Worcestershire Acute Hospitals NHS Trust

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Paediatric Penicillin Allergy – Diagnosis and De-labelling by Non-allergy Specialists

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

This guideline is for use by the following staff groups: All paediatric consultants, paediatric trainees, nursing and allied health professional staff

Lead Clinician(s)

Dr Tom Dawson	Paediatric Consultant
Approved by Paediatric Governance Meeting on:	17th April 2024
Approved by Medicines Safety Committee on:	10th July 2024
Review Date:	17th April 2027

This is the most current document and should be used until a revised version is in place

Key amendments to this guideline

Date	*Amendment*	*Approved by:*
	New guideline	

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Introduction

This guideline is intended to be used by non-allergy specialists working in the hospital setting to clarify the penicillin tolerance of their paediatric patients. The target population is children and adolescents with a label of 'penicillin allergy' but in whom the clinical history suggests they are in fact low risk for a true allergy. The guideline helps clinicians to categorise a patient's risk of a true penicillin allergy and identify those suitable to undergo drug challenge without prior investigation, with the aim of removing inaccurate penicillin allergy labels.

This guideline does not extend to other beta-lactam antibiotic allergies.

Non-allergy specialists of any grade can perform direct penicillin provocation testing as long as they have attended a teaching session on the subject and are trained in advanced paediatric life support.

Background

A label of penicillin allergy is carried by 5.6% of the general population, with an estimated 2.7 million people in the UK affected.[1] The incidence in hospitalized patients appears to be higher.[2, 3] About 95% of penicillin allergy labels are incorrect when tested.[4, 5]

True allergic reactions to penicillin are less common in children than in adults. Children treated with beta lactam antibiotics, particularly those under 4 years of age, frequently develop maculopapular or urticarial skin rashes. These reactions are rarely reproduced with challenge testing.

Over the past 10 years, the clinical ramifications of a label of "penicillin allergy" have been clearly defined. A diagnosis of penicillin allergy increases the risk of MRSA, C.difficile or VRE infections and death; presumably through increased use of alternatives to beta-lactam antibiotics.[1, 2, 6] It increases the duration of hospital admissions and has significant implications for the cost of health care.[7, 8] The economic impact of penicillin allergy labels has also been elucidated in recent years, with several studies demonstrating the healthcare costs of the label and the economic benefits of removing incorrect labels.[9-11]

Despite this clear association with harm, penicillin allergy testing is a scarce resource in the NHS.[12] Testing is currently largely performed by allergists and immunologists working in specialist clinics and is consequently limited to select patient groups (NICE CG 183).[13] This model cannot meet either current or future demand and leaves the vast majority of labelled

patients unable to access testing. The provision of de-labelling at-scale is therefore only possible with the engagement of clinicians who are not trained in allergy or immunology, referred to throughout this document as “non-allergists.” This guideline has been adapted from the British Society for Allergy and Clinical Immunology’s (BSACI) article, “Set-up of penicillin allergy de-labelling services by non-allergists working in a hospital setting.”[14]

All patients with a label of penicillin allergy should ideally have the diagnosis confirmed by testing but priority should be given to patients likely to require frequent or prophylactic antibiotics e.g. patients with primary or acquired immunodeficiency, asplenia, cystic fibrosis, or those with another antibiotic allergy.

Drug provocation testing

A drug provocation test (DPT) is considered the gold standard test to confirm or refute the diagnosis of allergy in individuals at low risk of an IgE-mediated type 1 immediate hypersensitivity reaction. Current UK and international guidelines for penicillin allergy testing recommend the use of skin testing prior to DPT as a means of assessing the likelihood of a positive provocation. However, in recent years, several studies have demonstrated that it is possible to identify patients who are at low risk of penicillin allergy with an allergy history alone.[15-19] It appears to be safe and efficacious to offer a direct DPT without prior skin testing in such patients. The term “direct drug provocation test” or direct DPT, in this guideline refers to the administration of single or multiple doses of the drug without prior skin testing. In some patients, the allergy history may indicate that there is no increased risk of allergy compared with that of the baseline population risk. In this group, no allergy testing is required before removing the allergy label.

In many of these studies, delabelling has been performed by non-allergists including allied medical healthcare workers such as pharmacists, nurses and associate physicians, working under immediate or remote medical supervision. There is currently no defined pathway or governance framework in the UK to support this practice. The definition of “low-risk” varies, but the proportion of patients deemed suitable for a direct DPT may be as high as 65%.[3] This novel approach offers the potential for testing at-scale within the NHS as it allows a significant proportion of patients to be delabelled in settings outside a specialist paediatric allergy clinic. It is also less costly and may be more acceptable to the patient since it is less invasive.

Penicillin allergy history

All paediatric patients attending secondary care should have any allergies documented, especially any history of drug allergy.

If a penicillin allergy is disclosed/reported, a focused history of the reaction should be documented including:

- Which penicillin antibiotic caused the reaction and route of administration e.g. oral/IV
- How long ago did the reaction occur?
- Symptom(s) of the reaction?
- Timing of the reaction i.e. time between administration of the antibiotic and symptom onset?
- Did the reaction occur after the first or subsequent doses?
- Was medical intervention sought? Was treatment required?
- Any concurrent medications given alongside penicillin?
- Has penicillin (oral or IV) been tolerated prior to the reported reaction, and which?
- Has any penicillin-based antibiotic been ingested (oral or IV) after the reported reaction, and which?
- Was penicillin allergy confirmed by any form of testing?

Confirming a penicillin allergy diagnosis

All paediatric patients labelled as “penicillin allergic” attending secondary care settings should be considered for penicillin allergy testing to confirm the diagnosis. It is important to risk stratify these patients in order to identify the most appropriate pathway for investigation.

For example, patients who report a family history of penicillin allergy only, or those with symptoms entirely in keeping with side effects of the antibiotic, can be delabelled of their penicillin allergy without any formal testing. Those patients reporting low risk symptoms for true allergy might be considered suitable for direct provocation testing by a non-allergist, whereas those with symptoms consistent with either type 1 (IgE mediated) immediate hypersensitivity reactions or type 4 (typically T Cell medicated) delayed reactions are considered not suitable for direct DPT by non-allergists and require referral to the paediatric allergy service for further evaluation.

Based upon the clinical history, patients should be categorised as either

1. No evidence of penicillin allergy
2. Low risk of penicillin allergy and suitable for direct DPT by non-allergist

3. Not suitable for direct DPT by non-allergist

1. No evidence of penicillin allergy

Patients who **do not** require allergy testing in the form of skin prick tests or DPT include:

- Patients reporting side effects including candidiasis (thrush), minor gastro intestinal upset (nausea, mild abdominal pain, diarrhoea)
- Minor symptoms unrelated to any form of allergic reaction, e.g. headache, arthralgia, strange taste in mouth
- Family history of penicillin allergy but without personal history of allergic reaction, even in the absence of exposure
- Patient has taken and tolerated the same penicillin subsequent to the index reaction

These patients can be delabelled of their 'penicillin allergy' on history alone, without further testing and prescribed penicillin-based antibiotics when required in the future. The GP should be informed and any electronic patient record alerts updated.
N.B. Some patients may continue to avoid penicillin if they do not have reassurance of a negative allergy test. In these circumstances, a direct DPT could be considered, as long as there are no exclusion criteria (listed in Table 2).

2. Low risk of true penicillin allergy and suitable for direct DPT by non-allergist

Patients are considered 'low risk for penicillin allergy' if they fall into any of the categories listed in Table 1 and would be suitable for a direct DPT in hospital by a non-allergy specialist, providing none of the exclusion criteria are met (see Table 2 below).

If any of the exclusion criteria are met, advise the patient to continue avoiding penicillin-based antibiotics and refer to the paediatric allergy service for advice or further investigation.

Table 1: Patients considered 'Low risk for a penicillin allergy' and suitable for a DPT by a non- allergist outside of an allergy clinic setting.

Patients considered 'Low risk' for a penicillin allergy/suitable for direct DPT
Patients reporting a benign* rash which developed more than 1 hour after the first dose of penicillin was given
Historic childhood rash with no other history available (where information has been sought from parents, carers, relatives and healthcare records where possible)
Patient cannot remember what happened during index reaction but was told it was not serious and did not require hospital treatment

*N.B. *Benign defined as non-blistering, non-purpuric, short lived (less than 24 hours), without mucosal involvement and not requiring any hospital treatment.*

Some patients may report a delayed urticarial rash occurring more than 1 hour after administration of the first dose of penicillin. This symptom, if in isolation, is unlikely to be caused by an IgE mediated reaction to the penicillin, but instead a viral urticaria. In this instance, it is acceptable for non-allergists to continue with a direct provocation test as long as no exclusion criteria apply. If there is any doubt, discuss the case with the paediatric allergy team before proceeding.

3. Children and young people not suitable for direct DPT by non-allergist

Patients reporting symptoms consistent with an immediate type 1 (IgE mediated) hypersensitivity reaction should not undergo direct DPT. This includes urticaria, angioedema, shortness of breath, wheeze, loss of consciousness or collapse usually occurring within 1 hour of administration of a penicillin-based antibiotic. These patients should instead be referred to the paediatric allergy service for further evaluation. They should be advised to continue avoiding penicillin-based antibiotics in the interim.

Table 2: Exclusion criteria for direct DPT by non-allergist outside of an allergy clinic setting

Exclusion criteria for direct DPT by non- allergist
Reported allergic reaction to penicillin occurred less than 6 months ago
Rash occurring within 1 hour of the first dose of penicillin
Non-immediate rash associated with blisters, skin peeling, mucosal inflammation (eyes, mouth, genitals) or purpura with or without systemic involvement (e.g. SJS/TEN, DRESS, AGEP)
Patients reporting any symptoms suggestive of a type 1 immediate hypersensitivity reaction to penicillin, including swelling, urticaria, angioedema, shortness of breath, wheeze, loss of consciousness, collapse, anaphylaxis
Patients who required hospital treatment due to their reaction
Patients who required treatment with adrenaline for their reaction
Patients who cannot remember what happened during the index reaction but were told it was serious and/or required medical intervention
Patients who, at the time they are being considered for DPT, are acutely unwell or clinically unstable. This includes patients with respiratory and/or cardiac compromise. These patients should be brought back for delabelling at a later date when they are well.
Severe or uncontrolled asthma (For example: symptoms in the daytime, symptoms on most or every night, ACT<20, >30% PEF diurnal variability, high dose ICS plus a controller medication or systemic steroids)
Severe aortic stenosis
Pregnancy
Unable to obtain informed consent e.g. Person with parental responsibility is unavailable or unwilling to give consent, child not Gillick/Fraser competent
Multiple drug allergies

Patients reporting symptoms consistent with a severe, non-immediate reaction to penicillins are also not suitable for direct DPT. This includes Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). Re-exposure to penicillin is contraindicated in these patients. Refer for further assessment to the allergy team.

Principles for the conduct of a direct DPT by a non-allergist in hospital

Where a patient reports a reaction to penicillin in which only symptoms from Table 1 occurred, and none of the exclusion criteria from Table 2, a direct DPT can be performed by a non-allergist in an appropriate hospital setting (Ward, Day case, Children's Clinic A&E).

All personnel administering a DPT should have up-to-date training in advanced paediatric life support and management of anaphylaxis, and immediate access to on-site resuscitation facilities.

Written informed consent should be obtained from Parents/Guardian and the patient, if appropriate. See appendix A for patient information.

Baseline observations including blood pressure, heart rate, temperature, respiratory rate and oxygen saturations should be checked prior to commencing the DPT. Peak flow should also be done if the patient is asthmatic and compared to the estimated for height.

The patient should be examined by a doctor or trained nurse prior to commencing the DPT to ensure they are well and there are no reasons to postpone the test.

Ensure the patient has not taken an antihistamine or an oral steroid within the past five days as this could mask symptoms of an allergic reaction.

Correct doses of IM adrenaline, PO cetirizine and Nebulised Salbutamol according to the BNFc should be prescribed on a drug chart and the medications easily accessible prior to commencement of the DPT.

If the index penicillin is not known, amoxicillin should be used. Amoxicillin is widely used in routine NHS practice for DPT and has a more favourable side effect profile compared with

other penicillins such as co-amoxiclav. One single full dose (as per BNFc) should be administered orally.

A pre and post DPT checklist for clinicians and nurses is available in Appendix E.

The patient should be observed for one hour after the dose of penicillin and vital signs repeated at the end of the test, or more frequently if clinical concern.

If symptoms or signs consistent with anaphylaxis develop during the test, treat the patient in accordance with the Resuscitation Council Guidelines for management of anaphylaxis.

If symptoms consistent with a mild to moderate allergic reaction develop give a dose of Cetirizine and monitor closely until symptoms have resolved. This includes rash, urticaria, pruritis, swelling, angioedema, rhinitis and eye symptoms with no evidence or airway, breathing or conscious level deterioration.

Parents/carers and patients should be counselled on the signs and symptoms of an allergic reaction. The patient should be provided with clear written instructions about what to do if symptoms develop after leaving the hospital. (See leaflet in appendix B and C).

The GP and other relevant healthcare professionals should be informed of the result of the DPT. (See appendix D for draft GP letters). Electronic patient alerts must also be updated.

All allergic reactions occurring during direct DPT should be reported to the paediatric allergy service for monitoring and audit purposes.

Use of prolonged DPT

A prolonged DPT should be considered when the index reaction occurred after the second or subsequent dose of a course of penicillin (or where the timing of the reaction is unknown). A prolonged DPT of 3 days is sufficient in the majority of patient. If the index reaction is clearly remembered to have occurred after more than 3 days, advice should be sought from the local allergy service as to how long to extend the DPT.

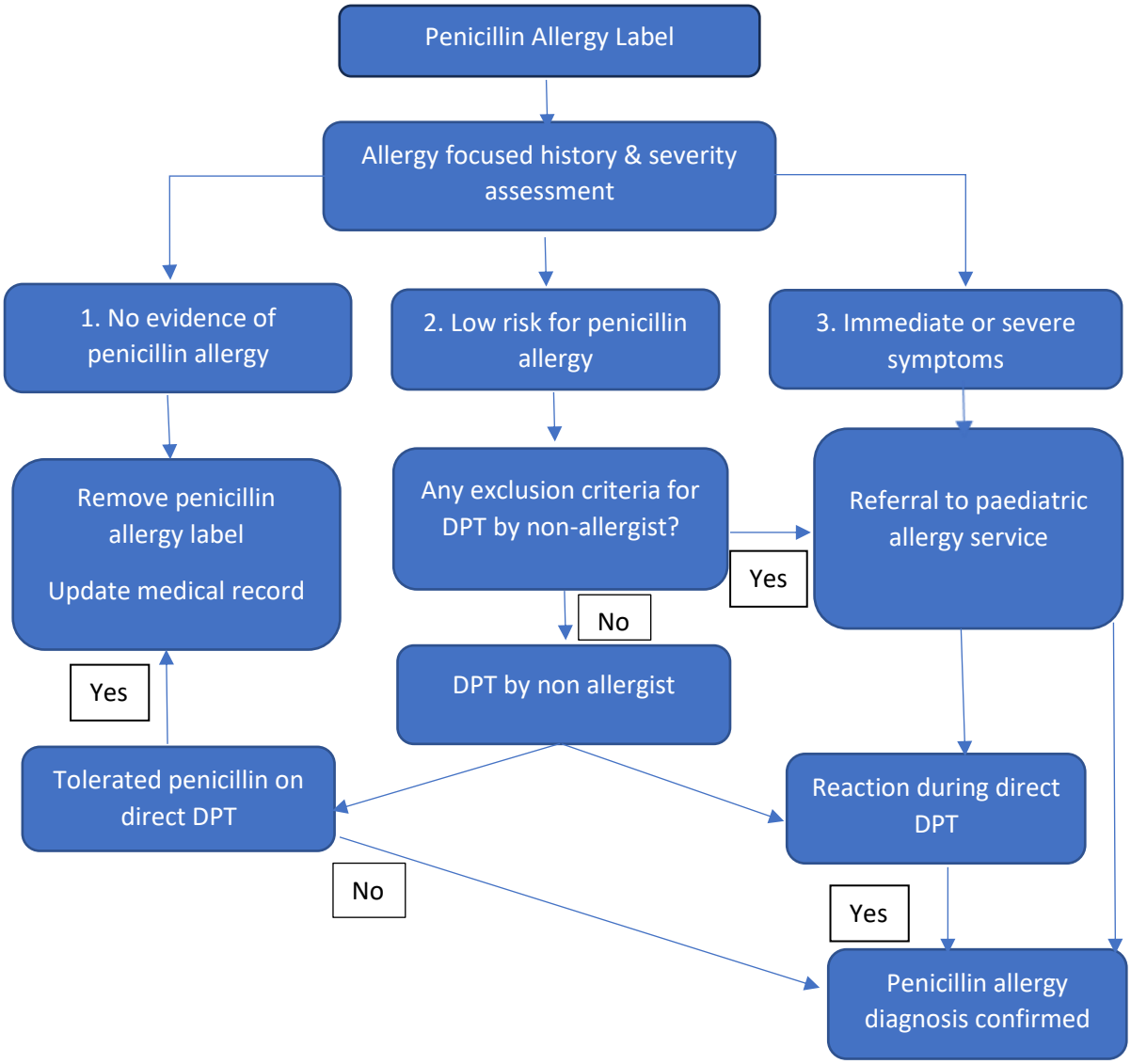
If a prolonged DPT is required, the first dose should be given in hospital as above. The remaining doses should be provided to the patient and an oral antihistamine should be available at home.

Parents/carers and patients should be counselled on the signs and symptoms of an allergic reaction and a written information leaflet should be provided on what to do if a reaction develops at home. The consultant overseeing the challenge should advise the family on the dose of antihistamine (cetirizine) to give. (See appendix B). It is recommended that children are given open access to Riverbank ward for the duration of their remaining doses to be given at home.

The patient must be contacted at the end of the antibiotic course to check that there have been no symptoms of an allergic reaction. This could be done by the professional conducting the DPT or by the supervising consultant's secretary.

The patient should then receive clear written information about the test result and its implications and the GP and other relevant healthcare professionals should be informed of the result of the DPT. Electronic patient alerts must also be updated. (See appendix D for draft GP letter).

Flow chart of delabelling pathway



Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the Policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.

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Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Hannah Clark – Paediatric registrar with SPIN in allergy
Phoebe Moulsdale – allergy specialist nurse for children and young people
Jo Colley – specialist respiratory physio in paediatrics
Paediatric Consultants at Worcester Acute Hospital

This key document has been circulated to the chair(s) of the following committees / groups for comments;

Committee
Medicines Safety Committee

APPENDICES

A Information leaflet – “Before your penicillin challenge”

B Information leaflet – “After your penicillin antibiotic challenge – negative challenge”

C Information leaflet – “After your penicillin antibiotic challenge – positive challenge”

D Draft GP letters (positive and negative challenge and prolonged course)

E Pre- and Post DPT Checklist for clinicians

Appendix A – Patient information

Name of procedure: Penicillin Drug Provocation Test (DPT)

It has been recommended that you/your child has a Penicillin Drug Provocation Test. This is also known as a '*drug challenge'*, '*antibiotic challenge'* or '*Penicillin challenge'*. These terms are used interchangeably and are used to describe the test we do to see if you/your child is allergic to penicillin.

This leaflet explains some of the benefits, risks and alternatives to the penicillin challenge. We want you and your child to have an informed choice so you can make the right decision. Please ask your medical team about anything you do not fully understand or want to be explained in more detail.

We recommend that you read this leaflet carefully. You and your doctor (or other appropriate health professional) will also need to record that you agree for you/your child to have the procedure by signing a consent form, which your health professional will give you.

What is Penicillin?

Penicillins are a group of antibiotics who all have a common feature. They are some of the most commonly used antibiotics in children and adults. There are many types of penicillin-based antibiotics. Some common penicillin-based antibiotics are:

- Amoxicillin
- Co Amoxiclav (sometimes known as Augmentin®)
- Flucloxacillin
- Penicillin V (Phenoxymethylpenicillin V)

This leaflet only covers a penicillin challenge and does not include other groups of antibiotics or medicines.

What are the benefits of the procedure?

A penicillin challenge test is used when we suspect that there is not an allergy to this medicine. It is beneficial to understand what medication you/your child is allergic to so that they can receive the most appropriate antibiotic if they become ill in the future. We know that children and young people who have penicillin allergy have worse health outcomes, spend longer in hospital when admitted and can be challenging to treat, requiring medications which may be more unpleasant to tolerate.

What are the risks involved?

There is a small risk of an allergic reaction. Allergic reactions can range from mild to severe. A severe reaction is called anaphylaxis. We do not challenge patients who we think might have an anaphylactic reaction. An anaphylactic reaction is a serious, life-threatening allergic reaction which develops rapidly after ingestion or administration of a drug. The symptoms of a severe allergic reaction involve problems with the airway, breathing or conscious level. Anaphylaxis has been reported in a small number of cases but it is rare.

Mild allergic reactions, which are the most common, include urticaria ('hives'), angioedema (deeper tissue swelling of the lips and eyes), itching, nasal congestion and sneezing, swollen or watery eyes and feeling sick.

Children and young people with eczema may develop a flare of their skin a few days afterwards but most children with eczema don't experience this.

Some children and young people may experience some side effects from the antibiotic, which is not an allergy. Common side effects of antibiotics include nausea, abdominal discomfort and loose stools. The side effects are also listed in the patient information leaflet provided with the antibiotic.

You/your child will be cared for by a skilled team of doctors, nurses and other healthcare professionals. If an allergic reaction occurs, we will be able to assess the symptoms and treat them appropriately. Mild or moderate reactions are treated with oral antihistamines. More serious reactions affecting breathing or consciousness, will be treated initially with an adrenaline injection in the leg and other treatments as appropriate.

Which other procedures are available?

There are no other procedures available to accurately diagnose a penicillin allergy.

We make an assessment before the challenge based on clinical information and the history of the previous reactions to make sure you/your child is suitable for this test.

This test is to prove the absence of a penicillin allergy in a controlled setting.

An outline of what to expect on the day of the challenge:

Before the challenge starts

We will check your/your child's details and fasten a wristband containing the hospital information to the wrist.

We will usually ask you to continue with your/your child's normal medication so please bring it with you. We will ensure you have not used any antihistamines in the 72 hours prior to a challenge as this may result in a falsely negative result. Examples of antihistamines are:

- Chlorphenamine (Piriton®)
- Cetirizine (Piriteze®, Zirtec®)
- Loratidine (Clarityn®)
- Fexofenadine (Telfast®)

We will ask you some questions about your/your child's health to make sure that they are well enough for the challenge. We will also do some observations and listen to your/your child's chest with a stethoscope. We will ask you to sign the consent form. The medical team looking after you/your child will check the emergency equipment and medication are appropriately prepared.

Preparation

Unless your child is too young to understand you should tell them:

- why they are in hospital
- that they will be given some medicine
- that we will need to look at their skin and check their physical health by using some machines
- encourage your child to talk about the procedure and ask questions.

We have nurses who can explain things to your child and encourage them to talk through play and appropriate communication if required.

Unless you/your child has a serious allergic reaction, it is not expected they will need to stay the night in hospital.

During the procedure

You/your child will be awake all the time. We will give you/your child the penicillin based antibiotic in one dose, in the mouth which should be swallowed. We will record your/your child's observations like blood pressure and pulse for the next one hour. We will also ask you/your child how you/they feel and if there is any itching, tingling or rash. If your child is very young, we will ask the accompanying adult.

If there are any signs of an allergic reaction, we will treat them.

After the procedure

We will ask you/your child to stay on the ward or day care unit for one hour after the drug has been ingested. You/they may have to stay longer if you/they have a reaction and require some treatment such as an antihistamine. The nurses will continue to check your/your child's observations if necessary. You/your child will be allowed home if there are no signs of an allergic reaction or any reaction has stabilised. Reactions usually occur within the first hour after administration, however occasionally, symptoms can develop up to 24 hours after the challenge. This is very rare but we will explain to you what to do if this happens.

Length of stay

How long you/your child will be in hospital varies from patient to patient and depends on how quickly we complete the procedure. Most children having this type of procedure will be in hospital for a couple of hours in total.

Medication when you leave hospital

In some cases, an additional course of treatment may need to be completed at home. If extra medication is required, we will arrange a prescription and explain how to give this.

What happens next?

No follow-up is arranged after a challenge where no reaction has occurred. We will write to your GP and ask them to remove the allergy label from you or your child's notes. We will also update our own records.

If you/your child needs to complete a course at home, we will ask you to contact your hospital doctor's secretary on finishing the recommended course to confirm it has been completed successfully. Contact details will be given to you and may vary between the team looking after you. Your GP will then be informed in writing and your/your child's medical record updated.

Appendix B – After your penicillin antibiotic challenge – negative challenge

Today (…… / …… / ……), you/your child has had an antibiotic challenge to …… … and received a total dose of ……..……

You/your child has not shown any symptoms of an allergic reaction. Most allergic reactions occur immediately or within one - two hours after consuming it**. This is called a negative challenge.**

We will write to your/your child's GP, to say that ……**is not allergic to the penicillin group of antibiotics,** and penicillins can be prescribed if needed, in the future. We will also amend any hospital records.

'Late Phase' Reactions

Very occasionally, 'late phase' reactions can occur. If in the unlikely event you/your child develops mild/moderate late phase reactions including hives, itchy skin, runny nose, swollen itchy eyes, vomiting or diarrhoea, then administer a dose of antihistamine, such as chlorphenamine or cetirizine. Late phase reactions are rarely serious but are important to document in your child`s medical record. You will need to contact us if this happens so we can amend records.

If the late phase reaction requires urgent medical attention. Dial 999 asking for an ambulance and say 'Anaphylaxis'.

Symptoms would include:

- Difficulty in breathing – wheezing, constant coughing, noisy breathing, laboured breathing, swollen tongue
- Change in consciousness level – fainting, floppy, unconscious

If you or your child has these symptoms and you have an Adrenaline Auto Injector, then please administer it and call 999.

Return to school/college/work:

You/your child should have a restful afternoon on the day of the drug challenge. If you/they are well then they can return to school/college/work the next day.

Extended course of antibiotics to be given at home

Occasionally, you/your child may be required to complete a longer course of the penicillin antibiotic at home. This is usually for a further three days. If this applies to ……. this will have been discussed with you before the challenge.

If ……. develops any signs of an allergic reaction during the prolonged course, stop giving the prescribed antibiotic and treat as above under 'Late Phase' Reactions.

After the antibiotic course at home has been completed:

Please contact your medical team (details provided below), to let them know the outcome of the course at home. We want to know if they have reacted AND if there have been no reactions.

Only after the antibiotic course has been completed will we write to your GP with the outcome.

Contact information for your medical team:
Name of paediatric consultant:
Contact number:
Children's clinic: 01905 733477

Appendix C - After your penicillin antibiotic challenge – positive challenge

Today (…… / …… / ……), you/your child has had an antibiotic challenge to …… … and received a total dose of ……..……

You/your child has had an allergic reaction. **This is called a positive challenge and they have a confirmed penicillin allergy.**

We will write to you/your child's GP, to say that **……is allergic to the penicillin group of antibiotics, and this should not be prescribed**. We will also amend any hospital records.

We have observed you/your child and feel that they have recovered from their reaction and are able to go home. Very occasionally, 'late phase' reactions can occur. If, in the unlikely event that you/your child develops further mild/moderate allergic reactions including hives, itchy skin, runny nose, swollen itchy eyes, vomiting or diarrhoea, then administer a dose of antihistamine, such as chlorphenamine or cetirizine.

Late phase reactions are rarely serious but are important to document in medical record. You will need to contact us if this happens.

If the late phase reaction requires urgent medical attention. Dial 999 asking for an ambulance and say 'anaphylaxis'.

Symptoms would include:

- Difficulty in breathing – wheezing, constant coughing, noisy breathing, laboured breathing, swollen tongue
- Change in consciousness level – fainting, floppy, unconscious

If you or your child has these symptoms and you have an Adrenaline Auto Injector, then please administer it and call 999.

Return to school/college/work:

You/your child should have a restful afternoon on the day of the drug challenge. If you/they are well and symptoms have fully resolved, then they can return to school/college/work the next day.

Follow up:
We will write to your GP to let them know. You or your child will not need any follow up for this unless there are other ongoing concerns.

Contact information for your medical team:
Name of paediatric consultant:
Contact number:
Children's clinic: 01905 733477

Appendix D - Draft GP letters (positive and negative challenge and prolonged course)

Re: Patient name:

DOB:

Hospital Number:

NHS number:

Address:

Diagnosis: Penicillin Allergy

Dear GP

…(Patient name).. underwent a penicillin provocation test at Worcester Royal Hospital on *…(insert date)...* They received a single dose of …(*Insert name of penicillin and dose received)…* and were observed for one hour post dose.

……(name)….experienced ……..and *(treatment)* ….was given with good effect.

They should avoid all penicillin based antibiotics.

Please update their medical record to reflect this.

Yours Sincerely

(Insert clinician name and responsible Consultant)

Cc parents

Re: Patient name:

DOB:

Hospital Number:

NHS number:

Address:

Diagnosis: No evidence of Penicillin Allergy

Dear GP

…(Patient name)... underwent a penicillin provocation test at Worcester Royal Hospital on *…(insert date)...* They received a single dose of *…(insert name of Penicillin and dose received)…* and were observed in hospital for one hour post dose. The dose was tolerated and there was no evidence of any allergic reaction. *…*

[(Patient name).. has subsequently completed a *(insert number of days)* day course of …(insert name of Penicillin)… and no symptoms of allergic reaction were experienced.] *Delete as applicable*

…(Patient name)... DOES NOT have penicillin allergy. Please update their medical record to reflect this.

Yours Sincerely

(Insert clinician name and responsible Consultant)

Appendix E – Checklist

Patient name:
DOB:
Hospital Number:
NHS number:

Consultant:
Date referred:
Date of Challenge:
Outcome: Positive/negative/prolonged course

Pre challenge checklist for clinicians:

1) Inclusion and exclusion criteria met (see overleaf) ☐
2) Information sheet given with discussion ☐
3) Written consent gained ☐
4) Confirm bed with Children's Clinic/inform nurse in charge ☐
5) Drug chart complete with prescribed: ☐
   a) Penicillin/amoxicillin/other
   b) Emergency medication: Adrenaline 1:1000, Cetirizine, Salbutamol

Checklist pre procedure:

6) Child/young person is well and observations documented ☐
7) Child/young person has not had antihistamine for 72 hours ☐
8) Emergency medication available ☐

Checklist at discharge:

9) Contact details for consultant secretary/admin team completed on discharge information ☐
10) Written discharge information given to patient/family ☐
11) Open access requested (if required) ☐ Or N/A ☐
12) Allergy Alert status updated on medical records ☐
13) Inform consultant of outcome of challenge ☐

It is essential that a GP letter, confirming outcome of penicillin challenge is sent to the patient's GP

Patients considered 'Low risk' for a penicillin allergy/suitable for direct DPT
Patients reporting a benign* rash which developed more than 1 hour after the first dose of penicillin was given
Historic childhood rash with no other history available (where information has been sought from parents, carers, relatives and healthcare records where possible)
Patient cannot remember what happened during index reaction but was told it was not serious and did not require hospital treatment

Exclusion criteria for direct DPT by non- allergist
Reported allergic reaction to penicillin occurred less than 6 months ago
Rash occurring within 1 hour of the first dose of penicillin
Non-immediate rash associated with blisters, skin peeling, mucosal inflammation (eyes, mouth, genitals) or purpura with or without systemic involvement (e.g. SJS/TEN, DRESS, AGEP)
Patients reporting any symptoms suggestive of a type 1 immediate hypersensitivity reaction to penicillin, including swelling, urticaria, angioedema, shortness of breath, wheeze, loss of consciousness, collapse, anaphylaxis
Patients who required hospital treatment due to their reaction
Patients who required treatment with adrenaline for their reaction
Patients who cannot remember what happened during the index reaction but were told it was serious and/or required medical intervention
Patients who, at the time they are being considered for DPT, are acutely unwell or clinically unstable. This includes patients with respiratory and/or cardiac compromise. These patients should be brought back for delabelling at a later date when they are well.
Severe or uncontrolled asthma (For example: symptoms in the daytime, symptoms on most or every night, ACT<20, >30% PEF diurnal variability, high dose ICS plus a controller medication or systemic steroids)
Severe aortic stenosis
Pregnancy
Unable to obtain informed consent e.g. Person with parental responsibility is unavailable or unwilling to give consent, child not Gillick/Fraser competent
Multiple drug allergies

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form

Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	**Dr Tom Dawson**

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Phoebe Moulsdale	**Allergy CNS for children and young people**	**Phoebe.moulsdale1@nhs.net**
Date assessment completed	**07/02/2024**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title: Paediatric Penicillin Allergy – Diagnosis and Delabelling by Non-allergy Specialists Guideline**			
What is the aim, purpose and/or intended outcomes of this Activity?	To confirm or remove a pencillin allergy label which may be inaccurate and prevent appropriate treatment.			
Who will be affected by the development & implementation of this activity?	❑ x ❑ ❑	Service User Patient Carers Visitors	x ❑ ❑ ❑	Staff Communities Other _____
Is this:	❑ Review of an existing activity x New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	See extensive reference list in main body. Guideline has been developed using experience of antibiotic challenges, peer reviewed publications and BSACI guidelines.			
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	This has been circulated amongst team members for review.			
Summary of relevant findings	No concerns raised			

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		x		
Disability		x		
Gender Reassignment		x		
Marriage & Civil Partnerships		x		
Pregnancy & Maternity			x	A penicillin challenge is contraindicated in pregnant women
Race including Traveling Communities		x		
Religion & Belief		x		
Sex		x		
Sexual Orientation		x		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		x		Consent before the challenge must be gained from legal guardian or parent
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		x		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	Challenge cannot be undertaken in pregnant women	**This will be discussed with young people (women) at consent**	**Consultant overseeing challenge**	**ongoing**
How will you monitor these actions?	**Audit of antibiotic challenge paperwork**			
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	**With guideline review**			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Phoebe Moulsdale and Dr Tom Dawson
Date signed	07/02/2024
Comments:	
Signature of person the Leader Person for this activity	
Date signed	07/02/2024
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	
2.	Does the implementation of this document require additional revenue	
3.	Does the implementation of this document require additional manpower	
4.	Does the implementation of this document release any manpower costs through a change in practice	
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.