

## **Independent Healthcare Inspection (Announced)**

Cardiac Health Diagnostics Ltd

Inspection date: 10 January 2018

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In writing:

**Communications Manager  
Healthcare Inspectorate Wales  
Welsh Government  
Rhydycar Business Park  
Merthyr Tydfil  
CF48 1UZ**

Or via

**Phone: 0300 062 8163  
Email: [hiw@wales.gsi.gov.uk](mailto:hiw@wales.gsi.gov.uk)  
Fax: 0300 062 8387  
Website: [www.hiw.org.uk](http://www.hiw.org.uk)**

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**Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales**

## **Our purpose**

To check that people in Wales are receiving good care.

## **Our values**

- **Patient-centred:** we place patients, service users and public experience at the heart of what we do
- **Integrity:** we are open and honest in the way we operate
- **Independent:** we act and make objective judgements based on what we see
- **Collaborative:** we build effective partnerships internally and externally
- **Professional:** we act efficiently, effectively and proportionately in our approach.

## **Our priorities**

Through our work we aim to:

**Provide assurance:**

Provide an independent view on the quality of care.

**Promote improvement:**

Encourage improvement through reporting and sharing of good practice.

**Influence policy and standards:**

Use what we find to influence policy, standards and practice.

# 1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced inspection of Cardiac Health Diagnostics Ltd on the 10 January 2018.

Our team, for the inspection comprised of one HIW inspector, one clinical peer reviewer and one lay reviewer. The inspection was led by a HIW inspection manager.

HIW explored how the service complied with the Care Standards Act 2000, requirements of the Independent Health Care (Wales) Regulations 2011 and met the National Minimum Standards for Independent Health Care Services in Wales.

Further details about how we conduct independent service inspections can be found in Section 5 and on our website.

## 2. Summary of our inspection

The service was registered with Healthcare Inspectorate Wales to provide mobile cardiac health screening service to persons over the age of five years old but predominantly for persons aged 16 - 35 years and occasionally older.

Arrangements were seen for providing patients with sufficient information about what to expect from the service.

No patients were attending for screening at the time of our inspection, so we spoke with randomly selected patients by the telephone to directly obtain patients' views on the service they had received.

The service also used patient questionnaires to obtain patients' feedback and the sample we saw included positive comments about the care provided at the service.

There were some areas identified for improvement but generally we were satisfied that the service was meeting the Independent Healthcare Regulations (Wales) 2011.

This is what we found the service did well:

- Patients we spoke with were very happy with the service provided
- Information was given regarding the service and what patients were to expect
- Patients records were detailed and stored securely
- There was evidence of some audit work, although the service had only been open for a short period of time
- There was evidence of good, open and transparent management

This is what we recommend the service could improve:

- Some minor amendments to the documentation
- Development of marketing plan and working agreements with stakeholders

- Development of a No Smoking Policy for staff
- Development of a robust training matrix to record current training and ensure staff are trained in the mandatory areas including Chaperone training
- Further development of roles and responsibilities to ensure clear accountability for directors.

We identified regulatory breaches during this inspection regarding – general amendments and development of documentation.

## 3. What we found

### **Background of the service**

Cardiac Health Diagnostics Ltd is registered to provide an independent medical agency at Room 508, Fifth Floor Business Centre, Institute of Life Sciences 2, Swansea University, Singleton Campus, Swansea, SA2 8PP.

The service is registered to provide mobile cardiac health screening services to persons over the age of 5 (five). Overnight accommodation is not provided.

The service was first registered on 6 May 2016.

The service employs a staff team which consist of 5 Directors, (one of which is also the Registered Manager) and part time cardiologists and physiologists.



## Quality of patient experience

*We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.*

Overall, we were satisfied that the clinic offered a service which met the needs of the patients in a safe and professional manner.

Patients were well informed prior to any consultation and their views on the service were very positive and satisfactory.

As patients do not attend at the service for screening we requested the names and contact details of four randomly selected patients to speak with on the telephone. We asked the Registered Manager to telephone the patients prior to our call to gain consent. Patient comments included the following:

*"Prevented my condition from deteriorating by making diagnoses from breathlessness"*

*"Cannot fault the service. Excellent preventative service for the whole family"*

*"Excellent service"*

*"Amazing, reassuring, cannot praise enough."*

## Health promotion, protection and improvement

Through conversation with the Registered Manager (RM) and the Responsible Individual (RI - the person who represents the company) we were told that at present there are no leaflets offered to patients promoting a healthy lifestyle, such as healthy eating, exercise or smoking cessation. Additionally the patient records that we looked at did not evidence that doctors discuss a healthy lifestyle choice with the patient during the consultation. It would be beneficial for the service to offer information to assist patients in making healthy lifestyle choices due to the nature of the screening.

### Improvement needed

The service should offer health promotion information at their screening clinics and doctors should be recording conversations / advice given during their consultations

The service would benefit from numbering patients records sequentially with a front page clearly displaying patient details.

### Dignity and respect

We were satisfied that patients received their consultations with the doctors in a private area away from the waiting area. This is because we saw the screening venue requirements requested by the service prior to agreeing to hold a clinic in a venue. The criteria included; four private rooms approx (7ft x 6 ft); a private room for consultations; waiting area for 15-20 people; reception area; and the venue must comply with all disability access, security, health and safety and fire regulations. Additionally the following is requested to be considered; screening, toilets, food and drink facilities, accessibility of venue by road and rail, sufficient parking, safe loading and unloading of equipment.

All patients, without exception, who responded to the questions asked on the telephone confirmed that the care and treatment being provided was excellent.

### Patient information and consent

We saw in the patients electronic records and were given a blank form to read which showed that patients were given clear information and consented to treatment prior to any screening intervention or consultation with the doctors. However this information was not always held in the paper copies of the patient records. We suggest that the service reviews all paper files to ensure that both electronic and paper files hold exactly the same information. We also read the information provided for both screening techniques offered i.e. Electrocardiogram (ECG)<sup>1</sup> and Echocardiogram (ECHO)<sup>2</sup>. Both were easily

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<sup>1</sup> Electrocardiography is the process of recording the electrical activity of the heart over a period of time using electrodes placed on the skin.

understood and very informative. We suggested that the service add to the ECHO leaflet the process that will follow if any abnormality was detected. This would be in line with the information already offered in the ECG leaflet.

We discussed the availability of this information in any other language including Welsh and were told that at present the information was only available in English.

### Improvement needed

The service should ensure that the electronic and paper records hold identical records

Patients would benefit from information regarding the process following the detection of any abnormalities after the ECHO screening.

The service should ensure that screening forms and information literature is available in alternative languages including Welsh.

### Communicating effectively

We looked at the referral letters to patients' GPs and found that they were robust and included the findings of the Cardiologist, a copy of the ECG and the ECHO (when both were screened). The dates on the letters evidenced that these were forwarded in a timely manner.

All patients who answered the questions on the telephone told us that they were given enough information about the screening, the risks, costs and implications of any abnormalities detected.

### Care planning and provision

We looked at a random sample of five patient records and found that the information was clear and satisfactory for the consultation process.

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<sup>2</sup> An echocardiogram – also known as an echo – uses sound waves to build up a detailed picture of your heart. The echo looks at the structure of your heart and the heart valves, and also gives information on the function and pumping action of your heart

We did not see any individual risk assessments for people accessing the service who may need assistance i.e. wheelchair access, communication issues, request for chaperone facility. Both the RM and the RI were receptive to these suggestions.

#### Improvement needed

The service need to ensure a risk assessment is undertaken prior to screening and that chaperone facilities are clearly offered.

#### Citizen engagement and feedback

We saw evidence of the patient feedback questionnaires given to all patients after attendance at the clinic. We also saw that the information had been collated into graph format and was easy to understand. Areas of improvement had been highlighted. Unfortunately, during the inspection we identified similar areas for improvement that had not been actioned from the feedback analysis such as information and forms in Welsh or bilingual and being given a copy of the patient guide.

## Delivery of safe and effective care

*We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.*

We were satisfied that the clinic offered safe and sensitive treatment tailored to meet individual patient needs.

Staff were appropriately trained for the service they provided.

### Managing risk and health and safety

We looked at a sample of five patient records and were satisfied that the clinical content offered adequate information for the purpose of the consultation.

We saw that the service had a risk register for probable occurrences which could affect the service and subsequently patient care. These had been RAG (Red, Amber, Green) rated and included identified solutions. This was an example of noteworthy practice.

### Infection prevention and control (IPC) and decontamination

There was an infection control policy available which gave satisfactory guidance for safe infection prevention and control. We tested through discussion how the service monitored infection rates and how they managed patients with infection especially high risk infections. The response was in line with their policy. We suggested that the pre-screening information includes a question on whether a patient has an infection or open wound so that this can be managed appropriately on the day of screening.

Personal protection equipment (PPE) such as aprons and gloves were the responsibility of the service and they had a building which was used to store all equipment. We were told that all probes and machinery were wiped with antibacterial wipes after each patient and again at the end of each session.

We could not ascertain whether staff had received appropriate training in hand hygiene nor was there a record of decontamination (cleaning) of shared equipment.

### Improvement needed

The service needs to establish training records in infection control specific to the service provided

The service needs to establish cleaning records of shared equipment.

### Safeguarding children and safeguarding vulnerable adults

There had been no safeguarding issues. The RM had attended training to level 3 however we could not ascertain what training other staff had received due to the lack of records. We looked at the Safeguarding policy and noted that local contact details were not held with the safeguarding policy. This needs to be addressed according to the authority the service is providing screening. Recruitment processes were looked at and staff had received the required checks prior to commencing work.

### Improvement needed

The service needs to amend the Safeguarding policy to include the contact details for all the authorities where it is likely to provide a service.

### Equipment and diagnostic systems

Equipment was not stored at the office and therefore we were unable to physically see the standard of equipment in use. However we were told by the RM that the equipment was either loaned from a local training service or if under contract from the manufacturer was brand new and was still within its warranty period. There were no records of annual maintenance of equipment as the service had not been established that long however we suggest that a record is kept of when individual equipment requires recalibration or maintenance checks. We were told in the case of an unexpected emergency situation Welsh Hearts<sup>3</sup> were always present with a portable defibrillator<sup>4</sup>

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<sup>3</sup> Charity for placing defibrillators in communities and delivering CPR and defibrillator training in Wales.

## Safe and clinically effective care

We were satisfied that the service offered a safe and clinically effective service because we saw the benefits for the patients with early detection and referrals for preventative measures.

We looked at the nutritional policy which stated that the service offered specialist advice in nutrition and weight management. We asked for further clarification on who offered the specialist advice and it was agreed that for patient safety, as there was no dietician involved in the screening process, it would be removed from the policy.

We were told that the service was led by NICE<sup>5</sup> guidance, the [Independent Health Care \(Wales\) Regulations 2011](#) and the National Minimum Standards for Independent Health Care in Wales.

### Improvement needed

The service needs to review the Nutritional policy and amend as required.

## Records management

We saw that records were stored in a safe and secure environment. Paper records were stored in a secure environment in a storage building whereas the electronic records were on the computer with an appropriate off site back up system in place.

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<sup>4</sup> A defibrillator is a device that gives a high energy electric shock to the heart through the chest wall to someone who is in cardiac arrest.

<sup>5</sup> The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.

## Quality of management and leadership

*We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Independent Health Care Regulations and National Minimum Standards.*

We were satisfied that there was strong management and leadership although lines of responsibility within the Director team were less clear.

The service development plan was unfinished this needs to be addressed to maintain continuity and growth of the business.

### Governance and accountability framework

There was evidence of strong, organisation and management with the RI and the RM working closely together.

There were no written reports of visit from the RI because there is constant daily involvement with the business. In line with Regulation 28 the RI needs to write a short overview report of the service every six months. These need to be kept for inspection.

We were concerned with the lack of clear responsibilities for each Director and this was discussed. For ease of reference it would be beneficial if each Director has designated responsibilities, who can oversee particular areas and then feed relevant information into the quarterly meetings. The Service Development Plan was work in progress and required a robust marketing plan to ensure equity of services across Wales whilst also maintaining continuity and growth for the business.



The Statement of Purpose<sup>6</sup> had been reviewed in April 2017 however there was no review date on the Patients Guide. Both these documents included the relevant information.

#### Improvement needed

The service needs to schedule regular meetings held by Directors which are minuted with actions to be taken recorded to ensure appropriate accountability

The RI needs to write an overview report of the current status of the service every six months

The Directors need to outline each individual's responsibility within the company.

#### Dealing with concerns and managing incidents

There had been no concerns/complaints from patients since the service had registered. However when we asked patients by telephone if they would know how to make a complaint all said they did not know. We saw that the complaint process and HIW address was included in the Patients' Guide, but in line with the comments from patients they were not routinely given the Patients' Guide during a screening appointment.

#### Improvement needed

The service needs to ensure that a Patients Guide is offered to each patient during the screening process. This will ensure they have the correct information regarding the service and that information is available should they wish to raise a concern.

#### Workforce planning, training and organisational development

Staff are employed by the service on an ad hoc basis. The RM told us that staff receive appropriate training to the clinical areas where they work, in their main employment. There was no training matrix available and staff files did not

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<sup>6</sup> A statement of purpose for a business describes what you do, who you are, where you do it and who you do it for.

contain copies of any training undertaken. Therefore neither the RM nor we could be assured that all staff were sufficiently trained/updated for the work they were to carry out. We discussed this with the RM and were assured that staff would be asked to bring in their training records for copying. This we understood would be actioned immediately.

### Workforce recruitment and employment practices

We looked at staff files and were satisfied that all documents were available as initial employment checks. However, we did not see updated professional qualifications and registration checks with appropriate bodies in the staff files such as evidence of doctor's revalidation<sup>7</sup> and annual registration.

All staff had a disclosure and barring services report from previous / permanent employment. The RM needs to be satisfied that there have been no changes to the check since it was originally applied for.

#### Improvement needed

The serviced needs to ensure updates of re validation and registration with appropriate professional bodies are recorded in staff files

The serviced needs to be satisfied that the DBS checks are current and valid.

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<sup>7</sup> Revalidation is the process for doctors to positively affirm to the General Medical Council (GMC) that they are up to date and fit to practice.

## 4. What next?

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a [non-compliance notice](#). The issuing of a non compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- Ensure actions taken in response to the issues identified are specific, measureable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

## 5. How we inspect independent services

Our inspections of independent services may be announced or unannounced. We will always seek to conduct unannounced inspections because this allows us to see services in the way they usually operate. The service does not receive any advance warning of an unannounced inspection. In some circumstances, we will decide to undertake an announced inspection, meaning that the service will be given up to 12 weeks' notice of the inspection.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

HIW inspections of independent healthcare services will look at how services:

- Comply with the [Care Standards Act 2000](#)
- Comply with the [Independent Health Care \(Wales\) Regulations 2011](#)
- Meet the [National Minimum Standards](#) for Independent Health Care Services in Wales.

We also consider other professional standards and guidance as applicable.

These inspections capture a snapshot of the standards of care within independent services.

Further detail about [how HIW inspects independent services](#) can be found on our website.

## Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
There were no immediate concerns identified on this occasion.			



Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
<p>and paper records hold identical records</p> <p>Patients would benefit from information regarding the process following the detection of any abnormalities after the ECHO screening.</p> <p>The service should ensure that screening forms and information literature is available in alternative languages including Welsh.</p>	and consent	<p>to ensure each are identical.</p> <p>Adjust echo information to include process following the detection of any abnormalities after the echo screening.</p> <p>Translate screening forms into Welsh using translators from the Professional Association for English/Welsh Translators and Interpreters</p>	<p>Shannon Stevens</p> <p>Subcontracted to professional body</p>	<p>01 Mar 2018</p> <p>30 Mar 2018</p>
The service need to ensure a risk assessment is undertaken prior to screening and that chaperone facilities are clearly offered.	8. Care planning and provision	Amend screening medical questionnaire to add patient risk assessment regarding accessibility requirements and chaperoning.	Shannon Stevens	01 Mar 2018
<b>Delivery of safe and effective care</b>				
<p>The service needs to establish training records in infection control specific to the service provided</p> <p>The service needs to establish cleaning records of shared equipment.</p>	13. Infection prevention and control (IPC) and decontamination	<p>Create training records to evidence the infection prevention control procedure.</p> <p>Create cleaning records to evidence cleaning process at each screening event.</p>	<p>Shannon Stevens</p> <p>Shannon Stevens</p>	<p>01 Mar 2018</p> <p>01 Mar 2018</p>

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
The service needs to amend the Safeguarding policy to include the contact details for all the authorities where it is likely to provide a service.	11. Safeguarding children and safeguarding vulnerable adults	Add annex to include contact details for all local authority safeguarding teams in Wales.	Shannon Stevens	01 Mar 2018
The service needs to review the Nutritional policy.	7. Safe and clinically effective care	Amend the nutritional policy to remove specialist dietary advice.	Shannon Stevens	01 Mar 2018
<b>Quality of management and leadership</b>				
<p>The service needs to schedule regular meetings held by Directors which are minuted with actions to be taken recorded to ensure appropriate accountability</p> <p>The RI needs to write an overview report of the current status of the service every six months.</p> <p>The Directors need to outline each individual's responsibility within the company.</p>	1 Governance and accountability framework	<p>Meetings to be scheduled every quarter with the directors which re minuted and actions are recorded.</p> <p>RI to write an overview report of the service for the last 6 months.</p>	<p>All Directors</p> <p>Chris James</p>	<p>From Mar 2018</p> <p>01 Mar 2018</p>
The service needs to ensure that a Patients Guide is offered to each patient during the screening process. This will ensure they have	23 Dealing with concerns and managing	Ensure each patient receives a copy of the patient guide at screening clinics by having multiple printed copies to hand to	Shannon Stevens	01 Mar 2018



Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
the correct information regarding the service and that information is available should they wish to raise a concern.	incidents	each individual		
<p>The serviced needs to ensure updates of re validation and registration with appropriate professional bodies are recorded in staff files</p> <p>The serviced needs to be satisfied that the DBS checks are current and valid.</p>	24. Workforce recruitment and employment practices	<p>Contact current screening staff to get copies of all validation and registration updates with appropriate professional bodies to record on file.</p> <p>Create training matrix to monitor training, validation and registration of staff with their respective professional bodies.</p> <p>Conduct DBS on all medical staff used for screening.</p>	<p>Shannon Stevens</p> <p>Shannon Stevens</p>	<p>27 Apr 2018</p> <p>27 Apr 2018</p>

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

**Service representative**

**Name (print): Shannon Stevens**

**Job role: Director and Registered Manager**

**Date: 07.02.2018**