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Full title of the Study: A Multicentre Study to Investigate a Protocol-Driven Multidisciplinary Service Model to Tackle 'Spurious Penicillin Allergy' in Secondary Care (SPACE study)

IRAS ID: 293544, REC Reference 21/PR/0814: Acknowledgement of end of study

Sponsor organisation name: University Hospitals Birmingham NHS Foundation Trust

Study start date: 01 May 2021

Study end date: 30 April 2023

Funders reference number: NIHR129069

Name of Registry: <https://doi.org/10.1186/ISRCTN55524365>

Date of Registration: 26/08/2021

Is the study protocol publicly available: Yes

Lay summary of results:

There is a huge burden of penicillin allergy in the NHS. Around six out of hundred people in England say they are allergic to penicillin. However, previous research has shown that 90-95% of patients are not actually allergic following specialist review and allergy skin tests. Allergy skin tests are not routinely available in all hospitals, as they are time consuming and there are very few allergy specialists in the NHS. Patients with penicillin allergy labels receive other antibiotics and these are not as effective in clearing infections, they cause more side effects and increase the risk of 'superbug infection'.

We developed a simple way to remove incorrect penicillin labels in patients who are at a very low risk of a genuine allergy. This involved a test dose or a challenge test in hospital after explaining the procedure and obtaining an informed consent. The challenge test was performed by nurses and pharmacists with supervision of a study consultant who had no specialist background in allergy. They were however trained to assess patients and do the challenge test as needed for the study. We included patients admitted in hospital wards and outpatients from surgery and cancer units in three hospitals.

We screened 2257 patients with penicillin allergy labels and 270 patients consented to participate. After review, 155 were considered as 'low risk' of penicillin allergy. 126 'low risk' patients had a challenge test and we showed that 122 (97%) did not have a true penicillin allergy. One patient developed stomach upset and three had mild rash.

A large number of patients that were screened did not make their way to the consent stage of the study. The main reasons were medical or mental health related at the time of screening, not being able to reach out to patients and inability to give informed consent to participate in this research. Also, the pandemic put some restrictions to research as normal flow of patients was affected in hospitals. We found outpatient settings offered better opportunities to do penicillin challenges compared to busy wards in hospitals.

We spoke to patients and healthcare staff about this pathway. Healthcare staff understood the importance of doing a challenge test and removing inaccurate penicillin allergy labels but thought that training, safety and resources were required. Patients were keen to find out if they were really allergic and felt safe doing the challenge test in hospital. Our study showed that the cost-saving appears small in the short-term and more research is needed to understand the longer-term benefits.

In this study, we showed that a penicillin challenge test can be delivered by non-allergy healthcare staff with appropriate training and in a safe hospital setting. We developed recommendations for wider roll-out of this pathway and gained good understanding of how it would work in the 'real-world'. Going forward, we need to look into ways in which we could reach out to more patients when they are well and clinically stable, offer the test to those who have mental health issues as well as to those that are unable to speak English language.

We have done presentations locally and at a national conference to share our findings with healthcare staff. Also, we have done a press release to share our findings with members of the public and highlighted in a letter to the Times newspaper (9.10.23). The clinical part of the study has been published in a medical journal

([https://www.journalofinfection.com/article/S0163-4453\(24\)00034-3/fulltext](https://www.journalofinfection.com/article/S0163-4453(24)00034-3/fulltext)). We are aiming to publish two more manuscripts. We are also planning to hold an event in Jun'24 to share our study findings with various stake holders and our patient partners.

Has the registry been updated to include summary of results:

Did you follow the dissemination plan submitted in the IRAS application form? YES

Have the patients been informed about the results of the study? NO

Have you enabled sharing of study data with others? NO

Have you enabled sharing tissue samples and associated data with others? N/A