

Supplementary material study

S1 - The live electronic patient identifier






The live feed (screen shot shown below) included the patients hospital number (blacked out in the image below), age, date of admission, bed space, details of the penicillin allergy and or sensitivity as per the electronic prescribing system, whether the patient was receiving concomitant antihistamines, a beta-blocker, supplemental oxygen, their BP and HR and their NEWS score, whether they were currently prescribed a penicillin (and name of penicillin), whether they were currently prescribed another antibiotic (name of antibiotic), the date the antibiotic was started, whether they had received a penicillin antibiotic on the EPMA system since EPMA inception (approximately 8 years ago), whether they had had an allergy history taken by the study team and the risk category of their penicillin allergy if they had. Whether there was an allergy history from the study team from a previous admission. The details of the above were visible when the computer cursor was hovered over the icon.






Penicillin Allergy Feed
 Current inpatients with penicillin allergy currently prescribed an antibiotic
 Data from: 09/01/2023 16:41

hospital no	age	admitted	bed	allergies	sensitivities	AH	BB	O2	BP	HR	NEWS	current penicillin	other abx	abx started	indication notes	prev penicillin	RIPAL note	
AMU 1 RCH																		
[blacked out]	80	07/01/2023 18:03	B6	⚠	⚠			✓	✓	✓	2			07/01/2023 18:34	⚠	✓	RIPAL unable to obtain hx (no revisit)	
[blacked out]	48	05/01/2023 15:12	D5	⚠	⚠			X	✓	✓	3			05/01/2023 15:31	⚠		RIPAL - Unable to obtain hx (re-visit)	
[blacked out]	72	05/01/2023 16:03	B5	⚠				X	✓	✓	1			05/01/2023 19:56	⚠		RIPAL HIGH	
[blacked out]	82	08/01/2023 11:11	B4	⚠				✓	✓	✓	2			08/01/2023 11:40	⚠	✓	RIPAL unable to obtain hx (revisit)	
AMU 2 RCH																		
[blacked out]	57	08/01/2023 03:03	SR7	⚠				X	✓	✓	0			08/01/2023 05:44			RIPAL HIGH	
[blacked out]	58	06/01/2023 09:46	F5	⚠				✓	✓	✓	3			06/01/2023 09:57	⚠		RIPAL HIGH	
[blacked out]	78	01/01/2023 10:10	SRS	⚠				✓	X	✓	0			07/01/2023 14:49				
[blacked out]	85	06/01/2023 12:51	E6	⚠				✓	✓	✓	2			06/01/2023 13:47	⚠		RIPAL - LOW - DOC	
DELIVERY SUITE																		
[blacked out]	21	09/01/2023 09:03	07A	⚠							0			09/01/2023 09:45				
ED - MAJORS 1																		
[blacked out]	79	09/01/2023 12:17		⚠							0			09/01/2023 13:11	⚠			
ED - MAJORS 2																		
[blacked out]	73	09/01/2023 02:01		⚠	⚠			✓			0			09/01/2023 09:30	⚠			
ED - MINORS																		
[blacked out]	54	09/01/2023 11:40		⚠	⚠						0			09/01/2023 13:27		✓		
ED - RESUS																		
[blacked out]	69	09/01/2023 10:59		⚠							0			09/01/2023 11:20	⚠	✓		
[blacked out]	76	09/01/2023 10:58		⚠				✓			0			09/01/2023 14:22		✓		
GASTRO UNIT																		
[blacked out]	07	07/01/2023 07:45	SR4	⚠	⚠						0			07/01/2023 18:00				
[blacked out]	20	03/01/2023 18:47	BB1	⚠	⚠			X	✓	✓	1	⚠		04/01/2023 03:18		✓		
[blacked out]	64	07/01/2023 13:19		⚠							0	⚠						
KERENSA WARD																		
[blacked out]	100	07/01/2023 19:15	D1	⚠	⚠			✓	✓	✓	3			07/01/2023 20:14			RIPAL HIGH	
[blacked out]	65	02/01/2023 13:00	A1	⚠	⚠			✓	✓	✓	2			02/01/2023 14:40		✓	RIPAL - unable to get history (revisit)	
LOWEN WARD																		
[blacked out]	66	29/12/2022 20:54	B3	⚠	⚠			✓	X	✓	0			03/01/2023 18:00				

S2 – Work Instructions and Toolkit

Work instruction and toolkit for Removal of Incorrect Penicillin Allergy Labels (RIPAL) study

Actions to be taken	Study documents
<p>The research study protocol is attached. Please review the protocol before proceeding.</p>	 RIPAL Study - Research protocol V
<p>Duty de-labeller to review the live web feed to identify patient likely eligible for allergy assessment and de-label (i.e. Low risk allergy history, or unverified allergy history (check RIPAL note), exclusion criteria not met, and prescribed a non-penicillin antibiotic.</p>	Crystal Report Viewer
<p>The duty de-labeller to review the medical notes to determine whether PADL would alter the antibiotic choice. If so, take an allergy focused history using the questions to guide you. Stratify the allergy risk using the decision support tool.</p> <p>Attach a “Pharmaceutical Care Plan” note to the EPMA chart and paste the allergy focused questions and responses into that note. Document the challenge dose prescribed and that there was no reaction to the challenge test after 1 hour observation. NB do not include the decision support tool in the note as it will crash EPMA (!)</p>	 RIPAL Study Penicillin allergy ass
<p>If patient eligible for de-label on history alone then seek patient consent before correcting the allergy record in the medical notes and removing it from EPMA and give the patient the ‘de-label on history alone PIS’ and the ‘patient information leaflet ‘de-label on history alone’.</p> <p>In EPMA prescribe either of the following two ‘drugs’ as stat doses:</p> <p>DELABEL OF PENICILLIN ALLERGY - HISTORY AND SUBSEQUENT ADMIN</p> <p>DELABEL OF PENICILLIN ALLERGY - DIRECT DELABEL ON HISTORY</p> <p>Ensure the appropriate letter is sent via email to the GP surgery notifying the GP of the patients new allergy status.</p>	 de-label on history alone PIS - V1 04-07
<p>Patients who meet the study inclusion criteria for a direct oral challenge (see RIPAL Study Research Protocol above) to be offered a PIS.</p>	 RIPAL PIS - V1.1 10-05-2022.docx
<p>Wait an hour before seeking consent. If the patient is not happy to proceed, then add a note to the ‘pharmaceutical care plan’ note stating why the patients does not want to proceed.</p>	 RIPAL Consent - V1.1 10-05-22.docx

<p>If patient eligible for challenge testing, then seek permission from the responsible clinician and document in section A of 'RIPAL Participant data collection sheet'</p>	
<p>Ensure 500mcg EpiPen is accessible, prescribe the challenge dose and record the patient observations as per <i>"RIPAL Study Penicillin allergy assessment and de-label Protocol"</i></p>	 RIPAL Study Penicillin allergy ass
<ol style="list-style-type: none"> 1. If the challenge test is negative prescribe 'ALLERGY TEST PENICILLIN - DELABEL NO REACTION' in the inpatient EPMA section of the drug chart. 2. Amend the letter <i>"RIPAL Study PENICILLIN ALLERGY TEST GP letter de-label V1 17-05-22"</i> and email to patient's GP. 3. Give the patient the <i>"RIPAL Study Patient information leaflet_not allergic V1 17-05-22"</i> letter and explain what a negative test means. 4. Give the patient a copy of the GP letter 5. Inform the patient a member of the study team will contact them in 5 days to see if they have experienced any delayed reactions. 	 RIPAL Study Patient information leaflet_1  RIPAL StudyPENICILLIN ALL
<ol style="list-style-type: none"> 1. If the challenge test is positive then prescribe 'ALLERGY TEST PENICILLIN - REACTION CONFIRMED' in EPMA and email <i>"RIPAL Study PENICILLIN ALLERGY TEST GP letter allergy retained V1 17-05-22"</i> letter to the GP. 2. Give the patient <i>"RIPAL Study Patient information leaflet_allergic V1 17-05-22"</i> and explain what their positive result means. 3. Give the patient a copy of the GP letter 4. When a reaction is confirmed add a Pharmaceutical Care Plan Note with the title RIPAL REACTION and detail the reaction. 	 RIPAL Study Patient information leaflet_1  RIPAL Study PENICILLIN ALLERGY

References

1. Devchand M, Urbancic K, Khumra S, et al. Pathways to improved antibiotic allergy practice - the validation of a beta-lactam antibiotic allergy assessment tool to aid accurate phenotyping and management. *Clinical and Translational Allergy* 2018; **8**(Supplement 3).

S3 - Education and training

De-labeller sign-off and accreditation

The education and sign-off process is shown below:

Key learning outcomes

- 1) A history of penicillin allergy
- 2) To be able to communicate the risks and benefits with patients of challenge testing
- 3) How to take a drug allergy history
- 4) To be able to differentiate low risk, high risk and intolerances from the allergy history using a decision support tool
- 5) The indications for challenge testing are and method for challenge testing
- 6) Understand how to conduct a direct drug provocation test
- 7) Understand how to conduct a direct de-label
- 8) understand the importance of communication with patient and other healthcare providers of new allergy status
- 9) Be able to explain the implications of a negative challenge test

These objectives are covered in the slide set below



PenA RIPAL slide set.pptx

De-labeller was asked to familiarise themselves with the study processes and documentation in the toolkit below; “Work instruction and toolkit for Removal of Incorrect Penicillin Allergy Labels (RIPAL) study”.

De-labeller was required to complete basic life support and training in the management of anaphylaxis.

Practical

- Complete Devchand’s 8 case studies¹
- Shadow a penicillin allergy de-labelling ward round led by Dan Hearsey or Neil Powell
- Lead a penicillin allergy de-labelling WR and discuss cases with Dan Hearsey or Neil Powell
- Direct drug provocation testing 5 patients, direct de-label 5 patients (Level 1)
- Direct drug provocation testing 10 patients direct de-label 10 patients (level 2)
- Direct drug provocation testing 15 patients, direct de-label 15 patients (level 3)

S4 - Additional data from the electronic prescribing and medicine administration (EPMA) system

Additional data from the electronic prescribing and medicine administration (EPMA) system for the study period: the number of patients that spent all or part of their inpatient stay on a ward visited by a member of the study team, the number with a penicillin allergy record at the time of admission to hospital, the number prescribed an antibiotic (any antibiotic), the number prescribed an antibiotic from the penicillin group, and the number who had their allergy record removed.

S5 – Additional Results Tables

Manifestation, reported nature of penicillin allergy	Number of patients
Angioedema	22
Urticaria	16
Anaphylaxis or unexplained collapse	11
Immediate diffuse rash	11
Diffuse rash or localized rash/swelling with no other symptoms < 10 years ago	8
Laryngeal involvement	8
Generalized Swelling	7
Pustular, blistering or desquamating rash	6
Respiratory compromise	6
Mucosal ulceration	3
Severe neurological manifestation	3
Diffuse rash or localized rash/swelling with no other symptoms > 10 years ago but required hospitalisation	2
Interstitial Nephritis	1
Unknown reaction, unknown timeframe, requiring hospitalisation	1
Total	105

Table 1. Penicillin allergy history phenotypes in patients classified as high risk.

Allergy manifestation	Patients successfully de-labelled by DDPT	Patients that did not undergo DDPT	Total
Childhood exanthem (unspecified)	3	4	7
Diffuse rash or localized rash/swelling with no other symptoms > 10 years ago	5	30	35
Family history of penicillin allergy only	1	0	1
Unknown >10 years ago	6	19	25
Unknown reaction, unknown timeframe	1	4	5
Total	16	57	73

Table 2. Penicillin allergy history phenotypes in patients classified as low risk and met criteria for direct drug provocation testing (DDPT). Subcategories show those that underwent DDPT and those that didn't undergo DDPT.

Allergy manifestation	Underwent DDL	Didn't undergo DDL
Angioedema	1	0
Childhood exanthem (unspecified)	2	0
Diffuse rash or localized rash/swelling with no other symptoms > 10 years ago	7	0
GI symptoms without other organ system symptoms	10	3
Mild neurological manifestation	2	2
Thrush	1	0
Unknown > 10 years ago	11	0
Unknown, unknown timeframe	6	0
Total	40	5

Table 3A Shows phenotypes of patients meeting eligibility criteria for direct de-label (DDL).

Allergy phenotype in those with subsequent tolerance to a penicillin since index reaction	Didn't undergo DDL
Angioedema	0
Childhood exanthem (unspecified)	0
Diffuse rash or localized rash/swelling with no other symptoms > 10 years ago	0
Unknown > 10 years ago	1
patient denies allergy	1
Total	2

Table 3B Shows patients phenotypes and subsequent tolerance to a penicillin since index reaction.

Reason for not obtaining penicillin allergy history	Number of patients
Patient behind curtain at time of visit	2
Patient does not consent to PADL	3
Patient is confused	11
Patient not at bedside during visit	12
Patient too unwell for PADL	5
Patient unable to give history	11
Unable to see patient - asleep	9
Unable to see patient - IPC precautions (COVID)	1
Unable to see patient - IPC precautions (norovirus)	3
Unknown	4
Total	61

Table 4. Recorded reasons for not obtaining penicillin allergy history from inpatients.

Reasons for patient exclusion from DDPT	Number of patients
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Consultant did not consent to PADL	1
Discharged before PADL could be completed	6
not study team member, ward team did	1
PADL would not have impacted on current antibiotic plan	3
Patient did not consent to PADL	14
Patient met exclusion criteria - Cardiac compromise	5
Patient met exclusion criteria - not receiving acute course of antibiotics	4
Patient met exclusion criteria - prescribed BB which could not be held for 24 hours prior	4
Patient met exclusion criteria - prescribed oxygen at time of review	6
Patient met exclusion criteria - prescribed steroids in the last 10 days	7
Patient met exclusion criteria - Respiratory compromise	4
Unable to obtain reliable allergy history	2
Total	57

Table 5. Shows reasons for patients with a penicillin allergy record suitable for direct drug provocation testing not undergoing direct drug provocation testing.

S6 - Removal of allergy records from GP electronic health systems and subsequent antibiotic prescribing

Of the 56 patients de-labelled by the study team, 9 had deceased by the time of GP record follow up and excluded. Of the remaining 47 patients, 29 (61.7%) did not have a penicillin allergy record, 17 (36.2%) did still have a penicillin allergy record on their GP records. One 1 (2.1%) didn't have an accessible electronic patient record. Of the 47 patients, 19 (40.4%) patients had received antibiotics from their GP post discharge of which 9 (47.4%) received a penicillin and 10 (52.6%) received a non-penicillin antibiotic.