Polypill Limited

Alto House

Inspection report

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Overall summary

We carried out an announced comprehensive inspection at Alto House (Head Office of Polypill Limited) on 1 February 2018 as part of our inspection programme.

Polypill is an online health programme for the prevention of cardiovascular disease, aimed at patients aged 50+. The programme combined the prescribing of medicines and provision of lifestyle advice. Patients initially completed a free online assessment, and if suitable for the programme patients could then order a prescription for the medicines, which was sent to Polypill's partner pharmacy who dispatched to the patient's address. When patients required a further supply of medicines they completed a further online questionnaire before a repeat prescription would be issued.

Our findings in relation to the key questions were as follows:

Are services safe? – we found the service was not providing a safe service in accordance with the relevant regulations. Specifically:

- Insufficient arrangements were in place to safeguard people; for example, staff were unfamiliar with the service's safeguarding policy.
- Patients were not made aware of the implications of taking a medicine that was unlicensed.
- Ordinarily, suitable numbers of staff were employed; however, we were told that the prescribing doctor continued to work remotely for the service whilst they were on holiday. Staff had not been appropriately recruited.

Are services effective? - we found the service was not providing an effective service in accordance with the relevant regulations. Specifically:

- Following patient consultations information was not always appropriately shared with a patient's own GP in line with GMC guidance.
- Quality improvement activity, including clinical audit, did not take place. The provider did not carry-out reviews of consultations by clinicians to ensure that appropriate decisions were made in relation to prescribing.
- Staff did not receive the appropriate training to carry out their role.

Are services caring? – we found some areas where the service was not providing a caring service in accordance with the relevant regulations. Specifically:

- The provider did not carry out checks to ensure consultations by clinicians met the expected service standards with regards to the care provided to patients.
- Patient feedback reflected they found the service treated them with dignity and respect.

Summary of findings

- Patients had access to information about clinicians working at the service.

Are services responsive? - we found the service was providing a responsive service in accordance with the relevant regulations. Specifically:

- Information about how to access the service was clear and where patients contacted the service to apply to join the programme or to raise a query, they were responded to promptly.
- The provider did not discriminate against any client group.
- Information about how to complain was available and complaints were handled appropriately.

Are services well-led? - we found the service was not providing a well-led service in accordance with the relevant regulations. Specifically:

- The service did not have clear leadership and governance structures, as some individuals working for the service were not employees and had no formal contractual arrangement with Polypill Ltd.
- The service did not have systems in place to monitor and improve the quality and performance of the service.
- Patient information was stored using a secure IT system; however, the service had failed to ensure that its own confidentiality policy was being followed, and were therefore not assured that individuals were maintaining the security of patient information.

The areas where the provider should make improvements are:

- Review the arrangements in place for the safe delivery of medicines to patients.
- Introduce arrangements to gather feedback from patients about the service being provided.

We identified regulations that were not being met and the provider must:

- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

You can see full details of the regulations not being met at the end of this report.

Enforcement action

We are now taking further action in relation to this provider and will report on this when it is completed.

Professor Steve Field CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found the service was not providing a safe service in accordance with the relevant regulations. Specifically:

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- Quality improvement activity, including clinical audit, did not take place. The provider did not carry-out reviews of consultations by clinicians to ensure that appropriate decisions were made in relation to prescribing.
- Staff did not receive the appropriate training to carry out their role.

Are services caring?

We found the some areas where the service was not providing a caring service in accordance with the relevant regulations. Specifically:

- The provider did not carry out checks to ensure consultations by clinicians met the expected service standards with regards to the care provided to patients.
- Patient feedback reflected they found the service treated them with dignity and respect.
- Patients had access to information about clinicians working at the service.

Are services responsive to people's needs?

We found the service was providing a responsive service in accordance with the relevant regulations. Specifically:

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Are services well-led?

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- The service did not have clear leadership and governance structures, as some individuals working for the service were not employees and had no formal contractual arrangement with Polypill Ltd.
- The service did not have systems in place to monitor and improve the quality and performance of the service.
- Patient information was stored using a secure IT system; however, the service had failed to ensure that its own confidentiality policy was being followed, and were therefore not assured that individuals were maintaining the security of patient information.

Alto House

Detailed findings

Background to this inspection

Polypill is an online health programme for the prevention of cardiovascular disease, aimed at patients aged 50+. The programme combines the prescribing of medicines and provision of lifestyle advice, which is available on their website.

Patients initially complete a free online assessment, which is reviewed by a doctor. If suitable for the programme, patients can then order a prescription for the combination of medicines, for which they pay a fee. The prescription is then, sent to Polypill's partner pharmacy who dispatch the medicines to the patient's address. When patients require a further supply of medicines they complete a further online questionnaire to confirm that they remain suitable before a repeat prescription is issued.

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; however, there are no formal arrangements in place to support this relationship.

The service is registered with the Care Quality Commission for the regulated activity of Treatment of disease, disorder or injury.

Are services safe?

Our findings

We found that this service was not providing safe care in accordance with the relevant regulations.

Keeping people safe and safeguarded from abuse

The provider had not ensured that staff working for the service had received training in safeguarding and whistleblowing and knew the signs of abuse; this included clinical staff. The prescribing doctor told us that they had received safeguarding training as part of their NHS employment; however, the provider was unaware of this. A safeguarding policy was in place which included details about how to report a concern; however, not all staff were aware of this, and the policy could not be accessed by the prescribing doctor whilst they were working remotely.

The service did not treat children.

Monitoring health & safety and responding to risks

The provider's headquarters was located within offices which housed the IT system and the two administrative members of staff. Patients were not treated on the premises, as the prescribing doctor carried out the online consultations remotely; usually from their home. There was no evidence that staff based in the premises had received training in health and safety including fire safety.

The provider expected that the prescribing doctor would conduct consultations in private and maintain the patient's confidentiality; however, there was no evidence that the prescribing doctor had been made aware of the provider's confidentiality policy as part of their induction, and they had not signed a confidentiality agreement. All staff used an encrypted, password secure laptop to log into the operating system, which was a secure programme. There was no evidence that doctors were required to complete a home working risk assessment to ensure their working environment was safe.

There were no established processes in place to manage any emerging medical issues during contact with patients; however, administrative staff said that they would refer to a doctor should they be concerned about the wellbeing of a patient.

Clinical consultations were not rated by the prescribing doctors for risk. We were told that the prescribing doctor could discuss patients with the clinical lead when necessary; however, there was no formal process in place in relation to assessing and escalating risk.

The service did not routinely hold staff meetings for the purpose of discussing topics such as significant events, complaints and service issues. We were told that the prescribing doctor regularly consulted with the clinical leads where there was a query about whether an individual was suitable for the programme. Of the five patient records we viewed, we found one record where a patient's eligibility for the programme was considered by one of the clinical leads; the patient was approved for the programme but the decision did not specify the basis for the decision made, nor did it document any discussion between the prescribing doctor and the clinical lead.

Staffing and Recruitment

Ordinarily, there were enough clinical and non-clinical staff to meet the demands for the service; however, we were told that the prescribing doctor (who worked remotely) continued to review prescribing requests whilst on holiday. None of the individuals working for the service were paid for their work.

The provider had a selection and recruitment process in place for all staff; however, this did not adequately outline the pre-employment checks required prior to employment. There was no evidence that pre-employment checks had been carried-out on the prescribing doctor prior to them being employed (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.); we were informed that the process laid out in the recruitment policy was not followed because the individual was known to a member of the clinical leadership team.

The administrative staff were not directly employed by the provider; they were employees of another company which was run by the Registered Manager, and had taken on administrative tasks relating to Polypill Limited as part of their role. These members of staff did not have a contract of employment with Polypill and had not signed a confidentiality agreement in relation to their role.

Are services safe?

There was no formal induction process for new members of staff. We were told that the prescribing doctor had been involved in the development of the service prior to commencing employment, and was therefore already familiar with the computer system when they started work and did not require a further induction. The prescribing doctor did not have access to the provider's policies and procedures when working remotely and there were no formal supervision arrangements in place.

Prescribing safety

The service prescribed medicines to patients as part of a programme to prevent heart disease and stroke. Potential patients completed an online form to assess their suitability for the programme. This questionnaire was then reviewed by a doctor who would decide whether the individual was eligible for the programme. Eligible patients were then 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 associated pharmacy to be dispensed and posted to the patient.

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. The medicine ordinarily being prescribed (Polytor) was unlicensed as a single tablet (although, all of the four medicines which made up the single pill were licensed for use when prescribed separately). In the email sent to the patient, informing them that they were suitable for the programme, the provider stated that the medicine prescribed in the preparation offered was unlicensed; however, there was no explanation of the implications of this for the patient (medicines are given licences after trials have shown they are safe and effective for treating a particular condition). At the time of the inspection the service was not prescribing the medicines as a single pill, as they had experienced problems in finding a supplier; as an interim measure they were prescribing the four medicines in a combination of three tablets.

When patients required further supplies of medicines, they completed a further online questionnaire in order to identify any changes to their circumstances since their last prescription. These questionnaires were reviewed by the prescribing doctor before a further prescription was issued.

Medicines were posted to patients using Royal Mail and were delivered without the recipient being required to provide a signature. The service informed us that there had been eight incidents where patients had contacted them because they had not received their medicines; however, these incidents had not prompted the service to amend their dispensing arrangements.

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 that 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. There was a lack of process in place to verify the identity of an individual when they contacted the service by phone, and therefore there was a risk that confidential patient information could be disclosed to a third party without the patient's knowledge or consent.

Management and learning from safety incidents and alerts

There were no formal systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. The service reported that they had recorded no significant events since they began treating patients; however, we noted events, such as patients failing to receive their order of medicines, which should have been recorded.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was not providing an effective service in accordance with the relevant regulations.

Assessment and treatment

The service carried-out some assessment of patients' suitability for the Polypill programme using a questionnaire which asked questions about the patient's general health and included some specific health questions intended to mitigate the risks associated with the prescribing of Polytor (the medicine prescribed as part of the Polypill programme). For example, two of the medicines which made up Polytor (Losartan and Hydrochlorothiazide) can affect patients' renal function. The patient questionnaire asked patients whether they had impaired kidney function which required dialysis, and we were told that if a patient reported that they did, they would not be accepted onto the programme.

The clinicians providing the service did not fully appreciate the risks associated with providing a service remotely. For example, they did not engage with patients' registered GPs in order to gather information to inform decision-making about whether a patient was suitable for the programme, and they had not considered how they would safely assess a patient's capacity to consent to treatment.

The service did not monitor prescribing decisions. We viewed five examples of patient records and found that in one of these there was insufficient information contained in the record to explain the grounds for a prescribing decision (the patient had been accepted onto the programme outside of the usual age limit), and in one there was no record of the identity of the person who had spoken to the patient about clinical issues.

Quality improvement

The service had not undertaken any monitoring of patients' care and treatment outcomes.

Staff training

There was no formal induction training in place for staff and the service did not require staff to undertake any regular training, nor did they maintain a record of training staff undertook whilst working for other organisations.

Administration staff were not formally employed by the service, and therefore did not receive performance reviews. The service did not carry-out appraisals of the prescribing doctor, and there was no evidence that they had satisfied themselves that the prescribing doctor had received an appraisal externally. The prescribing doctor was a training grade doctor in the NHS.

Coordinating patient care and information sharing

When a patient initially registered for the service, they were asked if the service could inform their registered GP that they were participating in the Polypill programme. If patients agreed, the service would write to their registered GP to inform them that the patient had been prescribed an initial supply of medicines; however, this letter did not make clear that the patient would be participating in a long-term programme. Where patients did not consent to their information being shared, the service did not engage with the patient to explain the benefits of information sharing or to conduct an assessment of whether it would be in the patients' best interest for the medicines to be prescribed.

The service did not engage with patients' GPs in order to gather information about the patient for the purpose of ensuring that they were suitable for the Polypill programme; for example, they did not consider it necessary or useful to request information that GPs may hold about the results of any biochemical tests which the GP may have held.

Supporting patients to live healthier lives

The provider made it clear to patients that in addition to participation in the Polypill programme, patients should take steps to maintain a healthy lifestyle. Advice on topics such as healthy eating, exercise and smoking cessation were available on the Polypill website.

Are services caring?

Our findings

We found that this service was not providing a caring service in accordance with the relevant regulations.

Compassion, dignity and respect

The service had a confidentiality policy in place which set out expectations and processes in place to keep information secure; however, they had not taken appropriate steps to ensure that the policy was followed. For example, the policy stated "There is a Confidentiality clause in the contract of all staff"; however, we found an example of an employee who had not signed a formal contract with the service. We were also told that the administrative staff working for the service were not employees and that they did not have contracts in place to work for the service, but these members of staff had access to confidential patient information. The confidentiality policy further stated that senior managers "must ensure that training is provided for all staff groups to further their understanding of the principles [of the confidentiality policy] and their application." We were told that the service had not provided training to staff in this area.

Involvement in decisions about care and treatment

The GMC's prescribing guidance ("Good practice in prescribing and managing medicines and devices (2013)") recommends that where a patient is prescribed a medicine which is unlicensed, providers should make patients aware of this and advise them on the implications of taking an unlicensed medicine. The medicine prescribed as part of the Polypill programme (Polytor) was unlicensed; in the email sent to the patient, informing them that they were suitable for the programme, the provider stated that the medicine prescribed in the preparation offered was unlicensed; however, there was no explanation of the implications of this for the patient.

Patient information guides about how to use the service and technical issues were available. There were administrative staff assigned to respond to any enquiries.

Patients had access to information about the clinicians working for the service. Language translation services were available where needed.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was providing a responsive service in accordance with the relevant regulations.

Responding to and meeting patients' needs

Patients accessed the service via the Polypill Ltd 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 two months' supply of medicine was issued, which was sent to the service's associated pharmacy who sent the medicines to the patient by post. The service contacted patients by email when they were due a repeat prescription. In order to request a further supply of the medicine, patients completed a further online questionnaire, which was reviewed by a 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 a doctor if the query was of a clinical nature.

Tackling inequity and promoting equality

The provider made the programme available to anyone who met the clinical eligibility criteria and paid the appropriate fee, and did not discriminate against any client group.

Patients could access a brief description of the clinicians available.

Managing complaints

There was information about how to make a complaint on the service's website. 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.

The service had not received any formal complaints; however, they had kept a record of feedback and suggestions from patients and we saw evidence that these had been discussed in a meeting. We were provided with examples of the service acting on feedback from patients; for example, following comments from patients about the repeat prescription reminder emails, the service had changed the timescales for sending these.

Consent to care and treatment

There was clear information on the service's website with regards to how the service worked and what costs applied 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 the service with any enquiries. Patients paid for two months' supply of medicines each time they requested a repeat prescription.

The service had not provided training about the Mental Capacity Act 2005 or ensured that staff had received this training elsewhere; the prescribing doctor told us that she had received some training in the area as part of her NHS role. Patients confirmed that they consented to treatment by ticking a box on the online questionnaire competed prior to treatment. The service's consent policy stated that patients would be 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 service's policy stated that where there were concerns about a patient's capacity to consent, the patient should be contacted in order for a more detailed assessment to be made. Where there were serious concerns about a patient's wellbeing, we were told that the service would consider contacting the patient's registered GP; however, it was not mandatory for patients to provide details of their GP, and the service did not have alternative arrangements in place for escalating concerns about a patient where they did not have details of their registered GP.

Are services well-led?

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

Our findings

We found that this service was not providing a well-led service in accordance with the relevant regulations.

Business Strategy and Governance arrangements

The provider told us they had a vision to develop and expand their service in order to provide a high quality service; however, in some areas governance arrangements were insufficient. For example, the service had not followed its own policies in relation to staff recruitment and information security. We reviewed the service's business plan, which briefly set out ways in which the business wanted to develop; however, this did not include details such as areas of responsibility or deadlines for actions to be completed.

The organisational structure was unclear with regards to the two members of administrative staff; these individuals were employed by a company of which the Managing Director of Polypill Ltd was also a director, and did not have a contract of employment with Polypill Ltd.

There was a range of service specific policies; however, all of the clinical staff worked remotely and policies were only available at the service's office.

The service did not have any system of regular checks in place to monitor the performance of the service or of individual members of staff.

There were some arrangements for identifying, recording and managing risks, issues and implementing mitigating actions. However, in some areas insufficient arrangements were in place to ensure that the service provided to patients was safe and effective; for example, in relation to sharing information with patients' registered GPs, safeguarding and ensuring fit and proper persons were employed.

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 systems in place to address any absence of this clinician.

The service had an open and transparent culture. We were told that 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 that patient information was stored securely using a secure IT system; however, the service had failed to enforce its own confidentiality policy in relation to providing staff with appropriate training in how to keep patient information secure. The service could not always 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 (ICO); however, in relation to the Data Protection Act, the service was unclear about implications of administrative staff, who were not employed by the service, having access to patient data and the need to clarify this with the ICO was raised during the inspection.

The service did not have arrangements in place to ensure that patient records could be retained for the required length of time should they cease to trade.

Seeking and acting on feedback from patients and staff

There was no formal process for patients to provide feedback on the service; however, we saw evidence of the service recording and discussing feedback provided by patients and of changes being made as a result; for example, the timescales for contacting patients to prompt them to re-order their medicines were revised following patient feedback.

We were told that the prescribing doctor had been involved in the testing of the service's IT system during the development stage in order to provide feedback from a user point of view.

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 was restricted to a small number of patients at the time of the inspection, as they had experienced

Are services well-led?

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

difficulties in the supply of the single Polytor tablet and had decided not to accept any new patients onto the programme until a new supplier was in place (as an interim measure, existing patients were being prescribed the four medicines which made up Polytor in three separate tablets). The service was in the process of identifying a reliable supplier of Polytor and planned to expand the business once this supply had been established.

This section is primarily information for the provider

Enforcement actions

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 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met:** **Systems and processes had not been established and operated effectively to ensure compliance with Regulation 17. In particular:** • The provider had failed to monitor the use of policies to ensure their efficacy; for example, staff were not aware of the service's safeguarding policy, and the recruitment and confidentiality policies were not being followed. • The provider had failed to ensure that arrangements were in place to allow safeguarding concerns relating to vulnerable patients to be escalated. • The service's process of checking whether patients had mental capacity to consent to treatment were not sufficient. • The provider had failed to ensure that operating policies were available to staff at all times whilst they were working for the service. • The service had not carried out any activity to monitor the quality and effectiveness of the service. • The provider had failed to put in place arrangements to share information with patients' registered GPs in line with GMC guidance, both in informing GPs of the treatment provided to patients and in gathering information from GPs to inform prescribing decisions. • The provider had failed to ensure that GMC guidance was followed with regards to making patients aware that the medicine they are being prescribed was unlicenced. • The provider had failed to ensure that processes in place for recording significant events were sufficient to allow all safety incidents to be recorded and addressed.

This section is primarily information for the provider

Enforcement actions

- The provider had failed to undertake appropriate pre-employment checks to ensure that fit and proper persons were employed.
- The provider had failed to ensure that arrangements were in place to support and review the performance of the prescribing doctor.
- The provider had failed to ensure that all patient records contained details of the person making the record and the rationale for treatment and prescribing decisions.
- The provider had failed to ensure that arrangements were in place to store patient records for the required length of time should they cease to trade.

This was a breach of regulation 17 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Good governance.