International Journal of Pharmacy Practice, 2025, **XX**, 1–10
https://doi.org/10.1093/ijpp/riaf004
Advance access publication 5 March 2025
Research Paper

IJPP International Journal of Pharmacy Practice

OXFORD

A mixed methods protocol for an impact and implementation evaluation of the Pharmacy First Services for management of common conditions in England

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Abstract

Objectives: In response to high levels of demand for primary medical services in England, characterized by longer appointment waiting times and delayed referrals, the Government developed its National Health Service (NHS) Primary Care Recovery Plan. A key component of the plan is Pharmacy First (PF), which involves participating community pharmacies supplying prescription-only medicine after consultation with a pharmacist for seven common conditions: earache, uncomplicated urinary tract infections in women, sore throat, sinusitis, impetigo, shingles, and infected insect bites. The study aims to evaluate the implementation of the PF service and its impact on the volume of prescribing, case mix of General Practitioner consultations, accident and emergency department and other hospital use, equity of access, and cost for different groups of patients in different contexts, as well as its acceptability and fidelity.

Methods: A 36-month, mixed methods evaluation with five elements, namely evidence synthesis, semi-structured interviews, focus groups, quantitative analysis of impacts before and after implementation (e.g. using interrupted time series analysis) using routine data, and an economic evaluation. Findings will be synthesized and interpreted using the Consolidated Framework for Implementation Research supplemented by Proctor's Implementation Outcomes Framework.

Conclusions: The evaluation should have service level, policy, professional, and research impact both in England and beyond. This includes generating evidence to show: whether PF contributes to improving primary healthcare access, assessing the quality of antimicrobial use, identifying the scope for refinements to PF, and, overall, informing better implementation of PF. The findings will also provide robust evidence to enable policymakers to determine how to enhance the role of community pharmacy in England in the future. Furthermore, the evaluation will develop a data dashboard, and the methods and codes used to interrogate it (though not the patient data), will be made publicly available that could support other similar evaluations in England and internationally.

Keywords: Community Pharmacy; Policy Evaluation; Mixed Methods; England

Background

In recent years, there has been an increase in the demand for healthcare globally, partly exacerbated by the Covid-19 pandemic. In the aftermath of the pandemic, longstanding supply-side issues such as limited financial resources and workforce shortages have further impaired the recovery of systems. These problems are keenly felt in primary care, where the build-up of patients with delayed diagnosis, care, and treatment has led to longer waiting times for appointments and delayed referral [1]. Hence, national governments are exploring different approaches, including substituting care traditionally provided by doctors with other healthcare professionals. In England, access to a primary care physician is seen as particularly problematic. In response, as part of the Government's National Health Service (NHS) Primary

Received: 9 October 2024 Accepted: 19 February 2025

Care Recovery Plan, NHS England (NHSE) developed and commissioned Pharmacy First (PF) [2]. Since February 2024, community pharmacies participating in PF are also able to supply prescription-only medicines for seven common conditions: earache, uncomplicated urinary tract infections (UTIs) in women, sore throat, sinusitis, impetigo, shingles, and infected insect bites, after consultation with a community pharmacist [3] through Patient Group Directions (PGDs).

PGDs are written instructions that allow registered healthcare professionals to supply or administer medicines to patients, usually in planned circumstances. Wales and some areas of England, PGDs have shifted some of the care for minor ailments to community pharmacies for over two decades for treatment PGDs of head lice, threadworm, bacterial conjunctivitis, insect bites, and cystitis. Research on PGDs has focussed on safety, antibiotic use, or impact on the healthcare system in a single area or a series of areas, therefore lacking generalizability; there have thus far been no in-depth evaluations of the impact and implementation of an England-wide scheme [4, 5]

PF also builds on the NHS Community Pharmacist Consultation Service, in which patients registered with a General Practitioner (GP) can be referred to community pharmacies for minor illness advice and treatment [6]. In the new PF service, potential users can walk into pharmacies to access care, assuming self-care has been unsuccessful. PF aims to reduce demand on GPs and Accident and Emergency (A&E), thus improving the timeliness of treatment. The extent to which PF will shift demand for the seven named conditions away from higher-cost settings, thereby, in principle, improving access overall, is uncertain. Evidence from a Scottish study of PF for UTI, impetigo, and COPD found that most GPs thought PF had reduced pressure on their appointments [7]. In the Welsh 'sore throat test and treat' service, 91% of consultations were managed in the pharmacy, and only 9.3% of people were referred to a GP and 0.2% to A&E [8]. An enhanced role for community pharmacy has been shown to improve access to health care in socioeconomically disadvantaged areas, thereby improving equity of access [9]. The impact of PF on patients, workforce, care pathways, and cost may differ geographically, across the seven conditions, and over time, hence the need for national evaluation.

The Government estimates that PF may release up to 10 million GP appointments annually [2] enabling GPs to provide more timely access to those with more urgent and complex needs. However, there is also a need to consider the unintended negative effects of PF such as avoidable adverse health sequelae. The effect of PF on other outcomes of interest is also unclear. It is not known if PF will unmask unmet needs, thereby increasing overall demand for treating these seven conditions and antibiotic prescribing. In turn, there are concerns that widening access to antibiotics may increase antimicrobial resistance (AMR) [10], by increasing population carriage of organisms resistant to first-line antibiotics, thus increasing second-line antimicrobial use (AMU) in the community. It will be critical to monitor population-level AMU and AMR. That said, there has been comprehensive antimicrobial stewardship training and resources developed and implemented in community pharmacies since 2020 [11].

Given the magnitude of the PF service and the multitude of possible intended and unintended outcomes, the study aims to evaluate the impact of PF by assessing; the volume of prescribing, case mix of GP consultations, A&E and hospital use, equity of access, AMR trends and cost for different groups of patients in different contexts.

Methods

Theoretical framework

The evaluation will be guided by the Consolidated Framework for Implementation Research (CFIR) [12], which will help identify the key factors likely to affect the implementation of PF. The CFIR is a 'meta-theoretical framework' drawing on 19 previous implementation models comprising 39 constructs arranged across 5 domains (outer setting, inner setting, individual characteristics, intervention characteristics, and implementation process). It is a practical guide for systematically assessing barriers and facilitators that affect implementation at different levels of a healthcare system. The CFIR has been used to assess the implementation of a range of policy and practice interventions in healthcare using mixed methods and qualitative designs [13, 14]. In this evaluation, the CFIR draws attention to the variation in impacts we are likely to see depending on context(s) and on how PF is implemented in different places, and will prompt an attempt to identify the factors that bring this about.

While the CFIR helps in understanding the factors that affect how and to what extent a policy or programme is implemented, it provides less direct information on outcomes, despite the addition of a new 'outcomes addendum' [15]. Hence, we will also use Proctor's framework of implementation outcomes [16], which aligns more closely with the outcomes of interest for this evaluation. Proctor's framework comprises eight discrete outcomes: acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration (integration of a practice within a specific setting), and sustainability.

The findings from the initial literature review and scoping interviews of the factors affecting the implementation of PGDs across the UK and which appear likely to shape future implementation of PF will be mapped to the CFIR domains and constructs. From this, we will be able to develop an understanding of the key intervention characteristics (of the PF service) that could affect its implementation. Later interviews will further establish the factors across the other CFIR domains and constructs that interviewees believe may impede or support future policy outcomes. These findings will be used to develop an initial theory of change for PF that will be periodically revised as findings emerge.

Study design

This protocol (version 1.0, 8 October 2024) has used the SPIRIT guidelines for study protocols, where applicable [17]. This study is a 36-month, mixed methods evaluation combining quantitative and qualitative data to assess the implementation and impact of PF exploring what works, for whom, and why, at local, regional, and national levels. Qualitative data collection will commence in July 2024. Quantitative data will be retrospectively requested back to 1 February 2024. All data collection will be completed by mid-2026 with final reporting scheduled for January 2027. Since the roll-out of PF is in its early stages, some of the designs and methods presented here are unavoidably open to revision. Emerging findings and insights from early work will shape lines of enquiry and design decisions in the subsequent research. Findings will be brought together and interpreted using the CFIR, supplemented by Proctor's implementation outcomes framework.

The study design has been guided by several outcomes of interest, including change in pharmacy, general practice, and

A&E department case mixes; comparative feasibility and cost of implementing PF for the seven conditions; volume of antibiotics and antivirals dispensed; differences in the roll-out of PF and its impact depending on the age, sex, socioeconomic group, ethnicity, or geography (especially urban/rural divides) of service users; impact on enrolled pharmacies in terms of staff, risk, data, safety, and behavioural implications; differences between how PF is implemented and the stated intention; potential consequences of PF for inequalities in access to health services and outcomes; and impact on national antimicrobial use and resistance for key antibiotic/bacterial organism combinations.

To evaluate a vast and complex set of outcomes using a mixed methods design requires a multi-disciplinary team of experts. Hence, in assembling the research team we selected individuals with a wide range of skills and knowledge pertaining to community pharmacy, general practice, health services and pharmacy practice research, health economics, medical sociology, health policy analysis, statistics, epidemiology, and big data science.

The evaluation comprises five Work Packages (WPs), described below, which integrate to answer all research questions. Fig. 1 shows the relationships between the WPs.

Work packages

Work package 1: Literature review and scoping to develop a theory of change

Work package 1 aims to provide a deeper understanding of the factors that affect implementation of PGDs. It will examine the factors underpinning the roll-out of PF and services like PF in England, Wales, and Scotland, including the intended goals and expectations of such initiatives. This will inform the development of a theory of change for PF and contribute to other WPs.

Literature review

A review of peer-reviewed and grey literature on pre-existing PGDs and similar programmes will be undertaken to complement the clinically oriented literature reviews developed to inform the design of the PF service by NHSE which is responsible on behalf of the Department of Health and Social Care for NHS governance in England. We will also seek to access unpublished policy documents related to the development of PF from NHSE and other relevant national agencies. We will review the literature on established PGDs, such as those for oral contraception, eye infections, and head lice, to provide a deeper understanding of the factors that affect the implementation of PGDs. Along with the CFIR, literature review findings will inform the development of the interview guide for the scoping interviews listed below.

Scoping interviews in England, Scotland, and Wales

We will conduct semi-structured interviews (n = 25–30) with purposively selected stakeholders involved in strategic, implementation, and delivery roles at local, regional, and national levels. These include policymakers, national sector leaders from community pharmacy and general practice and front-line pharmacists identified through snowball sampling (both those delivering the service and those not). We will re-interview a sub-set of these interviewees to contribute to WP4 (see below) in mid-2026, asking them to reflect on the PF implementation process over time and the extent to which the Programme has been implemented as intended. Scoping interviews will be undertaken using a semi-structured topic guide. Using a thematic framework approach [18], data will be analysed deductively and inductively, with the CFIR used as a coding framework to manage and organize the data.

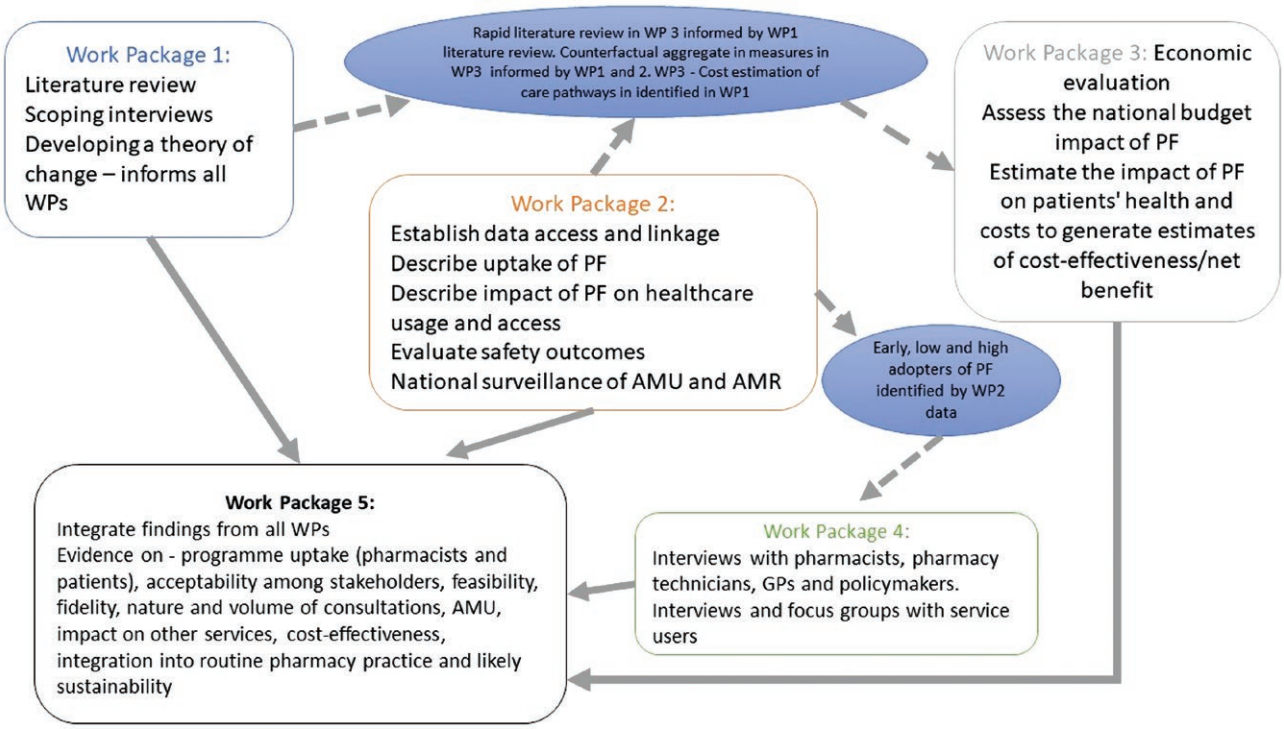

Figure 1. Workflow and integration of the evaluation work packages.

Interviews will be held online or in person depending on participants' preferences.

Programme theory of change

We will use findings from the literature reviews and scoping interviews mapped to the CFIR to develop an initial theory of change for PF. This will inform the other WPs. The goal will be to map all areas where care pathways change.

WP2: development of routine data linkages, and analysis of uptake and impact of PF on consultation patterns, workload, patient safety, antimicrobial use, and resistance

Work package 2 will initially establish data access and linkage. It will then describe the uptake of PF nationally and regionally, map how healthcare usage changes before and after the introduction of PF and assess the impact of PF on access to healthcare. Furthermore, it will evaluate safety outcomes and how antimicrobial use changes following introduction of PF and link analysis of antibiotic use to AMR indicators. As the PF service contains seven separate conditions, it is available to a wide range of patients. Specific eligibility criteria for each condition can be found in Supplementary File.

Establish data access and linkage

There will be two main sources of routine data: GP electronic records, linked to A&E department and acute hospital admission data from the OpenSAFELY platform; and England-wide pharmacy-level data captured as a PF consultation record at the point of service use from anonymized pharmacy datasets.

OpenSAFELY is a secure, open-source software platform for analysis of electronic health records data and was established in the early days of the pandemic and has been used to generate analyses since then to support the response to COVID-19 [19]. It provides access to the NHS records of over 58 million people (>99% of registered GP patients in England), linked to hospital admission data and A&E attendance.

As both the pharmacy consultation records and GP electronic records are routinely collected data, once access is secured, data will be retrospectively evaluated from the initiation of the Pharmacy First service (1 February 2024). Access to this data is via Freedom of Information requests to the NHS Business Authority for payment data on pharmacy consultations and via established permissions at OpenSAFELY, for which an application to access summary data is in progress.

Describe the uptake of PF nationally, regionally, and locally

Pharmacy-level data from all community pharmacies providing the service will be used to undertake a retrospective descriptive analysis at national, regional, and local levels at monthly intervals from 1 February 2024. Including, for example, for each of the seven PF conditions: number and type of medicine supplied via PGD; number of advisory consultations or advice plus OTC supply; number of community pharmacy referrals to GP, A&E, or other health services; and patient characteristics, including area deprivation level as linked by the pharmacy postcode to the Index of Multiple Deprivation. As of July 2024, there were known to be approximately 9900 community pharmacies providing the PF service out of a total of approximately 10 600 in England.

Describe how healthcare use changes after the introduction of PF and the impact of PF on access to healthcare:

(a) Change in GP consultations

Following the initiation of PF (1 February 2024), changes in GP consultation rates for each of the seven conditions included in the scheme will be examined, including investigating changes in total GP consultations and subgroup analyses, including by deprivation level. The main analysis will be done at the level of individual general practices using patient-level data. SNOMED-CT (a structured clinical vocabulary for use in an electronic health record) codes will be identified for each of the seven common conditions. Consultation rates will be calculated monthly per head of population in each general practice. All GP practices available in OpenSAFELY, where at least one PF consultation is recorded will be included in this evaluation.

i. *Data analysis*

Data from up to 24 months before the PF start date and for as long as follow-up data are available before undertaking the final analysis will be included. A quasi-experimental approach, using interrupted time series analysis (ITSA) or similar methods as previously used by the research team [20–22], with the intervention start date set as 1st February 2024 will be utilized. Alternatively, if uptake is more gradual, a similar approach to ITSA used previously to evaluate a large-scale intervention with staggered implementation dates will be used [20]. In this event, each General Practice will have a different start date according to receipt of the first electronic message from a community pharmacy to that General Practice indicating that a PF consultation has taken place. In addition, if a staggered uptake is seen, a concurrent counterfactual based on areas of no or delayed uptake of PF will be developed to allow for comparative ITSA (CITSA) or event study analysis to be undertaken. Analysis will also be undertaken at the local level (sub-ICB and potentially individual General Practice) to obtain disaggregate effect estimates, allowing variation in effects to be explored.

The ITSA will use generalized linear mixed models for the monthly GP consultation rates for each condition, to estimate changes in the level and trend in consultation rates after the PF intervention compared with before. Calendar time will be included as a covariate along with adjustment for seasonal effects and any within-practice covariates (such as the number of full-time equivalent GPs) identified prior to the analysis.

ii. *Sample size calculation*

There is a lack of robust literature on sample size calculations for ITSA; there is a complex relationship between number of time points, sample size per time point, and expected effect size [23]. In general, however, with over 24 time points >80% power can be achieved with as few as 150 subjects per time point [24]. A minimum of 24-time points (and a maximum of 48) and around 6500 general practices are included in this analysis; therefore, this study will be sufficiently powered to detect relevant changes in the outcomes of interest.

(b) *Change in A&E department and acute hospital admissions*

Using SNOMED-CT coding, the number of A&E attendances and acute hospital admissions related to the seven PF conditions within England will be analysed using secondary care data, available via OpenSAFELY, and linked to primary care records. Quasi-experimental methods such as ITSA (see above) will be used to estimate changes in rates following the PF intervention; however, as a secondary outcome, the study design has not been powered to detect this change.

(c) Potential impact of PF on access to healthcare

The socio-demographic and health factors across the population that may relate to both uptake and ongoing effectiveness of the PF initiative will be examined using the national health surveillance platform developed during the UK Research and Innovation COVID-19 Rapid-Response grant 'The CIVIC Project: A Sustainable Platform for COVID-19 syndromic-surveillance via Health, Deprivation and Mass Loyalty-Card Datasets' [25].

Factors influencing the uptake of PF related to inequality that are underpinned by prior theoretical literature will be focussed in Ref. [26]. A range of predictive models will be developed and Variable Importance Analysis [27] applied to this model, summarizing the influence that each explanatory variable (e.g. deprivation level) is estimated to have on the uptake of PF across neighbourhoods in England.

Evaluate safety outcomes following the introduction of Pharmacy First

Using quasi-experimental approaches (as described above), it will be determined if the introduction of PF is associated with changes in indicators of patient safety, including unintended consequences of antimicrobial use in PF. This will include:

1. Patient access to other health care settings (GP, A&E, hospital admission) within 1–30 days of a PF consultation for the same or related conditions, where no referral by the pharmacist has been made.
2. The frequency with which medication was supplied via PF where a documented allergy or contra-indication exists in the GP record.
3. The number of patients who received multiple courses of antibiotics, more frequently than the exclusion criteria allow in the clinical pathway for each condition; for example, for UTI treatment, this would be more than two episodes in the last 6 months or 3 in the last 12 months.
4. Comparison of rate of hospitalizations for patients who access PF care with that of those who access usual care, provided by GPs. Similar methods to a recent study on sore throat consultations in community pharmacies in Wales will be used [28].

National surveillance of antimicrobial use and resistance

The impact of PF on trends in the following will be evaluated:

1. Number and type of antimicrobial dispensed in the community in England, including total and patient age, with subgroup analysis by region, age group, and antibiotic class. Surveillance of antimicrobial use will be restricted to the antibiotics specified as part of the seven PF clinical pathways in the populations eligible for each clinical pathway, in addition to overall surveillance of total antibiotic use in primary careusing UKHSA's routine antimicrobial use surveillance data (obtained from ePACT2 from NHS BSA)
2. The number of community-associated urine samples positive (by causative organism, age group, sex, ethnicity, and deprivation) and the urine isolate AMR rates (by causative organism) using the UK Health Security Agency's Second Generation Surveillance System (SGSS) data.
3. The number of positive bacterial community-associated respiratory samples (by causative organism, age group, sex, ethnicity, and deprivation) and the respiratory isolate AMR rates (by causative organism) using SGSS data.

Surveillance of antimicrobial resistance will report on a range of antibiotics commonly reported on in surveillance of urinary tract and lower respiratory tract resistance. Quasi-experimental analyses will be conducted using ITSA, as described above, at two timepoints: 1 year and 2 years after PF introduction (Fig. 2), comparing monthly data up to 2 years after roll-out of PF with 2 years pre-PF for the seven PF conditions and in total.

Work package 3: economic evaluation

Work package 3 involves mapping processes of care with and without PF for the seven conditions. It will assess the national budget impact of PF from the NHS and personal social services' (PSS) perspective, and estimate the impact of PF on patients' health and costs in order to generate estimates of cost-effectiveness. The approach will be informed by a rapid literature review of economic studies that focus on other PF-type services, along with evidence from WP1.

We will conduct a national budget analysis to determine the impact of introducing PF on healthcare resource use from the NHS perspective and a cost-consequences analyses for the PF conditions. We will assess aggregate changes in prescribing activity, use of community health and social care services, primary care contacts, A&E visits, and hospitalizations deemed to be related to the PF conditions. These changes in activity will be costed using national unit costs from routine sources.

The cost of implementing and running PF will be based on data gathered in WP1. The PF service will attract a fee paid from the NHS to pharmacists if the consultation and nature of patients meet certain criteria. The following resource items will be measured for PF: implementation and service delivery costs, including NHS costs; workforce changes associated with PF; pharmacy costs; and data system maintenance. Pharmacies providing PF (identified in WP2) will be asked about the amount and allocation of PF funding and the costs (monetary and non-monetary) of set up and implementation.

The impact of the PF intervention on prescribing, primary care consultations, and any subsequent care, including secondary care will be estimated and costed. Costs associated with recorded AMR and safety-related events will be assessed.

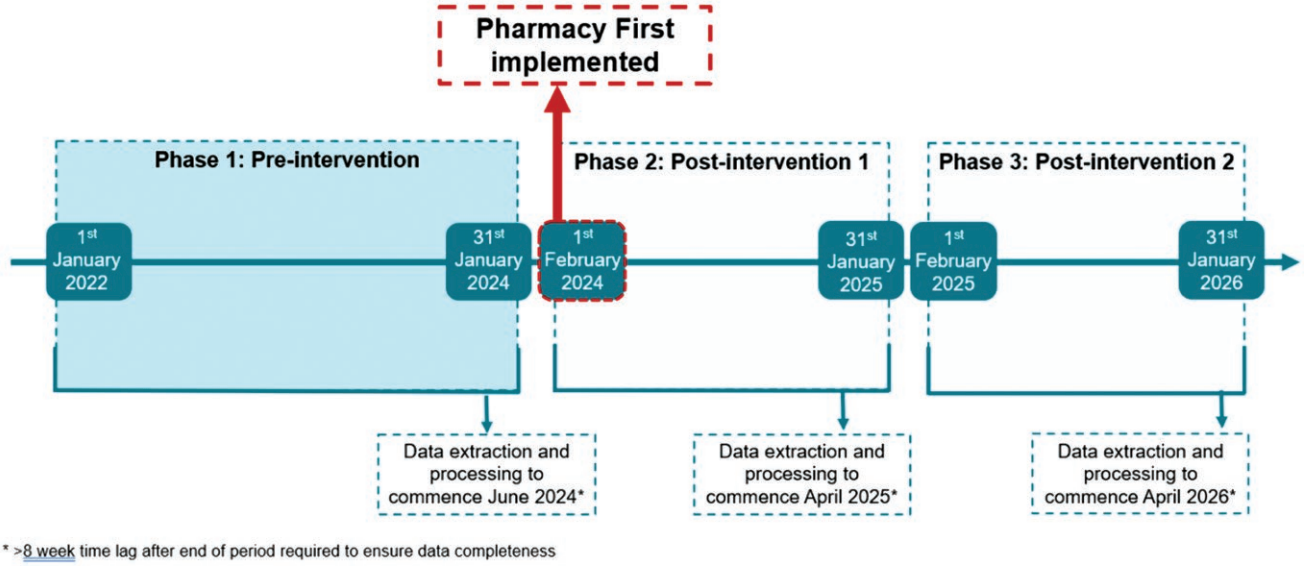

Figure 2. Interrupted time series analysis data extraction plan (ePACT2, NHS BSA and Second Generation Surveillance System, UKHSA).

We will examine changes in the cost of activity over time and by patient characteristics: age, gender, SEG, ethnicity, serious mental illness, learning disabilities, pharmacy density, and geography.

Economic modelling

Cohort-level state transition models for each condition will be developed and reported according to standard validation and reporting criteria [29, 30]. Processes of care will be mapped and validated for each condition, with input from service providers and patients.

We will estimate the effect of PF versus current care via its impact on quality-adjusted life years (QALYs) and costs from the NHS perspective using a one-year time horizon since the PF conditions are acute. QALYs and costs will not be discounted due to the 1-year time horizon [29]. The incremental costs and outcomes associated with each of the seven PF conditions will be incorporated additively, weighted according to the number of people who access each of the seven pathways, into a composite economic model to allow derivation of the difference in patient outcome and costs between PF and current care. This will enable estimation of the costs, outcomes, and net benefit of PF versus current care for the seven conditions. We will design the model using a combination of approaches, including existing literature, expert opinion, and what we can infer from the routine data such that we can estimate the QALY and cost differences associated with previously untreated episodes of the PF condition(s) (unmet need). The robustness of findings will be assessed via deterministic and probabilistic sensitivity analyses [31]. Cost-effectiveness acceptability curves [32] will be constructed to reflect decision uncertainty [33]. Costs associated with any change to AMR (based on the volume of antibiotics dispensed) attributable to changes in prescribing practice will be accounted for in a sensitivity analysis, with the costing approach informed by a review of the relevant literature [34, 35].

WP4: implementation and fidelity of the roll out

This WP aims to understand how and why PF is and is not taken up, including the fidelity of the scheme, with a focus on the effects of PF on the access to, and acceptability of, community pharmacy services to populations historically marginalized in terms of primary healthcare access. Furthermore, we will assess pharmacists' and GPs' perceptions of the safety of the scheme.

Semi-structured interviews with professionals and policymakers

We aim to understand how and why the programme is and is not taken up by interviewing professionals (mainly GPs, pharmacists, and pharmacy technicians). We will identify study sites (individual community pharmacies and neighbouring GP practices) using data obtained from WP2 where appropriate. Site selection will also be informed by organizations representing community pharmacy such as the Chemists Company Association (CCA) and Local Pharmaceutical Committees (LPC) who will have their own data on PF uptake at a national (CCA) and local level (LPC). We will undertake a purposive approach to sampling sites selecting early, high, and low adopter sites taking care to include participating and non-participant pharmacies. We will identify around 45–50 sites and aim to recruit around 50–75 GPs, pharmacists, and pharmacy technicians in total. Interviews will be undertaken until there is a consensus among the research team that 'saturation' (no new themes or insights are emerging) has been achieved in relation to the topics listed below. These interviews will cover pharmacies' capacity, capability, and experiences of the new PF service as well as the acceptability of the scheme. Data will be collected on the professionals' perceptions of, and explanations for, changes in service use that can help interpret the quantitative analyses of service use in WP2.

Interviews will also assess the impact of PF on self-care by exploring professionals' experiences of telling patients that they were unsuitable for PF or that they were not going to receive a prescription medicine. We will also explore: pharmacists' willingness to participate in PF; the perceived impact of PF on other work within pharmacies; and how they think PF has increased or decreased access among more disadvantaged and marginalized populations.

In addition, we will conduct follow-up interviews with the policymakers interviewed in WP1 to determine the implementation progress over time, assessing the fidelity of the programme to its original objectives.

The interviews with pharmacists and pharmacy technicians will also include their perceptions of safety, and how safety I and safety II principles develop in the PF roll-out [36]. Specifically, we will assess mechanisms for: recording and reporting adverse drug reactions; interactions and contra-indications (safety I); and assuring and improving the quality of care and safety such as adherence to PF guidelines and reasons (if any) for deviation, as well as issues of misdiagnosis and delayed referral (safety II). In addition, we will gather GPs' and patients' views on consent, access to electronic records, and broader perceptions of the risks to patient safety of accessing PF services.

Interviews will be undertaken using a semi-structured topic guide informed by the findings from WP1 and the CFIR. Data will be analysed as outlined under WP1. The interviews will be conducted either in person or online.

Interviews and focus groups with service users

Among the 45–50 sites where there are early and/or high adopters of the service identified in WP2, we will undertake interviews ($n = 30$) and focus groups ($n = 10$) with service users with help from lay researchers, whom we will train to capture the experiences of those using and not using the service, noting any reported changes in health-seeking behaviour. We will recruit through various intermediaries such as patient groups, action/interest groups, and non-governmental organizations as well as targeted local leafleting, and through local social media groups, at six sites across England, and two online fora. Guided by the analysis in WP2 and through the support of the CCA and LPC, we will identify areas and/or pharmacies with high numbers of consultations among unregistered patients and will be able to include historically marginalized in research and medically underserved populations. We will pay particular attention to issues raised in previous research on pre-PF pilots and self-care [37].

Service user participants will include people affected by homelessness and vulnerable migrants. Recruitment of marginalized groups can be challenging due to their often being absent from mainstream health services [38]. Low income, poor access to transport, and poor literacy pose barriers to participation in research [39, 40]. We will work with a diverse group of lay co-researchers, recruited through grassroots organizations (e.g. Revolving Doors) to ensure the accessibility of study materials. BSL interpreters and other reasonable adjustments will be provided if needed.

Work package 5: mixed methods analysis, consolidation of findings, and identification of policy implications

This WP will integrate findings from all strands of the evaluation bringing together evidence on the uptake of the programme among pharmacists and patients, acceptability among stakeholders, feasibility (e.g. capacity and capability of workforce, joined-up electronic systems), fidelity to the original aims, nature and volume of consultations, antibiotic use, impact on other services, cost-effectiveness, integration into routine pharmacy practice and likely sustainability. It will start as soon as findings begin to emerge and run throughout the study. The aim of the WP is to produce an integrated, multi-faceted evaluation of the implementation of PF, structured using the CFIR, and to provide insight as to how to improve the PF scheme, assuming it is sufficiently cost-effective to be continued.

Activity in this WP will take place at transition points between different stages and types of data collection and analysis, such as toward the end of the analysis of the interviews in WP1 but before initial analysis plans in WP2 have been finalized. This will enable discussion within the research team and more widely of the implications of the interview findings for the following analysis of administrative data. For example, the interviews may identify that pharmacists have reservations about managing patients on one of the seven clinical pathways. This would inform the analysis of consultations and prescribing patterns for that condition. At these transition points, the entire research team will meet and analyses from the preceding period will be presented and their implications both for ensuing analyses and for interim reporting will be identified.

As a result, WP5 will comprise a continuous process of *integration* and *triangulation* of the findings from the different types of data analysed during the evaluation. This process will be underpinned by a system of cross-work package team membership supported by regular meetings.

Co-production with lay researchers

The evaluation will be co-produced with lay researchers representing diverse groups of service users including those who have been historically marginalized in research and medically underserved, such as those from low socio-economic backgrounds, people affected by homelessness, people from racially marginalized groups, and vulnerable migrants. Co-researchers will contribute to the evaluation by orienting work WPs, participating in the ethics application process, designing inclusive data collection tools, participating in research activities (e.g. conducting interviews and focus groups), interpreting data, and formulating reports. They will also organize citizens' forums in the six regions where the research is being conducted.

Co-researchers will be recruited through patient groups, European Drom (Roma Association in Bradford, England), and Shaping Our Lives—a non-profit making user-led organization specializing in the inclusive involvement of Disabled people and people from other marginalized communities.

Ethics approvals and consent

Ethics approvals for WP1 and 4 have been obtained from the LSHTM's research ethics committee (ref no. 30430, 29 May 2024) and for WP2 and 3, from the University of Nottingham (ref no. FMHS 236-0724, 29 August 2024). We have also received approval from the Health Research Authority (for England and Wales) and NHS Research Scotland for interviews with pharmacists and GPs in Wales, Scotland, and England. An ethics application for WP2 and WP3 is currently under review by the University of Nottingham's ethics committee.

Recruitment and consent processes for primary data collection will ensure participation is informed and voluntary, and anonymity in reporting will be guaranteed. All potential participants will receive information about the study (purpose, design, timescales, what involvement would entail, how data will be managed, etc.) before deciding whether

to take part. We will work within best practice guidance and statutory regulations for all data access, storage, and processing.

Study Steering Committee

A Study Steering Committee (SSC), accountable to the NIHR's HS&DR Programme (the funder), will provide support in addressing challenges and managing risks associated with the study. The committee is comprised of an independent chair, representatives of a national arms-length body (NHS England), national community pharmacy and GP sector leaders, and academic experts in health care evaluation, pharmacy practice, and primary medical services.

Discussion

This evaluation is multi-disciplinary and based on a mixed methods design requiring multiple subject, method, and disciplinary experts to deliver a robust evaluation of the impact and implementation of PF's expansion.

Impact and implication of evaluation findings

The evaluation will have practice level, wider research, national, and international policy impact. At the practice level, the findings may contribute to improvements in access to primary healthcare while also providing an understanding of the progress made in achieving the Government's ambition for PF to release 10 million GP appointments annually. PF also represents a substitution of care from GPs to pharmacists [41]. The evaluation findings will provide further evidence as to whether 'task-shifting' from doctors to other professionals is safe, cost-effective, and acceptable both to the staff involved and service users. Also, the evaluation will generate evidence to further refine and improve PF (if PF is judged cost-effective). The perspectives of stakeholders, including pharmacists, GPs, and services users about PF should inform its future development. We also expect this evaluation to aid in AMU optimization revealing the extent to which pharmacists are engaging in antimicrobial stewardship and in the judicious supply of antibiotics. Evidence from a sore throat 'test and treat' pilot in Wales during a *Streptococcus A* outbreak, suggests that AMU was unaffected. Pharmacists' antibiotic supply rates were lower than those of GPs, partly due to the use of rapid antigen detection testing to detect the bacterium in the pharmacy setting [42]. It is worth noting, which no diagnostic tests are included in PF so this aid to deciding whether to prescribe is not available. Nonetheless, AMU is an important consideration in light of national and global concerns about the rise in AMR and the emerging evidence from the evaluation will provide further information on the risk of PF increasing AMR (if any).

In terms of wider policy and research impact, the findings may also provide robust evidence for policymakers on how best to enhance the role of community pharmacy in the NHS in England with specific relevance to the expansion of enhanced clinical services and the integration of pharmacist-independent prescribers into the NHS [43]. Finally, our research could be reused and adapted to similar health systems. For example, within OpenSAFELY, a data dashboard, and the methods and codes used to interrogate it (though not the patient data), will be made publicly available (via GitHub), allowing for a generalized and modifiable model that could be implemented elsewhere. This would save future researchers' time, save funders' money, and advance the field considerably.

Dissemination and knowledge translation

We will provide interim and final reports, translating the study findings into accessible, usable, and high-impact learning for practice. We will publish in specialist journals and the NIHR library. We will also disseminate findings through briefings to policy officials, scientific meetings, pharmacy and GP networks, patient organizations, and the mass media. Furthermore, our knowledge translation activities will include two animated outputs co-produced with lay researchers, and a podcast series documenting the process and challenges of the evaluation.

Supplementary Material

Supplementary data are available in *International Journal of Pharmacy Practice* online.

Author contributions

All authors had a role in the design of the study. R.G. and N.M. with support from all authors developed a research proposal that was selected for funding under a specific call by the NIHR Health and Social Care Delivery Research Programme. A.P. drafted an initial version of the protocol based on the original application. M.L. adapted the protocol for peer-review publication including drafting the 'Discussion' section. Under the 'Methods' section, M.L., with support from R.G., A.P., and N.M. revised content on Work Packages 1, 4, and 5. K.S. undertook revision of the Work Package 2 sub-section. Similarly, T.A. and R.E. revised the Work Package 3. Sections on co-production and ethical considerations were revised by A.P. All authors commented on a draft version of the manuscript before approving the final version.

Conflict of interests

None declared.

Funding

This study is funded by the NIHR Health and Social Care Delivery Research Programme, NIHR160217 Mixed-method impact and implementation evaluation of the "Pharmacy First" Services for the management of common conditions. The views expressed are those of the author(s) and are not necessarily those of the NIHR or the Department of Health and Social Care.

Data Availability

No new data were generated or analysed in support of this protocol. Data underlying the Pharmacy First evaluation will be made available where possible.

References

1. Nuffield Trust. Health system recovery from Covid-19: International lessons for the NHS. 2022. https://www.nuffieldtrust.org.uk/sites/default/files/2022-03/health-system-recovery-final-pdf-1-.pdf. Accessed 24 January 2025.
2. NHS England. *Delivery plan for recovering access to primary care*. 2023. https://www.england.nhs.uk/publication/delivery-plan-for-recovering-access-to-primary-care/. Accessed 24 January 2025.

3. NIHR. Evaluating "Pharmacy First" services for management of common conditions. 2023. https://fundingawards.nihr.ac.uk/award/NIHR160217. Accessed 24 January 2025.
4. Pumtong S, Boardman HF, Anderson CW. A multi-method evaluation of the Pharmacy First Minor Ailments Scheme. *Int J Clin Pharm* 2011;**33**:573–81. https://doi.org/10.1007/s11096-011-9513-2
5. Whittington Z, Cantrill J, Hassell K *et al*. Community pharmacy management of minor conditions-the 'Care at the Chemist' scheme. *Pharm J* 2001;**266**:425–8.
6. Seston EM, Schafheutle EI, Willis SC *et al*. Preparing pharmacists for the Community Pharmacist Consultation Service: a questionnaire survey. *Int J Pharm Pract* 2023;**31**:32–7. https://doi.org/10.1093/ijpp/riac076
7. Stewart F, Caldwell G, Cassells K *et al*. Building capacity in primary care: the implementation of a novel 'Pharmacy First' scheme for the management of UTI, impetigo and COPD exacerbation. *Prim Health Care Res Dev* 2018;**19**:531–41. https://doi.org/10.1017/S1463423617000925
8. Mantzourani E, Wasag D, Cannings-John R *et al*. Characteristics of the sore throat test and treat service in community pharmacies (STREP) in Wales: cross-sectional analysis of 11 304 consultations using anonymized electronic pharmacy records. *J Antimicrob Chemother* 2023;**78**:84–92. https://doi.org/10.1093/jac/dkac358
9. Iacobucci G. Primary care access plan could help narrow health inequalities, says pharmacy leader. *Br Med J* 2023;**381**:p1108. https://doi.org/10.1136/bmj.p1108
10. Costelloe C, Metcalfe C, Lovering A *et al*. Effect of antibiotic prescribing in primary care on antimicrobial resistance in individual patients: systematic review and meta-analysis. *Br Med J* 2010;**340**:c2096. https://doi.org/10.1136/bmj.c2096
11. Parekh S, Hayes CV, Loader J *et al*. The use of the TARGET Antibiotic Checklist to support antimicrobial stewardship in England's community pharmacies. *Antibiotics (Basel, Switzerland)* 2023;**12**:647. https://doi.org/10.3390/antibiotics12040647
12. Damschroder LJ, Aron DC, Keith RE *et al*. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;**4**:50. https://doi.org/10.1186/1748-5908-4-50
13. Morgan D, Kosteniuk J, O'Connell ME *et al*. Barriers and facilitators to development and implementation of a rural primary health care intervention for dementia: a process evaluation. *BMC Health Serv Res* 2019;**19**:1–18.
14. King ES, Moore CJ, Wilson HK *et al*. Mixed methods evaluation of implementation and outcomes in a community-based cancer prevention intervention. *BMC Public Health* 2019;**19**:1–18.
15. Damschroder LJ, Reardon CM, Opra Widerquist MA *et al*. Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum. *Implement Sci* 2022;**17**:7. https://doi.org/10.1186/s13012-021-01181-5
16. Proctor E, Silmere H, Raghavan R *et al*. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;**38**:65–76. https://doi.org/10.1007/s10488-010-0319-7
17. Chan AW, Tetzlaff JM, Altman DG *et al*. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;**158**:200–7. https://doi.org/10.7326/0003-4819-158-3-201302050-00583
18. Pope C, Mays N. Qualitative methods in health research. *Qual Res Health Care* 2006;1–11. https://doi.org/10.1002/9780470750841.ch1
19. Williamson EJ, Walker AJ, Bhaskaran K *et al*. Factors associated with COVID-19-related death using OpenSAFELY. *Nature* 2020;**584**:430–6. https://doi.org/10.1038/s41586-020-2521-4
20. Rodgers S, Taylor AC, Roberts SA *et al*. Scaling-up a pharmacist-led information technology intervention (PINCER) to reduce hazardous prescribing in general practices: multiple interrupted time series study. *PLoS Med* 2022;**19**:e1004133. https://doi.org/10.1371/journal.pmed.1004133
21. Bou-Antoun S, Costelloe C, Honeyford K *et al*. Age-related decline in antibiotic prescribing for uncomplicated respiratory tract infections in primary care in England following the introduction of a national financial incentive (the Quality Premium) for health commissioners to reduce use of antibiotics in the community: an interrupted time series analysis. *J Antimicrob Chemother* 2018;**73**:2883–92. https://doi.org/10.1093/jac/dky237
22. Balinskaite V, Bou-Antoun S, Johnson AP *et al*. An assessment of potential unintended consequences following a national antimicrobial stewardship program in England: an interrupted time series analysis. *Clin Infect Dis* 2019;**69**:233–42. https://doi.org/10.1093/cid/ciy904
23. Kontopantelis E, Doran T, Springate DA *et al*. Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. *Br Med J* 2015;**350**:h2750. https://doi.org/10.1136/bmj.h2750
24. Hawley S, Ali MS, Berencsi K *et al*. Sample size and power considerations for ordinary least squares interrupted time series analysis: a simulation study. *Clin Epidemiol* 2019;**11**:197–205. https://doi.org/10.2147/clep.s176723
25. Dolan E, Goulding J, Marshall H *et al*. Assessing the value of integrating national longitudinal shopping data into respiratory disease forecasting models. *Nat Commun* 2023;**14**:7258. https://doi.org/10.1038/s41467-023-42776-4
26. Todd A, Copeland A, Husband A *et al*. The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England. *BMJ Open* 2014;**4**:e005764. https://doi.org/10.1136/bmjopen-2014-005764
27. Smith G, Mansilla R, Goulding J. Model class reliance for random forests. *Adv Neural Inform Process Syst* 2020;**33**:22305–15.
28. Mantzourani E, Ahmed H, Bethel J *et al*. Clinical outcomes following acute sore throat assessment at community pharmacy versus general practice: a retrospective, longitudinal, data linkage study. *J Antimicrob Chemother* 2024;**80**:227–37. https://doi.org/10.1093/jac/dkae400
29. Husereau D, Drummond M, Petrou S *et al*; CHEERS Task Force. Consolidated health economic evaluation reporting standards (CHEERS) statement. *BMJ* 2013;**346**:f1049. https://doi.org/10.1136/bmj.f1049
30. Vemer P, Corro Ramos I, van Voorn GAK *et al*. AdViSHE: a validation-assessment tool of health-economic models for decision makers and model users. *PharmacoEcon* 2016;**34**:349–61. https://doi.org/10.1007/s40273-015-0327-2
31. Briggs A, Sculpher M, Claxton K. *Decision Modelling for Health Economic Evaluation*. Oxford: OUP, 2006.
32. Fenwick E, Byford S. A guide to cost-effectiveness acceptability curves. *Br J Psychiatry* 2005;**187**:106–8. https://doi.org/10.1192/bjp.187.2.106
33. Fenwick E, Claxton K, Sculpher M. Representing uncertainty: the role of cost-effectiveness acceptability curves. *Health Econ* 2001;**10**:779–87. https://doi.org/10.1002/hec.635
34. Wozniak TM, Dyda A, Merlo G *et al*. Disease burden, associated mortality and economic impact of antimicrobial resistant infections in Australia. *Lancet Reg Health–West Pac* 2022;**27**:100521. https://doi.org/10.1016/j.lanwpc.2022.100521
35. Shrestha P, Cooper BS, Coast J *et al*. Enumerating the economic cost of antimicrobial resistance per antibiotic consumed to inform the evaluation of interventions affecting their use. *Antimicrob Resist Infect Control* 2018;**7**:1–9.
36. Jones CE, Phipps DL, Ashcroft DM. Understanding procedural violations using Safety-I and Safety-II: the case of community pharmacies. *Saf Sci* 2018;**105**:114–20. https://doi.org/10.1016/j.ssci.2018.02.002
37. Pacho A, Mays N, Glover RE. "the best self-care for me […] would be to go and see a specialist". Evaluating the UK's antimicrobial resistance policy to encourage self-care for minor infections: a qualitative study with women from racialised minorities and in low-income households who experience urinary

tract infections. *J Health Serv Res Policy* 2025;**0**:0. https://doi.org/10.1177/13558196251313736
38. Smith LJ. How ethical is ethical research? Recruiting marginalized, vulnerable groups into health services research. *J Adv Nurs* 2008;**62**:248–57. https://doi.org/10.1111/j.1365-2648.2007.04567.x
39. Cassell J, Young A. Why we should not seek individual informed consent for participation in health services research. *J Med Ethics* 2002;**28**:313–7. https://doi.org/10.1136/jme.28.5.313
40. Rogers WA. Evidence based medicine and justice: a framework for looking at the impact of EBM upon vulnerable or disadvantaged groups. *J Med Ethics* 2004;**30**:141–5. https://doi.org/10.1136/jme.2003.007062
41. van Schalkwyk MC, Bourek A, Kringos DS *et al*; European Commission Expert Panel on Effective ways of Investing in Health. The best person (or machine) for the job: rethinking task shifting in healthcare. *Health Policy* 2020;**124**:1379–86. https://doi.org/10.1016/j.healthpol.2020.08.008
42. Mantzourani E, Evans A, Cannings-John R *et al*. Impact of a pilot NHS-funded sore throat test and treat service in community pharmacies on provision and quality of patient care. *BMJ Open Qual* 2020;**9**:e000833. https://doi.org/10.1136/bmjoq-2019-000833
43. Lovell T, Clews G. A prescribing service for England's pharmacies: everything you need to know. *Pharm J* 2024;**312**:312. https://doi.org/10.1211/PJ.2023.1.198108