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'First, Do No Harm': Factors that Influence Pharmacists Making Decisions about Over-the-Counter Medication

A Qualitative Study in Northern Ireland

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Abstract

Background: Little is known about how community pharmacists make decisions about which over-the-counter (OTC) medication to supply to a patient and the role of clinical evidence in making those decisions.

Objective: To explore factors that influence product selection by the pharmacist and the role of evidence-based practice in this decision.

Methods: In this qualitative study, community pharmacists registered in Northern Ireland and recruited via advertising and various qualitative sampling techniques, participated in face-to-face, semi-structured interviews (June 2007–September 2007) to discuss issues around OTC medication, including the use of evidence, how they judged a product to be effective, and their views on evidence-based medicine and its application to OTC medication. All interviews were digitally recorded, fully transcribed and analysed using the principles of constant comparison.

Results: Twenty-six pharmacists participated in interviews. Safety was the overarching consideration for pharmacists when making decisions. The subordinate themes were product, patient and professional factors. In terms of the product subordinate theme, use or consideration of evidence was secondary in the selection of OTC medicines. Pharmacists considered the potential for harm in the first instance and if the product was deemed safe, although lacking any evidence for effectiveness, the product was supplied. In relation to patient factors, it emerged that pharmacists were influenced by patient demand for a particular OTC product and wanted to meet patient expectations, provided that the requested product was judged to be safe. Similarly, professional factors such as ethical considerations (primarily in relation to safety) and respecting patient choice also influenced decision making. However, pharmacists recognized the conflict between professional requirements to practise according to evidence-based principles and patient demands.

Conclusion: This study suggests that pharmacists considered safety above all other factors when recommending OTC products to patients, and evidence of

effectiveness was seldom considered when selling OTC medicines. If evidence-based practice is to influence this type of decision, pharmacists need to use the evidence that is available and be prepared to discuss evidence with patients.

Background

Patients are becoming increasingly involved in self-diagnosis and treatment of common illnesses. In tandem, the over-the-counter (OTC) medication market has experienced rapid expansion, with OTC products accounting for over £2 billion of the £12.7 billion spent in the UK on all medications in 2004.[1,2] Between 1983 and 1999, 72 medicines were reclassified from prescription-only medicines (POM) to pharmacy medicines (P).[1] Currently in the UK, the latter can only be sold in a pharmacy under the supervision of a pharmacist, while other OTC medicines can be sold in other outlets. As part of this increased access to appropriate medical care and medicines, the transfer of managing minor ailments from general practitioners (GPs) to pharmacists should result in more patients preferentially seeking the advice of the pharmacist for such conditions. Furthermore, the recent deregulation of orlistat and tamsulosin,[3] and discussions surrounding the future reclassification of medications such as oral contraceptives[4,5] highlight the UK Government's commitment to expand the range of medicines available for self-medication towards long-term, chronic conditions.

More generally, there is the expectation that healthcare decisions should be informed by the promotion and adoption of evidence-based medicine and practice.[6] A widely used definition of evidence-based medicine is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients".[7] Healthcare professionals should know how to access, interpret and apply the principles of evidence-based medicine; pharmacists are no exception. The Code of Ethics of the Royal Pharmaceutical Society of Great Britain states that "you (a pharmacist) must maintain and improve the quality of your work by keeping your knowledge and skills up to date, evidence based …."[8] It is therefore important that pharmacists make choices that are informed by valid and clinically relevant research.

Pharmacists and their staff (counter assistants and pharmacy technicians) can now potentially treat a wide range of conditions, but there has been some debate whether OTC medicines are effective and supported by evidence. This may be less problematic for newer OTC products, e.g. those deregulated from POM to P, where the regulatory system requires evidence of safety and efficacy. Furthermore, there are a number of OTC products that have the potential for misuse and abuse, e.g. analgesics and laxatives.[9]

One controversial area involves treatments for upper respiratory tract infections. A critical review of clinical trials between 1950 and 1991 concluded that no good evidence has demonstrated the effectiveness of OTC cold medications in pre-school children.[10] Furthermore, a Cochrane review confirmed that there is no good evidence for or against the effectiveness of OTC cough preparations in acute cough.[11] Complementary and Alternative Medicine (CAM; e.g. homeopathy, herbal medicine, aromatherapy) has been heavily criticized for a lack of evidence base.[12-15] Given that these products are recommended by pharmacists in practice, it may appear that there is a conflict between the evidence-based practice espoused in the Code of Ethics and actual pharmaceutical practice. However, some also argue that treatment is about more than the evidence base, citing the 'placebo-effect' as being of clinical relevance.[16,17]

There is much literature on how to differentiate a minor ailment from a more serious condition,[18-21] but little research has been done on factors that influence product selection by the pharmacist and the role of evidence-based practice in this decision. Therefore, the aim of this study was, through qualitative methodology (semi-structured interviews), to explore the factors

(including the use of evidence) that influence community pharmacists when making decisions in relation to OTC medication.

Methods

The context for this study was community pharmacy practice in Northern Ireland. Ethical approval for the study was obtained from the Office of Research Ethics Committees Northern Ireland in April 2007 (reference number 07/NIR02/19). Qualitative, semi-structured, face-to-face interviews were conducted with each participating pharmacist to discuss their decision-making processes in relation to their supply of OTC medications; this qualitative interview approach is useful when research is exploratory and little is known about the subject area.[22,23] Sampling was initially carried out on a maximum variation basis.[24] The Northern Ireland Centre for Postgraduate Pharmaceutical Education and Training (now known as the Northern Ireland Centre for Pharmacy Learning and Development) agreed to facilitate recruitment. An invitation was placed in the Centre's May 2007 newsletter sent to all pharmacists across all branches of the profession (n = 2061), with the facility for pharmacists to reply using the 'free post' address. The inclusion criterion for this study was that participants had to be community pharmacists who were currently registered in Northern Ireland. Those who responded were contacted by telephone and further details about the study were given verbally. When the pharmacist confirmed that he/she wished to participate, he/she was sent an information sheet and consent form by post. Because of a poor response from the newsletter, participants interviewed during the early stages of the study were asked to refer new participants (snowball sampling). This evolved to a purposeful sampling strategy[25] involving participants who were specifically chosen for their particular characteristics, as we had reviewed the characteristics of those pharmacists recruited as the study progressed and attempted to recruit pharmacists with specific characteristics who had been absent, i.e. males and employers.

Table I. Outline of topic guide used in semi-structured interviews with community pharmacists

Factors that are considered when responding to symptoms or dealing with a specific product request
How pharmacists determine if a product is effective
Impact of deregulation on product selection
Effectiveness of OTC medication
Views on evidence-based medicine and its application to OTC medication
Placebo effect with OTC medication

OTC = over-the-counter.

The semi-structured interviews took place in the summer of 2007 (June to September) at a time and place convenient to each participant, and were conducted by one researcher (LAH). Participants who returned consent forms were contacted the day before their interview to confirm their availability.

Before each interview, participants were reminded that the discussion would be recorded and that everything discussed would not be linked to their names in order to preserve anonymity. The interview was initiated with a general discussion on the pharmacist's professional background in order to create a comfortable, non-threatening environment. The interview was based on the topic guide outline shown in table I, in addition to any issues raised by the participant. The guide was developed by reference to relevant literature and discussions within the research team.[12,26] During the interview, a standard definition of evidence-based medicine was provided to all participants, as previously stated in the Background section.[7] The guide was amended slightly after three interviews to include topics that were raised by participants and had not been considered by the researchers.[27]

Data Analysis

All interviews were recorded and transcribed verbatim by an experienced transcriber, and all files were encrypted to ensure participant confidentiality. Each transcript was then checked for accuracy against the original recordings by one researcher (LAH), and 25% were rechecked by a second researcher (CMH), thereby enhancing

reliability. All transcripts were anonymized with any identifiable details removed. The transcripts were read on a line-by-line basis, and text that represented a particular idea or concept was given a code.[28] All transcribed data were then entered into the QSR NVivo computer software package (version 7; QSR International, Southport, UK), which enabled complex organization, indexing, sorting and retrieval of the data. Constant comparative analysis was performed on an iterative basis, i.e. transcripts were analysed as the interviews progressed, so that emergent themes and theories could be tested and included in further research.[27] To assess participant validity, 25% of the transcripts were returned to the corresponding participants to check that their individual opinions had been accurately represented. These were returned with one minor amendment from one participant. The emerging themes were also discussed with these participants.[29] Consensus on the final themes was reached by discussion between the two researchers (another reliability check) and sampling ceased when data saturation was deemed to have been reached.

Table II. Participant characteristics of the pharmacist sample

Characteristics	No. of participants
Males	7
Females	19
Community pharmacy experience	
<1 y	4
≥1 y to <5 y	6
≥5 y to <10 y	9
≥10 y to <15 y	2
≥15 y to <20 y	3
≥20 y	2
Employment status	
employer	3
employee	20
self-employed locum	3
Type of pharmacy where participants worked	
small multiple (<5 pharmacies in the chain)	2
large multiple (>20 pharmacies in the chain)	17
independent	6
both multiple and independent	1

Results

From the initial mailing, six pharmacists were recruited to the study in the first instance. Snowball and purposeful sampling resulted in the recruitment of a further 20 pharmacists. Participant characteristics are shown in table II. There were more females than males, most were employees and most worked for large multiple (chain) pharmacies, but these characteristics had no impact on the final themes that emerged from the analysis. Interviews lasted from 33–60 minutes (average duration was 42 minutes).

Safety was the over-arching consideration for pharmacists when making decisions about OTC products, and represented the main theme emerging from the analysis. The subordinate themes, all of which were permeated by the safety theme, were product, patient and professional factors. In terms of the product subordinate theme, the use of evidence was secondary in the selection of OTC medicines; pharmacists considered the potential for harm in the first instance and if the product was deemed safe for the patient concerned (while considering their clinical characteristics), although lacking any evidence for effectiveness, it was supplied. In relation to patient factors, it emerged that pharmacists were influenced by patient demand for a specific OTC product and wanted to meet patient expectations, provided that the requested product was judged to be safe. Similarly, professional factors such as ethical considerations (primarily in relation to safety) and respecting patient choice also influenced decision making. These three subordinate themes are described in greater detail below.

In the following sections, illustrative verbatim quotes from participating pharmacists (identified by codes in parentheses) are provided in italicized text.

Product Factors

Although all participating pharmacists showed awareness that a number of OTC products lacked an evidence base, this did not prevent supply. The only reason why a sale was ever refused was in relation to safety, not lack of evidence of effectiveness. Sales were justified on a 'do no harm'

basis, with participants stating that they may be beneficial for some people.

"… as long as it is safe to use, it is up to them." (Community pharmacist [CP] 5)

"… so as long as I don't sell them something that harms them, I don't feel like I am exploiting them, I'd be happy to sell…. While there isn't the strong evidence for it [homeopathy], a lot of people do find it effective. It may not work but it definitely won't do you any harm." (CP9)

Conversely, for products recently deregulated and for which there was more evidence (e.g. omeprazole), participating pharmacists were often reluctant to recommend them because of safety issues.

"I'm very cautious with those types of medication. I still feel that the likes of that medication should be in the realms of the GP [general practitioner] personally." (CP1)

"Again I think if someone needs omeprazole, I would really recommend to see their GP in the first instance because I would not be confident enough that they didn't have an ulcer." (CP17)

The other category of product that pharmacists were reluctant to supply were those with misuse or abuse potential, such as sleep aids containing histamine H_1 receptor antagonists (antihistamines), combination analgesics containing opioids (codeine and dihydrocodeine), and kaolin and morphine mixture (for diarrhoea).

"I would be quite cautious with the products that are liable to abuse." (CP7)

Pharmacists judged effectiveness on their knowledge of pharmacology, feedback from patients, and personal use rather than considering the evidence base for a product.

"What customers have had in the past and coming back to tell me what has worked and what has not worked." (CP1)

"Sometimes it's because I have tried it myself … and I know it's very good." (CP4)

However, some pharmacists reported feeling uncomfortable when discussing lack of effectiveness with patients and would avoid discussing the issue.

"... nobody has ever asked me is there any evidence and if they did, I would be uncomfortable answering that." (CP9)

This coincided with pharmacists' perceptions that they should have a positive attitude about products in order to reassure patients.

"No I wouldn't go into that that much, I think. People sort [of] want you to be a bit more positive than that when they just want something that they think is going to help." (CP3)

"… not saying to them 'I'm sorry, but there is nothing works in this situation'. I think that is very unhelpful and I think that's actually detrimental to patient care." (CP26)

Pharmacists also recognized the importance of the placebo effect with conventional OTC and CAM products, and saw this as valuable, provided that there were no safety issues.

"You see, I am a strong believer in if you think it works it will work and if you do, as long as something doesn't do you any harm, if you believe that it is going to do you good, and it does do good, well then use it." (CP9)

Cost was also seen as influencing product requests, with pharmacists usually recommending a cheaper alternative. Lack of evidence, in conjunction with high cost of the product, was noted for simvastatin.

"10 mg simvastatin; the studies show again the evidence behind it that 10 mg really doesn't have much effect and what is the point in somebody wasting their money on it if it's not going to do much. Plus, as soon as they see the price £12.99 or whatever, 'Ah sure, I will just get it from the GP, it's £6.85'." (CP2)

Patient Factors

Participants discussed how the decision-making process was very patient-driven and emphasized the importance of meeting patient expectations, sometimes at the expense of effectiveness. Again, safety was the over-riding factor that ultimately influenced product choice.

"Sometimes you come up against the patient who although you give them all the evidence or

tell them all about the product that would be more effective, they don't want it because they have a preconceived idea that something else is better." (CP2)

"… at the end of the day, with OTC, a big part of it is what the patient wants themselves and a lot of times they know what they want and no matter how you counsel them, they leave with what they came in for as long as it is appropriate for them." (CP25)

However, although meeting patient expectations was recognized as being important, in some cases, pharmacists also appeared to be uncomfortable at being pressurized to do so.

"They feel they have to have something and it's exactly the same for doctors. They feel they have to prescribe something so you get an antibiotic even though they know in their heart of hearts …." (CP2)

"So some people do have an expectation where they want a product and that puts obviously you under pressure to give them one." (CP12)

The decision-making process as to what product to supply was also influenced by whether a patient described symptoms or requested a specific product. In the case of the former, pharmacists seemed to have more control and flexibility.

"I think sometimes with the symptom based request you are more sometimes in control initially of that scenario ... em, and you can define from that what the proper sym ... or what the symptoms are the person has, and recommend the product that, you know, has shown evidence to say that it will help those symptoms." (CP13)

"… if they have asked for a product and they have used it before and I suppose their body language is quite closed, possibly not. But if it is the situation we are talking about symptoms I would certainly recommend another product or a better product if I thought it was warranted." (CP19)

Professional Factors

Throughout the interviews, participants discussed being honest, having integrity and wanting to offer patients the best level of care. For some participants, as their interview proceeded, there was growing recognition of a potential conflict between practice and ethical guidance.

"It might sound contradictory, but if they are paying for something and I am selling them something that I know is no use, it's unethical and it's just wrong." (CP2)

"I suppose that's maybe where the placebo bit becomes unethical because are you giving somebody something that actually doesn't really work and you are just hoping that because they think it might that it will. Yes, that is quite a grey area …." (CP21)

Most participants had little understanding of the term 'evidence-based medicine' and none had been taught about its practice during their undergraduate training as pharmacists. However, during the interviews, participants discussed benefits of adopting an evidence-based approach for OTC medication. These centred on greater professional development and recognition for pharmacists, and improved standards of practice, with potentially better outcomes for patients.

"So I suppose if we are treating them more effectively when they first stop with us, then they won't have to go to the doctor and they won't have to make an appointment and the waiting list at the doctors won't be that long ... so it's sort of a knock-on effect on everything." (CP11)

"I think basically when pharmacists are recommending things and it's not based on evidence they are open to potential ridicule, I suppose, by other professions." (CP15)

Limitations of an evidence-based approach were also recognized.

"You are going to have situations where how do you look up that information there and then if I don't have access to internet blah-de-blah, how do I clinically then look at the evidence that's there on the spot to answer somebody's query. Not all patients are looking for that kind of thing either." (CP10)

"I think the limitations are around time. The time that it takes for pharmacists to actually learn the knowledge or receive this new information and

take it on board and filter it to make sure that it is relevant and valid for their own practice.'' (CP16)

However, ethical considerations such as patient safety and respecting patient choice were considered to be more important than having an evidence-based approach, again emphasizing the 'do no harm' philosophy.

''As I said earlier, as long as it's not detrimental or it's not inappropriate for that condition, it's their choice. As long as I feel that I have given them the choice and told them about why one would be maybe superior to another if they choose the lesser, then it's their choice.'' (CP2)

Discussion

This qualitative study has uncovered aspects of decision-making associated with the supply of OTC medicines by pharmacists and the role of evidence in informing those decisions. Decision-making was a complex process, but the overwhelming influence on such decisions was the safety of the product; evidence of effectiveness was seldom considered. The importance of safety when recommending OTC medicines has been highlighted previously, although more so in the context of avoiding misuse and abuse of certain products.[30] This latter study also found that evidence was seldom used in any pharmacist–patient consultations. This has been confirmed in this study, although pharmacists also admitted to the supply of products which they knew or suspected were not supported by clinical evidence. They wanted to meet patient expectations, respected patient choice and thought they should be involved in decisions, although some also recognized that it was an ethical dilemma to supply a product knowing it was ineffective. Ironically, for those products for which there was more evidence, pharmacists were reluctant to recommend them because they felt they were not safe to use for self-care. This interesting dichotomy suggests that in practice, pharmacists are not supportive of some deregulated products and this is justified on the basis of safety. The UK Government plans to extend deregulation further,[31-33] but based on the present findings, pharmacists may not recommend such deregulated products in routine practice.

In this study, the effectiveness of a product was assessed on the basis of anecdote and personal use, as has been previously reported for the community pharmacy setting.[30] Pharmacists felt there was a strong placebo element with a number of OTC products, but thought that this was useful. The placebo effect has often been used to justify the use of CAM products, notably homeopathy.[34] Pharmacists also wanted to reassure and appear positive to patients in their recommendations. This has also been found with GPs. In one study, GPs were interviewed about influences on their prescribing.[35] In order to maintain a good relationship with their patients, they prescribed drugs of 'limited clinical value' because they were cheap and seen as harmless. Bradley[36] has described uncomfortable prescribing decisions on the part of GPs, a number of which were made because of patient expectations and wanting to maintain a good relationship with the patient. This is analogous to what was found with the pharmacists. It could also be argued that the supply of these 'harmless' products may avoid a consultation with a doctor, thereby saving time for all concerned.[37] Conversely, supply of medication (albeit purchased) may reinforce medicalization of self-limiting conditions, thus encouraging other inappropriate health-seeking behaviour, e.g. an unnecessary consultation with a doctor.

The role of the patient in decision making was also important, with pharmacists reporting that they needed to meet expectations and facilitate patient choice, and admitting that they felt pressurized to do so. Patient preferences, choices and expectations have frequently been cited as being at odds with an evidence-based approach. Tracy et al.[26] interviewed family physicians in Canada who reported that when patient preferences were in conflict with other factors, such as evidence, most doctors did what the patient wanted. This was further supported by a postal survey to family physicians across Canada in which patient expectations dominated decision making that was contrary to evidence.[38] Concordance is a

concept that is gaining increasing importance within healthcare. It represents a way in which patients can assume responsibility and contribute to decisions in healthcare, particularly in relation to medication.[39,40] Concordance is at the heart of self-care and the pharmacists in this study frequently cited the importance of involving patients in decisions about products, despite lack of evidence for a number of products. Pharmacists perceived a tension between employing an evidence-based approach in community pharmacy practice and meeting patient expectations.

Other healthcare professionals have reported feeling pressurized by patients. Ring et al.[41] have reported that patients present their symptoms using graphic and emotional language, together with complex patterns of symptoms, and resist explanation, description of emotional and social effects of symptoms, the influence of other individuals and biomedical explanations. This could be transposed to the community pharmacy setting in which symptoms are described and a product is supplied. In addition, as was reported in this study, patients often requested a product by name. This gave little flexibility to pharmacists in selecting what they considered to be the most appropriate product for the patient, and reinforced their perceptions of having to respect a patient's choice.

However, responding to specific symptoms gave pharmacists a degree of control and input about which product to supply, a finding that has been noted before.[42,43] Watson et al.[43] reported that symptom presentation was more likely to result in an appropriate outcome for the treatment of vaginal candidiasis than patients asking for a specific product or the patient stating they had this condition.[43] It was easier to engage in information communication with customers making non-product requests as pharmacy staff were able to discuss different treatment options. Patient resistance to questioning and obtaining their stated product has been recognized as impeding communication in the pharmacy setting.[44,45]

However, through the course of the interviews, pharmacists were aware of the conflict between supplying products that lacked evidence of effectiveness and their professional ethics. Ernst[46] has stated that the sale of homeopathy products, herbal/flower remedies and aromatherapy oils from pharmacies represents an ethical dilemma for pharmacists and contravenes a pharmacist's ethical code. A similar view has also been taken with regard to OTC slimming aids.[47] These views may be seen as 'purist' and at odds with consumer choice, but the impact on pharmacy professionalism and the reputation of the profession cannot be ignored. Pray[12] has stated that "pharmacists who view themselves first and foremost as professionals should refuse to sell unproven medications and recommend unproven therapies, no matter what the ramifications might be".

The pharmacists had little knowledge of evidence-based medicine, but recognized the benefits and limitations of such an approach. Time was seen as a barrier and has often been cited as a problem for other healthcare professionals, along with limited resources.[26,38,48] Indeed, the barriers and tensions in trying to implement an evidence-based approach mirrored those that have been found in the medical profession. The nature of pharmacy consultations means that pharmacists and patients are often communicating in a busy environment, which is not conducive to an in-depth conversation and ready access to up-to-date evidence. Furthermore, there is a lack of centrally available evidence-based information that could be easily accessed in community pharmacies, not all of which will have internet connectivity.

Recent publications and advice from government agencies have brought the issues of safety and evidence of effectiveness of a number of long-established OTC products into sharp relief. Concerns have been raised with the US FDA about the safety of cough and cold remedies for children, particularly those aged <6 years.[49] Recently, the Medicines and Healthcare products Regulatory Agency in the UK has issued new advice on cough and cold products for children following a review of the available evidence.[50] These latest restrictions have been justified on the basis of lack of evidence of effectiveness and safety concerns, and it is likely that safety may

have been the predominant underlying reason for these decisions. However, scrutiny of these products may lead to other categories of OTC medicines being reviewed in a similarly systematic way. There have been growing concerns in the UK about the continuing availability of analgesics containing low doses of opioids, again from a safety viewpoint.[37] Therefore, continuing deregulation of some products from prescription-only status may be accompanied by increasing restrictions on the use of more established products.

As a qualitative study, this research has a number of limitations. We recruited a self-selected group of participants who may not be representative of their professional colleagues. However, the sample was broad in terms of participant characteristics and was drawn from across the community pharmacy sector. There were more employee pharmacists than employers, but this reflects the workforce profile within the profession at present. The sample was also dominated by pharmacists working in larger chain pharmacies but, again, this is reflective of community pharmacy in the UK. Reflexivity (i.e. the process of critical self-reflection on the part of the researchers to minimize bias) was employed throughout to improve the validity of the research.[51] As part of reflexivity, the interviewer (LAH) debriefed with the second researcher (CMH) following interviews and discussed initial findings/interpretations. Notes were made during these debriefing sessions and were referred to during analysis. As is the case with qualitative research, a formal sample size calculation was not performed, but achievement of data saturation indicated that further sampling was not required. Participants were frank and forthcoming in their views and the dominance of the superordinate and subordinate themes justified confidence in the robustness of the findings.

Conclusion

This study suggests that pharmacists considered safety above all other factors in their decisions on recommending OTC products to patients. Evidence of effectiveness was seldom considered when selling OTC medicines, and pharmacists recognized the conflict between recommending products that had little clinical evidence for effectiveness and their role as healthcare professionals. The study highlighted the role of patient choice and meeting expectations in making these decisions, but what is not known is the view of patients in relation to evidence of effectiveness and if this is important to them. Better communication between pharmacists and patients using the best available evidence may go some way to improving self-care with OTC medications.

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