

1. Introduction and Who Guideline applies to

This SOP is based on Guidelines developed by the British Association of Dermatologists (BAD) and the British Dermatology Nursing Group (BDNG)

In addition we have adopted the British Association of Dermatologists' guidelines for the management of contact dermatitis 2017 which focuses on the clinical procedures performed and their interpretation

This SOP allows UHL to meet these standards

Cutaneous allergy services involve the diagnosis and management of allergic contact dermatitis (eczema) and contact urticaria including occupational skin disease. The investigation of patch testing may also be of value in the investigation of some systemic drug reactions and reactions to implantable medical devices (e.g. hip replacements).

Patch testing is a specialist procedure carried out by dermatology consultants in the investigation of allergic contact dermatitis (eczema). This test has a sensitivity and specificity of between 70% and 80%.

This is an out patient investigation carried out in the UHL Department of Dermatology

2. Guideline Standards and Procedures

Background

Contact eczema or dermatitis is the medical diagnosis given to inflammatory changes in the skin caused by contact with a certain product or products. Symptoms include redness, dryness, blistering, cracking and/or scaliness. The cause of contact eczema can be either irritant or allergic in nature. Irritant contact eczema is more common than

allergic contact eczema but the prognosis for allergic contact eczema is worse unless the cause can be found and future contact avoided. (Johnston et al 2016).

Contact eczema accounts for 4 – 7% of dermatology consultations. By adulthood it is thought that up to 27% of the population in Europe are allergic to at least one allergen within the European baseline series (Mortz et al 2001).

Skin disease is the second commonest physical occupational disease in Europe, after musculoskeletal problems. Contact dermatitis makes up the majority of occupational skin disease, between 70 and 90% (Adisesh et al 2002).

Irritant Contact Eczema is a non-immunologic process that results from contact with agents that abrade, irritate, or traumatise the skin. It is a dose and time dependent process. Environmental factors such as wetting, drying, perspiration, or temperature extremes can also cause irritant contact dermatitis. The reaction to the irritant can occur with first exposure. This reaction is variable and can occur immediately or months/years after exposure.

Allergic Contact Eczema is an immunological response to a specific substance that leads to eczematous changes on the skin. Examples of allergens include nickel, fragrances, rubber and preservatives found in some creams and cosmetics

Clinically, irritant and allergic contact eczema can appear very similar. However, their aetiology is very different. If the cause of contact eczema can be established, this may result in a cure of the condition or significant improvement.

Taking an extensive history from a patient with contact eczema is vital; understanding a patient's occupational and social background can pinpoint clues to a possible cause of contact eczema (Bourke et al 2009). To establish if a person has allergic contact eczema there is a formal diagnostic tool, patch testing. This test can often identify culprit(s) of allergic contact eczema.

Who should be investigated?

As clinical features alone are unreliable in distinguishing allergic contact from irritant and endogenous dermatitis, patch testing should be carried out in any patient

- When contact allergic eczema is suspected
- No improvement in eczema despite appropriate treatment and avoidance of irritants
- Cause of eczema unknown/continued relapse of eczema once treatment has stopped
Changes in eczema (previously responded to treatment and was well controlled)
- Eczema worsens with treatment
- Eczema affecting and/or limiting work/everyday life of patient
- When eczema affects these common sites – face or eyelids, hands, leg ulcers, anus/vulva
- Occupational changes/issues

(Chen et al 2016; Johnston et al 2016; Wilkinson et al 2012)

Referral process

Patients are referred by a general practitioner (GP) or accredited community practitioner to secondary care consultant led 18 week services for cutaneous allergy investigations. Patch and photo patch tests will be prescribed by a Consultant Dermatologist or another accredited practitioner working under the supervision of a Consultant Dermatologist. The Consultant Dermatologist has, at all times, the overall responsibility for the assessment and care of the patient.

Consultant-to-consultant referrals directly to specialised centres are necessary for patients who require complex patch and photo patch tests to improve the management of unresponsive and severe skin diseases, including occupational dermatitis

List management and scheduling:

Patient meeting the above criteria are booked into the patch test clinic coded GAJP1

The prescribing of the patient's allergens and all decisions regarding the type of additional tests which may be applied during the course of application must be made following a face-to-face consultation with an accredited Consultant Dermatologist or other appropriately trained Clinician working under the direct supervision of a Consultant Dermatologist in the clinic.

All patients require:

An assessment on Day 0 (Monday) and application of patch tests

A visit on Day 2 (Wednesday) to remove patches and apply additional allergens as required

A visit on Day 4 (Friday) to read the results, communicate these to the patient and commence or alter treatment accordingly.

Patient preparation:

The patient should be counselled that the skin will be covered during testing and on the need to avoid exercise, to keep the back dry and of possible adverse effects. Informed consent should be taken and documented.

All patients must be offered a Patient Information Leaflet (PIL) prior to commencing the diagnostic test that covers the specific battery range of tests they are due to have.

Patients must supply their informed consent, before any investigation/treatment can occur; in line with Trust policy.

Signed and dated confirmation of consent should be present in the patient notes.

Adverse events associated with patch testing are rare. Patients should be counselled that a positive result will produce skin reddening, itching and occasionally blistering (Spornraft-Ragaller 2011) at the application site but that this usually disappears after a few days.

They should be warned that some positive test reactions, e.g. to gold, may persist for up to a month, that a positive patch test may be accompanied by a flare of existing or previous eczema at distant sites, that an increase or decrease in pigment may be seen at the site of patch tests and of the small possibility of infection or scarring at the treatment site.

Active sensitisation is also rare.

While it was reported as “possible” in 2 of 7163 patients patch tested to parthenolide it was not reported in any of 5,371 patients tested to formaldehyde or textile dyes and there is no significant increase in paraphenylenediamine (PPD) positive patch test reactions in individuals who undergo repeat patch tests compared to subjects who only had single patch tests.

The skin to be tested should be free from dermatitis, and skin disease elsewhere as well controlled as possible. This will help avoid the ‘angry back syndrome’ with numerous false positives.

If a patient applies potent topical steroids to the back up to 2 days prior to the test being applied or is taking oral corticosteroids, there is a significant risk of false negative results and decreased reactivity.

The effect of systemic corticosteroid treatment on weaker reactions has not been assessed but expert consensus is that if the daily dose is no higher than 10 mg prednisolone, suppression of positive patch tests is unlikely.³⁴ While positive patch test reactions can be elicited in patients taking immunosuppressant drugs or who are tanned due to sun bathing or treatment with ultraviolet (UV) radiation, any associated tanning may also suppress patch test reactions. However, the amount required to do so and the relevant interval between exposure and patch testing are poorly quantified. Where immunosuppressive treatment cannot be stopped safely, patch testing can yield positive results which, while possibly sub-optimal, may be preferable to not testing at all. Antihistamines do not need to be avoided unless testing for urticaria or contact urticarial reactions.

Patch testing should be deferred for 6 weeks after natural and artificial UV exposure, 3 months after finishing systemic agents and 6 months after finishing biologic agents to minimize the chance of false-negative reactions.

There is no evidence that patch testing when breastfeeding is harmful. Whilst there is no evidence that patch testing in pregnancy is harmful, no safety data is available. So patch testing should be undertaken only when required and after informed consent.

Workforce – staffing requirements:

Minimum safe staffing standards for a procedure list:

One dermatologist to take a history and prescribe patch tests

The named lead senior dermatologist should have received at least six months training at a recognised contact dermatitis investigation unit, or have accrued similar, equivalent experience and demonstrable maintenance of that competence (for a primary service, this should be equivalent to consultant training; for a tertiary referral service, this should be equivalent to post CCT fellow training).

One suitable trained and competent nurse to make up and apply allergens

Students and doctors in training will be directly supervised in area by the staff to observe and, where appropriate, apply and read the test

Newcomers to the area will have an induction

For doctors this will include face to face training by the consultant and signing of WPBAs

For nurses this will include face to face training and passing of the relevant assessments

Nurses must have at least six months dermatology and 3 months (in clinic) patch testing experience in order to provide holistic care.

Nurses must have completed a formal in-house training programme, including an understanding of irritant and allergic contact dermatitis and skin assessment. Nurses must be assessed as knowledgeable in the anatomy and physiology of cutaneous allergy and be assessed as competent in the education of patients with regards to skin care and topical therapies.

All staff will maintain an up-to-date development portfolio and be supported in this regard via training updates.

Medical workforce levels will be the responsibility of the Dermatology Service Manager

The provisioned appropriately trained nurses will be the direct responsibility of the Outpatient Matron who will maintain and monitor nurse staffing levels and provide assurance that procedures can safely proceed

Procedural Verification of Site Marking:

Patch tests are applied to the back and occasionally the arms

Patch tests are marked numerically and this is recorded on the patch test proforma sheet in the medical notes

Sign In:

The patient's details will be checked at:

Sign in to the outpatients department against the clinic list By the doctors assessing the patient

By the nurses applying the patches

Performing the procedure:

Patch test materials should be stored at 4° C and protected from light. Some contact allergens with high vapour pressure, such as some fragrance chemicals, acrylates, and isocyanates, are unstable and require more frequent renewal and strict storage conditions. For some of the products (or patch test substances), storage at -18° C is recommended, for example some diisothio-cyanates. Glutaraldehyde in petrolatum and formaldehyde in aqueous solution are also subject to instability and deterioration. It is important to keep a log of and respect expiry dates.

The critical factor for sensitization and elicitation of contact allergy is the 'dose per unit area'. It is important for the dose of allergen to be standardized for each type of test chamber.

The use of disposable containers, syringes, stirrers and spatulas should be used for preparing the test substances. Solid materials in crystal or powder form can be ground with a pestle and mortar. Liquids are diluted by using pipettes and syringes, and the percentage is given by volume (vol/vol). For solids distributed in a vehicle, the percentage is given by weight (wt/wt). Thorough mixing is important for a homogeneous distribution of the allergen in the vehicle.

It is essential for patch test services to have a standalone refrigerator and freezer for the safe storage of allergens at the required temperatures. Where drugs and other chemicals are used, these must have a Control of Substances Hazardous to Health (COSHH) assessment, and be stored securely both in a lockable unit and room.

The preparation and dosing of allergen should be accurately prepared using the right equipment for the respective test. In cases where photo patch testing is undertaken, the equipment must be regularly calibrated to ensure an accurate dose of UVA is administered.

Generally, petrolatum-based patch test substances should be loaded into the test chambers shortly before application of the patches (no longer than a few hours), liquids and some volatile petrolatum-based substances (e.g. acrylates) at the time of application

EQUIPMENT REQUIRED FOR PATCH TESTING

- Secure and lockable refrigerator for the storing of allergens at the temperature recommended by the manufacturer
- Patch testing chambers (e.g. Finn Chambers®, IQ Ultra Chambers®, True Tests®, Epiquick)
- Suitable equipment to secure the patches while drawing up Sticks to hold Finn Chambers together
- Application plates
- Skin marker pen
- Transpore®/Scanpore® tape to label chambers
- Patch test batteries/series
- Emollient to fix filter discs to chambers (50:50 Soft White Paraffin/Liquid Paraffin) if using Finn chambers.
- Forceps and Scissors
- Filter discs
- Necessary documentation
- Non- sterile nitrile gloves
- A suitably large flat surface area to prepare patch tests
- Equipment required for applying patients' own products:
 - o Selection of syringes
 - o Sterile bowls
 - o Filter discs
- Resuscitation trolley nearby in case of an anaphylactic reaction

PROCEDURE FOR PATCH TESTING

The procedure for the preparation of manually drawn up patches is described below.

- Quiet Environment, free from interruptions and time to prepare patch test. How much time needed will vary according to the experience of the healthcare professional. Wilkinson et al (2012) make recommendations for staffing levels and time required to prepare and carry out a patch testing clinic.
- Wash hands, gloves are suggested as best practice to minimise contact with Haptens/Allergens and paper towels to clean syringes
- It is important to label batteries prior to applying to patient to ensure the correct Hapten/Allergen is identified when reading the patch test results at 48 and 96hrs
- The British Series currently has 41 Haptens/Allergens. This series is usually labelled 1 to 41

- Other series should include an identifying/corresponding initial to ensure they are not confused, for example a corticosteroid series labeled with C (C1, C2, C3 etc.) and a facial series labelled with a F (F1, F2, F3 etc.)
- Index any extra samples being tested and label patches
- The batteries should be removed from the fridge
- Each series should be drawn up independently. The backing of the type of patch test/chamber being used should be removed according to the manufacturer's instruction. The patches should be placed on a table and held in place when being drawn up, either by using application plates/devices or by placing, for example, sticks across the top only of each patch to hold them together. This is to avoid movement and mistakes occurring through inadvertently placing the wrong allergen in the wrong chamber.
- The patches should be laid out in reverse order, so the first Hapten/Allergen is applied in the far upper right chamber
- Proceed to fill the correct Hapten/Allergen into the corresponding chambers until all are filled APART from fragrance mixes and liquids, which will need to be added just before applying to the patient.
- Apply enough of the Hapten/Allergen. For 8mm Finn chamber: 20mg pet: 15 microlitre liquid for IQ Ultra/Van der Bend: 25mg pet: 20 microlitre liquid.
- The applied Hapten/Allergen should not touch the rim. Ideally when applied to the back and pressed, the Hapten/Allergen should spread out across the whole of the chamber without spilling over the sides to avoid overlapping of reactions at readings.
- Filter paper for liquids – Finn only. Liquids- A filter paper should be placed onto the chamber by using a small amount of emollient to hold the filter paper. Place one drop of the allergen liquid onto the filter paper just prior to applying to the patient's back to avoid evaporation of liquid. The amount should just be enough to moisten the filter paper. IQ Ultra chambers already have filter paper within the chambers.
- All patients must receive a patient information leaflet about their patch test prior to their appointment. This leaflet must inform them about the patch test procedure, potential side effects from the test and benefits of the patch test. It is important to establish that they have read and understood this information to enable them to provide informed consent.
- Prior to applying the patches, a history should be taken from the patient using a Contact Dermatitis Clinic Proforma to ensure there are no contraindications for patch testing. Informed consent should be gained and documented.
- When applying patches on the patient ideally the upper back should be used avoiding the midline and scapula (Bourke et al 2009; Lovell 2004). If several are being applied this should be done in two rows with 4- 5 patch test panels in each row.
- To apply the patches, remove from the application device according to manufacturer's instructions. The patches should be placed on the back in the correct order starting with the baseline series, from left to right across the upper back.
- Ask the patient to relax their shoulders. The first patch should be applied to the upper left hand corner of the back. The patch should be applied starting at the bottom and run your hand up the patch to expel any air and to aid adhesion. Each chamber should be pressed onto the skin to ensure it makes contact with the skin and that the allergen spreads out across the whole of the chamber. Repeat the process with the remaining chambers.
- REMEMBER that when applied to the back, the order of the hapten/allergen will be left to right reversed, that is, the upper left chamber will be no.1.
- If patch tests cannot be applied to the upper back for example if the back is irritated, tanned, multiple moles/lesions and/or tattoos, these must be avoided and other areas used instead (Lachapelle and Maibach 2003). Other areas include the upper arms, thighs and lower back (Bourke et al 2009; Johnston et al 2016). Hairy backs should ideally be

clipped or gently dry shaved in the direction of the hair growth prior to the patches being applied to allow patches to adhere to the back. Consideration should be given that the combination of removing the hair and the adhesive from the tapes can potentially cause irritation and confusion when reading patch tests.

- A skin marker pen can be used to mark around some of the whole patch test to identify at least two of the chambers with the corresponding number/series to allow for correct identification upon reading two of the chambers with the corresponding number/series to allow for correct identification upon reading.
- As well as or instead of a skin marker, tape can be applied at the top of each chamber with the corresponding numbers for identification to stay in place until the final reading.
- Patches can be reinforced with extra tape to the margins to ensure adhesion. This is particularly helpful in hot temperatures
- Label clearly/document location of patches within patient's notes.
- If testing the patient's own products, the general rule is that leave-on products that do not need to be washed off (e.g. make-up/moisturisers) can be applied undiluted. A non-leave-on product (e.g. shampoo/conditioners) must be diluted to a non-irritant concentration. De Groot's (2008) documents test concentrations and vehicles for many chemicals to assist clinicians when patch testing patients to their own products.
- Industrial products must be handled according to the recommended safety data (Control of Substances Hazardous to Health (COSHH) 2002). These will need to be diluted prior to a patient coming for their patch test. Some hospitals provide this service through pharmacy or the company themselves arrange this and the patient should bring labelled samples and COSHH information with them. Guidelines for testing workplace products.

Handover

In the event that the same nurse or doctor is not present for all visits in the patch testing week it is essential that handover occurs

This will in the form of a written or verbal briefing and the medical notes will be used as the gold standard for recording allergens applied and their positions in the test

Post-procedural aftercare:

The patient will be given written information regarding how to care for their patch test and information about their follow up appointment. Contact details will be provided for any queries or problems the patient may have.

They should be asked to keep the area being patch tested dry, avoiding showering and bathing as steam and heat are likely to moisten and loosen the patches. Washing will also remove skin markings applied to the back.

Advice should be given to avoid bending and stretching the back and any exertion that involves getting hot and sweaty, as this may make the patch tests more likely to come away. Wearing a tight top in bed can help hold patches in place.

Patients should be advised that should the patches come off, they should not reapply them in case they are applied incorrectly, leading to misinterpretation of results. If the patch begins to peel away/lift off it can be pushed back down, or taped down.

Advise the patient that they may experience some itching and irritation because of not washing as usual and from the adhesive

Discharge:

Allergic contact dermatitis may completely resolve following successful education of the patient on allergen avoidance, with workplace conditions being addressed as required, provided that exposure can be sufficiently reduced.

Sufficient time will be allowed to discuss the allergies in detail with the patient, explaining potential sources of exposure and to advise on how to avoid future skin contact with the allergen.

Ingredient label reading of any personal products intended for use on their skin will be carried out, so that the patient can identify whether the product is free of the allergen

All patients will be given a clear plan for managing their dermatitis following the results of their patch tests, with all findings documented in the GP letter and their hospital record.

Patients will also be sent a copy of the discharge letter for their records, with a list of the allergens they should avoid and look for in products which they use daily.

Governance and Audit:

Patch testing is inherently safe

A safety incident in this area would be application of allergens to the wrong patient and a severe and unexpected adverse reaction to an allergen All incidents will be reported on Datix

Review, investigation, dissemination, and learning from incidents after a Datix is submitted will occur at the departmental M&M meetings

This SOP will be audited annually and results be presented and acted upon at the departmental audit meetings

Standards and KPIs that will be monitored will be those from the BAD Cutaneous Allergy services Standards for Accreditation

3. Education and Training

Staff will be trained in this SOP by:

Introduction of the SOP at departmental business meeting
Availability of SOP on departmental clinical shared care drive
Presentation of SOP at regular team briefing

Integration of SOP into induction training
Nursing competency

A nurse is competent when he/she possesses the knowledge, skills and abilities required for lawful, safe and effective professional practice. Being competent does not just mean that you are able to undertake a task satisfactorily according to a protocol, it also means that you have the cognitive skills of decision making and the theoretical knowledge that backs up what you do and why you do it.

Nurses have a legal requirement for competency to safeguard the health and wellbeing of patients (Nursing and Midwifery Council 2015). Whilst direct observation assessment is important in some circumstances, assessing competency can take place in many forms e.g. peer review, self-assessment and reflection.

Nurses' involvement in patch testing varies nationally.

The individual nurse's level of autonomy should be discussed and agreed locally with management and medical colleagues. A named experienced Lead Consultant should oversee the delivery of the Cutaneous Allergy Service. If nurses are involved in reading and interpreting patch tests results, they should undertake training in contact allergy comparable to medical speciality training.

Competency can be divided into three levels:

Level 1 – this defines the entry point for registered nurses to the speciality of dermatology. Nurses new to dermatology may be limited to supporting senior colleagues and doctors throughout individual episodes of patient care

Level 2 – this defines the competent nurse and establishes the minimum level of knowledge and skills required for all nurses working in a contact allergy clinic. This nurse should have at least six months experience in dermatology and three months experience in patch testing. Formal in house training should be available and this nurse should be competent in skin assessment.

Level 3 – this defines the Specialist Nurse and reflects the extension of the nurse's role. Dermatology Specialist Nurses typically undertake a diverse range of roles. Nurses at this level are able to work according to local protocols but can also work autonomously to co-ordinate and deliver comprehensive care for patients.

This nurse should have at least two years experience in patch testing, have undertaken formal training in cutaneous allergy equivalent to medical colleagues and have the opportunity for clinical placements in a recognised contact dermatitis investigation unit.

Competency should be assessed by the Lead Consultant and continuous exposure to the service to ensure this skill set is sustained at a high level. This nurse should also be a registered Non Medical Prescriber or have undertaken a recognised Health Assessment course. Ongoing Continuous Professional Development (CPD) should be in line with Nursing and Midwifery Council revalidation.

Standard indicators set out the level of knowledge

Documentation:

A dedicated multidisciplinary medical record will be used to document both medical and nursing activity
Copies will be kept in the clinic room

Data will be stored on a national database

References to other standards, alerts and procedures:

The BAD Cutaneous Allergy services Standards for Accreditation apply to seven aspects of the patch testing service:

Standard 1: Referral and Patient Assessment

Standard 2: Patient Information and Consent

Standard 3: Staff Training and Education

Standard 4: Clinical Management and Monitoring

Standard 5: Equipment and Facilities

Standard 6: Clinical Governance and Audit

Standard 7: Discharge Protocol

These standards meet national guidance from the DoH, GMC, NHSE, CQC, NICE, RCP, BAD and the BDNG as detailed in the appendix below

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
BAD Cutaneous Allergy services Standards for Accreditation	Departmental audit	G Johnston	4/12	In place

5. Supporting References (maximum of 3)

British Association of Dermatologists' Guidelines for the Management of Contact Dermatitis 2017.

GA Johnston, LS Exton, MF Mohd Mustapa, JA Slack, IH Coulson, JSC English

Brit J Dermatology (2017) 176, pp317–329. 318

6. Key Words

List of words, phrases that may be used by staff searching for the Guidelines on PAGL.

Patch testing

Contact dermatitis

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Graham Johnston – Consultant Dermatologist	Executive Lead Graham Johnston – Consultant Dermatologist
Details of Changes made during review:	

