SH24 C.I.C.

SH:24

Inspection report

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Ratings

Overall rating for this service

Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced comprehensive inspection at SH:24 on 12 July 2017.

SH: 24 is a community interest company that aims to improve access to sexual and reproductive health care through the provision of online sexual and reproductive health services. The services include testing for HIV, syphilis, chlamydia and gonorrhoea and the prescription of oral contraceptives and treatment of chlamydia.

Overall, we found this service provided effective, caring, and responsive and well led services in accordance with the relevant regulations; however, we identified some areas relating to the safe provision of services where the provider must make improvements.

Our key findings were:

- The service did not have processes in place to verify service user age to fulfil the age limitation requirements for all users.
- There were systems in place to mitigate safety risks including analysing and learning from significant events and safeguarding.
- The provider was aware of and complied with the requirements of the Duty of Candour.

Summary of findings

- There were appropriate procedures in place in relation to the recruitment of staff.
- An induction programme was in place for all staff and we saw evidence where staff had received specific induction training.
- Service users were treated in line with best practice guidance and appropriate medical records were maintained.
- Information about services and how to complain was available. We found the systems and processes in place to manage and investigate complaints were effective.
- There was a comprehensive business plan with detailed short term and long term plans to improve service.
- The service encouraged and acted on feedback from both patients and staff. Survey results showed that service users were very satisfied with the service as they rated the service 4.93 stars out of 5 for ease of access, rapidity of service and availability of support.
- The service had a programme of ongoing quality improvement activity. It was a research led service and findings were implemented to improve service and user outcomes.

We saw one area of notable practice:

- The service was research led and could demonstrate publication in peer reviewed journals where findings were shared with others nationally. Findings were implemented to improve service and user outcomes.
- The service provided numerous information videos and blogs to improve patient outcomes. For example, there was a link to a video on blood taking for STI testing. The return rate for tests involving blood samples ranged between 78% and 96% (depending on geographical region). The return rate of the National HIV Testing Programme was 51% which was the best comparator in the absence of a national comparator.

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

- Ensure arrangements are put in place to verify service user age to fulfil the age limitation requirements.

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 in one area this service was not providing safe services in accordance with the relevant regulations.

- The service did not have processes in place to check the identity of users. The service had recognised the risk and was making arrangements to access the NHS patient record system which would allow it to identify most users accessing the service. The service was given a timeframe of four to six weeks at the time of the inspection by NHS Digital.
- All staff had received safeguarding training appropriate for their role. All staff had access to local authority information if safeguarding referrals were necessary.
- There were enough clinicians to meet the demand of the service and appropriate recruitment checks for all staff were in place.
- The service had a business contingency plan.
- Prescribing was constantly monitored and the service's system flagged any contraindications for follow up to mitigate any risks.
- There were systems in place to meet health and safety legislation and to respond to risk.
- There were systems in place for identifying, investigating and learning from incidents relating to the safety of service users and staff members. The service was aware of and complied with the requirements of the Duty of Candour and encouraged a culture of openness and honesty.

Are services effective?

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

- Review of service user requests demonstrated that each clinician assessed their needs and delivered appropriate treatment in line with relevant and current evidence based guidance and standards.
- Consent to care and treatment was sought in line with the provider's policy. Service users were asked to agree to the terms of conditions on the website during the order process as a way of seeking consent. All relevant staff had appropriate awareness of the Mental Capacity Act.
- The service had a programme of ongoing quality improvement activity. For example we saw a number of audits and peer reviewed research publications to support better service user outcomes.
- There were induction, training, monitoring and appraisal arrangements in place to ensure staff had the skills, knowledge and competence to deliver effective care and treatment.
- The service had arrangements in place to signpost service users to appropriate clinics following return of a positive test for STIs.
- The service's web site contained information to help support patients lead healthier lives.

Are services caring?

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

- There were policies and processes in place to ensure service user information was kept confidential. All service users were telephoned in private and service users were asked to confirm personal data before commencing discussion.

Summary of findings

- We did not speak to patients directly on the days of the inspection. However, we reviewed the latest provider survey information. Results showed that 72% of service users provided feedback and the service had an average rating of 4.93 stars out of 5. This was linked to three key areas namely, ease of access, rapidity of the service (from ordering a test to receiving a result) and the information and support that was available during the service user journey.

Are services responsive to people's needs?

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

- There was information available to demonstrate how the service operated. Additional information in the form of blogs and videos helped to inform service users and improve outcomes.
- There was a complaints policy which provided staff with information about handling formal and informal complaints from patients.
- People could access the service through the website which was available 24 hours a day.

Are services well-led?

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

- There were business plans and an overarching governance framework to support clinical governance and risk management.
- There was a formal management structure in place and the staff we spoke with understood their responsibilities.
- The service engaged with users, clinicians and staff to develop user-friendly and accessible processes to help users access care and to maximise health benefit and reduce risk. It adopted a mix of design, lean and agile methodologies (along Government Digital Service (GDS) design principles) to achieve this.
- The service had developed a web-based administration portal which included service user personal identifiable details (PID), triage and order details, conversations, test results, prescriptions and clinical notes. The portal was securely hosted on the NHS-N3 network. The service was registered with the Information Commissioner's Office.
- The service was research led and consistently sought ways to improve and innovate. The service had carried out a randomised control trial (RCT) which demonstrated the digital STI testing service increased access for all socio-demographic groups and may increase diagnosis of STI. The service was able to demonstrate evidence of other research activities in regards to the service that were published or were pending publication in peer review journals. This demonstrated a research led organisation that sought to offer an effective and convenient sexual health service based on need and demonstrable outcomes.

SH:24

Detailed findings

Background to this inspection

SH: 24 is an online sexual health service, developed with grant funding from Guys and St Thomas's NHS Foundation Trust charity and delivered in partnership with the NHS. SH:24 has contracts with a range of organisations, including NHS Trusts and seven local authorities

to provide people with free sexually transmitted infection (STI) test kits, information and advice, 24 hours a day. The service can also offer online treatment for Chlamydia infection and contraceptive pills (fulfilled by post).

SH:24 was registered with the Care Quality Commission (CQC) on 26 September 2016 and have 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

Our inspection team was led by a CQC Lead Inspector accompanied by a second CQC Inspector, a GP specialist advisor and a pharmacist specialist advisor.

Before visiting, we reviewed a range of information we hold about the service and asked other organisations to share what they knew.

During our visits we:

- Spoke with a range of staff.
- Reviewed organisational documents.
- Examined anonymised patient records.

To get to the heart of patients' experiences of care and treatment, we always 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.

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

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

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 and to whom to report them. All clinical staff had received child safeguarding training and adult safeguarding training appropriate to their role and could access information about who to report a safeguarding concern to. Doctors and nurses were trained to level three. We saw evidence that effective safeguarding processes were in place.

The service provided testing kits for HIV, syphilis, chlamydia and gonorrhoea and the prescription of oral contraceptives including the progesterone only pill (POP) and the combined oral contraceptive (COC) and Azithromycin for the treatment of chlamydia. The service only prescribed oral contraception and treatment for chlamydia with (antibiotics) to patients aged over 18. Users were required to enter their date of birth during the order process on the online portal. Following completion of the order process they were sent a text message asking them to confirm their date of birth. If dates given did not match, the service took action as this was flagged for further review. However, this did not provide full assurance that under 18s were not accessing this service by providing a false date of birth, as there was no process in place to confirm user identity. This was a commissioned service available to people living in seven English local authority areas.

Monitoring health & safety and responding to risks

The provider's headquarters was located within modern offices, housing the IT system, management and administration staff. This was an online service and service users were not treated on the premises.

There were processes in place to manage the health and safety of staff who had received instruction in health and safety including fire safety. The service held monthly governance meetings and discussed any health and safety issues and risks such as contraindications following orders from service users. Clinical and non-clinical incidents were also discussed.

The service was not intended for use by patients as an emergency service. The website was able to signpost people for further support in their local area if they needed more urgent treatment or support.

The service had a staff confidentiality code of conduct. All staff were bound by contractual responsibilities to protect personal information they came into contact with during the course of their work.

Staffing and Recruitment

There were enough staff, both clinical and administrative, to meet the demands for the service. There was a process in place to manage planned absences and unplanned absences. There was a support team available to the clinical staff including health and safety and IT.

There was a selection process in place for the recruitment of all staff. Required recruitment checks were carried out for all staff prior to commencing employment. Potential medical candidates had to be registered with the General Medical Council (GMC). We saw evidence of medical indemnity for clinical staff were in place and all staff were required to undergo checks with the Disclosure and Barring Service (DBS) prior to employment. We reviewed five staff files which showed appropriate recruitment processes were followed with qualifications, references and proof of identify checked before recruitment. We saw evidence of training attended by relevant staff in safeguarding and the Mental Capacity Act. There was a system in place to flag up refresher training or renewal of documentation such as indemnity and professional registration.

Prescribing safety

The service only prescribed oral contraception and antibiotics for the treatment of chlamydia. The prescribers could only prescribe from a set list of medicines. In order for service users to receive chlamydia treatment or oral contraceptives, they needed to complete a remote risk assessment via telephone call or through the service's secure online portal. The risk assessment was based on recognised national guidelines and was designed to prompt the service user to provide information to ensure that prescribers are able to appropriately and safely prescribe the relevant medicine.

The risk assessment had an automatic flagging system identifying any potential contraindications that a service user may have to the relevant medicine. All flags were

reviewed by a registered nurse who initiated a telephone call to discuss any possible contraindications. Once the nurse made the decision that a service user was eligible to receive the relevant medicine, the patient record was flagged for review by a prescriber. The prescriber reviewed all relevant information obtained during the risk assessment and issued a private prescription where clinically appropriate.

Once a medicine was prescribed, an electronic prescription was generated and securely issued to the service's partner pharmacy, where the medicines were dispensed, packaged and posted. Medicines were accompanied by the manufacturer's instructions and an additional support card from the service. The online service also issued a series of text messages to inform the patient of the whereabouts of their order.

We looked at a sample of patient records. We saw that there was a contemporaneous record of prescriptions requested, declined and supplied, the records also showed communication between the prescriber and other health care professionals working at the service and the patient. This ensured information was available to other doctors and healthcare professionals working for the service.

Information to deliver safe care and treatment

Systems were in place to ensure that all patient information was stored and kept confidential; this included the encryption of data and the security of devices used by staff and clinicians.

There were processes in place to ensure prescriptions were monitored in particular for any form of abuse, for example, excessive requests. The service's electronic system generated a unique patient identifier (UID) which was able to merge accounts bearing the same name, mobile number, postcode and date of birth. This enabled the service to identify repeat users and/or multiple requests from the same address or mobile phone number (and ensured each user had their own unique registered mobile number for communication).

In certain situations the system could trigger a flag for clinical review and the kit would be held without dispatch until authorisation by appropriate staff. This may be due to the user having ordered more than one test kit, the same mobile phone number being used to order two or more kits (usually for different users) or the user being under 18 years of age. We saw an example of this, where the system had flagged a service user requesting test kits more frequently than permissible as stated in their policy.

Although the service's electronic system mitigated some of the risks relating to treating service user remotely, its processes were not sufficient for the service to assure itself that servicer users met the age requirements in place. However, the provider was aware of this risk and had asked for access to the NHS patient record system which would allow the service to identify patients on the NHS system. We were forwarded communication from NHS digital by the service following the inspection which gave a timeframe of access to the NHS system between four to six weeks at the time of the inspection.

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 10 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, a service user did not provide their surname when ordering contraceptives. This was flagged by a clinical member who contacted the service user to get their full name prior to the medication order being dispatched. This highlighted the importance of ensuring service users' first names and surnames were recorded prior to prescribing and also confirmed that there was effective clinical review process in place which flagged this as an issue. The service had implemented learning by optimising the website to ensure first and surname must be supplied prior to prescribing.

Incidents were discussed at monthly quality and risk management meeting (clinical) as well as the monthly management team meeting. Incidents were also discussed using an electronic application.

The service was aware of the Duty of Candour and we saw evidence which demonstrated the provider 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.

We asked how patient safety alerts were dealt with such as those issued by the Medicines and Healthcare products Regulatory Agency (MHRA), and were shown evidence that

these were reviewed by prescribers. There were records made to document that these had been actioned and there was a process within the organisation to review service users who may have been prescribed medicines which were the subject of these alerts.

Are services effective?

(for example, treatment is effective)

Our findings

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

Assessment and treatment

We reviewed 14 examples of service user requests which demonstrated that each clinician assessed their needs and delivered appropriate treatment in line with relevant and current evidence based guidance and standards. This included National Institute for Health and Care Excellence (NICE) as well as British Association of Sexual Health and HIV (BASHH) guidance.

All users who ordered an STI test kit or contraception completed the online order process which screened them for suitability to use the online service. They then entered personal details that included name, mobile phone number, postal address (including postcode), email address and date of birth. User authentication was secured as all users were texted a code to ensure that the service had access to the mobile phone number associated with the order. The order process could not be completed without entering this code.

In order for service users to receive chlamydia treatment or oral contraceptives, they needed to complete a remote risk assessment via telephone call or through the secure online portal. The risk assessment had an automatic flagging system identifying any potential contraindications that a service user may have to the relevant medication. All flags were reviewed by a registered nurse who initiated a telephone call to discuss any possible contraindications.

Evidence we looked at demonstrated that when service users were prescribed oral contraceptive tablets a follow up call was made by the prescriber or another health care worker to check if they were having any problems. The service also sent out text message reminders 14 days before the user would be expected to come to an end of their course to remind them that they need to order a further supply. If requests were made early then contact was made to establish the reason for the early request.

All medicines were sent out on behalf of the service by a partner pharmacy via tracked delivery. If a delivery failed then the pharmacy would provide feedback to the service and contact was then made with the service user to explain that they were not able to dispense again and the service user would be referred to an alternative supplier (either their own GP or a sexual health clinic).

Quality improvement

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

- The service used information about patient user outcomes to make improvements. The service was research led and had published in various peer review journals. Research findings were used to improve service user outcomes. For example, the service was able to demonstrate that the introduction of online services increased total testing activity across the whole sexual health economy which suggested unmet needs. Furthermore, the service was able to demonstrate how it used limited resources more effectively by signposting users towards online or face-to face services according to clinical need.
- The service sent out follow-up text messages to service users prescribed treatment to ensure there were no issues.
- The service took part in quality improvement activity, for example they had used audits to review their practice. This included an audit on the outcome of HIV and Syphilis reactive results. Other audits included the review of outcomes of positive Chlamydia and Gonorrhoea referrals following introduction of the service in a commissioned area. The service also regularly reviewed its performance during monthly management meetings, looking at key themes within the service such as the laboratory turnaround time for results and the return rates for the kits.

Staff training

All staff had to complete induction training which consisted of health and safety and safeguarding, as well as learning about the workings of the service's IT systems, an introduction to the service's policies and procedures and responsibilities in relation to patient confidentiality.

Administration staff received regular performance reviews. Nurses received reviews from the registered manager. The doctors had their professional appraisals for revalidation purposes undertaken through King's College Hospital where their work for this service was included. Evidence we looked at appraisals were all up to date.

Are services effective?

(for example, treatment is effective)

Coordinating patient care and information sharing

If a patient visits a sexual health clinic they do not have to provide their real name or give details of their GP. All information regarding a patients visit is treated confidentially and personal details and any information about the tests or treatments received does not have to be shared with anyone outside the sexual health service without the permission of the patient. This includes their GP. At this service, when a service user entered details through the website, a record was produced, which summarised the information they had entered and displayed it in the clinical system. If a service user ordered oral contraceptives there were opportunities for the service user to provide GP details. However, the service did not currently share information with their GP and did not ask for consent to share that information. The service was in the process of gaining access to the NHS patient record system and planned to share this information with service users GP subject to consent.

The service monitored the appropriateness of referrals/ follow ups from test results to improve patient outcomes. They had completed an audit reviewing the outcomes of positive Chlamydia and Gonorrhoea referrals. Other audits included outcome of HIV and Syphilis reactive results.

Supporting patients to live healthier lives

The service identifies users who may be in need of extra support and signposted them to appropriate services. If users tested positive for an STI, they were fast-tracked into clinic services using agreed local processes agreed by individual partner Trusts. This referral process was overseen by a clinical team. For a reactive HIV result or safeguarding concern, users received a telephone call from a qualified clinician to offer support, advice and appropriate referral into relevant services. The service's website has links with national and local organisations to signpost users to immediate support. SH:24 undertook follow-up reviews, tracking attendance at clinic.

We were told that the service liked to build strong and long lasting relationships with users who would then feel confident to seek help for other issues. For example, we saw evidence that a service user had been referred to mental health services.

The service provided numerous information videos and blogs to improve patient outcomes. For example, there was a link to a video on blood taking for STI testing. The return rate for tests involving blood samples ranged between 78% and 96% (depending on geographical region). The return rate of the National HIV Testing Programme was 51% which was the best comparator in the absence of a national comparator'.

The service also offered service users who tested positive for chlamydia and were treated for chlamydia by SH:24 an STI anonymous partner notification by text message. The tool anonymously informs the service users recent sexual partners (via text message) that they should take an STI test helping them to access the correct testing and treatment at the clinic.

Are services caring?

Our findings

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

Compassion, dignity and respect

The service provided an online sexual health service using the internet and telephone technologies to deliver sexual and reproductive health care remotely. There were policies and processes in place to ensure service user information was kept confidential. For example, all service users were telephoned in private and service users were asked to confirm personal data before commencing discussion.

All existing and new staff were appropriately trained and supported so they were aware of their duties and obligations related to information governance and security.

The service told us that they believed in building strong relationships with service users and were willing to enter into long term dialogue. This allowed the service users to develop confidence and trust in the service and the service could then signpost service users to other services. For example, we saw evidence where a vulnerable service user had asked to be signposted to mental health services.

We did not speak to service users directly on the day of the inspection. However, we reviewed the latest survey information. Service users who returned negative or incomplete results received a link to an online survey by SMS 48hrs after they received their results.

Service users who required treatment or confirmatory testing received a link to an online survey by SMS 14 days after they receive their results.

We were told that 72% of service users responded to the SMS feedback survey and users who were willing to discuss their feedback in more depth were contacted by the service. The service had also met face to face with service users on various occasions that initially completed the online survey to further discuss their experiences and feedback.

The survey results showed that service users were very satisfied with the service as the service received an average rating of 4.93 stars out of 5. This was linked to three key areas namely, ease of access, rapidity of the service (from ordering a test to receiving a result) and the information and support that was available during the service user journey.

Involvement in decisions about care and treatment

Patient information guides about how to use the service and technical issues were available. For example, there were links to videos on blood taking (for tests) and there were numerous blogs on a number of themes on the service's website. The service's return rate for tests involving blood samples ranged between 78% and 96% (depending on geographical region). The return rate of the National HIV Testing Programme was 51% which was the best comparator in the absence of a national comparator'.

Service users were able to leave comments and queries on the website and there was a dedicated team to respond to these. Service users had access to information about all the staff including clinicians working for the service.

Service users who return a negative test result were informed through text message. If users had a reactive result for an STI, they were fast-tracked into clinic services using agreed local process (signed off by individual partner Trusts). This referral process was overseen by a clinical team. For a reactive HIV result or safeguarding concern, users received a telephone call from a qualified clinician to offer support, advice and appropriate referral into relevant services.

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

The aim of the service was to improve access to sexual and reproductive health care through the provision of online sexual and reproductive health services. The services provided by SH: 24 included testing for HIV, syphilis, chlamydia and gonorrhoea and the prescription of oral contraceptives including the progesterone only pill (POP) and the combined oral contraceptive (COC) and Azithromycin for the treatment of simple chlamydia. This process included a remote risk assessment and postal delivery of prescription medicines.

The digital application allowed service users to request STI testing kits or oral contraceptives 24 hours a day. Clinicians reviewed service user requests and processed the order where appropriate.

This service has contrcats with a range of organisations including seven Local Authrities in England and NHS Trusts to provide people with free sexually transmitted infection (STI) test kits, information and advice, 24 hours a day. The service can also offer online treatment for Chlamydia infection and contraceptive pills (fulfilled by post).

users who lived in these local authorities were able to access the service. The provider made these criteria clear to patients on their website as service users were required enter their post code for eligibility.

Tackling inequity and promoting equality

The service provided free and confidential STI testing accessible 24 hours a day to anyone over the age of 16. However, this was restricted to those living within seven English regions due to the funding arrangements for the service. Patients were informed of this during the registration process which checked their eligibility. If the patient did not live in an eligible area the service's website provided advice and signposted them to other appropriate services.

The service worked with other charities such as those working with sex workers. The service allowed this charity to refer 10 service users each month to access its service. It also worked with other charities such as those working with refugees and offered signposting to other relevant providers even if they lived outside of the commissioned areas.

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. The service had received five formal complaints over the past 12 months. We reviewed the way these had been managed and found they had been approached in a transparent, open and timely manner. Minutes of meetings we looked at showed that learning from complaints had been discussed. For example, complaints records and minutes of meeting we looked at showed that a user was unable to order a test kit due to the cap being applied to the service to ensure it operated within local budget restrictions. As a result of the complaint, additional funding had been negotiated which enabled the service to increase the cap on the service, allowing more users to access STI testing.

Consent to care and treatment

The service had a consent policy which advised all staff that they have an obligation to act in accordance with the principles of the Mental Capacity Act and in the best interests of a person who may lack capacity to make specific decisions. Under normal circumstances the service considered that completion of the order process implied capacity to consent and at the start of the order process, service users were asked to agree to the terms of conditions of the website.

All staff had received training about the Mental Capacity Act 2005 and demonstrated understanding of the process of consent.

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 providing well led services in accordance with the relevant regulations.

Business Strategy and Governance arrangements

The provider had a clear vision to work together to provide a high quality responsive service that put quality care at its heart. We reviewed the service's business plan, which was comprehensive; the plan demonstrated an in depth understanding of the sector it was operating in and its place within it. The service had short term (next financial year) and long term (five year) plan with clear aims and objectives.

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. We saw that these policies were detailed adhering to latest guidelines and had been written prior to the service being launched and were subject to regular review.

There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions. There were a variety of checks in place to monitor the performance of the service. For example, monthly quality and risk meetings reviewed clinical performance and safety of the service. Monthly management meetings reviewed key themes within the service such as the laboratory turnaround time for results and the return rates for the kits.

The service also had comprehensive data on the demographics, age profile and sexual orientation of those accessing the service and these were shared with the commissioners.

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

Leadership, values and culture

The Registered Manager had overall responsibility for the service and there was a management team consisting of six executive directors and five non-executive directors. The executive directors met monthly to review core work streams of the service including clinical governance, business strategy, service development, evaluation and performance.

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

The service operated in line with the Data Protection Act and only captured and stored information that was necessary for the purpose of service delivery. Records were stored in line with the British Association of Sexual Health (BASHH) and HIV guidelines. The service had developed a web-based administration portal which included service user personal identifiable details (PID), triage and order details, conversations, test results, prescriptions and clinical notes. The portal was securely hosted on the NHS-N3 network.

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

Seeking and acting on feedback from patients and staff

The service aimed to develop a user-friendly and accessible process to help patients access care and to maximise health benefits and reduce risk. It adopted a mix of design, lean and agile methodologies (along Government Digital Service (GDS) design principles) to achieve this.

Service users were asked to provide feedback through SMS links. Service users were also contacted on the telephone and on some occasions service users were met face to face to discuss their experiences and recommendations.

To understand the needs of the service users, user group meetings were regularly held to test every aspect of the STI testing journey, online and offline. For one of its first meetings, 12 users representing a cross section of user types (ages, sexual preference, and risk profile) were included. They were recruited from colleges, the high street and sexual health clinics.

The group were asked to test the system, provide feedback on any problems as well as to suggest improvement. For

Are services well-led?

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

example, feedback from users on the language, visual identity of the web portal and the tone of voice used in some of the videos was used to enhance the service user experience.

Similarly, the service also held clinical user groups meetings to improve the system. Clinicians included staff members as well as those recruited from partner sexual health clinics. Evidence we looked at showed that improvements included development and improvement of the online signposting algorithm.

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

Continuous Improvement

The service consistently sought ways to improve and innovate and had received recognition from within the sector by means of several awards. 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. As discussed above, the service involved users, clinicians as well as commissioners to develop and make improvements.

The service had carried out a randomised control trial (RCT) which demonstrated the digital STI testing service increased access for all socio-demographic groups and may increase diagnosis of STIs. This research was published in a peer reviewed journal. This research activity also enabled the service to further improve by implementing findings. For example, findings identified that some users expected more links to specialist services both locally and nationally and as a result the service was continuing to add this content to the online portal.

The service was able to demonstrate evidence of other research activities in regards to the service that were published or were pending publication in peer review journals. This demonstrated a research led organisation that sought to offer an effective and convenient sexual health service based on need and demonstrable outcomes.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The provider had failed to assure itself that users fulfil the age limitation requirements. This was in breach of regulation 12(2) (b) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.