



medicines **partnership**

Project Evaluation Toolkit

The Task Force on Medicines Partnership is a Department of Health funded programme designed to involve patients as partners in prescribing decisions and support them in medicine taking, to improve health outcomes and satisfaction with care.

One of the main aims of the Medicines Partnership Programme is to demonstrate the benefits of concordance in the prescribing and taking of medicines. To do this, we want to evaluate the impact of concordance on various outcomes such as patients' use of medicines and health. We are also interested in assessing the financial cost of putting concordance into practice.

This toolkit is designed for people planning or carrying out projects in the field of concordance. Its aim is to help you plan how you will evaluate the impact and cost-effectiveness of your project rigorously. The toolkit outlines the different variables you can measure, the pros and cons of assessing each variable, and the best ways to measure them. We provide some specific examples of measures you can use to assess these variables.

If you need to create your own measures, or tailor existing measures, we can provide advice and support to help you. But wherever possible, it is recommended that you use validated measures, to improve the validity and accuracy of your evaluation. Using validated measures will also enable people to compare the findings of different projects.

 We are keen to find out what you think about the toolkit and any ways in which you think it can be improved in subsequent editions. Please send any comments you have by email to

info@medicines-partnership.org

or by post to:

Geraldine Mynors
Medicines Partnership
1 Lambeth High Street
London SE1 7LN

First edition, April 2003. © Medicines Partnership

The team on this guide

This guide was produced by:

Kate Cox

Concordance Unit, Department of General Practice & Primary Care, Guy's King's & St. Thomas' School of Medicine

Geraldine Mynors

Medicines Partnership

With thanks to the following people for their input:

Alison Blenkinsopp — Professor of Practice of Pharmacy, Keele University

Jonathan Boyce — Audit Commission

Nicky Britten — Professor, Peninsula Medical School, Universities of Exeter and Plymouth

Rob Horne — Director, Centre for Health Care Research, University of Brighton

Marshall Marinker — Co-chair, Medicines Partnership Task Force

Simon O'Neill — Head of Care Development, Diabetes UK

Theo Raynor — Head of Pharmacy Practice & Medicines Management, University of Leeds

Joanne Shaw — Director, Medicines Partnership

Jon Silcock — Pharmacy Practice and Medicines Management, University of Leeds

Fiona Stevenson — Lecturer in Medical Sociology, Royal Free & University College School of Medicine

Contents

Introduction	5
What is concordance?	5
How is concordance different from compliance?	6
What are Medicines Partnership projects?	6
Using this toolkit	7
Designing your project for measurement	8
1 What intervention are you assessing?	8
2 What are the objectives of your intervention?	8
3 How will you determine how effective your intervention is?	8
4 Should you use a quantitative or qualitative approach?	10
5 What types of questions should you ask?	11
6 Should you use questionnaires or interviews?	12
7 Do you need ethical approval to carry out your project?	12
Which variables to measure	14
Inputs	15
The nature of the intervention and who it involves	15
The number of interactions that took place for each patient and professional	15
The number and type of patients involved	15
The number and type of professionals involved	15
Where the intervention and interactions between patients and professionals take place	16
How long the patient–professional interactions were	16
Differences in the medicines information given to patients and by whom	16
How concordant discussions between patients and health professionals are	17
The cost of the intervention	18
Outputs	21
Patients’ satisfaction with the intervention and the care provided	21
Patients’ satisfaction with their consultation or communication with professionals	21
Patients’ satisfaction with the information they were given	22
Patients’ satisfaction with the treatment decisions made and the medicines prescribed	22
Patients’ evaluation of any new service	22
How to assess patients’ satisfaction	22
Professionals’ satisfaction with the intervention	23
Satisfaction with each specific interaction with patients	23
Satisfaction with the general service provided	23

If you're viewing this on-screen, you can click on any line in the Contents list to jump straight to the page you want. Wherever you are, you can press the Home button to return to the beginning of the document.

Professionals' attitudes to concordance	23
Patients' understanding of their condition and treatment	24
Patients' attitudes towards their medicines	25
Level and cost of prescribing	25
How to assess the level of prescribing	25
Which medicines should be assessed	26
Cost of prescribing	26
Outcomes	31
Patients' compliance with the agreed medication regime	31
Monitoring repeat prescriptions	32
Patient self-reporting	32
Assessment of unused medicine	33
Electronic monitoring	33
Monitoring attendance at appointments	34
Medicine-related problems	34
Patients' health	35
Quality of life	36
Long-term use and cost of services	37
Where to go for more information	40
References	42

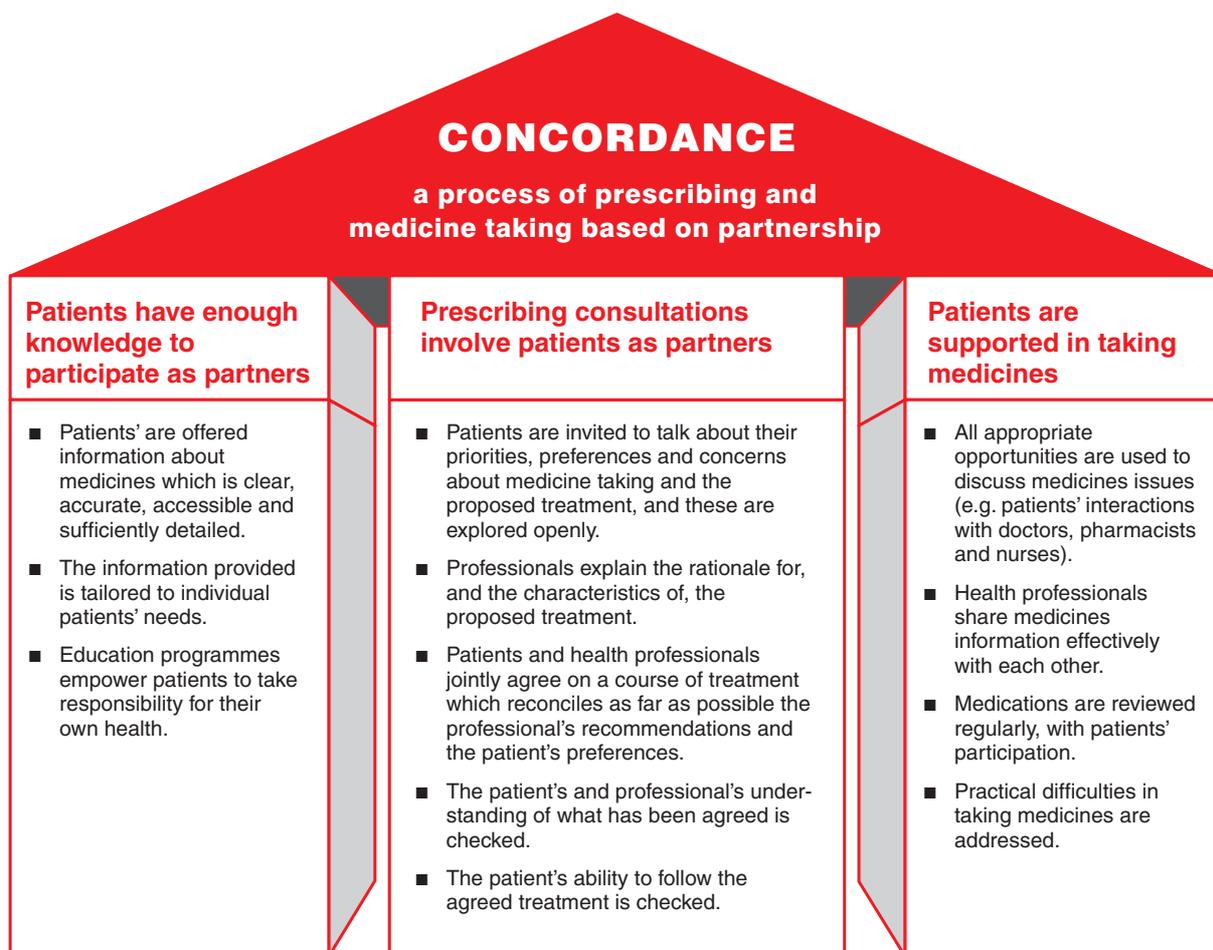
Introduction

What is concordance?

Concordance is a new approach to prescribing and taking medicines, based on partnership:

- The patient and the health care professional participate as partners to reach an agreement on the illness and treatment.
- Their agreement draws on the experiences, beliefs and wishes of the patient to decide when, how and why to use medicines.
- Health care professionals treat one another as partners, and recognise each other's skills to improve the patient's participation.

Concordance has three essential components:



How is concordance different from compliance?

Compliance (also called **adherence**) is the extent to which patients take as intended the medicines which they were prescribed. Non-compliance is a significant problem today, being a major cause of ill health, mortality and rising health service costs.

Research has shown that a primary reason why many patients do not comply with prescribed treatment is their beliefs about and attitudes towards medicines. For example, they may believe that medicines are unnatural or harmful, that they won't work; or they may find that the side effects they experience are incompatible with their lifestyles.

One goal of concordance in practice is to explore patients' beliefs and reach a shared agreement about medicines; this in turn can improve compliance.

But concordance is about *more* than just improving compliance — it should also increase patients' satisfaction with treatment decisions, increase their sense of control and ownership over their own health, and reduce other problems associated with taking medicines.

Traditional approaches to improving compliance — such as giving patients reminders to take their medicines and making the packaging of medicines more user-friendly — are valuable. But on their own they are not enough to bring about concordance, because **they do not involve patients as full partners in prescribing decisions.**

What are Medicines Partnership projects?

We are interested in projects which implement some or all of the components of concordance shown on page 5, using some kind of intervention to improve practice. Such interventions might include:

- **training** for professionals to improve their two-way communication about medicine issues
- a new interactive medicines information **website**
- **telephone support** for patients taking long-term medicines
- patient **support/discussion groups**
- patient **information leaflets** in different languages
- a pharmacist-led clinic to carry out **medication review**

 To find out more about concordance, and how to have your project formally recognised as a Medicines Partnership project, visit the Medicines Partnership website:

www.medicines-partnership.org

Using this toolkit

In this toolkit, we have recommended a number of measures, developed by academics and professionals, that you can use in your project. Some of these tools are included in full; in other cases, only sample questions have been provided.

To use some of these tools, you will need permission from the developers. Some developers have also requested that you send them the results of your project. To find out if you need permission to use a particular tool then please look at the downloadable word document that is available for each measure at

www.medicines-partnership.org/projects/resources



Throughout this toolkit, wherever there is a **downloadable document** to help you with a measurement, you will see a symbol in the margin.

The downloadable documents include:

- a copy of the tool (if we've already obtained permission for its use)
- instructions on how to use and score the tool
- reference for where tool was published
- the tool developer's contact details
- whether you need to get permission to use the tool and what details you will need to provide

Please note — if you write any reports or publications based on the findings you obtained using these tools, you should refer to where the tool was published (you'll find this information in the downloadable Word document for the tool).

Tools for which downloadable documents are available*



Code	Name	Code	Name
T01	Checklist for medicines information provided to patients (page 19)	T10	Medication Adherence Report Scale (MARS)
T02	Patient involvement checklist (page 19)	T11	TB Treatment Diary
T03	Patients' perception of their involvement questionnaire (page 20)	T12	Living with Asthma Questionnaire (LWAQ)
T04	Medical Interview Satisfaction Scale (MISS-21) (page 27)	T13	Diabetes Health Profile (DHP-1 and DHP-18)
T05	Satisfaction with Information about Medicines Scale (SIMS)	T14	Impact of Epilepsy Scale
T06	Satisfaction with Decision questionnaire (page 28)	T15	Hospital Anxiety and Depression Scale (HADS)
T07	Leeds Attitude Towards Concordance (LATCon) Scale (page 29)	T16	McGill Pain Questionnaire (MPQ)
T08	Type 2 diabetes knowledge questionnaire (page 30)	T17	MYMOP2 (pages 38 and 39)
T09	Beliefs about Medicines Questionnaire (BMQ)	T18	SF-12 Health Survey

* where a page number is given, the document is reproduced here

If you're viewing this on-screen, you can click on any page reference in the table above to jump straight to the tool you want.

Designing your project for measurement

Before deciding which variables to measure to assess the impact of your project, you need to consider some of important questions about the design of your project —

1 What intervention are you assessing?

Before you begin, it's important to be clear about what your project involves. In particular, you need to define the ways in which the intervention you are assessing will differ from or add to normal practice, and how it relates to the principles of concordance. You will need to have a clear idea about the nature of the intervention, what it involves and to whom it is targeted.

2 What are the objectives of your intervention?

You should have a clear picture of what you want and expect the positive effects of your intervention to be. You may have both short-term and long-term objectives. The measures you use to assess the impact of the intervention should relate directly to these objectives. Make sure your objectives are:

- specific
- measurable
- achievable

Examples of sound objectives	Examples of poor objectives
<ul style="list-style-type: none">■ To improve asthma patients' understanding of how to use their inhalers■ To reduce diabetes patients' concerns about their insulin■ To increase patients' compliance with their antihypertensive medicine■ To reduce the number of CHD patients' hospital admissions	<ul style="list-style-type: none">■ To increase patient satisfaction (<i>Not specific — satisfaction with what?</i>)■ To improve links between GPs and pharmacists (<i>How do you measure 'links'?</i>)■ To reduce GP prescribing of antibiotics by half (<i>Is this achievable?</i>)

3 How will you determine how effective your intervention is?

There are three ways to assess how effective an intervention is in comparison to normal practice:

- **'before and after' comparison**
- **comparison with external benchmarks or averages**
- **control group comparison**

‘Before and after’ comparison

With a basic before and after comparison, you measure the variables (e.g. patient satisfaction, compliance, prescribing rates) before and after your intervention is put into practice. Then you compare the two sets of results. If the variables change significantly after the intervention, you should be able to say that the change was due to the intervention.

The **disadvantage** of using this method is that you can’t be absolutely sure that the intervention was responsible for the change.

Comparison with external benchmarks or averages

Another approach is to compare the intervention group with average or benchmark data, if you can find a reliable measure. For example, you might want to compare the rate of hospitalisation, or the rate of a particular medication being prescribed for your intervention group, with some kind of regional or national average for that group of patients.

But with this method too, if you find a significant difference between your intervention group and the benchmark, you can’t be absolutely sure that your intervention was responsible for the difference.

Control group comparison

The most robust method of assessing whether any changes in the results are due to your intervention is to compare these changes with what happens in a control group. With a control group comparison design you need two groups of patients and/or practitioners. One group — the **intervention** group — experiences the intervention that you are assessing; the second group — the **control** group — does not.

You measure a variable after the intervention, for both groups. Then you compare the results. So you can compare the impact of your intervention with that of no intervention or normal care.

You need to consider a number of issues when choosing what kind of control group to use:

- You need to ensure as far as possible that the control group will not be influenced by the intervention.
For example, suppose the intervention involves giving information sheets to patients in a hospital ward. It would not be advisable to use patients in a nearby ward as a control group, as these patients might also get to see the information sheets.
- You need to choose a control group that will enable you to evaluate the impact of those aspects of your intervention that you are most interested in.
For example, consider an intervention in which pharmacists discuss a fact sheet with patients and answer the patients’ questions. If we are interested in the impact of the discussion, rather than of the fact sheet, then the control group should also be given the fact sheet. Then any differences in the results for the two groups should be due to the discussion rather than the fact sheet.

If possible, patients and/or practitioners should be randomly allocated to the control and intervention groups, so that you can be sure there are no differences between the

two groups before the intervention begins. However, random allocation is not always feasible or ethical. Also, if you randomly allocate patients into different groups, you may need to seek ethical approval for your research (see page 12).

Combining methods

For some projects, the best design may involve a combination of more than one method. For example, it is often helpful to assess variables for an intervention and a control group both before and after the intervention, so that you can:

- ensure that there were no differences between the two groups before the intervention
- compare the post-intervention changes for both groups to see the impact of the intervention
- be more confident that any differences you observe are due to your intervention

4 Should you use a quantitative or qualitative approach?

You need to decide whether you're going to use a quantitative or qualitative approach or a combination of the two.

- With a **quantitative** approach, you will use measures that give you **numerical** data.
- With a **qualitative** approach, you will use measures that give you **verbal** data.

The approach you use will depend on your aims, and on the number of participants you want and can get data for. If your project involves only a small number of patients (fewer than about 30), quantitative analysis will probably not be very accurate or revealing. But a qualitative approach will let you carry out an in-depth analysis of a small number of participants, providing you with rich and detailed data about some of the effects of your intervention on them.

If you have a large number of participants, as well as a quantitative analysis you may want to analyse a proportion of them in depth using a qualitative approach, to examine particular aspects of your intervention.

Qualitative data can be used to develop quantitative tools for evaluating a project. For example, in-depth interviews with patients can identify their attitudes towards an intervention, which can then be investigated further using a quantitative survey of a larger group of patients.

Quantitative analysis techniques

There are many different ways of analysing numerical data. Before you start your project, you need to decide how you're going to analyse your data, and make sure that the measures you use will give you the kind of data that you need.

The simplest way to analyse quantitative data is to calculate **percentages** for the different variables for each of the different groups and compare them. If you want to use sophisticated analysis techniques you may need advice about which types of analyses to use and how to carry them out (see **Where to go for more information** on page 40).

Qualitative analysis techniques

There are also many ways of analysing qualitative data. One of the easiest ways is to **categorise** the findings, or to try to identify different **themes**.

It may be helpful to have at least two people analyse the data independently. This way you can compare their findings in order to identify and resolve any differences in their interpretations. If you want to use sophisticated analysis techniques, you may want to get advice about the different kinds of analysis you can do (see **Where to go for more information** on page 40).

5 What types of questions should you ask?

For many of the variables you can measure to evaluate your intervention the easiest assessment tool is patient/practitioner **interviews or questionnaires**. Questionnaires and interviews tend to contain two broad types of questions: fixed-response and/or free-response.

Fixed-response questions

With this type of questions, people are given a limited choice of responses. Asking this type of question will give you quantitative data, and it is the easiest way to find out the number of people who give a particular response. However, because people are forced to answer in a limited number of ways, the answers they give may be quite different from how they would describe their experiences or views in their own words.

Here are some examples of fixed-response questions:

a. Did you receive a prescription today? (please circle) Yes No				
b. How satisfied were you with the information your doctor gave you? (please tick only one box)				
Very satisfied	Fairly satisfied	Neutral	Fairly unsatisfied	Very unsatisfied

Free-response questions

With this type of question, respondents answer in their own words. So free-response questions usually provide more detailed information about how people feel. Free responses provide qualitative data, although for some questions you may be able to generate quantitative data by categorising and counting the different responses.

If you want to use fixed-response questions so that you can quantify your findings, you may still want to have one or more free-response questions at the end of the interview or questionnaire to find out if there were any other important issues you had not asked about.

Here are some examples of free-response questions:

a. What are your concerns about your medicines?
b. What other services would you like your pharmacist to provide?

6 Should you use questionnaires or interviews?

Questionnaires

Questionnaires are usually highly structured, with mainly fixed-response questions. They can contain some free-response questions, although respondents may not provide very detailed answers.

One main **advantage** of questionnaires is that they are relatively cheap and easy to use. They can be distributed by post or by hand, by the project organisers or by health professionals. And respondents can usually fill them in at their own convenience. They also improve consistency across studies and situations, and they provide quantitative information so that you can assess changes over time. Using published validated questionnaires gives you confidence that you are measuring what you think you are measuring and that your measurements are reliable.

Interviews

Interviews vary as to how structured they are and the type of questions they contain. A highly structured interview involves mainly fixed-response questions and each interviewee is asked the same questions.

In less structured interviews, although the interviewer will have a rough idea about what they want to ask, the particular questions may be different for each interviewee. The interviewer asks more open-ended questions, then asks follow-up questions to find out more about particular aspects of the interviewee's answers.

The **advantages** of interviews are that they can provide more complete and detailed responses, and that they allow you to check the respondents' understanding of the questions. The **disadvantage** is that they are usually more difficult and expensive to conduct than questionnaires.

7 Do you need ethical approval to carry out your project?

Research projects involving patients usually need approval from the appropriate local research ethics committee(s) (LREC). But approval is not always necessary for medical or clinical audit projects. Therefore, whether or not you need ethical approval for your project will depend on whether it is classed as **research or audit**.

Unfortunately there is no clear rule about what counts as research and what counts as audit, although your LREC will have its own guidelines about what falls within its remit. The table shows some general differences between research and audit projects.

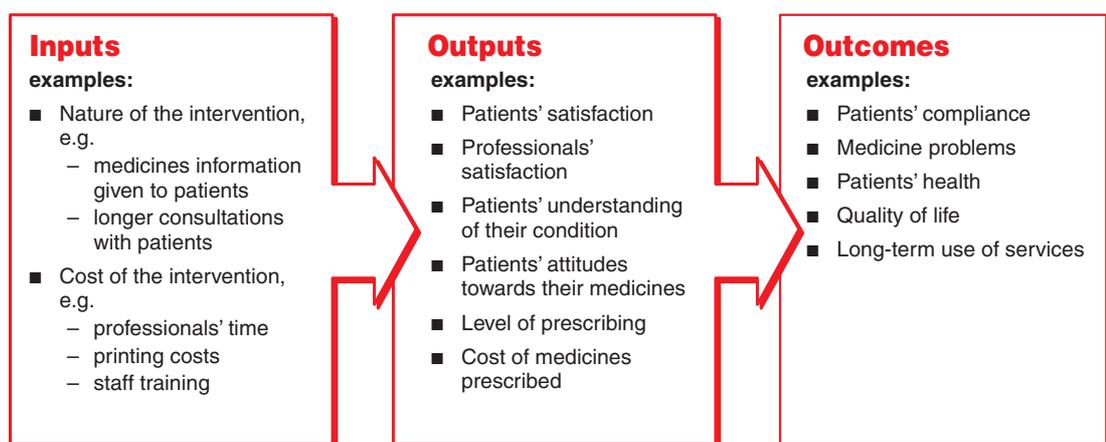
Research and audit projects compared

Research	Audit
Aims to increase the sum of knowledge through systematic investigation.	Systematically examines the peer review of care, treatments or services to identify opportunities for improvement.
May involve an element of randomisation to different treatments or services.	Never involves the random allocation of treatments or services.
May involve a new treatment or service.	Never involves a completely new treatment.
Often involves extra work over and above that involved in normal clinical management or service provision.	Never involves disturbance to the patients beyond that required for normal clinical management.
May involve the application of recruitment criteria before subjects are entered into a study.	May involve patients with the same problem receiving different treatments or services. However the patient has a choice of the treatment or service they receive after full discussion of the known advantages and disadvantages of each.
Adapted from <i>Manual for Research Ethics Committees (Fifth Edition)</i> . The Centre of Medical Law and Ethics, King's College, London (1997)	

Which variables to measure

There are many different variables you can measure to evaluate the impact of your intervention. When choosing which ones, you'll need to consider what the aims of your project are and what you can achieve with the resources you have available. Measurable variables fall into three main categories:

- **Inputs** — what your intervention involves, how it differs or adds to usual patient care, and how much it costs
- **Outputs** — the immediate impact of your project for patients and professionals
- **Outcomes** — the longer-term consequences of the project on health outcomes and cost



The **inputs** are the active ingredients of the intervention and how much it costs. By measuring the inputs, you assess what is actually taking place in the intervention and how it modifies standard patient care in ways that might help achieve concordance.



The **outputs** are the immediate effects of the intervention — for example, patients' and health professionals' satisfaction, improvements in patients' knowledge of their medicines, and changes in patients' attitudes towards their medicines. The aim of many projects will be to affect *long-term* outcomes, such as health or quality of life; but an intervention's *immediate* outputs also indicate its effectiveness and the extent to which its aims have been achieved. Outputs are often easier and quicker to assess than outcomes; so you may find that you prefer to measure them.



The **outcomes** are the longer-term effects of the project. In most cases, they will correspond to the main aims of the intervention — for example, patients' use of medicines and services, their health and quality of life and the resulting cost. So they are probably the most important aspects to measure, although they are often the most difficult to assess, as they usually need to be measured some time after the intervention has taken place.

Inputs

It's important to look at what the active ingredients of your intervention are, and how your project is putting concordance into practice. You will also need to show how your intervention differs from normal patient care or professional practice.

A major element of concordance is **improved two-way communication** between patients and professionals. So one of the most important aspects to measure is the impact of your intervention on communication.

The type of interaction between patients and professionals that needs to be assessed will vary according to the nature of the project. For example, there may be one-off interactions or a series of discussions. These may be in-person at a pharmacy, hospital or in a patient's home; or they may take place on the telephone. Interactions may involve one patient and one health professional; or a patient's family and/or additional professionals may be included.

You can measure a wide range of inputs, which fall into two main categories:

- the **nature** of the intervention and **who it involves**
- the **cost** of the intervention

The nature of the intervention and who it involves

To assess the effectiveness of different projects, it's important to know what these projects involve. In particular, it may be helpful to examine some of the following aspects of your intervention, although they may not all be relevant or feasible to measure for your particular project.

The number of interactions that took place for each patient and professional

The number and type of patients involved

You could record:

- patients' age
- patients' gender
- the medical conditions they have (if your project does not focus on patients with a particular condition)
- how long they have been ill and/or what stage illness they have
- what medicines they are using

The number and type of professionals involved

You could record:

- which professions they are
- the amount of training they've had



Where the intervention and interactions between patients and professionals take place

You could record:

- the setting (for example, pharmacy, hospital, by telephone)
- whether it is in primary, secondary or tertiary care
- which area of the country it's in
- the type of area it is (i.e. rural, urban, suburban)

How long the patient–professional interactions were

One of the criticisms of concordance is that it is too time-consuming. So it's particularly interesting to measure the duration of the interactions between patients and professionals. Data on the length of interactions may also be useful when calculating the cost of the intervention (see **Cost of the intervention** on page 17).

Your intervention may involve single or multiple interactions for each patient. You may choose to measure the **length of each interaction**; or, if multiple interactions are involved, you could measure the **length of the whole intervention process** (which may take many days or months). If your intervention involves more than one interaction, it may also be helpful to measure the **length of time between the different interactions** for each patient.

Your intervention may involve computer systems that automatically record the length of interactions such as telephone calls. If not, you can either ask the professional involved to measure the length of the interactions, or you can use a third party.

Differences in the medicines information given to patients and by whom

Giving patients appropriate information is an important element of concordance. So it's useful to measure the amount and type of information that patients are given about their medicines. If patients don't have sufficient information, it's difficult for them to be equal partners in the decision-making process.



You can assess the provision of information to patients about many different aspects of medicine-taking. **Checklist T01** (page 19) lists some types of information that you may want to measure. You may want to alter this list, and perhaps add other categories, depending on the types of patients and professionals involved in your project, and the medicines the patients need information about.

If you want to assess the oral or written information given to patients during an interaction the best way to do this is for a third party (researcher) to record on a checklist whether or not each type of information is provided. The researcher can observe the interaction in person, listen to an audiotape of it, or watch a videotape of it.

Another way to measure the amount of information given to patients is to ask the patients or health professionals about it. This can be done by questionnaire or interview. However, neither is as effective as having a third party assess the interaction, as patients and professionals are unlikely to remember accurately the information that was given. Alternatively, you could assess patients' **satisfaction** with the information about medicines they are given (see **Outputs — Patients' satisfaction with the interaction and the care provided** on page 21).



How concordant discussions between patients and health professionals are

For concordance to be achieved, patients need to be involved in discussions about medicines. In particular, they need to share their attitudes, beliefs and wishes about medicine-taking with professionals, and professionals need to encourage and enable this to happen.

The best way to assess how concordant discussions are would be to use a **checklist** of features that are necessary for concordance to be achieved:

- Patients are invited to talk about their priorities, preferences and concerns about medicine taking and the proposed treatment, and these are explored openly.
- Professionals explain the rationale for, and the characteristics of, the proposed treatment.
- Patients and health professionals jointly agree on a course of treatment which reconciles as far as possible the professional's recommendations and the patient's preferences.
- The patient's and professional's understanding of what has been agreed is checked.
- The patient's ability to follow the agreed treatment is checked.



Checklist T02 (page 19) has been developed to assess doctors' involvement of patients in discussions and decisions about medicines.

Another method of measuring patient participation is to **ask patients and/or professionals** about the patient's involvement. This is likely to give you quite different findings than if you have a third party assess the interaction. You are also likely to get quite different responses from patients and professionals. If you do ask patients or professionals about what occurred in the interaction, remember that this will tell you about *their perceptions of what occurred* — not necessarily *what actually occurred*. However, assessment of patients' and professionals' perceptions of what happened in an interaction is also useful in its own right. For example, you may be more interested in whether patients *felt* they participated, than whether or not it appeared to an observer that they did.



You can assess patients' or professionals' perceptions of many aspects of the interaction. A list of questions you could ask patients is given in **Questionnaire T03** (page 20). You could also adapt the questions in this form to measure professionals' perceptions of their interaction with patients.

A new validated measure of concordance is currently being developed (Chewning and Britten, in preparation). To find out more about this measure please contact the Medicines Partnership team (info@medicines-partnership.org).

The cost of the intervention

It's very important to measure the costs of the intervention, for two reasons:

- **to evaluate the costs compared to the benefits**
- **to assess how feasible it would be to put into practice in other sites or settings**

When calculating the costs of your intervention, try to keep things as simple as possible. A good way to start would be to go through the following steps:

Step 1: Identify different types of cost relevant to your project, for example:

- development and production of information materials
- computers and other equipment
- extra training for professionals
- health professionals' time
- advertising to patients to participate in the project
- costs specific to evaluating the project — for example paying a researcher to observe consultations

Step 2: Decide which costs are significant

Ignore costs which are trivial, such as the extra cost of paper used to record conversations with patients. But do keep a note of costs which may be trivial while your project is being piloted with a small group of patients, but which could be much more significant if the project is scaled up to include all patients — for example, time taken by receptionists to pull out additional records for medication reviews.

Step 3: Separate one-off costs from ongoing costs

Within your analysis, show any costs which do not recur — for example, the cost of buying a new PC for a member of staff, or of developing a new patient information leaflet — separately from ongoing costs per patient or per time period.

Step 4: Decide how to account for time

If you are paying staff extra money to undertake the project, accounting for their time is relatively easy. However, if you are not, you need to agree an approach to accounting for time. Your accountant should be able to provide you with an approximate hourly rate for different groups of staff. Make sure that this includes 'on costs' such as national insurance contributions, which are usually calculated as a percentage of gross salary.

Step 5: Decide how to treat overheads

All direct costs are accompanied by overhead costs such as the cost of heat and light, buildings, management and so on. For most projects, these are probably best ignored for simplicity; but you may want to include them for a major project involving new infrastructure (such as a new clinic which uses a clinic room every week).

When presenting the costs of your project, be as explicit as you can about the assumptions you have made.



Checklist for medicines information provided to patients					T01
Was the patient given information about:	Written info		Oral info		Who provided the info?
	Yes	No	Yes	No	
1 The name of the medicine?					
2 How to use it (e.g. dosage, frequency, interval, meals)?					
3 What the medicine is for?					
4 How effective it is?					
5 How to monitor the effects of the medicine?					
6 What side effects the patient may experience?					
7 What to do if the patient gets these side effects?					
8 Whether the medicine can interact with other medicines?					
9 Any contra-indications?					
10 What to do if the patient misses a dose?					
11 Other information? (please specify)					
Was a choice of information format given?					<input type="checkbox"/> Yes <input type="checkbox"/> No

Health professionals' involvement of patients in discussions and decisions about medicines checklist			T02
Please tick only one box for each question.			
	Yes	No	
1 Did the doctor* involve the patient in deciding upon a treatment plan?			
2 Did the doctor* provide patients with enough information to make a choice?			
3 Did the doctor* discuss patients' ability to follow the treatment plan?			
4 Did the doctor* find out what the patient thought about the medicine(s)?			
5 Did the doctor* explain all the benefits of the medicine(s)?			
6 Did the doctor* explain all the risks of the medicine(s)?			
7 Did the doctor* explain fully all possible side effects of the medicine(s)?			
*Substitute with pharmacist, nurse, etc. if applicable			
Adapted from Makoul, Arntson and Schofield, 1995			

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1 The doctor* gave me responsibility for deciding how to deal with my health problem.					
2 The doctor* asked me to choose a treatment for my health problem.					
3 The doctor* gave me enough information to make my own decision about treatment.					
4 The doctor* did not ask my opinion about my medicines.					
*Substitute with pharmacist, nurse, etc. if applicable					

Adapted from Makoul, Arntson and Schofield, 1995

T03

Assessment of patients' perceptions of their involvement in discussions

How much do you agree with the following statements?
(please tick only one box for each question)



Outputs

Immediate outputs are usually easier to measure than longer-term outcomes and may give you an indication of the effectiveness of your intervention and patients' and professionals' views about it. Most of the outputs can be assessed by patient or professional questionnaires before and/or after the intervention. Six outputs you might want to measure are:

- Patients' satisfaction with the intervention and the care provided
- Professionals' satisfaction with the intervention
- Professionals' attitudes to concordance
- Patients' understanding of their condition and treatment
- Patients' attitudes towards their medicines
- Level and cost of prescribing

Patients' satisfaction with the intervention and the care provided

One of the most useful outcomes to measure is patients' satisfaction with the intervention and their opinions about the care provided. An intervention may appear to be very successful in terms of its impact on patients' health and other outcomes, yet the patients may not *feel* that it was very helpful or may have found it too inconvenient or intrusive.

When assessing satisfaction, it's better to ask patients multiple questions about their satisfaction with different aspects of the intervention, rather than just one question about their overall satisfaction. By asking multiple questions, you'll get information about which parts of the intervention were particularly useful, and which were of less use. Another reason to ask multiple questions is that when patients are asked about their *general* satisfaction with health services, they tend to report a very high level of satisfaction; multiple questions may be more likely to reveal any areas of lower satisfaction.

There are many different aspects of satisfaction that you can assess. Obviously, the questions you'll ask will depend on the nature of your intervention and its intended impact. One way to find out about the best aspects to assess is to collect some qualitative data from patients about their positive and negative attitudes towards the intervention. This data can then be used to develop a questionnaire. Some specific aspects that you can measure are described below.

Patients' satisfaction with their consultation or communication with professionals



For example, did they feel that the professional was willing to listen to them, was interested in them as a person, was warm and friendly, etc? Document **T04**, the **Medical Interview Satisfaction Scale (MISS-21)** (page 27) has been adapted for use in British general practice. It measures four aspects of patient satisfaction: **distress relief**, **communication comfort**, **rapport** and **compliance intent**.



Patients' satisfaction with the information they were given



You may want to use **T05**, the **Satisfaction with Information about Medicines Scale (SIMS)**; Horne, Hankins and Jenkins, 2001; available for download but not reproduced here) in your study to assess how happy patients are with the information they have received.

Patients' satisfaction with the treatment decisions made and the medicines prescribed



You can use **T06**, the **Satisfaction with Decision questionnaire** (page 28), to examine how patients feel about treatment decisions.

Patients' evaluation of any new service

What do they see as its benefits and disadvantages compared with their usual or previous care?

How to assess patients' satisfaction

Patients' satisfaction can be assessed by self-completed questionnaires or interviews. You can use fixed response and/or free-response questions.

Using mainly **fixed-response** questions will make it easier for you to find out about people's satisfaction with particular aspects of the intervention and to calculate the number of people who were satisfied about each of these aspects.

Using mainly **free-response** questions will give you more detailed information on people's feelings about the intervention from their own perspective. If you decide to use fixed-response questions so you can quantify your findings, you may still want to have one or more free-response questions at the end of the interview or questionnaire to identify any important issues you hadn't asked about.

Here are some examples of fixed-response questions to assess patients' satisfaction:

a. Did you find the pharmacist-led clinic helpful? (please circle) Yes No				
b. How satisfied were you with the length of your appointment? (please tick only one box)				
Very satisfied	Fairly satisfied	Neutral	Fairly unsatisfied	Very unsatisfied

Here are some examples of free-response questions to assess patients' satisfaction:

1 What was the most positive effect of the website for you?
2 Please write any suggestions you have about how the telephone support service could be improved.



Professionals' satisfaction with the intervention

It's important to consider the impact of your intervention on professionals' satisfaction as well as on patients' satisfaction. Your intervention may have various positive or negative effects on professionals, which you will need to take account when evaluating its overall effectiveness.

As with measuring patient satisfaction, it may be more revealing to ask professionals multiple questions about their satisfaction with different aspects of the intervention, rather than to ask just one question about their overall satisfaction. You can use fixed response and/or free-response questions to assess satisfaction. The aspects of professional satisfaction that you may want to assess fall into two broad categories.

Satisfaction with each specific interaction with patients

For some projects, it may be useful to examine how professionals felt about their interactions with each patient involved in the intervention. In particular, you could examine how satisfied they were with the explanations they provided, their communication, and the treatment decisions that were made. One of the easiest ways of assessing professionals' satisfaction with their interactions is to ask them to fill out a questionnaire after each interaction. The **Satisfaction with Decision questionnaire** (**T06** on page 28) for patients can be modified to assess professionals' satisfaction with treatment decisions.



Satisfaction with the general service provided

It may also be useful to examine professionals' general views about the intervention and changes to the service provided. This can be assessed by a survey or interview at the end of the intervention. Aspects of satisfaction that you could examine include:

- whether professionals felt the service helped them to improve their practice
- whether it provided a learning experience for them
- whether they felt any of the aspects of the service were too time consuming for the benefits they provided

Professionals' attitudes to concordance

Little is known about how acceptable the concept of concordance is for health care professionals. So it's useful to assess professionals' attitudes towards concordance, because these attitudes will have a significant impact on the feasibility of putting concordance into practice.



Document **T07**, the 12-item **Leeds Attitude Towards Concordance (LATCon)** scale (page 29) was developed to measure these attitudes.



Patients' understanding of their condition and treatment

It's vital that patients should have a good understanding of their condition and treatment, so that they can make informed decisions about their care. Many patients lack important knowledge, or have misconceptions about their condition and treatment that may affect their behaviour in ways which have a serious impact upon their health (such as whether they take their medication as prescribed). Your intervention may involve giving patients information to improve their understanding, so it would be useful to assess the effectiveness of this approach.

The best way to assess patients' understanding is to use a **questionnaire**. Either this can be completed by the patient, or an interviewer can go through the questions with the patient. If patients were given (or were supposed to have been given) information about specific aspects of their condition, you may want to assess their knowledge of these aspects — perhaps before and after the intervention. Three types of questions are useful to assess patients' knowledge and understanding; examples are given overleaf.

True or False questions

Please tick only one box for each question

	True	False
1 High blood pressure that is untreated can lead to stroke.		
2 Antibiotic medication is an effective treatment for colds.		

Other fixed-response questions

1 Is there a cure for COPD? (please circle) Yes No

2 How many times a day has your doctor suggested you take your medicine?
(please tick only one box)

Once a day	Twice a day	Three times a day	Four times a day
------------	-------------	-------------------	------------------

Open-ended questions

1 What is the name of your medicine? _____

2 Name two possible side effects of your medicine _____



When assessing patients' understanding you need to be careful that patients don't feel like they are sitting an exam. It may be helpful to explain to patients that you are not assessing them, but instead are trying to measure how effective the intervention has been and/or whether they were provided with enough information.



Document **T08**, the **Type 2 diabetes knowledge questionnaire** (page 30) is an example of a measure to assess patients' understanding of their condition and its treatment. It would be important for a health professional to give the patient the answer sheet and go through it with them after the exercise.

Patients' attitudes towards their medicines

There are often major differences between patients' and professionals' beliefs about medicines. The concordance model states that the two parties need to share their views and negotiate in order to reach an agreement. Patients' beliefs about their condition and treatment also have a significant impact on their compliance. So it's both interesting and important to assess the impact of your intervention on patients' beliefs.

Patients' beliefs can be measured by questionnaire or interview, which can consist of fixed-response and/or free-response questions. If you ask mainly fixed-response questions, it will be easier for you to compare the beliefs of different groups of patients, and to compare patients' beliefs before and after the intervention. However, free-response questions (especially if used in an interview) might enable you to examine patients' beliefs in more depth. You could also ask patients if they felt the intervention had led them to change their views about their condition or medicines.



Document **T09**, the 10-item **Beliefs about Medicines Questionnaire (BMQ)** — available for download but not reproduced here) has been designed to assess patients' beliefs about their medicines (Horne, Weinman and Hankins, 1999). Disease-specific versions are available for a range of conditions (including HIV, diabetes and asthma). Versions to assess patients' partners' or parents' beliefs about medicines have also been developed.

Level and cost of prescribing

As patients often do not want to take their medicines or would prefer to use them less often, one possible outcome of increased concordance is a reduction in the prescribing of medicines. However, an intervention aimed at increasing patients' medicine knowledge, reducing their concerns about medicines or changing their attitudes towards them may make patients more willing to be prescribed medicines and therefore may result in increased prescribing. So for many projects it will be useful to assess the impact of the intervention on the level of prescribing.

How to assess the level of prescribing

In most cases, prescriptions will be automatically recorded by the professional using a computer or paper-based system. However, in some cases, you may want to check that professionals routinely record the information you are interested in, and that they do



so in an accurate and consistent manner. In some cases it may be easier to ask professionals to record the information in another way in order to standardise it, or to ask them to provide additional information.

The way you assess the level of prescribing will depend on the medicines that your project is concerned with:

- For **long-term** medicines you'll probably want to look at the **number of medicines prescribed per month** (or other period).
- For **short-term** medicines, you can either look at the **length of time** the medicine was prescribed for, or the **number of patients** who used that particular medicine.

Then, depending on the design of your project, you can compare the before and after measurements and/or the results for the intervention and control groups.

Which medicines should be assessed

For some projects, it may only be necessary to assess the level of prescribing of one particular medicine. In other cases it may be important to look at the level of prescribing of a number of medicines, as patients' use of one medicine may increase while their use of another medicine may decrease. For example, an intervention in which nurses encourage asthma patients to use their preventer inhaler more frequently may lead patients to use their reliever inhaler less often. So you need to consider what medicines are relevant to your intervention and the condition(s) that you are interested in.

Cost of prescribing

When examining the cost-effectiveness of your intervention, it's important to take into account the cost of medicines used by the patients involved. The cost of medicines may be increased or decreased by your intervention. In most cases it will be relatively easy to calculate the cost of medicines, or the change in cost, by finding out the number of medicines that have been prescribed and subsequently dispensed.

Each year, the Department of Health produces a **Prescription Cost Analysis**, which gives the cost per dose for all medicines. The latest version is available at

<http://www.doh.gov.uk/stats/pca2001.htm>



Medical Interview Satisfaction Scale**T04**

Circle one number for each statement, to show how much you agree or disagree with it

	very strongly disagree	strongly agree	disagree	uncertain	agree	strongly agree	very strongly agree
1 The doctor told me just what my trouble is.	1	2	3	4	5	6	7
2 After talking with the doctor, I know just how serious my illness is.	1	2	3	4	5	6	7
3 The doctor told me all I wanted to know about my illness.	1	2	3	4	5	6	7
4 I am not really certain about how to follow the doctor's advice.	1	2	3	4	5	6	7
5 After talking with the doctor, I have a good idea of how long it will be before I am well again.	1	2	3	4	5	6	7
6 The doctor seemed interested in me as a person.	1	2	3	4	5	6	7
7 The doctor seemed warm and friendly to me.	1	2	3	4	5	6	7
8 The doctor seemed to take my problems seriously.	1	2	3	4	5	6	7
9 I felt embarrassed while talking with the doctor.	1	2	3	4	5	6	7
10 I felt free to talk to this doctor about private matters.	1	2	3	4	5	6	7
11 The doctor gave me a chance to say what was really on my mind.	1	2	3	4	5	6	7
12 I really felt understood by my doctor.	1	2	3	4	5	6	7
13 The doctor did not allow me to say everything I had wanted about my problems.	1	2	3	4	5	6	7
14 The doctor did not really understand my main reason for coming.	1	2	3	4	5	6	7
15 This is a doctor I would trust with my life.	1	2	3	4	5	6	7
16 The doctor seemed to know what (s)he was doing.	1	2	3	4	5	6	7
17 The doctor has relieved my worries about my illness.	1	2	3	4	5	6	7
18 The doctor seemed to know just what to do for my problem.	1	2	3	4	5	6	7
19 I expect that it will be easy for me to follow the doctor's advice.	1	2	3	4	5	6	7
20 It may be difficult for me to do exactly what the doctor told me to do.	1	2	3	4	5	6	7
21 I'm not sure the doctor's treatment will be worth the trouble it will take.	1	2	3	4	5	6	7

Adapted from Meakin and Weinman, 2002



Satisfaction with Decision questionnaire		T06			
Please tick only one box for each question					
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1 I am satisfied that I am adequately informed about the issues important to my decision.					
2 The decision made was the best decision possible for me personally.					
3 I am satisfied that the decision was consistent with my personal values.					
4 I expect to successfully carry out (or continue to carry out) the decision made.					
5 I am satisfied that this was my decision to make.					
6 I am satisfied with the decision.					

Holmes-Rovner et al, 1996

Note: If you use this questionnaire, you should tell the patient (in writing or orally) what treatment decision you want them to answer the questionnaire about. The wording of the items can be altered (e.g. by saying what decision you are interested in) to make the questionnaire more relevant to your intervention.



Leeds Attitude Towards Concordance (LATCon) Scale**T07**

Please rate your agreement with the following statements.

Please tick only one box for each statement.

	Strongly disagree	Disagree	Agree	Strongly agree
1 The consultation between the prescriber and patient should be viewed as a negotiation between equals.				
2 Prescribers should respect the validity of their patients' personal beliefs and coping strategies.				
3 The best use of medicines is that which is compatible with what the patient wants and is capable of achieving.				
4 Just as prescribing is an experiment carried out by the prescriber, so too is medication taking an experiment carried out by the patient.				
5 Prescribers should give patients the opportunity to communicate their thoughts about their illness and negotiate how it is treated.				
6 Enhanced health outcomes would follow from mutual and co-operative interaction between prescribers and patients.				
7 A high priority in the consultation between prescriber and patient is to establish a 'therapeutic alliance'.				
8 Prescribers should be sensitive to patients' desires, needs and capabilities.				
9 Prescribers should try to assist patients to make as informed choice as is possible about benefits and risks of alternative treatments.				
10 During the prescriber-patient consultation, it is the patient's process of deciding that is most important.				
11 I believe that prescribers should be more sensitive to how patients react to the information they give.				
12 I believe that prescribers should try to learn about the beliefs their patients hold about their medicines.				

Raynor et al, 2001



Type 2 diabetes knowledge questionnaire**T08**

We want to find out about your understanding of your diabetes. Don't worry though — this is not a test! We just want to see whether we have given you enough information about your condition and have explained it well enough.

Please tick the box in the True or False column for each question. If you don't know the answer please leave it blank.

	True	False
1 Type 2 (non-insulin dependent) diabetes develops if the body is unable to produce any insulin.		
2 An important symptom of untreated diabetes is thirst.		
3 Hypoglycaemia is an abnormally high level of sugar in the blood.		
4 An immediate treatment for hypoglycaemia is to take sugar.		
5 Diabetics are recommended not to take too much exercise.		
6 Normal (non-diabetic) blood sugar readings are: — between 8 and 10 mmol/l before meals — and more than 10 mmol/l after meals.		
7 The recommended times to test your blood sugar level are just before meals, two hours after meals, and before bed.		
8 People with diabetes should not have any sugar in their diet.		
9 Insulin cannot be taken in tablet form because it would be broken down in the stomach before it could work.		
10 The most important part of treatment for people with diabetes is diet.		



Outcomes

By measuring outcomes, you can assess the most important long-term effects of the intervention, including health, quality of life and cost of services. Unfortunately, they are often more difficult to measure than the inputs or output indicators, as they may need to be assessed some time after the intervention. Five outcomes you might want to measure are:

- Patients' compliance with the agreed medication regime
- Medicine-related problems
- Patients' health
- Quality of life
- Long-term use and cost of services

Patients' compliance with the agreed medication regime

Compliance is clearly an important outcome to measure, because:

- it has a significant impact on patients' health
- one of the main aims of concordance is to improve patients' use of medicines.

According to the model of concordance, the patient and professional should agree on a treatment plan that is achievable and acceptable to the patient. So, in most cases, projects should assess whether or not patients take their medicines as they have *agreed* with their health care professional(s) to take them, rather than whether they take them as the professional(s) *wants* them to.

There are two main types of non-compliance: primary and secondary. **Primary non-compliance** is when patients do not have their prescriptions dispensed. **Secondary non-compliance** is when patients do not take their medicines the way in which they were prescribed. There are four main forms of secondary non-compliance:

- taking **incorrect dosages** — either too much or too little
- taking medicines at **incorrect dosing intervals** — either too frequently or not frequently enough
- taking medicines in **situations for which they are not suited** (for example, on an empty stomach)
- **not completing a course** of medicines

There are many ways of measuring compliance. All methods have their advantages and disadvantages and some methods are only possible with particular medicines. If possible, use more than one method to check the accuracy of your findings. Five of the most commonly used methods are:

- monitoring repeat prescriptions
- patient self-reporting
- assessment of unused medicine (for example, pill counts)
- electronic monitoring
- monitoring attendance at appointments



Monitoring repeat prescriptions

Although it's not a direct measure, probably the simplest way to measure compliance is to see how often patients get their repeat prescriptions. You can do this by looking at how often patients obtain repeat prescriptions from their General Practice. For patients who always use the same pharmacy, the pharmacy's patient medication records (PMRs) can be used to identify whether and when they get their prescriptions dispensed. At the very least, this gives an indication of whether the patient obtained enough medication to *be able to comply* over a given period. The amount of medicine the patients got in a given period, in relation to how much was prescribed for them can be expressed as a percentage.

The main advantages of this method are:

- You do not need to contact the patient to do it.
- You can get information about a large number of patients.
- In some cases, you can get information about patients' repeat prescription use over a long period of time.

The main disadvantages are:

- It does not show you whether the patient is taking the medicine as it was prescribed — how often they take it and in what doses. In some cases, patients collect prescriptions then don't use them at all.
- Patients may get prescriptions dispensed from more than one pharmacy, so pharmacy records may not give the full picture. One way to deal with this problem is for the pharmacist to ask patients about any prescriptions that they appear to have missed.

Patient self-reporting

Another common method of measuring compliance is to ask the patient about it. The simplest way to do this is by **interview** or **questionnaire**; or patients can be asked to report their use of medicines in a **diary**.

Questionnaires or interviews

These are usually the cheapest and easiest way to measure patients' compliance. However, the problem with this method is that patients greatly overestimate their compliance. If patients are asked about their compliance by their own health professionals, or if they think that these professionals will find out their answers, their over-reporting may increase, as they may worry that their professional will be annoyed about their non-compliance.

Also, patients may give more accurate responses if they are asked in a non-threatening way that makes it easier for them to admit to being non-compliant.



Document **T10**, the **Medication Adherence Report Scale (MARS)**; Horne, 1997), is a patient questionnaire to assess compliance with medicines. It is available for download but not reproduced here.



Diaries

Asking patients to complete a diary has the additional advantage of providing details of how and when the patient takes their medicine each day. A diary may in itself be an aid to compliance, although this is not proven. However, as with the other self-reporting methods, patients tend to overestimate their compliance. Another disadvantage is that patients are required to return their diaries, which may be difficult to achieve.



The **TB Treatment Diary (T11)**, produced by TB Alert, is an example of a patient-completed record of medicine taking, and can be adapted to other conditions.

Assessment of unused medicine

Another method of assessing compliance is to measure the amount of medicine that the patient has not used after a certain period, and to compare it with the amount that should be left according to the prescribed dose.

If the medicine is in the form of pills, then the number remaining in patients' medicine containers can be counted. With some other forms of medicines, the containers can be weighed to determine how much the patient has taken.

The advantage of this technique is that it is fairly simple and low-cost. The disadvantage is that, like patient self-reporting, it results in an overestimated level of compliance, as patients may remove pills but not take them. In addition, similar pill count results can be obtained from very different degrees of non-compliance — for example, patients prescribed one pill a day can achieve a 100% compliance rate by taking their medicine as prescribed or by taking it all in one go.

Electronic monitoring

A variety of electronic devices have been developed to record the time and date when patients use their medicines. These devices work by detecting when a pill box or bottle is opened, when a pill is removed from a blister pack, when an inhalation device is activated, or when bottles are inverted to dispense liquids.

The advantage of this technique is that it can give you objective information about when patients use their medicines and how well they comply with a particular regimen.

The disadvantages are:

- The devices are expensive to buy or rent and therefore will only be suitable for well-funded projects.
- They can still be inaccurate, as patients may accidentally or deliberately activate the device without taking the medicine.
- Patients may dislike having their medicine-taking behaviour continuously monitored (although it is sometimes done without their knowledge).

To find out more about electronic monitoring devices go to www.aardex.ch



Monitoring attendance at appointments

Failure to attend appointments is often one of the first signs that a patient is not complying with their treatment. So, given the difficulty of monitoring compliance directly, you may want to monitor patients' attendance at clinic appointments as a proxy measure.

Medicine-related problems

For some projects it may be helpful to assess how the intervention affects the number of problems patients have with their medicines. Such projects may involve interventions that aim to improve patients' knowledge about their medicines, or that give patients practical help to enable them to take their medicines more effectively.

There are a number of medicine-related problems that you may want to assess. Some of them are related to poor compliance or patients' lack of understanding of their condition or its treatment, which have been discussed earlier. Other medicine-related problems that you could assess include:

- **Patients' experience of side effects**
- **Conflict with patients' lifestyle**, for example:
 - difficulty in taking medicines at particular times of the day, due to work etc.
 - difficulty in taking medicines in the appropriate circumstances (such as on an empty stomach)
 - side effects (such as insomnia or drowsiness) that interfere with patients' sleeping patterns or work activities
 - patients are drinking alcohol, which interferes with their medication
- **Difficulty in using medicines**, for example:
 - complex dose regimen
 - difficulty opening the medicine's packaging
 - difficulty taking liquids, inhalers, drops
 - difficulty swallowing doses
 - difficulty ordering or collecting repeat prescriptions
 - difficulty reading labels — because of poor eyesight, illiteracy or language barriers
- **Professionals having inaccurate or incomplete data about patients' medicine use**, for example:
 - discrepancy between patients' understanding of the dose and/or frequency of their medicines and their pharmacy's or doctor's records
 - patients using medicines that are not in their records
 - conflict between OTC and prescription medicines



Patients' health

Improved health is clearly one of the most important aims of any intervention, and is therefore one of the most significant outcomes to measure. It will be easier to measure health outcomes if the all patients involved in your project have the same condition.

One of the main difficulties with assessing how an intervention affected patients' health is that you have to wait for long enough after the intervention has begun before there may have been a substantial effect. The length of time needed before assessing patients' health will depend on the condition and the intervention.

You could ask patients a very simple question to find out about their health, such as:

How would you rate your health?
(please tick only one box)

Excellent	Good	Fair	Poor
-----------	------	------	------

Alternatively you could ask a number of questions to find out about particular aspects of health that you think the intervention may affect. There are many different aspects of health you can assess; some specific outcomes that can be assessed for particular conditions are:

Condition	Outcome
Hypertension	Blood pressure
Asthma	Lung function
Diabetes	Glycaemic control
Epilepsy	Frequency of seizures
HIV	CD4 cell count
Coronary heart disease	Myocardial infarction

Many questionnaires or checklists have been developed to assess patients' health outcomes for particular conditions. Examples (available for download but not reproduced here) include:



- **Living with Asthma Questionnaire** — T12 (Hyland, 1991)
- **Diabetes Health Profile** — T13 (Meadows et al, 1996)
- **Impact of Epilepsy Scale** — T14 (Jacoby et al, 1993)
- **Hospital Anxiety and Depression Scale** — T15 (Zigmond and Snaith, 1983)



There are also a number of measures that can be used for various conditions:



- Pain intensity — you could use:
 - the **McGill Pain Questionnaire** — **T16** (Melzack, 1987)
 - or a very simple measure: for example, ask patients to rate their pain on a scale of 0 to 10 from ‘no pain’ to ‘pain as bad as can be’
- Number of days off work
- Survival or mortality rates



Another way to assess health is to ask patients how they feel about their health. One of the easiest ways to achieve this is to use document **T17**, the **Measure yourself medical outcome profile (MYMOP2)** on pages 38 and 39. (MYMOP was published by Paterson in 1996; MYMOP2 was created in 1998). This asks patients to rate the severity of their symptoms and their ability to do activities that are associated with their health problem. It is up to the patient to choose the symptoms and activities that are most relevant to them.

Patients can complete the questionnaire repeatedly over a period of days, weeks or months to detect changes in their health. In the **follow-up questionnaire** (page 39), patients are asked if they have any new symptoms. MYMOP2 can be used for patients with various conditions; it’s a useful way to see how patients’ perceptions of their health change over time (for example, before and after an intervention).

Quality of life

Assessment of patients’ quality of life provides one of the best indications of the impact of the intervention from the patient’s perspective. Many aspects relating to quality of life are discussed in other sections, including medicine-related problems, use of services, and satisfaction with care. There is also a significant overlap between quality of life and health outcomes, especially those outcomes that look at patients’ perceptions of their health.

There are many patient questionnaires and checklists that can be used to assess patients’ quality of life in relation to particular conditions. There are also general instruments that can be used to assess the quality of life of patients with a variety of conditions. These instruments may not be as sensitive as condition-specific measures, but they do allow you to compare patients with different conditions.



One of the most commonly used general quality of life instruments is **T18**, the **Short Form Health Survey** (Ware et al, 1996). This is available as a 36-item (SF-36) or 12-item (SF-12) questionnaire (see below). The SF-36 is more accurate but is much more time-consuming to complete.

Both versions assess eight aspects of quality of life:

- physical functioning
- role limitations due to physical health problems
- role limitations due to emotional health problems
- pain



- general health
- vitality
- social functioning
- mental health

The downloadable document on the Medicines Partnership web site gives you information on how to obtain the SF health surveys.

Long-term use and cost of services

There are a number of reasons why you may want to assess changes in patients' use of services and the financial cost:

- One of the aims of your intervention may be to improve patients' health, and this may affect how often patients need to use services.
- You may want to evaluate an intervention designed to reduce patients' use of other services, which may be over-stretched.
- Your intervention may be aimed at patients who do not use services frequently enough, so you may want to assess whether or not it has been successful in increasing their use.

Aspects of service use which you may want to assess and calculate the cost of include:

- number of GP visits
- number of attendances at Accident and Emergency
- number of referrals to secondary care
- number of hospital admissions
- length of hospital stays
- cost of prescribed medication

In each case, the use and cost of services should be compared with the findings for a control group, with those of the intervention group before the intervention, or with appropriate benchmark data.

MYMOP2**T17**

Full name _____ Date of birth _____

Address and postcode _____

Today's date _____ Practitioner seen _____

Choose one or two symptoms (physical or mental) which bother you the most. Write them on the lines.
Now consider how bad each symptom is, over the last week, and score it by circling your chosen number.

<u>SYMPTOM 1</u> _____	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

<u>SYMPTOM 2</u> _____	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevents you doing. Score how bad it has been in the last week.

<u>ACTIVITY</u> _____	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

How would you rate your general feeling of wellbeing during the last week?

<u>WELLBEING</u> _____	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

How long have you had Symptom 1, either all the time or on and off? Please tick the box:

0 to 4 weeks 4 to 12 weeks 3 months to 1 year 1 to 5 years over 5 years

Are you taking any medication FOR THIS PROBLEM? Please tick: YES NO

IF YES:

1. Please write the name of the medication, and how much you're taking each day or week

2. Is cutting down this medication (please tick):

not important? a bit important? very important? not applicable?

IF NO:

Is avoiding medication for this problem:

not important? a bit important? very important? not applicable?



MYMOP2 follow-up

T17

Full name _____ Today's date _____

Please circle the number to show how bad your symptoms have been IN THE LAST WEEK. This should be YOUR opinion — no-one else's.

<u>SYMPTOM 1</u>	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

<u>SYMPTOM 2</u>	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

What about your chosen activity — how bad it has been in the last week?

<u>ACTIVITY</u>	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

How would you rate your general feeling of wellbeing during the last week?

<u>WELLBEING</u>	0	1	2	3	4	5	6
	As good as it could be						As bad as it could be

If any important NEW symptom has appeared, please describe it and mark how bad it is. If you have no important new symptoms, leave these lines blank:

<u>NEW SYMPTOM</u>	0	1	2	3	4	5	6
_____	As good as it could be						As bad as it could be

The treatment you're receiving may not be the only thing affecting your problem. If there's anything else you think is important (such as changes you have made yourself, or other things happening in your life), please write it here. Carry on writing overleaf if you need more space.

Are you taking any medication FOR THIS PROBLEM? Please tick YES NO

IF YES:

Please write the name of the medication, and how much you're taking each day or week



Where to go for more information

Concordance

Medicines Partnership website
www.medicines-partnership.org

Research methods

MRC guidelines on good research practice:
http://www.mrc.ac.uk/pdf-good_research_practice.pdf

Article in BMJ on analysing qualitative methods:
<http://bmj.com/cgi/content/full/320/7227/114>

Article in BMJ on increasing the number of people who respond to your questionnaire:
<http://bmj.com/cgi/content/full/324/7347/1168>

Information about various methods for collecting data, including useful advice on topics including:

- focus groups
- qualitative interviews

<http://ag.arizona.edu/fcr/fs/cyfar/evaldata.htm>

Large collection of information about social science research methods — includes:

- online textbook on a wide range of topics, including: formulating research questions, sampling, research designs, data analysis, validity, reliability and ethics
- interactive tool to help you find out which statistical test to use on your data
- tutorial on research methods
- links to other useful websites

<http://trochim.human.cornell.edu/>

Statistics

Online lecture notes for statistics course — useful information about statistical tests. Topics include:

- Introduction to statistical methods
- Graphing and tabulating data
- Describing data sets: central tendency, variability and skew
- Correlation
- Sampling

<http://glass.ed.asu.edu/stats/>

Online textbook on statistics — topics include:

- How to design a study
- Different types of data
- How to present data

<http://www.anu.edu.au/nceph/surfstat/surfstat-home/surfstat.html>

Guide to choosing which statistical tests to use:

<http://www.graphpad.com/instatman/instat3.htm>

Ethical approval for research projects

Guidelines on research ethics — including useful information about many of the important issues relating to ethics:

<http://www.etikkom.no/Etikkom/Etikkom/Engelsk/Publications/NESHguide>

Local research ethics committees in the UK:

<http://www.corec.org.uk/LRECContacts.htm>

Variables to evaluate

Compliance

Electronic devices to assess compliance:

www.aardex.ch

Cost of medicines

DoH Prescription Cost Analysys:

<http://www.doh.gov.uk>

Patient satisfaction

Picker Institute website — information about surveys assessing the quality of patient care:

<http://www.pickereurope.org/>

Patients' health

Downloadable version of the Asthma Bother Profile questionnaire:

<http://www.psychology.plymouth.ac.uk/staff/shome.asp?43>

Patients' quality of life

Database of quality of life instruments:

<http://www.qolid.org/>

BMJ article on measuring quality of life

<http://bmj.com/cgi/content/full/322/7299/1417>

Quality of life surveys — information about and sample copies of the SF-8, SF-12, SF-36 questionnaires

<http://www.sf-36.org/>

<http://www.qualitymetric.com/>

References

- Holmes-Rovner M et al (1996). Patient satisfaction with health care decisions: The satisfaction with decision scale. *Medical Decision Making*, 16, 58–64
- Horne R (1997). *The nature and determinants and effects of medication beliefs in chronic illness* [PhD thesis]. London: University of London
- Horne R Hankins M and Jenkins R (2001). The Satisfaction with Information about Medicines Scale (SIMS): a new measurement tool for audit and research. *Quality in Health Care*, 10, 135–140
- Horne R, Weinman J and Hankins M (1999). The Beliefs about Medicines questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. *Psychology and Health*, 14, 1–24
- Hyland ME (1991). The Living with Asthma questionnaire. *Respiratory Medicine*, 85 (Supplement B), 13–16
- Jacoby A et al (1993). Measuring the impact of epilepsy: development of a novel scale. *Epilepsy Research*, 16, 83–88.
- Makoul G (1992). *Perpetuating passivity: a study of physician-patient communication and decision making* [Unpublished doctoral dissertation]. Evanston, IL, US: Northwestern University
- Makoul G, Arntson P and Schofield T (1995). Health promotion in primary care: physician-patient communication and decision making about prescription medications. *Social Science and Medicine*, 41(9), 1241–1254
- The Centre of Medical Law and Ethics, King's College, London (1997). *Manual for Research Ethics Committees (Fifth Edition)*. London: King's College London
- Meadows K et al (1996). The Diabetes Health Profile (DHP): a new instrument for assessing the psychosocial profile of insulin-requiring patients — development and psychometric evaluation. *Quality of Life Research*, 5, 242–254
- Meakin RP and Weinman J (2002). The 'medical interview satisfaction scale@146 (MISS-21) adapted for British general practice. *Family Practice*, 19, 257–263
- Melzack R (1987). The Short-Form McGill Pain Questionnaire. *Pain*, 30, 191–197
- Paterson C (1996). Measuring outcome in primary care: a patient-generated measure, MYMOP, compared to the SF-36 health survey. *British Medical Journal*, 312, 1016–1020
- Raynor DK, Thistlethwaite JE, Hart K and Knapp P (2001). Are health professionals ready for the new philosophy of concordance in medicine taking? *International Journal of Pharmacy Practice*, 9, 81–84.

Ware J Jr, Kosinski M and Keller SD (1996). A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Medical Care*, 34(3), 220–233.

Zigmond A and Snaith RP (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica*, 67, 361–370