Evaluating an audit and feedback intervention for reducing overuse of pathology test requesting by Australian general practitioners: protocol for a factorial cluster randomised controlled trial

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ABSTRACT

Introduction Consistent evidence shows pathology services are overused worldwide and that about one-third of testing is unnecessary. Audit and feedback (AF) is effective for improving care but few trials evaluating AF to reduce pathology test requesting in primary care have been conducted. The aim of this trial is to estimate the effectiveness of AF for reducing requests for commonly overused pathology test combinations by high-requesting Australian general practitioners (GPs) compared with no intervention control. A secondary aim is to evaluate which forms of AF are most effective.

Methods and analysis This is a factorial cluster randomised trial conducted in Australian general practice. It uses routinely collected Medicare Benefits Schedule data to identify the study population, apply eligibility criteria, generate the interventions and analyse outcomes. On 12 May 2022, all eligible GPs were simultaneously randomised to either no intervention control or to one of eight intervention groups. GPs allocated to an intervention group received individualised AF on their rate of requesting of pathology test combinations compared with their GP peers. Three separate elements of the AF intervention will be evaluated when outcome data becomes available on 11 August 2023: (1) invitation to participate in continuing professional development-accredited education on appropriate pathology requesting, (2) provision of cost information on pathology test combinations and (3) format of feedback. The primary outcome is the overall rate of requesting of any of the displayed combinations of pathology tests of GPs over 6 months following intervention delivery. With 3371 clusters, assuming no interaction and similar effects for each intervention, we anticipate over 95% power to detect a difference of 4.4 requests in the mean rate of pathology test combination requests between the control and intervention groups.

Ethics and dissemination Ethics approval was received from the Bond University Human Research Ethics Committee (#JH03507; approved 30 November 2021). The results of this study will be published in a peer-reviewed journal and presented at conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first nationwide factorial cluster randomised controlled trial testing variations in the design and delivery of audit and feedback to reduce pathology test combination requesting in primary care.
⇒ It includes general practitioners who request commonly overused combinations of pathology tests more than 90% of their peers.
⇒ The interventions were designed and refined with input from practising general practitioners prior to evaluation in the trial to optimise their acceptability and potential usefulness.
⇒ The trial uses routinely collected administrative data to identify the study population, apply eligibility criteria, generate individualised feedback and analyse trial outcomes.
⇒ A limitation is that volume not appropriateness of pathology test requesting is evaluated.

Reporting will adhere to Consolidated Standards of Reporting Trials.

Trial registration number ACTRN12622000566730.

INTRODUCTION

Consistent evidence suggests there is overuse of pathology services worldwide and that approximately 30% of testing is unnecessary. 1 In Australia, the volume and cost of pathology services has increased dramatically over the last decade, with over 150 million pathology services costing Medicare US$3.6 billion in 2020–2021 alone, with the majority of requests made in general practice. 2 On top of the increased costs and time spent by practitioners, patients and laboratory staff, unnecessary pathology testing increases the likelihood of false positive results which can
lead to unnecessary additional tests, incorrect diagnoses and unnecessary treatment with associated risk of patient harm.

Audit and feedback, which involves the provision of clinical performance data to healthcare providers with the aim of improving quality of care, represents a potentially low cost, scalable and sustainable intervention for reducing overuse of pathology services. To our knowledge, only three randomised trials have evaluated audit and feedback interventions for reducing overuse of pathology test requesting by general practitioners (GPs) with mixed effects.  

Baker et al found providing practice level (and, where available, individualised) audit and feedback on requesting of five pathology tests (thyroid function tests (TFTs), rheumatoid factor, urine culture, serum lipids and viscosity) at 3-month intervals over 12 months accompanied by guidelines to GPs in 33 practices in the UK did not significantly alter test requesting compared with control.  

However, Verstappen et al showed a multi-component intervention comprising individualised peer comparison audit and feedback on pathology requesting for various conditions (eg, cardiovascular disease/hypertension, upper and lower abdominal complaints, chronic obstructive pulmonary disease/asthma, fatigue, degenerative joint complaints) provided to GPs from 26 practices in the Netherlands at 2-month intervals over 6 months, accompanied by guidelines and three face-to-face small group meetings focused on identifying barriers to change and developing action plans, led to a 9% relative reduction in the total number of tests requested per practitioner over 6 months compared with control.  

Thomas et al showed providing practice-level audit and feedback on the requesting rates of nine pathology tests (autoantibody screen, carbohydrate antigen-125, carcinoembryonic antigen, ferritin, follicle-stimulating hormone, Helicobacter pylori serum, IgE, thyroid-stimulating hormone (TSH), vitamin B12) by GPs from 85 practices in Scotland at 3-month intervals over 12 months, accompanied by brief educational reminder messages added to pathology test result reports, led to a 22% relative reduction in request rates compared with control.  

Audit and feedback alone led to greater reductions in request rates compared with reminders alone although the model-based analyses suggested similar effects (OR for feedback=0.87, 95% CI 0.81 to 0.94, OR for reminders=0.89, 95% CI 0.83 to 0.93).  

While the latter two studies report benefit with audit and feedback, the approaches are resource intensive (ie, feedback provided on multiple occasions, accompanied by small group educational meetings/reminder messages on targeted test reports) and may not be feasible to implement at scale in many jurisdictions.  

The current study builds on our previous successful factorial cluster randomised controlled trial of audit and feedback on musculoskeletal diagnostic imaging in Australian general practice. It showed individualised audit and feedback provided to GPs known to request musculoskeletal imaging at much higher rates than their peers significantly decreased their requesting rate over 12 months compared with no intervention. It also showed 2 rounds of feedback (vs 1) and an enhanced visual display directing GPs attention to ordering rates greater than 80% of peer rates (vs standard display) led to further modest statistically significant reductions in request rates.

The primary objective of this trial is to estimate the effectiveness of individualised audit and feedback for reducing overall requests for 10 commonly overused combinations of pathology tests by high-requesting GPs in Australia compared with no intervention control. This includes requests for any combination of two or three pathology tests for iron studies, TSH, TFT, vitamin D and vitamin B12. A secondary objective is to evaluate which forms of audit and feedback are most effective in reducing requests for the pathology test combinations and to estimate their effects.

This trial is a collaboration between the Australian Government Department of Health and Aged Care, and Wiser Healthcare, a collaboration of researchers investigating the causes of, and solutions to, overtreatment in healthcare.  

**METHODS**  

**Trial design**  

This is a 9-arm 2×2×2 factorial cluster randomised controlled trial testing variations in the design and delivery of audit and feedback for reducing overall requests for 10 commonly overused combinations of pathology tests in Australian general practice. On 12 May 2022, clusters of general practices based on geographical location with at least one GP who was in the top 10% of requesters for 10 targeted combinations of pathology tests and for at least 2 of the individual pathology test combinations within the 24-month period from 1 July 2019 to 30 June 2021, were simultaneously randomised either to no intervention control or to 1 of 8 individualised written audit and feedback intervention groups.

Within those allocated to audit and feedback, GPs were first randomly allocated to receive an invitation to continuing professional development (CPD)-accredited education (yes vs no) (factor 1), then provision of cost information about pathology test combinations (yes vs no) (factor 2) and then feedback format (pamphlet vs letter) (factor 3).

The protocol received ethics approval from the Bond University Human Research Ethics Committee and the trial was prospectively registered on the Australian New Zealand Clinical Trials Registry (ACTRN12622000566730).

**Setting**  

General practices and included GPs, located in any state or territory of Australia.

**Eligibility and recruitment**  

**Inclusion criteria**  

We included GPs practising in Australia who were (1) in the top 10% of GP referrers for the 10 targeted combinations...
of pathology tests overall and (2) in the top 10% of GP referrers for at least two of the individual pathology test combinations within the 24-month period from 1 July 2019 to 30 June 2021. The 10 targeted combinations of pathology tests are: (1) iron studies, TSH and vitamin D, (2) iron studies, vitamin D and vitamin B_{12}, (3) iron studies, TSH and vitamin B_{12}, (4) iron studies, TFT and vitamin B_{12}, (5) iron studies, TFT and vitamin D, (6) TSH, vitamin D and vitamin B_{12}, (7) iron studies and vitamin D, (8) iron studies and vitamin B_{12}, (9) iron studies and TFT and (10) TSH and vitamin D. These pathology test combinations were selected for inclusion in the trial in consultation with stakeholders and the Department of Health and Aged Care and reflect commonly overused combinations of pathology tests in Australian general practice. Only pathology tests which originated with a GP request, were rendered by a pathologist and were claimed from the Australian Medicare Benefits Schedule (MBS) (ie, cost covered by the public health system) were included.

**Exclusion criteria**

We excluded GPs who: (1) did not request the targeted pathology test combinations within the nominated 24-month period from 1 July 2019 to 30 June 2021; (2) had less than 1000 category 1 consultations either between 1 July 2019 and 30 June 2020 or between 1 July 2020 and 30 June 2021. A category 1 consultation refers to a professional attendance by a GP for which benefits are paid under the Australian MBS; (3) participated in qualitative interviews with members of the research team to user test the interventions; (4) were involved in an Australian Government Department of Health and Aged Care compliance activity within the past 12 months and (5) had their primary practice address in a remote or very remote geographical area, as determined by the Modified Monash Model (MMM) classification 6–7, or had a hospital as their primary practice address.

**Randomisation and allocation concealment**

Clusters of general practices based on geographical location, with at least one eligible GP, were simultaneously randomised either to no intervention control or to one of eight intervention groups at baseline on 12 May 2022. The randomisation sequence was generated using a computer-generated randomisation algorithm in the statistical programme R Studio. Randomisation of clusters was stratified by geographic region (urban, regional/ rural-remote: MMM 1, MMM 2–5) to ensure geographical equivalence at baseline, to user test the interventions; (4) were involved in an Australian Government Department of Health and Aged Care compliance activity within the past 12 months and (5) had their primary practice address in a remote or very remote geographical area, as determined by the Modified Monash Model (MMM) classification 6–7, or had a hospital as their primary practice address.

**Interventions**

GP practices by geographical region across control and intervention groups.

**Blinding**

Trial participants (ie, GPs) were not blinded to group allocation but the risk of performance bias is considered to be minimal as GPs were not aware of the variations of audit and feedback being tested nor the outcome measures and analytical approach. The statistical analysis plan has been developed by the trial statistician blinded to group allocation. Analyses will be independently conducted by two statisticians using randomly shuffled group allocations. Real allocations will only be revealed once analyses are completed and agreement between the two statisticians is reached.
appropriate pathology requesting for selected tests (participants earned two CPD points) and to complete a self-directed review of their pathology requesting (participants earned 40 CPD points). The webinar was conducted 1 month following feedback delivery. A previous trial has shown that providing small group face-to-face education to primary care physicians with audit and feedback improves pathology requesting. To our knowledge, no studies have investigated the combination of audit and feedback with a scalable online educational webinar aimed at improving knowledge about appropriate pathology requesting compared with audit and feedback alone.

Factor 2: provision of cost information on pathology test combinations (yes vs no)
Participants randomised to receive costing information received data on the cost per displayed pathology test combination as well as the cost of an individual iron studies test and the total cost of all iron studies conducted in Australia over the 2-year period from 1 July 2019 to 30 June 2021. A hyperlink to a website containing the individual and cumulative costs of pathology tests was also provided. While cost information was included with requesting data, the design of the feedback emphasised use of clinical guidelines to inform appropriate pathology test requesting. Previous trials have shown that combining information about the cost of laboratory tests with performance feedback to physicians in hospital and outpatient medical settings can reduce request rates, although these studies included small numbers of physicians and clusters.

Factor 3: feedback format (pamphlet vs letter)
Participants randomised to receive the pamphlet format received the same content as per the standard feedback letter, except in a booklet format with coloured subheadings and text boxes. A more visually appealing feedback format was hypothesised to increase recipients’ interest and engagement with the feedback compared with the standard feedback format.

The interventions were designed and refined in user testing with practising GPs prior to use in the trial.

Data collection
The trial uses routinely collected Australian MBS administrative data to identify the study population, apply eligibility criteria, generate individualised feedback for the interventions and analyse trial outcomes. The MBS administrative data records the details of all claims made to Medicare. For example, it includes all pathology test requests that are rendered by a pathologist and claimed from Medicare, including details of the patient, requesting practitioner, pathologist, date of request, date of service, and the items requested and rendered. The Australian Government Department of Health and Aged Care will extract the relevant pathology test requesting data for GPs in the trial.

Trial outcomes
The primary outcome is the overall rate of requesting of any of the displayed combinations of pathology tests (listed below) by each GP per 1000 category 1 consultations over the 6 months following intervention delivery, rendered by a pathologist and assessed using MBS data. Targeted test pathology combinations are: (1) iron studies, TSH and vitamin D, (2) iron studies, vitamin D and vitamin B₁₂, (3) iron studies, TSH and vitamin B₁₂, (4) iron studies, TFT and vitamin B₁₂, (5) iron studies, TFT and vitamin D, (6) TSH, vitamin D and vitamin B₁₂, (7) iron studies and vitamin D, (8) iron studies and vitamin B₁₂, (9) iron studies and TFT and (10) TSH and vitamin D. Secondary outcomes include (1) the overall requesting rate of any of the displayed pathology test combinations at other time points, (2) the requesting rates of displayed individual pathology test combinations, (3) the requesting rates of individual pathology tests (ie, iron studies, TSH, vitamin D, vitamin B₁₂, TFT, ferritin), (4) the overall requesting rate of any of the 10 aforementioned targeted pathology test combinations, (5) the requesting rate of any of the pathology test combinations that were not displayed in recipients’ feedback and (6) the estimated number of requests for the targeted pathology test combinations saved as a result of any feedback intervention compared with control over 6 and 12 months (table 1). Rate of requests will be expressed per 1000 category 1 consultations rendered by a pathologist and assessed using MBS as the data source.

The following baseline data will also be collected: age, sex, geographical location of primary practice address (metropolitan vs other), state or territory of Australia, years practising as GP, total category 1 patient consultations provided during the baseline period (12 months prior to intervention delivery), total number of requests overall for the displayed pathology test combinations, and rates of pathology test combination requests for primary and secondary outcomes at baseline.

Analysis
The main analysis will consist of comparing the overall rate of pathology test combination requests between the control and all eight intervention groups combined. Data will be aggregated at the GP level and analysed using generalised linear regression. The dependent variable for the regression will, therefore, be the individual pathology request rate of each GP.

The analysis will be performed using multilevel mixed effect generalised linear regression model adjusted for the baseline rate of pathology requests of each GP as well as remoteness and years of practice. To remove skewness and potential heteroscedasticity, we will apply a natural log-transformation to the rate (dependent variable) as well as to the baseline rate included as a covariate. Resulting estimates and CIs will be back transformed to the original scale. Clustering of GPs by area-specific clusters will be accounted for by including a random intercept by statistical area level 1 classification. The effect of the
intervention will be estimated as the mean difference in the rate of pathology test combination requests between the intervention and control group together with its 95% CI.

Using the same regression model, we will also estimate the differential effect of separate elements of the intervention: (1) invitation for CPD-accredited education (yes vs no); (2) provision of cost information on pathology test combinations (yes vs no) and (3) format of feedback (pamphlet vs letter). Bonferroni correction will be used to account for multiplicity. We will also test for an interaction between the three elements of the intervention. A similar approach will be used to analyse the secondary outcomes.

Additional models with additional baseline covariates will be considered together with a limited number of subgroup analyses to identify potential differences in intervention effects for factors that have been prespecified in the statistical analysis plan. We expect the MBS data to capture all services rendered during the study period and will therefore assume no missing data. Analyses will be conducted using R or Stata software.

**Power**

The primary endpoint is the overall rate of requests of any of the displayed pathology test combinations for each GP per 1000 category 1 consultations measured over 6 months from intervention delivery. A total of 5964 GPs from 3371 area-specific clusters were identified as eligible for inclusion in the study. This sample size provides over 95% power to detect a 10% rate reduction (ie, a difference of 4.4 requests per 1000 category 1 consultations) in the mean rate of targeted pathology test combination requests between intervention and control, assuming 8:1 randomisation ratio between intervention and control groups, mean (SD) baseline pathology request rate of

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**Table 1** Outcome measures

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Source*¶†‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall rate of requesting of any of the displayed combinations of pathology tests by each GP per 1000 category 1 consultations over the 6 months following intervention delivery†‡‡</td>
<td>MBS</td>
</tr>
<tr>
<td>Overall rate of requesting of any of the displayed pathology test combinations by each GP per 1000 category 1 consultations over &gt;6 to 12 months and 0–12 months after intervention delivery†‡‡</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of each of the individual displayed combinations of pathology tests by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†‡‡</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of iron studies by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of TSH by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of vitamin D by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of vitamin B₁₂ by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of thyroid function tests (TFTs) by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of ferritin by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of any of the 10 targeted pathology test combinations by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†‡‡</td>
<td>MBS</td>
</tr>
<tr>
<td>Rate of requesting of any of the pathology test combinations that are not displayed in recipients individualised feedback by each GP per 1000 category 1 consultations over 0–6 months, &gt;6 to 12 months and 0–12 months after intervention delivery†‡</td>
<td>MBS</td>
</tr>
<tr>
<td>Estimated number of requests for the targeted pathology test combinations saved as a result of any audit and feedback intervention compared with control over 6 and 12 months†‡</td>
<td>MBS</td>
</tr>
</tbody>
</table>

*Primary outcome.
†Pathology test requests that led to a service being rendered by a pathologist.
‡Targeted test pathology combinations are: (1) iron studies, thyroid-stimulating hormone (TSH) and vitamin D, (2) iron studies, vitamin D and vitamin B₁₂, (3) iron studies, thyroid function tests (TFTs) and vitamin B₁₂, (4) iron studies, TFT and vitamin B₁₂, (5) iron studies, TFT and vitamin D, (6) TSH, vitamin D and vitamin B₁₂, (7) iron studies and vitamin D, (8) iron studies and vitamin B₁₂, (9) iron studies and TFT, (10) TSH and vitamin D.
§Ferritin is not one of the targeted pathology services but is a possible substitute for iron studies so it was included as a secondary outcome to check for switching.
¶Medicare Benefits Schedule (MBS) data.
GP, general practitioner.
44.4 (17.4), variable cluster size (mean cluster size is 1.7, range 1 to 11), intracluster correlation of 0.2 and a two-sided type-I error rate of 5%.

This sample size also provides over 85% power to detect a 5% rate reduction (ie, a difference of 2.2 requests per 1000 consultations) in the mean rate of pathology test combination requests between (1) GPs invited to CPD-accredited education versus not, (2) GPs receiving pathology test cost information versus not and (3) GPs receiving pamphlet format vs those receiving letter format, assuming a two-sided type-I error rate of 1.67% to control for multiplicity.

Patient and public involvement
Wiser Healthcare has a consumer advisory panel which includes members from the peak national health consumer organisation in Australia as well as state-based health consumer organisations. This advisory panel has operated for over 6 years providing high-level advice on Wiser Healthcare research projects. Patients and/or the public were not directly involved in the design of the interventions or the trial design, however, the Wiser Healthcare Consumer Panel will advise on, and assist with, dissemination of the study findings through their networks.

Trial status
The trial began on 12 May 2022 with 5964 GPs from 3371 clusters of general practices randomly allocated on a single occasion to 1 of 8 intervention arms and one control arm. The trial is ongoing. The relevant pathology test requesting outcome data will be available for extraction from the Australian MBS administrative database for statistical analysis on 11 August 2023.

ETHICS AND DISSEMINATION
Ethics approval for this trial was obtained from the Bond University Human Research Ethics Committee (#JH03507; approved 30 November 2021). The investigators will ensure the trial is conducted in compliance with this protocol and the Australian National Statement on Ethical Conduct in Human Research. Any modification to the protocol will be approved by the Bond University Human Research Ethics Committee prior to implementation. A waiver for participant consent was approved by the Bond University Human Research Ethics Committee. This was on the basis that involvement in the research carries no more than low risk to participants, the benefits from the research justify any risk of harm associated with not seeking consent and it was impractical to obtain consent, and there are robust measures in place to protect participants’ privacy and maintain the confidentiality of data.

The investigators will be responsible for ensuring the results of the trial are published in a peer-reviewed journal and presented at conferences within a reasonable time frame after conclusion of the trial. The results from the trial will be published regardless of the outcome. Reporting of this trial will adhere to the relevant, and most up to date, Consolidated Standards of Reporting Trials statements at the time of submission. This protocol (V2, 14 September 2022) adheres to the Standard Protocol Items for Randomised Trials (SPIRIT) statement (online supplemental additional files 2 and 3).

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Acknowledgements The Australian Government Department of Health and Aged Care and Wiser Healthcare.

Contributors DAO’C led the development of the protocol and all aspects of the study design. DAO’C, DS and AE designed the interventions with input from PG, RB, KM and RT. AG led the design of the statistical analysis plan with input from DAO’C, DS and AE. DAO’C and PG prepared the ethics submission. DAO’C registered the trial. All authors read and approved the final manuscript.

Funding This study is funded by the Australian Government Department of Health and Aged Care and supported by an Australian National Health and Medical Research Council (NHMRC) Centres of Research Excellence Grant on ‘Wiser healthcare: better value care for all Australians’ (APP2006545). PG, KM and RB are supported by Australian NHMRC Investigator Fellowships.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES
12 May 2022

Dear «title» «surname»

Your rate of requesting of combinations of pathology tests is higher than 90% of General Practitioners (GPs) practicing in similar geographical regions in Australia

You may be aware that overuse of pathology testing has become a problem in Australia. Many requested tests have a low diagnostic value and do not result in a change to patient management. As part of the Department of Health’s commitment to the best practice use of pathology requesting, I am writing to you because your requests for certain pathology test combinations are higher than 90% of GPs practicing in similar geographic regions in Australia.

We have identified combinations of pathology tests, rather than specific tests. This is because it is uncommon for a patient to require all these tests at the same time; however, you have repeatedly requested these tests in combination. Your requests for the two-year period between 1 July 2019 to 30 June 2021 are displayed in the table on page 3, while the graph below illustrates your rate of pathology requests for «page1combo» in combination.

GPs play an essential role in ensuring pathology requesting meets clinical guidelines and is limited to only those clinical situations where it has a reasonable likelihood of altering management and supports the sustainability of Medicare. This letter contains information and data to provide you with the opportunity to reflect on your pathology requesting in line with best practice guidance and make changes where appropriate.
For example, the Royal College of Pathologists of Australia (RCPA) recommends that pathology tests only be requested when:

- a patient history and physical examination have been conducted, including a review of previous pathology reports;
- if appropriate, a period of “watchful waiting” has been observed; and
- the patient’s presentation indicates a specific clinical need for each individual test requested and default test combinations are avoided.¹

There are no authoritative guidelines that recommend routine requesting of the pathology combinations noted on page 3 in patients who are well.

The benefits of reducing unnecessary pathology testing include: reducing the potential for false positive results, incidental findings, and unnecessary treatment; decreased patient expectations for future testing; reduced patient anxiety resulting from unnecessary testing; and reduced wastage of healthcare resources, funding, and time.

Resources to support you

Please visit https://www.health.gov.au/supporting-quality-pathology for best practice resources that may be useful for yourself and your patients. You can also access these resources by scanning the QR code on this page. These include but are not limited to:

<table>
<thead>
<tr>
<th>Resources for Medical Practitioners</th>
<th>Resources for Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>RACGP</td>
<td>RCPA</td>
</tr>
<tr>
<td>• Responding to patient requests for tests not considered clinically appropriate</td>
<td>• Manual for Pathology Tests</td>
</tr>
<tr>
<td>• Appropriate Diagnostic Testing – Patient Information Sheet</td>
<td>• Pathology: The Facts (pamphlet)</td>
</tr>
<tr>
<td></td>
<td>• Lab Tests Online (online tool)</td>
</tr>
</tbody>
</table>

Further guidance from RACGP and RCPA on pathology testing is provided on page 4.

We welcome your feedback

If you have any questions or feedback, including suggestions on how we can better support you, please contact my team at pathology.requesting@health.gov.au, or on 1800 565 778.

Please quote your reference number located on the top right corner of page 1 of this letter when contacting my team.

Yours sincerely

Professor Paul Kelly
Chief Medical Officer
Department of Health

¹https://www.rcpa.edu.au/Library/Publications/Common-Sense-Pathology
Your Pathology Requesting Data

In the two-year period from 1 July 2019 to 30 June 2021, your requests for the MBS pathology test combinations listed in the table are higher than 90% of GPs practicing in similar geographic regions.

<table>
<thead>
<tr>
<th>Test combination</th>
<th>Number you requested</th>
<th>Request rate of your GP peers</th>
<th>Your request rate</th>
<th>Your percentile</th>
<th>Cost per combination</th>
</tr>
</thead>
<tbody>
<tr>
<td>«highcombo»</td>
<td>«higheps»</td>
<td>«highpeers»</td>
<td>«highrate»</td>
<td>«highpercent»</td>
<td>«highcost»</td>
</tr>
<tr>
<td>«midcombo»</td>
<td>«mideps»</td>
<td>«midpeers»</td>
<td>«midrate»</td>
<td>«midpercent»</td>
<td>«midcost»</td>
</tr>
<tr>
<td>«lowcombo»</td>
<td>«loweps»</td>
<td>«lowpeers»</td>
<td>«lowrate»</td>
<td>«lowpercent»</td>
<td>«lowcost»</td>
</tr>
</tbody>
</table>

Request rate is calculated per 1,000 consultations. Your request rate is based on «services» consultations you conducted from 1 July 2019 to 30 June 2021. The request rate of your GP peers has been calculated using the median rate of the selected MBS item combinations by GPs. An individual iron studies test costs $27.70. During the two-year period from July 2019 to June 2021, the total cost of all iron studies conducted in Australia amounted to $446 million. More information on the individual and cumulative costs of pathology testing can be found at [https://www.health.gov.au/supporting-quality-pathology](https://www.health.gov.au/supporting-quality-pathology)

Why am I receiving pathology requesting data?

You are receiving this information because from 1 July 2019 to 30 June 2021 you requested the selected pathology combinations more often than 90% of GPs practicing in similar geographic regions in Australia (i.e., population density and remoteness similar to your primary practice address. See our resource page at [https://www.health.gov.au/supporting-quality-pathology](https://www.health.gov.au/supporting-quality-pathology) for more information).

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An individual iron studies test costs $27.70. During the two-year period from July 2019 to June 2021, the total cost of all iron studies conducted in Australia amounted to $446 million. More information on the individual and cumulative costs of pathology testing can be found at [http://www.health.gov.au/supporting-quality-pathology](http://www.health.gov.au/supporting-quality-pathology).

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Yours sincerely

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Your reference: «reference»
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<th>Your request rate</th>
<th>Your percentile</th>
<th>Cost per combination</th>
</tr>
</thead>
<tbody>
<tr>
<td>«highcombo»</td>
<td>«higheps»</td>
<td>«highpeers»</td>
<td>«highrate»</td>
<td>«highpercent»</td>
<td>«highcost»</td>
</tr>
<tr>
<td>«midcombo»</td>
<td>«mideps»</td>
<td>«midpeers»</td>
<td>«midrate»</td>
<td>«midpercent»</td>
<td>«midcost»</td>
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<th>Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Administrative information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td>Additional file 3</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
<td>22</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>23</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1, 23</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>Additional file 3</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>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</td>
<td>Additional file 3</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>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)</td>
<td>23</td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and rationale</td>
<td>6a</td>
<td>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</td>
<td>6-8</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Explanation for choice of comparators</td>
<td>12-14</td>
</tr>
<tr>
<td>Objectives</td>
<td>7</td>
<td>Specific objectives or hypotheses</td>
<td>8</td>
</tr>
<tr>
<td>Trial design</td>
<td>8</td>
<td>Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)</td>
<td>9</td>
</tr>
<tr>
<td>Study setting</td>
<td>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</td>
<td>9-10</td>
<td></td>
</tr>
<tr>
<td>---</td>
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<td></td>
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<tr>
<td>Eligibility criteria</td>
<td>Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)</td>
<td>10-11</td>
<td></td>
</tr>
<tr>
<td>Interventions</td>
<td>Interventions for each group with sufficient detail to allow replication, including how and when they will be administered</td>
<td>12-14, Additional file 1</td>
<td></td>
</tr>
<tr>
<td>11b</td>
<td>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)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>11c</td>
<td>Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)</td>
<td>N/A</td>
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<td>Relevant concomitant care and interventions that are permitted or prohibited during the trial</td>
<td>N/A</td>
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<td>Outcomes</td>
<td>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</td>
<td>15-18, Table 1</td>
<td></td>
</tr>
<tr>
<td>Participant timeline</td>
<td>Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)</td>
<td>11, 21</td>
<td></td>
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<tr>
<td>Sample size</td>
<td>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</td>
<td>20</td>
<td></td>
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<tr>
<td>Recruitment</td>
<td>Strategies for achieving adequate participant enrolment to reach target sample size</td>
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**Methods:**

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| Allocation: | Method of generating the allocation sequence (eg, computer generated random numbers), and list of any factors for | 11 |

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<td>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</td>
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<td>Implementation</td>
<td>16c</td>
<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions</td>
</tr>
<tr>
<td>Blinding (masking)</td>
<td>17a</td>
<td>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how</td>
</tr>
<tr>
<td></td>
<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
</tr>
<tr>
<td>Methods: Data collection, management and analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data collection methods</td>
<td>18a</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>18b</td>
<td>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</td>
</tr>
<tr>
<td>Data management</td>
<td>19</td>
<td>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</td>
</tr>
<tr>
<td>Procedures</td>
<td>20a</td>
<td>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</td>
</tr>
<tr>
<td>------------</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>20b</td>
<td>Methods for any additional analyses (eg, subgroup and adjusted analyses)</td>
</tr>
<tr>
<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
</tr>
<tr>
<td>Methods: Monitoring</td>
<td>21a</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>21b</td>
<td>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</td>
</tr>
<tr>
<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
</tr>
<tr>
<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
</tr>
<tr>
<td>Ethics and Dissemination</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>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)</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
<td>Description</td>
</tr>
<tr>
<td>------------------------------</td>
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<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Consent or assent</td>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
</tr>
<tr>
<td></td>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>27</td>
<td>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</td>
</tr>
<tr>
<td>Declarations of interests</td>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
</tr>
<tr>
<td>Access to data</td>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
</tr>
<tr>
<td>Ancillary and post-trial care</td>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
</tr>
<tr>
<td>Dissemination policy</td>
<td>31a</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
</tr>
<tr>
<td></td>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
</tr>
<tr>
<td>Appendices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informed consent materials</td>
<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
</tr>
<tr>
<td>Biological specimens</td>
<td>33</td>
<td>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</td>
</tr>
</tbody>
</table>
Additional file 3 World Health Organisation Trial Registration Data Set

<table>
<thead>
<tr>
<th>Data category</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary registry and trial identifying number</td>
<td>Australian New Zealand Clinical Trials Registry, ACTRN12622000566730</td>
</tr>
<tr>
<td>Date of registration in primary registry</td>
<td>13 April 2022</td>
</tr>
<tr>
<td>Secondary identifying numbers</td>
<td>None</td>
</tr>
<tr>
<td>Source(s) of monetary or material support</td>
<td>N/A</td>
</tr>
<tr>
<td>Primary sponsor</td>
<td>Australian Government Department of Health and Aged Care</td>
</tr>
<tr>
<td>Secondary sponsor(s)</td>
<td>N/A</td>
</tr>
<tr>
<td>Contact for public queries</td>
<td>Dr Dina Schram (<a href="mailto:dina.schram@health.gov.au">dina.schram@health.gov.au</a>)</td>
</tr>
<tr>
<td>Contact for scientific queries</td>
<td>Dr Denise O’Connor (<a href="mailto:denise.oconnor@monash.edu">denise.oconnor@monash.edu</a>)</td>
</tr>
<tr>
<td>Public title</td>
<td>Feedback for reducing overuse of pathology test requesting by Australian general practitioners</td>
</tr>
<tr>
<td>Scientific title</td>
<td>Evaluating a feedback intervention for reducing overuse of pathology test requesting by Australian general practitioners: a factorial cluster randomised controlled trial</td>
</tr>
<tr>
<td>Countries of recruitment</td>
<td>Australia</td>
</tr>
<tr>
<td>Health condition(s) for problem(s) studied</td>
<td>General practitioner test ordering</td>
</tr>
<tr>
<td>Intervention(s)</td>
<td>GPs allocated to one of eight intervention groups will receive individualised written performance feedback on their pathology test combination requesting rates from the Chief Medical Officer of Australia. The feedback provided to all intervention groups will be consistent in content and length other than three potential effect modifiers to be evaluated in the trial: (1) opportunity of Continuing Professional Development (CPD)-accredited online educational webinar and self-audit activity aimed at improving pathology requesting (no vs. yes); (2) provision of pathology test cost information (no vs. yes); and (3) feedback format (letter vs. pamphlet). The feedback will be delivered by mail and present the recipients’ rate of requesting of targeted combinations of pathology tests compared with the median request rate of their GP peers in the same geographic stratum. The targeted test pathology combinations are: 1. iron studies (66596), Thyroid Stimulating Hormone (TSH) (66716) and vitamin D (66833); 2. iron studies (66596), vitamin D (66833) and vitamin B12 (66838/66839);</td>
</tr>
</tbody>
</table>
3. iron studies (66596), TSH (66716) and vitamin B12 (66838/66839);
4. iron studies (66596), Thyroid Function Tests (TFT) (66719) and vitamin B12 (66838/66839);
5. iron studies (66596), TFT (66719) and vitamin D (66833);
6. TSH (66716) and vitamin D (66833) and vitamin B12 (66838/66839);
7. iron studies (66596) and vitamin D (66833);
8. iron studies (66596) and vitamin B12 (66838/66839);
9. iron studies (66596) and TFT (66719);
10. TSH (66716) and vitamin D (66833).

Performance feedback will be provided for up to three pathology test combinations where the recipient’s requesting rate is higher than 90% of their GP peers practicing in a similar geographic region.

GPs allocated to the control group will not receive any active intervention during the trial.

### Key inclusion and exclusion criteria

**Inclusion criteria:** GPs practising in Australia, who are in the top 10% of GP referrers overall for 10 targeted combinations of pathology tests and in the top 10% of referrers for at least 2 individual test combinations. Targeted combinations of pathology tests are:

1. iron studies (66596), TSH (66716) and vitamin D (66833);
2. iron studies (66596), vitamin D (66833) and vitamin B12 (66838/66839);
3. iron studies (66596), TSH (66716) and vitamin B12 (66838/66839);
4. iron studies (66596), TFT (66719) and vitamin B12 (66838/66839);
5. iron studies (66596), TFT (66719) and vitamin D (66833);
6. TSH (66716) and vitamin D (66833) and vitamin B12 (66838/66839);
7. iron studies (66596) and vitamin D (66833);
8. iron studies (66596) and vitamin B12 (66838/66839);
9. iron studies (66596) and TFT (66719);
10. TSH (66716) and vitamin D (66833).

Only pathology tests requests that lead to a service being rendered by a pathologist and for which a Medicare Benefits Schedule claim is made are in scope.

**Exclusion criteria:**

1. GPs with <1000 Category 1 services between 1 July 2019 and 30 June 2020, and/or <1000 Category 1 services between 1 July 2020 and 30 June 2021.
2. GPs who did not make any in-scope pathology test requests within the nominated 24-month period (1 July 2019 to 30 June 2021).
3. GPs who participated in user testing of the intervention.
4. GPs who are currently or have been involved in a Department of Health compliance activity commencing on or after 1 May 2021.
5. GPs with a hospital as their primary practice address.
6. GPs with a primary practice address in remote or very remote geographical areas (MM6-7).

<table>
<thead>
<tr>
<th>Study type</th>
<th>Interventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of first enrolment</td>
<td>12 May 2022</td>
</tr>
<tr>
<td>Target sample size</td>
<td>3,371 general practices containing 5,964 GPs</td>
</tr>
<tr>
<td>Recruitment status</td>
<td>Active, not recruiting</td>
</tr>
<tr>
<td>Primary outcome(s)</td>
<td>Overall rate of requesting of any of the displayed combinations of pathology tests (listed below) by each GP per 1,000 category 1 consultations over the six months following intervention delivery, rendered by a pathologist and assessed using MBS data. Targeted test pathology combinations are: 1) iron studies, TSH and vitamin D, 2) iron studies, vitamin D and vitamin B12, 3) iron studies, TSH and vitamin B12, 4) iron studies, TFT and vitamin B12, 5) iron studies, TFT and vitamin D, 6) TSH, vitamin D and vitamin B12, 7) iron studies and vitamin D, 8) iron studies and vitamin B12, 9) iron studies and TFT, 10) TSH and vitamin D.</td>
</tr>
</tbody>
</table>