

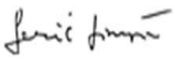


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18. Appendix 4: ALABAMA SOP, Oral Challenge Test – Penicillin

Standard Operating Procedure	Oral Challenge Test - Penicillins
Version No.	V5.0

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ALABAMA SOP- Oral Challenge Test - Penicillins Version 5.0 06/05/2022

Standard Operating Procedure

Oral Challenge Test to Penicillins

The following standard operating procedure outlines how to perform an Oral Challenge Test to penicillins and is applicable to all health care professionals undertaking this role.

In the diagnosis of drug allergy an oral challenge test is considered the 'gold standard' due to the unreliability of other testing methods. An oral challenge test (OCT) involves administering the test drug in increasing doses until a reaction occurs or the usual prescribed dose level is reached. Alternatively patients can be given a single dose, where the risk of possible reaction is judged to be extremely low.

Oral Challenge Testing to penicillins should only be performed by an appropriately trained and competent healthcare worker who is also trained in recognition and treatment of anaphylaxis.

EXCLUSIONS

- Antihistamines within 72 hours of OCT
- Beta-blocker within 24 hours of OCT
- Steroids within 10 days of OCT
- History of Anaphylaxis
- History of Stevens-Johnson syndrome, toxic epidermal necrolysis, serum sickness, acute interstitial nephritis, hemolytic anemia, and drug rash with eosinophilia and systemic symptoms (DRESS)
- Severe/brittle asthma or unstable coronary artery disease
- Pregnancy
- Currently taking antibiotics for active infection*

*Long term prophylactic antibiotics may be continued in certain scenarios after discussion with the medical team.

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EQUIPMENT:

- 100mL Amoxicillin 250mg/5mL (or different when index Penicillin is known)
- 50mL Sodium Chloride 0.9%
- Oral Challenge Test Prescription Chart (**Appendix 4**)
- Observational monitoring chart (**Appendix 3**)
- PPE - Follow current LTHT guidelines (available on LTHT Intranet)
- Syringes 1mL, 2.5mL & 10mL
- Sharps bin
- Timer (clock/watch)
- Emergency equipment available to treat anaphylaxis
- 18G Needles
- Needle free device (Bionector connector)
- IV cannulation pack: Steret, gauze, 20G cannula, tegaderm (n.b cannulation prior OCT is not needed routinely for patients deemed to have low risk of reaction)

PREPARATION:

The procedure should be undertaken in accordance with LTHT Covid-19 Coronavirus Guidelines and local infection control policy.

Perform positive ID check, ensure prescription is valid and rescue medications are prescribed (Refer to prescription chart). Discuss the procedure with the patient; written consent for the procedure must be obtained. The procedure must only be undertaken if the patient is well. Check current health status/ current medications with patient and SystemOne. The test must be cancelled if the patient has intercurrent infection, uncontrolled asthma, cardiac problems, or has taken medications likely to interfere with the challenge test (see Exclusions & Cautions).

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PROCEDURE:

1. Perform hand hygiene and don any outstanding PPE.
 2. Perform a set of baseline observations (BP, Pulse, SpO₂) and document.
 3. Ensure patient is in a comfortable position.
 4. Some patients will require cannulation as confirmed by the medic on duty.
 5. The following **standard** dosing regimen should be used routinely. For patients who are deemed **low risk** use the dosing schedule outlined in Appendix 5.
 6. Administer 10% of the standard dose of the test drug (e.g. usual dose of amoxicillin or penicillin V = 500mg - start with 50mg) and document.
 7. Ask the patient to report any adverse reaction (**Appendix 1**), monitor for 15-20 minutes and perform a set of observations (BP, Pulse, SpO₂) and document.
 8. If no reaction or significant change in observations then administer further 25% of the standard dose of the test drug (e.g. 125mg of amoxicillin or penicillin V when the standard dose is 500mg) and document.
 9. Ask the patient to report any adverse reaction (**Appendix 1**), monitor for 15-20 minutes and perform a set of observations (BP, Pulse, SpO₂) and document.
 10. If no reaction or significant change in observations then administer the final standard dose (500mg of amoxicillin or penicillin V) and document.
 11. Ask the patient to report any adverse reaction (**Appendix 1**), monitor for 30 minutes and perform a set of observations (BP, Pulse, SpO₂) and document.
 12. Document test result and reactions in **Appendix 3** and explain the results of the test to the patient.
 13. Supply the patient with the remaining 100ml of the appropriate antibiotic (amoxicillin/penicillin V or other) used in the challenge test, as prescribed for home dosing.
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14. Beginning with the first dose on the evening of the oral challenge test, instruct the patient to take the standard dose of the appropriate antibiotic (500mg of amoxicillin or penicillin V) three times daily until the course is completed.
15. Refer to AFTERCARE and provide the patient with the post allergy testing information sheet.
16. Once the D4-6 follow-up call is completed, scan and email appendix 3 (with all other PAAP testing documentation) to the Allergy/Immunology secretaries for upload to patient electronic health records (e.g.PPM+).

INTERPRETATION:

Any positive reaction (**Appendix 1**) should be documented and the test stopped.

Reactions should be treated appropriately - See **Appendix 2**.

COMPLICATIONS:

Although OCT is a common procedure and regarded as safe, the possibility of a systemic reaction remains a possibility.

AFTERCARE:

If no adverse reaction has occurred, the patient is free to leave the clinic.

In case of late phase response, the patient must be instructed to call 111 or visit their local Emergency Department should they develop symptoms of dyspnoea, wheezing, dizziness or severe pruritus.

19. Appendix 4.1: Signs & Symptoms of allergic reactions in various target organs.

Skin:	Urticaria/Angioedema
	Flushing
	Erythematous pruritic rash
	Atopic dermatitis
Gastro-intestinal tract:	Pruritis and /or swelling of the lips, tongue or oral mucosa
	Nausea
	Abdominal cramping or colic
	Vomiting or reflux
	Diarrhoea
Respiratory tract:	Nasal congestion
	Rhinorrhoea
	Pruritis/sneezing
	Laryngeal oedema, staccato cough and/or dysphonia
	Wheezing/ repetitive cough
Cardiovascular:	Hypotension/shock
	Dizziness

20. Appendix 4.2: Treatment of positive reactions during oral challenge testing.

Mild reactions:

- Ensure patient is comfortable
- Administer 10mg Cetirizine orally and monitor patient.

Severe reactions:

- Contact medical team
- Assist patient into a comfortable position; recovery position for hypotension/faintness, upright for dyspnoea
- Administer oxygen and nebulised salbutamol if required
- Prepare anaphylactic pack to administer 0.5mL adrenaline 1:1000 Intra-muscular
- Call Resuscitation Team if necessary
- Commence CPR if required.

21. Appendix 4.3: Observational monitoring chart.

Date:	Drug & Concentration Tested:	Patient Name:
		NHS No:

Time	Dose Administered	Blood Pressure	Pulse	SpO2	Symptoms/Reactions

Testing performed by :..... Signature:..... Date:.....

Document the result of the test clearly in the box below (After the D4-6 follow-up call):

RESULT OF TEST:	NEGATIVE	POSITIVE
ADVICE FOR PATIENT	SAFE TO TAKE DRUG AGAIN IN FUTURE	MUST AVOID DRUG IN FUTURE

Test result completed by: Signature:..... Date:.....

22. Appendix 4.4: Oral Challenge Test Prescription Chart (LTHT specific – other sites feel free to use own/localise this version)

First Name:		Surname: (Block Letters)	
Hospital No:	NHS No:	DOB:	
Consultant:	Ward:	Hospital:	
(Use addressograph if available)			
Allergies and Adverse Drug Reactions - List the medicines or substances & the nature of the reaction (write NKDA if none)		It is mandatory to complete this section	
Medicine/substance:		Sign (NAME):	
Reaction:		Date:	

Drug	Dose	Route	Prescribers Signature	PRINT name & Contact no.	Date	ADMINISTRATION		
						Date	Time	Sign

FOR EMERGENCY USE IN CASE OF ALLERGIC REACTION

Drug	Dose	Route	Prescribers Signature	PRINT name & Contact no.	Date	ADMINISTRATION	
						Date	Time
Cetirizine	10mg	PO					
Chlorphenamine	10mg	IV					
Hydrocortisone	100mg	IV					
Salbutamol	5mg	Nebs					
Adrenaline Auto-Injector	500mcg	IM					

Compiled by: *J. P. Miller* Date: 19 Aug 2019 Approved by: *Jenice James* Date: 02 Sep 2019

Oral Challenge Test Prescription Chart

1.0

02/09/2019

23. Appendix 4.5: Alternative dosing schedule for **low risk patients** (e.g. those who are suitable for direct oral challenge test without prior skin testing)

1. Perform a set of baseline observations (BP, Pulse, SpO₂) and document
2. Administer 100% of the standard dose of the test drug (e.g. usual dose of Amoxicillin or penicillin V = 500mg) and document.
3. Ask the patient to report any adverse reaction (**Appendix 1**), monitor for 30 minutes and perform a set of observations (BP, Pulse, SpO₂) and document.
4. Monitor for a further 30 minutes, ask the patient to report any adverse reactions (**Appendix 1**) and perform a set of observations (BP, Pulse, SpO₂) and document.

Appendix 4.6 Alternative dosing schedule (to be used if indicated after discussion with a consultant immunologist)

1. Administer 1% of the standard dose of the test drug (e.g. usual dose of amoxicillin or penicillin V = 500mg - start with 5mg) and document.
2. Ask the patient to report any adverse reaction (Appendix 1), monitor for 15-20 minutes and perform a set of observations (BP, Pulse, SpO₂) and document.
3. If no reaction or significant change in observations then administer further 10% of the standard dose of the test drug (e.g. 50mg of amoxicillin or penicillin V when the standard dose is 500mg) and document.
4. Ask the patient to report any adverse reaction (Appendix 1), monitor for 15-20 minutes and perform a set of observations (BP, Pulse, SpO₂) and document.
5. If no reaction or significant change in observations then administer further 50% of the standard dose of the test drug (e.g. 250mg of amoxicillin or penicillin V when the standard dose is 500mg) and document.

6. If no reaction or significant change in observations then administer the final standard dose (500mg of amoxicillin or penicillin V) and document.

BIBLIOGRAPHY:

Wood, P. (2016) Protocol for: Open oral drug challenge testing. Leeds Teaching Hospital NHS Trust.