Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Independent Healthcare Inspection (Announced)

Simbec Research Limited

Inspection date: 16 December 2019

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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 receive good quality healthcare

Our values

We place patients at the heart of what we do. We are:

- **Independent**
- **Objective**
- **Caring**
- **Collaborative**
- **Authoritative**

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 Simbec Research Limited on the 16 December 2019.

Our team, for the inspection comprised of one HIW inspector and one clinical peer 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.

For the purpose of this report, as the participants did not go to the clinic for health care and were offering their services to the research study, they will be referred to as “volunteers”.

2. Summary of our inspection

Overall, we found evidence that Simbec Research Limited, provided safe and effective care in clean and welcoming environment.

Volunteer notes were comprehensive and the volunteers were fully aware of the trial and the risks involved.

There were comprehensive policies and procedures documented for the management and control of the clinic.

We found staff friendly and professional. There was good leadership and management shown within the clinic.

However, we found some evidence that the clinic was not fully compliant with all standards in all areas.

This is what we found the service did well:

- Providing information to volunteers on the service provided
- The clinic was clean and tidy and arrangements were in place to reduce cross infection
- Volunteer records were comprehensive including a photograph of the volunteer for future reference
- Volunteers' records about the trial and inclusion information were kept in separate folders
- Policies and procedures were detailed and varied.
- Good management and leadership.

This is what we recommend the service could improve:

- Displaying the outcomes and any changes made as a result of volunteer feedback

We identified regulatory breaches during this inspection regarding the lack of the responsible individual producing a written report on the conduct of the

service, every six months. Further details can be found in Appendix B. Whilst this has 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.

3. What we found

Background of the service

Simbec Research Limited (the clinic) is registered to provide an independent research clinic at Merthyr Tydfil Industrial Park, Pentrebach, Merthyr Tydfil CF48 4DR. The clinic 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 were situated on the ground floor with an out-patient facility and an additional 10 beds.

The clinic was first registered on 11 December 2015.

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

The clinic provides Phase 1 clinical trials. Clinical trials are conducted in a series of steps, called phases, each phase is designed to answer a separate research question. Phase 1 usually tests 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 clinic only accepts adults (over the age of 18) as volunteers.

The main condition of registration is that medical practitioners are only permitted to treat patients for conditions as a direct result of licensed clinical research undertaken.

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 volunteers in a safe and professional manner.

Volunteers were provided with specific information regarding their trial.

Volunteers provided positive comments about their care and treatment.

Systems to capture volunteer feedback were available but the results of the feedback were not displayed at the clinic.

Prior to the inspection, we invited the clinic to distribute HIW questionnaires to volunteers to obtain their views on the care and support provided by the clinic. A total of 38 questionnaires were completed. Overall volunteer feedback was very positive and they rated the care and treatment provided as excellent. Comments included:

"Staff are always amazing"

"Very polite and helpful at Simbec thank you".

Health promotion, protection and improvement

There were few leaflets in the clinic relating to health promotion, protection and improvement. More should be done to help volunteers look after their own health and to provide leaflets on the types of illnesses, including smoking cessation, and injuries that occur and their prevention. We advised the clinic to consider providing information on fitness, healthy living and mental health.

Improvement needed

The service must ensure that sufficient health promotion information is provided for the service user group.

Dignity and respect

Volunteers were asked in the questionnaires whether they agreed or disagreed with a number of statements about the staff at the clinic. The vast majority of volunteers agreed that staff were always polite and listened to them. Volunteers also told us that staff were kind and sensitive when carrying out the trials.

During our visit we noticed that volunteers were arriving and being seen quickly. We saw reception staff welcoming volunteers in a friendly manner and being polite and courteous when speaking to them. There were ground floor consulting rooms that would be used, should volunteers wish to speak to staff in private.

There were separate wards available for use when there were male and female volunteers at the clinic, with each bed having a privacy curtain. There were also gender specific toilet and shower facilities.

There was an up to date privacy and dignity policy available to guide staff in their work. Information was displayed in the reception area and each consultation room informing volunteers of their right to have a chaperone present when being seen by healthcare staff. The use of chaperones aims to protect both the healthcare professional and volunteer when the volunteer is examined by the healthcare professional.

We saw that volunteers would be seen in a consulting room with a lockable door or in a three bay examination room with privacy curtains. We noted that the curtains were drawn when volunteers were being seen in the examination room. However, there were no privacy curtains in the consulting rooms around examination couches to further maintain volunteers' privacy and dignity.

Improvement needed

The clinic must ensure that all consulting rooms have a privacy curtain or screen to use when a volunteer is being examined.

Patient information and consent

All of the volunteers who completed a questionnaire agreed that staff provided them with enough information about their trial, including information about any associated risks, one volunteer commented in the questionnaire:

> *"Thoroughly enjoy the interaction with staff, they all feel extremely approachable and caring whilst maintaining an excellent level of professionalism."*

Detailed information about the drug on trial and what to do if the volunteer experienced any unwanted side effects was documented on detailed information leaflets, which were provided to the volunteer. These information leaflets were included in the volunteer notes.

Staff we spoke with said that if the General Practitioner (GP) notes, requested for each volunteer, indicated any possible capacity issues, then that volunteer would not be included in the trial. There was also evidence in the initial assessment notes and clinical research folder (CRF) notes that valid informed consent was obtained from the volunteer. For the sample of records checked these were all signed and dated.

Communicating effectively

The majority of volunteers that completed a questionnaire told us that they would know how to make a complaint if they were unhappy with the service provided at the clinic.

Generally, information was provided in English only, staff we spoke with said that key documents such as volunteer information and contract leaflets would be translated into Welsh and made available on request. As an independent clinic based in Wales, the registered provider should make more effort to have information available in Welsh without the need for volunteers to ask for it.

Additionally, information was given to volunteers following the first consultation on the intervention, length of commitment to the trial, payments and how to raise a concern, should the need arise.

We saw pictorial signs were displayed to assist volunteers to find a suitable emergency escape route in the event of a fire.

Information was not displayed about the staff working at the clinic and we recommended that this should be displayed, particularly in the ward areas, so that volunteers were aware of the staff on the ward and their roles.

Improvement needed

The clinic is to ensure that a staff who's who is displayed in the ward areas.

Care planning and provision

Each clinical investigation (trial) began with the development of a clinical protocol. The protocol is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and

organisation of a clinical trial) and ensures the safety of the trial volunteers and integrity of the data collected. The clinical protocols were from the organisations that contracted the clinic to trial their product. Risk management plans were developed for the study that showed:

- Brief of study and decision of what's required on the study
- Risk reporting and communications, medical areas and procedures, safety information and any risks such as cardiovascular (heart or blood vessels) or renal (kidneys)
- Predictable adverse events, risk control and mitigation, staffing levels and qualifications required
- Study schedule including staff allocated.

The initial assessment of a volunteer was to find out whether the subject was suitable for the trial. Initial risk assessments were for the purpose of suitability to be included in the trial, this suitability, or otherwise, was documented in the volunteer notes. Whilst on the trial the volunteers' notes were updated as per the protocol of that trial and further risk assessments were completed if any adverse events were documented. The sample selected did not include any volunteer where adverse events needed to be documented. This information was also passed on to their GP.

Equality, diversity and human rights

During the visit we did not identify any issues or procedures that would affect an individual's equality, diversity and human rights. There was disabled parking available and good level access to the premises. Access to the upper floors was by means of a stairway and/or a lift. All staff had completed the equality and diversity training required by the clinic.

Citizen engagement and feedback

A complaints policy was in place and included up to date details of HIW. This was displayed at the clinic and included in the statement of purpose[1] and volunteer guide.

The clinic had a system in place for volunteers to provide feedback on the trial and the care, to actively inform them how to improve services, on a volunteer experience questionnaire that was sent to users at the end of each trial. This information was then analysed internally and staff were informed of the results by email. Individual breakdown of volunteer feedback was provided to clinic staff only. The feedback that was seen during the inspection was positive. However, volunteers were not informed of the results of the feedback. In order to demonstrate to all volunteers that the clinic listens and acts on their feedback, we recommend that they display the outcomes or changes made, as of a result of volunteer feedback.

Improvement needed

The clinic is to display, in a prominent position, the outcomes and any changes made as a result of volunteer feedback.

[1] Every service provider is required by law (Care Standards Act 2000 and the Independent Healthcare (Wales) Regulations 2011) to have a statement of purpose and it should include specific details about the service, what treatments are provided, to who (age), by whom and any equipment used. By law, the statement of purpose must include the information listed in Schedule 1 of the Independent Health Care (Wales) Regulations 2011.

Delivery of safe and effective care

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

Overall, there were arrangements in place to ensure that volunteers received care and treatment in a safe and effective way.

The clinic was clean and tidy and arrangements were in place to reduce cross infection.

The volunteer records we reviewed were comprehensive and volunteers were provided with specific information regarding their trial.

The clinic would benefit from additional audits on infection prevention.

Managing risk and health and safety

Overall, we found arrangements were in place to protect the safety and wellbeing of staff working at, and volunteers visiting the clinic. Access to the building and to the various areas of the clinic was through authorised staff identity swipe cards.

We found the clinic to be well maintained and generally free from clutter and tripping hazards. The environment was in a good state of repair, with clean, tidy and well organised volunteer and staff areas, providing a comfortable, welcoming and suitable clinic for the services provided. There were no major concerns given by volunteers over the cleanliness of the clinic; all the volunteers that completed a questionnaire agreed, in their opinion, the environment was both clean and tidy.

The clinic had a number of policies relating to risk management and health and safety. There was an annual schedule for audits of health and safety in the clinic to help identify any areas for improvement.

Infection prevention and control (IPC) and decontamination

Staff we spoke with on duty on the day of the inspection were well aware of the importance of IPC and in their role to prevent cross contamination. They were

aware of good hand hygiene, when to use alcohol gel and when to wash their hands. There were suitable processes in place to help ensure the prevention of infections, which included the availability and use of personal protective equipment. Staff were practising a bare below the elbow[2] approach to their dress code.

The downstairs day room also had a number of overflow beds, with a dedicated smoking room and inhaler room that could both be used as part of a specific trial. At the time of the inspection the beds and the room were not in use and were being used as a storage area following a delivery that morning.

We noted several rooms where samples were being analysed that had hazard tape on the floor to designate the boundary between clean and unclean, to limit entry. We saw that medical sharps (such as needles) had been placed in appropriate containers for safe disposal. This helped reduce the risk of injury (to staff and volunteers) and cross infection from used sharps.

Staff we spoke with told us that equipment was wiped down before and after use, using disposable wipes. Disposable equipment was used where possible. The clinic beds were also cleaned and changed, in between volunteer use.

There was one chair in a downstairs consulting room in a poor state of repair with the internal “stuffing” exposed that would be a potential IPC risk. We saw evidence of a number of audits at the clinic within a regular audit programme, but these audits did not include IPC audits.

Improvement needed

The clinic is to ensure that:

- Equipment that is in a poor state of repair is disposed of, or repaired
- IPC audits are added to the audit programme.

[2] Recognised good practice enabling staff to effectively wash their hands and wrists.

Nutrition

There was a restaurant at the clinic for both staff and volunteers. Volunteers used a separate area of the restaurant to eat their meals or they would eat on the ward, where this was part of the trial. We did not observe volunteers eating on the wards during our inspection. We visited the restaurant and noted that the food appeared appetising.

Medicines management

There was a medicines management policy at the centre that covered all aspects of medicines management. Other than some over the counter medication, such as paracetamol, only trial drugs were kept on the premises. Records were maintained of the trial drugs given to volunteers and we were told that if the drug was stopped for any reason, this was also recorded. The volunteer records we checked did not include any instances where there was a requirement to stop the drug on trial. All the rooms used by volunteers and clinical staff had synchronised clocks showing the same exact time, so that precise timing of the drug administration was maintained.

The lead nurse was responsible for ordering, storing and accounting for emergency medication. The emergency medication and equipment was kept in a first response resuscitation bag and a resuscitation trolley. We saw evidence that the clinic followed their recently amended policy to check the medication and equipment on a weekly basis.

A pharmacist was employed by the clinic who helped in monitoring the drug on trial and was also able to give advice to clinicians as required.

We saw that there was a robust system in place to prescribe, order, store, administer and dispose of out of date medication. No human error or significant event regarding medicine management had been recorded since the last inspection.

Safeguarding children and safeguarding vulnerable adults

The clinic had not reported any safeguarding issues. There was an appropriate safeguarding policy in place to support staff if required. We viewed a number of training records and found that staff had received training in safeguarding on a regular basis, to a level appropriate to their roles. The lead clinician assumed the lead role in relation to safeguarding issues and was trained to the appropriate level. Due to the nature of the clinic, children would rarely attend the setting.

Staff we spoke with were clear of their responsibilities in relation to reporting safeguarding issues.

Medical devices, equipment and diagnostic systems

A range of equipment was available at the clinic to support the trial. We saw evidence that this equipment was tested and calibrated on a regular basis to ensure that they were safe to use and providing accurate readings.

Safe and clinically effective care

The service was led by a number of clinicians, nurses and support technicians. Staff we spoke with said that they believed that they had the appropriate equipment, training and facilities to undertake the work expected of them.

As stated above, each trial had a risk management plan to reduce any incidents or concerns. We were also told that all volunteers were expected to attend a follow-up appointment after the completion of the study. Volunteers would not be released from the trial until they had attended this appointment. This ensured the safe discharge of the volunteer from the study.

From the examination of a sample of volunteer records, we found that volunteers were receiving safe and clinically effective care.

Participating in quality improvement activities

The organisation was among the first group of Phase 1 units in the UK to pass the Medicine Healthcare Regulatory Agency (MHRA)[3] inspection for Standard and Supplementary Accreditation. This meant that the clinic was approved for the conduct of trials of all types of investigational medicinal products including those that needed review by the MHRA Expert Advisory Group[4].

The centre undertook a range of quality improvement activities to help identify areas for service improvement. This included satisfaction surveys and regular audits following an annual audit programme.

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[3] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

[4] http://www.ccra.org.uk

The clinic also worked with Cardiff Scintigraphics to design and deliver bespoke studies in both respiratory and G-1[5] tract scintigraphy[6] also known as gamma scan, a diagnostic test in nuclear medicine[7].

Additionally, there was a bioanalytical[8] laboratory located onsite to provide bioanalytical support.

Records management

The volunteer notes, as referred to above, mainly related to the background of the volunteer being included in the trial. Suitability assessment, relevant information tests and other information were included in these initial notes. The identity of the volunteer was confirmed in several different ways including, driving licence, passport, pay slip, photographic ID. There was a separate folder of notes for each volunteer called the CRF. This included information about what medication or trial drug was given and laboratory investigations and other investigations were also documented. There was also a third folder for every volunteer which contained details of communication with the volunteer's own GP. These GP notes were expected to have all up to date conditions and medications. The GP notes of all volunteers checked were up to date. Allergies and adverse reactions were noted in the initial assessment notes and GP notes. The separation of volunteers' notes about the trial and inclusion information in separate folders was considered to be a good practice.

However, there was no clear structure / lay out of the notes. Every entry in the notes was signed by the clinician but the entry did not make it clear if this was a nurse, doctor or other clinician eg. pharmacist. Although each entry in the notes

[5] The gastrointestinal tract is an organ system within humans and other animals which takes in food, digests it to extract and absorb energy and nutrients, and expels the remaining waste as faeces.

[6] Scintigraphy is a safe non-invasive method for determining the bio-distribution of drug delivery systems under physiological conditions.

[7] Nuclear medicine is a medical specialty involving the application of radioactive substances in the diagnosis and treatment of disease.

[8] The identification or measurement of substances (such as drugs, metabolites, or proteins) in a biological system (such as blood plasma, urine, or hair).

were signed, they were not clearly marked with who made the entry. However, there was a folder containing all the staff specimen signatures, which could be used to find out who made the entry.

The organisation had a strict policy on the suitability assessment of the subject for each trial. Overall assessment on this area were well documented in the subject notes. The decision was also supported by relevant investigations and physical examination. By checking the inclusion or exclusion of a subject, the assessment notes would include why a volunteer was excluded. In all notes seen, these were well documented.

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 found staff friendly and professional. There was good leadership and management shown within the clinic.

The arrangements to ensure appropriate staffing levels were well managed.

The centre must ensure that visits to the centre by the responsible individual are fully documented.

Governance and accountability framework

During our inspection we met with members of the management team and staff, who were very accommodating, open and honest, and engaged with the inspection process. Clear lines of management and accountability were demonstrated by all levels of staff. Staff we spoke with told us they were aware of their responsibilities and were confident to question any decisions made by management should the need arise. Staff also had the opportunity to voice any comments or feedback at meetings, anonymously or through staff questionnaires.

We saw that there were a number of relevant meetings to support the effective running of the clinic. There were clear processes in place to ensure that information was shared with staff and cascaded upwards and downwards.

The clinic had a comprehensive range of policies and procedures in place which had the issue and review date clearly shown, to evidence that they had been reviewed and updated where necessary on a regular basis.

The business continuity plan in place included disaster recovery and there was regular testing on scenarios that effected business continuity. Contracts and agreements were in place to send samples to local hospitals should the onsite laboratory be unavailable.

As referred to above, there was a statement of purpose that included the requirements of Schedule 1 to The Independent Health Care (Wales) Regulations 2011[9]. The patients' guide had also been completed in accordance with the above regulations. The clinic was in the process of re-writing the statement of purpose to include the required change to the responsible individual.

Whilst we were told that members of the wider senior management team had been to the clinic recently, a written report, from the responsible individual, in line with regulations had not been produced for over 12 months. The clinic were also in the process of changing the responsible individual.

Improvement needed

The responsible individual must ensure that formal visits to the centre are undertaken at least every six months and a written report produced on the conduct of the service.

Dealing with concerns and managing incidents

We saw that the service had a comprehensive complaints policy in place outlining the process for volunteers should they wish to raise a concern. We saw that two complaints had been received and observed that they had been dealt with promptly. Sufficient information was available to evidence that the process, outcome and lessons learned were documented.

Staff we spoke with described the arrangements for reviewing incidents called "non compliance relating to the study". This involved a root cause analysis, a systematic approach for uncovering the root cause of problems, preventative detective analysis[10] and lessons learned. There had not been any recent incidents to report.

[9] http://www.legislation.gov.uk/wsi/2011/734/made

[10] What could have been done to prevent and detect the problem before it occurred.

Workforce planning, training and organisational development

Staff we spoke with were able to describe their roles and how they contributed to the overall operation of the clinic. There were two vacancies at the clinic, at the time of the inspection, one for a research physician and one for a screening nurse.

The clinic was able to arrange its staffing and rota in advance of requirements as they were aware of the trials being conducted and the staffing levels needed. The procedure “Management of the Clinical Unit” detailed the staff allocation to study procedures. The rota was compiled by the senior nurse and checked by the clinical operations co-ordinator. This took into account the competencies of staff to perform the procedures assigned. We viewed a sample of two months staff rotas and found these to be in order.

Evidence of training records was kept by the clinic through a mixture of online evidence, heads of department records and appraisal documentation. We were satisfied for the sample checked that staff had completed the mandatory training. We were informed that the competency of staff to perform procedures was available on a skills matrix which contained all the clinic staff. Additional training opportunities were available for staff over and above the mandatory training including immediate life support[11] training for all staff.

There was a documented policy for staff appraisal and we found that, there was an effective appraisal process. Staff appraisals had been carried out for all staff in our sample.

Workforce recruitment and employment practices

The staff files that we reviewed showed that the clinic had followed the appropriate procedures and undertaken relevant recruitment checks prior to the commencement in post. We saw evidence to confirm that each member of staff that met and treated volunteers had undertaken a Disclosure and Barring

[11] https://www.resus.org.uk/information-on-courses/immediate-life-support

Service check. Additionally, there was evidence at the centre of the Hepatitis B Surface Antibody Blood Test[12] for all clinical staff.

[12] This test is used to determine the status of a person's immunity to the Hepatitis B virus (Hep B). Immunity is determined by screening for antibodies which provide protection against infection. The results of this test are quantitative.

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, measurable, 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
No immediate concerns were identified on this inspection.			

Appendix B – Improvement plan

Service: Simbec Research Limited

Date of inspection: 16 December 2019

The table below 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.

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
Quality of the patient experience				
The service must ensure that sufficient health promotion information is provided for the service user group.	3. Health promotion, protection and improvement	The Head of Enrolment Services (AK) will contact local GP surgeries and review NHS available material, in order to source an appropriate supplier for health promotion literature. Literature will be obtained and subsequently placed in the Enrolment Services reception area and in the Volunteer Reading Room.	AK	31 Mar 2020
The clinic must ensure that all consulting rooms have a privacy curtain or screen to use when a volunteer is being examined.	10. Dignity and respect	Facilities Manager (JF), has placed portable privacy screens in the doctor's consulting rooms.	JF	Completed – 12 Feb 2020

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
The clinic is to ensure that a staff who's who is displayed in the ward areas.	18. Communicating effectively	Suitable notice boards will be ordered (via liaison with JF, Facilities Manager), and placed in the main corridor of the Clinical Pharmacology Unit (CPU) displaying the photos, names and job titles of all CPU staff. Additionally, as Enrolment Services (ES) reception area is the initial physical point of contact for volunteers, a display board featuring ES staff members photos and details will also be added here. However, it should be noted that under the GDPR requirements, we need to obtain the consent of the individual members of staff in order to fulfil this action. This is because this display is not a legal requirement but legitimate interest. Consequently, not all staff may agree to this action.	AK/TO/KG	31 Mar 2020
The clinic is to display, in a prominent position, the outcomes and any changes made as a result of volunteer feedback.	5. Citizen engagement and feedback	Volunteer feedback is collated on a monthly basis, dependent on studies being conducted in the CPU.	JH/TO/KG	31 Mar 2020

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
		This is a two-stage response: Firstly, going forward, the Welfare Officer (JH) will print and display the most recent volunteer feedback on the notice board in the main corridor of the CPU. Secondly, as this will be a new process, subsequent volunteer feedback will be collated, and changes made as a result of volunteer feedback will be identified and highlighted. These highlighted changes will be displayed against the applicable comments/suggestions on the notice board in the CPU.		
Delivery of safe and effective care				
The clinic is to ensure that: • Equipment that is in a poor state of repair is disposed of, or repaired • IPC audits are added to the audit programme.	13. Infection prevention and control (IPC) and decontamination	Facilities Manager (JF) has made an initial check of CPU areas for damaged equipment/furniture and has removed and disposed of the one damaged chair in examination room. A second check has been actioned 17 Feb 2020.	JF/AH	Completed 17 Feb 2020

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
		Additionally, JF will add a check of equipment and/or furniture that is in a poor state of repair to his annual maintenance schedule. Internal IPC inspections are conducted as part of Simbec-Orion Health and Safety Audit Schedule. AH (H&S Chair Person) has scheduled the next IPC inspection for Q2 2020.		30 Jun 2020
Quality of management and leadership				
The responsible individual must ensure that formal visits to the centre are undertaken at least every six months and a written report produced on the conduct of the service.	1 Governance and accountability framework	The previous responsible individual was not based at the facility, however they regularly visited the unit and met with staff. We acknowledge that written reports were not produced by this responsible individual, and this was an oversight on our part. We are in the process of changing the responsible individual to the Managing Director, Clinical Pharmacology, whose primary place of work is the Clinical Pharmacology Unit in Merthyr. Written	CE	30 Sep 2020

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
		reports will be completed on a six monthly basis as required by the regulations.		

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): Sandra Davies

Job role: VP, Head of Quality Assurance

Date: 19 February 2020