Vir Health Limited

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Good
Are services safe?	Good
Are services effective?	Good
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 Good overall.

The key questions are rated as:

Are services safe? – Good

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Good

We carried out an announced comprehensive at Vir Health Limited on 15 & 17 March 2021 as part of our inspection programme and to provide a quality rating.

Vir Health Limited is a digital health service providing online consultations on a specified range of health conditions. It is a service aimed at adults; all patients must be over 18 years of age. It operates through the following website: www.numan.com

At this inspection we found:

- The service had good systems to manage risk so that safety incidents were less likely to happen. When they did happen, the service learned from them and improved their processes.
- The service routinely reviewed the effectiveness and appropriateness of the care it provided. It ensured that care and treatment was delivered according to evidence-based guidelines.
- 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 was a strong focus on continuous learning and improvement at all levels of the organisation.

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

- Improve the information available to patients before they request unlicensed medicines and ensure they acknowledge that they have seen and understood the information
- Improve the website to ensure that medicines without a product licence are described as unlicensed medicines, not as 'off-label' medicines which are licensed medicines used outside the terms of their product licence.
- Improve the information collected from patients with asthma to ensure that they limit the number of treatments prescribed prior to an annual review from a clinician trained in asthma management.
- Improve the sign-up process for the service to ensure patients are clear about the associated costs of prescriptions and that they are only prescribing the number of prescriptions they require.
- Improve the process of recording changes which patients have made in their responses to the questionnaires, so that clinicians can take that into account when deciding whether to prescribe.
- Improve the complaints process to include signposting to an arbitration complaints process.

Overall summary

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a specialist adviser and a member of the CQC medicines team.

Background to Vir Health Limited

Background

Vir Health is a digital health service providing online and telephone consultations on a specified range of health conditions. It is a service aimed at adults; all patients must be over 18 years of age. The service is mainly aimed at men's health addressing conditions affecting their self-esteem, confidence and lifestyle. The conditions treated are erectile dysfunction, hair loss and premature ejaculation with a combination of medical and non-medical products, supported by informational content that educates men around these issues. Other conditions treated are acid reflux and asthma as well as smoking cessation treatment which are available to both men and women.

People sign up for the service through the provider website, they complete online questionnaires which are reviewed by pharmacist independent prescribers with the support of the chief medical officer and the lead GP. Prescriptions are dispensed by a partner pharmacy and delivered to patients. Patients can also purchase blood test kits which are sent to an independent laboratory for screening. GP consultations following a blood test are provided to patients by a third party.

There are 12 pharmacist independent prescribers with clinical oversight provided by a lead GP and the chief medical officer. There is a management and administration team and a customer services team.

The provider is registered with the CQC to carry out the following Regulated Activities: Transport services, triage and medical advice provided remotely and treatment of disease, disorder or injury.

Vir Health Limited has a registered manager in place. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

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, chief medical officer, lead GP, two pharmacist independent prescribers and members of the management and administration team.

We also reviewed remotely specific documentation including policies and audits. (In light of the current Covid-19, CQC has looked at ways to fulfil our regulatory obligations, respond to risk and reduce the burden placed on practices by minimising the time inspection teams spend on site. In order to seek assurances around potential risks to patients, we are currently piloting a process of remote working as far as practicable. This provider consented to take part in this pilot and some of the evidence in the report was gathered without entering the practice premises).

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.

Good

Are services safe?

We rated safe as Good because:

- The service provided care in a way that kept patients safe and protected from avoidable harm.
- The service had clear systems to manage risk so that safety incidents were less likely to happen. When incidents did happen the service learnt from them.
- The service prescribed medicines in a safe way although we did identify some areas for improvement in relation to medicine management.

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 and where to report a safeguarding concern. The lead GP and pharmacists had received adult safeguarding training. It was a requirement for the pharmacists registering with the service to provide evidence of up to date safeguarding training certification.

The service did not treat children and safeguards were in place to ensure patients were over 18.

Monitoring health & safety and responding to risks

The supporting team carried out a variety of checks either daily or weekly. These were recorded and formed part of a clinical team weekly report which was discussed at clinical meetings.

The provider headquarters was located within modern offices which housed the IT system and a range of administration staff. Patients were not treated on the premises as pharmacists carried out online consultations remotely; usually from their home. All staff based in the premises had received training in health and safety including fire safety.

The provider expected that all pharmacists would conduct online consultations in private and maintain patient confidentiality. Pharmacists had access to the operating system via secure log in details. They were required to complete a home working risk assessment to ensure their working environment was safe.

There were processes in place to manage any emerging medical issues during a telephone consultation and for managing test results. The service was not intended for use by patients as an emergency service.

Risks identified during completion of the consultation questionnaire were flagged for review by the pharmacist.

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 a significant incident, clinical pathways in line with national guidance and a safeguarding concern.

Staffing and Recruitment

There were enough staff, including pharmacist independent prescribers, to meet the demands for the service and there was a rota for the pharmacists. There was a support team available to the pharmacists during consultations and a separate IT team. The prescribing pharmacists were paid on a sessional basis.

Good

Are services safe?

The provider had a selection and recruitment process in place for all staff. There were a number of checks that were 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 GPs had to be currently working in the NHS and be registered with the General Medical Council (GMC) with a license to practice. They had to provide evidence of having professional indemnity cover, an up to date appraisal and certificates relating to their qualification and training in safeguarding and the Mental Capacity Act. Potential pharmacist employees had to be registered with the General Pharmaceutical Council (GPhC) with an independent prescriber qualification for those employed as prescribers.

Newly recruited pharmacists were supported during their induction period and an induction plan was in place to ensure all processes had been covered. We were told that pharmacist independent prescribers only worked on consultations for conditions within their competence.

We reviewed three recruitment files which showed the necessary documentation was available. The pharmacists 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 lead GP and pharmacists and there was a system in place that flagged up when any documentation was due for renewal such as their professional registration.

Prescribing safety

The service offered treatment for a limited range of conditions. All medicines prescribed to patients from online forms were monitored by the provider to ensure prescribing was evidence based. If a medicine was deemed necessary following a consultation, the pharmacist independent prescriber could issue a private prescription. Prescribers told us that they would contact the patient, usually by email, for further details if needed. We saw that they did not issue a prescription if the patient did not provide information to satisfy the prescriber that it was safe to proceed. When completing the online consultation form, if a patient gave a response which meant it was not suitable to prescribe for them, they were shown a message asking whether they had made a mistake and allowing them to go back and change their response. If a patient did change their response this was flagged as a risk on their consultation form but the prescriber did not have access to the specific answers which had been changed.

The pharmacists could only prescribe from a set list of medicines which the provider had risk-assessed. There were no controlled drugs on this list. The service did not provide emergency supplies of medicines. The service prescribed a limited range of antibiotics to treat peptic ulcers, based on test results.

The service was based on the provision of treatment plans. Patients paid a monthly subscription for information and advice relating to their condition and a regular prescription which was dispensed by the affiliated pharmacy. The number of repeat prescriptions was determined by the prescriber, based on information supplied by the patient in the consultation questionnaire. Once the pharmacist prescribed the medicine and dosage of choice, 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. They were also informed of the number of times the prescription would be repeated. Patient feedback showed that they did not always realise that they were agreeing to a monthly subscription for repeat prescriptions. The provider told us that they had reviewed the information provided to patients to make this clearer.

Good

Are services safe?

One of the conditions patients were able to request medicines for was asthma, a long term condition which requires regular monitoring. Prescriptions were only issued if the patient agreed that the service could share this information with their regular GP. The information provided by patients in the consultation questionnaire led to an asthma control score. Patients with a low score were advised to contact their GP, and a prescription was not issued. Patients with a score which indicated well controlled asthma were issued up to twelve repeat prescriptions, with a three-monthly check. After twelve months the patient could complete another questionnaire and based on the asthma control test score, the pharmacist could authorise another treatment plan of up to twelve months. There was no process to check that the patient had been reviewed at least annually to include a measurement of peak flow and an assessment of inhaler technique.

The service prescribed some unlicensed medicines, for example for the treatment of hair loss and premature ejaculation. Medicines are given licences after trials have shown they are safe and effective for treating a particular condition. Use of a medicine which does not have a product licence is a higher risk because less information is available about the benefits and potential risks. There was information on the website to explain the use of medicines outside their product licence, but it did not make clear that these medicines did not have a product licence. It was not made clear in the questionnaire or the information sent to the patient before ordering, and there was no record to confirm that patients had acknowledged that they understood this information. Additional written information to guide the patient when and how to use these medicines safely was supplied with the medicine.

If a patient requested a new medicine when they had repeat prescriptions outstanding for a similar medicine, the prescriber would contact them to find out the reason for the request. If for example it was because the patient wanted a different dose, the first subscription would be cancelled so there was no duplication.

There were protocols in place for identifying and verifying the patient and General Medical Council guidance, or similar, was followed.

All medicines were supplied by a partner pharmacy. Prescriptions were transmitted to the pharmacy using a system which met the requirements of the Human Medicines Regulations in relation to electronic signatures. The service had a system in place to assure themselves of the quality of the dispensing process.

Information to deliver safe care and treatment

On registering with the service, and at each consultation patient identity was verified. The pharmacists had access to the patient's previous records held by the service.

Management and learning from safety incidents and alerts

There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. We reviewed three incidents and found that these had been fully investigated, discussed and as a result action taken in the form of a change in processes. For example, one incident was about a medicine that was requested fraudulently in the name of another person. A detailed investigation was undertaken and action taken to minimise the risk of similar incidents reoccurring. Learning from incidents was communicated to staff at team meetings and this was confirmed in the meeting minutes we reviewed.

We saw evidence from incidents which demonstrated 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.

Good

Are services safe?

There were systems in place to ensure that the correct person received the correct medicine.

Patient safety alerts were cascaded to the clinical team by the chief medical officer and we were shown evidence to confirm this. We were also shown records of the action taken in response to recent patient alerts.

Good

Are services effective?

We rated effective as Good because:

- Care was delivered in line with relevant and current evidence-based guidance.
- The service demonstrated quality improvement activity.
- Staff received support and training to carry out their roles effectively.
- The service sought patient consent appropriately.

Assessment and treatment

We were told that each prescriber 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.

Patients completed an online form which included their past medical history and details relevant to the condition they were requesting treatment for. Each questionnaire was reviewed by a pharmacist independent prescriber. There was a set template to complete for the consultation that included the reasons for the consultation and the outcome to be manually recorded, along with any notes about past medical history and diagnosis.

The pharmacists 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. If a patient needed further examination they were directed to an appropriate agency. 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 consultation and prescribing audits to improve patient outcomes. A sample of 25 consultation records was reviewed each month to ensure that the prescriber records the reasons for rejecting a request, and that correspondence with the patient was of appropriate quality.

Quality improvement

The service collected and monitored information on patients' care and treatment outcomes.

- The service used information about patients' outcomes to make improvements.
- The service took part in quality improvement activity, for example audits, reviews of consultations and prescribing trends.
- The service carried out an audit in December 2020 on prescribing for hair loss which resulted in a change to the standard operating procedure.
- The service carried out an audit in November 2020 to assess treatment compliance for smoking cessation, assess the quality of communication and identify any new approaches to improving outcomes.
- The service carried out an audit in August 2020 to give assurance that third party GP consultations were meeting the services quality requirements which showed an 85% compliance. The audit identified several areas for improvement.

Staff training

Good

Are services effective?

All staff completed induction training which consisted of health and safety training and role specific training. Staff also completed other training on a regular basis which included safeguarding, medical emergencies, information governance, equality and diversity, mental capacity act and complaints handling. The service manager had a training matrix which identified when training was due.

The lead GP and pharmacists registered with the service received specific induction training prior to treating patients. An induction log was held in each staff file and signed off when completed.

The pharmacists told us they had access to support from a duty doctor and other pharmacists at all times if there were any technical issues or clinical queries. Cases were reviewed at fortnightly meetings.

Administration staff received regular performance reviews. The GP had to have received their own appraisals before being considered eligible at recruitment stage.

Coordinating patient care and information sharing

Before providing treatment, pharmacists at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history, based on information provided by the patient. We saw examples of patients being signposted to more suitable sources of treatment where this information was not available to ensure safe care and treatment.

All patients were asked if they wished to consent to sharing details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service. The provider had risk assessed the treatments they offered. They had identified medicines that were not suitable for prescribing if the patient did not give their consent to share information with their GP, or they were not registered with a GP. For example, those for the treatment of asthma. Where patients agreed to share their information, we saw evidence of letters sent to their registered GP in line with GMC guidance.

Supporting patients to live healthier lives

In their consultation records we found patients were given advice on healthy living as appropriate, for example a patient prescribed medicine for acid reflux was given advice on diet and smoking. Patients who were prescribed the stop smoking treatment plan were offered a 30 minute 'Kick Off' consultation with a pharmacist and were sent emails, texts and offers of further telephone support throughout the programme.

Good

Are services caring?

We rated caring as Good because:

- Patient satisfaction was generally positive in relation to caring aspects of the service.
- The service had achieved 4.2 out of 5 stars based on 6,059 online reviews with 73% rating the service as excellent.
- Where feedback was negative, the provider had responded to the concerns.

Compassion, dignity and respect

We were told that the prescribing pharmacists undertook online consultations in a private room and were not to be disturbed at any time during their working time. The provider carried out regular audits to ensure the prescribing pharmacists were complying with the expected service standards and communicating appropriately with patients. Feedback arising from these audits was relayed to the clinician. Any areas for concern were followed up and the prescribing pharmacist was again reviewed to monitor improvement.

We spoke to one patient on the day of the inspection who told us they were treated with dignity and respect. We also reviewed online feedback from people who had used the service and did not note any common themes in relation to patients not being treated with compassion, dignity and respect.

Involvement in decisions about care and treatment

Patient information guides about how to use the service and technical issues were available. There was a dedicated customer services team to respond to any enquiries.

The clinical staff available could speak a variety of different languages to support patient involvement in decisions about care and treatment where their first language was not English.

Online feedback we reviewed showed that patients were satisfied with the explanation of their condition.

Patients could request information about themselves including consultation history only if they made a written request to the provider. Requests were dealt with by the data protection officer in line with General Data Protection Regulation (GDPR) requirements.

Good

Are services responsive to people's needs?

We rated responsive as Good because:

- Patients could access consultations at a time that suited them.
- Complaints were handled in a timely way and the service learnt from them.
- Consent to care and treatment was sought by the provider

Responding to and meeting patients' needs

Patients signed up to receiving this service via the providers website. The service offered flexibility in that access was 24 hours a day, seven days a week (consultations were provided seven days a week from 6am to 12am, but access via the website to request a consultation through completing an online questionnaire was all day every day.)

All pharmacist independent prescribers were required to be based within the United Kingdom. The provider's website allowed people to contact the service from abroad but they did not supply medicines outside of the UK. The patient had to confirm their UK address which was verified as part of the identity checks.

The provider made it clear to patients what the limitations of the service were.

Tackling inequity and promoting equality

The service was primarily offered to males over the age of 18 as most conditions and treatments were specific to this client group. The provider did not discriminate in relation to the maximum age of a client and some treatments such as those for asthma, acid reflux and smoking cessation were offered to females.

All staff had received training in equality and diversity and 22 different languages were spoken amongst staff. Therefore, the service could respond to the communication needs of patients whose first language was not English.

Managing complaints

Information about how to make a complaint was available on the service's web site. 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 the recording of complaints has been developed and introduced for use. We reviewed the complaint system and noted that comments and complaints made to the service were recorded. We reviewed three complaints out of 12 received in the past 12 months.

The provider was able to demonstrate that 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. However, we found a lack of signposting to an arbitration complaints process. The provider told us they would consider this.

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

Good

Are services responsive to people's needs?

conditions and details on how the patient could contact them with any enquiries. However, we noted a common theme with patient feedback that patients were not always clear whether they were signing up for a one-off payment or subscription service. The provider told us that they had reviewed online processes to make this clearer to patients and were continually improving transparency in relation to payments.

All pharmacist independent prescribers and the lead GP 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.

Good

Are services well-led?

We rated well-led as Good because:

- The leadership, governance and culture were used to drive and improve the delivery of care and treatment provided.
- There were effective systems to monitor risk and the quality of service provided.
- The provider sought and acted on feedback from patients and staff.

Business Strategy and Governance arrangements

The provider told us they had a clear vision to work together to provide a high quality responsive service that put caring and patient safety at its heart. We reviewed business plans that covered the next 12 months. The business plans covered the providers strategic direction including priorities and focus for 2021.

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 a variety of daily, weekly and monthly checks in place to monitor the performance of the service. These included random spot checks for consultations. The information from these checks was used to produce a clinical weekly team report that was discussed at weekly team meetings. This ensured a comprehensive 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 chief medical officer had responsibility for any medical issues arising. They attended the service seven days a week. A lead GP was available on an on-call basis seven days a week for any clinical advice. Third party GPs were also available to the pharmacist independent prescribers if they required any specific clinical advice. There were systems in place to address any absences to ensure effective clinical oversight.

The values of the service were stated in the business plan. The values included treating people with empathy and with dignity and respect.

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. This was supported by an operational policy.

Safety and Security of Patient Information

Systems were in place to ensure that 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. Both the service and the clinicians were registered with the Information Commissioner's Office. There were business contingency plans in place to minimise the risk of losing patient data.

Good

Are services well-led?

Seeking and acting on feedback from patients and staff

Patients could rate the service they received. This was constantly monitored and if it fell below the provider's standards, this would trigger a review of the consultation to address any shortfalls. In addition, patients were emailed at the end of each consultation with a link to a feedback form they could complete. Twenty-eight days after a consultation patients were also encouraged to leave online feedback on Trustpilot and quarterly surveys were sent out to patients. The saw evidence that the provider compiled a monthly patient satisfaction report to monitor and act upon patient feedback. Improvements made to the service as a result of patient feedback included improvements to the prescription delivery service and the implementation of a help centre on the provider website which included frequently asked questions to help patients understand what they were signing up for.

There was evidence that the pharmacists 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. The minutes of the Clinical Governance meetings showed that points raised by prescribers were discussed and prescribing guidance was updated where appropriate.

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 chief medical officer 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.

We saw from minutes of staff meetings where previous interactions and consultations were discussed.

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

There was a quality improvement strategy and plan in place to monitor quality and to make improvements, for example, through quality improvement initiatives. These included the development of clinical tools to better store all information and events relating to a particular patient, and systems to support safer decision making for prescribers by capturing more information up front on higher risk patients.