

Developing a behavioural intervention package to identify and amend incorrect penicillin allergy records in UK general practice

Marta Santillo (✉ marta.santillo@phc.ox.ac.uk)

University of Oxford <https://orcid.org/0000-0001-6345-7612>

Marta Wanat

University of Oxford

Mina Davoudianfar

University of Oxford

Emily Bongard

University of Oxford

Sinisa Savic

University of Leeds

Luoise Savic

University of Leeds

Catherine Porter

University of Leeds

Joanne Fielding

University of Leeds

Chris Butler

University of Oxford

Sue Pavitt

University of Leeds

Jonathan Sandoe

University of Leeds

Sarah Tonkin-Crine

University of Oxford

Research

Keywords: intervention development, penicillin allergy testing, general practice

Posted Date: December 18th, 2019

DOI: <https://doi.org/10.21203/rs.2.19097/v1>

License:  This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background: To develop a behavioural intervention package to support clinicians and patients to identify and amend incorrect penicillin allergy records in English general practice. The intervention aimed to: 1) support general practice clinicians to refer patients for penicillin allergy testing (PAT), 2) support patients to attend for PAT and 3) support clinicians and patients to prescribe or consume penicillin, when indicated, following a negative PAT result.

Methods: Theory-based, evidence-based and person-based approaches were utilised in the intervention development. We used evidence from a rapid review, two qualitative studies, one with patients and one with general practice clinicians, and expert consultation with the clinical research team in order to identify the intervention guiding principles and develop an intervention plan. Barriers and facilitators to the target behaviours were mapped to behaviour change theory in order to describe the proposed mechanisms of change. In the final stage, think-aloud interviews and consultations with the clinical research team were conducted to optimise intervention materials.

Results: The collated evidence showed that the key barriers to referral of patients by clinicians were limited experience of referral and limited knowledge of referral criteria and PAT. Barriers for patients attending PAT were lack of knowledge of the benefits of testing and lack of motivation to get tested. Intervention materials were designed and developed to address these barriers.

Conclusions: We present a novel behavioural intervention package designed to address the multiple barriers to uptake of PAT in general practice by clinicians and patients. The intervention development details how behaviour change techniques have been incorporated to hypothesise how the intervention is likely to work to help amend incorrect penicillin allergy records. The intervention will go on to be tested in a feasibility trial and randomised controlled trial in England.

Background

Incorrect penicillin allergy records are common, as side effects and symptoms of illness can be mistaken for allergic reaction symptoms (1). About 6% of the UK general practice population has a record of a penicillin allergy but fewer than 10% of these patients are likely to be truly allergic (2). As a result, a significant portion of the population is denied effective first line antibiotics for many common infections. Moreover, penicillin allergy records are also linked to antimicrobial resistance (AMR): evidence suggests that patients with a penicillin allergy label are more likely to be prescribed broad spectrum antibiotics and to acquire antibiotic resistance infections (3, 4).

Penicillin allergy testing (PAT) is already provided in the NHS in specialist clinics (5) and offers the opportunity to confirm or discount a penicillin allergy label. This service is only available to a subset of patients following NICE guidance (6). Current assessment is performed over two clinic visits.

The ALABAMA (Allergy Antibiotics and Microbial resistance) study aims to develop a behavioural intervention package for general practice to effectively amend incorrect penicillin allergy records. The intervention package is designed to target both general practice clinicians and patients with a suspected incorrect penicillin allergy record. It introduces a pre-emptive ‘penicillin allergy assessment pathway’ (PAAP) which targets patients assessed as “low risk” of true allergy, who are not at risk of anaphylaxis or other severe adverse reactions, and it aims to streamline the test process by undertaking patient history screening in general practice (Stage 1) and introducing an efficient one-stop procedure at a hospital clinic for the penicillin allergy test (PAT). The test includes either a skin test (ST), testing penicillin solution on the forearm (Stage 2), and oral challenge test (OCT), taking doses of penicillin solution over time (Stage 3), or just OCT depending on the individual patient. Following the PAT, patients and practices will receive confirmation of a patient’s allergy status.

This paper describes the planning, development and optimisation of the ALABAMA PAAP intervention package.

Methods

Intervention planning methodology

We followed an integrated approach to intervention development that combines theory-, evidence- and person-based approaches (7–9). This approach has been successfully used in the development of a variety of behavioural interventions including for reduction of antibiotic prescriptions in European general practice (10). The ALABAMA intervention package was developed in three stages; 1) collating evidence, 2) intervention planning, and 3) optimisation of intervention materials. In stage 1, a rapid review and a series of qualitative interviews were conducted to examine the behavioural needs, issues and challenges of clinicians about referring patients to PAT and of patients that are asked to attend PAT. We also explored the needs, issues and challenges of clinicians about prescribing penicillin after a negative penicillin allergy test results, and of patients about taking penicillin prescribed first line. As part of this first stage we consulted immunology and behaviour change experts in our wider clinical and research team.

In line with the person-based approach (5), the evidence collated from the rapid review, the qualitative interviews and the experts’ opinion discussions was brought together in Stage 2 to create the guiding principles, the behavioural analysis and the logic model. The guiding principles identified the intervention objectives and key design features. The behavioural analysis mapped the barriers and facilitators to the Theoretical Domains Framework (TDF) domains (10) and Behaviour Change Wheel (11). The logic model provided a visual representation of the intervention targets and the psychological mechanisms that explained the relationship between the intervention components and the outcomes. A description of the intervention was completed following the TIDieR (12) guidance (supplementary materials).

In stage 3 the intervention materials developed based on the evidence in stage 1 and the behavioural analysis in the stage 2, were optimised through the use of think-aloud interviews with GPs and patients and feedback from members of the wider research and clinical team.

The ALABAMA programme grant involved PPI members, as co-applicants, and study advisors from the start so research questions were informed by their input. Patients were involved as participants within the exploratory qualitative work and their experiences were used to inform intervention development. Patients were again involved in think aloud interviews to help develop specific materials within the intervention package. Results of all work from the ALABAMA programme will be disseminated with the help from our PPI co-apps and our existing PPI networks towards the end of the programme grant.

The methods and key results for each stage are presented below.

Results

Stage 1: Collating and analysing evidence

Rapid review

The full rapid review is available elsewhere (11). Rapid review is a form of synthesis which supports the review of existing evidence in a timely manner (12). It aimed to explore clinicians' and patients' views and experiences of penicillin allergy testing services.

Outcomes

The review identified only two studies which reported patients' views of PAT. All patients thought that PAT would provide valuable medical information. The majority of patients reported limited knowledge of penicillin allergy and PAT services. Clinicians reported several barriers to referring patients for PAT. These included difficulties establishing the allergy history, lack of knowledge on referral processes and organisational pressures making allergy testing a low priority. A number of clinicians and patients reported being reluctant to prescribe or consume penicillin after a negative PAT result.

Qualitative interviews

Full details of the qualitative work are available elsewhere (13). Two qualitative studies were undertaken by MW; one interviewing 31 patients with a penicillin allergy record (16 with previous experience of PAT) and the second interviewing 19 general practitioners. The aim was to identify patients' and clinicians' views on the barriers and facilitators for PAT and antibiotic use after a negative test. Semi-structured interviews were conducted over the phone by an experienced qualitative researcher (PhD qualified) with substantial previous experience of conducting qualitative research. Patients were identified from a

general adult hospital allergy clinic and from general practices in the same geographical area. Clinicians were identified in general practices and by the local microbiology services.

Outcomes

An inductive thematic analysis approach was used to analyse data. The majority of patients who were motivated to get tested had experienced a negative consequence of having a penicillin allergy label (such as limited availability of antibiotics they could use). Patients reported concerns about the possibility of having an allergic reaction during PAT; the degree of the severity of their previous reactions affected how apprehensive they were about the test. Moreover, when the test was perceived as more invasive, e.g. the OCT compared to the ST, patients reported being more concerned about PAT. Patients were also concerned about how much they would be monitored during the test and highlighted the importance of feeling informed, safe and observed by qualified professionals. Some patients reported being unsure about a negative test result and feeling anxious about taking penicillin if prescribed, as they doubted whether the test result was accurate.

Clinicians reported that they often felt that penicillin allergy records were incorrect however reported uncertainty about how to identify patients with true penicillin allergy and were reluctant to amend medical records without objective evidence. Penicillin allergy status was not seen to be a major problem in general practice due to the availability of alternative antibiotics and clinicians struggled to identify the risks of incorrect allergy records. Clinicians were seen to differ in their consultation styles when speaking to patients about their antibiotic prescribing decisions and allergy status. They reported lack of experience of PAT services and the need for more information on referral criteria. Regarding the process of changing a patients' record after a negative test result, clinicians reported being happy to update medical records on directions from secondary care but were unsure who was responsible for making sure that patients understood allergy test results.

Expert Discussions

As part of this first stage we consulted our wider clinical research team using monthly tele-conferences and emails to gain their feedback on several aspects of the intervention development, such as the interpretation of evidence collated in the rapid review and the qualitative studies, the development of early iterations of the intervention materials, and the development of the initial intervention plan and components. The clinical research team included a consultant immunologist, a consultant microbiologist, a consultant anaesthetist, a general practitioner and professors with expertise in applied health research.

Stage 2: Intervention planning and development

Creating guiding principles

In line with the person-based approach (7) brief guiding principles were created to be consulted through the whole intervention development process. This ensured that the intervention met the original objectives. Based on the findings of the rapid review, qualitative interviews and expert discussion, the characteristics and behavioural needs of the target users were identified. Guiding principles were then created to outline the intervention objectives and the key design features which addressed them.

Outcomes

Table 1 presents the ALABAMA guiding principles. These focused on increasing confidence to refer and attend for PAT and increasing motivation to prescribe/consume penicillin following a negative PAT result. Guiding principles also included increasing clinician confidence in discussing penicillin allergy with patients and improving communication between primary and secondary care about penicillin allergy status. Lastly the intervention needed to present the PAAP as reliable and trusted and provide accessible and easy to use materials for clinicians and patients.

Behavioural analysis

The aim of the behavioural analysis was to use behaviour change theory (14) to describe the content of the ALABAMA intervention package and map the evidence from the rapid review, qualitative studies and expert consultations.

The first step of the behavioural analysis process was to identify target behaviours, their barriers and facilitators, and how intervention components would support desired behaviour change based on evidence collated in stage 1. Intervention components were mapped to the TDF framework(15) and the Behaviour Change Wheel (BCW)(14) referring to the Behaviour Change Techniques Taxonomy (BCTv1) (16). This produced a list of TDF barriers, target constructs (what needs to change for the behaviour to occur), intervention functions (ways an intervention can change behaviour) and behaviour change techniques used for each of the barriers/facilitators.

Outcomes

The full behavioural analysis is presented in additional files (see Additional File 1). Firstly, we identified barriers and facilitators to referral of low risk patients to PAT and patient attendance to PAT. The analysis highlighted that both clinicians' and patients' knowledge and perceptions of penicillin allergy and test procedures could be modified; information needed to be supported by scientific evidence for clinicians and patients to be reassured that the test was safe. We designed a resource for clinicians entitled "Penicillin Allergy Testing: Information for general practice" which contained information on penicillin allergy and PAAP procedures. As part of the ALABAMA trial, this will be supported by site training and working instructions which provide practical guidance on screening patients and referral to PAT (relevant BCTs for clinicians were 'information about antecedents' and 'information about health consequences').

For patients we developed two patient booklets, one to be provided prior to PAT and one following a negative test result. All patients, on entering the trial, will have a consultation with a GP to answer questions and address concerns about PAT. We developed a patient booklet entitled “Penicillin Allergy Testing: going for a test” which included information on PAAP procedures and PAT safety (relevant BCTs for patients were ‘information about health consequences’ and ‘feedback on outcomes of the behaviour’).

The barriers to the prescription and consumption of first-line penicillin following a negative test result were patient and clinician beliefs about the accuracy of PAT and whether taking penicillin was safe. Clinicians also needed reassurance that colleagues saw de-labelling as beneficial and resources to support them in changing incorrect penicillin allergy records. We developed a second patient booklet entitled “Penicillin Allergy Testing: a negative test result”, which contained information about which antibiotics patients could safely take in the future following a negative test result, a negative result intervention card and a result letter which confirmed the patient allergy status to penicillin (relevant BCTs were ‘social support’ and ‘restructuring of the social and physical environment’). As part of the trial, clinicians received working instructions, which contained guidance on how to change the patient allergy label in medical records, result letter which confirmed the patient allergy status to penicillin, and an electronic-pop up, which included a reminder of the patient’s new allergy status (relevant BCTs were ‘feedback on outcomes of behaviour’ and ‘adding objects to the environment’).

Logic modelling

The next step included the development of a logic model, which summarised the behavioural analysis, providing a diagrammatic representation of the hypothesised processes and causal pathways from the intervention components to the desired outcomes (17, 18).

The research team opted for a process oriented iterative logic model which was refined during the whole intervention development stage.

Outcomes

The logic model (Figure 1) included four components:

Intervention components and techniques: Intervention components were organised based on the two target groups (clinicians and patients). Intervention techniques summarised the BCTs used as part of the intervention which were identified in the behavioural analysis.

Intervention processes: These were the psychological factors which explained the relationships between the intervention components and the outcome of the intervention: each intervention technique was hypothesised to mainly affect one of these processes. As part of the intervention, clinicians would receive information on penicillin allergy and implications of incorrect allergy records in order to increase their knowledge of PAT and allergies. In addition to this, providing medical and scientific evidence and current

guidelines on how to perform PAT would change their professional identity related to their role in the referral process and act as reinforcement to increase their motivation to refer patients in the future. Regarding the processes affecting patient's attendance of PAT, providing evidence of penicillin as best treatment and the safety of PAT would increase their beliefs of positive consequences of accurate records; informing them of common reactions during PAT and reassuring them of monitoring at the clinic and at home would increase their knowledge on PAT, decrease their negative emotions, such as anxiety, and act as positive reinforcement to attend the clinic.

Both patients and clinicians would receive evidence of the accuracy of PAT, and of safety of prescribing penicillin after a negative test result, in order to increase their belief about positive consequences of prescribing penicillin after a negative test result. Finally, providing a negative test result card to use with clinicians would affect patients' expectations of social influences regarding clinician's acceptance of the test result.

Purported mediators: These are the target behaviours of the intervention which directly affect the outcomes. In the logic model the assessment of potential incorrect penicillin records was operationalised as the referral of low risk patients to PAT and patient attendance at PAT. The introduction of the PAAP was hypothesized to affect the change of incorrect penicillin allergy records (clinician changing medical records and patient acceptance of change of penicillin allergy status) which would ultimately affect the consumption of penicillin.

Outcomes: The behavioural outcomes of the model were the prescription and consumption of first-line penicillin when indicated. The main outcome of the trial is "treatment response failure" to assess patient recovery from infection when taking antibiotics.

Stage 3: Optimising the intervention materials

Think-aloud interviews with GPs

Think aloud telephone interviews were conducted with 6 participants by MW; 2 additional participants provided feedback via email. Interviews asked about views of each section of the "Information for general practice leaflet" developed for clinicians.

Outcomes

The leaflet was well received. Participants reported that it was informative, useful and generally easy to read. The participants perceived it not only as information for themselves, but also a tool to use in a consultation with patients. Some participants felt that they knew about the consequences of incorrect penicillin allergy record; and therefore the leaflet could be shortened. Most participants understood the testing stages; however, a couple of participants were confused about which stages of the test patients

could skip. One participant wanted exact doses of penicillin specific (rather than just amounts). Regarding the section on patient discussions, some clinicians felt that there was no need to discuss the test with patients. Participants queried whether being tested with amoxicillin meant that the patient could now take all penicillin based antibiotics and wanted more information.

Clinicians' feedback was collated and organised in a 'table of changes' (see Additional Files 2) where suggested changes were listed and given a level of priority for that change, following the MoScoW framework (19), and the source of the suggested change (expert opinion, research team, clinical research team, literature review). Changes to the 'Information for general practice' included changes to the title, to the exact doses of penicillin given to the patients during the test, information about side effects and information about which antibiotics patients with a negative test result can take safely.

Think-aloud interviews with patients

Think aloud interviews telephone interviews were conducted with 7 patients (3 with experience of PAT and 4 with no experience) by MW. Interviews asked their views about the two patient booklets ("Penicillin Allergy Testing: going for a test", "Penicillin Allergy testing: a negative test result") and the intervention card.

Outcomes

The booklets and intervention card were very well received by the participants. Participants considered the booklets to have the right amount of information and felt they were generally easy to read. Patients reported that the booklets convinced them that going for a PAT could be beneficial. They felt that they could relate to the description of how people were given penicillin allergy labels. Patients thought the description of the test was clear and they knew what to expect. Statistics about the prevalence of allergy were not always understood by the participants, as the participants often thought that 1 in 10 people are allergic and they wanted a more visual presentation of this key information. Participants were unsure what narrow and broad spectrum antibiotics were and did not recognise MRSA abbreviation. Participants did not always know that penicillin is more than one antibiotic. The participants wanted to have a separate paragraph on what could happen during the test and what could happen during three days of taking penicillin at home. They also wanted reassurance that three days would be enough to detect delayed reactions. The participants wanted more reassurance that after being tested with one type of penicillin (e.g. amoxicillin), it would mean that they could safely take all penicillin antibiotics. The participants were slightly concerned about the risk of allergic reaction in the future (despite negative test results).

Patient feedback was collated in a table of changes. Changes made to the booklets were the selection of new images of patients for the front cover, inclusion of definitions of narrow and broad spectrum

antibiotics, and reassurance that 3 days of oral challenge would be enough to detect delayed reactions to penicillin.

Intervention components

All Working Instructions developed to support clinicians and research nurses activities as part of the ALABAMA intervention package were shown to a group of clinicians to gain their feedback on content and layout. Among the clinicians who provided feedback there were two practice managers, and one nurse. Their overall feedback was positive and the main changes to the intervention materials included the identification of the best way of updating the patient's medical records after PAT, and the introduction of screenshots of the medical record in the working instructions.

All participants letter (patient appointment letter, patient result letter, clinician result letter) were developed among the wider clinical and research team in order to make them effective in motivating patient to attend the penicillin allergy testing and in order to persuade clinician to change patient records and prescribe penicillin after a negative test result, and patient to consume penicillin after a negative test result.

At the end of the intervention development stage, a description of the intervention was completed following the TIDieR (20) guidance (see Additional Files 3) together with a description of the intervention components for clinicians and patients (Table 2).

The iterative process of intervention development and optimisation of intervention materials informed by the rapid review, qualitative work, expert consultation and think-aloud interviews is shown in Figure 2 and 3. It presents the example of this process for the development of one section of the "Penicillin allergy testing: going for a test" patient booklet and the "Information for General Practice" leaflet for clinicians.

Discussion

We the development of the ALABAMA intervention package which seeks to change behaviours to facilitate PAT to identify and amend incorrect allergy records in English general practice, that the PAT result is appropriately documented, and impacts on antibiotic prescribing and consumption. The approach used here has previously been used for the development of behaviour change interventions targeted to reduce antibiotic prescribing by clinicians in primary (21) and secondary care (22), but it is the first time that this approach has been used to develop an intervention to amend incorrect penicillin allergy records. The transparency of the intervention development process will inform intervention developers on how this methodology could be used in different contexts, and will facilitate the comparison with other interventions which have used similar processes.

The ALABAMA intervention package targets clinician referral of patients for PAT and updating incorrect penicillin allergy records; factors previously identified in previous qualitative research as barriers to

effective penicillin allergy de-labelling (11, 13). Recent exploration of clinician reported barriers and enablers to identifying and de-labelling hospital in patients with incorrect penicillin allergy records has highlighted the need to introduce patient education concerning the risks of avoiding penicillin (23). Inconsistencies in the management of penicillin allergic patients were reported, together with a lack of time to discuss allergy testing, and the need to improve communication between primary and secondary care about patient allergy status, as well as updating of patient medical records (23). A previous exploration of views about implementing de-labelling of patients ahead of elective surgery identified barriers to implementing it on a large scale, such as human factors linked to anxiety and financial implications. The human factors were: lack of interest from patients in undertaking an allergy test; lack of acceptance of the test result among clinicians; high proportion of patient re-labelled themselves after a negative testing for penicillin allergy or re-labelling by health care professionals. The financial barrier was significant despite long-term cost benefit, as there is an upfront cost to perform the test (24).

The evidence collated from the rapid review and qualitative interviews allowed in-depth understanding of participant needs (lack of knowledge of PAT, lack of knowledge of negative consequences of allergy labels) and which behavioural influences needed to be modified as part of the intervention. The mapping of these behavioural influences and the AIABAMA intervention package components to behaviour change theory and the logic model allowed a transparent reporting of the psychological processes that are hypothesized to explain the effect of the intervention components on the trial outcomes. More specifically it highlighted the BCTs used in each component of the AIABAMA intervention package and how they addressed the barriers identified in the rapid review and qualitative work. It also explained which psychological mechanisms were changed by the intervention components (clinicians' knowledge on penicillin allergy and PAT procedures, patients' beliefs about positive consequences of taking the PAT) and which target behaviours (referral and attendance to PAT, prescription and consumption of penicillin first line) affected the intervention primary outcome (the treatment "response failure"). Think-aloud interviews with patients and clinicians, and in-depth feedback from the clinical research team on the intervention materials, highlighted changes that needed to be made in order to increase their acceptability and potential effectiveness.

A limitation of the AIABAMA intervention package is to how widely applicable it might be. Allergy services across the UK vary significantly, and access to specialist testing ranges widely. The AIABAMA programme focuses on one geographical area (North of England), which is covered by the specialist unit used in the AIABAMA trial. Although the intervention is centred around functionality that has been incorporated into SystemOne, which is widely used, the intervention package is not necessarily suitable for use in other areas of England, the UK or wider and contextual factors to delivery should be considered. Moreover, it is only a small group of patients (around 25–30%) who are suitable to undergo the abbreviated test (patient history, skin test and oral challenge test). Many will still require full assessment by an immunologist or allergist as per current guidelines. Cost-effectiveness analysis of the PAT and intervention package as a whole will be carried out the in upcoming AIABAMA trial.

Conclusions

Current clinical practice involves referral to penicillin allergy testing with little attention to other elements of the pathway that help to ensure that testing impacts positively on patient care. This study presents the development of a behavioural intervention package to support the process of amending incorrect penicillin allergy records. Numerous barriers to the uptake of PAT have been identified as well as penicillin prescribing and consumption following a negative test. We have identified relevant behaviour change techniques to inform the development of the AIABAMA intervention package to overcome these barriers. The intervention is currently being tested in a feasibility trial in primary care to lead on to a randomised-controlled trial.

Declarations

Ethics approval: This study received ethical approval from the London Bridge Research Ethics Committee (Ref: 19/LO/0176).

Consent for publication: Not required

Availability of data materials: No additional data available

Competing Interests: The authors have received funding from the National Institute for Health Research.

Funding: This study summarises independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Number RP-PG-1214-20007). STC received additional funding from the National Institute for Health Research Health Protection Research Unit (NIHR HPRU) in Healthcare Associated Infections and Antimicrobial Resistance at the University of Oxford in partnership with Public Health England (PHE) [HPRU-2012-10041]. The research is supported by the National Institute for Health Research (NIHR) infrastructure at Leeds. The funder had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish.

Author contributions: All authors designed the study. MW, STC and MS led the intervention development, with input from the other co-authors. MW was responsible for the rapid review, recruitment, carrying out the interviews and analysing the data, under STC's supervision. MS drafted the manuscript with support from STC. All authors critically reviewed the manuscript and approved the final version of the manuscript.

Acknowledgements: The AIABAMA team consists of: Jenny Boards, Emily Bongard, Christopher C Butler, Mina Davoudianfar, Mandy East, Joanne Fielding, Philip Howard, Sue H Pavitt, Catherine E Porter, Jonathan AT Sandoe, Marta Santillo, Louise Savic, Sinisa Savic, Bethany Shinkins, Sarah Tonkin-Crine, Marta Wanat, Robert West, Ly-Mee Yu. Email address: alabama@phc.ox.ac.uk

Disclaimer: The views expressed are those of the authors and not necessary those of the NHS, NIHR or the Department of Health and Social Care.

Competing Interests: The authors have received funding from the National Institute for Health Research.

Patient Consent: Not required

Abbreviations

PAT: Penicillin Allergy Testing

PAAP: Penicillin Allergy Assessment Pathway

AMR: Antimicrobial Resistance

AIABAMA: ALLergy AntiBiotics And Microbial resistAnce

ST: Skin Test

OCT: Oral Challenge Test

TDF: Theoretical Domain Framework

BCW: Behaviour Change Wheel

BCTv1: Behaviour Change Technique

GP: General Practitioner

TIDieR: Template for Intervention Description and Replication

References

1. McLean-Tooke A, Aldridge C, Stroud C, Spickett GP. Practical management of antibiotic allergy in adults. *Journal of Clinical Pathology*. 2011;64(3):192-9.
2. Borch JE, Andersen KE, Bindslev-Jensen C. The prevalence of suspected and challenge-verified penicillin allergy in a university hospital population. *Basic Clin Pharmacol Toxicol*. 2006;98(4):357-62.
3. Reddy V, Baman NS, Whitener C, Ishmael FT. Drug Resistant Infections with Methicillin-Resistant Staphylococcus Aureus, Clostridium Difficile, and Vancomycin Resistant Enterococcus Are Associated with a Higher Prevalence of Penicillin Allergy. *J Allergy Clin Immunol*. 2013;131(2):AB170-AB.
4. West RM, Smith CJ, Pavitt SH, Butler CC, Howard P, Bates C, et al. "Warning: allergic to penicillin": association between penicillin allergy status in 2.3 million NHS general practice electronic health records, antibiotic prescribing and health outcomes. *J Antimicrob Chemother*. 2019;74(7):2075-82.

5. Krishna MT, Huissoon AP, Li M, Richter A, Pillay DG, Sambanthan D, et al. Enhancing antibiotic stewardship by tackling "spurious" penicillin allergy. *Clin Exp Allergy*. 2017;47(11):1362-73.
6. NICE. Drug allergy: diagnosis and management of drug allergy in adults, children and young people. NICE clinical guideline 183. 2014.
7. Yardley L, Morrison L, Bradbury K, Muller I. The Person-Based Approach to Intervention Development: Application to Digital Health-Related Behavior Change Interventions. *Journal of Medical Internet Research*. 2015;17(1).
8. Greenwell K, Sivyer K, Vedhara K, Yardley L, Game F, Chalder T, et al. Intervention planning for the REDUCE maintenance intervention: a digital intervention to reduce reulceration risk among patients with a history of diabetic foot ulcers. *BMJ Open*. 2018;8(5):12.
9. Band R, Bradbury K, Morton K, May C, Michie S, Mair FS, et al. Intervention planning for a digital intervention for self-management of hypertension: a theory-, evidence- and person- based approach. *Implementation Science*. 2017;12.
10. Little P, Stuart B, Francis N, Douglas E, Tonkin-Crine S, Anthierens S, et al. Effects of internet-based training on antibiotic prescribing rates for acute respiratory-tract infections: a multinational, cluster, randomised, factorial, controlled trial. *The Lancet*. 2013;382(9899):1175-82.
11. Wanat M, Anthierens S, Butler CC, Wright JM, Dracup N, Pavitt SH, et al. Patient and Prescriber Views of Penicillin Allergy Testing and Subsequent Antibiotic Use: A Rapid Review. *Antibiotics-Basel*. 2018;7(3).
12. Khangura S, Polisena J, Clifford TJ, Farrah K, Kamel C. RAPID REVIEW: AN EMERGING APPROACH TO EVIDENCE SYNTHESIS IN HEALTH TECHNOLOGY ASSESSMENT. *International Journal of Technology Assessment in Health Care*. 2014;30(1):20-7.
13. Wanat M, Anthierens S, Butler CC, Savic L, Savic S, Pavitt SH, et al. Patient and Primary Care Physician Perceptions of Penicillin Allergy Testing and Subsequent Use of Penicillin-Containing Antibiotics: A Qualitative Study. *Journal of Allergy and Clinical Immunology-in Practice*. 2019;7(6):1888+.
14. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science*. 2011;6.
15. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science*. 2017;12.
16. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. *Annals of Behavioral Medicine*. 2013;46(1):81-95.
17. Baxter S, Killoran A, Kelly MP, Goyder E. Synthesizing diverse evidence: the use of primary qualitative data analysis methods and logic models in public health reviews. *Public Health*. 2010;124(2):99-106.

18. Baxter SK, Blank L, Woods HB, Payne N, Rimmer M, Goyder E. Using logic model methods in systematic review synthesis: describing complex pathways in referral management interventions. *Bmc Medical Research Methodology*. 2014;14.
19. Bradbury K, Morton K, Band R, van Woezik A, Grist R, McManus RJ, et al. Using the Person-Based Approach to optimise a digital intervention for the management of hypertension. *PloS one*. 2018;13(5):e0196868.
20. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *Bmj- British Medical Journal*. 2014;348.
21. Anthierens S, Tonkin-Crine S, Douglas E, Fernandez-Vandellos P, Krawczyk J, Llor C, et al. General practitioners' views on the acceptability and applicability of a web-based intervention to reduce antibiotic prescribing for acute cough in multiple European countries: a qualitative study prior to a randomised trial. *BMC family practice*. 2012;13(1):101.
22. Santillo M, Sivyer K, Krusche A, Mowbray F, Jones N, Peto T, et al. Intervention planning for Antibiotic Review Kit (ARK): a digital and behavioural intervention to safely review and reduce antibiotic prescriptions in acute and general medicine. *J Antimicrob Chemother*. 2019.
23. Powell N, Wilcock M, Roberts N, Sandoe J, Tonkin-Crine S. Focus group study exploring the issues and the solutions to incorrect penicillin allergy-labelled patients: an antibiotic stewardship patient safety initiative. *European Journal of Hospital Pharmacy*. 2019:ejhpharm-2019-001863.
24. Savic L, Gurr L, Kaura V, Toolan J, Sandoe JAT, Hopkins PM, et al. Penicillin allergy de-labelling ahead of elective surgery: feasibility and barriers. *Br J Anaesth*. 2019;123(1):E110-E6.

Tables

Table 1: Guiding Principles for the ALABAMA intervention package.

PAAP =Penicillin Allergy Assessment Pathway; PAT = Penicillin Allergy Testing

| Intervention design objectives | Key features |
|--|--|
| To present the PAAP as a reliable and trusted approach to confirm allergy status | <ul style="list-style-type: none"> · Present the PAAP as a trusted/scientific/official way to get a confirmed PAT result, for both clinicians and patients |
| To increase clinician's confidence in referring patients, and patients' motivation to attend, for PAT | <ul style="list-style-type: none"> · Provide evidence on the potential harms of an incorrect penicillin allergy records and the process of testing in the Information Pack · Provide opportunity to address patients' concerns about potential benefits and risks of testing by both clinicians and allergists during consultations before the allergy test and during the appointment at the immunology clinic |
| To motivate clinicians/patients to prescribe/take penicillin following a negative PAT test result | <ul style="list-style-type: none"> · Provide information to clinicians about the clinical meaning of a test result and its implication as part of the Information Pack · Provide information to patients about the PAT (process) and the potential benefits of being able to take penicillin in the Pre-test Intervention Booklet |
| To increase clinicians' ability to discuss PAT with patients | <ul style="list-style-type: none"> · Provide training for general practice clinicians about penicillin allergy and PAT, including its accuracy, implications, benefits |
| To improve communication between primary and secondary care so that allergy status records are correct | <ul style="list-style-type: none"> · Provide a clear and consistent approach to de-labelling with support from colleagues in secondary care and preventing re-labelling in the future · Provide information about who is responsible for ensuring patients understand the results and for updating the medical records during the site training and in the Information Pack · Provide clear and precise documentation of side effects during future courses of penicillin in the Information Pack |
| To provide easily accessible tools that are suitable for use by general practice clinicians | <ul style="list-style-type: none"> · Make interventions materials for clinicians accessible, short, easy to follow, easy to implement and not increase workload |
| To provide easily accessible resources for patients | <ul style="list-style-type: none"> · Make patients materials brief, easy to read, accessible · Make materials easy to carry with them at all time and that provide evidence of the results of their test |

Table 2: Overview of the key intervention components of the ALABAMA intervention package.

PAT = Penicillin Allergy Testing

| Intervention components | Description |
|--|---|
| For clinicians | |
| 'Penicillin Allergy Testing: Information for general practice' sheet | Information sheet which includes evidence-based information to increase knowledge about penicillin allergy testing and motivation to refer patients to PAT and prescribe penicillin after a negative PAT result |
| Electronic health record pop-up | Electronic pop-up on medical records which tells clinicians that patient has had a negative test result and that their allergy status needs to be amended |
| Allergy result letter | A letter is sent to the GP to inform them of the patient's penicillin allergy test result, including details on which test(s) they undertook, whether it is safe or not to prescribe penicillin in the future and instructions on how to change the allergy label |
| Consultation with patients | Discussions with patients to check eligibility for the trial and to answer any queries about the trial and PAAP testing |
| Site Training and working instructions | Training in trial procedures delivered to GP leads including provision of information on penicillin allergy de-labelling, the referral process, the three stages of the PAAP and the interpretation of test results |
| For patients in intervention arm | |
| "Penicillin allergy testing: going for a test" booklet | A booklet to inform patients, in the PAAP intervention arm, about incorrect allergy records, how they may benefit from having a penicillin allergy test and what the test involves |
| Penicillin Allergy Test appointment letter | The letter includes information on the PAAP procedures in hospital, including pre-test assessment and monitoring during the test and at home |
| Penicillin Allergy Assessment Pathway (PAAP) | Appointment at the immunology clinic for patients in the PAAP intervention arm. At the appointment patients will complete Stage 1, Stage 2 and/or Stage 3 of the PAAP pathway |
| Allergy test result letter | Patient will receive a letter with information on the result of their allergy test and whether it is safe or not to take penicillin in the future |
| "Penicillin allergy testing: a negative test result" booklet | A booklet on the reliability of the test results and consequences of a negative test result (sent with allergy test result letter). |
| Post-test intervention card | Laminated credit card-sized card which says which test the patient has had and confirms the negative allergy result |
| <i>For all patients in control and intervention arm</i> | |
| An invitation letter and Participant information | An invitation letter and Participant information Sheet on the purpose of the trial and what the research study would involve for patient participants |

Discussion with clinicians Discussion with clinicians about attending the test to ask any queries around the benefits of taking the test and why removing the incorrect record might be good

Figures

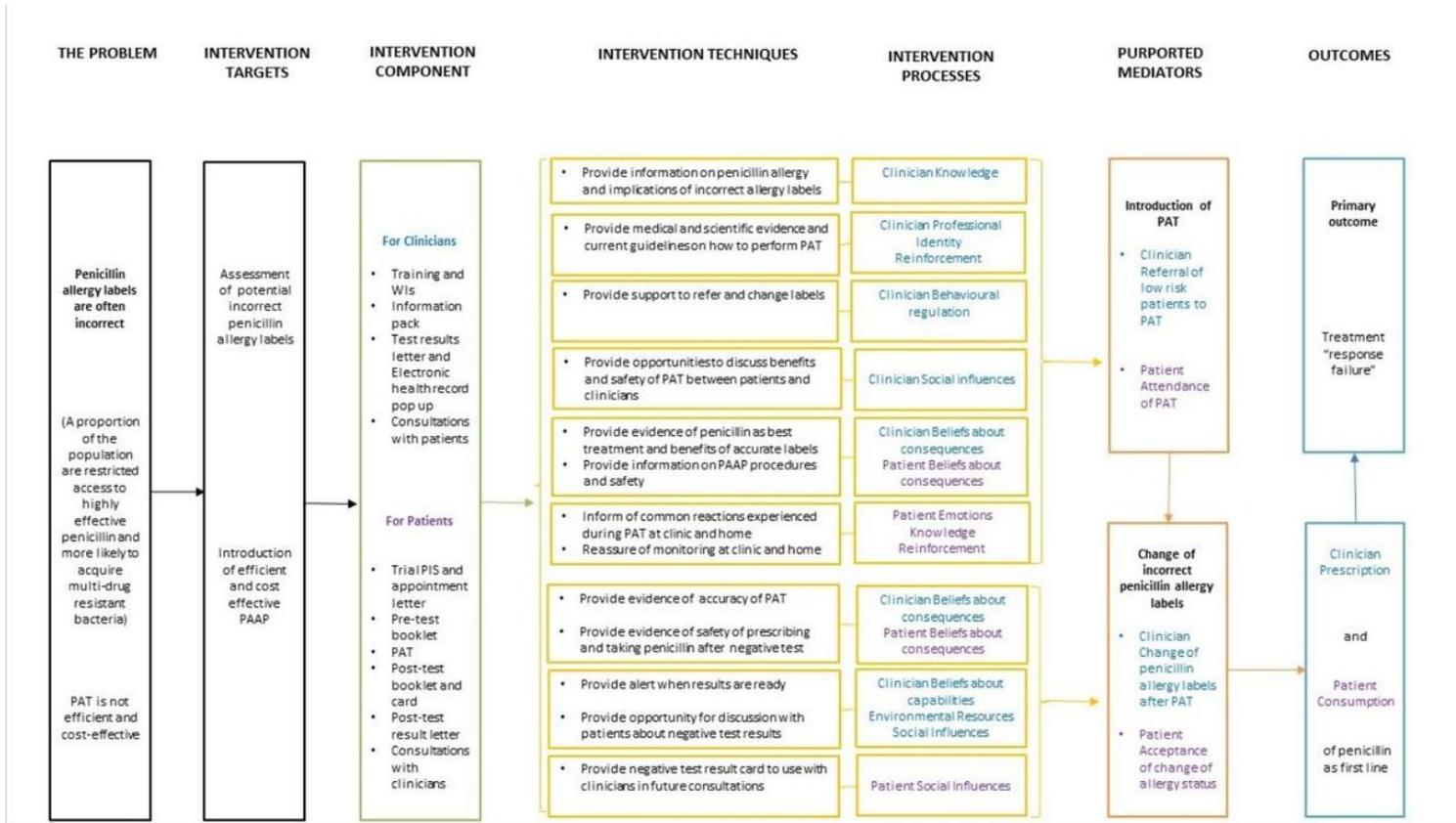


Figure 1

ALABAMA logic model

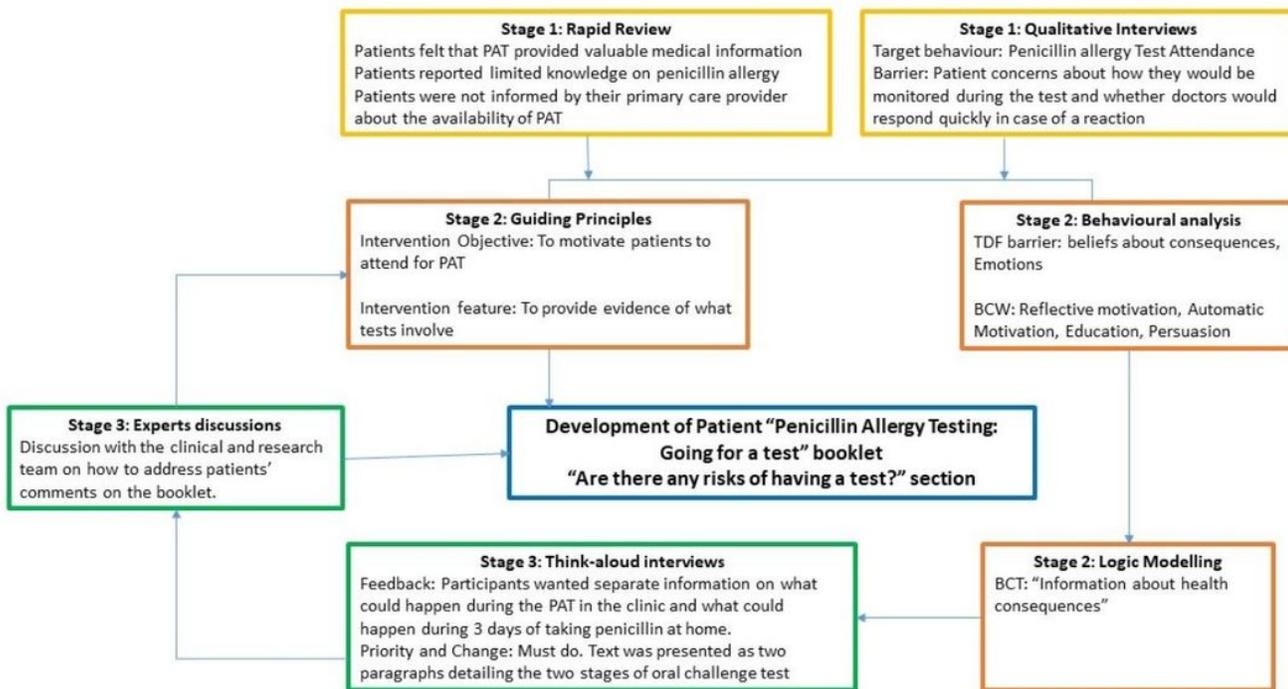


Figure 4

Example of intervention development for patient materials. PAT = Penicillin Allergy Testing

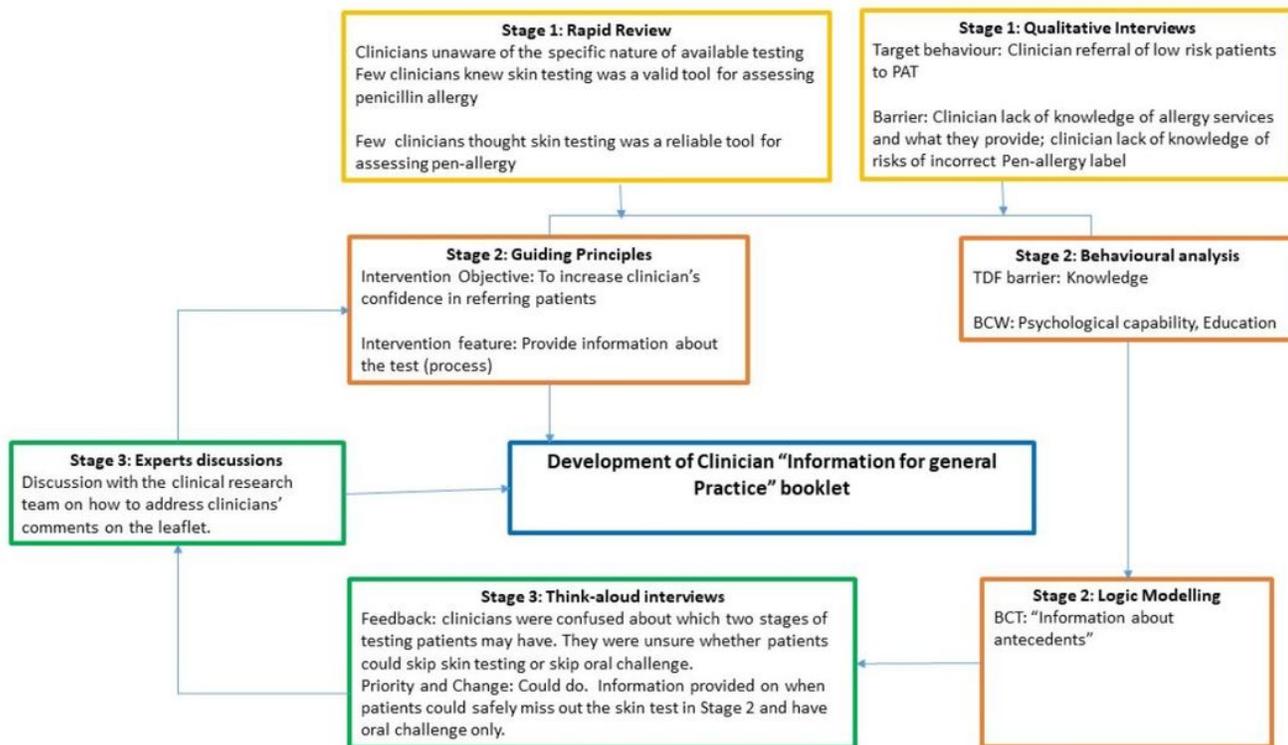


Figure 7

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [TiDiERChecklist.pdf](#)
- [TiDiERChecklist.pdf](#)
- [AdditionalFiles.pdf](#)
- [TiDiERChecklist.pdf](#)
- [AdditionalFiles.pdf](#)
- [AdditionalFiles.pdf](#)