Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

Independent Healthcare Inspection (Announced)

Simbec Research Ltd

Inspection Date: 14 February 2017

Publication Date: 15 May 2017

This publication and other HIW information can be provided in alternative formats or languages on request. There will be a short delay as alternative languages and formats are produced when requested to meet individual needs. Please contact us for assistance.
Copies of all reports, when published, will be available on our website or by contacting us:

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
Fax: 0300 062 8387
Website: www.hiw.org.uk

Digital ISBN 978-1-4734-9703-0

Contents

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 completed an announced inspection of Simbec Research Ltd part of the Simbec-Orion Group Ltd on 14 February 2017.

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.

Further details about our approach to inspection of independent services can be found in Section 6.

For the purpose of this report, as the participants do not requiring health care and are offering their services to the research study they will be referred to as "Volunteers".

2. Context

Simbec Research Ltd is registered to provide an independent research clinic at Merthyr Tydfil Industrial Park, Pentrebach, Merthyr Tydfil CF48 4DR. The service has three blocks which comprise of offices, laboratories and clinical pharmacology facilities. The clinical centre facilities include five wards with a total of 48 beds on the first floor. The pharmacy and aseptic suite are situated on the ground floor with an out-patient facility and an additional 10 beds. The service was first registered on 11 December 2015.

The service employees a staff team which includes research doctors, nurses, physiologists, physiology technicians, laboratory technicians and administrative staff. The service provides:

- **Phase I clinical trials**. Clinical trials are conducted in a series of steps, called phases-each phase is designed to answer a separate research question. **Phase I** usually test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

The service only accepts adults (over the age of 18) as volunteers.

3. Summary

Overall we found that arrangements were in place to provide a safe and effective service.

This is what we thought the service did well;

- Volunteers we spoke to were happy with the service provided
- The registered manager was responsible for the day to day management of the service and was supported by a friendly staff team, who demonstrated a commitment to providing a safe and high quality service.
- There was clear leadership and management
- Staff we spoke to were happy in their roles and understood their responsibilities
- Clinical facilities are well-equipped, visibly clean and tidy
- There were quality assurance audits throughout the process of each study

This is what we recommend the service could improve:

- Staff training in safeguarding adults and children
- Staff must have current Disclosure and Barring (DBS) checks
- Signage offering the chaperone service

We identified regulatory breaches during this inspection regarding and further details can be found in Appendix A.

Whilst these have not resulted in the issue of a non compliance notice, there is an expectation that the registered provider takes meaningful action to address these matters, as a failure to do so could result in non-compliance with regulations.

4. Findings

Quality of patient experience

Volunteers told us they were very satisfied with the service they had received at Simbec. Arrangements were in place to protect their privacy and we saw staff being friendly and respectful to volunteers.

Prior to the inspection, we asked the registered manager to distribute HIW questionnaires to volunteers to invite them to provide their views on the service they had received. In total 22 completed questionnaires were returned. Comments included:

> *'All the staff treat the volunteers with care, empathy and understanding. They all have a great sense of humour and make the process of staying in here a lot easier."*
>
> *'Professional and considerate.""*
>
> *'Staff go out of their way to help you and make you feel welcome and comfortable.'*

When invited to rate the service provided, volunteers rated this between eight and ten out of ten. The majority (15 volunteers) gave a rating of ten out of ten.

Dignity and respect

We found the service had suitable arrangements in place to protect and promote volunteers' rights to privacy and dignity. For example, although male and female volunteers could mix during the day, there were two separate wards for sleeping and each bed had a privacy screen. There were also gender specific toilet and shower facilities.

There were up to date privacy and dignity and equality and diversity policies available to guide staff in their work. The clinic environment facilitated the provision of private, confidential and dignified care, for example, although the clinical reception area was open, there were specific clinical rooms which provided a private area for conversations, consultations and assessments, prior to taking part in a programme. In addition, clinical staff had received chaperone training and this was offered when requested. However there was no signage advertising this facility in the waiting or clinical areas.

Improvement needed

The registered manger should ensure that volunteers are aware of the chaperone facility offered at Simbec.

Volunteers who completed and returned HIW questionnaires told us that staff treated them with respect and were polite to them. We also observed staff being friendly and professional to volunteers.

Volunteer information and consent

We saw that there were paper and electronic systems in place for gathering personal and medical information from volunteers. We also saw that consent, consultations and intervention plans were clear and provided an on-going account of the health and welfare of the volunteer.

Communicating effectively

Prior to the inspection, we read a copy of the Statement of Purpose and Service Users guide. These are documents which set out the terms of the service offered, the staff team, a review of the service and the outcome of engagement with volunteers. Both contained the required information.

Posters and leaflets were available to inform people about how to become a volunteer and what it would entail. The registered provider also gave us an example of the information given to volunteers after the first consultation; which offered guidance on the intervention, length of commitment to the project, payments and how to raise a concern, should the need arise.

There was no information available to volunteers in Welsh. We therefore discussed this with the registered provider and we were assured that key documents such as complaints and volunteer information/contract leaflets, would be translated into Welsh and made available on request. We were also informed that volunteers who requested translators in any language would receive appointments when translation services could be made available. This would be discussed during the first consultation.

Improvement needed

The registered provider needs to ensure key information is available in both Welsh and English.

Care planning and provision

Volunteers received individualised confidential intervention from the first point of contact. For example, volunteers' needs and health screening were initially assessed in the clinical day unit by clinical doctors and trained nurses. This allowed the assessment to be undertaken in a professional and discreet manner.

We looked at a sample of volunteer records and found that they were detailed and study specific. We saw letters from the Ethics Committee[1] confirming the proposed study, a schedule of events, consent form (also study specific), information regarding the study, possible side effects, volunteers expected commitment and any toxicology implications.[2] There were also recorded observations of the volunteers' vital signs i.e. blood pressure and weight. We were satisfied that the assessments and information included in these documents were robust.

[1] The Ethics Committee safeguards the rights, safety, dignity and well-being of research participants, independently of research sponsors. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical

[2] Toxicology is the scientific study of adverse effects that occur in living organisms due to chemicals. It involves observing and reporting symptoms, mechanisms, detection and treatments of toxic substances, in particular relation to the poisoning of humans.

Delivery of safe and effective care

Overall, HIW was assured that Simbec Research Ltd provided volunteers with safe intervention which was based on agreed best practice guidelines and complied with safety requirements.

Environment

The environment was spacious and made up of offices, laboratories and clinical pharmacology facilities in a purpose built complex. The buildings comprised of three blocks: A, B and C.

Block A housed the Bioanalytical Unit[3] on a single floor with laboratory facilities.

Block B was a two storey building, housing project management teams on the first floor and the main reception on the ground floor.

Block C was the main clinical building. On the ground floor was the pharmacy and aseptic suite along with the catering and recreational facilities. Additionally there was an out-patient facility with 10 beds, clinical rooms and reception area. The five ward (48 bed) Clinical Centre was on the second floor with the third floor housing the company's clinical testing laboratory facility and the administrative offices.

The building was clean, well organised and decorated to an acceptable standard. We saw that Portable Appliance Testing (PAT) had been undertaken and there were smoke alarms and fire extinguishers to provide a safe environment. This meant that the service placed an emphasis on the safety of volunteers and staff. We were therefore assured that the environment was suitable and safe for the volunteers.

Managing risk and health and safety

The service employed a security company between the hours of 6 pm and 7:30 am to ensure the premises were safe and secure. When volunteers were required to stay overnight the service employed a monitoring guard who was based on the ward to maintain a safe environment.

We saw that Control of Substances Hazardous to Health (COSHH) policies, guidance and training was up to date.

---

[3]Bioanalytical testing is the identification or measurement of substances (such as drugs, metabolites, or proteins) in a biological system (such as blood plasma, urine, or hair).

Infection prevention and control (IPC) and decontamination

There were schedules in place for cleaning and we saw contracts with regard to clinical waste and facility maintenance. We saw hand washing facilities and disinfecting hand gel in the clinical areas. Staff had received training in infection control and we saw the use of protective aprons, clothing, eye guards and gloves. Staff told us that they had all been screened and had received the vaccination against Hepatitis B.

Nutrition

There was a catering facility which provided food for both staff and volunteers. This had recently received a standard five health and safety rating from the Food Standards Agency. Volunteers we spoke with said that the food was good and portion size was satisfactory.

Medicines management

Due to the nature of the service there were strict guidelines regarding the administration of medicines. We observed a simulated drug administration (for our benefit) which showed us how exact the timing must be for the purpose of the study. To ensure safe practice two trained nurses check the volunteer details and the drug prior to administration. The drugs are already assigned to the individual volunteer in individual drug containers whilst in the pharmacy. Records of drug administration and their effects were closely monitored and recorded. We had no concerns regarding the safe storage, administration and disposal of medication.

Safeguarding children and safeguarding vulnerable adults

We discussed the relevance and issues surrounding safeguarding vulnerable adults / children and the registered manager stated that all volunteers were healthy and fit to take part in the study. However, further discussion relating to disclosure of abuse and the responsibility of professionals to act on this information, clarified the need for staff to attend safeguarding training and for the service to develop safeguarding policies and procedures.

Improvement needed

The registered provider must ensure that staff receive the relevant training in safeguarding according to the All Wales Safeguarding guidance.

Medical devices, equipment and diagnostic systems

There were strict requirements on calibration and testing of medical equipment to ensure the validity and reliability of the study. We spoke with staff who explained the processes in place to maintain 'service as usual' when equipment needed servicing or maintenance. This included back up equipment or the hiring of specific equipment for analysis of some studies.

We were shown the laboratories and the systems were explained. There were, again, strict guidelines and processes which all staff were aware of and incorporated into their daily work.

Safe and clinically effective care

We found that intervention and care was based on agreed best practice guidelines. The service was led by specialist clinicians, nurses and support technicians. Staff stated that they were satisfied that they had the appropriate environment, training and facilities to undertake the work expected of them.

We were assured that systems and facilities were safe because the service was regulated by numerous outside agencies and were scrutinised annually to meet with strict guidelines for accreditation to practice. Many of the inspections/accreditations were from 2016.

We also saw that each study had a risk management plan to reduce any incidents or concerns.

We saw and were told that all volunteers were expected to attend a follow-up appointment after the completion of a study. No volunteer would be 'signed off' until this appointment had been attended. This ensured the safe discharge of the volunteer from the study.

Participating in quality improvement activities

The service had a quality assurance department with a defined audit programme. This ensured that all aspects of the service provision from; each specific study (which may have set audits required), the volunteer enrolment process, audit of clinical processes to staff training records were scrutinised. We asked for examples of how the service ensures it is maintaining or improving the service provision and we were told about the quality assurance monitoring from the development of the study through to the final study report. Examples were; regular "in progress" clinical

audits, system and facility audits to ensure compliance and regular due diligence client audits[4].

[4] Due diligence is an investigation of a business or person prior to signing a contract, or an act with a certain standard of care.

Quality of management and leadership

We were satisfied that there was good leadership and management to support the established policies and procedures in place.

There was clear evidence that the service monitored its performance to identify where they could make improvements to the volunteers experience and after care.

We found regular audits had been carried out with outcomes or identified improvements recorded from the audits.

Governance and accountability framework

We saw that a range of monthly audits had been carried out. These related to infection control arrangements, documentation, risk assessments and volunteer feedback forms.

The service had regular outside agency inspections and audits to approve on-going studies. These agencies included Research Ethics Committee (REC) (last visited January 2017), Medicines and Healthcare products Regulatory Agency (MHRA-UK Competent Authority), Administration of Radioactive Substances Committee (ARSAC) for trials involving radiolabelled drugs and Research and Development Trust approvals for trials involving NHS sites/GP surgeries.

There were regular (approximately monthly) meetings between the registered manager and the registered provider, who, we were told, was very supportive, visible and pro-active within the service.

From these meetings information would be cascaded via weekly managers meetings. The clinicians also had meetings twice a month. We were satisfied that communication and shared practice was evident amongst the teams.

However, these meetings were not minuted and therefore there was no evidence of discussion regarding improvements, lessons learned or best practice initiatives.

Improvement needed

The registered manager needs to reinstate the recording of staff meetings.

Dealing with concerns and managing incidents

We saw that there was a policy and procedure for handling concerns (complaints) and this was available in the statement of purpose and the volunteers' records. There was a system in place to record details of any complaints investigation, outcome and action taken.

HIW had not received any regulation 30/31 notifications since the service had been registered in 2015. (These are notifications of any untoward incidents or events). Discussion with the registered provider indicated that there had not been any notifiable events however the service was also unaware of the need to notify HIW. We were assured that this would be undertaken if the situation arose in the future.

We were told that in the event of an emergency clinical incident there were agreements in place with the Welsh Ambulance Service Trust and the local district general hospital.

The service was also supported by experienced on-call Consultants.

Workforce planning, training and organisational development

We looked at the documentation for staff appraisals and personal development plans and were satisfied that these were being undertaken appropriately. Supervision was undertaken in a systematic cascaded line manager manner.

Staff training was on-going within the service. Staff told us that training was not a problem and they could access courses which would enhance their practice. We saw that areas such as immediate life support, advanced life support, infection control, and confidentiality were regularly updated. We were told that there was regular emergency scenario training which included first response and rapid resuscitation.

Clinical staff told us that there was no concern with meeting the requirements for re-validation of their professional qualification to practice.

HIW had no concern with staffing levels or retention of staff. However, when we scrutinised the recruitment process we saw that the service had not undertaken any Disclosure and Barring Service (DBS) checks prior to staff commencing work at the service. Regulation 21(3) provides that the criminal record certificate must be applied for by or on behalf of the registered person, for the purposes of assessing the suitability of a person for employment. This means that the registered person (or someone on his/her behalf – an umbrella organisation for example) must apply for a DBS check for a person before employing him or her as a worker. Once this is done, there is no requirement in the regulations to carry out a further DBS check in relation to the worker.

HIW had DBS checked the registered provider and registered manager as part of the registration process, to ensure compliance with Regulation 10 of the Independent Healthcare (Wales) Regulations 2011, which states that a criminal record certificate, which is less than three years old, must be seen to evidence that the person is fit to carry on a service. This means that the responsible individual and registered manger must have a DBS check every three years as part of their ongoing fitness requirement.

Improvement needed

The registered provider must undertake DBS checks on all members of staff and be mindful that the registered provider and registered manager will need updated DBS checks by December 2018.

5. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan (Appendix A) to address the key findings from the inspection.

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

The actions taken by the service in response to the issues identified within the improvement plan need to be specific, measureable, achievable, realistic and timed. Overall, the plan should be detailed enough to provide HIW with sufficient assurance concerning the matters therein.

Where actions within the improvement plan remain outstanding and/or in progress, the service should provide HIW with updates, to confirm when these have been addressed.

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

6. Methodology

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 Wales[5].

We conduct both announced and unannounced inspections of independent healthcare services and we inspect and report against three themes:

- **Quality of the patient experience:**
  We speak with patients (adults and children), their relatives, representatives and/or advocates to ensure that the patients' perspective is at the centre of our approach to inspection.

- **Delivery of safe and effective care:**
  We consider the extent to which services provide high quality, safe and reliable care centred on individual patients.

- **Quality of management and leadership:**
  We consider how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also consider how health boards review and monitor their own performance against the National Minimum Standards and Independent Health Care (Wales) Regulations.

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

[5] 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

- 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 notice[6]. 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.

[6] 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.

Appendix A

Improvement Plan

Service: Simbec Research Ltd

Date of Inspection: 14 February 2017

Page Number	Improvement Needed	Regulation / Standard	Service ActionReg	Responsible Officer	Timescale
Quality of Patient Experience					
Page 6	The registered manger should ensure that volunteers are aware of the chaperone facility offered at Simbec.	Reg 18 Standard 10	Notices have been posted in the main Enrolment Services office, examination area and in the physician's examination room stating that a chaperone service is offered if required.	Gareth Marshall	Completed 14th February 2017
Page 6	The registered provider needs to ensure key information is available in both Welsh and English.	Reg 18 Standard 18	The following participation information is to be translated into Welsh: • Chaperone information • Information on concomitant medication • Fire Alarm procedure	Gareth Marshall	30th April 2017

Page Number	Improvement Needed	Regulation / Standard	Service ActionReg	Responsible Officer	Timescale
			• Application process • Complaints procedure The information will be available in Welsh at the location the English version is available.		
Delivery of Safe and Effective Care					
Page 9	The registered provider must ensure that staff receive the relevant training in safeguarding according to the All Wales Safeguarding guidance.	Reg 16 Standard 11	A Safeguarding Vulnerable Adults (SOVA) on-line training course has been identified which provides training in accordance with the All Wales Safeguarding guidance. Participants in this training course will be members of Enrolment Services, Clinical Staff (including all shift workers) and Medical staff.	Deborah Evans Annelize Koch	31st May 2017
Quality of Management and Leadership					
Page 13	The registered manager needs to reinstate the recording of staff meetings.	Reg 18 Standard 18	The weekly managers meeting are now documented in minutes effective immediately. The meeting minutes are circulated to department managers who then circulate within the department.	Hemant Patel	Effective Immediately

Page Number	Improvement Needed	Regulation / Standard	Service ActionReg	Responsible Officer	Timescale
Page 15	The registered provider must undertake DBS checks on all members of staff and be mindful that the registered provider and registered manager will need updated DBS checks by December 2018.	Reg 21(2)(d) Schedule 2 Standard 24	Going forward, DBS checks will be conducted during the recruitment process on all new recruits. We acknowledge the registered provider and registered manager require updated DBS checks by December 2018.	Lynne Cox	Effective immediately

Service Representative:

Name (print): **Sandra Davies**

Title: **Group Head of Quality Assurance**

Date: **19 April 2017**