NIHR HS&DR Rapid Service Evaluation Team

Title: Investigating innovations in outpatient services

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Principal investigator: John Appleby* (Director of Research and Chief Economist)

Research team: Theo Georghiou* (Senior Fellow), Sarah Reed* (Senior Fellow), Jonathan Spencer* (Researcher), Jessica Morris* (Researcher), Dr Jean Ledger** (Research Fellow).

*Nuffield Trust, 59 New Cavendish Street London W1G 7LP

**Department of Applied Health Research, University College London

PLAIN ENGLISH SUMMARY

Outpatient hospital services are those where a patient goes to hospital for an appointment but is not given a bed and does not need to stay overnight. In England, the number of outpatient appointments has increased by two thirds since 2008, but this hasn't been matched by a similar increase in the number of clinical staff available. One result of this, it's believed, is that hospital outpatient services are overstretched and underperforming. Patients often have to endure long waits, appointment delays and rushed consultations.

As a result, there are efforts by national and local NHS and clinical organisations to try to improve outpatient services so that clinical staff time is better used and services are more convenient for patients.

This study aims to identify innovative changes made to outpatient services in hospitals in England, and to identify one or two specific promising examples for detailed evaluation.

The work will include an analysis of existing evidence of outpatient service changes to help us to understand the different types of innovations hospitals and health services have implemented, and their potential impacts on patient care.

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

In this way we aim to identify one or two such 'innovative' outpatient services to evaluate. We will design the evaluations to be relevant to the specific type of service, and will be looking to answer questions about the impact of the service on patients, staff and health outcomes. We will also think about the costs of the service, and think about how the service might be spread more widely.

Throughout this work, which will take place between April 2021 and April 2022, we will try to understand our findings as much as possible with the help of a small group of experts in outpatient care. A final report will summarise all of our findings, but we will also publish a separate report in early 2021 outlining how outpatient services have changed as a result of the COVID-19 pandemic.

SCIENTIFIC SUMMARY

Background In England, the number of outpatient appointments has increased by two thirds since 2008/09 to 125 million a year (NHS Digital, 2020), currently 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). 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 unattended appointments. 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 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 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.

Aims This study aims to identify innovations in outpatient services implemented in the English NHS, with a view to evaluating up to two such innovations. The work will include a review of published literature to understand the breadth of system innovations and their potential impacts. 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. Interviews with trusts will be used to determine whether these changes were potentially due to innovative changes to services, and for one or two of the most promising examples, we will carry out an evaluation appropriate to the service type and aims.

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 up to two outpatient services. The study includes the following workstreams:

1. **Evidence Review** We will conduct a rapid review of the literature to understand what is currently known about innovations and strategies and their relative effectiveness to improve outpatient service delivery. The review will follow a pre-defined protocol, and involve structured searches carried out in at least three databases. To manage scope, we will use existing systematic reviews as a starting point, and limit the review to published studies conducted between 2010 and 2020 in English from comparable health systems to the NHS. We will conduct the review using appropriate appraisal tools and guides available via the Joanna Briggs Institute (JBI) Manual for Evidence Synthesis to assess the quality of the articles, strength of evidence, and potential for bias, making adaptations as necessary (Aromataris, 2020). Included studies will have to have some impact on specialist/secondary care. Outcomes of interest may include, but are not limited to, access, patient experience and outcomes, staff experience and outcomes, and health resource use.
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 also 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. **Mixed methods evaluation of innovations** We will carry out evaluations of the one or two innovations identified in the previous section. The exact form of the evaluations will depend on the nature of the innovations, and their anticipated aims and potential impacts, however they will likely to seek to answer questions about the impacts on patients and staff, the impacts on care outcomes, and economic impacts.

Dissemination and outputs Potential outputs will include:

- A peer-reviewed paper on changes in outpatient activity during the first wave of the COVID-19 pandemic.
- An evidence review of outpatient service innovations.
- A peer-reviewed article addressing the benefits and difficulties in adopting this quantitative approach to searching for innovations in services.
- A final evaluation report: on the evaluation findings for up to two service innovations, also summarising the study's other published work.
- Web-based outputs, for example blogs and/or visualisations of key findings.

Study timeline The study will take place over thirteen months (April 2021 to April 2022).

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).

In recent months 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 has increased by two thirds since 2008/09 to 125 million a year (NHS Digital, 2020), currently accounting for 7 per cent of the NHS budget (NHS England, 2020). This is the largest increase in activity of any hospital service and, given the context of chronic financial constraint 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 unattended appointments. Between 2008/09 and 2018/19 'did not attends' 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 appointments, exacerbating problems of poor patient experience and signalling clear opportunities to improve efficiency (Royal College of Physicians, 2018).

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 a 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 - deferring non-essential appointments or switching to digital consultations,

for example - has accelerated changes in the way services are being delivered to patients. These changes prompt important questions about the effectiveness and cost effectiveness, as well as 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 - provides an illustration of common innovations taking place at each stage of the outpatient pathway (from referral to follow-up to discharge).

Table 1. Selected outpatient care innovations (identified via a brief literature review)

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 • Reduce the number of appointments	Specialties: many, including pulmonology, endocrinology, respiratory medicine Sites:

			• Improve patient experience, satisfaction and convenience • Free up clinical capacity	• 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 • Haemotology • 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 in order to evaluate one or two such innovations. The identification work will incorporate both qualitative and quantitative aspects, including an analysis of published literature to understand the breadth of system innovations and their potential impacts, and detailed data analysis of national outpatient activity data to identify hospital trusts or clinical specialties where notable and recent positive changes in measures of activity exist and where there may be opportunities for evaluation of service changes.

Objectives

1. To summarise the recent literature on the effectiveness of different innovations to improve outpatient service delivery, and to understand the factors that influence their implementation and variations in how they were applied across organisations.
2. To understand how the broader policy context may have contributed to changes in outpatient activity over time, and how current policy priorities may influence the way different system innovations are embedded and scaled nationally.
3. 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).
4. To investigate reasons that may explain some of the observed changes. These may include, for example, changes to outpatient service policy and practice, or data quality issues.
5. To undertake light-touch 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.
6. To evaluate up to two service innovation case studies, identified with the data analysis.

RESEARCH QUESTIONS

1. What is the evidence to support the use of different service innovations to improve efficiency, effectiveness and patient experience of outpatient care, and what factors might affect their implementation?
2. Are there 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 changes in outpatient activity identified be linked to specific innovations in care?
4. For one or two identified innovations: what are the impacts of these innovations on patients and staff, and in terms of activity and economic measures? How were the innovations implemented, what challenges were faced, and how might they be sustainable and scalable?

DESIGN AND METHODS

In order to address the specific research questions outlined above, this study consists of five linked workstreams, outlined below.

1. Evidence Review

In relation to **RQ1:** 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
- 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 (explained below in Section 2)

Following recommendations on conducting rapid reviews (Tricco et al. 2015; Hartling et al., 2015; Haby 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 a rapid review is appropriate given that there are recent systematic reviews conducted on this topic, we are primarily interested in recent innovations, and though the topic is broad, we do not require a high degree of certainty or detail at this stage.

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, 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 2020 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 have some impact on specialist/secondary care. 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), staff experience and outcomes (including capacity, satisfaction, and perception of service innovations), and health resource use (including activity levels, performance and costs).

We will conduct the review using appropriate appraisal tools and guides available via the JBI Manual for Evidence Synthesis to assess the quality of the articles, strength of evidence, and potential for bias, making adaptations as necessary (Aromataris, 2020). Two researchers will rate articles independently for quality and relevance. In cases of disagreement, the reviewers will discuss their responses until consensus is reached. The findings of the review will feed into the latter phases of the evaluation.

2. Analysis investigating potential impacts of innovations

In relation to **RQ2:** 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).

Box 1: The stages of analysis (investigating potential impacts of innovations)

Stage 1: Modelling each time series to detect change points

Apply modelling to each trust-specialty time series, to detect changes within each in trend.

Stage 2: Classifying change points of interest

Calculate a series of summary metrics that summarise individual change points (or adjacent groups of change points), in order to focus on those which might be candidates for selection. Such summary metrics might include the total variation in a time series, and the magnitude, direction, and consistency over time of changes in activity measures.

Stage 3: Finalising a shortlist of time series of interest

A small number of time series (up to ten), will finally be selected using:

- Change point summary metrics from stage 2
- The wider context of changes in the outpatient services in trusts and nationally
- Guidance on priorities (relative impacts of changes in different specialties, for different outpatient activity measures) from project advisory group

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.

2.1 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 2.2 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.

2.2 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**	**Likely preferred measure?**
Appointments	Number of scheduled outpatient appointments	Yes
Attendances	Number of attended outpatient appointments	Yes
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	Yes
Outpatient procedures	Proportion of appointments with a valid procedure code	
Follow-up to first appointment ratio	Ratio of follow-up appointments to first appointments	Yes
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 on the basis of 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, Reade and Succarat, 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.

2.3 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.

2.4 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.

2.5 Validation and discussion of the methods

We will assess the strengths and weaknesses of our methods for detecting changes in trends in outpatient activity measures where possible. For example, where there is published evidence – identified in the evidence review - of a positive, measurable change to any outpatient service in England (between 2015 and 2020) as the result of specific innovations (or changes in practice), we will document whether the methods we have used were able to identify and highlight those changes.

We will consider the strengths and weaknesses of the change detection methods we used in relation to alternative analysis methods. We will produce a report that outlines the methods and describes necessary analytical decisions we made. The report will consider generalisability of these methods to other situations, including different areas of care, and also for different purposes, for example, ongoing prospective monitoring of deliberate service changes.

3. Light touch interviews to identify innovations

In relation to RQ3: 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 data analysis (Section 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 from the hospital trust on the innovation (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.

The end point of this stage will be the identification - from within the list of ten initial services - of one or two that we will take forward for evaluation (Section 4). The selection criteria for these services 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.

4. Mixed methods evaluation of innovations

In this final stage (addressing RQ4), we will carry out evaluations of the one or two innovations identified in the previous section. The exact nature of the evaluations will depend on the innovations, and their anticipated aims and potential impacts, however they will likely to seek to answer questions about:

- The impacts of the innovations on patients (including on their experience of care), and on staff,
- The impacts on outcomes, and,
- Economic impacts.

At the start of this stage, we will develop draft research questions with those implementing the innovations and with the project advisory group. We anticipate that questions may include some of the following:

- What were the original aims for implementation?
- How was the innovation implemented?
- What national/network/other support was received?
- What implementation challenges were faced?
- What impact has the innovation had for patients and quality of care?
- What impact has the innovation had on hospital processes and out of hospital services?
- Have there been equity issues in adopting the innovation?
- What were patients' experiences of the innovations?
- How have hospitals monitored their progress?
- How sustainable are the innovations?
- What were the economic impacts of the innovations?

Detailed methods for the evaluations will depend on the research questions, and on practical considerations such as data availability, but we anticipate that they are likely to include qualitative methods in addition to quantitative and economic analyses.

In the quantitative analyses, we will consider using methods such as synthetic control matching to evaluate the effect of the specific trust innovations against similar trusts.

PROJECT ADVISORY GROUP

We will convene an external project group to oversee the progress of the project. The group will 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.

We will seek to include group members with various types of experience and responsibilities.

The group will also include one patient representative (see section Patient and Public Involvement).

The responsibilities of the group will 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.

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.

The evaluation of innovations are likely to include considerations of patient experience and acceptability.

Patient and public involvement will continue 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 will be identified as 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.

Researchers will conduct the study according to the highest ethical standards. 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

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.

Qualitative data

Interviews will be recorded on an encrypted, password-protected digital audio recorder to which only the evaluation team member knows the password. The recording data will be cleared from the digital audio recording device promptly when it has been successfully transferred to Nuffield Trust server.

The digital audio recordings of interviews will be then sent to a Cyber Essentials certified transcription service for transcription. Returned transcripts will be reviewed by a qualitative researcher for accuracy, any sensitive data will be removed and the file password protected. Participant identifier codes will be stored in a password-protected Excel file on the secure drive and stored separately from the transcripts.

The original interview audio 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. Access to data is granted after login with valid accounts and according to Nuffield Trust access permissions.

PROJECT MANAGEMENT

This study will be led by John Appleby (Nuffield Trust) and include team members 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.

In addition, we will recruit a Project Advisory Group (see above) to advise and review work as it proceeds.

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:

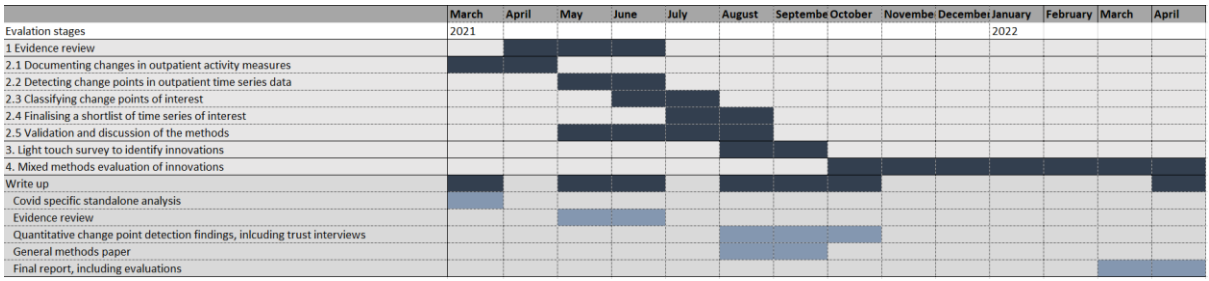
- A peer-reviewed paper on changes in outpatient activity during the first wave of the COVID-19 pandemic.
- An evidence review of outpatient service innovations.
- A peer-reviewed article addressing the benefits and difficulties in adopting this approach to searching for innovations in services.
- A final evaluation report: on the evaluation findings for up to two service innovations, also summarising the study's other published work.
- Web-based outputs, for example blogs and/or visualisations of key findings.

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.").

STUDY TIMELINE



RISK AND RISK MANAGEMENT

The timeline proposed above is based on the following assumptions: 1) the team have timely access to the data required for the quantitative and qualitative analyses; 2) the progress of COVID does not impede access to hospital staff. Where, at the end point of Section 3 (interviews with trusts) we have not found any plausible candidates for evaluation, we will discuss with both our Project Advisory Group and funders possible options, including whether we might continue to evaluate promising service innovations which have become apparent to the research team from a source other than the preceding quantitative analysis and interviews.

FUNDING

RSET is funded by the NIHR Health Services and Delivery Research (HS&DR) programme (HSDR 16/138/17).

QUALITY CONTROL

The study protocol has been reviewed by independent experts: an academic specialist in large database epidemiology, and a clinical director at RCP. 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 a NHS Trust or otherwise.

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