



Independent Healthcare Inspection (Announced)

Transcend Clinic / Circumcision Clinic

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1. Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales.

HIW's primary focus is on:

- Making a contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

HIW inspections of independent healthcare services seek to ensure services comply with the Care Standards Act 2000 and requirements of the Independent Health Care (Wales) Regulations 2011 and establish how services meet the National Minimum Standards (NMS) for Independent Health Care Services in Wales¹.

This report details our findings following the inspection of an independent health care service. HIW is responsible for the registration and inspection of independent healthcare services in Wales. This includes independent hospitals, independent clinics and independent medical agencies.

We publish our findings within our inspection reports under three themes:

- Quality of patient experience
- Delivery of safe and effective care
- Quality of management and leadership.

¹ The National Minimum Standards (NMS) for Independent Health Care Services in Wales were published in April 2011. The intention of the NMS is to ensure patients and people who choose private healthcare are assured of safe, quality services. <http://www.hiw.org.uk/regulate-healthcare-1>

2. Methodology

During the inspection we gather information from a number of sources including:

- Information held by HIW
- Interviews with staff (where appropriate) and registered manager of the service
- Conversations with patients and relatives (where appropriate)
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of equipment and the environment
- Information within the service's statement of purpose, patient's guide and website (where applicable)
- HIW patient questionnaires completed prior to inspection.

At the end of each inspection, we provide an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Any urgent concerns that may arise from an inspection will be notified to the registered provider of the service via a non-compliance notice². Any such findings will be detailed, along with any other improvements needed, within Appendix A of the inspection report.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

² As part of HIW's non-compliance and enforcement process for independent healthcare, a non-compliance notice will be issued where regulatory non-compliance is more serious and relates to poor outcomes and systemic failing. This is where there are poor outcomes for people (adults or children) using the service, and where failures lead to people's rights being compromised. A copy of HIW's compliance process is available upon request.

3. Context

Transcend Clinic/Circumcision Clinic³ is located at 98, Wentloog Road, Rumney, Cardiff, CF3 3XE. The service was first registered by Healthcare Inspectorate Wales on 13 November 2014.

The staff team includes the clinic owner (also the registered manager), patient support staff, a receptionist and a housekeeper. In accordance with the conditions of registration, only male circumcision procedures for non therapeutic reasons may be performed at the clinic.

HIW completed an announced inspection to the clinic on 16 August 2016.

³ Whilst referred to as a clinic, for the purposes of registration the service is defined as an independent hospital.

4. Summary

Parents/patients told us they were very satisfied with the service they had received at the clinic. Arrangements were in place to protect the privacy and dignity of patients and we saw staff being kind and respectful to parents/patients visiting the clinic.

Overall we found that arrangements were in place to provide patients with safe and effective care. Recognised techniques for performing circumcisions and a comprehensive care pathway were described.

Some of the clinic's policies required reviewing to include more detail, namely those for safeguarding children and handling complaints. Improvement was also needed around aspects of the cleaning and sterilising process for re usable instruments used at the clinic.

The clinic owner was responsible for the management of the clinic and was supported by a friendly staff team. The clinic team demonstrated a commitment to providing a safe and high quality service to patients. We identified improvement was needed around the information and documentation that needs to be available to demonstrate that staff are suitable to work at the clinic.

As described above, we identified areas for improvement during this inspection. Whilst this has not resulted in the issue of a non compliance notice, we did require that immediate improvement was made around aspects of the cleaning and sterilising process. There is an expectation that the clinic owner takes meaningful action to address these matters, as a failure to do so could result in non-compliance with regulations.

5. Findings

Quality of patient experience

Parents/patients told us they were very satisfied with the service they had received at the clinic. Arrangements were in place to protect the privacy and dignity of patients and we saw staff being kind and respectful to patients visiting the clinic.

Prior to the inspection, we asked the clinic owner to distribute HIW questionnaires to parents/patients to invite them to provide their views on the service they had received. In total, 26 completed questionnaires were returned. Parent/patient comments included:

'We are very pleased with the work of the clinic'

'Overall, excellent service and treatment provided...'

'We are very happy.'

When invited to rate the care and treatment provided by the clinic, parents/patients rated this between six and ten out of ten. The majority (18 patients) gave a rating of ten out of ten.

Equality, Diversity and Human Rights (Standard 2)

The clinic recognised its responsibilities under equality, diversity and human rights legislation.

The clinic was registered with HIW to provide a male circumcision service, solely for non therapeutic reasons. This was reflected in the information available to parents/patients within the clinic's statement of purpose and patients' guide. We saw that arrangements were in place to provide parents/patients with information about the procedure so that they could make an informed choice about whether to proceed. The statement of purpose also set out the clinic's arrangements for promoting patients' privacy and dignity and how they could make a complaint about the service they had received.

There were steps leading to the clinic entrance which made access by this entrance more challenging for people with mobility problems or people using wheelchairs. There was however a rear entrance that allowed level access to the clinic. Facilities within the clinic were on one level allowing easy access the reception, waiting room, consultation/treatment rooms and toilets.

Citizen Engagement and Feedback (Standard 5)

The clinic had a system for seeking parent/patient feedback on the service provided.

The arrangements for seeking feedback from parents/patients were described in the clinic's statement of purpose. This involved parents/patients being invited to complete a feedback form after treatment. We saw some completed feedback forms that showed this had taken place. The clinic owner explained that comments made within the feedback forms were shared with the staff team so that improvements could be made as necessary. In addition the views of the staff team must be regularly sought and a summary of both parents/patients and staff feedback included with the patients' guide.

Improvement Needed

In addition to seeking parent/patient feedback, the registered person must also make arrangements to regularly seek feedback from staff to form an opinion of the standard of care and treatment provided at the clinic.

A summary of the feedback obtained must be included in the patients' guide.

Care Planning and Provision (Standard 8)

A comprehensive patient care pathway which aimed to promote patient safety and wellbeing was in place.

The clinic owner was responsible for performing male circumcision procedures at the clinic. A pathway that included all aspects of care was described. This included referral, consultation, assessment, pre and post procedure care (including the action to take in the event of post procedure complications). Throughout the pathway it was evident that parents/patients were provided with relevant information and support with the aim of promoting patient safety and well being.

We saw that detailed patient care records had been maintained that demonstrated the pathway described.

Patient Information and Consent (Standard 9)

Parents/patients were provided with timely and accessible information about their care and treatment. A clear process was described for obtaining informed consent.

The clinic owner was the only person at the clinic who was allowed to perform male circumcision. He was able to describe the expected patient journey from the first point of contact with the clinic through to the post operative check appointment. The journey described allowed for parents/patients to meet the staff involved in their care and ask questions about the procedure.

The clinic owner described the process for obtaining informed consent. He was responsible for answering any questions and obtaining written consent from the parents/patient prior to the procedure. We found that the consent process was comprehensive and aimed to help parents/patients when making a decision. It provided opportunities for parents/patients to ask questions about the procedure and to change their mind if they decided not to go ahead. We saw completed consent forms and records showing the patient journey as described.

The patients' guide described the above arrangements. We were told that written and verbal information was provided in English only. Those parents/patients who did not speak English would be required to be accompanied by a friend/relative to act as an interpreter. Where an interpreter was involved, we were told that this would be recorded in the patients' records.

Patient information leaflets had been produced for younger and older children. These were presented as bullet points using text only. The clinic owner should consider reviewing the patient information leaflets to make them more child friendly and accessible by children.

Dignity and Respect (Standard 10) and Environment (Standard 12)

We found the clinic had suitable arrangements in place to protect and promote patients' rights to privacy and dignity. We found that parents/patients were treated with respect by the clinic staff.

The clinic's statement of purpose set out the arrangements for respecting patients' privacy and dignity. This included the safe keeping of patient records.

Doors to consultation rooms and the treatment room could be closed to protect patients' privacy and dignity. The reception area was enclosed and so provided an area to make telephone calls in private.

Parents/patients who completed and returned HIW questionnaires told us that staff treated them with kindness and were polite to them. We also observed clinic staff being kind and respectful to parents/patients.

The clinic provided a service mainly for children and we saw a selection of toys were available for them to play with. Consideration should also be given to making the waiting area more appealing for children through the use of age appropriate displays or pictures.

Delivery of safe and effective care

Overall we found that arrangements were in place to provide patients with safe and effective care. Recognised techniques for performing circumcisions and a comprehensive care pathway were described.

Some of the clinic's policies required reviewing to include more detail, namely those for safeguarding children and handling complaints. Improvement was also needed around aspects of the cleaning and sterilising process for reusable instruments used at the clinic.

Safe and Clinically Effective Care (Standard 7)

We found that arrangements were in place to provide patients with safe and effective care.

Recognised surgical techniques for performing male circumcision were described as being performed at the clinic. As previously described a comprehensive care pathway was described by the clinic owner.

The clinic owner described a system of regular audits to identify post procedure complications (for example bleeding and infection). This meant there were systems in place to help identify possible causes so that improvements could be made as necessary to ensure care was safe.

Safeguarding Children and Safeguarding Vulnerable Adults (Standard 11)

We were told that the majority of patients attending the clinic were children. The clinic had an up to date written policy to promote and protect the welfare and safety of children who may be at risk and staff had attended training.

Whilst a policy was in place, this would benefit from further information to guide staff on the action to take should they suspect abuse, including details of the local procedure to follow, together with the contact details of relevant safeguarding teams.

Improvement Needed

The clinic's written safeguarding procedure should clearly describe the procedure to follow should staff suspect abuse and include the contact details of relevant safeguarding teams.

We saw certificates that showed that staff working at the clinic had attended safeguarding training within the last year.

Infection Prevention and Control (IPC) and Decontamination (Standard 13)

All areas of the clinic were visibly clean and tidy. Re usable surgical instruments were being used and we identified improvement was needed around aspects of the cleaning and sterilising (decontamination) process to promote staff safety and to show instruments were safe to use.

The clinic had an up to date written infection control policy to guide staff on reducing cross infection.

We saw that re usable surgical instruments were being used. Specialist equipment and a process were in place to clean and sterilise these instruments to reduce cross infection. We saw, however, that the staff member cleaning instruments was not using adequate personal protective equipment (PPE) to protect against injuries associated with sharps. In addition, there was no specific written decontamination procedure to guide staff and no system to record when cleaned and sterilised instruments needed to be used by. Records to show that staff had received suitable training were not available. Maintenance certificates for cleaning and sterilising equipment were available confirming they were safe to use. Records to demonstrate regular testing of equipment had not been maintained. We informed the clinic owner of our findings and required that immediate improvement was made in this regard.

Immediate Improvement Needed

The registered person must make suitable arrangements to demonstrate that the decontamination process used at the clinic is safe and effective. These must include the development and implementation of a written decontamination process, provision of suitable personal protective equipment for staff, maintenance of appropriate records and providing staff with suitable training on decontamination.

The registered person should seek advice from a suitable person on safe and effective decontamination procedures as appropriate.

We required immediate written assurance of the action taken. The clinic owner submitted an immediate improvement plan to HIW within the agreed timescale. We were broadly assured that action had been taken to address the improvement needed. At the time of writing this report we required some further details and were following this up with the clinic owner. When we are assured the improvement needed has been addressed this will be reflected through the publication of the clinic's improvement plan (see section 5).

A contract was in place for the safe transfer and disposal of waste produced by the clinic. Suitable hand washing and drying facilities were also available within treatment rooms and the toilets to reduce cross infection.

During a tour of the clinic we found all areas to be very clean and tidy. Comments from parents/patients who returned an HIW questionnaire also told us that they felt the clinic was clean and tidy.

Medicines Management (Standard 15) and Emergency Planning Arrangements (Standard 4)

Medicines were managed safely at the clinic and arrangements were in place to respond to a patient emergency.

Only local anaesthetic and drugs and equipment for use in an emergency were kept at the clinic. These were stored safely away from public areas. We were told that pain killers would be prescribed as needed and parents/patients would be expected to collect these from their local chemist, who would be able to provide advice and instructions on how to take them.

Records we saw showed that staff had received training on the action to take in the event of a patient emergency (collapse). The clinic owner also described arrangements for responding to complications that may happen during a procedure and confirmed that an emergency transfer to hospital would be arranged.

Managing Risk and Health and Safety (Standard 22)

We found that the clinic had taken steps to identify hazards and reduce the risk of harm.

We saw that a written risk assessment had been completed and actions identified to manage and mitigate risk. These included environmental and procedural risk assessments. A written toy cleaning policy was in place and we recommended that this be expanded to include that regular checks be conducted to ensure they did not pose a choking hazard to children. The clinic owner agreed to do this.

We saw that fire safety equipment was placed around the clinic. Instructions to follow in the event of a fire were displayed and fire exits were clearly signposted. This meant that equipment and information was available for staff and patients so they could exit the building safely in the event of a fire. Whilst records had been maintained of checks on fire safety equipment, there was no fire equipment contract in place. We recommended that the clinic owner seek advice from the fire safety officer on other checks and maintenance that may be required and he agreed to do this.

Dealing with Concerns and Managing Incidents (Standard 23)

The clinic had an up to date complaints policy. This needed to be reviewed to include more detail on the procedure.

The written complaints procedure was available for inspection. This was also referred to within the statement of purpose and patients' guide. The procedure did not clearly show how complaints would be handled or the anticipated timescales for responding.

Improvement Needed

The clinic's complaint procedure must include more detail on how complaints will be handled and the anticipated timescales for responding.

The majority of patients who returned completed HIW questionnaires (21) told us knew how to make a complaint if they were unhappy with the service provided.

Quality of management and leadership

The clinic owner was responsible for the management of the clinic and was supported by a friendly staff team. The clinic team demonstrated a commitment to providing a safe and high quality service to patients.

We identified improvement was needed around the information and documentation that needs to be available to demonstrate that staff are suitable to work at the clinic.

Governance and Accountability Framework (Standard 1) and Participating in Quality Improvement Activities (Standard 6)

The clinic owner (also the registered manager) had overall responsibility for the management and care and treatment provided at the clinic. Discussions with the clinic owner demonstrated a commitment to providing patients with a safe and high quality service.

Care and treatment provided at the clinic was in accordance with the conditions of registration with HIW. The certificate of registration was displayed prominently at the clinic as required by the regulations. The clinic had an up to date statement of purpose. This needed to include details of the number, relevant qualifications and experience of staff working in the clinic. An up to date patients' guide was available. This needed to include the contact details of HIW. The clinic owner should therefore make arrangements for this information to be included.

Improvement Needed

The clinic's statement of purpose and patients' guide must include details of the number, relevant qualifications and experience of staff working in the clinic and the contact details of HIW respectively.

As previously described the clinic had systems in place to seek parent/patient feedback and for clinical audit.

Workforce Recruitment and Employment Practices (Standard 24) and Workforce Planning, Training and Organisational Development (Standard 25)

We identified that improvement was needed in relation to demonstrating staff were suitable to work at the clinic.

We reviewed the staff files for each member of staff who were working at the clinic at the time of our inspection. We saw that efforts had been made to assess their suitability to work at the clinic, however not all the information required by the regulations was available for inspection. Specifically, not all staff had two written references, an up to date photograph and a full employment history.

Improvement Needed

The registered person must make suitable arrangements to ensure all information and documentation required by the regulations to demonstrate a staff member's fitness to work at the clinic is available prior to any new person starting work at the clinic.

For staff currently working at the clinic and who did not have full information and documentation available, the registered person must assess whether those staff are suitable to work at the clinic and take action as appropriate. Where staff are assessed as suitable to work a note should be placed on their individual files to this effect.

Whilst all staff had Disclosure and Barring Service (DBS) certificates these had not always been requested by, or on behalf of the clinic owner as required by the regulations.

Improvement Needed

The registered person must make suitable arrangements to ensure DBS certificates for any new staff are requested by him or on his behalf.

Having the above information and documentation available would further demonstrate that the clinic owner has taken appropriate checks to assess a person's suitability to work at the clinic as part of the overall recruitment procedure.

Copies of job descriptions were not available on the staff files we saw. The clinic owner must make arrangements to ensure staff employed at the clinic are provided with up to date job descriptions.

Improvement Needed

The registered person must provide staff employed at the clinic with up to date job descriptions.

Staff we spoke to confirmed they were able to attend training relevant to their role. Training records were not available for all staff working at the clinic. The clinic owner should make arrangements to show that staff have received appropriate training relevant to their role.

6. Next Steps

This inspection has resulted in the need for the independent clinic to complete an improvement plan. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state how the improvement identified at the clinic will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.

Appendix A

Improvement Plan

Service: Transcend Clinic / Circumcision Clinic

Date of Inspection: 15 August 2016

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Quality of Patient Experience					
7	In addition to seeking parent/patient feedback, the registered person must also make arrangements to regularly seek feedback from staff to form an opinion of the standard of care and treatment provided at the clinic. A summary of the feedback obtained must be included in the patients' guide.	Regulation 19 National Minimum Standard 5	A Staff meeting has been held to discuss this Inspection report and this will be the start of a regular monthly cycle of meeting to seek feedback from the staff and to form an opinion of the standard of care and treatment provided at the clinic. Copies of the minutes will be enclosed with the patient's guide.	AK	
Delivery of Safe and Effective Care					
9	The clinic's written safeguarding	Regulation	The clinic has been in touch with the	AK	Immediately

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	procedure should clearly describe the procedure to follow should staff suspect abuse and include the contact details of relevant safeguarding teams.	16(1)(b) National Minimum Standard 11	local safeguarding team at Cardiff City Council who would be the initial contact point for reporting any case of suspected abuse. This would be the procedure for all cases regardless of the home address of the service user. In cases where physical abuse is suspected or imminent contact with local police force would apply. Safeguarding policy has been amended accordingly.		
10	<u>Immediate Improvement Needed</u> The registered person must make suitable arrangements to demonstrate that the decontamination process used at the clinic is safe and effective. These must include the development and implementation of a written decontamination process, provision of suitable personal protective equipment for staff, maintenance of appropriate records	Regulations 9(1)(n), 15(3), 15(4), 20(1)(a) and 20(2)a National Minimum Standards 13, 16, 22 and 25	The Clinic has immediately taken on board all the Inspectors recommendations and a full set of protective clothing items have been obtained. The use of these have been included in a revised written contamination process. This has been used for a full training / induction session with clinical staff to address issues raised on	AK	

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	<p>and providing staff with suitable training on decontamination.</p> <p>The registered person should seek advice from a suitable person on safe and effective decontamination procedures as appropriate.</p>		<p>procedure</p> <p>The Registered person has sought advice from the supplier of the cleaning equipment and an appropriated chemical cleaner is to be used with all ultrasonic cleaning.</p> <p>The Autoclave has been recently serviced and checked and the authorised agent has been contacted and all processes reviewed according to the manufacturers handbook</p>		
12	The clinic's complaint procedure must include more detail on how complaints will be handled and the anticipated timescales for responding.	Regulation 24 National Minimum Standard 23	The Clinics Complaint procedure has be reviewed and clear timescales for responding have been highlighted together with the contact addresses of both Health Inspectorate Wales and other appropriate bodies	AK	Immediately
Quality of Management and Leadership					
13	The clinic's statement of purpose and patients' guide must include details of	Regulation 6(1)	The clinics statement of purpose and patient guide has been	AK	

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	the number, relevant qualifications and experience of staff working in the clinic and the contact details of HIW respectively.	Schedule 1 Regulation 7(1)(f) National Minimum Standard 1	amended to include details of the number, relevant qualifications and experience of staff working in the clinic and the contact details of HIW respectively.		
14	<p>The registered person must make suitable arrangements to ensure all information and documentation required by the regulations to demonstrate a staff member's fitness to work at the clinic is available prior to any new person starting work at the clinic.</p> <p>For staff currently working at the clinic and who did not have full information and documentation available, the registered person must assess whether those staff are suitable to work at the clinic and take action as appropriate. Where staff are assessed as suitable to work a note should be placed on their individual files to this effect.</p>	Regulation 21(2)(d) Schedule 2 National Minimum Standard 24	<p>The Registered person has review all staff files and has ensured that all existing staff members have information and documentation required by the regulations.</p> <p>A note has been placed in individual files to the effect that current members have been assessed as suitable to work at the clinic.</p>	AK	From 29 th August 2016

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
14	The registered person must make suitable arrangements to ensure DBS certificates for any new staff are requested by him or on his behalf	Regulation 21(3) National Minimum Standard 24	The Registered Person will ensure that suitable arrangements to ensure DBS certificates for any new staff are requested by him or on his behalf	AK	
14	The registered person must provide staff employed at the clinic with up to date job descriptions.	Regulation 20(2)(c) National Minimum Standard 24	Job Descriptions have been provided for all members of staff and copies entered into the staff files.	AK	From 29/08/16

Service Representative:

Name (print): **Anwar Khan**.....

Title: **Mr.**.....

Date: **22/09/16**.....