

Registered pharmacy inspection report

Pharmacy Name: Well, 1 Restalrig Road, Leith, EDINBURGH,
Midlothian, EH6 8BB

Pharmacy reference: 1042678

Type of pharmacy: Community

Date of inspection: 10/06/2019

Pharmacy context

This is a community pharmacy beside other shops in a city suburb. People of all ages use the pharmacy. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines. It also supplies medicines in multi-compartment compliance packs.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

Follow this link to [find out what the inspections possible outcomes mean](#)

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not manage all risks. It does not always follow correct processes for dispensing, and it is behind with some dispensing.
		1.2	Standard not met	The pharmacy does not routinely review the reasons for dispensing mistakes so cannot learn from these.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy does not have enough suitably qualified staff to safely lead and deliver its services.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not deliver all services safely, especially medicines supplied in instalments. And it does not follow a robust process for clinically assessing prescriptions.
		4.3	Standard not met	The pharmacy does not store all medicines appropriately.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy has documented processes for all activities. Team members mostly follow these. But they do not always follow processes for instalment prescriptions. This increases the risk that they could make mistakes. The pharmacy has made some mistakes but not recorded them all. So, the pharmacy team members are missing learning opportunities. Some days the pharmacy makes a lot of mistakes. The pharmacy does not review these so cannot identify learning points to help prevent them happening again. The pharmacy mostly keeps the records that it needs to by law and usually keeps people's information safe.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) to assist staff in clearly knowing what they had to do. SOPs were reviewed every two years and signed off by the pharmacy superintendent. Staff roles and responsibilities were recorded on individual SOPs. Team members had read these and in most cases followed them. However they did not all follow all aspects of the SOP for the supply of medicines in instalments. As a result, several prescriptions for medicines to be supplied by instalment had been set up wrongly and there was evidence of the wrong quantity of tablets being supplied e.g. one tablet being supplied daily rather than two.

The pharmacy did not follow documented process for storage and security of some medicines that must only be accessed by a pharmacist or person working under their supervision.

Dispensing, a high-risk activity, was disorganised from preceding days, with several queries and 'owings' outstanding. Some processes were difficult to understand or follow, especially regarding instalment prescriptions. There were not clear records or notes of queries with some prescriptions. And in two examples observed there were prescriptions for more than one person in baskets. This made it very challenging to locate some items. And increased the risk of people getting additional or incorrect medicines.

Team members present during the inspection were attempting to follow a logical process. They were using different coloured baskets to separate patients' medicines, highlighting whether they were waiting, calling back or for delivery. They described the system in place with designated areas for prescriptions to be processed, labelling, dispensing, medicines waiting to be checked, and checking.

There was an audit trail in place for dispensed medicines in the form of dispensed and checked by signatures on labels. Near miss logs were available and had been routinely used since the previous week. The relief pharmacist had started paper records with the intention of transferring the information to Datix later when she had time and could access a computer. Datix was an electronic recording analysis tool. She believed the SOP allowed information to be recorded directly onto Datix, or added later. Sometimes it was difficult to access a computer at the time if it was being used for labelling. The pharmacist explained that she usually recorded as much information as she could.

It was noted that a dispensing error reaching a patient the previous week had not yet been recorded. The team members present during the inspection were aware that effective reviews could not be undertaken with limited data, and no evidence of the pharmacy reviewing incidents was seen.

During the inspection errors were being highlighted during the supply process, and at least one example of a person returning to the pharmacy to highlight a missing item was observed. Several prescriptions for medicines to be supplied by instalment had been set up wrongly and there was evidence of the wrong quantity of tablets being supplied e.g. one tablet per day being supplied rather than two.

Staff members could accurately explain which activities could not be undertaken in the absence of the pharmacist - this had been demonstrated on the Sunday, the day before the inspection. Team members had worked to try and clear the backlog, but there was no pharmacist during the afternoon.

There was a complaints procedure in place and during inspection several people were overheard complaining about waiting. Team members apologised. Indemnity insurance certificate was in place, expiring 29/06/19.

The following records were maintained in compliance with relevant legislation: Responsible Pharmacist notice displayed; Responsible pharmacist log was complete and in proper order; Private prescription records which included records of emergency supplies and veterinary prescriptions. A fax of a European prescription without the original was observed; and examples of a doctor self-prescribing, which is against GMC guidance. The pharmacy had not raised this with the doctor and had made the supplies.

Unlicensed specials records were complete and in proper order. Controlled drugs registers, with running balances maintained and regularly audited. The controlled drug (CD) destruction register for patient returned medicines was not inspected. The electronic patient medication records were backed up each night so that patient information would not be lost.

Team members were aware of the need for confidentiality and training was undertaken annually. Most confidential waste was segregated for secure destruction, but some labels with people's names on them were observed in general waste in the basement.

Team members also had awareness of safeguarding issues and how to raise concerns locally. The pharmacist was PVG registered.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy does not have enough qualified staff to provide services. And it is lacking leadership and continuity. This affects how it manages processes. Team members have access to training material. But the pharmacy does not always set aside time for them to read this during the working day. This makes it difficult for them to develop their skills and improve the services offered to patients.

Inspector's evidence

Staff numbers:

Two job-sharing pharmacists, one on long term absence, and the other on annual leave. A relief pharmacist was working at the time of inspection. One pharmacy technician, 16 hours per week, on annual leave. One full-time and one part-time dispenser. One part-time trainee medicines counter assistant, working afternoons only Tuesday to Friday, and alternate Saturdays. She had worked in the pharmacy for around seven weeks and had just been enrolled on the joint medicines' counter/dispensary assistant course. Two delivery drivers shared with other branches. A Saturday only team member had recently left, so part-time team members were covering Saturdays.

Typically, there were two team members working on the shop floor (dispensary and medicines counter), and one working in the basement on the management of multicompartamental compliance packs. At the time of inspection there was a relief pharmacist, two dispensers, the regional development manager (RDM) (who was a dispenser), and a manager from another branch who was also a dispenser. She had been appointed as temporary manager recently and planned to be in this pharmacy for three months.

Pharmacist absence was initially covered with a regular relief pharmacist, but over recent weeks there had been a variety of relief and locum pharmacists, which had been challenging for the team with a lack of consistency.

The full-time dispenser had recently completed her training. And the part-time dispenser spent most of her time in the basement managing multicompartamental compliance packs. Dispensers had to cover the medicines counter in the mornings. There had been a short period with a non-pharmacist manager which had come to an end, and recruitment was underway for another dispenser.

The previous week there had been an accumulation and backlog of dispensing, including regular prescriptions collected from the surgery, and prescriptions for multi-compartmental compliance packs. The pharmacy had become very untidy and dispensed items were stored on the floor. Team members had worked on the Sunday (the day before inspection) to address the backlog. They had managed to tidy the dispensary, undertake date checking, and clear all the standard prescriptions awaiting dispensing. But multicompartamental compliance packs were still behind schedule. At the time of inspection, dispensing for supply the following day was being undertaken. Usually, the team would aim to be around a week ahead to minimise pressure and risk.

The relief pharmacist had worked six days, or part days, in a row and was due to work the following day. The previous day, Sunday, dispensers and pharmacists had worked a variety of hours between 9am and 9pm. This had included team members from another branch and the regional development manager. There had been no pharmacist between 2:30pm and 5pm, so although other team members

were present no dispensing activities took place. One team member was alone on the premises between 3.30pm and 5pm.

Team members were observed to be going about their tasks in a professional manner, although they appeared stressed and under pressure at times. Three team members who were working, were not routinely in this pharmacy so were not familiar with the local procedures. They were Well employees, so were used to the company SOPs. There were many queries when people came to the pharmacy to collect prescriptions. This resulted in further delays.

Team members had not had development meetings over the past few years. They had been planned, then cancelled when the manager had left. Training was limited. Team members read SOPs which were mandatory, but some people had not undertaken any other training such as e-expert modules for over 6 months. Other team members did these at home, in their own time. Over the past few months, the pharmacy had only given protected learning time to those team members undertaking accredited courses.

Team members understood the importance of reporting mistakes and were comfortable owning up to their own mistakes. But, as noted above near misses were not routinely and consistently recorded, and a recent error had not yet been recorded.

Team members were aware of the company whistleblowing policy and knew how to raise concerns and who to contact. They had recently raised concern about staffing levels and this was being addressed over coming weeks and months. The relief pharmacist working at the time of inspection described a concern that she had raised with the RDM, and this was also being addressed.

Targets were set for various parameters, but not discussed.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is clean and suitable for its services. The pharmacy team members use a private room for some conversations with people. People cannot overhear private conversations. The pharmacy is secure when closed.

Inspector's evidence

This is a small pharmacy incorporating a retail area, a small dispensary and basement area providing staff facilities and an additional dispensing area. The premises were observed to be clean. Prescription medication waiting to be collected was stored in a way that prevented patient information being seen by any other patients or customers. There was a consultation room with a desk, chairs, sink and computer which was clean and tidy, and the door closed providing privacy. A hatch opened to the dispensary to allow supervision of methadone instalments. People were invited into the consultation room one at a time. Temperature and lighting were comfortable.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy is not providing all services safely. Some types of prescriptions are not set up correctly, so the pharmacy could supply the wrong quantity of medicines. Pharmacy team members give people information to help them use their medicines. They provide extra written information to people with some higher-risk medicines.

The pharmacy gets medicines from reliable sources and stores most of them properly.

Inspector's evidence

There was good physical access by means of a low step and assistance given with the door as required. This was observed during inspection, but for much of the time there were no team members in the front shop to see people trying to get in.

The pharmacy could provide large print labels for people with impaired vision. And team members removed tablets from blister packaging for patients with dexterity difficulties. The pharmacy displayed a list of its services and had leaflets available on a variety of topics and conditions.

Staff members wore badges showing their name and role. During the inspection, dispensing was observed to be somewhat hectic, with team members 'firefighting'. They were constantly being interrupted, looking for prescriptions that had not yet been completed and placed on shelves for collection. There were problems with most prescriptions – when people asked for their medicine, it was not ready, or prescriptions could not be found. In some cases, especially instalment prescriptions, mistakes were found, and they had been set up and dispensed incorrectly. The pharmacist was working through these to ensure that patients received the correct medicine at the time, and then records and instalments were corrected for future supplies. Several examples of this were observed. This was time consuming and impacting other services.

Team members prioritised dispensing for people who were waiting, highlighting these items to the pharmacist for immediate checking.

They initialled dispensing labels to provide an audit trail of who had dispensed and who had checked each item. The pharmacy had a logical process for dispensing although it seemed challenging to follow this. Coloured baskets were used to separate different people's prescriptions. However, two people's medicines and prescriptions were observed in one basket. A basket containing dispensed instalments also had another person's prescription in it. Team members explained that usually a dispenser labelled prescriptions placing each person's prescriptions and labels into a separate basket for another dispenser to assemble. There was no mechanism to highlight changes or new medicines to the pharmacist. And team members present during inspection explained that they did not know patients as they did not usually work in this pharmacy. So, they would be unlikely to know if there were any changes. There were dedicated areas for dispensing and pharmacist checking.

Patient information leaflets were printed and supplied to people who were not receiving these in original packs. This was observed to be very time-consuming as the system was slow. Owing were usually assembled later the same day or the following day.

The pharmacy provided a delivery service and obtained signatures from people when they received their medicines. Team members were unsure how items requiring cold storage were managed.

A part-time dispenser managed multi-compartment compliance packs on a four-weekly cycle with four assembled at a time. She did this in a room in the basement. The pharmacy was currently behind where it would usually be with this process. At the time of inspection, the dispenser was assembling some packs due out for the following day. The previous day, Sunday, several packs had been assembled. She explained that she had been behind with these for the past six months. And she was often assembling packs for the following day. Occasionally another dispenser assisted. The store manager on secondment from another branch was trained and competent to undertake this task. The full-time dispenser in the pharmacy was largely self-taught so could undertake some aspects of this process. But the experienced dispenser had not had time to coach her in all aspects.

Patient information leaflets (PILs) were supplied with the first pack of each prescription. Backing sheets had tablet descriptions and date of supply on them. Some backing sheets were attached with staples, meaning that they could become easily detached. This had been highlighted at the previous inspection, with some improvement made - some were also attached with tape, holding them firmer. The dispenser stored completed trays in named boxes for each patient on shelves labelled with the day of supply. The team used a tracker document to follow the progress of each person's packs. Records of changes were kept. There was a clipboard beside the phone in the dispensary for any messages to be recorded and the dispenser managing these packs checked this frequently, took appropriate action and updated people's records accordingly.

Dispensers usually poured methadone instalments, using the 'methameasure' pump device. They were checked by a pharmacist who supervised consumption. When prescriptions were received, dispensers entered the data onto the computer and this was checked by a pharmacist. Some people had photographs on their records to help identification, but others did not. And fingerprint recognition was not used. The regional development manager (RDM) explained that the regular team members knew the patients and checked their address at the point of supply. Used methadone instalments bottles were placed into general waste. Team members followed the SOP for dispensing and recording methadone instalments, but not for all other instalment dispensing. There were a lot of people receiving various medicines by instalment. Some were found to be incorrect, not yet assembled, labels missing, prescriptions missing, labelled incorrectly and in one case an empty tablet bag had been supplied to a patient. Several had been set up wrongly on the computer as a previous team member did not know how to do this. This resulted in incorrect quantities being dispensed, and endorsements on prescriptions being incorrect. One example showed seven tablets being supplied once each week. The prescription stated that these should be supplied in two instalments each week, one of two tablets and one of five tablets. Another suggested that a person had been receiving one tablet each day when it should have been two. One patient's tablets had been dispensed into strips cut from multicompartiment compliance packs which was unprofessional in appearance and not correctly labelled. These errors were being discovered by the relief pharmacist working at the time of inspection. She was correcting them and recording them on a paper document that she had started the previous week. In some cases it was difficult for her to determine what had been supplied previously as the record keeping on instalment prescriptions was sparse. In many cases the pharmacist making the previous supplies had not completed the 'PC 70' form which would have provided a chronological list of supplies. This was in breach of the SOP.

Clinical checks were undertaken by a pharmacist. A dispenser explained that people receiving high risk medicines including valproate, methotrexate, lithium, and warfarin were given appropriate advice and counselling. Written information and record books were provided if required. The valproate pregnancy prevention programme was in place. People who may become pregnant received prescribed valproate and they had been appropriately advised and counselled. The non-steroidal anti-inflammatory drug (NSAID) care bundle had been implemented and written and verbal information was given to people

supplied with these medicines over-the-counter, or on prescriptions. 'Sick day rules' were also discussed with people on certain medicines, so that they could manage their medicines when they were unwell. The relief pharmacist present during the inspection was familiar with these processes.

The pharmacy followed the service specifications for NHS services and had patient group directions (PGDs) in place for unscheduled care, pharmacy first, smoking cessation, emergency hormonal contraception, chloramphenicol ophthalmic products and chlamydia treatment.

The pharmacy was not currently delivering the chronic medication service. Pharmacists were not able to spend time registering patients as dispensing was usually behind, and it was the priority. Team members were empowered to deliver the minor ailments service (eMAS) within their competence. The pharmacy obtained medicines from licensed suppliers.

The pharmacy was not compliant with the requirements of the falsified medicines directive (FMD). There was no hardware on site yet and team members believed that it would be around six months before this was in place. It had been a requirement for the past four months.

Records of date checking were observed, and items inspected were found to be in date. Medicines were mostly stored in original packaging on shelves/in cupboards. The pharmacy had some tablets on shelves that were not in packaging or labelled e.g. dioctyl tablets. Items requiring cold storage were stored in a fridge with minimum and maximum temperatures monitored and action taken if there was any deviation from accepted limits. Pharmacy (P) medicines were protected from self-selection. Pharmacy team members followed the sale of medicines protocol for pharmacy medicines. NES pharmacy consultation guidance was on the wall close to the medicines counter. MHRA recalls and alerts were actioned on receipt.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment it needs for the delivery of its services. It looks after this equipment to ensure it works. But the pharmacy does not use all the features of some equipment.

Inspector's evidence

The pharmacy had texts available including current editions of the BNF and BNF for Children and it had internet access allowing online resources to be used. It had a blood pressure monitor which was calibrated annually and was kept in the consultation room where it was used with patients. And it had a carbon monoxide monitor which was maintained by the health board. The pharmacy kept Crown stamped measures by the sink in the dispensary, and separate marked ones were used for methadone. It had a 'methameasure' pump available for methadone use and team members cleaned it each evening when methadone solutions were removed and placed into a CD cabinet, and they calibrated it each day by pouring test volumes. The pharmacy did not use some of the features of it such as fingerprint recognition. It did not have a camera, so photographic identification could not be used. There were photos on some people's records. A team member described a pharmacist sharing her password for the 'methameasure' pump device with another team member. Clean tablet and capsule counters were also kept in the dispensary and were washed after using with cytotoxic tablets. Team members stored paper records in the dispensary and back-shop areas inaccessible to the public. Computers were never left unattended and were password protected. Screens were not visible to the public. Care was taken to ensure phone conversations could not be overheard.

What do the summary findings for each principle mean?

Finding	Meaning
✓ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✓ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✓ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.