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Statistical and Health Economic Analysis Plan for the QUIT hospital- based smoking cessation service

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Preface

This document details the proposed statistical and health economic analyses for the QUIT hospital-based tobacco dependence treatment service. The document is divided into sections that represent the main components of the analyses proposed. This document represents the 'core' statistical and health economic analysis plan, which was developed with a focus on the acute inpatient setting to stimulate ongoing discussions which will inform the development of supplementary analysis plans for the other settings (i.e., specific considerations for specific settings, but following the core analyses detailed in this document).

The results to be reported as part of future reports and/or publications will follow the strategy laid out here. Subsequent analyses of a more exploratory nature will not be bound by this strategy, although they are expected to follow the broad principles described. The principles are not intended to curtail exploratory analysis (for example, further subgroup analyses), nor to prohibit accepted practices (for example, data transformation prior to analysis), but they are intended to establish rules that will be followed, as closely as possible, when analysing and reporting on this real world, interventional study based on the use of routinely collected and linked data.

The analysis plan will be updated with new versions as necessary. Suggestions for subsequent analyses by report peer-reviewers or journal editors or referees will be considered carefully and carried out, as far as possible, in line with the principles of this analysis plan.

Any deviations from the analysis plan will be described and the rationale given in the final report of the study. The analysis will be carried out by an identified, appropriately qualified and experienced statistician, who will ensure the integrity of the data during processing. Examples of such procedures included quality control and evaluation processes.

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Contents

Preface	3
Glossary.....	5
Background	6
Sources of routinely collected data	7
The South Yorkshire and Bassetlaw ICB population	7
NHS hospital Trust electronic record systems	7
Community Stop Smoking Services electronic record systems	7
Information governance and data flows.....	8
Statistical Analysis Plan for the QUIT hospital-based smoking cessation service.....	9
Introduction	9
The acute inpatient pathway	10
Defining and quantifying outcomes.....	11
Aims and objectives of the analysis	12
Evaluation dataset design	13
Analysis populations	14
Sample size and completeness	18
Descriptive analysis.....	20
Statistical analysis of variation in the achievement of 4-week quits.....	22
Health Economic Analysis Plan for the QUIT hospital-based smoking cessation service.....	25
Introduction	25
Aims and objectives of the analysis	26
Approach to costing the service	27
Sunk costs of service setup	28
Staff costs.....	30
Non-staff costs	32
Pharmacotherapy costs	33
Return-on-investment	35
References	36

Glossary

List of abbreviations

BHNFT	Barnsley Hospital NHS Foundation Trust
CCG	Clinical Commissioning Group
CO	Carbon monoxide
CSSS	Community Stop Smoking Services / Integrated Wellbeing Services
DBTH	Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
DSCRO	Data Services for Commissioners Regional Offices
ENR	Electronic Nursing Records (electronic record system)
HEAP	Health Economic Analysis Plan
ICB	Integrated Care Board (formerly Integrated Care System)
ITT	Intention to Treat population
KPI	Key performance indicators of the service
LOS	Length of stay
NHS	National Health Service
NRT	Nicotine Replacement Therapy
PAS	Hospital-based patient administration system (electronic record system)
PP	Per protocol population
RDaSH	Rotherham Doncaster and South Humber NHS Foundation Trust
SAP	Statistical analysis plan
SCH	Sheffield Children's NHS Foundation Trust
ScHARR	School of Health and Related Research, University of Sheffield
SHEAP	Statistics and health economic analysis plan
SHSC	Sheffield Health and Social Care NHS Foundation Trust
STH	Sheffield Teaching Hospital NHS Foundation Trust
SUS	Secondary Uses Service (electronic record system)
SWYFT	Southwest Yorkshire Partnership NHS Foundation Trust
SYB	South Yorkshire and Bassetlaw (region)
TobTA	Tobacco Treatment Advisor (based in NHS Foundation Trusts)
TRFT	The Rotherham NHS Foundation Trust
TTA	To take away
UoS	University of Sheffield
VBA	Very Brief Advice
YCR	Yorkshire Cancer Research (funder)

Definition of key terms

Trust	An NHS healthcare provider institution. The QUIT service covers eight NHS hospital Trusts
Data field	A data structure for a single piece of data. The electronic record systems are comprised of several data fields that are used to inform the evaluation
Variable	Recorded characteristics and attributes. Variables can be defined at different levels, e.g., for individuals, trusts, of the QUIT service as a whole
Covariate	A variable that is considered to have a statistical relationship with the probability of success in quitting smoking

Background

The QUIT service (<https://sybics-quit.co.uk>) is a major investment across the South Yorkshire and Bassetlaw (SYB) Integrated Care Board (ICB), which aims to systematically treat tobacco addiction within secondary care. In 2021, 16.1% of adults over age 18 in the ICB area were smokers, compared to 13% in England as a whole [1].

QUIT is a complex service being delivered in partnership with eight NHS hospital Trusts, five community stop smoking services/integrated wellbeing services and community pharmacies. The service spans five local authority areas.

The QUIT service has four main strands (for a detailed service specification see <https://sybics-quit.co.uk/healthcare-professionals/quit-treatment-pathways>)

- QUIT for Patients: treatment of tobacco addiction by clinical teams and specialist Tobacco Treatment Advisors (TobTAs)
- QUIT for Parents: clinical teams will provide very brief advice and refer the parent of children who are receiving care from the trust to the tobacco treatment advisors
- QUIT for Staff: on site specialist support from tobacco treatment advisors and free medications for NHS Trust staff who would like to quit
- QUIT for a Smoke Free Hospital: promoting a smoke free environment for staff, patients, and visitors

The QUIT for Patients strand is composed of:

- **Acute Trust inpatients***
- Mental health Trust inpatients
- Children's inpatients
- Secondary care community mental health
- Acute Trust: A&E, Outpatients and Day Cases

*** This statistical and health economic analysis plan was developed with a focus on people who contact the QUIT service as inpatients in NHS Acute Trusts. Analysis plans for other tobacco dependence treatment pathways in the QUIT service are being developed separately.**

Trusts implementing each patient pathway.

Patient pathway	Trust
Acute Trust: Inpatients, A&E, Outpatients and Day Cases	Doncaster and Bassetlaw Hospitals NHS Foundation Trust (DBTH) Barnsley Hospitals NHS Foundation Trust (BHNFT) The Rotherham Hospital NHS Foundation Trust (TRFT) Sheffield Teaching Hospitals NHS Foundation Trust (STH)
Mental Health Trust Inpatients	Rotherham, Doncaster, and South Humber NHS Foundation Trust (RDASH) (Rotherham and Doncaster psychiatric sites and services only) Sheffield Health and Social Care NHS Foundation Trust (SHSC) Southwest Yorkshire Partnership NHS Foundation Trust (Barnsley psychiatric sites and services only) (SWYFT)
Secondary Care Community Mental Health	
Children and parents/carers	Sheffield Children's Hospital (SCH) Doncaster and Bassetlaw Hospitals NHS Foundation Trust (DBTH) Barnsley Hospitals NHS Foundation Trust (BHNFT) The Rotherham Hospital NHS Foundation Trust (TRFT) Sheffield Teaching Hospitals NHS Foundation Trust (STH)

Sources of routinely collected data

Data sources that will be used to estimate the relevant service metrics take the form of routinely collected aggregated and anonymised patient-level data relating to (i) identification of smokers, their health, and demographic characteristics; (ii) treatment for tobacco addiction; and (iii) outcomes data on quitting smoking.

The South Yorkshire and Bassetlaw ICB population

To quantify the representativeness of the cohort of people reached by the QUIT service, the profile of people arriving at the QUIT service will be compared to that of the population resident in the South Yorkshire and Bassetlaw ICB area. Key descriptive variables will be age, sex, Index of Multiple Deprivation quintile, ethnicity, and smoking behaviour. This comparison will be based on data from the Annual Population Survey [2].

NHS hospital Trust electronic record systems

Individual-level data from the following systems will be linked to provide information about QUIT service usage, individual health and clinical characteristics, smoking characteristics, and quitting outcomes:

- *Electronic Nursing Records (ENR)*: Used to record whether clinical staff ask patients if they smoke on admission, whether patients smoke or not, whether very brief advice is given, and whether NRT is given.
- *Tobacco Treatment Advisor records (TobTA records)*: For Tobacco Treatment Advisors to record patient contacts and patient characteristics, including managing their caseload e.g., patient assessments and follow-ups.
- *Patient Administration System (PAS) hospital records*: Contains data on each patient interaction within the hospital e.g., dates of admissions and discharge, and patient demographics.
- *Secondary Uses Services (SUS) data*: Contains information from the PAS and from the coding of health conditions from patient notes.

Community Stop Smoking Services electronic record systems

Five Community stop smoking services / Integrated Wellbeing Services are involved in the QUIT service. Each has an established e-record system, e.g., QuitManager. These systems are used for caseload management and local service monitoring with respect to client characteristics, contacts, and quitting outcomes.

Each CSSS has been asked by the ICB QUIT team to add fields to their e-record systems that notify the CSSS of a patient referral from a Trust and provide relevant information from Trusts. CSSS e-record systems also record whether a patient who has self-referred to the CSSS did so because of their contact with the QUIT service.

Two types of data will be used:

- Individual-level data from CSSS will be linked to individual-level data from Trusts to allow the tracking of quitting outcomes over the entire pathway in relation to patient and service characteristics.
- Aggregate data from CSSS will provide information on the relative use of CSSS by QUIT and non-QUIT derived clients. This will be a simple cross-tabulation of CSSS use and quit rates for QUIT vs. non-QUIT clients.

Information governance and data flows

Since this is a service evaluation, the aim is to make use of existing commissioning data flows. However, since this is a new service that is in the process of setting up its commissioning data flows, part of the role of the evaluation is to support the development of data flows.

The data flow as follows (see Figure 1):

- Care record data flow from Trusts to their regional Data Services for Commissioners Regional Office (DSCRO), which is the NHS body responsible for anonymising NHS commissioning data. The DSCRO also has ongoing data flows from Secondary Use Services (SUS).
- Community Stop Smoking Services will also be providing individual-level data to the DSCRO, who will link the Trust, SUS and CSSS datasets to give a whole pathway picture of patient characteristics, service use and quitting outcomes.
- Once data linkage between Trust and CSSS data is completed, an anonymization algorithm is run that converts individual information to a non-identifiable form – this will produce a pseudo-anonymised patient identifier that will be used in the individual-level evaluation dataset to track patient journeys through the service pathway.
- The South Yorkshire and Bassetlaw ICB will conduct data quality checks to identify issues with data recording, e.g., to identify if some Trust sites are not completing key data fields, which might then be followed-up by the ICB QUIT team.
- The South Yorkshire and Bassetlaw ICB will then forward anonymised data (i.e., removing identifiable data fields such as postcode and free text fields) to the University of Sheffield to use for the evaluation.

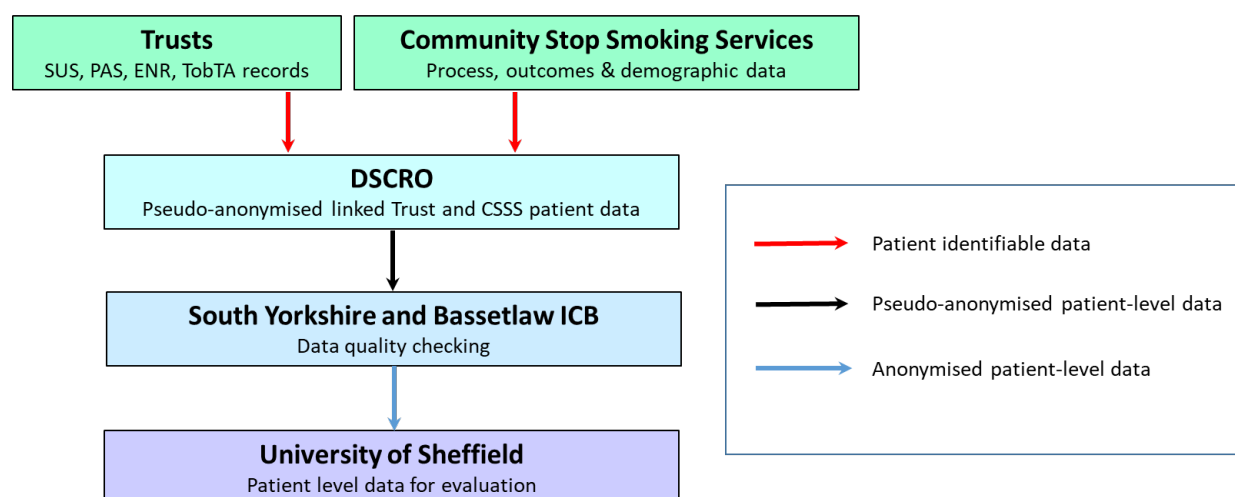


Figure 1. Data flows for routinely collected data for the service evaluation.

Statistical Analysis Plan for the QUIT hospital-based smoking cessation service

Core analysis plan: acute inpatient services

Introduction

This section details the proposed descriptive and statistical analyses for the acute hospital inpatient settings of the QUIT service. Although there is a recognition that the QUIT service encapsulates more than the acute inpatient setting, this section represents the *core* statistical analysis plan (SAP) focused on the acute inpatient setting to stimulate ongoing discussions which will inform the development of supplementary analysis plans for the other settings (i.e., specific considerations for specific settings, but following the core analyses detailed in this document).

The acute inpatient pathway

The description here is a simplified version of the QUIT service specification for the acute inpatient pathway (for the full specification and variations to the pathway see https://syics.co.uk/download_file/1907/337).

On admission

The admitting clinical staff will:

- Ask all patients whether they: have smoked in the last month, used nicotine containing e-cigarettes in the last month, or are already on NRT or other drugs to help them quit smoking.
- Give very brief advice (VBA) to patients who smoke or vape.
- Offer and provide short and long acting NRT on admission, on an opt-out basis, to a) smokers, b) those who vape nicotine e-cigarettes and c) to patients who were on NRT prior to admission. All patients accepting the offer of NRT should receive it within two hours of admission.

The Tobacco Treatment Advisors (TobTAs) will be automatically notified at the time of admission of anyone who falls into categories a, b, or c above.

Within the hospital spell

During the spell in hospital, the TobTAs will:

- Review and support all inpatients 7 days a week, with an initial assessment undertaken on the day of admission or following day. The initial one to one assessment will take about 45 minutes and include a treatment plan, review/provision of pharmacotherapy (if applicable) and a discharge plan.
- Provide additional follow-up reviews to patients who have a prolonged admission on a weekly basis.
- Provide a 2-week TTA (to take away) of the patient's pharmacotherapy.

If a smoker is discharged from hospital before being seen by the hospital TobTAs, then a TobTA will call the patient within 3 working days (for patients who are resident in the South Yorkshire and Bassetlaw ICB area only). If the patient is receptive to brief advice and interested in a quit attempt, then the TobTA will undertake a specialist assessment and initiate pharmacotherapy and then transfer care to their local Community Stop Smoking Service.

After discharge

Acute Trust inpatients have their care for tobacco addiction transferred to local Community Stop Smoking Services after discharge, which means that the acute inpatient pathway includes the new hospital-based tobacco dependence treatment service and support from existing Community Stop Smoking Services in the local area.

After the patient is discharged from hospital, the TobTAs will:

- Complete one follow-up phone call with smokers within a maximum of 3 working days (for patients who are resident in the South Yorkshire and Bassetlaw ICB area only).
- After the follow-up phone call, transfer the patient's treatment (unless the patient opts out) to a CSSS local to the patient for ongoing support and provision of pharmacotherapy.

Defining and quantifying outcomes

The primary outcome of the QUIT service is whether a patient has quit for 4 weeks after contact with the service. The quit could be recorded by the NHS hospital Trusts or by the Community Stop Smoking Services. For inpatients, the primary outcome will also include 4-week periods of continuous abstinence from tobacco smoking whilst an inpatient.

Defining a “quit”

A “quit” is defined using the standard definition: an individual shall not have smoked at all in the last two weeks when asked at four weeks (28 days) [3]. For acute inpatients who saw the TobTA during admission and had their care transferred to the CSSS the date of hospital discharge is set as the patient’s quit date, so a 4-week quit can come at any time within 12 weeks following their discharge date (first quit date). For inpatients who did not see the TobTA during admission but had a post discharge call from the TobTA and their care was then transferred to the CSSS, the following scenarios describe how a quit date is set and a 4-week quit can occur at any time within 12 weeks of this date.

- If the patient has not smoked since discharge, then their quit date is the date of discharge.
- If the patient has smoked since discharge, then they should be encouraged to have a CSSS referral and the 12-week period in which a 4-week quit might occur starts from quit date agreed with CSSS.
- If the patient has specialist assessment by a TobTA over phone and the TobTA initiates treatment, then a quit date should be agreed with the TobTA.
- If the patient does not want a CSSS referral or a specialist assessment by a TobTA over the phone, then they should be asked for consent to call again at 4 and 12 weeks to check their quit status and the date of the initial call is used as the quit date.

Resetting a quit date

A patient who fails at their first attempt at quitting is recorded as not achieving a quit at 4-weeks following their initial quit date. However, if they are still motivated and in contact with the TobTA or CSSS, then they can commence a new quit attempt and set a new quit date (a ‘repeat’ quit date).

- For patients having support from the CSSS, 4-week quits that are completed within the above 12-week periods can be counted towards the primary outcome.
- For patients who saw the TobTA as an inpatient, but who were not referred to the CSSS, their quit status will be in follow-ups by the Trust TobTAs at 4 and 12 weeks only. Only the patients who have given consent to have a quit status check at 4 and 12 weeks will be contacted.
- Patients who are referred to CSSS but who do not subsequently go on to engage with the CSSS and therefore do not continue with their quit attempt will be recorded as lost to follow up because these patients will not be followed up by the Trust TobTAs.

Readmission to hospital

If a patient receives an intervention from the QUIT service, initiates a quit attempt and then is re-admitted to hospital whilst still in the process of that quit attempt, then they will continue with this original attempt. They will not go back to the start of the QUIT service and their quit date based on their first contact with the QUIT service will remain. If the same patient is re-admitted to hospital but has relapsed back to smoking, then they will be referred back to the start of the QUIT service and will have a new quit date.

Aims and objectives of the analysis

The aim of this analysis plan is to support the improvement process of the QUIT service by gaining insights from quantitative service data. Since the service is new, the amount and quality of the quantitative data from the service that is available for analysis might be limited until the service has had more time to embed. The analyses will therefore be conducted from the point of view of producing insights to support service improvement rather than giving an ultimate verdict on service effectiveness.

Work will be towards the following three objectives:

- To work with QUIT ICB and Trust teams to develop data collection processes, to share experiences and work towards coherent and efficient data collection across the Trusts.
- To investigate the differential reach of the QUIT service by producing descriptive statistics that include:
 - Number of patients who are asked their smoking status (and the percentage who are smokers, vapers, already on stop smoking medications).
 - Number of current smokers available to the service who are seen by a smoking cessation advisor (TobTA) (as a percentage of total current smokers).
 - Number of current smokers who accept support to quit smoking and who are provided Very Brief Advice (VBA), behavioural support and pharmacotherapy.
 - Number of current smokers who accept and receive ongoing smoking cessation support (including behavioural support) in the community following a hospital discharge.
 - Number of current smokers for whom a self-reported 4-week quit is recorded (either from the original quit date or within 12 weeks of the original quit date). Due to COVID-19, all 4-week quits will be defined as self-reported rather than confirmed using an exhaled carbon monoxide (CO) test.
- To estimate service effectiveness as:
 - The number of treated smokers and their unadjusted (i.e., observed) rates of 4-week quits (which can be based on aggregated data provided by services).
 - If patient-level data is available, then to use the data on patient and service level factors to estimate probabilities of achieving a 4-week quit that have been statistically adjusted for the influence of these patient and service level variables. The results will allow for fairer comparisons of effectiveness across service settings and might allow for subsequent investigation of the factors that are most influential on achieving a 4-week quit.

This will allow two main questions to be answered about the QUIT service:

- Inequalities—What are the characteristics of the people being offered and subsequently taking up different components of the intervention in relation to the population who might have done so?
- Quitting—What are the quit rates generated by the QUIT service and what patient- and service-related factors moderate the success of a quit attempt?

Evaluation dataset design

The aim is to use the data fields in the service dataset that is transferred to the University of Sheffield to design an analysis dataset containing variables derived from the service data fields. This analysis dataset can then be used to efficiently produce descriptive statistics and to inform statistical models of quitting outcomes. Data quality improvement will be in line with NHS England principles (<https://www.england.nhs.uk/data-services/validate/>) with a focus on the consistency and completeness of recording of the data fields.

The design objectives for the analysis dataset are:

- To track unique individuals, who might contact the QUIT service more than once, e.g., if they have two separate admissions into hospital.
- To track key elements of service activity that occur during an individual contact with the QUIT service, considering the period from first contact with the service to opt-out, quit or loss to follow-up.
- To track the outcomes of attempts to quit tobacco smoking through the Trust and CSSS data, including loss to follow-up.

Process of dataset development

Based on the full specification of the new electronic record systems being implemented to administer and monitor the QUIT service, the evaluation team went through an iterative process to define the data fields from these systems that are likely to be important for the statistical analysis of the QUIT service. The process involved several iterations of feedback from the QUIT service team to arrive at a balance between the number of data fields and the burden of data collection on the practitioners delivering the service. For each data field, this involved consideration of the potential value of information and the acceptability and practicability for service staff of collecting the information. The data fields that were selected are listed in the “SchARR QUIT evaluation data dictionary”.

Format of analysis dataset

The variables in the analysis dataset will be given a new field code, the definition and derivation of this field can be found in the SchARR QUIT evaluation data dictionary, which links each derived variable back to the service data fields.

The proposed format of the analysis dataset is based on the format of the Hospital Episode Statistics [4]:

- A “tob-spell” would start when a patient first contacts the QUIT service and ends when a patient opts-out of care, dies, is lost to follow-up, or the quit attempt ends by the patient being recorded as having quit or not quit at 4 or 12 weeks. Tob-spells encompass the entire continuous sequence of care as an inpatient and after discharge, including treatment provided by community stop smoking services. Spell-level data would include an overview of the intervention and pharmacotherapy received.
- Tob-episodes could be of four types. (i) Current tobacco smokers who were screened by ward staff to ascertain their smoking status on admission to hospital will have a ‘screening’ episode as part of their tob-spell. (ii) Smokers who had a full assessment with a Trust tobacco treatment advisor will have a ‘TobTA’ episode. (iii) Smokers who receive post-discharge support from a Community Stop Smoking Service will have a ‘CSSS’ episode. (iv) Smokers will also have an ‘overview / discharge’ episode for information recorded in the records system on the pharmacotherapy recommended / used and the reason for the tob-spell ending.

Analysis populations

The primary analysis population will be patients living in the South Yorkshire and Bassetlaw ICB area. Patients who live outside the South Yorkshire and Bassetlaw ICB boundaries who access QUIT services will be asked about their smoking, advised, and treated during their inpatient admission. However, the QUIT service specification does not include follow-up of non SYB ICB patients after discharge from hospital. Non SYB ICB patients will therefore be excluded from the primary population for statistical analysis of quitting outcomes but will be included in an alternative version of the primary population used to estimate descriptive statistics of service outputs.

Intention-to-treat (ITT) populations

The primary analysis population will be based on an intention-to-treat (ITT) principle. This will include all eligible patient smokers who were offered the QUIT service in an inpatient setting who did not opt-out, regardless of treatment subsequently received. Since QUIT is an opt-out service for acute inpatients, there is an intention to treat all smokers admitted to hospital. All patients who have smoked tobacco in the last month will be defined as current tobacco smokers. Smokers can be in the ITT population regardless of whether they set a quit date or not. The ITT population will therefore capture quits achieved in hospital by a period of continuous abstinence of 4 or 12 weeks whilst an inpatient.

Two versions of ITT populations can be defined (Table 1):

- ITT0-ask-admission—smokers whose smoking status was recorded in the Electronic Nursing Records indicating that they were screened for smoking on admission.
- ITT1-smoke—a broader definition of smokers identified and recorded in the Electronic Nursing Records or Tobacco Treatment Advisor records at any time during their inpatient spell or by phone after discharge.

Two further ITT populations can be defined from the QUIT service specification – based on the QUIT service’s intention to support non-smokers who vape nicotine who would not be able to vape in hospital (ITT2-vape), and patients already in the middle of a quit attempt that was not initiated due to contact with the QUIT service (ITT3-quit). However, whilst descriptive statistics of the numbers and percentages of patients in these populations could be produced, no analysis of outcomes will be undertaken for these populations.

Table 1. Intention to treat populations

INTENTION-TO-TREAT POPULATION	DEFINITION	INCLUSION CRITERIA	EXCLUSION CRITERIA	VARIABLES NEEDED TO DEFINE POPULATION
ITT0-ASK-ADMISSION	All patients asked about their smoking status by ward staff on admission	- Adults (age 16+ at the point of hospital admission) - All non-elective and elective admissions with any length of stay, including 0 length of stay - Patients transferred between Trusts who have a new TobTA record created. - Patients discharged before being seen by TobTA while inpatient (or if due to COVID-19 adaptation all patients being called post discharge). - Patients with dementia and/or cognitive impairment, and/or learning disabilities. - Pregnant women admitted to general wards (with advice being sought from midwifery smoking cessation specialists if required and transfer of care to midwifery services after the initial assessment).	- Patients on maternity wards (patients on maternity wards should not be recorded in the TobTA records due to the service specification) - Day cases - Patients who use other forms of tobacco, e.g., oral, waterpipe, shisha. These patients may be referred to the Trust based TobTAs for initial advice.	- CCG (now ICB) - Age - Patient classification (to exclude day cases) - Type of client (adult, child, patent, staff) - Type of care (acute inpatient / day case / outpatient / A&E, mental health inpatient, community mental health)
ITT1-SMOKE	Patients recorded at any point on, during or after their admission as a current tobacco smoker			

Per-protocol (PP) populations

We define four per-protocol populations based on the key stages in the service pathway (Table 2):

- Per-protocol 1 (PP1-acute)—People who had a specialist assessment with a Trust tobacco treatment advisor. It is assumed that all inpatients receiving a specialist assessment by a Trust tobacco treatment advisor will have a preliminary quit date set as the date of discharge, whether or not they have stated an intention to quit.
- Per-protocol 2 (PP2-CSSS)—People attempting a quit and engaging with the Community Stop Smoking Services. These people are treated smokers whose tobacco dependence treatment was initiated by contact with a Trust TobTA and who subsequently went on to receive a support session from a CSSS tobacco treatment advisor.
- Per-protocol 3 (PP3-screen)—People attempting a quit who was also asked if they smoke on admission and has their smoking status recorded in the Electronic Nursing Record system. The definition of this population is meant to exclude smokers who were not identified on admission but who contacted the QUIT service as a result of case finding by TobTAs.
- Per-protocol 4 (PP4-FU)—People with all follow-up time points. These people are smokers who have a recorded quit date and who were able to be followed-up to ascertain whether or not they were still abstinent from smoking for 4 weeks. Follow-up to determine the quitting outcome can be done by either a Trust TobTA or a CSSS advisor.

Table 2. Per-protocol populations

PER-PROTOCOL POPULATION	DEFINITION	INCLUSION CRITERIA	EXCLUSION CRITERIA
PP1-ACUTE	Smokers who had a specialist assessment with a Trust tobacco treatment advisor	- ITT1-smoke - Has specialist assessment with a Trust tobacco treatment advisor	
PP2-CSSS	Smokers whose tobacco dependence treatment was initiated by contact with the QUIT service and who subsequently went on to receive a support session from a tobacco treatment advisor at a Community Stop Smoking Service.	- ITT1-smoke - Receive at least one specialist treatment session with a CSSS advisor - Referred from the QUIT service (referral by the service or self-referral) - Patients with dementia or cognitive impairment, who have their care transferred to a CSSS on an opt-in rather than opt-out basis - Had contact with the Trust within the 6 weeks when they first contact the CSSS.	- Contact with CSSS not recorded as being a result of contact with a QUIT service Trust - Pregnant smokers who have their care transferred to the local smoking in pregnancy service - Patients under the care of secondary mental health care teams, who have their care transferred to a mental health Trust tobacco treatment advisor - Patients with a goal to quit vaping rather than current tobacco smoking
PP3-SCREEN	Current tobacco smokers who were screened by ward staff to ascertain their smoking status on admission to hospital and subsequently had a specialist assessment with a Trust tobacco treatment advisor	- ITT0-ask-admission - Patient screened for their smoking by ward staff on admission and identified as a current tobacco smoker	Patients identified via case finding of smokers in hospital who have not been screened on admission – however, this may not be clear cut as some TobTAs are retrospectively filling in nursing assessment fields if they case find a smoker
PP4-FU	Treated smokers who set a quit date and who were able to be followed-up to determine their quitting outcome at 4 weeks.	- PP1-acute 4-week quit outcome known	

Sample size and completeness

Amount of data needed

Larger sample sizes are preferred due to the detailed nature of the proposed investigation. However, no minimum sample size is calculated for the quantitative evaluation of the QUIT service because this is a pragmatic service evaluation intended to utilise whatever data is available. No random allocation of individuals to treatments is designed nor permitted as part of this service evaluation. Allocation is based on individuals being identified as smokers by the QUIT service and then not opting out of support to stop smoking.

The main factors that will affect the available sample size are:

- *Time period of data collection.* This period would ideally be longer if small number of patients are using the QUIT service each month, there is a low rate of attempts to quit or a high loss to follow-up. Given the need to track quitting outcomes over 4 weeks, a minimum of three months of service data per Trust is suggested.
- *Number of Trusts and Community Stop Smoking services contributing data.* This depends on the setup of systems for data collection and the data flows for service monitoring and evaluation. There is a risk that some Trusts or CSSS are not able to contribute data or are delayed in doing so.
- *Data quality.* As the level of missing data on quitting outcomes or important patient and service level variables increases, the sample size available for 'complete case' analyses decreases. Missingness in key outcomes and variables also reduces the reliability of attempts to impute the values of missing data.

Missing data and loss to follow-up

The flow of participants through the study will be summarised using a flow diagram. Where possible, reasons for loss to follow-up will be obtained and summarised. Possible gaps in the checking of the quit status include:

- Patients who did not see the TobTAs and did not have a call from them within a few days post discharge to offer support – these patients must have only been seen by the nurse on admission.
- Patients who were transferred to the CSSS but did not engage with them or were subsequently lost to follow up.
- Patients who saw the Trust TobTA but did not give consent for either transfer to CSSS or a 4-week quit status follow up contact.
- Patients who did not respond to quit status contact by the Trust TobTA or CSSS.
- There may be issues with the administrative collection of data that cause patients to be lost to follow-up but are not a result of the behaviours of the patient themselves. This could include the service failing to attempt to contact the patient the required number of times at each follow-up point.

To determine the most appropriate way to handle loss to follow-up, the following procedure will be carried out:

1. We will assess mechanism for missingness by summarising the levels of missingness for each variable and comparing baseline characteristics between those who are lost to follow-up and those who are not lost to follow-up. If necessary, we will consider using multiple imputation by predictive mean matching to impute baseline data.
2. Using the results in step 1 we will determine whether the data are missing at random (MAR) or missing not at random (MNAR).
3. If the data are MNAR we will consider two scenarios
 - Assume that all patients lost to follow-up are not smokers, as per the Russell Standard [3].
 - Assume that all patients lost to follow-up are smokers, as conducted in the analysis of the CURE hospital based tobacco treatment service [5].
4. If the data are MAR, then we will use multiple imputation to impute the missing values.
5. We will also consider a complete case analysis where all patients without follow-up data are removed from the dataset.

A decision for the most appropriate procedure for the analysis of each ITT and PP population will be made once the mechanism for missingness has been determined.

Interim analyses

An interim analysis will be conducted at the point of the first data transfer to the University of Sheffield. The analysis will include providing descriptive statistics and reporting on the proportion of missing data for important data fields.

A minimum of data from one hospital Trust is needed to complete these checks, ideally linked to the corresponding CSSS data.

Having this data will allow testing and refinement of the statistical model of quitting outcomes at 4 weeks, e.g., to determine whether the data is sufficient to get a basic result out of that model and inform plans for dealing with missing data.

Descriptive analysis

In 2016, 2019 and 2021, the British Thoracic Society conducted national audits of smoking in NHS acute hospital trusts (excluding mental health and maternity services) [6-8]. In 2016, across 146 Trusts, the audit found that smoking status was documented in 73% of patient records, and that 25% of patients were current smokers. In 2019 and 2021, the documentation of smoking status rose to 77% and 79% of patients, with 24% and 21% being current smokers. The key characteristics used to describe variation in these service statistics were gender, age, consultant speciality, and route of contact with the service (i.e., having an elective or emergency admission). Further statistics described the numbers and percentages of smokers receiving very brief advice, having a consultation with a Trust tobacco treatment advisor, being offered pharmacotherapy, and being referred onwards to a Community Stop Smoking Service.

Key questions

The descriptive statistics will provide basic variation on inequalities in the reach of the QUIT service and in the quitting outcomes generated (Table 3).

Table 3. Descriptive statistics in relation to evaluation questions and patient and service factors.

EVALUATION QUESTION	PATIENT AND SERVICE FACTORS
INEQUALITIES —What are the characteristics of the people being offered and subsequently taking up different components of the intervention in relation to the population who might have done so?	• Trust • Age • Gender (Male, Female, Indeterminate, Not recorded) • Route of admission (elective / emergency) • Admitting consultant speciality • Dementia or learning disabilities • Pregnant or breastfeeding • Ethnicity (white, mixed, Asian, black, Chinese, other) • Index of Multiple Deprivation quintiles • Cigarettes smoked per day • Heaviness of smoking index
QUITTING —What are the quit rates generated by the QUIT service and what patient- and service-related factors moderate the success of a quit attempt?	

List of descriptive statistics

Statistics will be produced to describe:

- Representativeness of the study population**—the arrival profile of patients in hospital by age, gender, Index of Multiple Deprivation quintile and smoking status compared to the local population (relevant populations: ITT1-smoke and SYB ICB population data).
- Recording of smoking status**—the percentage of people admitted to hospital who have their smoking status recorded (ITT1-smoke and SUS data on hospital admissions).
- Smoking rates in hospital patients**—the percentage of people asked about their smoking status who are identified as current tobacco smokers (ITT1-smoke and ENR/TobTA records).
- Receiving VBA from ward staff on admission**—the percentage of smokers who are screened by ward on admission who are then recorded to have received VBA on their

smoking (ITT0-ask-admission). Further statistics might also be produced on the percentage advised about the smoke-free hospital site on admission, and the percentage started on NRT on admission.

- e. **Having a specialist TobTA assessment**—the percentage of people who are identified as smokers who subsequently have a specialist TobTA assessment (PP1-acute and ITT1-smoke). Smokers who decline a specialist TobTA assessment and only get VBA from the TobTA are not counted. Further statistics might also be produced on the location of the specialist TobTA assessment (inpatient vs. post-discharge), how the assessment was conducted (in-person, video link or phone), and the number of follow-up reviews given by the TobTA before the patient was discharged.
- f. **Receiving pharmacotherapy in hospital**—the percentage of smokers who are provided with pharmacotherapy during their hospital admission (ITT1-smoke).
- g. **Tobacco dependence treatment goal**—the percentage of smokers opting for temporary abstinence, reduction of amount smoked or a full quit attempt (ITT1-smoke).
- h. **Treated smokers with a recorded quit date**—the percentage of smokers who have a specialist TobTA assessment who subsequently have a quit date recorded (PP1-acute).
- i. **Smokers engaging with CSSS**—the percentage of treated smokers who subsequently receive a CSSS support session (PP2-CSSS and PP1-acute).
- j. **Unadjusted quitting outcomes (adjusted estimates from statistical analysis described in the next section)**—the percentage of smokers for whom a self-reported 4-week quit is recorded within a 12-week period (ITT0-ask-admission, ITT1-smoke, PP1-acute, PP2-CSSS, PP3-screen, and PP4-FU). Further statistics might also be produced on the percentage of smokers achieving a 4-week period of abstinence whilst still an inpatient.
- k. **Lost to follow-up**—the percentage of smokers with a recorded quit date who are lost to follow-up (PP1-acute and PP4-FU).

We will also explore the production of descriptive statistics in relation to NHS-England's intervention and pharmacotherapy categories.

Statistical analysis of variation in the achievement of 4-week quits

Aims and objectives

The aim is to use the data on patient and service level factors to estimate probabilities of achieving a 4-week quit that have been statistically adjusted for the influence of these patient and service level variables. The results will allow for fairer comparisons of effectiveness across service settings and might allow for subsequent investigation of the factors that are most influential on achieving a 4-week quit.

In addition to producing estimates of quitting outcomes that are adjusted for the influence of patient and service level covariates, the investigation will also estimate how the following three types of factors are associated with the achievement of 4-week quits:

- **Use of pharmacotherapy to support a quit attempt**—to investigate the associations between the use of pharmacotherapy or of different types of pharmacotherapies and quitting success.
- **Service setting**—to investigate the associations between different aspects of the service setting (e.g., Trust, site, or consultant speciality) and quitting success.
- **Socio-demographic and health variables**—to investigate the associations between a set of individual patient characteristics that are relevant to understanding inequalities in outcomes and quitting success.

Primary outcome and model specification

The primary outcome is binary (quit 1 vs. not quit 0) and indicates whether a 4-week quit was achieved within 12 weeks. Variation in this outcome will be investigated using a logistic generalised linear mixed model (GLMM) with a logit link function. In parameterising this model, we will consider the inclusion of random effects for Trust and site.

All fixed covariates will be included as part of a univariate and then multivariate analysis. All coefficients will be converted to odd ratios (ORs) for the purpose of reporting and interpretation of outputs; ORs will be reported based on the mean coefficient alongside the relevant 95% Confidence Intervals and associated p-value.

The model will be run based on all pre-specified covariates and then the model will be refined based on exploring the Akaike's Information Criterion (AIC) and the Bayesian Information Criterion (BIC), and/or statistical significance of the covariates using a backward stepwise regression approach. The outcomes from the fully specified model will be classed as the primary outcome, with the outcomes from the refined model (containing fewer covariates) to be reported in conjunction with the primary model analysis results.

Model goodness of fit will be investigated graphically by plotting model predicted values against corresponding descriptive summaries of the raw data. For logistic regressions fitted to binary data model predictive power and goodness of fit will be assessed statistically using model R^2 and Chi-squared statistics.

Covariates

To support the process of determining which variables were likely to be most important to include in a statistical analysis of quitting outcomes, a literature review was conducted [9]. The objective of the review was to identify a comprehensive set of variables associated with quitting success among

tobacco smokers contacting secondary healthcare services in the United Kingdom (UK) who are offered support to quit smoking and subsequently set a quit date. Covariates were noted if they had a statistically significant (i.e., p -value <0.05) association with quitting success.

The review identified 14 covariates of quitting success, which we grouped into four categories:

- **Demographics**—age, sex, ethnicity, socio-economic conditions, relationship status, cohabitation and social network
- **Individual health status and healthcare setting**—physical health, mental health
- **Tobacco smoking variables**—current tobacco consumption, smoking history, nicotine dependence, motivation to quit, quitting history
- **Intervention characteristics**—reduction in amount smoked prior to quitting, the nature of behavioural support, tobacco dependence treatment duration, use of pharmacological aids

The review findings were cross-referenced against the data fields being collected by the QUIT service to support decisions on the covariates to consider in our statistical model of quitting outcomes (Table 4). These covariates will be included in univariate and/or multivariate analyses as fixed effects. The final set of covariates that will be included in the statistical model will be refined after the service data has been transferred to the University of Sheffield and this data has been cleaned ready for statistical analysis.

Secondary outcome analysis

Secondary outcomes will be analysed using the same approach as the primary outcome and will focus on:

- Original 4-week quit achieved, i.e., was a 4-week quit achieved without the need to reset the quit date
- 12-week quit achieved

Subgroup analyses

No additional analyses will be conducted for subgroup analyses. Instead, the results from the primary analysis will be used to explore the quit rates for different subgroups. Using the whole sample size and holding all other things constant this approach allows us to explore what effect being in a certain subgroup has on the outcome. This approach predicts the marginal results for each subgroup. We have adopted this approach, rather than stratifying the data by subgroup and estimating the quit rate as, although this gives the observational result, it is based on a smaller sample size and does not account for confounding factors.

Statistical software employed

All analyses will be conducted using either the latest version of Stata or the R environment [10]. All analysis code will be made open source on the Github repository.

Table 4. Potential modifying factors of the quitting outcomes in treated smokers (codes refer to service data fields)

COVARIATE CATEGORY	RELEVANT MODERATING FACTOR IDENTIFIED IN LITERATURE REVIEW	SERVICE DATA FIELDS NEEDED TO INFORM COVARIATES IN STATISTICAL ANALYSIS
LOCATION		Trust (A9), Site (A10)
DEMOGRAPHICS	Age, Sex, Ethnicity, Socio-economic status (income, occupation, social grade, free prescriptions, social housing), Relationship / cohabitation status, Living with smokers in the same household	Age (C25), Gender (C26), Index of Multiple Deprivation quintile (based on postcode C14), Ethnicity (C31), Occupation (C32), Pregnant (E10), Breastfeeding (E22), Live with smokers (E24)
HEALTH	Depression, Substance abuse, Cardiovascular risk, Comorbidities	Type of admission (elective / not elective) (A53), Consultant specialty (A56), Learning disability (D7), On medications whose metabolism may be affected by stopping smoking (D13), Client reported recent mental health problems (D5), Diagnosis codes (ICD-10) for the admission (first) episode of care only (SUS records)
TOBACCO SMOKING VARIABLES	Daily cigarette consumption, Carbon monoxide level, Nicotine dependence, Most difficult situation not to smoke, Number and duration of previous quit attempts	Cigarettes smoked per day (F10, F11), Time after waking to first cigarette (F12), Heaviness of smoking Index score (F18), Number of previous attempts to stop smoking (F19)
INTERVENTION CHARACTERISTICS	Reduction in amount smoked or temporary abstinence prior to quitting, Behavioural support type, setting and mode of contact, Duration of support and number of contacts, Pharmacological aids	<u>Initial tobacco treatment advisor assessment:</u> Location (inpatient / post-discharge) (C6), How conducted (in person, video link, phone) (C8) <u>Type of support:</u> Behavioural support given (none, very brief advice, motivational interviewing, other) (I3) <u>Abstinence prior to quitting:</u> Achieve a 4-week period of continuous abstinence whilst in hospital (Q2) <u>Ongoing tobacco treatment advisor support:</u> Number of Trust tobacco treatment advisor assessments / reviews (aggregated summary derived from TobTA records) <u>Community Stop Smoking Service support:</u> Has session with a community stop smoking service advisor (CSSS records), Number of community stop smoking service sessions (CSSS records) <u>Pharmacotherapy:</u> Pharmacotherapy recommended to support the quit attempt (as many that apply: single NRT, combination NRT, Bupropion, Varenicline, e-cigarette) (derived from TobTA and CSSS records) (I4, I7, J1, J16, J102-104), E-voucher issued (yes/no) (J17)

Health Economic Analysis Plan for the QUIT hospital-based smoking cessation service

Core analysis plan: acute inpatient services

Introduction

This section details the proposed health economic analyses for the acute hospital inpatient settings of the QUIT service. Although this analysis plan is focused on estimating value for money for the acute inpatient pathway, some aspects of costing necessitate a consideration of costs across multiple pathways of the service e.g., because pharmacotherapy is bought by Trusts and then used to support both inpatients and staff smokers not to smoke. Thus, some aspects of this analysis plan consider how to estimate costs associated with multiple aspects of the QUIT service and then subsequently consider how to apportion costs relevant to the acute inpatient pathway.

This section represents the *core* health economic analysis plan (HEAP) focused on the acute inpatient setting to stimulate ongoing discussions which will inform the development of supplementary HEAPs for the other settings (i.e., specific considerations for specific settings, but following the core analyses detailed in this document).

Aims and objectives of the analysis

The aim of this health economic analysis plan is to support the improvement process of the QUIT service by using quantitative service data and data on the costs of service implementation to estimate a monthly trajectory of the return-on-investment in terms of the cost per 4-week quit.

This analysis plan focuses on estimating return-on-investment from the acute inpatient pathway; plans for other pathways will be developed based on this 'core' analysis plan.

Since the service is new, the expectation is that the cost per 4-week quit will be changing rapidly over time—a decreasing cost per quit would indicate greater value for money by virtue of having lower running costs or a higher number of quits. The health economic analyses will therefore be conducted from the point of view of producing insights into the factors that underpin the cost per quit to support service improvement, rather than giving an ultimate verdict on service return-on-investment.

Work will be towards the following two objectives:

- To quantify the relevant resources used (e.g., staff and non-staff elements) and apply unit costs to suggest the cost of the service (i.e., the cost of investment).
- To estimate service return-on-investment in the form of 'cost per quit'. Note that the estimation of service return-on-investment depends on the above estimates of service costs, and the estimation of the numbers of 4-week quits as detailed in the Statistical Analysis Plan.

Approach to costing the service

The approach to costing will initially consider how to cost the entire QUIT service, including costs to Community Stop Smoking Services due to receiving patients referred from the QUIT service. We will then consider how to apportion these costs between service pathways in order to estimate the cost of the acute inpatient pathway specifically.

Costing will be based on the standard approach used in economic evaluations, which follows a three-stage process of identification of resource use, measurement and valuation [11]. Costing will distinguish the sunk costs of service setup from the recurrent fixed and variables costs of service maintenance (Table 5). Sunk costs relate to resources and associated costs that have already been incurred or an investment that has already been made and cannot be recovered (e.g., software investment). Costs will be calculated in Great British Pounds corresponding to prices in the 'cost year' of evaluation (set at £GBP 2020/2021). Where costs are not available for this year they will be inflated using the NHS Cost Inflation Index for pay and prices [12].

The approach to costing the QUIT service was developed through discussion with the QUIT team and QUIT service stakeholders (including finance and business managers). These discussions are ongoing and might still result in refinements to the plan for costing the service. The aim of discussions was to agree an approach to credibly cost the service, whilst recognising that the service is still in an early stage of implementation and therefore the nature of the costs associated with the service are likely to be changing, having not yet reached a stable state. As a result, the definition of service costs is kept simple and focusses only on a necessary (often minimal) level of detail, whilst ensuring that the major expenditures associated with the service are appropriately captured.

Key questions with regard to costing the service identified so far through discussion with the QUIT team are:

- What has been spent on the service regarding new staff posts, pharmacotherapy, and commissioning of training programmes, communications, IT systems and software licenses?
- How much has been spent on key QUIT service staff: QUIT Programme Director, Healthy Hospital Programme Lead, Healthy Hospital Programme Managers, Health Improvement Practitioners, Tobacco Treatment Advisors? How much of this is recurrent vs. set up costs? (e.g., most of the QUIT Programme Director's time is during the initial set up phase of the QUIT service rather than a recurrent cost).
- How much is spent on pharmacotherapy in each service setting and how much of this is 'extra' compared to before the QUIT service? For mental health Trusts this includes the cost of vapes.
- What are the additional costs to the Community Stop Smoking Services (staff time, pharmacotherapy etc.) from clients referred via the QUIT service?

Table 5. Definitions of Fixed, Sunk and Variable costs

COST TYPE	DEFINITION
SUNK COSTS	Resource and associated costs that have already been incurred or an investment that has already been made and cannot be recovered (e.g., software investment). Sunk costs have been incurred by past decisions and are generally ignored in decision making, other than as learning experiences that may inform future decisions.
FIXED COSTS	Resource and associated costs that remain constant regardless of the levels of production (e.g., the cost of employing a tobacco treatment advisor dedicated to the QUIT service). Fixed costs are those which are associated with the start-up or running of an activity even if nobody uses it.
VARIABLE COSTS	Resource and associated costs that vary based on the amount of output produced (e.g., clinical staff who might put more or less time into the QUIT service depending on demand). Variable costs are those which increase with usage. These costs will vary with the number of smokers that use the service and might evolve over the course of service development as processes become more efficient.

Sunk costs of service setup

The sunk costs of the QUIT service cover the investment that has been made to get the QUIT service up-and-running. Since the QUIT service is a major change to NHS hospital services, requiring coordination of eight NHS hospital Trusts with Community Stop Smoking Services and pharmacies, the sunk costs of service setup are likely to be substantial. As sunk costs, they are not recoverable (compared to the recoverable fixed and variable costs of the daily running of the service). Including sunk costs in estimates of the cost-effectiveness of the QUIT service is not appropriate because these costs are not recoverable to invest in other forms of service should the QUIT service be cancelled. However, sunk costs are useful to include when calculating a variation of the return-on-investment in the QUIT service in which the total investment is considered, rather than just the investment needed to maintain the service. Another way of thinking about sunk costs is: 'If another Trust is setting up a service like this, what would they want to know about the resources and costs needed to set it up?'

How sunk costs are identified and measured is best informed by discussions with stakeholders about how to present the service setup costs most usefully. To support these discussions, we have adapted an existing framework for organising costs that was developed to quantify the implementation costs of another major health service system change [13]. A working list of items to be considered within the sunk cost estimate is given in Table 6. These are working specifications of the items to be costed and are likely to change after further consultation and refinement of the approach with QUIT service stakeholders.

Table 6. Sunk cost items for the QUIT service

ITEM	COMPONENT	DESCRIPTION
OPTIONS APPRAISAL, BIDDING PROCESS, AND EXTERNAL REVIEW PROCESS	Setup time additional to the time to support day-to-day service running	- Development of the QUIT business case, funding application & contract negotiations - Development of QUIT service specification
	STAKEHOLDER ENGAGEMENT AND GETTING BUY-IN	- Web site development - Workshops to design pathways - Meetings with Trusts to set up coordinated working - Meetings with Community Stop Smoking Services to set up coordinated working
PLANNING AND MONITORING MEETINGS	Planning meetings	QUIT Steering and Advisory group meetings
MAKING THE CHANGE	Recruitment of staff	Job advertisement, interviews, and induction
	Cost of new electronic record systems	IT database costs (new QUIT ENR and TobTA records)
	Set up costs for PharmOutcomes based e-voucher scheme	- Cost of technical support from PharmOutcomes supplier to set up new service and provide ongoing support - Support from ICB Medicines Management team - Pharmacy time set up costs to develop e-voucher software and Patient Group Directions - ICB contract manager's time to set up accreditation list - Local Pharmaceutical Committee time to support set up and engagement - ICB time to set up contracts, engagement, finance processing of invoices - Pharmacist awareness training and set up costs
	E-learning (training setup)	Design costs of e-learning materials
	IMPLEMENTING AUDIT SYSTEMS OR COLLECTING DATA FOR MONITORING PERFORMANCE	Discussions and planning to coordinate joint working between partners involved in monitoring and evaluation
	Database systems setup	- Trust IT staff & clinical systems staff time - Community Stop Smoking Service electronic systems setup
	Informatics team time - ICB	- Information governance advice - Development of method to present service data in dashboards - Set up of data flows for monitoring and evaluation - Analysis and reporting of Key Performance Indicators
	Informatics team time - Trusts	- Development of method to present service data in dashboards & running reports - Set up of data flows for monitoring and evaluation - Development of caseload management
	Informatics team time - Community Stop Smoking Services	- Development of method to present service data in dashboards & running reports - Set up of data flows for monitoring and evaluation - Development of caseload management

Staff costs

This section considers the costs of the staff time required to maintain the running of the QUIT service. These costs could be conceptualised as fixed or variable costs (Table 5). A list of staff whose time will be costed for the evaluation of the QUIT service is given in Table 7. The cost of these staff will be estimated based on pay grades; we will take the median spine point plus on-costs.

Fixed cost approach for Trust staff

Consultations with the ICB QUIT team indicated that, from a service perspective, the salary costs of staff recruited to work only on the QUIT service (e.g., tobacco treatment advisors) should be considered as fixed costs. The salary costs of other staff who need to spend a certain percentage of their time supporting the running of the QUIT service could also be included in the fixed costs assuming a constant effort (%WTE). The primary analysis for the evaluation will therefore take a fixed-cost approach.

Variable cost approach for Trust staff

Alternatively, the costing of key staff involved in service delivery could be treated as variable costs. This would have the advantage of reflecting that the time needed for QUIT related activities is closely related to the number of patients contacting the service. It could also reflect that the time spent on each patient can vary depending on the smoking, health and demographic characteristics of the patient and the clinical context. However, this option will only be considered if there is sufficient time and available data as it is likely to require additional 'time and motion' studies. For example, it would be necessary to estimate the time needed for activities such as initial patient assessments, additional patient reviews, plus time each day to review referral lists, liaison with wards and community stop smoking services, administration, and team meetings. Furthermore, the development of a variable costing approach should consider that these are all activities that could be expected to become more efficient as the service becomes more embedded, and staff become more experienced.

Community Stop Smoking Service staff

For Community Stop Smoking Services (CSSS), the costing of staff time will include the variable costs of the additional advisor time spent on contact with clients originating from the QUIT service. These costs will be estimated from the electronic records of the number of QUIT derived clients taking up support from each CSSS. Information on the number of QUIT clients will be combined with estimates of the number of contacts that each of these clients has with CSSS advisors and the time taken per contact. The data needed could be derived from the aggregate data on the number of QUIT clients attending CSSS, or from the linked individual-level data that tracks patients through the service pathway from hospital to CSSS.

Table 7. Staff time to be costed

ROLE	POSITION
SYSTEM LEADERSHIP AND COORDINATION	• Senior Responsible Officer • Consultant in Public Health Medicine/ QUIT Service Director • Healthy Hospital Programme Lead (band 8b) • Project manager (band 8a) • Admin support (band 4) • Finance support • Senior contract manager • Communications staff • Prevention support officer
HOSPITAL TRUST LEADERSHIP AND COORDINATION	• Executive sponsor • Human resources (for recruitment to deal with staff turnover) • Trust communications staff • Trust clinical leads • QUIT ward champions • Trust senior manager/ Chair of Trust steering group • Healthy Hospital Programme Manager (band 8a) • Admin support for HHPM and the hospital-based stop smoking service • Admin support for Trust staff training programme coordination
HOSPITAL BASED SPECIALIST STOP SMOKING EXPERTISE	• Health Improvement Practitioners (band 6) (mix of management and direct patient contact) • Tobacco treatment advisors (TobTAs) (Band 3 or 4) (training, admin, liaison, initial patient assessment, post-discharge follow-up, additional reviews, out of hospital support including travel time, referral of patients to CSSS)
TIME TO TAKE TRAINING (AND BACKFILL)	• Nurses • Clinical/ managerial leads and champions
NURSE TIME IN DELIVERING THE QUIT SERVICE	• Ward staff asking patients if they smoke on admission • Give smokers Very Brief Advice on their smoking on admission • Administration of nicotine replacement pharmacotherapy on admission • Add patient information to ENR system/ refer smokers onwards to TobTA • Additional admin time
COMMUNITY STOP SMOKING SERVICES SMOKING CESSATION ADVISORS	• Stop smoking specialist advisor support post discharge and for outpatients referred from hospital – initial assessments and ongoing reviews

Non-staff costs

Non-staff costs include consumables (e.g., mouth pieces for CO monitors), communications expenses, the cost of training courses, and the cost of maintaining software licenses (Table 8). For ease of estimating the non-staff costs required for the routine running of the QUIT service, these costs will be treated as fixed costs that can be apportioned approximately between months of service activity.

Table 8. Non-staff cost items

ITEM	COMPONENT
COMMUNICATIONS	• Printing costs of patient leaflets and treatment plans • Communication agency contract • Signage and other smoke free site related expenditure
EXPENSES / CONSUMABLES NEEDED TO DELIVER THE SERVICE	• CO monitors and mouth pieces • Travel expenses for home/ community visits (Mental Health Trusts)
TRAINING COURSE FEE	• Two-day specialist stop smoking training for tobacco treatment advisors, HIPs and HHPMs • Motivational interviewing training for tobacco treatment advisors, HIPs and HHPMs • Change management training for band 8as and band 6s
E-VOUCHERS	• Annual license costs for PharmOutcomes software for e-vouchers

Pharmacotherapy costs

Pharmacotherapy costs refer to:

- Pharmacotherapy items purchased by Trusts for use in the QUIT service.
- E-vouchers given to patients for them to obtain pharmacotherapy over the counter at pharmacies.
- Community Stop Smoking Service (CSSS) provision of pharmacotherapy to clients arriving at CSSS from the QUIT service.

These three types of pharmacotherapy cost represent the main expenditures needed to maintain the QUIT service (Table 9).

Pharmacotherapy purchased by Trusts

Top-down costing

The evaluation will take a top-down costing approach, i.e., taking the total cost of pharmacotherapy items purchased and then use data or expert judgement to divide the costs between months and the different QUIT treatment pathways in each Trust.

To estimate the total amount and cost of pharmacotherapy purchased (top-down costing), pharmacies will provide data on the total amount and cost of pharmacotherapy in a certain period, e.g., by month (example data fields: Quarter, Commissioner / Provider plus Code, BNF Presentation, Items, Quantity, Net Ingredient Cost). The resulting estimate of total cost will therefore represent the actual prices paid for pharmacotherapy by the service. This data will be provided for each Trust.

To calculate the pharmacotherapy cost per smoker in each month, the total cost of pharmacotherapy will be divided by the recorded numbers of smokers contacting the QUIT service in each Trust.

Bottom-up costing

The main reason for not doing a bottom-up, i.e., micro-costing, of pharmacotherapy use (e.g., based on drug, dose, actual product/brand, quantity supplied, actual cost, tariff cost) include:

- New data flows would need developing, e.g., linking patient level pharmacy data with other data for service evaluation via the local DSCRO.
- Some trusts do not have electronic prescribing records.
- The QUIT service e-records show how many patients have been advised to use the different drugs, rather than quantifying the amount used.
- The recording of pharmacotherapy advice by nurses and doctors in the service e-records could be incomplete, e.g., nurses will record that the drug has been given on the patient's drug chart but might not double record that the drug has been given in their electronic record system.
- CSSS could provide detailed information on pharmacotherapy use, but this would require further discussions about data access and linkage.
- Incomplete data recording could reduce the accuracy of estimates of pharmacotherapy costs, although this could be mitigated by statistical imputation and cross-checking estimates against the total amount of pharmacotherapy purchased.

However, if a micro-costing approach could be done, then it might allow the investigation of how pharmacotherapy costs vary by individual smoking and clinical characteristics.

Table 9. Categories of pharmacotherapy to be costed

ITEM	DESCRIPTION	MEANS OF ESTIMATING COST
TOTAL TRUST SPEND ON PHARMACOTHERAPY FOR QUIT	Aggregate data on the amount and cost of pharmacotherapy	• Provided from Trust pharmacist records
ADDITIONAL CSSS SPEND ON PHARMACOTHERAPY FOR CLIENTS FROM THE QUIT SERVICE	Aggregate data on the amount and cost of pharmacotherapy. Estimates adjusted to refer only to clients originating from the QUIT service	• CSSS pharmacotherapy records • Data or expert judgement to apportion total spend on QUIT clients
E-VOUCHER DRUGS AND DISPENSING COSTS	Drug costs, Pharmacy supply fee	• PharmOutcomes invoicing reports • NHS Business Authority's Dictionary of medicines and devices

E-vouchers

E-vouchers can be used in pharmacies for all types of pharmacotherapies, including NRT, Varenicline, except e-cigarettes/ vapes. They are issued when it is not possible to give pharmacotherapy directly to:

- Acute Trust inpatients (in hospital, on discharge, or after discharge)
- Acute Trust outpatients
- Mental Health Trust inpatients (after discharge)
- Community Mental Health Services outpatients
- Trust staff who wish to quit

In keeping with the top-down approach to costing pharmacotherapy purchased by Trusts, e-vouchers will be costed based on the number and cost of e-vouchers issued in a specified period. E-vouchers are valued at the rates at which community pharmacies are reimbursed for e-voucher use (NRT—£2.50 for single NRT, total of £3.50 if on dual NRT; Varenicline: £25 first supply, £5 subsequent supply).

Community Stop Smoking Services

Community Stop Smoking Services (CSSS) pharmacotherapy costs will consider the excess pharmacotherapy costs incurred by supporting clients who attend each CSSS due to contact with the QUIT service. The aim is to estimate how much the total CSSS pharmacotherapy spend has gone up due to receiving clients from the QUIT service.

However, uncertainty is introduced into this estimate because some CSSS clients who contacted the QUIT service might have arrived at CSSS anyway, i.e., they did not arrive because of their contact with the QUIT service. Sensitivity analysis will explore the effects of assuming that 0%, 5%, 10%,... of CSSS clients from the QUIT service would not have attended CSSS anyway.

Keeping with the top-down approach to costing, we will assume that pharmacotherapy use does not vary between QUIT and non-QUIT clients and apportion pharmacotherapy costs to QUIT based on the percentage of QUIT clients.

Return-on-investment

This section describes the estimation of the return-on-investment in the QUIT service in the form of 'cost per quit'. Return-on-investment is a metric indicating the 'rate of return' from an investment, which weighs up investment costs against benefits accrued over a defined period of time [14]. Return on investment in the form of the 'cost per quit' is a form of cost per unit of benefit ratio, i.e., the cost divided by the benefit.

The most relevant reference for the estimation of the cost-per-quit for a hospital-based tobacco dependence treatment service comes from the CURE pilot project in Wythenshawe Hospital in Manchester. The CURE pilot reported the cost per quit for a 6-month period: 22% of smokers admitted to hospital were abstinent from smoking 12 weeks after discharge at a cost of £183 per quit [15].

The aim for the QUIT service is to set up a system for estimating the monthly rolling cost-per-4-week-quit. The initial focus will be on estimating the cost-per-quit for the acute inpatient pathway. Once the method to estimate the cost-per-quit is established, the hope is that this will continue to be used for ongoing service evaluation, i.e., recognizing that the cost per quit will change as the service becomes more widely adopted and delivery improves over time.

Two versions of the 'quit' aspect of cost-per-quit will be used:

- The primary version will be based on the observed number of 4-week quits from the descriptive statistics, i.e., the 'unadjusted' number of quits. This is the method most likely to be used in ongoing evaluation of the service.
 - The secondary version will be based on combining the descriptive statistics for the number of quit attempts (quit dates set) with the primary statistical analysis of 4-week quitting success. This will produce an adjusted number of quits that allows fairer comparisons across service settings.

Three versions of the 'cost' aspect of cost-per-quit will be used:

- The primary version will include the fixed costs of staff recruited to work only on the QUIT service, variable costs of nurse and CSSS staff time to support QUIT clients, fixed non-staff costs incurred to maintain the running of the QUIT service, and pharmacotherapy costs for QUIT and CSSS.
 - Secondary version 1—including the sunk costs of service implementation. The National Institute for Health and Care Excellence recommends that the sunk costs of implementation are included as a sensitivity analysis in return-on-investment calculations [16] because this is useful information for the organisations paying for implementation [17].
 - Secondary version 2—QUIT tobacco treatment advisor time as a variable rather than a fixed cost. Tobacco treatment advisor time will vary by patient, with some patients having complex needs and taking more time. Time for data entry has also been raised in discussions and could be itemised separately in this cost estimation. However, the ability to estimate this version of the cost component will depend on having the time and resources to estimate the 'time and motion' of tobacco treatment advisor activities.

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