Original Article

Embedding penicillin de-labelling in the AMU: a feasibility and safety pilot study with exploratory economic and environmental analysis

Bernice Ng, J McGuigan, K Allen, T Brennan- Finucane, O Toner and A Brady & P Toner

Abstract

Background: Penicillin allergy labels affect 6-10% of the UK population, yet over 95% are inaccurate. These labels drive unnecessary broad-spectrum antibiotic use, antimicrobial resistance, healthcare costs, adverse patient outcomes and carbon emissions.

Methods: This pilot study embedded a penicillin allergy de-labelling (PADL) clinic within an Acute Medical Unit, using a direct oral amoxicillin challenge for patients identified as low-risk for a true allergy to penicillin according to BSACI guidelines and PEN-FAST scoring. Primary outcomes were feasibility and safety. Secondary outcome was subsequent antibiotic prescribing patterns. Exploratory outcomes included retrospective economic, antimicrobial resistance and environmental impact modelling.

Results: Sixty patients (mean age 56 years) were included in the study, of whom 59 (98%) were successfully de-labelled with one delayed type IV reaction but no anaphylaxis. Following de-labelling, 35% received subsequent antibiotic therapy and all were prescribed penicillin-based therapy. Retrospective analysis revealed antibiotic costs were approximately tenfold higher (£19,364 versus £2,092) due to allergy labels. Multidrug-resistant organisms were present in 47% of patients and 37% received unnecessary intravenous antibiotics.

Conclusion: This pilot suggests that AMUembedded penicillin delabelling is safe and feasible, and may be associated with important clinical, economic, antimicrobial stewardship and environmental benefits that warrant confirmation in larger studies.

Keywords

Penicillin allergy de-labelling, antimicrobial stewardship, public health, multi-drug resistance, environmental impact

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Introduction

Around 6–10% of the UK population, about 3 million people, carry a penicillin allergy label, yet over 95% can tolerate beta-lactams with true immune-mediated allergy affecting only about 1%.[1-3] Inaccurate penicillin allergy labels often stem from misclassified benign rashes, waning IgE-mediated sensitivity over time and self-reported intolerances that reflect viral illness or nonspecific adverse reactions rather than true allergy.[4-8]

Robust evidence supports penicillin allergy de-labelling (PADL) as safe, effective and integral to antimicrobial stewardship (AMS). For low-risk patients, direct oral challenge (DOC) has largely replaced traditional allergy testing, guided by British Society for Allergy and Clinical Immunology (BSACI) recommendations and the PENFAST score. PENFAST is a validated clinical decision rule that stratifies risk of true penicillin allergy based on time since reaction, the presence of anaphylaxis or angioedema and the need for adrenaline treatment. Scores range from 0 to 5, with a score of less than 3 indicating a low probability of true IgEmediated allergy and a reported negative predictive value of approximately 96%.[22,23]

The choice of an aminopenicillin is important to evaluate intolerance to both the beta-lactam core and the specific side chains. The two principal immunological triggers of penicillin allergy are the beta-lactam ring and the R-group side chain (Figure 1). While reactivity to the R-group side chain (e.g., in aminopenicillins) is globally uncommon, it is more frequently reported in European populations.[5]

Given that between 36 – 50% of hospitalised patients receive at least one course of antibiotics during their inpatient admission, and that misuse of antibiotics is acknowledged as the main driver of antimicrobial resistance (AMR), accurate identification and removal of an incorrect penicillin

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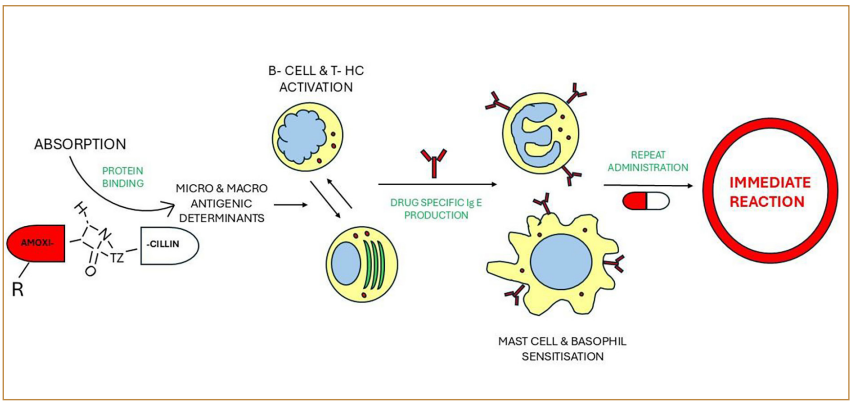


Figure 1. Diagrammatic representation of immunological sensitisation to amoxicillin.
Amoxicillin with highlighted R group and β-lactam ring undergoing protein binding, following absorption. The resulting antigenic determinants activate B- cells and T- helper cells. These activated cells subsequently produce specific IgE, which are expressed on mast cells and basophils, in preparation for repeat administration.

allergy label is of critical importance.[9] The Acute Medical Unit (AMU) is arguably the optimal setting to embed PADL. It is often the initial site for medicine reconciliation and treatment initiation and sits at the point of highest prescribing potential. Empirical antibiotics are commonly commenced on admission to an AMU and early optimisation of allergy status has significant downstream effect on the entire inpatient episode and subsequent readmissions. AMU pathways are typically protocolised, multidisciplinary and timedefined making the units well suited to standardised risk stratification, supervised DOC with reliable documentation and communication of updated allergy status.

Potential benefits include:

Patient Outcomes

Penicillin allergy labels result in displacement of first-line antimicrobial therapy and the increased use of broad-spectrum antibiotics.[10] Recent meta-analytic data confirm that penicillin allergy labelling is associated with a 6% increase in mortality risk, alongside elevated risks of acute heart failure, surgical site infections and intensive care unit (ICU) admissions.[11-13, 30]

Economic outcomes

Inpatients with a penicillin allergy label have significantly longer lengths of stay, higher hospital readmission rates upon discharge, and are at increased likelihood of requiring escalation to critical care.[13]

Economic modelling has demonstrated substantial savings in various methods of allergy challenge.[14,15] A cost-analysis reported that the total acquisition cost of second-line antibiotics prescribed for patients with penicillin allergy was 1.82 – 2.58 times higher than for first line (beta-lactam) antibiotics.[16] However more recent economic evaluations concluded no cost saving, and economic viability was highly dependent on setting and method of delivery.[29]

Antimicrobial Stewardship and Public health outcomes

The AMR crisis represents one of the most urgent threats to global public health, with the UK's 20-year vision prioritising its containment.[17] Despite national reductions in antimicrobial exposure, AMR infections continue to rise, partly driven by the inappropriate use of broad-spectrum agents in patients with unverified allergy status. Notably Northern Ireland has the highest consumption of antibacterials per capita in the UK, with usage continuing to trend upwards.[18-20]

Environmental outcomes

Medicines account for approximately 25% of the NHS's total carbon emissions, with antibiotics making a significant contribution.[33, 34] The environmental impact of pharmaceutical production, distribution, use and disposal creates a substantial and often overlooked dimension of the penicillin allergy problem. Importantly, the carbon footprint differential between oral and intravenous (IV) formulations is striking. A 2025 assessment comparing oral and IV penicillin treatments found that the overall environmental impact ranged from approximately 4% to 14% of that of IV treatment, with the majority of IV treatment emissions stemming from additional equipment required for administration.[35]

The **P**enicillin **A**llergy **N**on- Allergist **D**e- labelling in the **A**cute Medical Unit (**PANDA**) study is a single centre feasibility pilot. The primary objective was to assess the feasibility and safety of embedding a penicillin allergy delabelling service within an AMU using a direct oral amoxicillin challenge for lowrisk patients. Secondary objectives were to assess subsequent penicillin prescribing after delabelling. Exploratory objectives were to generate hypothesisforming estimates of the potential economic, antimicrobial resistance and environmental impacts of inaccurate penicillin allergy labels in this population.

Methods

This was a prospective feasibility and safety pilot study conducted in the Royal Victoria Hospital Belfast. The study was embedded within the AMU, which serves as the primary point of admissions for medical patients across all sub specialities.

During the pilot period, adult inpatients in the AMU were identified during routine medicines reconciliation or on consultant PTWR. Some patients were referrals from other specialities such as infectious diseases, nephrology, immunology or surgery. Recruitment was consecutive on weekdays during

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staffed hours; outofhours admissions were reviewed the next working day. Of the 64 patients approached 60 provided verbal and written informed consent and underwent DOC.

Risk stratification and clinical protocols for the drug challenge were developed in accordance with BSACI guidelines, current pharmacological literature and local immunology guidance. Prior to study initiation, all necessary governance approvals were secured, and PANDA staff underwent simulation-based training focused on the identification and management of anaphylaxis. Recruitment and initial risk stratification were undertaken by an acute medicine consultant together with a clinical pharmacist. PENFAST scores were assigned jointly by this clinician–pharmacist team based on the documented allergy history and patient interview. DOC prescriptions were issued by the responsible acute medicine doctor and administered by AMU nursing staff in an AMU clinical area, with immediate access to resuscitation facilities and anaphylaxis kits

Lowrisk histories were operationalised as: (i) isolated benign rash or nonurticarial (ii) nonspecific symptoms such as gastrointestinal upset, headache or 'intolerance'; or (iii) remote reactions more than 10 years previously, without features of anaphylaxis, angioedema or respiratory compromise. Patients with a confirmed history of Type I or severe Type IV hypersensitivity were excluded.

Physiological exclusion criteria (moderate–severe respiratory disease, severe aortic stenosis, pregnancy, NEWS ≥2 or recent ACE inhibitor/betablocker use) were selected on safety grounds to minimise the risk and consequences of haemodynamic compromise or bronchospasm in the event of an unexpected reaction and to align with BSACI recommendations for lowrisk DOC in nonallergy settings. (Figure 2).

Following informed consent, baseline physiological parameters were recorded. Participants were counselled on the clinical manifestations of hypersensitivity reactions and instructed to promptly report any symptoms to their assigned nurse.

Patients were observed in the AMU for 60 minutes after administration of a single 500 mg oral dose of amoxicillin, with physiological observations recorded at 10, 20, 40 and 60 minutes. A structured followup at 24 hours was undertaken to identify delayed reactions and reinforce removal of the allergy label. A formal communication was issued to both the patient and their GP to document the updated allergy status, ensuring integration into primary care records and future prescribing decisions.

Primary outcomes were feasibility and safety. Secondary outcome was subsequent antibiotic prescribing patterns over the succeeding 6 months. An exploratory retrospective cost comparison

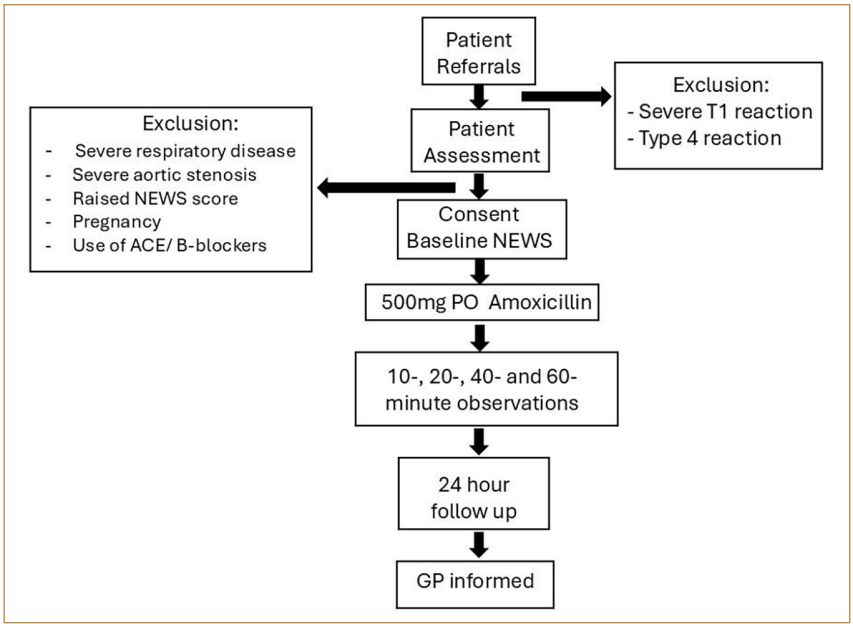


Figure 2. Diagrammatic representation of the process.

was undertaken. For each inpatient admission in the year preceding the PADL intervention, the antibiotic regimen prescribed to patients was compared with the guidelinerecommended firstline regimen that would likely have been used in the absence of such a label, based on diagnosis, microbiology and local protocols. This analysis was intended to generate hypothesisforming estimates of potential cost and environmental impact rather than a formal health economic evaluation, and did not include pathway delivery costs, LOS, complications or readmissions

Results

Demographic

A total of 60 patients were included, 59 (98.3%) were successfully de- labelled (47% male) with an overall mean age of 56 years (range 27–83). Most were identified in the AMU (47%), with others from medical referrals such as immunology, microbiology or infectious diseases services (Table 1).

A reported penicillin allergy since childhood was documented in 62% of participants; 26% had no recollection of the initial reaction but were informed by parents and 12% had received the label within the previous five years. Over half (52%) had no other recorded drug allergies, while 17% reported allergies to three or more additional classes of antibiotics. The most frequent adverse reactions reported were rash (48%) and gastrointestinal upset (26%), with 22% undocumented or unknown. Other reported symptoms included diarrhoea, acute kidney injury, peripheral oedema and abnormal liver function tests (Table 2).

Comorbidities were present in 71% of patients. These included type 2 diabetes (with or without ulceration),

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Table 1. Baseline data
Data are percentages of total patient population, except when indicated.

Baseline demographic	
Total (n)-	59
Gender-	
Female (%)	53
Male (%)	47
Mean age (years)	56
Referral-	
Acute Medical unit (%)	47
Nephrology (%)	15
Promotion (%)#	12
ID (%)	8
Immunology (%)	8
Oncology (%)	3
Microbiology (%)	3
From incident (%)	2
Surgical (%)	2
Comorbidities (%) *	
Respiratory	27
Cardiology	37
Haematology	17
Diabetes	15
Other	29

*Some patients had multiple comorbidities
#Patients referred either following presentations to raise awareness of service

Table 2. Allergy details
Data are percentages of total patient population.

Allergy details	
PEN- FAST Score (%):	
0 (very low)	92
1- 2 (low)	7
3 (moderate)	1
4-5 (high)	0
Other allergies (%):	
0	52
1-2	31
≥ 3	17
Date of allergy diagnosis (%):	
Childhood	62
Unknown	26
≤ 5 years	12
Type of reaction (%):	
Rash/ itch	48
GI upset	26
Unknown	22
Deranged LFTs	2
Other	2

intravenous drug use, chronic lung disease, chronic kidney disease and immunosuppression related to transplantation or oncology treatment.

Primary and safety outcomes

The success rate for de-labelling following DOC was 98.3% (59/60 patients). One patient developed a delayed type IV hypersensitivity reaction that did not require admission, their penicillin allergy status remains. No other adverse events were recorded, and no episodes of anaphylaxis occurred.

Secondary outcomes

In the 6 months following delabelling, 21/60 (35%) patients subsequently required a course of antibiotics, and all received penicillinbased antibiotics without any adverse effect.

Exploratory outcomes

Economic

Across 67 antibioticrelated admissions, total antibiotic acquisition costs in labelled patients were £19,364 compared with an estimated £2,092 had firstline penicillinbased regimens been used. These estimates are derived from retrospective modelling of likely prescribing and exclude downstream costs such as extended length of stay or complications.

Public Health

Retrospective analysis demonstrated that during these admissions patients received broad spectrum agents when targeted penicillin agents would have been first line. Furthermore, two cases of *C. difficile* infection and two cases of hospital-acquired pneumonia occurred. A total of 47% of patients had cultures positive for multidrug-resistant organisms.

Environmental

In 37% of cases an IV antibiotic was used when an oral penicillin-based antibiotic would have successfully treated the infection. The analysis is hypothesisgenerating and does not constitute a formal carbon footprint assessment.

Discussion

This PANDA pilot study suggests that a PADL embedded in AMU is both deliverable and safe. With a 98.3% successful de-labelling rate, these findings signal that non-allergist clinicians can safely deliver PADL using validated tools to develop simplified, scalable de-labelling protocols integrated into routine clinical practice. The strategic positioning of this

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service within acute medicine, rather than traditional allergy or infectious diseases services, offers a unique opportunity to meet patient safety imperatives, AMS priorities and environmental sustainability targets.

Clinical outcomes and Patient safety

The AMU provides an optimal environment for PADL. As the primary site for initial assessment and medicines reconciliation, the AMU carries significant prescribing influence, making early correction of inaccurate allergy labels impactful across the admission and future hospital encounters. In this pilot study, 21 patients subsequently received penicillin-based therapy, demonstrating clear immediate therapeutic benefit.

The AMU's multidisciplinary structure promotes knowledge sharing with multiple opportunities to identify and monitor de-labelling candidates, embedding PADL within routine acute care rather than as a standalone intervention. Acute Medicine teams are well placed to deliver PADL safely, supported by national training requirements in acute care, resuscitation, antimicrobial stewardship and safe prescribing. A comparatively high pharmacist-to-patient ratio further strengthens medicines reconciliation and candidate identification.

Economic Impact and Cost-Effectiveness Considerations

The economic burden of penicillin allergy labels operates through multiple mechanisms, and the PANDA study provides preliminary real-world signals of this financial impact. The economic findings should be interpreted as exploratory; they rely on retrospective counterfactual modelling and drug acquisition costs only. A full costeffectiveness evaluation would need to account for service delivery time, staff training, monitoring, and broader downstream impacts such as reduced LOS, complications and readmissions based analysis.[16] Most patients in our cohort had multiple comorbidities and immunosuppressive conditions, increasing their need for repeated antibiotic courses. This suggests that targeted de-labelling in medically complex patients may yield disproportionately greater economic benefits, meriting further cost-effectiveness evaluation. Differences in prescribing patterns between NI and GB may also contribute. A 2025 UK study similarly found no short-term cost savings from DOC outpatient clinics, highlighting the need to assess long-term impacts[29]. The PANDA model's integration within the AMU offers a cost-efficient alternative by utilising existing multidisciplinary staff, facilities and nursing support.

Antimicrobial Stewardship and Public Health Implications

In our PANDA cohort, broad-spectrum antibacterial agents such as fluoroquinolones, macrolides, glycopeptides and third-generation cephalosporins were prescribed when penicillin-based therapy could have been first-line. Each of these drug classes carries specific resistance selection risks. A total of 47% of participants in this study cultured multidrug-resistant organisms (in addition to two cases of *C. difficile* infection). This acutely demonstrates the AMR burden in populations with a penicillin allergy label. This finding also aligns with published data demonstrating that documented penicillin allergy is associated with an increased risk of MRSA and of *C. difficile.* [31]

The UK's 2024–2029 National Action Plan for Antimicrobial Resistance emphasises infection prevention, optimized antimicrobial use and strengthened surveillance as core pillars [32]. Systematic PADL programs offer a high-impact AMS intervention that directly addresses inappropriate broad-spectrum use while simultaneously improving patient outcomes.

Environmental Sustainability and NHS Net Zero Alignment

The environmental dimension of penicillin allergy labels has emerged as an increasingly noticeable concern within the context of NHS net zero commitments. Given published estimates that oral antibiotic regimens have significant environmental impact compared to IV treatment, replacing unnecessary IV broadspectrum therapy with appropriate oral penicillinbased regimens may contribute to antimicrobial stewardship and NHS Net Zero goals. However, the PANDA analysis was qualitative and did not quantify emissions, future studies should incorporate standardised medicine carbon footprint methodologies.[35]

By enabling appropriate oral narrow-spectrum therapy, PADL has the potential to simultaneously optimise patient care, reduce AMR selection pressure and minimise carbon emissions, aligning acute medicine practice with NHS sustainability commitments while maintaining clinical excellence.

Limitations and Future Directions

This feasibility study has several limitations. Firstly, the PANDA pilot study has a relatively modest sample size of 60 patients, limiting generalisability. Multi-centre implementation across diverse AMUs would strengthen the evidence base. Furthermore, we have not collected the complete screening denominator, largely because it was a feasibility pilot study with a pragmatic data collection design. However, the incidence of false allergy status is well described. The economic analysis was retrospective, based on modelled standard regimens and drug acquisition costs alone, and did not include service delivery costs, LOS or complications. Finally, the environmental assessment was descriptive rather than quantitative

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and did not include formal carbon foot printing of antibiotic pathways.

Conclusion

In this singlecentre feasibility pilot, an AMUembedded PADL service using direct oral amoxicillin challenge for lowrisk patients was safe and operationally deliverable, with a 98% delabelling success rate and no serious adverse reactions. The service generated early evidence of improved access to firstline penicillin therapy and highlighted potentially large differences in antibiotic acquisition costs and unnecessary IV use associated with inaccurate allergy labels, although these economic and environmental findings remain exploratory.

As the NHS confronts the emerging dual crises of AMR and climate change while navigating established resource constraints, interventions that simultaneously improve patient safety, optimise antimicrobial prescribing, reduce costs and decrease carbon emissions should be prioritised. Embedding PADL within AMU may represent a pragmatic, scalable strategy to improve patient safety and support both antimicrobial stewardship and sustainability goals, however larger multicentre studies with formal economic and carbon footprint evaluations are required to confirm impact. The integration into routine acute medical care should be regarded not as a specialty service but as a fundamental component of high-quality acute medicine practice.

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Transparency declarations

The authors have no financial or ethical conflicts of interest regarding the contents of this manuscript.

Ethics & Governance

This project was conducted as a service evaluation and service development initiative within Belfast Health and Social Care Trust. It was reviewed and approved by the Trust governance process and did not require formal research ethics committee review under UK Health Research Authority guidance. All patients provided informed consent for delabelling and for use of anonymised data in aggregate reporting.

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