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Evidence-based OTC "Prescribing"—A New Postgraduate Course at the Auckland School of Pharmacy

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The School of Pharmacy at the University of Auckland has recently developed a taught postgraduate course, evidence-based over-the-counter (OTC) prescribing, aimed specifically at community pharmacists and designed to develop the skills required to practise evidence-based medicine (EBM) utilising OTC "prescribing" as the vehicle for learning. The course forms an optional part of the postgraduate pharmacy programme available at the University of Auckland including PGCert/PGDip/Masters of Pharmacy Practice programmes and is designed to build on a compulsory course in clinical skills. This report describes the course objectives, course structure and assessments. Views of students are also presented.

Keywords: Community pharmacy; Evidence-based medicine; Over-the-counter; Prescribing; Postgraduate

INTRODUCTION

Evidence-based medicine (EBM) can be defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research" (Sackett *et al.*, 1996). It is now widely taught in medical degree programmes and associated professions. For example, 37% of the 269 respondents to a survey of 417 American medical residency programmes provided a freestanding EBM curriculum and it appears to be gaining favour in pharmacy education (Bryant *et al.*, 2001; Pepping, 2001). Articles describing the impact and importance of EBM to pharmacy have been published in recent years (Blenkinsopp and Black, 1997; Wiffen, 1997; Bhalla, 2000) particularly focusing on the importance of continuing education.

There are a number of reasons for pharmacists to learn about EBM. First, there is a continuous generation of new evidence concerning pharmacotherapy through research findings and pharmacists need to be able to access and evaluate the evidence for quality and relevance. Indeed, one of the many problems faced by practitioners is the ability to obtain evidence in a timely manner. Secondly, whilst pharmacists may be relatively up-to-date on registration, this knowledge and expertise deteriorates with time as newer evidence and practices emerge, newer drugs are licensed and conditions are better defined.

Whilst many pharmacists maintain their currency by attending lectures and reading updates, they often lack the skills required to put the evidence into practice. These skills include formulating clinical questions, obtaining and evaluating the evidence and making clinical decisions around whether or not the evidence is appropriate to the case at hand (Barnett *et al.*, 2000).

The utilisation of EBM skills is essential to many aspects of pharmacy practice including drug information, clinical pharmacy, prescribing advice, medicines management and pharmaceutical care. However, much of the work of community pharmacists involves responding to symptoms, "prescribing" over-the-counter (OTC) remedies and providing advice.

OTC prescribing can be likened to any clinical decision to prescribe and is based on a judgment of the patient's condition, including assessment of symptoms, age, gender, morbidity, social status and prior attempts to "heal." It is argued that the practice

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of EBM rarely informs community pharmacists' OTC prescribing decisions. There may be a number of explanations for this. A lack of EBM skills is a primary explanation, including the lack of evidence for some of the older OTC products (and even for newer products evidence may be sparse). Furthermore, many community pharmacists do not have direct contract with other health professionals or disciplines and are therefore unable to make use of opportunities for continuing education such as lunchtime seminars, journal clubs and routine inter-professional discussions about patient care.

Added to this, patients often self-medicate with little or no professional advice, relying on the lay health network for support. Many purchase OTC treatments by name, indicating a lack of desire for in-depth interventions by pharmacists. However, pharmacists were very influential in the choice of products where patients presented symptoms without a specific request for a product (Emmerton and Shaw, 2002). With this in mind, one might ask, "Why bother with EBM in responding to symptoms?".

On the other hand, governments have moved towards encouraging self-medication by shifting from a "prescription medicine" status to one which allows for their purchase under the supervision of the pharmacist, a strategy which has been supported by the World Health Organisation (Levin, 1998). This gives consumers a wider choice of medications with which to practise self-medication. Pharmacists also have a professional and ethical responsibility in endeavouring "to ensure that sufficient information is obtained to allow an assessment to be made that such is appropriate, safe and efficacious and to enable a suitable recommendation to be made" (Pharmaceutical Society of New Zealand, 2003). For pharmacists, such responsibilities raise the need to be up to date with evidence and to have the skills to apply it to practice-based situations.

It was with this in mind that a new postgraduate course was set up at the School of Pharmacy at the University of Auckland, aimed specifically at community pharmacists and designed to develop the skills required to practice EBM, utilising OTC "prescribing" as the vehicle for learning. The course forms an optional part of the postgraduate pharmacy programme available at the University of Auckland, including PGCert/PGDip/Masters of Pharmacy Practice programmes, and is designed to build on a compulsory course in clinical skills.

AIMS AND OBJECTIVES OF THE COURSE

The course aims are listed in Table I.

1. To define what is meant by EBM in an OTC context.
2. To develop the skills and understanding required to apply an evidence-based approach.
3. To raise awareness of the evidence base supporting OTCs.
4. To enhance pharmacists' skills in evaluating treatments for safety, efficacy, acceptability.
5. To improve diagnostic skills and
6. To encourage pharmacists to consider their product ranges from an EBM perspective.

TABLE I Course learning objectives

1.	Apply a reasoned approach to the identification and evaluation of a client's symptoms
2.	Critically review the literature with respect to OTC medicine
3.	Apply evidence-based pharmacological, pharmaceutical and clinical knowledge to the rational use of OTCs
4.	Effectively provide advice to clients and health professionals about the selection and use of OTCs alone and in combination with other treatment modalities from an EBM perspective
5.	Develop and utilise guidelines and formularies for OTC medicines in respect of the management of conditions
6.	Communicate effectively with patients and health professionals

Ambitious learning objectives, listed in Table I, were additionally set for the course.

COURSE STRUCTURE

The course was structured to include both on-site teaching and off-site study equating to about 120 h of student work. Prior to undertaking the course, students were asked to review the OTC products on sale in their pharmacies and to evaluate their own level of knowledge about the evidence base for the efficacy and safety of these products. Teaching and assignments were set, with objectives designed to help students meet the four main tasks of EBM:

1. Devising evidence-focused clinical questions from cases.
2. Performing a literature search.
3. Performing a critical appraisal of the evidence and
4. Putting the evidence into practice in a case-focused manner.

On-site Teaching and Assignments

The course was provided over a 15-week semester with approximately four study days-per-month. Study Day 1 was an introduction to EBM with a focus on defining the terms and skills required. Students were encouraged to discuss their impressions of the pre-class exercise and to think about some of the barriers they might expect with regard to practising evidence-based OTC

prescribing. A review of study design and research methodology was undertaken and students were given key reading materials. Most applicants had previously undertaken another postgraduate course in which some of the skills and practices of EBM had already been outlined. However, during the day students were required to develop EBM-type questions from a typical OTC case and to search for evidence to answer those questions utilising on-line databases and other available library facilities.

At the end of the day, each student was provided with an OTC area to review. They were required to search for the evidence available regarding the safety and efficacy of the treatments available, to prepare a presentation and to write a written report. Students were also required to keep a logbook of their experiences and to undertake reflective practice, utilising a cycle of learning approach. As part of the logbook, students were to write up case-studies from their own practice that related to patient interactions on OTC matters and that had required them to seek out evidence in order to manage the case appropriately.

On Study Day 2, students presented their practice-based case studies to the group, describing the pharmacist–patient interaction, the clinical questions which had arisen, any evidence they had found, the appraised and the outcome of the case. They also presented their evidence-based critical appraisal of the literature on the OTC areas they had been given (e.g. Echinacea for colds and flu, insect repellents, treatment of "cold sores"), thus providing the rest of the group with a résumé of the evidence around a number of different OTC areas.

Later in the day, students were introduced to the concept of guideline development. A number of exercises were developed which enabled them to familiarise themselves with the skills required, such as performing a suitability screen, grading the evidence and algorithm design. They were encouraged to review and critique published guidelines and to include local health professionals in the development work. At the end of the day, each student was provided with an area of OTC practice (different from those in the first assignment) on which they were required to develop "in-house" practice guidelines, e.g. management of vaginal itching and discomfort, management of premenstrual syndrome, management of constipation in under-16 s. It was explained to students that their completed guidelines would not be suitable for general dissemination (as they had not been subjected to an appropriate review process) but they could be used within their own practice.

Study Day 3 of the course focused on communicating evidence to patients, using the non-directive technique of motivational intervening (MI) (Miller and Rollnick, 2002). Time was also set aside for discussion, progress with guidelines and for reviewing some of the student case studies.

The final day was reserved solely for the presentation of the finished guidelines. Each student was allocated 20 min for an oral presentation to be accompanied by visuals and, in some cases, handouts to the audience. An expert in guideline development also attended the day's activities; along with the course tutor, the expert provided informal verbal and written formative assessment and feedback to students on the presentations for quality of presentation, content and accuracy of guidelines. A final completed printed version was submitted for formal evaluation.

Assessment

In addition to grading assignments, the students were required to undertake and pass a seven-station OSCE-type exam. The first station required students to respond in written form to a case study relating to calcium intake and osteoporosis. Responses were structured to include the clinical questions (which need to be answered) and a search strategy including which types of study design would be searched for and why.

Station 2 was an observed patient–student interaction utilising a professional role player. The student was assessed on their ability to interact with the patient about smoking cessation using an MI approach. At station 3, students had to construct an algorithm for managing smoking cessation in a community pharmacy setting using evidence provided at the station.

At station 4, students were requested to evaluate a website for a smoking cessation product with regard to quality of advice for smokers (in terms of smoking cessation), quality of the evidence provided and accuracy of the statements relating to the evidence. At station 5, students were provided with a short report on a research study and were expected to draft a "Discussion" section for the report. Station 6 required students to search Medline for evidence around the use of cranberry juice in cystitis. The final station required students to perform a structured critical evaluation of a published RCT.

COURSE EVALUATION AND FEEDBACK

In addition to the University of Auckland's standard requirement for completion of a course evaluation questionnaire, self-completion questionnaires were given to students requesting information on the impact of the course regarding the way in which students "respond to symptoms," on the stock held in the pharmacy and on barriers to implementing

evidence-based OTC prescribing. A focus group was run to look at these issues in more detail.

In the focus group particularly, students raised a number of interesting issues such as the lack of time available for practitioners to practice EBM, difficulty in obtaining research papers and the reluctance of older pharmacists to support this practice.

The lack of evidence was a problem:

> "Say you have one product that you are sure is not going to work. It is in the shop and the customer really wants it. I'm not sure how you feel about it but it is kind of hard. You know it is not going to work... On the other hand... it is not going to do any harm to them and it gives them a placebo effect plus it gives the pharmacy self respect."

A loss of professional reputation might be an issue in relaying a lack of evidence to patients:

> "I do encounter a few patients where you tell them it is not going to work and they get really upset and they just leave. It doesn't make you look good and they will go to another pharmacy and get it anyway."

For those students who were employee pharmacists, there was tension between the desire to sell only products for which there was clear evidence of benefit (or at least clear evidence of lack of harm) and the need to generate income. However, as one student stated:

> "[The course] has made me question why you recommend the drugs. Is it because you had a good deal with the company two months ago and [have] the buying package and the great discount? I think as well it has made you realise that, okay, you have control over buying what is in the shop, but the products are there and I've got to make it known that I won't recommend this product because I now know it might not be the best product in the range. It might not be the biggest seller that you are recommending but there are reasons behind it."

An increase in confidence in challenging "evidence" was also noted:

> "We have already bought in some of the product that we now have trials behind them. The other thing is that with reps coming in and showing you the latest product and their evidence, we can critically look at that evidence now and feel confident to dispute some of the so-called trials they have done."

WAS THE COURSE A SUCCESS?

Student feedback from the course revealed that some of them had expected a more didactic approach, whereby students would be learning about a wide-range of OTC products; this includes the products' actions, their adverse effects and when they should be recommended. However, students found that taking an evidence-based skills approach to the subject entailed rewarding, though very hard, work.

Overall, it is believed that the course has been successful in meeting its stated objectives. However, development is needed in a number of areas. The content of the face-to-face teaching and its association with assignments needs to be carefully reviewed. A greater emphasis needs to be placed on developing and practising basic skills such as literature searches and critical appraisal (these are skills which were assumed to be covered in enough depth in other courses). Also, whilst the students thoroughly enjoyed and valued learning an MI approach to communicating with patients, it should be decided whether that time might be better spent in revising skills and providing feedback and support to students. Nonetheless, we look forward to providing this course again as part of our developing portfolio of postgraduate courses.

The real success of this course has been in facilitating a change in mindset: getting students to challenge accepted folklore that often surrounds the practice of OTC prescribing. It is thus believe that, whether or not they find the time to routinely practice an evidence-based approach, Auckland's School of Pharmacy students will no longer look at the products in their pharmacies in quite the same way.

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