

# Polypill Limited

# Alto House

## Inspection report

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### Overall summary

Letter from the Chief Inspector of General Practice

Previous inspection February 2018 when the service was found to be not meeting some areas of the regulations.

We carried out an announced focused inspection at Polypill (Alto House) on 30 August 2018 to follow up on breaches of regulations. During this inspection we looked at the key questions: is the service safe, effective, caring and well led.

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 providing a safe service in accordance with the relevant regulations. Specifically:

- Arrangements were in place to safeguard people, including arrangements to check patient identity.

- Suitable numbers of staff were employed and appropriate background information about current staff had been obtained and recorded.
- Risks were assessed and action taken to mitigate any risks identified.

Are services effective? – we found the service was providing an effective service in accordance with the relevant regulations. Specifically:

- Information was appropriately shared with a patient's own GP in line with GMC guidance in cases where the patient consented to this. When the patient did not provide this consent, the service did not follow GMC guidance, as they did not explore the reasons why the patient did not want their GP to know about their participation in the programme or explain the benefits of information sharing. During the inspection the service committed to developing a process to achieve this.
- Quality improvement activity, including clinical review of prescribing decisions, took place.
- Staff received the appropriate training to carry out their role.

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

- The provider carried out checks to ensure consultations by clinicians met the expected service standards.

# Summary of findings

- Appropriate arrangements were in place to protect confidential patient information.

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

- The service had clear leadership and governance structures
- A range of information was used to monitor and improve the quality and performance of the service.
- Patient information was held securely.

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

- Develop and implement processes, in line with GMC guidance, for communicating with patients who choose not to consent to information about their participation in the programme being shared with their registered GP.
- Amend their process for identifying impaired kidney function in prospective patients.

**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 that this service was providing safe care in accordance with the relevant regulations.

### **Are services effective?**

We found that this service was providing effective care in accordance with the relevant regulations.

### **Are services caring?**

We found that this service was providing caring services in accordance with the relevant regulations.

### **Are services well-led?**

We found that this service was providing well-led care in accordance with the relevant regulations.

# Alto House

## Detailed findings

## Background to this inspection

### Background

Polypill is an online health programme whose aims are to contribute to 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.

### How we inspected this service

This inspection was carried out on 30 August 2018 by a lead CQC inspector, a second CQC inspector and a GP specialist advisor.

Following the previous inspection of the service in February 2018 the service submitted an action plan, outlining how they planned to address breaches of regulation and areas identified for improvement. This action plan was reviewed and formed the basis for the re-inspection of the service. During this inspection we spoke to the Registered Manager, prescribing doctor and members of the management and administration team.

During this inspection we looked at the key questions: is the service safe, effective, caring and well led.

### Why we inspected this service

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

# Are services safe?

## Our findings

During the previous inspection in February 2018 we found that the service was not providing safe care in accordance with the relevant regulations, as insufficient arrangements were in place to safeguard people, the service had failed to ensure that staff were recruited and supported appropriately, and the service had failed to make patients aware of the implications of taking a medicine outside of the terms of its licence.

We issued a Warning Notice in respect of these issues and the service submitted an action plan, outlining the action they would take to comply with regulations. We found arrangements had improved when we undertook the follow up inspection of the service in August 2018, and the service was now compliant with the relevant regulations.

### Keeping people safe and safeguarded from abuse

At the previous inspection in February 2018 we found that not all staff were aware of the service's safeguarding procedure and that the procedure was not available to staff working remotely. We also found that not all staff had received training in identifying and escalating safeguarding concerns.

When we returned to the service in August 2018 we saw evidence that all clinical staff had received training in general safeguarding principles, which covered areas relating to both children and vulnerable adults. At the time of the first inspection, members of the administrative team had not completed safeguarding training, and we were told that this was because they rarely had direct contact with patients. However, the service had identified patients' ability to navigate their website as forming part of the assessment of whether patients had capacity to consent to treatment; as queries about the use of the website were dealt with by the administrative staff, we discussed with the service the need for these members of staff to have an understanding of safeguarding principles and processes. Following the inspection the service immediately arranged for these staff members to complete a relevant online training module and provided us with evidence of completion.

During the follow-up inspection we also found that the service had made all procedures, including safeguarding procedures, available to staff online via a secure portal.

### Monitoring health & safety and responding to risks

During the previous inspection in February 2018 we found that the service had failed to ensure that all staff were familiar with the service's patient confidentiality policy. When we returned to the service in August 2018 we found that the confidentiality policy was available to all staff via the secure online portal, and that all staff had confirmed that they had read the policy.

During the previous inspection we found that there were no formal arrangements in place for staff to meet to discuss issues such as significant events, complaints and other issues relating to the service. When we returned to the service in August 2018 we saw evidence that the service had put in place quarterly staff meetings to discuss these issues, as well as to discuss clinical issues.

### Staffing and Recruitment

During the inspection in February 2018 we found that the service's recruitment policy did not specify which pre-employment checks would be carried-out. We also found that the policy had not been followed in respect of the prescribing doctor, as we were told that she was already known to members of the management team.

When we returned to the service in August 2018 we saw evidence that the service had revised their recruitment policy to specify exactly what background checks they would make prior to appointing a new member of staff. We also saw evidence that they had completed background checks retrospectively on the prescribing doctor and put in place a process of annual appraisals for them. There had been no further staff appointments since the last inspection.

### Prescribing safety

During the previous inspection we found that there had been eight incidents where patients had contacted the service because they had not received their medicine delivery. When we returned to the service in August 2018 we found that the service had liaised with the dispensing pharmacy about this issue, and following this a different member of staff had been put in charge of dispatch, which had resulted in no further failed deliveries.

### Information to deliver safe care and treatment

During the previous inspection in February 2018 we found that there was a lack of process in place to verify the

## Are services safe?

identity of an individual when they contacted the service by phone. When we returned to the service in August 2018, we saw evidence that all staff had read the service's confidentiality policy, and there was therefore a better understanding of confidentiality issues. Staff taking phone calls were able to cross-check information provided by the caller against information held about patients on their patient records system in order to verify identity.

### **Management and learning from safety incidents and alerts**

During the previous inspection in February 2018 we found that there was no formal system in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. When we returned in August 2018 we saw evidence that all staff had been made aware of how to report a safety incident, and the incident reporting form was available to all staff via the online secure portal. We saw evidence that the service had made discussions about significant events a standing item on the agenda for their quarterly governance meetings. There had not been any significant events recorded since the last inspection.

# Are services effective?

(for example, treatment is effective)

## Our findings

During the previous inspection in February 2018 we found that the service was not providing effective care in accordance with the relevant regulations, as the service had failed to follow GMC guidance in respect of sharing information with patients' registered GPs, there was no evidence of quality improvement activity, and there was no formal process in place to assess patients' capacity to consent to treatment.

We issued a Warning Notice in respect of these issues and the service submitted an action plan, outlining the action they would take to comply with regulations. We found arrangements had improved when we undertook the follow up inspection of the service in August 2018, and the service is now compliant with the relevant regulations.

### Assessment and treatment

During the previous inspection in February 2018 we found that the clinicians providing the service did not fully appreciate the risks associated with providing a service remotely, as 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. In particular, two of the medicines which made up the treatment can affect patients' renal function, but the patient questionnaire only asked prospective patients whether they had impaired kidney function which required dialysis. We discussed this with the service during the inspection in August 2018, and the provider agreed that they would amend their questionnaire to ask prospective patients whether they had ever had an abnormal result from a test of their kidney function, and if they responded that they had, they would contact the patient by telephone to clarify the history.

During the previous inspection we found that the service had not considered how they would safely assess a patient's capacity to consent to treatment. When we returned to the service, we were told that the service had considered how they could establish whether a patient had the mental capacity to consent to treatment, and had identified specific behavioural indicators which would prompt them to speak to the patient to explore their

capacity in more detail. We saw evidence that these indicators had been embedded within their policy, and that staff had a good understanding of the process and their responsibilities in relation to it.

### Quality improvement

During the initial inspection in February 2018 we found that the service had failed to undertake any monitoring of patients' care and treatment outcomes. When we returned to the service in August 2018 we saw evidence that the service had put processes in place to discuss clinical issues, such as patient outcomes, in their quarterly governance meetings. We also saw evidence that the service had engaged directly with its patients to gather feedback about their experiences of using the service, via a feedback survey, and that the service had used the feedback to make improvements to the way that the programme was delivered.

### Staff training

During the initial inspection in February 2018 we found that there was no formal induction training available to new staff, the service did not keep a record of training undertaken by staff and they did not have in place a process to review the performance of staff employed.

When we returned to the service in August 2018 we found that the service had begun to maintain a record of training undertaken by staff, and that all staff had completed training relevant to their role with the exception of safeguarding training for administrative staff, which was completed immediately after the inspection. We also saw evidence that the prescribing doctor (the service's only direct employee) had received an appraisal which included a personal development plan, and we were told that the service intended to undertake staff appraisals annually.

### Coordinating patient care and information sharing

During the initial inspection in February 2018 we found that where patients gave their permission for the service to inform their registered GP that they were participating in the Polypill Programme, the service would write to the GP with this information; however, the standard letter sent to GPs did not make clear that the patient was participating in a long-term programme, rather than receiving a single prescription. When we returned to the service in August 2018 we saw evidence that they had amended the standard letter to make it clear that the programme was long-term.

# Are services effective?

(for example, treatment is effective)

We also found during the initial inspection that where patients did not consent to information about their participation in the scheme being shared with their registered GP, the service did not take further action to discuss this decision with them or explain the benefits of the information being shared. When we returned for the re-inspection we found that the service had amended their website to make it mandatory for patients to provide their GP's details when they applied to join the programme. Patients then separately stated whether they provided their

consent for details of their participation in the programme to be shared with their GP. However, the service still did not have a process for contacting patients who failed to give consent, in order to explain the benefits of sharing information with their GP and to explore the reasons why they were reluctant for the registered GP to know that they were participating in the programme. This was discussed with the service during the inspection and they undertook to review their position and process.



# Are services caring?

## Our findings

During the previous inspection in February 2018 we found that the service was not providing a caring service in accordance with the relevant regulations, as the service did not carry out checks to ensure consultations by clinicians met the expected service standards with regards to the care provided to patients, and they had failed to ensure that all staff were aware of, and agreed to, the service's confidentiality policy.

We issued a Warning Notice in respect of these issues and the service submitted an action plan, outlining the action they would take to comply with regulations. We found arrangements had improved when we undertook the follow up inspection of the service in August 2018, and the service was now compliant with the relevant regulations.

### Compassion, dignity and respect

During the initial inspection in February 2018 we found that the service had a patient confidentiality policy, but a review of staff files found that not all staff had signed to agree to comply with the policy, and the policy was not available to staff working remotely. We also found that administrative staff were not directly employed by the service, but were employed by a separate company, owned by one of the directors of the service; an informal arrangement was in place for these members of staff to undertake an administrative function for Polypill, but there was no formal contract in place, and therefore, these members of staff were under no contractual obligation to abide by Polypill's policies, including their confidentiality policy.

When we returned to the service in August 2018 we saw evidence that all directly employed staff had signed the confidentiality policy and the policy was available to all staff via the secure online portal. We also saw evidence that

a formal contract had been put in place in respect of the work undertaken for Polypill by the administrative staff, which included these staff members signing a confidentiality agreement.

During the initial inspection we saw no evidence that the service was taking action to ensure that interactions between staff and clinicians met the expected service standards. When we returned to the service we found that records of consultations were reviewed and discussed in quarterly clinical governance meetings.

### Involvement in decisions about care and treatment

Prior to the inspection in February 2018, the service had for a time been prescribing the four medicines which made up their heart disease and stroke prevention programme as a single tablet, which was unlicensed in the single tablet form but contained medicines which were all individually licenced; however, due to issues with the manufacture of the single tablet, they had begun to prescribe the medicines as three tablets (two medicines as individual tablets and two as a combined tablet, all of which were licenced). We reviewed the information provided to patients about the previously supplied single tablet and found that whilst patients were informed that the medicine was unlicensed in its single tablet form, there was no information about the risks and implications of taking an unlicensed medicine.

When we returned to the service in August 2018 we found that the service was still prescribing the medicines using the licensed three tablet format. They told us that they intended to prescribe the single tablet in the future once they had identified a suitable manufacturer, and that at that time they would ensure that patients were provided with the necessary information.

# Are services well-led?

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

## Our findings

During the previous inspection in February 2018 we found that the service was not well led, in accordance with the relevant regulations, as the service did not have clear leadership and governance structures, there were no systems in place to monitor and improve the quality and performance of the service, and the service had failed to ensure that its own policies were being followed in relation to recruitment and confidentiality.

We issued a Warning Notice in respect of these issues and the service submitted an action plan, outlining the action they would take to comply with regulations. We found arrangements had improved when we undertook the follow up inspection of the service in August 2018, and the service was now compliant with the relevant regulations.

### **Business Strategy and Governance arrangements**

During the initial inspection in February 2018 we found that the service had failed to follow its own recruitment procedure when recruiting their sole employee (the prescribing doctor), as they had not carried-out background checks and the doctor had not signed a formal contract of employment. When we returned to the service we found that they had retrospectively completed background checks on this member of staff, and that a signed contract was now in place. The service had not recruited any new staff since the previous inspection. During the previous inspection we also found that there was no formal contractual arrangement in place between the service and the administrative staff, who were not directly employed by the service, but were employees of a separate business which was owned by one of the directors of Polypill. When we returned to re-inspect, we saw evidence that a formal contract had been put in place, which included these members of staff agreeing to comply with the service's confidentiality policy.

During the initial inspection we had found that staff working remotely were unable to access policies and procedures. During the re-inspection we saw evidence that

a secure online portal had been created to allow staff to access policies, procedures and other resources, such as the significant event reporting form, whilst working remotely.

### **Safety and Security of Patient Information**

During the initial inspection we found that the service had failed to put effective systems in place to ensure that all patient records contained a clear audit trail. For example, in some of the patient records we viewed, there was no record of the identity of the person making the record. When we returned to the service we found that they had amended their patient records system to make it mandatory for staff members to record their name when making a note.

We had also found during the previous 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. When we returned to the service we saw evidence that appropriate arrangements, with a supporting contract, had been put in place for records to be stored by an associated and long-established company should Polypill cease to trade.

### **Seeking and acting on feedback from patients and staff**

During the initial inspection we found that there was no formal process for patients to provide feedback on the service. When we returned to the service we saw evidence that the service had run a patient survey. Staff we spoke to told us that they found the feedback they had received from patients useful, and the service had identified actions as a result, such as providing the option for patients to purchase either a three-month or a six-month supply of medicines.

### **Continuous Improvement**

The service demonstrated their commitment to improving patients' experience of using the service; for example, by continuing to source a manufacturer to produce a single tablet to deliver the four medicines prescribed by the programme, in response to patient feedback about this being easier.