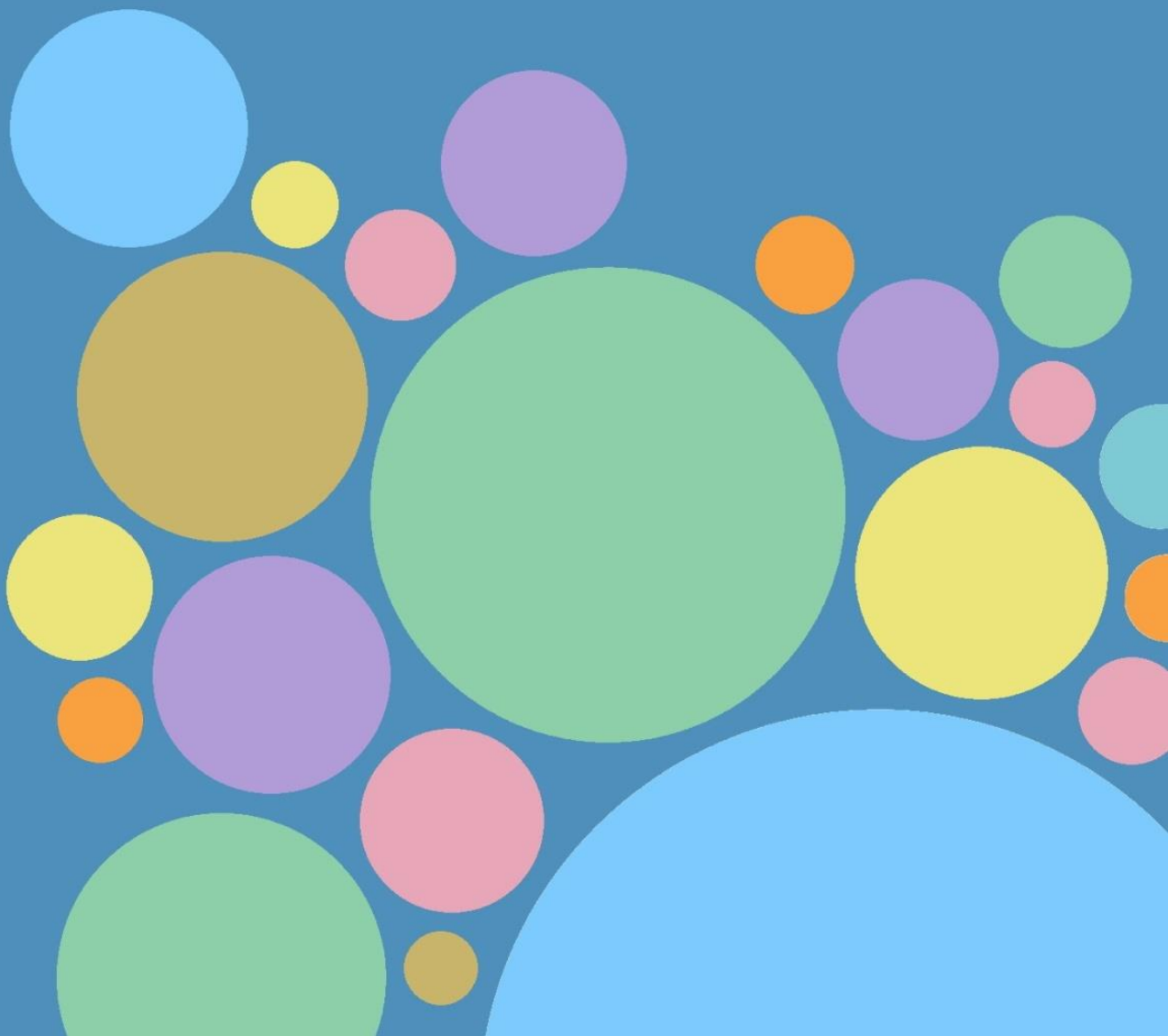
bpas
British Pregnancy Advisory Service

Pharmacy provision of emergency contraception:

A mystery shopper study



Pharmacy provision of emergency contraception: a mystery shopper study

Background

There has been considerable recent discussion around the provision of emergency contraception in the UK, and in 2017 the price of the progestogen-only version of emergency contraception, levonorgestrel 1.5mg (LNG-EC), fell considerably after a campaign by the British Pregnancy Advisory Service. Despite the fall in the price, emergency hormonal emergency contraception is still kept behind the counter in the UK and can only be obtained after a consultation with a pharmacist.

Elsewhere in Europe and in North America, LNG-EC can be purchased directly from the shelves without a mandatory consultation, as the pill is known to be extremely safe and there are no contra-indications to its use.

EC on the pharmacy shelf in Sweden

EC on the pharmacy shelf in the US

In the UK, the preservation of a mandatory consultation has been advocated for on the basis it provides an important opportunity to give a woman information about all her contraception options – both "emergency", including the copper coil (IUD) and ongoing – STI screening and any other sexual health questions she may have[1]. We undertook a study to explore what information was given during a consultation with a view to better understanding whether the value of that information offset the additional barriers created by requiring that emergency contraception can only be sold by a pharmacist (no other pharmacy staff including technicians) following a consultation, and to document what those barriers may be.

Study design: a mystery shopping exercise was conducted in 30 pharmacies across England, including cities, towns, villages, in chains, independent outlets and supermarkets. We did not explore information provided in a consultation when the pill was being supplied as part of an NHS scheme in pharmacy, but when it was available for purchase. Restrictions are often in

[1] https://www.rpharms.com/news/details/Emergency-contraception-needs-a-consultation-says-RPS

place on who can be supplied EC under an NHS scheme, and where and by whom it can be supplied, meaning many women are left with no choice but to purchase it.

3 separate scenarios were tested in the pharmacy:

- **Using condoms. Condom came off last night. Last used EC 2 years ago.**
- **Been happily using a fertility app for the last year. Condom came off during fertile window/app said protection was needed. Last used EC 2 years ago.**
- **Using condoms. Condom came off last night. Also happened exactly 1 week ago, took EC for that incident too (Levonelle). Very unlucky month. Prior to that have not used EC for 5 years.**

Our 22-year-old shopper simply stated she needed emergency contraception; she did not ask for a specific product, nor reveal the scenario unless asked, and she did not actively request any further information herself, with a view to establishing what information would be spontaneously provided. Notes from the consultation were recorded on paper immediately afterwards, including information within the store about EC on display, whether the product was visible behind the counter, and the number of people she had needed to ask before being served by the pharmacist. A copy of the document used to compile the notes is located at Appendix 1.

Results: With some notable exceptions, pharmacists provided a kind, swift and non-judgmental service, once they were dealing directly with the client, but in most cases the shopper had needed to ask at least 2 people before help could be offered (15/29), and in 2/30 cases the client was turned away without further help or told to come back later. Only a minority of pharmacies provided information about what is reported to be the more effective method of EC, EllaOne, even though it was appropriate to do so (6/23) and in 1/6 cases where EllaOne was inappropriate it was the only option offered. No pharmacy offered information about ongoing methods of contraception or STI testing, and where such help could be obtained. No pharmacy informed women that the IUD was the most effective method of emergency contraception and no pharmacy provided information on where that could be found. Less than 50% of pharmacies visited offered a private room for the consultation, and so it was often held in proximity to other pharmacy users which made the experience itself more awkward for the shopper, and constrained the likelihood of asking further questions. All of these aspects have been used to justify the need to preserve the consultation.

Conclusions: There are no clinical contraindications to the use of LNG-EC, no notable side-effects and it can be used by all women. LNG-EC can be used more than once in the same cycle and it cannot disrupt or harm a developing pregnancy. It poses no risk to future fertility.[2] It provides effective protection against unwanted pregnancy, which can pose a significant risk to a woman's health and wellbeing. LNG-EC is significantly safer than many pharmaceutical products which are available to buy straight from the shelf. A review of 2 General Sales List products currently available in the UK can be found at Appendix 2 as a useful comparison. In other countries women are allowed to buy LNG-EC directly from the shelf and ask for further information only if they need it. In the UK this has been resisted on the basis that the consultation provides an important opportunity to provide further information on other methods of contraception, STI testing, and answer other sexual health questions. For clarity, bpas believes

[2] https://www.who.int/news-room/fact-sheets/detail/emergency-contraception

this information should be optional and provided at the woman's request, in the same way that anybody buying medications in a pharmacy can seek advice without it being mandated. However our mystery shop makes clear that this information is in any event not being provided. The opportunity to ask further questions, should a woman wish, is also compromised by the lack of private space to do so.

One in six pregnancies is unplanned.[3] Bpas does not believe EC is a silver bullet for these; however it remains a significantly underused resource. We would like to see LNG-EC reclassified as a General Sales List product so it can be sold straight from the shelves of pharmacies without the need for a consultation, unless women request to speak to the pharmacist. This is also what women would prefer. Polling by bpas finds the majority of women would prefer the consultation to be optional (64% v 29%) and would prefer to be able to pick the product up directly from the shelf (58% v 35%).[4] We believe that the failure to remove obstacles in the way of women's access to EC can deny individual women the opportunity to avoid a pregnancy she has not planned and which can place her health and wellbeing at risk.

Introduction: the path to the consultation

LNG-EC has been available to buy from pharmacies since 2000. It can only be supplied by the pharmacist, following a consultation.

As this mystery shop was concerned with the nature of the consultation, rather than the wider availability of EC, we ascertained in advance that we were visiting pharmacies where emergency contraception was sold. Nevertheless in one pharmacy visited it was not available.

Once at the pharmacy, only 5/30 had any indication that EC was provided in the store, even though information was often provided about other services available. No information was provided in the women's health section of the stores. In only 4/30 stores the products were in plain sight behind the counter; in the vast majority of stores the products were kept completely obscured from view on the lowest shelf or kept at the back with prescription medicines. Our shopper also noted: *"I experienced instances of emergency contraceptives being displayed in plain white boxes with small text displayed on one side, again making it a challenge to identify them as the product I was searching for. Before I had even reached the counter in the majority of these pharmacies, several barriers had clearly stood in my way when trying to identify whether emergency contraception was available."*

While some larger pharmacies offer customers cards on the shelf informing them that a specific product is held behind the counter and instructing them to take the card to a member of staff for service, no store visited offered this for emergency contraception. This means that a woman must always verbally request the medicine.

In less than half of the pharmacies, the first person spoken to was the pharmacist, which meant the process could begin. In 16 pharmacies our shopper had to speak to one other member of staff before the pharmacist was able to speak to her, and in two pharmacies she had to speak to 2 other members of staff before the pharmacist. On one occasion, 4 different members of staff had become involved before she was able to leave with EC.

[3] Third National Survey of Sexual Attitudes and Lifestyles, *The Lancet,* November 2013
[4] Survey of 1001 women aged 18-45, conducted by Censuswide for bpas, November 2018

"A particularly drawn out experience took place in a pharmacy in xxx. After reaching the front of the queue, the employee on the counter told me she would be back in five minutes. Waiting for her to return, another member of staff served me, handing me a questionnaire to fill in. After completing the questionnaire, I waited again for an employee to take it from me and the pharmacist to check it through. I was finally sold the product by the pharmacist, who then had to seek the help of a fellow employee to work the till, prolonging the process further. Ultimately, four members of staff became involved in this experience, lengthening it considerably and unnecessarily adding to its complexity."

Location of the consultation

In 16/29 pharmacies, a consultation room was not offered. Instead, the consultation took place over the counter, usually with other customers present. In one pharmacy, "*two customers sat waiting to pick up their prescriptions next to the counter. As I asked the employee on the counter if they sold emergency contraception, I was very aware that these customers could both hear and see what I was asking for. The employee went on to ask me directly over the counter when I had last had unprotected sex and if I had already taken emergency contraception in my current cycle, all still within a noticeably close range of the other customers in the store".*

In the pharmacies where our shopper was taken to a separate room for the consultation, there were still privacy issues. In one pharmacy, for instance, *"the pharmacist took me straight to their consultation room and was friendly and informative throughout the consultation. The room itself, however, was clearly not soundproof as I could hear other customers at the counter, situated directly next to the consultation room. During the consultation I felt conscious that other customers could hear me being questioned about topics that I would otherwise have felt comfortable answering with the pharmacist alone…A lack of soundproofing was not the only issue I found with consultation rooms throughout this study, however, as I came across multiple rooms with uncovered windows and doors that were left open by the pharmacist giving the consultation."*

Content of the consultation

Following an episode of unprotected sex, there are 3 treatment possibilities. Hormonal emergency contraception, in the form of levonorgestrel 1.5mg (eg Levonelle One Step, Boots Emergency Contraception, Consilient and Ezinelle) which is licensed for use in the first 72 hours, or ullipristal-acetate (EllaOne), which can be used up to 120 hours later, and the copper IUD, which can also be inserted up to 120 hours later.

Guidance from the Faculty for Sexual and Reproductive Health (FSRH)[5] says women should be advised that EllaOne has been demonstrated to be more effective than LNG-EC following an episode of unprotected sex (ie not just beyond 72 hours).

In the 23 cases where it would have been appropriate to offer EllaOne, only 6 pharmacists did so, and of those only 2 said it was more effective than LNG-EC. One pharmacist was particularly

[5] FSRH Guideline Emergency Contraception; March 2017

unhappy with the price of EllaOne – which at £30-£35 is around £20 more expensive than the price of generic LNG-EC, and on that basis he recommended LNG-EC. In essence, only 7% of pharmacies visited provided accurate clinical information about EllaOne.

The FSRH and the Royal Pharmaceutical Society also advise that pharmacists tell women that the most effective method of emergency contraception is an IUD.[6] Bpas is unsure of the value of this information in the widespread absence of an accessible, local emergency fitting service and the fact that it is an invasive procedure which may require some consideration. However given that the opportunity to provide information about the IUD is one justification for the preservation of the consultation, it is interesting to note it was not mentioned at all during our mystery shop.

In most cases therefore the only option our shopper was given was LNG-EC.

As pharmacists know this medication is extremely safe and that the main risk to the woman standing before them is that of an unwanted pregnancy, some pharmacists asked relatively few clinical questions. A minority asked about ectopic pregnancy and allergies: it is now known that LNG-EC actually reduces the risk of ectopic pregnancy by reducing the risk of pregnancy; allergy to the active ingredient is a standard contraindication for every drug and allergy to levonorgestrel is undocumented. Use of other medication was asked by the majority: the medications which may be of relevance are the following:

- barbiturates and other medicines used to treat epilepsy (for example, primidone, phenytoin, and carbamazepine)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV (ritonavir, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's wort (*Hypericum perforatum*)

and only because they may make levonorgestrel less effective, they do not compromise the efficacy of the medications themselves or put women, for example in the case of epilepsy, at risk of seizures. In these cases a double dose of LNG-EC is recommended; indeed greater risks are posed by interactions between some of these medications and off the shelf medicines such as paracetamol or benadryl.[7] [8] There is clear information in the Patient Information Leaflet on the need to take a double dose to counter the potential of reduced efficacy.

There were significant variations in the range of questions asked:

QUESTION	HOW OFTEN ASKED
Have I ovulated yet	1
Is my cycle regular	2
When is my next period due	2
How old are you?	2
History of ectopic pregnancy	3
Are you pregnant/do you have pregnancy symptoms	5

[6] https://www.rpharms.com/resources/quick-reference-guides/oral-emergency-contraceptives-as-pharmacy-medicines

[7] https://www.nhs.uk/medicines/acrivastine/

[8] https://bnf.nice.org.uk/interaction/carbamazepine-2.html

Are you using contraception/have you considered using regular contraception	6
Have you reacted badly to Levonelle in the past	7
When was your last period	10
Crohns, bowel disease/other health conditions	10
Allergies	11
Have you taken it within this cycle	12
Have you taken levonelle before	21
Are you taking other medications	21
When did the intercourse take place	23

The question that is asked the most is the timing of intercourse. Indeed, the RPS says one of the primary aims of the consultation is to ensure that the tablet is being taken within the right time frame.[9]

However studies show that nearly 90% of women present with in the first 24 hours after an episode of unprotected sex, and the majority of the remainder within 48 hours. Presentations after 72 hours are negligible.[10] There is no need for this to be policed by the pharmacy.

Erroneous information

Apart from the challenges obtaining any information about EllaOne, and accurate information when it was offered, the information that was given was generally correct. About half of pharmacies advised our shopper to come back if she vomited within 3 hours, in keeping with FSRH guidance, although 2 suggested this was only if she vomited within 24 hours. Again, clear information is in the Patient Information Leaflet on this, and vomiting is any event unusal.

The principle instances of erroneous information came when our shopper presented having had a previous mishap with a condom a week before for which she had used EC. This was tested in 6 pharmacies. There are no contraindications to repeat use in the same cycle; however if LNG-EC had been used in the previous 7 days, LNG-EC should be offered again as EllaOne may theoretically be less effective.

Pharmacists employed within 2 of the same chains provided very different advice.

A pharmacist at one branch of one chain was relaxed about the fact she had used it the week before, non-judgmental, and said it was no problem to provide it again. However at a different branch of the same chain, the pharmacist said our shopper would need to take a pregnancy test and show him the result before he could sell it as he believed she may already be pregnant from the week before.

This is not rooted in either guidance, evidence or ethics. Even some of the most sensitive pregnancy tests would not be able to detect a pregnancy a week after an episode of unprotected sex. The FSRH guidance recommends a pregnancy test when there has been unprotected sex

[9] https://www.rpharms.com/news/details/Emergency-contraception-needs-a-consultation-says-RPS
[10] Use of and attitudes towards emergency contraception: A survey of women in five European countries; Nappi et al; The European Journal of Contraception and Reproductive Health Care, 2013

more than 21 days previously and no period since. Failure to provide EC in this instance could easily put a woman at risk of a genuine pregnancy when there is any event no evidence that providing EC to a pregnant woman causes any harm.

"I felt totally shocked. No other pharmacist had asked this of me. I thought on my feet and fabricated a story about having a train to catch and not having time for a pregnancy test at that moment. The pharmacist ultimately agreed to sell me the product on the condition that I took a pregnancy test after my train journey. Although I agreed, I felt like I wasn't in charge and that I had to bargain with him to get him to sell me something I needed. As I was leaving the consultation room the pharmacist commented further on my situation, claiming continuously buying emergency contraception was not a productive way of protecting myself from pregnancy. This comment was both inappropriate, as I had informed him that before last week I had not taken emergency contraception for years, and lacking in advice as he failed to discuss any other contraceptive options with me. I left the store feeling judged."

Although this was an uncomfortable experience, the most unpleasant took place in a different chain. At one branch of the chain*, "the pharmacist was not judgmental, although he did say that taking it regularly "was not good for my menstrual cycle or my body in general".* There is no evidence that repeat use causes harm to the body, but our shopper felt the pharmacist was clearly well intentioned. *"I felt little to no judgement. Instead he seemed most concerned about making sure that I could purchase the emergency contraception that I clearly needed."*

At the same chain in a different city: *"I informed the pharmacist that I had taken Levonelle the week before but, before this point, had not taken any form of emergency contraception for years. The pharmacist clearly did not believe me, as she cautioned me that emergency contraception was not a valid method of contraception or one that can be used over and over again. She went on to explain that she could not sell me the emergency contraception, as the influx of hormones would be too high having taken it last week also."*

This suggestion has no basis in evidence.

"The pharmacist proceeded to give justification of why I was not in need of emergency contraception, claiming that I would have already ovulated and was therefore not at risk of pregnancy. I replied explaining how I would still like to be safe and restated that emergency contraception was not my regular chosen method of contraception. Eventually, she agreed to sell it to me. In a similar vein to the pregnancy test scenario, I again felt like I had to prove myself and negotiate with the pharmacist to obtain emergency contraception. The pharmacist clearly did not believe that emergency contraception was not my go to method of contraception, leaving me feeling under suspicion. She only gave me the option of buying EllaOne, for £34.95. She did not explain how this was different to Levonelle or why she was selling me it. I came away from the consultation feeling judged and quite upset – I don't know how someone who actually needed EC would feel after this."

This is one of the few occasions during our mystery shop where EllaOne was offered – and it was not in fact appropriate to do so. The FSRH advises that if a woman requests EC having taken LNG-EC within the previous 7 days, the effectiveness of EllaOne could be reduced by residual circulating LNG. In this situation, an IUD should be offered if appropriate or further administration of LNG-EC.

Inappropriate behaviour

Generally our shopper found pharmacists non-judgmental. Many provided information swiftly and concisely. On some occasions the consultation itself lasted in the region of just 30 seconds.

However in addition to examples of poor advice coupled with a judgmental approach documented previously, in one case tested out using scenario 1 our shopper was repeatedly asked about her age, made to show ID, and asked whether she was purchasing the product for someone else.

"At the beginning of the consultation, the pharmacist asked how old I was, to which I replied twenty-two, then asked for my ID to check this information was correct. He further asked me to state my date of birth once I had handed over my ID, as if he still did not believe me. Once my age was firmly established, he asked me twice during the consultation if the emergency contraception was for me and finished by asking if I was pregnant."

Cost of the consultation

There was no relationship between the content and quality of the consultation and the price of the product, even though some pharmacies are selling exactly the same product at vastly different prices: the generic Consilient cost £11.49 in one pharmacy and £24.99 in another, with other price points of £13.49 and £19. The online pharmacy Chemist4U recently noted that women were being charged as much as 650% on the cost price of emergency contraception.[11]

Conclusion

As the WHO makes clear, the LNG-EC regimen is simple to follow, and medical supervision is not necessary for correct use. It is approved for over-the-counter or non-prescription use in

[11] Online pharmacy halves price of morning-after pill for Christmas party season, *The Sun,* December 2018

many countries. Research results have demonstrated that both young and adult women find the label and instructions easy to understand.

Our mystery shop shows that pharmacists know this is an extremely safe method, and so questions are brief and consultations often quite cursory.

As we have noted, no information about further sources of contraception information and services were provides, not was STI testing mentioned.

It ahs also been suggested that the consultation is a good opportunity for women to confide serious issues, such as rape or domestic violence. This was not area explored in our mystery shop for obvious ethical reasons.

But bpas, which has strong safeguarding protocols in place, does not believe a mandatory consultation is the way to achieve this, rather that all pharmacy locations where women can seek help or advice offer the opportunity for conversation whatever the purchase. It should be noted that the majority of the pharmacies we visited did not have consultation rooms, and even those that did often did not feel private. Putting a woman at risk of pregnancy by placing obstacles to emergency contraception in her way has the potential to put her at greater risk: pregnancy is a risk factor for domestic abuse. The Confidential Enquiry into Maternal and Child Health (CEMACH), for example, found that 30 per cent of domestic abuse begins during pregnancy.[12]

The very fact that EC is kept behind the counter – often completely hidden from sight with no in-store markings - can act as a barrier to women accessing advice and information, and there is no clinical justification for that location.

Progestogen-only emergency contraception should be treated in the same way as other medicines that are on the shelf, some of which have a considerably higher risk profile. After nearly 2 decades in pharmacies, bpas believes the time has come to reclassify LNG-EC as a GSL medication, with access to advice where requested but a mandatory consultation finally dispensed with.

Bpas is indebted to our mystery shopper Anna Soppelsa, who also co-authored this report.

[12] Domestic abuse, BMA, September 2014

Appendix 1

1. **Pharmacy: name and location**
2. **Are there any services advertised in the window?**
3. **If yes, is emergency contraception among them?**
4. **Is there any indication anywhere in the store that emergency contraception is available?**
5. **Can you see emergency contraception behind the counter?**
6. **How many people do you have to ask before the pharmacist who provides the consultation speaks to you?**
7. **Is the pharmacist who sells it available?**
8. **Is there any wait for the consultation? If so, how long?**
9. **Please list all the questions that are asked in the consultation.**
10. **Are the different emergency contraception offers discussed? If so, how are they presented? If there is more than one progestogen version (eg Levonelle and Ezinelle) how is the difference explained? What do they say about Ella One?**
11. **What other information are you given?**
12. **How long does the consultation take?**
13. **Buy the one they recommend. What is it and what is the cost?**
14. **General notes/observations about the experience.**

Appendix 2

The following 2 medications, which are available as General Sales List products, provide a useful point of comparison:

1) **Nicotine Replacement Therapies**

Dozens of NRTs are on the General Sales List in the UK, to improve access and improve public health by helping people to stop smoking. There are many NRTs to choose from and people may well need help in establishing which option is best for them, as well as further sources f help and support to stop smoking. Their pharmacist is well placed to help them with this, but the intervention is not mandatory.

All of them carry warnings within the patient information leaflet that doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal.

Patients with serious cardiovascular disease should be encouraged to stop smoking using non-pharmacological interventions; while there may be some risks for those stable cardiovascular disease **this product presents a lesser hazard than continuing to smoke.**

Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism.

GI disease: Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and oral NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

None of these contraindications – all of which are considerably greater than those presented by LNG-EC – nor the potential value of a mandatory consultation, are seen as significant enough for NRTs to sit behind a counter rather than on the shelf. The risks are seen to far outweight the advantages.

2) **Nexium:**

AstraZeneca's Nexium 20mg Tablets containing esomeprazole were first authorised as a Prescription Only Medicine (POM) in 2000. Esomeprazole is a proton pump inhibitor that decreases the amount of acid produced in the stomach and treats heartburn and other gastric symptoms. It became a P medicine in August 2013.Just a year later the MHRA granted the product GSL status, despite the opposition of pharmacist associations, including the Royal Pharmaceutical Society (RPS) who believed its use could disguise serious underlying gastric conditions such as cancer, that it had the potential to interact with other medicines, and that long term use increased the risk of gastrointestinal infections such as Clostridium difficile and also fractures. "Many will not realise, or will ignore the fact that Nexium should only be used for up to two weeks", the RPS argued in its submission.[13]

However the MHRA felt that those who did have any serious underlying disorders could be trusted to recognise "alarm symptoms", such as weight loss, passing black stools, or pain when eating. "The labelling and user tested PIL [Patient Information Leaflet] advise patients that if symptoms worsen or do not improve after 14 days of use then the doctor should be contacted…Such alarm symptoms and lack of treatment effect, are easily recognisable by patients who can take suitable action **without the need for pharmacist intervention**." (our emphasis). The MHRA added that "clinically important interactions of esomeprazole with commonly used medicines are considered rare" but that "to minimise the risk, the outer carton states "Talk to your pharmacist or doctor if you are taking any medicines listed in the package leaflet".[14]

There is simply no reason why LNG-EC could not be treated in the same way, and we hope our mystery shop provides useful information to further the debate on reclassification.

13 Royal Pharmaceutical Society, consultation response, Nexium, 2014
14 Public Assessment Report, Pharmacy to General Sales List Reclassification Nexium Control 20mg Gastro-Resistant Tablets