Care Quality Commission

Polypill Limited

Alto House

Inspection report

29-30 Newbury Street
London
EC1A 7HZ
Tel: 020 7600 3193
Website: www.polypill.com

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Ratings

Overall rating for this service	**Requires improvement**
Are services safe?	**Requires improvement**
Are services effective?	**Requires improvement**
Are services caring?	**Good**
Are services responsive to people's needs?	**Good**
Are services well-led?	**Good**

Overall summary

Letter from the Chief Inspector of General Practice

We rated this service as Requires improvement overall. (Previous inspection August 2018, when we found the provider was meeting the relevant standards).

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Requires improvement

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Good

We carried out an announced comprehensive inspection at Alto House on 2 May 2019, as part of our inspection programme,

Alto House (Polypill) is an online health programme for the prevention of cardiovascular disease, aimed at patients aged 50 and above. The programme combines the prescribing of medicines with the provision of lifestyle advice. Patients initially complete a free online assessment, and if suitable for the programme patients can then order a prescription for the medicines, which

Summary of findings

are sent to Polypill's designated pharmacy who dispatch them to the patient's address. When patients require a further supply of medicines they complete another online questionnaire before a repeat prescription is issued.

At this inspection we found:

- The service did not have sufficient safeguards in place to ensure all patients and applicants to join the programme were aged 18 or older.
- The service had a limited system to confirm patients' identities when registering with and contacting the service.
- Not all patients consented to information sharing with their NHS GPs to avoid any risks associated with interactions of the medicines it prescribed with other medicines prescribed
- There was a lack of completed, two-cycle, audits together with limited evidence of other quality improvement activities, to demonstrate the medicines being prescribed were effective in preventing in the conditions for which they were prescribed.
- The service collected and monitored information on patients' care and treatment outcomes.
- Staff involved and treated people with compassion, kindness, dignity and respect.
- Patients could access care and treatment from the service within an appropriate timescale for their needs.
- There were policies and IT systems in place to protect the storage and use of all patient information.

The areas where the provider **must** make improvements as they are in breach of regulations are:

- Ensure care and treatment is provided in a safe way to patients.

(Please see the specific details on action required at the end of this report).

The areas where the provider **should** make improvements are:

- Consider how to make clear to patients that not all medicines being prescribed were licensed for use as preventative of the conditions for which the service was prescribing them.
- Consider requiring a signature for receipt of medicines posted to patients to ensure medicines are delivered to the correct recipient.
- Consider requiring all clinical staff to receive an appropriate level of child safeguarding training to level three.

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

Alto House

Detailed findings

Background to this inspection

The provider, Polypill Limited, was incorporated in 2001 to offer an online health programme which aims to contribute to the prevention of cardiovascular disease, the service is provided to patients aged 50 and above, who are based in the United Kingdom. Its management offices are at 29-30 Newbury Street, London, EC1A 7HZ.

The service is founded on the findings of research projects. it relies on research findings by the founders of the service, published in 2003, supported by a study undertaken in 2012, in which 84 people participated.

It carries out asynchronous (text based) consultations and where there is a need for any clarification of a patient's suitability for the programme the clinician contacts them to clarify any issues. Patients participating in the programme are prescribed medicines and also provided with lifestyle advice via the services website. At the time we inspected, there were just over 100 active participants in the programme.

The administrative function of the service operates from an office in Central London. The clinical leadership team are based in the nearby Wolfson Institute for Preventive Medicine and the prescribing doctor works remotely. One prescribing doctor works for the service and is supported by two members of the clinical leadership team who are also doctors and cover the prescribing duties where necessary.

Two members of staff employed by another company run by the Registered Manager provide administrative support; there are formal arrangements in place to support this relationship.

How we inspected this service

Before the inspection we gathered and reviewed information from the provider. During this inspection we spoke to the Registered Manager, the prescribing doctor and members of the management and administration team.

To get to the heart of patients' experiences of care and treatment, we ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Requires improvement

Are services safe?

Our findings

We rated safe as Requires improvement because:

- The service was intended for people aged 50 years and over, however it did not have safeguards in place to ensure patients were over 18.
- There were limited checks undertaken to confirm patients' identities.

Keeping people safe and safeguarded from abuse

Staff employed at the headquarters had received training in safeguarding and whistleblowing and knew the signs of abuse. All staff had access to the safeguarding policies. The service had contact details for the local (City of London) adult and children's safeguarding teams. However, it did not have contact details for local authority safeguarding teams throughout the UK. As, unlike NHS GP practices, the service provided care and treatment for adults who resided throughout the UK the service recognised it was important to have direct contact with the appropriate local authority safeguarding team where a patient resided. Accordingly, during our inspection the service updated its policies and safeguarding posters to include a link to all local authority adult and children safeguarding teams throughout the UK.

The doctor who delivered the service had received adult and level two child safeguarding training. It was a requirement for the doctors registering with the service to provide evidence of up to date safeguarding training certification.

The service did not treat children, however it did not have safeguards in place to ensure patients were over 18. It told us the limited range of medicines it supplied under prescription were intended for use by patients aged 50 and over. The service considered the risk was mitigated as the medicines prescribed were not of a type that would be liable to abuse or misuse. During the inspection the service told us it was in the process of establishing identity checks to ensure only its target patient group could access the service.

Monitoring health & safety and responding to risks

The service carried out risk assessments at the completion of the initial consultation before issuing a prescription. It discussed and assessed risks at regular six-monthly clinical governance meetings. In addition, the prescribing doctor was in regular contact with the leadership team, so was able to raise any issues promptly.

The providers headquarters was located within purpose-built offices which housed the IT system and administration staff. Patients were not treated on the premises, the doctor carried out the online consultations remotely; either from their office or home. All staff based in the premises had received training in health and safety including fire safety.

The provider expected all doctors would conduct consultations in private and maintain patient confidentiality. Each doctor used an encrypted, password secure laptop to log into the operating system, which was a secure programme. Doctors were required to complete a home working risk assessment to ensure their working environment was safe.

The service was not intended for use by patients with either long term conditions or as an emergency service, though there were processes in place to manage any emerging medical issues during a consultation. In the event an emergency did occur during a consultation, the doctor would advise the patient to contact their NHS GP or, in case of urgency, to phone the emergency services on 999.

All clinical consultations were rated by the doctor for risk. For example, to ascertain whether there may be serious mental or physical issues which required further attention. Consultation records could not be completed without a risk rating. All risk ratings were discussed at six monthly clinical governance meetings. There were protocols in place to notify Public Health England of any patients who had notifiable infectious diseases.

A range of clinical and non-clinical meetings were held with staff, where standing agenda items covered topics such as significant events, complaints and service issues. Clinical meetings also included case reviews and clinical updates. We saw evidence of meeting minutes to show where some of these topics had been discussed, for example significant events.

Staffing and Recruitment

There were enough staff, including doctors, to meet the demands for the service. There were support and IT staff available to the doctors during consultations.

Requires improvement

Are services safe?

The provider had a selection and recruitment process in place for all staff. There were a number of checks required to be undertaken prior to commencing employment, such as references and Disclosure and Barring service (DBS) checks. DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable.

Potential Doctor employees had to be currently working in the NHS and be registered with the General Medical Council (GMC). They had to provide evidence of having professional indemnity cover (to include cover for online consultations), an up to date appraisal and certificates relating to their qualifications and training in safeguarding and the Mental Capacity Act.

We reviewed one recruitment file which showed the necessary documentation was available, with the exception of the contract of employment. Following our inspection, the service provided us with a copy of the doctors' contract. The doctor could not be registered to start any consultations until these checks and induction training had been completed. The provider kept records for all staff including the doctor and there was a system in place which flagged up when any documentation was due for renewal such as their professional registration.

Prescribing safety

The service prescribed a limited range of four medicines (atorvastatin for lowering cholesterol and amlodipine, irbesartan and hydrochlorothiazide used for a range of cardiac conditions). At the time of our inspection these were delivered to patients as three tablets, as part of a programme to help prevent heart attacks and stroke. Potential patients completed an online form to assess their suitability for the programme. This questionnaire was then reviewed by the prescribing doctor who decided whether the individual was eligible for the programme. Eligible patients were invited to participate, and if they decided to join the programme, having paid the appropriate fee, a prescription would be generated and sent to the designated pharmacy to be dispensed and posted to the patient.

When replacement or additional supplies of medicines were prescribed there was a clear record of the decisions made, and the service confirmed why the patient was requesting a further supply outside of their standard three-monthly schedule. The service told us almost all such requests were to replace misplaced medicines. Other patients had requested supplies to cover periods of time when they would be away from home.

Once the doctor prescribed the medicine, relevant instructions were given to the patient regarding when and how to take the medicine, the purpose of the medicine and any likely side effects and what they should do if they became unwell.

When the service was first established it supplied all four medicines as one tablet, which was unlicensed for use in the UK, however the supply of the single tablet had been withdrawn by the manufacturer prior to our inspection.

At the time of this inspection the service was prescribing a combination of four medicines within three tablets, these were all licenced for use, for treatment of the conditions for which the service was prescribing. However, the service was prescribing the medicines for prevention of illness, for which purpose they were not licenced. The service advised us that on initiation of prescribing they made it clear to patients that the use of the medicines for prevention was unlicensed, however, they were unable to provide evidence in support of this. Use of a medicine for a different medical condition than listed on its licence is called unlicensed (off-label) use and is a higher risk because less information is available about the benefits and potential risks. Medicines in the UK are given licences after trials have shown they are safe and effective for treating a particular condition.

In addition, the service was actively looking for potential collaborators, pharmaceutical specials manufacturers, to produce all four medicines in a single tablet, which would be unlicensed in that form. The service was aware that should it re-commence prescribing the single tablet it would need to make clear information available to patients on the consultation form to explain the product was unlicensed, and the patient would be required to acknowledge they understood this information. Additional written information to guide the patient when and how to use these medicines safely would be supplied with the medicine.

Requires improvement

Are services safe?

The service offered repeat prescriptions, on a three-monthly basis, to patients who were part of the programme. It did not prescribe to patients with long-term conditions who would need to be monitored, nor did it prescribe antibiotics.

Prescriptions were issued electronically to the designated pharmacy. The dispensed medicines were posted to the patient's nominated address using a postal delivery service. There was no system in place to ensure the correct person received the medicines as they were delivered without the recipient being required to provide a signature. The service told us on some previous occasions it posted medicines with a signature required for receipt. Patients had objected to this, so the service had reverted to posting the medicines via the standard postal service.

Information to deliver safe care and treatment

There were some arrangements in place for identifying and verifying the identity of patients; however, these relied on patients providing accurate information about their identity when they registered with the service. Staff at the service explained that due to the nature of the medicines being prescribed, they felt there was little chance of abuse. Patients logged onto the provider's secure system in order to request further prescriptions or to contact the provider with a query. However, there was a lack of processes in place to verify the identity of an individual when they contacted the service by phone, other than to ask patients to confirm their date of birth, and therefore there was a risk confidential patient information could be disclosed to a third party without the patient's knowledge or consent. The service told us that it was reviewing its procedures for confirming patients' identities.

Management and learning from safety incidents and alerts

There was an incident management policy and systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. We reviewed five incidents which had occurred over the past year and found these had been fully investigated, discussed and as a result action taken in the form of a change in processes. For example, a patient was admitted to hospital and placed onto an alternative medicine's regime. The service confirmed the patient should leave its programme and offered the patient a refund for his unused medicines.

We saw evidence from the regular clinical governance meetings of significant events being discussed, and decisions were implemented.

From the incidents we reviewed we saw the provider was aware of and complied with the requirements of the duty of candour by explaining to the patient what went wrong, offering an apology and advising them of any action taken.

The service responded to medicines safety alerts, and we were shown records of the action taken in response. For example, an alert in January 2019 had caused the service to issue replacement prescriptions to three patients on the programme.

Requires improvement

Are services effective?

(for example, treatment is effective)

Our findings

We rated effective as Requires improvement because:

- The service had not undertaken any completed, two-cycle audits, where findings were used to drive quality improvement, together with limited evidence of other quality improvement activities, to demonstrate the medicines being prescribed were effective in preventing in the conditions for which they were prescribed. Following our inspection the service carried out four single-cycle audits which they subsequently provided to us.
- It did not ensure that all patients had consented to information sharing with their NHS GPs to obviate any risks associated with interactions of the medicines it prescribed with other medicines prescribed by patients NHS GPs. The service subsequently provided us with a copy of a procedure it implemented in November 2018 requiring all new patients joining after that point to agree to the sharing of information with their NHS GP. However, this did not retrospectively apply to patients who were already participating in the programme prior to the implementation of the procedure

At our last inspection in August 2018 we found:

- Where a patient gave their consent, information was appropriately shared with the patient's GP according to GMC guidelines. However, if a patient refused consent the service was not exploring the reasons why consent was withheld. Nor did it explain the benefits of information sharing. During the inspection the service committed to developing a system to explain the benefits of information sharing with patients NHS GP.
- Clinicians providing the service did not fully appreciate the risks associated with providing a service remotely, as they did not gather sufficient information to inform decision-making as to whether a patient was suitable for the programme. In particular, two of the medicines prescribed could affect patients' renal function, however the patient questionnaire only asked patients whether they had impaired kidney function which required dialysis. During the inspection the service agreed to implement more robust arrangements.

Assessment and treatment

At our last inspection in August 2018 we found:

- The service was not gathering sufficient evidence from patients to ascertain any risk associated with a patient history of kidney disorder. During the inspection the service agreed to change its online consultation form to ask patients whether they had ever had an abnormal result from a test of their kidney function.

At this inspection we found:

- The service had amended its online consultation to include a question to patients to discover whether patients had ever had an abnormal kidney function test result. Any prospective patients who had had such a result were contacted by the doctor to confirm the details. Following contact if the patient was not suitable for the programme they were advised appropriately.

We reviewed 25 examples of medical records which demonstrated the doctor assessed patients' needs and delivered care in line with relevant and current evidence-based guidance and standards, including National Institute for Health and Care Excellence (NICE) evidence-based practice.

The service carried out asynchronous (text based, not in real-time) consultations and where there was a need for any clarification of a patient's suitability for the programme the clinician contacted them, either by phone or secure message through the patients account with the service, to clarify any issues. Patients participating in the programme were prescribed medicines and also provided with lifestyle advice via the services website.

Prior to joining the programme patients completed an online form which included their past medical history, with particular reference to any cardiovascular issues. There was a set template to complete for the consultation which included the reasons for the consultation and the outcome to be manually recorded, along with any notes about past medical history and diagnosis. We reviewed seven anonymised medical records which were complete records. We saw adequate notes were recorded, and the doctor had access to all previous notes.

The doctors providing the service were aware of both the strengths (speed, convenience, choice of time) and the limitations (inability to perform physical examination) of working remotely from patients. They worked carefully to maximise the benefits and minimise the risks for patients. The service had developed its own age-based risk

assessment tool which the doctor used for clinical assessment. If the provider could not deal with the patient's request, this was explained to the patient and a record kept of the decision.

The service monitored consultations and carried out single-cycle prescribing audits to improve patient outcomes. The prescribing audits were reviewed in clinical governance meetings. It also audited applicants to the programme, for example of the eight most recent applications to join the programme, seven did not join. Of those four were rejected as they resided outside of the UK, whilst three did not give reasons for not following through with their applications. Following the inspection the service provided us with four further single-cycle audits it had carried out after the inspection.

Quality improvement

The service collected and monitored information on patients' care and treatment outcomes, such as from patient feedback. It discussed clinical issues, including patient outcomes in its clinical governance meetings. In addition, a survey of 113 patients carried out in August 2018 asked for patients views about the service. It found, for example, of the 47 respondents 42 were satisfied with the level of information provided about the programme, while five patients expressed no opinion, with no patients stating that they were dissatisfied. The service had used feedback to make improvements to the way the programme was delivered.

At the time of our inspection the service prescribed licensed medicines, as three tablets, which it prescribed outside the terms of their licence (for prevention of heart disease and stroke), therefore they are termed as 'unlicensed medicines'. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy. The medicines used in combination at these doses by the provider for preventing these conditions are not currently recommended by the National Institute for Health and Care (NICE) or other national guidelines, and there is a limited set of evidence for the use of these medicines in preventing these conditions. Further, not all patients had consented to information sharing with their NHS GPs, with the risk of potential interactions with other prescribed medicines.

Staff training

The only employee of the service was the prescribing doctor. During the inspection the service was not able to provide evidence the doctor had completed all training relevant to their role. However, following the inspection the service provided us with evidence the doctor had already received up to date training in all areas the service considered mandatory. The service manager had developed a training matrix to identify when training was due.

The prescribing doctor had received specific induction training prior to treating patients. When updates were made to the IT systems, the doctor received further online training.

The doctor had to have received their own appraisal before being considered eligible at the recruitment stage. The doctor received a regular annual in-house appraisal covering their work with the service.

Coordinating patient care and information sharing

At our last inspection in August 2018 we found:

- Where a patient gave their consent, information was appropriately shared with the patient's GP according to GMC guidelines. However, if a patient refused consent the service was not exploring the reasons why consent was withheld. Nor did they explain the benefits of information sharing. During the inspection the service committed to developing a system to explain the benefits of information sharing with patients NHS GP.

At this inspection we found:

- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service, and the benefits of information sharing were explained where a patient refused consent. Of the four patients who had joined the programme since July 2018, three had consented to information sharing with their NHS GP.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history.

Requires improvement

Are services effective?

(for example, treatment is effective)

- When results indicated further investigation was needed, the service would refer the patient on to a named specialist, if the patient did not wish to see the chosen person, then they would be advised to contact their NHS GP.

Supporting patients to live healthier lives

The service identified patients who may be in need of extra support and had a range of information available on the website including links to NHS websites. For example, the services' website contained links to information about the benefits of regular exercise, a balanced diet, controlling alcohol consumption and stopping smoking.

Good

Are services caring?

Our findings

We rated caring as Good because:

- Patient information guides and information about the doctors who were part of the service was available on the service website.
- Translation services were available.

Compassion, dignity and respect

We were told the doctor undertook online consultations in a private room and was not to be disturbed at any time during their working time. The provider carried out reviews to ensure the doctor was complying with the expected service standards and communicating appropriately with patients. Feedback arising from these reviews were discussed in regular clinical governance meetings. The service told us if areas for concern were identified, these would be followed up and the doctor would be reviewed again to monitor improvement.

We did not speak to patients directly on the day of the inspection. However, we reviewed the latest survey information. At the end of every consultation, patients were able to give feedback on the service via their secure personal accounts. The service had also carried out a survey of 113 of its patients in August 2018. The survey asked patients, inter alia, to give feedback on the convenience of the service. Of the 47 responses received, 44 (94%) said they were satisfied with the service, only one patient expressed dissatisfaction with a delayed delivery.

Involvement in decisions about care and treatment

Patient information guides about how to use the service and technical issues were available. The service manager and doctor responded to any enquiries.

Patients had access to information about the doctor working for the service. The Doctor could speak a variety of languages.

The survey in August 2018 asked patients opinions on how to improve the service. Patients suggested ideas for further developing the service, including, offering the medicines as a single tablet. The service was actively seeking a pharmaceutical special manufacturer to produce a single tablet combining all four medicines, as it recognised potential participants in the programme were less likely to comply with a three-tablet regime.

Patients were able to access their records by logging into their secure accounts. Where patients wanted any further information, they could contact the service via a secure message from within their account, or by phone.

Patients could access to information about the clinicians working for the service on its website. Language translation services were available where needed.

Good

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We rated responsive as Good because:

- Patients could complete the online questionnaires 24 hours a day seven days a week, and the service aimed to respond to all prescription requests and patient questions within 24 hours.
- There was clear information on the service's website detailing how the service worked and what costs applied, including a set of frequently asked questions

Responding to and meeting patients' needs

Patients accessed the service via the providers website, where they initially completed a questionnaire about their health. The information submitted via the questionnaire was reviewed by a doctor who made a decision about whether they were eligible for the service. The patient was informed of the doctor's decision via email, and if they were eligible, they were invited to join the programme. If the patient joined the programme, they paid a fee and a prescription for three months' supply of medicine, it was sent to the service's designated pharmacy who dispensed and posted the medicines to the patient.

The service contacted patients by email to remind them when they were due a repeat prescription. To request a further supply of the medicines, patients completed a further online questionnaire, which was reviewed by the doctor before a further prescription was generated. Patients could submit queries to the service using the service's secure online portal. These queries were received by administrative staff and were assigned to the doctor if the query was of a clinical nature.

Patients could complete the online questionnaires 24 hours a day seven days a week. The doctor was available to review online prescription requests between 9.00am and 5.30pm on weekdays. The service aimed to respond to prescription requests and patient queries within 24 hours.

This service was not an emergency service. Patients who had a medical emergency were advised to ask for immediate medical help via 999 or if appropriate to contact their own GP or NHS 111.

The digital application allowed people to contact the service from abroad, however all medical practitioners were required to be based within the United Kingdom. Any prescriptions issued were delivered within the UK to the services' designated pharmacy, which dispensed and posted the medicines to patients.

Patients signed up to receiving this service on a mobile phone or other internet connected device, and the provider made it clear to patients what the limitations of the service were.

Tackling inequity and promoting equality

The provider offered consultations to anyone who met their prescribing criteria who requested and paid the appropriate fee and did not discriminate against any client group.

Patients could access a brief description of the doctors who were part of the service on the providers website.

Managing complaints

Information about how to make a complaint was available on the service's web site. Additionally, the provider had developed a complaints policy and procedure. The policy contained appropriate timescales for dealing with the complaint. There was escalation guidance within the policy. A specific form for recording complaints has been developed and introduced for use. We reviewed the complaint system and noted comments and complaints made to the service were recorded. We reviewed all four complaints received in the past 12 months. These all related to a safety alert concerning a batch of one of the medicines within the three tablets the service was providing. The service advised patients, in line with the safety alert, it was preferable to continue taking the medicine compared to the health risk of stopping. Following the advice three patients requested replacement medicine. The service issued replacement prescriptions, and these were sent to the patients.

The provider was able to demonstrate the complaints we reviewed were handled correctly and patients received a satisfactory response. There was evidence of learning as a result of complaints, changes to the service had been made following complaints, and had been communicated to staff.

Consent to care and treatment

There was clear information on the service's website detailing how the service worked and what costs applied,

Good

Are services responsive to people's needs?

(for example, to feedback?)

including a set of frequently asked questions for further supporting information. The website had a set of terms and conditions and details on how the patient could contact them with any enquiries. Information about the cost of consultation was known in advance and paid for before the prescription was issued. The costs of any resulting prescription or medical certificate were handled by the administration team at the headquarters following the consultation.

Patients confirmed they consented to treatment by ticking a box on the online consultation form which they competed prior to the provision of treatment. The service's consent policy stated patients were considered to have mental capacity to consent to treatment if they were able to successfully navigate the service's website and complete an online questionnaire. The policy stated where there were concerns about a patient's capacity to consent, the doctor would contact the patient in order for a more detailed assessment to be made. Where there were serious concerns about a patient's wellbeing, we were told the service would consider contacting the patient's NHS GP.

All patient facing staff had received training about the Mental Capacity Act 2005. Staff understood and sought patients' consent to care and treatment in line with legislation and guidance. Where a patient's mental capacity to consent to care or treatment was unclear the doctor was able to assess the patient's capacity and record the outcome of the assessment. However, the process for seeking consent was not monitored through audits of patient records.

Are services well-led?

Good

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

We rated well-led as Good because:

- There was a clear organisational structure and staff were aware of their own roles and responsibilities.
- The service had an open and transparent culture.

Business Strategy and Governance arrangements

The provider told us they had a clear vision to work together to provide a high-quality responsive service put caring and patient safety at its heart. We reviewed business plans covering the next year. The business plan centred around further marketing and identifying a suitable organisation to work with in order to produce a single tablet, rather than the currently prescribed three tablets.

There was a clear organisational structure and staff were aware of their own roles and responsibilities. There was a range of service specific policies which were available to all staff. These were reviewed annually and updated when necessary.

There were regular checks in place to monitor the performance of the service, for example it had recorded that since 26 October 2016 only seven patients had advised they were leaving the programme due to side effects. The information from these checks was used to produce a clinical team report for discussion at clinical governance meetings. This ensured an understanding of the performance of the service was maintained.

There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions.

Care and treatment records were complete, accurate, and securely kept.

Leadership, values and culture

The Registered Manager was the clinical lead for the service and had overall responsibility for it. They were available to be contacted by staff at the service daily. The prescribing doctor was responsible for the day to day clinical work and there were arrangements in place to address any absence of this clinician.

The values of the service were to provide preventative treatment to participants in order to reduce the risks of them suffering heart attacks and strokes.

The service had an open and transparent culture. We were told if there were unexpected or unintended safety incidents, the service would give affected patients reasonable support, truthful information and a verbal and written apology.

Safety and Security of Patient Information

Systems were in place to ensure all patient information was stored and kept confidential.

There were policies and IT systems in place to protect the storage and use of all patient information. The service could provide a clear audit trail of who had access to records and from where and when. The service was registered with the Information Commissioner's Office. There were business contingency plans in place to minimise the risk of losing patient data.

The service had arrangements in place to provide for the ongoing secure storage of patient records should the provider cease trading. The service showed us a memorandum of understanding it had arranged, with an associated and long-established company, for records to be stored should Polypill cease to trade.

Seeking and acting on feedback from patients and staff

Patients could give feedback by sending a message through their secure account with the service, in addition, the service asked patients for feedback on how to improve the service. Patients had fed back ideas for further marketing of the service. The service conducted a survey of 113 patients in August 2018, receiving 47 replies. Amongst the questions asked, the service asked patients about the responsiveness of the team to queries and the layout and structure of the website. In regard to the former, 36 (77%) were satisfied, with 10 patients expressing a neutral opinion. Only one respondent was dissatisfied as a result of lack of communication about a delayed delivery. In regard to the service website, 38 (81%) were satisfied, nine expressed a neutral opinion and none were dissatisfied with the layout.

There was evidence the doctor could provide feedback about the quality of the operating system and any change requests were logged, discussed and decisions made for the improvements to be implemented.

Are services well-led?

Good

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

The provider had a whistleblowing policy in place. A whistle blower is someone who can raise concerns about practice or staff within the organisation. The registered manager was the named person for dealing with any issues raised under whistleblowing.

Continuous Improvement

The service consistently sought ways to improve. All staff were involved in discussions about how to run and develop the service and were encouraged to identify opportunities to improve the service delivered.

Staff told us the team meetings were the place where they could raise concerns and discuss areas of improvement - state how often. However, as the management team and IT teams worked together at the headquarters there was ongoing discussions at all times about service provision.

On the day of inspection, the service was unable to provide us with any significant audits or other quality improvement activity. However, immediately following our inspection the service sent us some examples of quality improvement activities it had undertaken, including:

- The most recent 50 patients placing repeat prescription requests had been asked to consent to information sharing with their NHS GP to ensure their GP was aware of their participation in the programme and the medicines being prescribed. Of the 50 patients asked, 38 (76%) had agreed to information sharing. The service reviewed the results and agreed to ask the next batch of 25 patients to similarly agree to information sharing with their NHS GP.
- The service had reviewed patients records and found historically only 75% of patients joining the programme had agreed to provide their NHS GP name and contact details. From March 2018 all new participants joining the programme had agreed to provide their NHS GP name and contact details. The service agreed to continue to monitor this to ensure patients were aware of the benefits of providing their GPs contact details.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose How the regulation was not being met: The provider had failed to ensure: • It had adequate safeguards in place to ensure patients were aged over 18. • It was able to confirm patients' identities when registering with and contacting the service. • All patients consented to information sharing with their NHS GPs. • It could demonstrate the medicines being prescribed were effective in preventing in the conditions for which they were prescribed. This was in breach of Regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.