

Process of Penicillin Allergy De-labelling using Risk Stratification and Oral Challenge	
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### 1. **Introduction**

Approximately 10% of patients have a penicillin allergy label recorded, although the vast majority will have experienced intolerance to penicillin and not an allergic reaction.

Penicillin allergy patients who develop infection will receive alternative antibiotics which are often sub-optimal in treating infection and may also result in poorer outcomes, increased risk to *Clostridioides difficile*, increased risk of antimicrobial resistance development, longer hospital stays and other adverse events.

Penicillin Allergy De-labelling (PADL) is well evidenced as being safe and effective in optimising medicines utilisation. Through the implementation of a robust clinical assessment process, risk stratification and closely monitored oral challenge, patient safety is preserved and infection outcomes are optimised for current and future care episodes.

### 2. **Scope and Purpose of SOP**

The scope of this Standard Operating Procedure describes the process of assessing and de-labelling (where safe and appropriate) penicillin allergy in **adult** patients within NHS Tayside. The purpose of the SOP is to provide a comprehensive assessment of penicillin allergy, prevent harm, optimise the treatment of infection and minimise the development of antimicrobial resistance.

### 3. **Governance and Safety**

PADL process, progress and outputs to be reported through the Antimicrobial Management Group (AMG) which in turn feed into the Area Drugs and Therapeutics Committee (ADTC) (Appendix 1). PADL outcomes will be monitored and recorded in an electronic database to ensure appropriate governance of process. Adverse events will be recorded in DATIX and reviewed by the PADL team accordingly to ensure appropriate patient group was selected.

#### Education & Training

All staff involved in the PADL process must complete training on the use, assessment and interpretation of the [Scottish Antimicrobial Prescribing Group \(SAPG\) PADL Algorithm](#) (Appendix 2). Staff must also complete the [NHS Tayside Anaphylaxis LearnPro](#) prior to involvement in the PADL process. Education and Training must be evidenced and recorded with Line Manager.

Equipment and medicines to manage anaphylaxis should be readily available on the ward and be accessible prior to commencing oral challenge.

#### **Suggested items:**

[ALS Algorithm for anaphylaxis](#)

Adrenaline 1mg/ml (1:1000) concentration IM injection. (Adult & child >12yrs dose: 500mcg (0.5ml))

NHS Tayside PADL SLWG

Agreed: March 2022, interim update January 2024

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Oral cetirizine (Adult & child >12yrs dose:10-20mg)  
 Chlorphenamine 10mg injection  
 Hydrocortisone 200mg injection } May be required for management of refractory anaphylaxis  
 2 x 500ml bags of glucose free crystalloid fluid (e.g. 0.9% sodium chloride or Hartmann's)  
 Salbutamol 5mg nebuliser x 2  
 Nebuliser & mask  
 2 x PVC (green & pink)  
 2 x 10ml 0.9% sodium chloride (for flush)  
 2x 10ml syringes  
 Cannula dressings  
 Clinell wipes: green for devices & blue for skin

#### 4. Procedure

##### 4.1 Staff involved in PADL Process

A Clinical Lead (Consultant) who reports into the governance structure above must be identified to lead on the implementation of the PADL process. Once training and education has been completed at ward level, registered medical practitioners, nurses and pharmacists can be involved in the delivery of PADL.

##### 4.2 Inclusion/Exclusion Criteria

All adult patients with a documented history of penicillin allergy are eligible for initial assessment. Automatic exclusion criteria:

- Medically unstable (NEWS  $\geq$  2) except where there is clinical benefit/need and discussion/assessment has taken place with Consultant
- Pregnant
- Uncontrolled asthma (defined by having any one of: 1. Poor symptom control, 2. required 2 courses of oral corticosteroids in the past 12 months, 3. serious exacerbation requiring hospitalisation, 4. Fixed airflow obstruction i.e. FEV<sub>1</sub><80% predicated without bronchodilators.) Discuss with Respiratory Consultant if need outweighs risk.
- Unstable coronary artery disease
- Receiving ACE inhibitor or beta blocker (unless safe to withhold for 24hrs prior to assessment) except where there is clinical benefit/need

##### 4.3 Informed Consent

Patients considered for inclusion in the PADL process will be provided with the information leaflet: [Information for patients: Do I have a penicillin allergy?](#) (Appendix 3) and provided an opportunity to have questions answered by a member of the team. Where an individual is agreeable to proceeding, written consent (Appendix 4) must be obtained and recorded in the medical records.

##### 4.4 Risk Assessment

Where a patient reports penicillin allergy or where penicillin allergy is recorded in the notes AND patient is agreeable to proceeding to PADL test, follow the [SAPG PADL risk assessment algorithm](#) (Appendix 2).

###### Step 1:

Is there a history which suggests Type 4 hypersensitivity?

Were any of the following factors present:

- Rash with blistering
- Oral or genital ulceration or blistering?
- Severe systemic illness requiring hospital admission which is suspected to be associated with Penicillin use.

**Yes** – Stop and Do Not proceed to oral challenge

**No** – Proceed to Step 2

###### Step 2:

Assess the history of penicillin allergy to determine risk of type 1 hypersensitivity:

Following a dose of a penicillin antibiotic did any of the following occur within 1 hour:

- Collapse
- Facial/throat swelling
- Breathing difficulties
- Itchy rash

**No** – Low probability of type 1 hypersensitivity reaction to penicillin. Symptoms suggestive of intolerance rather than allergy. Proceed to oral challenge.

**Yes** – High probability of Type 1 hypersensitivity reaction. Do Not proceed to penicillin oral challenge. Avoid penicillin antibiotics and do not give other beta-lactam antibiotics without specialist review. If there is a genuine need for penicillin based antibiotics as approved by ID/micro then onward referral to immunology may be necessary. Give patient [allergy warning card](#) (Appendix 5)

**Uncertain** – Do any of the following criteria apply:

- Reaction occurred < 10yrs ago
- Patient was either admitted to hospital or required urgent medical care for the reaction
- Reaction definitely occurred within 1hr

**Yes** – Unsuitable for oral challenge without specialist allergy review. Consider referral to infectious disease team for assessment of need for penicillin based antibiotics.

**No** – Oral challenge possible as overall risk low. Consider oral challenge following senior medical review.

#### 4.5 Penicillin Oral Challenge

Preparation:

- Review exclusion criteria
- Where possible withhold antihistamines for 72hrs prior to the challenge as they may mask true allergy
- Medical staff to select the antibiotic to be used, ideally the agent the patient is thought to have had the reaction to. If this is unknown or not possible, amoxicillin is a suitable choice
- Provide patient with information leaflet and document in medical notes that consent has been obtained
- Place patient in bed/chair space with piped oxygen available

Procedure for Oral Challenge:

- Record baseline observations in eObs. If patient has asthma, record peak expiratory flow rate (PEFR) and ensure these parameters are within those safe to proceed
- Ensure the anaphylaxis equipment needed is available within the ward setting
- Medical staff or Non-medical Prescriber should prescribe test dose as a single oral dose on HEPMA by selecting either drug file **“Amoxicillin 500mg capsule (PADL use only) or Flucloxacillin 500mg capsule (PADL use only)“**.
- Registered medical or nursing staff administer the antibiotic noting exact time of administration in HEPMA
- Clinician initiating PADL to inform ward team that PADL has taken place and remain on the ward for at least 20mins post administration
- Member of staff to remain in patient vicinity for duration of test where possible.
- Place patient call buzzer next to patient and ask patient to immediately inform staff member if they experience any adverse symptoms
- Measure and record patients observations if they experience any symptoms **AND** at the following intervals post administration in eObs at 10 minutes, 20 minutes, 40 minutes, 60 minutes
- Document any symptoms the patient experiences
- If patient experiences itchy rash, breathing difficulties, facial swelling, hypotension or rising NEWS score, a review must be carried out immediately by ward clinical team and clinician who initiated PADL should be contacted
- If any suspicion of anaphylaxis then usual hospital policy for this should apply
- Document challenge finish time in medical notes and summarise events

#### 4.6 Interpretation of Oral Challenge

**Negative Test:**

No symptoms reported during the observation period and NEWS remained stable. Patient experiences nausea or itch in the absence of other features of a positive test.

**Equivocal Test:**

If there is any dubiety of the interpretation of the test this should be discussed with the senior clinician. Referral to the local allergy service should be considered if clinical need.

### Positive Test:

Patient experiences any of the following:

- Itchy rash
- Breathing difficulties
- Facial swelling
- Hypotension

#### 4.7 Post Procedure Care

Where the challenge is **negative**, discuss outcome with the patient and provide the patient with the information leaflet "[Patient information leaflet Penicillin allergy testing result: Negative](#)" (Appendix 6) Send communication letter (Appendix 7), OpComms form or document details in discharge letter to GP asking for practice records to be amended. Penicillin allergy labels can only be amended at practice level and this will automatically update hospital electronic systems such as ICE, Trakcare, Clinical Portal, HEPMA which hold this information.

Where the challenge outcome is **positive**, clearly document this in medical notes. Discuss outcome with the patient and provide [patient information leaflet](#) (Appendix 8) and [allergy card](#) (Appendix 5). Send communication letter (Appendix 9) to the GP informing them of challenge outcome.

#### 4.8 Management of Reactions

Patients who experience symptoms of mild to moderate allergy such as itch, urticaria, sneezing or rhinitis following an oral challenge should have their vital signs (heart rate, blood pressure, oxygen saturation and respiratory rate) monitored and recorded.

If symptoms remain stable and non life-threatening, prescribers may consider the following:

- Oral antihistamines (e.g. 10-20mg cetirizine)
- Inhaled bronchodilators (e.g. salbutamol 5mg nebulised)
- Oral steroids (e.g. 30mg prednisolone) for management of refractory anaphylaxis

Monitor patients closely and reassess NEWS at regular intervals. Where symptoms do not improve, or there is evidence of clinical deterioration, call for senior medical assistance. Supplementary oxygen should be given via a face mask and intravenous access obtained.

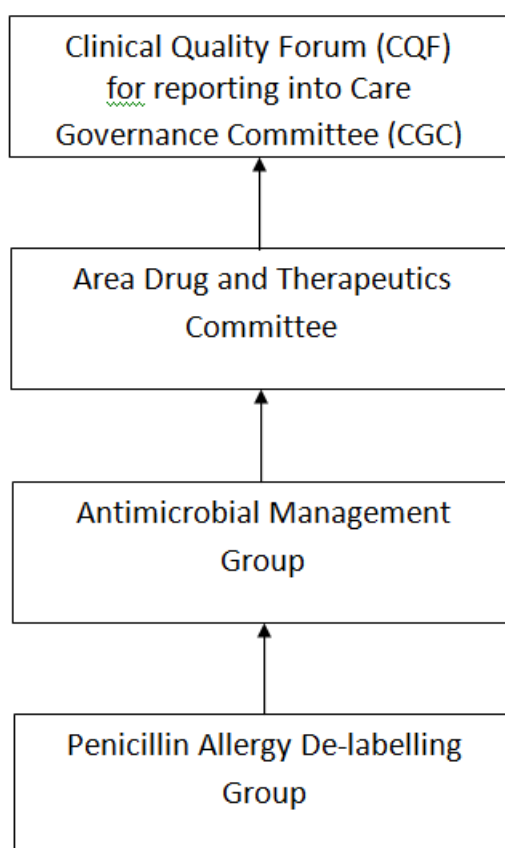
Hypotension or breathing difficulties necessitate immediate management of anaphylaxis, call for urgent senior medical review and consider contacting cardiac arrest team on 2222. Treat as per [UK Resuscitation Council guidelines](#) (Appendix 10).

## 5. References

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**Appendix 1**

## Penicillin Allergy De-Labeling Project Governance Route



## Appendix 2



October 2021 For review October 2024



## Information for patients: Do I have a Penicillin Allergy?

### What is a penicillin?

A penicillin is an important type of antibiotic that can be used to treat many common infections.

The first penicillin was discovered many years ago by Alexander Fleming and since then many other penicillin type antibiotics have been developed. Penicillin antibiotics are often the first choice antibiotic for common infections like pneumonia, skin infections and tonsillitis. They are widely used both in hospital and in the community.



### What is a penicillin allergy?

A penicillin allergy occurs when the body's immune system responds unusually to a penicillin type antibiotic.



#### Examples of penicillin antibiotics include:

phenoxymethylpenicillin (penicillin V)	amoxicillin
flucloxacillin	co-amoxiclav (Augmentin)

For most people an allergic reaction will be an unpleasant mild skin reaction or rash that develops slowly after several hours or days of taking the medicine. Sometimes a more severe reaction can occur called anaphylaxis. Anaphylaxis is extremely rare but can be life threatening.



#### People with anaphylaxis develop symptoms such as:

A widespread itchy rash (like nettle sting)
Breathing difficulties
Swelling and collapse very quickly, often within minutes of taking penicillin and always within two hours

### What is the difference between an allergy and side effects?

All medicines may cause unpleasant side effects such as a skin reactions/rashes, vomiting or diarrhoea. Side effects are different to allergic reactions. Having side effects to penicillin, whilst unpleasant, does not mean you need to avoid penicillin antibiotics completely. This is particularly true in severe infections where penicillin may be the best antibiotic. In these situations it is often best to receive penicillin and manage side effects if they happen.



## How common is penicillin allergy?

### 1 in 100

Approximately one in 100 people have a genuine penicillin allergy.

### 1 in 10,000

The most severe allergy, anaphylaxis occurs in about 1 in 10,000 people taking penicillin, however, it is extremely rare.

### 1 in 10

Despite real penicillin allergy being uncommon, about 1 in 10 people have either been told or have assumed they have a penicillin allergy.

### 9 in 10

Most people (about 9 in 10) recorded as having a penicillin allergy are not actually allergic.

## I have had a recorded penicillin allergy for a long time. Why should that change now?

Penicillins are very effective treatments for many infections including skin and chest infections. They are also commonly used in patients having a surgical procedure. Being unable to take penicillins may put you at a disadvantage especially if you are admitted to hospital with a severe infection.

## What are the benefits to me of finding out whether I am allergic to penicillin antibiotics?

We can carry out a simple test within the hospital that will tell you if you have a penicillin allergy. If your test results show that you are not allergic to penicillin then your medical records will be updated. Removing the penicillin allergy label from your record means you can be given penicillins when you really need them. It also means you will have more treatment options if you have an infection or require antibiotics before an operation.

## What does the test for penicillin allergy involve?

Your medical team will ask you about the symptoms you had in the past that led to the penicillin allergy label. If they decide you may have been incorrectly recorded as having an allergy, they will offer you a test to decide if the allergy label can be removed. You will only be offered this test if the medical team believe that it is safe to do so and there is a very low chance of an allergic reaction. The test involves giving you a penicillin antibiotic tablet under careful supervision in hospital. Your pulse and blood pressure will be monitored for one hour after you take the tablet.



## What happens after the test?

At the end of the test the hospital team will discuss with you what your test results mean. If you have not experienced any reaction, a letter will then be sent to your GP informing them of the result of the test. Your GP will be asked to remove the penicillin allergy label from your GP record. We will also give you an information leaflet to take home with you explaining the results and what they mean for your future care. If you need an antibiotic now or in the future for either treatment or before surgery, then your doctor will have the option to use a penicillin antibiotic.

If the test confirms that you are allergic to penicillin then we will advise your GP of the test result and ask them to record this in your GP record. We will also give you a leaflet about avoiding penicillin in future.







## Things to think about when deciding if you want to have a penicillin allergy test

### Do I have to take this test?

The benefits of having the test have already been outlined. If you do not want to be tested please let the medical team know. Your decision will not affect your ongoing care.

### Are there any risks or side effects?

There is a small chance that you may experience an unpleasant side effect such as nausea or an allergic reaction. Allergic reactions will usually be mild but a severe allergic reaction including anaphylaxis, although highly unlikely, is possible. You will be closely monitored during the test by staff trained in the recognition and treatment of allergic reactions and other side effects.

In the unlikely event you experience a severe allergic reaction, the medical team will give you treatment to reverse the reaction.

### What will happen if I do agree to have the test?

One of the medical team will ask you to read and sign a permission form indicating your consent to proceed with the test. The doctor will also sign this form and it will be retained in your medical notes as a record of your agreement to the test.

### What will happen if I don't have the test?

If you don't have the test then your medical notes will continue to state you are allergic to penicillin and you will not be given penicillin when you are treated for an infection or have a surgical procedure in the future. You can re-consider having the test at any time.

## Penicillin Allergy Test

Patient permission form to be signed if proceeding with test

I have read and understood the information in the patient information leaflet (including the benefits and risks) and wish to proceed with an oral penicillin challenge test.

- I have had the opportunity **to discuss** the test with the medical team
- **I agree** to the procedure described in the patient information leaflet.

You have the right to change your mind at any time, including after you have signed this form. Please speak to your medical team if you have any concerns.

### Patient

Signature .....

Date .....

Print name .....

### Doctor

Signature .....

Date .....

Print name .....

## Appendix 5

### **I have a penicillin allergy**

*Please check that my medicine does not have penicillin in it (see over)*

Reaction I had was:

On:

### **These antibiotics have penicillin in them:**

- Penicillin (phenoxymethylpenicillin)
- Amoxicillin
- Ampicillin
- Benzylpenicillin
- Flucloxacillin
- Co-amoxiclav (Augmentin®)
- Piperacillin/tazobactam (Tazocin®)
- Pivmecillinam
- Temocillin
- Co-fluampicil ( flucloxacillin + ampicillin)



Patient Sticker

## ***Patient information leaflet***

### **Penicillin allergy testing result: Negative**

The results of your penicillin allergy test show:

**YOU DO NOT HAVE AN IMMEDIATE/SEVERE ALLERGY TO PENICILLIN**

#### **What does this mean for me?**

You no longer need to tell medical teams looking after you that you are allergic to penicillin e.g. when you are taken into hospital.

This means if you ever need treatment for an infection in future you will now be able to receive antibiotics which contain penicillin.

If you had side effects when you took penicillin in the past e.g. nausea you may still want to tell your doctor as they may give you medication to take along with the antibiotics to reduce these.

If a rash develops within the next 72 hours please let your hospital doctor or GP (if you have been discharged from hospital) know.

#### ***What happens now?***

A letter will be sent to your GP to let them know the results of the test and to ask them to remove 'penicillin allergy' from your medical record. We will also remove it from your hospital record.

Please let any other healthcare staff who may prescribe or give you medicines know that your allergy record has been updated.

***If you have any questions about the penicillin allergy test or your results and what that means for you please speak to a member of the medical team looking after you.***

SAPG August 2020

## Appendix 7

### **PENICILLIN ALLERGY TEST, NO REACTION - REMOVE PENICILLIN ALLERGY LABEL [insert patient name].**

Dear Dr XXXXXXXXXX ,

Your patient [insert patient name].underwent assessment of their penicillin allergy label during a recent hospital attendance.

After review of their history, and discussion of the risk and benefits, a supervised oral challenge was performed. A dose of 500mg of **amoxicillin / flucloxacillin** was administered on [date] with no evidence of a type 1 hypersensitivity response.

Based on this we can advise you that **there is no evidence to now support a “penicillin allergy” label.** We request that you remove this allergy label from your patient’s medical record and record details of the allergy test (antibiotic and date). This information should be shared with other healthcare providers within your Practice.

The risk of allergic reaction to penicillin in a de-labelled patient is the same as that of the general population and **they can therefore receive penicillin antibiotics.** This is important for management of any future infections as penicillins are often recommended as first line therapy due to their effectiveness and lower risk of driving antimicrobial resistance.

**Your patient has also been informed that they can safely take penicillin based antibiotics in future** and a copy of the information which they received after the test is included with this letter.

If you have any queries regarding the test process or outcome please do not hesitate to contact me.

Thanks and best wishes

Name and Grade  
Enquiries contact:



Patient Sticker

## ***Patient information leaflet***

### **Penicillin allergy testing result: Positive**

As you know you had a reaction to penicillin during the test which confirms:

**YOU ARE ALLERGIC TO PENICILLIN**

You should continue to avoid taking antibiotics which contain penicillin.

Examples of these antibiotics include phenoxymethylpenicillin (penicillin V), amoxicillin, flucloxacillin and co-amoxiclav (Augmentin).

You will be given a card to carry with you to let people who need to give you medicine know that you have an allergy to penicillin and this will include all the medicines you should avoid.

Remember to ask any healthcare staff who may prescribe or give you medicines to check if it has penicillin in it.

A letter will be sent to your GP to tell them of the result of the test and will include the type of reaction you have had so that your medical record can be updated.

If you have any questions about the type of reaction you have had please ask the medical team looking after you to tell you more about what happened.

SAPG August 2020

## Appendix 9

### PENICILLIN ALLERGY TEST – REACTION CONFIRMED

Dear Dr XXXXXXXXXXXXXXXX,

Your patient XXXXXXXXXXXX XXXXXXXXXXXX underwent assessment of their penicillin allergy label during a recent hospital attendance.

After review of their history, and discussion of the risk and benefits, a supervised oral challenge was performed. A dose of 500mg of **amoxicillin / flucloxacillin** was administered on [date].

**There was evidence of an allergic reaction**, as detailed below:

Please record this description and date of observation in their medical record as confirmation of their allergy status. Please also ensure their allergy status is clearly documented in all future correspondence/records.

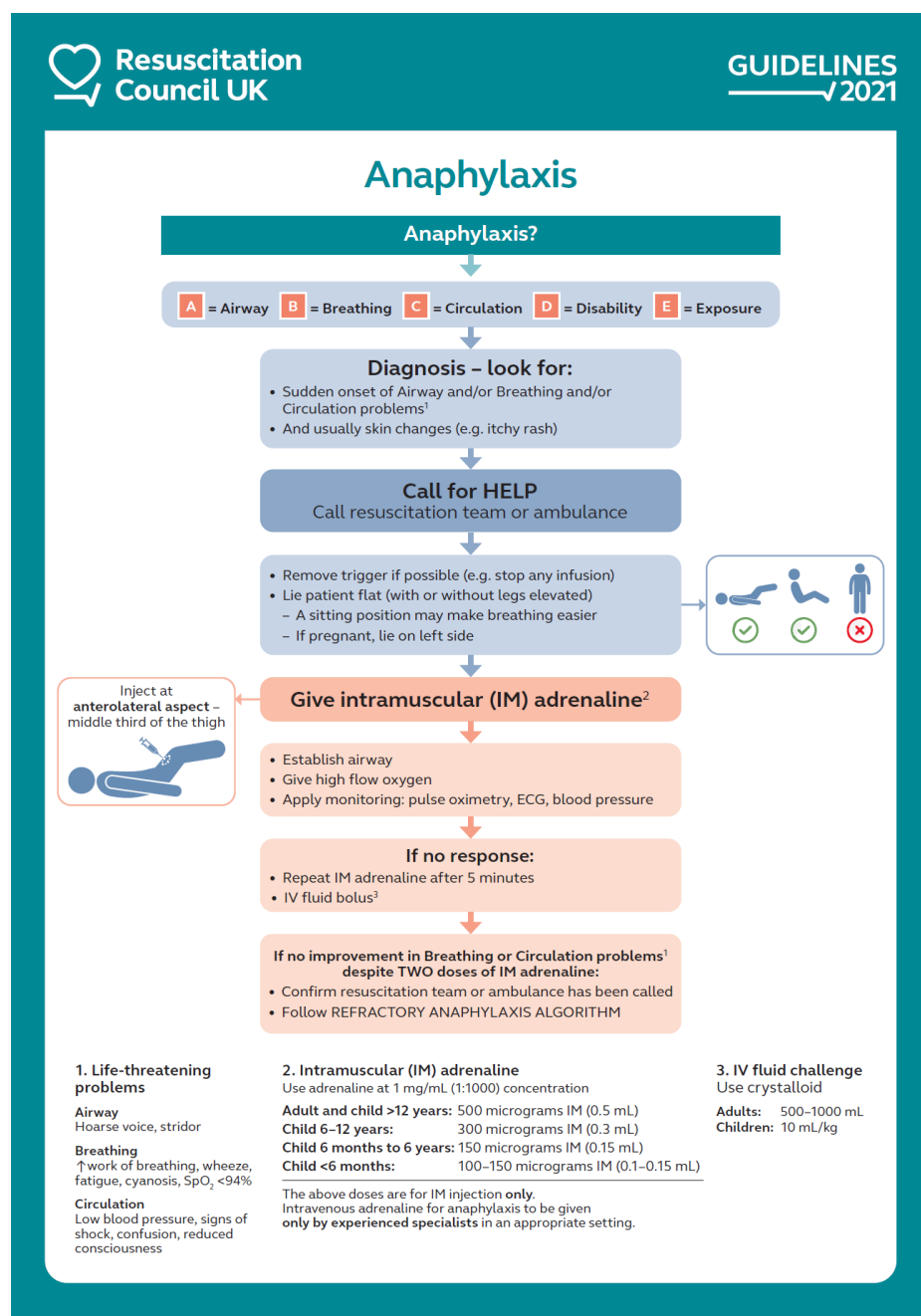
The patient has been informed that they **should not take penicillin based antibiotics** in future. A copy of the information which your patient has received after the test is included with this letter.

Thanks and best wishes

Name/Grade

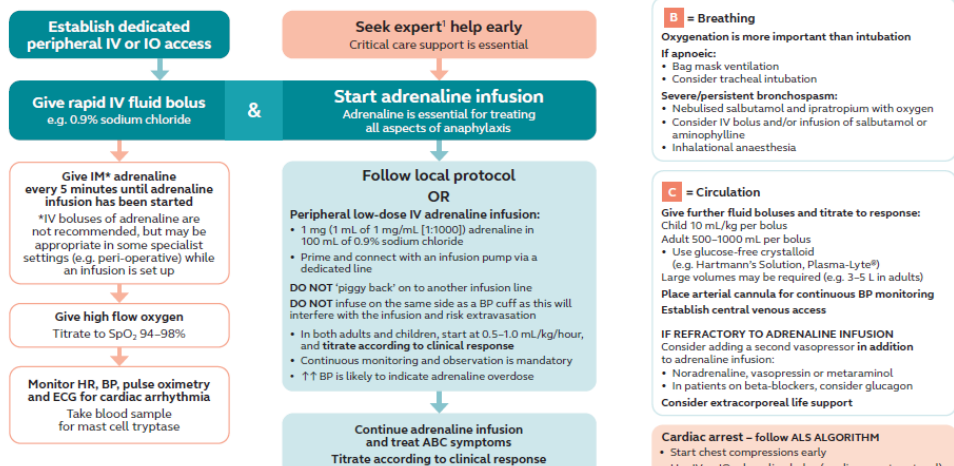
Enquiries/Contact:





## Refractory anaphylaxis

No improvement in respiratory or cardiovascular symptoms despite 2 appropriate doses of intramuscular adrenaline



<sup>1</sup>Intravenous adrenaline for anaphylaxis to be given only by experienced specialists in an appropriate setting.