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'Low-value' clinical care in general practice: associations of low value care in GP trainees' practice, including formative and summative examination performance – protocol for cross-sectional and retrospective cohort study analyses using the QUestionable In Training Clinical Activities (QUIT-CA) index

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ABSTRACT

Introduction 'Low value' clinical care and overuse of medical services are 'questionable' clinical activities that entail provision of medical services that are more likely to cause harm than good or whose benefit is disproportionately low compared with its cost. This study will seek to establish clinical practice associations of a non-observed work-based assessment of general practitioner (GP) trainees' (registrars') questionable practice (the QUestionable In Training Clinical Activities (QUIT-CA) index). We will also explore association of the QUIT-CA index with a formative observed work-based assessment, and will establish if registrars' QUIT-CA indexes are associated with summative examination performance.

Methods and analysis We will conduct three analyses, all using data from the Registrar Clinical Encounters in Training (ReCEnT) study. ReCEnT is an ongoing (from 2010) cohort study in which Australian GP registrars record details of their in-consultation clinical and educational practice. The QUIT-CA index is compiled from ReCEnT consultation data. A cross-sectional analysis, using negative binomial regression, will establish clinical practice associations of the QUIT-CA index. A cross-sectional analysis using linear regression will be used to establish associations of QUIT-CA index with formative observed in-practice assessment (the General Practice Registrar-Competency Assessment Grid). A retrospective cohort study analysis using linear regression will be used to establish associations of the QUIT-CA index with summative examination performance (Royal Australian College of General Practice fellowship examinations results).

Ethics and dissemination The study has ethical approval from the University of Newcastle HREC(H-2009-0323). Findings will be disseminated in peer-reviewed journal articles and conference presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The analyses will include data of registrars from a broad representative sample of Australian general practitioner registrars with detailed, contemporaneously recorded, linked in-consultation data.

⇒ The QUestionable In Training Clinical Activities (QUIT-CA) index is derived from an authoritative source— the Choosing Wisely Australia/NPS MedicineWise recommendations of peak Australian medical colleges and organisations.

⇒ The QUIT-CA index, however, does not include all general practice relevant Choosing Wisely recommendations (some recommendations were not compatible with our coding system).

⇒ As data are self-recorded, there is potential for social desirability bias in registrars' recording of 'questionable' clinical activities. This potential is mitigated by questionable activities not being the focus of data collection in the Registrar Clinical Encounters in Training study (which records a broad range of clinical and educational aspects of registrars' actions within multiple consultations).

⇒ The General Practice Registrar-Competency Assessment Grid is a validated measure of registrars' observed clinical performance.

INTRODUCTION
Background and rationale
Assessing trainees' competence is an essential function of medical education.[1] Clinical and professional competence is a complex construct and has been proposed to be 'the

habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values and reflection in daily practice for the benefit of the individuals and communities being served.'[2] A singular area where considerations of these complex components of competency come together is in decisions involving 'low value' clinical care and overuse of medical services. These 'questionable' clinical activities comprise provision of medical services that are more likely to cause harm than good[3] or whose benefit is 'disproportionately low compared with its cost' and 'potentially wastes limited resources'.[4 5]

A 2018 review found ongoing issues with such 'questionable' medical practice—many tests are overused, overtreatment is common, and unnecessary care can lead to patient harm.[6] This may not be surprising as clinicians have a formidable task to access and appraise the voluminous literature relevant to their clinical decision making.[7] Financial considerations, competing interests, as well as poor information, have been identified as drivers of poor care that occur across all systems and settings.[8] Given the breadth of practice, and the prevalence of undifferentiated disease, in general practice (with subsequent high levels of clinical uncertainty),[9] general practitioners (GPs) face a particular challenge with uncertainty-driven 'questionable' practice.[10]

This may be particularly so for GP specialist vocational trainees (in Australia, 'registrars') who have singular exposure to the consequences of clinical uncertainty[11] and have established high prevalence of test-ordering.[12 13] Another component of 'questionable' practice, inappropriate prescribing, including prescribing of benzodiazepines, opioids and antibiotics for self-limiting infections, has been established as being in excess of accepted benchmarks in registrars' practice.[14–18] It is essential, however, that GPs' decision making, including that of registrars, is evidence based. This is especially true for test-ordering, prescribing medicines and performance of procedures.

Choosing Wisely is an international doctor-led campaign. It involves identifying potentially unnecessary medical tests, treatments and procedures (via local expert evaluation of the relevant evidence), and engaging doctors and their patients in decisions about these unnecessary health services.[19] Choosing Wisely Australia is an initiative of the (Australian) National Prescribing Service's NPS MedicineWise in partnership with Australia's health professional colleges, societies and associations. The campaign supports clinicians, consumers and healthcare stakeholders to have important conversations about tests, treatments and procedures where evidence shows they provide no benefit or, in some cases, lead to harm.[5] Choosing Wisely seeks to enable clinicians to make right choices based on the best available evidence and discussion between consumers and clinicians.[5] Choosing Wisely has worked with medical colleges, societies and associations (including the Royal Australian College of General Practitioners; RACGP) to identify and prioritise, on evidence-based grounds, low-value activities (tests, treatments and procedures) within their areas of expertise and relevant to the Australian context, for healthcare providers and consumers to question.

The Choosing Wisely 'low-value activities' comprise the recommendations of 36 medical colleges, societies and associations. Each expert body has nominated at least five low value activities that 'clinicians and consumers should question'. A number of the expert bodies nominated more than five questionable practices. The RACGP nominated 10 clinical activities, including areas such as antibiotics for otitis media, screening thyroid function tests and chest X-rays for acute bronchitis. These authoritative recommendations are particularly relevant to early-career clinicians in the context of vocational training. These trainees are establishing what may well be persisting practice patterns.

Both summative and formative assessments have roles in medical trainee competence assessment,[1] including competence related to 'questionable practice'. Summative assessment is related to assessment of practitioner safety for independent practice and, often, subsequent licensing.[20] Formative assessment has a role in refining clinicians' clinical competency[1 20 21] and may also flag individual trainees whose competencies are not meeting expected standards.[20]

In Australian general practice, summative licensing assessment is conducted by the RACGP and the Australian College of Rural and Remote Medicine. Most GP registrars undertake the RACGP summative examinations as a route to independent practice.

There are multiple formative assessment modalities employed within Australian general practice vocational training. This includes work-based assessment (WBA) instruments.[22] WBA usually uses direct observation of performance.[23] In Australian vocational training, External Clinical Teaching Visits (ECTVs) are the main direct-observation WBA modality. During ECTVs (which happen five times during general practice-based training), an experienced GP from outside the practice observes a registrar for one clinical session (approximately 3 hours). A reliable, valid measure of registrars' ECTV performance, the General Practice Registrar-Competency Assessment Grid (GPR-CAG)[24] has been developed and implemented.

While observed practice is the most common WBA, non-observed WBAs such as the Registrar Clinical Encounters in Training (ReCEnT) project[25–27] can assess registrar-patient consultations in considerable detail without direct observation, via registrars' structured recording of aspects of their clinical consultations. Such non-observed WBAs are characterised as 'Patient Encounter Tracking And Learning' tools (PETALs).[28] To our knowledge, GP registrar clinical behaviours/performance measured via direct observation (such as the GPR-CAG) compared with via non-direct assessed performance (such as ReCEnT) has not been performed. Nor has the association of PETAL-assessed WBA clinical performance and summative examination performance been studied.

Objectives

In this study, we will seek to explore the relationship of non-observed WBA assessment (a ReCEnT-derived measure of 'questionable' practice: the QUestionable In Training Clinical Activities (QUIT-CA) index) with an observed WBA (the GPR-CAG). We will also establish if registrars' questionable' practice is associated with summative examination (RACGP Fellowship examinations) performance. We will also establish clinical practice associations of the QUIT-CA index.

METHODS

This study will comprise two cross-sectional analyses of data from the ReCEnT project. We will also analyse ReCEnT data and RACGP examination results as a retrospective cohort study.

Study setting and eligibility criteria

The QUIT-CA study is nested within the ReCEnT project. Data from 22 six-monthly rounds of data collection, 2010–2020, will be used in QUIT-CA analyses.

ReCEnT (study setting, eligibility criteria, recruitment, data collection)

ReCEnT is an ongoing cohort study of the in-consultation clinical and educational experiences of specialist general practice vocational trainees (in Australia, registrars). The participants of ReCEnT are registrars completing general practice training terms with participating Regional Training Providers (RTPs)/Regional Training Organisations (RTOs).

ReCEnT has been conducted since 2010.[25] From 2010 to 2015, it was conducted in the teaching general practices of five of Australia's then 17 RTPs in 5 Australian states—New South Wales (NSW), Victoria, Tasmania, South Australia and Queensland. From 2016 (following a major reorganisation of Australian general practice vocational training, it has been conducted in three of Australia's nine RTOs in three Australian states (NSW, Victoria, Tasmania) and a territory (the Australian Capital Territory). RTPs and RTOs were/are geographically defined not-for-profit organisations tasked with delivering specialist general practice training across Australia. The three current ReCEnT-participating RTOs train 43% of all Australian GP registrars.[29] Each registrar receives support and educational activities and resources from their RTO. The RTO also administers the registrars' training, including placing each registrar, each term, in a teaching practice. Most registrar education and training occurs in the practice, within an apprenticeship-like training model and under the supervision of an experienced GP.

Data collection for ReCEnT occurs during each of a registrar's three (6-month full-time equivalent) general practice training terms. Each term registrars complete a questionnaire eliciting information about themselves and the practice they are currently training in. At about the midpoint of each term, registrars record details of 60 consecutive consultations. From 2010 to 2019, this data collection was paper based—via a paper Case Report Form (CRF). From 2020, data collection has been electronic, via an online portal.

A large number of variables are collected across the questionnaire and in-consultation CRFs. Many of the variables (eg, medicines prescribed or pathology tests ordered) are linked to the problems(s)/diagnosis(es) to which they relate (eg, the problems(s)/diagnosis(es) for which a medicine is prescribed).

ReCEnT has both educational and research functions.[27] It is a routine component of the participating RTOs' education and training programmes.[26] Registrars may also provide voluntary informed consent for the collected data being used for research purposes. The data of registrars who do not provide consent is not used for research purposes, and will not be used in the QUIT-CA analyses.

Outcomes

Primary outcome factor

The primary outcome factor for the analyses in this study will be if a registrar's in-consultation action (eg, the ordering of a test or the prescribing of a medication) was consistent with a recommendation of National Prescribing Service (NPS) Medicine Wise's Choosing Wisely Australia's programme. The recommendations comprise a compilation of low-value activities—'tests, treatments and procedures for healthcare providers and consumers to question'.[30]

We conducted an initial scoping of the Choosing Wisely recommendations, aiming to exclude any recommendations which were, with certainty, either (1) not relevant to general practice or (2) for which ReCEnT data does not allow us to adequately assess registrars' actions related to the recommendation.

The full list of recommendations (n=208) was downloaded from the NPS Choosing Wisely website[30] on 8 October 2020. The initial scoping was completed over six 90 min meetings by the project chief investigator (CI), another GP investigator and two non-GP members of the study team with considerable experience using the ReCEnT database. Of the 208 recommendations, 143 were deemed certainly not suitable for our analyses. For example, from the Australasian College for Emergency Medicine 'For emergency department patients approaching end-of-life, ensure clinicians, patients and families have a common understanding of the goals of care' (not relevant to general practice) and from The Royal College of Pathologists of Australasia 'Do not perform PSA testing for prostate cancer screening in men with no symptoms and whose life expectancy is less than 7 years' (life expectancy is not recorded by ReCEnT).

The remaining 65 recommendations were taken to an expert panel to further determine their suitability for inclusion in our analyses. The expert panel consisted of the CI (a GP academic), six further GPs with academic/vocational training roles and two non-GP investigators

with experience of the ReCEnT project and dataset. This Panel met four times, determining that 55 recommendations met our criteria for inclusion in our analyses. Of these 55 recommendations, five were duplicate recommendations (from different colleges/associations) in relation to imaging for lower back pain; two were duplicates in relation to prescribing antipsychotics for dementia; and two were duplicates on imaging for syncope. Duplicate recommendations were collapsed, resulting in 49 recommendations for inclusion. There were also two recommendations that included more than one low-value clinical activity within the one recommendation—for example, both inappropriate prescribing and inappropriate imaging in the management of bronchiolitis in children. With these split into separate recommendations, there were 51 individual recommendations.

The next step was to specify how each of the conditions/problems (eg, low back pain) and the associated target activity (eg, X-ray or CT scan) mapped to International Classification of Primary Care, second edition (ICPC-2 plus) codes or, for medicines, Anatomical Therapeutic Chemical (ATC) classification codes. This was accomplished by six pairs of expert GPs (selected from an expanded expert panel). The pairs were tasked with selecting codes applicable to each of several recommendation assigned to them. The pairs discussed their assigned recommendations and assignment of codes. And then brought their findings to plenary meetings of the expert panel where difficulties and nuance in the mapping exercise were discussed, formulating general approaches to areas of uncertainty. The pairs then met to make penultimate assignment of ICPC-2 and ATC codes. Assignment was by discussion and mutual agreement. Any areas of disagreement were resolved by discussion with one of two senior Investigators (PM or MLvD). PM or MLvD also reviewed the collated recommendations and assigned codes, addressing any inconsistencies in the application of the general approach across the recommendations. This review of the mapping of recommendations to ICPC-2 codes led to recognition of two recommendations with inconsistencies in mapping—these recommendations did not map adequately to ICPC-2 codes.

Thus, we had a final total 49 items from 47 recommendations to be used in our analyses. See online supplemental table 1 for details of these items/recommendations and figure 1 for a summary of the process of selecting the appropriate items/recommendations for inclusion in the QUIT-CA index.

We also determined for which problems/diagnoses recorded by the registrar (and subsequently classified by ICPCC-2 codes) the registrar was 'at risk' of one of the questionable activities. For example, for a recorded problem/diagnosis of 'low back pain', a registrar was at risk of ordering a lumbosacral spine X-ray. Whereas a registrar seeing a patient with pneumonia was not at risk of any of our questionable activities.
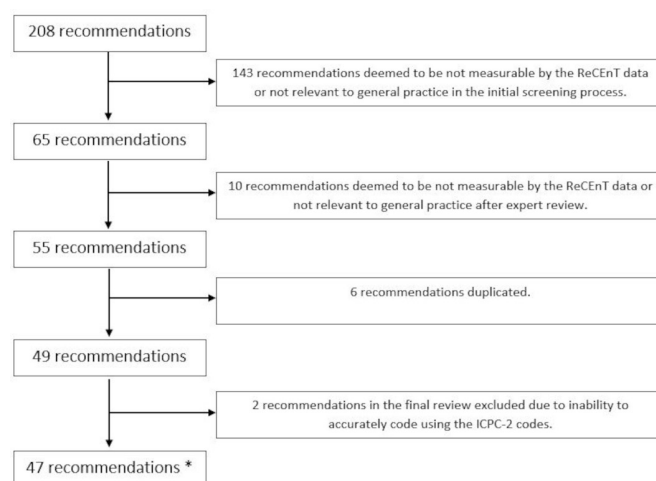
Figure 1 Process of selecting choosing wisely recommendations to include in the QUIT-CA index. *49 separate clinical activities. Two recommendations entailed two clinical activities. ICPC-2, International Classification of Primary Care, second edition; ReCEnT, Registrar Clinical Encounters in Training; QUIT-CA, QUestionable In Training Clinical Activities.

The QUIT-CA index
From this assignment of 'low-value activity' status, an index of individual registrars' 'questionable activities'—the QUIT-CA index—could be calculated. The numerator of the QUIT-CA index was the sum of questionable activities recorded in the registrar's ReCEnT data. The denominator was the number of ReCEnT-recorded problems/diagnoses for which the registrar was 'at risk' of a questionable activity. The ICPC-2 problems/diagnoses which placed a registrar 'at risk' were determined as part of the expert panel/pairs decision-making process, above.

Secondary outcome factors
There will be two types of secondary outcome factors:

Related to the GPR-CAG
The GPR-CAG was developed by GP Synergy, the largest Australian RTO (training, across NSW and the ACT, 33% of Australian registrars)[29] and is used to evaluate and document registrar performance during each of the five mandatory ECTVs that registrars receive during training.[24] During ECTVs, experienced GPs observe a session (approximately 3 hours) of a registrar's consultations with patients. GPR-CAG factor structures have been established for GP registrar term 1 and term 2 ECTVs—for term 1, a four-factor, 16-item structure and for term 2, a seven-factor, 27-item structure.[24] Scores on the four factors of the Term 1 GPR-CAG will be outcome factors in this study: (1) Consultation techniques subserving patient-centredness 'Caring'; (2) Skills in formulating and articulating coherent hypotheses and management plans; (3) Attention to basic-level clinical professional responsibilities; and (4) Proficiency in physical examination skills. Scores on the seven factors of the Term 2 GPR-CAG will also be outcome factors in this study: (1)

patient-centredness; 'sharing'; (2) structural aspects of history-taking; (3) higher-level 'caring' patient-centredness; (4) minimum-required performance in patient-centred 'caring'; (5) holistic proactive approach to patient presentations; (6) attention to minimum standards of professional communication and (7) high level but structured clinical tasks.

Related to performance on summative RACGP fellowship examinations

Outcome variables will be standardised scores for individual registrars' first attempt at each of the three RACGP fellowship examination components[31]:

1. The Applied Knowledge Test ('RACGP-AKT'—a multiple choice question-based examination).
2. The Key Features Problems examination ('RACGP-KFP'—a written short answer-based examination).
3. The Objective Structured Clinical Examination ('RACGP-OSCE'—a clinical 'stations' with patient presentations/role-playing examination).[31]
4. Result (pass/fail) on the Remote Clinical Exam ('RACGP-RCE'—a remotely delivered clinical simulated patient scenarios examination assessed via videoconference)
5. Performance across all three examination components. The pass all/fail any exam outcome is created using the result (pass/fail) of each exam component.

There have been regular iterations of RACGP fellowship examinations since 1968[31] but the essential structures remained the same. Reliability and content validity have been demonstrated.[32–34]

Raw scores for the RACGP-AKT, RACGP-KFP and RACGP-OSCE will be standardised by test and year using the z-score formula: (raw exam score − national mean)/national SD.

Independent variables

A large number of variables (related to patient, registrar, training practice, consultation clinical content and consultation educational content) are recorded in the ReCEnT project (either in the registrar questionnaire or the in-consultation CRF). Those to be considered in QUIT-CA analyses are listed in table 1.

Data management

All ReCEnT data collected is deidentified. Each participating registrar is assigned a unique ReCEnT study identifier (ID). A master list of ReCEnT IDs and registrar name is stored separately only accessible by specified members of the research team.

Construction of a separate dataset was required for analysis of the secondary outcomes. This involved merging of multiple data sources and was restricted to GP Synergy registrar data only. The existing ReCEnT project dataset served as the basis for construction of the dataset. To facilitate linking the outcome variables of interest to ReCEnT data, registrar name within the ReCEnT master ID list was used to match ReCEnT IDs with a separate registrar unique administrative identifier, which is assigned to each registrar on commencement of training and is stored/used within GP Synergy's routine administrative databases. The administrative ID was then used to match and merge GPR-CAG data extracted from GP Synergy's routine administrative database, and also facilitated the matching and merging of registrar RACGP examination results, which are routinely provided to GP Synergy by the RACGP after each examination round.

The deidentified ReCEnT, GPR-CAG and RACGP data are stored on the GP Synergy Microsoft Azure cloud account and uses state-of-the-art encryption. Within this account, access is further restricted by Microsoft Active directory which controls all authentication and authorisation for users and computers and enforces all security policies.

Statistical analyses

Descriptive characteristics of the participants and the outcome variables will be summarised using mean with SD and frequency with percent.

To estimate associations of registrar, patient, consultation and practice variables with the primary outcome (QUIT-CA index), negative binomial regression will be used within the generalised estimating equation (GEE) framework, to account for repeated measures across terms within registrars ('analyses A' in table 1). Data will be aggregated at the registrar-term level, with the response variable being the number of questionable items performed by the registrar during the term. The number of times 'at risk' during the term will be specified as an offset, and predictors will comprise registrar, patient, consultation and practice variables. Patient and consultation variables will be aggregated at the registrar-term level and expressed as a proportion or mean, as appropriate. This analysis will be conducted with data of all participating registrars in ReCEnT (2010–2020). That is, registrars from five RTPs (2010–2015) and three RTOs (2016–2020).

To estimate associations of the QUIT-CA index with the secondary outcomes of CAG factor scores, linear regression within the GEE framework will be used ('analyses B' in table 1). Data will be aggregated at the registrar-term level. The predictor of interest will be the QUIT-CA index for the term, expressed as a percentage; covariates will comprise registrar, patient, consultation and practice variables, with patient and consultation variables aggregated at the registrar-term level. This analysis will be conducted using the data of registrars from a single RTO, GP synergy.

To estimate associations of the QUIT-CA index with RACGP examination scores, linear regression will be used, with data aggregated at the registrar level ('analyses C' in table 1). The predictor of interest will be the QUIT-CA index across all terms, expressed as a percentage; covariates will comprise registrar, patient, consultation and practice variables, with patient, consultation and practice variables aggregated at the registrar level. This analysis

Table 1 Recent variables included in each model

Variables	Analyses A Outcome: QUIT-CA Index	Analyses B Outcome: GPR-CAG Factor scores	Analyses C and D Outcome: RACGP Examinations
Patient			
Age	Mean across term	Mean across term	Mean across training
Gender	Proportion of female patients across term	Proportion of female patients across term	Proportion of female patients across training
Aboriginal and Torres Strait Islander status	Proportion Aboriginal and Torres Strait Islander patients across term	Proportion Aboriginal and Torres Strait Islander patients across term	Proportion Aboriginal and Torres Strait Islander patients across training
Non-English Speaking Background (NESB)	proportion NESB patients across term	proportion NESB patients across term	proportion NESB patients across training
New to practice	Proportion patients new to practice across term	Proportion patients new to practice across term	Proportion patients new to practice across training
New to registrar	Proportion patients new to registrar across term	Proportion patients new to registrar across term	Proportion patients new to registrar across training
Registrar			
Age	Continuous	Continuous	Continuous
Gender	Categorical Male; female; non-binary	Categorical Male; female; non-binary	Categorical Male; female; non-binary
Training term	Categorical GPT1; GPT2; GPT3	Categorical GPT1; GPT2; GPT3	–
International medical graduate (IMG)/ Australian medical graduate (AMG)	Binary IMG; AMG	Binary IMG; AMG	Binary IMG; AMG
Worked at practice before	Binary Yes; no	Binary Yes; no	–
Regional Training Organisation (RTO)	Categorical RTO 1; RTO 2; RTO 3	–	–
Year of graduation	Continuous	Continuous	Continuous
Years hospital practice	Continuous	Continuous	Continuous
Full time/part time	Binary full time; part time	Binary full time; part time	–
Practice			
Rurality	Categorical major city; inner regional; outer regional or remote/very remote	Categorical major city; Inner regional; outer regional or remote/very remote	Categorical any training term in a major city practice yes; no Any training term in an outer regional or Remote/very remote practice yes; no
Practice size	Dichotomised Small ≤5; Large >5	Dichotomised Small ≤5; Large >5	Dichotomised Any training term in a small practice yes; no Any training term in a large practice yes; no
Fully bulk billing practice	Yes; No	Yes; No	Yes; No
Consultation clinical			
Consultation duration	Mean across term	Mean across term	Mean across training
No of problems seen	Mean across term	Mean across term	Mean across training
Follow-up organised by registrar	Proportion problems registrar organised follow-up for across term	Proportion problems registrar organised follow-up for across term	Proportion problems registrar organised follow-up for across training
Consultation educational			
Sources of assistance	Proportion problems where sources of assistance accessed across term	Proportion problems where sources of assistance accessed across term	Proportion problems where sources of assistance accessed across training
Learning goals	Proportion problems where learning goals generated across term	Proportion problems where learning goals generated across term	Proportion problems where learning goals generated across training

GPR-CAG, General Practice Registrar-Competency Assessment Grid; QUIT-CA, QUestionable In Training Clinical Activities; RACGP, Royal Australian College of General Practitioners.

will be conducted using the data of registrars from a single RTO, GP synergy.

To estimate associations of the QUIT-CA index with the RACGP-RCE outcome and the pass all/fail any exam outcome, logistic regressions will be used, with data aggregated at the registrar level ('analyses D' in table 1). The predictor of interest for both binary outcomes will be the QUIT-CA index across all terms, expressed as a proportion; covariates will comprise registrar, patient, consultation and practice variables, with patient, consultation and practice variables aggregated at the registrar level. This analysis will be conducted using the data of registrars from a single RTO, GP synergy.

Sample size and power calculation
The sample sizes for the QUIT-CA analyses are predetermined by the number of registrars participating in ReCEnT 2010–2020 (and by the number of problems/diagnoses they recorded as part of ReCEnT); and by the number of GP Synergy registrars who participated in ReCEnT and also sat RACGP examination components in the years 2012.2–2021.2; and by the number of GP Synergy registrars who participated in ReCEnT and also had GPR-CAG assessments completed 2016.1-2020.2

These estimated sample sizes are:
1. For the analysis of the QUIT-CA index and registrar, patient, practice and consultation associations, we anticipate 400 000 consultations of 2900 registrars.
2. For the analysis of Term 1 GPR-CAG factor scores and association with the QUIT-CA index, we anticipate 1480 registrars.
3. For the analysis of RACGP examination performance and association with the QUIT-CA index, we anticipate 1200 registrars.

We calculated the detectable effect of the QUIT-CA index on exam performance (fail any vs pass all). Since the distribution of the QUIT-CA index will be only known after research commencement, for the purposes of power calculation, we assumed the QUIT-CA index had been normalised and standardised. In ReCEnT, where ~36% of registrars fail at least one exam, 1200 registrars will enable detection of a 0.17 standardised difference in mean QUIT-CA index between outcome groups with 80% power at 0.05 significance. Since this is a small effect, the sample will provide ample power to detect clinically meaningful differences.

Patient and public involvement
It was not appropriate to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

ETHICS AND DISSEMINATION
Ethics approval and protocol amendments
Ethics approval was provided by the University of Newcastle Human Research Ethics Committee (ref.

H-2009-0323). A variation to this approval, covering the QUIT-CA project, was approved effective 8 June 2021.

Consent
The ReCEnT project has both educational and research functions.[26 27] Data collection for educational purposes is a routine part of the educational program of registrars in participating RTPs/RTOs. Registrars may also elect to provide informed, written consent for their data to be used for research purposes.

Confidentiality
ReCEnT-participating registrars are assigned a unique study identifier. All study data are linked to this unique identifier. The master lists of unique identifiers and registrar names is held by the registrars' own RTO in separate password-protected databases.

Dissemination policy
The findings from the QUIT-CA analyses will be presented in journal articles in peer-reviewed journals and at general practice and medical education conferences.

As with other analyses from the ReCEnT project, summaries of findings are presented in RTO newsletters (providing feedback of results to participating registrars and practices). Additionally, the GP Synergy Annual Research Unit Reports are publicly available.

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