation and pain may also be present
- **Xerosis ("dry skin")**: usually develops gradually and may present with eczema and/or fissuring
- **Nail changes**: include paronychia, onycholysis, splinter haemorrhages, and nail fold pyogenic granulomas
- **Hand-foot skin reaction**: dysaesthesia and paraesthesia can progress to localised, tender lesions, which may be bullous and severe. More common in plantar, pressure sites, heels and distal digits. Evolves to hyperkeratosis
- **Hair abnormalities**: classically a reversible inflammatory, non-scarring frontal alopecia. Hair growth is slowed and textural changes can occur. Increased hair growth is also seen, particularly of the eyelashes and eyebrows. Hypertrichosis can also involve the face and chest.

Initial Assessment: Clinical evaluation, history, physical examination, and review of observations.
Observations: Calculate and monitor NEWS score.
Investigations: If indicated bloods.
NB: Isotretinoin is not indicated for the treatment of papulopustular rash.

Grade 1 (Green)	Grade 2 (Amber)	Grade 3 (Red)	Grade 4 (Red)
Papules and/or pustules covering <10% BSA ± pruritus or tenderness	• Papules and/or pustules covering 10-30% BSA ± pruritus or tenderness • Limiting instrumental ADL • Associated with psychosocial impact.	• Papules and/or pustules covering >30% BSA ± pruritus or tenderness • Limiting self-care ADL • Associated with local super added infection.	• Papules and/or pustules covering any BSA ± pruritus or tenderness and are associated with extensive super added infection • Life-threatening.

• Topical acne treatment e.g. 1% Clindamycin lotion or gel.	• Topical emollients
	• Oral tetracyclines
	• Antihistamines for itch if required.
		• Consider delaying treatment
		• Management as for grades 1 and 2
		• PLUS:
		  • If local super added infection - Oral antibiotics are indicated
		  • If extensive super added infection - IV antibiotics are indicated
		  • Refer to dermatology.	

General management and advice (and management of other skin toxicity patterns)

- For hand-foot skin reaction, see guideline 16 on palmar-plantar erythrodysesthesia (PPE)
- Patients should be advised on general skin care at the commencement of treatment
- The use of soap substitutes, light emollients, sun cream and alcohol-free lotions should be advised
- Emollient creams are preferred over ointments as they can increase acneiform eruptions, e.g. aveeno, epaderm, hydromol
- Topical or oral steroids may be required
- Avoid tight footwear and damage to the nail and surrounding skin if nail changes are observed
- Trichomegaly of the eyelashes can cause discomfort and trichiasis, which should prompt referral to an Ophthalmologist.

Xerosis

- Eczema
  - Face & Neck: 1% hydrocortisone cream
  - Body: 0.05% clobetasone butyrate cream
  - Treat secondary bacterial superinfection as guided by microbiology swabs
- Fissures
  - Greasy emollients e.g. Hydromol ointment, 50% propylene glycol under clingfilm or plastic glove occlusion
  - Fludroxycortide impregnated tape or Zinc oxide paste with salicylic acid.

Nail changes

- Inflammation of nail folds
  - Milton sterilising solution for 20 minutes daily
  - Topical steroid/antifungal e.g. 1% hydrocortisone/ miconazole cream
- Purulent paronychia
  - Oral antibiotics
- Nail fold pyogenic granuloma
  - Curettage and cautery.

Always make sure that the Acute Oncology Team are informed of the patient's assessment and/or admission as soon as possible.
Immediate advice is available from the Acute Oncology Service or the 24-Hour Oncology on call rota.
WITHHOLD SACT, including oral therapy, until you have discussed with the Acute Oncology or Site Specific Team.

GUIDELINE 16.

Skin Toxicity: Palmar - Plantar Erythrodysesthesia (Hand foot syndrome)

A distinctive localised cutaneous reaction to certain SACT. Symptoms include tingling or burning, redness, flaking/dryness, swelling, small blisters, sores on palms and/or sole.

Questions:

- What SACT is the patient on? When was the last dose?
- Is this a continuous intravenous administration via pump? Does this need to be discontinued?
- Is the patient still taking oral SACT? Does this need to be discontinued?
- Is the patient otherwise well? Any other symptoms e.g. diarrhoea/stomatitis? if yes refer to specific management guidelines:
  - Diarrhoea- guideline 6, P.13
  - Mucositis/stomatitis- guideline 10, P.17
- Have they experienced this side effect before on previous treatment cycles?
- Any signs of infection in the affected areas? – Discuss treatment options with the acute oncology team.

Examination: Clinical evaluation, history, physical examination, and review of observations.
Observations: Calculate and monitor NEWS score.
Investigations: If indicated bloods.
Identify: Patients who have received/receiving systemic anti-cancer treatment or receiving radiotherapy or are at risk of disease related immunosuppression or a history of allogeneic stem cell transplant. These patients may be myelosuppressed / neutropenic and are at risk of neutropenic sepsis and/or thrombocytopenia due to reduced marrow production or marrow infiltration and/ or graft versus host disease: If present, this should be managed as per guideline 12 on P.19, immediate antibiotics if sepsis suspected.

Grade 1 (Green)	Grade 2 (Amber)	Grade 3 (Amber)
Minimal skin changes or dermatitis (e.g. erythema, oedema, or hyperkeratosis) without pain	Skin changes (e.g. bleeding, peeling blisters, fissures, oedema or hyperkeratosis) with pain. Limiting instrumental ADL.	Severe skin changes. (e.g. bleeding, peeling blisters, fissures, oedema or hyperkeratosis). With pain. Limiting self-care ADL
• Reassure the patient that this is recognised treatment related complication and generally nothing to worry about • Emphasise the importance of skin care regimen as per local policy • Encourage adequate hydration • Ask patient to contact 24-hour advice line if symptoms worsen.	• Stop the SACT until discussed with acute oncology or prescribing team • Reassure the patient that this is recognised treatment related complication and generally nothing to worry about • Emphasise the importance of skin care regimen • Consider prescription of high urea-based cream • Telephone/review patient within 24 hours and ask patient to contact the 24-hour advice line if symptoms worsen.	• Stop the SACT until discussed with the Acute Oncology Team. If receiving Capecitabine or 5FU consider DPD deficiency • Review current analgesia (with caution as may not then develop a temperature in response to infection) • Emphasise the importance of continuing skin care regimen as per local policy • Consider prescription of high urea-based cream • Consider specialist dermatology referral • Assess for SDEC or admission if clinically indicated • If discharged -telephone/review patient within 24 hours and ask patient to contact the 24-hour advice line if symptoms worsen.

Always make sure that the Acute Oncology Team are informed of the patient's assessment and/or admission as soon as possible.

Immediate advice is available from the Acute Oncology Service or the 24-Hour Oncology on call rota.

WITHHOLD SACT, including oral therapy, until you have discussed with the Acute Oncology or Site Specific Team.

GUIDELINE 26.
Immune-Related Adverse Event: Skin Toxicities

Immunotherapy administration is associated with immune-related adverse events (irAEs). Dermatological irAEs common and although they are typically mild to moderate in severity, if they are left unrecognised or untreated, they can become life-threatening. These toxicities can be managed effectively in almost all patients by using established guidelines that stress vigilance and the use of corticosteroids and other immunosuppressive agents when necessary, consider the rule of nines.

Mild (Grade 1)
- Localised macular/Papular eruption
- Asymptomatic.

Treatment
- Emollient with paraffin content (eg Cetraben®)
- Consider anti-histamines- regular chlorpheniramine 4mg qds tablet.

Actions
- Regular monitoring
- Continue immunotherapy.

Symptoms: WORSEN

Moderate (Grade 2)
- Rash affecting ≤ 50% skin surface
- Itchy
- Affecting ADL's/sleep.

Clinical Assessment

Investigations
- Vital signs
- FBC, chem profile, ALT, cortisol, TFT's and glucose
- Photograph rash
- Measure lesions.

Treatment
- Antihistamines- chlorpheniramine 4mg tablets qds
- Localised rash:
  - Betamethasone cream (eg Betnovate® cream bd)
  - Emollient with paraffin content (eg Cetraben®)
- Extensive rash:
  - Prednisolone - commence at 30mg OD and can be increased to 1mg/kg/day (max. 60mg/day) + gastric protection
  - Emollient with paraffin content (eg Cetraben®)
  - Betamethasone cream (eg Betnovate® cream bd).

Actions
- Withold treatment until ≤ grade 1
- Consider referral to local dermatology team
- Consider biopsy
- Monitor.

Symptoms: Resolve or Improve to Mild. See steroid tapering guidance

Symptoms: PERSIST (≥ 5 days) or WORSEN or RELAPSE

Severe or Life-Threatening (Grade 3 + 4)

Is defined as any of the following:
- >50% skin surface
- generalised
- exfoliative
- ulcerative
- bullous dermatitis.

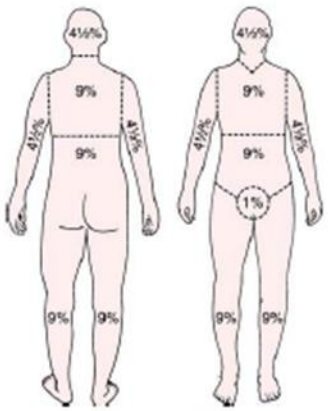
Admit patient

As per moderate (grade2) +

Investigations
- Antibiotics are not indicated unless there is a concern of recurrent infections and/or recommended by treating clinician.

Treatment
- Commence IV hydration
- IV methylprednisolone 2 mg/kg/day + gastric protection
- Regular vital signs and fluid balance
- Antihistamines- Chlorpheniramine 4mg QDS. Can add in fexofenadine Hydrochloride 120mg OD
- Emollient to 50:50 soft white paraffin (liquid paraffin).

Actions
- Consider discontinuing immunotherapy permanently.
- Urgent referral to local dermatology team for advice +/- biopsy
- Monitor daily.



The rule of Nines

Symptoms: Resolve or Improve to Mild. See steroid tapering guidance

Review patient daily, if no improvement within 72 hours, consider additional immunosuppression. Consider local or national subsequent management guidelines

Interrupt SACT immunotherapy until discussed with Acute Oncology Team.
Please contact 24-Hour on-call oncology/haematology team for advice.
Ensure that the patient has monitoring/follow up planned with their oncology/immuno-oncology team.