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BMJ Open Quality Improving the annual monitoring rates of testosterone replacement therapy patients in primary care

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ABSTRACT

Introduction Testosterone replacement therapy (TRT) is the treatment of choice for male hypogonadism. British Society for Sexual Medicine (BSSM) guidelines on adult testosterone deficiency recommend that TRT patients undergo annual monitoring of their testosterone levels and potential complications of treatment; though evidence suggests that substantial numbers of men on TRT are not monitored adequately.

Methods Review of the electronic patient record from a single general practice in southwest Scotland revealed that only 1 of 26 (4%) TRT patients had been monitored as per BSSM guidelines in the previous 12 months. Additionally, when monitoring was undertaken there was inconsistency in the blood tests requested. The use of quality improvement (QI) tools including process mapping and cause-and-effect diagram identified staff and patient knowledge of monitoring requirements and the lack of an effective recall system as areas for improvement. We tested three change ideas: the utilisation of an existing recall system for long-term therapies; a TRT Ordercomms blood group template (OBGT) to standardise monitoring; and a patient information leaflet (PIL) to improve patient education. The aim of this project was to achieve 60% annual monitoring rate.

Results The percentage of patients monitored for testosterone levels and potential TRT complications increased from 4% (1/26) to 65% (17/26) over a 7-week test period. The utilisation of the existing recall system was a particularly effective intervention, leading to an increase from 4% (1/26) to 31% (8/26) in the first 2 weeks.

Conclusion The use of QI tools was associated with over 60% of male TRT patients receiving comprehensive annual monitoring, as per BSSM guidelines. Our findings support the hypothesis that a patient recall system, combined with an OBGT and a PIL led to this increase.

PROBLEM

Testosterone replacement therapy (TRT) is the recommended treatment for male hypogonadism.¹ To optimise the efficacy of treatment and address concerns surrounding its safety—including prostate cancer and cardiovascular risks—it is recommended that all patients started on TRT are monitored at 3, 6, 12 months and annually thereafter.¹ The monitoring includes testosterone and prostate-specific antigen (PSA) levels, full

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Despite the significant benefits of testosterone replacement therapy (TRT) for hypogonadism patients, its safety remains controversial. Our aim was to increase the monitoring rates of TRT patients to optimise health and safety outcomes.

WHAT THIS STUDY ADDS

⇒ We have shown that an existing recall system for long-term therapies, a TRT blood group template and a patient information leaflet can substantially improve TRT monitoring.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ It seems likely that a similar approach could be used to improve monitoring of other long-term health conditions.

blood count (FBC) and screening for cardiovascular risk. Despite these recommendations, clinical audits in the UK^{2,3} and elsewhere⁴ have demonstrated persistently low rates of monitoring. Our project was carried out over a 7-week period at a single general practice in the Dumfries and Galloway region in southwest of Scotland, with a patient population of 12 000. Informal discussion with the team of general practitioners (GPs) at the practice suggested that TRT monitoring was not being performed as per guidelines. A review of the data at the practice confirmed this. Furthermore, there were no local guidelines addressing TRT monitoring in Dumfries and Galloway.

SPECIFIC AIMS

The specific aim of our project was that by May 2021, 60% of male patients on TRT at a single general practice in southwest Scotland will have attended for annual monitoring—namely PSA and testosterone levels, FBC, lipid profile, glucose, blood pressure (BP) and body mass index (BMI)—in accordance

with British Society for Sexual Medicine (BSSM) guidelines.¹

BACKGROUND

An increasing elderly population worldwide has shifted the focus of healthcare provision beyond merely prolonging life, towards ensuring better quality of life (QoL).⁵ For many male patients, a major contributor to the decline in QoL is hypogonadism.⁶ Male hypogonadism is a clinical and biochemical syndrome that is associated with ageing and characterised by symptoms such as a reduced sexual desire, erectile dysfunction and fatigue, as a result of low levels of the hormone testosterone.^{7,8} The condition significantly impacts the patient's physical and mental well-being with research demonstrating links to co-morbidities including osteoporosis, cardiovascular disease and depression.⁹ The burden of hypogonadism on the patient consequently translates into an increased burden on the healthcare system, and a consequent economic burden.¹⁰

Effective treatment of hypogonadism with TRT is associated with improved glycaemic control,¹¹ obesity-related parameters¹² and cardiovascular event risk.¹³ Despite these benefits, TRT safety remains controversial. The concerns surround the potential for increased risk of cardiovascular events,^{14,15} and a theoretical risk of prostate cancer.¹⁶ A recent important systematic review and network meta-analysis of testosterone therapy in hypogonadal men observed no statistically significant increase in the risk of these adverse events, though the authors advised longer term higher quality trials to fully assess the risk of harm.¹⁷ Considering the benefits of optimal treatment and uncertainties surrounding safety, effective monitoring is essential for optimising health and economic outcomes. Yet evidence suggests that substantial numbers of men on TRT lack adequate screening and monitoring.¹⁸ This is in line with the low annual monitoring rates found at our general practice.

A review of the research on improving the monitoring of TRT and hypogonadism patients revealed no study similar to the one described here. Nonetheless, the monitoring of similar chronic conditions, their associated therapies and potential side effects, has been the subject of several recent quality improvement (QI) papers. Mundell *et al* tested the use of a monitoring system, including annual audit, letter reminders and a patient information leaflet (PIL) and demonstrated an improvement in the uptake of blood monitoring from 18% to 60% in a cohort of 20 patients on long term oral corticosteroids.¹⁹ Willison *et al* tested a self-motivating PIL designed to ensure that a cohort of 20 diabetic patients received annual renal function monitoring. As a result of the leaflet 95% of patients stated that they understood why they required to present a urine sample for monitoring, compared with 85% not understanding prior to reading the leaflet, and 100% of patients expressed that the leaflet was a helpful resource.²⁰ Moffat and McNab tested the use of an Egton

Medical Information Systems (EMIS) template to standardise and improve the rates of the annual monitoring of serum uric acid in gout patients, together with 12 monthly letter reminders, and demonstrated success with monitoring rates increasing from 40% to 80% in a cohort of 126 patients in another primary care practice.²¹

BASELINE MEASUREMENT

The single general practice in Dumfries in the southwest of Scotland covers a patient population of 12 000 and treats 26 patients with male hypogonadism. A baseline survey showed that only one (4%) had been monitored correctly according to the BSSM guidelines on Adult Testosterone Deficiency¹ in the 12 months prior to the initiation of the project.

Outcome measure

The percentage of male TRT patients who have had all required monitoring blood tests and measurements done (testosterone, PSA, FBC, lipid profile, glucose, BP and BMI).

Process measures

1. Number of appointments booked by patients who received reminders following the introduction of the recall system between February and April 2021.
2. The percentage of monitoring appointments where the Ordercomms blood group template (OBGT) was used to select the required blood tests between March and April 2021.
3. Comparison of the average of 1–10 Likert scale responses expressed by five randomly sampled patients before and after reading the leaflet.

Balancing measures

The number of abnormal blood results that led to follow-up phone or face-to-face consultations.

DESIGN

We formed a QI Team consisting of a medical student, a supervising GP and an endocrinologist. Support and supervision on the application of QI tools and techniques was provided by AM. This project was carried out over a 15-week period between January and May 2021.

QI tools and techniques

During the initial stages of the project, it was important to identify the main stakeholders that would, directly or indirectly, be involved in, and influence, any changes made to the system.²² A discussion with GPs at the practice enabled a stakeholder analysis that was used to identify key parties, prioritise communication and manage relationships. Once all stakeholders were identified, a detailed process map was developed to visually illustrate the steps involved in the diagnosis and follow-up of hypogonadal patients. A cause-and-effect analysis was done using a fishbone diagram. This allowed the breakdown of the problem into various potential contributing factors

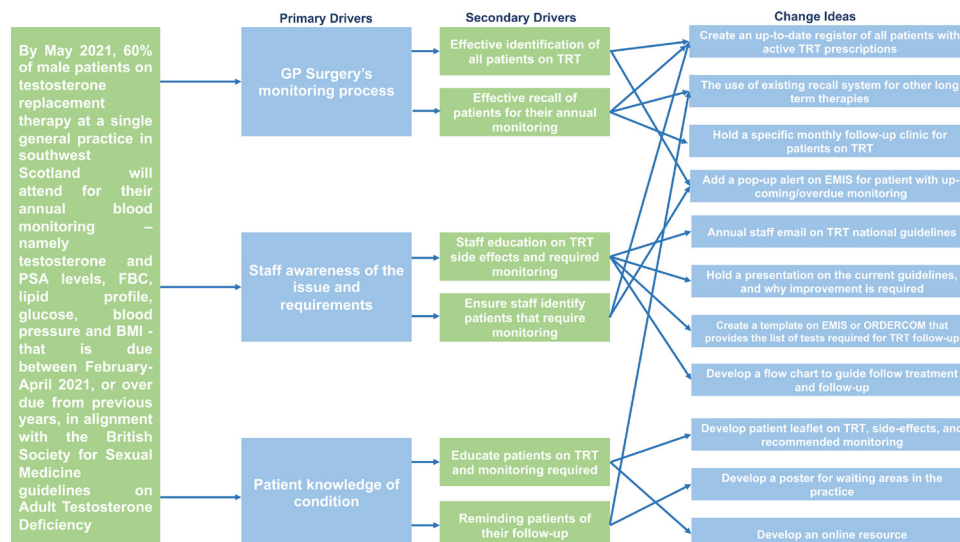


Figure 1 Driver diagram. BMI, body mass index; FBC, full blood count; GP, general practitioner; PSA, prostate-specific antigen; TRT, testosterone replacement therapy; EMIS, Egton Medical Information Systems.

that may have led to low monitoring rates. These activities formed the basis for the initial change ideas. A driver diagram was developed to articulate the theory of change between tests and the overall aim²³ (figure 1).

STRATEGY

We sent a survey to several general practices in southwest Scotland enquiring whether low monitoring rates were an issue elsewhere, and if there were any existing protocols for TRT monitoring that could be adopted at our practice. Six practices replied. No protocol was identified. A literature review was undertaken showing that structured systematic care is of paramount importance to enable adherence to evidence-based medicine and better health outcomes, a key component of which is a recall register.^{24–26}

The Plan Do Study Act (PDSA) method was used to test and inform changes. Three main change ideas were tested through a series of PDSAs which were undertaken sequentially. Building on the work of others^{19–21} our strategy was to test change ideas that were system-based rather than person-based where possible. Therefore, we used automatic recall systems and templates in order to increase reliability of the successful change ideas.

Change Idea 1: use pre-existing recall system for purposes of TRT monitoring

Through discussions with the GP supervisor and the practice's communications office supervisor (COS), it was agreed that the pre-existing recall system for long-term therapies at the practice could be utilised for TRT monitoring. The initial tests involved assessing the feasibility and suitability of using the existing recall system usually used for disease modifying antirheumatic drugs. Once confirmed with the COS, a text message reminder was drafted advising patients to book an appointment. However, following further discussion with the GP and

endocrinologist it was agreed that the information required by the patient was too long to be conveyed by text. As a result, a letter was used and its efficacy for encouraging patients to book monitoring appointments was tested instead.

Our initial cycle began on 8th March when patients were added to the recall system. We documented the number of appointments booked by patients who received reminders through the recall system between March and April 2021.

Change idea 2: developing a TRT OBGT to standardise monitoring

Change idea 1 increased the number of patients engaged with monitoring. Change idea 2 was related to the quality of that monitoring. For our second series of tests of change, we created an OBGT and documented the percentage of monitoring appointments where the OBGT was used to select the required blood tests from 22 March 2021.

A review of baseline data revealed that certain tests for TRT monitoring were done opportunistically by GPs, with variation in the individual tests requested. As this did not meet BSSM recommendations, an OBGT for TRT was suggested in order to standardise tests. Through a force-field analysis we were able to determine the lack of awareness of monitoring requirements by staff as a strong force against achieving our aim. A staff survey to assess baseline knowledge confirmed the analysis with responses demonstrating low awareness rates. Two PDSA cycles determined the correct tests to be included and the efficacy of the change.

Change idea 3: developing a PIL

It is well established that patient education in chronic conditions results in better health outcomes.²⁷ Hence the lack of patient education on TRT monitoring was

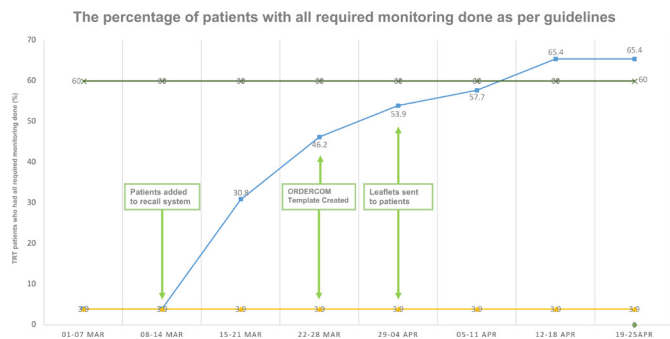


Figure 2 Line chart. TRT, testosterone replacement therapy.

recognised as a strong force against change. To address this, a PIL was written combining materials from the BSSM and Endocrine Society Clinical Practice Guidelines.^{1 28} We tested the content and design of the leaflet with the endocrinologist and GP supervisor. No issues were highlighted. The leaflets were posted (from 29 March 2021) and followed by phone calls to determine their impact.

In order to evaluate the efficacy of our PIL, we compared Likert scale responses expressed by five randomly sampled patients before and after reading the leaflet on their understanding of hypogonadism and of TRT, awareness of TRT side effects and of what monitoring involves, and their motivation to attend a monitoring appointment. The simplicity and efficacy of the Likert scale as a tool for assessing different aspects of the patient experience informed the choice for its use.²⁹

RESULTS

Outcome measures

The final data collection saw an increase in TRT monitoring, as per guidelines, from 1 (4%) to 17/26 (65%). Data were collected weekly and displayed using a line chart (figure 2).

Process measures

Utilisation of recall system

19 of 26 patients (73%) booked an appointment following receipt of a letter generated by the recall system and 17 (65%) were seen within the project timeline. This number includes the single patient who had been monitored correctly according to BSSM guidelines in the 12 months prior to the initiation of the project. The letter reminder we introduced in cycle 1 included the following advice: 'if you are applying gel please arrange appointment 2–4 hours after applying the gel, and if using injections please arrange the appointment 2 weeks before your next injection'.²⁸ The intervals between the injections used at the practice is 3 months, which may explain why seven patients had not booked an appointment by the end of the study.

Ordercomms blood group template

The OBG was used in 6/9 (67%) of the monitoring appointments that took place during the 4 weeks after its introduction.

Data from Patient Feedback on Information Leaflet

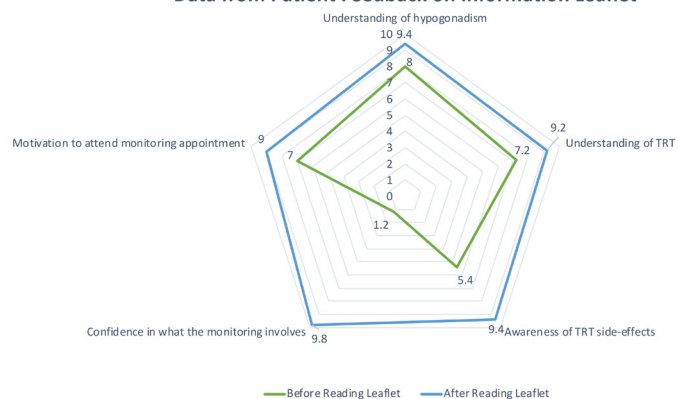


Figure 3 A spider diagram illustrating patients' Likert scale responses. TRT, testosterone replacement therapy.

Patient information leaflet

The PIL had a positive impact on patients' knowledge of TRT and motivation to book monitoring appointments. Patients' confidence in the monitoring process increased from an average of 1.2/10 to 9.8/10 on the 1–10 Likert scale after reading the PIL while their motivation to attend monitoring appointments improved from 7/10 to 9/10 (figure 3).

Balancing measure

Three of the 17 monitoring results included in our analysis were abnormal and led to follow-up phone or face-to-face consultations.

DISCUSSION

Lessons learnt

The recall system was an effective change. Once it was tested, the following week witnessed the biggest increase in monitoring rates. The strong GP–patient relationships observed at the practice may be reflected in this increase as strong doctor–patient relationships are commonly linked to better adherence.³⁰ The increase can also be viewed through the lens of the self-determination theory. Ng *et al* explain that the theory places patient autonomy as a vital factor in promoting patient motivation to achieve better health outcomes.³¹ Promoting patient autonomy when managing chronic conditions such as diabetes supports this theory with improved glycaemic control.³² The recall system we used requires the patient to book their own appointment while providing them with the required information. Therefore, alongside the PIL, it empowers the patient to make positive autonomous health decisions.

The OBG demonstrated promising results with an average of 67% uptake. Following discussion with the phlebotomists carrying out the monitoring it transpired that some did not know about the template. Now that they have been informed we anticipate that uptake of the template will increase to 100%. Moreover, the PIL achieved its aim of improving patients' confidence in monitoring requirements and motivation to attend. It

was only tested in the last 2 weeks of the project, so it is difficult to assess whether the improvement in knowledge and motivation will translate into further improvements in attendance.

Other impacts of the project relate to optimising TRT as a result of monitoring. Effective TRT has been shown to increase patient QoL and improve symptoms.³³ Therefore, monitoring results in better health outcomes. Furthermore, monitoring is also likely to save resources. One study demonstrated that men with low testosterone had a considerably higher number of outpatient visits per year with significantly higher outpatient costs.³⁴ Additionally, over a 10-year period, a UK study compared the costs associated with treatment vs no treatment and found a £3732 reduction in annual inpatient costs relating to treating co-morbidities in patients on TRT.³⁵ Therefore, by ensuring that treatment is having the intended effect through monitoring, a positive economic impact can be achieved.

The changes we introduced could also be used to monitor other chronic conditions in the future. A survey of local GP surgeries in the region highlighted a regional need for a TRT monitoring protocol as none had monitoring systems in place. The protocol developed in this project will be shared with other surgeries. This will not only help increase awareness of national guidelines but also address the lack of local guidelines.

Sustainability

The change ideas tested within this project were explicitly intended to be system focused in order to increase sustainability.¹⁹⁻²¹ The combination of the recall system, OBG and PIL seem likely to ensure the sustainability of this project. The recall system generates a monthly list of patients who require monitoring for different therapies based on when they are due. At the beginning of each month the COS managing the system will send out letter reminders to patients. The PIL will be attached to the letter which will also act as a reminder for the phlebotomist of the tests required and the OBG to be used. In this way all 26 TRT patients will be recalled annually for monitoring in the future. Moreover, the GPs agreed to add new patients to the recall system once they are referred back to primary care. This will be done through the use of the Docman system.³⁶ The change ideas are not reliant on the QI team for action and we believe, therefore, that this project has the potential for sustainable improvement.

Limitations

We recognise several limitations for this project. First, the TRT patient population at the practice is exclusively male, hence the project focused on the annual monitoring of male hypogonadism patients. Testosterone therapy, however, is also prescribed for female and transgender patients for which the results of this project may not be reproducible.^{37,38} Second, our patient recall system addressed the annual monitoring of TRT and consequently may not fully address the monitoring of new

TRT patients. For new patients monitoring at 3, 6 and 12 months following the initiation of therapy is also required prior to commencing the annual monitoring.¹

The addition of new patients to the recall system relies on GPs leaving a comment on the Docman system which will then be acted on by the communications team. Despite this being an established method, which works effectively for all other monitoring at the practice, there is a risk for human factor error where a GP may forget to do this. Particularly as new referrals from secondary care are sparse due to the nature of the condition. For this to be addressed, a further project can test the development of an electronic automatic method to add patients to the system.

The specific number of patients benefiting from this project is relatively low. However, it is known that monitoring of this patient group is poor across many settings.²⁻⁴ Sharing these effective change ideas enables other clinical teams to adapt and adopt them to improve monitoring for more patients.

Additionally, the principle of using existing recall systems and templates may prove to be useful for improving monitoring of other chronic conditions within primary care settings.

CONCLUSION

This project aimed to test changes that allow for effective monitoring of TRT to improve patient safety, health and economic outcomes.³⁹ The main focus of the project was to increase the annual monitoring rates of TRT, which was achieved. Our findings suggest that a recall system, combined with an OBG and PIL were responsible for this increase. The process map generated at the beginning of the project has been updated to reflect the new process and to facilitate staff education. The use of existing systems to support these change ideas may make the sustainability of the improvement more likely, and may increase the likelihood of other practices being able to adapt and adopt the ideas.

Contributors OH quality improvement project lead and guarantor. Participated in project design, research, implementing tests of change, data collection, data analysis and drafting and revision of drafts. MS participated in project design, revision of resources used for patient education, and facilitated tests of change. SH participated in cowriting and revising content of patient resources, research and clarification of guidelines. CI cowrote second draft and contributed to subsequent drafts including final draft. AM provided quality improvement methodology coaching, and review of paper. HS provided critical review and editing of drafts including the final draft.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Approval for the project was sought and granted by the practice's Caldicott Guardian. We did not seek formal ethical approval as no patient identifiable data were included in our analyses, in keeping with our health board's policy. Participants provided informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Not applicable.

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