Investigating innovations in outpatient services

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PLAIN ENGLISH SUMMARY

Why is this study needed?
Outpatient hospital services support patients who have a hospital appointment but do not need a bed or stay overnight. In England, the number of outpatient appointments has increased by two thirds since 2008, but this has not been matched by a similar increase in the number of clinical staff available. Therefore, hospital outpatient services are at greater risk of being overstretched and underperforming. Also, patients can endure long waits, appointment delays and rushed consultations.

To address this national and local NHS services are trying to improve outpatient services so that clinical staff time is better used and services are more convenient for patients. However, little is known about how effective these efforts would be within the NHS.

What we will do
We aim to identify new ways of working in outpatient services in NHS hospitals in England, and to study one example of this in depth.

We will study what is already known about changes in outpatient services. This will help us to understand the different types of innovations that hospitals and health services have implemented, and whether they improve patient care.

In addition, we will study national hospital data. from all English NHS hospitals from five recent years. We will see if we can find positive and uncommon changes in behaviour in outpatient departments that might result from new ways of working. We will then carry out brief interviews with staff at a small number of these hospitals. With these interviews we will aim to see if the changes we found in the data do indeed match with a significant change in how the hospital managed their outpatient service.

Later in this project we will study Patient-initiated follow-ups (PIFU), which is being implemented as part of plans to transform outpatient services across England. Under PIFU, patients decide themselves whether and when they want to attend for a follow-up appointment, rather than keeping to a time set by the hospital. The aim is for patients to be seen when they most need to be seen and to avoid unnecessary appointments. We will use a range of methods to study how PIFU is being put into action, the views of patients and staff, and the impact of PIFU on the use of hospital resources and clinical outcomes.

Sharing what we find

Throughout this work, which will take place between April 2021 and June 2023, we will discuss our developing findings with patient representatives and experts in outpatient care, including national leads, academic researchers, clinical directors, commissioners, and consultants from high-volume outpatient specialties. We will publish papers from the project and summarise all our findings in a final report.

SCIENTIFIC SUMMARY

Background

In England, the number of outpatient appointments has increased by two thirds since 2008/09 to 125 million a year in 2020 (NHS Digital, 2020), accounting for 7 per cent of the NHS budget (NHS England, 2020). This is the largest increase in activity of any hospital service, and yet it has not been matched with a commensurate increase in workforce or system capacity (NHS England, 2019). As a result, long wait times, delayed appointments, and rushed consultations have all become the norm, frustrating patients and staff alike (Castle-Clarke S and Edwards N, 2018).

In 2018, the Royal College of Physicians declared that the "traditional model of outpatient care is no longer fit for purpose" and that the NHS must change how it commissions and delivers the service if it is to be sustainable over the long-term. As part of its outpatient redesign programme, the NHS Long Term Plan seeks to avoid one third of face-to-face outpatient appointments by 2024 –claiming that this would save the NHS an estimated £1.1 billion a year (and patients 30 million visits to hospital) by streamlining service delivery through expanded technology at each stage of the pathway.

Across the outpatient care pathway, a broad range of innovations are being pursued to better manage outpatient care and reduce unnecessary appointments, but there is limited understanding of which interventions are most effective and what factors contribute to their success. The aims of outpatient transformation efforts have been varied, but coalesce around several common themes, including making better use of clinical space and staff time; increasing patient satisfaction, empowerment and convenience; reducing unnecessary in-person appointments; increasing savings

for the NHS and improving cost effectiveness; reducing greenhouse gases and other pollution through reduced travel; and decreasing waiting times for patients.

Also, under standard pathways, patients with long-term conditions or following surgery are automatically called back for outpatient appointments at regular intervals (for example, every six months). These timings are not necessarily decided by clinical need or when a patient wants extra support which means that when follow-ups do occur, they can fail to lead to further investigation or any meaningful change in patient management (Isherwood et al 2018). Conversely, when a patient's symptoms or circumstances do change, they may experience a long wait for an appointment as capacity has been devoted to routine follow-up. Within this context, one important intervention has been the implementing of patient-initiated follow-ups (PIFU) where patients themselves decide when they want to attend for a follow-up appointment, rather than keeping to a time pre-arranged by the hospital.

Aims

This study aims to identify innovations in outpatient services implemented in the English NHS and to carry out a more in-depth rapid evaluation of implementations of PIFU. The work will include two reviews of published literature; one evidence mapping approach to understand the breadth of system innovations being tested to improve outpatient service delivery and current evidence gaps, and the other focussing on the implementation and impact of PIFU. The quantitative work will include a detailed analysis of national outpatient activity data to identify hospital trusts or clinical specialties where notable and recent positive changes in measures of activity exist. We will then carry out interviews with staff from these trusts to understand whether, and how service innovations contributed to these changes.

The final aim of the project is a mixed-methods evaluation of PIFU as implemented across the English NHS. This will be carried out in two phases: the first phase being an assessment of what we can learn from the available national data and to identify issues raised by national and trust staff involved with PIFU services. Findings from Phase 1 will be taken forward to Phase 2 which will be a more in-depth study focussing on a few study sites and further data analysis.

Design and methods

This is a mixed methods study that will involve a review of the literature on outpatient service innovation, a retrospective analysis of outpatient service activity data across all English hospitals, light-touch interviews with a limited number of hospital staff and an evaluation of PIFU. The study includes the following workstreams:

1. **Evidence Mapping Review.** We will conduct a rapid scoping review of the literature to understand what innovations and strategies are being tested to improve the efficiency of outpatient service delivery and identify current gaps and future research needs. The evidence mapping exercise will follow a pre-defined protocol, and involve structured searches carried out in at least three databases. To manage scope, we will limit the review to published studies conducted between 2010 and 2022 in English from comparable health systems to the NHS. We will conduct the review using appropriate appraisal tools and guides developed by the Global Evidence Mapping (GEM) Initiative to describe existing research, inform future research efforts, and address evidence gaps, making adaptations as necessary (Bragge et al, 2011). Included studies will have to have some impact on specialist/secondary care activity and resources. Secondary outcomes of interest may include, but are not limited to, access, patient experience and outcomes, or staff experience and outcomes.

2. **Analysis investigating potential impacts of innovations.** We will apply a method called indicator saturation (Castle and Hendry, 2019) to outpatient activity time series data at the hospital-specialty level with the aim of detecting the existence of change points within the data - that is, periods where significant – and broadly positive - changes in the trend of the time series appear to have occurred. The outpatient service activity measures we will analyse will be determined with the help of the study's advisory group, and, to this end, we will carry out preliminary analyses of changes to activity measures using Hospital Episode Statistics outpatient data in England both before and after the start of the COVID-19 pandemic. The focus will be measures where atypical changes could plausibly reflect the impact of service innovations. Candidate metrics might include total numbers of attendances, numbers of tele-consultations, and follow-up to first appointment ratios. We will include data from January 2013 to December 2019, with the aim of detecting changes from January 2015 (i.e., during the five most recent calendar years). A key part of this workstream will be to prioritise between the numerous changes we are likely to identify over all trusts, specialties and included activity measures; the aim will be to end with a shortlist of up to ten specific changes most likely to be the result of a service change or innovation. To this end, we will create metrics to classify – and so to help prioritise - the change points and make use of relevant contextual information.

3. **Light touch interviews to identify innovations.** We will carry out telephone or video semi-structured interviews with two members of staff at each of the ten shortlisted hospital trusts. We will share with the interviewees a single page briefing, outlining the quantitative data analysis relevant to the service of interest. The interview questions will be formulated to seek out any service change or innovation implemented at the time of interest that might plausibly have contributed to the change. Where we are able to identify an innovation, we will request further documentation, which will be reviewed alongside the interviewee responses and the analysed data. Using selection criteria to be developed and agreed with our advisory group, we will select one or two services to take forward for evaluation.

4. **Evaluation of Patient-initiated follow-up (PIFU).** Our rapid evaluation of PIFU will start with an evidence review covering its implementation and impact. We will evaluate the impact of Patient Initiated Follow-up (PIFU) on measures of outpatient activity, especially with regard to frequency and time to follow up attendances. We will also interview patients and staff across several sites and develop an evaluation framework that can be used locally.

Dissemination and outputs

Potential outputs will include:

- A paper on changes in outpatient activity during the first wave of the COVID-19 pandemic.
- An evidence review of the impact of Patient-Initiated Follow-ups (PIFU).
- A slide pack of the results from the two phases of the PIFU evaluation.
- A final evaluation report, incorporating all our analyses and findings.
- Web-based outputs, for example blogs and/or visualisations of key findings.

Study timeline

The study will take place from April 2021 to June 2023.

BACKGROUND

The NHS Long Term Plan set out an ambitious programme to fundamentally redesign outpatient services in England, with the key aim of avoiding up to a third of face-to-face appointments by 2024. This is in part a response to the steady rise in outpatient attendances in the UK over the past decade, which has outstripped population growth and not been matched with a commensurate increase in workforce or system capacity (NHS England, 2019).

COVID-19 has prompted a broad range of service changes, dramatically reducing levels of activity and the way outpatient services are delivered. First outpatient attendances fell by over 1.1 million in April 2020 compared to April 2019 – a drop of 59 per cent (Appleby, 2020). While attendances have begun to recover, by August they remained 28 per cent lower than in August 2019 (Appleby, 2020). The health service's response to the pandemic - for example, to streamline referral pathways and broadly shift appointments virtually - has accelerated progress in service design, but questions remain about the desirability of maintaining changes in delivery and, if desirable, how practices will be maintained over the long-term.

In England, the number of outpatient appointments increased by two thirds since 2008/09 to 125 million a year in 2020 (NHS Digital, 2020), accounting for 7 per cent of the NHS budget in 2019/20 (NHS England, 2020). This is the largest increase in activity of any hospital service and, given the context of chronic financial constraints and system pressures, long wait times, delayed appointments, and rushed consultations, have all become increasingly common, frustrating patients and staff alike (Castle-Clarke S and Edwards N, 2018).

Traditional outpatient service models have relied on face-to-face consultations, which can require repeat hospital visits that prolong uncertainty and waste patient and staff time (Royal College of Physicians, 2018). As the number of appointments has grown, so too has the proportion of those that are unattended. Between 2008/09 and 2018/19 'did not attends' (DNAs) increased by 32.1 per cent, and hospital and patient cancellations have more than doubled (increasing by 150.1 per cent and 124.2 per cent, respectively) (NHS Digital, 2019). The high rate of missed appointments has led clinics to overbook, exacerbating problems of poor patient experience and signalling clear opportunities to improve efficiency (Royal College of Physicians, 2018). Part of the problem is that under standard pathways, patients with long-term conditions or following surgery are automatically called back for outpatient appointments at regular intervals (for example, every six months). These timings are not necessarily decided by clinical need or when a patient wants extra support. This means that when follow-ups do occur, they can fail to lead to further investigation or any meaningful change in patient management (Isherwood et al, 2018). Conversely, when a patient's symptoms or circumstances do change, they may experience a long wait for an appointment as capacity has been devoted to routine follow-up

These inefficiencies have made improving the value of outpatient care a key priority for the NHS. In 2018, the Royal College of Physicians declared that the "traditional model of outpatient care is no longer fit for purpose" and that the NHS must change how it commissions and delivers the service if

it is to be sustainable over the long term. As part of its outpatient redesign programme, the NHS Long Term Plan seeks to avoid one third of face-to-face outpatient appointments by 2024 – making the claim that this would save the NHS an estimated £1.1 billion per year (and patients 30 million visits to hospital) by streamlining service delivery through expanded technology at each stage of the pathway. Similar strategies have also been rolled out in Wales and Scotland to expand digital access and shift more care to community settings (NHS Scotland, 2017; Welsh Government, 2020). At the local system level, Sustainability and Transformation Partnerships (STP) and Integrated Care System (ICS) leads have also set ambitions to reduce outpatient activity by redesigning care pathways - for example, expanding digital access and changing access thresholds - with some targets for reduction ranging as high as 16 – 30 per cent (Castle-Clarke S and Edwards N, 2018).

COVID-19 has of course had a dramatic impact on NHS services. The health service's response to the onset of the pandemic – for example, by deferring non-essential appointments or switching to digital consultations- has accelerated changes in the way services are being delivered to patients. These changes prompt important questions about their impact and cost- effectiveness, as well as their sustainability, and patient and staff experience of these new ways of delivering outpatient care.

System innovations

Across the outpatient care pathway, a broad range of innovations have and are being pursued to better manage outpatient care and reduce unnecessary appointments, but there is limited understanding of which interventions are most effective and what factors contribute to their success. The aims of outpatient transformation efforts have been varied, but coalesce around several common themes, including:

- making better use of clinical space and staff time;
- increasing patient satisfaction, empowerment and convenience;
- reducing unnecessary in-person appointments;
- increasing savings for the NHS and improving cost effectiveness;
- reducing greenhouse gases and other pollution through reduced travel, and
- decreasing waiting times for patients.

Table 1 – developed from an initial brief review of relevant literature (performed in April 2021) - provides an illustration of common innovations taking place at each stage of the outpatient pathway (from referral to follow-up to discharge).

One important innovation in recent years has been the expansion of PIFU pathways in outpatient services. As the 2021/22 priorities and operational planning guidance update (for October 2021 to March 2022) states the NHS should "ensure that patient-initiated follow-up (PIFU) is in place for at least five major outpatient specialties, moving or discharging 1.5% of all outpatient attendances to PIFU pathways by December 2021, and 2% by March 2022".

While there are potential benefits of PIFU, to patients, clinicians and the NHS, there are relatively few studies exploring the benefits costs associated with PIFU (Reed and Crellin, 2022). Where evaluative evidence does exist, results are mixed both in terms of its impact on patient experience and satisfaction, as well as its ability to reduce volumes of appointments. Modelling carried out in December 2020 by the Outpatient Transformation team at NHS England and Improvement (based on two trusts for a number of specialties) suggested that PIFU can reduce follow up patient attendances

by between 0.81 and 1.77 follow ups per patient depending on the specialty (NHS England, 2020). Further evidence of the impact of PIFU on, for example, outpatient activity metrics (appointments, attendances, DNAs etc), waiting lists, the potential diversion of activity to other services, patient and staff experience, and variations in access and use of PIFU would help in refining its design and provision as it rolls out over the future.

Table 1. Selected outpatient care innovations (identified via a brief literature review – valid as of April 2021)

Stage of Pathway	Intervention	Description	Aims	Selected specialties and sites / localities where it's known to be happening
Optimising referral	Advice and guidance	Allows one clinician to seek advice from another to determine if referral is appropriate.	• Support general practitioners (GPs) to manage their patients' treatment • Manage demand and reduce the number of appointments in outpatient care • Improve quality of referrals	Specialties: Many, including haematology; rheumatology; neurology; paediatrics; ear, nose, and throat (ENT); etc. Sites: • York Teaching Hospital Foundation Trust • Gloucestershire Hospitals NHS Foundation Trust • Somerset NHS Foundation Trust
	First contact practitioners	A First Contact Practitioner service is provided by a registered health professional who is the first point of contact for patients, providing new expertise and increased capacity to general practice and faster access for patients. They are qualified autonomous clinical practitioners who are able to assess, diagnose, treat and discharge a person without a medical referral – where appropriate. The most widespread scheme is with physiotherapists for the musculoskeletal (MSK) population.	• Support patients to be treated closer to home within the community where possible	Specialties: MSK Localities: • Nottingham • Lincolnshire • Darlington • West Cheshire
	Direct access to diagnostic testing	GPs directly refer to specific diagnostic tests for the assessment of particular symptoms, bypassing the need for a specialist opinion.	• Reduce wait times for patients	Specialties: Cancer Localities: Northeast and Cumbria

	Referral streamlining and standardisation	Creates standardised form with set of structured questions for all referrals, which are monitored in outpatient clinics to ensure referrals meet criteria and are appropriate for the services.	• Manage demand and reduce the numbers of appointments in outpatient care • Improve quality of referrals • Improve timeliness of referrals for patients	Specialties: • Renal • General surgery • Cardiology • Gynaecology Localities: • St Helens • Halton • Knowsley • Southport & Formby • Greater Preston • Chorley & South Ribble • Eastern Cheshire
	Shared patient records	Allows for referral letters to be transferred immediately for clinical triage, and for consultants to choose from a host of options (e.g. teleconsultation, advice + guidance, in-person appointment, etc.)	• Reduce wait times for patients	Specialties: many Localities: • Oxfordshire • Bristol • North Somerset • South Gloucestershire
Modernising delivery	Virtual consultations	Replaces in-person appointment with telephone or online appointments, with various models for assessment and follow-up	• Support patients to be treated closer to home within the community where possible • Improve patient experience and satisfaction • Free up clinical capacity • Reduce wait times for patients	Specialities: many, including: • Pain clinics • Trauma and Orthopaedics (T&O) • Plastics • Endocrinology • Dieticians • Cancer • Geriatrics Sites / Localities: • Barts Health NHS Trust

				• Oxfordshire • Airedale NHS Trust
	'One Stop shops'	Brings together Multi-disciplinary Teams (MDTs) in one clinic to allow patients to receiving initial consultation, diagnostic testing, investigations, and any follow-up in the same day or across minimal visits	• Free up clinical capacity • Reduce the number of appointments • Improve patient experience, satisfaction and convenience • Reduce wait times for patients	Specialties: • Breast surgery • Urology • Gynaecology • Respiratory • Cancer Sites: • Royal Brompton and Harefield NHS Trust • Royal Berkshire NHS Trust • North Middlesex University Hospital NHS Trust • UCLH NHS Foundation Trust • Southend University Hospital NHS Foundation Trust • Barking, Havering, Redbridge University Hospitals NHS Trust • Royal Free NHS Foundation Trust • Leeds Teaching Hospitals NHS Trust • Airedale NHS Foundation Trust • Manchester University NHS Foundation Trust • Oxford University Hospitals NHS Trust
	Patient education / self-management support	Improved self-management to help patients understand condition and feel empowered to self-monitor	• Support patients to be treated closer to home within the community where possible	Specialties: many, including pulmonology, endocrinology, respiratory medicine

			• Reduce the number of appointments • Improve patient experience, satisfaction and convenience • Free up clinical capacity	Sites: • Blackpool Teaching Hospitals NHS Foundation Trust • University Southampton NHS Foundation Trust
	Workforce redesign	Physician associates or consultant nurses run high-volume, low-complexity clinics	• Free up clinical capacity • Reduce wait times for patients	Specialities: • ENT • T&O • Ophthalmology • Haematology • Respiratory Sites: • Guy's and St. Thomas' NHS Foundation Trust • Liverpool Heart and Chest Hospital NHS Foundation Trust • Surrey and Sussex NHS Trust
Personalising follow-up	Patient-initiated follow-up	Allow patients to make appointments when they need them related to their on-going health needs, rather than following a standardised one size fits all schedule. Implementation often involves self-management support, advice lines, and dedicated nurse specialist to help patients track and understand fluctuations in their condition and schedule appointments as needed.	• Free up clinical capacity for patients with more urgent needs • Reduce the number of appointments • Improve patient experience, satisfaction and convenience • Reduce did-not-attends (DNAs)	Specialities: • Rheumatology • Dermatology • Gynaecology • Gastroenterology Sites: • University Hospitals Plymouth NHS Trust • University Hospital Southampton NHS Foundation Trust

				• University Hospital Leicester NHS Trust • Stockport NHS Foundation Trust
	GP / Consultant e-clinic reviews	GPs and consultant conduct joint case review to determine if appointment is needed	• Free up clinical capacity • Reduce the number of appointments	Specialty: • Renal care Sites: Barts Health NHS Trust Imperial College Healthcare NHS Trust
	Virtual clinics	MDT hosts virtual group appointments for people with shared condition to answer questions, provide group education, etc.	• Support patients to be treated closer to home within the community where possible • Reduce the number of appointments • Free up clinical capacity	Specialities: • Renal care • Cardiology Locality: Berkshire West Integrated Care System
	Remote monitoring	IT systems monitor test results of patients with long-term conditions for abnormalities and alert patients in need of intervention.	• Free up clinical capacity for patients with more urgent needs • Reduce the number of appointments • Improve patient experience, satisfaction and convenience • Reduce DNAs	Specialities: • Rheumatology • Gastroenterology • Respiratory • Thoracic • Renal medicine Sites: • Lancashire Teaching Hospitals • Berkshire West Integrated Care System • SASH Surrey and Sussex NHS Trust • Southampton
Source: *Summary based on initial literature review of national outpatient transformation programme interventions and pilot evaluations.*				

AIMS AND OBJECTIVES

Aims

This study aims to identify innovations in outpatient services implemented in the English NHS in recent years and to carry out a rapid evaluation of one of the most important recent innovations: patient-initiated follow-up (PIFU). The identification work will incorporate both qualitative and quantitative aspects. We will review published literature to understand the breadth of system innovations and their potential impacts, and carry out detailed data analysis of national outpatient activity to identify hospital trusts or clinical specialties where notable and recent positive changes in measures of activity exist. The evaluation of PIFU will be a mixed methods study investigating the impact of PIFU on the hospital services and on patients and staff.

The specific aims are:

1. To understand the scope and breadth of interventions being pursued to improve efficiency in outpatient service delivery, and to understand key evidence gaps and future research needs.
2. To identify trusts and/or specialties where there is quantitative evidence of a change point that represents the start of potentially positive changes to outpatient activity, for example a reduction in the numbers of attendances, or a substitution between different modes of attendances (e.g. from face-to-face to tele-consultation).
3. To undertake interviews of selected trusts and specialties, to identify whether changes identified in their outpatient activity were potentially the result of specific innovations in care management.
4. To conduct a mixed methods evaluation of PIFU across several sites. This will include:
   a. an assessment of its impact on measures of outpatient activity, especially the volume and frequency of attendances.
   b. an investigation of the factors that influence its implementation and how it has been differently adopted across organisations and / or specialities.
   c. an understanding of the evidence underpinning PIFU and
   d. the development of an evaluation framework that can be used locally by trusts and commissioners to develop a theory of change for PIFU and monitor progress over time.

RESEARCH QUESTIONS

Our evaluation will include four workstreams associated with one each of the following research questions:

1. 1. What types of interventions have been studied to improve efficiency and effectiveness of outpatient care and where are the greatest gaps in evidence and understanding where future research is most needed?
2. Can we identify from routine data any trusts or trust specialties that have exhibited significant and sustained changes in outpatient activity that might be indicative of the impact of innovations in service design?

3. Can any of these identified changes in outpatient activity be linked to specific innovations in care?
4. What is the current evidence relating to the implementation and impact of PIFU? What is the impact of PIFU on measures of outpatient activity? What are the experiences of patients and staff?

Following information from earlier stages of the project and stakeholder prioritisation, this protocol is an update from previous versions. Originally, workstream 4 was to be an evaluation of one or more innovations that would be identified in earlier workstreams as particularly notable. This has now been replaced with a specific focus on evaluating PIFU, a decision which has also had an impact on the scope of the quantitative workstream 2.

DESIGN AND METHODS

To address the specific research questions outlined above, this study consists of four linked workstreams, outlined below.

Workstream 1: Evidence Review

Overview

The aim of Workstream 1 is to understand the scope and breadth of interventions being pursued to improve efficiency in outpatient service delivery, and to identify key evidence gaps and future research needs.

We will conduct a rapid review of the literature of different interventions being deployed to improve the delivery of outpatient services, such as those involving strategies to optimise referrals, modernise the mode of appointment delivery (e.g. digital consultations), and personalise patient follow-up. The review will involve clinical and researcher input and its goals are to:
- Provide an overview of what is currently known about innovations and strategies and their relative effectiveness to improve outpatient service delivery
- Summarise existing evidence of the impact of such interventions on wait times for outpatient care, the number of inappropriate appointments, patient health outcomes, and patient and staff experience
- Identify factors that might support or hinder the implementation and impact of different innovations in outpatient care
- Identify gaps in evidence
- Set up possible examples of interventions for us to use to validate our statistical search strategy and inform a set of interventions we may evaluate in more detail in subsequent phases of the analysis.

Following recommendations on conducting evidence mapping reviews (Bragge et al. 2011; Snilstveit et al., 2013; Miake-Lye et al, 2016), we aim to conduct a streamlined review in order to provide timely information to inform the later stages of our analysis. The NIHR Rapid Service Evaluation Team (RSET) have concluded that an evidence map is appropriate given this is a broad content area

and we do not require a high degree of certainty or detail in the initial stage of this work. And given the breadth of the research question, a systematic review is less suited and initial scoping review is needed to locate, organise, collate and synthesise information into a useful, understandable format.

Design

The review process will be conducted using a pre-defined protocol, to be finalised and agreed between members of the team and designed in consultation with an information specialist at UCL. It will be based on an initial review of innovations already conducted by a member of the team to identify the types of interventions currently being piloted and scaled across the English NHS (see Table 1). Following the design of the review protocol, structured searches will be carried out on more than three databases, including for example, Health Management and Information Consortium Health Management and Policy database, MEDLINE, EMBASE, ASSIA, CINAHL, Web of Science, and Scopus. We will also review PROSPERO, NIHR, and Cochrane for existing systematic reviews conducted on this topic. The search strategy will be developed in consultation with, and executed by, the University of Birmingham Health Services Management Centre library service (who provide library services to the Nuffield Trust).

To help manage the scope, we will use existing systematic reviews as a starting point and limit the review to published studies conducted between 2010 and 2022 in English from comparable health systems to the NHS. Conference abstracts, letters, commentaries, vignette studies, hypothetical cases and articles which were simply referral guidelines will be excluded.

Included studies will have to measure impact on health resource use (including activity levels, performance and costs) in specialist/secondary care. Secondary outcomes of interest may include, but are not limited to, access (including waiting times and referral rates), patient experience and outcomes (including health outcomes, satisfaction, and perceptions of service innovations), and staff experience and outcomes (including capacity, satisfaction, and perception of service innovations).

We will conduct the review using appropriate appraisal tools and guides developed by the Global Evidence Mapping (GEM) Initiative to describe existing research, inform future research efforts, and address evidence gaps. The findings of the review will feed into the latter phases of the evaluation.

Workstream 2: Analysis investigating potential impacts of innovations

We will adapt methods for analysing time series data to find change points in outpatient activity data. The methods will be applied to a large number of time series - potentially to each English hospital trust and constituent clinical specialty - for multiple measures of outpatient activity. We will create summary statistics to help us sort through the large number of time series and to identify a subset that exhibit potentially promising and practically significant 'positive' changes in outpatient activity (with a focus on changes in the most recent five years). We will make use of additional contextual information and data – including our overview of the evidence of innovations in outpatient services - before selecting a shortlist of up to ten of the most promising outpatient service changes (see summary Box 1).

Searching for 'positive' changes in this way (those, for example, where tele-consultations have increased) with the ultimate aim of identifying an associated and deliberate service change/innovation by definition will exclude innovations that have not had an impact or had a very slow or even adverse impact on performance. While there may be limitations to this strategy, it forms the first step of a positive deviance (Lawton et al, 2014) approach, with the intention that any proposed case evaluations (as set out in Section 4) would be designed to give a more holistic overview of the service change.

Documenting changes in outpatient activity measures

In preparation for the change point detection analyses (Section 2.2), we will carry out national analyses of changes in selected outpatient activity measures (including total attendances, attendances by clinical specialty, non-attendances/cancellations, and remote consultations). This analysis will make use of Hospital Episode Statistics (HES) Outpatient data from January 2013 (see the next section below for explanation of this date) to the latest data available at the time of analysis. These will be used by the research team and its advisory group to help prioritise decisions made in the subsequent analyses.

We will analyse and present the activity changes within two distinct periods: pre-2020, and 2020 onwards. The change point detection analysis will by necessity take place during the pre-pandemic period (i.e. the former of these periods), but the 2020 analysis will document the extraordinary impact of the COVID pandemic on outpatient activity. This will provide useful information to the research team as we consider competing innovations that might be evaluated. It is also likely to be of more general interest to NHS commissioners and providers as well as the health policy and evaluation community and so we will seek to publish this work as a standalone paper.

Detecting change points in outpatient time series data

We will apply a method called indicator saturation (Castle and Hendry, 2019) to outpatient activity time series data at the hospital-specialty level with the aim of detecting any significant changes in the trend of the time series.

Some initial candidate activity measures for investigation are shown in Table 2 (with likely preferred options noted), but we will consider additional measures which we are able to calculate from HES data. For each measure, we will have the option of documenting changes in the measure itself, or deviations from the national average. We will use the project advisory group to help prioritise the measures to focus on, i.e., those most likely to show a change in response to a service innovation, and those areas of activity that have the greatest need to be addressed nationally.

Table 2 – Candidate time series measures of outpatient activity for analysis of change point detection

Outpatient activity measure	Description
Appointments	Number of scheduled outpatient appointments
Attendances	Number of attended outpatient appointments
Patients	Number of unique patients
First appointments	Number of first appointments
Did not attend	Number (or proportion) of appointments not attended (did not attend/patient cancelled/provider cancelled)
Tele-consultations	Proportion of appointments recorded as telephone or telemedicine consultation
Outpatient procedures	Proportion of appointments with a valid procedure code
Follow-up to first appointment ratio	Ratio of follow-up appointments to first appointments
Excess follow-up appointments	Number of attended follow-up appointments beyond the upper quartile national average for the specialty

For the activity measures we take forward for analysis, we will construct time series datasets; generally, one for each specialty at each hospital provider. As this is potentially a very large number of time series, we will employ strategies (advised by the project advisory group) to prioritise the services and measures.

We will include data from 1 January 2013 to 31 December 2019 (explicitly ending before any possible impact of the COVID-19 pandemic), at a monthly or quarterly aggregation period (to be determined from analyses investigating the trade-offs of using each period). The seven-year period has been chosen to allow for detection of changes in activity within the five-year period from 2015, with the two earlier years providing baseline data. Only these most recent years will be included to increase the likelihood that there will exist within trusts some institutional memory with respect to specific service changes.

We will apply a method called trend indicator saturation to the time series data, adapting the method used by Walker et al (2019). This is a form of general-to-specific modelling (Pretis et al, 2018) with three steps. First, a time series regression model which includes a full set of linear time trend variables is estimated. Second, insignificant regressors are eliminated using backwards elimination; these are not removed in any particular order so the algorithm will try multiple paths

which can lead to different potential 'terminal' models. Third, the best terminal model is selected according to the Schwarz information criterion.

In applying these methods, we will need to address modelling parameters that could affect the models selected. We will carefully select a significance level and other modelling parameters such as the block size, with reference to the literature (e.g. Castle and Hendry, 2019) and modifying as necessary.

This stage of work, when applied to each individual trust-specialty time series, will identify all of the change points that exist for any given outpatient activity measure. This will potentially include a large number of trend changes that are not practically meaningful. The next stage is to classify these change points in such a way that we can prioritise those that might be most indicative of a significant, and meaningful (in terms of service delivery), change in activity.

Classifying change points of interest

We will not aim to classify every change point in each time series, but rather define a set of metrics that allow us to identify time series that contain change points (or sets of adjacent change points) which are of notable scale and are possible indicators of significant positive change in activity. Along with the contextual measures (Section 2.4), these metrics will help us prioritise the specific service time series we will investigate with trusts (Section 3).

There is limited available evidence to help guide the approach to creating these metrics, and so they will be developed empirically and pragmatically, informed by our analyses of the time series data.

One metric will quantify the total amount of variation in each time series; time series which exhibit little variation are poor candidates for selection. Other metrics will include those which measure:

- the direction of change – i.e., is the change in the direction we might expect to see if the service was improving?
- the magnitude of any change (in relative or absolute terms)
- the timescale over which the change happened
- the persistence of the change in the subsequent period
- the change in the context of longer-term trends
- others, to be determined in response to the trends observed.

Combining these metrics will inform the exclusion of time series (if they contain no changes of interest), and allow the prioritisation of those remaining, so that we can filter to a smaller set of time series that exhibit clear and sustained positive changes in trends that might be the result of innovations. The development and prioritisation of these metrics will be determined via examination of a small number of time series by the researchers, with a view to creating a set of generalisable rules applicable to all time series.

Finalising a shortlist of time series of interest

We will construct a series of a contextual measures that we can analyse alongside specific trust and specialty time series to guide the final selection of a small number (up to ten) of outpatient services showing promising changes in outpatient activity. These measures include:

- Whether there have been large changes in the number of patients seen during the period of the change point of interest,

- Whether there have been significant changes in case-mix over the relevant period,
- What changes there have been in the outpatient activity measure for the relevant specialty at a national level,
- What changes there have been in the trust overall.

This contextual information may allow us to exclude specific time series where the changes appear to be linked to factors not connected with innovations in service delivery.

Using the change point metrics alongside the contextual data, we will aim to select a shortlist of up to ten outpatient services where some unexplained and positive change has occurred

Note on amended approach, related to patient initiated follow up initiatives

During the development of methods for prioritisation of metrics (as described in the previous sections), the research team decided to focus the subsequent evaluation stages on patient initiated follow up (PIFU) initiatives. This had significant implications for this Workstream.

While methods were being developed to analyse multiple outpatient measures alongside one another (to potentially cover different types of potential innovation impacts), we switched instead to study only one measure: first to follow up appointment ratios. This activity measure is considered to be the one most directly related to the aims of PIFU initiatives, that of reduced follow up appointments.

The shortlist of ten outpatient services (conclusion of Section 2.4) would all, therefore, be ones with significant and unusual reductions in numbers of follow ups relative to first appointments.

The focus on a single outpatient activity measure would limit the extent to which we could appraise the general method developed; however, we will discuss this matter in detail in our final report.

Workstream 3: Interviews to identify innovations

We will carry out a series of telephone or video semi-structured interviews with staff at a selection of acute trusts to investigate whether identified changes in outpatient activity might plausibly be linked to specific innovations implemented by those trusts.

The key output of the quantitative data analysis (Workstream 2) will be a shortlist of up to ten outpatient services in England which appeared to show a positive, somewhat atypical change in outpatient activity (in terms of volume, or the type of appointment).

We will arrange separate interviews with two members of staff connected to each of these ten services. We will, in the first instance, approach an outpatient services manager at the trust and request to arrange interviews with the most appropriate people, given the service of interest, and the apparent time of the change.

The research team will, ahead of each interview, share with the interviewee a single page briefing, outlining the data analysis relevant to the service of interest. The briefing will include a description of the change that we found, including the scale of the change and a date at which the change first became apparent. It will also include any contextual information that might be relevant to the discussion.

The interview questions will be formulated to seek out any innovation implemented at the time of interest that might plausibly have contributed to the change. Where we are able to identify an innovation, we will request further information about it from the hospital trust (including business cases or implementation plans, training materials, impact analyses, and other relevant materials). These documents will be reviewed alongside the interviewee response and the data analysed.

If we find services that might benefit from further investigation, we will decide whether to evaluate one or two of them in the final stage of the study (Section 4). The selection criteria will be agreed with our advisory group but are likely to include: services which can be considered innovative, services that show potential for scalability and for large impacts, and services that could benefit from evaluation.

Workstream 4: Mixed methods evaluation of Patient Initiated Follow-up (PIFU)

The evaluation will comprise two phases preceded by an evidence review. Phase 1 is a rapid evaluation using national datasets alongside qualitative interviews with local and national stakeholders. Phase 2 will be informed by Phase 1 and consist of in-depth interviews with local staff and patients with further analysis of both local and national data.

PIFU Evaluation Phase 1

Aims

In Phase 1 we propose to evaluate the impact of the roll-out of PIFU services on relevant measures of outpatient activity using nationally collated data, including Provider Elective Recovery Outpatient Collections (P-EROC) and Outpatient Hospital Episode Statistics (HES). Alongside this analysis we will carry out rapid qualitative work to assist with interpretation. The latter will involve local site interviews with staff to understand the goals and expected outcomes of PIFU, and also how PIFU is being implemented across specialties and services. Documentary analysis will be conducted at a national and site level to understand the national policy context, develop a central logic model and assist with the interpretation of findings.

Phase 1 will have distinctive quantitative and qualitative workstreams with the following research questions:

Quantitative workstream

1. How well can national data be used to evaluate PIFU?
2. What are the impacts of PIFU on measures of outpatient activity, especially with regard to frequency and time to follow up attendances?

Qualitative workstream

1. How is PIFU being implemented, including its aims, components, processes and anticipated outcomes? How are data being used by services to monitor progress against expected outcomes?
2. How have staff engaged with PIFU and what is their experience of delivering the service?
3. What are staff perceptions of the opportunities and risks associated with PIFU?

Quantitative workstream

We will first assess a range of outcomes, definable from outpatient HES data, that might be impacted by implementation of PIFU pathways. These outcomes will include numbers of attendances and follow ups, time to follow up, return rates, rates of DNAs. Use of PIFU will be measured from the Provider Elective Recovery Outpatient Collections (P-EROC). We will consider the feasibility of using non-HES derived data, for example of RTT waiting list data.

We will carry out initial descriptive analyses of relevant measures over time at an aggregated level for different services, stratified by levels of PIFU (high, medium, low, for example – derived from P-EROC data). We may decide to restrict analyses to specific specialties dependant on assessments of the likelihood of detecting any impacts (e.g. specialties with larger proportions of patients on PIFU, or specialties with more frequent follow ups).

We will explore the use of statistical models to test the association between the amount of PIFU with outcomes of interest. Using the national data, we will apply difference in difference, or similar, methods to assess differences in outpatient attendance per patient before and after a trust specialty adopts a PIFU approach, compared with trusts that choose not to. We will also use survival analyses to analyse the influence on time to follow up appointments at an individual patient level, again comparing outcomes for patients in trusts that are not implementing PIFU, adjusting for specialty and patient characteristics. Key factors included in the models would be measures of the extent to which PIFU has been implemented at the relevant trust and specialty.

Since the P-EROC data is a new collection, we will attempt to assess its quality by looking for inconsistencies and discrepancies with HES.

Qualitative workstream

Sampling

To assist with the interpretation of quantitative findings and as scoping for a potential larger scale evaluation we will conduct qualitative interviews and documentary analysis.

Interviewees will be sampled purposively, covering national and service-level stakeholders. At a national level we will conduct interviews with national leaders involved with developing guidance and supporting the implementation and roll-out of PIFU. At site level, a sampling framework will be developed, and sites selected to represent a balance in types and size of trust and experience with PIFU and will be informed by national-level data collection to identify key gaps in understanding where deeper site analysis would hold the most value. Three to five sites will be selected in discussion with NHSEI and based on factors including specialty, geographic location, timing of implementation (i.e. early or late adopters) and type and size of Trust. We will also seek to interview staff from services not currently delivering PIFU to understand why.

National-level data collection

We will conduct two semi-structured interviews at a national level. The aim will be to identify the rationale behind the development of PIFU, understand the national policy context and develop a central logic model/theory of change. A documentary analysis of national level documents related to the implementation and roll-out of PIFU will also be conducted.

Site -level data collection

We will conduct semi-structured interviews with a purposive sample of staff members (2-4 at each site) involved with the delivery of services that have adopted PIFU. We will seek to interview a range of staff (e.g. service leads, clinical and non-clinical roles, support staff, administrative roles, data roles).

Interviews with staff members will focus on the aims and expected outcomes of PIFU, how it is being implemented (including components and processes, barriers and enablers, specialty-specific factors), staff experiences and staff perceptions of patient engagement. Interviews will also focus on mapping the data currently collected by sites and how these are being used to evaluate PIFU, how models are being monitored/evaluated, and if/how data are being used to inform clinical decisions.

Documentary analysis will be conducted using local documents related to PIFU developed by sites at a local level to increase understanding of PIFU processes/components, local adaptations and specialty-related considerations.

Analysis

Analysis of findings will take place simultaneously to data collection, whereby the evaluation team will take detailed notes during data collection and synthesise key points in summary documents called RAP sheets. These will be developed per site to facilitate cross-case comparisons. Key findings will be evidenced by supporting quotes. The categories used in the RAP sheets will be based on the questions included in the interview topic guide and will be reviewed and expanded as new themes and data emerge. These categories include: the PIFU model, (including components, context and use of technology); implementation factors such as barriers and facilitators; impact of the service; staff experiences of delivering the service; patient engagement with the service; opportunities and risk.

PIFU Evaluation Phase 2

Introduction

The second phase of this evaluation will be informed by the Phase 1 evaluation and our rapid evidence synthesis of PIFU. This will include further analysis of the national data as more months' worth become available, alongside a rapid mixed methods evaluation across a number of sites. We will also develop an evaluation framework that can be used locally.

Current evidence relating to the impact of PIFU is limited to a handful of specialties and clinical conditions and involves a range of design issues that limit the generalisability of findings (including selection bias, single site studies, low patient numbers, and models that are not clearly defined). While some previous research has focussed on patient outcomes, no evidence exists on inequalities in access or engagement. There is also limited qualitative evidence examining the implementation of PIFU, and there is a need to better understand this (the components, processes and contextual factors) including consequent staff experiences and resource requirements.

In this phase of the evaluation, we will aim to explore the impact of PIFU on service use (including outpatient and wider health services), examine how PIFU is being implemented in terms of components and processes involved (including how potential risks are being managed), patient engagement with and experience of PIFU (focusing on potential inequalities to access and experiences, and differences across patient groups), and staff experiences of delivering the service in terms of satisfaction, resources and capacity.

Sites will be selected based on a range of criteria such as specialty, clinical condition, length of time implementing PIFU, the PIFU model, and geographic location. Site selection will be informed by the scoping work conducted in phase one.

Although we will have gained some understanding of the quantitative impact of PIFU on outcomes during the Phase 1 evaluation, in Phase 2 we will aim to investigate these relationships in more depth. As well as a more in-depth analysis of P-EROC and HES data, aided by additional months of data, we will assess how outcomes are being monitored at local level and the potential of hospital data to effectively evaluate the local impact of PIFU on patient and service outcomes.

Research questions

Research questions for Phase 2 cover the following:

1. What are the relevant outcomes for evaluating the impact of PIFU services? To what extent can we measure the different impacts of these services? How are the data being used to monitor the progress against these outcomes and how can the data be used?

2. How is PIFU being implemented? What components and processes does it involve? What is the involvement of technology in the pathway?

3. What are the unintended consequences (for example, on other services) of PIFU and how are potential risks being managed? What strategies have been adopted to address potential inequalities along the PIFU pathway? What data are being collected to understand potential disparities? Is there variation in how different patient populations access and engage with PIFU?

4. What are patient experiences of engaging with PIFU services? What is the level of patient engagement?

5. What are staff experiences of delivering PIFU? What is the impact on staff satisfaction, workload and capacity across different roles?

Methods

The evaluation will use a mixed methods approach and comprise qualitative and quantitative analyses, and the development of an evaluation framework. Data from different streams of the project will be triangulated to inform analyses and aid the interpretation of findings.

Research question 1

For research question 1, much of the information on relevant outcomes would come from Phase 1, as will some assessment of impact at a national level. We would also update the analysis of Phase 1 as more recent data become available. Our capacity to undertake a more in-depth analysis of impact will depend on what data are available at a local level.

With local patient-level data from a hospital that can identify individuals on PIFU, we will use multivariate regression analysis to compare their outcomes to hospitals which have not applied PIFU within the same specialties. Comparisons will also be made to outcomes within the PIFU hospitals before PIFU was implemented, focusing on the pre-COVID period to avoid any local impact of COVID affecting the results. Again, these will be at the specialty level. To understand whether any observed differences are specific to the hospital, we will also compare against the control hospitals over the same two periods.

One aim of this phase is to expand the scope of our analysis beyond numbers and timings of appointments to wider impacts on other hospital attendance (e.g. visits to A&E or as an inpatient).

Understanding the ways data are being used will come from site interviews and documentary analysis. Assessments of the ways data can be used will be included in our evaluation framework.

Research questions 2 to 5For research questions 2 to 5, we will undertake in-depth case studies of sites including an analysis of internal documents and interviews with staff and patients. Topic guides will include questions to understand how PIFU might be implemented and its potential implications

for patients and services. We will use these insights to inform patient selection and the patient interview topic guide to understand how patient experiences may vary.

We will also interview patient advocacy groups such as Healthwatch and National Voices, and NHS patient advice and liaison (PALS) services. Qualitative data collection will be at a single time-point (we will not be looking at changes over time). We will triangulate data sources and explicitly recognise any potential bias.

Our evaluation framework will be developed for adoption by local services to evaluate the impact of PIFU. The development of the framework will be informed by the findings from Phase one and all Phase 2 workstreams. The framework will look to include both quantitative and qualitative elements, and will cover planning and design, data collection and analysis, and reflecting and reporting of results, and will draw on case study examples of selected sites.

PROJECT ADVISORY GROUP

A formal advisory group has been established to oversee the progress of the project. The group meet by video conference once at the start of the project and then at intervals as appropriate, including at key points where decisions need to be taken by the research team.

The group includes members with various types of experience and responsibilities including clinical and academic expertise. The group also includes one patient representative (see section Patient and Public Involvement).

The responsibilities of the group include:

- Providing context and general input to the research team, based on knowledge of outpatient service policy and delivery,
- Helping the team to prioritise between metrics of most utility in addressing the research questions,
- Providing a viewpoint with respect to detailed practical service issues around outpatient activity, and related data collection,
- Guiding the research team in seeking further expert advice,
- Sense-making when interpreting outputs, for example, activity patterns by specialty, or the long-list of trusts with potential innovations,
- Providing a perspective on services' responses to COVID-19,
- Supporting the research team in scoping out the final phase of the study.

They have provided feedback on key developments in the project. For example, our sampling framework was updated for the qualitative components was updated to include a balance of implementation experience, and not just focus on early adopters or trusts who have come closest to reaching the PIFU targets.

PATIENT AND PUBLIC INVOLVEMENT (PPI)

Patient and the public representatives will be actively involved in the project in the following ways:

- Design of the project
- Management of the project (e.g. advisory group)
- Developing participant information resources
- Contributing to the reporting of the project
- Dissemination of findings

Patient and public representatives have reviewed this protocol and have contributed to the design of this study. We will continue this approach throughout the project.

We have recruited a patient representative to be a member of the project advisory group, to provide perspectives on their experiences of care and different system innovations to guide our work.

We expect patient and public involvement to benefit the project in the following ways: ensuring the study focuses on issues that are of importance to service users; ensuring that this focus is reflected in our aims, objectives and research questions; ensuring that these are operationalised suitably in our approach to data collection and analysis; and ensuring that our findings are disseminated effectively and in a manner that is meaningful to patients, carers and the public.

Our patient representative will participate in all project advisory group meetings and comment on study documents such as plain English summary. Appropriate training and support will be offered for our patient representative, e.g., on how to effectively participate in meetings. We have budgeted to support our patient representatives in all these activities. To support effective participation, we will ensure that documents relating to meetings and events are distributed in a timely fashion (e.g. a week in advance). Also, a member of the team, Pei Li Ng, Research Project Manager, has been identified as the primary contact with whom patient representative may raise any issues or concerns.

ETHICAL ISSUES

On the basis of the NHS Health Research Authority's online decision tools, the study has been classified as a service evaluation. Nevertheless, we will share the protocol with UCL's Joint Research Office to confirm that the study is not classed as research, thus not requiring approval by a research ethics committee. However, for the patient aspects of the second phase of the PIFU evaluation we will seek HRA ethics committee approval prior to initiating any research activity."

Researchers will conduct the study according to the highest ethical standards. An informed consent process using participant information sheets for national and local interviews to ensure informed and voluntary participation. Information sheets will be provided to potential interviewees with information on the study (purpose, design, expectations, risks, benefits) before they are asked if they would like to take part in an interview. The information sheet will indicate that the researchers carrying out the study act independently, operate under a professional code of conduct, and are interested in potential changes to outpatient services. It will also make clear that participation is entirely voluntary, and that participants may withdraw from the study at any time.

DATA MANAGEMENT

Quantitative data

Quantitative data will be held by the Nuffield Trust and managed in line with legal and regulatory requirements, including the General Data Protection Regulation (GDPR) and the Data Protection Act (2018), and necessary research approvals.

HES data are held and analysed on a secure server based at the Nuffield Trust, which acts as the data processor for these data, with University College London and the Nuffield Trust acting as joint data controllers. The access and use of HES data for this project is governed by a data sharing agreement with NHS Digital covering NIHR RSET work DARS-NIC-194629-S4F9X.

For the PIFU evaluation (workstream 4), we will access a new dataset called Provider Elective Recovery Outpatient Collection (P-EROC) from NHS England & Improvement. The data transfer and its use will be governed by an appropriate Data Sharing Agreement between the Nuffield Trust and NHS England & Improvement.

Whenever we want to use an existing local dataset as individual person records, we will carry out Data Protection Impact Assessments (DPIAs) and set up Data Sharing Agreements (DSAs) in accordance with the HSCIC Code of Practice on Confidential Information good practice guidance. We will also ensure compliance with the Common Law Duty of Confidentiality and the Anonymisation Code of Practice.

Data will be safely transferred to the Nuffield Trust's secure research server using encrypted transfer protocols (SFTP) and, once there, access will be restricted to members of the project team. Researchers working on other datasets in the Trust would not have access to this data.

The trusted research environment at the Nuffield Trust means that we do not hold patient level identifiers in other datasets we have e.g., HES, this means there is no common identifier at patient level that could be used to link these datasets. Isolation of datasets will be maintained. We are also bound not to link HES data with additional datasets through our agreement with NHS Digital"

The Nuffield Trust is ISO27001 certified, BSI Certification Number: IS 648454.

With any outputs we will follow standard constraints on disclosure control.

Qualitative data

All staff interviews will be carried out on MS Teams or over the phone, and recorded using MS Teams or an encrypted, password protected digital audio-recorder (to which only the evaluation team member knows the password). All patient interviews will be carried out using the encrypted audio recorder.

The digital recordings of interviews will be then sent to a certified transcription service (TP transcription limited). Returned transcripts will be reviewed by a qualitative researcher for accuracy, any sensitive data will be removed and the file password protected. The data will be cleared from the digital audio recording device promptly when it has been successfully transferred to Nuffield Trust server.

Data confidentiality and anonymity will be ensured with appropriate data management and storage.

All information and data will be held securely at the Nuffield Trust and University College London. Participant identifier codes will be stored in a password-protected Excel file on the secure drive and separately from the transcripts.   For the national level and staff aspects of the evaluation the original interview recordings, transcripts, and materials for documentary analysis will be stored on

the secure Nuffield Trust drive accessible only via the Nuffield Trust password-protected IT network. For the patient aspects of the evaluation (conducted as part of phase two), the original interview recordings and transcripts will be stored on the UCL Data Safe Haven (a secure electronic environment, certified to ISO27001 information security standard and conforms to the NHS Information Governance Toolkit).

PROJECT MANAGEMENT

The early part of the study has been led by John Appleby (Nuffield Trust) and is now led by Chris Sherlaw-Johnson (Nuffield Trust). Pei Li Ng (UCL) is the project manager. Other team members are from the Nuffield Trust and UCL Department of Applied Health Research.

The team will meet weekly during the early phases of the project and at least fortnightly thereafter throughout the duration of the project. The evaluation will be discussed as a standing item at monthly NIHR RSET meetings, in terms of progress against project milestones and to address any practical or methodological issues, and to help maintain the independence of the evaluation.

With Workstream 4, we will have fortnightly meetings with the Outpatient Transformation Team at NHS England and Improvement to discuss progress, feedback interim findings and to keep informed about the latest developments in the national implementation of PIFU.

DISSEMINATION AND OUTPUTS

Projected outputs

The Nuffield Trust's communications team will develop a dissemination strategy for this work, with outputs also discussed by the Project's Advisory Group. Outputs will be designed to be relevant to policy and practice around outpatient service transformation. Provisional expected outputs include:

- A peer-reviewed paper on changes in outpatient activity during the first wave of the COVID-19 pandemic.
- A systematic evidence review of PIFU, including an explainer of the intervention and summary of key evidence for a broader public audience.
- A slide pack for NHS England summarising our findings from Phase 1 of the PIFU evaluation.
- A further slide pack for Phase 2 of the PIFU evaluation.
- A final evaluation report for NIHR, including all analyses and findings.
- Web-based outputs, for example blogs and/or visualisations of key findings.

Through NHSE, our qualitative engagement and our Patient Advisory Group we will identify other opportunities for disseminating findings, particularly to reach teams directly involved with implementing PIFU.

In addition, we plan a range of dissemination methods to reach different audiences. These will be developed with input from the Nuffield Trust communications team, NHS England and organisations that represent NHS staff as well as patients. These may include:

- A range of slide packs to share findings with a range of key audiences including clinicians, commissioners, policy makers and patients/carers facilitated through existing (the NHS Communities of Practice group, the FutureNHS platform) and new networks.
- Appropriate non-expert forms of dissemination e.g. videos, blogs, podcasts.
- Roundtables to test and disseminate findings with clinicians, policy makers, patient advocacy organisations, and other key stakeholders

Funder requirements

We will follow the guidance stipulated by the NIHR when communicating our research:

- Notification of outputs and copies of any paper/article should be sent to the funder 28 days before it is due to be published.
- The NIHR's contribution should be acknowledged in full by including a funding statement.
- Research articles should be published in journals as open access that make the output available using the Creative Commons Attribution (CC BY) licence and allow immediate deposit of the final published version in other repositories without restriction on re-use.
- The independent nature of the research and its intellectual property provenance should be emphasised by a disclaimer ("This article/paper/report presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.").

RISK AND RISK MANAGEMENT

Risks and mitigation for these risks are shown in Table 3.

Table 3: Risks associated with the project and mitigations for each

Risk	Mitigation
Quantitative analyses in the PIFU evaluation may not lead to definitive conclusions about the impact of PIFU, because of data, timing and the variation in implementation. Long-term impact after the activity settles into a steady state, may be difficult to ascertain over the course of this project.	If we are not able to make conclusions about the impact of PIFU, whether in the short- or long-term, we will make recommendations about what data, and other circumstances, may be necessary for an effective evaluation.
Some changes in reported PIFU activity may reflect changes in classifying activity that was already being carried out rather than genuinely new activity. This will obscure any true impact PIFU might be having.	We will consider removing specialties from the analysis where this is most likely to have happened. Although this can happen across trusts and specialties, we will assume that most reported increases in PIFU activity are genuine.
We may struggle to access a representative sample of staff and patients and therefore be	We will use our advisory group for support in making appropriate links within trusts and local regions in areas where we have gaps to achieve

Risk	Mitigation
limited in our understanding of the effects of PIFU on different patient and staff groups	as broad of a sample as possible. We will be clear in results and recommendations about any key gaps in perspective, and where further evaluation may be needed.
	The research time are very experienced in recruiting interviewees.
Non-engagement from sites	The research team is meeting regularly with NHS England at a national level, our advisory group and has built relationships with several sites during the phase 1 PIFU scoping work. Team members will have on-going meetings with site delegation teams/gatekeepers, to discuss the contribution required from each party for the duration of the evaluation and continue to engage with sites through national forums such as the FutureNHS platform.
Inability to recruit patients for interview There is a risk the study may be delayed in recruiting participants because it will be the responsibility of case study sites to identify patients to interview on behalf of the evaluation team.	At each case study site, the team will identify a key point of contact regarding participation and will be in regular contact with them. The team will produce detailed, descriptive information sheets to inform potential participants of the importance of the evaluation, why we have asked them to take part, their involvement, and associated risks and benefits.
	There may be an option to work with research nurses from the Clinical Research Networks to facilitate recruitment.

FUNDING

QUALITY CONTROL

The study protocol has been reviewed by independent experts: an academic specialist in large database epidemiology, and a clinical director at the Royal College of Physicians. It has also been reviewed by the full NIHR RSET programme as well as by two patient representatives. The final protocol will be approved by the funder (NIHR) and, once approved, be considered for publication.

INSURANCE/INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

STUDY TIMELINE

Workstream 1: April 2021 to June 2021

Workstream 2: April 2021 to Nov. 2021

Workstream 3: Dec. 2021 to Feb. 2022

Workstream 4 and final report: See Figure 1

Figure 1: Detailed timeline of the PIFU evaluation in Workstream 4 and final reporting.

	2022											2023					
	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April	May	June
PHASE 1																	
Develop protocol and analysis plan	▓	▓	▓	▓													
Arrange access to P-EROC, receive first data			▓														
Develop and test outcome measures				▓	▓												
Classify OP appointments (Strategy Unit method)				▓	▓												
Descriptive (aggregated) analyses					▓	▓											
Build initial models					▓												
Develop secondary sets of outcome measures						▓	▓										
Receive update of P-EROC to end March 2022						▓											
Finalise models							▓										
Carry out sensitivity analyses							▓										
Develop programme theory and site selection framework				▓	▓												
Develop qual data collection tools				▓	▓												
Conduct site-level interviews and analysis				▓	▓	▓											
External validation of qual analysis to advisory group and NHSEI						▓											
Produce slide set								▓	▓								
PHASE 2																	
Identify sites								▓									
Obtain necessary approvals						▓	▓										
Data collection & analysis								▓	▓	▓	▓	▓	▓	▓			
Development of evaluation framework										▓	▓						
Write-up													▓	▓	▓	▓	▓
Publish outputs/report																	▓

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