PENICILLIN ALLERGY AND DE-LABELLING GUIDANCE

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DOCUMENT CONTROL			
GUIDELINE No:	A&D.2025		
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Reviewers:	1. Full guidance written by Evelyn Yoong, Antimicrobial Pharmacist with input from Dr Sharon Irvine, ID consultant & OPAT lead, and Dr Jezmit Singh, IMT1 2. De-labelling poster and worksheet written by Dr Jezmit Singh, IMT1, with input from Dr Sharon Irvine, and Evelyn Yoong 3. Reviewed by Antimicrobial Management Team (AMT) members, Pharmacists D&G and a selection of medical consultants 4. No service/medicine costs inherent in guidance, so no review required by other services 5. Formatting following feedback and submitted back to stakeholders 6. Submitted document to ADTC for final approval		
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Impact Assessed:	No negative impact on individuals with protected characteristics is anticipated- See section 4.2	**Next review Date:**	27/08/2027

CONTENTS

1.0 PURPOSE AND SCOPE

This guidance is intended to assist healthcare professionals across NHS Dumfries & Galloway in the safe and effective documentation, assessment, and, where appropriate, removal ("de-labelling") of penicillin allergy labels. The goal is to enhance patient care by supporting the accurate identification of true penicillin allergies, thereby improving access to optimal treatment options and promoting responsible antimicrobial use.

This document covers the assessment of historical penicillin allergy reports, indications for specialist referral, and standard processes for penicillin allergy de-labelling, including documentation standards. It is relevant to clinicians working in hospital, primary, and community care settings.

This guidance does not replace individual clinical judgement. Prescribers should continue to determine the most clinically appropriate course of action for each patient, considering individual circumstances, comorbidities, and patient preferences. Where there are justifiable reasons not to follow the recommendations—following discussion with the patient or carer—these reasons should be clearly documented and communicated to all relevant members of the care team.

This guidance should be used alongside local and national antimicrobial stewardship policies and does not override the need for referral to an allergy specialist in cases of uncertain or severe reactions.

2.0 TAKEWAY POINTS ON PENICILLIN ALLERGIES

- **Penicillin allergies are over-reported**
  Although approximately 10% of the UK population reports a penicillin allergy, the actual risk of anaphylaxis from penicillin is about 0.002% of treated patients. However, it is crucial to note that anaphylaxis, although rare, can be life-threatening.

- **An accurate medical history is important**
  Taking a detailed and reliable medical history is critical. It is essential to clarify and document the nature of any past allergic reactions to distinguish between a true allergy to penicillin and other reactions such as intolerance or side effects. Up to 90% of those who report a penicillin allergy may have non-allergic reactions, such as an itch or gastrointestinal upset.

- **There are dramatic implications to incorrectly labelling patients as penicillin allergic**
  Incorrectly labelling patients as penicillin-allergic can lead to unnecessary use of less appropriate and more broad-spectrum antibiotics. This can drive treatment costs and foster antibiotic resistance, potentially increasing the risk of adverse outcomes, including Clostridium difficile infections and other resistant infections.

- **The management of confirmed penicillin allergies**
  In cases of confirmed Type 1 (immediate) and Type 4 (delayed) hypersensitivity reactions (such as drug reaction with eosinophilia and systemic symptoms [DRESS] or Stevens-Johnson Syndrome [SJS]), the avoidance of all penicillin, cephalosporins, and other beta-lactam antibiotics is advised. It is important to communicate and update any changes in allergy status across all healthcare settings to ensure patient safety.

2.1 RISK FACTORS FOR PENICILLIN ALLERGY

- Patients aged 20-49 years are at increased risk of anaphylaxis although reasons for this are unknown
- There is no evidence to suggest a hereditary link to anaphylaxis and therefore family history is irrelevant
- The latest data suggest there is no link between atopic disease (e.g. patients with asthma eczema or hay fever) and increased risk of penicillin allergy, although patients with atopic disease may experience more severe reactions

APPROXIMATELY 80% OF PATIENTS WITH AN IGE-MEDIATED PENICILLIN ALLERGY LOSE THEIR SENSITIVITY AFTER 10 YEARS

- A clinical history of penicillin allergy in the more distant past (>15yrs) is associated with a very low risk (0.4%) of reactions.
- Only 20-30% of patients positive on a penicillin skin test remain positive after 10 years.
- This allows consideration for **penicillin re-challenge* if previous reaction is deemed to be non-severe**. i.e. Not an immediate reaction which affected two or more systems.

2.2 CLASSIFYING ALLERGIES

<table>
<tr><th>TYPE</th><th>CLINICAL FEATURES</th><th>PENICILLIN USE GUIDANCE</th></tr>
<tr><td>Type I Hypersensitivity Reaction
IgE-mediated</td><td>Occurs within 1 hour (up to 72 hours)

Acute onset of skin and/or mucosal symptoms (e.g. hives, flushing, angioedema)

PLUS

One of the following:
• respiratory compromise (e.g. wheeze, stridor, hypoxemia), or
• reduced blood pressure/end-organ symptoms (e.g. collapse, syncope), or
• severe gastrointestinal symptoms (e.g. crampy pain, vomiting);

OR

Acute hypotension, bronchospasm, or airway obstruction after allergen exposure, even if skin symptoms are absent</td><td>STRICTLY AVOID PENICILLIN AND RELATED BETA-LACTAMS

Due to the unpredictability and severity of these reactions, strict and lifelong avoidance of penicillin and related beta-lactams is recommended</td></tr>
<tr><td>Type II Hypersensitivity Reaction
Cytotoxic (IgG/IgM against cell-bound antigen)</td><td>Occurs within days to weeks

Examples include haemolytic anaemia, thrombocytopenia, neutropenia</td><td rowspan="2">Type II and III hypersensitivity reactions can result in systemic and sometimes severe effects, but these reactions are typically delayed in onset—arising days after exposure

In cases where penicillin or a related beta-lactam is deemed the optimal agent, and no suitable alternatives exist; re-exposure may be considered only after careful clinical evaluation—ideally in discussion with an allergy or immunology specialist—and with appropriate precautions in place (such as inpatient monitoring and specialist input).

Cross-reactivity with other beta-lactams is thought to be low; however, the complexity of individual cases always requires consultation with an allergy/immunology specialist</td></tr>
<tr><td>Type III Hypersensitivity Reaction
Immune complex mediated</td><td>Occurs within 1 to 3 weeks

Examples include serum sickness: fever, urticaria/morbilliform rash, arthralgia, lymphadenopathy, nephritis and vasculitis</td></tr>
</table>

Type IV Hypersensitivity Reaction *Delayed, T-cell mediated*	Occurs more than 72 hours after index exposure Examples include drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and interstitial nephritis	**STRICTLY AVOID PENICILLIN AND RELATED BETA-LACTAMS** These are serious, potentially life-threatening conditions that can recur with re-exposure

2.3 WHAT CLASSIFIES AS AN ALLERGIC REACTION AND WHAT DOES NOT

MINOR ALLERGY	These have a low probability of acute Type I or Type IV hypersensitivity reaction Minor, non-itchy rashes developing slowly and localized are usually not a contraindication to future penicillin use, but should be documented and monitored
SEVERE ALLERGY	**Type I and Type IV hypersensitivity reactions** Severe, widespread, or systemic reactions (especially those involving mucous membranes, systemic symptoms, or organ dysfunction) are absolute contraindications to penicillin and related beta-lactams
MEDICATION SIDE-EFFECTS	Not classed as an allergy. These are common non-immune mediated side effects and should not be labeled as an allergy. They do not preclude future penicillin use unless severe intolerance is evidenced from concurrent (and related) use of the medication. Symptoms include: • Delayed onset diarrhea and vomiting • Nausea • Bloating and Indigestion • Abdominal pain • Loss of appetite

2.4 TAKING A GOOD PENICILLIN ALLERGY HISTORY

When assessing a patient with a reported penicillin allergy, the aim is to clearly define the type of reaction and assess risk by considering the following:

1. Which specific antibiotic caused the reaction?

2. What was the reaction / what were the symptoms?
    - Describe rash type (e.g. urticarial, pustular) or other symptoms (swelling, anaphylaxis)
    - Consider if rash could be from another cause (e.g. viral)
    - Timing: How soon after starting the commencing antibiotic did rash appear (minutes, hours, days)?

3. How severe was the reaction?
    - Did this reaction result in hospitalisation?
    - What treatment was needed (e.g. adrenaline/ antihistamines, steroids, no treatment

4. When did the reaction occur?
    - Days, weeks or years ago
    - When did the reaction occur in relation to taking the drug?

5. Did the reaction resolve on stopping the antibiotic?

6. Was the reaction diagnosed as an allergy by a healthcare professional?

7. Has the patient taken a penicillin or related antibiotics since the reaction?

8. Differentiate allergy from side effects: was the reaction a classic allergy or a side effect?
    - Was the reaction a true allergic reaction (immune-mediated) or a non-allergic side effect (e.g. nausea, GI upset etc.)

2.5 CROSS REACTIVITY OF OTHER CLASSES OF ANTIMICROBIALS IN PATIENTS WITH A TRUE PENICILLIN ALLERGY

CEPHALOSPORINS	There has been some evidence to suggest that overall hypersensitivity rate between penicillin and cephalosporin is between 0.5% and 6.5% (rather than being up to 10%) First and early second-generation cephalosporin (e.g. cephalexin, cefazolin) have a higher risk of cross-sensitivity, compared to other second and third-generation cephalosporins Second and third generation cephalosporins (e.g. cefuroxime, ceftriaxone, ceftazidime) are deemed low risk and unlikely to be associated with cross reactivity as they have different chemical structure side chains compared to penicillin and early cephalosporins
CARBAPENEMS **MONOBACTAMS**	Carbapenems (Meropenem, Ertapenem); Monobactams (Aztreonam) Recent evidence indicates that cross-reactivity between penicillins and carbapenems or aztreonam is extremely rare, at <1%. Usually, benefit of use as recommended within guidelines would outweigh the risk of cross-reactivity. Robust clinical assessment and close monitoring is advised when prescribing carbapenems in Type I penicillin allergy. Aztreonam is generally tolerated by patients with confirmed immediate and non-immediate sensitivity to beta-lactams, although cross sensitivity is observed with ceftazidime on occasion (ceftazidime and aztreonam have identical side chains)

Other important considerations

- Patients with no evidence of Type I allergy to penicillin may be treated with any cephalosporin or beta lactam antibiotic for infections of any severity.
- Patients with symptoms suggestive of a Type I allergy should avoid cephalosporins and other beta-lactam antibiotics for mild or moderate infections when a suitable alternative exists.
- In cases of life-threatening infection, where the use of a non-penicillin antibiotic would be sub-optimal, consider giving (under close observation) a second or third generation cephalosporin, even in patients with a history of penicillin allergy. Seek advice from ID or Microbiology prior to prescribing if uncertain about the safety profile.
- In cases of intolerance to penicillin (such as GI upset) or a minor rash occurring more than 72 hours after administration, these antibiotics need not necessarily be withheld in severe infection. However, ongoing use must be always monitored.

2.6 PENICILLIN ALLERGY AND CHALLENGE DE-LABELLING FOR D&G INPATIENTS

- For inpatients who meet the criteria for de-labelling and could benefit from a beta-lactam antibiotic, please use our **NHS D&G PENICILLIN ALLERGY CHALLENGE AND DE-LABELLING WORKSHEET** (sample on Appendix 2), which should be inserted into medical notes when considering a patient for a penicillin challenge).
    - This has been developed in line with the Scottish Antimicrobial Protection Guidelines (SAPG) guidance on penicillin de-labelling.
    - This straightforward test conclusively determines a patient's tolerance for penicillin.
- If further advice is needed, consulting with an Infectious Disease or Microbiology consultant, or antimicrobial pharmacist is advisable.
- Obtaining patient consent is mandatory prior to conducting a penicillin challenge.
- De-labelling can positively impact the range of options available to a patient during future antibiotic treatments.

2.7 CLINICIAN RESOURCES

- NHS D&G Penicillin Delabelling Poster (Appendix 1)
- Management of patients experiencing allergic symptoms (pdf)
- Frequently asked questions to support use of the penicillin allergy de-labelling algorithm and oral challenge test

2.8 PATIENT RESOURCES

- Patient information leaflet (PIL) - Pre test information for patients (pdf)
- Patient permission form to be signed if proceeding with test (docx)
- Patient post test result (positive) (pdf)
- Patient post test results (negative) (pdf)

2.9 OUTCOMES FROM THE PENICILLIN CHALLENGE

- Inform the patient of the outcome of the challenge
- Update allergy status on HEPMA or in primary care records *(to appear on ECS)*
    - If no reaction has occurred on challenge: "No allergy found - penicillin allergy label removed"
    - If reaction occurred on challenge: "Reaction observed - *describe reaction* - allergy label retained"
- For inpatients, notify GP via accurate documentation in the Immediate Discharge Letter (IDL)
- Update information onto Clinical Portal (refer to SOP- see appendix)

3.0 REFERENCES

1. SAPG Penicillin Allergy Delabelling toolkit- resources
2. Jetwa S. Penicillin allergy: identification and management. *Pharmaceutical Journal*. 2015. https://pharmaceutical-journal.com/article/ld/penicillin-allergy-identification-and-management
3. NHS Nottingham Area prescribing committee. Is it really penicillin allergy? 2019 https://www.nottsapc.nhs.uk/media/saolznyo/penicillin-awareness-leaflet.pdf
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5. NHS GGC Clinical Guideline on Penicillin (Adult). Ysobel Gourlay. 2021 https://rightdecisions.scot.nhs.uk/media/2150/penicillin-allergy.pdf
6. NHS East Kent Formulary: Penicillin allergy. 2024. https://eastkentformulary.nhs.uk/therapeutic-sections/5-infection/antimicrobial-guide-primary-care/supporting-information-antimicrobials/penicillin-allergy/
7. NHS Tayside. Guidance on antibiotic choice for patients with Penicillin Hypersensitivity. 2020
8. https://www.ebmconsult.com/articles/penicillin-allergy-cross-reactivity-cephalosporin-antibiotics
9. https://allsa.org/wp-content/uploads/2021/08/WAO-Anaphylaxis-2020.pdf

4.0 MONITORING OF DOCUMENT

The compliance and impact of this document will be monitored by the Antimicrobial Stewardship Management Team (ASMT) members. ASMT members will maintain overall responsibility for this document. Updates to this document will be submitted to ADTC for review.

4.1 EQUALITY AND DIVERSITY

No negative impact on individuals with protected characteristics is anticipated.

The penicillin allergy and de-labelling process improves care quality and access for all patient groups by supporting safe, evidence-based treatment choices. No group is unfairly disadvantaged by this guidance; any concerns identified during implementation will be reviewed and addressed as part of regular practice audit and governance.

4.2 KEY CONTACTS

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4.3 DOCUMENT CONTROL

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Author	Evelyn Yoong, Antimicrobial Pharmacist (Secondary Care) Jezmit Singh, IMT1 Dr Sharon Irvine, ID consultant & OPAT lead		
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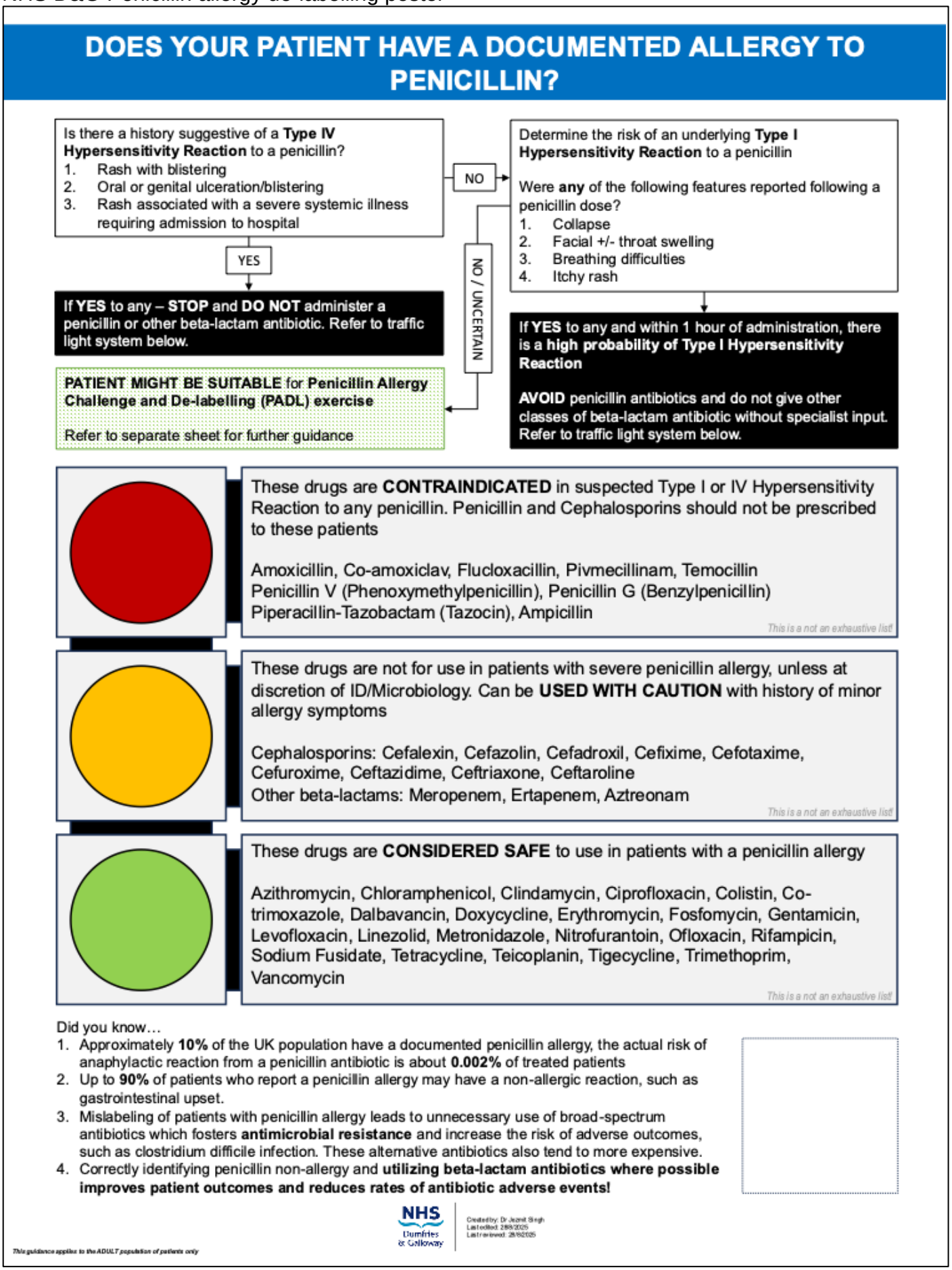
Version	**Sections(s)**	**Reason for update**	
1.0	All	New Guidance	
Distribution plan			
Name	**Responsibility**		**Version Number**
Evelyn Yoong	Submit guidance document to ADTC for review and approval prior to implementation.		1.0
Evelyn Yoong	Publish on NHS D&G Antimicrobial Handbook on Right Decision Platform		**1.0**
Implementation plan			
Lead Officer:	**Action:**		**Timeframe:**
AMT and ADTC Members	Approved		27/08/25
Evelyn Yoong	Publish on NHS D&G Antimicrobial Handbook on Right Decision Platform		15/09/2025
Dr Sharon Irvine and Dr Jezmit Singh	Education to the wider team		TBC

5.0 APPENDIX

NHS D&G Penicillin allergy de-labelling poster



NHS D&G Penicillin allergy challenge and de-labelling worksheet (front page)

THIS PATIENT IS BEING CONSIDERED FOR A PENICILLIN ALLERGY CHALLENGE AND DE-LABELLING (PADL) EXERCISE

Name: _____
CHI/DoB: _____
Address: _____
_____
Postcode: _____

This guidance applies to the ADULT population of patients only

START HERE

Is there a history suggestive of a **Type IV Hypersensitivity Reaction** to a penicillin?
1. Rash with blistering
2. Oral or genital ulceration/blistering
3. Rash associated with a severe systemic illness requiring admission to hospital

NO

Determine the risk of an underlying **Type I Hypersensitivity Reaction** to a penicillin

Were **any** of the following features reported following a penicillin dose?
1. Collapse
2. Facial +/- throat swelling
3. Breathing difficulties
4. Itchy rash

YES

If **YES** to any and within 1 hour of administration – There is a high probability of **Type I Hypersensitivity Reaction**

Patient is **UNSUITABLE** for penicillin challenge

YES

If **YES** to any – Patient is **UNSUITABLE** for penicillin challenge

NO / UNCERTAIN

NO

Do **any** of the following criteria apply?
1. Symptoms typical of intolerance rather than allergic reactions, such as **minor GI upset, nausea, headaches and fatigue**
2. Family history of penicillin allergy but with no personal history of penicillin allergy
3. History of tolerating a penicillin following the index reaction

If **YES**, history is inconsistent with allergy and can be **DIRECTLY DE-LABELLED** without need for an oral challenge

Patient disagrees with direct de-labelling

UNCERTAIN

Do **any** of the following criteria apply?
1. Reaction occurred less than 10 years ago
2. Patient was admitted to hospital or required urgent medical care because of the reaction
3. Reaction occurred within an hour

NO

YES

UNSUITABLE for penicillin challenge without specialist review

CONSIDER referral to a specialist for consideration of detailed allergy assessment (if available)

CONSIDER PENICILLIN CHALLENGE
The overall risk of immediate allergy is low. Refer overleaf and complete documentation below

CHALLENGE DOCUMENTATION

CIRCLE WHICHEVER IS APPLICABLE

I confirm that the patient is categorically eligible for *[penicillin challenge / direct de-labelling]*	❑ YES	❑ NO	
I have provided a PIL and *[obtained informed consent / Informed patient of direct de-label]*	❑ YES	❑ NO	
Penicillin allergy *[de-labelled / adverse reaction updated]* on *[HEPMA / ECS]*	❑ YES	❑ NO	
If inpatient, IDL updated with results of *[direct de-label / penicillin challenge]*	❑ YES	❑ NO	❑ N/A
Penicillin allergy de-labelling documented on Clinical Portal (see separate instructions)	❑ YES	❑ NO	❑ N/A

[AMOXICILLIN] < Patient challenged with > *[FLUCLOXACILLIN / OTHER (.....)]*

[DE-LABEL] < Result of penicillin challenge > *[CANNOT DE-LABEL]*

Prescriber name: _____ Designation: _____ Signature: _____ Date _____

NHS Borders

Created by Dr Jasmit Singh
Last edited: 4/10/2023
Last reviewed: 4/10/2023

PROTOCOL FOR THE ADMINISTRATION OF AN ORAL PENICILLIN CHALLENGE

This protocol is designed to be used in conjunction with the algorithm overleaf and should only be applied by staff trained and equipped in the management of an anaphylactic reaction. Antibiotic challenges can result in immediate allergic reactions, including **ANAPHYLAXIS**. Patients must be closely observed during the undertaking of this procedure and must not leave the ward.

Ensure that properly equipped resuscitation equipment is immediately available in the clinical area

PREPARATION

1. Review the exclusion criteria for oral challenge
   - **Oral antihistamines should be stopped for 72 hours prior to challenge as they may mask true allergy**
2. Select the antibiotic to be used.
3. Discuss the plan for an oral penicillin challenge with the patient and give them the patient information sheet
4. Record in the case notes that consent has been obtained

EXCLUSION CRITERIA

- Medically unstable (NEWS more than 2)
- Pregnant
- Uncontrolled asthma
- Unstable coronary artery disease
- Ongoing ACEi or Beta-blocker unless can be withheld 24 before challenge
- Antihistamine use within the past 72 hours

PROCEDURE

1. Measure the patient's observations (HR, BP, oxygen saturation, RR).
   - **If the patient has asthma, measure peak expiratory flow rate (PEFR)**
2. Medical staff should prescribe and administer the antibiotic and then remain within the clinical area for the first 20 minutes
3. The chosen antibiotic should be administered as a single oral dose
   - Amoxicillin 500mg OR Flucloxacillin 500mg
4. Inform the patient to notify you immediately if they experience any adverse symptoms
5. Measure the patient's observations (and PEFR if indicated) if they experience any symptoms and at regular intervals such as 10, 20, 40 and 60 minutes
6. Record any symptoms the patient experiences
7. **If the patient reports any of the symptoms of a positive test (see box) or they have a rising NEWS score, then the patient should be reviewed immediately by an appropriate senior member of staff**

MANAGING A REACTION

Severe symptoms such as **hypotension or breathing difficulties** institute immediate management of anaphylaxis, call for senior medical review and consider putting out a **2222**

Mild symptoms such as an isolated rash and an unchanged/unelevated NEWS score, administer an antihistamine and consider a single dose of prednisolone 30mg

POST-PROCEDURE CARE

1. Interpret the oral challenge as shown in the colored boxes below
2. If the challenge is negative (no reaction occurred)
   - Give the patient the patient information leaflet (PIL)
   - Record in the discharge letter and ask the patient's GP to amend their allergy on the practice records
   - Update HEPMA if inpatient
   - Update ECS if outpatient
   - Update Clinical Portal (see separate instructions on how to do this)
3. **If the challenge outcome is positive, written and electronic records must clearly state this**
   - Give the patient the patient information leaflet (PIL)
   - Record the outcome of the challenge in the discharge letter
   - Update HEPMA with reaction type if inpatient
   - Update ECS with reaction type if outpatient
4. The patient should be provided with the information leaflet and the GP informed of the outcome (if inpatient)

NEGATIVE TEST	EQUIVOCAL TEST	POSITIVE TEST
No symptoms reported during the period of observation and patient's NEWS score does not rise **Patient experiences isolated nausea or isolated itch without any other features of a positive test**	If there is doubt about the interpretation of the test, this should be discussed with a senior clinical and referral to a local allergy service (if available) should be considered	Patient experiences any of the following 1. Itchy rash 2. Breathing difficulties 3. Facial swelling 4. Hypotension
DE-LABEL		CANNOT DE-LABEL

THIS DOCUMENT IS DEVELOPED IN CONJUNCTION WITH THE PENICILLIN DE-LABELLING QUALITY IMPROVEMENT PROJECT

FOR THE RESPONSIBLE CLINICIAN
Help us improve this form by providing feedback whenever it gets used.

FOR INTERNAL USE ONLY
Please log your data on this form.

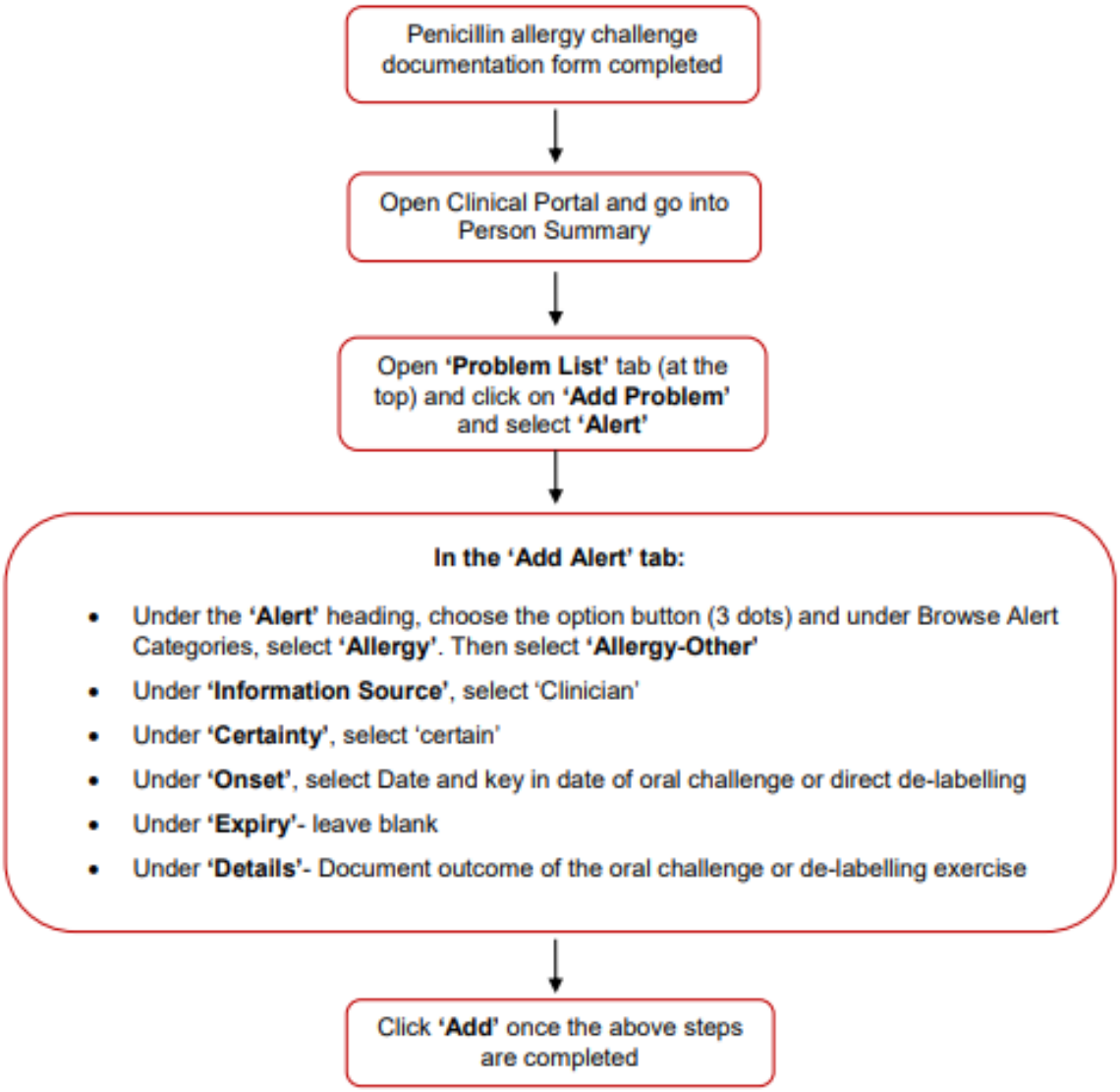
Adapted to fit local use based on the Scottish Antimicrobial Protection Group (SAPG) Penicillin de-labelling guidelines

NHS Dumfries And Galloway	
SOP	Recording Alerts and Outcomes for Penicillin De-labelling **on Clinical Portal**
SCOPE	Process for recording alerts and outcomes after a penicillin de-labelling exercise on **CLINICAL PORTAL**
RESPONSIBILITY	Antimicrobial Stewardship Management Team

Pre-requisites

The patient has been considered for a penicillin allergy challenge and de-labelling exercise, has either undergone an oral challenge or been directly de-labelled, and has completed the challenge documentation form.

Process adding alerts and outcomes after a penicillin de-labelling exercise on CLINICAL PORTAL



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