General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Shaunak's Pharmacy, 7 Flaxpitts Lane, Winterbourne, BRISTOL, Avon, BS36 1JY

Pharmacy reference: 1028745

Type of pharmacy: Community

Date of inspection: 04/09/2019

Pharmacy context

This is a community pharmacy in a shopping area in the large village of Winterbourne located to the north of Bristol. Most people using the pharmacy are elderly. The pharmacy dispenses NHS and private prescriptions and sells over-the-counter medicines. It also supplies medicines in multi-compartment compliance aids to help vulnerable people in their own homes to take their medicines.

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 team do not manage and identify risks well.
		1.2	Standard not met	The pharmacy team do not review and monitor the safety and quality of pharmacy services.
2. Staff	Standards not all met	2.4	Standard not met	There is insufficient reflection and learning from incidents to prevent them from happening again.
3. Premises	Standards not all met	3.1	Standard not met	Not all areas of the pharmacy look professional.
		3.2	Standard not met	The facilities for private consultations are not sufficient to protect dignity and confidentiality.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Not all the services are effectively managed to make sure that they are delivered safely.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy team do not manage and identify risks well. In particular, there is little reflection and learning from adverse incidents to prevent them from happening again. And, the work areas are not organised and this increases the risk of errors. There are written procedures but these are generic, with no changes since 2013. And, some written procedures are not adhered to. The pharmacy asks customers for their views but the team do not know the outcome of the surveys and so cannot act on the feedback. The team generally keep the up-to-date records that it must by law. The pharmacy is appropriately insured to protect people if things go wrong. The pharmacy team generally keep people's private information safe and they know how to protect vulnerable people.

Inspector's evidence

The pharmacy staff did not identify and manage risks. There had been several errors in the last few months, including two bagging errors. One of these involved a delivery to the wrong patient. The pharmacy did not routinely get signatures from the patient or the carer to indicate that the medicines had been delivered safely. No specific actions, as a result of either error, had been put in place to reduce the likelihood of similar recurrences. This showed insufficient reflection and learning. In addition, the checking bench, at the time of the visit was cluttered. Many baskets were stored on top of one another which increased the risk of errors. It was seen that more than one basket was placed in the checking area as a time. This increased the likelihood of bagging errors. Very few near misses had been recorded in the last few months. No learning points or actions taken to reduce the likelihood of similar recurrences were documented. Neither the actual errors nor the near misses were discussed with the team.

The pharmacy did have standard operating procedures (SOPs) but these were highly generic. No changes had been documented since their initial preparation in 2013 despite there being a sheet that they had been reviewed every two years. The SOPs, whist not stating that signatures should be obtained for all medicines that were delivered to patients, did state that medicines should not be left. However, the delivery driver said that he did leave medicines in so called 'safe places and several medicines were posted through letterboxes.

The roles and responsibilities were set out in the SOPs and the staff were clear about their roles. The company's sales protocol was displayed but did not include any recent changes to the legal status of medicines such as Viagra Connect and Nexium. It was not dated or signed. A NVQ2 trainee dispenser said that she would refer any person on prescribed medicines to the pharmacist. The pharmacy team were aware of the issues with codeine and said that anyone asking for multiple packs of this would be referred to the pharmacist.

The staff knew about the complaints procedure and said that feedback on concerns was encouraged. The pharmacy did an annual customer satisfaction survey. The results of the latest survey could not be located at the time of the visit and the staff said that the results had not been discussed with them. This meant they were unable to address any negative feedback.

Public liability and indemnity insurance provided by the National Pharmacy Association (NPA) and valid until 30 April 2020 was in place. The Responsible Pharmacist log, specials records, fridge temperature records and date checking records were in order. Four patient-returned controlled drugs, found in the

cabinet, had not been entered into the records. The private prescription records showed that the pharmacy regularly supplied a local dental practice (every six months or so) but they had no wholesale dealer authorisation (WDA) from the Medicine and Healthcare products Regulatory Agency (MHRA). Many emergency supplies were made, sometimes, three a day. Whist these were recorded correctly, the medicines were largely given when the surgeries were open.

There was an information governance procedure and the staff had also recently completed training on the new data protection regulations. The computers, which were not visible to the customers, were password protected. Confidential information was stored securely. Confidential waste paper information was shredded. No conversations could be overheard in the consultation room. But, the room used was also the staff room and it contained a clear glass panel which meant that patient confidentiality could not be maintained in here.

The staff understood safeguarding issues and had read the SOP on safeguarding. The pharmacist had completed the Centre for Pharmacy Postgraduate Education (CPPE) module on safeguarding. Local telephone numbers were available to escalate any concerns relating to both children and adults. All the staff had completed 'Dementia Friends' training.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy generally has enough staff to manage its workload safely. But, on the day of the visit, they were behind with their workload. The pharmacy team do not discuss or learn from adverse incidents to prevent them from happening again. They do not do regular on-going learning which means that their skills may not be up to date. And, some team members in training are not adequately supported.

Inspector's evidence

The pharmacy was in a large village in South Gloucestershire to the north of Bristol. They dispensed approximately 6,000 NHS prescription items each month with the majority of these being repeats. 120 domiciliary patients received their medicines in compliance aids. Few private prescriptions were dispensed.

The current staffing profile was one pharmacist, one pre-registration student (just three weeks in post), one part-time NVQ2 trained dispenser (enrolled on the technician course), one part-time NVQ2 trainee dispenser, one part-time medicine counter assistant and one part-time medicine counter assistant trainee. The newly appointed area manager was currently interviewing people in the hope that the trainee technician could work full-time at the branch.

There was some evidence that the pharmacy was behind with their workload on the day of the visit. Many baskets were waiting to be checked. About 40 electroniclly transferred prescriptions from the previous day had not been completed and a further 30 from the morning of the visit. The manager said that she believed she needed more staff. She said that the proposal of having the trainee technician at the branch full-time should help.

The staff said that in the past they had asked for help with unplanned absences but that this had not been provided. The part-time counter staff generally covered each other in the case of illness and holiday. But, planned leave could be booked as little as one month in advance. This did not give much time to ensure appropriate staffing levels at all times.

Staff performance was monitored, reviewed and discussed informally throughout the year. There was an annual performance appraisal where learning needs could be identified. The manager said that she would set review dates for this. The trainee technician said that she had no dedicated learning time for her course. The staff were signed up to ‘Virtual Outcomes’ regular learning but reported that they only did one or two modules each year. The staff did read some seasonal literature and completed some ‘Counter Skills’ booklets. But, they largely did this in their lunch break.

There were no formal staff meetings. And, as mentioned under principle 1, the staff did not discuss errors, near misses and other issues. This meant that they were denied the opportunity to learn from these in order to reduce the likelihood of them happening again. The pharmacist reported that she was set overall targets, such as 400 annual medicine use reviews (MURs). She said that she only did clinically appropriate reviews and did not feel unduly pressured by the targets.

Principle 3 - Premises **Standards not all met**

Summary findings

Not all areas of the pharmacy look professional. A small staff room is used for private consultations. This is not professional and the siting and design of the room increases the chance of breaches to people's confidentiality. Areas of the pharmacy are cluttered and this increases the risk of errors. And, there could be better security to some areas.

Inspector's evidence

The retail area of the pharmacy was spacious, tidy and well laid out. But, the staff room/kitchen was used as a consultation room. This was located to the back and side of the dispensary. People had to walk past the compliance aid assembly bench to access the room. In addition, there was a step down to the room and the door contained a clear glass panel. This meant that wheelchair users were unable to use the room and patient confidentiality could not be maintained in here. In addition, it did not present a professional pharmacy image to the people who were seeking a private consultation. Water-damaged ceiling tiles in the dispensary and the retail area and a water-damaged girder, following an issue with a flat roof, also, did not present a professional image. As mentioned under principle 1, the dispensary was cluttered at the time of the inspection. This increased the risk of errors. There was no clear workload priority. All the baskets seen were red.

The pharmacy computer screens were generally not visible to customers. But, there was a computer on the compliance aid bench and people could see this when they accessed the room used for consultations. In addition, the details of patients could also be seen on the compliance aid bench as people had to walk past this to use the consultation room. The telephone was cordless and all sensitive calls were taken in the staff/consultation room or out of earshot.

There was air conditioning and the temperature in the pharmacy was below 25 degrees centigrade. There was good lighting throughout. Most items for sale were healthcare related.

Principle 4 - Services **Standards not all met**

Summary findings

Most people can access the services the pharmacy offers. But, some people with specific mobility needs may not be able to talk to the pharmacist privately. Not all the services are effectively managed to make sure that they are delivered safely. And, signatures are not always obtained from people to indicate that they have received their medicines safely. Some medicines are posted through letterboxes and left in safe places. This poses a risk to people safety. The pharmacy generally gets its medicines from appropriate sources. But, some medicines could be more safely stored, particularly, to reduce the chance of errors.

Inspector's evidence

There was wheelchair access to the pharmacy with a signposted bell on the front door. But, there was no independent access to the consultation room for wheelchair-users because of a step down into this room. There was access to Google translate on the pharmacy computers for use by non-English speakers. The pharmacy printed large labels for sight-impaired patients.

Advanced and enhanced NHS services offered by the pharmacy were Medicine Use Reviews (MURs), New Medicine Service (NMS), sexual health, urgent repeat medicine service, supervised consumption of methadone and buprenorphine (currently one patient) and seasonal flu vaccinations. The services were well displayed and the staff were aware of the services offered.

The pharmacist had completed suitable training for the provision of seasonal flu vaccinations including face to face training on injection technique, needle stick injuries and anaphylaxis. She had also completed suitable training for the provision of the free NHS sexual health service.

Just one substance misuse client currently had their medicines supervised. The pharmacist said that she did this supervision at the medicine counter because of the siting of the consultation room. A second check on the methadone volume poured was not routinely done.

There were 120 domiciliary patients who received their medicines in compliance aids. These were done on a small separate area of bench but transported to the main dispensary for checking. Only one person, the trainee technician, was aware of the procedures for the trays. This presented a risk to the safe delivery of the service if she was ill. In addition, any changes or other issues were not recorded, and so, the checking pharmacist did not have a clear clinical history of the patient. The domiciliary dosettes were assembled on a four-week rolling basis and evenly distributed throughout the week to manage the workload.

The pharmacy supplied many medicines under the urgent repeat medicine service. And, these were done when the surgeries were open. This did not encourage people to take responsibility for managing their medicines. And, these procedures posed a risk to people's safety, such as, if there had been any changes or other concerns and a whole month's supply of medicines was given. In addition, the prescriber was not routinely contacted to make sure that the medicines were still appropriate.

There was a good audit trail for all items ordered on behalf of patients by the pharmacy and all for items dispensed (except for methadone) by the pharmacy. The pharmacist routinely counselled patients prescribed high-risk drugs such as warfarin and lithium. INR levels were asked about but not

recorded. She said that she also counselled patients prescribed amongst others, antibiotics, new drugs and any changes. CDs and insulin were packed in clear bags and these were said to be checked with the patient on hand-out. The staff were aware of the new sodium valproate guidance but the pharmacy had not conducted an audit identifying those patients prescribed sodium valproate who may become pregnant.

All prescriptions containing potential drug interactions, changes in dose or new drugs were said to be highlighted to the pharmacist, but the staff did not know how to print off any potential drug interactions. Signatures were only obtained indicating the safe delivery of controlled drugs requiring safe custody. On the day of the visit, it was seen that the medicines for four patients were going to be posted through their letterboxes. In addition, the delivery driver said that he left medicines in safe places. This was contrary to the SOPs. It was also seen on the delivery sheet, that the delivery driver had access to a person's home, via a key safe number.

Medicines and medical devices were obtained from AAH, Alliance Healthcare and Shaunaks warehouse. Some items obtained from the latter, such as thiamine 100mg were unlicenced. Specials were obtained from Lexon Specials. The CD cabinet was small for the stock and it was untidy. This increased the risk of errors. There were four patient-returned CDs that had not been entered into the records. This was poor practice. One bottle of Oramorph Concentrate had an expiry date of 09/2019. This had not been highlighted and so increased the likelihood taht this may be supplied past the expiry date. Fridge lines were correctly stored with signed records. But, the fridge too, was untidy and overstocked, which increased the risk of errors. Date checking procedures were in place with signatures recording who had undertaken the task. Bins were available for waste and used. There was a bin for cytotoxic and cytostatic substances and a list such substances that should be treated as hazardous for waste purposes.

There was a procedure for dealing with concerns about medicines and medical devices. Drug alerts received electronically, printed off and the stock checked. The mostly had 'stock checked' recorded on them and it was not clear if there were any affected batches. Any required actions were not recorded.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the appropriate equipment and facilities for the services it provided. The team members make sure that the equipment they use is clean.

Inspector's evidence

The pharmacy used British Standard crown-stamped conical measures (10 - 500ml) and an ISO stamped straight measures (50ml). There were two tablet-counting triangles, one of which was kept specifically for cytotoxic substances and one capsule counter. These were cleaned with each use. There were up-to-date reference books, including the British National Formulary (BNF) 76 and the 2018/2019 Children's BNF. There was access to the internet.

The fridge was in good working order and maximum/minimum temperatures were recorded daily. The pharmacy computers were password protected and generally not visible to the public (but see under principle 3). There was a cordless telephone and any sensitive calls were taken out of earshot. Confidential waste information was shredded.

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.