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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. 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 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 indexs 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 GP registrars with detailed, contemporaneously-recorded, linked in-consultation data.
- The QUIT-CA index is derived from an authoritative source - the Choosing Wisely Australia/ NPS MedicineWise recommendations of peak Australian medical colleges and organizations.
- The QUIT-CA index, however, does not include all general practice relevant Choosing Wisely recommendations (some recommendations were not compatible with our coding system).
- 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 in 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 prioritize, 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 utilizes 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 three 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 characterized 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 to 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.

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 2010-2015, it was conducted in the teaching general practices of five of Australia's then 17 RTPs in five Australian states – New South Wales (NSW), Victoria, Tasmania, South Australia, and Queensland. From 2016 (following a major reorganization 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 organizations 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 mid-point 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 (for example, medicines prescribed, or pathology tests ordered) are linked to the problems(s)/diagnosis(es) to which they relate (for example, 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 programs.[26] Registrars may also provide voluntary informed consent for the collected data being used for research purposes.

Outcomes

Primary outcome factor

The primary outcome factor for the analyses in this study will be if a registrar's in-consultation action (for example, the ordering of a test or the prescribing of a medication) was consistent with a recommendation of NPS Medicine Wise's Choosing Wisely Australia's program. 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 8th October 2020. The initial scoping was completed over six 90-minute 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 (e.g. low back pain) and the associated target activity (e.g. 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 MvD). PM or MvD 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 Supplementary Table 1 for details of these items/recommendations.

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.

The QUestionable In Training Clinical Activities index

From this assignment of 'low-value activity' status, an index of individual registrars' 'questionable activities' – the QUestionable In Training Clinical Activities (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:

1) Related to the General Practice Registrar-Competency Assessment Grid (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 External Clinical Teaching Visits (ECTVs) that registrars receive during training.[24] During ECTVs, experienced GPs observe a session (approximately three 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-centeredness '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 pro-active approach to patient presentations; (6) Attention to minimum standards of professional communication; and (7) High level but structured clinical tasks.

2) Related to performance on summative RACGP Fellowship examinations

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

a) the Applied Knowledge Test ('RACGP -AKT' - a multiple choice question-based examination)

b) the Key Features Problems examination ('RACGP-KFP' – a written short answer-based examination.

c) the Objective Structured Clinical Examination ('RACGP-OSCE' - a clinical 'stations' with patient presentations/role-playing examination[31]

d) result (pass/fail) on the Remote Clinical Exam ('RACGP-RCE' – a remotely delivered clinical simulated patient scenarios examination assessed via videoconference)

e) 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 standard deviation.

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.

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
Number of problems seen	Mean across term	Mean across term	Mean across training
Follow-up organized 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

Data management

All ReCEnT data collected is de-identified. 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 upon commencement of training and is stored/utilised 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 de-identified ReCEnT, GPR-CAG and RACGP data is 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 authorization 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 standard deviation 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 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 pre-determined 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:

a) For the analysis of the QUIT-CA index and registrar, patient, practice, and consultation associations, we anticipate 400,000 consultations of 2,900 registrars.

b) For the analysis of Term 1 GPR-CAG factor scores and association with the QUIT-CA index, we anticipate 1480 registrars.

c) 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 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 8th June 2021.

Consent

The ReCEnT project has both educational and research functions.[26,35] 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 is 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.

Declaration of Interests

PM, AT, AF, AR, LK and AD are employees of GP Synergy. NS is an employee of Eastern Victoria General Practice Training. KFG is an employee of General Practice Training Tasmania

Access to data

Human Research Ethics Committee (HREC) advice is that, as participants in earlier rounds of ReCEnT data collection did not provide permission for sharing of data, data will not be available.

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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These funding sources had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Roles and responsibilities: authors' contributions

PM conceived the study. PM, AT, AF, AD, LK, AR and MVD initiated the study design. PM, AT, MvD, LK, NS, KF, AD, EH, and AF are grant holders. EH and JB provided statistical expertise in clinical trial design. JB and EH are conducting the primary statistical analysis. PM and AR wrote the draft of the protocol (with statistical sections by EH and JB). All authors contributed to refinement of the study protocol and approved the final manuscript.

Competing interests statement

The authors have no competing interests

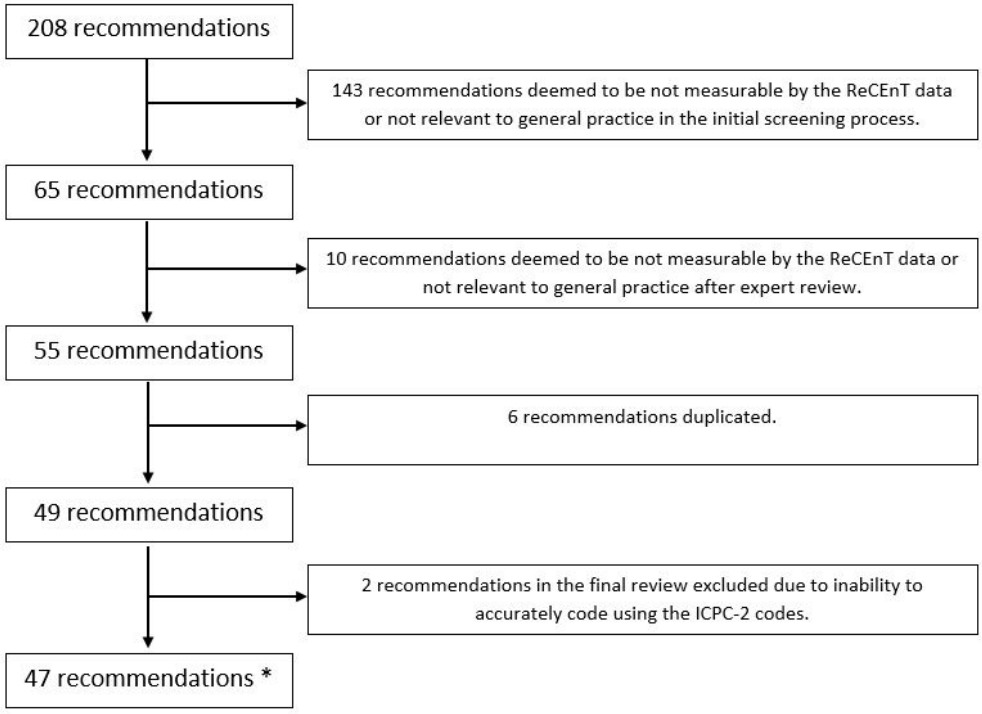

Figure 1: Process of selecting Choosing Wisely recommendations to include in the QUIT-CA index.

205x159mm (96 x 96 DPI)

Supplementary Table : Low-value, questionable clinical activities included in the QUestionable In Training Clinical Activities (QUIT-CA) index*

	Recommendation	Clinical outcome	Inclusions/duplications
Royal Australian College of General Practitioners	Don't order chest x-rays in patients with uncomplicated acute bronchitis.	Imaging	nil
Royal Australasian College of Physicians Paediatrics & Child Health Division Council	Do not routinely order abdominal X-rays for the diagnosis of non-specific abdominal pain in children	Imaging	<18yrs
Royal Australasian College of Physicians Paediatrics & Child Health Division^	Do not routinely undertake chest X-rays for the diagnosis of bronchiolitis in children [or routinely prescribe salbutamol or systemic corticosteroids to treat bronchiolitis in children]	Imaging	<3yrs
The Endocrine Society of Australia	Don't routinely order a thyroid ultrasound in patients with abnormal thyroid function tests if there is no palpable abnormality of the thyroid gland.	Imaging	nil
Royal Australasian College of Physicians Paediatrics & Child Health Division Council	Do not routinely order chest X-rays for the diagnosis of asthma in children	Imaging	<18yrs
Australasian Faculty of Occupational and Environmental Medicine	Do not request low back X-rays or other forms of low back imaging as part of a routine preplacement medical examination.	Imaging	nil
The Australian Physiotherapy Association The Royal Australian and New Zealand College of Radiologists Australasian Faculty of Occupational and Environmental Medicine Australasian Faculty of Rehabilitation Medicine	Don't request imaging for patients with non-specific low back pain and no indicators of a serious cause for low back pain. Don't perform imaging for patients with non-specific acute low back pain and no indicators of a serious cause for low back pain. Do not order X-rays or other imaging for acute non-specific low back pain, unless there are red flags or other clinical reasons to suspect serious spinal pathology. Do not use imaging for diagnosing non-specific acute low back pain in the absence of red flags.	Imaging	< 50yrs Some problems restricted to continuing problems Five recommendations

Australian Rheumatology Association	Do not undertake imaging for low back pain in patients without indications of a serious underlying condition.		
The Australia and New Zealand Child Neurology Society	Do not routinely perform electroencephalographs (EEGs) for children presenting with febrile seizures.	Imaging	<18yrs
The Australia and New Zealand Child Neurology Society	Do not routinely perform computed tomography (CT) scanning of children presenting with new onset seizures.	Imaging	<18yrs New problem
The Australia and New Zealand Child Neurology Society	Do not routinely perform electroencephalographs (EEGs) for children presenting with syncope (fainting).	Imaging	<18yrs
Australasian Faculty of Occupational and Environmental Medicine	Do not repeat chest X-rays when screening asbestos-exposed workers unless clinically indicated.	Imaging	Old problem
Royal Australasian College of Surgeons	Don't order computed tomography (CT) scan of the head/brain for sudden hearing loss.	Imaging	New problem
Royal Australasian College of Surgeons	Do not use ultrasound for the further investigation of clinically apparent groin hernias. Ultrasound should not be used as a justification for repair of hernias that are not clinically apparent.	Imaging	nil
Royal Australasian College of Surgeons	Don't routinely obtain radiographic imaging for patients who meet diagnostic criteria for uncomplicated acute rhinosinusitis.	Imaging	New problem
Australian and New Zealand Association of Neurologists Internal Medicine Society of Australia and New Zealand	Don't perform imaging of the carotid arteries for simple faints. Don't request Holter monitoring, carotid duplex scans, echocardiography, electroencephalograms (EEGs) or telemetry in patients with first presentation of uncomplicated syncope and no high risk features.	Imaging	Two recommendations
Australian and New Zealand Association of Neurologists	Don't perform imaging of the brain for non-acute primary headache disorders.	Imaging	Old problem
The Thoracic Society of Australia and New Zealand	Do not prescribe antibiotics for exacerbation of asthma.	Medication	nil

Royal Australasian College of Physicians Paediatrics & Child Health Division	Do not routinely treat gastroesophageal reflux disease (GORD) in infants with acid suppression therapy.	Medication	<12months
Royal Australasian College of Physicians Paediatrics & Child Health Division^	Do not [routinely undertake chest X-rays for the diagnosis of bronchiolitis in children or] routinely prescribe salbutamol or systemic corticosteroids to treat bronchiolitis in children	Medication	<3yrs
Royal Australasian College of Physicians Paediatrics & Child Health Division	Do not routinely prescribe oral antibiotics to children with fever without an identified bacterial infection	Medication	<18yrs Oral medication
College of Intensive Care Medicine of Australia and New Zealand	Avoid prescribing antibiotics for upper respiratory tract infection.	Medication	nil
The Thoracic Society of Australia and New Zealand	Do not use oral beta2 agonists as bronchodilators in asthma, wheeze or bronchiolitis.	Medication	Oral medication
The Society of Hospital Pharmacists of Australia Australian and New Zealand Society for Geriatric Medicine	Don't initiate and continue antipsychotic medicines for behavioural and psychological symptoms of dementia for more than 3 months. Do not use antipsychotics as the first choice to treat behavioural and psychological symptoms of dementia.	Medication	Continuing medication Two recommendations
Australian and New Zealand Society for Geriatric Medicine	Do not prescribe benzodiazepines or other sedative-hypnotics to older adults as first choice for insomnia, agitation or delirium.	Medication	≥65yrs
Australian and New Zealand Association of Neurologists	Don't use opioids for the treatment of migraine, except in rare circumstances.	Medication	nil
Faculty of Pain Medicine, ANZCA	Do not prescribe benzodiazepines for low back pain.	Medication	nil
The Australasian College of Dermatologists	Do not routinely prescribe antibiotics for inflamed epidermoid cysts (formerly called sebaceous cysts) of the skin.	Medication	nil
Royal Australasian College of Surgeons	Don't prescribe oral antibiotics for uncomplicated acute otitis externa.	Medication	New problem Oral medication
Royal Australian College of General Practitioners	Don't treat otitis media (middle ear infection) with antibiotics, in non-Indigenous children aged 2-12 years, where reassessment is a reasonable option.	Medication	New problem Non-Indigenous 2-12yrs

			Major city and Inner regional practices
Australasian Society of Clinical Immunology and Allergy	Don't use antihistamines to treat anaphylaxis – prompt administration of adrenaline (epinephrine) is the only treatment for anaphylaxis.	Medication	nil
Australasian Society for Infectious Diseases^	Do not [take a swab or] use antibiotics for the management of a leg ulcer without clinical infection.	Medication	nil
Faculty of Pain Medicine, ANZCA	Avoid prescribing pregabalin and gabapentin for pain which does not fulfil the criteria for neuropathic pain	Medication	nil
Australasian Society for Infectious Diseases	Do not use antimicrobials to treat bacteriuria in older adults where specific urinary tract symptoms are not present.	Medication	>65yrs
The Endocrine Society of Australia	Don't prescribe testosterone therapy unless there is evidence of proven testosterone deficiency.	Medication	nil
The Royal College of Pathologists of Australasia	Do not perform population based screening for Vitamin D deficiency.	Pathology	nil
Australasian Society for Infectious Diseases	Do not investigate or treat for faecal pathogens in the absence of diarrhoea or other gastro-intestinal symptoms.	Pathology	nil
Society of Obstetric Medicine of Australia and New Zealand	Do not measure erythrocyte sedimentation rate (ESR) in pregnancy	Pathology	nil
Society of Obstetric Medicine of Australia and New Zealand	Do not do repeat testing for proteinuria in established pre-eclampsia	Pathology	Old problem
The Royal College of Pathologists of Australasia	Restrict the use of serum tumour marker tests to the monitoring of a cancer known to produce these markers or where there is a strong known underlying predisposition or suspicion.	Pathology	nil
Royal Australian College of General Practitioners	Don't test thyroid function as population screening for asymptomatic patients.	Pathology	nil
Australasian Society for Infectious Diseases^	Do not take a swab [or use antibiotics for the management] of a leg ulcer without clinical infection.	Pathology	nil

Australasian Society for Infectious Diseases	In a patient with fatigue, avoid performing multiple serological investigations, without a clinical indication or relevant epidemiology.	Pathology	More than three tests for fatigue problem
Australian Rheumatology Association	Do not order antinuclear antibody (ANA) testing without symptoms and/or signs suggestive of a systemic rheumatic disease.	Pathology	nil
The Royal College of Pathologists of Australasia	Do not perform surveillance urine cultures or treat bacteriuria in elderly patients in the absence of symptoms or signs of infection.	Pathology	>65yrs
Australasian Chapter of Sexual Health Medicine	Do not order herpes serology tests unless there is a clear clinical indication.	Pathology	nil
The Endocrine Society of Australia	Don't order a total or free T3 level when assessing thyroxine dose in hypothyroid patients.	Pathology	nil
The Endocrine Society of Australia	Do not measure insulin concentration in the fasting state or during an oral glucose tolerance test to assess insulin sensitivity.	Pathology	nil
Gastroenterological Society of Australia	Do not undertake faecal occult blood testing in patients who report rectal bleeding, or require investigation for iron deficiency or gastrointestinal symptoms	Pathology	nil
Australian Rheumatology Association	Do not use ultrasound guidance to perform injections into the subacromial space as it provides no additional benefit in comparison to landmark-guided injection.	Referral (to radiologist)	nil

* Derived from items in the Choosing Wisely Australia Recommendations 'Tests, treatments, and procedures for healthcare providers and consumers to question' (https://www.choosingwisely.org.au/recommendations)

^ These recommendations contain two distinct clinical activities relating to the same recommendation

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	*1*
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	*N/A*
	2b	All items from the World Health Organization Trial Registration Data Set	*N/A*
Protocol version	3	Date and version identifier	*1*
Funding	4	Sources and types of financial, material, and other support	*26*
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	*1, 26*
	5b	Name and contact information for the trial sponsor	*N/A*
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	*26*
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	*N/A*
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	*5-7*
	6b	Explanation for choice of comparators	*N/A*
Objectives	7	Specific objectives or hypotheses	*8*

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	*8-9*
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	*8-9*
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	*8-9*
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	*N/A*
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	*N/A*
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	*N/A*
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	*N/A*
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	*9-16*
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	*9*
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	*18-19*

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	*8-9*
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	*N/A*
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	*N/A*
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	*N/A*
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	*N/A*
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	*N/A*
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	*9-16*
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	*N/A*

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	*16*
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	*17-18*
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	*17-18*
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	*N/A*
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	*N/A*
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	*N/A*
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	*N/A*
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	*N/A*
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	*3, 19*
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	*3, 19*

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	*19*
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	*19-20*
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	*20*
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	*20*
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	*20*
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	*N/A*
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	*20*
	31b	Authorship eligibility guidelines and any intended use of professional writers	*26*
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	*N/A*
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	*N/A*
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	*N/A*

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

'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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Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	General practice / Family practice
Keywords:	PRIMARY CARE, EDUCATION & TRAINING (see Medical Education &

	Training), MEDICAL EDUCATION & TRAINING

‘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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Key words

General Practice; Family Practice; Education, Medical, Graduate; Practice Patterns, Physicians'; Inappropriate Prescribing; Medical Overuse

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 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 indexs 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 GP registrars with detailed, contemporaneously-recorded, linked in-consultation data.
- The QUIT-CA index is derived from an authoritative source - the Choosing Wisely Australia/ NPS MedicineWise recommendations of peak Australian medical colleges and organizations.
- 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 is 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 ReCEnT (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 in 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 prioritize, 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 utilizes 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 three 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 characterized 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 to 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 2010-2015, it was conducted in the teaching general practices of five of Australia's then 17 RTPs in five Australian states – New South Wales (NSW), Victoria, Tasmania, South Australia, and Queensland. From 2016 (following a major reorganization 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 organizations 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 mid-point 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 (for example, medicines prescribed, or pathology tests ordered) are linked to the problems(s)/diagnosis(es) to which they relate (for example, 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 programs.[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 (for example, the ordering of a test or the prescribing of a medication) was consistent with a recommendation of NPS Medicine Wise's Choosing Wisely Australia's program. 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 8th October 2020. The initial scoping was completed over six 90-minute 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 (e.g. low back pain) and the associated target activity (e.g. 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 MvD). PM or MvD 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 Supplementary 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.

The QUestionable In Training Clinical Activities index

From this assignment of 'low-value activity' status, an index of individual registrars' 'questionable activities' – the QUestionable In Training Clinical Activities (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:

1) Related to the General Practice Registrar-Competency Assessment Grid (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 External Clinical Teaching Visits (ECTVs) that registrars receive during training.[24] During ECTVs, experienced GPs observe a session (approximately three 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-centeredness '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 pro-active approach to patient presentations; (6) Attention to minimum standards of professional communication; and (7) High level but structured clinical tasks.

2) Related to performance on summative RACGP Fellowship examinations

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

a) the Applied Knowledge Test ('RACGP -AKT' - a multiple choice question-based examination)

b) the Key Features Problems examination ('RACGP-KFP' – a written short answer-based examination.

c) the Objective Structured Clinical Examination ('RACGP-OSCE' - a clinical 'stations' with patient presentations/role-playing examination[31]

d) result (pass/fail) on the Remote Clinical Exam ('RACGP-RCE' – a remotely delivered clinical simulated patient scenarios examination assessed via videoconference)

e) 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 standard deviation.

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.

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
Number of problems seen	Mean across term	Mean across term	Mean across training

Follow-up organized 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

Data management

All ReCEnT data collected is de-identified. 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 upon commencement of training and is stored/utilised 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 de-identified ReCEnT, GPR-CAG and RACGP data is 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 authorization 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 standard deviation 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 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 pre-determined 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:

a) For the analysis of the QUIT-CA index and registrar, patient, practice, and consultation associations, we anticipate 400,000 consultations of 2,900 registrars.

b) For the analysis of Term 1 GPR-CAG factor scores and association with the QUIT-CA index, we anticipate 1480 registrars.

c) 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 8th June 2021.

Consent

The ReCEnT project has both educational and research functions.[26,35] 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 is 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.

Declaration of Interests

PM, AT, AF, AR, LK and AD are employees of GP Synergy. NS is an employee of Eastern Victoria General Practice Training. KFG is an employee of General Practice Training Tasmania

Access to data

Human Research Ethics Committee (HREC) advice is that, as participants in earlier rounds of ReCEnT data collection did not provide permission for sharing of data, data will not be available.

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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These funding sources had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Roles and responsibilities: authors' contributions

PM conceived the study. PM, AT, AF, AD, LK, AR and MVD initiated the study design. PM, AT, MvD, LK, NS, KF, AD, EH, and AF are grant holders. EH and JB provided statistical expertise in clinical trial design. JB and EH are conducting the primary statistical analysis. PM and AR wrote the draft of the protocol (with statistical sections by EH and JB). All authors contributed to refinement of the study protocol and approved the final manuscript.

Competing interests statement

The authors have no competing interests

Figures

Figure 1: Process of selecting Choosing Wisely recommendations to include in the QUIT-CA index

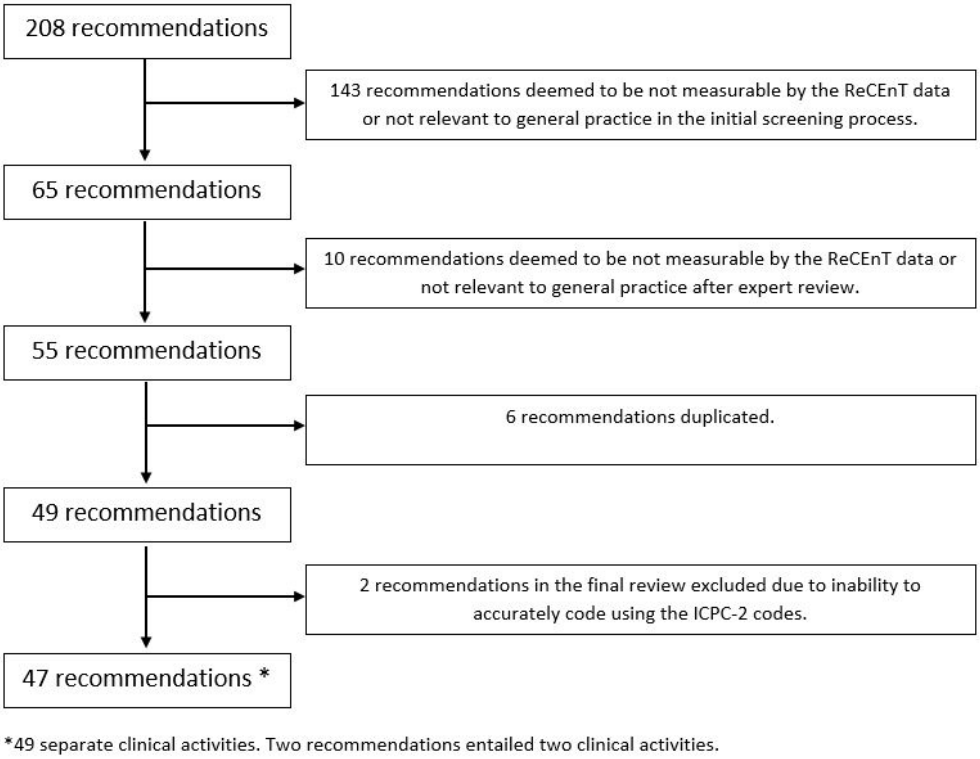

Figure 1: Process of selecting Choosing Wisely recommendations to include in the QUIT-CA index.

205x159mm (96 x 96 DPI)

Supplementary Table : Low-value, questionable clinical activities included in the QUestionable In Training Clinical Activities (QUIT-CA) index*

	Recommendation	Clinical outcome	Inclusions/duplications
Royal Australian College of General Practitioners	Don't order chest x-rays in patients with uncomplicated acute bronchitis.	Imaging	nil
Royal Australasian College of Physicians Paediatrics & Child Health Division Council	Do not routinely order abdominal X-rays for the diagnosis of non-specific abdominal pain in children	Imaging	<18yrs
Royal Australasian College of Physicians Paediatrics & Child Health Division^	Do not routinely undertake chest X-rays for the diagnosis of bronchiolitis in children [or routinely prescribe salbutamol or systemic corticosteroids to treat bronchiolitis in children]	Imaging	<3yrs
The Endocrine Society of Australia	Don't routinely order a thyroid ultrasound in patients with abnormal thyroid function tests if there is no palpable abnormality of the thyroid gland.	Imaging	nil
Royal Australasian College of Physicians Paediatrics & Child Health Division Council	Do not routinely order chest X-rays for the diagnosis of asthma in children	Imaging	<18yrs
Australasian Faculty of Occupational and Environmental Medicine	Do not request low back X-rays or other forms of low back imaging as part of a routine preplacement medical examination.	Imaging	nil
The Australian Physiotherapy Association The Royal Australian and New Zealand College of Radiologists Australasian Faculty of Occupational and Environmental Medicine Australasian Faculty of Rehabilitation Medicine	Don't request imaging for patients with non-specific low back pain and no indicators of a serious cause for low back pain. Don't perform imaging for patients with non-specific acute low back pain and no indicators of a serious cause for low back pain. Do not order X-rays or other imaging for acute non-specific low back pain, unless there are red flags or other clinical reasons to suspect serious spinal pathology. Do not use imaging for diagnosing non-specific acute low back pain in the absence of red flags.	Imaging	< 50yrs Some problems restricted to continuing problems Five recommendations

Australian Rheumatology Association	Do not undertake imaging for low back pain in patients without indications of a serious underlying condition.		
The Australia and New Zealand Child Neurology Society	Do not routinely perform electroencephalographs (EEGs) for children presenting with febrile seizures.	Imaging	<18yrs
The Australia and New Zealand Child Neurology Society	Do not routinely perform computed tomography (CT) scanning of children presenting with new onset seizures.	Imaging	<18yrs New problem
The Australia and New Zealand Child Neurology Society	Do not routinely perform electroencephalographs (EEGs) for children presenting with syncope (fainting).	Imaging	<18yrs
Australasian Faculty of Occupational and Environmental Medicine	Do not repeat chest X-rays when screening asbestos-exposed workers unless clinically indicated.	Imaging	Old problem
Royal Australasian College of Surgeons	Don't order computed tomography (CT) scan of the head/brain for sudden hearing loss.	Imaging	New problem
Royal Australasian College of Surgeons	Do not use ultrasound for the further investigation of clinically apparent groin hernias. Ultrasound should not be used as a justification for repair of hernias that are not clinically apparent.	Imaging	nil
Royal Australasian College of Surgeons	Don't routinely obtain radiographic imaging for patients who meet diagnostic criteria for uncomplicated acute rhinosinusitis.	Imaging	New problem
Australian and New Zealand Association of Neurologists Internal Medicine Society of Australia and New Zealand	Don't perform imaging of the carotid arteries for simple faints. Don't request Holter monitoring, carotid duplex scans, echocardiography, electroencephalograms (EEGs) or telemetry in patients with first presentation of uncomplicated syncope and no high risk features.	Imaging	Two recommendations
Australian and New Zealand Association of Neurologists	Don't perform imaging of the brain for non-acute primary headache disorders.	Imaging	Old problem
The Thoracic Society of Australia and New Zealand	Do not prescribe antibiotics for exacerbation of asthma.	Medication	nil
Royal Australasian College of Physicians Paediatrics & Child Health Division	Do not routinely treat gastroesophageal reflux disease (GORD) in infants with acid suppression therapy.	Medication	<12months

Royal Australasian College of Physicians Paediatrics & Child Health Division^	Do not [routinely undertake chest X-rays for the diagnosis of bronchiolitis in children or] routinely prescribe salbutamol or systemic corticosteroids to treat bronchiolitis in children	Medication	<3yrs
Royal Australasian College of Physicians Paediatrics & Child Health Division	Do not routinely prescribe oral antibiotics to children with fever without an identified bacterial infection	Medication	<18yrs Oral medication
College of Intensive Care Medicine of Australia and New Zealand	Avoid prescribing antibiotics for upper respiratory tract infection.	Medication	nil
The Thoracic Society of Australia and New Zealand	Do not use oral beta2 agonists as bronchodilators in asthma, wheeze or bronchiolitis.	Medication	Oral medication
The Society of Hospital Pharmacists of Australia Australian and New Zealand Society for Geriatric Medicine	Don't initiate and continue antipsychotic medicines for behavioural and psychological symptoms of dementia for more than 3 months. Do not use antipsychotics as the first choice to treat behavioural and psychological symptoms of dementia.	Medication	Continuing medication Two recommendations
Australian and New Zealand Society for Geriatric Medicine	Do not prescribe benzodiazepines or other sedative-hypnotics to older adults as first choice for insomnia, agitation or delirium.	Medication	≥65yrs
Australian and New Zealand Association of Neurologists	Don't use opioids for the treatment of migraine, except in rare circumstances.	Medication	nil
Faculty of Pain Medicine, ANZCA	Do not prescribe benzodiazepines for low back pain.	Medication	nil
The Australasian College of Dermatologists	Do not routinely prescribe antibiotics for inflamed epidermoid cysts (formerly called sebaceous cysts) of the skin.	Medication	nil
Royal Australasian College of Surgeons	Don't prescribe oral antibiotics for uncomplicated acute otitis externa.	Medication	New problem Oral medication
Royal Australian College of General Practitioners	Don't treat otitis media (middle ear infection) with antibiotics, in non-Indigenous children aged 2-12 years, where reassessment is a reasonable option.	Medication	New problem Non-Indigenous 2-12yrs Major city and Inner regional practices
Australasian Society of Clinical Immunology and Allergy	Don't use antihistamines to treat anaphylaxis – prompt administration of adrenaline (epinephrine) is the only treatment for anaphylaxis.	Medication	nil

Australasian Society for Infectious Diseases^	Do not [take a swab or] use antibiotics for the management of a leg ulcer without clinical infection.	Medication	nil
Faculty of Pain Medicine, ANZCA	Avoid prescribing pregabalin and gabapentin for pain which does not fulfil the criteria for neuropathic pain	Medication	nil
Australasian Society for Infectious Diseases	Do not use antimicrobials to treat bacteriuria in older adults where specific urinary tract symptoms are not present.	Medication	>65yrs
The Endocrine Society of Australia	Don't prescribe testosterone therapy unless there is evidence of proven testosterone deficiency.	Medication	nil
The Royal College of Pathologists of Australasia	Do not perform population based screening for Vitamin D deficiency.	Pathology	nil
Australasian Society for Infectious Diseases	Do not investigate or treat for faecal pathogens in the absence of diarrhoea or other gastro-intestinal symptoms.	Pathology	nil
Society of Obstetric Medicine of Australia and New Zealand	Do not measure erythrocyte sedimentation rate (ESR) in pregnancy	Pathology	nil
Society of Obstetric Medicine of Australia and New Zealand	Do not do repeat testing for proteinuria in established pre-eclampsia	Pathology	Old problem
The Royal College of Pathologists of Australasia	Restrict the use of serum tumour marker tests to the monitoring of a cancer known to produce these markers or where there is a strong known underlying predisposition or suspicion.	Pathology	nil
Royal Australian College of General Practitioners	Don't test thyroid function as population screening for asymptomatic patients.	Pathology	nil
Australasian Society for Infectious Diseases^	Do not take a swab [or use antibiotics for the management] of a leg ulcer without clinical infection.	Pathology	nil
Australasian Society for Infectious Diseases	In a patient with fatigue, avoid performing multiple serological investigations, without a clinical indication or relevant epidemiology.	Pathology	More than three tests for fatigue problem
Australian Rheumatology Association	Do not order antinuclear antibody (ANA) testing without symptoms and/or signs suggestive of a systemic rheumatic disease.	Pathology	nil
The Royal College of Pathologists of Australasia	Do not perform surveillance urine cultures or treat bacteriuria in elderly patients in the absence of symptoms or signs of infection.	Pathology	>65yrs

Australasian Chapter of Sexual Health Medicine	Do not order herpes serology tests unless there is a clear clinical indication.	Pathology	nil
The Endocrine Society of Australia	Don't order a total or free T3 level when assessing thyroxine dose in hypothyroid patients.	Pathology	nil
The Endocrine Society of Australia	Do not measure insulin concentration in the fasting state or during an oral glucose tolerance test to assess insulin sensitivity.	Pathology	nil
Gastroenterological Society of Australia	Do not undertake faecal occult blood testing in patients who report rectal bleeding, or require investigation for iron deficiency or gastrointestinal symptoms	Pathology	nil
Australian Rheumatology Association	Do not use ultrasound guidance to perform injections into the subacromial space as it provides no additional benefit in comparison to landmark-guided injection.	Referral (to radiologist)	nil

* Derived from items in the Choosing Wisely Australia Recommendations 'Tests, treatments, and procedures for healthcare providers and consumers to question' (https://www.choosingwisely.org.au/recommendations)

^ These recommendations contain two distinct clinical activities relating to the same recommendation

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	*1*
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	*N/A*
	2b	All items from the World Health Organization Trial Registration Data Set	*N/A*
Protocol version	3	Date and version identifier	*1*
Funding	4	Sources and types of financial, material, and other support	*26*
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	*1, 26*
	5b	Name and contact information for the trial sponsor	*N/A*
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	*26*
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	*N/A*
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	*5-7*
	6b	Explanation for choice of comparators	*N/A*
Objectives	7	Specific objectives or hypotheses	*8*

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	*8-9*
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	*8-9*
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	*8-9*
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	*N/A*
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	*N/A*
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	*N/A*
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	*N/A*
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	*9-16*
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	*9*
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	*18-19*

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	*8-9*
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	*N/A*
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	*N/A*
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	*N/A*
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	*N/A*
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	*N/A*
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	*9-16*
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	*N/A*

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	*16*
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	*17-18*
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	*17-18*
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	*N/A*
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	*N/A*
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	*N/A*
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	*N/A*
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	*N/A*
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	*3, 19*
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	*3, 19*

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	*19*
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	*19-20*
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	*20*
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	*20*
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	*20*
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	*N/A*
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	*20*
	31b	Authorship eligibility guidelines and any intended use of professional writers	*26*
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	*N/A*
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	*N/A*
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	*N/A*

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.