THE SCOTTISH OFFICE



National Health Service in Scotland

COUNSELLING AND ADVICE ON MEDICINES AND APPLIANCES IN COMMUNITY PHARMACY PRACTICE



COUNSELLING AND ADVICE ON MEDICINES AND APPLIANCES IN COMMUNITY PHARMACY PRACTICE

Pharmacy Practice Guidelines developed by a Steering Group and Working Group set up by the Clinical Resource and Audit Group

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FOREWORD

To achieve maximum therapeutic benefit from their prescribed medicines and appliances it is important that patients understand how to use the product. Since the pharmacist is normally the last health care professional whom patients see before therapy begins, he or she plays a key role in helping patients to understand their therapy. The counselling and advice given by the community pharmacist should complement and reinforce information provided by other members of the health care team and present the patient with a further opportunity to ask questions.

These guidelines have been the subject of consultation within pharmaceutical, medical and nursing professions in Scotland and have been welcomed by all three professions. They have also been successfully field tested within community pharmacy practice. The final document reflects comments arising from the consultation exercise and the field testing.

The guidelines are intended to assist pharmacists in their practice. I am grateful to those who have contributed to their production and commend the guidelines to you.

William Scotto

W SCOTT Chief Pharmaceutical Officer 1996

SUMMARY AND RECOMMENDATIONS

- 1. Pharmacists have a professional responsibility to recognise and/or assess and meet the counselling and advice needs of patients in relation to their use of medicines/appliances (Sections 2.1.1 and 2.1.4, Annex A2).
- 2. Patients should be made aware that counselling and advice on medicines/appliances is offered as a professional service by the pharmacy (Section 2.1.4).
- 3. Pharmacists must respect the confidentiality of information acquired in the course of professional practice relating to a patient and the patient's family. In this regard they are bound by Principle 4 of the Code of Ethics of the Royal Pharmaceutical Society of Great Britain (Annex A2).
- 4. Pharmacists should liaise closely with general practitioners and other health care professionals (Sections 1.4 and 1.5).
- 5. Pharmacists should ensure that they have the knowledge and skills required to provide counselling and advice to patients effectively and efficiently (Section 2.1.4 and Annex A3).
- 6. Counselling should be carried out in an environment which is nonthreatening and conducive to forming good relationships between the pharmacist and patients or carers (Section 2.1.4).
- 7. All appropriate sources of information should be used to assess relevant patient and medication/appliance factors in order to recognise and prioritise the needs for counselling and advice. The use of patient medication records is to be encouraged (Section 2.1.2).
- 8. For each identified need pharmacists should specify a desired output and method of assessing whether that output is achieved (Section 2.1.3).
- 9. Aids to comprehension and/or compliance should be used where necessary to meet an individual patient's needs (Section 2.1.4).
- 10. Pharmacists should ensure that patients have an appropriate level of understanding and are able to comply with instructions for the use of their medicines/appliances (Section 2.1.5).
- 11. Where direct patient contact is not possible, the pharmacist may have to assess the need for counselling indirectly by discussion with a carer, relative or representative of the patient (Section 2.1.1).
- 12. Documentation of counselling and advisory activities is to be encouraged for the purposes of continuity of care, self-audit or research. Audit and research may be used to review and develop standards of counselling and advice (Section 2.1.5 and Annexes A4 and A5).

13. Summary Of The Recommended Steps In The Counselling Process

PREPARATION	Be familiar with the recommended counselling points for the most commonly prescribed medicines and appliances		
	Consider patients' expectations, the counselling environment and the time available		
RECOGNISE THE NEED	 Establish what the patient already knows about the medicine/appliance Recognise characteristics of the medicine, appliance or patient which indicate particular needs 		
↓	noodo		
ASSESS AND PRIORITISE NEEDS	 Use all available sources of information, including as necessary, the patient, carers, relatives or health care professionals and patient medication records to assess relevant patient and medication/appliance factors and prioritise needs 		
\downarrow			
SPECIFY ASSESSMENT METHODS	 Decide for each identified need what it is you wish to achieve and how you will determine the output from the counselling process 		
V			
IMPLEMENT	 Counsel, introducing as necessary aids to comprehension and/or compliance and explain their use 		
	 Reinforce important points and invite patient to ask further questions 		
¥			
ASSESS	 Check knowledge and understanding by direct questioning 		
	 Where possible, assess actual compliance through follow-up 		
EVALUATION AND REVIEW	The counselling and advisory service which you offer may be evaluated, reviewed and developed through audit and/or practice research.		

Section 1

INTRODUCTION

1.1 Purpose of the Guidelines

Counselling and the provision of advice on medicines and appliances are traditional functions of the community pharmacist. The knowledge and skills for these functions are now established in undergraduate Pharmacy courses and developed through a combination of experience and continuing post qualification education. The purpose of these Guidelines is not to teach pharmacists what they already know, but to provide a framework within which pharmacy practice can further develop. Thus the Guidelines focus on the process of counselling and aim to provide a systematic and structured approach. In practice, methods of meeting the desired objectives for counselling will vary with the preferred styles of different practitioners and the variable needs of individual patients.

1.2 Who are the Guidelines aimed at?

These Guidelines are aimed at all community pharmacists and it is hoped that they will prove helpful to experienced pharmacists and newly qualified pharmacists alike. A one page 'Checklist for Counselling' is provided in Section 2.2 and reference to further practical guidance on counselling is given in the Bibliography (Annex A6).

1.3 Definitions

For the purpose of these Guidelines, the term "counselling" will be used to describe the interactive process involving a consultation about medicines or appliances between a pharmacist and a patient, and the term "advice" will be used to describe the oral or written provision of professional opinion. Further definitions of terms used in these Guidelines are given in the Glossary (Annex A1).

1.4 The importance of counselling and advice

Rational and effective therapy relies on competent diagnosis and prescribing. However of equal importance, is the need for the patient to have the necessary knowledge and understanding of their disease and their therapy, the ability to take or use their medicines and/or appliances correctly, and the motivation to follow the prescribed course of therapy. To achieve this requires skill, expertise and investment of time on the part of the professionals involved and the full attention and involvement of the patient.

For prescribed medicines the general practitioner has the primary responsibility tor counselling and advising patients at the time of writing the prescription. Barriers to effective communication at this point are well documented and include a shortage of time and the inability of patients to recall oral advice, particularly if it relates to a complex regimen and/or is given in a relatively stressful situation. The role of the community pharmacist therefore in complementing and reinforcing the counselling and advice given by physicians is essential. Independently, community pharmacists perform an important counselling and advisory function in relation to over-thecounter medicines. Uniquely, the pharmacist has the opportunity to ensure compatibility between prescribed medicines and those purchased over-thecounter, a role likely to increase as more potent medicines are released from the 'POM' to the 'P' category.

1.5 Interprofessional liaison

There should be close liaison between health care professionals involved in counselling and advising patients on medicines and appliances; in particular, care must be taken to assess the wishes of the prescriber. Meeting to discuss the nature and extent of counselling and advisory services offered to particular patient groups by each of the health care professions involved at a local level helps to structure and integrate the advice which patients receive from different sources. Whilst this will usually involve the community pharmacist and the general practitioner, effective liaison with other primary care team members who regularly visit patients is of obvious value. Where appropriate for particular patients and indications, referral and/or consultation between the health care professionals involved is necessary.

1.6 Developing practice

In line with other health care professions, pharmacists have an ethical and professional obligation to develop their practice to improve patient care. The fact that the counselling function is traditional and routine for all community pharmacists does not remove the need to ensure that standards of practice are high and that patients are receiving a good pharmaceutical service. Thus the Annexes within the Guidelines deal with Ethical and Legal Considerations (A2), Education and Training (A3), Clinical Audit (A4) and Research and Development (A5).

1.7 Scope of the Guidelines

It is not the purpose of these Guidelines to labour aspects of counselling with which pharmacists are already familiar. No attempt is made to provide the technical or scientific knowledge or to teach the communication skills which underpin the counselling process. However, extensive use is made of examples to illustrate the process.

The needs of patients for counselling and advice may extend beyond the areas of medicines and appliances. The role of the pharmacist in recognising such needs is outwith the scope of this document. It is an increasing role, however, as exemplified by topics such as infant feeding, aspects of adult nutrition, family planning, biochemical tests and screening, health education, travel advice and response to symptoms.

Section 2

GUIDELINES ON THE COUNSELLING PROCESS

Section 2.1

STEPS AND OBJECTIVES

The process of counselling and providing advice can be broken down into a series of steps, each of which has a particular objective. The purpose of this section is to distinguish between the different steps in the process and to give guidance on the achievement of the objective for each step. The steps and objectives are as follows:

STEP 1 : RECOGNISING THE NEED (Section 2.1.1)			
Objective 1:	To recognise the need for counselling and advice.		
STEP 2 : ASSESSING A	ND PRIORITISING NEEDS (Section 2.1.2)		
Objective 2:	To assess and prioritise the counselling and advice needs of the patient.		
STEP 3 : SPECIFYING ASSESSMENT METHODS (Section 2.1.3)			
Objective 3:	To specify for each identified need how the result of the counselling and advice will be determined.		
STEP 4 : IMPLEMENTATION (Section 2.1.4)			
Objective 4:	To implement the counselling and advice process.		
STEP 5 : ASSESSMENT (Section 2.1.5)			
Objective 5:	To assess the effectiveness of the counselling and advice process.		

These steps are not necessarily intended as a chronologically ordered sequence of events. On the one hand the real counselling and advice needs of a patient may only become apparent well into a counselling session and on the other, the process of assessment may be continuous, e.g. as a series of stepwise checks one or more counselling sessions for a particular patient. In practice a number of these steps may be achieved almost simultaneously and, for patients who are well known to the pharmacist, some of the steps may not prove to be necessary.

Section 2.1.1

STEP 1 : RECOGNISING THE NEED

Objective 1: To recognise the need for counselling and advice.

Guidance Notes

When a patient presents a prescription for dispensing the desired outcome is that the medicine or the appliance is used safely and effectively, in order to alleviate symptoms or effect a cure (see Case Example 1). There could be a need for counselling and advice in every such situation. The same need may also exist when a patient purchases an over-the-counter medicine or appliance.

In recognising and assessing needs, an essential first step is to establish what the patient already knows about a particular medicine or appliance, and what counselling and advice they have received at their GP surgery.

Particular factors related to the medicine or the patient, and commonly a combination of these factors, make counselling imperative (see Case Examples 2 and 3). Recognition of these various situations, where advice must be offered will facilitate the realisation of the potential benefit to the patient and minimisation of risk in vulnerable groups.

The responsibility for the provision of counselling and advice is that of the pharmacist who should normally be personally involved (see Case Example 4). Appropriately trained pharmacy staff may be involved in assisting both with the recognition of need for counselling and advice and in the actual provision of certain aspects of counselling and advice (see Case Example 5).

Some examples of situations in community pharmacy practice where counselling and advice may be offered are:

1. General Examples

1.1 **Prescription**

- is for a medicine new to the patient
- is for several items
- has ambiguous instructions or involves a complex regimen

1.2 Prescribed medicines

- have low safety margin
- require several additional labels

1.3 Patient

- has compliance problems, previously identified
- has physical disabilities, dexterity problems, dysphagia
- has problems with memory or is confused or anxious
- taking oral contraceptives or asks for contraceptive advice
- requires to be measured for an appliance

When patients are confined to the house, exceptionally, needs may be ascertained through a domiciliary visit. However in many circumstances there may be no direct patient contact and the pharmacist would have to assess the need for counselling indirectly by discussion with a carer, relative or representative of the patient. If advice is being given to the carer to relay to the patient, some form of written information may ensure that the patient receives full and accurate information.

2. Illustrated Examples

Prescription has special drug delivery system	– e.g. a transdermal patch
Prescribed medicines have potential for interactions	– e.g. warfarin
Prescribed medicines have well recognised side effects	 – e.g. NSAID producing gastro-intestinal upset
Prescribed medicines could be indicated for treatment of side effects of previously prescribed medicines	 e.g. an anticholinergic being given to treat the side effects of metoclopramide
Patient asks for an item not to be dispensed	 e.g. patient asks for the bronchodilator inhaler to be dispensed but not the steroid inhaler
Medicine to be given by non-oral route of administration	 – e.g. suppositories, pessaries
Patient asks for over-the-counter product incompatible with prescribed medicines	– e.g. pseudoephedrine with an MAOI
Patient asks for medicines which could potentially be used to treat side effects of previously prescribed therapy	 – e.g. patient taking compound analgesic requests laxative

3. Case Examples

EXAMPLE 1

A 5-year old girl with tonislitis is prescribed a 5 day course of Penicilin V Paediatric Syrup. Her mother presents the prescription at the pharmacy. The pharmacist checks with the mother whether the child has any history of allergy to penicillins and counsels her on the following points:

- The need to shake the bottle
- The medicine regimen in relation to food and times of the day
- The importance of completing the 5 day course
- The storage of the medicine

EXAMPLE 2

A patient presents a prescription of aspirin 150mg in the morning. The pharmacist counsels the patient on the benefits of low dose aspirin and advises against the use of additional aspirin or aspirin containing preparations whilst he is on this medication. (Reference to his patient medication record indicates that he occasionally purchases Askit powders for headaches.) Paracetamol is recommended as a suitable alternative for the treatment of the patient's headaches.

EXAMPLE 3

A patient asks for Pepcid AC which she has seen advertised on television. During the counselling and advice which followed, the pharmacist establishes that the patient is in the early stages of pregnancy. He sells her a small supply of Gaviscon and recommends that she consults her GP.

EXAMPLE 4

A patient requests a cough mixture for a persistent dry cough. The pharmacist establishes that he has no other related symptoms and that captopril has recently been added to his medication regimen. The pharmacist recognizes that this may be an adverse effect of captopril and, with the patient's agreement, contacts his general practitioner who suggests that the patient makes an appointment to see him again within the next few days.

EXAMPLE 5

An elderly patient well known to the pharmacy staff hands over a prescription for Trasicor which she has had previously. The counter assistant is concerned that this patient who is normally alert and sprightly, seems confused, aggressive, and a little unsteady. She reports this concern to the pharmacist who agrees and establishes that the patient, who has just returned from holiday, had received a supply of tablets whilst on holiday to see her daughter. It transpires that she received a supply of generic oxprenolol whilst on holiday which she continued to take on return in addition to her Trasicor which she had left at home. The pharmacist explains to the patient that the two medicines are the same and, with the patient's agreement, contacts her general practitioner to inform him of the situation and agree on a suitable course of action.

Section 2.1.2

STEP 2 : ASSESSING AND PRIORITISING NEEDS

Objective 2: To assess and prioritise the counselling and advice needs of the patient.

Guidance Notes

Once the indication for counselling and advice has been recognised, an individual patient's needs should be assessed by reference to accurate and appropriate patient and medicine information. Such information may be obtained from a number of sources including the patient or carer, hospital or community-based health care professionals, and clinical records, where available. As stated in the previous section, establishing what the patient already knows about the medicine is essential. Patient medication records (PMRs) held by community pharmacists may offer additional data on compliance and medication history, including problems with previous medication and use of over-the-counter (OTC) medicines.

In assessing needs for counselling and advice, various patient and medication/appliance factors should be considered. For individual patients, the pharmacist should obtain and assess only that data which is relevant to the patient's particular counselling and advice needs; thus not all of the factors listed below would be considered for each patient.

1. PATIENT FACTORS

- Patient Characteristics

e.g. age, height and weight, pregnancy or breast feeding, past medical history.

- Disease Characteristics

e.g. presenting complaint and diagnosis.

- Functional and Cognitive Characteristics

e.g. sight, hearing, dexterity, ability to swallow, comprehension.

- Social and Environmental Characteristics

e.g. occupational or domestic activities, home environment, support services.

2. MEDICATION / APPLIANCE FACTORS

- Current and Previous Drug Treatment Response

Any known response to current and previous treatment with prescription medicines, OTC medicines or complementary medicines may be relevant.

- Indication for Present Therapy

Consideration of the patient's knowledge of the indication for therapy should be considered in the light of the prescriber's intentions.

- Administration Factors

e.g. complexity of regimen, delivery devices, route of administration, duration of therapy.

- Expected Response

e.g. onset, duration of response, expected effect.

- Adverse Effects

Consideration of the patient's knowledge of potential adverse effects and how to deal with them should be considered (if possible, with a knowledge of the likely patient response and the prescriber's intentions).

- Precautions

e.g. contra-indications, interactions, special precautions in use, allergies/hypersensitivities.

Availability

e.g. legal status, source of supply, delivery time.

The patient's needs should be prioritised in order of potential risk to the patient and this should determine the timing of the counselling and advice given by the pharmacist. For example, if a patient has a number of needs for counselling and advice identified and prioritised and, in the pharmacist's opinion, there are too many to deal with on one occasion, the pharmacist may ask the patient to return for further counselling and advice, arrange to visit the patient at home, or arrange to provide further counselling through visiting community based health care professionals. It is the pharmacist's professional responsibility to ensure that the counselling and advice undertaken will allow the patient to use their medication or appliance in a safe and effective manner. Consideration should be given to any needs not yet addressed when re-evaluating priorities at a later stage.

EXAMPLE 6		
A patient presents a new prescription for:		
Salbutamol MDI	2 puffs when required	
Beclomethasone 100mcg MDI	2 puffs twice daily	
Desired outputs	Priority	
1. Patient understands asthma therapy		
– proper use	high	
 technique required to use an MDI 	high	
 expected outcomes of therapy 	medium	
2. Patient has correct inhaler technique and		
is able to comply with the instructions		
In the above scenario (a 30-year old male with asthma), there are a		
number of counselling and advice needs which may be prioritised. The		
pharmacist decides to deal with high priority issues only on the patient's first visit to the pharmacy and he is asked to return for further counselling		
and advice. However, patient information leaflets are supplied in case the		

patient does not return.

Section 2.1.3

STEP 3 : SPECIFYING ASSESSMENT METHODS

Objective 3:

To specify for each identified need how the result of the counselling and advice will be determined.

Guidance Notes

It is all too easy to cover the standard points of advice required for a particular prescription without checking the patient's knowledge, understanding or ability to use the medicine(s) and/or appliance(s) prescribed. Thus, before starting on any counselling and advice-giving process, the pharmacist should have a mental plan of how the success of the process can be determined.

Patient counselling and advice may improve therapeutic outcomes by helping the patient (or carer) to understand and use the medicine or appliance appropriately. It is important therefore, that for each identified need for counselling and advice, the pharmacist makes a mental note of a desired output, ie what wish the patient to know, understand or be able to do as a result of the counselling and advice. Achievement of the desired output should not be assumed and, where possible, it should be measured or verified objectively.

The methods of checking the success of any counselling and advice will vary widely depending on the type and complexity of advice being given and many of the patient/medication/appliance factors listed under the Guidance Notes for Objective 2. Other factors influencing the means by which Objective 3 is achieved include whether the pharmacist is dealing with the patient directly or indirectly and the pharmacist's knowledge of the patient.

EXAMPLE 7

A carer presents a prescription for erythromycin 500mg EC, one to be taken four times daily, for a housebound patient.

The patient is a regular customer of the pharmacy and reference to her patient medication record indicates that:

- she has poor eyesight and requires large print labels
- she is not currently on any prescribed medicines which would interact with erythromycin

The carer is counselled to advise the patient on the following points:

- swallow tablets whole (do not chew or crush)
- take with a large quantity of water with or after food
- avoid use of antacids within 2 hours of dosing
- take the medicine at regular intervals and complete the course

The counselling given to the carer is reinforced with written instructions and the latter, together with the label, is produced in large print. The carer is asked to return to confirm that the patient understood and can comply with the instructions.

EXAMPLE 8	
A patient presents a new prescription fo Sulphasalazine EC 500 mg T Hypromellose eye drops	or: 1 to be taken four times daily 1 drop to be used when required
From patient medication records curren Diclofenac Retard 100 mg T Ranitidine 150 mg T Maalox Suspension	nt drug therapy is as follows: 1 to be taken in the morning 1 to be taken twice daily 10 ml to be taken when required
 Desired Outputs 1. Patient understands new therapy for rheumatoid arthritis 	Method of Assessment Pharmacist asks patient about: – proper use – expected outcomes of therapy/ time for onset of action – potential adverse drug reactions
2. Patient is able to use eye drops as instructed	Pharmacist is asked to demonstrate instillation of eye drops Patient is questioned on: – use/frequency – purpose – expiry/storage
3. Patient understands the need to continue with existing drug therapy	 Patient is questioned on: need to continue Diclofenac need to continue Ranitidine need to continue Maalox but space dosing with Sulphasalazine
4. Patient is able to self-medicate	 In addition to 1, 2 and 3 above: patient is able to open containers patient is able to read labeling instruction

Section 2.1.4

STEP 4 : IMPLEMENTATION

Objective 4: To implement the counselling and advice process

Guidance Notes

As stated in the Introduction (Section 1.7), these Guidelines make no attempt to provide the technical or scientific knowledge or to teach the communication skills which underpin the counselling process. However, pharmacists should ensure that they have the knowledge and skills required to provide counselling and advice to patients effectively and efficiently (see Annex A3).

It should be apparent that counselling and advice is offered as a professional service by the pharmacy. This may be achieved through appropriate publicity in the window of the pharmacy and should be evident to customers/patients within the pharmacy premises. Practice leaflets are a useful means of advertising the professional services offered by a community pharmacy.

The Royal Pharmaceutical Society of Great Britain (RPSGB) directs that the pharmacist should ensure that the patient or his agent understands sufficient information and advice to enable safe and effective use of the medicine. Information and advice should normally be given personally by a pharmacist and when this is not practicable, it should be made clear that the advice of the pharmacist is available if required (RPSGB Code of Ethics Appendix). Effective preparation for this important function should include a consideration of patients' expectations, the counselling environment and the time available for counselling.

Counselling should be carried out in an environment which is nonthreatening and conducive to forming good relationships between the pharmacist and patients or carers. There is a need to establish a rapport with the patient/ carer. It is important to tell them what the counselling and advice process involves, how long it is going to take and where the counselling will be carried out. In designing or selecting an appropriate area for counselling, due attention should be paid to Principle 4 of the RPSGB Code of Ethics concerning the confidentiality of information relating to a patient and their family. All of this helps to ensure that the patient is receptive to the proposed counselling and advice. Time is probably the most important factor which governs the extent to which counselling takes place in the community. The pharmacist should allow enough time to complete the counselling and advice process. If time is limited, the pharmacist may agree with the patient to spread the counselling over a number of occasions.

Implementing the counselling and advice process

- 1. Giving the patient the appropriate advice on specified details previously identified.
- 2. Introducing, when necessary, aids to comprehension and/or compliance at this stage and explaining their use throughout the process. Aids to comprehension in the counselling and advice process may include general information leaflets, patient information leaflets (PIIs) on specific products, placebo inhalers and audio-visual aids.

Aids to compliance may range from simple (e.g. large print labels, plain caps), to more complex measures (e.g. individual patient charts and diaries).

- 3. Determining (as far as possible) that the patient is able to comply with the instructions for use of the appliance(s) and/or medicine(s) and determining the level of understanding of the patient. If the patient appears unable to understand or to implement the advice given then referral back to the general practitioner may need to be considered.
- 4. Inviting the patient to pose further questions and report any problems, giving a time scale which would be appropriate for the patient to return or to seek further help.
- 5. Discussing with the patient the time scale and methods of review.
- 6. Reinforcing the important points at the end of the counselling and advice process.
- 7. Where the patient is unable to attend the pharmacy, inviting the carer to provide feedback that the patient is able/unable to comply with the instructions for the use of the appliance and/or the medicine regimen.

EXAMPLE 9

A patient presents a prescription for: Triple Therapy

Omeprazole 20 mg twice daily

Amoxycillin 500 mg three times daily

all for 7 days

Metronidazole 400 mg three times daily

Implementation steps:

- The patient is given an estimation of the time that the counselling advice will take.
- Patient is given information regarding the association of peptic ulcers with particular bacteria in the stomach (Helicobacter pylori), and of the need to eradicate the bacteria.
- Patient is given advice on triple therapy and this is reinforced with a Patient Information Leaflet detailing the drug regimens, adverse effects and expected response.
- The importance of compliance with the regimen for the whole 7 days is stressed to ensure successful treatment.
- If there are any questions or problems at any time during treatment, the patient is advised to contact the pharmacist or the GP.
- The importance of compliance with the regimen is again reinforced at the end of the counselling and advice process.

EXAMPLE 10

A request is made at the counter for a tube of Zovirax Cold Sore Cream. The counter assistant refers the request to the pharmacist.

Implementation steps:

- The pharmacist explains to the customer that it is important to ensure firstly that the treatment is indicated and secondly that the customer knows how to use it.
- The patient's self diagnosis is confirmed.
- The stage of development of the lesion is assessed to be within 72 hours.
- The pharmacist confirms that there are no contra-indications or special precautions applying to this patient.
- The pharmacist gives the patient the instructions for use of the product with reference to the patient information leaflet.
- The patient's understanding of these instructions is confirmed.
- The patient is invited to ask any further questions and to report back on any problems.
- Important points are reinforced at end of the process.

Section 2.1.5

STEP 5 : ASSESSMENT

Objective 5:

To assess the effectiveness of the counselling and advice process

Guidance Notes

Assessment involves the comparison of the actual outputs with the desired outputs identified under Objective 3 (Section 2.1.3, page 11).

The patient's need for counselling and advice should be continuously reviewed. This review process can be used both to reinforce previous counselling, if necessary, and/or identify new needs.

1. Assessing knowledge and understanding

The importance of communication during the counselling process cannot be over-emphasized. For a variety of reasons a patient may not understand all of the information, instructions or advice which they receive during a counselling session. Thus it is important to check the patient's knowledge and understanding by direct questioning. The patient should again be given the opportunity at this stage to ask any further questions which they may have.

EXAMPLE 11

A patient presents with a prescription for hydrocortisone 1% cream (to be applied to the face) and Stiedex Oily Cream (to be applied to the upper trunk). The counselling process involves an explanation of the difference in potency between the creams. Instructions are given on the application of the creams to the face and upper trunk, respectively.

Following the counselling the pharmacist assesses the patient's knowledge and understanding by questioning the patient on the appropriate use of both creams.

2. Assessing ability to use the medication/appliance

For the same reasons as stated above under 1, there are occasions when it is important to give the patient the opportunity to demonstrate that they can use the medication/appliance appropriately.

EXAMPLE 12

An asthmatic patient with rheumatoid arthritis presents a prescription for metered dose inhalers. Despite introducing a Haleraid, it becomes apparent during counselling that he is unable to use these devices. With the pateint's agreement, the pharmacist contacts the GP and recommends an alternative device.

3. Assessing compliance

The pharmacist may have a record of a particular patient's history of noncompliance, may deduce it from the time between repeat prescriptions, or from discussions with the patient or other health care professionals.

EXAMPLE 13

An elderly patient presents a prescription for Timoptol eye drops. Reference to his patient medication record indicates that his previous prescription for this was dispensed seven weeks ago. On discussion with the patient it was confirmed that he had been using the same bottle of eye drops for the last seven weeks.

4. Evaluating the achievement of the counselling and advice process

It should be recognised that routine documentation of the counselling and advice process for all patients would not be feasible currently in most busy community pharmacies. However, pharacists may opt to document this activity for selected patients. For such patients a record of counselling and advice given would assist in providing a more comprehensive patient medication record which would aid future consultations. These may be with the patient through the same community pharmacy or with, for example, a hospital pharmacist, another community pharmacist or a physician requesting information when subsequently reviewing the patient.

Pharmacists may also wish to document their counselling and advisory activities for the purposes of self-audit, clinical audit (see Annex A4, page 26) or research (see Annex A5, page 30).

Assessing the level of compliance and follow-up of patients is difficult and the pharmacist may have no opportunity to do so, for example, if the patient does not return to the pharmacy. In certain cases pharmacists may learn of a patient's progress through other community based health care professionals who maintain contact with the patient. In this respect community nurses, practice nurses, midwives and health visitors may be well placed to refer suspected medicine related problems to pharmacists and/or GPs.

Methods of assessing patient compliance require to be investigated and validated as many existing methods have their limitations. In addition, since many factors other than the quality of counselling and advice can affect compliance with the prescribed regimen, well designed prospective research studies are required to investigate any relationship between the quality of counselling and advice given by the pharmacist and patient compliance with the prescribed regimen (see Annex A5, page 30).

Section 2.2

A CHECKLIST FOR COUNSELLING

PREPARATION	Be familiar with the recommended counselling points for the most commonly prescribed medicines and appliances		
	Consider patients' expectations, the counselling environment and the time available		
RECOGNISE	 Establish what the patient already knows about the medicine/appliance 		
THE NEED	 Recognise characteristics of the medicine, appliance or patient which indicate particular needs 		
V			
ASSESS AND PRIORITISE NEEDS	 Use all available sources of information, including as necessary, the patient, carers, relatives or health care professionals and patient medication records to assess relevant patient and medication/ appliance factors and prioritise needs 		
\downarrow			
SPECIFY ASSESSMENT METHODS	 Decide for each identified need what it is you wish to achieve and how you will determine the output from the counselling process 		
¥	 Counsel, introducing as necessary aids to 		
IMPLEMENT	comprehension and/or compliance and explain their use		
	 Reinforce important points and invite patient to ask further questions 		
\checkmark			
400500	 Check knowledge and understanding by direct questioning 		
ASSESS	 Where possible, assess actual compliance through follow-up 		
EVALUATION AND REVIEW	The counselling and advisory service which you offer may be evaluated, reviewed and developed through audit and/or practice research.		

Annex A1

GLOSSARY

The majority of the terms in these Guidelines are familiar and in everyday use. Most community pharmacists will know what they mean by them; however, they are defined here to aid interpretation.

Advice	The oral or written provision of professional opinion.	
Compliance	Adherence to a course of instructions for the use of a medicine or an appliance.	
Counselling	The interactive process involving a consultation about medicines or appliances between a pharmacist and a patient.	
ОТС	Over-the-counter (medicine).	
Output	A desired or actual result of the counselling and advice process which is able to be measure or verified objectively.	
Р	Pharmacy medicine.	
PIL	Patient information leaflet.	
РОМ	Prescription-only medicine.	
Patient	Anyone receiving pharmaceutical services.	
Patient medication record (PMR)	A record of the medicines and appliances dispensed for, and/or purchased by, or on behalf of, a patient, together with details of interventions, counselling, advice and outcomes where appropriate.	
RPSGB	Royal Pharmaceutical Society of Great Britain.	
SCPPE	Scottish Centre for Post Qualification Pharmaceutical Education.	
SODoH	Scottish Office Department of Health.	

Annex A2 ETHICAL AND LEGAL CONSIDERATIONS

1. Code of Ethics of the Royal Pharmaceutical Society of Great Britain

General and specific references relevant to counselling and advice on medicines and appliances in community pharmacy are to be found in the Code of Ethics of the RPSGB. It follows therefore that, whatever the contractual arrangements in existence to reimburse community pharmacists for this professional service, the provision of appropriate counselling and advice places an ongoing professional responsibility on the pharmacist which cannot be abdicated. The reference figures given below refer to sections in the Code and its Appendix which should be referred to for a further explanation.

As with all other professional activities, the pharmacist's approach to counselling and advice is governed by Principle 1 of the Code that a pharmacist's prime concern must be for the welfare of both the patient and other members of the public, and specifically (obligation 1.14), a pharmacist must conform to the obligations in the Standards of Good Professional Practice and with other guidelines or codes of practice appropriate to the relevant field of work.

Principle 4 of the Code requires a pharmacist to respect the confidentiality of information acquired in the course of professional practice relating to a patient and the patient's family. Such information must not be disclosed to anyone without the consent of the patient or appropriate guardian unless the interest of the patient or public requires such disclosure. Information includes that retained through memory as well as that held in records. Any disclosure of information relating to a patient and the patient's family (obligation 4.3), should be limited to the minimum necessary for the specific purpose involved. It should be noted that information can be shared with others who participate in, or assume a responsibility for, the care or treatment of the patient and who would be unable to provide that care or treatment without the necessary information; this is the "need-to-know" concept.

In relation to Principle 4 on confidentiality, the Code gives specific guidance relating to contraceptive advice or pregnancy testing for a girl under the age of 16.

In the Appendix to the Code of Ethics, the Guidance notes under Section 5 (Standards for dispensing procedures) state that "it is beneficial to maintain pharmacy records of medicines dispensed for and purchased by patients". To such records may be added information on counselling and advice given. The Guidance notes continue: "Where these records are kept on a computer, the pharmacy must register with the Data Protection Registrar" ... "Whatever method of keeping patient medication records is used, a pharmacist must ensure that the information held remains confidential and full regard is paid both to Principle 4 of the Code of Ethics and the Data Protection Act 1984".

As in contractual terms, provision of counselling and advice is a professional service, pharmacists are reminded that any reference to this service in publicity material should comply with Principle 7 of the Code. Thus any pharmacist or pharmacy owner must not claim or imply in publicity any superiority over the professional services provided by other pharmacists or pharmacies. Publicity must be dignified, and must not bring the profession into disrepute.

In the Code of Ethics Appendix, the thrust of the guidance concerns the provision of information and advice required for the safe and effective use of medicines, taking care to assess both the wishes of the prescriber and the information and counselling needs of the individual patient. The Appendix directs that the pharmacist should ensure that the patient is given and understands sufficient written and oral information to enable him/her to obtain maximum benefit from the medicine.

2. The Scottish Office Department of Health

The Scottish Office Department of Health (SODoH) Code of Practice on "Confidentiality of Personal Health Information" gives further guidance to all those employed by or contracted to the Scottish Health Service. Particular guidance is given on "Disclosure by Implied Consent" and "Disclosures Without Consent". The Code of Practice advises that disclosure without consent always raises extremely difficult questions involving moral, ethical and medical issues and such cases must be considered with great care. It points out that the Chief Administrative Medical Officer/Director of Public Health or his/her nominated deputy has responsibility for confidentiality, security and access to personal health information held by a Health Board and should be regarded as a source of advice on all aspects of disclosure. All disclosures and their extent should be recorded on the patient's record.

3. Patient Information Leaflets

When a medicine is prescribed for an indication which is not covered by the PIL for the product, pharmacists may wish to discuss the advice to be given to the patient with the prescriber.

4. General

The pharmacist is strongly urged to consult the ethical principles, obligations, and guidance of the Society, as outlined above in conjunction with the SODoH Code of Practice, the Data Protection Act 1984 and the information given in these practice guidelines. The Society's Cede of Ethics, and the Appendix relating to Standards of Good Professional Practice are found for example in the publication "Medicines, Ethics & Practice" sent to all practising pharmacists. As well as a professional requirement to observe the Society's Code of Ethics pharmacists who fail to perform to an acceptable professional level could find themselves in a position of legal liability.

Annex A3 EDUCATION AND TRAINING

1. The Pharmacist's Responsibility

The RPSGB recognises the individual pharmacist's responsibility to keep abreast of changes in pharmacy practice as itemised in the Code of Ethics and the Standards of Good Professional Practice.

To help fulfil this responsibility, pharmacists are encouraged to adopt the concept of continuing education. Continuing education is the on-going learning which professionals need to undertake throughout their careers as a contribution towards the maintenance and enhancement of their personal development and professional competence.

The increasing focus on individual patient care within Community Pharmacy Practice gives rise to new educational needs, both at present and in the future.

In identifying the education and training needs for pharmacists to undertake patient counselling, it is important to take into account the knowledge, skills and attitude required to effectively and efficiently provide counselling and advice to patients.

The Scottish Centre for Post Qualification Pharmaceutical Education (SCPPE) provides direct learning and distance learning courses to enable pharmacists to participate and update their knowledge and skills by utilising a variety of education and training methods.

2. Knowledge for Counselling and Advice

To undertake the counselling and advice process, pharmacists must have a sound knowledge of medicines and their clinical use. This includes the pharmacological profile of medicines, the appropriate knowledge of appliances and their place in practice with respect to individual patient care. The SCPPE knowledge-based courses include the major therapeutic areas. These areas are itemised in the SCPPE 5-year Rolling Programme which allows pharmacists the opportunity to update their knowledge.

3. Skills for Counselling and Advice

The skills important in facilitating patient counselling and advice include communication skills and the application of appropriate social and behavioural sciences within the professional role. Communication skills are of the utmost importance in counselling and advising. The term 'communication' can be interpreted in many different ways, according to the person's experience and background. The professional interaction between pharmacists and their patients calls upon the pharmacist's interpersonal skills and the application of appropriate language and behaviour. There should be opportunities for pharmacists to practice communication skills with feedback from more experienced practitioners. SCPPE provides education and training in aspects of *Communication and Presentation Skills* which would be relevant to the process of counselling and advice. The SCPPE Rolling Programme includes education and training provision in areas such as *Interpersonal Communication* and *Management of People*.

4. Education and Training Provision

It must be recognised that counselling and advice to patients is a process that has already been effectively undertaken by many pharmacists, however, as the focus on the patient-centred approach in pharmacy increases, it is vital that the knowledge and communication skills necessary to undertake counselling and advice is provided at all stages of pharmacists' education and training. Relevant education and training provision is an inherent part of the undergraduate Pharmacy course and should be continued through the pre-registration year. It is also important that experienced pharmacists are allowed the opportunities to update their knowledge and skills throughout their years in practice, and that they transfer their knowledge and skills to less experienced pharmacists.

Education and training should be provided in a flexible manner through inservice programmes, work-based learning and continuing education courses. Continuing education opportunities include various activities ranging from self-directed reading through participation at conferences, direct learning courses and distance learning courses, to undertaking formal postgraduate diploma/degree courses relevant to pharmacy practice.

5. Education, Training and Audit

It is vital that continuing education is accompanied by audit of activities. The use of professional audit in pharmacy helps to identify education and training needs. By participating in audit, pharmacists can increase the quality and relevance of counselling and advice to patients, thereby enhancing their contribution to patient care (see Annex A4, page 26).

Annex A4 CLINICAL AUDIT

1. What is Clinical Audit?

Clinical audit is a process of systematic, critical analysis used by health care professionals to evaluate and improve patient care.

All pharmacists should view clinical audit as an opportunity to improve standards of care and to further their own continuing professional development.

The approach should be non-threatening, educational and professionally led. The audit process is often represented as an audit cycle (Figure 1).

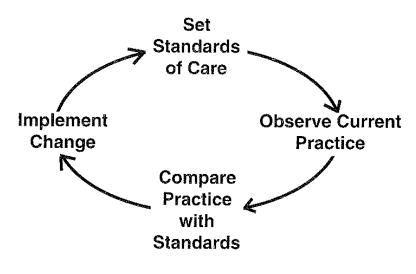


Figure 1: THE AUDIT CYCLE

2. Self Audit

2.1. Setting standards

This can involve any or all of the following methods; peer consensus, national guidelines, literature review, previous experience and best guess. Local circumstances can be taken into account when deciding on a desirable level of care. Agreeing standards is integral to audit: it ensures clear objectives and is a valuable educational experience.

2.2 Observing current practice

Methods of measuring current practice include survey by questionnaire or interview, direct observation, tally counts and recording practice details. Data collection should be kept as simple as possible, and existing documentation used where appropriate, e.g. patient medication records could indicate when a patient was last advised on correct inhaler technique. An example of data collection form which could be used to audit counselling services is given in Figure 2.

2.3 Comparing practice standards

This identifies those areas of care requiring change. An audit of counselling services may reveal that the proportion of patients receiving instruction on inhaler use is less than expected. Asking why this is so and what can be done may suggest a need to introduce new work practices in to the pharmacy to increase the numbers of patients offered instruction. Alternatively, the audit findings may be used to set realistic standards.

2.4 Implementing change

For audit to be successful it is important to act on the results. Readiness to change is fundamental. Planned changes may be incorporated into an action plan with an agreed timetable. To ensure effective and lasting change it is important to involve, at an early stage, all individuals whose co-operation is desirable.

The full benefits from audit will only be realised if the audit is repeated on a regular basis, changes are made where appropriate and their impact evaluated.

3. Research and Development in Partnership with Audit

Research, audit and service development are mutually supportive activities with a degree of overlap.

The following may help to distinguish these activities as they relate to patient care:

Research	– What is best care?		
Audit	– Is the best care being provided?		
Development	– How could this service be improved?		

TIME TO COUNSEL REASON FOR FOLLOW-UP COMMENTS		Steroid inhaler onset explained		MANUMANU AND
FOLLOW-UP	67 (N			\exists
REASON FOR	ITEMS: Patient Other Not Retused Accepted Wothen Verbal 1: 2 3 4 5 6 7 5 2 9 10 11 12 5 5 1 2 3 4 5 11 2			
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SEX	Rx OTC M F <16 18-60 04P	`		\exists
ATE MEDICINE SEX	PX OTC	4		
ă		18.1.94		ک_

DOCUMENTATION KEY

THE COUNSELLING SESSION Name and purpose of medication

- Dosage schedule, e.g. dose, frequency, quantity, duration
 - Additional cautionary & advisory labels Delivery systems, e.g. patches, inhalers Special administration devices, e.g. oral syringe

None Return visit Domiciliary visit

പ്രിത്

Other-specify under 'Comments'

Repeat prescription Complex regimen/device Time available

–് പ് ന് 4 ന്

New prescription

FOLLOW-UP

REASON FOR COUNSELLING

- - Side-effects
 - Interactions
- Storage requirements Missed a dose
- Disposal of unused medicines
- Knowledge/technique assessed Other-specify under 'Comments' ŝ

Figure 2: EXAMPLE OF AUDIT DOCUMENTATION



Clinical research aims to establish what is the best clinical practice and this information then feeds into the standard setting phase of the audit cycle. Audit examines if best clinical practice is actually being provided. Any deficiencies or problems highlighted may have research implications.

Audit, particularly the evaluation and monitoring stages, also has a valuable contribution to make to the processes of service development. By providing information on current practice, audit can justify the need for service changes. Alternatively, after a service development has been introduced, audit can monitor the impact of the change.

4. Support Structure for Audit

The initial approach of SODoH to establish uniprofessional audit was followed in 1993 by the development of multiprofessional collaborative audit. An audit framework exists at national and local level to promote both professional and clinical audit.

At national level The Clinical Resource and Audit Group (CRAG), a division of the National Health Service in Scotland Management Executive, exists to promote and support audit as does the more recently established Scottish Clinical Audit Resource Centre (SCARC) in Glasgow. Within each Health Board, Area Clinical Audit Committees exist primarily to develop area audit strategy and facilitate audit as a form of continuing education. Although the current aim is to progress to multiprofessional audit, a number of the uniprofessional Pharmaceutical Audit Committees have been retained.

The importance of audit has been recognised by SCPPE through the provision of both national and local direct learning courses. The distance learning package 'Moving to Audit : an educational package for pharmacists' provides an alternative resource for pharmacists unable to attend direct learning courses.

A natural progression from introductory courses is the formation of local audit groups, facilitated by co-ordinators. Audit toolkits are being developed to offer practical guidance to community pharmacists wishing to participate in audit. These packages contain all the necessary documentation and reference material needed to undertake a simple audit. The national pharmaceutical audit facilitators have prepared a package on "Patient Counselling for Prescribed Medicines" for use by community pharmacists.

Annex A5

RESEARCH AND DEVELOPMENT

1. Why research and development?

At both local and national levels research is an essential foundation for decision making. Within health care, research seeks to identify 'best care' by a systematic and structured approach which produces objective data on the quality of care and/or the efficiency of health care delivery. Information gained through research may be used to develop the service through improvements in the structure, process and outcome of health care.

Possible areas for research in the provision of counselling and advice might include:

- an assessment of patients' counselling and advice needs with respect to the use of a particular delivery device.
- an evaluation of the benefits and resource implications of documenting counselling and advice.

2. Sources of information, advice and support

There are many sources of help and support for research which may be intellectual, methodological or financial. They are invaluable to novice and expert researcher alike.

Information on research methods can be gained from background reading and distance learning courses but it is also beneficial to attend a course to meet other researchers as there is much to be gained from the resultant exchange of ideas. Various pharmacy meetings may provide this opportunity such as the British Pharmaceutical Conference, other courses and symposia organised nationally by RPSGB, The College of Pharmacy Practice or The United Kingdom Clinical Pharmacy Association, and those organised locally by Pharmacy Practice Units/Groups or SCPPE. More formal training is available through certain postgraduate diploma and degree courses. Direct approaches for advice on, or assistance with research may also be made to Schools of Pharmacy or to various other local or national centres of expertise. Information on Pharmacy Practice Groups is available from the Chief Pharmacist, SODoH or from National Specialists. The RPSGB offers research awards for practice research. The Chief Scientist Office, SODoH will support Health Services Research projects and also offer annual training research fellowships which provide total funding for a research project, including training, salary and materials. Funding for service lead development in health care is also available from the National Health Service in Scotland Management Executive. Dedicated funds for Pharmacy Practice Research are available annually through the Chief Pharmacist, SODoH; these tend to be for smaller amounts which would support materials and locum expenses, thus freeing the practitioner's time for research. The College of Pharmacy Practice publish an annual Practice Research Diary which gives details of research awards.

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