A mixed-methods investigation of the delivery, impact, and acceptability of a national de-adoption programme across Clinical Commissioning Groups in the English National Health Service

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1. Background

Health services worldwide are under constant pressure to provide high quality care with limited budgets. The NHS has felt these pressures acutely over the last decade as growth in the health budget has been insufficient to meet rising demands.[1, 2] Even with the recent cash injections, the NHS will struggle to maintain current care, let alone deliver improvements.[1, 2] The National Institute for Health and Care Excellence (NICE) uses established processes to assess whether new tests, drugs, and procedures ('technologies') should be funded, but many were adopted before these standards came into play.[3] 'Low-value' care refers to healthcare with risks or costs that outweigh its benefits, comprising care that is harmful, ineffective, or cost-ineffective.[4] Low-value care can have substantial opportunity costs by displacing 'high-value' treatments proven to improve patient health, and subjecting patients to unnecessary risk.

'De-adoption' is the process of stopping or reducing a clinical practice that has become embedded.[5] De-adoption of a health technology may entail complete removal, or restricting its use to groups of patients in whom the benefits are deemed to outweigh the costs/harms. De-adoption of low-value care is vital to sustaining health services, but changing entrenched practices is difficult. Many examples of low-value care have been identified, but implementation of de-adoption decisions is challenging.[6-8] Previous efforts have shown mixed results, and high-profile schemes such as NICE's 'Do not do' recommendations and the United States' 'Choosing Wisely' campaign have struggled to show impact.[6, 9]The literature consistently calls for evidence-based understanding of factors that support or hinder de-adoption, unintended consequences of de-adoption, and implications for patients and clinical professionals.[5, 7, 10-12]

There is now an opportunity to address these knowledge gaps by investigating the delivery of a national de-adoption initiative in the English NHS. The 'Evidence-Based Interventions' (EBI) Programme launched by NHS England aims to reduce the number of "inappropriate interventions" carried out in the NHS and concomitantly "improve the quality of care" patients receive.[13] At its core, the programme seeks to de-adopt health care interventions on the grounds of clinical effectiveness. The definitions, parameters, and thresholds of 'effectiveness' are not specified in the public-facing EBI documentation, but the programme is clear in its intention to de-adopt through its explicit references to reducing clinical activity. The programme initiated with identification of 17 interventions (all surgical procedures), categorised as procedures that should not be routinely conducted at all (category 1 procedures), or procedures that should only be conducted in select circumstances (category 2 procedures). EBI policies specifying the categorisation of each procedure, and the criteria for provision (for category 2) were published for implementation on 1 April 2019. Clinical Commissioning Groups were set a 12-month target to reduce activity to near zero for category 1 procedures and to the 25th percentile of their age-sex standardised rate of activity for category 2 procedures.[14] In November 2020, the EBI programme issued a second list comprising 31 procedures, treatments and diagnostic tests for Clinical Commissioning Groups (CCGs) to de-adopt, with indications that subsequent lists will follow.

The launch of the EBI programme provides a timely opportunity to address the evidence gaps around knowledge and understanding of de-adoption. The national scale and breadth of interventions identified for de-adoption in the EBI programme provides a unique window of opportunity to investigate whether and how de-adoption is delivered in practice, and the consequences of such actions (or lack thereof). This NIHR-funded Health Services and Delivery (HS&DR) study aims to investigate the delivery, impact, and acceptability of the EBI programme across CCGs in the English NHS, with a view to producing recommendations to guide future de-adoption of low-value care.

1.1 Existing literature

A 2015 scoping review by Niven and colleagues found 43 terms were used to describe cessation or reduction of health technologies, with the term 'disinvestment' appearing most frequently.[5] However, research by our team and others showed how the financial undertones of 'disinvestment' can complicate

efforts to engage clinicians in tackling low-value care.[15, 16] 'De-adoption' has been proposed as a more suitable term.[5] Although the literature summarised below uses a range of terms, we use 'de-adoption' for consistency.

'Passive de-adoption' refers to the natural attrition of a technology, because it falls out of favour or is replaced with improved alternatives. 'Active de-adoption', by contrast, represents the *managed* reduction or removal of a technology.[3] There is discussion in the literature around whether 'de-adoption' is simply the inverse of 'adoption'. Research and commentaries suggest there may be organisational and psychological challenges unique to de-adoption, including concerns about loss of revenue, 'loss aversion' (a preference for avoiding loss over acquiring equivalent gain), the 'prominence effect' (individual patient advocacy) and 'anticipated decisional regret', where the fear of negative consequences of inaction outweigh the negative consequences of action.[17, 18] The emerging consensus is that de-adoption should be considered a field of its own – at least at present, until further empirical research has been conducted.[19, 20]

1.1.1 Current knowledge and evidence gaps

In preparation for this application, we replicated the search strategy for the 2015 scoping review[5] between 2014 to January 2020 and performed backward and forward citation tracking of 7 other reviews. We also searched the NIHR journals library and funded projects (including pre-doctoral fellowships) and hand searched NHS England, the Scottish Access Collaboration's Effective and Quality Interventions Pathway (EQuIP), NHS RightCare, Getting it Right First Time, Choosing Wisely UK and National Audit Office websites.[13, 21-26]

De-adoption of healthcare is a relatively new field for research, with most literature having emerged post 2010. Reviews have generally set broad agendas of describing de-adoption activities worldwide and rely heavily on opinion, reflecting a paucity of evidence. Several similar frameworks have been proposed to describe the process of de-adoption, often identifying three phases: Phase 1 ('Technology'- identification and prioritisation of technologies for de-adoption); Phase 2 ('Evidence' - engagement with evidence to inform de-adoption decisions), and Phase 3 ('Execution'- implementation and evaluation of decisions).[27] Many tools and processes have been used to identify and prioritise technologies for de-adoption,[7, 8, 12] but there are recurring challenges around delivering de-adoption plans. The most pressing research priorities relate to Phase 3 – the implementation of de-adoption. Several reviews have highlighted how outcomes of de-adoption efforts are often not reported or plans are abandoned before implementation.[8, 11, 28] The Sustainability in Health care by Allocating Resources Effectively (SHARE) programme, for instance - a region-wide Australian initiative to deliver de-adoption - only implemented one of its four plans and did not have sufficient resources for evaluation.[28] Reviews consistently stress the need to investigate how de-adoption plans are delivered in practice.[5, 11, 12]

Knowledge of what supports successful de-adoption is constrained by the lack of prospective empirical research on the implementation and consequences of de-adoption. Case-studies of attempts to de-adopt from health technologies are increasingly being reported, but their findings are mixed, and few examine how or why efforts succeeded or failed.[29-32] The two most recent reviews could not confidently draw conclusions about factors that support or hinder de-adoption.[5, 6] Niven et al[5] observed that most successful de-adoption efforts involved market withdrawal (predominantly of unsafe drugs) and suggested this was less contentious than de-adoption driven by (cost)-ineffectiveness. Chambers et al[6] found only one third of de-adoption attempts reviewed led to reduced activity, but there was insufficient information to indicate why. Attempts to de-adopt have also been critiqued for their narrow focus, without consideration of consequences elsewhere in the system or implications for patients' and clinicians'.[33]

1.1.2 Forthcoming and ongoing research

The most recent synthesis of de-adoption knowledge - soon to report - was supported by the NIHR-HS&DR (16/115/18) programme, led by co-applicant CB.[34] This review used a realist approach to look for patterns across de-adoption case-studies, and aimed to propose a programme-theory of how and why de-adoption efforts succeed. Although individual studies are limited, realist synthesis allows for generation of 'best

explanations', guided by theory and stakeholder input. The emerging findings suggest that most existing evidence on de-adoption relates to drug prescribing within primary care. CB et al characterise these decisions in two ways. Some are 'fast, system 1' routine decisions, sensitive to interventions such as making low-value care options less prominent on electronic interfaces and using feedback to alert clinicians of habitual decision-making. More complex 'system 2 slow decision-making', such as whether to perform surgery, are seldom examined in this field. The review provides the most comprehensive synthesis of de-adoption to date but is acknowledged by the authors to be limited by the limited empirical evidence available. The research proposed in this application will develop and refine the programme theory, building on this HS&DR review.

Another highly relevant de-adoption initiative led by the Scottish Access Collaborative – the 'Effective and Quality Interventions Pathways (EQuIP)[24] – recently launched. This seeks to de-adopt low-value care, starting with four interventions also named on the EBI programme. Some pilot work has been undertaken and the programme has produced a toolkit comprising templates of documents geared towards facilitating de-adoption (e.g. template policies, template clinical pathways, patient information). There does not appear to be any empirical work aligned with the programme, but we will monitor its developments and invite representatives to join our Study Reference Group (Section 5.5) to promote shared learning in this developing area.

The field of de-adoption is also developing internationally. A systematic review will synthesize the literature on 'active interventions' to reduce low-value care, which should complement the realist synthesis above[35] and be useful for designing interventions to facilitate de-adoption. Studies in the United States, Sweden, and Canada are investigating de-adoption decisions instigated by local decision makers or in specific settings (such as intensive care units). Published findings will be incorporated in literature reviews over the course of this study. [36-38]

1.1.3 De-adoption in the English NHS

In 2010, local commissioners in England were tasked with identifying opportunities for de-adoption to achieve £20 billion in efficiency savings.[39] NIHR HS&DR-supported research by our team (WH, LR, JD, AOS) used clinical practice variation data to enable two CCGs to identify a case-study for local de-adoption, allowing us to examine implementation of the decision in two regions.[40] An embedded qualitative study found de-adoption was met with resistance where clinicians felt excluded from decision-making processes, confirming the theory that clinician engagement is crucial to success.[16] Our research showed how differences in the process of engagement affected clinicians' sense of involvement, and how different actions taken to deliver de-adoption had consequences for how care was delivered. We also found de-adoption efforts were undermined by assumptions of patient and public resistance and clinicians' variable interpretations of evidence, as supported by others.[41, 42] Although our research focussed only on one procedure in two CCGs, it was the first to show how local decision-makers can operationalise de-adoption differently, with different implications.

Another NIHR project by co-applicant (IW) investigated CCGs' practices and citizens' perspectives in relation to de-commissioning NHS services (rather than technologies).[11] Implementation issues were encountered in three of four case studies of service de-adoption, leading to the conclusion that the factors that influence de-adoption are likely to be different to adoption. The research called for specific investigation of implementation and evaluation of de-adoption, with exploration of patients' perspectives.

1.1.4 Why is this research needed now?

Concerns about financial sustainability of the NHS make it imperative to engage in de-adoption of low-value care. Much investment has been spent on identifying low-value care, but there is a block in translating these efforts into action. While some promising solutions are emerging, most comprise market withdrawal of drugs based on safety concerns or deprescribing in primary care. This provides a start, but most papers conclude that the evidence-base for understanding de-adoption needs considerable development. Factors that support or hinder de-adoption need to be prospectively studied on a broader scale, in a range of

contexts, and including more contentious (and potentially impactful) ambitions such as scaling back 'low-value' care.

The launch of the EBI programme provides a timely opportunity to address the gaps in evidence outline above. Our research will investigate the delivery, impact, and acceptability of the EBI programme in commissioning organisations (e.g. CCGs, Integrated Care Systems (ICSs)) across the NHS. The national scale of the EBI programme provides opportunities to select and understand de-adoption 'success stories'. It also enables comparison of how different CCGs respond to the same mandates for a range of procedures, enhancing generalisability and potential for impact.

2. Aim and objectives

2.1 Aim

The aim of this research is to understand the delivery, impact and acceptability of NHS England's EBI programme across English CCGs, with a view to producing evidence-informed recommendations to optimise future efforts to de-adopt low-value care.

2.2 Objectives

a) To investigate the impact of the EBI programme quantitatively, by examining changes in procedure rates and costs for procedures identified for de-adoption, any spillover effects on related procedures, and other changes in patient care pathways.
b) To investigate the local delivery of the EBI programme by exploring the actions taken by CCGs and health care professionals in response to de-adoption mandates.
c) To explore perceived consequences and acceptability of the EBI programme and its delivery from patients', clinical professionals', and commissioners' perspectives.
d) To consider findings from a-c in relation to up-to-date empirical literature and produce recommendations to optimise future de-adoption of low-value care, with patients, public members, clinical professionals, NHS managers, commissioners, and policy makers.

3. Study design and theoretical perspective

The study uses mixed-methods to address the objectives through three Work Packages:

Work Package 1 (objective 'a'): Quantitative analyses of routine primary and secondary care data to investigate changes in activity rates, referrals, patient care pathways and costs before and after publication of NHS England's EBI policies.

Work Package 2 (objectives 'b' and 'c'): Document (policy) analyses, qualitative interviews with commissioners, health care professionals, and patients, audio-recordings of clinical consultations, and a national survey to investigate individual, organisational and system-level actions taken in response to EBI policies, and their perceived consequences and acceptability from the above stakeholders' perspectives.

Work Package 3 (objective 'd'): Co-production of recommendations to optimise future de-adoption of low-value care (with patients, public members, clinical professionals, managers, commissioners and policy makers)

There are several frameworks that aim to guide the process of de-adoption, but these are designed for those who intend to instigate a de-adoption plan. The frameworks describe the steps of a de-adoption process, but there are no theories to guide the study of implementation or evaluation. One framework we considered in light of stage 1 feedback was the 'Non-adoption, Abandonment, Scale-up, Spread, and Sustainability' (NASSS) framework.[43] This is geared towards uptake and implementation, with 'non-

adoption' and 'abandonment' relating to 'failure to launch' and issues scaling-up new technologies. As discussed above, the literature indicates that processes to guide adoption and deadoption are likely to differ. Although there are no theoretical frameworks to guide the study of deadoption thus far, the realist synthesis led by co-applicant CB (NIHR HSDR 16/115/18) will soon report on a highly relevant programme theory. We will draw upon this work at the data interpretation and recommendations stage. The overall design of this study was shaped by the theoretical perspective that health systems such as the NHS are 'Complex Adaptive Systems' (CASs) with inter-related parts.[44] A 'CAS' is an ecosystem, containing linked structures, systems, and 'actors' that operate within it (e.g., patients, primary/secondary care doctors, commissioners, providers, etc.). A CAS can also consist of smaller systems: the NHS CAS, for example, consists of CCGs, Sustainability and Transformation Partnership (STPs), and the micro-systems within these. All of these are a CAS in their own right and inter-dependent. Actors within these have freedom to behave, governed by extrinsic and internal rules (e.g., habits, beliefs), and simultaneously shape and are influenced by the system they operate in. In relation to de-adoption, CAS principles suggest that actors and structures in the NHS influence one another, de-adoption processes, and the wider healthcare system in feedback loops, requiring a multi-dimensional and multi-disciplinary approach to investigation. The research seeks to examine the delivery, impact, and acceptability of NHS England's de-adoption policies by understanding responses and their implications at different levels of the health system, from different actors' perspectives. Our mixed-methods approach will allow us to achieve this through linked Work Packages.

3.1 Work Package relationship with NHS England's EBI programme timelines

The project Work Packages (WPs) have been designed with consideration to the EBI programme timelines. As of April 2021, the EBI programme has published two lists of healthcare interventions identified for de-adoption:

- List 1 comprises 17 surgical procedures, each with accompanying EBI policies. The list was subjected to public consultation from the 4 July-28 September 2018, and the final list (and accompanying policies) were published in April 2019, with the expectation that CCGs would implement the guidance from the 1st April 2019. CCGs were expected to reach specified activity targets for each procedure by 1st April 2020, although in actuality elective procedure rates began to be affected by the Covid-19 pandemic from March 2020 onwards.
- List 2 comprises 31 surgical and diagnostic procedures, and was subjected to public consultation from 13 July to 24 August 2020 and final guidance was published in November 2020.

WP1 investigates the impact of EBI policies for all procedures (List 1 and 2) and clinical pathway implications for select 'case-study procedures' from List 1. WP2 investigates actions taken in response to EBI policies and acceptability of these actions, using several methods: some consider all EBI procedures, while others focus on case-study procedures.

4. Case study selection

The selection of the case-study procedures from List 1 of the EBI programme was informed by prior engagement with the literature, feasibility considerations, and discussions with the patient and public advisory group (PPAG) and study management group (SMG).

The literature indicates that evidence of a health technology's effectiveness (or ineffectiveness) may influence de-adoption success and acceptability.[19] As such, we will include a range of interventions with different evidence-profiles, to investigate how evidence of effectiveness may shape de-adoption outcomes. We considered each of the 17 procedures from List 1 in relation to level of RCT evidence of (cost)-effectiveness - specifically, whether there was published RCT evidence of (cost)-effectiveness; ongoing RCTs evaluating (cost)-effectiveness, or 'no RCT evidence', indicating no prior or existing definitive RCT evidence of (cost)-effectiveness.

We considered 'feasibility' in relation to having sufficient opportunities to sample patients at the CCG level within the timeframes of the project. We examined 'national baseline volume' for the procedures (as of 2017/18, pre EBI publication) to safeguard against selection of rare procedures that would have limited patient referrals/opportunity for sampling.

Early discussions with the PPAG about case-study selection led to questions around how patients would be managed if there was 'no alternative' treatment to the de-adopted procedures. Although there appear to be alternative surgical and non-surgical options for most of the 17 List 1 EBI procedures, this criterion was borne in mind for final case-study selection.

Taking the above parameters into consideration, the following three case study procedures were shortlisted from List 1 of the EBI programme as candidate case-study procedures. Two of these will be taken forward, based on pragmatic considerations (e.g., commissioners' and/or surgeons and willingness to participate):

- **Arthroscopic Subacromial Decompression (ASAD)** - a surgical procedure that involves decompressing the sub-acromial space in the shoulder by arthroscopically removing bone spurs and soft tissue, to address subacromial impingement causing persistent shoulder pain.
- **Dupuytren's Contracture Release (DCR)** - Dupuytren's contracture is caused by fibrous bands in the palm of the hand which draw the finger(s) (and sometimes the thumb) into the palm and prevent them from straightening fully. Dupuytren's Contracture Release (DCR) relates to surgical treatments that aim to straighten the finger(s) to restore and retain hand function.
- **Tonsillectomy** – is a surgical procedure to remove the tonsils as a treatment for recurrent sore throats due to tonsillitis in adults and children.

Rationale for selection: The shortlisted case-study procedures have variable evidence profiles: ASAD has published RCT evidence indicating it is not an effective treatment for pure subacromial shoulder pain,[45,46] while the evidence profiles for DCR and Tonsillectomy are still developing with ongoing RCTs comparing treatments for Dupuytren's Contracture,[47] and tonsillectomy versus antibiotic treatment for recurrent sore throat.[48] The baseline activity levels for ASAD, DCR and Tonsillectomy suggest there will be sufficient patients to sample during the timeframe of this project, although, like any of the case-study procedures, it is difficult to ascertain if and how the EBI programme may affect number of referrals from primary to secondary care. The above selections also provide opportunities to explore what happens to patients when there are 'no alternatives' to de-adopted procedures. Potential alternatives to surgery exist for ASAD and tonsillectomy (e.g., physiotherapy and antibiotic treatments, respectively), but it is less clear what interventions will be offered for NHS patients suffering with DCR if they do not meet the eligibility criteria for surgery. Further to the above, inclusion of Tonsillectomy provides an opportunity to compare parental guardians' with patients' perspectives and experiences of de-adoption. To our knowledge, there is no current literature about de-adoption in the context of paediatric care.

Further case study procedures will be selected from List 2 of the EBI programme later in the project. This selection will be informed by the intention to develop and refine List 1 findings in new contexts. Findings from List 1 will be discussed in a dedicated PPAG workshop and Study Reference Group meeting mid-way through the project, to help inform sampling criteria for selection of List 2 case-study procedures.

5. Methods

5.1 Data collection and analysis for Work Package 1

5.1.1 Overview of WP1

We will use routine data from hospitals and primary care to study service provision before and after the publication of the EBI policies to quantify the broad system impacts.

NHS England's first list of 17 EBI procedures are all surgical. Surgical procedure rates cannot be viewed in isolation. In almost all the patient groups affected by EBI policies, patients may receive other NHS care if surgery is unavailable. Less invasive day-case or outpatient procedures might be substitutes for inpatient surgery (e.g., laser ablation rather than open surgery for varicose veins, needle fasciotomy rather than open fasciectomy for Dupuytren's contractures). Medications and devices may be used more extensively to conservatively manage symptoms in some conditions (e.g., pain medications for knee osteoarthritis, wrist splints for carpal tunnel syndrome) and physiotherapy referrals may increase. Some patients may still have surgery, but more stringent criteria may increase the time interval between symptom presentation and surgery, with potential to affect outcomes. The EBI policies may also have unintended consequences. For example, clinicians who believe that patients will benefit from the procedure have incentives to search for additional diagnoses to meet the criteria for surgery (e.g., diagnosing sleep apnoea with snoring), and reducing access to procedures on the NHS may lead some to seek private healthcare.

Full evaluation of EBI policies requires inclusion of as many of these system level impacts as possible. We will use routinely collected hospital and primary care data to:

1. Determine if NHS England target reductions were achieved by CCGs for each EBI procedure.
2. Identify any spillover effects on related inpatient and outpatient procedures
3. For two List 1 case-study procedures, examine whether EBI policies changed the pathway of care in General Practitioner (GP) practices across England, specifically: prescribed medications and other non-surgical care; specialist referrals; and the delay between symptom presentation, specialist care, and (if applicable) surgery.
4. Determine if initial reductions in List 1 procedure rates are sustained

5.1.2 Procedure rate analysis for EBI and substitute procedures (objectives 1,2,4)

5.1.2.1 Data sources for procedure rate analyses

We will use Hospital Episode Statistics (HES) admitted patient care (APC) and outpatient (OP) datasets to analyse procedure rates. HES APC is a routinely collected dataset that records episodes of care provided to all patients (NHS and privately funded) admitted in England to NHS hospitals and NHS-funded patients treated in independent sector hospitals.[49] HES APC is extensively used for research (including research by our group)[40, 50-54], due to its universal coverage and potential for linkage. HES APC provides detailed clinical, demographic and organisational information for each episode. HES records up to 24 clinical procedures (OPCS-4 codes) and up to 20 diagnoses (ICD-10 codes) which we will use to define the procedure/patient group dyads of interest. It contains information on geography enabling stratification by area (e.g., CCG of residence), individual level data on demographics and Healthcare Resource Group (HRG) codes used to cost care.

HES OP documents more than 100 million appointments annually.[55] The dataset includes appointment date, specialty, clinical and geographical information. Diagnosis codes are rarely recorded. Procedure codes are recorded in approximately 30% of attendances;[55, 56] it is likely that outpatient procedures with national tariffs (e.g. transluminal ablation of varicose veins) will be accurately recorded in order to receive

reimbursement. Pseudonymised patient identifiers enable all patient care to be linked within and across HES APC and OP datasets.

5.1.2.2 Study design for procedure rate analyses

Comparison of national procedure rates before and after NHS England's EBI policies.

5.1.2.3 Method

We have obtained 2019/20 HES APC and OP data up to 1st April 2020. 2019/20 data have been combined with historic data (from 2009/10). Based on these data we will evaluate List 1 procedure rates in the year after the EBI policies were issued and compare these to the trends in procedure rates prior (i.e., up to 3 years) to the implementation of the EBI policies. We have budgeted for a second extract of HES data to arrive in January 2022. This extract will allow us to evaluate the initial impact (to April 2021) of the List 2 policies. A final extract will be requested in January 2023 to evaluate the sustained impact of List 1 and List 2 policies to at least April 2022.

We use procedure and diagnosis codes to identify the procedures and patient groups targeted by the EBI programme. This will be based on the coding algorithms published by NHS England.[22] However, we will also seek advice from surgeons in the relevant specialties to identify potential 'substitute' procedure codes (e.g. T79.1 rotator cuff repair) that might be used instead of those procedures identified by the EBI programme. We will also identify 'related' procedures where the 'right' procedure code is used but in the 'wrong' position (e.g., secondary rather than primary) or the 'right' procedure code is combined with the 'wrong' diagnosis code. We will compare procedure rates in the EBI, 'related' and any 'substitute' procedures to evaluate any change in EBI procedures post EBI policy implementation and any spillover effect on 'substitute' or 'related' procedure rates.

We will extract continuous hospital spells (which may contain several consultant episodes) and outpatient attendances where these procedures were performed. For each of the EBI procedures we will use appropriate GLM segmented regression analyses (e.g., interrupted time series analysis using Poisson regression with populations as offset)[57, 58] of national monthly procedure volumes to identify any change in trend in procedure rates post publication of the EBI policies (1st April 2019). We will also use regression analyses to explore trends in 'related' and 'substitute' procedures to assess whether any reductions in the EBI procedures coincide with increases in other surgical procedures. Seasonality will be accounted for in the interrupted time series analysis deterministically by adding 'season' or 'month' terms into the regression model, or alternatively by fitting periodic functions (Fourier terms of sine-cosine functions) with a 1-year period. Indices of deprivation are publicly available at lower-super-output-area (LSOA), which can be aggregated to other geographies (CCGs or ICSs) and adjusted for as a covariate in the regression models.[59]

We will combine this analysis with NHS tariffs[60] to evaluate whether the EBI policy achieved the targeted reduction in procedure rates and cost savings. For the more common procedures (including, for instance, ASD and CTR) we will stratify this analysis by locality (e.g., CCG or ICS or Sustainability and Transformation Plans (STP)) and plot findings on maps to identify localities that have had greater or lesser success in reducing procedure rates. For the less common procedures (e.g., dilation and curettage for heavy menstrual bleeding) the stratification would be at a broader level (e.g., STP or ICS).

5.1.3 Care pathway analysis (objective 3)

5.1.3.1 Data sources for care pathway analysis

The CPRD Aurum database contains routinely collected data from the electronic health records of more than 1,000 (≈12%) primary care practices in England, capturing diagnoses, symptoms, prescriptions, referrals and tests for over 10 million patients[61] with a median of 9 years' follow up since 1995. Patients are representative of the broader English population in geographical spread, deprivation, age and gender.

Diagnoses, symptoms and other observations are coded using a combination of SNOMED CT (UK edition), Read Version 2 and local EMIS Web® codes. Drug and device prescriptions are coded using the Dictionary of Medicines and Devices (dm+d) codes. These data are linked by NHS Digital to HES APC & OP, accident and emergency, diagnostic imaging, death registration and other healthcare datasets. CPRD Aurum approved research projects include health services and policy evaluation, pharmacovigilance and drug prescribing patterns. CPRD provides a patient-level data quality metric (a binary 'acceptability' flag) and a practice-level data quality metric (up-to-standard date).

5.1.3.2 Study design

Cohort study using routine linked primary and secondary care data to compare surgical and non-surgical care for the List 1 case-study procedures (i.e., ASAD, DCR, and tonsillectomy) before and after the publication of the EBI policy.

5.1.3.3. Method

We will use CPRD-Aurum data to explore how pathways of surgical and non-surgical care have changed before and after publication of EBI policies for the case-study procedures. For illustrative purposes we describe the process for care of shoulder pain. Incident cases will be identified using Read and SNOMED high specificity diagnosis (e.g. N212400 Impingement syndrome of shoulder) and treatment codes (e.g. ZK6WX00 Arthroscopic subacromial decompression) based, where possible, on algorithms used in previous epidemiological studies and independent clinical review.[58] In these cases, the index date will be defined as the first primary care presentation with a related symptom (e.g. 'shoulder pain') or diagnosis code without a prior record of such codes during a 2-year run-in period. The definition is necessarily pragmatic (e.g. it would not readily distinguish new symptoms from recurrence after a long asymptomatic period).

Two patient cohorts will be defined based on the index date: before publication of NHS England's EBI policies for the first list (index date 1/4/16 to 31/3/17) and after publication (index date 1/4/19 to 31/3/20). We will compare demographic characteristics (e.g., age, gender, deprivation, Charlson comorbidity score) of the cohorts to assess equivalence. Our analysis will then compare the pathways of care up to two years post index date. Key outcome measures include time to first specialist referral and carpal tunnel release surgery; number of primary care consultations, prescribed medications, radiological investigations and other diagnostic tests; number of referrals to physiotherapy, hand/ plastic surgeons; and estimated cost of care. The lack of diagnostic coding in outpatient datasets makes it difficult to identify, with certainty, care related to the condition. Some aspects of outpatient care (e.g., MRI of the wrist) will be highly specific while others (e.g., outpatient physiotherapy) are less specific for carpal tunnel syndrome. In areas of uncertainty, our analysis will distinguish between care considered probably related or unrelated to the condition (based on clinical opinion – provided by our collaborators – who will be blind to cohort identity). WP2 qualitative interviews with clinicians will also provide insight into clinical pathways for the List 1 case-study procedures selected (see 5.2). Reference costs for health and social care will be used to cost primary care pathways. Simple comparisons between the process and costs of care in cohorts before/after the EBI policies will be made using appropriate regression analyses accounting for right censored data (e.g., due to leaving the practice, censored practice data, death). Our analysis and reporting will be in accordance with the RECORD guidelines for research on routinely collected data.[62]

We will apply for CPRD Aurum data (estimated November 2021) to ensure that linked data up to approximately April 2021 are available for analysis. Members of the research group have significant experience working with linked CPRD datasets.[63-68]

5.1.4 Potential barriers, limitations, and solutions for WP1

The protocol was originally written before the Covid-19 pandemic and its aftermath which is now part of the landscape for de-adoption efforts in healthcare settings worldwide, including the NHS. Analytically, the interrupted time series methods we propose are flexible enough to accommodate such exogenous system

shocks by defining multiple 'treatment' phases in the regression. For List 1 procedures we will have data from a pre-EBI/pre-pandemic phase, a post-EBI/pre-pandemic phase, a pandemic phase, and a post-EBI/post-pandemic phase. Similarly, for List 2 procedures we have data from a pre-EBI/pre-pandemic phase, a pandemic phase, and a post-EBI/post-pandemic phase. We will explore whether EBI policies produced a step-change and/or trend change in procedure rates compared to the expected rate, had trends from the pre-EBI/pre-pandemic phase continued throughout the pandemic period. We can also estimate the impact of the pandemic on procedure rates and explore whether this impact was greater on EBI compared to 'related' and 'substitute' procedures.

The care pathway analyses (based on CPRD data) for the two case-study procedures will be affected by the pandemic. Patients with index GP visits before the EBI policies were issued will have two years of unaffected follow up data. In contrast, patients with index visits after publication of the EBI policies will have up to one year of unaffected follow up data before the pandemic. Therefore, we will conduct analyses comparing care pathways in the first year after index visit and separately comparing care pathways up to two years after index visit. The latter analysis will allow us to explore the impact of the pandemic on primary and secondary care pathways.

Although not perfect, diagnosis and procedure codes in HES APC have high accuracy, particularly since the introduction of payment by results, and are sufficiently robust for use in epidemiological research.[69] Preliminary discussions with CCGs in WP2 will check the validity of the procedure rates observed in WP1. Read codes recorded by GPs in the EHR have been shown to accurately identify patients with a number of health conditions.[70-74] Although diagnosis codes are frequently missing from HES OP data, the combination of OP specialty and primary care signs and symptoms prior to referral will enable us to make a judgement with our collaborators about care related to the condition of interest.

5.2 Sampling, Data collection and analysis for Work Package 2

Work Package 2 addresses objectives 'b' and 'c' of the project. It comprises several methods to investigate the local actions taken in response to the EBI programme (objective 'b'), and the perceived consequences and acceptability of these actions from commissioners', clinical professionals', and patients' perspectives (objective 'c'). It comprises:

- **Documentary analysis** of select CCGs' written policies for each of the EBI procedures
- **Qualitative investigation** of commissioners' and clinical professionals' actions taken in response to EBI policies, and perceptions of the consequences and acceptability of these actions from professionals' and patients' perspectives through: i) semi-structured interviews and ii) audio-recordings of clinical consultations in which EBI procedures are discussed with patients* (**supported through an NIHR ARC-funded PhD studentship*)
- **A survey** to CCGs across England to capture the breadth and frequency of actions taken in response to de-adoption and their perceived acceptability.

5.2.1 Documentary analysis of CCGs' written policies for accessing EBI procedures

One action CCGs may take in response to the EBI programme is (re)-formulation and enforcement of local written policies for accessing EBI procedures. There can be variation in whether CCGs have policies for accessing treatments. Where policies do exist, criteria for accessing treatment and methods of enforcement can vary. For example, 'Prior approval' processes require commissioners to assess whether criteria are fulfilled (before treatment provision), whereas 'criteria-based access' processes allow clinicians to proceed with treatment as long as they record evidence to document fulfilment of the criteria.[16] The EBI programme has issued policies stating that category 1 procedures should not carried out, and category 2 procedures should only be carried out if criteria are met. CCGs have been asked to pay "due diligence" to these EBI policies from the 1st April 2019[13] and retain autonomy over deciding who is responsible for

demonstrating fulfilment of criteria (e.g. GPs or secondary care clinicians) and methods for enforcing local policies (e.g. prior approval, criteria-based access).

We will analyse CCGs' written policies for the EBI procedures and compare these with EBI policy criteria. This will begin with List 1 procedures (months 2-6) and will be repeated for List 2 later (months 11-15). We will do this because there are several indications CCGs will not simply use the new EBI policies. In NHS England's consultation process for List 1, many CCGs indicated they already had policies in place for the 17 procedures. Some expressed concern that changing their policies would undermine the legitimacy of their processes for evidence-informed policy formation.[22] Informal discussions held with CCGs in preparation for this proposal showed some felt their existing policies were more stringent than EBI policy criteria, prompting concern that changing their local policies could increase activity and pressure on services. A recent check of a sample of policies for the 17 procedures (Jan 2020) showed differences in some criteria compared with EBI policy criteria.

5.2.1.1 Sampling CCGs and identifying policies

We will conduct content analysis of CCGs' policies for all 17 List 1 procedures. 20 CCGs will be selected for each procedure, to include representation from different quartiles (i.e., Q1 highest to Q4 lowest) of 2019/20 procedure rates identified in WP1. We will sample 5 CCGs from each quartile, ensuring CCGs are not from the same STP. For List 1, this will result in a list of 20 CCGs for each of the 17 procedures (i.e., up to 340 policies). We will then search for published polices through web searches. We piloted this in an NIHR CLAHRC West project and found policies were easily accessible through CCGs' websites or web searches.[75] If no policy is identified, this will be recorded.

5.2.1.2 Data extraction and analysis

PDFs of policies will be imported into NVivo and key information will be extracted (title, version number, date of creation, date of latest review, evidence cited, and information pertaining to who is responsible for assessing fulfilment of policy criteria). Policy criteria will be compared with EBI policy criteria for each procedure. Where policies differ, we will examine CCG policy criteria in further detail. This will be facilitated through use of a coding framework inductively developed in the pilot which compared several CCGs' policies for 10 musculoskeletal surgical procedures.[75] The framework captures differences in:

- Types of treatments and investigations patients need to undergo
- Parameters of management approaches (e.g. length of time on conservative care)
- Requirements relating to diagnoses and clinical severity
- Relationships between criteria ('AND'/'OR' operators) and 'get out clauses'
- Specified patient involvement in decision-making (e.g. use of decision-aids)

The outcomes of this content analysis will show:

- The percentages of CCGs with/out publicly accessible policies for each procedure
- The percentage of policies created after EBI policies were issued (i.e. 01 April 2019)
- The percentage of policies that cite sources different from EBI policies
- The percentage of policies that use EBI criteria for accessing the procedures
- For policies where criteria deviate from the relevant EBI policy, we will record the nature of differences in relation to the above categories.

As policy analysis proceeds, memos will be kept to document issues that can be explored in interviews (e.g., how policies are used in practice).

5.2.2 Qualitative investigation to understand actions taken in response to EBI policies and perceived consequences and acceptability of these actions

Work package 2 entails investigation of reported actions taken in response to the EBI programme (objective 'b'), and the consequences and acceptability of these actions from commissioners', healthcare

professionals', and patients' perspectives (objective 'c'). This work will be focused around the selected case-study procedures from lists 1 and 2.

We will conduct semi-structured interviews with the above stakeholder groups and audio-record clinical consultations to explore how de-adoption affects front-line practice. We will focus on purposefully selected geographic regions (demarcated by CCGs) with contrasting activity changes for each case-study procedure to develop nuanced understandings of WP1 findings (i.e., why some CCGs successfully reduced activity but others do not). The list 1 case-study procedures selected will be the same as those studied in the WP1 clinical pathway analysis. Two new procedures will be selected from List 2 in the later stages of the project. The following methods - described below for list 1 case-study procedures - will also be used for list 2 procedures.

5.2.2.1 Sampling and recruitment for qualitative work

The following sub-sections describe the sampling and recruitment approaches for each of the stakeholder groups to be approached for the qualitative investigation: commissioners, healthcare professionals, and patients/carers.

Sampling will be driven by intentions to reach data saturation in relation to the study objectives. This is likely to be assessed at the level of each geographic region and then at the level of case-study procedure, although saturation may also be assessed in relation cross-cutting issues that span the regions/case studies. For instance, emerging findings may need to be explored across specific stakeholder groups (e.g., commissioners, surgeons, GPS). Sampling will also be bounded by pragmatic considerations, such as the availability of relevant experts in each region, numbers of patient referrals, and the time-constraints of the study.

With these factors in mind, we estimate that 7-8 interviews with healthcare professionals and 3-5 interviews with commissioners per CCG will be feasible (and thus, an upper estimate of 40 commissioners and 64 healthcare professionals in total across the project). Unlike commissioners and most healthcare professionals, there is more potential for continued sampling of patients/carers for each case study, although pragmatic considerations, such as EBI policies themselves or COVID-19 related restrictions may influence referrals and thus recruitment. We have budgeted for up to 60 patient/carer participants over the course of the study, based on the study time-scales and staff resources available, but actual numbers interviewed may be fewer if data saturation is achieved. We will prioritise attaining depth of understanding in relation to individual case-study procedures over global numbers of patients/carers recruited across the case-studies, which may result in focusing patient recruitment to just a sub-set of the four case-study procedures.

a. Sampling geographic locations (CCGs) and commissioners

We will use WP1 findings to inform selection of CCGs for the in-depth qualitative work. Interviews will explore actions taken in response to the EBI programme in general, then focus in detail on the case-study procedure relevant to that CCG. For each procedure, we will rank CCGs in terms of activity reductions (WP1). Considering the CCGs in the top and bottom quartiles, we will select those with high and low activity reduction (1 high, 1 low) for each case-study procedure. These 4 CCGs will become the geographic regions where data collection will occur for commissioning interviews, followed by all subsequent qualitative data collection activities with healthcare professionals and patients.

i. Sampling geographic locations

As stated in the 'Background', the EBI programme has set targets for CCGs to reduce activity to "near zero" for category 1 procedures (procedures that should not be routinely commissioned), and to the 25th percentile of the age-sex standardised rate of CCGs for category 2 procedures (procedures for which specific patient criteria must be met).[13] CCGs were expected to reach these targets for List 1 procedures by

April 2020 – one year after the EBI policies were published for implementation. The latest CCG activity levels are publicly available via an online EBI dashboard.[76] Taking each case-study procedure in turn, we will rank CCGs' activity according to:

- Absolute reduction in procedure numbers between April 2019 and February 2020.
- Distance to EBI annual procedure target – defined as the absolute difference between April 2019 to February 2020 procedure numbers and the EBI target.

February 2020 (rather than April 2020) has been selected to mitigate the influence of changes to hospital activity related to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - in particular, NHS England's recommendation to suspend elective surgery in March 2020.[77]

The above process will generate two ranked lists of CCGs: one showing CCGs in order of absolute reduction in procedure numbers conducted, and another ranking CCGs in terms of their distance to their respective EBI targets. A 'top 10' and 'bottom 10' list of CCGs to target will be generated for each case-study procedure, to account for the possibility of decliners/non-responders. CCGs will be prioritised for approach based on their rankings on both lists, although we will prioritise absolute reduction in activity if needed. We will also consider spread of geographic localities in prioritising which sites to approach. Generating the final sample of CCGs will be a pragmatic process, partly dependent on response rates from those approached and geographic locations of those who have already agreed to participate.

Approaching CCGs will entail inviting members of the CCG to formally participate in (and endorse) the study, as described below. Where CCG professionals decline participation or fail to respond, the next CCG on the target list will be approached.

Further CCGs will be selected when list 2 case-study procedures have been identified, later in the project. The criteria for sampling CCGs for list 2 are likely to be similar to the above, although there is a possibility that findings arising from list 1 will inform new criteria to inform sampling.

ii. Sampling and recruitment of NHS commissioners

The following steps will be taken to identify and recruit relevant commissioning participants from shortlisted CCGs.

Early engagement with CCG leads/Directors

Key contacts for CCG organisations and/or CCG Directors will initially be contacted to introduce the research and gauge support for the study. Commissioner collaborators at our hosting organisation (Bristol, North Somerset and South Gloucestershire (BNSSG) CCG) may support this process by facilitating initial contact between the University of Bristol research team and the shortlisted CCG organisation. If the CCG organisation declines participation or no response is received, we will approach another CCG from the shortlist described above.

Sampling and recruitment of individual commissioners

Key informants working in the CCG organisations will be identified for potential interview, defined as any individual deemed to have a specialist interest in the EBI programme by virtue of their role or experience of formulating/reviewing/working with EBI policies. CCG Directors or leads may facilitate identification of key informants. Once initial interview(s) have been conducted, snowball sampling will be employed to identify other individuals with a commissioning role who may be appropriate to approach for interview.

Potential participants will be sent a Participant Information Sheet (PIS) via email and asked to respond to the research team if they are interested in taking part. Individuals who do not respond will be sent a reminder a week after the initial invitation was sent out. No further contact will be made with non-responders thereafter.

A member of the research team will obtain informed consent from individuals who respond to the study invitation. If conducted remotely, this will entail a verbal consent process conducted over the phone (or web-conferencing software). The researcher will check the individual has read and understood the participant information sheet and address any questions about the study. If the individual is happy to proceed, the researcher will read each statement on the consent form, initial these as is appropriate, and sign the form on their behalf. The consent discussion will be audio-recorded and a copy of the completed form will be sent to the participant for their records. If 'in person' research is permitted at the time of interview and the informant has opted to be interviewed in person, they will be asked to read and complete the consent form themselves. We will use distinct 'verbal' and 'in person' consent forms to distinguish between these two modes of consent.

b. Sampling and recruitment of healthcare professionals for interviews

Health care professionals will be invited to take part in two elements of the study: interviews, and audio recording of clinical consultations for individuals who provide front-line patient care.

A purposive, key informant approach will be adopted to sample relevant healthcare professionals. A 'key informant' in this context is defined as any healthcare professional responsible for caring for patients who are candidates for the case-study procedure of interest in that geographic location. This will include - but not be limited to - secondary care professionals (e.g., surgeons), allied health professionals (AHPs) who may assess/treat patients prior to referral to secondary care (e.g., physiotherapists), and GPs.

Key informant healthcare professionals will be identified through searching relevant NHS hospital/intermediary care and General Practice websites/primary care networks and through liaison with NHS commissioners (see above) and Trust Medical Directors. In addition, snowball sampling will be employed, whereby study participants will be asked to suggest others who may be appropriate to approach. A combination of these approaches and snowball sampling with surgeons was effective in our previous de-adoption study.[40]

Depending on the clinical pathway in the CCG, there may be relevant intermediary services that provide assessment and care for the conditions underlying the case-study procedure. We will clarify the local clinical pathways through interviews with healthcare professionals and commissioners (where relevant), web searches, and the policy analyses described above. Professionals working in intermediary services who assess and treat patients will be approached for interview (e.g., physiotherapists and specialist GPs). We will identify other GPs via CCG members' recommendations, and we will use the organisation code of practices recorded in HES data to recruit from practices referring high and low numbers of patients for the case-study procedure prior to 2019 (from WP1).

Recruitment: Healthcare professionals identified via the channels above will be contacted via email and invited to take part in the study. A copy of the appropriate PIS and consent form will be attached to the email. The PIS and consent form will cover the interview and consultation recording components of the study. Potential participants will be asked to get in touch with the qualitative researcher via email to accept/decline participation in one (or both) elements of the research. Individuals who do not respond will be sent a reminder a week after the initial invitation was sent out. No further contact will be made with non-responders thereafter.

A member of the research team will obtain informed consent from individuals who respond to the study invitation. If conducted remotely, this will entail a verbal consent process conducted over the telephone (or web-conferencing software). The researcher will check the individual has read and understood the participant information sheet and address any questions about the study. If the individual is happy to proceed, the researcher will read each statement on the consent form, initial these as is appropriate, and sign on their behalf. The consent discussion will be audio-recorded and a copy of the completed form will be sent to the participant for their records. If 'in person' research is permitted at the time of interview and the informant has opted to be interviewed in person, they will be asked to read and complete the consent

form themselves. We will use distinct 'verbal' and 'in person' consent forms to distinguish between these two different modes of consent.

c. Sampling and recruitment of patients/carers for interviews

Patients and carers will be invited to participate in two elements of the study: interviews with the research team, and audio-recordings of their clinical consultations with specialists aligned with the case-study procedures. Given that one of the case-study procedures is likely to be tonsillectomy, there is a possibility that parents/guardians of children aged under 16 may be approaches as research participants. The term 'parental guardian' has been used in reference to this group of potential participants from here onwards.

Eligibility criteria: Any individual whom health care professionals deem to be potential candidates for the case-study procedure of interest (e.g. DCR, ASAD, Tonsillectomy) will be eligible to take part in this qualitative study as long as they are aged 16 or over and have capacity to provide full informed consent. If the patient undergoing care is aged under 16 (e.g., as may be the case with Tonsillectomy), the patient's representative ('carer') will be approached to participate and provide informed consent. Patients aged under 16 who are present in consultations may be approached to provide assent for the recording to take place, if the parental guardian deems this appropriate.

Sampling: NHS professionals will send study invitations to all patients who meet the eligibility criteria and have an upcoming clinic appointment. Where patients are aged under 16, the study invite will be sent to their parental guardian, with additional information sent for the child. This appointment may take place at intermediary or secondary care. As data collection and analysis proceed, we will employ more purposeful sampling approaches, with the intention of building a sample of maximum variation in terms of age, gender, ethnic background, area of residence (captured by postcode) and whether patients were listed (or referred) to receive the case-study procedure. Further sampling will also be informed by intentions to develop and refine emerging insights from concurrent analysis. To assist with such sampling decisions, consenting participants will be asked to provide demographic information at the time of consenting to the study (date of birth, gender, postcode, and ethnicity).

Recruitment: Healthcare professionals, research nurses, and/or non-clinical professionals in participating study sites will assist in identifying eligible patients by screening scheduled clinic lists. Patients or their parental guardians may be identified and approached for study participation at multiple time-points throughout a clinical pathway. This flexibility is essential, given that clinical pathways and service set-up may differ from one geographic location to another. In all cases, the following principles will apply for identifying/approaching eligible patients:

- Where possible, patients/parental guardians will be approached to take part in a 'pre-consultation interview' prior to their/their child's first specialist consultation, with a view to capturing their experiences of primary care and expectations of upcoming specialist care. Pre-consultation interviews will be followed by audio-recording the patient's first specialist clinical consultation. This may be followed by a post-consultation interview, and further cycles of audio-recording future consultations and follow-up interviews throughout the project's data collection period.
- If it is not possible to conduct a 'pre-consultation' interview, patients/parental guardians will still be approached for permission to audio-record upcoming (and future) specialist consultations, and invited to take part in post-consultation and follow-up interviews.

Given the potential for varying referral pathways and unpredictable levels of research administrative support, three models have been developed for patient recruitment, each with distinct patient-facing documentation (PISs and consent forms). Any of these three models may be used to recruit patients:

Model 1: Informed consent obtained by University of Bristol research team prior to patient's clinic attendance

1. Eligible patients will be identified from clinic lists in intermediary or secondary care settings, by the healthcare professional overseeing their care and/or a research nurse.
2. A research nurse or member of the NHS service team will send out a study pack to eligible patients/parental guardians, comprising: the appropriate PIS reply slip and a pre-paid envelope addressed to the University of Bristol (UOB) research team.
3. If patients/parental guardians are interested in study participation, they will be asked to indicate this through completion and return of the reply slip or by sending an email to the study account (an 'NHS' email address) specified in the PIS.
4. A member of the University of Bristol research team will contact the patient/parental guardian, answer any questions, and take informed consent if the patient/parental guardian agrees to participate in one or more elements of the study. 'In person' or remote consent will be obtained for interviews and audio-recordings of clinical consultations through separate clauses on the consent form.

If the patient/parental guardian has consented to interviews, the researcher will seek to arrange this at the participant's convenience. This may constitute a 'pre-consultation' interview, if time permits. If the patient/parental guardian has consented to audio-recording of their clinical consultations, the clinical team will be informed so that up-coming consultation(s) can be recorded (subject to the healthcare professional conducting the consultations having also provided informed consent).

A member of the research team – ideally the researcher who conducted any prior interviews – will continue to liaise with the patient/parental guardian to arrange post-consultation interviews, recording of further specialist clinical consultations, and further follow-up interviews. Consent for these activities will have been obtained at the outset of the research, where patients/parental guardians will have been informed of their right to withdraw at any point. The researchers will check participants are happy to continue with follow-up interviews at the point of scheduling them, and on the day of interview.

Model 2: Informed consent obtained by NHS staff in clinics/over the phone

1. Eligible patients/parental guardians will be identified from clinic lists in intermediary or secondary care settings, by the healthcare professional overseeing their care and/or a research nurse.
2. A research nurse or member of the NHS service team will send out the appropriate PIS
3. A Good Clinical Practice (GCP)-trained health care professional will obtain informed consent from the patient/parental guardian before or during their scheduled clinical appointment. As above, consent will be obtained for interviews and audio-recordings of clinical consultations through separate clauses on the consent form. Consent may be obtained 'in person' or remotely
4. If patient/parental guardian has not read or received the PIS, this will be handed/sent to them during or after the clinic appointments. The health care professional conducting the consultation will seek verbal permission to audio-record the appointment and document the patient's/parental guardian's response in a 'verbal permission' investigator-signed document. They will then proceed to record the consultation and hold the recording on NHS premises.
5. A GCP-trained health care professional will contact the patient/parental guardian within 2 weeks to answer questions about the study and obtain remote or 'in person' informed consent if they are happy to participate. On receipt of consent, any audio-recordings previously obtained will be sent to the research team. If consent is not given, any recordings previously obtained will be deleted.
6. If the patient/parental guardian consents to an interview, their contact details will be shared with the University of Bristol research team via telephone or NHS email.

Model 3: Informed consent obtained by University of Bristol researcher team following consultation attendance

1. Eligible patients/parental guardians attend clinic appointments with no prior knowledge of the study (e.g., given challenges disseminating study packs).

1. A study information pack will be handed/sent to the patient/parental guardian during or after the clinic appointments, comprising: the appropriate PIS, reply slip and a pre-paid envelope addressed to the University of Bristol (UOB) research team.
2. The health care professional conducting the consultation will seek verbal permission to audio-record the appointment and document the patient's/parental guardian's response in a 'verbal permission' investigator-signed document. They will then proceed to record the consultation but will not transfer this to the research team.
2. If patients/parental guardians are interested in study participation, they will be asked to indicate this through completion and return of the reply slip or by sending an email to the study account (an 'NHS' email) specified in the PIS.
3. A member of the University of Bristol research team will contact the patient/parental guardian, answer any questions, and take informed consent if they agree to participate in one or more elements of the study. 'In person' or remote consent will be obtained for interviews and audio-recordings of clinical consultations through separate clauses on the consent form.

The above models will rely on researchers liaising closely with NHS site staff. NHS site staff will be asked to keep a record of information packs they disseminate and to whom. A suggested log will be provided by the research team, for use if NHS site staff deem it appropriate. The researchers will inform NHS staff where patients return their reply slips. NHS staff will be asked to issue reminders to patients/parental guardians who have not returned their reply slips.

d. Sampling for audio-recording clinical consultations

Healthcare professionals will be asked to provide global consent to audio-record consultations with eligible patients (subject to consent) over an agreed initial period, determined through early discussion with the site Principal Investigators. The end-date for audio-recording consultations will be kept under review, given the difficulties of predicting the number of recordings likely to be returned per geographic location/case-study procedure. Audio-recording of routine consultations relating to de-adopted procedures has, to our knowledge, never been attempted for research purposes, and the study is taking place in the wake of an unprecedented pandemic that has unknown implications for elective procedure referrals. We will closely monitor the receipt of audio-recordings and assess the need for further data collection. This will be assessed in the light of emerging findings and the demographics of those who have already taken part. We will ask clinicians to stop or pause audio-recording if we believe we have reached saturation: the point at which further recordings are unlikely to yield new analytical insights.

5.2.2.2 *Data collection processes for interviews*

a. Interviews with commissioners and healthcare professionals

Remote interviews will take place via telephone or a secure web-platform, as per the participant's preference. 'In person' interviews may be conducted if national guidance allows at the time of data collection. If permitted, 'in person' interviews will be conducted in a quiet space conducive to audio-recording, either in a professional and/or public location (e.g., NHS organisation office, cafes) as per the participant's preference. The latest governmental/NHS infection transmission guidelines will be adhered to throughout any field work; as these are subject to change, the research leads will take responsibility for ensuring those conducting field work are familiar with the latest guidance and policies. The researchers conducting interviews will follow the University of Bristol lone workers' policy for any field work conducted over the course of the project.

Interviews are anticipated to last between 30-60 minutes and will be audio-recorded using an encrypted recording device and/or a secure web platform (e.g., Microsoft Teams, Zoom) that is approved for research according to the latest University of Bristol guidance. Interviews will be conducted by following a semi-structured topic guide, to ensure similar topics are covered across participants. Distinct topic guides have

been created for commissioners and health care professionals, informed by the literature. Some core topics will be explored with both groups, including: awareness of the EBI programme, interpretations of its aims, reflections on whether it will succeed in its aims, and suggested refinements to the programme. De-adoption processes will be explored in more depth in relation to the case-study procedure to understand informants' explanations for changes (or lack thereof) in activity rates. Informants will be asked to consider the implications of any changes in commissioning the case-study procedure, in relation to patient care, their organisation, and the local health system. All informants will be asked to reflect on the perceived acceptability of changes (or lack thereof) and the EBI programme more generally.

In addition to the above generic topics, interviews with commissioners will additionally explore:

- Actions taken in response to the EBI programme and the rationale for these actions
- Approaches to public and clinician consultation, their aims, and outcomes
- Any direct contacts with patients regarding eligibility criteria (e.g. through individual funding requests)
- Difficulties encountered and solutions adopted throughout the above processes

Interviews with health care professionals will additionally explore:

- How NHS England's EBI policies compare with practices before/after local changes
- Experiences and views about consultation processes with commissioners
- Whether (and how) their clinical practice has been impacted by changes prompted by EBI policies (e.g. engaging with written policies, interactions with patients, patterns of care provided (or prescribed), process of performing the case-study procedure)
- Their interpretations of patient's reactions/satisfaction and perceived implications for patients (e.g. health outcomes, self-care, private care).
- Perceived implications for professional practice (e.g. training, private clinics)

b. Interviews with patients/carers

Interviews with patients/carers will explore their experiences of care along the clinical pathway in relation to the case-study procedure. Interviews will be conducted by the qualitative researcher(s) appointed and a separately funded NIHR ARC PhD student (discussed below), under the supervision of the project lead (LR) and co-applicants (AOS, JLD).

Interviews will be semi-structured, informed by a topic guide that encourages patients/parental guardians to recount their pathway of care, starting from when symptoms began. Informants will be encouraged to discuss their decisions to seek care, expectations of care, interpretations of the care they received, and satisfaction throughout the pathway.

The qualitative researchers involved in this project have experience of conducting patient interviews to explore de-adoption and access to restricted procedures and are mindful of the possibility of participant distress (e.g. through perceptions of denial of care, or provision of care that did not align with preferences).[78-80] We will follow a specified protocol for identifying and managing distress (e.g. pausing the recoding, checking if participants wish to continue, ending the interview early), and use an open-ended questioning technique that encourages participants to share their experiences and perspectives. We will encourage patients/parental guardians to share their interpretations and views in relation to de-adoption if they raise these, as suggested by the PPAG. The PPAG noted that participants may find the interview process cathartic, highlighting the potential benefits of being offered the opportunity to share views and experiences. Our team have considerable experience interviewing highly vulnerable groups, and have empirical evidence that supports the PPAG's comments.[79] Interview conduct will be monitored, in close liaison with the PPAG throughout data collection.

c. Audio-recording of clinical consultations

Audio-recorded clinical consultations could enhance our understanding of the actions taken in response to the EBI programme and their consequences for practice, by providing opportunities to triangulate clinicians' 'actual practices' (and patients'/parental guardians' reactions) with reported accounts from interviews. Our experience of using this method in other contexts suggest these data can add considerable richness and contribute to a more comprehensive understanding of the phenomena of investigation.[76, 79] Recording consultations can however be challenging and will require dedicated additional researcher time.

Since stage 1, we have clarified the aims of a PhD studentship, which seeks to investigate patients' and service users' experiences of NHS care for symptoms that may be treated with procedures identified for de-adoption. The studentship is being supervised by this project's leads and co-applicants (LR, WH, AOS, JLD) and will entail audio-recording clinical consultations in which procedures identified for de-adoption are discussed. The PhD will run in parallel with the qualitative research described above. Though complementary, the success or failure of the PhD and the HS&DR project are not contingent on each other. There is, however, opportunity to align these separate NIHR-funded studies for added value and rigour. We describe the work in brief here to explain how it will be integrated with this proposal's WP2 interviews.

Recording consultations is novel in the context of de-adoption research, although we (LR, AOS, JD, JMB) have experience of audio-recording consultations across many surgical specialties, including restricted procedures.[78, 80] We will guide the PhD student to apply the same methods to capture recordings of consultations where the case-study procedures are discussed. We will invite the secondary and intermediary care clinicians who participate in the interviews (above) to audio-record their consultations and use snowball sampling by asking clinicians to suggest colleagues who may be willing record. Clinicians will be asked to sign a global consent form to cover audio-recording all their prospective relevant consultations over approximately 6 months and will be provided with an encrypted audio-recorder to record discussions with consenting patients/parental guardians. Eligible individuals will be the same as those identified and approached for the interviews, described above. Our PPAG suggested streamlining the process so that audio-recordings of consultations and interviews are described in the same study invitation letter and information sheet. This also means that healthcare professionals will only need to identify eligible patients once. Patients/parental guardians will be able to indicate their consent for the audio-recording of consultations, interviews, or both via a single consent document that outlines clauses for each elements of the research.

5.2.2.3 *Qualitative data analysis*

Qualitative interviews and audio-recorded consultations will be transcribed and analysed thematically using the constant comparison method (adopted from Grounded Theory).[81] Analysis will be led by the qualitative researcher. LR and AOS will oversee analysis and double code a sub-set of transcripts from each data collection method. We do not wish to constrain opportunity for novel insights to emerge from our analysis - especially given the limited empirical work in this area. However, it is important this research builds on, or seeks to develop, prior work. The programme theory that has emerged from the realist synthesis recently led by CB (NIHR HSDR 16/115/18) will be considered at the data interpretation stage (i.e. when writing descriptive accounts), with a view to confirming or developing the 'Context-Mechanism-Outcome' (CMO) configurations that make up the programme theory. We will also consider other theories that have been proposed as relevant to the study of de-adoption, such as 'loss aversion' and 'anticipated decisional regret'.[17, 82] In light of calls for exploration of the extent to which theories of implementation are relevant to de-adoption, we will also pay close attention to frameworks including the NASSS framework suggested by the Stage 1 panel, and the Consolidated Framework for Implementation Science [83] which has been suggested as a potentially useful for understanding de-adoption.[84]

LR, AOS and JLD will meet regularly with the qualitative researcher (and PhD student as part of her supervision) to discuss interpretations of data, guided by evolving descriptive accounts that will be written iteratively for each group of interview informants and recorded consultations. Co-applicant and PPI

representative GT and co-applicant CB will join some of these meetings and review evolving descriptive accounts. Once data collection for List 1 case-study procedures is complete, the descriptive accounts will be synthesised using triangulation to crystallise key findings.[85] Approaches to triangulation will include: methodological triangulation (e.g. clinicians' accounts in interviews examined in relation to their practices in consultations; patient accounts in interviews compared with their reactions in consultations); data/source triangulation (e.g. comparisons of key stakeholders' accounts within CCGs, comparisons of similar groups' accounts across CCGs); and theory triangulation, where we will interpret findings in relation to theories described above.

5.2.3 Survey of CCGs' actions in response to EBI policies for List 2 (month 21-25)

The findings from the documentary analysis of policies and qualitative research will inform a short survey aimed at CCGs to capture the breadth and frequency of actions taken in response to the EBI programme. Example domains include:

- Policy-related actions (e.g. access policies for procedures, reimbursement policies).
- Approaches to enforcing policies
- Public consultation processes
- Clinician engagement processes
- Suggestions for refining future national de-adoption initiatives

The survey will be compiled with input from KT (co-applicant and member of Bristol, North Somerset and South Gloucestershire (BNSSG) CCG), and will be piloted within our local CCG. The survey will consist largely of multiple-choice tick box responses and Likert scales to gauge acceptability of the EBI programme. It will be created in online software and sent electronically to CCGs' email addresses via an email account hosted by our contracting organisation (NHS BNSSG CCG). CCGs' email details are publicly available through the NHS England and Department of Health website. The survey link will be live for two months. A Reminder will be issued if no response is received within 2 weeks. If there is still no response after a further week, we will resend the survey as a freedom of information (FoI) request as these have generated response rates between 65-100% in studies with CCGs.[86, 87] Data will be analysed descriptively.

5.2.4 Potential barriers, limitations, and solutions for WP2

Initial contact and early engagement with CCG directors/research leads will be key to ensuring timely recruitment for the qualitative work. We have experience of recruiting commissioners and managers to de-adoption research in our previous study, having recruited 18 commissioners and managers from two CCG regions (over a year).[16] To mitigate against delays posed by slow CCG responses, we have planned for initial contact to be made via our hosting CCG organisation and will ensure the flexibility of interview timings and approach (telephone/in person) are clearly communicated. Other elements of WP2 can be pursued (policy analyses) during recruitment of CCGs. We also have contingency plans to select reserve CCGs in the highest and lowest quartiles of activity, if needed. We will pilot the survey with our contracting CCG to enhance ease of completion and have contingency plans to issue FoI requests in the event of poor responses to ensure high rates of completion.

5.3 Synthesising mixed-methods findings from WP1 and WP2

The quantitative and qualitative researchers will write reports of analyses from each data collection method as the study progresses. We will merge these a synthesised report, structured according to the research objectives. Objective 'a' (impact) will focus on WP1 analyses, with some qualitative data that informed the CPRD pathway analyses. Objective 'b' (actions) will comprise: findings from the documentary analysis of CCG policies; qualitative findings relating to actions taken in response to the EBI policies for the case-study procedures (presented according to CCGs' activity rate reductions, to contextualise WP1 findings); and the survey data capturing CCGs' actions, which will be considered in relation to WP1 findings,

to explore patterns in CCGs' activity reductions and the types of actions reported in the survey. Objective 'c' (acceptability) will bring together qualitative data from WP2 and CCG survey responses to acceptability questions. The report will be shared with the SMG for comment, with a view to producing a finalised report with execute summary for purposes of sharing with Study Reference Group and PPAG. This will provide a foundation for recommendation development in Work Package 3 (see below).

5.4 Work Package 3: developing recommendations

We will co-produce recommendations based on the study findings with key stakeholders to ensure relevance and practicability. 'Co-production' is a systematic and interdisciplinary approach involving sustained engagement with stakeholders to generate implementable knowledge with impact.[87] We will involve stakeholders throughout this research, including patients and public members (through the PPAG), clinical professionals, commissioners, and policy leaders. These stakeholders will make up the 'Study Reference Group' (SRG). The Director for NHS RightCare (Matthew Cripps), senior members of NHS England's EBI Programme (Aoife Malloy and Hannah Comer), a leading orthopaedic surgeon (Andrew Carr) and a leading commissioner (Ellen Rule, NHS Gloucestershire CCG) will join the SRG. All have confirmed acceptance. Co-applicant JMB has networks with clinicians across all specialties and will facilitate recruitment of additional SRG members to ensure broad representation of speciality/practice. SMG members will also join the SRG. As the study progresses, new stakeholders may be invited to join the SRG, based on identification of new structures, organisations and groups that emerge as relevant to the conduct of the study and translation of its findings. Lists of potential stakeholders will be drawn up early on in the project and iteratively developed over the course of the study. Stakeholder categories will include service users/patients; service providers; commissioners; and other relevant bodies (e.g. professional and governmental bodies and policy-makers). Individuals will be invited to join the SRG as core members, or may have less active involvement as 'affiliates'; affiliates will, at the very least, be kept up to date with study progress and consulted to support dissemination of findings to key audiences.

The SRG will meet at three time-points. A half day meeting will be arranged in month 13 to discuss emerging findings from WP1 and WP2. Selection of the two case-study procedures from List 2 will be considered in this meeting. The criteria will be determined by the SRG, but may include clinical speciality, age groups affected, or care setting (e.g. acute or planned care). The SRG will advise on topics to be covered in the CCG survey (month 20) and will comment on a draft version (via email) closer to the time. The SRG will also take part in two workshops to co-produce recommendations, as follows.

5.4.1 Recommendations co-production workshops

Two workshops will take place one month apart (October and November 2022). Ideally the same SRG members will participate in both, but the methods used in the first will support continuation into the second. The workshops will include the following activities:

Workshop 1: Participants will share their perspectives in relation to the findings generated from this study (made available in different formats such as qualitative quotes, extracts of written policies, tables/graphs of survey findings). Participants will be encouraged to express their views in ways that can be understood by all and will be provided with a variety of media to facilitate this (images, facilities to sketch, building 3D models (e.g., Lego Serious Play ©)). Participants will draw on questions and provocations supplied by workshop lead (CB) and a facilitator (LR) to generate suggestions for successful de-adoption. Ideas will be considered in relation to simple categories of feasibility, desirability and viability.[88] The workshop will result in a collection of models and images that represent a shared understanding and appreciation of the evidence, experiences, practice and contexts relevant to de-adoption, and at least 15 suggestions for successful de-adoption. The researchers will consider these suggestions in relation to study findings and other theories and evidence after Workshop 1.

Workshop 2: The suggestions from workshop 1 will be further refined and considered in relation findings/theory prepared by the researchers. We will seek to prioritise recommendations to cover different stakeholder groups' priorities and needs (patients, clinical professionals, commissioners). Depending on the nature of the draft suggestions from Workshop 1, we will invite relevant experts/leaders to Workshop 2, so that participants can 'pitch' suggestions (e.g., a 'Dragon's Den' style or similarly engaging activity, as is appropriate for the nature of the suggestions). This will involve all participants critically reviewing and refining the ideas and suggestions. The research team will make further adjustments based on feedback and developments from the co-design workshops, ensuring compliance with NIHR requirements for recommendations from research. The workshop will result in a list of practical recommendations, grounded in inquiry, to enhance the success of future de-adoption initiatives.

The SRG will discuss relevant groups/organisations for dissemination in the second workshop. Representatives from these groups will be invited to a 'Knowledge mobilisation meeting' (month 28) with options to join remotely, to determine the best routes to disseminating the recommendations. Some routes have already been planned, as outlined below.

6. Project / research timetable

Project months	Description
-2-0	Execute contracts. Staff recruitment, protocol development, sponsor review.
-2-3	Obtain ethics/HRA approvals for WP2 qualitative work
1-90	WP1 procedure rate/cost analysis for List 1
2-6	WP2 policy analyses for List 1
4-15	WP2 qualitative work for List 1 case-study procedures
10-16	WP1 procedure rate/cost analysis for List 2 EBI procedures
11-15	WP2 policy analyses for List 2
13	Mid-point Study Reference Group Meeting (early September 2021)
13-24	WP1 pathway analysis (CPRD data) for List 1 case-study procedures
15-25	WP2 qualitative work for List 2 case-study procedures (tbc).
21-25	WP2 CCG survey dissemination and analysis
22-25	WP1: HES analysis for List 1 and 2 procedures (sustained impact)
25-26	Synthesis of reports from WP1 and WP2.
26-28	WP3 Recommendation workshops (2 workshops, one month apart)
28	Knowledge mobilisation meeting, animation production
28-31	Dissemination activities
17-30	Write NIHR report (begin early and proceed over course of final year)

7. Project management

The project leads (LR and WH) will meet every two weeks to monitor progress in relation to milestones. LR, JLD and AOS will meet once a month to monitor progress with the qualitative research. The Study Management Group (all co-applicants) will meet at five points throughout the project (with the option of Skype/Zoom). Meetings will be held approximately every 6 months to monitor progress, with timings dependent on key decisions/events in the project. The PPAG will meet for six workshops, timed according

to the specific aims of each workshop. The Study Reference Group (SRG) will meet at the mid-point of the study (month 13) to input into key decisions about ongoing data collection/sampling and plans for dissemination, and twice for the co-production workshops. Study progress will also be monitored once a year by a Study Steering Committee, comprising independent health economist, qualitative methodologist, policy/commissioner, Implementation Scientist, and an independent PPI contributor.

8. Ethics / Regulatory Approvals

The qualitative work will require HRA approval (application and documents will be prepared from notification of award, ready for submission by the beginning of month 3). GT (PPI co-applicant) will initially review ethics documentation, followed by review in the first PPAG workshop (month 2). Anonymised HES data process, storage and destruction will be conducted in accordance with GDPR under the 'public interest' lawful basis under the auspices of an NHS Digital data sharing agreement. Anonymised CPRD AURUM data processing will be conducted following protocol approval from the CPRD Independent Scientific Advisory Committee (ISAC). These processes are in place at our institution.

A dedicated protocol outlining the procedures for the qualitative elements of the study has been produced. This provides details around ethical considerations relating to the qualitative research running throughout the project. It will be updated to include details of the survey research in due course, once plans for this element of Work Package 2 have been formulated in line with emerging findings.

9. Patient and Public Involvement

Patient and public members have shaped the project's objectives, sampling decisions and data collection plans (e.g. the decision to include pathway analyses for WP1 to examine the impact of EBI policies on referrals and primary care management; selection of case-study procedures from List 1; processes for conducting patient interviews). The PPAG will shape data collection tools (e.g. topic guides), contribute to data interpretation (workshops in months 7, 19), shape recommendations through membership of the SRG, and contribute to dissemination, including the Public Engagement Event (planning workshop in month 26). GT and MB (co-applicants) will hold the dual role of SMG and PPAG membership to ensure full and accurate relaying of information between these fora. MB's role will also entail organising and facilitating the 6 PPAG workshops. GT's role will entail working with LR to produce documentation for the PPAG to review; initial review of research ethics applications and documentation; and contribution to qualitative data analyses, by joining data interpretation meetings with the qualitative team and reviewing draft 'descriptive accounts' of findings.

9. Dissemination plans

We will disseminate our work widely, with an intention of sharing findings beyond academic circles, using technology and environmentally friendly solutions, and recording talks/presentation so that these can be shared freely for continued impact. Some of the channels for communicating our feedback to target audiences (patient/public members, clinical professionals, commissioners, and policy makes) are outlined below:

1. Presentations: We will present findings to NHS England and other national bodies (NHS RightCare, NICE) at the interim and end stages of the study to share findings from work packages and the co-produced end-of-study recommendations.

2. Public Engagement Event: We will share the study findings with patients and public members at an evening event held in central Bristol. The event will be publicised through social media, the People in Health West of England initiative (led by co-applicants AG, MB), and the UoB Communications team. The PPAG will help write the agenda and materials presented. Presentations will be made publicly available through Figshare.com.

3. Talks to clinical professionals – We will share emerging and end-of-study findings regularly through our Biomedical Research Centre's Surgical Innovation theme (led by co-applicant JMB), which holds regular engagement and training events attended by practising and 'next generation' surgeons from around the UK.

4. Webinars and talks for CCGs: We will host a webinar to share the above outputs with commissioners and policy makers around England, advertised through our NHS England collaborators and CCG hosting organisation. We will write personal invitations to all CCGs who participated in this research. All webinars will recorded and made available online.

5. Sharing multi-media outputs: The animations of recommendations, infographics, recorded webinars, presentations, and open access articles will be stored on 'Figshare'.

Ongoing stakeholder engagement throughout the project, via the SRG, will be pivotal to an effective dissemination strategy. As described above, we will keep a live, evolving list of key stakeholders throughout the project, which will form 'core' or 'affiliate' members of the SRG. This is important, given that the landscape of the NHS may change over the next 3 years, and thus our definition of 'key stakeholders' may also evolve. The above channels of dissemination are not exhaustive, as effective dissemination will need to take account of key stakeholders, and the best means of ensuring the relevant research findings are clearly communicated to these groups in an accessible way. This will be a core focus of the Knowledge Mobilisation meeting, scheduled after the recommendation-development workshops. Core and affiliate members of the SRG will be invited to attend this meeting.

Our dissemination activities and engagement with key stakeholders will be underpinned by a comprehensive social media strategy, which will also be iteratively reviewed to ensure it is up-to-date and relevant. For instance, we intend to publicise study progress, findings, and engagement events via a study Twitter handle and our CCG host organisation's Twitter account and will ensure these accounts/tweets link to relevant stakeholders and organisations. As social media trends can rapidly evolve, we will ensure a dedicated member of the team (LR) periodically reviews our social media strategy to ensure it continues to be relevant and effective throughout the course of the project, and communication of its findings.

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